

# **Management of Rotator Cuff Injuries**

# **Evidence-Based Clinical Practice Guideline**

Adapted by: The American Academy of Orthopaedic Surgeons Board of Directors March 11, 2019

Endorsed by:









American Physical Therapy Association.

Please cite this guideline as:

American Academy of Orthopaedic Surgeons. Treatment of Pediatric Diaphyseal Femur Fractures Evidence-Based Clinical Practice Guideline. www.aaos.org/pdffcpg. Published March 23, 2020.

#### Disclaimer

This Clinical Practice Guideline was developed by an AAOS physician volunteer Clinical Practice Guideline development group based on a systematic review of the current scientific and clinical information and accepted approaches to management of rotator cuff injuries. This clinical practice guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

#### **Disclosure Requirement**

In accordance with AAOS policy, all individuals whose names appear as authors or contributors to the clinical practice guideline filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to voting on the recommendations contained within this clinical practice guideline.

#### **Funding Source**

This clinical practice guideline was funded exclusively by the American Academy of Orthopaedic Surgeons who received no funding from outside commercial sources to support the development of this document.

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## SUMMARY OF RECOMMENDATIONS

## MANAGEMENT OF SMALL TO MEDIUM TEARS

Strong evidence supports that both physical therapy and operative treatment result in significant improvement in patient-reported outcomes for patients with symptomatic small to medium full-thickness rotator cuff tears.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## LONG TERM NON-OPERATIVE MANAGEMENT

Strong evidence supports that patient reported outcomes (PRO) improve with physical therapy in symptomatic patients with full thickness rotator cuff tears. However, the rotator cuff tear size, muscle atrophy, and fatty infiltration may progress over 5 to 10 years with non operative management.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## **OPERATIVE MANAGEMENT**

Moderate evidence supports that healed rotator cuff repairs show improved patient reported and functional outcomes compared to physical therapy and unhealed rotator cuff repairs.

Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

## **ACROMIOPLASTY & ROTATOR CUFF REPAIR**

Moderate strength evidence does not support the routine use of acromioplasty as a concomitant treatment as compared to arthroscopic repair alone for patients with small to medium sized full-thickness rotator cuff tears.

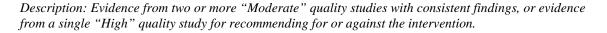
Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

## **DISTAL CLAVICLE RESECTION**

Moderate strength evidence supports the use of distal clavicle resection as a concomitant treatment to arthroscopic repair for patients with full-thickness rotator cuff tears and symptomatic acromioclavicular joints.

# Strength of Recommendation: Moderate



### **DIAGNOSIS (CLINICAL EXAMINATION)**

Strong evidence supports that clinical examination can be useful to diagnose or stratify patients with rotator cuff tears; however, a combination of tests will increase diagnostic accuracy.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

### **DIAGNOSIS (IMAGING)**

Strong evidence supports that MRI, MRA, and ultrasound are useful adjuncts to a clinical exam for identifying rotator cuff tears.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

#### **POST-OP MOBILIZATION TIMING**

Strong evidence suggests similar postoperative clinical and patient-reported outcomes for small to medium sized full-thickness rotator cuff tears between early mobilization and delayed mobilization up to 8 weeks for patients who have undergone arthroscopic rotator cuff repair.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## **CORTICOSTEROID INJECTIONS FOR ROTATOR CUFF TEARS**

Moderate evidence supports the use of a single injection of corticosteroids with local anesthetic for short-term improvement in both pain and function for patients with shoulder pain.

# Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

## HYALURONIC ACID INJECTIONS FOR ROTATOR CUFF TEARS

Limited evidence supports the use of hyaluronic acid injections in the non-operative management of patients with rotator cuff pathology.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

## PLATELET RICH PLASMA (PRP) INJECTION IN PARTIAL-THICKNESS **TEARS**

Limited evidence does not support the routine use of platelet rich plasma for the treatment of rotator cuff tendinopathy or partial tears.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

## HIGH-GRADE PARTIAL THICKNESS ROTATOR CUFF TEARS

Strong evidence supports the use of either conversion to full-thickness or transtendinous/in-situ repair in patients that failed conservative management with high-grade partial thickness rotator cuff tears.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## **PROGNOSTIC FACTORS (AGE)**

Strong evidence supports that older age is associated with higher failure rates and poorer patient reported outcomes after rotator cuff repair.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## **PROGNOSTIC FACTORS (HIGHER BMI)**

Moderate evidence supports that higher BMI is correlated with higher re-tear rates after rotator cuff repair surgery; however, strong evidence supports that there is no correlation between higher BMI and worse patient-reported outcomes following rotator cuff repair.

Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

## **PROGNOSTIC FACTORS (WORKER'S COMPENSATION)**

Strong evidence supports the presence of a worker's compensation claim is associated with poorer patient reported outcomes after rotator cuff repair.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## **PROGNOSTIC FACTORS (COMORBIDITES)**

Moderate evidence supports the association of poorer patient reported outcomes in patient with more comorbidities.

Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

## **PROGNOSTIC FACTORS (DIABETES)**

Moderate evidence suggests that patients with diabetes will have higher re-tear rates and poorer quality of life and patient reported outcome scores after rotator cuff repair.

Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

## **PROGNOSTIC FACTORS (PATIENT EXPECTATIONS)**

Moderate evidence correlates higher preoperative patient expectations for surgery with higher patient reported outcomes after rotator cuff repair.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

## **BIOLOGICAL AUGMENTATION WITH PLATELET DERIVED PRODUCTS**

Strong evidence does not support biological augmentation of rotator cuff repair with platelet-derived products on improving patient reported outcomes; however, limited evidence supports the use of liquid platelet rich plasma in the context of decreasing re-tear rates.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## SINGLE-ROW VS DOUBLE-ROW REPAIR

Strong evidence does not support double row rotator cuff repair constructs on improving patient-reported outcomes compared to single row vertical mattress repair constructs.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## SINGLE-ROW VS DOUBLE-ROW REPAIR RE-TEARS

Strong evidence supports lower re-tear rates after double row repair compared to single row vertical mattress repair when evaluating for both partial and full thickness retears after primary repair; however, when evaluating the data for only full thickness retears, limited evidence does not support lower re-tear rates after double row primary repair.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## MARROW STIMULATION

Limited evidence suggests that marrow stimulation at the time of rotator cuff repair does not improve patient-reported outcomes; however, this technique may decrease re-tear rates in patients with larger tear sizes.

Strength of Recommendation: Limited 📩

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

## **DERMAL ALLOGRAFTS**

Limited evidence supports the use of dermal allografts to augment the repair of large and massive rotator cuff tears to improve patient reported outcomes.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

## **XENOGRAFTS**

Limited evidence does not support the use of xenografts to augment the repair of large and massive rotator cuff tears.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

## **OPEN VS ARTHROSCOPIC REPAIR**

Strong evidence supports no difference in long-term (> 1 year) patient-reported outcomes or cuff healing rates between open and arthroscopic repairs; however, arthroscopic-only technique is associated with better short-term improvement in post operative recovery of motion and decreased visual analog score (VAS) scores.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

## **POSTOPERATIVE PAIN MANAGEMENT**

Moderate strength evidence supports the use of multimodal programs or non-opioid individual modalities to provide added benefit for postoperative pain management following rotator cuff repair.

Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

# SUMMARY OF CONSENSUS STATEMENTS

There is no or conflicting supporting evidence. In the absence of reliable evidence, the systematic literature review development group is making a recommendation based on their clinical opinion.

## SUPERVISED EXERCISE VS UNSUPERVISED EXERCISE

In the absence of reliable evidence, it is the opinion of the work group that supervised physical therapy is more appropriate than unsupervised home exercise for some patients following rotator cuff repair.

Strength of Recommendation: Consensus

## MULTIPLE STEROID INJECTIONS FOR ROTATOR CUFF TEARS

In the absence of reliable evidence, it is the opinion of the work group that multiple steroid injections may compromise the integrity of the rotator cuff, which may affect attempts at subsequent repair.

Strength of Recommendation: Consensus

## PLATELET RICH PLASMA (PRP) INJECTION IN FULL-THICKNESS TEARS

In the absence of reliable evidence, it is the consensus of the work group that we do not recommend the routine use of platelet rich plasma in the non-operative management of full-thickness rotator cuff tears.

Strength of Recommendation: Consensus

## PARTIAL ROTATOR CUFF TEAR

In the absence of reliable evidence, the work group is unable to define a preference for the choice of debridement versus repair of high-grade partial-thickness cuff tears that have failed physical therapy, however repair of high grade partial tears could improve outcomes.

Strength of Recommendation: Consensus

# UNREPAIRABLE TEARS WITHOUT ARTHROPATHY (BIOLOGIC PROCEDURES)

In the absence of reliable evidence, it is the opinion of the work group that physical therapy, biceps tenotomy/tenodesis, partial repair, tendon transfer, superior capsular reconstruction, arthroscopic debridement, or allograft augmentation (non-porcine) can improve patient reported outcomes.

Strength of Recommendation: Consensus

# MASSIVE, UNREPAIRABLE ROTATOR CUFF TEAR (REVERSE ARTHROPLASTY)

In the absence of reliable evidence, it is the opinion of the work group that in patients with massive, unrepairable rotator cuff tears and pseudoparalysis who have failed other treatments, reverse arthroplasty can improve patient reported outcomes.

Strength of Recommendation: Consensus

## UNREPAIRABLE TEARS WITH ARTHROPATHY

In the absence of reliable evidence, it is the opinion of the workgroup that after failure of conservative treatment, reverse shoulder arthroplasty for unrepairable tears with glenohumeral joint arthritis can improve patient reported outcomes.

Strength of Recommendation: Consensus

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# **INTRODUCTION**

## **OVERVIEW**

This clinical practice guideline is based on a systematic review of published studies with regard to the management of rotator cuff tears. In addition to providing practice recommendations, this guideline also highlights limitations in the literature and areas that require future research.

This guideline is intended to be used by all qualified and appropriately trained physicians and surgeons involved in the management of rotator cuff tears. It is also intended to serve as an information resource for decision makers and developers of practice guidelines and recommendations.

## **GOALS AND RATIONALE**

The purpose of this clinical practice guideline is to help improve treatment based on the current best evidence. Current evidence-based medicine (EBM) standards demand that physicians use the best available evidence in their clinical decision making. To assist them, this clinical practice guideline consists of a systematic review of the available literature regarding the management of rotator cuff tears. The systematic review detailed herein was conducted between February 2017 and August 2018 and demonstrates where there is good evidence, where evidence is lacking, and what topics future research must target in order to improve the management of rotator cuff tears. AAOS staff and the physician work group systematically reviewed the available literature and subsequently wrote the following recommendations based on a rigorous, standardized process.

Musculoskeletal care is provided in many different settings by many different providers. We created this guideline as an educational tool to guide qualified physicians through a series of treatment decisions in an effort to improve the quality and efficiency of care. This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

## **INTENDED USERS**

This guideline is intended to be used by orthopaedic surgeons and physicians managing patients with rotator cuff tears. Typically, orthopaedic surgeons will have completed medical training, a qualified residency in orthopaedic surgery, and some may have completed additional sub-specialty training. Adult primary care physicians, geriatricians, hospital based adult medicine specialists, physical therapists, occupational therapists, nurse practitioners, physician assistants, emergency physicians, and other healthcare professionals who routinely see this type of patient in various practice settings may also benefit from this guideline.

Rotator cuff tear management is based on the assumption that decisions are predicated on the patient and / or the patient's qualified heath care advocate having physician communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient and or their advocate have been informed of available therapies and have discussed these options with his/her physician, an informed decision can be made. Clinician input based on experience with conservative management and the clinician's surgical experience and skills increases the probability of identifying patients who will benefit from specific treatment options.

This guideline is not intended for use as a benefits determination document.

## PATIENT POPULATION

This document addresses the management of rotator cuff tears in adults. It is not intended to address management of pediatric patients with rotator cuff tears.

## **BURDEN OF DISEASE**

Shoulder disease is a major cause of musculoskeletal disability in the United States. Chronic shoulder pain has been estimated to affect approximately 8% of all American adults, second only to chronic knee pain in our society's burden of musculoskeletal disease. Rotator cuff pathology is the leading cause of shoulder-related disability seen by orthopaedic surgeons, and surgical volume is on the rise (Narvy 2016). One study, for example, notes a 141% increase in rotator cuff repairs from 1996 to 2006 in the United States (Colvin, 2012).

Societal costs of a medical condition include direct and indirect costs. Direct costs are those associated with diagnosis and treatment, while indirect costs include lost income due to inability to work or lower wages, missed workdays, and disability payments (Mather, 2013). Approximately 250,000 rotator cuff repairs (\$13,771 per patient) are performed annually in the U.S. This calculates to a cost of \$3,442,750,000 per annum.

## ETIOLOGY

Rotator cuff tears have two main causes: injury and degeneration. Acute tears are usually due to injury. This type of tear can occur in isolation or with other shoulder injuries, such as a broken collarbone or dislocated shoulder. Degenerative tears are more common and are the result of a wearing down of the tendon that occurs slowly over time. This degeneration naturally occurs as we age. Rotator cuff tears are more common in the dominant arm (OrthoInfo, 2007).

## INCIDENCE AND PREVALENCE

Approximately 4.5 million patient visits related to shoulder pain occur each year in the United States. More than two-thirds of patients treated with rotator cuff repair are of working age. The prevalence of rotator cuff tears increases with age, with 54% of asymptomatic patients aged 60 years and greater having sustained either a partial or complete RCT on magnetic resonance imaging. Ultrasound (US) studies by Tempelhof et al. reveal that 13% of individuals in their fifth decade, 20% in their sixth decade, and 31% in their seventh decade of life have RCTs. From their study on 306 cadavers, Lohr and Uhthoff noted a 19% and 32% prevalence of full and partial thickness tears, respectively (Sher, 1995; Tempelhof, 1999; Lohr, 2007). Not all of these tears are symptomatic.

## **RISK FACTORS**

Because most rotator cuff tears are largely caused by the normal wear and tear that goes along with aging, people over 40 are at greater risk.

People who do repetitive lifting or overhead activities are also at risk for rotator cuff tears. Athletes are especially vulnerable to overuse tears, particularly in the setting of repetitive microtrauma as observed in tennis players and baseball pitchers. Painters, carpenters, and others who do overhead work also have a greater chance for tears.

Although overuse tears caused by sports activity or overhead work also occur in younger people, most tears in young adults are caused by a traumatic injury, like a fall or shoulder dislocation (OrthoInfo, 2007).

## POTENTIAL BENEFITS, HARMS, AND CONTRAINDICATIONS

There are risks associated with both surgical and non-operative treatment of rotator cuff tears, including, but not limited to, infection, stiffness, complications, and recovery time for surgical management, and increased structural damage and functional limitations for non-surgical management Contraindications vary widely based on the treatment and the patient.

## **FUTURE RESEARCH**

Consideration for future research is provided for each recommendation within this document. High quality studies comparing the outcomes of operative and non-treatment of rotator cuff pathology of all types remains a major gap in knowledge. These need to continue out to five years, to fully understand the efficacy of each treatment. Future studies should focus more on strengthening the literature for the association between RCTs and factors such as diabetes mellitus, hypertension, cholesterol, smoking and BMI. Questions persist regarding the timing of physical therapy after surgery, and the need for formal therapy versus a supervised home program. While widely employed in practice, the risks and benefits of corticosteroid injections in patients with rotator cuff tears remain unclear. The repair of high-grade partial rotator cuff tears has been widely adopted by the orthopedic community, but there exists minimal evidence to support this choice. The risk and expense of orthobiologics in rotator cuff surgery remains difficult to fully assess, even though multiple high quality studies are currently available. The use of either allograft or xenograft patches to either augment rotator cuff repair or as a superior capsular reconstruction requires additional high quality studies to prove efficacy. Finally, given the opioid epidemic, high-quality studies of multimodal analgesia for rotator cuff surgery would seem to be a matter of public policy. Consideration for future research is provided for each recommendation within this document. High-strength, level one studies comparing the outcomes of operative and non-treatment of rotator cuff pathology of all types remains a major gap in knowledge. Future studies should focus more on strengthening the literature for the association between RCTs and factors such as diabetes mellitus, hypertension, smoking and BMI.

## **METHODS**

The methods used to perform this clinical practice guideline were employed to minimize bias and enhance transparency in the selection, appraisal, and analysis of the available evidence. These processes are vital to the development of reliable, transparent, and accurate clinical recommendations for management of rotator cuff tears. To view the full AAOS clinical practice guideline methodology please visit the <u>eAppendix 1</u> or <u>https://www.aaos.org/additonalresources/</u>.

This clinical practice guideline evaluates the effectiveness of approaches in the management of rotator cuff tears. The AAOS approach incorporates practicing physicians (clinical experts) and methodologists who are free of potential conflicts of interest relevant to the topic under study, as recommended by clinical practice guideline development experts.

This clinical practice guideline was prepared by the AAOS management of rotator cuff injuries clinical practice guideline physician development group (clinical experts) with the assistance of the AAOS Clinical Quality and Value (CQV) Department (methodologists). To develop this systematic literature review , the systematic literature review development group held an introductory meeting on February 26, 2017 to establish the scope of the systematic literature review. As the physician experts, the systematic literature review development group defined the scope of the clinical practice guideline by creating PICO Questions (i.e. population, intervention, comparison, and outcome) that directed the literature search. The AAOS Medical Librarian created and executed the search (see <u>eAppendix 1</u> for search strategy).

#### **BEST EVIDENCE SYNTHESIS**

We included only the best available evidence for any given outcome addressing a recommendation. Accordingly, we first included the highest quality evidence for any given outcome if it was available. In the absence of two or more occurrences of an outcome at this quality, we considered outcomes of the next lowest quality until at least two or more occurrences of an outcome had been acquired. For example, if there were two 'moderate' quality occurrences of an outcome that addressed a recommendation, we did not include 'low' quality occurrences of this outcome. A summary of excluded articles can be viewed in <u>eAppendix 1</u>. All of the detailed data for each recommendation can be found via <u>eAppendix 2</u>.

## LITERATURE SEARCHES

The medical librarian conducted a comprehensive search of PubMed, Embase, and the Cochrane Central Register of Controlled Trials based on key terms and concepts from the systematic literature review development group's preliminary recommendations. Bibliographies of relevant systematic reviews were hand searched for additional references. All databases were last searched on June 6, 2018 with limits for publication dates from 1966-2018 and English language.

#### DEFINING THE STRENGTH OF THE RECOMMENDATIONS

Judging the strength of evidence is only a stepping stone towards arriving at the strength of a systematic literature review recommendation. The strength of recommendation (Table 1) also takes into account the quality, quantity, and the trade-off between the benefits and harms of a treatment, the magnitude of a treatment's effect, and whether there is data on critical outcomes. Table 2 addresses how to interpret the strength of each recommendation.

#### VOTING ON THE RECOMMENDATIONS

The recommendations and their strength were voted on by the guideline development group members during the final meeting. If disagreement between the guideline development group occurred, there was further discussion to see whether the disagreement(s) could be resolved. Recommendations were approved and adopted in instances where a simple majority (60%) of the guideline development group voted to approve; however, the guideline development group had

consensus (100% approval) when voting on every recommendation for this guideline.

## **INTERPRETING THE STRENGTH OF EVIDENCE** Table 1. Strength of Recommendation Descriptions

Strength	Overall Strength of Evidence	Description of Evidence Quality	Strength Visual
Strong	Strong	Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.	****
Moderate	Moderate	Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.	****
Limited	Low or Conflicting Evidence	Evidence from two or more "Low" quality studies with consistent findings <b>or</b> evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	****
Consensus	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the systematic literature review development group is making a recommendation based on their clinical opinion.	****

## Table II. Clinical Applicability: Interpreting the Strength of a Recommendation

Strength of Recommendation	Patient Counseling (Time)	Decision Aids	Impact of Future Research
Strong	Least	Least Important, unless the evidence supports no difference between two alternative interventions	Not likely to change
Moderate	Less	Less Important	Less likely to change
Limited	More	Important	Change possible/anticipated
Consensus	Most	Most Important	Impact unknown

#### PEER REVIEW

Following the final meeting, the systematic literature review draft undergoes a two week peer review for additional input from external content experts. Written comments are provided on the structured review form (RC CPG Peer Review and Public Comment eReport). All peer reviewers are required to disclose their conflicts of interest.

#### PUBLIC COMMENTARY

After modifying the draft in response to peer review, the clinical practice guideline was subjected to a two week period of "Public Commentary." Commentators consist of members of the AAOS Board of Directors (BOD), members of the Council on Research and Quality (CORQ), members of the Board of Councilors (BOC), members of the Board of Specialty Societies (BOS), and members of the Committee on Evidence-Based Quality and Value. The systematic literature review is automatically forwarded to the AAOS BOD and CORQ so that they may review it and provide comment prior to being asked to approve the document. Members of the BOC and BOS are solicited for interest. If they request to see the document, it is forwarded to them for comment. Based on these bodies, over 200 commentators have the opportunity to provide input into this systematic literature review. To view comments, visit the RC CPG Peer review/Public Comment eReport.

#### THE AAOS CLINICAL PRACTICE GUIDELINE APPROVAL PROCESS

This final clinical practice guideline draft must be approved by the AAOS Committee on Evidence-Based Quality and Value Committee, the AAOS Council on Research and Quality, and the AAOS Board of Directors. These decision-making bodies are described in <u>eAppendix 1</u>. Their charge is to approve or reject its publication by majority vote.

#### **REVISION PLANS**

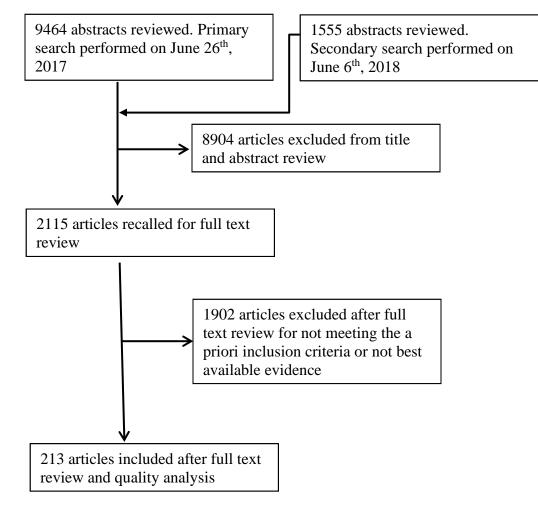
This clinical practice guideline represents a cross-sectional view of current treatment and may become outdated as new evidence becomes available. This clinical practice guideline will be revised in accordance with new evidence, changing practice, rapidly emerging treatment options, and new technology. This clinical practice guideline will be updated, re-issued, or withdrawn in five years.

#### SYSTEMATIC LITERATURE REVIEW DISSEMINATION PLANS

The primary purpose of the present document is to provide interested readers with full documentation of the best available evidence for various procedures associated with the topic of this review. Publication of most systematic literature reviews is announced by an Academy press release, articles authored by the systematic literature review development group and published in the Journal of the American Academy of Orthopaedic Surgeons, and articles published in AAOS *Now*.

Selected clinical practice guidelines are disseminated by webinar, AAOS Online Learning, the Orthopaedic Video Theater (OVT), Media Briefings, and by distributing them at relevant Continuing Medical Education (CME) courses and at the AAOS Resource Center.

## STUDY ATTRITION FLOWCHART



## RECOMMENDATIONS

## MANAGEMENT OF SMALL TO MEDIUM TEARS

Strong evidence supports that both physical therapy and operative treatment result in significant improvement in patient-reported outcomes for patients with symptomatic small to medium full-thickness rotator cuff tears.

# Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

#### Rationale

Two prospective randomized controlled trials comparing physical therapy to operative repair for treatment of small to medium rotator cuff tears showed substantial improvement in patient reported outcomes (PROs)and strength over time; however, there were no clinically meaningful difference in PROs between the groups. (Moosmayer, 2014, Kukkonen 2015) At 5-year follow up, Moosmayer, et.al., reported that the results of primary repair were superior to physical therapy, with the mean group differences in PROs were below the accepted minimal clinically important difference. (Moosmayer 2014) Both physical therapy and operative repair groups demonstrated clinically meaningful improvement from baseline in the Constant score, ASES score, SF-36 score, and strength. (Moosmayer 2014) At 2-years, Kukkonen, et.al., reported no significant (p=0.38) differences in the mean change of the Constant score between physical therapy and repair, both treatments resulted in substantial clinical improvement from pre-to-post treatment. (Kukkonen 2015)

## **Risks and Harms of Implementing this Recommendation**

There are no harms in associated in implementing this recommendation. There were no reported statistical differences between primary or secondary repair, when physical therapy fails (p=0.23). (Moosmayer S 2014)

#### **Future Research**

Continued comparative studies between physical therapy and surgical repair investigating larger tear sizes and modern approaches and fixation methods. The studies need to continue beyond 5-years to fully understand the true efficacy of each treatment.

## LONG TERM NON-OPERATIVE MANAGEMENT

Strong evidence supports that patient reported outcomes (PRO) improve with physical therapy in symptomatic patients with full thickness rotator cuff tears. However, the rotator cuff tear size, muscle atrophy, and fatty infiltration may progress over 5 to 10 years with non operative management.



Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

#### Rationale

Two prospective randomized controlled trials comparing physical therapy to operative repair for treatment of small to medium rotator cuff tears have showed that physical therapy can result in clinical improvements, but the rotator cuff tears continue to enlarge with time. (Moosmayer 2014, Kukkonen 2015) In 37% of the rotator cuff tears treated with physical therapy in whom the tear size increased > 5 mm over five years; tear progression did not occur (0/60) in the repaired group (Moosmayer 2014) At 2-years, Kukkonen, et.al., reported that the tears treated with physical therapy instructed home exercise program enlarged from an average of 9.6 mm to 11.7 mm, while the repaired tendons tear size decreased from 8.4 mm to 4.2 mm (p<0.01). (Kukkonen 2015) After an average of 8.8 years, patients who were treated non-operatively showed substantial muscle atrophy in 49% (18/37) and fatty infiltration in 41% (15/37). (Moosmayer 2017)

#### **Risks and Harms of Implementing this Recommendation**

Patients treated non-operatively are at risk for reduced strength with rotator cuff tear progression. Moosmayer, et.al., compared patients treated with physical therapy that had an increase the tear size  $\leq$  5mm to those that progressed to > 5mm and reported the > 5mm group showed a loss of strength (between-group difference of 4.2 kg, p=0.02). (Moosmayer 2014) In a prospective cohort study, the Constant score was 81points for patients with tear size increases < 20 mm compared to 58.5 points in those  $\geq$  20 mm (p=0.008). (Moosmayer 2017) Patients who select physical therapy should be informed that over a 9 year period their tear size may progress and this could lead to a substantial decline in their perceived and measurable outcome.

#### **Future Research**

Continued long term comparative studies between physical therapy and surgical repair investigating larger tear sizes with pre-and postoperative advanced imaging studies. It is still unclear what factors influence tear progression and if tear progression advances enough to preclude future repair and subsequent resolution of symptoms.

## **OPERATIVE MANAGEMENT**

Moderate evidence supports that healed rotator cuff repairs show improved patientreported and functional outcomes compared to physical therapy and unhealed rotator cuff repairs.

# Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

#### Rationale

In a 1-year prospective randomized controlled trial (RCT) comparing physical therapy to surgical repair for treatment of small to massive rotator cuff tears, Lambers Heerspink, et.al., reported a superior Constant score for intact repairs (88.5) compared to physical therapy (75.6, p<0.05) and re-tears (73.2). (Lambers Heerspink 2015) A 5-year prospective RCT of small to medium sized rotator cuff tears comparing physical therapy with an option of surgical treatment (what the authors termed secondary surgery) to primary surgical repair reported that 24% (12/51) patients failed to substantially improve their Constant score (mean increase of 1.8 points) with physical therapy and opted for surgical repair within the first two years. (Moosmayer 2014). The post hoc as-treated analysis comparing primary tendon repair, physical therapy only, and secondary surgery after failed physical therapy showed a significantly larger Constant score in favor of primary repair over physical therapy (between-group difference of 9.7 points, p=0.006), but no significant difference between primary and secondary tendon repair (p=0.23). (Moosmayer 2014) At 5 years, re-tears were diagnosed by ultrasound in 25% (15/60) of the patients; 7 partial and 8 full thickness tears. The partial thickness tears showed significant inferior results compared to intact repairs (mean Constant score difference of 23.1 points, p=0.001); full thickness tears demonstrated no difference in Constant score compared to intact repairs (p=0.92). (Moosmayer 2014) However, in a level II cross-sectional study, healed rotator cuff repairs compared to full thickness re-tears showed significant improvement in the ASES and SST scores; intact ASES 91, SST 10.2 verses fullthickness defect ASES 69, SST 6.5 (p<0.01). (Kim 2014)

#### **Risks and Harms of Implementing this Recommendation**

There are no harms in associated in implementing this recommendation. There were no reported statistical differences between primary or secondary repair, when physical therapy fails (p=0.23). (Moosmayer 2014)

#### **Future Research**

Continued long term comparative studies between physical therapy and surgical repair investigating larger tear sizes with pre-and postoperative advanced imaging studies. The long-term consequences of a persistent rotator cuff tear or a re-tear is currently not known.

## **ACROMIOPLASTY & ROTATOR CUFF REPAIR**

Moderate strength evidence does not support the routine use of acromioplasty as a concomitant treatment as compared to arthroscopic repair alone for patients with small to medium sized full-thickness rotator cuff tears.



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

#### Rationale

Five high quality studies (Abrams, G. 2014; Gartsman, G. 2004; MacDonald, P. 2011; Milano, G. 2007; Shin S. 2012) evaluated the effect of acromioplasty on rotator cuff repair of small and medium sized tears. Overall, acromioplasty did not have an effect on outcomes with the exception of one study which found a higher reoperation rate in patients without acromioplasty. Gartsman, et al. performed a randomized study on patients with supraspinatus tears and Type 2 acromions, with no difference in outcome. Milano, et al. randomized 80 patients and similarly found no difference in outcomes after 2 years. Abrams, et al. evaluated 52 patients, and also found no difference between groups. Shin, et al. similarly found no differences in randomized groups with varying acromial morphology included in both groups.

MacDonald, et al. evaluated 86 randomized patients with and without acomioplasty and also found no difference in patients reported outcomes, however, there was a higher reoperation rate in the group without acromioplasty. Four of the patients subsequently had second surgery for acromioplasty. One had a type 2 acromion and the others had type 3 acromions.

#### **Risks and Harms of Implementing this Recommendation**

There are no harms in associated in implementing this recommendation. There were no reported statistical differences between primary or secondary repair, when physical therapy fails (p=0.23). (Moosmayer S 2014)

#### **Future Research**

Continued long term comparative studies between physical therapy and surgical repair investigating larger tear sizes with pre-and postoperative advanced imaging studies. The long-term consequences of a persistent rotator cuff tear or a re-tear is currently not known.

## DISTAL CLAVICLE RESECTION

Moderate strength evidence supports the use of distal clavicle resection as a concomitant treatment to arthroscopic repair for patients with full-thickness rotator cuff tears and symptomatic acromioclavicular joints.



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

#### Rationale

Two studies (Oh, J. 2014 and Park, Y. 2015) showed no difference in patients with and without distal clavicle resection. One study (Oh) included patients with symptomatic AC joint arthrosis, and while the outcomes were the same, a distal clavicle resection resulted in symptomatic instability in a small number.

Another study (Kim, J. 2011) studied the use of DCR in asymptomatic AC joint arthrosis however, this study may not be generalizable to most patients as this included patients with asymptomatic AC joints with inferior spurs.

#### **Risks and Harms of Implementing this Recommendation**

There is no known harm to patients by implementing this recommendation, but there could potentially be a slightly higher reoperation rate on patients who did not undergo the concomitant procedures.

#### **Future Research**

Future research could be performed to elucidate risk factors for reoperation rates in certain groups who did not undergo concomitant procedures.

## DIAGNOSIS (CLINICAL EXAMINATION)

Strong evidence supports that clinical examination can be useful to diagnose or stratify patients with rotator cuff tears; however, combination of tests will increase diagnostic accuracy.

## Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

#### Rationale

Evidence from 8 high quality studies (Liu 2016, Lin 2015, Castoldi 2009, Park 2005, Litaker 2000, Villafane 2015, Holtby 2004, Gillooly 2010) indicate that the following tests are useful to diagnosis full-thickness rotator cuff tear: bear hug test, belly press test, empty can test, external rotator lag sign, external rotation resistance test, full can test, Hawkins test, Hug up test, internal rotation lag sign (IRLS) test, internal rotation resistance test (IRRT) test, Internal rotation resistance test at maximal 90 degrees of abduction and maximal external rotation (IRRTM) test, Jobe Test, Lateral Jobe Test, Lift off test, NEER test, Patte Test, and Yocum test. Generally, these tests are better to diagnose (rule in), than screening (rule out) full thickness rotator cuff tears.

Bear hug test summary

Combined full/partial thickness tears:

One high quality study evaluated the bear hug test to diagnose any rotator cuff tear (Lin 2015). The test results produce a small but sometimes important change in probability of rotator cuff tears (positive LR=3.49, negative LR=0.37).

Belly press test summary

Combined full/partial thickness tears:

One high quality study evaluated the belly press test to diagnose any rotator cuff tear (Lin 2015). The test results produce a small, but sometimes important change in the probability of a tear (positive LR=3.18, negative LR=0.45).

Empty can test summary

Combined full/partial thickness tears:

One high quality study evaluated the empty can test for diagnosing any rotator cuff tear (Liu 2016). The test results produce a small, but sometimes important change in the probability of a tear (positive LR=3.30, negative LR=0.21).

External rotator lag sign summary

Partial Thickness Tears:

One high quality study evaluated the external rotator lag sign test to diagnose partial thickness tears (Castoldi 2009). A positive test resulted in a moderate sized increase in probability of a partial thickness tear (positive likelihood ratio(LR)= 6.44). However, the test was poor for ruling out partial thickness tears, with a negative test producing a very small decrease in probability of a partial thickness tear(negative LR=0.89).

External Rotation Resistance Test (Resisted ER).

One high quality (Park 2005) and one low quality (Litaker 2000) evaluated External Rotation Resistance Test.

Full thickness tear:

Park found that resisted ER maybe useful for ruling in full thickness tears (positive LR=3.16), but was poor at ruling them out (negative LR=0.59).

Partial Thickness Tear:

Park found resisted ER to be poor at ruling in and ruling out partial tears (positive LR=0.63 negative LR=1.17).

Combined partial and full thickness:

Litaker found resisted ER to be a poor rule-in test(positive LR=1.78) in diagnosing combined full/partial thickness tears, but may be somewhat useful for ruling out tears Negative LR=0.42).

#### Full Can Test summary

Combined full/partial thickness tears:

One high quality study evaluated the full can test to diagnose any rotator cuff tear (Liu 2016). The test results produce a small, but sometimes important change in the probability of a tear (positive LR=4.10, negative LR=0.27).

Hawkins Test summary

Two high quality studies and one low quality study evaluated the Hawkins test (Liu 2016, Villafane 2015, Park 2005).

Combined full/partial thickness tears:

Liu used the test to diagnose any rotator cuff tear, and found a positive test produced a small, but sometimes important increase in probability of a tear with a positive test (positive LR=2.82). However, the same study found it was a poor test for ruling out a tear (negative LR=0.73).

Full Thickness Tears:

A moderate quality study by Park(2005) found the Hawkins test to be poor at ruling in and ruling out full thickness tears (Positive LR=1.33, negative LR=0.65).

#### Partial Thickness Tears:

The Villafane (2015) study used the test to diagnose partial tears. A positive test produced a large and conclusive increase in probability of a partial tear (positive LR=10.25), and a negative test produced a moderate decrease in probability of a partial tear(negative LR=0.20). However, a moderate quality study by Park (2005) found the test to be poor at both ruling in and ruling out a partial tear (positive LR=1.36, negative LR=0.55).

Hug up test summary

Combined full/partial thickness tears:

One high quality study evaluated the hug up test for diagnosis of any rotator cuff tear (Liu 2016). A positive test produced a small, but sometimes important increase in probability of a tear (positive LR=4.02), and a negative test produced a large decrease in probability of a tear (negative LR=0.08). Internal Rotation Lag Sign (IRLS) test summary

Combined full/partial thickness tears:

One high quality study evaluated the IRLS test to diagnose any rotator cuff tear(Lin 2015). A positive test produced a small, but sometimes important increase in probability of a tear(positive LR=4.21). The test

was poor for ruling out a tear, with a negative test producing a very small decrease in probability of a tear(negative LR=0.74).

Internal rotation resistance test (IRRT) test summary

Combined full/partial thickness tears:

One high quality study (Lin 2015) evaluated the IRRT test to diagnose any rotator cuff tear. A positive test produced a small, but sometimes important increase in probability of a tear (Positive LR=2.59). However, it was a poor rule out test (negative LR=0.51).

Internal rotation resistance test at maximal 90 degrees of abduction and maximal external rotation (IRRTM) test summary

Combined full/partial thickness tears:

One high quality study evaluated the IRRTM test to diagnose any rotator cuff tear (Lin 2015). Both positive and negative test results produced a small, but sometimes important change in probability of any rotator cuff tear (positive LR=3.91, negative LR=0.29).

Jobe Test summary Two high quality studies evaluated the Jobe test (Holtby 2004, Villafane 2015) for FTT and PTT tears.

Full-Thickness Tears : Holtby(2004) was the only study to specifically evaluate full thickness tears. The study found the test results produced a very low change in probability of a full-thickness tear(positive LR=1.36, negative LR=0.84).

Partial-Thickness Tears: Two studies evaluated the Jobe test for diagnosing a partial tear (Holtby 2004,Villafane 2015). The results were varied between the two studies. The rule in test strength ranged from poor (positive LR=1.34, Holtby 2004) to moderately strong (positive LR=9.50, Villafane 2015). The Villafane study found that a negative test produced a small, but sometimes important decrease in probability of a partial tear(negative LR=0.26). However, the Holtby study found the test to be poor at ruling out a partial tear (negative LR=0.71).

Lateral Jobe Test Summary

Combined full/partial thickness tears:

Gillooly(2010) found the Lateral Jobe test to be moderately good at ruling in any tear (positive LR=7.43), and a negative test produced a small but sometimes important decrease in probability of a tear(negative LR=0.21). The same study evaluated the Lateral Jobe test when combined with other physical exams, and found the test results produced a small but sometimes important change in probability of a tear(positive LR=4.69, negative LR=0.48).

Lift off test summary

Combined full/partial thickness tears:

Lin(2015, high quality) evaluated the lift off test for diagnosing any rotator cuff tear. The test was poor at ruling in and ruling out a tear (positive LR=1.92, negative LR=0.58).

#### NEER test summary

Three high quality studies and one moderate quality study evaluated the Neer test (Liu 2016,Villafane 2015, Park 2005). Liu tested for any rotator cuff tear, Villafane tested for partial tears, and Park stratified by tear size.

Combined full/partial thickness tears:

Liu found the test to be moderately strong at ruling in any tear (positive LR=5.90), and may be useful for ruling out any tear (negative LR=0.42).

Full Thickness Tear:

Park evaluated the tests ability to diagnose full thickness tears. The study found the test was poor at both ruling in and ruling out full tears (positive LR=1.12, negative LR=0.86).

#### Partial Thickness Tears:

The Villafane and Park studies evaluated the neer test for diagnosing partial tears. As a rule in test, the results were inconsistent between studies. Villafane found the test to be moderately strong at ruling in partial tears (positive LR=7.00), but Park found it to be poor at ruling in a tear (positive LR=1.44). Both studies showed the test to be poor at ruling out partial tears (negative LR range=0.52-0.75).

#### Patte Test summary

Partial Thickness Tears:

One high quality study evaluated the Patte test to diagnose a partial tear (Villafane 2015). A positive test result produced a large and conclusive increase in probability of a partial tear(positive LR=19.0). However, it was a poor rule out test (negative LR=0.63).

#### Yocum test summary

Partial Thickness Tears:

One high quality study evaluated the Yocum test for partial tears (Villafane 2015). A positive test result produced a large and conclusive increase in probability of a partial tear (positive LR=19.5). A negative test produced a small, but sometimes important decrease in probability of a partial tear (negative lr=0.23).

#### **Risks and Harms of Implementing this Recommendation**

There is no known harm to patients by implementing this recommendation, but there could potentially be a slightly higher reoperation rate on patients who did not undergo the concomitant procedures.

#### **Future Research**

Future research could be performed to elucidate risk factors for reoperation rates in certain groups who did not undergo concomitant procedures.

## **DIAGNOSIS (IMAGING)**

# Strong evidence supports that MRI, MRA, and ultrasound are useful adjuncts to a clinical exam for identifying rotator cuff tears.

# Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

#### Rationale

<u>Ultrasound</u>

Six high quality studies evaluated the use of ultrasound for diagnosing rotator cuff tears (Cheng 2015, Day 2016, Gormeli 2014, Moosmayer 2007, Ok 2013, Waldt 2007).

Four of the studies tested for the presence of any rotator cuff tear (full/partial thickness) vs no tear (Day 2016, Gormeli 2014, Moosmayer 2007, Waldt 2007). A meta-analysis of these four studies was conducted (see figures 1 and 2 for ROC curve and forest plot in eAppendix 2). The pooled positive LR was 3.60 (2.10,6.00) indicating that a positive result produced a small, but sometimes important increase in probability of a tear. The confidence interval for this pooled effect crosses 5(the threshold for a moderate effect), so we cannot rule out the possibility that the test is of moderate strength for ruling in a tear. The pooled estimate of the negative LR revealed substantial heterogeneity, with an I-squared of 50.10%. Therefore, only the range of negative LRs from the included studies are reported in the summary of findings tables. Negative LRs ranged from 0.07 (indicating a strong rule-out test) to 0.53 (indicating a poor rule out test).

Four studies evaluated the ability of ultrasound to distinguish between full thickness tears and either partial or no tear (Cheng 2015, Gormeli 2014, Ok 2013, Waldt 2007). A meta-analysis of positive and negative LRs produced consistent estimates, with I squared heterogeneities of 0 and 22.15%. The Meta-Analysis ROC curves and forest plots can be found in figures 3 and 4. A positive ultrasound test produced a moderate increase in probability of full thickness tears vs partial/no tears (pooled positive LR=5.20 (3.20,8.20)). A negative test produced a small, but sometimes important decrease in the probability a patient did not have a full thickness tear, but instead either had a partial tear or no tear (negative LR=0.28 (0.20,0.38)).

#### Magnetic Resonance Arthrography (MRA)

12 high quality studies tested MRA for the diagnosis of rotator cuff tears. (Anbar 2015, Dae 2009, Duc 2006, Lee 2018, Magee 2014, Magee 2016, Ok 2013, Pfirrmann 1999, Probyn 2007, Schaeffeler 2012, Schreinemachers 2009, Waldt 2007).

Five studies used MRA to distinguish between any tear (full/partial thickness) and no tear (Dae 2009, Pfirrmann 1999, Probyn 2007, Schaeffeler 2012, Schreinemachers 2009). A meta-analysis was attempted, but pooled estimates of positive and negative LRs revealed substantial heterogeneity, with I squared statistics of 85.16 and 80.33% respectively. Therefore, the range of positive and negative LRs are presented, rather than the pooled estimates. The positive LRs ranged from 1.6 (poor test) to 53.57 (Strong test) for ruling in any tear vs no tear. The negative LRs ranged from 0 (strong test) to 0.65 (poor test) for ruling out any tear vs no tear. Given these results, MRA may provide a benefit for diagnosing any tear, but the exact strength of the test is unclear given widely heterogeneous results between studies.

Four studies tested the ability of MRA to distinguish between full thickness tears and partial or no tears (Duc 2006, Lee 2018, Ok 2013, Waldt 2007). A meta-analysis was conducted(see figures 5 and 6 for ROC curve and forest plot). The meta-analysis produced consistent estimates of the positive LR, indicating that a positive MRA test for full thickness tears produced a large increase in probability that a patient truly had a full tear instead of a partial or no tear (pooled positive LR= 19.55 (5.73,55.72)). Pooled estimates for the negative LR had high heterogeneity (I squared=91.15%), so the pooled result is not reported. The negative LR in the included studies ranged from 0 (strong rule out test) to 0.68 (poor rule out test).

Three studies tested the ability of MRA to distinguish between a full thickness tear and no tear (Anbar 2015, Magee 2014, Magee 2016). These could not be meta-analyzed because a minimum of four studies is required. A positive test produced a moderate to large increase in probability of a full thickness tear versus no tear(positive LR range=7.33 to 100). The negative LR was more variable, ranging from 0(a strong decrease in probability of a full tear with a negative test) to 0.25(a small but sometimes important decrease in probability).

Two studies evaluated MRA for diagnosing partial tears vs no tears (Dae 2009, Lee 2018). Positive LRs ranged from a small(but sometimes important) increase in probability of a partial tear with a positive test (positive LR=4.16) to a large increase in probability of tear(positive LR=13.42). Negative LRs ranged from a strong decrease in probability of a partial tear with a negative test(negative LR=0.03), to a small but sometimes important decrease in probability of a partial tear(negative LR=0.44).

#### Magnetic Resonance Imaging (MRI)

Thirteen high quality studies evaluated MRI for the diagnosis of rotator cuff tears (Binkert 2001, Herold 2006, Lee 2016, Lee 2018, Magee 2014, Magee 2016, Mohtadi 2004, Razmjou 2016, Ryu 2016, Shellock 2001, Tuite 1994, VanBeek 2014, Yıldız2017).

Seven studies used MRI to test for any rotator cuff tear(full or partial thickness) versus no tear (Herold 2006, Lee 2018, Ryu 2016, Shellock 2001, Tuite 1994, VanBeek 2014, Yıldız 2017). An attempt was made to meta-analyze these studies, but there was very high heterogeneity in estimates of the positive and negative LRs between studies (I squared=91.94% and 91.8% respectively). Therefore, only the range of estimates from the studies is reported. The positive likelihood ratios ranged from 1.18(poor rule in test) to 97.06 (strong rule in test). The negative LRs also ranged from a strong rule out test (negative LR=0.03) to a poor rule out test (0.79).

Six high quality studies used MRI to distinguish full thickness tears from no tear (Binkert 2001, Magee 2014, Magee 2016, Mohtadi 2004, Razmjou 2016, Tuite 1994). Again, meta-analysis results revealed high heterogeneity, and likelihood ratio ranges are presented here. The studies indicated that MRI was a moderate to strong test for ruling in a full thickness tear over no tear (positive LR range=6.82-100). The negative LR ranged from a large decrease in probability of a full tear with a negative test (negative LR=0) to a small, but sometimes important decrease in probability of a full tear(negative LR=0.47).

Five studies evaluated the ability of MRI to distinguish between partial tears versus no tear. A metaanalysis produced consistent estimates of the positive LR, but negative LRs were inconsistent between studies. The ROC curve and forest plot can be found in figures 7 and 8. The pooled positive LR was 3.40 (2.10,5.40), indicating that a positive MRI produced a small, but sometimes important increase in probability of a partial tear. The negative LR ranged from 0.27 (a small but possibly important decrease in probability of a partial tear with a negative test) to 0.84 (a poor rule out test).

## **POST-OP MOBILIZATION TIMING**

Strong evidence suggests similar postoperative clinical and patient-reported outcomes for small to medium sized full-thickness rotator cuff tears between early mobilization and delayed mobilization up to 8 weeks for patients who have undergone arthroscopic rotator cuff repair.



Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

#### Rationale

Six high quality randomized controlled trials (Cuff, D. 2012; De Roo, P. 2015; Duzgun, I. 2014; Keener, J. 2014; Koh, K. 2014; Mazzocca, A. 2017) evaluated post-operative mobilization paradigms following rotator cuff repair. All 6 studies compared the outcomes of patients who began mobilization exercises of their shoulder within 0-2 weeks post-operatively against patients who delayed mobilization exercises for between 4-8 weeks post-operatively. In each of the reviewed studies, patients were immobilized in a sling for an equivalent length of time irrespective of group assignment. The consistency of sling use between groups allows our analysis to focus on "mobilization" as defined by thetiming the first visit of supervised physical therapy. For nearly all measures, including post-operative rotator cuff healing, patient reported outcome measures, and post-operative medication use, early and delayed mobilizationparadigms yield similar outcomes.

Early mobilization favors improved range of motion (Cuff et. al. 2012; Duzgun et. al.2014, Keener et. al. 2014; Mazzocca et al. 2017) and quality of life patient reported outcome measures (Mazzocca et al.) when compared to patients who delayed mobilization, but these differences become negligible by 6 months post-operatively.

Delayed mobilizationuntil 4-8 weeks post-operatively is associated with higher rates of post-operative healing. However, these differences do not reach statistical significance in the 5 best available evidence studies which analyzed rotator cuff integrity (Cuff et. al. 2012, DeRoo et. al.2015, Keener et al.2014, Koh et. al. 2014, Mazzocca et. al.2017). Post-operative healing was analyzed by US and/ or MRI from 7 days (Mazzocca et. al. 2017) through up to 2 years post-operatively (Keener et. al. 2014, Koh et. al. 2014).

In summary, early (0-2 weeks) or delayed (4-8 weeks) mobilizationyields similar outcomes in rotator cuff healing, range of motion, and patient reported outcome scores. Early mobilization tends to favor improved range of motion through the first 6 months post-operatively while delaying mobilization exercises is associated with higher rates of post-operative healing particularly for tears of larger size.

#### **Risks and Harms of Implementing this Recommendation**

Because the early and delayed mobilization protocols yield similar results there is no known harm from implementing this recommendation.

#### **Future Research**

This question centers on the timing of post-operative mobilization exercises, defined in the 6 studies reviewed here, as the initiation of supervised physical therapy. Although easy to quantify, a physical therapy visit may not be the measure most indicative of stress on the healing repair. Absolute load and cyclic loading have been identified as factors affecting suture durability in biomechanical studies.

Counting the number of physical therapy visits assumes that the amount of load and the cycles across the tendon-suture-bone interface are consistent across rehabilitation protocols. Perhaps it is not surprising that there are few differences between early and delayed rehabilitation protocols when the measure of dosing is a physical therapy visit. If researchers want to further elucidate the differential impacts of loading a rotator cuff repair either a more finite measure of dosing should be used (number of total cycles), the study period should be shorter (12 weeks), or the rehabilitation protocols need to be more disparate. At minimum, future research should examine the dose and load of exercise (as measured by consistent attendance at supervised physical therapy visits and consistent completion of a home exercise program) over the course of post-operative care. Finally, , more patient centric outcome measures such as the WORC quality of life score (Mazzocca et. al.) should be routinely incorporated to determine the direct impact on the patient of differing rehabilitation protocols.

# CORTICOSTEROID INJECTIONS FOR ROTATOR CUFF TEARS

Moderate evidence supports the use of a single injection of corticosteroids with local anesthetic for short-term improvement in both pain and function for patients with shoulder pain.



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

### Rationale

One high quality study (Eyigor, C., 2010) compared corticosteroid injections with transcutaneous electrical nerve stimulator (TENS) treatment for the treatment of rotator cuff tendinitis. It showed an advantage in favor of injections with improvement in pain and functional scores for up to 12 weeks following the injection.

One high quality study (Rabini, A, 2012) compared corticosteroid injections with hyperthermia via localized microwave diathermy for rotator cuff tendinopathy with a follow up of 24 weeks. Both treatment groups showed equivalent improvement in functional scores but steroid injections showed better pain scores.

One high quality study (Penning, L. I. F., 2012) compared subacromial corticosteroid injections with hyaluronic acid injections or lidocaine (placebo injections in patients with subacromial impingement. There was no convincing benefit detected from hyaluronic acid injections compared with corticosteroid or placebo injections, whereas corticosteroid injections produced a better reduction in pain compared with placebo at 12 weeks but not at 26 weeks.

One high quality study (Alvarez, C. M., 2005) compared subacromial injection of corticosteroid injection to placebo (xylocaine) in chronic rotator cuff tendinosis. They were 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 for all follow-up time intervals evaluated.

One high quality study (Kang, H., 2016) compared the efficacy of subacromial injection with sodium bicarbonate versus corticosteroid in patients with chronic subacromial bursitis: Both injections were equivalent in functional and pain scores for up to 4 weeks.

Despite the high quality of the above studies, the strength of the recommendation was downgraded to *moderate* due to variability of study findings.

### **Risks and Harms of Implementing this Recommendation**

Corticosteroid injections in the setting of rotator cuff tears may be detrimental to the healing potential following cuff repair. Considering that rotator cuff diagnoses are clinical, a single corticosteroid injection may be given to confirm the presence of a symptomatic rotator cuff tear, but may adversely affect surgical outcomes.

### **Future Research**

Further research is recommended to determine the role of corticosteroid injections in the various settings of rotator cuff pathology. Currently there is no high quality studies specifically addressing the role of corticosteroid injections in partial and / or full thickness cuff tears.

# HYALURONIC ACID INJECTIONS FOR ROTATOR CUFF TEARS

Limited evidence supports for the possible use of hyaluronic acid injections in the nonoperative management of rotator cuff pathology with no tears.

# Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

# Rationale

One high quality study (Penning, L. I. F., 2012) compared subacromial corticosteroid injections with hyaluronic acid injections or lidocaine (placebo) injections in patients with subacromial impingement. There was no convincing benefit detected from hyaluronic acid injections compared with corticosteroid or placebo injections for up to 26 weeks.

One moderate quality study (Moghtaderi, A. 2013) compared ultrasound guided subacromial sodium hyaluronate injection saline in patients with impingement syndrome without complete tear of rotator cuff at 12 weeks. Both injections showed improvement, but sodium hyaluronate showed better results.

One moderate quality study (Byun, S. D. 2011) sono-guided subacromial bursa injection of steroid injection followed by sodium hyaluronate injection once a week for 3 weeks with a sono-guided subacromial bursa steroid injection once a week for 3 weeks for patients with subacromial bursitis, partial or complete rotator cuff tear. The study concluded that Subacromial bursa injection of hyaluronate with steroid in patients with peri-articular shoulder disorders has additive effects on functional improvement.

One moderate quality study (Ozgen, M.; 2012) compared short- and long-term effect of intraarticular sodium hyaluronate injection in patients with supraspinatus tendinitis (ST) with conventional physiotherapy methods. Both groups received home exercise programs. The study concluded that physical therapy modalities and SH application had similar effects in short- and long term for painful ST.

One moderate quality study (Meloni, F 2008) examined the effect of ultrasound guided periarticular injection of hyaluronate into shoulders with supraspinatus tendinosis compared to saline injections. Both were done weekly for a total of 5 injections. At 12 months follow up, sodium hyaluronate had better clinical outcomes.

Despite the medium-high quality of the above studies, the strength of the recommendation was downgraded to limited due to variability of study findings.

### **Risks and Harms of Implementing this Recommendation**

There are no known risks to hyaluronic acid injections that are specific to shoulders or the rotator cuff.

### **Future Research**

Further research may be conducted to further define the role of hyaluronic acid injections in rotator cuff pathology.

# PLATELET RICH PLASMA (PRP) INJECTION IN PARTIAL-THICKNESS TEARS

# Limited evidence does not support the routine use of platelet rich plasma for the treatment of cuff tendinopathy or partial tears.

# Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

### Rationale

Three high quality studies (Najati 2017, Kesikburun 2013, Rha 2013) provided conflicting evidence regarding the role of platelet rich plasma (PRP) in cuff tendinopathy or partial tears.

One high quality study (Najati 2017) compared PRP to exercise therapy for the treatment of subacromial impingement. Both PRP and exercise therapy showed improvement up to 6 months but exercise was more effective.

One high quality study (Kesikburun 2013) compared PRP to placebo (saline) injection therapy for the treatment of rotator cuff tendinopathy or partial tears for up to one year. Both treatments shows improvement in QoL, Function and pain scores but were equivalent at all time points.

One high quality study (Rha 2013) compared PRP to dry needling for up to 6 months. Functional scores of the platelet-rich plasma injection were superior to those of dry needling.

Despite the high quality of the above studies, the strength of the recommendation was downgraded to limited due to variability of study findings.

#### **Risks and Harms of Implementing this Recommendation**

There are no known risks to PRP injections that are specific to shoulders or the rotator cuff.

#### **Future Research**

Further research may be conducted to further define the role of PRP injections in rotator cuff pathology. Future studies should standardize the type of PRP formulation utilized or at the very least measure the concentrations of key constituents.

# HIGH-GRADE PARTIAL THICKNESS ROTATOR CUFF TEARS

Strong evidence supports the use of either conversion to full-thickness or transtendinous/in-situ repair in patients that failed conservative management with high-grade partial thickness rotator cuff tears.

# Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

# Rationale

There were two high quality study (Kim Y-S et al. 2015, and Shin et al. 2012) and two moderate quality studies (Castagna et al., Franceschi et al.). The remainder of published studies either had too few subjects (<20) or were low quality level IV studies. Kim Y-S et al. in a level II study noted no difference in either clinical outcomes or re-tear rates comparing transtendinous versus tear completion in Ellman III partial thickness rotator cuff tears. Bursal side cuff tears had a higher re-tear rate with either technique. Shin et al. in a level II study noted similar outcomes for the two groups but noted a significantly faster recovery with tear completion. Retears were higher in the tear completion group but did not reach statistical significance. Castagna et al. looked at a total of 74 patients randomized to transtendinous versus tear completion. There were no significant differences between the two groups. Franceschi et al. in a level II study felt that outcomes and re-tear rates were comparable between transtendinous repair and tear completion.

# Risks and Harms of Implementing this Recommendation

None.

# **Future Research**

Additional high quality level one studies with longer follow-up would be useful to establish if the results of these techniques hold up with time. Larger studies might also establish risk of retear with differing techniques.

# **PROGNOSTIC FACTORS (AGE)**

Strong evidence supports that older age is associated with higher failure rates and poorer patient reported outcomes after rotator cuff repair.

# Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

### Rationale

Three high quality studies (Deniz 2014, Park 2015, Rashid 2017) demonstrated higher re-tear rates are associated with advanced age. Four high quality studies (Chung 2012, Deniz 2014, Kim 2016, Robinson 2013) demonstrated worse patient reported outcomes in patients with older age.

### **Risks and Harms of Implementing this Recommendation**

While older age is associated with higher failure rates and poorer patient reported outcomes, age alone should not be used as a contraindication for rotator cuff repair, as failure to heal is related to multiple features. Older patients should be counseled that they would be at increased risk for failure and poorer outcomes than younger patients who undergo rotator cuff repair.

### **Future Research**

Degenerative rotator cuff disease is a phenomenon of aging, yet there is great variability in this phenomenon. Future research is needed to distinguish chronological age from physiologic age, and healing will likely improve when *age related* changes to the rotator cuff are better understood and manipulated.

# **PROGNOSTIC FACTORS (HIGHER BMI)**

Moderate evidence supports that higher BMI is correlated with higher re-tear rates after rotator cuff repair surgery; however, strong evidence supports that there is no correlation between higher BMI and worse patient-reported outcomes following rotator cuff repair.



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

### Rationale

One high quality study (Kim 2018) demonstrated that higher BMI was associated with higher re-tear rates after rotator cuff repair.

Four high quality studies demonstrated either no difference in patient reported outcomes for patients with high BMI (Namdari 2010, Potter 2015, Wylie 2018), or improved patient reported outcomes in patients with higher BMI (Chalmers 2018) after rotator cuff repair, in part related to a lower starting ASES scores and pain VAS in patients with higher BMI.

# **Risks and Harms of Implementing this Recommendation**

Patients with higher BMI may be at higher risk for perioperative complications, yet the literature supports that these patients should be treated surgically if indicated, as they can expect improved patient reported outcomes.

### **Future Research**

Patients with higher BMI generally start with lower scores on patient reported outcome measures. Future research should investigate if this starting point changes with weight loss, and how this affects the improvement in patient reported outcomes after surgery.

# PROGNOSTIC FACTORS (WORKER'S COMPENSATION)

Strong evidence supports the presence of a worker's compensation claim is associated with poorer patient reported outcomes after rotator cuff repair.

# Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

### Rationale

Two high quality studies (Millett 2017, Namdari 2010) demonstrate poorer patient reported outcomes after rotator cuff repair in patients who have a worker's compensation claim.

### **Risks and Harms of Implementing this Recommendation**

There are no undue risks or harms when performing rotator cuff repair on patient who have pending worker's compensation claims, however patients should be counseled that patient reported outcomes are better when no claim is present.

#### **Future Research**

It would be important to know what features (job satisfaction, manual labor job, resiliency, etc.) might predict poorer patient reported outcomes after rotator cuff repair in the population of worker's compensation patients.

# **PROGNOSTIC FACTORS (COMORBIDITIES)**

# Moderate evidence supports the association of poorer patient reported outcomes in patient with more comorbidities



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

#### Rationale

Two high quality studies (Namdari 2010, Tashjian 2006) correlated the number of comorbidities to worse patient reported outcomes in patients who underwent rotator cuff repair surgery.

#### **Risks and Harms of Implementing this Recommendation**

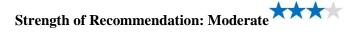
While perioperative complications could be increased when performing rotator cuff repair surgery on patients with multiple comorbidities, this should not be used as a contraindication for surgery. Patients should be counseled that they may be at increased risk for poorer outcomes compared to patients who are healthier.

#### **Future Research**

While the number of comorbidities does influence patient reported outcomes after rotator cuff repair surgery, it would be important to understand the risk stratification of specific comorbidities to accurately make recommendations about the expected outcomes.

# **PROGNOSTIC FACTORS (DIABETES)**

Moderate evidence suggests that patients with diabetes will have higher re-tear rates and poorer quality of life and patient reported outcome scores after rotator cuff repair.



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

#### Rationale

One high quality study (Kim 2018) demonstrated higher rotator cuff repair re-tears in patients with diabetes. One high quality study (Chung 2012) demonstrated poorer patient reported outcome scores using the HRQOL physical health-related quality of life in patients with diabetes.

#### **Risks and Harms of Implementing this Recommendation**

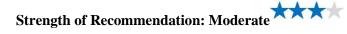
There are no undue risks or harms when performing rotator cuff repair on patient who have diabetes, other than perioperative complications related to having diabetes (e.g. adhesive capsulitis). Patients should be counseled that patient reported outcomes are poorer compared to patients without diabetes.

#### **Future Research**

Future research should determine if adequate control of diabetes will improve patient reported outcomes and improve healing after rotator cuff repair.

# PROGNOSTIC FACTORS (PATIENT EXPECTATIONS)

Moderate evidence correlates higher preoperative patient expectations for surgery with higher patient reported outcomes after rotator cuff repair.



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

### Rationale

One study (Henn 2007) correlated the score from the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) questionnaire-used to measure patient expectations- to SST, VAS, SF-36, SST, DASH and found that greater preoperative expectations correlated with better postoperative patient reported outcome scores.

# **Risks and Harms of Implementing this Recommendation**

There are no undue risks or harms when performing rotator cuff repair on patients different expectations after surgery, however patient reported outcomes may be lower in patients with lower expectations and patients should be advised of this finding.

### **Future Research**

There is currently very little research on optimal ways to evaluate and influence patient expectation.

# **BIOLOGICAL AUGMENTATION WITH PLATELET DERIVED PRODUCTS**

Strong evidence does not support biological augmentation of rotator cuff repair with platelet-derived products on improving patient reported outcomes; however, limited evidence supports the use of liquid platelet rich plasma (PRP) in the context of decreasing re-tear rates.



Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

### Rationale

Several high strength studies confirm that the addition of liquid platelet-rich plasma or platelet-rich fibrin does not significantly change patient-reported outcomes.

Seven high quality studies (Jo, C.H. 2015; Malavolta, E.A. 2014; Pandey, V. 2016; Randelli, P., 2011; Wang, A. 2015; Zhang, Z. 2016; Flury 2016) that investigated the effect of liquid platelet rich plasma (PRP) on post-operative full thickness re-tear rates. A pooled analysis of randomized trials demonstrated a lower relative risk of full thickness re-tear [RR=0.43 (95% CI 0.26 - 0.69)] when patients treated PRP were compared with controls. While there was minimal statistical heterogeneity (I2=3.6%) in this analysis, there was a significant amount of clinical variability in the size of the tears, the type of PRP kit that was utilized, PRP application techniques, and fixation constructs. Given that an uncontrolled analysis was conducted (i.e. not enough studies for a meta-regression), the results should be interpreted with caution. With respect to platelet rich fibrin, there is insufficient evidence to make a recommendation for or against its utilization in reducing post-operative rotator cuff re-tear rates. Due to limited numbers in the pooled analysis, subgroup analyses for rotator cuff tear size could not be performed.

# **Risks and Harms of Implementing this Recommendation**

There are no known harms associated with the use of PRP.

### **Future Research**

Future studies should standardize the type of PRP formulation utilized or at the very least measure the concentrations of key constituents. Furthermore, larger studies will allow for controlled statistical analyses that consider the effect of confounders such as fixation constructs, marrow venting, size of tears, etc. Consistency in the definition of rotator cuff re-tear is also encouraged.

# SINGLE-ROW VS DOUBLE-ROW REPAIR

Strong evidence does not support double row rotator cuff repair constructs on improving patient-reported outcomes compared to single row vertical mattress repair constructs.

# Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

### Rationale

Nine high quality randomized controlled trials (RCTs) comparing single row versus double row constructs for full thickness rotator cuff tears reported significant improvement in all patient reported outcomes (PROs) at final follow-up; however, there were no clinically meaningful difference in PROs between the two repair groups (Aydin 2010, Barber 2016, Burks, 2009, Franceschi 2016, Franceschi 2007, Koh 2011, Lapner 2012, Ma 2012, Carbonel 2012). Two high quality RCTs reported significant improvement in PROs (UCLA scores, ASES scores, or strength testing) favoring double row repair in patients with >3cm full thickness rotator cuff tears (Ma 2012, Carbonel 2012) Aydin et al reported no difference in the Constant scores or complication rates between the two groups of single row (N=34) and double row (N=34) repair at final follow-up. Barber et al also reported no difference in all PROs between single row (N=20) compared to double row (N=20) repair for full thickness cuff tears less than 3cm augmented with platelet-rich plasma fibrin membrane. The failure rate at final follow-up was also similar between both groups, 3 out of 20 (15%) in each group. Furthermore, Burks et al, Franceschi et al, , Koh et al, and Lapner et al also found no clinically meaningful difference in the PROs between single row and double row repair for full thickness rotator cuff tears at final follow-up. Ma et al also reported similar UCLA and ASES scores at final follow-up comparing single to double row repair. However, in the subset of patients with >3cm full thickness tears, the authors reported significantly better shoulder strength in abduction and external rotation with double row repair at final follow-up. In the largest RCT comparing the outcome of single row versus double row repair, Carbonel et al reported similar PROs in patients with 1cm to 3cm tears. However, in patients with >3cm tears, double row repair showed superior results in both UCLA and ASES scores compared to single row repair.

### **Risks and Harms of Implementing this Recommendation**

There is no harm to patients by implementing this recommendation for small to medium size rotator cuff tears. However, in patients with larger rotator cuff tears (>3cm), single row vertical mattress repair may result in inferior PROs and higher failure rates compared to double row repair constructs.

### **Future Research**

Future research needs to be performed to evaluate for both PROs and failure rates on imaging and reoperation rates between single row compared to double row repair for larger full thickness rotator cuff tears >3cm in size.

# SINGLE-ROW VS DOUBLE-ROW REPAIR RE-TEARS

Strong evidence supports lower re-tear rates after double row repair compared to single row vertical mattress repair when evaluating for both partial and full thickness retears after primary repair; however, when evaluating the data for only full thickness retears, limited evidence does not support lower re-tear rates after double row primary repair.

# Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

### Rationale

Eight high quality randomized controlled trials (RCTs) utilized magnetic resonance imaging (MRI) reported the re-tear rates after single row versus double row repair in patients with full thickness rotator cuff tears (Barber 2016, Burks, 2009, Franceschi 2016, Franceschi 2007, Koh 2011, Lapner 2012, Ma 2012, Carbonel 2012).

When the re-tear rates include both partial and full thickness tears, a meta-analysis of the pooled data from these eight RCTs . identified the relative risk (RR = 0.58 (0.43-0.78)) of re-tear is significantly lower after double row repair compared to single row repair for full thickness rotator cuff tears. Thus, there is strong evidence that supports lower re-tear rates (partial and full thickness) after double row repair compared to single row repair for full thickness rotator cuff tears.

However, when re-tears are defined as full thickness only, the relative risk (RR = 0.71 (0.45-1.11)) is 0.71 with a wider confidence interval (0.45 – 1.11) which indicates limited evidence to support lower risk of re-tear (Full thickness) after double row compared to single row repairs.

### **Risks and Harms of Implementing this Recommendation**

There is no harm to patients by implementing this recommendation. However, partial and full thickness re-tear rates may be higher after single vertical mattress repair compared to double row in patients with full thickness rotator cuff tears. The clinical significance is unknown.

### **Future Research**

Future research should be performed to evaluate for failure rates on imaging and reoperation rates between single row compared to double row repair for full thickness rotator cuff tears. Research also needs to be done to better identify the clinical significance of a partial thickness re-tear after arthroscopic rotator cuff repair.

# MARROW STIMULATION

Limited evidence suggests that marrow stimulation at the time of rotator cuff repair does not improve patient-reported outcomes; however, this technique may decrease re-tear rates in patients with larger tear sizes.



Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

### Rationale

Three low to high quality studies (Milano G. 2010, Osti, L. 2010, Taniguchi, N. 2015) demonstrated that marrow stimulation (MS) does not have an effect on patient reported outcomes such as the constant score. One low quality study (Taniguchi) did demonstrate a decrease in re-tear rates. A high quality study by Milano demonstrated decreased re-tear rates in larger tears.

#### **Risks and Harms of Implementing this Recommendation**

The risk of complications with MS is low. If several microfracture holes are made in the footprint that are too close together there is the theoretical potential of comprising the fixation strength of suture anchors.

#### **Future Research**

Future studies should be large enough such that the statistical analyses will allow for consideration of confounders such as fixation constructs, size of tears, etc.. Consistency in the definition of a rotator cuff re-tear is also encouraged.

# DERMAL ALLOGRAFTS

Limited evidence supports the use of dermal allografts to augment the repair of large and massive rotator cuff tears to improve patient reported outcomes.

# Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

### Rationale

There was one moderate strength study (Barber et al. 2016) and one low strength studies (Gilot et al. 2015). The remainder of published studies either had too few subjects (<20) or involved interposition rather than augmentation of rotator cuff repair. Barber et al., in a moderate quality study, involved a comparison of two-tendon three-centimeter tears with or without an acellular human dermal matrix allograft augmentation. Both Constant scores and re-tear rates were significantly improved with use of the allograft augmentation, with no adverse events related to the allograft. Gilot et al. in a low quality study of 20 acellular dermal matrix augmented repairs versus 15 unaugmented repairs, noted a significantly decreased rate of retears and significantly improved outcome scores with augmented repairs. There were no graft related complications in the study of Gilot.

### **Risks and Harms of Implementing this Recommendation**

The use of dermal allografts increases operating time and thus may increase infection rates and other surgical time-related complications. Use of dermal allografts will also substantially increase the cost of rotator cuff surgery.

### **Future Research**

Given the risks and costs involved with these devices, high quality studies would be useful to definitively establish the benefits of these device.

# **XENOGRAFTS**

# Limited evidence does not support the use of xenografts to augment the repair of large and massive rotator cuff tears.

# Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

#### Rationale

One high quality study (Bryant, D. 2016), one moderate quality study (Ianotti, J. 2006), and three low quality studies (Flury, M. 2018, Walton, J. 2007, Ciampi, P. 2015) addressed xenografts as an ancillary surgical technique. The remainder of published studies either had too few subjects (<20) or involved interposition rather than augmentation of rotator cuff repair.

In a high quality study, Bryant et al. 2016 compared a porcine xenograft patch to no augmentation in the repair of moderate and large size rotator cuff tears. While they demonstrated non-inferiority for the porcine xenograft, no significant difference was found between the two groups for either re-tear or patient reported outcomes (PROs), although there was a trend to better PROs for the xenografts.

In a moderate quality study, Ianotti et al. 2006 compared a porcine xenograft augmentation in the repair of two tendon tears. While not statistically significant (p=0.08), the study trended towards worse outcomes in the xenograft augmented group. Three of 15 developed wound problems in the xenograft group. The authors did "not recommend using porcine small intestine submucosa to augment repairs of massive chronic rotator cuff tears done with the surgical and postoperative procedures described in this study."

In a low quality study, Flury et al. 2018 compared the outcome of porcine xenograft augmentation in patients age>60 using a matched-pair comparative trial design. No difference in outcomes was noted, with a trend (p=0.343) towards more local complications in the xenograft group. In a different low quality study, Walton et al. 2007 also evaluated a porcine xenograft. This study noted "no recognizable benefit" with the porcine xenograft, and 4/10 had a severe post-operative reaction requiring further surgical treatment in the xenograft group. In a low quality cohort study, Ciampi et al. evaluated the results of augmentation with a bovine xenograft augmentation versus no graft in two arms of the study, with a third arm being synthetic patch augmentation. No difference was noted in strength, elevation, or re-tear rates with xenograft augmentation, compared to no augmentation of the repairs. No local inflammation was noted in the xenograft group.

#### **Risks and Harms of Implementing this Recommendation**

There are no known harms associated with implementing this recommendation. Multiple other option for augmentation of rotator cuff repairs exist besides xenograft.

#### **Future Research**

While the evidence available to recommend for or against xenograft augmentation is mixed, the absence of clear benefit associated with these grafts, and the increased incidence of post-operative reaction coupled with the absence of reports of these reactions with allograft augment would seem to indicate that further research is not warranted at this time on xenografts in their current form.

# **OPEN VS ARTHROSCOPIC REPAIRS**

Strong evidence supports no difference in long-term (> 1 year) patient-reported outcomes or cuff healing rates between open and arthroscopic repairs; however, arthroscopic-only technique is associated with better short-term improvement in post operative recovery of motion and decreased visual analog scale (VAS) scores.



Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

# Rationale

There were four high quality studies (Carr 2017, Liu, J. 2017, Mohtadi, N. 2008; Van der Zwaal, P. 2013) comparing the outcome of arthroscopic and either open or mini-open repair and two moderate quality studies comparing perioperative pain and morbidity between arthroscopic and open rotator cuff repair. None of these six studies reported any significant difference in the outcome of any of the three techniques. Multiple other comparative studies of lower quality exist regarding this topic, some with differing outcomes, but only the best available evidence was considered in the development of this recommendation.

In a prospective, randomized high quality study, Carr et al. (2017) evaluated the outcome of 273 patients randomized to either open/mini-open, or all-arthroscopic repair. There was no difference in outcome scores, with a 40% healing rate in both groups. This study extended the preliminary results of Carr et al. study reported in 2014.

In a high quality prospective randomized study of 100 patients, Liu et al. 2017 showed no difference in outcome between all-arthroscopic and mini-open repairs for either patient reported outcomes, retear rates, or occurrence of adhesive capsulitis at one year.

Mohtadi et al. 2008 published a high quality study comparing open to mini-open repair showed no difference in PROs with either technique at average follow-up of 28 months. No post-operative imaging was performed.

Van der Zwaal et al. 2013 presented a high quality study comparing all-arthroscopic to mini-open repair at one year. Final PROs, retear rates, and presence of associated adhesive capsulitis were similar between both groups.

In evaluating the literature which forms the basis for this recommendation, two high-quality studies (Liu et al. 2017 and Van der Zwaal et al. 2013) showed faster short-term recovery with all-arthroscopic repair. Liu et al. 2017 showed significant difference in both range of motion and VAS scores as well as superior scores on both the DASH and Constant PRJOs up to one-month postoperatively. Liu concluded that the all-arthroscopic procedure has better recovery at short-term follow-ups. Similarly, Van der Zwaal et al. noted improved range of motion, VAS, and DASH scores at six weeks comparing all-arthroscopic to mini-open repair. They felt that "Patients do attain the benefits of treatment somewhat sooner (6 weeks) with the arthroscopic procedure."

# **Risks and Harms of Implementing this Recommendation**

There are no risks associated with implementing this recommendation.

# **Future Research**

Given the conflicting information available regarding improvements in post-operative pain and early recovery with all-arthroscopic repair, further studies are needed in this area to establish benefits of this procedure.

# POSTOPERATIVE PAIN MANAGEMENT

Moderate strength evidence supports the use of multimodal programs or non-opioid individual modalities to provide added benefit for postoperative pain management following rotator cuff repair.



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

#### Rationale

A number of articles, of both high and moderate quality (Bain, G. I. 2001, Banerjee, S. S. 2008, Bang, S. R. 2010, Behr, A. 2012, Borgeat, A. 2010, Ciccone, Ii W. J. 2008, Clendenen, S. R. 2010, Coghlan, Ja 2009, Culebras, X 2001, Desmet, M. 2013, Desmet, M. 2015, Faria-Silva, R. 2016, Fredrickson, M. J. 2011, Hadzic, A. 2005, Hartrick, Ct 2012, Hoe-Hansen, C. 1999, Kim, Jy 2016, Klein, Sm 2000, Ko, S. H. 2017, Kraeutler, M. J. 2015, Lee, Ar 2012, Lee, Hj 2015, Lee, J. J. 2017, Lee, J-H 2011, Lee, Jj 2014, Lee, Jj 2015, Lin, Y. H. 2015, Liu, X. N. 2017, Mahure, S. A. 2017, Malik, T. 2016, Merivirta, R. 2012, Oh, J. H. 2009, Osti, L. 2015, Park, J. Y. 2016, Schwartzberg, Rs 2013, Shin, H. J. 2016, Sun, Z. 2018, Takada, M. 2009, Thackeray, E. M. 2013, Watanabe, K. 2016, Yamakado, K. 2014, Yun, M. J. 2012), addressed a variety of individual and multimodal pain management modalities. Based on this literature, it is clear that any one of a variety of pain management non-opioid medications or modalities has a positive impact on patient pain control in the post-operative period. It should be noted that most of the literature validated a singular approach against a singular control group and did not perform a direct comparison against all other options, nor were indirect comparisons of the literature review findings using network meta-analysis statistically feasible. . This led to the inability to rank-order pain management modalities in a "most effective" to "least effective" manner. Because of this, the guideline development group framed the pain management recommendations as a more general list of pain management modalities, both singular and multimodal, which exhibited comparative efficacy, as compared to their within-study comparisons.

Defining multimodal therapy as using multiple but different modalities of pain management therapies simultaneously in the same post-operative period, the study group was able to arrive at the second multimodal pain management recommendation (recommendation B). The evidence assessing multimodal pain management supported the use of multimodal pain management treatment compared to a single modal approach. In particular, four high quality studies (Jo, 2014; Perdreau, 2015; Syed, 2018; Han, 2013) support the concept of multimodal therapy although the specifics of which mix of options is the most optimal requires further research.

### **Risks and Harms of Implementing this Recommendation**

While the study group's conclusion that there are various successful options of both singular and multimodal post-operative pain management has moderate strength of evidence, the analysis did not include a risk benefit comparison of options. Each individual medication or modality carries its own inherent risks and benefits which should be taken into account by the health care provider prescribing the intervention.

### **Future Research**

The analysis of this question has exposed the need for future research particular into the pros and cons of each medication, modality, and multimodal program as they are compared to each other. The collective

data and indirect comparisons from the high quality articles cited in this recommendation could be used to perform a network meta-analysis, providing valuable information to best guide future management.

# **CONSENSUS STATEMENTS**

# SUPERVISED EXERCISE VS UNSUPERVISED EXERCISE

In the absence of reliable evidence, it is the opinion of the work group that supervised physical therapy is more appropriate than unsupervised home exercise for some patients following rotator cuff repair.

Strength of Recommendation: Consensus

# MULTIPLE STEROID INJECTIONS FOR ROTATOR CUFF TEARS

In the absence of reliable evidence, it is the opinion of the work group that multiple steroid injections may compromise the integrity of the rotator cuff, which may affect attempts at subsequent repair.

Strength of Recommendation: Consensus

# PLATELET RICH PLASMA (PRP) INJECTION IN FULL-THICKNESS TEARS

In the absence of reliable evidence, it is the consensus of the work group that we do not recommend the routine use of PRP in the non-operative management of full-thickness rotator cuff tears.

Strength of Recommendation: Consensus

# PARTIAL ROTATOR CUFF TEAR

In the absence of reliable evidence, the work group is unable to define a preference for the choice of debridement versus repair of high-grade partial-thickness cuff tears that have failed physical therapy, however repair of high grade partial tears could improve outcomes.

Strength of Recommendation: Consensus

# Rationale

The limited publications comparing debridement to partial tear repair of the rotator cuff all are excluded under the exclusion criteria for the Guidelines. Only two retrospective, comparative studies exist, both of which are case series studies that have non-consecutive enrollment of patients and so were excluded. Weber SC (Weber, 1999) published a low quality study comparing an early series of debrided patients outcomes to a later series of repaired partial rotator cuff tears and had superior clinical outcomes and lower reoperation rates with partial tear repair. Ogilvie-Harris et al. (Ogilvie-Harris,1993) evaluated a similar non-consecutive group. The open repair group scored better for function, strength and overall score, but patient satisfaction was similar in the two groups. They recommend repair for active patients, and debridement for low activity patients.

# **Risks and Harms of Implementing this Recommendation**

While, given the level of evidence, overtreatment of partial rotator cuff tears may occur, what data is available suggests that only minimal harm would be associated with implementing this recommendation.

### **Future Research**

High strength comparative studies between debridement and partial tear repair may further clarify the utility of these two techniques in managing partial rotator cuff tears.

# UNREPAIRABLE TEARS WITHOUT ARTHROPATHY (NON-REVERSE ARTHROPLASTY)

In the absence of reliable evidence, it is the opinion of the work group that physical therapy, biceps tenotomy/tenodesis, partial repair, tendon transfer, superior capsular reconstruction, arthroscopic debridement, or graft augmentation (non-porcine) can improve patient reported outcomes.



# MASSIVE, UNREPAIRABLE ROTATOR CUFF TEAR (REVERSE ARTHROPLASTY)

In the absence of reliable evidence, it is the opinion of the work group that in patients with massive, unrepairable tears and significant functional loss who have failed other treatments, reverse arthroplasty can improve patient reported outcomes.

Strength of Recommendation: Consensus

# UNREPAIRABLE TEARS WITH ARTHROPATHY

In the absence of reliable evidence, it is the opinion of the workgroup that after failure of conservative treatment, reverse shoulder arthroplasty for unrepairable tears with glenohumeral joint arthritis can improve patient reported outcomes.

Strength of Recommendation: Consensus

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# **GUIDELINE DEVELOPMENT GROUP DISCLOSURES**

Prior to the development of this clinical practice guideline, group members disclose conflicts of interest (COI). They disclose COIs in writing to the American Academy of Orthopaedic Surgeons via a private on-line reporting database and also verbally at the recommendation approval meeting.

**Disclosure Items:** (n) = Respondent answered 'No' to all items indicating no conflicts. 1 = Royalties from a company or supplier; 2 = Speakers bureau/paid presentations for a company or supplier; 3A = Paid employee for a company or supplier; 3B = Paid consultant for a company or supplier; 3C = Unpaid consultant for a company or supplier; 4 = Stock or stock options in a company or supplier; 5 = Research support from a company or supplier as a PI; 6 = Other financial or material support from a company or supplier; 7 = Royalties, financial or material support from publishers; 8 = Medical/Orthopaedic publications editorial/governing board; 9 = Board member/committee appointments for a society.

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Submitted on: 05/19/2017