

Comparative Effectiveness Review

Draft

Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears

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www.ahrq.gov

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Prepared by:

University of Alberta Evidence-based Practice Center
Edmonton, Alberta, Canada

Research Team:

Jennifer C. Seida, M.P.H. (project coordinator)
Janine R. Schouten, B.Sc.
Shima S. Mousavi, M.D.
Lisa Tjosvold, M.L.I.S.
Ben Vandermeer, M.Sc.
Andrea Milne, B.Sc.N.
Kenneth Bond, B.Ed., M.A.
Lisa Hartling, B.Sc.P.T., M.Sc.

Clinical Investigators:

David M. Sheps, M.D., M.Sc., F.R.C.S.C.
Claire LeBlanc, M.D., F.R.C.P.C.

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Preface

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We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to epc@ahrq.gov.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Beth A. Collins Sharp, R.N., Ph.D.
Director, EPC Program
Agency for Healthcare Research and Quality

CAPT. Karen Lohmann Siegel, P.T., M.A.
EPC Program Task Order Officer
Agency for Healthcare Research and Quality

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Structured Abstract

Objectives: To review and synthesize the evidence on nonoperative and operative interventions and postoperative rehabilitation for the treatment of rotator cuff tears in adults. Key outcomes include health-related quality of life, disability, time to return to work, pain, range of motion, strength, and cuff integrity.

Data Sources: Comprehensive literature searches were conducted in 12 electronic databases from 1990 to January 2009. Trial registries and the reference lists of previous systematic reviews were screened to identify additional studies.

Methods: Study selection and quality assessment were conducted independently by several investigators in duplicate. Discrepancies were resolved by consensus or third-party adjudication. Data were extracted by one reviewer and verified by a second reviewer. Descriptive analysis is presented for all studies and meta-analysis was conducted where appropriate.

Results: In total, 122 studies were included in the review (20 trials, 30 cohort studies, 71 uncontrolled studies). All of the trials were considered to be at high risk for bias. The methodological quality of the cohort and uncontrolled studies was moderate.

No studies were identified that compared early versus delayed surgery. The majority of the included studies (n=102, 82 percent) examined the effectiveness of operative interventions. There was moderate evidence showing no statistical or clinically important differences in function between open and mini-open repairs, but results indicated an earlier return to work by approximately 1 month for mini-open repairs. There was no difference in function between open/mini-open and arthroscopic repairs and between arthroscopic repairs with acromioplasty and without acromioplasty. Open repairs showed greater improvement in function when compared with arthroscopic debridement. There was moderate evidence indicating no difference in function between single-row and double-row fixation, but a potential for greater cuff integrity with double-row fixation. The evidence was too limited to make conclusions for all other operative interventions examined.

For postoperative rehabilitation, there was moderate evidence showing no statistical or clinically important difference in function between continuous passive motion with physical therapy and physical therapy treatment alone; however, there was some evidence indicating earlier return to work for the combination therapy group. For all other postoperative interventions, as well as nonoperative treatments and nonoperative and operative comparisons, the evidence was too limited to make conclusions.

The rates of complication were low and the majority of complications were not deemed to be clinically important or were reported in few studies.

Conclusion: There was moderate evidence for some interventions, yet data was too limited to make definite conclusions for the majority of intervention examined. Few differences of clinical importance are evident when comparing the relative effectiveness of the various treatments.

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Executive Summary

Introduction

The rotator cuff (RC) is comprised of four muscle-tendon units which stabilize the humeral head within the shoulder joint and aid in powering the movement of the upper extremity.¹ RC tears refer to a partial or full discontinuation of one or more of the muscles or tendons and may occur as a result of traumatic injury or degeneration over a period of years. The incidence of RC tears is related to increasing age; 54 percent of patients over the age of 60 years have a partial or complete RC tear compared with only 4 percent of adults under 40 years of age.² Although not a life-threatening condition, RC tears may cause significant pain, weakness, and limitation of motion.¹

Both nonoperative and operative treatments are used in an attempt to relieve pain and restore movement and function of the shoulder.³ The majority of patients first undergo 6 weeks to 3 months of nonoperative treatment, which may consist of any combination of pain management (medications and injections), rest from activity, passive and active exercise, and modalities such as heat, cold or ultrasound. Failing nonoperative treatment, the cuff may be surgically repaired using an open, mini-open or all-arthroscopic approach. A variety of postoperative rehabilitation programs are used to restore range of motion, muscle strength, and function following operative treatment.

Earlier operative treatment has been proposed to result in better patient outcomes, earlier return to work, and decreased costs;^{4,5} therefore, patients and clinicians face the difficult decision of when to forego attempts at nonoperative treatment in favour of operative treatment. Moreover, the comparative effectiveness of the various nonoperative and operative treatment options for patients with RC tears remains uncertain.

Key Questions

The following key questions were investigated for a population of adult patients with partial- and full-thickness RC tears:

1. Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
2. What is the comparative effectiveness of operative approaches (e.g., open surgery, mini-open surgery, arthroscopy) and postoperative rehabilitation on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
 - a. Which operative approach should be used for different types of tears (e.g., partial-thickness, full-thickness, small, medium, large or massive, with or without fatty infiltration of muscle tissue)?

3. What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, other treatments and modalities typically delivered by physical therapists, osteopaths and chiropractors.
 - a. Which nonoperative treatment approach should be used for different types of tears (e.g., partial-thickness, full-thickness, small, medium, large or massive, with or without fatty infiltration of muscle tissue)?
4. Does operative repair compared to nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
5. What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?
6. Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size / severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment?
 - a. Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?

Methods

Literature Search

The following bibliographic databases were searched systematically for studies published from 1990 to 2009: MEDLINE[®], EMBASE, EBM Reviews – The Cochrane Library, AMED, CINAHL[®], SPORTDiscus with Full Text, Academic Search Elite, Health Source, Science Citation Index Expanded (via Web of Science[®]), Scopus[®], BIOSIS Previews[®], CRISP, Current Controlled Trials, ClinicalTrials.gov and the Netherlands Trial Register. Abstracts from the following scientific meetings were hand searched: Arthroscopy Association of North America (2007-2009), American Academy of Orthopaedic Surgeons (2007-2009), American Physical Therapy Association (2006-2008), American Shoulder and Elbow Surgeons (2005-2008), American Society of Shoulder and Elbow Therapists (2004-2008), European Congress of Physical and Rehabilitation Medicine 2008 and the Mid-America Orthopaedic Association (2006-2008). Reference lists of relevant reviews were searched to identify additional studies. No language restrictions were applied.

Study Selection

Two reviewers independently screened titles and abstracts using general inclusion criteria. The full text publication of all articles identified as “include” or “unclear” were retrieved for formal review. Each full text article was independently assessed by two reviewers using detailed a priori inclusion criteria and a standardized form. Disagreements were resolved by consensus or by third-party adjudication.

Controlled and prospective uncontrolled studies were included in the review if they were published in 1990 or later, included a minimum of 11 participants, focused on adults with a partial or full-thickness tear that was confirmed by imaging or intraoperative findings and examined any operative or nonoperative intervention or postoperative rehabilitation. In addition, studies were required to report on at least one outcome of interest (quality of life, function, time to return to work, cuff integrity, pain, range of motion, strength) and have a minimum followup duration of 12 months for operative studies.

Quality Assessment and Rating the Body of Evidence

Two reviewers independently assessed the methodological quality of included studies. The Cochrane Collaboration’s risk of bias tool was used to assess randomized controlled trials and controlled clinical trials. Observational analytic studies were assessed using modified cohort and case-control Newcastle-Ottawa Quality Assessment Scales. The methodological quality of uncontrolled studies was assessed using a quality checklist developed by the UAEPC; the checklist consisted of three items: consecutive enrollment, incomplete outcome data, and standardized/independent approach to outcome assessment. In addition, the source of funding was recorded for all studies.

The body of evidence was rated by one reviewer using the EPC GRADE approach. The strength of evidence was assessed for four key outcomes considered by the clinical investigators to be most clinically relevant: health-related quality of life, functional outcomes, time to return to work, and cuff integrity. The following four major domains were assessed: risk of bias (low, medium, high), consistency (no inconsistency, inconsistency present, unknown or not applicable), directness (direct, indirect), and precision (precise, imprecise).

Data Extraction

Data were extracted by one reviewer using a standardized form and verified for accuracy and completeness by a second reviewer. Extracted data included study characteristics, inclusion/exclusion criteria, participant characteristics, interventions, and outcomes. Reviewers resolved discrepancies by consensus or in consultation with a third party.

Data Analysis

Evidence tables and qualitative description of results were presented for all included studies. Comparative studies were considered appropriate to combine in a meta-analysis if the study design, study population, interventions being compared, and outcomes were deemed sufficiently similar. Results were combined using random effects models. Statistical heterogeneity was quantified using the I-squared (I^2) statistic. Graphs were created to display the preoperative and

postoperative scores of uncontrolled studies, cohort studies, and trials, over the duration of the study followup period.

Results

Description of Included Studies

The search strategy identified 5,307 citations; 122 unique studies met the eligibility criteria and were included in the review. The studies included 20 trials, 31 cohort studies, and 71 uncontrolled studies. The number of participants in the studies ranged from 12 to 224 (median=53 [interquartile range (IQR): 30 to 85]). The mean age of study participants ranged from 41.2 to 80 years.

Methodological Quality of Included Studies

All of the randomized controlled trials and controlled clinical trials were considered to have a high risk of bias. The most common sources of potential bias were inadequate blinding, inadequate allocation concealment, and incomplete outcome data. The methodological quality of the cohort studies was moderate, with a median score of 5 stars on a possible score of 8 stars (IQR: 4 to 6). Common weaknesses in the design of the studies included lack of independent blind outcome assessment and failure to adequately control for potential confounding factors. Uncontrolled studies generally had moderate quality, with consecutive enrollment, adequate followup, and standardized outcome assessment being reported in 63, 77, and 44 percent of studies, respectively. Across all studies, source of funding was rarely reported (n=81, 66 percent).

Results of Included Studies

The results of the included studies are presented by the key question(s) they address. A table with the summary of findings for nonoperative and operative interventions is presented below.

Early versus late surgical repair. No studies compared early surgical repair versus late surgical repair after failed nonoperative treatment.

Comparative effectiveness of operative interventions and postoperative rehabilitation. A total of 102 studies examined the effectiveness of operative interventions, while nine studies evaluated postoperative rehabilitation protocols following surgery. A median of 56 patients (IQR: 33.3 to 94.5) with a median age of 59 years (IQR: 55.7 to 62) were included in the operative studies. Males comprised an average of 55.9 percent of the study participants. For postoperative rehabilitation, studies included a median of 61 participants (IQR: 41 to 79) with a median age of 58.0 (IQR: 55.8 to 60.2). Males comprised an average of 51.4 percent of study participants.

Studies assessing operative treatments were categorized as focusing on an operative approach (e.g., open, mini-open, arthroscopic, debridement), technique (i.e., suture or anchor type or configuration) or augmentation for RC repair. The majority of surgical studies (26 comparative studies and 58 uncontrolled studies) evaluated operative approaches. The comparative studies provided moderate evidence indicating no statistical or clinically important differences in function between open and mini-open repairs; however, there was some evidence suggesting an earlier return to work by approximately 1 month for mini-open repairs. Similarly, there was

moderate evidence demonstrating no difference in function between mini-open and arthroscopic repair and arthroscopic repair with and without acromioplasty. There was moderate evidence for greater improvement in function for open repairs compared to arthroscopic debridement. The strength of evidence was low for the remaining comparisons and outcomes examined in the studies, precluding any conclusions regarding their comparative effectiveness. The uncontrolled studies consistently reported functional improvement from preoperative to postoperative scores, regardless of the type of approach used (open, mini-open or arthroscopic), the study design, the sample size of the study or the type of outcome measure used.

Operative techniques were examined in 11 comparative studies. Four studies compared single-row versus double-row fixation of repairs, providing moderate evidence of no difference in function, but potential for greater cuff integrity with double-row fixation. The evidence was too limited to make conclusions for the other techniques.

Seven studies, including two comparative and five uncontrolled studies, assessed augmentations for operative repair. As the two comparative studies were relatively small and evaluated different augmentation techniques, no overall conclusions were possible. Although the five uncontrolled studies evaluated different types of augmentations, they all indicated improvement in functional score from baseline to final followup.

Of the nine postoperative rehabilitation studies (eight comparative, one uncontrolled), three compared continuous passive motion with physical therapy versus physical therapy alone. These three studies provided moderate evidence of no clinically important or statistically significant difference in function, but some evidence for earlier return to work with continuous passive motion. Each of the remaining studies examined different rehabilitation protocols; therefore, the evidence was too limited to make any conclusions regarding their comparative effectiveness.

Comparative effectiveness of nonoperative interventions. Nonoperative interventions were examined in three comparative and seven uncontrolled studies. The studies included a median of 42 patients (IQR: 25.3 to 73.3), with a median age of 61 years (IQR: 60.4 to 61.5). Males comprised an average of 50 percent of participants. Each of the comparative studies assessed different interventions, including: sodium hyaluronate versus dexamethasone, rehabilitation versus no rehabilitation (not otherwise specified), and physiotherapy, oral medications, and steroid injection versus physiotherapy, oral medications, and no steroid injection. The limited evidence precludes conclusions of comparative effectiveness. The degree of improvement in functional outcome scores varied considerably across the uncontrolled studies.

Comparative effectiveness of nonoperative versus operative interventions. Only three studies compared nonoperative to operative treatments, with sample sizes of 19, 40 and 108 participants. The mean ages in the studies were 46.9, 61.3 and 64.8 years. Males represented 21 and 83 percent of study participants in the two studies reporting gender. The interventions varied across studies, but generally the nonoperative arms included components such as steroid injection, stretching, and strengthening and were compared with open repair or debridement. The evidence was too limited to make conclusions regarding the comparative effectiveness of the interventions.

Complications. A total of 88 studies provided data on 29 different complications of nonoperative, operative, and postoperative rehabilitation interventions. Complications were poorly reported, with studies providing limited information on how complications were defined and assessed. In 29 studies, it was reported that no complication occurred during the course of

the study. In general, the rates of complication were low and the majority of complications were not deemed to be clinically important or were reported in few studies.

Effect modifiers. Overall, 66 of the 122 studies examined the impact of effect modifiers on patient outcomes. General conclusions are limited due to the varied methodologies across studies, particularly the different outcomes for which prognostic factors were evaluated. There is some evidence that tear size, age, and extent of preoperative symptoms may modify outcomes; while, workers’ compensation board (WCB) status, sex, and duration of symptoms generally showed no significant impact.

Summary of findings for nonoperative and operative interventions for RC tears

| Comparison (number of studies) | Strength of evidence | Summary |
|--|----------------------|---|
| Operative approaches | | |
| Open RCR vs. mini-open RCR (n=3) | Moderate | No statistically significant or clinically important difference for function. Some evidence for earlier return to work or sports (by approximately 1 month) with mini-open repairs. |
| | Low | The evidence was too limited to make a conclusion for health-related quality of life. |
| Mini-open RCR vs. arthroscopic RCR (n=8) | Moderate | No difference in function. |
| Open RCR vs. arthroscopic RCR (n=1) | Low | The evidence was too limited to make a conclusion. |
| Open or mini-open RCR vs. arthroscopic RCR (n=2) | Moderate | No difference in function. |
| | Low | The evidence was too limited to make a conclusion for cuff integrity. |
| Open RCR vs. arthroscopic debridement (n=4) | Moderate | Some evidence for greater improvement in function for open RCR. |
| Arthroscopic RCR with acromioplasty vs. without acromioplasty (n=2) | Moderate | No difference in function. |
| Biceps tenotomy vs. tenodesis (n=1) | Low | The evidence was too limited to make a conclusion. |
| Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy (n=1) | Low | The evidence was too limited to make a conclusion. |
| Mini-open RCR plus tenodesis with detachment vs. without detachment (n=1) | Low | The evidence was too limited to make a conclusion. |
| Arthroscopic debridement with biceps tenotomy vs. without tenotomy (n=1) | Low | The evidence was too limited to make a conclusion. |
| Complete open RCR vs. partial open RCR vs. debridement (n=1) | Low | The evidence was too limited to make a conclusion. |
| Open RCR with classic open acromioplasty vs. open RCR with modified open acromioplasty (n=1) | Low | The evidence was too limited to make a conclusion. |
| Operative techniques | | |
| Single-row vs. double-row suture anchor fixation (n=4) | Moderate | No clinically important difference for function. Some evidence for improved Cuff integrity with double-row sutures. |
| Bioabsorbable tacs vs. suture tying (n=1) | Low | The evidence was too limited to make a conclusion. |
| Nonabsorbable vs. absorbable sutures (n=1) | Low | The evidence was too limited to make a conclusion. |
| Bioabsorbable corkscrews vs. metal suture | Low | The evidence was too limited to make a |

anchor (n=1)

conclusion.

RCR = rotator cuff repair; SLAP = superior labral from anterior to posterior; vs. = versus

Summary of findings for nonoperative and operative interventions for RC tears (continued)

| Comparison (number of studies) | Strength of evidence | Summary |
|---|-----------------------------|---|
| <i>Operative techniques (continued)</i> | | |
| Mattress locking vs. simple stitch (n=1) | Low | The evidence was too limited to make a conclusion. |
| Mattress vs. transosseous suture (n=1) | Low | The evidence was too limited to make a conclusion. |
| Ultrasonic welding vs. hand-tied knots (n=1) | Low | The evidence was too limited to make a conclusion. |
| Staple fixation vs. side-to-side suture (n=1) | Low | The evidence was too limited to make a conclusion. |
| <i>Operative augmentation</i> | | |
| Porcine small intestine submucosa vs. no augmentation (n=1) | Low | The evidence was too limited to make a conclusion. |
| Patch graft vs. no augmentation (n=1) | Low | The evidence was too limited to make a conclusion. |
| <i>Postoperative rehabilitation</i> | | |
| Continuous passive motion with PT treatment versus PT treatment (n=3) | Moderate | No clinical or statistical difference in function. Some evidence for earlier return to work with continuous passive motion. |
| Aquatic therapy with land-based therapy versus land-based therapy (n=1) | Low | The evidence was too limited to make a conclusion. |
| Inpatient versus day patient rehabilitation (n=1) | Low | The evidence was too limited to make a conclusion. |
| Individualized PT program with home exercise versus home exercise (n=1) | Low | The evidence was too limited to make a conclusion. |
| Standardized versus non-standardized PT program (n=1) | Low | The evidence was too limited to make a conclusion. |
| Videotape versus PT home exercise instruction (n=1) | Low | The evidence was too limited to make a conclusion. |
| <i>Nonoperative interventions</i> | | |
| Sodium hyaluronate vs. dexamethasone (n=1) | Low | The evidence was too limited to make a conclusion. |
| Rehabilitation vs. no rehabilitation (n=1) | Low | The evidence was too limited to make a conclusion. |
| Physiotherapy, oral medications and steroid injection vs. physiotherapy, oral medications and no steroid injection (n=1) | Low | The evidence was too limited to make a conclusion. |
| <i>Nonoperative vs. operative treatment</i> | | |
| Steroid injection, physical therapy, and activity modification versus open repair (n=1) | Low | The evidence was too limited to make a conclusion. |
| Physical therapy treatment, oral medication, and steroid injection versus arthroscopic debridement versus open repair (n=1) | Low | The evidence was too limited to make a conclusion. |
| Passive stretching, strengthening, and corticosteroid injection versus open repair with acromioplasty (n=1) | Low | The evidence was too limited to make a conclusion. |

Future Research

Recommendations for further research:

- There is need for primary evidence comparing the effectiveness of early versus delayed surgery and nonoperative versus operative interventions.
- All future studies should employ a comparison or control group and ensure comparability of treatment groups, optimally through the use of randomization.
- Future research should seek to minimize bias by blinding outcome assessors, use of objective outcome assessment instruments, adequate allocation concealment (where applicable), and appropriate handling and reporting of missing data.
- Interventions and comparisons chosen for study should be guided by consensus regarding the most promising and/or controversial interventions in order to avoid numerous studies on disparate interventions.
- Consensus is needed on outcomes that are important to both clinicians and patients to ensure consistency and comparability across future studies. Moreover, consensus on minimal clinically important differences is needed to guide study design and interpretation of results.
- Future research needs to be reported in a consistent and comprehensive manner to permit the appropriate interpretation of results

Conclusions

For the majority of interventions, there are only sparse data available, precluding firm conclusions for any single approach or for the optimal overall management of this condition. The paucity of evidence related to early versus delayed surgery is of particular concern, as patient and providers must decide whether to attempt initial nonoperative management or immediately proceed with surgical repair. The majority of the data is derived from studies of low methodological quality or from study designs associated with higher risk of bias (e.g., observational and before-and-after studies). Overall, the evidence shows that all interventions result in substantial improvements; however, few differences of clinical importance are evident when comparisons between interventions are available. The rates of complication were generally low and the majority of complications were not deemed to be clinically important, therefore the benefit of receiving treatment for rotator cuff tears appears to outweigh the risk of associated harms.

Review Draft – Do Not Cite

Comparative Effectiveness Review

Chapter 1. Introduction

Condition and Prevalence

The rotator cuff (RC) is comprised of four muscle-tendon units (supraspinatus, infraspinatus, subscapularis, and teres minor) that originate on the scapula and combine to form a covering or "cuff" around the top of the humeral head.¹ The RC helps to stabilize the humeral head within the shoulder joint and aids in powering the upper extremity through the movements of flexion, extension, abduction, adduction and external and internal rotation.

A "tear" is the term given to a discontinuation in either one or more of the tendons or muscles that make up the RC; tears are classified as either partial or full thickness. Partial-thickness tears involve only a portion of the tendon thickness and do not lead to retraction of the muscle-tendon unit.⁶ In contrast, full-thickness tears refer to a complete discontinuity of RC fibers, resulting in contact between the articular and bursal spaces. RC tears are rated as small (<1 cm), medium (1-3 cm), large (3-5 cm), and massive (>5 cm). Tears that involve two or more tendons may also be classified as massive and may require more complex reconstruction.⁷ The degree of functional impairment of the muscle depends in part on the size of the tear.⁸

The RC can be torn from a single traumatic injury or, more commonly, a tear may result from overuse of the muscles and tendons over a period of years, leading to degeneration of the tendon that progresses to a tear.⁹ A cuff tear may also occur concurrently with another injury to the shoulder, such as a fracture or dislocation, or be the result of poor vascular supply, impingement, glenohumeral instability, scapulothoracic dysfunction or congenital abnormalities, such as os acromiale.¹⁰ RC tears also occur in the shoulders of overhead or throwing athletes, whose throwing motion involves maximum abduction and external rotation making the shoulder vulnerable to injury from repetitive high energy forces.¹¹ Once a tear occurs, it is unlikely to heal without treatment.⁶ Left untreated, large tears may result in chronically retracted muscle-tendon units that undergo fatty degeneration resulting in weakness, a potentially irreversible process.⁹

The incidence of RC tears is expected to increase with the growth of an aging population that is more active and less willing to accept functional limitations.¹² Magnetic resonance imaging (MRI) studies have shown partial or complete tears in only 4 percent of patients under 40 years of age compared with 54 percent of patients over 60 years of age.² Larger tear size and occurrence of bilateral RC tears also increase with age.¹³ Although large proportion of patients with RC tears are asymptomatic, research has shown that over 50 percent of individuals with asymptomatic RC tears will develop pain over an average of 2.8 years.¹⁰

Although not a life-threatening condition, RC tears may cause significant pain, weakness, and limitation of motion.¹ A shoulder disorder can increase functional dependency in the elderly due to difficulties in completing activities of daily living.¹³ In younger adults, this morbidity may also lead to significant disability, including absenteeism from work and lost productivity. The impact of RC disease on lost productivity is reflected in the high costs associated with shoulder injuries in the workers' compensation system, and has been found to be the second most common cause after back pain for time away from work in manual laborers.¹⁴⁻¹⁶ According to data from the United States Department of Labor, 253,670 occupational shoulder injuries were reported in 2007. The average time off of work due to occupational shoulder injuries ranged from 4.3 to 7.5 days; however, 41.5 percent of occupational shoulder injuries required more than

31 days away from work in 2007.¹⁷ In addition, severe pain may affect sleep. The impact of RC disease on health-related quality of life, as measured by the SF-36, is comparable to the effects of hypertension, myocardial infarction, congestive heart failure, diabetes mellitus, and clinical depression.¹⁸

Diagnosis and Treatment

Diagnosis of an RC tear involves a complete history, appropriate physical examination, and a comparison of the involved shoulder to the uninjured side. The shoulder is palpated to identify areas of tenderness and range of motion of the shoulder is assessed both actively and passively.¹⁹ RC strength is evaluated and a number of provocative maneuvers are completed to assist in the development of a differential diagnosis. As clinical assessment of shoulder function has been found to give a poor estimate of cuff tear size,²⁰ diagnostic imaging may be employed as part of the preliminary work-up for chronic shoulder pain. Radiographs may be used initially followed by MRI, arthrography, computed tomography (CT) or ultrasound for further evaluation and clarification of possible pathology.¹⁹

Two treatment modalities, nonoperative and operative, are used in an attempt to relieve pain and restore movement and function of the shoulder.³ Most patients initially undergo 6 weeks to 3 months of nonoperative treatment; however, surgical repair may be indicated early on in the appropriate patient with a traumatic RC injury and a significant functional deficit.²¹ The most common nonoperative interventions include pain management (medications and injections), rest from activity, and a variety of treatments, both passive and active, delivered by physical therapists. Success rates with nonoperative treatments vary from less than 50 percent to greater than 90 percent; however, studies have used a variety of interventions and evaluation tools.²¹

Modalities used to decrease pain include heat or cold, ultrasound, and iontophoresis,^{13,22} as well as medications such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injections. When pain is controlled the patient can participate in physical therapy exercises designed to increase shoulder flexibility and strength. These exercises are designed to return the shoulder to optimal functioning through improvements in range of motion, proprioception and strength.²² When other nonoperative modalities have failed to reduce pain (e.g., relative rest, activity modification, physical therapy, and NSAIDs), corticosteroid injections combined with a local anesthetic may be used.²³ Controversy exists regarding the benefit of corticosteroid injections in the treatment of RC tears. Study results investigating the efficacy of injections vary, and it is unclear if corticosteroid injections provide significant benefit to the patient over treatment with NSAIDs.^{13,22}

Failing nonoperative treatment, there are three surgical approaches to rotator cuff repair (RCR): open, mini-open, and arthroscopic, the last two of which have evolved throughout the last decade.²⁴ The first surgical repair of a torn RC was performed in 1909 by Ernest Codman.²⁵ In 1972, Charles Neer developed an open surgical technique, which uses a large (9-centimetre) incision over the shoulder from the anterior edge of the acromion to a point just lateral to the coracoid. The deltoid is split (5 centimetres) and dissected from the anterolateral acromion and the distal clavicle. This allows for adequate visualization of the RC tear. A small wedge-shaped piece of bone is removed from underneath the acromion, as is the coracoacromial ligament. In the case of acromioclavicular osteophytes and acromioclavicular arthritis, up to 2 centimetres of the

distal clavical may be excised along with any prominences on the acromial side. Careful reattachment of the deltoid to the acromion and clavicle is required following the repair.²⁶

A mini-open repair combines an open technique with arthroscopy to reduce the size of the incision required to perform the repair. Initially, portals are created to allow the insertion of the arthroscope and arthroscopic tools. To perform the repair, an additional incision is created to visualize the RC. The surgeon reaches the RC tear by splitting the deltoid muscle in line with its fibers rather than releasing it from the acromion. A temporary suture is placed in the deltoid to prevent further tearing of the muscle and damage to the axillary nerve while the RCR is completed. Mini-open repair is currently considered best suited for small and medium tears, but may be used for larger tears.²⁵ The mini-open approach reduces the chance of deltoid injury and failure of the deltoid repair that may occur with a traditional open technique.²⁷

Arthroscopic surgery uses specially designed instruments (a camera, a fiberoptic light source, and the instruments required for the repair) that are inserted into the joint through a series of small incisions or portals. Modern arthroscopic techniques now allow for not only the evaluation of both the bursal and articular surfaces of the RC, as well as other structures within the shoulder joint, but also allow for definitive treatment of the injured RC.¹¹ Most authors agree that indications for arthroscopic repair are similar to those for open repair.²⁶ Arthroscopic repair has a number of benefits over open repair including: shorter hospital stays, lower levels of pain, better cosmetic outcomes, preservation of the deltoid muscle, and direct inspection of the glenohumeral joint.²⁶

Regardless of whether surgery is open, mini-open, or arthroscopic, treatment may involve any combination of RCR, debridement, and acromioplasty. The repair itself involves suturing the torn edges of the involved tendon(s) together and repair of the tendon back to the humeral head. A full or partial repair may be performed, depending on the severity of the tear. As its name implies, full repair is the complete repair of the tear. When a complete repair is not feasible, such as when the tear is extremely large, a partial tear may be performed in order to restore adequate function and delay the progression of the tear.⁸ Debridement involves removing loose fragments of tendon, bursa, and other debris from the space in the shoulder where the RC moves.¹¹ Acromioplasty involves the removal of bone from the underside of the anterolateral acromion (the tip of the shoulder blade), thus creating more room in the subacromial space, and decreasing mechanical impingement of the acromion on the RC. Subacromial decompression combines an acromioplasty with the removal of the subacromial bursa and coracoacromial ligament. Though performed on their own, debridement, acromioplasty and/or subacromial decompression are often performed in combination with an RCR.

Other procedures that may accompany RCR include labral repair, biceps tenotomy or tenodesis, and acromioclavicular joint arthroplasty. A labral repair involves the surgical repair of the labrum, a cuff of cartilage that circles the glenoid or socket of the shoulder and helps to stabilize the shoulder. A labral tear may occur as a result of trauma to the shoulder or fray and tear as part of the aging process. A biceps tenodesis detaches the tendon from its insertion at the top of the labrum and reattaches the tendon in the bicipital groove at the anterolateral aspect of the proximal humerus. Biceps tenotomy involves the release of the biceps tendon from its attachment without reattachment to the proximal humerus, thus allowing the tendon to retract distally in the upper arm outside of the shoulder joint. These procedures are performed for partial tears of the biceps tendon that cannot be repaired, bicep tendons that are subluxed or dislocated, or in situations when tears of the superior glenoid labrum cannot be repaired.

The final step in the surgical treatment of RC tears is a program of rehabilitation, the development of which is based on the type of surgery, size of tear, tissue quality, fixation methods, and patient characteristics.³ Following surgery, the shoulder is generally immobilized using a sling, both as a comfort measure and as a reminder to the patient to avoid use of the shoulder. Passive motion, continuous passive motion (the continuous movement of the repaired shoulder by a machine), and unassisted exercises are then used to restore range of motion and muscle strength, and to re-establish shoulder stability and function. Strengthening exercises are generally added gradually with progressive levels of resistance as sudden increases in exercise demands may lead to a failure of the repair. The primary goal of rehabilitation should be to protect the cuff repair, promote healing, restore passive and active motion, and increase muscular strength.³

It has been proposed that earlier surgical intervention may result in better outcomes, earlier return to work and decreased costs;^{4,5} thus, clinicians face the difficult decision of when to forego attempts at nonoperative management in favour of surgical treatment. Despite the significant morbidity and cost associated with RC tears, there remains much uncertainty regarding the comparative effectiveness of the many nonoperative and operative treatment options.

Outcome Assessment Scales

A wide variety of outcome measures have been used to evaluate the efficacy of RC treatments by assessing changes in patient function over the study period. A list of the frequently reported outcome measures is provided in Table 1. The majority of scales used in the RC literature are disease-specific questionnaires developed for the assessment of the shoulder; however, generic scales (e.g., SF-36) have also been used. The scales can broadly be classified into health-related quality of life and functional outcome measures. Health-related quality scales are developed with the intent of assessing patients' perception of the impact of their condition on their physical, social, psychological/emotional, and cognitive state. Functional outcome measures evaluate a patient's ability to perform activities of daily living and frequently incorporate objective, clinically assessed components, such as range-of-motion or strength.

Three health-related quality of life measures were used in the studies reviewed in this report: the Rotator Cuff Quality of Life (RC-QOL) scale, the Short-Form-36 (SF-36) and the Western Ontario Rotator Cuff (WORC) index. These self-reported scales assess similar domains, such as pain, physical symptoms, social and emotional functioning. The RC-QOL and SF-36 are scored on a scale of 0 to 100 points, where higher scores indicate better quality of life, while the WORC Index provides a score of up to 2,100 points with higher scores indicating poorer outcomes. There is evidence to support the reliability and convergent validity of each of the scales.

Nine scales assessing functional outcomes were frequently used in the included studies. Of these, four scales were entirely patient self-reported, while the remaining five included both self-reported and health professional-assessed components. The majority of the measures assessed pain, activities of daily living, range of motion and strength. Less commonly evaluated domains included patient satisfaction, joint stability, and recreation activities. Most scoring systems calculated an overall score out of 100 points, however the distribution of the points by domain varied across the tools. Psychometric properties also varied across the scales. The majority of the

scales have evidence to support their reliability. In addition, some scales demonstrated strong correlations with other commonly used shoulder assessment scales.

Table 1. Summary of most frequently reported outcome measures

| Health-related quality of life scales | | | |
|---|--|---|--|
| Outcome measure | Domains | Scaling | Psychometric properties |
| Rotator Cuff Quality of Life (RC-QOL) ²⁸ <i>Subjective</i> | Symptoms & physical complaints (16 items) Work-related concerns (4 items) Sports & recreation (4 items) Lifestyle issues (5 items) Social & emotional issues (5 items) | 34 items, each rated on a 100-point VAS. Total score ranges from 0 (worst) to 100 (best). | Correlation with SF-36, $r=0.778$; correlation with ASES, $r=0.842$ |
| Short Form-36 (SF-36) <i>Subjective</i> | Physical function (10 items) Role-physical (4 items) Bodily pain (2 items) General health (5 items) Vitality (4 items) Social function (2 items) Role-emotional (3 items) Mental health (5 items) | Items are scored using 5-level response options. Domains are summed & translated to two aggregate summary measures (physical health & mental health), with scores ranging from 0 (worst health) to 100 (best health) | Cronback's alpha exceeded recommended minimum of 0.85; reliability greater than 0.75 for all dimensions except social functioning. |
| Western Ontario Rotator Cuff Index (WORC) ²⁹ <i>Subjective</i> | Physical Symptoms (6 items) Sports/Recreation (4 items) Work (4 items) Lifestyle (4 items) Emotions (3 items) | 21 items, each rated on a 100-point VAS. Total score ranges from 0 points (best/ asymptomatic) to 100 points (worst/most symptomatic) | Overall ICC=0.96; As a discriminative instrument, correlated most strongly with ASES ($r=0.68$) & DASH ($r=0.63$); as a evaluative instrument, correlated with ASES ($r=0.75$) & UCLA ($r=0.65$) |
| Functional outcome scales: self-reported | | | |
| Outcome measure | Domains | Scaling | Psychometric properties |
| Disabilities of the Arm, Shoulder and Hand (DASH) ^{30,31} <i>Subjective</i> | Items related to activities of daily living, pain, weakness & function. *Optional modules to assess: high performance sport/ music or work. | 30 items, rated on a 5-point Likert scale. Total score ranges from 0 points (best) to 100 points (worst). | Test-retest reliability, ICC=0.96; Correlates well with other measures; Responsiveness similar to other joint-specific measures. |
| Insalata Shoulder Rating Questionnaire (SRQ) ³² <i>Subjective</i> | Global Assessment Domain (10-point VAS) Pain (4 items) Activities of Daily Living (6 items) Recreation & Athletic Activities (3 items) Work (4 items) Satisfaction (1 item) Importance (patients ranks the 2 areas most important for improvement) | 18 items rated using 5-level response options; one item rated on a 10-point VAS. Total scores range from 17 (worst) to 100 (best) points & are calculated using a weighting system. | Cronbach's alpha=0.86; Spearman rank correlation ranges from $r=0.81$ to 0.96; Spearman-Brown test-retest analysis ranges from 0.94 to 0.98; High correlation with Shoulder Rating Questionnaire & the Arthritis Impact Measurement Scales 2. |
| Simple Shoulder Test (SST) ³³ <i>Subjective</i> | Items related to activities of daily living. | 12 questions, rated Yes/No. Total score is the number of "yes" responses, where higher number indicates better the shoulder function) | Fair correlation with CMS & UCLA |
| Shoulder Pain and Disability Index (SPADI) ^{34,35} <i>Subjective</i> | Pain (5 items) Disability (8 items) | 13 items each scored on a scale from 0 to 10. Total score ranges from 0 points (best) to 100 points (worst) | ICC=0.66; Cronbach's alpha=0.95 |

ASES = American Shoulder and Elbow Surgeons scale; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand; ICC = interclass correlation coefficient; JOA = Japanese Orthopaedic Association scale; PENN = University of Pennsylvania Shoulder Score; RC-QOL = Rotator Cuff Quality of Life questionnaire; ROM = range of motion; SF-36 = Short Form-36; SST = Simple Shoulder Test; SPADI = Shoulder Pain and Disability Index; SRQ = Shoulder Rating Scale; UCLA = University of California Los Angeles scale; UEFI = upper extremity functional index; VAS = visual analogue scale; WORC = Western Ontario Rotator Cuff Index

Table 1. Summary of most frequently reported outcome measures (continued)

| Functional outcome scales: self-reported and clinician assessed | | | |
|---|--|---|---|
| Outcome measure | Domains | Scaling | Psychometric properties |
| American Shoulder and Elbow Surgeons (ASES) ^{36,37} <i>Subjective / objective</i> | Pain (1 item, 10-point VAS) Activities of daily living (10 items, rated on 4-point scale) ROM – active & passive Physical signs (0 to 3) Strength (0 to 5 grade) Instability (0 to 3) | Shoulder score derived from subjective components (pain & cumulative activities of daily living score), ranging from 0 points (worst) to 100 points (best). | Acceptable test-retest reliability, internal consistency, criterion & construct validity & responsiveness to change for patients with RC disease. |
| Constant-Murley Score (CMS) ³⁸⁻⁴⁰ <i>Subjective / objective</i> | Pain (15 points) Activity limitation (20 points) ROM (40 points) Strength (25 points) | Total score ranges from 0 points (worst) to 100 points (best); Global score based on weighted components | Some evidence to support reliability Moderately correlated with ASES, UEFI & WORC. |
| Japanese Orthopaedic Association (JOA) <i>Subjective / objective</i> | Pain (30 points) Function (strength in abduction, endurance, activities of daily living) (20 points) ROM (30 points) Radiographic evaluation (5 points) Joint stability (15 points) | Total score ranges from 0 points (worst) to 100 points (best). | Spearman's rank correlation coefficient between observers: $r > 0.78$ |
| University of California Los Angeles (UCLA) ^{39,41} <i>Subjective / objective</i> | Pain (10 points) Function (10 points) ROM (5 points) Strength (5 points) Patient satisfaction (5 points) | Maximum 35 points (best). | Fair correlation with CMS & SST. |
| University of Pennsylvania Shoulder Score (PENN) ⁴² <i>Subjective / objective</i> | Pain (30 points) Satisfaction Function (20 items, 4-category Likert scale) ROM Strength | Maximum 100 points for each the subjective & objective measures; higher scores indicate greater (best) function | ICC = 0.94; Cronbach's alpha = 0.93 |

Objectives

The objective of this review is to provide a comprehensive synthesis of the evidence examining the effectiveness of nonoperative and operative interventions for the treatment of RC tears. Outcomes of interest include health-related quality of life, shoulder function, time to return to work, cuff integrity, pain, range of motion and strength of the shoulder. The key questions investigated in this report are presented below, alongside an analytic framework (Figure 1).

Key Questions

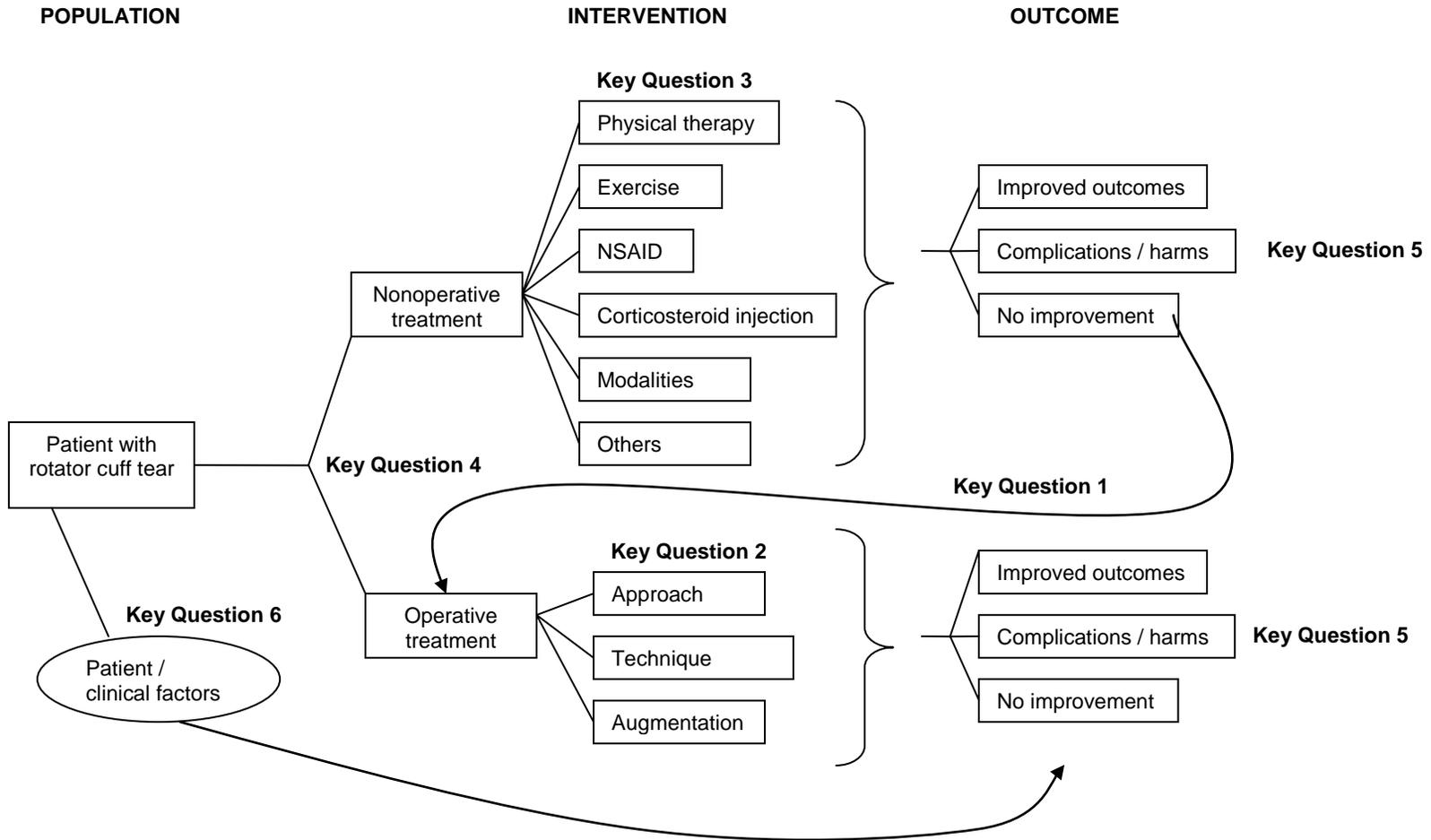
The following key questions were investigated for a population of adult patients with partial- and full-thickness RC tears:

1. Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
2. What is the comparative effectiveness of operative approaches (e.g., open surgery, mini-open surgery, arthroscopy) and postoperative rehabilitation on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
 - a. Which operative approach should be used for different types of tears (e.g., partial-thickness, full-thickness, small, medium, large or massive, with or without fatty infiltration of muscle tissue)?
3. What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, other treatments and modalities typically delivered by physical therapists, osteopaths and chiropractors.
 - b. Which nonoperative treatment approach should be used for different types of tears (e.g., partial-thickness, full-thickness, small, medium, large or massive, with or without fatty infiltration of muscle tissue)?
4. Does operative repair compared to nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
5. What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?
6. Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size / severity of tear, duration of injury, fatty infiltration of

muscle) prognostic factors predict better outcomes following nonoperative and operative treatment?

- c. Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?

Figure 1. Analytic framework corresponding to the key questions



Chapter 2. Methods

This chapter describes the prospectively designed protocol that the University of Alberta Evidence-based Practice Center (UAEPC) used to synthesize the evidence on nonoperative and operative interventions for RC tears. The topic refinement process for developing the key questions is described. We then outline the literature search strategy, the selection process for identifying relevant articles, the process for extracting data from eligible studies, the methods for assessing the methodological quality and applicability of individual studies and for rating the overall body of evidence, and our approach to data analysis and synthesis.

Topic Refinement and Technical Expert Panel

The UAEPC was commissioned to conduct a preliminary literature review to gauge the availability of evidence and to draft the key research questions for a full comparative effectiveness review. In consultation with AHRQ and the Scientific Resource Center, a Technical Expert Panel (TEP) was invited to provide input in the development of the key questions and scope of the evidence report. The public was invited to comment on these questions over a period of 3 months. After reviewing the public commentary, the key questions were finalized and submitted to AHRQ for approval.

The TEP was subsequently invited to provide high-level content and methodological expertise throughout the development of the comparative effectiveness report. The names of technical experts are available in Appendix A.

Literature Search Strategy

Search strategies were designed and implemented to identify evidence relevant to the report (Appendix B). The following bibliographic databases were searched systematically for studies published from 1990 to 2009: MEDLINE[®], EMBASE, EBM Reviews – The Cochrane Library, AMED, Cinahl[®], SPORTDiscus with Full Text, Academic Search Elite, Health Source, Science Citation Index Expanded (via Web of Science[®]), Scopus[®], BIOSIS Previews[®], CRISP, Current Controlled Trials, ClinicalTrials.gov and the Netherlands Trial Register.

Search terms were identified by reviewing search strategies of systematic reviews on similar topics and by looking at how potentially relevant studies were indexed in various databases. A combination of subject headings and textwords were adapted for each electronic resource which included terms for rotator cuff (“rotator cuff*” or “rotator interval*” or “supraspin?tus” or “infraspin?tus” or “teres minor” or “subscapularis” or “anterosuperior” or “posterosuperior”) and tear terms (“tear” or “tears” or “tore” or “torn” or “lesion*” or “rupture*” or “avuls*” or “injur*” or “repair*” or “debride*”). Searches were limited from 1990 to January 2009. No language restrictions were applied.

Hand searches were conducted to identify abstracts from the following scientific meetings: Arthroscopy Association of North America (2007-2009), American Academy of Orthopaedic Surgeons (2007-2009), American Physical Therapy Association (2006-2008), American Shoulder and Elbow Surgeons (2005-2008), American Society of Shoulder and Elbow Therapists (2004-2008), European Congress of Physical and Rehabilitation Medicine 2008 and the Mid-America Orthopaedic Association (2006-2008). Ongoing studies were identified by searching

clinical trials registers and contacting experts. Reference lists of relevant reviews were screened to identify additional relevant studies.

The results from the literature searches were entered into a Reference Manager[®] for Windows™ bibliographic database version 11.0 (2004-2005 Thomson ResearchSoft, Carlsbad, CA) for management.

Criteria for Study Selection

The study inclusion and exclusion criteria were developed in consultation with the TEP (Table 2). In consultation with the TEP, a post hoc decision was made to exclude uncontrolled studies that were either retrospective or unclear in their direction, as well as case series. Due to lack of translation resources, the decision was made to include only English studies, with the exception of French and German studies that examined a nonoperative intervention or postoperative rehabilitation (n=6). This resulted in the exclusion of 79 of the 879 studies (9 percent) retrieved for selection.

Table 2. Eligibility criteria for the review

| Category | Criteria |
|----------------------|---|
| Publication type | <i>Include:</i> Primary research published in 1990 or later <i>Exclude:</i> Non-English studies, with the exception of nonoperative studies published in French or German |
| Study design | <i>Include:</i> Any controlled study design and prospective uncontrolled studies <i>Exclude:</i> Studies with ≤10 participants |
| Population | Adults (≥18 years) with partial- or full-thickness RC tear(s), confirmed by imaging or intraoperative findings. Excluded were studies whose primary intention is not the treatment of RC tears, or in which greater than 20% of participants have rheumatoid or other inflammatory arthritis (not OA), or are undergoing revision of failed RC tears. |
| Intervention | Operative, nonoperative or postoperative rehabilitation interventions for the treatment of RC tears. Studies examining tendon transfers, arthroplasty or postoperative pain management were excluded. |
| Comparator | Any operative, nonoperative or postoperative rehabilitation intervention was an eligible comparator. |
| Outcomes of interest | Studies must report at least one of the following outcomes: quality of life, disability, time to return to work / activities, shoulder pain, range of motion, strength. Minimum duration of followup was 12 months for operative studies. |

Article screening was conducted in two steps. First, two reviewers (AM, DJ, LH, JS, NH) independently screened the titles, keywords and abstracts (when available) to determine if an article met the general inclusion criteria. Each article was rated as “include,” “exclude,” or “unclear”. The full text of all articles classified as “include” or “unclear” by one or both of the reviewers was retrieved for detailed review. Second, two reviewers independently assessed each study using a standard inclusion/exclusion form (Appendix C1). Disagreements were resolved by consensus or third-party adjudication. Non-English studies were assessed by only one reviewer.

Assessment of Methodological Quality

The internal validity of randomized controlled trials (RCTs) and controlled clinical trials (CCTs) was assessed using the Cochrane Collaboration Risk of Bias tool.⁴³ (Appendix C2) This

tool consists of six domains (sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and “other” sources of bias) and a categorization of the overall risk of bias. Each separate domain is rated “yes,” “unclear,” or “no.” Blinding and incomplete outcome data were assessed separately for subjective outcomes (e.g., quality of life or function scales) and objective clinical outcomes (e.g., range of motion). The overall assessment was based on the responses to individual domains. If one or more individual domains were assessed as having a high risk of bias, the overall score was rated as high risk of bias. The overall risk of bias was considered low only if all components were rated as having a low risk of bias. The risk of bias for all other studies was rated as unclear. In addition, information was collected for each study on the source of funding⁴⁴ and whether an intention-to-treat analysis was performed.^{45,46}

Observational analytic studies were assessed using modified cohort and case-control Newcastle-Ottawa Quality Assessment Scales (NOQAS) (Appendix C).⁴⁷ The NOQAS includes seven items assessing sample selection, comparability of cohorts, and the assessment of outcomes. One star was allotted for each item that was adequately addressed in the study, with the exception of the comparability of cohorts, for which a maximum of two stars could be given. The overall score was calculated by tallying the stars, with a total possible score of eight stars. In addition, information regarding the source of funding was collected.⁴⁴

The methodological quality of uncontrolled studies was assessed using a quality checklist developed by the UAEPC (Appendix C). The checklist assessed three components theoretically associated with bias in observational studies: consecutive enrollment, incomplete outcome data and standardized/independent approach to outcome assessment. In addition, the source of funding was documented for each study.⁴⁴

Two reviewers (JS, JRS, KB, SM) independently assessed the methodological quality of the included studies. Non-English studies were assessed by only one reviewer (LH, JS) due to limited translation resources. Each assessment form was pilot tested on a sample of studies. Decision rules regarding application of the tools was developed a priori through discussions with content and methodology experts. Discrepancies in quality assessment were resolved through consensus or third-party adjudication.

Data Extraction

Data were extracted using a standardized form and entered into a Microsoft Excel™ database (Microsoft Corp., Redmond, WA) (Appendix C3). Data were extracted by one reviewer (AM, JS, JRS, KB, LH, SM) and checked for accuracy and completeness by a second (JS, JRS, KB, SM). Extracted data included study characteristics, inclusion/exclusion criteria, participant characteristics, interventions, and outcomes. Reviewers resolved discrepancies in data extraction by consensus or in consultation with a third party.

Operative studies were divided into three broad categories by type of intervention: approach, technique, and augmentation. Studies which focused on the use of an open, mini-open or arthroscopic approach to RC repair (RCR), debridement, acromioplasty or other procedure were categorized as “operative approach”. Studies that compared the effectiveness of different suture or anchor types or configurations were labelled as investigating an “operative technique”. “Operative augmentation” was reserved for studies that examined the use of a surgical augment, such as the use of grafts or patches in the repair of an RC tear.

Before-and-after (BA) studies were defined as single-arm studies that report both baseline and followup data scores. Cohort studies that compared the effectiveness of a single intervention across two patient populations (e.g., open repair in older versus younger patients) were classified as “cohort studies with BA data”. For the purposes of examining the effectiveness of operative procedures (Key Question 2), the data across the patient groups was combined and analysed as for a BA study. BA studies and cohort studies with BA data are collectively referred to as uncontrolled studies. The effects of prognostic variables on treatment outcomes were explored separately in Key Question 6.

A post hoc decision was made to extract data on cuff integrity as an additional outcome of interest. For the uncontrolled studies, the decision was made to examine only four key outcomes considered to be the most clinically relevant by the clinical investigators (DS, CL): health-related quality of life, functional outcomes, time to return to work, and cuff integrity.

Applicability

The applicability of the body of evidence was assessed following the PICOTS (population, intervention, comparator, outcomes, timing of outcome measurement, setting) format used to assess study characteristics. Factors that may potentially weaken the applicability of individual studies were extracted and presented in the evidence tables (Appendix E).

Rating the Body of Evidence

We used the EPC GRADE approach, based on the standard GRADE approach,^{48,49} to assess the quality of the body of evidence for each outcome. The strength of evidence was assessed for four key outcomes identified by the clinical investigators to be most clinically important: health-related quality of life, functional outcomes, time to return to work, and cuff integrity. The following four major domains were examined: risk of bias (low, medium, high), consistency (no inconsistency, inconsistency present, unknown or not applicable), directness (direct, indirect), and precision (precise, imprecise). When no studies were available for an outcome or comparison of interest, the evidence was simply graded as insufficient. Each key outcome on each comparison of interest was given an overall evidence grade based on the ratings for the individual domains. The overall strength of evidence was graded as high (further research is very unlikely to change our confidence in the estimate of effect), moderate (further research may change our confidence in the estimate of effect and may change the estimate), low (further research is likely to change the confidence in the estimate of effect and is likely to change the estimate) or insufficient (evidence either is unavailable or does not permit estimation of an effect). The body of evidence was graded by one reviewer (LH).

Data Analysis

The following data assumptions were made and imputations performed to transform reported data into the form required for analysis. Graphical data was extracted using CorelDRAW® 9.0 (Corel Corp., Ottawa, Canada). If necessary, means were approximated by medians, and 95 percent confidence intervals (95% CI) were used to calculate approximate standard deviations (SD).

Evidence tables and qualitative description of results are presented for all included studies. When appropriate, meta-analyses were performed to support inferences on the effectiveness of nonoperative and operative interventions for treatment of RC tears. We reported outcomes only if numeric data were available in the study or could be derived from graphs. Outcomes that were only described qualitatively (e.g., “pain improved by 6 weeks”) or reported only as a p-value were not included in the evidence tables or data analysis.

Decision-making criteria regarding the instances in which pooled estimates should be derived from individual studies were established a priori. Comparative studies were considered appropriate to combine if the study design, study population, interventions being compared, and outcomes were sufficiently similar. Trials (RCTs and CCTs) and cohort studies were analysed separately. Study populations were considered similar if the type of tear (full-thickness or partial-thickness) and size of tear was common among eligible studies. More than two studies comparing the same intervention arms were necessary in order to conduct a meta-analysis. Finally, studies were only combined when they reported the use of similar outcome measures. Scales were classified as being either health-related quality of life measures (subjective rating only) or as functional outcome scales (subjective and objective components), and meta-analyses were only conducted within scales of the same classification.

Graphs were created to display the preoperative and postoperative scores of uncontrolled studies, cohort studies and trials, over the duration of the study followup period. Due to the low level of evidence represented by uncontrolled studies, these studies were not analyzed quantitatively.

Quantitative results were meta-analyzed in Review Manager version 5.0 (The Cochrane Collaboration, Copenhagen, Denmark). For continuous variables measured on the same scale (e.g., range of motion), mean differences were calculated for individual studies, and weighted mean differences (WMD) was calculated for the pooled estimates. For continuous variables measured on different scales (e.g., health-related quality of life or functional outcome scales), mean differences were calculated for separate studies and standardized mean differences (SMD) were calculated for the pooled estimates. All results are reported with 95% CI when possible.

Results were combined using random effects models. Statistical heterogeneity was quantified using the I-squared (I^2) statistic. A value greater than 50 percent was considered to be substantial heterogeneity.^{50,51}

Chapter 3. Results

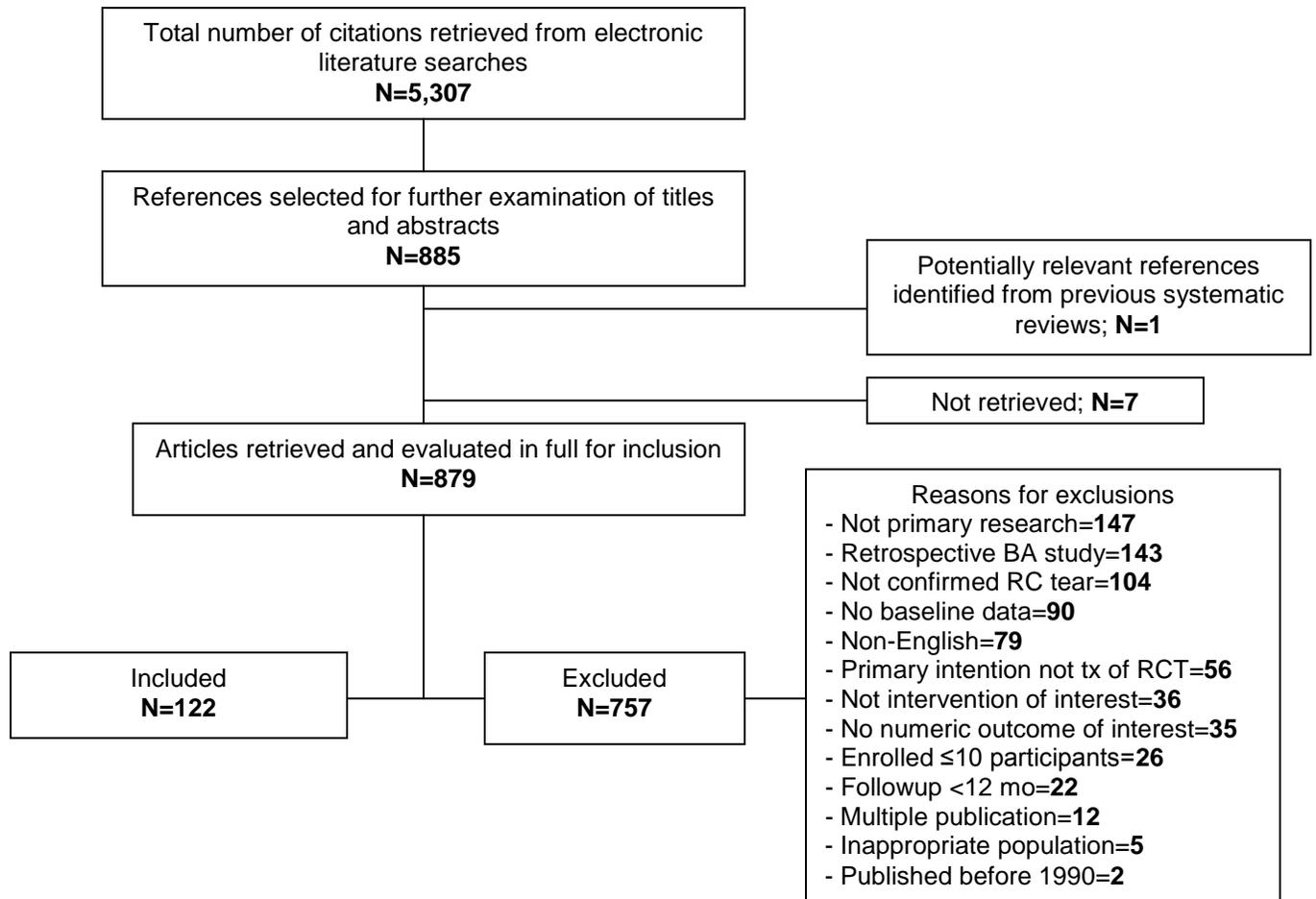
Literature Search

The search strategy identified 5,307 citations from electronic databases. After screening titles and abstracts, 885 studies were assessed to be potentially relevant. One additional study was identified for further examination by hand searching the reference lists from previous systematic reviews. The full text articles of seven studies could not be retrieved through the university interlibrary loan service (Appendix F). Therefore, the full text of 879 potentially relevant reports was retrieved and evaluated for inclusion in the review. The application of the selection criteria to the 879 reports resulted in 122 studies being included and 757 excluded (Figure 2).

The five main reasons for excluding studies from this review were (1) the article did not report on primary research (n=147), (2) uncontrolled study in which data collection was retrospective (n=143), (3) the diagnosis of RC tear was not confirmed using imaging or intraoperative findings (n=104), (4) no baseline data was reported in a single-arm study (n=90), and (5) the study was not published in English (n=79). One hundred and ninety-four studies were excluded for other reasons. A complete list of excluded studies and reasons for exclusion are identified in Appendix F.

Twelve studies were excluded because they were considered to be multiple publications; that is, they were either abstracts of full reports, reports published subsequent to the primary study or reported secondary outcomes. Generally, the report that provided the longest followup data or the largest sample size was regarded as the primary study. In two instances, both the primary publication^{52,53} and their respective secondary publications^{54,55} were included in the review, since the articles focused on different key questions.

Figure 2. Flow-diagram for study retrieval and selection



Description of Included Studies

One hundred and twenty-two studies provided evidence on the six key questions addressed in this report. Appendix F describes the key characteristics of the studies included in the review. There were no studies that examined the effect of early versus late surgical RCR (Question 1). All of the included studies addressed the effectiveness of an intervention for the treatment of RC tears (Questions 2 to 4). Operative treatments (Question 2) were evaluated in 102 (82 percent) studies,⁵²⁻¹⁵³ while postoperative rehabilitation procedures (Question 2) were examined in nine (7 percent) studies.¹⁵⁴⁻¹⁶² Ten (8 percent) studies^{145,163-171} examined the effectiveness of nonoperative treatments (Question 3) and three (2 percent) studies^{145,172,173} compared nonoperative therapy to operative intervention (Question 4). One of the studies¹⁴⁵ included four study arms (two operative and two nonoperative) and was included in three categories: operative interventions, nonoperative interventions and nonoperative versus operative interventions. Complications (Question 5) were addressed in 88 studies.^{53-57,59-65,67-71,73,75-83,85,87-91,93-98,100-}

108,110,112-115,118-121,123,125-128,131-133,135-139,141-143,147,149-153,155,158,159,161,163,166,167,171,172 Prognostic factors as effect modifiers (Question 6) were examined in 66 studies.^{52,54,55,57,59-65,67,70-72,74,75,77,78,83-85,87,88,90-94,96,98-100,102-108,111,113,114,116,117,122,123,125,126,128,129,131,134,137,140,142,144,146,152-154,158,161,164,165,173}

The studies were published between 1991 and 2009 (median=2005 [interquartile range (IQR): 2003 to 2007]). All of the studies were published as peer reviewed articles, with the exception of one abstract.¹⁶⁰ Studies were conducted in the United States (n=47, 39 percent), Europe (n=47, 39 percent), Asia (n=17, 14 percent) and other regions (n=11, 9 percent). The studies were published in English, with the exception of three French (two nonoperative^{163,167} and one postoperative rehabilitation¹⁵⁶) and three German (two nonoperative^{165,170} and one postoperative rehabilitation¹⁵⁹) studies. The number of participants in the studies ranged from 12 to 224 (median=53 [IQR: 30 to 85]). The mean age of study participants 41.2 to 80 years.

Of the 122 included studies, 15 (12 percent) were RCTs. All were parallel, two-arm, superiority trials. One RCT¹⁷¹ examined nonoperative interventions, nine^{61,68,80-82,86,93,116,118} evaluated operative interventions and five^{157-159,161,162} assessed postoperative rehabilitation. Five (4 percent) of the included studies were CCTs, of which four assessed operative treatments^{98,119,124,143} and one¹⁵⁵ assessed postoperative rehabilitation. Ten prospective cohort studies were included. Operative interventions were evaluated in eight,^{54,60,65,73,96,101,112,128} while one study¹⁷² compared operative to nonoperative treatments, and one¹⁵⁶ evaluated postoperative rehabilitation. There were 21 retrospective cohort studies included in the review, including one postoperative rehabilitation study,¹⁶⁰ 17 operative studies,^{53,57,63,89,97,102,108,115,120,121,134,137,139,147,150-152} one nonoperative study¹⁶⁸ and two studies comparing nonoperative versus operative treatments.^{145,173}

There were 71 uncontrolled studies, including 55 BA studies, 10 prospective cohorts with BA data, and five retrospective cohort with BA data. Of the BA studies, six^{163,164,166,167,169,170} evaluated a nonoperative intervention, 48 examined an operative intervention,^{55,56,58,59,62,64,66,67,69-71,74-76,79,83-85,87,88,91,92,94,95,99,100,103-107,110,113,114,123,126,131-133,135,136,138,140,141,146,148,149,153} and one¹⁵⁴ assessed postoperative rehabilitation. Nine of 10 prospective cohort studies with BA data evaluated operative interventions,^{52,72,77,78,90,109,122,125,127} while the remaining study¹⁶⁵ examined a nonoperative intervention. All five retrospective cohorts with BA data examined operative interventions.^{111,117,129,130,142} One case-control BA study¹⁴⁴ assessed an operative procedure.

Methodological Quality of Included Studies

The methodological quality of each included study was assessed by two independent reviewers and the consensus ratings are presented in Appendix D, Tables D1 to D3. A summary of the overall quality trends by study design is presented below.

Randomized Controlled and Controlled Clinical Trials

The risk of bias assessments for each of the RCTs and CCTs is presented in Appendix D, Table D1. All of the 15 RCTs were rated as having high risk of bias for both patient-rated and clinically assessed outcomes. The allocation sequence was adequately generated in 12 trials.^{61,80-82,86,93,116,118,157-159,162} Allocation concealment was adequate in four trials,^{80,82,116,118} inadequate in three trials,^{61,68,157} and unclear in the remaining trials. No trial used sufficient methods to ensure

the blinding of participants and outcome assessors for either patient-reported or clinically assessed outcomes. Half of the RCTs adequately addressed incomplete outcome data (n=8).^{61,68,81,86,93,118,159,171} Only one trial appeared to have selective outcome reporting,¹¹⁸ and other sources of bias were identified in four trials.^{93,118,159,161} Four trials reported conducting an intention-to-treat analysis.^{80,82,118,159}

The five CCTs were similarly all rated as having high risk of bias. None of these trials reported adequate sequence generation, allocation concealment or blinding. Two trials addressed incomplete outcome data adequately.^{98,143} All of the trials were free of suggestion of selective outcome reporting. The impact of other sources of bias was unclear in four studies.^{98,119,143,155} Intention-to-treat analysis was reported in one CCT.¹⁵⁵

The source of funding was not reported in the majority of the trials (n=12, 60 percent). For studies that reported funding, sources included an academic institution,¹¹⁸ government,^{93,118,157} foundation^{118,162} and industry.^{93,159} Three studies reported receiving no funding.^{61,124,158}

Cohort Studies

The Newcastle-Ottawa quality assessment of the 31 cohort studies is presented in Appendix D, Table D2. Data was prospectively collected in 10 cohort studies^{54,60,65,73,96,101,112,128,156,172} and retrospective in 21 studies.^{53,57,63,89,97,102,108,115,120,121,134,137,139,145,147,150-152,160,168,173} Overall, the methodological quality of the cohort studies was moderate (median score=5/8 stars; IQR: 4 to 6). The majority enrolled patients that were rated to be truly or somewhat representative of average patients in the community (n=22, 73 percent). The nonexposed cohort was drawn from the same community as the exposed cohort in 29 studies; in two studies, the nonexposed cohort was drawn from a different source.^{121,173} All studies ascertained the exposure status from a secure source, most commonly from surgical records. Nearly half of the studies (n=13, 42 percent) controlled for potential confounding variables in their design or analysis.^{60,63,65,96,102,108,128,134,139,145,147,152,172} In two studies, there was independent blind outcome assessment;^{96,128} the remaining studies had self-reported outcomes (n=15, 48 percent), were described as unblinded (n=6, 20 percent), or did not describe methods for outcome assessment (n=8, 26 percent). All of the cohort studies had a followup duration of at least 12 months, with the exception of two postoperative rehabilitation studies^{156,160} and one nonoperative study.¹⁶⁸ The rate of followup was considered unlikely to introduce bias in the majority of studies (n=21, 68 percent); however, eight studies were rated as having inadequate followup,^{60,97,102,112,115,137,147,156} and two did not describe the followup rate.^{89,120}

Source of funding was not reported by 25 of the cohort studies (81 percent). One study received government and foundation funding,⁶⁰ while five studies reported receiving no funding.^{57,63,89,108,128}

Uncontrolled Studies

The methodological quality of the 55 BA studies, 15 cohort studies with BA data, and one case-control study with BA data was assessed for three domains: consecutive enrollment, incomplete outcome data, and approach to outcome assessment. The quality assessment is presented in Appendix D, Table D3. Of the 71 studies, 45 (63 percent) reported consecutive enrollment of participants, three (4 percent) did not use consecutive enrollment^{64,66,78} and the remaining 23 studies were unclear. The majority of studies (n=55, 77 percent) adequately

addressed incomplete outcome data. Seven studies^{58,100,114,123,140,154,164} had inadequate followup and nine were unclear.^{74,90,106,107,129,138,163,166,167} A standardized approach was used to assess outcomes in 29 studies (41 percent). Of the remaining studies, 31 (44 percent) were unclear and 11 used no standardized assessment approach.^{67,75,78,84,85,114,129,140,141,148,154}

Source of funding was not reported in the majority of studies (n=44, 62 percent). No funding was received in 22 studies (31 percent).^{62,67,70,83,84,90,94,95,103-106,110,114,117,122,125,133,138,140,144,153} The remaining studies were supported through foundations,^{100,148,164} industry,¹⁷⁰ or professional associations.¹⁵⁴

Results of Included Studies

This section is organized by the six key research questions addressed in this report. For each intervention category, the evidence from comparative studies (trials and cohorts) and uncontrolled studies is presented separately. A summary of key findings is provided, followed by a description of the characteristics and findings of the individual trials and cohort studies. Tables summarizing the general patient and summary characteristics, as well as the outcome data, are presented for each comparative study. In addition, a grading of the body of evidence is based on the comparative studies only and presented by key outcome. The uncontrolled studies are described in aggregate form and the results are presented visually for each intervention category. Appendix E presents detailed evidence tables on each of the included studies.

Question 1: Early Surgical Repair versus Late Surgical Repair

There were no studies identified which compared early surgical repair versus late surgical repair after failed nonoperative treatment. The paucity of evidence related to this question is of particular concern, as primary care providers are frequently faced with the dilemma of whether to refer patients to surgery immediately or delay surgery by opting for initial nonoperative treatment. A number of studies conducted a subgroup or regression analysis to assess whether time to surgery was a significant factor in predicting operative outcomes. Results of these studies are presented under Question 6 (prognostic variables).

Question 2: Comparative Effectiveness of Operative Interventions and Postoperative Rehabilitation

One hundred and two studies examined the comparative effectiveness of operative interventions, while an additional nine studies evaluated postoperative rehabilitation therapies. Studies assessing operative treatments were categorized as focusing on an operative approach (e.g., open, mini-open, arthroscopic, debridement), technique (i.e., suture or anchor type or configuration) or augmentations for RCR.

Overall, operative approaches were examined in 84 studies (26 comparative studies, 58 uncontrolled studies). Operative techniques were evaluated in 11 comparative studies. Augmentations for RCR were assessed in seven studies (two comparative studies, five uncontrolled studies). Nine studies examined postoperative rehabilitation (eight comparative studies, one uncontrolled study).

Operative Approach—Comparative Studies

Summary. Twenty-six controlled studies making 12 comparisons assessed the effectiveness of different operative approaches for RCR. The following is a summary of results by comparison:

- One RCT and two retrospective cohort studies compared open RCR against mini-open RCR. Overall there was no statistically significant difference in function; however, the two cohort studies demonstrated significantly earlier return to work or sports by approximately 1 month for mini-open repairs. The individual studies showed no

statistical or clinically important differences between groups for health-related quality of life, range of motion, or strength.

- One CCT and seven retrospective cohort studies compared mini-open versus arthroscopic RCR. All studies measured function and overall there was no difference between groups. Other outcomes were assessed across the studies and no differences were found for range of motion (n=4), strength (n=2), cuff integrity (n=2), and visual analogue scale (VAS) for pain (n=3). While the majority of these studies were retrospective cohorts, the studies were relatively well done and generally scored highly on the relevant quality assessment instrument. Further, the findings were heterogeneous for the CCT and the retrospective cohorts with the latter producing more conservative and not statistically significant results.
- One prospective cohort study compared open RCR versus arthroscopic RCR. Two prospective cohort studies compared open/mini-open RCR with arthroscopic RCR. There were no differences between the groups for function. One study found better pain relief for the group receiving arthroscopic repair than the open/mini-open group at final followup.
- Two CCTs and two retrospective cohort studies compared open RCR with open or arthroscopic debridement. Overall, improvement in function was significantly greater for open RCR. The magnitude of the difference varied across studies from an absolute difference of 2.2 on a 35-point scale to 11.5 on an 83-point scale; the cohort studies showed larger absolute differences than the trials. One of the cohort studies showed a significantly shorter time to maximum range of motion in the arthroscopic debridement group (3.2 versus 6.8 months).
- Two RCTs compared arthroscopic RCR with acromioplasty versus arthroscopic RCR alone. Overall, there was no difference in function between groups.
- Six additional studies compared different operative approaches: biceps tenotomy versus tenodesis, arthroscopic RCR plus superior labral from anterior to posterior (SLAP) lesion repair versus arthroscopic RCR plus biceps tenotomy, arthroscopic RCR plus tenodesis with proximal biceps detachment versus without proximal biceps detachment, arthroscopic debridement with tenotomy versus without tenotomy, complete open RCR versus partial open RCR versus debridement, and open RCR plus classic open acromioplasty versus open RCR plus modified open acromioplasty. There were few clinically important differences between groups being compared across studies. No differences in function were observed for five of the comparisons. One study showed greater postoperative University of California Los Angeles (UCLA) index scores for arthroscopic RCR with biceps tenotomy compared with arthroscopic RCR plus SLAP repair; however, the absolute difference of 4 points on the 35-point scale is of questionable clinical importance.

Overall conclusions for operative approaches are challenging due to the wide variation in comparisons across studies. Generally, the studies showed few differences in function between interventions. One exception was greater improvement for open RCR compared with arthroscopic debridement; the strength of evidence for this finding was considered moderate. Further, one small study suggested greater postoperative function for arthroscopic RCR with

biceps tenotomy compared to arthroscopic RCR plus SLAP repair; the strength of evidence for this finding was low and needs replication in future studies before general conclusions can be made.

Results by individual study. Twenty-six studies^{53,57,60,63,65,80,81,86,89,96,98,102,108,116,118-121,124,134,137,143,145,147,150,152} examined the effectiveness of different operative approaches for RCR. Five of the studies were RCTs, four were CCTs, three were prospective cohort designs, and 14 were retrospective cohort designs. Sample sizes ranged from 21 to 127 participants. The following operative approaches were assessed: open versus mini-open RCR,^{57,89,118} mini-open versus arthroscopic RCR,^{98,102,108,134,137,147,150,152} open versus arthroscopic RCR,⁹⁶ open or mini-open RCR versus arthroscopic RCR,^{60,65} open RCR versus arthroscopic debridement,^{119,121,124,145} arthroscopic RCR with acromioplasty versus arthroscopic RCR alone,^{86,116} biceps tenotomy versus tenodesis,⁶³ arthroscopic RCR with SLAP repair versus arthroscopic RCR with biceps tenotomy,⁸⁰ RCR with tenodesis with proximal biceps detachment versus RCR with tenodesis without proximal biceps detachment,⁸¹ arthroscopic debridement with biceps tenotomy versus without biceps tenotomy,⁵³ complete open RCR versus partial open RCR versus debridement.¹²⁰ open RCR with classic versus modified acromioplasty.¹⁴³ Four comparisons contained studies that were sufficiently similar in terms of conditions, interventions, and outcomes that meta-analysis was possible: open RCR versus mini-open RCR, mini-open versus arthroscopic RCR, open or mini-open RCR versus arthroscopic RCR, and open RCR versus arthroscopic debridement. Table 17 summarize the rating of the body of evidence for operative approaches.

Open versus mini-open RCR. Three studies (one RCT¹¹⁸ and two cohort studies^{57,89}) compared open RCR against mini-open RCR. Pooled results are shown in Figure 3 and Figure 4. Patient and study characteristics and outcome data are presented in Table 3 and Table 4, respectively.

Mohtadi et al.¹¹⁸ conducted a RCT in patients with small to massive full-thickness tears. Seventy-three patients were randomly assigned to the interventions (37 to open surgical repair and acromioplasty, 36 to mini-open repair with arthroscopic acromioplasty) and 60 were followed up for at least 2 years. Patient quality of life was assessed using the RC-QOL and function was assessed using the American Shoulder and Elbow Surgeons (ASES) index, Shoulder Rating Questionnaire (SRQ), range of motion (flexion, external and internal rotation), and functional shoulder elevation test (FSET). At the 2-year followup, mean RC-QOL score had improved for both groups, but the differences were not statistically significant ($p=0.94$). Mean ASES and SRQ scores had improved for both groups, but there was no statistically significant differences between the postoperative scores ($p=0.94$ and $p=0.806$, respectively). Range of motion and FSET were assessed at 12 months. Both groups showed some improvement in range of motion measures at 12 months; however, the difference between groups was not statistically significant. Both groups also showed improvement in FSET scores; however, the differences in postoperative scores were not statistically significant ($p=0.899$).

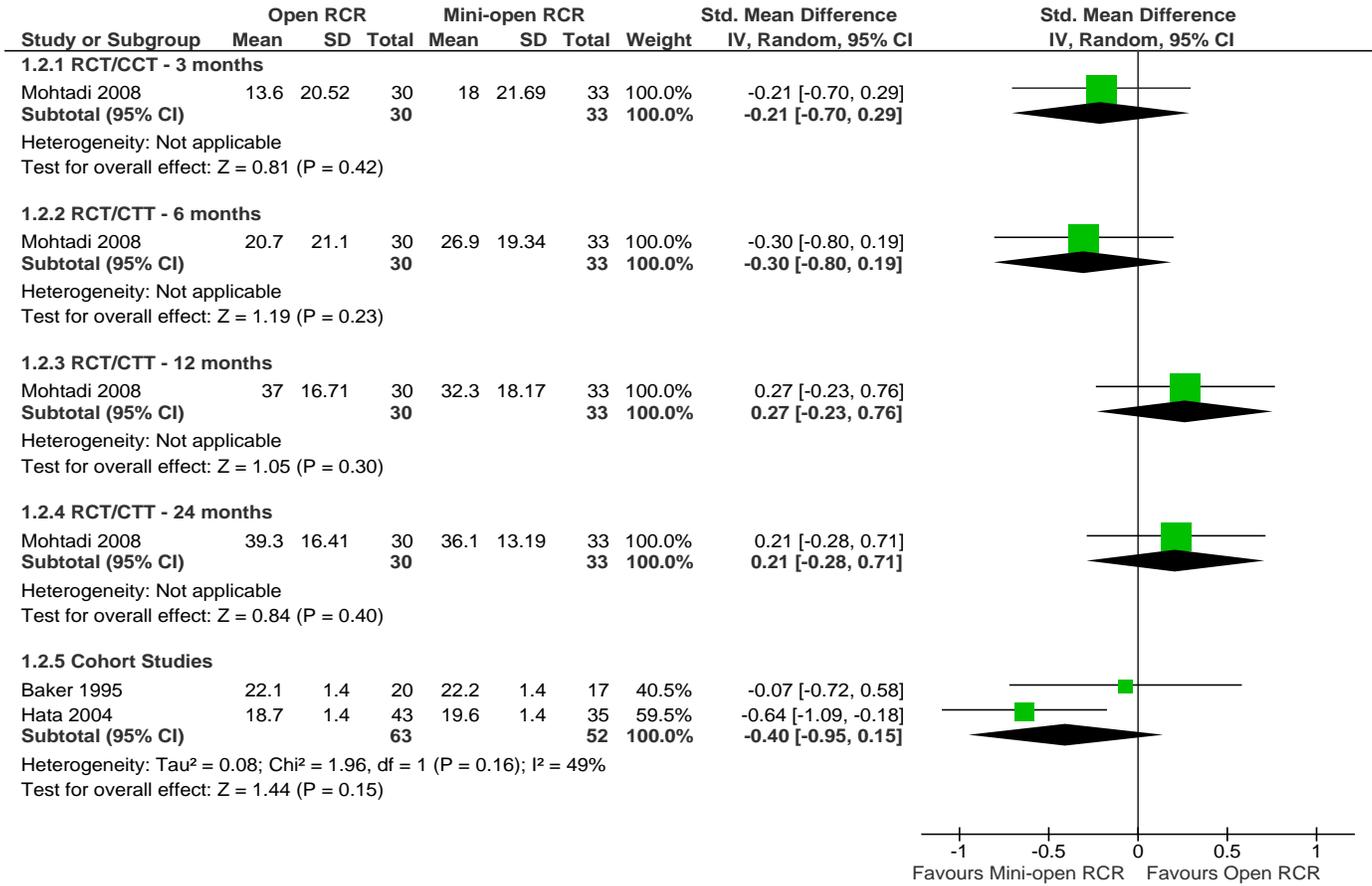
Baker et al.⁵⁷ conducted a retrospective cohort study in patients with small, medium, and large full-thickness tears. Thirty-six patients were evaluated (20 received open repair with acromioplasty, 16 received mini-open repair with arthroscopic acromioplasty), and all patients were followed for at least 2 years. The mean followup was 3.3 years. Patients were evaluated using the UCLA score, range of motion (flexion, external rotation, and abduction), strength (flexion, external rotation, and abduction), and time to return to work. At final postoperative

followup, the two groups both demonstrated improvement in the UCLA score and range of motion, but the difference between the two groups was not statistically significant ($p>0.05$). Strength scores also improved from baseline to endpoint, however there were no significant differences between the groups at endpoint except in abduction strength ($p=0.002$), which favored mini-open repair. The mean time to return to work was 5.6 months (range: 4.2 to 7.2) for the open repair group and 4.5 months (range: 3.7 to 6.5) for the mini-open group. Cuff integrity was examined at final followup using arthrography. In the open RCR group, 10 patients (50 percent) had an intact cuff, compared with nine patients (52.9 percent) in the mini-open group. There was no significant difference between the groups for cuff integrity.

Hata et al.⁸⁹ conducted a retrospective cohort study in patients with small, medium, and large RC tears. Seventy-eight patients were evaluated (43 received open repair with acromioplasty, 35 received mini-open repair with acromioplasty), and all patients were followed for at least 2 years. The mean followup was 4 years. Patient function was assessed using the UCLA score and time to return to work. At the 2-year followup, mean UCLA score improved for both groups; however, the difference between the postoperative scores was not statistically significant. For the mini-open group, the mean time to return to work or sports activities (2.4 months) was significantly shorter than in the open repair group (3.4 months) ($p\leq 0.05$). Cuff integrity was examined at 12 months using MRI. No ruptures were detected in either group.

One RCT¹¹⁸ and two cohort studies^{57,89} provided data for a meta-analysis of the effects of open versus mini-open RCR on functional outcome measures (Figure 3). Data from the trial at various time points (3, 6, 12, 24 months) and two cohorts is presented separately. The ASES is presented for the RCT,¹¹⁸ while the cohort studies both used the UCLA score. For all studies, mean change scores between preoperative and postoperative scores were compared between groups. The combined estimate of change in function for the cohort studies shows no significant difference between the interventions, yet favors mini-open repair (SMD=-0.40; 95% CI, -0.95 to 0.15). There was moderate heterogeneity between the studies ($p=0.16$; $I^2=49$ percent). Differences in the patient population may account for some of the heterogeneity between studies, since the study population for Baker et al.⁵⁷ included a substantial proportion of both recreational athletes and manual laborers.

Figure 3. Open versus mini-open RCR on measures of functional outcome



Data from two cohort studies^{57,89} was pooled for time to return to work (Figure 4). The pooled estimate indicates significantly shorter time to return to work for the mini-open RCR group compared with the open RCR group (mean difference=1.08; 95% CI, 0.63 to 1.52). There was no evidence of heterogeneity between the two studies (p=0.85, I²=0 percent).

Figure 4. Open versus mini-open RCR on time to return to work

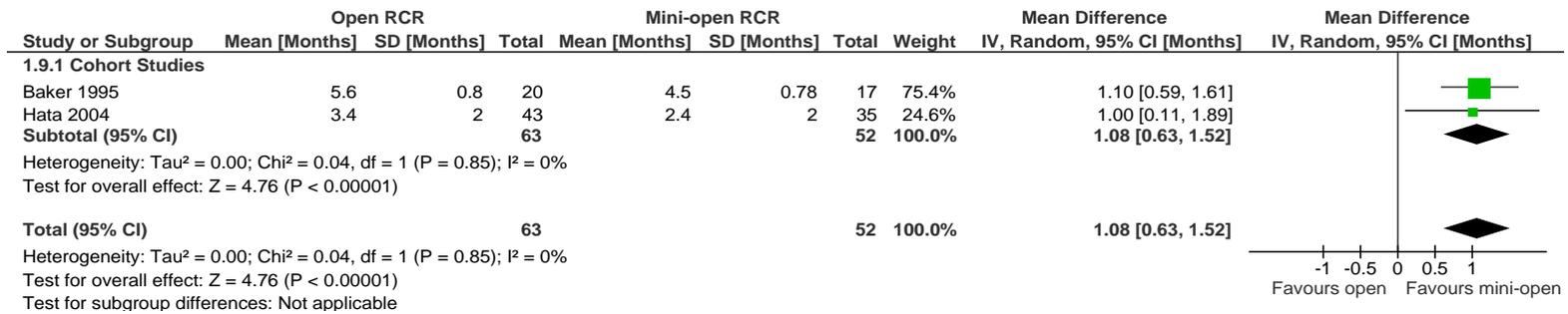


Table 3. Study and patient characteristics for studies assessing open versus mini-open RCR

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range) |
|---------------------------------|---|---|---|
| Baker CL, ⁵⁷ 1995 | G1: Open RCR (20) G2: Mini-open RCR (16) Retrospective cohort | G1: 62 yr (38–81) / Males: 12 (60) Athletes: 4 (20) Manual laborers: 6 (30) G2: 59 yr (41–71) / Males: 9 (56) Athletes: 4 (25) Manual laborers: 5 (31) | FTT; Sm, Med, Lg NR |
| Hata Y, ⁸⁹ 2004 | G1: Open RCR (43) G2: Mini-open RCR (35) Retrospective cohort | G1: 58.1 yr (31–78) / Males: 25 (58.1) G2: 60.6 yr (39–71) Males: 21 (60) | NR; Sm, Med, Lg NR |
| Mohtadi NG, ¹¹⁸ 2008 | G1: Open RCR (37) G2: Mini-open RCR (36) RCT | G1: 56.2 yr (44–77) / Males: 22 (59.5) G2: 57 yr (33–82) / Males: 20 (55) | FTT; Sm, Med, Lg, Mass >3 mo |

FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; NR = not reported; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small

Table 4. Outcome data for studies assessing open versus mini-open RCR

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post- op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post- op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|------------------------------------|---|--------------------------------------|---|---|--|
| Baker CL, ⁵⁷ 1995 | G1: Open RCR (20) G2: Mini-open RCR (16) | UCLA* | 9.1 / 31.2, p≤0.05 | 10.5 / 32.7, p≤0.05 | p>0.05 |
| | | Time to return to work (mo) | 5.6 (4.2–7.2) | 4.5 (3.7–6.5) | NR |
| | 3.3 yr | ROM (degrees) | F: 99 / 153, p≤0.05 ER: 30 / 155, p≤0.05 ABD: 96 / 47, p≤0.05 | F: 104 / 161, p≤0.05 ER: 34 / 49, p≤0.05 ABD: 100 / 159, p≤0.05 | p>0.05 p>0.05 p>0.05 |
| | | Strength | F: 2.4 / 4.5, p≤0.05 ER: 3 / 4.2, p≤0.05 ABD: 3.2 / 4.4, p≤0.05 | F: 2.7 / 4.6, p≤0.05 ER: 2.9 / 4.8, p≤0.05 ABD: 3.4 / 4.7, p≤0.05 | NR NR p=0.002 |
| | | Cuff integrity (arthrograph y) | 10 / 20 shoulders (50) | 9 / 17 shoulders (52.9) | p=1.0‡ |
| Hata Y, ⁸⁹ 2004 | G1: Open RCR (43) G2: Mini-open RCR (35) | UCLA* 2 yr | 14.3 (6–26) / 33.0, p<0.01 | 13.8 (6–26) / 33.4, p<0.01 | p>0.05† |
| | | Time to return to work (mo) | 3.4 | 2.4 | p≤0.05 |
| | 4 yr (2–6.8) | Cuff integrity (MRI, 12 mo) | 0 / 43 (0) | 0 / 35 (0) | NA |
| Mohtadi NG, ¹¹⁸ 2008 | G1: Open RCR (29) G2: Mini-open RCR (31) | RC-QOL | 40.9 (95% CI, 35.5–46.2) / | 45.5 (95% CI, 38.5–52.5) / | |
| | | 3 mo | 55.6 (47.5–63.7) / | 71.3 (63.8–78.9) / | p=0.005 |
| | 2 yr | 6 mo | 72.4 (65.0–79.8) / | 82.3 (78.3–86.3) / | p=0.015 |
| | | 12 mo | 85.0 (79.2–90.8) / | 88.5 (84.1–92.9) / | p=0.34 |
| | | 2.3 yr | 86.9 (81.8–92.0) | 87.2 (80.6–93.8) | p=0.94 |
| | | ASES | 48.2 (95% CI, 40.7–55.6) / | 53.8 (95% CI, 47.1–60.5) / | |
| | 3 mo | 61.8 (54.8–68.7) / | 71.8 (64.4–79.1) / | p=0.048 | |
| | | 6 mo | 68.9 (61.7–76.1) / | 80.7 (74.2–87.3) / | p=0.016 |
| | | 12 mo | 85.2 (79.5–90.9) / | 86.1 (79.9–92.2) / | p=0.84 |
| | | 2 yr | 87.5 (81.9–93.1) | 89.9 (85.4–94.4) | p=0.94 |
| | SRQ | 46.7 (95% CI, 41.3–52.1) / | 50.3 (95% CI, 45.2–55.4) / | | |
| | | 3 mo | 63.3 (57.5–69.1) / | 69.4 (62.6–76.3) / | p=0.170 |
| 6 mo | | 73.6 (68.2–79.1) / | 79.8 (74.7–84.9) / | p=0.096 | |
| 12 mo | | 83.4 (78.1–88.8) / | 85.2 (81.2–89.2) / | p=0.587 | |
| 2 yr | 85.1 (80.2–90.1) | 85.9 (81.7–90.0) | p=0.806 | | |

ABD = abduction; ASES = American Shoulder and Elbow Scale; ER = external rotation; F = flexion; FSET = functional shoulder elevation test; G = group; IR = internal rotation; mo = month; MRI = magnetic resonance imaging; N = number; NA = not applicable; NR = not reported; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; RC-QOL = rotator cuff quality of life scale; ROM = range of motion; SD = standard deviation; SRQ = Shoulder Rating Questionnaire; UCLA = University of California Los Angeles Scale

*Subscales reported

†No significant differences were detected between groups at 3, 6, 12 mo or 2 yr

‡Calculated by UAEPC

§Vertebral level, involved-uninvolved difference

Table 4. Outcome data for studies assessing open versus mini-open RCR (continued)

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post- op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post- op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|---|---|---------------------------|--|--|---|
| Mohtadi NG, ¹¹⁸ 2008 (continued) | G1: Open RCR (29) G2: Mini-open RCR (31) 2 yr | ROM (degrees) 12 mo | F: 147.7±35.1 / 162.3±19.2 ER on side: 46.1±15.3 / 54.1±28.6 ER at 90°: 73.1±27.6 / 78.4±16.7 IR§ (range): 2.3 (-1– +9) / 1.2 (-5– +7) | F: 155.2±35.2 / 158.3±22.61 ER on side: 46.6±22.3 / 48.1±29.7 ER at 90°: 78.8±16.8 / 79.0±13.6 IR§ (range, n): 3.0 (-3 –+12) / 0.96 (-5–+5) | F: p=0.46‡ ER on side: p=0.43‡ ER at 90°: p=0.88‡ |
| | | FSET 6 mo | 31.4 (19.2–43.6) (95% CI) / 53.4 (35.7–71.1) / | 34.1 (21.6–46.6) (95% CI) / 58.7 (46.0–71.4) / | p=0.601 |
| | | 12 mo | 74.8 (61.0–88.5) | 75.9 (63.3–88.5) | p=0.899 |

Mini-open versus arthroscopic RCR. Eight studies (one CCT,⁹⁸ seven retrospective cohort studies^{102,108,134,137,147,150,152}) compared mini-open RCR against arthroscopic RCR. Pooled results are shown in Figure 5 and Figure 6. Patient and study characteristics and outcome data are presented in **Error! Reference source not found.** and Table 6, respectively.

Kim et al.⁹⁸ conducted a CCT in patients with medium or large full-thickness tears. Seventy-six patients were analyzed in the two treatments (34 received mini-open repair with acromioplasty, 42 received all-arthroscopic repair with acromioplasty) and were followed for at least 2 years. The mean followup was 3.3 years (2.0 to 5.3 years). Patients were evaluated on ASES and UCLA scores, percent function on a visual analogue scale, pain, range of motion, and strength. Shoulder scores improved in all ratings in both groups ($p \leq 0.05$) at followup; however, no statistically significant differences were seen between the two groups at study endpoint ($p > 0.05$).

Kose et al.¹⁰² conducted a retrospective cohort study with patients with small, medium, and large tears. Fifty-seven patients were selected and 50 evaluated (25 received mini-open repair with acromioplasty, 25 received arthroscopic repair with acromioplasty) at 2.2 years (range: 12 months to 6.8 years). Patients' function was evaluated using the Constant-Murley Score (CMS) and UCLA score. The improvements between pre- and postoperative CMS and UCLA scores were statistically significant within both groups ($p < 0.01$); however, the difference in postoperative scores between the two groups was not significant ($p = 0.24$ and $p = 0.63$, respectively).

Liem et al.¹⁰⁸ conducted a retrospective cohort study of patients with small, medium, and large tears. Seventy-seven patient were selected and 38 evaluated (19 received mini-open repair with acromioplasty, 19 received arthroscopic repair with acromioplasty) at a minimum of 12 months. Patient function was evaluated using the CMS and early range of motion (flexion, abduction, and external rotation). At followup, both groups showed statistically significant improvement in the CMS ($p = 0.0001$) and for all range of motion tests, except abduction and external rotation in the open RCR group. However, the between group differences in all scores were not statistically significant. Cuff integrity was evaluated at followup using MRI. Seven patients in the mini-open group and six in the all-arthroscopic group experienced retears; the difference between the groups was not statistically significant.

Sauerbrey et al.¹³⁴ conducted a retrospective cohort study in patients with medium, large, and massive full-thickness tears. Sixty-three patients were selected and 54 evaluated (26 received mini-open repair with acromioplasty, 28 received all-arthroscopic repair with acromioplasty) at 2.1 years (range: 13 months to 4 years). At followup, both groups showed significant improvement in ASES score ($p < 0.05$); however, the difference between postoperative scores was not statistically significant ($p = 0.33$).

Severud et al.¹³⁷ conducted a retrospective cohort study with patients with small, medium, and large partial- and full-thickness tears. Sixty-four of 82 enrolled shoulders were evaluated (29 shoulders received mini-open repair with subacromial decompression, 35 received all-arthroscopic repair with subacromial decompression) at a minimum of 24 months. The mean followup time was 3.7 years (range: 2 to 6.8 years). Patient function was evaluated using the ASES and UCLA scores. At followup, there were no statistically significant differences between the groups for either ASES or UCLA scores.

Verma et al.¹⁴⁷ conducted a retrospective cohort study with patients with small and large full-thickness tears. One hundred twenty-seven patients were selected (58 received mini-open repair

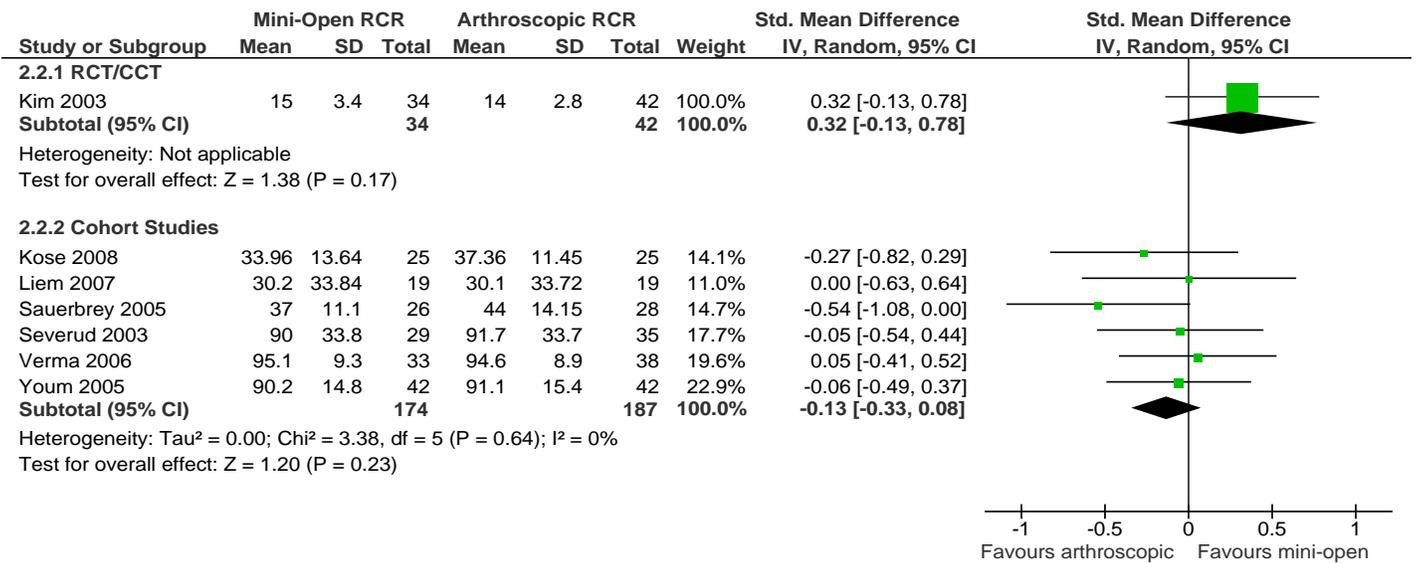
with acromioplasty, 69 received arthroscopic repair with acromioplasty), of which 71 were evaluated at a minimum of 2 years. The mean followup was 3.2 years (range: 2 to 8.1 years). Patient function was assessed using the ASES, Insalata, and Simple Shoulder Test (SST). Pain on a visual analogue scale and range of motion were also assessed. Preoperative and postoperative measures were not compared for any outcome. At followup, there were no statistically significant differences between groups for any of the outcome measures. Cuff integrity was found in 17 (68 percent) and 20 (90.9 percent) patients in the mini-open and arthroscopic repair groups, respectively; the difference between the groups was not significant.

Warner et al.¹⁵⁰ conducted a retrospective cohort study in patients with full-thickness tears. Twenty-one patients were selected (12 received mini-open repair with acromioplasty, nine received all-arthroscopic repair with acromioplasty). All patients were evaluated at a minimum of 2.3 years. The mean followup duration was 4.2 years. Patients were assessed using the SST, pain, range of motion (flexion and external rotation) and strength. Postoperative pain scores for both groups were significantly improved from preoperative measures ($p < 0.01$). A statistically significant improvement in strength ($p < 0.01$) was also observed in the arthroscopic group. Within and between group differences for all remaining outcome measures were not statistically significant.

Youm et al.¹⁵² conducted a retrospective cohort study in patients with small, medium, and large tears. Ninety-five patients were selected and 84 evaluated (42 received mini-open repair with acromioplasty, 42 received all-arthroscopic repair with acromioplasty) at a mean of 3.0 years (range: 2 to 5.8 years). Patient function was assessed using the ASES and UCLA scores. At followup, the differences between groups for both scores were not statistically significant.

One CCT and six retrospective cohort studies provided data for meta-analysis of the effects of mini-open versus arthroscopic repair on functional outcome measures (Figure 5). Data from the trial and cohort studies was analyzed separately. The following outcome measures were included in the meta-analysis: ASES,^{134,137,147,152} UCLA,⁹⁸ and CMS.^{102,108} The mean change between preoperative and postoperative scores was compared for four studies.^{98,102,108,134} The remaining studies provided no baseline data, therefore the endpoint scores are compared between groups.^{137,147,152} There were no significant differences between the mini-open and arthroscopic repair groups on functional outcome measures, either for the one CCT or the pooled estimate of five cohort studies. The CCT favored mini-open repair (MD=0.32; 95% CI, -0.13 to 0.78). The combined estimate of functional outcomes from cohort studies slightly favored arthroscopic repair (SMD=-0.13, 95% CI, -0.33 to 0.08) There was no evidence of heterogeneity between the pooled studies ($p=0.64$; $I^2=0$ percent).

Figure 5. Mini-open versus arthroscopic RCR on measures of functional outcome



Two cohort retrospective studies provided data for meta-analysis of the effects of mini-open versus arthroscopic repair on cuff integrity (Figure 6). The pooled estimate of effect showed no significant difference between the surgical approaches on the proportion of patients with intact RCs, however there was a trend favoring arthroscopic RCR (relative risk=0.80; 95% CI, 0.62 to 1.02). There was no evidence of heterogeneity between the two studies (p=0.44, I²=0 percent).

Figure 6. Mini-open versus arthroscopic RCR on cuff integrity

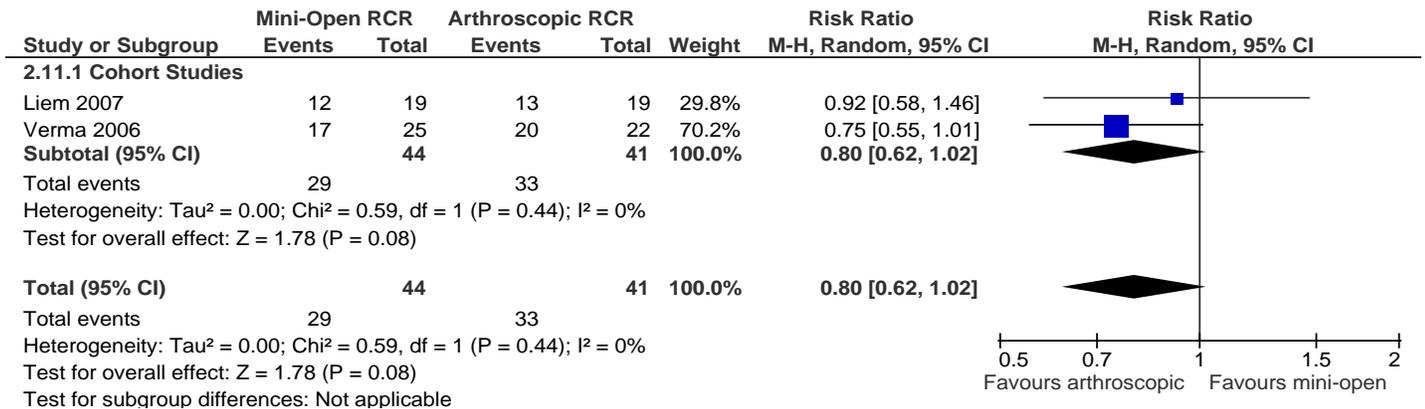


Table 5. Study and patient characteristics for studies assessing mini-open versus arthroscopic RCR

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range) |
|-----------------------------------|---|---|---|
| Kim SH, ⁹⁸ 2003 | G1: Mini-open RCR (NR) G2: Arthroscopic RCR (NR) | G1: 58±9 yr (42–68) / Males: 22 (64.7) G2: 55±10.5 yr (42–75) / Males: 27 (64.3) | FTT; Med, Lg NR |
| | CCT | | |
| Kose KC, ¹⁰² 2008 | G1: Mini-open RCR (NR) G2: Arthroscopic RCR (NR) | G1: 62±10 yr (32–75) / Males: 4 (16) G2: 55±7.6 yr (34–72) / Males: 7 (28) | NR; Sm, Med, Lg NR |
| | Retrospective cohort | | |
| Liem, D, ¹⁰⁸ 2007 | G1: Mini-open RCR (24) G2: Arthroscopic RCR (53) | G1: 62.9±6.7 yr / Males: 16 (66.7) G2: 61.9±6.6 yr / Males: 16 (30.1) | NR; Sm, Med, Lg G1: 10.6±7.9 mo, G2: 9.6±5.2 mo |
| | Retrospective cohort | | |
| Sauerbrey AM, ¹³⁴ 2005 | G1: Mini-open RCR (NR) G2: Arthroscopic RCR (NR) | G1: 57 yr (40–84) / Males: 16 (61.5) Athletes: 16 (61.5) G2: 56 yr (38–86) / Males: 16 (57.1) Athletes: 9 (32.1) | FTT; Med, Lg, Mass NR |
| | Retrospective cohort | | |
| Severud EL, ¹³⁷ 2003 | G1: Mini-open RCR (NR) G2: Arthroscopic RCR (NR) | G1: 63.3 yr / Males: 18 (62.1) WCB: 3 (10.3) G2: 58.7 yr / Males: 21 (60) WCB: 6 (17.1) | FTT / PTT; Sm, Med, Lg G1: 10.8 mo, G2: 15.7 mo |
| | Retrospective cohort | | |
| Verma NN, ¹⁴⁷ 2006 | G1: Mini-open RCR (58) G2: Arthroscopic RCR (69) | G1: 60.7±10.4 yr / Males: 23 (39.7) G2: 59.5±8.6 yr / Males: 22 (31.9) | FTT; Sm, Med, Lg, Mass NR |
| | Retrospective cohort | | |
| Warner JJ, ¹⁵⁰ 2005 | G1: Mini-open RCR (12) G2: Arthroscopic RCR (9) | G1: 55±8 yr / Males: 8 (66.7) WCB: 1 (8.3) G2: 53±10 yr / Males: 5 (55.5) WCB: 0 (0) | FTT; NR G1: 9±4 mo, G2: 12±4 mo |
| | Retrospective cohort | | |
| Youm T, ¹⁵² 2005 | G1: Mini-open RCR (NR) G2: Arthroscopic RCR (NR) | G1: 60 yr / NR G2: 57.9 yr / NR | NR; Sm, Med, Lg NR |
| | Retrospective cohort | | |

CCT = controlled clinical trial; FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; N = number; NR = not reported; PTT = partial-thickness tear; RCR = rotator cuff repair; SD = standard deviation; Sm = small; WCB = workers' compensation board

Table 6. Outcome data for studies assessing mini-open versus arthroscopic RCR

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|-----------------------------------|--|---|--|--|--|
| Kim SH, ⁹⁸ 2003 | G1: Mini-open RCR (34) G2: Arthroscopic RCR (42) 3.3 yr (2.0-5.3) | ASES | 59±12 (30-80) / 95±7.3 (75-100), p<0.001 | 61±16 (34-87) / 95±7.2 (75-100), p<0.001 | p=0.67 |
| | | UCLA | 18±2.6 (12-22) / 33±3.4 (25-35), p<0.001 | 19±4.3 (12-26) / 33±2.8 (26-35), p<0.001 | p=0.65 |
| | | Percent Function (VAS) | 54±12 (30-80) / 93±8.3 (70-100), p<0.001 | 57±16 (20-80) / 93±8.8 (70-100), p<0.001 | p=0.99 |
| | | Pain (VAS) | 3.2±1.6 (1-6) / 1.0±1.5 (0-6), p<0.001 | 4.2±2.5 (1-8) / 0.7±1.1 (0-5), p<0.001 | p=0.81 |
| | | ROM (degrees) | F: 30±26 (0-130) / 4.0±6.9 (0-25), p<0.001 ER: 16±19 (0-35) / 1.3±2.6 (0-10), p<0.001 IR: 4±2.6 (0-8) / 0.6 ± 1.2 (0-4), p<0.001 | F: 27±21 (0-110) / 3.2±6.8 (0-25), p<0.001 ER: 12±18 (0-35) / 1.1±2.6 (0-10), p<0.001 IR: 4±3.2 (0-9) / 0.4±0.9 (0-3), p<0.001 | F: p=0.51 ER: p=0.50 IR: p=0.31 |
| | | Strength grade (gr), manual muscle testing, n (%) | gr 5: 9 (27) / 25 (73), p<0.001 gr 4: 17 (50) / 6 (18) gr 3: 8 (23) / 3 (9) | gr 5: 11 (26) / 35 (83), p<0.001 gr 4: 24 (57) / 4 (10) gr 3: 7 (18) / 3 (7) | p=0.33 |
| Kose KC, ¹⁰² 2008 | G1: Mini-open RCR (25) G2: Arthroscopic RCR (25) 2.2 yr (12 mo–6.8 yr) | CMS* | 45.6±12.4 / 79.56±13.64, p<0.01 | 46.2±11.8 / 83.56±11.45, p<0.01 | p=0.24 |
| | | UCLA* | 10.6±4.5 / 28.8±3.42, p<0.01 | 11.2±5.6 / 29.76±4.5, p<0.01 | p=0.63 |
| Liem D, ¹⁰⁸ 2007 | G1: Mini-open RCR (19) G2: Arthroscopic RCR (19) 12 mo (minimum) | CMS* | 53.5 / 83.7, p=0.0001 | 53.8 / 83.9, p=0.0001 | NR |
| | | ROM (degrees) | F: 154 / 175, p=0.01 ABD: 148 / 164, p=0.22 ER: 52 / 56, p=0.43 | F: 155 / 176, p=0.006 ABD: 149 / 173, p=0.016 ER: 47 / 59, p=0.011 | p>0.05 |
| | | Cuff integrity (MRI) | 12 / 19 (63.1) | 13 / 19 (68.4) | p=1.0† |
| Sauerbrey AM, ¹³⁴ 2005 | G1: Mini-open RCR (26) G2: Arthroscopic RCR (28) 2.1 yr (13 mo–4 yr) | ASES* | 52 (17-75) / 89 (56-100), p≤0.05 | 42 (9-47) / 86 (43-100), p≤0.05 | p=0.33 |

ABD = abduction; ASES = American Shoulder and Elbow Scale; CMS = Constant-Murley score; ER = external rotation; F = flexion; G = group; gr = grade; IR = internal rotation; Insalata = Insalata Shoulder Rating Questionnaire; MRI = magnetic resonance imaging; NR = not reported; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SST = simple shoulder test; UCLA = University of California Los Angeles Scale; VAS = visual analogue scale

*Subscores reported

†Calculated by UAEPC

Table 6. Outcome data for studies assessing mini-open versus arthroscopic RCR (continued)

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 | | Group 2 | | Group 1 vs. Group 2 Post-op p-value |
|------------------------------------|---|----------------|--|--|--|--|--|
| | | | Pre-op mean±SD (range)/ Post-op mean±SD (range) | | Pre-op mean±SD (range)/ Post-op mean±SD (range) | | |
| Severud EL, ¹³⁷ 2003 | G1: Mini-open RCR (29 shoulders) G2: Arthroscopic RCR (35 shoulders) | ASES | NR / 90.0 | | NR / 91.7 | | p>0.05 |
| | | UCLA | NR / 31.4 | | NR / 32.6 | | p>0.05 |
| | 3.7 yr (2–6.8) | | | | | | |
| Verma NN, ¹⁴⁷ 2006 | G1: Mini-open RCR (33) G2: Arthroscopic RCR (38) | ASES | NR / 95.1±9.3 | | NR / 94.6±8.9 | | p>0.05 |
| | | Insalata | NR / 94.2±8.8 | | NR / 92.7±9.0 | | p>0.05 |
| | | SST | NR / 11.3±1.4 | | NR / 11.4±0.9 | | p>0.05 |
| | | Pain (VAS) | NR / 0.4±1.0 | | NR / 0.7±1.2 | | p>0.05 |
| | | ROM (degrees) | F: NR / 169.4± 6.9 ABD: NR / 168.9± 8.4 ER: NR / 70.2±14.4 IR: NR / 9.2±3.1 | | F: NR / 170.5±6.9 ABD: NR / 169.6±7.5 ER: NR / 68.2±16.7 IR: NR / 9.8±3.1 | | p>0.05 |
| | | Cuff integrity | 17/25 (68.0) | | 20/22 (90.9) | | p=0.079† |
| Warner JJ, ¹⁵⁰ 2005 | G1: Mini-open RCR (12) G2: Arthroscopic RCR (9) | SST | NR / 12 (9-12) | | NR / 12 (5-12) | | p=0.28 |
| | | Pain (VAS) | 7 (6-9) / 0 (0-2), p<0.01 | | 7 (5-8) / 0 (0-2), p<0.01 | | p=0.92 |
| | | ROM (degrees) | F: 150 (30-160) / 155 (110- 170), p>0.2 ER: 50 (30-50) / 50 (25-60), p>0.2 | | F: 145 (120-160) / 160 (130- 170), p>0.2 ER: 50 (40-60) / 50 (30-60), p>0.2 | | F: p=0.25 ER: p=0.80 |
| | | Strength grade | 4 (2-5) / 4 (4-5), p=0.26 | | 4 (3-5) / 5 (4-5), p<0.01 | | p=0.08 |
| Youm T, ¹⁵² 2005 | G1: Mini-open RCR (42) G2: Arthroscopic RCR (42) | ASES | NR / 90.2±14.8 | | NR / 91.1±15.4 | | p>0.05 |
| | | UCLA | NR / 32.3±3.3 | | NR / 33.2±2.5 | | p>0.05 |
| | 3.0 yr (2.0-5.8) | | | | | | |

Open RCR versus arthroscopic RCR. One prospective cohort study⁹⁶ compared open RCR against arthroscopic RCR. Patient and study characteristics and outcome data are presented in Table 7 and Table 8, respectively. Ide et al.⁹⁶ conducted the study in patients with small, medium, large, and massive full-thickness tears. One hundred patients were evaluated (50 received open repair with acromioplasty, 50 received all-arthroscopic repair with acromioplasty) at a mean of 4.1 years (range: 2.1 to 6.9 years). Patient function was assessed using UCLA and Japanese Orthopaedic Association (JOA) index scores. At followup, statistically significant differences were observed within both groups for both scores ($p < 0.0001$); however, the differences between the two groups were not statistically significant ($p > 0.05$).

Table 7. Study and patient characteristics for studies assessing open versus arthroscopic RCR

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range) |
|---------------------------|--|--|--|
| Ide J, ⁹⁶ 2005 | G1: Open RCR (NR) G2: Arthroscopic RCR (NR) Prospective cohort | G1: 57.1 yr (24–72) / Males: 39 (78) Athletes: 2 (4) G2: 57 yr (25–78) / Males: 41 (82) Athletes: 3 (6) | FTT; Sm, Med, Lg, Mass G1: 8 mo (2–24), G2: 6.4 mo (2–36) |

FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; NR = not reported; RCR = rotator cuff repair; SD = standard deviation; Sm = small

Table 8. Outcome data for studies assessing open versus arthroscopic RCR

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|---------------------------|--|---------|---|---|--|
| Ide J, ⁹⁶ 2005 | G1: Open RCR (50) G2: Arthroscopic RCR (50) 4.1 yr (2.1–6.9) | UCLA | 15.5 (7-26) / 31.6 (26-35), p<0.0001 | 16.1 (8-24) / 32.0 (21-35), p<0.0001 | p>0.05 |
| | | JOA* | 56.9 (27-68) / 92.1 (67-100), p<0.0001 | 58.7 (32-64) / 94.0 (60-100), p<0.0001 | p>0.05 |

G = group; JOA = Japanese Orthopaedic Association scale; N = number; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; SD = standard deviation;

UCLA = University of California Los Angeles Scale

* Subscores reported

Open or mini-open RCR versus arthroscopic RCR. Two prospective cohort studies^{60,65} compared open or mini-open RCR against arthroscopic RCR. These studies are presented as a separate category, since the study outcome data was not reported separately for patients who received open or mini-open repair. Pooled results are shown in Figure 7. Patient and study characteristics and outcome data are presented in Table 9 and Table 10, respectively.

Bishop et al.⁶⁰ conducted a prospective cohort study in patients with small, large, and massive full-thickness tears. One hundred and two patients were selected and 72 evaluated (32 received open repair [24 patients] or mini-open repair [8 patients] and 40 received arthroscopic repair) at 1 year. Patient function was assessed using the ASES score, CMS, pain, and range of motion (forward elevation and external rotation). Within group differences for all measures were statistically significant. All between group differences were not significant with the exception of an improvement in external rotation, which was significantly greater for the open and mini-open group ($p \leq 0.05$). Cuff integrity was evaluated using MRI at 12 months; 22 patients (69 percent) and 21 patients (52.5 percent) had intact cuffs in the open or mini-open versus arthroscopic group, respectively. The difference between groups was not significant.

Buess et al.⁶⁵ conducted a prospective cohort study in patients with all tear sizes. Ninety-six patients (99 shoulders) were selected and 92 evaluated (29 received open or mini-open repair and 63 received arthroscopic repair) at a mean followup of 2 years (range: 15 months to 3.3 years). Patients were evaluated on the SST, a visual analogue scale for pain, and number of days until pain free. The arthroscopic group had significantly better pain relief on the visual analogue scale than the open / mini-open group at final followup ($p = 0.02$). Postoperative SST scores were not statistically significant between the groups ($p = 0.33$). Both groups showed similar duration in the mean number of days until pain free (95.6 for the open and mini-open group, 94.4 for the arthroscopic group).

A meta-analysis was conducted using visual analogue pain data from the two cohort studies (Figure 7).^{60,65} The mean preoperative to postoperative change scores for both treatment arms were compared. The studies both found a statistically significant difference between the groups; in Bishop et al.⁶⁰ the open or mini-open group was favored, while in Buess et al.⁶⁵ the arthroscopic group was favored. The combined estimate of change in pain scores showed no difference between the interventions (SMD = -0.58; 95% CI, -2.64 to 1.48). There was significant heterogeneity between the studies ($p < 0.0001$; $I^2 = 97$ percent). The heterogeneity may be attributable, in part, to differences between the study populations. Buess et al.⁶⁵ included younger patients, of which a large proportion were manual laborers (nearly 50 percent), while the population in Bishop et al.⁶⁰ was significantly older.

Figure 7. Open or mini-open versus arthroscopic RCR for pain VAS

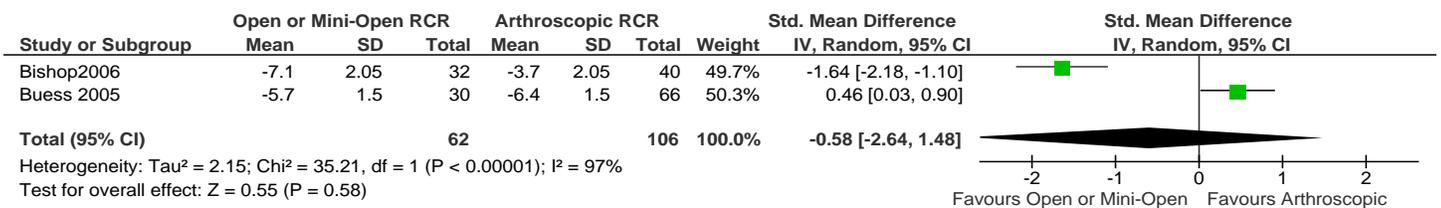


Table 9. Study and patient characteristics for studies assessing open or mini-open versus arthroscopic RCR

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range) |
|------------------------------|---|--|---|
| Bishop J, ⁶⁰ 2006 | G1: Open or mini-open RCR (47) G2: Arthroscopic RCR (55) Prospective cohort | G1: 64 yr / NR G2: 64 yr / NR | FTT; Sm, Lg, Mass NR |
| Buess E, ⁶⁵ 2005 | G1: Open or mini-open RCR (32 shoulders) G2: Arthroscopic RCR (67 shoulders) Prospective cohort | G1: 48.3 yr (18–73) / Males: 21 (72.4) Manual laborers: 13 (44.8) G2: 53.2 yr (20–77) / Males: 44 (69.8) Manual laborers: 30 (47.6) | NR; Sm, Med, Lg, Mass NR |

FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; N = number; NR = not reported; RCR = rotator cuff repair; SD = standard deviation; Sm = small; yr = year

Table 10. Outcome data for studies assessing open or mini-open versus arthroscopic RCR

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|------------------------------|---|------------------------------------|---|---|--|
| Bishop J, ⁶⁰ 2006 | G1: Open or mini-open RCR (32) | ASES | 40 / 85, p<0.0001 | 46 / 84, p<0.0001 | p=0.73 |
| | | CMS | 53 / 80, p<0.0001 | 52 / 75, p<0.0001 | p=0.13 |
| | G2: Arthroscopic RCR (40) | Pain (VAS) | 8.2 / 1.1, p<0.0001 | 5.2 / 1.5, p<0.0001 | p=0.41 |
| | | ROM (lb) | F: 6.2 / 12.8, p<0.005 ER: 10 / 18, p<0.01 | F: 5.8 / 10.4, p<0.01 ER: 9.5 / 13.6, p<0.01 | F: p=0.220 ER: p≤0.05 |
| | 12 mo | Cuff integrity | 22 / 32 (68.8) | 21 / 40 (52.5) | p=0.23* |
| | | MRI | | | |
| Buess E, ⁶⁵ 2005 | G1: Open or mini-open RCR (29) | SST | NR / 8.7 | NR / 9.7 | p=0.33 |
| | | Pain (VAS) | 7.8 (4.5-10) / NR | 8.0 (2.5-10) / NR | p=0.02 |
| | G2: Arthroscopic RCR (63) | Days until pain free, mean (range) | 95.6 (7–360) | 94.4 (2–375) | NR |
| | | 2 yr (15 mo–3.3 yr) | | | |

ASES = American Shoulder and Elbow Scale; CMS = Constant-Murley score; ER = external rotation; F = flexion; G = group; lb = pound; MRI = magnetic resonance imaging; NR = not reported; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SST = simple shoulder test; VAS = visual analogue scale

* Calculated by UAEPC

Open RCR versus open or arthroscopic debridement. Four studies (two CCTs,^{119,124} and two cohort studies^{121,145}) compared open RCR versus arthroscopic debridement. Pooled results are shown in Figure 8. Patient and study characteristics and outcome data are presented in Table 11 and Table 12, respectively.

Montgomery et al.¹¹⁹ conducted a CCT comparing open RCR versus arthroscopic debridement. All patients had full-thickness tears; tear size ranged from small to massive. One hundred and six patients (107 shoulders) were randomly assigned to the interventions (58 to open repair and acromioplasty, 49 to arthroscopic debridement and subacromial decompression) and 87 patients (88 shoulders) were included in final analysis. Followup evaluations were conducted 2 to 5 years postoperatively. The UCLA shoulder scale was used to evaluate patient function. There was improvement from the preoperative to postoperative scores in both groups. At final evaluation, there was a significant difference between two groups ($p=0.0028$), in favor of the open RCR group.

Motycka et al.¹²¹ conducted a retrospective cohort study comparing open RCR versus open or arthroscopic debridement in patients with large and massive tears. Overall, 76 patients were enrolled in the study; of these, 64 were included in the final analyses (33 received open repair with acromioplasty, 31 received open debridement with acromioplasty [15] or all-arthroscopic debridement and acromioplasty [16]). The mean length of followup was 5.7 years (range: 2.1 to 14.2). Patients were evaluated using the CMS. There was no statistically difference between the endpoint scores of the two groups ($p=0.73$).

Ogilvie-Harris et al.¹²⁴ conducted a CCT comparing open RCR versus arthroscopic debridement in patients with RC tears 1 to 4 cm in size. Fifty patients were assigned to the interventions (25 patients received open repair with acromioplasty, 25 received all-arthroscopic debridement with acromioplasty); 45 were included in the final analyses. Followup duration ranged from 2 to 5 years. Patient function was evaluated using the UCLA scale. Both groups showed a significant improvement in UCLA subscores (pain, function, active forward flexion, and strength of forward flexion) from preoperative to postoperative measures. The difference between the postoperative scores of the two groups was statistically significant ($p=0.017$), favoring the open RCR group.

Vad et al.¹⁴⁵ conducted a retrospective cohort study comparing open RCR versus arthroscopic debridement in patients with massive full-thickness tears. Sixty-eight patients were enrolled in the two operative arms (36 received open repair, 32 received all-arthroscopic debridement). All patients were followed up for at least 2 years; mean follow up duration was 3.2 years (range: 2 to 7). Patients were evaluated using the Insalata shoulder rating scale, range of motion (abduction), and time to maximal range of motion. For both groups, there were statistically significant improvement between the preoperative and postoperative scores for the Insalata rating and range of motion ($p<0.05$). The Insalata scores at final followup were significantly different between groups, favoring open repair. The time to maximal range of motion differed between the groups, with 6.8 months for the open RCR group and 3.2 months in the arthroscopic debridement group.

Two CCTs^{119,121} and two cohort studies^{124,145} provided data for meta-analysis of the effects of open repair versus arthroscopic debridement on functional outcome measures (Figure 8). Data from the trials and cohort studies was analyzed separately. The following measures were included in the meta-analysis: CMS,¹²¹ UCLA score,^{119,124} and the Insalata shoulder rating scale.¹⁴⁵ The preoperative to postoperative change score was compared between groups for Vad

et al.¹⁴⁵ and Montgomery et al;¹¹⁹ the remaining studies did not report baseline data, therefore the postoperative scores were compared between groups. The combined estimate of changes in measures of functional outcomes indicated a significant improvement in favor of open RCR for both the trials (SMD=0.52; 95% CI, 0.17 to 0.87) and the cohort studies (SMD=1.00; 95% CI, 0.11 to 1.90). There was no evidence of heterogeneity for the trials (p=0.41; I²=0 percent), however there was substantial heterogeneity for the cohort studies (p=0.03; I²=79 percent).

Figure 8. Open RCR versus open or arthroscopic debridement for measures of functional outcome

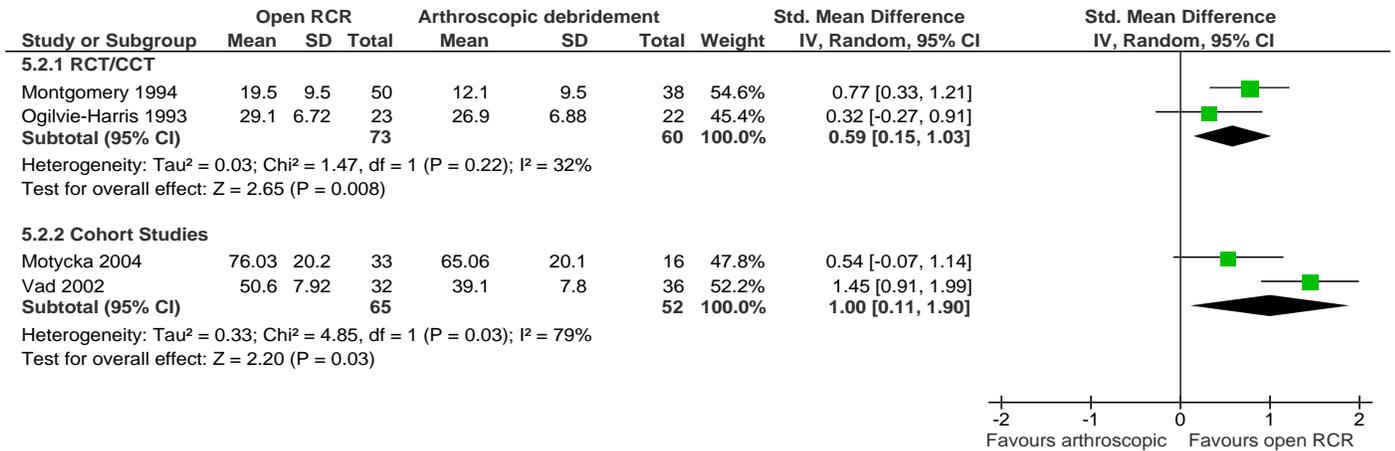


Table 11. Study and patient characteristics for studies assessing open RCR versus arthroscopic debridement

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range) |
|--|--|--|---|
| Montgomery TJ, ¹¹⁹ 1994 | G1: Open RCR (58 shoulders) G2: Arthroscopic debridement (49 shoulders) CCT | G1: 58±11.6 yr (32–79) / NR G2: 60±12.2 yr (36–79) / NR | FTT; Sm, Med, Lg, Mass NR |
| Motycka T, ¹²¹ 2004 | G1: Open RCR (NR) G2: Open or arthroscopic debridement (NR) Retrospective cohort | G1: NR / NR G2: NR / NR | NR; Lg, Mass NR |
| Ogilvie-Harris DJ, ¹²⁴ 1993 | G1: Open RCR (25) G2: Arthroscopic debridement (25) CCT | G1: NR / NR G2: NR / NR | NR; Sm, Med, Lg NR |
| Vad VB, ¹⁴⁵ 2002 | G3*: Open RCR (36) G4: Arthroscopic debridement (32) Retrospective cohort | G3: 59.4 yr / NR G4: 62.9 yr / NR | FTT; Mass 6.3 mo (1–17) |

CCT = controlled clinical trial; FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; NR = not reported; RCR = rotator cuff repair; SD = standard deviation; Sm = small

*Groups 1 and 2 are nonoperative interventions

Table 12. Outcome data for studies assessing open RCR versus arthroscopic debridement

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|--|--|---|---|--|--|
| Montgomery TJ, ¹¹⁹ 1994 | G1: Open RCR (50 shoulders) G2: Arthroscopic debridement (38 shoulders) 2–5 yr | UCLA* | 11 / 30.5 | 13 / 25.1 | p=0.0028 |
| Motycka T, ¹²¹ 2004 | G1: Open RCR (33) G2: Open or arthroscopic debridement (31) 5.7 yr (2.1–14.2) | CMS* | NR; 76 (16–100) | NR; 65.1 (10–98) | p=0.73 |
| Ogilvie-Harris DJ, ¹²⁴ 1993 | G1: Open RCR (23) G2: Arthroscopic debridement (22) 2–5 yr | UCLA* | NR / 29.1 | NR / 26.9 | p=0.017 |
| Vad VB, ¹⁴⁵ 2002 | G3†: Open RCR (36) G4: Arthroscopic debridement (32) 3.2 yr (2–7) | Insalata* ROM (degrees) Time to maximal ROM, mean (range) | 33±1.2 / 83.6±1.4, p≤0.05 ABD: 72 / 116, p≤0.05 6.8 mo (4–16) | 42.3±1.4 / 81.4±1.3, p≤0.05 ABD: 74 / 110, p≤0.05 3.2 mo (1–8) | p≤0.01‡ NR NR |

ABD = abduction; CMS = Constant-Murley score; G = group; Insalata = Insalata Shoulder Rating Questionnaire; NR = not reported; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; UCLA = University of California Los Angeles Scale; vs. = versus

*Subscores reported

†Groups 1 and 2 are nonoperative interventions

‡Calculated by UAEPC

Arthroscopic RCR with acromioplasty versus without acromioplasty. Two studies (two RCTs^{86,116}) compared arthroscopic RCR with acromioplasty vs. arthroscopic RCR alone. Pooled results are shown in Figure 9. Patient and study characteristics and outcome data are presented in Table 13 and Table 14, respectively.

Gartsman et al.⁸⁶ conducted a RCT in patients with full-thickness tears limited to the supraspinatus tendon. Ninety-three patients were randomized (47 received all-arthroscopic repair with acromioplasty, 46 received all-arthroscopic repair with no additional procedures). All patients were followed up for at least 1 year; the mean followup duration was 15.6±3.3 months. In the group treated with arthroscopic RCR and acromioplasty, the mean tear size was 2.1 cm; in the group treated with arthroscopic RCR alone, the mean tear size was 2.3 cm. The ASES index was used to evaluate patient function. There was no statistical difference in the postoperative endpoint scores between the two groups (p=0.39).

Milano et al.¹¹⁶ conducted a RCT in patients with full-thickness tears. Overall, 80 patients were randomly assigned to the interventions (40 received arthroscopic repair and acromioplasty, 40 received arthroscopic repair without acromioplasty); 71 were included in the final analyses. Followup duration was 2 years. Patients were evaluated using the CMS, the Disabilities of the Arm, Shoulder and Hand (DASH) score, and the Work-DASH score. Endpoint scores were comparable between the groups, with the arthroscopic group with acromioplasty scoring slightly higher on the postoperative CMS, and the group without acromioplasty scoring somewhat higher on the DASH and Work-DASH. Baseline and p-values for between and within-group differences were not reported.

Two RCTs^{86,116} provided data for meta-analysis of the effects of arthroscopic repair with acromioplasty versus without acromioplasty on functional outcomes (Figure 9). Outcome measures used in the analysis include the ASES index⁸⁶ and the CMS.¹¹⁶ The difference between endpoint scores was analyzed in both studies.

Figure 9. Arthroscopic RCR with acromioplasty versus without acromioplasty for measures of functional outcome

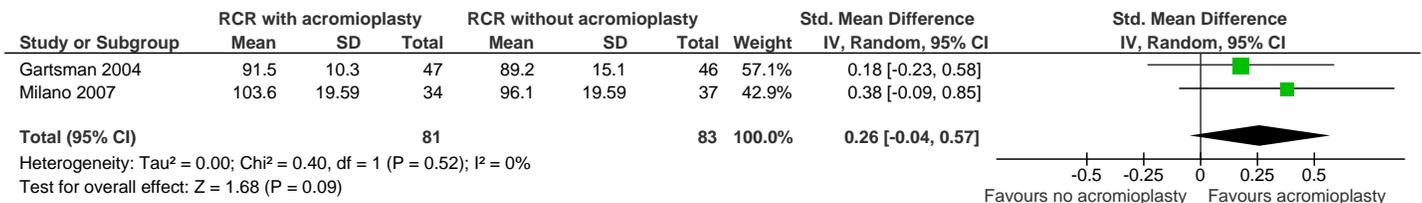


Table 13. Study and patient characteristics for studies assessing arthroscopic RCR with versus without acromioplasty

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range) |
|---------------------------------|---|--|---|
| Gartsman GM, ⁸⁶ 2004 | G1: Arthroscopic RCR & acromioplasty (47) G2: Arthroscopic RCR (46) RCT | G1: 59.3 yr (39–81) / Males: 27 (57.4) G2: 60 yr (37–79) / Males: 24 (52.2) | FTT; G1: 2.1 cm, G2: 2.3 cm NR |
| Milano G, ¹¹⁶ 2007 | G1: Arthroscopic RCR & acromioplasty (40) G2: Arthroscopic RCR (40) RCT | G1: 61±7 yr / Males: 20 (50) G2: 59.7±9.7 yr / Males: 19 (47.5) | FTT; NR NR |

cm = centimetre; FTT = full-thickness tear; G = group; mo = month; N = number; NR = not reported; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; yr = year

Table 14. Outcome data for studies assessing arthroscopic RCR with versus without acromioplasty

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|------------------------------------|---|--------------------------|---|---|--|
| Gartsman GM, ⁸⁶ 2004 | G1: Arthroscopic RCR & acromioplasty (47) G2: Arthroscopic RCR (46) 15±3.3 mo (NR) | ASES | 31.1 (20–46.7) 91.5±10.3 | 31 (18.3–41.7) 89.2±15.1 | p=0.39 |
| Milano G, ¹¹⁶ 2007 | G1: Arthroscopic RCR & acromioplasty (37) G2: Arthroscopic RCR (34) 2 yr | CMS DASH Work-DASH | NR / 103.6 NR / 18.2 NR / 23.7 | NR / 96.1 NR / 23.1 NR / 26.2 | NR NR NR |

ASES = American Shoulder and Elbow Surgeon scale; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand scale; G = group; mo = month; N = number; NR = not reported; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; SD = standard deviation; vs. = versus; yr = year

Other operative approaches. There were six studies (two RCTs,^{80,81} one CCT,¹⁴³ and three retrospective cohort studies^{53,63,120}) that could not be classified into one of the above categories. The intervention comparisons examined in these studies included: biceps tenotomy versus tenodesis,⁶³ arthroscopic repair with SLAP repair versus arthroscopic repair with biceps tenotomy,⁸⁰ arthroscopic RCR plus tenodesis with proximal biceps detachment versus without proximal biceps detachment,⁸¹ arthroscopic debridement with biceps tenotomy versus without biceps tenotomy,⁵³ complete RCR versus partial RCR versus debridement,¹²⁰ and classical versus modified open acromioplasty.¹⁴³ None of the studies could be pooled in a meta-analysis, as each study examined a different treatment comparison. Patient and study characteristics and outcome data are presented in Table 15 and Table 16, respectively.

Boileau et al.⁶³ conducted a retrospective cohort study in patients with massive irreparable tears. Overall, 78 patients (82 shoulders) were enrolled in the study; of these, 68 patients (72 shoulders) were included in analyses (39 shoulders received biceps tenotomy, 33 shoulders received biceps tenodesis). The mean length of followup was 2.9±0.6 years (range: 2 to 6.3 years). Patients were evaluated using the CMS and active and passive range of motion (flexion, external and internal rotation). Together, the groups showed significant improvement in the CMS and active flexion from preoperative to postoperative measures ($p<0.001$), however the mean change from baseline to endpoint was not reported separately by group. There was no statistically significant between-group differences at endpoint scores.

Franceschi et al.⁸⁰ conducted a RCT in patients with RC tears limited to supraspinatus and infraspinatus tendon; tear size ranged from small to large. Sixty-three patients were randomly assigned to the interventions (31 received arthroscopic repair with SLAP repair, 32 received arthroscopic repair with biceps tenotomy) and evaluated at a mean length of followup of 5.2 years (range: 2.9 to 7.8 years). Patients were assessed using the UCLA shoulder scale and range of motion (flexion, external and internal rotation). For both groups, there was significant improvement in total UCLA scores and range of motion from preoperative to postoperative scores ($p<0.001$). Moreover, there was a significant difference in total postoperative UCLA scores and range of motion between the two groups, in favour of the arthroscopic RCR with biceps tenotomy group ($p\leq 0.05$).

Franceschi et al.⁸¹ conducted a RCT in patients with massive full-thickness tears. Twenty-two patients were randomly assigned to the interventions (11 to tenodesis without detachment, 11 to tenodesis with detachment) and followed for a mean of 3.9 years (range: 3 to 4.9 years). All patients were evaluated using the UCLA shoulder scale and range of motion (flexion, external and internal rotation). For both groups, there was significant improvement in total UCLA scores and range of motion from preoperative to postoperative scores ($p\leq 0.05$). However, neither the difference between the groups in total postoperative UCLA scores nor in range of motion was statistically significant ($p>0.05$).

Klinger et al.⁵³ conducted a retrospective cohort study in patients with massive irreparable tears. Forty-one patients were enrolled in the study (24 received arthroscopic debridement and acromioplasty, 17 received arthroscopic debridement, acromioplasty and biceps tenotomy). All patients were followed up for at least 2 years; mean followup was 2.6 years (range: 2 to 4 years). All patients were assessed using the CMS. There was no statistically significant difference between the groups in the endpoint score ($p>0.05$).

Moser et al.¹²⁰ conducted a retrospective cohort study in patients with massive full-thickness tears. Thirty-eight patients were enrolled in the study (21 received open repair, 11 received

partial open repair, 6 received debridement). All patients were evaluated using the Shoulder Pain and Disability Index (SPADI) score, range of motion (protraction, external and internal rotation) and strength (protraction, external rotation), and for at least 2 years. There were no significant endpoint differences between the groups on any outcome, with the exception of external rotation range of motion ($p=0.029$), which favored complete RCR.

Torrens et al.¹⁴³ conducted a CCT in patients with small to massive tears. Forty-two patients were enrolled in the study (20 received open repair with classic open acromioplasty, 22 received open repair with modified acromioplasty). All patients were followed up for at least 1 year; the mean followup was 18 months. The CMS was used to evaluate patient function. For both groups, the CMS improved from baseline to endpoint.

Table 15. Study and patient characteristics for studies assessing other operative approaches

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range) |
|----------------------------------|--|--|---|
| Boileau P, ⁶³ 2007 | G1: Biceps tenotomy (NR) G2: Biceps tenodesis (NR) Retrospective cohort | Total: 68 yr (52–85) / Males: 26 (38) | FTT; Mass NR |
| Franceschi F, ⁸⁰ 2008 | G1: Arthroscopic RCR & SLAP repair (31) G2: Arthroscopic RCR & biceps tenotomy (32) RCT | G1: 61.8 yr (51–79) / Males: 18 (58.1) G2: 64.7 yr (53–81) / Males: 15 (46.9) | NR; Sm, Med, Lg 21 mo |
| Franceschi F, ⁸¹ 2007 | G1: Tenodesis without detachment (11) G2: Tenodesis with detachment (tenotomy) (11) RCT | G1: 60.3±12.4 yr (41–79) / Males: 6 (54.5) Manual laborers: 3 (27.3) G2: 58.1±14.5 yr (40–81) / Males: 5 (45.5) Manual laborers: 3 (27.3) | FTT; Mass NR |
| Klinger HM, ⁵³ 2005 | G1: Arthroscopic debridement (24) G2: Arthroscopic debridement & biceps tenotomy (17) Retrospective cohort | G1: 66 yr (61–79) / Males: 15 (62.5) G2: 68 (63–82) / Males: 10 (58.8) | FTT; Mass G1: 11 mo (6–23), G2: 10 mo (6–18) |
| Moser M, ¹²⁰ 2007 | G1: Complete RCR (21) G2: Partial RCR (11) G3: Debridement (6) Retrospective cohort | Total: 62.5 yr (33–81) / Males: 28 (73.7) | NR; Mass NR |
| Torrens C, ¹⁴³ 2003 | G1: Classical open acromioplasty (20) G2: Modified open acromioplasty (22) CCT | G1: 55.9 yr / Males: 4 (20) G2: 63.8 yr / Males: 4 (18.2) | NR; Sm, Med, Lg, Mass NR |

CCT = controlled clinical trial; FTT = full-thickness tear; G = group; Lg = large; Med = medium; Mass = massive; NR = not reported; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small

Table 16. Outcome data for studies assessing other approaches

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|-------------------------------------|--|---------------|---|---|--|
| Boileau P, ⁸³ 2007 | G1: Biceps tenotomy (39 shoulders) G2: Biceps tenodesis (33 shoulders) 2.9±0.6 yr (2–6.3) | CMS | NR / 61.2±18 | NR / 72.8±12 | p>0.05 |
| | | ROM | F (active): NR / 146.2±34.8 F (passive): NR / 166.4±21.3 ER (active): NR / 32.2±22.0 ER (passive): NR / 51.3±16.8 IR: NR / L3 | F (active): NR / 164.2±27.6 F (passive): NR / 173±10.5 ER (active): NR / 40.5±20.9 ER (passive): NR / 52.3±16.9 IR: NR / L3 | p>0.05 |
| Franceschi F, ⁸⁰ 2008 | G1: Arthroscopic RCR + SLAP repair (31) G2: Arthroscopic RCR + biceps tenotomy (32) 5.2 yr (2.9–7.8) | UCLA* | 10.4 (6-14) / 27.9 (24-35), p<0.001 | 10.1 (5-14) / 32.1 (30-35), p<0.001 | p≤0.05 |
| | | ROM (degrees) | F: 107 (30-140) / 139 (120-170), p<0.001 ER: 81.7 (65-95) / 121.4 (90-140), p<0.001 IR: 26.0 (20-33) / 34.4 (26-40), p<0.001 | F: 99 (30-140) / 166 (140-170), p<0.001 ER: 76.6 (60-90) / 134.3 (90-140), p<0.001 IR: 29.1 (21-35) / 40.0 (30-45), p<0.001 | p≤0.05 |
| | | | | | |
| Franceschi F, ⁸¹ 2007 | G1: Tenodesis without detachment (11) G2: Tenodesis with detachment (tenotomy) (11) 3.9 yr (3-4.9) | UCLA | 10.5 (5-15) / 33 (29-35), p≤0.05 | 11.1 / 32.9, p≤0.05 | p>0.05 |
| | | ROM (degrees) | F: 102 (30-140) / 161 (150-170), p≤0.05 ER: 37 (30-60) / 59 (45-70), p≤0.05 IR†: L5 - T10 / T11 - T5 | F: 110 (30-150) / 159 (140-170), p≤0.05 ER: 41 (30-60) / 60 (45-90), p≤0.05 IR†: L5 - T12 / T12 - T5 | p>0.05 |
| | | | | | |
| Klinger HM, ⁵³ 2005 | G1: Arthroscopic debridement (24) G2: Arthroscopic debridement + biceps tenotomy (17) 2.6 yr (2–4) | CMS | 39 (19-54) / 67 (41-87) | 41 (16-60) / 69 (49-87) | p>0.05 |

ASES = American Shoulder and Elbow Scale; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand; ER = external rotation; F = flexion; IR = internal rotation; ft-lbs = foot pounds; G = group; Nm = nanometer; NR = not reported; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SLAP = superior labral tear from anterior to posterior; SPADI = Shoulder Pain and Disability Index; UCLA = University of California Los Angeles Scale

*Subscores reported

†vertebral level

Table 16. Outcome data for studies assessing other approaches (continued)

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|-----------------------------------|--|---------------|--|--|--|
| Moser M, ¹²⁰ 2007 | G1: Complete RCR (NR) G2: Partial repair (NR) G3: Debridement (NR) 2 yr (minimum) | SPADI* | NR / 17.9 | NR / 29.5 Group 3: NR / 38.4 | p=0.235 |
| | | ROM (degrees) | Protraction: NR / 124.5 ER: NR / 45.6 IR: NR / T9 | Protraction: NR / 120 ER: NR / 27 IR: NR / T11 | Protraction: p=0.78 ER: p=0.029 IR: p=0.08 |
| | | Strength | Protraction: NR / 16.1 Nm, 11.9 (ft-lbs) ER: NR / 19.3 Nm, 14.2 (ft- lbs) | Protraction: NR / 16.8 Nm, 12.4 (ft-lbs) ER: NR / 16.9 Nm, 12.5 (ft-lbs) | Protraction: p=0.48 ER: p=0.08 |
| | | | Group 3: Protraction: NR / 110.8 ER: NR / 41.6 IR: NR / T5 | | |
| Torrens C, ¹⁴³ 2003 | G1: Classical open anterior acromioplasty (20) G2: Modified open anterior acromioplasty (22) 18 mo (NR) | CMS | 46.7 / 74 | 53.3 / 80 | NR |

Table 17. Strength of evidence for operative approaches

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|---|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Open RCR vs. mini-open RCR | 1; 73 (60) | HRQL | RCT | Unknown | n/a | Imprecise | Absent | Low |
| | 3; 187 (174) | Function | RCT, cohorts | Consistent | Direct | Precise | Present | Moderate |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 2; 114 | Time to return to work | Cohorts | Consistent | Direct | Precise | Present | Moderate |
| Mini-open RCR vs. arthroscopic RCR | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 8; 591 (508) | Function | CCT, Cohorts | Consistent | Direct | Imprecise | Present | Moderate |
| | 2 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Open RCR vs. arthroscopic RCR | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 100 | Function | Cohort | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Open or mini-open RCR vs. arthroscopic RCR | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 2; 198 (194) | Function | Cohorts | Consistent | Direct | Imprecise | Absent | Moderate |
| | 1; 102 | Cuff integrity | Cohort | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Open RCR vs. arthroscopic debridement | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 4 | Function | RCT, CCT, Cohorts | Consistent | Direct | Precise | Present | Moderate |
| | 0 | Cuff integrity | Cohort | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Arthroscopic RCR with acromioplasty vs. without acromioplasty | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 2; 173 (164) | Function | RCTs | Consistent | Direct | Precise | Absent | Moderate |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

CCT = controlled clinical trial; HRQL = health-related quality of life; n/a = not applicable; RCR = rotator cuff repair; RCT = randomized controlled trial; SLAP = superior labral tear from anterior to posterior

* number analyzed if different from number studied

Table 17. Strength of evidence for operative approaches (continued)

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|---|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Biceps tenotomy vs. tenodesis | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 78 (68) | Function | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 63 | Function | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Arthroscopic RCR plus tenodesis with detachment vs. without detachment | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 22 | Function | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Arthroscopic debridement with vs. without biceps tenotomy | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 41 | Function | Cohort Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Complete open RCR vs. partial open RCR vs. debridement | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 38 | Function | Cohort Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Open RCR with classic open vs. modified open acromioplasty | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 42 | Function | CCT Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

Operative Approach—Uncontrolled Studies

Fifty-eight uncontrolled studies (43 BA,^{55,58,59,62,64,66,67,69-71,74-76,79,84,85,87,88,91,92,94,95,99,100,103-107,110,113,114,123,126,131,133,136,138,140,141,146,148,149} 9 prospective cohorts with BA data,^{52,72,77,78,90,109,122,125,127} 5 retrospective cohorts with BA data^{111,117,129,130,142} and one case-control study with BA data¹⁴⁴) assessed the effectiveness of operative approaches in the RC tear population. The studies were published from 1993 to 2009 (median=2005; IQR: 2002 to 2007).

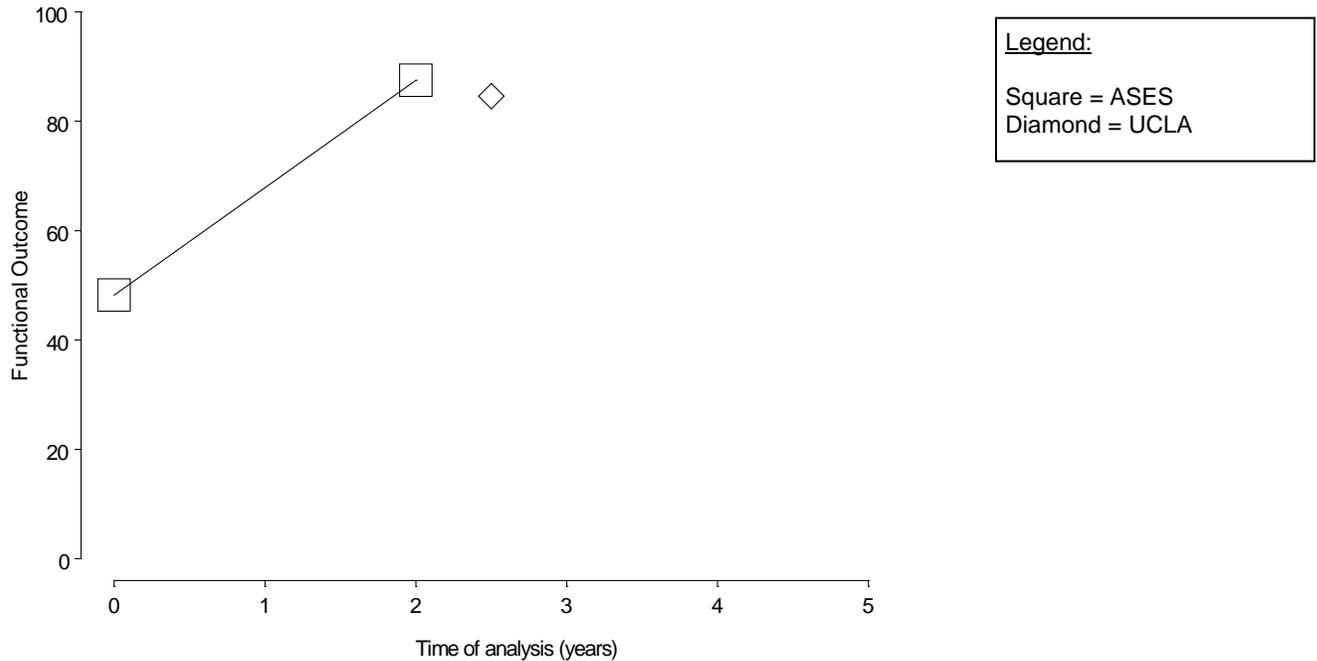
Open RCR. Fourteen uncontrolled studies (10 BA,^{66,70,87,91,92,99,114,126,131,133} one prospective cohorts with BA data,⁷² two retrospective cohorts with BA data,^{111,117} and one case-control study with BA data¹⁴⁴) evaluated the effectiveness of open RCR. The studies were published from 1993 to 2007, with 2001 the median year of publication (IQR: 1995 to 2005).

The number of participants enrolled in the studies ranged from 25 to 224 (median=57; IQR: 43 to 97). The median followup duration was 2.2 years (IQR: 18 months to 4 years). The mean age of the participants ranged from 41 to 65 years. Of the 10 studies that reported type of tear, eight studies included only patients with full-thickness tears (80 percent) and two studies^{91,144} examined patients with partial- or full-thickness tears (20 percent). All tear sizes were included in six studies,^{66,70,99,117,126,131} small to large tears were included in two studies,^{72,92} medium to massive¹⁴⁴ and large to massive¹³³ in one study each. The tear size was not clearly described in four studies.^{87,91,111,114} Recreational athletes were included in three studies,^{70,92,117} and smokers in one study.¹¹¹ One study reported the proportion of patients in jobs with strenuous manual labour¹¹⁷ and three studies included patients with a workers' compensation board (WCB) claim.^{92,117,144}

Health-related quality of life was reported in one study,¹¹⁴ while 10 studies used a functional outcome measure.^{66,72,87,91,92,111,114,117,131,133} Three studies reported either the time until patients returned to work,⁹² or the proportion of patients that returned to work.^{70,117} Cuff integrity was reported in one study.⁸⁷

The figures below present the preoperative and postoperative functional scores over time for the BA studies (Figure 10), cohort studies (Figure 11), and trials (Figure 12) that examine open RCR. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Regardless of the outcome measure used and the study design (trial, cohort or uncontrolled study), the studies all indicate improvement in functional score from baseline to final followup.

Figure 12. Trials examining functional outcomes for open RCR



Mini-open RCR. Two BA studies^{58,64} examined the effectiveness of mini-open RCR. The studies were published in 2004⁶⁴ and 2005.⁵⁸ The number of enrolled participants was 84 in both studies. The mean followup was 12 mo.⁵⁸ and 35 mo.⁶⁴ The mean ages were 53⁵⁸ and 54 years.⁶⁴ One study⁵⁸ included full-thickness tears of all sizes and participants with WCB claims (n=20, 24 percent), while tear characteristics were not reported in the other study.⁶⁴

The reported outcomes included functional outcome scales,^{58,64} and return to work.⁵⁸ The figures below present the preoperative and postoperative functional scores over time for the uncontrolled studies (Figure 13), cohort studies (Figure 14), and trials (Figure 15) that examine mini-open RCR. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. The studies all indicate improvement in functional score from baseline to final followup, regardless of the outcome measure used and the study design (trial, cohort or uncontrolled study).

Figure 13. Uncontrolled studies examining functional outcomes for mini-open RCR

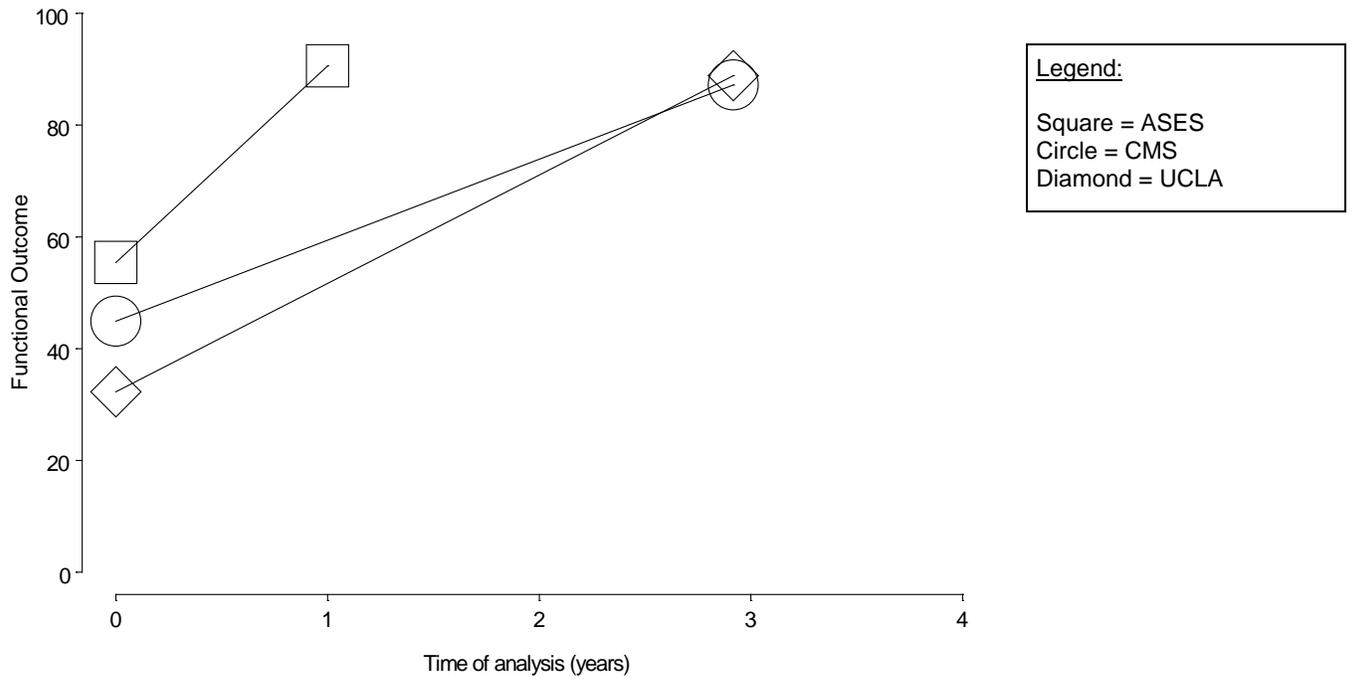


Figure 14. Cohort studies examining functional outcomes for mini-open RCR

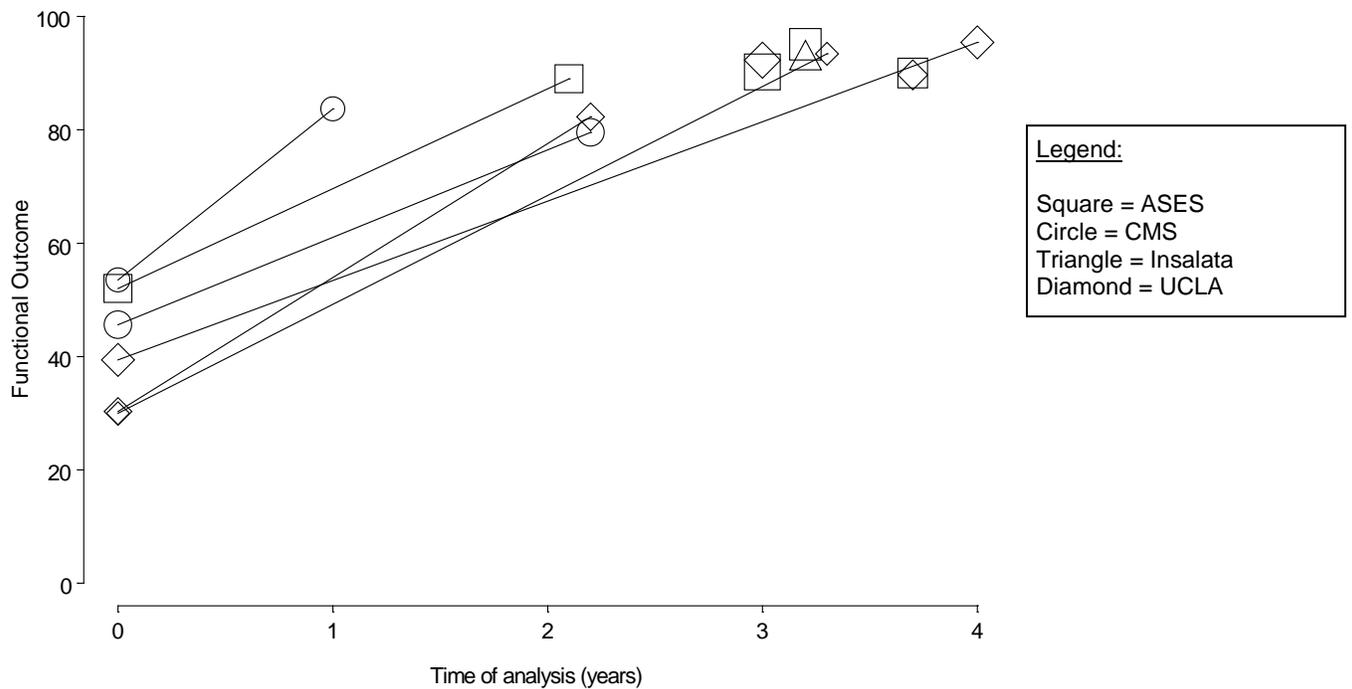
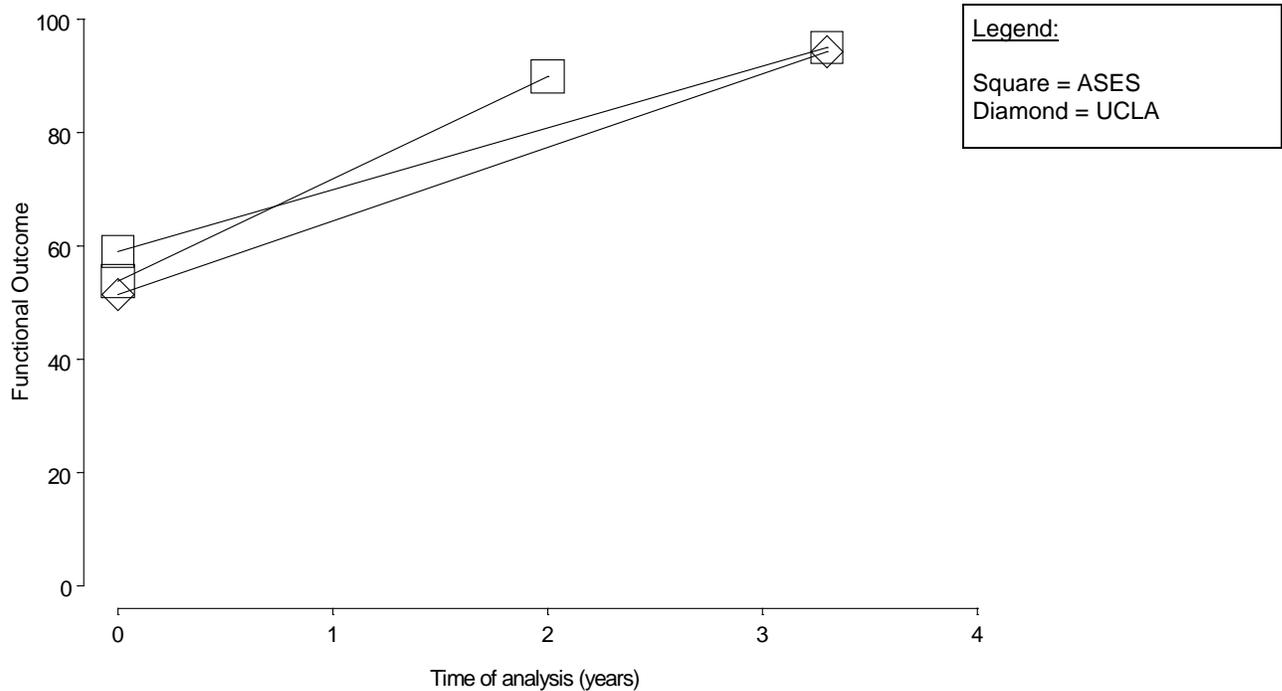


Figure 15. Trials examining functional outcomes for mini-open RCR



Arthroscopic RCR. Twenty-seven uncontrolled studies (19 BA,^{59,62,67,71,75,76,84,94,95,103-107,113,123,138,141,149} five prospective cohorts with BA data,^{52,77,78,122,127} three retrospective cohorts with BA data^{129,130,142}) examined the effectiveness of arthroscopic repair in patients with RC tears. The studies were published from 1993 to 2009 (median=2006; IQR: 2004 to 2007).

The total number of participants enrolled in the studies ranged from 16 to 193 (median=48 [IQR: 34 to 77]). The median duration of followup was 2.7 years (IQR: 2.2 to 3 years). The mean age of participants ranged from 42 to 70 years. The majority of the studies included on patients with full-thickness RC tears (n=15 studies, 56 percent), while the remaining studies included only partial-thickness tears,^{76,95,149} both tear types^{75,103,105,127,129,130} or did not report type of tear.^{106,123,141} Of the studies that reported tear size categories, eight included all tear sizes,^{71,78,104,106,113,122,123,138} two included small to large tears,^{62,105} three included small or medium tears only,^{59,75,94} and one study included only massive tears.⁵² One study reported including a small proportion of patients who were recreational athletes,⁷⁶ while two studies including smokers.^{75,123} Manual labour jobs were reported in one study.⁶⁷ Six studies reported including patients with a WCB claim^{62,67,71,76,113,129} and four studies reported excluding WCB patients.^{75,94,95,122}

Health-related quality of life was reported in four studies,^{71,75,84,113} and all of the studies reported at least one functional outcome measure. Two studies reported return to work¹⁰⁶ or physical activity.⁷⁵ Cuff integrity was examined in 12 studies.^{62,67,71,75,77,94,104-107,123,138}

The figures below present the preoperative and postoperative functional scores over time for the uncontrolled studies (Figure 16), cohort studies (Figure 17), and trials (Figure 18) that examine arthroscopic RCR. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Regardless of the outcome measure used and the study design (trial, cohort or uncontrolled study), the studies

all indicate improvement in functional score from baseline to final followup. Figure 19 plots the proportion of patients with and intact cuff after arthroscopic RCR over the followup period. The results were variable across the studies and showed no pattern with respect to study design.

Figure 16. Uncontrolled examining functional outcomes for arthroscopic RCR

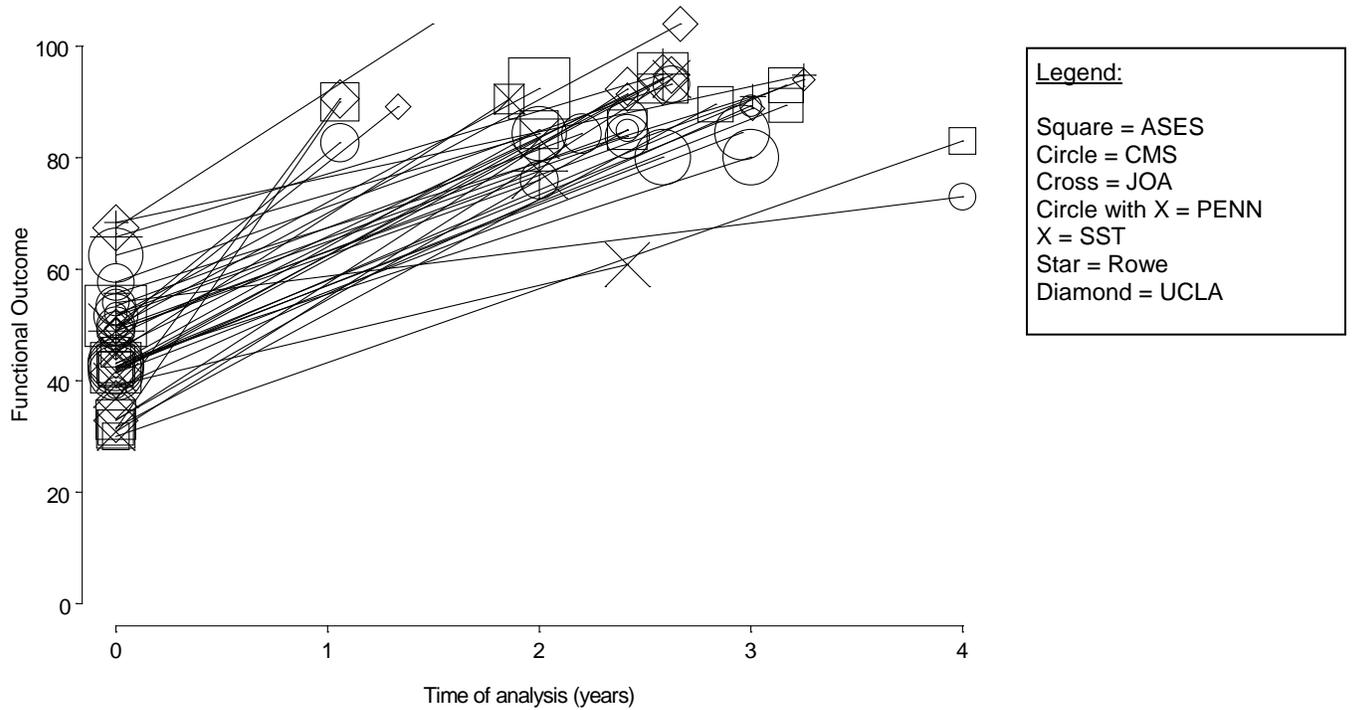


Figure 17. Cohort studies examining functional outcomes for arthroscopic RCR

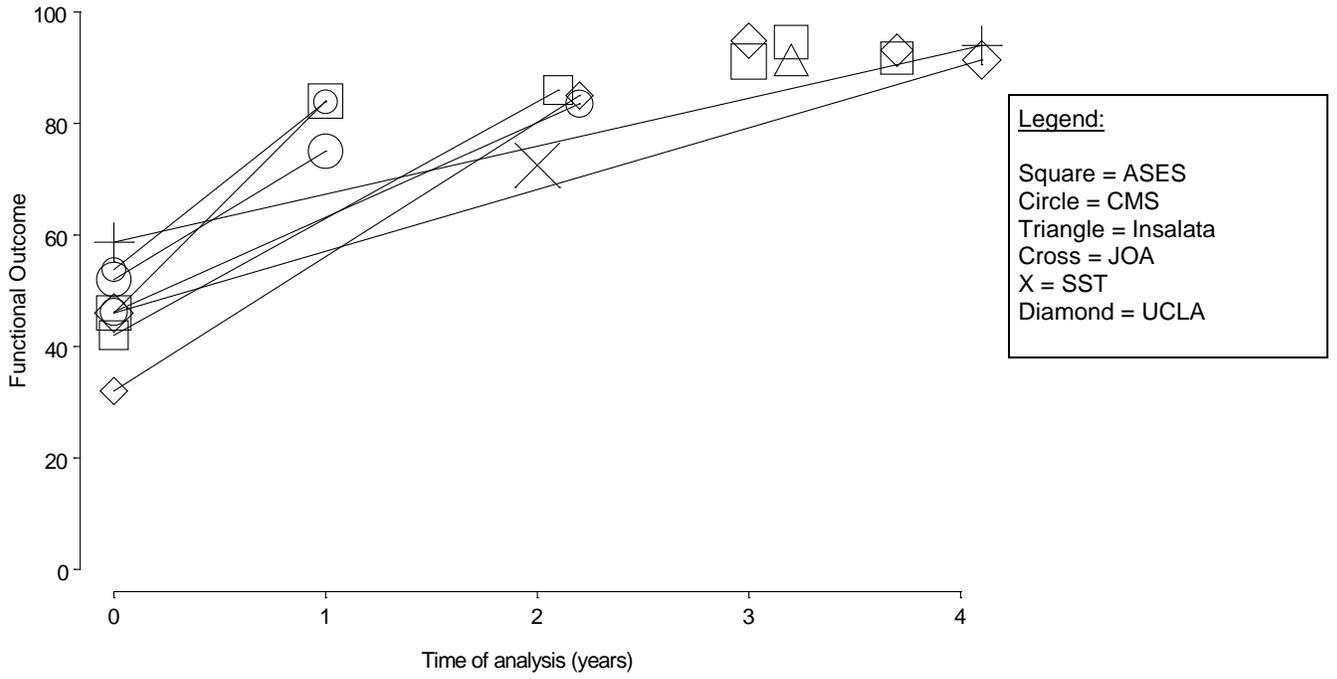


Figure 18. Trials examining functional outcomes for arthroscopic RCR

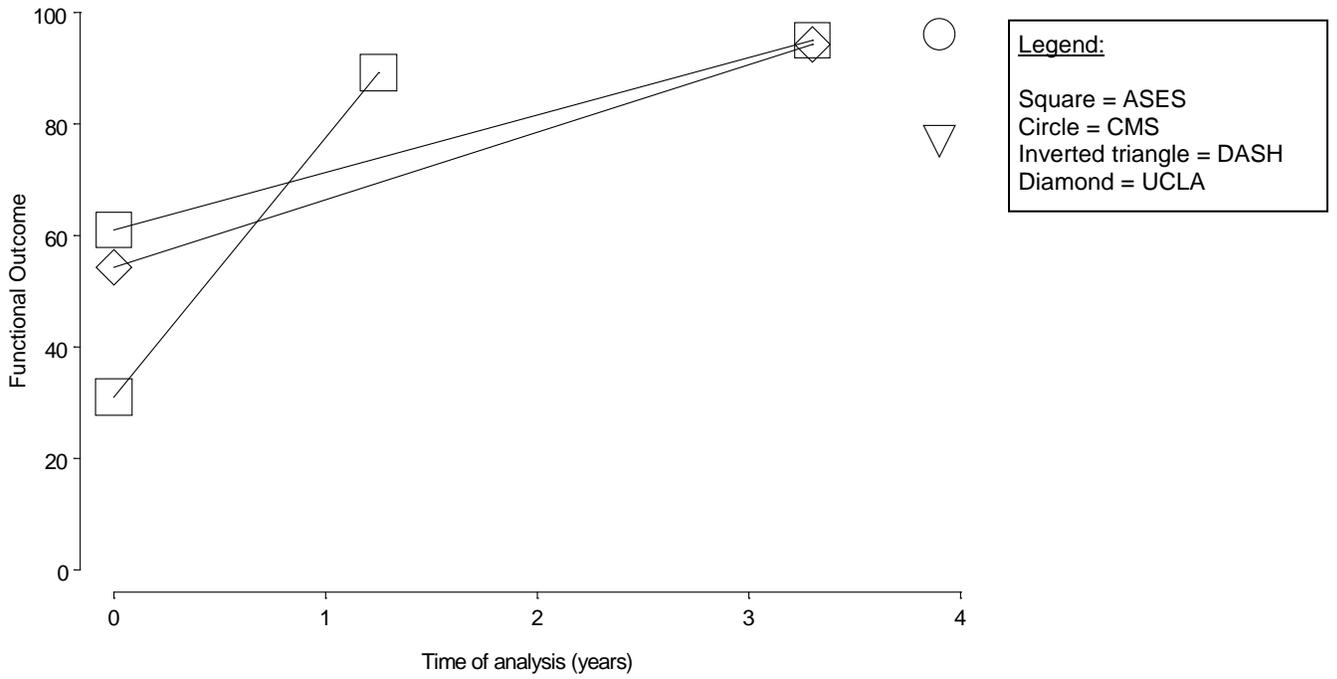
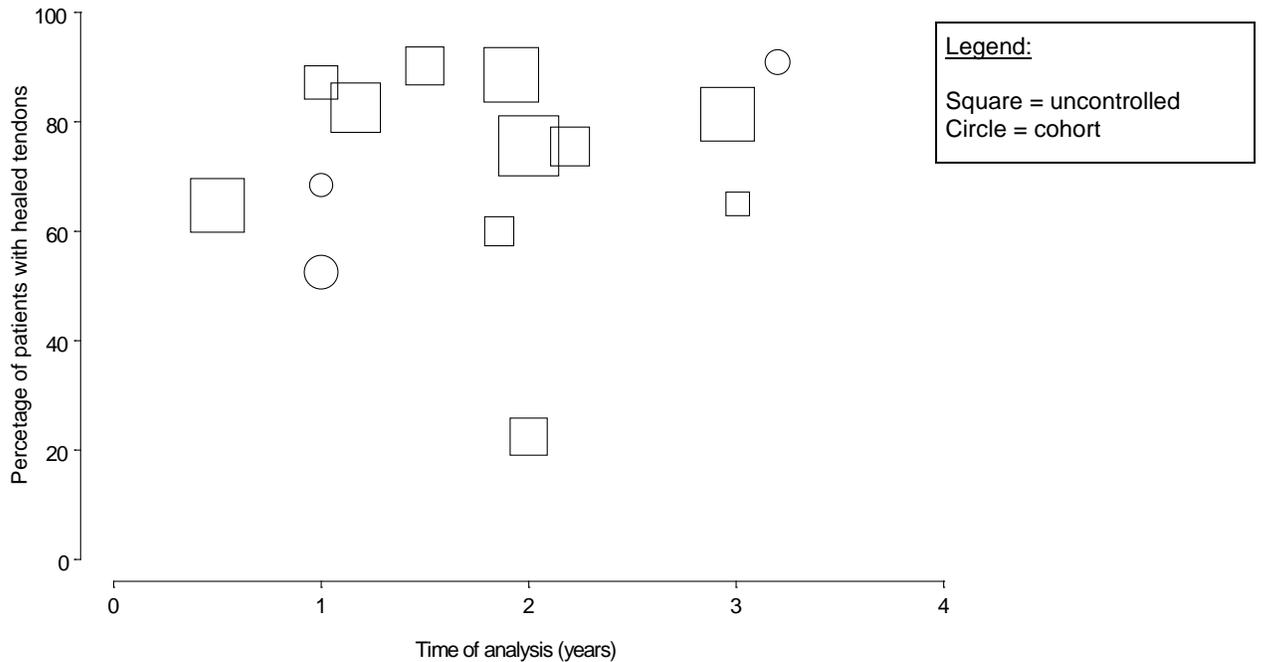


Figure 19. Studies examining cuff integrity for arthroscopic RCR

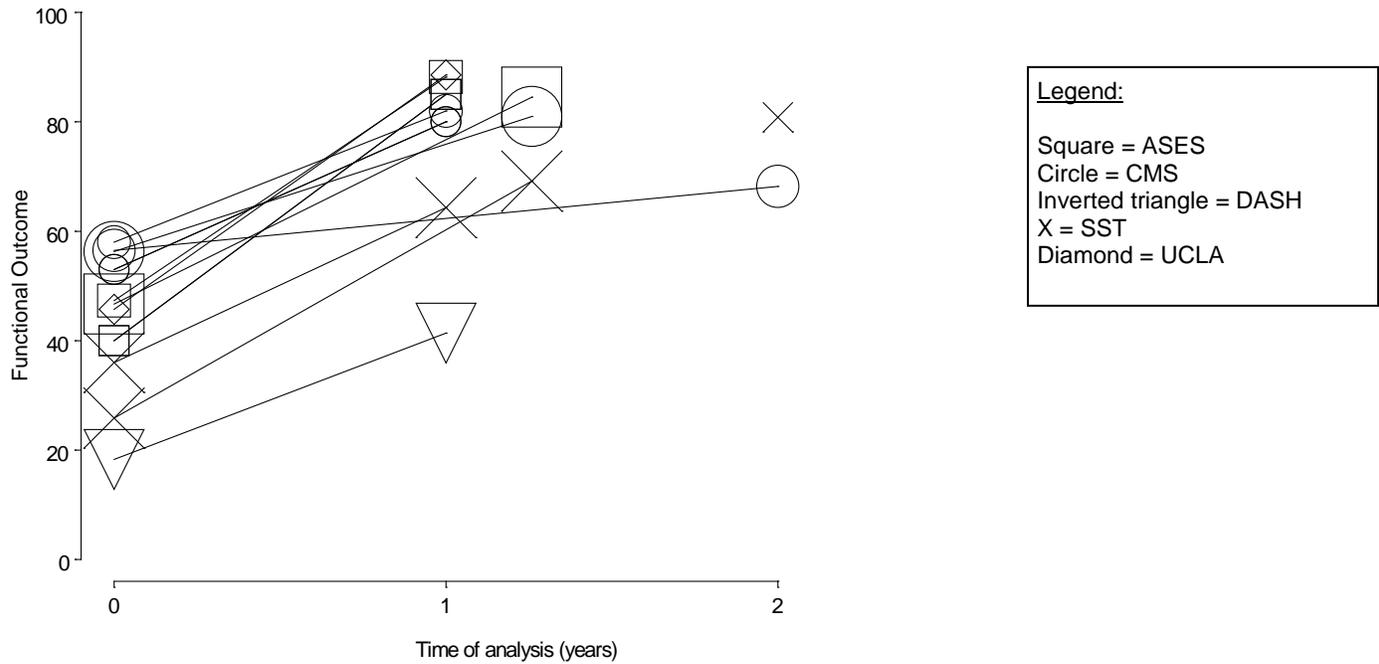


RCR combination approaches. Seven uncontrolled studies (five BA^{74,88,100,140,148} and two prospective cohorts with BA data^{90,125}) examined the effectiveness of RCR using a combination of approaches. Two studies used either an open or mini-open approach,^{100,148} two used either an open or arthroscopic approach,^{74,125} and three used one of open, mini-open or arthroscopic approaches when performing RCRs on the study participants.^{88,90,140} The studies were published between 2000 and 2008 (median=2007; IQR: 2005 to 2008).

The number of participants enrolled in the studies ranged from 38 to 125 (median=87 [IQR: 55 to 125]). The median duration of the followup period was 12 months (IQR: 12 to 14 months). Mean ages in the studies ranged from 56 to 64 years. Six studies included only patients with full-thickness tears, while the remaining study did not specify type of tear.¹⁴⁸ All of the three studies reporting tear size included patients with a range of tear sizes.^{100,125,140} One study⁹⁰ included patients with manual labour jobs, those with WCB claims and smokers.

Reported outcomes included health-related quality of life,^{90,140,148} functional measures,^{74,88,90,100,125,140} and cuff integrity.^{88,100} None of the study reported time to return to work. Figure 20 presents the preoperative and postoperative functional scores over time for the all studies that examine a combination of RCR approaches. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. The studies all indicate improvement in score from baseline to followup, with the exception of one study in which CMS remained relatively stable over the 2 year followup period.

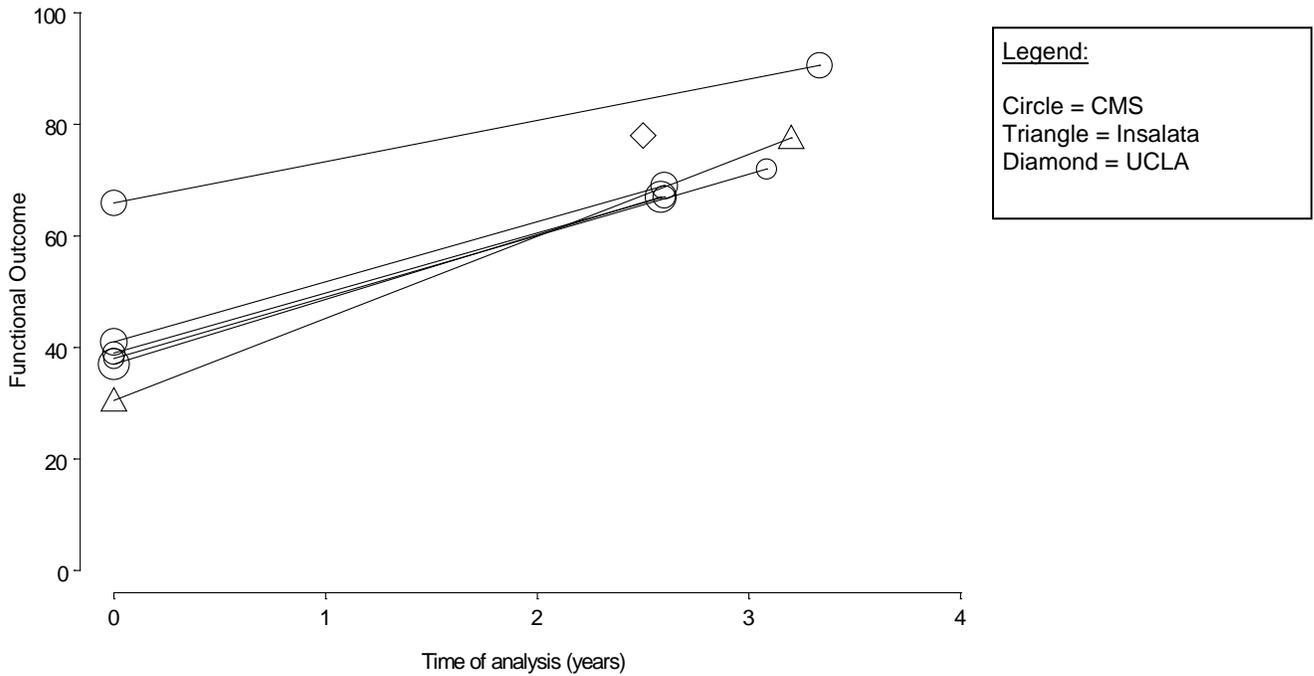
Figure 20. Studies examining functional outcomes for combined RCR approaches



Arthroscopic debridement. Three BA studies,^{55,136,146} assessed the effectiveness of the arthroscopic debridement in the RC tear population. The studies were published from 2000 to 2005 (median=2004; IQR: 2002 to 2005). The number of participants enrolled in the studies ranged from 14 to 33 (median=22 [IQR: 18 to 28]). The median followup duration was 3.1 years (IQR: 2.8 to 3.2 years). The mean age of participants was 69 years in two studies^{55,136} and not reported for one study.¹⁴⁶ Two studies included only full-thickness tears (^{55,136}) and one study¹⁴⁶ examined patients with partial- or full-thickness tears. For the two studies that reported tear size, one⁵⁵ included only large RC tears and one¹³⁶ included only massive RC tears.

All studies assessed function,^{55,136,146} while one study also assessed time to return to work.¹⁴⁶ Health-related quality of life and cuff integrity were not examined in any of the studies. The preoperative and postoperative scores for all studies examining arthroscopic debridement are plotted in Figure 21. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Similar to the other operative approaches, the scores consistently show marked improvement over time, regardless of the study design and outcome measure used.

Figure 21. Studies examining functional outcomes for arthroscopic debridement



Other approaches. Five BA studies^{69,79,85,109,110} assessed various other operative approaches in RC tear population. The studies were published from 1997 to 2007 (median=2005; IQR: 2002 to 2005). The number of participants enrolled in the studies ranged from 15 to 33 (median=21 [IQR: 19 to 23]). The median followup duration was 2.3 years (IQR: 24 months to 2.7 years). For the four studies^{69,79,85,110} that reported age of participants, the mean age ranged from 51 to 63 years. Of the four studies that reported type of tear, three studies^{69,85,109} included only full-thickness RC tears and one study⁷⁹ included partial- or full-thickness tears. Two studies^{79,85} included only massive RC tears, while tear characteristics were not reported in the other studies.^{69,109,110} Recreational athletes were included in one study.⁶⁹ One study reported the proportion of patients manual labor jobs⁷⁹ and two studies included patients with a workers' compensation board (WCB) claim.^{79,85}

Four studies (^{79,85,109,110}) used a functional outcome measure. Since the interventions varied widely, the preoperative and postoperative outcomes were not plotted on a graph.

Operative Technique—Comparative Studies

Summary. The variety of operative techniques compared across the included studies precludes conclusions and recommendations regarding most techniques. For all patient groups, regardless of technique, there were significant improvements in the postoperative functional and pain outcome measures compared to preoperative scores. However, few of the techniques demonstrated clinically important differences between their respective groups on any of the postoperative measures. Overall the methodological quality of the studies was modest. There were three RCTs^{61,68,82} and eight cohort studies.^{54,73,101,112,115,128,139,151}

The most frequently studied techniques were single-row versus double-row suture anchor fixation, which were compared in four studies.^{68,82,128,139} There was moderate evidence in favour of double-row repair for function based on a meta-analysis of all four studies. While the meta-analysis showed statistically significant results, the absolute differences in the change scores were as small as 5 points on the 100-point CMS⁶⁸ and 1.8 points on the 35-point UCLA scale⁸² which puts into question the clinical importance of this finding. One study showed “clinically” and statistically significant difference in function favouring the double-row technique among the subgroup of patients with large or massive tears. There was also moderate evidence for cuff integrity: three of the studies examined this outcome, two of which found a significant difference favouring double-row fixation.^{68,139} There was a low level of evidence for return to work: only one study examined return to work and found no significant difference between the two techniques.

A variety of other techniques were studied across the remaining seven studies; however, there was only one study for each specific comparison. Overall the level of evidence was low for the remaining techniques. The outcome most often assessed was function. Only one study found a significant difference between the groups examined: metal suture anchors versus headed bioabsorbable corkscrews showed a 15 point difference on the 100-point CMS. Cuff integrity was assessed in four studies: a statistically significant difference was found for modified mattress locking stitch versus simple stitch; no significant difference was observed for nonabsorbable versus absorbable sutures; and, no comparison was possible for transosseus versus mattress suture and staple fixation versus side-to-side suture and anchor repair due to incomplete data reporting.

In summary, there is some evidence that double-row fixation may perform better than single-row in terms of cuff integrity but results suggest little difference for function. There are insufficient or low levels of evidence for the remaining operative techniques.

Results by individual study. Eleven studies^{54,61,68,73,82,101,112,115,128,139,151} examined the effectiveness of different operative techniques for the repair of RC tears. Sample sizes ranged from 27 to 100 patients. The following operative techniques were assessed: single-row versus double-row suture anchor repairs,^{68,82,128,139} bioabsorbable tacs versus suture tying,⁵⁴ nonabsorbable suture with Mason-Allen technique versus absorbable sutures with Kessler technique,⁶¹ headed bio-corkscrews versus metal anchor suture,⁷³ mattress locking versus simple stitch,¹⁰¹ mattress versus transosseous suture,¹¹² ultrasonic suture welding versus hand-tied knots,¹¹⁵ and staple fixation versus side-to-side suture and anchor repair.¹⁵¹ With the exception of studies comparing single-row versus double-row suture anchor repairs, the studies could not be pooled because the operative techniques were different. Patient and study characteristics, as well

as study outcome data, are presented in Table 18 and Table 19, respectively. A grading of the body of evidence for operative technique studies is available in Table 20.

Single-row versus double-row suture anchor repairs. Four studies (two RCTs^{68,82} and two cohort studies^{128,139}) compared single-row versus double-row suture anchor repairs. Pooled results are shown in Figure 22 and Figure 23.

Charousset et al.⁶⁸ conducted a RCT comparing single-row versus double-row suture anchor repairs in patients who underwent arthroscopic RCR. Sixty-six patients were randomly assigned to the interventions (31 to double-row RCR, 35 to single-row RCR). All patients were followed for at least 2 years; mean followup was 2.3 years (range: 2 to 3.3). Patient function was evaluated using the CMS. At the date of last followup, the CMS had improved for both groups, but there was no statistically significant difference between the groups in the postoperative scores. Overall, more than 85 percent of patients who were employed prior to surgery returned to work. For the single-row group, the mean time to return to work was 5.3 months (range: 1 to 20); for the double-row group, it was 4.2 months (range: 1 to 12). The difference was not statistically significant ($p=0.28$). Cuff integrity was assessed using CT arthrography at 6 months following surgery. Anatomic healing was obtained in 14 (40.0 percent) cases in the single-row group compared with 19 (61.3 percent) in the double-row group. The difference was statistically significant ($p=0.03$), in favor of the double-row group.

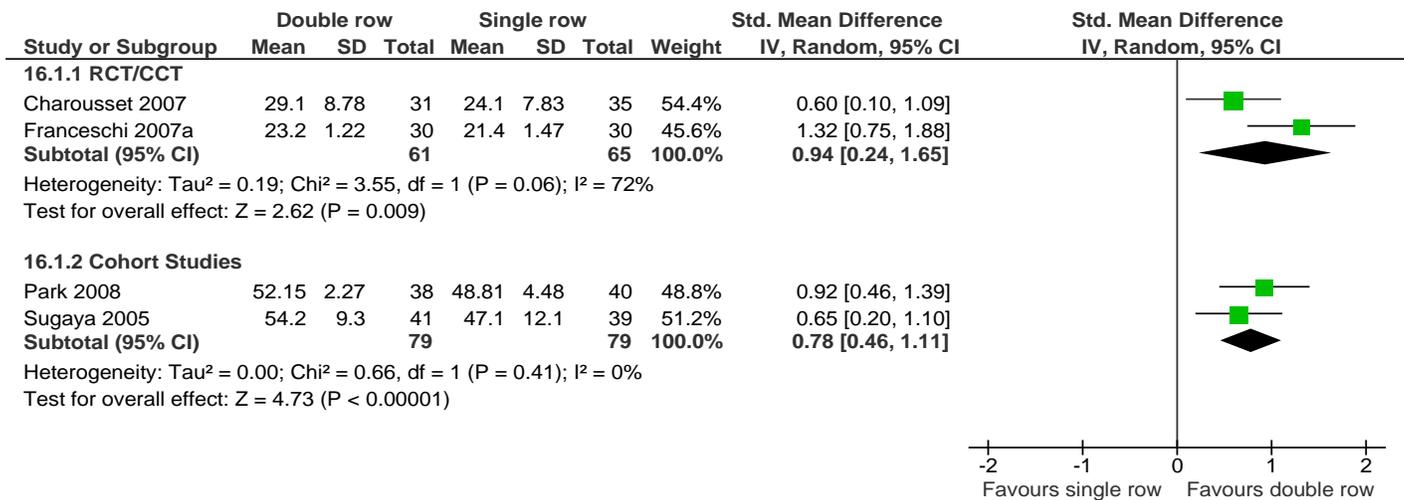
Franceschi et al.⁸² conducted a RCT comparing single-row versus double-row fixation in patients with large and massive full-thickness RC tears. All patients underwent arthroscopic RCR. Sixty patients were randomly assigned to the interventions (30 to each group); 52 (86.7 percent) were included in the final analyses. The mean length of followup was 22.5 months (range: 18 months to 2.1 years). Patients were evaluated using the UCLA shoulder scale and range of motion (flexion, external and internal rotation). For both groups, there was significant improvement in total UCLA scores and range of motion from preoperative assessment to the final postoperative evaluation. However, the differences between the groups in the postoperative scores for all measures were not statistically significant. Cuff integrity was assessed using MRI arthrography at 2 years following surgery. Intact tendons were shown in 14 (53.8 percent) patients in the single-row group compared with 18 (69.2 percent) in the double-row group. The difference between groups was not statistically significant.

Park et al.¹²⁸ conducted a prospective cohort study comparing single-row versus double-row fixation in patients undergoing arthroscopic RCR. Eighty-five patients were enrolled in the study (42 received double-row RCR, 43 received single-row RCR); 78 (91.7 percent) were included in the final analyses. All patients had full-thickness tears; tear size ranged from small or medium ($n=46$) to large or massive ($n=32$). The mean length of followup was 2.1 years (range: 22 months to 2.5 years). Patients were evaluated using the ASES index, the CMS and the Shoulder Strength Index (SSI; abductor, internal rotator and external rotator). For all patients, the mean postoperative ASES index and CMS improved significantly from the preoperative levels. The differences between the two groups on their postoperative scores for either measure were not statistically significant. Similarly, both groups had significant improvement in SSI after surgery, but the difference between the two groups was not statistically significant. The authors conducted a subgroup analysis of patients with tears less than 3 cm and those whose tears were greater than 3 cm. For patients with large or massive tears (>3 cm), the double-row fixture group showed clinically and statistically significant improvements in the ASES index, CMS, and SSI (abductor) than the single-row repair groups.

Sugaya et al.¹³⁹ conducted a retrospective cohort study comparing single-row versus double-row fixation in patients undergoing arthroscopic RCR. All patients had full-thickness tears; tear size ranged from small to massive. The mean length of followup was 2.9 years (range: 2 to 5). Patients were evaluated using the ASES index and the UCLA shoulder scale. Overall, 104 patients (106 shoulders) were enrolled in the study (55 received double-row RCR, 51 received single-row RCR). Of these, 80 (76.9 percent) were included in the final analyses. For all patients, the mean postoperative ASES and UCLA scores improved significantly from the preoperative levels. However, the differences between the two groups on their postoperative scores were not statistically significant. Postoperative MRI examination revealed 18 (46.2 percent) and 30 (73.2 percent) intact cuffs in the single-row versus double-row anchorage groups, respectively. The difference between the groups was statistically significant ($p < 0.01$).

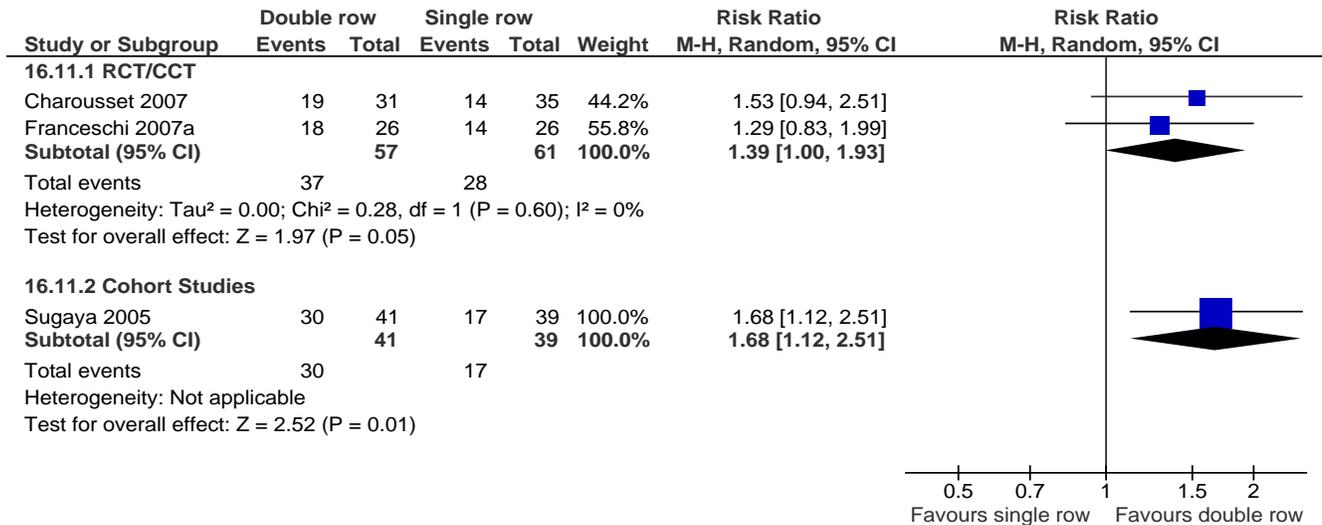
The two RCTs^{68,82} and two cohort studies^{128,139} provided data for meta-analysis of the effects of single-row versus double-row suture anchor fixation on functional outcome measures. Data from the trials and cohort studies was analyzed separately. The following measures were included in the meta-analysis: CMS,⁶⁸ the UCLA score,⁸² and the ASES index.^{128,139} For all of the studies, the average change between preoperative and postoperative scores were compared between groups. The pooled estimate of change in function indicates a significant improvement in favor of double-row fixation (SMD=0.94; 95% CI, 0.24 to 1.65 for trials; SMD=0.78; 95% CI, 0.46 to 1.11 for cohort studies). There was heterogeneity between the two trials ($p = 0.06$; $I^2 = 72$ percent); however, no evidence of heterogeneity between the two cohort studies ($p = 0.41$; $I^2 = 0$ percent).

Figure 22. Single-row versus double-row fixation on measures of functional outcome



Two RCTs and one retrospective cohort study provided data for a meta-analysis of the effects of single-row versus double-row fixation on cuff integrity (Figure 23). Data from the trials and cohort study is presented separately. The pooled risk ratio from the trials significantly favors double-row fixation over single-row fixation (SMD=1.39; 95% CI, 1.00 to 1.93). There was no evidence of heterogeneity between the two RCTs ($p = 0.60$; $I^2 = 0$ percent). The one cohort study followed a similar trend to the RCTs, showed a statistically significant difference in the proportion of patients whose cuff was found to be intact, in favor of the double-row group.

Figure 23. Single-row versus double-row fixation on cuff integrity



Bioabsorbable tacs versus suture tying. Bennett et al.⁵⁴ conducted a prospective cohort study comparing repair of the subscapularis tendon using 8 mm bioabsorbable tacs (Suretac; Accuflex, Mansfield MA) with suture tying techniques using No. 2 Tevdeks and 5 mm metal screws (Metal Corkscrew; Arthrex, Naples FL). All patients had full-thickness tears and underwent arthroscopic repair and debridement. Thirty-one patients were enrolled in the study; 19 were included in the analysis (nine in the bioabsorbable tacs group, 10 in the suture tying group). Patients were allocated to the interventions based on tear patterns. Patients were followed for a minimum of 2 years (range: 2 to 4). Patient function was assessed using the ASES index, the CMS and a single question of percent function compared with the contralateral shoulder. A visual analogue scale was used to evaluate pain. For both groups showed significant improvement at endpoint compared to their baseline score ($p < 0.05$). The ASES score at final followup was significantly different between groups, favoring the bioabsorbable tacs group. All other outcomes showed no significant differences between groups.

Nonabsorbable versus absorbable sutures. Boehm et al.⁶¹ conducted a RCT comparing transosseous repair using a modified Mason-Allen technique with nonabsorbable sutures (No. 3 Ethibond) versus a modified Kessler technique with absorbable sutures (1.0 mm polydioxanone cord). All patients had full-thickness tears and underwent open RCR with acromioplasty. One hundred patients were randomly assigned to the interventions (50 to each group). All patients were followed for at least 2 years; mean followup was 2.3 years (range: 2 to 2.5) in the Mason-Allen group and 2.2 years (range: 2 to 2.4) in the Kessler group. Patients were assessed using the CMS and a visual analogue scale for pain. At the date of last followup, the CMS had improved for both groups, but there was no statistically significant difference between the groups in the postoperative scores. Similarly, there was no difference between the groups in terms of pain. Ultrasound was used to evaluate cuff integrity. There was no significant difference between the proportion of intact cuffs in the Mason-Allen group (77.5 percent) compared with the Kessler group (81.8 percent).

Headed bioabsorbable corkscrew versus metal suture anchor. Cummins et al.⁷³ conducted a prospective cohort study comparing Mitek RC metal suture anchors (Norwood, MA) versus Headed Bio-Corkscrews (Arthrex, Naples, FL), a knotless device made of L-poly(lactic acid). All patients were treated with open RCR and acromioplasty. Twenty-seven patients were enrolled in

the study (18 received metal suture anchors, 9 received corkscrews) and all were included in the analysis. In the group treated with suture anchors (n=18), the mean tear size was $1.9 \pm 1.0 \text{ cm}^2$ (p=0.03); in the group treated with bioabsorbable screws (n=9), the mean tear size was $1.1 \pm 0.9 \text{ cm}^2$. The CMS scoring system was used to assess shoulder function at 12 months following surgery. Based on the CMS, the suture anchors group demonstrated significantly higher function than the bioabsorbable screws group (88 ± 9 versus 73 ± 17 , p=0.016). Abduction improved for both groups, however there was a statistically significant difference at the 12 month followup favoring the metal suture anchor group (p<0.01). From 6 weeks to 12 months following surgery, the suture anchors group graded their “overall” shoulder rating higher than the corkscrew group (p<0.1); however, for both groups the overall rating was “fair”.

Modified mattress locking versus simple stitch. Ko et al.¹⁰¹ conducted a prospective cohort study comparing a modified mattress locking stitch (MMLS), a simple modification of the Mason-Allen stitch, versus a simple stitch in patients undergoing arthroscopic RCR. All patients had medium full-thickness tears. The mean length of followup was 2.6 years (range: 2 to 3.1). Patients were evaluated using the ASES index, the UCLA shoulder scale and a visual analogue scale (VAS) for pain. Overall, 78 patients were enrolled in the study (39 per group). For all patients, the mean postoperative ASES index, UCLA score and VAS improved significantly from the preoperative levels. The differences between the two groups on their postoperative scores for all measures were not statistically significant. At 6 months to 3 years following surgery, MRIs were performed on 69 patients to examine cuff integrity. Repaired cuffs remained intact in 30 of 36 (83.3 percent) cases in the MMLS group compared with 24 of 33 (72.7 percent) in the simple stitch group (p=0.03).

Mattress versus single transosseous suture. Matis et al.¹¹² conducted a prospective cohort study comparing single transosseous suture versus transosseous mattress suture in patients who underwent arthroscopic RCR and acromioplasty. Patients with full- and partial-thickness tears were included; tear size ranged from small to medium. Seventy-five patients were treated with transosseous sutures; the mean followup period was 2.2 years (range: 5 months to 4.9 years). Twenty-four patients were treated with mattress sutures; mean length of followup was 1.2 years (range: 0.4 to 2.8 years). Patients were evaluated using the CMS. At the date of last followup, the CMS had improved for both groups. Cuff integrity was assessed by ultrasonography for the transosseous suture group. Intact tendons were shown in 66 cases (88 percent).

Ultrasonic suture welding versus hand-tied knots. McIntyre et al.¹¹⁵ conducted a retrospective cohort study comparing ultrasonic suture welding using No. 2 polypropylene to fix the tendon versus hand tied knots using No. 2 braided polyester suture. All patients were treated with a mini-open RCR and acromioplasty. The mean tear size was 3.4 cm (range: 1 to 6 cm) and 3.0 cm (range: 1 to 6 cm) in the suture welding and hand tied knot groups, respectively. The type of tear was not reported. Patients were evaluated using the UCLA shoulder scale. The mean length of followup for the suture weld group was 2.3 years (range: 18 months to 3.3 years). For patients treated with hand tied knots, 40/55 (72.7 percent) were available for followup compared to 47/50 (94.0 percent) for the suture weld group. For both groups, the mean postoperative UCLA score improved significantly from the preoperative levels. However, the difference between the two groups on their postoperative scores was not statistically significant.

Staple fixation versus side-to-side suture. Wilson et al.¹⁵¹ conducted a retrospective cohort study comparing staple fixation (Instrument Makar, Okemos, MI) versus side-to-side suture and anchor repair (G-4 or Stealth, Mitek, Westwood MA) in patients undergoing arthroscopic RCR. All patients had small to large sized full-thickness tears. One hundred patients were enrolled and

included in the analysis (35 received staple fixation, 65 received side-to-side suture and anchor). The mean length of followup for the staple group was 7.9 years (3 to 14); for the suture anchors group it was 4 years (2 to 7). Patients were evaluated using the UCLA shoulder scale. For all patients, the mean postoperative UCLA score significantly improved from the preoperative levels. However, the difference between the two groups on their postoperative scores was not statistically significant. Cuff integrity was assessed in the staple fixation group. Of the 33 patients evaluated, the tendon was completely healed in 22 (66.7 percent).

Table 18. Study and patient characteristics for studies assessing operative techniques

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; size of tear Duration of symptoms (mo), mean±SD (range) |
|----------------------------------|--|---|---|
| Bennett WF, ⁵⁴ 2003 | G1: Bioabsorbable tacs (NR) G2: Suture tying (NR) Prospective cohort | G1: 58 yr / Males: 5 (55.6) G2: 64 yr / Males: 7 (70) | FTT; NR NR |
| Boehm TD, ⁶¹ 2005 | G1: Nonabsorbable sutures (Mason-Allen technique) (50) G2: Absorbable sutures (Kessler technique) (50) RCT | G1: 56 yr (38-69) / Males: 36 (72) WCB: 5 (10) G2: 57 yr (41-71) / Males: 32 (64) WCB: 4 (8) | FTT; Sm, Med, Lg NR |
| Charoussat C, ⁶⁸ 2007 | G1: Double-row anchor RCR (31) G2: Single-row anchor RCR (35) RCT | G1: 60 yr (37-62) / Males: 16 (51.6) Athletes: competitive 2 (6.5), recreational 2 (6.5) Manual Labourers: 6 (19.4) WCB: 2 (6.5) G2: 58 yr (32-74) / Males: 15 (42.9) Athletes: competitive 1 (2.9), recreational 5 (14.3) Manual Labourers: 10 (28.6) WCB: 4 (11.4) | NR; NR G1: 14.7 (1-73), G2: 11.9 (1-52) |
| Cummins CA, ⁷³ 2003 | G1: Metal suture anchors (18) G2: Headed bio-corkscrews (9) Prospective cohort | G1: 63±8 yr / Males: 12 (66.7) G2: 58±10 yr / Males: 7 (77.8) | NR; G1: 1.9 cm ² , G2: 1.1 cm ² NR |
| Franceschi F, ⁸² 2007 | G1: Double-row anchor RCR (30) G2: Single-row anchor RCR (30) RCT | G1: 59.6 yr (45-80) / Males: 16 (53.3) G2: 63.5 yr (43-76) / Males: 12 (40) | FTT; Lg, Mass ≥ 3 mo |
| Ko SH, ¹⁰¹ 2008 | G1: Modified mattress locking stitch (39) G2: Simple stitch (39) Prospective cohort | G1: NR G2: NR | FTT; Med NR |
| Matis N, ¹¹² 2006 | G1: Transosseus suture (75) G2: Mattress suture (24) Prospective cohort | G1: 58.2 yr (35-75) / Males: 51 (68) G2: 58.0 yr (35-75) / Males: 16 (66.7) | FTT / PTT; Sm, Med |

cm = centimeter; FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; NR = not reported; PTT = partial-thickness tear; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small; WCB = workers' compensation board

Table 18. Study and patient characteristics for studies assessing operative techniques (continued)

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; size of tear Duration of symptoms (mo), mean±SD (range) |
|----------------------------------|--|--|---|
| McIntyre LF, ¹¹⁵ 2006 | G1: Suture welding (50) G2: Hand-tied knots (55) Retrospective cohort | G1: 55.7 yr (37–78) / Males: 29 (58) G2: 54.7 yr (17–78) / Males: 38 (69.1) | NR; G1: 3.4 cm (1–6), G2: 3.0 cm (1–6) G1: 9.9 mo (1–36), G2: 10.4 mo (1–36) |
| Park JY, ¹²⁸ 2008 | G1: Double-row anchor RCR (42) G2: Single-row anchor RCR (43) Prospective cohort | G1 : 54.4 yr (28–76) / Males : 22 (52.4) G2 : 57 yr (39-78) / Males : 20 (46.5) | FTT; Sm, Med, Lg, Mass NR |
| Sugaya H, ¹³⁹ 2005 | G1: Double-row anchor RCR (55 shoulders) G2: Single-row anchor RCR (51 shoulders) Retrospective cohort | G1 : 58.1 yr (36–73) / Males : 28 (50.9) G2 : 57.7 yr (34–72) / Males : 28 (54.9) | FTT; Sm, Med, Lg, Mass NR |
| Wilson F, ¹⁵¹ 2002 | G1: Staple fixation (35) G2: Side-to-side suture & anchor (65) Retrospective cohort | G1 : 49 yr (20–69) / Males : 27 (77.1) G2 : 52 yr (32–70) / Males : 38 (58.5) | FTT; Sm, Med, Lg G1: 48 wk (1–312), G2: 46 wk (2–312) |

Table 19. Outcome data for studies assessing operative techniques

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 | Group 2 | Group 1 vs. Group 2 |
|-------------------------------------|---|---|--|--|---------------------|
| | | | Pre-op mean±SD (range)/ Post-op mean±SD (range) | Pre-op mean±SD (range)/ Post-op mean±SD (range) | Post-op p-value |
| Bennett WF, ⁵⁴ 2004 | G1: Bioabsorbable tacs (9) G2: Suture tying (10) NR (2–4 yr) | ASES | 33±15 / 88±12, p=0.001 | 31±23 / 72±11, p=0.002 | p=0.003‡ |
| | | CMS* | 50±10 / 77±12, p=0.001 | 55±16 / 77±8, p=0.001 | p=1.0‡ |
| | | percent function | 36±16 / 86±17, p=0.001 | 47±16 / 83±12, p=0.002 | p=0.66‡ |
| | | VAS pain | 7±2 / 1±1, p=0.001 | 7±3 / 2±2, p=0.002 | p=0.16‡ |
| Boehm TD, ⁶¹ 2005 | G1: Nonabsorbable sutures (Mason-Allen technique) (49) G2: Absorbable sutures (Kessler technique) (44) 2.2 yr (2–2.5) | CMS | NR / 78 | NR / 76 | p=0.33 |
| | | Pain (VAS – 15 point) | NR / 13.1 | NR / 12.9 | p=0.65 |
| | | Cuff integrity N (%) US | 38/49 (77.5%) | 36/44 (81.8) | p=0.37 |
| Charousset C, ⁶⁸ 2007 | G1: Double-row anchor RCR (28) G2: Single-row anchor RCR (33) 2.3 yr (2–3.3) | CMS* | 53.6 (17–75) / 82.7 (58–94), p<0.001 | 56.6 (33–77) / 80.7 (62–95), p<0.001 | p=0.4 |
| | | Return to work, mean (range) mo; Number of patients | 4.2 (1–12); 12 | 5.3 (1–20); 14 | p=0.28 |
| | | Cuff integrity N (%) CTA (after 6 mo) | 19/31 (61.3) | 14/35 (40.0) | p=0.03 |
| Cummins CA, ⁷³ 2003 | G1: Metal suture anchors (18) G2: Headed bio-corkscrews (9) 12 mo | CMS | NR / 88±9 | NR / 73±17 | p=0.016 |
| | | ROM (degrees: 6 wk, 3 mo, 6 mo, 12 mo) | ABD: 113.6±8.1 / 112.8±7.3, 120.8±8.0, 144.8±4.6, 164.4‡ | ABD: 116.7±18.7 / 80.5±11.0, 99.9±11.7, 126.31±7.1, 141.1±9.9‡ | p <0.01 |
| | | Overall shoulder rating (6 wk, 3 mo, 6 mo, 12 mo) | 1.4±0.6 / 3.1±0.2 , 3.3±0.2 , 3.4±0.2 , 3.6±0.1 | 1.1±1.3 / 2.3±0.3 , 2.5±0.2 , 2.5±0.4 , 3.1±0.3 | P<0.1 (significant) |

ABD = abduction; ADL = activities of daily living; ASES = American Shoulder and Elbow Surgeons score; CMS = Constant-Murley score; CTA = computed tomography arthrogram; ER = external rotation; F = flexion; G = group; IR = internal rotation; MRI = magnetic resonance imaging; NR = not reported; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SSI = shoulder strength index; UCLA = University of California Los Angeles; US = ultrasonography; VAS = visual analogue scale

*Subscales reported

‡Data extrapolated from graph

‡Calculated by UAEPC

Table 19. Outcome data for studies assessing operative techniques (continued)

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 | Group 2 | Group 1 vs. Group 2 |
|-------------------------------------|--|---|--|--|---------------------|
| | | | Pre-op mean±SD (range)/ Post-op mean±SD (range) | Pre-op mean±SD (range)/ Post-op mean±SD (range) | Post-op p-value |
| Franceschi F, ⁸² 2007 | G1: Double-row anchor RCR (26) G2: Single-row anchor RCR (26) | UCLA | 10.1 (5–14) / 33.3 (30–35), p<0.05 | 11.5 (6–14) / 32.9 (29–35), p<0.05 | p>0.05 |
| | | ROM (degrees) | F: 100 (30–150) / 156 (140– 170), p <0.05 | F: 110 (30–140) / 159 (150– 170), p<0.05 | p>0.05 |
| | 22.5 mo (18 mo–2.1 yr) | ER: 79.6 (62–93) / 131.3 (85– 137), p <0.05 | ER: 83.2 (65–95) / 132.4 (90– 140), p<0.05 | | |
| | | IR: 28.6 (22–35) / 40.3 (26– 43), p <0.05 | IR: 27.3 (20–33) / 37.3 (27–42), p<0.05 | | |
| | Cuff integrity N (%) MRI (2 years) | 18/26 (69.2) | 14/26 (53.8) | p>0.05 | |
| Ko SH, ¹⁰¹ 2008 | G1: Modified mattress locking stitch (NR) G2: Simple stitch (NR) | ASES (ADL score only) | 11 / 27, p<0.05 | 10.6 / 27.1, p<0.05 | p=0.99 |
| | | UCLA | 13.4 / 32.7, p<0.05 | 13.7 / 31.9, p<0.05 | p>0.99 |
| | 2.6 yr (2–3.1) | Pain (VAS) | 6.5 / 0.9, p<0.05 | 7 / 1.1, p<0.05 | p=0.08 |
| | | Cuff integrity N (%) MRI (at 6-37mo after surgery) | 30/36 (83) | 24/33 (73) | p=0.03 |
| Matis N, ¹¹² 2006 | G1: Transosseus suture (75) G2: Mattress suture (21) | CMS* | 55.8 (29–78) / 80.4 (59–105), p=NR | 59 (32–75) / 83 (65–100), p=NR | NR |
| | | Cuff integrity N (%) US | 66/75 (88%) | NR | NR |
| | 23.8 mo (5 mo–4.9 yr) | | | | |
| McIntyre LF, ¹¹⁵ 2006 | G1: Suture welding (47) G2: Hand-tied knots (40) | UCLA | 12.5 / 29.6, p<0.05 | 13.2 / 31.5, p<0.05 | p=0.297 |
| | | 2.3 yr (18 mo–3.3 yr) | | | |

Table 19. Outcome data for studies assessing operative techniques (continued)

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 | Group 2 | Group 1 vs. Group 2 |
|----------------------------------|--|--|--|--|----------------------------|
| | | | Pre-op mean±SD (range)/ Post-op mean±SD (range) | Pre-op mean±SD (range)/ Post-op mean±SD (range) | Post-op p-value |
| Park JY, ¹²⁸ 2008 | G1: Double-row anchor RCR (38) | ASES | 40.82±16.8 / 92.97±2.27, p<0.01 | 42.79 ±19.23 / 91.6±4.48, p<0.01 | p=0.09 |
| | | G2: Single-row anchor RCR (40) | 44.16±6.96 / 79.66±4.52, p<0.01 | 41.63±9.84 / 76.68±8.56, p<0.01 | p=0.06 |
| | 2.1 yr (22 mo–2.5 yr) | SSI | ABD: 0.53±0.22 / 0.79±0.11, p<0.01 | ABD: 0.52±0.25 / 0.74±0.14, p<0.01 | p=0.81 p=0.57 p=0.78 |
| | | | ER: 0.66±0.18 / 0.77±0.15, p<0.01 | ER: 0.64±0.23 / 0.79±0.14, p<0.01 | |
| | | | IR: 0.71±0.16 / 0.81±0.11, p<0.01 | IR: 0.69±0.20 / 0.78±0.15, p=0.39 | |
| Sugaya H, ¹³⁹ 2005 | G1: Double-row anchor RCR (41) | ASES* | 40.4±12.3 (10-65) / 94.6±9.3 (60-100), p <0.01 | 45.8±19.4 (5-70) / 92.9±12.1 (45-100), p <0.01 | p=0.49 |
| | G2: Single-row anchor RCR (39) | UCLA* | 14.4±4.5 (5-21) / 33.1±3.4 (19- 35), p<0.01 | 14.8±5.8 (3-22) / 32.4±4.7 (16- 35), p <0.01 | p=0.44 |
| | 2.9 yr (2–5) | Cuff integrity N (%) MRI (average of 14.4 mo [G1], 13.6 mo [G2]) | 30/41 (73.2) | 18/39 (46.2) | p<0.01 |
| Wilson F, ¹⁵¹ 2002 | G1: Staple fixation (35) G2: Side-to-side suture & anchor (65) | UCLA* | 18.6 / 31.5 (14-35), p=NR | 21.1 / 32.5 (16-35), p=NR | p>0.05 |
| | | Cuff integrity N (%) Arthroscopy | 22/33 (67%) | NR | NR |
| | 5 yr (2–14) | | | | |

Table 20. Strength of evidence for operative techniques

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|--------------------------------------|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Single vs. double row suture anchors | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 4; 315 (276) | Function | RCTs, cohorts Medium | Consistent | Direct | Precise | Absent | Moderate |
| | 3; 230 (198) | Cuff integrity | RCTs, cohort Medium | Consistent | Direct | Precise | Absent | Moderate |
| | 1; 66 | Time to return to work | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| Bioabsorbable tacs vs. suture tying | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 31 (19) | Function | Cohort Low | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Nonabsorbable vs. absorbable sutures | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 100 | Function | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 1; 100 | Cuff integrity | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Bio-corkscrews vs. metal suture | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 27 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Mattress locking vs. simple stitch | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 78 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 1; 78 | Cuff integrity | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Mattress vs. transosseous suture | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 99 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

CCT = controlled clinical trial; HRQL = health-related quality of life; n/a = not applicable; RCR = rotator cuff repair; RCT = randomized controlled trial

* Number analyzed if different from number studied

Table 20. Strength of evidence for operative techniques (continued)

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|---|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Ultrasonic welding vs. hand-tied knots | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 105 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Staple fixation vs. side-to-side suture | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 100 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 1; 100 (35) | Cuff integrity | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

Operative Augmentation—Comparative Studies

Summary. Only two small comparative studies (32 and 28 participants) were identified that assessed biologic augmentation of a RCR. One RCT compared porcine small intestine submucosa versus no augmentation and found no statistically significant differences in function or cuff integrity. The trial was at high risk of bias due to lack of blinding and baseline imbalances between groups. One retrospective cohort study compared patch graft versus no augmentation and found no statistically significant difference in function or pain. The study evaluated range of motion for three movements and found a statistically significant difference favoring the patch for abduction (absolute difference between groups of 40 degrees), but no differences for flexion and external rotation. The study suffered from several methodological limitations including retrospective design, no control for confounding, and 25 percent loss to followup. Overall, the level of evidence is low for operative augmentations, which precludes any definitive conclusions in this area.

Results by individual study. Two studies (one RCT⁹³ and one retrospective cohort study⁹⁷) compared the use of an operative biologic augmentation of RCR versus no augmentation. The studies could not be pooled because the operative augmentation devices were different. Patient and study characteristics, as well as study outcome data, are presented in Table 21 and Table 22, respectively. Grading of the body of evidence is presented in Table 23.

Porcine small intestine submucosa versus no augmentation. Iannotti et al.⁹³ conducted a RCT comparing porcine small intestine submucosa augmentation versus no augmentation in patients who underwent open RCR. All patients had large or massive full-thickness tears of the supraspinatus and infraspinatus tendons (two-tendon tears). Thirty-two patients were randomly assigned to the interventions (16 to each group); 30 were included in the final analyses. The mean length of followup was 14 months (12 mo to 2.2 yr). Patients were evaluated using the University of Pennsylvania Shoulder Score (PENN), which showed no significant difference between the groups at followup ($p=0.07$). Cuff integrity was assessed using MRI at 12 months following surgery. Anatomic healing was obtained in 4 (26.7 percent) cases in the porcine small intestine submucosa augmentation group compared with 9 (60 percent) in the group without augmentation. The difference was not statistically significant ($p=0.11$).

Patch graft versus no augmentation. Ito et al.⁹⁷ conducted a retrospective cohort study comparing use of patch grafts, consisting of a double layer of freeze-dried fascia lata (Biodynamics, Germany), versus no augmentation in patients with large or massive full-thickness RC tears. All patients underwent open RCR with acromioplasty. A total of 28 patients were enrolled in the study; 21 were included in the final analyses (9 in the patch graft group, 12 in the no augmentation group). The mean length of followup was 3 years (2 to 8.4). Patients were evaluated using the JOA score and range of motion (flexion, abduction, external rotation). For both groups, there was a significant difference in the JOA score, flexion and abduction from baseline to followup. No significant between-group differences were reported on any outcome measure.

Table 21: Study and patient characteristics for studies assessing operative augmentations

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; size of tear Duration of symptoms (mo), mean±SD (range) |
|---------------------------------|--|---|---|
| Iannotti JP, ⁹³ 2006 | G1: Porcine small intestine submucosa augmentation (16) G2: No augmentation (16) RCT | G1: 58 yr / Males: 11 (73) WCB : 3 (20) G2: 57 yr / Males: 6 (40) WCB: 0 (0) | FTT; Lg, Mass ≥ 3 mo |
| Ito J, ⁹⁷ 2003 | G1: Patch graft (NR) G2: No augmentation (NR) Retrospective cohort | G1: 62.8±6.9 (49–70) / Males: 6 (67) G2: 52.3±8.6 (36–66) / Males: 10 (83) | FTT; Lg, Mass G1: 4.1±2.9 mo, G2: 5.8±4.7 mo |

FTT = full-thickness tear; G = group; Lg = large; mass = massive; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; WCB = workers' compensation board

Table 22: Outcome data for studies assessing operative augmentations

| Author, year | Intervention (N analysed) Followup, mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|---------------------------------|---|-------------------------------|--|--|---|
| Iannotti JP, ⁹³ 2006 | G1: Porcine small intestine submucosa augmentation (15) G2: No augmentation (15) 14 mo (12 mo–2.2 yr) | PENN* | 42 / 83 (IQR: 70–92) | 34 / 91 (IQR: 81–99) | p=0.07 |
| | | Cuff integrity (MRI at 12 mo) | 4 / 15 (26.7) | 9 / 15 (60.0) | p=0.11 |
| Ito J, ⁹⁷ 2003 | G1: Patch graft (9) G2: No augmentation (12) 3 yr (2–8.4) | JOA* | 47.9±13.3 / 91.7±7.0, p=0.0077 | 54.2±9.7 / 92±7.6, p=0.0022 | p=0.93† |
| | | ROM (degrees) | F: 84.4±32.4 / 159.6±14.8, p=0.0005 ABD: 62.2±31.1 / 163.3±28.7, p=0.0007 ER: 43.9±16.9 / 41.7±24.7, p>0.05 | F: 94.6±43.9 / 145.8±27.1, p=0.0032 ABD: 85.0±43.9 / 146.4±27.1, p=0.0019 ER: 36.3±44.6 / 35.4±37.8, p>0.05 | F: p=0.14† ABD: p=0.17† ER: p=0.64† |

ABD = abduction; ER = external rotation; F = flexion; G = group; JOA = Japanese Orthopaedic Association scale; mo = month; MRI = magnetic resonance imaging; NR = not reported; PENN = University of Pennsylvania Shoulder Score; pre-op = preoperative; post-op = postoperative; ROM = range of motion; SD = standard deviation

*Subscales reported; † Calculated by UAEPC

Table 23: Strength of evidence for operative augmentation

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|---|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Porcine small intestine submucosa vs. no augmentation | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 32 (30) | Function | RCTs Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 1; 32 (30) | Cuff integrity | RCTs Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Patch graft vs. no augmentation | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 28 (21) | Function | Cohort Low | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

HRQL = health-related quality of life; n/a = not applicable; RCT = randomized controlled trial

*number analyzed if different from number studied

Operative Augmentation—Uncontrolled Studies

Five BA studies^{56,83,132,135,153} evaluated the effectiveness of the operative augmentation in RC repair. Four studies^{56,83,135,153} assessed augmentation with open RCR, and one study¹³² assessed arthroscopic RCR with platelet-rich plasma augmentation. The studies were published from 2006 to 2008 (median=2007; IQR: 2006 to 2008).

The number of participants enrolled in the study ranged from 13 to 39 (median=23 [IQR: 20 to 32]). The median followup duration was 3.2 years (IQR: 24 months to 3.6 years). The mean age of participants ranged from 54 to 67 years. All these studies included only patients with full-thickness tears. Medium to massive tears were included in one study,¹³⁵ only massive RC tears in one study,¹⁵³ and only large RC tears in one study.⁵⁶ Tear size was not reported in two studies^{83,132}. One study included smokers.¹³⁵

All studies assessed function, while four assessed cuff integrity.^{56,83,135,153} Health-related quality of life and time to return to work were not reported for any of the studies. Figure 24 presents the preoperative and postoperative functional scores over time for all studies that examine operative augmentation with repair. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Although the studies evaluated different types of augmentations, measured outcomes using different scales, had various followup durations and different study designs, they all indicate improvement in functional score from baseline to final followup. Figure 25 shows the proportion of patients with an intact rotator cuff at followup. While the BA studies showed a consistent trend of moderate to high cuff integrity, the one trial⁹³ showed a poor outcome.

Figure 24. Studies examining functional outcomes for operative augmentation with repair

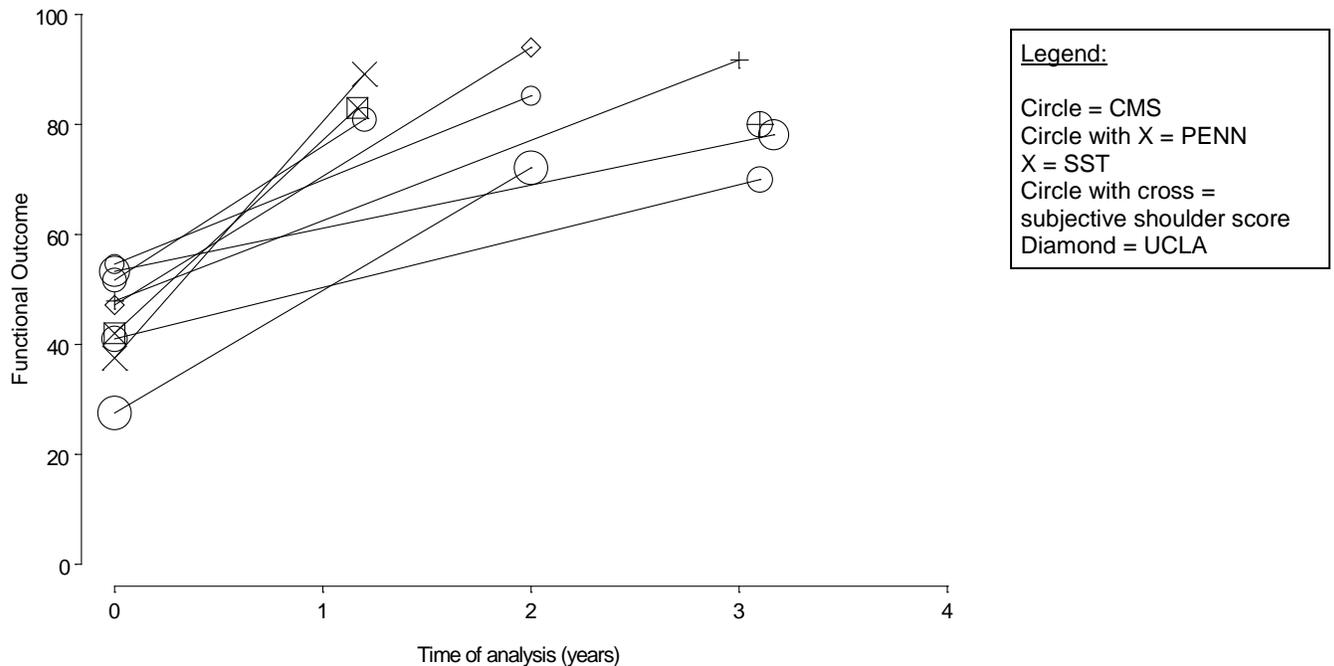
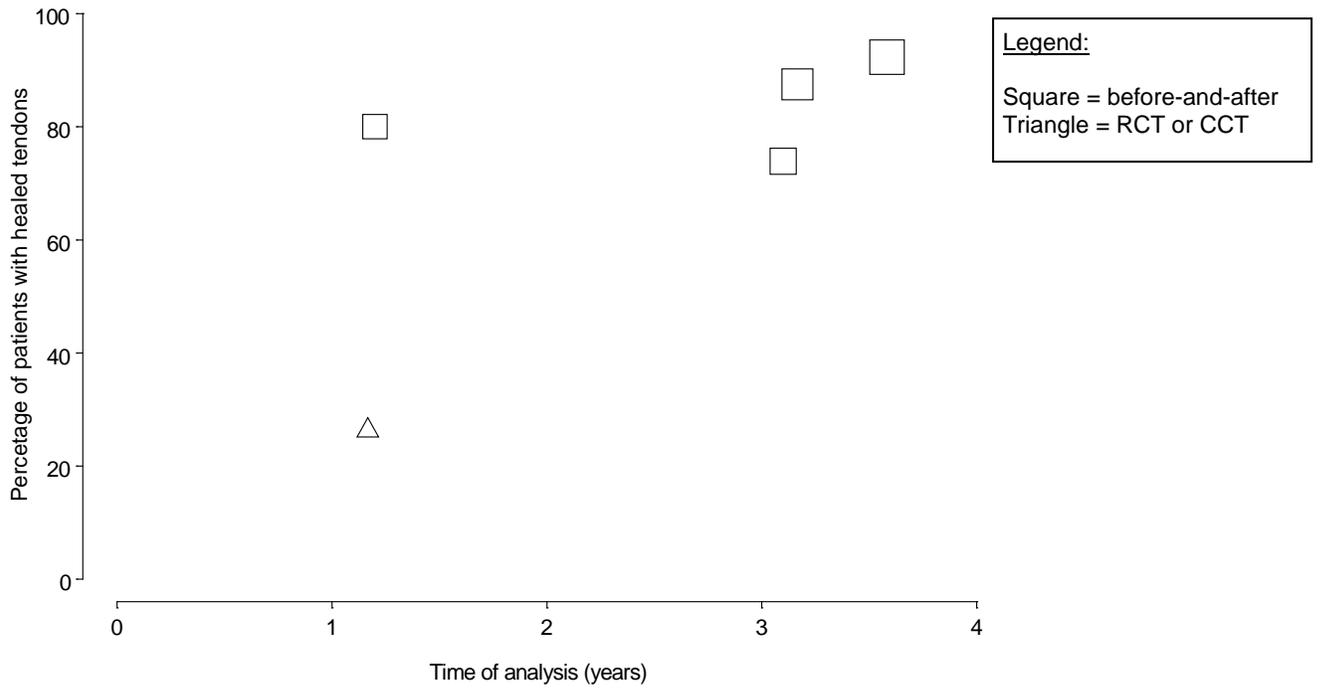


Figure 25. Studies examining cuff integrity for operative augmentation with repair



Postoperative Rehabilitation—Comparative Studies

Summary. Eight comparative studies evaluated postoperative rehabilitation. While most studies included some physical therapy component, the comparisons varied across studies.

- Three RCTs studied the addition of continuous passive motion to physical therapy. Overall, there was moderate evidence showing no difference in function or pain. One study showed a difference favouring continuous passive motion for time to 90 degrees abduction and time to return to work (absolute difference of 12 and 21 days, respectively). This suggests that continuous passive motion may affect the course of recovery over the short-term but not result in functional differences over the long-term. The trials were all at high risk of bias due to lack of blinding and inadequate allocation concealment.
- One CCT evaluated aquatic therapy in addition to a land-based program and found no differences in function or range of motion at the end of the study (12 weeks); however, there were significant differences between groups in flexion at the 3 and 6-week time-points (absolute differences 46.6 and 28.6 degrees, respectively). The study involved only 18 patients and had substantial methodological flaws.
- A prospective cohort study compared inpatients with day patients, all of whom underwent a structured rehabilitation regime. There were no significant differences in pain or range of motion over the 60-day followup.
- One RCT evaluated individualized physical therapy in addition to home exercise and found no significant differences for function, range of motion, or strength over the 24 week followup.
- A retrospective cohort studies comparing standardized versus non-standardized physical therapy found that patients receiving standardized treatment had significantly greater improvement in function.
- One RCT compared videotape-based versus physical therapy-based home exercise instruction and found no differences in function over the 54 week followup.

The evidence does not clearly identify treatments or treatment variations that alter the postoperative course of patients following RCRs; the overall level of evidence was low with few studies comparing any single therapeutic approach. There were significant differences over the course of postoperative followup for all patients but few significant differences between study groups. This may suggest a “ceiling effect:” patients may achieve their final functional outcome regardless of the type or intensity of the specific intervention. One issue that was consistently problematic across the studies was the poor reporting of physical therapy, both in terms of intervention components and delivery (frequency, intensity, dosage, etc). The studies in this area also suffer from a number of methodological flaws. Though there was a large proportion of RCTs, representing the highest level of evidence for therapeutic interventions, these were all at high risk of bias due to lack of blinding, missing outcome data, and/or inadequate concealment of allocation. Moreover, the studies tended to measure intermediate or surrogate outcomes (e.g.,

range of motion) rather than outcomes that may be most important to the patients, healthcare practitioners, and decisionmakers (e.g., health-related quality of life, time to return to work).

Results by individual study. Eight studies (five RCTs,^{157-159,161,162} one CCT¹⁵⁵ and two cohort studies^{156,160}) evaluated the effectiveness of various postoperative rehabilitation treatments. Sample sizes ranged from 31 to 129 participants. The following postoperative rehabilitation techniques were assessed: continuous passive motion with physical therapy versus physical therapy alone,^{158,159,161} aquatic and land-based therapy versus land-based therapy alone,¹⁵⁵ inpatient versus day patient rehabilitation,¹⁵⁶ home exercise with versus without the addition of an individualized physical therapy program,¹⁵⁷ standardized versus non-standardized physical therapy program¹⁶⁰ and videotape versus physical therapy home exercise instruction.¹⁶² The outcomes of three studies evaluating the addition of continuous passive motion to physical therapy could be pooled in a meta-analysis, shown in Figure 26 and Figure 27. Patient and study characteristics, as well as study outcome data, are presented in Table 24 and Table 25, respectively. The grading of the body of evidence for postoperative rehabilitations studies is found in Table 26.

Continuous passive motion with physical therapy versus physical therapy. Three studies assessed use of continuous passive motion, however the protocols and followup durations varied across the studies. Lastayo et al.¹⁵⁸ conducted a RCT comparing the addition of continuous passive motion using a mechanical device (Thera-kinetics, Mount Laurel, New Jersey) versus no continuous passive motion in patients who received manual range of motion and strengthening exercises. The former group received continuous passive motion for flexion and external rotator for four hours per day (three or four periods, each lasting 1–1.5 hours). All patients had undergone open RCR. Tear sizes ranged from small to large and were balanced between the two groups. Thirty-one patients (32 shoulders) were randomly assigned to the interventions (17 to continuous passive motion, 15 to no continuous passive motion). The mean length of followup was 22±9.8 months (6 months to 3.8 years). Patients were evaluated using the pain VAS score, passive and active range of motion, and isometric strength. There were no significant between-group differences in any of the outcome measures at any time points ($p>0.05$).

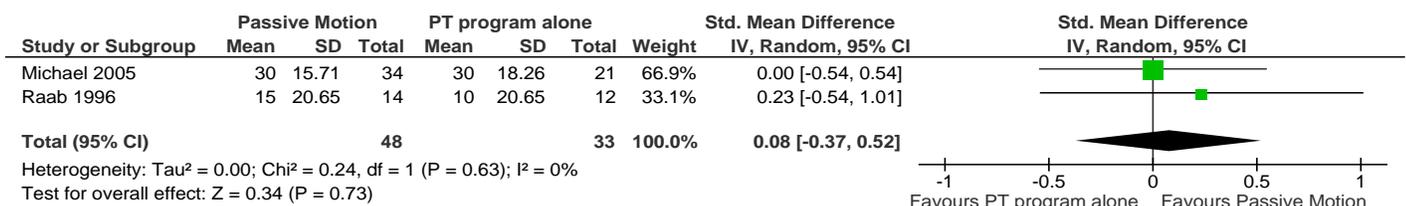
Michael et al.¹⁵⁹ conducted a RCT comparing continuous passive motion using a mechanical device (five times per day at 20 minutes per session) plus a physical therapy program versus physical therapy alone in patients who underwent open or mini-open RCR. The same physical therapy program was provided for both group and consisted of passive and active range of motion and strengthening exercise. All patients had partial- or full-thickness tears limited to the supraspinatus tendon. Sixty-one patients were randomly assigned to the interventions (40 to the continuous passive motion plus physical therapy group, 21 to the physical therapy group); 55 were included in the final analyses. The followup period was 56 days. Patients were evaluated using the CMS, the pain VAS score, time until 90 degree abduction was achieved, and time to return to work. There were no significant between-group differences for the CMS and pain scores. However, there was a significant difference between the groups in the postoperative duration needed until 90 degree abduction was achieved ($p=0.03$), in favour of the continuous passive motion group (31 versus 43 days). The time to return to work was 21 days sooner in continuous passive motion group.

Rabb et al.¹⁶¹ conducted a RCT comparing continuous passive motion (8 hours per day) using a mechanical device (Thera-kinetics, Mount Laurel, New Jersey) plus a physical therapy program versus physical therapy alone in patients who had RCR for a partial- or full-thickness tear. Tear size ranged from small to massive. The continuous passive motion plus physical therapy group

had a much greater proportion of patients with large or massive tears (57 percent) compared to the physical therapy alone group (25 percent). Forty-one patients were randomly assigned to the interventions; 26 were included in the final analyses (14 in the continuous passive motion plus physical therapy group, 12 in the physical therapy group). Patients were evaluated at 3 months following surgery using a 100-point shoulder score. For both groups, there was no significant difference in the Shoulder score from baseline to endpoint ($p>0.05$). Similarly, there was no significant difference between the groups in the endpoint shoulder score ($p>0.05$).

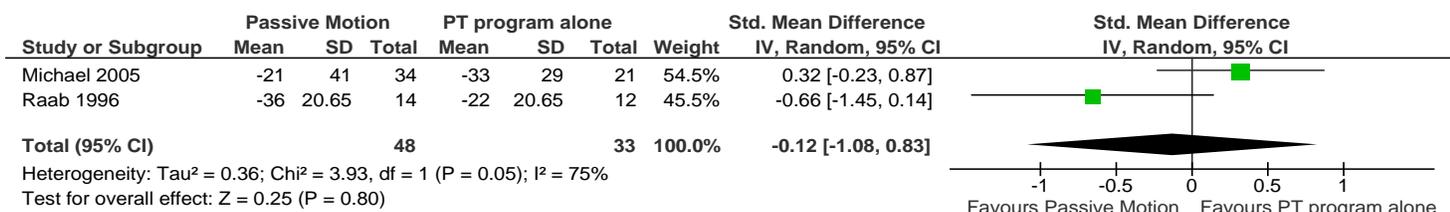
Two RCTs^{159,161} provided data for meta-analysis of the effects of continuous passive motion versus no continuous passive motion on functional outcome measures (Figure 26). The CMS of Michael et al.¹⁵⁹ and the shoulder score of Rabb¹⁶¹ were used in the analysis. The baseline to endpoint change scores were compared between groups. The pooled estimate showed no difference between the studies (SMD=0.08; 95% CI, -0.37 to 0.52). There was no evidence of heterogeneity between the studies ($p=0.63$; $I^2=0$ percent).

Figure 26. Continuous passive motion with physical therapy versus physical therapy alone for measures of functional outcome



A meta-analysis was conducted comparing continuous passive motion versus no continuous passive motion for pain using two RCTs (Figure 27). The pain VAS in Michael et al.¹⁵⁹ was compared with the pain subscore of the shoulder score index in Raab et al.¹⁶¹ using change scores. No differences was found between the interventions for pain (SMD=-0.12; 95% CI, -1.08 to 0.83) There was substantial heterogeneity between the two studies ($p=0.05$; $I^2=75$ percent). The heterogeneity may be partly attributable to a difference in the timing of outcome assessment; Michael et al.¹⁵⁹ followed patients for 2 months, compared to Rabb et al.¹⁶¹ assessed patient outcomes at 3 months postoperatively.

Figure 27. Forest plot comparing pain in continuous passive motion versus no continuous passive motion groups



Aquatic therapy with land-based therapy versus land-based therapy. Brady et al.¹⁵⁵ conducted a CCT comparing a combination aquatic and land-based program versus a land-based program alone in patients who underwent RCR. Tear size ranged from small to massive and were balanced between groups. Eighteen patients were enrolled in the study (12 received aquatic and land-based treatment, 6 received only land-based treatment). All patients were evaluated at 3, 6, and 12 weeks postoperatively. The WORC Index and range of motion (flexion and external

rotation) were used to assess patients. For both groups, there were significant differences in the WORC Index and range of motion from baseline to endpoint scores ($p < 0.0001$). There were no significant differences between the groups at endpoint in the WORC Index or external rotation at any measurement point. At 3 and 6 weeks postoperatively, there were significant differences in flexion between the groups ($p = 0.005$ and $p = 0.01$, respectively), but not at 12 weeks ($p > 0.05$).

Inpatients versus day patient rehabilitation. Delbrouck et al.¹⁵⁶ conducted a prospective cohort study comparing inpatient versus day patient rehabilitation in patients who had undergone RCR. Patients had partial- or full-thickness tears; tears sizes ranged from small to massive and were similar between groups. Seventy-nine patients (84 shoulders) were enrolled in the study; 71 (76 shoulders) were included in the final analyses (53 in the inpatient group, 23 in the day patient group). Pain and range of motion were used to evaluate patients at various points over the 60-day followup period. Only one statistically significant difference was observed: pain at day 15 was less among the inpatient group, yet no difference was found at 30 days. Inpatients were more frequently prescribed NSAIDs and calcitonin for pain management compared with outpatients (11 and 4 patients, respectively). No other differences in pain or range of motion were observed.

Individualized physical therapy program with home exercise versus home exercise. Hayes et al.¹⁵⁷ conducted a RCT comparing individualized physical therapy with home exercise program versus a home exercise program alone in patients who underwent open RCR. All patients received the same standardized home exercise regime, which was issued by the treating surgeon. Patients in the home exercise group received no other rehabilitation. For patients in the individualized physical therapy group, treatment content, rate of rehabilitation progression and total number of sessions were determined by the treating physical therapist. The treatment regime in this group may have consisted of any combination of exercises, manual therapy techniques, physical modalities of ice and moist heat, and rehabilitation and home exercise advice. Patients with full- and partial-thickness tears were included; the mean tear size was 5 cm^2 in the individualized physical therapy with home exercise program group and 6 cm^2 in the home exercise program group. Fifty-eight patients were randomly assigned to the interventions (26 to physical therapy and home exercise, 32 to the home exercise alone); 42 were included in the final analyses. Patients were reevaluated at 6, 12, and 24 weeks postoperatively. The Shoulder Service Questionnaire (SSQ), passive range of motion (flexion, abduction, and external rotation), and manual muscle test for strength were used to assess patients. There were no differences between groups in any of the outcomes or measurement time points ($p > 0.05$).

Standardized versus non-standardized physical therapy program. Milroy et al.¹⁶⁰ conducted a retrospective cohort study comparing a standardized versus non-standardized physical therapy program in patients who had had RCR. The treatment components of the physical therapy programs were not described. Sixty-seven patients were enrolled in the study (28 received standardized physical therapy, 39 received non-standardized physical therapy). Patients were evaluated using the DASH score and a numeric pain rating scale. There was significantly greater improvement on the DASH in the standardized physical therapy group ($p \leq 0.05$). However, there were no differences between the groups in pain scores ($p > 0.05$).

Videotape versus physical therapy home exercise instruction. Roddey et al.¹⁶² conducted a RCT comparing videotape-based versus physical therapy instruction home exercise programs in patients who had undergone arthroscopic repair. Patients in the first group received exercise instruction solely through a videotape given them by a physical therapist during their hospital stay. The second group received four one-on-one instruction sessions with a physical therapist throughout the course of the study. All patients had full-thickness RC tears. The mean tear size was 2.5 cm (1 to 5 cm) for the videotape-based instruction group and 2.6 cm (1.5 to 4.0) in the

physical therapy instruction group. Overall, 129 patients were randomly assigned to the interventions, of which 108 were included in the final analyses (54 in each group). Patients were evaluated at 12, 24, and 54 weeks following surgery. The SPADI and the PENN shoulder scores were used to assess patients. There were no differences between the groups at any measurement time point for both the SPADI and the PENN indices ($p>0.05$).

Table 24. Study and patient characteristics for studies assessing postoperative rehabilitations

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; size of tear Duration of symptoms (mo), mean±SD (range) |
|----------------------------------|---|--|---|
| Brady B, ¹⁵⁵ 2008 | G1: Land-based & aquatic therapy program (12) G2: Land-based program (6) CCT | G1: 56.3±9 yr (41–67) / Males: 8 G2: 53.5±16 yr (26–69) / Males: 3 | NR; Sm, Med, Lg, Mass NR |
| Delbrouck C, ¹⁵⁶ 2003 | G1: Inpatient rehabilitation (NR) G2: Day patient rehabilitation (NR) Prospective cohort | G1: 52.7±8 yr / Males: 25 G2: 55±5 yr / Males: 16 | PTT; Sm, Med, Lg, Mass NR |
| Hayes K, ¹⁵⁷ 2004 | G1: Individualized PT & standard home exercise regime (26) G2: Standardized home exercise regime (32) RCT | G1: 58±10 yr (41–81) / Males: 20 WCB: 4 G2: 62±11 yr (42–83) / Males: 20 WCB: 6 | PTT, FTT; G1: 5.0 cm ² , G2: 6.0 cm ² G1: 12±16 mo (0–48 mo), G2: 19±27 mo (1–96 mo) |
| LaStayo PC, ¹⁵⁸ 1998 | G1: CPM (17 shoulders) G2: Manual passive ROM exercises (15 shoulders) RCT | G1: 62.8 yr (30–80) / Males: 8 (47) G2: 63.7 yr (45–75) / Males: 6 (40) | NR; Sm, Med, Lg NR |
| Michael J, ¹⁵⁹ 2005 | G1: CPM & PT program (40) G2: PT program (21) RCT | G1: 58 yr (35–70) / Males: 25 Manual Labourers (light, moderate, heavy, overhead): 12, 12, 6, 4 G2: 58 yr (43–71) / Males: 12 Manual Labourers (light, moderate, heavy, overhead): 8, 6, 6, 1 | PTT, FTT; NR NR |
| Milroy DR, ¹⁶⁰ 2008 | G1: Standardized PT (28) G2: Non-standardized PT (39) Retrospective cohort | G1: 57±10.9 yr / Males: 16 G2: 57.8±9.81 yr / Males: 27 | NR; NR NR |
| Raab MG, ¹⁶¹ 1996 | G1: CPM & PT (NR) G2: PT only (NR) RCT | G1: 54 yr / Males: 9 G2: 58 yr / Males: 9 | PTT, FTT; Sm, Med, Lg, Mass NR |
| Roddey TS, ¹⁶² 2002 | G1: Videotape instruction (NR) G2: PT instruction (NR) RCT | G1: 58.7±10.6 yr (34.6–78.0) / Males: 36 G2: 57.2±9.1 yr (40.0–75.8) / Males: 33 | FTT; G1: 2.5 cm (1–5 cm), G2: 2.6 cm (1.5–4.0 cm) NR |

CCT = controlled clinical trial; CPM = continuous passive motion; FTT = full-thickness tear; G = group; Mass = massive; Med = medium; Lg = large; NR = not reported; PT = physical therapy; PTT = partial-thickness tear; RCT = randomized controlled trial; ROM = range of motion; SD = standard deviation; Sm = small; WCB = workers' compensation board

Table 25. Outcome data for studies assessing postoperative rehabilitation

| Author, year | Intervention (N analysed) Followup mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|-------------------------------------|---|---|---|--|---|
| Brady B, ¹⁵⁵ 2008 | G1: Land-based & aquatic therapy program (NR) | WORC Index (95% CI) | 1163 (925–1402) | 1003 (482–1525) | p>0.05 |
| | | 3 wk | 1468±490† | 1502±226† | |
| | G2: Land-based program (NR) | 6 wk | 1267±289† | 1335±500† | |
| | | 12 wk | 635±260†, p<0.0001 | 728±421†, p<0.0001 | |
| | | ROM (degrees) (95% CI) | F: 135 (125–145) ER: 31 (22–40) | F: 141 (120–161) ER: 30 (14–46) | |
| | | 3 wk | F: 59.8±26.6† ER: 18.7±8.0† | F: 106.4±17.2† ER: 22.1±14.7† | F/3 wks: p=0.005 ER/p>0.05 |
| 6 wk | F: 94.3±26.6† ER: 28.9±15.1† | F: 122.9±16.8† ER: 30.9±17.6† | F/6 wks: p=0.01 ER/p>0.05 | | |
| 12 wk | F: 148.7±16.8†, p<0.0001 ER: 67.5±17.4†, p<0.0001 | F: 160.1±9.8†, p<0.0001 ER: 57.7±12.3†, p<0.0001 | p>0.05 | | |
| Delbrouck C, ¹⁵⁶ 2003 | G1: Inpatient rehabilitation (53 shoulders) | Pain (VAS) | NR / 1.1, 1.3, 1.2, 0.7 | NR / 2.3, 2.0, 2.2, 1.2 | day 15: p=0.012 day 30, 45, 60: p>0.05 |
| | | ROM, baseline / day 30, day 45, day 60 | ABD: 146 / 102 / 100 / 118 F: 141 / 109 / 107 / 122 ER: 55 / 18 / 20 / 30 | ABD: 153 / 91 / 125 / 128 F: 153 / 104 / 119 / 130 ER: 61 / 22 / 23 / 31 | p>0.05 |
| | G2: Day patient rehabilitation (23 shoulders) | 60 days | | | |
| Hayes K, ¹⁵⁷ 2004 | G1: Individualized PT & standard home exercise regime (20) | SSQ (95% CI) | 65 (57–73) | 75 (67–83) | |
| | | 6 wk | 35 (28–42) | 35 (28–42) | p>0.05 |
| | G2: Standardized home exercise regime (22) | 12 wk | 24 (15–33) | 30 (20–40) | p>0.05 |
| | | 24 wk | 14 (7–21) | 32 (21–43) | p>0.05 |
| | 24 wk | | | | |

ABD = abduction; CI = confidence interval; CMS = Constant-Murley score; CPM = continuous passive motion; DASH = Disabilities of the Arm, Shoulder and Hand; ER = external rotation; G = group; IR = internal rotation; F = flexion; NR = not reported; pre-op = preoperative; post-op = postoperative; PT = physical therapy; pts = patients; ROM = range of motion; SD = standard deviation; SE = standard error; SSQ = Shoulder Service Questionnaire; SPADI = Shoulder Pain and Disability Index; UCLA = University of California Los Angeles Scale; PENN = University of Pennsylvania Shoulder Score; VAS = visual analogue scale; WORC = Western Ontario Rotator Cuff Index;

* Subscales reported

† Data extrapolated from graph

Table 25. Outcome data for studies assessing postoperative rehabilitation (continued)

| Author, year | Intervention (N analysed) Followup mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|------------------------------------|--|---|---|---|--|
| | | ROM (passive, degrees) (95% CI) | F: 148 (139–157) ABD: 133 (122–144) ER: 55 (49–61) | F: 134 (122–146) ABD: 120 (108–132) ER: 47 (40–54) | |
| | | 6 wk | F: 130 (118–142) ABD: 108 (93–123) ER: 34 (26–36) | F: 111 (99–123) ABD: 95 (85–105) ER: 31 (26–36) | p>0.05 |
| | | 12 wk | F: 141 (129–153) ABD: 125 (110–140) ER: 42 (34–50) | F: 136 (125–147) ABD: 119 (106–132) ER: 41 (34–48) (29) | p>0.05 |
| | | 24 wk | F: 150 (142–158) ABD: 142 (130–154) ER: 51 (46–56) | F: / 144 (132–156) ABD: 130 (117–143) ER: 43 (36–50) | p>0.05 |
| | | Strength manual muscle test grades (median, 95% CI) | IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4.5–5) | IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–4.5) | |
| | | 6 wk | IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–5) | IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–4.5) | p>0.05 |
| | | 12 wk | IR: 5 (5–5) ER: 5 (5–5) F: 4.5 (4–5) | IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–5) | p>0.05 |
| | | 24 wk | IR: 5 (5–5) ER: 5 (5–5) F: 5 (4.5–5) | IR: 5 (5–5) ER: 5 (5–5) F: 5 (4.5–5) | p>0.05 |
| Lastayo PC, ¹⁵⁸ 1998 | G1: CPM (NR) G2: Manual passive ROM exercises (NR) 22±9.8 mo (6 mo–3.8 yr) | Pain VAS(1, 2, 4 wk) | NR / 4.9, 3.8, 1.7† | NR / 8.0, 5.9, 1.6† | p>0.05 |
| | | Passive ROM (degrees: 12 wk, 6 mo, 12 mo, 2 yr) | ER: NR / 48.4, 63.3, 80.5, 102.5† F: NR / 128.2, 141.8, 155.7, 170.7† | ER: NR / 56.3, 76.2, 99.4, 129.8† F: NR / 128.2, 146.3, 164.7, 185.1† | p>0.05 |
| | | Active ROM (degrees: 12 wk, 6 mo, 12 mo, 2 yr) | ER: NR / 58.1, 62.4, 66.7, 71.6† F: NR / 114.1, 128.1, 142.5, 158.4† | ER: NR / 55.0, 61.6, 66.7, 71.6† F: NR / 102.0, 113.3, 124.6, 137.2† | |
| | | Strength kg (SE) (6 mo, 12 mo) | ER: NR / 9.9 (9.3–10.5), 11.1 (10.4–11.9) † F: NR / 9.4 (8.9–9.9), 10.3 (9.4–11.3) † | ER: NR / 9.0 (8.4–9.9), 9.6 (8.8–10.4) † F: NR / 8.0 (7.4–8.5), 9.6 (8.5–10.5) † | p>0.05 |

Table 25. Outcome data for studies assessing postoperative rehabilitation (continued)

| Author, year | Intervention (N analysed) Followup mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|-----------------------------------|---|---|---|---|--|
| Michael J, ¹⁵⁹ 2005 | G1: CPM & PT program (34) | CMS | 39 (7–74) / 69 (28–94) | 36 (13–57) / 66 (27–96) | NR |
| | | Pain VAS | 62 / 41 | 62 / 29 | NR |
| | G2: PT program (21) 56 days | Time until 90° ABD (days) | 31 days | 43 days | p=0.03 |
| | | Return to work (mean days) | (21 days sooner than G2) | NR | NR |
| Milroy DR, ¹⁶⁰ 2008 | G1: Standardized PT (NR) | Mean difference on DASH (pts, 95% CI) | 12.4, -1.60, -23.2 | | p≤0.05 |
| | G2: Non-standardized PT (NR) | | Improvement in pain scores | NR | NR |
| | NR | | | | |
| Rabb MG, ¹⁶¹ 1996 | G1: CPM & PT (14) G2: PT only (12) 3 mo | Shoulder Score* | 68 / 83, p>0.05 | 63 / 73, p>0.05 | p>0.05 |
| Roddey TS, ¹⁶² 2002 | G1: Videotape instruction (54) | SPADI | 60.4±22.1 | 52.3±21.6 | |
| | | 12 wk | 32.0±19.7 | 26.7±18.8 | p=0.17 |
| | | 24 wk | 18.1±16.1 | 15.3±15.2 | p=0.40 |
| | G2: PT instruction (54) 52 wk (NR) | 52 wk | 12.3±14.3 | 12.4±14.4 | p=0.99 |
| | | PENN | 37.9±15.7 | 40.9±16.3 | |
| | | 12 wk | 62.6±17.7 | 66.2±17.5 | p=0.32 |
| | 24 wk | 79.4±15.5 | 79.6±17.3 | p=0.95 | |
| | 52 wk | 85.6±13.8 | 85.9±16.7 | p=0.94 | |

Table 26: Strength of evidence for postoperative rehabilitation

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|--|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Continuous passive motion with PT treatment vs. PT treatment | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 3; 133 (122) | Function | RCTs | Consistent | Direct | Precise | Absent | Moderate |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 61 (55) | Time to return to work | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| Aquatic therapy with land-based therapy vs. land-based therapy | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 18 | Function | CCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Inpatient vs. day patient rehabilitation | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Function | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Individualized PT program with home exercise vs. home exercise | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 58 (42) | Function | Cohort Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Standardized vs. non-standardized PT program | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 67 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Videotape vs. PT home exercise instruction | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 129 (108) | Function | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

HRQL = health-related quality of life; n/a = not applicable; PT = physical therapy; RCT = randomized controlled trial;

*Number analyzed if different from number studied

Postoperative Rehabilitation—Uncontrolled Studies

Only one BA study evaluated a postoperative rehabilitation program consisting of passive and active stretching and strengthening exercises.¹⁵⁴ The study was published in 2007 and enrolled 118 patients with a mean age of 67 years. The type and size of patient RC tears was not reported. There were 14 (12 percent) smokers among the included patients. The only outcome measure used to assess patients was the DASH scale. Since only one uncontrolled study evaluated postoperative rehabilitation, a visual display of the preoperative and postoperative scores is not presented.

Question 3: Comparative Effectiveness of Nonoperative Treatments

The comparative effectiveness of nonoperative interventions was examined in a total of 10 studies (three comparative and seven uncontrolled studies). Various types of interventions were examined across the individual studies, including stretching and strengthening, steroid injections, oral medications, among others.

Nonoperative—Comparative Studies

Summary. Only three comparative studies were identified that assessed nonoperative interventions. Pooling of data was not possible as the interventions compared in each study varied. One RCT compared sodium hyaluronate versus dexamethasone in terms of function and range of motion. The authors reported results comparing patients who were and were not satisfied with their degree of improvement within each group, therefore the data available did not allow for a head-to-head comparison regarding the relative efficacy of the two interventions under study. The trial was at high risk of bias due to a number of methodological weaknesses; in particular, the patient self-selection of treatment at 4 weeks based on satisfaction is an important source of bias. One retrospective cohort study compared rehabilitation focusing on protecting the cuff through reliance on other muscles (deltoid, pectoralis major and latissimus dorsi) versus no rehabilitation and found statistically significant and clinically important differences favoring the rehabilitation group in terms of function (absolute difference between groups of 26.9 points on a 100-point scale). The study had several methodological limitations, most importantly a loss to followup of 46 percent. Differential loss to followup across the groups may yield exaggerated estimates of treatment effects. While rehabilitation may appear to be a promising intervention based on statistically and clinically important differences when compared to no rehabilitation, there is no evidence regarding how rehabilitation would compare to other interventions, such as steroid injections. Finally, a retrospective cohort study compared steroid injection versus no steroid injection among participants undergoing physical therapy (not specified) and receiving oral medications (not specified). The results showed a significant difference in terms of function (absolute difference of 11 on an 83-point scale) and time to maximum range of motion (absolute difference of 4 months). The study had several methodological limitations which may bias the effects observed including retrospective timing and self-reporting of outcomes; further, the authors studied a select group which may affect generalizability of results beyond the population studied.

Overall, the level of evidence is low for nonoperative interventions due the variety of interventions examined across the body of evidence and methodological limitations of the individual studies. Treatment components were poorly described across the studies, both in term of content (e.g., components included in “physical therapy” treatment) and delivery (e.g., frequency, intensity), limiting the usefulness of the studies to clinicians attempting to determine the most effective ways to manage patients nonoperatively. In addition, outcomes such as range of motion were insufficiently described, as it was unclear whether active, active-assisted or passive motion was being assessed.

Results by individual study. Three studies (one RCT¹⁷¹ and two retrospective cohort studies^{145,168}) compared the effectiveness of nonoperative treatments in patients with RC tears. The studies could not be pooled because different nonoperative interventions were compared in

each study. Patient and study characteristics, as well as study outcome data, are presented in Table 27 and Table 28, respectively. Grading of the body of evidence is presented in Table 29.

Sodium hyaluronate versus dexamethasone. Shibata et al.¹⁷¹ conducted a RCT comparing sodium hyaluronate with dexamethasone steroid injection in patients with full-thickness RC tears. The size of tears was not reported. Seventy-eight patients were randomly assigned to the interventions (38 to sodium hyaluronate, 40 to dexamethasone). In addition, patient in both groups received Loxoprofen (180 mg/day) and physical therapy including heat and cuff strengthening exercise. All patients were evaluated at 4 weeks, at which point patients who were unsatisfied with their degree of improvement could elect to have surgical RCR. Only satisfied patients, who continued the nonoperative treatment to which they had been allocated, were assessed at 24 weeks using the UCLA shoulder score and range of motion (abduction, external and internal rotation). Compared to satisfied patients, those who were unsatisfied and opted for surgery at 4 weeks were more likely to have a manual labour job ($p < 0.01$). At 4 weeks, there were significant differences between the satisfied and unsatisfied patients in the endpoint UCLA score and abduction, regardless of the type of nonoperative intervention to which they had been assigned. Satisfied patients showed significant improvement in UCLA score, abduction, and external rotation, but not internal rotation at 24 weeks compared with baseline measures. Head-to-head comparison of the two nonoperative interventions was not made.

Rehabilitation versus no rehabilitation. Leroux et al.¹⁶⁸ conducted a retrospective cohort study comparing rehabilitation with no rehabilitation in patients with full-thickness tears. The rehabilitation program focused on protecting the cuff through reliance on other muscles (deltoid, pectoralis major and latissimus dorsi). Overall, 112 patients were enrolled in the study; of these, 60 were included in the final analyses (42 in the rehabilitation group, 18 in the no rehabilitation group). The mean length of followup was 3.8 month (range: 5 days to 24 months). Patients were evaluated using the Scapular functional index. The difference in Scapular functional score from baseline to endpoint score was significant in the rehabilitation group ($p \leq 0.05$); however, this difference was not significant in the no rehabilitation group. There was statistically significantly difference between the groups in the endpoint postoperative Scapular function score ($p < 0.001$), in favour of the rehabilitation group.

Steroid versus no steroid injection. Vad et al.¹⁴⁵ conducted a retrospective cohort study comparing physical therapy with oral medication versus physical therapy with oral medication and steroid injection. The study did not specify the components of the physical therapy treatment protocol or the type of oral medication or steroid. All patients had massive full-thickness RC tears. Forty patients were enrolled in the study (12 received the steroid injection, 28 received no steroid). All patients were followed for at least 2 years; the mean followup duration was 3.2 years (range: 2 to 7). Patients were evaluated using the Insalata shoulder rating scale, range of motion (abduction), and time to maximum range of motion. For both groups, there were significant differences in the Insalata scores and range of motion from preoperative to postoperative scores ($p \leq 0.05$). Moreover, there were significant and clinically important differences between the group endpoint Insalata scores and time to maximum range of motion ($p \leq 0.05$), in favour of physical therapy with oral medication and steroid injection group.

Table 27. Study and patient characteristics for studies assessing nonoperative interventions

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; size of tear Duration of symptoms (mo), mean±SD (range) |
|--------------------------------|---|--|---|
| Shibata Y, ¹⁷¹ 2001 | G1: Sodium hyaluronate (38) G2: Dexamethasone (40) RCT | G1: 59.5±9.1 yr / Males: 27 (71) Manual Labourers: 10 (26) G2: 62.4±8.6 yr / Males: 28 (74) Manual Labourers: 11 (28) | FTT; NR G1: 5.8±5.4 mo, G2: 4.7±5.7 mo |
| Leroux JL, ¹⁶⁸ 1993 | G1: No rehabilitation (NR) G2: Rehabilitation (NR) Retrospective cohort | G1 and G2: 61.5 yr (36–85) / Males: (61) | FTT; NR 7.5±0.5 mo |
| Vad VB, ¹⁴⁵ 2002 | G1: PT & oral medication (28) G2: PT & oral medication & steroid injections (12) Retrospective cohort | G1 and G2: 63.2 yr / Males: NR | FTT; Mass 6.3 mo (1–17) |

FTT = full-thickness tears; G = group; Mass = massive; NR = not reported; PT = physical therapy; RCT = randomized controlled trial; SD = standard deviation

Table 28: Outcome data for studies assessing nonoperative interventions

| Author, year | Intervention (N) Followup mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | | Group 1 vs. Group 2 Post-op p-value | |
|-----------------------------------|--|---|---|---|---|--|--|--|
| Shibata Y, 2001 ¹⁷¹ | G1: Sodium hyaluronate (38) G2: Dexamethasone (40) 24 wks | UCLA* | Satisfied patients (n=16) | Unsatisfied patients (n=22) | Satisfied patients (n=15) | Unsatisfied patients (n=25) | Satisfies vs. unsatisfied at 4wks: | |
| | | Pre-op / 4 wk | 13.6±2.6/ 27.6±3.1, p<0.0001/ 26.2±3.1, p<0.0001 | 12.8±3.5/ 14.9±4.4 / NR | 11.9±3.6/ 26.5±2.0, p<0.0001/ 25.3±2.5, p<0.0001 | 12.6±3.9/ 15.0±4.0/ NR | Group1: p<0.0001 Group2: p<0.0001 | |
| | | / 24 wk | ROM (degrees) | ABD:122.8±32.1/ 151.6±10.6, p<0.01/ 147.7±9.9, p≤0.05 | ABD:124.3±44.2/ 130.7±36.8/ NR | ABD:111.0±37.6/ 143.7±47.3, p<0.01/ 139.6±13.8, p≤0.05 | ABD:117±47.3/ 112.4±38.2 / NR | Satisfies vs. unsatisfied at 4wks: |
| | | Pre-op / 4 wk / 24 wk | ER : 43.8±12.7/ 52.2±10.6, p<0.001/ 49.6±9.0, p≤0.05 | ER: 54.1±22.8/ 55.5±19.7/ NR | ER: 37.3±15.1/ 45.3±7.2, p≤0.05/ 46.5±8.5, p≤0.05 | ER: 46.8±20.0/ 39.0±18.3 / NR | Group1: ABD: p≤0.05 ER: p>0.05 IR: p>0.05 | |
| | | IR † : T12.3±1.8/ T11.3±2.0, p≤0.05/ T11.8±2.6, p>0.05 | IR † : T12.2±3.0/ T10.6±3.1/ NR | IR †: L1.1±4.0/ T12.3±2.8, p>0.05/ NR, p>0.05 | IR †: L1.2±2.9/ T12.6±3.1 / NR | Group2: ABD: p≤0.01 ER: p>0.05 IR: p>0.05 | | |
| Leroux JL, 1993 ¹⁶⁸ | G1: No rehabilitation (18) G2: Rehabilitation (42) 3.8 mo (5 days–24 mo) | Scapular Functional Index, baseline to endpoint change | -6.6±5.2, p>0.05 | +20.3±2.5, p≤0.05 | p<0.001 | | | |
| Vad VB, 2002 ¹⁴⁵ | G1: PT & oral medication (28) G2: PT & oral medication & steroid injections (12) 3.2 yr (2-7) | Insalata* | 44.4±1.7 / 63.6, p≤0.05 | | 44.4±1.7 / 74.5, p≤0.05 | | p≤0.05 | |
| | | ROM (degrees) | ABD: 68 / 108, p<0.05 | | | | NR | |
| | | Time to maximum ROM (mo) | 9.3 (3–18) | | 5.3 (1–11) | | p≤0.05 | |

ABD = abduction; ER = external rotation; G = group; Insalata = Insalata Shoulder Rating Questionnaire; IR = internal rotation; NR = not reported; pre-op = preoperative; post-op = postoperative; PT = physical therapy; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; UCLA = University of California Los Angeles Scale

* Subscales reported

† vertebral level (active ROM)

Table 29. Strength of evidence for nonoperative interventions

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|--|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Sodium hyaluraonate vs. dexamethasone | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 78 | Function | RCT Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Rehabilitation vs. no rehabilitation | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 112 (60) | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| PT, oral medications and steroid injection vs. PT, oral medications and no steroid injection | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 40 | Function | Cohort Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

HRQL = health-related quality of life; n/a = not applicable; PT = physical therapy; RCT = randomized controlled trial
 *Number analyzed if different from number studied

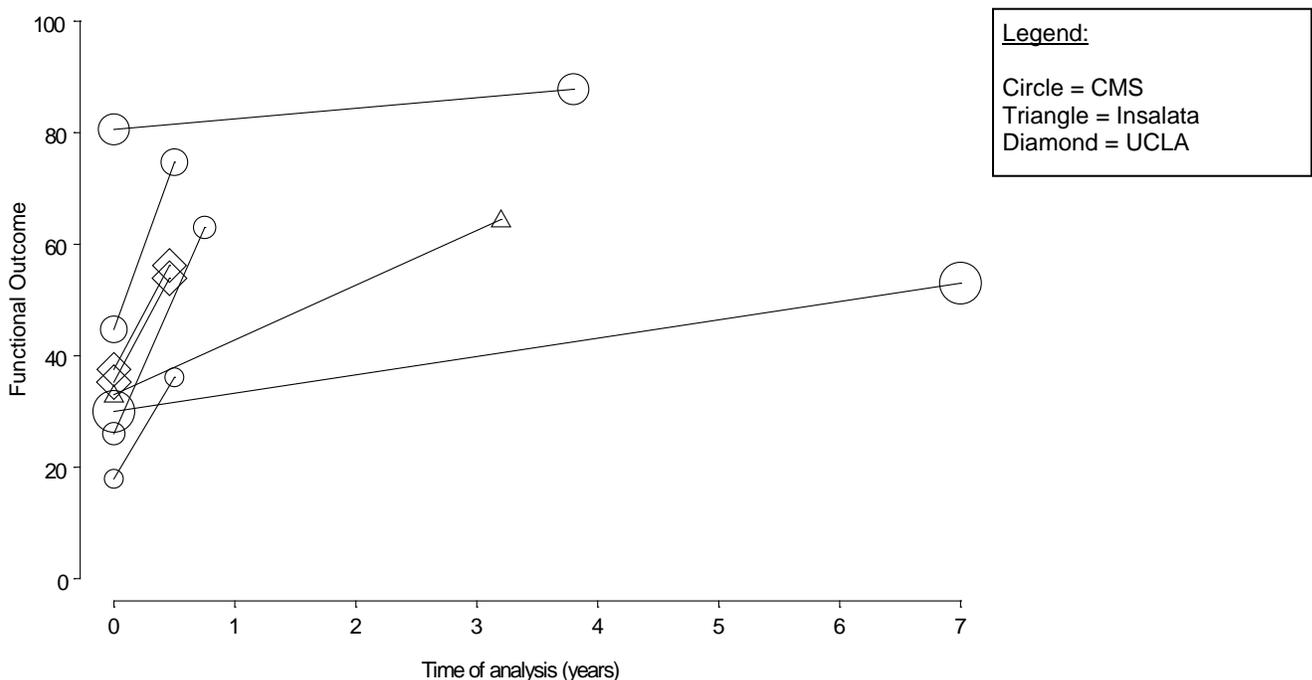
Nonoperative Treatments—Uncontrolled Studies

Seven uncontrolled studies, including six BA^{163,164,166,167,169,170} and one prospective cohort with BA data,¹⁶⁵ examined the effectiveness of nonoperative treatment for RC tears. Interventions evaluated in the studies included exercise protocols,^{164,165} programs consisting of analgesic, NSAID, steroid injection and reeducation interventions,^{163,167} pulsed radiofrequency ablation,¹⁶⁶ anterior deltoid rehabilitation program,¹⁶⁹ and early functional physical therapy and active shoulder support.¹⁷⁰ The studies were published from 1991 to 2008, with 2006 the median year of publication (IQR: 2000 to 2008).

The number of participants enrolled in the studies ranged from 12 to 59 (median=29 [IQR: 21 to 42]). The median followup duration ranged from 25 days to 7 years (median=6 months). The mean age of participants ranged from 59 to 80 years. Full-thickness tears were included in three studies,^{164,167,169} both partial- and full-thickness tears were included in two studies,^{163,165} and two did not report type of tear.^{166,170} Only two studies reported tear size; one included all sizes¹⁶⁴ and one included only massive tears.¹⁶⁹ Recreational athletes and smokers were not reported in any of the studies. WCB patients were included in one study¹⁶⁴ and manual labourers in another.¹⁶³

Functional outcome measures were reported in all but one study.¹⁷⁰ Only one study reported health-related quality of life¹⁶³ and three reported proportion of patients who returned to work.^{163,164,167} Function was reported in six studies.^{163-167,169} Tendon healing were not reported in any of the nonoperative studies. Figure 28 presents the preoperative and postoperative functional scores over time for all studies that examine nonoperative treatments. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Followup durations and the degree of improvement in outcome scores varied considerably across studies.

Figure 28. Studies examining functional outcomes for nonoperative treatments



Question 4: Comparative Effectiveness of Nonoperative versus Operative Treatments

The comparative effectiveness of nonoperative versus operative interventions was examined in three comparative studies.

Nonoperative versus Operative Treatments—Comparative Studies

Summary. Three cohort studies compared nonoperative treatment versus operative RCR. The nonoperative treatments across the three studies varied slightly in their components, but all included steroid injections and either physical therapy (treatment components not specified) or stretching and strengthening activities. All studies compared the nonoperative treatments to open repair, and one study included an additional group undergoing arthroscopic debridement. All groups showed significant improvements over the study period regardless of the intervention. Overall there was no significant difference in function between nonoperative and operative interventions; however, the results were highly heterogeneous with one study showing an absolute difference of 24.5 points on an 83-point scale in favour of the operative repair. This same study showed a significantly shorter time to maximum range of motion among the group undergoing arthroscopic debridement (3.2 months) compared to the nonoperative and open repair groups (6.8 months each). In general the level of evidence is low for nonoperative versus operative interventions. The findings were inconsistent within and across studies. Further, as with complex interventions, it is difficult to determine the relative contributions of each of the components in the nonoperative treatment regimes.

Results by individual study. Three cohort studies^{145,172,173} compared nonoperative with operative treatment regimes. Pooled analyses are presented in Figure 29 and Figure 30. Summary tables of the patient characteristics and outcome data are available in Table 30 and Table 31. The body of evidence for key outcomes was graded and is shown in Table 32.

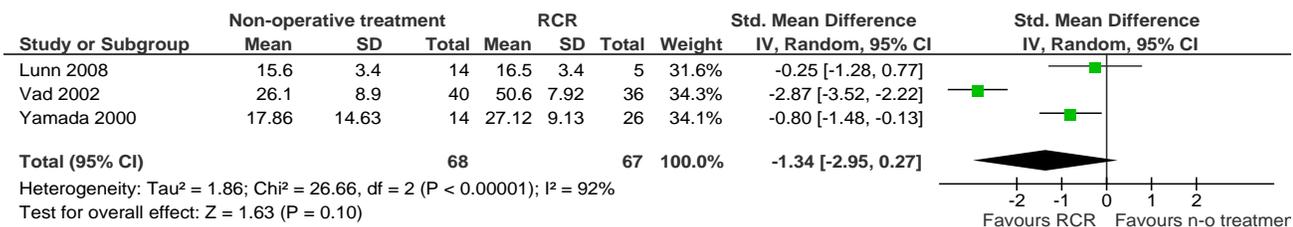
Steroid injection, physical therapy and activity modification versus open RCR. Lunn et al.¹⁷² conducted a prospective cohort study comparing nonoperative treatment consisting of steroid injections, physical therapy and activity modification versus open repair. The type of steroid, physical therapy treatment components and type of activity modification of the nonoperative group were not reported in the study. All patients had full-thickness RC tears. The mean length of followup was 4.2 years (range: 2 to 6.6). Nineteen patients were enrolled in the study (14 received nonoperative interventions, 5 received open RCR). All patients were evaluated using the CMS, range of motion (flexion, external and internal rotation), and strength. For both groups, there was a significant difference between the preoperative and postoperative CMS ($p=0.009$). However, the difference between the groups at endpoint was not significant ($p=0.61$). For both range of motion and strength, data was not presented separately by treatment group. Range of motion differed between the affected and normal side at final followup (158 versus 176 degrees in flexion, 48 versus 58 degrees in external rotation, and T12 versus T7 in internal rotation). Similarly, there was a significant difference in strength between the affected and normal side at final followup ($p<0.001$). Cuff integrity was assessed using MRI at an average of 4.2 years. Anatomic healing was obtained in 3 cases (60 percent) in the operative group; cuff healing was not assessed in the nonoperative group.

Physical therapy, oral medication and steroid injection versus open RCR versus arthroscopic debridement. Vad et al.¹⁴⁵ conducted a retrospective cohort study comparing four treatment arms: physical therapy and oral medication alone and with the addition of steroid injection, open RCR and arthroscopic debridement. The physical therapy treatment components, type of oral medication and steroid were not specified in the study. One hundred and eight patients with massive full-thickness RC tears were enrolled in the study (28 received nonoperative treatment without steroid, 12 received nonoperative treatment with steroid, 36 received open RCR and 32 received debridement). The study reported combined outcome data for the two nonoperative treatment arms. All patients were followed for a minimum of 2 years; the mean followup duration was 3.2 years. Patients were evaluated using the Insalata shoulder rating scale, range of motion (abduction), and time to maximum range of motion. For all groups, there were significant differences in the Insalata score and range of motion from preoperative to postoperative scores ($p \leq 0.05$). In addition, there were significant between-group differences in the Insalata score at final followup, favoring surgery over nonoperative treatment. The time to maximal range of motion was significantly different between the groups, with 6.8 months for the nonoperative and open RCR groups, and 3.2 months for the arthroscopic debridement group.

Steroid injection, stretching and strengthening versus open RCR. Yamada et al.¹⁷³ conducted a retrospective cohort study comparing nonoperative treatment (passive stretching, strengthening and corticosteroid injections) versus open repair with acromioplasty. The type of steroid was not specified. Forty patients with massive tears enrolled in the study (14 received the nonoperative treatment, 26 received surgical repair). All patients were followed for a mean length of 4 years (12 months to 23 years). The JOA shoulder scale and strength score were used to evaluate patients. There was significant improvement in the JOA score for both the nonoperative treatment group ($p = 0.0012$) and the operative group ($p < 0.0001$). However, the difference in the JOA score between the groups at final followup was not significant ($p > 0.05$). At study endpoint, muscle strength was greater in the operative group than the nonoperative group; however the statistical significance of this difference was not reported.

All three cohort studies^{145,172,173} provided data for meta-analysis of the effects of nonoperative treatment versus surgical repair on functional outcome measures (Figure 29). The scales used to measure function included the CMS,¹⁷² Insalata,¹⁴⁵ and the JOA.¹⁷³ The pooled estimate of change in function shows no significant difference between groups, although the surgical repair is favored (SMD = -1.32; 95% CI, -2.95, 0.27). There was substantial heterogeneity between the three studies ($p < 0.0001$, $I^2 = 92$ percent).

Figure 29. Nonoperative treatment versus RCR for measures of functional outcome



Two cohort studies^{172,173} provided data for meta-analysis for the effects of nonoperative treatment versus surgical repair on pain (Figure 30). The pain subscales of the CMS¹⁷² and JOA¹⁷³ scales were used in this analysis. Baseline to followup change scores were compared between groups. The pooled analysis showed no statistically significant difference between the

two treatments for pain (SMD=0.81; 95% CI, -1.26 to 2.88). Heterogeneity between the studies was substantial ($p=0.001$, $I^2=90$).

Figure 30. Nonoperative treatment versus RCR for pain

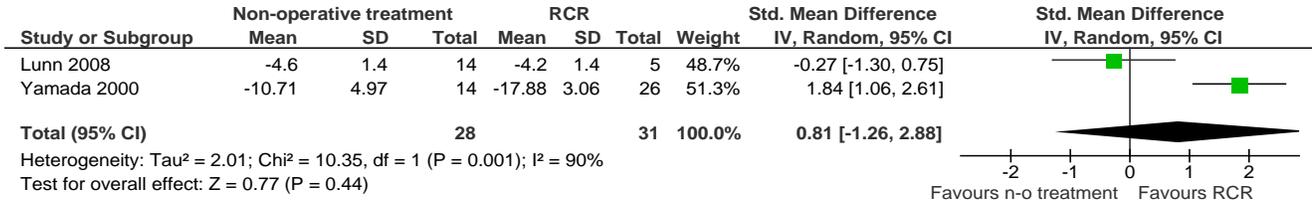


Table 30. Study and patient characteristics for studies assessing operative versus nonoperative interventions

| Author, year | Intervention (N participants enrolled) Study design | Age (yr), mean±SD (range) / Males, N (%) Other characteristics | Type of tear; size of tear Duration of symptoms (mo), mean±SD (range) |
|-------------------------------|---|---|---|
| Lunn JV, ¹⁷² 2008 | G1: Steroid injection, PT & activity modification (14) G2: Open RCR (5) Prospective cohort | G1: 47.1 yr (30–66) / Males: 1 (7.1) G2: 46.2 yr (38–59) / Males: 3 (60) | FTT; NR 4.3 yr (6 mo–10 yr) |
| Vad VB, ¹⁴⁵ 2002 | G1: PT & oral medication (28) G2: PT, oral medication & steroid injection (12) G3: Open RCR (36) G4: Arthroscopic debridement (32) Retrospective cohort | G1 & 2: 63.2 yr / NR G3: 59.4 yr / NR G4: 62.9 yr / NR | FTT; Mass 6.3 mo (1–17 mo) |
| Yamada N, ¹⁷³ 2000 | G1: Steroid injection, stretching, strengthening (14) G2: Open RCR (26) Retrospective cohort | G1: 70 (55–81) / Males: 9 (64.3) G2: 62 (47–82) / Males: 24 (92.3) | FTT; Mass G1: 44 mo (12 mo–11 yr); G2: 13 mo (1 mo–4.5 yr) |

FTT = full-thickness tear; G = group; Mass = massive; NR = not reported; PT = physical therapy; RCR = rotator cuff repair; SD = standard deviation

Table 31. Outcome data for studies assessing operative versus nonoperative interventions

| Author, year | Intervention (N analysed) Followup mean (range) | Outcome | Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range) | Group 1 vs. Group 2 Post-op p-value |
|----------------------------------|--|---|--|---|--|
| Lunn JV, 2008 ¹⁷² | G1: Steroid injection, PT & activity modification (14) G2: Open RCR (5) 4.2 yr (2–6.6) | CMS* | 51 (24.5–65) / 66.6 (37.5–87), p=0.009 | 53 (32–78.5) / 69.5 (44–95), p=0.009 | p=0.61 |
| | | ROM (degrees; affected, normal sides) | F: NR / 158, 176 (NR by group) ER: NR / 48, 58 IR: NR/ T12, T7 | | NR |
| | | Strength (kg; affected, normal sides) | ER: NR / 3.2, 6, p<0.0001 (NR by group) | | NR |
| | | Cuff integrity N (%) MRI | NR | 3 / 5 (60) | NA |
| Vad VB, 2002 ¹⁴⁵ | G1 & G2: PT & oral medication (± steroid injection) (40) G3: Open RCR (36) G4: Arthroscopic debridement (32) 3.2 yr (2–7) | Insalata | G1 & G2: 44.4±1.7 / 70.5±1.4, p≤0.05 | G3: 33±1.2 / 83.6±1.4, p≤0.05 G4: 42.3±1.4 / 81.4±1.3, p≤0.05 | p<0.01‡ p<0.01‡ |
| | | ROM (degrees) | G1 & G2: ABD: 68 / 108, p≤0.05 | G3: ABD: 72 / 116, p≤0.05 G4: ABD: 74 / 110, p≤0.05 | NR |
| | | Time to maximal ROM | G1 & G2: 6.8 mo (2–16) | G3: 6.8 mo (4–16) G4: 3.2 mo (1–8) | NR |
| | | JOA* | 53.2 (40–65) / 71.1 (48–88), p=0.0012 | 58.8 (43–73) / 85.9 (67–100), p<0.0001 | p>0.05 |
| Yamada N, 2000 ¹⁷³ | G1: Steroid injection, stretching, strengthening (14) G2: Open RCR & acromioplasty (26) 4 yr (12 mo–23 yr) | Strength score (Manual muscle test) | ABD& ER: NR / 4- (n=3) | ABD& ER: NR / 5- (n=9) | NR |

ABD = abduction; CMS = Constant-Murley score; ER = external rotation; F = flexion; G = group; Insalata = L'Insalata Shoulder Rating Questionnaire; IR = internal rotation; JOA = Japanese orthopaedic association; kg = kilogram; MRI = magnetic resonance imaging; NR = not reported; pre-op = preoperative; post-op = postoperative; PT = physical therapy; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation

*Subscales reported

‡No group specification

‡Calculated by UAEPC

Table 32. Strength of evidence for nonoperative versus operative treatment

| Technique | Number of studies; subjects (analyzed)* | Outcome | Strength of evidence domains | | | | | Strength of evidence |
|--|---|------------------------|------------------------------|-------------|------------|-----------|-------------|----------------------|
| | | | Risk of bias | Consistency | Directness | Precision | Confounding | |
| Steroid injection, PT, and activity modification vs. open repair | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 19 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| PT, oral medication, and steroid injection vs. arthroscopic debridement vs. open repair | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 108 | Function | Cohort Medium | Unknown | Direct | Imprecise | Absent | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |
| Passive stretching, strengthening, and corticosteroid injection vs. open repair with acromioplasty | 0 | HRQL | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 1; 40 | Function | Cohort Medium | Unknown | Direct | Imprecise | Present | Low |
| | 0 | Cuff integrity | n/a | n/a | n/a | n/a | n/a | Insufficient |
| | 0 | Time to return to work | n/a | n/a | n/a | n/a | n/a | Insufficient |

HRQL = health-related quality of life; n/a = not applicable; PT = physical therapy

*Number analyzed if different from number studied

Question 5: Complications

Summary. Overall, 89 of the 122 studies included in this review reported data for 29 different complications across all interventions, while 21 studies reported no complications and 33 studies did not report on complications. In general, the rates of complication were low and the majority of complications were not deemed to be clinically important or were reported in few studies. A priori, we identified the following complications to be the most clinically important:

- **Retears:** This complication was reported in 12 studies. Among the 10 studies examining operative approaches, the rates of re-tear were generally low (≤ 0.07), with the exception of two studies using stabilization of the long head of biceps (LHB) with open RCR and arthroscopic RCR, with rates of 0.10 and 0.27, respectively. One study examining operative augmentation (patch graft) found a re-tear rate of 0.18. Two studies examining postoperative rehabilitation reported low rates (≤ 0.05).
- **Infection:** 27 studies provided data on infections. Among 20 studies that examined operative approaches, the rate of infection was low with the majority of studies reporting no infections. Studies of operative techniques and augmentations generally reported low rates of infection, except for one prospective cohort study that reported a rate of 0.11 among the group receiving headed bio-corkscrews. Two studies examining postoperative rehabilitation reported low rates (≤ 0.05).
- **Stiffness:** 22 studies provided data on stiffness following treatment. The rates were low (≤ 0.08) among 18 studies examining operative approaches. Higher rates of postoperative stiffness were observed for mini-open RCRs with two of the six studies reporting rates of 0.14¹³⁷ and 0.17.¹⁵⁰ Likewise, two of the 10 studies examining arthroscopic RCR reported rates of 0.13⁶⁵ and 0.11.¹⁵⁰ One study examining operative technique and one on augmentation both reported low rates of postoperative stiffness, with 0.06 and 0, respectively. Similarly, two nonoperative studies reported low rates of 0.04 and 0.07.
- **Reflex sympathetic dystrophy:** In general the rates of reflex sympathetic dystrophy were low across the seven studies examining operative approaches; however, higher rates were observed in a BA study of arthroscopic RCR (0.12) and a retrospective cohort study of arthroscopic debridement with tenotomy (0.13). One study evaluating postoperative rehabilitation reported one case of reflex sympathetic dystrophy among the 32 patients studied.
- **Neurological injury:** The rates of postoperative neurological injury were low in 12 studies examining operative approaches or techniques.

Results by complication. Of the 122 studies included in this review, 88 provided data on 29 different complications for nonoperative and operative interventions (see tables below); 33 studies (five trials,^{86,116,124,157,162} five retrospective cohort,^{134,145,160,168,173} 13 BA studies,^{58,66,74,84,92,99,140,146,148,154,164,169,170} nine cohort studies providing BA data,^{52,72,109,111,117,122,129,130,165} and one case-control study¹⁴⁴) did not report complications. The tables report complications for study arms separately. The majority of complications were

reported for operative studies; only two studies^{163,167} reported complications associated with nonoperative treatments, while three postoperative rehabilitation studies^{158,159,161} reported complications. Complication rates for studies focusing on postoperative rehabilitation may be attributable to either the preceding surgery or the rehabilitation components.

Twenty-one studies (six trials,^{80-82,143,155,171} one prospective cohort,¹³⁹ two retrospective cohorts,^{115,120} and 12 BA studies^{71,76,79,83,95,104,114,132,133,138,153,166}) reported that no complications occurred during the course of the study (Table 57). The remaining 67 studies provided data on specific complications in the course of a nonoperative, operative, or postoperative rehabilitation treatment. Of these 67, nine were trials: six^{61,68,93,98,118,119} that compared operative interventions, and three^{158,159,161} compared postoperative rehabilitation. Twenty-one studies used cohort or case-control design: 20 studies^{53,54,57,60,63,65,73,89,96,97,101,102,108,112,121,128,137,147,150,152} compared operative interventions, and one¹⁷² compared an operative with a nonoperative intervention. Thirty-seven studies used a BA design: 35 studies,^{55,56,59,62,64,67,69,70,75,77,78,85,87,88,90,91,94,100,103-107,110,113,123,125-127,131,135,136,141,142,149} examined operative interventions and two^{163,167} examined nonoperative interventions. No BA studies provided data on complications for postoperative rehabilitation.

Retears. Twelve studies (Table 33) reported data on postoperative retears (two trials,^{159,161} five cohort studies,^{65,96,97,137,152} five uncontrolled studies^{59,70,110,125,131}). These studies used clinical evaluation or imaging to identify the presence of retears in patients with who were unsatisfied with their postoperative outcome. Studies which systematically examined all patients using imaging to investigate what proportion had an intact cuff are reported under the key outcome “tendon integrity” above. Overall, the rates of retears from 10 studies that examined operative approach were consistent. With the exception of two studies, rates ranged from 0.01 to 0.07. Patch graft⁹⁷ reported a rate of 0.18. Studies examining physical therapy alone¹⁵⁹ and physical therapy with continuous passive motion¹⁶¹ reported rates of 0.05 and 0.04, respectively.

Table 33. Re-tear

| Intervention | Author, year Category Design | Patients evaluation; Evaluation criteria (imaging/ clinical) | Events | Sample size | Rate (95% CI) |
|------------------|---|---|--------|----------------|----------------------|
| Operative | | | | | |
| Open RCR | Cofield 2001 ⁷⁰ Operative approach BA | Unsatisfied; Clinical | 1 | 105 | 0.01 (0.002-0.05) |
| Mini-open RCR | Prasad 2005 ¹³¹ Operative approach BA | Unsatisfied; Clinical | 1 | 40 | 0.03 (0.004-0.13) |
| | Severud 2003 ¹³⁷ Operative approach Retrospective cohort | Unsatisfied; Clinical | 1 | 29 | 0.03 (0.01-0.17) |
| | Youm 2005 ¹⁵² Operative approach Retrospective cohort | Unsatisfied; Clinical | 3 | 42 | 0.07 (0.02-0.19) |

BA = before-and-after; CI = confidence interval; CTA = computed tomography arthrography; LHB = long head of biceps; MRI = magnetic resonance imaging; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial; USG = ultrasonography

*Re-tear was not considered as a complication

†Only 15 of 30 (G1) and 60 of 97 (G2) were evaluated for tendon integrity.

Table 33. Re-tear (continued)

| Intervention | Author, year Category Design | Patients evaluation; Evaluation criteria (imaging/ clinical) | Events | Sample size | Rate (95% CI) |
|--|--|---|--------|----------------|----------------------|
| Arthroscopic RCR | Bennett 2003 ⁵⁹ Operative approach BA | Unsatisfied; Clinical | 1 | 24 | 0.04 (0.01-0.20) |
| | Buess 2005 ⁶⁵ Operative approach Prospective cohort | Unsatisfied; Clinical | 2 | 30 | 0.07 (0.18-0.21) |
| | Ide 2005 ⁹⁶ Operative approach Prospective cohort | Unsatisfied; MRI | 1* | 50 | 0.02 (0.003-0.10) |
| | Oh 2008 ¹²⁵ Operative approach Cohort – BA data | Sample; † CTA / USG | 4 | 15 | 0.27 (0.11-0.52) |
| | Youm 2005 ¹⁵² Operative approach Retrospective cohort | Unsatisfied; Clinical | 1 | 42 | 0.02 (0.004-0.12) |
| Stabilization of LHB & open RCR | Maier 2007 ¹¹⁰ Operative approach BA | Unsatisfied; Clinical | 2 | 21 | 0.10 (0.03-0.29) |
| Patch graft RCR | Ito 2003 ⁹⁷ Operative augmentation Retrospective cohort | Unsatisfied; Clinical | 3 | 17 | 0.18 (0.06-0.41) |
| Postoperative Rehabilitation | | | | | |
| PT alone | Michael 2005 ¹⁵⁹ Post-op rehab RCT | Unsatisfied; Clinical | 1 | 21 | 0.05 (0.01-0.23) |
| Continuous passive motion & PT program vs. PT alone | Raab 1996 ¹⁶¹ Post-op rehab RCT | Unsatisfied; Clinical | 1 | 26 | 0.04 (0.01-0.19) |

Technical failure. Ten studies provided data on the failure of anchors or other surgical constructs (four cohort studies^{73,101,128,147} and six uncontrolled studies^{56,69,105,127,141,149}) (Table 34). Overall, the rates of technical failure from six studies that examined operative approach ranged from 0 to 0.12, with two studies^{69,105} reporting rates higher than 0.05. Rates for technical failure for a variety of operative techniques were provided by single studies and ranged from 0 to 0.33, and for one operative augmentation study was 0.03.

Table 34. Technical failure

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|------------------|---|--------|----------------|---------------------|
| Operative | | | | |
| Mini-open RCR | Verma 2006 ¹⁴⁷ Operative approach Retrospective cohort | 0 | 33 | 0 (0.00-0.08) |
| Arthroscopic RCR | Lafosse 2007 ¹⁰⁵ Operative approach BA | 2 | 17 | 0.12 (0.03-0.34) |
| | Park 2004 ¹²⁷ Operative approach Cohort – BA data | 0 | 22 | 0 (0.00-0.11) |

BA = before-and-after; CI = confidence interval; RCR = rotator cuff tear

Table 34. Technical failure (continued)

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|--------------------------------------|---|--------|----------------|----------------------|
| | Tauro 2004 ¹⁴¹ Operative approach BA | 1 | 42 | 0.02 (0.004-0.12) |
| | Verma 2006 ¹⁴⁷ Operative approach Retrospective cohort | 1 | 38 | 0.03 (0.005-0.13) |
| | Waibl 2005 ¹⁴⁹ Operative approach BA | 1 | 22 | 0.05 (0.008-0.22) |
| Arthroscopic RCR & biceps tenodesis | Checchia 2005 ⁶⁹ Operative approach BA | 1 | 15 | 0.07 (0.01-0.30) |
| Single-row fixation | Park 2008 ¹²⁸ Operative technique Prospective cohort | 1 | 40 | 0.03 (0.004-0.13) |
| Double-row fixation | Park 2008 ¹²⁸ Operative technique Prospective cohort | 1 | 38 | 0.03 (0.005-0.13) |
| Simple stitch | Ko 2008 ¹⁰¹ Operative technique Prospective cohort | 9 | 39 | 0.23 (0.005-0.13) |
| Modified mattress locking stitch | Ko 2008 ¹⁰¹ Operative technique Prospective cohort | 6 | 36 | 0.17 (0.08-0.32) |
| Mitek metal suture anchor (open RCR) | Cummins 2003 ⁷³ Operative technique Prospective cohort | 0 | 18 | 0 (0.00-0.13) |
| Headed bio-corkscrews (open RCR) | Cummins 2003 ⁷³ Operative technique Prospective cohort | 3 | 9 | 0.33 (0.12-0.65) |
| Open RCR & augmentation | Audenaert 2006 ⁵⁶ Operative augmentation BA | 1 | 39 | 0.03 (0.005-0.13) |

Reoperation. Seven studies provided data on the need for reoperation (three trials,^{98,118,119} two cohort studies,^{63,73} and two uncontrolled studies^{55,70}) (Table 35). Overall, the rates of reoperation from six studies that examined operative approach ranged from 0 to 0.24; one study¹¹⁹ reported a rate higher than 0.04. Rates of reoperation for a variety of operative techniques were provided by single studies and ranged from 0 to 0.06.

Table 35. Reoperation

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|------------------|--|---|----------------|---------------------|
| Operative | | | | |
| Open RCR | Cofield 2001 ⁷⁰ Operative approach BA | 4 (hypertrophic bursal scar excision (2); glenohumeral arthritis (1); unknown (1)) | 105 | 0.04 (0.02-0.09) |

AC = acromioclavicular; BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair; RCT = randomized controlled trial
*No group specification

Table 35. Reoperation (continued)

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|--------------------------------------|--|-------------------------------|----------------|----------------------|
| Open RCR (continued) | Mohtadi 2008 ¹¹⁸ Operative approach RCT | 0 | 29 | 0 (0.00-0.09) |
| | Montgomery 1994 ¹¹⁹ Operative approach CCT | 4 | 50 | 0.08 (0.03-0.19) |
| Mini-open RCR | Kim 2003 ⁹⁸ Operative approach CCT | 0 | 34 | 0 (0.00-0.07) |
| | Mohtadi 2008 ¹¹⁸ Operative approach RCT | 0 | 31 | 0 (0.00-0.08) |
| Arthroscopic RCR | Kim 2003 ⁹⁸ Operative approach CCT | 0 | 42 | 0 (0.00-0.06) |
| Arthroscopic debridement | Montgomery 1994 ¹¹⁹ Operative approach CCT | 9 | 38 | 0.24 (0.13-0.39) |
| | Klinger 2005 ⁵⁵ Operative approach BA | 1 (AC joint tenderness) | 33 | 0.03 (0.005-0.15) |
| Biceps tenotomy vs. tenodesis | Boileau 2007 ⁶³ Operative approach Retrospective cohort | 2 * | 72 | 0.03 (0.008-0.10) |
| Mitek metal suture anchor (open RCR) | Cummins 2003 ⁷³ Operative technique Prospective cohort | 1 | 18 | 0.06 (0.01-0.26) |
| Headed bio-corkscrews (open RCR) | Cummins 2003 ⁷³ Operative technique Prospective cohort | 0 (irritable shoulder) | 9 | 0 (0.00-0.23) |

Infection. Twenty-seven studies provided data on infections (four trials,^{61,118,158,159} seven cohort studies,^{57,63,65,73,97,102,128} and 16 uncontrolled studies^{55,62,67,69,70,85,87,91,94,105,107,113,126,127,135,141}) (Table 36). Overall, the rates of infection from 20 studies that examined operative approach ranged from 0 to 0.06 with most studies (13/20) reporting no infections. Rates of infection for various operative techniques and augmentations were provided by single studies and ranged from 0 to 0.11. Two RCTs^{158,159} provided data on infection rates for postoperative rehabilitation, both reporting similar infection rates (range: 0 to 0.06).

Table 36. Infection

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|------------------------------|--|--------|----------------|----------------------|
| Operative Open RCR | Baker 1995 ⁵⁷ Operative approach Retrospective cohort | 1 | 20 | 0.05 (0.01-0.24) |
| | Cofield 2001 ⁷⁰ Operative approach BA | 2 | 105 | 0.02 (0.005-0.07) |

BA = before-and-after; CI = confidence interval; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial; w/ = with

Table 36. Infection (continued)

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) | |
|----------------------|--|--|----------------|----------------------|----------------------|
| Open RCR (continued) | Gazielly 1994 ⁸⁷ Operative approach BA | 0 | 100 | 0 (0.00-0.03) | |
| | Hsu 2007 ⁹¹ Operative approach BA | 0 | 47 | 0 (0.00-0.05) | |
| | Mohtadi 2008 ¹¹⁸ Operative approach RCT | 0 | 29 | 0 (0.00-0.09) | |
| | Pai 2001 ¹²⁶ Operative approach BA | 2 | 58 | 0.04 (0.01-0.12) | |
| Mini-open RCR | Baker 1995 ⁵⁷ Operative approach Retrospective cohort | 1 | 16 | 0.06 (0.01-0.28) | |
| | Kose 2008 ¹⁰² Operative approach Retrospective cohort | 1 | 25 | 0.04 (0.007-0.20) | |
| | Mohtadi 2008 ¹¹⁸ Operative approach RCT | 0 | 31 | 0 (0.00-0.08) | |
| Open / mini-open RCR | Buess 2005 ⁶⁵ Operative approach Prospective cohort | 1 | 29 | 0.03 (0.006-0.17) | |
| Arthroscopic RCR | Boileau 2005 ⁶² Operative approach BA | 0 | 65 | 0 (0.00-0.04) | |
| | Buess 2005 ⁶⁵ Operative approach Prospective cohort | 0 | 30 | 0 (0.00-0.08) | |
| | Charousset 2008 ⁶⁷ Operative approach BA | 0 | 104 | 0 (0.00-0.03) | |
| | Ide 2007 ⁹⁴ Operative approach BA | 0 | 20 | 0 (0.00-0.12) | |
| | Kose 2008 ¹⁰² Operative approach Retrospective cohort | 0 | 25 | 0 (0.00-0.10) | |
| | Kose 2008 ¹⁰² Operative approach Retrospective cohort | 0 | 25 | 0 (0.00-0.10) | |
| | Lafosse 2007 ¹⁰⁵ Operative approach BA | 0 | 17 | 0 (0.00-0.14) | |
| | Lichtenberg 2006 ¹⁰⁷ Operative approach BA | 0 | 53 | 0 (0.00-0.05) | |
| | McBirnie 2005 ¹¹³ Operative approach BA | 1 | 53 | 0.02 (0.003-0.10) | |
| | Arthroscopic RCR (continued) | Park 2004 ¹²⁷ Operative approach Cohort – BA data | 0 | 22 | 0 (0.00-0.11) |
| | | Tauro 2004 ¹⁴¹ Operative approach BA | 1 | 42 | 0.02 (0.004-0.12) |

Table 36. Infection (continued)

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|--|--------|----------------|----------------------|
| Arthroscopic RCR & biceps tenodesis | Checchia 2005 ⁸⁹ Operative approach BA | 0 | 15 | 0 (0.00-0.15) |
| Open debridement | Gartsman 1997 ⁸⁵ Operative approach BA | 1 | 33 | 0.03 (0.005-0.15) |
| Arthroscopic debridement | Klinger 2005 ⁵⁵ Operative approach BA | 0 | 33 | 0 (0.00-0.08) |
| Biceps tenotomy vs. tenodesis | Boileau 2007 ⁶³ Operative approach Retrospective cohort | 1 † | 72 | 0.01 (0.003-0.07) |
| Double-row fixation | Park 2008 ¹²⁸ Operative technique Prospective cohort | 0 | 38 | 0 (0.00-0.07) |
| Single-row fixation | Park 2008 ¹²⁸ Operative technique Prospective cohort | 2 | 40 | 0.05 (0.01-0.17) |
| Mason-Allen technique with non-absorbable sutures | Boehm 2005 ⁶¹ Operative technique RCT | 2 | 49 | 0.04 (0.01-0.14) |
| Kessler technique with absorbable sutures | Boehm 2005 ⁶¹ Operative technique RCT | 1 | 44 | 0.02 (0.004-0.12) |
| Mitek metal suture anchor | Cummins 2003 ⁷³ Operative technique Prospective cohort | 0 | 18 | 0 (0.00-0.13) |
| Headed bio-corkscrews | Cummins 2003 ⁷³ Operative technique Prospective cohort | 1 | 9 | 0.11 (0.02-0.44) |
| Open RCR & augmentation | Scheibel 2007 ¹³⁵ Operative augmentation BA | 1 | 20 | 0.05 (0.01-0.24) |
| RCR w/ McLaughlin procedure | Ito 2003 ⁹⁷ Operative augmentation Retrospective cohort | 0 | 17 | 0 (0.00-0.14) |
| RCR w/ patch graft | Ito 2003 ⁹⁷ Operative augmentation Retrospective cohort | 0 | 13 | 0 (0.00-0.17) |
| Postoperative Rehabilitation | | | | |
| Continuous passive motion & PT program | LaStayo 1998 ¹⁵⁸ Post-op Rehab RCT | 1 | 17 | 0.06 (0.01-0.27) |
| | Michael 2005 ¹⁵⁹ Post-op rehab RCT | 2 | 34 | 0.06 (0.02-0.19) |
| PT alone | LaStayo 1998 ¹⁵⁸ Post-op Rehab RCT | 0 | 15 | 0 (0.00-0.15) |
| | Michael 2005 ¹⁵⁹ Post-op rehab RCT | 1 | 21 | 0.05 (0.01-0.23) |

Local reaction to suture material (sinus tract). One retrospective cohort study¹³⁷ provided data on local reaction to suture material (Table 37). The rate of local reaction to suture material ranged from 0 in the mini-open RCR to 0.03 in the arthroscopic RCR.

Table 37. Local reaction to suture material (sinus tract)

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|------------------|---|--------|----------------|----------------------|
| Operative | | | | |
| Mini-open RCR | Severud 2003 ¹³⁷ Operative approach Retrospective cohort | 0 | 29 | 0 (0.00-0.09) |
| Arthroscopic RCR | Severud 2003 ¹³⁷ Operative approach Retrospective cohort | 1 | 35 | 0.03 (0.005-0.15) |

CI = confidence interval; RCR = rotator cuff repair

Biceps tendon disruption/inflammation. One prospective cohort study⁵⁴ provided data on biceps tendon disruption/inflammation (Table 38). The rate of biceps tendon disruption/inflammation in arthroscopic RCR of bioabsorbable polymerized lactic acid tacs versus suture tying was 0.16 (0.05 for disruption/ 0.10 for inflammation) with no group specification.

Table 38. Biceps tendon disruption/inflammation

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|---|--------|----------------|---------------------|
| Operative | | | | |
| Bioabsorbable PGA tacs vs. suture tying (arthroscopic RCR) | Bennett 2004 ⁵⁴ Operative technique Prospective cohort | 3 * | 19 | 0.16 (0.06-0.38) |

CI = confidence interval; PGA = Polymerized lactic acid tack; RCR = rotator cuff repair

*No group specification

Reactive synovitis. One BA study⁵⁶ provided data on reactive synovitis (Table 39). There were no reactive synovitis events in 39 patients undergoing open RCR with augmentation.

Table 39. Reactive synovitis

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|--|--------|----------------|------------------|
| Operative | | | | |
| Open RCR & augmentation (polyester graft) | Audenaert 2006 ⁵⁶ Operative augmentation BA | 0 | 39 | 0 (0-0.06) |

BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair

Tendon necrosis. One prospective cohort study¹¹² and one retrospective cohort study¹⁵¹ provided data on tendon necrosis (Table 40). The rates from the two studies were dissimilar with the prospective cohort reporting a rate of 0.01 and the retrospective cohort reporting a rate of 0.23.

Table 40. Tendon necrosis

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|---|--------------------------------|----------------|----------------------|
| Operative | | | | |
| Mattress suture vs. transosseus suture (arthroscopic RCR) | Matis 2006 ¹¹² Operative technique Prospective cohort | 1 * (aseptic necrosis) | 96 | 0.01 (0.002-0.06) |
| Staple fixation (arthroscopic RCR) | Wilson 2002 ¹⁵¹ Operative technique Retrospective cohort | 8 | 35 | 0.23 (0.12-0.39) |
| Side-to-side suture (arthroscopic RCR) | Wilson 2002 ¹⁵¹ Operative technique Retrospective cohort | NR (mild & medium necrosis) | 65 | NR |

CI = confidence interval; RCR = rotator cuff repair

*No group specification

Wound dehiscence. One CCT¹¹⁹ provided data on wound dehiscence (Table 41). The rate of dehiscence ranged from 0 for arthroscopic debridement and 0.02 for open RCR.

Table 41. Wound dehiscence

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|--------------------------|---|--------|----------------|----------------------|
| Operative | | | | |
| Open RCR | Montgomery 1994 ¹¹⁹ Operative approach CCT | 1 | 50 | 0.02 (0.004-0.11) |
| Arthroscopic debridement | Montgomery 1994 ¹¹⁹ Operative approach CCT | 0 | 38 | 0 (0.00-0.07) |

CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair

Delayed wound healing. One prospective cohort study¹²⁸ provided data on wound healing (Table 42). The rate of delayed wound healing ranged from 0 in single-row arthroscopic RCR to 0.03 in double-row arthroscopic RCR.

Table 42. Delayed wound healing

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---------------------|---|--------|----------------|----------------------|
| Operative | | | | |
| Single-row fixation | Park 2008 ¹²⁸ Operative technique Prospective cohort | 0 | 40 | 0 (0.00-0.06) |
| Double-row fixation | Park 2008 ¹²⁸ Operative technique Prospective cohort | 1 | 38 | 0.03 (0.005-0.13) |

CI = confidence interval

Reflex sympathetic dystrophy. Eight studies (one trial,¹⁵⁸ two cohort studies,^{53,63} and five uncontrolled studies^{87,91,105,113,126}) provided data on reflex sympathetic dystrophy (Table 43). Overall, the rates of dystrophy from seven studies that examined operative approach were consistent and ranged from 0 to 0.13. One study¹⁵⁸ compared physical therapy alone with continuous passive motion and physical therapy and reported rates of 0.7 and 0, respectively.

Table 43. Reflex sympathetic dystrophy

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|--|----------------|----------------|----------------------|
| Operative | | | | |
| Open RCR | Hsu 2007 ⁹¹ Operative approach BA | 1 | 47 | 0.02 (0.004-0.11) |
| | Gazielly 1994 ⁸⁷ Operative approach BA | 2 | 100 | 0.02 (0.006-0.07) |
| | Pai 2001 ¹²⁶ Operative approach BA | 1 | 58 | 0.02 (0.003-0.09) |
| Arthroscopic RCR | Lafosse 2007 ¹⁰⁵ Operative approach BA | 2 | 17 | 0.12 (0.03-0.34) |
| | McBirnle 2005 ¹¹³ Operative approach BA | 1 | 53 | 0.02 (0.003-0.10) |
| Arthroscopic debridement with tenotomy | Klinger 2005 ⁵³ Operative approach Retrospective cohort | 3 | 24 | 0.13 (0.04-0.31) |
| Arthroscopic debridement without tenotomy | Klinger 2005 ⁵³ Operative approach Retrospective cohort | 0 | 17 | 0 (0.00-0.14) |
| Biceps tenotomy vs. tenodesis | Boileau 2007 ⁶³ Operative approach Retrospective cohort | 1 [†] | 72 | 0.01 (0.003-0.07) |
| Postoperative Rehabilitation | | | | |
| Continuous passive motion & PT program | LaStayo 1998 ¹⁵⁸ Post-op rehab RCT | 0 | 17 | 0 (0.00-0.14) |
| PT alone | LaStayo 1998 ¹⁵⁸ Post-op rehab RCT | 1 | 15 | 0.07 (0.01-0.30) |

BA = before-and-after; CI = confidence interval; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial

[†]No group specification

Neurologic injury. Twelve studies (Table 44) (three trials,^{93,98,119} two cohort studies,^{96,97} and seven uncontrolled studies^{55,62,87,91,94,126,141}) provided data on postoperative neurologic injury. Overall, the rates of injury from 10 studies that examined operative approach were consistent and ranged from 0 to 0.06. Two studies examining operative augmentation reported no events.

Table 44. Neurological injury

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|------------------|---|--------|----------------|----------------------|
| Operative | | | | |
| Open RCR | Gazielly 1994 ⁸⁷ Operative approach BA | 2 | 100 | 0.02 (0.006-0.07) |
| | Hsu 2007 ⁹¹ Operative approach BA | 0 | 47 | 0 (0.00-0.05) |

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair; RCT = randomized controlled trial

Table 44. Neurological injury (continued)

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|---|--|----------------|----------------------|
| Open RCR (continued) | Iannotti 2006 ⁹³ Operative augmentation RCT | 0 | 15 | 0 (0.00-0.15) |
| | Ide 2005 ⁹⁶ Operative approach Prospective cohort | 3 | 50 | 0.06 (0.02-0.16) |
| | Montgomery 1994 ¹¹⁹ Operative approach CCT | 1 | 50 | 0.02 (0.004-0.11) |
| | Pai 2001 ¹²⁶ Operative approach BA | 2 | 58 | 0.02 (0.01-0.12) |
| Mini-open RCR | Kim 2003 ⁹⁸ Operative approach CCT | 0 | 34 | 0 (0.00-0.07) |
| Arthroscopic RCR | Boileau 2005 ⁶² Operative approach BA | 0 | 65 | 0 (0.00-0.04) |
| | Ide 2007 ⁹⁴ Operative approach BA | 1 | 20 | 0.05 (0.01-0.24) |
| | Ide 2005 ⁹⁶ Operative approach Prospective cohort | 0 | 50 | 0 (0.00-0.05) |
| | Kim 2003 ⁹⁸ Operative approach CCT | 0 | 42 | 0 (0.00-0.06) |
| | Tauro 2004 ¹⁴¹ Operative approach BA | 0 | 42 | 0 (0.00-0.06) |
| | Arthroscopic debridement | Klinger 2005 ⁵⁵ Operative approach BA | 0 | 33 |
| Montgomery 1994 ¹¹⁹ Operative approach CCT | | 0 | 38 | 0 (0.00-0.07) |
| Open RCR & porcine augmentation | Iannotti 2006 ⁹³ Augmentation RCT | 0 | 15 | 0 (0.00-0.15) |
| Repair w/ McLaughlin procedure | Ito 2003 ⁹⁷ Operative technique Retrospective cohort | 0 | 17 | 0 (0.00-0.14) |
| Repair w/ Patch graft | Ito 2003 ⁹⁷ Operative technique Retrospective cohort | 0 | 13 | 0 (0.00-0.17) |

Fracture of the greater tuberosity. One prospective cohort study¹¹² provide data on fracture of the greater tuberosity of humerus bone (Table 45). The rate of fracture of the greater tuberosity was 0.01 in the study with no group specification.

Table 45. Fracture of the greater tuberosity

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|--|--|--------|----------------|----------------------|
| Operative | | | | |
| Mattress suture vs. transosseus suture (arthroscopic RCR) | Matis 2006 ¹¹² Operative technique Prospective cohort | 1 * | 96 | 0.01 (0.002-0.06) |

CI = confidence interval; RCR = rotator cuff repair;

*No group specification

Heterotopic bone formation. One retrospective cohort study¹²¹ provided data on heterotopic bone formation (Table 46). The rate of heterotopic bone formation ranged from 0.19 in the arthroscopic debridement to 0.27 in the open RCR.

Table 46. Heterotopic bone formation

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|--------------------------|---|--------|----------------|---------------------|
| Operative | | | | |
| Open RCR | Motycka 2004 ¹²¹ Operative approach Retrospective cohort | 9 | 33 | 0.27 (0.15-0.44) |
| Arthroscopic debridement | Motycka 2004 ¹²¹ Operative approach Retrospective cohort | 6 | 31 | 0.19 (0.09-0.36) |

CI = confidence interval; RCR = rotator cuff repair

Postoperative sudden pain / impingement syndrome. One RCT¹⁵⁹ provided data on postoperative sudden pain and impingement syndrome (Table 47). The rate of postoperative sudden pain ranged from 0 in physical therapy alone to 0.03 in continuous passive motion with physical therapy program, while the rate of postoperative impingement syndrome ranged from 0 in continuous passive motion with physical therapy program to 0.05 in physical therapy alone.

Table 47. Postoperative pain or impingement syndrome

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|--|---|--------|----------------|--------------------------|
| Postoperative Rehabilitation | | | | |
| Continuous passive motion & PT program | Michael 2005 ¹⁵⁹ Post-op rehab RCT | 1 / 0 | 34 | 0.03 (0.005-0.15) / 0 |
| PT alone | Michael 2005 ¹⁵⁹ Post-op rehab RCT | 0 / 1 | 21 | 0 / 0.05 (0.009-0.23) |

CI = confidence interval; PT = physical therapy; RCT = randomized controlled trial

Arthropathy. One retrospective cohort study¹²¹ and one BA study¹³⁶ provided data on arthropathy (Table 48). The cohort study compared open RCR with arthroscopic debridement and rates for the two arms were 0.88 and 0.32, respectively. The BA study examined arthroscopic debridement and reported a rate of 0.04.

Table 48. Arthropathy

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|-------------------------------|---|---|----------------|----------------------|
| Operative | | | | |
| Open RCR | Motycka 2004 ¹²¹ Operative approach Retrospective cohort | 29 (Post-op AC joint arthrosis) | 33 | 0.88 (0.73-0.95) |
| Arthroscopic debridement | Motycka 2004 ¹²¹ Operative approach Retrospective cohort | 10 (Post-op AC joint arthrosis) | 31 | 0.32 (0.19-0.50) |
| Arthroscopic debridement only | Scheibel 2004 ¹³⁶ Operative approach BA | 1 (Cuff tear arthropathy/ was excluded finally, because of treatment with prosthesis) | 23 | 0.04 (0.008-0.21) |

AC = acromioclavicular; BA = before-and-after; CI = confidence interval; post-op = postoperative; RCR = rotator cuff repair

Glenohumeral instability. One postoperative rehabilitation study¹⁵⁸ provided data glenohumeral instability in patients undergoing continuous passive motion or manual passive range of motion exercises (Table 49). In both treatment arms, there were no cases on glenohumeral instability reported.

Table 49. Glenohumeral instability

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|-------------------------------------|---|--------|----------------|------------------|
| Postoperative Rehabilitation | | | | |
| Continuous passive motion | LaStayo 1998 ¹⁵⁸ Post-op rehab RCT | 0 | 17 | 0 (0-0.14) |
| Manual passive ROM exercises | LaStayo 1998 ¹⁵⁸ Post-op rehab RCT | 0 | 15 | 0 (0-0.15) |

CI = confidence interval; RCT = randomized clinical trial; ROM = range of motion; post-op = postoperative

Stiffness. Twenty-two studies provided data on stiffness following treatment (four trials,^{68,93,118,119} five cohort studies,^{65,137,147,150,152} three cohort studies with BA data,^{90,127,142} and ten BA studies^{55,62,64,67,103,107,126,131,163,167}) (Table 50). Overall, the rates of postoperative stiffness from 18 studies that examined operative approach ranged from 0 to 0.17 with only four studies reporting no events.^{93,107,118,127} Rates for operative techniques and nonoperative treatment were generally provided by single studies and ranged from 0 to 0.6 and 0.04 to 0.07, respectively. One study⁹³ examining operative augmentation reported no events.

Table 50. Stiffness

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|--|--|----------------|----------------------|
| Operative | | | | |
| Open RCR | Henn 2008 ⁹⁰ Operative approach Cohort – BA data | 1 | 39 | 0.03 (0.005-0.13) |
| | Iannotti 2006 ⁹³ Operative augmentation RCT | 0 | 15 | 0 (0.00-0.15) |
| | Mohtadi 2008 ¹¹⁸ Operative approach RCT | 0 | 29 | 0 (0.00-0.09) |
| | Montgomery 1994 ¹¹⁹ Operative approach CCT | 1 | 50 | 0.02 (0.004-0.11) |
| | Pai 2001 ¹²⁶ Operative approach BA | 1 | 58 | 0.02 (0.003-0.09) |
| | Prasad 2005 ¹³¹ Operative approach BA | 1 | 40 | 0.03 (0.004-0.13) |
| | Mini-open RCR | Boszotta 2004 ⁶⁴ Operative approach BA | 1 | 84 |
| Mohtadi 2008 ¹¹⁸ Operative approach RCT | | 0 | 31 | 0 (0.00-0.08) |
| Severud 2003 ¹³⁷ Operative approach Retrospective cohort | | 4 | 29 | 0.14 (0.06-0.31) |
| Verma 2006 ¹⁴⁷ Operative approach Retrospective cohort | | 0 | 33 | 0 (0.00-0.08) |
| Warner 2005 ¹⁵⁰ Operative approach Retrospective cohort | | 2 | 12 | 0.17 (0.05-0.45) |
| Youm 2005 ¹⁵² Operative approach Retrospective cohort | | 0 | 42 | 0 (0.00-0.06) |
| Open / mini-open RCR | | Buess 2005 ⁶⁵ Operative approach Prospective cohort | 1 | 29 |
| Arthroscopic RCR | Boileau 2005 ⁶² Operative approach BA | 1 | 65 | 0.02 (0.003-0.08) |
| | Buess 2005 ⁶⁵ Operative approach Prospective cohort | 4 | 30 | 0.13 (0.05-0.30) |
| | Charousset 2008 ⁶⁷ Operative approach BA | 8 | 104 | 0.08 (0.04-0.14) |
| | Kreuz 2005 ¹⁰³ Operative approach BA | 1 | 16 | 0.06 (0.01-0.28) |
| | Lichtenberg 2006 ¹⁰⁷ Operative approach BA | 0 | 53 | 0 (0.00-0.05) |

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; NSAID = non-steroidal anti-inflammatory drug; RCR = rotator cuff repair; RCT = randomized controlled trial

Table 50. Stiffness (continued)

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|---|--|----------------|----------------------|
| Arthroscopic RCR (continued) | Park 2004 ¹²⁷ Operative approach Cohort – BA data | 0 | 22 | 0 (0.00-0.11) |
| | Severud 2003 ¹³⁷ Operative approach Retrospective cohort | 0 | 35 | 0 (0.00-0.07) |
| | Tauro 2006 ¹⁴² Operative approach Cohort – BA data | 3 | 72 | 0.04 (0.01-0.12) |
| | Verma 2006 ¹⁴⁷ Operative approach Retrospective cohort | 1 | 38 | 0.03 (0.005-0.13) |
| | Warner 2005 ¹⁵⁰ Operative approach Retrospective cohort | 1 | 9 | 0.11 (0.02-0.44) |
| | Youm 2005 ¹⁵² Operative approach Retrospective cohort | 2 | 42 | 0.05 (0.1-0.16) |
| | Arthroscopic debridement | Klinger 2005 ⁵⁵ Operative approach BA | 1 | 33 |
| Montgomery 1994 ¹¹⁹ Operative approach CCT | | 1 | 38 | 0.03 (0.005-0.13) |
| Single-row arthroscopic RCR | Charousset 2007 ⁶⁸ Operative technique RCT | 2 | 33 | 0.06 (0.02-0.20) |
| Double-row arthroscopic RCR | Charousset 2007 ⁶⁸ Operative technique RCT | 0 | 28 | 0 (0.00-0.09) |
| Open RCR & porcine augmentation | Iannotti 2006 ⁹³ Operative augmentation RCT | 0 | 15 | 0 (0.00-0.15) |
| Nonoperative | | | | |
| Nonoperative treatment (analgesic, NSAID, steroid injection, reeducation program) | Koubaa 2006 ¹⁶⁷ Nonoperative BA | 1 | 24 | 0.04 (0.007-0.20) |
| | Ghroubi 2008 ¹⁶³ Nonoperative BA | 4 | 59 | 0.07 (0.03-0.16) |

Secondary rupture of long head of biceps. One BA study¹¹⁰ provide data on secondary rupture of the long head of biceps (LHB) (Table 51). The rate of secondary rupture of LHB in operative stabilization of LHB was 0.05.

Table 51. Secondary rupture of LHB

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|----------------------------------|---|--------|----------------|----------------------|
| Operative | | | | |
| Stabilization of LHB w/ open RCR | Maier 2007 ¹¹⁰ Operative approach BA | 1 | 21 | 0.05 (0.009-0.23) |

BA = before-and-after; CI = confidence interval; LHB = long head of biceps; RCR = rotator cuff repair; w/ = with

Seroma. Five uncontrolled studies^{64,70,77,78,85} provided data on seroma for operative approaches (Table 52). The rates of seroma were consistent and ranged from 0.01 to 0.06.

Table 52. Seroma

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|----------------------------------|--|--------------------------------|----------------|----------------------|
| Operative | | | | |
| Open RCR | Cofield 2001 ⁷⁰ Operative approach BA | 1 (at graft donor site) | 105 | 0.01 (0.002-0.05) |
| Mini-open RCR | Boszotta 2004 ⁶⁴ Operative approach BA | 1 (in the area of incision) | 84 | 0.01 (0.002-0.06) |
| | Deutsch 2008 ⁷⁷ Operative approach Cohort – BA data | 1 | 39 | 0.03 (0.005-0.13) |
| | Ellman 1993 ⁷⁸ Operative approach Cohort – BA data | 1 | 40 | 0.03 (0.004-0.13) |
| Open debridement & acromioplasty | Gartsman 1997 ⁸⁵ Operative approach BA | 2 | 33 | 0.06 (0.02-0.20) |

BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair

Lymphedema. One BA study¹⁶³ provided data on lymphedema (Table 53). The rate of lymphedema in the nonoperative treatment was 0.02.

Table 53. Lymphedema

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|---|--------|----------------|----------------------|
| Nonoperative | | | | |
| Nonoperative treatment (Analgesic, NSAID, steroid injection, reeducation program) | Ghroubi 2008 ¹⁶³ Nonoperative BA | 1 | 59 | 0.02 (0.003-0.09) |

BA = before-and-after; CI = confidence interval; NSAID = non-steroidal anti-inflammatory

Hematoma. Three BA studies^{59,103,136} provided data on hematoma (Table 54). The rates from all three studies were consistent, 0.08, 0.06, and 0.05, respectively.

Table 54. Hematoma

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|--------------------------|--|--------|----------------|----------------------|
| Operative | | | | |
| Arthroscopic RCR | Bennett 2003 ⁵⁹ Operative approach BA | 2 | 24 | 0.08 (0.02-0.26) |
| | Kreuz 2005 ¹⁰³ Operative approach BA | 1 | 16 | 0.06 (0.01-0.28) |
| Arthroscopic debridement | Scheibel 2004 ¹³⁶ Operative approach BA | 1 | 22 | 0.05 (0.008-0.22) |

BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair

Cosmetic deformity. Three studies (one trial,⁹⁸ one cohort study,⁵³ and one uncontrolled study⁵⁵) provided data on cosmetic deformity for operative approaches (Table 55). The rates from the three studies were consistent among designs and ranged from 0 to 0.08.

Table 55. Cosmetic deformity

| Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|--|--------|----------------|----------------------|
| Operative | | | | |
| Mini-open RCR | Kim 2003 ⁹⁸ Operative approach CCT | 2 | 34 | 0.06 (0.02-0.19) |
| Arthroscopic RCR | Kim 2003 ⁹⁸ Operative approach CCT | 0 | 42 | 0 (0.00-0.06) |
| Arthroscopic debridement only | Klinger 2005 ⁵⁵ Operative approach BA | 1 | 33 | 0.03 (0.005-0.15) |
| Arthroscopic debridement with tenotomy | Klinger 2005 ⁵³ Operative approach Retrospective cohort | 2 | 24 | 0.08 (0.02-0.26) |
| Arthroscopic debridement without tenotomy | Klinger 2005 ⁵³ Operative approach Retrospective cohort | 0 | 17 | 0 (0.00-0.14) |

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair

Other medical complications. Six studies reported on six other medical complications (Table 56): skin hypersensitivity,⁹⁸ deep vein thrombosis,^{70,159} myocardial infarction,⁷⁰ laryngeal nerve palsy,¹²⁷ allergic reaction to oral anti-inflammatory drugs,¹¹³ and massive intraoperative swelling of the neck.¹¹² The rates for all events were consistent and ranged from 0 to 0.05.

Table 56. Other medical complications

| Complication | Intervention | Author, year Category Design | Events | Sample size | Rate (95% CI) |
|---|---|--|--------|----------------|----------------------|
| Skin hypersensitivity | Mini-open vs. arthroscopic RCR | Kim 2003 ⁹⁸ Operative approach CCT | 1 * | 76 | 0.01 (0.002-0.07) |
| DVT | Open RCR | Cofield 2001 ⁷⁰ Operative approach BA | 1 | 105 | 0.01 (0.002-0.05) |
| | Continuous passive motion & PT program | Michael 2005 ¹⁵⁹ German Post-op rehab RCT | 0 | 34 | 0 (0.00-0.07) |
| | PT alone | Michael 2005 ¹⁵⁹ German Post-op rehab RCT | 1 | 21 | 0.05 (0.009-0.23) |
| MI | Open RCR | Cofield 2001 ⁷⁰ Operative approach BA | 1 | 105 | 0.01 (0.002-0.05) |
| Laryngeal nerve palsy | Open RCR | Park 2004 ¹²⁷ Operative approach Cohort – BA data | 1 | 22 | 0.05 (0.008-0.22) |
| Allergic reaction to oral anti-inflammatory drugs | Arthroscopic RCR | McBirnie 2005 ¹¹³ Operative approach BA | 1 | 53 | 0.02 (0.003-0.10) |
| Massive intraoperative swelling of the neck | Mattress suture vs. transosseus suture (arthroscopic RCR) | Matis 2006 ¹¹² Operative technique Prospective cohort | 1 | 96 | 0.01 (0.002-0.06) |

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; DVT = deep vein thrombosis; MI = myocardial infarction; PT = physical therapy; RCR = rotator cuff repair; RCT = rotator cuff repair;
*No group specification

Table 57. No complications

| Intervention | Author, year Category Design |
|--|---|
| Open RCR | McCallister 2005 ¹¹⁴ Operative approach BA |
| | Rokito 1999 ¹³³ Operative approach BA |
| Arthroscopic RCR | Cole 2007 ⁷¹ Operative approach BA |
| | Lafosse 2007 ¹⁰⁴ Operative approach BA |
| | Sugaya 2007 ¹³⁸ Operative approach BA |
| | Deutsch 2007 ⁷⁶ Operative approach BA |
| | Ide 2005 ⁹⁵ Operative approach BA |
| Open debridement & tuberplasty | Fenlin 2002 ⁷⁹ Operative approach BA |
| Arthroscopic RCR & SLAP repair vs. arthroscopic RCR & biceps tenotomy | Franceschi 2008 ⁸⁰ Operative approach RCT |
| RCR & tenodesis with detachment vs. RCR & tenodesis without detachment | Franceschi 2007b ⁸¹ Operative approach RCT |
| Classic open acromioplasty vs. modified open acromioplasty | Torrens 2003 ¹⁴³ Operative approach CCT |
| Complete open RCR vs. partial open RCR vs. debridement | Moser 2007 ¹²⁰ Operative approach Retrospective cohort |
| Open RCR & augmentation | Zumstein 2008 ¹⁵³ Operative augmentation BA |
| | Funch 2006 ⁸³ Operative augmentation BA |
| Double-row vs. single-row arthroscopic RCR | Franceschi 2007a ⁸² Operative technique RCT |
| | Sugaya 2005 ¹³⁹ Operative technique Prospective cohort |
| Ultrasonic suture welding vs. hand-tied knots (mini-open RCR) | McIntyre 2006 ¹¹⁵ Operative technique Retrospective cohort |
| Arthroscopic RCR & platelet-rich plasma augmentation | Randelli 2008 ¹³² Operative augmentation BA |

BA = before-and-after; CCT = controlled clinical trial; RCR = rotator cuff repair; RCT = randomized controlled trial; SLAP = superior labrum from anterior to posterior

Table 57. No complications (continued)

| Intervention | Author, year Category Design |
|---|---|
| Land-based & Aquatic therapy program vs. land-based program | Brady 2008 ¹⁵⁵ Post-op rehab CCT |
| Sodium hyaluronate vs. dexamethasone | Shibata 2001 ¹⁷¹ Nonoperative approach RCT |
| Pulsed radiofrequency ablation | Kane 2008 ¹⁶⁶ Nonoperative approach BA |

Table 58. Complications not reported

| Intervention | Author, year Category Design |
|---|--|
| Open RCR | Caniggia 1995 ⁶⁶ Operative approach BA |
| | Cools 2006 ⁷² Operative approach Cohort – BA data |
| | Iannotti 1996 ⁹² Operative approach BA |
| | Kirschenbaum 1993 ⁹⁹ Operative approach BA |
| | Mallon 2004 ¹¹¹ Operative approach Cohort – BA data |
| | Misamore 1995 ¹¹⁷ Operative approach Cohort – BA data |
| | Trenerly 2005 ¹⁴⁴ Operative approach Case control – BA data |
| | Baysal 2005 ⁵⁸ Operative approach BA |
| | Vitale 2007 ¹⁴⁸ Operative approach BA |
| | Tashjian 2006 ¹⁴⁰ Operative approach BA |
| Open <u>or</u> mini-open RCR | Davidson 2000 ⁷⁴ Operative approach BA |
| Open <u>or</u> mini-open <u>or</u> arthroscopic RCR | Sauerbrey 2005 ¹³⁴ Operative approach Retrospective cohort |
| Open <u>or</u> arthroscopic RCR | Bennett 2003 ⁵² Operative approach Cohort – BA data |

BA = before-and-after; CCT = controlled clinical trial; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial

Table 58. Complications not reported (continued)

| Intervention | Author, year Category Design |
|---|--|
| | Gartsman 1998 ⁸⁴ Operative approach BA |
| | Nam 2008 ¹²² Operative approach Cohort – BA data |
| | Porcellini 2006 ¹³⁰ Operative approach Cohort – BA data |
| | Pillay 1994 ¹²⁹ Operative approach Cohort – BA data |
| Open RCR vs. arthroscopic debridement | Ogilvie-Harris 1993 ¹²⁴ Operative approach CCT |
| Arthroscopic debridement only | Vaz 2000 ¹⁴⁶ Operative approach BA |
| Arthroscopic RCR & acromioplasty vs. arthroscopic RCR alone | Gartsman 2004 ⁸⁶ Operative approach RCT |
| | Milano 2007 ¹¹⁶ Operative approach RCT |
| Arthroscopic decompression | Lim 2005 ¹⁰⁹ Operative approach Cohort – BA data |
| Rehabilitation vs. no rehabilitation | Leroux 1993 ¹⁸⁸ Post-op rehab Retrospective cohort |
| Individualized PT & home exercise program vs. home exercise program | Hayes 2004 ¹⁵⁷ Post-op rehab RCT |
| Home exercise: Videotape-based vs. PT instruction | Roddey 2002 ¹⁶² Post-op rehab RCT |
| Standardized vs. non-standardized PT program | Milroy 2008 ¹⁶⁰ Post-op rehab Retrospective cohort |
| Postoperative rehabilitation | Boissonnault 2007 ¹⁵⁴ Post-op rehab BA (Rehabilitation protocol) |
| Nonoperative treatment | Hawkins 1995 ¹⁶⁴ Nonoperative approach BA (Exercise protocol) |
| | Heers 2005 ¹⁶⁵ Nonoperative approach Cohort – BA data (Home exercise program) |
| | Levy 2008 ¹⁶⁹ Nonoperative approach BA (Anterior deltoid rehabilitation program) |

Table 58. Complications not reported (continued)

| Intervention | Author, year Category Design |
|--------------------------------|---|
| | Scheuermann 1991 ¹⁷⁰ Nonoperative approach BA (Early functional PT and active shoulder support) |
| Nonoperative treatment vs. RCR | Vad 2002 ¹⁴⁵ Operative approach vs. nonoperative approach Retrospective cohort |
| | Yamada 2000 ¹⁷³ Operative approach vs. nonoperative approach Retrospective cohort |

Question 6: Evidence on the Role of Prognostic Factors on Treatment Outcomes

Summary. Overall, 66 of the 122 studies examined the impact of prognostic factors on patient outcomes. General conclusions are limited due to the varied methodologies across studies, particularly the different outcomes for which prognostic factors were evaluated. Variations in findings may also be due to limited sample sizes and potential for type II errors, i.e., failing to find a difference when one actually exists.

Among operative studies, 60 of 102 studies examined effect modifiers. The effect modifiers most often examined were:

- Tear size (n=35): Twenty-one studies found evidence of worse outcomes for larger tears, while 14 studies found no impact of tear size. Most of the studies evaluated operative approaches and there were no patterns in terms of findings by specific operative approach.
- Age (n=25): Fourteen studies found evidence of worse outcomes among older patients, while 11 studies found no impact of age. Most of the studies evaluated operative approaches, and no patterns were seen by operative approach.
- Sex (n=14): Nine studies found no differences in outcomes for men and women. Five studies found differences, however the findings differed with two studies showing better outcomes for women (both evaluating arthroscopic RCR) and three studies favouring men (open RCR, arthroscopic RCR, nonabsorbable versus absorbable sutures).
- WCB status (n=12): Ten studies found no impact of WCB status for open RCR (n=4), arthroscopic RCR (n=5), and nonabsorbable versus absorbable sutures (n=1). Two studies (open RCR; mini-open, open, or arthroscopic RCR) showed worse outcomes for patients with WCB claims.
- Duration of symptoms (n=12): Twelve studies showed no evidence for different outcomes based on duration of symptoms. These included evaluations of arthroscopic RCR (n=5), mini-open or arthroscopic (n=1), open (n=4), and arthroscopic debridement (n=1).
- Preoperative stiffness, range of motion, or strength (n=8): Five studies examining arthroscopic (n=2) and open (n=3) repairs showed worse outcomes with greater preoperative symptoms. Three studies of arthroscopic repairs showed no difference.

Among the others interventions examined in this report, three of nine studies that evaluated postoperative rehabilitation, two of 10 studies evaluating nonoperative interventions, and one study comparing operative with nonoperative interventions examined the impact of various effect modifiers. The variation in interventions, effect modifiers that were examined, and findings across studies preclude any overall interpretations or conclusions.

Effect modifiers by intervention and outcome. We aimed to identify the role of effect modifiers (e.g., patient and clinical characteristics) as moderators of the treatment effect measured in nonoperative, operative and postoperative rehabilitation studies assessing RC tears. Overall, the impact of effect modifiers on patient outcomes was assessed through either subgroup or regression analysis in 66 studies. Due to the small number of studies addressing each intervention and comparison, meta-regression analysis was not feasible. Therefore, the findings from the individual studies that reported data on the role of effect modifiers are presented.

Operative Studies

Of the 102 studies examining the effectiveness of operative interventions, 60 studies (three RCTs,^{61,93,116} one CCT,⁹⁸ five prospective cohort studies,^{54,60,65,96,128} seven retrospective cohort studies,^{57,63,102,108,134,137,152} 12 cohort studies with BA data,^{52,72,77,78,90,111,117,122,125,129,142,144} and 32 BA studies^{55,59,62,64,67,70,71,74,75,83-85,87,88,91,92,94,99,100,103-107,113,114,123,126,131,140,146,153}) explored the role of various patient or clinical factors as effect modifiers. Three of the studies focused on operative techniques,^{54,61,128} three focused on augmentations,^{83,93,153} and the remaining 54 studies examined operative approaches. The effect modifiers were examined using subgroup analysis in 43 studies, regression analysis in 13 studies, both subgroup and regression in two studies, non-parametric tests in one study, and both subgroup analysis and non-parametric tests in one study. The analysis was planned a priori in 35 studies, while 25 studies conducted the analysis post hoc.

Five studies^{60,84,90,125,140} conducted an analysis of the role of effect modifiers on health-related quality of life. The studies used multiple regression models¹⁴⁰ or subgroup analysis^{60,84,90,125} to examine a variety of effect modifiers, including age,⁸⁴ sex,⁸⁴ tear size,^{60,84} WCB status,⁹⁰ number of comorbidities,¹⁴⁰ and preoperative stiffness.¹²⁵ A variety of potential confounding factors were controlled in two studies^{125,140} but they were not explored in the analysis. The investigators of one study concluded that age, but not sex, influences health-related quality of life outcomes. They found that older patients had less improvement in the SF-36 after arthroscopic repair.⁸⁴ In studies investigating tear size, no significant differences in health related quality of life outcomes for patients with small and large tears were found.^{60,84} The author conclusions for other prognostic factors are presented in Table 59.

Fifty-one studies^{52,54,55,57,59-61,63-65,67,71,72,74,77,78,83-85,88,90-92,96,98,100,102-108,111,113,114,116,117,122,123,125,126,128,129,131,134,137,140,146,152,153} conducted an analysis of the role of effect modifiers on functional outcome measures. The studies used subgroup analysis,^{52,54,55,57,59,60,64,65,71,77,78,83-85,90-92,96,98,100,102,103,106-108,113,114,117,122,125,126,128,129,131,134,137,146,152,153} multiple regression analysis^{61,63,67,75,88,93,104,105,111,116,123,140} to examine a various effect modifiers, including age,^{59,61,64,67,71,84,91,102,104,105,107,108,111,113,114,116,123,126,131,146} sex,^{54,59,67,84,111,113,114,116,131,146} tear size,^{57,60,64,65,77,78,84,88,92,96,98,100,104-108,111,113,123,126,128,131,134,137,152} duration of symptoms,^{67,77,98,104,105,126,131} etiology of tear,^{98,104,116} tear pattern,^{64,77} tear type,^{52,55,63,83,91,103,129,153} number of tendons torn,^{63,77,114,123,153} hand dominance,^{61,67,116,146} preoperative strength,^{72,98,126} preoperative shoulder stiffness,^{122,125} preoperative range of motion,^{55,126} preoperative latency,¹⁴⁶ mechanism of injury,¹⁰⁵ smoking status,^{111,131} body mass index,¹³¹ number of comorbidities,¹⁴⁰ WCB status,^{61,67,71,90,92,104,105,113,117} upper-limb heavy work,⁶⁷ nature of work,¹⁴⁶ repair tension,⁷⁴ fatty infiltration,^{63,88,105,116} muscle atrophy,⁸⁸ quality and condition of the biceps tendon,^{64,77,92,105,107,116} tissue quality,^{92,126,146} difficulty of repair,⁹² tendon retraction,¹⁰⁷ acromion type,^{64,98,116,146} acromiohumeral distance,^{63,64} atrophy of teres minor,⁶³ duration of immobilization,⁶⁴ diabetes,⁹¹ glenohumeral arthritis,⁵⁵ presence of subscapularis tear,^{55,116} and

superior migration of humeral head.⁵⁵ The majority of studies found that age was not associated with functional outcome,^{59,64,67,102,104,105,111,114,126} while one found older age to predict better functional score¹¹⁶ and two concluded older age to predict poorer scores.^{61,131} Similarly, gender did not predict functional outcomes in five studies,^{54,59,114,116,131} whereas two studies found males to have better^{61,67} or worse^{84,111} outcomes compared with females. Authors' conclusions regarding the role of tear size on functional outcomes was inconsistent across studies. Studies either reported that small tear size predicted better function,^{57,60,64,78,91,92,96,98,100,106,126,128,131} or reported no influence of tear size on functional outcome.^{61,63,65,77,107,108,111,113,129,134,137,152,153} All of the studies which examined the symptom duration found no effect on functional outcomes.^{67,104,105,126,131} Authors' conclusions for the remaining factors are displayed in Table 59.

Fourteen studies^{57,60,62,71,75,77,83,87,88,93,94,100,107,108,123} assessed the role of effect modifiers on cuff integrity. The studies used subgroup analysis^{57,60,71,77,83,87,94,100,107,108} or multiple regression analysis^{62,75,88,93,123} to examine the effect of various patient factors on cuff integrity, including tear size,^{57,60,62,77,87,88,93,94,100,107,108,123} number of tendons torn,^{77,123} age,^{62,71,75,87,94,107,108,123} sex,⁶² duration of symptoms,⁶² tendon retraction,^{94,107} strength,⁶² fatty infiltration and muscle atrophy,^{83,88} tear pattern,^{71,77,94} biceps pathology,^{71,77,107} tear type,⁸³ time to surgery,⁷¹ duration of preoperative symptoms,⁷⁷ hand dominance,⁷¹ WCB status,^{62,71} and degree of occupational use.⁸⁷ The authors found that the most significant factors affecting cuff integrity were age and tear size. Older age was consistently found to be associated with recurrent tears in all studies investigating this factor.^{62,71,75,87,94,107,108,123} Increased tear size was found to be a significant risk factor for tendon defects in several studies,^{57,60,62,87,88,93,100,123} while four studies found no significant effect of tear size on cuff integrity.^{77,94,107,108} No association was found between sex^{62,71} or duration of preoperative symptoms^{62,71,77} on cuff integrity. Table 59 presents the authors' conclusions for the role of the remaining prognostic factors on cuff integrity.

Fifteen studies^{52,54,59,60,70,71,74,77,98,100,104,111,122,131,140} examined the role of effect modifiers on pain. The studies used subgroup analysis^{52,54,59,60,70,71,77,98,100,111,122,131} or multiple regression analysis^{74,104,140} to examine the effect of various prognostic factors on pain, including age,^{59,70,71,104,111,131} sex,^{54,59,70,71,111,131} tear size,^{60,70,77,98,100,104,111,131} duration of preoperative symptoms,^{70,71,77,98,104,131} WCB,^{71,104,111} etiology of tear,^{70,98,104} biceps pathology or procedure,^{70,71,77} smoking,^{111,131} hand dominance,^{70,71} acromion morphology,^{70,98} tear pattern,^{71,77} side affected,⁷⁰ location of tear,⁷⁰ repair tension,⁷⁴ number of tendons torn,⁷⁷ preoperative strength,⁹⁸ preoperative stiffness,¹²² BMI,¹³¹ and number of comorbidities.¹⁴⁰ The authors' conclusions on the role of these effect modifiers on pain were variable. Older patients were found to have significantly more pain,⁷¹ and significantly less improvement in outcome,¹³¹ in two studies, while two other studies found no association between age and pain level.^{59,104,111} Sex was found not to affect outcomes in three studies,^{54,59,131} yet one study found that men had significantly less postoperative pain than women.⁷⁰ For tear size, several studies found that smaller tear size was associated with less pain than large or massive tears, yet the difference was not statistically significant^{60,70,100} in all but one study.¹³¹ Three studies found no effect of tear size on outcomes.^{77,98,111} Symptom duration was consistently found not to influence the outcome.^{71,98,104,131} The author conclusions for other prognostic factors are presented in Table 59 below.

Nine studies^{60,63,70,77,104,108,122,142,144} examined the role of effect modifiers on range of motion. The studies used subgroup analysis^{60,70,77,108,122,142,144} or regression analysis^{63,104} to examine various prognostic factors including age,^{63,70,104,144} sex,^{63,70,144} tear size,^{60,70,108,142,144} duration of preoperative symptoms,^{77,104,144} biceps pathology,^{77,104} etiology of tear,^{104,144} WCB,^{104,144} time to followup,⁶³ preoperative function,⁶³ number of tendons torn,⁷⁷ preoperative stiffness,¹²² hand

dominance,¹⁴⁴ tear type,¹⁴⁴ and comorbidities.¹⁴⁴ Author conclusions regarding the prognostic factors for range of motion varied. Cofield⁷⁰ reported that older age was associated with lower active range of motion, whereas the results from Deutsch⁷⁷ indicated that age had no affect. Cofield⁷⁰ further reported that men demonstrated significantly better active abduction than women. Four authors^{77,104,108,142} found that tear size had no affect on range of motion, comparatively, two^{60,70} studies found that smaller tears showed better range of motion outcomes after surgery than larger tear sizes. Tauro¹⁴² reported tear size was positively correlated to range of motion. Duration of preoperative symptoms was found to have no effect on postoperative range of motion. Table 59 presents authors’ conclusions for the remaining prognostic factors examined in the studies.

Eleven studies^{62,70,72,77,85,88,99,104,108,122,128} assessed the role of effect modifiers on strength. The studies used subgroup analysis,^{70,72,74,77,85,108,122,128,133} multiple regression analysis,^{62,88,104} or analysis using non-parametric tests.⁹⁹ The patient factors that were examined include age,^{62,70,104,133} sex,^{62,70,72} tear size,^{70,88,99,108,128,133} duration of preoperative symptoms,^{77,104} biceps pathology,^{77,104} preoperative strength,⁶² number of tendons torn,⁷⁷ type of tendon,⁸⁵ fatty infiltration and muscle atrophy,⁸⁸ etiology of tear,¹⁰⁴ preoperative shoulder stiffness,¹²² general health status,¹³³ and WCB.¹⁰⁴ The majority of the 11 studies investigating strength concluded that tear size affected post operative strength; however, results varied. Two studies^{77,108} found no significant effect between tear size and strength, whereas the remaining authors^{62,70,85,99,104,128} concluded that the greater the tear size, the poorer the result achieved for post operative strength. Authors’ conclusions for the remaining factors are displayed in Table 59.

Table 59. Effect modifiers in operative studies

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors’ conclusions |
|--|--|--|-----------------------------------|---|
| Baker CL, ⁵⁷ 1995 Retrospective cohort | G1: Open RCR G2: Mini-open RCR 3.3 yr | Subgroup analysis by tear size (post hoc) | UCLA cuff integrity | All small tears had good-to-excellent results. With large tears, more patients had good-to-excellent results in open than mini-open repair group. Cuff was more likely to be intact for smaller size tear. |
| Bennett WF, ⁵² 2003 BA | Open RCR 3.2 yr (2–4) | Subgroup analysis by tear type (a priori) | ASES CMS % function pain | There is no statistical difference between anterosuperior and posterosuperior tear types for any of the outcomes. |
| Bennett WF, ⁵⁹ 2003 BA | Arthroscopic RCR NR (2–4 yr) | Subgroup analysis by age and sex (post hoc) | ASES CMS pain | Age or sex were not associated with outcomes. |
| Bennett WF, ⁵⁴ 2003 Prospective cohort | G1: Bioabsorbable tacs G2: Suture tying NR (2–4 yr) | Subgroup analysis by sex (a priori) | ASES CMS pain | No significant impact of sex on outcomes. |

AC joint = acromioclavicular joint; ASES = American Shoulder and Elbow Scale; BA = before-and-after; BMI = body mass index; CCT = controlled clinical trial; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand; DM = diabetes mellitus; G = group; JOA = Japanese orthopaedic association; LHB = long head of biceps; NR = not reported; PENN = University of Pennsylvania Shoulder Score; post-op = postoperative; pre-op = preoperative; QOL = quality of life; RCR = rotator cuff repair; RCT = randomized controlled trial; ROM = range of motion; SF-12 = Short form-12; SF-36 = Short Form-36; SSI = shoulder strength index; SST = simple shoulder test; UCLA = University of California Los Angeles Scale; VAS = visual analogue scale; WCB = workers’ compensation board

Table 59. Effect modifiers in operative studies (continued)

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|---|--|---|---|---|
| Bishop J, ⁶⁰ 2006 Prospective cohort | G1: Open / mini- open RCR G2: Arthroscopic RCR 12 mo | Subgroup analysis by tear size (post hoc) | SF-36 ASES CMS ROM pain cuff integrity | In the open repair group, smaller tear size tended to have better, but non-significant, functional outcomes, pain scores, F and ER strength testing. In the arthroscopic group, smaller tears have significantly better outcomes except in pain which showed non-significant improvement. Tear size was associated with cuff integrity in the arthroscopic group but not in the open group. |
| Boehm TD, ⁶¹ 2005 RCT | G1: Nonabsorbable sutures (Mason- Allen technique) G2: Absorbable sutures (Kessler technique) 2.2 yr (2–2.5) | Regression analysis controlling for hand dominance, WCB status, age, sex, tear size, and type of suture (a priori) | CMS | No significant influence of hand dominance, WCB status, tear size, and suture type on outcome. Male gender and older patients had significantly worse outcomes. |
| Boileau P, ⁶³ 2007 Retrospective cohort | G1: Biceps tenotomy G2: Biceps tenodesis 2.9±0.6 yr (2–6.3) | Regression analysis controlling for number of tendons torn, extension of tear, fatty infiltration, acromiohumeral distance, and atrophy of teres minor (post hoc) | CMS ROM | No significant effect of number of tendons torn or the extension of tear on functional outcomes. Fatty infiltration and acromiohumeral distance did not have a measurable effect on the outcome. Pre-op absence or atrophy of teres minor was associated with fatty infiltration of infraspinatus and significantly worse outcomes compared to patients with healthy teres minor. |
| Boileau P, ⁶² 2005 BA | Arthroscopic RCR 2.4 yr (2–3.8) | Multiple regression analysis controlling for age, sex, (a priori) tear size, duration of symptoms, WCB status, additional procedures (post hoc) | cuff integrity | Tendon healing was negatively associated with increasing age and delamination of the subscapularis or infraspinatus tendon. Small tear size was positively associated with tendon healing. No association between tendon healing and sex, duration of symptoms, previous injections, WCB status, or additional procedures. |
| Boszotta H, ⁶⁴ 2004 BA | Mini-open RCR 2.9 yr (2.3–3.7) | Subgroup analysis by age, tear size, tear pattern, closure technique, number of sutures, quality and condition of long biceps tendon, acromion type, acromiohumeral distance, and immobilization (post hoc) | CMS UCLA | Larger tear size was associated with worse outcome. The quality and condition of long biceps tendon was associated with outcome. Patients with curved or hooked acromion types have significantly better outcomes than patients with flat-shaped acromion. There was no significant influence of age, pre-op acromiohumeral distance, tear configuration, closure technique, number of sutures or type / duration of immobilization on outcome. |
| Buess E, ⁶⁵ 2005 Prospective cohort | G1: Open or mini- open RCR G2: Arthroscopic RCR 2 yr (15 mo–3.3 yr) | Subgroup analysis by tear size (a priori) | SST | No significant effect of tear size on outcome for both groups. |

Table 59. Effect modifiers in operative studies (continued)

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|---|---|--|--|--|
| Charoussat C, ⁶⁷ 2008 BA | Arthroscopic RCR 2 yr (maximum) | Multiple regression analysis controlling for age, sex, dominant side affected, upper-limb heavy work, WCB status, duration of symptoms, mechanism of tearing, number of tendons torn, extension and retraction of lesion, tendon quality, bone quality, and tendon reducibility (a priori) | CMS | Women had significantly worse outcome than men. Upper-limb heavy work was negatively associated with outcome. Poor bone quality was found to be associated with poor functional recovery. No significant effect of age, dominant side, duration of symptoms, mechanism of tearing, type of job, involvement of multiple tendons, fatty degeneration, supraspinatus tear extent in sagittal or coronal planes, or AC joint involvement on functional outcome. Sex, age, tears involving 3 tendons and pre-op strength were predictive of post-op strength recovery. No effect of WCB on functional outcome but time to recovery was longer. |
| Cofield RH, ⁷⁰ 2001 BA | Open RCR 13.4 yr (2–22) | Subgroup analysis by age, sex, tear size, etiology of tear, side affected, hand dominance, duration of symptoms, shape of acromion, location of the tear, biceps tenodesis, and type of immobilization (post hoc) | pain active ROM strength | Patients with large or massive tears had lower active ROM and strength measures than patients with smaller tears. There was a trend for more pain with a larger tear size but this association was not significant. Men had significantly better active abduction and less pain than women. Older age was associated with lower active ROM and strength. Pre-op ROM and strength was associated with post-op ROM and strength. Etiology of tear, side of the repair, hand dominance, symptom duration, shape of acromion, location of the tear, biceps tenodesis, and type of immobilization did not influence outcome. |
| Cole BJ, ⁷¹ 2007 BA | Arthroscopic RCR 2.7 yr (2–3.8) | Subgroup analysis by age, sex, hand dominance, time to surgery, WCB status, biceps procedure, number of suture anchors and tear pattern (post hoc) | CMS Rowe score SST pain cuff integrity | Older patients had significantly more pain and less ER power. WCB status did not affect pain assessment, functional outcome scores, or ROM. Older age and pre-op extension of the tear into the infraspinatus were associated with recurrent tears. Concomitant biceps procedures, number of suture anchors used, time to surgery, gender, dominant or non dominant side, WCB status, and tear pattern were not associated with recurrent tears. |
| Cools A, ⁷² 2006 Prospective cohort as BA | Open RCR 18 mo (12–20) | Subgroup analysis by pre-op strength (post hoc) | CMS | Pre-op strength was positively correlated with functional outcome. |
| Davidson PA, ⁷⁴ 2000 BA | Open <i>or</i> arthroscopic RCR 2 yr (minimum) | Regression analysis controlling for repair tension (a priori) | CMS pain | Increased tension on RCR was significantly associated with worse outcomes. |
| DeFranco MJ, ⁷⁵ 2007 BA | Arthroscopic RCR 22.3 mo (12 mo–3 yr) | Multiple regression analysis controlling for age (a priori) | cuff integrity | Younger patients had significantly better outcomes than older patients. |
| Deutsch A, ⁷⁷ 2008 Prospective cohort as BA | Arthroscopic RCR 3.2 yr (2–5) | Subgroup analysis by number of tendons torn, tear size, tear pattern, presence of biceps tearing, and duration of pre-op symptoms (a priori) | ASES ROM strength pain cuff integrity | No significant effect of number of tendons torn or tear size on outcomes. Tear recurrence was significantly correlated with asymmetric retraction. No significant influence of biceps tears or duration of pre-op symptoms on tear recurrence. |

Table 59. Effect modifiers in operative studies (continued)

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|---|---|--|---|--|
| Ellman H, ⁷⁸ 1993 Prospective cohort as BA | Arthroscopic RCR 3.6 yr (2–7.3) | Subgroup analysis by tear size (a priori) | UCLA | Small tears associated with higher UCLA score than large tears. |
| Fuchs B, ⁸³ 2006 BA | Open RCR & augmentation 3.2 yr (2–4.4) | Subgroup analysis by tear type, muscle atrophy (a priori). | CMS cuff integrity | There was no significant difference in the total CMS score between patient with supraspinatus tears and those with subscapularis tears. However, patients with subscapularis tears experienced significantly more pain at followup, as measured by the CMS pain subscale. Muscle atrophy approached significance as a predictor for retear. |
| Gartsman GM, ⁸⁴ 1998 BA | Arthroscopic RCR 12.7 mo (11–21) | Subgroup analysis by age, sex, and tear size (a priori) | SF-36 ASES CMS | Older patients had significantly less improvement in SF-36. Female patients had significantly greater improvements in CMS and ASES than male patients. Tear with a greater length, width, and area had significantly less improvement in the strength score in CMS. |
| Gartsman GM, ⁸⁵ 1997 BA | Open debridement & acromioplasty 5.3 yr (4–9.8) | Subgroup analysis by type and condition of tear (post hoc) | CMS UCLA SSI | All patients with severe superior migration had poor ROM, function, and strength. Poor outcomes were associated with irreparable tears of the subscapularis or teres minor, muscular atrophy of these two muscles, and moderate-to-severe superior migration of the humeral head. |
| Gazielly DF, ⁸⁷ 1994 BA | Open RCR 4 yr (2–6) | Subgroup analysis by tear size, degree of occupational use, age (a priori) | cuff integrity | Age, size of tear, and occupational use was associated with tear recurrence. |
| Gladstone JN, ⁸⁸ 2007 BA | Open <u>or</u> mini-open <u>or</u> arthroscopic RCR 12 mo (12–15) | Regression analysis controlling for fatty infiltration and muscle atrophy of supraspinatus and infraspinatus, and tear size (a priori) | ASES CMS strength cuff integrity | Patients with poor muscle quality had significantly less improvement in outcomes. Muscle atrophy and fatty infiltration have a strong negative effect on functional outcomes and strength. Pre-op tear size was the only significant predictor of cuff integrity. |
| Henn RF, ⁹⁰ 2008 Prospective cohort as BA | Open <u>or</u> mini-open <u>or</u> arthroscopic RCR 12.3 ± 1.7 mo (7.4– 20.2) | Subgroup analysis by WCB status. Multiple regression analysis controlling for multiple confounders (age, sex, smoking, expectations, number of comorbidities, education, marital status, work demands, and tear size) (a priori) | SF-36 DASH | Patients with WCB claims reported worse outcomes, after controlling for confounding factors. WCB patients were significantly younger, had greater work demands, and had lower marital rates, education levels, and pre-op expectations for the outcome. |
| Hsu SL, ⁹¹ 2007 BA | Open RCR 4.1 yr (2–7.1) | Subgroup analysis by presence of diabetes, and tear type (a priori). Non-parametric analysis for age (post hoc). | CMS | No statistical difference between patients with and without DM in total CMS. Patients with partial tears had significantly better total CMS scores than those with complete or large tears. Age was associated with strength score. |

Table 59. Effect modifiers in operative studies (continued)

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|--|---|--|---|---|
| Iannotti JP, ⁹³ 2006 RCT | G1: Porcine submucosa augmentation G2: No augment 14 mo (12 mo–2.2 yr) | Regression analysis controlling for tear size (a priori) | cuff integrity | Large tears were significantly more likely to heal than massive tear in both groups. |
| Iannotti JP, ⁹² 1996 BA | Open RCR NR | Subgroup analysis by WCB status, tear size, biceps tendon rupture, quality of remaining cuff tissue, and difficulty of repair (a priori) | CMS | WCB status and pre-morbid activity level did not influence functional outcome. Patients with larger tear sizes had significantly worse outcomes than patients with smaller tear sizes. Biceps tendon rupture, poor tissue quality, and difficulty of tendon mobilization were adversely associated with functional outcome. |
| Ide J, ⁹⁴ 2007 BA | Arthroscopic RCR 3 yr (2–5) | Subgroup analysis by age, degree of tendon retraction, tear pattern and size (post hoc) | cuff integrity | Patients with severe tendon retraction had significantly more recurrences than those with minimal or moderate retraction. Significantly more failed repairs in older age than younger age. No significant effect of tear pattern and size on tear recurrence. |
| Ide J, ⁹⁶ 2005 Prospective cohort | G1: Open RCR G2: Arthroscopic RCR 4.1 yr (2.1–6.9) | Subgroup analysis by tear size (post hoc) | UCLA JOA | Small tears had significantly better outcomes compared with large tears regardless of operative group. |
| Kim SH, ⁹⁸ 2003 CCT | G1: Mini-open RCR G2: Arthroscopic RCR 3.3 yr (2.0–5.3) | Subgroup analysis by tear size, etiology of tear, acromial morphology, symptoms duration, and pre-op strength (a priori) | UCLA ASES pain | Larger tears had significantly worse scores on the UCLA, ASES, and function-VAS, but not pain- VAS. No other pre-op factors had a significant correlation with outcomes. |
| Kirschenbaum D, ⁹⁹ 1993 BA | Open RCR 12 mo (maximum) | Non-parametric analysis of tear size (post hoc) | Strength | Tear size was not significantly associated with strength; however, abduction and flexion strength was consistently less in patients with large or massive tears. |
| Klepps S, ¹⁰⁰ 2004 BA | Open <u>or</u> mini-open RCR 12 mo (minimum) | Subgroup analysis by tear size (post hoc) | ASES CMS UCLA pain cuff integrity | Larger or massive tear size was associated with worse, but non-significant, functional outcomes (CMS, UCLA, ASES) and pain score, and were more likely to re-tear than small or medium tears. |
| Klinger HM, ⁵⁵ 2005 BA | Arthroscopic debridement only 2.6 yr. (2–3.8) | Subgroup by tear type, presence of subscapularis tear, superior migration of humeral head, decreased ROM, glenohumeral arthritis (post hoc) | CMS | The presence of two or more of these prognostic factors is correlated with poor outcome. |
| Kose KC, ¹⁰² 2008 Retrospective cohort | G1: Mini-open RCR G2: Arthroscopic RCR 2.2 yr (12 mo–6.8 yr) | Subgroup analysis by age (post hoc) | CMS UCLA | There was a significant negative association between age and pain in the mini-open group. Age was not associated with the CMS score. |
| Kreuz PC, ¹⁰³ 2005 BA | Arthroscopic RCR 3 yr (2–4) | Subgroup analysis by tear thickness (a priori) | CMS | Complete tears had significant improvement in outcomes compared to partial tears. Delay between trauma and outcome was inversely proportional. |

Table 59. Effect modifiers in operative studies (continued)

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|--|---|--|---------------------------------------|---|
| Lafosse L, ¹⁰⁴ 2007 BA | Arthroscopic RCR 3 yr (2–4.8) | Regression analysis controlling for etiology of tear, age, duration of symptoms, WCB status (a priori) and tear size (post hoc). | CMS pain active ROM strength | Etiology of tear, age, duration of symptoms, concomitant biceps procedures, pre-op status of the biceps tendon, degree of fatty infiltration, and WCB status did not affect outcomes. Large / massive tears were associated with more post- op weakness than small tears. |
| Lafosse L, ¹⁰⁵ 2007 BA | Arthroscopic RCR 2.4 yr (2–3.3) | Multiple regression analysis controlling for age, mechanism of injury, duration of symptoms, and degree of fatty infiltration (a priori); WCB status, tear size and biceps pathology (post hoc) | CMS UCLA | No significant effect of age, duration of symptoms, WCB status, tear etiology, tear size, and biceps pathology on outcomes. The effect of rerupture and persistent fatty degeneration could not be determined. |
| Levy, ¹⁰⁶ 2008 BA | Arthroscopic RCR 3.2 yr (2–6.1) | Subgroup analysis by tear size (a priori) | CMS | Small tears had significantly better outcomes than large tears. |
| Lichtenberg S, ¹⁰⁷ 2006 BA | Arthroscopic RCR 2.2 yr | Subgroup analysis by age, tear size, grade of retraction, and biceps pathology (post hoc) | CMS cuff integrity | No significant effect of tear size, retraction, or biceps pathology on outcome measures. Age was a negative prognostic factor for retears. |
| Liem D, ¹⁰⁸ 2007 Retrospective cohort | G1: Mini-open RCR G2: Arthroscopic RCR 12 mo (minimum) | Subgroup analysis by age and tear size (post hoc) | CMS ROM cuff integrity | No significant effect of tear size on outcomes. Age was a negative prognostic factor for retears. |
| Mallon WJ, ¹¹¹ 2004 Retrospective cohort as BA | Open RCR 12 mo (minimum) | Subgroup analysis by smoking status and sex (a priori). Multiple regression analysis controlling for age, smoking status, tear size, and WCB status (a priori). | UCLA pain | Non-smokers had significantly greater improvement in UCLA and post-op pain scores than smokers. Women had greater improvement in the UCLA score between pre-op and post-op assessment, compared with men. Age, tear size and WCB status were not found to predict outcomes. |
| McBirnie JM, ¹¹³ 2005 BA | Arthroscopic RCR 2.4 yr (2–5) | Subgroup analysis by age, sex, WCB status (a priori), and tear size (post hoc) | CMS | No significant effects of WCB status, tear size, and additional procedures on outcome. No analysis of age and sex as planned. |
| McCallister WV, ¹¹⁴ 2005 BA | Open RCR 5.5±2.2 yr (2–10) | Subgroup analysis by age, sex, and number of tendons torn (post hoc) | SST | No significant effect of age and sex. Participants with a lower number of tendons torn had significantly better outcomes than patients with a higher number. |
| Milano G, ¹¹⁶ 2007 RCT | G1: Arthroscopic RCR & acromioplasty G2: Arthroscopic RCR 2 yr | Multiple regression analysis controlling for age, sex, dominance, location, shape, area, retraction, reducibility of cuff tear, fatty degeneration, involvement of subscapularis tendon, LHB treatment and type of acromion (a priori) | CMS DASH | Age was significantly positively associated with DASH scores. Gender and dominance did not significantly influence outcomes. There was no significant effect of location and area of tears on outcome. Tears that were U-shaped, retracted, partially reducible, involved the subcapularis, or had severe fatty degeneration had significantly worse outcomes. |

Table 59. Effect modifiers in operative studies (continued)

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|--|--|---|---|---|
| Misamore GM, ¹¹⁷ 1995 Retrospective cohort as BA | Open RCR 3.8 yr (2–5.7) | Subgroup analysis by WCB status (a priori) | UCLA return to work | Patients without a WCB claim had significantly better outcomes as measured by the UCLA total score and individual subscores compared to those with a WCB claim. A significantly higher proportion of patients not receiving WCB returned to work compared to those receiving WCB. |
| Nam SC, ¹²² 2008 Prospective cohort as BA | Arthroscopic RCR 2.6 yr (16 mo–6.2 yr) | Subgroup analysis by pre- op shoulder stiffness (a priori) | CMS SST UCLA pain ROM strength | Pre-op shoulder stiffness was not associated with outcomes. |
| Nho SJ, ¹²³ 2009 BA | Arthroscopic RCR 2.4 yr | Multiple regression analysis controlling for age, tear size and number of torn tendons (a priori) | ASES cuff integrity | Increased age, tear size and number of torn tendons were found to be significant predictors of tendon defect after repair. Patients without biceps or AC joint pathology and with normal tissue quality were significantly less likely to have a post-op tendon defect. Concomitant AC joint coplaning or distal clavicle excision was significantly negatively associated with ASES score. |
| Oh JH, ¹²⁵ 2008 Prospective cohort as BA | Open <i>or</i> arthroscopic RCR 15.1 mo (12 mo– 2.7 yr) | Subgroup analysis by pre- op stiffness (a priori) | SF-36 ASES CMS SST | No significant effect of shoulder stiffness on outcomes. |
| Pai VS, ¹²⁶ 2001 BA | Open RCR 2.8 yr | Subgroup analysis by age, duration of symptoms, pre-op range of motion and strength, tear size, and quality of tendon (a priori) | CMS UCLA | No significant effect of age and duration of symptoms on outcome. Patients with poor pre-op ROM and strength or poor tendon quality had worse outcomes. Patients with massive tears had significantly worse outcomes than patients with other tear sizes but there was no overall significant effect of tear size on outcome. |
| Park JY, ¹²⁸ 2008 Prospective cohort | G1: Double-row anchor RCR G2: Single-row anchor RCR 2.1 yr (22 mo–2.5 yr) | Subgroup analysis by tear size (post hoc) | ASES CMS SSI | Large to massive tears had significantly poorer outcomes than small tears when treated with single-row repair fixation. |
| Pillay R, ¹²⁹ 1994 Retrospective cohort as BA | Arthroscopic RCR 18.6 mo (6 mo–2.5 yr) | Subgroup analysis by tear type (a priori) | UCLA | There was no association between tear type and UCLA functional score. |
| Prasad N, ¹³¹ 2005 BA | Open RCR 2.2 yr (12 mo–4.2) | Subgroup analysis by age, sex, tear size, BMI, smoking status, and duration of symptoms (post hoc) | CMS pain | Older patients and patients with massive tears showed significantly less improvement in outcome compared to younger patients and patients with smaller tears. BMI, gender, smoking, and duration of symptoms did not affect the outcome. |
| Sauerbrey M, ¹³⁴ 2005 Retrospective cohort | G1: Mini-open RCR G2: Arthroscopic RCR 2.1 yr (13 mo–4 yr) | Subgroup analysis by tear size (a priori) | Modified ASES | Surgical approaches were effective regardless of tear size. |

Table 59. Effect modifiers in operative studies (continued)

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|---|--|--|---|---|
| Severud EL, ¹³⁷ 2003 Retrospective cohort | G1: Mini-open RCR G2: Arthroscopic RCR 3.7 yr (2–6.8) | Subgroup analysis by tear size (post hoc) | ASES UCLA | No significant effect of tear size on outcomes. |
| Tashjian RZ, ¹⁴⁰ 2006 BA | Open <u>or</u> mini-open <u>or</u> arthroscopic RCR 12 mo (maximum) | Multivariate regression analysis for number of comorbidities, with age, sex, WCB status, number of prior non- shoulder surgeries, smoking, tear size, symptom duration, and expectation as confounding variables (a priori). | SF-36 DASH SST VAS (pain, function, QOL) | Greater number of comorbidities was associated with significantly worse final scores on four SF- 36 subsections (bodily pain, general health, role emotional, and vitality). Patients with more comorbidities showed significantly greater improvement on the VAS, DASH and SST than patients with fewer comorbidities. |
| Tauro JC, ¹⁴² 2006 Retrospective cohort as BA | Arthroscopic RCR 2 yr | Subgroup analysis by tear size, pre-op stiffness (a priori) | Total passive ROM deficit (TROMD) | Tear size represented as a cuff tear index (CTI) was positively correlated with TROMD, where larger tear size was associated with more stiffness. Patients with pre-op stiffness were more likely to experience post-op stiffness. |
| Trenerry K, ¹⁴⁴ 2005 Case-control as BA | Open RCR 17.3 mo (15.5–19) | Subgroup analysis by age, sex, hand dominance, affected side, symptom duration, mechanism of onset, WCB status, tear size, tear type, shoulder comorbidities, pre-op ROM (a priori) | ROM | There were no significant effects of any factors, with the exception of pre-op ROM restriction of hand behind the back, which was a significant predictor of post-op shoulder stiffness. |
| Vaz S, ¹⁴⁶ 2000 BA | Arthroscopic debridement only 3.1 yr (12 mo–4 yr) | Subgroup analysis by age, sex, side of tear, nature of job, pre-op latency, acromion morphology and condition of cuff (post hoc) | CMS | There was no significant impact of any of the factors on outcome, except that patients with sedentary jobs returned to work significantly sooner than manual laborers. |
| Youm T, ¹⁵² 2005 Retrospective cohort | G1: Mini-open RCR G2: Arthroscopic RCR 3.0 yr (2.0–5.8) | Subgroup analysis by tear size (post hoc) | ASES UCLA | No significant effect of tear size within or between operative groups. |
| Zumstein MA, ¹⁵³ 2008 BA | Open RCR & augmentation 9.9 yr (6.7–12.8) | Subgroup analysis by number of tendons torn and tear type (post hoc) | CMS | Number of tendons torn and tear type had no impact on post-op functional scores. However, patients with anterosuperior tears and those with three-tendon tears showed significantly greater gain compared to their pre-op state than did the two-tendon tears and posterosuperior tears. |

Postoperative Rehabilitation Studies

Of the nine studies evaluating the effectiveness of postoperative rehabilitation treatments, three studies (two RCTs,^{158,161} and one BA study¹⁵⁴) explored the role of various patient or clinical factors as effect modifiers (Table 60). The effect modifiers were examined using subgroup analysis in two studies,¹⁶¹ multiple regression analysis in one study¹⁵⁸ and both subgroup and regression analysis in the remaining study.¹⁵⁴ All studies planned the analyses a priori. Patient variables examined in the studies included age,^{154,158,161} sex,^{154,158,161} tear size,^{154,158,161} number of comorbidities,¹⁵⁴ smoking,¹⁵⁴ and type of preoperative treatment.¹⁵⁴ The role of effect modifiers was evaluated for functional outcomes in all of the studies, as well as for health-related quality of life,¹⁵⁴ pain, range of motion, and strength.¹⁵⁸ In one study,¹⁵⁴ greater number of comorbidities was found to be correlated with significantly worse health-related quality of life scores, but not functional outcome scores, in one study. Two studies found that age, sex, and tear size were not associated with outcomes, except that women had greater improvement in pain subscales, while men had greater improvement in range of motion.^{158,161}

Table 60. Effect modifiers in postoperative rehabilitation studies

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|---|--|--|----------------------------------|---|
| Boissonnault WG, ¹⁵⁴ 2007 BA | Rehabilitation protocol 13 wk ±5.1 (3–28) | Subgroup analysis by number of comorbidities. Multiple regression analysis controlling for age, sex, smoking, tear size, pre-op treatment. (a priori) | SF-36 DASH | A greater number of comorbidities was associated with significantly worse SF-36 scores, but not with DASH scores. |
| LaStayo PC, ¹⁵⁸ 1998 RCT | G1: CPM G2: Manual passive ROM exercises 22±9.8 mo (6 mo–3.8 yr) | Regression analysis controlling for age, sex, and tear size (a priori). | SPADI pain ROM strength | No significant effect of age, sex, or size of tear on outcomes, except that women indicated significantly less pain than men. |
| Raab MG, ¹⁶¹ 1996 RCT | G1: CPM & PT G2: PT only 3 mo | Subgroup analysis by age, sex, and tear size (a priori) | Shoulder score | Age, sex, and tear size were not associated with the overall shoulder score. For the subscores, women showed a significant improvement in the pain and men showed significant improvement in the ROM. |

BA = before-and-after; CPM = continuous passive motion; DASH = Disabilities of the Arm, Shoulder and Hand; G = group; PT = physical therapy; RCT = randomized controlled trial; ROM = range of motion; SF-36 = Short Form-36; SPADI = Shoulder Pain and Disability Index

Nonoperative Studies

Of the 10 studies examining the effectiveness of nonoperative interventions, two studies (one prospective cohort¹⁶⁵ and one BA study¹⁶⁴) explored the role of various patient or clinical factors as effect modifiers (Table 61). The analysis of effect modifiers was specified a priori in one study¹⁶⁵ and post hoc the other study.¹⁶⁴ The studies used subgroup analysis to examine the effect

of tear type,¹⁶⁵ cause of tear,¹⁶⁴ duration of symptoms,¹⁶⁴ pain,¹⁶⁴ sleep loss,¹⁶⁴ and WCB status¹⁶⁴ on functional outcome scores.^{164,165} Functional scores were found to be negatively correlated with preoperative sleep loss and WCB claim in one study.¹⁶⁴ In contrast, functional improvement was shown to be independent of tear type,¹⁶⁵ duration of symptoms, degree of pain, and cause of tear.¹⁶⁴

Table 61. Effect modifiers in nonoperative studies

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|---|--|--|---------------------|--|
| Hawkins RH, ¹⁶⁴ 1995 BA | Exercise protocol 3.8 yr (2.6–4.6) | Subgroup analysis by WCB status, sleep loss, duration of symptoms, degree of pain, and cause of tear (post hoc) | ASES CMS | WCB claim and pre-op sleep loss was associated with unsatisfactory functional outcome. None of the other patient variables were found to predict treatment outcome. |
| Heers G, ¹⁶⁵ 2005 Prospective cohort as BA | Home exercise program 2.7 mo (maximum) | Subgroup by tear type (a priori) | CMS | Patients showed significant functional improvement regardless of type of tear. |

ASES = American Shoulder and Elbow Scale; BA = before-and-after; CMS = Constant-Murley score; pre-op = preoperative; WCB = workers' compensation board

Operative Versus Nonoperative Studies

Of the three studies that examined the effectiveness of nonoperative versus operative interventions, one retrospective cohort study¹⁷³ conducted a post hoc subgroup analysis to explore the effect of age and timing of surgery on functional outcomes (Table 62). The authors found that age had no significant effect on function, as measured by the JOA scale. Time between symptom onset and surgery affected outcomes, where intervals longer than 12 months were associated with postoperative difficulties.

Table 62. Effect modifiers in postoperative rehabilitation studies

| Author, year Study design | Intervention Followup, mean (range) | Type of analysis | Outcome variable | Authors' conclusions |
|---|--|--|---------------------|---|
| Yamada N, ¹⁷³ 2000 Retrospective cohort | G1: Steroid injection, stretching, strengthening G2: Open RCR 4 yr (12 mo–23 yr) | Subgroup analysis by age and timing of surgery (post hoc) | JOA | Age had no significant effect on function, as assessed by the JOA scale. Time between symptom onset and surgery was associated with outcomes, where intervals longer than 12 months were associated with post-op difficulties. |

G = group; JOA = Japanese orthopaedic association; post-op = postoperative; RCR = rotator cuff repair

Chapter 4. Discussion

Summary of Findings

This report provides a comprehensive synthesis of the evidence on the comparative effectiveness of nonoperative and operative interventions for RC tears. The findings and strength of evidence for comparative studies are summarized in Table 63. The variability in the studies in the table illustrates the numerous comparisons that have been made across the studies in this area. Uncontrolled studies were not included in the table, as they represent an extremely low grade on the hierarchy of evidence. The result is that there are sparse data available for most interventions. This precludes firm conclusions for any single approach or for the optimal overall management of this condition. The majority of the data is derived from studies of low methodological quality or lower in the hierarchies of evidence. Sample sizes were generally moderate and varied considerably from study to study, with an overall median of 53 patients per study (IRQ 30 to 85). Overall, the evidence shows that all interventions result in substantial improvements; however, few differences of clinical importance are evident when comparisons between interventions are available. The following is a summary of the evidence for the different types of interventions.

Operative approaches. The most frequent comparison was mini-open versus arthroscopic rotator cuff repair; this comparison provided moderate evidence for no difference in function between the two approaches. There was also moderate evidence showing no statistical or clinically important differences in function between open and mini-open repairs; however, there was some evidence suggesting an earlier return to work by approximately 1 month for mini-open repairs. There was moderate evidence for no difference in function between open or mini-open vs. arthroscopic repairs and arthroscopic repairs with and without acromioplasty. There was moderate evidence for greater improvement in function for open repairs compared to arthroscopic debridement. The strength of evidence was low for the remaining comparisons and outcomes; hence, the evidence was too limited to make a conclusion.

Operative techniques. The most frequent comparison was single versus double row suture anchors. There was moderate evidence demonstrating no difference in function but potential for greater cuff integrity with double-row sutures. The evidence was too limited to make conclusions for the other techniques studied.

Operative augmentation. Two relatively small studies evaluated different augmentation techniques, hence no overall conclusions were possible.

Postoperative rehabilitation. The most frequent comparison was continuous passive motion with physical therapy versus physical therapy alone. This resulted in moderate evidence showing no clinical or statistical difference in function but some evidence for earlier return to work with continuous passive motion. The evidence for other aspects of postoperative rehabilitation was too limited to make conclusions.

Nonoperative interventions. Three studies compared different nonoperative interventions; hence, no overall conclusions were possible regarding any single approach.

Nonoperative versus operative treatment. Three studies compared different nonoperative and operative interventions. Because the interventions and comparisons differed across the studies, the evidence was too limited to make conclusions regarding the relative effectiveness of the individual modalities.

Complications. A total of 29 different complications were reported in 88 studies. The incidence of complications was generally low, yet studies varied considerably in their risk

estimates. In 29 studies, it was reported that no complication occurred during the course of the study. Generally, the benefit of receiving treatment for RC tears appears to outweigh the risk of associated harms.

Prognostic factors. The variety of effect modifiers examined across many different outcomes and the inconsistency among authors’ conclusions make it difficult to identify predictors of good outcome for nonoperative and operative treatments. However, older age and increasing tear size were consistently found to be associated with recurrent tears. Sex, WCB status, and duration of symptoms were not found to be associated with poorer outcomes in the majority of studies that examined these variables.

Table 63. Summary of strength of evidence for nonoperative and operative interventions for RC tears

| Comparison (number of studies) | Strength of evidence | Summary |
|--|----------------------|---|
| Operative approaches | | |
| Open RCR vs. mini-open RCR (n=3) | Moderate | No statistically significant or clinically important difference for function. Some evidence for earlier return to work or sports (by approximately 1 month) with mini-open repairs. |
| | Low | The evidence was too limited to make a conclusion for health-related quality of life. |
| Mini-open RCR vs. arthroscopic RCR (n=8) | Moderate | No difference in function. |
| Open RCR vs. arthroscopic RCR (n=1) | Low | The evidence was too limited to make a conclusion. |
| Open or mini-open RCR vs. arthroscopic RCR (n=2) | Moderate | No difference in function. |
| | Low | The evidence was too limited to make a conclusion for cuff integrity. |
| Open RCR vs. arthroscopic debridement (n=4) | Moderate | Some evidence for greater improvement in function for open RCR. |
| Arthroscopic RCR with acromioplasty vs. without acromioplasty (n=2) | Moderate | No difference in function. |
| Biceps tenotomy vs. tenodesis (n=1) | Low | The evidence was too limited to make a conclusion. |
| Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy (n=1) | Low | The evidence was too limited to make a conclusion. |
| Mini-open RCR plus tenodesis with detachment vs. without detachment (n=1) | Low | The evidence was too limited to make a conclusion. |
| Arthroscopic debridement with biceps tenotomy vs. without tenotomy (n=1) | Low | The evidence was too limited to make a conclusion. |
| Complete open RCR vs. partial open RCR vs. debridement (n=1) | Low | The evidence was too limited to make a conclusion. |
| Open RCR with classic open acromioplasty vs. open RCR with modified open acromioplasty (n=1) | Low | The evidence was too limited to make a conclusion. |
| Operative techniques | | |
| Single-row vs. double-row suture anchor fixation (n=4) | Moderate | No clinically important difference for function. Some evidence for improved Cuff integrity with double-row sutures. |
| Bioabsorbable tacs vs. suture tying (n=1) | Low | The evidence was too limited to make a conclusion. |
| Nonabsorbable vs. absorbable sutures (n=1) | Low | The evidence was too limited to make a conclusion. |

RCR = rotator cuff repair; SLAP = superior labral from anterior to posterior; vs. = versus

Table 63. Summary of strength of evidence for nonoperative and operative interventions for RC tears (continued)

| Operative techniques (continued) | | |
|---|----------|---|
| Bioabsorbable corkscrews vs. metal suture anchor (n=1) | Low | The evidence was too limited to make a conclusion. |
| Mattress locking vs. simple stitch (n=1) | Low | The evidence was too limited to make a conclusion. |
| Mattress vs. transosseous suture (n=1) | Low | The evidence was too limited to make a conclusion. |
| Ultrasonic welding vs. hand-tied knots (n=1) | Low | The evidence was too limited to make a conclusion. |
| Staple fixation vs. side-to-side suture (n=1) | Low | The evidence was too limited to make a conclusion. |
| Operative augmentation | | |
| Porcine small intestine submucosa vs. no augmentation (n=1) | Low | The evidence was too limited to make a conclusion. |
| Patch graft vs. no augmentation (n=1) | Low | The evidence was too limited to make a conclusion. |
| Postoperative rehabilitation | | |
| Continuous passive motion with PT treatment versus PT treatment (n=3) | Moderate | No clinical or statistical difference in function. Some evidence for earlier return to work with continuous passive motion. |
| Aquatic therapy with land-based therapy versus land-based therapy (n=1) | Low | The evidence was too limited to make a conclusion. |
| Inpatient versus day patient rehabilitation (n=1) | Low | The evidence was too limited to make a conclusion. |
| Individualized PT program with home exercise versus home exercise (n=1) | Low | The evidence was too limited to make a conclusion. |
| Standardized versus non-standardized PT program (n=1) | Low | The evidence was too limited to make a conclusion. |
| Videotape versus PT home exercise instruction (n=1) | Low | The evidence was too limited to make a conclusion. |
| Nonoperative interventions | | |
| Sodium hyaluronate vs. dexamethasone (n=1) | Low | The evidence was too limited to make a conclusion. |
| Rehabilitation vs. no rehabilitation (n=1) | Low | The evidence was too limited to make a conclusion. |
| Physiotherapy, oral medications and steroid injection vs. physiotherapy, oral medications and no steroid injection (n=1) | Low | The evidence was too limited to make a conclusion. |
| Nonoperative vs. operative treatment | | |
| Steroid injection, physical therapy, and activity modification versus open repair (n=1) | Low | The evidence was too limited to make a conclusion. |
| Physical therapy treatment, oral medication, and steroid injection versus arthroscopic debridement versus open repair (n=1) | Low | The evidence was too limited to make a conclusion. |
| Passive stretching, strengthening, and corticosteroid injection versus open repair with acromioplasty (n=1) | Low | The evidence was too limited to make a conclusion. |

Applicability

The study populations in this body of evidence were relatively homogeneous. The vast majority included only patients with full-thickness tears. There was more variation in the number of tendons involved with many studies including patients with only one torn tendon (e.g., supraspinatus) while others included any tendon or tendon combination (e.g., supraspinatus, supraspinatus plus infraspinatus, supraspinatus plus subscapularis, supraspinatus plus infraspinatus plus subscapularis). The mean age was clustered between 50 and 65 years, with males comprising an average slightly more than half of the study participants. The duration since symptom onset was not reported in the majority of studies, but when reported was generally between 12 and 18 months.

The other issue regarding applicability for this body of evidence relates to the practitioners administering the interventions (e.g., surgeons, therapists, or other healthcare providers). Outcome effects may differ between the trials and real life practice based on practitioners' skills and experience, volume of surgery, and variations or rigor surrounding cointerventions or procedural protocols.

Limitations of the Existing Evidence

The strength of evidence was low for the majority of interventions that were evaluated and compared in the management of RC tears. The low grade was driven by the high risk of bias within individual studies and the lack of consistency and precision across studies. The majority of studies in this field are lower in the hierarchies of evidence, with most studies lacking an independent comparison or control group.

Overall, there were 15 RCTs and 5 CCTs; however, all of these were assessed as high risk of bias based on an empirically derived tool for assessing risk of bias developed by The Cochrane Collaboration. The trial features that were most problematic were inadequate blinding, inadequate allocation concealment, and incomplete outcome data. Inadequate blinding is an important limitation in this body of research due to the nature of the intervention and can lead to exaggerated effect estimates. Methodological approaches to adequately prevent knowledge of the intervention should be employed, such as blinding outcome assessors to treatment status and the use of objective outcome measures. While blinding is not always feasible, adequate allocation concealment is always possible in an RCT and should be routinely employed. Incomplete outcome data or missing data was a problem in a number of trials due to loss to followup and inadequate handling of missing data in the reporting and/or analysis. Loss to followup was more problematic in studies that extended over a longer period of time. While attrition might be expected when the followup is over a number of years, it can exaggerate treatment effects and the potential for this bias should be considered when designing, conducting, and interpreting research.

One of the values of randomization is that all potential confounders, both known and unknown, are accounted for; hence, the results observed can be more closely attributed to the treatment under study. The majority of studies that were included in this report were not randomized; therefore, they are particularly vulnerable to bias resulting from lack of comparability between the groups under study. Moreover, the majority of studies did not control for important potential confounders in their design or analysis.

The strength of evidence was also rated low due to the lack of consistency and precision of results across studies. This is primarily due to the varied comparisons made across this body of

literature with relatively few studies comparing the same interventions. Also contributing to the lack of consistency and precision was the variability in outcomes assessed across the studies.

The choice of outcomes and measurement tools needs attention in this area of research. The most common outcome assessed was function; however, 16 different tools were used for this purpose and often multiple tools were used within the same study. This makes comparisons across studies challenging. Moreover, it is unclear whether these functional scores are measuring the same construct to allow comparisons across studies that use different tools. There was also inconsistency in which ranges of motion were assessed in the studies and the vast majority of studies failed to report whether measurements were obtained actively or passively. Contributing to the inconsistency was the varied time points at which outcomes were assessed.

There was a paucity of evidence for some key questions that were considered clinically important. In particular, there were no studies that addressed whether early versus late surgical repair results in better patient outcomes (Question 1). This question was identified as a critical issue by our technical expert panel, as there is uncertainty regarding whether, for what duration, and for which patients nonoperative treatment should be attempted prior to surgery. In addition, only three studies were identified that compared the effectiveness of nonoperative with operative treatment. Thus, firm conclusions on the optimal management of RC tears could not be made.

The body of evidence was insufficient for many outcomes that were considered by our review team to be clinically important a priori. These included health-related quality of life, function, return to work, and tendon healing. Consensus on clinically and patient-important outcomes is needed. Many studies only reported results for one or two outcomes which may suggest selective outcome reporting or may simply reflect the retrospective nature of the studies.

Discussion and consensus is required regarding what differences are clinically important when comparing interventions. In some meta-analyses, a statistically significant difference was observed but the difference on the measurement scale was not deemed to be clinically important (e.g., less than 10 points on a 100-point scale). Such information is critical for designing future research (e.g., planning for adequate sample sizes) and interpreting the findings.

A further limitation of this body of evidence was the limited or inconsistent reporting with respect to a number of variables and design considerations. For instance, some of the interventions were inadequately described to allow for replication in practice or determining applicability. This was more problematic for the nonoperative interventions. Specifically, studies often reported using physical therapy as an intervention, without further description of treatment components or delivery. Sufficient detail should be reported regarding the specific components of the interventions; timing, and frequency of each component; training and experience of the individuals implementing the interventions; and, cointerventions. As another example, lack of comprehensive assessment and reporting across studies for complications resulted in challenges for interpreting these data. For instance, some studies reported no complications while others did not comment on complications. It is not known whether these investigators looked for complications systematically or which complications they looked for. Further, definitions of the same complications and assessment of complications (e.g., clinical versus imaging) may have varied across studies.

Future Research

The following recommendations for future research are based on the preceding discussion regarding the limitations of the current evidence base:

- There is need for primary evidence comparing the effectiveness of early versus delayed surgery and nonoperative versus operative interventions.

- All future studies should employ a comparison or control group and ensure comparability of treatment groups, optimally through the use of randomization.
- Future research should seek to minimize bias by blinding outcome assessors, using objective outcome assessment instruments, adequately concealing allocation (where applicable), and handling and reporting missing data appropriately.
- Interventions and comparisons chosen for study should be guided by consensus regarding the most promising and/or controversial interventions in order to avoid numerous studies on disparate interventions.
- Consensus on clinically and patient-important outcomes is needed to ensure consistency and comparability across future studies. Moreover, consensus on minimal clinically important differences is needed to guide study design and interpretation of results.
- Future research needs to be reported in a consistent and comprehensive manner to allow for appropriate interpretation of results.

Conclusions

Numerous interventions and comparisons have been studied for the nonoperative and operative management of RC tears. The data are sparse for most interventions which prevents making firm conclusions for any single approach or for the optimal overall management of this condition. Overall, the evidence shows that all interventions result in substantial improvements; however, few differences of clinical importance are evident when comparisons between interventions are available. The majority of the data were derived from studies of low methodological quality or lower in the hierarchies of evidence.

In terms of operative approaches, there is moderate evidence demonstrating no difference in function between mini-open and arthroscopic repairs, open and mini-open repairs, open or mini-open and arthroscopic repairs, and arthroscopic repairs with and without acromioplasty. There is some evidence suggesting an earlier return to work for mini-open as compared with open repairs and greater improvement in function for open repairs compared with arthroscopic debridement. For operative techniques, there is moderate evidence for no difference in function between single-row and double-row suture anchors, but some potential for greater cuff integrity with double-row sutures. The evidence was too limited to make conclusions regarding comparative effectiveness for the other surgical approaches and techniques studied. In terms of postoperative rehabilitation, there is moderate evidence demonstrating no difference in function but earlier return to work for continuous passive motion with physical therapy compared with physical therapy alone. No conclusions were possible for studies evaluating operative augmentation, nonoperative interventions, and those comparing nonoperative and operative treatments. In general the rates of complications were low across all interventions. There is some evidence that tear size, age, and extent of preoperative symptoms may modify outcomes; while, WCB status, sex, and duration of symptoms generally showed no significant impact.

Future research should incorporate design elements to minimize bias in treatment effects including randomization where possible, blinding of outcome assessors, comparability of study groups, and appropriate handling and reporting of missing data. Consensus is needed on clinically and patient-important outcomes, as well as minimum clinically-important differences. Consistency across studies is needed in choice of outcomes and measurement tools. Comprehensive and consistent reporting in future studies will allow for more accurate

comparisons and the interpretation of findings across studies as well as greater understanding with respect to the applicability of the findings.

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Abbreviations

| Abbreviation | Description |
|---------------------|--|
| AHRQ | Agency of Healthcare Research and Quality |
| ASES | American Shoulder and Elbow Surgeons |
| BA | Before-and-after |
| EPC | Evidence-based Practice Center |
| CI | Confidence interval |
| CCT | Controlled clinical trial |
| CMS | Constant-Murley Score |
| CT | Computed tomography |
| DASH | Disabilities of the Arm, Shoulder, and Hand |
| FSET | Shoulder Elevation Test |
| IQR | Inter-quartile range |
| JOA | Japanese Orthopaedic Association |
| LHB | Long head of biceps |
| MMLS | Modified mattress locking stitch |
| MRI | Magnetic resonance imaging |
| NOQAS | Newcastle-Ottawa Quality Assessment Scales |
| NSAID | Non-steroidal anti-inflammatory drugs |
| RC | Rotator cuff |
| RC-QOL | Rotator Cuff Quality of Life scale |
| RCR | Rotator cuff repair |
| RCT | Randomized controlled trial |
| SF-36 | Short Form (36) Health Survey |
| SLAP | Superior labral from anterior to posterior |
| SMD | Standardized mean difference |
| SPADI | Shoulder Pain and Disability Index |
| SRQ | Shoulder Rating Questionnaire |
| SSQ | Shoulder Service Questionnaire |
| SST | Simple Shoulder Test |
| TEP | Technical expert panel |
| UAEPC | University of Alberta Evidence-based Practice Center |
| UCLA | University of California, Los Angeles |
| PENN | University of Pennsylvania Shoulder Score |
| VAS | Visual analogue scale |
| WCB | Workers' compensation board |
| WMD | Weighted mean difference |
| WORC | Western Ontario Rotator Cuff Index |