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Management of irreparable massive rotator cuff tears: a systematic review and meta-analysis of patient-reported outcomes, reoperation rates and treatment response

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Abstract

Background: There is no consensus on treatment of irreparable massive rotator cuff tears (MRCT). The goal of this systematic review and meta-analysis was to (1) compare patient-reported outcome (PRO) scores, (2) define failure and reoperation rates, and (3) quantify magnitude of patient response across treatment strategies.

Methods: MEDLINE, Embase, CENTRAL, and Scopus databases were searched for studies including physical therapy and operative treatment of MRCT. The criteria of the Methodological Index for Nonrandomized Studies were used to assess study quality. Primary outcome measures were PRO scores as well as failure, complication and reoperation rates. To quantify patient response to treatment, we compared changes in the Constant-Murley (CMS) and American Shoulder and Elbow Surgeons (ASES) score to previously reported minimum clinically important difference (MCID) thresholds.

Results: No level I or II studies were found that met the inclusion / exclusion criteria. Physical therapy was associated with a 30% failure rate and another 30% went on to have surgery. Partial repair was associated with a 45% re-tear rate and 10% reoperation rate. Only graft interposition was associated with a weighted average change that exceeded the MCID for both CMS and ASES score. Latissimus tendon transfer techniques utilizing humeral bone tunnel fixation were associated with a 77% failure rate. Superior capsular reconstruction with fascia lata autograft was associated with a weighted average change that exceeded the MCID for ASES score. Reverse arthroplasty was associated with a 10% prosthesis failure rate and 8% reoperation rate.

Conclusion: There is a lack of high-quality comparative studies to guide treatment recommendations. Physical therapy compared to surgery is associated with a lower improvement in perceived functional outcome and higher clinical failure rate.

Level of Evidence: Level IV; Systematic Review

Keywords

As the most common upper extremity condition in people over 50 years old,[54] rotator cuff tears represent a significant clinical challenge in our aging population. The overall incidence

of rotator cuff tears ranges from 5–40%,[52, 53] with approximately 54% of individuals over the age of 60 having a partial or complete rotator cuff tear.[63] Massive rotator cuff tears (MRCT), commonly defined as involving a full-thickness tear of at least two tendons[10] or measuring greater than five centimeters in the coronal plane,[23] are estimated to comprise approximately 20% of all rotator cuff tears and 80% of recurrent tears.[5, 43]

Increasing rotator cuff tear size is associated with poor outcomes and high structural failure rates following surgical repair.[37, 58] A review of 18 studies reporting outcomes after repair of massive tears found a re-tear rate of 78%. Despite the high rate of structural failure, much of the published literature supports an attempt at primary repair.[4] However, a number of these MRCT are retracted or lack tendon length so that they cannot be re-attached to their footprint and thus are irreparable. Numerous treatment strategies, such as physical therapy, débridement, partial repair, graft interposition, tendon transfer, superior capsular reconstruction, balloon arthroplasty, and reverse shoulder arthroplasty, have been proposed to treat irreparable MRCT. The comparative efficacy of these treatments remains unclear.

The purpose of this systematic review and meta-analysis was to evaluate the highest quality clinical evidence currently available to recommend either for or against the various treatment options for irreparable MRCT. This was accomplished by (1) comparing patient-reported outcome (PRO) scores across treatment strategies, (2) reporting failure and reoperation rates, and (3) quantitatively evaluating the magnitude of patient response to treatment. We hypothesized that (1) there is a lack of a consistent definition of irreparable MRCT, (2) operative treatment of the irreparable tear leads to greater improvement in PRO scores when compared with nonoperative treatment, and (3) there is no single superior operative treatment strategy due to a lack of high-quality evidence.

Materials and Methods

Search Rationale

This systematic review and meta-analysis followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement guidelines. MEDLINE, Embase, CENTRAL (Cochrane Central Register of Controlled Trials), and Scopus databases were searched in November 2019 for studies addressing eight treatment methods for irreparable MRCT: physical therapy, débridement, partial repair, graft interposition, tendon transfer, superior capsular reconstruction, balloon arthroplasty, and reverse shoulder arthroplasty. Separate searches were carried out for each treatment. Search terms included "massive rotator cuff tear" AND terms associated with each treatment: ("physical therapy OR rehabilitation") / "debridement" / "partial repair" / ("scaffold OR patch OR graft interposition OR platelet rich plasma OR augmentation OR stem cell") / ("tendon transfer OR latissimus dorsi tendon transfer OR lower trapezius tendon transfer") / ("superior capsular reconstruction OR superior capsule reconstruction") / ("(subacromial OR sub-acromial) AND (balloon OR spacer)) OR balloon arthroplasty") / ("reverse total shoulder arthroplasty OR reverse shoulder arthroplasty OR reverse shoulder prosthesis"). Titles, abstracts, and full texts were screened to identify potentially relevant studies.

Study Eligibility

Eligibility criteria were determined a priori. Inclusion criteria included studies of any level of evidence with a minimum two-year clinical follow-up with criteria defining MRCT and reporting of validated PROs and/or range of motion data. Exclusion criteria included studies that included patients with a repairable rotator cuff tear, rotator cuff tear arthropathy with Hamada stage ≥ 3 (glenohumeral arthritis),[28] fractures, rheumatoid arthritis, or instability, as well as case reports, biomechanical studies, reviews, surgical techniques, or studies written in a language other than English. Studies that included patients with or without glenohumeral arthritis were included if data for patients without glenohumeral arthritis were reported separately.

Data Abstraction

Extrapolated data were recorded using a standardized data collection spreadsheet for all sections. This included study design and patient demographics (Supplemental Tables 1a–9a), MRCT diagnosis criteria (Supplemental Tables 1b–9b), clinical outcomes before and after treatment intervention, including VAS pain scores (range 0–10), range of motion, PRO scores, radiographic analysis, failure and revision rates, and complications (Supplemental Tables 1c–9c). All continuous variables were reported as a mean ± standard deviation, unless the standard deviation was unavailable, in which case range was reported, if available.

Assessment of Study Quality

Two reviewers (R.J.S. and D.K.) independently assessed the methodologic quality of all included studies with the Methodological Index for Nonrandomized Studies (MINORS) scoring system.[64] Studies with a MINORS score <75% were excluded.

Response to Treatment

To determine variation in magnitude of response to treatment of the Constant-Murley Score (CMS) and the American Shoulder and Elbow Surgeons (ASES) score, we compared pre-to-post-treatment score changes to the minimally clinical important difference (MCID) thresholds determined by previous rotator cuff studies.[21, 32] The CMS and ASES were chosen because they were the most frequently reported PROs among included studies. The change in ASES and CMS for each study reporting either PRO as well as the weighted average change in score for each treatment modality were graphically compared to previously reported MCID thresholds. The weighted average change in PRO score was influenced by sample size. For CMS, we used an MCID of 15 for nonoperative treatment and an MCID of 30 for operative management.[31] For ASES, we used an MCID of 17 for nonoperative and 39 for operative management.[20] All selected MCID threshold values were calculated by prior studies via an anchor-based approach, in which the change in PRO score is anchored to a separate global rating of change questionnaire that determines overall patient improvement with their treatment outcome at final follow-up.

Results

Search Strategy and Data Aggregation

We identified 120 relevant studies with 77 not meeting the inclusion criteria, leaving 43 studies included in this review (Figure 1). All 43 studies were included in the qualitative synthesis and 37 studies were included in the quantitative synthesis. The most common reasons for exclusion were insufficient follow-up, inclusion of rotator cuff tear sizes other than massive (without a subgroup analysis of massive tears), and failure to define the criteria for MRCT. For each treatment strategy, the data were aggregated and pooled where appropriate, such that Table I provides a summary of study design and demographics, Table II includes criteria for defining MRCT, and Table III outlines clinical outcomes, failure rates, and reoperation rates.

Physical Therapy

Study Design and Patient Demographics—All three studies were of level III or IV evidence with two prospective and one retrospective study and an average follow-up of 32 months.[11, 69, 70] Patients lost to follow-up ranged from 0% to 35%. The number of patients ranged from 19 to 45 (total 94). Nonoperative treatment strategies varied between studies. One study used a home-based three-month anterior deltoid rehabilitation program,[69] a second restored passive range of motion and strength without a described duration,[70] and a third focused on periscapular and intact rotator cuff muscles and described deltoid muscle coaptation only when the arm was elevated.[11]

Definition of a MRCT—All three studies defined MRCT as two or more tendon involvement and defined irreparable as fatty muscle infiltration of grade   3.[11, 69, 70]

Clinical Outcomes—Complete PRO scores were available for two studies with +13-point and +23-point mean change in CMS and ASES scores, respectively.[9;69] Pain scores improved 3 points after physical therapy.[69] Complete range of motion data were available from two studies,[11, 69, 70] with forward elevation improving by 25°. Meanwhile, Collin et al demonstrated that 53% of patients (24/45) achieved more than 160° forward elevation after treatment.[11] Those with subscapularis involvement performed worse than postero-superior rotator cuff tears. Strength improved from 1.1kg to 1.9 kg.[69]

Survival and Complications—For patients treated with anterior deltoid rehabilitation, 40% (12/30) had a successful outcome, 30% (9/30) chose surgery, and 30% (9/30) did not improve with the rehabilitation program.[69] In another study, 18% (7/40) of patients elected to undergo surgery after failing nonoperative treatment.[70]

Débridement

Study Design and Patient Demographics—All seven articles were of level III or IV evidence with five retrospective[22, 30, 35, 38, 41] and two prospective studies.[36, 48] All articles had minimal loss to follow-up. The number of patients ranged from 23 to 57 (total 256) with an average age of 65.7 years. Average follow-up was 48 months with two studies reporting follow-up of at least 5 years.[22, 38]

Definition of a MRCT—There was variability in the criteria used for defining MRCT. The most common were ≥2-tendon involvement or >5 cm anterior-posterior width size. One study referenced either two tendons torn or retraction past the glenoid.[41]

Clinical Outcomes—Five studies used the CMS with +26-point mean change in scores before and after surgery,[22, 30, 35, 36, 41] while two studies used the ASES with +37-point mean change in scores.[22, 41] Three studies reported pain scores with an average improvement of 4.5 points.[22, 30, 41] Range of motion data were available from five studies,[22, 30, 35, 36, 41] but only two measured motion both before and after surgery,[22, 30] with forward elevation increasing by 32°.

Survival and Complications—Complications were seldom reported. One study reported 4.9% of patients (2/41) developing complex regional pain syndrome type 1[35] while another study reported 6.1% (2/33) and 3.0% (1/33) developed seromas and infections, respectively.[22]

Partial Repair

Study Design and Patient Demographics—All seven articles were of level III[55] or IV evidence.[30, 48, 55][9, 12, 16, 21] Study sample size ranged from 11 to 90 (total 226) with an average age of 62.7 years. Two studies had greater than 5% loss to follow-up.[12, 21] Average follow-up was 45.2 months with two studies reporting follow-up of at least 5 years.[12, 21]

Definition of a MRCT—All studies defined MRCT by number of tendons torn (two torn tendons in five studies[12, 16, 21, 48, 55] and three torn tendons in two studies.[9, 30] Three studies included tear size (≥5 cm) as an additional criterion.[16, 48, 55] Three studies reported preoperative fatty infiltration,[9, 30, 55] three the acromiohumeral interval,[9, 16, 21] and two the Hamada classification,[9, 12] demonstrating variability in criteria used for defining MRCT.

Clinical Outcomes—Six studies reported PROs both before and after surgery. The mean change in scores with CMS[30;21;55] and ASES[16;48;9] was +32 points and +35 points, respectively. Pain scores improved by about 4.5 points.[16; 9;12;30] Three studies reported motion both before and after surgery, with forward elevation and external rotation improving on average by 30° and 11°, respectively.[12, 16, 30]

Survival and Complications—Pooled rates for re-tear defined as re-rupture on postoperative MRI or ultrasound,[9, 30] unsatisfactory outcomes,[12, 21] and revision surgery[16;48;30;21] were 45% (25/55), 14% (16/111), and 9.7% (16/165), respectively. Reasons for revision surgery included re-tear (12/16), infection (2/16), anchor loosening (1/16), or AC joint cyst (1/16).

Graft Interposition

Study Design and Patient Demographics—The three articles were of level IV evidence with one prospective study and two retrospective studies.[2, 44, 51] (Supplemental Table 5d) The number of patients ranged from five to 41 (total 67) with an average age of 68.2 years and an average follow-up of 34.3 months.

Definition of MRCT—There was variability in the criteria used for defining MRCT with two tendon involvement reported in two articles.[2, 44, 51] All three articles quantified tear size with two reporting > 5cm[44, 51] and one > 4cm^2 tear size for the diagnosis of MRCT.

Clinical Outcomes—Two of three studies used the CMS with +42-point mean change in scores before and after surgery,[2, 51] while one study used the ASES with +45-point mean change in scores.[44] Two studies reported pain scores with an average improvement of 5 points.[44, 51] Range of motion before and after surgery was reported for two studies,[2, 51] with forward elevation and external rotation improving on average by 61° and 12°, respectively.[2, 51]

Survival and Complications—Pooled rates for re-tear[2, 51] and revision surgery[2, 51] were 20% (1/5) and 20% (1/5), respectively.

Tendon Transfer

Study Design and Patient Demographics—All eleven articles were of level III[49] or IV evidence.[8, 14, 17, 18, 24, 25, 27, 32–34, 49] Study sample size ranged from 14 to 86 (total 506) with an average of 59 years. Average follow-up was 57.7 months with two studies reporting follow-up of at least 9 years.[17, 25] It is worth noting that there was overlap in the cohorts of patients reported by two separate pairs of studies,[25, 27, 34;24] (Supplemental Table 6a) which slightly skews conclusions drawn from analysis of all patients between the eleven studies.

All studies utilized the latissimus dorsi tendon[8, 14, 17, 24, 25, 27, 32–34, 49] except for Elhassan et al who transferred the lower trapezius.[18] The latissimus transfer surgeries were performed either using the open two-incision technique popularized by Gerber[26] or an arthroscopic-assisted approach.[14, 27, 33, 34] Operative technique details are outlined in Supplemental Table 6d.

Definition of MRCT—All studies defined MRCT as either involving ≥ 2 tendons (i.e., supraspinatus and infraspinatus),[17, 18, 24, 25, 33, 34, 49] or measuring ≥ 5 cm,[8, 24, 32, 34, 49] with two studies[24, 49] requiring both criteria. Nine of eleven articles reported tendon retraction to at least the level of the glenoid or medial to it[5; 11;17, 18, 27, 33, 34; 44] and all studies observed fatty infiltration of Goutallier grade ≥ 3.[8, 14, 17, 18, 24, 25, 27, 32–34, 49]

Clinical Outcomes—All but one study[18] reported CMS, with a mean change of +28 points (+30 points for arthroscopic treatment and +26 points for open treatment). The mean change in ASES was +33 points.[17, 49] Pain scores improved by about 5.1 points.[17, 33] All studies reported motion both before and after surgery, with forward elevation and external rotation improving on average by 43° and 15°, respectively.

Survival and Complications—Pooled rates for tendon transfer re-tear,[14, 17, 18, 25, 27, 34] rotator cuff tear,[24, 25, 34] deltoid deficiency,[17, 24, 25] and revision surgery[17, 18, 24, 25, 27, 34] were 14.6% (35/239), 6.6% (8/122), 1.6% (2/122), 6.7% (24/356), respectively. Twenty-seven of the 35 tendon transfer failures (77%) occurred secondary to humeral bone tunnel fixation with tendon tubularization compared to eight failures with greater tuberosity footprint fixation (23%).[27, 34] Postoperative complications included hematoma (8%;

23/286),[17, 18, 27, 32, 34] greater tuberosity fracture (7.3%; 4/55),[27] deep infection (3.3%; 7/214),[14, 18, 27, 32, 34] stiffness (3.1%; 6/193),[17, 25, 32] and nerve dysesthesias (2.1%; 9/431).[14, 17, 24, 25, 27, 32, 34, 49]

Superior Capsular Reconstruction

Study Design and Patient Demographics—All four retrospective articles were of level IV evidence including 177 patients with an average age of 64.7 years and an average follow-up of 44.5 months.[45–47, 57] There was overlap in the cohorts reported by three studies,[45–47] which slightly skews conclusions drawn from analysis of patients receiving fascia lata autograft. There was variability noted concerning graft characteristics (i.e., type, size, thickness) and glenoid fixation. (Supplemental Table 7d).

Definition of MRCT—Pennington *et al* defined MRCT using tear size ≥ 5 cm and further characterized muscle quality with the Goutallier grading classification,[57] while Mihata et al defined MRCT by two or more tendon invlovement.[45–47] All studies reported preoperative fatty infiltration and average changes in the acromiohumeral interval (AHI) ranging from 3.4 mm preoperatively to 9.6 mm postoperatively.[45–47, 57]

Clinical Outcomes—All studies used the ASES score with +57-point mean change in scores before and after surgery (+36 points for human dermal allograft and +64 points for tensor fascia lata autograft). Two studies reported pain scores with an average improvement of 3.9 points.[45, 57] Range of motion before and after surgery was reported for all studies, with forward elevation improving on average by 57°.

Survival and Complications—Pooled rates for structural failure and revision surgery were 6.1% (11/180) and 4.8% (6/126), respectively. Rates of graft tear and revision surgery were 7.9% (3/38) and 2.6% (1/38) with use of human dermal allograft, respectively.[57]. Rates of infraspinatus re-tear, graft tear, and revision surgery were 12.5% (3/24), 5.6% (8/142), and 5.7% (5/88) with use of tensor fascia lata autograft, respectively.[45–47]

Balloon Arthroplasty

Study Design and Patient Demographics—Two articles, one retrospective case series and one prospective case series, were included and both were of level IV evidence including 25 patients with an average age of 68.8 years and an average follow-up of 42 months.[59, 62]

Definition of MRCT—Both studies defined MRCT using tear size ≥ 5 cm. Ricci et al[59] also required ≥ two tendons to be torn and Goutallier grade ≥ 3, while Senekovic noted the presence of substantial fatty infiltration deemed unsuitable for repair in all patients without qualitatively assessing its severity.[62]

Clinical Outcomes—Both studies used the CMS with +29-point mean change in scores before and after surgery. One study reported pain scores with an average improvement of 3.8 points.[59] Range of motion before and after surgery was reported for one study, with forward elevation improving on average by 58°.[62]

Survival and Complications—No complications were noted and one patient (5%; 1/20) needed eventual conversion to RSA within the five-year follow-up period.[62]

Reverse Shoulder Arthroplasty

Study Design and Patient Demographics—All six articles were retrospective case series of level IV evidence.[3, 19, 29, 50, 65, 67] The number of patients included ranged from 17 to 64 (total 247) with an average age of 67.5 years and an average follow-up of 39.4 months. Age data were available from only three studies.[19, 29, 50]

Definition of MRCT—Tendon number was the most commonly referenced criterion, with a minimum two tendon tear.[29, 50, 67;3, 65;15] All studies referenced either the acromiohumeral interval[3, 19] or the Hamada classification,[27, 29, 50, 67; 60] but the Hamada classification was primarily used to exclude arthritis and not to diagnose MRCT. Of the three studies that assessed tendon retraction,[3, 19, 65] a common value for the degree of retraction was not identified. Three studies used the Goutallier classification and considered grade 3 to be consistent with MRCT.[3, 19, 67]

Clinical Outcomes—Three studies reported the CMS with +32-point mean change in scores before and after surgery,[3;67;19] while two studies reported the ASES score with +37-point mean change in scores.[29;50] Two studies reported pain scores with an average improvement of 3.9 points.[29;50] Range of motion before and after surgery was reported for three studies, with forward elevation improving on average by 64°.[27, 29, 50, 67]

Survival and Complications—Pooled rates for prosthesis failure,[3, 19, 29, 50, 65, 67] fracture,[3, 19, 29, 50, 65, 67] instability,[3, 19, 29, 50, 65, 67] and revision surgery[3, 19, 29, 50, 65, 67] were 10.1% (16/159), 6.1% (14/231), 1.9% (4/206), and 8.2% (19/231), respectively. One study provided an estimated 90.7% survival at 52 months, with the end-point defined as component revision, removal, loosening, or a worsening ASES score.[50]

Response to Treatment

The magnitude of change in CMS and ASES score for each treatment strategy compared to the MCID threshold for nonoperative and operative treatment are provided in Figures 2 and 3. Twenty-six studies reported sufficient data for CMS score comparison to MCID. The weighted average change in CMS was greater than MCID for partial repair, graft interposition, balloon arthroplasty, and reverse shoulder arthroplasty. Fifteen studies reported sufficient data for ASES score comparison to MCID. The weighted average change in ASES score was greater than MCID for physical therapy, graft interposition, and superior capsular reconstruction with tensor fascia lata autograft.

Discussion

Our study findings clearly show the absence of high-quality literature on irreparable MRCT. Of all 43 studies, only 9.3% (4/43) were of level III evidence with the remaining of level IV evidence. As such, it is difficult to definitively recommend either for or against one treatment strategy over another for the management of irreparable MRCT. These findings

agree with the recommendations provided by the American Academy of Orthopaedic Surgeons 2019 clinical practice guideline on management of rotator cuff injuries. The authors found insufficient evidence to support the efficacy of physical therapy, partial repair, tendon transfer, superior capsular reconstruction (SCR), débridement, allograft augmentation, or RSA in the treatment of irreparable tears, instead concluding based on consensus clinical opinion alone that these treatments may improve patient reported outcomes.[1]

Treatment decisions when the rotator cuff cannot be repaired will have to be made with professional judgement, surgeon experience, patient expectations, ability to complete postoperative rehabilitation, and a shared decision making process between the surgeon and the patient. In such scenarios, appropriate use criteria (AUC) can provide guidance by considering clinical experience, patient factors (smoking status, worker's compensation, etc.), and disease type (tear size and fatty infiltration) to indicate the appropriateness of a given intervention for a specific clinical scenario.[56, 60]

Our current study suggests that physical therapy compared to surgery may lead to high failure rates and inferior clinical outcomes for irreparable MRCT. Physical therapy is promoted to be the first line of treatment when a patient is medically unfit, does not wish to proceed with surgery, or demonstrates a positive response to non-operative care.[60] However, with the numbers available, 60% of the patients (18/30) in this review did not respond to physical therapy or went on to have surgery.

Débridement and partial repair showed improvements in VAS pain scores, functional range of motion and PRO scores with lower reoperation rates compared to physical therapy. The majority of débridement studies did not meet the MCID threshold, and as such, débridement may not be a successful treatment strategy. However, Walch et al[66] investigated débridement with concomitant biceps tenotomy in 307 patients with full-thickness rotator cuff tears, finding that this combination of procedures led to significant clinical improvement. While this study did not exclusively investigate MRCT, this treatment strategy may be considered in the appropriate patient. A drawback to partial repair was the high re-tear rate (45%; 25/55) and the majority of studies did not meet the MCID threshold.

Surgical reconstruction (graft interposition / tendon transfer) compared to physical therapy showed superior improvements in pain scores, forward elevation, and mean change in CMS and ASES scores. All three graft interposition studies exceeded the MCID threshold, and as such, graft interposition should be investigated further. Arthroscopic-assisted tendon transfer utilizing greater tuberosity fixation techniques are favored over humeral bone tunnel fixation techniques as the latter are associated with a high failure rate (77%; 27/35). Based on the available evidence, open tendon transfer may not be a successful treatment strategy as the majority of studies did not meet the MCID for either ASES or CMS.

SCR and balloon arthroplasty are relatively new procedures with a paucity of data reporting clinical outcomes and rates of failure, revision surgery, and complications. With the numbers available, both SCR and balloon arthroplasty led to an improvement in pain scores, forward elevation, and PRO scores. However, of concern is the high structural failure rate of SCR

using human dermal allograft, which has been reported to range from 15–75%[6, 7, 15, 39, 57, 68], compared to SCR using tensor fascia lata autograft, with failure rates reported to range from 5–36%[13, 40, 42, 45–47] (Table IV). Based on the available evidence, SCR may be considered using fascia lata autograft, and further studies are needed to determine success of SCR with human dermal allograft and efficacy of balloon arthroplasty.

Reverse shoulder arthroplasty was found to improve pain scores, functional motion and PRO scores compared to physical therapy. However, this treatment strategy has an 8.2% (19/231) reoperation rate and a 10.1% (16/159) prosthesis failure rate. In light of this, we agree with the AUC that reverse arthroplasty should be considered only in a healthy elderly patient with pseudoparalysis from a chronic irreparable massive tear.[56, 60]

We found considerable variability in the definition of MRCT. Thirty-two studies required a minimum tear size for diagnosis (i.e., 5cm), and twenty-three studies required a minimum number of involved tendons (i.e., two). Meanwhile, thirteen studies required both a minimum tear size and a minimum number of involved tendons, and two studies required either a minimum tendon retraction length or a minimum amount of fatty infiltration. Clearly, there is inconsistent reporting on what defines MRCT. How to define MRCT may depend on treatment strategy and patient expectations (i.e., pain relief, restore motion, limit progression of radiographic changes). A recent study using the Delphi method determined with 90% agreement that MRCT should be defined as either axial or coronal tendon retraction to the glenoid rim and/or a tear with 67% of the tuberosity exposed in the sagittal plane.[61]

The major limitation of this review is the lack of high-quality evidence available on the treatment of irreparable MRCT. There were only three comparative studies, all of which compared débridement to partial repair, while the majority were case series (72%; 31/43). Without better quality studies, it is difficult to make evidence-based recommendations for clinical care. Second, we observed an inconsistent reporting of PROs, pain scores, range of motion, strength, failure rates, revision surgery, and complication rates across all treatment strategies. There were twelve different PROs used, with CMS (27 studies) and ASES (17 studies) scores most commonly reported. Similarly, six of 43 studies (14%) reported motion data in four planes (forward flexion, internal rotation, external rotation, and abduction) before and after surgery. Third, we were unable to perform a comprehensive quantitative synthesis due to inconsistent outcome instrument selection. Standardized data collection and reporting are keys to data transparency, and instituting a minimum data set requirement could improve the quality of future studies. Fourth, the results of our quantitative analysis are highly dependent on MCID values selected from prior studies. While separate MCIDs were chosen for operative and nonoperative treatments, the operative MCID available was calculated using data from patients undergoing complete rotator cuff repair only. It is highly likely that each treatment strategy will have a unique MCID threshold if separately determined by anchor-based methodology.

Further limitations of our quantitative analysis are those inherent to anchor-based MCID methods. First, MCID values are highly impacted by the patient population being studied, with less healthy cohorts having lower baseline scores and more opportunity for score

improvement. This is particularly relevant when considering the functional impairment seen in patients with irreparable MRCT. Second, anchor-based approaches are subject to recall bias. Results of the global rating of change questionnaire administered to patients at final follow-up are likely influenced by recent developments in each patient's health status and therefore may reflect a single time-point snapshot of health status rather than magnitude of change from baseline. Third, the timing of MCID determination influences the magnitude of recall bias, with a longer follow-up duration introducing more susceptibility to bias. Lastly, many studies determining MCID are limited by small subject numbers and wide confidence intervals. Gagnier et al evaluated 222 patients with full-thickness rotator cuff tears, but only 22 patients had a minimal clinical improvement. This small subset was further evaluated to determine the ASES MCID for surgical treatment, which was found to have a fragile confidence interval of −7.57 to 85.57.[20] Robust MCID values for each treatment strategy matched for age, gender, and racial differences need to be determined through studies with larger sample sizes utilizing a combination of anchor- and distribution-based approaches.

Conclusions

Due to the paucity of high-quality clinical studies available for guiding management of irreparable MRCT, it is currently not possible to recommend for or against any specific treatment strategy. Rather, clinical experience, patient factors, patient expectations, and rotator cuff tear characteristics should guide clinical decision-making. Physical therapy compared to surgical treatments may have inferior outcomes. Standardized data collection, reporting, and terminology are key to enhancing the quality of evidence-based medicine. There is a need to unequivocally define the MCID for various MRCT treatment strategies that will lead to improved interpretation of outcomes. Significant opportunities exist for multi-center research groups to embark on high-quality comparative clinical studies to improve our understanding and management of MRCT.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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	PT	D	PR	GI	TT	SCR	BA	RSA
Database Search n=1791	369	236	318	225	310	193	19	121
Duplicates Removed n=576	106	96	161	35	134	11	7	26
Records Screened n=1215	263	140	157	190	176	182	12	95
Records Excluded n=1054	240	125	135	171	136	175	1	71
Records Assessed for Eligibility n=161	23	15	22	19	40	7	11	24
Records Excluded (Reasons) n=118	20 5 other tear sizes 8 short FU 3 no PT group 3 reviews 1 lacking outcomes	8 2 other tear sizes 2 short FU 1 no MRCT def. 1 abstract only 1 patients with RA 1 review	15 6 other tear sizes 4 short FU 4 surg. techniques	16 5 other tear sizes 9 short FU 1 no MRCT def. 1 superficial graft application	29 3 short FU 13 MINORS<80% 3 surg. techniques 4 lacking outcomes 6 lack of primary vs. revision patients	3 1 other tear sizes 1 short FU 1 no MRCT def.	9 2 no MRCT def 3 short FU 4 surg. techniques	18 14 arthritis 2 tendon transfer 1 short FU 1 duplicate cohort
Records Included in Qualitative Synthesis n=43	3	7	7	3	11	4	2	6
Records Included in Quantitative Synthesis n=37	2	5	6	3	10	4	2	5

Stages (left column): Identification and Screening; Eligibility; Included

Figure 1.

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram representing search and screen process of studies reporting on nonoperative and operative treatment of irreparable massive rotator cuff tears. *CENTRAL*, Cochrane Central Register of Controlled Trials; *PT*, Physical therapy; *D*, Débridement; *PR*, Partial repair; *GI*, Graft interposition; *TT*, Tendon transfer; *SCR*, Superior capsular reconstruction; *BA*, Balloon arthroplasty; *RSA*, Reverse shoulder arthroplasty; *FU*, Follow-up; *MRCT*, Massive rotator cuff tear; *RA*, Rheumatoid arthritis.
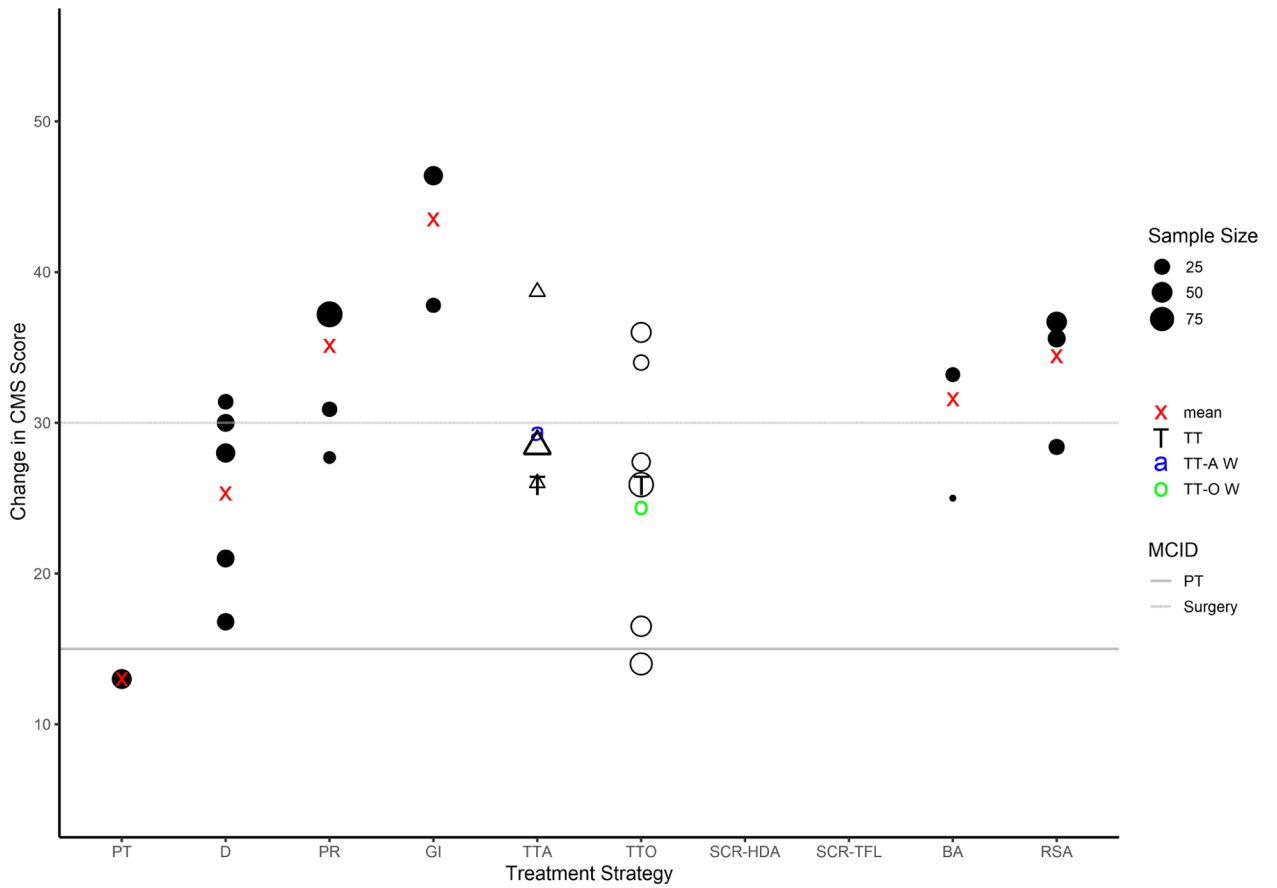
Figure 2.
Change in CMS for each treatment strategy compared to MCID threshold for either nonoperative or operative intervention. Sample size is directly proportional to the size of the circle (or triangle for arthroscopic tendon transfer). Influenced by the sample size, the red "x" denotes the weighted average change in CMS for all treatment strategies except tendon transfer. The "T" denotes the weighted average change in CMS for *all* tendon transfers. The blue "a" represents the weighted average change in CMS for arthroscopic tendon transfer. The green "o" represents the weighted average change in CMS for open tendon transfer. *PT*, Physical therapy; *D*, Débridement; *PR*, Partial repair; *GI*, Graft interposition; *TTA*, Arthroscopic tendon transfer; *TTO*, Open tendon transfer; *SCR-HDA*, Superior capsular reconstruction—human dermal allograft; *SCR-TFL*, Superior capsular reconstruction—tensor fascia lata autograft; *BA*, Balloon arthroplasty; *RSA*, Reverse shoulder arthroplasty; MCID, Minimum clinically important difference.
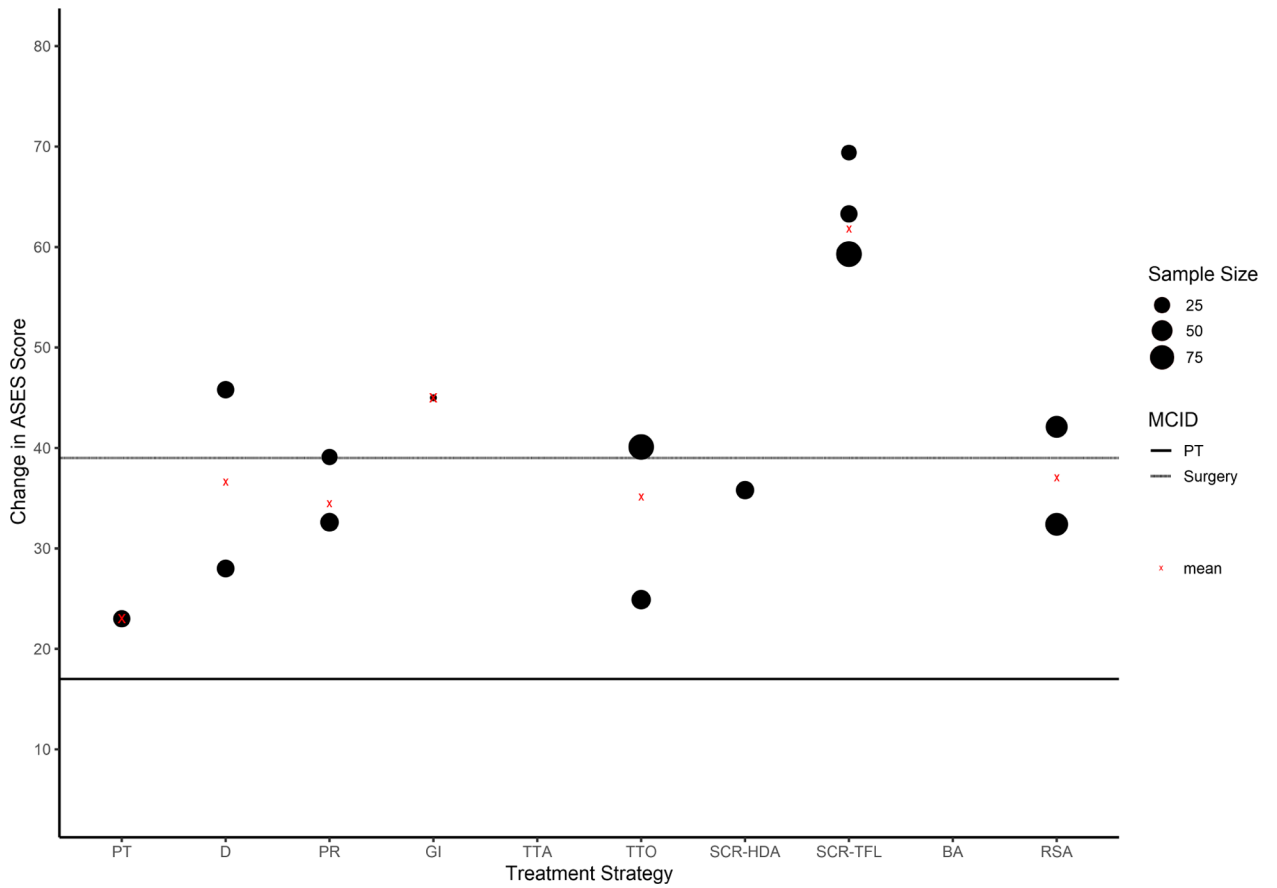
Figure 3.
Change in ASES score for each treatment strategy compared to MCID threshold for either
nonoperative or operative intervention. Sample size is directly proportional to the size of the
circle. The red "x" denotes the weighted average change in CMS for all treatment strategies,
which is influenced by sample size. *PT*, Physical therapy; *D*, Débridement; *PR*, Partial
repair; *GI*, Graft interposition; *TTA*, Arthroscopic tendon transfer; *TTO*, Open tendon
transfer; *SCR-HDA*, Superior capsular reconstruction—human dermal allograft; *SCR-TFL*,
Superior capsular reconstruction—tensor fascia lata autograft; *BA*, Balloon arthroplasty;
RSA, Reverse shoulder arthroplasty; MCID, Minimum clinically important difference.

Table I

Study design and patient demographics

Treatment	No. Papers	LOE	MINORS Score	N (M/F)	Age (y)	Follow-up (months)
Physical Therapy	3	III (1); IV (2)	89.6%	94 (59/35)	68.3 (54–89)	32 (24–65)
Debridement	7	III (1); IV (6)	88.8%	256 (160/96)	65.7 (33–82)	48 (24–120)
Partial Repair	7	III (1); IV (6)	89.0%	226 (122/93) *	62.7 (33–81)	45.2 (24–90)
Graft Interposition	3	IV (3)	85.4%	67 (39/28)	68.2 (51–85)	34.3 (24–86)
Tendon Transfer	11	III (1); IV (10)	88.1%	506 (319/187)	59.2 (53–64.2)	57.7 (24–147)
Arthroscopic-Assisted	4	IV (4)	89.1%	144 (68/76)	61.7 (59–64.2)	70.2 (24–147)
Open	7	III (1); IV (6)	87.5%	362 (251/111)	57.7 (53–61)	35.8 (24–77)
SCR	4	IV (4)	81.3%	179 (12/11) *	64.7 (43–82)	44.5 (24–60+)
HDA	1	IV	87.5%	38	59.4	24
TFL	3	IV (3)	79.2%	141 (12/11) *	66.4 (65.1–68.0)	51.4 (24–110)
Balloon	2	IV (2)	93.8%	25	68.8 (54–85)	42 (24–60)
RSA	6	IV (6)	85.4%	247 (48/74) *	67.5 (34–86)	39.4 (24–118)

MINORS score represented as weighted average for each treatment strategy.

N=Total number of patients per treatment group reported; M=male; F=female.

Age and follow-up reported as mean (range) in years and months, respectively.

LOE Level of evidence

SCR Superior Capsular Reconstruction

RSA Reverse Shoulder Arthroplasty

AA Arthroscopic-Assisted

HDA Human Dermal Allograft

TFL Tensor Fascia Lata Autograft

*
Incomplete reporting of number of patients based on gender

Table II

Massive rotator cuff tear criteria

Treatment	No. Papers	Tear Size	Tendon No.	Tendon Retraction (Patte)	Goutallier Fatty Infiltration (SITS)	AHI (mm) or Hamada Classification
Physical Therapy	3	NR	2 (3)	Stage 3(1)	Grade 4(1) Grade 3–4 (2)	**AHI** Preop 8.2 (1), Postop 5.6 (1) **Hamada** Stage 1–2 (1)
Debridement	7	5cm (5)	2 (5)	Stage 2 (1) Stage 3 (1) 4–5cm (1) "Unable to Reattach" (1)	Grade 3–4 (1) 19 (1)	**AHI** Preop <5 (1), Preop 5.1 (1)
Partial Repair	7	5cm (3)	2 (5) 3 (2)	Stage 2(1)	Grade 3–4 (1) Grade 1.9 (1.5–2.2) (2)	**AHI** Preop <7 (1) **AHI** Preop 8.8 (1) **Hamada** Stage 1 (1) **Hamada** Stage 1–2 (1)
Graft Interposition	3	5cm (2) 4cm (1)	2 (2)	NR	Grade 3.75 (1)	**AHI** Preop 7.7 (1), Postop 8.6 (1)
Tendon Transfer	11	5cm (5)	2 (7)	Stage 2–3 (2) Stage 3 (5) "Excessive" (2)	Grade 3–4 (11)	**AHI** Preop 4.2 (2.3–5.9) (4), Postop 5.1 (4.7–5.7) (3) **AHI** Preop <5 (1) **AHI** Preop <7 (1) **AHI** decreased by 1.5 (1) **Hamada** Preop 1.7 (0–2) (2), Postop 2.2 (1–5) (2) **Hamada** Preop Grade 1–2 (1) **Hamada** Postop Grade 2–3 (1)
AA	4	5cm (1)	2 (2)	Stage 2–3 (2) Stage 3(1)	Grade 3–4 (4)	**AHI** Preop 3.13 (1), Postop 5.7 (1) **AHI** Preop <5 (1) **Hamada** Preop Grade 1–3 (1)
Open	7	5cm (4)	2 (5)	Stage 3 (4) "Excessive" (2)	Grade 3–4 (7)	**AHI** Preop 4.6 (2.3–5.9) (3), Postop 4.8 (4.7–4.9) (2) **AHI** Preop <7 (1) **AHI** decreased by 1.5 (1) **Hamada** Preop 1.7 (0–2) (3), Postop 2.2 (1–5) (3) **Hamada** Preop Grade 1–2 (1) **Hamada** Postop Grade 2–3 (1)
SCR	4	5cm (1)	2 (3)	5cm (1)	Grade 3–4 (1) Grade 2.6 (2.0–3.7) (3)	**AHI** Preop 4.9 (4.6–7.3) (4), Postop 9.1 (8.1–9.9) (4)
HDA	1	5cm	-	5cm	Grade 3–4	**AHI** Preop 7.3, Postop 9.9
TFL	3	-	>2 (3)	-	Grade 2.6 (2.0–3.7) (3)	**AHI** Preop 4.1 (3.4–4.6) (3), Postop 8.8 (8.1–9.7) (3)
Balloon	2	5cm (2)	2 (1)	NR	Grade 3–4 (1) "Unsuitable for Repair" (1)	**AHI** Preop 6.7 (1), Postop 8.0 (1)
RSA	6	5cm (1)	2 (6)	Stage 2(1) Stage 3(1)	Grade 3–4 (3)	**AHI** Preop <6 (1) **AHI** Preop <7 (1) **Hamada** Preop <4 (4)

SCR Superior Capsular Reconstruction

RSA Reverse Shoulder Arthroplasty

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SITS Supraspinatus, Infraspinatus, Teres Minor, Subscapularis

AHI Acromiohumeral Interval

AA Arthroscopic-Assisted

HDA Human Dermal Allograft

TFL Tensor Fascia Lata Autograft

NR Not Recorded

Table III

Clinical outcomes, failure, and reoperation rates

Treatment	No. Papers	VAS Initial	VAS Final	ROM Initial	ROM Final	PRO Initial	PRO Final	Failure / Survival	Revision/Reoperation
Physical Therapy	3	6.7 (1)	3.7 (1)	FF 97 (76–115) (3), Abd 118 (1), ER 44 (1), IR 76 (1)	FF 133 (129–136) (2), Abd 136 (1), ER 39 (1), IR 66 (1)	CMS 43 (1), ASES 39 (1), SSV 45 (1)	**CMS** 62.4 (56–69) (2), **ASES** 62 (1), **SSV** 64 (60–68) (2)	12/30 (40%) Success 9/30 (30%) Failed PT	9/30 (30%) Surgery
Debridement	7	7.6 (7–7.9) (3)	3.1 (2–4.3) (3)	FF 106 (96–115) (2), Abd 74 (57–90) (2), ER 20 (1)	FF 137 (118–155) (2), Abd 118 (85–150) (2), ER 42 (1), IR T12 (1), Scaption 111 (1)	CMS 42.7 (31–72.2) (5), ASES 25.5 (24–27) (2), UCLA 11.5 (1), SSV 35.2 (1), qDASH 63.4 (1)	**CMS** 63.9 (42.3–89) (6), **ASES** 62.4 (55–69.8) (2), **UCLA** 21 (1), **SSV** 73.2 (1), **DASH** 41.3 (1), **qDASH** 24.1 (1), **SPADI** 38.4 (1)	NR	1/23 (4.2%) (1)
Partial Repair	7	6.3 (5.6–7) (4)	1.8 (1.5–2) (4)	FF 126 (95–168) (3), Abd 90 (1), ER 34 (20–44) (3), IR 84% (1)	FF 160 (154–172) (4), Abd 150 (120–169) (3), ER 39 (27–54) (5), IR T9 (2)	CMS 39.6 (36.6–43.1) (3), ASES 44.5 (41–46.6) (3), SSV 34.7 (1), SST 5.6 (1), qDASH 52.5 (1), Oxford 17.8 (1)	**CMS** 71.5 (67.5–76.3) (3), **ASES** 79.3 (78.6–80.1) (3), **SSV** 74.0 (1), **SST** 9.1 (1) **qDASH** 55.8 (1), **Oxford** 37.1 (1), **SANE** 96 (1), **SPADI** 29.5 (1)	16/111 (14.4%) unsatisfactory outcome (2) 25/55 (45.4%) re-rupture (2)	16/165 (9.7%) (4)
Graft Interposition	3	6.9 (6.8–7) (2)	1.9 (1–2.8) (2)	FF 67 (65–69) (2), Abd 64 (60–68) (2), ER 36 (32–39) (2), IR 3.8/10 (3.4–4.2) (2)	FF 128 (120–136) (2), Abd 127 (120–134) (2), ER 48 (38–57) (2), IR 8.0/10 (7.5–8.4) (2)	CMS 36.2 (25.7–46.7) (2), ASES 29 (1), UCLA 10.2 (1), SST 2.4 (1)	**CMS** 78.3 (72.1–84.5) (2), **ASES** 74 (1), **UCLA** 29.4 (1), **SST** 7.8 (1)	1/5 (20%) re-rupture (1)	1/5 (20%) (1)
Tendon Transfer	11	7.7 (7.5–7.8) (2)	2.6 (2.4–2.8) (3)	FF 95 (58–134) (11), Abd 84 (40–112) (11), ER 18 (12–29) (11), IR L3 (1)	FF 137 (120–157) (11), Abd 123 (90–154) (11), ER 33 (23–50) (11), IR L3 (1)	CMS 35.9 (21–47.3) (10), ASES 39.2 (30.1–48.3) (2), UCLA 6.5 (1), SSV 31.3 (19.3–54) (5), DASH 52 (1)	**CMS** 63.5 (58–69.5) (10), **ASES** 71.7 (66.7–73.2) (3), **UCLA** 27.5 (1), **SSV** 66.8 (48.9–78) (5), **SST** 7 (1), **DASH** 18 (1)	29/184 (15.8%) LD re-rupture (4), 8/122 (6.6%) SSC insufficiency (2), 2/122 (1.6%) deltoid avulsion (2), 2/55 (3.6%) stiffness (1), 6/55 (10.9%) LD insufficiency (1)	24/356 (6.7%) (6)
AA	4	7.5±1.0 (1)	2.7 (2.5–2.8) (2)	FF 97 (58–134) (4), Abd 64 (51–80) (4), ER 19 (13–29) (4)	FF 140 (130–157) (4), Abd 115 (93–130) (4), ER 33 (28–42) (4)	CMS 30.1 (21–37) (4), UCLA 6.5 (1), SSV 22.7 (19.3–26) (2)	**CMS** 60.5 (58–65.4) (4), **ASES** 66.7 (1), **UCLA** 27.5 (1), **SSV** 60.0 (48.9–71.1) (2)	28/129 (21.7%) LD re-rupture (3)	10/115 (8.7%) (2)
Open	7	7.8±1.5 (1)	2.4±1.9 (1)	FF 93 (70–118) (7), Abd 87 (40–112)	FF 136 (120–151) (7), Abd 128 (90–154) (7)	CMS 39.8 (32–47.3) (6)	**CMS** 65.4 (60–69.5) (6), **ASES** 71.7 (70.2–73.2)	1/55 (1.8%) LD re-rupture(1)	14/241 (5.8%) (4)

Treatment	No. Papers	VAS Initial	VAS Final	ROM Initial	ROM Final	PRO Initial	PRO Final	Failure / Survival	Revision/Reoperation
	(7)			(7) ER 19 (14–23) (7) IR L3 (1)	ER 33 (23–50) (7) IR L3 (1)	ASES 39.2 (30.1–48.3) (2) SSV 37.0 (28–54) (3) DASH 52 (1)	(2) SSV 71.4 (60–78) (3) DASH 18 (1)	8/122 (6.6%) SSC insufficiency (2) 2/122 (1.6%) deltoid avulsion (2) 2/55 (3.6%) stiffness (1) 6/55 (10.9%) LD insufficiency (1)	6/126 (4.8%) (2)
SCR	4	5.6 (4.3–6.9) (2)	1.1 (0.9–1.2) (2)	FF 97 (84–123) (4) Abd 106 (1) ER 27 (26–27) (3) IR L3 (1)	FF 154 (148–162) (4) Abd 160 (1) ER 41 (40–43) (3) IR L1 (1)	ASES 34.3 (23.5–49.5) (4) UCLA 9.9 (1) JOA 50.9 (48.3–53.0) (3)	ASES 91.2 (85.3–94.3) (4) UCLA 32.4 (1) JOA 92.4 (91.4–93.2) (3)	11/180 (6.1%) graft failure (4) 3/24 (12.5%) retear of ISP (1)	
HDA	1	4.3	1.2	FF 123 Abd 106	FF 162 Abd 160	ASES 49.5	ASES 85.3	3/38 (7.9%) graft failure	1/38 (2.6%)
TFL	3	6.9 (1)	0.9 (1)	FF 89 (84–123) (3) ER 27 (26–27) (3) IR L3 (1)	FF 152 (148–156) (3) ER 41.4 (40–43) (3) IR L1 (1)	ASES 29.2 (23.5–35) (3) UCLA 9.9 (1) JOA 50.9 (48.3–52) (3)	ASES 93.2 (92.3–94.3) (3) UCLA 32.4 (1) JOA 92.4 (91.4–93.2) (3)	8/142 (5.6%) graft failure (3) 3/24 (12.5%) retear of ISP (1)	5/88 (5.7%)
Balloon	2	6.6 (1)	2.8 (1)	FF 71 (1) Abd 65 (1)	FF 129 (1) Abd 125 (1)	CMS 38.0 (34.2–41.8) (2) SAS 6.7 (1)	CMS 67.1 (66.8–67.4) (2) SAS 8.0 (1)	NR	1/20 (5%) (1)
RSA	6	5.9 (5.5–6.3) (2)	2.0 (1.9–2.0) (2)	FF 69 (53–94) (3) ER 29 (21–40) (3)	FF 133 (122–143) (3) ER 40.2 (29–51) (3)	CMS 26.5 (23–27.8 (3) ASES 37.5 (33.3–41.6) (2) SST 1.0 (1.6–2.2) (2)	CMS 59.4 (55–63.4) (3) 74.7 (74–75.4) (2) SST 7.1 (6.5–7.6) (2)	16/159 (10.1%) prosthesis failure (3) 14/231 (6.1%) fracture (4) 4/206 (1.9%) instability (3)	19/231 (8.2%) (4)

AA Arthroscopic-Assisted

SCR Superior Capsular Reconstruction

HDA Human Dermal Allograft

TFL Tensor Fascia Lata Autograft

RSA Reverse Shoulder Arthroplasty

VAS Visual Analogue Scale

PRO Patient-Reported Outcome

CMS Constant-Murley Score

ASES American Shoulder and Elbow Surgeons

UCLA University of California Los Angeles

SSV Subjective Shoulder Value

SST Simple Shoulder Test

SANE Single Assessment Numeric Evaluation

SPADI Shoulder Pain and Disability Index

SAS Shoulder Activity Scale

DASH Disabilities of Arm, Shoulder, and Hand

qDASH Quick Disabilities of Arm, Shoulder, and Hand

JOA Orthopedic Association

ROM Range of Motion

FF Forward Flexion

Abd Abduction

ER External Rotation

IR Internal Rotation

NR Not Reported

PT Physical Therapy

LD Latissimus Dorsi

SSC Subscapularis

ISP Infraspinatus

Table IV.

Superior capsular reconstruction graft failure rates

Author (Year)	Graft Type	N	n with Post-Op MRI	Timing of Imaging (years)	Graft Failure Rate
Hirihara (2017)	HDA	8	5	2	1/5 (20%)
Denard (2018)	HDA	59	20	1	11/20 (55%)
Pennington (2018)	HDA	88	4	2	3/4 (75%)
Burkhart (2019)	HDA	10	10	1	3/10 (30%)
Woodmass (2019)	HDA	34	Not Reported	Not Reported	22/34 (65%) *
Burkhart (2020)	HDA	41	26	1	4/26 (15%)
Lacheta (2020)	HDA	22	21	0.2	9/21 (43%)
HDA Total		**262**	**86**		**32/86 (37%)**
Mihata (2013)	TFL	24	24	3	4/24 (17%)
De Campos Azevedo (2018)	TFL	22	22	0.5	2/22 (9%)
Lee (2018)	TFL	36	36	1	13/36 (36%)
Lim (2018)	TFL	31	31	1	9/31 (29%)
Mihata (2018)	TFL	88	88	5	4/88 (5%)
Mihata (2019)	TFL	30	30	2.5	3/30 (10%)
TFL Total		**231**	**231**		**35/231 (15%)**

SCR: Superior Capsule Reconstruction

HDA: Human Dermal Allograft

TFL: Tensor Fascia Lata Autograft

N=Total number of patients

*
Graft failure rate determined by clinical examination rather than advanced imaging