

Does structural integrity following rotator cuff repair affect functional outcomes and pain scores? A meta-analysis

Aziz Haque and Harvinder Pal Singh

Abstract

Background: To assess whether the integrity of rotator cuff repairs has an impact on functional outcomes, as well as pain scores, after surgery.

Methods: Systematic review and meta-analyses performed for Level I, II and III studies that presented functional outcome scores and radiological assessment of integrity following rotator cuff repair. Extracted data included patient demographics, functional outcome scores [Constant Score, University of California at Los Angeles (UCLA) shoulder score, American Shoulder and Elbow Surgeons (ASES) shoulder score, visual analogue scale (VAS) Pain score], as well as assessment of repair integrity on radiological investigations. A meta-analysis was performed using weighted means and a random effects model.

Results: Twelve studies were included in the final analysis. Average re-tear rate for the 800 included patients was 22% at a mean follow-up of 27.5 months after surgery. Patients with intact repairs had a significantly higher Constant Score (8.61 points, $p < 0.00001$), UCLA shoulder score (2.96 points, $p < 0.0001$) and ASES shoulder score (9.49 points, $p < 0.0006$). Patients with intact repairs also reported lower pain VAS Pain scores by 0.62 points ($p < 0.0004$)

Conclusions: Our results show better functional outcome and pain scores in patients with intact rotator cuffs at follow-up when compared to those that have re-torn. This difference is equivalent to the published Minimal Clinically Important Difference for the ASES but not Constant Scores. This review has also highlighted that shoulder strength in patients with intact cuff repairs is likely to be greater than in patients with a failed repair.

Keywords

functional outcome, integrity, repair, re-tear, rotator cuff

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Introduction

Rotator cuff tear is a common cause of shoulder pain. Cadaveric studies have reported a prevalence of tears between 17% to 30% of population depending on age.^{1,2} Rotator cuff repair (RCR) can reliably reduce pain and improve shoulder function, with a number of studies reporting good clinical outcomes at follow-up.^{3–6} Cuff surgery has evolved over the last 20 years with techniques ranging from open surgery, using trans-osseous sutures, to purely arthroscopic surgery using single-row or double-row suture anchor repairs. Biomechanical studies have shown improved repair strength with newer techniques; however, this has not translated into better clinical outcomes.⁷

Although reported re-tear rates following RCR vary between 13% and 68%, some studies have shown this

to be as high as 94%.^{8–10} Re-tears are associated with increasing age, larger tears, tendon quality, muscle atrophy, multiple tendon involvement and tension of repair.¹¹ There are differences in the published literature whether a re-tear leads to poorer functional outcome. One previous systematic review suggested a difference existed between those repairs that had healed versus those that had re-torn;¹⁰ however, a meta-analysis later concluded that the difference was not clinically significant.¹² The searches in the most

Leicester Royal Infirmary, University Hospitals of Leicester, Leicester, UK

Corresponding author:

Aziz Haque, Leicester Royal Infirmary, Leicester Square LE1 5WW, UK.
Email: aziz.leicester@gmail.com

recent study were undertaken in June 2012; therefore, the evidence is 4 years out of date. An update would be useful in the planning of future trials.

A recently concluded randomised controlled trial suggested that a healed repair (a participant having no tear on magnetic resonance imaging (MRI) assessment at 12 months) resulted in greater improvement in patient reported outcome scores compared to patients in whom repaired tears had re-torn.¹³ Clinical experience suggests that shoulder strength is poorer in patients in whom the rotator cuff has re-torn. Our aim was to perform an updated meta-analysis to assess the impact of re-tears on functional outcome and pain scores after surgery. In addition, we wanted to review whether rotator cuff integrity following repair had an impact on shoulder strength.

Materials and methods

Search methodology

A comprehensive literature search was performed in January 2015 using Medline, CINAHL (Cumulative Index to nursing and Allied Health Literature), PubMed search engines, as well as the central register of controlled trials for all peer-reviewed literature published between January 1996 to December 2015. A search strategy was formulated with a clinical librarian using keywords: shoulder, rotator cuff, rotator cuff tear, rotator cuff repair, re-tear, integrity, healed, ultrasound, MRI and computed tomography arthrography. To ensure all possible articles were considered, references from important studies and review articles were also checked and manually included.

Selection criteria

Level I, II and III studies with at least one patient outcome measure following RCR for full-thickness tears and a radiological assessment of repair integrity were included for consideration.

Exclusion criteria included a follow-up of less than 1 year, studies that only included massive (>5 cm) cuff tears, isolated subscapularis tears and the use of platelet rich plasma (PRP). Massive cuff tears were excluded as they are often not directly repairable and require additional techniques making comparisons difficult. PRP can significantly alter the tissue characteristics in tendons after surgery with reduced vascularity and increased apoptosis. Their role remains unclear and certain studies indicate that their use may be detrimental to the rotator cuff. They were therefore excluded.¹⁴ We included studies irrespective of surgical technique (all arthroscopic, mini-open and open).

A title review was performed by two independent reviewers and studies not related to our systematic review were excluded. Abstracts were then assessed for eligibility using the above inclusion criteria followed by full text review of all eligible studies. A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for this process is available below (Fig. 1). Studies were assessed for their quality and a level of evidence assigned to them.

Extracted data from studies included patient demographics, imaging modality used, functional outcome measures [American Shoulder and Elbow Surgeons (ASES) shoulder score, Constant Score and University of California at Los Angeles (UCLA) shoulder scores], VAS Pain score, as well as imaging results commenting on the structural integrity of the repair. We contacted the authors requesting further data in instances where published data were incomplete for our analysis.

A meta-analysis was performed comparing functional outcome measures, strength in forward elevation and pain scores of patients with intact repairs versus those with re-tears. Differences were assessed using the *t*-test and weighted mean differences with 95% confidence intervals using a random effects model. RevMan 5 (Cochrane Tech; <http://community.cochrane.org/tools/review-production-tools/revman-5>) was used to generate forest plots for our results and Minimal Clinically Important Differences (MCID) were extracted from the available literature.

Results

A total of 49 full text articles were assessed for our meta-analysis and thirteen studies were suitable for inclusion in our final analysis (Fig. 1). Four out of these thirteen studies were included after correspondence with authors allowed collation of additional data. The included studies were a mixture of Level I, II and III studies with 800 patients in total, mean patient age of 60.4 years and a mean follow-up of 27.5 months with an overall re-tear rate of 22%.

Seven studies used MRI to assess postoperative structural integrity whereas four used ultrasound sonography (USS), one a combination of MRI and USS, and another that used magnetic resonance (MR) arthrography.

Patient outcome scores

Seven studies with 342 patients were included in the final analysis for pooled Constant Score data.^{8,15–20} Patients with intact or healed cuff repairs reported a significantly higher Constant Score (Fig. 2) by 8.61 points [95% confidence interval (CI) = 6.01 to 11.22, $p < 0.00001$].

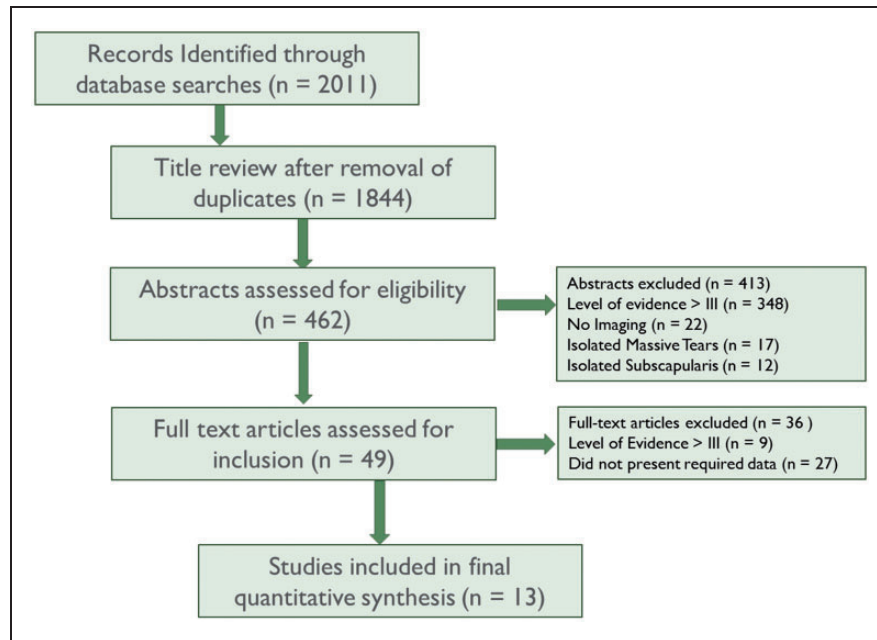


Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart showing the process of study inclusion for the meta-analysis.

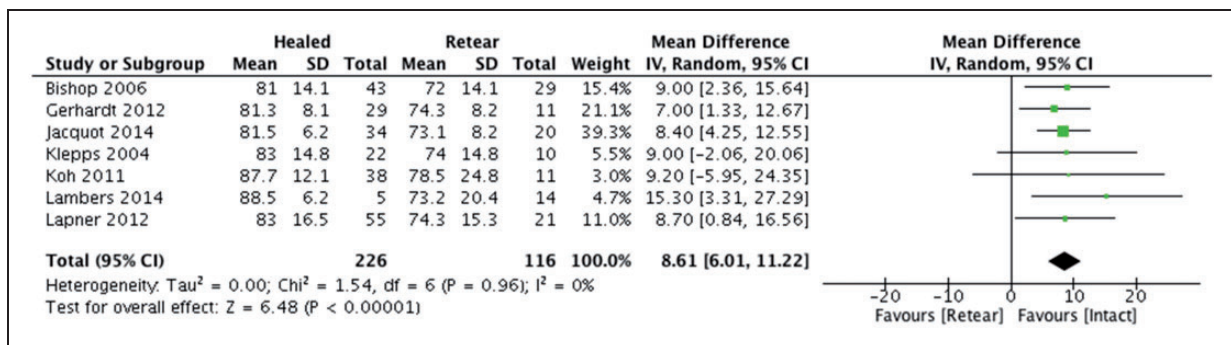


Figure 2. Meta-analysis comparing the Constant score of patients with a cuff re-tear with those that have healed following repair. CI, confidence interval.

Six studies with 500 patients were included in the final pooled ASES shoulder score analysis.^{8,17,19,21-23} Patients with intact cuff repairs reported a significantly higher ASES shoulder score (Fig. 3) by 9.49 points (95% CI = 4.09 to 14.90, *p* < 0.0006).

Six studies with 468 patients were included in the final pooled UCLA shoulder score analysis.^{17,21,23-26} Patients with intact cuff repairs reported a significantly higher UCLA shoulder score (Fig. 4) by 2.96 points (95% CI = 1.52 to 4.39, *p* < 0.0001). Intact repairs also reported significantly lower VAS Pain scores (Fig. 5) by 0.68 points (95% CI = 1.10 to 0.27, *p* < 0.001).

Three studies with 180 patients were included in the pooled strength in forward elevation analysis.^{8,17,20}

Patients with intact cuff repairs had stronger forward elevation strength (Fig. 6) by 5.31 pounds (95% CI = 3.35 to 7.25, *p* < 0.00001).

Discussion

Rotator cuff re-tear is the most common complication following repair. Significant work has looked into the impact that rehabilitation protocols, operative and repair techniques have on postoperative re-tear rates. It is also unclear whether these re-tears lead to adverse clinical outcomes. A number of retrospective studies²⁷⁻²⁹ showed a significant correlation between rotator cuff integrity and functional outcomes, although

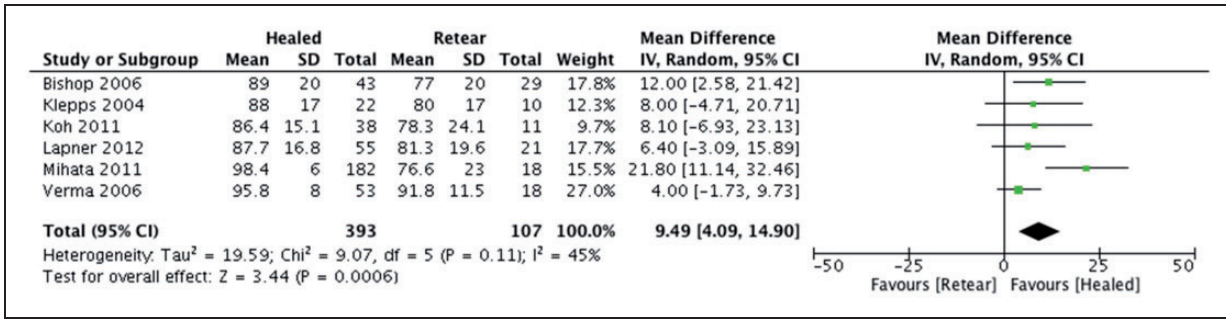


Figure 3. Meta-analysis comparing the American Shoulder and Elbow Surgeons Shoulder (ASES) score of patients with a cuff re-tear with those that have healed following repair. CI, confidence interval.

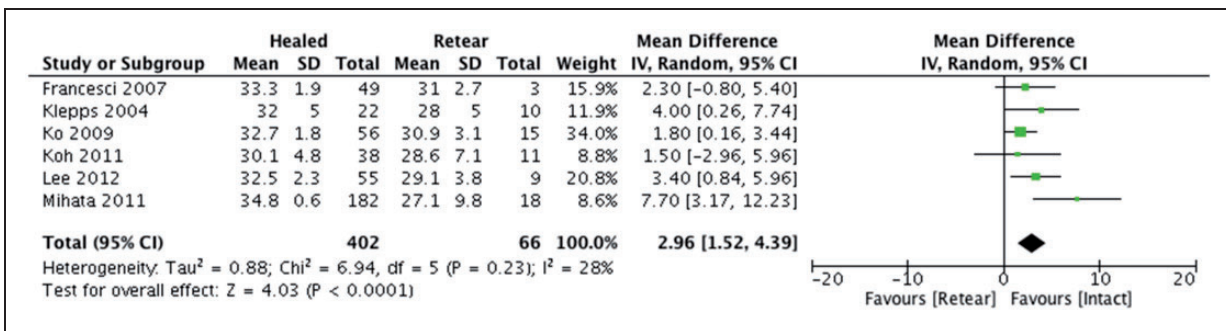


Figure 4. Meta-analysis comparing the University of California at Los Angeles (UCLA) shoulder score of patients with a cuff re-tear with those that have healed following repair. CI, confidence interval.

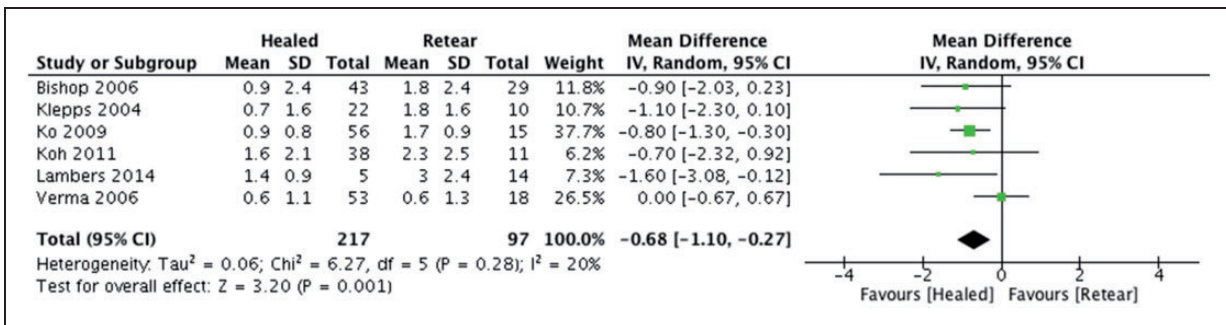


Figure 5. Meta-analysis comparing visual analogue scale (VAS) Pain scores of patients with a cuff re-tear with those that have healed following repair. CI, confidence interval.

this was questioned by other studies that showed no difference in clinical outcomes.^{9,13,30}

Slabaugh et al.¹⁰ performed a systematic review in 2010 and concluded that important differences likely existed for patients with intact repairs. This conclusion was based on the fact that six out of the nine studies that they reviewed showed higher Constant Scores and one out of two studies showed higher UCLA shoulder

scores with intact repairs. None of their studies showed a difference in ASES shoulder scores. Because the majority of their studies were Level 4 case series, a meta-analysis was not performed.

In 2014, Russell et al.¹² presented their meta-analysis and concluded that, although significant differences in Constant Score (8.93 points) and UCLA shoulder scores (2.95 points) were found, they did not meet the

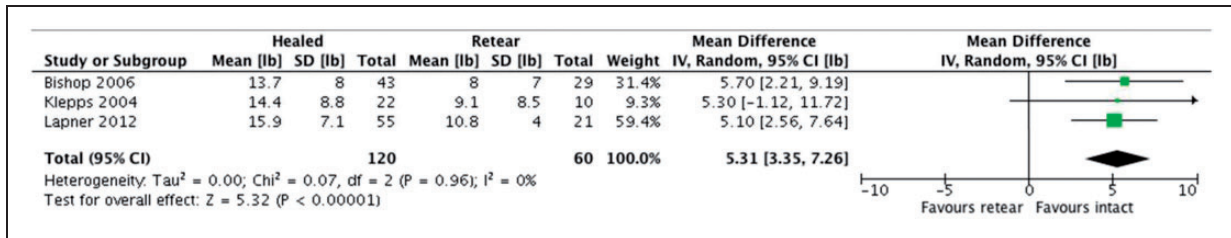


Figure 6. Meta-analysis comparing shoulder strength in forward elevation (Lb) of patients with a cuff re-tear with those that have healed following repair. CI, confidence interval.

criteria for clinical importance. They also did not find a significant difference in the ASES shoulder scores for those patients with intact repairs compared to those that had re-tears. They had included seven Level I and II studies published before June 2012 with 451 patients in their final analysis.

The present study included twelve Level I, II and III studies published before December 2015 with 800 patients in our final analysis. We found significant differences in patient outcomes for all three of our functional outcome measures and strength in forward elevation.

Constant Score is a widely used outcome measure tool and only recently has its MCID been calculated.³¹ We found a difference of 8.61 points between our groups, whereas the published MCID for Constant Score is 10.4. In their analysis Kukkonen et al.³¹ noted that, by using various statistical methods for calculating the MCID, they had five different values ranging between 2 points and 16 points. Constant Score is also the only scoring system used in the present study that includes an objective measurement of strength. In our meta-analysis, we found a significant difference in forward elevation strength between cuffs that had healed and those that had re-torn and this could account for the difference seen in the constant scores of the two groups.

The ASES shoulder score was first introduced in 1994 and is validated for a number of shoulder pathologies. It does not include an objective measurement of shoulder function or shoulder strength. This may be the reason why previous studies^{10,12} did not find a correlation between ASES shoulder scores and structural integrity. Its MCID has been calculated to be 6.4 points³² in one study and 12 points in another.³³ We have demonstrated a significant 9.49 point difference in ASES shoulder scores between intact and re-torn cuffs.

Unfortunately, the UCLA shoulder score does not have a published MCID; however, we found a significant difference of 2.96 points (35-point scale).

The MCID for VAS Pain score³⁴ in rotator cuff disease is reported as 1.4 points on a 10-point scale.

Our finding of a 0.68-point difference therefore did not reach clinical significance.

Functional outcome and pain score measures are important in research for comparing patient-reported outcomes following a clinical intervention. Calculating the MCID for these scoring systems has the additional benefit of allowing us to arrive at conclusions based on clinical significance rather than just statistical ones. However, because there are still various statistical methods being implemented to calculate MCIDs, it is important to exercise caution when using them to inform clinical decisions.

Shoulder strength is an important outcome measure and part of the Constant Score. The impact rotator cuff re-tears have on shoulder strength has not been investigated thoroughly. We only found three studies that compared strength in forward elevation, although the difference was significant.^{8,17,20} In their prospective comparative study looking at outcomes of open versus arthroscopic RCR, Bishop et al.⁸ found a significant improvement in shoulder strength postoperatively with intact repairs. Lapner et al.²⁰ and Verma et al.²² found significant differences in forward elevation strength with intact repairs but not for external rotation. The matched pair analysis of Gerhardt et al.¹⁵ found a correlation between repair integrity and Constant Score (81.3 versus 74.3; $p = 0.045$). In addition, having broken down the Constant Scores, Gerhardt et al.¹⁵ found that the difference only existed in its strength category. Other studies have shown trends but not any statistical significance towards improved strength with intact repairs.¹⁷

A possible limitation of the present study is our inclusion of four Level III studies^{15,21,22,24} in the meta-analysis with three being retrospective cohort studies. Currently, a large number of Level I and II studies do not report on outcomes based on structural integrity and we therefore considered that the inclusion of Level III studies would allow a better analysis than the existing literature.

Various imaging modalities were used in the included studies to assess cuff integrity (USS, MRI and MR arthrography). The accuracy of these

modalities can vary and be user dependant. However, there have been a number of studies that have compared MRI with USS and found their sensitivities and specificities to be similar.^{35,36} A recent meta-analysis did find MR arthrography to be more sensitive and specific compared to MRI and USS,³⁶ which may introduce another limitation to the present study. Because all three imaging modalities have been validated for use in diagnosing rotator cuff tears and re-tears following repair, we accepted this variation.

The recently concluded UKUFF trial also warrants further discussion. It was a large UK based multicentre trial looking to compare open with arthroscopic rotator cuff repair. In addition to finding no difference in the effectiveness between open and arthroscopic cuff repair, Carr et al.¹³ a re-tear rate of 43%, with this adversely affecting outcomes in terms of the Oxford Shoulder Score at follow-up. This is in keeping with our findings; however, we were not able to include this data in our meta-analysis because this was the only study to report outcomes using the Oxford Shoulder Score.

In conclusion, data from our meta-analysis shows that there is a statistically significant difference in patients' functional outcome and pain scores with an intact rotator cuff repair compared to those that have re-torn. Based on the published MCIDs for these outcome scores, this difference may not be clinically relevant. We have also found that strength is better for those cuff repairs that have healed versus those that have failed. We suggest further research into the long-term outcomes following rotator cuff re-tears and their impact on shoulder strength. More work is also needed to develop new strategies to improve tendon healing and, in turn, patient outcomes.

Declaration of Conflicting Interests

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Ethical Review and Patient Consent

Not required for this study.

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