Clinical Outcomes of Superior Capsular Reconstruction for Massive, Irreparable Rotator Cuff Tears: A Systematic Review Comparing Acellular Dermal Allograft and Autograft Fascia Lata


Purpose: To investigate clinical outcomes after superior capsular reconstruction (SCR) for the treatment of massive and/or irreparable rotator cuff tears treated with either allograft or autograft. Methods: Using the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) guidelines, in April 2020 a systematic review was performed using PubMed, MEDLINE, EMBASE, and Cochrane databases. Clinical studies were assessed for patient-reported outcomes and range of motion, comparing dermal allografts to fascia lata autografts, with a minimum follow-up of 12 months. Results: A total of 16 clinical studies involving 598 patients (606 shoulders) were included for data analysis, with a weighted mean follow-up of 36.9 months (range 12 to 60). Visual analogue scale (VAS) pain scores decreased from 4.0 to 6.9 mm preoperatively to 0 to 2.5 mm postoperatively. American Shoulder & Elbow Surgeons score increased from 20.3 to 54.5 preoperatively to 73.7 to 97.0 postoperatively. Forward flexion increased from 27.0° to 142.7° preoperatively to 134.5° to 167.0° postoperatively. External rotation increased from 13.2° to 41.0° preoperatively to 30.0° to 59.0° postoperatively. Acromiohumeral distance increased from 3.4 to 7.1 mm preoperatively to 6.0 to 9.7 mm postoperatively. The total rates of complications, graft failure, and revision surgery were 5.6%, 13.9%, and 6.9%, respectively. Conclusions: Irrespective of tissue source, SCR serves as a reasonable joint-preserving option for massive, irreparable rotator cuff tears, with favorable short- to midterm improvements in patient-reported outcomes and range of motion. Level of Evidence: IV, systematic review of level III and IV studies.

The management of massive or irreparable rotator cuff tears is particularly complex for orthopedic surgeons. Technical challenges include the presence of muscle atrophy, fatty infiltration, scarring or adhesions, myotendinous retraction, tendon inelasticity, superior migration of the humeral head, and ultimately, osteoarthritis.1-5 In addition, retear rates of primary repair for massive rotator cuff tears have been reported to be as high as 94% within 36 months.6 Treatment options vary and include arthroscopic debridement, tendon transfer, interpositional arthroplasty, subacromial spacer interposition, reverse shoulder arthroplasty (RSA), and superior capsular reconstruction (SCR). RSA has become increasingly popular over the last 2 years.


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decades and accounts for nearly half of all shoulder arthroplasty performed today. However, there are concerns regarding the complication rate of RSA and the associated revision burden, particularly in younger patients.

Historically, rotator cuff surgery has focused on reestablishing the tendinous attachment to its footprint. More recently, authors have proposed that the superior capsule may serve as a more integral structure, whereby restoration of superior capsular defects may have a greater impact on subsequent glenohumeral biomechanics. SCR has become increasingly popular in the United States and Europe for the treatment of massive or irreparable rotator cuff tears. However, the justification for its exponential growth has been questioned, as the literature regarding SCR is limited to several small case series and biomechanical studies. The purpose of this study was to investigate clinical outcomes after SCR for the treatment of massive or irreparable rotator cuff tears treated with either allograft or autograft. The authors hypothesized that postoperative clinical outcomes would demonstrate pain reduction, improved shoulder function, and improved range of motion, and that SCR with fascia lata grafts would demonstrate outcomes superior to those of dermal matrix grafts.

Methods

Literature Search
A systematic review was registered with PROSPERO and performed using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. A comprehensive literature search was performed using PubMed, Medline (Ovid), EMBASE (Elsevier), and Cochrane Library (Wiley) electronic databases in April 2020. MeSH terms were used to increase sensitivity. Additionally, all references in the included studies were cross-referenced for inclusion if any were missed by the initial search. The final search was completed on April 10, 2020, independently, by 2 authors (T.J.S., L.K.).

Study Eligibility
Trials were eligible for inclusion if they met the following criteria: human or cadaveric subjects with documented massive or irreparable rotator cuff tears, superior capsular reconstruction, and patient outcome after ≥12 months of follow-up for clinical trials. Studies involving animals, partial rotator cuff tear, rotator cuff repair, operative technique articles without reported outcomes, cadaver studies, biomechanical studies, review articles, comments, letters, editorials, duplicates, and nonrelevant studies were excluded. Case reports, abstracts without available full text, and foreign language articles without direct translation were excluded.

Study Selection and Data Abstraction
A full-text review was performed by 2 authors (T.J.S., L.K.) to confirm appropriateness for inclusion. Any disagreement between authors during each step of the review process was resolved by discussion. If consensus could not be reached, final inclusion was decided by a third reviewer (B.R.W.). A flow diagram outlining the selection process can be found in Fig 1.

Clinical studies were assessed for multiple outcomes of interest, including level of evidence, concomitant procedures, visual analogue scale (VAS), Constant score, Oxford Shoulder Score (OSS), UCLA shoulder score, American Shoulder & Elbow Surgeons score (ASES), Subjective Shoulder Value (SSV), acromial humeral distance (AHD), range of motion (ROM), patient satisfaction, complications, reoperations, revision surgery, conversion to reverse shoulder arthroplasty, and graft failure. Graft failure was defined as retear confirmed by magnetic resonance imaging (MRI) or ultrasound, partially healed graft confirmed by MRI or ultrasound at final radiologic follow-up, or loss of graft fixation resulting in functional deficit. Descriptive statistics were calculated from each included study. For continuous data, weighted means and standard deviations were calculated for all subjects and outcome parameters. Clinical studies were assessed for patient-reported outcomes and ROM in comparison of fascia lata autografts to acellular dermal allografts.

Data Analysis
The Metafor package as part of RStudio software version 1.0.143 (R Foundation for Statistical Computing, Vienna, Austria) was used for data analysis. Forest plots were created for VAS, ASES, and ROM (forward flexion [FF] and external rotation [ER]) (Figs 2, 3, 4, and 5, respectively). The I² index was used to measure heterogeneity of included studies. Effect sizes were calculated using random-effects models with the DerSimonian-Laird estimator, as high heterogeneity precluded use of a fixed-effects model.

Risk of Bias Assessment
A funnel plot was created to assess publication bias. Estimated treatment effect for the change in ASES score was plotted on the x axis, and effect sizes were plotted on the y axis. Study methodological quality was assessed independently by 2 authors (T.J.S., J.K.) using the Methodological Index for Non-randomized Studies (MINORS) score (Table 1; Appendix).

Results

Study Identification and Assessment
The following terms were used as keywords and appeared in the title, abstract, or keyword fields: (1) massive rotator cuff tear (n = 463); (2) irreparable rotator cuff tear (n = 278); (3) superior capsular
reconstruction (n = 98); and (4) superior capsule reconstruction (n = 73). The initial keyword search returned 912 articles for review. After screening for duplicate citations, 472 articles remained. After screening for appropriateness based on the title and abstract, 440 articles were excluded, leaving 32 articles.
for full text review. Of those 32, 5 were case reports, 8 were abstracts without available full text, and 3 did not meet the minimum follow-up. Sixteen studies, all level of evidence III or IV, reporting clinical outcomes were included in the final review for data extraction and analysis (Fig 1).\textsuperscript{12,17-31} All studies lacked randomization or a control group. The mean MINORS score for all studies included was 12.4 (Table 1; Appendix). A funnel plot was created to assess publication bias. Estimated treatment effect for the ASES were plotted on the x axis, and effect sizes were plotted on the y axis. Point estimates were verified to be symmetric around the real estimated treatment effect to demonstrate limited publication. However, 7 studies were outside the funnel, which would suggest heterogeneity in results (Fig 6).\textsuperscript{16}

Fig 3. Forest plot demonstrating change in American Shoulder & Elbow Surgeons Score (ASES) after superior capsular reconstruction (SCR) with dermal matrix versus fascia lata grafts. Abbreviation: CI confidence interval.

Fig 4. Forest plot demonstrating change in forward flexion (FF) after superior capsular reconstruction (SCR) with dermal matrix versus fascia lata grafts. Abbreviation: CI confidence interval.
Fig 5. Forest plot demonstrating change in external rotation (ER) after superior capsular reconstruction (SCR) with dermal matrix versus fascia lata grafts. Abbreviation: CI confidence interval.

Study and Patient Characteristics
Of the 16 clinical studies, 6 involved fascia lata autografts,12,18,22-24,31 8 involved acellular dermal matrix allografts,17,19,20,25,27-30 1 involved both fascia lata and dermal matrix grafts,21 and 1 study involved autologous hamstring grafts.26 In total, 606 shoulders (598 patients) treated with superior capsular reconstruction were pooled for evaluation, with a weighted mean follow-up of 36.9 months (range 12 to 60). Graft types were fascia lata in 294 patients (49.2%), dermal matrix in 264 (44.1%), hamstring autograft in 8 (1.3%), and not disclosed in 32 (5.4%). Graft thickness was a minimum of 5 mm (range 5 to 8) in 294 patients (49.2%), 1 to 3.5 mm in 264 (44.1%), and not disclosed in 40 (6.7%). All of the 5- to 8-mm grafts were fascia lata grafts, and all of the 1- to 3.5-mm grafts were dermal matrix grafts. The mean follow-up by graft type was 46.8, 24.2, and 12 months for fascia lata, dermal matrix, and hamstring grafts, respectively.

Clinical Outcomes
After SCR, the standard mean difference between postoperative and preoperative state was demonstrated with respect to the VAS score, ASES score, FF, and ER (Figs 2, 3, 4, and 5, respectively). VAS scores were reported in 10 studies, and all studies reported improvements from preoperative (range 4.0 to 6.9 mm) to postoperative (range 0 to 2.5 mm) values.17,19,20,22-25,27,28,30,31 ASES scores were reported in 13 studies, and all studies reported improvements from preoperative (range 20.3 to 54.5) to postoperative (range 73.7 to 97.0) values.12,17,19,20,22-24,27,29,30,31 The change in FF was reported in 12 studies, with all studies reporting improvements from preoperative (range 27.0° to 142.7°) to postoperative (range 134.5° to 167.0°) values.12,17-19,21-24,27,29,30,31 The change in ER was reported in 10 studies, with all studies reporting improvements from preoperative (range 13.2° to 41.0°) to postoperative (range 30.0° to 59.0°) values.12,17-19,21-23,27,30,31 Constant scores were reported in 4 studies, all demonstrating improvements from preoperative (range 17.5 to 56.3) to postoperative (range 63.7 to 83.5) values.18,21,22,26 Japanese Orthopaedic Association scores were reported in 3 studies, all demonstrating improvements from preoperative (range 40.6 to 61.2) to postoperative (range 90.6 to 95.2) values.12,24,31 AHD was reported in 12 studies, and demonstrated improvements from preoperative (range 3.4 to 7.1 mm) to postoperative (range 6.0 to 9.7 mm) values in 11 studies.12,18,22-25,27,30,31 One study demonstrated a decreased mean AHD postoperatively; however, this finding was not statistically significant (P = .6).17

Clinical Outcomes by Graft Type
Clinical studies were differentiated by graft type for subgroup analysis. One study using both fascia lata and dermal matrix grafts did not differentiate outcomes for each subgroup and was therefore excluded.21 For SCR with dermal allografts, mean VAS improved from 4.0 to 6.3 mm preoperatively to 0 to 1.7 mm postoperatively, mean ASES 41.8 to 54.0 versus 73.7 to 92.3, mean FF from 27.0° to 140.0° versus 137.0° to 167.0°, mean ER from 24.0° to 41.0° versus 35.0° to 59.0°, and mean AHD from 3.4 to 7.1 mm versus 6.0 to 9.7 mm. For SCR with fascia lata autografts, mean VAS improved from 6.0 to 6.9 mm preoperatively to 0.9 to 2.5 mm postoperatively, mean ASES from 20.3 to 54.4 versus 77.5 to 97.0, mean FF from 36.7° to 142.7° versus 143.8° to 163.6°, mean ER from 13.2° to 32.0° versus 30.0° to 44.0°, and mean AHD from 4.6 to 6.4 mm versus 6.4 to 8.7 mm.
Table 1. Study Demographic Characteristics and Design

<table>
<thead>
<tr>
<th>Reference</th>
<th>Patients/Shoulders</th>
<th>Mean Age (y)</th>
<th>Mean Follow-Up (mo)</th>
<th>Study Design/Methodology</th>
<th>MINORS Score</th>
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<td>Mihata et al. 2013⁷⁷</td>
<td>23/24</td>
<td>65.1</td>
<td>34.1</td>
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<td>12 /16</td>
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<td></td>
<td>No adjustment of confounding variables</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>No control</td>
<td></td>
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<td>69</td>
<td>12.9</td>
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<td>14 /16</td>
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<tr>
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<td></td>
<td>Power analysis included</td>
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<td>No control/comparison groups</td>
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<td>No adjustment of confounding variables</td>
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<td>Lee and Min 2018</td>
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<td>de Campos Azevedo</td>
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<td>Subgroup comparisons between 12 mo and 24 mo follow-up</td>
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<td>Subgroup comparisons between ultrasounds performed &lt;6 and &gt;12 mo</td>
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<td>Polacek 2019⁹³</td>
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<td>Minimum 12, no mean reported</td>
<td>Subgroup comparisons between 6- and 12-mo follow-up</td>
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</table>

(continued)
By comparison, the post-published Catapano et al. initially described SCR 30/30 68 Minimum 60, no Until recently, few studies have Mihata et al. published a qualitative review of 5 clinical and 5 cases (16.9%), and at the glenoid side in 37 cases (69.8%), intrasubstance in 9 of retear or graft failure. Failure occurred on the humeral graft at final radiologic follow-up (range 0% to 47.6%).

Of the 82 reported failures, 53 reports included the site SCR in both subjective and objective outcomes, primarily described signiﬁcant improvements in forward elevation and ER. Catapano et al. published a qualitative review of 10 clinical studies in 2019. They reported improvements in VAS, ASES, FF, and ER, with a retear rate ranging from 3.4% to 36.1%. However, that review included 2 studies that were excluded from our review (1 case report, 1 abstract only). Galvin et al. published a qualitative review of 5 clinical studies and 5 biomechanical SCR studies in 2019 and reported mean improvements in VAS, ASES, FF, and ER. The average complication, reoperation, and graft failure rates were 3.8%, 11.7%, and 14.2%, respectively. However, that review involved only 6 clinical studies, one of which was a case report.

**Complications, Reoperations, and Graft Failures**

From all cases of SCR, there were 82 incidences (13.9%) of retear, loss of ﬁxation, or partially healed graft at ﬁnal radiologic follow-up (range 0% to 47.6%). Of the 82 reported failures, 53 reports included the site of retear or graft failure. Failure occurred on the humeral side in 37 cases (69.8%), intrasubstance in 9 cases (16.9%), and at the glenoid ﬁxation in 7 cases (13.2%). There were 42 revision surgeries performed (6.9%, range 0% to 36.1%; 19 revision SCR, 11 RSA, and 2 balloon spacers). No studies disclosed whether grafts were reused during revision SCR procedures. There were 34 complications among all surgeries (5.6%, range 0% to 15%) (Table 2).

**Discussion**

This systematic review suggests that SCR for massive or irreparable rotator cuff tears produces favorable short-term outcomes, with resultant improvements in pain, ROM, and other patient-reported outcomes, irrespective of graft type. In addition, the ﬁndings demonstrated low rates of SCR graft failure (13.9%), complications (5.6%), and revision surgeries (6.9%) at a mean follow-up of >3 years. These outcomes are especially encouraging given the reported retear rates after primary repair of massive, irreparable rotator cuff tears being as high as 94%. By comparison, the post-operative complication rate of RSA has been reported to be as high as 39%, with increasing rates among younger patient groups. Recently published systematic reviews have echoed these ﬁndings, reporting short-term improvements after SCR in both subjective and objective outcomes, including signiﬁcant improvements in forward elevation and ER. Catapano et al. published a qualitative review of 10 clinical studies in 2019. They reported improvements in VAS, ASES, FF, and ER, with a retear rate ranging from 3.4% to 36.1%. However, that review included 2 studies that were excluded from our review (1 case report, 1 abstract only). Galvin et al. published a qualitative review of 5 clinical studies and 5 biomechanical SCR studies in 2019 and reported mean improvements in VAS, ASES, FF, and ER. The average complication, reoperation, and graft failure rates were 3.8%, 11.7%, and 14.2%, respectively. However, that review involved only 6 clinical studies, one of which was a case report.

**Graft Type and Thickness**

The native superior capsule ranges in thickness from 4.4 to 9.1 mm. Mihata et al. initially described SCR with a folded, 6- to 8-mm fascia lata autograft. However, concerns of donor site morbidity, shorter operative duration, and ease of graft preparation have led authors in North America to primarily use thinner, 1- to 3-mm commercially available dermal allografts. Until recently, few studies have compared the 2 most popular graft types. Galvin et al. in the qualitative review of 5 clinical and 5 cadaveric studies, suggested improved glenohumeral stability and decreased subacromial contact pressures with 8-mm fascia lata grafts compared with 4-mm acellular dermal allografts. This conclusion was drawn mainly from the biomechanical cadaveric studies by Mihata and colleagues, which demonstrate improved restoration of glenohumeral mechanics, decreased thinning, and decreased elongation with a thicker graft. In their recent systematic review, Makovicka et al. described SCR outcomes among various graft types in 9 clinical and 8 biomechanical studies. They reported improvements in superior humeral...
Interestingly, our analysis of the available data indicated that as imaged by ultrasound, Mihata and colleagues reported that 76.7% of graft failures in their review occurred at the humeral fixation site. These findings may be related to (1) greater tensile forces on the humeral fixation site during glenohumeral ROM and (2) acromiohumeral contact abrasion. However, it should be noted that 1 study included in the present review that reported 13 of 36 failures, all occurring on the humeral side, performed graft fixation with a single-row technique. Conversely, other authors have suggested that graft failure occurs most commonly at the glenoid fixation or midsubstance. Additional clinical studies with long-term follow-up data are needed to determine ideal graft tensioning, as well as to assess whether there are significant clinical manifestations of the elongation and thinning of the dermal allograft as observed in biomechanical studies. Interestingly, Polacek reported a 15% rate of early graft failure secondary to immunologic rejection of the dermal allograft. All patients had underlying immunologic disorders and experienced graft disintegration within several weeks of surgery. The optimal graft choice for SCR in patients with autoimmune or immunologic conditions remains unclear.

The merits of this systematic review include its large sample size, with 606 shoulders in 598 patients. In addition, the 16 included studies involve a variety of graft types (fascia lata autograft, acellular dermal matrix, and hamstring autograft) and a variety of graft thicknesses (range 1 to 8 mm). This review also includes a subjective synthesis of outcomes between graft types, which has not been analyzed in prior reviews on this topic. In addition, although previous reviews have demonstrated only moderate levels of heterogeneity, the mean MINORS score for our pooled clinical studies demonstrated a high level of methodological quality as well as a high degree of interobserver reliability.

**Limitations**

We acknowledge that our analysis has several limitations. First, evaluation of ROM varied between studies, with some authors using a goniometer and others reporting values from visual inspection. In addition, ER was primarily measured with the arm at the side; however, several studies reporting ER did not specify arm position. Second, all of the articles included are level of evidence III and IV, and although several studies performed subgroup comparisons, no studies involved a control group or randomization. In addition, many studies failed to control for confounding patient and/or procedural variables such as preoperative shoulder function and concomitant surgeries. Third, 7 of the included studies also demonstrated heterogeneity among results during the risk of bias.
assessment. Although no level I or II studies currently exist on the topic, the low level of evidence limits the ability to pool data and provide a true quantitative analysis, and therefore also limits the overall strength of our conclusions. Fourth, the mean follow-up for our clinical studies is 36.9 months. Although this is a relatively short follow-up period, the longest follow-up of any study included is 60 months. Finally, a significant portion of the studies in this review were performed by small groups of researchers. This may introduce bias and falsely elevate the number of patients included in this review, as some patients may have been included in multiple studies.

**Conclusion**

Irrespective of tissue source, SCR serves as a reasonable joint-preserving option for massive, irreparable rotator cuff tears with favorable short- to midterm

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Tendon Involvement</th>
<th>Complications</th>
<th>Graft Failures (%)</th>
<th>Revision rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mihata et al. 2013</td>
<td>SS (24/24)</td>
<td>NR</td>
<td>4/24 (16.7)</td>
<td>1 revision SCR</td>
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<tr>
<td>Burkhardt and Hartzler 2019</td>
<td>Unspecified: 2 tendons fully torn or tear dimension &gt;5 cm</td>
<td>NR</td>
<td>3/10 (30)</td>
<td>0</td>
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<td>Rosales-Varo et al. 2019</td>
<td>SS (4/8)</td>
<td>None</td>
<td>0/8 (0)</td>
<td>None</td>
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<td>Pennington et al. 2019</td>
<td>SS (36/36)</td>
<td>NR</td>
<td>4/88 (4.5)</td>
<td>1 RSA</td>
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<tr>
<td>Lee and Min 2018</td>
<td>SS (22/22)</td>
<td>Surgical site infection (1)</td>
<td>2/22 (9.1)</td>
<td>0</td>
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<td>de Campos Azevedo et al. 2018</td>
<td>SS (59/59)</td>
<td>Deep infection (1)</td>
<td>11/59 (18.6)</td>
<td>2 revision SCR</td>
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<td>Denard et al. 2018</td>
<td>SS (88/88)</td>
<td>Suture-anchor pullout (3)</td>
<td>4/88 (4.5)</td>
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<td>Mihata et al. 2018</td>
<td>SS (41/41)</td>
<td>Traumatic rupture of biceps tenodesis (1)</td>
<td>4/26 (15.4)</td>
<td>1 revision SCR</td>
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<td>Hirahara et al. 2019</td>
<td>SS (20/20)</td>
<td>Immunologic graft rejection (3)</td>
<td>1/18 (5.6)</td>
<td>1 RSA</td>
</tr>
<tr>
<td>Polacek 2019</td>
<td>SS (22/22)</td>
<td>Recurrent loss of function (1)</td>
<td>4/22 (18.2)</td>
<td>1 revision SCR</td>
</tr>
<tr>
<td>Lacheta et al. 2020</td>
<td>SS/IS (16/30)</td>
<td>Suture anchor pullout (1)</td>
<td>3/30 (10)</td>
<td>0</td>
</tr>
</tbody>
</table>

IS, infraspinatus; NR, not reported; RSA, reverse shoulder arthroplasty; SCR, superior capsular reconstruction; SS, supraspinatus; SSc, subscapularis; Tm, teres minor.
improvements in patient-reported outcomes and range of motion.

References
16. Stuck AE, Rubenstein LZ, Wieland D. Bias in meta-analysis detected by a simple, graphical test. Asymmetry detected in funnel plot was probably due to true heterogeneity. BMJ 1998;316:469.
32. Ferreira Neto AA, Malavolta EA, Assunção JH, Trindade EM, Gracitelli MEC. Reverse shoulder
arthroplasty: Clinical results and quality of life evaluation.


Appendix

Methods and Results for MINORS Criteria Scoring

Methods—Quality Assessment

The Methodological Index for Non-randomized Studies (MINORS) checklist was used to assess the methodologic quality of included studies. The checklist assigns a score of 0-2 for 8 items applicable to non-randomized studies, with a maximum score of 16 indicating the highest possible score for an individual non-randomized study. The items were scored 0 if not reported; 1 when reported but inadequate; and 2 when reported and adequate. A minimum of 12 months was deemed appropriate length of follow-up. After thorough review of MINORS scoring guidelines, 2 authors independently reviewed and scored each included study. Any disagreements in scoring were resolved by consensus discussion with the senior author.

Results—Study Quality

The included studies were composed of 15 case series and 1 retrospective comparative study. All clinical studies were non-randomized. The mean MINORS score was 12.4 of 16.