



OPTIMIZING THE MANAGEMENT OF ROTATOR CUFF PROBLEMS

GUIDELINE AND EVIDENCE REPORT

**Adopted by the American Academy of Orthopaedic Surgeons
Board of Directors
December 4, 2010**

This Clinical Practice Guideline was developed by an American Academy of Orthopaedic Surgeons (AAOS) physician volunteer workgroup based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. 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.

This guideline and the systematic review upon which it is based were funded exclusively by the AAOS. All panel members gave full disclosure of conflicts of interest prior to participating in the development of this guideline. The AAOS received no financial support from industry or other commercial sponsors to develop this guideline or the underlying systematic review.

Disclaimer

An AAOS physician volunteer Work Group developed this clinical practice guideline based on a systematic review of the current scientific and clinical information as well as accepted approaches to treatment and/or diagnosis. This clinical practice guideline is not intended to be used as 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 this 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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Suggested Citation for referencing this document:

American Academy of Orthopaedic Surgeons Clinical Practice Guideline on the Diagnosis and Treatment of Osteochondritis Dissecans Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2010

Published 2010 by the American Academy of Orthopaedic Surgeons
6300 North River Road
Rosemont, IL 60018
First Edition
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Summary of Recommendations

The following is a summary of the recommendations in the AAOS' clinical practice guideline, *Optimizing the Management of Rotator Cuff Problems*. This summary does not contain rationales that explain how and why these recommendations were developed nor does it contain the evidence supporting these recommendations. ***All readers of this summary are strongly urged to consult the full guideline and evidence report for this information.*** We are confident that those who read the full guideline and evidence report will see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility. This summary of recommendations is not intended to stand alone. Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient and physician.

Full Thickness Tears and Asymptomatic Patients

1. In the absence of reliable evidence, it is the opinion of the work group that surgery not be performed for asymptomatic, full thickness rotator cuff tears.

Strength of Recommendation: Consensus

Description: The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Full Thickness Tears and Symptomatic Patients

2. Rotator cuff repair is an option for patients with chronic, symptomatic full thickness tears.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" strength studies with consistent findings, or evidence from a single "Moderate" quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rotator Cuff Tears and Exercise

3. a. We cannot recommend for or against exercise programs (supervised or unsupervised) for patients with rotator cuff tears.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rotator Cuff Tears and Corticosteroid Injections

3. b. We cannot recommend for or against subacromial injections for patients with rotator cuff tears.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rotator Cuff Tears and NSAIDs, Activity Modification, Ice, Heat, Iontophoresis, Massage, T.E.N.S., PEMF, and Phonophoresis

3. c. We cannot recommend for or against the use of NSAIDs, activity modification, ice, heat, iontophoresis, massage, Transcutaneous Electrical Nerve Stimulation (TENS), Pulsed Electromagnetic Field (PEMF), or phonophoresis (ultrasound) for nonoperative management of rotator cuff tears.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rotator Cuff Related Symptoms and Exercise or Nonsteroidal Anti-Inflammatory Medication

4. a. We suggest that patients who have rotator cuff-related symptoms in the absence of a full thickness tear be initially treated non-operatively using exercise and/or non-steroidal anti-inflammatory drugs.

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Rotator Cuff Related Symptoms and Corticosteroid Injections or PEMF

4. b. We cannot recommend for or against subacromial corticosteroid injection or Pulsed Electromagnetic Field (PEMF) in the treatment of rotator cuff-related symptoms in the absence of a full thickness tear.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rotator Cuff Related Symptoms and Iontophoresis, Phonophoresis, Transcutaneous electrical nerve stimulation (TENS), ice, heat, massage or activity modification

4. c. We cannot recommend for or against the use of iontophoresis, phonophoresis, transcutaneous Electrical Nerve Stimulation (TENS), ice, heat, massage, or activity modification for patients who have rotator cuff related symptoms in the absence of a full thickness tear.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Acute Traumatic Rotator Cuff Tears and Surgery

5. Early surgical repair after acute injury is an option for patients with a rotator cuff tear.

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Perioperative Interventions –Corticosteroid Injections/NSAIDS

6. We cannot recommend for or against the use of perioperative subacromial corticosteroid injections or non-steroidal anti-inflammatory medications in patients undergoing rotator cuff surgery.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Confounding factors – Age, Atrophy/Fatty Degeneration and Worker’s Compensation Status

7. a. It is an option for physicians to advise patients that the following factors correlate with less favorable outcomes after rotator cuff surgery:
- Increasing Age
 - MRI Tear Characteristics
 - Worker’s Compensation Status

Strength of Recommendation: Increasing Age: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

MRI Tear Characteristics: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Worker’s Compensation Status: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Confounding Factors - Diabetes, Co-morbidities, Smoking, Infection, and Cervical Disease

7. b. We cannot recommend for or against advising patients in regard to the following factors related to rotator cuff surgery:

- Diabetes
- Co-morbidities
- Smoking
- Prior Shoulder Infection
- Cervical Disease

<u>Confounding Factor</u>	<u>Strength of Recommendation</u>
Diabetes	Inconclusive
Co-morbidities	Inconclusive
Smoking	Inconclusive
Infection	Inconclusive
Cervical Disease	Inconclusive

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Surgery - Acromioplasty

8. We suggest that routine acromioplasty is not required at the time of rotator cuff repair.

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Surgery – Partial Rotator Cuff Repair, Debridement, or muscle transfers for patients with irreparable rotator cuff tears when surgery is indicated.

9. It is an option to perform partial rotator cuff repair, debridement, or muscle transfers for patients with irreparable rotator cuff tears when surgery is indicated.

Strength of recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Surgery – Tendon to Bone Healing

10. a. It is an option for surgeons to attempt to achieve tendon to bone healing of the cuff in all patients undergoing rotator cuff repair.

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Surgery - Suture Anchors and Bone Tunnels

10. b. We cannot recommend for or against the preferential use of suture anchors versus bone tunnels for repair of full thickness rotator cuff tears.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Surgery – Arthroscopic, Open, Mini-Open

10. c. We cannot recommend for or against a specific technique (arthroscopic, mini-open or open repair) when surgery is indicated for full thickness rotator cuff tears.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Surgery - Non-Crosslinked, Porcine Small Intestine Submucosal Xenografts

11. a. We suggest surgeons not use a non-crosslinked, porcine small intestine submucosal xenograft patch to treat patients with rotator cuff tears.

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Surgery - Allografts and Xenografts

11. b. We cannot recommend for or against the use of soft tissue allografts or other xenografts to treat patients with rotator cuff tears.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Post-Operative Treatment - Cold Therapy

12. In the absence of reliable evidence, it is the opinion of the work group that local cold therapy is beneficial to relieve pain after rotator cuff surgery.

Strength of Recommendation: Consensus

Description: The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Post-Operative – sling, shoulder immobilizer, abduction pillow, or abduction brace

13. a. We cannot recommend for or against the preferential use of an abduction pillow versus a standard sling after rotator cuff repair.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Post-Operative Rehabilitation – Range of Motion Exercises

13. b. We cannot recommend for or against a specific time frame of shoulder immobilization without range of motion exercises after rotator cuff repair.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Post-Operative Rehabilitation – Active Resistance Exercises

13. c. We cannot recommend for or against a specific time interval prior to initiation of active resistance exercises after rotator cuff repair.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Post-Operative Rehabilitation – Home Based Exercise and Facility Based Rehabilitation

13. d. We cannot recommend for or against home-based exercise programs versus facility-based rehabilitation after rotator cuff surgery.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Post-Operative - Infusion Catheters

14. We cannot recommend for or against the use of an indwelling subacromial infusion catheter for pain management after rotator cuff repair.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

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Peer Review

Participation in the AAOS peer review process does not constitute an endorsement of this guideline by the participating organization.

The following three organizations participated in peer review of this clinical practice guideline and gave their explicit consent to have their names listed in this document:

American Society for Surgery of the Hand (ASSH)

American Society of Shoulder and Elbow Therapists (ASSET)

American Physical Therapy Association (APTA)

Participation in the AAOS peer review process does not constitute an endorsement of this guideline by the participating organization.

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DO YOU OR A MEMBER OF YOUR IMMEDIATE FAMILY RECEIVE ROYALTIES FOR ANY PHARMACEUTICAL, BIOMATERIAL OR ORTHOPAEDIC PRODUCT OR DEVICE?262

IF YES, PLEASE IDENTIFY PRODUCT OR DEVICE:262

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SOMEWHAT SOMEWHAT264

DISAGREE DISAGREE AGREE AGREE264

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.....264

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I. INTRODUCTION

OVERVIEW

This clinical practice guideline is based on a systematic review of published studies on the treatment of rotator cuff problems in adults (>19 years). In addition to providing practice recommendations, this guideline also highlights gaps in the literature and areas that require future research.

GOALS AND RATIONALE

The purpose of this clinical practice guideline is to use the best currently available evidence to improve treatment. This is in keeping with current evidence-based practice (EBP) standards. To assist in this decision making, this clinical practice guideline consists of a multiple systematic reviews of the available literature regarding the treatment of rotator cuff problems. The systematic reviews detailed herein include evidence published from 1966 through October 1, 2008 and demonstrates where there is good evidence, where evidence is lacking, and what topics future research must target in order to improve the treatment of patients with rotator cuff problems. AAOS staff and the physician work group responsible for developing this guideline systematically reviewed the available literature and subsequently wrote its recommendations based on a rigorous, standardized process.

Musculoskeletal care is provided in many different settings by many different providers. This guideline is an educational tool to assist qualified physicians in a series of treatment decisions, and is an effort to improve the quality and efficiency of patient 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 all qualified clinicians managing patients with rotator cuff problems. Typically, orthopaedic surgeons will have completed medical training, a qualified residency in orthopaedic surgery, and some may have completed additional sub-specialty training.

The guideline is intended to both guide clinical practice and to serve as an information resource for medical practitioners. An extensive literature base was considered during the development of this guideline. In general, practicing clinicians do not have the resources necessary for such a large project. The AAOS hopes that this guideline will assist practitioners not only in making clinical decisions about their patients, but also in describing, to patients and others, why the chosen treatment represents the best available course of action.

This guideline is not intended for use as a benefits determination document. Making these determinations involves many factors not considered in the present document, including available resources, business and ethical considerations, and need.

Users of this guideline may also want to consider any appropriate use criteria (AUC) that the AAOS has developed on the topic of this guideline. The focus of AAOS guidelines is on the question “Does it work?” When an AAOS guideline or an AAOS-endorsed guideline shows effectiveness, the AAOS may undertake development of AUC that ask the question “In whom does it work?” This dichotomy is necessary because the medical literature (both orthopaedic and otherwise) typically does not adequately address the latter question.

That having been said, evidence for the effectiveness of medical services is not always present. This is true throughout all areas of medicine. Accordingly, all users of this clinical practice guideline are cautioned that an absence of evidence is not evidence of ineffectiveness. An absence means just that; there are no data. It is the AAOS position that rigorously developed clinical practice guidelines should not seek to guide clinical practice when data are absent unless the disease, disorder, or condition in question can result in loss of life or limb. The AAOS incorporates expert opinion into a guideline under these circumstances, and only under these circumstances. Accordingly, when the AAOS states that it cannot recommend for or against a given intervention or service, it is stating that currently available data do not provide clear guidance on which course of action is best, and that it is therefore reluctant to make a recommendation that has potentially national ramifications. Although true in all circumstances, the AAOS believes that when evidence is absent, it is particularly important for the treatment of rotator cuff problems to be based on mutual patient and physician communication, with discussion of available treatments and procedures applicable to that patient, and with consideration of the natural history of the disease and current practice patterns. Once the patient has been informed of available therapies and has discussed these options with his/her physician, an informed decision can be made. Clinician input based on experience with both conservative management and surgical skills increases the probability of identifying patients who will benefit from specific treatment options.

PATIENT POPULATION

This document addresses the treatment of rotator cuff problems in adults (defined as patients 19 years of age and older). The guideline provides information on patient management after diagnosis of a rotator cuff tear or rotator cuff related symptoms. Surgical technique recommendations in this guideline are only applicable to patients with full thickness rotator cuff tears. This guideline does not address patients diagnosed with adhesive capsulitis/frozen shoulder, inflammatory arthropathies, or co-existing fractures of the shoulder. Patients undergoing shoulder arthroplasty and patients with wheelchair/weight bearing shoulders (i.e. polio patients, paraplegics, crutches) are not addressed by this guideline.

INCIDENCE & PREVALENCE

Rotator cuff disease is one of the most common musculoskeletal disorders in the adult population. Approximately 18 million Americans self-reported shoulder pain in 2005, meaning that it follows only knee complaints in prevalence.¹ Rotator cuff tears were noted in 39% of cadaver shoulders in the classic study of De Palma et al.² and a high prevalence of asymptomatic cuff tears was noted in contemporary studies^{3,4,5}. A substantial proportion of asymptomatic cuff tears become symptomatic over time³,

begging the question of the impact and efficacy of earlier diagnosis and treatment upon the ultimate clinical outcome and cost of rotator cuff treatment. The incidence of full thickness rotator cuff tears increases as a function of age. With the “graying” of the baby boomer generation, we can therefore expect the prevalence of rotator cuff disorders to increase over the next two decades.¹

BURDEN OF DISEASE

Rotator cuff disorders comprise a large subset of shoulder disorders overall and are one of the most common causes of shoulder pain in the upper extremity, especially when pooled as a continuum from sub-acromial impingement/bursitis to rotator cuff degeneration/tear.⁶ In 2007, 76,000 work-related shoulder injuries and illnesses involving days away from work were reported in the United States.⁷ The potential cost burden of rotator cuff disease is worth acknowledging particularly when calculated as a summation of costs related to diagnostic imaging, therapy services, and surgical intervention.

ETIOLOGY

Rotator cuff degeneration (tendinosis) begins in the early decades of life, with partial thickness cuff tears and full thickness cuff tears increasing in frequency in the later decades. Cuff tears are occasionally truly traumatic in nature; however tendon tears usually occur in the presence of some degree of tendinosis. In some cases, extrinsic damage related to acromial spurring co-exists, however current opinion places greater emphasis upon the intrinsic nature of rotator cuff degeneration, including the inherent vascularity of the rotator cuff. Unfortunately, the fundamental pathoetiology of intrinsic tendinosis is not well understood.

RISK FACTORS

Increasing age is a positive risk factor for development of a rotator cuff tear, and repetitive trauma may play a role as well (for example industrial exposure, some high demand sports activities).⁸

EMOTIONAL AND PHYSICAL IMPACT OF ROTATOR CUFF PROBLEMS

Rotator cuff disorders substantially affect quality of life, including disordered activities of daily living, altered sleep patterns, and adverse impact on work and recreation. This impact ranges from a chronic low level nuisance to un-remitting and severe pain and disability. Although post-operative recovery is most dramatic in the first few months, patients report gradual improvement in function and decreased pain for a year or more after surgical intervention. Some patients become physically dependent during the early post-operative phase, since they are unable to utilize the operated extremity for activities of daily living. This is a particular burden in the elderly, especially for patients who were living alone and independently prior to surgery.

POTENTIAL HARMS AND CONTRAINDICATIONS

Most treatments are associated with some known risks, especially invasive and operative treatments. In addition, contraindications vary widely based on the treatment administered. Therefore, discussion of available treatments and procedures applicable to

the individual patient rely on mutual communication between the patient and physician, weighing the potential risks and benefits for that patient.

II. METHODS

This clinical practice guideline and the systematic reviews upon which it is based evaluate the effectiveness of treatments for rotator cuff problems. This section describes the methods used to prepare this guideline and the systematic reviews, including search strategies used to identify literature, criteria for selecting eligible articles, grading the evidence, data extraction, methods of statistical analysis, and the review and approval of the guideline. We employed systematic review methods to minimize bias.^{8,9}

The physician members of the AAOS Rotator Cuff Problems work group prepared this guideline and systematic review with the assistance of the AAOS Clinical Practice Guidelines Unit (Appendix I). When information from the literature was sparse or lacking, it was supplemented by the consensus opinion of the work group.

To develop this guideline, the work group initially met in an introductory meeting on March 14 and 15, 2008 to establish the scope of the guideline and systematic review. Upon completion of the systematic reviews the work group participated in a two-day recommendation meeting on November 1 and 2, 2008. An initial draft was completed and submitted for peer review in January 2009. As a result of input received during peer review, the work group agreed to meet for an additional meeting on January 16 and 17, 2010 at which the final recommendations and rationales were edited, written and voted on.

The resulting draft guidelines are then peer-reviewed, edited in response to that review, and then sent for public commentary whereafter additional edits are made. Thereafter, the draft guideline is sequentially sent for approval by the AAOS Evidence Based Practice Committee, the AAOS Guidelines and Technology Oversight Committee, the AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (Appendix II provides a description of the AAOS bodies involved in the approval process). All AAOS guidelines are reviewed and updated or retired every five years in accordance with the criteria of the National Guideline Clearinghouse.

SIMULATED RECOMMENDATIONS

The work group began work on this guideline by constructing a set of simulated recommendations. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. They function as questions for the systematic review, not as final recommendations or conclusions. Simulated recommendations are almost always modified on the basis of the results of the systematic review. These recommendations also form the guideline's scope and guide the searches for literature. These *a priori* simulated recommendations are inviolate in that, once specified, they cannot be modified, they must all be addressed by the systematic review, and the relevant review results must be presented in the final guideline. The *a priori* and inviolate nature of the simulated recommendations combats bias.

STUDY SELECTION CRITERIA

TYPES OF STUDIES

We developed *a priori* article selection criteria for our review. Specifically, to be included in our systematic reviews an article had to be a report of a study that:

- Evaluates a treatment for rotator cuff problems including:
 - rotator cuff tear or
 - rotator cuff related symptoms
 - Impingement syndrome (Subacromial impingement syndrome)
 - Rotator cuff disease
 - Rotator cuff tendonitis
 - Shoulder tendonitis
 - Subacromial bursitis
 - Subacromial tendonitis
 - Supraspinatus tendonopathy (tendonitis)
- Is a full article published in the peer reviewed literature.
- Is an English language article published after 1965.
- Is not a cadaveric, animal, or in vitro study.
- Is not a retrospective case series, medical records review, meeting abstract, unpublished study report, case report, historical article, editorial, letter, or commentary.
- Is the most recent report of a study or the report with the largest number of enrolled patients in a study with multiple publications.
- Enrolled ≥ 10 patients in each of its study groups.
- Enrolled a patient population of at least 80% of patients with rotator cuff problems 19 years of age and older.
- Enrolled $> 90\%$ patients without pre-existing shoulder surgery.
- Reports quantified results.

- Enrolled only patients with full thickness rotator cuff tears (for surgical techniques and post-operative treatment recommendations).
- Enrolled patients without the following conditions
 - arthroplasty (shoulder replacement)
 - concomitant capsular release for adhesive capsulitis /frozen shoulder
 - inflammatory arthropathy (i.e. rheumatoid arthritis, systemic lupus erythematosus)
 - coexisting fractures of the shoulder, proximal humerus, or greater tuberosity
 - wheelchair/weight bearing shoulder (i.e. polio patients, paraplegics, crutches)

BEST AVAILABLE EVIDENCE

When examining primary studies, we analyzed the best available evidence. We first considered the randomized controlled trials identified by the search strategy. In the absence of two or more RCTs, we sequentially searched for prospective controlled trials, prospective comparative studies, retrospective comparative studies, and case-series studies. Only studies of the highest level of available evidence are included, assuming that there are 2 or more studies of that higher level. For example, if there were two Level II studies that addressed a recommendation, Level III and IV studies were not included.

We did not include systematic reviews compiled by others or guidelines developed by other organizations. These documents are developed using different inclusion criteria than those specified by the AAOS work group. Therefore they may include studies that do not meet our inclusion criteria. We recalled these documents, if the abstract suggested they might provide an answer to one of our recommendations, and searched their bibliographies for additional studies to supplement our systematic review.

We included only patient-oriented outcomes and did not include surrogate/intermediate outcomes. Patient-oriented outcomes are outcomes that directly show whether a patient is living longer, healthier, and/or happier. Surrogate outcomes are substitutes for these outcomes. Surrogates include laboratory measurements and other physical signs.¹⁰

When study authors reported outcomes that were measured using “paper and pencil” instruments, we considered only results from instruments for which validation was attempted. That such attempts were made does not imply that all of these instruments are valid. Table 1 identifies the “paper and pencil” instruments used in the studies that met all inclusion criteria listed above and the key psychometric properties on which attempts at validation were made. In order to include an instrument in this guideline, the instrument must have had at least two of the four key psychometric properties tested.

Table 1 Validation of Outcome Instruments

Instrument	I.C.	Rep.	Val.*	Res.
ASES ¹¹ (American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form)	X ¹²	X ¹²	X ^{13, 12}	X ¹²
Constant-Murley Score ¹⁴ (CMS or Constant Score)		X ^{15‡}	X ^{16, 17, 18}	
DASH ¹⁹ (Disabilities of the Arm, Shoulder and Hand)	X ²⁰	X ²¹	X ²¹	X ²¹
FSET ²² (Functional Shoulder Elevation Test)				
Functional Assessment Questionnaire ²³		X ²³		
JOA ²⁴ (Japanese Orthopaedic Association)				
Neer Guidelines ²⁵				
OSS ²⁶ (Oxford Shoulder Scores)	X ²⁶	X ²⁶	X ²⁶	X ²⁶
PENN Shoulder Score ²⁷ (PSS)	X ²⁷	X ²⁷	X ²⁷	X ²⁷
RC-QOL ²² (Rotator Cuff Quality-of-Life Measure)		X ²²	X ²²	
SDQ ^{28, 29} (Shoulder Disability Questionnaire)			X ³⁰	X ³⁰
SF-36 ²⁸ (Short Form 36 Health Questionnaire Survey)	X ³¹	X ³¹	X ^{17, 31}	
SRQ ³¹ (Shoulder Rating Questionnaire or L' Insalata)	X ²⁸	X ³¹	X ³¹	X ³¹
SPADI ³² (Shoulder Pain and Disability Index)	X ^{32,33}	X ³²	X ^{33,29}	
SST ³³ (Simple Shoulder Test)	X ³³		X ^{33,35,18}	
UCLA Shoulder Score ³⁴		X ³⁷	X ^{33,18}	
VAS (Visual Analogue Scale)		X ³⁵	X ³⁵	
WORC ³⁶ (Western Ontario Rotator Cuff Index)		X ³⁷	X ³⁷	

I.C. = Internal Consistency (Reliability); Rep.= Reproducibility (Reliability); Val. = Validity; Resp. = Responsiveness; X = psychometric property addressed by study; *Construct or convergent validity; ‡ Authors note, “Reliability of the score was low, with a 95% confidence limit of between 15 and 20 points out of 100 for a single observation on a single patient.”

We only considered an outcome if $\geq 80\%$ of the patients were followed for that outcome (for example, some studies reported short-term outcomes data on nearly all enrolled patients, and reported longer-term data on only a few patients. In such cases, we did not include the longer-term data). We also excluded outcomes for study groups that did not have at least 10 patients.

MINIMAL CLINICALLY IMPORTANT IMPROVEMENT

Wherever possible, we considered not only whether a study result was statistically significant, but also whether the effect of a treatment achieved a minimal clinically important improvement (MCII). The MCII is the smallest clinical change that is important to patients, and recognizes the fact that there are some treatment-induced statistically significant improvements that are too small to matter to patients. We derived the values we used for MCII from the published studies that enrolled only patients with rotator cuff tears (Table 2). For all calculated MCII, we standardized the effect size for an instrument by dividing the reported minimal clinically important difference between baseline and follow-up scores by the standard deviation of the mean baseline score.

Table 2 MCII of Validated Outcomes

Outcome Measure	Study	MCII	
		Points	Effect Size
American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES)	Michener, et al. ¹²	6.4	0.379
Disabilities of the Arm, Shoulder and Hand (DASH)	Gummesson, et al. ²⁰	10	0.455
PENN Shoulder Score (PSS)	Leggin, et al. ²⁷	11.4	0.585
Shoulder Rating Questionnaire or L' Insalata (SRQ)	L' Insalata, et al. ²⁸	12	0.896

When possible we describe the results of studies using terminology based on that of Armitage et al.³⁸ The associated descriptive terms we use in this guideline and the conditions for using each of these terms, are outlined in the following table:

Table 3 Description of Results with MCII

Descriptive Term	Condition for Use
Clinically Important	Statistically significant and lower confidence limit > MCII
Possibly Clinically Important	Statistically significant and confidence intervals contain the MCII
Not Clinically Important	Statistically significant and upper confidence limit < MCII
Negative	Not statistically significant and upper confidence limit < MCII
Inconclusive	Not statistically significant but confidence intervals contain the MCII

LITERATURE SEARCHES

We searched for articles published up to October 1, 2008. The work group reviewed search strategies prior to conducting the searches. All literature searches were supplemented with manual screening of bibliographies of all publications retrieved. We

also searched the bibliographies of recent systematic reviews and other review articles for potentially relevant citations. Three potentially relevant studies not identified by the literature search were also provided by the work group members for evaluation for inclusion. These three studies were published in September 2008 and had not been entered to the Pub Med database. One article, provided by a work group member, met all inclusion criteria and was subsequently included.

SEARCH FOR RCTS AND OTHER STUDY DESIGNS

To identify primary studies for this guideline, we searched four electronic databases; PubMed, EMBASE, CINAHL, and The Cochrane Central Register of Controlled Trials. The search strategies we used are provided in Appendix III.

We used a previously published search strategy³⁹ to identify relevant randomized controlled trials. In the absence of relevant RCTs, we modified the search strategy to identify studies of other designs.

The study attrition diagram in Appendix IV provides details about the inclusion and exclusion of these studies. A total of seventy-five studies met the inclusion criteria for this guideline; fifteen of these studies answered at least two of the recommendations.

JUDGING THE QUALITY OF EVIDENCE

We rated the quality of evidence using an evidence hierarchy in which the Level of Evidence was determined from a checklist. The hierarchy and checklist are provided in Appendix V.

For “Therapeutic Studies” investigating the results of a treatment, randomized controlled trials were initially categorized as Level I studies, but the level of evidence was reduced by one level if there was a “No” or “Not Reported by Authors” to any of the following checklist questions:

- Was randomization stochastic? (i.e. at the time of assignment to groups, did all patients have an equal probability of being assigned to any given group)
- Was there concealment of the allocation to groups?
- Were the patients, caregivers, or evaluators blinded?

According to the AAOS Levels of Evidence for “Therapeutic Studies”, non-randomized controlled trials and other prospective comparative studies were categorized as Level II studies. Retrospective comparative studies and case-control studies were initially categorized as Level III studies and case-series studies/reports were categorized as Level IV studies.

Some randomized controlled trials were included that enrolled patients relevant to the recommendation but the comparisons between the treatments were not relevant to the specific recommendation. When this occurred, we considered the relevant data from such

studies as coming from a prospective case series (because we were evaluating only one of the study's groups). Accordingly, we appraised this evidence as Level IV.

For “Prognostic Studies” investigating risk or prognostic factors, high quality prospective studies were categorized as Level I studies. A high quality study is defined as a study with a “yes” to all of the following checklist questions:^{40,41}

- Were participants at a common point in the course of their disease?
- Were participants, health workers, researchers blind to prognostic factors?
- Were all groups/participants treated with the same intervention?
- Was follow up time sufficiently long to detect important prognostic factors?

According to the AAOS Levels of Evidence for “Prognostic Studies”, lower quality prospective studies and retrospective comparative studies were categorized as Level II studies. Retrospective case control studies were initially categorized as Level III studies and case-series studies/reports were categorized as Level IV studies.

Downgrading of Level I studies, regardless of whether a study was of a treatment or a prognostic, was not cumulative. If a Level I study had more than one of the methodological flaws listed above, it would only decrease by a single level. The downgrading of the formal level of evidence of a study indicates the discrepancy between claims of the study authors and the results of the critical appraisal process.

DATA EXTRACTION

Data elements extracted from studies were defined in consultation with the physician work group. Five reviewers completed data extraction independently for all studies. Disagreements were resolved by consensus and by consulting the work group. We report the elements extracted in Appendix VI

Evidence tables were constructed to summarize the best evidence for each simulated recommendation. These tables appear in a supplemental document on the AAOS website [[insert link here](#)]. The evidence tables include complete lists of included and excluded articles, quality and design parameters of the included studies, and raw data extracted from the included studies.

GRADING THE RECOMMENDATIONS

Following data extraction and analyses, each guideline recommendation was assigned a preliminary rating that was based on the total body of evidence available using the following system:

Table 4 Grade of Recommendation Description

Statement Rating	Description of Evidence Strength	Implication for Practice
Strong	<p>Evidence is based on two or more “High” strength studies with consistent findings for recommending for or against the intervention.</p> <p>A Strong recommendation means that the benefits of the recommended approach clearly exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a strong negative recommendation), and that the strength of the supporting evidence is high.</p>	Practitioners should follow a Strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Moderate	<p>Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention.</p> <p>A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.</p>	Practitioners should generally follow a Moderate recommendation but remain alert to new information and be sensitive to patient preferences.
Limited	<p>Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single Moderate quality study recommending for or against the intervention or diagnostic.</p> <p>A Limited recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.</p>	Practitioners should be cautious in deciding whether to follow a recommendation classified as Limited , and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.
Inconclusive	<p>Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention.</p> <p>An Inconclusive recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.</p>	Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as Inconclusive and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.
Consensus^a	<p>The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment.</p> <p>A Consensus recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria.</p>	Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus , although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

^a The AAOS will issue a consensus-based recommendation only when the service in question has virtually no associated harm and is of low cost (e.g. a history and physical) or when not establishing a recommendation could have catastrophic consequences.

Final grades were based upon preliminary grades assigned by AAOS staff. Preliminary grades took into account only the quality and quantity of the available evidence as listed in the table above. Work group members then modified the grade using the ‘Form for Assigning Grade of Recommendation (Interventions)’ shown in Appendix VII. This form, which is based on recommendations of the GRADE work group, requires consideration of the harms, benefits, and critical outcomes associated with a treatment. It also requires the work group to evaluate the applicability of the evidence. The final grade is assigned by the physician work group, which modifies the preliminary grade on the basis of these considerations.

CONSENSUS DEVELOPMENT

The recommendations and their grades of recommendation were voted on using a structured voting technique known as the nominal group technique.⁴² We present details of this technique in Appendix VIII. Each recommendation was constructed using the following language which takes into account the final grade of recommendation.

Table 5 AAOS Guideline Language

Guideline Language	Strength of Recommendation
We <i>recommend</i>	Strong
We <i>suggest</i>	Moderate
Is an <i>option</i>	Limited
We are <i>unable to recommend for or against</i>	Inconclusive
In the absence of reliable evidence, it is the <i>opinion</i> of this work group	Consensus

*Consensus based recommendations are made according to specific criteria. These criteria can be found in Appendix VIII.

STATISTICAL METHODS

When possible we report the results of the statistical analyses conducted by the authors of the included studies. In some circumstances, the authors did not perform statistical tests, but sufficient quantitative data, including measures of dispersion or patient level data were reported by the authors. In these circumstances we performed our own statistical analyses. To do so we used the statistical program STATA (StatCorp LP, College Station, Texas). P-values that were < 0.05 were considered statistically significant. In the evidence tables, we note if the analysis was that of the study authors or our own.

STATA was also used to determine 95% confidence intervals. When authors of the included studies reported counts or proportions we used the method of Wilson,⁴³ to compute these intervals. We also used STATA to determine the magnitude of the treatment effect. For data reported as means (and associated measures of dispersion) we calculated a standardized mean difference by the method of Hedges and Olkin.⁴⁴ For proportions, we calculated the odds ratio as a measure of treatment effect.

We used G*Power 3 (Franz Faul, Universitat Kiel, Germany) to determine if a study was sufficiently powered to detect the MCII. Our power calculations were based on 80% power and an alpha of 0.05 stratifications.

When published studies only reported the median, range, and size of the trial, we estimated their means and variances according to a published method.⁴⁵ We used the program TechDig 2.0 (Ronald B. Jones, Mundelein, Illinois) to estimate means and variances from studies presenting data only in graphical form.

STRATIFICATIONS

When reported in included articles, outcomes stratified by the following factors were analyzed:

- Time: from injury to surgery
- Time: duration of symptoms
- Gender
- Age
- Size of rotator cuff tear
- Degree of muscle degeneration/fatty infiltration
- Etiology of tear
- Duration of non-operative treatment
- Location of tear (tendons involved)
- Hand dominance
- Time from surgery to rehab
- Duration of sling treatment
- Number of pre-operative cortisone injections
- Acromial morphology
- Acromial humeral interval

PEER REVIEW

The draft of the guideline and evidence report were peer reviewed for content. The work group nominated outside specialty societies *a priori* to the development of the guideline who then chose content experts to review the document on their behalf. The physician members of the AAOS Guidelines and Technology Oversight Committee and the Evidence Based Practice Committees also peer reviewed this document. Peer review was accomplished using a structured peer review form (Appendix IX). The draft guideline was sent to ten review organizations and fifteen reviewers returned comments. Based on the initial period of review, the work group convened for a third meeting to address peer reviewers' concerns. The guideline was edited and resubmitted for a second round of peer review. Original peer reviewers were solicited to reevaluate the guideline, as well as additional peer reviewers, at this time. The disposition of all non-editorial peer review comments was documented and accompanied this guideline through Public Commentary and the subsequent approval process.

PUBLIC COMMENTARY

After modifying the draft in response to peer review, the guideline was subjected to a thirty day period of “Public Commentary.” Commentators consist of members of the AAOS Board of Directors (BOD), members of the AAOS Council on Research, Quality Assessment, and Technology (CORQAT), members of the Board of Councilors (BOC), and members of the Board of Specialty Societies (BOS). Based on these bodies, up to 185 commentators had the opportunity to provide input into the development of this guideline. Of these, one member returned public comments.

THE AAOS GUIDELINE APPROVAL PROCESS

Following peer review, the final guideline draft was approved by the AAOS Guidelines and Technology Oversight Committee, the AAOS Evidence Based Practice Committee, the AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors. Descriptions of these bodies are provided in Appendix II.

REVISION PLANS

This guideline represents a cross-sectional view of current treatment and will become outdated when more sophisticated tests, more objective assessments, and more rigorous differential diagnoses are possible. All AAOS guidelines are updated or retired after five years, in accordance with the criteria of the National Guideline Clearinghouse.

III.RECOMMENDATIONS AND SUPPORTING DATA

RECOMMENDATION 1: FULL THICKNESS TEARS AND ASYMPTOMATIC PATIENTS

In the absence of reliable evidence, it is the opinion of the work group that surgery not be performed for asymptomatic, full thickness rotator cuff tears.

Level of Evidence: V

Strength of Recommendation: Consensus

Description: The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Rationale:

Although there is a growing awareness that a large proportion of our population can have full thickness rotator cuff tears that are asymptomatic, we were unable to find quality literature that addressed the issue of operative vs. non-operative treatment for such patients. The issue of appropriate treatment of asymptomatic full thickness tears is potentially important given the high prevalence rate, concerns regarding progression in the form of an enlarging tear, or deterioration into a symptomatic process. Given the potential importance of this patient population, the work group felt that a consensus opinion would be appropriate in light of a paucity of published evidence. The opinion that surgery not be performed for asymptomatic, full thickness rotator cuff tears was based on the following considerations:

- Asymptomatic rotator cuff disease is highly prevalent in the older population. A large percentage of our population will have full thickness rotator cuff tears without any apparent difficulties. Thus, the presence of a tear in and of itself is not clinically significant for many people as they have no pain or apparent lack of function.
- For patients with bilateral asymptomatic shoulders, there is no reliable evidence that surgery prevents long-term clinical deterioration of a rotator cuff tear.
- Post-surgical healing rates are inconsistent in elderly patients - the patients most likely to have asymptomatic rotator cuff tear.
- Surgical repair of the rotator cuff has peri-operative morbidity and risks, including pain and loss of use of the arm for a significant time period, infection, deltoid injury, implant failure, and arthrofibrosis. The morbidity and risk are probably not warranted in absence of symptoms.

- Currently, the primary indication for rotator cuff repair is significant pain or dysfunction affecting quality of life; neither indication is present in patients with asymptomatic rotator cuff tears.

Given the above considerations, it is the opinion of this work group that patients with asymptomatic full thickness tears not be treated with operative repair.

RECOMMENDATION 2: FULL THICKNESS TEARS AND SYMPTOMATIC PATIENTS

Rotator cuff repair is an option for patients with chronic, symptomatic full thickness tears.

Level of Evidence: IV

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Our systematic review identified one Level III study⁴⁶ that compared conservative to surgical treatment of rotator cuff tears. In this study, sixty patients treated without surgery were compared to seventy-seven with rotator cuff repair. Per this study, in group A, tears were non-traumatic in 73% of cases and traumatic in 27% of cases. In group B, tears were non-traumatic in 32% of cases and traumatic in 68% of cases. Statistically significant less pain on shoulder range of motion and at night was seen in those patients who had surgery as compared to those with conservative treatment. Eighty-one percent of the surgical patients reported excellent results as compared to thirty-seven percent with conservative treatment although the authors did not report statistical significance in this comparison. Because there was only one Level III study to support this recommendation, we also examined Level IV articles.

We identified multiple Level IV articles⁴⁷⁻⁵² on the influence of advanced muscle disease on rotator cuff repair. Six studies⁴⁷⁻⁵² assessed MRI tear characteristics of fatty infiltration and/or muscle atrophy on outcome. One study⁴⁷ reported that patients undergoing open, mini-open or arthroscopic repairs of full thickness tears had fatty atrophy or infiltration of the infraspinatus that led to lower ASES scores. Atrophy and infiltration of the supraspinatus did not correlate with ASES scores. Another study⁵¹ reported that the degree of preoperative supraspinatus atrophy correlated with postoperative Constant-Murley scores. Constant-Murley scores in patients with greater atrophy were associated with poorer outcome. Another study⁴⁸ did not show a statistically significant correlation between preoperative fatty infiltration and postoperative Constant-Murley score. A final study⁵⁰ showed positive correlation between decreasing postoperative UCLA scores and greater preoperative muscle degeneration as assessed by MRI. While these studies in total suggest that greater post operative functional deficits may occur in the presence of more

significant muscle disease, the overall positive outcome of the surgery still suggests that operative treatment of chronic rotator cuff tears is an option.

Because this recommendation is supported by a single Level III article and several Level IV articles, the strength of the evidence that supports it is limited.

SUPPORTING EVIDENCE- SURGICAL VERSUS CONSERVATIVE TREATMENT:

Tables relevant to this recommendation are: Table 6

Figures relevant to this recommendation are: Figure 1 through Figure 3

SURGICAL VERSUS CONSERVATIVE TREATMENT

One Level III study comprised of 150 patients with complete tears of the rotator cuff compared conservative to surgical treatment. Patients in the surgically treated group averaged fifty-nine years while patients treated conservatively averaged sixty-three years.

Table 6 Results of conservatively and surgically treated patients

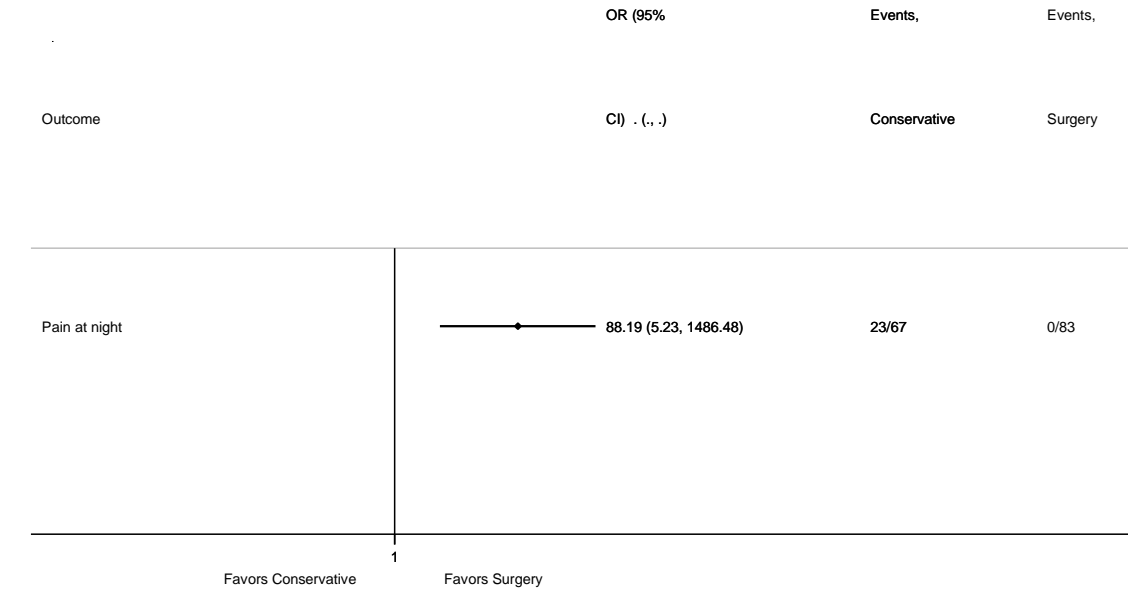
Author	LoE	n	Comparison	Outcome	Final Visit*
Tabata et al.	III	150	Surgical vs. Conservative Treatment	Pain: At night	□s
				Pain: On motion	□s
				Response to Treatment	nr

- = statistically significant results
- s = favoring surgical treatment
- nr = statistical significance not reported by authors
- LoE = level of evidence
- * = final visit not defined by author

PAIN: AT NIGHT

One Level III study by Tabata, et al.⁴⁶ assessed patients with complete tears of the rotator cuff treated surgically or conservatively. The authors did not define conservative treatment. Patients reporting pain at night were assessed. AAOS calculations found statistically significantly fewer patients reporting pain at night when treated by surgery than when treated conservatively (OR = 88.19, 95% CI 5.23 – 1486.48; see Figure 1).

Figure 1 Patients reporting pain at night

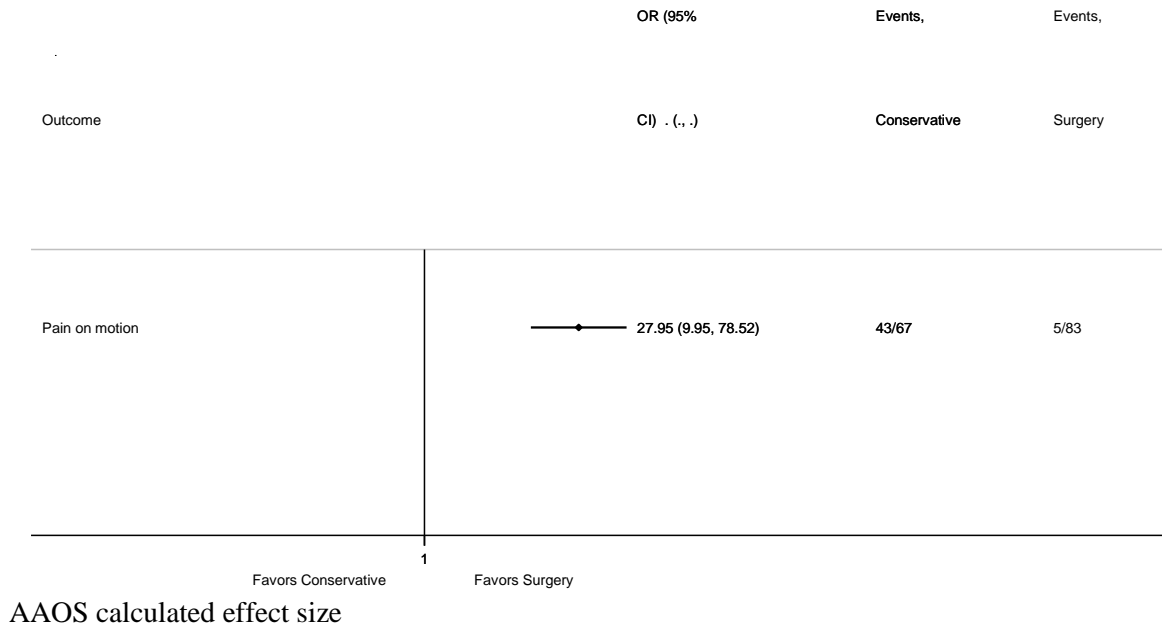


AAOS calculated effect size; OR = Odds Ratio

PAIN: ON MOTION

One Level III study by Tabata, et al. assessed patients with complete tears of the rotator cuff treated surgically or conservatively. The authors did not define “conservative treatment”. Patients reporting pain on motion were assessed. AAOS calculations found statistically significantly fewer patients reporting pain on motion when treated by surgery than when treated conservatively ($OR = 27.95$, 95% CI 9.95 – 78.52; see Figure 2).

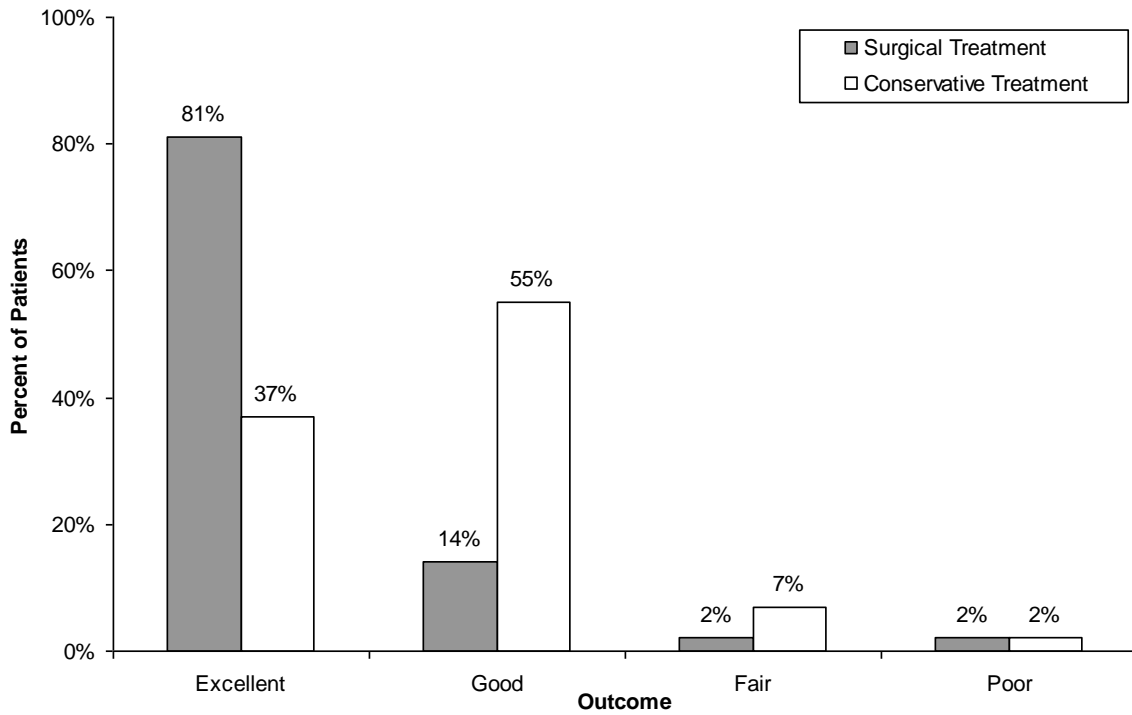
Figure 2. Patients reporting pain on motion



RESPONSE TO TREATMENT

One Level III study by Tabata, et al. assessed response to treatment in patients treated surgically or conservatively. The authors did not define “conservative treatment”. Patients were rated according to the cumulative score of pain, range of motion, muscle strength and activities of daily living outcomes (see Figure 3). The authors did not report statistical analyses and time of final evaluation.

Figure 3 Response to treatment of conservatively and surgically treated patients



Authors report no statistical analyses

SUPPORTING EVIDENCE- MRI TEAR CHARACTERISTICS:

Tables relevant to this recommendation are: Table 7 through Table 10
Figures relevant to this recommendation are: Figure 4 through Figure 6

MRI TEAR CHARACTERISTICS

Six Level IV studies⁴⁷⁻⁵² assessed the MRI tear characteristics of fatty infiltration and/or muscle atrophy.

ASES SCORE

One Level IV study by Gladstone et al. assessed patients undergoing open, mini-open or arthroscopic repair of a full thickness rotator cuff tear and patient pre-operative muscle quality (muscle atrophy and fatty infiltration). Muscle atrophy was graded using a system by Warner and fatty infiltration was graded using a system by Goutallier. The authors first examined the correlation between preoperative muscle quality and post-operative Constant-Murley score (see Table 7). The authors then performed a stepwise regression analysis and found muscle atrophy and fatty infiltration of the infraspinatus to be a statistically significant predictor of the ASES score ($p = 0.001$ and $p = 0.01$ respectively). Muscle atrophy and fatty infiltration of the supraspinatus was not a statistically significant predictor of the ASES score. The authors did not provide the regression coefficients used in the analysis.

Table 7 Correlation of muscle quality and ASES score

		ASES Score	
		r	p-value
Infraspinatus	FI	-0.364	0.027
	MA	-0.401	0.014
Supraspinatus	FI	-0.231	0.17
	MA	-0.354	0.034

MA = muscle atrophy; FI = fatty infiltration

CONSTANT-MURLEY SCORE

Three Level IV studies assessed pre-operative muscle atrophy and fatty infiltration in relation to the post-operative Constant-Murley score.

Gladstone et al. assessed patients undergoing open, mini-open or arthroscopic repair of a full thickness rotator cuff tear and patient pre-operative muscle quality (muscle atrophy and fatty infiltration). Muscle atrophy was graded using a system by Warner and fatty infiltration was graded using the Goutallier staging system. The authors first examined the correlation between preoperative muscle quality and post-operative Constant-Murley score (see Table 8). The authors then performed a stepwise regression analysis and found muscle atrophy (but not fatty infiltration) of the infraspinatus is a statistically significant predictor of the Constant-Murley score ($p = 0.033$). Muscle atrophy and fatty infiltration of the supraspinatus was not a statistically significant predictor of the Constant-Murley score. The authors did not provide regression coefficients.

Table 8 Correlation of muscle quality and Constant-Murley score

		Constant-Murley score	
		r	p-value
Infraspinatus	FI	-0.359	0.029
	MA	-0.440	0.006
Supraspinatus	FI	-0.236	0.160
	MA	-0.402	0.015

MA = muscle atrophy; FI = fatty infiltration

Shen et al. assessed patients undergoing mini-open repair of a rotator cuff tear. Authors assessed atrophy by calculating a ratio between the atrophic and total area (A/T ratio). AAOS calculations found postoperative Constant-Murley score was statistically significantly correlated to pre-operative A/T ratios with greater atrophy of the supraspinatus and subscapularis being associated with a poorer outcome (see Table 9).

Table 9 Correlation of muscle quality and Constant-Murley score

	Constant-Murley score	
	r	p-value
Infraspinatus & teres minor	0.1934	0.3339
Subscapularis	0.5612	0.0023
Supraspinatus	0.6146	0.0006

Gerber et al. (2007) assessed patients undergoing surgical repair of a full-thickness supraspinatus tear. Authors assessed fatty infiltration according to the Goutallier staging system. AAOS calculations found no statistically significant correlation between pre-operative fatty infiltration and postoperative Constant-Murley (see Table 10).

Table 10 Correlation of fatty infiltration and Constant-Murley score

	Constant-Murley score	
	r	p-value
Infraspinatus	-0.264	0.384
Subscapularis	0.263	0.385
Supraspinatus	-0.120	0.696

UCLA SCORE

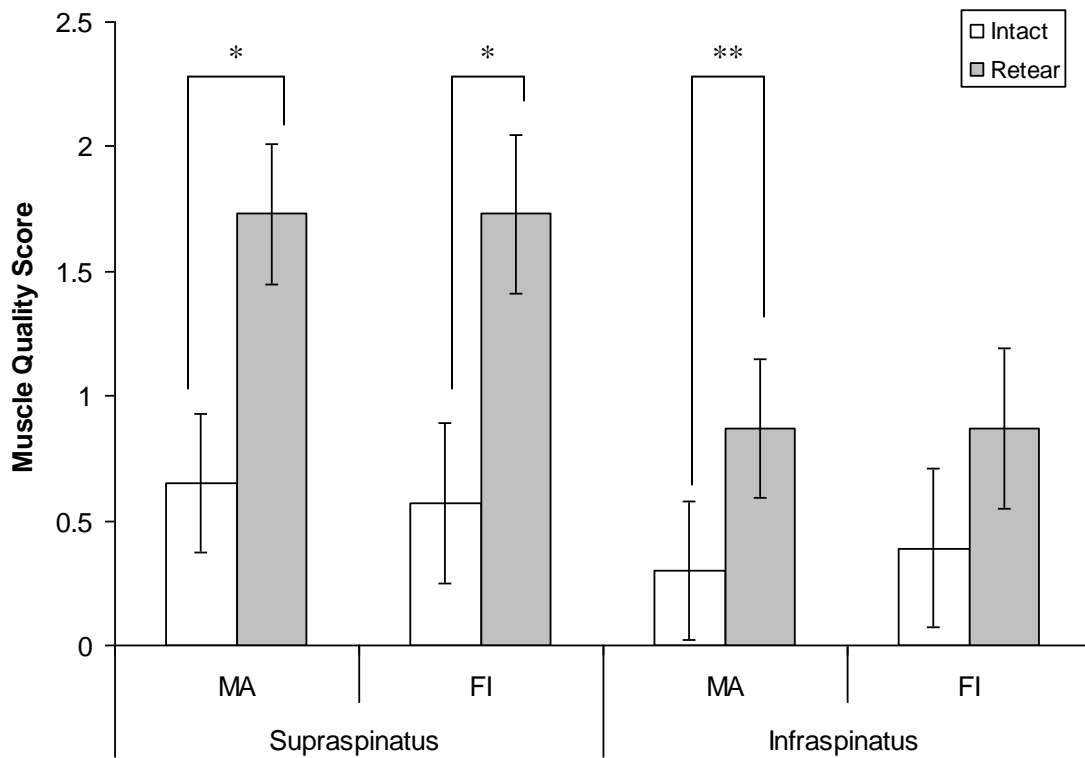
One Level IV study by Mellado et al. correlated preoperative fatty degeneration and postoperative UCLA Score. Twenty-eight patients diagnosed as having massive rotator cuff tears were surgically repaired. Diagnosis was confirmed intraoperatively and complete repair was performed whenever possible. Prior to surgery, muscle degeneration and atrophy were assessed using MRI. Authors report preoperative fatty degeneration of the infraspinatus muscle was negatively correlated with the postoperative UCLA Score ($r = -0.4, p = 0.03$). Authors report no additional preoperative muscle disease characteristics in relation to postoperative outcomes.

RE-TEAR

Three Level IV studies assessed pre-operative muscle atrophy and fatty infiltration in relation to post-operative re-tear rates.

Gladstone et al. assessed patients undergoing open or arthroscopic repair of a full thickness rotator cuff tear and patient pre-operative muscle quality (muscle atrophy and fatty infiltration). Muscle atrophy was graded using a system by Warner and fatty infiltration was graded using a system by Goutallier whereby higher scores indicate greater atrophy or infiltration. The authors examined pre-operative muscle quality scores and patients who develop re-tears post-operatively (see Figure 4).

Figure 4 Pre-operative muscle quality in patients with and without rears

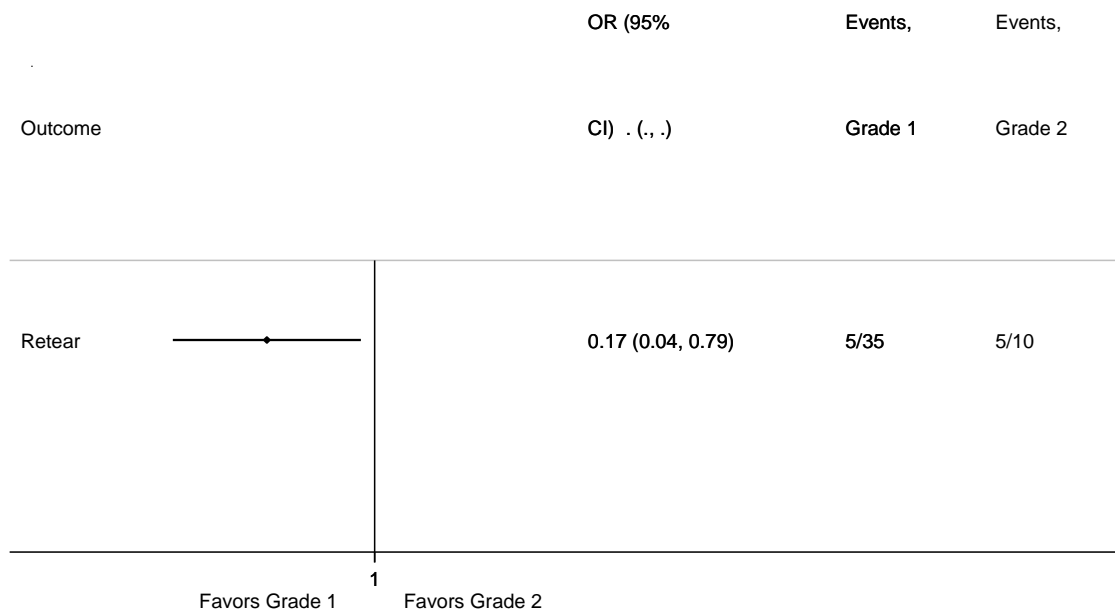


* Authors report, $p < .01$; ** Authors report, $p < .05$; MA = muscle atrophy; FI = fatty infiltration; AAOS calculated confidence intervals uses standard deviation estimated from range.

Liem et al. assessed patients undergoing arthroscopic repair of an isolated supraspinatus tear and pre-operative muscle quality. Supraspinatus atrophy was graded using a system by Thomazeau and fatty infiltration was graded using a system by Goutallier. Authors compared post-operative re-tear rates in patients with grade one supraspinatus atrophy to those with grade two and report a statistically significant effect favoring Grade 1 ($p = 0.018$; see Figure 5). Additionally, authors compared post-operative re-tear rates in patients with either stage zero or one to patients with stage two fatty infiltration and report a statistically significant effect favoring Stage 0 and 1 ($p = 0.021$); however, AAOS calculations failed to find a statistically significant effect (see Figure 6).

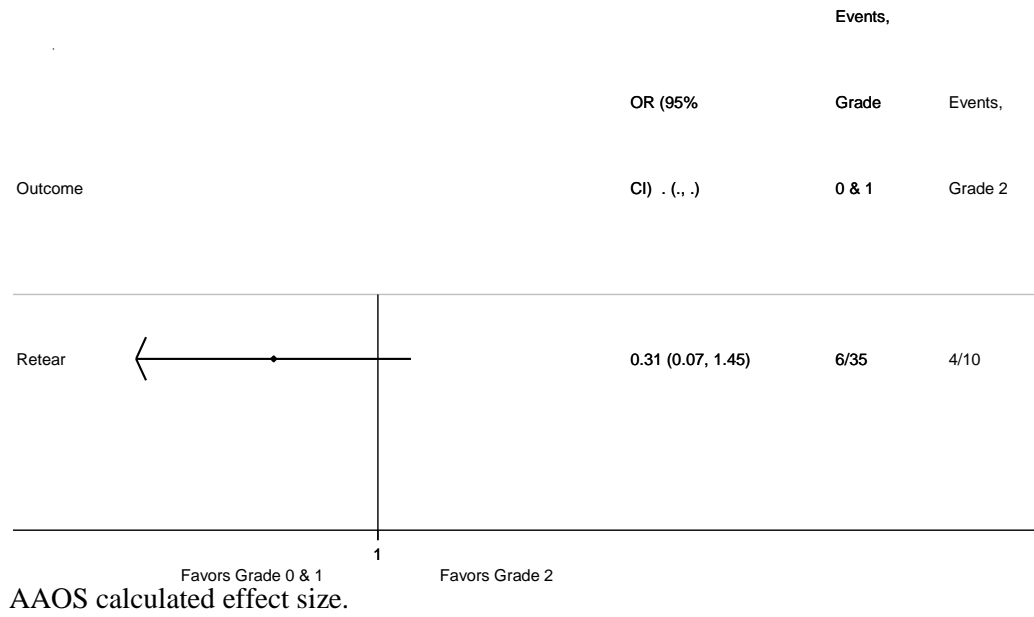
Thomazeau et al. report, "...preoperative atrophy of the supraspinatus muscle was the main anatomic predictive factor for a postoperative re-tear ($p = 0.0028$).” The value of the correlation coefficient could not be determined.

Figure 5 Re-tear occurrence by supraspinatus atrophy grade



AAOS calculated effect size

Figure 6 Re-tear occurrence by fatty infiltration stage



RECOMMENDATION 3A: ROTATOR CUFF TEARS AND EXERCISE

We cannot recommend for or against exercise programs (supervised or unsupervised) for patients with rotator cuff tears.

Level of Evidence: IV

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

When the patient and physician select non-operative management of a rotator cuff tear, the primary objectives are to decrease pain, increase function, and enhance activities of daily living (while mitigating potential long term adverse outcomes). We found no quality evidence that demonstrated a specific impact of an exercise program, compared to the natural history of disease without other interventions. Similarly, we found no reliable evidence demonstrating that the efficacy of an exercise program is predicated upon a specific form of education, supervision, or exercise environment.

Although reliable evidence was not found to definitively support a positive impact, we also found no such evidence to suggest that there are adverse impacts of exercise programs upon rotator cuff disease.

One Level IV study⁵³ addressed a physical therapy program. This study observed statistically significant improvement on the Oxford shoulder disability questionnaire and the SF-36 for General Health at three months in a cohort of ten patients treated with a physical therapy-supervised program for massive irreparable cuff tears. It is not possible to generalize this study across patients with different severities and durations of rotator cuff tears.

A second Level IV study⁵⁴ reported inconsistent results on the Simple Shoulder Test (SST) but did observe improvement at an average of 2.5 years in three scales with a home exercise program in a larger group of patients with chronic rotator cuff tears.

SUPPORTING EVIDENCE- PHYSICAL THERAPY

Tables relevant to this recommendation are: Table 11 through Table 12
 Figures relevant to this recommendation are: Figure 7 through Figure 10

PHYSICAL THERAPY

One Level IV study assessed a physical therapy program in ten patients diagnosed with massive, irreparable rotator cuff tears (see Table 11).

Table 11 Results of physical therapy intervention

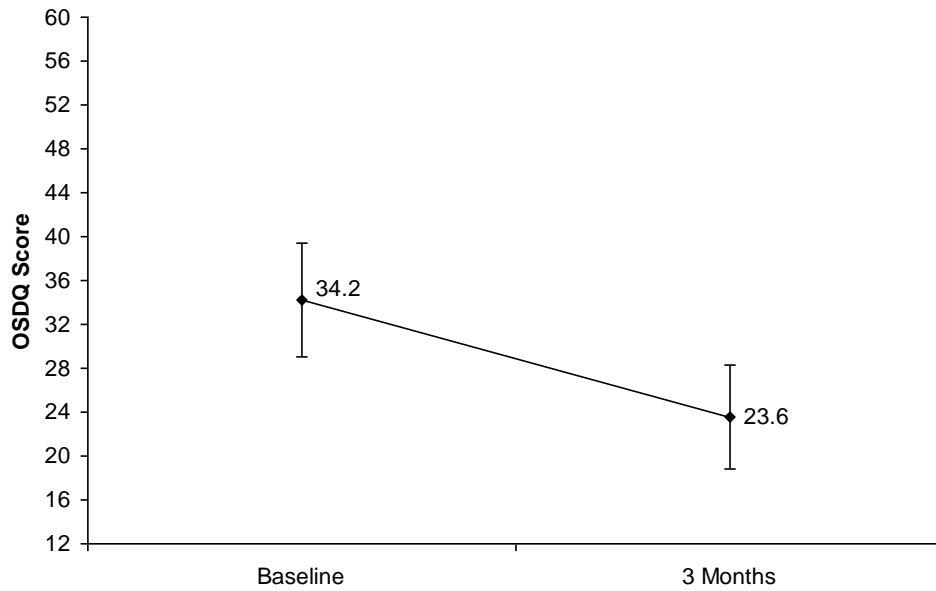
Author	LoE	n	Comparison	Outcome	Duration 3 months
Ainsworth et al.	IV	10	Change from baseline	OSDQ	□ □ ↑
				SF-36: Physical Health	□ □
				SF-36: Emotional Health	□ □
				SF-36: General Health	□ □ ↑

- = not statistically significant result
- = statistically significant result
- ↑ = improved
- LoE = level of evidence
- PT = physical therapy
- OSDQ = Oxford shoulder disability questionnaire

OXFORD SHOULDER DISABILITY QUESTIONNAIRE (OSDQ)

One Level IV study by Ainsworth et al. assessed ten patients with massive, irreparable rotator cuff tears using the OSDQ (see Figure 7). The OSDQ consists of twelve questions with five point responses. The scale ranges from twelve (best score) to sixty (worst score).

Figure 7 Patient shoulder disability measured by OSDQ

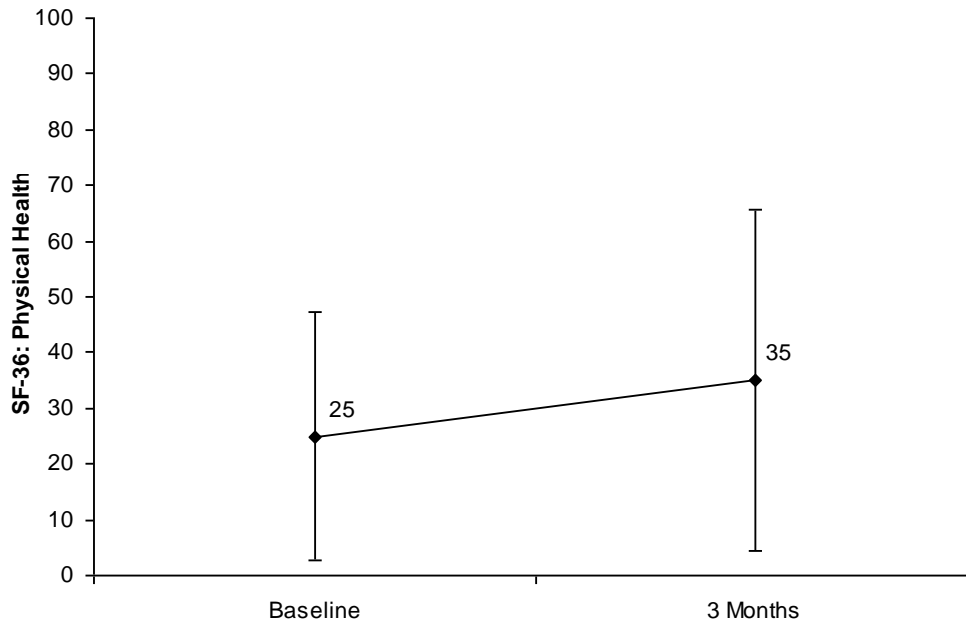


AAOS calculated paired t-test, $p < 0.01$.

SHORT FORM-36 (SF-36)

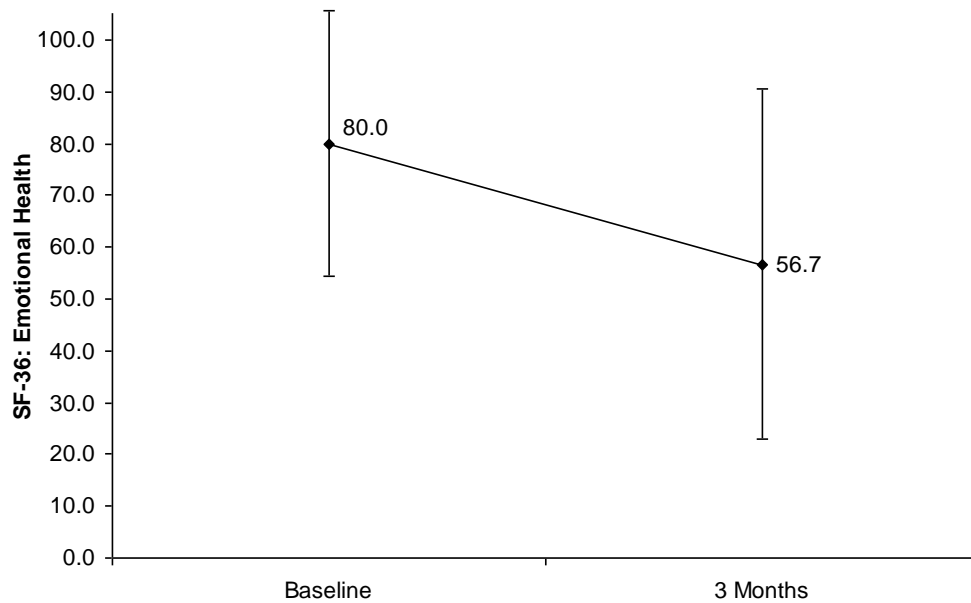
Ainsworth et al. also assessed patients with massive, irreparable rotator cuff tears using the SF-36. The physical health (see Figure 8), emotional health (see Figure 9), and general health (see Figure 10) subscales were reported.

Figure 8 Patient physical health measured by SF-36



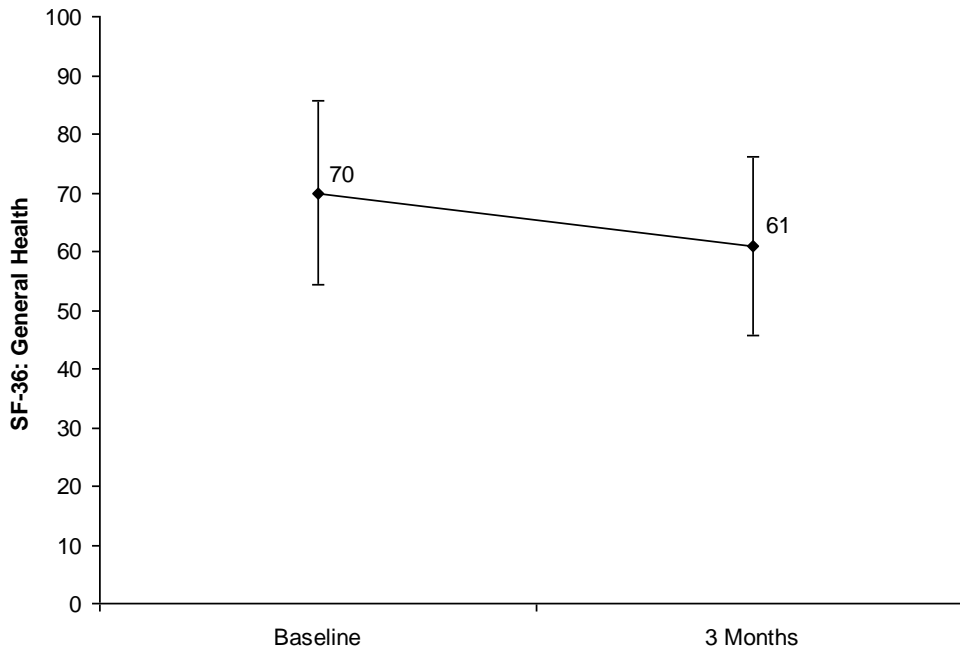
AAOS calculated paired t-test, not statistically significant (*ns*).

Figure 9 Patient emotional health measured by SF-36



AAOS calculated paired t-test, *ns*.

Figure 10 Patient general health measured by SF-36



AAOS calculated paired t-test, $p < 0.05$.

STRATIFICATIONS

Ainsworth et al. provided patient characteristics for age, gender and duration of symptoms. AAOS calculated correlations with the final outcome (SF-36 subscales) and patient characteristics (see Table 12).

Table 12 Rotator cuff tear stratifications pertaining to physical therapy treatment

Stratification	SF-36 Subscales*		
	Physical Health	Emotional Health	General Health
Age	-0.57 (p = 0.08)	-0.50 (p = 0.14)	-0.58 (p = 0.08)
Gender	-0.45 (p = 0.19)	0.03 (p = 0.93)	-0.29 (p = 0.41)
Duration of Symptoms	0.15 (p = 0.67)	-0.10 (p = 0.77)	0.14 (p = 0.70)

*AAOS calculated Pearson correlation (p-value)

SUPPORTING EVIDENCE- EXERCISE

Tables relevant to this recommendation are: Table 13 through Table 16

Figures relevant to this recommendation are: None

EXERCISE

One Level IV study assessed an exercise program in forty-six patients diagnosed with chronic, full-thickness rotator cuff tears (see Table 13).

Table 13 Results of exercise intervention

Author	LoE	n	Comparison	Outcome	Duration
					2.5 years*
Goldberg et al.	IV	46	Change from baseline	SST: Comfortable at side	□○
				SST: Sleep on side	□●↑
				SST: Tuck in shirt behind	□○
				SST: Hand behind head	□●↑
				SST: Place coin on shelf	○
				SST: Place pound on shelf	○
				SST: Place 8 lbs on shelf	○
				SST: Carry 20 lbs	○
				SST: Toss underhand	○
				SST: Throw overhand	○
				SST: Wash opposite shoulder	○
				SST: Do usual work	○
				SF-36: Physical role	○
				SF-36: Comfort	□●↑
				SF-36: Vitality	□●↓
				SF-36: Physical function	□●↓
				SF-36: Emotional role	○
				SF-36: Social function	○
SF-36: Mental health	○				
SF-36: General health	□●↓				

○ = no statistically significant difference

● = statistically significant detriment

↑ = improved

↓ = worsened

LoE = level of evidence

* = final visit 2.5 ± 0.46 years after baseline

SIMPLE SHOULDER TEST (SST)

One Level IV study by Goldberg et al. utilized the SST to assess a home exercise program in forty-six patients diagnosed with chronic, full-thickness rotator cuff tears (see Table 14). The program focused on stretching and strengthening the remaining rotator cuff, deltoid, pectoralis major and trapezius muscles. The SST is a function-based outcome assessment tool consisting of twelve "yes" or "no" questions. The authors reported the results as the percent of patients able to perform each task. Patients averaged sixty-five years of age (95% CI 62.33 – 67.67 years).

Table 14 SST results at baseline and final visit

Function	Baseline %	Outcome* %	p-value
Comfortable at side	67%	75%	<i>ns</i>
Sleep on side	37%	67%	<i>p < .01</i>
Tuck in shirt behind	61%	72%	<i>ns</i>
Hand behind head	54%	80%	<i>p < .01</i>
Place coin on shelf	70%	74%	<i>ns</i>
Place pound on shelf	46%	61%	<i>ns</i>
Place 8 lbs on shelf	20%	26%	<i>ns</i>
Carry 20 lbs	48%	57%	<i>ns</i>
Toss underhand	54%	52%	<i>ns</i>
Throw overhand	24%	24%	<i>ns</i>
Wash opposite shoulder	41%	61%	<i>ns</i>
Do usual work	39%	54%	<i>ns</i>

Statistical significance as reported by authors; *Final visit averaged 2.5 ± 0.46 years after baseline.

SHORT FORM-36 (SF-36)

One Level IV study by Goldberg et al. utilized the SF-36 to assess a home exercise program in forty-six patients diagnosed with chronic, full-thickness rotator cuff tears averaging sixty-five years of age (95% CI 62.33 – 67.67 years). The program focused on stretching and strengthening the remaining rotator cuff, deltoid, pectoralis major and trapezius muscles. A statistically significant improvement was found on the subscale comfort; however, a statistically significant decline was found on the vitality, physical function, and general health subscales (see Table 15).

Table 15 SF-36 scores at baseline and final visit

Parameter	Baseline Score	Outcome* Score	p-value
Physical role	35.3	33.2	ns
Comfort	48.3	58.5	0.0010
Vitality	60	49.6	<0.01
Physical function	60.4	48.3	<0.01
Emotional role	73.2	73.9	ns
Social function	79.7	73.4	ns
Mental health	76.9	73	ns
General health	76.4	60.8	<0.01

Statistical significance as reported by authors; *Final visit averaged 2.5 ± 0.46 years after baseline.

STRATIFICATIONS

Goldberg et al. reported, "Although the outcome of nonoperative treatment could not be predicted from the patient age, gender, or tear size, some factors were statistically associated with improvement. Patients who improved were more likely to have a rotator cuff tear of the dominant extremity (p= 0.02)..." (see Table 16).

Table 16 Rotator cuff tear stratifications pertaining to exercise treatment

<u>Stratification</u>	<u>p-value</u>
Gender	ns
Age	ns
Size of tear	ns
Hand dominance	0.02*

ns = not statistically significant

* = favoring tear of dominant extremity

RECOMMENDATION 3B: ROTATOR CUFF TEARS AND CORTICOSTEROID INJECTIONS

We cannot recommend for or against subacromial injections for patients with rotator cuff tears.

Level of Evidence: IV

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

One level II study⁵⁵ found no statistically significant difference in pain or tenderness up to six weeks after injection of steroid with lidocaine compared to lidocaine injection alone.

In contrast, three Level IV^{56, 57, 58} studies noted short term improvement with corticosteroid injection compared to baseline status, without comparison to a placebo control. We found no specific, compelling evidence to provide evidence-based recommendations concerning an ideal / absolute / safe number or frequency of subacromial corticosteroid injections in the setting of a rotator cuff tear. While it is logical for clinicians to consider potential adverse effects of corticosteroid injection upon rotator cuff tendon biology and healing capacity with rotator cuff repair (based upon general concerns across other areas of orthopaedic practice), there was no quality evidence to guide recommendations in this regard. Because the evidence that addresses this recommendation is limited and conflicting, the strength of this recommendation is Inconclusive.

SUPPORTING EVIDENCE- CORTICOSTEROID

Tables relevant to this recommendation are: Table 17 through Table 19

Figures relevant to this recommendation are: Figure 11 through Figure 16

CORTICOSTEROID INJECTIONS

One Level II⁵⁵ and three Level IV^{56, 57, 58} studies examined the use of cortisone injections. See Table 17 (next page) for a summary of results.

Table 17 Results of cortisone injection interventions

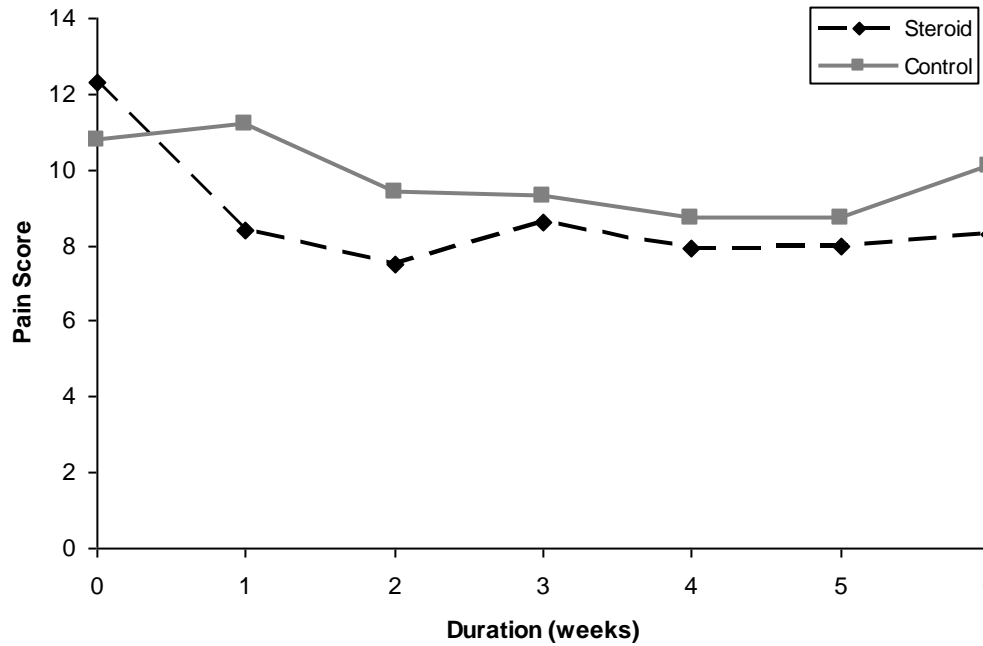
Authors	LoE	n	Comparison	Outcome	Duration						
					Final Visit*	1 week	2 weeks	3 weeks	4 weeks	5 weeks	6 weeks
Darlington et al.	II	37	Steroid vs. Control	Pain: Likert-like		○	○	○	○	○	○
Darlington et al.	II	37	Steroid vs. Control	Analgesic Consumption		○					
Darlington et al.	II	37	Steroid vs. Control	Tenderness		○	○	○	○	○	○
Shibata et al.	IV	40	Change from baseline	Pain: UCLA					●↑		
Shibata et al.	IV	40	Change from baseline	Function: UCLA					●↑		
Fearnley et al.	IV	38	Change from baseline	Response to Treatment			●↑				
Weiss	IV	15	Change from baseline	Response to Treatment	●↑						

○ = no statistically significant difference
 ● = statistically significant result
 ↑ = improved
 LoE = Level of Evidence
 * = final visit not defined by author

PAIN: LIKERT-LIKE SCALE

One Level II study by Darlington et al. assessed the use of cortisone injections in forty patients with supraspinatus tendon lesions. Patients received either a lidocaine injection plus steroid or lidocaine only (control). Pain was measured on a four point, Likert-like scale (none, mild, moderate or severe, scored 0-3). Authors report no statistically significant difference between groups at any time point (see Figure 11).

Figure 11 Pain measured by four-point Likert-like scale

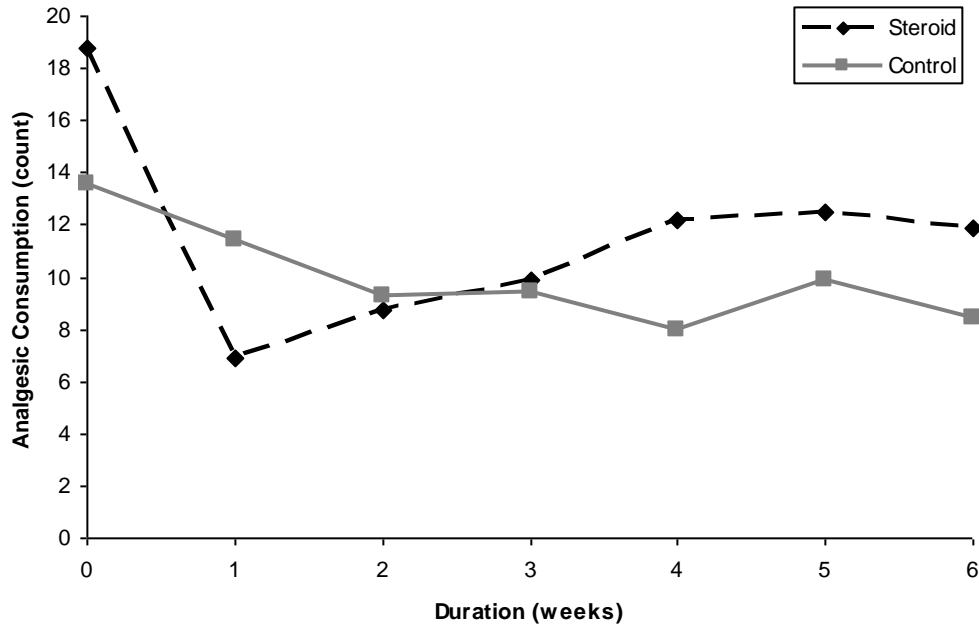


Authors do not provide dispersions for point estimates; authors report no statistically significant difference between groups at any time point.

ANALGESIC CONSUMPTION

One Level II study by Darlington et al. assessed the use of cortisone injections in forty patients with supraspinatus tendon lesions. Patients received either a lidocaine injection plus steroid or lidocaine only (control). Analgesic consumption (soluble aspirin) was compiled on a weekly basis (see Figure 12). Authors report no statistically significant difference between groups at week one. No other between group comparisons were reported by the authors.

Figure 12 Analgesic consumption per week

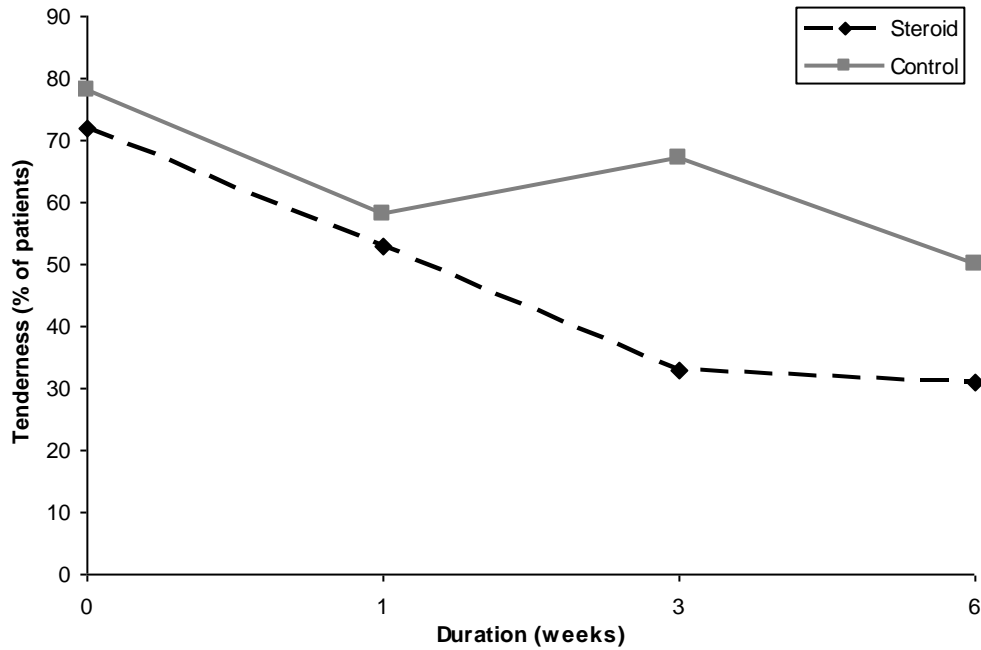


Authors do not provide dispersion for point estimates; authors report no statistically significant difference between groups at week one. No other between group comparisons were reported by the authors.

TENDERNESS

One Level II study by Darlington et al. assessed the use of cortisone injections in forty patients with supraspinatus tendon lesions. Patients received either a lidocaine injection plus steroid or lidocaine only (control). Patients were examined for tenderness at each assessment. Authors reported no statistically significant difference between groups at any time point (see Figure 13).

Figure 13 Percent of patients with tenderness

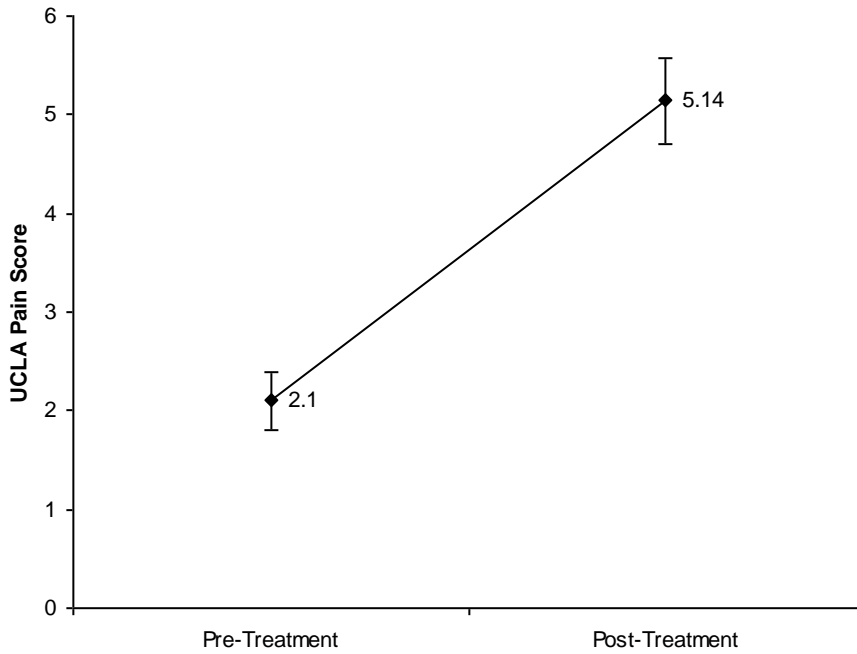


Authors do not provide dispersion for point estimates; authors reported no statistically significant difference between groups at any time point.

PAIN: UCLA SCORE

In a randomized, controlled trial by Shibata et al. patients with full-thickness rotator cuff tears received either cortisone injections (plus lidocaine) or sodium hyaluronate. We classified this study as Level IV because we included only the cortisone injection data (this recommendation pertains to non-operative treatments) from this group, and did not include data from the study’s other groups. Accordingly, we are analyzing these data as if they were derived from a case series. Pain was assessed using the UCLA Score pain subscale at four weeks (see Figure 14).

Figure 14 Pain as measured by UCLA Score

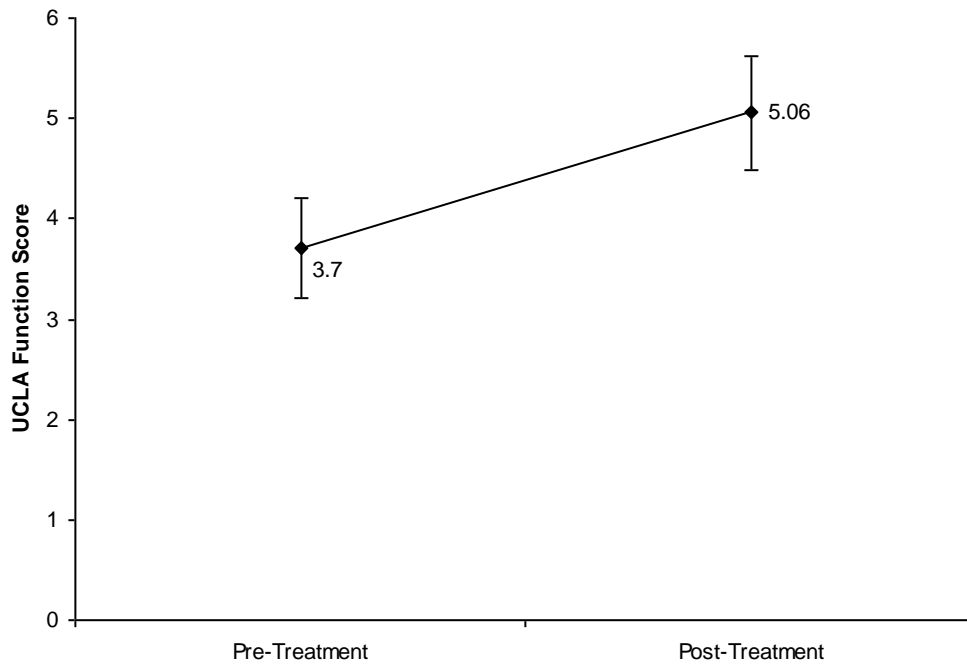


AAOS calculated independent t-test, $p < .05$; post-treatment confidence interval derived from pooled standard deviation.

FUNCTION: UCLA SCORE

In a randomized, controlled trial by Shibata et al. patients with full-thickness rotator cuff tears received either cortisone injections (plus lidocaine) or sodium hyaluronate. We classified this study as Level IV because we included only the cortisone injection data (this recommendation pertains to non-operative treatments) and did not include data from the study's other groups. Accordingly, we are analyzing these data as if they were derived from a case series. The authors assessed function using the UCLA Score function subscale at four weeks (see Figure 15).

Figure 15 Function as measured by UCLA Score

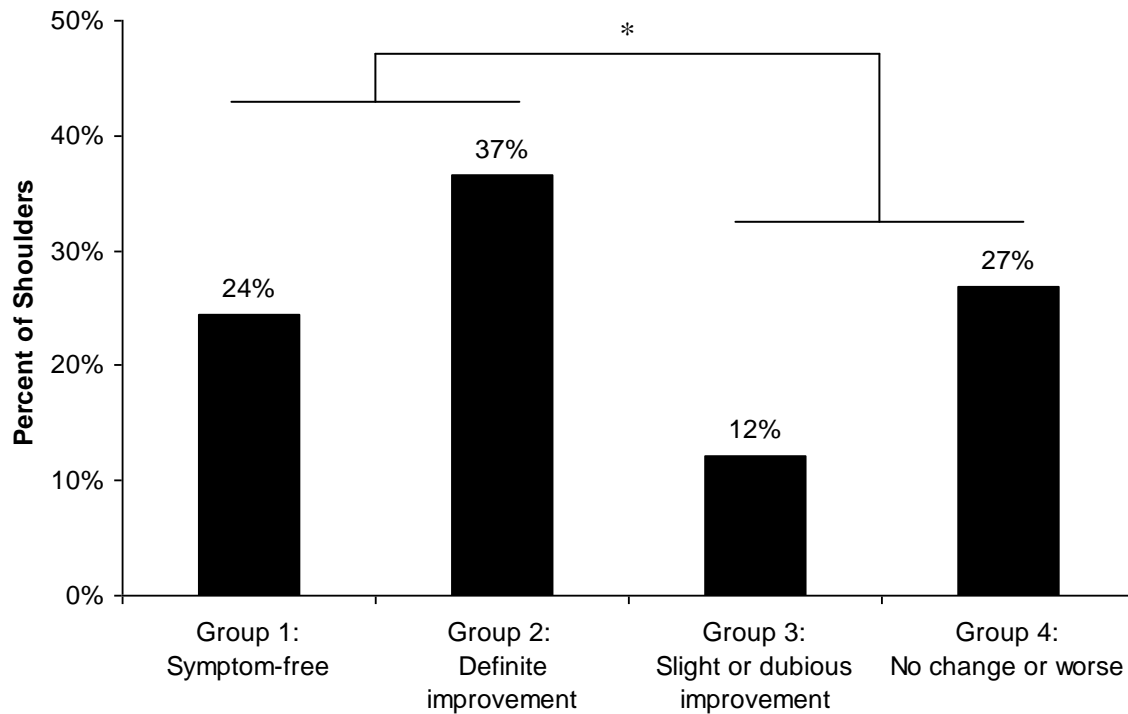


AAOS calculated independent t-test, $p < .05$; post-treatment confidence interval derived from pooled standard deviation.

RESPONSE TO TREATMENT

Two Level IV studies assessed response to treatment. Fearnley and Vadasz assessed thirty-eight patients diagnosed with a rotator-cuff lesion two weeks after a cortisone injection with lidocaine. Patient response to treatment was categorized on a four-point Likert-like scale: symptom free, definite improvement, slight or dubious improvement, no change or worse. AAOS calculations found significantly more patients classified as “symptom free” or “definite improvement” than “slight or dubious improvement” or “no change or worse” ($p = 0.049$; Figure 16).

Figure 16 Patient response to treatment



AAOS calculated odds ratio, OR = 2.441 (95% CI 1.01 - 5.93), $p = 0.049$.

Weiss reported the results of fifteen patients with a diagnosis of rotator-cuff tear at a maximum of 3-4 weeks after cortisone injection (see Table 18). Results were classified on a three-point Likert-like scale: good (pain free motion, able to resume previous activities without restrictions), satisfactory (some pain on motion, partial limitation of motion but able to return to work and recreational activities) or poor (painful motion and unable to undertake usual activities). The authors did not report duration at which the final assessment took place.

Table 18 Patient results after cortisone injection

No. of injections	Results			n
	Poor	Satisfactory	Good	
1	1	1	3	5
2	1	2	4	7
3	0	1	2	3
Total	2	4	9	N = 15

STRATIFICATIONS

Darlington et al. and Shibata et al. examined stratifications pertaining to: duration of symptoms, gender, age, or hand dominance.

Darlington et al.⁵⁵ reported, "There was no significant correlation between the duration of symptoms and any response to treatment evaluated in this study....The sex of the patient had no significant effect upon the response to treatment."

Shibata et al. reported, "...no difference was found between satisfied and unsatisfied patients in age, dominant side...disease duration..." (see Table 19).

Table 19 Rotator cuff tear stratifications pertaining to cortisone injection(s)

Stratification	Author Reported p-value	
	Shibata et al.	Darlington et al.
Duration of symptoms	ns	ns
Gender	-	ns
Age	ns	-
Hand dominance	ns	-

ns = not statistically significant

- = not addressed by authors

RECOMMENDATION 3C: ROTATOR CUFF TEARS AND NSAIDS, ACTIVITY MODIFICATION, ICE, HEAT, IONTOPHORESIS, MASSAGE, T.E.N.S., PEMF AND PHONOPHORESIS

We cannot recommend for or against the use of NSAIDS, activity modification, ice, heat, iontophoresis, massage, Transcutaneous Electrical Nerve Stimulation (TENS), Pulsed Electromagnetic Field (PEMF), or phonophoresis (ultrasound) for nonoperative management of rotator cuff tears.

Level of Evidence: None

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

In symptomatic patients with full thickness rotator cuff tears, treatment objectives are decreased pain, increased function, and enhancement of activities of daily living. Although we found no specific evidence demonstrating treatment efficacy, neither did we find evidence that the following modalities were ineffective non operative treatment alternatives for rotator cuff tears: NSAIDS, activity modification, ice, heat, iontophoresis, massage, TENS, PEMF, phonophoresis (ultrasound).

RECOMMENDATION 4A: ROTATOR CUFF RELATED SYMPTOMS AND EXERCISE OR NONSTEROIDAL ANTI-INFLAMMATORY MEDICATION

We suggest that patients who have rotator cuff-related symptoms in the absence of a full thickness tear be initially treated non-operatively using exercise and/or non-steroidal anti-inflammatory drugs.

Level of Evidence: II

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Rationale:

Several Level II studies^{59, 60, 23} report the beneficial effects of exercise in decreasing pain and improving function in patients with rotator cuff related symptoms without a full-thickness tear. One study²³ reported on 24 patients undergoing an exercise program and noted significantly improved pain scores on the VAS [visual analog scale] after 8 weeks of treatment; post hoc pairwise comparisons of the two groups in this study showed significantly more improvement in the exercise plus manual therapy group using a composite pain measure. Another study⁵⁹ reported patients had significant improvements in pain at rest, pain at night and Constant-Murley scores after 3 months of a home exercise program. A third study⁶⁰ randomized patients between a group undergoing exercise and a control group. The group undergoing exercise had statistically significant improvements in pain levels at rest, pain with movement and upper extremity function (DASH-Laborers subscale). No statistically significant difference was reported in patients who participated in supervised and unsupervised exercises.

Our systematic review also identified two Level II studies^{61, 62} that found better results with non-steroidal anti-inflammatory medications than with placebo in the treatment of rotator cuff-related symptoms in the absence of a full-thickness rotator cuff tear. The first study⁶³ was a prospective, double-blinded placebo-controlled study in which 20 patients treated with oral diclofenac had significant improvements in pain (VAS) and shoulder function at four weeks compared to patients taking a placebo. The second study⁶⁴ reported significant improvements in shoulder function VAS scores in 10 patients treated with naproxen compared to 10 patients receiving a placebo.

SUPPORTING EVIDENCE- EXERCISE

Tables relevant to this recommendation are: Table 20

Figures relevant to this recommendation are: Figure 17 through Figure 32

EXERCISE

Table 20 Results of patients treated with an exercise program

Authors	LoE	n	Comparison	Outcome	Duration			
					Final Visit*	6 weeks	8 weeks	12 weeks
Bang et al.	II	49	Exercise with manual PT vs. Exercise	Pain: Composite VAS	●ept			
Lombardi et al.		60	Exercise vs. Control	Pain: At Rest (VAS)			●e	
				Pain: On Movement (VAS)			●e	
				DASH-Laborers			●e	
				DASH-Activities of Daily Living			○	
				SF-36: Physical Function			○	
				SF-36: Role-physical			○	
				SF-36: Bodily Pain			○	
				SF-36: General Health			○	
				SF-36: Vitality			○	
				SF-36: Social Function			○	
Walther et al.		60	Self-training vs. PT vs. Shoulder brace	Pain: At Rest		○		○
				Pain: On Activity		○		○
				Pain: At Night		○		○
	Constant-Murley Score				○		○	

○ = no statistically significant difference

● = statistically significant result favoring treatment

ept = favoring exercise with manual PT

e = favoring exercise treatment

* = 3-4 weeks from baseline

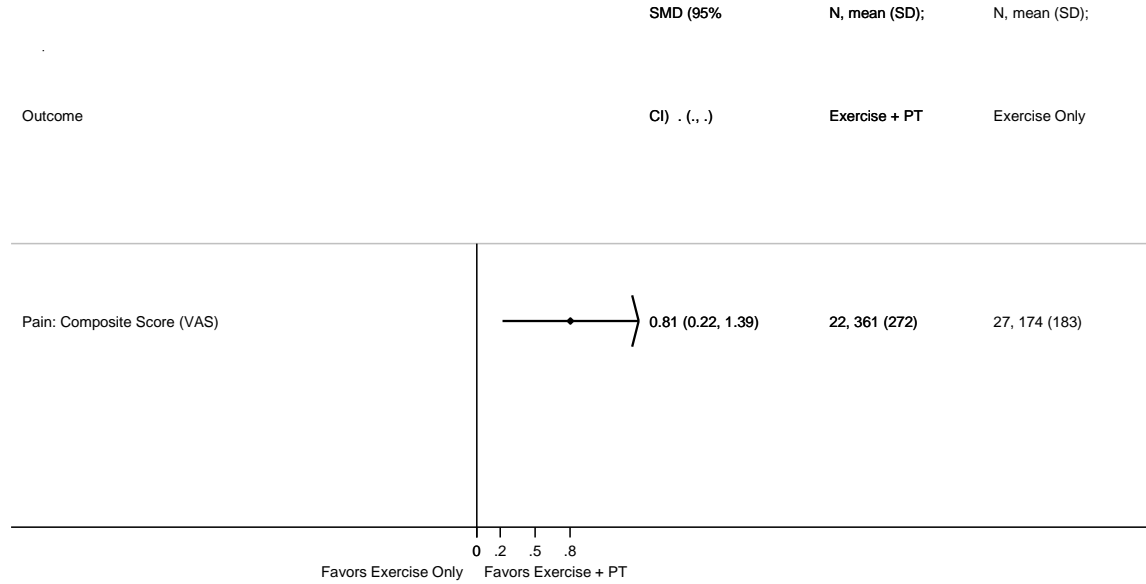
LoE = level of evidence

DASH = disability of the arm, shoulder and hand

PAIN: COMPOSITE VAS SCORE

One Level II study by Bang & Deyle assessed patients diagnosed as having subacromial impingement syndrome treated by either a supervised exercise program (group Exercise) or a supervised exercise program with manual physical therapy (group Exercise + PT). Patients' pain was assessed by VAS and calculated as the sum of pain measures for a) function, b) active abduction and resisted break tests for internal/external rotation, c) abduction (see Figure 17).

Figure 17 Composite pain score measured by VAS

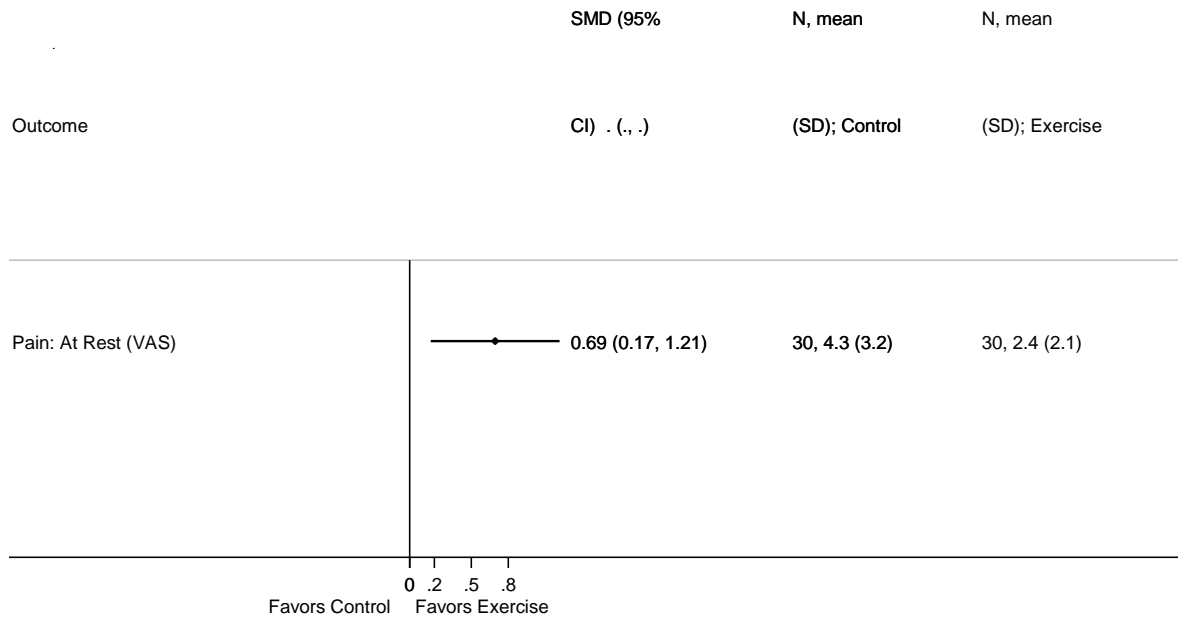


AAOS calculated effect size

PAIN: AT REST

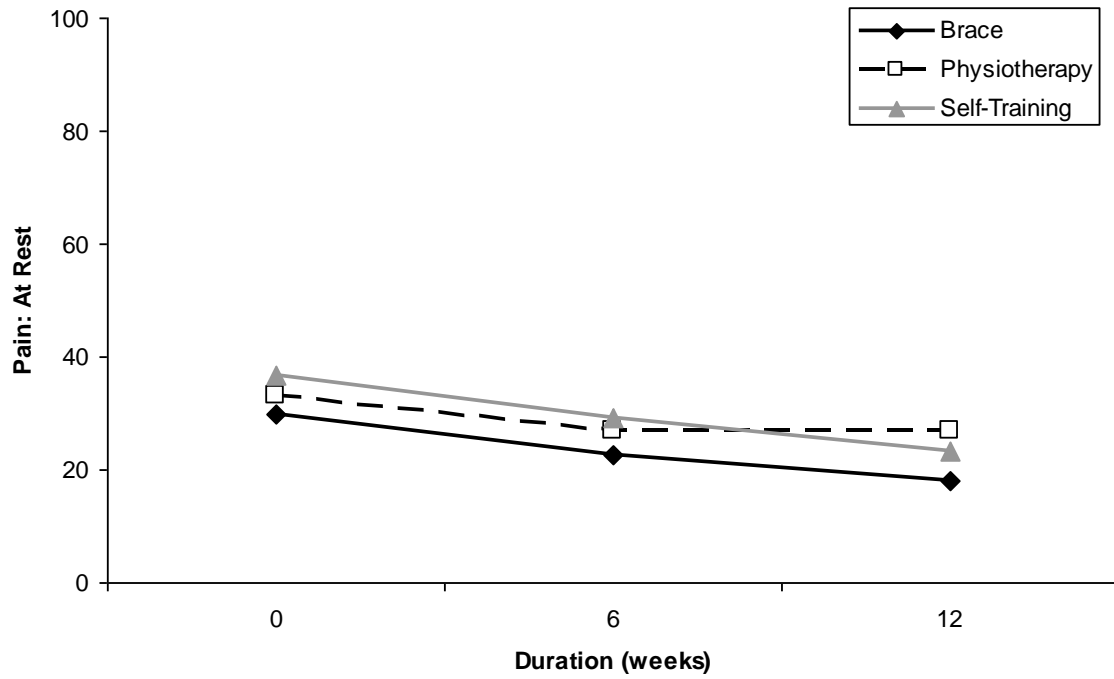
Two level two studies examined pain at rest measured by VAS. Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found a statistically significant improvement in pain at rest in the exercise group compared to the control group ($ES = 0.69$, 95% CI 0.17 – 1.21; see Figure 18). Walther et al. assessed patients diagnosed as having subacromial impingement syndrome treated with either: physiotherapy (ten sessions), self-training (centering and stretching exercises), or shoulder brace (to be worn as long as possible). There were twenty patients per treatment arm and all treatments lasted twelve weeks. Pain at rest was assessed using VAS. Authors report a statistically significant reduction in pain at rest for all three groups ($p < 0.05$); however, there were no differences noted between groups (see Figure 19).

Figure 18 Pain at rest as measured by VAS



AAOS calculated effect size

Figure 19 Pain at rest measured by VAS

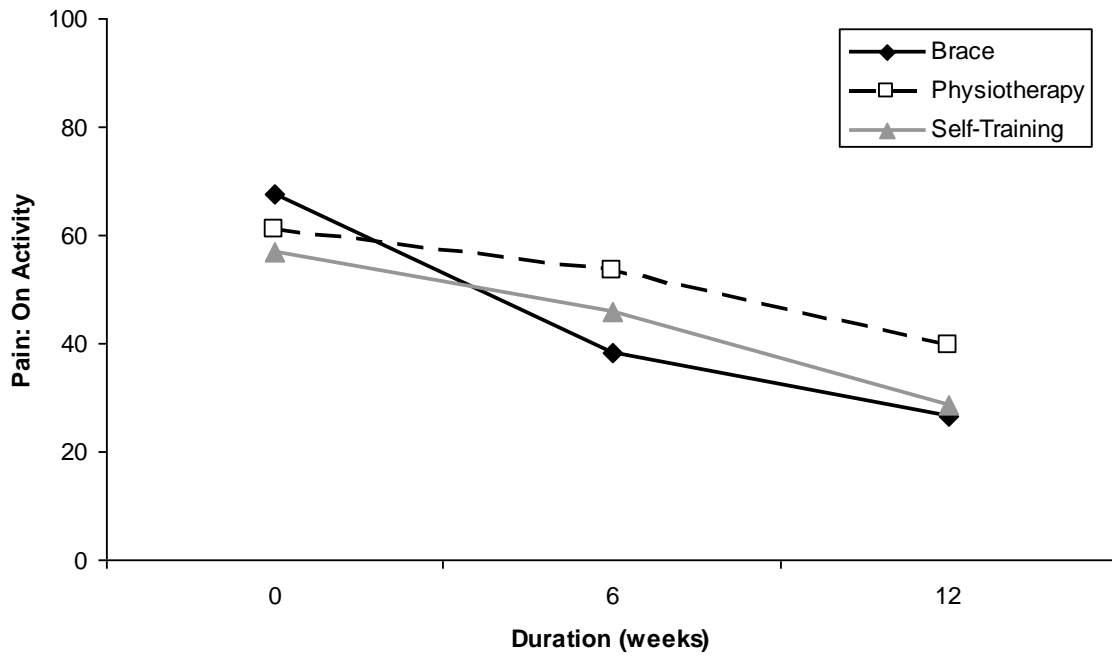


Authors do not provide dispersion for point estimates; authors report a statistically significant reduction for all three groups ($p < 0.05$); however, there were no between group differences.

PAIN: ON ACTIVITY

One Level II study by Walther et al. assessed patients diagnosed as having subacromial impingement syndrome treated with either: physiotherapy (ten sessions), self-training (centering and stretching exercises) or shoulder brace (to be worn as long as possible). There were twenty patients per treatment arm and all treatments lasted twelve weeks. Pain on activity was assessed using VAS. Authors report a statistically significant reduction in pain on activity for all three groups ($p < 0.05$); however, there were no statistically significant differences noted between groups (see Figure 20).

Figure 20 Pain on activity measured by VAS

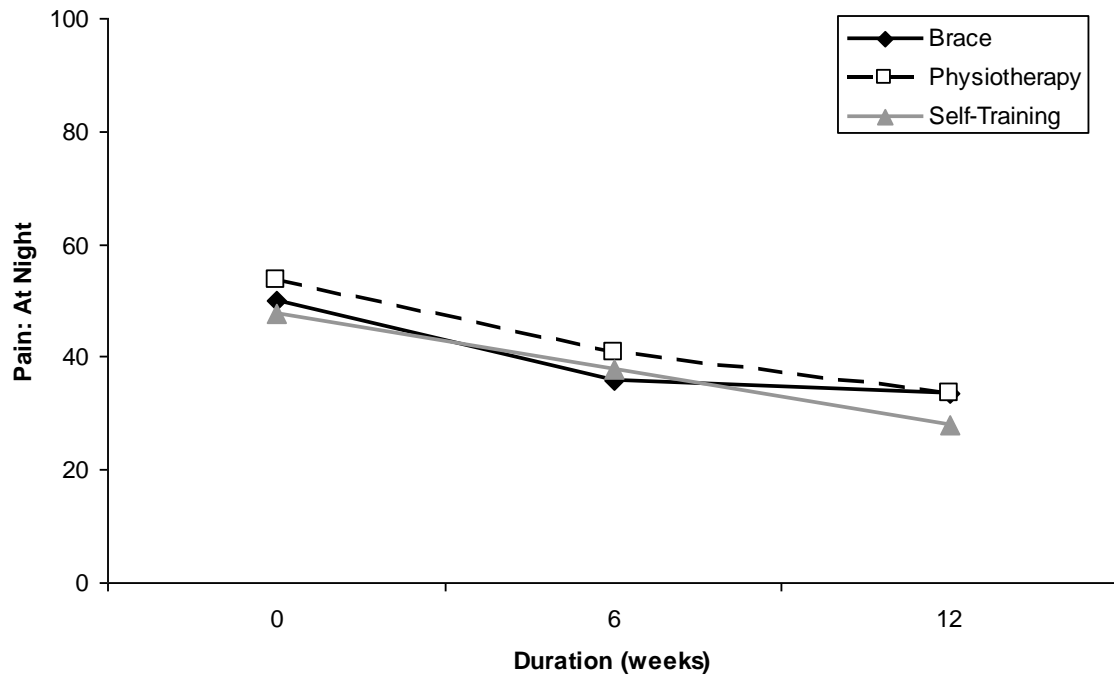


Authors do not provide dispersion for point estimates; authors report a statistically significant reduction for all three groups ($p < 0.05$); however, there were no statistically significant between group differences.

PAIN: AT NIGHT

One Level II study by Walther et al. assessed patients diagnosed as having subacromial impingement syndrome treated with either: physiotherapy (ten sessions), self-training (centering and stretching exercises) or shoulder brace (to be worn as long as possible). There were twenty patients per treatment arm and all treatments lasted twelve weeks. Pain at night was assessed using VAS. Authors report a statistically significant reduction in pain at night for all three groups ($p < 0.05$); however, there were no statistically significant differences noted between groups (see Figure 21).

Figure 21 Pain at night measured by VAS

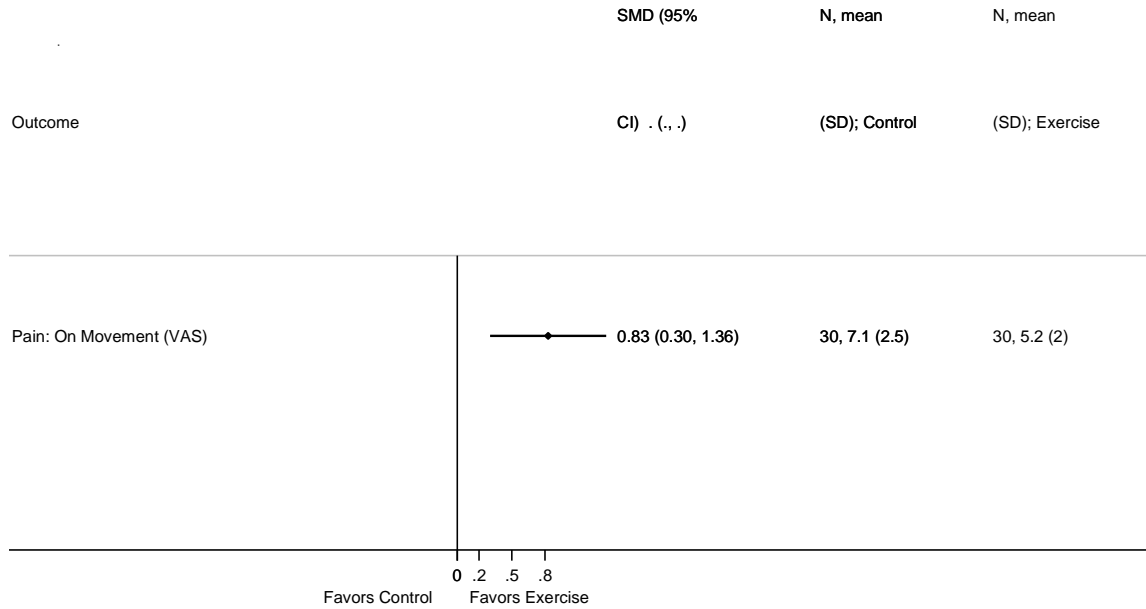


Authors do not provide dispersion for point estimates; authors report a statistically significant reduction for all three groups ($p < 0.05$); however, there were no statistically significant between group differences.

PAIN: ON MOVEMENT

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found a statistically significant improvement in pain on movement (measured by VAS) in the exercise group compared to the control group ($ES = 0.83$, 95% CI 0.30 – 1.36; see Figure 22).

Figure 22 Pain on movement as measured by VAS

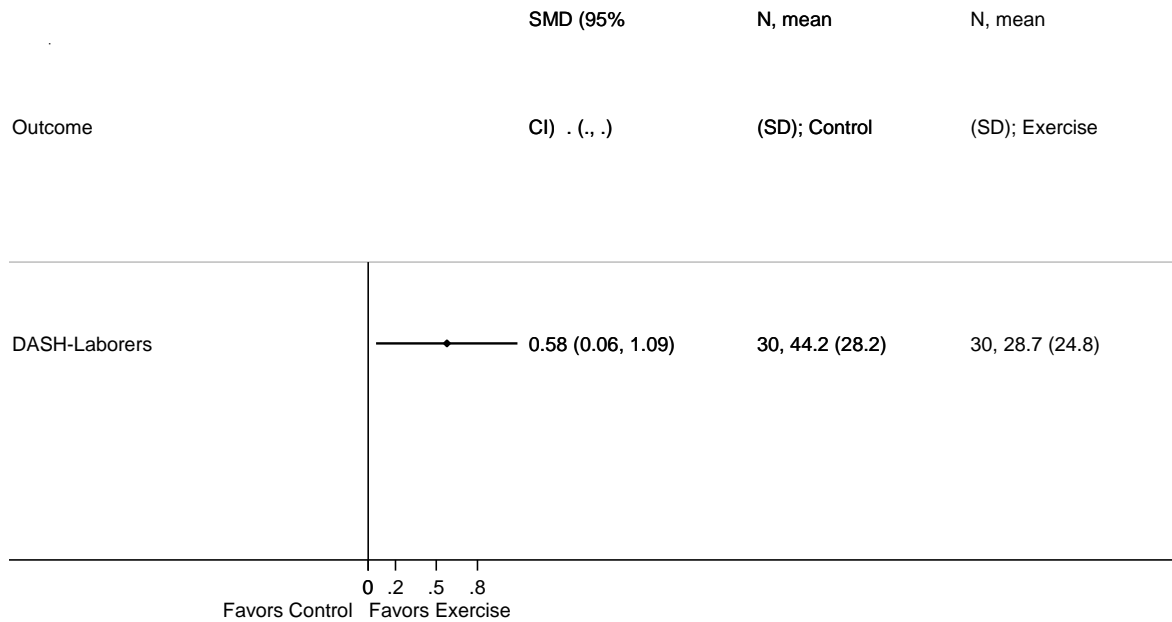


AAOS calculated effect size

DASH: LABORERS

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found a statistically significant improvement in the DASH subscale pertaining to laborers in the exercise group compared to the control group ($ES = 0.58$, 95% CI 0.06 – 1.09; see Figure 23).

Figure 23 DASH subscale pertaining to laborers

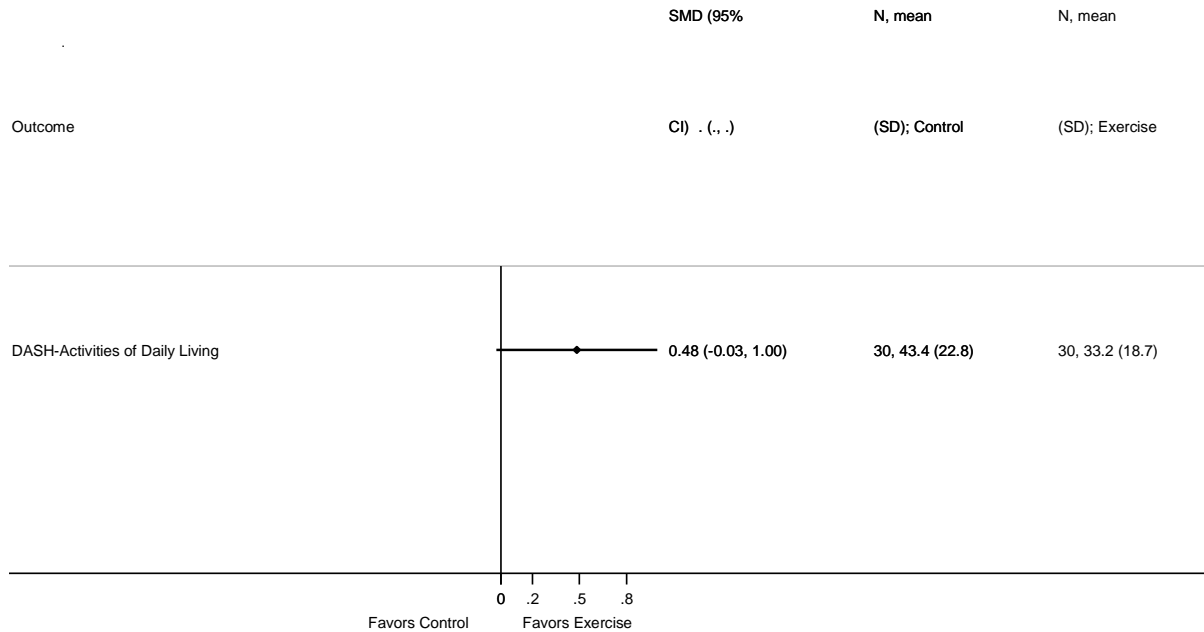


AAOS calculated effect size

DASH: ACTIVITIES OF DAILY LIVING

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the DASH subscale pertaining to activities of daily living ($ES = 0.48$, 95% CI - 0.03 – 1.00; see Figure 24).

Figure 24 DASH subscale pertaining to activities of daily living

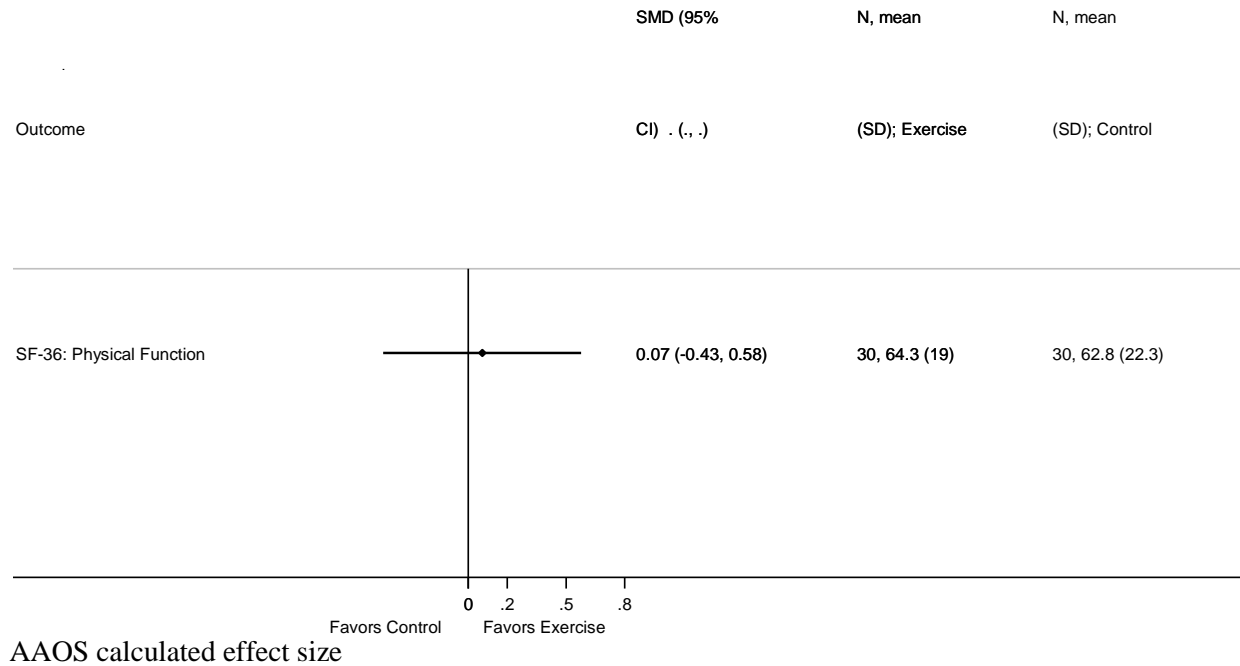


AAOS calculated effect size

SHORT FORM 36-ITEM (SF-36): PHYSICAL FUNCTION

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to physical function ($ES = 0.07$, 95% CI -0.43 – 0.58; see Figure 25).

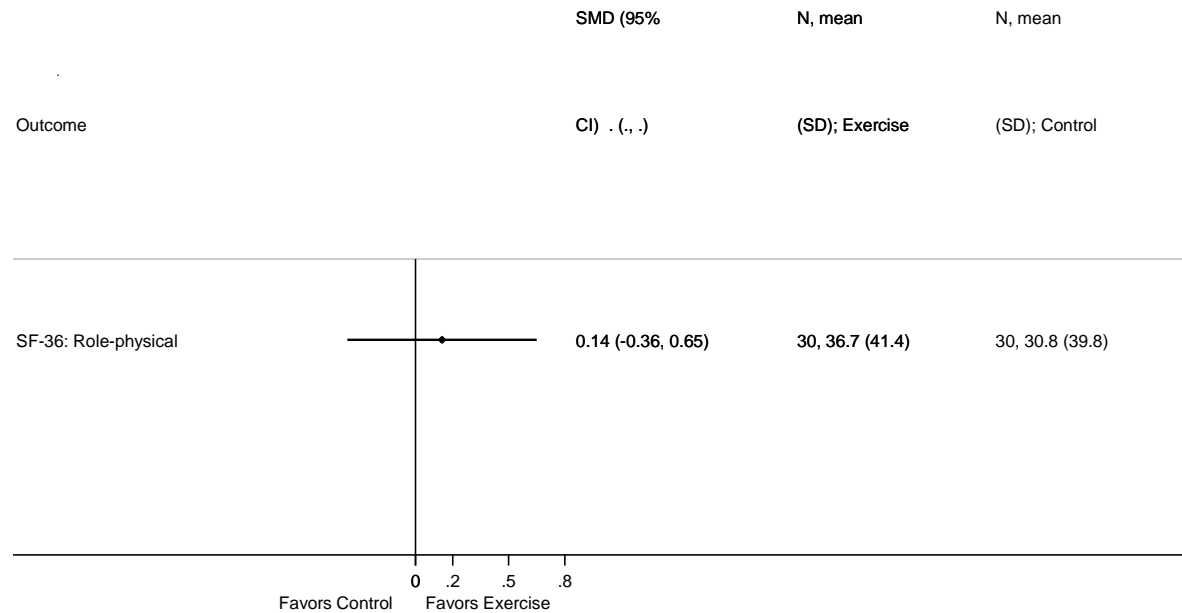
Figure 25 Physical function as measured by SF-36



SF-36: ROLE-PHYSICAL

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to physical role ($ES = 0.14$, 95% CI $-0.36 - 0.65$; see Figure 26). The physical role assesses problems with work or other daily activities as a result of physical health.

Figure 26 Physical role as measured by SF-36

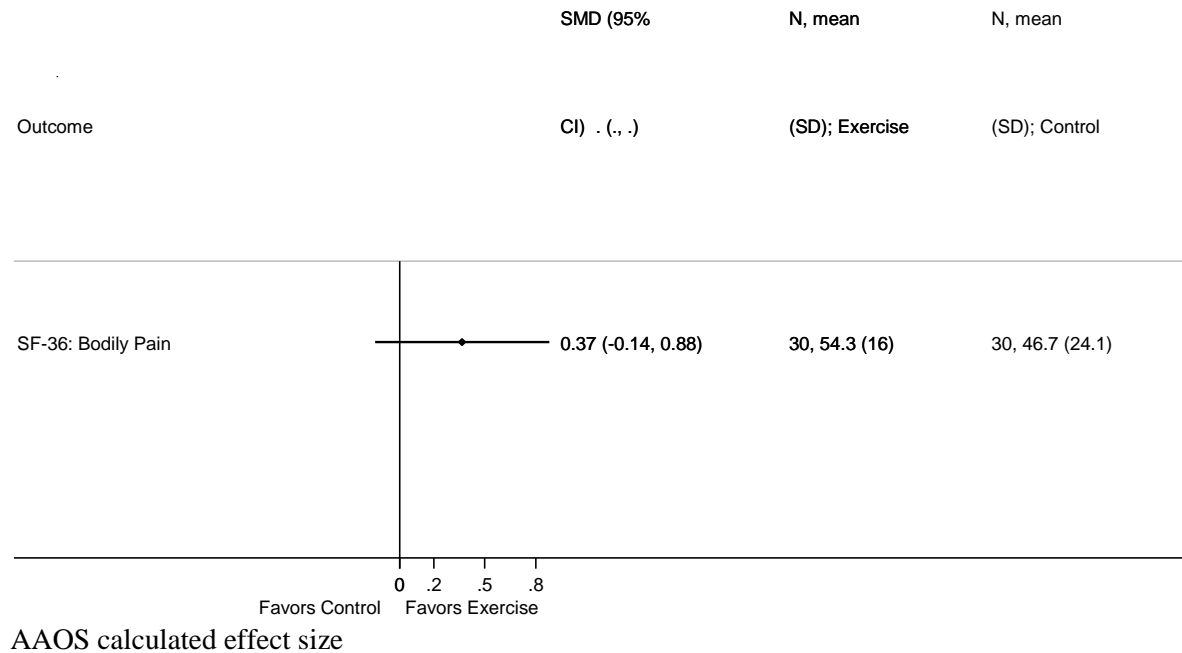


AAOS calculated effect size

SF-36: BODILY PAIN

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to bodily pain ($ES = 0.37$, 95% CI $-0.14 - 0.88$; see Figure 27).

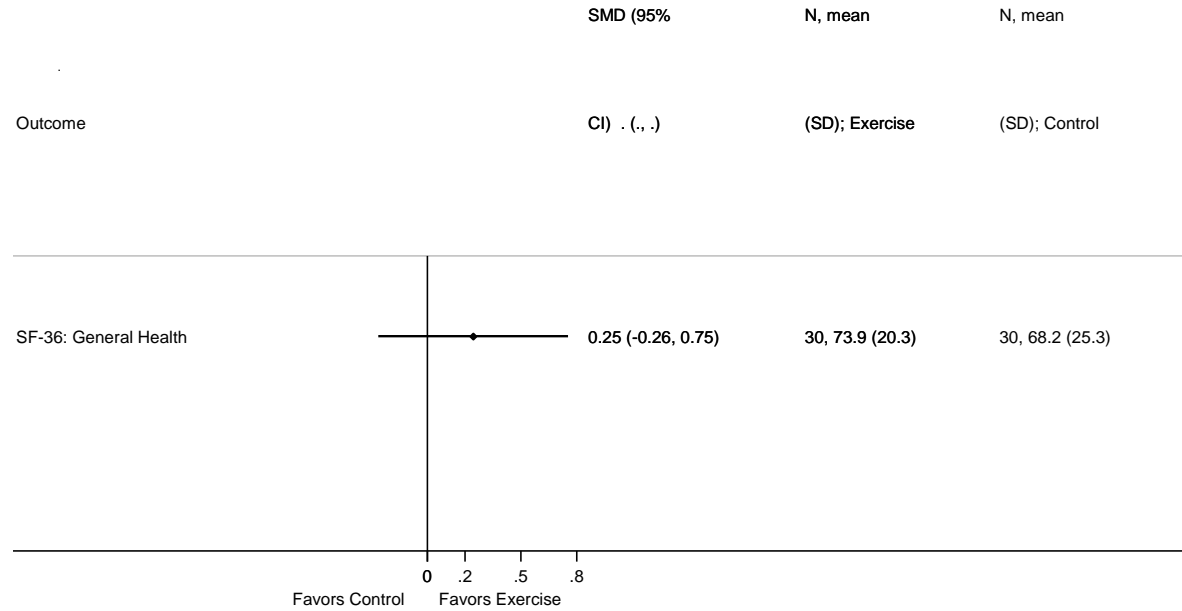
Figure 27 Bodily pain as measured by SF-36



SF-36: GENERAL HEALTH

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to general health ($ES = 0.25$, 95% CI $-0.26 - 0.75$; see Figure 28).

Figure 28 General health as measured by SF-36

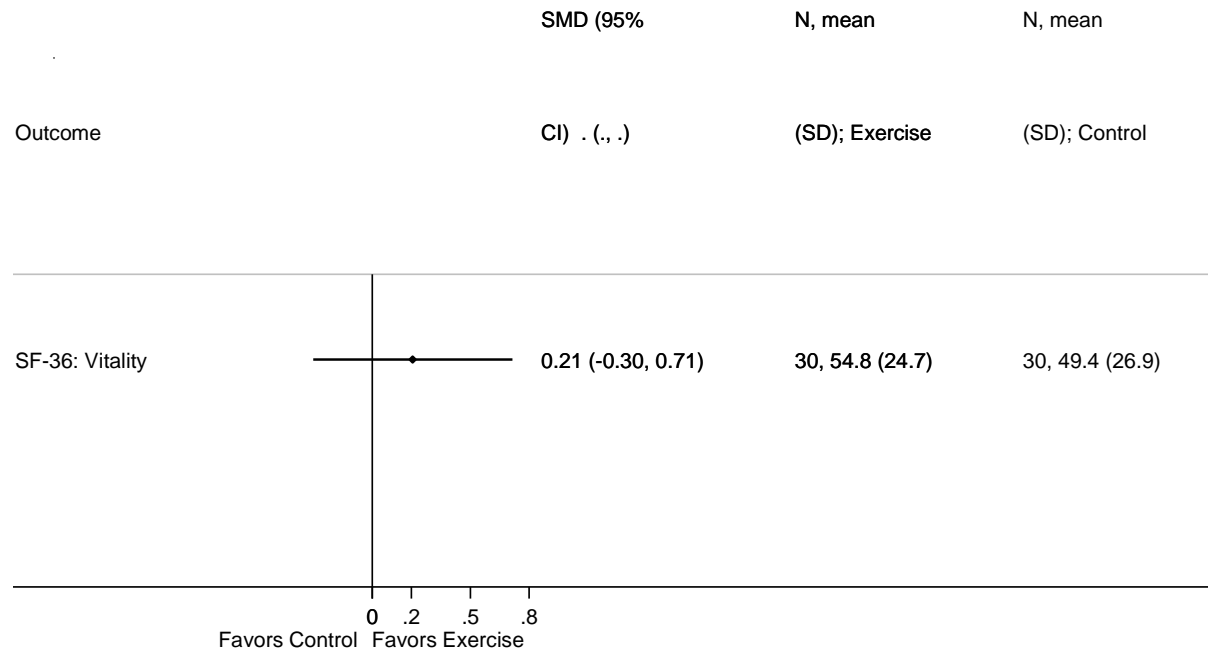


AAOS calculated effect size

SF-36: VITALITY

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to vitality ($ES = 0.21$, 95% CI $-0.30 - 0.71$; see Figure 29). The vitality subscale assesses the degree to which patients feel tired or worn-out.

Figure 29 Vitality as measured by SF-36

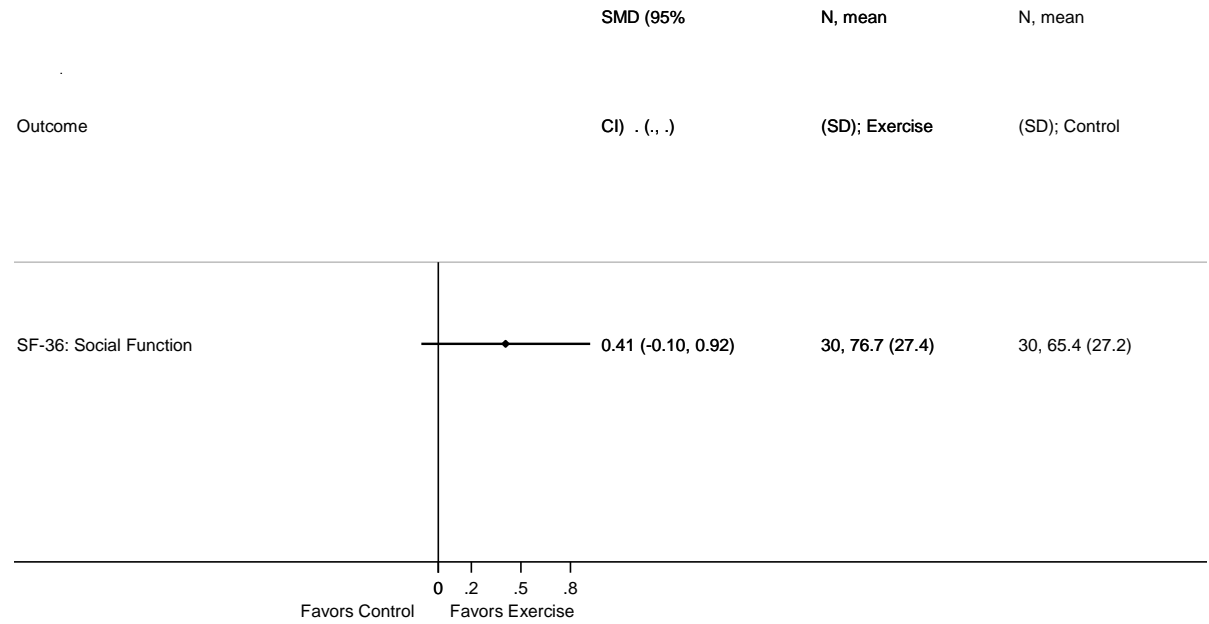


AAOS calculated effect size

SF-36: SOCIAL FUNCTION

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to social function ($ES = 0.41$, 95% CI -0.10 – 0.92; see Figure 30).

Figure 30 Social function as measured by SF-36

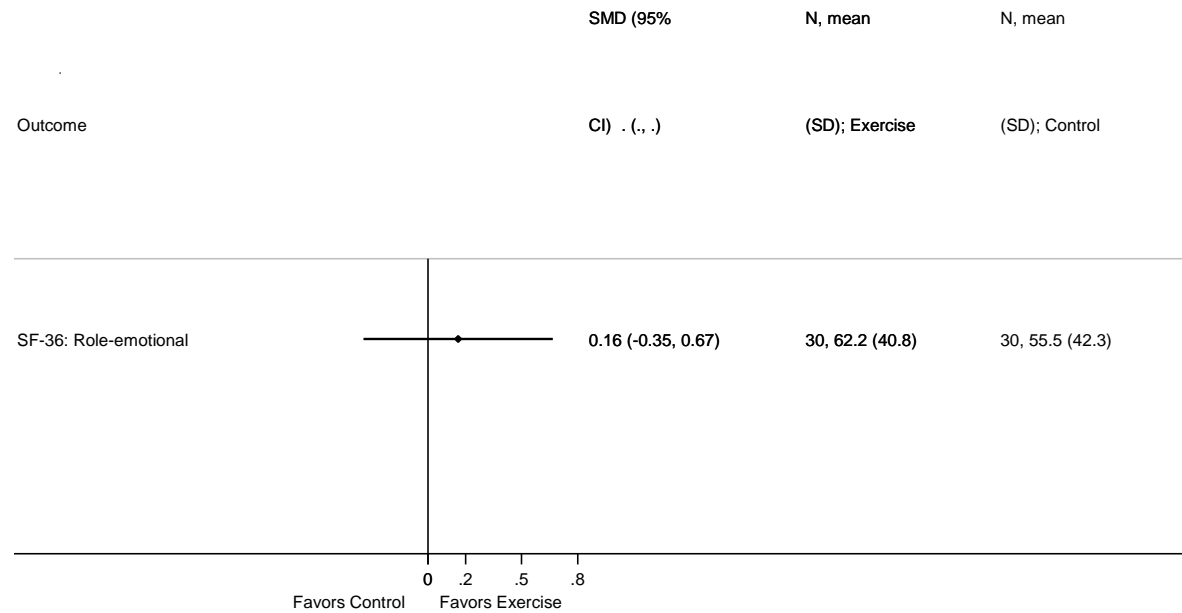


AAOS calculated effect size

SF-36: ROLE-EMOTIONAL

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to emotional role ($ES = 0.16$, 95% CI $-0.35 - 0.67$; see Figure 31). The emotional role assesses problems with work or other daily activities as a result of emotional problems.

Figure 31 Emotional role as measured by SF-36

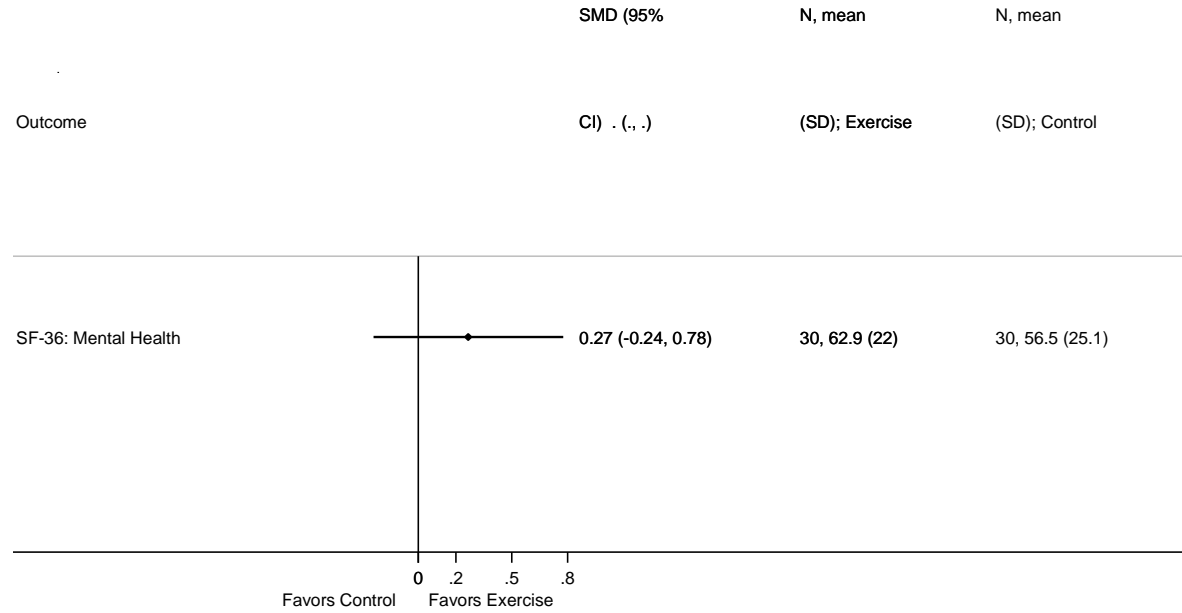


AAOS calculated effect size

SF-36: MENTAL HEALTH

One Level II study by Lombardi et al. examined the use of exercise in patients diagnosed with impingement syndrome after two months of treatment. Patients participated in twice-weekly strength training and results were compared to a wait-list control group. AAOS calculations found no statistically significant difference between exercise and control groups on the SF-36 subscale pertaining to mental health ($ES = 0.27$, 95% CI $-0.24 - 0.78$; see Figure 32).

Figure 32 Mental health as measured by SF-36



AAOS calculated effect size

SUPPORTING EVIDENCE- NSAIDS

Tables relevant to this recommendation are: Table 21

Figures relevant to this recommendation are: Figure 33 through Figure 35

NSAIDS

Table 21 Results of patients treated with NSAIDs

Author	LoE	n	Comparison	Outcome	Duration	
					2 weeks	4 weeks
Adebajo et al.	II	40	NSAIDs vs. Placebo	Pain: VAS		●N
England et al.		20	NSAIDs vs. Dummy Laser	Function: VAS	●N	
Adebajo et al.		40	NSAIDs vs. Placebo	Function: Limitations		●N
Adebajo et al.		40	NSAIDs vs. Placebo	Response to Treatment		○

○ = no statistically significant difference

● = significant result

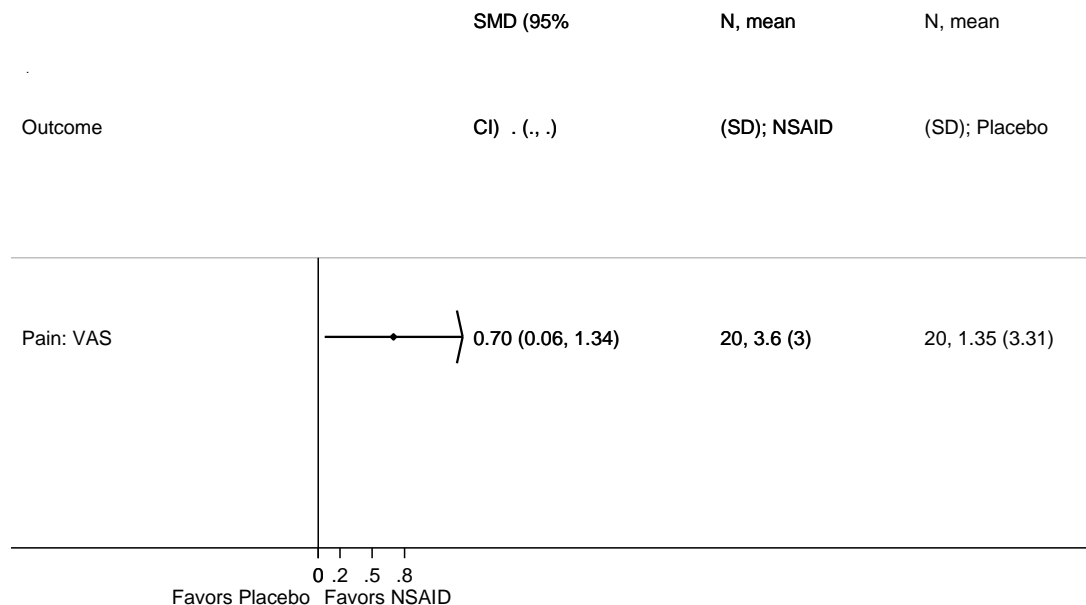
N = favoring NSAIDs

LoE = level of evidence

PAIN: VAS

One Level II study by Adebajo et al. assessed patients diagnosed as having rotator cuff tendonitis. Patients were treated with either NSAID (oral NSAID plus injection of lidocaine) or placebo (placebo pill plus injection of lidocaine) and pain was measured using a VAS. AAOS calculations found a statistically significant effect in favor of NSAID treatment at four weeks ($ES = 0.70$, 95% CI 0.06 – 1.34; see Figure 33).

Figure 33 Improvement in pain score in patients treated with NSAID or placebo



AAOS calculated effect size

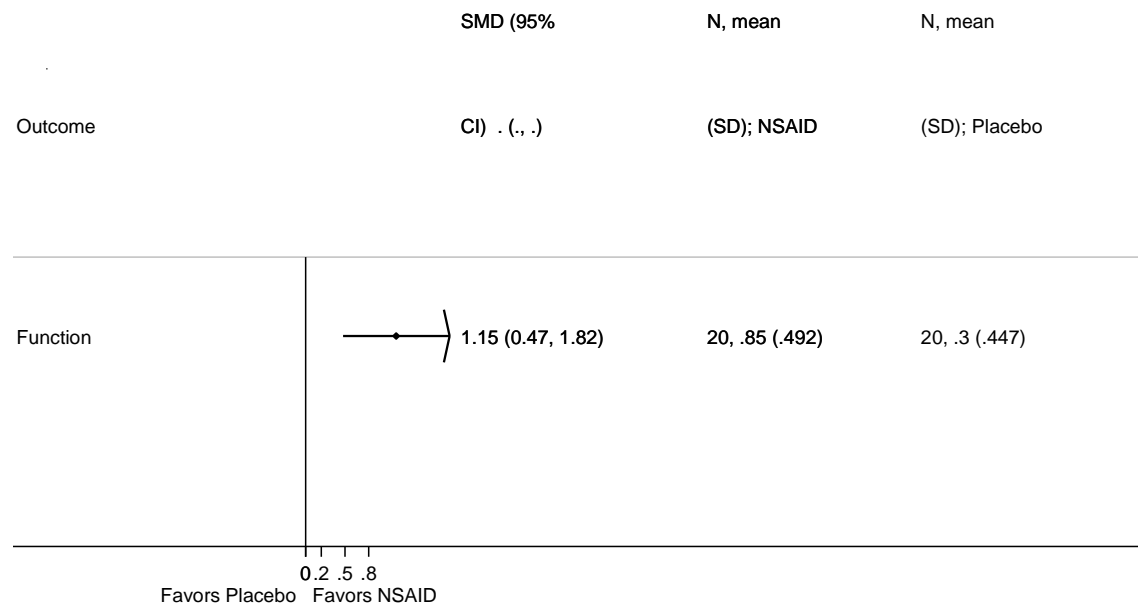
FUNCTION: VAS

One Level II study by England et al. examined the effect of laser treatment, drug treatment (naproxen sodium) or dummy laser treatment on function measured by VAS. Laser treatment data was not examined as this treatment was not considered for this recommendation. Authors report that patients in the drug treatment group had a significant improvement in function compared to the dummy laser treatment (-1cm difference between medians, 95% CI -2, 0; $p = 0.05$).

FUNCTION: LIMITATIONS

One Level II study by Adebajo et al. assessed patients diagnosed as having rotator cuff tendonitis. Patients were treated with either NSAID (oral NSAID plus injection of lidocaine without steroid) or placebo (placebo pill plus injection of lidocaine). Authors reported patient function on a four point scale as: 0 = no limitation of function, 1 = mild limitation of function, 2 = moderate limitation of function, 3 = sever limitation of function. AAOS calculations found a statistically significant effect in favor of NSAIDs treatment at four weeks ($ES = 1.15$, 95% 95% CI 0.47 – 1.82; see Figure 34).

Figure 34 Improvement in function score in patients treated with NSAID or placebo

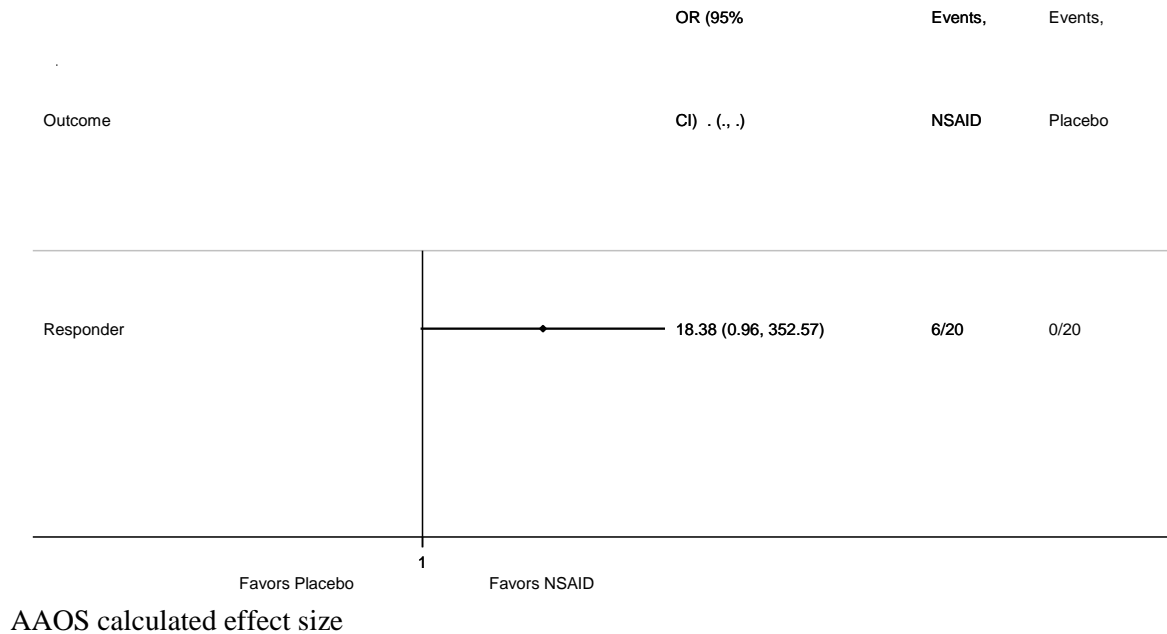


AAOS calculated effect size

RESPONSE TO TREATMENT

One Level II study by Adebajo et al. assessed patients diagnosed as having rotator cuff tendonitis. Patients were treated with either NSAID (oral NSAID plus injection of lidocaine without steroid) or placebo (placebo pill plus injection of lidocaine). Patients were considered to have responded to treatment if they improved in all three outcomes examined: pain, range of active abduction and limitation of function. AAOS calculations failed to find a statistically significant effect for NSAIDs treatment at four weeks ($ES = 18.38$, 95% CI 0.96 – 352.57; see Figure 34).

Figure 35 Patients responding to treatment after receiving NSAID or placebo



RECOMMENDATION 4B: ROTATOR CUFF RELATED SYMPTOMS AND CORTICOSTEROID INJECTIONS OR PEMF

We cannot recommend for or against subacromial corticosteroid injection or Pulsed Electromagnetic Field (PEMF) in the treatment of rotator cuff-related symptoms in the absence of a full thickness tear.

Level of Evidence: II

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

We found one Level I study⁶³ that evaluated the effect of subacromial corticosteroid injections on patients who had previously had 6 weeks of unsuccessful physical therapy and 2 weeks of NSAIDs for rotator cuff-related symptoms in the absence of a full-thickness tear. The authors reported no differences at 3 and 6 months in ASES scores, DASH scores or pain with impingement testing between groups. However, five Level II studies^{61, 64, 65, 66, 67} report conflicting results for the effect of subacromial steroid injections for durations between 2 and 6 weeks. These studies report various results for outcomes of pain and function and also vary in that some studies report results for one steroid injection while others report results for multiple steroid injections. The work group's overall assessment of this evidence was conflicting. Because of these conflicting results, this recommendation is supported by inconclusive evidence.

Two Level II studies^{68, 69} also examined the use of pulsed electromagnetic field (PEMF) in patients diagnosed with rotator cuff related symptoms. One study⁶⁹ reported no statistically significant differences in pain or Constant-Murley scores in patients treated with PEMF as compared to those treated with sham-controls. In the second study⁶⁸ the authors measured pain on the VAS scale and found a statistically significant difference in favor of PEMF. Based on these conflicting results, the work group does not have sufficient evidence to provide specific treatment recommendations in regard to PEMF.

SUPPORTING EVIDENCE- CORTICOSTEROID

Tables relevant to this recommendation are: Table 22

Figures relevant to this recommendation are: Figure 36 through Figure 52

CORTICOSTEROID INJECTIONS

Table 22 Corticosteroid Injections

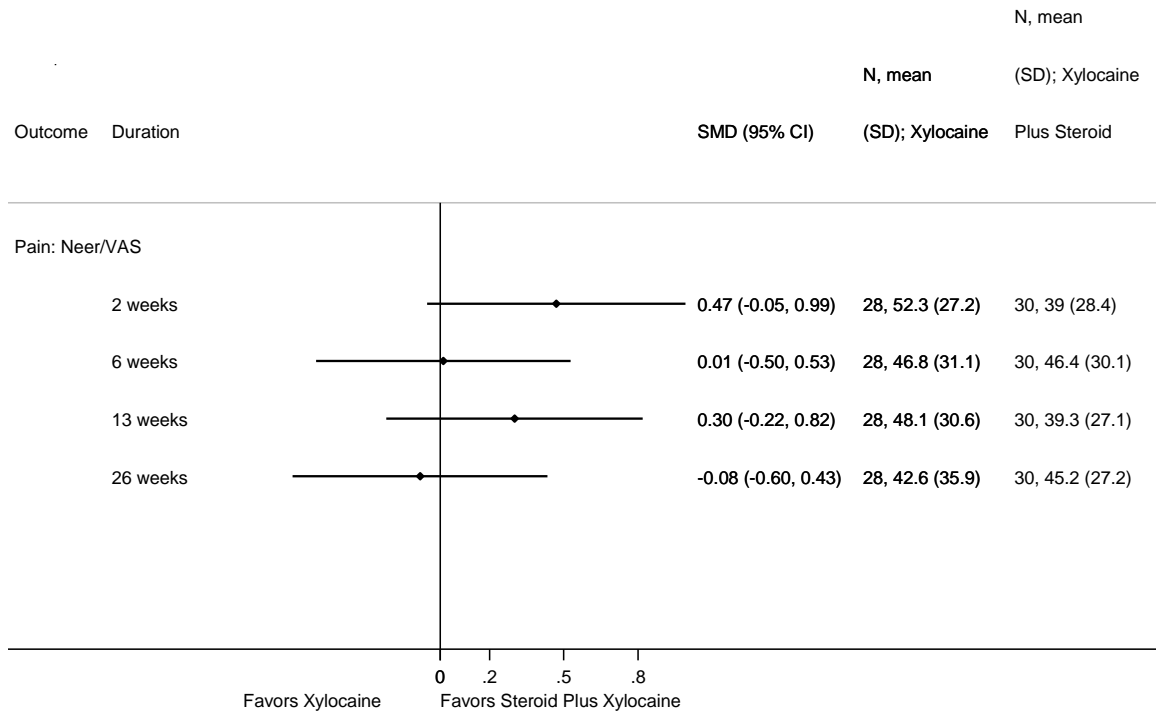
Authors	LoE	n	Comparison	Outcome	Duration						
					Final Visit*	2 weeks	4 weeks	6 weeks	8 weeks	3 months	6 months
Alvarez et al.	I	58	Steroid vs. Control	Pain: VAS		○	○			○	○
				ASES		?	?			?	?
				DASH		?	?			?	?
				WORC		○	○			●s	○
				WORC:Sports Subscale		○	○			○	○
Adebajo et al.	II	40	Steroid vs. Control	Pain: VAS			●s				
Withrington et al.		25	Steroid vs. Placebo	Pain: VAS		○			○		
Blair et al.		37	Steroid vs. Control	Pain: Likert-like	●s						
Vecchio et al.		55	Steroid vs. Control	Composite Pain: VAS		○	○			○	
Akgun et al.		48	Steroid vs. Control	Pain: At Rest			nr			○	
Akgun et al.		48	Steroid vs. Control	Pain: On Activity			nr			○	
Akgun et al.		48	Steroid vs. Control	Pain: Disturbing Sleep			●ss			○	
Akgun et al.		48	Steroid vs. Control	Function: Constant-Murley Score			●ss			○	
Adebajo et al.		40	Steroid vs. Control	Function: Limitations			●s				
Akgun et al.		48	Steroid vs. Control	Constant-Murley Score			nr			○	
Adebajo et al.		40	Steroid vs. Control	Response to Treatment			●s				
Withrington et al.		25	Steroid vs. Placebo	Acetaminophen Consumption		○					

- = no statistically significant difference
- = statistically significant result favoring steroid
- ? = not sufficiently powered to detect the MCII; neither statistically or clinically significant
- s = favoring one steroid injection
- ss = favoring two steroid injections over one or no steroid injection
- nr = authors examined this outcome but did not report if the results were statistically significant
- * = 8.29 ± 0.26 months from baseline
- LoE = level of evidence
- ASES = American Shoulder and Elbow Surgeons
- DASH = Disabilities of the Arm, Shoulder and Hand
- WORC = Western Ontario Rotator Cuff Index

PAIN: VAS

One Level I study by Alvarez et al. assessed patients diagnosed as having rotator cuff disease treated with injections of either xylocaine or xylocaine plus a steroid. Pain with the Neer impingement sign was measured using a 100-mm VAS (see Figure 36).

Figure 36 Pain with the Neer impingement sign measured by VAS

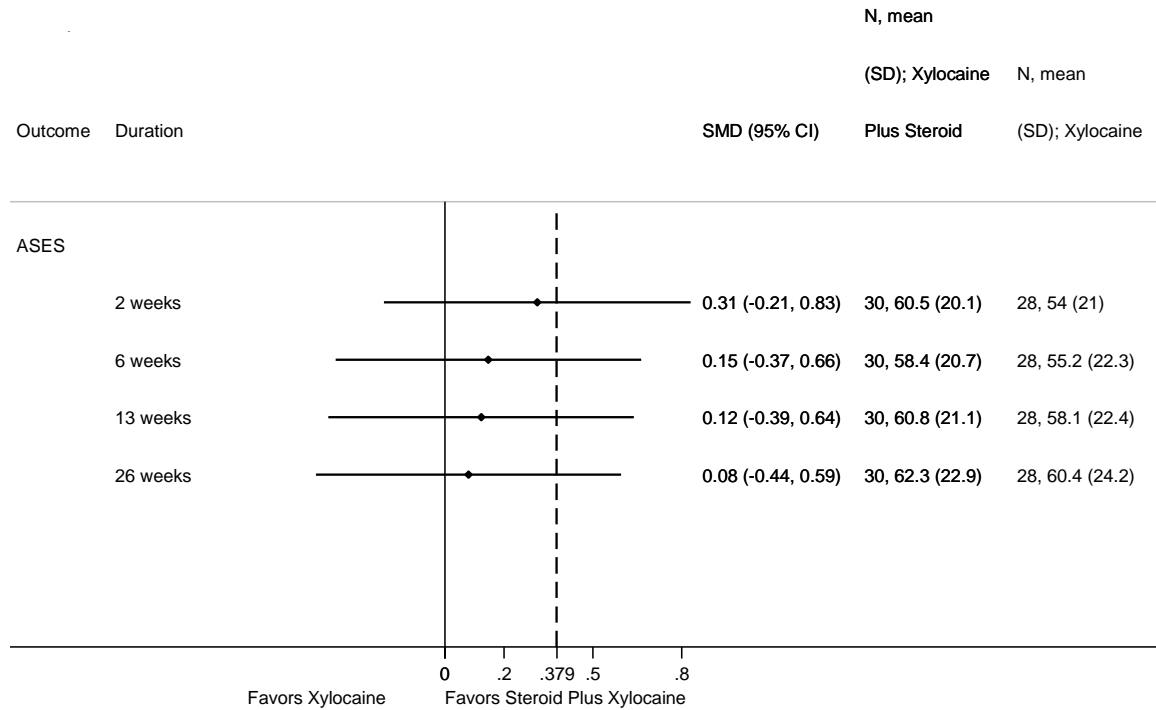


AAOS calculated effect size

ASES SCORE

One Level I study by Alvarez et al. assessed patients diagnosed as having rotator cuff disease treated with injections of either xylocaine or xylocaine plus a steroid using the ASES score (see Figure 37).

Figure 37 Patient ASES score

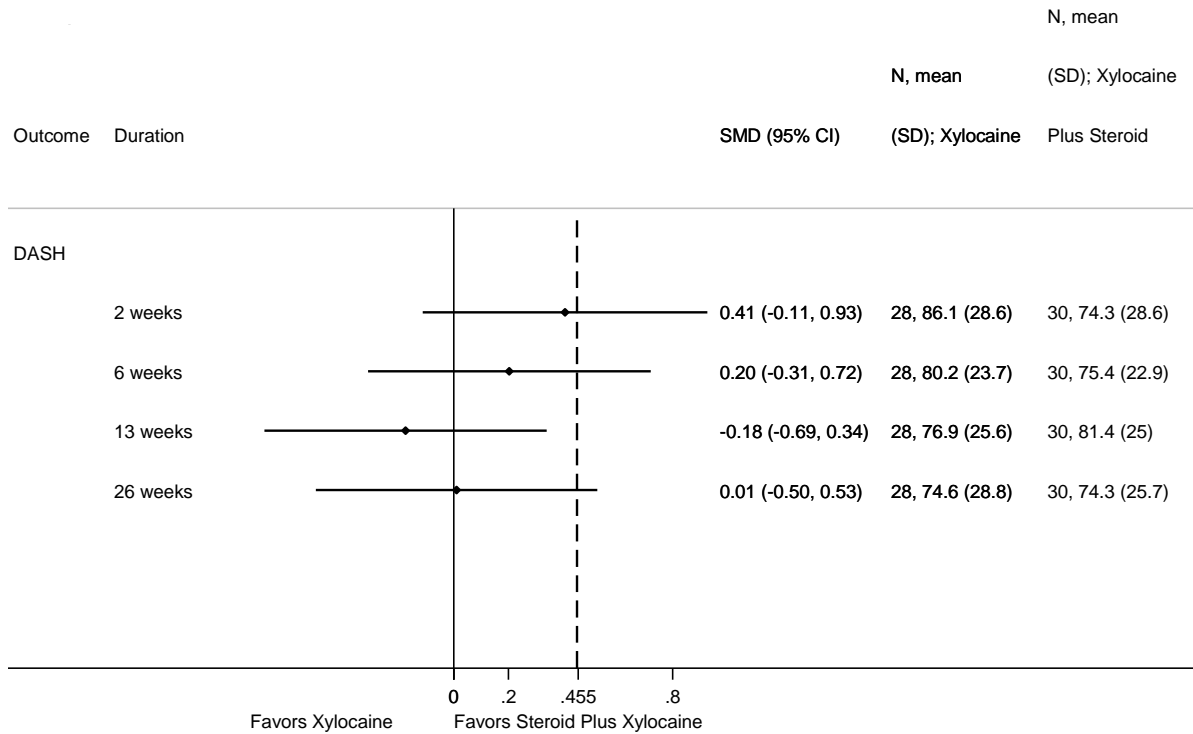


AAOS calculated effect size; MCII indicated by dashed line; MCII value was determined for patients with rotator cuff tears; this study was not sufficiently powered to detect the MCII. Therefore, its' results are inconclusive.

DASH

One Level I study by Alvarez et al. assessed patients diagnosed as having rotator cuff disease treated with injections of either xylocaine or xylocaine plus a steroid using the DASH score (see Figure 38).

Figure 38 Patient DASH score

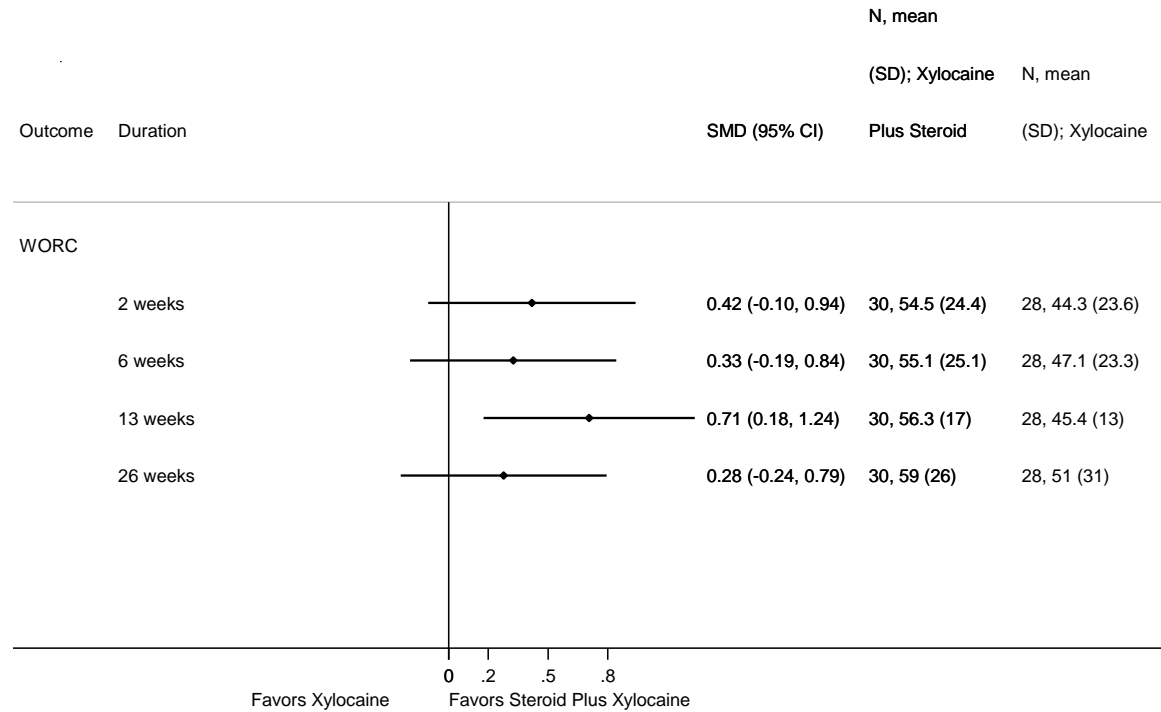


AAOS calculated effect size; MCII indicated by dashed line; MCII value was determined for patients with rotator cuff tears; this study was not sufficiently powered to detect the MCII. Therefore, its' results are inconclusive.

QUALITY OF LIFE: WESTERN ONTARIO ROTATOR CUFF INDEX (WORC)

One Level I study by Alvarez et al. assessed patients diagnosed as having rotator cuff disease treated with injections of either xylocaine or xylocaine plus a steroid. Patient quality of life was measured using WORC (see Figure 39).

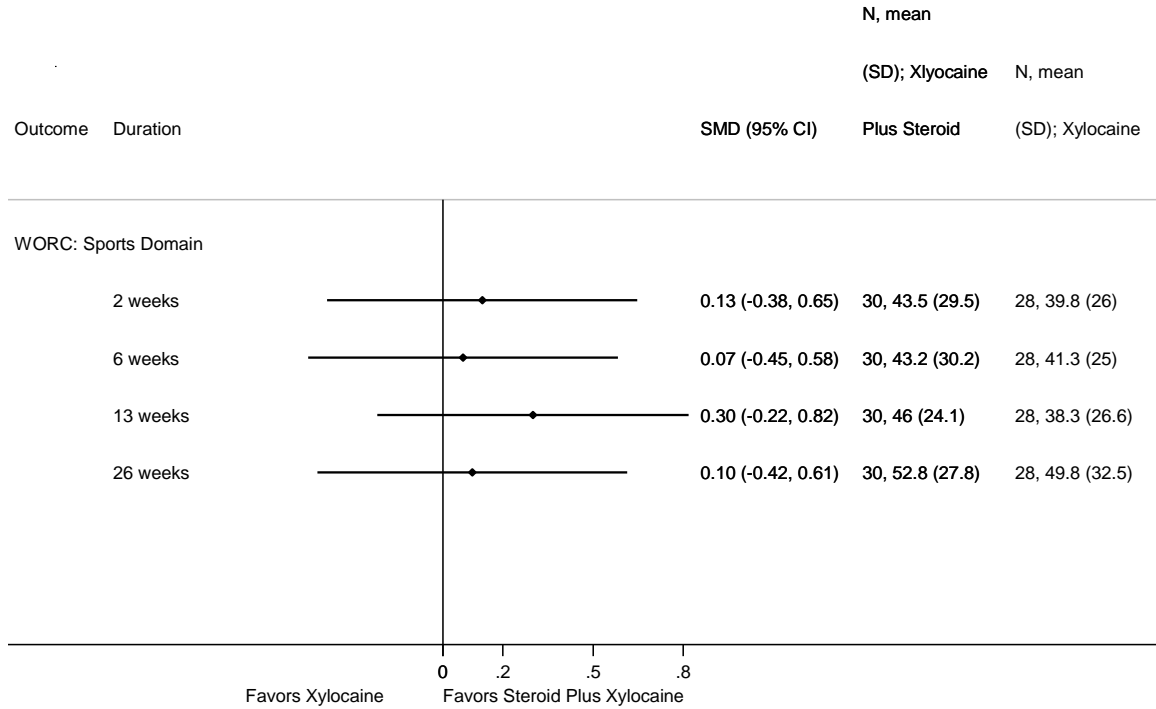
Figure 39 Patient quality of life as measured by WORC



QUALITY OF LIFE: WORC SPORTS DOMAIN

One Level I study by Alvarez et al. assessed patients diagnosed as having rotator cuff disease treated with injections of either xylocaine or xylocaine plus a steroid. Authors report the sports domain of the quality of life assessment tool WORC (see Figure 40).

Figure 40 Patient score on sports domain of WORC

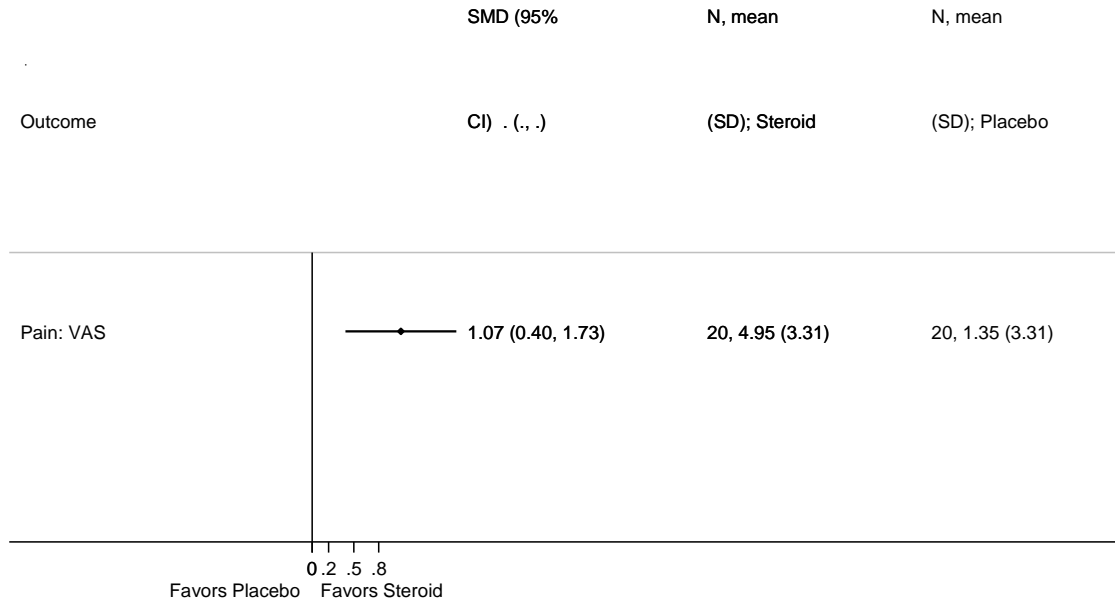


AAOS calculated effect size

PAIN: VAS

Two Level II studies assessed pain measured by VAS. Adebajo et al. treated patients diagnosed as having rotator cuff tendonitis with either steroid (injection of lidocaine with steroid plus a placebo pill) or placebo (placebo pill plus injection of lidocaine) and pain was measured using VAS. AAOS calculations found a statistically significant effect in favor of steroid treatment ($ES = 1.07$, 95% CI 0.40 – 1.73; see Figure 41).

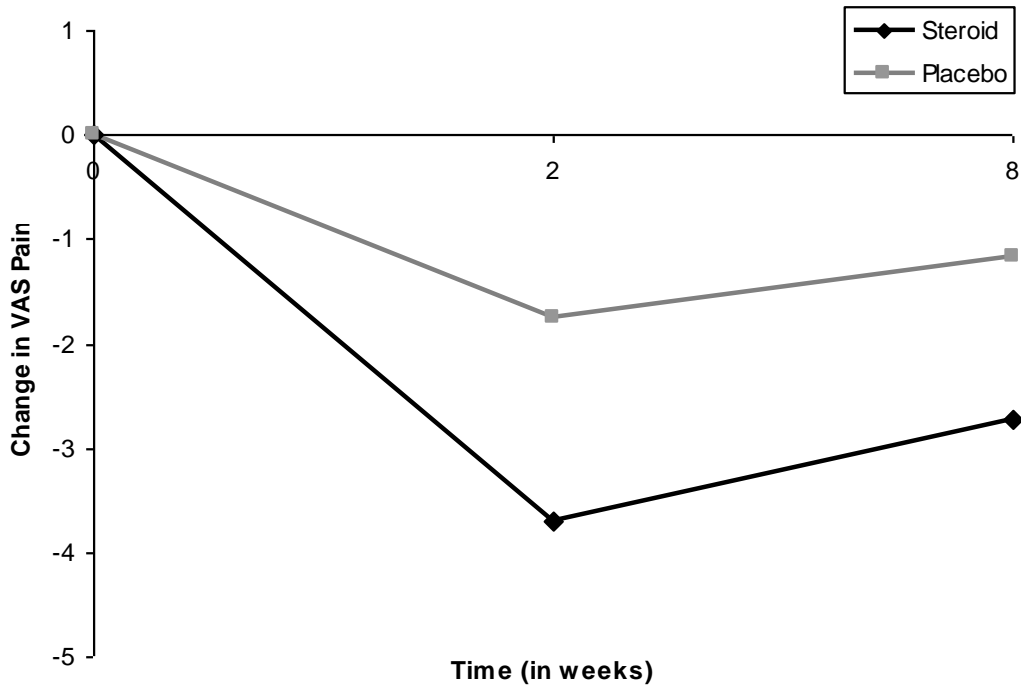
Figure 41 Improvement in pain score in patients treated with steroid injection or placebo



AAOS calculated effect size

Withrington et al. assessed patients diagnosed as having supraspinatus tendinopathy. Patients received an injection of either cortisone with lidocaine or saline (placebo). Authors report no statistically significant difference between groups in pain scores at either two ($t = 1.57, p > 0.05$) or eight weeks ($t = 1.30, p > 0.05$; see Figure 42).

Figure 42 Change in pain measured by VAS

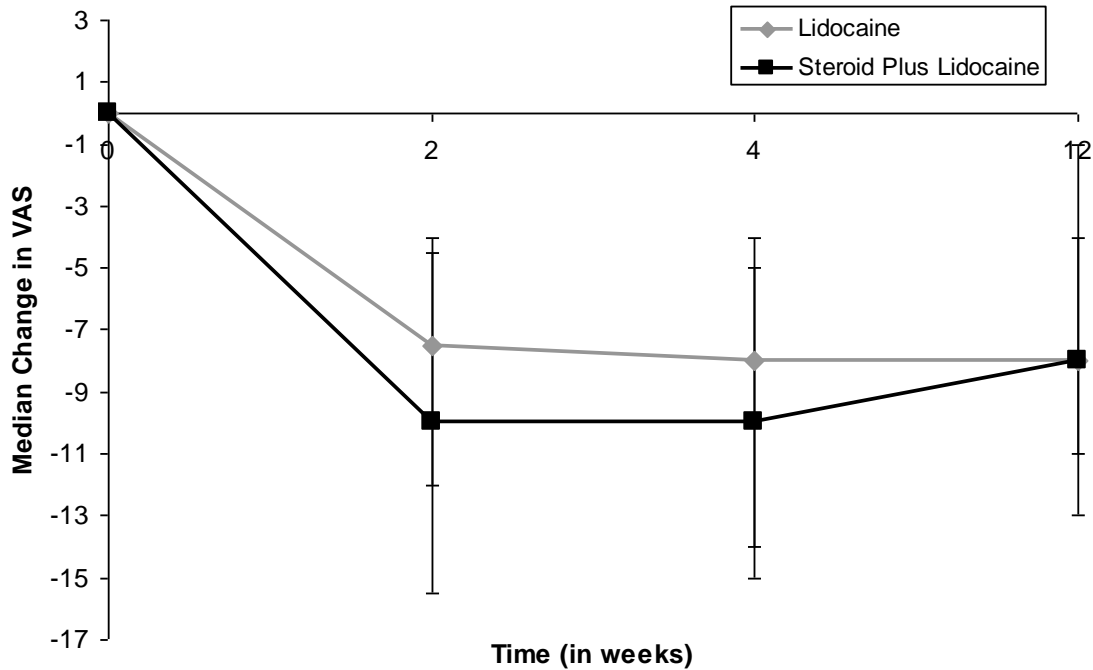


Authors do not provide dispersions for point estimates; authors report no statistically significant difference between groups ($p > 0.05$).

COMPOSITE PAIN: VAS

One Level II study by Vecchio et al. examined the effect of a cortisone injection with lidocaine or lidocaine alone in patients diagnosed with rotator cuff tendonitis. Pain was measured as the composite score of pain at rest, night and movement. Authors report no statistically significant difference between groups at two, four or twelve weeks using a non-parametric analysis ($p = 0.16, 0.36, 0.96$ respectively; see Figure 43).

Figure 43 Median change in composite pain measured by VAS

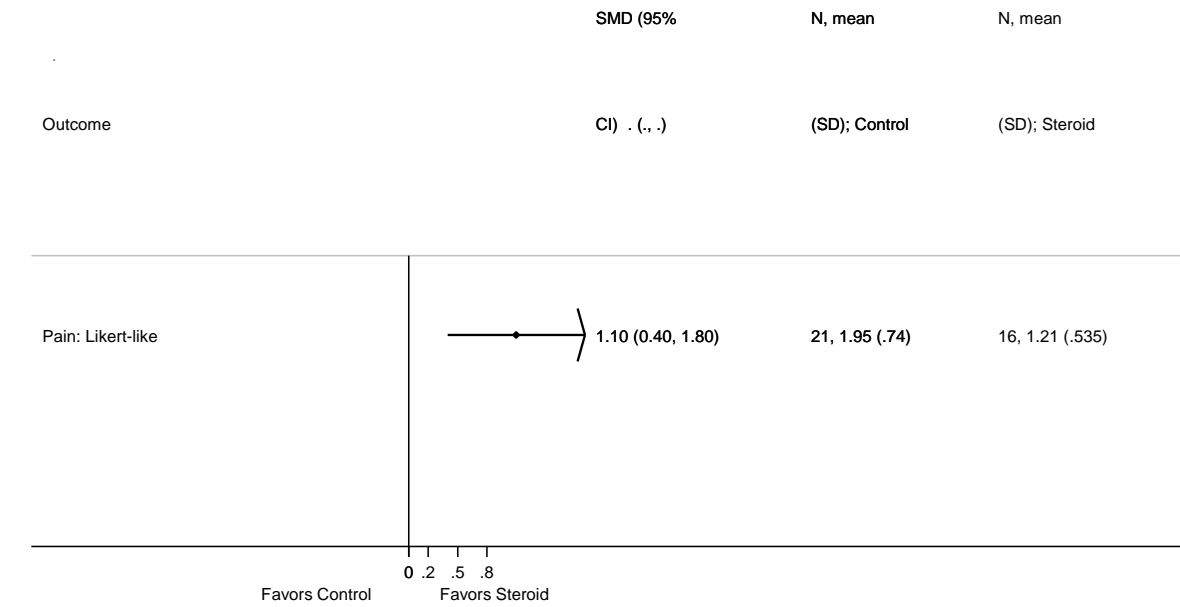


Dispersion shown as interquartile range; authors report no statistically significant difference between groups at any time point ($p = 0.16, 0.36, 0.96$ respectively).

PAIN: LIKERT-LIKE SCALE

One Level II study by Blair et al. assessed patients diagnosed as having subacromial impingement syndrome treated by corticosteroid injection. All patients participated in a physical therapy program and received either a steroid injection with lidocaine or a lidocaine only injection (control) with a final assessment at approximately 8.29 months (95% CI 8.03 – 8.55 months). Pain was measured on a four-point Likert-like scale ranging from 0 (no pain) to 3 (severe pain). Authors report a statistically significant difference between groups for pain at final assessment (see Figure 44).

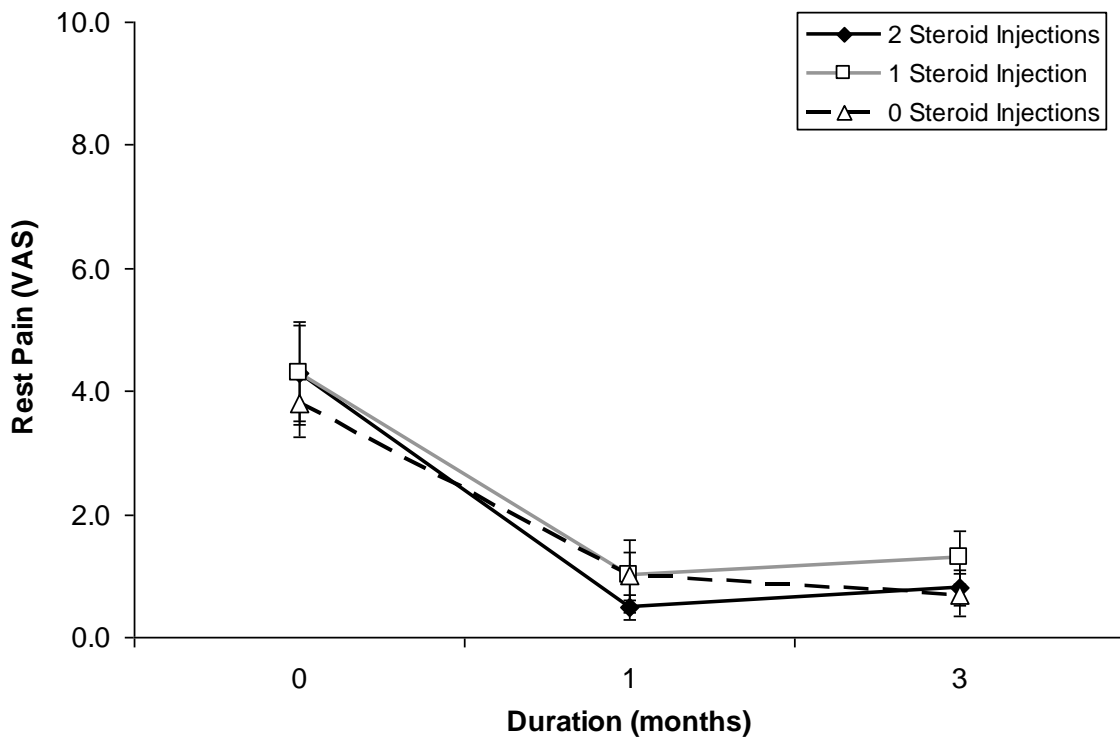
Figure 44 Pain as measured by a Likert-like scale



PAIN: AT REST

One Level II study by Akgun et al. assessed patients diagnosed as having subacromial impingement syndrome treated with corticosteroid injection(s). Patients received two injections within a ten day interval of either: two steroid injections with lidocaine (group “2 steroid injections”), one steroid injection with lidocaine followed by one lidocaine only injection (group “1 steroid injection”) or two injections of lidocaine only (group “0 steroid injections”). Pain at rest was measured using a VAS (see Figure 45). Authors report no statistically significant differences at baseline ($p > 0.05$) and statistically significant improvements at one and three months in all of the groups ($p < 0.05$). Additionally, authors report no statistically significant difference between groups at three months ($p > 0.05$). Authors did not report between group comparisons at one month.

Figure 45 Pain at rest measured by VAS

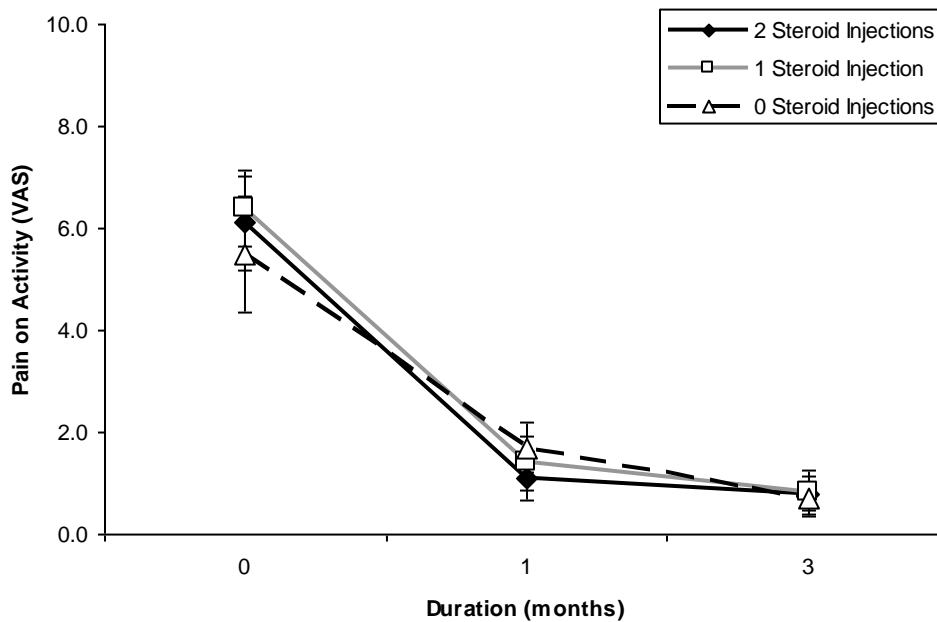


Authors report no statistically significant difference between groups at zero or three months ($p > 0.05$). Between group comparisons at month one were not reported; authors report a statistically significant improvement at one and three months for all groups ($p < 0.05$).

PAIN: ON ACTIVITY

One Level II study by Akgun et al. assessed patients diagnosed as having subacromial impingement syndrome treated with corticosteroid injection(s). Patients received two injections within a ten day interval of either: two steroid injections with lidocaine (group “2 steroid injections”), one steroid injection with lidocaine followed by one lidocaine only injection (group “1 steroid injection”) or two injections of lidocaine only (group “0 steroid injections”). Pain on activity was measured using a VAS (see Figure 46). Authors report no statistically significant differences at baseline ($p > 0.05$) and statistically significant improvements at one and three months in all of the groups ($p < 0.05$). Authors report no statistically significant difference between groups at three months ($p > 0.05$); however, a between group comparison at month one was not reported.

Figure 46 Pain on activity measured by VAS

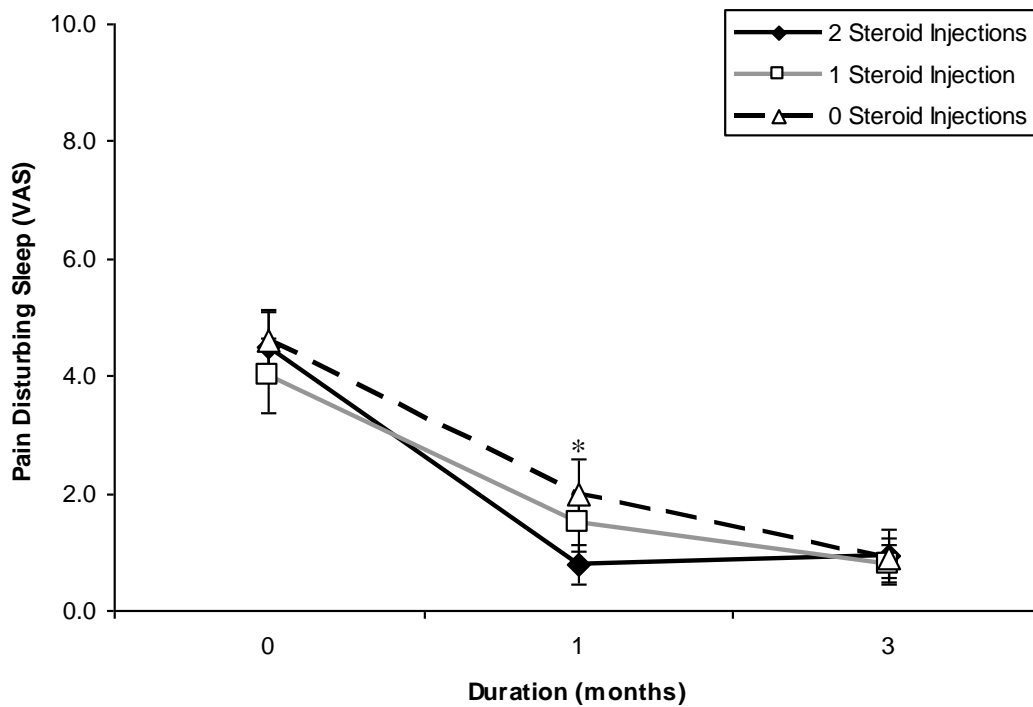


Authors report no statistically significant difference between groups at zero or three months ($p > 0.05$). Between group comparisons at month one were not reported; authors report a statistically significant improvement at one and three months in all of the groups ($p < 0.05$).

PAIN: DISTURBING SLEEP

One Level II study by Akgun et al. assessed patients diagnosed as having subacromial impingement syndrome treated with corticosteroid injection(s). Patients received two injections within a ten day interval of either: two steroid injections with lidocaine (group “2 steroid injections”), one steroid injection with lidocaine followed by one lidocaine only injection (group “1 steroid injection”) or two injections of lidocaine only (group “0 steroid injections”). Pain disturbing sleep was measured using a VAS (see Figure 47). Authors report no statistically significant differences at baseline ($p > 0.05$) and statistically significant improvements at one and three months in all of the groups ($p < 0.05$). Further, authors report greater improvement in patients receiving two steroid injections at one month than patients in the other two groups ($p < 0.001$); however, no statistically significant difference was found between groups at three months ($p > 0.05$).

Figure 47 Pain disturbing sleep measured by VAS

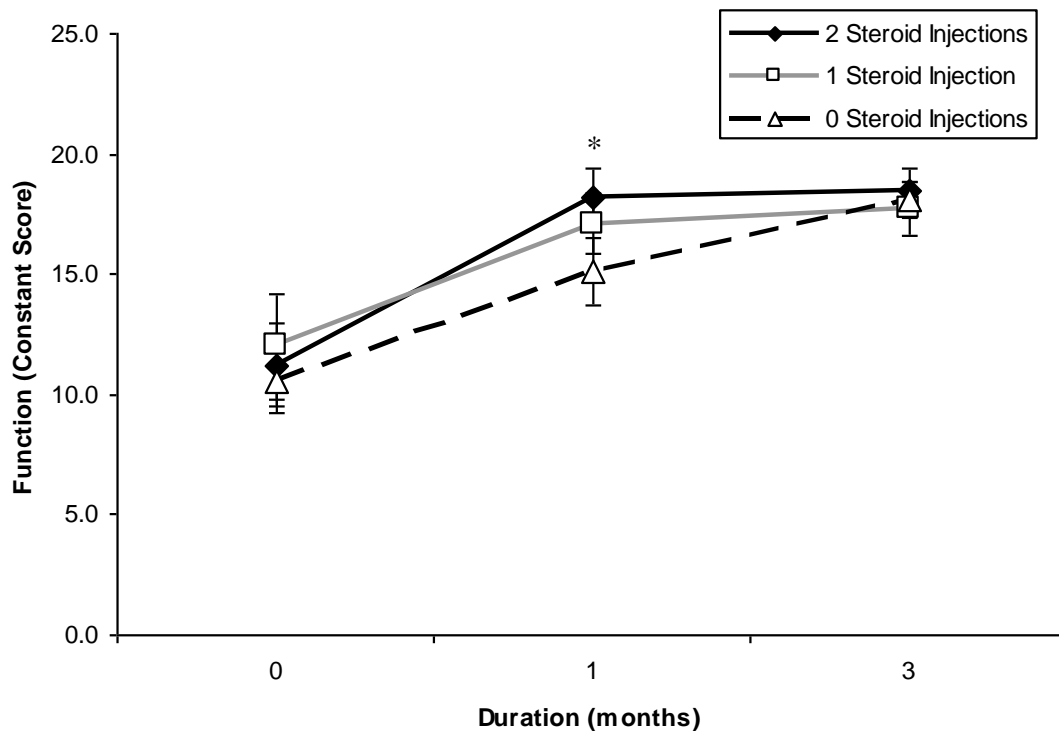


*Authors report statistically significantly greater improvement in patients receiving two steroid injections at one month than patients in the other two groups ($p < 0.001$); authors report no statistically significant differences between groups at zero or three months ($p > 0.05$); authors report a statistically significant improvement at one and three months in all of the groups ($p < 0.05$).

FUNCTION: CONSTANT-MURLEY SCORE

One Level II study by Akgun et al. assessed patients diagnosed as having subacromial impingement syndrome treated with corticosteroid injection(s). Patients received two injections within a ten day interval of either: two steroid injections with lidocaine (group “2 steroid injections”), one steroid injection with lidocaine followed by one lidocaine only injection (group “1 steroid injection”) or two injections of lidocaine only (group “0 steroid injections”). Function was measured using the Constant-Murley score (daily living activities subscale; see Figure 48). Authors report no statistically significant differences at baseline ($p > 0.05$) and statistically significant improvements at one and three months in all of the groups ($p < 0.05$). Further, authors report greater improvement in patients receiving two steroid injections at one month than patients in the other two groups ($p < 0.001$); however, no statistically significant difference between groups at three months was found ($p > 0.05$).

Figure 48 Function as measured by Constant subscale daily living activities

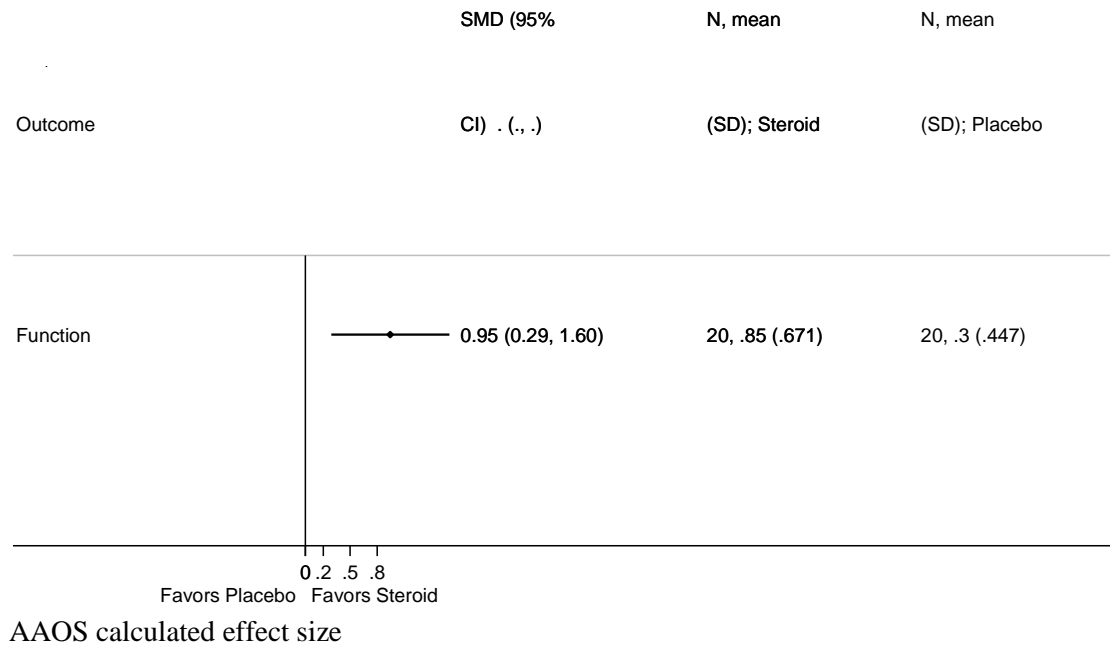


*Authors report statistically significantly greater improvement in patients receiving two steroid injections at one month than patients in the other two groups ($p < 0.001$); authors report no statistically significant differences between groups at zero or three months ($p > 0.05$); authors report statistically significant improvements at one and three months in all of the groups ($p < 0.05$).

FUNCTION: LIMITATIONS

One Level II study by Adebajo et al. assessed patients diagnosed as having rotator cuff tendonitis. Patients were treated with either steroid (injection of lidocaine with steroid plus a placebo pill) or placebo (placebo pill plus injection of lidocaine). Authors reported patient function on a four point scale as: 0 = no limitation of function, 1 = mild limitation of function, 2 = moderate limitation of function, 3 = severe limitation of function. AAOS calculations found a statistically significant effect in favor of steroid treatment ($ES = 0.95$, 95% CI 0.29 – 1.60; see Figure 49).

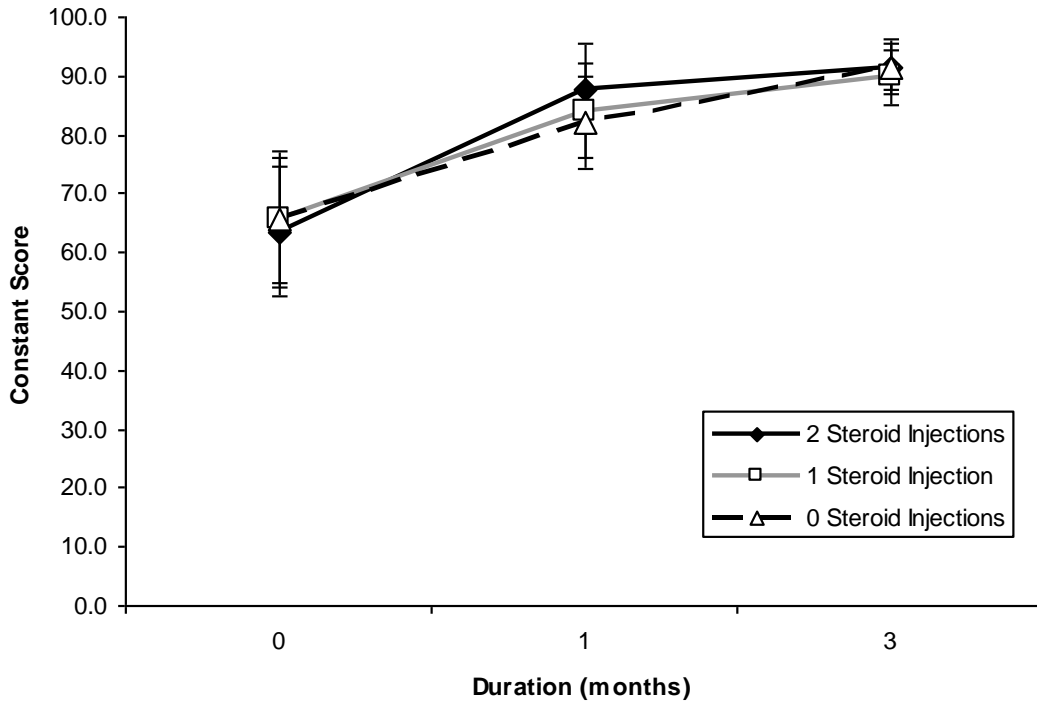
Figure 49 Patient function measured by Likert-like scale after receiving steroid injection or placebo



CONSTANT-MURLEY SCORE

One Level II study by Akgun et al. assessed patients diagnosed as having subacromial impingement syndrome treated with corticosteroid injection(s). Patients received two injections within a ten day interval of either: two steroid injections with lidocaine (group “2 steroid injections”), one steroid injection with lidocaine followed by one lidocaine only injection (group “1 steroid injection”) or two injections of lidocaine only (group “0 steroid injections”). Patient improvement was measured using the Constant-Murley score (daily living activities, range of motion and strength; see Figure 50). Authors report no statistically significant differences at baseline ($p > 0.05$) and statistically significant improvements at one and three months in all of the groups ($p < 0.05$). Authors report no statistically significant difference between groups at three months ($p > 0.05$). Between group comparisons at month one were not reported by the authors.

Figure 50 Patient Constant-Murley score

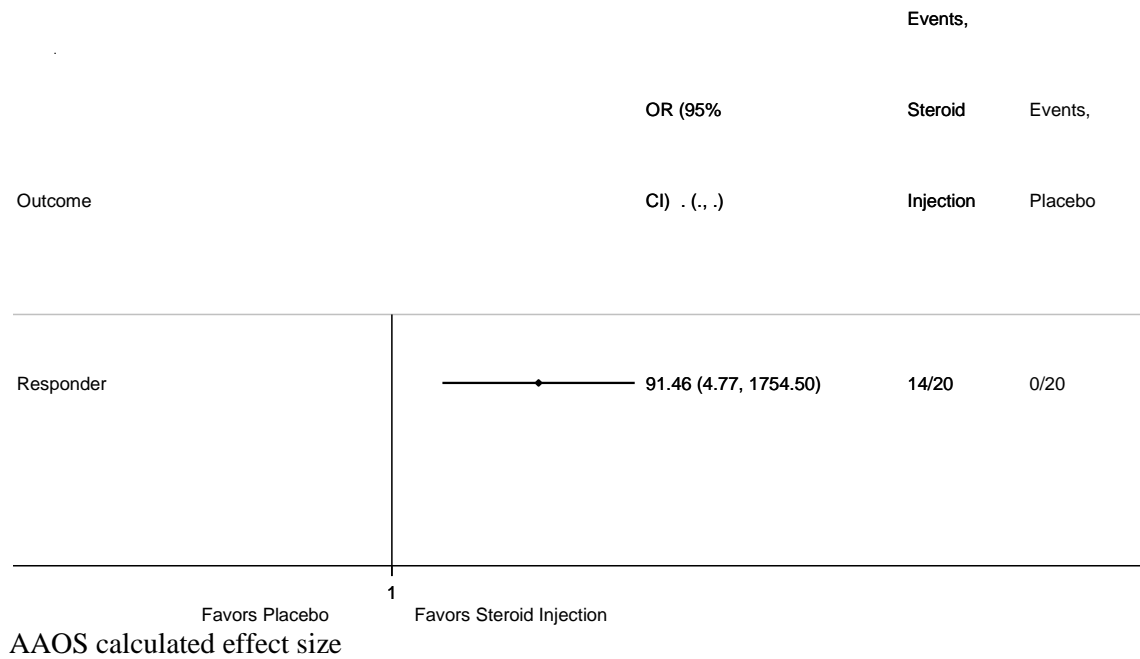


Authors report no statistically significant differences between groups at zero or three months ($p > 0.05$). Between group comparisons at month one were not reported; authors report a statistically significant improvement at one and three months in all of the groups ($p < 0.05$).

RESPONSE TO TREATMENT

One Level II study by Adebajo et al. assessed patients diagnosed as having rotator cuff tendonitis. Patients were treated with either steroid (injection of lidocaine with steroid plus a placebo pill) or placebo (placebo pill plus injection of lidocaine). Patients were considered to have responded to treatment if they improved in all three outcomes examined: pain, range of active abduction and limitation of function. AAOS calculations found a statistically significant effect in favor of steroid treatment ($OR = 91.46$, 95% CI 4.77 – 1754.50; see Figure 51).

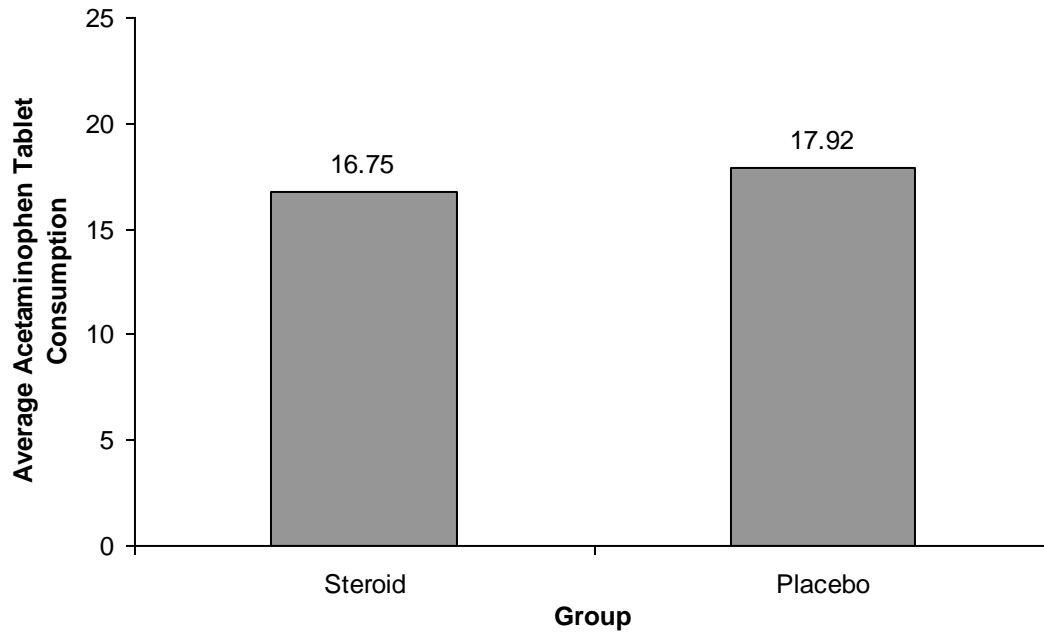
Figure 51 Patients responding to treatment after receiving steroid injection or placebo



ACETAMINOPHEN USE

One Level II study by Withrington et al. treated patients with either an injection of cortisone with lidocaine or saline (placebo). Authors report no statistically significant difference between groups in acetaminophen consumption at two weeks (see Figure 52).

Figure 52 Acetaminophen consumption



Authors do not provide dispersions for point estimates; authors report no statistically significant difference between groups.

PEMF

SUPPORTING EVIDENCE- PEMF

Tables relevant to this recommendation are: Table 23

Figures relevant to this recommendation are: Figure 53 through Figure 60

Table 23 Results of patients treated with PEMF

Authors	LoE	n	Comparison	Outcome	Duration		
					Final Visit*	2 weeks	4 weeks
Binder et al.	II	29	PEMF vs. Sham	Pain: VAS		●p	●p
Aktas et al.		40		Pain: Constant-Murley Score	○		
Aktas et al.		40		Pain: At Rest	○		
Aktas et al.		40		Pain: On Activity	○		
Aktas et al.		40		Pain: Disturbing Sleep	○		
Aktas et al.		40		Function: Constant-Murley Score	○		
Aktas et al.		40		Function: SDQ	○		
Aktas et al.		40		Constant-Murley Score	○		

○ = no statistically significant difference

* = final visit not defined by authors

p = favoring PEMF treatment

LoE = level of evidence

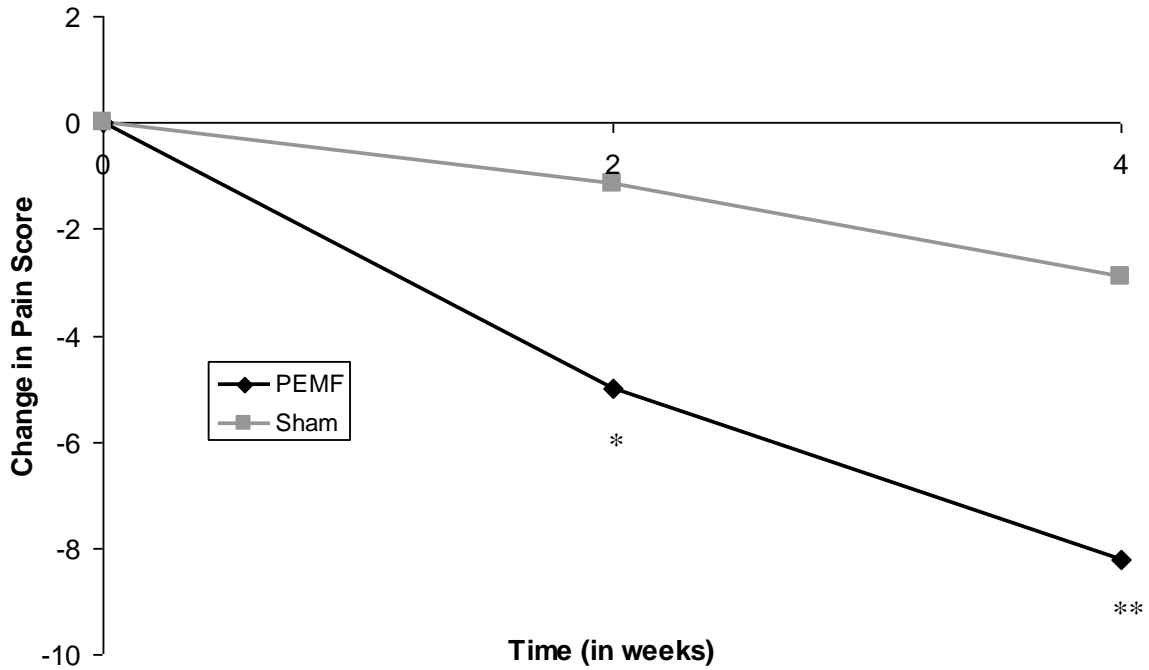
PEMF = pulsed electromagnetic field

SDQ = shoulder disability questionnaire

PAIN: VAS

One Level II study by Binder et al. examined the effect of pulsed electromagnetic field therapy (PEMF) compared to sham PEMF. Pain was assessed as the sum of pain at night, on movement and at rest. Authors report a statistically significant greater reduction in pain at weeks two and four in the PEMF group compared to the sham group ($p < 0.05$, $p < 0.02$ respectively; see Figure 53).

Figure 53 Change in pain score measured by VAS

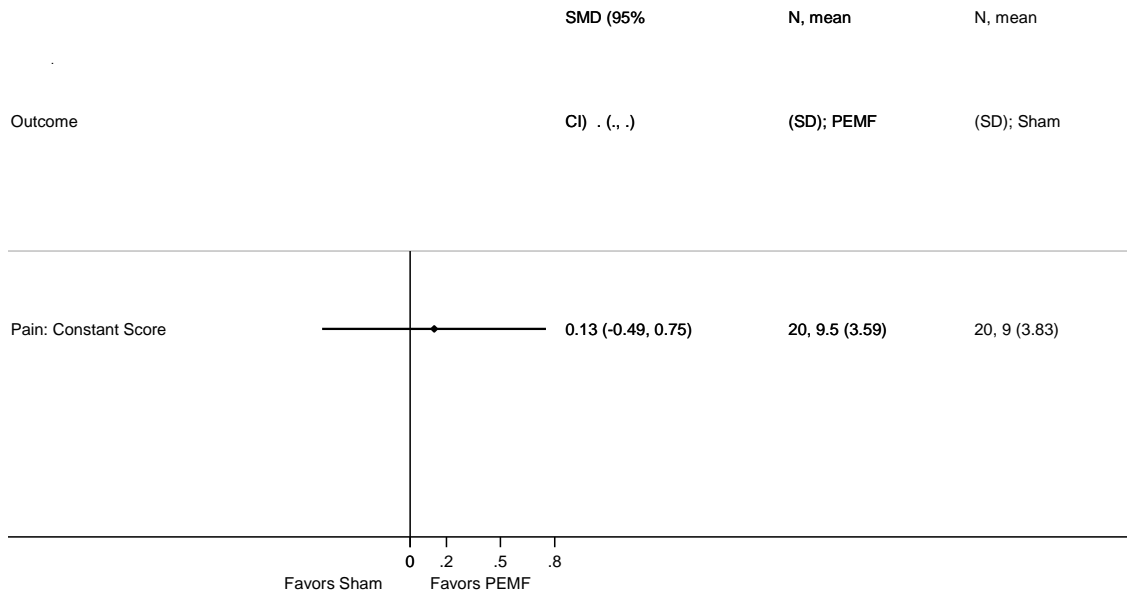


*Authors report significant differences between groups, $p < .05$; ** Authors report significant differences between groups, $p < .02$; authors do not provide dispersions for point estimates.

PAIN: CONSTANT-MURLEY SCORE

One Level II study by Aktas et al. assessed patients diagnosed as having subacromial impingement syndrome treated with PEMF. All patients received a three week treatment program that included either true PEMF or sham PEMF. Pain was measured using the subscale from the Constant-Murley score. Authors report there were no statistically significant differences noted between groups (see Figure 54).

Figure 54 Pain measured by Constant-Murley score

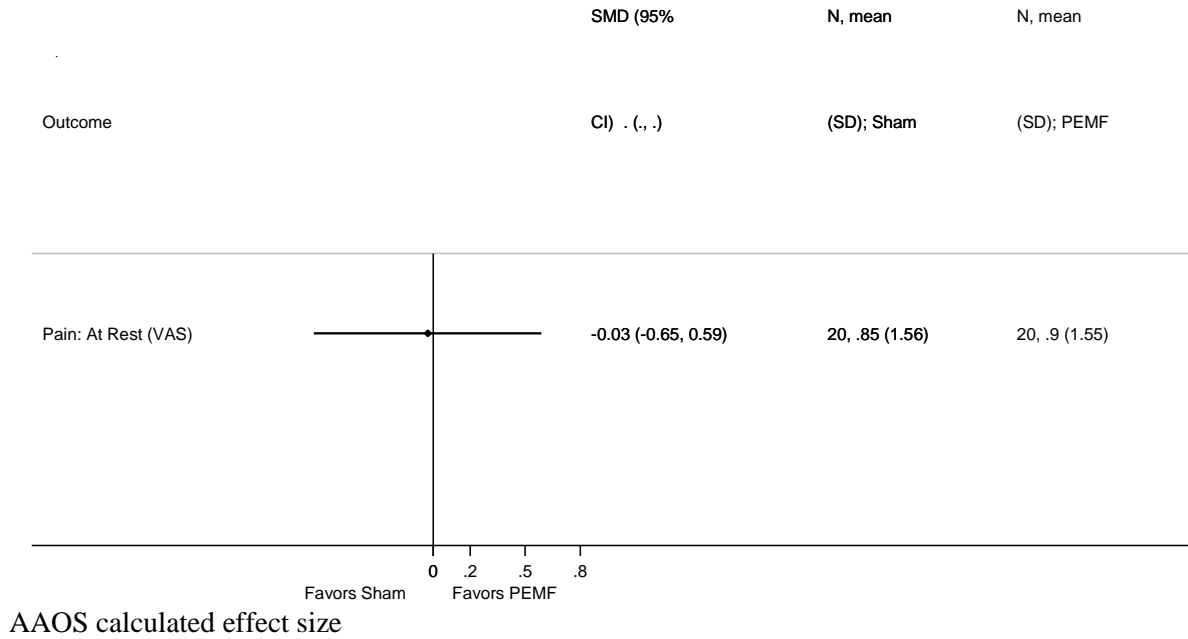


AAOS calculated effect size

PAIN: AT REST

One Level II study by Aktas et al. assessed patients diagnosed as having subacromial impingement syndrome treated with PEMF. All patients received a three week treatment program that included either true PEMF or sham PEMF. Pain at rest was measured by VAS. Authors report there were no statistically significant differences noted between groups (see Figure 55).

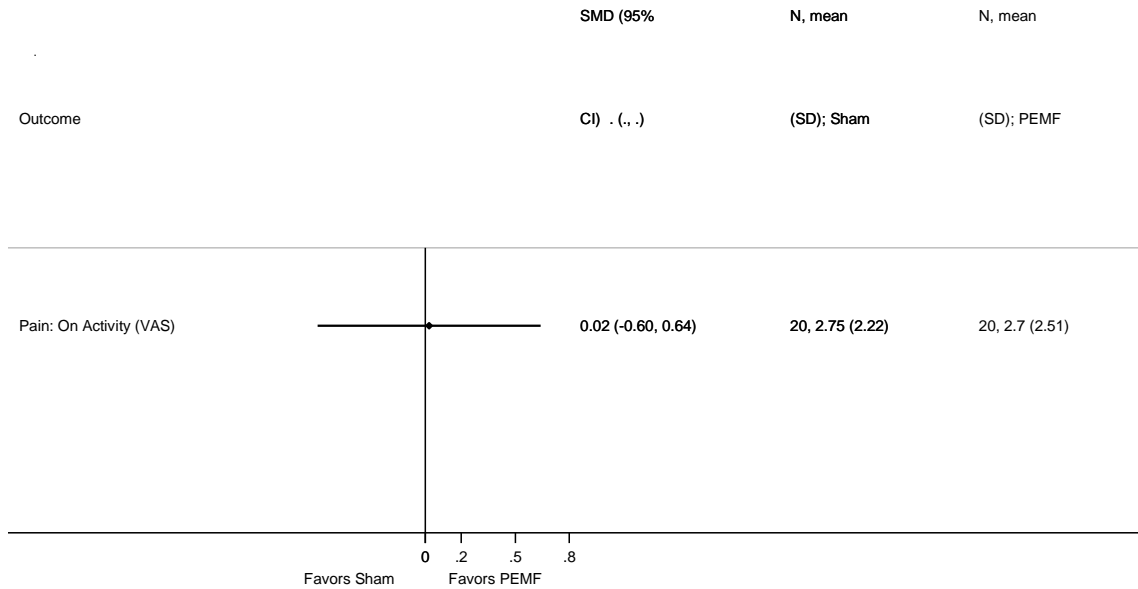
Figure 55 Pain at rest measured by VAS



PAIN: ON ACTIVITY

One Level II study by Aktas et al. assessed patients diagnosed as having subacromial impingement syndrome treated with PEMF. All patients received a three week treatment program that included either true PEMF or sham PEMF. Pain on activity was measured by VAS. Authors report there were no statistically significant differences noted between groups (see Figure 56).

Figure 56 Pain on activity measured by VAS



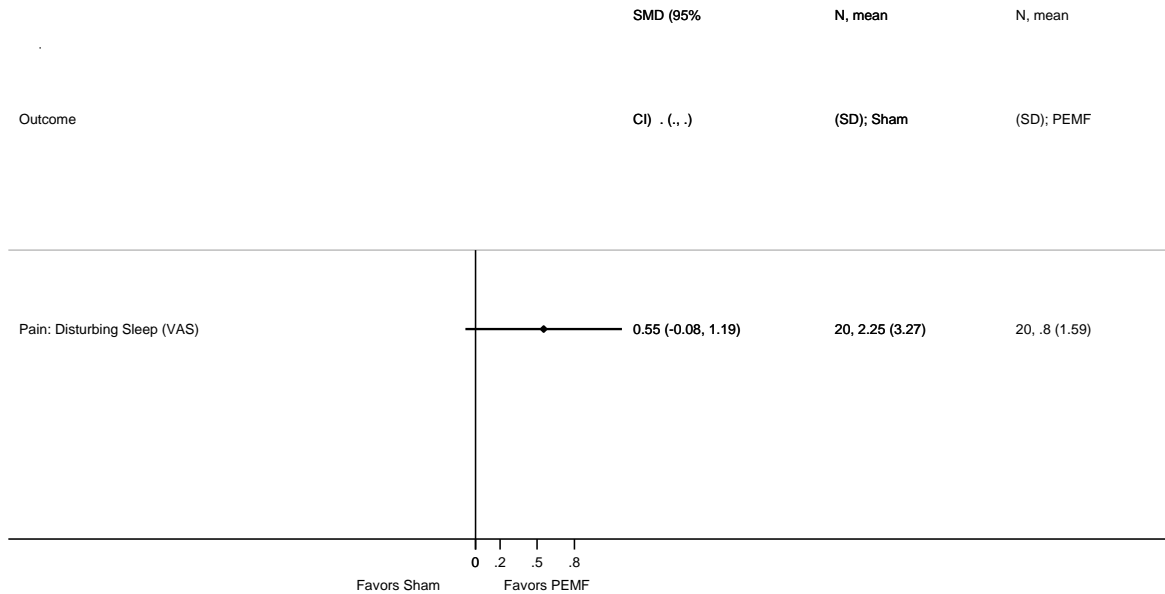
AAOS calculated effect size

PAIN: DISTURBING SLEEP

Two Level II studies assessed pain disturbing sleep measured by VAS.

One Level II study by Aktas et al. assessed patients diagnosed as having subacromial impingement syndrome treated with PEMF. All patients received a three week treatment program that included either true PEMF or sham PEMF. Pain disturbing sleep was measured by VAS. Authors report there were no statistically significant differences noted between groups (see Figure 57).

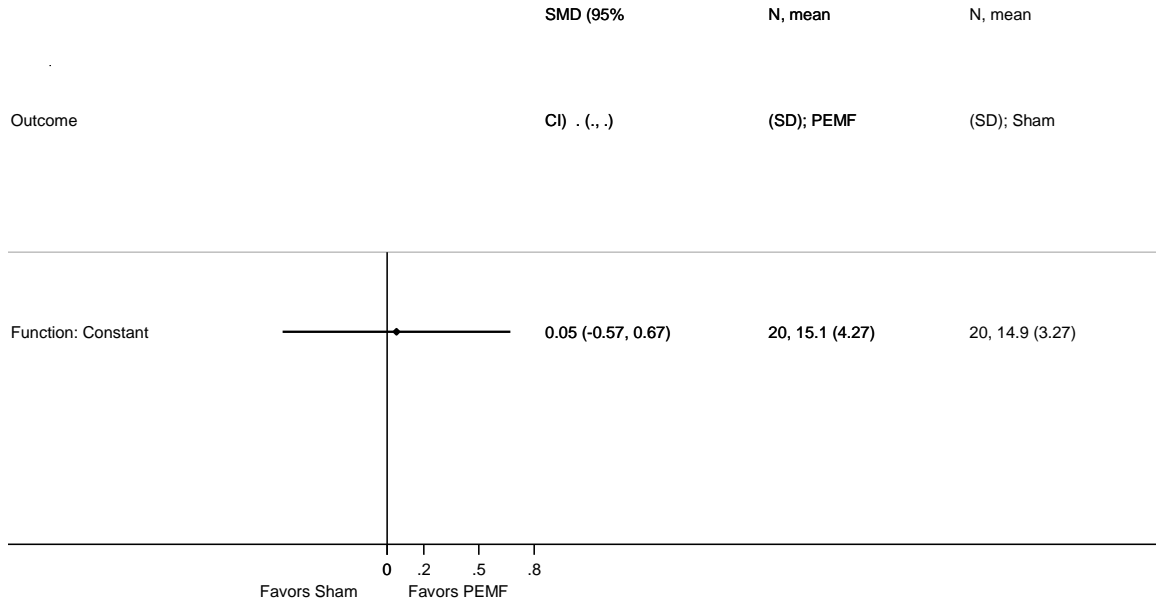
Figure 57 Pain disturbing sleep measured by VAS



FUNCTION: CONSTANT-MURLEY SCORE

One Level II study by Aktas et al. assessed patients diagnosed as having subacromial impingement syndrome treated with PEMF. All patients received a three week treatment program that included either true PEMF or sham PEMF. Function was assessed using the Constant-Murley score subscale daily living activities. Authors report there were no statistically significant differences noted between groups (see Figure 58).

Figure 58 Function measured by Constant-Murley score subscale daily living activities

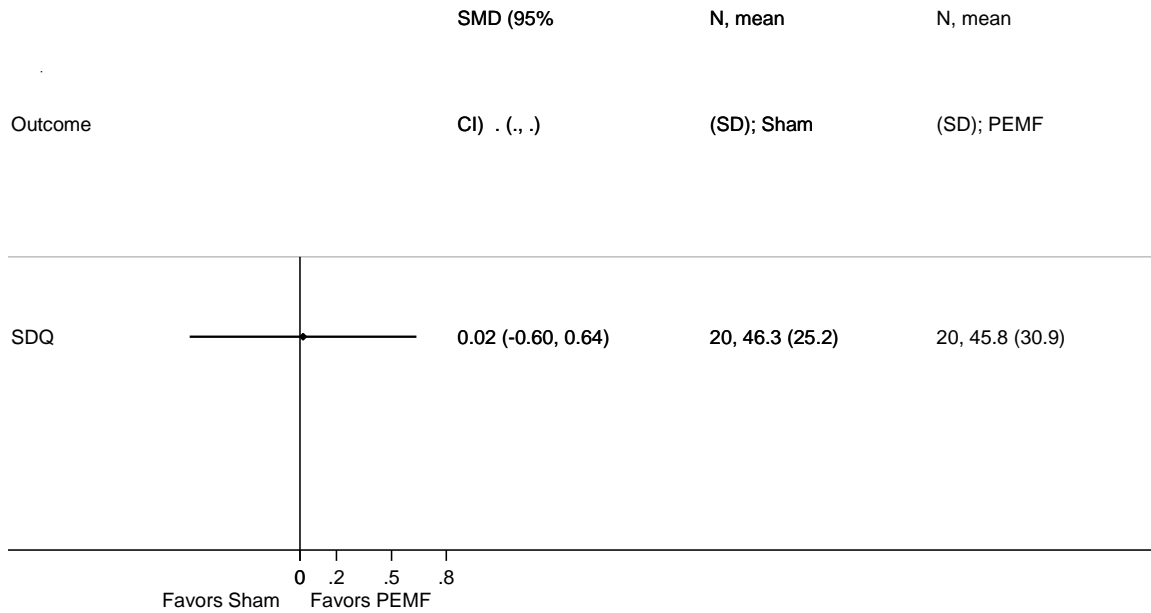


AAOS calculated effect size

FUNCTION: SHOULDER DISABILITY QUESTIONNAIRE (SDQ)

One Level II study by Aktas et al. assessed patients diagnosed as having subacromial impingement syndrome treated with PEMF. All patients received a three week treatment program that included either true PEMF or sham PEMF. Function was assessed using the shoulder disability questionnaire (SDQ) which evaluates daily living activities. Authors report there were no statistically significant differences noted between groups (see Figure 59).

Figure 59 Function as measured by SDQ

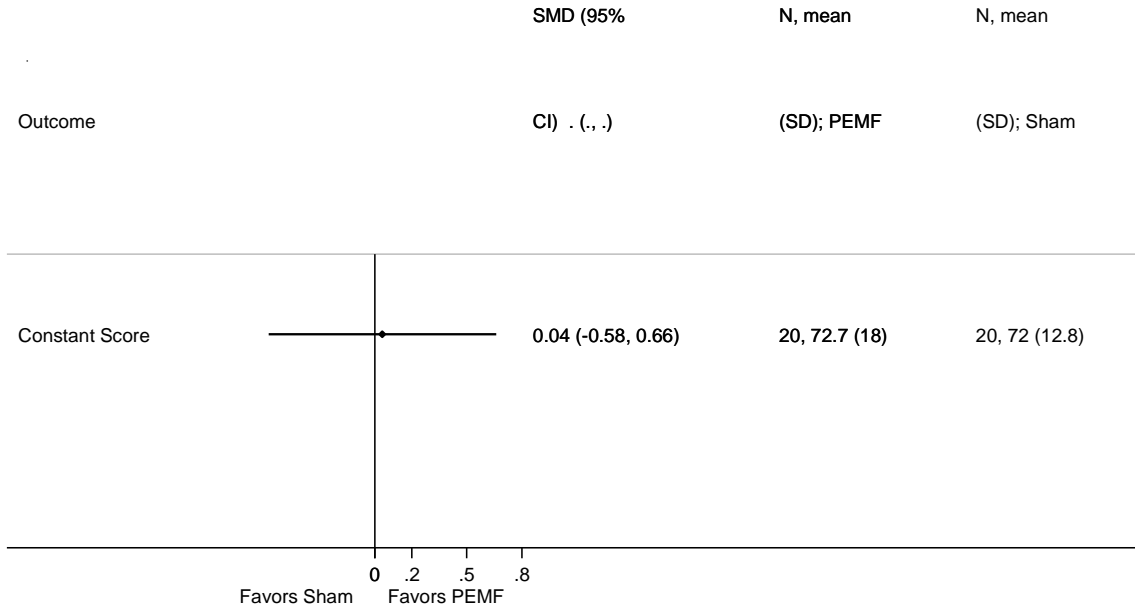


AAOS calculated effect size.

CONSTANT-MURLEY SCORE

One Level II study by Aktas et al. assessed patients diagnosed as having subacromial impingement syndrome treated with PEMF. All patients received a three week treatment program that included either true PEMF or sham PEMF. Patient improvement was measured by Constant-Murley score. Authors report there were no statistically significant differences noted between groups (see Figure 60).

Figure 60 Patient Constant-Murley score



AAOS calculated effect size

RECOMMENDATION 4C: ROTATOR CUFF RELATED SYMPTOMS AND IONTOPHORESIS, PHONOPHOREIS, TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS), ICE, HEAT, MASSAGE, OR ACTIVITY MODIFICATION

We cannot recommend for or against the use of iontophoresis, phonophoresis, Transcutaneous Electrical Nerve Stimulation (TENS), ice, heat, massage, or activity modification for patients who have rotator cuff related symptoms in the absence of a full thickness tear.

Level of Evidence: None

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

There were no studies identified examining iontophoresis, phonophoresis, TENS (transcutaneous electrical nerve stimulation), ice, heat, or massage as non-operative treatments in patients with rotator cuff-related symptoms.

RECOMMENDATION 5: ACUTE TRAUMATIC ROTATOR CUFF TEARS AND SURGERY

Early surgical repair after acute injury is an option for patients with a rotator cuff tear.

Level of Evidence: IV

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Rotator cuff tears are a common cause of shoulder pain and dysfunction.⁶⁴ The prevalence of rotator cuff tears, even asymptomatic tears, increases with advancing age.^{6,7} Treatment options for traumatic rotator cuff tears include a number of non-operative options as well as surgical repair. Delaying repair of acute traumatic rotator cuff tear may lead to the development of pathology associated with chronic rotator cuff tears including tendon retraction, and fatty infiltration and atrophy of the rotator cuff muscles with associated detrimental effects on upper extremity function. In earlier surgery after acute injury, the surgeon is more likely to encounter healthier tissue with better healing potential which may lead to better outcome.

Our systematic review did not identify any quality literature that addresses the issue of timing of surgery after acute rotator cuff injury. The evidence that we considered included five level IV case series^{70, 71} (limited evidence) of rotator cuff repair that focused on early surgical repair of rotator cuff tears. One study⁷⁰ reported on a series of subjects with a history of a significant acute injury that were treated with surgery within three months of injury. This cohort represented less than 10 percent of the repairs that they performed in their overall experience, thus demonstrating that acute rotator cuff injuries are relatively uncommon. The patients repaired within 3 weeks of injury had better results than those repaired after 3 weeks. The second study⁷¹ reported the results of rotator cuff repair in a series of 26 patients who had a history of trauma with an acute onset of symptoms and a full thickness rotator cuff tear. All of the repairs were performed within 3 weeks of the injury. Similar to the findings of the first study, these cases only represented about 5 percent of the cases of full thickness rotator cuff tear that the authors treated. Although they reported a high rate of successful results (20 excellent, 4 good, 1 fair, and 1 poor) they did not determine whether the timing of surgery affected the outcome.

A third study⁷² reported the outcome of repair of traumatic anterior superior rotator cuff tears with combined subscapularis and supraspinatus tears. The patients had open repair at an average of 4.5 months after injury. Outcome assessment demonstrated restoration of subscapularis related function. The authors did not find a correlation between outcome and duration of symptoms. Two additional studies^{73, 74} addressed repair of traumatic anterior superior rotator cuff tears with combined subscapularis and supraspinatus tears. One study reported on thirty patients with a traumatic tear who had open repair at an average of 4.5 months after injury and the other reported on twenty-four patients of which twenty-two recalled a specific incident at which the injury occurred. (See Table 26 for the summary of these results.) One study reported there were no significant correlations between outcome and a number of preoperative factors including duration of symptoms. The other study did not provide statistical analyses.

Defining whether a rotator cuff tear is acute has relevance to this discussion. In evaluating patients, the surgeon should attempt to properly identify patients with acute tears as opposed to patients with pre-existing chronic tears that become symptomatic after an injury event. A discrete traumatic event is more suggestive of acute tear. Physical examination findings including supraspinatus and infraspinatus muscle atrophy as well as internal and external rotation lag signs may be indicative of larger and more chronic rotator cuff tears.

Evaluation of rotator cuff muscle quality with CT or MRI is an important consideration. Six Level IV case series⁴⁷⁻⁵² addressed the MRI findings of fatty infiltration and muscle atrophy in relation to the outcome of rotator cuff repair. Chronic and larger tears are associated with muscle atrophy and fatty replacement, both of which correlate with inferior functional outcome after rotator cuff repair. It is thought that early repair of acute rotator cuff tears might mitigate the development of chronic tendon and muscle pathology and improve functional outcomes (see Recommendation 2: Full Thickness Tears and symptomatic Patients: Supporting Evidence- MRI Tear Characteristics:

Tables relevant to this recommendation are: Table 7 through Table 10
Figures relevant to this recommendation are: Figure 4 through Figure 6

MRI Tear Characteristics
Tables relevant to this recommendation are: Table 24 through Table 25

Figures relevant to this recommendation are: Figure 61 through Figure 66

Table 24 Results of acute, traumatic rotator cuff tear repair

Authors	LoE	n	Surgical Repair	Comparison	Outcome	Duration	
						5.9 years*	7 years**
Bassett et al.	IV	37	3 - 12 weeks	Change from baseline	Pain: Likert-like Scale		●↑
Bassett et al.		31	3 - 12 weeks	3 Weeks vs. 6-12 Weeks	Patient Satisfaction		●3
Lahteenmaki et al.		26	Within 3 Weeks	Change from baseline	Pain: UCLA	●↑	
Lahteenmaki et al.		26	Within 3 Weeks	Change from baseline	Function: UCLA	nr	
Lahteenmaki et al.		26	Within 3 Weeks	Change from baseline	Complications	nr	

● = statistically significant result favoring treatment

↑ = improved

3 = statistically significant result favoring 3 weeks duration

LoE = level of evidence

nr = authors examined this outcome but did not report if the results were statistically significant

* = final visit 5.9 ± 0.70 years after baseline

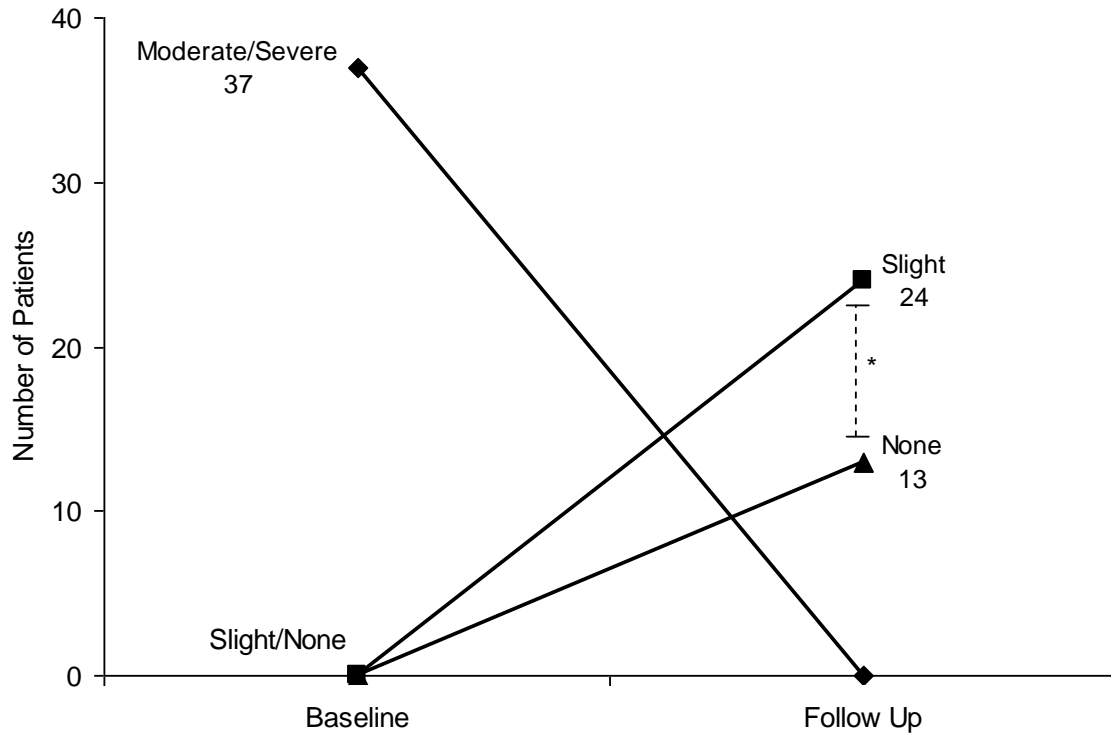
** = final visit 7 ± 0.72 years after baseline

ACUTE TRAUMATIC TEARS

PAIN: LIKERT-LIKE SCALE

One Level IV study by Bassett and Cofield assessed patients receiving rotator cuff repair of acute, traumatic rotator cuff tear. Patients were asked to describe their pain at various durations of follow-up rated on a four-point Likert-like scale: none, slight, moderate, severe (see Figure 61).

Figure 61 Pain Reported by patient

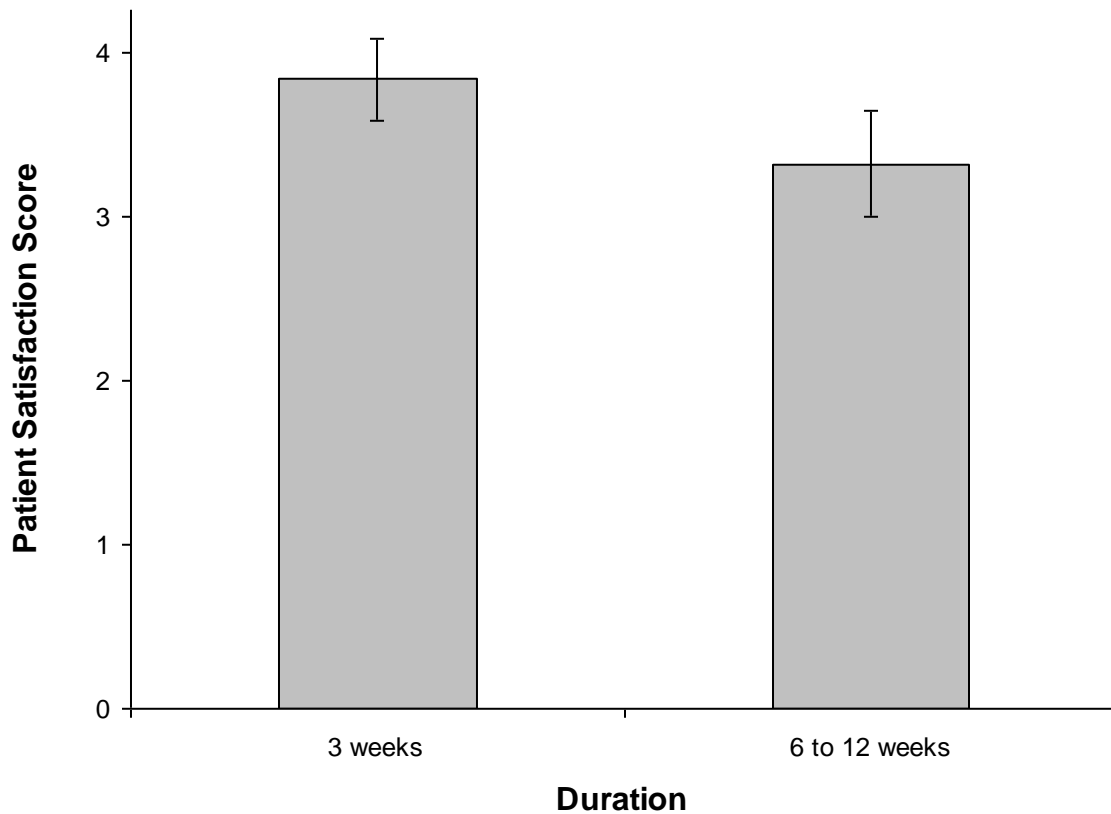


*AAOS calculated OR = 3.4 (95% CI 1.3 - 8.9), $p = 0.012$; average patient follow-up of 7 ± 0.72 years from baseline.

PATIENT SATISFACTION

One Level IV study by Bassett and Cofield detailed the level of satisfaction with surgical repair as reported by the patient at various follow-up durations. The patients were divided into groups based on the duration from injury to surgery: within three weeks, three to six weeks, and six to twelve weeks. We are not reporting data pertaining to duration three to six weeks as less than ten patients were included in this group ($n = 6$). Patient satisfaction was rated on a four-point scale ranging from much better to worse. AAOS calculations found a statistically significant difference between patients treated within three weeks compared to patients treated after six to twelve weeks with the latter having poorer satisfaction scores ($p < 0.05$; see Figure 62).

Figure 62 Patient satisfaction score at follow-up

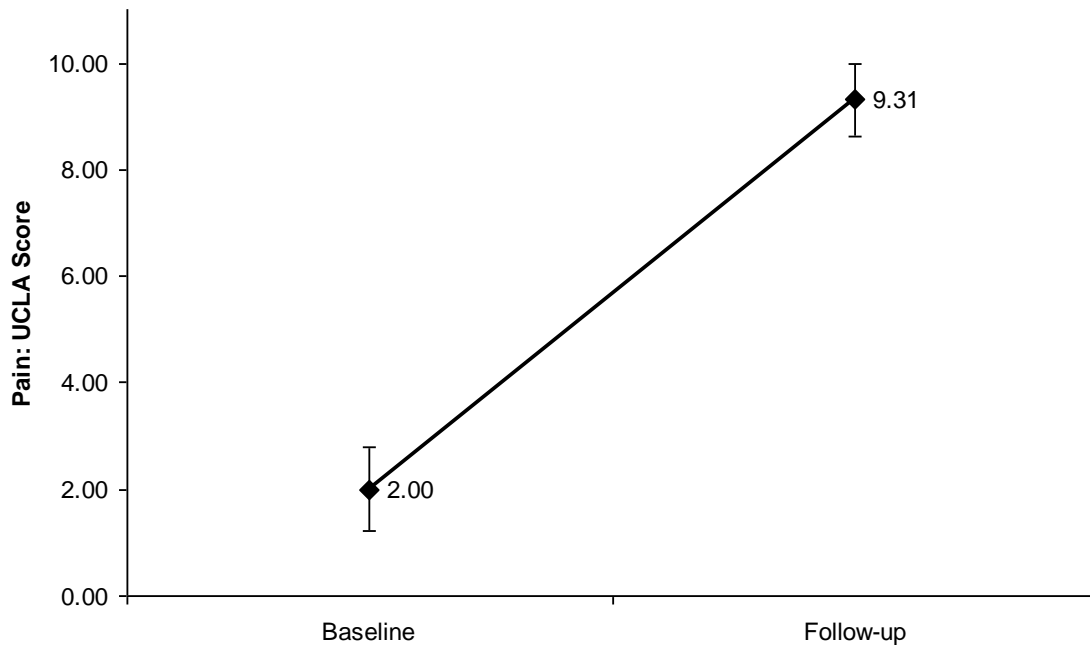


AAOS calculated independent t-test, $p < 0.05$; average patient follow-up of 7 ± 0.72 years from baseline.

PAIN: UCLA

One Level IV study by Lahteenmaki et al. used the UCLA Score to assess the results of patients undergoing surgical repair of rotator cuff tears within 3 weeks of injury. Change in UCLA pain subscale score pre-operatively to follow-up is statistically significant ($p < 0.001$) as determined by AAOS analysis (see Figure 63).

Figure 63 Pain as measured by UCLA scale

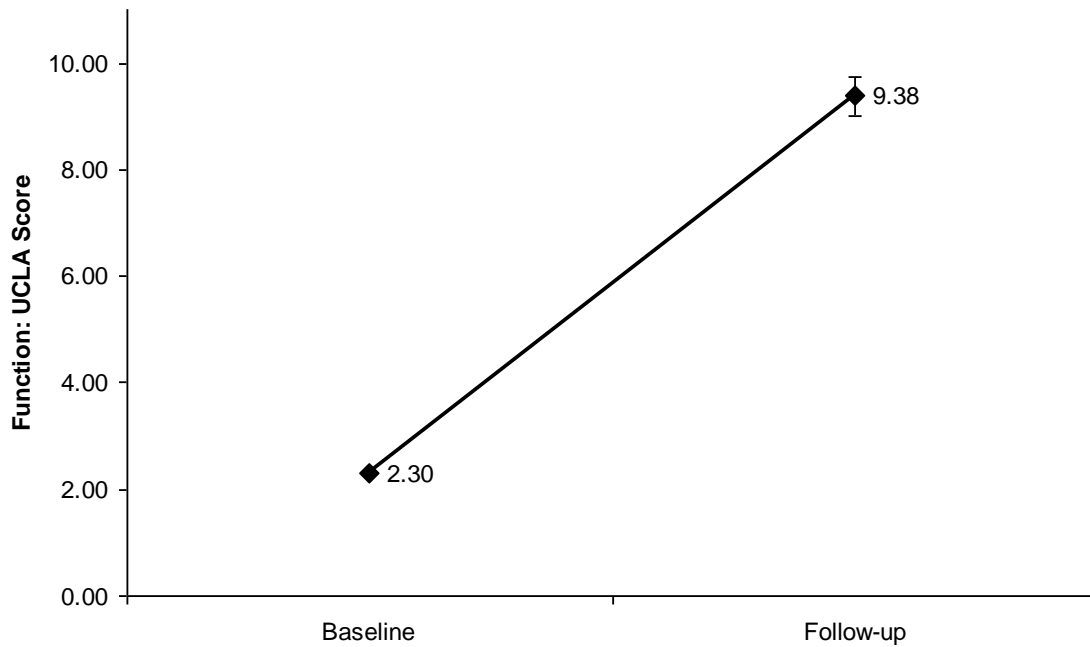


AAOS calculated independent t-test, $p < 0.001$; average patient follow-up of 5.9 ± 0.70 years from baseline; *Confidence interval at baseline used standard deviation estimated from a range.

FUNCTION: UCLA

One Level IV study by Lahteenmaki, et al. used the UCLA Score to assess the results of patients undergoing surgical repair of rotator cuff tears within 3 weeks of injury. Authors do not report variance at baseline or if change from baseline was statistically significant (see Figure 64).

Figure 64 Function as measured by UCLA



Average patient follow-up of 5.9 ± 0.70 years from baseline; *Dispersion of point estimate not reported by authors

COMPLICATIONS

One Level IV study by Lahteenmaki, et al. reported patient complications related to repair of acute, traumatic rotator cuff tears within 3 weeks of injury (see Table 24).

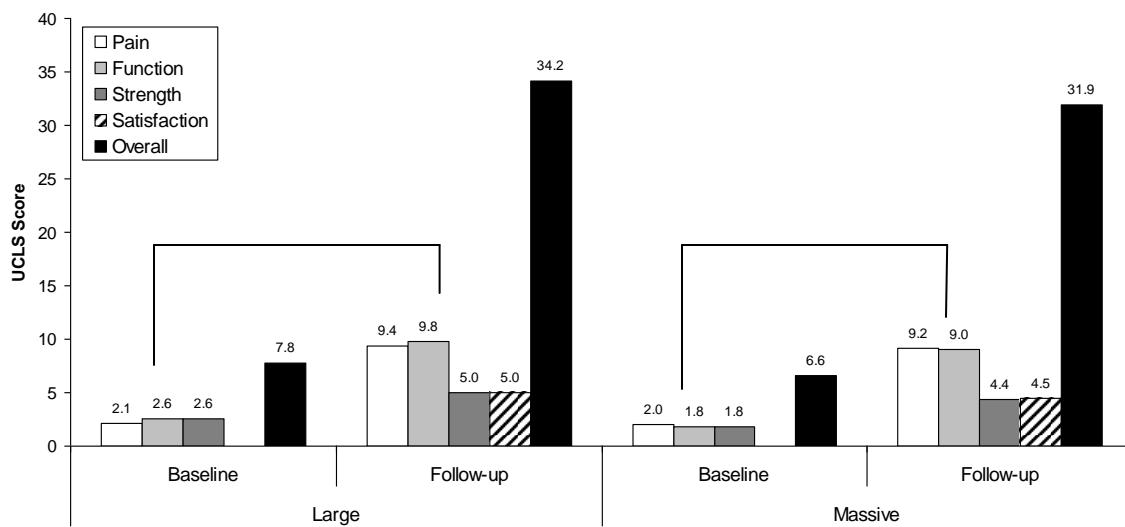
Table 25 Patient complications

Complication	Percent of Patients
Superficial Wound Infection	4%
Major Complications	0%

STRATIFICATIONS

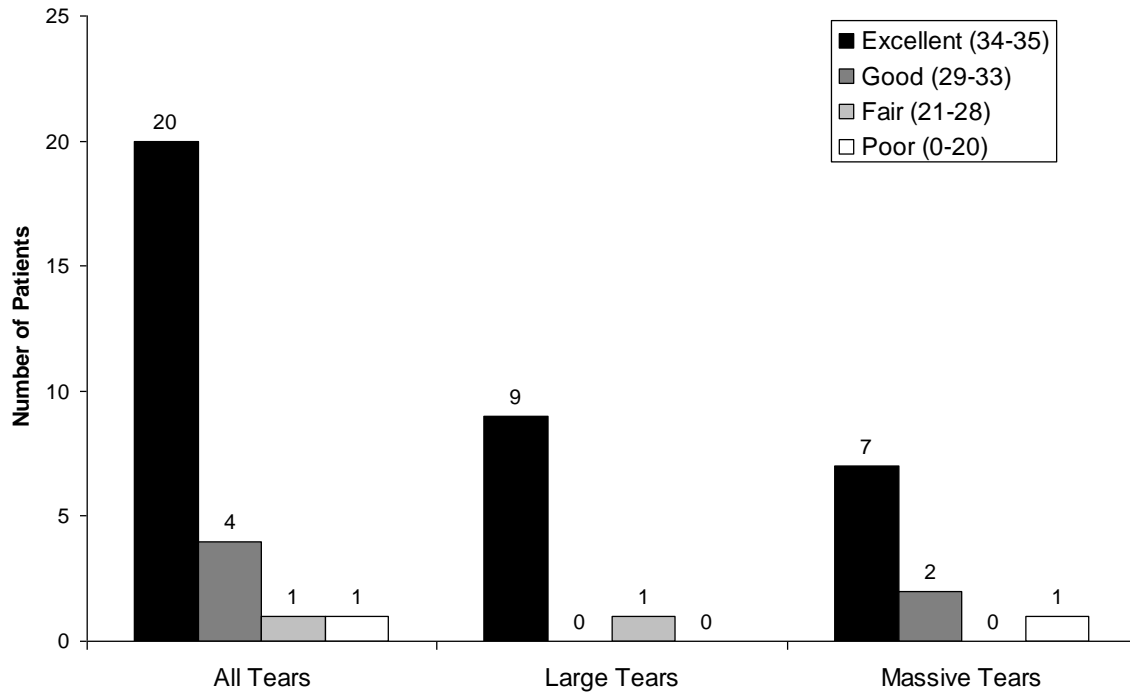
Lahteenmaki, et al. examined tear size in patients undergoing surgical rotator cuff repair within 3 weeks of injury. Tears were categorized into one of four categories as described by Post et al. We are not reporting data pertaining to medium tears as less than ten patients were included in this group ($n = 6$). The authors report statistically significant improvement in function in all three tear size groups ($p < 0.05$). Additionally, authors report size of the tear had no influence on relief of pain or overall results. No other statistical testing for change preoperatively to follow-up by tear size is reported. The authors report no statistically significant difference between tear size groups for function, strength, and overall UCLA score. UCLA results were categorized as excellent, good, fair, or poor for each tear size group (see Figure 66).

Figure 65 UCLA scores by tear size at baseline and follow-up*



* Author reported statistically significant improvement, $p < 0.05$; average patient follow-up of 5.9 ± 0.70 years from baseline; baseline patient satisfaction not reported (nr).

Figure 66 UCLA ratings at follow-up* by tear size



*Average patient follow-up of 5.9 ± 0.70 years from baseline

SUPPORTING EVIDENCE- SUBSCAPULARIS TEARS

Tables relevant to this recommendation are: Table 26 through Table 28

Figures relevant to this recommendation are: Figure 67 through Figure 85

SUBSCAPULARIS TEARS

Table 26 Results of subscapularis tear repair

Authors	LoE	n	Comparison	Outcome	Duration		
					29 months*	40 months**	56 months***
Namdari et al.	IV	30	Change from baseline	Pain: VAS			●↑
Lafosse et al.		17		Pain: Constant-Murley Score	●↑		
Namdari et al.		30		SF-36: Bodily Pain			●↑
Namdari et al.		30		SF-36: Physical Functioning			●↑
Lafosse et al.		17		Constant-Murley Score	●↑		
Namdari et al.		30		DASH			○↑
Lafosse et al.		17		UCLA Score	●↑		
van Riet et al.		24		UCLA Score		nr	
van Riet et al.		24		ASES		nr	
Namdari et al.		30		SST			●↑
Namdari et al.		30		SF-36: Role-Physical			●↑
Namdari et al.		30		SF-36: General Health			○
Namdari et al.		30		SF-36: Vitality			●↑
Namdari et al.		30		SF-36: Social Functioning			●↑
Namdari et al.		30		SF-36: Role-Emotional			●↑
Namdari et al.		30		SF-36: Mental Health			○
Lafosse et al.		17		Patient Satisfaction	●↑		
Namdari et al.		30		Patient Satisfaction-Current Symptoms			●↑
Namdari et al.		30		Patient Satisfaction-Chosen Treatment			●↑
Lafosse et al.		17		Complications		nr	

○ = no statistically significant difference

● = statistically significant difference favoring treatment

● = statistically and clinically significant

↑ = improved

LoE = level of evidence

DASH = disability of the arm, shoulder and hand

ASES = American shoulder and elbow score

SST = simple shoulder test

* = final visit 29 ± 0.92 months after baseline

** = final visit 40 ± 1.8 months after baseline

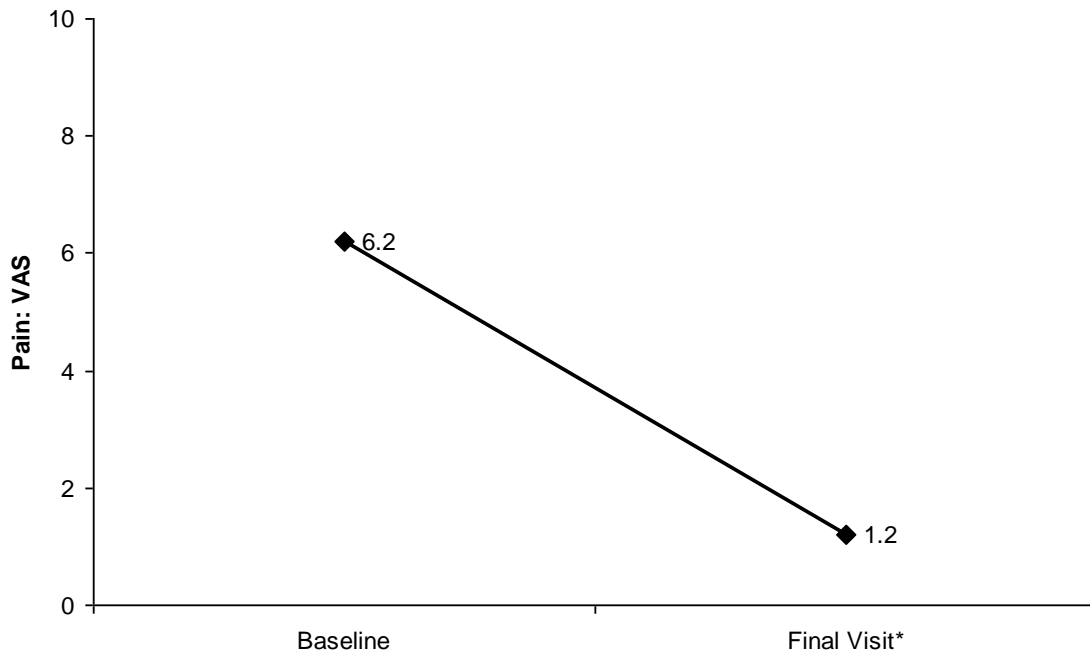
*** = final visit 56 ± 1.43 months after baseline

nr = authors examined this outcome but did not report if the results were statistically significant

PAIN: VAS

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant reduction in pain measured by VAS ($p < 0.001$; see Figure 67).

Figure 67 Change in pain score measured by VAS

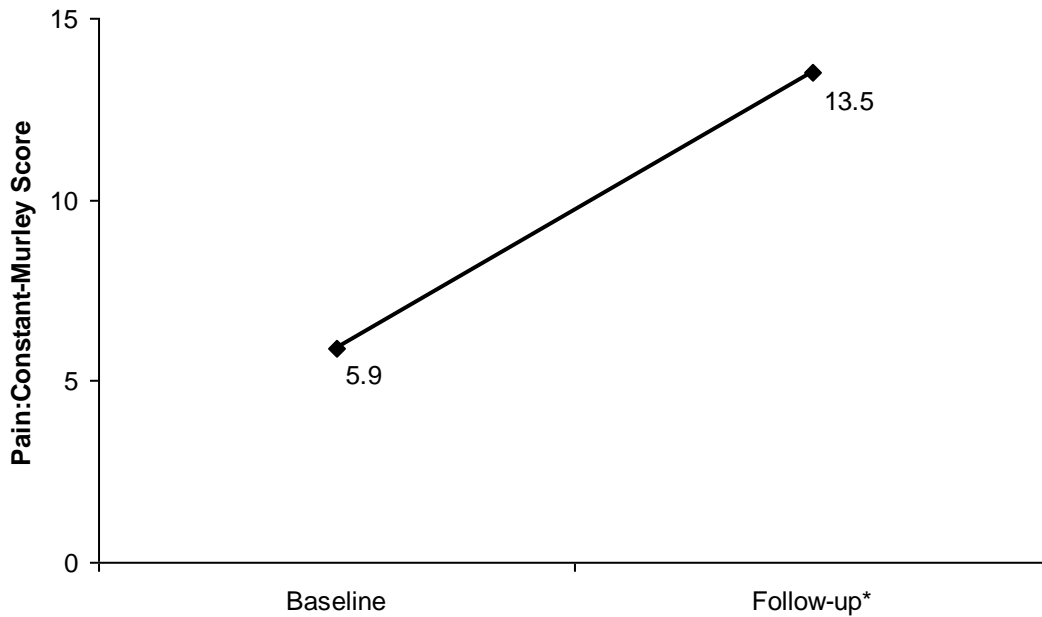


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p < 0.001$.

PAIN: CONSTANT-MURLEY SCORE

One Level IV study by Lafosse, et al. used the Constant-Murley Score (CMS) pain subscale to assess pain before surgery and at various follow-up durations in patients with isolated subscapularis tears. The authors reported a statistically significant reduction in pain (Wilcoxon signed-rank, $p < 0.001$; see Figure 68).

Figure 68 Pain measured by Constant-Murley subscale

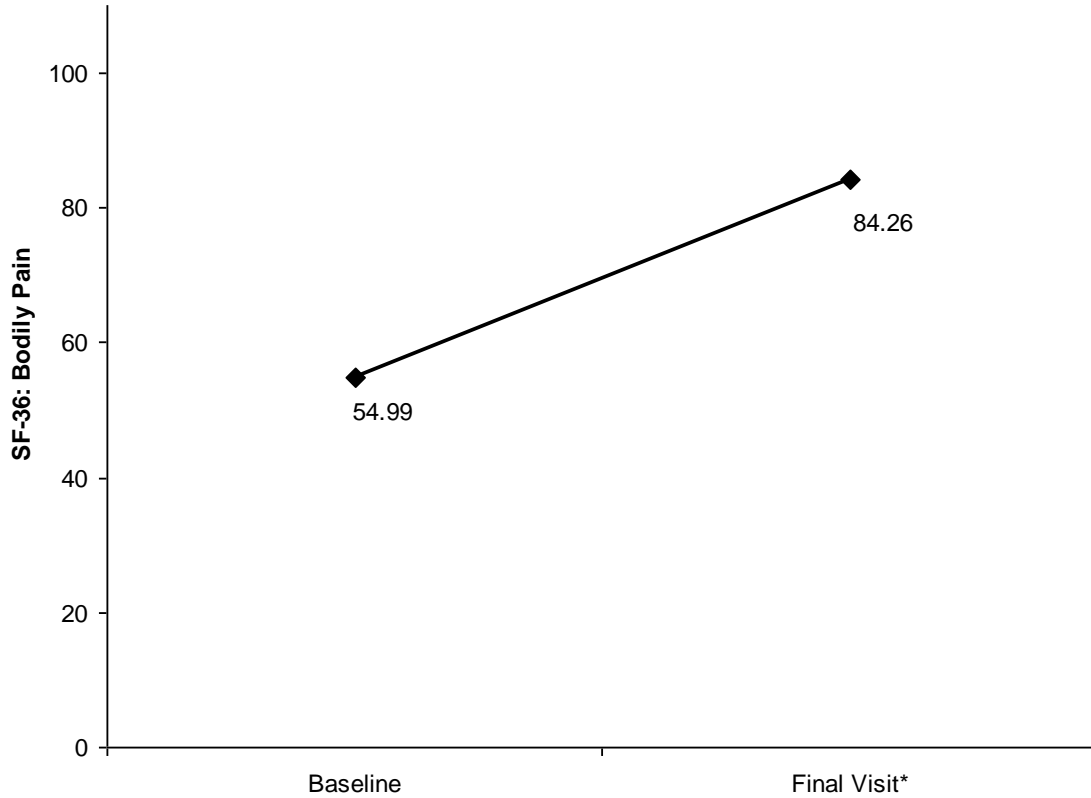


*Average patient follow-up of 29 ± 0.92 months from baseline; authors do not provide dispersions for point estimates; authors reported Wilcoxon signed-rank, $p < 0.001$.

SF-36: BODILY PAIN

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant difference in bodily pain as measured by SF-36 ($p < 0.001$; see Figure 69).

Figure 69 Bodily pain as measured by SF-36

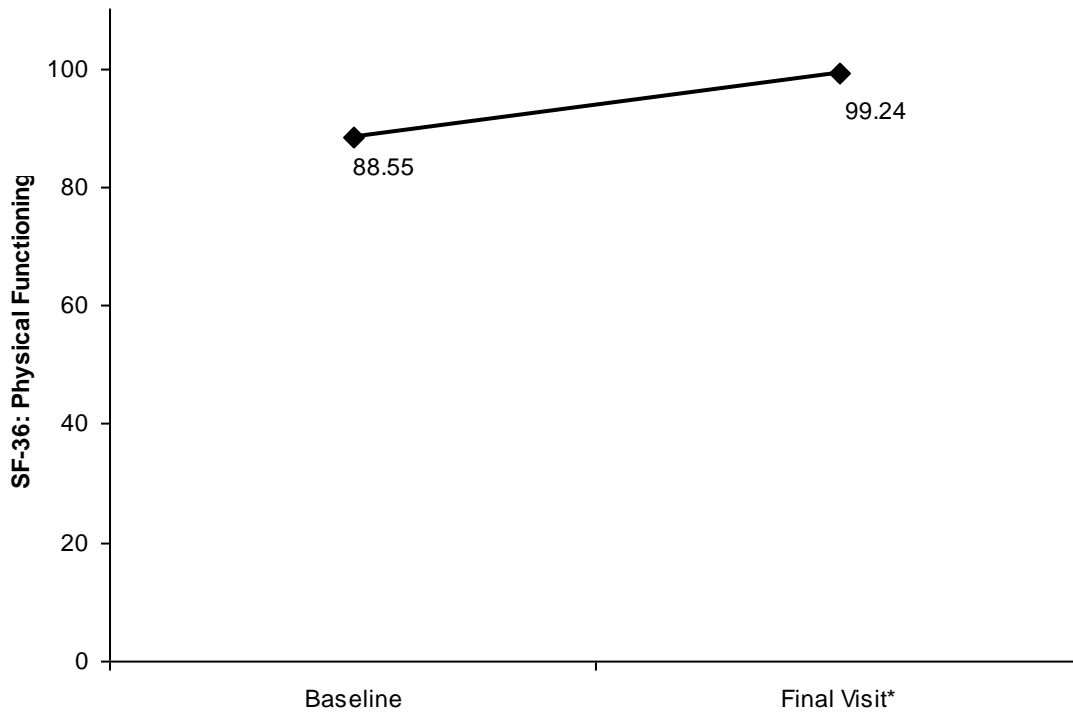


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p < 0.001$.

SF-36: PHYSICAL FUNCTIONING

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant improvement in physical functioning as measured by SF-36 ($p < 0.001$; see Figure 70).

Figure 70 Physical functioning as measured by SF-36

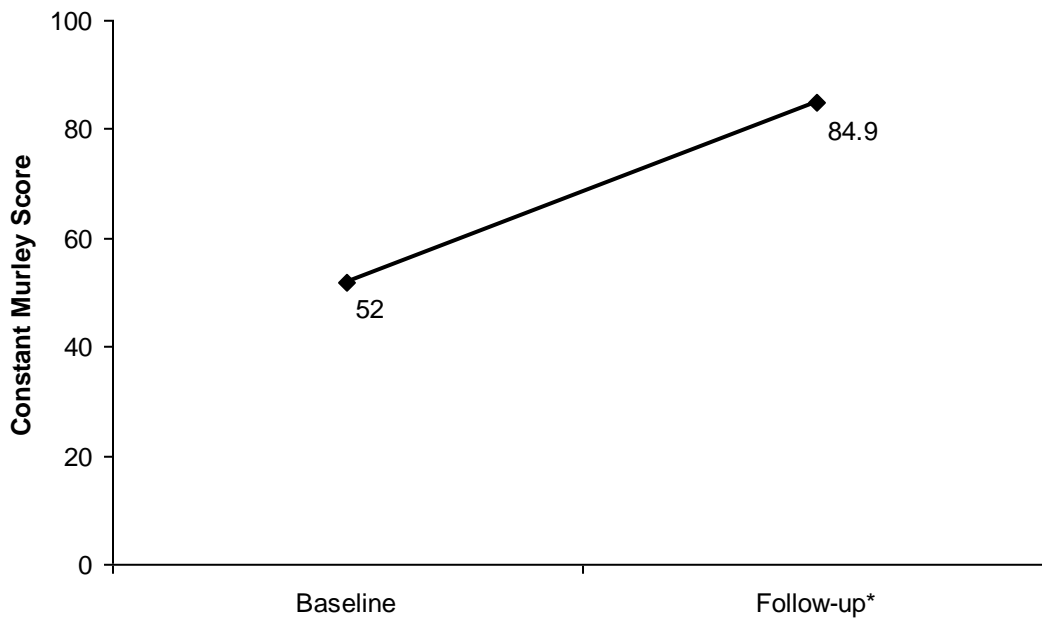


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p < 0.001$.

CONSTANT-MURLEY SCORE

One Level IV study by Lafosse, et al. used the Constant-Murley Score to assess the results of patients undergoing surgical repair of isolated subscapularis rotator cuff tears at various follow-up durations. The authors reported a statistically significant reduction in pain (Wilcoxon signed-rank, $p < 0.001$; see Figure 71).

Figure 71 Constant Score

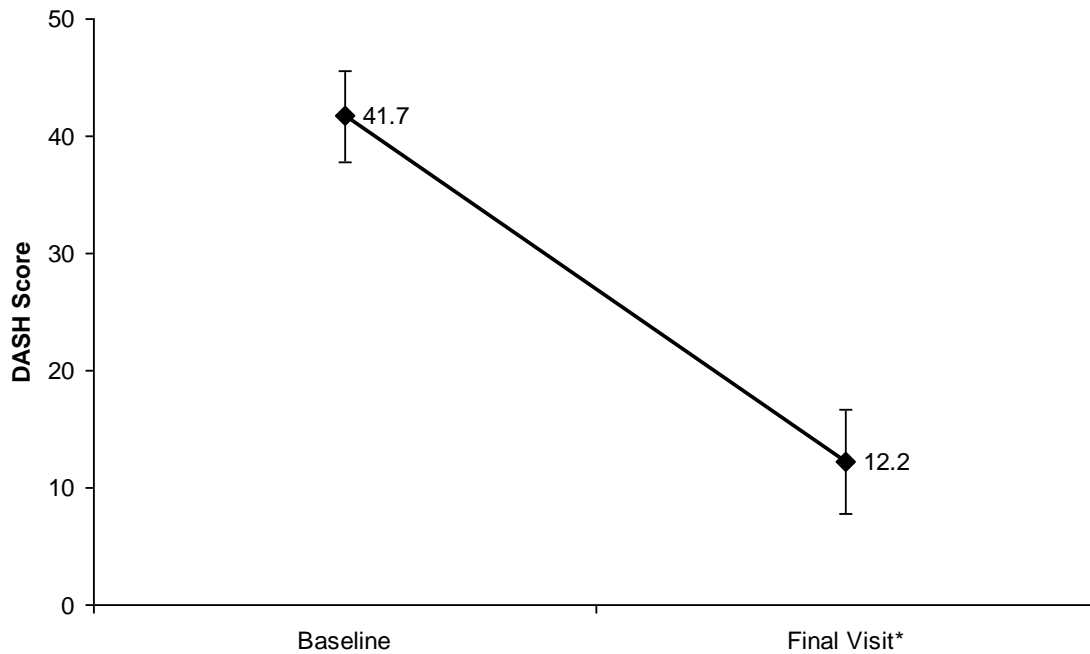


*Average patient follow-up of 29 ± 0.92 months from baseline; authors do not provide dispersions for point estimates; authors reported Wilcoxon signed-rank, $p < 0.001$.

DASH

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant improvement in patient DASH score ($p < 0.001$; see Figure 72).

Figure 72 Patient DASH score

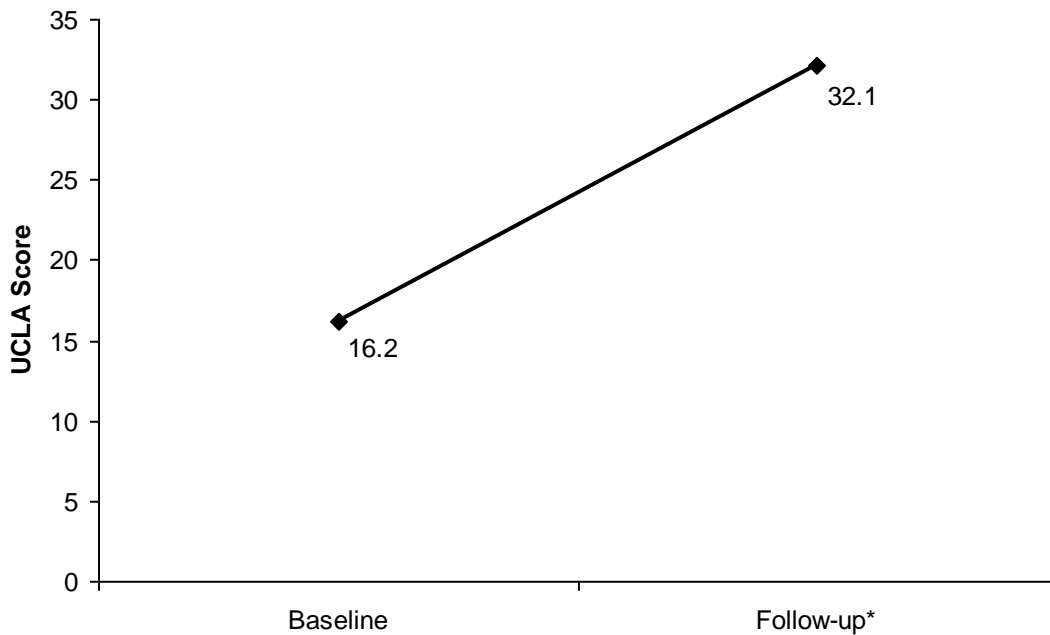


*Average patient follow-up of 56 ± 1.43 months from baseline; AAOS calculated confidence interval at baseline used standard deviation estimated from a range; authors calculated paired t-test, $p < 0.001$.

UCLA SCORE

Two Level IV studies examined UCLA Score. Lafosse, et al. used the UCLA Score to assess the results of patients undergoing surgical repair of isolated subscapularis rotator cuff tears at various follow-up durations. The authors reported a statistically significant reduction in pain (Wilcoxon signed-rank, $p < 0.001$; see Figure 73).

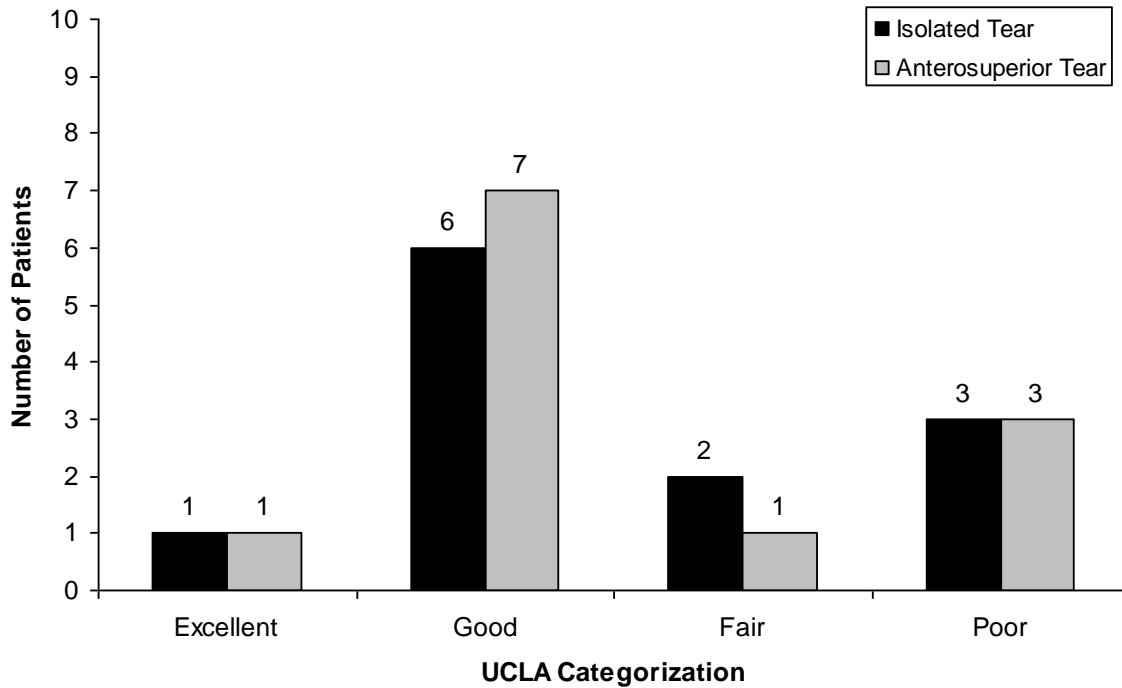
Figure 73 UCLA Score



*Average patient follow-up of 29 ± 0.92 months from baseline; authors do not provide dispersions for point estimates; authors calculated Wilcoxon signed-rank, $p < 0.001$.

Van Riet et al. assessed twenty-four patients after open repair of full-thickness subscapularis tears. Twelve of the patients had isolated subscapularis tears and twelve had anterosuperior tears. The post-operative UCLA Score was categorized as: excellent, good, fair or poor (see Figure 74). Authors report no statistical analyses pertaining to UCLA Score categorization and do not report baseline values.

Figure 74 UCLA Score categorization by tear type

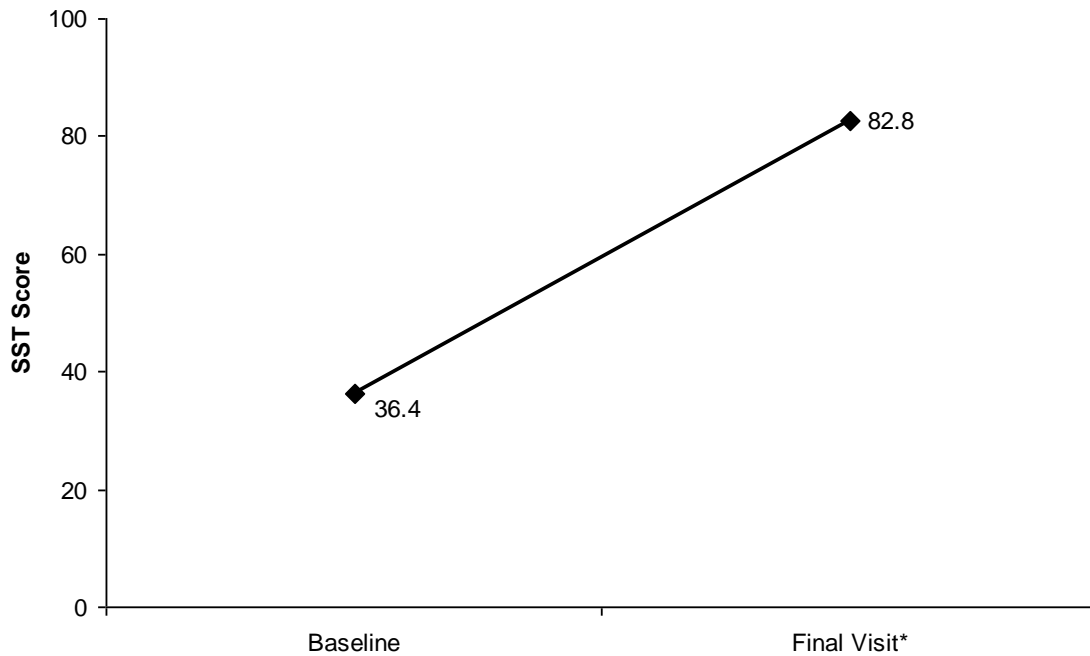


Authors report no statistical analyses.

SST

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant difference in patient SST score ($p < 0.001$; see Figure 75).

Figure 75 Patient SST score

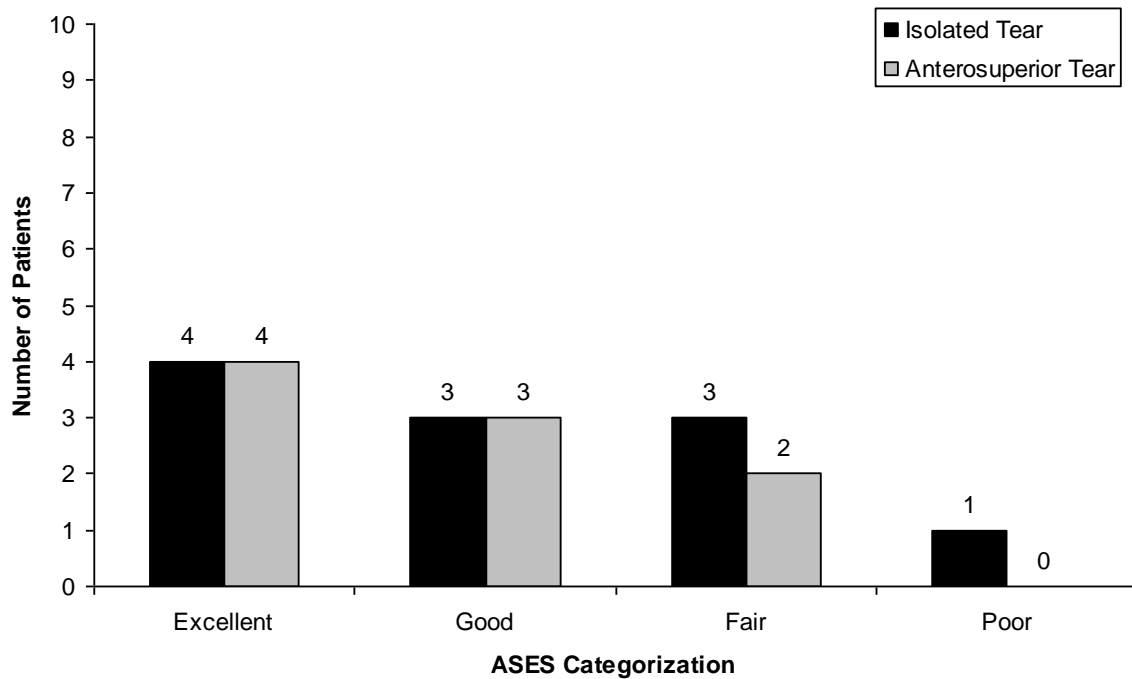


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p < 0.001$.

ASES

One Level IV study by Van Riet et al. assessed twenty-four patients after open repair of full-thickness subscapularis tears. Twelve of the patients had isolated subscapularis tears and twelve had anterosuperior tears. Post-operative ASES scores were categorized as: excellent, good, fair or poor (see Figure 76). Authors report no statistical analyses pertaining to ASES categorization and do not report baseline values.

Figure 76 ASES Categorization

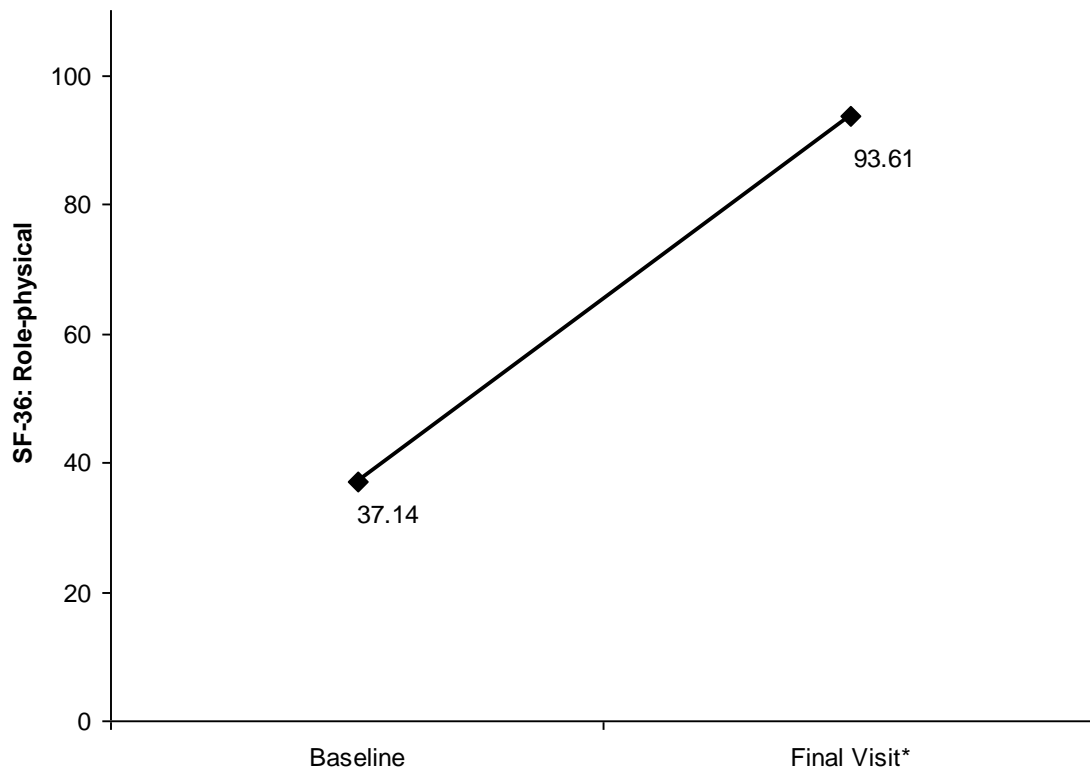


Authors report no statistical analyses.

SF-36: ROLE-PHYSICAL

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant improvement in the physical role subscale of the SF-36 ($p < 0.001$; see Figure 77). The physical role assesses problems with work or other daily activities as a result of physical health.

Figure 77 Physical role as measured by SF-36

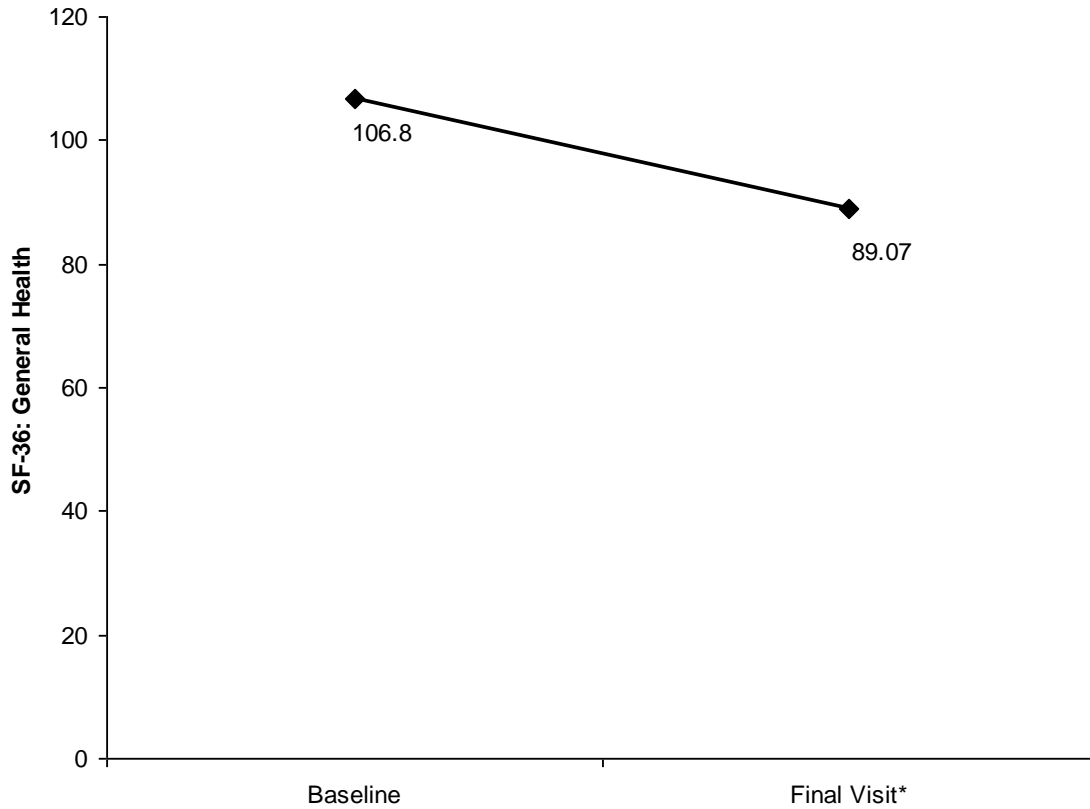


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p < 0.001$.

SF-36: GENERAL HEALTH

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported no statistically significant difference in general health as measured by SF-36 ($p < 0.001$, see Figure 78).

Figure 78 General health as measured by SF-36

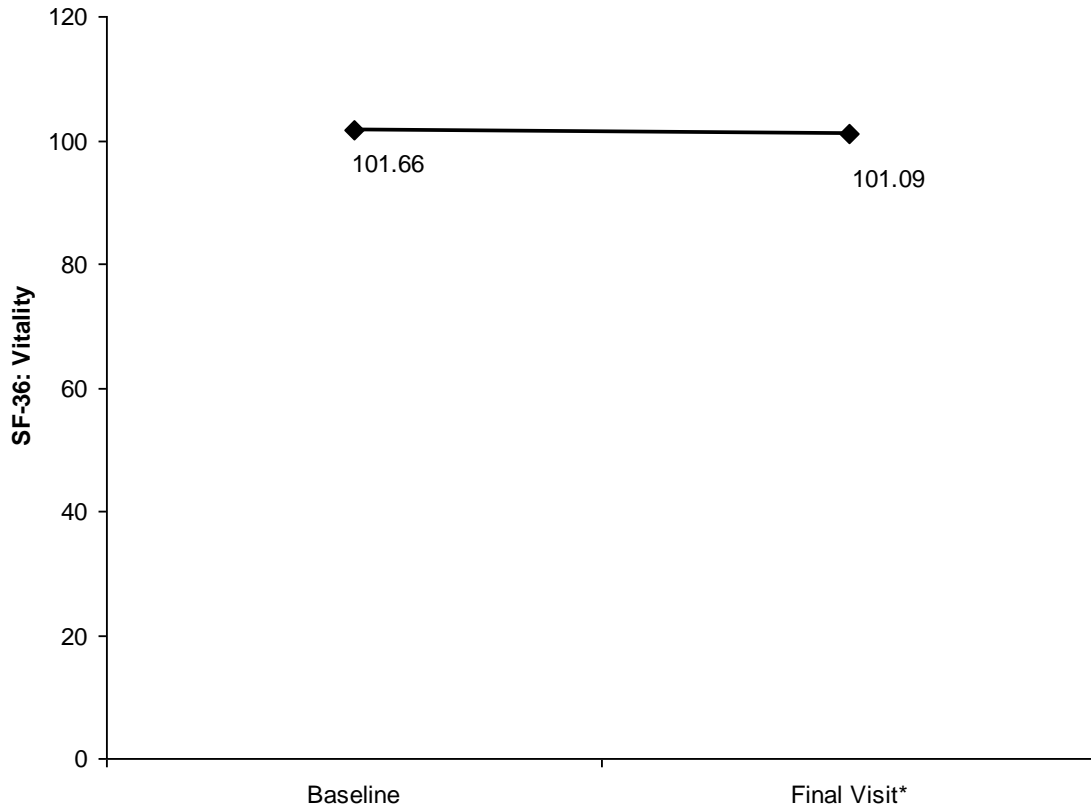


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p = 0.990$.

SF-36: VITALITY

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant difference in vitality subscale of the SF-36 ($p = 0.005$; Figure 79). The vitality subscale assesses the degree to which patients feel tired or worn-out.

Figure 79 Vitality as measured by SF-36

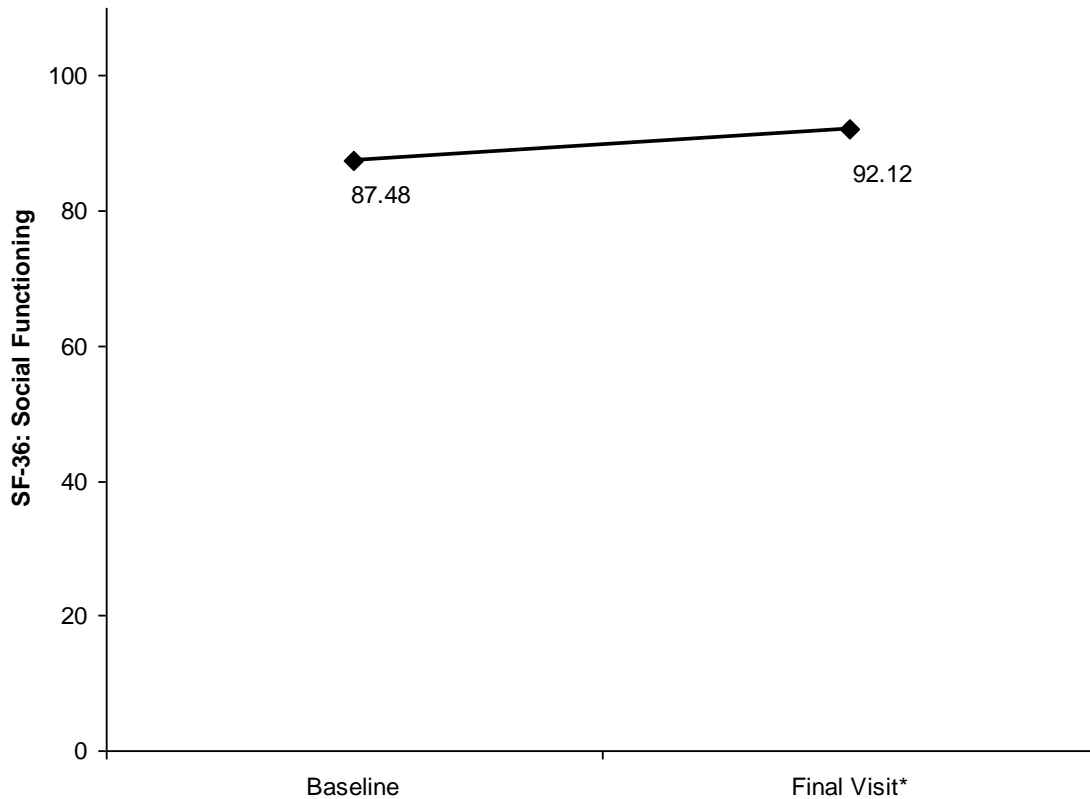


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p = 0.005$.

SF-36: SOCIAL FUNCTIONING

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant difference in social functioning as measured by SF-36 ($p = 0.025$; see Figure 80).

Figure 80 Social functioning as measured by SF-36

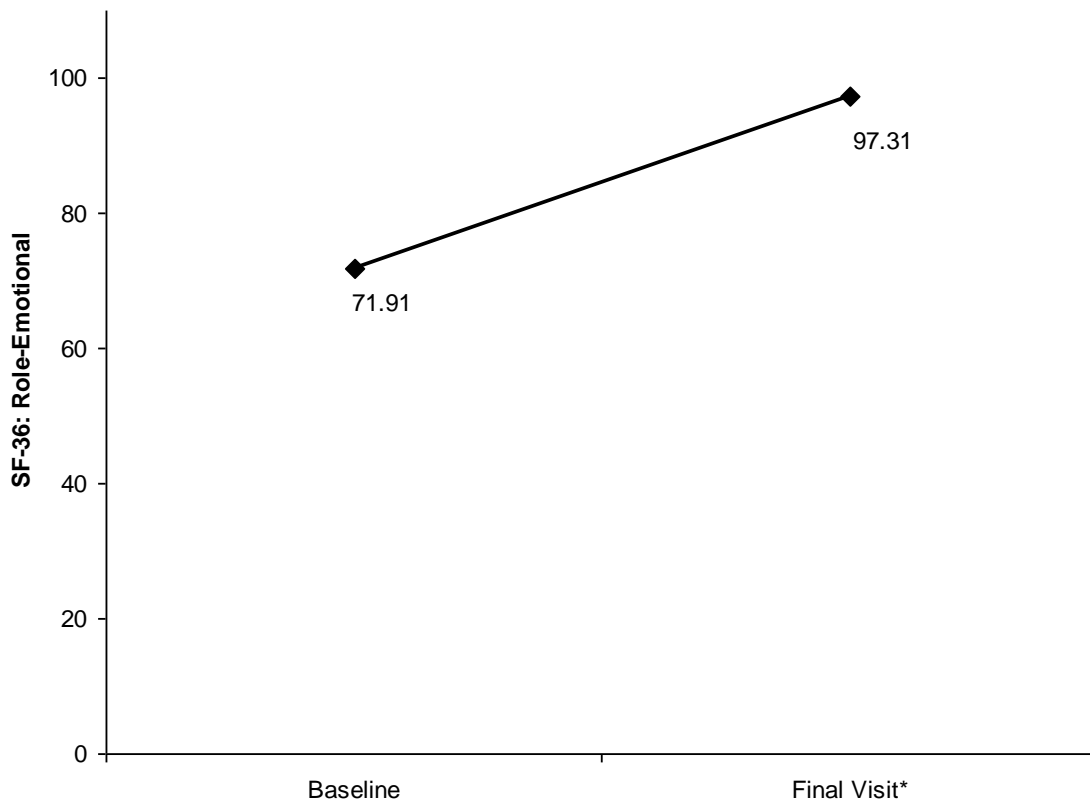


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p = 0.025$.

SF-36: ROLE-EMOTIONAL

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported a statistically significant difference in the emotional role subscale of the SF-36 ($p = 0.001$; see Figure 81). The emotional role assesses problems with work or other daily activities as a result of emotional problems.

Figure 81 Emotional role as measured by SF-36

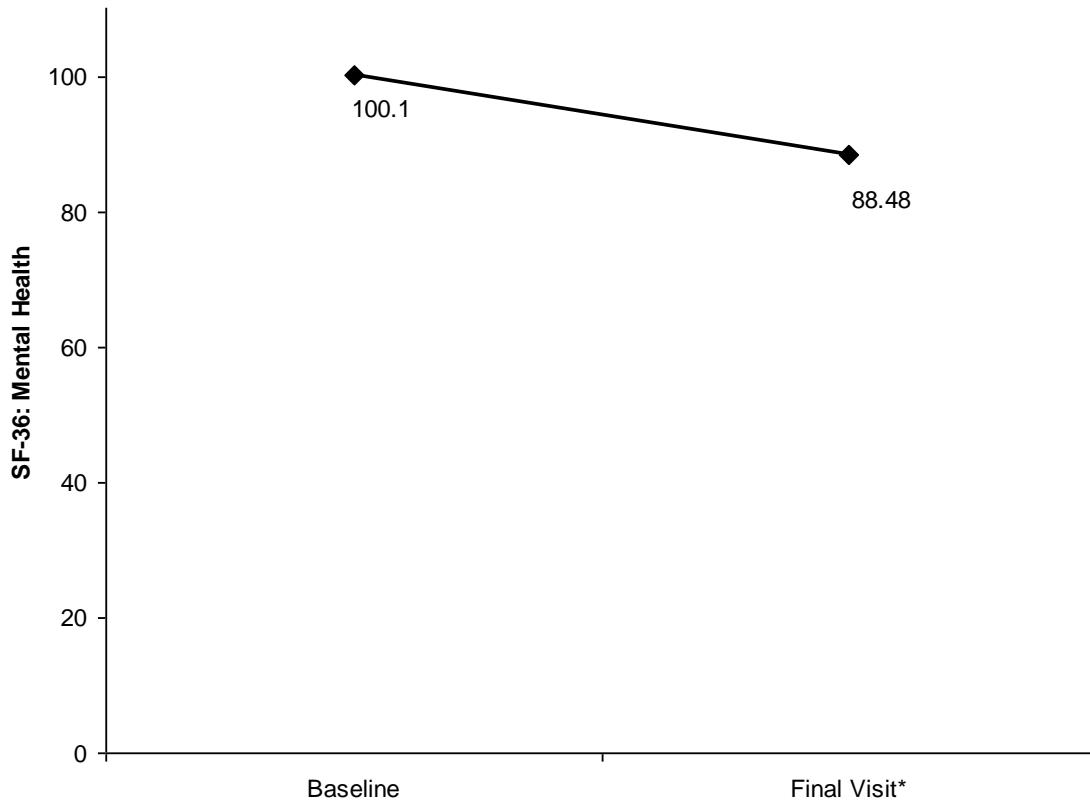


*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p = 0.001$.

SF-36: MENTAL HEALTH

One Level IV study by Namdari et al. examined open repair of thirty patients with anterosuperior rotator cuff tears (a subscapularis tear in addition to a supraspinatus tear). Patients underwent repair an average of 4.5 months after injury. Authors reported no statistically significant difference in the mental health subscale of the SF-36 ($p = 0.640$; see Figure 82).

Figure 82 Mental health as measured by SF-36



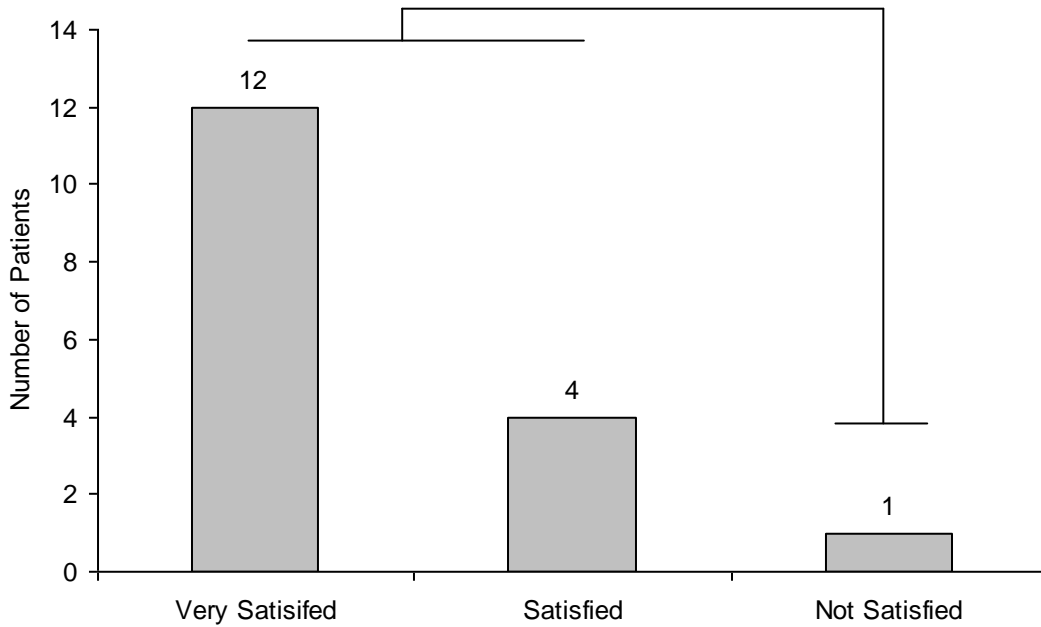
*Average patient follow-up of 56 ± 1.43 months from baseline; authors do not provide dispersions for point estimates; authors calculated paired t-test, $p = 0.640$.

PATIENT SATISFACTION

Two Level IV studies assessed patient satisfaction.

Lafosse, et al. reported the level of satisfaction with surgical repair as reported by the patient at various follow-up durations (see Figure 83). Authors reported no statistical analyses for this outcome.

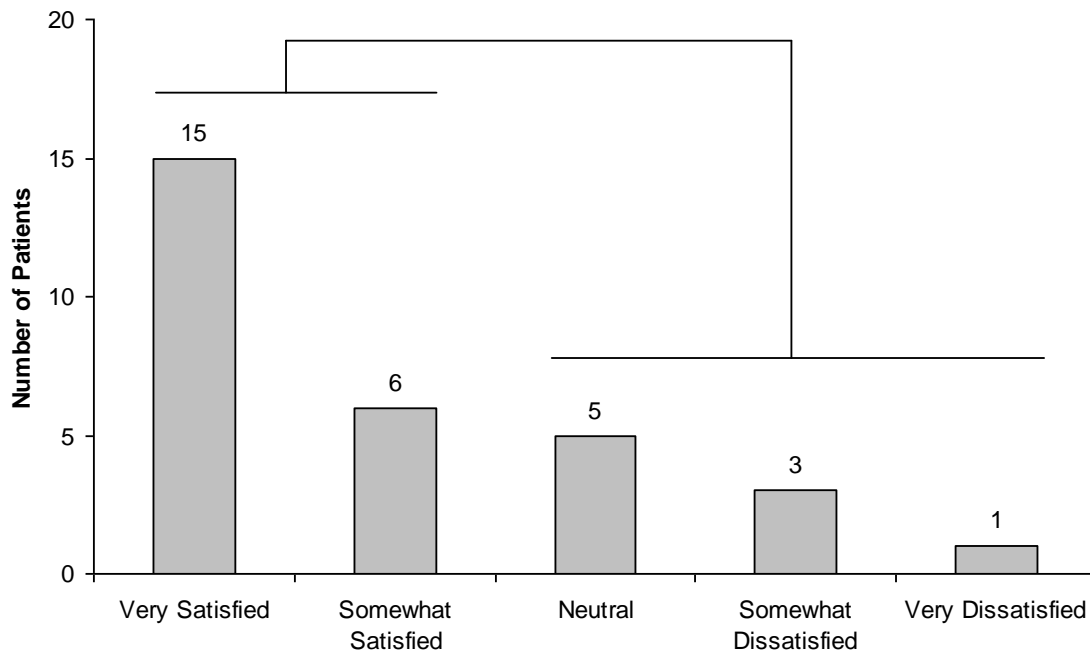
Figure 83 Patient Satisfaction



*AAOS calculated OR = 240.00 (95% CI 13.746 – 4190.405); average patient follow-up of 29 ± 0.92 months from baseline.

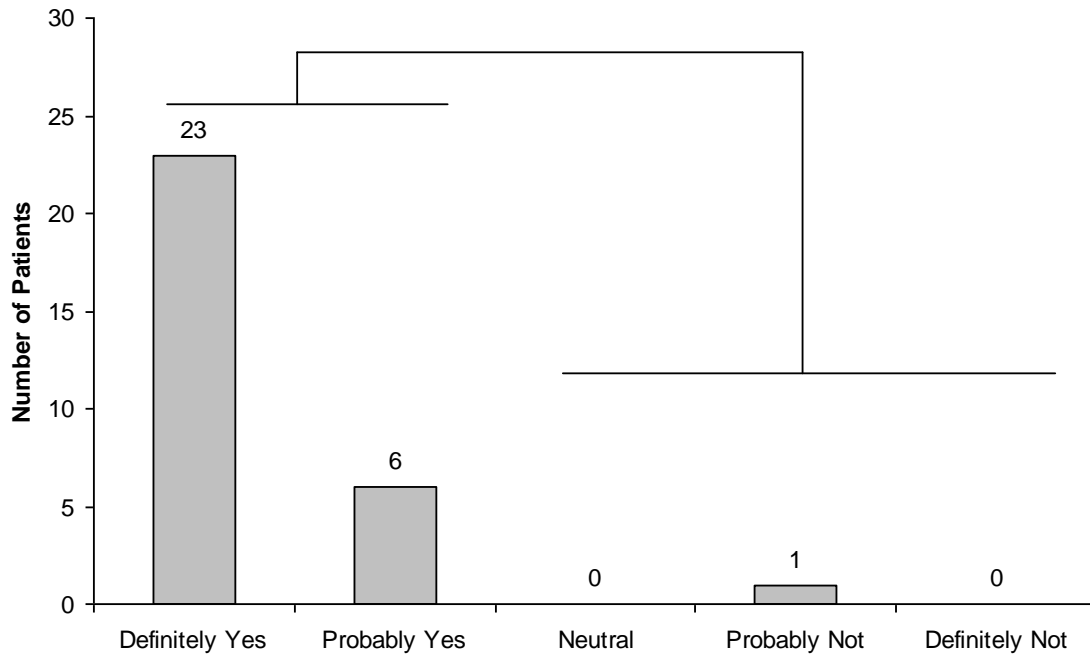
As part of the MODEMS questionnaire, Namdari et al. asked patients, “If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?” Responses were made using a five-point Likert-like scale ranging from “very satisfied” to “very dissatisfied” (see Figure 84). Patients were also asked, “If you could go back in time and make the decision again, would you choose the same treatment for your musculoskeletal condition/problem?” Responses were made using a five-point Likert-like scale ranging from “definitely yes” to “definitely not” (see Figure 85). Authors reported no statistical analyses for this outcome.

Figure 84 Patient satisfaction – current symptoms



*AAOS calculated OR = 5.44 (95% CI 1.804 – 16.427); average patient follow-up of 56 ± 1.43 months from baseline.

Figure 85 Patient satisfaction – happy with chosen treatment



*AAOS calculated OR = 841.00 (95% CI 50.169 – 14000); average patient follow-up of 56 ± 1.43 months from baseline

COMPLICATIONS

One Level IV study by Lafosse, et al. reported patient complications related to arthroscopic repair of isolated subscapularis rotator cuff tears (see Table 26).

Table 27 Complications

Complication	Percent of Patients
Infection	0%
Complex Regional Pain Syndrome	12%
Structural Failure of Repair	12%

STRATIFICATIONS

Lafosse et al. and Namdari et al. examined stratifications pertaining to either: duration of symptoms, gender, age, size of tear, or hand dominance.

Lafosse et al. reported, "...multiple-regression analysis of our data did not reveal any relationship between age at the time of surgery, the duration of symptoms prior to surgery...and the ultimate clinical outcome. In addition...size of the rupture...did not have significant influence on the ultimate outcome in our study population."

Namdari et al. reported, "...there were no significant correlations between outcome and a number of preoperative factors including patient age, sex, medical co morbidities, duration of symptoms, involvement of the dominant extremity or extent of subscapularis tear."

Table 28 Stratifications pertaining to subscapularis tears

Stratification	Author Reported p-value	
	Namdari et al.	Lafosse et al.
Duration of symptoms	ns	ns
Gender	ns	-
Age	ns	ns
Size of tear	ns	ns
Hand dominance	ns	-

ns = not statistically significant

- = not addressed by authors

RECOMMENDATION 6: PERIOPERATIVE INTERVENTIONS – CORTICOSTEROID INJECTIONS/NSAIDS

We cannot recommend for or against the use of perioperative subacromial corticosteroid injections or non-steroidal anti-inflammatory medications in patients undergoing rotator cuff surgery.

Level of Evidence: Insufficient

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

After a systematic search of the literature, we found no clinical data that supported or refuted a negative or positive effect of subacromial corticosteroid injections on tendon healing or outcomes after rotator cuff repair. Therefore, the work group could not recommend for or against their use in the perioperative period as the evidence was inconclusive.

Non-steroidal anti-inflammatory medications have the potential benefits of limiting pain and swelling associated with rotator cuff repair surgery. While the clinical effects of NSAIDs have been evaluated in the non-operative treatment of patients with rotator cuff symptoms in the absence of a full-thickness tear, we found no evidence supporting or refuting their usage in the postoperative period after rotator cuff repair. Specifically, the work group was concerned about the possible negative affects of NSAIDs on tendon healing. There is no clinical data supporting or refuting a negative or positive affect on rotator cuff tendon healing therefore the group found that the evidence with regard to NSAIDS on healing was inconclusive. If NSAIDs are utilized, appropriate prudence should be exercised as this treatment modality is associated with potential adverse side effects including gastrointestinal bleeding, renal injury and platelet dysfunction.

RECOMMENDATION 7A: CONFOUNDING FACTORS - AGE, ATROPHY/FATTY DEGENERATION, AND WORKERS COMPENSATION STATUS

It is an option for physicians to advise patients that the following factors correlate with less favorable outcomes after rotator cuff surgery:

- Increasing Age
- MRI Tear Characteristics
- Worker's Compensation Status

INCREASING AGE - RATIONALE

Level of Evidence: IV

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Increasing patient age has been identified as a potential factor influencing outcomes and healing after rotator cuff surgery. Healing and strength (as indirectly measured by the Constant-Murley score) are critical factors in evaluating surgical success. Several studies determined that the Constant-Murley score (as a measure of shoulder strength) was negatively correlated with increasing age after rotator cuff repair.^{75, 51, 47, 54, 76} Similarly, numerous authors concluded that age was a negative predictor of posterosuperior rotator cuff healing after repair.⁷⁷⁻⁷⁹

Age has also been shown to correlate with subjective outcomes after rotator cuff repair although the associations are not as strong as those for healing and strength. A number of studies have found increasing age to be negatively associated with clinical outcomes after rotator cuff surgery.^{47, 76, 80, 79, 51, 77, 75, 81, 82, 83} However, some studies found no effect of increasing age on clinical outcomes^{49, 72, 73, 84, 85, 86, 87, 88, 89, 90-92, 93}

Out of all 23 studies included, one author reported a negative correlation between increasing age and a patient-reported outcome measure.⁸¹ This study reported on 80 patients at 2 years after rotator cuff repair and concluded that older age was associated with worse DASH scores. The authors did perform a multivariate analysis confirming the

relationship; therefore, this should be recognized as a significant finding. One other author⁸² reported VAS pain and reported age ranges for comparison groups. The findings are statistically significant but the authors do not define the size or direction of the effect. A third author reported “Treatment Response”, but this outcome is a composite of pain and internal/external rotation. It is therefore a composite of a patient-oriented outcome and a surrogate measure making it difficult to interpret.

MRI TEAR CHARACTERISTICS - RATIONALE

Level of Evidence: IV

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Rotator cuff muscle quality has been implicated as having a direct effect on the ability of a repair to heal and the functional outcome after a repair. Both fatty degeneration (comparative amount of muscle tissue to fat as determined by MRI or CT scan) and muscle atrophy (volume of rotator cuff muscle as determined by MRI or CT scan) have been evaluated in regards to their effects on tendon repair healing and outcomes. Based upon six Level IV studies^{48, 47, 49, 50, 51, 52} it is an option for a surgeon to advise a patient undergoing rotator cuff repair about the negative affects of supraspinatus and infraspinatus muscle atrophy and fatty degeneration on both tendon healing and clinical outcomes.

One study⁴⁸ evaluated 38 patients prospectively who underwent a rotator cuff repair with MRI and outcome scores (ASES score, Constant-Murley score) at baseline and at 1 year postoperative. The authors reported that worse infraspinatus muscle atrophy and fatty degeneration were correlated with worse ASES and Constant-Murley scores. Also, worse fatty degeneration correlated with poorer infraspinatus healing. Worse supraspinatus atrophy correlated with worse ASES scores, Constant-Murley scores and tendon healing. Finally, worse supraspinatus fatty degeneration correlated with worse tendon healing.

A second study⁵⁰ evaluated twenty-eight patients who underwent repair of a massive rotator cuff tear at 44 months postoperative with UCLA scores. Preoperative fatty degeneration of the infraspinatus correlated with inferior postoperative UCLA scores.

Several authors focused their evaluation on the correlation of just supraspinatus muscle quality to tendon healing and outcomes. One study evaluated twenty-seven⁴⁷ patients after a mini open rotator cuff repair for an isolated supraspinatus tear with an MRI and Constant- Murley score at an average of 67 months postoperative. This study determined that preoperative supraspinatus muscle atrophy correlated negatively with postoperative Constant-Murley scores. Another study⁴⁹ evaluated 53 patients after isolated arthroscopic supraspinatus repair with Constant-Murley scores and MRI at an average of 26 months postoperative. Preoperative supraspinatus fatty degeneration and muscle atrophy

correlated with worse healing rates. A final study⁵¹ prospectively evaluated 30 chronic rotator cuff tears of varying sizes, which underwent an open rotator cuff repair, with an MRI at an average of 21 months postoperative. The authors determined that preoperative supraspinatus muscle atrophy correlated with poorer healing rates.

Based upon these studies, preoperative infraspinatus fatty degeneration and muscle atrophy correlated with worse outcomes and healing. Preoperative supraspinatus muscle atrophy correlated with worse outcomes and healing. Finally, preoperative supraspinatus fatty degeneration was correlated with worse healing, but not necessarily worse outcomes.

WORKERS' COMPENSATION STATUS - RATIONALE

Level of Evidence: II/III

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Rationale:

Several authors^{94, 95, 96} have evaluated the effect of Workers' compensation on surgical treatment for rotator cuff disease including acromioplasty for tendonitis and repair of full-thickness tears. Based upon one Level II study⁹⁶ and two Level III studies,^{97, 98} the work group has determined that it is an option for physicians to advise their patients that workers' compensation status correlates with less favorable outcomes after rotator cuff repair.

One study⁹⁶ prospectively evaluated 107 shoulders (23 of which were receiving workers' compensation) at an average of 45 months postoperative from an open rotator cuff repair with the UCLA score. Both groups were comparable with regards to patient age, sex, tear size, preoperative strength and active motion. At final follow-up, patients receiving workers' compensation had significantly worse UCLA scores compared to those not receiving workers' compensation. Another study⁹⁴ prospectively evaluated 106 patients (40 of which were receiving workers' compensation) at an average of 32 months after arthroscopic acromioplasty for rotator cuff tendonitis with the ASES score, the Simple Shoulder Test and a VAS pain scale. The authors report no statistically significant differences between groups with regards to each of these outcomes although the AAOS work group re-calculated the statistics and found workers' compensation patients had significantly worse SST and VAS pain scores than those not receiving a claim. The last study⁹⁵ prospectively evaluated 24 patients (12 receiving workers' compensation) at an average of 3 years postoperative from an open acromioplasty for rotator cuff tendonitis with UCLA scores. At final evaluation, workers' compensation patients had significantly worse improvements in pain compared to those not receiving Workers' compensation.

Based upon the above data, shoulder function as evaluated by the UCLA score, the Simple Shoulder Test and VAS pain scores were all inferior in workers' compensation patients treated surgically for acromioplasty for rotator cuff tendonitis or rotator repairs compared to a non-workers' compensation group. This data supports the option of advising patients that workers' compensation status correlates with less favorable outcomes after rotator cuff surgery.

SUPPORTING EVIDENCE- INCREASING AGE

Tables relevant to this recommendation are: Table 29 through Table 38

Figures relevant to this recommendation are: Figure 86 through Figure 92

INCREASING AGE - DATA

Table 29 Studies addressing the effect of age on outcome sorted by sample size (n)

Authors	LoE	n	Outcome															
			Pain Measures	Function: UCLA	Constant Measures	Re-Tear	DASH	Work DASH	SF-36	UCLA	WORC	ASES Score	M-ASES	SPADI	SSI	SSRS	SST	Treatment Response*
Gerber et al.	IV	13			○													
Lafosse et al.		17																○
Shen et al.		27			●													
Namdari et al.		30																○
DeFranco et al.		30				●												
Prasad et al.		40			●													
Murray et al.		45																○
Cole et al.		49	●			●												
Liem et al.		53			●													
Lichtenberg et al.		53				●												
Rebuzzi et al.		54								○								
Pai et al.		56								○								
McKee et al.		67						○										
Lam et al.		69			●													
Wordland et al.		69																○
Gartsman et al.		73								○								
Baysal et al.		74									○	○						
Motycka et al.		79			○								○	○	○	○	○	
Milano et al.		80			○			●	○									
Hattrup et al.		88																●
Boehm et al.		93			●													
Gazielly et al.		98					○											
Lahteenmaki et al.		246	○	○						○								

○ = no statistically significant difference

● = statistically significant

■ = performed by the AAOS

* = authors group treatment response at final outcome as excellent, satisfactory, unsatisfactory

** = clinical outcome not defined

LoE = level of evidence

ASES = American shoulder and elbow surgeons

QOL = quality of life measure

SPADI = shoulder pain and disability index

SSI = shoulder severity index

SSRQ = subjective shoulder-rating scale

SST = simple shoulder test

DASH = disability of the arm, shoulder, and hand

Table 30 Studies addressing the effect of age on outcome sorted by mean age

Authors	LoE	Age (Mean)	Age (Range)	Outcome																		
				Pain Measures	Function: UCLA	Constant Measures	Re-Tear	DASH	Work DASH	SF-36	UCLA	WORC	ASES Score	M-ASES	SPADI	SSI	SSRS	SST	Treatment Response*	Clinical Outcome**		
Lafosse et al.	IV	47	29 - 59																		○	
Lahteenmaki et al.		53	35 - 71	○	○						○											
Baysal et al.		53.2	22 - 82									○	○									
Gazielly et al.		56	35 - 77				○															
Gerber et al.		56	41 - 68			○																
McKee et al.		56.1	32 - 78								○											
DeFranco et al.		56.3	30 - 78				●															
Boehm et al.		56.5	38 - 71			●																
Namdari et al.		56.9	43 - 73																			○
Cole et al.		57	34 - 80	●			●															
Motycka et al.		57.5	38.4 - 76.7			○								○	○	○	○	○				
Murray et al.		57.6	38 - 80																			○
Milano et al.		60	nr			○			●	○												
Gartsman et al.		60.7	31 - 82									○										
Lichtenberg et al.		60.9	46 - 74				●															
Liem et al.		60.9	nr			●																
Shen et al.		62.7	41 - 85			●																
Prasad et al.		64	22 - 82			●																
Pai et al.		65	32 - 82									○										
Hattrup et al.		65.8	44.6 - 84.5																		●	
Rebuzzi et al.	67.7	61 - 78									○											
Lam et al.	75	65 - 91			●																	
Worland et al.	75	70 - 90																			○	

○ = no statistically significant difference

● = statistically significant

■ = performed by the AAOS

* = authors group treatment response at final outcome as excellent, satisfactory, unsatisfactory

** = clinical outcome not defined

LoE = level of evidence

ASES = American shoulder and elbow surgeons

QOL = quality of life measure

SPADI = shoulder pain and disability index

SSI = shoulder severity index

SSRQ = subjective shoulder-rating scale

SST = simple shoulder test

DASH = disability of the arm, shoulder, and hand

Table 31 Studies addressing the effect of age on outcome sorted by age range length

Authors	LoE	Age (Mean)	Age (Range)	Outcome															
				Pain Measures	Function: UCLA	Constant Measures	Re-Tear	DASH	Work DASH	SF-36	UCLA	WORC	ASES Score	M-ASES	SPADI	SSI	SSRS	SST	Treatment Response*
Rebuzzi et al.		67.7	61 - 78									○							
Worland et al.		75	70 - 90																○
Lam et al.		75	65 - 91			●													
Gerber et al.		56	41 - 68			○													
Lichtenberg et al.		60.9	46 - 74				●												
Lafoose et al.		47	29 - 59																○
Namdari et al.		56.9	43 - 73																○
Boehm et al.		56.5	38 - 71			●													
Lahteenmaki et al.		53	35 - 71	○	○						○								
Motycka et al.		57.5	38.4 - 76.7			○						○	○	○	○	○			
Hattrup et al.		65.8	44.6 - 84.5															●	
Gazielly et al.	IV	56	35 - 77				○												
Murray et al.		57.6	38 - 80																○
Shen et al.		62.7	41 - 85			●													
McKee et al.		56.1	32 - 78							○									
Cole et al.		57	34 - 80	●			●												
DeFranco et al.		56.3	30 - 78				●												
Pai et al.		65	32 - 82								○								
Gartsman et al.		60.7	31 - 82								○								
Baysal et al.		53.2	22 - 82									○	○						
Prasad et al.		64	22 - 82			●													
Milano et al.		60	nr			○		●	○										
Liem et al.		60.9	nr			●													

○ = no statistically significant difference

● = statistically significant

■ = performed by the AAOS

* = authors group treatment response at final outcome as excellent, satisfactory, unsatisfactory

** = clinical outcome not defined

LoE = level of evidence

ASES = American shoulder and elbow surgeons

QOL = quality of life measure

SPADI = shoulder pain and disability index

SSI = shoulder severity index

SSRQ = subjective shoulder-rating scale

SST = simple shoulder test

DASH = disability of the arm, shoulder, and hand

PAIN: VAS

One Level IV study by Cole et al. assessed the effect of age in patients undergoing arthroscopic repair of a full-thickness rotator cuff tear. The authors report statistically significant difference in VAS pain scores when comparing age groups ≤ 49 vs. 60-69 ($p = 0.036$) and 50-59 vs. 60-69 ($p = 0.037$); however, no difference was found when comparing age group ≤ 49 vs. 50-59. Authors do not report size or direction of the effect.

PAIN: UCLA SCORE

One Level IV study by Lahteenmaki et al. assessed the effect of age in patients undergoing surgical repair of a full-thickness rotator cuff tear. Authors report no statistically significant relationship between patient age and post-operative UCLA pain score ($p = 0.57$).

FUNCTION: UCLA

One Level IV studies assessed function using the UCLA. Lahteenmaki et al. assessed the effect of age in patients undergoing surgical repair of a full-thickness rotator cuff tear. Authors report no statistically significant relationship between patient age and post-operative UCLA function score ($p = 0.096$).

CONSTANT-MURLEY SCORE

Eight Level IV studies examined the relationship between patient age and Constant-Murley score.

One Level IV study by Shen et al. assessed the effect of age in patients undergoing mini-open repair of a rotator cuff tear. AAOS calculations found a statistically significant, negative correlation between age and Constant-Murley score ($p < .05$; see Table 31).

Table 32 Correlation between age and post-operative Constant-Murley score

	Age	
	r	p-value
Constant-Murley score	-0.612	0.0007

AAOS calculated correlation

One Level IV study by Gerber et al. assessed the effect of age in patients undergoing surgical repair of a full-thickness supraspinatus tear. AAOS calculations found no statistically significant relationship between age and Constant-Murley score ($p > 0.05$; see Table 32).

Table 33 Correlation between age and post-operative Constant-Murley score

	Age	
	r	p-value
Constant-Murley score	-0.293	0.3308

AAOS calculated correlation

One Level IV study by Liem et al. assessed the effect of age in patients undergoing arthroscopic repair of an isolated supraspinatus tear. Authors report, “The only factor with significant influence on the clinical outcome was the patient’s age ($p = 0.002$).”

One Level IV study by Prasad et al. assessed the effect of age in patients undergoing open repair of a full-thickness tear. Authors report a statistically significant effect of patient age on post-operative Constant-Murley score ($p = 0.04$).

One Level IV study by Lam and Mak assessed the effect of age in patients undergoing open repair of a massive rotator cuff tear. Authors report a statistically significant negative correlation between patient age and post-operative Constant-Murley score ($p < 0.01$).

One Level IV study by Motycka et al. assessed the effect of age in patients undergoing open repair of a full-thickness rotator cuff tear. Authors report no statistically significant difference in post-operative Constant-Murley scores in patients under 60 years of age compared to those over 60 years (mean of 73.0 to 69.7 respectively).

One Level IV study by Milano et al. assessed the effect of age in patients undergoing repair of a full-thickness tear. Authors report no statistically significant of age on the Constant-Murley score using univariate analyses (see Table 33).

Table 34 Correlation between age and post-operative Constant-Murley score

	Age	
	r	p-value
Constant-Murley Score	-0.051	0.672

As reported by authors.

One Level IV study by Boehm et al. assessed patients undergoing rotator cuff repair using bone tunnel technique. Using linear regression, authors report a statistically significant positive correlation between age and gender adjusted Constant-Murley score (see Table 34).

Table 35 Correlation between age and gender adjusted post-operative Constant-Murley score

	Age	
	r	p-value
Constant-Murley Score	0.243	0.019

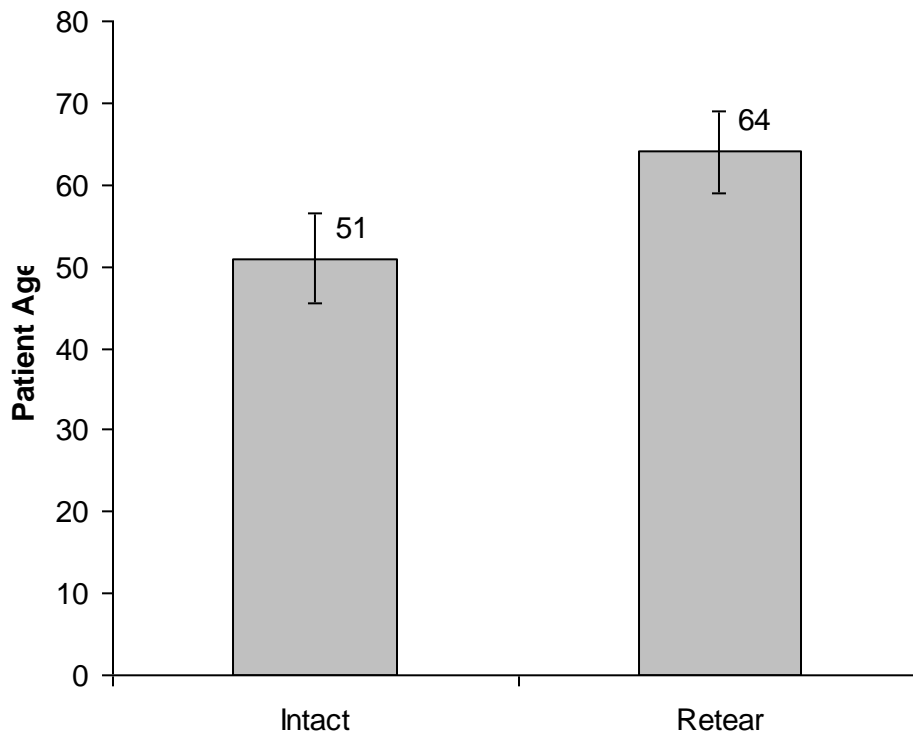
As reported by authors

RETEAR

Four Level IV studies examined the relationship between patient age and re-tear occurrence.

One Level IV study by DeFranco et al. assessed the effect of age on re-tear rates in patients undergoing arthroscopic repair of an isolated supraspinatus tendon tear. Authors report that patients with re-tears were statistically significantly older than those with intact repairs ($p < 0.01$; see Figure 86).

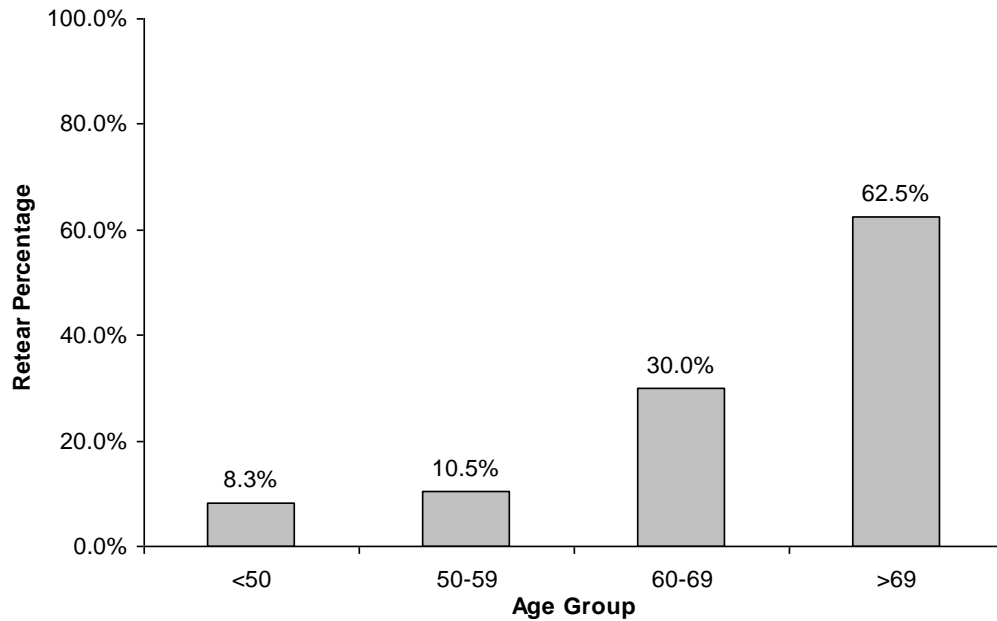
Figure 86 Age of re-tear and intact patient groups



AAOS calculated independent t-test, $t=3.19$, $p < .01$.

One Level IV study by Cole et al. assessed the effect of age in patients undergoing arthroscopic repair of a full-thickness rotator cuff tear. Authors report that a statistically significant correlation was found between re-tear and age group ($r = 0.407$, $p = 0.004$) and that patients with re-tears were significantly older than those with intact repairs (64 to 55 respectively, $p = 0.009$; see Figure 87).

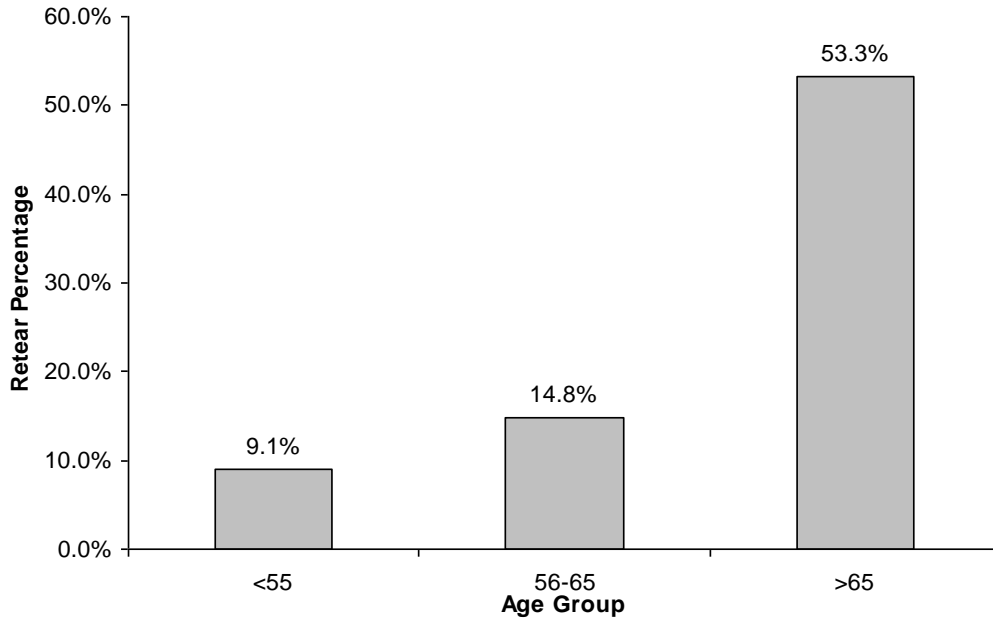
Figure 87 Percent of patients with re-tears by age group



Authors calculated correlation between re-tear and age group, $r = 0.407$, $p = 0.004$.

One Level IV study by Lichtenberg et al. assessed the effect of age in patients undergoing arthroscopic repair of an isolated full-thickness supraspinatus tear. Authors report that patients with re-tears were statistically significantly older than those with intact repairs (65.3 to 59.5 respectively, $p = 0.0122$; see Figure 88).

Figure 88 Percent of patients with re-tears by age group



Authors report patients with re-tears were statistically significantly older, $p = 0.0122$.

One Level IV study by Gazielly et al. assessed the effect of age in patients undergoing surgical repair of a full-thickness rotator cuff tear. Authors report no statistically significant relationship between age and re-tear ($p = 0.063$).

DASH

One Level IV study by Milano et al. assessed the effect of age in patients undergoing repair of a full-thickness tear. Authors report a statistically significant relationship between age and the DASH score using univariate analyses (see Table 35).

Table 36 Correlation between age and post-operative DASH score

	Age	
	r	p-value
DASH	0.255	0.032

As reported by authors.

WORK-DASH

One Level IV study by Milano et al. assessed the effect of age in patients undergoing repair of a full-thickness tear. Authors report no statistically significant effect of age on the Work-DASH score using univariate analyses (see Table 36). The Work-DASH is an optional module of the DASH that measures work capacity.

Table 37 Correlation between age and post-operative Work-DASH score

	Age	
	r	p-value
Work-Dash	0.127	0.292

As reported by authors.

SF-36

One Level IV study by Mckee et al.⁸⁸ assessed the effect of age in patients undergoing surgical repair of rotator cuff disease (defined as impingement or tearing, or both). Authors report age was not a statistically significant predictor of post-operative SF-36 score ($p = 0.55$).

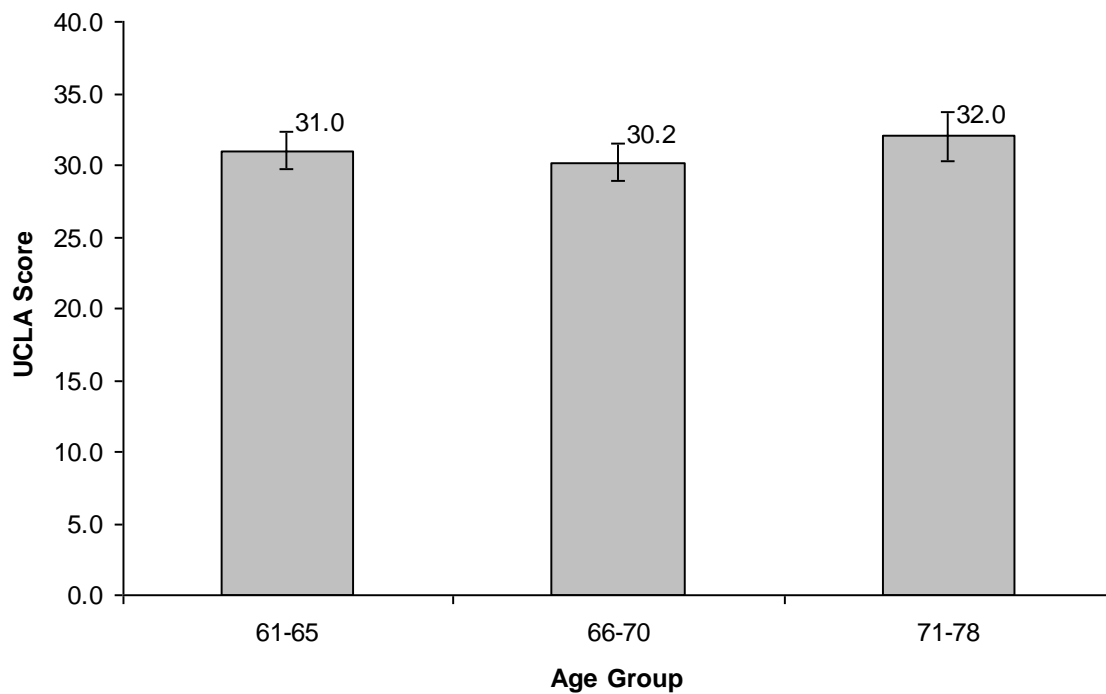
UCLA SCORE

Four Level IV studies examined the relationship between patient age and UCLA Score.

One Level IV study by Lahteenmaki et al. assessed the effect of age in patients undergoing surgical repair of a full-thickness rotator cuff tear. Authors report no statistically significant relationship between patient age and post-operative UCLA Score ($p = 0.41$).

One Level IV study by Rebuzzi et al. assessed the effect of age in patients undergoing arthroscopic repair of rotator cuff tear. Authors report no statistically significant difference between groups on post-operative UCL Score by age group ($p = 0.40$; see Figure 89).

Figure 89 Post-operative UCLA Score by age group

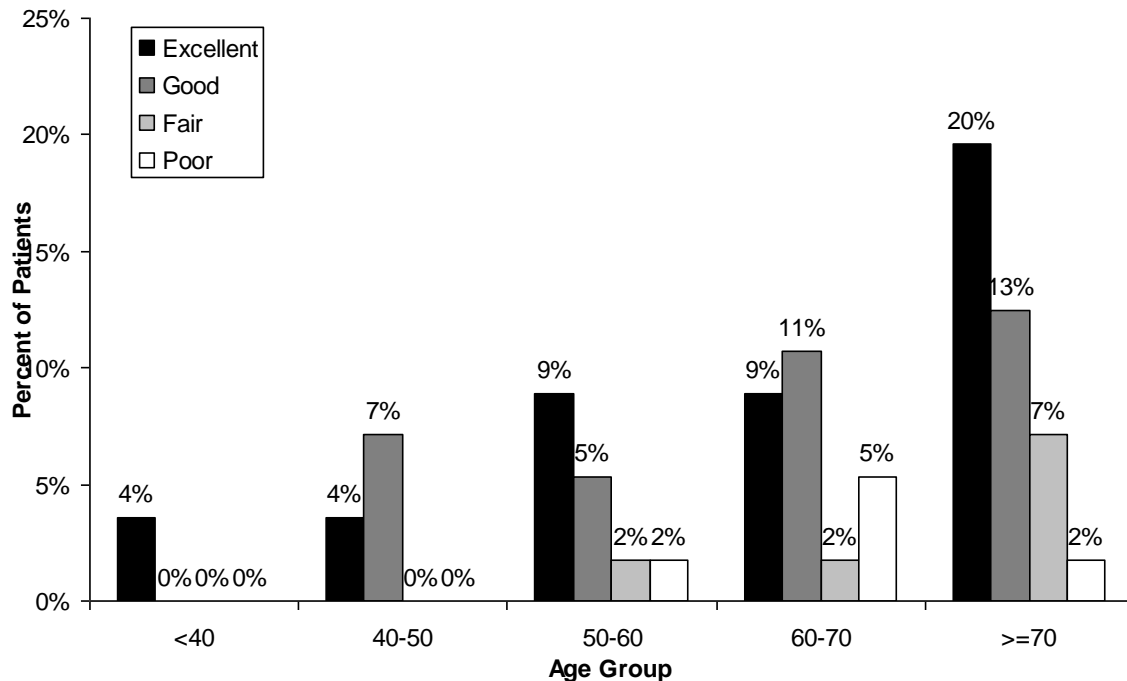


One Level IV study by Pai et al. assessed the effect of age in patients undergoing surgical repair of a full-thickness rotator cuff tear. Authors report, “no significant correlation of poor outcome with old age” (see Table 37 and Figure 90).

Table 38 Patient rating according to UCLA Scale by age group

Age	n	UCLA Results			
		Excellent	Good	Fair	Poor
<40	2	2	0	0	0
40-50	6	2	4	0	0
50-60	10	5	3	1	1
60-70	15	5	6	1	3
>=70	23	11	7	4	1

Figure 90 UCLA Score rating by age group

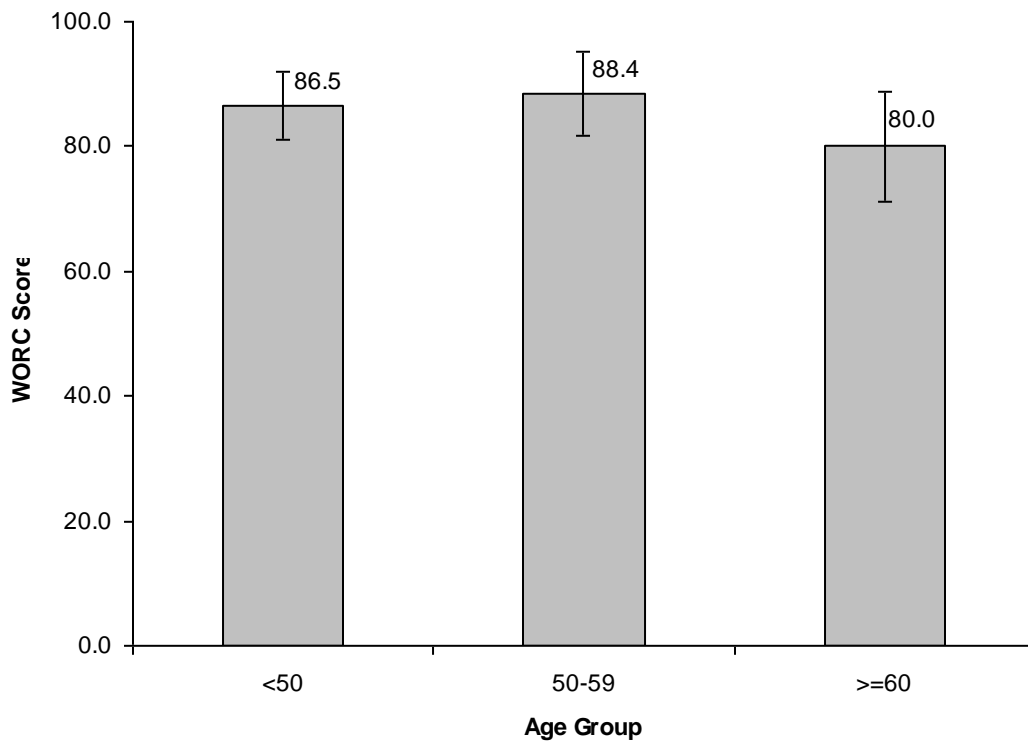


One Level IV study by Gartsman et al. assessed the effect of age in patients undergoing arthroscopic repair of a full-thickness rotator cuff tear. Authors reported no statistically significant correlation between age and post-operative UCLA Score ($r = -0.157, ns$).

WORC

One Level IV study by Baysal et al. assessed the effect of age in patients undergoing mini-open repair of a full-thickness rotator cuff tear. Authors report no statistically significant difference between groups on post-operative WORC score by age group (see Figure 91).

Figure 91 Post-operative WORC score by age group

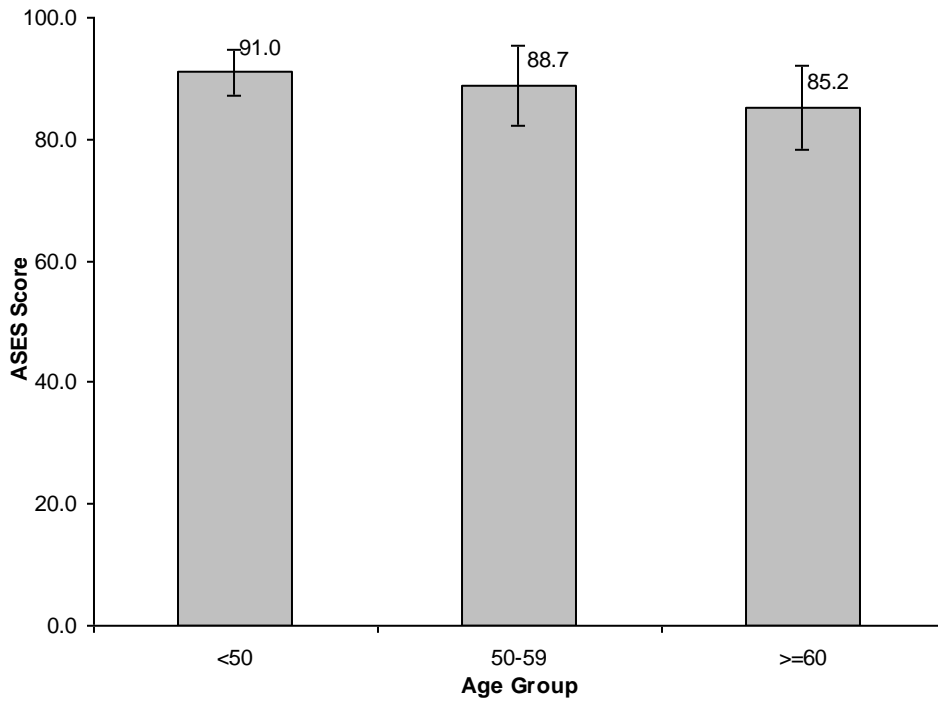


Authors report no statistically significant difference between groups.

ASES SCORE

One Level IV study by Baysal et al. assessed the effect of age in patients undergoing mini-open repair of a full-thickness rotator cuff tear. Authors report no statistically significant difference between groups on post-operative ASES score by age group ($p > 0.05$; see Figure 92).

Figure 92 Post-operative ASES score by age group



Authors report no statistically significant difference between groups, $p > 0.05$.

MODIFIED AMERICAN SHOULDER & ELBOW SURGEONS (M-ASES)

One Level IV study by Mckee et al. assessed the effect of age in patients undergoing surgical repair of rotator cuff disease (defined as impingement or tearing, or both). Authors report no statistically significant effect of age on the M-ASES score ($p = 0.43$ to 0.65) [sic]. Authors assessed the effect of age on all outcomes and reported studies with no statistically significant results as a p-value range.

SHOULDER PAIN & DISABILITY INDEX (SPADI)

One Level IV study by Mckee et al. assessed the effect of age in patients undergoing surgical repair of rotator cuff disease (defined as impingement or tearing, or both). Authors report age was not a statistically significant predictor of post-operative SPADI score ($p = 0.43$ to 0.65) [sic]. Authors assessed the effect of age on all outcomes and reported studies with no statistically significant results as a p-value range.

SHOULDER SEVERITY INDEX (SSI)

One Level IV study by Mckee et al. assessed the effect of age in patients undergoing surgical repair of rotator cuff disease (defined as impingement or tearing, or both). Authors report age was not a statistically significant predictor of post-operative SSI score ($p > 0.40$).

SUBJECTIVE SHOULDER-RATING SCALE (SSRS)

One Level IV study by Mckee et al. assessed the effect of age in patients undergoing surgical repair of rotator cuff disease (defined as impingement or tearing, or both). Authors report age was not a statistically significant predictor of post-operative SSRS score ($p = 0.43$ to 0.65) [sic]. Authors assessed the effect of age on all outcomes and reported studies with no statistically significant results as a p-value range.

SST

One Level IV study by Mckee et al. assessed the effect of age in patients undergoing surgical repair of rotator cuff disease (defined as impingement or tearing, or both). Authors report age was not a statistically significant predictor of post-operative SST score ($p = 0.43$ to 0.65) [sic]. Authors assessed the effect of age on all outcomes and reported studies with no statistically significant results as a p-value range.

TREATMENT RESPONSE

One Level IV study by Hattrup et al. assessed the effect of age in patients undergoing surgical repair of a full-thickness rotator cuff tear. Surgical results were classified as excellent (no or mild discomfort, active abduction of at least 145° and active external rotation of 55°), satisfactory (occasional moderate discomfort, active abduction of more than 100° and external rotation of 30°) or unsatisfactory (all other patients and those dissatisfied with their results). Authors report that patients with excellent results ($n = 88$) were statistically significantly younger than those with non-excellent results ($n = 16$; 69 years vs. 65 years respectively; Wilcoxon rank-sum, $p = 0.018$)

CLINICAL OUTCOME

One Level IV study by Lafosse et al. assessed the effect of age in patients undergoing arthroscopic repair of an isolated subscapularis tear. Utilizing multiple-regression analysis, the authors report no statistically significant relationship between age and the patients' ultimate clinical outcome. Authors do not provide significance values or define "clinical outcome."

One Level IV study by Murray et al. assessed the effect of age in patients undergoing arthroscopic repair of an isolated subscapularis tear. Authors report no statistically significant correlation between age and outcome scores ($r > 0.6$). Authors do not specify which outcome scores were examined.

One Level IV study by Namdari et al. assessed the effect of age in patients undergoing open repair of traumatic anterosuperior rotator cuff tears. Authors report no statistically significant correlation between age and outcome. Authors do not provide significance values or define "outcome."

One Level IV study by Worland et al. utilized multivariate logistic regression in examining patients aged 80 or greater. All patients had undergone open repair of a massive rotator cuff tear. Authors reported, "The multivariate logistic regression analysis showed that no preoperative variable was independently associated with a favorable outcome." Authors do not specify which outcome was examined or define favorable.

SUPPORTING EVIDENCE- MRI TEAR CHARACTERISTICS

Tables relevant to this recommendation are: Figure 93 through Figure 95
Figures relevant to this recommendation are: Table 39 through Table 42

MRI TEAR CHARACTERISTICS - DATA

ASES SCORE

One Level IV study by Gladstone et al. assessed patients undergoing open, mini-open or arthroscopic repair of a full thickness rotator cuff tear and patient pre-operative muscle quality (muscle atrophy and fatty infiltration). Muscle atrophy was graded using a system by Warner and fatty infiltration was graded using a system by Goutallier. The authors first examined the correlation between preoperative muscle quality and post-operative Constant-Murley score. The authors then performed a stepwise regression analysis and found muscle atrophy and fatty infiltration of the infraspinatus to be a statistically significant predictor of the ASES score ($p = 0.001$ and $p = 0.01$ respectively). Muscle atrophy and fatty infiltration of the supraspinatus was not a statistically significant predictor of the ASES score. The authors did not provide regression coefficients.

Table 39 Correlation of muscle quality and ASES score

		ASES Score	
		r	p-value
Infraspinatus	FI	-0.364	0.027
	MA	-0.401	0.014
Supraspinatus	FI	-0.231	0.17
	MA	-0.354	0.034

MA = muscle atrophy; FI = fatty infiltration

CONSTANT-MURLEY SCORE

Three Level IV studies assessed pre-operative muscle atrophy and fatty infiltration in relation to the post-operative Constant-Murley score.

Gladstone et al. assessed patients undergoing open, mini-open or arthroscopic repair of a full thickness rotator cuff tear and patient pre-operative muscle quality (muscle atrophy and fatty infiltration). Muscle atrophy was graded using a system by Warner and fatty infiltration was graded using the Goutallier staging system. The authors first examined the correlation between preoperative muscle quality and post-operative Constant-Murley score. The authors then performed a stepwise regression analysis and found muscle atrophy (but not fatty infiltration) of the infraspinatus is a statistically significant predictor of the Constant-Murley score ($p = 0.033$). Muscle atrophy and fatty infiltration of the supraspinatus was not a statistically significant predictor of the Constant-Murley score. Regression coefficients were not provided by the authors.

Table 40 Correlation of muscle quality and Constant-Murley score

		Constant-Murley score	
		r	p-value
Infraspinatus	FI	-0.359	0.029
	MA	-0.440	0.006
Supraspinatus	FI	-0.236	0.160
	MA	-0.402	0.015

MA = muscle atrophy; FI = fatty infiltration

Shen et al. assessed patients undergoing mini-open repair of a rotator cuff tear. Authors assessed atrophy by calculating a ratio between the atrophic and total area (A/T ratio). AAOS calculations found postoperative Constant-Murley score was statistically significantly correlated to pre-operative A/T ratios with greater atrophy of the supraspinatus and subscapularis being associated with a poorer outcome.

Table 41 Correlation of muscle quality and Constant-Murley score

	Constant-Murley score	
	r	p-value
Infraspinatus & teres minor	0.1934	0.3339
Subscapularis	0.5612	0.0023
Supraspinatus	0.6146	0.0006

Gerber et al. assessed patients undergoing surgical repair of a full-thickness supraspinatus tear. Authors assessed fatty infiltration according to the Goutallier staging system. AAOS calculations found no statistically significant correlation between pre-operative fatty infiltration and postoperative Constant-Murley.

Table 42 Correlation of fatty infiltration and Constant-Murley score

	Constant-Murley score	
	r	p-value
Infraspinatus	-0.264	0.384
Subscapularis	0.263	0.385
Supraspinatus	-0.120	0.696

UCLA SCORE

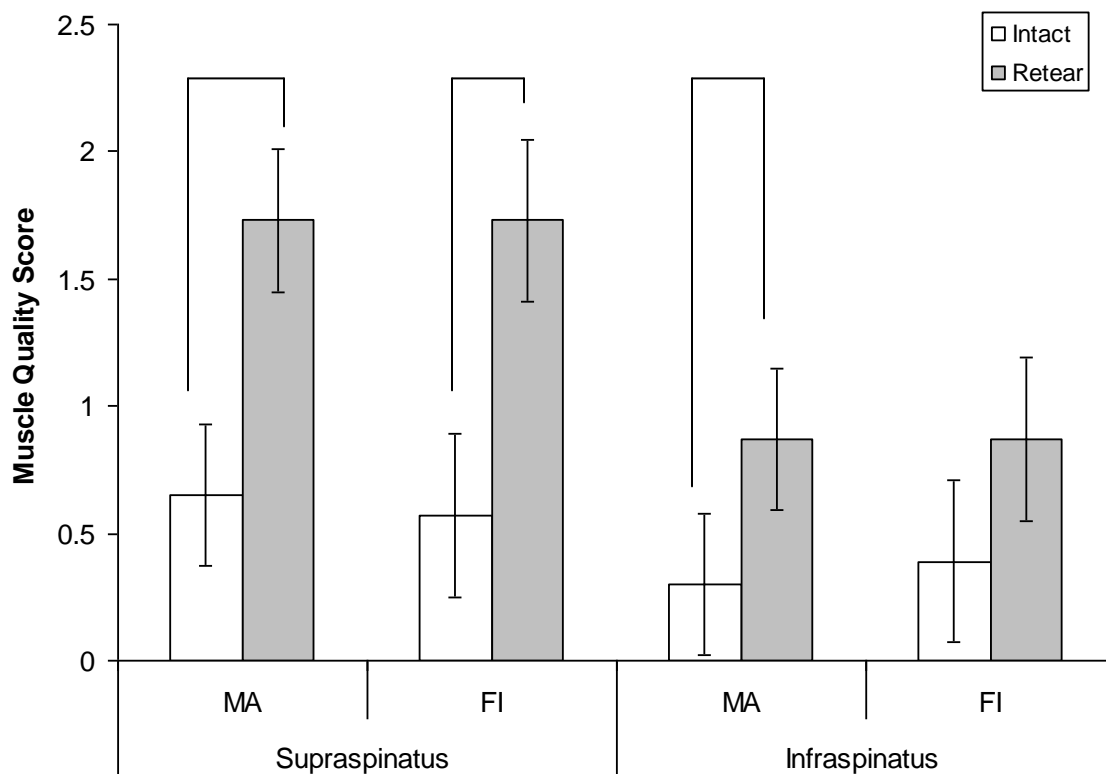
One Level IV study by Mellado et al. correlated preoperative fatty degeneration and postoperative UCLA Score. Twenty-eight patients diagnosed as having massive rotator cuff tears were surgically repaired. Diagnosis was confirmed intraoperatively and complete repair was performed whenever possible. Prior to surgery muscle degeneration and atrophy were assessed using MRI. Authors report preoperative fatty degeneration of the infraspinatus muscle was negatively correlated with the postoperative UCLA Score ($r = -0.4, p = 0.03$). Authors report no additional preoperative muscle disease characteristics in relation to postoperative outcomes.

RE-TEAR

Three Level IV studies assessed pre-operative muscle atrophy and fatty infiltration in relation to post-operative re-tear rates.

Gladstone et al. assessed patients undergoing open or arthroscopic repair of a full thickness rotator cuff tear and patient pre-operative muscle quality (muscle atrophy and fatty infiltration). Muscle atrophy was graded using a system by Warner and fatty infiltration was graded using a system by Goutallier whereby higher scores indicate greater atrophy or infiltration. The authors examined pre-operative muscle quality scores and patients who develop re-tears post-operatively.

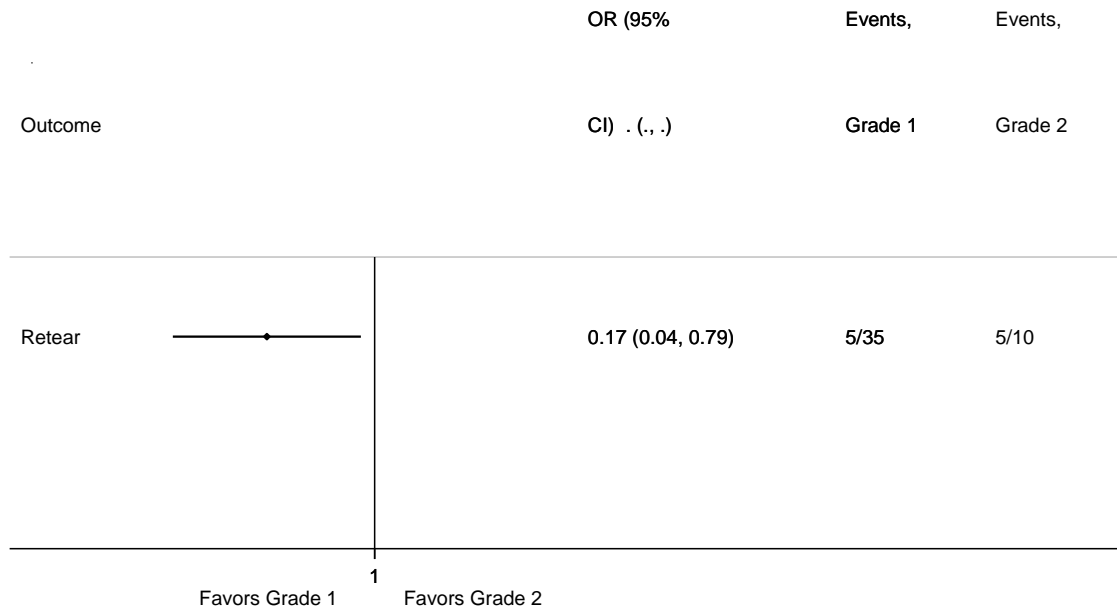
Figure 93 Pre-operative muscle quality in patients with and without re-tears



* Authors report, $p < .01$; ** Authors report, $p < .05$; MA = muscle atrophy ; FI = fatty infiltration ; AAOS calculated confidence intervals uses standard deviation estimated from range.

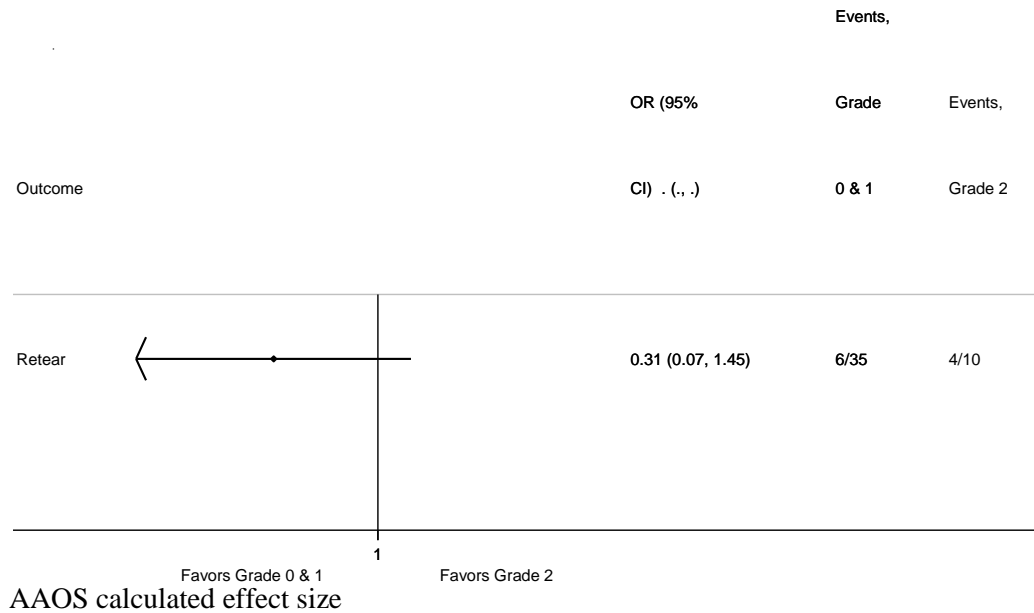
Liem et al. assessed patients undergoing arthroscopic repair of an isolated supraspinatus tear and pre-operative muscle quality. Supraspinatus atrophy was graded using a system by Thomazeau and fatty infiltration was graded using a system by Goutallier. Authors compared post-operative re-tear rates in patients with grade one supraspinatus atrophy to those with grade two and report a statistically significant effect favoring Grade 1 ($p = 0.018$; see Figure 5). Additionally, authors compared post-operative re-tear rates in patients with either stage zero or one to patients with stage two fatty infiltration and report a statistically significant effect favoring Stage 0 and 1 ($p = 0.021$); however, AAOS calculations failed to find a statistically significant effect.

Figure 94 Re-tear occurrence by supraspinatus atrophy grade



AAOS calculated effect size

Figure 95 Re-tear occurrence by fatty infiltration stage



Thomazeau et al.⁵² report, "...preoperative atrophy of the supraspinatus muscle was the main anatomic predictive factor for a postoperative re-tear ($p = 0.0028$).” The value of the correlation coefficient could not be determined.

SUPPORTING EVIDENCE- WORKERS' COMPENSATION STATUS

Tables relevant to this recommendation are: Table 43

Figures relevant to this recommendation are: Figure 96 through Figure 102

WORKERS' COMPENSATION STATUS - DATA

Table 43 Results of patients with or without workers' compensation

Authors	LoE	n	Comparison	Outcome	Duration		
					32 months*	36 months**	45 months***
Nicholson	II	106	Workers Compensation vs. Non-workers' Compensation	Pain: VAS	●non		
Nicholson	II	106		ASES	?		
Nicholson	II	106		SST	●non		
Lopez et al.	III	23		Pain: UCLA		●non	
Lopez et al.	III	23		Function: UCLA		○	
Misamore et al.	III	103		UCLA Score			●non

? = not sufficiently powered to detect MCI; neither statistically or clinically significant

○ = no statistically significant difference

● = statistically significant difference

non = favors non-workers' compensation patients

ASES = American shoulder and elbow score

SST = Simple shoulder test

LoE = Level of Evidence

* = final visit 32 ± 0.49 months after baseline

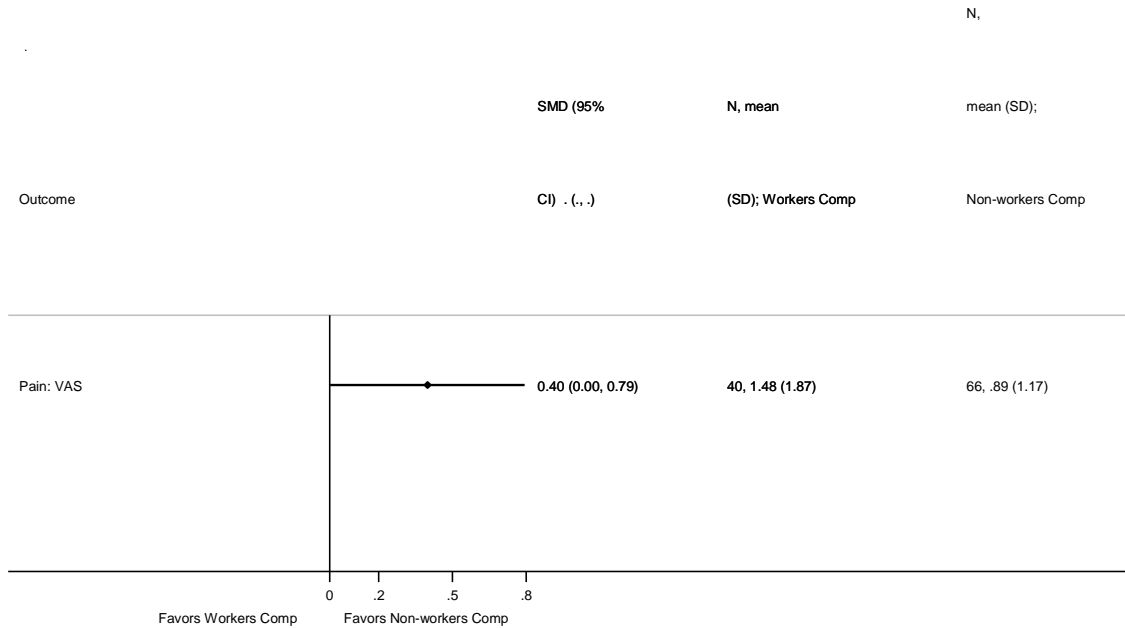
** = final visit 36.8 ± 1.27 months after baseline

*** = final visit 45 ± 0.64 months after baseline

PAIN: VAS

One Level II study by Nicholson compared pain scores (measured by VAS) in patients receiving workers' compensation to those not receiving workers' compensation after arthroscopic subacromial decompression. The author reports no statistically significant difference between groups in post-operative pain scores ($p = 0.0807$); however, AAOS calculations do not confirm this finding ($ES = 0.40$, 95% CI 0.001 – 0.79; see Figure 96).

Figure 96 Pain as measured by VAS in patients receiving or not receiving workers' compensation

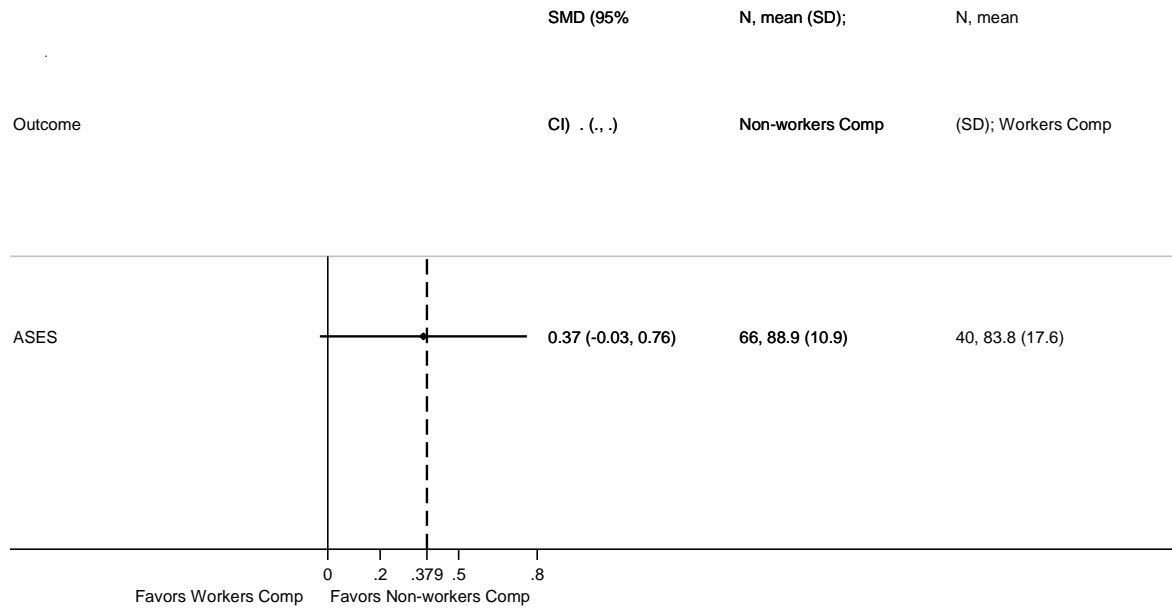


AAOS calculated effect size

ASES SCORE

One Level II study by Nicholson compared ASES scores in patients receiving workers' compensation to those not receiving workers' compensation after arthroscopic subacromial decompression. The author reports no statistically significant difference between groups in post-operative ASES scores ($p = 0.1080$; see Figure 97).

Figure 97 ASES score in patients receiving or not receiving workers' compensation

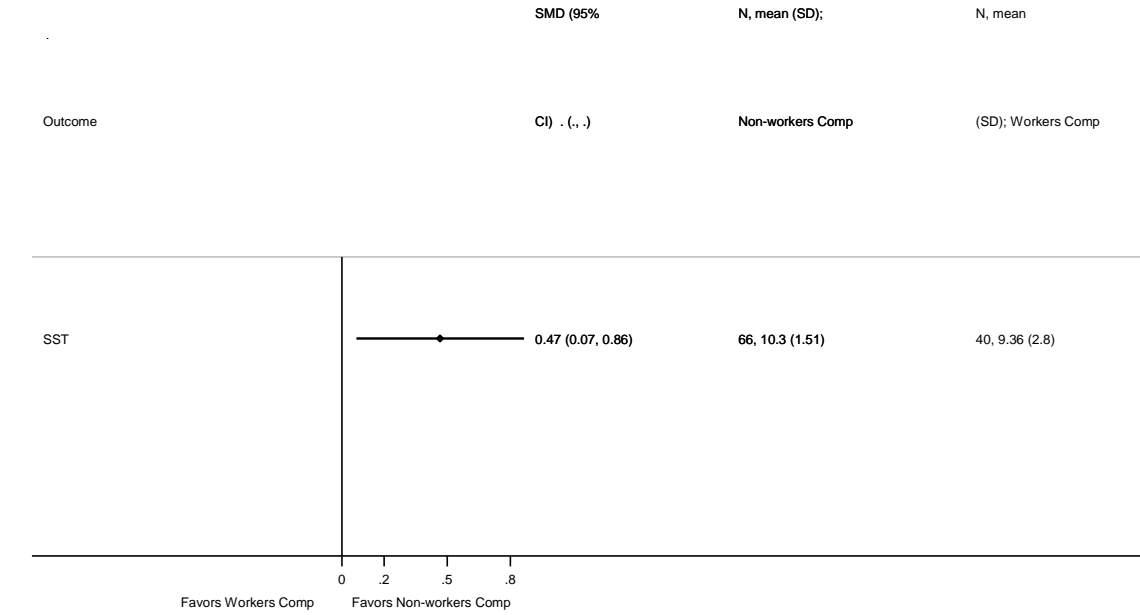


AAOS calculated effect size; MCII indicated by dashed line; this study was not sufficiently powered to detect the MCII therefore, its' results are inconclusive.

SST

One Level II study by Nicholson compared SST scores in patients receiving workers' compensation to those not receiving workers' compensation after arthroscopic subacromial decompression. The author reports no statistically significant difference between groups in post-operative SST scores ($p = 0.0501$); however, AAOS calculations do not confirm this finding (ES = 0.47, 95% CI 0.07 – 0.86; see Figure 98).

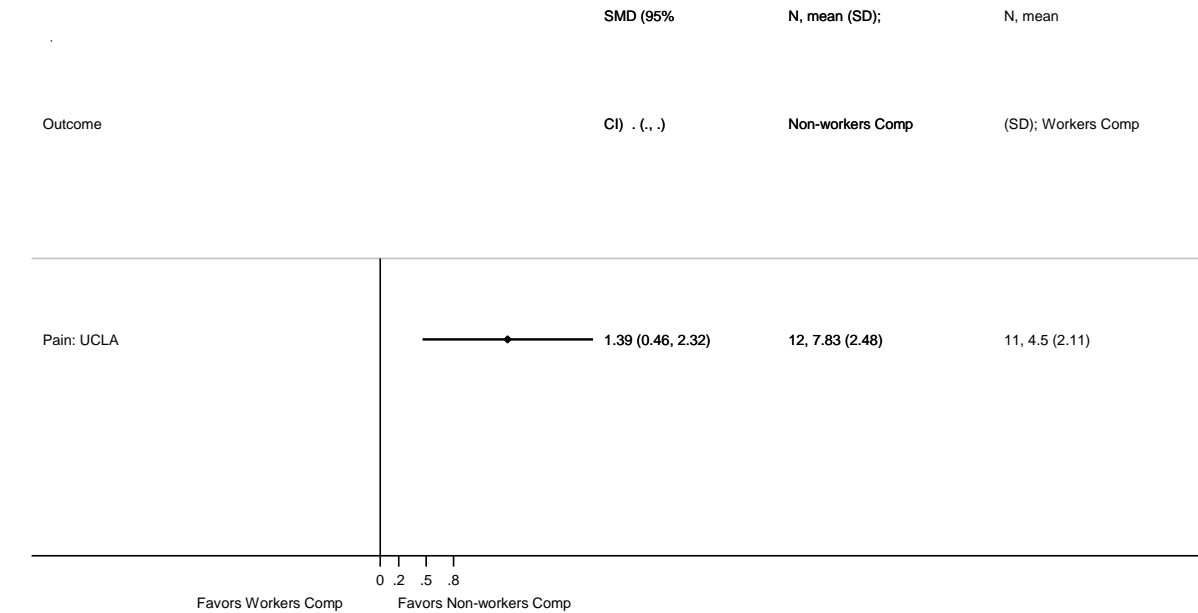
Figure 98 SST score in patients receiving or not receiving workers' compensation



PAIN: UCLA SCORE

One Level III study by Lopez et al. assessed pain measured by UCLA Score in patients receiving workers' compensation to those not receiving workers' compensation after acromioplasty (performed either open or arthroscopically). The authors report a statistically significant difference between groups in post-operative pain ($p < 0.0003$; see Figure 99).

Figure 99 Pain as measured by UCLA Score in patients receiving or not receiving workers' compensation

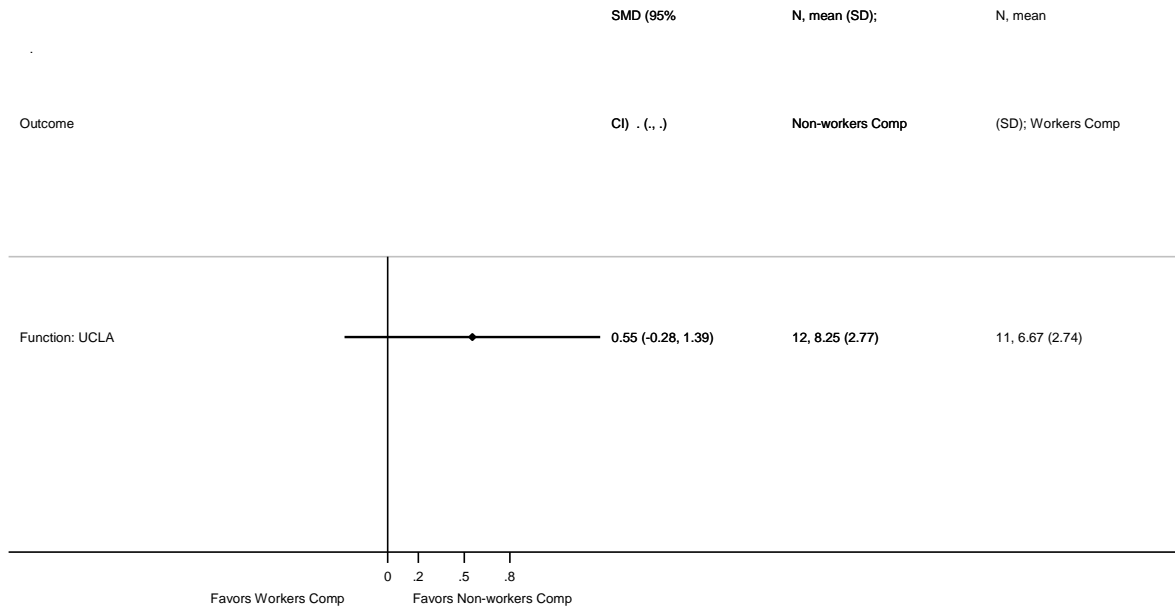


AAOS calculated effect size

FUNCTION: UCLA SCORE

One Level III study by Lopez et al. assessed function measured by UCLA Score in patients receiving workers' compensation to those not receiving workers' compensation after acromioplasty (performed either open or arthroscopically). The authors report a statistically significant difference between groups in post-operative function ($p < 0.0404$) [sic]; however, AAOS calculations do not confirm this finding (ES = 0.55, 95% CI -0.28 – 1.39; see Figure 100).

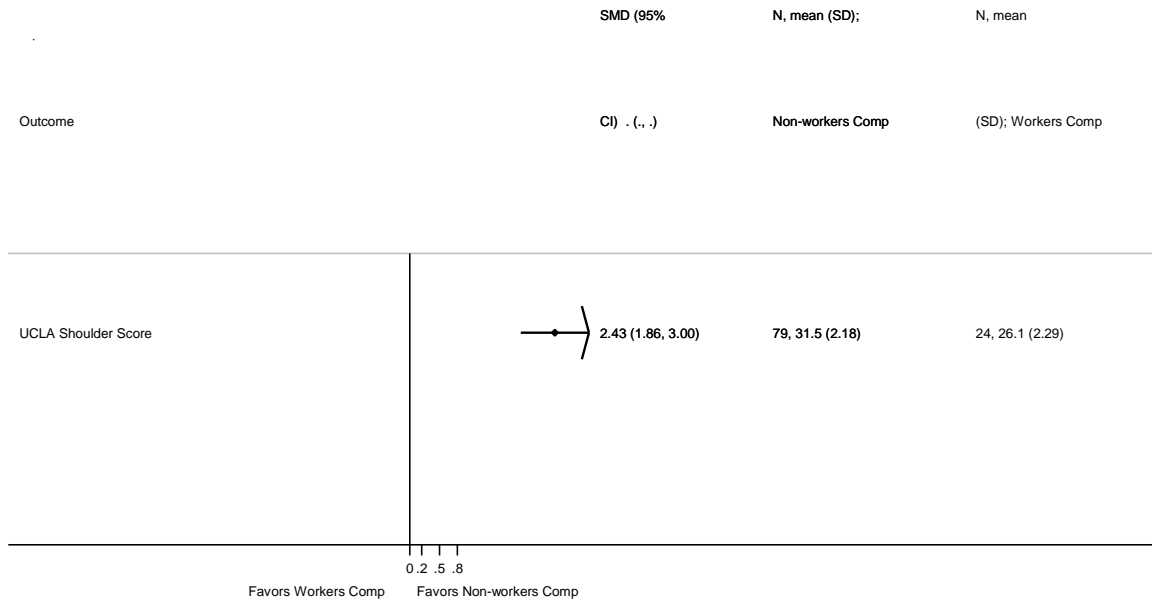
Figure 100 Function as measured by UCLA Score in patients receiving or not receiving workers' compensation



UCLA SCORE

One Level III study by Misamore et al. compared overall surgical outcome (measured by UCLA Score) in patients receiving workers' compensation to the outcomes of those not receiving workers' compensation after rotator cuff repair (see Figure 101). The authors report a statistically significant difference between groups in post-operative UCLA Scores ($p < 0.0004$) [sic].

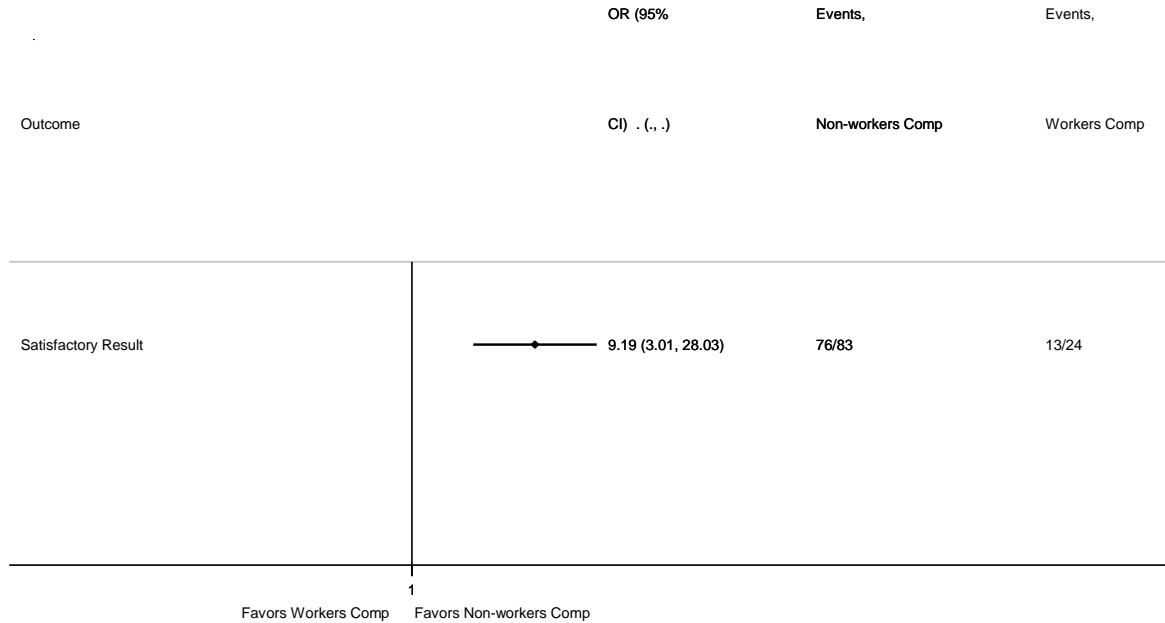
Figure 101 UCLA Score in patients receiving or not receiving workers' compensation



AAOS calculated effect size; 95% confidence interval calculated using a standard deviation estimated from range.

Misamore et al. categorized post-operative UCLA Scores as excellent (34-35), good (28-33), fair (21-27) or poor (0-20). An excellent or good result was considered a satisfactory result while a fair or poor result was considered an unsatisfactory result (see Figure 102). AAOS calculations, using authors' groupings, found a statistically significant result with non-workers' compensation patients having greater satisfaction than patients with workers' compensation (EOR= 9.19, 95% CI 3.01 – 28.03; see Figure 102).

Figure 102 UCLA score categorized as satisfactory or unsatisfactory



AAOS calculated effect size

RECOMMENDATION 7B: CONFOUNDING FACTORS - DIABETES, CO-MORBIDITIES, SMOKING, INFECTION, AND CERVICAL DISEASE

We cannot recommend for or against advising patients in regard to the following factors related to rotator cuff surgery:

- Diabetes
- Co-morbidities
- Smoking
- Prior Shoulder Infection
- Cervical Disease

Confounding Factor	Strength of Recommendation	Level of Evidence
Diabetes	Inconclusive	III
Co-morbidities	Inconclusive	IV
Smoking	Inconclusive	Insufficient
Infection	Inconclusive	Insufficient
Cervical Disease	Inconclusive	Insufficient

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Various patient-related factors may influence clinical outcomes after rotator cuff surgery. These factors may affect functional outcomes or tendon healing, hence the work group systematically searched for data on diabetes, smoking, co morbidities, prior shoulder infection and cervical disease.

Two Level III studies^{97,98} compared the outcomes of diabetic and non-diabetic individuals after rotator cuff surgery. One study⁹⁸ found no statistically significant difference between the two groups on postoperative stiffness using the Constant Murley Score at 46 months. The second study⁹⁷ found a statistically significant difference and possible clinically important difference in the ASES score favoring patients without diabetes. This study found no statistically significant difference in the occurrence of infection between the two groups of patients. Since these studies assessed different outcomes with varying results, the work group found this evidence inconclusive.

One Level IV study⁷³ assessed the effect of medical co-morbidities in patients undergoing open repair of traumatic anterosuperior rotator cuff tears. The authors reported no statistically significant correlation between medical co-morbidities and outcome. They did not provide significance values or define “outcome.” Again, the work group evaluated this as a single study that contained limited evidence. They concluded overall that the evidence is inconclusive concerning the presence of medical co-morbidities and patient outcomes.

There were no studies found that addressed the effects of smoking, prior shoulder infection, or cervical disease as they relate to rotator cuff surgery outcomes.

Although we found no specific evidence demonstrating a significant effect for any of these factors, neither did we find evidence that the above factors had no effect on clinical outcomes after rotator cuff surgery. Therefore, the work group found there to be inconclusive evidence regarding the affects (either positive or negative) of these factors on outcomes after rotator cuff surgery.

SUPPORTING EVIDENCE- DIABETES

Tables relevant to this recommendation are: Table 44

Figures relevant to this recommendation are: Figure 103 through Figure 105

DIABETES

Table 44 Results of patients with or without diabetes

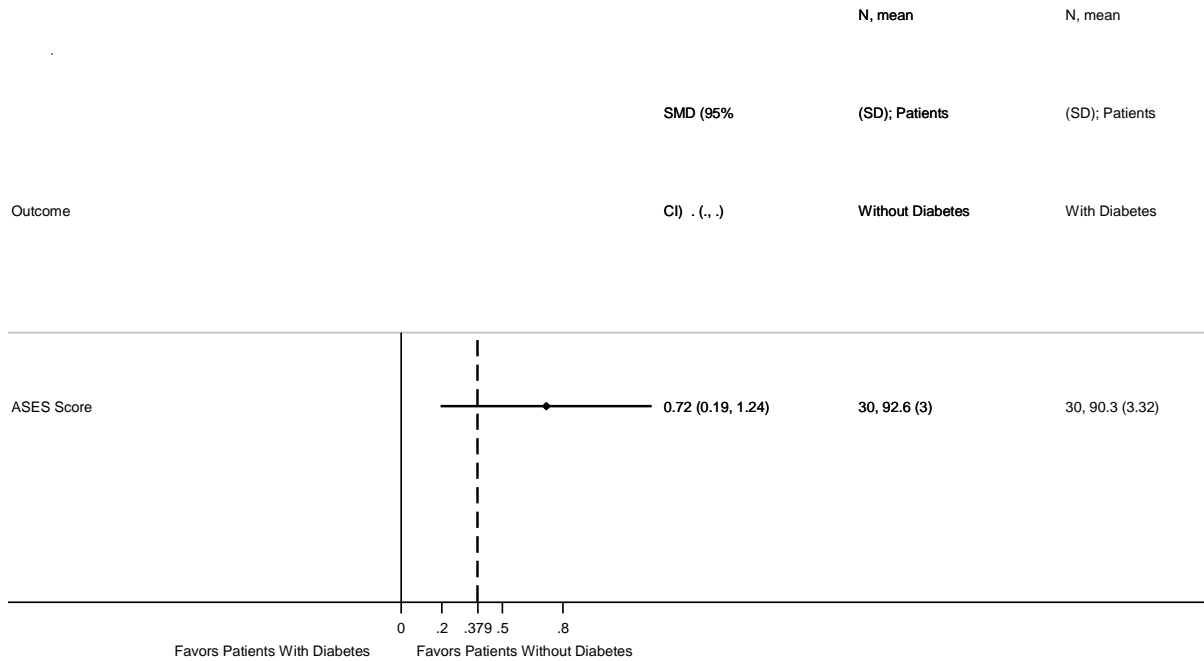
Author	LoE	n	Comparison	Outcome	Duration	
					33 months*	46 months**
Chen et al.	III	60	Patients with diabetes vs. Patients without diabetes	ASES Score	◐wo	
Hsu et al.		43		Constant Score		○
Chen et al.		60		Infection	○	

- = no statistically significant difference
- ◐ = statistically significantly and possibly clinically important
- wo = favoring patients without diabetes
- *** = possibly clinically important
- LoE = level of evidence
- * = final visit 33 ± 1.01 months
- ** = final visit 46 ± 5.38 months

ASES SCORE

One Level III study by Chen et al. assessed post-operative ASES scores in patients with or without diabetes. All patients underwent open surgical repair of full-thickness rotator cuff tears. Authors report no statistically significant difference between groups on overall ASES scores; however, AAOS calculations fail to confirm this finding (ES = 0.72, 95% CI 0.19 – 1.24; see Figure 103).

Figure 103 ASES score in patients with or without diabetes

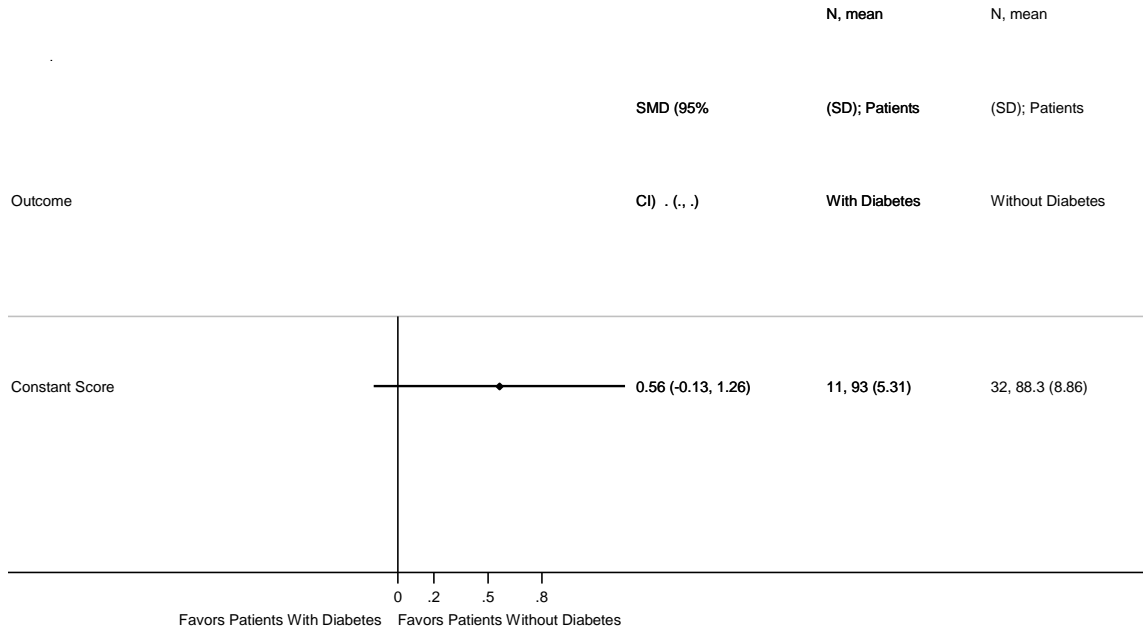


AAOS calculated effect size; MCII indicated by dashed line; this study was not sufficiently powered to detect the MCII, its' results are possibly clinically important; 95% confidence interval calculated using a standard deviation estimated from range.

CONSTANT-MURLEY SCORE

One Level III study by Hsu et al. assessed post-operative Constant-Murley scores in patients with or without diabetes. All patients were diagnosed and surgically treated for a rotator cuff tear with concomitant shoulder stiffness. Authors report no statistically significant difference between groups post-operatively on the Constant-Murley score ($p = 0.123$; see Figure 104).

Figure 104 Constant-Murley score in patients with or without diabetes

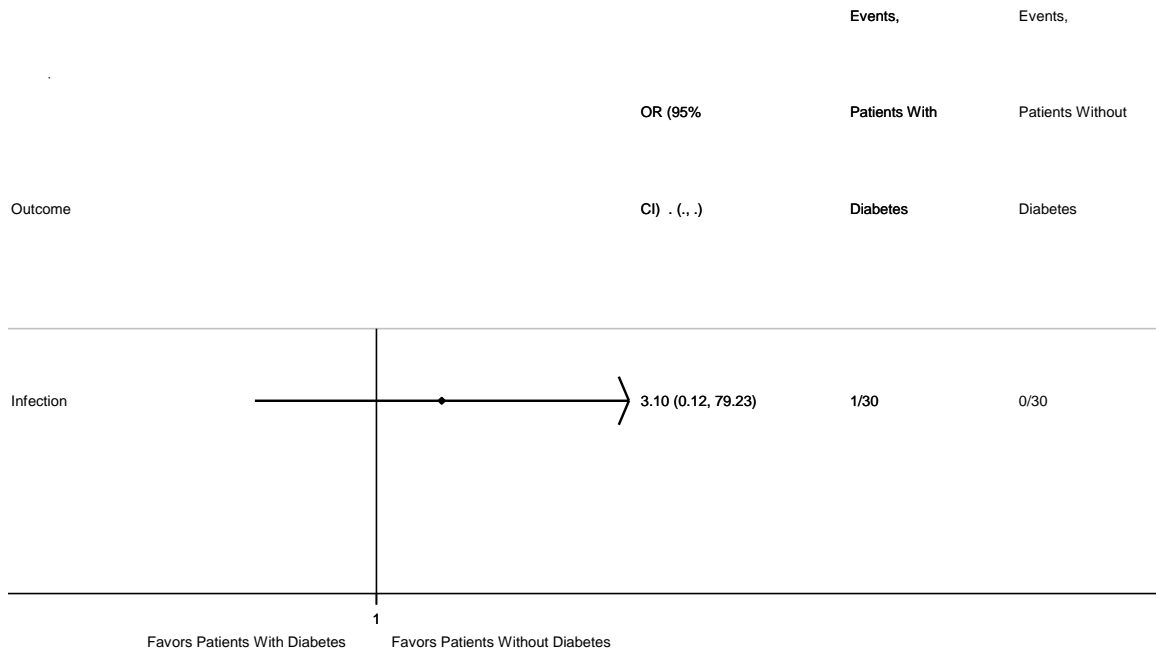


AAOS calculated effect size

INFECTIONS

One Level III study by Chen et al.¹⁰⁰ assessed occurrence of infection in patients with or without diabetes (see Figure 105). All patients underwent open surgical repair of full-thickness rotator cuff tears. One patient with diabetes experienced an infection (defined by local wound erythema and tenderness). No infectious complications were observed in patients without diabetes.

Figure 105 Occurrence of infection in patients with or without diabetes



AAOS calculated effect size

SUPPORTING EVIDENCE- CO-MORBIDITIES

Tables relevant to this recommendation are: Table 45

Figures relevant to this recommendation are: None

MEDICAL CO-MORBIDITIES

Table 45 Studies addressing the effect of co-morbidities on outcome

Author	LoE	n	Outcome	Duration
				56 months*
Namdari et al.	IV	30	Clinical Outcome**	○

○ = no statistically significant difference

* = final visit 56 ± 4 months after baseline

** = clinical outcome not defined

LoE = level of evidence

One Level IV study by Namdari et al. assessed the effect of medical co-morbidities in patients undergoing open repair of traumatic anterosuperior rotator cuff tears. Authors report no statistically significant correlation between medical co-morbidities and outcome. Authors do not provide significance values, define “outcome,” or specify co morbidities considered.

SMOKING

There were no studies identified addressing smoking as it relates to rotator cuff surgery.

HISTORY OF INFECTION

There were no studies identified addressing a patient’s history of infection as it relates to rotator cuff surgery.

CERVICAL DISEASE

There were no studies identified addressing cervical disease as it relates to rotator cuff surgery.

RECOMMENDATION 8: SURGERY - ACROMIOPLASTY

We suggest that routine acromioplasty is not required at the time of rotator cuff repair.

Level of Evidence: II

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Rationale:

Acromioplasty and release of the coracoacromial ligament is often included as part of a rotator cuff repair. Theoretical benefits of an acromioplasty in the setting of a rotator cuff repair include increasing the subacromial space available to facilitate the repair and also relieving extrinsic compression on the repair after completion. Despite these theoretical benefits, one quality study¹⁰¹ suggests that an anterior acromioplasty has no effect on final outcomes after rotator cuff repair. Two studies^{89, 81} reviewed the results of removing acromial bone (Bigliani type II and III acromions) and did not find any benefit in postoperative functional results.

One Level II randomized prospective study⁸⁹ performed a comparison of 47 patients treated with an arthroscopic rotator cuff repair plus an associated anterior acromioplasty and coracoacromial ligament release with 46 patients who underwent rotator cuff repair alone. All patients had isolated supraspinatus rotator cuff tears with Bigliani type II acromion. The patients were evaluated preoperatively and an average of 15 months postoperatively with the American Shoulder and Elbow Surgeons Score. The authors reported no significant difference between groups of both final ASES scores and improvement from baseline. While these results suggest there was no difference in ASES scores between groups, this study was not sufficiently powered to detect the minimally clinically important improvement.

Another randomized, prospective study⁸¹ compared 40 patients treated with an arthroscopic rotator cuff repair, anterior acromioplasty and coracoacromial ligament release with 40 patients who underwent rotator cuff repair alone. All patients had a repairable full thickness tear and either a Bigliani type II or III acromion. At two years postoperatively, the authors reported no significant differences in final Constant-Murley scores or DASH scores. The Constant-Murley scores are suggestive that acromioplasty has no effect on outcome. The work group considered the DASH result a true negative because this study was sufficiently powered to show the nonsignificant result was also

not clinically significant. These results suggest that acromioplasty has little or no effect on postoperative clinical outcomes; therefore it is not required for the management of normal acromial bone (including type II and III morphology at the time of rotator cuff repair).

Acromial spurs are independent from normal acromial bone. Spurs have been identified as acquired ossifications of the coracoacromial ligament on the undersurface of the acromion. This ossification is considered in excess of normal acromial bone and may have a pathological role in the process of rotator cuff disease. The work group recognizes that acquired acromial spurs are a topic of interest to many surgeons; however they are beyond the scope of the current guideline.

SUPPORTING EVIDENCE- ROUTINE ACROMIOPLASTY

Tables relevant to this recommendation are: Table 46 through Table 47

Figures relevant to this recommendation are: Figure 106 through Figure 109

ROUTINE ACROMIOPLASTY

Table 46 Results of repair with or without acromioplasty

Authors	LoE	n	Comparison	Outcome	Duration	
					6-12 Months	2 Years
Gartsman et al.	II	93	Acromioplasty vs. No Acromioplasty	ASES Score	○	
Milano et al.		80	Acromioplasty vs. No Acromioplasty	Normalized Constant-Murley Score		○
Milano et al.		80	Acromioplasty vs. No Acromioplasty	DASH Score		⊖
Milano et al.		80	Acromioplasty vs. No Acromioplasty	Work DASH Score		○

○ = no statistically significant difference

⊖ = not statistically or clinically significant

LoE = level of evidence

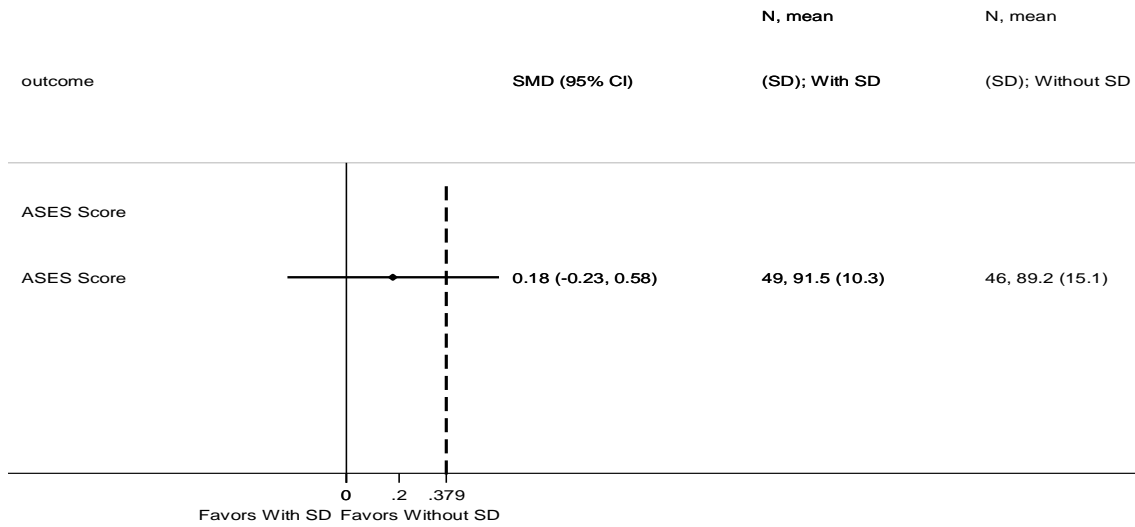
ASES = American shoulder and elbow score

DASH = disability of the arm, shoulder and hand

ASES SCORE

In one Level II study by Gartsman et al., ninety-three patients with full thickness supraspinatus tendon tears and type 2 acromion were randomized to receive either arthroscopic rotator cuff repair with subacromial decompression or without subacromial decompression. Shoulders were assessed using the ASES scoring system at either a 6 month or 1 year follow up. Results are neither statistically significant or clinically important³⁸ (see Figure 106).

Figure 106 ASES Score of patients with and without subacromonial decompression

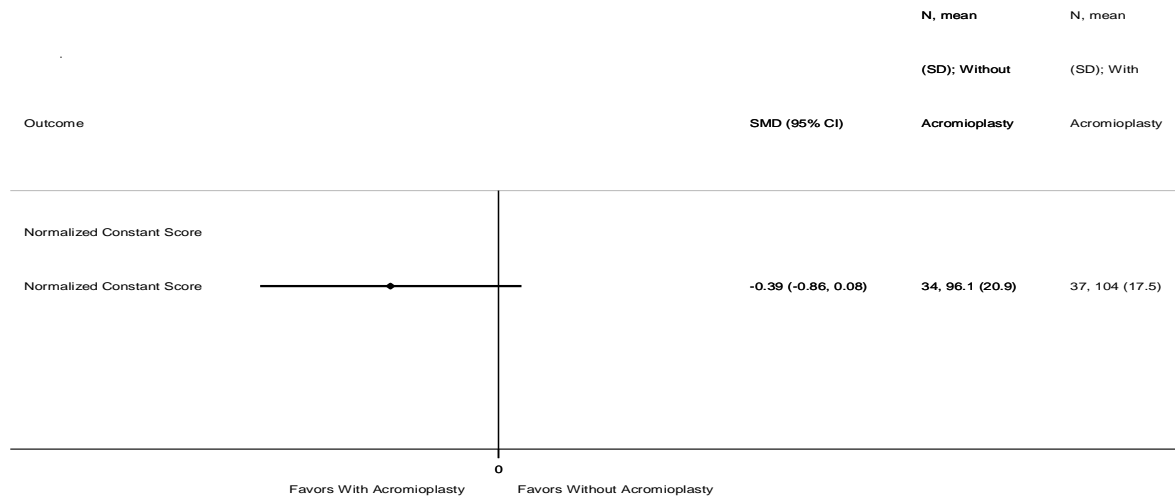


AAOS calculated effect size; Dashed line indicates MCII for ASES Score; This study was not sufficiently powered to detect the MCII therefore, its' results are inconclusive.

NORMALIZED CONSTANT-MURLEY SCORE

In one Level II study by Milano et al. eighty patients were randomized to receive either: arthroscopic rotator cuff repair and subacromial decompression, consisting of anterior-inferior acromioplasty, release of the coracoacromial ligament and subacromial bursectomy or repair with subacromial bursectomy only. Shoulders were assessed using the Normalized Constant-Murley Scoring System two years postoperatively. The results showed no statistically significant difference between rotator cuff repair surgery including acromioplasty and repair without acromioplasty (see Figure 107).

Figure 107 Normalized Constant-Murley Score

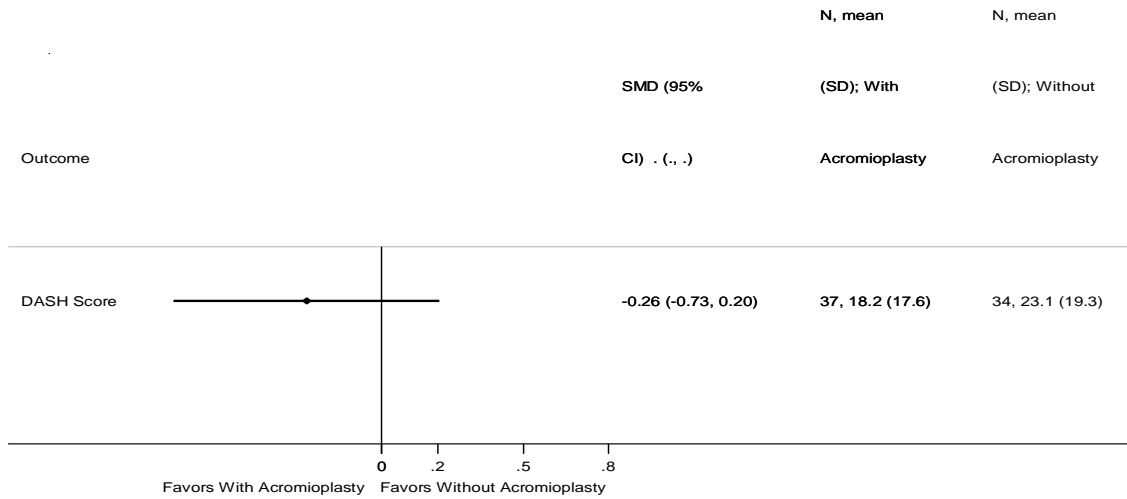


AAOS calculated effect size

DASH SCORE

In one Level II study by Milano et al. eighty patients were randomized to receive either: arthroscopic rotator cuff repair and subacromial decompression, consisting of anterior-inferior acromioplasty, release of the coracoacromial ligament and subacromial bursectomy or repair with subacromial bursectomy only. Shoulders were assessed using the DASH Score two years postoperatively (see Figure 108).

Figure 108 DASH Score

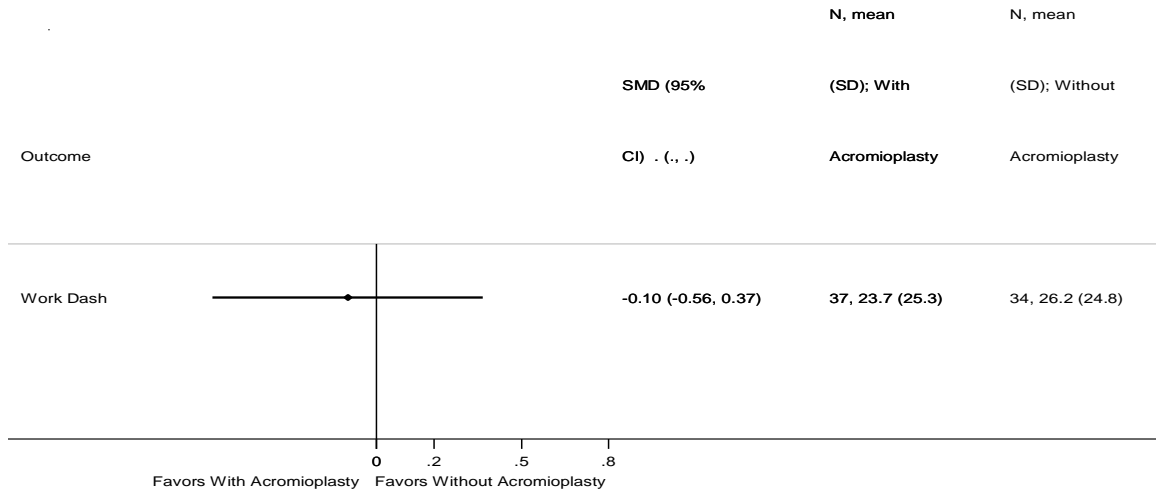


AAOS calculated effect size

WORK-DASH SCORE

In one Level II study by Milano et al., eighty patients were randomized to receive either: arthroscopic rotator cuff repair and subacromial decompression, consisting of anterior-inferior acromioplasty, release of the coracoacromial ligament and subacromial bursectomy or repair with subacromial bursectomy only. Shoulders were assessed using the Work-DASH score two years postoperatively (see Figure 109). The Work-DASH is an optional module of the DASH for work capacity.

Figure 109 Work-DASH score



AAOS calculated effect size

STRATIFICATIONS

Milano et al. utilized univariate analysis in examining stratifications pertaining to: age, gender, tear location, hand dominance and muscle degeneration. Authors reported the outcomes: Constant-Murley score, DASH and Work-DASH (see Table 47).

Table 47 Stratifications pertaining to anterior inferior acromioplasty

Stratification	Constant-Murley		DASH		Work-DASH	
	Linear Correlation	<i>p</i> -value	Linear Correlation	<i>p</i> -value	Linear Correlation	<i>p</i> -value
Age	-0.051	0.672	0.255	0.032	0.127	0.292
Gender	nr	0.603	nr	0.624	nr	0.441
Tear location	nr	0.333	nr	0.713	nr	0.34
Hand dominance	nr	0.216	nr	0.604	nr	0.899
Muscle degeneration	-0.168	0.161	0.197	0.1	0.297	0.012

nr = not reported by authors

RECOMMENDATION 9: SURGERY - PARTIAL ROTATOR CUFF REPAIR, DEBRIDEMENT, OR MUSCLE TRANSFER

It is an option to perform partial rotator cuff repair, debridement, or muscle transfers for patients with irreparable rotator cuff tears when surgery is indicated.

Level of Evidence: IV

Strength of recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Five Level IV⁹⁹⁻¹⁰³ studies addressed the use of operative debridement, limited repair, or muscle transfer for an irreparable rotator cuff tear. These studies found an improvement in pain and function after repair of a portion of a chronic full thickness rotator cuff tear when a complete repair can not be achieved.⁹⁹ They also found clinically important improvement with arthroscopic debridement without partial repair of the rotator cuff with or without release of the long head of the biceps¹⁰² and improvement in pain and function with transfer of the latissimus or teres major for irreparable tears involving the supraspinatus and infraspinatus tendons.¹⁰⁰ Comparative studies on the superiority of one surgical technique or option over another for surgical management of irreparable full thickness rotator cuff tears have not been reported. All studies reported intermediate term results 3-4 years after surgical treatment. Long term results were not reported. Complications reported after muscle transfer include temporary Complex Regional Pain Syndrome and cosmetic deformity of the biceps.

SUPPORTING EVIDENCE- OPERATIVE DEBRIDEMENT, LIMITED REPAIR, OR MUSCLE TRANSFER

Tables relevant to this recommendation are: Table 48 through Table 49

Figures relevant to this recommendation are: Figure 110 through Figure 115

Table 48 Results of operative debridement, limited repair, or muscle transfer

Authors	LoE	n	Comparison	Outcome	Duration (months)			
					30	31	36	40.7
Celli et al.	IV	20	Muscle Transfer: Change from baseline	Pain: Constant-Murley Score			●↑	
Burkhart		25	Debridement: Excellent/Good vs. Fair/Poor Results	UCLA Grade	nr			
Celli et al.		20	Muscle Transfer: Change from baseline	Constant-Murley Score			●↑	
Guyen et al.		14	Muscle Transfer: Change from baseline	Constant-Murley Score				●↑
Klinger et al. ¹⁰⁷		33	Debridement: Change from baseline	Constant-Murley Score		●↑		
Klinger et al. ¹⁰⁸		41	Debridement: Change from baseline	Constant-Murley Score		●↑		
Guyen et al.		14	Muscle Transfer: Change from baseline	Complications				nr

● = statistically significant result

↑ = improvement

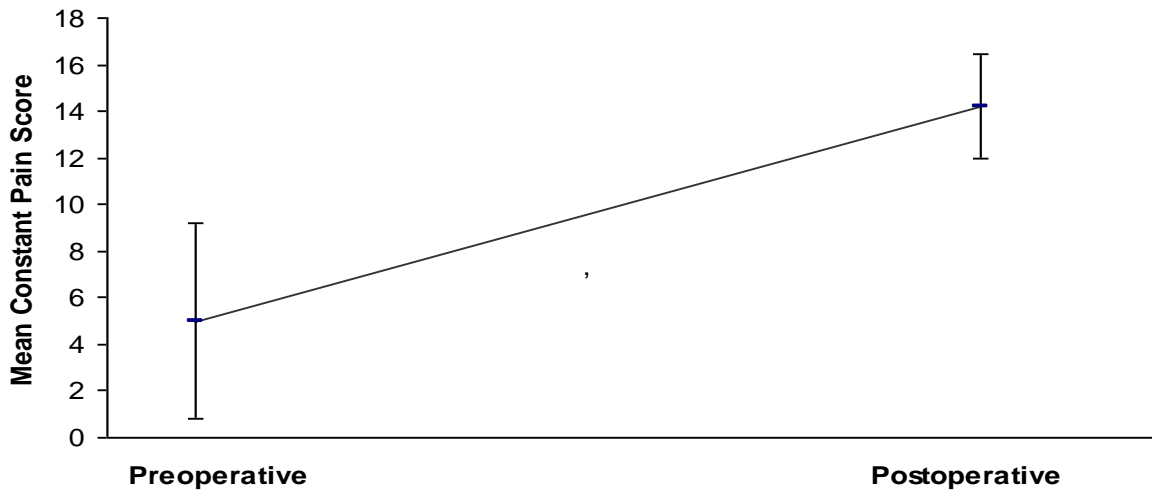
LoE = level of evidence

nr = authors examined this outcome but did not report if the results were statistically significant

PAIN: CONSTANT-MURLEY SCORE

In one Level IV study by Celli et al., twenty patients underwent muscle transfer of the teres major for treatment of irreparable rotator cuff tear. Shoulders were assessed using the Constant-Murley Score and the Constant-Murley Pain Score after 36 months (see Figure 110).

Figure 110 Pain as measured by Constant-Murley

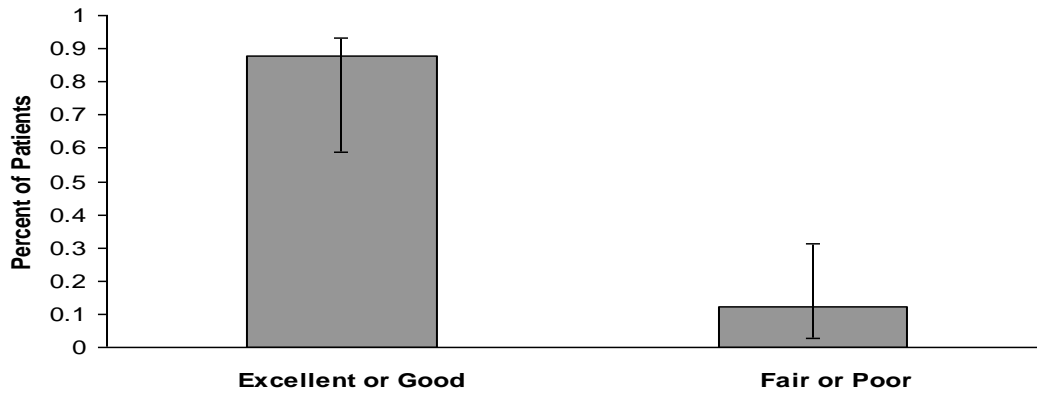


AAOS calculated independent t-test, $p < 0.0001$

UCLA SHOULDER SCALE

In one Level IV study by Burkhart, twenty-five patients underwent arthroscopic debridement and decompression for irreparable rotator cuff tears. Shoulders were assessed using the UCLA shoulder rating system at an average of 30 months after surgery (see Figure 111).

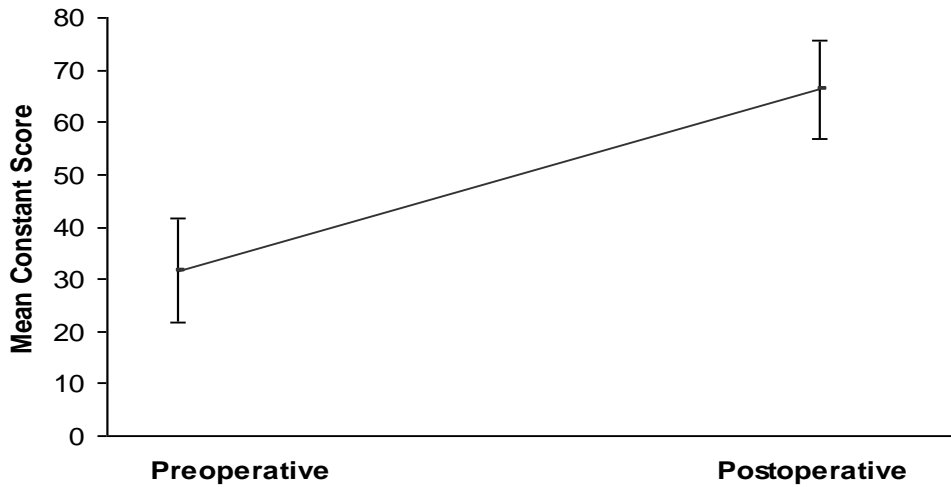
Figure 111 UCLA shoulder rating



CONSTANT-MURLEY SCORE

In one Level IV study by Celli et al., twenty patients underwent muscle transfer of the teres major for treatment of irreparable rotator cuff tear. Shoulders were assessed using the Constant-Murley Score and the Constant-Murley Pain Score after 36 months (see Figure 112).

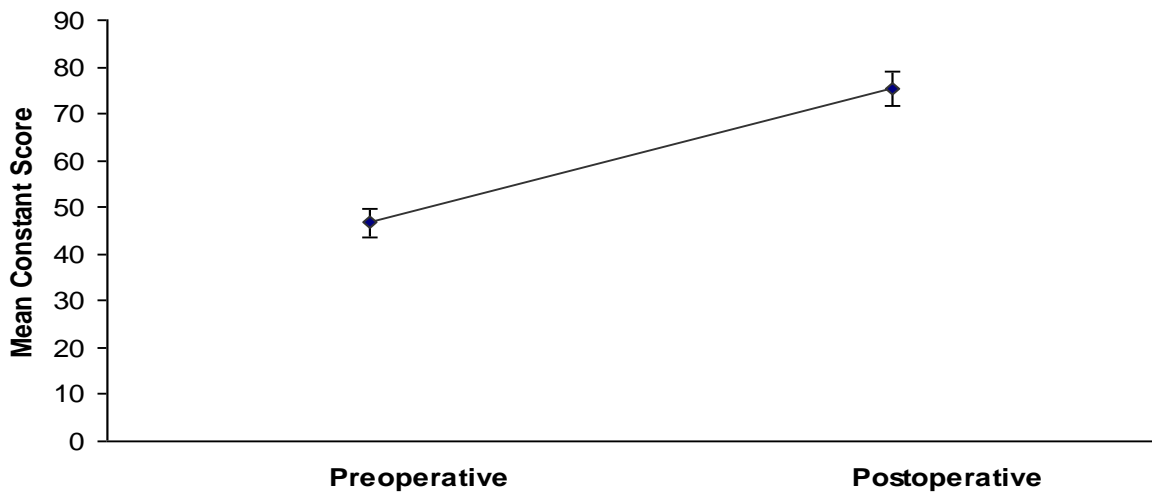
Figure 112 Constant-Murley Score



AAOS calculated independent t-test, $p < 0.0001$

In one Level IV study by Guven et al., fourteen irreparable rotator cuff tears were reconstructed with the biceps tendon. Shoulders were assessed 40.7 months after surgery using the Constant-Murley Score (see Figure 113).

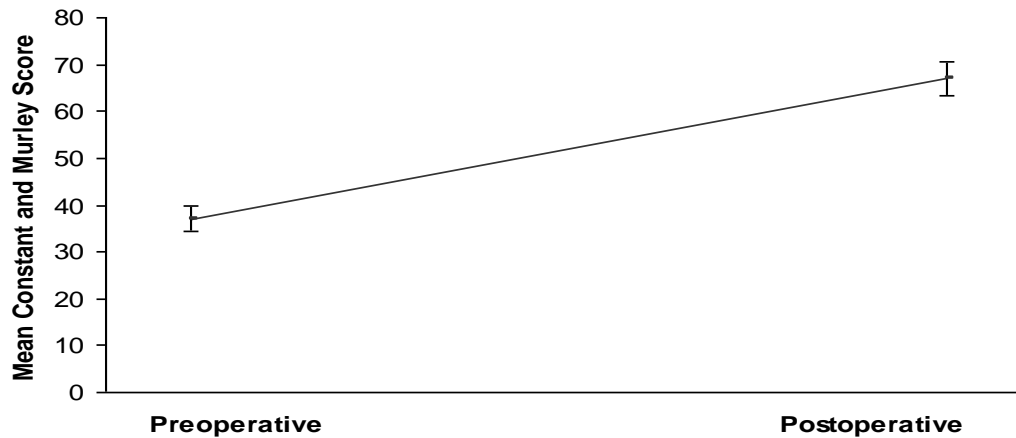
Figure 113 Constant-Murley Score



AAOS calculated independent t-test, $p < 0.0001$

In one Level IV study by Klinger et al., thirty-three patients with massive irreparable rotator cuff tears underwent arthroscopic debridement. Patients were followed for 31 months. Their shoulders were assessed using the Constant-Murley Score (see Figure 114).

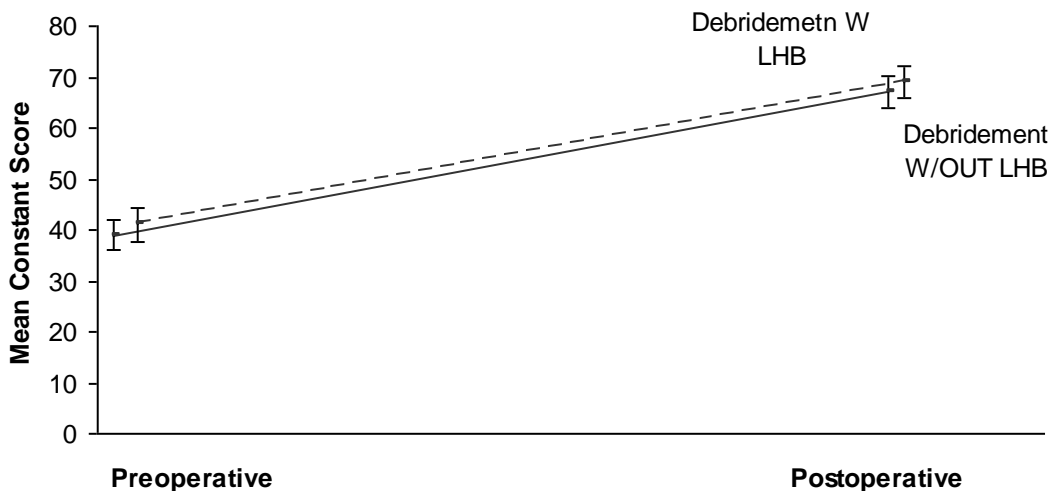
Figure 114 Constant-Murley Score



AAOS calculated independent t-test, $p < .0001$

In one Level IV study by Klinger et al., 41 patients with arthroscopic debridement with and without long head of the biceps (LHB) tenotomy were followed for 31 months. AAOS classified this study as level IV because we examined each treatment group independently (this recommendation compares arthroscopic debridement to other surgical treatments). Accordingly, we are analyzing these data as if they were derived from a case series. Patients were assessed using the Constant-Murley Score (see Figure 115).

Figure 115 Constant-Murley Score



AAOS calculated independent t-test, change from baseline; debridement with LHB tenotomy, $p < .0001$, debridement without LHB tenotomy, $p < 0.001$

COMPLICATIONS

Complications were reported in one Level IV study by Guven et al., in patients with irreparable rotator cuff repairs reconstructed with the biceps tendon (see Table 48).

Table 49 Complications

<u>Complication</u>	<u>Percent of Patients</u>
Temporary Complex Regional Pain Syndrome	7%
Cosmetic Deformity of Biceps	4%

RECOMMENDATION 10A: SURGERY - TENDON TO BONE HEALING

It is an option for surgeons to attempt to achieve tendon to bone healing of the cuff in all patients undergoing rotator cuff repair.

Level of Evidence: IV

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

While the primary clinical goal of rotator cuff repair surgery is improvement in pain, strength and function, a primary biological goal of the surgery is to achieve healing of the tendon to bone. Three Level IV^{77, 83, 104} studies addressed tendon to bone healing of the cuff in patients with full thickness rotator cuff tears. The first study^{77, 77, 83, 104} reported on MRI-confirmed status of the integrity of rotator cuff repairs in 63 subjects at two years from surgery. Patients with intact cuff repairs demonstrated improved outcomes over those found to have re-tears. The authors also reported a significant negative correlation with age but did not report magnitude of the correlation. Similarly, the second study¹⁰⁴ reported superior outcomes, favoring intact cuffs over re-tears in a cohort of 49 subjects who underwent open repair with nonabsorbable suture at four year follow-up. In the last study, the rating of the tendon after repair was correlated with the UCLA score after surgery, but the authors did not report if the results were statistically significant for the outcome.

SUPPORTING EVIDENCE- TENDON TO BONE HEALING

Tables relevant to this recommendation are: Table 50 through Table 51

Figures relevant to this recommendation are: Figure 116 through Figure 119

Table 50 Results of studies addressing tendon to bone healing

Authors	LoE	n	Comparison	Outcome	Duration (months)	
					26.4	48
Lichtenberg et al.	IV	53	Re-tear vs. intact group	Normalized Constant-Murley Score	●i	
Lichtenberg et al.		53	Re-tear vs. intact group	Strength: Normalized Constant-Murley Score	●i	
Boehm et al.		44	PDS: Re-tear vs. intact group	Normalized Constant-Murley Score		○
Boehm et al.		49	Ethibond: Re-tear vs. intact group	Normalized Constant-Murley Score		●i
Worland et al.		69	Tendon to bone repair: good vs. fair vs. poor	UCLA Score		nr

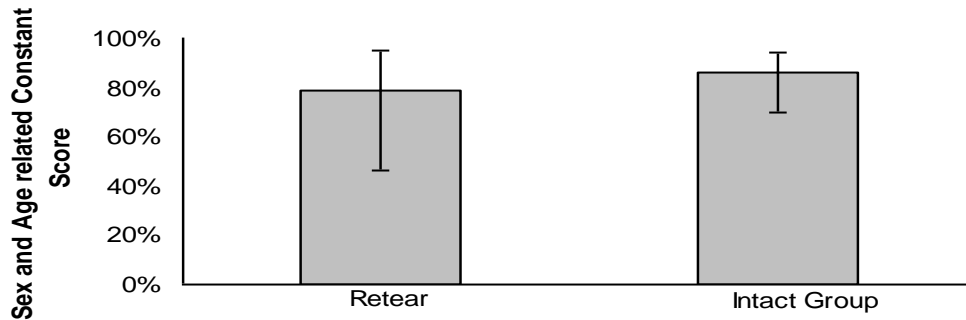
○ = no statistically significant results

● = statistically significant results

CONSTANT-MURLEY SCORE

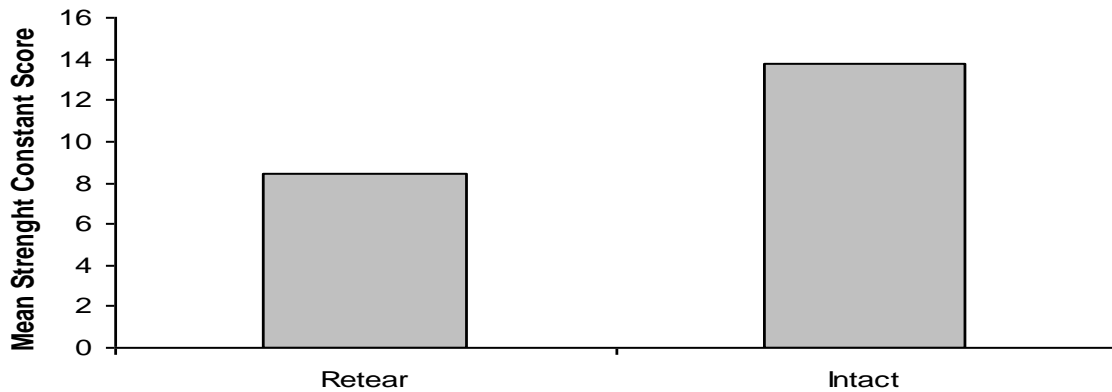
In one Level IV study by Lichtenberg et al. fifty-three patients with full-thickness tears of the supraspinatus tendon were assessed 26.4 months after repair surgery. Examiners used a MRI to detect re-tear and compared the normalized Constant-Murley Score (see Figure 116) and the normalized Constant-Murley Strength Score (see Figure 117) with re-tear and intact tendons.

Figure 116 Mean normalized Constant-Murley Score



Authors reported a statistically significant difference between groups, Mann-Whitney test, $p = 0.0095$

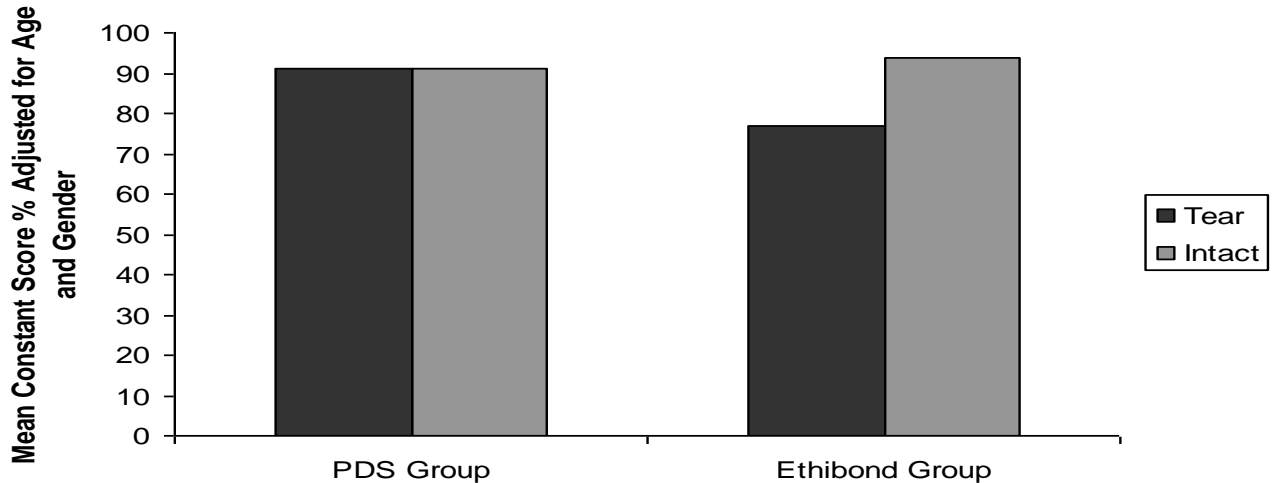
Figure 117 Mean normalized Constant-Murley strength score



Authors reported a statistically significant difference between groups, Mann-Whitney test, $p = 0.0043$

In one Level IV study by Boehm et al. patients with full-thickness tears were treated using open, transosseous repair. Forty-nine patients were treated using No. 3 Ethibond while forty-four patients were treated using a 1.0 mm polydioxanone cord (PDS). AAOS classified this study as Level IV because each group of this study is examined independently (this recommendation pertains to muscle integrity). Accordingly, we are analyzing these data as if they were derived from a case series. Patients were assessed two years post-operatively using the normalized Constant-Murley Score (see Figure 118).

Figure 118 Normalized Constant-Murley Score

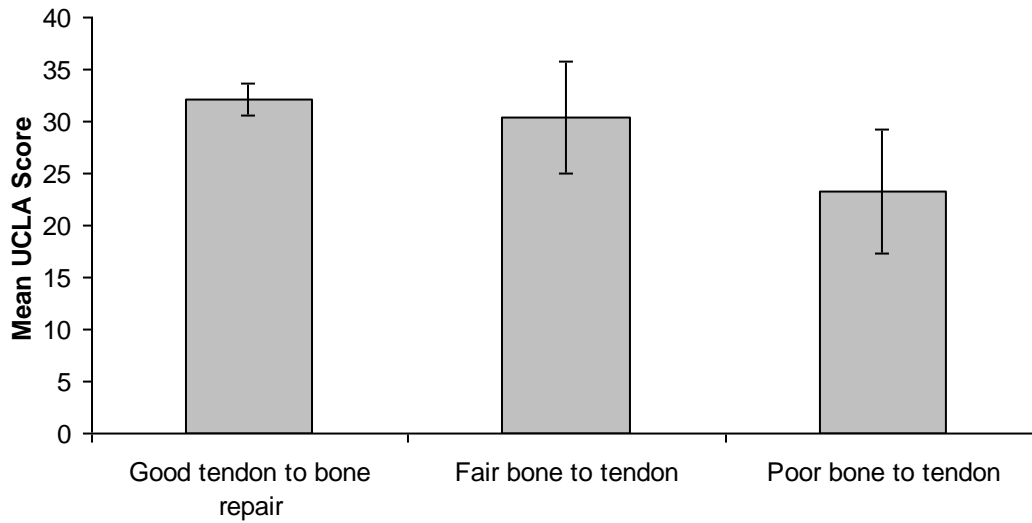


The number of patients in tear group and intact group was not reported by authors; Authors calculated Chi Squared difference between tear integrity within groups: PDS group, $p = 0.646$, Ethibond group, $p = 0.005$.

UCLA SCORE

In one Level IV study by Worland et al. the rating of the tendon after repair was correlated with the UCLA score after surgery (see Figure 119). Tendons were rated as a good repair if a fluid-tight reconstruction was achieved or 100% of the tear was repaired. A fair bone-tendon repair was repaired between 50% and 99% of the tear size, and a poor repair was defined as less than 50% of the tendon could be repaired.

Figure 119 Mean UCLA Score



Authors reported no statistical analyses

STRATIFICATIONS

Lichtenberg et al. examined stratifications pertaining to age and tear size. The authors calculated correlations according to Pearson (see Table 50).

Table 51 Stratifications pertaining to re-tear

Stratification	Re-tear	
	Linear Correlation	<i>p</i> -value
Age	nr	0.012
Tear size	0.0906	0.5187

nr = not reported by authors

RECOMMENDATION 10B: SURGERY - SUTURE ANCHORS AND BONE TUNNELS

We cannot recommend for or against the preferential use of suture anchors versus bone tunnels for repair of full thickness rotator cuff tears.

Level of Evidence: IV

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

The primary technical goal of rotator cuff repair surgery is the stable fixation of the torn tendon to the tuberosity of the humerus. Numerous repair techniques have been described, the two most common of which rely upon the use of bone tunnels (trans-osseous technique) or suture anchors. We identified no studies that specifically compared suture anchor to bone tunnel fixation in rotator cuff repair surgery. Three studies^{105, 106, 107} address the use of suture anchors while one study⁸³ addresses bone tunnel technique. Since no comparative studies were identified and since the four studies found were evaluated as limited evidence, we cannot recommend one fixation technique over another. Based on the available evidence, either fixation technique, when applied properly, can result in favorable outcomes.

SUPPORTING EVIDENCE- SUTURE ANCHORS AND BONE TUNNELS

Tables relevant to this recommendation are: Table 52 through Table 53

Figures relevant to this recommendation are: Figure 120 through Figure 125

Table 52 Results of tendon repair using bone tunnel (transosseous) or suture anchor techniques

Authors	LoE	n	Comparison	Outcome	Duration (months)			
					Final Visit*	22.5	28	30
Charousset et al.	IV	66	Suture Anchors: Change from baseline	Pain: Constant-Murley Score			●↑	
Charousset et al.		66	Suture Anchors: Change from baseline	Activity: Constant-Murley Score			●↑	
Anderson et al.		48	Suture Anchors: Change from baseline	L'Inslata Score				●↑
Boehm et al.		98	Bone Tunnel: Change from baseline	Patient Reported Satisfaction	nr			
Francheschi et al.		52	Suture Anchors: Change from baseline	UCLA Score		●↑		
Charousset et al.		66	Suture Anchors: Change from baseline	Constant-Murley Score			●↑	
Charousset et al.		66	Suture Anchors: Change from baseline	Activity Score			●↑	
Charousset et al.		66	Suture Anchors: Change from baseline	Mobility Score			●↑	
Charousset et al.		66	Suture Anchors: Change from baseline	Constant-Murley Strength Score			●↑	

● = statistically significant result

↑ = improvement

nr = authors examined this outcome but did not report if the results were statistically significant

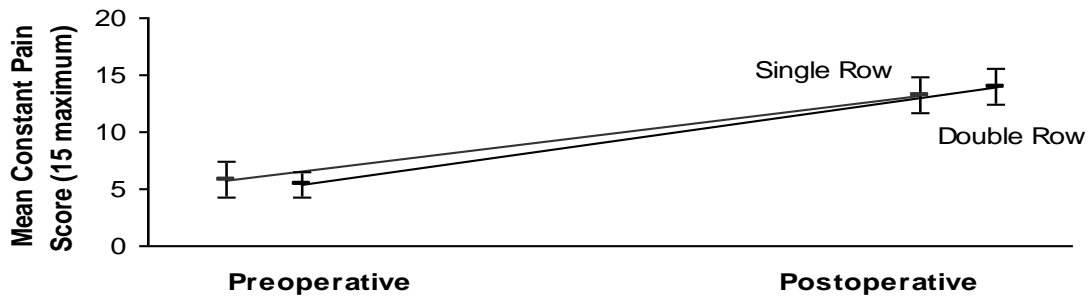
LoE = level of evidence

* = final visit not defined by the authors

PAIN: CONSTANT-MURLEY SCORE

One Level IV study by Charousset et al. assessed shoulder pain using the Constant-Murley Score when either single or double row suture anchors were used (see Figure 120). This study was classified as Level IV because AAOS examined data in each treatment group independently (this recommendation compares suture anchors to transosseous repair). Accordingly, we are analyzing these data as if they were derived from a case series.

Figure 120 Mean Constant-Murley Pain Score

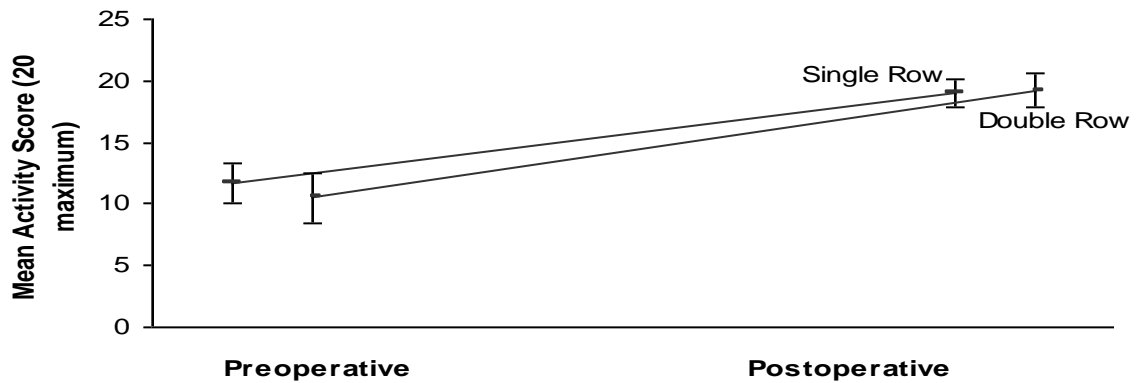


AAOS calculated independent t-test, change from baseline in both groups, $p < 0.001$

ACTIVITY: CONSTANT-MURLEY SCORE

One Level IV study by Charousset et al. assessed patient activity using the Constant-Murley Score when either single or double row suture anchors were used (see Figure 121). This study was classified as Level IV because AAOS examined data in each treatment group independently (this recommendation compares suture anchors to transosseous repair). Accordingly, we are analyzing these data as if they were derived from a case series.

Figure 121 Mean Constant-Murley Activity Score

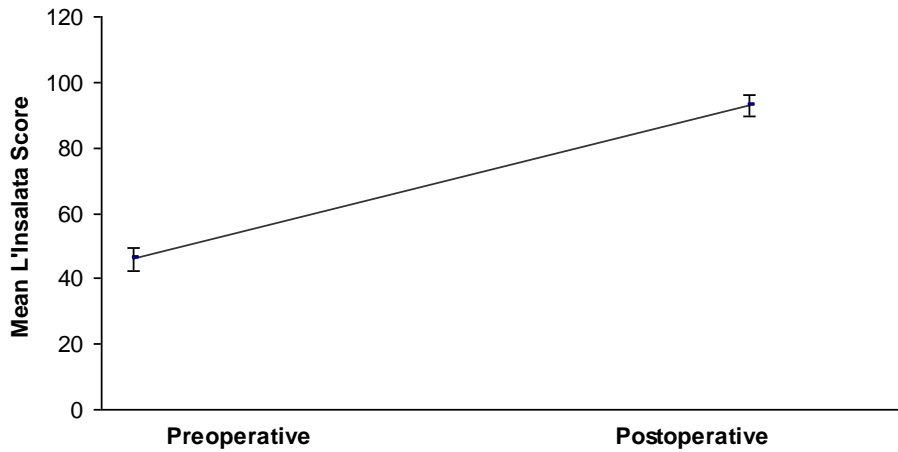


AAOS calculated independent t-test, change from baseline in both groups, $p < 0.001$

L'INSALATA SCORE

In one Level IV study by Anderson et al. forty-eight patients with full thickness rotator cuff tears were treated with arthroscopic rotator cuff repair using medial and lateral row of suture anchors. Patients were assessed using the L'Insalata Score preoperatively and at 30 months postoperatively (see Figure 122).

Figure 122 Mean L'Insalata Score

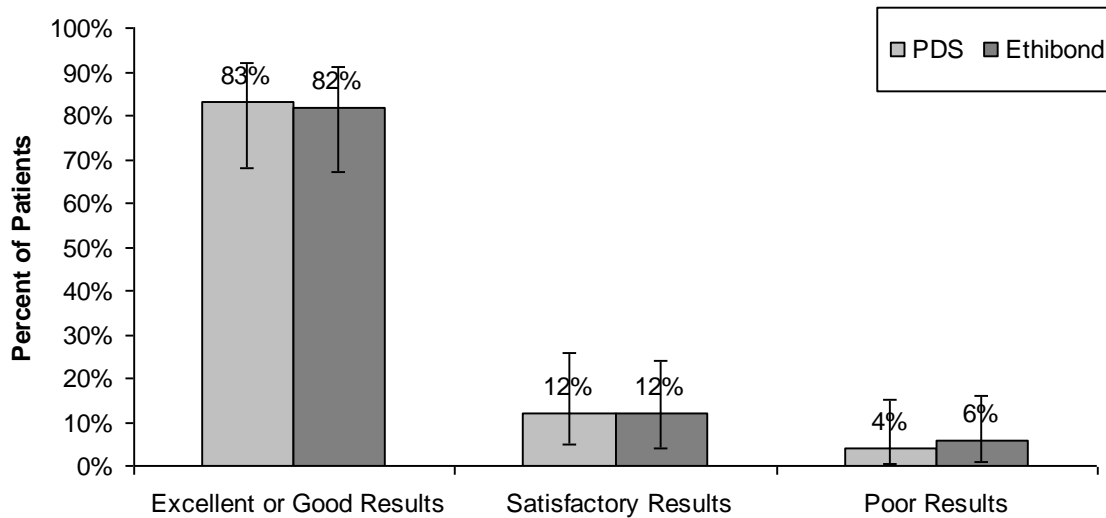


AAOS calculated independent t-test, $p < 0.0001$

SELF REPORTED RESULTS

In a Level IV study by Boehm et al. ninety-eight patients reported their post-operative satisfaction after open, transosseous repair of a full-thickness tear (see Figure 123). Surgical repair was performed using either No. 3 Ethibond or a 1.0 mm polydioxanone cord (PDS). AAOS classified this study as Level IV because we examined each treatment group independently (this recommendation compares suture anchors to transosseous repair). Accordingly, we are analyzing these data as if they were derived from a case series. Post-operative satisfaction was measured on a scale from one to six with one being excellent and six being poor.

Figure 123 Self Reported Results

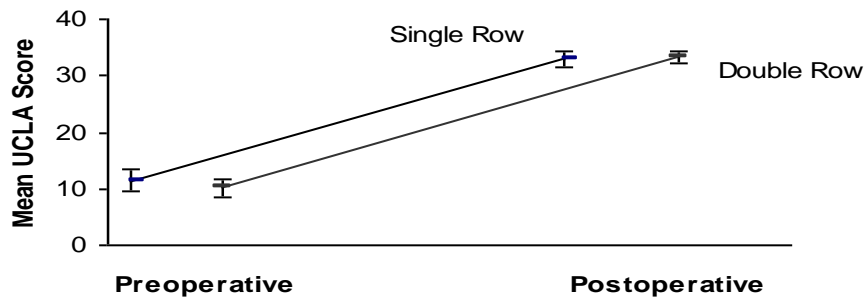


Authors report no statistical analyses

UCLA SCORE

One study by Franceschi et al. reported UCLA scores in patients with single row and double row suture anchors preoperatively and 2 years postoperatively (see Figure 124). AAOS classified this study as Level IV because we examined the data within two treatment groups independently (this recommendation compares suture anchors to transosseous repair). Accordingly, we are analyzing these data as if they were derived from a case series.

Figure 124 Mean UCLA Score

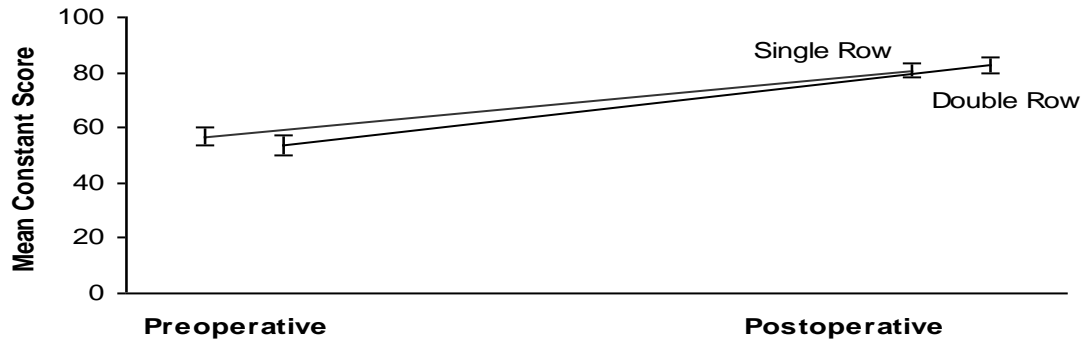


AAOS calculated independent t-test, change from baseline in Single Row and Double Row, $p < 0.001$.

CONSTANT-MURLEY SCORE

One study by Charousset et al. assessed shoulders using the Constant-Murley Scores preoperatively and 6 months postoperatively (see Figure 125). This study was classified as Level IV because AAOS examined data in each treatment group independently (this recommendation compares suture anchors to transosseous repair). Accordingly, we are analyzing these data as if they were derived from a case series.

Figure 125 Mean Constant-Murley Score



AAOS calculated independent t-test, change from baseline in both groups, $p < 0.001$

STRATIFICATIONS

Boehm et al. utilized linear regression analysis in examining stratifications pertaining to: age, gender, hand dominance, and size of tear. Authors reported regression coefficients in terms of the Constant-Murley score (see Table 52).

Table 53 Stratifications pertaining to tendon-to-bone repair

Stratification	Constant-Murley	
	β Coefficient	<i>p</i> -value
Age	0.243	0.019
Gender	0.212	0.044
Hand dominance	-0.027	0.792
Size of tear	-0.131	0.212

RECOMMENDATION 10C: SURGERY - ARTHROSCOPIC, OPEN, MINI-OPEN

We cannot recommend for or against a specific technique (arthroscopic, mini-open or open repair) when surgery is indicated for full thickness rotator cuff tears.

Level of Evidence: III

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

A recent trend in rotator cuff repair surgery has been an apparent evolution from open repair techniques to “mini-open” repairs and, most recently, to arthroscopic repairs. The systematic review found no single comparative study that included all three techniques. One Level II¹⁰⁸ and two Level III^{109, 110} studies address arthroscopic versus open rotator cuff repair in patients with full thickness tears.

The first study¹⁰⁸ compared open acromioplasty and rotator cuff repair to arthroscopic subacromial decompression with mini-open repair in a randomized trial with 73 patients. This study found early results favoring the mini-open technique up to one year after surgery (ASES, Rotator Cuff – Quality of Life Scale, and Shoulder Rating Questionnaire), but no statistically significant differences at 2-year follow-up. The second study¹⁰⁹ reported no statistically significant differences at 49 month follow-up on results of a non-randomized comparison of open and arthroscopic repair techniques. Lastly, in a non-randomized but controlled study comparing arthroscopic to mini-open repairs, the third author¹¹⁰ reported no differences at 36 months in the ASES and UCLA scores. The lack of comparisons between all three techniques makes it difficult to determine if any one technique should be preferred over another. Additionally, the apparent disagreement between the results of the included studies makes it difficult to recommend for or against a specific technique.

SUPPORTING EVIDENCE- ARTHROSCOPIC, OPEN, AND MINI-OPEN

Tables relevant to this recommendation are: Table 54

Figures relevant to this recommendation are: Figure 126 through Figure 131

Table 54 Results or surgery performed open or arthroscopic

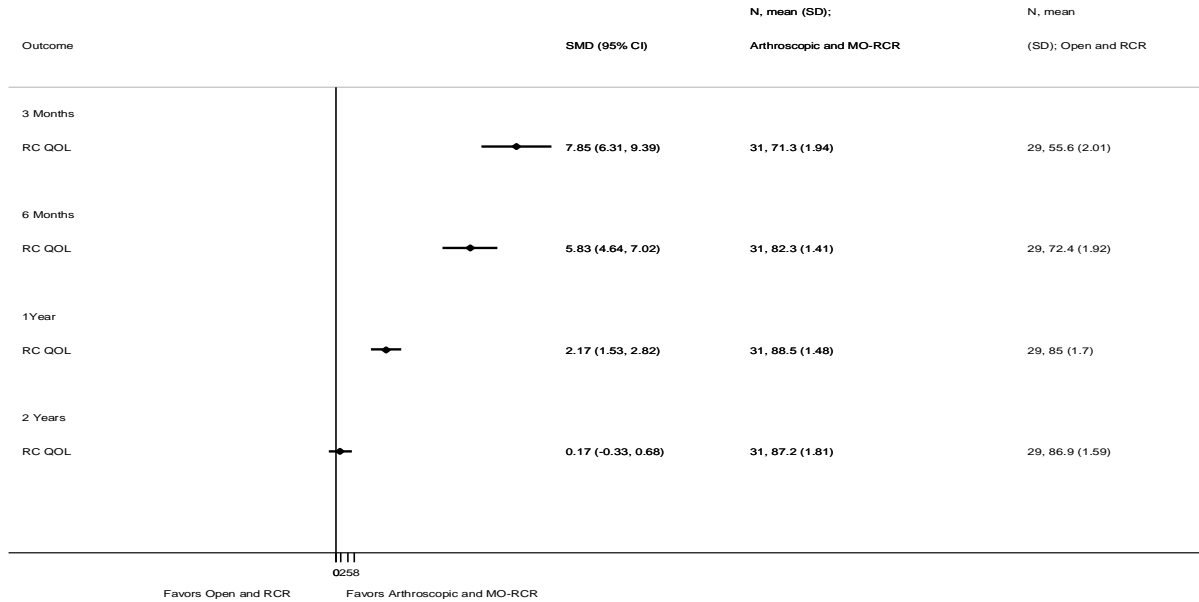
Authors	LoE	n	Comparison	Outcome	Duration					
					3 months	6 months	1 year	36.3 months	49 months	2 years
Mohtadi et al.	II	73	Arthroscopic/Mini-Open* vs. Open repair	Rotator Cuff-Quality of Life	●a	●a	●a			○
Mohtadi et al.	II	73	Arthroscopic/Mini-Open* vs. Open repair	ASES	○a	○a	?			?
Mohtadi et al.	II	73	Arthroscopic/Mini-Open* vs. Open repair	Shoulder Rating Questionnaire	○a	○a	◐a			◐a
Ide et al.	III	100	Open vs. Arthroscopic repair	UCLA Score					○	
Youm et al	III	84	Mini-Open vs. Arthroscopic Repair	ASES				?		
Youm et al.	III	84	Mini-Open vs. Arthroscopic Repair	UCLA Score				○		

- = no statistically significant difference
- = statistically significant difference
- ◐ = statistically and clinically significant
- ◑ = statistically significant and possibly clinically important
- ? = not sufficiently powered to detect the MCI; neither statistically or clinically significant
- a = favoring arthroscopic repair
- LoE = level of evidence
- ASES = American shoulder and elbow score
- * = arthroscopic acromioplasty and mini-open rotator cuff repair

ROTATOR CUFF – QUALITY OF LIFE (RC-QOL)

In one Level II study by Mohtadi et al. seventy three patients with full thickness rotator cuff tears were randomized to receive either open acromioplasty and rotator cuff repair or arthroscopic acromioplasty and mini-open rotator cuff repair. Shoulders were assessed using the Rotator Cuff-Quality of Life Scale at 3, 6, 12, and 24 months (see Figure 126).

Figure 126 RC-QOL

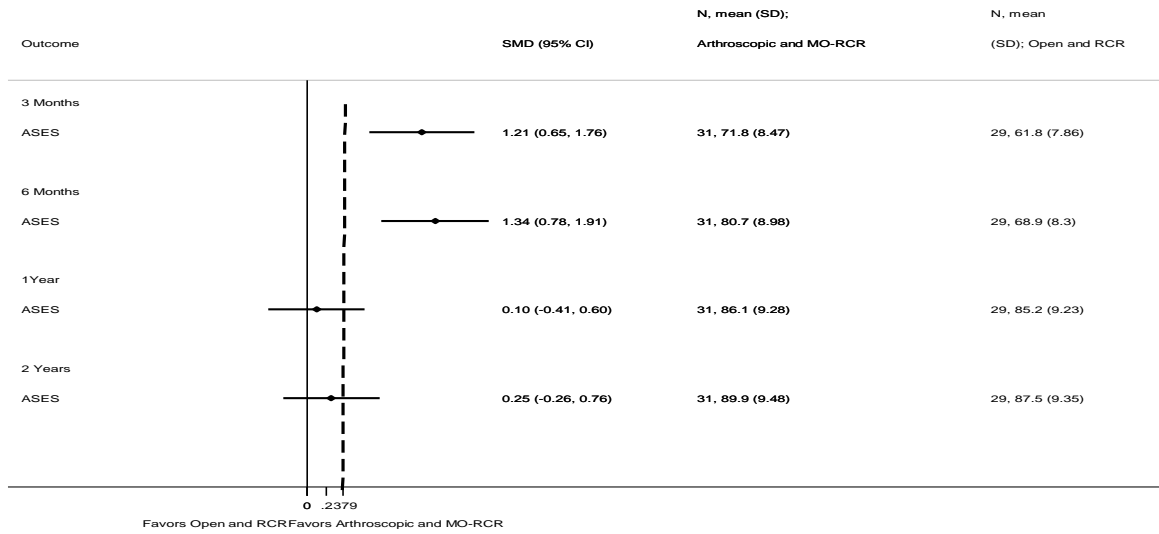


AAOS calculated effect size

ASES

In one Level II study by Mohtadi et al. seventy three patients with full thickness rotator cuff tears were randomized to receive either open acromioplasty and rotator cuff repair or arthroscopic acromioplasty and mini-open rotator cuff repair. Shoulders were assessed using the American Shoulder and Elbow and Society Scale at 3, 6, 12, and 24 months. Results at 3 and 6 months are statistically significant and clinically important and results at 1 and 2 years are neither statistically significant nor clinically important (see Figure 127).

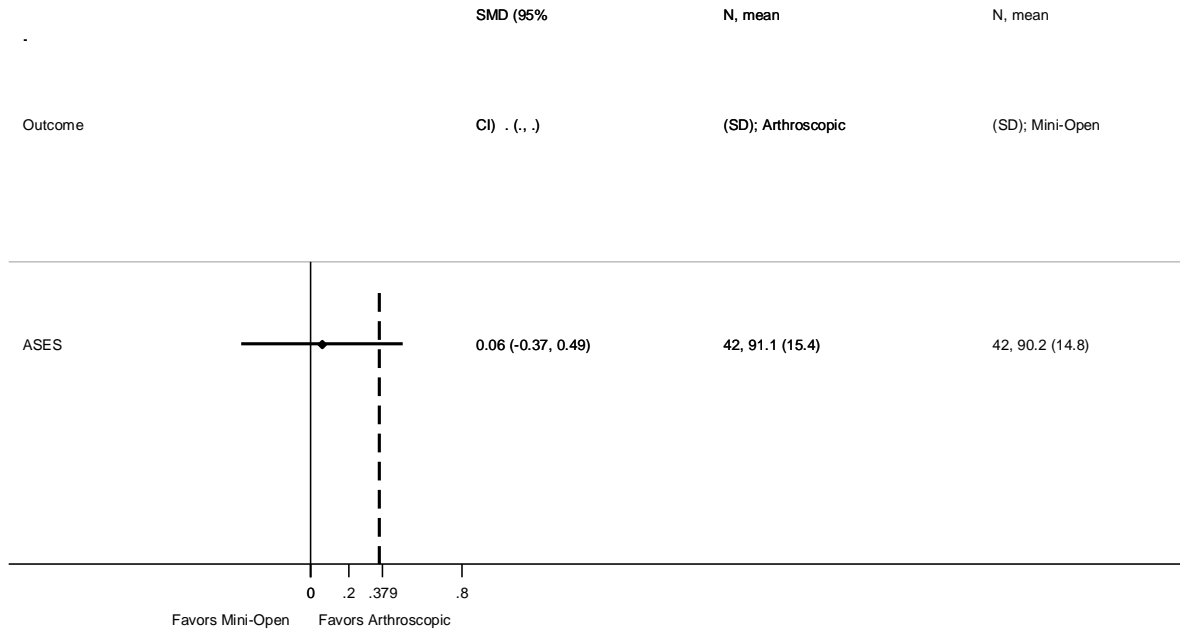
Figure 127 ASES Scale



AAOS calculated effect size; Dashed line indicates MCII for ASES Score; this study was not sufficiently powered to detect the MCII at 1 and 2 years.

In one Level III study by Youm et al., eighty-four patients with full thickness rotator cuff tears received either all arthroscopic repairs or a mini-open repair. Shoulders were assessed using the American Shoulder and Elbow and Society Scale 36.3 months postoperatively (see Figure 128). Results are neither statistically significant nor clinically important.

Figure 128 ASES Scale

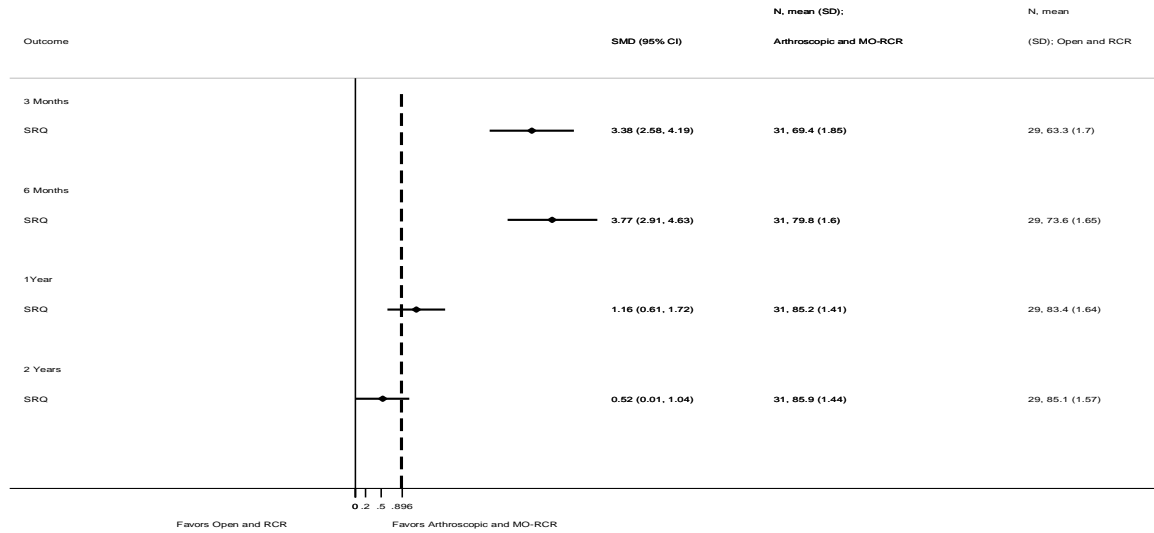


AAOS calculated effect size; Dashed line indicates MCII for ASES Score; this study was not sufficiently powered to detect the MCII.

SHOULDER RATING QUESTIONNAIRE (SRQ)

In one Level II study by Mohtadi et al. seventy three patients with full thickness rotator cuff tears were randomized to receive either open acromioplasty and rotator cuff repair or arthroscopic acromioplasty and mini-open rotator cuff repair. Shoulders were assessed using the Shoulder Rating Questionnaire at 3, 6, 12, and 24 months. Results at 3 and 6 months are clinically important, results at 1 and 2 years are possibly important (see Figure 129).

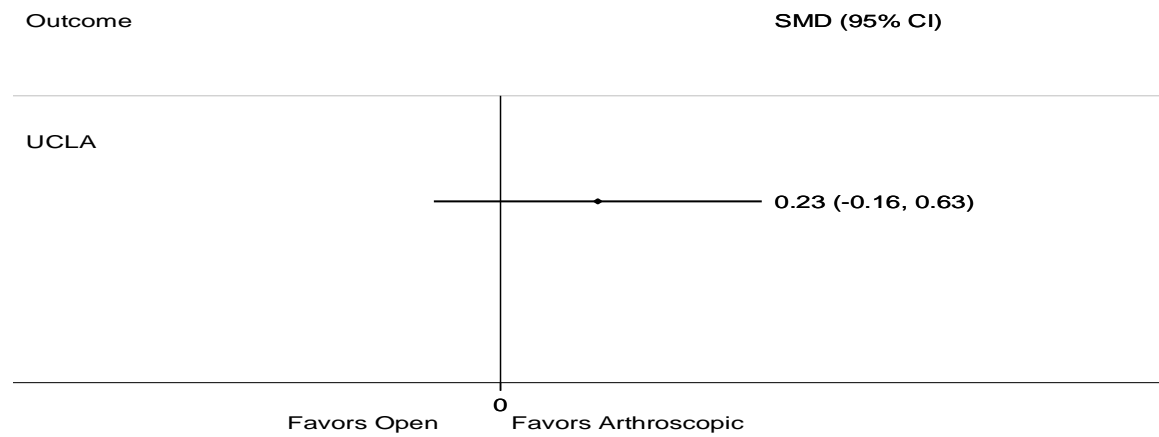
Figure 129 SRQ



UCLA SCORE

In one Level III study by Ide et al., one hundred patients with full thickness rotator cuff tears received either an open rotator cuff repair or arthroscopic rotator cuff repair. Shoulders were assessed using the UCLA scoring system 49 months postoperatively (see Figure 130).

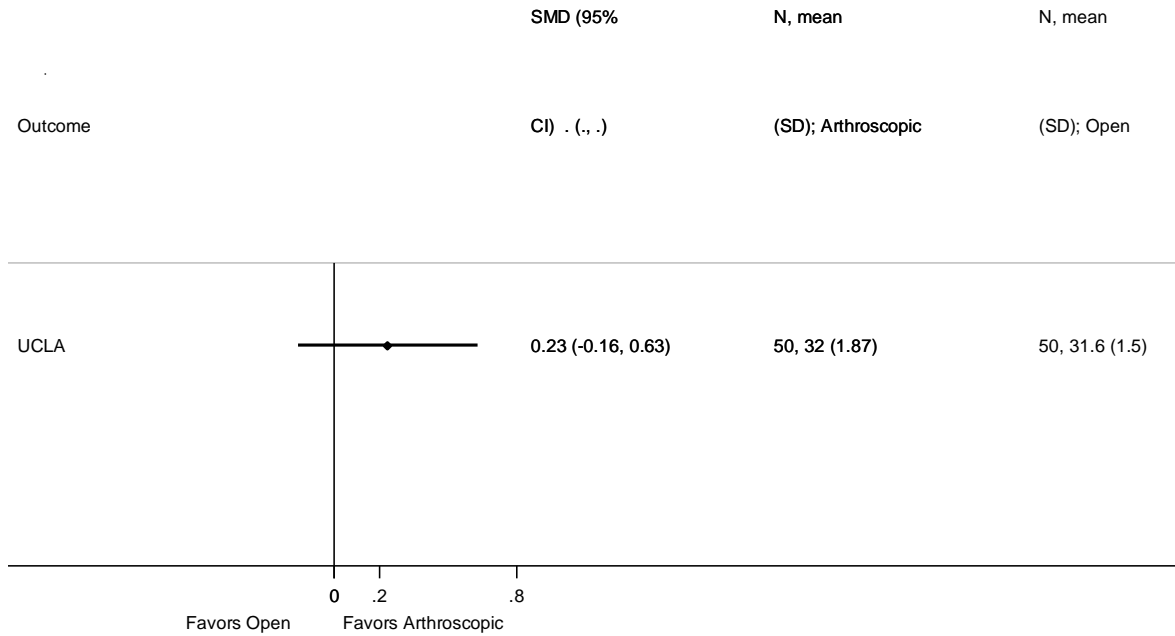
Figure 130 UCLA Score in patients with open or arthroscopic repair



AAOS calculated effect size

In one Level III study by Youm et al., eighty-four patients with full thickness rotator cuff tears received either an all arthroscopic repair or a mini-open repair. Shoulders were assessed using the UCLA Scale 36.3 months postoperatively (see Figure 131).

Figure 131 UCLA Score



AAOS calculated effect size; SMD = Standardized mean difference

RECOMMENDATION 11A: SURGERY - NON-CROSSLINKED, PORCINE SMALL INTESTINE SUBMUCOSAL XENOGRAFTS

We suggest surgeons not use a non-cross linked, porcine small intestine submucosal xenograft patch to treat patients with rotator cuff tears.

Level of Evidence: III

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Rationale:

One level II study¹¹¹ and one level III¹¹² study evaluated the results of open repair of medium to massive rotator cuff tears with and without the use of a non cross linked, porcine small intestine submucosal xenograft as augmentation to the primary tendon to bone repair. In these studies, there was less favorable outcome (pain and function) with the use of this graft when compared to primary repair alone. The complication rate of hypersensitivity reaction was approximately 20-30 % of cases with the use of this graft.¹¹⁴ Based on these results, the work group suggests that non-cross linked, porcine small intestine submucosal xenograft patches not be used to treat patients with rotator cuff tears.

SUPPORTING EVIDENCE- NON-CROSSLINKED PORCINE SMALL INTESTINE SUBMUCOSAL XENOGRAFTS

Tables relevant to this recommendation are: Table 55

Figures relevant to this recommendation are:Figure 132 through Figure 138

Table 55 Summary of results for porcine SIS ortho-biological patch use

Authors	LoE	n	Comparison	Outcome	Duration		
					14 Months	3 Months	2 Years
Iannotti et al.	II	30	Xenograft vs. Control	UPenn Score	?		
				Upenn Function	● _c		
				UPenn Pain	○		
				Upenn Satisfaction	○		
				Healed Rotator Cuff Tear	○		
Walton et al.	III	31	Xenograft vs. Control	Pain: During Activity			● _c
				Patient Satisfaction		○	

○ = no statistically significant difference

● = statistically significant results

? = not sufficiently powered to detect the MCII; neither statistically or clinically significant

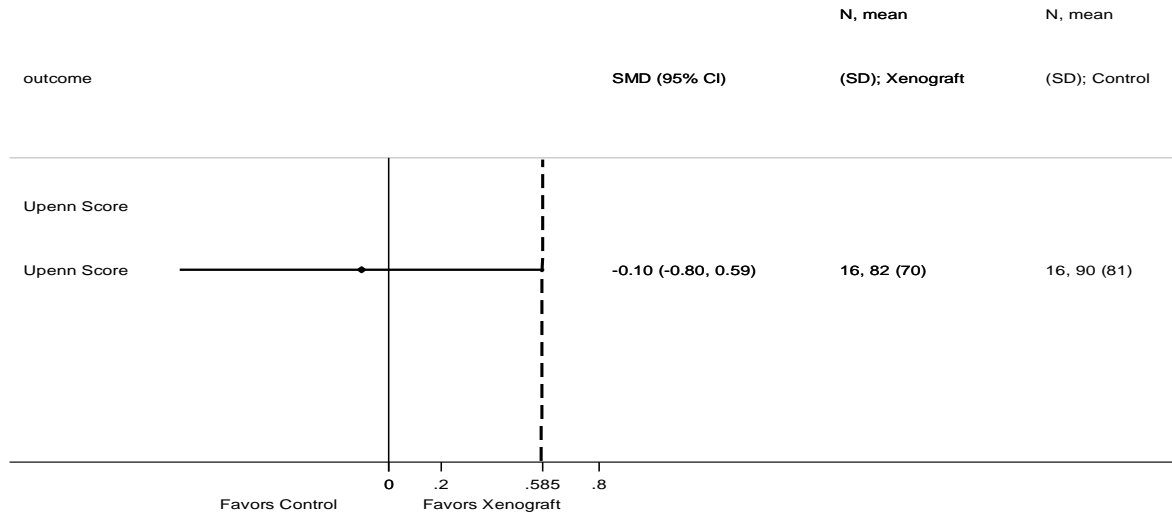
c = favoring control group

LoE = level of evidence

UPENN SCORE

In one Level II study by Iannotti et al., fifteen patients who received a xenograft and fifteen controls were assessed with the UPenn shoulder-specific questionnaire fourteen months postoperatively.

Figure 132 UPenn Score

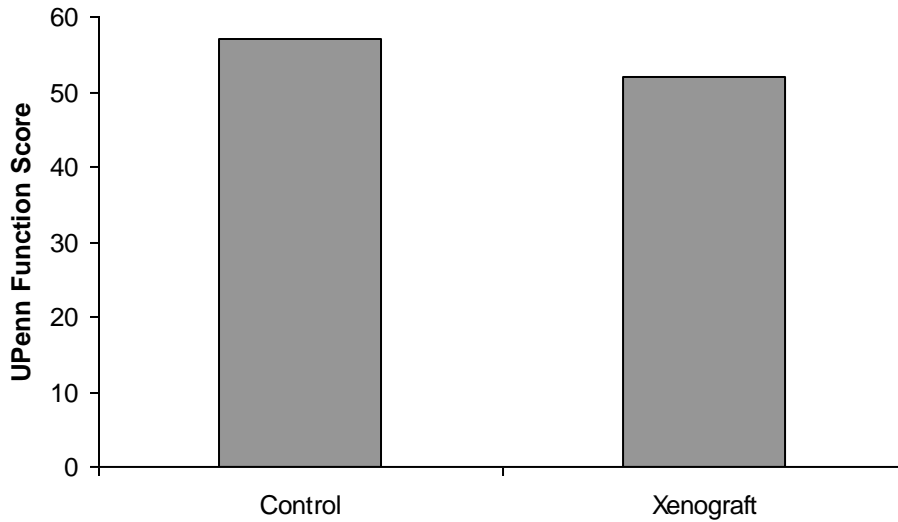


AAOS calculated effect size

UPENN FUNCTION SUBSCALE

In one Level II study by Iannotti et al.,¹¹³ fifteen patients who received a xenograft and fifteen controls were assessed with the UPenn shoulder-specific questionnaire fourteen months postoperatively. Function subscale results are reported in Figure 133.

Figure 133 Median UPenn Function Score

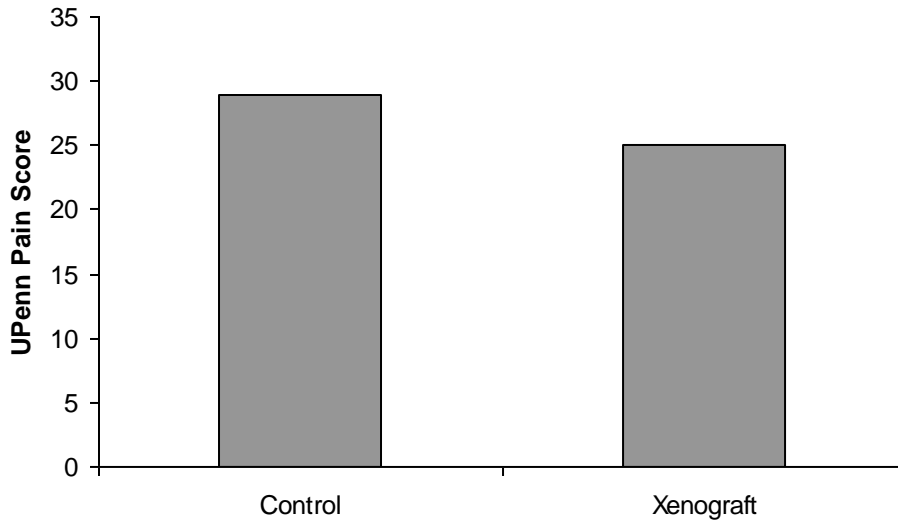


Authors reported a statistically significant difference between groups, Fisher exact test, $p = 0.03$

UPENN PAIN SUBSCALE

In one Level II study by Iannotti et al., fifteen patients who received a xenograft and fifteen controls were assessed with the UPenn shoulder-specific questionnaire fourteen months postoperatively. Pain subscale results are reported in Figure 134.

Figure 134 Median UPenn Pain Score

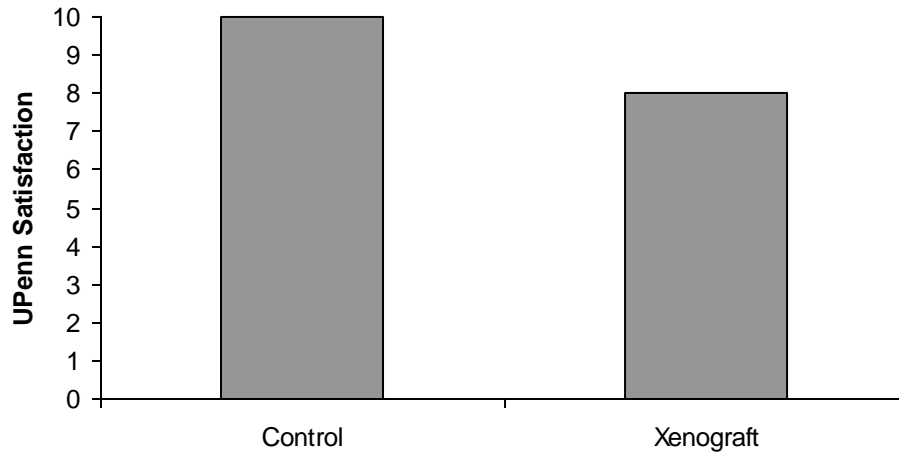


Authors reported no statistically significant difference between groups, Fisher exact test, $p=.18$

UPENN SATISFACTION SUBSCALE

In one Level II study by Iannotti et al., fifteen patients who received a xenograft and fifteen controls were assessed with the UPenn shoulder-specific questionnaire fourteen months postoperatively. Pain subscale results are reported in Figure 135.

Figure 135 Median UPenn Satisfaction Score

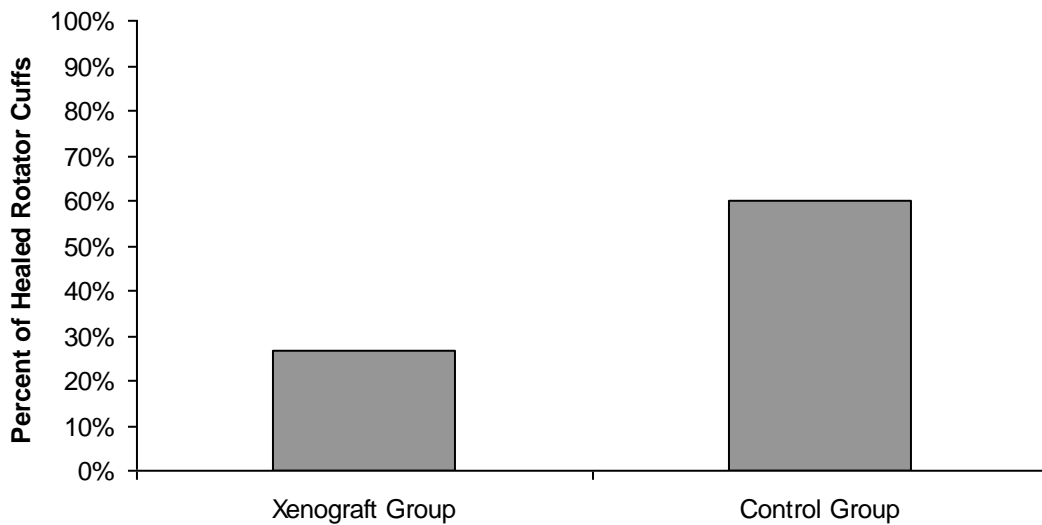


Authors reported no statistically significant difference between groups, Fisher exact test, $p = 0.09$

PERCENT OF PATIENTS WITH HEALED ROTATOR CUFF

In one Level II study by Iannotti et al., fifteen patients who received a xenograft and fifteen controls were assessed using a magnetic resonance imaging scan with intra-articular gadolinium. The status of the rotator cuff was recorded as healed, partially healed, or not healed (see Figure 136).

Figure 136 Percent of patients with a healed rotator cuff

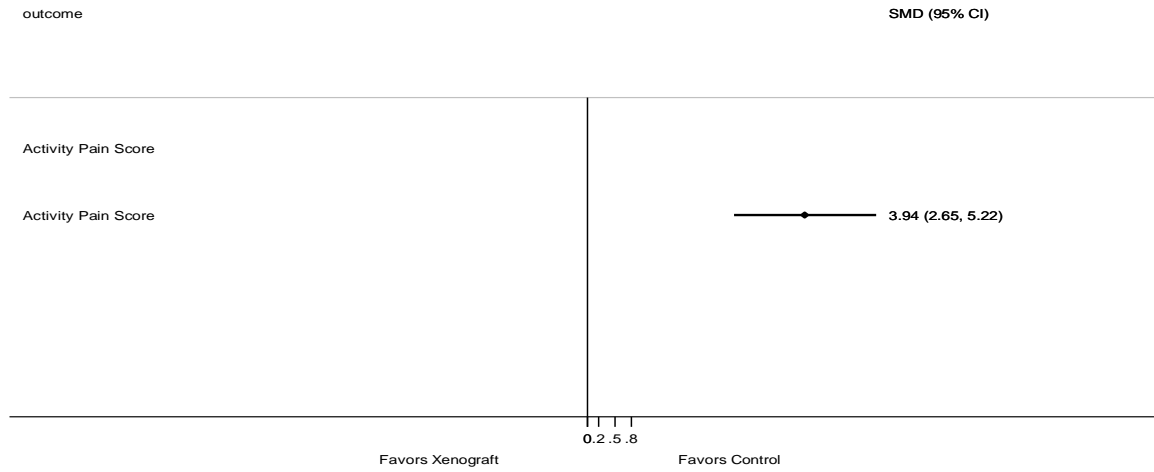


Authors reported no statistically significant difference between groups, Fisher exact test, $p = 0.11$

PAIN: DURING ACTIVITY

In one Level III study by Walton et al., pain during activity was assessed using a modified L'Insalata Questionnaire in fifteen patients who received a xenograft and sixteen controls (see Figure 137).

Figure 137 Pain during activity as measured by modified L'Insalata questionnaire

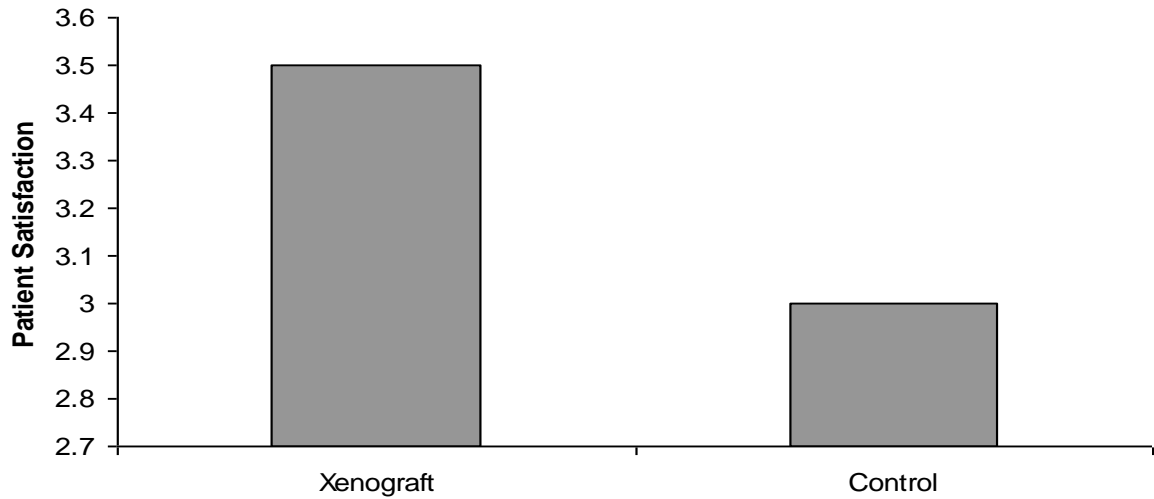


AAOS calculated effect size

PATIENT SATISFACTION

One Level II study by Walton et al. reported patient satisfaction at two years in fifteen xenograft treated patients and sixteen controls (see Figure 138).

Figure 138 Patient Satisfaction



Authors reported Mann-Whitney rank sum test, $p = 0.43$

RECOMMENDATION 11B: SURGERY - ALLOGRAFTS AND XENOGRAFTS

We cannot recommend for or against the use of soft tissue allografts or other xenografts to treat patients with rotator cuff tears.

Level of Evidence: IV

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

The work group recognizes that different graft materials and different methods of graft processing have different biologic and mechanical properties which may result in differences in clinical effectiveness or complications between graft materials. Two level IV studies^{113, 114}, one addressing the use of xenograft and one addressing the use of allografts, were included. In both cases the graft was used to close an irreparable rotator cuff defect. These studies had small treatment groups (n=10 and n=16 respectively) and were of low quality. Based on the evidence, the work group had insufficient data to make specific recommendations for or against the use of other xenografts or allografts to treat reparable or irreparable full thickness rotator cuff tears.

SUPPORTING EVIDENCE- ALLOGRAFTS AND XENOGRAFTS

Tables relevant to this recommendation are: Table 56

Figures relevant to this recommendation are: Figure 139 through Figure 144

Table 56 Results of patients treated with xenografts or allografts

Authors	LoE	n	Comparison	Outcome	Duration	
					26.7 Months	3-5 Years
Badhe et al	IV	10	Xenograft change from baseline	Pain: Constant Murley Score		●↑
Badhe et al.	IV	10	Xenograft change from baseline	Activities of Daily Living: Constant Murley Score		○
Badhe et al.	IV	10	Xenograft change from baseline	Constant Murley Score		●↑
Bond et al.	IV	16	Allograft: Change from baseline	Pain: UCLA Score	●↑	
Bond et al.	IV	16	Allograft: Change from baseline	Constant Murley Score	●↑	

○ = no statistically significant difference

● = statistically significant results

? = not sufficiently powered to detect the MCII; neither statistically or clinically significant

c = favoring control group

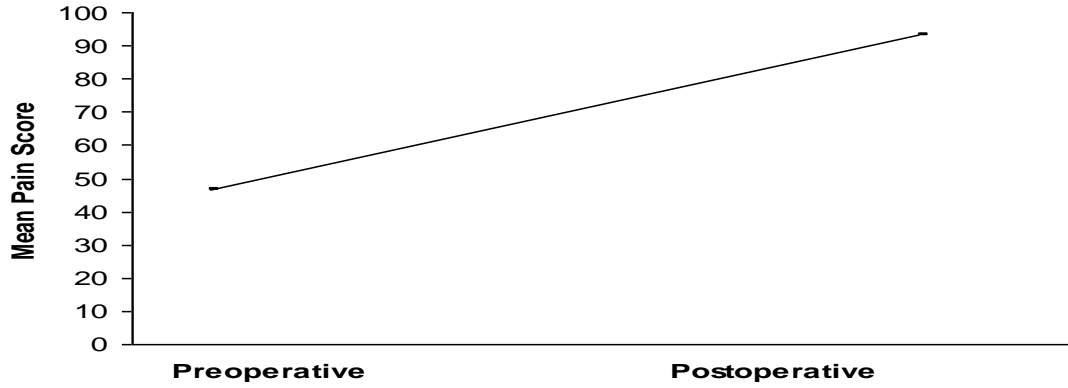
↑ = improvement

LoE = level of evidence

PAIN: CONSTANT-MURLEY SCORE

In one Level IV study by Badhe et al. ten patients were treated for an extensive rotator cuff tear using a dermal xenograft. Pain was assessed preoperatively and between 3-5 years postoperatively using the Constant-Murley Score (see Figure 139).

Figure 139 Pain as measured by Constant-Murley Score

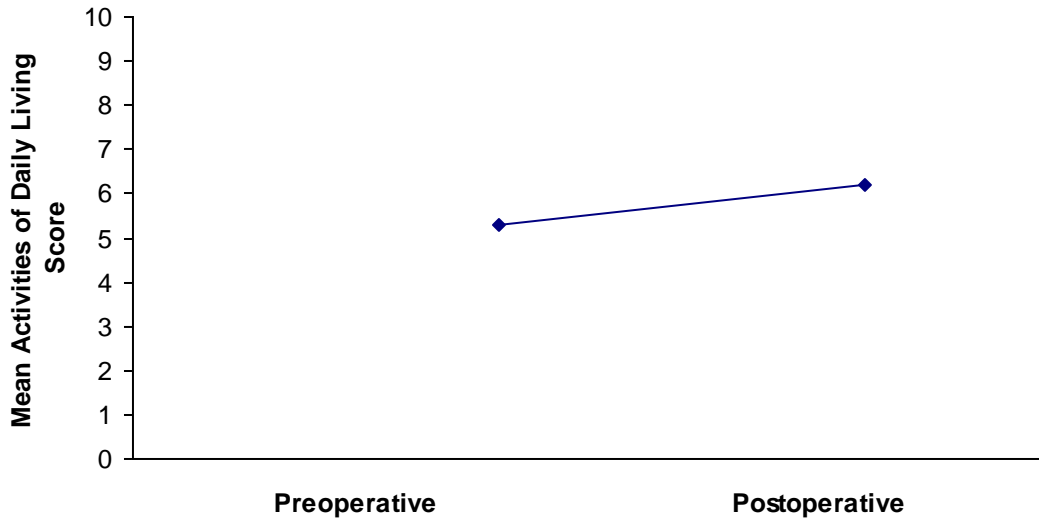


Authors reported change from baseline, $p = 0.0003$

ACTIVITIES OF DAILY LIVING: CONSTANT-MURLEY SCORE

In one Level IV study by Badhe et al. ten patients were treated for an extensive rotator cuff tear using a dermal xenograft. Activities of daily living were assessed preoperatively and between 3-5 years postoperatively using the Constant-Murley Score (see Figure 140).

Figure 140 Activities of daily living as measured by Constant-Murley Score

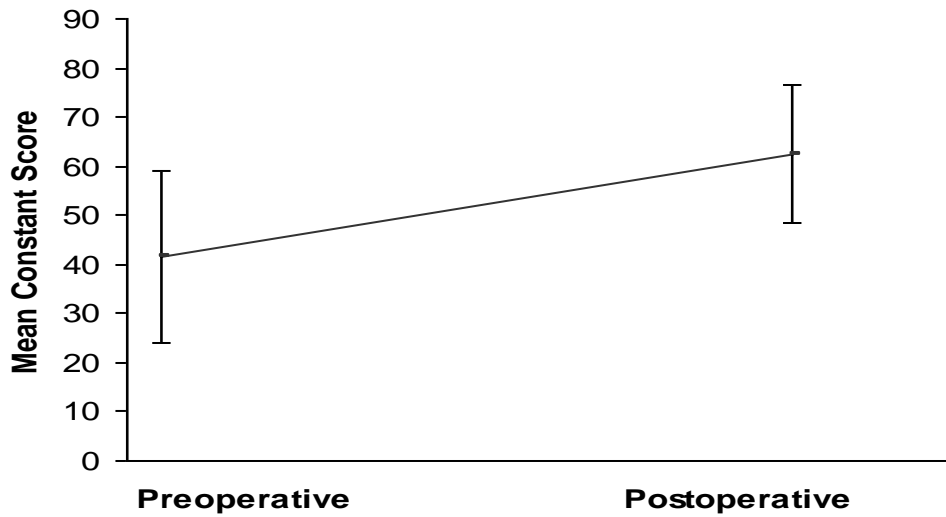


Authors reported change from baseline, $p = 0.3$

CONSTANT-MURLEY SCORE

In one Level IV study by Badhe et al. ten patients were treated for an extensive rotator cuff tear using a dermal xenograft. Shoulders were assessed preoperatively and between 3-5 years postoperatively using the Constant-Murley Score (see Figure 141).

Figure 141 Mean Constant-Murley Score

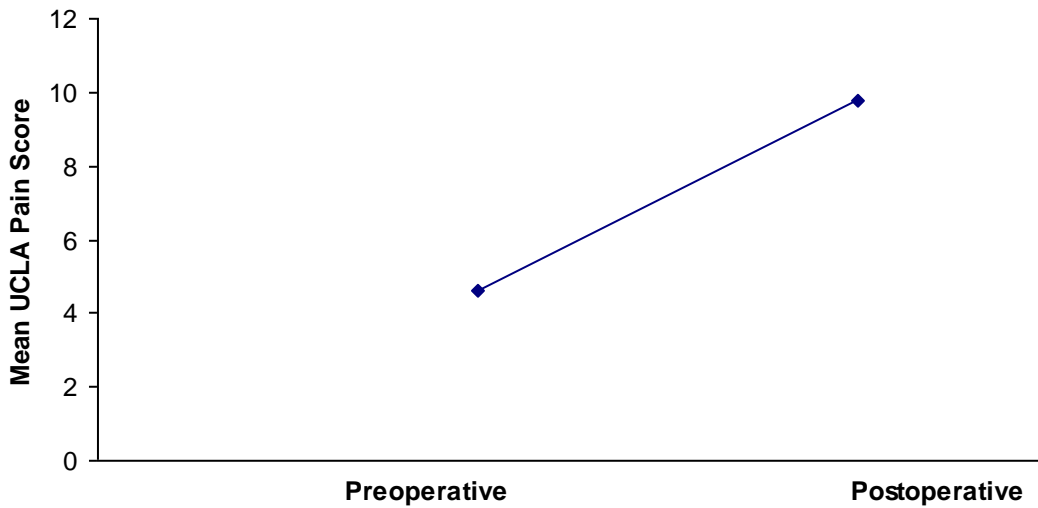


Author reported change from baseline, $p = 0.0004$

PAIN: UCLA SCORE

In one level IV study by Bond et al. sixteen patients with massive rotator cuff tears, defined as tears ≥ 5 cm or involving 2 tendons, were treated with arthroscopic allograft procedures. Shoulders were assessed preoperatively and at 26.7 months (range, 12 to 38 months) using the UCLA pain score (see Figure 142).

Figure 142 Mean Pain measured by UCLA

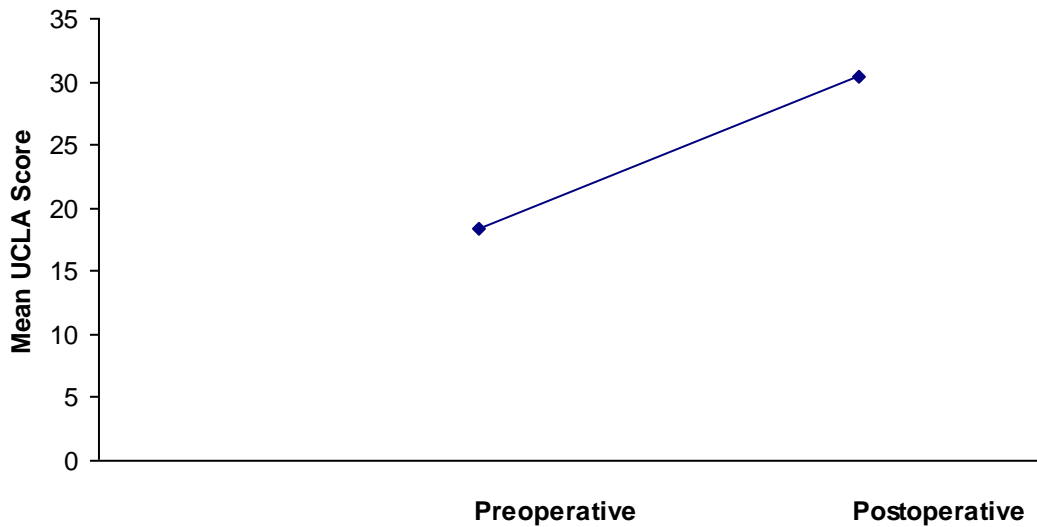


Author reported change from baseline, $p < 0.0001$

UCLA SCORE

In one level IV study by Bond et al. sixteen patients with massive rotator cuff tears, defined as tears ≥ 5 cm or involving 2 tendons, were treated with arthroscopic allograft procedures. Shoulders were assessed preoperatively and at 26.7 months (range, 12 to 38 months) using the UCLA score (see Figure 143).

Figure 143 Mean UCLA Score

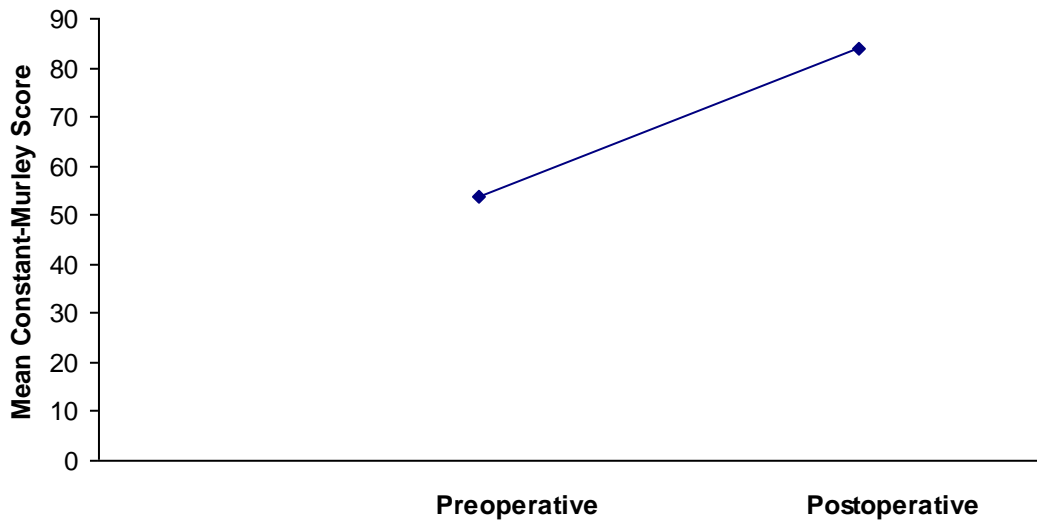


Author reported change from baseline, $p < 0.001$

CONSTANT-MURLEY SCORE

In one level IV study by Bond et al. sixteen patients with massive rotator cuff tears, as defined as tears ≥ 5 cm or involve 2 tendons, were treated with arthroscopic allograft procedures. Shoulders were assessed preoperatively and at 26.7 months (range, 12 to 38 months) using the Constant-Murley score (see Figure 144).

Figure 144 Constant-Murley Score



Author reported change from baseline, $p < 0.001$

RECOMMENDATION 12: POST-OPERATIVE - COLD THERAPY
In the absence of reliable evidence, it is the opinion of the work group that local cold therapy is beneficial to relieve pain after rotator cuff surgery.

Level of Evidence: None

Strength of Recommendation: Consensus

Description: The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Rationale:

One of the primary objectives of patient care is the alleviation of pain and suffering. Pain has been coined one of the 'vital signs' of patient management. It is therefore reasonable to encourage pain control methods, especially when there is broad experience with their application in general clinical practice across multiple specialties.

Cold therapy has been utilized in the postoperative setting for a variety of orthopaedic procedures, including shoulder surgery, to aide in pain control and possibly to decrease tissue swelling. Based on these observations, there may be beneficial effects of cold therapy after shoulder surgery; however, there is no compelling or strong, quality evidence that pertains specifically to rotator cuff repair. Studies evaluating the effect of cold therapy are limited by a lack of standardized methodology and by variability in the methods of cold application.

Based upon the expert opinion of the work group, local cold therapy is a reasonable treatment for pain control after rotator cuff surgery. Surgeons should be aware of the possibilities of local tissue injury and generalized hypothermia related to excessive cold application, although these complications are quite rare.

We found no quality studies to help decipher any potential clinical differences between intermittent crushed ice, continuous cold therapy, and other forms of cryotherapy after rotator cuff surgery.

RECOMMENDATION 13A: POST-OPERATIVE - SLING, SHOULDER IMMOBILIZER, ABDUCTION PILLOW, OR ABDUCTION BRACE

We cannot recommend for or against the preferential use of an abduction pillow versus a standard sling after rotator cuff repair.

Level of Evidence: Insufficient

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

After a systematic search, no clinical data was found supporting or refuting a negative or positive effect of a sling, shoulder immobilizer, abduction pillow, and/or abduction brace after repair of a full thickness rotator cuff tear on tendon healing or outcomes after rotator cuff repair. Therefore, the work group could not recommend for or against their use in the post-operative period.

RECOMMENDATION 13B: POST-OPERATIVE REHABILITATION - RANGE OF MOTION EXERCISES

We cannot recommend for or against a specific time frame of shoulder immobilization without range of motion exercises after rotator cuff repair.

Level of Evidence: Insufficient

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

After a systematic search, no clinical data was found supporting or refuting a negative or positive effect of range of motion exercises (passive, active or active assisted) for post-operative rehabilitation after repair of a full thickness rotator cuff tear on tendon healing or outcomes after rotator cuff repair. Therefore, the work group could not recommend for or against the timing of range of motion exercises in the post-operative period.

RECOMMENDATION 13C: POST-OPERATIVE REHABILITATION - ACTIVE RESISTANCE EXERCISES

We cannot recommend for or against a specific time interval prior to initiation of active resistance exercises after rotator cuff repair.

Level of Evidence: Insufficient

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

After a systematic search, no clinical data was found supporting or refuting a negative or positive effect of active resistance exercises for post-operative rehabilitation after repair of a full thickness rotator cuff tear on tendon healing or outcomes after rotator cuff repair. Therefore, the work group could not recommend for or against the timing of active resistance exercises in the post-operative period.

RECOMMENDATION 13D: POST-OPERATIVE REHABILITATION - HOME BASED EXERCISE AND FACILITY BASED REHABILITATION

We cannot recommend for or against home-based exercise programs versus facility-based rehabilitation after rotator cuff surgery.

Level of Evidence: II

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Our systematic search of the literature yielded two quality studies^{115, 116} providing data comparing the efficacy of a home based exercise program to referral to a facility based rehabilitation program following rotator cuff repair. Both studies reported large loss to follow-up at longer durations (24 and 52 weeks) and found conflicting results among the outcomes reported at shorter durations (6 and 12 weeks). Further, patient compliance was not measured in both studies. Based on the conflicting results and varied outcomes reported, the work group could not recommend for or against a specific post-operative rehabilitation protocol.

SUPPORTING EVIDENCE- SUPERVISED PHYSICAL THERAPY

Tables relevant to this recommendation are: Table 57 through Table 58

Figures relevant to this recommendation are: Figure 145 through Figure 151

Table 57 Results of home-based or supervised physical therapy

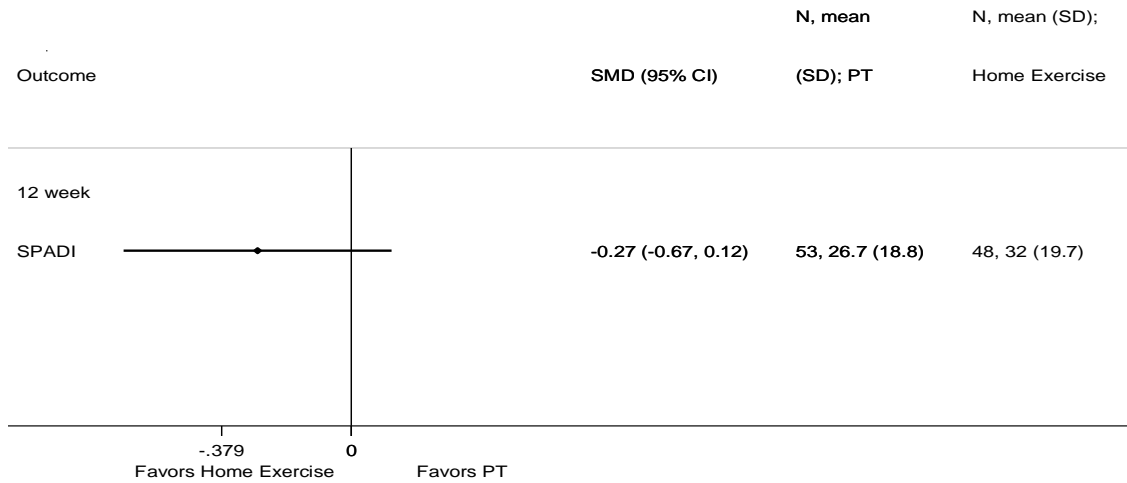
Authors	LoE	n	Comparison	Outcome	Duration	
					6 weeks	12 weeks
Roddey et al.	II	128	Video vs. Supervised PT	SPADI		○
Roddey et al.		128	Video vs. Supervised PT	UPENN		?
Hayes et al.		58	PT vs. Home Exercise	Physical Symptoms		●pt
Hayes et al.		58	PT vs. Home Exercise	Work Subscale		○
Hayes et al.		58	PT vs. Home Exercise	Lifestyle	○	●h
Hayes et al.		58	PT vs. Home Exercise	Overall Shoulder Status		●h
Roddey et al.		128	Video vs. Supervised PT	Patient Compliance		○

- = no statistically significant difference
- = statistically significant difference
- ? = neither statistically or clinically significant
- pt = favoring physical therapy treatment
- h = favoring home exercise treatment
- LoE = level of evidence
- PT = physical therapy

SPADI

In one Level II study by Roddey et al. one hundred and twenty-eight patients were randomized to receive either exercise instruction via a videotape or 4 separate one-on-one instruction sessions with a physical therapist. Shoulders were assessed using the SPADI scale at 12, 24, and 52 weeks post surgery. However, data for weeks 24 and 52 follow-up is not reported due to an attrition rate greater than 20% (see Figure 145).

Figure 145 SPADI

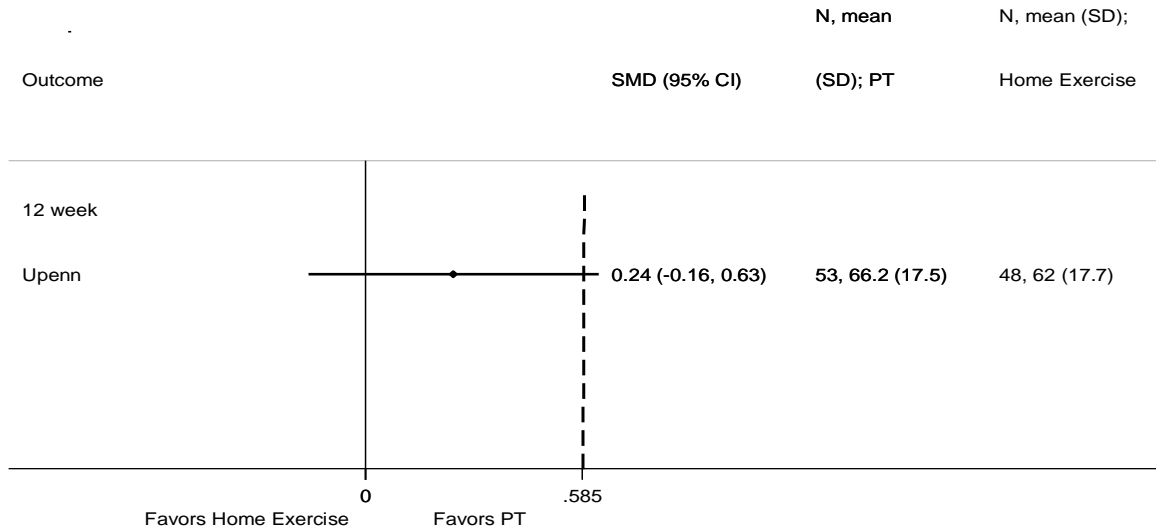


AAOS calculated effect size

UPENN

In one Level II study by Roddey et al. one hundred and twenty-eight patients were randomized to receive either exercise instruction via a videotape or 4 separate one-on-one instruction sessions with a physical therapist. Shoulders were assessed using the UPenn scale at 12, 24, and 52 weeks post surgery. Data for weeks 24 and 52 follow-up is not reported due to attrition rate. Results at 12 weeks were inconclusive (see Figure 146).

Figure 146 UPenn

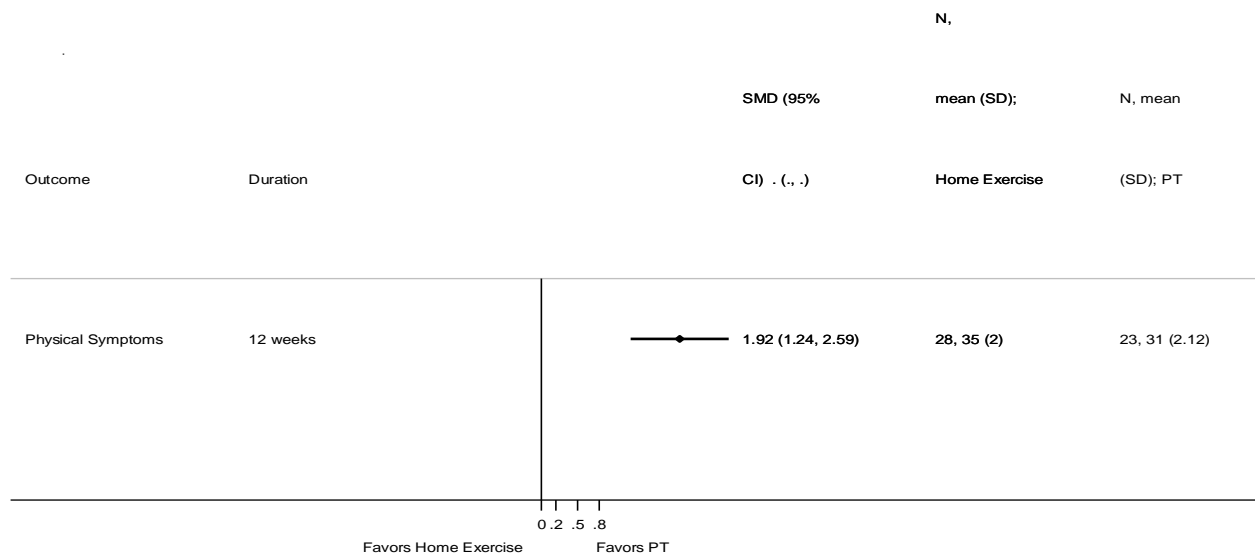


AAOS calculated effect size; Dashed line indicates MCII for the UPenn Scale; this study was sufficiently powered to detect the MCII therefore, its' results are inconclusive.

MODIFIED L'INSALATA QUESTIONNAIRE

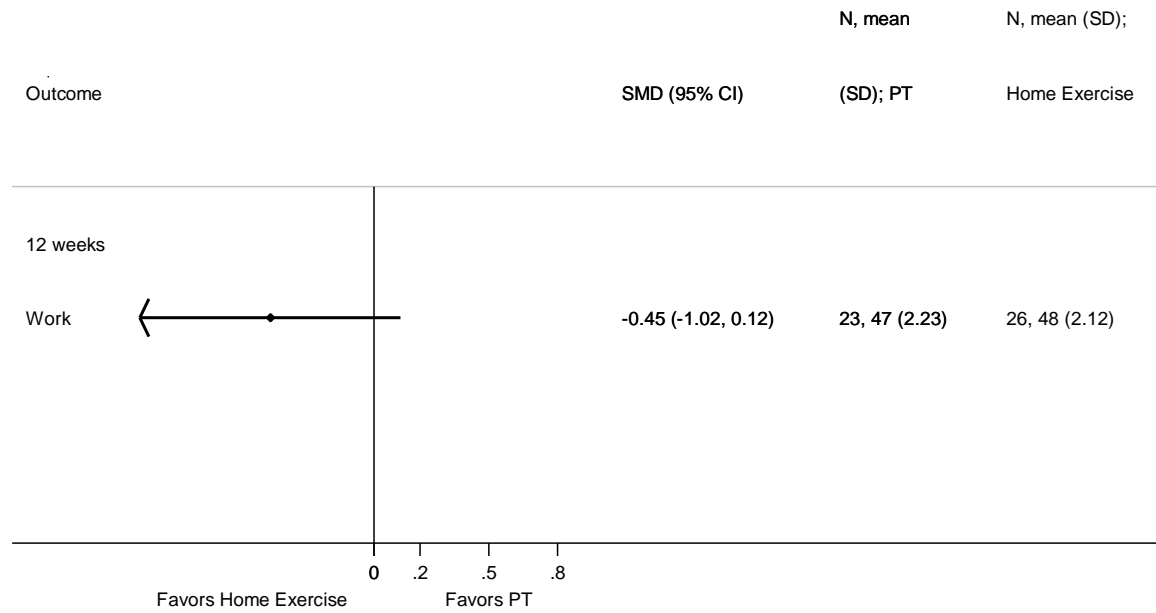
In one Level II study by Hayes et al., fifty-eight subjects were randomized after surgery to receive either individualized physiotherapy or standardized home exercise. The physiotherapy group received sixteen treatments (plus or minus 11) over seventeen weeks (plus or minus 9). The authors did not attempt however, to monitor compliance of the home exercise group. Shoulders were assessed by physical symptoms, work, lifestyle, and overall shoulder status at baseline, 6 weeks, 12 weeks, and 24 weeks. Because loss to follow-up is greater than 20%, only the following outcomes and durations are reported: physical symptom, 12 weeks; work, 12 weeks; lifestyle, 6 and 12 weeks; and overall shoulder status, 12 weeks (see Figure 147 to Figure 150).

Figure 147 Physical Symptoms



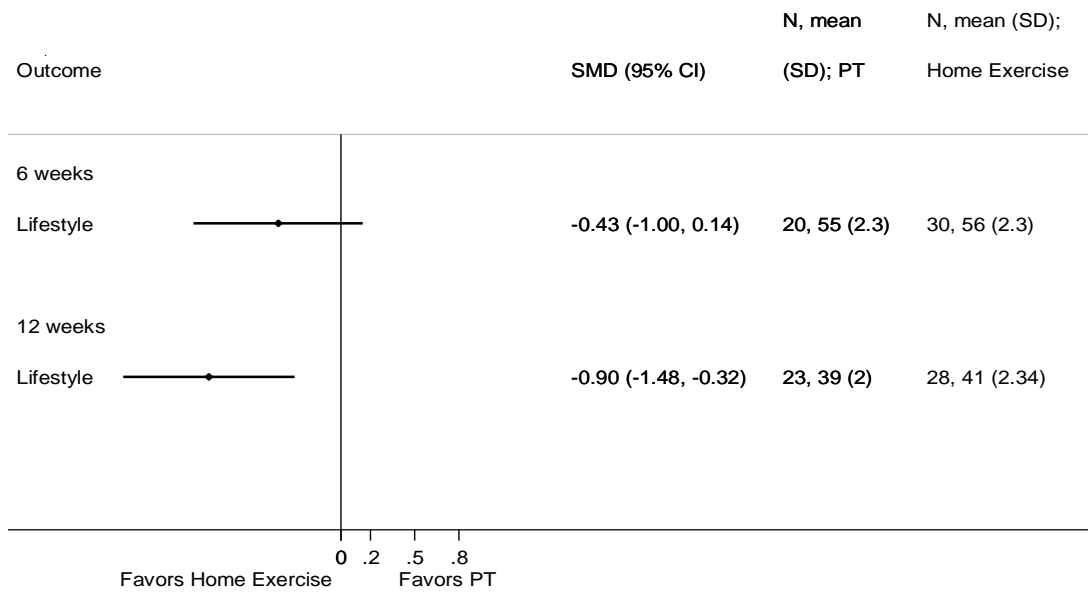
AAOS calculated effect size

Figure 148 Work Status



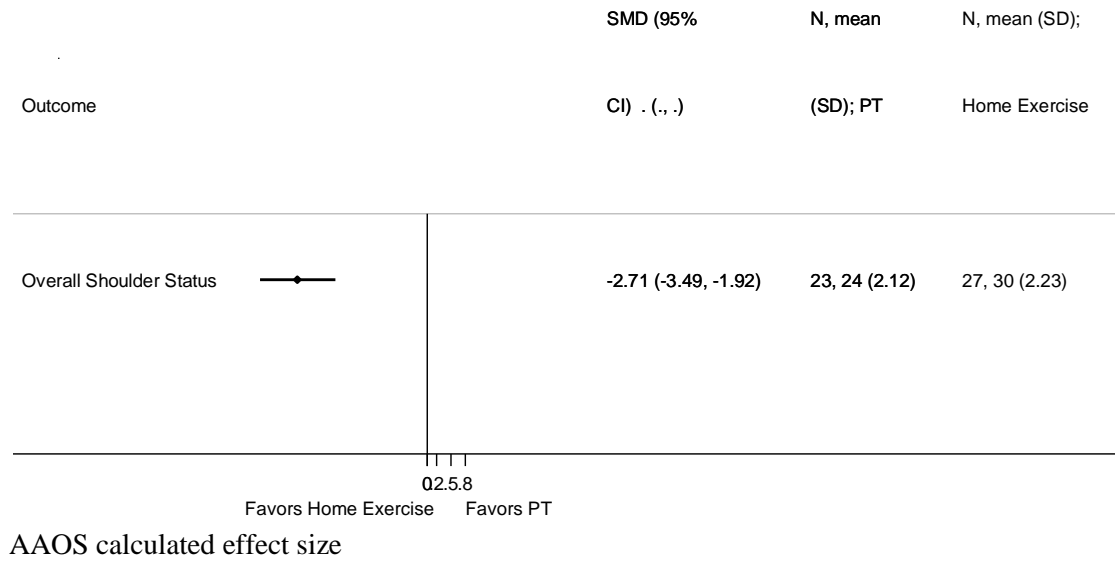
AAOS calculated effect size

Figure 149 Lifestyle Subscale



AAOS calculated effect size

Figure 150 Overall Shoulder Status



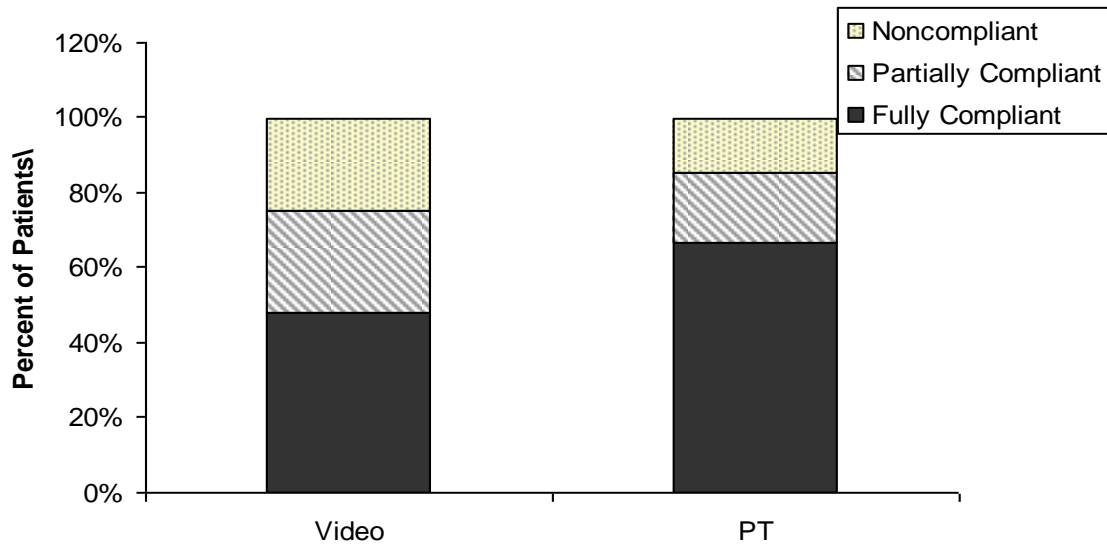
PATIENT COMPLIANCE

One Level II study by Roddey et al. assessed patient compliance level for those receiving either video physiotherapy or one-on-one instruction (see Figure 151). Three *a priori* compliance levels were determined (see Table 57).

Table 58 Compliance levels

Level	Criteria
Fully Compliant	Subject returned all 4 logs and reported completing exercises >70% of the time.
Partially Compliant	Subject returned 3-4 logs and reported completing exercises 50%-69% of the time.
Noncompliant	Subject either returned less than 3 logs or reported completing the exercises less than 50% of the time.

Figure 151 Patient Compliance



Author reported between-group ANOVA, $p = 0.18$

RECOMMENDATION 14: POST-OPERATIVE - INFUSION CATHETERS

We cannot recommend for or against the use of an indwelling subacromial infusion catheter for pain management after rotator cuff repair.

Level of Evidence: Insufficient

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Post-operative pain control is an important objective for improving the patient's overall surgical experience. For this recommendation, we only considered studies of indwelling infusion catheters for the management of pain after rotator cuff repair. We did not consider evidence related to possible benefits of infusion catheters after shoulder procedures without rotator cuff repair.

One Level II study¹¹⁷ compared intravenous injection of fentanyl and ketorolac tromethamine with subacromial infusion of bupivacaine up to 120 hours after rotator cuff repair. There was no statistically significant difference in pain measured by visual analog score between the two groups. Impact on long term clinical outcome was not measured. The authors did not compare these treatments against a clinically-relevant control group (for example oral analgesic medications only). It is not possible to extrapolate the findings of this study to typical clinical situations, since intravenous fentanyl and ketorolac are not routinely used in general orthopaedic practice. Therefore, we can not provide specific recommendations about the use of subacromial indwelling infusion catheters, particularly in the setting of outpatient rotator cuff repair. The work group did not consider risks or benefits of infusion catheter utilization in other clinical conditions.

SUPPORTING EVIDENCE- PAIN CATHETER USE

Tables relevant to this recommendation are: Table 59

Figures relevant to this recommendation are: Figure 152 through Figure 153

Table 59 Results of pain catheter use

Author	LoE	n	Comparison	Outcome	Duration (Hours)										
					0	12	24	36	48	60	72	84	96	108	120
Cho et al.	II	40	Intravenous injection vs. Subacromial infusion	Pain: At Rest	○	○	○	○	○	○	○	○	○	○	○
				Pain: During Motion	○	○	○	○	○	○	○	○	○	○	○

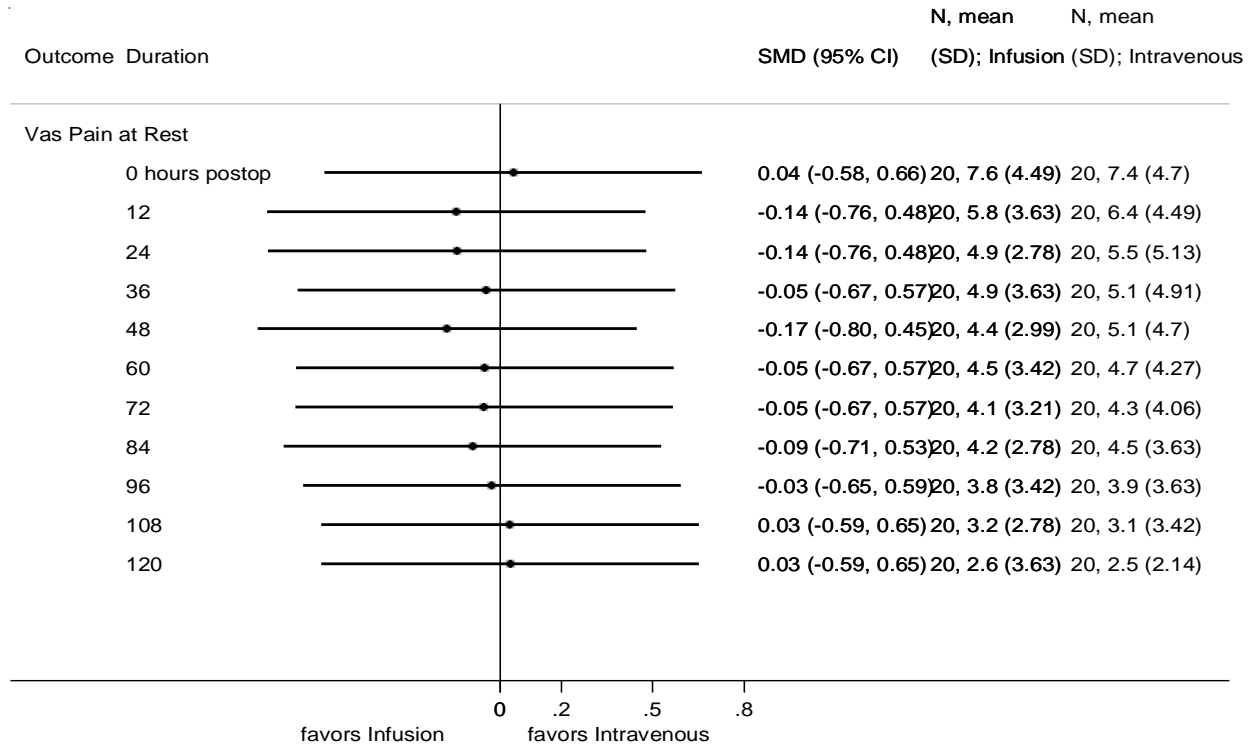
○ = no statistically significant difference

LoE = level of evidence

PAIN: AT REST

In one Level II study by Cho et al. forty patients with full thickness rotator cuff tears were randomized to receive either a subacromial infusion with bupivacaine or intravenous injection with fentanyl and ketorolac tromethamin. Pain at rest was evaluated every 12 hours after surgery for 120 hours (see Figure 152).

Figure 152 Pain at rest as measured by VAS

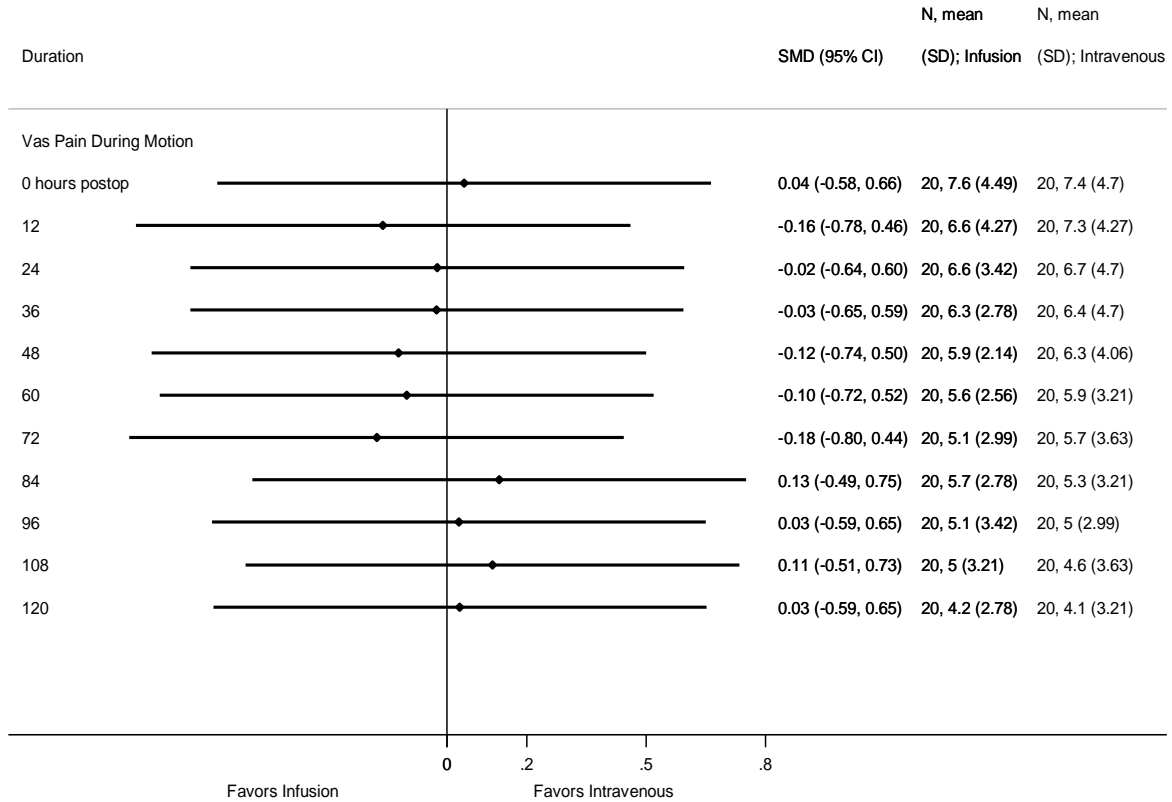


AAOS calculated effect size

PAIN: DURING MOTION

In one Level II study by Cho et al. forty patients with full thickness rotator cuff tears were randomized to receive either a subacromial infusion with bupivacaine or intravenous injection with fentanyl and ketorolac tromethamin. Pain during motion was evaluated every 12 hours after surgery for 120 hours (see Figure 153).

Figure 153 Pain during motion as measured by VAS



AAOS calculated effect size

FUTURE RESEARCH

The process for development of this guideline included preliminary “framing” of the clinically-important questions by a team of knowledgeable and experienced shoulder surgeons. Following a comprehensive search of the English literature, seventy-four studies were of sufficient evidence-based quality to be utilized in the current guidelines. The high number of studies that did not meet inclusion criteria suggests considerable future opportunities for research with higher levels of evidence. That was not to say that our present level of scientific and clinical literature was without value - quite the contrary. Many of the non-included articles were both important and clinically-relevant, but fell below the quality criteria for evidence-based guidelines. This huge mass of non-included published information, combined with clinical experience and basic science knowledge, formed the basis for guidelines arrived by expert consensus; however, clinical and surgical tradition are clearly not the ideal methods for defining treatment guidelines. Therefore, one of the most important consequences of developing this guideline is better appreciation and understanding for areas that should be rigorously investigated in the future to establish evidence-based clinical treatment algorithms (see below).

We recognize the many logistical, financial, and ethical challenges imposed when conducting high quality, prospective, randomized clinical research. We believe that some of these studies must be strategically encouraged by carefully-allocated research funding and programmatic support. In addition, while our evidence-based guidelines were based upon clinical research only, we understand that basic research will also play a fundamental role in the clinical development of rotator cuff treatment.

Recommended Focus Areas:

- The basic biology for mechanisms of rotator cuff tendon degeneration, tendon healing, and muscle-tendon disease after tear.
- Epidemiology and demographics of natural history of tendinosis, partial thickness cuff tears, asymptomatic full thickness cuff tears, and symptomatic rotator cuff tears.
- Development of non-invasive methods (i.e., advanced imaging modalities, biomarkers) for assessment of disease state, healing, and treatment impact.
- Rigorous correlation of these non-invasive methods with validated clinical outcome variables to create objective “surrogate” outcome variables for prospective clinical research.
- Effects of timing of intervention, particularly timing of surgery, upon disease progression and clinical outcome.
- Impact of surgical approach (open, mini-open, arthroscopic), rehab methods and fixation methods upon rates of rotator cuff healing.

- Studies investigating the impact of lack of healing on long-term clinical outcome.
- Clinical efficacy and cost-benefit of office-based physical therapy versus home exercise programs for non-surgical and post-surgical management of rotator cuff disease.
- Operative indications and intervention strategies for massive rotator cuff tears with advanced muscle disease.
- Intervention strategies to halt or reverse muscle atrophy or fatty degeneration.
- Impact of NSAIDs and corticosteroid injections upon rotator cuff tendon – bone healing and clinical outcome.
- Impact of healing augmentation strategies (i.e., platelet rich plasma, growth factors, structural patches, matrix delivery) on rotator cuff healing and clinical outcome.

IV.APPENDIXES

APPENDIX I: WORK GROUP

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APPENDIX II

AAOS BODIES THAT APPROVED THIS CLINICAL PRACTICE GUIDELINE

Guidelines and Technology Oversight Committee

The AAOS Guidelines and Technology Oversight Committee (GTOC) consists of sixteen AAOS members. The overall purpose of this Committee is to oversee the development of the clinical practice guidelines, performance measures, health technology assessments and utilization guidelines.

Evidence Based Practice Committee

The AAOS Evidence Based Practice Committee (EBPC) consists of ten AAOS members. This Committee provides review, planning and oversight for all activities related to quality improvement in orthopaedic practice, including, but not limited to evidence-based guidelines, performance measures, and outcomes.

Council on Research, Quality Assessment, and Technology

To enhance the mission of the AAOS, the Council on Research, Quality Assessment, and Technology promotes the most ethically and scientifically sound basic, clinical, and translational research possible to ensure the future care for patients with musculoskeletal disorders. The Council also serves as the primary resource to educate its members, the public, and public policy makers regarding evidenced-based medical practice, orthopaedic devices and biologics regulatory pathways and standards development, patient safety, occupational health, technology assessment, and other related areas of importance.

The Council is comprised of the chairs of the AAOS Biological Implants, Biomedical Engineering, Evidence Based Practice, Guidelines and Technology Oversight, Occupational Health and Workers' Compensation, Patient Safety, Research Development, and US Bone and Joint Decade committees. Also on the Council are the AAOS second vice-president, representatives of the Diversity Advisory Board, the Women's Health Issues Advisory Board, the Board of Specialty Societies (BOS), the Board of Councilors (BOC), the Communications Cabinet, the Orthopaedic Research Society (ORS), the Orthopedic Research and Education Foundation (OREF), and three members at large.

Board of Directors

The 17 member AAOS Board of Directors manages the affairs of the AAOS, sets policy, and determines and continually reassesses the Strategic Plan.

DOCUMENTATION OF APPROVAL

AAOS Work Group Draft Completed May 20, 2010

REVIEW PROCESS

Peer Review Completed June 30, 2010

Public Commentary Completed September 30, 2010

APPROVAL PROCESS

AAOS Guidelines and Technology Oversight Committee November 18, 2010

AAOS Evidence Based Practice Committee November 18, 2010

AAOS Council on Research Quality Assessment
and Technology November 19, 2010

AAOS Board of Directors December 04, 2010

APPENDIX III LITERATURE SEARCHES

The search for eligible literature began with a search of the following databases on October 6, 2008:

- PubMed (from 1966 through October 1, 2008)
- EMBASE (from 1966 through October 1, 2008)
- CINAHL (from 1982 through October 1, 2008)
- The Cochrane Central Register of Controlled Trials (through October 1, 2008)

This initial search (after removal of duplicates) yielded 5644 articles, of which 388 were retrieved and evaluated. The full search strategies are listed below.

All literature searches were supplemented with manual screening of bibliographies in publications accepted for inclusion into the evidence base. In addition, the bibliographies of recent systematic reviews and other review articles were searched for potentially relevant citations.

SEARCH STRATEGIES

The search for relevant studies using PubMed included the follow search strategy:

rotator cuff OR shoulder impingement OR supraspinatus tendonitis OR subacromial bursitis OR glenohumeral instability OR cuff tear OR cuff tears OR supraspinatus atrophy OR subacromial atrophy OR ((infraspinatus OR supraspinatus OR subscapularis OR teres minor) AND (tear or impingement OR augmentation)) NOT "comment"[Publication Type] NOT "editorial"[Publication Type] NOT "letter"[Publication Type] NOT "Addresses"[Publication Type] NOT "News"[Publication Type] NOT "Newspaper Article"[Publication Type] NOT "Case Reports"[Publication Type] AND (("1"[PDat]:"2008/10/01"[PDat]) AND (Humans[Mesh]) AND (English[lang]))

The search for relevant studies using EMBASE included the follow search strategy:

'rotator cuff' OR 'shoulder impingement' OR 'supraspinatus tendonitis' OR 'subacromial bursitis' OR 'glenohumeral instability' OR 'cuff tear' OR 'cuff tears' OR 'supraspinatus atrophy' OR 'subacromial atrophy' OR ((infraspinatus OR supraspinatus OR subscapularis OR teres minor) AND (tear OR impingement OR augmentation)) AND ([article]/lim OR [conference paper]/lim OR [review]/lim) AND [english]/lim AND [humans]/lim AND [embase]/lim NOT [10-01-2008]/sd

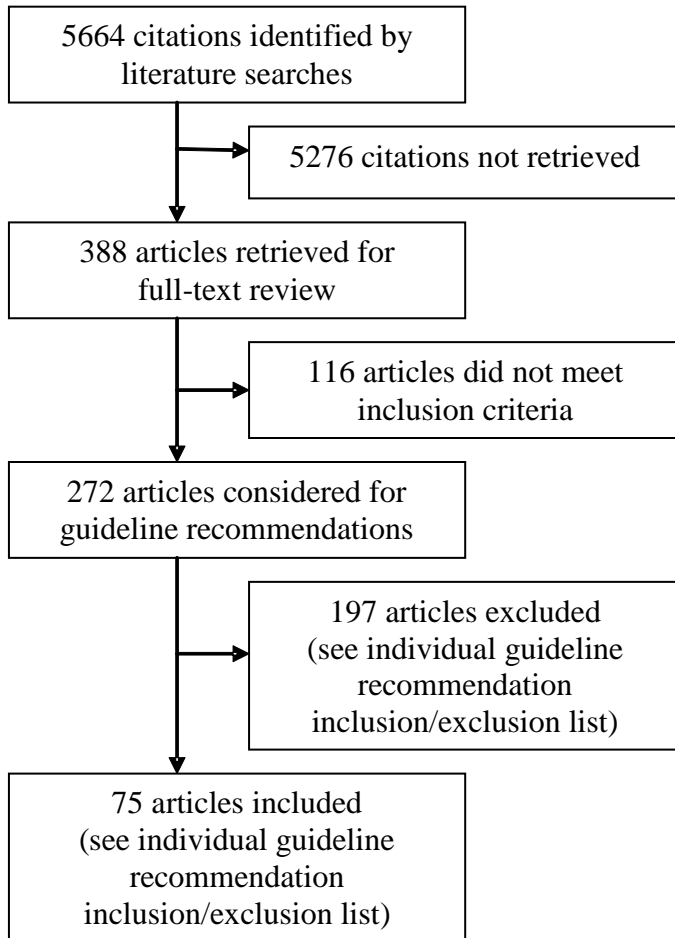
The search for relevant studies using CINAHL included the follow search strategy:

'rotator cuff' OR 'shoulder impingement' OR 'supraspinatus tendonitis' OR 'subacromial bursitis' OR 'glenohumeral instability' OR 'cuff tear' OR 'cuff tears' OR 'supraspinatus atrophy' OR 'subacromial atrophy' OR ((infraspinatus OR supraspinatus OR subscapularis OR teres AND minor) AND (tear OR impingement OR augmentation)), limited to ENGLISH.

The search for relevant studies in the Cochrane Central Register of Controlled Trials included the follow search strategy:

'rotator cuff' OR 'shoulder impingement' OR 'supraspinatus tendonitis' OR 'subacromial bursitis' OR 'glenohumeral instability' OR 'cuff tear' OR 'cuff tears' OR 'supraspinatus atrophy' OR 'subacromial atrophy' OR ((infraspinatus OR supraspinatus OR subscapularis OR teres AND minor) AND (tear OR impingement OR augmentation))

**APPENDIX IV
STUDY ATTRITION FLOWCHARTS**



APPENDIX V LEVEL OF EVIDENCE

Levels of Evidence For Primary Research Question¹

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic Review² of Level I RCTs (and study results were homogenous³) 	<ul style="list-style-type: none"> High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) Systematic review² of Level I studies 	<ul style="list-style-type: none"> Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review² of Level I studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review² of Level I studies
Level II	<ul style="list-style-type: none"> Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) Prospective⁴ comparative study⁵ Systematic review² of Level II studies or Level I studies with inconsistent results 	<ul style="list-style-type: none"> Retrospective⁶ study Untreated controls from an RCT Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) Systematic review² of Level II studies 	<ul style="list-style-type: none"> Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review² of Level II studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review² of Level II studies
Level III	<ul style="list-style-type: none"> Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Level III studies 	<ul style="list-style-type: none"> Case control study⁷ 	<ul style="list-style-type: none"> Study of non-consecutive patients; without consistently applied reference “gold” standard Systematic review² of Level III studies 	<ul style="list-style-type: none"> Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies
Level IV	Case Series ⁸	Case series	<ul style="list-style-type: none"> Case-control study Poor reference standard 	<ul style="list-style-type: none"> Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g. failed total arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

APPENDIX VI

DATA EXTRACTION ELEMENTS

The data elements below were extracted into electronic forms in Microsoft® Access. The extracted information includes:

Study Characteristics (for all relevant outcomes in a study)

- methods of randomization and allocation
- use of blinding (patient, caregiver, evaluator)
- funding source/conflict of interest
- intention to treat analysis
- duration of the study
- number of subjects and follow-up percentage
- experimental and control groups
- a priori power analysis
- patient inclusion/exclusion criteria

Results (for all relevant outcomes in a study)

- outcome measure (including adverse events)
- is the outcome measure patient-oriented? validated? objective/subjective?
- duration at which outcome measure was evaluated
- statistic reported (for dichotomous results)
- mean value and measure and value of dispersion (continuous results)
- statistical test used, value of test statistic, and p-value
- verification of calculations

**APPENDIX VII
FORM FOR ASSIGNING GRADE OF RECOMMENDATION
(INTERVENTIONS)**

GUIDELINE RECOMMENDATION _____

PRELIMINARY GRADE OF
RECOMMENDATION: _____

STEP 1: LIST BENEFITS AND HARMS

Please list the benefits (as demonstrated by the systematic review) of the intervention

Please list the harms (as demonstrated by the systematic review) of the intervention

Please list the benefits for which the systematic review is not definitive

Please list the harms for which the systematic review is not definitive

STEP 2: IDENTIFY CRITICAL OUTCOMES

Please circle the above outcomes that are critical for determining whether the intervention is beneficial and whether it is harmful

Are data about critical outcomes lacking to such a degree that you would lower the preliminary grade of the recommendation?

What is the resulting grade of recommendation?

STEP 3: EVALUATE APPLICABILITY OF THE EVIDENCE

Is the applicability of the evidence for any of the critical outcomes so low that substantially worse results are likely to be obtained in actual clinical practice?

Please list the critical outcomes backed by evidence of doubtful applicability:

Should the grade of recommendation be lowered because of low applicability?

What is the resulting grade of recommendation?

STEP 4: BALANCE BENEFITS AND HARMS

Are there trade-offs between benefits and harms that alter the grade of recommendation obtained in STEP 3?

What is the resulting grade of recommendation?

STEP 5 CONSIDER STRENGTH OF EVIDENCE

Does the strength of the existing evidence alter the grade of recommendation obtained in STEP 4?

What is the resulting grade of recommendation?

NOTE: Because we are not performing a formal cost analyses, you should only consider costs if their impact is substantial.

APPENDIX VIII

VOTING BY THE NOMINAL GROUP TECHNIQUE

Voting on guideline recommendations and performance measures will be conducted using a modification of the nominal group technique (NGT), a method previously used in guideline development.⁴² Briefly each member of the guideline work group ranks his or her agreement with a guideline recommendation or performance measure on a scale ranging from 1 to 9 (where 1 is “extremely inappropriate” and 9 is “extremely appropriate”). Consensus is obtained if the number of individuals who do not rate a measure as 7, 8, or 9 is statistically non-significant (as determined using the binomial distribution). Because the number of work group members who are allowed to dissent with the recommendation depends on statistical significance, the number of permissible dissenters varies with the size of the work group. The number of permissible dissenters for several work group sizes is given in the table below:

work group Size	Number of Permissible Dissenters
≤ 3	Not allowed. Statistical significance cannot be obtained
4-5	0
6-8	1
9	1 or 2

The NGT is conducted by first having members vote on a given recommendation/performance measure without discussion. If the number of dissenters is “permissible”, the recommendation/measure is adopted without further discussion. If the number of dissenters is not permissible, there is further discussion to see whether the disagreement(s) can be resolved. Three rounds of voting are held to attempt to resolve disagreements. If disagreements are not resolved after three voting rounds, no recommendation/measure is adopted.

OPINION-BASED RECOMMENDATIONS

A guideline can contain recommendations that are backed by little or no data. Under such circumstances, work groups often issue opinion-based recommendations. Although doing so is sometimes acceptable in an evidence-based guideline (expert opinion is a form of evidence), it is also important to avoid constructing a guideline that liberally uses expert opinion; research shows that expert opinion is often incorrect.

Opinion-based recommendations are developed only if they address a vitally important aspect of patient care. For example, constructing an opinion-based recommendation in favor of taking a history and physical is warranted. Constructing an opinion-based recommendation in favor of a specific modification of a surgical technique is seldom warranted. To ensure that an opinion-based recommendation is absolutely necessary, the AAOS has adopted rules to guide the content of the rationales that underpin such recommendations. These rules are based on those outlined by the US Preventive Services Task Force (USPSTF).¹¹⁸ Specifically, rationales based on expert opinion must:

- Not contain references to or citations from articles not included in the systematic review that underpins the recommendation.
- Not contain the AAOS guideline language “We Recommend”, “We suggest” or “treatment x is an option”.
- Contain an explanation of the potential preventable burden of disease. This involves considering both the incidence and/or prevalence of the disease, disorder, or condition and considering the associated burden of suffering. To paraphrase the USPSTF, when evidence is insufficient, provision of a treatment (or diagnostic) for a serious condition might be viewed more favorably than provision of a treatment (or diagnostic) for a condition that does not cause as much suffering. The AAOS (like the USPSTF) understand that evaluating the “burden of suffering” is subjective and involves judgment. This evaluation should be informed by patient values and concerns. The considerations outlined in this bullet make it difficult to recommend new technologies. It is not appropriate for a guideline to recommend widespread use of a technology backed by little data and for which there is limited experience. Such technologies are addressed in the AAOS’ Technology Overviews.
- Address potential harms. In general, “When the evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television).”¹¹⁸
- Address apparent discrepancies in the logic of different recommendations. Accordingly, if there are no relevant data for several recommendations and the work group chooses to issue an opinion-based recommendation in some cases but chooses not to make a recommendation in other cases, the rationales for the opinion-based recommendations must explain why this difference exists. Information garnered from the previous bullet points will be helpful in this regard.
- Consider current practice. The USPSTF specifically states that clinicians justifiably fear that not doing something that is done on a widespread basis will lead to litigation.¹¹⁸ The consequences of not providing a service that is neither widely available nor widely used are less serious than the

consequences of not providing a treatment accepted by the medical profession and thus expected by patients. Discussions of available treatments and procedures rely on mutual communication between the patient's guardian and physician, and on weighing the potential risks and benefits for a given patient. The patient's "expectation of treatment" must be tempered by the treating physician's guidance about the reasonable outcomes that the patient can expect.

- Justify, why a more costly device, drug, or procedure is being recommended over a less costly one whenever such an opinion-based recommendation is made.

Work group members write the rationales for opinion based recommendations on the first day of the final work group meeting. When the work group re-convenes on the second day of its meeting, it will vote on the rationales. The typical voting rules will apply. If the work group cannot adopt a rationale after three votes, the rationale and the opinion-based recommendation will be withdrawn, and a "recommendation" stating that the group can neither recommend for or against the recommendation in question will appear in the guideline.

Discussions of opinion-based rationales may cause some members to change their minds about whether to issue an opinion-based recommendation. Accordingly, at any time during the discussion of the rationale for an opinion-based recommendation, any member of the work group can make a motion to withdraw that recommendation and have the guideline state that the work group can neither recommend for or against the recommendation in question.

CHECKLIST FOR VOTING ON OPINION-BASED RECOMMENDATIONS

When voting on the rationale, please consider the following:

1. Does the recommendation affect a substantial number of patients or address treatment (or diagnosis) of a condition that causes death and/or considerable suffering?
2. Does the recommendation address the potential harms that will be incurred if it is implemented and, if these harms are serious, does the recommendation justify;
 - a. why the potential benefits outweigh the potential harms and/or
 - b. why an alternative course of treatment (or diagnostic workup) that involves less serious or fewer harms is not being recommended?
3. Does the rationale explain why the work group chose to make a recommendation in the face of minimal evidence while, in other instances, it chose to make no recommendation in the face of a similar amount of evidence?

4. Does the rationale explain that the recommendation is consistent with current practice?
5. If relevant, does the rationale justify why a more costly device, drug, or procedure is being recommended over a less costly one?

**American Academy of Orthopaedic Surgeons
[Optimizing the Treatment of Rotator Cuff Problems]
Guidelines Peer Review Form**

**APPENDIX IX
STRUCTURED PEER REVIEW FORM**

ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:

Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments

Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:

Name of Reviewer _____

Address _____

City _____ State _____ Zip Code _____

Phone _____ Fax _____ E-mail _____

Specialty Area/Discipline: _____

Work setting: _____ Credentials: _____

May we list you as a Peer Reviewer in the final Guidelines (GL)? Yes No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes.

However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? Yes No

If yes, may we list your society as a reviewer of this guideline? Yes No

Society Name: _____

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

If the boxes below are not checked and/or the reviewer does not attach his/her conflicts of interest, the reviewer's comments will not be addressed by the AAOS nor will the reviewer's name or society be listed as a reviewer of this GL. If a committee reviews the guideline, only the chairperson/or lead of the review must declare their relevant COI.

I have declared my conflicts of interest on page 2 of this form.

I have declared my conflicts of interest in the AAOS database; my customer # is _____

I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.

**American Academy of Orthopaedic Surgeons
[Optimizing the Treatment of Rotator Cuff Problems]
Guidelines Peer Review Form**

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

<p>Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?</p> <p>If YES, please identify product or device:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company?</p> <p>If YES, please identify company:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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<p>Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?</p> <p>If YES, please identify company or supplier:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?</p> <p>If YES, please identify company or supplier:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Do you or a member of your immediate family own stock or stock options in any pharmaceutical,</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

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<p>biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds)</p> <p>If YES, please identify company or supplier:</p>	
<p>Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?</p> <p>If YES, please identify company or supplier:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier?</p> <p>If YES, please identify company or supplier:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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<p>Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?</p> <p>If YES, please identify:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society?</p> <p>If YES, please identify:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

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Reviewer Instructions

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments **in WORD format** by end of day **June 30, 2010**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.				
	Somewhat Disagree	Somewhat Disagree	Somewhat Agree	Somewhat Agree
1. The recommendations are clearly stated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. There is an explicit link between the recommendations and the supporting evidence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Given the nature of the topic and the data, all clinically important outcomes are considered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The guideline's target audience is clearly described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The patients to whom this guideline is meant to apply are specifically described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The criteria used to select articles for inclusion are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The reasons why some studies were excluded are clearly described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. All important studies that met the article inclusion criteria are included	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The validity of the studies is appropriately appraised	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. The methods are described in such a way as to be reproducible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. The statistical methods are appropriate to the material and the	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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objectives of this guideline				
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Health benefits, side effects, and risks are adequately addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. The writing style is appropriate for health care professionals.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. The grades assigned to each recommendation are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

- Strongly recommend
- Recommend (with provisions or alterations)
- Would not recommend
- Unsure

PEER REVIEW

Participation in the AAOS peer review process does not constitute an endorsement of this guideline by the participating organization.

The following three organizations participated in peer review of this clinical practice guideline and gave their explicit consent to have their names listed in this document:

American Society for Surgery of the Hand (ASSH)

American Society of Shoulder and Elbow Therapists (ASSET)

American Physical Therapy Association (APTA)

Individuals who participated in the peer review of this document and gave their consent to be listed as reviewers in this document are:

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Participation in the AAOS peer review process does not constitute an endorsement of this guideline by the participating organization.

PUBLIC COMMENTARY

A period of public commentary follows the peer review of the draft guideline. If significant non-editorial changes are made to the document as a result of public commentary, these changes are also documented and forwarded to the AAOS bodies that approve the final guideline.

Public commentators who gave explicit consent to be listed in this document include the following:

James R. Andrews, MD

David C. Ring MD and Joy C. MacDermid PT, PhD Co-Chairs of the ASSH Evidence Based Practice Committee

Participation in the AAOS guideline public commentary review process does not constitute an endorsement of the guideline by the participating organizations or the individual listed nor does it in any way imply the reviewer supports this document.

APPENDIX X CONFLICT OF INTEREST

All members of the AAOS work group disclosed any conflicts of interest prior to the development of the recommendations for this guideline. Conflicts of interest are disclosed in writing with the American Academy of Orthopaedic Surgeons via a private on-line reporting database and also verbally at the recommendation approval meeting. For blinding purposes, work group members are identified by number only.

Christopher S Ahmad, MD 3B (Acumed, LLC; Arthrex, Inc); 5 (Stryker); 6 (Zimmer); Submitted on: 09/29/2010. *

Robert T Burks, MD 1 (Arthrex, Inc); 2 (Arthrex, Inc); 3B (Arthrex, Inc); 9 (Arthroscopy Association of North America); Submitted on: 10/06/2010. *

Evan L Flatow, MD 1 (Zimmer); 2 (Zimmer); 3C (Zimmer); 5 (Wyeth); 7 (Wolters Kluwer Health - Lippincott Williams & Wilkins); 9 (American Shoulder and Elbow Surgeons; Arthroscopy Association of North America); Submitted on: 04/25/2010 and last confirmed as accurate on 09/24/2010. *

Andrew Green, MD 1 (Tornier); 2 (DJ Orthopaedics); 3B (IlluminOss; Tornier); 4 (IlluminOss Medical; Pfizer); 5 (Arthrex, Inc; Smith & Nephew; Wyeth); 7 (Elsevier); 8 (Journal of Bone and Joint Surgery - American; Journal of Orthopaedics and Traumatology); 9 (AAOS); Submitted on: 10/06/2010. *

Joseph P Iannotti, MD, PhD 1 (DePuy, A Johnson & Johnson Company); 3B (DePuy, A Johnson & Johnson Company; Tornier; Wyeth); 7 (Wolters Kluwer Health - Lippincott Williams & Wilkins); 8 (Journal of Shoulder and Elbow Surgery); Submitted on: 10/05/2010. *

Bruce S Miller, MD 8 (American Journal of Sports Medicine; Journal of Knee Surgery); 9 (American Orthopaedic Society for Sports Medicine); Submitted on: 09/13/2010 and last confirmed as accurate on 10/14/2010. *

Robert A Pedowitz, MD 7 (Springer; Wolters Kluwer Health - Lippincott Williams & Wilkins); 8 (Arthroscopy); 9 (AAOS; American Orthopaedic Society for Sports Medicine; Arthroscopy Association of North America); Submitted on: 09/15/2010. *

Robert Tashjian, MD (Salt Lake City, UT): (n). Submitted on: 02/19/2008.

William Charles Watters III, MD 3B (Stryker); 4 (Intrinsic Orthopedics); 8 (Official Disability Guidelines; Spine; The Spine Journal); 9 (American Board of Spine Surgery; North American Spine Society); Submitted on: 05/26/2010 and last confirmed as accurate on 09/14/2010. *

Ken Yamaguchi, MD 8 (AAOS Now; Journal of Bone and Joint Surgery - American); Submitted on: 04/30/2010 and last confirmed as accurate on 10/15/2010. *

*** Disclosure Items Answered: (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.

Disclosure Items: (n) = Respondent answered 'No' to all items indicating no conflicts. 1=Board member/owner/officer/committee appointments; 2= Medical/Orthopaedic Publications; 3= Royalties; 4= Speakers bureau/paid presentations; 5A= Paid consultant; 5B= Unpaid consultant; 6= Research or institutional support from a publisher; 7= Research or institutional support from a company or supplier; 8= Stock or Stock Options; 9= Other financial/material support from a publisher; 10= Other financial/material support from a company or supplier.

APPENDIX XI REFERENCES

* For a list of included articles applicable to each recommendation, please consult the accompanying evidence tables.

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