

American College of Occupational and Environmental Medicine

## SHOULDER DISORDERS GUIDELINE

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## IMPACT

Shoulder disorders are the third most common reason patients seek health care treatment for musculoskeletal pain. (Urwin 98; Chard 91; Bongers 01; Speed 01; Dinnes, HTA 03) These disorders are also among the five most common causes of reported work-related musculoskeletal disorders (MSDs) in workers' compensation claims in the United States. (Silverstein 02, Silverstein 98; Punnett 99; Waehrer 05; Brown 03) Annual health care costs for shoulder pain in the United States in 2000 have been estimated at more than \$7 billion. (Meislin 05) Musculoskeletal shoulder disorders account for about 3 to 5% of total lost workdays and 10 to 11% of claims and costs in workers' compensation, ranking them in the top five for financial severity, although much of the total expense is related to surgical procedures. (Silverstein 98a, Silverstein 98b) Workers' compensation status is associated with higher costs, worse prognosis, and worse outcomes than patients without workers' compensation status or litigation. (Holtby 10; Frieman 95; Misamore 95; Koljonen 09; Smith 00; Henn 08) In general, shoulder disorders are prone to recur, (Croft 96; van der Windt Ann Rheum Dis 95; van der Windt 99; Winters 96), and are often associated with actual or perceived worse general health status. (Gartsman 98; Largacha 06; Viikari-Juntura 08; Harryman 03; Largacha 06; Kaergaard 00; Silverstein 06; Green 98)

## **OVERVIEW**

This clinical practice guideline presents recommendations on assessing and treating adults with shoulder disorders. Topics include the initial assessment and diagnosis of patients with acute, subacute, and chronic shoulder disorders with particular emphasis on work related factors; identification of red flags that may indicate the presence of a serious underlying medical condition; initial management, diagnostic considerations, and special studies for identifying clinical pathology; work-relatedness, return to work, modified duty and activity; and further management considerations, including the management of delayed recovery.

Algorithms for patient management are included. The guideline's master algorithm schematizes the manner in which practitioners may generally manage patients with shoulder problems. The following text, tables, and numbered algorithms expand upon the master algorithm.

## **GENERAL APPROACH**

The principle recommendations for assessing and treating patients with shoulder disorders are as follows:

- The initial assessment focuses on detecting indicators of potentially serious disease, "red flags," and making an accurate diagnosis.
- In the absence of red flags, work-related shoulder disorders may generally be safely and effectively managed by non-operative means. The focus is on using the most efficacious treatment strategy(ies), monitoring for progression and complications, modifying treatment to facilitate the healing process, and facilitating return to work in a modified- or full-duty capacity. Including patient's treatment preferences may be helpful. (Thomas 04)
- Nonprescription analgesics (NSAIDS and acetaminophen) may provide sufficient pain relief for most patients. If treatment response is inadequate (i.e., if symptoms and activity limitations continue), incrementally expand treatment to include prescription medications, treatment modalities such as physical or occupational therapy, steroid injections, and/or surgery. Pain relief may be accomplished by activity modification, commonly limiting shoulder activities to below shoulder level for those significant exposure activities.<sup>i</sup>
- Identifying the worker's job tasks and functional goals, including return to work, can aid the formulation of an appropriate treatment plan and work restrictions.
- Patients recovering from work-related shoulder injuries are encouraged to return to modified work and normal activity levels as soon as their condition permits.

<sup>&</sup>lt;sup>1</sup>Ninety to 120° of abduction and forward flexion is the most compromised biomechanical position for the shoulder in biomechanical experimental studies. Maintaining higher overhead height is less compromising to the shoulder than lowering to 90° if the object cannot be lowered substantially. (Garg 02, 05, 06)

 Nonphysical factors such as psychosocial, workplace, or socioeconomic problems should be assessed early in and over the course of care and addressed in an effort to prevent or resolve delayed recovery. (Main/Williams BMJ 02)

## **OVERVIEW OF SHOULDER DISORDERS**

This guideline addresses the following shoulder disorders which might present to the health care provider – acromioclavicular arthrosis and glenohumeral arthrosis; acromioclavicular sprain, separation or dislocation; adhesive capsulitis; bicipital tendinitis and tears; brachial plexus injuries; calcific tendinitis; degenerative joint disease (including osteoarthrosis); dislocation (glenohumeral); fractures; instability; labral tear; non-specific shoulder pain; osteonecrosis; rotator cuff syndromes; rotator cuff tears; thoracic outlet syndrome; and trigger points/myofascial pain.

## Acromioclavicular (AC) Arthrosis, Glenohumeral Arthrosis

Arthroses in the acromioclavicular and glenohumeral joints are common, although less common than those of the hand, knees and hips. Radiographs show degenerative joint disease and may suggest an etiology. Etiologies for arthroses include developmental anomalies, rheumatoid arthritis, other rheumatological disorders, crystal diseases, post-infectious complications and systemic factors. Most cases are assumed to be degenerative osteoarthroses, although inherited tendencies appear common.

## Acromioclavicular (AC) Sprain, Separation, Dislocation

Sprains involve high force falls and accidents that produce a disruption of the ligaments about a joint. Commonly, these injuries occur by direct blow from a fall onto the shoulder or a fall on an outstretched hand or direct trauma to the joint. AC joint separation ("shoulder separation") and dislocation are more severe than a Grade I AC joint sprain.

## Adhesive Capsulitis (Frozen Shoulder)<sup>ii</sup>

Adhesive capsulitis involves a reduction in passive range of motion of the shoulder in three or more directions. As range of motion (ROM) differs widely in the population, the affected shoulder's ROM should be compared with the unaffected side. Frozen shoulder causes can be classified as idiopathic adhesive capsulitis or secondary to trauma or underlying shoulder pathology. The most common cause is idiopathic and associations with diabetes mellitus, hypothyroidism and female gender have been reported. Glenohumeral contracture can also occur after traumatic injury, in association with rotator cuff disorders, or after shoulder surgery.

## **Bicipital Tendinitis and Tears**

Anterior shoulder pain may be caused by bicipital tendinitis. Bicipital tears are believed to result from mechanisms similar to rotator cuff tears. Many are thought to be a result of chronic tendinopathy followed by tears while others are a result of an acute traumatic event. They generally occur in conjunction with rotator cuff pathology. Another sometimes related but infrequent entity is biceps subluxation and dislocation.

## **Brachial Plexus Injuries**

Brachial plexopathies might be caused by forceful stretching of the nerves that travel from the spine to the upper extremity and are thought to occur after accidents, falls from heights, and sports (e.g., "stingers"). However, reliable etiological and epidemiological data are not available. Idiopathic brachial plexopathy occurs infrequently, and parsonage tumor syndrome should be considered.

## **Calcific Tendinitis**

Calcium deposits in the rotator cuff tendons as degeneration progresses. The course of onset is similar to rotator cuff syndromes in those with chronic non-severe pain. It can also present as acute severe onset of atraumatic shoulder pain, an unusual presentation for rotator cuff syndromes. The risk factors, evaluation, diagnosis, and some treatments tend to be similar to rotator cuff tendinopathies although there are differences (Jim 93).

<sup>&</sup>lt;sup>ii</sup>Nomenclature has long been problematic and the term periarthritis has also been used. (Dickson 32; Lippmann 43)

## Degenerative Joint Disease (including Osteoarthrosis)

Degenerative joint disease involves any degenerative or age-related changes in any joint. While osteoarthritis (OA) is the more common name for this entity, osteoarthrosis is more technically precise as there is no overt inflammation with redness, swelling, and palpable warmth. Other arthritic disorders that cause joint degeneration include inflammatory disorders (e.g., rheumatoid arthritis, systemic lupus erythematosus, and psoriasis) and crystalline arthropathies (e.g., gout, pseudogout, apatites). As inflammatory and crystalline arthropies are non-occupational, they are not included in this discussion.

Other than intervertebral discs, joints in the body are typically synovial fluid filled, synovium lined, ligamentously encapsulated joints that allow for low friction movement between adjacent bones. OA, an age-related degenerative change in the joint particularly affecting the cartilage on the articular surface, is marked by thinning of that cartilage, osteophyte formation, and subchondral sclerosis. Pain on movement and stiffness develop. OA may develop in only one joint after a significant traumatic injury (e.g., fracture), in which case it is often delayed by many years. If this injury was occupational, then the subsequent osteoarthrosis is also considered, at least in part, occupational.

## **Dislocation (Glenohumeral)**

Shoulder dislocation occurs when such high force is applied that the shoulder musculature and joint capsule are unable to resist, resulting in stretching and partial rupture of the joint capsule. Labral tearing also usually accompanies this injury. As this injury involves disrupting ligaments, it is technically a true sprain. Frequently, the shoulder will require relocation, although sometimes the patient accomplishes this prior to seeking medical care. Once dislocated, the shoulder is prone to feel unstable and to re-dislocate. Older patients frequently have associated rotator cuff tears and fractures.

## Fractures

Fractures occur due to trauma from many causes including falls and motor vehicle accidents. Pathologic fractures are the primary exception as minimal force may be required for these fractures.

#### Instability

Shoulder instability is associated with a tendency to sublux or dislocate, a feeling of instability, and concerns about potential dislocation. Instability is a frequent sequelae of dislocation. Instability can be classified as traumatic, atraumatic instability or multi-directional instability. Instability can be a result of congenital laxity or micro-trauma to the shoulder over time as well as high force acute trauma.

#### Labral Tear

The labrum is a wedged-shaped fibrocartilaginous structure at the rim of the glenoid that is a transitional tissue from the articular cartilage of the glenoid to the capsuloligamentous tissue/structures of the glenohumeral joint. The two commonly reported types of tears along the superior labrum (SLAP) and the anterior inferior portion (Bankart) are discussed below, although the labrum may tear at any point. The long head of the biceps attaches to the superior labrum, and therefore biceps pathology can be concomitant pathology with superior labral tears. The labrum is intimately involved in mechanisms of shoulder stability. The labrum is susceptible to age-related degeneration and it may be that acute injuries can occur superimposed on a degenerative process. A labral tear can be associated with shoulder instability or dislocation.

#### **Non-Specific Shoulder Pain**

Some cases of shoulder pain do not clearly fit diagnostic criteria and are considered non-specific. These cases may resolve prior to identifying a clear diagnosis or a specific diagnosis may become clear with time.

#### Osteonecrosis

Osteonecrosis (avascular necrosis) is particularly likely to occur in areas of tenuous blood supply that lacks collateral blood flow. It most commonly affects the femoral head. Shoulder osteonecrosis involves

impairment of the blood supply to the humeral head. It can progress to degeneration and ultimately humeral had collapse. Reported risk factors for osteonecrosis in any region of the body include male gender, (Talamo 05) diabetes mellitus, glucocorticosteroid treatment or excess, (Talamo 05) sickle cell anemia or trait, alcohol, organ transplantation, (Helenius 06) and multiple myeloma. (Talamo 05) The most prominent occupational risk factors are proximal humerus fractures and barotrauma (the bends), which may occur both in diving, as well as working in compressed air environments (e.g., certain types of tunneling projects through unstable sediments requiring compressed air to maintain the workspace). Trauma is a risk factor. Non-traumatic job physical factors are controversial, and there is no evidence to support this link.

## Rotator Cuff Syndromes (including rotator cuff tendinosis, rotator cuff tendinitis, supraspinatus tendinitis, rotator cuff partial tears, impingement syndrome, bursitis)

Rotator cuff-related disorders as listed above are generally considered closely related if not the same degenerative condition, and the various entities are not well distinguished. (Codman 11a,b,27,34, Wilson 43; Olsson 53; Keyes 33, 35; von Meyer 37; Skinner 37; Cotton 64; Macnab 73; Fu 91; Schellingerhout 08; Neer 82; Hijioka 93; Ishii 97; Chard 94; Belling Sorensen 00; Itoi 06) There has long been evidence of insufficient blood supply in the typical area(s) of rupture (Lindblom 39; Rathbun 70; Moseley 63; Rothman 65; Chansky 91; Brooks 92) and recent evidence points to numerous atherosclerotic disease risk factors (Viikari-Juntura 08; Morken 00; Silverstein 08; Miranda 01, 05; Luime 04; Wendelboe 04; Skov 96; Stenlund 93; Kane 06; Kaergaard 00) strongly suggesting a primarily pathophysiological mechanism of atherosclerosis of the arterial supply to the tendons.<sup>III</sup> The other primary competing theory is biomechanical, particularly with impingement of the acromion first described in the 1920s by Meyer (Meyer 21; Meyer 24; Meyer 26) and advanced by Neer (Neer 72, 82) that develops as a consequence of the agerelated degenerative processes. (Milgrom 95; Worland 03; Zuckerman 94; Bigliani 91; Neer 72; Bonsell 00) Both theories may play a role, although the atherosclerotic vascular supply mechanism appears of primary importance. (Viikari-Juntura 08; Hegmann 98) Patients with tendon pathology often have shoulder pain that radiates to the upper arm and deltoid region, and some even report more distal radiation without paresthesias. Bursitis tends to have non-radiating shoulder joint pain, although it too may present with deltoid region pain. Partial-thickness tears cannot reliably be distinguished from the other rotator cuff entities clinically or with imaging. Many of the symptoms and examination maneuvers used to assign a diagnosis of "rotator cuff syndrome" are not specific to a cause. The supraspinatus tendon is the most commonly affected tendon in the rotator cuff. Tendon pathology most commonly progresses posteriorly to the infraspinatus. Tendonopathies are generally considered the most important of the occupational shoulder disorders based on high prevalence. (Needell 96; Reilly 06)

## Rotator Cuff Tears (including supraspinatus, other full-thickness tears and bicipital tears)

Rotator cuff tears appear to predominantly occur over years of degenerative rotator cuff tendinopathy, culminating in a full-thickness rotator cuff tear and presentations vary from severe symptoms to asymptomatic despite presence of a tear. (Lewis 09a, b) It is not clear if or to what extent tears are caused by trauma. Most rotator cuff tears develop at the anterior aspect of the midsubstance of the supraspinatus tendon and progress posteriorly. Full-thickness rotator cuff tears predominantly develop first in the supraspinatus and can progress to tears of the infraspinatus and teres minor. Involvement of the subscapularis is less common, but should always be considered. The prevalence of rotator cuff tears is 6-51% for full-thickness tears in asymptomatic patients over age 50. (Worland 03; Sher 95; Yamamoto 09;Yamamoto 10; Reilly 06; Tempelhof 99; Schibany 04; Sakurai 98; Linsell 06; Cassou 02; Roquelaure 06; Clayton 08; Yamaguchi 06; Miranda 05; Siverstein 08; Wilson 43; Moosmayer 09; Neer 72; Milgrom 95; Miniaci 95; Codman 34; Keyes 35; Cotton 64)

## **Thoracic Outlet Syndrome**

Thoracic outlet syndrome (TOS) involves compression of the neurological and/or vascular supply to the upper extremity. A few cases involve discrete compression by the first thoracic rib or cervical rib. Scalene muscle tightness has been described as a cause. Other causes of what could be termed physiologic TOS are controversial regarding whether there is true compression of structures.

<sup>&</sup>lt;sup>iii</sup>This does not rule out contributing mechanical factor(s).

## Trigger Points/Myofascial Pain, Muscle Tension Syndrome

Myofascial pain syndrome involves trigger points, which are tender areas that with palpation feel dense and can elicit pain locally and distally. Patients with muscle tenderness are diagnosed with "myofascial pain." Prolonged muscular pain is often linked to underlying psychosocial issues that foster inactivity and dependence on passive modalities and pharmacologic interventions. Most randomized control trials (RCTs) have not distinguished between tender and trigger points, though they frequently note pain limited to muscles of a body region.

## SUMMARY OF RECOMMENDATIONS AND EVIDENCE

All *Guidelines* include analyses of numerous interventions, whether or not they are approved by the U.S. Food and Drug Administration (FDA). For non-FDA-approved interventions, recommendations are based on available evidence, and this is not an endorsement of their use. Many of the medications recommended are utilized off-label.

The following is a general summary of the recommendations contained in this Guideline:

## Occupational Issues

- Identifying the worker's job tasks and functional goals, including return to work, can aid the formulation of an appropriate treatment plan and work restrictions.
- Patients recovering from work-related shoulder injuries are encouraged to return to modified work and normal activity levels as soon as their condition permits.
- Ergonomic interventions and training may reduce the risk for shoulder disorders and symptoms.

## Diagnostic Testing

- Shoulder x-rays for diagnosis in traumatic injuries and as an initial study, if diagnostic imaging is needed, for non-traumatic shoulder problems is recommended (Insufficient Evidence (I)).
- Magnetic resonance imaging (MRI) is recommended (Insufficient Evidence (I) and some evidence for advanced imaging of soft tissues such as rotator cuff tears, particularly in patients who are not recovering as expected or where additional diagnostic information would change the treatment plan).
- MR arthrography is recommended (Insufficient Evidence (I) and some evidence to diagnose labral tears in patients who are not recovering as expected or where additional diagnostic information would change the treatment plan).
- Computerized Tomography (CT) is recommended (Insufficient Evidence (I)) for advanced imaging of bone, if needed, particularly if fractures are suspected but not seen on x-ray. CT or CT arthrography may be used for advanced imaging when MRI is contraindicated.

## Adaptive Equipment/Assistive Devices and Other Physical Methods

- There is little quality evidence for use of heat or cold, although many patients find these treatments helpful for symptom management particularly in acute shoulder pain. Patients' at home applications of heat or cold packs may be used before or after exercises and are likely as effective as those performed by a therapist.
- Some quality studies have supported using acupuncture especially for treatment of myofascial pain and shoulder girdle pain (see below), but referral appears dependent on the availability of experienced providers with consistently good outcomes.
- Mobilization has been described as effective for patients with adhesive capsulitis (frozen shoulders), rotator cuff tendinopathies, (Bang 00; Senbursa 07; Conroy 98) and general shoulder pain. (Bergman 04) The period of treatment is limited to a few weeks, as results decrease with time. Scalene-stretching and trapezius-strengthening exercises have been reportedly effective in relieving thoracic outlet compression symptoms.
- Slings are recommended (Insufficient Evidence (I)) for initial treatment and pain control of glenohumeral dislocation and acromioclavicular severe sprain or separation.

- Physical modalities, such as massage, diathermy, laser treatment, ultrasound treatment, transcutaneous electrical neurostimulation (TENS) units, biofeedback, and acupuncture are mostly unsupported by moderate- or high-quality studies, but some of these may be useful in the treatment of shoulder symptoms.
- Significant differences between traditional approaches and various alternative and multidisciplinary intervention programs for chronic shoulder pain have not been demonstrated in the medical literature to date. Recommendations, prescription, or referral regarding such multidisciplinary programs or alternative care can be based on the practitioner's professional judgment and the patient's individual condition or situation (psychosocial, workplace and socioeconomic).

## Exercise Issues

- Rehabilitation or exercise programs are recommended (Insufficient Evidence (I) and some evidence to progress from ROM to strengthening exercises after injury and/or surgery). Exercise initiation (passive and active) is delayed depending on the injury (e.g. unstable fracture) or repair (rotator cuff tear) to allow for healing or protect the repair.
- Instruction in home exercise is recommended. Except in cases such as unstable fractures, patients can be advised to do early pendulum or passive range of motion (ROM) exercises at home.
- Active exercises are advocated over passive for longer term functional restoration. Passive exercises
  are much better in early phases to prevent shoulder stiffness and overcome stiffness.
- A quality exercise program is generally recommended for most patients with rotator cuff tendonopathies or impingement syndrome prior to considering surgical repair. (Brox 93, Haahr 05, 06)

## Medications

- High quality evidence supports NSAIDs for treatment of shoulder disorders with concomitant cytoprotective medications. High quality of evidence supports proton pump inhibitors and misoprostol to treat patients at risk for gastrointestinal bleeding. Low to moderate quality evidence supports treatment with sucralfate and H2 blockers for cytoprotection.
- Moderate-quality evidence supports treating rotator cuff tendinopathies with subacromial glucocorticoid injection usually combined with a local anesthetic. This may be indicated if there is insufficient improvement after other non-invasive therapy (e.g., strengthening exercises and NSAIDs) for 2 to 3 weeks.
- Judicious short term use of opioids to treat acute severe shoulder pain or severe post-operative pain are recommended (Insufficient Evidence (I)) when NSAIDS, acetaminophen or aspirin are inadequate or inappropriate (e.g., potential bleeding complications).

## Surgical Issues

- Moderate-quality evidence documents success of surgical rotator cuff repairs, whether arthroscopic or open.
- Moderate-quality evidence supports the efficacy of surgical subacromial decompression to treat impingement syndrome that has not improved sufficiently with NSAIDs and a quality exercise program.
- High quality evidence supports surgery for treatment of select initial acute, traumatic anterior shoulder dislocation.
- Low quality evidence supports surgical repair of high grade acromioclavicular joint separation and select patients with displaced proximal humeral or clavicular fractures.

## **BASIC PRINCIPLES AND DEFINITIONS**

Acute, Subacute, or Chronic Pain: For purposes of identifying interventions at different stages of diseases, acute pain is defined as pain for up to 1 month; subacute is pain from 1 to 3 months; and chronic is pain of more than 3 months duration (see Chronic Pain Guidelines for additional information).

Active Therapy: The term "active therapy" is commonly used to describe treatment that requires the patient to assume an active role in rehabilitative treatment. Although there is no one specific treatment defined by this term, it most commonly includes therapeutic exercises (particularly aerobic activities), functional activities, and muscle reconditioning (weight lifting or resistance training). (Mannion 01) Some studies have included active stretching and treatment with psychological, social, and/or educational components requiring active participation from the patient. (Kankaanpää 99)

Active Exercise Therapy: Active exercise therapy typically consists of cardiovascular training and muscle strengthening, (Cohen 02; Danielsen 00) although it may also include progressive or occasionally active stretching, especially in patients with substantially reduced ranges of motion. Active exercise therapy is used as a primary treatment for chronic pain, is frequently initiated in the course of treating subacute pain, and is a primary treatment after various surgeries. The goal of active exercise therapy is to improve function. (Cohen 02) The word "active" is used to differentiate individualized exercise programs designed to address and rehabilitate specific functional, anatomic or physiologic deficits from passive treatment modalities or from forms of "exercise" that require little effort or investment on the part of the patient or provider.

**Brachial Plexus:** The nerves traveling from the spinal cord levels C5 to T1 ventral rami to the upper extremity in aggregate are termed the brachial plexus. This includes subdivisions of these nerves that are anatomically labeled roots, trunks, divisions, cords, and branches. The anatomic region the plexus involves extends from the tissue adjacent to the spinal cord to the axilla, or arm pit. Injuries to these structures are frequently termed brachial plexopathy.

**Bursae**: Bursae are small, fluid-filled sacs within the body that are typically located adjacent to bones where movement occurs such as between overlying muscles, tendons, or skin. These fluid filled structures reduce the friction as movement occurs.

**Bursitis**: Bursitis is inflammation of a bursa, and may be marked by pain when the proximate tissue is used or the bursa is compressed.

**Delayed Recovery:** Delayed recovery is an increase in the period of time prior to returning to work or to usual activities, when compared with the length of time expected, based on reasonable expectations, disorder severity, age, and treatments provided.

**Functional Capacity Evaluation (FCE):** A comprehensive battery of performance-based tests used to attempt to assess an individual's ability for work and activities of daily living. (Gross 06) An FCE may be done to identify an evaluee's ability to perform specific job tasks associated with a job – a job-specific FCE, or his or her ability to perform physical activities associated with any job – a general FCE (see Chronic Pain Gudeilines and Low Back Complaints). Results should be interpreted with caution. The testing should be preferably conducted by someone (e.g., occupational or physical therapist) well experienced in dealing with patients who may self-limit due to pain."

**Functional Improvement (especially objective evidence):** Functional improvement entails tracking and recording evidence that the patient is making progress toward increasing his or her functional state (validated tools preferred).

**Functional Restoration:** Functional restoration is a term initially used for a variant of interdisciplinary pain alleviation or at least amelioration characterized by objective physical function measures, intensive graded exercise, and multi-modal pain/disability management with both psychological and case management features. (Mayer 85, Mayer 86, Mayer 87, Mayer 88, Rainville 07, Jousset 04, Hildebrandt 97) The term has become popular as a philosophy and an approach to medical care and rehabilitation. In that sense, it refers to a blend of various techniques (physical and psychosocial) for evaluating and treating the chronic non-malignant pain patient, particularly in the workers' compensation setting (see Chronic Pain Guidelines).

**Pain Behavior:** Pain behavior includes verbal and non-verbal actions (e.g., grimacing, groaning, limping, using pain relieving or support devices/slings, requesting pain medications, etc.) which communicate the concept of pain.

**Passive Modality:** Passive modality refers to various types of provider-given treatments in which the patient is not an active participant. These treatments include medication, injection, surgery, allied health therapies (e.g., massage, acupuncture, and manipulation), and various physical modalities such as hydrotherapy (e.g., whirlpools, hot tubs, spas, etc.), ultrasound, TENS, other electrical therapies, heat, and cryotherapies.

**Rehabilitation**: The term "rehabilitation" is used in these *Guidelines* to mean physical medicine, therapeutic and rehabilitative evaluations, and procedures. Rehabilitation services are delivered under the direction of trained licensed individuals such as physicians, occupational therapists, or physical therapists. Mental health professionals may also be incorporated in the treatment team, particularly for select chronic pain patients. Jurisdictions may differ on qualifications for licensure to perform rehabilitative evaluations and interventions.

**Shoulder Impingement**: A theoretical construct advanced over the past 40 years proposing that the supraspinatus tendon is compressed between the acromion and humeral head, resulting in degenerative tendinopathy and tears.

**Shoulder Joint**: The shoulder (glenohumeral) joint is a shallow synovial ball-and-socket joint based on the articulation of the head of the humeral head and glenoid fossa of the scapula. The supraspinatus, infraspinatus, teres minor, and subscapularis muscles and their tendons comprise the rotator cuff, and contribute to holding the humeral head in the glenoid fossa.

**Tendinitis**: Inflammation within the tendon or tendon insertion with the clinical signs of redness, heat, and swelling accompanied by pain and decreased range of movement. While "tendinitis" is a widely used term diagnostically, there is a general supposition that inflammation is present.

**Tendinosis**: Tendinosis is a chronic degenerative tendon injury, unaccompanied by redness or heat. It is associated with pain and limited movement. (Kahn 00) Tendinosis may be due to an interaction of individual and physical factors, which may include vocational and avocational activities. In theory, microinjuries gradually accumulate faster than they can heal and become clinically apparent when the area becomes painful (see Elbow Disorders for severity and susceptibility).

**Sprain:** A sprain is the disruption of a ligament. Sprains are typically graded I-III, ranging from modest ligamentous tears but no laxity (I) to complete disruption of the ligament (III).

**Strain:** Strain is the disruption of a myotendinous junction or sometimes of a muscle, usually from a highforce unaccustomed exertion. It may also occur during an accident. This term is occasionally used to describe non-specific muscle pain in the absence of knowledge of an anatomic pathophysiological correlate.

- S, grade I: overstretching or slight tearing.
- S, grade II: incomplete tearing.
- S, grade III: complete tear or rupture.

## **INITIAL ASSESSMENT**

Thorough medical and work histories and a focused physical examination (see General Approach to Initial Assessment and Documentation) are sufficient for the initial assessment of most workers with potentially work-related shoulder symptoms. The medical history and physical examination include evaluations for serious underlying conditions, red flags, and consideration for possible referred shoulder pain due to a disorder in another part of the body (most commonly from the cervical spine and sometimes viscera). The absence of red flags largely rules out the need for special studies, referral, or inpatient care during the first 4 to 6 weeks for most patients, by when spontaneous recovery is expected. Shoulder disorders may be classified into one of three somewhat arbitrary categories:

- Potentially serious conditions: including fractures, glenohumeral dislocation, infection, or neurological or circulatory conditions, including referred cervical, cardiac, or intra-abdominal pain. Glenohumeral dislocations are considered here, until it is confirmed there is not concomitant fracture or nerve damage.
- Specific shoulder disorders: including full-thickness rotator cuff tears, rotator cuff syndromes (impingement syndrome, rotator cuff tendinoses, rotator cuff tendinitis and tendinopathy, supraspinatus tendinitis, partial-thickness rotator cuff tears, bursitis), bicipital tendonitis, acromioclavicular (AC) joint sprain or separation, labral tears, thoracic outlet syndrome (TOS), brachial plexus injury, adhesive capsulitis (frozen shoulder), calcific tendinitis, and instability.
- Nonspecific shoulder disorders: suggesting neither internal derangement nor referred pain including trigger points/myofascial pain (including muscle tension syndrome), fibromyalgia (see Chronic Pain Guidelines), degenerative joint disease (including osteoarthrosis), and nonspecific pain.

## **MEDICAL HISTORY**

The initial evaluation of patients with shoulder pain should include a thorough medical history, as the vast majority of data to successfully evaluate and treat these patients is found in the history. A complete occupational history is necessary to assist the patient with successful accommodation and rehabilitation, as well as to determine work-relatedness (see General Approach to Initial Assessment and Documentation). Standardized questionnaires of functional loss and disability are often utilized to adequately assess shoulder function and disability (e.g., Disability of the Arm, Shoulder and Hand (DASH) questionnaire, Shoulder Pain and Disability Index (SPADI) questionnaire). (Constant 87; Williams 99; Godfrey 07; Beaton 96, 98, 01, 03; Bot 04; Cook 01; Kirkley 03; Kocher 05; L'Insalata 97; Lippitt 93; Lohr 96; Ohlsson 94; Michener 02; Roach 91; Roddey 00; Leggin 06; Gabel 06; Gabel 09; Dawson 99; Richards 99)

Asking the patient open-ended questions, such as those listed below, allows the physician to gauge the need for further discussion or specific inquiries to obtain more detailed information. Start eliciting a history with open-ended questions, such as: "What may I do for you today?" This approach helps to frame the discussion towards what the patient feels is the main purpose of the visit. Elicitation of the patient's concerns may include issues seemingly tangential in the initially, but may prove important later and helps ensure that the physician is able to address issues important to patient satisfaction.

- 1. PREVIOUS SHOULDER PROBLEMS
  - Have you had similar episodes previously?
  - Have you had previous testing or treatment? What treatment? What were the results? With whom? How long did it take to get back to work? To light duty? (Was recovery similarly delayed?)
  - Did this previous shoulder problem resolve completely? (Did you get a disability award?)

## 2. SYMPTOM ONSET

- What were your symptoms?
- Where did symptoms first occur? Were there symptoms down the arm, hand or up in the neck?
- When did your symptoms begin?
- What do you think caused the problem? How did it occur? Do you recall a specific inciting event?
- How do you think it is related to work? (It is important to obtain all information necessary to document the circumstances and biomechanical factors of injury to assist the patient in obtaining compensation, where appropriate.)
- Was there acute or gradual onset of pain or limitation of motion? For traumatic injuries: Was the area deformed?
- What is the day pattern to your pain? When is it worst? Do you have a problem sleeping?
- How does having this pain affect your life?
- 3. PROGRESS OF SHOULDER CONDITION
  - Since these symptoms began, have your symptoms changed? How?
  - Have your activities been limited? How long have your activities of daily living been limited? For how long?
  - What tests or imaging have you had?
  - Have you had specialist consultations?

- What treatments have you had so far, including over the counter and prescription medication?
- 4. PRESENT SYMPTOMS
  - What are your symptoms currently? How does the worker act when describing them (may help ascertain the expression of and meaning of pain to the worker, while simple hand gestures and postures taken while describing the pain are often highly useful for diagnosis)?
  - Are you experiencing pain, weakness, or limited motion (stiffness) in your shoulder?
  - Are you experiencing popping, clicking, or catching in your shoulder?
  - Does your shoulder feel unstable?
  - Are your symptoms currently located primarily in the shoulder joint?
  - Is your shoulder pain associated with pain, numbness, tingling, swelling, or color change in the hand or arm?
  - Are your symptoms constant or intermittent?
  - What makes the problem worse or better?
  - Do you have pain or other symptoms elsewhere (e.g., neck, chest, or abdomen)? Do you have fever, night sweats, or weight loss?
- 5. PRESENT SHOULDER CAPABILITIES
  - Can you move your arm over your head?
  - Can you tuck in your shirt, reach your back pocket, or put on a jacket?
  - Can you do overhead activities or work? For how long?
  - Can you wash your hair?
  - How much weight can you lift? What could you have lifted before?
  - Can you move your shoulder without pain?
  - Can you sleep on the affected shoulder?
  - Does wearing a bra, suspenders, or tool belt harness make your shoulder pain worse or cause pain?
  - How heavy is your purse/shoulder bag? Have you changed purses/bag (lightened) or changed how you carry it (to the other shoulder or rolling bag)?
  - Do you have weakness in your hand, arm, or shoulder?
  - Have you noticed any loss of muscle mass?
- 6. JOB DEMANDS
  - What are your specific job duties? Do you rotate jobs?
  - What does your work require you to do with your shoulder?
  - What postures and activities are required at work? How much do you lift at work as a maximum? Usual lift?
  - Do you have assistance of other people or lifting devices?
  - How often are shoulder activities required?
- 7. OFF-THE-JOB ACTIVITIES (AVOCATIONAL ACTIVITIES)
  - What other activities (hobbies, workouts, sports) do you engage in at home or elsewhere (outside of work)?
  - Do you use your shoulder to perform these activities?
  - Do you do any overhead arm actions? How? How often?
  - Can you perform activities of daily living (e.g., dressing, bathing, grooming, etc.) or instrumental activities of daily living (e.g., shopping, food preparation, housekeeping, etc.)?
- 8. DO YOU HAVE OTHER MEDICAL PROBLEMS?
  - Osteoarthrosis, rheumatoid arthritis or other arthritides or auto-immune disorders (lupus, psoriasis)?
  - Fractures, upper extremity surgeries?
  - Cardiovascular disease?
  - Pulmonary disease? Do you smoke? Did you smoke? How much?
  - Gastrointestinal problems or liver disorder?
  - Diabetes mellitus? Thyroid disorder?

- Do you have neck pain or trauma?
- Neurological disorders (including neuropathies, radiculopathies, headaches)?
- Psychophysiologic disorders (e.g., irritable bowel syndrome, chronic fatigue syndrome, sick building syndrome, fibromyalgia, or multiple chemical sensitivities)?
- Do you have symptoms of infection? Fever, chills, symptoms of infection elsewhere?
- Have you ever had cancer?
- Medications:
- Over the counter medications?
  - Narcotics or prescription medications?
  - Injections into the shoulder?
  - Steroids and immunosuppressants?
- 9. IS THERE ANY PSYCHOLOGICAL, PSYCHIATRIC, MENTAL HEALTH, SUBSTANCE USE, OR ALCOHOL HISTORY?

• Have you ever had a substance use problem? Driving while under the influence of alcohol? Detoxification?

- Have you ever had an alcohol problem? (CAGE or MAST screening especially required for possible osteonecrosis)
- Is there use of other drugs? (Current and prior use)
- 10. WHAT IS THE OCCUPATIONAL PSYCHOSOCIAL CONTEXT?
  - Do you like your job?
  - What is your relationship with your co-workers and supervisor and how do they treat you?

## 11. ASSESS WHETHER THERE ARE PROBLEMS AT HOME/SOCIAL LIFE. DOES THE PATIENT FEEL IN CONTROL OF MOST SITUATIONS? IS THERE SUPPORT?

- How do your family members get along with each other?
- How do they help and support you, including assistance with chores?
- Does your family treat you differently now that you are in pain? Have your roles at home changed because of your injury?
- How do your friends treat you differently?
- Do you get increased symptoms when you are dealing with problems with your family and friends? How often? When? Why?
- 12. ARE THERE ADVOCAGENIC (LITIGIOUS) INFLUENCES?
  - Do you have a workers' compensation claim for this injury? Do you have a lawsuit or other legal action involving this pain problem?
- 13. WHAT ARE YOUR GOALS IN RELATION TO THIS SHOULDER PROBLEM?

## PHYSICAL EXAMINATION

The objective of the physical examination of the shoulder is to define physical abnormalities, narrow the diagnostic considerations, and focus the treatment plan. (Tennent 03; Mirkovic 05; Walton 08; Wilk 05; Berg 98; Holtby 04; Ben Kibler 09; Myers 05; Mimori 99; Ebinger 08; Stetson 02; Liu 96; Swaringen 06; Green 08; Jones 07; Dessaur 08; Calvert 09; Oh 08; Rhee 09; McCaughey 09; Kim 07) Physical examination data, including vital signs, should be reviewed for potential inferences regarding infectious or neoplastic origins.

The physical examination should begin the moment the physician sees the patient. Observing how the patient holds the shoulder, uses the shoulder, sits, walks, and moves is of major importance, often more important than any other aspect of the exam. It also helps to have the patient demonstrate what positions seem to provoke or cause the symptoms as the demonstration is invariably of greater help than verbal descriptions.

Guided by the medical history, the physical examination includes:

- General observation of the patient;
- General level of fitness and physical condition;

- Deper quarter screen for neck involvement, and other upper extremity disorders, including elbow;
- Neurovascular screening;
- Testing for various specific shoulder disorders as appropriate to the history; and
- Monitoring for pain behavior during range of motion, changing postures as a clue to origin of the problem.

## A. REGIONAL SHOULDER EXAMINATION

The entire shoulder girdle should be visible and viewed from all angles. Asking the patient to point to the area of discomfort may be helpful for discrete entities such as AC joint or long head biceps pathology. Pointing helps determine if the discomfort is at the shoulder joint or if the patient is referring to the shoulder in general (e.g., the upper trapezius). Many shoulder disorders present with pain that is too diffuse to point to with one finger. Observe asymmetry or deformity at rest and during movement. Atrophy of the deltoid or scapular muscles is an objective finding, but arises only after weeks to months of symptoms; atrophy of the spinati muscles is the most clinically relevant. Deformities due to acromioclavicular separation are visible (scapular winging at rest, shoulder girdle ptosis), as are many signs of infection (elevated temperature, redness, heat, fluctuance) or gross tumor (visible vessels, palpable mass). Palpate neck, shoulder and arm structures, noting patient's behavior and tenderness.

Shoulder range of motion (ROM) should be determined actively and passively. Active ROM should be performed before passive to determine how far the patient can move prior to applying overpressure. Essential active motions to assess are shoulder elevation in flexion and abduction, external rotation, and internal rotation with the arm at the side and at 90° of abduction. (Green 98) Passive ROM should be performed for the same motions. Passive motion is best assessed with the patient supine. The examiner may also determine passive ROM by eliminating gravity with overpressure, having the patient in the pendulum position or by the patient using his or her other arm to aid elevation. While checking ROM, watch for scapular mobility and stability. Movement of the scapula should be observed for winging or dysrhythmia during active elevation in flexion and/or abduction. (McClure 09; Uhl 09) Both can be enhanced by fatiguing the shoulder with repeated active range of elevation and lowering the arm. Strength should be assessed, resisting isometric contractions of the same essential motions for ROM described above, including supraspinatus and infraspinatus assessment. The choice of which specific tests (see Table 1) to use may be guided by the synthesis of the information obtained from the history and physical examination. However, many examination maneuvers have not been validated in guality clinical trials, and do not have well established sensitivities and specificities. Many exam maneuvers are also reportedly non-specific and of questionable value. (Dinnes, HTA 03; Luime 04; Hegedus 08; Munro 09; Beaudreuil 09; Hughes 08; Beaudreuil 09; Park 05: Silva 08: Hanchard 08) It is important to correlate data from history (demographics, type and location of symptoms, mechanism of injury) with findings on physical examination. For example, findings of instability maneuvers are irrelevant if instability is not the problem. If certain shoulder problems (pain) are sufficiently severe, other diagnostic tests may not be helpful, e.g., in the presence of substantial joint stiffness and capsulitis, impingement maneuvers are invalid.

The following table includes common tests and citations for accuracy when available.

Test	Shoulder Area Examining	Maneuver	Positive criteria	Issues and Interpretation†
Apprehension (Farber 06; Lo 04)	GH joint instability	Anterior directed force is applied to proximal humerus in shoulder abduction and external rotation.	Subjective feeling of anterior instability and fear of anterior glenohumeral (re)dislocation.	Subjective test interpretation although thought to be accurate.
Posterior Drawer/Relocatio n (Gerber JBJS 1984)	GH joint instability	Patient is supine with shoulder abducted and externally rotated (Anterior apprehension position). Force on anterior humerus is directed posteriorly.	Pain or apprehension. May appreciate posterior laxity in thin patients. It eliminates the	Relatively uncommon type of instability. Operant characteristics of the test are unclear.

## Table 1. Common Physical Examination Maneuvers\*‡

			positive findings on anterior apprehension maneuver.		
Anterior Release Test (Gross 97)	GH joint instability	Posterior directed force is released from the humerus with shoulder in abduction and external rotation.	Subjective feeling of anterior instability and fear of anterior glenohumeral (re)dislocation when pressure is released.	May be positive with an increase in sensation of anterior instability when pressure is released.	
Anterior Slide Test (Ben Kibler 09)	GH joint instability	Applying an anteriorly and superiorly directed force on glenohumeral joint while patient rests hand on ipsilateral hip, thumb posterior.	Pain or painful click on the anterior or posterior joint line.	Positive test associated with labral tears.	
<b>Sulcus</b> (Nakagawa 05)	GH joint instability	Apply an inferior traction to the humerus at the elbow (Pull humerus downward).	Visible or palpable inferior translation of the humeral head.	Positive confirms possible glenohumeral joint instability. Suggests multidirectional instability in some patients. Objective finding not dependent upon patient response.	
Relocation Test (Speer AJSM 94) Jobe Relocation (Speer 94; Pandya Arthroscop 08)	GH joint instability	Shoulder is placed in abduction and external rotation then posterior directed force applied to humeral head.	Subjective feeling of instability or fear of re-dislocation reduced or abolished when anterior pressure applied.	Test for instability. May be positive with reduction of sensation of anterior instability when pressure is applied.	
Wright's Test (Safran AJSM 04; Mackinnon CPS 02)	Thoracic outlet syndrome	Shoulder gradually hyperabducted, externally rotated. Assess effect on radial pulse.	Symptoms are reproduced and/or radial pulse ablated. Should compare with asymptomatic shoulder.	Definition of a positive test varies between studies and reports. Test used to infer thoracic outlet syndrome. Many asymptomatics have pulse diminuation or ablation.	
Adson (Safran AJSM 04; Mackinnon CPS 02)	Thoracic outlet syndrome	Shoulder abducted about 90° and externally rotated. Patient extends and rotates cervical spine towards affected hand. Patient then takes a deep breath and holds his or her breath.	Reproduction of symptoms and radial pulse diminution or ablation. Should compare with asymptomatic shoulder.	Some variability in description of this maneuver (e.g., whether to extend neck). Test used for thoracic outlet syndrome. High rate of pulse ablation in normal population.	
Roos (elevated arm stress test) (Safran AJSM 04; Mackinnon CPS 02; Nord 08)	Thoracic outlet syndrome	Patient assumes position of 90° shoulder abduction and external rotation with 90° elbow flexion. Patient opens and closes fists for several minutes.	Reproduction of symptoms or sense of heaviness or fatigue.	Operant characteristics unclear. Should be carefully compared with contralateral extremity.	
Active Compression/ O'Brien (O'Brien 98)	Labrum, AC joint	Patient stands, shoulder forward flexed 90° with elbow extended, then arm adducted 10° to 15° medial to body's sagittal plane and internally rotated so thumb pointed downward. Examiner stands behind patient, applies uniform downward force to arm. With arm in same position, palm then fully supinated and maneuver repeated.	Pain elicited during first maneuver, reduced or eliminated with second. Pain at acromioclavicular joint or "on top," diagnostic of AC joint abnormality. Pain or painful clicking described as "inside" shoulder considered positive for labral	Test used for both AC joint and SLAP lesions. Frequently positive with rotator cuff syndromes and tears	

			disorder.	
Clunk Sign (Nakagawa 05)	Labrum	Rotation of loaded shoulder from extension to forward flexion.	Painful clunk	Felt to suggest labral disorder; non-specific. May be positive with rotator cuff related disorder or glenohumeral arthrosis, and AC joint arthrosis.
Cross-arm (Park 05; Chronopoulos 04)	AC joint	Forward flexion to 90° and active adduction usually adducted passively.	Pain in acromioclavicular joint	Positive thought to suggest degenerative arthrosis in AC joint. May be positive with rotator cuff tendinosis and glenohumeral arthrosis.
Painful Arc (Park 05; Chronopoulos 04; Calis 00; Michener 09; (McGee 07))	Non-specific shoulder pain, rotator cuff syndrome	Patient is asked to raise their arm into full shoulder abduction.	Pain in shoulder joint with active elevation and lowering of arm in mid range of elevation (60-120)	While a functional test, it is typically painful with any shoulder condition. Likely not helpful to diagnose a specific shoulder pathology as an individual test.
Internal Rotation Resistance Strength Test (Zaslav 01)	Non-specific shoulder pain	Resist external rotation then internal rotation with arm at 90° external rotation and 85° internal rotations.	Pain and/or weakness.	Differentiation of impingement/rotator cuff tendinopathy from other joint pathology. Not widely investigated; limited data.
Drop-arm (Park 05; Murrell 01; Hertel 96; Chronopoulos 04; (McGee 07))	Supraspinat us tendon	Arm raised and held in 90° of abduction then released.	Inability to hold the arm in place or inability to subsequently lower the arm smoothly.	Positive helpful to confirm rotator cuff full-thickness tear. Most likely to be positive in context of a massive tear and weak deltoid. (See below).
Hawkins (Park 05; MacDonald 00; Parentis 06; Calis 00; Nakagawa 05; Chronopoulos 04; Michener 09; McGee 07)	Supraspinat us tendon	Arm internally rotated while shoulder flexed to 90° with elbow flexed 90°.	Pain in shoulder joint and/or reduced ROM.	May be positive with arthrosis. As an individual test, is helpful to screen (rule out) but not confirm presence of rotator cuff tendinopathy.
Supraspinatus/ Jobe Empty Can Test (Park 05; Boileau 04; Holtby 04; Litaker 00; Itoi 99, 06; Hertel 96; Leroux 95; Michener 09)	Supraspinat us tendon	Resisted arm elevation with shoulder in 90° scapular place elevation and internal rotation.	Reproduction of pain in shoulder joint or weakness due to pain in the shoulder compared with the unaffected side.	Positive for painful superspinatus pathology.
Rent test (Wolf 01; Lyons 92; Codman 34; McGee 07)	Supraspinat us tendon	Transdeltoid palpation with feeling of a rent, sulcus or depression where the supraspinatus tear is present.	Rent in rotator cuff consistent.	Positive rent consistent with large superspinatus tear. Utility likely reduced with obesity.
Internal Rotation Lag Sign (Scheibel 05; Hertel 96; Miller 08) Lift-off (Barth 06; Scheibel 05; Hertel 96; Itoi 06; Gill 07; Leroux 95; Gerber 91)	Subscapulari s tendon	Patient places hand over posterior lumbar region, hand passively lifted away from back. Patient to maintain position. Attempted lifting of arm off back at level of the waist.	Inability to maintain position or pain or weakness.	Rotator cuff tears, thought to be specific for subscapularis. Confounded by limitation of passive shoulder internal rotation.
Belly Press (Tokish 03)	Subscapulari s strength	Performed particularly on patients who cannot fully internally rotate. Patient pushes against their belly (approximately 45° shoulder abduction, internally rotated with 90°	Arm drops posteriorly or unable to elbow maintain in plane of body.	Inferred weakness of subscapularis. Operant characteristics unclear.

		elbow flexion). Sometimes performed with examiner pushing posteriorly on elbow.		
External Rotation Resistance Test (Park 05; Michener 09; Litaker 00; Murrell 01)	Infraspinatus and teres minor	Resist isometric contraction of shoulder external rotation	Pain or weakness	Marked weakness has ability to confirm and screen for full-thickness RC tears while milder weakness indicates rotator cuff tendinopathy. Limited ability to screen for and confirm rotator cuff tendinopathy.
External Rotation Lag Sign (Walch 98; Miller 08; Hertel 96; Castoldi 09)	Infraspinatus and teres minor	Shoulder maximally externally rotated when examiner behind patient, elbow flexed 90° and shoulder forward flexed 20°. Examiner releases arm.	Positive test is inability to maintain the position.	Rotator cuff full-thickness tears, particularly involving infraspinatus or teres minor. Stiffness (adhesive capsulitis) may confound exam.
Posterior Impingement Sign (Heyworth 09; Meister 04)	Infraspinatus tendon or supraspinatu s tendon	Arm is brought into a position similar to that noted during the late cocking phase of throwing – abduction to 90° to 110°, extension to 10° to 15°, and maximal external rotation.	Presence of deep posterior shoulder pain	Used to detect presence of articular-sided rotator cuff tears and posterior labrum lesions in patients with posterior shoulder pain.
Neer (Neer 72; Park 05; Guanche 03; Calis 00; Parentis 06; Nakagawa 05; MacDonald 00; Michener 09; McGee 07)	Impingement	Arm raised in forward flexion by examiner who holds down the spine of the scapula	Pain in the shoulder joint. Thought consistent with impingement syndrome.	May be positive with arthrosis. As an individual test, is contributes to ruling out, but not confirm or eliminate presence of rotator cuff tendinopathy.
Speed (Chronopoulos 04; Ardic 06; Gill 07; Guanche 03; Parentis 06; Nakagawa 05; Holtby 04; Ben Kibler 09; Morgan 98)	Biceps tendon	Resisted shoulder elevation with the shoulder in 90° of forward elevation and forearm in supination.	Pain in the bicipital tendon area.	Positive pain infers bicipital tendinosis or biceps tendon instability. Biceps tendinosis and elbow disorders may confound test. Can be positive with a labral tear and rotator cuff tendinopathy.
Yergason's (Guanche 03; Ben Kibler 09; Parentis 06; Nakagawa 05; Holtby 04; Morgan 98; McGee 07)	Biceps tendon	Resisted elbow flexion and forearm supination.	Pain in the bicipital tendon area signifying biceps or rotator cuff origin of pain.	Positive infers bicipital tendinosis or instability. Helpful to confirm rotator cuff tendonitis – not shoulder instability. Biceps tendinoses and elbow disorders may confound test.
Spurling's (Tong 02)	Neurological : neck	Neck extension with head rotated towards affected extremity. As traditionally taught, axial load is applied by the examiner. <sup>II</sup>	Reproduction of radicular pain into the extremity.	Helpful to confirm, but not helpful to screen (rule out) cervical radiculopathy.
Hoffmann-Tinel's (or "Tinel's")	Peripheral neuropathy	Tapping approximately 3-4 times over a peripheral nerve (or brachial plexus), generally with a reflex hammer. Most classically performed over discrete location such as carpal tunnel, but can be performed over any nerve or location.	Distal dysesthesias in the distribution of the nerve being tapped.	Thought to denote peripheral neuropathy. Increasing concerns it has too many false positives to be useful; and may be a normal finding.

\*Adapted particularly from Woodward 2000 and Dinnes, HTA 2003.

\$\$ Some caution is warranted as there are considerable methodological weaknesses of studies evaluating utility of clinical examination maneuvers, including poor descriptions of tests performed, lack of blinding, small sample sizes and evaluation in select populations. (Dinnes, HTA 03; Luime 04; Hegedus 08; Munro 09; Beaudreuil 09; Hughes 08; Beaudreuil 09; Park 05; Silva 08; Hanchard 08; Kim 07; Hughes 08; Miller 08; Jia 08)

#### †Column added to above references.

Caution is warranted as some patients have neck pain after this maneuver. Some examiners omit active compression of the head-neck.

## **B. NEUROLOGIC AND VASCULAR SCREENING**

As C5 or C6 radiculopathy may present as shoulder pain or dysfunction, and soft tissue disorders of the neck also sometimes present as shoulder pain. Examine the neck and cervical nerve root function with palpation, reflexes, strength (motor), and sensitivity to touch (sensory), guided by history and previous exam findings. Assess the vascular status of the shoulder, proximal upper extremity, and neck by checking peripheral pulses in neutral and stress positions, and edema and/or color changes. Thoracic outlet syndrome (TOS) has signs and symptoms of scalene tenderness and positive maneuvers that provoke neurovascular signs and symptoms; for example, Hofmann-Tinel's sign may be positive over the brachial plexus. Tests for TOS are most useful in the correct context. Once all other diagnoses have been ruled out and TOS is suspected, referral to a surgeon is recommended if entertaining an option of invasive treatment.

## C. ASSESSING RED FLAGS

Physical examination evidence of septic arthritis, neurologic compromise, cardiac disease, or intraabdominal pathology that correlates with the medical history and test results may indicate a need for immediate consultation. Consultation may further reinforce or reduce suspicions of tumor, infection, fracture, or dislocation. A medical history that suggests pathology originating in a part of the body other than the shoulder might warrant examining the cardiovascular and respiratory systems, abdomen, or other areas. Painless full ROM of the shoulder suggests referred pain.

Disorder	Medical History	Physical Examination
Fractures	History of significant trauma (e.g., direct, deceleration, slip, trip, fall, motor vehicles) Severe pain and inability to move the shoulder	Generally severe pain Inability to move or use the arm and shoulder Significant bruising or hemarthrosis Deformity consistent with displaced fracture (with fracture, check for pulmonary injury and rib fracture as well) Significant swelling
Dislocation (glenohumeral joint)	History of significant trauma History of prior dislocation Presence of deformity, some with history of spontaneous reduction or self-reduction Severe pain and inability to move the shoulder	Deformity consistent with unreduced dislocation Anterior more common than posterior Inability or reduced ability to move the shoulder
Infection	<ul> <li>History of systemic symptoms of infection (e.g., fevers, chills)</li> <li>Persistent, severe shoulder pain</li> <li>May have other, distant sites with symptoms of infection</li> <li>Diabetes mellitus</li> <li>History of immunosuppression (e.g., transplant, chemotherapy, HIV)</li> </ul>	Limited range of motion due to severe pain Systemic signs of sepsis (elevated temperature, chills, hypotension, tachycardia) If AC joint, will usually have effusion, tenderness and may have overlying erythema. If subacromial, may have erythema and swelling. If glenohumeral joint, often no findings other than limited shoulder range of motion and pain.
Tumor	Pain at rest History of smoking or other risk factor History of any cancer present or prior (especially lung) History of immunosuppression (transplant, chemotherapy, HIV)	Palpable mass Tumor vessels Distant findings of cancer Compression neuropathy (see Neurologic compromise)
Progressive or	Progressive or acute decreased sensation and	Decreased upper-extremity sensation, strength,

## Table 2. Red Flags for Potentially Serious Shoulder Conditions

acute neurologic compromise	weakness History of neurologic disease History of diabetes mellitus Degenerative disk disease or disk herniation with cervical root impingement(s) or spinal stenosis History of trauma	and/or reflexes with peripheral neuropathy. Possibly pain. Myotomal and dermatomal deficits and reduced reflexes if nerve root(s) involvement
Progressive vascular compromise	Generally unrelenting painful and cold extremity History of vascular disease History of diabetes mellitus History of atherosclerosis (or usually multiple cardiovascular disease risk factors) History of syphilis History of dislocation, fracture, etc. History of high-impact collision	Decreased pulses in the upper extremities Cold, pulseless extremity Pain-free full shoulder range of motion Differential blood pressure in upper extremities Bruit (e.g., with thoracic aortic aneurysm)
Cardiac condition	History of angina or coronary disease History of cardiac risk factors (smoking, high cholesterol, high blood pressure, obesity) Family history of heart disease, especially under age 55 in affected relatives	S3 or S4 heart sounds Dysrhythmia Cold, clammy skin Mood appears apprehensive Hypotension Pain-free full shoulder range of motion
Subdiaphragma tic conditions	History of subdiaphragmatic condition (gallbladder, pancreatic or liver disorder, perihepatic, pelvic inflammatory disease, or cervicitis) Perforated viscus	Tender right upper quadrant Palpable mass in right upper quadrant Evidence of pelvic infection Evidence of perforated viscus, free abdominal air

## **DIAGNOSTIC CRITERIA**

The cause of patient's shoulder complaints should be determined as accurately as clinically possible at the time the patient presents. Some imaging may be appropriate acutely – e.g., x-ray in trauma cases. (Consensus recommendations for imaging can be found on the American College of Radiology Appropriateness Criteria web site at

<u>www.acr.org/secondarymainmenucategories/quality\_safety/app\_criteria.aspx</u>.) If red flags are present (see above), enact or arrange definitive care or treatment. (Brox 03; Linsell 06) If no red flags for serious conditions are present, then develop a plan of care. As many patients will have significant and sufficient improvement in the first weeks, only some will need additional examination and imaging to confirm or refine the diagnosis, prognosis, and surgery or further treatment or MRI showing a labral or rotator cuff tear. The criteria presented in Table 3 follow the clinical thought process for non-red flag conditions, from the mechanism of illness or injury to unique symptoms and signs of a particular disorder, and to test results, if any tests are needed to guide treatment at this stage.

Probable Diagnosis or Injury	Mechanism	Unique Symptoms	Unique Signs	Tests and Results
Nonspecific shoulder pain	No known specific mechanism.	No unique symptoms. Pain in shoulder musculature.	None	None indicated for most acute presentations.
				All with persistent symptoms should have plain radiographs to rule out occult tumor.
Impingement/Rotator Cuff Tendinopathy; rotator cuff tendinosis, including partial thickness	Generally gradual onset of shoulder pain. May have more acute presentation. Pain becomes symptomatic or increases with overhead	No unique symptom. Non-radiating pain in shoulder and/or deltoid area.	Negative Neer and Hawkins impingement sign are helpful to rule out/screen. Many non-specific	Initial imaging should be plain radiographs to evaluate for glenohumeral arthritis,

## Table 3. Diagnostic Criteria for Non-red Flag Shoulder Disorders

tears	use.	Night pain in shoulder joint.	signs, such as Neer's and Hawkins' impingement signs and painful arc may be positive.	degenerative changes associated with rotator cuff pathology, calcific tendinitis, degenerative acromial changes (type II or III). MRI with chronic rotator cuff degenerative changes. Many patients with rotator cuff disorders can have normal or non-specific MRI findings.
Calcific tendinitis	Degeneration Chronic pain: some present with acute onset of severe atraumatic pain. Location of pain and physical exam findings relate to the location of the calcific lesion. Most commonly in supraspinatus tendon but can also present in subscapularis, infraspinatus and teres minor, much less commonly in biceps long head.	Chronic non-severe pain: no unique symptom. Onset similar to rotator cuff syndromes. Acute severe pain: severe onset of atraumatic shoulder pain	When calcific lesion is in supraspinatus, patients often have pain with abduction and limitation of motion, but not with scapular plain elevation (atypical presentation for rotator cuff syndrome). Subscapularis lesion more likely to have pain anteriorly.	Plain radiographs able to identify calcium in tendon. Chronic pain: calcium in tendon(s) Acute severe pain: often large well- defined lesions although some have more diffuse calcification that probably represents rupture of the lesion. Occasionally, patients with rotator cuff syndromes have small incidental calcifications in the mid-substance or near the cuff insertion.
Subacromial Bursitis	No different than impingement and rotator cuff syndromes. Possibly due to forceful or unaccustomed use. Commonly occurs in conjunction with degenerative rotator cuff tendinopathies. Rheumatoid arthritis, other systemic rheumatological disorders.	No unique symptoms. Night pain thought to be more common with this disorder.	No unique sign. Tenderness over subacromial bursa. See also above regarding rotator cuff tendinopathy.	Same as other rotator cuff syndromes. None usually indicated.
Rotator cuff tear, acute and chronic	Degenerative condition with superimposed forceful use. May occur without any inciting event. Inciting events include heavy lifting, sudden pull, fall on outstretched arm.	Symptom presentation is dependent on many factors including speed of tear (acuity) and size along with compensatory mechanisms. Acute moderate to large tears: marked decreased ability to abduct arm and moderately painful, non-radiating shoulder pain. Symptoms may be	To support diagnosis, weakness of shoulder in "thumbs down" abduction (Empty can test), weak external rotation, lag sign, and lift-off test may be helpful, but specificity is questionable. May have normal or near normal strength. Positive drop-arm test is most specific examination finding for large tears.	MRI positive for acute tears in younger workers. Arthrography positive for full thickness tears (if MRI or CT arthrography unavailable). MRI may show partial-thickness tears. Ultrasound exam

		less pronounced or absent.		
Labral tear	Direct trauma laterally to shoulder. Fall on outstretched hand. Dislocation. Throwing motions. May occur without specific injury.	Mechanical symptoms, painful catching sensation. Usually also have nonspecific, non- radiating shoulder joint pain. Pain with movement. Labral tear presentation can depend on kind of tear: SLAP tear, tear of other parts of labrum without instability, labral tear with instability.	Anterior slide test is reportedly 78.4% sensitive and 91.5% specific. (Kibler 95) Sensitivity of O'Brien's test 90%, Mayo shear (Dynamic Labral Shear test) 80% and Jobe's relocation test 76% when compared with arthroscopy. (Pandya 08; Ben Kibler 09)	MRI, MR arthrography. Often accompanied by other shoulder pathology.
Shoulder instability	Trauma Acquired non-traumatic Congenital anatomic problem or laxity	Slipping Popping Feeling of instability "Dead arm" syndrome	Positive apprehension test, relocation and anterior release test for anterior stability. Positive sulcus test with multidirectional instability (MDI)	Plain radiographs to demonstrate glenoid rim fracture or Hill- Sachs lesion. CT arthrogram evaluates bone lesions and labral pathology.
Recurrent dislocation (nonacute)	Previous dislocation from any cause. May recur due to a fall or direct impact or without significant event.	Recurrent dislocation. Fear of dislocation when shoulder is abducted in external rotation.	Positive apprehension test, relocation, and anterior release test with anterior instability	MRI/MR arthrogram. Radiographic films (including lateral axillary) positive for dislocation if humerus has not spontaneously reduced.
AC joint sprain	Fall on top of shoulder.	Pain over AC joint.	Tender over AC joint. May have swelling of joint, but not deformity as with AC separation.	Consider radiographic films to rule out fracture.
AC joint separation	Fall on top of shoulder. Object falling from above onto shoulder.	Severe pain over AC joint.	Deformity over AC joint (i.e., high-riding distal clavicle)	Plain radiographs with separation (>5mm).
Osteonecrosis	Multifactorial. Occupational factors include compression/decompression (dysbarism). Non- occupational factors include glucocorticoids, alcohol, diabetes, and smoking.	Progressive, non- radiating pain in head of humerus. Pain tends to be at rest as well as with use.	May have pain with use of movement, but exam may also be relatively normal. If bony collapse, marked pain with movement.	Plain radiographs. MRI usually used and shows diagnostic findings.
Adhesive capsulitis	Idiopathic Failed treatment or inactivity Diabetes mellitus Hypothyroidism	Limited range of motion. Pain end range of all motions. May have night pain in shoulder joint.	Limited passive range of motion in 3 or more directions, as well as active ranges of motion.	Plain radiographs to rule out glenohumeral arthritis, calcific tendinitis. MRI if indication of red flag (infection, tumor) or if initial non-operative treatment fails.

## WORK-RELATEDNESS

A thorough work history is important to establish work-relatedness (see General Approach to Initial Assessment and Documentation Guidelines for components of work history). Acute occupational shoulder injuries are related to a specific acute traumatic event – the location of the event determines work-relatedness and is non-controversial if the effects are immediate and visible. Most jurisdictions also request an expert opinion as to whether a disease or disorder should be considered work-related for the purpose of workers' compensation. The physician's role is to supply opinion based on medical evidence. The "medical/scientific" answer and the "legal" answer as determined by regulations and case law precedents in a particular jurisdiction (workers' compensation system) are different physician have an ethical responsibility not to simply advocate for their patients. (AMA Council Ethical Judicial Aff 02) Despite the fact that most physicians should not be expected to know details of the law in the jurisdiction in which they render an opinion, they should know most shoulder disorders involve underlying chronic disease conditions and work-relatedness is often unclear.

Most epidemiological studies of shoulder disorders are retrospective and either include body regions beyond the shoulder such as the interscapular region, (Harkness 03; Andersen 93a, 03, Bernard 94; Burdorf 91; Burt 90; Chiang 93; Flodmark 92; Hales 89; Hoekstra 94; Hughes 97; Ignatius 93; Jonsson 88; Kiken 90; Kilbom 86; Kvarnstrom 83; Magnusson 96; Milerad 90; Ohara 76; Ohlsson 89; Onishi 76; Ostergren 05; Picavet 03; Punnett 85; Rossignol 87; Sakakibara 87, 95; Schibye 95; Partridge 68; Ekberg 95; Sweeney 94; Wells 83) Combine shoulder pain with neck pain, (Aaras 94; Alipour 09; Andersen 93a,b, 03; Bergqvist 95a,b; Bjelle 81; Blader 91; Brandt 04; Ekberg 94, 95; Eltayeb 09; Feveile 02; Fredriksson 2000; Ghaffari 06; Grooten 07; Hagberg 87; Holmstrom 92a,b; Hooftman 09; Hunting 81; Jonsson 88; Kaergaard 00; Kilbom 86, 87; Lapointe 09; Linton 89; Luime 04; Milerad 90; Nyman 09; Ohara 76; Ohlsson 95; Punnett 91; Rossignol 87; Ryan 88; Tola 88; Tornqvist 09; van den Heuvel 06; Vihma 82; Viikari-Juntura 91) rely solely on subjective data (such as questionnaires for disease and/or exposure data), and fail to measure job physical factors. (Bernard NIOSH 97; Kuorinka 95; Welch 95; Kamwendo 91; Punnett 85; Trinkoff 02; Roquelaure 02; Frost 99) This produces considerable uncertainty in these data; statements referable to or actions resulting from these studies should reflect the weakness of the evidence. For most disorders, there is insufficient evidence to conclude causal occupational associations.

No quality ergonomic assessment tools have been developed or validated to establish work-relatedness. For the distal upper extremity, the Strain Index (Moore 95) appears to be the most reliable tool. It has been reported to have some predictive power for shoulder disorders (Hegmann 06) despite including some components such as hand/wrist posture that are presumably irrelevant. Force is believed to be the major risk for shoulder disorders, (Silverstein 08; Garg 02, 05, 06) which may provide some basis for ergonomic assessments of jobs. The lack of quality ergonomic-epidemiological studies combined with the lack of quality ergonomic job assessment tools is markedly limiting for purposes of both prevention of disorders as well as assessments of work-relatedness of individual cases.

## Rotator Cuff-related Disorders (including tendinoses, partial- and full-thickness tears, impingement syndrome and subacromial bursitis)

Risk factors for rotator-cuff related disorders are not well defined. There are no large prospective cohort studies that include physical examinations and detailed job physical exposure measurements to compare, contrast, or quantify purported job physical factor risks. There also are no quality studies of bursitis and few of impingement syndrome. In the absence of other evidence or disorders (e.g., rheumatoid arthritis), it is suggested the following discussion of shoulder tendinoses applies to those conditions.

Shoulder tendinitis was found to be elevated in a cross-sectional study of shipyard welders (Herberts 81) and another study of shipyard plate workers. (Herberts 84) However, both studies were limited by retrospective methods without adjustments for potential confounders. EMG evidence of supraspinatus fatigue was found with overhead shipyard welding. (Herberts 76) A small case-control study of shoulder tendinitis cases found elevated risks among those with hand use at or above the shoulder. (Bjelle 79) Another case-control study which measured job physical factors found elevated risks among those with frequent activity and abduction or forward flexion more than 60° (Bjelle 81); another found force to be associated with increased risk. (Roquelaure 02) A moderately large cross-sectional study reported 5-fold

increased risks for a composite of multiple shoulder disorders (rotator cuff tendinosis, frozen shoulder, acromioclavicular and glenohumeral degenerative joint disease) among those with using high force or high repetition. (Silverstein 85) Other cross-sectional studies found elevated risks of rotator cuff syndrome among sewing machine operators, (Andersen AmJIndMed 93b) grocery checkers, (Baron 91) and fish processing workers. (Ohlsson 94) A population-based registry study of fishery workers found elevated risks for rotator cuff syndrome. (Kaerlev 08) A cross sectional study from a retrospective cohort found elevated risks of shoulder impingement syndrome among meat processing workers. (Frost 99) Another large cross sectional study that included ergonomic assessments found high force and repetition to be associated factors of up to 3- to 4-fold magnitudes. (Frost 02) Workers with higher force requirements appear to have increased risk of shoulder tendinosis and rotator cuff tears when identified in large administrative databases. (Silverstein 02; Zakaria 04)

One prospective cohort study suggested high-hand force was associated with an increased risk of rotator cuff tendinosis. (Silverstein 06, 08, 09) However, not all data support that supposition. (Miranda 05; Yamamoto 09) High force and high repetition, and repetition alone (Descatha 09) are reported risk factors. (Melchior 06; Roquelaure 06) Other data suggest working with the hands above the shoulder is a risk factor (Miranda 05) and another suggested long duration of shoulder flexion. (Silverstein 08) However, these results are not consistent among studies. Other studies have not found elevated risks of shoulder tendinitis, including one of assembly line packers (Luopajarvi 79) and others of manufacturing workers, (McCormack 90) sewing machine workers, (McCormack 90) heavy work, (Bergenudd 88) bricklayers, (Stenlund 93) rockblasters, (Stenlund 93) and data entry workers.<sup>iv</sup> (Kukkonen 83) A prospective cohort study to evaluate risks of shoulder postures found large within-group variance in exposures and an inability to detect postural risks for shoulder disorders. (Fallentin 01) Unaccustomed use is believed to be a risk factor, particularly involving forceful use that the individual does not normally perform.

Psychosocial factors have been associated with the presentation of rotator cuff tendinitis, including self perception of poor health. (Kaergaard 00; van Eijsden-Besseling 10; Macfarlane 08) However, most studies of psychosocial factors evaluated combined neck-shoulder disorders or shoulder girdle pain. These studies found risks that included stress, (Kaergaard 00; Bernard 94) job demand, (Johansson 94; Cassou 02; Andersen 03; Eltayeb 09; ven den Heuvel Pain 05) high distress, (Andersen 03; Manninen 97) high psychological demand, (Leroyer 06; Roquelaure 09) low job control, (Cassou 02; Andersen 03; Skov 96; Silverstein 08) job strain, (Grooten 07; Torngvist 09; Östergren 05) low social support, (Kaergaard 00; Andersen 03; Harkness 04) job dissatisfaction, (Andersen 07; Harkness 04) depressive symptoms, (Mäntyselkä 10) low job security, (Silverstein 08; Cassou 02) smoking, (Kane 06; Kaergaard 00) living alone with children, (Kaergaard 00) low socioeconomic status, (van Eijsden-Besseling 10), and work organizational issues. (Myers 02) Risks of disability were higher among foreign-born workers and women in a Swedish population-based prospective cohort study. (Borg 01) Reduction in risk of shoulder and neck pain has been reported with regular leisure time physical activity. (van den Heuvel 05) However, another study suggested inconclusive evidence of the relationship between physical capacity and risk of shoulder pain. (Hamberg-van Reenen 07) A Finnish study reported increased risk of early retirement particularly among those with both heavy physical work combined with low cardiorespiratory fitness. (Karpansalo 02)

Non-occupational risks for rotator cuff-related disorders: Rotator cuff disorders are not characterized by frank inflammation; however, inflammatory mediators may be present in rotator cuff tear, tendinitis and impingement patients. These include increased: interleukin-1, (Sakai 01; Gotoh 01; Voloshin 05) interleukin-6, (Voloshin 05) tumor necrosis factor-alpha, (Voloshin 05; Sakai 01) basic fibroblast growth factor, (Sakai 01) transforming growth factor, (Sakai 01) metalloproteinases, (Voloshin 05) CD2-positive T-lymphocytes, (Santavirta 92) tenascin-C, (Hyvönen 03) substance P (Gotoh 98) and vascular endothelial growth factor. (Yanagisawa 01) It is unknown whether these factors precede or are a consequence of the disease

<sup>&</sup>lt;sup>iv</sup> Many of the epidemiological studies are sufficiently old that the work tasks likely are no longer performed or are substantially different today. Regardless, these studies are included to provide the references of the exposures, not the job tasks per se.

processes. Associations have been found between severity of musculoskeletal disorders (MSDs) and inflammatory mediators. (Carp 07)

Some factors increase risk for shoulder pain, rotator cuff related disease, and atherosclerosis, (Wendelboe 04; Viikari-Juntura 08) including obesity (Morken 00; Silverstein 08; Miranda 01; Luime 04; Wendelboe 04; Roquelaure 09) smoking, (Skov 96; Morken 00; Stenlund 93; Kane 06; Kaergaard 00; Baumgarten 10; Leino-Arjas 98), hypercholesterolemia (Abboud 10), and diabetes mellitus. (Miranda 05; Roquelaure 09; Cole 09) These factors may be reduced with active exercise. (Miranda 01) Genetic factors are also reported risks (Nyman 09; Tashjian 09).

The prevalence of full-thickness rotator cuff tears in asymptomatic individuals over age 50 is reported to be 6 to 51%. (Worland 03; Sher 95; Yamamoto 10) In cadavers, 23.1% had partial or full-thickness tears. (Reilly 06) Age is a major risk factor for tendinitis and full and partial-thickness rotator cuff tears. (Worland 2003; Sher 95; Tempelhof 99; Schibany 04; Sakurai 98; Yamamoto 09, 10; Linsell 06; Cassou 02; Roquelaure 06; Clayton 08; Yamaguchi 06; Miranda 05; Silverstein 08; Wilson 43; Moosmayer 09; Neer 72; Milgrom 95; Miniaci 95; Reilly 06; Codman 34; Keyes 35; Cotton 64) Risk is greater on the dominant side, (Yamamoto 09, 10; Silverstein 08) although that is not a universal finding (Milgrom 95).

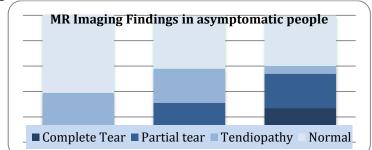


Figure 1. Prevalence of Rotator Cuff Abnormalities on MRI by Age

Adapted from Needell S, Zlatkin M, Sher J, Murphy B, Uribe J. MR imaging of the rotator cuff: peritendinous and bone abnormalities in an asymptomatic population. *Am J Roentgenol*. 1996;166(4):863-7.

Tears of the supraspinatus tendon have been associated with tears of the remaining rotator cuff tendons, including the subscapularis, (Sakurai 98) as well as bicipital tendon tears. (Beall 03) The prevalence of Type II and III acromions rises with age and is associated with rotator cuff pathology and tears in asymptomatic (Worland 03; Zuckerman 94) and symptomatic patients. (Gill 02) Over age 70, the prevalence of Type II and III acromions is 80 to 93%. (Worland 03; Milgrom 95) Evidence also suggests a relatively weak association between cuff tears and acromial types. The reliability of classifying acromial type is poor, although large spurs have been associated with a higher risk of tear. (Ogawa 05)

Degenerative processes tend to occur in both shoulders. (Yamaguchi 06) Risk factors reported for degenerative processes include heredity, (Tashjian 09) ankylosing spondylitis, (Lambert 04) rheumatoid arthritis, crystal diseases (gout, pseudogout, hydroxyapatite), trauma, (Yamamoto 09) and sports activities. (Stenlund 93)

## Acromioclavicular (AC) Sprain, Separation and Dislocation

AC joint sprains and separations are mostly reported in sports from blows to the shoulder or falls (Stuart 95; Dohjima 01; Webb 92; Nordqvist 95); predominately among young males in the second and third decades of life. (Clayton 08) Some AC injuries may occur as a result of occupational injuries including falls. Shoulder separation should be visible, or at least documentable, by radiographic study.

## Acromioclavicular (AC) and Glenohumeral Arthrosis

The shoulder is sometimes clinically affected by arthrosis. (Petersson 83) In symmetrical cases, an occupational basis is difficult to identify. There are no consistent findings of one job type or class to be associated with shoulder arthroses involving either joint. There is also an unfortunate propensity towards osteoarthrosis to develop in other joints in the body once an individual has already developed

symmetrical arthrosis in another body region, likely signifying genetic or other systemic predispositions (systemic osteoarthrosis). Age is a clear osteoarthrosis risk. (Bonsell 00) All joints are susceptible to involvement with systemic rheumatological conditions, including rheumatoid arthritis. (Lehtinen 99) These joints are also affected by crystal arthropathies including gout and pseudogout. Obesity may act through a systemic mechanism. (Felson 00, 88; Oliveria 99; Acheson 75) Anatomic evidence of AC joint arthrosis is common with an estimated prevalence of 29% of cadavers that included apparent age-related effects (Bonsell 00) as well as more AC arthrosis on the right side. (Mahakkanukrauh 03) Elevated risks of acromioclavicular arthrosis have been reported in fish-processing workers, (Ohlsson 94) bricklayers, (Stenlund 92) and those active in sports. (Stenlund 93) Glenohumeral arthroses are much less investigated for work-relatedness, although some cases likely occur after work-related fractures and are thus occupational.

## **Adhesive Capsulitis**

Most cases of adhesive capsulitis are idiopathic. Although some persons may claim to develop pain or limited mobility after a minor injury, and subsequently be assigned a diagnosis of adhesive capsulitis, there are currently no quality studies demonstrating cause and effect. Adhesive capsulitis may occur due to systemic risk factors. Some patients develop adhesive capsulitis based on systemic risks such as diabetes mellitus and hypothyroidism. (Balci 99; Arkkila 96) Shoulder contracture after surgery may present similarly to adhesive capsulitis.

#### **Fractures**

All shoulder fractures, except for pathologic fractures, are the result of trauma. Fractures can occur due to sporting or occupational accidents. Fractures in younger adults are more likely to involve higher energy trauma than those in the elderly, potentially due to osteoporotic changes with aging. Falls are the most common cause of shoulder fractures among the elderly. (Lind 89)

## **Glenohumeral Dislocation, Instability**

A first-time occurrence of dislocation in the context of a discrete violently-traumatic event is work-related. In individuals with a prior history of dislocation, there is an increased risk of re-dislocation and/or instability. Redislocation in the absence of a significant work accident or event is non-occupational. There are less clear cases in which there is prior instability but an occupational event that sometimes results in the cases being considered work-related, depending on the magnitude of the event. Multiple studies show that recurrence of shoulder dislocation is common in multiple population and clinical studies, (Hovelius 08; Griffith 08; Owens 07; Headey 07; Cho 06; Vermeiren 93) with some studies of shoulder dislocation showing the majority of persons who experienced shoulder dislocation had recurrence, (Headey 07; Vermeiren 93; Myers 04; Moreau 01) with re-dislocation rates up to 62% (Myers 04) and 68%, (Moreau 01) depending on the population. Overall, the earlier (younger) the initial dislocation, the likelier redislocation. (Hovelius 08) Depending upon the age of the patient, glenohumeral dislocation can cause substantial rotator cuff injury. Proprioceptive (position-sense) deficits might contribute to shoulder instability and injury. (Myers 04; Shibata 04; Moreau 01) It is unknown whether proprioceptive deficits precede and dispose to injury or result from injury.

#### Labral Tears

There are no quality epidemiological studies of causes of labral tears or the reasons labral tears become symptomatic. Labral tears frequently accompany glenohumeral dislocation (dislocated shoulder). Aging may be a risk factor. (DePalma 49)

#### Trigger Points/Myofascial Pain/Muscle Tension Syndromes

No quality epidemiological studies demonstrate a work relationship for myofascial pain and trigger points. There is epidemiological evidence that certain cases of muscle tension syndrome may be occupational and that this disorder may be related to myofascial pain. (Kuorinka 79; Knave 85; Rossignol 87; Viikari-Juntura 83; Yu 96; Milerad 90; Onishi 76; Kaergaard 00) However, the quality of studies reported has been suboptimal. True risk factors are not well defined. (Rudolph 97) Myofascial pain is often determined to be work-related when the pain arises in a body part subject to a clear occupational injury or when there is an inciting event without prior history, the pain and signs are limited to one body region, and are not bilateral or

disseminated. Myofascial pain syndrome has been reported to be related to years of sewing with higher prevalence in those inexperienced and those with long years on the job, i.e., a U-shaped relationship. (Kaergaard 00) Stress has also been associated with myofascial pain syndrome. (Kaergaard 00) Fibromyalgia is a non-occupational condition and is reviewed in the Chronic Pain Guidelines (see Appendix 1).

## **Thoracic Outlet Syndrome**

There are no quality studies that address thoracic outlet syndrome. Thus, work-relatedness is unknown and cases without an identifiable cause of compression are controversial. (Sheth 01; Wilbourn 90) Some cases occur due to neurovascular compression, including cervical ribs, and thus are congenital. Others occur due to sequelae of trauma (e.g., scar tissue) or secondary to another shoulder disorder. Many occur without a clear provoking cause, although some patients report worse symptoms at work. (Wilbourn 90; Watson 09) However, reported worsening with activities or at work does not show a cause-and-effect relationship.

## **Nonspecific Shoulder Pain**

There are no quality studies documenting that non-specific shoulder pain is or is not an occupational condition. Non-specific pain has been associated with keyboarding. (Yu 96) In non-specific shoulder pain, psychosocial issues including depression and stress are more prevalent. (Miranda 05) There is evidence that non-specific shoulder pain is also commonly related to sports, particularly swimming. (McMaster 93; Rupp 95; Richardson 80; Penny 80; Kennedy 78; Bak 97; Stocker 95)

# ERGONOMIC INTERVENTIONS FOR SHOULDER DISORDERS WITH AN OCCUPATIONAL BASIS

In order to facilitate recovery and prevent recurrence of shoulder disorders, the physician may recommend work and activity modifications or ergonomic redesign of the workplace. (Keogh 00) The employer's role in accommodating activity limitations and preventing further problems through ergonomic changes is believed to be crucial in hastening the employee's return to full activity. It may be desirable to conduct an ergonomic analysis of the activities that may be contributing to the symptoms. There are no quality validated ergonomic surveys or instruments available at this time for evaluating shoulder exposures. (Garg 02, 05, 06; Cann 08; Stephens 06; Rucker 02) Evaluations of force (weights of parts and tools lifted, moment arms, torque), duration of exertion, and shoulder posture (forward flexion, abduction, horizontal relationships and job satisfaction should also be assessed. Modifications of activity, workstation redesign, or organizational and management changes may be considered. Consultation with a certified ergonomist, occupational or physical therapist, human factors engineer, or occupational medicine physician is suggested.

1. Recommendation: Ergonomic Interventions for Shoulder Disorders, Particularly Rotator Cuff Tendinopathies

Ergonomic interventions are recommended in settings with combinations of risk factors (e.g., high force combined with forward flexion and/or abduction and high repetition) to reduce risk factors for rotator cuff tendinopathies.

Strength of Evidence – Recommended, Insufficient Evidence (I)

 Recommendation: Typing Posture for Prevention and Treatment of Shoulder Disorders Mandating the traditional sitting posture at a keyboard or desk with elbows, hips, and knees at 90° of flexion is not recommended for prevention or treatment of shoulder/neck disorders. Strength of Evidence – Not Recommended, Evidence (C) – Prevention

Not Recommended, Insufficient Evidence (I) – Treatment

3. Recommendation: Keyboarding Breaks for Patients with Shoulder Disorders and for Primary Prevention Keyboarding and computer (mousing) breaks are recommended for primary prevention and for patients with symptoms of shoulder disorders.

Strength of Evidence – Recommended, Insufficient Evidence (I)

4. Recommendation: Forearm Support for Typing to Prevent Neck/Shoulder Symptoms Forearm support for frequent computer keyboard users is recommended for potential prevention of neck and/or shoulder symptoms.

Strength of Evidence – Recommended, Evidence (C)

- 5. Recommendation: Ergonomics Training in Moderate- or High-risk Manufacturing Settings Ergonomics training is recommended in moderate- or high-risk manufacturing settings. Strength of Evidence – Recommended, Insufficient Evidence (I)
- 6. Recommendation: Ergonomics Training for Prevention of Musculoskeletal Disorders (MSDs) in Office Settings

There is no recommendation for or against the use of ergonomics training for the prevention of MSDs in office settings.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendations

Quality studies of ergonomics interventions have been reported only for office settings. (Verhagen 06; Rempel 99, Rempel 06; Gerr 05; Tittiranonda 99) Nevertheless, in jobs with high ergonomic factors, particularly combined high force, shoulder postures between 90 and 120° of forward flexion or abduction and highrepetition, interventions are recommended to reduce exposures (Garg 02, 05, 06; Herbert 00)

Quality evidence has reported no beneficial effects of the 90° typing posture (seated erect; feet on floor; knees, hips, and elbow joints all at 90° angles), instead it has the same injury rates as a laid-back posture when examining distal upper extremity disorders of neck/shoulder symptoms. (Gerr 05) Quality evidence suggests reductions in neck/shoulder symptoms might be realized through utilization of a forearm support. (Rempel 06)

Breaks from computer typing have been addressed in a low-quality study that reported reductions in symptoms, but no additional benefit from utilizing exercise during breaks. (van den Heuvel 03) Various types of breaks have been utilized including stretching breaks and exercise programs. (Lee 92; Galinsky 00, 07; Carter 94; Silverstein 88; Feuerstein 04; Fenety 02; Balci 04; Henning 97) Quality evidence supporting the efficacy of breaks is weak, especially for symptomatic patients. (Galinsky 00, 07; van den Heuvel 03) One low-quality randomized study among an apparently asymptomatic population of temporary data-entry workers suggested fewer symptoms among those taking breaks; however, compliance was low (ranging from 25 to 39%). Breaks are not invasive, have no substantial adverse effects, are low cost, and do not appear to impair productivity. (Henning 97; Galinsky 00; Balci 03, 04; McLean 01; van den Heuvel 03; Floru 87; Sauter 92; Kopardekar 94) Widespread use of these programs has not been reported in quality studies; however, with no apparent significant cost impacts and studies suggesting potential benefits, breaks are recommended for both primary prevention and treatment of symptomatic patients.

While quality evidence is lacking regarding the use of ergonomics training, it is thought to be beneficial in high-risk settings. One study suggested that training is inferior to a combination of other interventions in an office setting (Rempel 06) and another found benefits for the neck, but not distal upper extremity. (Ketola 02) An RCT comparing wrist splinting with ergonomic education found splinting superior. (Werner Arch Phys Med Rehabil 05) If there is a benefit of ergonomic training, it may be modest. Training should consist of quality information.

## **RETURN-TO-WORK PROGRAMS**

Return-to-work programs have not been well studied among patients with shoulder disorders (see Chronic Pain Guidelines). Generally, these programs include gradual increase in shoulder use, especially focusing on strength, repetition, and endurance. Several studies suggest that job physical demands, lack of job accommodation, and psychosocial conditions are the most important factors in predicting work disability. (Turner 07; Bonzani 97; Gimeno 05)

1. Recommendation: Return-to-work Programs for Treatment of Subacute or Chronic Shoulder Disorders Return-to-work programs are recommended for treatment of subacute or chronic shoulder disorders, particularly in patients with significant lost time.

*Indications* – Patients with subacute or chronic shoulder disorders who have completed acute treatment. Generally should have attempted at least 1 trial of return to work that was unsuccessful. May also have trialed a second, more graded return to work, both of which were unsuccessful. (Acute pain patients generally resolve and do not require a formal return to work program).

Strength of Evidence - Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

There are no quality studies that review the types of return-to work programs typically found in the U.S. There is one quality study from Spain; (Abasolo 07) however, the patients had spine disorders and the program otherwise may have limited applicability due to longstanding, early active management of these issues in the U.S. Thus, this study has limited if any applicability to the U.S. These programs are thought to reduce morbidity and improve function. They are not invasive, have minimal potential for adverse effects, and are not costly. Return-to-work programs are recommended for management of select patients with shoulder disorders with lost time, and may be helpful for proactive emphases on functional recovery.

## WORK ACTIVITIES

Work-activity modifications are often necessary during the treatment course for patients with acute and chronic shoulder pain, regardless of cause. Advice on how to avoid exacerbating activities that at least temporarily increase pain includes a review of work duties to decide whether or not modifications can be accomplished without employer notification and to determine whether modified duty is appropriate and available. Continuing activity helps prevent weakness atrophy and mobility loss. Slings generally should be avoided. For cases with moderately severe to severe pain, it may be reasonable to rest the shoulder by using a sling for no more than a few days. Gentle ROM exercises (e.g., pendulum) should be performed at least twice daily, even when a sling is provided. Patients should avoid work activities that precipitate or significantly increase symptoms during the acute phase of treatment, but should continue general activities and motion. Every attempt should be made to maintain patients at the maximal levels of activity, including work, hobbies, and sports activities as it is in patients' best interest. (Arnetz 03) Poorer prognosis with longer persistence of pain has been associated with slower onset of pain, higher pain severity at presentation, and longer duration of symptoms. (Kuijpers 06; Descatha 09)

The first step in determining whether work-activity modifications are required usually involves a discussion with the patient regarding whether he or she has control over his or her job tasks, the nature of those tasks, and the overall job physical demands. (Lotters 06) In such cases where the worker can make modifications, e.g., receive assistance to lift a box or reduce reaching, there may be no requirement to write any restrictions even if strength, ROM, or pain are limiting. In some situations, it may be advisable to confirm this report with the patient's supervisor to signal that the person is under treatment. In some cases, specified limitations may be a better treatment strategy. Assessment of work activities and potential for modifications may also be facilitated by a worksite visit and analysis by a health care provider with appropriate training (e.g., typically a physician, occupational therapist, physical therapist, or some ergonomists). Despite their limitations, ergonomic guidelines should be considered when assigning activity limitations.

Work limitations should be tailored by taking into account the following factors: 1) job physical requirements; 2) the safety of the tasks in consideration of the diagnosed condition, age, and relevant

biomechanical limitations; 3) severity of the problem; 4) work organizational issues (overtime, work allocation, wage incentives); and 5) the patient's understanding of his or her condition. Sometimes it is necessary to write limitations or to prescribe activity levels that are above what the patient feels he or she can do, particularly when the patient wants to avoid all activity. In such cases, the physician should be careful not to overly restrict the patient; education about the pain problem and the need to remain active should be provided.

It is best to communicate early in the treatment that limitations will be progressively reduced as the patient progresses. Experienced physicians communicate the intended changes in restrictions for the coming week (similar to forecasting increases in exercise program components) at the current visit to reduce the element of surprise and help actively facilitate the patient's most important elements of an active, functional restoration program. Tailoring restrictions is required in nearly all patients with chronic shoulder pain as there is great variability in symptoms and dysfunction. The employer should also be consulted when developing strategies to expedite and support integrating the patient back into the workplace (see Low Back Disorders). The physician can make it clear to patients and employers that:

- Patients sometimes have increased pain performing almost any function (even light duty) early in rehabilitation;
- Increases in symptoms should be heard with sympathy, and factors which are associated with significant increases in pain should be addressed;
- Increases in pain do not equate to injury;
- Any restrictions are intended to allow for time to build activity tolerance through exercise and work reconditioning; and
- Where appropriate, it may help to mention to the patient that this rehabilitative plan will also help him
  or her regain normal non-occupational activities.

The following are common limitations that may be needed for acute shoulder pain patients:

- No lifting more than 10 pounds (this may require adjusting up or down based primarily on the patients pre-morbid capabilities and the severity of the condition).
- Avoid more than 60° abduction or forward flexion. Although not necessarily anatomically correct, this
  is sometimes described as avoiding lifting with the hands above shoulder height to facilitate
  implementation.
- Some additionally required limitations such as avoiding static use or highly repetitive use.

The physician may also need to educate the employer that:

- Even moderately heavy (more than 20 pounds) unassisted lifting or repeated work at "shoulder level" (90° forward or sideways) or overhead may increase shoulder symptoms due to rotator cuff tendinopathy, rotator cuff tears, inflammatory conditions, ligament sprains, or impingement syndrome.
- Any restrictions are intended to allow for spontaneous recovery or time to (re)build activity tolerance through graded exercise.

As recovery occurs, as well as to facilitate recovery, gradual reduction in activity limitations is recommended. This generally involves progressive advancement such as no lifting more than 15 pounds for 1 to 2 weeks, then no lifting more than 20 pounds, etc., until the patient returns to normal activities. This is often accomplished in concert with supervised physical or occupational therapy, use of functional activities and/or home exercise program(s). Table 4 provides a guide for recommendations about durations of activity modification from initial injury. They are targets to provide a guide from the perspective of physiologic recovery and may assist in focusing on return of function. (Faber 06) Orthopedic surgeons often see patients who have failed initial non-operative management thus might have more patients who fall outside these targets. For example, post-operative shoulder patients often require greater initial limitations of no lifting of any weight and no use of the arm with gradually increased activity.

			led Target for Duration**	NHIS Experience Data***	
Disorder	Activity Modifications and Accommodation‡	With Modified Duty****	Without Modified Duty	Median (cases with lost time)	Percent (no lost time)
Acute tears in rotator cuff in younger workers	Refer for possible repair. Avoid work at a 90° forward or sideway position, pushing, pulling, and heavy lifting if patient wishes to avoid surgical repair.	1-2 days <sup>∎</sup>	21 days <sup>ii</sup>	27 days	66%
Symptomatic rotator cuff tear	Avoid work at a 90° forward or sideway position, pushing, pulling, and heavy lifting. Re-evaluate treatment approach if symptoms not resolved with non-operative treatment.	1-2 days <sup>∎</sup>	21 days <sup>⊪†</sup>	27 days	66%
Rotator cuff repair or subacromial decompression for impingement	Graded increase in activity. Generally return to unlimited work over approximately 3 months. Highly physically demanding jobs may require up to 6 months if the person is able to return to that position at all. Some will require permanent limitations.	2-6 weeks	2-6 months (Some patients will be permanently disabled in this setting.)		
Impingement syndrome, rotator cuff tendinoses, bicipital tendinosis, subacromial bursitis	Avoid overhead work, pushing, pulling, and heavy lifting.	0-1 day	3-7 days <sup>†</sup>	14 days	65%
Shoulder instability	Avoid pushing, pulling, and heavy lifting	0-3 days	21 days <sup>†</sup>	9 days	50%
Acute Glenohumeral Dislocation	No use of the affected extremity. May require surgical intervention	3-14 days	2-6 months	1 month	
Recurrent dislocation	Avoid overhead work, pushing, and pulling	0 days	21 days <sup>†</sup>	12 days	35%
AC joint sprain	Avoid activities that cause significant symptoms or apply excessive force to the affected ligament. Typically requires avoiding overhead work, pushing, and pulling.	0-1 day	3-7 days <sup>†</sup>	14 days	23%
AC joint separation	Allow activity as tolerated, with arm in immobilizer	3-7 days	21 days	14 days	18%
Non-specific shoulder pain	Allow all activities as tolerated – consider modification of activities that aggravate symptoms, but range-of-motion and conditioning exercises should be performed by patient.	0 days	0-7 days <sup>†</sup>	4 days	49%
Shoulder fracture	No use of fractured shoulder Most shoulder fractures will require longer limitations, particularly depending on fracture type, severity of fracture, work demands and accommodations	1-4 weeks	Depending on treatment, generally up to 8-12 weeks if unable to accommodat e and forceful use of arm is		

## Table 4. Guidelines for Modification of Work Activities and Disability Duration\*

			required. May be up to 6 months in cases of subsequent debility and need of rehabilitation	
Labral tear	Allow activity as tolerated. (Labral tear is more likely to be identified early with traumatic injury.)	3-7 days	21 days <sup>†</sup>	
Adhesive capsulitis	Generally require increasing activities and ranges of motion. Limitations depend heavily on job physical demand requirements.	0-21 days	1 to 6 months	
	Idiopathic adhesive capsulitis typically has a course or natural history well over 1 year.			

\*These are general guidelines for the provider based on consensus or population sources and are never meant to be applied to an individual case without consideration of injury or disorder severity, workplace factors, concurrent disease or other social or medical factors that can affect recovery. Occupational factors, especially the physical demands of the job may have considerable impacts; especially in high job physical demands tasks or positions. Thus, some workers will fall out of these ranges.

\*\*These parameters for disability duration are consensus optimal targets as determined by a panel of ACOEM members in 1996 and reaffirmed by a panel in 2002 and subsequently revised in 2010. In most cases, persons with one non-severe extremity injury can return to modified duty immediately.

\*\*\*Based on the CDC NHIS (National Health Interview Survey)

\*\*\*\*If the workplace has the ability to accommodate one handed use, then there is no time loss that is generally justifiable. Situations of severe injuries with considerable pain may be limited exceptions.

†Many of these cases require no lost time.

Limitations assume significant exposure is present, otherwise permissible to maintain usual job functions during treatment and ascertain whether condition will resolve without limitations.

†Many of these cases require no lost time.

IAssumes rotator cuff tear and surgical repair is not performed.

## **INITIAL CARE**

Assuring that there are no red flags is the treating physician's first concern. Next, consider the patient's comfort. Nonprescription analgesics may provide sufficient pain relief for most patients with shoulder pain. If treatment response is inadequate (i.e., if symptoms and activity limitations continue) or the physician judges the condition limitations to be more significant, prescribed pharmaceuticals or physical methods may be added. Co-morbid conditions, invasiveness, adverse effects, cost, and physician and patient preferences guide the choice of treatment. Initial care and comfort items may include non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, heat, exercises, and/or advice on activities. Education about shoulder pain should begin at the first visit.

Initial treatment should be guided by implementing conservative care supported by the strongest evidence for treating the presumed diagnosis. For many disorders, there is no high-quality evidence to guide treatment. If there is also no moderate-quality evidence to guide treatment, the provider should consider including non-invasive, convenient, and inexpensive treatments that are widely accepted, but have not been subjected to RCTs or crossover trials (e.g., pendulum exercises for acute shoulder pain patients to facilitate recovery and prevent adhesive capsulitis). Careful consideration of the indications and limitations described in the rationale for each recommendation is critical to understanding the best application for each intervention. If treatment response is inadequate (that is, if symptoms and activity limitations continue), 2<sup>nd</sup>- and 3<sup>rd</sup>-line recommendations may be considered. Physicians should consider the possibilities of diagnosed and previously undiagnosed medical diseases such as diabetes mellitus and various arthritides.

## Recommendation: Education for Shoulder Disorders Education is recommended for patients with shoulder disorders.

*Frequency* – 1 or 2 appointments for educational purposes; may include information about self care and rehabilitation, and teach adaptive techniques and use of adaptive equipment (as indicated) to facilitate continued participation in daily activities despite shoulder limitations. Additional appointments may be needed if education is combined with physical therapy or occupational therapy treatments. Follow-up educational visit(s) for more severe disorders as part of a progression towards normal functional use is sometimes helpful.

## Strength of Evidence - Recommended, Insufficient Evidence (I)

## Rationale for Recommendation

One moderate-quality trial appears to have largely focused on educational interventions, although it also appears to have included exercises and have suffered a randomization failure that may have biased towards the null. (DeBruijn 07) There are no other quality studies specifically evaluating efficacy of patient education for utility or necessity in the treatment of shoulder disorders. Yet, for many disorders (e.g., importance of performing pendulum exercises, advancement of activity levels) education appears essential. Some providers accomplish this in the course of extended patient visits, while others routinely refer patients to a physical or occupational therapist for education. Regardless of the approach, a few appointments for educational purposes are recommended as a low-cost treatment adjunct for many patients. The number of appointments is dependent on the diagnosis, severity of the condition, and coexisting conditions. Although education is usually incorporated as part of the overall treatment plan, an additional 1 or 2 appointments for purely educational purposes may be helpful midway through a treatment course for the more severely affected patient.

## Evidence for the Use of Education

There is 1 moderate-quality RCT incorporated into this analysis.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments						
Physical therapy and /or exercises vs. Injection												
De Bruijn 2007 RCT	5.5	N = 111 with acute or subacut e shoulde r pain	Education and activation program (2-6 sessions over 6 weeks, up to 20 minutes per session, focus to maintain or induce cognitions and stimulate adequate behavior with advice on ADLs through operant conditioning) vs. usual care; 26 weeks follow-up.	Catastrophizing at baseline related to functional limitations (p <0.0001). SDQ score at baseline also related to functional limitations (p <0.0001).	"The EAP has no significant effect on the outcome of SCs [shoulder complaints] after 6 and 26 weeks. The relation between catastrophising at baseline and functional limitations suggests that an intervention focusing specifically on catastrophising may be more successful in reducing functional limitations in the long term."	Some baseline differences, % very low catastrophizing category usual care 49% vs. EAP 27% (p = 0.02). Appears to have randomization failure and may have biased towards null.						

## **ACTIVITY MODIFICATION**

Shoulder disorders may lead to joint stiffness more often than other joint disorders. Once red flags have been ruled out, careful advice regarding maximizing activities within the limits of symptoms is imperative because patients with shoulder disorders tend to have stiffness followed by weakness and atrophy. Generally avoid use of a sling due to potential complications of weakness and adhesive capsulitis. For cases with moderately severe to severe pain requiring joint rest, brief sling use for a few days may be reasonable. However, gentle ROM exercises (e.g., pendulum) are desirable even during this time. Patients acutely should avoid activities that precipitate or significantly increase symptoms while continuing general activities and motion. Therapeutic exercise, including strengthening, should start as soon as possible without aggravating symptoms. Patients can usually tolerate pendulum exercises even when discomfort is pronounced, and this method can preserve ROM. Manipulative techniques have demonstrated decrease in shoulder symptoms for some diagnoses (see below).

Activities and postures sometimes significantly increase symptoms and should be avoided especially for acute rotator cuff tears, rotator cuff tendinoses, AC sprain or separation and impingement. The following are common limitations needed for shoulder pain patients:

- No lifting more than 10 pounds (this may require adjusting up or down based primarily on the patient's pre-morbid capabilities and the severity of the condition).
- Avoid more than 60° abduction or forward flexion. Although not necessarily correct, this is sometimes described as avoiding lifting with the hands above shoulder height to facilitate implementation.
- Some additionally require limitations such as avoiding static use or highly stereotypical use

As recovery occurs, careful monitoring of activity levels is required. Gradual advancement in activity levels both at work and avocationally is advised to facilitate functional restoration. Ideally, activity levels may be advanced incrementally in and out of work with recovery of full function, or in cases of permanent impairments, optimal function.

## EXERCISE

Exercise has long been used for treatment of shoulder injuries, particularly those involving the rotator Cuff. (Kuhn 09; Bang 00; Brox 93, 99; Conroy 98; Haahr 05; Ludewig 03; Rahme 98; Senbursa 07; Walther 04; Werner 02; Bernaards 06; Geraets 04; McClure 04; Bennell 07; Bergman 04; Kelly 10; Kromer 09; Ainsworth 07) The necessity for exercise as a treatment for these disorders is underscored by the large number of trials of many interventions that implemented exercises across patients randomized for assessment of other treatments. (Smith 86; van der Heijden 99; Ginn 05; Geraets 05, 06; Johansson 05; Herrera-Lasso 93; Bal 09; Aktas 07; Bang 00; Citaker 05; Conroy 98; Senbursa 07; Gerdesmeyer 03; Blair 96; McInerney 03; Plafki 00; Akgun 04; Brox 93; Brox 99; Haahr 05; Hay 03; Giombini 06) Despite beliefs in the importance of exercise, quality evidence in support of exercise itself, rather than its use as a multimodal intervention or adjunct, is sparse. (Philly Panel 01; Johansson 02; Koester 05; Souza 09; Kuhn 09; Green BMJ 98; van der Heijden 97; Thomas 05; Desmeules 03; Kelly 10; Kromer 09) The available quality trials are relatively few in number; nearly all have mixed different types of exercises, and individualized treatments based on perceived patient characteristics. Additionally, other types of co-interventions also are common. These factors all sharply limit the ability to draw evidence-based conclusions (Desmeules 03; Michener 04).

1. Recommendation: Range-of-motion Exercises for Shoulder Pain

## Range-of-motion exercises are recommended for treatment of patients with shoulder pain.

## Indications – Shoulder pain

*Frequency/Duration* – A self-directed program as tolerated (patients who have a rotator cuff tear or labral tear will not be able to tolerate strenuous stretching). Supervised programs may be indicated for patients who require supervision initially or otherwise need assistance with motivation or concomitant fear avoidant belief training (see Chronic Pain Gudeilines and Low Back Complaints) for a few appointments to help initiate the program. Additional supervised appointments are indicated for patients who fail to progress or need greater supervision, such as for ongoing fear avoidant beliefs. (Ludewig 03) Dose unclear for patients with shoulder pain; common regimens of ROM exercises performed 1 to 3 times a day.

Indications for Discontinuation - Non-compliance, development of other disorders.

## Strength of Evidence – Recommended, Evidence (C)

## 2. Recommendation: Strengthening Exercises for Shoulder Disorders

## Strengthening exercises are recommended for treatment of patients with shoulder disorders.

*Indications* – Shoulder disorders, added after instituting stretching exercises and the acute pain phase has past. (Ludewig 03)

*Frequency/Duration* – Home program frequency 2 to 3 times a day for shoulder disorders. Supervised treatment frequency and duration dependent on symptom severity and acuity and comorbid conditions. In severe disorders, possibly 3 appointments a week for 2 to 3 weeks, generally tapering to twice weekly for 2 to 3 weeks, then weekly for an additional 4 weeks. *Dose* – For strengthening progression, start with rotator cuff and scapular muscle strengthening, progressing to strengthening of arm elevation as guided by symptoms and ability to perform exercises. One successful regimen implemented exercises 2 times a week for 8 weeks with 6 repetitions at maximal exertion, then training with 2 series of 8 repetitions at 50% of maximal strength and a 2nd series at 70% maximal strength for flexion, extension, medial rotation, and lateral rotation. (Lombardi 08)

Indications for Discontinuation – Development of a strain, noncompliance, failure to improve.

## Strength of Evidence – Recommended, Evidence (C)

2. Recommendation: Aerobic Exercises for Shoulder Disorders There is no recommendation for or against the use of aerobic exercise for patients with shoulder disorders, including rotator cuff tendinopathies.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

## Rationale for Recommendations

There are multiple moderate-quality trials evaluating exercise for treatment of shoulder injuries; however, they are prone towards multiple co-interventions and other weaknesses that considerably limit the utility of the available data. One trial found a home-exercise program of stretching and strengthening successful for treating construction workers with impingement syndrome. (Ludewig 03) Another trial found no benefits of supervised therapy compared with a home-exercise program or a sling; however, as more than 50% were previously treated by therapy, it appears to have been potentially biased. (Walther 04) Two trials compared exercise interventions with wait-listed controls and were interpreted as suggesting efficacy; however, these trials are likely biased in favor of the intervention due to use of controls who knew they are not being treated. (Lombardi 08; Ginn 97) Yet, one of these trials included specific exercise benchmarks for strengthening, and documented considerable benefits, (Lombardi 08) suggesting benefits beyond the biases of the study design. A trial of physiotherapy compared with manual therapy and injection found injection superior and manual therapy approximately equivalent over the longer term. (Winters 97) Another trial that attempted to confirm that postural exercises were beneficial, instead found some evidence that the fitness and strengthening exercise arm was superior in the short-term. (Van Eijsden-Besseling 08) Another found a standardized protocol was equivalent to an individualized exercise prescription. (Wang 06)

A retrospective study of prognostic factors associated with impingement syndrome found active treatment and fewer prescription medications and sick leave to be associated with better prognosis. (Brox 96) An experimental study in healthy volunteers found the empty-can and full-can exercises were most effective at activating the supraspinatus, and thus were predicted to be most effective for strengthening this muscle. (Takeda 02) However, because the empty-can exercise has greater potential to cause pain and decrease the subacromial space, (Burke Clin Orthop Rel Res 02; Thigpen AJSM 06) the full-can is recommended for use over the empty can. A randomized trial in healthy subjects found eccentric training superior to concentric and eccentric training group for purposes of increasing peak force and peak torque. (Bast 98) A small, uncontrolled experimental study among patients with impingement syndrome found a painful eccentric supraspinatus (empty can) and deltoid training program effective. (Jonsson 06) There is a single RCT indicating efficacy of active exercise over placebo laser for patients with rotator cuff tendinopathy/impingement syndrome. (Brox 93; Brox 99) Thus, there is limited evidence in support of stretching and strengthening exercises and they are recommended. There is no evidence in support of aerobic exercises for typical shoulder joint disorders (see Myofascial Pain).

Physical therapy has also been reported as successful for most patients with full-thickness rotator cuff tears. However, modestly superior results over 1 to 5 years of follow-up have been reported among surgically treated patients (Moosmayer 10, 14) as well as in a large cohort study. (Kuhn 13)

Exercises are not invasive, have low adverse effects, and are not costly when performed as a selfdirected program. They may be high cost when performed as part of a lengthy supervised program; however, they are recommended in some severe cases and may be necessary, particularly with cases of fear avoidant beliefs and catastrophizing.

## Evidence for the Use of Exercise

There is 1 high and 15 moderate-quality RCTs (one with two reports) incorporated into this analysis. There are 2 low-quality RCTs (Gin 05; Gin 97) in Appendix 2.

Author/	Score	Sample Size	Comparison	Results	Conclusion	Comments			
Title Study Type	(0-11)		Group						
Shoulder Tendinopathies: Exercises vs. No intervention Controls									
Ludewig 2003 RCT	7.0	Shoulder N = 67 male construction workers with shoulder pain and at least 2 positive impingement tests who also have "overhead work" (sheet metal, electrical, plumbing, pipefitting, insulation); includes asymptomatic	Tendinopathies: Exer Home exercise program (stretches, pectoralis minor stretch, posterior shoulder stretch, progressive resistance strengthening exercises, theraband) vs. no intervention controls. Follow up after 8- 12 weeks after treatment.	<b>cises vs. No intervention</b> SRQ score (baseline/post): HEP (65.9±1.96/78.0±2.31) vs. symptomatic controls (72.5±1.99/71.1±2.24) vs. asymptomatic controls (93.8±2.28/94.0±2.64) (p <0.01). Work- related disability also favored intervention (4/2.5 vs. 3.8/3.7).	*Results suggest a home exercise programme can be effective in reducing symptoms and improving function in construction workers with shoulder pain."	Non- interventional control biases in favor of intervention. Data suggest efficacy of home exercise program.			
		controls.							
	S		pathies: Exercises vs	. Physiotherapy vs. Self	-training vs. Brace				
Walther 2004 RCT	4.0	N = 60 with disabling impingement syndrome (require relief with 10mL bupivacaine subacromial injection).	Physiotherapy (10 sessions, 2-3 per week, centering training, stretching; data indicate average 30 visits total) vs. self- training (centering and stretching exercises, Theraband strengthening up to 4 supervised sessions, individualized, self exercise at least 5 times a week for 10-15 minutes) vs. Functional brace (Coopercare Lastrap). 12-week follow-ups.	VAS pain scores, pain at night, pain with load, mobility, all without differences between groups, though improved over study interval ( $p < 0.05$ ). Muscle strength improved most in brace group (Constant- Murley strength score at 12 weeks: brace 14.4 $\pm$ 5.4 vs. PT 10.9 $\pm$ 4.6 vs. self 11.8 $\pm$ 5.4).	"There were no statistically significant differences among the groups. Guided self-training can lead to results similar to those of conventional physiotherapy. The comparable effect of the functional brace remains unclear and might be explained by an influence on proprioception."	Over 50% treated with physiotherapy prior to the study may have biased against physiotherapy (more of same). Intermediate follow-up (12 weeks and no long term follow- up.			
Lombardi 2008 RCT	6.5	N = 60 with impingement syndrome.	Muscle strengthening group (2 times a week for 8 weeks with 6 repetitions at maximal exertion, then training at 2 series of 8 reps at 50% maximum strength and	rapy and Exercises vs. V Pain at rest (baseline/2 months): exercise $(4.2\pm 2.4/2.4\pm 2.1)$ vs. controls $(3.9\pm 2.6/4.3\pm 3.2)$ , p = 0.001. Pain with movement also p <0.001. Disabilities of Arm, Shoulder, and Hand (DASH) 2 and 3	"The progressive resistance training program for the musculature of the shoulder in patients with shoulder impingement syndrome was effective in	Controls wait- listed which biases in favor of intervention. Study has fewer co-interventions as concentrated on strengthening exercises.			

Ginn 1997 RCT	4.5	N = 66 with shoulder pain "believed to be of local mechanical origin".	second series at 70% max at flex, extend, medial rotation and lateral rotation) vs. wait- listed controls. Wait-listed controls vs. Individualized treatment regimen (may have included stretching exercises, strengthening exercises, motor retraining or variably type, frequency and duration); 4-10	also significant. Flexion not different (p = 0.90). Abduction increased with exercise (p = 0.001). Physical function SF- 36 p = 0.044 in favor of exercise group. More improvement in symptoms in treatment group (median score 2 vs. 4, p <0.001). VAS pain trended, but not significant. Increased pain-free abduction (p = 0.006).	reducing pain and improving function and quality of life." "[T]he physical therapy approach used in this study is effective in improving shoulder function in subjects experience pain of mechanical origin."	Wait-listed controls biases in favor of intervention, as already referred for physical therapy. Variable length of treatments (4-10 appointments). Individualized treatment reatment
			treatments over 1 month period.			regimen all limit utility of results.
	Sh	oulder Tendinon		apy and /or Exercises vs	. Other Treatments	
Hay 2003 RCT	8.0	N = 207 with unilateral shoulder "region" pain; included patients with a "broad range of shoulder problems".	Methylprednisolone 40mg plus 4mL lidocaine and second injection at 4 weeks if symptoms recurred vs. physiotherapy (8 x 20-minute sessions with education, exercises; ultrasound and manual therapy based on symptoms); 6 months follow-up.	Successful outcomes at 6 weeks/6 months: physiotherapy 30/60% vs. injections 36/53% (NS). Number of reconsultations at 6 weeks/6 months: physiotherapy 18/39% vs. injection 27/53%. Saw other practitioner: Physiotherapy 6/35% vs. injection 2/44%.	"Community physiotherapy and local steroid injections were of similar effectiveness for treatment new episodes of unilateral shoulder pain in primary care, but those receiving physiotherapy had fewer co- interventions."	Diagnoses not specified, appears multiple. Symptoms included "severe" neck restrictions among 27%. Some may have received injections without clear indication(s). Individualized physiotherapy. With diagnoses apparently heterogeneous, utility and applicability of data unclear.
Moosmayer 2010 RCT	7.5	N = 103 with symptomatic small (< 1 cm) or medium- sized (1 cm to 3 cm) tears of rotator cuff. Mean age 59 years (surgery group) vs. 61 years (physiotherap y).	Mini-open or open tendon repair surgery. Post- operatively, the arm was immobilized in a sling and passive range-of-movement exercises commenced (n = 52) vs. physiotherapy (n = 51). Treatment sessions of 40 minutes were given on average twice weekly for 12 weeks with increasing intervals	Mean±SD Constant score improved from baseline to 12 months by 41.4±19.6 surgery group vs. 28.4±21.9 physiotherapy group; p = 0.002 between group difference. Mean values for patient satisfaction after 12 months (VAS scale): 9.0 (1.0 to 10.0) surgery group vs. 7.2 (0.0 to 10.0) physiotherapy group; p<0.0005.	"[B]oth approaches can be considered in the treatment of patients with small and medium-sized rotator cuff tears but better results can be expected after primary surgical repair."	Pragmatic RCT with 1-year follow-up of non- standardized PT vs. surgery for small to moderate (3mm) RC tears showed better outcomes for surgery. PT group had 82% (42/51) satisfied but 18% (9/51) opted for surgical repair.

			during the following 6 to 12 weeks. 12 month follow-up.			
Moosmayer 2014 RCT	7.5	See Moosmayer 2010	See Moosmayer 2010	Baseline score and age-adjusted treatment benefits after primary tendon repair were 5.3 points greater for the Constant Score 95% CI: -0.05 to 10.7 points; (p = 0.05). Patient satisfaction (VAS): 9.2 cm tendon repair vs. 8.3 cm in the physiotherapy (mean difference, 1.0 cm, 95% CI, 0.1 to 1.8 cm; (p = 0.03).	"Although primary repair of small and medium-sized rotator cuff tears was associated with better outcome than physiotherapy treatment, the differences were small and may be below clinical importance. In the physiotherapy treatment group, there were increasing tear sizes and inferior outcomes in one- third of patients who did not undergo repair."	Pragmatic RCT. 5 year follow-up to original RCT. PT not standardized. Surgery showed modestly better outcomes vs. PT. At 5 years, 37% of PT group had increasing cuff tear size (>5mm) and 24% (12/51) required surgery after conservative treatment failure.
Brox 1993 RCT	7.0	N = 125 with rotator cuff disease for at least 3 months, resistant to outpatient physiotherapy and NSAID.	Arthroscopic surgery vs. 12 sessions of detuned soft laser treatment for 6 weeks vs. 3-6 months of supervised exercises; 6 months follow-up.	Mean outcome scores comparing surgery group vs. placebo laser group vs. exercise group at baseline/3/6 months. Overall: surgery 64/84/87 vs. placebo 65.5/61/66 vs. exercise 67.5/74/86. Pain: 15/25/25 vs. 15/15/15 vs. 15/15/25. Function: 24/28/28 vs. 21/20/15 vs. 24/24/ 25. ROM: 18/19/22 vs. 21/19/ 22 vs. 19 vs. 19/21.5/23.	"Surgery or a supervised exercise regimen significantly, and equally, improved rotator cuff disease compared with placebo."	Baseline fewer women in surgery may bias against surgery. All required to have reduced pain at 15 minutes after lignocaine injection. Baseline requirement for resistant to physiotherapy likely biases in favor of surgery.
Brox 1999 RCT follow- up of Brox 1993 above	7.0	N = 125 with rotator cuff disease (same as above).	Arthroscopic surgery vs. supervised exercise regimen, 3-6 months vs. placebo, 6 weeks (same as above)	15/28 (53.6%) placebo laser and 11/44 (25.0%) physiotherapy crossed over to surgery. Success rate for surgery 26/38 (68.4%) and exercises	"[A]fter 2 <sup>1</sup> / <sub>2</sub> years of follow-up, both arthroscopic surgery and supervised exercises are better treatments	2.5 year follow- up of above trial. High crossover rates to surgery limit conclusions regarding prognosis over

				27/44 (61.4%) superior to placebo laser 7/28 (25%) ( $p < 0.01$ ). Neer scores (excellent) at 2.5 years surgery 22/38 (57.9%) vs. supervised exercises 23/44 (52.3%) vs. placebo laser 4/28 (14.3%).	than placebo. The difference between the 2 active treatments was not significant."	2.5 year period from various treatment options.
De Bruijn 2007 RCT	5.5	N = 111 with acute or subacute shoulder pain.	Education and activation program (2-6 sessions over 6 weeks, up to 20 minutes per session, focus to maintain or induce cognitions and stimulate adequate behavior with advice on ADLs through operant conditioning) vs. usual care; 26 weeks follow-up.	Catastrophizing at baseline related to functional limitations (p <0.0001). SDQ score at baseline also related to functional limitations (p <0.0001).	"The EAP has no significant effect on the outcome of SCs [shoulder complaints] after 6 and 26 weeks The relation between catastrophising at baseline and functional limitations suggests that an intervention focusing specifically on catastrophising may be more successful in reducing functional limitations in the long term."	Some baseline differences, % very low catastrophizing category usual care 49% vs. EAP 27% (p = 0.02). Appears to have randomization failure and may have biased towards null.
Geraets 2005 RCT	5.0	N = 176 with mostly chronic shoulder pain; diagnoses unclear; 79% over 6 months duration, 47% with neck complaints.	Graded exercise program (behavioral treatment program, operant conditioning, maximum 18x1- hour exercise sessions) vs. usual care (information, wait and see, analgesics or NSAIDs if necessary). 12 weeks follow-up.	Main complaints improvements at 12 weeks: GET $(32.8\pm25.7)$ vs. usual care $(25.3\pm24.5)$ , p = 0.05. Shoulder disability questionnaire not different (p = 0.64). Shoulder pain not different p = 0.17.	"Results showed that graded exercise therapy is more effective in restoring the ability to daily [sic] activities in patients with chronic shoulder complaints than usual care, although beneficial effects are small."	Quality of usual care unclear, but presumably more of same; if so, considerable bias. Large number of providers (20 physiotherapists. 32 GPs) likely included much heterogeneity of interventions. Several differences at baseline (e.g., behavioral therapy 88% vs. 73%; manual therapy 80% vs. 59%; NSAIDs 36% vs. 20%; psychosocial distress) suggest randomization failure. Higher contact time in exercise program biases in favor of intervention. Relatively diffuse area of shoulder and upper arm complaints

Eijsden- Besseling 2008 RCT	0.0	non-specific upper extremity symptoms.	per Mensendieck/Cesa r approach (2x 1- hour sessions Weeks 1-3, 1 x 1-	0/3/6/12): Postural ( $2.9\pm1.5/1.9\pm1.9/1.3\pm1$ . $3/1.4\pm1.7$ ) vs. Strengthening Fitness ( $2.6\pm1.8/1.1\pm1.3/1.1\pm1$	exercises did not result in a better outcome than strength and fitness exercises.	vs. population- based. Baseline differences with greater catastrophizing
Van	6.0	<b>Sho</b> N = 88 with	oulder Disorders: Cor Postural exercise	<b>nparing Exercise Regim</b> Pain VAS (months	ens "Postural	Patients solicited
Geraets 2006 RCT Second report of Geraets 2005 Winters 1997	5.0	Same as above N = 198, 58 with shoulder girdle and 114 synovial disorder.	Same as above. Physiotherapy 2 times a week (exercise therapy, massage, physical applications) vs. manipulation 1 week up to 6 appointments. (mobilization and manipulation of cervical spine, upper thoracic spine, upper ribs, AC joint, glenohumeral joint) vs. corticosteroid injection (if synovial group) with triamcinolone acetonide 40mg plus 9mL 10mg/mL lignocaine; up to 3 injections weeks 0, 1, 2). Randomization after 1 week diclofenac 50mg TID. 11-week follow-up.	Data suggest effects on main complaints continued to 52 weeks ( $p = 0.025$ ), although other measures were not different between groups. Total costs GET €530 vs. usual care €377 ( $p = 0.001$ ). Pain scores in shoulder girdle group (baseline/post): manipulation 14.8±4.2/9.9±3.5 vs. physiotherapy 14.4±3.5/12.0±4.4. Patients who were "cured" 8.7 vs. 9.6 (NS). Pain scores in synovial group: corticosteroid injection (16.3±4.8/9.2±3.7) vs. manipulation (15.7±4.2/12.6±5.1) vs. physiotherapy (16.3±3.3/11.5±4.4).	"GET proved to be more effective in the short- and long-term and reduces direct health care costs and direct non- health care costs but is associated with higher costs of the intervention itself." "For treating shoulder girdle disorders, manipulation seems to be the preferred treatment. For the synovial disorders, corticosteroid injection seems the best treatment."	cervical areas. Utility of trial appears limited as patients appear to largely have involved prior treatment failures. Trial has numerous issues outlined above, which limit this cost- effectiveness analysis. Costs higher in graded exercise therapy arm. Trial mixes shoulder girdle and joint pain sources. Limited description of exercise therapy or manipulation. Number of injections not controlled. High dropouts with manipulation (59%) and physiotherapy (51%), but not injection. Data suggest corticosteroid superior for synovial pain. Manipulation superior to physiotherapy for pain relief in shoulder girdle group.
						allowed in trial. Excluded solely affected in paraspinal and

			hour sessions a week Weeks 4-6, 1 x 0.5 hour session a week, Week 9 HEP only, 0.5 hour session Week 10) vs. strengthening and fitness exercise group (3x0.5 hour a week Weeks 1-3, 2 x 0.5 hour a week Weeks 4-6, 1 x 0.5 hours a week Weeks 7-8, HEP Week 9 and 0.5 hour session Week 10); 10 week intervention; 12 month follow-up.	.3/1.4±1.5) (NS other than 3 months where p=0.05). No differences in DASH disability and SF-36.	However, 55% of visual display unit workers with early non-specific work- related upper limb disorders reported being free of complaints one year after both interventions were commenced."	in fitness/ strengthening group. Greater contact time in postural group may bias slightly in favor of postural group. Mixed pain issues may limit applicability. Data suggest fitness group resulted in faster improvements by 3 months in VAS pain. With efficacy of fitness exercise for reducing cardiovascular disease, the results raise doubts about emphasizing postural exercises for these patients.
Wang	5.5	N = 38 with	Customized vs.	d vs. Standard Exercise VAS pain (baseline/4	"The customized	Baseline
2006 RCT		shoulder disorders and pain over 10 days.	standard exercise. Customized (stretching and strengthening exercises based on "hypothesized impairments attributing to signs and symptoms" of scapular downward rotation syndrome, scapular depression syndrome, scapular abduction syndrome, scapular winging syndrome, humeral anterior glide syndrome, humeral superior glide syndrome, humeral medial rotation syndrome or humeral hypomobility syndrome) vs. standard exercise (5 strengthening exercises). Exercises twice a day, 5 reps each. PT appointments weekly for 8 weeks; 8 weeks follow-up.	weeks/8 weeks): customized (47.3±28.6/20.1±14.5/ 21.6±12.5) vs. standard (48.4±25.4/23.1±18.0/ 21.2±17.6) (NS). Flex-SF score, ROM, strength measures also not different.	shoulder exercises did not provide additional benefit to our shoulder patients than the standard exercises	differences with standard exercise group 10.6 years older (39.3 vs. 49.9 years). Exercise regimens appear somewhat dissimilar with stretching in the customized, but not standard. High dropout rate in customized exercise group. Results raise concerns this shoulder classification system may be invalid and/or stretching exercises are ineffective and/or a standardized protocol is sufficient.

	Shoulder Tendinopathies: Hyperthermia vs. Ultrasound												
Giombini 2006	5.5	N = 37 athletes with supraspinatus	Hyperthermia 434 MHz 3 times a week vs. continuous	VAS pain (baseline/post/6 weeks): hyperthermia	"Hyperthermia is effective in the management of	No long-term follow-up, only 2 weeks post-							
RCT		tendinopathy by clinical and ultrasound.	ultrasound at 1MHz at 2.0W/cm <sup>2</sup> 3 times a week vs. exercises (pendulum, stretching twice a day). All treatments for 4 weeks; 6-week follow-up.	$(5.96\pm0.83/2.4\pm0.46/$ 1.2±0.63) vs. ultrasound (6.3±0.86/ 5.8±0.96/5.15±0.87) vs. exercise (6.1± 0.89/5.3±0.65/4.9± 0.88). Comparable results with constant scores (p <0.05 comparing hyperthermia to other groups).	established supraspinatus tendinopathy. This modality warrants further studies with a greater number of patients."	treatment. Data suggest hyperthermia superior to ultrasound.							

## FOLLOW-UP VISITS

Patients with acute shoulder disorders may benefit from a small number of follow-up visits in the first 2 to 4 weeks with a health professional who can counsel the patient to avoid static positions, perform gentle ROM exercises, alter activities, and adjust medication use. The practitioner should address questions and make these sessions interactive so that the patient is fully involved in his or her recovery. These interactions may be done in a clinic or by telephone. Physician follow-up is generally required when changes in activity limitations are needed or to check that the patient is healing at an appropriate pace in order to advance treatment or intervene to prevent delays in recovery. Physician follow-up might be expected every 4 to 7 days if the patient is off work and every 7 to 14 days if the patient is working. More severe disorders and post-operative patients may require follow-up for up to 1 year after surgery as there is evidence these conditions improve up to 1 year post-op. (Holtby 10)

## SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS

For most patients with non-traumatic shoulder problems, special studies are not needed, absent red flags, unless a 4- to 6-week period of non-operative care and observation fails to improve symptoms. Most patients improve quickly, provided red-flag conditions are ruled out. There are a few exceptions:

- X-ray is required for most traumatic situations to rule out fracture. There may be exceptions involving minor trauma.
- Stress films of the AC joints (views of both shoulders, with and without patient holding 15-lb weights) may be indicated if the clinical diagnosis is AC joint separation and examination and standard radiographs are inconclusive. Care should be taken when selecting this test because the disorder is usually clinically obvious; the test only serves to differentiate between Grade 1 and 2; and has little utility as both are treated non-operatively.
- If an initial or recurrent shoulder dislocation presents in the dislocated position, shoulder films before and after reduction are indicated. Post reduction films (lateral axillary view) must clearly demonstrate that the humeral head is reduced.
- Persistent shoulder pain, associated with neurovascular compression symptoms (particularly with abduction and external rotation), may indicate the need for an AP cervical spine radiograph to identify a cervical rib and electrodiagnostic testing for nerve injury.
- The threshold for obtaining x-rays whenever there is an unusual clinical presentation should also be particularly low. This includes symptoms suggestive of potential intra-abdominal or cardiac problems presenting as shoulder problems, as well as neoplasias.

Subsequent, additional indications include:

- Traumatic injury with shoulder weakness suggesting rotator cuff tear.
- Traumatic shoulder dislocation in patients over age 40 high incidence of concomitant rotator cuff tear.

- Physiologic evidence of tissue insult or neurovascular dysfunction (e.g., cervical root problems presenting as shoulder pain, weakness from a massive rotator cuff tear, or presence of edema, cyanosis or Raynaud's phenomenon).
- Failure to respond to treatment as expected.
- Failure to progress in a strengthening program intended to avoid surgery.
- Clarification of the anatomy prior to an invasive procedure (e.g., a full thickness rotator cuff tear not responding to non-operative treatment).

There are considerable methodological weaknesses among the studies of diagnostic tests that include small sample sizes, incomplete assessments of the patients with all tests under consideration, frequent use of retrospective methods, utilization of arthrography for gold standard comparison, and inclusion of patients who had previously been evaluated with the same test or procedure. (Dinnes HTA 03) These weaknesses provide substantial concerns about the accuracy of reported test performance characteristics such as sensitivity, positive predictive value and likelihood ratios. Quality, head-to-head comparisons of diagnostic tests are extremely rare, making quality comparisons between the available diagnostic tests difficult. (Dinnes HTA 03) Lastly, relying solely on imaging studies to evaluate the source of shoulder symptoms carries a significant risk of diagnostic confusion, especially false-positive test results, since there is a high probability of identifying a finding that was present before symptoms began (for example, degenerative partial thickness rotator cuff tears), and therefore may have no temporal association with the symptoms.

Routine testing (laboratory tests, plain-film radiographs of the shoulder) and more specialized imaging studies are not recommended during the first month to 6 weeks of activity limitation due to non-traumatic shoulder symptoms, except when a red flag noted on history or examination raises suspicion of a serious shoulder condition, calcific tendinitis or referred pain. Cases of impingement syndrome are similarly managed.

Suspected acute tears of the rotator cuff in younger workers (typically considered to be <40 years) are usually surgically repaired acutely to restore function; in older workers, these tears are typically treated conservatively at first. Partial-thickness tears should be treated the same as impingement syndrome regardless of magnetic resonance imaging (MRI) findings, although large partial thickness tears may be considered for earlier surgical treatment. Shoulder instability can be treated with stabilization exercises; radiographs may help demonstrate relevant bony pathology. For patients with limitations of activity after four weeks and unexplained physical findings (weakness, stiffness), such as localized pain (especially following exercise), specialized imaging, such as an MRI, may be indicated to clarify the diagnosis and assist reconditioning. Imaging findings can be correlated with physical findings.

Laboratory studies, such as liver or gallbladder function tests and tests for pelvic disease may be useful to determine if pain is being referred to the shoulder from a subdiaphragmatic source. Electrocardiography and possibly cardiac enzyme studies may be needed to clarify apparent referred cardiac pain. Chest radiographs may be needed to elucidate shoulder pain that could be the result of pneumothorax, apical lung tumor, or other apical disease such as tuberculosis. An erythrocyte sedimentation rate (ESR), complete blood count (CBC), and tests for autoimmune diseases (such as rheumatoid factor) can be useful to screen for inflammatory or autoimmune sources of joint pain.

## DIAGNOSTIC TESTING AND OTHER TESTING

## ANTIBODIES

There are numerous antibodies that are markers for specific rheumatic diseases (e.g., rheumatoid factor, anti-nuclear antibodies, anti-Sm, anti-Ro, anti-La for rheumatoid arthritis, systemic lupus erythematosus, Sjogren's, mixed connective tissue disorder, etc.). Patients with rheumatic disorders are at increased risk for degenerative joint disease of the shoulder as well as subacromial bursitis.

1. Recommendation: Antibodies for Diagnosing Shoulder Pain with Suspicion of Rheumatological Disorder

Antibody levels are recommended to evaluate and diagnose patients with shoulder pain that have reasonable suspicion of rheumatological disorder. However, ordering of a large, diverse array of antibody levels without targeting a few specific disorders diagnostically is not recommended.

Indications – Patients with shoulder pain with suspicion of rheumatological disorder.

Strength of Evidence - Recommended, Insufficient Evidence (I)

2. Recommendation: Antibodies to Confirm Specific Disorders Antibody levels are strongly recommended as a screen to confirm specific disorders (e.g., rheumatoid arthritis).

Indications – Shoulder pain and a presumptive diagnosis of a rheumatological disorder.

#### Strength of Evidence – Strongly Recommended, Evidence (A)

#### Rationale for Recommendations

Elevated antibody levels are highly useful for confirming clinical impressions of rheumatic diseases. However, routine use of these tests in shoulder pain patients is not recommended, especially as wideranging, non-focused test batteries are likely to result in inaccurate diagnoses due to false positives and low pre-test probabilities. Providers should also be aware that false-negative results occur. Measurement of antibody levels is minimally invasive, unlikely to have substantial adverse effects, and is low to moderately costly depending on the specific test ordered. They are recommended for focused testing of a limited number of diagnostic considerations.

## C-REACTIVE PROTEIN, ERYTHROCYTE SEDIMENTATION RATE, AND OTHER NON-SPECIFIC INFLAMMATORY MARKERS

There are many markers of inflammation that may be measured serologically in patients. (Sakai 01; Gotoh 98, 01; Voloshin 05; Santavirta 92; Hyvönen 03; Yanagisawa 01) These include C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), interleukins, ferritin, and an elevated total protein-albumin gap.

# Recommendation: Non-specific Inflammatory Markers for Screening for Inflammatory Disorders in Subacute or Chronic Shoulder Pain

Erythrocyte sedimentation rate and other inflammatory markers are recommended for screening for inflammatory disorders with reasonable suspicion of inflammatory disorder in patients with subacute or chronic shoulder pain. However, ordering of a large, diverse array of antiinflammatory markers without targeting a few specific disorders diagnostically is not recommended.

Indications – Shoulder pain with suspicion of rheumatological disorder.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

Erythrocyte sedimentation rate (ESR) is the most commonly used systemic marker for non-specific inflammation. It is elevated in numerous inflammatory conditions including rheumatological disorders as well as infectious diseases. C-reactive protein (CRP) is a marker of systemic inflammation that has been associated with an increased risk of coronary artery disease. It is also a non-specific marker for other inflammation. Both ESR and CRP are also markers of infection. Numerous inflammatory markers have been found to be elevated in patients with musculoskeletal disorders but because it is not known whether these factors precede or are a consequence of the disease processes, their utility in patient management is unclear. Other non-specific markers of inflammation include elevated ferritin and an elevated proteinalbumin gap, neither of which have known clinical roles. Serological studies for non-specific inflammatory markers are minimally invasive, have low risk of adverse effects, and are low cost. They are recommended as a reasonable screen for systemic inflammatory conditions especially if the patient also

has other pain without clear definition of a diagnosis or those with fibromyalgia or myofascial pain syndrome, although specificity is not high.

Evidence for the Use of C-Reactive Protein, Erythrocyte Sedimentation Rate, and Other Non-specific Inflammatory Markers

There are no quality studies to address the use of C-reactive protein, erythrocyte sedimentation rate, and other non-specific inflammatory markers for shoulder pain.

## CYTOKINES

See Chronic Pain Guidelines.

## **ROENTGENOGRAMS (X-RAYS)**

X-ray is the most basic of the anatomical tests, show bony structure and, after many decades of use, are the initial test for evaluation of most cases of shoulder pain. (Bonsell 00; Hardy 86) They may also help to suggest soft tissue pathology, including large chronic rotator cuff tears. As x-ray has been performed for more than 120 years as a diagnostic procedure, it is unsurprising that there is no quality evidence to support its use. Two or three views of the shoulder are generally performed. The threshold for x-ray of the cervical spine and/or elbow joint should be low, particularly if the findings on shoulder x-ray are either normal or do not readily explain the degree of abnormality. Age has been found to be a potent predictor of increased degenerative changes found on x-ray in the acromioclavicular joint. (Bonsell 00) Reportedly, x-ray has been helpful for diagnosing os acromiale in shoulder pain patients who were otherwise thought to not have the condition. (Burbank 07) Patients with shoulder pain might show greater tuberosity osteopenia, cystic degenerative changes, and spurring, thought to be a marker of chronicity of rotator cuff tears. (Cadet 08) Glenohumeral arthrosis is also more likely if there is a full-thickness rotator cuff tear. (Gartsman 97) Plain radiographic findings are used to stage disease involvement in osteonecrosis or humeral avascular necrosis. Early x-rays are usually normal or have less distinct trabecular patterns since the living part of the bone does not image. (Harreld 09; Ficat 85) As the disease progresses, x-rays begin to show osteoporotic areas, progressing to sclerotic areas and finally flattening and bony collapse. (Harreld 09; Ficat 85)

Recommendation: X-rays for Acute, Subacute, or Chronic Shoulder Pain X-ray is recommended for evaluation of acute, subacute, or chronic shoulder pain.

Indications – Most patients with shoulder pain.

*Frequency/Duration* – Obtaining x-rays once is generally sufficient. For patients with chronic or progressive shoulder pain, it may be reasonable to obtain a second set of x-rays months to years subsequently to re-evaluate the patient's condition, particularly if symptoms change.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

X-ray is helpful to evaluate most patients with shoulder pain, both to diagnose and to assist with the differential diagnostic possibilities such as tendinoses and arthroses. X-ray is particularly helpful for diagnosis of calcific tendinitis, which results in different treatment options (see below). There are no quality studies. X-ray is non-invasive, low to moderate costly, and has little risk of adverse effects and therefore, is recommended.

#### Evidence for the Use of X-rays

There are no quality comparative studies evaluating the use of x-ray for shoulder pain.

## SHOULDER ARTHROSCOPY

Arthroscopy may used for diagnostic confirmation as part of a therapeutic surgical treatment. (Dinnes HTA 03; Fouse 07; Abrams 06; Baker 03; Ahmad 04; Boszotta 04) Arthroscopy is thought to be superior to MRI and ultrasound for diagnosing partial thickness rotator cuff tears. Arthroscopy has been used to evaluate glenohumeral arthrosis. (Guyette 02) Arthroscopic approaches have been found to be effective for treatment of rotator cuff tears, impingement, glenohumeral instability, recurrent dislocations, labral tears,

acromioclavicular arthritis, and long-head biceps tendon pathology syndrome (see below). Some caution is indicated because intrasubstance tears are not well visualized arthroscopically.

#### Recommendation: Diagnostic Arthroscopic Surgery for Shoulder Pain

# Diagnostic arthroscopy is recommended for evaluation of carefully select patients with shoulder pain, including subsequent, definitive operative approaches.

*Indications* – One or more of the following: 1) rotator cuff tear with surgical indications with the expectation that surgical treatment will immediately follow arthroscopy (see below); 2) labral tear with surgical indications (see below); 3) impingement syndrome with surgical indications (see below); 4) other moderate or severe shoulder joint pain, acromioclavicular arthritis, or mechanical symptoms with substantially reduced ROM or functional impairment and failure to resolve with at least 1 trial of glucocorticosteroid injection and/or physical or occupational therapy (or exercise program). See specific diagnoses for additional considerations, discussion and specific indications.

#### Strength of Evidence – **Recommended**, **Insufficient Evidence (I)** Rationale for Recommendation

Arthroscopy is performed nearly universally in a context of a pre-operative diagnosis thought to be a treatable abnormality, rather than merely for diagnostic purposes. If a specific diagnosis is not suggested by and supported by the evaluation with history, physical examination, and imaging studies, then surgical intervention is much less likely to be successful and caution should be taken in doing a purely diagnostic arthroscopy. There are no quality studies of arthroscopy for diagnostic purposes due to many methodological weaknesses in the available literature. (Dinnes HTA 03) It appears helpful for diagnosis and subsequent operative approaches. (Baumann 08, Bishop 03) Diagnostic arthroscopy is invasive, has adverse effects and is high cost. However, in select patients there may be no other option for addressing the condition if a patient is not responding to conservative care. Additionally, it is highly useful for operative planning and to help determine whether arthroscopy is recommended.

## BONE SCANS

Bone scans involve intravenous administration of Technetium Tc-99m, a radioactive tracer medication that is preferentially concentrated in areas of metabolic activity (turnover) in bone. The radioactivity is then detected by a large sensor and converted into skeletal images showing the increased uptake. There are many causes for abnormal radioactive uptake, including multiple myeloma, metastases, infection, inflammatory arthropathies, fracture, or other significant bone trauma. Thus, positive bone scans are not highly specific. Bone scans have been used for diagnosis of early osteonecrosis of the humeral head prior to findings on x-ray, among other uses.

 Recommendation: Bone Scanning for Select Use in Acute, Subacute, or Chronic Pain Bone scanning is recommended for select use to evaluate acromioclavicular joint pain or where there is more than one joint to be evaluated in patients with acute, subacute, or chronic pain to assist in the diagnosis of osteonecrosis or other conditions with increased bone metabolism.

*Indications* – Shoulder pain with suspicion of osteonecrosis or other increased polyostotic bone metabolism in multiple joints and bones or acromioclavicular joint pain.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Routine Use of Bone Scanning for Routine Shoulder Joint Evaluations Bone scanning is not recommended for routine use in shoulder joint evaluations. It is generally thought to be inferior to MRI, as MRI is specific and sensitive.

## Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

Bone scanning may be a helpful diagnostic test to evaluate suspected metastases (multiple sites), infected bone (osteomyelitis), inflammatory arthropathies, and trauma (e.g., occult fractures), particularly

if MRI is not available or is contra-indicated. It may be helpful in those with suspected, early osteonecrosis (avascular necrosis) without x-ray changes. In cases where the diagnosis is felt to be secure, there is no indication for bone scanning as it does not alter the treatment or management. Bone scanning is minimally invasive, has minimal potential for adverse effects (essentially equivalent to a blood test), but is high cost.

## **COMPUTERIZED TOMOGRAPHY (CT)**

Computerized tomography remains an important imaging procedure, particularly for bony anatomy, whereas MRI is superior for soft tissue abnormalities. However, most patients have issues with soft tissue rather than bony abnormalities in the shoulder, thus on a population-basis, far fewer CT scans are ordered. CT may nevertheless be useful for shoulder joint abnormalities where advanced imaging of the bones is required (i.e., complex proximal humerus fracture, scapular fracture). CT also may be useful to evaluate the anatomy in patients with contraindications for MRI (most typically an implanted metallic-ferrous device). CT arthrogram is often preferred when evaluating posterior or anterior glenohumeral instability when the bony anatomy needs to be better defined – glenoid deficiency and humeral Hill-Sachs – as MRI is not as good for bone imaging. CT arthrogram can be used in place of MRI to evaluate for rotator cuff tear.

1. Recommendation: Routine CT for Evaluating Acute, Subacute, or Chronic Shoulder Pain Routine CT is not recommended for the evaluation of acute, subacute, or chronic shoulder pain.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

2. Recommendation: Routine CT for Evaluation of Complex Proximal Humeral and Glenoid/Scapular Fractures

Routine CT is recommended for the evaluation of complex proximal humeral and glenoid/scapular fractures.

Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: CT for Evaluating Patients with Osteonecrosis (AVN)

CT is recommended for the evaluation of select patients with osteonecrosis, particularly in whom subchondral fractures are being sought. It is also recommended for those who need advanced imaging, but have contraindications for MRI. Otherwise, MRI is thought to be superior.

*Indications* – Shoulder pain from osteonecrosis with suspicion of subchondral fracture(s) or increased polyostotic bone metabolism.

Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

MRI is considered superior to computerized tomography for imaging most shoulder abnormalities where advanced imaging of soft tissues is usually the primary concern. However, where imaging calcified structures is required, CT is considered superior. This includes complex proximal humeral and glenoid/scapular fractures. A contrast CT study is minimally invasive, has few, if any, adverse effects but is costly. It is recommended for select use.

#### Evidence for the Use of CT

There are no quality studies evaluating the use of CT for shoulder pain.

## **HELICAL CT SCANS**

Helical CT scans are sometimes used for diagnosing osteonecrosis. There is quality evidence that they are superior to MRI or x-ray for identifying subchondral fractures in the femoral head. (Stevens 03; Jurik 94)

Bone scans were traditionally used for diagnosis and may be positive even though an x-ray may be normal. (Ficat 85; Sinha 99; Svahn 75; Harreld 09) However, they have largely been replaced by MRI scans.

1. Recommendation: Routine Helical CT for Evaluating Acute, Subacute, or Chronic Shoulder Pain Routine helical CT is not recommended for evaluation of acute, subacute, or chronic shoulder pain.

#### Strength of Evidence - Not Recommended, Insufficient Evidence (I)

2. Recommendation: Helical CT for Evaluating Osteonecrosis Helical CT is recommended for evaluation of patients with osteonecrosis who have contraindications for MRI.

*Indications* – Patients with shoulder pain from osteonecrosis with contraindications for MRI (e.g., implanted hardware) or increased polyostotic bone metabolism.

Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Helical CT for Select Acute, Subacute, or Chronic Shoulder Pain Helical CT is recommended for select patients with acute, subacute, or chronic shoulder pain in whom advanced imaging of bony structures is thought to potentially be helpful. It is also recommended for those who need advanced imaging, but have contraindications for MRI.

*Indications* – Patients with acute, subacute or chronic shoulder pain with need for advanced bony structure imaging. Patients needing advanced imaging, but with contraindications for MRI (e.g., implanted hardware) are also candidates.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

Helical CT scanning has been largely replaced by MRI. However, there are patients who have contraindications for MRI (e.g., implanted ferrous metal) helical CT is recommended. Helical CT scan has been thought to be superior to MRI for evaluating subchondral fractures; however, a definitive study has not been reported. (Stevens 03)

Helical CT has few if any adverse effects, but is costly. It is recommended for select use.

Evidence for the Use of Helical CT Scans

There are no quality studies evaluating the use of helical CT scans for diagnosing shoulder pain.

## LOCAL ANESTHETIC INJECTIONS FOR SHOULDER PAIN DIAGNOSIS

See for Rotator Cuff Tendinosis Injections.

## ELECTROMYOGRAPHY (INCLUDING NERVE CONDUCTION STUDIES)

See the Neck and Upper Back Complaints and Hand, Wrist, Forearm Complaintsfor discussion regarding use of electrodiagnostic studies for evaluation of cervical and distal upper extremity-related disorders that may present as shoulder pain. Electrodiagnostic studies have also been used to confirm diagnostic impressions of other peripheral nerve entrapments, brachial plexopathies, and neurologic component of thoracic outlet syndrome. (Moghekar 07; Wilbourn 07)

Recommendation: Electromyography for Diagnosing Subacute or Chronic Peripheral Nerve Entrapments Electrodiagnostic studies are recommended to assist in the diagnosis of subacute or chronic peripheral nerve entrapments, including the long thoracic nerve, brachial plexopathies, and suprascapular nerve.

*Indications* – Patients with subacute or chronic paresthesias with or without pain, particularly with unclear diagnosis.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

Rationale for Recommendation

Electrodiagnostic studies may assist in confirming peripheral nerve entrapments such as the long thoracic nerve and suprascapular nerve. These studies are minimally invasive, have minimal potential for adverse effects, and are moderate to high cost depending on the extent of the testing required.

#### Evidence for the Use of Electromyography

There are no quality studies evaluating the use of electrodiagnostic studies for diagnosing peripheral nerve entrapments relevant to the shoulder.

## FUNCTIONAL CAPACITY EVALUATIONS

See Chronic Pain Guidelines.

## MAGNETIC RESONANCE IMAGING (MRI)

Magnetic resonance imaging (MRI) is often used as a secondary test after x-ray for many shoulder joint problems since it tends to be helpful for imaging soft tissues, particularly the rotator cuff. (Mulyadi 09; Chang 06; Ardic 06; Tuite 00; Connell 99; McFarland 09; Pandya 08; Cartland 92; Chang 08; Tirman 94; Wnorowski 97; Tung 00; Reuss 06) Although studies are not heterogeneous, pooled estimates of the sensitivity for full-thickness tears has been calculated and is 89% with specificity 93%, while for partial thickness tears, these estimates are only 44% sensitivity and 90% specificity. (Dinnes 03) Similarly accuracy is lower for smaller than larger tears. (Yamakawa 01) MRIs are considered the gold standard for evaluation of osteonecrosis patients and are used to quantify volume of affected tissue including marrow edema which is inversely correlated with prognosis. (Harreld 09; Jones 04; Koo 95; Coombs 94; Cherian 03; Radke 03; Scheiber 99; Helenius 06)

1. Recommendation: MRI for Diagnosing Rotator Cuff Tears, Tendinoses, Impingement, or Subacromial Bursitis

MRI is recommended for patients suspected of having acute, clinically significant rotator cuff tears. It is also recommended for select patients with subacute or chronic shoulder pain thought to potentially have a symptomatic rotator cuff tear.

Indications – Patients with an acute, clinically significant rotator cuff tear or subacute or chronic shoulder pain suspected of having a clinically meaningful rotator cuff tear. If there is significant rotator cuff weakness, immediate imaging may be indicated. (Exceptions include elderly patients or those who have substantial signs of pre-existing large/massive rotator cuff tear. It is also reasonable to wait for 1 or 2 weeks to ascertain whether the condition is likely to resolve with conservative care without obtaining an MRI.) Most acute tears without significant weakness should wait approximately 2 weeks prior to imaging as some patients with acute pain and limited ROM resolve clinically. Those with subacute or chronic pain should generally have failed additional non-operative treatment including NSAID, exercise and injection(s).

*Dose/Frequency* – Repeat MRI based on significant change in symptoms and/or examination findings.

Strength of Evidence – Recommended, Insufficient Evidence (I)

#### 2. Recommendation: MRI for Diagnosing Osteonecrosis (AVN) MRI is recommended for diagnosing osteonecrosis.

*Indications* – Patients with subacute or chronic shoulder pain thought to be related to osteonecrosis (AVN), particularly in whom the diagnosis is unclear or in whom additional diagnostic evaluation and staging is needed.

Strength of Evidence - Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

There is one moderate-quality study comparing MRI with arthrography, suggesting MRI is superior to arthrography; (Blanchard 99) however, arthrography alone has been largely replaced by other procedures. Otherwise, MRI has not been evaluated in high-quality studies for shoulder joint pathology. (Kassarjian 05; Leunig 04; Dinnes 03) MRI appears particularly helpful for soft tissue abnormalities. MRI has been suggested for evaluations of patients with symptoms over 3 months. (Kassarjian 05; Armfield 06; Bredella 05) MRI was

compared with arthroscopy in 57 patients with shoulder pain of unclear cause. (Torstensen 99) MRI was found to be accurate in detecting 68% of rotator cuff tears and 62% accurate in detecting labral injuries. MRI sensitivity for RC tears was 96% and specificity 49% (for labral tears, 73% sensitive, 58% specific). The authors concluded that "MRI does not appears to be an accurate effective tool for assessing shoulder pathologic conditions in patients in whom the clinical picture is not clear and therefore may not be of assistance in surgical planning for patients with these difficult conditions." MRI was compared with arthroscopic findings among 16 patients with trauma. (Kirkley 03) The authors found moderate correlation for superior labral lesions (k = 0.60), fair agreement for rotator cuff tear (k = 0.355), Hill-Sachs (k = 1.0), and moderate for size (k = 0.44). A consecutive case series of 104 patients with shoulder problems were evaluated and randomized to MRI first versus arthrography first. There were modestly fewer changes in diagnostic categories with MRI (30%) than arthrography (37%), p >0.5. MRI led to slightly more changes in planned therapy (36% vs. 25%, p >0.3). MRI was found to be 79% accurate, 81% sensitive and 78% specific for full-thickness rotator cuff tears. Arthrography was found to be 82% accurate, 50% sensitive and 96% specific. (Blanchard 99) A cross-sectional comparison of MRI (1.5T loop-gap resonator surface coil), double contrast arthrography, high resolution sonography and surgery among 38 patients with suspected rotator cuff tears did not include all patients receiving all tests or surgery (other than MRI and arthrography) and reported a sensitivity of MRI of 100%. (Burk 89). Ultrasound detected 9/15 (60%) of tears. However, the study population was small and biased in favor of overestimating the tests' sensitivity.

MRI has shown increased changes in the rotator cuff and tears with increased age, (Needell 96; Sher 95) as well as a high prevalence of bony and peritendinous shoulder abnormalities among those without symptoms. (Needell 96) MRI has reasonably good operant characteristics for full-thickness tears, although it does not have good sensitivity for partial thickness tears. (Dinnes 03) Fatty infiltration of the rotator cuff tendons is also found on MRI and thought to signify chronicity as well as portending a poorer surgical outcome. (Berhouet 09) A comparative assessment of T-2 weighted fast spin-echo technique with vs. without fat-suppression MRI for assessment of rotator cuff tears among 177 patients thought to have tears found no differences in assessments of complete tears, but differed in interpretations of partial tears. (Singson 96) Compared with surgery, sensitivity was 100% for full-thickness tears and specificity for intact tendons was 86%. Fat suppression was felt helpful for partial tears. MRI demonstrates acromial abnormalities and there is a higher prevalence of Type 3 acromion processes among those with either rotator cuff tear or impingement syndrome. (Epstein 93) It has been suggested increased T2 signal in the distal clavicle may be an indication for surgical resection.

There are no quality studies evaluating the use of MRI for osteonecrosis, although it appears helpful for staging osteonecrosis. There is low-quality evidence that MRI may be less sensitive for detection of subchondral fractures than helical CT or plain x-ray in patients with osteonecrosis. (Stevens 03) There are concerns that MRI is inferior to MR arthrography for evaluating the labrum, (Schmerl 05) thus MRI is recommended for evaluation of the joint. MRI is suboptimal for the labrum. MRI is not invasive, has potential adverse effects from issues of claustrophobia or complications of medication, but is costly. MRI is not recommended for routine shoulder imaging, but is recommended for select shoulder joint pathology particularly involving concerns regarding soft tissue pathology.

#### Evidence for the Use of MRI

There is 1 moderate-quality randomized study incorporated into this analysis.

Author/Titl e Study Type	Score (0-11)	Sample Size	Compariso n Group	Results	Conclusion	Comments
				MRI vs. Arthrography		
Blanchard 1999	4.0	N = 104 shoulde r pain	MRI first followed by arthrography	Modestly fewer changes in diagnostic categories with MRI (30%) than	"Magnetic resonance imaging and arthrography had fairly	Patients not well described. Baseline comparability not
RCT			or arthrography	arthrography (37%), p >0.5. MRI led to slightly	similar diagnostic and therapeutic impact and	shown. Data suggest MRI

	followed by MRI	more changes in planned therapy (36% vs. 25%, p >0.3). MRI found 79% accurate, 81% sensitive, and 78% specific for full- thickness rotator cuff tears. Arthrography 82% accurate, 50% sensitive and 96% specific.	comparable accuracy, although MRI was more sensitive and less specific. Magnetic resonance imaging may be the preferred investigation because of its better demonstration of soft tissue anatomy."	superior to arthrography. Data derived from case series rather than population base, likely overestimates value of tests. Arthrography alone has been largely replaced by other procedures.
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## MAGNETIC RESONANCE (MR) ARTHROGRAM

Magnetic resonance (MR) imaging is combined with arthrography to overcome MRI limitations and is usually performed in preference to CT arthrography unless bony structure definition is needed as well. (Hunter 92; Palmer 97) It is particularly thought to be effective for imaging labral pathology. (Peh 02; Waldt 04; Jee 01; Lin 09; Bencardino 00; Monu 94; Stetson 02) MR arthrography combines MRI with an arthrogram to identify both findings available with MRI, as well as the better capability to define labral tears among patients with symptoms of labral injuries in the shoulder or hip. (Beall 03)

1. Recommendation: MR Arthrogram for Diagnosing Labral Tears in Patients with Subacute or Chronic Shoulder Pain

# MR arthrography is recommended for diagnosing labral tears in patients with subacute or chronic shoulder pain.

*Indications* – Patients with subacute or chronic shoulder pain with symptoms or clinical suspicion of labral tears. Patients should generally have failed non-operative treatment including NSAID and waiting 4 to 6 weeks without trending towards resolution.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

 Recommendation: MR Arthrogram for Select Diagnosis of Impingement, Rotator Cuff Tendinosis or Tears, and Subacromial Bursitis in Patients with Subacute or Chronic Shoulder Pain MR arthrography is recommended for diagnosing articular side partial thickness rotator cuff tears, subscapularis tears, and labral tears in select patients with subacute or chronic shoulder pain.

*Indications* – Patients with subacute or chronic shoulder pain with symptoms or clinical suspicion of impingement, rotator cuff tendinosis or tears and subacromial bursitis or other concerns about the shoulder joint requiring MR imaging. Those with subacute or chronic pain should generally have failed additional non-operative treatment including NSAID, exercise and injection(s).

## Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

MR arthrograms have not been evaluated in quality studies. Although studies are heterogeneous, pooled estimates of the sensitivity for full-thickness tears is estimated at 95% with specificity 93%. (Dinnes 03) There is high prevalence for labral injury with first shoulder dislocation based on MR arthrography (MRA). (Antonio 07) Arthrography with low-field MR was found to be equivalent to high-field in a series of 38 patients. (Loew 00) A comparison of high- versus low-field MR imaging for SLAP tears among symptomatic patients found high field superior for diagnosing SLAP. (Tung 00) The sensitivity of high field MRA was 90% and specificity 63%, while sensitivity for low field was 64% and 70% specificity. MRA was found superior to CT arthrography (CTA) and marginally better than MRI for identification of labral tears in a case series of patients with recurrent anterior instability, prior anterior dislocation or shoulder pain of unknown cause. (Chandnani 93) MRA sensitivity for a labral tear was 96.4%, MRI was 92.9%, and CTA was 73.1%. Specificity was 100% for all three tests; however, this appears overstated as there were only two patients without a tear in this small case series. MR arthrography is invasive, has adverse effects including a low, but definite risk of infection and is painful. It is also costly, although MRA has been felt to provide better cost effectiveness than MRI or CT arthrography for select diagnoses. (Oh 99) It is likely the

best imaging procedure available for patients thought to have labral tears or patients with good strength in order to assess the labrum and rotator cuff with traumatic injury simultaneously, and is recommended for select use.

#### Evidence for the Use of MR Arthrogram

There are no quality studies evaluating the use of MR arthrography for shoulder pain.

## ULTRASOUND

Diagnostic ultrasound has been used for evaluating rotator cuff tears. (Naqvi 09; Ianotti 05; Moosikasuwan 05; Crass 88; Shahabpour 08; Ardic 06) Considerable methodological flaws in the available heterogenous studies have been previously described (Dinnes HTA 03) yet, ultrasound has been reported to have 87% sensitivity and 96% specificity for detection of full-thickness tears; for partial-thickness tears, the sensitivity was reportedly 67% (Dinnes HTA 03). Since then, image quality has improved, which has likely increased the sensitivity, particularly if conducted by an experienced technician.

#### Recommendation: Ultrasound for Diagnosing Rotator Cuff Tears, Tendinoses, or Impingement Ultrasound is recommended for selective use on patients suspected of having rotator cuff tears, tendinoses, or impingement.

*Indications* – Ultrasound technicians should have sufficient skill to obviate the need for scanning (Boykin 10; Hanchard 13), otherwise the test introduces unnecessary redundancy. Patients with symptoms and signs of a clinically significant acute rotator cuff tear or subacute or chronic shoulder pain suspected of having a symptomatic rotator cuff tear. (Ardic 06; Iannoti 05; Wall 12; Naredo 99) Most clinical presentations should wait approximately 2 weeks prior to imaging as some patients with acute pain and limited range of motion resolve clinically; obvious tears are an exception to waiting two weeks. Those with subacute or chronic pain should generally have failed additional non-operative treatment including NSAID, exercise and injection(s) (Ottenheijm 10, Moosikasuwan 05) A MR arthrogram is recommended for suspected labral injury (see below). (Ardic 06)

*Dose/Frequency* – Repeat ultrasound should be based on significant change in symptoms and/or examination findings.

#### Strength of Evidence – Recommended, Evidence (C)

#### Rationale for Recommendation

Ultrasound has been compared with physical examination findings, suggesting physical exam identified fewer abnormalities compared with ultrasound, though there was not clinical correlation with treatment outcomes. (Kim ModRheum 07) Ultrasound utilized to evaluate asymptomatic shoulders found increased prevalence of full-thickness tears with increased age (Sher 95; Templehof 99; with approximately 6% among 212 individuals (Schibany 04) and in 7.6% of 420. (Moosmayer 09) Asymptomatic tears increase in prevalence by age - 50 to 59 (2.1%) versus 60 to 69 (5.7%) versus 70 to 79 (15%). (Moosmayer 09) Ultrasound is thought to be relatively effective for identifying full-thickness tears; (Hedtmann 95; Zehetgruber 02; Brenneke 92; Furtschegger 88; Mack 88a & 88b; Middleton 86; Jannotti 05; Smith 11; Ottenheijm 10; Awerbuch 08) however, it appears somewhat less effective for identifying partial-thickness tears. (Buchbinder 13; Brenneke 92; Awerbuch 08; Naredo 99) A surgical case series of 42 patients attempted to determine the diagnostic accuracy of ultrasound. Ultrasound detected all full-thickness tears (100% sensitive, 97% specific), but only 6 of 13 of the partialthickness tears (46% sensitive, 97% specific). One full-thickness tear was falsely diagnosed. Another study has suggested sensitivity for detection of tear size of 83 to 86%. (Ianotti 05) Ultrasound has advantages of being able to move the arm actively or passively during the examination; it is less expensive; and it may be available in most centers. (Boykin 10) When conservative treatment failed, skilled physician's usingultrasound reportedly had high diagnostic accuracy identifying tendinopathy, calcifying tendonitis, and partial- and full- thickness tears. (Ottenheijm 10, Moosikasuwan 05) SLAP lesions cannot be well visualized using ultrasound. (Hanchard 13) Impingement was felt to have been diagnosed in 27 of 34 cases (79% sensitive, 96% positive predictive value). (Read 98) A small study of ultrasound the day before surgery for shoulder arthritis in 20 patients suggested that ultrasound was accurate for evaluating hypertrophy of the bursa (93% sensitive, 83% specific), biceps tendon rupture (70% sensitive, 100%

specific) and rotator cuff tear (83% sensitive, 57% specific). (Alasaarela 98) Ultrasound-guided MR arthrography was evaluated in an RCT with anterior versus posterior approaches and found equal ratings of discomfort. (Koivikko 08) Ultrasound is not invasive, is of low to moderate cost, and has little risk of adverse effects; therefore, although there are concerns that MRI may be superior for imaging most of shoulder soft tissue, ultrasound is recommended particularly for evaluation of rotator cuff tears. The main disadvantage is the high dependency on the physician's skills. (Boykin 10; Hanchard 13)

#### Evidence for the Use of Ultrasound

There are 14 high- and 7 moderate-quality studies incorporated into this analysis.

We searched Ultrasonography for rotator cuff tears, massive rotator cuff tears, tendon rotator cuff tears, rotator cuff partial- and full-thickness tears, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, impingement syndrome, bursitis, supraspinatus tendinitis, and bicipital tears. Seventeen new articles were included.

Score Author/Year Study Type	Diagnoses Shoulder muscle group N	Myelography Blinding of rater More than on rater MRI Used CT used Type of Ultrasonography	Results Long term follow-up (mean when noted) Clinical outcomes Surgery Performed	Comments Conclusion
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Ardic 2006 Cross- sectiona I clinical study	9.0	58	Not menti oned	Shoulde r impinge ment syndro me	7.5 MHz linear array and 5 MHz curved array		+		+			+	Non e	Sensitivity for Cuff tears: 52/53(98.1 %); specificity: 3/5 (60%); positive predictive value (PPV): 52/54 (96.3%); negative predictive value (NPV): ¾ (75%) Impingem ent test maneuver s: sensitivity: 36/46 (78.3%); specificity: 6/12 (50%); PPV: 36/42 (85.7%); NPV: 6/16 (37.5%)	"Ultrasonog raphy and magnetic resonance imaging had comparable high accuracy for identifying the biceps pathologies and rotator cuff tears. The basic clinical tests had modest accuracy in both disorders."	Study suggests MRI is superior to US for glenoid labral tears, bone erosions, and synovial effusions. For rotator cuff tears, US had comparable results with MRI.
Iannotti 2005 Prospec tive study	9.0	98	Rotat or cuff	Rotator cuff tears	Agilent Image Point HC ultraso und unit, L- 1038 linear transd ucer, 7.5 MHz	-	+	+	-	-	-	-	Non e	Ultrasono graphy: full- thickness tears: sensitivity: 0.88, PPV: 0.79, NPV: 0.90. MRI: full thickness tears: sensitivity: 0.95, PPV: 0.85, NPV: 0.96.	"[W]e recommend the use of ultrasonogr aphy in an office setting when a patient has a clinical diagnosis of a rotator cuff tear and there is little concern about additional diagnoses related to intra- articular lesions."	Data suggest US is similar in sensitivity and specificity compared with MRI for full- thickness RC tears. US had higher negative predictive value than PPV in this study.

Wall 8 2012 Prospec tive study	3.5	83	Bicep s, subsc apular is, supra spinat us, infras pinatu s, and teres minor	Rotator cuff tears, fatty degener ation around muscles	Elegra, Anatar es, iU22 or E9 scanne r, 7.5 10 15 MHz	-	+	+	+	-	-	Non e	All percentag es are for ultrasonog raphy. Supraspin atus muscle: sensitivity: 84.6%, specificity: 96.3%, PPV: 91.7%, NPV: 92.9%; infraspinat us: sensitivity: 95.6%, specificity: 91.2%, PPV: 81.5%, NPV:	"The diagnostic performanc e of ultrasonogr aphy in identifying and grading fatty degeneratio n of the rotator cuff muscles was comparable with that of MRI. Ultrasonogr aphy can be used as the primary diagnostic imaging modality for fatty	Study suggests US is viable option for muscle fatty degeneratio n in spraspinatu s, and teres minor in patients with evidence of rotator cuff pathology on physical exam.
													sensitivity: 95.6%, specificity: 91.2%, PPV: 81.5%,	aphy can be used as the primary diagnostic imaging modality for	on physical
													teres minor: sensitivity: 8735%, specificity: 87.5%, PPV: 43.8%, NPV:	rotator cuff muscles."	

Naredo 1999 Prospec tive study	8.5	34	Not specif ied	Shoulde r pain	7.5 MHz linear- phased -array transd ucer		+		+				Non e	Supraspin atus (SS) tendonitis: Sensitivity: 92.85%, specificity: 100%, PPV: 100%, NPV: 95.65%. SS full thickness tear: sensitivity: 88.88%, specificity: 100%, PPV: 100%, NPV: 90%. SS partial thickness tear: sensitivity: 90%. SS partial thickness tear: sensitivity: 92.30%, specificity: 91.30%, PPV: 85.71%, NPV: 94.45%. Infraspinat us full thickness tear: 100 for sensitivity, specificity,	"[U]S is an accurate, noninvasive , and dynamic imaging technique for evaluating patient with painful shoulder, mainly those with suspected rotator cuff injuries."	Data suggest US diagnoses full thickness tears more accurately than partial- thickness tears. Overall, U.S. had high sensitivity and specificity compared to shoulder MRI.
Misamo re 1991 Prospec tive study	8.5	32	Rotat or cuff	Degene rative lesions of the rotator cuff	Not specifi ed	-	-	+	-	-	-	-	Non e	PPV and NPV. Arthrograp hy: sensitivity: 0.85; specificity: 1.00. Ultrasono graphy: sensitivity: 0.33; specificity: 0.60	"[A]Ithough ultrasonogr aphy is a relatively inexpensive and non- invasive technique for the evaluation of lesions of the rotator cuff, it is not very accurate in the diagnosis of degenerativ e disorders."	Data suggest when not using echogenicit y to diagnose a RC disorder sentivitiy and specificity of US decreased signigicantl y in degenerativ e disorders of the RC.

Wallny 2001 Prospec tive study	8.0	40	Not menti oned	Rotator cuff tears	10 MHz transd ucer, for 2-D and 3- D					-	+	-	Non e	2-D sonograph y: sensitivity: 73.9%, specificity: 82.3%, PPV: 85.0%, NPV: 70.0%. 3-D sonograph y: sensitivity: 91.3%, specificity: 82.3%, PPV: 87.5%, NPV: 87.5%.	"Larger studies are necessary to assess if the use of 3-D imaging can increase the validity of sonographi c diagnosis of the shoulder joint."	Study should be repeated to compare to MRI, also with larger numbers and intraobserv er determinati ons. No discussion of cost- benefit or improveme nt in outcome. Data suggest 3- D US superior to 2-D US in distinguishi ng partial thickness RC tears and non- pathologic rotator
Van Moppes 1995 Prospec tive study	8.0	41	Rotat or cuff muscl es	Signs or sympto ms of rotator cuff impinge ment or tear, biceps tendiniti s, labrum and capsular abnorm alities or nonspec ific shoulde r pain	7.5 MHz linear transd ucer	+	-	-	-	-	-	-	Non e	Sensitivity: 86%, specificity: 91%, PPV: 96%, NPV: 73%.	"[W]e believe sonography of the shoulder is the method of choice after plain radiography in patients with shoulder symptoms and positive symptoms of impingeme nt or suspected tears, and facilitates the selection of the correct treatment."	cuffs. Small numbers not compared to other diagnostic modality. Data suggest ultrasound can aid in the diagnosis of supraspinat ut rotator cuff pathology.

I I I I I I I I I I I I I I I I I I I	Teefey 2000 Prospec tive study	8.0	98	Rotat or cuff	Shoulde r pain	ATL HDI 3000 or Sieme ns Elegra Scann er, 7.5 to 10 MHz	-	-	+		-	+		Non e	Full thickness of rotator cuff tears: sensitivity: 100%; specificity: 85%, PPV: 96%, NPV: 100%. Partial thickness of Rotator cuff tears: sensitivity: 67%, specificity: 85%, PPV: 77%, NPV: 77%.	"Ultrasonog raphy was highly accurate for detecting full- thickness rotator cuff tears, characterizi ng their extent, and visualizing dislocations of the biceps tendon. It was less sensitive for detecting partialthick ness rotator cuff tears and ruptures of the biceps tendon."	No comparison to other diagnostic modalities. If they had a normal U.S. and didn't get surgery – they were not included. Data suggest ultrasound has good diagnostic accuracy with rotator cuff pathology. Specifically, full- thickness rotator cuff tears. It was less accurate with partial- thickness
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Sipola 2010 Prospec tive study	8.0	77	Subsc apular is (SSC) , supra spinat us (SSP)	Chronic shoulde r pain and suspicio n of rotator cuff disease	Aloka SSD- 500 scanne r, 7.5 MHz	-	+	+	+	-	+	-	Non e	Ultrasono graphy: no tear vs. full or partial thickness tear: sensitivity: 92%,	"[O]ur results suggest that US could be used as a screening test to confirm a	Data suggest a positive finding on U.S. is helpful in diagnosing RTC tears, however a
			(SSP) , and infras pinatu s (ISP)	disease										92%, specificity: 45%, PPV: 91%; NPV: 50%; No full thickness tears vs. full thickness tear: sensitivity: 83%, specificity: 53%, PPV: 84%, NPV: 50%; Magnetic resonance artrograph y: No tear vs. full or partial thickness tear: sensitivity: 97%, specificity: 82%, PPV: 82%, PPV: 82%, NPV: 82; No full thickness tears vs. full thickness tear: sensitivity: 97%, specificity: 82%, PPV: 82%, PPV: 84%, Specificity: 82%, Specificity: 82%, Specificity: 82%, Specificity: 82%, Specificity: 82%, Specificity: 82%, Specificity: 84%, Specificity:	confirm a suspected rotator cuff tear. In patients with negative findings, an MRA should be considered for substantiati on."	however a negative U.S. result cannot be used to rule out the diagnosis of RTC tear. It also suggests U.S. cannot reliably distinguish between partial and full thickness tears.
														PPV: 98%, NPV: 71%.		

Paavola	8.0	49	Rotat	Chronic	Toshib	-	+	+	+	-	+	-	Non	Ultrasono	"[A]Ithough	Data
inen	0.0	-3	or cuff	dysfunct	a SAL	_	т	т	т	_	т	_	e	graphy:	the	suggest
1994			tendo	ion of	100,								C	full	accuracy of	U.S. is less
1994			ns	the	7.5									thickness	ultrasonogr	accurate
			and		7.5 MHz									tear of the		than
Deserves				shoulde											aphy in the	
Prospec			bicep	r	transd									rotator	diagnosis	arthrograph
tive			S	seconda	ucer									cuff:	of lesions	y in
Study			tendo	ry to										sensitivity:	of the	detecting
			n	degener										74%,	tendon is	RTC tears.
				ative										specificity:	less than	
				changes										95%,	that of	
				and a										PPV:	arthrograph	
				partial										95%,	у,	
				or full										NPV:	evaluation	
				thicknes										75%;	of the	
				s tear of										Arthrograp	painful	
				the										hy:	shoulder	
				rotator										sensitivity:	may be	
				cuff										93%,	started with	
														specificity:	non-	
														95%,	invasive	
														PPV:	ultrasonogr	
														96%,	aphy, with	
														NPV:	use of local	
														91%.	thinning	
															and	
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															diagnostic	
															criteria of a	
															tear of the	
															cuff."	

Milosavl jevic 2005 Diagnos tic	8.0	18 5	Rotat or cuff	Shoulde r sympto ms longer than 3 months	10 MHz linear- array transd ucer		-	-	-		+		Non e	Ultrasono graphy: rotator cuff tears: sensitivity: 95%, specificity: 94%, PPV: 97%, NPV: 91%; full- thickness tears: sensitivity: 100%, specificity: 91%, NPV: 91%, NPV: 91%, NPV: 100%; partial thickness tears: sensitivity: 80%, specificity: 98%, PPV: 86%, NPV: 96%	"US is a highly accurate diagnostic method for detecting full- thickness rotator cuff tears, but is less sensitive in detecting partial- thickness rotator cuff tears."	Data suggest U.S. has a high sensitivity/s pecificity in the diagnosis of full thickness RTC tears.
Friedma n 1993 Prospec tive study	8.0	46	Rotat or cuff	Shoulde r pain and signs and sympto ms of impinge ment but negative radiogra phs	Diason ics Spectr a Ultraso und, 5.0 MHz or a 7.5 MHz transd ucer	-	-	-	-	-	-	-	Non e	Ultrasono graphy: rotator cuff tears: sensitivity: 81%, specificity: 100%, PPV: 100%, NPV: 71%.	"Ultrasound of the shoulder should be considered for imaging the rotator cuff because of its accuracy, low cost, and high patient satisfaction. It can be reliably performed by radiologists with state- of-the-art equipment who are interested in and have experience with the procedure."	Authors looked at cost of U.S. vs. arthrograph y vs. MRI. Data suggest ultrasound is more accurate with RTC tears >1 cm and most accurate with tears >2 cm.

Frei 2008 Retrosp ective study	8.0	20	Rotat or cuff tear	Shoulde r pain	Toshib a DSC- V machin e, 9-13 MHz linear probe	-	+	+	-		+	+	Non e	Ultrasono graphy: rotator cuff tears: sensitivity: 1.0, specificity: 0.9	"Ultrasound and magnetic resonance imaging are both very sensitive techniques for diagnosis of rotator cuff abnormaliti es. Ultrasonogr aphy can be used as a primary method owing to its fast procedure and affordable cost."	Data suggest U.S. is highly sensitive and specific in the diagnosis of RTC tear.
Roberts 2001 Prospec tive study	8.0	24	Rotat or cuff	Impinge ment syndro me, adhesiv e capsuliti s, partial- and full thicknes s rotator cuff tears, and arthritis	Aloka Model 650, 7.5 MHz transd ucer	-	-	-	-	-	+	-	Non e	Ultrasono graphy: full- thickness rotator cuff tears: sensitivity: 80%; specificity: 100%; PPV: 100%; NPV: 88%. Partial thickness: sensitivity: 71%; specificity: 100%; PPV: 100%; NPV: 88%.	"Ultrasound of the shoulder in the hands of an orthopedic surgeon is very accurate in the imaging full thickness rotator cuff tear. Further studies are needed prior to full scale use of shoulder ultrasound in clinical practice."	Study suggests ultrasound of the shoulder has a high sensitivity/s pecificity for indication of both partial and complete rotator cuff tears.

Fotiado u 2008 Prospec tive study	7.0	88	Rotat or cuff tears	Impinge ment and suspect ed rotator cuff tear	Sieme ns Antare s Sonoli ne Syste m, 8- 13 MHz	-	+	-	-	-	-	-	Non e	Ultrasono graphy: sensitivity: 90%	"In experience d hands ultrasonogr aphy should be considered as an accurate modality for the initial investigatio n of rotator cuff, especially supraspinat us, tears."	Data suggest U.S. is accurate in diagnosing both full and partial- thickness tears of the RTC. U.S. was done by a trained examiner and high resolution linear-array system.
Nelson 1991 Prospec tive study	7.0	21	Rotat or cuff	Pain in the shoulde r more than 3 months	Acuso n 128 scanne r5 MHz linear- array transd ucer	+	+	+	+				Non e	MRI: full- thickness tear of rotator cuff: sensitivity: 86%, specificity: 93%; Partial thickness of rotator cuff: sensitivity: 67%, specificity: 89%. Computeri zed Tomograp hic Arthrograp hic Arthrograp hic Arthrograp hic Arthrograp hic Arthrograp hic Arthrograp hic Arthross: 86%, specificity: 86%. Partial thickness: 2 true positives Ultrasono graphy: full thickness: sensitivity: 60%, sensitivity: 92%; partial thickness, sensitivity: 36%, specificity: 36%,	"[M]agnetic resonance imaging was more accurate than either computeriz ed tomographi c arthrograph y or ultrasonogr aphy in identifying partial thickness tears."	Data suggest MRI is the most accurate study in detecting shoulder pathology confirmed with surgery.

Crass 1985 Prospec tive study	7.0	12 2	Rotat or cuff	Shoulde r pain	Diason ics DS- 11, 10 MHz transd ucer	-	-	-	-	-	+	_	Non e	Ultrasono graphy: rotator cuff tear: sensitivity: 100%, specificity: 94%. Arthrograp hy: sensitivity: 61%, specificity: 93%.	"We have found ultrasonogr aphy to be more reliable than arthrograph y in the diagnosis of the normal rotator cuff; we have seen no patient with a normal sonographi c pattern who had an abnormal rotator cuff at surgical exploration.	Data suggest U.S. is both sensitive and specific in diagnosing RTC tears when compared with finding during surgery.
Furtsch egger 1988 Prospec tive study	7.0	40 6	Rotat or cuff tears	Shoulde r pain	LSC 7000, 5 MHz, 7.5 MHz	-	-	-	-	-	+	-	2 to 18 mont hs after surg ery	Ultrasono graphy: Sensitivity: 91% for surgical and imaging findings	"[T]he many advantages of ultrasonogr aphy make it the method of choice in the diagnosis of rotator cuff tears. If the ultrasonogr aphic findings are unequivoca I, the performanc e of an arthrograph y is not necessary."	Data suggest U.S. is highly sensitive for RTC tears >1 cm in length when comaped to surgical finding.

Takagis	6.0	12	Rotat	Rotator	Hitachi	-	-	+	-	-	+	-	Non	Full	"[A]ccurate	Data
hi 1996		2	or cuff	cuff	EUB-								е	thickness	ultrasonogr	suggest
				tears	340,									tears:	aphic	ultrasound
Prospec					EUB-									sensitivity:	diagnosis	is more
tive					415, or									76%,	of rotator	helpful in
study					EUB-									specificity:	cuff tear	detecting
					515									100%;	requires a	full-
														Partial	high-	thickness
														Thickness:	resolution	rotator cuff
														sensitivity:	machine,	tears than
														50%,	as well as	partial-
														specificity:	considerabl	thickness
														90%.	е	tears.
														Sensitivity	experience	
														of Partial	in	
														tears:	interpretatio	
														EUB-515	n." <sup>'</sup>	
														vs. EUB-		
														340:		
														p<0.05.		

Bryant	5.0	53	Rotat	Signs	Acuso	-	+	-	+	-	+	-	Non	Area	"[T]he	Data
2002	5.0	55	or cuff	and	n		-		т	_	т	-	e	estimates	ability of	suggest
1			-	sympto	128XP,									based on	ultrasonogr	U.S. and
				ms of	5 to 10									global	aphy to	MRI do well
Prospec				rotator	MHz									clinical	determine	at
tive				cuff tear										history	the size of	estimating
study														and examinati	rotator cuff	the size of full-
														on	tears was very similar	thickness
														correlated	to that of	RTC tears,
														poorly with	MRI. This	but not
														the actual	does not	partial
														size of full-	mean to	tears.
														thickness	say that	
														rotator cuff	there was	
														tears found at	no	
														surgery,	advantage to using	
														r=0.41	MRI; this	
														(p=0.02),	modality	
1														underesti	may give	
1														mated	additional	
1														size by	information	
1														38%. Area	about	
														estimates based on	muscle degeneratio	
1														ultrasound	n and other	
														correlated	coexistent	
														well to	pathologic	
														actual size	processes."	
														at surgery,	-	
														r=0.73		
														(p<0.001), underesti		
														mated		
														size by		
														33%. Area		
														estimates		
														based on		
														MRI		
														correlated		
														well to actual size		
														at surgery,		
														r=0.74		
														(p<0.001),		
1														underesti		
1														mated		
1														size by 30%. Area		
1														estimates		
1														based on		
1														arthroscop		
														у		
1														correlated		
1														well with		
1														actual size		
1														at surgery, r=0.92		
1														(p<0.001),		
1														underesti		
1														mated		
1														size by		
1														12%.		
1														Estimates		
1														for partial		
														tears did not		
1														correlate		
1														with		
-														-		

Ahovuo 1989	5.0	88	Rotat or cuff	Chronic shoulde	Toshib a SAL	-	-	-	-	-	+	-	Non e	Ultrasono graphy,	"[U]S of the shoulder	Data suggest
				r pain	100,									post-	joint	U.S. was
Prospec				and	7.5									surgery:	reveals full-	more
tive				dysfunct	MHz									21/88, true	thickness	accurate in
study				ion from										positive;	tears of the	diagnosing
				lesions										3/88 false	rotator cuff.	RTC tears
				of the										positive;	However, in	>2 cm in
				tendons										57/88 true	the	diameter.
				of the										negative;	diagnosis	
				rotator										and 7/88	of small-	
				cuff										false	sized, full-	
														negative	thickness	
															tears of the	
															tendinous	
															cuff, there	
															may be difficulties	
															with static scans. US	
															helps to	
															show	
															tendinitis	
															and	
															dislocation	
															of the	
															biceps."	

# SINGLE PROTON EMISSION COMPUTED TOMOGRAPHY (SPECT) AND POSITRON EMISSION TOMOGRAPHY (PET)

See Chronic Pain Guidelines.

## ARTHROGRAPHY

Arthrography involves the injection of contrast into the joint. It was modified in the 1970s to include injection of air ("double contrast"). (Guckel 97) Arthrography under fluoroscopy in isolation has now been almost entirely replaced by other procedures, including MRI and MR arthrography, primarily due to its low sensitivity for full-thickness tears and essentially no sensitivity for partial thickness tears. (Blanchard 98) Most arthrograms including MR arthrogram and CT arthrogram are performed using fluoroscopy to localize the joint and inject the contrast agent.

## **DIAGNOSTIC INJECTIONS**

Diagnostic injections particularly of the subacromial space, glenohumeral joint and acromioclavicular joint are sometimes performed. However, they are nearly always performed in combination with a therapeutic intervention, such as a glucocorticosteroid injection. Injection with a therapeutic agent is nearly always preferable due to less overall invasiveness with 1 injection rather than 2, as well as the potential to assess the patient both immediately post-injection for diagnostic purposes as well as longer term for therapeutic purposes (see Injections).

## ROTATOR CUFF TENDINOPATHIES, INCLUDING ROTATOR CUFF TENDINITIS, ROTATOR CUFF TEARS (PARTIAL- OR FULL-THICKNESS TEARS), SUPRASPINATUS TENDINITIS, CALCIFIC TENDINITIS, IMPINGEMENT SYNDROME, BICIPITAL TENDINITIS, ROTATOR CUFF TEARS AND SUBACROMIAL BURSITIS

Degenerative tendinopathy is the primary pathology underlying this closely related group of disorders, whether these conditions are primarily related to aging, insufficient vascular supply to the tendon, (Viikari-Juntura 08; Morken 00; Silverstein 08; Miranda 01; Miranda 05; Luime 04; Wendelboe 04; Skov 96; Stenlund 93; Kane 06; Kaergaard 00) and/or mechanical impingement. (Neer 72) The majority of rotator cuff tears initiate in the

supraspinatus tendon. They can extend posteriorly into the infraspinatus and teres minor or be associated with subscapularis tears. Subscapularis tears can present in isolation. The supraspinatus tendon is prone to degeneration such that it appears that most people develop degenerative tendons over a lifetime. (Needell 96; Reilly 06; Worland 03; Sher 95; Reilly 06; Tempelhof 99; Schibany 04; Sakurai 98; Yamamoto 09; Clayton 08; Yamaguchi 06; Miranda 05; Silverstein 08; Wilson 43; Moosmayer 09; Neer 72; Milgrom 95; Miniaci 95; Codman 34; Keyes 35; Cotton 64) A study of patients without shoulder problems found 15% had full- and 20% had partial-thickness rotator cuff tears with the frequency of tears increasing with age. (Sher 95) Another study (Tempelhof 99) found asymptomatic rotator cuff tears overall in nearly one-quarter of the subjects with tears in 13% of the youngest (50 to 59 years), 20% (60 to 69) and 31% (70 to 79) of the middle-aged, and 51% of the oldest (age >80 years). The study concluded that rotator cuff tears should be regarded as "normal' degeneration, not necessarily causing pain and functional impairment." A systematic review exploring the frequencies of rotator cuff tears in asymptomatic and symptomatic tear was approximately 40%, with symptomatic tears occurring from about the same to nearly double the frequency, depending on the method of detection used.

The supraspinatus tendon was thought to be susceptible to mechanical impingement between the head of the humerus and the acromion process, thus the term impingement syndrome is also popular, particularly when symptoms are elicited with overhead use, (Neer 72) but might not be primary cause of pathology in many rotator cuff syndromes. The subacromial/subdeltoid bursa is a contiguous space that overlies the rotator cuff tendons. Consequently, bursitis or degenerative bursal changes often accompany these conditions.

 Table 5. Prevalence of Rotator Cuff Tears in Asymptomatic and Symptomatic Persons As

 Detected by Ultrasound and MRI

Technique	Asymptomatic/Symptomatic	Number of	Prev	alence of Tear	s (%)
rechnique	Asymptomatic/Symptomatic	Scans	Any	Partial	Full
Ultrasound	Asymptomatic	591	38.9	17.2	21.7
Ull'asound	Symptomatic	1038	41.4	6.7	34.7
MRI	Asymptomatic	271	26.2	15.9	10.3
	Symptomatic	490	49.4	8.6	40.8

Over a 5-year period, 51% of previously-asymptomatic tears became symptomatic with a mean of 2.8 years to onset of symptoms in subjects who had documented bilateral rotator cuff tears with one side asymptomatic. (Yamaguchi 01) The age the newly-found, asymptomatic tears was unknown; thus, the average time it took a tear to become symptomatic was over 2.8 years. The effect of one symptomatic shoulder on the eventual occurrence of symptoms in the asymptomatic shoulder is unknown.

Adapted from Reilly P, MacLeod I, MacFarland R, Windley J, Emery R. Dead men and radiologists don't lie: a review of cadaveric and radiological studies of rotator cuff tear prevalence. *Ann Royal College of Surg Engl.* 2006; 88:116-21.

## **DIAGNOSTIC CRITERIA**

Patients with rotator cuff tendinoses have varying clinical presentations, thus there are no consensus diagnostic criteria that have proven effective. Patients generally have gradual onset, non-radiating glenohumeral joint pain. There are no distal paraesthesias. Rotator cuff tears may present with either acute or gradual onset pain. Impingement signs are often positive.

## SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS

Patients are clinically diagnosed based on their history and physical examination. Additional tests are frequently performed on initial evaluation for more severe presentations, but often are not required in mild cases. X-ray is recommended and may be needed of both shoulders, particularly if there is a bilateral injury or need for comparison with the unaffected shoulder. Other studies are often helpful, including MRI, especially for evaluation of potential rotator cuff tears or SLAP tears.

Recommendation: X-ray to Diagnose Shoulder Joint Pain
 X-ray is recommended to diagnose shoulder joint pain.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: MRI and MRA to Diagnose Causes of Rotator Cuff Tears MRI or MRA is recommended to diagnose rotator cuff tears.

Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Ultrasound to Diagnose Rotator Cuff Tears Ultrasound is recommended to diagnose rotator cuff tears.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

X-ray is the initial diagnostic test, particularly to help identify the presence and extent of any additional, especially treatable, conditions that might be contributing to the shoulder joint pain. X-rays are useful to rule out fracture in trauma cases where there may also be a rotator cuff tear. MRI and diagnostic ultrasound are recommended particularly for evaluation of rotator cuff tears. MRA may be considered if there is concomitant belief a significant labral tear may be present.

## WORK ACTIVITIES

Patients with shoulder pain related to tendinoses should generally be encouraged to perform work activities within limitations of pain. However, some explicit limitations are often needed, especially for more physically demanding work activities. Such limitations are gradually reduced as recovery progresses and most commonly include limitations in heavy lifting and forward flexion and abduction, especially beyond 60°.<sup>V</sup> As the condition improves, limitations should be reduced or eliminated. Patients with clinically significant rotator cuff tears may need either surgery, or if non-operative management is planned, (Bokor 93; Itoi 92; Goldberg 01) longer duration of workplace limitations to allow for sufficient pain reduction and recovery of sufficient strength. If surgery is performed, there is a similar need for workplace limitations that are gradually reduced.

## **INITIAL CARE**

Initial care of rotator cuff tendinopathies nearly always involves non-operative treatment during which time it often becomes clearer whether a tear is present, and if so, how significant it is. Educating the patient regarding the generally good long-term prognosis and need to continue use and ROM exercises to prevent potential adhesive capsulitis is recommended. For patients with significant pain, over-the-counter (OTC) analgesics and self-applications of heat and ice are recommended. Slings and immobilizers are not recommended, and if used, should be used with daily range of motion exercises and for only a brief course.

1. Recommendation: Over-the-counter Analgesics and Self-applications of Heat and Ice for Treatment of Rotator Cuff Tendinopathies

Over-the-counter analgesics and self-applications of heat and ice are recommended for the treatment of rotator cuff tendinopathies.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Slings and Braces for Treatment of Rotator Cuff Tendinopathies Slings and braces are not recommended for the treatment of rotator cuff tendinopathies.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

There are no quality trials evaluating analgesics, ice, heat, or slings and braces for managing rotator cuff tendinopathies. However, analgesics and OTC NSAIDs are likely helpful and there is some quality evidence for the use of prescription NSAIDs (see below). Self-applications of heat and ice may be helpful for self-management of symptoms, are not invasive, have low adverse effects, not costly, and are

<sup>&</sup>lt;sup>v</sup>It may be necessary to describe this as not lifting the hand above the shoulder or most commonly no "overhead use." Also, 90 to 120° of abduction and forward flexion is the most compromised biomechanical position for the shoulder in biomechanical experimental studies. Maintaining higher overhead height is less compromising to the shoulder than lowering to 90° if the object cannot be lowered substantially. (Garg 02, 05, 06)

believed to be helpful for treating symptoms; thus, they are recommended. Slings and braces are not recommended as they promote debility and are thought to increase the risk for adhesive capsulitis.

## FOLLOW-UP VISITS

Patients with rotator cuff tendinopathies usually require follow-up appointments, particularly if they are undergoing active treatment(s), need assistance with advancing a course of exercises, and/or require significant work limitations that need frequent adjustments. Frequencies of appointments may also be greater when more workplace limitations are required and job demands are greater. Patients with rotator cuff tears who undergo surgical repair may require at least several weeks to a few months of post-operative rehabilitation. Patients with rotator cuff tears managed non-operatively (generally small tears and/or with minimal or short-duration impairment and/or with other comorbid conditions) may require longer duration limitations and slower recovery may occur. In those cases, the patient may require therapy on a prolonged basis in order to recover as much function as possible.

#### MEDICATIONS NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND ACETAMINOPHEN

Nonsteroidal anti-inflammatory drugs (NSAIDs) have been widely used to treat shoulder pain, including tendinoses (Brox 03; Green 00; van der Windt J Clin Epidemiol 95; Ginsberg 85; Calabro 85; Abdul-Hadi 09; Itzkowitch 96) as well as in post-operative patients (see Chronic Pain Guidelines). Acetaminophen and paracetamol are sometimes utilized to treat shoulder pain, although their effects on cyclooxygenase activity are minimal and they are not anti-inflammatory.

1. Recommendation: NSAIDs for Treatment of Acute, Subacute, or Chronic Shoulder Pain or Postoperative Pain

# NSAIDs are recommended for treatment of acute, subacute, or chronic shoulder pain, particularly rotator cuff tendinopathies and for post-operative pain.

Indications - Shoulder or post-operative pain. (Adebajo 90; Petri 87; Berry 80; Mena 86)

*Frequency/Dose* – Numerous NSAIDs have been utilized in quality trials, including celecoxib, diclofenac, fentiazac, flurbiprofen, ibuprofen, indomethacin, meloxicam, naproxen, nimesulide, piroxicam, sulindac, and tolmetin – see manufacturer's recommendations. Generally, treat post-operative patients for 2 to 8 weeks post-op unless complications occur.

Indications for Discontinuation – Resolution of pain, adverse effects, intolerance.

Strength of Evidence – Strongly Recommended, Evidence (A) – Acute, subacute, chronic Recommended, Evidence (C) – Post-operative

2. Recommendation: Acetaminophen for Acute, Subacute, Chronic, or Post-operative Shoulder Pain Acetaminophen is recommended for acute, subacute, chronic or post-operative shoulder pain, particularly for those with contraindications for NSAIDs.

*Indications* – Shoulder pain, including acute, subacute, chronic or post-operative.

*Frequency/Dose* – See manufacturer's recommendations; may be utilized on an as-needed basis. It has been suggested that 1gm doses are more effective than 650mg doses particularly in post-operative patients. (Med Let 09; McQuay 02) However, this level is now above the maximum dose recommended by an FDA advisory committee of 650mg. Evidence of hepatic toxicity has been reported at 4gms a day in a few days particularly among those consuming excessive alcohol. (<u>http://edocket.access.gpo.gov/2009/pdf/E9-9684.pdf</u>)

Indications for Discontinuation – Resolution of pain, adverse effects, intolerance.

Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: NSAIDs for Patients at Risk for GI Adverse Effects Concomitant prescriptions of cytoprotective medications are recommended for patients at substantially increased risk for gastrointestinal bleeding. *Indications* – Patients with a high-risk factor profile who have indications for NSAIDs, particularly if longer term treatment is contemplated; at-risk patients (e.g., those with a history of prior gastrointestinal bleeding, or elderly, diabetics, or cigarette smokers). Providers are cautioned that H2 blockers might not protect from gastric ulcers. (Robinson 89, 91; Ehsanullah 88)

*Frequency/Dose/Duration* – For proton pump inhibitors, misoprostol, sucralfate, and H2 blockers, dose and frequency as recommended by manufacturer. Duration either extent of NSAID therapy or permanent for those with recurrent bleeds or other complications.

*Indications for Discontinuation* – Intolerance, development of adverse effects, or discontinuation of NSAID.

Strength of Evidence – Strongly Recommended, Evidence (A) – Proton pump inhibitors, misoprostol

Moderately Recommended, Evidence (B) – Sucralfate Recommended, Evidence (C) – H2 blockers

4. Recommendation: NSAIDs for Patients at Risk for Cardiovascular Adverse Effects Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Strength of Evidence – Recommended, Insufficient Evidence (I)

Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse effects to use for these patients with cardiovascular disease risk factors.

#### Strength of Evidence – Strongly Recommended, Evidence (A)

If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or 8 hours before the daily aspirin. (Antman 07)

#### Rationale for Recommendations

NSAIDs have been evaluated in quality studies that include placebo-controlled trials and at least one high-quality trial. (Adebajo 90) All trials demonstrate superiority compared to placebo. Thus, there is quality evidence that NSAIDs are effective for treating shoulder pain, particularly tendinitis and bursitis. (Adebajo 90; Petri 87; Mena 86; Berry 80) There also is quality evidence of their efficacy for post-operative shoulder patients. (Hoe-Hansen 99)

There are numerous moderate-quality trials comparing NSAIDs head-to-head, however, there is no clear evidence of superiority or inferiority of any particular NSAID. (Bertin 03; Vidal 01; Wober 98, 99; Lecomte 94; Zuinen 93; Smith 86; Friis 92; McIlwain 88; Huskisson 83; Valtonen 78; Duke 81; Yamamoto 83; Thumb 87; Ginsberg 85; Rhind 82; Famaey 84; Hayes 84; Wielandts 79) One moderate-quality trial suggested comparable efficacy of an NSAID compared to a glucocorticosteroid injection for treatment of acute and subacute shoulder pain. (White 86) NSAIDs and acetaminophen are not invasive and have low adverse effects profiles, particularly when used for short courses in occupational populations. Generic or over-the-counter formulations are low cost. NSAIDs and acetaminophen may avoid treatment with opioids, which have far worse adverse effect profiles (see Chronic Pain Guidelines). NSAIDs and acetaminophen are recommended for treating acute, subacute, chronic, and post-operative patients. By analogy to treatment of other musculoskeletal conditions such as low back pain (see Low Back Complaints), acetaminophen is believed to be less efficacious, though it generally has a lower adverse effect profile.

There are four commonly used cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers (famotidine, ranitidine, cimetidine, etc.), and proton pump inhibitors (esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole). Generally, there is not believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding at pharmacologically equivalent dosing (Graham 02) although evidence suggests the histamine-2 blockers are less effective for protection of the

gastric mucosa and sucralfate is weaker than proton pump inhibitorsThere are NSAID/misoprostol combination products that have documented reductions in risk of endoscopic lesions (see evidence table).

#### Evidence for the Use of NSAIDs for Shoulder Pain

There are 3 high-quality and 22 moderate-quality RCTs (one with two reports) incorporated into this analysis. There is 1 low-quality RCT (Heere 88) in Appendix 2.

			RCT (Heere 88) III /			•
Author/Title Study Type	Score (0-11)	Sample Size	Comparison	Results	Conclusion	Comments
Study Type	(0-11)	5126	Group	D vs. Placebo		
Adebajo 1990 RCT	8.0	N = 60 acute or subacute rotator cuff tendinitis	Diclofenac 50mg TID vs. triamcinolone hexacetonide 80mg vs. placebo (lignocaine injections). Double dummy; 4-week follow-up.	Diclofenac superior to placebo (p = 0.027) triamcinolone injection (p = 0.027).	"Both forms of treatment were superior to placebo in reducing pain, improving active3 abduction and reducing functional limitation. Triamcinolone showed the greatest effect in these respects, and was significantly superior to diclofenac when patients showing improvements in all 3 variables together (responders) were considered."	Injection and NSAID superior to placebo. Trend towards best results with injection for all outcome variables.
Petri 1987 RCT	7.5	N = 100 painful shoulders; no adhesive capsulitis. 20% with calcific tendinitis and 24% AC arthrosis (appears to include acute to chronic patients)	<ol> <li>Injection with</li> <li>4mL 1% lidocaine</li> <li>plus naproxen</li> <li>500mg BID vs. 2)</li> <li>injection 3mL</li> <li>lidocaine plus</li> <li>triamcinolone 40mg</li> <li>plus naproxen vs.</li> <li>injection with</li> <li>lidocaine plus</li> <li>triamcinolone plus</li> <li>triamcinolone plus</li> <li>triamcinolone plus</li> <li>placebo vs. 4)</li> <li>injection with</li> <li>lidocaine plus</li> <li>placebo. Naproxen</li> <li>treatment 30 days;</li> <li>4 weeks follow-up.</li> </ol>	Percent remission at 2/4 weeks: Group 1 12/20% vs. Group 2 20/28% vs. Group 3 8/28% vs. Group 4 4/8%. Naproxen not superior to placebo at 4 weeks. Post hoc analyses of outcomes showed pretreatment clinical index most predictive (p = 0.00005) than treatment of duration of symptoms (p = 0.004).	"[B]oth triamcinolone (p=0.00005) and naproxen (P=0.02) are superior to placebo in the treatment of the painful shoulder."	Data suggest injection superior to naproxen and both superior to placebo. Naproxen plus injection trended towards superior to injection alone at 2 weeks. Patients' baseline status main determinant of outcome.
Itzkowitch 1996 RCT	6.0	N = 80 acute or subacute rotator cuff tendinitis	Tenoxicam 20mg vs. placebo injections "directed towards the glenohumeral joint and the subacromial space" weekly for 1 to 4 weeks.	Global impressions of patients marked improvement/cured (Days 8/15/22/28/last visit): tenoxicam (11/19/ 22/26/27) vs. placebo (5/11/9/12/ 13), p = 0.088, p = 0.006, p = 0.012, p <0.001, p < 0.001. Overall tolerability trended slightly to placebo.	"Local injection of tenoxicam seems to be a promising new treatment of acute, painful, local inflammatory processes."	Sparse details; more mobility restrictions in placebo group. Unclear if injection is superior to oral NSAIDs and warrants the increased pain and discomfort of multiple injections.
Mena 1986 RCT	5.0	N = 68 acute bursitis or tendinitis; symptoms	Flurbiprofen 300mg QID vs. placebo. Dose decreased to 200mg QID after 1 day if symptoms	Better (%) at day 1/3-4/7/final: flurbiprofen (51.9%/88.2%/100% /	"Flurbiprofen was significantly more effective than placebo according to investigators' overall	Data suggest efficacy for acute shoulder tendinitis/bursiti s patients.

		under 4 days duration	sufficiently improved, withdrawn from study if insufficient relief after 3 days; 14 day follow-up.	85.7%) vs. placebo (22.2/62.9/64.0/59.4 %).	assessments of disease improvement at all follow-up periods."	
				ucocorticosteroid Injec		
Berry 1980 RCT	4.0	N = 60 painful stiff shoulder	Acupuncture (classic Chinese with moxibustion 1 week) vs. steroid injection (methylprednisolo ne 40mg plus 2mL 2% lignocaine) plus placebo tolmetin vs. steroid injection plus tolmetin 400mg TID vs. ultrasound (8 sessions, 10 minutes per session) vs. sham ultrasound plus placebo tolmetin; 4 weeks follow-up.	VAS pain (weeks 0/2/4) acupuncture (41.3 $\pm$ 33.2/38.6 $\pm$ 26.7/34.1 $\pm$ 27.2) vs. steroid injection plus placebo tolmetin (39.0 $\pm$ 26.3/20.6 $\pm$ 20.5/26.6 $\pm$ 22.5) vs. steroid injection plus tolmetin (39.1 $\pm$ 27.3/ 26.2 $\pm$ 21.3/29.2 $\pm$ 24.3) vs. ultrasound (48.2 $\pm$ 29.9/33.7 $\pm$ 34.0/41.2 $\pm$ 36.6) vs. sham ultrasound and placebo tolmetin (52.2 $\pm$ 26.0/ 29.4 $\pm$ 23.6/22.0 $\pm$ 28.6). Mean ROM improved. More successes in placebo group than others (9/12 75% vs. 50%) (NS).	"It is suggested that the results show that the painful stiff shoulder may be a self-limiting condition and that any beneficial effect was really due to natural recovery."	Appears to target adhesive capsulitis patients. Small sample size in each arm. VAS pain ratings not normally distributed. Data suggest equal (in)efficacy.
		1		der Surgery: NSAID vs.		1
Hoe- Hansen 1999 RCT	7.0	N = 41 undergoin g subacromi al decompres sion for impingeme nt syndrome resistant to NSAIDs, rest, physical therapy, injections; had positive lidocaine test	Ketoprofen 200mg QD vs. placebo for 6 weeks post- op after arthroscopic subacromial decompression, bursectomy and anteroinferior acromial resection. Treatment begun in recovery room. All treated with exercises; 2 year follow-up.	UCLA scores (pre- op/6 weeks/2 years): ketoprofen (16/30/31) vs. placebo (16/26/29), p <0.05 at 6 weeks. Percentages with mild or no pain and satisfied with treatment ketoprofen (84%/82%) vs. placebo (47%/67%), p <0.05 at 6 weeks.	"Patients receiving ketoprofen had significantly less need for additional analgesia (P<.05). At the 2-year follow-up, there were no differences in the scores between the ketoprofen and placebo group."	Some details sparse. Data on less need for additional analgesics not provided. Data suggest ketoprofen resolves post- operative condition more rapidly with less pain and greater satisfaction.
Bertin	9.0	N = 202	Celecoxib 400mg	Change in maximum	"Celecoxib 400	Acute shoulder
2003 RCT	0.0	shoulder tendinitis or bursitis onset in prior 14 days	a day vs. naproxen 1g a day for 14 days. Double dummy; 28 days follow-up.	pain intensity celecoxib: $53.0\pm2.7$ vs. naproxen: $47.7\pm2.6$ , p = 0.16. Patient overall assessment as good	mg/day was at least as effective as naproxen 1 g/day in managing pain in this condition."	pain patients. Data suggest equivalency.

				assessments: 76.3% vs. 67.3%.		
Vidal 2001 RCT	8.0	N = 599 soft-tissue rheumatis m of shoulder (RC tendinitis, impingem ent, bicipital tendinitis)	Meloxicam 15mg QD vs. 7.5mg QD vs. piroxicam 20mg QD for 14 days; double dummy.	Pain on active movement (Day 3/7/14): meloxicam 7.5mg (28/47/60) vs. meloxicam 15mg (29/46/58) vs. piroxicam 20mg (23/43/54) (p = 0.0054, p = 0.20, p = 0.066). Shoulder scores (Days 3/7/14): meloxicam 7.5mg (24/42/53) vs. 15mg (25/39/50) vs.	"Treatment with meloxicam was at least as effective as treatment with piroxicam, with a favourable global tolerability for both doses of meloxicam."	Large sample size. Data suggest comparable efficacy with some data statistically but some trends favoring meloxicam.
Lecomte 1994 RCT	7.5	N = 205 tendinitis and bursitis of shoulder, elbow, wrist, ankle or knee	Nimesulide 100mg BID vs. naproxen 550mg BID for 14 days.	piroxicam (19/37/48), p = 0.0062, p = 0.095, p = 0.10 Pain intensities baseline/Day 7: nimesulide 73.95± 11.74/36.75±21.57 vs. naproxen 72.93±11.39/ 37.23±21.07 (NS). Number completely recovered and prematurely withdrawn 11.9% nimesulide vs. 5.8%	"There was no statistical difference between the two treated groups regarding the general clinical examination and the biological follow-up."	Study on shoulder, but enrollments slow, so expanded to multiple diagnoses; 62% shoulder. Data suggest comparable efficacy, although complete cures trended in favor
Wober 1998, 1999 RCT	7.5	N = 122 acute bicipital tendinitis or subdeltoid bursitis less than 7 days duration	Nimesulide 100mg BID vs. diclofenac 75mg BID. Double dummy; 14 day treatment.	naproxen. Completions lower for diclofenac (78.3% vs. 93.5%), largely related to adverse effects. Mean symptom scores (baseline/Day 14): nimesulide (15.4± 3.13/4.2±3.07) vs. diclofenac (15.5± 2.99/5.4±4.4).	"Nimesulide in the recommended dose of 100 mg twice daily was shown to beat least as efficacious as other NSAIDs but superior in several aspects of safety and tolerance."	of nimesulide. Some details sparse. Data suggest equivalency for efficacy. Greater dropouts with diclofenac.
Smith 1986 RCT	7.0	N = 40 chronic shoulder pain; symptoms of at least 1 month	Piroxicam 20mg QAM vs. naproxen 250mg BID. Both treated with exercises; 3 week follow-up.	Pain on movement (baseline/Weeks1/2/ 3): piroxicam 5.2/4.5/ 4.4/4.0 vs. naproxen 4.8/4.9/4.5/4.4 (NS). Abduction with elbow straight: piroxicam (78.2/88.7/ 93.2/95.3) vs. naproxen (75.6/83.6/ 92.5/94.2).	"No difference between the drugs was demonstrated regarding their effect on pain on active movement of the shoulder and external rotation."	Submaximal doses. Data suggest comparable efficacy for improving ROM, although minimal effect on pain ratings in this study population.
Zuinen 1993 RCT	6.5	N = 372 acute shoulder tendinitis/ bursitis (most RC tendinitis); symptoms within 72 hours	Diclofenac 50mg/misoprostol 200µg BID-TID vs. diclofenac 50mg/placebo BID-TID for 14 days.	No differences in physician or patient global assessments (graphic data). Higher abdominal pain (15.1% vs. 8.6%), nausea (11.9% vs. 5.9%), vomiting (5.4% vs. 2.1%) for diclofenac/	"[I]n the short term treatment of acute tendinitis/bursitis of the shoulder diclofenac/ misoprostol possesses efficacy similar to that with diclofenac alone and provides the	Variable dose of BID-TID, though fixed throughout trial. Data suggest comparable efficacy, however higher adverse effects for misoprostol

		before treatment. BID vs. TID selected based on clinical status at baseline		misoprostol group.	gastroprotective benefit of misoprostol."	group.
Friis 1992 RCT	6.5	N = 147 shoulder tendinitis	Ibuprofen 600mg QID vs. sustained release 1200mg BID for 3 weeks. Double dummy. All corticosteroid injection (2mg soluble, 5mg crystalline betamethasone plus lidocaine 1%). Repeat injection "if necessary."	Patient global assessments: ibuprofen better/complete relief 56/73 (76.7%) vs. SR 48/72 (66.7%) (NS). Doctor's assessments better 58/73 (79.5%) vs. SR 51/70 (72.9%).	"[T]he two treatment regimens can be rates as clinically equivalent."	Combination(s) with injections limits interpretation of results. Data suggest comparable efficacy.
Huskisson 1983 RCT	6.0	N = 40 painful stiff shoulder	Diclofenac 50mg TID vs. ibuprofen 400mg TID for 2 weeks	Patient's overall assessments excellent/good diclofenac 3/20 (15%) vs. ibuprofen 2/19 (10.5%).	"[D]iclofenac sodium was at least as effective as ibuprofen"	Patients not well described; submaximal dose ibuprofen. Data suggest comparable efficacy, but neither appears highly or moderately
Valtonen 1978 RCT	6.0	N = 120 soft-tissue rheumatis m; most subacute or chronic pain of neck, shoulder or back	Diclofenac 25mg TID vs. naproxen 250mg BID for 2 weeks. Double dummy.	Pain at rest improved diclofenac 58%/60% at days 7/14 vs. naproxen 39/48%. Sum of symptom scores diclofenac 75/80% vs. naproxen 61/72%.	"In most indications the therapeutic efficacy of the two preparations was similar. In patients suffering from diseases affecting the shoulder region, however, diclofenac sodium was significantly more effective "	effective. Heterogenous population of patients; submaximal dose.
Yamamoto 1983 RCT	6.0	N = 313 cervicobrac hial syndrome and stiff shoulder	Piroxicam 20mg QD vs. indomethacin 25mg TID. Double dummy.	Not stratified on enrollment, but results stratified. Cervicobrachial syndrome patients markedly improved 27.9% piroxicam vs. 27.2% indomethacin. Periarthritis scapulohumeralis piroxicam 25.3% vs. indomethacin 25.4%. Adverse effects among 14.3% piroxicam vs. 18.2% indomethacin.	effective." "The drugs were found to have comparable overall efficacy, with over 75% of the patients in both groups experiencing some improvement."	Patients not well described.
Duke 1981	5.5	N = 59 shoulder	Naproxen 275mg TID vs.	Physician assessment at 2/4	"[A]nti-inflammatory drugs probably have	Data suggest equivalency.

RCT		periarthriti s, including mostly adhesive capsulitis (64%), some tendinitis/ bursitis	indomethacin 25mg plus 50mg HS; 4 weeks follow-up.	weeks, cured plus better: naproxen 13/30(43.3%)/11/30 (36.7%) vs. indomethacin 14/29(48.3%)/11/29 (37.9%), NS. Patient assessments comparable.	a useful, though limited, part to play in the management of painful shoulder conditions."	
Thumb 1987 RCT	5.5	N = 38 peri- arthritis (adhesive capsulitis)	Fentiazac 200mg BID vs. diclofenac 50mg BID for 3 weeks	Non/mild pain at rest (weeks 0/1/2/3) fentiazac (36.8%/ 73.7%/82.4%/94.1%) vs. diclofenac (31.6%/ 73.7%/82.4%/88.2%). Adverse effects comparable (26 vs. 21%).	"[F]eniazac (400 mg/day) and diclofenac sodium (100 mg/day) were equally effective within 1 week in decreasing pain severity and improving shoulder mobility."	Data suggest comparable efficacy.
Ginsberg 1985 2 RCTs, 1 report	5.5	N = 60 acute bicipital tendinitis or subdeltoid bursitis	Slow release fentiazac 300mg QD vs. fentiazac 100mg QID. Second trial slow release fentiazac 300mg QD vs. fentiazac 200mg BID. Double dummy; 14day follow-up.	No differences in tenderness, swelling, redness or range of motion in either study.	"[N]o significant difference between those receiving the slow-release form or the standard tablets."	Two trials with one report. Methods details sparse. Comparable efficacy.
Famaey 1984 RCT	5.0	N = 50 adhesive capsulitis	Ibuprofen 400mg QID vs. diclofenac 25mg QID for 2 weeks.	Degree of pain (days 0/7/14): ibuprofen (3.0/1.78/1.35) vs. diclofenac (3.0/1.48/1.09) (p = 0.52). No differences in ROM.	"[I]buprofen and diclofenac are of virtually equal efficacy and tolerability in the treatment of patients with periarthritis of the shoulder."	Methods for blinding unclear. Data suggest comparable efficacy.
Rhind 1982 RCT	4.5	N = 41 shoulder pain, reduction in passive ROM (most adhesive capsulitis); mostly chronic with mean 8 and 12 months duration	Naproxen 250mg QAM plus 500mg QPM vs. Indomethacin 50mg BID; 4 weeks follow-up.	Cured or better were naproxen 8/20 (40.0%) vs. indomethacin 10/21 (47.6%) (NS). No differences in ROM between groups.	"[B]oth drugs were equally effective in treating the pain of periarthritis of the shoulder but did little to change the partial loss of movement associated with the disorder."	Data suggest equivalency.
McIlwain 1988 RCT	4.5	N = 38 athletes who had acute symptoms including one of the following: sprained ankle, sprained	Piroxicam 40mg QD for 2 days, then 20mg QD vs. Naproxen 500mg BID for 2 days, then 375mg BID for 7 days.	Measures of physical discomfort improved ( $p < 0.001$ ) after 3, 7 days both treatments. Mean reduction in spontaneous pain, swelling, tenderness statistically superior ( $p < 0.05$ ) in piroxicam group. Overall patient impressions of	"Both piroxicam and naproxen showed reduction of pain, tenderness and swelling after three days of treatment, with piroxicam-treated patients having a larger mean reduction from baseline values of spontaneous pain,	Heterogeneity in disorders treated (e.g., sprains of ankle, AC, hand IP, soft tissue injuries of shoulder, knee or hip). No placebo group. Data suggest piroxicam

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		acromio- clavicular joint, sprained interphala ngeal joint of hand, or acute soft-tissue shoulder, knee or hip injury		efficacy (excellent): piroxicam 11/16 (68.8%) vs. naproxen 7/18 (38.9%). No difference between treatments for days lost to injury. Piroxicam had larger mean reductions from baseline for spontaneous pain ( $p =$ 0.047), swelling ( $p =$ 0.035), tenderness ( $p =$ 0.017) at 1st return visit vs. naproxen.	swelling and tenderness after three days of treatment. All other measures of efficacy were statistically equal."	superior to naproxen.
Hayes 1984 RCT	4.0	N = 191 acute sprains and strains of ankle, hip, shoulder or knees	Sulindac 200mg BID vs. ibuprofen 400mg TID for 4 days.	Patient evaluation of efficacy (combined scores 3 and 4/4): sulindac 57/89 (64.0%) vs. ibuprofen 52/81 (64.2%) (NS). No differences in day or night pain, active motion, tenderness of swelling.	"The vast majority of patients had a successful outcome whichever treatment they were taking."	Mixed disorders. Acute pain patients only. Minority with shoulder symptoms. No placebo; submaximal ibuprofen dose. Data suggest equivalency.
Wielandts 1979 RCT	4.0	N = 26 acute tendinitis, nearly all shoulder; minority with symptoms 3-12 months	Fentiazac 100mg QID vs. phenylbutazone 100mg QID for 1 week.	Improvement in range of motion: fentiazac 42.9% vs 71.4%. (NS). No differences in tenderness or pain on motion.	"Some improvement in symptoms was noted, particularly in tenderness in the fentiazac group, but the difference between the two groups was not significant."	Small sample size. High dropout in phenylbutazone. Data suggest equivalency.
		Sh		vs. Glucocorticosteroid		
Adebajo 1990 RCT	8.0	N = 60 with acute or subacute rotator cuff tendinitis	Diclofenac 50mg TID vs. triamcinolone hexacetonide 80mg vs. placebo (lignocaine injections). Double dummy; 4 week follow-up.	Diclofenac superior to placebo (p = 0.027). Triamcinolone injection superior to placebo (p = 0.027).	"Both forms of treatment were superior to placebo in reducing pain, improving active3 abduction and reducing functional limitation. Triamcinolone showed the greatest effect in these respects, and was significantly superior to diclofenac when patients showing improvements in all 3 variables together (responders) were considered."	Injection and NSAID superior to placebo. Trend towards best results with injection for all outcome variables.
Petri 1987 RCT	7.5	N = 100 painful shoulders. No adhesive capsulitis. 20% with calcific	1) Injection with 4mL 1% lidocaine plus naproxen 500mg BID vs. 2) injection with 3mL lidocaine plus triamcinolone 40mg plus	Percent remissions at 2/4 weeks: Group 1 12/20% vs. Group 2 20/28% vs. Group 3 8/28% vs. Group 4 4/8%. Naproxen not superior to placebo at 4 weeks. Post hoc	"[B]oth triamcinolone (p=0.00005) and naproxen (P=0.02) are superior to placebo in the treatment of the painful shoulder."	Data suggest injection superior to naproxen and both are superior to placebo. Naproxen plus injection trended towards superior

		tendinitis and 24% AC arthrosis. Appears to include acute to chronic patients.	naproxen vs. 3) injection with lidocaine plus triamcinolone plus placebo vs. 4) injection with lidocaine plus placebo. Naproxen treatment for 30 days; 4 weeks follow-up.	analyses of outcomes showed pre-treatment clinical index most predictive ( $p =$ 0.00005) vs. treatment of duration of symptoms ( $p =$ 0.004).		to injection alone at 2 weeks. Patients' baseline status main determinant of outcome.
White 1986 RCT	6.0	N = 40 acute rotator cuff tendinitis less than 12 weeks duration. No patients with adhesive capsulitis	Triamcinolone acetonide 40mg subacromial injection vs. indomethacin 25mg QID. Double dummy (saline injections). All treated with home exercises. Re-injected patients at 3 weeks if more than minimal symptoms.	Global assessment scores (baseline/final): indomethacin 6.4±1.6/3.6±3.1 vs. injection 6.5±1.1/3.6±2.6 (NS). ROM also comparable.	"[T]here is essentially no difference in the short term efficacy of oral nonsteroidal therapy compared to local corticosteroid injection(s) in the treatment of rotator cuff tendinitis."	Patients with acute and subacute tendinitis. Data suggest comparable efficacy.

# ANTI-DEPRESSANTS

1. Recommendation: Norepinephrine Reuptake Inhibiting Anti-depressants for Subacute or Chronic Shoulder Girdle Pain, including Myofascial Pain Syndrome and Select Cases of Rotator Cuff Tendinopathy

Norepinephrine reuptake inhibiting anti-depressants are recommended for subacute or chronic myofascial pain syndrome and shoulder girdle pain (see Chronic Pain Guidelines), and a reasonable option for select rotator cuff tendinopathy patients.

*Indications* – Subacute and chronic myofascial pain and shoulder girdle pain; may be particularly helpful if there is nocturnal sleep disruption, mild dysthymia, which may allow for nocturnal dosing of a mildly sedating TCA.

*Frequency/Duration* – Low dose at night, gradually increased (e.g., amitriptyline 25mg QHS, increase by 25mg each week) until a sub-maximal or maximal dose achieved, sufficient effects are achieved, or adverse effects occur. Lower doses (e.g., amitriptyline, 25 to 75mg a day) avoid adverse effects and the necessity of blood level monitoring, particularly as there is no evidence of increased pain relief at higher doses. Imipramine is less sedating, thus if carryover daytime sedation, it may be a better option. If patient cannot sleep, amitriptyline is the recommended initial medication in this class. Duration for patients with subacute and chronic shoulder pain may be indefinite, although most of these patients do not require indefinite treatment, particularly if they are compliant with elements of a functional restoration program.

Indications for Discontinuation – Resolution of pain, intolerance, development of adverse effects.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Norepinephrine Reuptake Inhibiting Anti-depressants for Acute Shoulder Pain Norepinephrine reuptake inhibiting anti-depressants are not recommended for acute shoulder pain.

Strength of Evidence - Not Recommended, Insufficient Evidence (I)

3. Recommendation: Selective Serotonin Reuptake Inhibitors for Acute, Subacute, or Chronic Shoulder Pain

# Selective serotonin reuptake inhibitors (SSRIs) are not recommended for treatment of acute, subacute, or chronic shoulder pain.

# Strength of Evidence - Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

Norepinephrine reuptake inhibiting anti-depressants (e.g., amitriptyline, doxepin, imipramine, desipramine, nortriptyline, protriptyline, maprotiline, and clomipramine) and mixed norepinephrine and serotonin inhibitors (venlafaxine, bupropion, and duloxetine) have evidence of efficacy for treatment of chronic low back pain and some other chronic pain conditions (see Low Back Complaints). There is no quality evidence evaluating these medications for treatment of shoulder pain; however, they appear likely to be mildly effective for some shoulder pain patients, especially involving shoulder girdle and myofascial pain. Selective serotonin reuptake inhibitors (SSRIs) are not recommended for treatment of acute, subacute, or chronic shoulder pain as there is strong evidence of their lack of efficacy for treatment of chronic low back pain, thus they appear unlikely to successfully treat acute, subacute, or chronic shoulder pain.

# Evidence for the Use of Norepinephrine Reuptake Inhibiting Anti-depressants and Mixed Norepinephrine and Serotonin Inhibitors

There are no quality studies evaluating the use of norepinephrine reuptake inhibiting anti-depressants and mixed norepinephrine and serotonin inhibitors for patients with shoulder pain.

# ANTI-CONVULSANT AGENTS (INCLUDING GABAPENTIN AND PREGABALIN)

Anti-convulsant agents have been utilized off-label for treating some chronic pain syndromes since the 1960s, (Wiffen 05) particularly neuropathic pain. (Challapalli 05) Anti-convulsants are thought to have analgesic properties. Several have been used to manage chronic pain conditions including carbamazepine, valproic acid, gabapentin, phenytoin, clonazepam, lamotrigine, tiagabine, pregabalin, topiramate, levetiracetam, oxcarbazepine, and zonisamide (see Chronic Pain Guidelines).

1. Recommendation: Anti-convulsants for Subacute or Chronic Shoulder Pain There is no recommendation for or against the use of anti-convulsants including topiramate, gabapentin, or pregabalin for treatment of subacute or chronic shoulder pain.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

2. Recommendation: Anti-convulsants for Acute Shoulder Pain Anti-convulsants are not recommended for the treatment of acute shoulder pain.

# Strength of Evidence – Not Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

There are no quality studies involving the use of anti-convulsant agents for patients with shoulder pain. By analogy, there is quality evidence topiramate is weakly effective for treatment of low back pain patients and gabapentin is not helpful. However, there is quality evidence that gabapentin reduces need for opioids when administered as part of perioperative hip surgery patients' pain management.(Pandey 04, Pandey 05, Radhakrishnan 05, Turan 04)

#### Evidence for the Use of Anti-convulsant Agents

There are no quality studies evaluating the use of anti-convulsant agents for shoulder pain.

# OPIOIDS

See Opioids Guidelines for recommendations and evidence.

# SKELETAL MUSCLE RELAXANTS

Skeletal muscle relaxants comprise a diverse set of pharmaceuticals designed to produce muscle relaxation through different mechanisms of action, generally considered to be effects on the central nervous system (CNS) and not on skeletal muscle. (Abbruzzese 02, Elenbaas 80) These medications are

widely used in primary care to treat painful conditions, most prominently LBP, (Cherkin 98, Di Iorio 00, van Tulder 97, Schnitzer J Pain Symptom Manage 04, Deyo 90, Baratta 76, Arbus 90) muscle spasms, (Preston 84) and myalgias. They are sometimes used to treat shoulder disorders, but are generally not indicated for chronic shoulder pain.

# Recommendation: Muscle Relaxants for Acute or Subacute Shoulder Pain with Significant Muscle Spasm

# Muscle relaxants are recommended for acute or subacute, moderate to severe shoulder pain from muscle spasm that is unrelieved by NSAIDs, avoidance of exacerbating exposures or other conservative measures.

Indications – Moderate to severe acute and subacute shoulder pain with significant muscle spasm.

*Frequency/Dose* – Initial dose in evening (not during workdays or if patient operates a motor vehicle, though daytime use acceptable if minimal CNS-sedating effects). If significant daytime somnolence results, particularly if it interferes with performance of conditioning exercises and other components of the rehabilitation process or treatment plan, discontinue or prescribe a reduced dose. Duration for exacerbations of chronic pain is limited to a couple weeks. Longer term treatment is generally not indicated.

*Indications for Discontinuation* – Resolution of pain, non-tolerance, significant sedating effects that carry over into the daytime, other adverse effects.

# Strength of Evidence - Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

There are no quality studies of these agents for treatment of patients with shoulder pain. Skeletal muscle relaxants have been evaluated in guality studies evaluating chronic back and neck, (Brown 78, Hingorani 71, Bercel 77) although there are far more studies on acute LBP (see Chronic Pain Guidelines, Low Back Complaints, and Neck Complaints). (Salzmann 92) The quality of the studies comparing these agents to placebo are likely overstated due to the unblinding that would be inherent in taking a drug with substantial CNS-sedating effects. The adverse effect profile is concerning, (Lotland 01) with CNS-sedation rates ranging from approximately 25 to 50% and a low, but definite, risk of abuse. (Littrell 93, Toth 04) Thus, prescriptions for skeletal muscle relaxants for daytime use should be carefully weighed against the need to drive vehicles, operate machinery, or otherwise engage in occupations where mistakes in judgment may have serious consequences (e.g., crane operators, air traffic controllers, operators of motorized vehicles, construction workers, etc.). Skeletal muscle relaxants have beneficial uses, particularly for nocturnal administration to normalize sleep patterns disrupted by skeletal muscle pain, as well as for daytime use among the few patients who do not suffer from CNS depressant effects, and are low cost if generic medications are prescribed. Skeletal muscle relaxants are not recommended for continuous management of subacute or chronic shoulder pain, although they may be reasonable options for select acute pain exacerbations or for a limited trial as a third- or fourth-line agent in more severely affected patients in whom NSAIDs and exercise have failed to control symptoms.

# Evidence for the Use of Skeletal Muscle Relaxants

There are no quality studies evaluating skeletal muscle relaxants for treatment of patients with shoulder pain.

# SYSTEMIC GLUCOCORTICOSTEROIDS (AKA "STEROIDS")

# ORAL

Glucocorticosteroids are infrequently used to treat rotator cuff tendinoses, as subacromial injections are normally utilized (see below).

Recommendation: Glucocorticosteroids for Treatment of Acute, Subacute, or Chronic Rotator Cuff Tendinopathies

There is no recommendation for or against the use of oral glucocorticosteroids for treatment of rotator cuff tendinopathies.

# Strength of Evidence - No Recommendation, Insufficient Evidence (I)

(Note: injections are recommended below)

# Rationale for Recommendation

There is strong evidence that glucocorticosteroids injected in the subacromial space are effective for treatment of rotator cuff tendinopathies (see below). There are no quality placebo-controlled trials of oral glucocorticoids. There is one moderate quality trial that compared subacromial injection with intramuscular, with some outcomes suggesting injections are superior and no outcomes suggesting intramuscular administrations are superior. (Ekeberg 09) Thus, by further extension from intramuscular glucocorticoids, there is no recommendation for use of oral glucocorticosteroids for treatment of rotator cuff tendinopathies; particularly as there is considerable evidence subacromially injected glucocorticoids are efficacious. It may be reasonable to use oral steroids in those who declined injection, but continue to have an inadequate result with NSAIDs and exercises.

# Evidence for the Use of Glucocorticosteroids

There is 1 moderate-quality RCT incorporated into this analysis.

Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments				
	Shoulder Tendinopathies: Intramuscular Injection vs. Subacromial Injection									
Ekeberg	7.0	N = 106	Triamcinolone 20mg	Shoulder pain and	"No important	No placebo				
2009		chronic	plus lidocaine 5mL	disability index (SPADI)	differences in	control. Both				
		rotator	subacromial injection	(baseline/2 weeks/6	short term	groups improved.				
RCT		cuff-	(7mL total) plus	weeks): Local group	outcomes were	Patients not well				
		related	lidocaine intramuscular	(53±18/32±25/ 29±21)	found between	described. Data				
		pain; >3	injection vs.	vs. systemic	local ultrasound	suggest				
		months	triamcinolone 20mg	(51±17/28±23/ 32±23) (p	guided	subacromial				
		duration	plus lidocaine	= 0.32). Western Ontario	corticosteroid	injection superior				
			intramuscular plus	rotator cuff index (67 vs.	injection and	or trends to				
			lidocaine subacromial	60, p = 0.32), change in	systemic	superior				
			injection. Ultrasound-	main complaint (6.0 vs.	corticosteroid	depending on				
			guided injections; 6	2.0, p = 0.009) favored	injection in	outcome				
			weeks follow-up.	local steroid injection.	rotator cuff	evaluated.				
					disease."					

# **TOPICAL MEDICATIONS, LIDOCAINE PATCHES**

Topical medications include patches, capsaicin and sports creams, NSAIDs, wheatgrass cream, dimethyl sulfoxide (DMSO), N Acetylcysteine (NAC), and eutectic mixture of local anesthetics (EMLA). Topical glyceryl trinitrate has been utilized for treatment of rotator cuff disease. (Cumpston 09) Capsaicin is applied to the skin as a cream or ointment. Possible mechanisms for pain reduction include distraction by stimulating other nerve endings or killing afferent sensory nerve fibers that subsequently regenerate. Rado-Salil ointment is a proprietary formulation of 14 agents, the two most common are menthol (55.1%) and methylsalicylate (26.5%). There are many other commercial products that similarly cause a warm or cool feeling in the skin. All of these agents are thought to work through a counter-irritant mechanism (i.e., feel the dermal sensation rather than the pain). Topical NSAIDs have been used to treat many different MSDs, including arthritis, lateral epicondylitis, and other tendinoses. (Ritchie 96, Lin 04) Many different NSAIDs are compounded, including ibuprofen, naproxen, ketoprofen, piroxicam, and diclofenac.

1. Recommendation: Capsicum Creams for Acute, Subacute, or Chronic Shoulder Pain Capsicum is recommended for short-term treatment of acute or subacute shoulder pain, as well as acute flares of chronic shoulder pain as a counter-irritant.

Indications – Temporary flare ups of chronic shoulder pain or acute or subacute shoulder pain.

*Frequency/Duration* – Duration for patients with chronic pain is limited to an acute flare-up period, generally lasting no more than 2 weeks. Not to be used continuously or more than 1 month as cost is high compared to alternative treatments of greater or equal efficacy. Patient should transition to an active treatment program.

Indications for Discontinuation – Resolution of pain, lack of efficacy, development of adverse effects.

Strength of Evidence - Recommended, Insufficient Evidence (I)

2. Recommendation: Topical NSAIDs, Topical Glyceryl Trinitrate, Lidocaine Patches, Eutectic Mixture of Local Anesthetics (EMLA), Other Creams/Ointments for Shoulder Joint Pain There is no recommendation for or against the use of topical NSAIDs, topical glyceryl trinitrate, lidocaine patches, eutectic mixture of local anesthetics (EMLA), or other creams/ointments for shoulder pain as it is unclear whether the target tissue is sufficiently superficial to be treated topically.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

# Rationale for Recommendations

Evidence of efficacy is relatively sparse for any disorder. There is moderate-quality evidence that 3 days treatment with transdermal nitroglycerin patches is effective compared with placebo for shoulder tendinitis. (Berrazueta 96) Quality evidence for efficacy of other agents or for other shoulder disorders is not available. However, there are some quality studies suggesting short- to intermediate-term benefits for some of these agents for more superficial tissues (see Chronic Pain Guidelines, Elbow Disorders, Hand, Wrist, and Forearm Complaints). These agents, when demonstrated to have efficacy, appear weakly effective. They might cause deleterious effects if used long-term. Topical applications of anesthetic agents over large areas are thought to carry significant risk of potentially fatal adverse effects. (FDA March 09) There are many other commercially available creams and ointments, but no quality studies for the purposes of treating shoulder pain and the target tissue is relatively deep to the skin surface in many patients. Capsicum is recommended as a counterirritant option for treatment of shoulder pain based on analogy to treatment of LBP and other chronic pain conditions. (Frerick 03, Keitel 01)

# Evidence for the Use of Topical Medications

There is 1 moderate-quality RCT incorporated into this analysis for transdermal nitroglycerin patch. There are no quality studies that evaluate the use of topical medications, including lidocaine patches, capsaicin and sports creams, NSAIDs, wheatgrass cream, DMSO, NAC, and EMLA for shoulder pain.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Compariso n Group	Results	Conclusion	Comments
		Shoul	der Tendinopat	thies: Transderr	nal nitroglycerin vs. Placeb	0
Berrazuet	4.5	N = 20	Transdermal	Pain intensity	"NTG is useful in the	Small sample size.
а		acute	nitroglycerin	(baseline/24	treatment of shoulder pain	Somewhat shorter duration
1996		shoulder	5mg vs.	hours/48	syndrome caused by	of symptoms in NTG group
		pain	placebo	hour): NTG	supraspinatus tendinitis	at baseline. Very short
RCT		<7days	patch. 1	(7.05±0.4/4.5	and that this treatment	duration study precludes
		diagnosed	patch a day	±0.4/2.0±0.3)	could be a useful	evaluation of efficacy for
		with	applied over	vs. placebo	approach in the	most patients, except
		supraspinat	most painful	[6.0/5.5/5.5	management of this	maybe in acute setting.
		us tendinitis	area for 3	(graphic	common disturbance and	Study has insufficient
			days; 14-day	data)], p	probably also in other	sample size and follow-up
			follow-up.	<0.0001.	tendon musculoskeletal	to warrant evidence-based
					disorders."	guidance.

# DEVICES/PHYSICAL METHODS

Some patients with shoulder pain may benefit from limited use of appliances/devices, particularly as a means of assisting with resting the injured shoulder, as well in assisting in supporting the upper extremity after surgery. These aids include many different types of slings and supports. However, the shoulder is unusually prone to development of complications from immobility, including adhesive capsulitis and debility development. Thus prescriptions of these appliances should be done with care and, for non-operative patients, usually accompanied by at least a gradually progressive range of motion (ROM) exercise prescription. For post-operative patients, these are usually prescribed with a plan to wean off their use at the earliest possible date and implement a progressive exercise program.

# SLINGS AND SHOULDER SUPPORTS

1. Recommendation: Slings and Shoulder Supports for Acute Severe Shoulder Pain Slings and shoulder supports are recommended for acute severe pain when the appliance is used to briefly rest the shoulder and then promptly, gradually advance the activity level.

*Indications* – Acute severe shoulder pain, traumatic and atraumatic, particularly where appliance is utilized as part of a plan to briefly rest the shoulder and promptly, gradually increase activity level. Non-operative patients are recommended to have an ROM exercise program instituted in nearly all circumstances.

# Strength of Evidence - Recommended, Insufficient Evidence (I)

2. Recommendation: Slings and Shoulder Supports for Post-operative Shoulder Pain Slings and shoulder supports are recommended for post-operative shoulder pain when the appliance is used to advance the activity level.

*Indications* – Post-operative patients, particularly where appliance is utilized to increase activity level. Operative patients require management to gradually decrease use of the appliance and institute exercises.

Strength of Evidence - Recommended, Insufficient Evidence (I)

 Recommendation: Slings and Shoulder Supports for Subacute or Chronic Shoulder Pain Slings and shoulder supports are not recommended for subacute or chronic shoulder pain or mild to moderate acute pain.

Strength of Evidence – Not Recommended, Evidence (C)

#### Rationale for Recommendations

There is one moderate-quality trial of a sling for treatment of disabling impingement syndrome, but it failed to find evidence of efficacy. (Walther 04) Slings and supports may be helpful for acute, severe injuries during the recovery phase to produce relative rest. They also may be useful for post-operative patients. Use of these devices should generally be accompanied by an ROM exercise program and progress be carefully monitored in patients as the shoulder is particularly prone towards debility as well as adhesive capsulitis.

Author/Titl e Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
	1	Shoulder	<b>Tendinopathies: Physic</b>	therapy vs. Self-traini	ng vs. Brace	
Walther 2004 RCT	4.0	N = 60 disabling impingeme nt syndrome (require relief with 10mL bupivacaine subacromia I injection)	Physiotherapy (10 sessions, 2-3 a week, centering training, stretching; data indicate average 30 visits total) vs. self- training (centering and stretching exercises, therabands up to 4 supervised sessions, individualized, self exercise at least 5 times a week for 10-15 minutes) vs. functional brace (Coopercare	VAS pain scores, pain at night, pain with load, mobility, all without differences between groups, though improved over study interval (p <0.05). Muscle strength improved most in brace group (Constant-Murley strength score at 12 weeks: brace 14.4±5.4 vs. PT	"There were no statistically significant differences among the groups. Guided self-training can lead to results similar to those of conventional physiotherapy. The comparable effect of the functional brace remains unclear and might be explained by an	Over 50% treated with physiotherapy prior to the study may have biased against physiotherapy (more of same). Intermediate follow-up (12 weeks and no long term follow-up.
			Lastrap). 12 week follow-ups.	10.9±4.6 vs. self 11.8±5.4).	influence on proprioception."	

#### *Evidence for the Use of Shoulder Slings and Supports* There is 1 moderate-guality RCT incorporated into this analysis.

# TAPING AND KINESIOTAPING

Taping (non-elastic, thick tape) and kinesiotaping (elastic, thinner tape) are used on the extremities, particularly in sports settings, as well as the shoulder. (Copping 05; Alexander 03; Lewis 05; Ackermann 01; Thelen 08; Kaya 10; Lewis 05; Zanella 01; Pogliaghi 98) Taping (white athletic taping, cotton mesh adhesive tape often over gauze) is intended to stabilize and support, but restrict ROM, and thus is used for treatment and preventive purposes. (Cools 02; Baquie 02; Host 95; Smith 09) It is often utilized immediately prior to an activity and then removed, or the cotton mesh may be applied and removed after hours of use. Kinesiotaping has also been used for treatment, including pain relief; however, it is intended to allow full ROM in contrast with traditional taping. (Hsu 09; Host 95; Miller 09; Hadala 09; Fu 08; Walsh 10; Yoshida 07; Kalichman 10; Kaya 10: Garcia-Muro10; Thelen 08) Kinesiotaping is proprietary; proponents believe the tape should be applied in specific patterns and may or may not be stretched depending on the injury. Regardless, all types of taping are utilized to attempt to treat musculoskeletal disorders. Difficulty with tolerating the various types of tape may be problematic for some patients.

#### Recommendation: Taping or Kinesiotaping for Shoulder Pain

There is no recommendation for or against the use of taping or kinesiotaping for treatment of shoulder pain.

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There is one high-quality very short-term trial of kinesiotaping for treatment of shoulder pain which failed to show improvements in pain. (Thelen 08) A moderate-quality pilot study evaluated facilitatory taping as an adjunct to routine physiotherapy management and found some preliminary evidence for a short-term role of scapula taping with physiotherapy. However, it was a small sample size with high dropouts in the taping group. (Miller 09) Kinesiotaping and taping have not been shown to have sustained efficacy. There is little evidence for efficacy of correcting posture, including a slouched forward position. (Lewis 05) Kinesiotaping or taping for patients with shoulder pain has demonstrated increased muscle activity. (Hsu 09; Selkowitz JOSPT 07) These interventions are not invasive. Taping and kinesiotaping have potential adverse effects among those who do not tolerate it or the adhesives, but they are generally minor. When fees for both the tape and its application are considered, taping is costly, especially since there are alternative interventions that have been shown to be effective. As there is no quality evidence of durable effects, there is no recommendation for or against their use.

# Evidence for the Use of Taping

There is 1 high- and 1 moderate-quality RCT incorporated into this analysis.

Author/Titl	Score	Sample Size	Comparison	Results	Conclusion	Comments
e Study Type	(0-11)	Sample Size	Group	Results	Conclusion	Comments
Thelan 2008 RCT	9.0	N = 42 college students with rotator cuff tendonitis/im pingement	Kinesio Tape (KT) vs. sham tape.	ROM mean increase, 16.9° +/- SD 23.2°; p = .005; potential weakness: no comparison group to monitor natural history of improvement with time.	"KT may be of some assistance to clinicians in improving pain-free active ROM immediately after tape application for patients with shoulder pain. Utilization of KT for decreasing pain intensity or disability for young patients with suspected shoulder tendonitis/ impingement is not supported."	No differences in self-report pain or disability. Military academy college student limits applicability to broad population.
Miller	4.0	N = 22	Scapular taping 3	SPADI total	"This study provides	Pilot study. Small
2009		shoulder	times a week for 2	scores (baseline/2	preliminary evidence	sample size.
		pain, >6	weeks (tape	weeks/6 weeks):	for a short-term role for	Multiple co-

RCT	weeks	removed after 2	tape plus PT	scapula taping as an	interventions that
	duration	days), then	(47.7/18.4/13.1)	adjunct to routine	are not
		physiotherapy	vs. PT alone	physiotherapy in the	controlled. High
		(STM, joint	(54.4/41.5/19.7), p	management of	dropouts in
		mobilization,	= 0.90, p = 0.60, p	shoulder impingement	taping group
		exercise, stretches	= 0.76. SPADI	symptoms."	(40%). Results
		strengthening)	pain, disability		mostly negative.
		between weeks 2	scores also		
		to 6 vs.	negative. Flexion,		
		physiotherapy	flexion VAS,		
		alone (unclear if	abduction,		
		for 4 or 6 weeks);	Abduction VAS		
		6 weeks followup.	also all negative.		

# MAGNETS AND MAGNETIC STIMULATION

High-intensity magnetic stimulation purportedly causes depolarization of nerves and has been found to result in an antinociceptive effect in rats. (Lin 02) Electromagnetic fields have been known to increase osteoblastic activity. Therefore, proponents believe magnetic fields have therapeutic value in the treatment of musculoskeletal disorders.

Recommendation: Magnets and Magnetic Stimulation for Acute, Subacute, or Chronic Shoulder Pain Magnets and magnetic stimulation are not recommended for the treatment of acute, subacute, or chronic shoulder pain.

# Strength of Evidence - Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality studies of magnets for the treatment of shoulder pain. However, there is quality evidence for lack of efficacy in treatment of low back pain. (Collacott 00) Magnets are not invasive, have no adverse effects, and are low cost; however, other treatments have proven efficacy.

# Evidence for the Use of Magnets and Magnetic Stimulation

There are no quality studies evaluating the use of magnets and magnetic stimulation for osteoarthrosis or acute, subacute and chronic shoulder pain.

# ACUPUNCTURE

Acupuncture has been primarily used to treat myofascial (Nabeta 02) and shoulder girdle pain (see Myofascial Pain section of this guideline). While it has also been used to treat rotator cuff tendinopathies, (Guerra de Hoyos 04; Green 05; Green 06; Green 09; Kleinhenz 99; Kong 09; Vas 08) a Cochrane review noted there were few trials of quality with "little can be concluded" (Green 05; Green 09), while one systematic review recommends acupuncture as a conservative treatment option. (Grant 04) There are different techniques utilized, including acupuncture, superficial dry needling and deep dry needling. (Baldry 02) Acupuncture is further discussed in the Low Back Disorders and Chronic Pain Guidelines.

# Recommendation: Acupuncture for Chronic Rotator Cuff Tendinopathies, including Impingement Syndrome, or Post-operative Pain

Acupuncture is recommended for select use in chronic rotator cuff tendinopathies or postoperative pain only as an adjunct to more efficacious treatments.

*Indications* – As a tertiary treatment if NSAIDs, active exercises, injections, and surgery (if indicated) fail to resolve or sufficiently improve pain.

*Frequency/Duration* – Frequency and duration pattern in the quality trial was weekly for 8 weeks. An initial trial of 4 appointments would appear reasonable in combination with a conditioning program of aerobic and strengthening exercises. An additional 4 appointments should be tied to improvements in objective measures after the first 4 treatments, for a total of 8. (Guerra de Hoyos 04) If acupuncture is trialed in a patient, objective functional improvement should be demonstrated after 6 visits.

*Indications for Discontinuation* – Resolution, intolerance, non-compliance including non-compliance with aerobic and strengthening exercises, no functional gains demonstrated.

# Strength of Evidence – Recommended, Evidence (C)

# Rationale for Recommendation

The overall body of evidence for the use of acupuncture is relatively weak. There are four moderatequality trials suggesting improvements from acupuncture or electroacupuncture compared with sham. (Guerra de Hoyos 04; Kleinhenz 99; Gilbertson 03; Moore 76) The results of one trial persisted beyond discontinuation of the treatment. (Guerra de Hoyos 04) A trial in post-operative patients suggested benefits. (Gilbertson 03) Additional quality trials for rotator cuff tendinopathies are needed. One trial attempted to assess efficacy of naturopathic treatment, but included acupuncture, thus precluding assessment of those effects. (Szczurko 09) Acupuncture when performed by experienced professionals is minimally invasive, has minimal adverse effects, and is moderately costly. Despite significant reservations regarding its true mechanism of action, a limited course of acupuncture may be recommended for treatment of rotator cuff tendinopathies as an adjunct to an efficacious exercise program. Acupuncture is recommended to assist in increasing functional activity levels more rapidly; the primary attention should remain on the exercise program and document functional gain. In those not involved in an exercise program, or who are non-compliant with graded increases in activity levels, this intervention is not recommended.

# Evidence for the Use of Acupuncture

There are 10 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality study (Peng 87) in Appendix 2.

inciuaea.	ncluded.								
Author/Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments			
	Electroacupuncture vs. Sham								
Guerra de Hoyos 2004 RCT	6.5	rotator cuff tendinitis, capsulitis, bicipital tendinitis, bursitis; mostly chronic patients with tendinitis	Electroacupuncture (Jianyu LI 15, Jianliao TE 14, Yanglingquan GB 34, Zhongping Extra point 1-2 cm below Zusanli ST 36) with stimulation at 5-10Hz to cause light muscle twitch vs. placebo acupuncture (hollow, non-penetrating needle) Q week for 8 weeks. Diclofenac as needed; 6-month follow-up.	VAS pain (baseline/7 weeks/3 months/6 months): electro- acupuncture (6.1±2.5/1.1±1.3/1.3± 2.1/1.2±1.9) vs. placebo (6.3±1.9/2.8±2.6/3.0± 2.8/3.5±3.0). Other significant differences for Lattinen index, ROM, SPADI global index, quality of life (p <0.0005).	"The acupuncture group had consistently better results in every secondary outcome measure than the control group."	Not true sham- control as electroacupunct ure to cause muscle twitching, likely unblinded the study (blinding success not reported). Data suggest efficacy and persistence of benefits beyond treatment.			
			Acupunct	ure vs. Sham					
Gilbertson 2003 RCT	5.5	N = 40 underwent arthroscopic acromioplast y for shoulder impingemen t syndrome; most had	Acupuncture vs. Sham acupuncture begun 3 to 8 days after surgery. Locations not noted. Appears all also had physical therapy (treatment(s)	UCLA Shoulder Scale scores favored real acupuncture (graphic data, p <0.001) (no baseline values given). First values at Visit 4 and different, approximately 14 vs. 18. rose to 23 vs. 34	"Following arthroscopic acromioplasty, real acupuncture compared to sham acupuncture offered significantly	Blinding procedures not described. Acupuncture needle placement not standardized. "Some" needles stimulated 2.5-			
		distal	included passive	at 4 months. Less	greater	150Hz. High			

We searched acupuncture for rotator cuff tears, massive rotator cuff tears, tendon rotator cuff tears, rotator cuff partial- and full-thickness tears, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, impingement syndrome, bursitis supraspinatus tendinitis, and bicipital tears. Six RCTs were included.

Nabeta 2002 RCT	5.0	claviculecto my N = 34 chronic pain, stiffness, no arm pain; symptom duration not noted; mapped location of "tender" points suggests myofascial pain and/or fibromyalgia	ROM, active ROM, strengthening, hot packs, cold packs). Acupuncture 3 treatments each week for 3 weeks (insert to muscle, 5 times sparrow packing technique) vs. sham acupuncture (dull needles, no needle insertion); 1 month follow-up.	analgesic use in real acupuncture group (p <0.008). 65% acupuncture vs. 53% sham felt had needle insertion to muscle; 24% vs. 35% felt had no penetration of needle. VAS scores (pre/9 days post 3rd treatment): acupuncture (52.8/44.1) vs. sham (51.9/49.7).	improvement" "Acupuncture applied to tender points appears to have short-term effects on neck and shoulder pain and stiffness, but this study was unable to demonstrate any long-term superiority over sham acupuncture."	dropouts in sham group. Some details sparse. Patients not well described. Sham not well described. Data suggest comparable efficacy between "real" and sham acupuncture.
Kleinhenz 1999 RCT	4.5	N = 52 athletes with Stage I or II impingemen t and rotator cuff tendinitis (ultrasound excluded RC tears) more than 4 weeks duration	Acupuncture (traditional Chinese: TE 3,14,15; B44; Taijian; SI3,6,9,11,12,14; LI11,14, 15; S38; G34;L2;H1;P2) vs. sham acupuncture; 2 sessions/week for 4 weeks; 4 months follow-up.	Constant score changes were (baseline/post): acupuncture $60.4\pm$ 12.3/79.6± 17.1 (change 19.2) vs. controls 53.9± 14.0/62.3± 17.9 (change 8.37), p = 0.014.	"No conclusions can be derived from this study concerning the importance of choosing points and the rules of Traditional Chinese Medicine."	Evaluated new sham acupuncture needle that elicits symptoms. Acupuncture individualized based on tenderness over points. Sparse results. Data suggest acupuncture superior to sham.
Moore 1976 RCT	4.0	N = 42 shoulder tendonitis, bursitis or osteoarthriti s	2x2 factor trial. Acupuncture (Ho- ku, ChuChih, Chu- ku, Chien-yu, Chiennei-lin, Nao- yu, Chien-chen; 0.5-1.0cm insertion depths) vs. sham (same locations, prick skin, stimulation through tapping needle on skin. Further divided into positive vs. negative enthusiasm regarding treatment efficacy; 1 treatment/week for 3 weeks; 4 weeks follow-up.	Improvement compared with baseline: 23% acupuncture vs. 39% sham. Improvement compared with pre- treatment in acupuncture positive setting 33% vs. 14% negative setting. Sham-positive setting 38% vs. negative setting 41%. Little or no hypnotic susceptibility/slight to moderate/marked: 21% of little/no vs. 38% slight to moderate vs. 40% marked had more than 60% improvement.	"[R]ange of motion did not improve, the majority of patients reported significant improvement in shoulder discomfort to a blind evaluator after treatment; placebo and acupuncture groups did not differ in this respectIn all groups, those who were not rated as highly susceptible to hypnosis tended to fail to achieve the highest levels of relief, but such differences were not statistically significant."	No description of patients. Data suggest variability in outcomes based on hypnotic susceptibility.
Vas	7.0	N = 425	Acupuncture vs Acupuncture (once a	. Other Treatments Constant overall	"Single-point	Large sample
2008	7.0	N = 425 chronic	week , 1 point,	scores (ITT month 1	acupuncture in	size. High

RCT		>3months symptoms of rotator cuff tendinitis, subacromi al bursitis, some associated capsulitis	Tiaokou S38, 4.5- 5.0cm depth, de qi) vs. Sham TENS (once a week for 3 weeks), once a week for 3 weeks. All received 15 sessions of physiotherapy ("superficial thermotherapy", recentering humeral head with active maneuvers, passive maneuvers, dynamic control of scapula, cryotherapy, and education).	and per protocol other months) (baseline/1/3 months): Acupuncture plus physiotherapy (44.1 $\pm$ 13.8/60.6 $\pm$ 17.6/70.1 $\pm$ 1 4.9) vs. mock TENS plus physiotherapy (42.0 $\pm$ 13.0/52.5 $\pm$ 13.1/57.1 $\pm$ 16.6), p <0.05. Night pain (baseline/1/3/6/12 months): acupuncture plus physiotherapy 5.3/3.5/2.6/1.8/1.2 vs. mock TENS plus physiotherapy 5.2/5.1/ 4.2/4.5/3.9 (p <0.05). 53% acupuncture vs. 30% controls reduced analgesic consumption, p <0.001.	association with physiotherapy improves shoulder function and alleviates pain, compared with physiotherapy as the sole treatment.	dropouts. Multiple co- interventions. Mixed diagnoses limit applicability. Data suggest acupuncture added to physiotherapy resulted in benefits compared with sham TENS.
Johansson 2005 RCT	6.5	N = 85 impingeme nt syndrome confirmed with injected anesthetic	Acupuncture {traditional Chinese [LI 14 (Binao), LI 15 (Jianyu), LU 1 (Zhongfu) and TE 14 (Jianliao), and LI 4 (Hegu)], with rotated needles and "de qi"} vs. ultrasound (10min at 1W/cm2) 2 times a week for 5 weeks. All treated with home exercise program. 12 month follow-up.	Combined scores among those adhering to protocol (n = 64) (baseline/post/3 months/6 months/12 months): acupuncture (61/79/84/90/93) vs. ultrasound (63/76/83/88/89). ITT results comparable and not significant.	"The results suggest that acupuncture is more efficacious than ultrasound when applied in addition to home exercises."	High dropout and noncompliance rates. More additional treatments in ultrasound group. Data support largely comparable (in)efficacy.
Razavi 2004 Quasi-RCT	4.0	N = 37 (age range 27-77 years old); patients included were diagnosed with rotator cuff tendinitis and showed two of the following: pain on palpitation, isometric contraction , and/or passive stretching in at least one rotator cuff muscle	Both Group I and Group II received 10 physical therapy treatments 1-2 times per week, consisting of strength and endurance exercises of the rotator cuff muscles designed by the authors. Group I received 10 treatments of manual acupuncture 1-2 times a week by a physical therapist in addition to training. Group II received 10 treatments of placebo TENS 1-2 times per week in addition to training. They were told they would not feel anything during	Both groups improved regarding pain at rest (VAS scale) after the treatment period as well as at the 6 month follow-up (p <0.001). No significant difference was found between the groups. Both groups improved with respect to passive movement (measured with goniometer). No significant differnce was found between the groups. (no p values reported). Both groups showed significant improvement in the pour out of a pot test and there was no difference between	The results of this study to do not show any significant improvement on rotator cuff tendinitis when comparing acupuncture with placebo TENS. Both groups showed significant reduction of pain at 6 months.	On first visit, patients were examined by the first author and acupuncture treatments provided by same author. Small sample size. No meaningful difference between groups. Not randomized.

			treatment. Patients were assessed at baseline, directly following completion of treatment, and at a 6 month follow-up appointment.	the groups (no p values reported). Group I showed significant improvement in the functional hand in neck test (HIN) directly following treatment (p <0.01) but the difference did not remain at the 6 month follow-up.		
		Acupund	cture plus Naturopathic	treatments vs. Physica	I Exercises	
Szczurko 2009 RCT	7.0	N = 85 rotator cuff tendinitis symptoms for at least 6 weeks	Combined acupuncture (LI 15, SJ14, SI10-13, 19, BL41-46, up to 4 Ashi points), dietary changes (anti- inflammatory diet with omega -3 polyunsaturated fatty acids, soybeans, cherries, flavenoids), supplement Phlogenzym (bromelain 90mg, trypsin 48mg, rutin 100mg) 2 tablets TID vs. physical exercises (passive, active- assisted, active ROM, muscle strengthening) plus placebo pills. Patients seen weekly for 12 weeks. No additional follow-up.	Total SPADI (baseline/post): Naturopathic combined (77.64±29.38/35.30±3 1.57) vs. physical exercise (69.61±24.11/56.24±3 6.57), p <0.0001. Pain SPADI: NC (34.73±9.11/16.03±13 .30) vs physical exercise (31.93±9.49/26.24±14 .34), p <0.0001.	"(Naturopathic and physical exercise) provided significant improvements, with greater improvement in shoulder function in the (naturopathic) group compared with the (physical exercise) group. Statistically significant improvements in quality of life measures were observed in the (naturopathic) group as compared with the (physical exercise) group."	No non- interventional control or sham. Multiple co- interventions, including acupuncture prevent assessment of benefits of naturopathic treatment. Trial may be acupuncture vs. non- acupuncture.
		<b>I</b>		Platelet-rich Plasma		
Rha 2013 RCT	6.0	N = 39 patients (age range, 39- 79 years) with > 6 months of shoulder pain, VAS pain score of > 5, painful arc and/or an impingeme nt sign, no weakness upon resisted testing of the rotator cuff, diagnosed supraspina tus	Dry needling (DN) group (n = 19) received ultrasound guided dry needling localized to the site of maximal tenderness, performed twice with a 4 week interval between injections vs. platelet-rich plasma (PRP) group (n=20) received platelet-rich plasma injections prepared using the Prosys PRP Platelet Concentration System, performed twice with a 4 week interval between injections.	Both PRP and DN groups showed significant reduction in SPADI scores and significant improvement of range of motion from baseline through 6 months after initial treatment. ( $p < 0.05$ ) Reduction of SPADI in the PRP group was significantly different from DN group from 6 weeks to 6 months after initial treatment. Week 6: 27.4 ± 4.1 vs. 41.2 ± 4.2; 3 months: 21.1 ± 3.9 vs. 34.6 ± 4.0 6 months: 17.7 ± 3.7 vs. 29.5 ± 3.8 (p <0.05).	Platelet-rich plasma injections provided more pain relief and improved arm function, but not range of motion of the shoulder, in patients with supraspinatus tendon lesions (tendinosis or partial tear of less than 1.0 cm) when compared to dry needling. Dry needling itself also shows good results in some patients. Benefits are still present at 6 months after treatment.	Platelet-rich plasma injections were performed using a "similar technique" to dry needling. Platelet rich plasma injections trended or were statistically superior to dry needling.

tendinosis or tendon partial- thickness tear of less than 1 cm, and little to no response to conservati ve therapy for 3 months. measured by blinded inves after 1 <sup>st</sup> injec right before t injection (4 v weeks after 2 injection (6 v months, and months.	stigatorsignificant difference2 weekswas found when thetion,total pain score andhe 2 <sup>nd</sup> total disability scoreveeks), 2were analyzed2 <sup>nd</sup> separately.veeks), 3
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# HOT AND COLD THERAPIES

It has been proposed that cold and heat have actual therapeutic benefits to modify the disease processes (e.g., cold to allegedly reduce acute inflammation and swelling, and heat to speed healing through increased blood supply). (Grana Instr Course Lect 93, Michlovitz 96) However, others propose that these various modalities are distractants that apparently do not materially alter the clinical course. (Melzack 80) Still others postulate that the distractants allow increased activity levels, thus even though distractants might not directly modify the disease processes, this theory supports using these modalities through indirect mechanism(s) of action. (Nadler 04) Many patients with pain report a temporary soothing effect from the application of heat or the use of ice packs in the home setting.

# **CRYOTHERAPIES**

Cold or cryotherapies involve applications of cold or cooling devices to the skin. They have been used for treatment of non-operative pain and post-operative pain. (Saito 04)

Recommendation: Home Use of Cryotherapies for Acute, Subacute, Chronic, or Peri-operative Shoulder Pain

Cryotherapies are recommended for home use if efficacious for the temporary relief of acute, subacute, chronic, or peri-operative shoulder pain.

Indications – Acute, subacute, chronic, or peri-operative shoulder pain.

Indications for Discontinuation - Non-tolerance, including exacerbation of shoulder pain.

# Strength of Evidence - Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

There are no quality trials for treatment of shoulder pain patients. There is one moderate-quality trial for post-operative treatment; however, there were no clinical results. (Osbahr 02) Education regarding home cryotherapy application may be part of the treatment if cold is effective in reducing pain. Self applications of cryotherapies using towels or reusable devices are non-invasive, minimal cost, and without complications. Other forms of cryotherapy can be considerably more expensive, including chemicals or cryotherapeutic applications in clinical settings and are not recommended.

# Evidence for the Use of Cryotherapy for Rotator Cuff Tendinopathies

There is 1 moderate-quality RCT incorporated into this analysis. There are 2 low-quality RCTs (Speer 96; 01) in Appendix 2.

			Comparison	Results	Conclusion	Comments
Study Type	e (0-	Size	Group			
	11)					

Osbahr	5.0	N = 20	Cryotherapy	Data suggest	"Continuous cryo-therapy	Study claims
2002		full	(Polar Care	lower	causes a statistically	blinding; however,
		thickness	300, Breg) vs.	temperatures in	significant reduction of both	this is not described.
RCT		rotator	controls over	cryotherapy	glenohumeral joint and sub-	Very short-term
		cuff tears	23 post-	group, p = 0.049	acromial space	study. No clinical
			operative	at 23 hours.	temperatures in the shoulder	results. Study
			hours.		at variable times during the	suggests theoretical
					first 23 post-operative	support for
					hours."	cryotherapy.

# **HEAT THERAPIES**

Many forms of heat therapy have been used to treat musculoskeletal pain including hot packs, moist hot packs, sauna, warm baths, infrared, diathermy, and ultrasound. The depth of penetration of some heating agents is minimal since transmission is via conduction or convection, but other modalities have deeper penetration. (Vasudevan 97) A particular methodological problem with most studies of heat therapy is that despite occasional attempts at, and claims of successful blinding, it is essentially impossible to blind the patient from these interventions as they produce noticeable, perceptible tissue warming. Not surprisingly, some of these heat-related modalities have been shown to reduce pain ratings more than placebo for low back pain patients (see Low Back Complaints). It is less clear whether there are meaningful, long-term benefits. Heat therapies are passive treatments. In chronic pain settings, use of heat should be minimized to self-treatments of flare-ups with primary emphasis on functional restoration elements (e.g., exercises).

# Recommendation: Self-application of Heat Therapy for Acute, Subacute, or Chronic Shoulder Pain Self-application of low-tech heat therapy is recommended for acute, subacute, or chronic shoulder pain.

Indications – Acute, subacute, or chronic shoulder pain.

*Frequency/Duration* – Applications may be periodic or continuous. Applications should be home-based as there is no evidence for superiority of provider-based heat treatments. Primary emphasis should generally be on functional restoration program elements, rather than on passive treatments in patients with chronic pain. Education regarding home heat application should be part of the treatment plan if heat has been effective for reducing pain.

*Indications for Discontinuation* – Intolerance, increased pain, development of a burn, other adverse event.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

Self applications of heat using towels or reusable devices are non-invasive, minimal cost and without complications. Heat is not commonly used in acute situations (first few days); however, evidence suggests heat is effective for acute LBP (see Low Back Complaints). Thus, efficacy for acute pain is unclear. Other forms of heat can be considerably more expensive, including chemicals or cryotherapeutic applications in clinical settings and are not recommended. There is one moderate quality study suggesting hyperthermia is superior to ultrasound for patients with supraspinatus tendinopathies in athletes, although that did not involve self-application of heat. (Giombini 06)

# Evidence for the Use of Heat Therapy

There is 1 moderate-quality RCT incorporated into this analysis.

Author/Titl e Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
		Rotate	or Cuff Tendinopath	ies: Hyperthermia vs. Ul	trasound	
Giombini 2006	5.5	N = 37 athletes with supraspinatu	Hyperthermia by microwave 434 MHz 3 times a	VAS pain (baseline/post/6 weeks): Hyperthermia	"Hyperthermia is effective in the management of	No long-term follow-up, only 2 weeks post-

RCT	S	week vs.	(5.96±	established	treatment. Data
	tendinopathy by clinical and	continuous ultrasound at 1MHz at	0.83/2.4±0.46/1.2±0.63 ) vs. ultrasound (6.3± 0.86/5.8±0.96/5.15±0.8	supraspinatus tendinopathy. This modality	suggest hyperthermia superior to
	ultrasound	2.0W/cm <sup>2</sup> 3 times a week vs. exercises (pendulum, stretching 2 times a day). All treatments for 4 weeks; 6 week follow-up.	7) vs. exercise (6.1±0.89/ 5.3±0.65/4.9±0.88). Comparable results with constant scores (p <0.05 comparing hyperthermia to other groups).	warrants further studies with a greater number of patients."	ultrasound, however there is insufficient follow- up to support evidence-based guidance.

# DIATHERMY AND INFRARED THERAPY

There are many commercial modalities used to deliver heat; these generally differ on how deeply the heat is felt. None of these modalities other than ultrasound have demonstrated major efficacy for any disorder, however, there have been limited uses for treatment of specific disorder with a specific intervention (see Hand, Wrist, and Forearm Complaints, Elbow Disorders, Low Back Complaints, and Chronic Pain Guidelines).

Recommendation: Diathermy or Infrared Therapy for Acute, Subacute, or Chronic Shoulder Pain There is no recommendation for or against the use of diathermy or infrared therapy for the treatment of acute, subacute, or chronic shoulder pain.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

# Rationale for Recommendation

There are no quality studies evaluating the use of diathermy or infrared for shoulder pain patients. While they are not invasive and have low complication rates, diathermy and infrared therapy are moderate to high cost depending on the number of treatments. Thus, there is no recommendation for or against their use to treat shoulder pain.

# Evidence for the Use of Diathermy and Infrared Therapy

There are no quality studies evaluating the use of diathermy or infrared therapy for shoulder pain.

# ULTRASOUND

Ultrasound has been used for treatment of rotator cuff tendinitis and calcific tendinitis. (Robertson 01; Philadelphia Panel 01; Green 06; Berry 80; Downing 86; van der Heijden 97; Nykanen 95; van der Heijden 99; Ebenbichler 99)

1. Recommendation: Ultrasound for Acute, Subacute, or Chronic Shoulder Tendinopathies Ultrasound is not recommended for the treatment of acute, subacute, or chronic shoulder tendinopathy.

# Strength of Evidence – Not Recommended, Evidence (C)

Recommendation: Ultrasound for Calcific Tendinitis
 Ultrasound is recommended for the treatment of calcific tendinitis. (Ebenbichler 99)
 Indications – Calcific rotator cuff tendinitis.

*Frequency/Duration* – Ultrasound (0.89MHz, 2.5W/cm<sup>2</sup>) up to 24, 15-minute sessions, daily for 5 weeks, then 3 a week for 3 weeks. (Ebenbichler 99)

Indications for Discontinuation - Intolerance, adverse effect or resolution of pain.

# Strength of Evidence – Recommended, Evidence (C)

# Rationale for Recommendations

The largest, highest quality blinded study of shoulder soft tissue disorders found a lack of efficacy of ultrasound vs. sham. (Van der Heijden 99) Most of the other trials found no benefits compared to sham or other active treatments. (Johansson 05) One moderate-quality trial found efficacy for treatment of patients

with calcific tendinitis. (Ebenbichler 99) Another moderate-quality trial with a much smaller sample size that combined ultrasound with acetic acid iontophoresis found a lack of efficacy. (Perron 97) Ultrasound is not invasive, has low adverse effects, but is moderate to high cost depending on the number of treatments. It is recommended for treatment of calcific tendinitis as the highest quality, largest sample sized-study documents efficacy. However, it is not recommended for shoulder pain to include tendinopathies other than calcific tendinitis, as there is not clear documentation of efficacy for other than patients with calcific tendinitis.

#### Evidence for the Use of Ultrasound

There are 6 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT (Herrera-Lasso 93) in Appendix 2.

_asso 93) in A	Scor	Sample	Comparison Group	Results	Conclusion	Comments
Study	e (0-	Size	Companson Group	Nesulis	Conclusion	Comments
Туре	11)	0.20				
		Shoulde	r Tendinopathies: Inter	ferential vs. Ultrasoun	d vs. Placebo	
Van der Heijden 1999 RCT	7.0	N = 180 soft tissue shoulder disorders (had to fail 6 sessions of exercise therapy in 2 weeks)	1) active interferential electrotherapy (IE) (4kHz, amplitude modulated between 60-100Hz) plus ultrasound vs. 2) active IE plus dummy ultrasound vs. 3) dummy IE plus active ultrasound vs. 4) dummy IE plus dummy ultrasound vs. 5) no adjuvants. All had 12 sessions; exercise booklet, exercise program (active, passive); 12 months follow-up.	Electrotherapy recovery rates (6 weeks/3 months/6 months/9 months/12 months): active treatment (23/41/32/40/37) vs. sham (22/39/46/49/53) vs. none (20/42/34/31/37). Ultrasound recovery rates: active (26/42/40/41/42) vs. sham (19/38/38/47/47) vs none (20/30/34/31/37).	"Neither (interferential electrotherapy) nor (ultrasound) prove to be effective as adjuvants to exercise therapy for soft tissue (shoulder disorders)."	Patient's diagnoses not well described and heterogeneous mix of disorders and results not stratified by type of diagnosis. Data suggest interferential and ultrasound ineffective.
Ebenbichler 1999 RCT	7.0	N = 63 70 shoulders with Gartner I or II calcific tendinitis	Ultrasound (0.89MHz, 2.5W/cm <sup>2</sup> ) vs. sham. 24 15-minute sessions, daily for 5 weeks, then 3 times week for 3 weeks; 6 weeks follow-up for x- rays.	Unchanged or worse x-rays: ultrasound 53% vs. sham 90%; 19% ultrasound resolved vs. 0% sham, p = 0.003. Follow-up visit 9 months, unchanged or worse 35% ultrasound vs. 80% sham; 42% vs. 8% resolved, p = 0.002. Constant scores (baseline/3 month change/9 month change): ultrasound 74.5/17.8/15.7 vs. sham 71.7/3.7/12.4 (p <0.001 at 3 months; p = 0.23 at 9 months).	"In patients with symptomatic calcific tendinitis of the shoulder, ultrasound treatment helps resolve calcifications and is associated with short-term clinical improvement."	Data suggest efficacy.
			er Tendinopathies: Ultra			
Johansson 2005 RCT	6.5	N = 85 impingement syndrome confirmed with injected	Acupuncture {traditional Chinese [LI 14 (Binao), LI 15 (Jianyu), LU 1 (Zhongfu) and TE 14	Combined scores among those adhering to protocol (n = 64) (baseline/post/3	"The results suggest that acupuncture is more efficacious than ultrasound	High dropout and noncompliance rates. More additional treatments in
		anesthetic	(Jianliao), and LI 4 (Hegu)], with rotated	months/6 months/12 months): acupuncture	when applied in addition to home	ultrasound group. Data support

			needles and de qi} vs. ultrasound (10 minute at 1W/cm <sup>2</sup> ) 2 times a week for 5 weeks. All treated with home exercise program; 12 month follow-up.	(61/79/84/90/93) vs. ultrasound (63/76/83/88/89). ITT results comparable and not significant.	exercises."	largely comparable (in)efficacy.
Downing 1986 RCT	6.0	N = 20 apparent mix of supraspinatu s tendinitis, subacromial bursitis or adhesive capsulitis and symptoms over 1 month, mostly chronic	Ultrasound (1.2W/cm <sup>2</sup> , 6 minute sessions, 3 times a week, for 4 weeks) vs. sham (same procedure, dialed off).	Scapulothoracic flexion change ultrasound 15±6 vs. sham 20±7. Scapulothoracic abduction change: ultrasound 14±7 vs. sham 28±13. No differences in other ROMs.	"Although the study group was small, the results suggest that [ultrasound] US [ultrasound] is of little or no benefit when combined with ROM exercises and NSAIDs or ROM exercises in the treatment of SSA."	Patients not well described. Title suggests study of subacromial bursitis alone; abstract/ introduction suggest mixed supraspinatus tendinitis, subacromial bursitis or adhesive capsulitis. As apparently mixed and stratified results not presented, utility of study is limited.
Perron 1997 RCT	4.5	N = 22 Gartner I or II calcifying tendinitis with at least 50mm <sup>2</sup> calcific deposit; assignments based on Type 1 vs. 2 calcific deposit	Acetic acid 5% iontophoresis (5mA galvanic, 20 minutes) plus ultrasound (0.8W/cm <sup>2</sup> , 1MHz, 5 minutes) 3 times a week for 3 weeks vs. no treatment; 3 weeks follow-up.	No differences between groups in calcium deposit over time (-20% vs36% controls, NS). No differences in density of calcium deposits (graphic data). Percentage change in calcium deposit area greater in type I vs II (p = 0.01).	"The reduction in (calcium deposit) area and density likely results from a natural process rather than treatment Reduction of the CD area does not necessary [sic] result in a functional improvement."	Small sample size. No short- or long-term follow- up. Data suggest iontophoresis with acetic acid plus ultrasound ineffective.
Olembiai				: Hyperthermia vs. Ultra		No long to war
Giombini 2006 RCT	5.5	N = 37 athletes with supraspinatu s tendinopathy by clinical and ultrasound	Hyperthermia 434 MHz 3 times a week vs. continuous ultrasound at 1MHz at 2.0W/cm <sup>2</sup> 3 times a week vs. exercises (pendulum, stretching 2 times a day). All treatments for 4 weeks; 6-week follow-up.	VAS pain (baseline/post/6 weeks): Hyperthermia $(5.96\pm0.83/2.4\pm0.46/1$ $.2\pm0.63$ ) vs. ultrasound $(6.3\pm0.86/5.8\pm0.96/5.$ $15\pm0.87$ ) vs. exercise $(6.1\pm0.89/5.3\pm0.65/4.$ $9\pm0.88$ ). Comparable results with Constant scores (p <0.05 comparing hyperthermia to other groups).	"Hyperthermia is effective in the management of established supraspinatus tendinopathy. This modality warrants further studies with a greater number of patients."	No long term follow-up, only 2 weeks post- treatment. Data suggest hyperthermia superior to ultrasound.

# LOW-LEVEL LASER THERAPY

Low-level laser treatment (LLLT) usually involves laser energy that does not induce significant heating. It is theorized that the mechanism of action is through photoactivation of the oxidative chain and has been used for treatment of rotator cuff tendinopathies. (Fitz-Ritson 01; Bal 09; Santamato 09; England 89; Vecchio 93; Philadelphia Panel 01; Tumilty 10)

# Recommendation: Low-level Laser Therapy for Rotator Cuff Tendinopathies Low-level laser therapy is not recommended for treatment of rotator cuff tendinopathies.

# Strength of Evidence – Not Recommended, Evidence (C)

# Rationale for Recommendation

There are six sham-controlled trials, nearly all assessing additive benefit to exercise programs. (Abrisham 11; Vecchio 93; England 89; Bingöl 05; Yeldan 09; Dogan 10) Four of the six found no benefits of the laser. (Vecchio 93; Bingöl 05; Yeldan 09; Dogan 10) One of the two studies suggesting benefits only followed patients for two weeks, (Abrisham 11) thus insufficient for producing a guideline recommendation on efficacy for chronic pain conditions. Thus, the literature largely suggests LLLT is ineffective for shoulder pain. LLLT is not invasive, has few adverse effects, but is costly. As most data suggest a lack of efficacy, LLLT is not recommended for treatment of rotator cuff tendinopathies.

#### Evidence for the Use of Low-Level Laser Therapy

There are 8 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

(Saunders 95)

We searched Low level laser therapy, rotator Cuff/injuries, rotator cuff tears, rotator cuff tear, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, Shoulder Impingement Syndrome, Bursitis, supraspinatus tendinitis, bicipital tears, controlled clinical trial, controlled trials, randomized controlled trials, random allocation, random, randomized, randomization, randomly; systematic, systematic review, retrospective studies, prospective studies, epidemiological studies, epidemiological research, and Nonexperimental Studies. In PubMed we found and reviewed 17 articles, and considered 9 for inclusion. In Scopus, we found and reviewed 88 articles, and considered 1 for inclusion. In Cochrane Library, we found and reviewed 4 articles, and considered 1 for inclusion. In Cochrane and reviewed 4 articles, and considered for inclusion. The sources. Of the 15 articles considered for inclusion, 7 randomized trials and 3 systematic studies met the inclusion criteria.

Author/Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			Shoulder Tendinopath	nies: Laser vs. Sham		
Abrisham 2011 RCT	7.5	N = 80 subacromial syndrome. Age ≥18 years old.	Group 1 treated with low-level laser therapy (LLLT) and exercise therapy. Infrared laser radiation, 10 sessions over 2 weeks, three points on the shoulder including anterior, posterior and lateral were irradiated per session for 2 mins (n = 40) vs. Group 2: placebo laser and the same exercise therapy and same sessions	Group 1 Vs. Group 2 in pain severity (VAS (cm)/Active flexion, mean (°)/passive flexion, mean (°)/active abduction, mean (°)/passive abduction, mean (°)/active external rotation, mean (°)/passive external rotation, mean (°)/passive external rotation, mean (°)) (4.4±1.2 vs.2.9±1.1/ 43.1±2.5 vs. 25.3±2.4/ 50.2±3.0	"[T]his study indicates that LLLT combined with exercise therapy is more effective than exercise therapy alone in relieving pain and in improving the shoulder joint ROM in patients with subacromial syndrome (rotator cuff and biceps	Data suggest LLLT plus exercise superior to placebo over very short time. Short follow-up time of 2 weeks without longer follow-up.
			within same period of time. However, laser beams were transferred to the treated area. (n = 40). Follow-up period of 2 weeks.	vs. 29.1±3.0/ 43.1±2.2 vs. 25.2±5.7/ 43.2±2.5 vs. 29.1±3.1/ 18.6±1.9 vs. 14.9±1.6/ 22.5±2.1 vs. 15.3±1.8) p = 0.00 between both groups.	tendinitis)."	
Vecchio 1993	6.0	N = 35 rotator cuff tendinitis.	Active: 830nm GaAsAl diode (n = 19) vs. sham laser, 10 minute	Movement range (baseline/4/8 weeks): laser (2.2/-0.8/-1.5)	"These results fail to demonstrate the effectiveness	Baseline data sparse. Eight weeks follow-

RCT		Mean age: 54.4 years.	sessions, twice weekly for 8 weeks. Also	vs. sham (2.3/-0.5/- 0.8), p = 0.81-0.23.	of laser therapy in rotator cuff	up. Data suggest laser
			treated with exercises. (n = 16) Outcomes assessed at baseline and week 2, 4, and 8 after treatment.	Painful arc, resisted movement score, VAS night pain, VAS rest pain, VAS movement pain, VAS functional limitation all not significant.	tendinitis."	not effective.
Bingöl 2005 RCT	6.0	N = 40 with shoulder pain. Age range of 39- 80.	Group 1: GaAs diode laser to the tubercululum and minus, bicipital groove and anterior plus posterior faces of capsule, for 1 minute at each location, frequency of 2000 Hz (n = 20) vs. Group 2: Placebo laser (n = 20). Both groups performed exercise program for 15 minutes and 10 sessions of laser plus exercise within 2 weeks. Follow-up period of 2 weeks.	Improvement rate, difference scores, and percent changes after treatment between the two groups (palpation sensitivity/passive extension range) vs. placebo. $(17/20 / 7.41 \pm 11.61)$ Vs. $(6/20 / 0.73 \pm 9.13)$ . p <0.05; p <0.001.	"The results of our study have shown better results in palpation sensitivity and passive extension, but no significant improvement in pain, active range, and algometric sensitivity in laser treatment group compared to the control group in the patients with shoulder pain."	Short follow up (2). Both groups improved, but few meaningful or statistical change between groups.
England 1989 RCT	5.5	N = 30 supraspinat us or bicipital tendinitis, subacute and chronic symptoms (mean 12.5 weeks).	Low power laser 3 times a week for 2 weeks (Ga-As diode at 904nm, 4,000Hz, 5 minutes of 3mW) vs. sham laser vs. naproxen 550mg BID for 2 weeks. No follow-up beyond treatment. Outcomes assessed at baseline and week 2.	Differences in medians compared over treatment period include 6° extension ( $p = 0.05$ ), 15° flexion ( $p = 0.005$ ), 20° abduction ( $p = 0.005$ ). Subjective pain difference 2.5cm ( $p =$ 0.001).	"These results demonstrate the effectiveness of laser therapy in tendonitis of the shoulder."	Small sample sizes (10/group), no data on groups. Sparse descriptions, including of results.
Yeldan 2009 RCT	5.5	N = 67 subacromial impingeme nt syndrome (SAIS).	3 pulses each session to 5 tender points. Treatment concentrated in the subacromial and anterior shoulder regions. GaAs diode laser 90s/location at 2000 Hz (n = 34) vs. placebo laser (n = 26) Both groups completed 3-week rehabilitation programme. Duration of each exercise session was 15 to 30 minutes, and cold pack applied around	Mean VAS pain score before treatment and after treatment for Group 1 vs. Group 2 while active: $5.91\pm1.92$ and $3.70\pm1.69$ (p = 0.00) vs. $6.26\pm2.06$ and $4.11\pm2.19$ (p = 0.00). Mean VAS pain score before and after treatment for Group 1 vs. Group 2 while resting: $3.08\pm2.56$ and $1.61\pm1.96$ (p = $0.01$ ) vs. $3.96\pm2.69$ and $1.92\pm1.89$ (p = 0.01).	"[T]here is no fundamental difference between LLLT and placebo LLLT when they are supplementing an exercise programme for rehabilitation of patients with shoulder impingement syndrome."	No between group differences, although both groups' VAS improved. Functional outcomes did not differ.

Dogan 2010 RCT	4.5	N = 52 subacromial impingeme nt syndrome. Mean age: 53.59±11.3 4 years.	the shoulder for 15 minutes. The treatment duration for both groups was 8 minutes. Follow-up at 3 three weeks. Group 1 (n = 30) low- level GaAlAs 850nm 100mV continuous wave and 0.07cm2 spot area laser and cold pack plus exercise program, over max. 5-6 painful points for 1 minute/point. Group 2 (n = 22) placebo laser and cold pack plus exercise program. Both groups, cold pack applied for 10 minutes. Exercise program once for 10- 15 repetitions. Therapy 5 times a week and once a day for 14 days.	Mean SDQ pain score before and after treatment for Group 1 vs. Group 2: 77.23±19.99 and 51.76±24.04 (p = 0.00) vs. 81.60±20.68 and 51.26±29.97 (p = 0.00). No significant difference between groups. No significant differences between the two groups (p >0.05) Improvements in pain severity, ROM except internal and external rotation and SPADI scores were observed compared to baseline scores in Group 1 (p <0.05). All parameters except ROM of external rotation improved in Group 2 (p <0.05).	"The Low level laser therapy seems to have no superiority over placebo laser therapy in reducing pain severity, range of motion and functional disability."	Both groups improved, but no change between groups observed.
			Follow-up for 2 weeks.			
	·	S	Shoulder Tendinopathies	s: Laser vs. Ultrasound	l 	
Santamato 2009 RCT	5.0	N = 70 Stage 1 or 2 impingeme nt syndrome by ultrasound or MRI; pain duration at ≥ 4 weeks. Mean age 54.1 years.	High-intensity laser therapy: neodymium- yttrium aluminum garnet laser, high peak power 1kW, 1,064nm, maximum 150MJ single impulse, average 6W, fluency of 760mJ/cm <sup>2</sup> and duration of single impulse <150ms, 3 phases and total 2,050J administered (n = 35) vs. ultrasound:1MHz, 2W/cm <sup>2</sup> , transducer head 5.8cm <sup>2</sup> (n = 35); 10 treatments, 10 minutes per session, over 2 weeks. Follow-up: 2 weeks.	VAS pain (pre/post): HILT (6.28±1.8/2.42±1.42) vs. ultrasound (6.6±1.53/4.44±1.37), p <0.01. No differences in CMS or SST scores.	"(High intensity laser therapy) was shown to have greater benefit for (impingement syndrome) than US [ultrasound] therapy."	Short-term, intensive treatment trial. No intermediate term or longer follow-up.

Bal 2009	6.0	N = 44 newly	Ga-As laser therapy (10 minute sessions, 5	Night pain: mean change Laser plus	"Our study was unable to	Data suggest no additive
RCT		diagnosed with impingeme nt syndrome. Required relief with anesthetic injection. Age range: 18-70 years.	times a week, 2 weeks, 904nm, 5500Hz, 27W max power per pulse, 13.2mW average power, 0.8cm <sup>2</sup> spot size, 1.6J total energy, 16.5mW/cm <sup>2</sup> ) with 12- week comprehensive home exercise program consisting of pendulum, self- stretching, then isometrics, theraband, strengthening, advanced strengthening with dumbbells (n = 22) vs. home exercise program alone (n = 22). 12 weeks follow-up. Outcomes assessed at baseline and week 2 and 12.	HEP (-22.7±24.36) vs. HEP (- 21.7±19.21), p = 0.66. SPADI measures also not different.	demonstrate any distinct advantage of low- level laser therapy over exercise alone. Comprehensive home exercise programs should be the primary therapeutic option in the rehabilitation process in SIS."	benefit of laser plus exercise.

# PULSED ELECTROMAGNETIC FIELD

Pulsed electromagnetic field (PEMF) treatments have been utilized to treat shoulder pain patients. (Binder 84)

#### Recommendation: Pulsed Electromagnetic Field for Rotator Cuff Tendinopathies **PEMF is moderately not recommended for treatment of rotator cuff tendinopathies.** (Aktas 07)

# Strength of Evidence – Moderately Not Recommended, Evidence (B)

# Rationale for Recommendation

There is one high-quality study of PEMF suggesting lack of benefit. Thus, pulsed electro is not recommended for treatment of rotator cuff tendinopathies.

# Evidence for the Use of PEMF

There is 1 high-quality RCT incorporated into this analysis. There is 1 low-quality RCT (Chard 88) in Appendix 2.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			Shoulder Tendinopath	ies: PEMF vs. Placebo		
Aktas 2007 RCT	8.0	N = 46 subacromia l impingeme nt syndrome with subacute and chronic pain	PEMF (50Hz, 30G for 25-minute session, 5 sessions a week for 3 weeks) vs. sham PEMF. Both groups Codman's pendulum exercises, cold pack gel 5 times a day, restriction from overhead use, meloxicam 15mg a day; 3 weeks total follow-up.	VAS rest pain (pre/post): PEMF (3.3±3.01/ 0.9±1.55) vs sham (2.5±1.76/0.85±1.56). Activity pain VAS and pain disturbing sleep VAS not different. Constant scores not different. SDQ scores not different.	"There is no convincing evidence that electromagnetic therapy is of additional benefit in acute phase rehabilitation program of (shoulder impingement syndrome)."	Data suggest lack of efficacy.

# MANUAL THERAPY, MANIPULATION AND MOBILIZATION

Manual therapy, manipulation, and mobilization to the shoulder girdle and spine have been used to treat shoulder problems, mostly in patients with adhesive capsulitis, some with impingement syndrome, (Green 06; Bang 00; Teys 08; Trampas 06; Ho 09; Desmeules 03; Senbursa 07; Citaker 05; Conroy 98) and general shoulder pain. (Bergman 04) This has included thoracic spine thrust manipulation utilized for treatment of impingement syndrome. (Boyles 09; Strunce 09; Mintken 10)

Recommendation: Manual Therapy, Manipulation, or Mobilization for Acute, Subacute, or Chronic Rotator Cuff Tendinopathies

Manual therapy, manipulation, or mobilization is recommended for treatment of acute, subacute, or chronic rotator cuff tendinopathies.

Strength of Evidence - Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

There is sparse quality evidence of efficacy of manual therapy, manipulation, or mobilization for treatment of rotator cuff tendinopathies. There is one moderate-quality trial assessing a specific mobilization (Mulligan's mobilization) compared to sham which suggested modest benefit (Teys 08); however, patients are not well described and it is unclear for whom the treatment would be effective. A study assessing efficacy found modest benefits, comparing the potential additive benefits of manual therapy in addition to an exercise program. (Bang 00) Another moderate-quality trial compared combined physical and manual therapy with wait-listed controls, thus preventing assessment of the effect of manual therapy. (Dickens 05) A study of heterogeneous shoulder disorders comparing manipulation with usual care found greater improvements in the groups with manipulation. (Bergman 04) Lastly, a trial of manual therapy with physical therapy and injection suggested manual therapy was most helpful for shoulder girdle pain, rather than rotator cuff tendinopathies. (Winters 97) Thus, manual therapy, mobilization, or manipulation is recommended for treatment of rotator cuff tendinopathies.

Author/ Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
				tion, Mobilization, Manu		
Teys 2008	5.5	N = 24 inability to elevate arm	Mulligan's mobilization with movement (post-	ROM (pre/post): Mulligans (102.2/117.8) vs.	"The results indicate that this specific manual	Patients not well described. No short- or long-term
RCT		>100° due to anterior shoulder pain and pain >1month duration	erolateral glide to glenohumeral joint) vs. sham (hand position altered and minimal pressure) vs. control.	sham (103.9/107.9) vs control (106.2/106.4). Pressure pain threshold: Mulligans (310.8/373.4) vs. sham (302.5/328.3) vs control (307.1/327.1).	therapy treatment has an immediate positive effect on both ROM and pain in subjects with painful limitation of shoulder movement."	follow-up or health outcomes.
Conroy 1998	4.0	N = 14 shoulder impingement	Experimental (subacromial and glenohumeral	24-hr pain (baseline/post): mobilization	"Mobilization decreased 24-hour pain and pain with	Small group of 7 subjects each. Baseline
RCT		syndrome	mobilization techniques) vs. control group. All received hot packs, active ROM, physiologic stretching, muscle strengthening, soft	$(47.8\pm27.9/12.0\pm14.4)$ vs. controls $(46.2\pm20.5/44.1\pm32.0)$ , p = 0.008. Subacromial compression test pain also differed (p=0.032). ROM not	subacromial compression test in patients with primary shoulder impingement syndrome, but larger replication studies are needed	differences in ROM. Methods claim subject and examiner blind, but this is unclear.

Evidence for the Use of Manual Therapy, Manipulation and Mobilization

There are 7 moderate-quality RCTs incorporated into this analysis. There are 2 low-quality RCTs (Citaker 05; Senbursa 07) in Appendix 2.

Dickens 2005 RCT	<b>Sho</b> u 6.0	N = 85 wait- listed for surgery; failed injection	Physical therapy (supervised therapy, HEP and manual therapy) vs. wait-listed controls.	different. apy Plus Manual Thera Constant scores baseline 56, mean improvement 0.65. Number of patients requiring surgery	to assess more clearly mobilization's influence on motion and function." <b>by vs. Wait-listed Con</b> "All patients in this study improved with physiotherapy."	Limited description of patients or outcomes. Individualized
		(excluded Type 3 acromion)	Need for joint mobilization therapist's decision; 6-month follow-up	(34/45 vs. 40/40) favored PT (p = 0.0008).		treatment limits conclusions. Wait- listed controls biases in favor of intervention.
Bang	Shoulde 4.0	er Tendinopath N = 52	ies: Exercise with vs. Manual therapy	without Manipulation, Functional	Mobilization, Manual ************************************	Therapy Baseline
RCT	4.0	impingement syndrome, rotator cuff tendinitis, or shoulder tendinitis; subacute to chronic symptoms	(treatment directed at movement limitations, 2 a week for 3 weeks) vs. no manual therapy. All treated with active exercise program (flexibility with 2 stretch exercises and 6 strengthening exercises); 2 month follow-up.	assessment questionnaire scores improved 35% manual group vs. 17% exercise alone (p<0.05). VAS pain scores decreased more with manual therapy (70% vs. 35%).	therapy applied by experienced physical therapists combined with supervised exercise in a brief clinical trial is better than exercise alone for increasing strength, decreasing pain, and improving function in patients with shoulder impingement syndrome."	differences. Manual therapy not well described. Many co- interventions. Data suggest improvements with manual therapy.
	Shoul	der Tendinopa		Mobilization, Manual The	erapy vs. Other Treat	
Bergman 2004 RCT	7.0	N = 150 shoulder symptoms and shoulder girdle dysfunction; 1 year follow-up	Manipulative therapy (6 treatments over 12 weeks: low- amplitude, high- velocity thrust; specific mobilizations to improve overall joint function and decrease restrictions) plus usual medical care (advice, NSAIDs; if ineffective, steroid injections in subacromial or glenohumeral spaces; physiotherapy if symptoms beyond 6 weeks) vs. usual medical care alone.	Patients "cured" (6/12/26/52 weeks): usual care (18/34/41/42%) vs. usual care plus manipulative (24/46/52/59%). Mean improvement in severity of main complaint: usual care (2.2/2.9/3.5/3.6) vs. usual plus manipulative (3.1/4.4/4.7/5.0).	"Manipulative therapy for the shoulder girdle in addition to usual medical care accelerates recovery of shoulder symptoms."	High prevalence of prior neck symptoms (62%). Usual care suboptimal, not active exercise- based, likely bias as more of same. Much higher contact time in combined group biases toward that group, although results modestly better for combined. Presumably heterogeneous disorders, yet no diagnoses or stratified results by diagnosis. Thus, limited applicability of these data.
Winters 1997 RCT	4.0	N = 198, n = 58 shoulder girdle and n = 114 synovial	Physiotherapy 2 times a week (exercise therapy, massage, physical applications) vs.	Pain scores in shoulder girdle group (baseline/post): manipulation 14.8±4.2/9.9±3.5 vs.	"For treating shoulder girdle disorders, manipulation seems to be the	Trial mixes shoulder girdle and joint pain sources and analyzed

		disorder	manipulation once a week up to 6 appointments (mobilization and manipulation of cervical spine, upper thoracic spine, upper ribs, AC joint, glenohumeral joint) vs. corticosteroid injection (synovial group) triamcinolone acetonide 40mg plus 9mL 10mg/mL lignocaine; up to 3 injections Weeks 0, 1, 2). Randomization after 1 week diclofenac 50mg TID; 11-week follow-up.	physiotherapy 14.4±3.5/12.0±4.4. Patients who were "cured" 8.7 vs. 9.6 (NS). Pain scores in synovial group: corticosteroid injection (16.3±4.8/9.2±3.7) vs. manipulation (15.7±4.2/12.6±5.1) vs. physiotherapy (16.3±3.3/11.5±4.4).	preferred treatment. For the synovial disorders, corticosteroid injection seems the best treatment."	separately. Limited description of exercise therapy or manipulation. Number of injections not controlled. High dropout rates with manipulation (59%) and physiotherapy (51%), but not injection. Data suggest corticosteroid superior for synovial pain. Manipulation superior to physiotherapy for pain relief in shoulder girdle group.
Winters 1999 RCT ; Follow-up of Winters 1997	4.0	N = 172 same as above; 76% questionnair e response rate	Physiotherapy vs. manipulation vs. corticosteroid injection (as above).	Physiotherapy group 59% current complaints. Manipulation group with 33% current symptoms. No differences between groups.	"The positive results of both injection therapy and manipulation versus physiotherapy in the original trial seemed to be short term effects."	Brief report of 2 pages.

# MASSAGE

Massage is a commonly used treatment for chronic muscular pain administered by multiple health care providers as well as family or friends. It is most typically used for treatment of spine and torso pain (see Chronic Pain Gudeilines and Low Back Complaints). It has been utilized for treatment of shoulder disorders. Alternatively, deep friction massage (DFM), a manual treatment intended for tendon disorders, purportedly has some evidence in a foreign language publication for the treatment of tendinopathy. However, there is a lack of supportive English-language publications or isolated evaluation of DFM as a treatment modality. (Joseph 12)

#### Recommendation: Massage for Rotator Cuff Tendinopathies There is no recommendation for or against use of massage for rotator cuff tendinopathies.

# Strength of Evidence - No Recommendation, Insufficient Evidence (I)

# Rationale for Recommendation

Massage is a commonly used treatment for musculoskeletal pain, but few studies evaluated disorders other than low back pain. (Melzack 83, Preyde 00, Kalauokalani 01) There is one quality trial of massage for shoulder disorders, but it evaluated a list of diagnoses, precluding an assessment of benefits for treatment of rotator cuff tendinopathy patients. (van den Dolder 03) There is no recommendation for or against use of massage for treatment of shoulder tendinopathies.

# Evidence for the Use of Massage

There is 1 high-quality RCT incorporated into this analysis.

Author/ Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments			
	Shoulder Tendinopathies: Massage vs. Wait-Listed Controls								
van den	8.0	N = 29 shoulder pain	Soft tissue	Patient specific	"[S]oft tissue	Wait-listing biases			

Dolder	(diagnoses:	massage	functional disability	massage	towards intervention.
2003	impingement,	around	score (pre/post):	around the	Large list of
	supraspinatus/RC	shoulder (6	massage (9.5±4.6/	shoulder is	diagnoses, with no
RCT	tear, shoulder pain,	times, 15-20	17.6±8.0) vs.	effective in	preponderance of 1
	supraspinatus	minutes	control	improving	diagnosis. Location of
	tendinitis, biceps	treatments	(10.9±5.5/10.4±5.6)	range of	pain not noted.
	[sic?] tendinitis, soft	over 2 weeks)	. Abduction in	motion, pain	Limited utility of study
	tissue injury,	vs. wait-listed;	degrees:	and function in	for purposes of
	degenerative	2 week follow-	102.2/135.6 vs.	patients with	identifying
	arthritis, RC	up.	100.1/91.2.	shoulder pain."	appropriate patients
	tendonitis				for treatment.

# REFLEXOLOGY

Reflexology is a complementary or alternative treatment. It entails the physical act of applying pressure to the feet and hands with specific thumb, finger and hand techniques without the use of oil or lotion. Reflexology is based on a system of zones and reflex areas that reflect an image of the body on the feet and hands with a premise that such work effects a physical change to the body.

#### Recommendation: Reflexology for Shoulder Pain

Reflexology is not recommended for treatment of shoulder pain including rotator cuff tendinopathies.

#### Strength of Evidence - Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality studies of reflexology. It also has not been shown to be efficacious for the treatment of chronic LBP in a moderate-quality study. (Poole 07) Other treatments have been shown to be efficacious.

# Evidence for the Use of Reflexology

There are no quality studies evaluating reflexology for shoulder pain including rotator cuff tendinopathies.

# **ELECTRICAL THERAPIES**

There are multiple forms of electrical therapies used to treat musculoskeletal pain. These include highvoltage galvanic, H-wave<sup>®</sup> Device Stimulation, interferential therapy (IFT or IT), iontophoresis, microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, and transcutaneous electrical stimulation (TENS). The mechanism(s) of action, if any, are unclear.

1. Recommendation: Interferential Therapy for Treatment of Rotator Cuff Tendinopathies Interferential therapy is not recommended for treatment of rotator cuff tendinopathies.

#### Strength of Evidence – Not Recommended, Evidence (C)

2. Recommendation: Other Electrical Stimulation Therapies for Treatment of Rotator Cuff Tendinopathies

There is no recommendation for or against the use of other electrical therapies outside of research settings for treatment of rotator cuff tendinopathies.

# Strength of Evidence - No Recommendation, Insufficient Evidence (I)

# Rationale for Recommendations

There is one moderate-quality study suggesting interferential therapy is ineffective for treating rotator cuff tendinopathies. (van der Heijden 99) One trial of H-wave<sup>®</sup> Device Stimulation with invasive electrodes in post-operative rotator cuff tendinopathy patients suggested some modest range-of-motion benefits, but applicability to surface electrodes or to other patients is unknown. (Blum 09) There are no quality studies for any of the other electrical therapies in occupational populations with rotator cuff tendinopathies. These therapies are mostly non-invasive with low adverse effects, but are moderate to high cost when

examined in aggregate. There is no recommendation for or against use of these therapies. There are alternate treatments that are effective.

#### Evidence for the Use of Electrical Therapies

There are 2 moderate-quality RCTs incorporated into this analysis. (van der Heijden 99; Blum 09) There are 2 low-quality RCTs (Herrera-Lasso 93; Baskurt 06) in Appendix 2.

We searched TENS for rotator cuff tears, massive rotator cuff tears, tendon rotator cuff tears, rotator cuff partial- and full-thickness tears, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, impingement syndrome, bursitis, supraspinatus tendinitis, and bicipital tears. One-low quality RCT was found for shoulder impingement and one RCT was found for Rotator cuff tears.

Author/Title	Score	Sample	Comparison Group	Results	Conclusion	Comments
Study Type	(0-11)	Size	r Tandinanathiaa, Intarf	arontial vo. Illtropound v	Dissehe	
van der	7.0	<b>Shoulde</b> N = 180	1) active interferential	erential vs. Ultrasound vs Electrotherapy	"Neither	Patient's
Heijden 1999 RCT		soft tissue shoulder disorders (had to fail 6 sessions of exercise therapy in 2 weeks)	electrotherapy (IE) (4kHz, amplitude modulated between 60-100Hz) plus ultrasound vs. 2) active IE plus dummy ultrasound vs. 3) dummy IE plus active ultrasound vs. 4) dummy IE plus dummy ultrasound vs. 5) no adjuvants. All had 12 sessions; exercise booklet and program (active, passive); 12 months follow-up.	recovery rates (6 weeks/3 months/6 months/9 months/12 months): active treatment (23/41/32/40/37) vs. sham (22/39/46/49/53) vs. none (20/42/34/31/37). Ultrasound recovery rates: active (26/42/40/41/42) vs. sham (19/38/38/47/47) vs none (20/30/34/31/37).	(interferential electrotherapy) nor (ultrasound) prove to be effective as adjuvants to exercise therapy for soft tissue (shoulder disorders)."	diagnoses not well described and heterogeneous mix of disorders and results not stratified by type of diagnosis. Data suggest interferential and ultrasound ineffective.
	<u> </u>	Rotator cu	uff Tendinopathies: H-wa	ave® Device Stimulation	vs. Placebo	
Blum 2009	5.5	N = 22	Implanted H-wave®	External rotation in	"HWDS	Small sample
RCT	5.5	who underwent rotator cuff reconstruc tion	Device Stimulation (HWDS); 1 hour twice a day for 90 days (n = 12) vs. Sham device (PLACEBO); same instructions as HWDS (n = 10). Follow-up: 45 and 90 days.	external rotation in degrees: HWDS vs. PLACEBO: 45 days: 22.75 vs. 33.00, p = 0.007; 90 days: 11.67 vs. 21.65, p = 0.007. Internal rotation in degrees: HWDS vs. PLACEBO: 45 days: 23.75 vs. 33.00, p = 0.007; 90 days: 13.33 vs. 23.25, p = 0.006.	rowpared to PLACEBO induces a significant increase in range of motion in positive management of rotator cuff reconstruction Interpretation of this preliminary investigation while suggestive of significant increases in Range of Motion of Post- Operative Rotator Cuff Reconstruction, warrants further confirmation in a larger double- blinded sham	size. Methodological details sparse. Possible different istructions to each group. Data suggest potential modest efficacy for ROM but not strength. May be underpowered and wehther applicable to surface device unknown

		controlled	
		randomized	
		study."	

# EXTRACORPOREAL SHOCKWAVE THERAPY ("SHOCKWAVE")

Extracorporeal shockwave therapy (ESWT) has been utilized for treatment of shoulder tendinitis, (Huisstede 11; Harniman 04; Grant 04) but has been particularly used for calcific tendinitis. (Mouzopoulos 07; Rompe 98; Rompe 01; Sems 06; Harniman 04; Chung 02; Loew 99; Cosentino 03; Ioppolo 13) Calcific tendinitis should be diagnosed with imaging for confirmation of presence of calcium. However, there have been some challenges noted in interpreting studies of efficacy including amount of energy delivered, method of focusing shock waves, treatment frequency, timing, and use of anesthetics. (Sems 06).

1. Recommendation: Extracorporeal Shockwave Therapy for Calcific Rotator Cuff Tendinitis Extracorporeal shockwave therapy is strongly recommended for treatment of calcific rotator cuff tendinitis.

*Indications* – Symptomatic calcific rotator cuff tendinitis that has been diagnosed with imaging. Patients should have failed at least 6 months of time with symptoms without resolution as well as failed physical or occupational therapy with both active and passive exercises, NSAIDs, and glucocorticosteroid injection(s). (Gerdesmeyer 03; Peters 04; Albert 07; Hsu 08; Hearnden 09; Pleiner 04; Cacchio 06; Sabeti 07)

*Frequency/Duration* – Treatment frequency and duration patterns varied in quality studies. These ranged from a single session (Hearnden 09; Sabeti 07; Krasny 05) to a second session in 1 week (Haake 02) to weekly sessions for 4 weeks (Cacchio 06) to an average of 4 sessions every 6 weeks over 6 months. (Peters 04) Most commonly and including the highest quality studies, patients treated with 2 sessions that were approximately 14 days apart. (Gerdesmeyer 03; Albert 07; Hsu 08; Pleiner 04; Pan 03) **Thus, up to 2 sessions, approximately 2 weeks apart are recommended.** Energy levels with documented success varied as well, ranging from 0.28 to 0.55 mJ/mm<sup>2</sup> in the most successful quality shamcontrolled trials. (Gerdesmeyer 03; Albert 07; Hsu 08; Hearnden 09; Pleiner 04) There is evidence that low energy levels such as 0.15 mJ/mm<sup>2</sup> are less effective. (Peters 04) **Thus, while an optimal dose is unclear, the recommended dose ranges from 0.28 to 0.55 mJ/mm<sup>2</sup>**. There is quality evidence the focus should be on the calcium deposits and not the tendon insertion. (Haake 02) Some protocols combined this therapy with an exercise program.

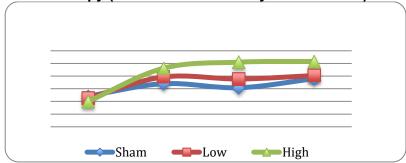
Indications for Discontinuation – Resolution, intolerance, non-compliance.

Strength of Evidence – Strongly Recommended, Evidence (A)

# Rationale for Recommendation

There are three high-quality (Gerdesmeyer 03; Peters 04; Cacchio 06) and seven moderate-quality trials (Albert 07; Hsu 08; Hearnden 09; Pleiner 04; Sabeti 07; Kolk 13; loppolo 12) comparing extracorporeal shockwave therapy with either sham or low energy for treatment of chronic calcific tendinitis. The quality literature nearly uniformly supports efficacy of ESWT for treatment of calcific tendinitis whether measured by pain, function, or disappearance of calcium deposits on x-rays. (Gerdesmeyer 03; Peters 04; Cacchio 06; Albert 07; Hsu 08; Hearnden 09; Pleiner 04; Sabeti 07; Harniman 04) There also is evidence of efficacy compared with treatment with TENS. (Pan 03) There is a low-quality study suggested surgical extirpation of calcium deposits is equally effective compared with ESWT. (Rompe 01) Needling is sometimes used as an adjunct, has some evidence of efficacy, and is reviewed elsewhere. (Krasny 05). There are no RCTs comparing ESWT with ultrasound-guided needling, which makes a direct comparison and recommendation between these treatments difficult. (Louwerens 14) ESWT is minimally invasive (Louwerens 14) as it is often performed with an injected anesthetic, has some adverse effects, is moderate to high cost depending on the number of treatments yet is quite effective, thus it is strongly recommended for treatment of calcific rotator cuff tendinitis.

# Figure 2. Chronic Calcific Tendinitis Treatment with High vs. Low vs. Sham Extracorporeal Shock Wave Therapy (Total Constant Murley Scale Scores)



Data graphed from Gerdesmeyer L, Wagenpfeil S, Haake M, et al. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. *JAMA*. 2003;290(19):2573-80.

2. Recommendation: Extracorporeal Shockwave Therapy for Acute, Subacute, or Chronic Non-calcific Rotator Cuff Tendinitis

Extracorporeal shockwave therapy is not recommended for treatment of acute, subacute, or chronic non-calcific rotator cuff tendinitis.

Strength of Evidence – Not Recommended, Evidence (C) – Chronic Not Recommended, Insufficient Evidence (I) – Acute, subacute

#### Rationale for Recommendation

There are four moderate-quality trials evaluating efficacy of ESWT for treatment of patients with chronic, non-calcific tendinitis. (Schmitt 01; Speed 02; Schofer 09; Galasso 12) Three of the four studies suggest a lack of efficacy, (Schmitt 01; Speed 02; Schofer 09), while one smaller study has suggested efficacy.(Galasso 12) Additional studies are needed. There are other treatments reviewed elsewhere with documented efficacy for treatment of these patients. ESWT is minimally invasive as often performed with an injected anesthetic, has some adverse effects, is moderate to high cost depending on numbers of treatments and appears ineffective, thus it is not recommended for treatment of non-calcific rotator cuff tendinitis.

# Evidence for the Use of Shockwave Therapy

There are 3 high-quality and 15 moderate-quality RCTs incorporated into this analysis. There are 6 lowquality RCTs or comparative clinical trials (Rompe 98; Cosentino 03; Loew 99; Rompe 01; Sabeti-Aschraf 05) in Appendix 2.

We searched "extracorpeal shockwave therapy" and rotator cuff tears, massive rotator cuff tears, tendon rotator cuff tears, rotator cuff partial- and full-thickness tears, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, impingement syndrome, bursitis, supraspinatus tendinitis, and bicipital tears. Six new RCTs were found.

Author/Title Study Type	Scor e (0- 11)	Size	Comparison Group	Results	Conclusion	Comments
		Calo	cific Tendinitis: ESWT	vs. Sham or Very Low	Energy	
Gerdesmey	8.5	N = 144	High-energy ESWT	Constant scores	"Both high-energy	Somewhat
er		chronic	(1500 of	(baseline/3/6/12	and low-energy	unblinded study.
2003		calcifying	0.32mJ/mm <sup>2</sup> per	months): High (60.0/	ESWT appeared to	Somewhat less
		rotator cuff	treatment) vs. low-	86.2/91.0/91.6) vs.	provide a beneficial	calcific deposit
RCT		tendinitis (at	energy ESWT	Low	effect on shoulder	size in sham
		least 6	(6000 of	(62.7/79.3/77.7/80.4)	function, as well as	group. Higher
		months pain	0.08mJ/mm <sup>2</sup> per	vs. Sham	on self-rated pain	surgery rate in
		resistant to	treatment) vs sham	(64.2/74.0/70.8/77.9)	and diminished size	sham group, as
		conservative	treatment (no	(All comparisons with	of calcifications,	well as
		treatment,	coupling gel).	sham p <0.05 except	compared with	receiving other
		calcium	Active treatments	Low at 12 months. All	placebo.	treatments.

		deposits 5mm or greater on x-rays); negative MRI for tear	with same cumulative energy dose and at 120 impulses per minute. Same treatments repeated at 12-16 days. All treated with 10 physiotherapy appointments (active, passive exercises, mobilization, massage, manual therapy). Fluoroscopic guidance; 12- month follow-up.	high vs. low comparisons p <0.004). Complete disappearance of calcific deposits (6/12 months): High (60/86%) vs. Low (21/37%) vs. Sham (11/25%). Numbers of surgeries 0 (0%), 2 (4.2%) and 5 (10.4%). Total known treatment failures: 5 (10.4%) vs. 4 (8.3%) vs. 12 (25%).	Furthermore, high- energy ESWT appeared to be superior to low- energy ESWT."	Data suggest efficacy including pain, function and disappearance of calcific deposits. Greater success with high- energy vs. low.
Peters 2004 RCT	8.0	N = 90 Gartner I or II chronic calcific tendinitis (1- 3cm diameter) with symptoms at least 6 months, resistant to at least 10 PT sessions	ESWT (1500 impulses, high 0.44mJ/mm <sup>2</sup> ) vs. low (0.15mJ/mm <sup>2</sup> ) vs. sham (switch off); 1 session every 6 weeks until symptoms resolved or 5 treatments administered. 6 months follow-up.	More treatments in low energy protocol required (mean 4.1±0.8 vs. high mean 1.2±0.4, p <0.001). Recurrence of pain at 6 months in 0% vs. 87% vs. 100%. All calcifications resolved in high energy group, but not other 2 groups.	"ESWT in calcific tendinitis of the shoulder is very effective."	Limited description of patients. Somewhat sparse description of outcomes. Data suggest superiority to sham, as well as lower energy levels.
Albert 2007 RCT	6.5	N = 80 calcifying tendinitis (calcifications maximum diameter 10mm) and at least 3 months of symptoms; failed prior NSAID, steroid injection, calcification needling or physiotherapy	High (1 Hz first 200 impulses, then 2 Hz, up to 0.45mJ/ mm <sup>2</sup> per impulse) vs. low energy (energy increased from 0.02mJ/mm <sup>2</sup> per impulse to 0.06mJ/ mm <sup>2</sup> ) ESWT. Both treated with 2 sessions or 2500 impulses each, 14 days apart; fluoroscopic guidance; 3-month follow-up.	Change in total constant scores: High 12.5 vs. control 4.5, p = $0.026$ . ADLs also superior with active treatment (3.2 vs. 1.1, p = $0.037$ ). Pain scores borderline (p = 0.085).	"High-energy shock-wave therapy significantly improves symptoms in refractory calcifying tendinitis of the shoulder after three months of follow- up, but the calcific deposit remains unchanged in size in the majority of patients."	More injections in control group at baseline. Results suggest mean 1210 mJ/mm <sup>2</sup> more effective than low dose at 283mJ/mm <sup>2</sup> .
Kolk 2013 RCT	6.5	N = 82 with chronic tendinitis 6+ mos, diagnosed clinically and no treatment for tendinitis for 6+ weeks prior to study Ages 18-67 years.	Extracorporeal shock wave therapy at 2000 pulses of .11 mJ/mm2 (n = 44) vs. placebo extracorporeal shockwave therapy via sham (n = 38) Patients treated for 3 sessions with interval of 10-14 days.	VAS scores for treatment group: Baseline (mean, SD, 95% Cl) - 65, 20, 59.1 to 70.9), 6 months- 30, 26, 21.4 to 38.6 (p-value baseline vs. 6 months: < .001). VAS scores for the placebo group: Baseline (mean, SD, 95% Cl) - 70, 16, 64.9 to 75.1), 6 months- 38, 28, 28.6 to 47.4 (p-value baseline vs. 6 months: < .001).	"Low-dose rESWT does not seem to be effective compared with placebo in reducing symptoms in patients with chronic rotator cuff tendinitis and we cannot recommend this form of treatment in these patients."	Placebo treatment blinding questionable. No meaningful differences comparing low dose ESWT and placebo.

Hsu 2008 RCT	6.0	N = 46 Gartner I or II calcific tendinitis and failure of at least 3 months nonoperative treatment (NSAIDs, injections, physical therapy, exercise, immobilization )	ESWT (1000 impulses at 0.55mJ/mm <sup>2</sup> , 2 pulses per second) vs. Sham (dummy electrode). 10mL of 2% lidocaine injected in affected area before treatment. 2 treatment courses, 2 weeks apart. 1 year follow-up.	Pain scores (baseline/6 weeks/12 weeks/6 months/1 year): ESWT (7.2/3.7/2.1/1.6/1.3) vs. Controls (7.4/7.6/7.0/ 6.9/7.1) (graphic data interpretation for controls), p <0.05 all follow-up intervals. Constant scores: ESWT (57.3/74.3/82.8/85/88) vs. controls (56.2/57.3/54.3/56.8) (p <0.001). Calcium deposits completely or partially eliminated in 21.2/36.3% ESWT vs. 0/15.3% controls.	"ESWT shows promise for pain relief and functional restoration of calcific tendinitis with negligible complications."	Small number of controls (13) due to 2:1 allocation ratio. Data suggest efficacy for pain, function and reduction in calcifications.
Hearnden 2009 RCT	5.5	N = 20 with chronic calcifying tendinitis with Gartner I or II calcific deposits on x- ray, pain greater than 12 months and failed conservative therapy	ESWT (2000 shocks at 0.28mJ/mm <sup>2</sup> ) vs. sham (20 shocks at 0.03mJ/mm <sup>2</sup> ). Ultrasound used to mark skin for treatment location. Local anesthetic injection. Ultrasound imaging, and then adjusted focus to point of maximal tenderness; 6 month follow-up.	Final outcomes of complete resolution or satisfactory improvement in 45% vs. 0% (graphic data interpretation). 'Happy with result' was 45.4% vs. 0%. Constant scores did not change in controls but increased with ESWT, p <0.03.	"This study confirms that extracorporeal shock wave therapy is effective in treating chronic calcific tendonitis when compared with a placebo group."	Small sample size. Did not image with fluoroscopy; 1 treatment session. No description of population, limited description of results. Appears underpowered, though still suggested efficacy.
Pleiner 2004 RCT	5.0	N = 45 calcific tendinitis and at least 6 months shoulder pain, calcifications exceeded 5.0mm, failure of at least 3 of injections, physiotherapy , electrotherap y, ultrasound, NSAIDs	ESWT with high (0.28 mJ/mm <sup>2</sup> ) vs. low energy (<0.07mJ/mm <sup>2</sup> ). 2x2000 shocks at 2.5Hz in 2 sessions, 2 weeks apart; 7-month follow-up.	Improvements in constant pain scores (1 week/3 months/7 months): Treatment $(4\pm4/5\pm4/5\pm5)$ vs. control $(1\pm5/3\pm6/3\pm7)$ (p <0.05 at 1 week). At 3 months, 13% of active treatment vs. 8% sham resolved calcifications. Resolution of calcifications at 7 months in 6/31 (19.4%) shoulders vs. 2/26 (7.7%) (p = 0.07).	"ESWT with an energy flux density of 0.28mJ/mm <sup>2</sup> . Led to a significantly greater improvement in shoulder function and a slightly higher, non- significant, rate of >50% disintegration of calcific deposits compared with the control group."	Some details of blinding not clear. Treated both shoulders when both symptomatic. Appear to have included both shoulders in analyses, thus potentially double counting results. High dropout rate at 7 months.
				liddle vs. Low Energy E		
Cacchio 2006 RCT	8.5	N = 90 Gartner Type I or II calcific tendinitis and 6+ months pain and failed conservative treatments.	ESWT (2500 impulses/session, 500 at 1.5 bar pressure, 4.5Hz and 2000 impulses with 2.5bar and 10Hz; energy flux density 0.10mJ/mm <sup>2</sup> ) vs.	UCLA scores (pre/post/6 months): ESWT ( $1.39\pm0.97$ / 7.90 $\pm1.09$ /7.95 $\pm0.92$ ) vs. controls ( $1.04\pm1.03$ / 2.85 $\pm2.03$ /2.64 $\pm1.14$ ), p = 0.90/p = 0.0044/p = 0.0023 respectively.	"RSWT[leads] to a significant reduction in pain and improvement of shoulder function after 4 weeks, without adverse effects."	Data suggest strong efficacy of high energy protocol for pain and reduction in calcifications.

			less active similar therapy/sham (25 impulses at 1.5 bar, 2.5Hz and 20 impulses at 2.5 bar and 10Hz); 4 sessions at 1 week intervals; 6-month follow-up.	Active forward flexion, strength, function and satisfaction all strongly in favor of treatment. VAS scores (pre/6mo): ESWT (7.96/0.95) vs. controls (7.72/6.84), p = 0.001. Average calcium deposit diameter (pre/post): ESWT (21.30/0.85) vs. controls (19.7/18.85), p = 0.0001. Additional treatment of injections in 0 ESWT vs. 6 control group patients.		
Peters 2004 RCT	8.0	N = 90 Gartner I or II chronic calcific tendinitis (1- 3cm diameter) with symptoms at least 6 months, resistant to at least 10 PT sessions	ESWT (1500 impulses, high 0.44mJ/mm <sup>2</sup> ) vs. low (0.15mJ/mm <sup>2</sup> ) vs. sham (switch off). 1 session every 6 weeks until symptoms resolved or 5 treatments administered; 6 months follow-up.	More treatments in low energy protocol required (mean 4.1±0.8 vs. high mean 1.2±0.4, p <0.001). Recurrence of pain at 6 months in 0% vs. 87% vs. 100%. All calcifications resolved in high energy group, but not other 2 groups.	"ESWT in calcific tendinitis of the shoulder is very effective."	Limited description of patients. Somewhat sparse description of outcomes. Data suggest superiority to sham, as well as lower energy levels.
Sabeti 2007 RCT	7.5	N = 50 calcific tendinitis on x-rays, symptoms of at least 6 months and failure of 2 other treatments.	Navigated ESWT at 0.08mJ/mm2, 1000 impulses, no local anesthesia vs. Navigated ESWT, 0.2mJ/mm2, 2000 impulses with local anesthesia; 3 months follow-up.	VAS (baseline/12 weeks): low (69.95 $\pm$ 14.47/16.43 $\pm$ 13.06) vs. high (65.57 $\pm$ 22.37/ 19.09 $\pm$ 21.97), p = 0.42. Constant scores also improved, but not different, p = 0.69.	"Navigated shock- wave therapy significantly improves pain and shoulder function. Patients obtained nearly equal results after three low- energy or two middle-energy sessions of shock- wave treatment."	Limited description of patients at baseline. Data suggest equal efficacy.
loppolo 2012 RCT	7.0	N = 46 with supraspinatus calcifying tendinitis and shoulder pain for 4 to 6+ months.	Treatment group A Extracorporeal shock wave therapy at 0.10 mJ/mm <sup>2</sup> (n = 23) vs. Treatment group B Extracorporeal shock wave therapy at 0.20 mJ/mm <sup>2</sup> (n = 23). Both groups received 2,400 pulses once a week for 4 weeks. Patient follow-ups at 3, 6, and 12 months	After 6 months, treatment Group A showed improvement vs. Group B in regards to CMS and VAS scores. Group A CMS and VAS at 6 months: CMS Mean (SD: 79.43 (10.33) and VAS Mean (SD: 2.09 (1.54). Group B CMS and VAS at 6 months: CMS Mean (SD) - 57.91 (6.53) and VAS Mean (SD) - 5.36 (0.78).	"In ESWT for SCT, an energy level of 0.20 mJ/mm2 appears to be more effective than an energy level of 0.10 mJ/mm2 in pain relief and functional improvement."	High dropout between 6 months and 1 year assessments. No difference between groups at 3 months. Data favor higher energy; 1 year results minimally reported.

		(	Calcific Tendinitis: E	SWT vs. Other Treatmer	nts	
Pan 2003 RCT	5.5	N = 60 calcific tendinitis and 6+ months pain	ESWT (2000 shock waves 2Hz, energy between 0.26 and 0.32 mJ/mm <sup>2</sup> . Treatment in 2 sessions 14 days apart) vs. TENS (3 times a week, 4 weeks); 12 weeks follow-up.	Constant score changes from baseline (2 weeks/4 weeks): ESWT (13.79±11.25/24.21± 13.68) vs. TENS (3.52±6.73/9.59±9.62 ), p <0.001.	"ESWT is more effective in the treatment of chronic calcific tendinitis of the shoulder than is TENS therapy, especially for arc- type calcific plaque."	Baseline differences with higher age, manual muscle testing. Data suggest ESWT superior to TENS.
Krasny 2005	6.0	N = 80 Gartner I or II calcific	ESWT (200 low energy impulses, then 2500 impulses	Improvements in ESWT needling 30/40 (75%) vs. 24/40	"Ultrasound-guided needling in combination with	Baseline differences in gender of
RCT		tendinitis and symptoms averaging 30- 36 months scheduled for arthroscopic calcium removal in 6 months.	at 0.36mJ/mm <sup>2</sup> ) with prior ultrasound-guided needling (repeated, 18g needle) vs. ESWT without needling. Treatments not repeated. Variable follow-up, mean 4.1 months.	(60%), p = 0.25. Total constant scores (pre/post): ESWT needling (46.3 $\pm$ 12.7/76.8 $\pm$ 20.4 ) vs. ESWT (44.2 $\pm$ 11.9/67.3 $\pm$ 20.7 ). Patients reaching 75 Constant points were 62.5% vs. 32.5%, p = 0.021. Disappearance of calcific deposits in 60.0% vs. 32.5%, p <0.05.	high-energy shock- wave therapy is more effective than shock-wave therapy alone in patients with symptomatic calcific tendonitis, giving significantly higher rates of elimination of the calcium deposits, better clinical results and reduction in the need for surgery."	uncertain significance. Likely underpowered for some outcomes. Data suggest addition of needling successful for reduction of symptoms and more resolution of calcium deposits.
	1	Calcific T		endon Insertion vs. Calo	cific Deposit	<u>.</u>
Haake 2002 RCT	7.0	N = 50 Gartner I or II chronic calcifying tendinitis, at least 5.0mm diameter calcification, 6 months symptoms, failed 10 physiotherapy sessions, 2 injections, 6 PT sessions plus NSAIDs	2 ESWT sessions, 1 week apart, 1 group focused at origin [sic] of supraspinatus tendon vs. focus over calcified area. ESWT 2000 impulses, 0.35mJ/mm <sup>2</sup> ). Local anesthetic injection of 15mL mepivacaine 1%. Fluoroscopic guidance. 1-year follow-up. on-calcific Tendinitis	Successful treatment at 12 weeks/1 year: focus on calcific deposit [20/25 (80%)/25/25 (100%)] vs. tuberculum majus [7/24 (29.2%)/10/24(41.7%)]. Constant scores (baseline/12 weeks/1 year): focus on calcium (49.96/104.59/116.24) vs. insertion (47.17/73.08/83.51). Rate of calcium resorption not different between groups (58.3% vs. 36.4%). <b>S: ESWT vs. Sham vs. O</b>	"[E]xtracorporeal shock wave application should be focused fluoroscopically with appropriate shock wave generators."	Sparse description of patients. May be underpowered for calcium resorption rate differences. Data do not address whether fluoroscopic guidance is required. Focus of ESWT on calcified area supported by data.
Galasso 2012	6.0	N = 20 with	Extracorporeal shock wave	Total shoulder function ratings for	"Patients suffering from NCST may	Small sample size. Data
RCT		non-calcifying supraspinatus tendinopathy who had limited success with conservative treatment for 4+ months	shock wave therapy, 3000 shockwaves at energy flux density of 0.068 mJ/mm <sup>2</sup> separated by a 7 day interval (n = 11) vs. placebo/sham with shockwave generator disconnected (n = 9).	the ESWT group: Baseline (mean $\pm$ SD) - 42.45 $\pm$ 9.83, 6 weeks- 64 $\pm$ 16.6 (p- value: .004), 3 months- 74.09 $\pm$ 20.56 (p-value: .003). Total shoulder function ratings for the placebo group: Baseline (mean $\pm$ SD) - 41.67 $\pm$ 12.53, 6	benefit from low energy ESWT, at least in short-term. The application protocol of ESWT is likely to play a key-role in a successful treatment. Future investigations should be undertaken on the	size. Data suggest ESWT superior to placebo for measured outcomes. Limited patient population and generalizability to other groups questionable.

O.L. '''			Patients had physical, blood and CMS follow-up evaluations at 6 and 12 weeks.	weeks- 43.11 ± 19.6 (p-value: .368), 3 months- 48 ± 22.3 (p- value: .260).	long-term effects of this technique for the treatment of NCST."	
Schmitt 2001 RCT	6.0	N = 40 supraspinatus tendinitis without calcification, at least 6 months symptoms; failed NSAID, 10 plus PT sessions, 2 plus injections	ESWT (6000 impulses, 0.11mJ/mm <sup>2</sup> , 1 session Qweek for 3 weeks) vs. sham ESWT (not otherwise specified). Ultrasound guidance; 12 weeks follow-up.	Constant Scores (baseline/6 weeks/12 weeks): ESWT (40.7± 13.3/61.0±29.6/66.5± 37.9) vs. Sham (42.4± 13.0/64.2±25.2/64.4± 32.7), NS. Subjective improvement, pain during rest and pain during activity all NS.	"We found an increase in function and a reduction of pain in both groups therefore do not recommend ESWT for the treatment of tendinitis of supraspinatus."	Patients not well described. Data suggest ineffective for non-calcific tendinitis.
Speed 2002 RCT	5.0	N = 74 chronic, non- calcific (x-ray and ultrasound negative) rotator cuff tendinitis of at least 3 months	ESWT (1500 impulses at 0.12mJ/mm <sup>2</sup> ) vs. sham (treatment head deflated, no coupling gel, 1500 impulses at 0.04mJ/mm <sup>2</sup> ). No anesthesia. Treatments monthly for 3 months.	Percentage improvement 3 months: ESWT 35.0% vs. sham 45.0%, p = 0.48. SPADI (baseline/1 month/2 months/3 months/6 months): ESWT (53.6/48.7/46.1/34.7/ 24.1) vs. sham (59.5/58.5/48.6/39.7/3 4.9) (NS between groups).	"[T]here is a significant and sustained placebo effect after moderate doses of ESWT in patients with non-calcific tendonitis of the rotator cuff, but there is no evidence of added benefit when compared with sham treatment."	High overall dropout rate. Data suggest lack of efficacy.
Schofer 2009 RCT	4.5	N = 40 with rotator cuff tendinopathy who did not benefit from conservative treatments. Patients excluded for rotator cuff tear or osteoarthritis of glenohumeral and acromio- clavicular joints.	High energy extracorporeal shock wave therapy at 6000 impulses (ED+ 0.78 mJ/mm <sup>2</sup> ) in 3 sessions under local anesthesia (n = 20) vs. Low energy extracorporeal shock wave therapy at 6000 impulses (ED+ 0.33 mJ/mm <sup>2</sup> ) under local anesthesia (n = 20). Patient follow-ups at 12 weeks and 1 year after selected treatment. Treatment included 10 sessions of physiotherapy, two subacromial injections with steroids and intake of nonsteroidal anti- inflammatory drugs.	Pain at rest VAS scores: High energy group: pre- intervention- $5.65 \pm$ 2.52 (p-value: .006, 95 % CI: .68 to 3.82), 12 weeks – $3.47 \pm$ 3.29 (p-value: .220, 95 % CI: -73 to 3.08), 1 year– $2.11 \pm 2.71$ (p-value: .899, 95 % CI: -1.66 to 1.77), Low energy group: pre-intervention- $3.45 \pm 2.44$ (p-value: .006, 95 % CI: .68 to $3.82$ )12 weeks – $2.30 \pm 2.56$ (p-value: .220, 95 % CI: -73 to 3.08), 1 year – $2.00 \pm 2.25$ (p-value: .899, 95 % CI: -1.66 to 1.77). Pain during activity VAS scores: High energy group: pre- intervention- 7.10 $\pm$ 2.47(p-value: .668, 95 % CI:-1.70 to 1.10), 12 weeks – $4.58 \pm$ 3.60 (p-value: .720, 95 % CI: -1.74 to $2.50$ ), 1 year – $3.53 \pm$	"No statistically significant differences were found between the outcome of high- energy and low- energy ESWT treatment of rotator cuff tendinopathy. Pain reduction and improvement in the Constant score was noted in both groups between pre-treatment and follow-up examinations.	Both groups showed improvement, however there were no meaningful differences between groups.

				3.44 (p-value: .979, 95 % Cl: -2.26 to 2.22). Low energy group: pre- intervention- 7.40 ± 1.88 (p-value: .668, 95 % Cl:-1.70 to 1.10), 12 weeks – 4.20 ± 2.93 (p-value: .720, 95 % Cl: -1.74 to 2.50), 1 year – 3.56 ± 3.29(p-value: .979, 95 % Cl: -2.26 to 2.22).		
				ESWT vs. Other Treatm		
Engebretse n 2011 RCT	6.5	N = 104 with subacromial shoulder pain lasting 3+ months Ages ranged 18-70 years.	Radial Extracorporeal shockwave therapy (rESWT) (n = 52) vs. supervised exercises (SE) (n = 52). Treatment 1x/week for 4 to 6 weeks and treated 3 to 5 tender points each time. Patient follow up was conducted at 18 weeks and 12 months.	At the 12 month follow-up, the primary outcome measure (95% CI: -16.6 to .5 and p-value: .09) between the two groups and pain (p- value: .83), function (p-value: .36) and medication use (p- value: .65) showed no significant differences.	"No significant difference was found between the SE and rESWT groups at the 1- year follow-up. More participants in the SE group had returned to work."	No meaningful differences between groups at 1 year followup.

## INJECTIONS

Several types of glucocorticoid injections have been used to treat patients with rotator cuff tendinopathies. Viscosupplementation, prolotherapy, and botulinum injections have also been utilized.

## SUBACROMIAL GLUCOCORTICOSTEROID INJECTIONS

Glucocorticosteroids are widely used for treatment of rotator cuff-related disorders. (Brox 03; van der Windt Ann Rheum Dis 95; Park 08; Petri 87; Adebajo 90; Buchbinder 03; Goupille 96; Arroll 05) A Cochrane review concluded there is benefit compared with placebo for treatment of rotator cuff disease, but no significant benefit of injection compared with NSAID when pooling three studies. (Buchbinder 03) These injections are sometimes performed to attempt to deliver medication to the subacromial bursa, rotator cuff and surrounding tissue with minimal systemic effects. (Brox 03; van der Windt Ann Rheum Dis 95; Petri 87; Adebajo 90) These injections are usually performed without imaging guidance, though, some advocate ultrasound guidance. (Naredo 04) Approaches utilized include anterior, anteromedial, lateral and posterior. A cadaveric study found no differences in accuracy for anteriolateral versus posterior approaches. (Mathews 05)

## Recommendation: Subacromial Glucocorticosteroid Injections for Acute, Subacute, or Chronic Rotator Cuff Tendinopathies

Subacromial glucocorticosteroid injections are moderately recommended for treatment of acute, subacute and chronic rotator cuff tendinopathies (including rotator cuff tendinoses, supraspinatus tendinitis, impingement syndrome, and subacromial bursitis).

Indications – Shoulder joint pain from rotator cuff tendinopathies that control with NSAID(s) or acetaminophen is unsatisfactory. (Adebajo 90; Petri 87; Blair 96; Akgun 04; Plafki 00)

*Frequency/Duration* – Single injection should be scheduled and results evaluated, rather than scheduling a series of injections. A second injection after waiting at least 2 weeks may be reasonable if the response is suboptimal or the subacromial space was felt to have not been accessed, though it would be appropriate to consider a different technique or imaging. (Naredo 04) Medications used in the successful

RCTs included triamcinolone acetonide, triamcinolone hexacetonide, methylprednisolone, and betamethasone. (Adebajo 90; Petri 87; White 86; Blair 96; Alvarez 05; Withrington 85; McInerney 03) Sometimes these injections are performed without glucocorticosteroid for diagnostic purposes. (Mair 04) In most cases, glucocorticoid is added to local anesthetic for diagnostic confirmation and treatment with 1 injection.

*Dose* – Multiple doses have been utilized with only one head-to-head comparative trial that suggested no differences. (Chavez-Lopez 09) Medication doses used in the successful RCTs included triamcinolone 40mg to 80mg, (Adebajo 90; Petri 87; White 86; Blair 96) betamethasone 6mg, (Alvarez 05) and methylprednisolone 40mg to 80mg. (Withrington 85; McInerney 03) It appears important that the negative trials tended to utilize smaller doses of steroid, such as triamcinolone 20mg (Ekeberg) or methylprednisolone 40mg. (Vecchio 93) Nearly all combined the corticosteroid with variable doses of anesthetic, generally ranging from 2 to 10mL of lidocaine or bupivacaine (see evidence table). There are no head-to-head comparisons in quality studies of different medications to ascertain the optimum medication(s) or doses.

*Indications for Discontinuation* – A second glucocorticosteroid injection is not recommended if the first injection has resulted in significant reduction or resolution of symptoms. If there has not been a response to a first injection, there is generally less indication for a second. If the interventionalist believes the medication was not well placed and/or if the underlying condition is so severe that one steroid bolus could not be expected to adequately treat the condition, a second injection may be indicated. The (first or) second injection may be performed under ultrasound guidance for increased accuracy, if available, as there is evidence suggesting superior placement with ultrasound guidance. (Naredo 04; Chen 06; Uncuncu 09) While ultrasound has been used in some studies, (Plafki 00; Chavez-Lopez 09, Dehghan 13; Ekeberg 09; DeWitte 13) there is little evidence to suggest outcomes superiority associated with using ultrasound for administration.

### Strength of Evidence – Moderately Recommended, Evidence (B)

#### Rationale for Recommendation

There are two high- and seven moderate-quality trials that compared subacromial glucocorticosteroid injection with saline of anesthetic placebos. (Alvarez 05; Adebajo 90; Petri 87; Blair 96; McInerney 03; Akgun 04; Withrington 85; Vecchio 93; Plafki 00) Patients assessed included acute, (Petri 87; McInerney 03; Adebajo 90) subacute, (Adebajo 90; Petri 87; Blair 96; Withrington 85; Vecchio 93) and chronic rotator cuff tendinopathies. (Alvarez 05; Petri 87; Blair 96; Akgun 04; Withrington 85; Plafki 00) All patient groups appeared to benefit without a clear pattern of response based on duration of symptoms with one exception. One trial of acute post-traumatic pain did not find benefit from these injections, (McInerney 03) likely reflecting the excellent natural recovery from acute traumatic pain.

Most, but not all studies showed benefits. It may not be coincidental that the high-quality study that was negative also utilized the lowest dose of 20mg triamcinolone in chronic shoulder pain patients. (Ekeberg 09) Another of the negative studies also utilized a lower dose of steroid, (Vecchio 93) while the last of the negative studies had the smallest sample size. (Withrinton 85) One trial was stopped due to the lack of efficacy of the placebo arm, while the corticosteroid arm was documenting benefits. (Plafki 00) Thus, quality evidence documents efficacy of these injections. There also are two high-quality trials with injected NSAIDs, but they conflict regarding superiority, (Karthikeyan 10; Min 13) resulting in no evidence-based recommendation on that approach and a need for further investigations.

One moderate-quality study (Naredo 04) and one low-quality study (Chen 06) demonstrated increased efficacy, improved shoulder symptoms, of steroids injected under ultrasonic guidance. However, the studies discussed above that compared steroid injection with placebo did not use ultrasound guidance and still resulted in good outcomes.

Another utility of these injections is to predict surgical success. The impingement test with subacromial anesthetic injection was reported to result in 88% positive predictive value of surgical success vs. 60% in those negative, (Mair 04; Oh AJSM 10) thus another rationale for injection includes prognosis.

Subacromial glucocorticosteroid injections are invasive, have a low risk of adverse effects and are moderately costly. They have the potential to increase blood glucose, thus monitoring will be appropriate

in some diabetic patients. They are effective; two of the three comparative trials against NSAIDs have found these injections are superior, (Adebajo 90; Petri 87) thus these injections are recommended for management of these patients. Most should generally have failed prior treatment with NSAIDs and exercise.

*Evidence for the Use of Glucocorticosteroid Injections for Shoulder Pain* There are 6 high-quality and 24 moderate-quality RCTs incorporated into this analysis. There are 5 lowquality RCTs or comparative clinical trials (Chen 06; Ginn 05; Hardy 86; Valtonen 78; Watson 08) in Appendix 2.

We searched steroid injections for rotator cuff tears, massive rotator cuff tears, tendon rotator cuff tears, rotator cuff partial- and full-thickness tears, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, impingement syndrome, bursitis, supraspinatus tendinitis, and bicipital tears. Seven new RCTs were included.

Author/Title Study Type	Scor e (0-	Sample Size	Comparison Group	Results	Conclusion	Comments
	11) Should	l der Tendinona	thies: Glucocorticoid l	Injection vs. Placebo (Sali	ne or Local Anesthe	atic)
Alvarez 2005 RCT	9.0	N = 58 at least 6 months duration, failure of 6 weeks physical therapy and 2 weeks NSAIDs	Xylocaine 2% 5mL vs. betamethasone 6mg plus xylocaine 2% 4mL subacromial injections. Required post-procedure 50% pain reduction for continued study inclusion.	DASH 3/6 months: xylocaine 76.9 $\pm$ 25.6/ 74.6 $\pm$ 28.8 vs. betamethasone 81.4 $\pm$ 25/ 74.3 $\pm$ 25.7 (NS). No differences WORC, ASES, Neer impingement test. Active external rotation (3/6 months): xylocaine (68.2° $\pm$ 21.4/63.7° $\pm$ 25.0) vs. betamethasone 76.5° $\pm$ 20.1/75.7° $\pm$ 23.6 (p = 0.04, p = 0.02).	"With the numbers available for this study, the authors found betamethasone to be no more effective in improving the quality of life, range of motion, or impingement sign than xylocaine alone in patients with chronic rotator cuff tendinosis"	Chronic shoulder pain patients. Appears underpowered as trend towards benefit.
Adebajo 1990	8.0	See above				
Petri 1987 RCT	7.5	N = 100 painful shoulders, no adhesive capsulitis. 20% with calcific tendinitis and 24% AC arthrosis (appears to include acute to chronic patients)	1) Injection 4mL 1% lidocaine plus naproxen 500mg BID vs. 2) injection 3mL lidocaine plus triamcinolone 40mg plus naproxen vs. 3) injection lidocaine plus triamcinolone plus placebo vs. 4) injection lidocaine plus placebo. Naproxen treatment 30 days; 4 weeks follow-up.	Percent remissions at 2/4 weeks: Group 1 12/20% vs. Group 2 20/28% vs. Group 3 8/28% vs. Group 3 8/28% vs. Group 4 4/8%. Naproxen not superior to placebo at 4 weeks. Post hoc analyses of outcomes showed pre-treatment clinical index most predictive (p = 0.00005) than treatment of duration of symptoms (p = 0.004).	"[B]oth triamcinolone (p=0.00005) and naproxen (P=0.02) are superior to placebo in the treatment of the painful shoulder."	Data suggest injection superior to naproxen and both superior to placebo. Naproxen plus injection trended towards superior to injection alone at 2 weeks. Patients' baseline status main determinant of outcome.
Blair 1996 RCT	6.5	N = 40 impingemen t syndrome with subacute and chronic symptoms	Subacromial injections of lidocaine 1% 6mL vs. triamcinolone acetonide 80mg (2mL) plus 4mL lidocaine. All treated with physical therapy including exercises. Mean 28 and 33 weeks follow-up.	Mean pain score after injection 1.2 vs. 2.0 points, p <0.005. Steroid 16/19 (84.2%) vs. controls 8/21 (38.1%) had decreased pain, p <0.05. Less impingement signs after injection in steroid group (15/19 negative vs. 4/21, p <0.005). No differences in ADLs.	"[S]ubacromial injection of corticosteroids is an effective short- term therapy for the treatment of symptomatic subacromial impingement syndrome."	Somewhat variable lengths of follow-up. Data suggest injections reduce pain.

McInerney 2003 RCT	6.0	N = 98 post- traumatic impingemen t pain at 7 days after trauma, normal x- rays; required resolution of pain with injection 8mL 0.5% bupivacaine prior to enrollment	Injection of methylprednisolone 40mg plus 2mL 0.5% bupivacaine vs. bupivacaine alone (dose/volume unclear) Both prescribed exercises; 12 weeks follow-up.	VAS pain scores not different at 3,6,12 weeks. Mean pain scores at 12 weeks both 1.38. No differences in shoulder abduction at 3, 6, 12 weeks.	"Single subacromial injection of methylprednisolon e has no beneficial impact on reducing the pain, or the duration of immobility in patients with persistent post- traumatic impingement of the shoulder."	Acute traumatic pain patients. Results suggest injection unhelpful for acute trauma- related shoulder pain.
Akgün 2004 RCT	5.5	N = 48 Stage 2 impingemen t and mostly chronic shoulder pain	Two injections 10 days apart of methylprednisolone 40mg plus lignocaine 1% 10mL (steroid) vs. steroid for 1st injection and lignocaine 1% 10mL (anesthetic) for second vs. 3) anesthetic for both injections. All treated with naproxen 500mg BID, rest, Codman's pendulum exercises for 15 days and HEP; 3 months follow-up.	Rest pain (baseline/1 month/3 months): Group 1 ( $4.3\pm1.6/0.5\pm0.4/$ $0.8\pm0.6$ ) vs. 2 ( $4.3\pm1.7/1.0\pm0.8/1.3\pm$ $0.9$ ) vs. 3 ( $3.8\pm1.2/1.0\pm$ $0.9/0.7\pm0.6$ ) (NS between groups). Pain disturbing sleep superior at 1 month in 2 injection group vs. 1 or none (p < $0.05$ ). Constant scores: Group 1 ( $63.6/87.8/91.6$ ) vs. 2 ( $65.6/84.1/89.8$ ) vs. 3 ( $65.5/92.1/91.6$ ).	"[S]ubacromial corticosteroid injections in the acute or subacute phase of SIS provided additional short- term benefit without any complication when used together with nonsteroidal anti- inflammatory drugs (NSAIDs) and exercise."	Baseline differences in symptom duration with longer duration in 2 injection vs. 1 vs. 0 (all placebo). Data suggest no to modest benefits depending on outcomes assessed.
Withrington 1985 RCT	5.5	N = 25 supraspinat us tendinitis, presumably subacute and chronic symptoms	Methylprednisolone 80mg in 2mL 2% lignocaine vs. 4mL saline. Lateral approaches; 8 weeks follow-up.	7/12 (58.3%) steroid patients responded at 2 weeks; 2 relapsed at 8 weeks (41.7% success at 8 weeks). In control group, 4/13 (30.8%) responded at 2 weeks and 1 relapsed (23.1% success at 8 weeks).	"This trial cases further doubt on the efficacy of such treatment in soft tissue lesions around the shoulder."	Small sample size. Sparse description of patients or methods. Mean age 61.3 years. Underpowered; results trended towards efficacy.
Vecchio 1993 RCT	5.0	N = 55 rotator cuff tendinitis of up to 12 weeks duration	Methylprednisolone 40mg plus lignocaine 1% 1mL vs. lignocaine 1% 1mL. Anterolateral approaches; 12 weeks follow-up	No differences in VAS pain scale at 2,4,12 weeks. No differences in range of motion or total resisted movement scores.	"[S]ubacromial steroid methylprednisolo ne and lignocaine is no better than lignocaine alone in treatment of early RCT."	Trends toward higher rates of injury, overuse, strain, more manual work in steroid group may have biased towards null. Blinding methods not specified.
Plafki 2000 RCT	4.5	N = 50 >3months impingemen t pain refractory to long-term conservativ e treatment	Ultrasound-guided injections of: 1) bupivacaine 0.5% 10mL vs. 2) triamcinolone acetonide 10mg plus bupivacaine 0.5% 10mL vs. 3) dexamethasone-21- palmitat 4mg (`2.5mg	Pain relief lasting >1 week in 3 of each steroid Group; 5/20 (25%) in Group 2; 2/20 (10%) in Group 3 relief between 1 and 6 weeks. Excellent relief at 26 weeks in 8/20 (40%) Group 2 vs. 11/20 (55%) Group 3 (Group 1 not stated). Score	"This study supports the efficacy and importance of subacromial steroid injections for patients with chronic refractory impingement syndrome. Short- term results	Placebo control arm stopped early due to lack of efficacy compared with other arms. Detailed results on placebo group not provided. Limited results reported.

Chavez- Lopez	<b>Sh</b> 6.5	oulder Tending N = 24 subacromial	dexamethasone) plus bupivacaine 0.5% 10mL. All treated with exercises; 26 weeks follow-up. <b>pathies: Glucocortico</b> Ultrasound-guided injections of	evaluation at 26 weeks showed a mean result of 83% within Group 2 (n = 16); 81% within Group 3 (n = 16); 8 patients had surgery. Did Injection vs. Glucocort Mean pain relief 61% at 2 weeks in both groups.	indicate that surgery may be prevented in at least half of them." icosteroid Injection "Patients with painful shoulder	Approximately 50% of subjects
2009 RCT		bursitis, partial or full- thickness rotator cuff tears on ultrasound; symptoms averaged 6 months	methylprednisolone acetate 40mg vs. triamcinolone 40mg; 2 months follow-up	Range of motion improved 33% both groups.	receiving an ultrasound-guided injection of MTP or TMC have a rapid and sustained overall response. Relief of pain tends to be more rapid with MTP than TMC."	with comorbidities (e.g., RA, OA). Short term follow- up. Some details sparse. Data suggest equivalency.
Karthikeyan 2010 RCT	8.5	N = 58 subjects diagnosed with subacromial impingemen t symptoms ≥3 months, and have undergone conservativ e therapy.	Single injection of 20mg tenoxicam + 5ml 1% lignocaine (n = 31) vs. 40mg methylprednisolone + 5ml 1% lignocaine (n = 27). Final follow-up at week 6.	Differences between groups for disability of the arm, shoulder, and hand scores/Oxford shoulder score measured at 2, 4, and 6 weeks: p <0.001/p <0.001, p <0.001/p = 0.003, p = 0.02, p = 0.055.	"[A] single subacromial injection of 20 mg tenoxicam does not have the same efficacy as corticosteroid injection for disease of the rotator cuff, the effect may be small and short- lived and no better than NSAIDs."	Data suggest glucocorticosteroi d superior to tenoxicam over 5 weeks.
Min 2013 RCT	8.0	N = 48 patients with diagnosed with external shoulder impingemen t syndrome.	NSAID group (n = 17), mean age 39.6 years, received a 6cc injection of 1% lidocaine with epinephrine and 60mg ketorolac vs. steroid group (n = 15), mean age 39.1 years, received a 6cc injection of 1% lidocaine with epinephrine and 40mg triamcinolone.	Assessments were performed just prior to injection, approximately 5 minutes after, and at a 4-week visit. The NSAID group had a change in UCLA should rating scale of 7.15 from pre- injection to week 4 (p = 0.03). Steroid group UCLA change was 2.13. Change in VAS scores from follow-up were 1.83 and 0.90 for NSAID and Steroid groups respectively, but were not statistically significant (p = 0.225). Pre-injection active abduction averages were 129° and 137° for NSAID and Steroid respectively. At week 4, the average for NSAID increased to 151° and steroid decreased to 134° (p = 0.03).	"[A]n injection of ketorolac resulted in greater improvements in the UCLA shoulder rating scale than an injection of triamcinolone at 4 weeks follow-up."	Significant number of participants were were excluded from analyses due to rotator cuff tear diagnosed post-treatment. Data suggest NSAID superior to corticosteroid for active abduction. High loss to follow-up for both groups over 4 week follow-up period.

		Shoul	der Tendinopathies: (	Sucocorticoid Injection ve	s. NSAID	
Adebajo	8.0	See above				
1990 Petri	7.5	See above				
1987						
White 1986 RCT	6.0	N = 40 acute rotator cuff tendinitis less than 12 weeks duration; no patients with adhesive capsulitis	Triamcinolone acetonide 40mg subacromial injection vs. indomethacin 25mg QID. Double dummy (saline injections). All treated with home exercises. Re- injected at 3 weeks if more than minimal symptoms.	Global assessment scores (baseline/final): indomethacin 6.4±1.6/3.6±3.1 vs. injection 6.5±1.1/3.6±2.6 (NS). ROM also comparable.	"[T]here is essentially no difference in the short term efficacy of oral nonsteroidal therapy compared to local corticosteroid injection(s) in the treatment of rotator cuff tendinitis."	Patients with acute and subacute tendinitis. Data suggest comparable efficacy.
<u>Electron</u>	<b>Shoι</b> 7.0	N = 106		Blucocorticosteroid vs. Int		
Ekeberg 2009 RCT	7.0	n = 100 chronic rotator cuff- related pain with >3months duration.	Triamcinolone 20mg plus lidocaine 5mL subacromial injection (7mL total) plus lidocaine intramuscular injection vs. triamcinolone 20mg plus lidocaine intramuscular plus lidocaine subacromial injection. Ultrasound-guided injections; 6-weeks	Shoulder pain and disability index (baseline/2 weeks/6 weeks): Local group (53 $\pm$ 18/32 $\pm$ 25/29 $\pm$ 21) vs. systemic (51 $\pm$ 17/28 $\pm$ 23/32 $\pm$ 23) (p = 0.32). Western Ontario rotator cuff index (67 vs. 60, p = 0.32) and change in main complaint (6.0 vs. 2.0, p = 0.009) favored local steroid injection.	"No important differences in short term outcomes were found between local ultrasound guided corticosteroid injection and systemic corticosteroid injection in rotator cuff disease."	No placebo control. Both groups improved. Patients not well described. Data suggest subacromial injection superior or trends to superior depending on outcome evaluated.
	Shou	Ider Tendinon:	follow-up.	Injections: Comparison of	Different Approach	06
Kang 2008 RCT	7.5	N = 60 shoulders in 58 patients; subacute and chronic pain with symptoms for at least 2 months	Anterolateral vs. lateral vs. posterior approaches of 1 to 3 injections. All depomedrol 80mg plus 2mL 0.25% bupivacaine plus omnipaque. All treated with physical therapy (active, active-assisted, passive ROM and RC strengthening plus naproxen.	Overall accuracy anterolateral 15/20 (75%) vs. posterior 15/20 (75%) vs. lateral 12/20 (60%) ( $p = 0.49$ ). Neer impingement signs used for assessments; 90% with accurate injection had immediate relief post-injection vs. 56% with inaccurate injection ( $p = 0.009$ ). Mean VAS pain pre- injection/post/3 months: 7.2/ 3.31/3.43 ( $p$ <0.001). UCLA scores increased 26.2/27.6/ 32.2 ( $p$ <0.001).	"[T]he accuracy of injection was 70%. Clinical improvement did not correlate with accuracy; however, accuracy did reliably produce a positive impingement test [sic?]. This multimodal treatment plan did produce significant improvement in shoulder function and pain level in	No placebo control. No differences with increased BMI up to cutpoint of 29kg/m <sup>2</sup> . Data suggest comparable efficacy.
Marder 2012 RCT	6.5	N = 75 patients, mean age 54 years, with overhead shoulder pain during	Posterior Route (PR) group (n = 25) received an injection immediately inferior and medial to the posterolateral corner of the acromion, with the	Accuracy of injection varied significantly among three groups (p = 0.006): PR – 56% success rate AR – 84% success rate LR – 92% success rate Compared with PR,	the short term." "In conclusion, our data support subacromial injection in the office setting with use of either the anterior or lateral route."	Short follow-up time. Accuracy as primary outcome, with VAS as secondary outcome. Data suggest lateral

	activity, night pain,	needle being angled cephalad along the	injection accuracy was 1.6 times greater for LR		andanterior more accurate than
	and a positive impingemen t	undersurface of the acromion toward the anterior edge of the acromion vs. Anterior Route (AR) group (n = 25) received an injection immediately inferior to the anterior edge of the acromion, starting at the depression immediately lateral to the acromioclavicular joint and with the needle being aimed cephalad and slightly lateral vs. Lateral Route (LR) group (n = 25) received an injection just inferior to the midlateral aspect of the acromion, with the needle being angled slightly cephalad.	(p = 0.008) and 1.5 times greater for AR (p = 0.04). For successful (intrabursal) injections, 33% of patients reported complete pain relief (VAS = 0) within 1 hour post-injection. Zero unsuccessful (extrabursal) injections reported complete pain relief. Mean improvement in VAS for Intrabursal was 5, compared to Extrabursal of 3, the difference being significant (p <0.001).		posterior.
		All three groups received a subacromial injection with 5mL of 1% lidocaine, 2mL of iopamidol injection contrast medium, and 1mL (40mg) of triamcinolone.			
Henkus 5.5 2006 RCT	N = 33 impingemen t syndrome; pain duration unclear	All shoulders injected 40mg methylprednisolone plus 4mL 0.25% bupivacaine plus gadolinium-DTPA. Randomized posterior vs. anteromedial approach for injections; 1 day follow-up.	Accuracy 69% with anteromedial approach vs. 76% with posterior approach. Successful injection of bursa resulted in reduced pain ( $p = 0.004$ ), but injection of rotator cuff increased pain ( $p = 0.032$ ). No effect of BMI on accuracy, although mean BMIs 26-27kg/m <sup>2</sup> .	"Injections in the (subacromial bursa) are inaccurate, despite the confident feeling of the clinician."	Differences in Constant scores at baseline; 1- day follow-up. No outcomes reported. Slight, NS trend toward improved accuracy with posterior approach. Data document majority are given accurately based on data provided.

	Sho	ulder Tendinor	athies Glucocorticoid	I Injections: Blind vs. Imag	jing During Injection	ns
De Witte 2013 RCT	8.0	N = 48 patients with calcific tendinitis of the rotator cuff (RCCT)	Ultrasound guided barbotage and injection with corticosteroids, subacromial bursa, 5mL of bupivacaine and 1mL of DepoMedrol (n = 23) vs. ultrasound guided injection with corticosteroids, subacromial bursa (n = 25) 100mg celecoxib 2 times a day for 3 days, 1000mg paracetamol, 4 times a day. Follow- up: baseline, 6 weeks, 3 months; and 1 year.	Mean (95% CI) for constant shoulder score at 1 year: difference between groups: 12.1 (3.9 to 20.2), p = 0.005.	"On average, there was improvement at 1-year follow-up in both treatment groups, but clinical and radiographic results were significantly better in the barbotage group."	Minimal differences between groups with any constant shoulder score showing meangful difference in Barbotage group.
Ucuncu 2009 RCT	7.5	N = 60 consecutive patients with shoulder pain due to soft tissue disorders	Triamcinolone 40mg injection either Landmark-guided (LMG) (n = 30) or ultrasonography guided (USG). Evaluated 0 and 6 weeks.	At 6-week evaluation: VAS USG 4.0+/-1.7 vs LMG 2.2+/10.9 (p <0.05). Constant scale for function USG 32.2 vs LMG 12.2 (p <0.05). Significant number of USG vs LMG with limited ROM initially regained normal ROM at 6 weeks.	"Injection of corticosteroids to patients with shoulder pain due to soft tissue disorders under the USG- guidance may improve therapeutic effectiveness and reduce adverse effects."	Excluded patients who had PT or corticosteroid injections, no PT during follow-up. Heterogenous shoulder diagnoses accepted: Acromioclavicular degeneration, rotator cuff lesions (rupture, partial rupture, tendinosis, impingement, calcification) fluid accumulation in biceps tendon, partial rupture in biceps tendon and bursitis (subdeltoid, subacromial)
Naredo 2004 RCT	6.5	N = 41 painful shoulder, including impingement , rotator cuff lesions, subacromial bursitis and/or biceps tendon abnormalities	All injected with triamcinolone 20mg. Blind vs. Sonographic-guided injections. Subacute and chronic patients, having failed at least 1 month including NSAID; 6-week follow-up.	Decrease in VAS score: blind 7.1 $\pm$ 8.2 vs. sonographic 34.9 $\pm$ 21.3, p <0.001. Increases in SFA were: blind 5.6 $\pm$ 7.7 vs. 15 $\pm$ 13.9, p <0.05.	"We suggest that sonographic- guided corticosteroid injections should be indicated, at least, in patients with poor response to previous blind injection to ensure accurate medication placement in order to improve therapeutic effectiveness."	Trial used different techniques with imaging based on ultrasound findings (e.g., directing needle towards bicipital tendon). Some non-significant differences in baseline job demands higher in blind group (high 25% vs. 5%). No long- term outcomes.

						Data suggest ultrasound imaging helpful.
Dogu 2012 RCT	5.0	N = 46 patients with subacromial impingemen t syndrome with shoulder pain for at least 3 months	Ultrasound guided subacromial injections (n = 23) vs. blind corticosteroid injections (n = 23). Injection fluid: 1.5 ml of 5 mg.ml beta- methadone dipropionate, 9ml of 10mg/ml prilocaine hydrochloride and 0.0 ml or 0.01mmol gadolinium diethylenetriaminep entaacetic acid. Follow-up: baseline, 6 weeks.	No statistically significant differences to report between the two groups.	"[B]lind injections given in the subacromial region were as reliable as US- guided injection accuracy and could therefore be used in daily routines. Injection performed with US guidance require experience and may be a useful alternative in difficult cases such as in patients with postoperative anatomical changes."	No difference between treatment groups for any outcome.
Hollingworth 1983 RCT (with partial crossover)	<u>Sh</u> 4.5	oulder Tendino N = 77 capsulitis (n = 25), tendinitis (n = 45), bursitis (n = 11), AC joint "strain" [sic]; mean symptom duration 8.5 months	Pathies Glucocortico Tender or trigger point injection (methylprednisolone acetate 2mL, 40mg plus 1% lignocaine) vs. anatomical injection (e.g., for tendinitis, placement "around, deep, and superficial to the tendon"; 8 weeks follow-up.	id Injections: Trigger vs. 1 Success for functional bursal/tendinitis injection 73% vs. 29%, p <0.001). Adhesive capsulitis success 0% with tender point vs. 6/23 (26.1%) functional.		Data presented by number of injections resulting in difficulty interpreting per patient results. Cross-over for treatment failures. Data suggest targeting presumptive anatomic source of pain rather than most tender point. Exact location of injections unclear based on description (e.g., unclear if attempted RC injections in glenohumeral space +/- bursal).

	Ŧ	Shoulder Te	ndinopathies Glucoco	rticoid Injections: Combir		
Hay 2003 RCT	7.5	N=207 subjects with new episodes of unilateral shoulder pain.	40mg methylprednisolone + 4ml 1% lidocaine injection in the subcromial space (n = 104) vs. physiotherapy (n = 103) Physiotherapy	Physiotherapy vs. injection patients's global assessment, no (%), in overall change from baseline-6 weeks for the shoulder being completely recoverd, some improvement no	"[S]ubacromial injection with methylprednisolo ne and primary care physiotherapy were similarly effective at each	Pragmatic design with physical therapy individualized. Data suggest comparable results.
			consisted of eight 20-minute sessions in a 6-week period. Final follow-up at 6 months.	change, and much worse: $6(6)/18(19)$ , 71(72)/51(54), 14(14)/16(17), $6(6)/8(8)$ , 1(1)/2(2). At 6 months: 23(24)/17(18), 59(61)/63(65), $7(7)/6(6)$ , 7(7)/10(10), $0/1(1)$ . Physiotherapy/injection/ difference(95% CI) no.(%) of subjects achieving at least 50% drop in disability score at 6 weeks and 6 months: 30(30)/35(36)/-5.4%(-18.2 to 7.6), 59(60)/51(53)/7.0%(-6.8 to 20.4). Mean±SD improvement in disability score from baseline at 6 weeks and 6 months: $2.56\pm5.4/3.03\pm6.3/-0.5$ (- 2.1 to 1.2), $5.97\pm5.4/4.55\pm5.9/1.4$ (- 0.2 to 3.0).	outcome point, but those receiving physiotherapy had fewer reconsultations with their general practitioners for additional treatment during the follow up period."	
Crawshaw 2010 RCT	6.0	N = 232 participants age 40 or older with unilateral shoulder pain, subjectively rate their pain as moderate or severe on a 3 point scale (mild/modera te/severe), and have non- capsular pattern of restriction	Subacromial corticosteroid injections combined with exercise and manual therapy (n = 115) vs. exercise plus manual therapy (n = 117); 24-week follow-up.	Change in mean scores on shoulder pain and disability index over time. Week 1 Exercise only: Total -1.53 (-3.11 to 0.056), Injection plus exercise -8.08 (-9.69 to - 6.47); Difference (95% CI) $6.56$ (4.30 to $8.82$ ), p-value < 0.001. Week 6 Exercise only: Total - $6.88$ (- $8.99$ to - $4.76$ ), Injection plus exercise - $14.24$ (- $16.40$ to - 12.09), Difference (95% CI) 7.37 (4.34 to 10.39), p-value < 0.001. At Week 12, no significant difference between groups in change in total pain and disability index (mean difference between change in groups 3.26 (95% confidence interval -0.81 to 7.34), p = 0.116). Improvement significantly greater in injection plus exercise group at Week 1 ( $6.56$ ,	"In the treatment of patients with subacromial impingement syndrome, injection plus exercise and exercise only are similarly effective at 12 weeks."	Pragmatic individualized with 23 exercise and 6 mobilization. 1, 2, 12, 24 weeks follow up with low dose TA. Suggests short but not long term benefit and would be very difficult to duplicate due to individualized combinations.

Cloke 2008 RCT	5.0	N = 112 subjects with <6 months of painful arc/subacro mial impingemen t.	40mg methylprednisolone + 10 ml 1% lidocaine into the subacromial space (3 injections at 6 week intervals, n = 28) vs. exercise + manual therapy package (EMTP, 6 sessions during 18 weeks, n = 29) vs. both interventions combined (n = 28) vs. NSAID control (n = 27). All subjects underwent a clinical review at 6, 12, and 18 weeks. Final follow-up at 12 months.	4.30 to 8.82) and Week 6 (7.37, 4.34 to 10.39) for total pain and disability index (p < 0.001), with no differences at Week 24 (-2.26, -6.77 to 2.25, p = 0.324). There was a significant difference from 18 weeks-12 months in the combined intervention group using the Medical Outcomes Study Short Form 36 (SF-36) Health Survey, p=0.029. There was a significant difference at baseline for Oxford Shoulder score, p<0.001.	"No significant differences were found within groups between the OSS scores or the Physical Health total of the Medical Outcomes Study Short Form 36 (SF-36) Health Survey at the beginning and end of the trial or at 1 year."	Pilot study. Only 2 follow-ups. Patients not well described. Data suggest no differences and full RCT would require sample size of 800 to detect differences.
Penning 2012 RCT	10.5	N = 159 with a painful arc, with or without abnormal scapulohum eral movement.	Hyaluronic acid injections administered via a dorsolateral approach (n = 51) vs. Corticosteroid injections administered via a dorsolateral approach (n = 53) vs. NaCl injections administered via a dorsolateral approach (n = 55). Follow-up for 26 weeks.	Hyaluronate vs. CorticosAt weeks 3: $p = 0.004$ , 6 $p < 0.001$ and 12 $p <$ $0.001$ , the differencebetween Group A and Bwas significantly in favorof corticosteroids.The mean reduction inpain at 12 weeks was7% ( $p = 0.084$ ) in GroupA, 28% ( $p < 0.001$ ) inGroup B and 23% ( $p <$ 0.001) in Group C.The mean reduction inpain at 26 weeks was15% ( $p = 0.002$ ) inGroup A, 20% ( $p =$ 0.001) in Group B, and21% ( $p < 0.001$ ) inGroup C.	"Corticosteroid injections produced a significant reduction in pain in the short term (three to 12 weeks), but in the long term the placebo injection produced the best results."	No significant differences at 26 weeks at which time placebo and corticosteroid both trending better than Hyaluronic for most outcomes with placebo group showing best mean improvement in pain and functional mobility.
Rabini 2012 RCT	7.5	Sho N = 92 with shoulder pain lasting for at least 3 months.	ulder tendinopathies: Group 1 corticosteroid injections (n = 46) vs. Group 2 (microwave diathermy) or hyperthermia (n = 46). Follow-up for 24 weeks.	Hyperthermia vs. Corticos A significant overall time effect was determined in both treatment arms, $F =$ 5.39, p = 0.006 with no significant time-by group interaction, F = 2.25, p = 0.112. Both treatment groups experienced improvements in disability, shoulder	steroid "The effect of adalimumab on frozen shoulder has not previously been examined."	Both treatments improved with minimal difference between groups at any time point. Only statistically significant difference between groups was at week 12 for VAS outcome.

				function, and pain compared with baseline, and no differences over time between interventions.		Data suggest no difference between groups.
		Sho	ulder tendinopathies:	Acupuncture vs. Corticos	steroid	
Johansson 2011 RCT	4.5	N = 123 participants with subacromial impingemen t syndrome (SIS) and pain for longer than 2 months, diagnosed by a research PT using the Neer impingemen t sign and test.	Corticosteroid group (n = 65) (mean age of 50 ± 9) received an injection of methylprednisolone + prilocaine. If pain pursued they were allowed to ask for a second injection. vs. Acupuncture Group (n = 58; mean age of 51 ± 9) received needling treatment bi-weekly for 5 weeks and put on a home exercise program first targeting motion restoration then rotator cuff strengthening. Both groups were assessed with the Adolfsson-Lysholm shoulder assessment score for pain and disability at baseline, 6 weeks, 3, 6, and 12 months.	91 participants were included in the analysis of efficacy (6 were lost in $1^{st}$ two week due to frozen shoulder and 26 were lost in follow-up). No significant difference was found in pain and shoulder function measured by AL-score and HRQL (including EQ-5D and EQ-VAS) between groups (no p value reported). Both treatment groups showed significant improvement over time (p <0.001). At 6 months, patients reported recovery or larger improvements in the acupuncture group (p = 0.048). But at 12 months, no significant difference was found between treatments (p = 0.16).	Both subacromial corticosteroid injection and a series of acupuncture treatments combined with home exercises significantly decreased pain and improved shoulder function in patients with SIS, but neither treatment group showed a significantly difference when compared to the other.	Analysis was also done using 99 participants (to include the 8 participants that switched treatment groups) and the same results were found. Only demographic was presented for participating who completed the study. No meaningful differences between treatment arms.
		R	otator Cuff Tear: Intra	-articular Injection vs. Cor	ntrol	
Gialanella 2011 RCT	4.0	N = 60 with rotator cuff tears (RCT)	Group TA1: single intra-articular injection, 40mg triamcinolone acetonide (TA) (n = 20) vs. Group TA2: two injections of 40mg TA (first after baseline evaluations, second 21 days after) (n = 20) vs. control group: no treatment (n = 20). Follow-up: baseline, 1, 3 and 6 months.	Mean $\pm$ SD for VAS: Rest Pain: 1 month: Group TA1 vs. baseline: 0.5 $\pm$ 1.1, p <0.05; 3 months: 0.0 $\pm$ 1.2, p < 0.05. Activity Pain: Group TA1 vs. Group TA2: 1 month: 3.8 $\pm$ 1.8 vs. 3.9 $\pm$ 1.7, p < 0.001; 3 months: 3.7 $\pm$ 1.8 vs. 4.0 $\pm$ 1.8, p <0.001; 6 months: 5.4 $\pm$ 1.9 vs. 5.4 $\pm$ 2.0, p <0.001. Pain at Night: Group TA1 vs. Group TA2: 1 month: 2.1 $\pm$ 2.1 vs. 1.8 $\pm$ 2.2, p < 0.001; 3 months: 2.7 $\pm$ 1.9 vs. 1.9 $\pm$ 2.4, p < 0.001; 6 months: 3.5 $\pm$ 2.2 vs. 2.9 $\pm$ 2.8, p <0.001.	"Our study indicates that intraarticular injection of triamcinolone improves pain relief for 3 months in RCT and its action is not prolonged or potentiated by two injections of the drug done at 21-day intervals."	Methodological details sparse. Both active treatment groups improved over time and data suggest injections more efficacious than no treatment arm.
		i	Rotator Cuff Tear: Intra	a-articular Injection vs. TE	NS	
Eyigor 2010 RCT	5.0	N = 40 patients aged 18-80 years with	Intra-articular corticosteroid injection of 0.5cc triamcinolone	Mean±SD for VAS at night (pre-treatment/1 week/4 week/12 week): Group I	"[C]onventional TENS and intra- articular injection of corticosteroid	Data suggest intra-articular steroid injections superior to

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	shoulder pain for at	(40mg/ml), 3.5 cc bupivacaine	(5.9±1.9/2.1±2.0/1.7±1.2 /1.2±0.9) vs. Group II	are efficient applications in	TENS, although both treatments
	least 3	(5mg/ml), and 3cc	(5.8±1.4/4.2±1.8/2.7±1.6	terms of pain,	demonstrated
	months with	serum physiologic	/2.0±0.9), p <0.05 in	ROM, disability,	improvement.
	rotator cuff	into the	favor of Group I at	and quality of life	
	pathology.	acromioclavicular	weeks 1, 4 and 12.	in the treatment	
	P	joint (Group I, N=20)	Mean±SD for VAS at	of rotator cuff	
		vs. conventional	rest (pre-treatment/1	tendinitis."	
		TENS on the	week/4 week/12 week):		
		anterior and	Group I		
		posterior parts of	(3.7±1.3/1.5±1.0/0.6±0.4		
		the joint, 30 minutes	/0.2±0.4) vs. Group II		
		5 times/week for 15	(3.6±1.7/2.3±1.2/1.8±1.5		
		sessions with a	/1.0±0.7), p<0.05 in		
		mean frequency of	favor of Group I at in		
		100 Hz, 15 mA	weeks 1, 4 and 12.		
		amplitude, 150 µsn	Mean±SD for VAS		
		(Group II, N=20).	during movement (pre-		
			treatment/1 week/4		
		Both groups	week/12 week): Group I		
		performed ROM	$(7.1\pm1.4/3.5\pm1.4/1.9\pm1.2)$		
		exercises,	/1.2±0.7) vs. Group II		
		strengthening	$(7.5\pm1.2/4.5\pm1.0/2.6\pm1.6)$		
		exercises, Codman	/2.1±1.3), p<0.05 in		
		exercises, pulley	favor of Group I for weeks 1 and 12.		
		exercises, and finger ladder	Mean±SD for ROM		
		exercises.	passive abduction (pre-		
		0701010000	treatment/1 week/4		
		Patients were asked	week/12 week): Group I		
		to avoid use of	(136.5±23.0/161.3±22.4/		
		NSAIDs before and	174.1±12.3/177.5±7.0)		
		during the study	vs. Group II		
		period, patients	(146.8±21.4/153.8±15.9/		
		could take a	172.8±9.2/177.3±6.0), p		
		maximum of 4g of	<0.05 in favor of Group I		
		paracetamol/day.	at week 1. Mean±SD for		
			ROM active internal		
		Follow-up at 1, 4,	rotation (IR) movement		
		and 12 weeks	(pre-treatment/1 week/4		
			week/12 week): Group I		
			(45.0±19.8/59.0±14.8/66		
			.7±14.2/68.6±7.9) vs.		
			Group II		
			(39.4±14.2/48.3±13.3/63 .0±11.3/68.4±11.8),		
			p<0.05 in favor of Group		
			I at week 1. Mean±SD		
			for ROM passive IR		
			(pre-treatment/1 week/4		
			week/12 week): Group I		
			(57.9±20.0/69.8±12.5/76		
			.7±8.4/77.8±4.6) vs.		
			Group II		
			(55.0±14.8/60.8±11.5/72		
			.8±6.0/77.0±4.4), p		
			<0.05 in favor of Group I		
			at week 1. Mean±SD		
			Shoulder Disability		
			Questionnaire (SDQ)		
			scores (pre-treatment/1		
			week/4 week/12 week):		
			Group I		
			(80.7±12.9/37.9±22.6/22 .1±15.9/13.7±11.5) vs.		
L I			.1110.0/10.1111.0/ VS.		

	Group II ( $82.3\pm9.9/67.6\pm15.9/42$ . $5\pm14.7/28.5\pm13.2$ ), p<0.05 in favor of Group I at week 1. Mean $\pm$ SD paracetamol consumption (1 week/2 week/3 week/4 week): Group I ( $4.40\pm4.64/3.65\pm4.04/2$ . $67\pm3.02/2.00\pm2.38$ ) vs. Group II ( $6.65\pm3.22/6.10\pm4.24/4$ . $82\pm3.43/4.35\pm3.26$ ), p<0.05 at weeks 3 and 4.	
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## SUBACROMIAL EDTA MESOTHERAPY

Calcium disodium EDTA is a powerful chelator traditionally used to treat lead poisoning, although it also chelates other divalent cations. Subacromial EDTA injections and mesotherapy have been used to treat calcific tendinitis that has been unresponsive to other treatments. (Cacchio 09)

Recommendation: Subacromial EDTA Mesotherapy Injections for Shoulder Calcific Tendinitis There is no recommendation for or against the use of subacromial EDTA mesotherapy for treatment of shoulder calcific tendinitis.

## Strength of Evidence - No Recommendation, Insufficient Evidence (I)

## Rationale for Recommendation

There is one moderate-quality trial comparing EDTA plus ultrasound versus placebo plus sham ultrasound suggesting reductions in all measures including pain, motion, Constant Murley scores, and calcifications. (Cacchio 09) Thus, there is evidence suggesting potential efficacy of EDTA instilled for calcific tendinitis with duration of improvement documented at 1 year. EDTA has some risk of serious renal effects though there was no increase in serum creatinine and BUN in this trial. The treatments are high cost, invasive, and require multiple treatments; there is no recommendation for this treatment.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			EDT	TA Chelation		
Cacchio 2009 RCT	7.0	N = 80 calcific tendinitis (Type I or II) at least 6 months symptoms with failure of NSAIDs, ultrasound, exercises, laser therapy, acupuncture and steroid injection (unclear how many/which treatments at baseline)	Disodium EDTA "1mL" (dose not specified) plus 1mL 1% procaine plus 3mL injectable water weekly mesotherapy 3 weeks vs. placebo (procaine plus injectable water). Ultrasound vs. sham ultrasound 1MHz, 2.5 W/cm <sup>2</sup> , pulse mode 1:4; ultrasound 5 times a week for 3 weeks.	Total Constant Murley scores (pre/post/1yr): EDTA ( $47.68\pm5.79$ / $75.62\pm3.96/75.50\pm4.0$ 7) vs. Sham ( $46.57\pm6.94$ / $45.85\pm6.25/46.42\pm8.5$ 2), p <0.01 both post and 1 year. CMS sub- scores (pain, motion, power, activity) all p <0.01. VAS pain also p <0.01 (at 1 year, 2.0\pm1.3 vs. 7.01\pm0.30. Calcification sizes (pre/post): EDTA ( $18.5\pm1.57/3.16\pm3.28$ ) vs. sham ( $17.85\pm1.19$ / $16.92\pm4.03$ ), p <0.01.	"[T]he use of disodium EDTA for the management of calcific tendinitis of the shoulder is safe and effective, leading to a significant reduction in pain, improvement in shoulder function, and disappearance of calcifications after 4 weeks, without adverse effects."	Blinding procedures not well described. Combination of 2 interventions precludes assessment of effect of one, but ultrasound not believed to have major efficacy. Creatinine levels did not increase, but sample size may be too small to adequately assess renal risks with procedure. Data suggest EDTA successful at

Evidence for the Use of Subacromial EDTA Mesotherapy Injections

There is 1 moderate-quality RCT incorporated into this analysis.

## VISCOSUPPLEMENTATION INJECTIONS

Viscosupplementation injections have been used for treatment of impingement syndrome. (Sengul 08)

Recommendation: Subacromial Viscosupplementation Injections for Rotator Cuff Tendinopathies There is no recommendation for or against the use of subacromial viscosupplementation injections for the treatment of chronic rotator cuff tendinopathies (including rotator cuff tendinoses, supraspinatus tendinitis, impingement syndrome, and subacromial bursitis).

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials. There is one low-quality trial without a placebo-control suggesting few differences between hyaluronate injections and local modalities. (Sengul 08) Thus, there is no recommendation for or against these injections for rotator cuff tendinopathies.

Evidence for the Use of Viscosupplementation Injections for Impingement Syndrome There are 2 low-quality RCTs Appendix 2. (Kim 12; Sengul 08)

## NEEDLING AND BURSOSCOPY

Needling of calcium deposits and bursoscopy for removal of calcific tendinitis has been performed. (Albert 07; Farin 1996; Krasny 05; Maugars 09) Needling is a precise procedure used to treat calcific deposits. It makes small needle sized holes in the tissue overlying the calcific deposit. Needling has been studied in conjunction with shockwave therapy, (Krasny 05) and involves "several tens of intra-calcic drillings in the axis of calcification" needling of the calcific deposits. (Maugars 09) Bursoscopy is arthroscopic removal/excision of the bursa.

1. Recommendation: Needling with or without Extracorporeal Shockwave Therapy for Calcific Rotator Cuff Tendinitis

There is no recommendation for or against the use of needling with or without extracorporeal shockwave therapy for treatment of calcific rotator cuff tendinitis.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

 Recommendation: Bursoscopy for Calcific Rotator Cuff Tendinitis Bursoscopy (arthroscopic removal/excision of bursa) is recommended for treatment of calcific rotator cuff tendinitis.

*Indications* – Gartner Type I or II calcium deposits of calcific tendinitis. (Maugars 09) Patients should generally have failed prior treatment with NSAIDs, exercise, and injection(s). (Maugars 09)

*Frequency/Duration* – Treatment in the quality trial is a single treatment. It may be reasonable to attempt a second treatment if the initial treatment was partially, but inadequately effective.

Indications for Discontinuation - Resolution or intolerance.

### Strength of Evidence – Recommended, Evidence (C)

#### Rationale for Recommendations

There is one moderate-quality trial suggesting needling or bursoscopy is superior to a non-interventional control. Another moderate-quality trial suggested adding needling is effective when used as an adjunct with shockwave therapy. (Krasny 05) Needling a calcific deposit is minimally invasive and less costly than surgery with minimal adverse effects. Nevertheless, there is insufficient evidence to support a recommendation of needling compared to arthroscopic surgery. Additional quality trials appear necessary prior to recommending its widespread use. Bursal arthroscopic removal/excision is more invasive, but is selective in its ability to remove tissue, has evidence of efficacy, and thus is recommended.

#### Evidence for Needling and Bursoscopy There are 2 moderate-quality RCTs incorporated into this analysis

Author/Titl	Score	Sample	CTs incorporated i	Results	Conclusion	Comments
e Study Type	(0-11)	Size	Group			
			Calcific Tendinitis: ES	WT with vs. without Ne	edling	
Krasny 2005 RCT	6.0	N = 80 Gartner I or II calcific tendinitis and symptoms averaging 30-36 months scheduled for arthroscopi c calcium removal in 6 months	ESWT (200 low energy impulses, then 2500 impulses at 0.36mJ/mm <sup>2</sup> ) with prior ultrasound- guided needling (repeated, 18g needle) vs. ESWT without needling. Treatments not repeated. Variable follow-up, mean 4.1 months.	Improvement in ESWT needling 30/40 (75%) vs. 24/40 (60%), p = 0.25. Total constant scores (pre/post): ESWT needling $(46.3\pm12.7/$ $76.8\pm20.4)$ vs. ESWT $(44.2\pm11.9/67.3\pm20.7)$ ). Patients reaching 75 constant points 62.5% vs. $32.5%$ , p = 0.021. Disappearance of calcific deposits in 60% vs. $32.5%$ , p < $0.05$ .	"Ultrasound-guided needling in combination with high-energy shock- wave therapy is more effective than shock- wave therapy alone in patients with symptomatic calcific tendonitis, giving significantly higher rates of elimination of the calcium deposits, better clinical results and reduction in the need for surgery."	Baseline differences in gender of uncertain significance. Likely underpowered for some outcomes. Data suggest addition of needling successful for reduction of symptoms and more resolution of calcium deposits.
		Ca	Icific Tendinitis: Need	ling vs. Bursoscopy vs	s. Control	L .
Maugars 2009 RCT	4.5	N = 53 randomized with at least 4 months painful shoulder from calcific tendinitis (>5mm diameter), failed NSAIDs, injection	102 initially treated with unblinded fluoroscopically guided corticoid injection (cortivazol 3.75mg) yielding 53 for randomization. Re-randomized injection failures. Needling fragmentation irrigation (15-30mL lidocaine 1% infiltration, fluoroscopy, 2-18g needles, "several tens of intra-calcic drillings in the axis of calcification," 2nd stage of drillings, irrigation) vs. bursoscopy (curette or high pressure water jet to remove calcium) vs. control; 24 months follow-up.	Improvement >90% in 44% NFI vs. 10% bursoscopy vs. 12% control, p = 0.02). Patient >70% improved 62% vs. 65% vs. 29%. Control group patients eventually were mostly (64.7%) randomized due to treatment failure. VAS pain improvements 36.9 vs. 29.3 vs. 11.1. Area calcification decreased -57.8 vs. -77.1 vs. +4.3mm <sup>2</sup> .	"NFI and BS are now validated removal techniques of shoulder calcifications when there is chronic pain and other medical treatments had failed."	Some baseline differences. Data suggest efficacy and equivalency of needling and bursoscopy vs. control.

## SURGICAL CONSIDERATIONS

This guideline will address only the non-emergent surgical treatment of the most common acute, subacute, or chronic shoulder disorders. The indications for emergent surgery for red-flag conditions including unstable fractures, abscess, or hematoma, etc., particularly with neurological compression, are not discussed, as treatment of these conditions is outside the scope of these guidelines, as are other indications for surgery (e.g., neoplasia). Early recognition of red-flag conditions that require expedited referral to a surgeon qualified to deal with shoulder emergencies is recommended (see Red Flags). This section of this guideline addresses surgical indications including rotator cuff tears and surgery for impingement syndrome.

## **ROTATOR CUFF TEARS**

Many individuals with rotator cuff tears have minimal or no functional deficits, (Sher 95; Needell 96; Schibany 04; Moos-mayer 05) thus careful evaluation of the patient's functional status is required. Many patients function normally with rotator cuff tears, while others have incapacitating problems that may require physical theapy (Moosmayer 10, 14; Ainsworth 07) and/or attempts at surgical repair or debridement. Rotator cuff tears have the potential to progress. (Matava 05; Yamaguchi 06) For patients with tears accompanied by functional deficits, rotator cuff repairs appear to speed recovery. There also are reports of improved overall health status after rotator cuff surgery. (McKee 00) It is unclear whether surgical repair of the rotator cuff changes the risk of future surgery. There are different rating systems for grading rotator cuff tears including consideration of the size of the tear, the extension of tear retraction, and the quality of the rotator cuff muscles (DeORio 84; Patte 90; Goutallier 94) (see Table 6). Repairs of larger tears have increased rate of healing failure which correlates with outcomes. (Milano 07; Wilson 02; Habernek 99; Iannotti 06; Warner 01)

#### Table 6. Rotator Cuff Tear Size

Category	Tear Size	
Small	<1cm	
Medium	1 to 3cm	
Large	>3 to 5 cm	
Massive	>5 cm	

\*Adapted from DeOrio JK, Cofield RH. Results of a second attempt at surgical repair of a failed initial rotator-cuff repair. *J Bone Joint Surg Am.* 1984; 66(4):563-7 and Bateman JE. The diagnosis and treatment of ruptures of the rotator cuff. *Surg Clin North Am.* 1963; 43:1523-30.

There are many purported and documented risk factors for poorer surgical outcomes. These most common risk factors include low-volume surgical practice (physician performs less than 6 rotator cuff repairs per year), (Sherman 08) age (older patients), (Ogilvie-Harris 90; Boehm 05; Sherman 08; Watson85) female gender, (Boehm 05; Lindh 93) larger rotator cuff tears, (Milano 07; Wilson 02; Warner 01Habernek 99; Bartolozzi 94; Rokito 96; lannotti 06) retraction, (Milano 07) concomitant subscapularis tears, (Milano 07) fatty tendon degeneration, (Milano 07; Costouros 07) diabetes, smoking, (Mallon 04) overweight or obesity, weakness of shoulder (strength of abduction and external rotation), pre-operative activity level, (lannotti 96; Ellman 86) preoperative stiffness, (Namdari 10) abnormal mental status, involvement in litigation or workers' compensation (Ogilvie-Harris 90; Spangehl 02; Kempf 99; Misamore 95) or sick-leave, (Brox 99) regular "pain medication use," (Brox 99) excessive post-operative hyperalgesic crises, (Kempf 99) non-compliance with rehabilitation programs, and otherwise unhealthy individuals. (Sherman 08) One report found shorter interval between symptom onset and massive rotator cuff repair to be negatively correlated with outcomes. (Gerber 00) Post-operative shoulder stiffness was found to be best predicted by pre-operative limitation in ROM, (Namdari 10) especially the "hand behind the back" maneuver. (Trenerry 05) Work with the "hand above the level of the head" trended towards significance in one possibly underpowered study. (Brox 99) A case series suggested delayed treatment resulted in worse outcomes among patients with rotator cuff tears, (Habernek 99) but no quality study has addressed that question.

If surgery is a consideration, counseling regarding likely outcomes, risks, and benefits, and especially expectations, is important. Ideally, this education begins with the referring physician who may note that post-operative physical or occupational therapy exercises are essential in comparison to non-operative treatment for good clinical results. These exercises might be difficult to comply with for some rotator cuff repair patients. The decision as to which type of rotator cuff repair procedure to perform – arthroscopic, open, or mini-open repair – should be left to the surgeon and patient until quality evidence demonstrating procedural superiority becomes available to provide evidence-based guidance. Achievement of a plateau in improvement and assessment for final results after surgical repair of a rotator cuff tear has been found to require 1 year. (van Linthoudt 03) Revision surgeries are particularly challenging, usually result in inferior results compared with primary repairs, and should be undertaken with a good deal of caution. (Djurasovic 01)

1. Recommendation: Rotator Cuff Repair for Small, Medium, or Large Tears

# Rotator cuff repair is moderately recommended for treatment of small, medium, or large tears (<5cm).

*Indications* – All the following: 1) shoulder joint pain; 2) reduced ROM of the shoulder or impaired function; 3) imaging findings by MRI, MR arthrography, or ultrasound of rotator cuff tear. Patient must agree to participate fully in post operative active rehabilitation and understand there is a long recovery time. Pre-operative physical therapy is an option (but not a pre-operative requirement) as many pataients sufficiently recover without surgery. (Moosmayer 10, 14; Kukkonen 14)

## Strength of Evidence – Moderately Recommended, Evidence (B)

2. Recommendation: Addition of Claviculectomy or Subacromial Decompression to a Rotator Cuff Repair for Isolated Supraspinatus Tears

Adding claviculectomy or subacromial decompression to a rotator cuff repair is moderately not recommended for treatment of isolated supraspinatus tears.

## Strength of Evidence – Moderately Not Recommended, Evidence (B)

## Rationale for Recommendations

While surgery tends to produce modestly superior outcomes over 1 to 5 years (Moosmayer 10,14), nonoperative treatment is often successful.(Moosmayer 10, 14; Kukkonen 14) Thus, physical therapy is a reasonable option for many patients, (Moosmayer 10, 14; Kukkonen 14) although data are insufficient to make it a pre-operative requirement. Surgical cuff repair is believed to be a superior option among patients for whom occupational shoulder exposures and demands are greater, although quality data that address this issue are not available. Many quality studies necessitated non-operative treatment prior to surgery (see evidence table). (Mohtadi 08; Spangehl 02) Some have included non-operative treatment for prolonged periods of at least 3 months prior to surgery (Mohtadi 08; Franceschi 07, 08; Iannotti 06) and up to 33 months (these trials are typically reported from countries with waiting lists for procedures). (Ko 08) Some studies have required failure of a glucocorticosteroid injection. (Franceschi 07; Dorrestijen 07)

There are a few quality studies comparing surgical repair of rotator cuff tears with non-operative treatment (see evidence table) that suggest physical therapy may be a reasonable option for initially presenting rotator cuff tear patients. (Moosmayer 10, 14; Kukkonen 14 MacDermid 06; Ejnisman 04) There are no sham-controlled trials.

Rotator cuff repair has evolved from open to mini-open to all arthroscopic techniques. Currently, arthroscopic techniques are evolving with the advent of new technology and instrumentation. (Neviaser InsCourseLect 89; Neer JBJS 1972; Hata 01; Rockwood 93; Ellman 93; Baker 95; Sauerbrey 05; Verma 06; Skoff 95; Youm 05; Ogilvie-Harris 93; Seida 10) Rates of arthroscopic anterior acromioplasty have increased 5.8-fold from 1980 to 2005. (Yu 10) There are quality studies available on short- and long-term comparisons between arthroscopic and open or mini-open repairs. (Nho 07; Morse 08) Arthroscopic repair is associated with lower complication rate- infection, deltoid dehiscence. There is high-quality evidence there are no long-term differences associated with arthroscopic repair and mini-open compared to open repair, (Mohtadi 08; Spangehl 02)<sup>vi</sup> although evidence suggests a modest short-term advantage of arthroscopic mini-open repair versus open repair of rotator cuff tears. (Mohtadi 08)

There is moderate-quality evidence suggesting there is no demonstrable benefit in adding subacromial decompression to a rotator cuff repair for treatment of isolated supraspinatus tears with a Type II acromion in quality studies with up to 2 years follow-up data (Milano 07; Rubenthaler 03; Gartsman 04; Chahal 12; Kukkonen 14; Oh 14) or a repair using transosseous equivalent suture-bridge technique along with subacromial decompression. (Cuff 2012) There are two moderate quality studies comparing arthroscopic debridement and subacromial decompression in treatment of full-thickness tears of the rotatior cuff. (Melillo 97; Montgomery 94) There is one moderate-quality trial suggesting SLAP lesions found at the same

<sup>&</sup>lt;sup>vi</sup>Low-quality evidence also suggests the same conclusion. (Sauerbrey 05; Verma 06; Youm 05)

time as rotator cuff tears in those over 50 years old do not require repair, rather biceps tenotomy outperforms the SLAP repair. (Franceschi 08)

Post-operative rehabilitation results have been found to be comparable regardless of early or delayed range of motion (Cuff 12) and in comparing 4 with 8 weeks of postoperative immobilization. (Koh 14) Post-operative anesthetic injections have been used, but without a placebo group. (Lee 15)

Re-tear rates vary widely, depending on numerous factors especially the size of the tear and the quality of the tendon and rotator cuff muscles. The re-tear rate for a single row arthroscopic repair has been estimated at 40%, but varies considerably depending on the size of original tear. (Burks 09; Bishop 06; Fealy 06; Galatz 04; Gladstone 07; Liu 94) There is little quality evidence for superiority of one type of repair over another (e.g., single stitch versus double stitch); (Franceschi 07, Grasso 09, Lapner 12; Carbonel 12, Ma 12, Burks 09, Koh 11) or No. 3 Ethibond Mason-Allen sutures versus 1.0 mm polydioxanone cord with modified Kessler sutures. (Boehm 05) A meta-analysis and systematic review found double-row repair to have lower re-tear rates and greater internal rotation ROM but showed no other differences compared to single-row repair. (Xu 14, Saridakis 10) There is one moderate-quality study that has suggested a modified mattress-locking stitch is modestly superior to simple stitches; however, the study has considerable weaknesses that raise questions about the validity of the conclusions. (Ko 08) One study of arthroscopic repairs with long-term follow-up of up to 14 years looked at staple fixation repairs and side-to-side suture and anchor repairs; both kinds of repairs appear to document surgical success, although larger tears appear associated with lower success rates. (Wilson 02). Almost all repairs require reattachment of tendon to bone. Isolated side-to-side repair or margin convergence means that there is an incomplete repair as is usually present in cases of chronic massive tears. Tendon to bone repair has been suggested to be modestly better than side-toside repair in one moderate-guality study. (Bigoni 09) Re-tears do not necessarily equate to pain and functional loss, just as some people have primary asymptomatic rotator cuff tears.

Most quality evidence included patients with small to moderate tears. Patients who are candidates for surgery generally have pain and impaired function. There are no quality studies suggesting better or worse results for earlier or delayed surgery (see evidence table), and current evidence does not support a need to rush surgical decisions. Until quality evidence becomes available to provide evidence-based guidance, the decision as to which surgical procedure to perform should be left to the surgeon and patient as there appear to be only modest short-term improvements for arthroscopic rotator cuff repair over open rotator cuff repairs (Mohtadi 08) or for impingement syndrome including trends towards shorter sick leave in one study (mean 10 versus 5.7 weeks); (Husby 03) but not all. (Rubenthaler 03) Early surgery should be considered in cases of acute traumatic tears; especially larger tears in healthy, active individuals. Surgery is invasive, involves prolonged recovery (many months), has adverse effects, and is costly. However, benefits appear to outweigh risks for most patients and surgery is recommended.

1. Recommendation: Rotator Cuff Repair for Acute Massive Tears

## Rotator cuff repair is recommended for treatment of acute massive tears (>5cm).

*Indications* – All of the following: 1) shoulder joint pain; 2) reduced range of motion of the shoulder or impaired function; 3) imaging findings by MRI, MR arthrography, or ultrasound of massive rotator cuff tear.

## Strength of Evidence – Recommended, Evidence (C)

## 2. Recommendation: Rotator Cuff Repair for Chronic Massive Tears

**Rotator cuff repair is not generally recommended for treatment of chronic massive tears (>5cm).** *Indications* – While generally not recommended, if surgery is felt to be indicated for a particular patient, all of the following should be present: 1) shoulder joint pain; 2) reduced range of motion of the shoulder or impaired function; and 3) imaging findings by MRI, MR arthrography, or ultrasound of massive rotator cuff tear, 4) poor function that is felt to both necessitate surgical intervention and, 5) there is likelihood for significant improvement with surgery for that particular patient.

## Strength of Evidence – Not Recommended, Evidence (C)

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

3. Recommendation: Rotator Cuff Repair for Massive Tears Using Porcine Xenograft Material Porcine small intestine submucosa graft for surgical repair is not recommended for treatment of large or massive tears that are otherwise unrepairable.

Strength of Evidence – Not Recommended, Evidence (C)

4. Recommendation: Rotator Cuff Repair for Massive Tears Using Tissue Augmentation There is no recommendation for or against tissue augmentation to surgically repair large or massive tears that are otherwise unrepairable.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

### Rationale for Recommendations

Repair of massive rotator cuff tears is technically more difficult and has a worse prognosis. (Matthews 06; Galatz 04)There are no quality studies comparing these repairs with non-operative treatment, although many surgeons will recommend an initial trial of non-operative care for elderly patients with massive rotator cuff tears. Some chronic massive tears can be repaired and some can also undergo successful partial repair, although this does not apply for most patients. Most repairs are tendon to bone. One quality study solely addressed surgical repair of massive rotator cuff tears. (lannotti 06) Surgical repairs have utilized multiple different techniques, with a preference for primary repair when the patient's tissue may be approximated. A study of 27 shoulders found primary rotator cuff repair was often infeasible when the length was greater than 4cm, the width was greater than 4cm, the supraspinatus muscle was thin at the superior glenoid margin, and the signal intensity was high. (Sugihara 03)

Techniques include open repair, (Worland 99) arthroscopic, arthroplasty-related procedures, (Chun 08; Boileau 08) as well as tissue transfers (latissimus dorsi) (Costouros Arthroscopy 07)<sup>vii</sup> and tissue grafting (autograft, allograft, xenograft) (Tsiridis 08) and combination procedures. (Boileau 08) Two studies suggest no meaningful differences between arthroscopic and mini-open repairs. (Kasten 11; Cho 12) Tissue grafts are intended to augment a repair, not fill a tissue defect. There is insufficient evidence currently to recommend a particular type of graft. Cases of margin convergence may be amenable to a primary closure, if the tendon edges can be approximated without undue tension on the patient's remaining rotator cuff. A few of these repairs were included in the available quality literature (see evidence table), but did not present stratified analyses specific to massive rotator cuff tears. Even so, there is some limited evidence suggesting repair is superior to debridement with considerably better results in the surgical repaired group (Melillo 97) and thus, there is limited evidence to recommend attempted repair of massive rotator cuff tears. (lannotti 06)

When primary closure with approximation of the tendon tissue is not possible, utilization of graft material, including the patient's bicipital tendon<sup>viii</sup> (Cho 09) or subscapularis, (Tanaka 06) is sometimes utilized (i.e., autografts). Additional materials interposed include porcine dermal xenograft (Badhe 08) and porcine small intestinal submucosa. (Sclamberg 04) Neither of the latter appeared to fair well, and the sole quality trial that included only patients with massive tears failed to find improvements with a porcine small intestinal submucosa graft (Iannotti 06); thus, is not recommended.

Hemiarthroplasty has also been used to treat select patients with massive tears (see Arthroplasty), but there are no quality studies of hemiarthroplasty for treatment of massive rotator cuff tears. (de Cupis 08; Boileau 05) Reverse total shoulder replacement is being used more often currently with more predictable results. It also is used to treat selected patients with unrepairable massive rotator cuff tears. (Matsen 07)

Case series of patients who have reportedly undergone debridement and subacromial decompression as part of treatment of full-thickness, irreparable rotator cuff tears have found some decrease in pain and

<sup>&</sup>lt;sup>vii</sup>Costouros et al, concluded from their case series that the treatment was ineffective, especially for those patients with atrophy.

<sup>&</sup>lt;sup>viii</sup>A comparative clinical trial found better strength and forward flexion compared to repairs with compared to without biceps augmentation. (Cho 09)

improved ROM, although post-operative strength was reduced. (Gartsman 97) A review suggested debridement alone was insufficient for treatment for massive rotator cuff tears. (Melillo 97) A case series found biceps tenotomy did not add benefits over debridement of irreparable massive rotator cuff tears. (Klinger 05) Reverse total shoulder has been used for shoulder osteoarthritis associated massive cuff ruptures. (de Cupis 08; Boileau 05; Young 09) In a case series, the reverse total shoulder appears to improve function. (de Cupis 08)

In the quality trials that included a minority of patients with massive tears, there are no stratified analyses presented to identify outcomes for this specific population of patients. It has been suggested that the outcomes for patients with larger tears are inferior to smaller tears. (Milano 07; Wilson 02; Habernek 99) Patients who are candidates for surgery should have pain and reduced function and understand the risks and benefits of these procedures. Infections are generally rare and are most commonly associated with mini-open repair. (Herrera 02) The decision as to which type of rotator cuff repair procedure to perform for massive tears must be left to the surgeon and patient until quality evidence becomes available to provide evidence-based guidance. Surgical repair of massive rotator cuff tears is invasive, has adverse effects, and is costly. Rehabilitation is often considerably longer and more complicated than for smaller rotator cuff tears. However, particularly in younger patients with massive rotator cuff tears, benefits appear to outweigh risks for most patients and surgery is generally recommended.

*Evidence for the Use of Surgery for Patients with Rotator Cuff Tears* There are 3 high-quality and 35 moderate-quality RCTs incorporated into this analysis. There are 4 lowquality RCTs in Appendix 2. (Flurin 13; Aydin 10; Gartsman 13; Kraeutler 15)

We searched Open rotator cuff repair, arthroscopic rotator cuff repair and mini open repair, ; disorder terms- rotator cuff/injuries, rotator cuff tears, rotator cuff tear, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, shoulder impingement syndrome, supraspinatus tendinitis, and bicipital tears; controlled clinical trial, controlled trials, randomized controlled trial, randomized controlled trials, random allocation, random\*, randomized, randomization, randomly; systematic, systematic review, retrospective studies, prospective studies, epidemiological studies, epidemiological research, and Nonexperimental Studies. In PubMed we found and reviewed 160 articles, and considered 18 for inclusion. In Scopus, we found and reviewed 555 articles, and considered 1 for inclusion. In CINAHL, we found and reviewed 23 articles, and considered 3 for inclusion. In Cochrane Library, we found and reviewed 17 articles, and considered 1 for inclusion. We also considered for inclusion 0 articles from other sources. Of the 23 articles considered for inclusion, 13 randomized trials and 10 systematic studies met the inclusion criteria. Three RCTs were low quality. The following treatments for the above listed disorders was also searched: Surgical Repair, Xenograft, Allograft, H-Wave, TENS, LLLT, Extracorporeal shock wave, Massage, Acupuncture, Steroid injections, and Ultrasonography.

Author / Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
		R	otator Cuff Tear: Oper	n vs Mini-Open Arthroscopic	c Repair	
Mohtadi 2008 RCT	8.0	N = 73 with unremitting pain in the affected shoulder who have failed nonoperative treatment of at least 3 months.	Open acromioplasty rotator cuff repair with a standard vertical incision was made (n = 37) vs. mini-open acromioplasty repair with a general anesthetic and were positioned in the sitting position (n = 36). Average 2 years follow-up.	Mean Rotator Cuff-Quality of Life scores (composite VAS score) differed at 3 months ( $p = 0.005$ ) and 6 months ( $p = 0.015$ ), but not different at 1 year ( $p = 0.34$ ), although difference from baseline not significant at 6 months.	"There was no difference in outcome at 1 and 2 years after surgery between the scope mini- open and open procedures. The quality of life of patients undergoing the arthroscopic acromioplasty with mini- open rotator cuff repair improved statistically significantly and clinically at 3 months compared with the open group."	More use of anchors in scope mini-open group (30 vs. 18); 8 massive tears, no data stratified by tear size. Data suggest slight superiority of arthroscopic approach for short- to intermediate-term (approximately 3 months), but no long-term

	0.5		NC 10		<u> </u>	differences.
Van der Zwaal 2013 RCT	6.5	N = 100 with a small to medium-sized full-thickness supraspinatus and/or infraspinatus tendon tear, younger than 70 years old.	Mini-Open acromioplasty repair group ( $n = 50$ ) vs. All-arthroscopic repair a standard arthroscopic pump maintained fluid pressure at 40 mm Hg ( $n = 50$ ). Follow-up the same for both groups, 6, 12, 26 and 52 weeks.	The mean postoperative DASH score for the arthroscopic group was 65.6 (95% CI, 60.8-70.5) and $69.1 (95\% CI, 64.3-73.9)$ in the mini-open repair group. These results were not significant. Ultrasonographic assessment showed intact repairs in 83% of patients in the arthroscopic group and 87% of patients in the mini-open group, (p = 0.74).	"In the first year after surgery, functional outcome, pain, range of motion, and complications do not significantly differ between all- arthroscopic repair and mini-open repair. Patients do attain the benefits of treatment somewhat sooner (6 weeks) with the arthroscopic procedure."	No differences between groups. Both groups generally improved over time.
Spangehl 2002 RCT	5.0	N = 71 with impingement syndrome refractory to non-operative treatment	Arthroscopic acromioplasty (n = 32) vs. open acromioplasty in patients with impingement syndrome (n = 30). At least 1 year follow-up.	VAS scores before/after surgery: arthroscopic 7.2/4.3 vs. open 7.6/3.3. Open group significantly more improvement than arthroscopic, $p = 0.01$ . No difference for overall satisfaction. UCLA scores (excellent plus good): arthroscopic 18/27 (66.7%) vs. open 16/24 (66.7%).	"Open acromioplasty was equivalent to arthroscopic acromioplasty for UCLA scores and patient satisfaction. For pain and function, both gave significant improvement but the open technique may be superior. Unsettled compensation is a predictor of poor outcome."	Suggests no difference between open and arthroscopic. No short or intermediate term follow-up where benefit from one procedure may be present. Workers comp, especially "comp not settled" a risk for worse outcome.
Kasten 2011 RCT	4.5	N = 34 with an isolated rupture of the supraspinatus tendon.	Arthroscopic rotator cuff repair group or ASC (n = 17) vs. Mini-Open repair technique group (MO) (n = 17). Follow-up at 1-12 weeks and 6 months.	VAS pain scores lower in MO group (3.3) after 4 weeks compared to ASC (4.7; $p < 0.042$ ) and at 8 weeks (2, 3.5 respectively; ( $p < 0.042$ ). In first week, fewer NSAID tablets needed in ASC group (1.6) compared to MO group (2.2; $p = 0.027$ ). After 6 months, Constant-Murley score improved in both groups compared to baseline; however, there were no significant differences between groups.	"There was less use of NSAIDS in the first postoperative week in the ASC group, indirectly indicating less pain, but higher pain scores (weeks 4-8) compared to the MO group."	No differences between intervention arms.
Cho 2012 RCT	4.0	N = 60 with supraspinatus tear smaller than 3 centimeters.	Mini-Open Repair with a 3- to 4-cm skin incision (n = 30) vs. Arthroscopic repair tear repaired using either single or double row repair technique (n = 30). Follow-up for at 1, 2 and 5 days, 2 and 6 weeks, and 3 and 6 months post-op.	No significant difference was found between groups for the VAS pain score at and 5 days, 2 and 6 weeks, and 3 and 6 months. (P > 0.05) The mean VAS scores were significantly lower compared to the mini-open group at 1 and 2 days post-operation. (p = 0.02 and p = 0.04 respectively). There were no significant differences in mean range of motion between groups	"The hypothesis that arthroscopic repair would cause less postoperative pain and allow faster recovery of range of motion in the early postoperative period compared with mini-open repair was not supported."	Data suggest no meaningful differences between groups.

				at any follow-up date.		
Freedman 2007 RCT	4.0	N = 17 AC joint pain from osteoarthritis, post- traumatic, osteolysis	Arthroscopic distal clavicle resection was performed via the indirect/subacromial approach (n = 8) vs. indirect arthroscopic distal clavicle resection a 2-cm incision, centered over AC joint (n = 9). Follow-up at 6	VAS pain scores (baseline/6/12 months): open (3.7/ 2.1/1.75) vs. arthroscopic (4.3/2.7/1.0) (NS). SF-36 bodily pain scores improved, but no between-group differences.	"Arthroscopic and open distal clavicle excisions both provide significant pain reduction at 1 year."	Study targets AC degenerative joint disease.
			months and 1 year.	thurse an is the New Assession	alaatu	
	1			throscopic vs Non-Acromio	-	
Abrams 2014 RCT	5.0	N = 114 undergoing arthroscopic repair of full- thickness rotator cuff tears.	Acromioplasty underwent release of coracoacromial ligament and flattening of anteriorinferior surface of acromion (n = 65) vs. non- acromioplasty group (n = 49). Follow-up at 6 months, 1 year and 2 years. ASES, SST, UCLA, VAS, and Constant functional scores used to assess patients at follow-up.	83% of patients were available for the 2-year follow-up. In both groups, there was significant improvement at in all functional scores at all follow-up points when compared to pre-operative scores. For both groups, scores did not significantly improve between year 1 and year 2 of follow-up. No significant differences between groups was found.	"This investigation did not demonstrate a difference in clinical outcomes after arthroscopic repair of full-thickness rotator cuff tears with or without concomitant acromioplasty at short- term follow-up."	No meaningful difference between groups observed.
MacDonald 2011 RCT	4.5	N = 86 with a diagnosis of a full-thickness rotator cuff tear by clinical and imaging criteria. Tears of ≤4cm were included.	Arthroscopic repair with acromioplasty intervention (n = 41) vs. arthroscopic repair without acromioplasty intervention (n = 44). Follow-up measurements were taken at 3, 6, 12 and 18 months post- operatively.	The WORC and ASES scores improved significantly in both groups compared to baseline (p <0.001). However, there were no significant differences between groups for WORC and ASES scores at any time point, with the exception of a significant difference at 6 months with respect to the ASES score (p=0.043).	"We did not observe any significant differences in patient- reported pain, function, and quality-of-life scores between the groups up to two years after surgery. The findings of this study do not support the routine use of acromioplasty as an adjunct to arthroscopic cuff repair."	Possibly same population as: Lapner, 2012. There were no meaningful differences between groups.
		Rotator Cu		with vs without Subacromia		
Milano 2007 RCT	6.5	Rotator Cu N = 80 full thickness rotator cuff tear	Iff Tear: Arthroscopic Group 1, arthroscopic rotator cuff repair and subacromial decompression, anterior-inferior acromioplasty, release of coracoacromial ligament (n = 40) vs. Group 2, sub- acromial bursectomy sub- acromial bursectomy and	with vs without Subacromia DASH score (pre/2 year): acromioplasty (-/18.2) vs. no acromioplasty (-/23.1) (NS).	Decompression "[T]he functional and objective outcome of arthroscopic rotator cuff repair was not significantly affected by subacromial decompression."	No short- or intermediate- term evaluation, only 2-year data. Suggests subacromial decompression does not add to rotator cuff tear repairs

			rotator cuff repair (n = 40).			
Rubenthale r 2003 RCT	5.0	N = 38 chronic calcifying tendinopathy with failure of "intensive nonoperative trootmonto"	Endoscopic with calcium deposit removal (n = 19) vs. open decompression with calcium deposit removal (n = 19).	Constant and Murley assessment of regaining full shoulder motion: endoscopic mean 33/40 points (82%) vs. open 29/40 (72.5%) (NS).	"Endoscopic or open surgery can be recommended as valuable treatment modalities in patients with chronic calcifying tendinopathy."	Sparse baseline data. Only follow-up at 15.7- 17.1 months, so no short to intermediate follow-up.
Gartsman 2004 RCT	4.5	treatments" N = 93 needing rotator cuff repair limited to supraspinatus and Type 2 acromion.	Subacromial decompression (n = 47) Vs. without subacromial decompression (n = 46).	ASES scores (pre/post- op): subacromial decompression 31.1/91.5±10.3 vs. no SA decompression 31.0/89.2±15.1 (NS).	"[A]rthroscopic subacromial decompression does not appear to change the functional outcome after arthroscopic repair of the rotator cuff."	Sparse details; excluded workers' comp. States patients blinded. Tear longer in group without subacromial decompression (22.5 vs. 20.1mm, p = 0.032), but multi- variate suggested no difference. No short- to intermediate- term follow-up.
	I	Rota	tor Cuff Tear: Acromic	plasty vs Subacromial Deco	ompression	
Melillo 1997 RCT	4.0	107 full- thickness, chronic tears of the rotator cuff that were managed surgically.	repair and Neer anterior acromioplasty (n = 29) vs. arthroscopic debridement, subacromial decompression and abrasion of the greater tuberosity (n = 27). 6-9 years follow-up.	score was 32.5 vs. 19 with debridement (p <0.05). 87% repaired vs. 8% debrided considered satisfactory.	"The findings of the studyindicate that repair of these tears in the treatment of choice."	Methods are sparse. Follow- up report of Montgomery 1994. Some baseline differences with more massive tears in arthroscopic group (70.4% vs. 48.3%). Results suggest repair superior to debridement.
Montgomer y 1994 RCT	4.0	N = 87 with chronic, full thickness rotator cuff tears.	Group 1, open surgical tendon repair and anterior acromioplasty (n = 50) vs. Group 2, arthroscopic debridement and subacromial	Post-op UCLA 35 point scale: G1 31 vs. G2 25 (p = 0.0028). Greater satisfaction with surgery regardless of tear size in repair group. Variable satisfaction in debridement group; 3-5 year follow-up:	"The rotator cuff repair group did significantly better than the group managed by debridement and decompression alone."	Minimum 3 months rehab prior to surgery (aggressive physical therapy, anti-inflammatory medication, selective steroid

			decompression (n = 38).	G1 4 re-operation (2 inadequate acromioplasties, 1 adhesive capsulitis, 1 subacromial scar tissue). G2 -9 re-operation, 5 large or massive tears deteriorated after 12-48 months then developed rotator tear arthroplasty; 2 rotator cuff repairs for pain, 2 arthroscopies with debridement and resection of bursal scar tissue to treat pain.		injection, avoidance off pain inducing activities). Debridement group had disproportionate # (19) of massive rotator cuff tears but similar # of large+ massive tears. Passive stretching followed by active rehab for all post- op. Unusual long follow-up. Suggests initial repair of rotator cuff can improve outcomes overall.
			Rotator Cuff Te	ar: Postoperative Treatment		
Cuff 2012 RCT	5.5	N = 68 with an arthroscopic subacromial decompressio n in combination with rotator cuff repair, isolated full- thickness crescent shaped supraspinatus tear repaired using a transosseous equivalent suture-bridge technique, and an ultrasound at least 9 months after surgery to assess healing	Early range of motion group beginning 2nd post- op day; physical therapy 3 times per week, outpatient exercises 3 times daily for 5 minutes each session (n = 33) vs. delayed range of motion group; outpatient exercises (circular pendulum) 3times a day per week for 5 minutes for 1st 6 weeks, receiving no physical therapy until 6 weeks post- op (n = 35). Both received shoulder immobilization treatment after surgery for 6 weeks. Respective treatments for 12 weeks. Assessments at baseline, 6 and 12 months.	Both groups showed improvement. No significant results reported between groups at follow up for rotator cuff healing, range of motion or patient satisfaction.	"Patients who underwent arthroscopic repair of a full-thickness supraspinatus tear and were then prescribed a postoperative protocol of early or delayed initiation of passive range of motion demonstrated very similar clinical outcomes and range of motion at 1 year after surgery."	Dropouts and compliance unclear. Similar efficacy in both groups at 12 months.
Ciccone 2008 RCT	4.5	N = 76 with postoperative pain control after arthroscopic subacromial decompressio n with or without arthroscopic	Interscalene regional block (n = 20) vs. infusion pump with 0.5% bupivacaine (n = 19) vs. interscalene block combined with infusion pump containing 0.5% bupivacaine (n =19)	76 patients 21 years and older undergoing outpatient shoulder arthroscopy VAS scores from postoperative day 1 to day 6 tended to be larger to the block only group compared to the other 3 groups.	"[I]nterscalene blocks provided better pain relief than infusion pumps immediately after arthroscopic subacromial decompression with or without rotator cuff repair. Infusion pumps did not provide a	High dropous and non- compliance. Interscalene blocks associated with less post- operative pain.

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		rotator cuff repair.	vs. interscalene block combined with infusion pump containing 0.9% saline solution (n = 18).		significant benefit after the blocks wore off."	
Lee 2015 RCT	6.0	N=121 patients having had rotator cuff repair surgery. Mean age Group 1: 57.2 years. Group 2: 58.1 years. Group 3: 58.6 years.	Group 1: post-op glenohumeral injection of 20ml bupivacaine and lidocaine (n = 40) vs. Group 2: subacromial space injection of 20ml bupivacaine and lidocaine (n = 42) vs. Group 3: same injections but $\frac{1}{2}$ injected into glenohumeral joint and $\frac{1}{2}$ injected into subacromial space (n = 39). Follow-up for 24 hours after surgery.	VAS score directly after surgery vs. 24hours: Group 1: 7.0 vs. 3.0; p=0.014. Group 2: 6.4 vs. 3.9; p=0.023. Group 3: 6.5 vs. 3.5; p=0.018. No statistically significant differences between groups.	"Injection of local analgesics after arthroscopic rotator cuff repair relieves postoperative pain regardless of the injection location."	Short followup period. No control. Injection location not important in pain relief after RC surgery.
Koh 2014 RCT No COI. Sponsorship , supported by a Samsung Medical Center grant.	5.5	N = 100 arthroscopic single-row repair of posterosuperi or rotator cuff tear (mean, 2.3cm in coronal- oblique plane and 2.0cm in sagittal- oblique plane. Mean age 59.9 years.	Immobilization for 4 weeks vs. immobilization for 8 weeks. Immobilization consisted of no passive or active range-of-motion exercise, including pendulum exercise. A sling with an abduction pillow was applied. After 4 (or 8 weeks), passive range-of-motion exercises were begun.	Both groups showed no differences in range of motion or clinical scores. Stiffness was higher in the eight-week group (38% compared with 18%, p=0.038).	"Eight weeks of immobilization did not yield a higher rate of healing of medium- sized rotator cuff tears compared with four weeks of immobilization."	Baseline comparability differences between flex- extension (31.8 vs. 25 degrees). Comparable outcomes from trial.
			Follow-up at 24 months.			
Malayatta	0.0	NI 75		elet-rich Plasma	"Distalat rick relations	l Inglograuthat tha
Malavolta 2014 RCT No COI. No mention of sponsorship	8.0	N = 75 complete supraspinatus tears with retraction <3cm. Mean±SD age PPR group: 55.30±8.30 years. Control group: 54.07±6.59 years.	Platelet-rich plasma (24.6ml) used in arthroscopic single row repair with absorbable double loaded suture anchors (n = 39) vs. control group (n = 36). Follow-up up to 24 months after surgery.	Mean $\pm$ SD functional assessment UCLA score at 24 month follow-up: PPR group 32.44 $\pm$ 4.318 vs. control group 32.70 $\pm$ 3.635; p = 0.916. No differences between groups in constant score or VAS score at 24 months.	"Platelet-rich plasma prepared by apheresis and applied in the liquid state with thrombin did not promote better clinical results at 24- month follow-up. Given the numbers available for analysis, the retear rate also did not change."	Unclear what the control group received. At 2 years, comparable efficacy between PRP and control.
Weber 2013	6.0	N = 60 who required	Commercially available platelet-	Mean±SD surgery time: PRFM 83.28±17.13	"Platelet-rich fibrin matrix was not shown	At 3, 6, 9, 12 weeks and 1-

RCT COI, research was supported by a grant from the Sutter Institute for Medical Research.		arthroscopic rotator cuff surgery. Mean±SD age PRFM group: 59.67±8.16 years. Control group: 64.50±8.59 years.	rich fibrin matrix (PRFM) used during surgery vs. surgery without PRFM. Follow-up for 12 weeks.	minutes vs control group: 73.28±17.18 minutes, p <0.02). Mean UCLA shoulder scores: PRFM 27.94±4.98 vs. control 29.59±1.68; p <0.046.	to significantly improve perioperative morbidity, clinical outcomes, or structural integrity. While longer term follow-up or different platelet-rich plasma formulations may show differences, early follow-up does not show significant improvement in perioperative morbidity, structural integrity, or clinical outcome."	year post-op, PRFM not superior to standard treatment.
Dezaly 2011 RCT	4.5	N = 142 with rotator-cuff tear involving supraspinatus tendon. Patients were all 60 years or older.	Biceps acromioplasty- tenotomy and repair or CR group (n = 68) vs. Isolated biceps acromioplasty- tenotomy or AT group (n = 59). Follow-up at 1 year post-op.	<b>Scopic vs Biceps long-head</b> Data available for 127 patients. At 1 year follow- up, mean weighted Constant score showed significant improvement in both groups: $43.8\% \pm 12$ (18-73, pre-operatively) vs. 72.6%±1 (43-95, post- operatively), p < 0.05. CR group [75.8%±10 (45-95)] showed a significant difference compared to AT group [68.8% ± 7(43-93)], (p < 0.05).	"Rotator-cuff tear repair in patients aged over 60 years improves clinical results as compared to isolated acromioplasty- tenotomy."	Sample population was older than 60 years. Both groups improved overtime with a larger and meaningful difference in favor of arthroscopic rotator-cuff repair.
				nagement of SLAP lesions a	nd Rotation Cuff Tear	
Franceschi 2008 RCT	6.0	N = 63 with rotator cuff tears associated with Type II SLAP lesions and at least 3 months symptoms with failure of NSAIDs, physiotherapy, rest, 1 corticoid injection; over	Arthroscopic repair of the type II SLAP, plus standard radiographs (anteroposterior projections; neutral, external, and internal rotation etc.) and MRI scans (n = 31) vs. arthroscopic repair of rotation cuff tear, plus standard radiographs and MRI scans (n = 32).	Total UCLA scores (pre/post op): RC plus SLAP repair (10.4/27.9) vs. RC repair plus biceps tenotomy (10.1/32.1). Forward flexion: RC plus SLAP repair (107/139°) vs. RC repair plus biceps tenotomy (99/166°).	"[N]o advantages in repairing a type II SLAP lesion when associated with a rotator cuff tear in patients over 50 years of age. The association of rotator cuff repair and biceps tenotomy provides better clinical outcome compared with repair of the type II SLAP lesion and the rotator cuff."	Some baseline differences. Some given acromioplasty. Long term outcomes. Data suggest biceps tenotomy superior to repair of SLAP in these patients.
Oh 2014 RCT No mention of sponsorshi p. No COI.	4.5	50 years old. N = 100 with rotator cuff tears confirmed radiographica Ily who underwent acromioplasty and arthroscopic rotator cuff repair, who had no symptoms (i.e., joint tenderness, positive	5.2 years follow-up. Additional concomitant arthroscopic distal clavicle resection (A/S DCR) group (n = 50) vs. no additional A/S DCR group (n = 50) Assessments at baseline, postoperatively, 6 weeks, 3, 6 and 12 months.	No significant results reported between DCR and no-DCR groups for constant pain score, tear size, healing rate, ASES score, VAS score, internal rotation, abduction, external rotation and forward flexion postoperatively at follow- ups.	"[W]e conclude that preventive arthroscopic DCR in patients with rotator cuff tears and concomitant asymptomatic radiological ACJ arthritis did not guarantee better clinical or structural outcomes. In addition, it can lead to symptomatic ACJ instability in some patients."	High dropout with 22 lost to follow-up. Short folowup. No apparent benefit in arthroscopic distal clavicle resection vs. arthroscopic RC repair alone. Some in ADC had post-op complications.

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		compression				
		test) of acromioclavic				
		ular joint; Mean (±SD)				
		age 63.6				
		(±6.5) for				
		DCR group				
		and 64.0				
		(±7.5) for no-				
		DCR group.				
			or Cuff Tears: Single v	vs. Double Row Technique		
Franceschi	8.0	N = 60 had a	Group 1, single-row	Clinical findings Group 1	"A double-row	Results suggest
2007		rotator cuff	suture anchor	vs. group 2 pre/postop:	technique produces a	no differences in
		tear	technique (n = 30)	Group 1 single-row 11.5	mechanically superior	clinical
RCT		diagnosed on	vs. Group 2, double-	(6-14)/32.9 (29-35) vs.	construct compared	outcomes.
		clinical	row suture anchor	Group 2 double row 10.1	with the single-row	
		grounds.	technique (n = 30).	(5-14)/33.3 (30-35) for	method in restoring the	
				University of California,	anatomical foot-print of	
				Los Angeles; Group 1	the rotator cuff, but	
				single row 110/159 vs.	these mechanical	
				Group 2 double row	advantages do no	
				100/156 for forward flexion, degree.	translate into superior clinical performance."	
Grasso	6.5	N = 80 with	Arthroscopic repair	DASH scores 15.4± 15.6	"At short-term follow-	Data suggest
2009	0.5	full-thickness	with single suture	vs. $12.7 \pm 10.1$ , p = 0.48.	up, arthroscopic rotator	comparable
2003		rotator cuff	anchors ( $n = 40$ ) vs.	Work-DASH, constant	cuff repair with the	efficacy.
RCT		tears.	double row suture	scores, strength not	double-row technique	emeacy.
ROT		tears.	anchors repairs (n =	significantly different. Post-	showed no significant	
			40).	analyses suggest age,	difference in clinical	
			10).	gender, baseline strength	outcome compared	
			2-year follow-up.	associated with outcomes.	with single-row repair."	
Boehm	6.0	N = 100 with	Anterior	Re-tears on ultrasound in	"No significant	Variable follow-
2005		full thickness	acromioplasty with	8/44 PDS vs. 11/49 (22%)	difference was seen	up times. Data
		rotator cuff	transosseous	Ethibond, ( $p = 0.37$ ). Pain	between the two	suggest no
RCT		tear; did not	repairs with No. 3	12.9 PDS vs. 13.1	groups."	significant
		include	Ethibond Mason-	Ethibond ( $p = 0.65$ ).		differences.
		repairs	Allen sutures (n =	Constant score 76 PDS		
		requiring	unknown) vs.	vs. 78 Ethibond (p = 0.33).		
		tendon	1.0mm			
		transfer.	polydioxanone cord			
			with modified			
			Kessler sutures (n =			
			unknown).			
			Follow-up 24-30			
			months.			
Bigoni	5.5	N = 50 with	Arthroscopic side-to-	Constant score (pre/3/6/12	"[T]hrough a tendon-to-	Patients with
2009	-	full-thickness	side repair with	months): Side to side	bone technique, we can	different sized
		tears;	permanent sutures	(32/41/70/78) vs. tendon-	achieve better strength	tears and not
RCT		excluded	(n = unknown) vs.	to-bone (30/46/ 73/88).	recovery, although a	stratified
		partial or	tendon-to-bone	Percent internal rotator	simple side-to-side	randomization
		massive tears	fixation with 1 metal	peak torque STS	repair produces	may limit
			suture anchor	(34/30/25/17%) vs. TTB	satisfactory clinical	conclusions.
			loaded with double	(32/25/14/9%). Results	outcomes."	Conclusions
			sutures (n =	similar for small, medium		regarding value
			unknown).	and large tears.		of isokinetic
						training not
			1 year follow-up.			tested in study.
						Data suggest
	1					slightly better
						results with
Carbonel	5.0	N = 160 with	Single-row anchor	Both groups showed	"This prospective	results with tendon to bone. Minimal

2012		rotator cuff	repair (n = 80) vs.	significant improvement in	randomized evaluation	differences
RCT.		tear larger than ten millimeters underwent arthroscopic repair.	double-row anchor repair (n = 80). Follow-up time was 2 years for each group.	functional scores compared with pre- operative scores. No significant differences between groups for ASES index ( $p = 0.269$ ) or constant score ( $p = 0.447$ ). Double row showed significantly superior results compared to single row group in UCLA score at 2-year follow-up ( $p < 0.019$ ).	of single-row compared with double-row rotator cuff fixation shows a significant improvement with the double-row technique in clinical evaluation."	between groups for small tears (10.30mm), but larger differences observed among larger tears (30- 50mm).
Lapner 2012 RCT	4.5	N = 90 with a diagnosis of a full-thickness tear of rotator cuff according to clinical criteria (including MRI in all patients)	Double row intervention (n = 42) vs. single row intervention (n = 48). Follow-up dates at 3 months, 6 months, 12 months, 24 months.	Both groups showed significant improvement in all clinical outcomes at final follow-up compared to baseline ( $p < 0.001$ ). No significant differences were shown between groups. Healing rate was 67% in single-row group compared to 78% in double-row group ( $p = 0.254$ ).	"In summary, the results of this trial did not demonstrate significant differences in functional or quality- of-life outcomes between single-row and double-row repair. However, smaller tears and double-row fixation were associated with greater healing rates of the rotator cuff."	Few meaningful differences between treatment arms. Methodological details sparse.
Ko 2008 RCT	4.0	N = 78 moderate size tears, patients performed passive stretches for average 12 months pre- op	Arthroscopic repair with modified mattress locking stitch (MMLS) (n = 39) vs. simple stitches (n = 39).	VAS pain (pre/last): MMLS (6.5/0.9) vs. SS (7.0/1.1) (NS). UCLA score MMLS (13.4/ 32.7) vs. SS (13.7/31.9) (NS). Satisfaction MMLS (0.4/4.7) vs. SS (0.5/4.3) (p = 0.04). Failure rate 16.7% (MMLS) vs. 27.3%, (p = 0.03).	"Arthroscopic repair of medium-sized (1.5-3- cm) full-thickness rotator cuff tears by use of an MMLS improves patient satisfaction rates and radiographic repair integrity in comparison to simple stitch repair."	Sparse details. Unclear if standardized suture material, resulting in questions regarding robustness of the conclusions. Most results not different between groups, including pain.
Ma 2012 RCT	4.0	N = 53 with a full-thickness tear measuring more than 1 cm in diameter.	Single-row repair group (n = 27) vs. double-Row repair group (n = 26). Follow-up at 6 and 24 months. Mean final follow up time was 33.4 months.	UCLA score, ASES index and shoulder abduction and external rotation strength all significantly improved in both groups compared with pre-op values ( $p < 0.01$ ). No significant differences found between groups. When analysis was limited to patients with a tear size larger than 3cm, double- row group showed significantly better results for abduction strength ( $p =$ 0.04) and external rotation strength, ( $p = 0.03$ ).	"At minimum 2-year follow-up, arthroscopic repair for with the double –row suture showed better should strength in patients with tear size larger than 3 cm compared with the single-row suture."	No difference between groups. Both groups improved overtime.
Burks 2009 RCT	4.0	N = 40 with complaints of shoulder pain or loss of function underwent routine	Single-row rotator cuff repair (n = 20) vs. double-row rotator cuff repair (n = 20). 1-year follow-up.	Two re-tears each group at 1 year; 2 additional tendons thinned at 1 year in double row group. WORC (pre/1 year): single (30.3/84.8) vs. double (31.8/87.9) (NS). Constant, ASES, UCLA,	"No clinical or MRI differences were seen between patients repaired with a SR or DR technique."	Some details sparse. Baseline data not provided. Dropout rate unclear.

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		standard of care		SANE all not significant.		
		evaluation				
		and				
K 1 00 <i>11</i>		treatment.			<b>«</b>	
Koh 2011 RCT	5.5	N = 71 with 2- to 4cm rotator cuff tear. Mean (range)	Single-row suture anchor repair (SR) (n = 37) vs. double- row suture anchor repair (DR) (n = 34).	No differences between groups at 24 month in VAS score, constant score and UCLA score.	"[T]he clinical results and retear rates of DR repair with 1 additional medial suture anchor were not significantly	Study suggests similar re-tear rates in both groups.
		age: 61.3 (43- 78) years.	Follow-up at 2 weeks, 6 weeks, and 3, 6, 12 and 24 months post-op.	Mean±SD surgical time: 115.8±25.0 minutes SR vs. 124.5±19.7 minutes DR; p = 0.033.	different from those of SR repairs with 2 lateral suture anchors in patients with medium to large rotator cuff tear."	
		Shoulder	Surgery: Wound Drain	age System vs. No Wound I		
Gartsman 1997 RCT	4.0	N = 300 with rotator cuff tear, instability, had arthroplasty performed.	Group 1 rotator cuff repair (complete tear) (n = 100) vs. Group 2 anterior reconstruction for chronic instability/ recurrent dislocation (n = 100) vs. Group 3 total or hemi- arthroplasty for	Mean hospital stays not different (Group 1 drain $4.1 \pm 0.7$ days vs. no drain $4.0 \pm 0.7$ days). Group 2 ( $1.1\pm 0.3$ vs. $1.2 \pm 0.4$ ). Group 3 $4.9\pm 1.1$ vs. $5.1\pm 1.1$ . No differences in other outcomes including hematoma, wound dehiscence, infections,	"[T]here is no measurable benefit to closed wound drainage in this patient population."	Sparse details, no baseline data by randomized groups provided. Three different patient populations studied. Stratified results suggest no
			glenohumeral arthritis (n = 100).	transfusions, re-operation rates.		benefit for any of the 3 outcomes studied.
	1		Intrao	perative Irrigation		Studieu.
Jensen 2001 RCT	7.5	N = 54 arthroscopic shoulder surgery.	Dilute epinephrine (n = 28) vs. saline irrigation by pressure controlled pump (n = 26).	VAS bleeding score: epinephrine 8.07 vs. saline 5.92. Bleeding: 6.79mL vs. 12.87.	"The addition of epinephrine to irrigation fluid seems to reduce intra-articular bleeding during routine arthroscopic shoulder surgery and may improve visualization."	Patients not described and procedures not well described especially between groups. Patient outcomes not noted, only modest bleeding issues. Study not helpful for development of
Chaul	don Suna	Nomu Deveine Sn	all Intecting Submuse	Augmentation vo. Drime	ny Donoir for Lorgo or Mo	guidance.
	-			sa Augmentation vs. Prima		
lannotti 2006 RCT	5.0	N = 30 large or massive rotator cuff tear.	Open repairs with Neer acromioplasties with (n = 15) vs. without	Median PENN total point scores: porcine 83 vs. controls 91, $p = 0.07$ . Satisfaction trended to	"Augmentation of the surgical repair of large and massive chronic rotator cuff tears with	Results only applicable to rotator cuff tears that could have
			porcine submucosa augmentation (n = 15). All immobilized in sling for 1 week and passive forward flexion and external rotation for 8 weeks. Follow-up MRIs at 1 year.	Satisfaction trended to favoring controls (Change from pre-operative, 350% vs. 187%, $p = 0.09$ ). Healing rates for massive tears 5/21 (24%) vs. large tears 8/9 (89%). Trend in total shoulder scores for fully healed, partially healed and non-healed repairs (96, 80, 81.5, $p =$ 0.007). <b>Repair vs. Physiotherapy</b>	porcine small intestine submucosa did not improve the rate of tendon healing or the clinical outcome scores."	undergone primary closure. Some baseline differences with trend to lower ROM in porcine group. Data suggest porcine augmentation inferior for these repairs.
Moosmayer	7.5	N= 103 with	Mini-open or open	Mean±SD Constant score	"[B]oth approaches can	Pragmatic RCT
2010		symptomatic	tendon repair	improved from baseline to	be considered in the	with 1-year

RCT		small (< 1cm) or medium- sized (1cm to 3cm) tears of rotator cuff. Mean age 59 years (surgery group) vs. 61 years (physiotherap y).	surgery. Post- operatively, arm immobilized in a sling and passive range-of-movement exercises commenced (n = 52) vs. physiotherapy (n = 51). Treatment sessions of 40 minutes given on average twice weekly for 12 weeks and with increasing intervals during following 6 to 12 weeks. 12 Month follow-up.	12 months by 41.4±19.6 surgery group vs. 28.4±21.9 physiotherapy group; p = 0.002 between group difference. Mean values for patient satisfaction after 12 months (VAS scale): 9.0 (1.0 to 10.0) surgery group vs. 7.2 (0.0 to 10.0) physiotherapy group; p <0.0005.	treatment of patients with small and medium- sized rotator cuff tears but better results can be expected after primary surgical repair."	follow-up.of non- standardized PT vs. surgery for small to moderate (3mm) RC tears showed better outcomes for surgery. PT group had 82% (42/51) satisfied but 18% (9/51) opted for surgical repair.
Moosmayer 2014 RCT	7.5	See Moosmayer 2010	See Moosmayer 2010	Baseline score and age- adjusted treatment benefits after primary tendon repair were 5.3 points greater for the Constant score 95% CI: -0.05 to 10.7 points; (p = 0.05) Patient satisfaction (VAS): 9.2 cm tendon repair vs. 8.3 cm in the physiotherapy (mean difference, 1.0 cm, 95%CI, 0.1 to 1.8 cm; (p = 0.03).	"Although primary repair of small and medium-sized rotator cuff tears was associated with better outcome than physiotherapy treatment, the differences were small and may be below clinical importance. In the physiotherapy treatment group, there were increasing tear sizes and inferior outcomes in one-third of patients who did not undergo repair."	Pragmatic RCT; 5 year follow-up to original RCT. PT not standardized. Surgery showed modestly better outcomes vs. PT. At 5 years, 37% of PT group had increasing cuff tear size (>5mm) and 24% (12/51) required surgery after conservative treatment failure.
Kukkonen 2014 RCT No sponsorship . No mention of COI.	5.0	N = 180 shoulders (173 patients) with supraspinatus tendon tears and full range of motion of shoulder. Mean±SD age group 1: 65±5.8 years. Group 2: 65±5.1 years. Group 3: 65±6.0 years.	Group 1: physiotherapy (n = 60) vs. Group 2: acromioplasty and physiotherapy (n = 60) vs. Group 3: rotator cuff repair, acromioplasty and physiotherapy (n = 60). 12 month follow up.	Mean $\pm$ SD constant score at 12 months: 74.1 $\pm$ 14.2 Group 1 vs. 77.2 $\pm$ 13.0 Group 2 vs. 77.9 $\pm$ 12.1 Group 3; p = 0.34. Mean $\pm$ SD operating time: 34 $\pm$ 11 minutes Group 2 vs. 67 $\pm$ 22 minutes Group 3; p <0.001.	"[A]t one year follow- up, operative treatment is no better than conservative treatment with regard to non- traumatic supraspinatus tears, and that conservative treatment should be considered as the primary method of treatment for this condition."	At 1 year, surgery not superior to non-operative treatment.

## **POST-OPERATIVE REHABILITATION: ROTATOR CUFF TEARS**

Post-operative rehabilitation has been empirically derived and has emphasized a graded return to normal function. It is generally believed that earlier advancement of flexibility, strengthening, and conditioning exercises results in faster recovery; (Klintberg 08) however, initiating rehabilitation early in the healing process has also been thought to increase potential for failure of surgical repairs such as rotator cuff repairs and has provided some caution regarding early use of exercise. Initial emphasis is on both

protecting the repair and regaining shoulder motion. The usual progression is passive range of motion (self-assisted which some consider to be active assisted), isometrics (about 6 weeks post-op), and progressive resisted exercises (after 12 weeks). There are multiple variables that affect the timing of exercises after shoulder surgery. These include the procedure performed, pre-operative physical condition, age, and patient compliance. (Conti 09) See Postsurgical Treatment Gudeilines for impingement syndrome and tendinoses for general recommendations. These recommendations should be adapted to the more extensive surgery for rotator cuff tears and therefore slower initial recovery.

## IMPINGEMENT SYNDROME AND ROTATOR CUFF TENDINOSES WITHOUT TEARS

Surgery for impingement syndrome has been developed over the past 35 years. (Neer 72; Post 86; Ellman 87; Budoff 05; Checroun 98; Taverna 07; Schroder 01; Hawkins 88; Coghlan 09; Ingvarsson 96; Dorrestijn 09) It was originally described by Neer in 1972 as part of a continuum including surgery for rotator cuff tears, and subsequently modified to less invasive techniques. Arthroscopic approaches were then developed to attempt to further minimize surgical morbidity from large incisions and, by avoiding direct trauma to the deltoid, promote earlier active exercises and recovery and utilize lasers. (Ellman JBJS 91; Altchek JBJS 90; Ellman Arthroscopy 87; Ellman Arthroscopy 87; Gartsman 90; Kempf 99; Paulos Am J Sports Med 90; Boult 01; Speer Arthroscopy 91) Arthroscopy also enhances ability to identify relevant associated pathology – partial articular side cuff tears, biceps tears, labral pathology. Impingement syndrome and rotator cuff tendinoses without tears are sometimes treated surgically, particularly after failure of non-operative treatments (Haahr 05, 06; Brox 93, 99, 03; Rahme 98; Sachs 94; Husby 03; Lindh 93; T'Jonck 97; Ingvarsson 96; Green 98; Odenbring 08; Dorrestijn 09) with some arguing for aggressive treatment. (Matava 05) As the prevalence of these conditions is exceedingly high and many individuals with tendinoses are apparently asymptomatic (see above), careful incorporation of accurate diagnosis, the patient's condition, functional status and response to prior treatments appears particularly important. Risk factors for adverse outcomes are believed to be mostly similar to those for full-thickness rotator cuff tears and may be particularly important in the setting of workers' compensation (see above). Education regarding post-operative rehabilitation is thought to be important for these patients, as it is for those with rotator cuff tears.

Recommendation: Subacromial Decompression Surgery for Impingement Syndrome/Rotator Cuff Tendinoses

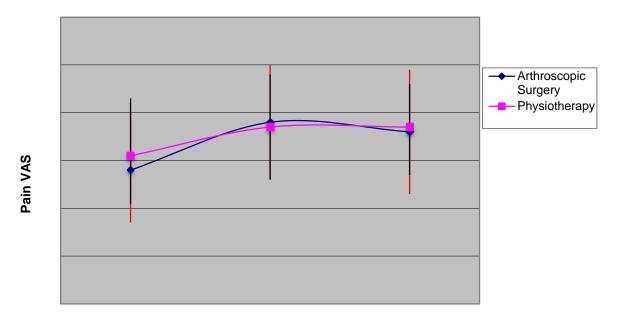
## Subacromial decompression surgery is recommended for treatment of select patients with impingement syndrome/rotator cuff tendinoses.

*Indications* – All of the following: 1) shoulder joint pain (e.g., symptomatic with positive supraspinatus test, impingement signs); 2) reduced active shoulder ROM or impaired function 3) imaging findings by MRI or ultrasound of rotator cuff tendinoses consistent with symptoms; and 4) temporary resolution or marked reduction in pain immediately after injection of a local anesthetic into the subacromial space. Patients should also have failed one or more glucocorticosteroid injections (see above) and at least one trial of a quality rehabilitation program that follows evidence-based guidelines (see above). (Haahr 05, 06; Brox 93, 99; Rahme 98; Sachs 94; Husby 03; Lindh 93; Michener 04)

Counter-indications – Adhesive capsulitis or shoulder stiffness.

Strength of Evidence – Recommended, Evidence (C)

Figure 3. Constant's Shoulder Score Change from Baseline (95% CI)



Months

Adapted from Haahr JP, Ostergaard S, Dalsgaard J, et al. Exercises versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up. *Ann Rheum Dis.* 2005; 64(5):760-4.

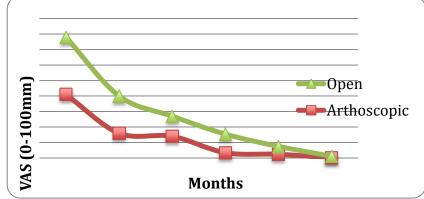


Figure 4. Arthroscopic vs. Open Subcromial Decompression for Impingement Syndrome

Adapted from Husby T, Haugstvedt JR, Brandt M, Holm I, Steen H. Open versus arthroscopic subacromial decompression: a prospective, randomized study of 34 patients followed for 8 years. *Acta Orthop Scand*. 2003; 74(4):408-14.

#### Rationale for Recommendation

There are no sham-surgery controlled trials of surgical interventions for impingement syndrome. There are three moderate quality RCTs with four total reports that compared subacromial decompression plus physical therapy versus physical therapy exercises for treatment of impingement syndrome. (Brox 93, 99; Rahme 98; Haahr 05, 06; Constant 89) Importantly, one of these trials included a comparison with both exercise as well as sham-laser treatment. (Brox 93; Brox 99) That trial found surgery and rehabilitation superior to placebo laser and provides the primary basis for an evidence-based recommendation in favor of surgery. All of these trials comparing physical therapy/exercise with surgery appear to have considerable biases

in favor of surgery over physiotherapy/exercise for at least two major reasons: 1) patients invariably appear to have been required to fail prior non-operative treatment that when described included considerable exercise components (thus a "more of the same" bias against physical therapy/ exercise); and 2) likely greater treatment contact time in the surgical groups which were combined with physical therapy/exercise. Except for Rahme's 1998 study, these studies reported mostly failed prior rehabilitation and found surgery superior to physical therapy exercise. (Brox 93, 99; Haahr 05, 06) However, it also has been noted that there is a high rate of crossover to surgery over time. (Brox 99)

There is moderate-quality evidence that there are no long-term differences associated with arthroscopic compared to open decompression to treat impingement syndrome/rotator cuff tendinoses, (Husby 03; Lindh 93; Sachs 94) although there is some evidence of a modest short-term advantage of arthroscopy over open decompression for faster recovery. (Sachs 94) (A low-quality trial also reported similar evidence. (T'Jonck 97)) Open acromioplasty in patients with impingement syndrome appears not to prevent progression to rotator cuff tear in a nine-year followup study. (Hyvonen 98) A case-control study found no evidence that calcium deposits in the rotator cuff seen on x-ray affected outcomes at 2 years after arthroscopic subacromial decompression. (Tillander 98) Experience of the surgeon and patient factors require judgment in selecting operative approaches. Long-term outcomes of up to 25 years have also reported excellent or good results in 77% of patients with various arthroscopic decompression techniques. (Odenbring 08; Ellman 91; Chin 07; Budoff 05)

Limited motion may indicate adhesive capsulitis or capsular stiffness that would be a contraindication to surgery. Patients with rotator cuff syndromes or impingement typically do not have significant limitations of passive motion and if they do, then the diagnosis may be in doubt. Surgery is invasive, has adverse effects, and is costly. However, in carefully select patients with impingement syndrome/rotator cuff tendinoses who have failed quality non-operative treatments, benefits appear to outweigh risks and surgery is recommended.

Evidence for the Use of Surgery for Patients with Impingement Syndrome and/or Rotator Cuff Tendinoses without Tears

There is 1 high-quality and 13 moderate-quality RCTs incorporated into this analysis. There are 5 lowquality RCTs or other studies in Appendix 2.

Author/Title Study	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments			
Туре	, ,		•						
Imp	Impingement Syndrome: Subacromial Decompression vs. Physiotherapy/Exercise (also vs. Placebo)								
Haahr 2005 RCT	7.0	N = 90 rotator cuff disease plus positive impingement signs	Arthroscopic subacromial decompression vs, physiotherapy with strengthening exercises lasting 60 minutes for 19 sessions; 1 year follow-up.	Mean VAS pain scores comparing physiotherapy vs. surgery at $3/6/12$ months follow-up: $3.1$ vs.2.8; p = $0.69/3.7$ vs. $3.8$ ; p = $0.92/3.7$ vs. $3.6$ ; p = $0.93$ . The change in function, ROM, force and constant scores are also not significant.	"[W]e are now more reluctant to recommend surgery in cases with stage II impingement. There is a need for larger scale studies with sufficient numbers of participants to allow for stratification into subgroups with different baseline levels of disability, whatever functional score one uses, before rigorous recommendations are made about who should have arthroscopic decompression and who could benefit from physiotherapy with training, maybe	Large proportion of workers' comp cases (75%). Data suggests no differences between PT and surgery plus PT.			

					in combination with other medical treatments."	
Brox 1993 RCT	7.0	N = 125 rotator cuff disease for at least 3 months, resistant to outpatient physiotherap y and NSAID	Arthroscopic surgery vs. 12 sessions of detuned soft laser treatment for 6 weeks vs. 3-6 months of supervised exercises; 6 months follow- up.	Mean outcome scores comparing surgery group vs. placebo laser group vs. exercise group at baseline/3/6 months. Overall: surgery 64/84/87 vs. placebo 65.5/61/66 vs. exercise 67.5/74/86. Pain: 15/25/25 vs. 15/15/15 vs. 15/15/25. Function: 24/28/28 vs. 21/20/15 vs. 24/24/ 25. ROM: 18/19/22 vs. 21/19/ 22 vs. 19 vs. 19/21.5/23.	"Surgery or a supervised exercise regimen significantly, and equally, improved rotator cuff disease compared with placebo."	Baseline fewer women in surgery may bias against surgery. All required to have reduced pain at 15min after lignocaine injection. Baseline requirement for resistant to physiotherapy likely biases in favor of surgery.
Brox 1999 RCT follow- up of Brox 1993 above	7.0	N = 125 rotator cuff disease (same as above)	Arthroscopic surgery vs. supervised exercise regimen, 3-6 months vs. placebo, 6 weeks (same as above)	15/28 (53.6%) placebo laser and 11/44 (25.0%) physiotherapy crossed over to surgery. Success rate for surgery 26/38 (68.4%) and exercises 27/44 (61.4%) superior to placebo laser 7/28 (25%) (p <0.01). Neer scores (Excellent) at 2.5years surgery 22/38 (57.9%) vs. supervised exercises 23/44 (52.3%) vs. placebo laser 4/28 (14.3%).	"[A]fter 2 years of follow-up, both arthroscopic surgery and supervised exercises are better treatments than placebo. The difference between the 2 active treatments was not significant."	2.5 year follow- up of above trial. High crossover rates to surgery limit conclusions regarding prognosis over 2.5 year period from the various treatment options.
Rahme 1998 RCT	5.0	N = 49 subacromial impingement syndrome for duration of at least 1 year	Anterior acromioplasty (NEER) vs. physiotherapy. PT also started 3 months after surgery for 2-3 times a week. PT regimen not well described, but appears to have included education, advise to avoid positions, unloaded movement of shoulder, measures to normalize scapulohumeral rhythm and increase postural awareness and strengthening and endurance.	Total pain score for those who achieved a >50% pain reduction surgical group vs. physiotherapy group: 12/21(57%) vs. 6/18(33%).	"[S]urgical treatment is more effective than a standardized physiotherapy regime in patients with long-standing pain due to impingement syndrome."	Patients not well described. PT regimen does not appear to emphasize functional exercises, especially before 3 months may bias in favor of surgery.

Haahr 2006 RCT Long-term follow-up of above study (Haahr 2005)	4.0	N = 90 subacromial impingement (81 responded to questionnair e)	Subacromial decompression vs. conservative treatment with exercises; 4 to 8 year follow-up	Mean marginalization index comparing physiotherapy vs. surgery at 1st and 2nd year before treatment/1st/2nd/ 3rd/4th year after treatment: 0.29 $\pm$ 0.30 vs. 0.28 $\pm$ .25/0.25 vs. 0.45/ 0.27 vs. 0.40/0.26 vs. 0.30/0.24 vs. 0.20. Self-reported work status: working (%): 21 (53) vs. 20 (51); p = 0.88. Recovered or improved: 27 (67.5) vs. 23 (60.0). Worse or much worse: 3 (7.5) vs. 9 (23.1).	"The results of surgical decompression were equal to those of conservative treatment, and the surgery group had more income transferrals during the first year of follow-up."	Variable follow- up times for some outcome. Large database capture of functional and cost information.
				e: Open vs. Arthroscop		
Sachs 1994 RCT	5.0	N = 44 Stage II impingement, lack of response to at least 6 months non- operative treatment; negative arthrograms	Open surgery (n = 22) vs. arthroscopic surgery (n=19). 1 year follow-up.	Complete improvement in 13/22 (59.1%) open vs. 13/19 (68.4%) arthroscopic (NS). No differences in ROM at final 52-week assessment.	"[A]rthroscopic acromioplasty should become the procedure of choice for patients with impingement syndrome refractory to conservative treatment."	Faster return to work and recovery of range of motion at 2 weeks, but equivalent at 6 weeks or later.
Husby 2003 RCT	5.5	N = 39 impingement syndrome (Neer grade II)	Arthroscopic subacromial decompression (ASD) vs. open subacromial decompression (OSD); 8 year follow-up.	Pre-and post-op recordings (1month) of mean pain VAS comparing ASD vs. open: 41±25 vs. 37±25/16±18 vs. 24 vs. 24; p <0.05. UCLA scores (baseline/1/3/6/ 12/96 months): ASD (14/19/26/28/30/ 32) vs. open (16/18/26/27/31/ 32) (NS). Overall satisfaction 96 months ASD 95% vs. open 93% (NS).	This study found "[N]o differences in the clinical tests between the groups during this period. The use of ASD or OSD seems to be a matter of cosmesis and personal preference."	Long-term study (8 years). Tendency for longer duration of symptoms at baseline in open group (mean 32 vs. 19 months, NS) may bias against open. Data suggest long-term equivalency.
Lindh 1993 RCT	4.5	N = 20 impingement syndrome. Failed non- operative treatment and 3-8 injections	Arthroscopic subacromial decompression (n = 10) vs. open acromioplasty according to Neer $(n = 10)$ . 2- year follow-up.	No full-thickness tears found at surgery. No differences at 2 years for ROM. Mean UCLA scores 29 both groups. Women 24 points vs. men 32 points (p <0.005).	"Long-term functional results level [sic] those after the open anterioracromioplasty [T]he arthroscopic method is the authors' method of choice for treating shoulder impingement surgically."	Sparse details. Small sample size. No short or intermediate term follow-up, only 2- yr follow-up.
Norlin 1989 RCT	4.5	N = 20 impingement syndrome, failing non-	Arthroscopic decompression vs. Neer open acromioplasty; 3	Greater active flexion and abduction in arthroscopic group (p = 0.015 and p =	"Arthroscopic subacromial decompression appears to be	Small sample size. Data suggest superior short to

Weber 1997 RCT	4.0	operative treatment and average 3.6 and 5.1 years duration N = 65 with partial thickness rotator cuff tears	Months follow- up.	0.004). UCLA scores: arthroscopic 22.7 vs. open 31.6 (p <0.05). Excellent/good results: arthroscopic 14/31 (45.2%) vs.	superior to open acromioplasty as a treatment for impingement syndrome." "The outstanding results of prior studies of cuff debridement were not duplicated in this series of patients	intermediate term results with arthroscopic decompression Results suggest mini-open repair superior to debridement.
Ingvarsson 1996 RCT	4.0	N = 20 with chronic impingement syndrome of shoulder	Anterior acromioplasty following Neer technique (Group A, n = 10) vs. anterior acromioplasty following modified Neer (Group B, n = 10); 8 weeks follow-up.	31/33 (93.9%). Range of motion (pre/4 weeks/8 weeks): flexion; Group A (115/130/150) vs. group B (125/140/160), p >0.05, abduction; Group A (105/120/145) vs. Group B (80/135/160), p <0.05.	with long-term follow- up." "This modification of the Neer acromioplasty spares the deltoid origin and has benefits as an alternative to the standard procedure."	Small sample sizes. Minimal description of patients and methods.
	1	Imr	pingement Syndron	ne: Comparisons of Teo	chniques	
Taverna 2007 RCT	8.5	N = 60 Stage 2 impingeme nt and Type 2 acromion	Arthroscopic decompression vs. radiofrequency- based plasma microtenotomy; 12-month follow- up.	ASES score >90 (3/6/12months): microtenotomy (16.7%/80%/100%) vs. subacromial decompression (0/50%/100%). SF-36 physical function results nearly identical.	"Both procedures were associated with significant improvement postoperatively, but the RF-based plasma microtenotomy procedure draws into question the need for a more extensive procedure such as subacromial decompression in this patient population."	Data suggest comparable efficacy.
Diab 2009 RCT	5.0	N = 40 chronic shoulder impingeme nt	Subacromial arthroscopic decompression with bipolar vs. monopolar radio- frequency. No follow-up beyond OR.	Procedure time for coblation group 13 minutes vs. 21 for monopolar, p <0.0001. Cost differences £111 more in coblation group, p <0.003.	"Bipolar RD is the instrument of choice inn arthroscopic shoulder surgery, as it saves time and money."	No baseline description of patients. No clinical outcomes or follow-up of any duration beyond operative suite limits utility for guidance.
Murphy 1999 RCT	4.5	N = 49 refractory Neer stage II impingemen t, failed PT, at least 4 months duration; good pain relief with lidocaine injection	Arthroscopic sub- acromial decompression with electrocautery (n = 25) vs. holmium Yag laser 20W (n = 24) to ablate bursa and periosteum, release coracoacromial ligament,	No difference in operative times (122 vs. 124 minutes). Hospital charges for laser significantly different than electrocautery at \$1127 more, p = 0.003 (total mean \$6,166 vs. \$5,039). UCLA scores (pre/1 month/1 year): cautery	"Our data show no medical advantage in laser assistance for arthroscopic subacromial decompression."	Baseline differences with higher UCLA scores, more workers' comp in cautery group. Laser requires laser tech or specially trained nurse and payment to help cover capital cost of system.

	maintain hemostasis.	(20±4/24±5/30±5) vs. laser (18±3/23±5/32±4).	Hospital charges 23% higher with laser (increased \$1,127), but outcomes not different.
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## POST-OPERATIVE REHABILITATION: ROTATOR CUFF TENDINOPATHY

Post-operative rehabilitation has been empirically derived and has emphasized a graded return to normal function. It is generally believed that earlier advancement of flexibility, strengthening, and conditioning exercises results in faster recovery; (Klintberg 08) however, initiating rehabilitation early in the healing process has also been thought to increase potential for failure of surgical repairs such as rotator cuff repairs and has provided some caution regarding early use of exercise. There are multiple variables that affect the timing of exercises after shoulder surgery. These include the procedure performed, pre-operative physical condition, age, and patient compliance. (Conti 09) The following recommendations assume that the patient is in satisfactory physical condition, has had a good immediate surgical result, is adequately compliant, and has no contraindications to initiating a rehabilitation program.

1. Recommendation: Exercise or Rehabilitation Programs for Post-operative Rotator Cuff Tendinopathy A post-operative exercise or rehabilitation program is recommended for post-operative rotator cuff tendinopathy patients.

Indications - All rotator cuff tendinopathy patients.

*Frequency/Duration* – Programs need to be individualized based on factors including age, preoperative condition, immediate surgical results, contraindications, and other medical conditions; advancement of the program also must be individualized based on progress. Programs and protocols should be closely coordinated with the treating orthopedist, particularly as variability in patients is wide – although workers' compensation patients tend to be younger, in better condition, and able to advance conditioning exercises more rapidly than the elderly. Duration is based primarily on progress. Highly motivated patients may require only weekly sessions for advancement of home exercise program components and may achieve comparable outcomes to a supervised program. (Roddey 02; Andersen 99) Others require more supervision, particularly if there is significant pain with use. Programs generally begin with appointments 2 or 3 times weekly and gradually taper as home exercises are instituted and the patient's recovery advances. Courses of up to 3 months in more severe cases may be needed, although most patients require 6 to 8 weeks of supervised programs.

Strength of Evidence – **Recommended**, Evidence (C)

2. Recommendation: Post-operative Acupuncture for Rotator Cuff Tendinopathy Post-operative acupuncture is recommended particularly for post-operative rotator cuff tendinopathy patients with significant pain as an adjunct to an active exercise rehabilitation program. (Gilbertson 03)

*Frequency/Duration* – See Acupuncture Medical Treatment Gudeilines for recommended frequency, duration, and discontinuation.

## Strength of Evidence – Recommended, Evidence (C)

#### Rationale for Recommendations

There are six moderate-quality trials involving rotator cuff tendinopathy patients. The highest quality study followed patients for more than 2 years and compared a traditional group (active-assisted ROM on day of surgery, dynamic exercises for rotator cuff after 6 weeks, and strengthening after 8 weeks) versus progressive group (active-assisted ROM and dynamic RC exercises day of surgery, strengthening after 6 weeks) versus home exercise. Many outcome measures favored the progressive exercise group. Two moderate-quality trials suggested that weekly supervised appointments to advance a home-exercise program was equivalent to a traditional rehabilitation program. (Roddey 02; Andersen 99)

There is one moderate-quality trial suggesting no benefits of continuous passive motion (CPM) postoperatively; however, this study appears underpowered (Raab 96) and thus there is no recommendation. Another moderate-quality trial suggested this CPM device may have benefits among patients living alone, concerns about adhesions or adhesive capsulitis, repeat rotator cuff repairs, and repair of massive tears. (Lastayo 98)

There are other regimens utilized in quality surgical trials that demonstrate good surgical outcomes, yet there are considerable differences among the reported post-operative rehabilitation studies and trials. These include active-assisted ROM 5 times daily and restoration of rotator cuff muscles and scapular stabilizers after full flexibility is accomplished; (Jackins 04) submaximum training begun 3 months after surgery; (Rahme 98) active-assisted ROM immediately after surgery; and eccentric and concentric, isokinetic and manual strengthening at 6 to 12 weeks. (Wilk 93) "No prospective randomized studies have shown rehabilitation with graded exercises to be more effective than other interventions after arthroscopic subacromial decompression. Neither has different progression in workload intensity after this procedure." (Klintberg 08)

The highest quality surgical trial comparing detailed exercise with arthroscopic decompression for impingement syndrome utilized a regimen of exercise, hot and cold applications, and soft tissue treatments followed by active periscapular muscle training for strengthening the rotator cuff. There were 19 total sessions until discharge to a home-exercise program. (Haahr 05) A second trial is not well described. (Brox 93) Another trial included active and passive shoulder mobilization and stabilizing muscle training. (Rubenthaler 03) Exercise programs are not invasive, have low potential for adverse effects, but generally involve at least moderate to high aggregate costs. They are recommended, although individualization appears necessary and supervised home-exercise programs may suffice for some patients.

Author/Titl e Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			Post-surger	y Rehabilitation		
Klintberg 2008 RCT	5.5	N = 34 shoulders underwent subacromial decompressi on	Traditional group (TG) active- assisted ROM day of surgery, dynamic exercise for cuff after 6 weeks and strengthening after 8 weeks vs. progressive group (PG) active- assisted ROM and dynamic RC exercises day of surgery, strengthening after 6 weeks vs. home exercise. Possibly both PT groups had manual stretching for flexibility; 2-year follow-up.	Trends towards earlier reductions (baseline/6 weeks/6 months/24 months): in pain with activity, increased strength measures, flexion, constant scores (PG 57/67/84/87 vs. TG 46/48/72/67); functional index of shoulder (PG 41/39/15/6 vs. TG 55/61/17/23) among progressive vs. traditional group (several of these outcome measures significant, p <0.05).	"Early activation using a comprehensive, well-defined and controlled physiotherapy protocol can be used safely after arthroscopic subacromial decompression."	Pilot study; baseline not well described. Different sample sizes for reasons unclear: 20 vs. 14 vs. 6. "This third group was originally included in the study but was excluded due to a small sample size, as only 4 patients fulfilled inclusion criteria after surgery." (Criteria not specified). Data suggest considerable improvements with earlier active exercises in progressive group.

Evidence for Post-operative Rehabilitation for Rotator Cuff Tendinopathy

There are 6 moderate-quality RCTs incorporated into this analysis. There are 4 low-quality RCTs in Appendix 2.

Roddey 2002 RCT (Roddey 2005, second report of same study).	4.0	N = 129 arthroscopic repairs of full-thickness rotator cuff tears	Rehabilitation consisting of exercise instructions via videotape vs. 4 one-on-one instruction sessions given by a physical therapist; 1-year follow-up.	Mean SPADI (VAS) pain scores comparing video vs. PT group pre- surgical/12/24/52 weeks: $60.4\pm22.1$ vs. $52.3\pm21.6$ ; p = $0.06/32.0\pm19.7$ vs. $26.7\pm18.8$ ; p = $0.17/18.1\pm16.1$ vs. $15.3\pm15.2$ ; p = $0.40/12.3\pm14.3$ vs. $12.4\pm14.4$ ; p = 0.99.	"With a therapist available for questions, patients who utilized the videotape method for their home program instruction had self-reported outcomes equal to patients instructed in their home program personally by a physical therapist. Self- reported compliance with the rehabilitation program had little effect on the outcomes."	Home exercise pro- gram had 4 visits that included assessments of progress/ advancement of program, thus appears not totally self-directed. Trend towards more compliance in PT group [fully compliant 25/54 (46.3%) video vs. 36/54 (66.7%) PT p = 0.07]. Data suggest no differences despite different compliance.
Andersen 1999 RCT	4.0	N = 43 subacromial shoulder impingement resistant to conservative therapy over 8 months without full thickness tears	Self-training (n = 22) vs. physiotherapy (n = 21) 6 weeks arthroscopic subacromial decompression; 1 year follow-up. All patients pendulum exercises 2 weeks, sling for comfort, active training at 2 weeks, and strengthening exercises with rubber tubes at 6 weeks.	Pain scores (baseline/3/6/12 months): self- training (7.0/10.6/12.9/12.5 ) vs. PT (6.0/8.8/11.6/12.2), p = 0.032 for worse pain scores in PT group at 3 months. Constant scores: self- training (53/69/77/79) vs. PT (54/66/76/80).	"[T]here is no beneficial effect of physiotherapist- guided rehabilitation when compared with a simple self-training regimen in patients with subacromial impingement treated with arthroscopic decompression."	Some baseline differences. Data suggest no benefit for PT over self- training.
	ĩ		surgery Rehabilitatio			
Raab 1996 RCT	5.5	N = 32 having undergone rotator cuff tear repair.	Physical therapy with vs. without continuous passive motion (recovery room and for 3 weeks); 3-month follow-up.	Shoulder score (pre-op/3 months): CPM+PT (68/83) vs. PT (63/73). Large tears: CPM +PT (64/82) vs. PT (60/76). Age ≥60 years: CPM+TP (60/79) vs. PT (63/65), p = 0.036.	"CPM has no effect on overall shoulder score at 3-month follow-up. CPM has a beneficial effect on ROM for all patients, as well as on pain relief in female patients and patients of ≥60 years of age."	More large, massive tears in CPM group (57 vs. 25%) may have biased towards null. Most results trended in favor of CPM, but NS. Significant increase in 60+ year-old group. Results suggest under- powering.
Lastayo 1998 RCT	4.0	N = 31 (32 open repaired rotator cuffs – 5 small, 18 medium, 9 large)	Continuous passive motion for 4 weeks post-op (n = 17) vs. manual passive ROM exercise (n = 15); mean 22 months follow-up.	SPADI scores not different between groups. Pain scores first 4 weeks higher with manual ROM than CPM, especially 1st week (p = 0.046). Decrease in pain for both groups at post- operative Weeks 1 and 4, but no	"[C]ontinuous passive motion and manual passive range-of- motion exercises contributed postoperatively to the range of motion, strength, function, and relief of pain; however, we could detect no significant	No major benefits of continuous passive motion compared with manual passive ROM; data trended to reduced pain especially 1st week; pain scores 8.1 vs. 5.1 (interpretation of graphic data). ROM did not favor either

				significant differences between groups. No significant difference between groups for ROM, p >0.20.	difference in the clinical outcome between the two groups."	group. Authors recommend CPM for patients living alone, concerns about adhesions, repeat RC repairs, adhesive capsulitis, and repair of massive tear.
			Post-surgery Reha	bilitation: Acupunctu	ire	
Gilbertson 2003 RCT	5.5	N = 40 having undergone arthroscopic acromioplast y for shoulder impingement syndrome; most had distal claviculectom y	Acupuncture vs. sham acupuncture 3-8 days after surgery. Locations not noted. Appears all had physical therapy that included passive ROM, active ROM, strengthening, hot packs, cold packs)	UCLA shoulder scale scores favored real acupuncture (graphic data, p <0.001). (Baseline values not given. First values at Visit 4 different, 14 vs. 18, and rose to 23 vs. 34 at 4 months. Less analgesic use in real acupuncture group (p <0.008).	"Following arthroscopic acromioplasty, real acupuncture compared to sham acupuncture offered significantly greater improvement."	Blinding procedures not described. Acupuncture needle placement not standardized. "Some" needles stimulated 2.5- 150Hz. High dropouts in sham group.

## BICIPITAL TENDINOSIS AND RUPTURED BICIPITAL TENDON

Bicipital tendinosis involving the proximal long head of the biceps tendon (bicipital tendon) is usually due to degenerative changes in the tendon or wear in the bicipital groove. It is believed to be analogous to and have the same pathophysiological basis as the rotator cuff. It is recommended that bicipital tendinosis be managed as noted in the Rotator Cuff Tendinopathies section, including the use of low-dose glucocorticosteroid injection. Bicipital tendon rupture may be managed non-operatively as there is no accompanying functional disability. Surgery, a tenodesis, may be desired for cosmetic reasons, especially in bodybuilders or others concerned with cosmesis, but it is not necessary for restoration of function. (Baumann 08)

#### Recommendation: Surgery for Select Patients with Bicipital Tendon Tears Surgery is recommended for select patients with bicipital tendon tears.

*Indications* – Rare patients with significant incapacity due to the tear, generally having high demand jobs. Surgical procedure is usually tenodesis and not repair.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

## PECTORAL STRAINS AND TEARS

Pectoral muscle tears or strains usually occur in the course of overwhelming force, particularly in athletics involved in football or weight lifting. The most common mechanism is tear while bench pressing heavy weight or similar trauma with eccentric loading of the pectoralis major muscle. There can be actual tendon avulsion of the sternal head of pectoralis major (rarely entire including clavicular head) or injury a myotendinous or intra muscular site. (The term "strain" is sometimes erroneously utilized to label virtually any muscle pain or ache, rather than the denotation of a muscle-tendon junction partial or complete disruption.) Rare cases are related to occupational injuries, typically involving exertion of a supramaximal force. There are no quality studies evaluating treatment for these disorders. As these strains are true muscle-tendon unit strains, limitations are particularly indicated to alleviate forceful exertions while allowing sufficient time to health the strain (see Rotator Cuff Tendinopathies). For complete tears or ruptures of the pectoralis insertion, surgical repair is recommended.

Recommendation: Surgery for Patients with Complete Tears or Ruptures of the Pectoralis Insertion Surgery is recommended for patients with complete tears or ruptures of the pectoralis insertion.

Strength of Evidence – Recommended, Insufficient Evidence (I)

## SHOULDER DISLOCATION AND INSTABILITY

Shoulder dislocation typically occurs after trauma including athletic injury, (Kirkley 99; Sherbondy 00) although some dislocations may occur in the absence of trauma with conditions such as hyperlaxity. (Kakar 07; Reinold 03) The general prevalence of shoulder dislocation is noted to be about equal before and after age 40 years old, although the pathophysiology and associated injuries change with advancing age. Individuals under 40 generally have dislocations due to accidents, (Hovelius 87) with increased risk in the elderly likely related to falls. (Simonet 84) The primary pathology in younger patients is labral tearing and capsular stretching. With advancing age, rotator cuff tear and associated proximal humerus fracture become more common. The lifetime cumulative incidence has been estimated at 2%. (Kirkley 98) A population-based incidence estimate of initial traumatic anterior shoulder dislocations was 8.2/100,000 person-years. (Simonet 84) The most common type of dislocation is caused by forced abduction with external rotation and results in anterior and inferior dislocation of the humeral head. Posterior dislocation of the humeral head typically results from direct blow to anterior shoulder (posteriorly directed force) or fall onto outstretched hand; it is much less common than anterior dislocation (Kakar 07) The classic presentation of a posterior glenohumeral dislocation is an internally rotated shoulder with inability to elevate or externally rotate. The anterior shoulder appears flattened and the posterior shoulder is more prominent. After an initial shoulder dislocation, recurrence is the most commonly reported sequela with rates as high as 100% in adolescent athletes. (Good 05) Recurrences generally occur with a less traumatic event or no trauma at all. The direction of the dislocation and resultant instability is important for diagnostic purposes, as well as planning potential surgical repair. (Dalton 89)

Once a shoulder has dislocated, it can be prone to symptoms of instability, termed "shoulder instability." (Friedman 95) Shoulder instability is defined as pain associated with loss of shoulder function due to excessive translation of the humeral head in the glenoid fossa. (Friedman 95) Instability is more commonly anterior, however posterior, multi-directional and inferior instability also occur. When instability has been identified, non-operative treatment is usually recommended prior to attempted surgical repair. (Friedman 95; Buss 04)

Non-operative treatment has been traditionally recommended for anterior dislocation, (Hovelius 96; Wen 99; Aronen 84; Burkhead 92; Line 99; Liu 96) although recent evidence supports early surgical repair after the first dislocation in younger patients in order to prevent recurrence. (Kirkley 99, 05; Bottoni 02; Jakobsen 07; Robinson 08) Regardless, surgery has been traditionally utilized among patients with recurrent dislocations or among athletes. (Bottoni 02; Edmonds 03; Larrain 01)

## **DIAGNOSTIC CRITERIA**

The literature on physical examination maneuvers for instability has major limitations. (Luime 04) The relocation and anterior release tests and apprehension signs may be used to demonstrate instability to aid diagnosis.(Luime 04) Biceps load I and II tests and internal rotation resistance strength are thought to be more helpful for diagnosing labral lesions; (Luime 04) however, there are no standardized diagnostic criteria.

## SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS

X-ray and MRI are used to diagnose shoulder dislocation or instability. Dislocations require plain radiograph (axillary lateral view) or CT scan to visualize the humeral head in glenoid. X-rays may be needed of both shoulders, particularly if there were a bilateral injury or a need for comparison with the unaffected shoulder. Other studies may be helpful, including MRI, MR arthrogram, or CT arthrogram, especially for evaluation of potential concomitant Bankart lesions or labral or rotator cuff tears. (Kirkley 03; Friedman 95; Sherbondy 00)

- Recommendation: X-ray to Diagnose Shoulder Dislocation or Instability X-ray is recommended to diagnose shoulder dislocation or instability.
   Strength of Evidence – Recommended, Insufficient Evidence (I)
- Recommendation: CT to Diagnose Fracture after Dislocation
   CT is recommended to diagnose shoulder dislocation or instability.
   Strength of Evidence Recommended, Insufficient Evidence (I)
- 3. Recommendation: MRI to Diagnose Shoulder Dislocation or Instability MRI is recommended to diagnose shoulder dislocation or instability.

Strength of Evidence – Recommended, Insufficient Evidence (I)

## WORK ACTIVITIES

Patients with acute dislocations are generally able to return to occupational activities; however, rates of return appear lower for highly physically demanding jobs and athletic endeavors. (Zamora-Navas 01) Limitations, if needed, are gradually reduced as recovery progresses. Most workers continue to perform their job tasks while avoiding activities that provoke feelings of instability or frank dislocations even without formal restrictions. If surgery is performed, there is a similar need for workplace limitations which are gradually reduced.

## **INITIAL CARE**

In the absence of fractures, initial care of a dislocation involves relocation as soon as possible. Anesthesia may be required if there is sufficient muscle tightness or spasm and manual relocation is unsuccessful. Surgery may be required for cases with fractures (see Surgery). Over-the-counter analgesics and self-applications of heat and ice are recommended, and slings may be attempted for treatment acutely, with use gradually weaned. Patients with instability generally require no treatment other than attempts at exercises and surgery.

- 1. Recommendation: OTC Analgesics for Treatment of Shoulder Dislocation Over-the-counter analgesics are recommended for treatment of shoulder dislocation. Strength of Evidence – Recommended, Insufficient Evidence (I)
- 2. Recommendation: Self-application of Heat or Ice for Treatment of Shoulder Dislocation Self-application of heat or ice is recommended for treatment of shoulder dislocation. Strength of Evidence – Recommended, Insufficient Evidence (I)
- 3. Recommendation: Slings, Including an External Rotation Brace, for Initial Treatment Acutely for Shoulder Dislocation

Slings, especially an external rotation brace, are recommended for initial treatment acutely for shoulder dislocation.

*Frequency/Duration* – Gradually wean. Pendulum exercises are generally recommended including within the first few days after injury.

## Strength of Evidence – Recommended, Evidence (C)

#### Rationale for Recommendations

There are no quality trials evaluating analgesics, ice, or heat for management of acute shoulder dislocations. Slings are often helpful for managing acute pain and help soft tissue healing. An external rotation brace may be used instead of a sling and is intended to reduce a labral tear accompanying an anterior dislocation so that it can heal in a more normal position and prevent recurrence. (Finestone 09; Itoi 03, 07) These treatments are not invasive, have low adverse effects, are not costly, and are believed to be helpful for treating symptoms. Thus, they are recommended for management and treatment of acute shoulder dislocations.

Evidence for the Use of Slings for Shoulder Dislocation

Author/Title	Scor	Sample	Comparison	Results	Conclusion	Comments
Study Type	e (0- 11)	Size	Group			
Type			External Rotatio	n Bracing vs. Simple SI	ing	
ltoi 2007 RCT	6.0	N = 198 with initial anterior dislocation of shoulder, reduced manually (age 12-90 years, average 37 years)	IR group = 94 shoulders conventional immobilization (sling and swathe), ER group = 104 shoulders immobilized in 10 deg external rotation. Immobilization 3 weeks.	Intention-to-treat analysis showed recurrence rate IR = 42%, ER = $26%$ (p = 0.033) with relative risk reduction $38.2\%$ . In patient subgroup 30 years of age or younger, relative risk reduction was $46.1\%$ . Recurrence rate $21$ - 30 years IR = $52%$ , ER = $24\%$ (p = 0.037).	"Immobilization in external rotation after an initial shoulder dislocation reduces the risk of recurrence compared with that associated with the conventional method of immobilization in internal rotation. This treatment method appears to be particularly beneficial for patients who are thirty years of age or younger."	Poor compliance in IR group; 82 to 84% of recurrences noted within 12 months after injury. Possible bias instructing immobilization leading to better compliance. Positioning seemed to make a difference when immobilization started day of injury, but few patients seen on day 2 or 3. Data suggest external bracing superior.
Finestone 2009 RCT	5.5	N = 51 males (age 17-27, mean 20.3) with primary traumatic anterior dislocation shoulder (n = 40 soldiers)	IR group = 24 tradition immobilization internal rotation. ER group = 27 immobilized in 15- 20 deg external rotation. Immobilization 4 weeks.	Mean follow-up 33.4 months (24-48 months). Further dislocation: IR = 41.7%, ER = 37% (p = 0.74). No statistical difference in the rate of recurrence between those immobilized in external or internal rotation.	"Our findings show that external rotation bracing may not be as effective as previously reported in preventing recurrent anterior dislocation of the shoulder."	Subjects very dissimilar to Itoi studies. Compliance excellent in both groups. Data suggest comparable efficacy.
ltoi 2003 RCT	5.0	N = 40 initial anterior dislocation of shoulder, after manual reduction (age 17-84)	IR group = 20 conventional immobilization (sling and swathe), ER group = 20 immobilized in 10 degrees external rotation. Immobilization 3 weeks.	IR group 30% recurrence rate of dislocation, ER group 0% ( $p = 0.008$ ) Patients under 30: 45% IR recurrence, 0% ER ( $p = 0.011$ ). Mean follow-up 15.5 months.	Immobilization in external rotation after shoulder dislocation is better than conventional immobilization in a sling in internal rotation in terms of reducing recurrent dislocations.	Short-term follow- up/few patients. Based on patient report of dislocations and anterior apprehension test. Data suggest external rotation better.
Liavaag	5.5	N = 55 with	parison of Immobiliz Immobilization with	ation: external vs. inter Before treatment, 47	"nal rotation "Immobilization in	Data suggest that
2009 RCT		primary anterior shoulder dislocation. Age 16-40.	arm in external rotation (ER; n = 28) vs. immobilization with arm in internal rotation (IR; n =27). All patients used immobilizer more than 16 hours every day and night for 3 weeks.	of 55 patients had Bankart lesion. There was a difference (p = 0.04) between groups in favor of ER group vs. IR group [OR: 3.8 95% Cl: 1.1–13.3)] in the Bankart lesions detected in MRI and in MRI arthrography.	ER results in improved coaptation of the labrum after primary traumatic shoulder dislocation."	immobilizations in external rotation had better outcomes than immobilization in internal rotation. Follow-up was highly variable.

## **FOLLOW-UP VISITS**

Generally, patients with instability require few follow-up appointments unless undergoing active treatment(s). Patients with dislocation generally require periodic appointments to follow the clinical course. Appointment frequency may be greater if workplace limitations are required and job demands are greater. Post-operative rehabilitation can be lengthy, particularly in older patients with associated injuries such as those of the rotator cuff. In those cases, therapy may be required on a prolonged basis in order for the patient to recover as much function as possible.

## **MEDICATIONS**

NSAIDs and acetaminophen are recommended for pain management for patients with shoulder dislocation. Prescription medications might be needed in moderate to severe cases (see Medications, Rotator Cuff Tendinopathy). In select cases, patients may require judicious short term use of opioids for acute pain management. Other recommended medications for pain management include muscle relaxants, capsaicin, tricyclic anti-depressants or dual reuptake inhibiting anti-depressants for chronic pain (but not SSRI antidepressants which are not effective for nociceptive pain), or gabapentin for perioperative use. Patients with instability generally require no medication other than post-operatively.

1. Recommendation: NSAIDs and Acetaminophen for Acute, Subacute, or Chronic Shoulder Dislocation or Post-operatively

NSAIDs and acetaminophen are recommended for acute, subacute, or chronic shoulder dislocations or for use post-operatively.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Opioids for Pain Management for Select Patients with Acute Shoulder Dislocations

Judicious short term use of opioids is recommended for pain management for select patients with acute moderate to severe pain associated with shoulder dislocation.

Indications – Patients should meet all of the following:

- 1) Severe injury with a clear rationale for use (objective functional limitations due to pain resulting from the medical problem.<sup>ix</sup>
- Other more efficacious treatments should have been instituted,<sup>x</sup> and either:
   2a) failed and/or

2b) have reasonable expectations of the immediate need for an opioid to obtain sleep the evening after the injury.

- Where available, prescription databases (usually referred to as Prescription Drug Monitoring Program (PDMP)) should be checked and not show evidence for conflicting opioid prescriptions from other providers or evidence of misreporting.<sup>xi</sup>
- 4) Non-opioid prescriptions (e.g., NSAIDs, acetaminophen) absent contraindication(s) should nearly always be the primary treatment and accompany an opioid prescription.
- 5) Low-dose opioids may be needed in the elderly who have greater susceptibility to the adverse risks of opioids. Those of lower body weight may also require lower opioid doses.
- 6) Dispensing quantities should be only what is needed to treat the pain. Short-acting opioids are recommended for treatment of acute pain. Long-acting opioids are not recommended.
- 7) Due to greater than 10-fold elevated risks of adverse effects and death, considerable caution is warranted among those using other sedating medications and substances including: i) benzodiazepines, ii) antihistamines (H<sub>1</sub>-blockers), and/or iii) illicit substances.<sup>(105, 109, 167, 168)</sup> Patients should not receive opioids if they use illicit substances unless there is objective evidence of significant trauma or moderate to severe injuries. Considerable caution is also warranted among those who are unemployed as the reported risks of

<sup>&</sup>lt;sup>ix</sup>Other indications beyond the scope of this guideline include acute myocardial infarction or agitation interfering with acute trauma management.

<sup>&</sup>lt;sup>x</sup>Treatments to have tried generally include NSAIDs and acetaminophen. For LBP patients, additional considerations include muscle relaxants, progressive aerobic exercise, and directional exercise.

<sup>&</sup>lt;sup>xi</sup>Exceptions such as acute, severe trauma should be documented.

death are also greater than 10-fold.<sup>(109, 167)</sup> Due to elevated risk of death and adverse effects, caution is also warranted when considering prescribing an opioid for patients with any of the following characteristics: depression, anxiety, personality disorder, untreated sleep disorders, substance abuse history, current alcohol use or current tobacco use, attention deficit hyperactivity disorder (ADHD), post-traumatic stress disorder (PTSD), suicidal risk, impulse control problems, thought disorders, psychotropic medication use, chronic obstructive pulmonary disease (COPD), asthma, or recurrent pneumonia.<sup>(78, 102, 104, 108, 109, 169-186)</sup> Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis and/or cirrhosis,<sup>(187)</sup> as well as coronary artery disease, dysrhythmias, cerebrovascular disease, orthostatic hypotension, asthma, recurrent pneumonia, thermoregulatory problems, advanced age (especially with mentation issues, fall risk, debility), osteopenia, osteoporosis, water retention, renal failure, severe obesity, testosterone deficiency, erectile dysfunction, abdominal pain, gastroparesis, constipation, prostatic hypertrophy, oligomenorrhea, pregnancy, human immunodeficiency virus (HIV), ineffective birth control, herpes, allodynia, dementia, cognitive dysfunction and impairment, gait problems, tremor, concentration problems, insomnia, coordination problems, and slow reaction time. There are considerable drug-drug interactions that have been reported (see Opioids Guideline, Appendices 2-3).

*Frequency/Duration* – Generally, opioids should be prescribed at night or while not working.<sup>(82)</sup> Lowest effective, short-acting opioid doses are preferable as they tend to have the better safety profiles, less risk of escalation,<sup>(188)</sup> less risk of lost time from work,<sup>(112)</sup> and faster return to work.<sup>(189)</sup> Short-acting opioids are recommended for treatment of acute pain and long-acting opioids are not recommended. Recommend opioid use as required by pain, rather than in regularly scheduled dosing.

If parenteral administration is required, ketorolac has demonstrated superior efficacy compared with opioids for acute severe pain,<sup>(190, 191)</sup> although ketorolac's risk profile may limit use for some patients. Parenteral opioid administration outside of obvious acute trauma or surgical emergency conditions is almost never required, and requests for such treatment are clinically viewed as red flags for potential substance abuse.

*Indications for Discontinuation* – Resolution of pain, sufficient improvement in pain, intolerance or adverse effects, non-compliance, surreptitious medication use, consumption of medications or substances advised to not take concomitantly (e.g., sedating medications, alcohol, benzodiazepines), or use beyond 2 weeks.

Harms - Adverse effects are many (see section below on "Opioids Benefits and Harms").

Benefits - Improved short-term pain control.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Opioids for Acute, Severe Post-operative Shoulder Pain from Shoulder Dislocation Judicious short term use of opioids is recommended for treatment of acute, severe post-operative pain due to shoulder dislocation.

Indications - Patients should meet all of the following:

- 8) Severe injury with a clear rationale for use (objective functional limitations due to pain resulting from the medical problem.<sup>xii</sup>
- 9) Other more efficacious treatments should have been instituted,<sup>xiii</sup> and either:
   2a) failed and/or

2b) have reasonable expectations of the immediate need for an opioid to obtain sleep the evening after the injury.

 Where available, prescription databases (usually referred to as Prescription Drug Monitoring Program (PDMP)) should be checked and not show evidence for conflicting opioid prescriptions from other providers or evidence of misreporting.<sup>xiv</sup>

<sup>&</sup>lt;sup>xii</sup>Other indications beyond the scope of this guideline include acute myocardial infarction or agitation interfering with acute trauma management.

x<sup>iii</sup>Treatments to have tried generally include NSAIDs and acetaminophen. For LBP patients, additional considerations include muscle relaxants, progressive aerobic exercise, and directional exercise.

- 11) Non-opioid prescriptions (e.g., NSAIDs, acetaminophen) absent contraindication(s) should nearly always be the primary treatment and accompany an opioid prescription.
- 12) Low-dose opioids may be needed in the elderly who have greater susceptibility to the adverse risks of opioids. Those of lower body weight may also require lower opioid doses.
- 13) Dispensing quantities should be only what is needed to treat the pain. Short-acting opioids are recommended for treatment of acute pain. Long-acting opioids are not recommended.
- 14) Due to greater than 10-fold elevated risks of adverse effects and death, considerable caution is warranted among those using other sedating medications and substances including: i) benzodiazepines, ii) antihistamines (H<sub>1</sub>-blockers), and/or iii) illicit substances.<sup>(105, 109, 167, 168)</sup> Patients should not receive opioids if they use illicit substances unless there is objective evidence of significant trauma or moderate to severe injuries. Considerable caution is also warranted among those who are unemployed as the reported risks of death are also greater than 10-fold.<sup>(109, 167)</sup> Due to elevated risk of death and adverse effects, caution is also warranted when considering prescribing an opioid for patients with any of the following characteristics: depression, anxiety, personality disorder, untreated sleep disorders, substance abuse history, current alcohol use or current tobacco use, attention deficit hyperactivity disorder (ADHD), post-traumatic stress disorder (PTSD), suicidal risk, impulse control problems, thought disorders, psychotropic medication use, chronic obstructive pulmonary disease (COPD), asthma, or recurrent pneumonia.<sup>(78, 102, 104, 108, 109, 169-186)</sup> Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis and/or cirrhosis,<sup>(187)</sup> as well as coronary artery disease, dysrhythmias, cerebrovascular disease, orthostatic hypotension, asthma, recurrent pneumonia, thermoregulatory problems, advanced age (especially with mentation issues, fall risk, debility), osteopenia, osteoporosis, water retention, renal failure, severe obesity, testosterone deficiency, erectile dysfunction, abdominal pain, gastroparesis, constipation, prostatic hypertrophy, oligomenorrhea, pregnancy, human immunodeficiency virus (HIV), ineffective birth control, herpes, allodynia, dementia, cognitive dysfunction and impairment, gait problems, tremor, concentration problems, insomnia, coordination problems, and slow reaction time. There are considerable drug-drug interactions that have been reported (see Opioids Guideline, Appendices 2-3).

*Frequency/Duration* – Generally, opioids should be prescribed at night or while not working.<sup>(82)</sup> Lowest effective, short-acting opioid doses are preferable as they tend to have the better safety profiles, less risk of escalation,<sup>(188)</sup> less risk of lost time from work,<sup>(112)</sup> and faster return to work.<sup>(189)</sup> Short-acting opioids are recommended for treatment of acute pain and long-acting opioids are not recommended. Recommend opioid use as required by pain, rather than in regularly scheduled dosing.

If parenteral administration is required, ketorolac has demonstrated superior efficacy compared with opioids for acute severe pain,<sup>(190, 191)</sup> although ketorolac's risk profile may limit use for some patients. Parenteral opioid administration outside of obvious acute trauma or surgical emergency conditions is almost never required, and requests for such treatment are clinically viewed as red flags for potential substance abuse.

*Indications for Discontinuation* – Resolution of pain, sufficient improvement in pain, intolerance or adverse effects, non-compliance, surreptitious medication use, consumption of medications or substances advised to not take concomitantly (e.g., sedating medications, alcohol, benzodiazepines), or use beyond 2 weeks.

Harms - Adverse effects are many (see section below on "Opioids Benefits and Harms").

Benefits – Improved short-term pain control.

#### Strength of Evidence - Recommended, Insufficient Evidence (I)

4. Recommendation: Opioids for Pain Management of Subacute or Chronic Pain from Shoulder Dislocation

Opioids are not recommended for pain management for patients with subacute or chronic pain associated with shoulder dislocation.

Strength of Evidence - Not Recommended, Insufficient Evidence (I)

<sup>&</sup>lt;sup>xiv</sup>Exceptions such as acute, severe trauma should be documented.

 Recommendation: Other Medications for Chronic Pain Management of Shoulder Instability Muscle relaxants, capsicum, tricyclic antidepressants, or dual reuptake inhibiting antidepressants (but not SSRI anti-depressants which are not effective for nociceptive pain) are recommended to control chronic pain associated with shoulder instability.

Strength of Evidence – Recommended, Insufficient Evidence (I)

6. Recommendation: Other Medications for Acute, Subacute, or Post-operative Pain Management of Shoulder Dislocation

There is no recommendation for or against the use of muscle relaxants, capsicum, tricyclic anti-depressants, dual reuptake inhibiting anti-depressants, or gabapentin to control pain associated with acute or subacute shoulder dislocation or for post-operative pain.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendations

There are no quality trials evaluating treatment of shoulder dislocations with medication. Instability with recurrent dislocation is more likely to cause acute pain with each dislocation rather than chronic pain. Chronic pain is more likely to be associated with a concurrent shoulder problem. The use of NSAIDs has been evaluated to treat many musculoskeletal disorders and found uniformly effective (see Rotator Cuff Tendinopathies). NSAIDs and acetaminophen are not invasive and have low adverse-effects profiles, particularly when used for short courses in occupational populations. Generic or over-the-counter formulations are low cost. Use of NSAIDs and acetaminophen also may help avoid treatment with opioids which have far worse adverse effect profiles (see Chronic Pain Guidelines). NSAIDs and acetaminophen are recommended for treatment of acute and post-operative dislocation patients. By analogy to treatment of other musculoskeletal conditions such as low back pain (see Low Back Complaints), acetaminophen is believed to be less efficacious, although it generally has a lower adverse effect profile.

There are no quality studies evaluating opioids for treatment of shoulder dislocation (see Rotator Cuff Tendinopathies and Chronic Pain Guidelines). Opioids have adverse effects with published evidence of high mortality risks. However, there are patients with severe pain, particularly acute dislocation patients, for whom the brief use of opioids, especially to facilitate sleep, is recommended. Opioids are not invasive, have high adverse effects for a pharmaceutical (although tolerance to many can develop relatively rapidly), and are low cost when generic formulations are used.

Other medications are rarely required for patients with dislocations, as the associated pain is usually acute and not subacute or chronic. Norepinephrine reuptake inhibiting anti-depressants (e.g., amitriptyline, doxepin, imipramine, desipramine, nortriptyline, protriptyline, maprotiline, and clomipramine) and mixed norepinephrine and serotonin inhibitors (e.g., venlafaxine, bupropion, and duloxetine) have evidence of efficacy for treating chronic low back pain and other chronic pain conditions (see Low Back Complaints and Chronic Pain Guidelines). However, while there is no quality evidence evaluating these medications for treating shoulder pain, they appear likely to be mildly effective for some shoulder pain patients, especially in cases involving the shoulder girdle and myofascial pain.

There are no quality studies that address the use of anti-convulsant agents to treat patients with shoulder pain. By analogy, there is quality evidence that topiramate is weakly effective for treating low back pain patients, and gabapentin is unhelpful (see Low Back Complaints). However, there is quality evidence that gabapentin reduces the need for opioids when administered as part of peri-operative hip surgery patients' pain management. (Pandey 04, Pandey 05, Radhakrishnan 05, Turan 04)

Skeletal muscle relaxants may be a reasonable alternative to spare opioid requirements in the acute recovery period and to facilitate sleep. However, they also can cause daytime somnolence, thus limiting their use. Skeletal muscle relaxants are not recommended for continuous management of subacute or chronic shoulder pain, although they may be reasonable options for select acute pain exacerbations or

for a limited trial as a 3rd- or 4th-line agent in more severely affected patients in whom NSAIDs and exercise have failed to control symptoms.

## DEVICES/PHYSICAL METHODS

A sling may be helpful for acute rehabilitation and for treatment of acute dislocations that have been relocated. A sling is not recommended for treatment of recurrent glenohumeral instability. Self-applications of heat or cryotherapies might be helpful for symptom modulation. Numerous other therapies including acupuncture, ultrasound, massage, education, and exercise, etc., have been used to treat dislocations. Taping, magnets, pulsed electromagnetic frequency and interferential have also been used to treat to treat shoulder dislocation and instability.

1. Recommendation: Slings for Acute Rehabilitation and Treatment of Acute Shoulder Dislocations Slings are recommended for acute rehabilitation and treatment of acute shoulder dislocations.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Slings for Treatment of Shoulder Instability Slings are not recommended for treatment of shoulder instability.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

3. Recommendation: Self-application of Heat or Cryotherapies for Treatment of Shoulder Dislocation Self-application of heat or cryotherapies is recommended for symptom modulation for shoulder dislocation.

Strength of Evidence – Recommended, Insufficient Evidence (I)

- 4. Recommendation: Acupuncture for Treatment of Chronic Pain from Shoulder Instability Acupuncture is recommended for treatment of chronic pain from shoulder instability. Strength of Evidence – Recommended, Insufficient Evidence (I)
- 5. Recommendation: Education and Exercise for Treatment of Shoulder Dislocation or Instability Education and exercise are recommended for treatment of shoulder dislocation and instability.

Strength of Evidence – Recommended, Insufficient Evidence (I)

Recommendation: Other Physical Methods for Treatment of Shoulder Dislocation or Instability
There is no recommendation for or against the use of diathermy, infrared therapy, ultrasound,
laser therapy, manual therapy, mobilization, manipulation, massage, high-voltage galvanic, Hwave stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation
(PENS), sympathetic electrotherapy, or transcutaneous electrical stimulation (TENS) for
treatment of shoulder dislocation or instability.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

7. Recommendation: Taping, Magnets, Pulsed Electromagnetic Frequency, or Interferential Therapy for Treatment of Shoulder Dislocation

Taping, magnets, pulsed electromagnetic frequency and interferential therapy are not recommended for the treatment of shoulder dislocation.

#### Strength of Evidence – Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

Slings often help manage acute pain associated with shoulder dislocations and help soft tissue healing. An external rotation brace may be used instead of a sling to treat anterior glenohumeral dislocations as most of these have an anterior inferior labral tear. The external rotation position reduces the labrum so that it can heal in a more anatomic position. (Itoi 01; Miller 04) Performance of pendulum exercises is usually indicated in part to prevent the potential development of adhesive capsulitis. Slings are not recommended for shoulder instability as the condition is chronic and slings promote debility over time. Education is often helpful for patient understanding of the condition and to facilitate exercises, especially in the post-operative period.

Acupuncture may be effective for treatment of chronic shoulder pain (see Rotator Cuff Tendinopathies). However, most patients with a dislocation or instability do not have chronic pain. Acupuncture might be indicated for select patients with chronic pain who do not have sufficient pain control with other interventions. Education and exercise may be useful to teach patients adaptive techniques and to facilitate continued participation in daily activities despite limitations of shoulder. While there is experimental evidence in cadavers supporting capsular shrinkage with thermal heating, (Hayashi 97) there is no quality evidence and thus there is no recommendation for the use of diathermy, infrared, ultrasound, laser, manual therapy, mobilization, manipulation, massage, high-voltage galvanic, H-wave stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, or transcutaneous electrical stimulation (TENS) for treatment of shoulder dislocation or instability.

## **INJECTIONS**

Injections are generally not required for dislocations and are not recommended for treatment of acute dislocations. Injections are occasionally needed subsequently for concomitant rotator cuff tendinopathies or among patients who have delayed recovery for unclear reasons and in whom an empiric injection for diagnostic and therapeutic purposes is performed (see Rotator Cuff Tendinopathy Injections).

Recommendation: Injections for Treatment of Acute Shoulder Dislocation Injections are not recommended for treatment of acute shoulder dislocation.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## SURGICAL CONSIDERATIONS

Non-operative treatment has been widely used for dislocations; techniques vary depending on kind of dislocation, comitant injuries, timing after injury as well as the skills and strength of the treating provider, among other considerations. Recreational and occupational demands might lead one to have surgery after an initial dislocation but for most patients the results of surgery after a recurrence should be equivalent to surgery after first dislocation. The dislocation recurrence rate has been reported at 17 to 96%. (Arciero 94, 95; Bottoni 02; Rowe 56,78; DeBerardino 96, 01; Good 05; Wintzell 99; Salmon 98; Simonet 84; Larrain 01;Wheeler 89; Valentin 98; Brophy 09; Yoneda 82; Aronen 84; Handoll 2004; Thomas 89; Henry 82; Hoelen 90; Hovelius 78, 83a,83b, 87, 96, 99; O'Neill 99; Kirkley 99, 05; Kazar 69; Kiviluoto 80; McLaughlin 67) Recurrence of dislocation has been attributed to anterior labral injuries (Angelo 03; Hayashida 98; Larrain 01; Stefko 97; Taylor 97; Kirley 05) and has been used to justify attempted repairs. Younger age has been consistently associated with increased risk of recurrence of dislocation (Hawkins 90; Hovelius 87; McLaughlin 67; Rowe 78; Robinson 08), providing some rationale for greater use of surgical treatments in younger patients with dislocations.

Surgical approaches to shoulder instability include arthroscopic (Resch 97; Wiley 88; Freedman 04; Geiger 97; Steinbeck 98; Pulavarti 09; Hintermann 95; Wolf 88; Lane 93; Coughlin 92; Hawkins 89; Robinson 04; Hurley 93; Wall 95; Rook 01; Levine 05; Armstrong 04; Budoff 06; Stokes 03; Abrams 03; Abrams 07; Swenson 95; Antoniou 00; Cole 00; Angelo 03; Sandow 95,96; McIntyre 97; Rose 96; De Mulder 99; Hawkins 01; Copeland 98; Nelson 00; Long 96; Neleolung 02; Stein 02; Fealy 01; Mayfield 01; Ryu 03; Millett 03; Walch 95; Grana 93; Arciero 94; Guanche 96; Landsiedl 92; Hobby 07; Benedetto 92; Caspari 91; Morgan 87; Altchek 95; Kropf 07; Yanmis 03; Abouali 13; Friedman 14) and open procedures, most frequently Bankart (capsule and labral repairs) repairs. (Bankart 38; Rowe 78; Caprise 06; Hovelius 79; Millett 05; Provencher 08; Zamora-Navas 01; Ejerhed 00; Karlsson 01; Itoi 01; Handoll 09) Trials comparing arthroscopic and open approaches for patients with recurrent anterior dislocations found no unequivocal evidence of superiority of one approach over the other, (Sperber 01; Fabbriciani 04; Rhee 07) although overall there appears to be modestly faster recovery the first several post-operative months with arthroscopic approaches. (Rhee 07) Arthroscopic capsulolabroplasty and capsulolabral augmentation have been reported for management of posteroinferior instability. (Kim 04; Antoniou 00) For posterior instability, no differences between open and arthroscopic approaches have been reported; (Kakar 07) none of the available studies are RCTs. (Kakar 07) Studies have suggested that open repairs are superior for violent contact sports. (Roberts 99) Three meta-analyses or systematic reviews comparing arthroscopic and open surgical approaches concluded that the open procedure had a more favorable outcome (Mohtadi 05; Lenters 07; Freedman 04); however, a Cochrane review concluded there is insufficient evidence after reviewing

RCTs comparing arthroscopic with open surgical approaches. Since these reviews, arthroscopic repair has improved which could lead to improved outcomes compared to open repair, but new RCTs do not exist.

- 1. Recommendation: Relocation of Dislocated Shoulders
  - Relocation is recommended after dislocation. Relocation under anesthesia is recommended if an attempted relocation without anesthesia is unsuccessful.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Surgery for First Traumatic Anterior Shoulder Dislocation Arthroscopic or open surgery is recommended for acute, first traumatic anterior shoulder dislocation.

Indications - Acute, first traumatic anterior shoulder dislocation, particularly in patients under age 27.

#### Strength of Evidence – Recommended, Evidence (C)

#### Rationale for Recommendations

There are three high- or moderate-quality studies with four reports comparing surgical treatment to nonoperative treatment after an acute, traumatic anterior shoulder dislocation. Another high-quality trial compared arthroscopic lavage with lavage plus Bankart repair and documented marked benefits of surgery. (Robinson 08). All trials document significantly lower rates of redislocation after repair (arthroscopic (Kirkley 99, 05; Bottoni 02) or open (Jakobsen 07)) in younger patients, from their teens to age 39, and most either under 30 and/or athletes. Trials also have shown improved shoulder function and less disability after surgery. The quality RCTs comparing arthroscopic and open approaches for patients with recurrent dislocations found no unequivocal evidence of superiority of one approach over the other, (Sperber 01; Fabbriciani 04; Rhee 07; Friedman 14; Ng 07) although overall there appears to be modestly faster recovery the first several post-operative months with arthroscopic approaches. (Rhee 07) However, non-operative treatment has been traditionally recommended for anterior dislocation, (Hovelius 96; Wen 99; Aronen 84; Burkhead 92; Line 99: Liu 96) and although recent evidence supports early surgical repair after the first dislocation in younger patients in order to prevent recurrence, whether this applies to all patients is unclear. Surgery is invasive, has adverse effects, and is high cost. However, quality evidence documents clear superiority of surgical management compared to non-operative treatment particularly for younger patients and thus surgery is recommended.

A meta-analysis comparing transglenoid sutures with bioabsorbable tacks found a higher rate of recurrent dislocation (12.6 versus 3.4%); however, it largely relied on case series. (Freedman 04) An experimental cadaveric study evaluated capsular plication versus anchor repair. (Provencher 08) There is insufficient evidence to recommend for or against specific intraoperative techniques.

3. Recommendation: Surgery for Multidirectional Instability

Inferior capsular shift procedure, capsular plication or superior shift of redundant inferior capsule is recommended for multidirectional and posterior instability.

Indications - Recurrent, multidirectional shoulder instability or dislocation.

Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality studies evaluating treatment of multidirectional and posterior instability and no randomized comparative trials of available operative approaches. (Hewitt 03) Surgical results in case series have suggested some benefits. (Bak 00; Choi 02; Fronek 89; Neer 80; Pollock 93, 00; Hamada 99; Hurley 92; McIntyre 97; Antoniou 00; Duncan 93; Tauro 00; Schwartz 87; Treacy 99; Tibone 90, 93; Wolf 98) Currently arthroscopic capsular placation is replacing open capsular shifts. There are few options for these patients other than muscle strengthening. Surgery is invasive, has adverse effects, and is high cost. However, for some patients there is no other reasonable alternative for treatment, thus surgery is recommended.

4. Recommendation: Arthroscopic Lavage for Shoulder Dislocations

## There is no recommendation for or against the use of arthroscopic lavage for shoulder dislocations.

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendations

There are three moderate-quality trials with four reports all suggesting arthroscopic lavage reduces risk of subsequent dislocation. (Wintzell 96, 99a, 99b, 00) However, there are no quality trials available evaluating a less-invasive procedure. Arthroscopic lavage is invasive, has adverse effects, is costly, is less invasive than surgical repair, but does not achieve repair of damaged tissue and there is no recommendation for or against arthroscopic lavage alone.

Evidence for Surgery for Shoulder Dislocation

There are 2 high- and 19 moderate-quality RCTs incorporated into this analysis. There are 5 low-quality RCTs in Appendix 2. (Steinbeck 98; Hiemstra 08; Norlin 94; Sandow 95; Salomonsson 09)

				n 94, Sandow 95, Salom	· · · · · · · · · · · · · · · · · · ·	Commonto
Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
	/	Acute Anterio	r Dislocation: Arthro	scopic Lavage vs. Non	-operative Treatment	
Wintzell 1999 RCT	4.5	N = 60 traumatic primary anterior shoulder dislocation.	Arthroscopic lavage within 10 days vs. non- operative care (optional sling 1 week, then free mobilization). Rehab programs "identical." Weekly ultrasound used; 1- year follow-up.	Joint effusion reduced 33% more rapidly in arthroscopic lavage group ( $p = 0.02$ ). At 1-year, 4/30 (13%) lavage vs. 13/30 (43%) non-operative group ( $p = 0.01$ ). Rowe shoulder scores (excellent and good): 24/30 (80%) vs. 12/30 (40%), $p =$ 0.003.	"[A]rthroscopic lavage reduced the recurrent rate and produced functional outcome at 1-year follow-up than the non-operative treatment in young individuals."	Patients not well described. Data suggest lavage reduces redislocation, especially in younger patients.
Wintzell 2000 RCT	4.5	N = 16 traumatic primary anterior shoulder dislocation ages 17-31	Arthroscopic lavage within 10 days vs. non- operative care (optional sling 1 week, then free mobilization). Rehabilitation programs "identical." Followed weekly by ultrasound to assess joint effusion between the humeral head and glenoid	Joint effusion decreased more rapidly (33%, p = 0.02) in lavage group over a period up to 8 weeks (until steady state reached).	"Arthroscopic lavage following traumatic primary anterior shoulder dislocation increased the speed of reduction in the pathological joint effusion compared with the speed of reduction after conventional non- operative treatment."	Patients not well described. Study did not address clinical or functional utility.
Wintzell 1996 RCT	4.5	N = 30 traumatic primary anterior dislocation ages 18-30	Arthroscopic lavage within 10 days vs. non- operative treatment (free mobilization, sling for 1 week, oral analgesics).	At 6 months, 1/15 (7%) in arthroscopic lavage group dislocated com-pared with 7/15 (47%) non- operative group, p <0.05. At 12 months, results were 13% vs. 53%, p <0.05. Differences in shoulder stability not significant. Normal ROM in 87% vs. 47%, p <0.05 in favor of lavage. Excel-	"Results at 6- and 12-month check-ups showed a statistically significantly lower rate of redislocation and wider range of motion for the group treated with acute arthroscopic lavage."	Unclear if assessor was blinded. Appears to have included no surgical procedure other than lavage. Data suggest lavage reduces redislocation.

Wintzell 1999 RCT (follow- up Wintzell 96)	4.5	N = 30, same as above	Same as above; 2- year follow-up of above.	lent/good results by Lysholm shoulder score at 1 month good/ excellent in 73% vs. 47% and at 1 year, 93% vs. 66%. 3/15 (20%) of lavage patients vs. 9/15 (60%) non-operative patients re-dislocated over 2 year period.	"[A]rthroscopic lavage reduced the risk for recurrent dislocation when compared with non- operative treatment."	Results suggest lavage superior to non-operative treatment.
				rgery vs. Non-operative		
Kirkley 1999 RCT	8.5	N = 40 acute, traumatic first anterior dislocation' surgery within 4 weeks of dislocation; minimum 24 months, average 32 months follow-up	Arthroscopic surgical repair (transglenoid suturing of anterior labral lesion) vs. nonoperative treatment. Both groups shoulder immobilizer 3 weeks then physiotherapy (active-assisted ROM Weeks 4-6; isometric strengthening, external rotation to 45°. Weeks 7-8; isotonic strengthening, active ROM with terminal stretch. Weeks 9-12; limited sports 3 months; full sports as tolerated at 16 weeks).	3/19 (15.9%) surgery group re-dislocated vs. $9/19$ (47%) non- operative group (p = 0.008). Total WOSI scores surgery 287.01±290.19 vs. nonoperative $633.93\pm547.25$ , p = 0.03. Return to sport WOSI 7.95 surgery vs. 27.77 nonoperative, p = 0.05.	"At an average 32 months follow-up, a significant reduction in redislocation and improvement in disease-specific quality of life is afforded by early arthroscopic stabilization in patients less than 30 year of age with a first, traumatic, anterior dislocation of the shoulder."	Variable follow-up times. One septic joint in surgery group. Data support surgery as initial treatment for patients under age 30 with acute, traumatic, first anterior shoulder dislocation.
Kirkley 2005 RCT, 2nd Report of Kirkley 1999	6.0	N = 40 surgery within 4 weeks of dislocation; average 75 months follow-up.	Arthroscopic surgical repair (transglenoid suturing of anterior labral lesion) vs. nonoperative treatment. Details given above.	No additional new dislocations after above study reported. Additional 3 recurrences in surgical group and 9 in non-operative group. Western Ontario Shoulder Instability Index scores at 32 months surgical 86.3% vs. $69.8\%$ (p = 0.03). WOSI at 79 months 86% vs. 74.8%, p = 0.17. DASH 95.8% vs. 94.1% (p = 0.57).	"[I]mmediate arthroscopic stabilization is the treatment of choice in a small subset of patients who are younger than 30 years and are higher level athletes."	Variable follow-up times; dropout rate high (22.5%). Data suggest operative treatment superior to nonoperative treatment. "In the traditional group, only 7 patients underwent surgery versus all 19 in the surgical group (plus 2 revision surgeries). When viewed from this perspective, traditional treatment saved a significant proportion of patients from the risk and

						discomfort associated with surgery."
Bottoni 2002 RCT	6.0	N = 24 athletes ages of 18 and 26 with acute, first traumatic dislocation requiring manual relocation; 24 months follow-up, some up to 56 months	Arthroscopic stabilization (debride, decorticate glenoid rim, bioabsorbable tack through capsule-labral tissue vs. non- operative treatment. Both groups 4 weeks sling, limited active ROM. Codman's exercises, isometric muscle contractions performed. Next 4 weeks, progressive passive motion exercises then active- assisted ROM exercises. Next 4 weeks full active ROM with progressive resistance. Full sports/full active duty at 4 months.	Treatment failure in 75% nonoperative treatment vs. 11.1% surgery group failed. No differences in ROM. SANE scores 57 nonoperative group vs. 88 surgery group (p <0.002).	"Arthroscopic stabilization of traumatic, first-time anterior shoulder dislocationssignifi cantly reduces the recurrence rate of shoulder dislocations in young athletes when compared with conventional, nonoperative treatment."	Pseudo- randomized on SSN (even/odd). Data suggest surgery superior to nonoperative treatment.
Edmonds 2003 RCT	5.0	N = 24 primary traumatic anterior dislocation	Immobilization vs. arthroscopic stabilization. Both groups with same rehabilitation.	No differences in post-treatment proprioception via threshold to detection of passive motion and reproduction of passive positioning.	"[T]reatment by early arthroscopic stabilization and rehabilitation after primary traumatic anterior dislocation of the shoulder does not enhance proprioception more than standard immobilization and rehabilitation."	Somewhat longer time from injury in non-operative group (15.8 vs. 21.1 months). Primary emphasis on proprioception. Results suggest no advantage or arthroscopic stabilization with proprioception.
	Ar	nterior Disloca	tion: Arthroscopic La	avage with vs. without	Surgical Bankart Repa	
Robinson 2008 RCT	9.0	N = 88 primary traumatic anterior shoulder dislocation under 35 years of age and dislocation under 2 weeks old	Arthroscopic lavage with vs. without Surgical Bankart Repair. All treated postoperatively with sling, pendulum exercises, rehabilitation at 6 weeks; 2 year follow-up.	Dislocations over 2 years of follow-up in 3/42 (7%) arthroscopic repair group vs. 16/42 (38%) lavage group. Recurrent instability in 0% vs. 10%. 76% reduced risk of dislocation/instability (p <0.05). Costs higher in lavage-only group (3531 vs. 2782£), p = 0.012. No differences in work lost time. Risk of discontinuing contact sport higher in lavage alone (RR = 3.4, 95%	"Following a first- time anterior dislocation of the shoulder, there is a marked treatment benefit from primary arthroscopic repair of a Bankart lesion, which is distinct from the so-called background therapeutic effect of arthroscopic examination and lavage of the joint."	Radiographic confirmation of re- dislocations. Data suggest arthroscopic repair of Bankart superior to arthroscopic lavage alone for reducing dislocations, costs and maintaining function.

				Cl 1.3-9.2, p = 0.007).		
	Anterio	r Dislocation:	Arthroscopic Diagno	sis and Surgical Repair	vs. Non-operative Tre	atment
Jakobsen 2007 RCT	7.0	N = 76 acute, traumatic anterior dislocation, age under 40, all underwent arthroscopy and lavage within 1 week of injury; 10 year follow- up.	Surgical repair (open Bankart, Mitek anchors), vs. conservative treatment. Both immobilized for 2 days with fixed sling, then nonfixed sling for 1 week, then passive movement without rotate, lift or push; active internal rotation and abduction at 3 weeks and external rotation exercises at 8 weeks. Swimming and light sports at 12 weeks and overhead sports at 6 months.	At 2-years, 21/39 (53.8%) nonsurgical treatment dislocated vs. 1/37 (2.7%) open Bankart repair group, p = 0.0011.64% recurred first 11 months, all with Baker type 2 or 3 lesion. Among non- dislocators at 24 months, 39% in conservative group had positive apprehension test vs. 7% surgical ( $p =$ 0.014). At 10 years, 3/ 37 (8.1%) surgery group had dislocated vs. 24/39 (61.5%) conservative group. Satisfactory results in 70% surgery vs. 26%	"Arthroscopic evaluation after first- time anterior shoulder dislocation revealed a Baker type 2 or 3 lesion in 93.5% of patientsBecause open repair produces superior results compared with conservative treatment, we recommend that the surgeon consider performing primary repair in active patients to reduce the risk of recurrence."	Study suggests open Bankart repair superior to conservative treatment for prevention of recurrence of dislocation after initial acute traumatic anterior dislocation. As trial includes arthroscopy for all, excluded from Cochrane review (Handoll 09) due to "actually comparing different surgical methods."
				conservative group.		
	1	Po	st-traumatic Instabili	ty: Arthroscopic vs. Op	en Repair	
Sperber 2001 RCT	6.5	N = 56 post- traumatic recurrent anterior dislocation, most with >6 dislocations; all had diagnostic arthroscopy and showed Bankart lesion for inclusion; 2- year follow- up	Arthroscopic repair (intra-articular labral fixation with absorbable tacks, Suretac) vs. open repair of Bankart lesion. All arm swath 3 weeks; external rotation gradually increased Weeks 4-6; unrestricted ROM at 6 weeks; overhead motion and contact sports discouraged for 6	7/30 (23%) arthroscopic re- dislocated vs. 3/26 (12%) open group (NS). 23/30 (76.7%) arthroscopic vs. 23/26 (88.5%) open shoulders stable. Constant scores 100 vs. 98 (NS). Rowe scores 100 vs. 95 (NS).	"A tendency was seen toward more redislocations in the arthroscopic group, which emphasizes the importance of correct patient selection and careful surgical technique in the difficult surgical procedure."	Eligible patients had recurrent dislocations; baseline difference in affected dominant side. Time from trauma to surgery 3.5-4.8 years. Data trend in favor of open repair.
Fabbriciani 2004 RCT	6.5	N = 60 post- traumatic anterior shoulder instability, all with diagnostic arthroscopy showing Bankart lesion for inclusion; 2- year follow- up.	months. Arthroscopic (3 mini-Revo suture anchors) vs. open repair (SCOI technique) of Bankart lesion. All sling 6 weeks. After 3 weeks, passive and assisted active motion exercises with T-bar. Subsequent isometric and isotonic strengthening. After 3 months, advanced muscle strengthening and capsular stretching	No redislocation occurred in either group. Constant pain scores identical (13.5). Improvement in points: arthroscopic 23 $\pm$ 5.89 vs. open 20.2 $\pm$ 8.22, p = 0.39. Rowe function scores: arthroscopic 45.5 $\pm$ 7.25 vs. open 41.0 $\pm$ 7.75 (p = 0.196). Pain scores identical (8.5). ROM scores arthroscopic 10 $\pm$ 0 vs. open 8.5 $\pm$ 2.42, p = 0.065.	"Arthroscopic repair with suture anchors is an effective surgical technique for the treatment of an isolated Bankart lesion. Open repair does not offer a significantly better 2-year result in terms of stability, and furthermore, can negatively affect the recovery of full range of motion of the shoulder."	No major differences in outcomes. No dislocations in either group suggests both highly successful approaches.

			exercise. Sports after 6 months.			
Rhee 2007 RCT	5.5	N = 60 anterior shoulder instability and isolated Bankart lesion	Open Bankart repair vs. arthroscopic repair. Post-operative rehabilitation with 3 weeks isometric exercise, then 3 weeks passive elevated and external rotation, then muscle strengthening. Sports after near normal muscle strength and ROM after 6 months.	UCLA scores (pre-op/ 12 months): open 27.6/ 33.5 vs. arthroscopic 27.4/33.9 (NS) (shorter term data not given). Forward flexion strength (pre/6 weeks/3 months/6 months/9 months/12 months): Open (95.0/52.8/76.3/ 85.8/93.4/97.4) vs. Arthroscopic (97.3/ 80.6/84.8/ 90.6/95.5/ 99.0), (p = 0.24, p <0.001, p = 0.003, p = 0.074, p = 0.38, p = 0.50). Similar results for ER, IR strengths.	"Muscle strength recovered faster with an arthroscopic procedure than with an open procedure during the early postoperative periods, and strength was restored to the level of the unaffected side at 6 months postoperatively."	Study labeled a cohort study. However, assignments were randomized. Dropout rate unclear. Data suggest modestly faster recovery with arthroscopic approach.
Bottoni 2006 RCT	5.5	N = 64 recurrent anterior shoulder instability; failure of at least 6 months supervised rehabilitation ; mean 32 months follow-up	Arthroscopic vs. open stabilization. All with same post- op rehabilitation. 1 month immobilized in sling and pendulum and elbow exercises; 1 month to restore full ROM. 1 month periscapular strengthening. Return to sports/full duty at 4-6 months.	SANE (pre/post): arthroscopic (53.3± 14.8/93.5±8.3) vs. open (52.7±15.0/90.6±7.6) (NS). UCLA scores, SST, WOSI, range of motion all NS.	"Clinical outcomes after arthroscopic and open stabilization were comparable."	Suggests no significant differences.
Archetti Netto 2012 RCT	5.0	N = 42 with traumatic anterior shoulder instability and the presence of an isolated Bankart lesion confirmed.	Open surgery (n = 25) vs. Arthroscopy (n = 17). Follow-up from 20 to 56 months.	At primary outcome, statistically significant difference in favor of arthroscopy group vs. open surgery group in DASH questionnaire (2.65 (7.3) vs. 4.22 (5.8), p = 0.031). No statistically significant differences in secondary outcomes, technique scores, and shoulder range of motion.	"On the basis of this study, the open and arthroscopic techniques were effective in the treatment of traumatic anterior shoulder instability. The arthroscopic technique showed a lower index of functional limitation of the upper limb, as assessed by the DASH questionnaire; this, however, was not clinically relevant."	Small sample size. Patients less than 40 years old. The study design did not permit blinding of participants, surgeons, and outcome assessors. Both interventions showed improvement, but there were no differences between groups.
Jorgensen 1999 Pseudo- Randomized Trial	4.5	N = 41 recurrent anterior shoulder instability	Arthroscopic (Bankart repair with Morgan and Bodenstable's technique, additional anterior capsular tightening/ application vs.	Less hospitalization time in arthroscopic (2.3 vs. 0.8 days, $p =$ 0.000002). One redislocation in arthroscopic group vs. none in open ( $p =$ 0.61). Rowe scores 92.5 vs. 95 (NS).	"Both methods solve the main problem of recurrent dislocation satisfactorily with results comparable to those in the literature."	Pseudo- randomization by address. Some baseline differences with older injury in the arthroscopic group. Results suggest minimal

			open repair (Bankart repair with 2-3 Mitec (R) suture anchors, repair of capsule- labral complex and reefing inferior recess). Median 36 months follow-up.	Constant scores 62 vs. 59.5 (NS).		differences.
Castagna 2009 RCT	5.0	N = 40 traumatic uni- directional instability and <3 dislocations	Bioabsorbable anchors with polyester sutures for Bankart lesion vs. 2 posterior- inferior capsular plications with polydioxanone capsulorraphy; 2- year follow-up	nchors vs. other approv Forward flexion in- creased in anchor group 3.5° vs. decreased 14.5° in plication group. UCLA scores increased 45.2% vs. 43.1%. One (non- plicated) vs. no (plicated) redislocations.	"[A]rthroscopic posterior-inferior plications associated with a Bankart lesion repair in a selected group of patients seem to reduce only (for-ward flexion), without any effect on rotation."	Patients not well described. Dropout rate unclear. Primary emphasis on ROM. Appears underpowered for detecting differences in redislocations
		Anterior S	Shoulder Instability: (	<b>Comparing Different An</b>	chors and Tacks	
Tan 2006 RCT	7.5	N = 130 traumatic shoulder instability	All surgically repaired with either absorbable (Panalok) 0 vs. nonabsorbable (G II) anchors. Means 2.4, 2.6 years follow-up.	Oxford instability shoulder score (pre/ post): P anchor (36±7/20±10) vs. G (36±8/18±6), NS. 85% re-turned to prior sporting level. Recurrent dislocations in 4 vs. 3 patients (NS).	"No differences in outcomes of arthroscopic Bankart repair were seen whether absorbable or nonabsorbable anchors were used."	Variable follow- ups (means 2.4, 2.6 years).
Monteiro 2008 RCT	7.0	N = 50 athletes with traumatic anterior shoulder instability; 24 months follow-up	Absorbable (Panacryl) vs. non- absorbable (Ethicon) sutures using same anchor type (Panalok) with Bankart lesions repaired 2, 4, 5 o'clock for right shoulder; 7, 8, 11 o'clock for left. Both sling for 3 weeks, passive assisted ROM after 3 weeks. Active assisted motion and strengthening begun at 5 weeks. Full sports activity at 5 months if near normal ROM and no clinical strength deficit.	Good or excellent results in 90.5% of absorbable vs. 87.5% nonabsorbable. Mean Rowe score 83.8 vs. 79.5. Mean ASOSS scores 84 and 79.2. Two failures (9.5%) in absorbable vs. 3 (12.5%) in non- absorbable. All results NS.	"The type of suture used, absorbable or nonabsorbable, did not influence the functional results of arthroscopic treatment for traumatic anterior shoulder instability in this series."	Data suggest suture type not materially important for results over 24 months.
Warme 1999 RCT	5.5	N = 40 recurrent anterior shoulder instability	Open surgical repairs with nonabsorbable (polyacetyl, Acufex TAG Rod II, 3.7mm) versus absorbable (copolymer of polyglycolic acid	Pre/post-op Rowe scores: nonabsorbable (47/96) vs. absorbable (47/93), NS between groups. 17/18 (94.4%) vs. 18/20 (90%), NS. Failures of 1	"[I]n this application, bioabsorbable suture anchors are a viable option for the repair of soft tissue to bone."	Data suggest comparable efficacy.

			and trimethylene carbonate, Acufex TAG Rod II, 3.7mm) suture anchors. Follow-up unclear; appears 2 years.	recurrent dislocation vs. 1 dislocation plus 1 resubluxation (NS)		
Magnusson 2006 RCT	5.5	N = 40 recurrent uni- directional post- traumatic shoulder instability; failed non- operative treatment	Arthroscopic Bankart repairs with Polygluconate co-polymer vs. self-re-inforced poly-L-lactic acid polymer tack implants. Slings 4 weeks with ROM, then advanced ROM and strengthening at 4 weeks, throw/con- tact sports 6 months; 2 years follow-up.	No differences at 2 years in external ROM, isobex strength, constant scores (A 84 vs. 87, p = 0.30).	"Two years after arthroscopic Bankart reconstruction using either PGA polymer or PLA polymer implants, the overall clinical results were comparable."	Trend of lower age in PLLA group (26 vs. 30 years, p = 0.13). Data suggest comparable efficacy.

## POST-OPERATIVE REHABILITATION: SHOULDER INSTABILITY AND DISLOCATION

There are many different post-operative rehabilitation regimens reported in quality surgery trials and elsewhere to treat patients with shoulder instability. (Kirkley 99, 05; Bottoni 02; Monteiro 08; Sperber 01; Fabbriciani 04; McDermott 99; Jakobsen 07) However, there are scant quality studies reported that evaluate these different regimens to help define superior treatment programs. Individualization of programs based on various factors, including age, conditioning, and immediate post-surgical results is needed. (O'Brien 87; O'Brien 02)

1. Recommendation: Accelerated Rehabilitation for Patients after Arthroscopic Bankart Repairs Accelerated rehabilitation (compared with standard rehabilitation) is recommended for select patients after arthroscopic Bankart repairs. (Kim 03)

*Indications* – Arthroscopic Bankart repairs for traumatic recurrent anterior instability in select, particularly younger patients.

*Frequency/Duration* – Two to 3 appointments a week for 3 weeks, then twice a week for 2 weeks and once weekly to every other week for 6 to 9 additional weeks. (Kim 03) Exact regimen requires individualization; however, the accelerated rehabilitation regimen has been successful and is in general recommended.

*Discontinuation* – Recovery, plateau in recovery, noncompliance, intolerance.

Strength of Evidence – Recommended, Evidence (C)

2. Recommendation: Accelerated Rehabilitation for Post-operative Shoulder Instability Patients There is no recommendation for or against accelerated rehabilitation for patients after other surgical procedures for shoulder instability.

Frequency/Duration – Same as above if implemented for other patients.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

3. Recommendation: Rehabilitation for Post-operative Shoulder Instability Patients Rehabilitation is recommended for patients undergoing surgery for shoulder instability who do not undergo an accelerated rehabilitation program (see above).

*Indications* – Patients undergoing surgery for shoulder instability or dislocation not addressed above. *Frequency/Duration* – Two to 3 appointments a week for 3 weeks, then 2 a week for 2 weeks, and once a week to every other week for 6 additional weeks.

## Discontinuation – Recovery, plateau in recovery, noncompliance, intolerance. Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

There is one moderate-quality study comparing traditional with accelerated rehabilitation of patients, mean age 29 years, having undergone arthroscopic Bankart repairs for traumatic recurrent anterior instability. (Kim Arthroscopy 03) The trial documented multiple advantages of accelerated rehabilitation including greater satisfaction, lower pain scores, and faster recovery. The dislocation rate was not increased by early rehabilitation during the study period (range 27 to 45 months). Caution should be used as excessive early range of motion in first 6 weeks will over stretch repair. Accelerated rehabilitation, however, similar cautions exist. (Wintzell 99, 00) Early rehabilitation is not invasive, appears to result in lower risks of adverse effects, is likely less costly, and thus is recommended.

			There is 1 moderate-quality RCT incorporated into this analysis.					
Author/Title	Scor	Sample	Comparison	Results	Conclusion	Comments		
Study Type	e (0-	Size	Group					
	11)							
	T			rated vs. Standard Reh	abilitation			
Kim	7.5	N = 62	Accelerated	No recurrent	"Early [controlled]	Data favor		
Arthroscop		traumatic	(staged ROM and	dislocation or	mobilization of the	accelerated		
у		recurrent	strengthening	subluxation either	operated shoulder	rehabilitation in		
2003		anterior	beginning	group. No differences	after arthroscopic	select patients		
		instability	immediately post-	in shoulder scores.	Bankart repair does	with		
RCT		having	op) vs. standard	Pain scores at 6	not increase the	unidirectional		
		undergone	rehab (3 weeks	weeks less in	recurrence rate in a	instability,		
		arthroscopi	immobilization with	accelerated group (p	selected group of	healthy labrum		
		c Bankart	abduction sling	= 0.013). Pain	patients. Although	and limited		
		repair with	then rehab with	eventually	the final outcomes	capsular laxity.		
		suture	pendulum	comparable. Faster	are approximately the			
		anchors,	exercises,	resumption of ROM	same for both			
		non-athlete,	progressive active-	with accelerated (p	groups, the			
		ages 15-39,	assisted forward	<0.001). Mean time	accelerated			
			flexion, internal	for 90% activity return	rehabilitation			
			rotation, then	9.1±2.5 vs. 12.4 ±2.1	program promotes			
			external rotation	weeks, p <0.001.	functional recovery			
			vigorous cuff		and reduces			
			strengthening		postoperative pain,			
			exercises).		which allows patients			
			Average 31		an early return to			
			months follow-up.		desired activities."			

#### Evidence for Post-operative Rehabilitation for Shoulder Dislocation/Instability There is 1 moderate-quality RCT incorporated into this analysis.

## SUPERIOR LABRAL ANTERIOR POSTERIOR AND LABRAL TEARS

Labral tear management is complex. Appropriate management begins with an understanding of the anatomy, etiology of pathology, and clinical correlation of pathology with symptoms and shoulder dysfunction. Labral tears are more prevalent with advancing age and thus beyond age 40 commonly represent a natural degenerative process in the shoulder not unlike meniscal pathology in the knee. Most SLAP tears over age 40 do not require repair. (Parentis 02; Altchek 92; Berg 97; Burkhart 98; Cordasco 93; Handelberg 98; Morgan 98; Kim 03; Pearce 00; Payne 94; Resch 93; Segmuller 97; Snyder 95; Warner 94) By the 8th decade of life 100% of cadaver specimens have labral tearing. Superior labral anterior posterior (SLAP) and other labral tears have been clinically recognized for approximately 25 years. (DePalma 49; Andrews 85; Snyder 90, 95 Kippe 07) Labral tears can be considered in conjunction with dislocation and instability for anatomic reasons. The overall prevalence at time of arthroscopy has been estimated at 6%. (Snyder 95) In certain cases, SLAP tears may occur with acute traumatic dislocations, (Beltran 03) but are associated

most commonly with other trauma and disorders such as rotator cuff tendinopathies and acromioclavicular disorders. (Altchek 92; Berg 97; Burkhart 98; Cordasco 93; Handelberg 98; Morgan 98; Pearce 00; Resch 93; Kim 03; Segmuller 97; Snyder 95; Warner 94)

Superior labral tears are either the result of acute traumatic injury or chronic degenerative pathology. The most common acute mechanism of injury reported is a compressive force on shoulder or a subluxation injury, such as from a fall on an outstretched arm (Snyder 90, 95; Resch 93; Handelberg 98; Maffet 95; Levine 00; Mileski 98; Morgan 98; Burkhart 92, 98, 00) or overhead athletic or comparable traction injuries (Trantalis 08; Burkhart 00). Nevertheless, overhead athletes (e.g., baseball, tennis, handball, badminton, softball, swimming, volleyball, and squash) with SLAP tears seem to not do as well after arthroscopic surgery compared to nonthrowing athletes. (Sayde 12) SLAP tears in the younger, athletic throwers and overhead athletes are dissimilar from the general population and need to be considered differently. Extrapolation of management of throwing athletes to the general population is inappropriate and has led to overtreatment of SLAP tears. Labral tears occurring in an older population are most commonly associated with other largely degenerative conditions and thus might have relationships to underlying degenerative conditions and not require repair. (Parentis 02; Altchek 92; Berg 97; Burkhart 98; Cordasco 93; Handelberg 98; Morgan 98; Kim 03; Pearce 00; Payne 94; Resch 93; Segmuller 97; Snyder 95; Warner 94) For the purposes of this guideline, these tears are considered distinct from the acute traumatic labral tears that can occur with dislocations. Initial patient management is non-operative. (Parentis 02; Edwards 10) Surgery has been utilized for patients who fail non-operative treatment and may be considered in active, younger patients. (Parentis 02)

The presence of a labral tear does not in and of itself necessitate surgery. Labral tears are often identified at surgery concurrently with other pathology such as rotator cuff tears, acromial spurring, and glenohumeral arthritis. In many of these cases, especially with advancing age, the labral tear may be irrelevant to the patient's condition and not require specific treatment. For example, if a patient's clinical evaluation is consistent with rotator cuff tear, an incidental labral tear does not need to be fixed (except perhaps in younger patients) and if it is fixed there is a greater chance that the patient will have postoperative stiffness. Though there are no RCTs comparing repair of rotator cuff tears with versus without surgical repair or debridement of labral tears, literature suggests there are no advantages to repairing Type II lesions associated with rotator cuff tears in patients over age 50. (Franceschi 08) Indications for surgery for SLAP tears are not standardized and remain somewhat controversial. Expert opinion, including that of the American Academy of Orthopedic Surgeons, recommends initial conservative care management for SLAP tears. In general conservative care management should last a minimum of 6 to 12 weeks. Early surgery should only be considered in cases where there is evidence of suprascapular nerve compression. The evidence for or against repairing SLAP tears over age 40 is mixed with no highor moderate-quality studies. (Provencher 13) Evidence suggests no improvement with SLAP repair at the time of rotator cuff repair and trends towards worse stiffness with simultaneous surgical repairs. (Alpert 10) For many years rotator cuff tears were repaired without ever seeing the inside of the glenohumeral joint (labral pathology was not surgically repaired). The patients had equivalent outcomes to current reports.

## **DIAGNOSTIC CRITERIA**

There are no consensus diagnostic criteria for labral tears; the diagnosis has been described as difficult and nonspecific. (Parentis 02; Mileski 98; Nam 03; Bedi 08; Maurer 03-04) Symptoms generally include nonradiating shoulder joint pain, increased pain with overhead activity, and painful catching or popping sensations. (Snyder 90; Powell 04; Gartsman Clin Sports Med 00) Typical physical examination maneuvers are thought to be mostly nonspecific. (Burkhart 00; Craig 96; Handelberg 98; Maffet 95; Parentis 02) Other maneuvers have been developed. (Mimori 99; Liu 96; Kibler 95; Kim 99) A comparative study found the most sensitive maneuvers to be active compression (65.2%), Hawkin's (65.2%) and Speed's (47.8%). These relatively low sensitivity values indicate that these tests will perform poorly except in high pre-test probability circumstances. This suggests clinical suspicion and confirmatory imaging or arthroscopy appear to be the best diagnostic methods. (Parentis 02) The most commonly used classification system is based on the initial large case series by Snyder, although additions have been made by several authors. (Morgan 98; Maffet 95; Nord 04; Powell 04) The most common system has been suggested to be unduly complex. The primary issues are proposed to be instability of the biceps tendon anchor or glenohumeral ligaments which then dictate operative approaches of repair of capsuloligamentous structures back to the bony glenoid rim or biceps tenodesis (Parentis 02) (see Table 7).

Туре	Description
Type I	Superior labrum marked fraying with degenerative appearance. Peripheral labral edge firmly attached to glenoid and biceps tendon intact.
Type II	Fraying and degenerative changes. Superior labrum and biceps tendon stripped off glenoid. Labral-biceps anchor unstable.
Type III	Bucket-handle tear in superior labrum. Central portion of tear displaceable into joint. Peripheral portion firmly attached to glenoid and biceps tendon also intact.
Type IV	Bucket-handle tear of superior labrum as in Type III, but tear extends into biceps tendon.
Type V	Anteroinferior Bankart lesion continuing superiorly to include separation of biceps tendon
Type VI	Includes biceps separation with unstable labral flap tear
Type VII	Superior labrum-biceps tendon separation extending anteriorly beneath middle glenohumeral ligament.
Type VIII	SLAP extension along posterior glenoid labrum as far as 6 o'clock
Type IX	Pan-labral SLAP tear around glenoid circumference
Туре Х	Superior labral tear associated with posterior-inferior labral tear (reverse Bankart lesion)

#### Table 7. Classification of Superior Labrum Anterior and Posterior (SLAP) Lesions\*

\*Adapted from Snyder 1990, Maffet 95, Powell 04

# SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS MR ARTHROGRAPHY

Magnetic resonance (MR) arthrography is thought to be effective for imaging superior labral anterior posterior (slap) or other labral tears. (Peh 02; Waldt 04; Jee 01; Lin 09; Bencardino 00; Monu 94; Stetson 02; Karzel 93; Smith 93; Nam 03) MR arthrography combines MRI with an arthrogram to identify both findings available with MRI, as well as the better capability to define labral tears among patients with symptoms of labral injuries in the shoulder. (Beall 03)

MR arthrography is especially recommended for evaluation of potential concomitant Bankart lesions or labral or rotator cuff tears. (Parentis 02; Kirkley 03; Friedman 95; LaBan 95; Bencardino 00; Sherbondy 00) Single or double-contrast CT arthrography might be a reasonable alternative when there is a lack of MRI availability, contraindications for MRI, or bony structure definition is needed as well. (Musgrave 01; Callaghan 88) X-rays might be needed of one or both shoulders, particularly if there was a bilateral injury or need for comparison with the unaffected shoulder. Most MR and CT arthrograms are performed using fluoroscopy to localize the joint and inject the contrast agent.

Recommendation: MR Arthrography to Diagnose Superior Labral Anterior Posterior or Other Labral Tears

## MR arthrography is recommended to diagnose superior labral anterior posterior (SLAP) or other labral tears.

*Indications* – Patients with subacute or chronic shoulder pain with symptoms or clinical suspicion of labral tears. Patients should generally have failed non-operative treatment including NSAID and waiting 4 to 6 weeks without trending towards resolution.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendation

X-ray is helpful to evaluate most patients with shoulder pain, both to diagnose and to assist with the differential diagnostic possibilities such as arthroses that might accompany SLAP tears. MR arthrograms have not been evaluated in quality studies. Studies comparing diagnosis of SLAP lesions with low- to high-field MR arthrography have had inconsistent results. (Loew 00; Tung 00) MR arthrography is invasive, has adverse effects including a low risk of infection, and is painful. It is also costly, although MR arthrography has been felt to provide better cost effectiveness than MRI or CT arthrography for select diagnoses. (Oh 99) MR arthrography is likely the best imaging procedure available for patients thought to have labral tears and is recommended for select use.

## WORK ACTIVITIES

Patients with acute significant labral tears may be able to return to occupational activities. However, limitations are generally required to avoid symptomatic aggravation especially for more physically demanding work. Limitations may include no overhead use, no lifting more than 15 pounds, no repeated forceful use, and avoidance of other activities that significantly increase symptoms. Limitations are gradually reduced as recovery progresses. If surgery is performed, there is a similar need for workplace limitations that are gradually reduced.

## **INITIAL CARE**

Initial care of a labral tear involves identification of other accompanying disorders, such as rotator cuff tendinopathies, tears, and acromioclavicular joint issues, and treated accordingly. (Enad 07) Over-the-counter (OTC) analgesics and self-applications of heat and ice have been used to treat labral tears. Slings are generally not required, although they might be reasonable for treatment of severe symptomatic tears, with use gradually weaned.

1. Recommendation: OTC Analgesics for Treatment of Superior Labral Anterior Posterior or Other Labral Tears

Over-the-counter analgesics are recommended for treatment of superior labral anterior posterior (SLAP) or other labral tears.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Self-application of Heat or Ice for Treatment of Superior Labral Anterior Posterior or Other Labral Tears

Self-application of heat or ice is recommended for treatment of superior labral anterior posterior (SLAP) or other labral tears.

Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Slings for Treatment of Severe Symptomatic Superior Labral Anterior Posterior or Other Labral Tears

Slings are recommended for treatment of severe symptomatic superior labral anterior posterior (SLAP) or other labral tears.

Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

There are no quality trials evaluating analgesics, ice, heat, or slings for management of acute SLAP and other labral tears. These are not invasive, have low adverse effects, are not costly, and are believed to be helpful for treating symptoms; thus, they are recommended.

## **FOLLOW-UP VISITS**

Patients with labral tears generally require a few follow-up appointments for purposes of monitoring symptoms, advancing treatment, and gradually reducing limitations if the tear is gradually resolving with non-operative care. Patients with slower resolution, need of operative care, or with other accompanying disorders will require a considerably greater number of appointments. Frequencies of appointments may also be greater if workplace limitations are required and job demands are higher. Post-operative rehabilitation can be extensive, particularly in older patients with other associated injuries such as rotator cuff injuries. In those cases, there may be a requirement for therapy on a prolonged basis to recover as much function as possible.

## **MEDICATIONS**

Over-the-counter medications may be helpful for pain associated with labral tears. Generally, the only medications commonly used for labral tears are NSAIDs. (Trantalis 08; D'Alessandro 00; Higgins 01; Dodson 09; Keener 09) Prescription medications such as opioids (see Medications for Rotator Cuff Tendinopathy) for pain management require judicious use and should only be considered in select cases. Patients may also require medications post-operatively.

1. Recommendation: NSAIDs or Acetaminophen for Pain Management for Superior Labral Anterior Posterior or Other Labral Tears

NSAIDs and acetaminophen are recommended for management of pain from superior labral anterior posterior (SLAP) or other labral tears.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Opioids for Pain Management for Select Patients with Superior Labral Anterior Posterior or Other Labral Tears

Judicious use of opioids is recommended for pain management for select patients with severe pain associated with superior labral anterior posterior (SLAP) or other labral tears.

Indications – Patients should meet all of the following:

- 15) Severe injury with a clear rationale for use (objective functional limitations due to pain resulting from the medical problem.<sup>xv</sup>
- 16) Other more efficacious treatments should have been instituted,<sup>xvi</sup> and either:2a) failed and/or

2b) have reasonable expectations of the immediate need for an opioid to obtain sleep the evening after the injury.

- 17) Where available, prescription databases (usually referred to as Prescription Drug Monitoring Program (PDMP)) should be checked and not show evidence for conflicting opioid prescriptions from other providers or evidence of misreporting.<sup>xvii</sup>
- 18) Non-opioid prescriptions (e.g., NSAIDs, acetaminophen) absent contraindication(s) should nearly always be the primary treatment and accompany an opioid prescription.
- 19) Low-dose opioids may be needed in the elderly who have greater susceptibility to the adverse risks of opioids. Those of lower body weight may also require lower opioid doses.
- 20) Dispensing quantities should be only what is needed to treat the pain. Short-acting opioids are recommended for treatment of acute pain. Long-acting opioids are not recommended.
- 21) Due to greater than 10-fold elevated risks of adverse effects and death, considerable caution is warranted among those using other sedating medications and substances including: i) benzodiazepines, ii) anti-histamines (H<sub>1</sub>-blockers), and/or iii) illicit substances.<sup>(105, 109, 167, 168)</sup> Patients should not receive opioids if they use illicit substances unless there is objective evidence of significant trauma or moderate to severe injuries. Considerable caution is also warranted among those who are unemployed as the reported risks of death are also greater than 10-fold.<sup>(109, 167)</sup> Due to elevated risk of death and adverse effects, caution is also warranted when considering prescribing an opioid for patients with any of the following characteristics: depression, anxiety, personality disorder, untreated sleep disorders, substance abuse history, current alcohol use or current tobacco use, attention deficit hyperactivity disorder (ADHD), post-traumatic stress disorder (PTSD), suicidal risk, impulse control problems, thought disorders, psychotropic medication use, chronic obstructive pulmonary disease (COPD), asthma, or recurrent pneumonia.<sup>(78, 102, 104, 108, 109, 169-186)</sup> Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis and/or cirrhosis,<sup>(187)</sup> as well as coronary artery disease, dysrhythmias, cerebrovascular disease, orthostatic hypotension, asthma, recurrent pneumonia, thermoregulatory problems, advanced age (especially with mentation issues, fall risk, debility), osteopenia, osteoporosis, water retention, renal failure, severe obesity, testosterone deficiency, erectile dysfunction, abdominal pain, gastroparesis, constipation, prostatic hypertrophy, oligomenorrhea, pregnancy, human immunodeficiency virus (HIV), ineffective birth control, herpes, allodynia, dementia, cognitive dysfunction and impairment, gait problems, tremor, concentration problems, insomnia, coordination problems, and slow reaction time. There are considerable drug-drug interactions that have been reported (see Opioids Guideline, Appendices 2-3).

<sup>&</sup>lt;sup>xv</sup>Other indications beyond the scope of this guideline include acute myocardial infarction or agitation interfering with acute trauma management.

<sup>&</sup>lt;sup>xvi</sup>Treatments to have tried generally include NSAIDs and acetaminophen. For LBP patients, additional considerations include muscle relaxants, progressive aerobic exercise, and directional exercise.

<sup>&</sup>lt;sup>xvii</sup>Exceptions such as acute, severe trauma should be documented.

*Frequency/Duration* – Generally, opioids should be prescribed at night or while not working.<sup>(82)</sup> Lowest effective, short-acting opioid doses are preferable as they tend to have the better safety profiles, less risk of escalation,<sup>(188)</sup> less risk of lost time from work,<sup>(112)</sup> and faster return to work.<sup>(189)</sup> Short-acting opioids are recommended for treatment of acute pain and long-acting opioids are not recommended. Recommend opioid use as required by pain, rather than in regularly scheduled dosing.

If parenteral administration is required, ketorolac has demonstrated superior efficacy compared with opioids for acute severe pain,<sup>(190, 191)</sup> although ketorolac's risk profile may limit use for some patients. Parenteral opioid administration outside of obvious acute trauma or surgical emergency conditions is almost never required, and requests for such treatment are clinically viewed as red flags for potential substance abuse.

*Indications for Discontinuation* – Resolution of pain, sufficient improvement in pain, intolerance or adverse effects, non-compliance, surreptitious medication use, consumption of medications or substances advised to not take concomitantly (e.g., sedating medications, alcohol, benzodiazepines), or use beyond 2 weeks.

Harms - Adverse effects are many (see section below on "Opioids Benefits and Harms").

Benefits – Improved short-term pain control.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Other Medications for Pain Management of Superior Labral Anterior Posterior or Other Labral Tears

Muscle relaxants, capsicum, tricyclic antidepressants or dual reuptake inhibiting antidepressants for chronic pain (but not SSRI antidepressants which are not effective for nociceptive pain), or gabapentin for peri-operative use are recommended to control pain associated with superior labral anterior posterior (SLAP) or other labral tears.

Strength of Evidence - Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

There are no quality trials evaluating treatment of labral tears with medications. NSAIDs have been evaluated for the treatment of many musculoskeletal disorders and found uniformly effective (see Rotator Cuff Tendinopathies). NSAIDs and acetaminophen are not invasive and have low adverse effects profiles, particularly when used for short courses in occupational populations. Generic or over-the-counter formulations are low cost. NSAIDs and acetaminophen also may help avoid treatment with opioids which have far worse adverse effect profiles (see Chronic Pain Guidelines). By analogy to treatment of other musculoskeletal conditions such as low back pain (see Low Back Complaints), acetaminophen is believed to be less efficacious, although it generally has a lower adverse effect profile.

There are no quality studies evaluating opioids for treatment of shoulder labral tear patients (see Rotator Cuff Tendinopathies and Chronic Pain Guidelines); thus quality evidence of long-term efficacy is lacking. Opioids have adverse effects with published evidence of high mortality risks. There are patients with severe pain, particularly select acute tear patients, for whom the brief use of opioids, especially to facilitate sleep, are recommended. Opioids are not invasive, have high adverse effects for a pharmaceutical (although tolerance may develop relatively rapidly), and are low cost when generic formulations are used.

Other medications are rarely required for labral tear patients, as the associated pain is usually acute and not subacute or chronic. Norepinephrine reuptake inhibiting anti-depressants (e.g., amitriptyline, doxepin, imipramine, desipramine, nortriptyline, protriptyline, maprotiline, and clomipramine) and mixed norepinephrine and serotonin inhibitors (e.g., venlafaxine, bupropion, and duloxetine) have evidence of efficacy for treatment of chronic low back pain and some other chronic pain conditions (see Low Back Complaints). However, while there is no quality evidence evaluating these medications for treatment of shoulder pain, they appear likely to be mildly effective for some patients, especially in cases involving the shoulder girdle and myofascial pain.

There are no quality studies that address the use of anti-convulsant agents to treat patients with shoulder pain. By analogy, there is quality evidence that topiramate is weakly effective for treatment of low-back pain patients and gabapentin is unhelpful. However, there is quality evidence that gabapentin reduces the need for opioids when administered as part of peri-operative hip surgery patients' pain management. (Pandey 04, Pandey 05, Radhakrishnan 05, Turan 04)

Skeletal muscle relaxants may be a reasonable alternative to spare opioid requirements in the acute recovery period and to facilitate sleep. However, daytime somnolence limits their use. Skeletal muscle relaxants are not recommended for continuous management of subacute or chronic shoulder pain, although they may be reasonable options for select acute pain exacerbations or for a limited trial as a 3rd- or 4th-line agent in more severely affected patients in whom NSAIDs and exercise have failed to control symptoms.

## DEVICES/PHYSICAL METHODS

Self-applications of heat or cryotherapies may be helpful for symptom modulation and are recommended to treat labral tears. Therapy including education and exercise is also recommended. Acupuncture and other physical methods such as massage, diathermy, and magnets have been used to treat labral tears. A sling may be helpful for more severe acute cases associated with SLAP and labral tears (they are not recommended for subacute or chronic symptoms as they promote debility over time), while an immobilizer is usually utilized for post-operative rehabilitation.

1. Recommendation: Acupuncture for Chronic Pain from Superior Labral Anterior Posterior or Other Labral Tears

## Acupuncture is recommended to control chronic pain associated with superior labral anterior posterior (SLAP) or other labral tears.

*Indications*- Highly selected patients with chronic pain who have inadequate relief and incapacity after multiple interventions including NSAIDs, a quality active exercise program with which there has been compliance, and potentially surgical repair. Caution that use may augment reliance on passive modalities instead of active, self-care treatment strategies.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Other Modalities for Treatment of Superior Labral Anterior Posterior or Other Labral Tears

There is no recommendation for or against the use of diathermy, infrared therapy, ultrasound, laser therapy, manual therapy, mobilization, manipulation, massage, high-voltage galvanic, H-wave stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, or transcutaneous electrical stimulation (TENS) for the treatment of superior labral anterior posterior (SLAP) or other labral tears.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

 Recommendation: Taping, Magnets, Pulsed Electromagnetic Frequency, or Interferential Therapy for Treatment of Superior Labral Anterior Posterior or Other Labral Tears
 Taping, magnets, pulsed electromagnetic frequency and interferential therapy are not recommended for the treatment of superior labral anterior posterior (SLAP) or other labral tears.

## Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

Acupuncture may be effective for treatment of chronic shoulder pain (see Rotator Cuff Tendinopathies above). However, most patients with SLAP and labral tears do not have chronic pain. Acupuncture may be indicated for select patients with chronic pain who do not have sufficient control with other interventions. There is no quality evidence and thus there is no recommendation for the use of

diathermy, infrared, ultrasound, laser, manual therapy, mobilization, manipulation, massage, high-voltage galvanic, H-wave stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, or transcutaneous electrical stimulation (TENS) to treat labral tears.

### **INJECTIONS**

Injections are generally not indicated for labral and SLAP tears. However, they are sometimes utilized to treat patients who have other conditions such as rotator cuff tendinopathies or who have an injection for combined diagnostic and therapeutic purposes; thus an injection may also be indicated for patients who have delayed recovery for unclear reasons (see Rotator Cuff Tendinopathy Injections). Intra-articular injection is occasionally used to help diagnoses SLAP tears.

Recommendation: Injections for Treatment of Superior Labral Anterior Posterior or Other Labral Tears Injections are not recommended for treatment of acute isolated labral or superior labral anterior posterior (SLAP) tears.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There is no evidence injections are efficacious for treatment of labral or SLAP tears. Injections are invasive, have adverse effects, and are moderately costly. Thus, they are not recommended, unless there is a simultaneous indication such as rotator cuff tendinopathy (see Rotator Cuff Tendinopathy).

## SURGICAL CONSIDERATIONS

Non-operative treatment has been widely used for labral tears. Surgical repair will not improve the clinical outcome if the labral tear is not the cause of the problem. When the tear is the cause of the problem, then repair is usually the treatment if the patient does not improve with non-operative management. The rate of success is unclear as there are no large population-based studies available, although some believe that patients who engage in throwing motions have a worse prognosis. (Dodson 09) A considerable proportion of these cases do not resolve with non-operative treatment. Primarily arthroscopic (Kippe 07; DaSilva 08; O'Brien 02; Oh 08; Yian 04; Gregush 07; Brockmeier 09; Coleman 07; Yung 08; Pinto 01; Keener 09; Westerheide 03; Neri 09) and some open techniques (Kartus 98) or combined approaches (Kippe 07) have been utilized for treatment. Some include addressing other abnormalities such as ganglion cysts along with the surgical approach. (Westerheide 03) Surgical approaches involving debridement alone or removal of the SLAP/labral lesion have been mostly abandoned due to low success rates and high rates of subsequent impairment and disability. (Altcheck 92; Cordasco 93) Subsequent attempts at repair of the tears (SLAP/labral lesion) have reported better results in case series than non repair approaches. (Segmuller 97; Field 93; Yoneda 91; Rhee 05; Brockmeier 09; Wilk 05; Trantalis 08) The risk for poor outcomes after surgery and rehabilitation has been estimated at 32%, (Katz 09) and are thought to be worse in workers' compensation patients. (Verma 07)

The type of tear is believed to guide the most appropriate surgical treatment, (Parentis 02; Rames 93; Bedi 08) although there is not complete agreement on the approaches. For Type I, debridement is most recommended, (Parentis 02; DaSilva 08; D'Alessandro 00; Nam 03) although some have recommended no debridement as the fraying is believed to be normal. (Gartsman Clin Sports Med 00) There are several different Type II lesions and these as well as other types of unstable tears have been recommended for repair with sutures or tacks. (DaSilva 08; D'Alessandro 00; Parentis 02; Cohen 06; Park 08; Nam 03; Morgan 98; Synder 90, 95; Warner 94; Field 93; Pagnani 95; Grauer 92; Resch 93; Yoneda 91) Biceps tenodesis has also been reportedly successful for treatment of some but not all Type II lesions, particularly in patients over 40 years old in whom repairing SLAP tears is associated with increased post-operative stiffness. (Boileau 09; Cordasco 93; Grauer 92) Type III lesions have been recommended for treatment with debridement involving the bucket handle tear and attempted repair with larger labral tears. (DaSilva 08; Nam 03; Parentis 02) Type IV lesions have been recommended for biceps debridement if there is less than 40% involvement and either repaired or tenodesed if greater than 30 to 50% involved. (Burkhart 93; Nam 03; Mileski 98; Pinto 01; Higgins 01; Baker 09) Specific labral pathologies are associated with shoulder injury and dysfunction. Some of these patients will need surgery to treat instability which will involve labral repair. Labral debridement in these

cases does not treat the instability. Some chronic degenerative SLAP tears that can be correlated with the patient's symptoms may require repair for management.

#### Recommendation: Arthroscopic or Open Surgery for Labral or Superior Labral Anterior Posterior Tears Arthroscopic or open surgery is recommended for select treatment of labral or superior labral anterior posterior (SLAP) tears.

*Indications* – Symptoms, MRA or MRI findings and clinical suspicion of labral or SLAP tear that does not resolve after approximately 4 to 6 weeks of non-operative treatment. Most individuals over age 40 do not appear to require surgical repair, although a minority that fail to either resolve or trend towards resolution may need operative repair. (Parentis 02; Altchek 92; Berg 97; Burkhart 98; Cordasco 93; Handelberg 98; Morgan 98; Kim Arthroscopy 03; Pearce 00; Payne 94; Resch 93; Segmuller 97; Snyder 95; Warner 94)

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials comparing non-operative with operative management of labral and SLAP tears. The current low-quality evidence suggests results with surgical repair are superior to non-operative management. There is one quality trial among patients with SLAP and rotator cuff tears that reported biceps tenotomy plus rotator cuff tear was superior to repair of the SLAP; (Franceschi 08) however, this trial is unable to address the central issue of appropriateness of surgery and surgical indications. Thus, while surgery is invasive, has adverse effects, and is high cost, surgical repair is recommended for patients whose labral tears are likely the cause of the clinical picture and do not resolve or trend towards resolution over approximately 4 to 6 weeks.

## Evidence for Surgery for SLAP Tears

There are 4 moderate-quality RCT incorporated into this analysis.

We searched PubMed, Scopus, CINAHL and Cochrane Library using the following terms: disorder terms-Labrum tears, Labrum tear, Labral tears, Labral tear, Labral Lesions, SLAP tear, SLAP tears, SLAP lesions, SLAP lesion, Bankart; RCT terms- controlled clinical trial, controlled trials, randomized controlled trial, randomized controlled trials, random allocation, random\*, randomized, randomization, randomly; systematic reviews terms- systematic, systematic review; Population studies terms: retrospective studies, prospective studies, epidemiological studies, epidemiological research, Nonexperimental Studies. In PubMed we found and reviewed 175 articles, and kept 23. In Scopus, we found and reviewed 176 articles, and kept 0. In CINAHL, we found and reviewed 25 articles, and kept 1. In Cochrane Library, we found and reviewed 2 articles, and kept 0.

Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			Comparison o	f Operative Technique	S	
Franceschi 2008 RCT	6.0	N = 63 over age 50 with rotator cuff tears associated with Type II SLAP lesions and at least 3 months symptoms with failure of NSAIDs, physiotherapy, rest, 1 corticoid injection	Arthroscopic repair of rotator cuff and type II SLAP lesion vs. rotator cuff repair and biceps tenotomy. 5.2 years follow- up.	Total UCLA scores (pre/post operative): RC plus SLAP repair (10.4/27.9) vs. RC repair plus biceps tenotomy (10.1/32.1). Forward flexion: RC plus SLAP repair (107/139°) vs. RC repair plus biceps tenotomy (99/166°).	"[N]o advantages in repairing a type II SLAP lesion when associated with a rotator cuff tear in patients over 50 years of age. The association of rotator cuff repair and biceps tenotomy provides better clinical outcome compared with repair of the type II LSAP lesion and the rotator cuff."	Some baseline differences. Some given acromioplasty. Long-term outcomes. Data suggest biceps tenotomy superior to repair of SLAP in these patients.
Abbot 2009	5.0	N = 48 with type II SLAP and	All patients had	Postoperatively, the debridement group	"In patients over the age of 45 years with a	Small sample size. Many

RCT		rotator cuff tears	arthroscopic	showed better UCLA	minimally retracted	methodological
KC1		rotator cuff tears	arthroscopic rotator cuff repair and subacromial decompressio n. Patients divided into two groups. Debridement group (n = 24): arthroscopic debridement of their Type II SLAP tears vs. repair group (n = 4): anchor placement and suture repair of their Type II SLAP tears. Post-op follow-up at 1 and 2 years.	showed better UCLA scores/pain/function and functional improvement vs. repair group: $34\pm2.1$ vs. $31\pm2.7$ ; p < $0.001/9.6\pm0.8$ vs. $7.7\pm1.4$ ; p < $0.001/9.6\pm0.8$ vs. $8.8\pm1.0$ ; p < $0.005$ , and $5.5\pm1.1$ vs. $3.8\pm1.9$ ; p < $0.001$ . At 1 year post-op, debridement group showed significantly improvements vs. repair group in internal rotation ( $69.3\pm11.3$ vs. $36.1\pm23.9$ ; p < $0.001$ ), external rotation ( $84.3\pm9.8$ vs. $68.6\pm12.8$ ; p < $0.001$ ), and forward flexion ( $166.0\pm4.8$ vs. $161.9\pm10.5$ ; p = 0.05). At 2 years post-op, debridement group showed significantly improvements vs. repair group in internal rotation ( $69.8\pm11.8$ vs. $37.8\pm23.8$ ; p < $0.001$ ) and external rotation ( $84.8\pm9.0$ vs. $69.7\pm12.5$ ; p	minimally retracted rotator cuff tear and associated SLAP lesion, arthroscopic repair of the rotator cuff with combined debridement of the type II SLAP lesion may provide greater patient satisfaction and functional outcome in terms of pain relief and motion."	methodological details sparse and randomization unclear. Data suggest debridement superior to repair.
Silberberg 2011 RCT	4.5	N = 32 underwent arthroscopic fixation for unstable isolated type II SLAP lesions.	Group 1 (n = 15): vertical suture configuration vs. Group 2 (n = 17): horizontal suture configuration. Mean follow- up of 37 months (range, 26 to 60 months).	<pre>&lt;0.001). Group 1 experienced significant differences between pre-op vs. post-op in VAS (7.7± 1.5 vs. <math>3.8\pm1.2</math>; p &lt; 0.05) and ASES (68± 12 vs. 91.9±14; p &lt; 0.05) scores. Group 2 experienced significant differences between pre-op vs. post-op in VAS (7.5±1.3 vs. <math>2.9\pm1.2</math>; p &lt; 0.05) and ASES (65± 13 vs. 95.8±12; p &lt; 0.05). No significant difference between groups after surgery.</pre>	"The results of this study suggest that the repair of an isolated type II SLAP lesion through a single anterior portal is clinically and functionally beneficial to patients regardless of the suture configuration performed (vertical or horizontal suture) because no differences were observed between these configurations after repair of an isolated type II SLAP lesion."	Small sample size. Did not randomize, but performed minimization to divide into groups. Both groups showed improvement, but no differences between groups after treatment.
Ok 2012	4.0	N = 28 with 29	Group 1 (n =	Significant difference	"This new technique	Small sample

RCT	shoulders, who had undergone arthroscopic repair of the superior labrum anterior- posterior (SLAP) lesion.	<ul> <li>13, 14</li> <li>shoulder):</li> <li>new fixation</li> <li>technique of</li> <li>Type II SLAP</li> <li>repair using</li> <li>double</li> <li>anchors vs.</li> <li>Group 2 (n =</li> <li>15, 15</li> <li>shoulders):</li> <li>Bioknotless</li> <li>suture anchor</li> <li>in</li> <li>conventional</li> <li>technique.</li> </ul> Follow-up at <ul> <li>6, 12 months</li> <li>and last visit</li> <li>after surgery.</li> <li>Group 1 had</li> <li>mean post-op</li> <li>follow-up of</li> <li>30.4 months</li> <li>(range, 12-62</li> <li>months) and</li> <li>29.7 months</li> <li>(range, 12-61</li> <li>months) in</li> </ul>	in the post-op ASES/Constant Scoring System/VAS pain scores in Group 1 vs. Group 2 at 12 months (91 $\pm$ 7.9 vs. 79 $\pm$ 15.0; p = 0.04/75 $\pm$ 2.6 vs. 69 $\pm$ 8.2; p = 0.03/ 2.1 $\pm$ 1.1 vs. 3.2 $\pm$ 1.8; p = 0.03) and at last visit (91 $\pm$ 11.9 vs. 82 $\pm$ 10.9; p = 0.03/ 76 $\pm$ 7.7 vs. 70 $\pm$ 4.0; p = 0.01/ 1.3 $\pm$ 1.5 vs. 2.5 $\pm$ 1.7; p = 0.04). At 6 and 12 months, group 1 showed more improvements in the ranges motion of forward flexion (145 $\pm$ 5.8 vs. 140 $\pm$ 10.1; p = 0.03 and 150 $\pm$ 1.7 vs. 146 $\pm$ 4.6; p = 0.04) and external rotation (88 $\pm$ 4.8 vs. 84 $\pm$ 9.2; p = 0.03 and 90 $\pm$ 3.8 vs. 87 $\pm$ 4.6; p =	provides anatomical restoration of a SLAP lesion and yields successful clinical and structural outcomes at a short-term follow-up."	size. Much variability in "last" follow-up (range 12-62 months).
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## **POST-OPERATIVE REHABILITATION**

Many different rehabilitation protocols have been reported that address rehabilitation for labral and SLAP tears. (Powell 04; DaSilva 08; O'Brien 87; O'Brien 02; Wilk 05; Dodson 09) One protocol involved immobilizer use for 3 weeks with passive forward elevation and full elbow ROM. During weeks 4 to 6, ROM is increased up to 90° of abduction and flexion. After 6 weeks, full ROM is begun; with gradual strengthening, biceps contraction begins. Overhead activities and strenuous biceps activity are avoided for 12 weeks. At 12 to 16 weeks, physical therapy is discontinued and normal activities resumed. Throwing does not resume for 4 to 5 months with full return to overhead sports at 8 to 9 months. (Powell 04)

Another protocol used an immobilizer for 4 weeks with active/active-assisted to 40° external rotation, 140° forward flexion and exercises of wrist, hand, elbow ROM; grip strengthening; isometric abduction; internal/external rotation at side. Weeks 4 to 6 used increased ROM to full and exercises of wrist/hand ROM, grip strengthening, theraband for isometrics, prone extensions, scapular stabilizing. In weeks 6 to 12, patients progressed to full active ROM and exercises, advanced to weights, and began upper-body ergometer. Weeks 12 to 6 months included full active motion without discomfort and exercises of progression to work/sport, return to weight room at 3 months and return to contact sports at 6 months. (DaSilva 08) However, another protocol utilized an immobilizer for 7 to 10 days followed by gentle pendulum exercises and passive ROM and isometric strengthening. Active-assisted exercises were added at 4 weeks with a goal of full ROM at 6 to 8 weeks. Rotator cuff and periscapular strengthening with Theraband was added at 6 weeks and progressive strengthening at 16 weeks with a goal for return to usual activities at 4 to 6 months. (Neri 09) Individualization of programs based on various factors, including age, conditioning, and immediate post-surgical results is needed.

Recommendation: Rehabilitation for Patients after Arthroscopic or Open Labral and Superior Labral Anterior Posterior Tear Repairs

## Rehabilitation is recommended for patients after arthroscopic or open labral and superior labral anterior posterior (SLAP) tear repairs.

Indications - Arthroscopic or open repairs of labral and SLAP tears.

*Frequency/Duration* – Two to 3 appointments per week for 3 weeks, then 2 a week for 2 weeks and once weekly to every other week for 6 to 9 additional weeks. (Kim 03) Exact regimen requires individualization; however, regimens are provided for guidance as examples of published protocols and are recommended.

Indications for Discontinuation – Recovery, plateau in recovery, noncompliance, or intolerance.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendation

There are no quality trials that address rehabilitation for labral and SLAP tears. However, exercise appears necessary and education with a home-exercise program appears to be required for nearly all patients. Rehabilitation is not invasive, has low adverse effects, but is moderate to high cost; however, it seems necessary and is thus recommended.

## ACROMIOCLAVICULAR SPRAINS AND DISLOCATIONS

Acromioclavicular (AC) sprains and dislocations are common injuries, especially in contact sports, (Kaplan 05; Thorndike 42) but can also occur in settings of automobile and other accidents and falls. (Simovitch 09; Post 85) Thus, they are occasionally work-related conditions. Long-term risks include secondary rotator cuff syndromes, acromioclavicular instability and osteoarthrosis in 50%. (Bergfeld 78)

## **DIAGNOSTIC CRITERIA**

The most commonly used scale grades AC sprains and dislocations from I to VI. (Allman 67, Tossy 63, Rockwood 91) Grades I and II are managed non-operatively. Grade III includes severe dislocation of the AC joint with elevation of the distal clavicle of at least 1 clavicular diameter on AP radiograph. Grades IV to VI are believed to require surgery. (Rockwood 91; Post 85; Simovitch 09)

Grade	Pathophysiology	Primary Treatment
1	Mild disruption of AC joint ligaments	Non-operative
II	Moderate force and disruption of AC ligaments and sprained coracoclavicular ligaments	Non-operative
	Severe force with disruption of AC and CC ligaments. Joint dislocation usually present.	Mostly non-operative. Sometimes operative, especially if heavy physical demands on shoulder
IV	Severe force usually with disruption of AC and CC ligaments. Posterior clavicle displacement present	Operative
V	Severe force with marked superior displacement of lateral clavicle. Disrupted AC and CC ligaments as well as deltoid and trapezius attachment to clavicle.	Operative
VI	Severe force with lateral clavicle displacement under the coracoid.	Operative

#### Table 8. Acromioclavicular Joint Disruptions with Pathophysiology and Basic Treatment\*

\*Adapted from Tossy 63; Allman 67; Rockwood 89; Post M, Clin Orthop Relat Res 1985; 200:234-47.

# SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS X-RAY

X-ray is the main diagnostic test for AC sprains and dislocations. (Simovitch 09) X-rays may occasionally be needed of both shoulders, particularly if there is a bilateral injury or need for comparison with the unaffected shoulder. Associated abnormalities among Grades III through V sometime occur, including SLAP lesions and rotator cuff tears (Tischer 09; Pauly 09) which sometimes require evaluation.

Recommendation: X-ray to Diagnose Acromioclavicular Sprains or Dislocations

# X-ray is recommended to diagnose acromioclavicular sprains or dislocations.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

X-ray is the main diagnostic test to detect changes in bony positioning and fractures.

# WORK ACTIVITIES

Patients with AC sprains may be able to return to occupational activities; however, limitations are generally required to avoid symptomatic aggravation especially for more physically demanding work. Limitations may include no overhead use, no lifting of more than 10 to 15 pounds with the affected arm, no repeated forceful use, and avoidance of other activities that significantly increase symptoms. Limitations are gradually reduced as recovery progresses. Frequent advice includes avoiding contact sports and heavy lifts for 2 to 3 months. If surgery is performed, there is a similar need for workplace limitations that are more gradually reduced.

# **INITIAL CARE**

Initial care of an AC sprain or separation involves identification of the grade of injury, as well as of other accompanying disorders such as fractures, rotator cuff tendinopathies, and labral injuries, and treated accordingly. (Simovitch 09) Over-the-counter analgesics and self-applications of ice and heat are recommended. Slings may be helpful acutely. Early range-of-motion exercises are recommended.

1. Recommendation: OTC Analgesics for Treatment of Acromioclavicular Sprains or Dislocations Over-the-counter analgesics are recommended for treatment of acromioclavicular sprains or dislocations.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Self-application of Heat or Ice for Treatment of Acromioclavicular Sprains or Dislocations

Self-application of heat or ice is recommended for treatment of acromioclavicular sprains or dislocations.

Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Slings for Treatment of Acromioclavicular Sprains or Dislocations Slings are recommended for treatment of acromioclavicular sprains or dislocations.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

There are no quality trials evaluating analgesics, ice, heat, or slings for management of AC sprains and separations. These are not invasive, have low adverse effects, are not costly, and are believed to be helpful for treating symptoms; thus, they are recommended.

# **FOLLOW-UP VISITS**

Patients with AC sprains generally require a few follow-up appointments for purposes of monitoring symptoms, advancing treatment, and gradually reducing limitations as the sprain resolves. Patients with more severe sprains, slower resolution, in need of operative care, or with other accompanying disorders will require a considerably greater number of appointments. Frequencies of appointments may also be greater where workplace limitations are required and job demands are higher. Early post-operative rehabilitation is advanced slowly to protect the repair.

# **MEDICATIONS**

Over-the-counter (OTC) medications, particularly NSAIDs, may be helpful for pain management and provide sufficient relieve for many Grade I and II AC sprains, (Post 85; Rockwood 91; Simovitch 09) (see Medications for Rotator Cuff Tendinopathy). Select patients may require judicious use of opioids for pain management. Patients may also require medications post-operatively.

1. Recommendation: Over-the-counter (OTC) Medications and NSAIDs for Pain Management of Acromioclavicular Sprains or Dislocations

Over-the-counter (OTC) medications such as acetaminophen, and particularly NSAIDs, are recommended to control pain associated with acromioclavicular sprains or dislocations.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Opioids for Pain Management for Select Patients with Acromioclavicular Sprains or Dislocations

Judicious use of opioids is recommended for pain management for select patients with severe acromioclavicular sprains or dislocations.

Indications - Patients should meet all of the following:

- 22) Severe injury with a clear rationale for use (objective functional limitations due to pain resulting from the medical problem.<sup>xviii</sup>
- 23) Other more efficacious treatments should have been instituted,<sup>xix</sup> and either:
  - 2a) failed and/or

2b) have reasonable expectations of the immediate need for an opioid to obtain sleep the evening after the injury.

- 24) Where available, prescription databases (usually referred to as Prescription Drug Monitoring Program (PDMP)) should be checked and not show evidence for conflicting opioid prescriptions from other providers or evidence of misreporting.<sup>xx</sup>
- 25) Non-opioid prescriptions (e.g., NSAIDs, acetaminophen) absent contraindication(s) should nearly always be the primary treatment and accompany an opioid prescription.
- 26) Low-dose opioids may be needed in the elderly who have greater susceptibility to the adverse risks of opioids. Those of lower body weight may also require lower opioid doses.
- 27) Dispensing quantities should be only what is needed to treat the pain. Short-acting opioids are recommended for treatment of acute pain. Long-acting opioids are not recommended.
- 28) Due to greater than 10-fold elevated risks of adverse effects and death, considerable caution is warranted among those using other sedating medications and substances including: i) benzodiazepines, ii) antihistamines (H<sub>1</sub>-blockers), and/or iii) illicit substances.<sup>(105, 109, 167, 168)</sup> Patients should not receive opioids if they use illicit substances unless there is objective evidence of significant trauma or moderate to severe injuries. Considerable caution is also warranted among those who are unemployed as the reported risks of death are also greater than 10-fold.<sup>(109, 167)</sup> Due to elevated risk of death and adverse effects, caution is also warranted when considering prescribing an opioid for patients with any of the following characteristics: depression, anxiety, personality disorder, untreated sleep disorders, substance abuse history, current alcohol use or current tobacco use, attention deficit hyperactivity disorder (ADHD), post-traumatic stress disorder (PTSD), suicidal risk, impulse control problems, thought disorders, psychotropic medication use, chronic obstructive pulmonary disease (COPD), asthma, or recurrent pneumonia.<sup>(78, 102, 104, 108, 109, 169-186)</sup> Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis

Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis and/or cirrhosis,<sup>(187)</sup> as well as coronary artery disease, dysrhythmias, cerebrovascular disease, orthostatic hypotension, asthma, recurrent pneumonia, thermoregulatory problems, advanced age (especially with mentation issues, fall risk, debility), osteopenia, osteoporosis, water retention, renal failure, severe obesity, testosterone deficiency, erectile dysfunction, abdominal pain, gastroparesis, constipation, prostatic hypertrophy, oligomenorrhea, pregnancy, human immunodeficiency virus (HIV), ineffective birth control, herpes, allodynia, dementia, cognitive dysfunction and impairment, gait problems, tremor, concentration problems, insomnia, coordination problems, and slow reaction time. There are considerable drug-drug interactions that have been reported (see Opioids Guideline, Appendices 2-3).

<sup>&</sup>lt;sup>xviii</sup>Other indications beyond the scope of this guideline include acute myocardial infarction or agitation interfering with acute trauma management.

xixTreatments to have tried generally include NSAIDs and acetaminophen. For LBP patients, additional considerations include muscle relaxants, progressive aerobic exercise, and directional exercise.

<sup>&</sup>lt;sup>xx</sup>Exceptions such as acute, severe trauma should be documented.

*Frequency/Duration* – Generally, opioids should be prescribed at night or while not working.<sup>(82)</sup> Lowest effective, short-acting opioid doses are preferable as they tend to have the better safety profiles, less risk of escalation,<sup>(188)</sup> less risk of lost time from work,<sup>(112)</sup> and faster return to work.<sup>(189)</sup> Short-acting opioids are recommended for treatment of acute pain and long-acting opioids are not recommended. Recommend opioid use as required by pain, rather than in regularly scheduled dosing.

If parenteral administration is required, ketorolac has demonstrated superior efficacy compared with opioids for acute severe pain,<sup>(190, 191)</sup> although ketorolac's risk profile may limit use for some patients. Parenteral opioid administration outside of obvious acute trauma or surgical emergency conditions is almost never required, and requests for such treatment are clinically viewed as red flags for potential substance abuse.

*Indications for Discontinuation* – Resolution of pain, sufficient improvement in pain, intolerance or adverse effects, non-compliance, surreptitious medication use, consumption of medications or substances advised to not take concomitantly (e.g., sedating medications, alcohol, benzodiazepines), or use beyond 2 weeks.

Harms - Adverse effects are many (see section below on "Opioids Benefits and Harms").

Benefits - Improved short-term pain control.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

There are no quality trials evaluating the use of medications for treatment of AC sprains and separations. One trial compared naproxen to piroxicam for treatment of disparate acute MSDs, but that trial did not primarily involve these patients. (McIlwain 88) However, NSAIDs have been evaluated in many musculoskeletal disorders and found to be uniformly effective (see Low Back Complaints and Rotator Cuff Tendinopathies). NSAIDs and acetaminophen are not invasive and have low adverse effects profiles, particularly when used for short courses in occupational populations. Generic or over-the-counter formulations are low cost. NSAIDs and acetaminophen also may help avoid treatment with opioids which have worse adverse effect profiles (see Chronic Pain Guidelines). NSAIDs and acetaminophen are recommended for treatment of acute, subacute, chronic, and post-operative AC sprain and separation patients. By analogy to treatment of other musculoskeletal conditions such as low back pain (see Low Back Complaints), acetaminophen is believed to be less efficacious, although it generally has a lower adverse effect profile.

There are no quality studies evaluating opioids for treatment of AC sprain and separation patients (see Rotator Cuff Tendinopathies and Chronic Pain Guidelines), thus quality evidence of long-term efficacy is lacking. Opioids have adverse effects with considerable risk of mortality. For patients with severe pain, particularly acute sprain or dislocation patients, in whom a brief use of opioids, especially to facilitate sleep, is recommended. Opioids are not invasive, have high adverse effects for a pharmaceutical (although tolerance may develop relatively rapidly), and are low cost when generic formulations are used.

Author/ Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
McIlwain	4.5	N = 38	Piroxicam	Measures of physical discomfort	"Piroxicam and	Heterogeneity in
1988		athletes	40mg QD for	improved (p <0.001) after 3, 7	naproxen are	disorders treated
		who had	2 days then	days both treatments. Mean	effective and	(e.g., sprains of
RCT		acute	20mg QD vs.	reduction in spontaneous pain,	well-tolerated	ankle, AC, hand
		symptoms	naproxen	swelling, tenderness statistically	short-term	IP, soft tissue
		including	500mg BID	superior (p <0.05) in piroxicam	treatments for	injuries of
		one of the	for 2 days	group. Overall patient	acute	shoulder, knee or
		following:	then 375mg	impressions of efficacy	musculoskeletal	hip). No placebo

Evidence for NSAIDs for Acromioclavicular Sprains or Dislocations There is 1 moderate-quality RCT incorporated into this analysis.

sprained ankle, sprained acromio- clavicular joint, sprained interphalan geal joint of hand, or acute soft- tissue shoulder, knee or hip injury	BID for 7 days.	(excellent): piroxicam 11/16 (68.8%) vs. naproxen 7/18 (38.9%). No difference between treatments for days lost to injury. Piroxicam had larger mean reductions from baseline for spontaneous pain ( $p = 0.047$ ), swelling ( $p = 0.035$ ), tenderness ( $p = 0.017$ ) at 1st return visit vs. naproxen.	injuries in athletes."	group. Data suggest piroxicam superior to naproxen.
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# DEVICES/PHYSICAL METHODS SLINGS OR SHOULDER IMMOBILIZERS

A sling or shoulder immobilizer may be helpful for more severe acute cases of AC separation (see Rotator Cuff Tendinopathies). Self-applications of heat or cryotherapies are recommended as potentially helpful for symptom modulation. Physical therapy is generally not needed for patients with isolated low-grade sprains. Therapy, including exercises and education, is more likely to be needed with either greater sprain severity or need for surgery.

Recommendation: Slings or Shoulder Immobilizers, but not compressive immobilizers, for Treatment of Severe Acromioclavicular Sprains or Dislocations

# Slings or shoulder immobilizers, but not compressive immobilizers, are recommended for treatment of severe acromioclavicular sprains or dislocations.

Indications - Acromioclavicular sprains and separations. (Lemos 98; Nuber 97)

*Frequency/Duration* – Daily use initially. Sling use for up to 7 to 10 days in Grades I to II sprains, then gradual weaning. Pendulum exercises are generally prescribed during the time of sling use. Six weeks of sling or immobilizer use is typically prescribed for post-operative treatment. In more severe cases, additional exercises are helpful.

Indications for Discontinuation – Recovery, plateau in recovery, noncompliance, or intolerance.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

Slings, but not compressive immobilizers, are often helpful for acute pain associated with AC sprains and separations. However, performance of pendulum exercises is usually indicated in part to prevent the potential development of limited ROM or adhesive capsulitis. **Slings are not recommended for subacute or chronic symptoms as they promote debility over time.** 

# EXERCISE

Recommendation: Therapy for Treatment of Severe Acromioclavicular Sprains or Dislocations Therapy, including exercises and education, is recommended for patients with severe acromioclavicular sprains or dislocations or who are in need of surgery.

*Indications* – Acromioclavicular sprains and separations, as well as post-operative use. (Lemos 98; Nuber 97)

*Frequency/Duration* – Pendulum exercises are generally initiated, along with other ROM exercises and education. These are typically followed by isometric strengthening program, then isotonic strengthening and endurance exercises. Programs require individualization based on factors such as patient's injury severity, age, experience, comorbid conditions, and compliance. A range of options includes weekly appointments to oversee and advance a home exercise program for several weeks until sufficiently recovered for lower grade injuries and self-motivated patients. Patients with more severe injuries or need

for supervision may require appointments 2 to 3 a week to initiate program exercises, tapering to 1 a week in approximately 4 weeks before being discharged to a home-exercise program in approximately 2 months for more severe injuries.

Indications for Discontinuation – Recovery, plateau in recovery, noncompliance, or intolerance.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

Education is often helpful for patient understanding of the condition and to facilitate exercises, especially in the post-operative period.

# DIATHERMY, INFRARED THERAPY, ULTRASOUND, LASER THERAPY, AND ELECTRICAL THERAPIES (INCLUDING TENS), TAPING, MAGNETS AND MAGNETIC STIMULATION, AND PULSED ELECTROMAGNETIC FREQUENCY

Recommendation: Other Modalities for Treatment of Acromioclavicular Sprains or Dislocations
 There is no recommendation for or against the use of diathermy, infrared therapy, ultrasound,
 laser therapy, manual therapy, mobilization, manipulation, massage, high-voltage galvanic, H wave stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation
 (PENS), sympathetic electrotherapy, or transcutaneous electrical stimulation (TENS) for
 treatment of acromioclavicular sprains or dislocations.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

 Recommendation: Taping, Magnets, Pulsed Electromagnetic Frequency, or Interferential Therapy for Treatment of Acromioclavicular Sprains or Dislocations
 Taping, magnets, pulsed electromagnetic frequency, or interferential therapy are not recommended for the treatment of acromioclavicular sprains or dislocations.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

Acupuncture may be effective for treating chronic shoulder pain (see Rotator Cuff Tendinopathies). However, most patients with AC sprains and separations do not have chronic pain. Acupuncture may be indicated for select patients with chronic pain who do not have sufficient control with other interventions.

There is no quality evidence evaluating the use of diathermy, infrared, ultrasound, laser, manual therapy, mobilization, manipulation, massage, high-voltage galvanic, H-wave® Device Stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, or transcutaneous electrical stimulation (TENS) for treatment of AC sprains and separations. Thus, there is no recommendation for their use.

# **INJECTIONS**

Injections are generally not indicated for AC sprains and separations. However, they are sometimes utilized for treatment of patients who have other conditions such as rotator cuff tendinopathies or who have an injection for combined diagnostic and therapeutic purposes. An injection may be indicated for patients who have delayed recovery for unclear reasons in whom an empiric injection for diagnostic and therapeutic purposes is performed (see Rotator Cuff Tendinopathy Injections). An injection is recommended prior to consideration of distal clavicle resection for patients with ongoing pain of at least 6 to 12 months to ascertain whether the injection will resolve the pain and, if the pain recurs, whether distal clavicle resection may be successful and should be recommended for grade I or II acromioclavicular dislocations.

1. Recommendation: Injections for Treatment of Acute Isolated Acromioclavicular Sprains or Dislocations Injections are not recommended for the treatment of acute isolated acromioclavicular sprains or dislocations.

# Strength of Evidence - Not Recommended, Insufficient Evidence (I)

2. Recommendation: Injections for Consideration of Distal Clavicle Resection for Select Patients An injection is recommended prior to consideration of distal clavicle resection for patients with ongoing pain of at least 6 to 12 months to ascertain whether the injection will resolve the pain and, if the pain recurs, whether distal clavicle resection might be successful and should be recommended provided there is no acromioclavicular instability.

*Indications* – Patients with ongoing pain of at least 6 to 12 months and in for whom surgery is considered.

*Dose/Frequency* – Dose is unclear as there are no controlled trials evaluating dosage. Simultaneous administration of a local anesthetic with a glucocorticosteroid is recommended to ascertain whether there is immediate relief on injection.

Strength of Evidence – Recommended, Insufficient Evidence (I)

# SURGICAL CONSIDERATIONS

Grade I and II AC sprains are managed non-operatively.(Mignani 02; Larsen 86; Bannister 89; Powers 74; Taft 87; Simovitch 09) Patients with AC joint separation managed non-operatively should anticipate pain for approximately 3 weeks, with pain gradually decreasing. If pain persists after recovery and return to activities, resection of the outer clavicle may be indicated after 6 months to 1 year, although local cortisone injection(s) should generally be attempted. The initial deformity may decrease as healing and scar contracture takes place. Persistence of the deformity is not an indication for surgery. In one series, 79% of patients with moderate-to-severe AC separations had good-to-excellent late results with nonoperative treatment; of the remainder, 90% had good-to-excellent results with simple excision of the outer clavicle.

Grade III separations have been managed both surgically and non-operatively; however, multiple reviews have opined the evidence fails to support a need for surgery and some outcomes were better in the non-operatively treated patients, (Phillips 98; Skjeldal 88; Taft 87; Powers 74; MacDonald 88; Larsen 86) other than potentially improved appearance. (Phillips 98; Galpin 85; Lancaster 87; Taft 87) A recent review reported there are no quality studies of Grade III sprains, (Simovitch 09) and a comparative clinical trial did not find differences between outcomes, (Press 97) while suggesting patients with Grade III separations may consider surgical stabilization if of younger age or who high job or sports demands. (Simovitch 09) Late symptoms, without surgery, include popping (sometimes painful), clicking, painful AC joint, and arthrosis.

Grades IV to VI have been mostly managed surgically. (Wang 08) Surgical approaches include acromioclavicular reduction, coracoclavicular ligament repair, coracoclavicular screw fixation, cerclage wire, autologous tissue coracoclavicular ligament reconstruction, acromioclavicular ligament reconstruction, and hook plates. (Simovitch 09; Norrell 65; Sethi 76; Faraj 01; Sim 95; Bosworth 41; Morrison 95; Boldin 04; Stewart 04; Dewar 65; Ferris 89; Lafosse 05; Jones 01; LaPrade 05; Yoo 06; Levine 98; Wang 08; Phillips 98; Allman 67; Avikainen 79; Bannister 89; Bargren 78; Ejeskar 74; Eskola 87; Galpin 85; Ho88; Jalovaara 91; Katznelson 75; Paavolainen 83; Skjeldal 88; Taft 87; Weaver 72; Vainionpaa 81; Vandekerckhove 85) However, there are no quality trials to define an optimal surgical approach or procedure. The AC joint has a fibrocartilaginous disk that exists, but degenerates and involutes with age, (DePalma 59) although it is frequently removed from injured joints of younger patients.

1. Recommendation: Surgical Repair of Acromioclavicular Joint Separation – Grades IV to VI Surgical repair is recommended for treatment of Grades IV to VI acromioclavicular joint separation.

Indications - Symptomatic Grade IV to VI acromioclavicular joint separation.

Strength of Evidence – Recommended, Insufficient Evidence (I)

 Recommendation: Routine Surgical Repair of Acromioclavicular Joint Separation – Grade III Routine surgical repair is moderately not recommended for Grade III acromioclavicular joint separations. (Larsen 86; Bannister 89)

Strength of Evidence – Moderately Not Recommended, Evidence (B)

3. Recommendation: Surgical Repair of Acromioclavicular Joint Separation for Select Patients – Grades III

# Surgical repair is recommended for highly select patients with Grade III acromioclavicular joint separations.

*Indications* – Symptomatic Grade III acromioclavicular joint separation in patients with concerns about cosmesis, or those with unusually high physical occupational or sports demands. (Larsen 86)

Strength of Evidence – Recommended, Insufficient Evidence (I)

 Recommendation: Non-operative Management of Acromioclavicular Joint Sprain – Grades I to II Non-operative management is recommended for patients with Grade I to II- acromioclavicular joint sprains.

Indications - Grade I to II acromioclavicular joint sprains.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

There are no quality trials comparing surgical with non-operative management of Grades I to II and IV to VI acromioclavicular joint separation. The former are believed to be satisfactorily addressed conservatively with excellent results and the latter are thought to be an indication for surgical treatment. The controversy is regarding management of Grade III separations. There are two moderate-quality trials comparing non-operative with operative management of Grade III AC separations. (Larsen 86; Bannister 89) Both studies documented better results with non-operative treatment, including faster recovery and earlier return to work and sports. Additionally, one study documented higher complications in the operatively managed group, (Bannister 89) and multiple other case series document complications in surgically managed patients. Surgery is invasive, has adverse effects, and is high cost. It is not recommended for the vast majority of Grade III AC separations. However, there may be patients with either particularly severe separations or with high physical demands who may theoretically benefit, thus there is a recommendation for consideration of surgery for those highly select groups.

Author/	Scor	Sample	Comparison	Results	Conclusion	Comments
Title	e (0-	Size	Group			
Study	11)					
Туре						
		Acron	nioclavicular Disloca	ation: Surgery vs. Non-Opera	tive Treatment	
Larsen	6.5	N = 84	Surgical treatment	Excellent/good results at 3	"For most patients with	Some details
1986		acute	(modified	months: operative group	total acromio-clavicular	sparse. Little
		acromio-	Phemister	34/39 vs. 39/40. At 13	dislocation we	description of
RCT		clavicular	procedure, intra-	months, operative group	recommend	subjects. High
		dislocatio	articular meniscus	38/39 vs. 39/40. Two in	conservative treatment	complication
		n with at	removed, AC joint	operative group vs. 3 non-	with a sling until the	rate in surgical
		least 75%	reduced, bones	operative required	patient is free of pain.	group. Data
		of width of	fixed with K-wires,	(re)operations. No	Operation should be	suggest non-
		clavicle	ends of AC and	complications in non-	considered in thin	operative
			CC ligaments	operative group vs. 11 in	patients who have a	treatment is
			sutured) vs. non-	surgical group (6 superficial	prominent lateral end	superior to this
			operative care	infection, 5 migrations of	of the clavicle, in those	surgical
			same as surgical	smooth K-wires).	who do heavy work,	procedure for
			group (sling, PT at	Borderline shorter sick-	and in patients whose	these patients.
			1 month after	leaves in non-operative	daily work requires that	High
			injury, no	group (median 6 vs. 8	the shoulder often be	complication

# Evidence for Surgical Repair of Acromioclavicular Joint Separation

			restrictions at 6 weeks). Mean 13 months follow-up.	weeks, p = 0.067).	held in about 90 degrees of abduction and flexion."	rate in part related to use of k-wire fixation of AC joint. Superficial infection rate is unusually high.
Bannister 1989	4.0	N = 60 acute	Open surgery (meniscus	Perfect/good or excellent results (1-4 years):	"Conservatively treated patients	Patients not well described.
1909		acromio-	removed, K-wire	conservative (50/38 to	regained movement	Some work-
RCT		clavicular	to hold joint and	59/41%) vs. surgical (50/27	significantly more	related events.
		dislocatio	AO cancellous or	to 60/ 24%). Results for	quickly and fully,	Data suggest
		n <10 dove old	malleolar screw	those with severe	returned to work and sport earlier and had	non-operative treatment
		days old	and washer; then arm sling for 2	dislocation: 1 good/excellent vs. 4 fair/poor in	fewer unsatisfactory	superior except
			weeks, then	conservative vs. 5	results than those	for severe
			rehab) vs.	good/excellent vs. 2	having early	dislocations.
			conservative	fair/poor surgical. Manual	operation. For severe	
			management (2	workers conservatively	dislocations, with	
			weeks in arm sling and same rehab	treated RTW at 4 weeks vs. 11 weeks (p <0.01) for	acromioclavicular displacement of 2 cm	
			protocol as	surgical. Clerical workers,	or more, early	
			operative arm); 4	RTW at 1 vs. 4 weeks (p	surgery produced	
			years follow-up.	<0.01). Conservatively	better results."	
				treated returned to sports earlier.		

# POST-OPERATIVE REHABILITATION: ACROMIOCLAVICULAR SEPARATIONS

Different rehabilitation protocols have been reported for AC separations. (Simovitch 09) One post-operative rehabilitation protocol entails use of a sling and cold therapy device. At 2 weeks, active and passive ROM exercises are instituted. Full active and passive ROM exercises are added when the screw is removed at 2 to 3 months. Progressive strengthening is then prescribed for 6 to 8 weeks. (Simovitch 09) Individualization of these protocols is likely required based on various factors, including immediate operative results, age, conditioning, compliance, and prior experiences. Rehabilitation programs should include education.

#### Recommendation: Rehabilitation for Patients after Surgical Repair of AC Separations Rehabilitation is recommended for patients after surgical repair of AC separations.

*Indications* – Surgical repairs of AC separations. Individualization is recommended based on various factors, including immediate operative results, age, conditioning, compliance, and prior experiences.

*Frequency/Duration* – Weekly to 3 times a week for first 2 weeks, then weekly to twice weekly for next 4 weeks, then weekly to twice weekly for following 6 to 8 weeks.

Indications for Discontinuation – Recovery, plateau in recovery, noncompliance, or intolerance.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials evaluating rehabilitation for AC separation patients. (Simovitch 09) However, exercises appear necessary and education along with a home-exercise program appears to be required for nearly all patients. Rehabilitation is not invasive, has low adverse effects, is moderate to high cost, but appears necessary for recovery for many of these patients and is thus recommended.

# SHOULDER (GLENOHUMERAL and ACROMIOCLAVICULAR JOINT) OSTEOARTHROSIS

The shoulder joints are substantially less likely to be affected by degenerative joint disease than other joints such as the knees, hips, spine, or fingers. As with other joints, there are many causes of degenerative findings on x-ray, only one of which is osteoarthrosis. Careful evaluation is required to

obtain the correct diagnosis. While most osteoarthrosis cases are not work related, some cases, especially unilateral, ipsilateral post-occupational fracture-related arthroses, are thought to be occupationally related.

# DIAGNOSTIC CRITERIA

Degenerative joint disease diagnosis is requires non-radiating pain and degenerative findings on x-ray. Confirming a diagnosis of osteoarthrosis requires attention to the history, evaluation of other joints, and exclusion of other causes, such as rheumatological or crystal disorders.

# SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS X-RAYS

X-rays may be needed of both shoulders, particularly if there was a bilateral injury or need for comparison with the unaffected shoulder. Other studies are usually unnecessary. CT scan may be used to clarify glenoid anatomy for surgical planning.

MRI may be helpful, particularly if there are concerns for rotator cuff tendinopathies but is not routinely needed.

Recommendation: X-ray to Diagnose Degenerative Joint Disease

X-ray is recommended to diagnose degenerative joint disease.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

X-ray is the main diagnostic test, particularly to help identify presence and extent of degenerative joint disease.

# WORK ACTIVITIES

Glenohumeral and AC joint osteoarthroses generally do not require work limitations. Occasionally limitations are required in severe cases to preclude symptomatic aggravation especially for more physically demanding work such as preventing overhead use, lifting of more than 15 pounds, repeated forceful use, and/or avoidance of other activities that significantly increase symptoms. Shoulder arthroplasty generally precludes return to physically demanding work.

# **INITIAL CARE**

Initial care of a patient with osteoarthrosis generally involves education. Identification of accompanying disorders, such as rotator cuff tear, allows for treatment of a second condition to substantially reduce or resolve the symptoms. Over-the-counter analgesics, self-applications of heat and ice, and slings have been used to treat osteoarthrosis and manage pain.

- 1. Recommendation: OTC Analgesics for Treatment of Osteoarthrosis Over-the-counter analgesics are recommended for treatment of osteoarthrosis. Strength of Evidence – Recommended, Insufficient Evidence (I)
- 2. Recommendation: Self-application of Heat or Ice for Treatment of Osteoarthrosis There is no recommendation for or against the use of self-application of heat or ice for treatment of osteoarthrosis.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

3. Recommendation: Slings for Treatment of Osteoarthrosis Slings are not recommended for treatment of osteoarthrosis.

# Strength of Evidence – Not Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

There are no quality trials evaluating analgesics, ice, heat or slings for management of shoulder osteoarthrosis. However, there are many trials nearly universally documenting efficacy of NSAIDs and acetaminophen for treatment of other joints with osteoarthrosis, particularly the hip and knee. OTC

analgesics are not invasive, have low adverse effects, are not costly, and are believed to be helpful for treating symptoms, thus they are recommended. There is no recommendation for or against use of heat or ice, although they might be helpful for symptomatic flares. Slings are not recommended as they promote debility.

# **FOLLOW-UP VISITS**

Patients with osteoarthrosis generally require a few follow-up appointments for purposes of monitoring symptoms, advancing treatment, and gradually reducing limitations especially if treatment of a coexistent condition substantially resolves the symptoms. Patients with more advanced disease may require a greater number of appointments to attempt other treatments as well as to teach about adaptive techniques and use of adaptive equipment (as indicated) to facilitate continued participation in daily activities despite limitations of the shoulder. Frequencies of appointments may also be greater if workplace limitations are required and job demands are higher or may require job modifications or adaptive equipment. Post-operative rehabilitation can be considerable, particularly in older patients with other associated injuries such as rotator cuff injuries. In those cases, there may be a requirement for therapy on a prolonged basis to recover as much function as possible.

# **MEDICATIONS**

Over-the-counter medications may be helpful to manage pain. These especially include acetaminophen and NSAIDs, (Bellamy 95; Diamond 76) with NSAIDs showing greater efficacy, but overall acetaminophen has a generally greater safety profile. Generally, the only medications commonly used for osteoarthrosis patients are NSAIDs, but patients may require other medications post-operatively. Select patients may require the judicious use of opioids for pain management. Other medications that have been used to treat osteoarthrosis include glucosamine, chondroitin, methylsulfonylmethane (see discussion below). Topical agents, such as capsaicin have also been utilized.

1. Recommendation: NSAIDs and Acetaminophen for Pain Management of Osteoarthrosis NSAIDs and acetaminophen are recommended to manage pain from osteoarthrosis.

Frequency/Duration - NSAIDs and acetaminophen are often used chronically, consideration of gastrointestinal and cardiovascular effects is recommended.

# Strength of Evidence – Recommended, Evidence (C)

2. Recommendation: Opioids for Pain Management for Select Patients with Severe Osteoarthrosis Judicious use of opioids is recommended for pain management for select patients with severe osteoarthrosis.

Indications – Patients should meet all of the following:

- 208-217)
- 2) A severe disorder warranting potential opioid treatment is present [e.g., advanced degenerative joint disease (DJD)].<sup>(1)</sup>
- 3) Other more efficacious treatments have been documented to have failed.<sup>(1)</sup> Other approaches that should have been first utilized include physical restorative approaches, behavioral interventions, self-applied modalities, non-opioid medications (including NSAIDs, acetaminophen, topical agents, norepinephrine adrenergic reuptake blocking antidepressants or dual reuptake inhibitors; also antiepileptic medications particularly for neuropathic pain) and functional restoration. For DJD, this includes NSAIDs, weight loss, aerobic and strengthening exercises.
- 4) An ongoing active exercise program is prescribed and complied with.
- 5) Non-opioid prescriptions (e.g., NSAIDs, acetaminophen) absent a contraindication should nearly always be the primary pain medication and accompany an opioid prescription. Other medications to consider include topical agents, norepinephrine adrenergic reuptake blocking antidepressants or dual reuptake inhibitors; also antiepileptic medications particularly for neuropathic pain).
  6) The lowest effective dose should be used.<sup>(188)</sup> Weaker opioids should be used whenever possible.<sup>(112, 189)</sup>

Meperidine is not recommended for chronic pain due to bioaccumulation and adverse effects.

- 7) Low-dose opioids may be needed in the elderly who have greater susceptibility to the adverse risks of opioids. Those of lower body weight may also require lower opioid doses.
- 8) Dispensing should be only what is needed to treat the pain.<sup>xxi</sup>
- 9) Extended-release/long-acting opioids are recommended to be used on a scheduled basis, rather than as needed.<sup>(1)</sup> As needed opioids should generally be avoided for treatment of chronic pain, although limited use for an acute painful event (e.g., fracture, sprain) is reasonable. Sublingual fentanyl is not recommended for treatment of subacute or chronic pain. Caution is warranted with fentanyl patches due to unpredictable absorption.
- Where available, prescription databases (usually referred to as Prescription Drug Monitoring Program (PDMP)) should be checked for conflicting opioid prescriptions from other providers or evidence of misreporting.
- 11) Due to greater than 10-fold elevated risks of adverse effects and death, considerable caution is warranted among those using other sedating medications and substances including: i) benzodiazepines, ii) anti-histamines (H<sub>1</sub>-blockers), and/or iii) illicit substances.<sup>(105, 109, 167, 168)</sup> Patients should not receive opioids if they use illicit substances unless there is objective evidence of significant trauma or moderate to severe injuries. Considerable caution is also warranted among those who are unemployed as the reported risks of death are also greater than 10-fold.<sup>(109, 167)</sup>

Due to elevated risk of death and adverse effects, caution is also warranted when considering prescribing an opioid for patients with any of the following characteristics: depression, anxiety, personality disorder, untreated sleep disorders, substance abuse history, current alcohol use or current tobacco use, ADHD, PTSD, suicidal risk, impulse control problems, thought disorders, psychotropic medication use, COPD, asthma, recurrent pneumonia.<sup>(79, 102, 104, 108, 109, 169-176, 179-186)</sup> Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis and/or cirrhosis,<sup>(187)</sup> as well as coronary artery disease, dysrhythmias, cerebrovascular disease, orthostatic hypotension, asthma, recurrent pneumonia, thermoregulatory problems, advanced age (especially with mentation issues, fall risk, debility), osteopenia, osteoporosis, water retention, renal failure, severe obesity, testosterone deficiency, erectile dysfunction, abdominal pain, gastroparesis, constipation, prostatic hypertrophy, oligomenorrhea, pregnancy, HIV, ineffective birth control, herpes, allodynia, dementia, cognitive dysfunction and impairment, gait problems, tremor, concentration problems, insomnia, coordination problems, and slow reaction time. There are considerable drug-drug interactions that have been reported (see Appendices 2-3).

*Frequency/Duration* – Opioids use is generally initiated as a "trial" to ascertain whether the selected opioid produces functional improvement (see Appendix 1). Opioid use is generally prescribed on a regular basis,<sup>(218)</sup> at night or when not at work.<sup>(82)</sup> Only one opioid is recommended to be prescribed in a trial. More than one opioid should rarely be used. Lower opioid doses are preferable as they tend to have the better safety profiles, less risk of dose escalation,<sup>(188)</sup> less work loss,<sup>(112)</sup> and faster return to work.<sup>(189)</sup> Patients should have ongoing visits to monitor efficacy, adverse effects, compliance and surreptitious medication use. Opioid prescriptions should be shorter rather than longer duration.<sup>(219)</sup>

*Indications for Discontinuation* – Opioids should be discontinued based on lack of functional benefit<sup>(115)</sup> (see Appendix 1), resolution of pain, improvement to the point of not requiring opioids, intolerance or adverse effects, non-compliance, surreptitious medication use, medication misuse (including self-escalation and sharing medication), aberrant drug screening results, diversion, consumption of medications or substances advised to not take concomitantly (e.g., sedating medications, alcohol, benzodiazepines).

*Harms* – Adverse effects are many (see Opioids Guideline section on "Opioids Benefits and Harms"). May initiate path to opioid dependency.

*Benefits* – Improved short-term pain ratings. Theoretical potential to improve short-term function impaired by a painful condition.

<sup>&</sup>lt;sup>xxi</sup>Generally, this should be sufficient to cover one week of treatment at a time during the trial phase. If a trial is successful at improving function, prescriptions for up to 90-day supplies are recommended.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Other Medications for Pain Management of Osteoarthrosis Capsicum, tricyclic antidepressants or dual reuptake inhibiting anti-depressants for chronic pain (but not SSRI antidepressants which are not effective for nociceptive pain), and gabapentin for peri-operative use are recommended for select use to control pain associated with osteoarthrosis.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

4. Recommendation: Over-the-counter Nutraceuticals for Pain Management of Osteoarthrosis There is no recommendation for or against the use of over-the-counter nutraceuticals (glucosamine, chondroitin, and methylsulfonylmethane) to control pain associated with osteoarthrosis.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendations

There is one moderate-quality trial suggesting equivalent efficacy of nabumetone and diclofenac for treatment of shoulder OA although the trial included patients with other joint OA. (Bellamy 95) There are numerous high- and moderate-quality RCTs and crossover trials documenting the efficacy of NSAIDs and acetaminophen for treatment of osteoarthrosis of the knee and hip, as well as superiority of NSAIDs to acetaminophen for this purpose. NSAIDs and acetaminophen are not invasive, have low though appreciable adverse effects particularly among employed populations, are low cost and effective, thus they are recommended for comprehensive review of cardiovascular and gastrointestinal protection issues).

There are no quality studies of opioids for treatment of shoulder osteoarthrosis (see Rotator Cuff Tendinopathies section and Chronic Pain Guideline), and there is a lack of quality evidence of long-term efficacy. Opioids have adverse effects and there is published evidence of high risks of mortality. There are select patients with severe pain in whom NSAIDs appear inadequate, thus limited use of opioids may be a consideration for select shoulder OA patients. Opioids are not invasive, have high adverse effects for a pharmaceutical, although tolerance for many of these develop relatively rapidly, and are low cost when generic formulations are used.

Glucosamine, chondroitin, and methylsulfonylmethane (MSM) are over-the-counter nutraceuticals that are advocated to modify or slow the progression of osteoarthrosis. However, there is no quality evidence evaluating their use to treat shoulder osteoarthrosis. There are 13 quality studies that included a comparison of glucosamine sulfate with placebo. Of the five highest quality studies, one (Mazieres 07) was negative, but also trended towards benefits. There are four quality studies that included a comparison of chondroitin sulfate with placebo. (Uebelhart 04; Clegg 06; Mazieres 07; Michel 05) The studies on chondroitin are somewhat mixed - two studies suggest x-ray benefits; however, symptoms were not improved in two other studies (Michel 05; Mazieres 07) although trended towards benefit in one study. (Mazieres 07) One quality study included an assessment of MSM and found that it appeared beneficial. (Usha 04) Overall, studies suggest benefits at rates well above chance associations. These preparations are not invasive, appear safe, and do not result in gastrointestinal erosions or other common side effects of NSAIDS, are relatively inexpensive, and provide modest relief of knee OA pain, particularly in patients with more advanced pain. These medications might also modify or slow the progression of knee OA as measured by slowing of cartilage destruction and joint narrowing, (Pavelka 02; Reginster 01; Michel 05) although the clinical significance of this effect has not be fully identified; the sole study following hip joint spaces was statistically negative though also trending towards efficacy. (Rozendaal 08) There is preferential evidence for the use of the sulfate salt rather than the hydrochloride formulation of glucosamine. There is one quality study involving MSM. (Usha 04) There is some evidence that a single daily dose might be more effective than divided doses. Thus, there is quality evidence that glucosamine with or without chondroitin is efficacious for treatment of osteoarthrosis. There is one trial that included rose hip powder. (Rein 04)

However, primarily due to lack of uniformity and standardization in preparations, some inconsistency in studies, most of the studies involve the knee, and no studies involving the shoulder, there is no recommendation for or against the use of these preparations for shoulder OA.

# Evidence for NSAIDs for Osteoarthrosis

There is 1 high- and 1 moderate-quality RCT or crossover trial incorporated into this analysis. There is 1 low-quality crossover trial in Appendix 2.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Bellamy 1995 RCT	6.0	N = 382 hip, knee or shoulde r OA	Nabumetone 1,000mg vs. diclofenac SR 200mg QPM for 3 months. Dose could be titrated once after 2 weeks of initial dose. Double dummy.	NSAID vs. NSAID More on Nabumetone titrated to higher dose (69% vs. 53%, p = 0.002). Physician assessments of disease activity: 63% improved on nabumetone vs. 70% on diclofenac. Pain ratings reduced approximately 40% by either treatment. Adverse effects in 43 diclofenac vs. 27 nabumetone patients (p <0.04).	"Nabumetone is efficacious and well tolerated in patients with OA of the hip, knee or shoulder. In this group of patients it is similar in efficacy and superior in tolerability to diclofenac SR."	Variable doses used. High dropout rate (43%) at 6 months precludes strong conclusions.
2004 Crossover Trial	8.5	N = 112 OA in hip, knee, hand, shoulde r, neck	Rose-hip powder 5g a day vs. placebo for 3 months each treatment arm.	Se-Hip Powder vs. Placebo Pain reduction in placebo first group: $1.02\pm1.45$ vs. $1.91\pm1.43$ , p = 0.008. Among those given rose hip first, pain reduction $1.45\pm1.28$ vs. $1.72\pm1.37$ , p = 0.61. Consumption of rescue medication had similar effects.	"Hyben Vital reduces the symptoms osteoarthritis. We interpret the marked differences in the response of the two groups as indicating a strong "carryover" effect of Hyben Vital."	Dropout rate high. Article assumes lack of pain rebound in group given active medication first is due to carry forward effect of prior active treatment. No data to show wearing off over time.

# DEVICES/PHYSICAL METHODS SLINGS AND BRACES

Slings generally promote debility in osteoarthrosis and are believed to predispose towards adhesive capsulitis, thus they are not recommended to treat shoulder OA. However, the use of slings and functional braces in the post-operative setting is frequently needed.

Recommendation: Slings and Functional Braces for Post-operative Treatment of Osteoarthrosis Slings and functional braces are recommended for post-operative treatment of osteoarthrosis.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

Slings and braces have been used for post-operative management of osteoarthrosis patients and are recommended. Early mobilization is also recommended to promote recovery.

# ACUPUNCTURE

Acupuncture has been used for treatment of patients with chronic shoulder osteoarthrosis. (Moore 76) It has most commonly been used as an adjunct to more efficacious treatments.

# Recommendation: Acupuncture for Treatment of Select Patients with Chronic or Post-operative Osteoarthrosis Acupuncture is recommended for select use in patients with chronic or post-operative osteoarthrosis as an adjunct to more efficacious treatments.

*Indications* – As a tertiary treatment if NSAIDs, activity modifications, and exercises result in failure to either resolve the pain or improve it sufficiently.

*Frequency/Duration* – Frequency and duration pattern in the quality trial was weekly for 3 weeks. An initial trial of 4 appointments would appear reasonable in combination with NSAIDs and activity modifications, as well as a conditioning program of aerobic and strengthening exercises for most patients. An additional 4 appointments should be tied to improvements in objective measures after the first 4 treatments, for a total of 8 appointments. (Guerra de Hoyos 04)

*Indications for Discontinuation* – Resolution, intolerance, or non-compliance including non-compliance with aerobic and strengthening exercises.

# Strength of Evidence – Recommended, Evidence (C)

# Rationale for Recommendation

There is one moderate-quality trial that included patients with shoulder osteoarthrosis with some indication of efficacy of acupuncture. (Moore 76) There are multiple other trials involving chronic shoulder conditions including rotator cuff tendinopathies with quality evidence suggesting efficacy (see Rotator Cuff Tendinopathies). Acupuncture is minimally invasive as typically performed, has low adverse effects, is moderately costly depending on numbers of treatments, and is recommended for select use in patients in whom other interventions, particularly if NSAIDs and activity modifications are insufficient.

# Evidence for Acupuncture for Osteoarthrosis

There is 1 moderate-quality RCT incorporated into this analysis.

Author/ Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Moore 1976 RCT	4.0	N = 42 shoulder tendonitis, bursitis or osteoarthrit is	2x2 factor trial. Acupuncture (Ho- ku, ChuChih, Chu- ku, Chien-yu, Chiennei-lin, Nao- yu, Chien-chen; 0.5-1.0cm insertion depths) vs. sham (same locations, prick skin, stimulation through tapping needle on skin. Further divided into positive vs. negative enthusiasm regarding treatment efficacy. 1 treatment a week for 3 weeks. 4 weeks follow-up.	Improvement compared to baseline: 23% acupuncture vs. 39% sham. Improvement compared with pre- treatment in acupuncture positive setting 33% vs. 14% negative setting. Sham positive setting 38% vs. negative setting 41%. Little or no hypnotic susceptibility/ slight to moderate/ marked: 21% of little/no vs. 38% slight to moderate vs. 40% marked had more than 60% improvement.	"[R]ange of motion did not improve, the majority of patients reported significant improvement in shoulder discomfort to a blind evaluator after treatment; placebo and acupuncture groups did not differ in this respectIn all groups, those who were not rated as highly susceptible to hypnosis tended to fail to achieve the highest levels of relief, but such differences were not statistically significant."	No description of patients. Data suggest variability in outcomes based on hypnotic susceptibility.

# MANUAL THERAPY, MOBILIZATION, MANIPULATION, MASSAGE

Manual therapy, mobilization, manipulation, and massage have been used to treat patients with osteoarthrosis.

Recommendation: Manual Therapy, Mobilization, Manipulation, or Massage for Treatment of Osteoarthrosis of the Shoulder

# There is no recommendation for or against the use of manual therapy, mobilization, manipulation, or massage for patients with osteoarthrosis of the shoulder.

# Strength of Evidence – No Recommendation, Insufficient Evidence (I)

# Rationale for Recommendation

There are no quality trials demonstrating efficacy of these treatments for these OA patients, thus there is no recommendation for or against their use.

# HOT AND COLD THERAPIES

Hot or cold therapies have been used to treat osteoarthrosis. Patients with osteoarthrosis tend to prefer heat.

#### Recommendation: Hot or Cold Therapies for Treatment of Osteoarthrosis

There is no recommendation for or against the use of hot or cold therapies to treat patients with osteoarthrosis.

# Strength of Evidence - No Recommendation, Insufficient Evidence (I)

# Rationale for Recommendation

There are no quality trials evaluating ice or heat for management of shoulder osteoarthrosis. These are not invasive, have low adverse effects, are not costly when self-applied, although there is no evidence of their efficacy for this chronic condition and thus there is no recommendation for their use. Thresholds for use to help manage symptomatic flares are suggested to be low.

# DIATHERMY, INFRARED THERAPY, ULTRASOUND, LASER THERAPY, AND ELECTRICAL THERAPIES (INCLUDING TENS), TAPING, MAGNETS AND MAGNETIC STIMULATION, AND PULSED ELECTROMAGNETIC FREQUENCY

Various means of delivering heat, as well as electrical therapies for purposes of distraction have been utilized for treatment of osteoarthrosis, although no quality studies for treatment of shoulder osteoarthrosis have been identified.

1. Recommendation: Other Modalities for Treatment of Shoulder Osteoarthrosis

There is no recommendation for or against the use of diathermy, infrared therapy, ultrasound, laser therapy, high-voltage galvanic, H-wave stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, interferential therapy, or transcutaneous electrical stimulation (TENS) for the treatment of shoulder joint osteoarthrosis.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

2. Recommendation: Taping and Magnets for Treatment of Shoulder Osteoarthrosis Taping, magnets and magnetic stimulation, or pulsed electromagnetic frequency are not recommended for treatment of shoulder osteoarthrosis.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

There is no quality evidence evaluating diathermy, infrared, ultrasound, laser, high-voltage galvanic, Hwave stimulation, iontophoresis, microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, and transcutaneous electrical stimulation (TENS) for shoulder osteoarthrosis, thus there is no recommendation for their use. Taping is generally not thought to be indicated for chronic conditions. Magnets and magnetic stimulation have been evaluated in quality trials for other MSDs, including LBP and found to be ineffective and thus are not recommended for treatment of shoulder osteoarthrosis.

# **INJECTIONS**

# INTRA-ARTICULAR GLUCOCORTICOSTEROID INJECTIONS

Intra-articular glucocorticosteroid injections are sometimes performed to attempt to deliver medication with minimal systemic effects to the shoulder joints, especially the glenohumeral joint and sometimes the acromioclavicular joint. These injections are both performed with and without fluoroscopic or ultrasound guidance. Their usual purpose is to gain sufficient relief to either resume conservative medical management or to delay surgical intervention. There is quality evidence of short-term efficacy in treatment of hip and knee osteoarthrosis patients (see Knee Complaints), with duration of benefits of approximately 3 months.

Recommendation: Intra-articular Glucocorticosteroid Injections for Shoulder Glenohumeral or Acromioclavicular Joint Osteoarthrosis

# Intra-articular glucocorticosteroid injections are recommended for treatment of shoulder osteoarthrosis.

*Indications* –Glenohumeral or acromioclavicular joint pain from osteoarthrosis sufficient that control with NSAIDs, acetaminophen, and potentially exercise is unsatisfactory.

*Frequency/Duration* – Schedule an injection, rather than scheduling a series of 3 injections. Medications used in the RCTs for the comparably-sized hip joint were triamcinolone hexacetonide 40mg or triamcinolone acetonide 80mg, or methylprednisolone 40 or 80mg. Anesthetics have most often been bupivacaine or mepivacaine. There are no head to head comparisons in quality studies of different medications to ascertain the optimum medication(s).

*Dose* – Multiple doses have been utilized with no head-to-head comparisons in trials; however, a comparative clinical trial found greater efficacy for methylprednisolone 80mg over 40mg in treatment of hip osteoarthrosis. (Robinson 07)

Indications for Discontinuation – A second glucocorticosteroid injection is not recommended if the first has resulted in significant reduction or resolution of symptoms. If there has not been a response to a first injection, there is generally less indication for a second. If the interventionalist believes the medication was not well placed and/or if the underlying condition is so severe that 1 steroid bolus could not be expected to adequately treat the condition, a second injection may be indicated and should be performed under ultrasound or fluoroscopic guidance. In patients who respond with a pharmacologically appropriate several weeks of temporary, partial relief of pain, but who then have worsening pain and function and who are not (yet) interested in surgical intervention, a repeat steroid injection is an option. There are not believed to be benefits beyond approximately 3 of these injections in a year. Patients requesting a fourth injection should have reassessment of conservative management measures and be counseled for possible surgical intervention.

# Strength of Evidence - Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

There are no quality trials evaluating intra-articular glucocorticosteroid injections for treatment of shoulder joint OA. However, there are quality trials for treatment of both hip and knee osteoarthrosis patients with documented efficacy lasting approximately 3 months. These injections are invasive, have a low risk of adverse effects, but are relatively costly. They are an option for treatment of moderate to severe shoulder osteoarthrosis patients particularly after inadequate results from NSAID trials, activity modification, exercise, or other conservative interventions.

# **VISCOSUPPLEMENTATION INJECTIONS**

Viscosupplementation has been performed particularly for knee osteoarthrosis and hip osteoarthrosis. (Caglar-Yagci 05; Tikiz 05; Abate 08; van den Bekerom 08; Dagenais 07) These injections have been performed in the shoulder as well. (Blaine 08; Kwon 13; Colen 14)

Recommendation: Intra-articular Glenohumeral Viscosupplementation Injections for Shoulder Osteoarthrosis

# Intra-articular glenohumeral viscosupplementation injections are not recommended for treatment of shoulder osteoarthrosis.

# Strength of Evidence – Not Recommended, Evidence (C)

# Rationale for Recommendation

There are three moderate-quality trials that included shoulder osteoarthrosis patients. None of them suggest efficacy. (Kwon 13; Blaine 08; Shibata 01) However, most of the highest quality trials for treatment of knee and hip osteoarthrosis suggest short- to intermediate-term efficacy (see Knee Complaints). Viscosupplementation injections are invasive, have a low risk of adverse effects, but are relatively costly. A high-quality trial showed glucocorticosteroid injections are superior, thus steroid injections should generally be used initially. (Qvistgaard 06) Viscosupplementation injections do not have evidence of efficacy for treatment of shoulder osteoarthrosis and are generally not recommended.

Author/	Scor	Sample	RCIs incorporated Comparison	Results	Conclusion	Comments
Title	e (0-	Size	Group	Nesuits	Conclusion	Comments
Study	11)	0126	Oroup			
Туре	,					
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		S	Shoulder Pain: Sodium	h Hyaluronate vs. Saline	e Placebo	_
Kwon	7.0	N = 300	Sodium	A difference of	"Numeric	HA versus buffered
2013		with	Hyaluronate group	4.0mm noted in VAS	advantage, but	saline for 3 times per
		glenohumer	(HA)- 3 weekly	pain score over 26	no statistically	week. Study claims
RCT		al	injections for 26	weeks in favor of HA	significant	blinded treater but the
		osteoarthriti	weeks (n=150)	group (p = 0.038).	differences, in	viscosity would
		s; Mean	vs. Phosphate-	From baseline, VAS	efficacy were	potentially clue.
		age 66.1	buffered saline	improvement was	found between	Apparent post hoc
		years for	(PBS)- 3 weekly	21.04mm for HA	HA- and PBS-	analysis suggest
		both groups	injections for 26	group and 15.67 in	treated ITT	possible efficacy but
			weeks (n=150).	PBS group at 26	patients with	overall trial negative.
				week final follow-up.	GH-OA."	
			Follow-up	This difference was		
			assessments made	not statistically		
Dising	0.5	NL 000	to 26 weeks.	significant, (p >0.05).	"[Ole diume	
Blaine 2008	6.5	N = 660	Five weekly injections of	Mean reductions in pain from baseline	"[S]odium hyaluronate	Heterogeneous patients, mostly OA.
2008		mostly osteo-	hyaluronate vs. 3	(Weeks 7/13/26): 5-	(500 to 730	High dropouts. Mostly
RCT		arthrosis	hyaluronate plus 2	Hy injections	kDa) is effective	lacking efficacy.
NO1		(58-62%)	saline vs. 5 saline	(26.0±1.8/26.4±	and well	Blinding not described.
		(00 02 /0)	injections.	1.8/27.8±1.9) vs. 3-	tolerated for the	Compliance unclear.
			Fluoroscopic	Hy-injections	treatment of	Higher % increased BMI
			guidance not used;	(22.9±1.8/	osteoarthritis	in 5 injection
			26-week follow-up.	26.3±1.8/30.9±1.9)	and persistent	hyaluronate group may
				vs. 5 saline	shoulder pain	be biased as MI is likely
				(20.1±1.8/	that is	correlated with systemic
				23.0±1.8/23.6±1.9).	refractory to	osteoarthrosis. Data do
					other standard	not clearly support
					nonoperative	efficacy.
01.11	1.0	NI 70 ( "	NA7 11 1 1 1		interventions."	NI I I ( )
Shibata	4.0	N = 78 full	Weekly injections	No differences in dis-	"These results	No placebo control.
2001		thickness	for 5 weeks of	ability between groups after	suggest that SH is an effective	Injected glenohumeral joint. Compliance
RCT		rotator cuff tears on	sodium hyaluronate	groups after injections. Satis-	is an effective conservative	Joint. Compliance unclear as allowed to
RUI		MRI or	25mg plus 3mL 1% lidocaine vs.	faction with treatment	treatment for	dropout. Data do not
		arthrograph	dexamethasone	among 42% SH vs.	patients with	support efficacy for this
		y annograph	2mg plus 3mL 1%	37.5% steroid (NS).	rotator cuff	purpose as appears
		y	lidocaine. Injections	Results (such as	tears."	equally ineffective.
			in glenohumeral	UCLA scores)		equally monocuro.
			joint; 4 weeks	presented stratified		
			follow-up.	by whether patient		
			· I	satisfied or		
				unsatisfied.		

Evidence for the Use of Viscosupplementation Injections for Osteoarthrosis There are 3 moderate-guality RCTs incorporated into this analysis.

# **PROLOTHERAPY INJECTIONS**

Prolotherapy injections have been utilized to treat a wide array of musculoskeletal disorders.

#### Recommendation: Prolotherapy Injections for Treatment of Shoulder Osteoarthrosis Prolotherapy injections are not recommended for treatment of osteoarthrosis.

# Strength of Evidence - Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

Prolotherapy injections have no quality evidence for efficacy for treatment of shoulder osteoarthrosis patients. These injections are invasive, have adverse effects, and are moderate to high cost; thus, they are not recommended for treatment of shoulder osteoarthrosis.

# SURGICAL CONSIDERATIONS ARTHROSCOPY AND CHONDROPLASTY

Arthroscopy is thought to have a role in glenohumeral arthrosis with purposes including diagnosis, debridement, capsular release, subacromial decompression, planning an operative approach, and synovectomy. (Bishop 03; Guyette 02; Sperling 06) It is particularly thought to be helpful for treatment of other conditions, such as SLAP tears and rotator cuff tendinopathies. (Sperling 06) Chondroplasty has often been performed for treatment of osteoarthrosis patients and involves abrading of the cartilage surfaces (see Knee Complaints). (Moseley 02) Arthroscopy is not indicated in presence of advanced glenohumeral arthritis.

1. Recommendation: Arthroscopy for Evaluation and Treatment of Shoulder Osteoarthrosis Arthroscopy is recommended for evaluation and treatment of shoulder osteoarthrosis particularly when an associated disorder is felt to be present, symptomatic, and treatable.

*Indications* – Shoulder joint pain from osteoarthrosis to the extent that control with NSAID(s), acetaminophen, and exercise strategies is unsatisfactory. Patients should generally have a treatable, symptomatic associated condition (e.g., rotator cuff tendinopathy, impingement syndrome, SLAP tear), with the expectation that resolution of the associated condition will improve the patients' overall condition. Appropriate diagnostic testing of the associated condition should have been performed (e.g., injection, MRI or MRA) to confirm a treatable associated condition.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Chondroplasty for Treatment of Shoulder Osteoarthrosis Chondroplasty is not recommended for treatment of shoulder osteoarthrosis.

# Strength of Evidence - Not Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

There are no quality trials evaluating arthroscopy for patients with OA of the shoulder. Arthroscopy is believed to be particularly helpful for planning an operative approach and for evaluating and treating nonosteoarthrosis conditions such as rotator cuff tendinopathies, SLAP tears, etc. (Sperling 06) Arthroscopy is invasive, has adverse effects, and is costly. However, it is also the primary means to address these other associated conditions, thus it is recommended for patients thought to have those conditions. Chondroplasty is invasive, has adverse effects, is costly, and lacks efficacy in the knee according to high quality evidence (see Knee Complaints). (Moseley 02) Thus, chondroplasty is not recommended for treatment of shoulder osteoarthrosis.

# **DISTAL CLAVICLE RESECTION**

Distal clavicle resection has been performed for chronic, significant acromioclavicular joint pain with either open (Freedman 07; Berg 97; Bigliani 93; Cook 88; Corso 95; Flatow 95; Gartsman 93; Lesko 01; Levine 98; Petersson 83; Gurd 41; Mumford 41) or arthroscopic approaches. (Bigliani 93; Corso 95; Charron 07; Flatow 92; Gartsman 93; Lesko 01)

#### Recommendation: Distal Clavicle Resection for Treatment of Acromioclavicular Joint Pain Distal clavicle resection either arthroscopic or open is recommended for treatment of acromioclavicular joint pain.

*Indications* – X-ray or other imaging evidence of acromioclavicular degenerative joint disease and confirmation with a local anesthetic injection relieving all or nearly all pain. Patients should have reproducible acromioclavicular joint pain with insufficient pain relief with NSAIDs, activity modification, and injection(s) (Freedman 07)

# Strength of Evidence – Recommended, Evidence (C)

## Rationale for Recommendation

There are no quality trials comparing arthroscopy to non-surgical treatment. However, there is a moderate-quality trial suggesting arthroscopic or open approaches to distal clavicle resection are equivalent and result in good outcomes at 1 year. (Freedman 07) Arthroscopy and open approaches are invasive and have adverse effects, (Chronopoulos 08) but are recommended for treatment of acromioclavicular pain that is refractory to non-operative approaches.

# Evidence for Distal Clavicle Resection

There is 1 moderate-quality RCT incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
		Acromioclavicu	lar Joint Pain: A	rthroscopic vs. Open Distal	<b>Clavicle Excision</b>	า
Freedman 2007 RCT	4.0	N = 17 acromioclavicul ar joint pain (8 OA, 4 post- traumatic, 5 osteolysis); at least 6 months non-operative treatment (cryo, NSAIDs, activity modification, most injected)	Arthroscopic vs. open distal clavicle excision; 1year follow- up	Arthroscopic arm had occult labral pathology in 4 (50%) with 3 SLAP tears. VAS pain scores (baseline/6 months/12 months): arthroscopic (3.7/2.11/1.75) vs. open (4.3/2.7/ 1.0). MASES scores not changed significantly. At 1 year, 100% of arthroscopic vs. 50% open returned to sports.	"Both are effective surgeries for the treatment of refractory acromioclavicu lar joint pain."	Small sample, sparse details. Little subject description. Different pain etiologies. Data suggest comparable efficacy; however, with small sample size and a heterogenous populations, study underpowered for all but major differences.

# SHOULDER ARTHROPLASTY

Shoulder arthroplasty has been used to treat glenohumeral degenerative joint disease.(Orfaly 03; Smith 98; Sperling 06; Ballmer 94; Neer 74, 82; Bell 86; Cofield 92; Edwards J Shoulder Elbow Surg 03; Radnay 07; Parsons 04; Weber J Bone Joint Surg Am 98; Brostrom 92; Matsen 96; Amstutz 88; Cofield 84; Torchia 97; Barrett 87; Clayton 82; Boyd 90; Norris 96, 02; Gartsman J Bone Joint Surg Am 00; Lo 04; Blevins 98) Shoulder resurfacing and partial resurfacing procedures have also been performed. (Fuerst 07; Radnay 07; Burgess 09; Ellenbecker 08; Burkhead 95; 07; Raiss 07; Harryman 95; Thomas 05a,b; Levy 01, 04a,b; Copeland 06; Savoie 09; Alund 00; Fink 04; Buchner 08; Scalise 07) A meniscal allograft and other soft tissue interposition, as well as glenoid reaming without replacement are alternative treatments when the glenoid is arthritic and total shoulder arthroplasty is contraindicated, i.e., young patients. Overall outcomes of arthroplasties have generally been good. (Misamore 97)

The vast majority of these patients are not believed to have occupational conditions. However, in cases where the initiating event was an occupational fracture or the patient has work-related osteonecrosis, some of these resultant arthroplasties are considered work-related. The volume of quality literature is much less for shoulder arthroplasties than for those of the hip where there are numerous trials with durations of follow-up lasting many years. Humeral head resurfacing is thought to have advantages for

younger and/or more physically active patients. (Burgess 09) There is controversy as to whether a humeral hemiarthroplasty or total arthroplasty should be performed, (Burgess 09) with concerns about excessive wear of the glenoid if it is not replaced. (Radnay 07; Burgess 09) It has been suggested the decision should depend on adequacy of bone, extent of articular damage, and presence of irreparable rotator cuff tears. (Copeland 06; Burgess 09)

Recommendation: Total Shoulder Arthroplasty or Resurfacing for Moderate to Severe Arthritides Total shoulder arthroplasty or hemiarthroplasty is moderately recommended for moderate to severe arthritides. Humeral resurfacing (similar to humeral head replacement) is recommended as an option.

*Indications* – Moderate to severe arthritides with symptoms of at least 6 to 12 months that are insufficiently managed with non-operative measures. (Lo 05; Gartsman 05) Patients should generally have failed at least 2 different NSAIDs or analgesics, activity modification(s), exercises, viscosupplementation, and/or glucocorticosteroid injection(s). Patients with diffuse degenerative joint disease whether OA, rheumatoid arthritis or other cause, are generally good candidates for total joint arthroplasties, (Lo 05; Gartsman 05) although some may be candidates for hemiarthroplasties. (Smith 98) Hemiarthroplasties have been generally recommended for patients with massive rotator cuff tears combined with degenerative joint disease. (Smith 98)

# Strength of Evidence – Moderately Recommended, Evidence (B) – Total or hemiarthroplasties Recommended, Insufficient Evidence (I) – Resurfacing

# Rationale for Recommendation

There are no quality trials comparing shoulder arthroplasty with either no intervention or a quality nonoperative management protocol. However, there is one high- and one moderate-quality trial each comparing total shoulder arthroplasty with hemiarthroplasty for the treatment of glenohumeral osteoarthritis, both of which suggest total shoulder arthroplasty is superior or trends toward superiority over hemiarthroplasty. Both trials document major improvements compared with pre-operative measures of pain and function among these patients. (Lo 05; Gartsman J Bone Joint Surg Am 00) There are few quality trials comparing different operative approaches and none address long-term outcomes. Shoulder arthroplasty is invasive, has adverse effects, and is costly. These procedures are recommended for select patients who failed multiple attempts at controlling symptoms short of arthroplasty.

#### Evidence for Shoulder Arthroplasty

There is 1 high- and 2 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality study in Appendix 2.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			<b>Total Shoulder</b> A	Arthroplasty vs. Hemiarthro	oplasty	
Lo 2005	8.0	N = 42 primary osteoarthrosi	Hemiarthroplas ty vs. total shoulder	Western Ontario Osteoarthritis of Shoulder scores	"Both total shoulder arthroplasty and hemiarthroplasty	No non-operative or other control. Unique study
RCT		s, failure of at least 6 months NSAIDs and physiotherap y; excluded over 1cm RC tear	arthroplasty. Neer Series-II implants; 24 months follow- up.	(baseline/2 years): hemi (33.5±19.7/81.5±24.1) vs. total shoulder (31.4±17.7/90.6±13.2), p = 0.18. McGill Pain questionnaire at 2 year: 2.7±6.8 hemi vs. 0.9±1.4 total, p = 0.27. UCLA scores trended in favor of total shoulder, p = 0.10. Hemi failure rate of	improve disease- specific and general quality-of-life measurements With the small number of patients in our study, we found no significant differences in these measurements between the two	design to blind patient to type of surgery, but not clear how maintained over 2 years as details sparse. Data show no differences, but modest trend in favor of total

Gartsman J Bone Joint Surg Am 2000 RCT	5.5	N = 51 patients, accounting for 55 shoulders with primary osteoarthritis unresponsiv e to medical treatment; required intact rotator	Total shoulder arthroplasty (uncemented, global) with glenoid vs. hemiarthroplast y; 1+ years follow-up.	19.0%. ASES shoulder pain scores (pre/post-op): TSA (9.6/ 41.1) vs. hemi (9.4/30.2). Greater pain relief in total shoulder vs. hemi ( $p = 0.002$ ). Total scores: TSA (22.7±14.4/77.3±18.2) vs. hemi (22.6±15.1/65.2±24.9). UCLA scores also trended in favor of TSA.	groups." "Total shoulder arthroplasty provided superior pain relief compared with hemiarthroplasty in patients who had glenohumeral osteoarthritis, but it was associated with an increased cost of \$1177 per patient."	shoulder. Variable length follow-up and unclear which follow-ups are presented at "post-op" scores. A considerable number of hemiarthroplasty patients required revision to total shoulder.
		cuff				
	T	1		on of Operative Technique		
Boileau 2002 RCT	6.5	N = 40 primary degenerative glenohumer al osteoarthritis without rotator cuff tear	All total shoulder arthroplasties; cemented polyethylene vs. uncemented, tissue-ingrowth metal-backed glenoid components. All humeral components Aqualis cemented; 36 months follow- up.	Constant pain scores (baseline/1/2/3 years): PE ( $3.6/12.5/12.5/12$ ) vs. MB ( $3.4/12/13/13$ ). Total constant scores PE ( $25.2/66/67/68$ ) vs. MB ( $27.5/73/75/73$ ). Anterior active elevation: PE ( $88/136/137/139$ ) vs. MB ( $94/147/149/146$ ). Peri-prosthetic radiolucent lines greater polyethylene ( $85\%$ vs. 25%, p <0.01).	"The high rate of loosening, because of the absence of ingrowth and/or the accelerated polyethylene wear, has led us to abandon the use of metal-backed glenoids."	Clinical data from 3 years not different for functional outcomes. However, radiolucent lines data suggest eventual failure rate of the metal- backed group would be higher. Prosthesis used in this study no longer in available.

# SHOULDER FRACTURES

Shoulder fractures are common in all age groups, from youth engaged in sports to adults in motor vehicle accidents to elderly who have fallen. (Kristiansen 87; Kannus 96; Paivanen 06; Baron 96; Bengner 88; Singer 98; Donaldson 90; Court-Brown 01; Horak 75) Many elderly patients are in relatively poor health and susceptible to other fractures. (Court-Brown 02; Fink 03; Lee 02; Nguyen 01Kelsey 92; Lauritzen 93; Rose 82) A minority of shoulder fractures occur in the course of employment, from simple falls and falls from heights, motor vehicle crashes, (Changulani 07; Chapman 00; McCormack 00) and industrial crush injuries. (Chapman 00) Most quality evidence for osteopenic and osteoporotic patients is found in the literature addressing hip fractures. Among patients with fractures, especially those with risks for osteoporosis, assessment of bone quality is recommended. Treatment options include calcium and vitamin D supplementation to correct deficiencies (USPSTF; Doetsch 04) or bisphosphonates for those with low bone mass density, but adequate calcium and vitamin D. (Harris 08; USPSTF 07)

# **PROXIMAL HUMERAL FRACTURES**

Proximal humeral fractures are among the most common fractures and are the predominant shoulder fracture in the elderly. (Nguyen 01; Palvanen 06; Court-Brown 01, 04; Lee 02; Horak 75; Palvanen 06) Approximately 50 to 80% of proximal humeral fractures may be treated non-operatively. (Court-Brown 01, 02, 04; Neer 70; Young 85; Mills 85; Rasmussen 92; Guix 09; Fjalestad 05; Jakob 91; Lanting 08; Palvanen 06) Surgery has been suggested for more complex fractures, (Neer 70; Parnes 10) but there is not consensus on that opinion. (Zyto 97) Surgery increases rates of complications including hardware-related, osteonecrosis, and infection. (Brunner 09; Neer 70; Knight 57; Szyszkowitz 93; Qian 05; Jones 87; Sturzenegger 82) The overall quality of available evidence is weak.

1. Recommendation: Non-operative Treatment for Proximal Humeral Fractures

# Non-operative treatment for proximal humeral fractures is recommended for most patients with non- or minimally displaced fractures.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

 Recommendation: Surgical Treatment for Proximal Humeral Fractures Surgical intervention for proximal humeral fractures is recommended for select patients with displaced fractures.

*Indications* – Based on numerous factors assessed and evaluated in aggregate by the orthopedic surgeon, including surgeon's preferences and experiences, open fractures, multiple-part fractures, associated vascular injuries, polytrauma, age, bone quality, status of the rotator cuff, hand dominance, smoking status, preexisting pathology, medical comorbidities, bilateral humeral fractures, radial nerve palsy after manipulation, neurological loss after penetrating injuries, and unacceptable alignment. (Changulani 07; Bell 85; Brumback 86; Robinson 93; Drosdowech 08)

Strength of Evidence – Recommended, Insufficient Evidence (I)

# 3. Recommendation: Arthroplasty for Proximal Humeral Fractures Arthroplasty, most commonly hemiarthroplasty, is recommended for select patients with displaced proximal humeral fractures.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

For proximal humeral fractures, there are few quality trials comparing operative treatment with nonoperative treatment or comparing various operative treatments and approaches. Two moderate-quality trials have compared operative with non-operative treatments in fairly narrow indications, thus the value of these trials is sharply limited in their ability to address the operative vs. non-operative indications for the broad group of proximal humeral fracture patients. (Zyto 97; Kristiansen 88) One moderate-quality trial evaluating 3 or 4-part displaced proximal humeral fractures in the elderly failed to find superiority of the operative approach. (Zyto 97) The second trial found an external fixator, although not commonly used, was superior to a sling to manage displaced proximal humeral fractures that had been reduced. (Kristiansen 88)

A moderate-quality trial found pulsed high-frequency electromagnetic energy is ineffective for healing minimally displaced humeral fractures. (Livesley 92) Most proximal humeral fractures are treated non-operatively with good results. (Mills 85; Balfour 82; Neer 70a,b) Surgical indications are numerous and listed above. Fracture classification systems have been developed for these fractures, (Kocher 1896; Codman 34; Neer 70; Hertel 04; Guix 09) although interrater reliability is low and their impact on management remains unclear. (Brien 95; Sidor 93; Siebenrock 93)

Though proximal humeral fractures have a relatively high incidence, the great variability in the fractures themselves and number of viable options for surgical treatment leads to difficulty comparing treatment modalities. The lack of quality literature comparing options has been widely noted and confirmed by this review. (Lanting 08; Brorson 09; Misra 01; Handoll 03; Bhandari 04; Nijs 09; Handoll 09) Operative procedures include conventional, angular stable and locked plates, (Brunner 09; Lin 06; Szyszkowitz 93; Sturzenegger 82; Sehr 88; Plecko 05: Moda 90: Misra 01: Fankhauser 05: Esser 94: Rouleau 09: Drosdowech 08: Südkamp 09) external fixators. (Kristiansen 87, 88, 89; Karatosun 02) partial or hemiarthroplasty, (Neer 70, 86; Mighell 03; Kay 88; Kontakis 08a,b; Moeckel 92; Bosch 98; Brorson 09; Green 93; Hartsock 98; Hasan 02; Movin 98; Nijs 09; Zyto 95, 98; Hasan 02; Robinson 03; Rietveld 88; Kraulis 76; Boileau 01; Demirhan 03; Dimakopoulos 97; Paavolainen 83; Tanner 83; Stableforth 84; Goldman 95; Prakash 02; Szyszkowitz 93; Jones 87; Skutek 98; Wretenberg 97; Hawkins 93) reverse arthroplasty, (Matsen 07; Rockwood 07; Kontakis 08; Martin 08) screws and cannulated screws, (Sturzenegger 82; Zingg 02; Bungaro 98; Chen 98) nails, (Lee 81; Young 08; Rodriguez-Merchan 95; Chiu 97) compression plates, (Rodriguez-Merchan 95; Chiu 97) cerclage wire, (Szyszkowitz 93; Lee 81) Kirschner wires, (Jakob 91; Bungaro 98; Darder 93) use of intramedullary bone cement, (Matsuda 99) and a combination tension band technique. (Zyto 97; Wijgman 02; Kristiansen 89; Darder 93; Hawkins 86) Pins are usually removed in 3 to 6 weeks. Despite a plethora of techniques, quality comparative trials are nearly completely lacking. (Lanting 08) Conclusions for younger populations and high-energy patients are less certain. Additionally, the variability of the types of fractures provides

additional uncertainty regarding optimal intervention(s). Thus, there is no recommendation for or against the use of a specific product.

Evidence for Proximal Humeral Fractures

There are 6 moderate-quality RCTs incorporated into this analysis. There are 2 low-quality RCTs or comparative clinical trials in Appendix 2.

Author/Titl	Score	al triais in A Sample	Comparison	Results	Conclusion	Comments
е	(0-11)	Size	Group			
Study						
Туре						
					s. Operative Managemen	
Zyto 1997 RCT	5.5	N = 40 elderly with 3 or 4-part displaced proximal humeral fractures	Non-operative (sling 7-10 days, then physiotherapy) vs. tension- band surgery plus same physiotherapy program; 50 months follow- up.	Sleeping on fractured side at 12/50 months: surgically treated 68/78% vs. 79/86%. Able to reach top of head: surgically treated 84/78% vs. 100/100%. Reach to T7 32/35% vs. 42/66%. Carry 5kg: surgical 47/64% vs. 57/53%. Constant scores at 50 months: surgical 60±19 vs. 65±15. Complications of infections (surgical/ non-operative): infection 2/0; pulmonary embolus 1/0, AVN 1/0, nonunion 1/0, K-wire penetration 1/0 and OA 2/2.	"Semi-rigid fixation with tension-band wiring of displaced multifragment fractures of the proximal humerus in the elderly did not improve the functional outcome when compared with conservative treatment."	Some details sparse. Physiotherapy protocol not specified. Low dropouts to 1st year, but subsequently high. Results not significantly different though many trends in favor of non- operative management. Major complications only in surgery group. Trial may be underpowered.
Kristianse n 1988 RCT	4.0	N = 31 displaced proximal humeral fractures	Closed manipulation under general anesthesia and application of sling vs. transcutaneous reduction and external fixation; 12 months follow-up.	Failure of treatment: 2/16 (12.5%) poor reduction in closed group. 1/15 (6.7%) loosening pins. 4/10 (40%) closed vs. 8/11 (73%) pinned were satisfactory or excellent function at 12 months (high dropouts). Quality of reduction: closed, good 2/16 (12.5%) vs. pinning good 11/15 (73.3%).	"The external fixation method gave better reduction, safer healing and superior function."	Details sparse. Low dropouts at 3 months, but high at 12 months. Data suggest pinning may be superior to closed reduction; however, high dropouts temper conclusions.
	1			physeal Fractures: Hard	ware	l i
Changula ni 2007 RCT	6.5	N = 47 diaphyseal humeral fractures, Grade 1 or 2a	Internal fixation with intra- medullary nail (Russell Taylor IMN) vs. dynamic	Mean duration of injury 45 and 38 days at enrollment. Non-union in all but 3 in each group. Good functional results in 85.7% (IMN)	"This study proves that (intramedullary nail) can be considered a better surgical option for the management of diaphyseal fractures of	Patients mostly represent failures of non-operative treatment. Data suggest comparable
		compound , polytrauma , or early failure of non- operative	compression plate (AO 4.5mm 8 DCP). All treated with isometric exercises from Day 1; 12	vs. 87.5% (DCP). No differences in non- union rates. Union times 6.3 weeks in IMN vs. 8.9 weeks DCP. ASES scores 44 vs. 45. Infections in	the humerus as it offers a short union time and lower incidence of serious complications However, there appears to be no	efficacy, although faster union in IMN and lower infections in IMN.

Chapman 2000 RCT	5.0	treatment or unstable fractures N = 84 acute humeral diaphyseal fractures	months follow- up.	4.5% vs. 20.8%. 93% PLT vs. 87% IMN united by radiographs at 16 weeks, p = 0.70. Total complications in 22/38 vs. 20/46 plated. Nail group with 6 with shoulder pain and decreased shoulder ROM (p = 0.007).	difference between the two groups in terms of the rate of union and functional outcome." "For patients requiring surgical treatment of a humeral shaft fracture, intramedullary nailing and compression plating both provide predictable methods for achieving fracture stabilization and ultimate healing."	Somewhat unequal groups due to non- compliance with treatment assignment. Variable follow- ups.
McCormac k 2000 RCT	4.0	N = 44 humeral shaft fractures 5cm distal to surgical neck to 5cm proximal to olecranon fossa	Fixation with dynamic compression plate vs. humeral intra- medullary nail (Russell Taylor). Variable follow- ups.	ASES functional scores 48 plated vs. 47 nailed. latrogenic radial nerve palsies 0 plated vs. 3 nailed. Overall complications 3 plated vs. 13 nailed. 1 plated re-operated with non- union vs. 7 nailed (many reasons).	"[O]pen reduction and internal fixation with a DCP remains the best treatment for unstable fractures of the shaft of the humerus."	Data suggest higher complications in nailed group.
			I Fractures: Pulse	d High Frequency Electr	omagnetic Energy	
Livesley 1992 RCT	5.5	N = 48 minimally displaced humeral neck fractures	Pulsed high frequency electromagnetic energy (cura- pulse) intensity "3," pulse repetition frequency 35, maximum pulse power 300W vs. sham for 10 days. All physiotherapy; 6 month follow-up.	All results "good." Pain scores noted to be not different between groups (data not provided).	"The use of PHFE did not improve the result further."	Many details sparse. Data suggest PHFE is either ineffective, or good results in all patients precluded finding a benefit.

# EARLY MOBILIZATION, EXERCISE, EDUCATION, THERAPY AND REHABILITATION

Therapy including education and exercise is thought to be particularly important, especially for more severely affected patients, those with complications, the elderly, or those with comorbidities. (Lundberg 79; Bertoft 84; Kristiansen 89) There are variable durations of immobilization prior to exercise that have been used to treat non-operatively treated impacted proximal humeral fractures. (Young 85; Clifford 80; Kristiansen 89; Court-Brown 04; Handoll 03; Brostrom 43; Mills 85; Hodgson 03) Slings have been utilized especially for the first 1 to 3 weeks of treatment. (Court-Brown 02; Karatosun 02; Kristiansen 88; Calvisi 91; Zyto 95) Early ROM has been advocated (Brostrom 43; Jull 79; Einarsson 58)

# 1. Recommendation: Early Mobilization for Proximal Humeral Fractures

# Early mobilization is strongly recommended for most stable, proximal humeral fractures patients.

*Indications* – Most patients with stable proximal humeral fractures. (Lefevre-Colau 2007; Hodgson 03, 07; Kristiansen 1989; Agorastides 07)

*Dose/Frequency* – Treating orthopedist must ascertain whether early mobilization is appropriate. Considerations include patient age, fracture type, post-reduction or post-surgical results, comorbidities. Early mobilization generally starts within 1 week.

# Strength of Evidence – Strongly Recommended, Evidence (A)

2. Recommendation: Education and Exercises for Proximal Humeral Fractures

Education and exercise are strongly recommended for most proximal humeral fracture patients.

*Indications* – Most patients with proximal humeral fractures. *Dose/Frequency* – Education may include adaptive techniques and use of adaptive equipment (as indicated) to facilitate continued participation in daily activities despite limitations of shoulder.

# Strength of Evidence – Strongly Recommended, Evidence (A)

3. Recommendation: Self-Training for Proximal Humeral Fractures Self-training exercise is moderately recommended for select proximal humeral fracture patients.

*Indications* – Patients with proximal humeral fractures who are motivated and compliant with exercises to rehabilitate the injury. (Revay 92; Lundberg 79; Bertoft 84)

# Strength of Evidence – Moderately Recommended, Evidence (B)

# Rationale for Recommendations

Four high- and moderate-quality trials have evaluated early mobilization in patients with various types of proximal humeral fractures. All quality trials either show superiority or equivalency of early mobilization. A high-quality trial of impacted proximal fractures treated non-operatively suggested early mobilization is superior. (Lefevre-Colau 07) An early mobilization program for minimally displaced 2-part non-operatively managed proximal humeral fractures was compared with delayed with the beginning within 1 week. (Hodgson 03, 07) A moderate-quality study of an early mobilization program for fractures that were reduced found less pain and better function with earlier mobilization. (Kristiansen 89) An additional trial in postoperative patients also suggested early mobilization was superior. (Agorastides 07) The goal is to begin range of motion as early as possible to help prevent stiffness. Frequent followup may help to transition the patient from immobilization to motion. Begin range of motion once fracture is stable- very early for stable impacted fractures. Other fractures can wait until the proximal humerus moves as if it is one unit- up to four weeks for most fractures. Early mobilization is not invasive, appears to have few adverse effects. and likely is cost effective; therefore, it is recommended in select patients. Three moderate-quality trials have documented self-training is equivalent to supervised training, (Bertoft 84; Revay 92; Lundberg 79) thus self training is also recommended. Education and exercise are not invasive, have few adverse effects, and are low to moderate cost; thus they are recommended for most proximal humeral fracture patients.

Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments		
Humeral Fractures: Immobilization								
Lefevre- Colau 2007	8.5	N = 74 impacted proximal humeral	Non-operative treatment. Early passive mobilization (2-hour	Constant scores (6 weeks/3 months/6 months): early (44.0±16.5/71.0±14.6/8	"Early mobilization for impacted nonoperatively treated proximal	Highly intensive physiotherapy with 32 sessions. Data		
RCT		fracture	sessions with	1.5±11.2) vs.	humeral fractures is	suggest early		

Evidence for Early Mobilization and Exercise for Proximal Humeral Fractures There are 3 high- and 6 moderate-guality RCTs incorporated into this analysis

		treated non- operatively	physiotherapist 5 days a week for 2 weeks with oral analgesics; icing, massage, passive motion; 2 times a week, Weeks 3 to 6; weekly to 3 months) vs. conventional treatment (at 3 weeks, begin 2- hour sessions 4 times a week for 4 weeks; 2 times a week for 5 weeks; then 2 times a month until 6 months); 6 month follow-up.	conventional (33.9 $\pm$ 16.5/61.1 $\pm$ 17.0/7 5.4 $\pm$ 14.4), p = 0.01, p = 0.02, p = 0.11. Pain intensity favored early mobilization at 3 months (p = 0.05). Most ROM measures favored early mobilization at 6 weeks.	safe and is more effective for quickly restoring the physical capability and performance of the injured arm than is conventional immobilization followed by physiotherapy."	mobilization superior.
Hodgson 2003 RCT	8.0	N = 86 minimally displaced, 2-part, non- operatively managed proximal humeral fractures	Immediate (begin within 1 week; 2 weeks pendular exercises, education, passive ROM, HEP; Weeks 2-4 with progressive full passive flexion, light functional exercises; progressive functional exercises starting Week 4) vs. delayed physiotherapy (begin same program at 3 weeks); 1-year follow-up.	Constant scores (8/16/52 weeks): Immediate mobilization (0.57 $\pm$ 0.26/ 0.70 $\pm$ 0.21/0.82 $\pm$ 0.23) vs. Delayed (0.39 $\pm$ 0.19/0.54 $\pm$ 0.20/0. 75 $\pm$ 0.25), p = 0.001 at 16 weeks and p = 0.002 at 52 weeks. SF36 role limitation and pain scores different at 16 weeks and 16 and 52 weeks respectively.	"[P]atients with two- part fractures of the proximal humerus who begin immediate physiotherapy, experience less pain. The gains in shoulder function persist at 52 weeks which suggests that patients do not benefit from immobilisation before beginning physiotherapy."	Study supports early mobilization within 1 week.
Hodgson 2007 2-year follow-up of above RCT	8.0	N = 86 as above	Immediate vs. delayed physiotherapy as above; 2-years follow-up.	Croft shoulder disability scores $\frac{1}{2}$ years (scores 0): immediate 24 (57.2%)/ 21(56.8%) vs. delayed 11 (27.5%)/15(40.5%). Scores ≥5: immediate 13 (30.9%)/12 (32.4%) vs. delayed 17(42.5%)/ 13(35.2%). Overall at 1 year, 42.8% vs. 72.5% reported shoulder disability, p <0.01. At Year 2, 43.2% vs. 59.5%.	"Delayed rehabilitation by 3 weeks of shoulder immobilization produces slower recovery, which continues for at least 2 years after the time of injury."	Data support early immobilization and suggest delay is associated with long-term worse outcomes.

Kristiansen 1989 RCT	4.0	N = 85 proximal humeral fractures	Closed or open reduction; then 1 vs. 3 weeks immobilization in sling and body bandage; then pendulum exercises; 24 month follow-up.	Pain score (0-35) (1/3/6/12/24 months): 1 week immobilization (20/27/30/32/35) vs. 3 weeks (10/20/28/30/35), p < 0.01 at 1 and 3 months. Total pain, function and motion scores also superior for 1 week immobilization group at 1 and 3 months, $p < 0.001$ .	"One week of immobilization resulted in a better total score due to less pain during the first 3 months."	Sparse details. Data suggest shorter 1 week immobilization superior to longer 3 weeks immobilization.
		Post-opera	ative Hemiarthroplast	y for Humeral Fractures:	Immobilization	
Agorastides 2007 RCT	6.5	N = 59 with 3 and 4- part fractures or articular fractures in physiologic ally old patients with poor bone quality	Early (sling for 2 weeks with pendulum and elbow exercises, then progressive active-assisted exercises weeks 3- 6, then active assisted exercise weeks 7+) vs. late mobilization (sling 6 weeks with only elbow exercises, then pendulum, progress to active assisted exercises Weeks 7-12, then active exercises Weeks 13+).	Constant scores (6/12mo): early mobilization (46/47) vs. late (47/50), p-0.74, p = 0.57. No differences in Oxford scores. Tuberosity migration occurred in 14% vs. 27%, p = 0.61. Superior subluxation occurred in 6 vs. 4, p = 0.73.	"There was no significant difference in the Constant Shoulder Assessment and Oxford scores between the 2 groups. Although there was a decreased incidence of tuberosity migration in the group undergoing late mobilization, this was not statistically significant."	Data suggest no differences in outcomes between early vs. late mobilization.
		•				1
		NL 22	Humeral Fractures:	Exercises and Rehabilita		
Bertoft 1984 RCT	5.5	N = 20 non- or slightly displaced proximal humeral fractures		Exercises and Rehabilita ROM not different at Weeks 3, 8, 16, 24, 1 year (NS). Pain (3/8/16/24/1 year): instruction (3.4/2.2/1.0/0.7/0.6) vs. conventional (4.1/1.9/1.3/1.0/1.0).	tion "No significant differences were found between the two groups in any of the tests. Instruction in self-training with control of results including objective assessments are therefore an adequate method in the rehabilitation of these patients."	Small sample sizes. Data suggest self- training is as effective as formal PT.
1984	5.5	or slightly displaced proximal humeral	Humeral Fractures: Instruction (3 visits of advancing exercises) vs. conventional treatment (9 sessions, 1-2 treatments a week of 20-30 minutes);	ROM not different at Weeks 3, 8, 16, 24, 1 year (NS). Pain (3/8/16/24/1 year): instruction (3.4/2.2/1.0/0.7/0.6) vs. conventional	"No significant differences were found between the two groups in any of the tests. Instruction in self-training with control of results including objective assessments are therefore an adequate method in the rehabilitation of	sizes. Data suggest self- training is as effective as

1979 RCT		undisplace d proximal humeral neck fractures with less than 1cm displaceme nt or 45° angulation	immobilization 1 week, then physiotherapy (active shoulder/arm movements for 20- 30 minutes, 1-2 times a week, 2-3 months plus HEP) vs. self exercise instruction (HEP at 1 week, repeated 1 and 3 months; at 1 month, exercise 5- 10 minutes, 4-5 times a day); 3	of pain (1 month/3 months) severe plus moderate: PT (63.6%/9.1%) vs. self- training (65%/25%). ROM not different at 1 and 3 months. Pain was same in both groups at Month 1 and 3. No statistical difference between groups.	indicates that good results can be achieved in nondisplaced proximal humeral fractures by giving instructions for independent exercises without having a deterious effect on the patient's condition."	self-training sufficient compared to supervised therapy plus self-training.
			month follow-up.	s: Calcium plus Vitamin	D	
Doetsch 2004 RCT	6.0	N = 35 proximal humeral fractures treated non- operatively with T- score -1 to -2.5+	Calcium 1mg (formulation not noted) plus Vitamin D <sub>3</sub> 800 IU vs. placebo BID for 12 weeks. Evaluated all with bone mass density scanning	Bone mass density (baseline/2/6/12 weeks): Calcium plus vitamin D (0.534±0.049/0.588± 0.066/0.623±0.060/ 0.621±0.077) vs. placebo (0.518± 0.067/ 0.548±0.056/0.570± 0.037/0.564±0.039), p = 0.006 Week 6.	"Women with reduced bone mass (osteopenia or osteoporosis) and an acute PHF might benefit from a supplementation of oral calcium plus vitamin $D_3$ during the healing process."	Mostly elderly (limited patient description). Suggests modest efficacy for proximal humeral fracture patients with proven osteoporosis or osteopenia.

# **CLAVICULAR FRACTURES**

Fractures of the clavicle are among the most common fractures, constituting an estimated 35 to 66% of shoulder fractures. (Postacchini 02; Nordqvist 94; Robinson 98; Herscovici 95; Neer 60; Neviaser 87; Boehme 91) They occur particularly in children and young adults, although the elderly are not immune, and are typically related to falls on point of shoulder or an outstretched arm, or sports and accidents. (Eiff 97; Der Tavitian 02) Most fractures involve the middle third of the clavicle. (Eiff 97; Postacchini 02; Nordqvist 94; Allman 67; Stanley 88; Sankarankutty 75; Zlowodzki 05) "Floating shoulder" is a term used to describe ipsilateral fractures of the clavicular shaft and the scapular neck. (DeFranco 06; Ganz 75; Goss 93; Hardegger 84; van Noort 01; Labler 04; Ada 91; Ramos 97; Egol 01; Herscovici 92; Owens 06) X-ray is used for diagnosis, although CT is sometimes needed to diagnose clinically suspected fractures of the proximal 1/3 of the clavicle. (Eiff 97)

Clavicular fractures are managed non-operatively (sling and figure-of-8) (Grassi 01; Lenza 09a; Zenni 81) as well as surgically with various techniques and procedures including open reduction internal fixation with plates, (Shen 99; Lee 08; Pai 09; Kloen 09; Lenza 09b) pins, (Lee 07, 08; Chu 02; Grassi 01; Lenza 09b; Boehme 91) wires, and nails. (Lenza 09b; Lee 08; Zlowodzki 05; Potter 07; Chu 02) Increased risks for nonunions include increasing age, female gender, comminution, and displacement. (Robinson 04) Low-intensity pulsed ultrasound has also been used to attempt to accelerate healing of these fractures. (Duarte 83; Dyson 83; Heckman 94; Kristiansen 97; Mayr 00; Rue 04; Schortinghuis 05; El-Mowafi 05; Tsumaki 04; Ricardo 06; Handolin 05a,b; Emami 99; Leung 04)

#### 1. Recommendation: Non-operative Treatment for Clavicular Fractures Non-operative treatment is recommended for clavicular fractures.

*Indications* – Clavicular fractures particularly in younger patients and those with 2-part fractures that are non-displaced.

*Dose/Frequency/Duration* There is quality evidence some closed displaced midclavicular fractures may be successfully treated with a sling. (Judd 09) Either sling or Figure-of-8 braces may be used with evidence suggesting a simple sling is superior to figure-of eight bracing for midclavicular fractures. (Andersen 87). Non-displaced fractures can be treated with either and there is not a consensus on

preferred treatment as the figure-of-8 allows distal extremity movement. (Stanley 88; Andersen 87; McCandless 79; Eiff 97; Khan 09) Slings and braces are used until tenderness and crepitance is resolved. (Eiff 97)

# Strength of Evidence – Recommended, Evidence (C)

#### 2. Recommendation: Surgical Treatment for Clavicular Fractures

# Surgical intervention is moderately recommended for select patients with clavicular fractures.

*Indications* – Surgical indications are largely based on numerous factors that are assessed and evaluated in aggregate by the orthopedic surgeon, including surgeon's preferences and experiences, open fractures, multiple-part fractures, degree of displacement, associated vascular injuries, polytrauma, increasing age, bone quality, hand dominance, medical comorbidities, bilateral fractures, neurological loss after penetrating injuries, unacceptable alignment, and failure of non-operative treatment. (Smekal 09; Judd 09; Canadian 07; Altamimi 08) Fractures of the lateral end of the clavicle are recommended for surgical treatment.

# Strength of Evidence – Moderately Recommended, Evidence (B)

Recommendation: Low-intensity Pulsed Ultrasound for Treatment of Type I Clavicular Fractures
 Low-intensity pulsed ultrasound is moderately not recommended for treatment of Type I (mid shaft) clavicular fractures.

# Strength of Evidence – Moderately Not Recommended, Evidence (B)

4. Recommendation: Low-intensity Pulsed Ultrasound for Treatment for Other Clavicular Fractures There is no recommendation for or against the post-operative use of low-intensity pulsed ultrasound for treatment of all other (non-Type 1) clavicle fractures or non-unions.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

# Rationale for Recommendations

There is one trial comparing non-operative treatments and evidence in evaluating different outcome or complication factors is not uniformly in favor of one treatment approach. Thus, either a simple sling or a figure-of-8 brace is recommended. (Andersen 87) The majority of clavicular fractures are believed not to require Surgery. (Khan 09; Kim 08; Jeray 07; Denard 05; Zlowodzki 05; Craig 90; Graves 05; Eiff 97; Miller 92; Quigley 50; Smekal 09; Preston 09) However, a sizeable minority of these fractures may be better treated with surgery which is often recommended for all open fractures, and for many patients with neurovascular compromise, (Barbier 97; Chen 00, 02; Connolly 89; Howard 65; Fujita 01; Miller 69; Kay 86; Bateman 68) multiple trauma, displaced fractures, (Smekal 09) floating shoulders, Type II distal fractures and proximal fractures associated with sternoclavicular dislocations, coracoclavicular ligament disruption, (Chen 02) malunions, and painful non-unions. (Jeray 07; Graves 05; Chen 02; Jones 00; Eiff 97) Treatment for simple displaced fractures is controversial. (Judd 09; Khan 09)

Fractures of the lateral end of the clavicle have a high rate of non-union (see Table 9). Type II fractures of the distal third of the clavicle (Neer 68) (coracoclavicular ligaments remain attached to distal fragment and proximal fragment displaced superiorly) are recommended for referral to an orthopedist for consideration of operative treatment due to high rates of non-union. (Anderson Clin Sports Med 03; Eiff 97; Heppenstall 75; Edwards 92; Eskola 87; Post 89; Katznelson 76; Hessman 96; Herscovici 95; Poigenfurst 92; Zenni 81) Fractures of the proximal 1/3 of the clavicle with either significant displacement or sternoclavicular dislocation are recommended for referral to an orthopedist. (Eiff 97) Surgical fixation of mid-shaft fractures most commonly involves intramedullary fixation (Grassi 01; Neviaser 75) and plate fixation. (Graves 05; Hill 97; Kabak 04; Kloen 09; Bradbury 96; Jupiter 87)

There are a few moderate-quality trials comparing operative treatment with non-operative treatment for mid-shaft fractures. The available evidence shows higher rates of union in those receiving surgery; however, the overall numbers of complications are not improved with surgery. While the quality evidence in favor of lower non-union and malunion rates moderately supports surgical approaches, the total numbers of complications is higher in the operative than non-operative group. Thus, careful consideration must be used with either approach. (Smekal 09; Judd 09; Canadian 07; Altamimi 08)

An analysis of 2,144 midshaft clavicle fractures found non-unions in 5.9% of non-operatively managed, 5% of plated, and 6% of intramedullary pinned clavicles. Infections occurred in 5.4 % of patients receiving surgery. Fixation failures occurred in 3.1% of the plated and 4.1% of the pinned groups. (Zlowodzki 05) However, these data are not randomized.

# Table 9. Calculated Probability of a Nonunion at 24 Weeks after a Lateral-end Clavicular Fracture. Based on Age and Displacement in a Series of 263 Patients\*

Age (year)	Not Displaced	Displaced
20	1%	16%
30	3%	21%
40	5%	27%
50	6%	37%
60	10%	44%
70	17%	52%

\*Adapted from Khan LA, Bradnock TJ, Scott C, and Robinson CM. Fractures of the clavicle. *J Bone Joint Surg Am.* 2009; 91(2):447-60. Data from Robinson CM, Dobson RJ. Anterior instability of the shoulder after trauma. *J Bone Joint Surg Br.* 2004; 86(4):469-79.

Mid-shaft fractures are fixed with either intramedullary screws/pins or plates with screws; however, there are few quality trials comparing the different options. Thus, the overall evidence is not definitive. There are many studies of biomechanical responses to assess risks of fracture, (Kemper 09) as well as failure of surgical fixation. (Celestre 08; Proubasta 02; Robertson 09) One set of values is listed in Table 10 below. Importantly, these failure rates might be more important for patients with higher physical activities.

# Table 10. Bending Failure Stiffness Calculated Between 10-30N\*

Plate Type	Failure Stiffness
Anterior-inferior Contourable Dual Reconstruction Compression Plate	4.3±1.2 N/mm
Anterior-inferior Locking Contourable Dual Reconstruction Compression Plate	3.1±2.0 N/mm
Superior Contourable Dual Reconstruction Compression Plate	7.5±4.6 N/mm
Superior Locking Contourable Dual Reconstruction Compression Plate	7.5±3.7 N/mm

\*Data from Robertson C, Celestre P, Mahar A, Schwartz A. Reconstruction plates for stabilization of mid-shaft clavicle fractures: differences between nonlocked and locked plates in two different positions. *J Shoulder Elbow Surg.* 2009; 18(2):204-9.

One high-quality RCT of Type I clavicle (diaphyseal) fractures has found no evidence of efficacy of ultrasound to accelerate healing, (Lubbert 08) thus this intervention is not recommended for those fractures. However, favorable results reported for healing disparate nonunion fracture types in uncontrolled studies (Nolte 01) and some evidence for other fractures (Busse 09) does suggest that there may be some role for low-intensity pulsed ultrasound for select clavicle fractures that has not yet been defined but, if successful, may involve more severe fracture types, risks for non-unions, or post-operative settings with risks of non-union.

# Evidence for Clavicular Fractures

There is 1 high- and 9 moderate-quality RCTs or comparative clinical trials incorporated into this analysis. There are 2 low-quality studies in Appendix 2.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
		C	lavicular Fracture	es: Comparison between Sp	lints and Slings	
Andersen 1987 RCT	4.0	N = 79 simple mid- clavicular fractures	Figure of 8 bandage vs. simple sling. 3 months follow- up.	Median score figure of eight 8 (mean 10.3, range 0-31) vs. 4 (mean 6.0, range 0-22), p = 0.01. Discomfort with figure of 8 drove ratings. No differences in fracture healing vs. initial displacement.	"[T]reatment with a simple sling caused less discomfort and perhaps fewer complications than with the figure-of-eight bandage."	High dropouts in figure-of-8 group. Minimal descriptions of patients. Results suggest simple sling preferable.

		C	lavicular Fracture	s: Operative vs. Non-opera	ative Treatment	
Smekal 2009 RCT	6.5	N = 60 fully displaced midshaft clavicular fractures	Non-operative treatment (simple shoulder sling) vs. elastic stable intra- medullary nailing (within 3 days); 2 year follow-up.	Time to union operative 12.1 $\pm$ 8.6 vs. non- operative 17.6 $\pm$ 10.7, p = 0.04. Total complications in 10 vs. 14, p = 0.43. Delayed union in 1 vs. 6, p = 0.02.	"ESIN of displaced midshaft clavicular fractures resulted in a lower rate of nonunion and delayed union, a faster return to daily activities, and a better functional outcome."	Data support less union in non- operative group, but total complications not different.
Judd 2009 RCT	6.5	N = 57 closed, angulate d or displaced midshaft clavicle fractures	Non-operative treatment (sling) vs. Operative treatment (modified Hagie pin); 1 year follow-up.	Mean initial fracture angulation, shortening, and displacement non- operative vs. operative: 12.7 <sup>0</sup> , 12mm, 98% vs. 7.7 <sup>0</sup> , 13.4, 99%; p >0.992. SANE scores (baseline/3 weeks/6 weeks/ 3 months/6 months/1 year): Sling (16.1/36.4/56.1/70.7/ 85.8/97.0) vs. operative (10.3/49.8/65.9/78.5/87.1 /93.5). One non-union, 1 refracture in both groups.	"[T]hough patients with midshaft clavicle fractures had higher functional scores at short-term follow-up after internal fixation, functional scores were similar at 6 months and 1 year."	Data suggest comparable results radiographic results, but complication rate higher in operative group.
Canadian Orthopaedi c Trauma Society 2007; Altamimi 2008 RCT 2 reports	4.0	N = 132 displaced midshaft clavicular fractures	Non-operative treatment vs. plate fixation. Surgery within 28 days; 1 year follow-up.	Mean time to union 16.4 weeks vs. 28.4 weeks, p = 0.001. Non-union in 2/62 (3.2%) operative vs. 7/49 (14.3%) non- operative, p = 0.042. Malunion requiring further treatment 0% vs. 18.4%, p = 0.001. Wound infections 4.8% vs. 0%, p = 0.25. Hardware removal 5 vs. 0, p = 0.065.	"Operative fixation of a displaced fracture of the clavicular shaft results in improved functional outcome and a lower rate of malunion and nonunion compared with nonoperative treatment at one year of follow-up."	Differences at baseline and in numbers in each group despite stated 1:1 randomization. Presumed large dropouts non- operative group. Weaknesses preclude strong conclusions. Data suggest some advantages to each approach.
		Clav	vicular Fractures: 0	Comparisons Between Ope	erative Treatments	Г · ·· · ·
Shen 2008 RCT	5.5	N = 133 displaced midshaft clavicular fractures	Open reduction and internal fixation with reconstruction plate placed superiorly vs. 3- dimensionally; 12 months follow-up.	Healing of fractures on x- rays at 4 months in 63 (94%) of 3D vs. 43 (65.2%) superior plated. 15(22.7%) superior group symptomatic vs. 3(4.5%) 3D. Delayed union in 1.5% 3D vs. 12.1% superior plated, p = 0.018.	"If fixation of midshaft fractures of the clavicle with a plate is indicated, a 3D reconstruction plate is better than one placed superiorly, because it is consistent with the stress distribution and shape of the clavicle."	High dropout rate. Limited statistics and results.
Kabak 2004 RCT	4.5	N = 33 mid- clavicular nonunion s	Fixation with dynamic compression plate (3.5mm AO DCP, Synthes) vs. low-contact dynamic compression plating (Ti 3.5mm LC- DCP, Synthes).	Union rate of 100% in LC-DCP vs. 87.5% DCP. Mean union of 9.2±1.7 vs. 11.9±2.3 weeks, p <0.001. Time to RTW 6.1 weeks vs. 9.6 weeks, p <0.001. DASH functional outcome scores (baseline/3/6/12 months): LC-DCP (64.3±8.8/29.2±3.2/16.6± 2.4/8.7±1.0) vs. DCP	"The addition of internal fixation of the clavicle with DCP or LC-DCP to application of autogenous corticocancellous chips, or sculptured graft on nonunion areas in patients with midclavicular nonunion, shortens the time to union, increases union	Data support LC- DCP at all follow- up intervals.

			At least 18 months follow- up, mean 44 months follow- up.	$(61.4\pm11.3/43.1\pm7.4/29.8\pm6.9/17.6\pm5.7)$ , p <0.001 at all follow-ups.	rates, and provides satisfactory functional outcomes."	
			w Intensity Pulsed	Ultrasound to Stimulate F	Fracture Healing	
Lubbert 2008 RCT	8.0	N = 120 Type I clavicle fractures	Low intensity pulsed ultra- sound (Exogen 2000; 30mW/ cm <sup>2</sup> , burst width 200µs in 1.5MHz sine waves at 1kHz) vs. sham for 28 days treatment	Mean time to clinical fracture healing (active vs. sham): 26.8 vs. 27.1 days, $p = 0.91$ ; 10 patients (5 each group) had non-unions (NS). No differences in use of paracetamol or naproxen, modestly higher in active treatment group ( $p = 0.66$ ). VAS pain scores 3.55 vs. 3.51, $p = 0.90$ . RTW in 15-17 days. Sports resumption in 24 days vs. 26 days, $p = 0.07$ . <b>Pins and Plates</b>	These "findings did not confirm that LIPUS accelerates clinical healing time of fresh clavicle shaft fractures."	Baseline differences in occupations of unknown impact. Data suggest ultrasound not effective for this type of fracture, possibly due to naturally good prognoses.
	4.0	NL CO	Kasudaa aira		(if a second of usid thind	De su de ren de suiz sti
Lee 2007 RCT	4.0	N = 62 elderly with mid- clavicular fractures	Knowles pins and plates (A) vs. plating (B). 30 months follow-up.	Hospital stays of 6.2 vs. 9.1days, $p = 0.03$ . Complications in 0% vs. 13%, $p = 0.04$ . Mean wound size (cm) and operating time (minutes) Group A vs. B: 4.2 vs 7.8 ( $p < 0.001$ ); 36 vs 64 ( $p < 0.001$ ). Knowles pin superior for less meperidine ( $p = 0.02$ ), and symptomatic hardware (12.5 vs. 40.0%, $p = 0.015$ ).	"If surgery of mid-third clavicular fractures is indicated, fixation with a Knowles pin has more advantages than plate fixation in elderly patients."	Pseudorandomizati on by every other, assignments by shift. Study design strengths including baseline comparability, suggesting pseudorandomizatio n may not be a critical failure. Low dropout rate. Data suggest Knowles pin superior to plate.
Lee 2008 Comparativ e Clinical Trial	4.5	N = 88 mid- clavicular fractures	Knowles pin vs. plate; 1 year follow-up.	6 months healed in 100% Knowles vs. $31/32$ (96.9%) plated (NS). Constant scores: pin 95.3±4.1 vs. plate 93.1±3.8, p = 0.84.	"[I]f the surgery of mid- third clavicular fractures is indicated, fixation with a Knowles pin has more advantages than plate fixation."	Not randomized, thus a low-quality. Some study design strengths including low dropout rate, baseline appears comparable. Patients treated by different orthopedists who had different preferences.
Pai 2009 RCT	4.5	N = 64 elderly with mid- clavicular fractures	Operative treatment with locking vs. non- locking plates.	Trend towards lower complication rate in locking plate ( $p = 0.087$ ). Locking compression plates with higher RTW ( $p = 0.02$ ) and exercise ( $p = 0.016$ ).	"If surgery of elderly patients with midclavicular fractures is indicated, internal fixation with a locking compression plate is preferable to a nonlocking plate."	Not randomized. Data suggest locking plate superior to nonlocking plate.

# EARLY MOBILIZATION, EXERCISE, EDUCATION, THERAPY AND REHABILITATION

Supervised physical or occupational therapy is thought to be rarely required for clavicular fractures. (Khan 09) Exceptions may include complicated fractures or fractures in the elderly or in those with comorbidities.

1. Recommendation: Early Mobilization for Clavicular Fractures

There is no recommendation for or against early mobilization for clavicular fractures.

# Strength of Evidence – No Recommendation, Insufficient Evidence (I)

2. Recommendation: Education and Exercises for Clavicular Fractures

# Education and exercise are recommended for select patients with clavicular fractures.

*Indications* – Select patients with clavicular fractures, particularly the elderly or those with comorbidities or complicated fractures including other injuries.

*Dose/Frequency* – Education may include adaptive techniques and use of adaptive equipment (as indicated) to facilitate continued participation in daily activities despite limitations of shoulder.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

There are no quality trials evaluating early mobilization, exercise, education, therapy, and/or rehabilitation of patients with clavicular fractures. The prognosis for these fractures is generally good and supervised physical or occupational therapy is believed to be rarely required. (Khan 09) Select modalities such as electrotherapy and hydrotherapy have been not recommended. (Hodgson 06) Education and formal exercise are thought to be potentially helpful particularly for debilitated patients, the elderly, or those with comorbidities and/or complicated fractures.

# SCAPULAR FRACTURES

Fractures of the scapula occur infrequently and constitute less than 5% of shoulder fractures. (Imatani 75; Rowe 63; Thompson 85; Ideberg 95) However, nearly all scapular fracture patients have other injuries, such as thoracic and/or head injuries, (Guttentag 88; Ada 91; Ideberg 95; McGahan 80; Pasapula 04; van Noort 06; Armstrong 84; Goss 92; McGinnis 89; Thompson 85; Guttentag 88) thus careful evaluation and management in an emergency department is recommended. There are no quality trials evaluating scapula fracture treatment; many scapular fractures can be managed non-operatively. (Cole 02; Goss 96; Guttentag 88) Some fractures are managed surgically, particularly when they involve the displaced glenoid or scapular neck fractures, lateral margin of the acromial process, or displaced coracoids fractures, severely displaced scapular body fractures. (Wong-Pack 80; Zilberman 82; Cole 02; Lantry 08; Lapner 08; Benchetrit 79; Heyse-Moore 82; Izadpanah 75; Kinzi 82; Li 06; Esenkaya 03; Adam 02; Oh 02; Schandelmaier 02; Ada 91; Vecsei 90; Ecke 87; Kavanagh 93; Zlowodzki 06; Bauer 95; Leung 93; Goss 96)

# LACERATIONS

See Hand, Wrist, and Forearm Complaints.

# WORK HARDENING, WORK CONDITIONING

See Chronic Pain Guidelines.

# INTERDISCIPLINARY PAIN REHABILITATION PROGRAMS

See Chronic Pain Guidelines.

# ADHESIVE CAPSULITIS ("FROZEN SHOULDER" AND "PAINFUL STIFF SHOULDER")

Adhesive capsulitis is also known as frozen shoulder, painful stiff shoulder, periarthrosis, or periarthritis. (Dacre 89; Duplay 1872; Codman 84; Neviaser 45; Itoi 04) However, no commonly used term adequately describes the condition as the shoulder is neither frozen, nor are there always adhesions and inflammation, (Lundberg 69; Wiley 91) nor is it necessarily painful. Reported findings include histologic evidence of chronic inflammation, perivascular infiltration, fibrosis of the subsynovial layer, and sometimes associated subacromial bursitis. (Lundberg 69; Bunker 95; Wiley 91) Parallels with complex regional pain syndrome have been noted. (Müller 00; Noël 00) For lack of a better term, the term "adhesive capsulitis" will be used in this guideline. The lifetime cumulative of adhesive capsulitis incidence has been estimated at 2 to 5%. (Lundberg 69; Carette 00) Most cases begin gradually, although some occur after discrete events such as trauma. (Rizk 82; Ogilvie-Harris 95; Bulgen 84) Idiopathic adhesive capsulitis most commonly affects females between age 45 and 65 (80% of cases). There is a 15-20% chance of having bilateral (not concurrent) adhesive capsulitis. There are three clinical phases – inflammatory (pain), stiff (pain and limited motion), and thawing (resolution). The majority of patients resolve with resolution of pain and recovery of close to normal motion. (Griggs 00) It has been described as a self-limited disease lasting up to 2 to 3 years (Rizk 82; Grubbs 93; Lundberg 69; Andersen 98; Loew 05; Quraishi 07; Griggs 00; Codman 84; Binder 84; Grey 78; Reeves 75; Hannafin 00; Miller 96; Rowe 88; Siegel 99; Diercks 04; Shaffer 92) with 10 to 20% of patients having long-term debility; (Ogilvie-Harris 95; Noel 00; Shaffer 92; Binder 84; Grey 78; Reeves 75; Murnaghan 90) others have described it as a chronic disorder associated with prolonged disability. (Vecchio 95; Simmonds 49; Hazleman 72; Croft 96; Reeves 75; Waldburger 92; Binder 84; Murnaghan 88)

Adhesive capsulitis continues to be a poorly understood entity that might be spontaneous and idiopathic, primary, (Hannafin 00; Waldburger 92; Bulgen 84; Murnaghan 90; Fleming 75; Lundberg 69; Noel 00) as well as caused by, or secondary to injuries, (Bulgen 84) prolonged immobilization, rotator cuff tendinopathies, (Andersen 98; Mulcahy 94; Hamer 76) surgery, and predisposing medical conditions. (Murnaghan 90; Fleming 75; Reeves 75; Codman 34) Any factor that results in reduced ROM is thought to be a risk for adhesive capsulitis. There is no quality evidence that work activities are a direct cause. (Bulgen 84)

Diseases associated with adhesive capsulitis include diabetes mellitus, (Massoud 02; Hamdan 03; Kivimaki 07; Bridgman 72; Pal 86; Ogilvie-Harris 97; Wohlgethan 87; Fisher 86; Dacre 89; Quraishi 07; Coventry 53) Crystal arthropathies, rheumatoid arthritis, ankylosing spondylitis, (Bulgen 76) other rheumatological diseases, (Ross 83) paresis and hemiplegia, (Hakuno 84) hypothyroidism, (Massoud 02; Bowman 88; Ogilvie-Harris 97; Dacre 89) and thyrotoxicosis. (Dacre 89) Immunological abnormalities have also been reported. (Bulgen 78) However, the most commonly used classification systems have generally excluded arthroses and crystal arthropathies. (Zuckerman 94) While studies of risk and prognostic factors are notably quite weak, poorer prognostic factors include diabetes, (Esch 94; Janda 93; Pollock 94; Wiley 91) prior episodes of shoulder pain, duration of more than 1 month at presentation, passive elevation less than 101°, concomitant neck pain, severe daytime pain, and psychosocial stress. (Lorenz 52; Oesterreicher 64) The quality of the overall evidence base for treatment of adhesive capsulitis is weak. (Green 98, 05; Baslund 90; van der Heijden 97, 99)

# **DIAGNOSTIC CRITERIA**

Criteria that have been used vary; therefore, there are no consensus diagnostic criteria. (Carette 00) Criteria used include gradual onset of global limitation of active and passive motion and normal radiographs other than osteopenia, which might or might not be present. (Zuckerman 94)

# SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS

Adhesive capsulitis diagnosis is primarily clinical based on the history and physical examination. Additional tests are often performed largely to exclude other treatable conditions. X-ray is recommended and may be needed of both shoulders, particularly if there was a bilateral injury or need for comparison with the unaffected shoulder. Other studies are often helpful, including MRI, especially for evaluation of potential rotator cuff tendinopathies or SLAP tears.

# X-RAYS

Recommendation: X-ray to Diagnose Adhesive Capsulitis X-ray is recommended to diagnose adhesive capsulitis.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

# Rationale for Recommendation

X-ray is the main initial diagnostic test, particularly to help identify the presence and extent of any additional treatable conditions that might be contributing to adhesive capsulitis. MRIs and MRAs are generally not required, although they may be reasonable for select cases of rotator cuff tendinopathies, SLAP tears, or other treatable contributing conditions.

# WORK ACTIVITIES

Patients with adhesive capsulitis should be encouraged to perform work activities to the extent possible, as these activities may be therapeutic. However, some limitations are often needed, especially for more physically demanding work activities. Such limitations are gradually reduced as recovery progresses and may include limitations in heavy lifting and overhead activities. If surgery is performed, there is a similar need for workplace limitations that are gradually reduced.

# **INITIAL CARE**

Initial care of adhesive capsulitis involves identification and treatment of potential confounding conditions (e.g., diabetes, other medical disorders, rotator cuff tendinopathies, etc.). Non-operative treatment has been traditionally recommended. (Loew 05; van Royen 96; Omari 01; Ogilvie-Harris 95; Noel 00; Saccomanni 09; Fareed 89; Gam 98) Educating the patient regarding the generally good long-term prognosis and need to persist in performing progressive exercises is recommended. For patients with significant pain, over-the-counter analgesics and self-applications of heat and ice are recommended. (Lee 74; Waldburger 92; Hamer 76; Leung 08; Hamer 76) Slings and immobilizers are not recommended.

1. Recommendation: Over-the-counter Analgesics and Self-applications of Heat and Ice for Treatment of Adhesive Capsulitis

Over-the-counter analgesics and self-applications of heat and ice are recommended for treatment of significant pain from adhesive capsulitis.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Slings and Braces for Treatment of Adhesive Capsulitis Slings and braces are not recommended for treatment of adhesive capsulitis.

Strength of Evidence – Not Recommended, Insufficient Evidence (I)

# Rationale for Recommendations

There are no quality trials evaluating analgesics, ice, heat, or slings and braces for management of adhesive capsulitis. However, analgesics and OTC NSAIDs are likely helpful and there is some quality evidence for the use of prescription NSAIDs. One moderate-quality trial included heating pad treatments as a physical therapy treatment, but also included other treatments, (Leung 08) precluding an evaluation of efficacy of heating pads alone as self-treatment. One moderate-quality trial that included cryotherapy in one treatment arm did not find benefits compared with other treatments. (Bulgen 84) Self-applications of heat and ice may be helpful for self-management of symptoms. These are not invasive, have low adverse effects, are not costly, and are believed to be helpful for treating symptoms; thus, they are recommended. Slings and braces are not recommended as they promote debility

# Evidence for Initial Care for Adhesive Capsulitis

Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Leung	5.0	N = 30	Diathermy 3 times a week	Shoulder Score	"The addition of	Small sample
2008		frozen	for 4 weeks, 27.12 MHz	Index (baseline/2	deep heating to	sizes (10 subjects
		shoulde	adjusted to subjective	weeks/4 weeks/8	stretching	each), sparse
RCT		r of 8	comfortable warmth plus	weeks) diathermy	exercises	descriptions.
		plus	stretching (4 stretching	(41.5±12.1/	produced a	Differences in
		weeks	exercises, plus HEP QD)	56.3±15.0/67.8±15.1	greater	attention may bias
		duration	vs. heat pack (3 times a	/71.3±19.3) vs.	improvement in	in favor of
			week for 4 weeks,	heating pad	pain relief, and	diathermy. No
			electrical hot pack, 35.5	(389±11.8/54.2±	resulted in better	intermediate or
			times 68.5cm, 63º C) plus	15.4/56.5±14.1/57.8	performance in	longer follow-up.
			stretching vs. stretching	±16.3) vs. stretching	the activities of	Many results
			alone (not described,	alone (33.3±12.5/	daily living and in	trended in favor of
			unclear if supervised); 4	45.3±11.2/46.1±12.7	range of motion	diathermy, but

There are 2 moderate-quality RCTs incorporated into this analysis. There are 3 low-quality RCTs in Appendix 2.

			weeks follow-up.	/53.8±16.5). Only 2 week data different (p = 0.046), including for other ROM measures.	than did superficial heating."	statistically negative, suggesting underpowering.
Bulgen 1984 RCT	4.5	N = 42 frozen shoulde r of 1 plus months	Pendulum exercises as HEP 2-3 minutes/hour vs. exercise plus intra-articular steroid (methylprednisolone acetate 20mg plus 1% lignocaine HCI 0.5mL 1/2 subacromial and 1/2 anterior route "into shoulder joint" weekly for 3 weeks) vs. Maitland mobilization 3 times a week for 6 weeks vs. ice therapy (ice packs then proprioceptive neuromuscular facilitation 3 times a week for 6 weeks; 8 months follow-up.	Average improvement in flexion, abduction, external rotation and total rotation suggest steroid was superior Weeks 1-6, but then no clear superiority of any treatment (graphic data).	"[T]here is little long-term advantage of any of the treatment regimens but that steroid injections may benefit pain and range of movement in the early stages of the condition."	Small sample size in each arm, thus likely underpowered for all but major differences. Low dose of steroid may underestimate effect of corticosteroid injection. All treated with salicylates.

# **FOLLOW-UP VISITS**

Patients with adhesive capsulitis often require many follow-up appointments, particularly if they are undergoing active treatments, need assistance with advancing a course of exercises, and/or require significant work limitations that need frequent adjustments. Frequencies of appointments may also be greater when more workplace limitations are required and job demands are greater. In the few patients who undergo surgical procedures, post-operative rehabilitation can be considerable, particularly in older patients with other associated injuries such as rotator cuff injuries. In those cases, the patient may require therapy on a prolonged basis in order to recover as much function as possible.

# **MEDICATIONS**

Over-the-counter medications may help manage pain associated with adhesive capsulitis. These medications especially include acetaminophen and NSAIDs, (Patel 00; Loew 05; Rizk 82; Saeidian 07) with NSAIDs showing greater efficacy in treatment of other MSDs, but acetaminophen having a generally greater safety profile. Select patients may require the judicious use of opioids for pain management. Other medications that have been used to treat adhesive capsulitis include glucosamine, chondroitin, methylsulfonylmethane, and topical agents such as capsaicin. Oral glucocorticosteroids have also been utilized for treatment of adhesive capsulitis. (Buchbinder 06; Blockey 54; Widiastuti-Samekto 04; Saeidian 07)

1. Recommendation: NSAIDs and Acetaminophen for Pain Management of Adhesive Capsulitis NSAIDs and acetaminophen are recommended for pain management of adhesive capsulitis.

# Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Opioids for Pain Management for Select Patients with Adhesive Capsulitis Judicious use of opioids is recommended for pain management for select patients with severe adhesive capsulitis.

Indications - Patients with acute pain should meet all of the following:

- 1) Severe injury with a clear rationale for use (objective functional limitations due to pain resulting from the medical problem.<sup>xxii</sup>
- Other more efficacious treatments should have been instituted,<sup>xxiii</sup> and either: 2a) failed and/or

<sup>&</sup>lt;sup>xxii</sup>Other indications beyond the scope of this guideline include acute myocardial infarction or agitation interfering with acute trauma management.

<sup>&</sup>lt;sup>xxiii</sup>Treatments to have tried generally include NSAIDs and acetaminophen. For LBP patients, additional considerations include muscle relaxants, progressive aerobic exercise, and directional exercise.

2b) have reasonable expectations of the immediate need for an opioid to obtain sleep the evening after the injury.

- Where available, prescription databases (usually referred to as Prescription Drug Monitoring Program (PDMP)) should be checked and not show evidence for conflicting opioid prescriptions from other providers or evidence of misreporting.<sup>xxiv</sup>
- 4) Non-opioid prescriptions (e.g., NSAIDs, acetaminophen) absent contraindication(s) should nearly always be the primary treatment and accompany an opioid prescription.
- 5) Low-dose opioids may be needed in the elderly who have greater susceptibility to the adverse risks of opioids. Those of lower body weight may also require lower opioid doses.
- 6) Dispensing quantities should be only what is needed to treat the pain. Short-acting opioids are recommended for treatment of acute pain. Long-acting opioids are not recommended.
- 7) Due to greater than 10-fold elevated risks of adverse effects and death, considerable caution is warranted among those using other sedating medications and substances including: i) benzodiazepines, ii) antihistamines (H<sub>1</sub>-blockers), and/or iii) illicit substances.<sup>(105, 109, 167, 168)</sup> Patients should not receive opioids if they use illicit substances unless there is objective evidence of significant trauma or moderate to severe injuries. Considerable caution is also warranted among those who are unemployed as the reported risks of death are also greater than 10-fold.<sup>(109, 167)</sup> Due to elevated risk of death and adverse effects, caution is also warranted when considering prescribing an opioid for patients with any of the following characteristics: depression, anxiety, personality disorder, untreated sleep disorders, substance abuse history, current alcohol use or current tobacco use, attention deficit hyperactivity disorder (ADHD), post-traumatic stress disorder (PTSD), suicidal risk, impulse control problems, thought disorders, psychotropic medication use, chronic obstructive pulmonary disease (COPD), asthma, or recurrent pneumonia.<sup>(78, 102, 104, 108, 109, 169-186)</sup> Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis and/or cirrhosis,<sup>(187)</sup> as well as coronary artery disease, dysrhythmias, cerebrovascular disease, orthostatic hypotension, asthma, recurrent pneumonia, thermoregulatory problems, advanced age (especially with mentation issues, fall risk, debility), osteopenia, osteoporosis, water retention, renal failure, severe obesity, testosterone deficiency, erectile dysfunction, abdominal pain, gastroparesis, constipation, prostatic hypertrophy, oligomenorrhea, pregnancy, human immunodeficiency virus (HIV), ineffective birth control, herpes, allodynia, dementia, cognitive dysfunction and impairment, gait problems, tremor, concentration problems, insomnia, coordination problems, and slow reaction time. There are considerable drug-drug interactions that have been reported (see Opioids Guideline, Appendices 2-3).

*Frequency/Duration* – Generally, opioids should be prescribed at night or while not working.<sup>(82)</sup> Lowest effective, short-acting opioid doses are preferable as they tend to have the better safety profiles, less risk of escalation,<sup>(188)</sup> less risk of lost time from work,<sup>(112)</sup> and faster return to work.<sup>(189)</sup> Short-acting opioids are recommended for treatment of acute pain and long-acting opioids are not recommended. Recommend opioid use as required by pain, rather than in regularly scheduled dosing.

If parenteral administration is required, ketorolac has demonstrated superior efficacy compared with opioids for acute severe pain,<sup>(190, 191)</sup> although ketorolac's risk profile may limit use for some patients. Parenteral opioid administration outside of obvious acute trauma or surgical emergency conditions is almost never required, and requests for such treatment are clinically viewed as red flags for potential substance abuse.

*Indications for Discontinuation* – Resolution of pain, sufficient improvement in pain, intolerance or adverse effects, non-compliance, surreptitious medication use, consumption of medications or substances advised to not take concomitantly (e.g., sedating medications, alcohol, benzodiazepines), or use beyond 2 weeks.

Harms - Adverse effects are many (see section below on "Opioids Benefits and Harms").

Benefits - Improved short-term pain control.

Indications - Patients should meet all of the following:

<sup>&</sup>lt;sup>xxiv</sup>Exceptions such as acute, severe trauma should be documented.

1) Reduced function is attributable to the pain. Pain or pain scales alone are insufficient reasons.<sup>(1, 118, 120, 167, 208-217)</sup>

2) A severe disorder warranting potential opioid treatment is present [e.g., advanced degenerative joint disease (DJD)].<sup>(1)</sup>

3) Other more efficacious treatments have been documented to have failed.<sup>(1)</sup> Other approaches that should have been first utilized include physical restorative approaches, behavioral interventions, self-applied modalities, non-opioid medications (including NSAIDs, acetaminophen, topical agents, norepinephrine adrenergic reuptake blocking antidepressants or dual reuptake inhibitors; also antiepileptic medications particularly for neuropathic pain) and functional restoration. For DJD, this includes NSAIDs, weight loss, aerobic and strengthening exercises.

4) An ongoing active exercise program is prescribed and complied with.

5) Non-opioid prescriptions (e.g., NSAIDs, acetaminophen) absent a contraindication should nearly always be the primary pain medication and accompany an opioid prescription. Other medications to consider include topical agents, norepinephrine adrenergic reuptake blocking antidepressants or dual reuptake inhibitors; also antiepileptic medications particularly for neuropathic pain).

- 5) The lowest effective dose should be used.<sup>(188)</sup> Weaker opioids should be used whenever possible.<sup>(112, 189)</sup> Meperidine is not recommended for chronic pain due to bioaccumulation and adverse effects.
- 6) Low-dose opioids may be needed in the elderly who have greater susceptibility to the adverse risks of opioids. Those of lower body weight may also require lower opioid doses.
- 7) Dispensing should be only what is needed to treat the pain.<sup>xxv</sup>
- 8) Extended-release/long-acting opioids are recommended to be used on a scheduled basis, rather than as needed.<sup>(1)</sup> As needed opioids should generally be avoided for treatment of chronic pain, although limited use for an acute painful event (e.g., fracture, sprain) is reasonable. Sublingual fentanyl is not recommended for treatment of subacute or chronic pain. Caution is warranted with fentanyl patches due to unpredictable absorption.
- 9) Where available, prescription databases (usually referred to as Prescription Drug Monitoring Program (PDMP)) should be checked for conflicting opioid prescriptions from other providers or evidence of misreporting.
- 10) Due to greater than 10-fold elevated risks of adverse effects and death, considerable caution is warranted among those using other sedating medications and substances including: i) benzodiazepines, ii) anti-histamines (H<sub>1</sub>-blockers), and/or iii) illicit substances.<sup>(105, 109, 167, 168)</sup> Patients should not receive opioids if they use illicit substances unless there is objective evidence of significant trauma or moderate to severe injuries. Considerable caution is also warranted among those who are unemployed as the reported risks of death are also greater than 10-fold.<sup>(109, 167)</sup>

Due to elevated risk of death and adverse effects, caution is also warranted when considering prescribing an opioid for patients with any of the following characteristics: depression, anxiety, personality disorder, untreated sleep disorders, substance abuse history, current alcohol use or current tobacco use, ADHD, PTSD, suicidal risk, impulse control problems, thought disorders, psychotropic medication use, COPD, asthma, recurrent pneumonia.<sup>(79, 102, 104, 108, 109, 169-176, 179-186)</sup> Considerable caution is also warranted among those with other comorbidities such as chronic hepatitis and/or cirrhosis,<sup>(187)</sup> as well as coronary artery disease, dysrhythmias, cerebrovascular disease, orthostatic hypotension, asthma, recurrent pneumonia, thermoregulatory problems, advanced age (especially with mentation issues, fall risk, debility), osteopenia, osteoporosis, water retention, renal failure, severe obesity, testosterone deficiency, erectile dysfunction, abdominal pain, gastroparesis, constipation, prostatic hypertrophy, oligomenorrhea, pregnancy, HIV, ineffective birth control, herpes, allodynia, dementia, cognitive dysfunction and impairment, gait problems, tremor, concentration problems, insomnia, coordination problems, and slow reaction time. There are considerable drug-drug interactions that have been reported (see Appendices 2-3).

*Frequency/Duration* – Opioids use is generally initiated as a "trial" to ascertain whether the selected opioid produces functional improvement (see Appendix 1). Opioid use is generally prescribed on a regular basis,<sup>(218)</sup> at

<sup>&</sup>lt;sup>xxv</sup>Generally, this should be sufficient to cover one week of treatment at a time during the trial phase. If a trial is successful at improving function, prescriptions for up to 90-day supplies are recommended.

night or when not at work.<sup>(82)</sup> Only one opioid is recommended to be prescribed in a trial. More than one opioid should rarely be used. Lower opioid doses are preferable as they tend to have the better safety profiles, less risk of dose escalation,<sup>(188)</sup> less work loss,<sup>(112)</sup> and faster return to work.<sup>(189)</sup> Patients should have ongoing visits to monitor efficacy, adverse effects, compliance and surreptitious medication use. Opioid prescriptions should be shorter rather than longer duration.<sup>(219)</sup>

*Indications for Discontinuation* – Opioids should be discontinued based on lack of functional benefit<sup>(115)</sup> (see Appendix 1), resolution of pain, improvement to the point of not requiring opioids, intolerance or adverse effects, non-compliance, surreptitious medication use, medication misuse (including self-escalation and sharing medication), aberrant drug screening results, diversion, consumption of medications or substances advised to not take concomitantly (e.g., sedating medications, alcohol, benzodiazepines).

*Harms* – Adverse effects are many (see Opioids Guideline section on "Opioids Benefits and Harms"). May initiate path to opioid dependency.

*Benefits* – Improved short-term pain ratings. Theoretical potential to improve short-term function impaired by a painful condition.

## Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Over-the-counter Nutraceuticals for Treatment of Adhesive Capsulitis There is no recommendation for or against the use of over-the-counter nutraceuticals (glucosamine, chondroitin, and methylsulfonylmethane) for treatment of adhesive capsulitis.

## Strength of Evidence – No Recommendation, Insufficient Evidence (I)

4. Recommendation: Oral Glucocorticosteriods for Treatment of Adhesive Capsulitis Oral glucocorticosteroids are recommended for treatment of adhesive capsulitis.

Indications - Adhesive capsulitis patients who decline injection.

*Dose/Frequency/Duration* – One course of treatment. Medication and course used in the higher quality trial was triamcinolone 4mg PO TID for 1 week, then 4mg BID for 1 week, then 4mg QD for 1 week. (Widiastuti-Samekto 04) Another moderate-quality RCT utilized cortisone acetate 50mg QID for 3 days, then 25mg QID until Day 14. (Blockey 54) There are no head-to-head comparisons in quality studies of different oral medications to ascertain the optimum medication(s) or dose(s).

*Indications for Discontinuation* – Generally only 1 course administered. Premature discontinuation of medication is usually based on intolerance, although a lower dose is sometimes used to attempt to ascertain whether there is tolerance at a lower dose that might still be potentially effective.

## Strength of Evidence – Recommended, Evidence (C)

5. Recommendation: Other Medications for Pain Management of Adhesive Capsulitis in Select Patients Muscle relaxants, capsicum, tricyclic antidepressants or dual reuptake inhibiting antidepressants for chronic pain (but not SSRI antidepressants which are not effective for nociceptive pain), and gabapentin for peri-operative use are recommended for select patients to control pain associated with adhesive capsulitis.

Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

NSAIDs and acetaminophen are recommended for managing pain from adhesive capsulitis (Loew 05) (some trials evaluating other interventions treated all adhesive capsulitis patients with NSAIDs). (Sun 01) Oral glucocorticosteroids have also been utilized to treat adhesive capsulitis. (Buchbinder 04; Binder 86; Widiastuti-Samekto 04) There are two moderate-quality trials that suggest modest improvements in the oral steroid group. However, the moderate-quality trial that compared injection with oral steroids found substantially faster improvements in the injection group. (Widiastuti-Samekto 04) Oral glucocorticosteroids are not invasive, have adverse effects, and are low cost. As the speed of recovery appears substantially faster via the injected route, (Widiastuti-Samekto 04) oral glucocorticosteroids are recommended for patients

who decline injection. There are no quality trials evaluating muscle relaxants and other medications used to treat chronic nociceptive pain; however, these medications may have limited roles in select patients who have more severe symptoms that are being insufficiently managed with other treatments, particularly for those who need nocturnal doses to facilitate sleep. (Bulgen 84)

## Evidence for Medications for Adhesive Capsulitis

There are 2 moderate-quality RCTs incorporated into this analysis. There are 3 low-quality RCTs in Appendix 2.

Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			Oral Gluc	ocorticosteroids		
Widiastuti- Samekto 2004 RCT	6.5	N = 26 frozen shoulder, mostly 1-3 months duration	Triamcinolone acetonide 40mg intra-articular injection vs. oral triamcinolone 4mg PO TID 1 week, then BID 1 week, then QD 1 week. All treated with physiotherapy on Day 4 with 12 sessions of active exercise, passive joint mobilization, ice or heat.	Cure rate in first week (62% vs. 14%) 5.8-fold higher with injection.	"[I]ntra-articular corticosteroid injection provide [sic] faster improvement compared to oral route."	Results suggest faster resolution of symptoms with injection.
Blockey 1954 RCT	5.0	N = 32 periarthritis of variable duration of symptoms	Cortisone acetate 50mg QID 3 days, then 25mg QID to Day 14 vs. placebo. All to exercise "vigorously." MUA if not satisfactory at 4 weeks. If manipulated, 2nd cortisone course; 18 weeks follow-up.	Pain ratings (pre/1 week/4 weeks/18 weeks): cortisone (1.4/0.9/0.5/0.6) vs. placebo (1.4/1.3/0.8/ 0.5). ROM total abduction cortisone (82/103/125/153) vs. placebo (75/89/106/154).	"Cortisone therapy appeared to expedite the relief of pain and the recovery of shoulder motion and to reduce the number of patients requiring manipulation, but there was great individual variation in response to treatment, so that none of the differences between the two treatment groups reached conventional levels of statistical significance."	Randomized block design for symptoms over/under 6 months.

# **DEVICES/PHYSICAL METHODS**

As previously noted, slings or immobilizers are not recommended because they inhibit use and activity. A sling is also generally not recommended after injections, hydrodilatation, or post-operatively as immediate ROM is desired. Self-applications of heat or cryotherapies (Hamer 76) might be helpful for symptom modulation.

# EDUCATION, EXERCISE, AND THERAPY AND CONTINUOUS PASSIVE MOTION

Therapy, including education and exercise, is thought to be particularly important, especially for more severely affected patients. (Ng 09; Castellarin 04; Neviaser Clin Orthop Relate Res 87; Griggs 00; Bulgen 78, 84; van der Heijden 99; Hamer 76; Sveistrup 2003; Diercks 04; Saeidian 07; Hazleman 72; Noël 00; Baslund 90; Harryman 97) Exercise has been utilized in multiple trials for all patients enrolled, (Binder 86; Kivimäki 07; Quraishi 2007; Bulgen 84; Lathia 09; Sun 01; Carette 03) precluding an assessment of efficacy while documenting the beliefs in the importance of this intervention for treatment of adhesive capsulitis patients. Continuous passive motion (CPM) has been utilized for treatment of adhesive capsulitis (Dundar 09; Laupattarakasem 88) as well as a post-surgical treatment. (Raab 96; Michael 05) There also is evidence of somatic anxiety that has been reported that may be relevant for some patients. (Fleming 76; Lorenz 52; Coventry 53; Oesterreicher 64)

1. Recommendation: Exercise, Education, and Therapy for Treatment of Adhesive Capsulitis Education, exercise, and therapy are recommended for treatment of adhesive capsulitis.

*Indications* – All adhesive capsulitis, especially moderate to severely affected patients. (Loew 05; Lee 73, 74)

*Frequency/Duration* – Education is needed, particularly to provide longer-term perspective regarding the need for persistent advances in ROM and participation in activities, especially meaningful employment, as a method for improving motion. Progressive passive ROM exercises, (Nicholson 85; van der Windt 98) including a home exercise program (HEP) are thought to be essential. Frequency of appointments varies based on condition severity, compliance, need for encouragement, comorbid conditions, and prior patient experiences. ROM exercises are the primary exercises for this disorder, although they are typically followed by isometric strengthening program, then isotonic strengthening and endurance exercises. Options include weekly appointments to oversee and advance a home exercise program for several weeks until sufficient recovered for lower grade injuries and self-motivated patients. Patients with a more severe disorder or need of supervision may require appointments 2 to 3 per week to initiate program exercises, tapering to 1 per week in approximately 4 weeks before being discharged to a home exercise program in approximately 2 months for more severe injuries.

*Indications for Discontinuation* – Recovery, plateau in recovery, noncompliance, or intolerance. *Strength of Evidence* – **Recommended, Evidence (C)** 

2. Recommendation: Continuous Passive Motion for Treatment of Adhesive Capsulitis Continuous passive motion (CPM) is recommended in conjunction with a home exercise program for treatment of adhesive capsulitis.

*Indications* – All adhesive capsulitis patients, especially moderate to severely affected patients. (Dundar 09)

*Frequency/Duration* – CPM for 1 hour per day, 5 days per week for 20 appointments, combined with a daily home exercise program of progressive stretching and pendulum exercises (Dundar 09); additional supervised physical or occupational therapy appointments may be needed for more severely affected patients (see above). Limited evidence CPM may be superior to conventional physiotherapy. (Dundar 09)

Indications for Discontinuation – Recovery, plateau in recovery, noncompliance, or intolerance.

Strength of Evidence – Recommended, Evidence (C)

## Rationale for Recommendations

There are several quality trials evaluating exercise, education, and/or therapy for adhesive capsulitis, although few compare exercise or physiotherapy with no treatment. Overall details vary in the available trials. One moderate-quality trial comparing exercise plus placebo injection compared with placebo injection suggested modestly better effects with exercise, (Ryans 05) although the same trial suggested glucocorticoid injections are superior. There are three moderate-quality trials suggesting injections are superior to physiotherapy (van der Windt 98; Ryans 05; Carette 03) (see graph in injections below) and one lower quality study suggesting equal efficacy. (Dacre 89) There is evidence that arthrographic distension with steroid plus exercise is superior to exercise alone. (Khan 05) One moderate-quality trial suggested exercise in combination with either electroacupuncture or interferential therapy is superior to no treatment. (Cheing 08) Exercise is not invasive, has low adverse effects, and is moderately costly for aggregate appointments. There is quality evidence of efficacy for treatment of adhesive capsulitis, thus it is recommended.

There is one moderate-quality trial comparing continuous passive motion plus home exercise program of stretching and pendulum exercises versus a conventional physiotherapy program plus the same HEP program. (Dundar 09) This trial suggested CPM is superior to conventional physiotherapy for pain relief at both 4 and 12 weeks follow-up. CPM is not invasive, has low adverse effects, and is moderately costly in aggregate appointments. There is quality evidence of CPM's efficacy, thus it is recommended.

Evidence for the Use of Exercise for Adhesive Capsulitis

There are 6 moderate	e-quality F	RCTs incorporated i	nto this analysis.	There are 4 low-qualit	y studies in
Appendix 2.					

Appendix 2 Author/Title Study	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Туре			Triomoinglass		"The herefield	Anneous to ba
Van der Windt 1998 RCT	7.0	N = 109 painful, stiff shoulder, complaints from <1 month to >12 months	Triamcinolone acetonide 40mg injection(s) up to 3 in 6-week period vs. physiotherapy (12 sessions 30 minute, passive joint mobilization, exercise, ice, hot packs, electrotherapy); 52 weeks follow-up.	Improvement in rating of severity $(3/7/13/26/$ 52 weeks): Injections (32/58/66/63/70) vs. PT $(17/32/47/54/59)$ , p = 0.071. Improvement in day pain: Injections (22/35/36/32/38) vs. PT $(10/23/27/32/35)$ , p <0.001. Night pain, observer rating, shoulder disability and ROM all favored injection. Additional treatments in 75% of physiotherapy group vs. 42% injection group.	"The beneficial effects of corticosteroid injections administered by general practitioners for treatment of painful, stiff shoulder are superior to those of physiotherapy. The differences between the intervention groups were mainly the result of the comparatively faster relief of symptoms that occurred in patients treated with injections."	Appears to be primarily trial of adhesive capsulitis. Data suggest glucocorticoster oids more effective than relatively unstructured physiotherapy using numerous measures.
Ryans 2005 RCT	7.5 for injection s 5.5 for physio- therap y	N = 80 shoulder capsulitis, 1 to 6 months duration	Triamcinolone 20mg injection (1/2 anterior shoulder, ½ lateral) plus physiotherapy 8 sessions (proprioceptive neuromuscular facilitation, Maitland mobilization, progressive exercise, interferential, active exercises, gym equipment), HEP standardized] vs triamcinolone injection alone vs. physiotherapy plus placebo injection vs. placebo injection alone; 24 weeks follow-up.	Shoulder Disability Questionnaire (SDQ) mean changes from baseline ( $6/16$ weeks): A -7.8 $\pm$ 5.7/- 7.6 $\pm$ 5.8 vs. B - $6.1\pm$ 6.4/-7.8 $\pm$ 5.9 vs. C -3.5 $\pm$ 4.9/-5.6 $\pm$ 5.8 vs. D -3.1 $\pm$ 3.4/ -6.6 $\pm$ 5.4 (p = 0.004 comparing groups C and D at 6 weeks; no differences at 16 weeks). VAS pain better in A than D at 6 weeks, p <0.05. Physiotherapy showed passive external rotation improvement at 6 weeks (p = 0.020), NS at 16 weeks.	"[C]orticosteroid injection is effective in improving shoulder-related disability at 6 weeks following treatment. Physiotherapy treatment is effective in improving the range of external rotation at 6 weeks after commencement of treatment."	High dropouts in groups B&D. Some baseline differences.
Bulgen 1984 RCT	4.5	N = 42 frozen shoulder of 1 plus month duration	Pendulum exercises as HEP 2-3 minutes an hour vs. exercise plus intra-articular steroid (methylprednisolone acetate 20mg plus 1% lignocaine HCI 0.5 mL ½ subacromial and ½ anterior route "into the shoulder joint" weekly for 3 weeks) vs. Maitland mobilization 3 times a week 6 weeks vs.	Average improvement in flexion, abduction, external rotation and total rotation suggest steroid was superior Weeks 1-6, but then no clear superiority of any treatment (graphic data).	"[T]here is little long- term advantage of any of the treatment regimens but that steroid injections may benefit pain and range of movement in the early stages of the condition."	Small sample size in each arm, thus likely underpowered for all but major differences. Low dose of steroid used may underestimate effect of corticosteroid injection. All treated with salicylates.

Dacre 1989 RCT	4.5	N = 62 painful stiff shoulder at least 4 weeks duration	ice therapy (ice packs then proprioceptive neuromuscular facilitation 3 times a week for 6 weeks; 8 months follow-up. Local steroids (triamcinolone 20mg with 1mL 2% lignocaine) "anteriorly around the shoulder joint" vs. physiotherapy (not standardized, relied primarily on mobilization for 4-6 weeks) vs. combination; 6 month follow-up.	VAS pain scores (0/6/ 26 weeks) interpretations from graphic data: injection (58/27/ 16) vs. physiotherapy (56/22/18) vs. both (53/22/22), NS between groups in total abduction, active movement, internal rotation. After 6 weeks, all groups had reduced pain (p <0.001).	"[L]ocal steroid injections are as effective as physiotherapy alone or a combination of both; they both provide rapid treatment and are less expensive."	No placebo or sham control. PT not standardized. Sparse methods/ results. All groups improved, no differences between groups, suggests comparable efficacy. Cost data suggest injection superior.
Cheing 2008 RCT	4.5	N = 70 idiopathic frozen shoulder	Electroacupuncture (10 sessions for 4 weeks, 2-3 a week; 1 trigger point, LI 15 and ST38; de qi; EA device, 2-100Hz at 100-400µs 20 minutes) plus exercise (4 directional exercises; HEP 5 times a day) vs. interferential electrotherapy (10 sessions, 4 weeks; IRE machine current swept 80-120Hz, 4 suction electrodes in shoulder region) plus exercise vs. no treatment controls (wait-listed); 6-month follow-up for active treatment vs. 1 month for controls.	Graphic data presented. Mean Constant scores improved: EA 65.5±16.7 to 86.0±8.2 (31.5%) vs. IFE 59.6±15.4 to 84.9±8.4 (42.2%) vs. controls 6.6%, p <0.001.	"Either electroacupuncture or interferential electrotherapy in combination with shoulder exercises is effective in treating frozen shoulder patients. However, no significant different was found between these types of treatment."	Patients not well described. Paper reports double blinding, but this seems not possible. Wait-listed controls biases in favor of intervention. No table of results. Graphic data suggest no differences between active treatments.
Dundar 2009	Contin 4.5	N = 57 adhesive	Motion plus Home Ex Continuous passive motion (gradually	ercises vs. Physiothera ROM flexion	"CPM treatment	Identical
RCT		capsulitis mean durations 6.3 and 5.9 months	increasing ROM, 1 hour a day, 5 days a week, 4 weeks) vs. physiotherapy protocol (active stretching and pendulum, 1 hour a day, 5 days a week for 4 weeks). Both groups treated with HEP of passive ROM and pendulum	(baseline/4/12 weeks): CPM (112/134/139) vs. PT (112/1323/139), NS. No differences in abduction, IR, ER. VAS at rest: CPM (5.44±1.51/2.86±1.96/ 2.41±1.72) vs. PT (5.54±1.64/4.11±2.03/ 3.76±1.91), p <0.001 at 4 and 12 weeks. VAS pain with	provides better response in pain reduction than the conventional physiotherapy treatment protocol in the early phase of treatment in adhesive capsulitis."	treatment contact times. Results suggest CPM plus HEP superior to physiotherapy plus HEP as measured by 3 VAS pain measures and SPADI pain scores.

we	eeks; 12 weeks low-up.	movement and night also favor CPM (p <0.001). Constant scores not different. SPADI pain scores favor CPM (p <0.001), but not SPADI disability scores.		
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# MOBILIZATION AND MANUAL THERAPY

Manipulation has been performed while under anesthesia (MUA) as well as mobilization and manual therapy without anesthesia to increase ROM. (Placzek 98; Ng 09; Haines 82; Hill 88; Harryman 97; Hazleman 72; Rizk 82; Uitvlugt 93; Carter 02; Murnaghan 90; Reichmister 99; Kessel 81; Bulgen 84; Binder 84; Guler-Uysal 04; Melzer 95; Maricar 99; Nicholson 85; Vermeulen 06)

#### Recommendation: Mobilization and/or Manual Therapy for Treatment of Adhesive Capsulitis Mobilization and/or manual therapy are moderately recommended for the treatment of adhesive capsulitis.

Indications - Adhesive capsulitis, especially moderate to severely affected patients. (Loew 05)

Frequency/Duration – Mobilization and/or manual therapy generally 1 to 2 appointments a week with intervening home exercises for 3 to 4 weeks. High-grade mobilization techniques are particularly recommended. (Vermeulen 06) Additional 2 sets of up to 8 appointments based on ongoing improvement in condition and ROM. Maximum 24 appointments. (Vermeulen 06) Some patients will not tolerate mobilization of the shoulder without anesthesia: in such cases additional mobilization treatments are not recommended. Encourage patients to use the affected shoulder whenever possible. (Vermeulen 06) and continue home exercises and education.

Indications for Discontinuation – Recovery, plateau in recovery, noncompliance with exercise program, intolerance.

## Strength of Evidence – Moderately Recommended, Evidence (B)

## Rationale for Recommendation

There are no quality trials evaluating mobilization or manual therapy to a sham. However, one highquality trial suggested high-grade mobilizations are modestly superior to low-grade mobilizations. (Vermeulen 06) thus supporting an evidence-based graded recommendation for use of mobilizations for treatment of adhesive capsulitis. One trial comparing mobilizations with injection and cold therapy appears underpowered to detect differences. (Bulgen 84) The other available quality trials include manipulation under anesthesia (MUA); many others included mobilization or manual therapy as part of physiotherapy, thus precluding assessment of its benefits. For those who can tolerate it, mobilization or manual therapy without anesthesia may be beneficial and without some of the considerable adverse effects documented with MUA. (Loew 05) Mobilization and manual therapy of the shoulder are not invasive, have low adverse effects, are moderately costly for aggregate appointments, and thus are recommended.

Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Vermeulen	8.0	N = 100	High-grade mobilization	Number of	"(High-grade	Variable length
2006		unilater al	techniques (mobilization into end of ROM, Maitland	appointments Hi 18.6±4.9 vs. Lo	mobilization techniques"	of treatment depending on
RCT		adhesiv	grades III and IV to	21.5±2.3, p <0.001. No	appear to be mo	responses.
		е	tolerance) vs. low-grade	differences in	re effective in	Shorter length
		capsuliti	mobilization (mobilization	medication use. No	improving	required with
		s at	only within pain-free zone).	significant differences	glenohumeral	high-grade
		least 3	Began with inferior glides,	in percentage	joint mobility and	mobilization,

Evidence for Mobilization for Adhesive Capsulitis

. . . . . .

		months duration	oscillatory caudal/lateral/anterior movements, anterior and medial glides. Both 2 times a week, 30 minutes; maximum 12 weeks, 24 sessions; 12 months follow- up.	indicating better/much better (87-88% at 3 months. Greater active external rotation with Hi vs. Lo at 12 months. Trend toward greater active abduction (data not provided).	reducing disabilitywith the overall differences between the 2 interventions being small."	which was more effective.
Bulgen 1984 RCT	4.5	N = 42 frozen shoulde r of 1 plus months	Pendulum exercises as HEP 2-3 minutes an hour vs. exercise plus intra- articular steroid (methylprednisolone acetate 20mg plus 1% lignocaine HCI 0.5mL ½ subacromial and ½ anterior route "into the shoulder joint" weekly for 3 weeks) vs. Maitland mobilization 3 times a week for 6 weeks vs. ice therapy (ice packs then proprioceptive neuromuscular facilitation 3 times a week for 6 weeks; 8 months follow-up.	Average improvement in flexion, abduction, external rotation and total rotation suggest steroid was superior Weeks 1-6, but then no clear superiority of any treatment (graphic data).	"[T]here is little long-term advantage of any of the treatment regimens but that steroid injections may benefit pain and range of movement in the early stages of the condition."	Small sample size in each arm, thus likely underpowered for all but major differences. Low dose of steroid used may underestimate effect of corticosteroid injection. All treated with salicylates.

# MANIPULATION UNDER ANESTHESIA (MUA)

Manipulation under anesthesia (MUA) has been long used to treat adhesive capsulitis. (Loew 05; Kivimaki Arch Phys Med Rehabil 01; Othman 02; Ng 09; Quraishi 07; Andersen 96, 98; Haines 82; Castellarin 04; Helbig 83; Hill 88; Neviaser 80; Reichmister 99; Thomas 80; Pollock 94; Uitvlugt 93; Wiley 91; Dodenhoff 00; Farrell 05) Some studies have reported normal ROM under anesthesia, suggesting pain-limited ROM and highlighting the difficulty in diagnosing adhesive capsulitis as well as a potential diagnostic advantage to MUA. (Ng 09) However, this intervention has also been shown to result in injuries including hemarthrosis (100%), localized or disseminated synovitis, capsule rupture, SLAP tears, proximal humerus fracture, rotator cuff tear, and articular damage that have been identified on arthroscopy. (Loew 05) Exercises after MUA are believed to be crucial, (Ng 09) and should include passive exercise (Neviaser 87) or continuous passive exercise. (Andersen 98)

# Recommendation: Manipulation under Anesthesia for Treatment of Adhesive Capsulitis in Select Patients

# Manipulation under anesthesia is recommended for treatment of adhesive capsulitis in select patients.

*Indications* – Adhesive capsulitis, especially moderate to severely affected patients with pain and loss of active motion who do not respond sufficiently to NSAIDs, injection(s), and hydrodilatation. (Quraishi 07; Loew 05)

Frequency – Generally, only 1 treatment performed; adequate, safe monitoring of anesthesia is required.

## Strength of Evidence – Recommended, Evidence (C)

## Rationale for Recommendation

There are a few quality trials evaluating MUA for adhesive capsulitis. (Kivimäki 07; Quraishi 07; Jacobs 09) The highest moderate-quality studies suggested modest benefits when comparing MUA with physiotherapy to physiotherapy alone and suggested modest improvements in ROM. (Kivimaki 07) A moderate-quality trial suggested that injections are of comparable efficacy to MUA. (Jacobs 09) Another moderate-quality trial suggested that hydrodilatation is superior to MUA. (Quraishi 07) One moderate-quality trial assessed adjunctive use of intra-articular glucocorticosteroid and found no evidence of benefit of the steroid. (Kivimäki 01) MUA is minimally invasive, except for the anesthesia, but has documented adverse effects,

(Loew 05) and is high cost. MUA is recommended for limited use in select patients who fail other treatments with documented efficacy, but who have lower risks for adverse effects.

Author/Title	Scor	Sample	Comparison	Results	Conclusion	Comments
Study Type	e (0- 11)	Size	Group	Results	Conclusion	Comments
		<u> </u>	Manipulat	ion under Anesthesia (	(MUA)	
Kivimäki 2007 RCT	6.5	N = 125 frozen shoulder	Manipulation under short general anesthesia vs. control group. All treated with physiotherapy with 2	Work ability (6 weeks/ 3, 6, 12 months): manipulation (6.6/7.1/7.8/8.3) vs. controls (6.2/7.1/7.3/	"The exercise program that patients received instruction for and carried out themselves was as effective as the same program that complemented manipulation under anesthesia. It remains to be shown in future trials whether a training program is more effective than no treatment at all."	Both groups treated with HEP. Data suggest MUA has minimal short-term effect in addition to HEP on ROM, but not most measures including work ability. Data also support condition is mostly self-limited.
Quraishi 2007 RCT	6.0	mean 34 weeks duration	acetonide plus 2mL 2% lignocaine) vs hydrodilatation (imaging, mostly 30- 40mL). All treated with exercises; 6 months follow-up.	at 2 and 6 months.	"[W]e recommend hydrodilatation for patients with adhesive capsulitis resistant to conservative treatment. MUA is a more costly inpatient procedure, whereas hydrodilatation can be carried out as an outpatient without general anesthetic."	Data suggest superiority of hydrodilatation to MUA.
Jacobs 2009 RCT	5.5 Ma		Manipulation under anesthesia vs 3 glenohumeral joint injections, posterior route no imaging Q 6 weeks (triamcinolone acetate 40mg plus lignocaine 2% 5mL plus bupivacaine 0.25% 10mL plus 5mL air); 2 years follow-up.	Study reports 2 years follow-up, but results primarily 15 weeks. VAS weeks 1-15 mean (SE): Injection - 2.75 (0.42) vs. MUA - 2.77 (0.33), NS. Constant mean (SE): Injection 3.23 (0.42) vs. MUA 3.13 (0.24), NS.	"[W]e recommend the use of these injections, rather than MUA and physiotherapy, as a first- line treatment for patients in the freezing phase of idiopathic (primary) frozen shoulder."	Baseline differences with more females in injection (80% vs. 54%) of unclear significance (authors state no difference). Sparse details. Data suggest injections comparable to MUA
Kivimäki	1		-			Patients not well
Kivimäki 2001 RCT	4.5	N = 24 frozen shoulder; duration unclear	MUA with vs. without intra- articular glucocorticosteroid injection (betamethasone 6mg plus 4mL lidocaine); 4 months follow-up.	Flexion (pre/1 day/4 months) steroid (101/ 148/156) vs. without (109/157/159). Abduction (83/145/ 147) vs. without (85/ 144/150).	"Manipulation under anesthesia without intraarticular corticosteroids is recommended as the therapy for frozen shoulder."	described. Data suggest corticosteroid as an adjunct is unhelpful.

## *Evidence for Manipulation under Anesthesia for Adhesive Capsulitis* There are 4 moderate-quality RCTs incorporated into this analysis.

## ACUPUNCTURE

Acupuncture has been used to treat patients with adhesive capsulitis. (Favejee 11; Maund 12, Rookmoneea 10) However, there has not been many significant findings regarding acupuncture compared to placebo or

other interventions; when comparing within different types of acupuncture, deep acupuncture seems to be more effective than shallow acupuncture. (Green 05)

Recommendation: Acupuncture for Treatment of Adhesive Capsulitis in Select Patients Acupuncture is recommended for treatment of adhesive capsulitis in select patients.

*Indications* – Adhesive capsulitis, especially moderate to severely affected patients with pain and loss of motion who do not respond sufficiently to NSAIDs, injection(s), and hydrodilatation; (Quraishi 07; Loew 05) recommended to be accompanied by an active exercise program. (Lathia 09; Sun 01)

*Frequency* – Regimens vary widely in quality trials. An initial trial of 4 appointments would appear reasonable combined with a conditioning program of aerobic and strengthening exercises. An additional 4 appointments should be tied to improvements in objective measures after first 4 treatments, for a total of 8 appointments. (Guerra de Hoyos 04)

*Indications for Discontinuation* – Recovery, plateau in recovery, noncompliance with exercise program, intolerance.

## Strength of Evidence – Recommended, Evidence (C)

## Rationale for Recommendation

There are a few moderate-quality trials of acupuncture that appear to have included adhesive capsulitis patients. (Lathia 09; Sun 01; Cheing 08; Berry 80) One moderate-quality trial found acupuncture superior to sham acupuncture. (Lathia 09) A second moderate-quality trial suggested exercise plus acupuncture was superior to acupuncture alone. (Sun 01) However, one lower quality trial suggested there was no difference between electroacupuncture plus exercise and interferential plus exercise (Cheing 08) and the lowest quality study appears to have found no benefit of acupuncture compared with placebo (Berry 80). Acupuncture is minimally invasive, has minor adverse effects provided needles are not inserted deeply, is moderate cost in aggregate, and the highest quality studies suggest benefits. Therefore, acupuncture is recommended as an adjunct to an active exercise program for select, limited use in patients failing other treatments with documented efficacy.

Author/ Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Lathia 2009 RCT	7.0	N = 31 adhesive capsulitis, rotator cuff syndrome, rotator cuff tear, osteo- arthritis, biceps tendonitis, subacromi al bursitis.	Acupuncture (individualized, traditional Chinese, different locations accessed 1/8-1 inch insertions, de qi) vs. standardized acupuncture (7 points consistently accessed) vs. sham acupuncture (non- penetrating, Streitberger needles). All treated with HEP; twice a week for 6 weeks; no subsequent follow-up.	SPADI scores mean changes from baseline: Traditional - 22.7±4.9 vs. Standard protocol:-23.8±3.9 vs. sham:-6.5±4.2	"Acupuncture may be an effective treatment for chronic shoulder pain. There may be no difference in efficacy between individualized and standardized acupuncture treatment."	Patients not well described. Small groups and sample size. Some base- line differences. Diagnoses mixed and unclear which diagnosis (es) may have predominated, if any. Thus applicability of results limited. Data suggest traditional and standardized approaches equivalent, but superior to sham.
Koh 2013 RCT	7.0	N = $68$ mean age $54.35\pm7.2$ 1 years, with adhesive capsulitis	Bee venom acupuncture (BV) 1 group (n = 22) received dry bee venom powder diluted with saline to 1:10,000	SPADI, VAS, and active/passive ROM scores were reported at 2, 4, 8 and 12 weeks. All 3 groups showed statistically significant	"BVA combined with physiotherapy may have better clinical effectiveness in functional improvement and	Although these patients were requested not to receive any other intervention during follow-up period, they were allowed

# Evidence for Acupuncture for Adhesive Capsulitis

		(AC), pain symptoms lasting 1- 12 months, and limited ROM in 1 shoulder.	concentration vs. BV 2 group (n = 23) received dried bee venom powder diluted with saline to 1:30,000 concentration vs. normal saline (NS) group (n = 23) received intramuscular injections of saline. All groups received total of 0.4ml BVA or NS injected at 4 points on first visit, 0.6ml at 6 points on second, 0.8ml at 8 points on third, and 1.0ml at 10 points for remainder of 16 total visits over 8 weeks. All groups were given PT reported to be effective for frozen shoulder.	improvement in SPADI, VAS, and ROM as treatment progressed from 2-12 weeks post treatment initiation ( $p < 0.01$ ). BV1 and NS, SPADI at week 8 was 23.15 ± 12.82 and 37.44 ± 19.84 respectively ( $p=0.025$ ), and week 12 was 15.42 ± 12.63 and 30.21 ± 20.94 ( $p =$ 0.017). No significant difference between BV1 and BV2 groups at any time. For BV1 and NS, VAS at rest at week 8 was 2.66±1.69 and 4.15± 2.12 ( $p = 0.048$ ). VAS during motion at week 12 was 2.21±21.88 and 3.65±2.20 ( $p =$ 0.029). No significant difference between BV1 and BV2 groups. All ROMs showed no significant difference among groups.	pain reduction than physiotherapy alone on AC patients. Even though the 1:10,000 concentration bee venom acupuncture showed generally better effects compared to the 1:30,000 concentration, there was no statistical difference."	to receive other interventions if there was intractable pain. All groups improved over time, however few statistically significant differences between groups.
Sun 2001	6.5	N = 35 frozen	Exercise 2 times a week, 6 weeks with	Improvement in constant scores (pre/6	"[C]ombination of acupuncture with	22 in exercise group vs. 13 in
RCT		shoulder	education, gentle stretching, HEP 10 reps each 3 times a day vs. exercise plus traditional Chinese acupuncture (extra point of Zhong-ping, contralateral acupoint, strong stimulation, de qi, 2 times a week for 6 weeks). All treated with ketoprofen; 20 weeks follow-up.	weeks/20 weeks): exercise ( $42.8\pm$ $14.0/57.6\pm15.1/57.9\pm$ 15.1) $39.8%$ vs. exercise plus acupuncture ( $41.3\pm$ $14.9/66.8\pm10.9/67.3\pm$ 11.5) $76.4%$ (p = 0.95/p = 0.056/p = 0.048). Percentage improvement from baseline favored combined treatment at ( $6/20$ weeks): $39.8/$ 40.3% vs. $76.4/$ $77.2%$ , p = $0.048/p = 0.025$ .	shoulder exercise may offer effective treatment for frozen shoulder."	other, yet does not describe why such a large difference in groups. Trend towards longer treatment in exercise group.
Cheing 2008	4.5	N = 70 idiopathic	Electroacupuncture (10 sessions over 4	Graphic data presented. Mean	"Either electroacupunctur	Patients not well described. Paper
RCT		frozen shoulder	weeks, 2-3 a week; used 1 trigger point, LI 15 and ST38; de qi; EA device, 2- 100Hz at 100-400µs for 20 min) plus exercise (4 direction exercises; HEP 5 times a day) vs. interferential electro- therapy (10 sessions over 4 weeks; IRE machine current	Constant scores improved: EA 65.5±16.7 to 86.0±8.2 (31.5%) vs. IFE 59.6±15.4 to 84.9±8.4 (42.2%) vs. controls 6.6%, p <0.001.	e or interferential electrotherapy in combination with shoulder exercises is effective in treating frozen shoulder patients. However, no significant different was found between these types of	reports double blinding, however this seems not possible. Wait- listed controls biases in favor of intervention. No table of results. Graphic data suggest no differences between active treatments.

extension, active internal rotation, Physical Function (PF), Body Pain (BP), and Vitality (VT) (p <0.05 for each).	
After 4 weeks Krusal- Wallis test: all 3 groups showed significant improvement in static pain, dynamic pain, active flexion, and active external rotation (p <0.05 for each).	

## DIATHERMY, INFRARED THERAPY, ULTRASOUND, LASER THERAPY, ELECTRICAL THERAPIES (INCLUDING TENS), MAGNETS, TAPING AND PULSED ELECTROMAGNETIC FREQUENCY

Various means of delivering heat, (Leung 08; Cheing 08; Stergioulas 2008; Biswas 79; Herrera-Lasso 93; Simmonds 49; Saeidian 07; Hamer 76) as well as electrical therapies (Leandri 90; Herrera-Lasso 93) for purposes of distraction have been utilized to treat osteoarthrosis patients, although few quality studies for treatment of adhesive capsulitis have been identified. Magnets have also been used to treat adhesive capsulitis. (Leclaire 91)

1. Recommendation: Shortwave Diathermy for Treatment of Adhesive Capsulitis Shortwave diathermy is recommended for the treatment of adhesive capsulitis.

*Indications* – Adhesive capsulitis of at least 8 weeks duration; (Leung 08) consideration but not a requirement of inadequate response to injection.

*Frequency* – Three times a week up to 4 weeks (Leung 08) combined with exercises. (Leung 08) *Indications for Discontinuation* – Resolution, sufficient improvement, intolerance, noncompliance with exercises.

Strength of Evidence – Recommended, Evidence (C)

Recommendation: Other Physical Methods for Treatment of Adhesive Capsulitis
 There is no recommendation for or against the use of infrared therapy, ultrasound, laser
 therapy, high-voltage galvanic, H-wave stimulation, iontophoresis, microcurrent,
 percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, interferential
 therapy, or transcutaneous electrical stimulation (TENS) for treatment of adhesive capsulitis.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

- 3. Recommendation: Magnets for Treatment of Adhesive Capsulitis Magnets are not recommended for the treatment of adhesive capsulitis. (Leclaire 91) Strength of Evidence – Not Recommended, Evidence (C)
- 4. Recommendation: Taping or Pulsed Electromagnetic Frequency for Treatment of Adhesive Capsulitis Taping or pulsed electromagnetic frequency is not recommended for the treatment of adhesive capsulitis.

## Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

There is one moderate-quality trial suggesting that diathermy plus stretching exercises is superior to a heating pad plus stretching exercises or to stretching exercises alone for frozen shoulder. (Leung 08) Diathermy is not invasive, has low adverse effects, and is moderately costly in the regimen used in the quality trial; thus, diathermy is recommended for treatment of patients with adhesive capsulitis. There is one moderate-quality trial of low level laser treatment (LLLT) that suggested benefits. (Stergioulas 08) However, LLLT is not recommended because it is a high-cost intervention for which the overall evidence

for LLLT conflicts across numerous trials for various MSDs (see Chronic Pain Guidelines and Low Back Complaints); quality trials suggest other treatments are effective.

One moderate-quality trial suggests magnets are not effective. (Leclaire 91) Magnets are not recommended because they have been shown to be ineffective for treatment of other musculoskeletal disorders.

There is no quality evidence and thus no recommendation for the use of infrared, ultrasound, (Hamer 76) high-voltage galvanic, H-wave stimulation, iontophoresis, interferential therapy, (Cheing 08) microcurrent, percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, or transcutaneous electrical stimulation (TENS), although several of these have been trialed in adhesive capsulitis patients. (Loew 05) Taping is generally not indicated for chronic conditions.

*Evidence for Heat Therapy, Low-Level Laser Therapy, Magnets, Ultrasound for Adhesive Capsulitis* There are 4 moderate-quality RCTs incorporated into this analysis. There are 2 low-quality RCTs in Appendix 2.

Appendix 2 Author/ Title	Scor e (0-	Sample Size	Comparison Group	Results	Conclusion	Comments
Study	11)	5126				
Туре			Methods fo	r Heat Treatments		
Leung 2008 RCT	5.0	N = 30 frozen shoulder, 8 plus weeks duration	Diathermy (3 times a week for 4 weeks, 27.12 MHz, adjusted to subjective comfortable warmth) plus stretching (4 stretching exercises, plus HEP QD) vs. heat pack (3 times a week for 4 weeks, electrical hot pack, 35.5x68.5cm, 63°C) plus stretching vs. stretching alone (not described/unclear if supervised); 4 weeks follow-up.	Shoulder Score Index (baseline/2 weeks/4 weeks/8 weeks): diathermy (41.5 $\pm$ 12.1/ 56.3 $\pm$ 15.0/67.8 $\pm$ 15.1/ 71.3 $\pm$ 19.3) vs. heating pad (389 $\pm$ 11.8/54.2 $\pm$ 15.4/56.5 $\pm$ 14.1/57.8 $\pm$ 16.3) vs. stretching alone (33.3 $\pm$ 12.5/45.3 $\pm$ 11.2/46.1 $\pm$ 12.7/53.8 $\pm$ 16.5); 2-week data different (p = 0.046), including for other ROM measures.	"The addition of deep heating to stretching exercises produced a greater improvement in pain relief, and resulted in better performance in the activities of daily living and in range of motion than did superficial heating."	Small sample sizes (10 subjects each). Sparse subject descriptions. Differences in attention may bias in favor of diathermy. No intermediate or longer follow-up. Many results trended in favor of diathermy, but were statistically negative, underpowering.
Cheing 2008 RCT	4.5	N = 70 idiopathic frozen shoulder	Electroacupuncture (10 sessions for 4 weeks, 2-3 a week; 1 trigger point, Ll 15 and ST38; de qi; EA device, 2-100Hz at 100-400µs for 20 minutes) plus exercise (4 directional exercises; HEP 5 times a day) vs. interferential electrotherapy (10 sessions for 4 weeks; IRE machine current swept 80-120 Hz, 4 suction electrodes in shoulder region) plus exercise vs. no treatment controls (wait-listed); 6-month follow-up active treatment vs. 1 month controls.	Graphic data presented. Mean constant scores improved: EA 65.5±16.7 to 86.0±8.2 (31.5%) vs. IFE 59.6± 15.4 to 84.9±8.4 (42.2%) vs. controls 6.6%, p <0.001.	"Either electroacupunctur e or interferential electrotherapy in combination with shoulder exercises is effective in treating frozen shoulder patients. However, no significant different was found between these types of treatment."	Patients not well described. Paper reports double blinding, however this seems not possible. Wait- listed controls biases in favor of intervention. No table of results. Graphic data suggest no differences between active treatments.

	Low Level Laser Therapy									
Stergioula s 2008 RCT	6.5	N = 63 frozen shoulder; mean durations 26.5 and 27.1 weeks	LLLT (810nm Ga-Al-As laser, 60mW to 8 shoulder points 30 seconds each, total 1.8J/point and 14.4J/session) vs. placebo laser; 2 sessions a week for 4 weeks, then 1 session a week for 4 weeks; 16 weeks follow-up.	VAS scores (base- line/4/8/16 weeks): LLLT (71/32/ 28/24) vs. sham (66/51/40/ 38) (interpretations of graphic data). P <0.005, p <0.05 and p <0.05 at each follow- up respectively. SPADI scores also favored LLLT.	"The results suggested that laser treatment was more effective in reducing pain and disability scores then placebo at the end of the treatment period."	Some details sparse, particularly co- interventions, compliance and dropouts. Data suggest LLLT laser superior to sham.				
		1	Ň	lagnets	1					
Leclaire 1991 RCT	6.5	N = 47 shoulder periarthritis ; mean 17 weeks duration	Magnetotherapy plus hot packs, passive manual stretching and pulley exercises vs. sham plus same treatments, 3 times a week for maximum of 3 months.	Flexion ROM (base- line/4/8/12 weeks): magnetotherapy (133/ 149/159/163) vs. sham (137/154/167/171) (NS). Abduction: magnetotherapy (99/ 115/130/135) vs. sham (101/120/136/142) (NS). Pain index (baseline/12 weeks): magnetotherapy 1.9± 0.8/1.5±0.61 vs. sham 1.8±1.05/1.4±0.65 (NS).	"[T]his study showed no benefit from magnetotherapy in the pain score, range of motion, or improvement of functional status in patients with periarthritis of the shoulder."	Patients not well described. Study suggests lack of efficacy.				

## INJECTIONS GLUCOCORTICOID INJECTIONS

Glucocorticoid injections are commonly performed for treatment of adhesive capsulitis. (Loew 05; Binder 86; Bulgen 78, 84; Quraishi 07; Carette 03; Ryans 05; Dacre 89; Hollingsworth 83; Valtonen 74; Lee 74; Winters 97; Hay 03; Rizk 91; Gam 98; Valtonen 74a, 74b; de Jong 98; van der Windt 98; van der Heijden 96; Weiss 78; Aroll 05; Steinbrocker 74; Haines 82; Hazleman 72; Noël 00; Rizk 82; Dehghan 13; Oh 11; Shin 13; Lee 09; Park 13)

# Recommendation: Glucocorticoid Injections for Treatment of Adhesive Capsulitis Glucocorticoid injections are strongly recommended for treatment of adhesive capsulitis.

*Indications* – Adhesive capsulitis, mild cases with insufficient control or progress with NSAID, or moderate or severe cases. (Loew 05)

*Frequency/Duration* – One injection recommended and results assessed. Injections have been performed in the glenohumeral joint, (Jacobs 09) subacromial space, (de Jong 98; Valtonen 74) 2 injection points, (Ryans 05) as well as targeting the shoulder capsule. (Dacre 89) One trial suggested no differences in outcomes between bursal injections and intra-articular injections. (Rizk 91) There are no quality trials comparing these different approaches. A second injection may be reasonable, particularly if the initial results are partial but insufficient. Subsequent injection(s) should generally be based on objective evidence of progress attributable to the injection(s), but with insufficient or incomplete results. If an initial injection is unsuccessful, a different approach is suggested. A third injection is not recommended if there is not objective response to the 2 prior injections. Injection combined with exercises is recommended. (Carette 03)

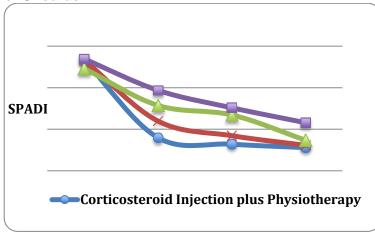
*Dose* – Quality trials have utilized triamcinolone hexacetonide 40mg, (Carette 03) triamcinolone acetonide 10mg, (de Jong 98) and 40mg. (de Jong 98; van der Windt 98) Trials have both used fluoroscopy (Carette 03), ultrasound, (Lee 09) and have used no imaging for the injection(s). There is only one study suggesting better results with ultrasound than blind injections, (Lee 09) resulting in limited evidence on that question and need for further studies. One high-quality trial suggested triamcinolone acetonide 10mg was inferior to 40mg, thus, triamcinolone acetonide 40mg is the recommended dose for that glucocorticoid. (de Jong

98) Quality trials have suggested superior results with injection compared with oral steroids (Widiastuti-Samekto 04), but not NSAIDs where two studies conflict regarding superiority. (Dehghan 13; Shin 13)

Indications for Discontinuation - Recovery, plateau in recovery, intolerance.

Strength of Evidence – Strongly Recommended, Evidence (A)

# Figure 5. Physiotherapy vs. Injection vs. Combined vs. Placebo Injection for Adhesive Capsulitis of Shoulder



SPADI=Total Shoulder Pain and Disability Index Score

Adapted from Carette S, Moffet H, Tardif J, Bessette L, Morin F, Frémont P, Bykerk V, Thorne C, Bell M, Bensen W, Blanchette C. Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder. A placebo-controlled trial. *Arthritis Rheum.* 2003;48(3):829-38.

## Rationale for Recommendation

There are multiple high- and moderate-quality trials that have evaluated glucocorticoid injections for treatment of adhesive capsulitis. (Carette 03; de Jong 98; Ryans 05; van der Windt 98; Jacobs 09; Dacre 89; Valtonen 74; Rizk 91; Gam 98; Widiastuti-Samekto 04) The highest quality trial found the injection group or the injection plus physiotherapy groups to be superior to the saline injections are more effective than physiotherapy. (Carette 03) The next highest quality trial suggests injections are more effective than physiotherapy. (Ryans 05) Other studies have found no differences in corticosteroid injections compared with NSAID (Dehghan 13) and hyaluranoic acid. (Park 13) Injections are invasive, have some adverse effects, and are moderate cost. However, they appear quite effective and thus are recommended for treatment of adhesive capsulitis.

## Evidence for Glucocorticoid Injections for Adhesive Capsulitis

There are 4 high- and 18 moderate-quality RCTs incorporated into this analysis. There are 5 low-quality RCTs in Appendix 2. (Dehghan 12; Lakse 09; De Carli 12; Schydlowsky 12; Lorbach 10)

Author/Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			Glucocort	ticosteroid Injections		
Carette	10.5	N = 93	All taught HEP	SPADI total scores	"[A] single	Physiotherapy arm
2003	for	adhesive	(10 minutes ROM	mean changes from	intraarticular	appears to have
	injecti	capsulitis	BID for 3 months)	baseline: group 1 -	injection of	included non-
RCT	on	up to 1	and triamcinolone	46.5±5.3 vs. group	corticosteroid	randomized treatment
		year	hexacetonide	2 -36.7±5.1 vs.	administered under	based on acute or
	5.5 for	duration	40mg joint	group 3 -22.2±4.8	fluoroscopy,	chronic criteria. No
	physio		injection	vs. group 4 -	combined with a	descriptions of
	-		(fluoroscopic	18.9±5.1, p <0.05	simple home	patients in those
	therap		guidance) plus	comparing groups 1	exercise program, is	subcategories.
	y .		physiotherapy (12	and 2 vs. group 4.	effective in	Diminishes the value
			1-hour sessions	Group 3 vs. 4 NS.	improving shoulder	of the trial to evaluate

			"acute" treated with TENS, mobilization, active ROM, ice. "Chronic" treated with ultrasound, heat, mobilization, active and auto- assisted ROM, isometric strengthening exercise, ice) vs. injection alone vs. saline injection plus PT vs. saline injection alone; 12 months follow- up.	SF-36 physical component scores all not significant. Active ROM superior in group 1 than others, p <0.05. At 3 months the combination group and corticosteroid group were significantly better than placebo (p <0.05). At 6 months, no groups statistically different.	pain and disability in patients with adhesive capsulitis."	efficacy of physiotherapy interventions. Data suggest physiotherapy alone ineffective and injection superior to physiotherapy.
de Jong 1998 RCT	8.5	N = 57 adhesive capsulitis	Triamcinolone acetonide 10mg vs. 40mg subacromial injections at 0, 1 and 3 weeks; 6 weeks follow-up.	VAS pain improvements from baseline at 6 weeks: 10mg 31.2 vs. 40mg 49.3 (p <0.01). VAS scores ≤ 20 in 50% at 10mg vs. 71% at 40mg. No movement restrictions in 14% vs. 38%.	"[I]n the treatment of frozen shoulder greater symptom relief is obtained with a dose of 40 mg triamcinolone acetonide intra- articularly than with a dose of 10 mg."	Series of 3 injections. Some baseline differences of uncertain significance. Data suggest higher dose more effective.
Valtonen 1974 RCT	8.5	N = 50 frozen shoulder (32) or supra- spinatus tendinitis (18); mean 3.7, 3.9 months duration	Subacromial betamethasone phosphate 2mg plus betamethasone dipropionate 5mg vs. methylprednisolo ne acetate 40mg injections; 8 weeks follow-up.	Numbers dropped from study for lack of efficacy 15 vs 16 (NS). Trend in favor of betamethasone at 6 weeks for pain (p <0.09).	"The results showed that in nearly all parameters the betamethasone group gave a better response."	Graphs suggest minimal and no consistent effects. Graph data note lack of statistical significance, though some trends (e.g., p <0.08).
Ryans 2005 RCT	7.5 for injecti on; 5.5 for physio - therap y	N = 80 shoulder capsulitis, 1 to 6 months duration	Triamcinolone 20mg injection (½ inch anterior shoulder and ½ in lateral shoulder) plus physiotherapy 8 sessions (proprioceptive neuro-muscular facilitation, Maitland mobilization, progressive exercise, interferential, active exercises, gym equipment), HEP standardized] vs. triamcinolone injection alone vs.	Shoulder Disability Questionnaire (SDQ) mean changes from baseline ( $6/16$ weeks): A -7.8±5.7/- 7.6±5.8 vs. B - $6.1\pm6.4/-7.8\pm5.9$ vs. C - $3.5\pm4.9/-5.6\pm5.8$ vs. D - $3.1\pm3.4/-$ $6.6\pm5.4$ (p = 0.004 comparing groups C and D at 6 weeks; no differences at 16 weeks). VAS pain better in A than D at 6 weeks, p <0.05. Physiotherapy showed passive external rotation improvement at 6 weeks (p = 0.020),	"[C]orticosteroid injection is effective in improving shoulder-related disability at 6 weeks following treatment. Physiotherapy treatment is effective in improving the range of external rotation at 6 weeks after commencement of treatment."	High dropouts in groups B&D. Some baseline differences.

			physiotherapy plus placebo	NS at 16 weeks.		
			injection vs placebo injection alone; 24 weeks follow-up.			
Van der Windt 1998 RCT	7.0	N = 109 painful, stiff shoulder with complaints ranging from <1 month to >12 months	Triamcinolone acetonide 40mg injection(s) up to 3 in a 6 week period vs. physiotherapy (12 sessions of 30 minutes, passive joint mobilization, exercise, ice, hot packs, electro- therapy); 52 weeks follow-up.	Improvement in rating of severity (3/7/13/ 26/52 weeks): Injections (32/58/66/ 63/70) vs. PT (17/32/ 47/54/59), p = 0.071. Improvement in day pain: Injections (22/35/36/ 32/38) vs. PT (10/23/ 27/32/35), p <0.001. Night pain, observer rating, shoulder disability, ROM all favored injection. Additional treatments in 75% of physiotherapy group vs. 42% injection group.	"The beneficial effects of corticosteroid injections administered by general practitioners for treatment of painful, stiff shoulder are superior to those of physiotherapy. The differences between the intervention groups were mainly the result of the comparatively faster relief of symptoms that occurred in patients treated with injections."	Appears to be primarily trial of adhesive capsulitis. Data suggest glucocorticosteroids more effective than relatively unstructured physiotherapy using numerous measures.
Widiastuti- Samekto 2004 RCT	6.5	N = 26 frozen shoulder, mostly 1-3 months duration	Triamcinolone acetonide 40mg intra-articular injection vs. oral triamcinolone 4mg PO TID for 1 week, then BID 1 week, then QD 1 week, then QD 1 week. All treated with physiotherapy Day 4 with 12 sessions of active exercise, passive joint mobilization, ice or heat.	Cure rate in first week (62% vs. 14%) 5.8-fold higher with injection.	"[I]ntra-articular corticosteroid injection provide [sic] faster improvement compared to oral route."	Results suggest faster resolution of symptoms with injection.
Gam 1998 RCT	6.0	N = 22 frozen shoulder with mean durations 4.5 and 5 months	Triamcinolone hexacetonide 20mg alone vs. distension with 19mL lidocaine 0.5% plus steroid, 1 treatment a week for 6 weeks; 12 weeks follow-up.	Graphic data presented. Data suggest no differences in pain ratings. VAS function favored distension from Week 8 on. Analgesic use lower Week 11, p = 0.03. Physician impression also favored distension.	"[D]istension with steroid can seem to help in management of "Frozen Shoulder."	Claims envelope method of allocation, but 12 got distension and 8 received injection. Regimens unusually invasive.
Rizk 1991 RCT	5.5	N = 48 frozen shoulder less than 6 months duration	3 injections weekly intervals for each patient in 4 groups: intra- articular methylprednisolo ne 40mg/mL plus lidocaine 2mL 1%	Mean pain scores (baseline/4/11/24 weeks): Intraarticular steroid (3.88/3.87/3.47/3.20 ) vs. intrabursal steroid (3.70/3.71/3.36/3.00	"There was no significant difference in outcome between intrabursal injection and intra-articular injection. Injection of steroid with	Steroid dose not clearly noted but appear to be 40mg. Data suggest minimal efficacy of steroid, although dose used in this study is low.

			vs. intrabursal methyl- prednisolone plus lidocaine vs. intra-articular lidocaine vs. intra-bursal lidocaine. All received physical therapy; 6 month follow-up.	) vs. lidocaine (4.07/3.93/3.13/3.00). Mean total degrees of shoulder motion: intra- articular steroid (303/305/318/321/3 51) vs. intrabursal (307/306/318/331/3 52) vs. lidocaine (300/305/ 311/314/347).	lidocaine had no advantage over lidocaine alone in restoring shoulder motion, but partial, transient pain relief occurred in two thirds of the steroid- treated patients."	
Jacobs 2009 RCT	5.5	N = 53 adhesive capsulitis	Manipulation under anesthesia vs 3 glenohumeral joint injections, posterior route without imaging Q 6 weeks (triamcinolone acetate 40mg plus lignocaine 2% 5mL plus bupivacaine 0.25% 10mL plus 5mL air); 2 years follow-up.	2.75 (0.42) vs. MUA - 2.77 (0.33), NS. Constant mean (SE): Injection 3.23 (0.42) vs. MUA 3.13 (0.24), NS.	use of these injections, rather than MUA and physiotherapy, as a first-line treatment for patients in the freezing phase of idiopathic (primary) frozen shoulder."	with more females in injection (80% vs. 54%) of unclear significance (authors state no difference). Sparse details.
Oh 2011 RCT	5.0	N = 71 patients with shoulder pain and limitation of both active and passive motion in at least 2 directions (frozen shoulder).	subacromial space. Both groups received a 1mL triamcinolone	and 12 after injection. For passive range of motion (ROM) and all ROM positive improvements were measured reported at	"The GH steroid injection was not superior to a SA injection for patients with primary frozen shoulder even though injection at the GH joint led to earlier pain relief compared with the SA injection."	Data suggest no difference between study groups

Sakeni	5.0	N = 135	Triamcinolone	For moderate pain,	"[T]riamcinolone	47% of patients with
2007 RCT	0.0	frozen shoulder; mean 5.0,	acetonide 40mg vs. methylprednisolone acetate 60mg.	100% improved in	acetonide is a good rescue for painful stiff shoulder particularly for resistant cases as	diabetes. Numbers of injections varied. Limited results,
		5.8 months durations	Injections every 3 weeks up to 3 injections; 8 weeks follow-up.	(67.5%) methylprednisolone improved. Overall, 76.5% of triamcinolone vs. 39 (58.2%) methylprednisolone		combined with lack of control over numbers of injections limits robustness of results.
				improved.		
Dacre 1989 RCT	4.5	N = 62 painful stiff shoulder at least 4 weeks duration	Local steroids (triamcinolone 20mg with 1mL 2% lignocaine) "anteriorly around the shoulder joint" vs physiotherapy (not standardized, describes relied primarily on mobilization for 4- 6 weeks) vs combination; 6 month follow-up.	VAS pain scores (0/6/26 weeks) interpretations from graphic data: injection (58/27/16) vs. physiotherapy (56/22/18) vs. both (53/22/22), NS between groups. No differences between groups in total abduction, active movement, internal rotation. After 6 weeks, all groups had reduced pain (p <0.001).	"[L]ocal steroid injections are as effective as physiotherapy alone or a combination of both; they both provide rapid treatment and are less expensive."	No placebo or sham control. PT not standardized. Sparse methods and results. All groups improved, but no differences between groups, suggesting comparable efficacy. Cost data suggest injection superior.
Bulgen 1984 RCT	4.5	N = 42 frozen shoulder of 1 plus months duration	Pendulum exercises as HEP 2-3minutes an hour vs. exercise plus intra-articular steroid (methylprednisolo ne acetate 20mg plus 1% lignocaine HCI 0.5mL 1/2 sub- acromial and 1/2 anterior route "into the shoulder joint" weekly for 3 weeks) vs. Maitland's mobilizations 3 times a week for 6 weeks vs. ice therapy (ice packs then proprioceptive neuro-muscular facilitation 3 times a week for 6 weeks; 8 months follow-up.	Average improvement in flexion, abduction, external rotation and total rotation suggest steroid was superior Weeks 1-6, but then no clear superiority of any treatment (graphic data).	"[T]here is little long-term advantage of any of the treatment regimens but that steroid injections may benefit pain and range of movement in the early stages of the condition."	Small sample size in each arm, thus likely underpowered for all but major differences. Low dose of steroid used may underestimate effect of corticosteroid injection. All treated with salicylates.
Hollingworth 1983 RCT	4.5	N = 77 capsulitis (25), tendinitis	Tender or trigger point injection (methylprednisolo ne acetate 2mL,	Success for functional bursal/tendinitis injection 73% vs.	"The method of anatomical injection after diagnosis by the technique of	Data presented by numbers of injections resulting in difficulty interpreting per
(with partial crossover)		(45), bursitis	40mg plus 1% lignocaine) vs.	29%, p <0.001). Adhesive capsulitis	selective tissue tension gave 60%	patient results. Crossover for

		(11), AC joint "strain" [sic]; mean symptoms duration 8.5 months	anatomical injection (e.g., for tendinitis, placement "around, deep, and superficial to the tendon"; 8 weeks follow-up.	success 0% with tender point vs. 6/23 (26.1%) functional.	success compared with the method using tender or trigger point localization, giving 20% success (p <0.001)."	treatment failures. Data suggest targeting presumptive anatomic source of pain, rather than most tender point. Exact location of injections unclear based on description (e.g., unclear if attempted RC injections in the glenohumeral space +/- bursal).
	Man	ipulation und	er Anesthesia (MUA	): with vs. without Glu	ucocorticosteroid Inje	ction
Kivimäki 2001 RCT	4.5	N = 24 frozen shoulder; duration unclear	MUA with vs. without intra- articular glucocorticosteroid injection (betamethasone 6mg plus 4mL lidocaine); 4 months follow-up.	Flexion (pre/1 day/4 months): with steroid (101/148/ 156) vs. without (109/ 157/159). Abduction: with (83/145/147) vs. without (85/144/150).	"Manipulation under anesthesia without intraarticular corticosteroids is recommended as the therapy for frozen shoulder."	Patients not well described. Data suggest corticosteroid as an adjunct is unhelpful.
	1			omparison of Differen		
Tveita 2008 RCT	5.5	the glenohumer al joint compared with the unaffected side, more than 30 degrees and with previous adhesive capsulitis in opposite shoulder.	injection.	Both groups had significant improvement from baseline. At follow-up, 5 patients or 13% in DIL group and 3 patients or 8% in INJ group were taking analgesics on daily basis. Effect of dilatation was a mean improvement of 3 points (CI: -5 to 11) on the Shoulder Pain and Disability Index or SPADI 0–100 scale.	steroid injections alone."	Data suggest no difference between treatments for outcomes measures.
Shin 2013 RCT	4.0	shoulder pain with limitation of both active and passive shoulder movement in at least 2 directions (forward flexion <120° or 50% restriction of	40mg of triamcinolone, 1 mL (n = 49) vs. Group II or IA; glenohumeral joint	Pain relief achieved significantly faster after corticosteroid injection in Groups I, II, and III compared to Group IV. This difference was maintained for up to 16 weeks: $1.4\pm0.5$ in Group I, $1.4\pm0.4$ in Group II, $1.2\pm0.8$ in Group II, $1.2\pm0.8$ in Group III, and $3.1\pm0.5$ in Group IV, p <0.05. At 24 weeks follow- up, pain gradually improved in Group IV; no significant intergroup differences found, p = 0.670; at		Statistical differences in subjective measures and observed between INJX and NSAID. Few differences in functional outcomes between groups. All differences that were statistically significant were only different from NSAID group. Data suggest corticosteroid subjection better than NSAIDS.

		3 months.	aceclofenac 100mg twice daily (n = 49). Follow-up for 24 weeks.	week 16, Group I showed significantly better patient satisfaction for up to 16 weeks. At final follow-up; shoulder motion and all shoulder functiona outcomes recovered significantly improved in all 4 groups, p <0.05.		
Yoon 2013 RCT /Triple- blind /Dose- comparative	8.5	Shoulder N = 53 with shoulder pain; ages 20 and 70 years who had adhesive capsulitis with normal radiograph finding of affected shoulder and restriction of passive motion of greater than 30° in 2 or more planes of movement	Adhesive Capsulitis High-dose group or ultrasound- guided intra- articular injections with 40mg triamcinolone acetonide (n = 20) vs. low-dose group or 20mg triamcinolone acetonide, plus and 1mL 1% lidocaine, 2mL 10mg/mL triamcinolone acetonide and 3mL 1% lidocaine (n = 20) vs. placebo or normal saline group (n = 13). Follow-up at weeks 1, 3, 6,	intra-articular Corti No significant difference between 3 groups in age, sex, duration of shoulder pain, and dominance. Between-group comparisons revealed significant improvement in low- and high- dose groups compared with placebo group, but no significant difference found between low- and high-dose groups.	"We assessed the efficacy of corticosteroid injections according to 2 different doses that are most widely used in intra-articular injections for adhesive"	Small sample size in each treatment area. Data suggest Corticosteroid superior to placebo, however no difference between high and low dose corticosteroid observed.
Bal 2008 RCT	7.0	N = 80 patients with adhesive capsulitis of shoulder	and 12. Group 1, intra- articular 1mL, 40mg methylprednisolo ne acetate, 12 week comprehensive home exercise program (n = 40) vs. Group 2, intra-articular 1mL serum physiologic (0.9% sodium chloride), 12 week comprehensive home exercise program (n = 40). Follow up: baseline, 2 and 12 weeks	Mean (IQR) for night pain: baseline vs. 2nd week: Group 1: night pain: 77.5 (20.0) vs. 30.0 (50.0), p <0.001. flexion: 137.5 (30.0) vs. 160.0 (38.7), p <0.001; abduction: 107.5 (41.2) vs. 137.5 (60.0); internal rotation: 55.0 (25.0) vs. 80.0 (30.0), p <0.001; external rotation: 50.0 (31.2) vs. 75.0 (45), p <0.001; baseline vs. 12th week: night pain: 50.0 (31.2) vs. 7.5 (30.0), p <0.001;	"Intraarticular corticosteroids have the additive effect of providing rapid pain relief, mainly in the first weeks of the exercise treatment period. In patients with adhesive capsulitis who have pain symptom predominantly, intraarticular corticosteroid therapy could be advised concomitantly with exercise."	No statistically significant differences between groups. High dropout in placebo arm.

				1	1	
Lee 2009	5.5	N = 43 patients	Ultrasound- Guided (US)	flexion: 137.5 (30.0) vs. 180.0 (16.2), $p < 0.001$ ; abduction: 107.5 (41.2) vs. 180.0 (22.5), $p < 0.001$ ; internal rotation: 55.0 (25.0) vs. 90.0 (15.0), $p < 0.001$ ; external rotation: 50.0 (31.2) vs. 90.0 (20.0). Group 2: baseline vs. 2nd week: night pain: 70.0 (40.0) vs. 50.0 (38.7), $p < 0.001$ ; flexion: 130.0 (27.5) vs. 150.0 (37.5), $p < 0.05$ ; abduction: 90.0 (27.5) vs. 110.0 (46.2), $p < 0.05$ ; external rotation: 40.0 (17.5) vs. 50.0 (18.7), $p < 0.05$ ; baseline vs. 12th week: night pain: 70.0 (40.0) vs. 12.5 (50.0), $p < 0.001$ ; flexion: 130.0 (27.5) vs. 165.0 (27.5), $p < 0.001$ ; flexion: 130.0 (27.5), $p < 0.001$ ; flexion: 90.0 (27.5), $p < 0.001$ ; internal rotation: 47.5 (10.0) vs. 90.0 (30.0), $p < 0.001$ ; internal rotation: 47.5 (vs. 70.0 (37.5), $p < 0.001$ ; both groups evaluated before	"We found that for intra-articular	No statistical difference at 6 weeks.
Lee 2009 RCT	5.5					

			with 1.5mL of 2% lidocaine and 3mL of normal saline in the first	VAS: US group – Before: 5.4 + 0.5; Week 6: 0.9 + 0.3; Blind group –		
			week. This was followed by a 2.5mL injection of sodium hyaluronate (25mg) once weekly for 5 weeks.	Before: $6.0 + 0.4$ ; Week 6: $0.9 + 0.3$ . US group has greater VAS improvement at week 1 and 2 for both daytime and before sleep (p < 0.01).		
				For total functional scores, US group had significant improvement from week 1 onward compared to baseline, and Blind group from week 2 onward (p = 0.003). Total Function Scores: US group – Before: 27.3+2.7; Wk 6: 38.0+2.1; Blind group – Before: 26.7+1.8; Week 6: 37.1+2.1. US group had greater significant improvement than Blind at week 1, 2, and 3 (p <0.005).		
Roh 2012	4.0	Shoulder Adh N = 45	esive Capsulitis: Di Diabetic	abetic Corticosteroi Mean score for	d vs. Non-corticosteroi "A corticosteroid	d No statistically
RCT		patients with adhesive capsulitis of the shoulder	corticosteroid group, 40mg triamcinolone acetonide with 3mL 2% lidocaine (n = 23) vs. non- corticosteroid group (n = 22). Both groups instructed to participate in home exercising	VAS Pain score: diabetic corticosteroid group vs. non- corticosteroid group: 4 weeks: 4.5 vs. 5.0, p = 0.020. Range of Motion: corticosteroid group vs. non- corticosteroid	injection in diabetic patients decreases the pain perception and accelerates the functional recovery in the early post- injection period. An intra-articularm corticosteroid injection is considered a viable option for the	significant differences between groups @most time points.
			program by a physical therapist; forward elevation, external and internal rotation, and cross-body adduction. Follow-up: baseline, 4, 12, and 24 weeks.	group: forward elevation: 12 weeks: 105 vs. 100, p <0.05; internal rotation: 5.5 vs. 5.0, p <0.05.	treatment for adhesive capsulitis with diabetes." Hyaluronic Injections	

	with	corticosteroid	passive ROM	with IA hyaluronic	treatment arms are
RCT	adhesive	injections every 2	were improved at	acid injection was	comparable
	capsulitis	weeks for a total	2 and 6 weeks in	shown to be a	suggesting no
	of	of 3 times (n =	both groups.	treatment method as	difference between
	shoulder	50) vs. Group B	-	effective as the	Triamcinolone and
		received	Statistical	steroid injection alone	Hyaluronic for these
		hyaluronic acid	differences not	in pain relief and	outcomes.
		injections and	observed in	functional	
		capsular	SPADI and VNS	improvement;	
		distension every	between groups (p	additionally, it was	
		2 weeks for total	<0.05), and	more effective in	
		of 3 times	shoulder passive	passive external	
		(n = 50).	external/rotation	rotation improvement	
			more improved in	than steroid injection	
		Follow-up at 2	Group B than	alone."	
		and 6 weeks.	Group A, p <0.05.		

## SUPRASCAPULAR NERVE BLOCKS

Suprascapular nerve blocks have been used to treat adhesive capsulitis. (Dahan 00)

Recommendation: Suprascapular Nerve Blocks for Treatment of Adhesive Capsulitis

Suprascapular nerve blocks are recommended for treatment of adhesive capsulitis.

*Indications* – Adhesive capsulitis, moderate or severe cases; failure of adequate response with NSAID, exercises and injection(s).

*Frequency/Duration* – One block recommended and results assessed. Patients should be given exercises to perform. (Dahan 00) A second block recommended if there is a partial, but inadequate response to initial block.

Dose – The quality trial utilized bupivacaine 0.5%, 10mL.

*Indications for Discontinuation* – Recovery, plateau in recovery, intolerance, non-compliance with exercise program.

## Strength of Evidence – Recommended, Evidence (C)

#### Rationale for Recommendation

One moderate-quality trial suggests suprascapular nerve block efficacy compared with a placebo block for treatment of adhesive capsulitis. (Dahan 00) Nerve blocks are invasive, have adverse effects, and are of moderate cost; however, a block is recommended for select patients.

There is 1 n				· · · · · · · · · · · · · · · · · · ·	O an alwalan	0
Author/Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
			NSAID vs. Glucoco	rticosteroid Injection		JI.
Dahan	7.5	N = 34	Series of 3 (7 days	No difference	"The use of	Some baseline
2000		frozen shoulder,	between) modified indirect	between groups for VAS scores at 1	bupivacaine suprascapular	differences of uncertain
RCT		pain at least 1 month duration; mean 1 year	suprascapular nerve blocks with bupivacaine 0.5% 10mL vs. saline 10mL. All taught HEP with ROM exercises BID.	month. Treatment group with higher percentage of improvement at 1 month (25% vs. 75%, p = 0.008).	nerve blocks was effective in reducing the pain of frozen shoulder at one month."	significance. High dropouts in placebo. Data suggest block superior to saline.

Evidence for Suprascapular Nerve Blocks for Adhesive Capsulitis

# **HYDRODILATATION**

Hydrodilatation, also known as distension arthrography, involves an injection into the glenohumeral joint under pressure and has been utilized to treat adhesive capsulitis with the intent to rupture contractures. (Quraishi 07; Buchbinder 08; Andren 65; Hamdan 03; Bell 03; Fareed 89; van Royen 96) An open trial with arthrographic distension also documented capsular tears, bursal ruptures, and ruptured distal bicipital sheaths (the

latter were not associated with pain relief). (Rizk 94) Hydrodilatation has been performed and accomplished variously as an isolated intervention, (Fareed 89; Hsu 91; Jacobs 91; Gam 98) accompanied by arthrography, (Morency 89; Wybier 97; Mulcahy 94) or accompanied by manipulation under anesthesia, (van Royen 96) as well as with arthroscopy. (Andren 65; Bell 03; Rizk 94; Corbeil 92; Hsu 91)

#### Recommendation: Hydrodilatation for Treatment of Adhesive Capsulitis in Select Patients Hydrodilatation is recommended for treatment of adhesive capsulitis in select patients.

*Indications* – Adhesive capsulitis, especially moderate to severely affected patients with pain and loss of motion who do not respond sufficiently to NSAIDs, exercises, and/or injection(s). (Loew 05)

## Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendation

Hydrodilatation has been evaluated in moderate-quality trials, with and without arthrography, usually with steroid instillation. One moderate-quality trial suggests hydrodilatation was ineffective compared with a sham, (Buchbinder 07) and has been interpreted as suggesting the natural course is towards resolution. A moderate-quality trial found distension without arthrography superior to glucocorticosteroid injection. (Gam 98) Another moderate-quality trial suggested arthrographic distension was superior to physiotherapy alone. (Khan 05) On balance, these studies somewhat conflict, but overall appear to suggest that hydrodilatation may be effective. Hydrodilatation is invasive, has adverse effects, and is moderate to high cost. However, it is recommended for select patients in whom less invasive treatments, including injections, have failed to provide sufficient treatment.

## Evidence for Hydrodilatation for Adhesive Capsulitis

There are 2 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality comparative clinical trial/RCT in Appendix 2.

Author/Title Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Buchbinder 2007 RCT	7.5	N = 144 adhesive capsulitis for at least 3 months	All arthrographic glenohumeral joint distension, then manual therapy/directed exercise (passive and active stretching, cervical and thoracic spine mobilization, strength and coordination of RC and scapular stabilizers and proprioceptive challenge) vs. sham ultrasound plus non- therapeutic gel (placebo). All treatments 2 times a week for 2 weeks, then once a week for 4 weeks, then HEP; 6 month follow-up.	SPADI (6/12/26 weeks): physiotherapy ( $38.0\pm20.4/41.4\pm20.9/4$ $0.0\pm21.8$ ) vs. placebo ( $38.5\pm23.5/39.3\pm22.0/4$ $2.4\pm22.8$ ), p = 0.84, p = 0.30, p = 0.62. No differences in high pain, pain with use, or any functional measure such as quality of life or SF36. Superior ranges of motion in physiotherapy group that trended to lack of significance at 6 months.	"We found no additional benefits of an active physiotherapy program consisting of manual techniques and directed exercises for adhesive capsulitis compared with arthrographic joint distension with saline and steroids alone in terms of pain, function, or quality of life."	Some baseline differences (prior injection 45.3% PT vs. 31.1% placebo). Active treatment group provided HEP, presumably biasing in favor of physiotherapy. Data suggest physiotherapy provides limited, short-term benefit above hydrodistension using saline and steroids.
Gam 1998 RCT	6.0	N = 22 frozen shoulder with mean durations 4.5 and 5 months	Triamcinolone hexacetonide 20mg alone vs. distension with 19mL lidocaine 0.5% plus steroid, 1 treatment a week for 6 weeks; 12 weeks follow- up.	Graphic data presented. Data suggest no differences in pain ratings. VAS function favored distension from Week 8 on. Analgesic use lower at Week 11, p = 0.03. Physician's impression also favored distension.	"[D]istension with steroid can seem to help in management of "Frozen Shoulder."	Claims envelope method of allocation, but 12 received distension, 8 injection. Regimens unusually invasive.

# SURGICAL CONSIDERATIONS

## ARTHROSCOPY

Arthroscopy for diagnostic purposes, (Binder 84; Bulgen 78; Corbeil 92; Bradley 91; Harryman 97; Uitvlugt 93; Ha'eri 81; Andersen 98) as well as to release contractures associated with the disorder and/or manipulation under anesthesia, has been used to evaluate and treat patients with adhesive capsulitis. (Loew 05; Quraishi 07; Chambler 03; Ogilvie-Harris 95, 97; Pollock 94; Wiley 91; Beaufils 99; Bennett 00; Bradley 91; Pearsall 99, 00; Warner 96; Watson 00; Ozaki 96) Arthroscopy has also been combined with hydrodistension. (Hsu 91; Noël 00; Mulcahy 94)

#### Recommendation: Arthroscopy for Treatment of Adhesive Capsulitis Arthroscopy is recommended to treat select cases of adhesive capsulitis.

*Indications* – Adhesive capsulitis, especially moderate to severely affected patients with pain and loss of motion who do not respond sufficiently to NSAIDs, injection(s), and potentially to hydrodilatation or MUA and in whom there is believed to be a remediable, intra-articular or periarticular defect. (Loew 05; Andersen 96, 98; Pollock 94; Uitvlugt 93; Wiley 91; Ogilvie-Harris 95)

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials evaluating the use of arthroscopy alone to treat adhesive capsulitis. Arthroscopy is invasive, has adverse effects, and is high cost. For adhesive capsulitis patients in whom there is believed to be a remediable defect, arthroscopy is recommended if less invasive treatments are unable to sufficiently resolve the disorder, or in whom there are concerns about a resolvable intraarticular process that may be contributing to the reduction in ROM, such as rotator cuff tendinopathy or SLAP tears.

# Evidence for the Use of Arthroscopy for Adhesive Capsulitis

There is 1 low-quality comparative clinical trial in Appendix 2.

## **OPEN RELEASE SURGERY**

Open release of contractures has been used to treat patients with adhesive capsulitis. (Omari 01) Analgesia has included general as well as continuous epidural anesthesia. Continuous epidural analgesia with opioids has been used for treatment of patients after surgery for adhesive capsulitis and has been reported to have favorable effects in a small case series. (Narouze 09) A large (n = 76) retrospective case series of regional and general anesthetic techniques found interscalene anesthesia to be effective and have a low complication rate. (Tetzlaff 94) However, others have found high complication rates.

# Recommendation: Open Release of Contractures for Select Patients with Adhesive Capsulitis **Open release surgery is recommended for select patients with adhesive capsulitis.**

*Indications* – Adhesive capsulitis, especially moderate to severely affected patients with pain and loss of motion who do not respond sufficiently to NSAIDs, injection(s), hydrodilatation, MUA and particularly if there is another coexistent disorder that is felt to require open surgical procedure(s) to resolve. (Loew 05)

## Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials of open release of contractures from adhesive capsulitis. Open surgical procedures are invasive, have adverse effects, and are high cost. They may be indicated for limited use in adhesive capsulitis patients, mostly in whom there is believed to be a resolvable process that can be addressed through an open procedure (e.g., rotator cuff tear). Thus, they are indicated for limited purposes.

# **OSTEONECROSIS**

Osteonecrosis of the humerus is considerably less common than involvement of the femoral head (Harreld 09) (the following is an abbreviated discussion of osteonecrosis –Osteonecrosis, or avascular necrosis, is a complex pathological process involving increased bone marrow pressure and ischemia with loss of vascular supply to the bone with subsequent bone death initiated by vascular occlusion. (Ficat 85; Woodhouse 64; Rosingh 69; Harreld 09; Sarris 04) It tends to occur in areas of the body with more tenuous blood supply, including the heads of the femur, humerus, and other ends of long bones, although it can occur in any bone. (Hattrup 99; Jones 94) If the process advances, the bone collapses. (Volokh 06) Some cases are considered occupational disorders, particularly in the setting of dysbarism (atmospheric compression, decompression) workers including divers and others in compressed air atmospheres who experience impaired blood supply to the femur due to nitrogen gas in the blood during excessively rapid decompression. Major trauma is another reported cause. (Ficat 85; Harreld JAmAcadOrthSurg 09; Jacobs 78) Thus, if a humeral fracture is occupational, a subsequent case of osteonecrosis arising out of that humeral fracture is usually considered occupational. Whether or not stereotypical forceful use of the joint is a risk is speculative. The greatest risk for osteonecrosis of the humerus is believed to be glucocorticosteroid USE (Harreld JAmAcadOrthSurg 09; Cruess 76; Usher 95; Loebenberg 99; Nixon 83; Pritchett 01; Mankin 92; Mont 95; Cruess 85; Valencia 03; Jones 03; Jacobs 78) or endogenous excess. (Jones 03) And, similar to the hip, other risk factors appear to include diabetes mellitus, arteriovascular disease, (Chang 93; Nixon 83; Ficat 85) hyperlipidemia, sickle cell anemia, (Mont 95; Chung 71) coagulopathies, (Jones 03) Gaucher's disease, (Nixon 83; Ficat 85; Mankin 92; Mont 95) HIV, (Glesby 03; Valencia 03) post-irradiation, (Nixon 83; Ficat 85; Mont 95) alcoholism, (Chang 93; Nixon 83; Ficat 85; Mont 95; Valencia 03; Jones 03) and smoking. (Chang 93; Nixon 83; Ficat 85; Jones 03; Pritchett 01; Mankin 92; Glesby 03; Mont 95; Valencia 03) Many cases are idiopathic; (Ficat 85; Babis 04) genetic factors are also believed to be important. (Harreld JAmAcadOrthSurg 09) Although somewhat less clear in the shoulder, alcoholism is often the predominant cause of osteonecrosis in the hip. (Koo 95; Wang 05)

In osteonecrosis, there appears to be a clinically silent, pre-clinical state (most frequently identified in the asymptomatic hip) (Hungerford 79; Ficat 85) that when found first in the shoulder is often present elsewhere, such as in the hips or knees. (Harreld 09; Cruess 85; LaPorte 98) Patients present with either acute or insidious onset of persistent shoulder pain worsened by overhead use. (Ficat 85) Pain is often worse at night and might be somewhat worse with activity. Reduced shoulder ROM can occur and will nearly always be present if there is bony collapse. Pain and ROM worsen as the degree of impairment progresses. (Ficat 85; Harreld 09) The disease is likely, not invariably, progressive – in the hip there appears to be potential for recovery at any of the early stages; (Ficat 85) the same is thought to be true for the humerus. (Harreld 09)

## **WORK ACTIVITIES**

As previously noted, some cases of osteonecrosis are considered occupational disorders. Workers at risk include divers and others in compressed air atmospheres who experience impaired blood supply to the bone due to nitrogen gas in the blood during excessively rapid decompression. Reducing or eliminating activities that significantly provoke symptoms including avoidance of dysbaric exposures is recommended. Major trauma, such as a humeral fracture, is another reported cause of osteonecrosis. (Ficat 85; Harreld J Am Acad Orthop Surg 09; Jacobs 78) There is no quality evidence regarding reducing forceful use, though limitations are sometimes instituted for months, therefore, there is no recommendation for or against reducing forceful use in the workplace.

## **INITIAL CARE**

The focus on early treatment of osteonecrosis is to identify and treat reversible risk factors. Control of diabetes mellitus, elimination or reductions in glucocorticosteroid use, and elimination of alcohol and

tobacco products are all recommended at the time the diagnosis is considered. As there is evidence that statins reduce risk, (Pritchett 01) the composite data suggest aggressive targeting of all coronary artery disease risk factors is recommended.

## **MEDICATIONS**

Over-the-counter medications may help manage pain associated with osteonecrosis. Bisphosphonates have been used to prevent bone loss in the hip (this is believed to be analogous to the shoulder). Other medications include glucosamine, chondroitin, methylsulfonylmethane, and topical agents such as capsaicin.

1. Recommendation: Bisphosphonates to Treat Osteonecrosis Bisphosphonates are recommended to treat osteonecrosis

Strength of Evidence – Recommended, Insufficient Evidence (I)

- 2. Recommendation: NSAIDs for Pain Management of Osteonecrosis NSAIDs are recommended for pain management of osteonecrosis. Strength of Evidence – Recommended, Insufficient Evidence (I)
- Recommendation: Glucocorticoids (including Injections) for Treatment of Osteonecrosis Glucocorticoids (including injections) are not recommended for treatment of osteonecrosis. Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

There are no quality studies evaluating treatments for osteonecrosis of the humerus. Thus, where available, guidance is drawn from analogy to hip trials. Bisphosphonates have been evaluated in one quality study of the hip. Results suggest large differences between bisphosphonates versus no treatment, (Lai 05; Cardozo 08) thus bisphosphonates are recommended for shoulder treatment. Other treatments have included watchful waiting and nonsteroidal anti-inflammatory medications. Glucocorticosteroids, including by injection, are not recommended in early disease stages as there is evidence that systemic glucocorticoid exposure increases risk for the disorder, but there may be indications in selected patients with more advanced disease.

# PHYSICAL METHODS HYPERBARIC OXYGEN

Hyperbaric oxygen has been used for treatment of osteonecrosis of the jaw and hip. (Shimura 06)

#### Recommendation: Hyperbaric Oxygen for Treatment of Osteonecrosis There is no recommendation for or against the use of hyperbaric oxygen for the treatment of osteonecrosis.

## Strength of Evidence – No Recommendation, Insufficient Evidence (I)

## Rationale for Recommendations

There are no quality studies evaluating hyperbaric oxygen therapy for humeral osteonecrosis treatment. Hyperbaric oxygen has been used to treat osteonecrosis of the jaw, (Shimura 06) but a study following pediatric hip osteonecrosis from chemotherapeutics found no improvements with hyperbaric oxygen, thus, there is no recommendation for or against its use.

# SURGICAL CONSIDERATIONS

There are multiple surgical procedures that have been used for treatment of osteonecrosis including core decompression similar to that for the hip, (Harreld JAmAcadOrthoSurg 09; Harreld AmJOrtho 09; Hungerford 79; Kim 04; Marker 08; Mont 04; Mont 93; Hardy 00; Shannon 04; Castro 00; Learmonth 90; Scully 98) arthroscopy with or without core decompression, (Chapman 04; Dines 07; Hardy 00; Hayes 89) vascularized and devascularized bone grafting, (Scully 98; Aldridge 07; Nakagawa 99; Rindell 87; Yajima 98; Seyler 08) humeral head resurfacing, (Parsch 03; Mansat 05; Orfaly 07; Cruess 78; Lau 07; Levy 01; Scalise 07;Barnes 91; Adili 03) and arthroplasties. (Parsch 03; Mansat 05; Orfaly 07; Cruess 78; Lau 07; Levy 01;

scalise 07) Electrical stimulation is also used on the hip, although there are no quality studies of the procedure. (Aaron 91)

Core decompression with or without bone grafts is the surgical procedure that has been utilized most frequently to treat osteonecrosis of either the hip or humerus. (Harreld AmJOrtho 09; Steinberg 01; Ficat 85; Warner 87; Rijnen 03; Stulberg 91; Castro 00) The primary purpose of the procedure is to relieve the elevated intramedullary pressure that stagnates microvascular circulation. (Ficat 85; Harreld Am J Orthop 09)

- 1. Recommendation: Core Decompression for Treatment of Osteonecrosis Core decompression is recommended for treatment of osteonecrosis. Strength of Evidence – Recommended, Insufficient Evidence (I)
- 2. Recommendation: Arthroplasty for Treatment of Osteonecrosis Arthroplasty is recommended for treatment of osteonecrosis.

Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

There are no studies evaluating core decompression for osteonecrosis of the shoulder. Two adult hip studies of moderate quality were found, (Stulberg 91; Koo 95) but these studies conflict. (Castro 00) In a hip case series, results were good in 94% of Stage I, and 82% in Stage II; however, a case series cannot prove superior results with earlier treatment as results may mislead through spectrum and other biases. Although the two quality studies of a coring procedure conflict, core decompression is recommended when other methods of pain control are ineffective. Arthroplasty is the most common treatment for humeral head collapse. Early case series reported high revision rates that have declined recently to approximately 6%. (Harreld JAmAcadOrtho Surg 09) Arthroplasty is recommended to treat osteonecrosis as the prognosis appears to be reasonably good in the available studies.

# **BRACHIAL PLEXUS INJURIES**

Brachial plexopathies have many causes including motor vehicle accidents, sporting activities (especially football), bicycle accidents, industrial accidents, falls from heights, objects falling on a shoulder, sequelae of fractures, birth palsies, use of backpacks (Rucksack paralysis), autoimmune neuropathies, infections, space occupying vascular lesions, hematomas from axillary artery punctures and procedures, sequelae of orthopedic shoulder or chest procedures, and primary tumors, metastases and post-radiation. (Allieu 88; Azze 94; Blaauw 08; Wittenberg 00; Miller 00; Wilbourn 07; Castagno 87; Dart 70; McLoud 89; Levin 98; Heelan 89; Bowen 96; Hems 99; Doi 02; Brandt 93; Brunelli 85; Doi 99, 00) Brachial plexus injuries from trauma in the context of work are occupational. (Midha 97; Wilbourn 07) Moderate to severe brachial plexus injuries previously had poor prognoses and amputation was sometimes performed. (Fletcher 69) More recent results are considerably more promising. Only injuries will be reviewed in this section. Thoracic outlet syndrome is addressed separately in Appendix 1.

Brachial plexus injuries are quite heterogenous, ranging from mild "burner" or "stinger" symptoms from football injuries (Safran 04) to complete avulsions of nerve roots. (Shin 05) Depending on the degree of axonal damage, the prognoses vary from excellent to poor. (Shin 05) These injuries have been divided into supraclavicular and infraclavicular injuries based on the main location of the injury as proximal or distal to nerve branches, (Wilbourn 07) with the supraclavicular thought to be more severe and more painful. (Midha 97) Case series suggest most of these injuries occur in young males involved in motor vehicle accidents. (Midha 97; Narakas 85) They are frequently accompanied by other injuries including concussions, other head trauma, rib fractures, shoulder girdle fractures, shoulder dislocations, humeral fractures, cervical spine injuries, and internal thoracic injuries, suggesting an associated death rate of 3.7% for those presenting to a regional trauma facility; (Midha 97) many additional mild or isolated cases are not treated in trauma facilities.

## SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS

Clinical suspicion leading to a careful history and focused physical examination is usually diagnostic. (Shin 05; Wilbourn 07) Weakness is present, sometimes with pain. (Wilbourn 07) Evaluating traumatic cases often involves x-ray to screen for fractures, potentially including the humerus, clavicle, scapula, cervical spine, and chest. (Shin 05; Wilbourn 07) Computerized tomography, sometimes with myelography, may be helpful in select cases for imaging the spine. (Shin 05) However, MRI is generally the imaging procedure of choice after fractures have been ruled out or if additional studies are necessary. (Sureka 09; Wilbourn 07; Bowen 04; Rapoport 88; Yoshikawa 06; Shin 05) Electrodiagnostic studies are thought to be confirmatory in moderate to severely affected patients when performed at least 3 to 4 weeks after the injury to allow sufficient time for Wallerian degeneration (Wilbourn 07; Shin 05); electrodiagnostics are also used for intraoperative assessments. (Shin 05)

Recommendation: X-ray to Diagnose Brachial Plexopathies
 X-ray is recommended to screen for fracture of the humerus, clavicle, scapula, cervical spine, and/or chest in patients with brachial plexus injuries.

Strength of Evidence – Recommended, Insufficient Evidence (I)

 Recommendation: MRI to Diagnose Brachial Plexopathies MRI is recommended to diagnose brachial plexopathies.
 Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

There are no quality trials on treatment of brachial plexopathies and the disparate nature of the injuries requires an individualized approach, particularly for the more severe cases.

# **MEDICATIONS**

Mild cases of brachial plexopathy, such as mild football traction injuries, have an excellent prognosis with non-operative treatment. (Wilbourn 07; Shin 05; Safran 04) Provided the extent of axonal damage is minimal, non-operative treatment has been recommended. (Shin 05; Wilbourn 07) In the absence of quality evidence, these mild injuries should be treated as neuropathic pain (see recommendations in the Chronic Pain Guidelines). Briefly, recommended medications include NSAIDs (Evidence C); concomitant use of cytoprotective agents in patients with a high risk factor profile who also have indications for NSAIDs (Evidence C); acetaminophen particularly if NSAIDs are contraindicated (Evidence C); tricyclic anti-depressants (Evidence C); carbamazepine as a potential adjunct as a 4th- or 5th-line treatment for neuropathic pain (Evidence C); carbamazepine as a potential adjunct as a fourth- or fifth-line treatment (Evidence I); gabapentin and pregabalin (Evidence A); dextromethorphan for select patients (Evidence C); muscle relaxants for brief use as a 2nd- or 3rd- line agent in acute exacerbations (Evidence I); and opioids for select patients (Evidence I).

# PHYSICAL AND OTHER METHODS

As noted above, in the absence of quality evidence, it is recommended that brachial plexopathies be treated as neuropathic pain and managed according to the recommendations in the Chronic Pain Guideline. Briefly, these recommendations include altering of sleep posture to determine if there is a reduction in pain or other symptoms (Evidence I); aerobic exercise (Evidence A); trial of aquatic therapy for patients who meet referral criteria for supervised exercise therapy and have co-morbidities that preclude effective participation in a weight-bearing physical activity (Evidence I); self-application of low-tech heat therapy (Evidence I); transcutaneous electrical nerve stimulation (TENS) as an adjunct for more efficacious treatments (Evidence C); psychological evaluation as part of evaluation and management of patients with chronic pain in order to assess whether psychological factors will need to be considered and treated as part of treatment plan (Evidence I); cognitive-behavioral therapy as an adjunct to an interdisciplinary program for the treatment of chronic pain (Evidence C); multidisciplinary or interdisciplinary pain rehabilitation program with a focus on behavioral or cognitive-behavioral approaches combined with conditioning exercise for patients with chronic pain who demonstrate partial

or total work incapacity due to pain (Evidence I); and work conditioning, work hardening, and early intervention programs (Evidence I).

## SURGICAL CONSIDERATIONS

Immediate surgery has been recommended for patients who sustain penetrating trauma. (Shin 05) Delayed surgical exploration for non-penetrating trauma cases that fail to resolve sufficiently at 3 to 6 months has also been recommended. (Shin 05; Wilbourn 07) Extensive physical or occupational therapy is recommended for treating cases with limited debility. Some cases are severe and may require surgical exploration and reconstructions. (Midha 97) Techniques have evolved over time (Hendry 49; Yeoman 61; Fletcher 69) to include neurolysis, (Kim 03) nerve grafting, (Kim 03) nerve transfer (neurotization), (Teboul 04; Gu 96, 98; Chuang 95; Songcharoen 96, 01; Merrell 01) and free muscle transfer. (Ruch 95; Mikami 97; Chuang 92; Akasaka 91; Doi 96,97a,97b,95,93; Manktelow 84; Chung 96) Evidence-based guidance on surgical approaches and techniques is not possible at this time as there is a combination of wide array of injuries with a lack of quality trials. Post-operative extensive rehabilitation generally is required.

## TRIGGER POINTS/MYOFASCIAL PAIN

"Tender points" is a term used to characterize unusually tender areas of muscle, tendon, or over boney prominences that reproduce the patient's pain when palpated. (Lucas Clin J Pain 09; Gerwin 05; Myburgh APMR 08; Nice APMR 92; Levoska Clin J Pain 93; Njoo 94; Gerwin 97) Trigger points include those points with tenderness, "knots" of muscle or overlying connective tissue, reproduction of the patient's pain when palpated, and elicitation of symptoms distally during palpation. (Gerwin 05; Myburgh 08; Hwang Pain 05; Farasyn 07) As the diagnostic entity heavily relies upon subjective complaints without purely objective findings, the existence of this condition has been questioned. (Simons AJPM 08; Wheeler Drugs 04; Pearce Eur Neurol 04) Work-relatedness of the condition is controversial with an absence of quality data.

There are lower quality studies of prevalence or incidence. Lifetime prevalence has been estimated at up to 85%. (Fleckenstein BMC Musculo 10) A survey of pain practitioners estimated a point prevalence of 46.1±27.4%. (Fleckenstein 10) A cross-sectional study of 9,952 patients found 345 (3.5%) with widespread pain, 4.5% with widespread allodynia, and 2.5% with fibromyalgia. (Cöster Eur J Pain 08)

Patients with muscle tenderness are often given the diagnosis of "myofascial pain." This terminology was initially developed to characterize patients presenting with muscle tenderness accompanied by trigger points, "taut bands," subtle shortening and weakness of involved muscles, referred symptoms on compression or needling, and postural abnormalities, which were hypothesized as reflective of microtrauma and the generation of excessive force per muscle fiber leading to hypoxia, acidosis, and metabolic depletion. However, multiple aspects of this construct have been disproven, thus it is now controversial, particularly as it has become increasingly clear that the development of prolonged and disabling muscular pain is often linked to the presence of underlying psychosocial issues that foster inactivity and dependence on palliative modalities and pharmacologic interventions. (Friedrich Phys Ther 09; Giannakopoulos JDent 10; Coster 08; Wheeler 04; Mongini Pain 07; Velly Pain 03; AltindagPainMed 08) Hence, in the absence of a clear objective anatomic abnormality to differentiate between patients with various forms of muscle pathology, they will be characterized by the descriptive diagnosis of "trigger points."

Most RCTs reviewed herein and in the fibromyalgia appendix of the Chronic Pain Guidelines have not distinguished between tender and trigger points. However, these studies frequently note pain limited to a body region, suggestive of trigger points/myofascial pain. Most RCTs of fibromyalgia have cited adherence to the American College of Rheumatology case definition, which requires widespread tender points (11 of 18 anatomically defined points).(Wolfe 90) Quality literature shows that the presentation, risk factors, and management of patients with fibromyalgia differs markedly from other patients with chronic

pain.<sup>xxvi</sup> Treatment of this condition has primarily involved active exercise and medications. Judicious use of injections and acupuncture has also been widely used (see Appendix, Chronic Pain Guidelines).

# PHYSICAL EXAMINATION

The physical examination of a patient with trigger points is typically normal other than for muscle tenderness (and frequent evidence of depression, dysthymia or other affective disorders in fibromyalgia). (Wheeler 04; Yap 07) Myofascial pain-related tenderness should be isolated to the body part affected by pain and not be widespread as with fibromyalgia. It also should generally not cross the midline if there was an inciting event to one side of the body. Trigger Points/myofascial pain most commonly involves the periscapular muscles on one side of the body. This condition may be indistinguishable from "muscle tension syndrome." Most patients have an apparent "knot" or tender point in the muscle. That tenderness is perceived as unusually tender to palpation compared with surrounding tissue, as well as compared with other patients' perceptions. Trigger points require the elicitation of distal symptoms in addition to usually being painful on palpation. The amount of palpatory force used to elicit pain complaints is unclear. The most widely used criteria have been 4kg of force, which is also the same criteria for fibromyalgia. (Wolfe 90) A physical examination of a patient with muscle tenderness also requires palpating other structures that are not involved in the complaints to ascertain the distribution and character of potential tender points and trigger points. Diffuse pain complaints, while needing to be clinically addressed, may be reflective of a chronic pain syndrome and do not require a diagnostic label of myofascial pain or fibromyalgia. There may be some limitation of ROM, but in general, while active ROM to an extreme may elicit or augment the patient's pain, the final extent is usually nearly or completely normal.

# WORK-RELATEDNESS

Work-relatedness of trigger points/myofascial pain is controversial as there are no quality epidemiological studies demonstrating a relationship to work. There is epidemiological evidence that certain cases of muscle tension syndrome may be occupational and that disorder may be related to myofascial pain. However, the quality of the studies reported has been suboptimal and true risk factors are not well defined. (Rudolph 97) There is less controversy about work-relatedness of trigger points/myofascial pain when the disorder arises in a body part subject to a clear occupational injury. In practice, a fair number of these cases are determined to be occupational (especially if there is an inciting event, no prior history, and the pain and signs are limited to one body region and not bilateral or disseminated), although supportive epidemiological evidence may be lacking. There is no quality epidemiological evidence that tender points/fibromyalgia (or the closely related condition of chronic widespread pain) are occupational conditions (see Appendix 2 in Chronic Pain Guidelines).

# SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS DIAGNOSTIC CRITERIA

Diagnostic testing is generally not required for myofascial pain patients. Occasionally, testing for rheumatological disorders is indicated. This may include erythrocyte sedimentation rate, sedimentation rate, C-reactive protein, anti-rheumatoid factor, anti-nuclear antibodies, anti-Sm, anti-Ro, anti-La for rheumatoid arthritis, lupus, Sjogren's, and evaluation for mixed connective tissue disorder.

Probable Diagnosis or Injury	Symptoms	Signs	Tests and Results
Trigger Points/	Non-radiating, usually	Muscle taut band or knot with	None

## Table 11. Diagnostic Criteria for Non-red-Flag Conditions

<sup>&</sup>lt;sup>xxvi</sup>There are RCTs of temporomandibular joint syndrome and facial pain that are classified as addressing myofascial pain syndrome. (Anderson 91; Rubinoff 87; Raustia 86; Magnusson 99; deLaat 03; Dahlstrom 85; Turk 93; Monteiro 88; Okeson 83; Dao 94; Winocur 02) However, as these condition(s) is (are) not considered occupational, they are not reviewed in detail.

peris unila	riscapular (generally		Occasionally, rheumatological testing is helpful to demonstrate an alternative disorder.
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Adapted from AMA Guides to Impairment Rating, 6<sup>th</sup> edition and Sanders et al. Evidence-based clinical practice guidelines for interdisciplinary rehabilitation of chronic nonmalignant pain syndrome patients. *Pain Prac.* 2005; 5(4), 303-15.

# **ACTIVITIES AND ACTIVITY ALTERATION**

Patients with myofascial pain/trigger points should be maintained as physically active as possible. Patients with limited activity levels require advancement of activity levels and education as inactivity is detrimental despite the temporary relief of symptoms that may accompany it.

# WORK ACTIVITIES

There is no evidence that activity limitations are beneficial for myofascial pain patients. It is recommended that patients be maintained at the maximal levels of activity. Those with limitations are recommended to have their limitations gradually reduced.

		Recommended Target for Disability Duration*		
Disorder	Activity Modifications and Accommodation	Modified Duty Available	Modified Duty Not Available	
Trigger points and Myofascial Pain Syndrome	Ideally no limitations. May need graded increase in activity levels to regain normal function if significantly debilitated.	Activity limitations should be avoided. If debility: Mild 0 days Moderate 0-7 days Severe 7-14 days	Activity limitations should be avoided. If debility: Mild 0-3 days Moderate 3-7 days Severe 7-21 days	

Table 12. Guidelines for Modification of Work Activities and Disability Duration
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\*Mild, Moderate, and Severe are defined by the degree to which the condition affects activities of daily living; e.g., mild involves little to no impairment in the impact on the patient's ability to perform ADLs, while severe involves marked impairment in the ability to perform ADLs. The physician should make these determinations based on the presumed impairment specifically due to the underlying condition, noting that reported limitations in ADL are often a function of psychological and occupational factors, which are typical in chronic pain. Where suspected, they should be ruled out or explicated in the process of determining what actual disability duration is warranted based on the specific underlying condition.

Disability durations are primarily consensus from the Chronic Pain Panel. Disability durations also incorporate data used with permission from Reed Group, Ltd. Reed P. *The Medical Disability Advisor. Workplace Guidelines for Disability Duration, 5<sup>th</sup> Edition.* 2005. Westminister, Colorado: Reed Group, Ltd.

# EXERCISE

Exercise has been used to treat trigger points/myofascial pain. Most studies are low quality and appear to have emphasized stretching exercises. (Edwards 03; Gam 98) However, there are few quality studies that assess which types of exercise and what regimens are most efficacious. Aerobic exercise and strengthening exercises are also believed to be important, but quality studies are not available to support those beliefs.

1. Recommendation: Aerobic Exercise for Trigger Points/Myofascial Pain

Aerobic exercise is recommended for treatment of trigger points/myofascial pain, although quality evidence is lacking regarding its efficacy.

*Indications* – Trigger points/myofascial pain. Patients with potential for or with significant cardiac disease should be evaluated prior to institution of vigorous exercises. Follow *ACSM's Guidelines for Exercise Testing and Prescription* (7<sup>th</sup> Ed) for health screening and risk stratification.

*Frequency/Duration* – A structured, progressive walking program (at least 4 times a week) at an intensity to reach at least 60% of predicted maximum heart rate is recommended. Activity can be gradually increased over days to weeks. Stationary exercise cycles and bicycling are generally not

recommended due to static use considerations. The activity that the patient will adhere to is the one most likely to be effective, given that compliance is a recognized problem.

Indications for Discontinuation – Intolerance (rarely occurs), development of other disorders.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: Stretching Exercises for Trigger Points/Myofascial Pain Stretching exercises are recommended for treatment of trigger points/myofascial pain, accompanied by a loss of joint range of motion, to increase connective and muscle tissue extensibility and to attempt to increase overall capacity and activity tolerance.

Indications - Mild, moderate, severe pain.

Frequency/Duration – Stretching exercises with transition to home exercise program.

Indications for Discontinuation – Restoration of full joint ROM that is pain free or fails to improve.

Strength of Evidence – Recommended, Insufficient Evidence (I)

3. Recommendation: Strengthening Exercises for Trigger Points/Myofascial Pain Strengthening exercises are recommended for treatment of trigger points/myofascial pain to increase capacity and activity tolerance.

Indications – Mild, moderate, or severe pain.

*Frequency/Duration* – Progressive strengthening exercises with transition to home exercise program. When pain is severe, generally slow, judicious introduction of strengthening is required.

Indications for Discontinuation – Development of a strain during treatment course, failure to improve.

Strength of Evidence – Recommended, Insufficient Evidence (I)

4. Recommendation: Inclusion of Fear Avoidance Belief Training for Trigger Points/Myofascial Pain Inclusion of Fear Avoidance Belief Training during the course of treatment is recommended.

Strength of Evidence – Recommended, Insufficient Evidence (I)

## Rationale for Recommendations

There are few quality studies evaluating efficacy for treatment of trigger points/myofascial pain. Overall, the quality of the available studies is not particularly high due to combinations of exercises and lack of detailed descriptions of exercise programs (one study used wait-listed controls). (Gam 98) The most common exercise used in studies has been stretching, but there is insufficient evidence to recommend specific dose or types of stretching exercises. Aerobic and strengthening exercises are also believed to be important, but quality studies are not available to support those beliefs. Stretching, aerobic, and strengthening exercises are not invasive, have low risk for adverse effects, and are low to moderate cost depending on the extent to which supervised exercise is required while transitioning to a home-based program. Fear Avoidance Belief Training (FABT) and principles are believed to be important in the management of these patients. Inclusion of these principles in the course of exercise training or supervision appears highly desirable. This would also strengthen the education of the patient about these problems that should be a message in unison with other members of the team treating the patient.

Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Edwards 2003	6.5	N = 40 musculoskelet	Superficial dry needling	Mean±SD SFMPQ scores at M1 (pre-	"SDN followed by active stretching is	Means 3-4 trigger points per patient. Mild

Evidence for the Use of Exercise for Trigger Points/Myofascial Pain

There are 2 moderate-quality RCTs incorporated into this analysis. (Edwards 03; Gam 98)

RCT		al pain, mean symptoms duration ranged in groups from 10±12 to 16±23 months	of trigger points (no needle manipulation) and active stretching exercises (G1) vs. stretching exercises (G2) vs. no treatment (G3). Number of treatments varied by perceived severity.	intervention), M2 (3 weeks), M3 (6 weeks): G1: 24.3 $\pm$ 6.3, 13.0 $\pm$ 10.2, 9.1 $\pm$ 11.6; G2: 23.1 $\pm$ 7.0, 17.1 $\pm$ 9.4, 15.2 $\pm$ 8.8; G3: 20.2 $\pm$ 8.0, 16.5 $\pm$ 10.2, 14.9 $\pm$ 11.0. PPT scores G1: 1.4 $\pm$ 0.9, 1.8 $\pm$ 1.0, 2.7 $\pm$ 1.4; G2: 1.7 $\pm$ 1.0, 1.8 $\pm$ 1.1, 1.8 $\pm$ 0.9; G3: 1.4 $\pm$ 1.0, 2.0 $\pm$ 1.4, 2.0 $\pm$ 1.6.	more effective than stretching alone in deactivating (trigger points) (reducing their sensitivity to pressure), and more effective than no treatment in reducing subjective pain. Stretching without prior deactivation may increase (trigger point) sensitivity. There were no differences between stretching and no- treatment groups."	baseline differences may have favored stretching-alone group. Describes assessor blinding, but procedures seem to at least partially unblind through marking skin for measurements. Differences in numbers of treatments between groups (4.6 vs. 2.9) and individualization of treatments may substantially bias study and limit strength of conclusions.
Gam 1998 RCT	6.0	N = 67 myofascial trigger points (MTrP) in neck and shoulder (at least 3 months duration)	Ultrasound plus exercise plus massage vs. sham ultrasound plus exercise plus massage vs. a control group twice a week for 4 weeks.	No significant differences were found in analgesic usage and VAS scores at rest and on function between groups (graphic data). No differences in "good" preference at 6 months (23% vs. 22%).	"[M]assage and exercise reduces the number of intensity of MTrP, but this reduction had little impact on the patients' neck and shoulder complaints."	Compliance with exercise 68% at 6 months. Control group's worse ratings week after randomization and treatment initiation, and higher medication tablets consumed, suggest problems with using wait-listed control groups. Baseline differences considerable; control group had substantially longer duration of symptoms (12 months vs. 7.5 months for placebo ultrasound vs. 4 months for active ultrasound). Data suggest therapists not well blinded. Use of massage in first 2 groups is co-intervention and limits conclusions regarding utility of ultrasound or massage.

#### **AQUATIC THERAPY**

Aquatic therapy involves the performance of aerobic and/or flexibility and/or strengthening exercises in a pool to minimize the effects of gravity, particularly where reduced weight-bearing status is desirable.

Recommendation: Aquatic Therapy for Myofascial Pain/Trigger Points Aquatic therapy is not recommended for myofascial pain/trigger points as other therapies are likely more efficacious.

#### Strength of Evidence – Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

Aquatic exercise may be beneficial for the rehabilitation of chronic pain conditions in which it is advantageous to reduce the effects of gravity. However, other forms of exercise have been shown to be effective treatment. It is not recommended other than for the few, select patients who are unable to tolerate land-based therapies. Aquatic therapy is moderate cost, not invasive, and has little potential for adverse effects.

#### Evidence for the Use of Aquatic Therapy

There are no quality studies evaluating the use of aquatic therapy for myofascial pain/trigger points.

## YOGA

Yoga for the treatment of myofascial pain/trigger points has not been standardized, but tends to include postures that involve isometric muscle activity, stretches, breath control, and relaxation. Traditional yoga also involves rules for personal conduct, sense withdrawal, concentration, meditation, and self-realization" (Taimini 86; Williams 05) and different versions are practiced. This review focuses on the exercise aspects of yoga and does not endorse nor support spiritual elements or specific religious beliefs, nor does it cover non-occupational conditions such as chronic pancreatitis. (Sareen 07)

#### Recommendation: Yoga for Trigger Points/Myofascial Pain There is no recommendation for or against the use of yoga for treatment of trigger points/myofascial pain.

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There is moderate-quality evidence of effectiveness of yoga for the treatment of chronic LBP. (Sherman 05; Galantino 04; Williams 05) There are no quality trials for treatment of myofascial pain/trigger points. Yoga is not invasive, has low potential for adverse effects, and is low cost. There is much self-selection in the above studies – evidence suggests that patient motivation must be high, otherwise compliance and adherence reportedly is poor.

#### Evidence for the Use of Yoga

There are no quality studies evaluating the use of yoga for myofascial pain/trigger points.

## **FOLLOW-UP VISITS**

Patients with trigger points/myofascial pain generally require a few too many follow-up appointments depending on severity, persistence, response to therapy, and compliance with treatments including exercises. Follow-up appointments are required every 2 to 4 weeks until resolution or an end-of-improvement plateau is reached.

## MEDICATIONS

## NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs) AND ACETAMINOPHEN

Nonsteroidal anti-inflammatory drugs (NSAIDs) have been widely used to treat myofascial pain/trigger points. However, there are no quality trials of efficacy (see Chronic Pain Guidelines for gastrointestinal protection.)

1. Recommendation: NSAIDs and Acetaminophen for Treatment of Acute, Subacute, or Chronic Myofascial Pain/Trigger Points

NSAIDs are recommended for treatment of acute, subacute, or chronic myofascial pain/trigger points. Acetaminophen may be a reasonable alternative.

*Indications* – Acute, subacute, or chronic myofascial pain/trigger points. Over-the-counter (OTC) agents may suffice and be tried first.

*Frequency/Duration* – Per manufacturer recommendations; as needed use reasonable for many patients. However, nearly all trials for other MSDs utilized scheduled doses.

*Indications for Discontinuation* – Resolution, lack of efficacy, or development of adverse effects that necessitate discontinuation.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: NSAIDs for Patients at Risk for GI Adverse Effects Concomitant prescriptions of cytoprotective medications are recommended for patients at substantially increased risk for gastrointestinal bleeding.

Indications – Patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers. Providers are cautioned that H2 blockers might not protect from gastric ulcers. (Robinson 89, 91; Ehsanullah 88)

Frequency/Dose/Duration – Dose and frequency per manufacturer recommendations. Duration is either length of the NSAID therapy, or permanent for those with recurrent bleeds or other complications.

Indications for Discontinuation - Intolerance, development of adverse effects, or discontinuation of NSAID.

Strength of Evidence – Strongly Recommended, Evidence (A) – Proton pump inhibitors, misoprostol

Strength of Evidence – Moderately Recommended, Evidence (B) – Sucralfate Strength of Evidence – Recommended, Evidence (C) – H2 Blockers

Recommendation: NSAIDs for Patients at Risk for Cardiovascular Adverse Effects Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Strength of Evidence – Recommended, Insufficient Evidence (I)

Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse effects to use for patients with cardiovascular disease risk factors.

Strength of Evidence – Strongly Recommended, Evidence (A)

If needed, NSAIDs that are non-selective are generally preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or 8 hours before the daily aspirin. (Antman 07)

#### Rationale for Recommendations

There are no quality studies identified that evaluate the efficacy of NSAIDs for treating trigger points/myofascial pain. The only trial used an NSAID as a control group and did not report the scheduling or use of the NSAID. (Birch 98) NSAIDs are not invasive, have low adverse effect profiles in healthy working-age adults, and when generic medications are used, are low cost; thus, they are recommended.

There is 1 m	There is 1 moderate-quality RCT incorporated into this analysis. (Birch 98)									
Author/Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments				
Birch 1998 RCT	4.0	N = 46 chronic myofascial neck pain (at least 6 months duration)	"Relevant" acupuncture (SI-3, BL-62, GB-41, TW- 5; with diode stimulation; GB- 12/20/21, BL-10/11, GV-14 plus infrared) vs. placebo acupuncture (LI-5, GB-42, TW-8, ST- 41; BL-16, SI-9, LI- 15 plus light without heat vs. NSAID controls (Trilisate; dose, frequency unclear.)	Patients assigned acupuncture had significantly lower average hourly pain ratings after treatment (1.87±1.90) vs. placebo acupuncture (3.37±2.14) vs. NSAID controls (4.76±2.05); p <0.05. Pre- and post- treatment changes in hourly pain intensity significantly different among groups: 1.82±2.13 vs. 0.75±1.34 vs 0.64±1.96; p <0.05.	"Relevant acupuncture with heat contributes to modest pain reduction in persons with myofascial neck pain. Previous experience with and confidence in treatment help to predict benefit. Measurement of nonspecific effects of alternative therapy is recommended in future clinical trials."	Significant baseline differences in prior acupuncture experience of uncertain impact (relevant acupuncture group far more experienced than other two). No true placebo group for evaluation of NSAID.				

## Evidence for the Use of NSAIDs and Acetaminophen

## **ANTI-DEPRESSANTS**

There is quality evidence evaluating anti-depressants for the treatment of chronic pain, but not specifically for treatment of trigger points/myofascial pain. For use in LBP patients, there is no quality evidence of an association between serum levels and pain relief, suggesting that doses less than those used for depression may be sufficient. (Alcoff 82, Atkinson Pain 98) While most patients may not require these agents, in those with more severe symptoms, these may be reasonable treatment considerations.

1. Recommendation: Norepinephrine Reuptake Inhibitor Anti-depressants for Trigger Points/Myofascial Pain

Norepinephrine reuptake inhibitor anti-depressants (TCAs) are recommended for the treatment of more severe cases of trigger points/myofascial pain.

*Indications* – Chronic pain not fully treated with NSAIDs and an exercise program, particularly if there is nocturnal sleep disruption and mild dysthymia, which may allow for nocturnal dosing of a mildly sedating tricyclic antidepressant.

*Frequency/Duration* – Low dose at night, gradually increased (e.g., amitriptyline 25mg QHS, increase by 25mg each week) until a sub-maximal or maximal dose is achieved, sufficient effects are achieved, or adverse effects occur. Use lower doses, (e.g., amitriptyline 25 to 75mg a day) to avoid adverse effects and necessity of blood level monitoring, particularly if no evidence of increased pain relief at higher doses. Imipramine is less sedating, thus if there is carryover daytime sedation, it may be a better option. If patient cannot sleep, amitriptyline is the recommended initial medication. Duration of use may be indefinite, although most patients do not require indefinite treatment as the condition usually either resolves or improves, particularly if compliant with functional restoration program elements.

Indications for Discontinuation – Resolution of pain, intolerance, or development of adverse effects. Strength of Evidence – **Recommended**, **Insufficient Evidence (I)** 

2. Recommendation: Selective Serotonin Reuptake Inhibitors, Bupropion, or Trazodone for Trigger Points/Myofascial Pain

Selective serotonin reuptake inhibitors, bupropion, or trazodone are not recommended for the treatment of trigger points/myofascial pain.

Strength of Evidence - Not Recommended, Insufficient Evidence (I)

3. Recommendation: Duloxetine for Muscle Tenderness and Trigger Points There is no recommendation for or against the use of duloxetine for the treatment of muscle tenderness and trigger points. A trial of duloxetine may be considered after other treatments with documented efficacy (e.g., different NSAIDs, aerobic exercise, targeted range of motion exercise, TCAs) have been attempted. However, use is generally not warranted.

Strength of Evidence – No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendations

There are no quality trials evaluating treatment of these patients. Norepinephrine reuptake inhibitor antidepressants are not invasive, have low to moderate, dose-dependent adverse effects, and are not costly in their generic formulations. As there is evidence for efficacy of norepinephrine reuptake inhibitors (TCAs, SNRIs) for treatment of LBP and other nociceptive pain, these are recommended (see Chronic Pain Guidelines and Low Back Complaints). As there is strong evidence SSRIs are ineffective for treatment of LBP, they are not recommended. The degree to which depression or dysthymia is present necessitates understanding of these complex issues and may impact these recommendations. (They may be nevertheless recommended for treatment of depression.) Discussions with mental health professionals are recommended, particularly when mental health conditions are more severe. There is strong evidence that treatment with SSRIs is not of benefit in patients with chronic pain, thus their use is not recommended for the management of trigger points without depression.

## ANTI-CONVULSANT AGENTS (INCLUDING CARBAMAZEPINE)

Anti-convulsant agents have been utilized off-label for some chronic pain syndromes since the 1960s. (Wiffen 05) They have been particularly used for treating neuropathic pain. (Challapalli 05)

Recommendation: Anti-convulsant Agents for Trigger Points/Myofascial Pain Anti-convulsant agents are not recommended for treatment of trigger points/myofascial pain.

## Strength of Evidence – Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendations

There are no quality studies evaluating these medications for treatment of trigger points/myofascial pain. There is some evidence of efficacy for treatment of radicular or neuropathic pain symptoms. However, this condition is not analogous and thus these agents are not recommended.

#### Evidence for the Use of Anti-convulsants

There are no quality studies evaluating the use of anti-convulsant agents for trigger points/myofascial pain.

## GABAPENTIN AND PREGABALIN

Gabapentin and pregabalin have evidence of efficacy for short-term treatment of neuropathic pain and neurogenic claudication. (Backonja 98; Lesser 04; Richter 05; Dworkin 03; McCleane 01; Yaksi 07)

#### Recommendation: Gabapentin or Pregabalin for Trigger Points/Myofascial Pain

There is no recommendation for or against the use of gabapentin or pregabalin for treatment of trigger points/myofascial pain.

#### Strength of Evidence – No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials for treatment of these patients. Gabapentin and pregabalin appear useful for selected patients with severe fibromyalgia (see Appendix 2 in Chronic Pain Guidelines) which might suggest they would be useful in patients with severe myofascial pain; however, there is no evidence to support use in this context. Gabapentin and pregabalin are not invasive, but have significant adverse effects in some patients, largely central nervous system-related which are of concern in employed populations. Release of a generic form of gabapentin has reduced its cost, though pregabalin remains moderately costly.

#### Evidence for the Use of Gabapentin and Pregabalin

There are no quality studies evaluating the use of gabapentin and pregabalin for trigger points/myofascial pain.

## GLUCOCORTICOSTEROIDS (AKA "STEROIDS")

Glucocorticosteroids have been used to treat acute radicular pain syndromes thought to be related to herniated discs and to treat complex regional pain syndrome (CRPS). (Sharma 06; Beniczky 05) They are not commonly used for treatment of trigger points, although they have commonly been used by injection (see below).

#### Recommendation: Glucocorticosteroids for Trigger Points/Myofascial Pain

Glucocorticosteroids administered by systemic or topical routes are not recommended.

#### Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendation

Evidence in support of glucocorticosteroids to treat radiculopathy and CRPS is available. However, there is no quality evidence to support treatment for trigger points/myofascial pain. These agents are not invasive if prescribed for oral administration, are low cost, but have considerable adverse effects. Thus, they are not recommended.

Evidence for the Use of Oral Glucocorticosteroids

There are no quality studies evaluating the use of oral glucocorticosteroids for trigger points/myofascial pain.

## HERBAL AND OTHER PREPARATIONS

See Chronic Pain Guidelines.

## SKELETAL MUSCLE RELAXANTS

Skeletal muscle relaxants comprise a diverse set of pharmaceuticals designed to produce muscle relaxation through different mechanisms of action generally considered to be effects on the central nervous system (CNS) and not on skeletal muscle. (Abbruzzes 02; Elenbaas 80) These medications are widely used in primary care to treat painful conditions, most prominently LBP, (Cherkin 98; Di Iorio 00; van Tulder 97; Schnitzer 04, Deyo 90; Baratta 76; Arbus 90) muscle spasms, (Preston 84) and myalgias. As these drugs produce CNS depression, (Browning 01) there is a low, but definite risk of abuse. This risk appears to be substantially lower than with opioids; however, there are patients in whom abuse has been reported involving some if not all of these agents. (Littrell 93; Toth 04) Carisoprodol is more commonly abused because an active metabolite is meprobamate, a potent and highly abused sedative-hypnotic. (Littrell 93) Regardless, it is recommended that caution be exerted involving all of these agents when there is a history of substance abuse or requests for specific medications. (Krismer 07)

#### Recommendation: Muscle Relaxants for Trigger Points/Myofascial Pain

Muscle relaxants are not recommended for patients with trigger points/myofascial pain.

## Strength of Evidence – Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials for treatment of these patients. Skeletal muscle relaxants have been widely used for the treatment of tender and trigger points on the supposition that prescription of the muscle relaxant will directly treat the disorder. However, there is no evidence to support this theory. These agents are not invasive, have significant adverse effects, and are low to moderately costly. Skeletal muscle relaxants have largely been used in the setting of acute pain and there is much less evidence for their efficacy for the treatment of chronic pain, especially trigger points/myofascial pain. *Evidence for the Use of Skeletal Muscle Relaxants* 

There are no quality studies evaluating the use of skeletal muscle relaxants for trigger points/myofascial pain.

#### **OPIOIDS**

See Opioids Guidelines.

## DEVICES/PHYSICAL METHODS TAPING AND KINESIOTAPING

Taping and kinesiotaping are used on the extremities, particularly in sports settings. Taping (white athletic taping, cotton mesh adhesive tape often over gauze) is intended to stabilize and support while restricting ROM; thus is used for treatment and preventive purposes. (Cools 02; Baquie 02; Host 95; Smith 09) Taping has been used to treat myofascial pain. (Garcia-Muro 10) It is often utilized immediately prior to an activity and then removed, or the cotton mesh may be applied and removed after hours of use. Kinesiotaping (thinner, elastic tape) is also intended for treatment, including pain relief; however, it allows full ROM in contrast with traditional taping. (Hsu 09; Host 95; Miller 09; Hadala 09; Fu 08; Walsh 10; Yoshida 07; Kalichman 10; Kaya 10: Garcia-Muro10; Thelen 08) Kinesiotaping is proprietary; proponents believe the tape should be applied in specific patterns and may or may not be stretched depending on the injury. Regardless, all types of taping are utilized to attempt to treat musculoskeletal disorders. Difficulty with tolerating the various types of tape may be problematic for some patients.

Recommendation: Taping and Kinesiotaping for Trigger Points/Myofascial Pain

## There is no recommendation for or against the use of taping and kinesiotaping for the treatment of trigger points/myofascial pain.

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There is one high-quality trial of kinesiotaping for treatment of shoulder pain, of short-term duration that failed to show improvements in pain (Thelen 08); there are no other quality trials. Kinesiotaping and taping have not been shown to have sustained efficacy. As use and movement are thought to be helpful for treating trigger points/ myofascial pain, the rationale for taping the shoulder and back for myofascial pain/trigger points seems limited. These interventions are not invasive. Taping and kinesiotaping have potential adverse effects among those who do not tolerate it or the adhesives, but they are generally minor. When the fees for both the tape and its application are considered, taping is costly, especially since there are alternative interventions that have been shown to be effective. As there is no quality evidence of durable effects, there is no recommendation for or against their use.

## Evidence for the Use of Taping and Kinesiotaping

There are no quality studies evaluating the use of kinesiotaping and taping for trigger points/myofascial pain.

## MAGNETS AND MAGNETIC STIMULATION

High intensity magnetic stimulation purportedly causes depolarization of nerves and has been found to result in an antinociceptive effect in rats. (Lin 02) Electromagnetic fields have been known to increase osteoblastic activity. Therefore, proponents believe that magnetic fields have therapeutic value in the treatment of MSDs.

#### Recommendation: Magnets and Magnetic Stimulation for Trigger Points/Myofascial Pain Magnets and magnetic stimulation are not recommended for the treatment of trigger points/myofascial pain.

## Strength of Evidence - Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There is no significant evidence base from which to draw conclusions on the utility of magnets as a treatment of these patients. Magnets have proven unsuccessful in quality studies of other MSDs including back pain and plantar fasciitis (see Low Back Complaints and Ankle and Foot Complaints). Other treatments have demonstrated efficacy. Magnets are not invasive, have no adverse effects, and are low cost.

#### Evidence for the Use of Magnets and Magnetic Stimulation

There are no quality studies evaluating the use of magnets and magnetic stimulation to treat trigger points/myofascial pain.

## ACUPUNCTURE

Acupuncture has been used for treatment of chronic pain patients including trigger points/myofascial pain. (Edwards 03)

#### Recommendation: Acupuncture for Chronic Trigger Points/Myofascial Pain

## Acupuncture is recommended for select use in chronic moderate to severe chronic trigger points/myofascial pain as an adjunct to more efficacious treatments.

*Indications* – Moderate to severe chronic trigger points/myofascial pain. Prior treatments should include NSAIDs, exercise, and a trial of dry needling or injection(s) with bupivacaine.

*Frequency/Duration* – A limited course as an adjunct to a conditioning program that has both graded aerobic exercise and strengthening and stretching exercises for treatment of trigger points/myofascial pain during which time there are clear objective and functional goals that are to be achieved.

Indications for Discontinuation – Resolution, intolerance, non-compliance including non-compliance with aerobic and strengthening and stretching exercises.

## Strength of Evidence – Recommended, Evidence (C)

## Rationale for Recommendation

There are few quality studies evaluating acupuncture for the treatment of tender and trigger points; they tend to have significant design flaws which limit the strength of conclusions. Efficacy of acupuncture for this indication is suggested by the highest quality available study that has a non-acupuncture comparison group, (Edwards 03) yet that study has significant flaws. Considering acupuncture's efficacy in treating chronic LBP, efficacy for this indication would not be surprising. For LBP, there is no quality evidence suggesting that one type of acupuncture is superior to another (e.g., Chinese vs. Japanese). High-guality studies with sizable populations and long follow-up periods are needed. Acupuncture is minimally invasive, has low adverse effects, and is moderately costly. Acupuncture is recommended to assist in increasing functional activity levels more rapidly and the primary attention should remain on the conditioning program. In patients not involved in a conditioning program, or who are non-compliant with graded increases in activity levels, this intervention is not recommended.

There are 6 moderate-quality RCTs incorporated into this analysis.									
Author/Titl e Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments			
Ceccherelli 2002 RCT	7.0	N = 42 with chronic lumbosacral myofascial pain.	Superficial acupuncture vs. deep acupuncture.	Mean McGill pain scores comparing superficial vs. deep acupuncture before therapy/end of therapy/ follow up: $34.7\pm11.43/$ $22.25\pm16.08/18.00$ $\pm 17.16$ vs. $35.4\pm14.53/$ $14.54\pm10.88/7.50\pm$ 12.94; p <0.05.	"[D]eep stimulation has a better analgesic effect when compared with superficial stimulation."	Patient blinding questionable as depth of needle penetration may be unblinded. Complications not noted and incidence of hematomas from deep needling would be anticipated to be greater. Study cannot address utility of acupuncture to treat condition as no control group.			
Edwards 2003 RCT	6.5	N = 40 with musculoskelet al pain; mean symptoms duration ranged in groups from 10±12 to 16±23 months.	Superficial dry needling of trigger points (no needle manipulation) and active stretching exercises (G1) vs. stretching exercises (G2) vs. no treatment (G3). Number of treatments varied by perceived severity.	Mean±SD SFMPQ scores at M1 (pre- intervention), M2 (3 weeks), M3 (6 weeks): G1: 24.3±6.3, 13.0±10.2, 9.1±11.6; G2: 23.1±7.0, 17.1±9.4, 15.2±8.8; G3: 20.2±8.0, 16.5±10.2, 14.9±11.0. PPT scores G1: 1.4±0.9, 1.8±1.0, 2.7±1.4; G2: 1.7±1.0, 1.8±1.1, 1.8±0.9; G3: 1.4±1.0, 2.0±1.4, 2.0±1.6.	"SDN followed by active stretching is more effective than stretching alone in deactivating (trigger points) (reducing their sensitivity to pressure), and more effective than no treatment in reducing subjective pain. Stretching without prior deactivation may increase (trigger point) sensitivity."	Means 3-4 trigger points per patient. Mild baseline differences may have favored stretching alone group. Describes assessor blinding, but procedures seem to partially unblind through marking skin for measurements. Differences in numbers of treatments between groups (4.6 vs. 2.9) and individualization of treatments may substantially bias study/limit strength of conclusions.			
Ceccherelli 2006 RCT	6.0	N = 62 with cervical myofascial pain.	Somatic acupuncture vs. somatic acupuncture paired with auriculotherap	Mean VAS score Group A vs. Group B before treatment/after treatment/1 month/3 months:	"Somatic plus auriculotherapy was therefore not statistically significantly superior to	Data suggest no additive benefit of auriculotherapy in addition to somatic acupuncture.			

#### Evidence for the Use of Acupuncture

			y for a duration of 8 sessions.	Group A: 57.90±18.87/ 15.64± 12.69/15.34±15.69/ 18.96±15.50; p <0.05 vs. 61.00±20.73/ 19.50±19.31/18.50 ±	somatic therapy alone in the treatment of cervical myofascial pain."	
Fu 2007 RCT	5.5	N = 47 with trigger points in neck and upper back (for at least 10 days and less than 1 year).	Along group (insertion points were along direction of muscle fibers) vs. across group (insertion points across direction of muscle fibers) with soft tube remaining under skin for 8-24 hours.	$\begin{array}{l} 17.96/21.00\pm19.88.\\ \hline \text{Mean value of}\\ motion-related-pain\\ comparing Along vs\\ Across group pre-intervention/ post-intervention:                                    $	"Immediate effects of FSN on alleviating MTrP in the neck were not relevant to the needling directions."	Study states single blinding, but who is blinded and how not clear. Leaving soft tube of needle under skin for 8-24 hours after treatment likely impractical. Technique described for completeness; however, may not represent quality evidence for or against efficacy of acupuncture for trigger points.
ltoh 2007 RCT	4.5	N = 40 with non-radiating CNP for at least 6 months.	Standard acupuncture (SA) vs. trigger point acupuncture (TrP) vs. non- trigger point acupuncture (non TrP) vs. sham acupuncture (SH) over 13 weeks.	Reduction in pain intensity between treatment and interval for TrP group (0.01).	"[T]rigger point acupuncture therapy may be more effective on chronic neck pain in aged patients than the standard acupuncture therapy."	Study claims blinding, but unless procedures identical, could be somewhat unblinded; assessment of blinding scores appear to indicate standard acupuncture group more likely to believe they had true insertion of needles. Also, attempt to find trigger points would inadvertently include massage that was potentially unequal between 4 small groups.
Birch 1998 RCT	4.0	N = 46 with chronic myofascial neck pain (at least 6 months duration)	"Relevant" acupuncture (SI-3, BL-62, GB-41, TW-5; with diode stimulation; GB-12/20/21, BL-10/11, GV- 14 plus infrared) vs. placebo acupuncture (LI-5, GB-42, TW-8, ST-41; BL-16, SI-9, LI- 15 plus light without heat vs. NSAID controls (Trilisate; dose, frequency unclear.)	Patients assigned acupuncture had significantly lower average hourly pain ratings after treatment (1.87±1.90) vs. placebo acupuncture (3.37±2.14) vs. NSAID controls (4.76±2.05); p <0.05. Pre- and post-treatment changes in hourly pain intensity also significantly different among groups: 1.82±2.13 vs. 0.75±1.34 vs 0.64±1.96; p <0.05.	"Relevant acupuncture with heat contributes to modest pain reduction in persons with myofascial neck pain. Previous experience with and confidence in treatment help to predict benefit. Measurement of nonspecific effects of alternative therapy is recommended in future clinical trials."	Significant baseline differences in prior acupuncture experience of uncertain impact (relevant acupuncture group far more experienced than other two groups). No true placebo group for evaluation of NSAID.

## HOT AND COLD THERAPIES

It has been proposed that cold and heat have actual therapeutic benefits to modify the disease processes (e.g., cold to allegedly reduce acute inflammation and swelling and heat to speed healing through increased blood supply). (Grana 93; Michlovitz 96) However, others propose that these various modalities are all distractants that do not materially alter the clinical course. Still others postulate that the distractants allow increased activity levels, thus even though there may be no direct action of these modalities and the disease processes, this theory supports using these modalities through indirect mechanism(s) of action. Many patients with chronic pain report a temporary soothing effect from the application of heat or the use of ice packs in the home setting.

## **CRYOTHERAPIES**

Cold or cryotherapies involve applications of cold or cooling devices to the skin and have sometimes been used for treatment of trigger points/myofascial pain.

#### Recommendation: Home Use of Cryotherapies for Trigger Points/Myofascial Pain There is no recommendation for or against the home use of cryotherapies for trigger points/myofascial pain.

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials. Self applications of cryotherapies using towels or reusable devices are not invasive, without complications and do not have any appreciable costs. As there is no evidence as well as there are concerns cryotherapy may be unhelpful for these patients, there is no recommendation.

#### Evidence for the Use of Cryotherapies

There are no quality studies evaluating the use of cryotherapies for trigger points/myofascial pain.

## **HEAT THERAPIES**

There are many forms of heat therapy for treatment of musculoskeletal pain including hot packs, moist hot packs, sauna, warm baths, infrared, diathermy and ultrasound. Many of these have been utilized for treatment of patients with myofascial pain/trigger points.

# Recommendation: Self-application of Heat Therapy for Trigger Points/Myofascial Pain Self-application of low-tech heat therapy is recommended for treatment of trigger points/myofascial pain.

*Indications* – Applications may be periodic or continuous. Applications should be home-based as there is no evidence for efficacy of provider-based heat treatments. Primary emphasis should generally be on functional restoration program elements, rather than on passive treatments in patients with chronic pain.

*Frequency/Duration* – Periodic self-applications. Education regarding home heat application should be part of the treatment plan if heat has been effective for reducing pain.

*Indications for Discontinuation* – Intolerance, increased pain, development of a burn, other adverse event.

## Strength of Evidence - Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials for treatment of trigger points/myofascial pain patients. There is a pilot study suggesting that those with trigger points may respond differently to heat applied prior to exercise. (Nadler 01) Non-proprietary, self applications of heat therapies are not invasive, have low adverse effects provided excessive heat is not used, and may have no associated costs and are recommended.

## Evidence for the Use of Heat Therapies

There are no quality studies evaluating heat therapies for trigger points/myofascial pain.

## DIATHERMY

Diathermy is a heat treatment that has been used clinically to heat tissue. There are two forms of diathermy – short wave and microwave. (High-dose diathermy is also used to coagulate tissue.) Proponents believe diathermy penetrates deeper than hot packs or heating pads and stimulates healing.

## Recommendation: Diathermy for Trigger Points/Myofascial Pain Diathermy is not recommended for treatment of trigger points/myofascial pain.

## Strength of Evidence - Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendation

Diathermy has not been shown to be more effective than placebo diathermy for treatment of multiple conditions, (Sweetman 93; Koes BMJ 92, Koes Spine 92, Koes JManip 92, Koes 93) although trigger points/myofascial pain have not been studied. Diathermy is not invasive, has low adverse effects, but is moderately costly and lacks evidence of efficacy, thus it is not recommended for treatment of trigger points/myofascial pain.

## Evidence for the Use of Diathermy

There are no quality studies evaluating the use of diathermy for trigger points/myofascial pain.

## **INFRARED THERAPY**

Infrared therapy is a heat treatment created by various devices producing electromagnetic radiation in the infrared spectrum.

## Recommendation: Infrared Therapy for Trigger Points/Myofascial Pain Provider-based infrared therapy is not recommended for trigger points/myofascial pain.

## Strength of Evidence – Not Recommended, Insufficient Evidence (I)

## Rationale for Recommendation

There are no quality trials on infrared therapy for trigger points/myofascial pain. Infrared is not invasive, has low potential for adverse effects, but is moderate cost and thus is not recommended.

## Evidence for the Use of Infrared Therapy

There are no quality studies evaluating the use of infrared therapy for trigger points/myofascial pain.

## ULTRASOUND

Therapeutic ultrasound has been used for treatment of myofascial pain/trigger points. (Gam 98)

#### Recommendation: Ultrasound for the Treatment of Trigger Points/Myofascial Pain Ultrasound is not recommended for treatment of trigger points/myofascial pain.

## Strength of Evidence – Not Recommended, Evidence (C)

## Rationale for Recommendation

There is one quality trial that evaluated ultrasound for treatment of trigger points/myofascial pain which found ultrasound to be ineffective. (Gam 98) The other trial compared two different active ultrasound techniques for acute pain of less than 2 weeks duration, raising questions about applicability to the typical trigger point/myofascial pain patient. (Majlesi 04) Ultrasound is not invasive, has few adverse effects, but is moderately costly and appears ineffective and is thus not recommended.

## Evidence for the Use of Ultrasound

There are 2 moderate quality RCTs incorporated into this analysis. (Gam 98; Majilesi 04)

Author/Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Majlesi 2004	6.5	N = 72	High-power,	Mean number of	"High-power,	No placebo control. Claims
		with	pain-threshold	sessions required:	pain-threshold,	double blinding, but techniques
RCT		acute	static	conventional	static	applied not similar. Variable
		unilateral	ultrasound vs.	11.82±2.47 vs.	ultrasound	number of sessions. Patient
		neck pain	conventional,	2.83 ±1.48, p	technique may	definition of acute pain raises
		of 0-2	stroking	<0.001. VAS after	be considered	questions about diagnostic
		weeks	ultrasound;	1st session	in the	categorization of myofascial
		duration	1.5W/cm <sup>2</sup> for 5	7.72±1.19 vs.	treatment of	pain. Questions about

			minutes. Variable number of sessions: 1-15 sessions.	3.32±1.73, p <0.001. ROM improved more with high-power technique.	patients with acute myofascial pain syndrome."	generalizability of results to typical MPS patient. Data suggest high-power pain threshold technique superior.
Gam 1998 RCT	6.0	N = 67 with myofasci al trigger points (MTrP) in neck and shoulder (at least 3 months duration)	Ultrasound plus exercise plus massage vs. sham ultrasound plus exercise plus massage vs. control group twice a week for 4 weeks.	No significant differences in analgesic usage and VAS scores at rest and on function between groups.	"[M]assage and exercise reduces the number of intensity of MTrP, but this reduction had little impact on the patients' neck and shoulder complaints."	Compliance with exercise 68% at 6 months. Control group worse ratings week after randomization and treatment initiation, as well as higher medication tablets consumed, demonstrates problem of bias from using wait-listing control groups. Baseline differences considerable; control group substantially longer duration of symptoms (12 vs. 7.5 months placebo ultrasound vs. 4 months active ultrasound). Use of massage in first 2 groups a co-intervention and somewhat limits conclusions regarding utility of ultrasound or massage for these patients.

## LOW-LEVEL LASER THERAPY

Low-level laser treatment usually involves laser energy that does not induce significant heating. It is theorized that the mechanism of action is through photoactivation of the oxidative chain. (Fitz-Ritson 01)

#### Recommendation: Low-level Laser Therapy for Trigger Points/Myofascial Pain There is no recommendation for or against the use of low-level laser therapy for the treatment of trigger points/myofascial pain.

#### Strength of Evidence – No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are quality trials for treatment of trigger points/myofascial pain, however different lasers and treatment regimens have been used and no long-term results have been reported. Quality evidence is conflicting, (Gur 04; Dundar 07; Altan 05) with the highest quality studies finding no benefit. (Dundar 07; Altan 05) The quality study that showed benefit found minimal difference between the treatment groups. (Gur 04) Low-level laser therapy is not invasive, is unlikely to have significant adverse effects, but is moderate to high cost. Longer term evaluation, utilization of objective measures, and standardization of the treatment regimens is required in addition to consistent, quality evidence of efficacy. Thus, there is no recommendation for or against low-level laser therapy for treating trigger points/ myofascial pain patients.

Evidence for the Use of Low-level Laser Therapy

There are 3 moderate quality RCTs incorporated into this analysis.

Author/Title S	Score	Sample	Comparison	Results	Conclusion	Comments
Study Type (	(0-11)	Size	Group			

Dundar 2007 RCT	7.5	N = 64 with myofascial pain syndrome	Ga-As-Al laser treatment bilaterally once a day for 15 days vs. placebo laser.	Mean VAS pain at rest scores laser vs. placebo laser group pre-/post- treatment: $4.1\pm1.9/$ $3.2\pm2.5$ ; p = 0.014 vs. $4.2\pm2.2/3.2\pm2.3$ ; p = 0.023. Pain at movement VAS scores: $6.0\pm2.0/3.9\pm2.5$ ; p = 0.000 vs. $5.1\pm2.0/$ $3.5\pm2.4$ ; p +0.001. Mean VAS pain at rest: - $0.24\pm0.20$ vs0.16 $\pm$ 0.18; p = 0.388. Pain at movement: -0.34 $\pm$ 0.14 vs. -0.29 $\pm$ 0.19; p = 0.971.	"Although the laser therapy has no superiority over placebo groups in this study, it cannot exclude the possibility of effectivity with another treatment regimen including different laser wavelengths and dosages (different intensity and density and/or treatment interval)."	Both groups performed daily isometric exercises and stretching exercises for cervical region under supervision of a physiotherapist.
Altan 2005 RCT	7.5	N = 53 with cervical myofascial pain syndrome	GaAs laser treatment over 3 trigger points bilaterally plus 1 point in taut bands in trapezius muscle bilaterally vs. placebo.	Mean VAS pain score Group 1 vs. Group 2 pre- /post-treatment/14th week: 6.85±0.35/4.13±0.58/ 3.17±0.58; p (pre- treatment/14th week) <0.001 vs. 6.24±0.32/ 3.92±0.42/3.80±0.51; p (pre-treatment/14th week) <0.001.	"[T]he results have not shown the superiority of GaAs laser therapy over placebo in the treatment of cervical MPS."	Baseline pain scores appear borderline statistically worse in the active laser group.
Gur 2004 RCT	7.0	N = 60 with chronic myofascial pain syndrome	Actual laser treatment vs. placebo laser treatment daily for 2 weeks.	Mean VAS pain at rest comparing active laser vs. placebo laser at baseline/2nd/3rd/12th week: 7.39±2.28/3.11±2.29/ 2.45±2.92/ 4.18±2.65 vs. 6.87±1.96/5.79±3.12/ 4.81±2.76 (p <0.01)/ 6.29±3.52.	"This study revealed that short-period application of LLLT is effective in pain relief and in the improvement of functional ability and QoL in patients with MPS."	Duration of pain >1 year. No specifics on etiology of pain; 10 treatments over 2 weeks. Assessments baseline, 2, 3, 12 weeks. Did not measure beliefs of participants in therapy. At 12 weeks, number of trigger points and NPDS scores significantly improved compared to placebo.

## MANIPULATION AND MOBILIZATION

Manipulation and mobilization are two types of manual therapy that have been used widely to treat musculoskeletal disorders, although mostly spine disorders. (Hurwitz 02; Cleland 07; Sloop 82; Wood 01; van Schalkwyk 00; Bronfort 01; Giles 03; Skargren 97; Koes Spine 92, Koes BMJ 92,93) or in patients with shoulder pain not of trigger points/myofascial pain origin. (Mintken 0; Strunce 09; Bergman 04)

Recommendation: Manipulation and Mobilization for Trigger Points/Myofascial Pain There is no recommendation for or against the use of manipulation and mobilization for trigger points/myofascial pain.

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality studies. Manipulation and mobilization are not invasive, have some adverse effects and are moderately costly depending on numbers of treatments. In the absence of evidence of efficacy for patients specifically with trigger points/myofascial pain, there is no recommendation.

## MASSAGE

Massage is a commonly used treatment for chronic muscular pain administered by providers as well as others. It is sometimes referred to as soft tissue mobilization. A complicating factor in this review is the varying methods of massage that are employed, including in more recent trials described below.

#### 1. Recommendation: Massage for Trigger Points/Myofascial Pain

Massage is recommended for select use in patients with trigger points/myofascial pain as an adjunct to active treatments consisting primarily of a graded aerobic and strengthening exercise program.

*Indications* – Moderate to severe chronic pain associated with trigger points/myofascial pain without underlying serious pathology is as an adjunct to a conditioning program that has both graded aerobic exercise, strengthening, and stretching exercises. The intervention is recommended to assist in increasing functional activity levels more rapidly and the primary attention should remain on the conditioning program. In those not involved in a conditioning program, or who are non-compliant with graded increases in activity levels, this intervention is not recommended.

*Frequency/Duration* – Three to 5 visits; if ongoing objective improvement, up to 8 to 10 additional treatments appropriate. In unusual circumstances involving more severe cases with ongoing transitions to an active treatment program and with evidence of improvement, an additional 3 to 5 treatments may be indicated.

*Indications for Discontinuation* – Resolution, intolerance, lack of benefit, non-compliance with aerobic and strengthening exercises.

#### Strength of Evidence - Recommended, Insufficient Evidence (I)

 Recommendation: Mechanical Massage Device for Trigger Points/Myofascial Pain The use of mechanical massage devices applied by rehabilitation service providers or massage therapists to administer massage is not recommended for trigger points/myofascial pain. (Melzack 83; Ferrell 97; Werners 99)

#### Strength of Evidence – Not Recommended, Evidence (C)

#### Rationale for Recommendations

Massage is a commonly used treatment for musculoskeletal pain, (Cen 03) but few studies evaluated disorders other than LBP (Preyde 00; Kalauokalani 01; Melzack 83) and there are few quality studies for treatment of trigger points/ myofascial pain. One study of myofascial trigger points was negative. (Gam 98) Another of neck pain was negative. (Irnich 01) However, a third of diffuse musculoskeletal pain showed massage was superior to relaxation therapy. (Hasson 04) Thus, the literature suggests massage is a weakly effective treatment that is not as effective as active exercise or acupuncture. Massage is not invasive, has low risk of adverse effects aside from short-term pain, (Cherkin 01) and is moderately costly. It is recommended for treatment of chronic pain as an adjunct to a conditioning program. Mechanical devices are not recommended. The better quality studies utilized massage therapists to administer the massage treatments, suggesting that the experience of the professional and quality of the massage may be important factors.

#### Evidence for the Use of Massage

There are 12 moderate-quality RCTs incorporated into this analysis.

We searched Massge for rotator cuff tears, massive rotator cuff tears, tendon rotator cuff tears, rotator cuff partial- and full-thickness tears, rotator cuff tendinopathy, rotator cuff tendinosis, rotator cuff tendinitis, impingement syndrome, bursitis, supraspinatus tendinitis, and bicipital tears. We included 1 RCT.

Author/Title	Scor	Sample	Comparison	Results	Conclusion	Comments
Study Type	e (0- 11)	Size	Group			
Cherkin 2001 RCT	7.0	N = 262 with chronic LBP.	Traditional Chinese acupuncture (n = 94) vs. therapeutic massage (n = 78) vs. self-care educational materials (n = 90)	At 10 weeks, massage superior to self-care for symptom scale, (3.41 vs. 4.71; p = .01) and disability scale (5.89 vs. 8.25; p = .01). Massage superior to acupuncture on disability scale (3.08 vs. 4.74; p = .002).	At 10 weeks, massage superior to self-care for symptom scale, (3.41 vs. 4.71; p = 0.01) and disability scale (5.89 vs. 8.25; $p = 0.01$ ); also superior to acupuncture on the disability scale (3.08 vs. 4.74; $p = 0.002$ ). After 1 year massage no longer better than self-care but still superior to acupuncture on symptom scale (3.08 vs. 4.74, $p = 0.002$ ), dysfunction scale (6.29 vs. 8.21, $p = 0.05$ ).	Data suggest efficacy of massage.
Preyde 2000 RCT	7.0	N = 107 with subacute LBP.	Comprehensive massage therapy vs. soft-tissue manipulation only vs. remedial exercise with posture education only vs. placebo sham laser therapy.	Massage therapy group had improved function mean RDQ score 1.54, p <0.001 and less intense pain mean PPI score 0.42, p <0.001 compared to other groups.	"Patients with subacute low-back pain were shown to benefit from massage therapy, as regulated by the College of Massage Therapists of Ontario and delivered by experienced massage therapists."	At 1-month follow up, 63% of comprehensive massage subjects reported pain resolution compared to 27% in soft-tissue group, 14% in exercise group, 0% in sham laser group.
Imich 2001 RCT	6.5	N = 177 with chronic neck pain.	Acupuncture vs. massage vs. "sham" laser acupuncture for 3 weeks.	Mean (SD) VAS scores comparing acupuncture vs. massage vs. sham laser: 33.87±16.06 vs. 34.88±19.55 vs. 35.82±21.10. Mean improvement on VAS score for acupuncture vs. massage: 16.32, p = 0.0052. Acupuncture vs. sham laser: 6.93, p = 0.327.	"Acupuncture is an effective short term treatment for patients with chronic neck pain, but there is only limited evidence for long term effects after five treatments."	Data suggest acupuncture superior to massage.

Kalauokala ni 2001 RCT	6.0	N = 135 with chronic LBP.	Acupuncture vs. massage vs. sham laser acupuncture for 10 treatments within 10 weeks.	Participants with higher expectations had greater baseline functional disability than those with lower expectations, as measured by baseline Roland score (mean, 13.2 vs. 11.1, $p = 0.01$ ) and by mean summary of SF-12 Physical Health score (35.7 vs. 38.8, $p = 0.05$ ).	"The results of this study suggest that patient expectations may influence clinical outcome independently of the treatment itself. In contrast, general optimism about treatment, divorced from a specific treatment, is not strongly associated with outcome."	Data suggest patient expectations influence outcomes.
Gam 1998 RCT	6.0	N = 67 with myofasci al trigger points (MTrP) in neck and shoulder (at least 3 months duration).	Ultrasound plus exercise plus massage vs. sham ultrasound plus exercise plus massage vs. a control group twice a week for 4 weeks.	No significant differences found in analgesic usage and VAS scores at rest and on function between groups.	"[M]assage and exercise reduces the number of intensity of MTrP, but this reduction had little impact on the patients' neck and shoulder complaints."	Compliance with exercise 68% at 6 months. Control group worse ratings week after randomization and treatment initiation, and higher medication use suggest problem of bias from using wait-listing controls. Baseline differences considerable; controls had longer symptom duration (12 vs. 7.5 months for placebo ultrasound vs. 4 months active ultrasound). Utilization of massage in first 2 groups co- intervention and somewhat limits conclusions regarding utility of ultrasound or massage.
Melzack 1983 RCT	5.5	N = 41 with LBP (mean duration 36 weeks).	TENS vs. massage twice a week for 30 minutes each.	No statistically significant differences between two groups on any pain or ROM measures before treatment. Negative correlations between pain scores and SLR indicate that large pain decreases are associated with large negative scores (improved).	"The results indicate that pain-relief scores provide valuable information and can easily be obtained from patients for whom pain is a major symptom."	Data suggest comparable in efficiency.
Werners 1999 RCT	5.0	N = 152 with LBP.	Inferential therapy vs. motorized lumbar traction and massage for 6 sessions over a 2-to 3-week	Mean VAS score before treatment was 50 (inferential therapy) and 51 (motorized lumbar traction and massage). After treatment VAS scores	"This study shows a progressive fall in Oswestry Disability Index and pain visual analog scale scores in patients with low back pain treated with	Data suggest comparable in efficiency.

			period.	dropped to 46 and 44 and to 42 and 39 at 3 months.	either interferential therapy or motorized lumbar traction and massage. There was no difference in the improvement between the two groups at the end of treatment. Although there is evidence from several trials that traction alone is ineffective in the management of low back pain, this study could not exclude some effect from the concomitant massage."	
Cen 2003 RCT	4.5	N = 31 with neck pain.	In phase I, Group A received TCTM treatment, Group B received exercise; Group C was the control. In phase II, Groups A and B discontinued treatment program to evaluate follow- up effects; Group C received both TCTM and exercise.	Mean (SD) ROM scores in extension normal range group A vs. B vs. C before phase 1/after phase l/after phase II: $40.38\pm12.52/49.38\pm13$ . 71 (p <0.01 compared with pre-test)/49.25± 11.18 (p <0.01 compared with pre- test) vs. 44.38\pm12.96/ 48.38\pm11.8/47.38± 11.11 vs. 46.5\pm15.26/ 46.8\pm13.59/53.1± 11.84 (p <0.05).	"Traditional Chinese Therapeutic Massage provided significant benefit to those suffering from neck pain. Further studies need to address the combination of the treatments using TCTM and the therapies in mainstream medicine."	Study emphasized ranges of motion and not more functional outcomes. Data suggest minimal differences of unclear significance.
Yang 2012 RCT	4.0	N = 52 with glenohu meral internal rotation limitation.	Massage, PT provided massage to posterior deltoid, infraspinatus, and teres minor, 18 minutes, 2 times a week for 4 weeks (n = 29) vs. controls, physical therapist applied light hand touch on the muscles, 10 minutes, 2 times a week for 4 weeks (n = 23). Follow-ups: baseline and 4 weeks	Mean degree internal rotation ROM: massage vs. control: $54.9^{\circ}$ vs. $34.9^{\circ}$ , p $\leq$ 0.001. FLEX-SF: 40.5° vs. 31.7, p $\leq$ 0.001. Mean muscle tightness: 0.42 vs. 0.51, p $\leq$ 0.05.	"Massage was an effective treatment for patients with posterior shoulder tightness, but was less effective in patients with longer duration of symptoms, higher functional limitation, and less posterior deltoid tightness."	Many methodological details sparse, impairing strong conclusions.

Hsieh 1992 RCT	4.0	N = 85 with subacute and chronic LBP.	Manipulation vs. massage vs. use of a corset vs. use of transcutaneous muscle stimulation (TMS) for 3 weeks.	Both ROLBPQ and RMAS showed good internal consistency with alpha co-efficients ranging from 0.77 to 0.93. Both instruments showed a significant difference between chiropractic manipulation and massage (p <0.05).	"Traditional Chinese Therapeutic Massage provided significant benefit to those suffering from neck pain. Further studies need to address the combination of the treatments using TCTM and the therapies in mainstream medicine."	Data suggest massage effective.
Ferrell 1997 RCT	4.0	N = 33 with elderly patients with chronic pain.	Walking (6-week supervised walking program) vs. a pain education program (heat, cold, massage, relaxation and distraction) vs. usual care.	Both intervention groups improved in pain and performance- based measures of functional status (p <0.05).	"[D]ata suggest that patient education and fitness walking can improve overall pain management and related functional limitations among elderly people with chronic musculoskeletal pain."	Mixed patients, may not be relevant to trigger points. Data suggest fitness exercise effective.
Hasson 2004 RCT	4.0	N = 129 with diffuse and long- term musculo- skeletal pain.	Massage vs. mental relaxation for 6-10 sessions, each 30 minutes.	Mean (SD) muscle pain massage vs. mental relaxation before intervention/ after intervention/3 months: 45.6±22/ 60.1±25/45.3±27.1 vs. 49.5±24.1/ 51.6 ±30/50.3±27.7; p <0.01.	"Massage, but not mental relaxation, is beneficial in attenuating diffuse musculoskeletal symptoms. Beneficial effects were registered only during treatment."	Many details sparse. Co- interventions uncontrolled. Data suggest modest differences between groups mostly massage better at post interventions, no meaningful differences at 3 months.

## **MYOFASCIAL RELEASE**

Myofascial release is a soft-tissue treatment technique that is most commonly used to treat myofascial pain. There are no quality studies identified regarding myofascial release. It is sometimes performed in conjunction with massage. Other providers may use this therapy in conjunction with or instead of trigger point injections or needling.

Recommendation: Myofascial Release for Trigger Points/Myofascial Pain

There is no recommendation for myofascial release for trigger points/myofascial pain. It may be used as an option in place of trigger point injections (not to exceed 4 to 6 treatments).

Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

Myofascial release has not been shown to be effective. It is not invasive, but the treatment is passive and moderately costly. There are active interventions shown to be efficacious.

#### Evidence for the Use of Myofascial Release

There are no quality studies evaluating the use of myofascial release for trigger points/myofascial pain.

## **ELECTRICAL THERAPIES**

There are multiple forms of electrical therapies used to treat musculoskeletal pain. These include transcutaneous electrical stimulation (TENS), percutaneous electrical nerve stimulation (PENS), H-

Wave<sup>®</sup> stimulation, sympathetic electrotherapy, microcurrent, and interferential. The mechanism(s) of action, if any, are unclear.

## HIGH VOLTAGE GALVANIC, H-WAVE STIMULATION, INTERFERENTIAL THERAPY, MICROCURRENT, IONTOPHORESIS

High voltage galvanic, H-wave stimulation, interferential therapy, microcurrent, and iontophoresis are electrical therapies. They are commonly believed to be efficacious through distraction or through promoting healing. Iontophoresis additionally attempts to transdermally deliver medications, typically glucocorticosteroids NSAIDs, lidocaine, etc., through the dermis to the target tissue.

## Recommendation: High Voltage Galvanic Therapy, H-Wave Stimulation, Interferential Therapy, Microcurrent, or Iontophoresis for Trigger Points/Myofascial Pain

There is no recommendation for or against high voltage galvanic, H-wave stimulation, interferential therapy, microcurrent, or iontophoresis for the treatment of trigger points/myofascial pain.

## Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials for these electrical therapies. Electrical therapies are not invasive, have low adverse effects and are moderately costly. As there is no quality evidence, there is no recommendation for or against these treatments.

## Evidence for the Use of High Voltage Galvanic, H-Wave Stimulation, Interferential Therapy, Microcurrent, or Iontophoresis

There are no quality studies evaluating the use of high voltage galvanic, H-wave stimulation, interferential therapy, microcurrent, or iontophoresis for trigger points/myofascial pain.

## PERCUTANEOUS ELECTRICAL NERVE STIMULATION (PENS)

Percutaneous electrical nerve stimulation involves inserting needles to a depth of 1 to 4 centimeters around a nerve serving a painful area. The techniques described in available studies differ.

#### Recommendation: PENS for Trigger Points/Myofascial Pain PENS is not recommended for treating trigger points/myofascial pain.

## Strength of Evidence - Not Recommended, Insufficient Evidence (I)

#### Rationale for Recommendation

PENS has been evaluated in small scale, short-term studies of LBP, but no quality studies have been reported for treatment of trigger points/myofascial pain. PENS is minimally invasive and no significant adverse effects have been reported (although most articles failed to include a section on complications). However, it is high cost and with absence of evidence of efficacy, it is not recommended.

#### Evidence for the Use of PENS

There are no quality studies evaluating the use of PENS for trigger points/myofascial pain.

## TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS)

Transcutaneous electrical nerve stimulation (TENS) is a modality to control pain through electrical stimulation delivered by pads placed on the surface of the skin for the treatment of many painful conditions, including both non-inflammatory and inflammatory disorders. (Gemignani 91; van Tulder 06; Long 91; Khadilkar 06; Shealy 03; Richardson 81; Rushton 02) Either a low-intensity prolonged (30 plus minutes) stimulation through an active electrode over the painful area or a higher intensity over the painful area for a brief (15 to 30 minutes) amount of time (commonly referred to as hyperstimulation analgesia) are the two most common treatment protocols. (Robinson 96) There are reports that both low- and high-frequency TENS stimulate the endogenous opioid system, but the type of response is dependent on frequency of stimulation. Through these mechanisms, it is theorized that there may be a mechanism for increased

physical activity in TENS users. (Richardson 80) Low intensity, high-frequency stimulation is generally 80 to 200Hz, whereas brief higher intensity low frequency is generally 4 to 8Hz. Some studies do not report the frequency of the stimulation.

Recommendation: TENS for Trigger Points/Myofascial Pain

There is no recommendation for or against use of TENS for treatment of trigger points/myofascial pain.

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality studies for trigger points/myofascial pain. (Hsueh 97; Chee 86) Most of the quality evidence is available on treating spine pain. (Oosterhof 06; Oosterhof 08; Koke 04; Chiu 05; Vitiello 07; Bloodworth 04; Deyo 90; Jarzem 05) TENS is not invasive, has no significant adverse effects, and is moderately costly, but there is no evidence of efficacy for trigger points/myofascial pain. Other treatments have documented efficacy. There is no recommendation for or against the use of TENS.

## Evidence for the Use of TENS

There are no quality studies evaluating the use of TENS for trigger points/myofascial pain.

## INJECTION THERAPIES ANESTHETIC AND/OR CORTICOSTEROID INJECTIONS

These injections are targeted directly into those muscle knots or clinically tender spots and typically consist of an anesthetic with or without glucocorticoid. (Han 97; Eff Hither 00) The goal is to resolve the muscle knot.

#### 1. Recommendation: Trigger Point Injections Using Local Anesthetic

Trigger point injections consisting solely of a topical anesthetic such as bupivacaine are recommended as a second or tertiary option for subacute or chronic trigger points that are not resolving. (Adjunctive use of a glucocorticosteroid is not recommended. (Porta 00))

*Indications* – Persistent moderate to severe trigger points not resolving with more conservative means (e.g., NSAID, progressive aerobic exercises, and other exercises).

*Frequency/Duration* – Up to 4 injections a session with a follow-up appointment to assess subjective and objective measures of efficacy. Injections should not be repeated more than every 3 to 4 weeks. (Ojala 06) If results are not satisfactory after the first injection, a second may be attempted. If there are not subjective and objective improvements at that point, further injections are not recommended. (Ojala 06) In general, up to 3 injections are recommended to allow sufficient time to (re)establish a program of active therapy or identify modalities for successful self-application. Repeated injections should be linked to subjective and objective functional improvements. The use of therapeutic injections without participation in an active exercise or rehabilitation program is not recommended. (Kamanli 05, Wheeler 01)

*Indications for Discontinuation* – Resolution, intolerance, completion of 2 set(s) of injections without materially affecting the condition.

## Strength of Evidence – Recommended, Evidence (C)

2. Recommendation: Trigger Point Injections Using Glucocorticosteroids Glucocorticosteroids are not recommended for use in trigger point injections. (Porta 00)

## Strength of Evidence – Not Recommended, Evidence (C)

#### Rationale for Recommendations

The literature on this subject is heterogeneous. Study designs, health outcomes assessed, interventions performed all differ widely across these studies. (Byrn 93; Sonne 85) The highest quality study that addressed a typical patient with periscapular or cervical tender points or trigger points found no difference between bupivacaine and botulinum other than much lower cost for bupivacaine. (Graboski 05) The next highest quality study of typical patients suggests anesthetic injections were superior to saline. (Hameroff 81) There

are no long-term studies or follow-up to suggest enduring benefits of these injections. There is no evidence that a steroid is required for efficacy of these injections, particularly those that are tender point injections. (Porta 00) Considering glucocorticosteroids also have adverse effects, use of glucocorticosteroids in these injections is not recommended. A study evaluated injection with 1% lidocaine versus lidocaine/water mixture and suggested that the lidocaine/water mixture had less injection site pain and better pain outcomes at 14 days after injection, (Iwama 00) however, another report by the same author found no differences among 4 injection mixtures. (Iwama 01) These injections are invasive, have rare adverse effects, (Garvey 89) and are moderately costly depending on number. An injectable anesthetic, typically either lidocaine or bupivacaine are recommended. (Iwama 00, Kamanli 05) There are no studies evaluating them on a longer term basis, though there are studies suggesting benefits lasting up to 14 days. (Collee 91) Acupuncture is an alternative to these injections.

#### *Evidence for the Use of Anesthetic and/or Corticosteroid Injections* There is 1 high- and 7 moderate-quality RCTs or crossover trials incorporated into this analysis.

Author/Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Collée 1991 RCT	8.5	N = 41 with iliac crest pain syndrome.	Single local injection of 5ml lignocaine, 0.5% (L) vs. 5ml isotonic saline (S).	In L group, mean pain score at Day 14 30.5, in S group 43.8; difference between both treatment groups significant (p <0.05).	"Our data demonstrate an effect of a local injection with lignocaine that is somewhat larger than an injection with saline which also has some beneficial effect. The difference is evident in the rheumatology setting but not in the general practice setting."	Data suggest injections with lignocaine are superior to saline.
Hameroff 1981 RCT	7.0	N = 18 with myofascial syndrome.	Trigger point injections of bupivacaine 0.5% vs. etidocaine 1% vs. saline.	Significant improvement compared with saline was found for both injections for average pain, percent time pain felt, and effect of pain on activity.	"[T]rigger point injections with bupivacaine and etidocaine were generally preferred over saline in several pain- related categories"	Small sample size. Injection with anesthetics appear superior to saline injections.
Garvey 1989 RCT	7.0	N = 63 with subacute low back strain.	Lidocaine (n = 13), lidocaine plus steroid (n = 14), acupuncture (n = 20) vs. vapocoolant plus acupressure (n = 16).	Results indicated that therapy without injected medication (63% improvement rate) at least as effective as therapy with drug injection (42% improvement rate), $p = 0.09$ .	"Trigger-point therapy seems to be a useful adjunct In treatment of low-back strain. The injected substance apparently is not the critical factor, since direct mechanical stimulus to the trigger- point seems to give symptomatic relief equal to that of treatment with various types of injected medication."	Patients had low back strain, raising questions whether data are applicable to trigger points. Data suggest injections effective, but medication used is not.
Tschopp 1996 RCT	6.0	N = 107 with trigger points in masticator y muscles; minority in neck.	Most painful trigger point injected with 1mL of bupivacaine 0.25% vs. lignocaine 1% vs. NS. Up to 7 injection sessions.	Numbers of injection sessions required were 1 (10.3%), 2 (57.9%) 3 (27.1%) and 4 (4.7%). No differences in numbers of sessions required	"[R]elief of pain is mainly due to reflex mechanisms rather than to the pharmacological effects of the injected solutions. Physiological saline solution is recommended for use in local injection therapy."	Some baseline differences, especially in NS group. Variable numbers of injections. Data suggest no differences between

				between 3 groups.		groups.
Byrn 1993 RCT	5.5	N = 40 with whiplash syndrome.	Normal saline vs. sterile water subcutaneous injections.	After 3 months, minimum pain level fell from 2.2 to 1.4 in sterile water group; not reduced in saline group (p <0.02); maximum fell from 8.1 to 3.8 in sterile water group, 8.3 to 7.5 in saline group (p <0.001). After 3 months, 19 of 20 in sterile water group assessed their condition as generally improved; 6 in saline group felt they were better.	"After 8 months there were still significant differences for minimum pain score and for mobility but not for maximum pain or for self-assessment of improvement."	Details of randomization not presented and randomization is inferred from balance between 2 groups. Complications of sterile water injections include severe pain requiring pre-medication in some individuals and muscle spasm lasting 10 minutes in some.
Iwama 2001 Crossover Trial	4.5	N = 20 with "various chronic myofascial pains to the same degree in both sides of neck, shoulder, or lumbar regions".	0.5mL 1% lidocaine plus 1.5mL water vs. 0.5mL 1% lidocaine plus NS vs. 0.5mL 1% mepivacaine plus 1.5mL water vs. 0.5mL 0.25% bupivacaine plus 1.5mL water.	Lower pain scores after injection with water diluted lidocaine (1) and mepivacaine (1) vs. saline-diluted lidocaine (2.5) and bupivacaine (2). No differences in analgesic scores at follow-up.	"The suitable type of local anesthetic may be lidocaine or mepivacaine, and the most effective water- diluted concentration is considered to be 0.2% to 0.25%."	Study may have mixed symptomatic and asymptomatic patients/voluntee rs (not well described). Small sample sizes. Blinding unclear. Follow- up times unclear. Patient's side apparently randomized to 1 treatment. Short- term trial. Whether pain on injection is helpful or harmful for treatment of trigger point patients unclear. Data suggest no longer term differences.
Iwama 2000 Crossover Trial	4.5	N = 20 with trigger points in bilateral supra- scapular regions.	2mL of 0.5mL lidocaine 1% plus 1.5mL water vs. 2mL lidocaine 1%. 2 weeks follow-up	Injection pain score 1.3±0.2 lidocaine/water vs. 3.0±0.4 lidocaine (p <0.05).	"[T]rigger-point injection with a mixture of 1% lidocaine with water at a ratio of 1:3 is more effective than injection with neat 1% lidocaine."	Patient's side apparently randomized to 1 treatment and opposite treatment on other side. Short-term trial. Data suggest Lidocaine diluted with water superior.

Porta	4.0	N = 40	Botulinum plus	Reduction in pain	"These results indicate	Lack of a
2000		with	bupivacaine vs.	score in BTX-A	the superior efficacy of	placebo control
		myofascial	depot	group at 60 days	BTX-A over	limits
RCT		pain	methylprednisolone	post-injection	conventional steroid	conclusions.
		syndrome.	plus bupivacaine.	greater than at 30	treatment in patients	
				days (-5.5 vs3.9),	suffering from MPS,	
				whereas effect of	when combined with	
				steroid had begun	appropriate	
				to wane.	physiotherapy."	

## **BOTULINUM INJECTIONS**

Botulinum injections have antinociceptive properties and have been used to produce muscle paresis. (Gobel 06; Qerama 06; Richards 07; Ferrante 05) Adherents believe that this pharmacologically induced resting of the muscle is useful as a treatment for a number of MSDs. However, these injections have primarily been used for numerous non-occupational conditions such as cervical dystonia (Lew 97,00; Benecke 05; Brans 96, 98; Brashear 98; Brin 99; Tassorelli 06; Poewe 98; Pappert 08; Ostergaard 94; Odergren 98; Laubis-Herrmann 02; Ranoux 08; Naumann 02; Lu 95; Comella 05; Truong 05), torticollis (Tsui 86; Blackie 90; Lorentz 91; Moore 91; Koller 90; Greene 90; Gelb 89), strabismus, migraine prophylaxis (Evers 04), blepharospasm, (Charles 04) neuropathic pain after neck dissection, (Wittekindt 06) and severe primary axillary hyperhidrosis (see Chronic Pain Guidelines). (Charles 04; Naumann 01) They have also been used to treat upper back and myofascial pain, (Gobel 06, Porta 04; DeAndres 03) Botulinum injections have been used to treat trigger points and myofascial pain. These injections are thought to directly treat a taut muscle band and to have analgesic properties. (Qerama 06; Richards 07; Ferrante 05)

#### Recommendation: Botulinum Injections for Trigger Points/Myofascial Pain Botulinum injections are moderately not recommended for treating trigger points/myofascial pain.

## Strength of Evidence – Moderately Not Recommended, Evidence (B)

#### Rationale for Recommendation

Botulinum toxin A to treat trigger points/myofascial pain has been evaluated in multiple quality studies with nearly all studies finding a lack of benefit when compared with saline. Within this body of evidence, there are five high-quality studies with the four largest studies all finding a lack of clear benefit. (Göbel 06; Ferrante 05; Lew 08; Ojala 06) One study suggested some modest results compared with saline injection (Göbel 06) but this study utilized a more severely affected patient population, suggested low magnitude of benefit, and the benefit was eliminated by the end of the trial. Moderate-quality studies also failed to find benefits from botulinum injection. (Ojala 06; Qerama 06) There is one positive study in favor of botulinum, (Porta 00) but the control group utilized a depot preparation of methylprednisolone and thus, that study cannot directly address the utility of botulinum injections. Botulinum does not appear superior to bupivacaine (Graboski 05) and the latter has a much lower adverse effect profile. Those studies that evaluated botulinum injections for the management of neck pain or tension headaches did not demonstrate benefits greater than placebo. (Wheeler 98, 01; Silberstein 06) Botulinum injections are invasive, have adverse effects that include fatalities (Li 05) and are costly. There are no quality studies available with long-term follow-up. (Argoff 03, Difazio 02) These injections induce weakness, yet many of the most successful interventions identified in other sections of this guideline build strength and/or endurance. There are other types of successful treatments identified elsewhere that are recommended. With quality evidence lacking of meaningful benefits, botulinum injections are moderately not recommended for treatment of trigger points/myofascial pain.

#### Evidence for Botulinum Injections

There are 5 high- (one with two reports) and 6 moderate-quality RCTs or crossover trials incorporated into this analysis.

е	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Study Type						

Göbel 2006 RCT	9.0	N = 145 with moderate to severe cervical and/or shoulder myofascial pain syndrome.	Botulinum type A injections (40U per site) vs. saline injections for 12 weeks.	No differences between groups in duration of daily pain, sleep, and number of trigger points over course of study. Mean pain intensity scores lower with Dysport® than with placebo at Week 4 (p = 0.001), which persisted until end of study (p = 0.02).	"[I]njections of 400 Ipsen units of Dysport at 10 individualized trigger points significantly improved pain levels 4-6 weeks after treatment."	Excluded 24 (17%) "major protocol deviations." Recommendation s for repeat injections (patients: 82% botulinum vs. 60% saline; physicians: 89% vs. 68%) suggest high saline response rate. Adverse effects more common with botulinum, mostly muscle soreness. Data suggest no long-term benefits.
Ojala 2006 Crossover Trial	9.0	N = 31 with myofascial pain in neck and shoulder of 2 plus months duration.	Botulinum toxin A (5U in 3 to 7 trigger points, mean 28U total) vs. saline given on 2 occasions 4 weeks apart; 4 weeks follow- up.	Pain ratings (baseline/4 weeks after 1st injection/4 weeks after second injection): saline-BTA 5.2±2.2/4.0±2.0/ 3.3±2.3 vs. BTA-saline 4.2±2.2/ 3.2±2.1/2.6±1.8. No difference between small doses of botulinum toxin A; NS.	"Our study shows that there was no difference between the effect of small doses of botulinum toxin A and those of physiological saline in the treatment of myofascial pain syndrome."	Data suggest Botulinum toxin type A has no benefit over saline in trigger point injections.
Freund 2000, 2002 RCT	9.0	N = 30 with chronic neck pain and with musculoske letal signs of 6> months duration.	Patients receiving botulinum injections (100U, 40ng) diluted in 1ml saline vs. 1mL saline; 4 weeks follow-up.	Mean (SE) total pain Botox group vs. saline group at preinjection/ Week 4: 16.2 vs. 13.3/ 10.0 vs. 14.1; p<0.01. No significant preinjection difference between both groups with respect to mean ROM.	"BTX-A treatment of subjects with chronic WAD II neck pain resulted in a significant (p < 0.01) improvement in ROM and subjective pain compared to a placebo group, but only a trend to improvement in subjective functioning. We do not draw any specific conclusions due to small sample size and short follow-up period."	Two reports of apparently 1 trial. Some details not well described, but combined between 2 reports. Results suggest minimal differences. Short- term follow-up.
Ferrante 2005 RCT	8.0	N = 132 cervical and/or thoracic myofascial pain.	Botulinum toxin type A (10, 25 or 50U) vs. saline into up to 5 trigger points. Maximum doses each group: 0, 50, 125, 250U per patient. Patients subsequently received myofascial	No dose-response relationship between dose administered and pain ratings (placebo - 403.8 vs. 10U -510.2 vs. 25U -256.5 vs. 50U - 767.9). Pain scores at 12 weeks: 49.3±33.1 vs. 52.2±31.4 vs. 50.2±23.9 vs. 51.0±25.8 respectively.	"[I]njection of BoNT-A directly into trigger points did not improve cervicothoracic myofascial pain."	Multiple co- interventions over duration of observations. No dose-response. Data suggest lack of efficacy.

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Lew	8.0	N = 29	release physical therapy and amitriptyline, ibuprofen, and propoxyphene- acetaminophen napsylate; 8 weeks follow- up. Injection of	VAS scores NS	"Trends toward	Data suggest
2008 RCT		cervical or upper back pain of myofascial origin at least 2 months duration.	Botox A (BTX-A 50U per site) vs. saline injection; 6 months follow- up.	between groups (p- value ranges 0.18- 0.59). SF-36 scores had better outcomes in the BTX-A group compared to controls at month 4 for the bodily pain scale, ( $p = 0.016$ ), but not at other intervals (0.5, 1, 2, 3, 6 months). BTX-A had greater improvements in mental health scale compared to controls at 1 month follow up, ( $p = 0.005$ ) but not other intervals.	improvements in VAS and NDI scores of the BTX- A group are encouraging, but they were possibly due to a placebo effect and were not statistically significant."	botulinum injections not different from saline.
Qerama 2006 RCT	7.0	N = 30 chronic myofascial pain with trigger points in infraspinatu s muscle.	Botulinum toxin A (50 units/0.25mL of BTXA) vs. 0.25mL of isotonic saline.	Pain reductions tended to favor botulinum group, but not significant. The "results do not support a specific antinociceptive and analgesic effect of botulinum toxin A." While a tendency for groups to differ in baseline median pain score, both groups had a similar reduction in pain scores from baseline to end of follow-up. "Thus, differences in baseline pain score have had little influence on the results."	"The results do not support a specific antinociceptive and analgesic effect of botulinum toxin A."	Non-statistically significant baseline differences may have favored botulinum, as initial severity measures worse in saline group. Isolation of study population to limited disease affecting infraspinatus is both unique study strength to evaluate a more homogeneous population, yet may limit generalizability. EMG activity suggested reduction in muscle activity but no effect on pain scores.
Braker 2008 RCT	6.0	N = 20 cervical myofascial pain 2-48 weeks (median 5 months) after whiplash injury.	BTXA 50U vs. saline into 4 "tender" points. Injections with "electromyogra m guidance"; 24 weeks follow- up.	BTXA had lower VAS pain ratings at Weeks 9 and 18, but NS. ROM not different. Global assessments not different.	"BTXA treatment has some efficacy when administered within 1 year of the (whiplash injury). However, a large, well-designed clinical trial is needed to draw final conclusions."	Small sample size. Trend towards more adverse effects in BTXA group (40% vs. 0%, p = 0.07). Data not different for outcomes.
Wheeler 1998	6.0	N = 33 chronic predominan	Botulinum toxin A 50U vs. 100U vs. placebo; 4	Neck pain and disability VAS scores not different. 100U	"Although no statistically significant benefit	Both groups had significant improvement.

RCT		tly unilateral neck pain attributed to a trigger point in cervico- thoracic paravertebr al musculatur e.	month follow- up.	botulinum injection appeared to trend toward superiority over placebo at 4 months by algometer. No clear dose-response relationship. Trend towards more clinical improvement in the 100U group (54%) compared to the other two groups (both 36%), but NS.	of botulinum toxin type A over placebo was demonstrated in this study, the high incidence of patients who were asymptomatic after a second injection suggests that further research is needed to determine whether higher dosages and sequential injections in a larger cohort might show a botulinum toxin type A effect."	Those who underwent 2nd injection of 100 U had results that trended more toward greater improvement over placebo. Results suggest an injection of Botulinum A 100 Units does not appear more beneficial than saline.
Wheeler 2001 RCT	6.0	N = 50 chronic neck pain.	Botulinum toxin A (dose per site unclear, mean 207-231U) vs. placebo; 4 month follow- up.	NPAD (0/4/8/12/16 weeks): BTXA (54.2/ 52.2/45.6/38.0/40.1) vs. saline (48.2/39.0/36.6/ 34.6/32.9).	"[A] single dose treatment without physical therapy is not effective for chronic neck pain."	Blinding procedures not well described. Data suggest not efficacious.
Cheshire 1994 Crossover Trial	5.5	N = 6 myofascial pain syndrome, mean 3 years duration.	Botulinum toxin A vs. saline injections. 8 weeks follow- up.	4/6 experienced at least 30% reduction in pain on at least 2 occasions vs. none for saline.	"Botoxappears to be an effective treatment for focal myofascial pain disorders."	Excluded as tiny sample size (n = 6). Details sparse, especially for randomization and blinding.
Porta 2000 RCT	4.0	N = 40 myofascial pain syndrome.	Compared botulinum injections plus bupivacaine vs. depot methylprednisolon e plus bupivacaine.	Reduction in pain score in BTX-A group at 60 days post-injection was greater than at 30 days (-5.5 vs. -3.9), whereas effect of steroid had begun to wane.	"These results indicate the superior efficacy of BTX-A over conventional steroid treatment in patients suffering from MPS, when combined with appropriate physiotherapy."	Lack of a placebo control limits conclusions.

## **PSYCHOLOGICAL SERVICES**

Psychological and behavioral factors are key components of chronic nonmalignant pain conditions. Evaluation of patients with chronic trigger points/myofascial pain or pain that is not resolving as expected for psychological factors is frequently utilized (see Chronic Pain Guidelines for indications for cognitive behavioral therapy).

Recommendation: Psychological Evaluation for Chronic Trigger Points/Myofascial Pain

A psychological evaluation is recommended as part of the evaluation and management of patients with chronic trigger points/myofascial pain to assess whether psychological factors will need to be considered and treated as part of the overall treatment plan.

#### Strength of Evidence – Recommended, Insufficient Evidence (I)

#### Rational for Recommendation

There are no quality trials. Psychological assessments are routinely accomplished to evaluate for the existence and impacts of psychological factors. Evaluations are generally low cost and, when done

appropriately, present little risk of harm. In patients with chronic pain, psychological evaluation is recommended to evaluate these issues and potentially assist in developing a better treatment plan.

#### Evidence for Psychological Evaluations

There are no quality studies of psychological evaluation for trigger points/myofascial pain.

#### BIOFEEDBACK

Biofeedback has been used for myofascial pain/trigger points.

#### Recommendation: Biofeedback for Trigger Points/Myofascial Pain

There is no recommendation for or against the use of biofeedback for treatment trigger points/myofascial pain.

#### Strength of Evidence - No Recommendation, Insufficient Evidence (I)

#### Rationale for Recommendation

There are no quality trials addressing biofeedback for myofascial pain/trigger point patients. There are few quality trials of low back pain and other disorders and the available moderate quality trials of LBP conflict. (Altmaier 92; Bush 85; Donaldson 94; Asfour 90) Biofeedback is not invasive, has no complications, is moderately expensive, but with a lack of demonstrated efficacy, there is no recommendation.

## WORK CONDITIONING, WORK HARDENING, AND EARLY INTERVENTION PROGRAMS

Few patients with myofascial pain syndrome/trigger points require these programs (see Chronic Pain Guidelines).

## INTERDISCIPLINARY PAIN REHABILITATION PROGRAMS

These programs are generally not required for trigger point/myofascial pain patients (see Chronic Pain Guidelines).

## **APPENDIX 1. THORACIC OUTLET COMPRESSION SYNDROME (TOS)**

Thoracic outlet syndrome (TOS) is one of the most controversial entrapment syndromes (Sheth 01; Peet 56; Huang 04; Wilbourn 90, 99; Roos 90; Fechter 93; Franklin 00, 13) with some experts questioning its existence. (Campbell 91; Sheth 01; Huang 04) There are no quality epidemiological studies linking this disorder to work. The most commonly reported cause is congenital. As there are no quality trials for treatment, it is included in this Appendix for informational purposes as there are patients affected with this condition who require evaluation and consideration of treatment.

Generally, when an anatomic cause of neurovascular compression includes unequivocal objective evidence of sequelae of compression, the syndrome is not controversial. (Wilbourn 90; Watson 09) The vast majority of cases include vague symptoms without a clearly identifiable source of compression (e.g., cervical rib); thus, those cases are often controversial. (Sheth 01; Wilbourn 90) Additional evidence from cadaver studies suggests only approximately 10% of people have bilaterally normal anatomy with most individuals having anomalous bands in the thoracic outlet, raising concerns about the implications of congenital bands identified in the context of a diagnosis of TOS. (Juvonen 95; Roos 90) While there are different classification schemes, (Campbell 91) there are 3 syndromes that are generally recognized (Sheth 01; Huang 04; Watson 09):

- 1. Compression of the brachial plexus (neurogenic TOS)
- 2. Compression of the subclavian vein or artery (vascular TOS)
- 3. Non-specific or Disputed TOS (aka symptomatic TOS)

Vascular TOS is thought to be relatively rare, affecting approximately 5% of cases, (Fechter 93; Campbell 91; Roos 71, 87; Rob 58; Sanders 90; Huges 48) involving thrombosis rarely. (Schubart 86; Perler 86) The majority of TOS cases are believed to have neurological symptoms and are disputed. (Wilbourn 90; Roos 87) Only 1 to 3% of cases are believed to have true neurogenic TOS in a C8/T1 distribution. (Wilbourn 90; Gilliatt 84; Wilbourn 88) Adding to the confusion is the diversity of symptoms that purportedly may include facial pain, visual disturbances, tachycardia, dyspnea, dysphagias, vertigo, tinnitus, and sleep disturbances. (Atasoy 96; Fechter 93; Kaymak 04; Ozcakar 05) Many of these symptoms are also characteristic of anxiety disorders.

Thoracic outlet syndrome is believed to involve compression of the neurological or vascular structures connecting the arm to the torso due to any cause. (Peet 56) Syndrome labels that have been used and causes include cervical rib syndrome, costoclavicular syndrome, first thoracic rib syndrome, scalenus anticus syndrome, hyperabduction syndrome, cervicobrachial neurovascular compression syndrome, shoulder-arm syndrome, hyperextension-hyperflexion cervical injury, brachial plexus adhesions, clavicular fracture malunion, effort vein thrombosis syndrome, macromastia, pneumatic hammer syndrome, brachial plexus syndrome, Adson's syndrome, Paget-Schroetter syndrome, shoulder-girdle syndrome, fractured clavicle syndrome, cervical brachial compression syndrome, pectoralis minor syndrome, humeral head syndrome, and Rucksack paralysis. (Sheth 01; Singh 09; Iwuagwu 05; Alexandre 05; Crotti 05; Yoo 09) The most common cause is believed to be congenital. (Fechter 93)

There are 3 broad anatomic locations for compression: 1) scalene triangle; 2) costoclavicular triangle; and 3) the subcoracoid space. (Watson 09) The scalene triangle is mostly muscular along with the first thoracic rib and transmits the nerve trunks between the scalenus muscles as well as the subclavian vein and artery near the first rib. The costoclavicular triangle is formed by the first rib, clavicle, subclavius muscle, upper border of the scapula, and subscapularis muscle. The subcoracoid space is beneath the coracoid process and is closely related to the clavipectoral fascia and costocoracoid ligament. Patients are often thought to have multiple abnormalities, (Pang 88) which adds to confusion and controversies.

It has been speculated there may be occupational physical factors associated with TOS, (Parziale 00) but there are no confirming quality epidemiological studies. Also, there is no consistent pattern of work tasks that has been postulated as risk factors as both heavy work and sedentary work have been proposed. (Parziale 00) Similarly, overhead work is another purported factor for which quality evidence is lacking. There are no quality studies evaluation treatments for TOS. (Vanti 07; Povlsen 10) Non-operative treatment

has been implemented for initial patient management. Surgery has been utilized for those who fail non-operative treatment. (Sheth 01)

## **DIAGNOSTIC CRITERIA**

There are no consensus diagnostic criteria for TOS. Symptoms in vascular TOS cases include reduced pulses, ischemia, venous engorgement, and edema that may vary depending on the degree of arterial and/or venous narrowing. (Huang 04; Wilbourn 99; Sheth 01) Symptoms in many cases of neurogenic TOS include shoulder and neck pain, pain radiating into the upper extremity, muscle weakness in the upper extremity, and loss of sensation in the distribution of the affected neurological structure(s). Poorly defined symptoms largely lacking specificity contribute to the controversial nature of, and difficulty diagnosing, disputed TOS. (Wilbourn 90; Mackinnon 96) The differential diagnosis of neurogenic TOS as well as disputed TOS is thought to prominently include cervical radiculopathy, cervical spondylosis, carpal tunnel syndrome, pronator syndrome, radial nerve entrapments, ulnar neuropathies, fibromyalgia, multiple sclerosis, vasculitis, and Horner's syndrome. (Campbell 91; Mackinnon 96; Muscolino 08; Huang 04; Watson 09)

The false positive rates of normal patients vs. CTS in a comparative study for common physical examination maneuvers used for TOS raise considerable concern about diagnostic accuracy of common physical examination maneuvers. (Nord 08) The false-positive rate for the Adson A test in normals was 9% vs. 42% in CTS patients. For Adson B, the false positive rate was 20% vs. 45%. For the costoclavicular maneuver, the rates were 48% vs. 16%, for the Roos elevated arm test the values were 77% vs. 30% and the supraclavicular pressure test 94% vs. 56%. Similar results have been elsewhere reported. (Seror 05) Similar findings have been reported in healthy subjects, although requiring at least 3 of 4 positive maneuvers (Adson's (paresthesias or loss radial pulse with deep inspiration and head rotated, hands in lap), costoclavicular maneuver (shoulders in an exaggerated military narrowing space between the clavicle and first rib), elevated arm stress test (Roos), supraclavicular pressure in supraclavicular fossa causing pain and paresthesias in upper extremity) (Nord 08) with provocation of arm symptoms has been reported to decrease the false positive rate. (Plewa 98) Clinical tests are also reportedly poor predictors for surgical outcomes. (Sadeghi-Azandaryani 09)

## SPECIAL STUDIES AND DIAGNOSTIC AND TREATMENT CONSIDERATIONS

There are no quality studies of diagnostic tests for any of the types of TOS; an evidence-based work-up protocol is not available. Specific tests are recommended to focus on the type of TOS thought to be present. For all types of TOS, x-ray is recommended. X-rays may be needed of shoulders, neck, and chest. (Vanti 07) Other studies may be helpful, including MRI with contrast and CT. (Vanti 07) MRI with provocative maneuvers has been reported to improve the value of the MRI. (Demirbag 07) Electrodiagnostic studies are also recommended, particularly to attempt to seek objective evidence of neurological impingement.

1. Recommendation: X-ray to Diagnose TOS X-ray is recommended to diagnose TOS.

Strength of Evidence – Recommended, Insufficient Evidence (I)

2. Recommendation: MRI or CT to Diagnose TOS MRI or CT is recommended to diagnose TOS.

Strength of Evidence – Recommended, Insufficient Evidence (I)

 Recommendation: Electrodiagnostic Studies to Diagnose TOS Electrodiagnostic studies are recommended to diagnose TOS, and are required prior to surgery. (Washington State 10)

Strength of Evidence – Recommended, Insufficient Evidence (I)

Rationale for Recommendations

Although there are no quality studies, (Tolson 04; Vanti 07; Tsao 14) electrodiagnostic studies are recommended. Prior to considering surgery, they are recommended as the outcomes in workers' compensation patients are reportedly poor. (Franklin 00, 13; Washington State 10) For vascular TOS cases, diagnostic test considerations may include duplex scanning, Dopplers, venography, venous pressure measurements, (Sanders 90) as well as coagulation studies, chest radiography, spiral CT, MRI and ventilation/ perfusion nuclear scanning. Arterial TOS is evaluated with diagnostic tests that may include duplex scanning, Dopplers, and arteriograms. (Sanders 08) Additional studies may be required to evaluate other potential disorders in the differential such as neoplasia.

## WORK ACTIVITIES

There are no quality studies of work activities for patients with TOS. Patients appear able to return to occupational activities. Limitations are sometimes utilized to avoid symptomatic aggravation especially for more physically demanding work. Limitations may include no overhead use, no lifting more than 15 pounds, no heavy carrying, no repeated forceful use and avoidance of other activities that significantly increase symptoms. (Sheth 01) Limitations are gradually reduced as recovery progresses. If surgery is performed, there is a similar need for workplace limitations that are gradually reduced.

## **INITIAL CARE**

Initial care of TOS is based on the exact type of compression. For acute venous TOS with potential thrombus, evaluation and confirmation of the thrombus is urgent. Treatment is based on confirmation of thrombus; otherwise there usually are no urgent care requirements. For arterial TOS cases, evaluation and urgent management may be required depending on the severity of the compression and vascular impairment. Disputed TOS cases require evaluation of disparate conditions in the differential diagnosis. Initial care may include symptomatic management with over-the-counter analgesics, self-applications of heat and ice.

## **FOLLOW-UP VISITS**

Patients with TOS generally require at least a few, and generally many follow-up appointments for purposes of performing diagnostic tests, monitoring symptoms and signs for consistent findings, evaluating and advancing treatment, and gradually reducing limitations if the progress allows. Patients with slower resolution, those in need of operative care, or those with other accompanying disorders will require considerably greater numbers of appointments. Frequencies of appointments may also be greater where workplace limitations are required and job demands are higher. Post-operative rehabilitation can be considerable, particularly in disputed TOS cases with workers compensation. (Goff 98; Green 91; Franklin 00) In those cases, there may be a requirement for therapy on a prolonged basis to recover as much function as possible.

## **MEDICATIONS**

Arterial TOS treatment is thought to generally require surgery to address a structural defect. (Watson 09; Jamieson 96; Huang 04; Sultan 01) Medications are generally not indicated as a primary initial focus, although some use of thrombolytics and anticoagulation may be required acutely.

Acute venous TOS with documented thrombosis is often treated by anticoagulation (Adams 65; Drapanas 66; Swinton 68; Tilney 70; Dalal 72; Prescott 79; Campbell 77; Glovickzki 86; Ameli 87; Brochner 89) and may involve fibrinolytics depending on severity of the condition and perceived risks. (de Leon 09; Tilney 70; Ameli 87; Becker 83; Taylor 85; Druy 85; Vogel 85; Glovickzki 86; Smith-Behn 86; Huey 87; Landercasper 87; O'Leary 87; Shuttleworth 87; Wiles 87) Thrombectomy (Sanders 90; Drapanas 66; DeWeese 70; Gaylis 74) and venoplasty (de Leon 09) are options for treatment of moderate to severe clots.

True neurological TOS is thought to be largely associated with anatomic defects. (Watson 09) However, authors have required a trial of non-operative care and reserved surgical treatment for those with advancing neurological symptoms or signs. (Watson 09; Dale 82; Mingoli 95; Sanders 02; Degeorges 04) For disputed TOS, the existence of the condition, evaluation, and treatment are controversial. (Wilbourn 90) Non-operative treatments are generally the first interventions attempted. (Lindgren 97; Sharp 01) Specific

recommendations have included NSAIDs, (Parziele 00; Crosby 04) muscle relaxants, (Parziele 00; Crosby 04) biofeedback, (Parziale 00; Crosby 04) and anti-depressants. (Parziale 00)

In the absence of quality evidence, it is recommended that neurogenic TOS and disputed TOS be treated as neuropathic pain and managed according to the recommendations in the Chronic Pain Guideline. Briefly, **recommended medications** include: NSAIDs (Evidence C); concomitant use of cytoprotective agents in patients with a high-risk factor profile who also have indications for NSAIDs (Evidence C); acetaminophen particularly if NSAIDs are contraindicated (Evidence C); tricyclic anti-depressants (Evidence C); duloxetine for limited use in select diabetic peripheral neuropathy and peripheral neuropathic pain patients (Evidence B); carbamazepine as a potential adjunct as a 4th- or 5th-line treatment for neuropathic pain (Evidence C); carbamazepine as a potential adjunct as a fourth- or fifth-line treatment (Evidence I); gabapentin and pregabalin (Evidence A); dextromethorphan for select patients (Evidence C); muscle relaxants for brief use as a second- or third-line agent in acute exacerbations (Evidence I); and opioids for select patients (Evidence I).

## PHYSICAL METHODS

Use of orthoses have been reported, (Nakatsuchi 95) but there are no quality trials evaluating their use. The general tendency is for the conditions to improve, thus it is unclear whether the orthosis improves the condition beyond what would otherwise occur and thus there is no recommendation for or against their use [No Recommendation, Insufficient Evidence (I)]. Therapy including exercise (Hanif 07; Kenny 93; Crosby 04; Vanti 07; Lindgren 97; Campbell 91; Peet 56; Anthony 93; Leffert 91, 94; Parziale 00; Sucher 90; Buonocore 98; Bilancini 92) and education (Leffert 91, 94; Novak 95, 96; Walsh 02; Tyson 75; Crosby 04; Liebenson 88) is recommended [Recommended, Insufficient Evidence (I)]. Exercise has often been prescribed. (Hanif 07; Kenny 93; Crosby 04; Vanti 07; Lindgren 97) However, the diversity of exercise regimens with completely different emphases underscores the lack of quality evidence. Some emphasize strengthening of the shoulder girdle (Campbell 91; Peet 56; Vanti 07) with most patients reporting improvement in their symptoms. (Peet 56; Kenny 93) Studies recommending therapy programs include postural training; (Crosby 04; Anthony 93; Leffert 91, 94; Parziale 00) exercises emphasizing stretching; (Sucher 90) massage traction and isometric exercises; (Buonocore 98) massage and acupuncture; (Peng 99) and exercises emphasizing postural physiotherapy including diaphragmatic breathing. (Bilancini 92) Evidence of efficacy is poor and it has been suspected many patients naturally improve over time. (Campbell 91) Thus, there is no recommendation for any particular exercise regimen.

There is no quality evidence for other treatments and there is no recommendation for or against [**No Recommendation**, **Insufficient Evidence (I)**] all of the following: acupuncture, diathermy, infrared, ultrasound, laser, manual therapy, mobilization, (Boissonot 99) manipulation, massage, high-voltage galvanic, H-wave stimulation, iontophoresis, microcurrent, (Crosby 04) percutaneous electrical nerve stimulation (PENS), sympathetic electrotherapy, transcutaneous electrical stimulation (TENS), (Crosby 04) taping, magnets, pulsed electromagnetic frequency, and interferential.

Home exercise programs have been utilized with 88% satisfaction at 2 years in a large longitudinal case series (Lindgren 97) and are recommended [**Recommended**, **Insufficient Evidence (I)**]. Weight loss has been used as a treatment (Crosby 04; Leffert 91; Novak 95; Parziale 00) and is recommended [**Recommended**, **Insufficient Evidence (I)**] particularly among obese patients. Psychological distress has been reportedly elevated in these patients with a suggestion for psychological care, relaxation and endurance training (Gockel 95) which are recommended for select patients [**Recommended**, **Insufficient Evidence (I)**].

In the absence of quality evidence, it is recommended neurogenic TOS and disputed TOS be treated as neuropathic pain and managed according to the recommendations in the Chronic Pain Guideline. Briefly, **recommended physical/other methods** include altering sleep posture to determine if there is reduction in pain/other symptoms (Evidence I); aerobic exercise (Evidence A); trial of aquatic therapy for patients who meet referral criteria for supervised exercise therapy and have co-morbidities that preclude effective participation in a weight-bearing physical activity (Evidence I); self-application of low-tech heat therapy (Evidence I); transcutaneous electrical nerve stimulation (TENS) as an adjunct for more efficacious

treatments (Evidence C); psychological evaluation as part of evaluation and management of patients with chronic pain in order to assess whether psychological factors will need to be considered and treated as part of treatment plan (Evidence I); cognitive-behavioral therapy as an adjunct to an interdisciplinary program for the treatment of chronic pain (Evidence C); multidisciplinary or interdisciplinary pain rehabilitation program with a focus on behavioral or cognitive-behavioral approaches combined with conditioning exercise for patients with chronic pain who demonstrate partial/total work incapacity due to pain (Evidence I); and work conditioning, work hardening, and early intervention programs (Evidence I).

## **INJECTIONS**

Injections are thought to have generally limited indications in TOS patients. Primarily, trigger point injections and limited use of blocks have been used. (Crosby 04) Trigger point injections are recommended for patients with discrete trigger points that are consistent in location **[Recommended, Insufficient Evidence (I)]**. Based on quality evidence in the thoracic spine, it is suggested that these consist solely of an injectable anesthetic or dry needling, rather than include a glucocorticosteroid.

## SURGICAL CONSIDERATIONS

Patients with vascular TOS, especially arterial, are thought to have surgical indications. Additionally, surgery is often considered for patients with venous TOS. Chronic venous symptoms are typically treated with non-operative treatments including exercises, avoiding exacerbating symptoms and surgical treatments if symptoms are sufficiently severe and non-operative means are unsuccessful. Surgical treatments for intrinsic venous obstruction include endovenectomy, (Campbell 77; Jacobson 77; Aziz 86; Gloviczki 86) patch graft, or venous bypass. (Sanders 90; Inahara 68; Rabinowitz 71; Hashmonai 76; Campbell 77; Jacobson 77; Pittam 87; Jain 88) As mentioned above, thrombectomy and venoplasty are options for treatment of moderate to severe clots. Surgical treatments for extrinsic compression include first rib resection, (Etheredge 79; Siegel 67; Adams 68; Gergoudis 80; Urschel 91; Bondarev 92; Atasoy 96; Pupka 04; Mercier 73; Glass 75; Etheredge 79; Druy 85; Vogel 85; Taylor 85; Gloviczki 86; Brochner 89; Salo 88; Pittam 87; Shuttleworth 87) clavulectomy, (Lord 88; Pairolero 81; Adams 68; Rabinowitz 71; Etheredge 79; Gloviczki 86) or costoclavicular ligament and subclavius muscle division. (Sanders 90; McLaughlin 39; McCleery 51; Adams 68; Rabinowitz 71; Daskalakis 80; Salo 88) Surgery is recommended for treatment of vascular TOS **[Recommended, Insufficient Evidence (I)]**.

For neurogenic TOS and, particularly disputed TOS, surgical treatment has been considered controversial. Prior to considering surgery, treatment should consist of a supervised exercise and postural program with documented compliance from at least 8 to 12 weeks (Parziale 00) to 3 to 6 months and failure to improve then documented. (Kenny 93) Impairment of work or activities of daily living should also be present. (Washington State 10) Surgery is recommended for highly select cases of neurogenic TOS [Recommended, Insufficient Evidence (I)]. There is no recommendation for or against surgery for disputed TOS [No Recommendation, Insufficient Evidence (I)].

Surgery has most often involved resection of either a cervical rib or the first thoracic rib via supraclavicular, infraclavicular or transaxillary approaches. (Sheth 01; Murphy 1910; Clagett 62; Roos 66; Molina 98; Edwards 99; Toso 99; McCarthy 99; Sanders 96; Donaghy 99) Additional operative procedures include neurolysis, (Sheth 01) fasciectomy, (Sheth 01) and scalenectomy or scalenotomy. (Cina 94; Mattson 04; Qvarfordt 84; Roos 82) The only RCT is of low quality, although it suggests transaxillary rib resection was superior to supraclavicular neuroplasty of the brachial plexus. (Sheth 05)

Some studies report excellent or good post-operative results in approximately 80% of patients. (Degeorges 04; Green 91; Mattson 04; Sanders 96) However, post-surgical prognoses of disputed TOS in a workers' compensation population is reportedly poor (Goff 98; Green 91) with a population-based study reporting 60% remaining disabled from work at 1 year after surgery. (Franklin 00) Similar relatively poor surgical results have been reported in a pain clinic treating patients who sustained their injuries in motor vehicle crashes with 47% reporting very good pain relief vs. 20% with non-operative treatment, (Mailis 95) as well as a study that found accidents similarly conveyed a worse prognosis. (Green 91) Surgical complications are high; these procedures are sources of malpractice exposure. (Parziale 00) A considerable minority of patients undergoing surgery redevelop symptoms, estimated at 15 to 30%. (Sanders 90; Atasoy 04)

## *Evidence for Thoracic Outlet Syndrome* There is 1 low-quality RCT comparing operative techniques for thoracic outlet syndrome.

Author/ Title Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments	
	Comparison of Operative Techniques						
Sheth 2005	3.0	N = 55 with TOS with mainly	Supraclavicular neuroplasty of brachial plexus vs.	Pain (pre/post) TFRR (77±3/ 39±7) vs. (82±3/	"Transaxillary first rib resection provided better	Different follow-up intervals in the 2 groups (31 vs. 42	
RCT		pain. Excluded cervical rib, intrinsic weakness or primarily vascular findings.	transaxillary first rib resection. Mean 37 months follow-up.	61 $\pm$ 7), p = 0.03. Percentage pain relief 52 $\pm$ 8% vs. 30 $\pm$ 7%, p <0.005. Good or excellent results in 75% vs. 48%, p = 0.02.	relief of symptoms than (supraclavicular neuroplasty of brachial plexus)."	months) and results reported for "post-op" timeframe. Post- op care is unspecified. Data appear to suggest TFRR superior.	

## APPENDIX 2: EVIDENCE TABLES FOR LOW-QUALITY RANDOMIZED CONTROLLED TRIALS AND NON-RANDOMIZED STUDIES

The following low-quality randomized controlled studies (RCTs) and other studies were reviewed by the Evidence-based Practice Shoulder Panel to be all inclusive, but were not relied upon for purposes of the development of this document's guidance on treatments because they were not of high quality due to one or more errors (e.g., lack of defined methodology, incomplete database searches, selective use of the studies and inadequate or incorrect interpretation of the studies' results, etc.), which may render the conclusions invalid. ACOEM's Methodology requires that only moderate- to high-quality literature be used in making recommendations. (Harris 08)

EVERCISE	<u>// /// S</u>					
Author/Yea r Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Ginn 2005 RCT	3.5	N = 138 with "unilateral shoulder pain of local mechanic al origin"; mostly chronic pain, mean7.3 months.	2x3 trial with 3 interventions and allocations based on whether painful ROM or pain free arc. Injection (methylprednisolone acetate 40mg subacromial space "under local anaesthesia with lignocaine") vs. exercise (stretches to restore normal ROM, HEP, appointments 1 a week) vs. MPM [electrophysical modalities (interferential therapy, ultrasound, hot packs, ice packs), passive joint mobilization (shoulder, SC and AC joints), ROM exercises and strengthening exercises], 2 times a week; 5 weeks follow-up.	Percentages improved over 5 weeks: 78% injection vs. 77% exercise vs. 85% MPM (NS). In painful ROM subgroup, these were 77% vs. 74% vs. 85%. Pain intensity (baseline/5 weeks): injection (1.9/0.2) vs. exercise (1.5/0.3) vs. MPM 2.6/1.0).	"Exercise therapy aimed at restoring neuromuscular control, corticosteroid injection and multiple physical modalities and range of motion exercises are equally effective in the short-term treatment of shoulder pain, with exercise therapy and corticosteroid injection being less costly to administer."	Diagnoses unclear. Some baseline differences. Unclear if anesthetic injected into subacromial space or volume used. Attention bias may overstate value of MPM program.
Ginn 1997 RCT	3.5	N = 66 mostly tendinitis; however, included frozen shoulder, OA, etc., 8 with "no diagnosis" ; symptom duration unclear.	Individualized physical therapy (1 month, stretching, strengthening, motor retraining exercises) vs. non- interventional controls; 1 month treatment with no follow-up beyond that time.	Worse disability scores at end of treatment in 11% of PT vs. 50% of wait-listed controls, p <0.001. Greater pain- free ROM in treatment group, p = 0.006.	"[T]he physical therapy approach used in this study is effective in improving shoulder function in subjects experiencing pain of mechanical origin."	Non-interventional wait-listed controls bias in favor of intervention. Therapy group younger at baseline (56 vs. 63). Many diagnoses included, but not described if differed between groups. No follow- up beyond treatment interval.

## **EXERCISE/PHYSICAL THERAPY**

#### ROTATOR CUFF TENDINOPATHIES, INCLUDING ROTATOR CUFF TENDINITIS, ROTATOR CUFF TEARS, SUPRASPINATUS TENDINITIS, CALCIFIC TENDINITIS, IMPINGEMENT SYNDROME, BICIPITAL TENDINITIS, ROTATOR CUFF TEARS AND SUBACROMIAL BURSITIS

		BURSITIS				
Author/	Scor	Sample	Comparison	Results	Conclusion	Comments
Year Study Type	e (0- 11)	Size	Group			
Study Type			N	ISAIDs		
Heere 1988	3.0	N = 1,290	Piroxicam 40mg QD	Able to accomplish	"There was no	Three studies, 1
3 RCTs, 1 Report	3.0	acute sprains and tendinitis of ankle, shoulder, hand, foot.	for 2 days, then 20mg QD vs. Indomethacin 50mg TID for 2 days, then 25mg TID vs. naproxen 500mg BID for 2 days then 250mg AM and 500mg PM vs. aspirin 4g/day. Usual treatment 14 days, but ranged 7- 28 days.	Able to accomplish activity in 16 days: study 1 Piroxicam 74% vs. Indomethacin 73%. Study 2 piroxicam 79% vs. naproxen 69% (p<0.025). Study 3 piroxicam 80% vs. aspirin 65% (p<0.02). Trend towards more excellent results in tendinitis group with piroxicam.	difference between piroxicam and indomethacin in the number of patients who were able to accomplish normal daily activity within 16 days. Furthermore, although efficacy was comparable among the NSAIDs, piroxicam was significantly better-tolerated than either naproxen or indomethacin."	report, details sparse. Heterogenous, large patient population; 49 patients on aspirin. Variable duration of treatment length.
			Аси	puncture		
Peng 1987	1.5	N = 37	Electroacupuncture	Percentage pain	"A double blind	Patients not well
r ong roor	1.0	chronic	with selection of	improvements in the	evaluation of	described
Case series		neck/	regional tender	case series ranged	acupuncture	(included
		shoulder pain >3 months (all failed "convention al and placebo treatments for their pain," and failed 1 or more treatments.	points and traditional acupuncture points "in the vicinity of the lesion." Up to 15 appointments.	from 0-100%.	results and hypnotic profiles failed to demonstrate any correlation between the two."	neck/shoulder patients with wide variety of unspecified conditions). Methods sparse; appears a case series with main purpose to determine effect of hypnotic score.
0 4000	0.5	N 50		otherapy	(0.A./	
Speer 1996 RCT	3.5	N = 50 shoulder surgeries, all interscalene blocks.	Cryotherapy (Cryo/Cuff) vs. no cryotherapy; 21 days follow-up.	Less post-operative pain (56.49 vs. 30.90); more comfort lying in bed ( $p = 0.02$ ); less perceived need for narcotics (65.93 vs. 85.17, $p = 0.02$ ). Less pain post-op Day 10 ( $p = 0.007$ ).	"We speculate that the effectiveness of cryo-therapy seen in our patients was mainly due to cutaneous and subcutaneous analgesia."	Subjects not well described. Sparse methods. Data suggest efficacy.
Speer 2001	3.5	N = 70	Cryotherapy (Polar	Limited data provided.	"Continuous cryo-	Subjects not well
RCT		arthroscopic or open shoulder surgery; all interscalene blocks.	Care, Breg) vs. no cryotherapy; 21 days follow-up.	Less pain at Day 14, p = 0.043, and Day 21, p = 0.06.	therapy is an efficacious and safe adjunct to postoperative pain control."	described. Results suggest cryotherapy associated with lower post- operative pain.
			Ult	rasound		

Herrera- Lasso 1993	3.5	N = 30 untreated "painful shoulder syndrome" (includes bicipital tendinitis, supraspinat us tendinitis, subdeltoid bursitis, peri- arthritis.	Ultrasound (10 minutes, start at 0.5W/cm <sup>2</sup> , increasing to 1W/cm <sup>2</sup> ) vs. TENS (20 minutes at 50Hz). Variable number of treatments, stated to be up to "maximum" 13 (but, numbers in table state mean 13±3 and 13±5). All treated with exercises and infrared.	VAS pain (pre/post): Ultrasound 7/2 vs. 6.7/2.1 (graphic interpretations), p = 0.94. No differences in flexion (p = 0.38) or abduction (p = 0.50).	"A statistically significant and clinically important improvement in pain and range of flexion was shown for both packages of treatment but no statistically significant difference was found between them."	Mix of diagnoses, limiting value of study. No stratified analyses. Variable number of treatments. Some baseline differences, e.g., longer duration in ultrasound (9 vs. 5 months). Sparse results. Data suggest equal (in)efficaciousnes s.
Chard 1000	0.5	NL 40 with		tromagnetic Field	"Deee record	Ne sleest -
Chard 1988 RCT	3.5	N = 43 with rotator cuff tendinitis at least 3 months despite conservativ e treatment.	Long (8 hour) vs. short (2 hour) low pulsed electro- magnetic field (72±3 Hz, 380±10µs pulse duration) QD for 8 weeks.	Improvement in total pain scores over 8 weeks not different (graphic data). Improvement in painful arc and pain on resisted abduction both significantly favored 8- hour treatment group at 4 weeks, but not other time intervals.	"Dose response was therefore not linear, both high and low dose regimes producing similar overall outcome."	No placebo control. Double blinded between 2 groups, but no sham group limits utility. No dose response noted, suggest pulsed EMF may be ineffective, but modest trends favor long- treatment group.
Citakar 2005	25	N = 40		nipulation and Mobilizatio		Limited baseline
Citaker 2005 RCT	2.5	impingemen t syndrome.	Mobilization group (hot packs, manual mobilization, theraband exercises) vs. proprioceptive neuromuscular	No between group differences in ranges of motion. Both groups improved equally. No between group differences in USLA scores.	"[M]obilization and proprioceptive neuromuscular facilitation methods are both similarly effective,	Limited baseline patient description and other methods. Numerous co- interventions, which are not
Senbursa	2.5	N = 30	facilitation (PNF) (hot packs, PNF and theraband). Hot packs for 20 minutes. Rehab program of 20 minutes session and "3 weeks of theraband exercises." Daily home	Night pain (pre/post):	but mobilization was painless and better tolerated than (proprioceptive neuromuscular facilitation)."	well described and limit findings. Sparse

			scapular mobilization, glenohumeral joint mobilization, proprioceptive neuromuscular facilitation techniques), 3 times week for 4 weeks (12 sessions).	Shoolwaye Theremy	and improving function."	
Rompe 1998	3.5	N = 100	High-energy ESWT	Shockwave Therapy Complete	"Treatment of	High dropouts in
RCT		Gartner I or II chronic calcific tendinitis (at least 5mm diameter) ≥12 months duration, failing 6 months conservative therapy.	(1500 impulses of 0.06mJ/mm <sup>2</sup> ) vs. low ESWT (1500 impulses of 0.28mJ/mm <sup>2</sup> ). All in high-energy given brachial plexus anesthesia. 24 weeks follow-up.	disintegration of calcium deposit in 64% high vs. 50% low energy groups, p<0.01. Excellent or good results at 24 weeks in 68% high vs. 52% low energy, p<0.01. No improvements in 10% vs. 24%.	calcific tendinitis of the shoulder with ESWT needs further study to determine the most efficient energy densities and the optimal number of shock wave applications."	first 6 weeks with reasons not well described. High non-compliance rate. Patients not described.
Cosentino 2003 RCT	3.5	N = 70 chronic calcific tendinitis (minutes 10mm diameter) and at least 10 months symptoms.	ESWT (1200 chocks/session, 120 shocks a minute, 0.03mJ/mm <sup>2</sup> for first 5 minutes, then progressively increased to 0.28mJ/mm <sup>2</sup> ) vs. Sham (0mJ/mm <sup>2</sup> ). 4 treatments, every 4- 7 days	Constant Scores (baseline/6mo): ESWT (45/71) vs. sham (48/50), p <0.001. Partial/complete resorption of calcium in 40/31% ESWT.	"Because of its good tolerance, safety, and clinical radiological response, ESWT can be considered as an alternative treatment for chronic calcific tendinitis of the shoulder."	Patients not well described. Data suggest efficacy.
Sabeti- Aschraf 2005 RCT	3.5	N = 50 with calcific tendinitis of the rotator cuff verified radiographi cally	Treatment Group A: wxtracorporeal shockwave therapy (1000 impulses of 0.08 mJ/mm2 with a frequency of 4 Hz) on maximum tenderness point found via therapist (n= 25) vs. treatment Group B: extracorporeal shockwave therapy (1000 impulses of 0.08 mJ/mm2 with a frequency of 4 Hz) administered and located via 'Lithotrack system' (n = 25). Follow-up at 12 weeks.	Group A VAS scores:Mean (SD) -Baseline- 68.36 (±15.26), 12 weeks-33.36 (± 20.05).Group B VAS scores:Mean (SD) -Baseline- 65.96 (±21.71), 12 weeks-18.21 (± 21.32).Group A CMSscores: Mean (SD) -Baseline- 55.64 (±12.5), 12 weeks- 73.0(± 16.25).Group B CMSscores: Mean (SD) -Baseline- 49.4 (±12.33), 12 weeks-79.48 (± 15.1).	"Three-dimensional, computer-assisted navigation reveals significantly better results and is therefore recommended when extracorporeal shock wave therapy is used in the treatment of calcific tendinitis of the rotator cuff."	Methodological details sparse.
Loew	3.0	N = 195	RCT (A) (n = 80):	RCT (A): Constant	"Shockwave	Combination of 2
1999 2 RCTs in one report	2.0 (2 RCT	total with Gartner I or II chronic calcific	Groups 0 (no treatment) vs. 1 (1 session, 2000 impulses of	scores (baseline/3 months): group 0 (44.5/47.8) vs. 1 (39.4/51.6) vs. 2	therapy should be considered for chronic pain due to calcific tendinitis	trials in 1 report with limited descriptions of each RCT.

	s)	tendinitis (at least 1.5cm diameter) with symptoms at least 12 months, resistant to physiothera py and injections chronic calcifying tendinitis.	0.1mJ/mm <sup>2</sup> ) vs. 2 (1 session, 2000 impulses of 0.3mJ/mm <sup>2</sup> ) vs. 3 (same as Group 2, but 2 sessions 1 week apart). 3 months follow-up. RCT (B) (n = 115): group 2B (1 session, 2000 impulses of 0.3mJ/mm <sup>2</sup> ) vs. 3B (same as group 2B, but 2 sessions 1 week apart); 6 months follow-up. All local anesthetic injections and fluoroscopic	(39.0/63.7) vs. 3 (43.5/68.5). Percents improved by group: 5%/30%/60%/70%. Numbers with radiological disappearance of disintegration of calcium $2/4/1//12$ . RCT (B): Constant scores (pre/6 months): group 2B $(49.3\pm13.4/67.7\pm17.8)$ ) vs. 3B $(44.4\pm12.2/69.6\pm19.8)$ ).	which is resistant to conservative treatment."	Patients not well described. Many other details sparse. High dropouts in RCT (B) due to decisions for other treatments including surgery. Data suggest efficacy compared with no treatment.
Rompe 2001 Comparative Clinical Trial	2.0	N = 79 chronic calcifying tendinitis.	guidance. Surgical extirpation vs. EWST (3000 impulses at 0.6mJ/mm <sup>2</sup> ); 2-year follow-up.	UCLA scores (0/12 months-24 months): Surgery (17.8/30.3/32.4) vs. ESWT (19.0/28.3/29.1).	"For patients with inhomogenous deposits, high- energy extracorporeal shock wave therapy was equivalent to surgery and should be given priority because of its noninvasiveness."	Study claims quasi- randomized, assignment to group based on health insurance claims acceptance vs. denial. Data suggest comparable efficacy for inhomogenous deposits, but surgery modestly superior for homogenous calcium deposits, (not randomized on that facto)r.
	μ		Glucocortico	steroid Injections		on mar laotojn.
Chen 2006 RCT Watson	3.5	N = 40 sonographic confirmation of subacromial bursitis over 1 month duration. N = 200	Blind vs. ultrasound-guided injection of betamethasone 1mL (dose used not published) and 1mL 1% lidocaine. 1 week follow-up.	Shoulder abduction ROM (baseline/1 week): blind (71.0±12.4/100±18.2) vs. ultrasound-guided (69.0±14.7/139.3±20. 1), p <0.05 between groups.	"Ultrasound may be used as an adjuvant tool in guiding the needle accurately into the inflamed subacromial bursa. The ultrasound- guided injection technique can result in significant improvement in shoulder abduction range of motion as compared with the blind injection technique I treating patients with subacromial bursitis."	Minimal results and no description of patients; 1 week follow-up and no longer term results. Ultrasound guided with better outcomes of short term ROM. Randomized by
2008		with shoulder	randomized from 5 centers;	differences between the 3 groups at	diagnosis and treatment of	training of providers. Data

RCT		pain	trained/untrained/an d expert practices randomized patients into: corticosteroid injection group patients received 2 weeks of oral therapy 400mg of ibuprofen, 3 times/day with their appointment for shoulder injection from (n = 54/24/and 21) vs. Lignocaine injection group 2 weeks of oral therapy 400mg of ibuprofen, 3 times/day with their appointment for the shoulder injection (n = 52/25/and 24). Follow-up for 12 months.	baseline for age, gender, employment status and baseline British Shoulder Disability Questionnaire or BSDQ score. No statistical differences between groups for training/substance/un equal recruitment rates/ nd follow-up.	shoulder disorders does not make any difference to the outcome, in terms of pain and disability, 1 year later. Further, there is no advantage to injecting steroid in a group with predominant rotator cuff disorder."	suggest no difference between lignocaine and corticosteroid.
Ginn 2005	3.5	N = 138 with "unilateral	2x3 trial with 3 interventions and allocations based on	Percentages improved over 5 weeks: 78% injection	"Exercise therapy aimed at restoring neuromuscular	Diagnoses unclear. Some baseline
RCT		shoulder pain of local mechanical origin"; mostly chronic pain, mean7.3 months.	if painful ROM or pain free arc. Injection (methylprednisolone acetate 40mg subacromial space "under local anaesthesia with lignocaine") vs. exercise (stretches to restore normal ROM, HEP, appointments 1 week) vs. MPM [electrophysical modalities (interferential therapy, ultrasound, hot packs, ice packs), passive joint mobilization (shoulder, SC and AC joints), ROM exercises and strengthening exercises], 2 times a week; 5 weeks follow-up.	vs. 77% exercise vs. 85% MPM (NS). In painful ROM subgroup, these were 77% vs. 74% vs. 85%. Pain intensity (baseline/5 weeks): injection (1.9/0.2) vs. exercise (1.5/0.3) vs. MPM 2.6/1.0).	control, corticosteroid injection and multiple physical modalities and range of motion exercises are equally effective in the short-term treatment of shoulder pain, with exercise therapy and corticosteroid injection being less costly to administer."	differences. Unclear if anesthetic injected into subacromial space or volume used. Attention bias may overstate value of MPM program.
Hardy 1986 RCT	3.0	N = 40 with "acute" impingement syndrome. Symptoms	Placebo injection plus indomethacin 25mg QID vs. triamcinolone acetonide 40mg	Data not provided. "Changes in the clinical parameters measured were similar in each group	"The results suggest that radiographic findings are extremely common	Some details sparse. Report suggests although study is labeled as RCT,
		under 12 weeks, required	plus placebo indomethacin. Double dummy. May	and suggested that there is no difference in the short-term	in patients with the acute impingement syndrome, but that	main report is regarding x-ray findings.

		improved ROM with lidocaine injection.	reinject at 3 weeks. 6 weeks follow-up.	efficacy of these two methods of treatment." No differences between clinical responders and non-responders by x-ray findings.	they are not useful as prognostic indicators of the short-term response to medical treatment."	
Valtonen 1978 Comparative Clinical Trial	3.0	N = 60 with supraspinat us tendinitis.	Subacromial injection(s) of triamcinolone hexacetonide vs. methylprednisolone	General symptomatology scores (baseline/Week 1/Week 2/Week 3/Week 4/Week 6/Week 8): triamcinolone (3.77/0.97/1.24/1.43/1.26/.39/1.43) vs. methylprednisolone (3.70/0.73/0.93/1.04/1.17/1.20/1.30). Duration of relief of 56 days among 20/30 (66.7%) triamcinolone vs. 11/30 (36.7%) methylprednisolone (p = 0.046).	"Triamcinolone hexacetonide reduced pain, local tenderness and functional impairment to a greater degree than did methylprednisolone acetate."	Randomization process not described. Patients not well described, but appear mostly chronic. Methods appear consistent with comparative clinical trial. Optional 2nd injection after 1st ineffective. Variable follow- ups.
		Surgery: Imping	ement Syndrome and	(p = 0.046). d/or Rotator Cuff Tendir	oses without Tears	
Henkus	3.5	N = 57 with	Arthroscopic	Constant Score:	"No statistically	Baseline
2009 RCT		impingement syndrome.	bursectomy vs. acromioplasty. All treated with exercise program post-operatively.	bursectomy $69.6\pm18.2$ vs. acromioplasty $75.8\pm16.7$ , p=0.19. VAS pain scores also not different, though favored acromioplasty as well (p = 0.13).	significant differences were found between the two treatments [P]rimary subacromial impingement syndrome is largely intrinsic degenerative condition rather than an extrinsic mechanical disorder."	differences in gender, type 3 acromia. Variable follow-ups.
Connor 2000 RCT	3.0	N = 36 with failed prior impingement decompressio n.	Arthroscopic vs. open decompression.	94% arthroscopic vs. 44% open satisfied with procedure. ROM not different.	"Overall, revision arthroscopic subacromial decompression was superior to open revisionSince subacromial scaring may be the most important pathology, arthroscopy is less invasive, allowing earlier, unrestricted postoperative rehabilitation and proving more effective."	Large differences in workers compensation at baseline (72% open vs. 39% arthroscopic), represents randomization failure. Results may be substantially unreliable.
Montgomery 1994 Partially	2.0	N = 87; 88 with chronic, full-thickness rotator cuff	Open repair plus arthroplasty vs. arthroscopic debridement plus	Open repair group with 19/50 (38%) small or medium tears vs. 11/38	"Surgical repair of full-thickness rotator cuff tears provided results superior to	Patient selection entered into allocation (unclear number

randomized		tears with failure of rehabilitation.	subacromial decompression; 2- 5 year follow-up.	(28.9%). Massive tears in 14/50 (28%) of open repairs vs. 19/38 (50%). Mean UCLA scores 31 vs. 25, $p = 0.0028$ (no standard deviations provided). Satisfactory results in 78% vs. 61%.	those of arthroscopic debridement and subacromial decompression."	of patients randomized) with unequal group sizes (50 vs. 38). Baseline differences with more massive tears in debridement group. Uneven follow-up periods 2-5 years; sparse results. Low- quality trial as not fully randomized.
Mohtadi 2006 RCT	1.5	N = unknown Abstract states 40/group, however, intervention section states 43 in PT group.	Graded physiotherapy training (19 x 1- hour sessions; heat, cold, soft tissue therapy, active periscapular muscle training shoulder stabilizer strengthening; 3 a week, then tapered to 1 a week by Week 12) vs. arthroscopic subacromial decompression, then instructed in increasing active exercises (type, appointments not specified). 1-year follow-up	Constant scores (baseline/1 year): PT (34.8/57.0) vs. surgery (33.7/52.7) (NS).	"Neither physiotherapy nor surgery were very effective in reducing pain, improving activities of daily living, improving range of motion, or increasing strength in patients with rotator cuff disease with subacromial impingement."	Abstract form of paper only. Limited description. Data suggest equal (in)efficacy.
Watson 1985 RCT	0.5	N = Unclear; rotator cuff tears.	Apparently trial of different splinting techniques.	No quantified results	"A randomised prospective study showed that repair followed by splinting in abduction gave no better results than repair followed by resting the arm at the side."	Sparse discussion.
		Rotat	or Cuff Tendinopath	y: Post-operative Reha	bilitation	
Ogilvie- Harris 1993 RCT	3.5	N = 50 with rotator cuff tears ranging from 1 to 4cm.	Arthroscopic debridement (n = 25) vs. 25 patients with open rotator- cuff repair (n = 25). Surgical repair not described. Over 2 year follow-up.	Significant improvement in pain score post-op, $p =$ 0.0001. But no difference between groups for that improvement, $p =$ 0.51. 22% of open repair group; 64% arthroscopic debridement group had moderate loss of function, $p = 0.006$ in favor of open repair.	"We recommend the use of arthroscopic subacromial decompression and debridement for low- demand patients who require mainly pain relief and range of motion. Open repair is necessary if strength and functional recovery are the prime objectives."	Quasi- randomized every other patient. Sparse details; patients not well described. No short-term follow- up.
T'Jonck 1997	3.0	N = 32 with impingement at Stage II.	Open subacromial decompression (OSD), n = 15 vs.	UCLA score favored ASD (28.3±5.6 vs. OSD 24.5±5.45), p =	"Arthroscopic acromioplasty for impingement	Sparse details; no description of post-op

RCT			arthroscopic subacromial decompression (ASD), n = 17. 1- year follow-up.	0.046. Physical examinations not significant between groups.	syndrome without full thickness tears has been shown to result in rapid recovery and greater patient satisfaction; it is effective although not necessarily better than open standard acromioplasty in long term results."	rehabilitation or exercise and small sample size. Base-line differences in follow-up differed. (16 months for open vs. 12 for ASD). Data suggest arthroscopic advantages are short-term.
Singh 2001 RCT	2.5	N = 70 with undergoing arthroscopic (38) or open (32) shoulder surgeries.	Continuous cryo- therapy (Polar Care; n = 32) every 4 to 6 hours vs. non-cryo- therapy (n = 32) vs. warm water in continuous cryo- therapy unit (n = 5) for 21 days.	Sparse data. Greater reduction in pain at all intervals for cryo- therapy group at Day 14, p = 0.041 (apparently stratified results for arthroscopic group). Trend towards less pain Days 7-21 in open procedure treated patients (data not provided).	"Continuous cryotherapy is an efficacious and safe adjunct to post- operative pain control. It has been objectively shown to have a positive impact on subjective comfort variables such as pain, comfort, and sleep."	Sparse details; mixes procedures including open anterior/posterior shoulder stabilization, biceps tenodesis; arthroscopic subacromial decompression, biceps tenotomy, capsulorrhaphy, labral repair. Data suggest cryotherapy reduces short- term pain.
Speer 1996 RCT	2.5	N = 50 who underwent a shoulder operation (anterior shoulder stabilization (30), RC repair (24), Total shoulder arthroplasty (6).	Cryotherapy (Cryo/Cuff) 4 to 6 times daily and whenever necessary for 10 days post surgery (n = 25) vs. no cryotherapy (n = 25); 10-day follow- up.	Evening after surgery, cryotherapy group had worse pain (31.3%) vs. non-cryotherapy (56.5%), $p = 0.001$ . Less perceived need for narcotics evening of operation in cryo- therapy group (65.9) vs. non-cryotherapy (85.2), $p = 0.02$ . Day 10, cryo-therapy less severe pain 32.6 vs. 46.6, $p = 0.03$ . Post- op Day 10, cryo- therapy group less pain in shoulder than non-cryotherapy, $p =$ 0.007. Cryotherapy group less pain during rehab exercises than non- cryotherapy, $p =$ 0.001. Stiffness during exercises not significant.	"Cryotherapy offers a number of benefits for care of patients in the immediate postoperative period."	Mixed disorders; some details sparse. No intermediate or longer term follow-up. Data suggest some short-term benefits.
		·		pathies: Laser vs. Shar		
Saunders 1995 RCT	3.0	N = 24 with supraspinatu s tendinitis. Age 35-65 years.	Group 1 (n = 12) Laser (L) Low- power laser therapy. Treated using 820nm,	Laser vs. Dummy Laser (pain/muscle force/tenderness); 80% improved/improved/g	"[L]ow- power laser therapy with the parameters and dosage used in this study is	Small sample size. Details sparse.

			40mW laser probe working at 5000 Hz to produce dose of 30 J/cm2. vs. Group 2 (n = 12) Dummy laser (DL) treated using an identical probe Both groups received 9 different treatments over period of 3 weeks, 3 times per week for 180 seconds. Follow-up for 3	reater reduction) vs. 20% of patients improved/unchanged /no reduction) (p <0.05/p <0.001/p = 0.06)	recommended as a useful treatment for tendinitis.	
			weeks.	TENS	<u> </u>	
Baskurt 2006 RCT	3.5	N = 92 with stage I shoulder impingement syndrome.	Heat application 39°C for 20 minutes (n = 31) vs. TENS 100 Hz 0.1ms pulse duration for 20 minutes (n = 30) vs. heat plus TENS for 40 minutes (n = 31). Assessments (pressure pain threshold (PPT) and VAS) immediately after treatment.	No significant differences between groups.	"No statistically significant difference was found in PPT values and VAS scores before and immediately after the applications among the groups (p>0.05)."	Methodological details sparse.
				hies: Hyaluronate Inje		
Kim 2012 RCT	3.5	N = 105 patients diagnosed with subacromial impingement syndrome without a rotator cuff tear, age 40 and more.	Hyaluronate group mean age $55.9\pm7.9$ years, received 1 injection of 20mg pure Hyaluronate in 2ml each week for 3 weeks in subacromial space (n = 38) vs, corticosteroid group mean age $54.1\pm7.7$ years, received a 1-time injection of 5mg dexamethasone disodium phosphate diluted with 4ml lidocaine and 5ml saline (n = 42).	Both groups reported significantly different VAS scores in weeks 3, 6, and 12 compared to baseline ( $p < 0.0001$ ). Hyaluronate: Baseline – 58.6+19.3 Week 3 – 31.2+20.4 Week 6 – 27.4+21.2 Week 12 – 24.6+23.1 Corticosteroid: Baseline – 57.2+19.9 Week 3 – 46.8+20.9 Week 6 – 40.1+21.5 Week 12 – 36.9+26.5 Statistically, pain decreased more in hyaluronate group compared to corticosteroid ( $p =$ 0.0180). No significant differences seen in	"In the present study, a hyaluronic acid injection relieved pain better than a corticosteroid injection and improved the ROM and functional level as much as a corticosteroid injection for subacromial impingement syndrome."	80 patients analyzed of the 105: follow-up rate of 76%. Methodological details sparse. Data suggest no functional difference between groups, however Hyaluronate performed better in VAS measure.

Sengul 2008 RCT	3.5	N=50 patients with shoulder impingement syndrome.	Subacromial injections of sodium hyaluronate (n = 25) once weekly for 3 weeks vs. a daily program of local modalities (n = 25) for 2 weeks.	American Shoulder and Elbow Surgeons standardized shoulder assessment (ASES) or range of motion (ROM) either between weeks 3, 6, 12 and baseline, or between groups. No significant changes were found in ASES, or CMS scores and ROM between the groups.	"Sodium hyaluronate injections and local modalities have been found to be similarly effective. Either one of these methods may be included in a treatment program for patients with shoulder impingement syndrome."	Sparse details. No placebo. Injections compared with mix of treatments of questionable efficacy. Few differences statistically significant.
	Bat			/Middle vs. Low Energy		
Flurin 2013 RCT	2.0	N = 154 patients age 70 years or older with complete supraspinatu s tear that can be reduced without tendon release.	Decompression group (n = 73) vs. decompression + repair (Arthroscopic Group; n = 70). Follow-up time was 1 year for both groups.	with vs. without Subac All clinical outcomes significantly improved for both groups. Repair/decompressio n showed significant improvement compared with decompression only. Constant Score 36.39 vs. 31.27 (p = 0.041). ASES score 55.93 vs. 46.81 (p = 0.010). SST score 6.17 vs. 5 (p = 0.020).	"The clinical scores used in this study (Constant, ASS, SST) revealed that repair was better than decompression, which improved strength as expected, but surprisingly also pro- vided more pain relief."	Older population (<70 years old). Randomization not followed by 5/12 of centers originally in the centers. Methodological details sparse.
		Rotat	or Cuff Tears: Suture	Anchor Techniques C	ompared	
Aydin 2010 RCT	3.5	N = 68 patients with a full- thickness rotator cuff tear as shown by MRI.	Single-row arthroscopic repair group (n = 34) vs. double-row arthroscopic repair group (n = 34). Patients followed at 3, 6, 12 and 24 months. Mean last follow-up time was 36 months (range 24-40 months).	Mean pre-op constant 40.4 points in single-row group and 38.8 points in double-row group. At follow-up, constant score was 82.2 in single-row group compared to 78.8 in double-row group. No significant difference found between groups at any follow-up time.	"This prospective randomized evaluation of single- row compared with double-row rotator cuff fixation did not show a significant difference in outcome in terms of clinical results in small to medium tears."	No differences between groups.
Gartsman 2013 Randomized Study	2.5	N = 90 with repairable, full thickness rotator cuff tear limited to supraspinatu s.	Single-row arthroscopic repair (n = 43) vs. double-row arthroscopic repair (n = 47). Follow-up visits were at 3 months	83 patients had complete data to be evaluated; 40 from single-row repair group and 43 from double-row repair group. At 6 months follow-up, 40/43 patients in double-	"As a result, we currently perform double row suture bridge (transosseous equivalent) repairs for all full-thickness supraspinatus rotator cuff tears."	Methodological details sparse.

			and 6 months for each group.	row group healed. This difference was significant compared to single row group (30/40) (p = 0.024)		
Kraeutler 2015 RCT	3.5	N = 57 receiving subacromial decompressi on or unilateral rotator cuff repair, between 18- 75 years; Mean age 55.4 for compressive cryotherapy group and 55.8 for comparison group.	Compressive cryotherapy (CC) group using Game Ready (CoolSystems) device (n = 25) vs. cryotherapy-only (IW) comparison group (n = 21), Both groups received treatment for first 7 post-op days. Treatment was to be applied every other hour for 3 days, followed by 2 to 3 applications (for an hour) per day for remaining 4 days. Assessments at baseline and 7-10 days post-op.	Post-operative Treatme No significant results reported between groups for worst pain, average pain or morphine equivalent dosage for first post- op week.	"CC using the Game Ready device did not demonstrate significant reduction in postoperative pain or narcotic use in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression."	No placebo or sham. Sparse baseline data. Compliance issues with 11 participants excluded for noncompliance. Comparable results in both groups.

## SHOULDER DISLOCATION

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments				
	Surgery									
Steinbeck 1998 Partially RCT	3.5	N = 62 with recurrent traumatic anterior instability.	Arthroscopic vs. open anchor suturing (see comments); 2 year follow-up.	Redislocation in 6% open vs. 17% arthroscopic (p >0.05). Rowe good/excellent results in 90.6% open vs. 80% arthroscopic. Little or no limitations in sports in 94% open vs. 83% arthroscopic.	"Despite similar patient populations and using arthroscopic examination to select the type of repair in both groups, the results of arthroscopic shoulder stabilization are inferior to those of the classic open Bankart procedure."	Study began as an RCT. If at arthroscopy had intact detached labral-ligamentous complex and non- overstretched anterior aspect of capsule. If labrum thin, frayed or ruptured, glenohumeral ligaments poor, or Bankart with bony fragment then all converted to non- randomized open Bankart repair.				
Hiemstra 2008 RCT	3.5	N = 48 with recurrent anterior shoulder instability.	Open vs. arthroscopic stabilization. Shoulder immobilizer 2-4 weeks, passive and active assisted ROM at 2 weeks; at 6	No differences in strength measures including internal rotation and external rotation. Deficits compared with non- operative arm (p <0.02).	"[T]here are no side- to-side isokinetic strength deficits between patients having an open stabilization using a subscapularis splitting approach versus arthroscopic	Trial piggy-backed on existing trial. No short to intermediate term results. Dropout rate unclear. Data suggest no longer term differences.				

Nordin 1994         3.0         N = 40 with anterior c instability of the shoulder and c instability of the shoulder and barkart lesion.         Anchor group anchors (K-78) vs. 72         Bankart repair excellent treatment recourser anterior instability of the shoulder and Bankart lesion.         Small sample           Salomonsson RCT         2.5         N = 66 shoulders surgery.         N = 66 shoulders weeks, 3 months, and 2 years after surgery.         Anchor group had anchors (H-78) vs. 72         "Bankart repair is an excellent treatment for recurrent anterior instability of the shoulder. Numerous other technically developed, at least party because surgery.         Small sample           Salomonsson RCT         2.5         N = 66 shoulders shoulders patients instability of the imatomic operation surgery.         Before surgery patients combined with comparison surgery.         Group P experienced a derease in the external rotation by- erapair with anterior opstach shoulders shoulders in andomized to either Bankart completed 10-year group B (p = 0.03). Signer (C) shoulders in and general shoulder function (Group B; n = 33), s. Pin and group P (p = 10) (Group B; n = 33), s. Pin and group P (p = 10) (Group B; n = 33), s. Pin shoulders after surgery.         Small sample size.           Salomoneson RCT         2.5         N = 66 shoulders shoulders instability of the size.         Before surgery patients combined with combined with combined with combined with combined with external rotation by- shoulders still had impared function in active external rotation post-p in group Signer (Sroup B (n = 1, p = 0.003).         Small sample size.           Salomoneson RCT         2.5         N = 60 sho				weeks active		stabilization1 year	
Norfin 1994         3.0         N = 40 with Ametric postraumati cinstability of the shoulder and shoulder and shoulder and bankart repair eston.         Anchor group: Bankart repair with Mike suture anchors (n = 20).         Anchor group: (65 (44-78) vs. 72 (48-92); p < 0.01].         Bankart repair is an constraint or recurrent anterior instability of the shoulder and shoulder and bankart lesion.         Small sample sample sutures (n = 20).           Salomonsson 2009         2.5         N = 66 shoulders with anterior postraumati c shoulders with anterior postraumati c shoulders in technically demanding.         M = 66 shoulder in the surgery.         Group P experience a decrease in the external totalon by -67 vs57 (69% CL - 57) (64°-657) vs57 (69% CL - 50° (54°-657) vs57 (69% CL - 50° (54°-657) vs57 (69% CL - 50° shoulders The marked function by -67 vs57 (69% CL - 50° (54°-657) vs5				shoulder exercises and			
Nortin 1994 RCT       3.0       N = 40 with anterior group had postraumati c instability of the shoulder and bankart lesion.       Anchor group had shorter surgela ture with Mitek surue s. bone suture or. bone suture ys. bone suture tepair with bone sutures (n = 20).       Anchor group had shorter surgela ture ys. bone suture (86 (44.78) ys. p < 0.01].				strengthening. Return to sports			
RCT       posttraumati c instability of the shoulder and Bankart lesion.       with Mitek surue c instability of the shoulder and Bankart lesion.       with Mitek surue shoulders (n = 20).       s. bone suture (B6 (44-78) ys - 20.01].       for recurrent anterior shoulder. Numerous other techniques Bankart repair with bone surgery.       Methodological (B6 (44-78) ys - 20.01].       Methodological shoulder. Numerous other techniques Bankart repair with bone surgery.       Methodological (B6 (44-78) ys - 20.01].       Methodological shoulder. Numerous other techniques Bankart procedure is technically because       Methodological other techniques Bankart reatachment of the anterior capsule is shoulders with anterior repair using anter sugery.       Salomonson (Group P experienced a decrease in the storeal rotation by- 10 (95% CI: - -07' to 17) in the shoulders in active external imprice function capsular imprice function capsular in active external imprice function capsular in active external imprice function experienced slighty more pain during morement vs. Group Bankart lesion.       Small sample size.       Small sample size.         Salomonson RCT       2.5       N = 66 shoulders in active external imprice capsular informed with lesion.       Before surgery sale surgery.       Group P (95% CI: 97 Group P (195% CI:	Norlin 1994	3.0		Anchor group:			•
2009 RCTshoulders with anterior postraumal c shoulder instability, 58 had a Bankart lesion.patients randomized to either Bankart repair using Mitek GI/GII anchorsa decrease in the external rotation by - 10° (95% CI: -15° to 1°) in the group B (p = 0.03). Significant difference was found between the usomethods. The WOSI scores for stable shoulders indicated that some shoulder still had impaired function (Group P; n = 33) vs. Putti- Plati procedure (Group P; n = and 10 years after surgery.patients a decrease in the external rotation by - 10° (95% CI: -7° to 1°) in the group B (p = 0.03). Group P (p = 0.03). Group P (n = 10) experienced slightly more pain during movement vs. Group B (n = 1; p = 0.003).pain and general shoulder function difference was found between the womsthods. The WOSI scores for shoulders still had impaired function even though the shoulders still had impaired function even though the shoulders that some shoulders still had impaired function even though the shoulders (n = 1; p = 0.003).size. Methodological details sparse. Some long term follow-up, the mean WOSI score was 87% for stable shoulders (n = 34) (p = 0.005).pain and general shoulder function womethods. The WOSI scores that become stable."Sandow1.0N = 20 withArthroscopicOne recurrence"These resultsAbstract only.	RCT		posttraumati c instability of the shoulder and Bankart lesion.	with Mitek suture anchors (n = 20) vs. bone suture group: Bankart repair with bone sutures (n = 20). Follow-up at 6 weeks, 3 months, and 2 years after	vs. bone suture group [56 (44-78) vs. 72	for recurrent anterior instability of the shoulder. Numerous other techniques have been developed, at least partly because Bankart procedure is technically demanding. However, the use of suture anchors shortens surgical time significantly, because reattachment of the anterior capsule is simplified. No metal- related complications had occurred at the time of the 2-year follow- up evaluation."	Methodological
Sandow         1.0         N = 20 with         Arthroscopic         One recurrence         "These results         Abstract only.	2009	2.5	shoulders with anterior posttraumati c shoulder instability, 58 had a Bankart	patients randomized to either Bankart repair using Mitek GI/GII anchors combined with capsular imbrication (Group B; n = 33) vs. Putti- Platt procedure (Group P; n = 33). Follow-up at 2 and 10 years	a decrease in the external rotation by – $10^{\circ}$ (95% CI: –15° to $-6^{\circ}$ ) vs. –3° (95% CI: $-7^{\circ}$ to 1°) in the group B (p = 0.03). Significant difference in active external rotation post-op in Group P [95% CI: 59° (54°–65°)] vs. Group B [95% CI: 68° (62°– 73°), (p = 0.03)]. Group P (n = 10) experienced slightly more pain during movement vs. Group B (n = 1; p = 0.003). 62 patients completed 10-year questionnaire. At 10- year follow-up, the mean WOSI score was 87% for stable shoulders (n = 28) vs. 77% for unstable shoulders (n = 34) (p	pain and general shoulder function, only a small difference was found between the two methods. The WOSI scores for stable shoulders indicated that some shoulders still had impaired function even though the shoulders had	size. Methodological details sparse. Some long term
	Sandow 1995	1.0	N = 20 with apparently	Arthroscopic repair within 1		"These results suggest that primary	Abstract only. Sparse details.

RCT	all athletes; duration of follow-up unclear, but appears to be 12 months.	week of dislocation with Suretac repair vs. nonoperative care (not otherwise specified). All	arthroscopically repaired group vs. 4 recurrences in non- operative group (40%) plus 1 subluxation.	Suretac arthroscopic repair of acute shoulder dislocation reduces the incidence of recurrence but recovery of range of	Apparently never published in full- length text. Small sample size.
	monuis.	treated with sling for 4 weeks.		motion is slower."	

## SHOULDER (GLENOHUMERAL AND ACROMIOCLAVICULAR JOINT) OSTEOARTHROSIS

Author/	Scor	Sample	Comparison		Conclusion	Comments
Year Study Type	e (0- 11)	Size	Group	Results		Comments
- 71				NSAIDs		
Diamond 1976 Crossover trial	3.0	N = 34 with spine, hip, knee or shoulder OA.	Fenoprofen 200mg to 600mg Q6Hr vs. aspirin 325mg to 975mg Q6Hr for 6 weeks. Doses titrated.	Little difference in efficacy between fenoprofen and ASA. Data presented were largely versus placebo and not well described.	"Fenoprofen in a dose of 200-600 mg, four times daily, showed similar efficacy to 325 to 975 mg of ASA, four times daily, in the treatment of osteo- arthritis of the spine and large joints. The overall incidence of side effects was similar on the two drugs."	Lack of study details. Study used placebos in 1-week washout phases that were used to compare with active medications; however, duration may not have been sufficient and it is unclear if that was blinded.
			Distal (	Clavicle Resection		
Charron 2007 RCT	3.5	N = 38 with osteolysis of distal clavicle or isolated post- traumatic AC arthrosis, required relief of pain with AC lidocaine injection; 2-year follow-up.	Arthroscopic superior approach vs. indirect subacromial approach.	ASES scores (pre- operative/2 weeks/6 weeks/final): direct ( $62.9/81.7/88.4/95.7$ ) vs. indirect ( $61.4/64.4/77.4/91.2$ ) (p = 0.35, p = 0.00006, p = 0.00051, p = 0.0085 respectively).	"Both the direct superior approach and the indirect subacromial approachresult in successful clinical outcome with clinically insignificant difference at final follow-up."	All sports related and prior AC sprain. Trend of superiority of direct approach.
			Shou	Ider Arthroplasty		
Boyd 1990 Retrospecti ve Case Series	1.5	N = 64 Neer hemi- arthroplas ties vs. 146 Neer total shoulder arthroplas ties in 134 patients.	Total shoulder arthroplasty vs. hemiarthroplasty. At least 2 years follow-up.	Complete pain relief in 55% TSA vs. 47% hemi. Good results in 93% TSA vs. 92% hemi.	"Total shoulder arthroplasty is recommended for patients with inflammatory arthropathies, and hemiarthroplasty is recommended for patients with osteoarthritis, avascular necrosis, and four-part fractures with preservation of	At baseline, patients with total arthroplasties were more likely to have RA and OA.

Ī			glenoid congruity and absent	
			synovitis."	

#### **PROXIMAL HUMERAL FRACTURES**

Author/Yea r Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments				
	Pulsed High Frequency Electromagnetic Energy									
Rodriguez- Merchan 1995 Comparativ e Clinical Trial	3.0	N = 40 with closed transverse middle 1/3 humeral fractures.	AO compression plating vs. intra- medullary fixation with Hackethal nail. Mean 18 month follow-up.	Delayed union in 1 in each group. Excellent results in 12/20 nailing vs. 13/20 compression plating. (NS).	"[N]o differences have been found between the two investigated surgical procedures."	Many details sparse. Variable follow-up. Study states randomized, but also by physician preference, thus not RCT. May be underpowered.				
Chiu 1997 Pseudo- RCT	2.5	N = 91 with acute displaced closed humeral shaft fracture.	Open reduction plus fixation with Dynamic compression plate vs. ORIF with DCP with iliac crest bone graft vs. closed reduction plus internal fixation with Ender Nail. Mean 32 months follow-up.	Overall complication rates 30 vs. 6.9 vs. 21.8%; time to union in weeks: 12.5 vs. 9.4 vs. 9.9. latrogenic nerve injuries in 6.7 vs. 3.4 vs. 0%. Nonunions in 16.7 vs. 0 vs. 9.4%.	"(Ender nail) is better than (rigid dynamic compression plate) without (bone graft). When (dynamic compression plating) is chosen for the means of fixation, prophylactic (bone graft) is recommended, especially in cases with more comminution."	Randomization by medical record chart number. Patients not well described. Many details sparse.				

### **CLAVICULAR FRACTURES**

Author/Yea r Study Type	Scor e (0- 11)	Sample Size	Comparison Group	Results	Conclusion	Comments			
	Comparison Between Splints and Slings								
McCandles s 1979	1.0	N = 40 with displaced clavicle fractures	Figure of 8 vs. sling	After 3 weeks, 5 with sling vs. 4 with figure-of-eight bandage were tender. 4 with figure of 8 developed ipsilateral swollen blue arm.	"A triangular sling was found to be adequate treatment and was less complicated."	Every other 'randomization.' Sparse descriptions of methods and results.			
Non-operative Treatment vs. Operative Treatment									
Grassi 2001 Retrospectiv e	3.0	N = 80 with uncomplicate d mid- clavicular fractures.	Non-operative treatment (figure- of-8) vs. open reduction and intramedullary fixation. Mean 63.7 months follow-up.	Higher complications in operative group. RTW or sports at 2.6 months non-operative vs. 3.2 months operative, p = 0.014. No differences in Constant scores at mean 63.7 months. Same rate of satisfaction in both groups.	"[N]onoperative treatment appears more advantageous than open intramedullary fixation for the management of most midclavicular fractures."	Not an RCT. Data mildly supportive of nonoperative approach.			

# **ADHESIVE CAPSULITIS**

	Author/Yea r	Score (0-11)		Comparison Group	Results	Conclusion	Comments
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Study Type						
				itial Care		
Lee 1974 RCT	3.0	N = 65 with frozen shoulder, <1 month to >1 year duration.	Heat plus exercise vs. analgesics vs. hydrocortisone to the joint plus exercises vs. hydrocortisone to the biceps plus exercise. Details of interventions not provided.	Effects of interventions on ranges of motion suggest hydrocortisone to joint plus exercises superior to others for nearly all time intervals and for nearly all range of motion measures (graphic data). All 3 interventions superior to analgesics, p <0.01.	"[F]rom the point of view of movement, the analgesic group fared worse than any of the others, and that hydrocortisone to the joint and exercise was the best of the treatments given."	Sparse details. One intervention described in introduction as injection to bicipital tendon and in methods as injection to "biceps." Overall results suggest superiority of injection to joint plus exercises. Details too limited to allow evidence- based guidance.
Waldburger 1992 RCT	3.0	N = 50 with frozen shoulder, up to 3 months duration.	Active mobilization plus TENS and cryotherapy 4 times a week vs. Same treatments plus salmon calcitonin 100U QD for 21 days.	Calcitonin treatment superior to treatment without calcitonin for all cases, traumatic cases and idiopathic cases (graphic data).	"There was no significant differencein the speed of recovery of function between the two treatment groups. These observations strengthen the hypothesis that adhesive capsulitis behave like an algoneuro- dystrophic process."	Limited description of patients.
Hamer 1976 RCT	2.5	N = 32 with frozen shoulder, mean 17.7 weeks duration.	Cryotherapy (towels in crushed ice, applied for 15 minutes) vs. ultrasound (0.5W/cm <sup>2</sup> for 5- 8 minutes), then passive shoulder movements, then active exercises including pendular and elevation.	Mean treatments 12.4 ice vs. 14.8 ultrasound. Pain grade improvement 2 ice vs. 2.3 ultrasound, $p > 0.1$ . Rotational "lack improvement, ice 14.1cm vs. ultrasound 12.4cm, p > 0.1.	"No significant advantage of one treatment over the other could be demonstrated."	Study design unclear as details sparse. Possibly comparative clinical trial (allocated sequentially) vs. quasi-randomized. Baseline differences especially in duration of symptoms (21.7 vs. 13.7 months). Treatment details sparse; differing numbers preclude evidence-based guidance.
Detel	25	N 407		edication		
Patel 2000 RCT	3.5	N = 127 mixed disorders, including RA, OA, cervical spondylosis, tendinitis, frozen shoulder, prolapsed	Meloxicam 15mg QD vs. subsyde CR 7.5mg QD; 28 days follow-up.	Overall evaluation by patients: meloxicam 69% excellent or good vs. 83%, p = 0.055. Identical results by physicians (?). No significant differences in functional impairments.	"[A] controlled release formulation of diclofenac based on the DRCM technology offers a safe and effective alternative to other non-steroidal anti- inflammatory drugs such as meloxicam."	Study includes numerous different disorders. Details sparse. Utility for guidance is unclear.

		disc, ankylosing spondylitis.				
Binder 1986 RCT	3.0	N = 40 with painful stiff shoulders for at least 1 month duration.	Oral prednisolone 10mg QAM 4 weeks plus home pendular exercises vs. home exercises alone; 8 months follow-up.	Both groups improved over time, with no differences between groups. At end of 8 months, 1 in steroid vs. 2 in controls had severe pain. (NS)	"There was no difference between the patient groups at the end of the study (8 months follow-up) and patients still had a marked restriction in rangewhen compared to normal controls."	Some details sparse. Suggests mild earlier efficacy with oral glucocorticosteroid
Biswas 1979 RCT	1.0	N = 120 with periarthritis of shoulder, 3-12 months duration.	Hydrocortisone injection "in shoulder joints" (does not noted) vs. short-wave diathermy (no frequency or duration noted) vs. ASA 0.7gm TID. All treated with passive mobilization and active exercise.	Results not well quantified and reported.	"[T]here is little difference in the rate and extent of improvement in movement among these 3 different types of proceduresIt seems that exercise is of utmost importance in the treatment of periarthritis of shoulder."	Methods sparse. Appears to be RCT, but no clear description of randomization ("divided"). Dropout rate (60.8%) so high, results appear unusable.
Diercks 2004 Comparativ e Clinical Trial	3.0	N = 77 with idiopathic frozen shoulder of 3 plus months duration.	Neglect group (HEP with pendulum exercises; active exercises within painless ROM) vs. physical therapy (active exercises up to/beyond pain threshold, manipulation, HEP, NSAID); 24 months follow- up.	At 2 years, 89% of neglect vs. 64% of PT groups had reached Constant score of 80. Time to reach 80, 15 months in neglect vs. 24 months in PT group (interpretation of graphic data).	"Both the level of the Constant score at the end of the study and the moment a Constant score of 80 or higher was reached confirm that supervised neglect yields better outcomes than intensive physical therapy and passive stretching in patients with frozen shoulder."	2 consecutive cohorts, but of different sized groups prevent robust conclusions. Neglect group encouraged to do exercises, thus not a true "neglect" group.
Hamer 1976 Comparativ e Clinical Trial	2.5	N = 32 with frozen shoulder.	Ice (towels in ice water applied for 15 minutes) vs. ultrasound (0.5W/cm2 for 5 increasing to 8 minutes). All treated with passive ROM and HEP. Variable numbers of treatments and apparently variable length of treatment.	Quantified results not reported. Number of treatments: ice $(12.4\pm2.6)$ vs. ultrasound $(14.8\pm7.4)$ . Pain grade improvement: ice $(2\pm0.98)$ vs. ultrasound $(2.3\pm0.95)$ , p >0.1. No difference in rotational lack improvement in cm.	"[B]oth of these physiotherapy methods can shorten the painful stage of the condition and, in conjunction with specific exercises, hasten recovery of the range of shoulder movement."	Study design unclear. Randomization not discussed. Baseline data do not clearly suggest 2 groups comparable (duration of symptoms 22 vs. 14 weeks). Sparse methods. Number of treatments not standardized. Sparse results.
Dundar 2009 RCT	1.5	N = 57 with adhesive capsulitis.	Continuous passive motion (1 hour a day, 20 days for 4 weeks) vs.	No data provided. "In both groups, statistically significant improvements were	"CPM treatment pro- vides better response in pain reduction than the conventional	Abstract. Full report also published and reviewed in main part of guideline.

Sveistrup 2003 2 Quasi- randomized Trials	1.5	N = 14 with frozen shoulder or traumatic brain injury at least 6 months earlier.	conventional physiotherapy (active stretching and pendulum exercises, 1hour/ day, 20 days over 4 weeks); 12 weeks follow-up. Exercise (virtual- reality delivered vs. conventional) 3 sessions a week for 6 weeks (15 minute warm-up, 30 minute active exercise, 15 minutes of ice).	detected in all outcome measures compared with baseline. Pain re- duction, however, evaluated with respect to pain at rest, at movement and at night was better in CPM group." Only 3 frozen shoulder patients had completed the trial.	physiotherapy treatment protocol in the early phase of treatment in adhesive capsulitis." "VR is a new technology and the possibilities for rehabilitation are only just beginning to be assessed."	Tiny sample sizes. Details sparse, including how quasi-randomized.
	l	l		Itrasound	l	
Herrera- Lasso 1993 RCT	3.5	N = 30 with painful shoulder, including bicipital tendinitis, supraspinatu s tendinitis, bursitis, periarthritis.	Ultrasound 0.5W/ cm <sup>2</sup> for 10 or 20 minutes (paper differs on length) increasing to 1W/ cm <sup>2</sup> vs. TENS mean frequency 50Hz, 20 minutes per session; 2-5 sessions a week for 13 sessions. All treated with pendular and stretching exercises.	Pain, ROM improved in both groups, but not different between groups (limited data.)	"[P]ackages of treatment including pendular exercises, superficial heat and either TENS or ultrasound are effective therapeutic alternatives for relief of Painful Shoulder Syndrome."	Patients include mixture of disorders. Treatment lengths in abstract 20 minutes, but 10 minutes ultrasound vs. 20 minutes TENS in methods. No placebo/ sham control. Minimal results given. Data suggest ultrasound and TENS equally effective or ineffective.
	I	ŀ	D	iathermy		
Biswas 1979 RCT	1.0	N = 120 with periarthritis of shoulder of 3-12 months duration.	Hydrocortisone injection "in shoulder joints" (does not noted) vs. short-wave diathermy (no frequency or duration noted) vs. ASA 0.7gm TID. All treated with passive mobilization and active exercise.	Results not well quantified and reported.	"[T]here is little difference in the rate and extent of improvement in movement among these 3 different types of proceduresIt seems that exercise is of utmost importance in the treatment of periarthritis of shoulder."	Methods Sparse. Appears to be RCT, but no clear description of randomization ("divided"). Dropout rate (60.8%) so high, results appear unusable.
				rodilatation		
Hamdan 2003 Comparativ e Clinical Trial vs. RCT	3.0	N = 100 with idiopathic frozen shoulder of 3 plus months duration.	MUA vs. MUA plus steroid vs. MUA plus normal saline injection; 6-8 months follow- up.	"Good" results after MUA: MUA with NS 25/29 (86.2%) vs. MUA with steroid 14/28 (50%) vs. MUA alone 13/29 (44.8%).	"[P]atients who had MUA with an intra- articular normal saline injection had better results than those who had MUA either alone or with an injection of	Methods sparse and study design un-clear. Data suggest MUA with saline injection is superior to glucocorticoid or no injection.

					steroid."	
		l	Art	throscopy		
Ogilvie- Harris 1995 Comparativ e Clinical Trial	2.0	N = 40 with frozen shoulder and functional loss at least 1 year.	Arthroscopy (divided contractures, resected inflamed synovium, division of anterior superior glenoid humeral ligament and anterior capsule, division of sub- scapularis tendon but not muscle) vs. arthroscopy with manipulation. 2 to 5 years follow-up.	Normal function pre/post: manipulation 5.2%/40.9% vs. division 5.2%/85%. (unclear how any could have normal function and have been eligible at baseline). Overall outcomes with full function and no pain: manipulation 9/18 (50%) vs. division 17/20 (85%).	"Patients with diabetes did worse initially, but the outcome was similar to patients without diabetes. Patients with diabetes in particular may benefit from early intervention>"	No randomized. Allocations by first 20 batched. Patients not described. Variable follow-up. Outcomes reportedly similar in those without diabetes, though only 11 had diabetes thus power for that risk unclear.
				teroid Injections	"D	
Dehghan 2013 RCT	3.5	N = 57 diabetic patients with adhesive shoulder capsulitis	NSAID, 500 mg Naproxen twice daily (n = 28) vs. ultrasound guided 40mg triamcinolone, 1 injection (n = 29); home exercise program: moving shoulder in 3 directions (flexion, abduction, and external rotation). Follow-up: baseline, 2, 6, 12, and 24 weeks.	Mean $\pm$ SD for NSAID group: 1st vs. 5th visit: flexion (degree): 107.6 $\pm$ 15.7 vs. 167.6 $\pm$ 22, p = 0.001; abduction (degree): 99.2 $\pm$ 22.6 vs. 170 $\pm$ 22.9, p = 0.001; external rotation (degree): 28.2 $\pm$ 9.5 vs. 45.7 $\pm$ 9.8, p = 0.001; internal rotation: 2.6 $\pm$ 0.87 vs. 0.32 $\pm$ 0.54, p = 0.001; pain score: 5.64 $\pm$ 2.43 vs. 1.99 $\pm$ 1.98, p = 0.001. Mean $\pm$ SD for triamcinolone group: 1st vs. 5th visit: flexion (degree): 103.7.6 $\pm$ 22.3 vs. 167.4 $\pm$ 24.2, p = 0.001; abduction (degree): 90.6 $\pm$ 21.3 vs. 172.9 $\pm$ 21.6, p = 0.001; external rotation (degree): 30.8 $\pm$ 11.7 vs. 47.4 $\pm$ 11.4, p = 0.001; internal rotation: 2.5 $\pm$ 1.01 vs. 0.24 $\pm$ 0.43, p = 0.001; pain score: 6.18 $\pm$ 2.17 vs. 2.24 $\pm$ 2.06, p = 0.001.	"Based on our study, both intraarticular corticosteroid and NSAID are effective in treatment of adhesive capsulitis and there is no significant difference between efficacies of these 2 treatment modalities in diabetic patients."	Methodological details sparse. Both groups meanningfully improved but there were no differences between groups for any outcome.

Lakse 2009	2.5	N = 38	Control Group (n	Both groups had	"Adding	Exercise
		patients who	= 17) received	significant	corticosteroid	intervention poorly
RCT		had a stroke	transcutaneous	improvement in all	injection to	described
		at least 8	electrical nerve	range of motion	conventional	methodological
		weeks prior	stimulation	(ROM) directions	treatment in	details sparse only
		to study and	(TENS) and	and VAS scores	hemiplegic shoulder	stroke patients
		were	exercise	between baseline	pain improved	used.
		diagnosed	programs	and first and fourth	shoulder range of	
		with	applied as	weeks.	motion and	
		hemiplegic	physical therapy	When compared	decreased pain	
		shoulder pain (HSP)	modalities once a day for 15	When compared, increased ROM and	scores before treatment to the first	
		caused by	sessions over 3	decreased VAS	and fourth weeks of	
		frozen	weeks. Injection	were significantly	treatment."	
		shoulder or	Group (n = $21$ ),	greater in the	ucaunent.	
		subacromial	mean age 62.2 <u>+</u>	Injection Group		
		impingement	9.1 years,	between baseline		
			received TENS	and 1st and 4th		
			and participated	weeks.		
			in same			
			exercise	Difference between		
			program and	Groups from		
			also received 1	baseline to 1st		
			injection of	week/baseline to		
			corticosteroid	4th week		
			and anesthetic.	respectively.		
			Injections were	Flexion: 0.00 / 0.04;		
			a mixture of 1mL	Abduction: 0.10 /		
			of triamcinolone	0.04; Int Rotation:		
			acetonide and 9mL of prilocain.	0.85 / 0.86; Ext Rotation: 0.03 / 0.02		
			15 patients	Rest VAS: 0.01 /		
			diagnosed with	0.03		
			frozen shoulder	Activity VAS: 0.02 /		
			received intra-	0.03.		
			articular	Night VAS: 0.00 /		
			injections. 6	0.01		
			patients			
			diagnosed with			
			impingement			
			syndrome			
			received			
			subacromial			
			space injections.			
			Evaluation			
			performed			
			before treatment			
			and at 1st and			
			4th week of			
			treatment for			
			both groups.			
L	I	L	~ 311 gi 6 a poi	1		

De Carli	2.0	N = 82 (46	Group A,	Mean degree for	"Both types of	Methodological
2012	2.0	shoulders)	shoulder	range of motion:	treatment were	details sparse.
5.07		with	manipulation	Group A: pre vs. 12	effective in	
RCT		shoulder adhesive	under general	months: 60° vs.	improving final	
		capsulitis	anesthesia and subsequent	154º, p < 0.03; external rotation:	range of motion; however, while	
		Capsullis	arthroscopic	20° vs. 40°, p <	patients of group A	
			arthrolysis;	0.04; flexion: 75° vs.	accomplished their	
			shoulder	174º, p < 0.03; 3	goal by the six-week	
			movements of	weeks vs. 6 months:	follow-up, in group B	
			flexion, abduction, and	abduction: 79º vs. 158º, p < 0.03;	the same result was obtained at the 12-	
			rotating	flexion: 80º vs. 178º,	week follow-up."	
			externally and	p < 0.03. Group B:		
			internally (n =	pre vs. 12 months:		
			25) vs. Group B,	76º vs. 145º, p		
			intra-articular	<0.03; external		
			steroid injections, 4cc of	rotation: 20º vs. 35º, p < 0.04; flexion:		
			2% lidocaine	115º to 164º, p		
			and 1cc of	<0.04.		
			methylprednisol			
			one acetate; 3			
			injections, 1 for each week (n =			
			21).			
			Follow-up: 3, 6,			
			and 12 weeks; 6 and 12 months.			
Schydlowsk	2.0	N = 18 with	Treatment group	An overall	"[N]o effect was	Small sample size;
У		frozen	A or 1ml	statistically	demonstrated for	methodological
2012		shoulder or	adalimumab by	significant difference	subcutaneous	details sparse.
RCT		FS.	subcutaneous injection (n = 10)	between time points found for all tests in	adalimumab compared to	
NOT			vs. Group B or	glucocorticoid	intraarticular steroid	
			intra-articular	group, p <0.05 –	injections in patients	
			steroid injection;	0.0001. Most of the	with FS."	
			4ml of lidocain	scores were		
			1% plus 40mg methylprednisol	significantly improved compared		
			one acetate in	to that in baseline, p		
			affected	<0.05.		
			glenohumeral			
			joint under			
			ultrasonographic guidance (n =			
			8).			
			Follow-up at 1, 3			
Lorbach	1.5	N = 45	and 6 months.	VAS scores for pain,	"[T]he use of	Methodological
2010	1.5	patients with	cortisone	p < 0.0001, function	cortisone in the	details sparse.
		idiopathic	injections, 3	p <0.0001 and	treatment of	Statistical
RCT		Stage II	fluoroscopically	satisfaction p	idiopathic adhesive	significant
		capsulitis of	controlled intra-	<0.000 showed	capsulitis of the	difference
		the shoulder were treated	articular injections	significant improvements at	shoulder led to fast pain relief and	between groups for satisfaction but
		in our	administrated	first follow-up after 4	improved range of	no difference
		shoulder	under sterile	weeks.	motion."	observed for pain
		service.	conditions;			or function. Range
			including the	Range of motion:		showed
			following medications:	Flexion increased from 102°±32°		differences during
			medications.	110111 102 ±32	l	follow-up.

	5mL bupivacaine 0.5%, 5mL of mepivacaine 0.5%, and 40mg of triamcinolone (n = 20) vs. oral cortisone application of prednisolone beginning with 40mg and decreasing the dose every 5 days (n = 20). Follow-up for 4, 8, and 12 weeks, and 6 and 12 months.	before treatment to $118^{\circ}\pm 33^{\circ}$ after 4 weeks p <0.0001, to $137^{\circ}\pm 3^{\circ}$ after 8 weeks p <0.0001, to $156^{\circ}\pm 34^{\circ}$ at 3 months p <0.0001, to $154^{\circ}\pm 30^{\circ}$ at 6 months p <0.0001, and to $158^{\circ}\pm 30^{\circ}$ at 6 months p <0.0001, After 1 year; mean external rotation was $68^{\circ}\pm 14^{\circ}$ , p <0.0001.		
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