Superior Capsular Reconstruction Using Dermal Allograft Is a Safe and Effective Treatment for Massive Irreparable Rotator Cuff Tears: 2-year Clinical Outcomes

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Purpose: To evaluate functional, symptomatic, and diagnostic imaging outcomes after arthroscopic superior capsular reconstruction (SCR) using dermal allograft in patients with massive irreparable rotator cuff tears. Methods: From 2015 to 2017, this multicenter study retrospectively evaluated patients undergoing arthroscopic SCR for treatment of symptomatic massive rotator cuff tears. Study criteria included the presence of a massive irreparable rotator cuff tear with retraction to the glenoid without diffuse bipolar cartilage loss, Grade 4 or 5 Hamada classification, and subscapularis pathology that could not be addressed. All SCR procedures were performed with neutral abduction of the arm at the time of implantation. Outcome measures included visual analog pain scale (VAS) score, the American Shoulder and Elbow Surgeons (ASES) score, Single Assessment Numeric Evaluation (SANE) score, and active forward elevation (FE) through 2 years postoperatively. Imaging analyses included radiographs, ultrasound, and magnetic resonance imaging at 6 months and 1 year. Results: Fourteen patients met all study criteria including required follow-up. There were statistically significant improvements in VAS pain (3.3-0.6, *P* = .001), ASES (55.0-86.5, *P* < .0001), SANE (33.1-71.5, *P* < .0001), and active FE (128-172, P = .0005) with mean follow-up of 2.1 years. Twelve patients (86%) met the minimum clinically important difference in VAS pain, ASES, and SANE. Thirteen grafts (93%) had ultrasonographic evidence for vascularity by 1 year postoperatively. There were 2 graft complications (14%) with one (7%) requiring revision to reverse total shoulder arthroplasty. **Conclusions:** Arthroscopic SCR using dermal allograft can be a safe and effective treatment option for patients with massive irreparable rotator cuff tears with statistically significant improvements in VAS pain, ASES, SANE, and active FE at 2-years postoperatively, with 93% of grafts demonstrating vascularity at 1-year postoperatively.

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T. D. PASHUCK ET AL.

Neutral abduction of the arm at the time of implantation resulted in positive clinical outcomes and may decrease graft failure rate. **Level of Evidence:** Level IV, case series.

Introduction

assive rotator cuff tears can cause significant pain Mand disability. Arthroscopic repair for massive tears can be challenging due to tendon retraction with inelasticity, muscle atrophy, structural failure, and poor outcomes when compared with smaller rotator cuff tears.¹⁻⁴ In the setting of massive irreparable rotator cuff tears, tendon transfers and reverse total shoulder arthroplasty (rTSA) can be effective procedures to reduce pain and improve function. However, tendon transfers are associated with an increased risk of wound complications, nerve injury, and often require the addition of allograft tissue.⁵ rTSA is not ideal for the young or active patients without significant arthropathy due to the associated morbidity including stiffness, infection, instability, concerns with implant longevity, and the potential need for revision surgery.^{6,7}

Superior capsular reconstruction (SCR) has gained popularity as a joint-preserving treatment for massive irreparable rotator cuff tears in patients with limited glenohumeral arthritis. In their original description of this technique, Mihata et al.⁸ reported excellent shortterm clinical outcomes after SCR using tensor fascia lata autograft. While these initial clinical results were very positive, the donor-site morbidity and increased operative time associated with use of tensor fascia lata autograft motivated surgeons to develop and assess SCR techniques using alternative materials. Acellular dermal allografts have become an appealing option for SCR based on availability, biomechanical properties, and initial clinical outcomes.⁹⁻¹⁷ However, given that there has been relatively little published on clinical and radiographic outcomes of SCR, a better understanding of this healing process in correspondence with functional clinical outcomes is necessary.¹¹⁻¹⁷ Therefore, the purpose of this study was to evaluate functional, symptomatic, and diagnostic imaging outcomes after arthroscopic SCR using dermal allograft in patients with massive irreparable rotator cuff tears. We hypothesized that SCR would be consistently associated with diagnostic imaging evidence for graft integrity and healing during the initial year of healing, resulting in significant reductions in pain and improvements in shoulder function at 2 years postoperatively.

Methods

From 2015 to 2017, patients were recruited from the clinics of 2 authors after institutional review board (IRB) approval was obtained (#2002074 from the

University of Missouri IRB and protocol #614 from the Sacramento Orthopedic Center [Salus IRB]). Patient data were included for analyses when the subject had provided informed consent, were indicated for unilateral SCR by the attending surgeon (M.J.S. or A.M.H.) based on a priori patient selection criteria, completed SCR surgery as intended, completed standard-of-care and study-specific follow-up including the 2-year follow-up, and had required data available for analysis. Patient selection was based on the presence of symptomatic massive rotator cuff tears defined by at least 2-tendon involvement or at least 5 cm of retraction, which were typically retracted to the level of the glenoid in this study, without deltoid, latissimus dorsi, or pectoralis muscle dysfunction (Appendix Table 1, available at www.arthroscopyjournal.org). Patients with less than 3 of 5 external rotation strength determined by the operative surgeon with the elbow at the side, grade 4 or 5 on the Hamada classification, intra-articular corticosteroid injection within 1 month of surgery, or greater than 20° of decreased passive range of motion compared with contralateral side were excluded.¹⁸ Patients who had undergone previous rotator cuff repair were not excluded from the study. Patients with intraoperative findings of a supraspinatus tear that was reparable, damaged coracoacromial ligament, diffuse bipolar cartilage loss, subscapularis pathology that could not be addressed, or if the graft was not able to be fixated on the humeral side using a double row repair were excluded from the study. SCR surgery was only performed on patients with symptomatic massive rotator cuff tears meeting all inclusion criteria.

Pre- and postoperative outcome analysis was performed via an electronic data capture system (Surgical Outcomes System, Arthrex, Naples, FL). Evaluations included the American Shoulder and Elbow Score (ASES) objective scores, ASES subjective score, Single Assessment Numeric Evaluation score (SANE), and the visual analog score (VAS).

Standard shoulder radiographs including an upright anteroposterior (AP) view were performed pre- and postoperatively to assess the acromiohumeral (AH) interval and level of arthritic changes as determined by the Hamada classification.¹⁸ Preoperative magnetic resonance imaging (MRI) was completed on all patients for evaluation including supraspinatus \pm infraspinatus tear size, retraction, and atrophy. MRI also was performed at the 6-month and 1-year postoperative time points to assess SCR graft integrity and size, as well as the status of the remaining rotator cuff

tendons. Ultrasound was performed and interpreted by a board-certified radiologist at the 6-month and 1-year time points to assess graft thickness at the greater tuberosity and vascularization (both intrasubstance and on the graft periphery). The standard shoulder ultrasonography protocol used a 10-14 MHz linear transducer to obtain coronal and sagittal calibrated images of relevant structures for measurements and scoring. Graft vascularity was determined by color Doppler, which detects flow moving towards (red) or away from (blue) ultrasound transducer.

Technique

Arthroscopic SCR was performed using the technique described by Hirahara and Adams.¹⁹ A 3.0-mm thick acellular dermal allograft (ArthroFLEX 301; Arthrex) was used to reconstruct the superior capsule in all patients. The medial-to-lateral length of the graft was measured using suture and calibrated instruments. Measurements were taken while the patient's arm was in neutral abduction and rotation, which is defined as the arm resting on the patient's side. AP measurements of the graft were obtained using the same methods. The graft was sized in the AP direction to allow coverage of the entire defect.

We pre-placed 1-mm to 2-mm holes in the graft for passing of suture before graft implantation. In addition, a micro drill or power rasp (PowerPick or PowerRasp; Arthrex) device was used to create bleeding bone on the glenoid and humerus footprints of the SCR graft. Care was taken to not violate the cortical bone in areas in which suture anchors were placed to avoid compromise of anchor fixation.

The graft was fixed to the neck of the glenoid using two 3.0-mm anchors (BioComposite SutureTaks; Arthrex). The suture from the anchors were used to place a pulley stitch in the graft outside the patient. The pulley stich was used to shuttle the graft into the shoulder and then completed to fix the graft on the neck of the glenoid. Per surgeon discretion, the secondary limb of the pulley was fixed medially using 3.5-mm anchors (BioComposite SwiveLock; Arthrex) placed medially to the other anchors. If a third anchor was not added, the pulley stitch was secured using an arthroscopic knot.

The graft was fixed onto the humerus using 4.75-mm anchors (BioComposite SwiveLocks) and nonabsorbable suture tape (FiberTape; Arthrex). The following 3 variants are allowable for fixation of the graft:

- 4-anchor knotless repair with flat tape (SpeedBridge; Arthrex)
- 4-anchor knotless repair with flat tape with double pulley, or
- 6-anchor knotless repair with flat tape.

Residual rotator cuff tissue was managed with posterior convergence on all patients after fixation of the graft. Infraspinatus tears were covered with more anchors and a bigger allograft. Anterior convergence was performed only if there was tissue posterior to the bicipital grove.

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Data were sorted and analyzed using commercially available software (Excel [Microsoft, Redmond, WA] and SigmaStat [Systat Software, San Jose, CA]). Descriptive statistics were calculated and reported as means, standard deviations, ranges, and percentages. Outcomes were analyzed for statistically significant differences over time using repeated measures analysis of variance for continuous data and repeated-measures analysis of variance on ranks for categorical data. Fisher exact tests were used to assess the data for significant differences in proportions. Significance was set a priori at P < .05.

Results

A total of 20 patients were enrolled in the study after meeting preoperative study criteria. Six patients were excluded due to a combination of intraoperative screen fails (repairable rotator cuff or diffuse bipolar cartilage loss) or did not complete follow-up. Fourteen patients (12 male, 2 female; 8 right shoulders, 6 left shoulders) met all study criteria and completed follow-up data collection with mean follow-up of 2.1 years (range 1.9-2.1 years). Average patient age was 58.9 ± 11 years (range 37-74 years) with average body mass index of 27.2 ± 9 . Average surgery time was 148.5 ± 28 minutes (Table 1).

There were statistically significant (P < .05) improvements for VAS pain, ASES function, ASES index, SANE, and active forward elevation (FE) at the 6-month, 1-year, and 2-year time points when compared with preoperative values, with the exception of the 1-year SANE results. Furthermore, each assessment continued to improve from 6-month to 1-year to 2-year time points, again with the exception of the 1year SANE results. VAS pain decreased (P = .001) from mean of 3.3 preoperatively to 0.6 at 2 years. Twelve patients (86%) met the minimum clinically

Table 1. Patient Demographics and Surgical Data

| Age, y | 58.9 ± 11 (range 37-74) |
|----------------------------|--------------------------------------|
| BMI | 27.2 ± 9 |
| Male/female, n | 12/2 |
| Right/left, n | 8/6 |
| Surgical time, min (range) | $148.5 \pm 28 \; (110 \text{-} 180)$ |
| Anterior graft size, mm | 41.9 ± 10 |
| Posterior graft size, mm | 38.9 ± 10 |
| Medial graft size, mm | 22 ± 4.6 |
| Lateral graft size, mm | 28.4 ± 9.5 |
| | |

NOTE. Data reported as mean \pm standard deviation. BMI, body mass index.

T. D. PASHUCK ET AL.

| Outcome Measure | Preoperative | 3 Month | 6 Month | l Year | 2 Year |
|-----------------|--------------|-----------------------------|-------------------------------|--------------------------------|---------------------------------|
| Pain (VAS) | 3.3 ± 2 | $1.1 \pm 1^* \ (P = .0034)$ | $1.2 \pm 1^* \ (P = .0051)$ | $1.1 \pm 2^* \ (P = .012)$ | $0.6 \pm 1^* (P = .001)$ |
| ASES Function | 12.8 ± 4 | 14.8 ± 6 | $19.1 \pm 6^* \ (P = .0025)$ | $23.2 \pm 4^{*} \ (P < .0001)$ | $23.7 \pm 4^{*} \ (P < .0001)$ |
| ASES Index | 55 ± 17 | 69.2 ± 11 | $76 \pm 13^* \ (P = .0009)$ | $83.3 \pm 16^* \ (P < .0001)$ | $86.5 \pm 9^* \ (P < .0001)$ |
| SANE | 33.1 ± 14 | 53.7 ± 22 | $62.6 \pm 22^* \ (P = .0002)$ | 59.5 ± 31 | $71.5 \pm 23^{*} \ (P < .0001)$ |
| Active FE | 128 ± 36 | 126 ± 44 | $163 \pm 16^* \ (P = .0028)$ | $170 \pm 7^* \ (P = .0003)$ | $172 \pm 4^{*} \ (P = .0005)$ |

Table 2. Preoperative and Postoperative SCR Clinical Outcomes Data

NOTE. Repeated-measures ANOVA or repeated measures ANOVA on ranks.

ANOVA, analysis of variance; ASES, American Shoulder and Elbow Score; FE, Forward Elevation; SANE, Single Assessment Numeric Evaluation; SCR, superior capsular reconstruction; VAS, visual analog scale.

*Significantly (P < .05) different from preoperative.

important difference of ≥ 2 units change in VAS. ASES index increased (P < .0001) from mean of 55 preoperatively to 86.5 at 2 years. Twelve patients (86%) met the minimum clinically important difference of ≥ 11 units change in ASES.²⁰ Twelve patients (86%) met the minimum clinically important difference of ≥ 17 units change in SANE.²⁰ Active FE increased (P = .0005) from mean of 128 degrees preoperatively to 172° at 2 years (Table 2). There were no infections reported for patients included in the present study.

The results of imaging including radiographs, MRI, and ultrasound are shown in Table 3. Radiographs showed an increased AH distance from an average of 6.0 mm preoperatively to 8.0 mm at the 6-month time point. The AH distance decreased to 7.4 mm at 1 year and further decreased to 6.7 at the 2-year time points. These differences were not statistically significant (P > .1). MRI results revealed an average graft thickness at the greater tuberosity of 3.0 mm at 6 month and 2.6 mm at 1 year. Ultrasound measurements for graft thickness showed means of 4.0 mm at 6 months and 4.3 mm at 1 year. Ten grafts had documented vascularity at 6 months and eight had documented vascularity at 1 year (Fig 1). These differences in graft thickness at 6 months and 1 year were not statistically significant (P > .1).

Ten of 12 grafts were found to be intact by ultrasound imaging at 1 year. MRI found all grafts to be intact at the humerus at 1-year, with 8 of 12 (75%) being intact at the glenoid. Only 2 of 14 (14.2%) of the patients had symptoms consistent with a complication of graft failure (Fig 1).

The average anterior graft size was 41.9 ± 10 mm, average posterior graft size was 38.9 ± 10 mm, average medial graft size was 22 ± 4.6 mm, and average lateral graft size was 28.4 ± 9.5 mm. The graft was used to span the supraspinatus and infraspinatus in six patients. The infraspinatus was torn in all patients and repaired in 5 patients. The subscapularis was repaired in 5 patients with the remainder being intact. The biceps tendon remained intact in 2 patients, 5 were tenotomized, 4 were torn and not addressed surgically, 1 was tenodesed, and 2 were not recorded.

Complications

There was a 14.3% complication rate determined by a combination of history, examination, and advanced imaging in the present study. These complications included a SCR graft detachment from the medial aspect of the repair site and another patient who had failure of the SCR graft. There was a 7.1% (1/14) revision surgery rate with conversion to rTSA in this study.

Table 3. Preoperative and Postoperative SCR Imaging Data

| Outcome Measure | Preoperative | 3 Month | 6 Month | l Year | 2 Year |
|----------------------------------------------------|--------------|---------|-----------|-------------|-----------|
| AH distance radiograph, mm | 6 ± 2 | na | 8 ± 2 | 7.4 ± 2 | 6.7 ± 2 |
| Hamada grade | G1 (9) | na | G1 (12) | G1 (8) | G1 (4) |
| | G2 (5) | | G2 (2) | G2 (2) | G2 (1) |
| AP cuff tear size MRI, mm | 38.9 ± 6.9 | na | na | na | na |
| No. cuff tears with retraction to level of glenoid | 14/14 | na | na | na | na |
| Goutallier stage (MRI) | 2.7 ± 0.8 | na | na | na | na |
| MRI graft intact glenoid, mm | na | na | 8/12 | 8/12 | na |
| MRI graft intact humerus, mm | na | na | 12/12 | 12/12 | na |
| MRI graft thickness, mm | na | na | 3 ± 0.4 | 2.6 ± 1 | na |
| US graft intact, mm | na | na | 10/12 | 10/12 | 5/5 |
| US graft thickness, mm | na | na | 4 ± 1.4 | 4.3 ± 1 | 3.7 ± 1 |
| | | | | | |

Repeated measures ANOVA or repeated measures ANOVA on ranks.

AH, acromiohumeral; ANOVA, analysis of variance; AP, anteroposterior; MRI, magnetic resonance imaging; na, not available; US, ultrasound. *Significantly (P < .05) different from preoperative.

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Fig 1. Ultrasound images of right shoulder SCR 1-year postoperatively. (A) Long-axis view demonstrating SCR allograft (large arrow) with insertion starting at the right side of the image at the articular margin (small arrow). (B) Magnified long-axis view using color Doppler mode to detect pulsatile vessels both within graft substance and within bursal tissues near graft insertion onto the greater tuberosity. Color Doppler mode detects flow within the yellow box on the image. Blue color represents blood flow away from ultrasound transducer. Red color represents blood flow towards ultrasound transducer. (SCR, superior capsular reconstruction.)

Discussion

The results of this study show that arthroscopic SCR with dermal allograft is a safe procedure with functional short-term clinical outcomes. SCR patients in this study experienced statistically significant improvements in shoulder pain and function that continued in a positive trajectory up to 2 years out from surgery. Diagnostic imaging data suggested that the majority of dermal grafts used for SCR remained intact, attached, and were vascularized such that function was maintained through at least 1 year after surgery. Two of the 14 patients (14%) had graft complications, with only one of those patient's requiring reoperation with rTSA.

None of the patients had evidence for superficial or deep infection.

Patient outcomes in the present study were comparable to previous reports of SCR using autograft or allograft.^{8,10-17} Patients in the present study showed statistically significant improvements in the ASES score of 32 points, increasing from a mean of 55 preoperatively to 87 at 2 years. This increase followed a common theme of improvements continuing from 6-month (ASES score 76) to 1-year (ASES score 83) and from 1-year to 2-year time points in our study. The current literature shows ASES scores increasing with SCR by an average of 29.4 to 69.4 in the short-term.^{8,10-17} Mihata et al.⁸ demonstrated a larger ASES improvement with SCR using fascia lata autografts, increasing from 23.5 to 92.9 over mean follow-up of 34.1 months. Both our study and their results had similar values at short-term follow-up, but they reported lower values for ASES before SCR surgery. Functional outcomes of this presents study were comparable with rTSA in the younger patient population. Sershon et al.⁶ reported a similar increase in ASES scores, SANE scores and active FE at mean follow up of 2.8 years with rTSA in patients younger than 60 years old. However, the complication rate was much lower when compared with the results of Ek et al.,⁷ who reported a 37% complication rate in their study of rTSA in patients younger than 65 for massive irreparable rotator cuff tears. Their results included a 27.5% reoperation rate, 17.5% dislocation rate, and 13% deep infection rate.

Mean active elevation and VAS pain also significantly improved for patients in the present study. Active elevation increased by 44 degrees going from 128 to 172°. VAS pain significantly improved from 3.3 preoperatively to 1.1 at 1-year and 0.6 at 2 years. These results are also consistent with previous reports, which show average increases of active elevation ranging from 22 to 66° and average decrease in pain from 5.0 preoperatively to 1.5 at 26 months after SCR with allograft or autograft.^{8,10-17}

A key difference in this study was the placement of the arm in neutral abduction and rotation during SCR surgery instead of the more common placement of 30 to 40° of abduction. We define neutral abduction and rotation as 0° of flexion–extension and 0° of rotation with the patient in resting abduction. The degree of abduction may vary depending on the patient's body habitus and is positioned where the arm sits naturally against the body. While it has not been specifically studied, a graft that is too tight would likely over constrain the shoulder and increase joint reaction forces. We could extrapolate the situation of closing the rotator interval, which has been shown to over constrain the joint, increase joint reaction forces, increase pain, and increase early degenerative joint changes. Thus, we hypothesize that this would

T. D. PASHUCK ET AL.

ultimately generate more pain and increase the risk of fixation failure and graft failure.²¹

The distances between the anchor positions on the humerus and glenoid change throughout range of motion. Measuring the graft size with the arm in any other position than neutral abduction and rotation will result in a graft that is sized to this position in space. This also applies to fixing the graft in a position other than neutral. If the graft is measured and fixed in 30° of abduction as proposed in some techniques, the distance between the humeral and glenoid anchors is shortened. While the graft may be in good position and tension at this angle, once the arm is brought to its side, the graft will be subjected to significant strain that could compromise its fixation or integrity. The same principle is true if the shoulder is brought into some kind of rotation. Internal rotation would result in the anterior humeral and glenoid anchors being in closer proximity while lengthening the distance between the posterior anchors. This would again create a tension mismatch that would compromise the graft when brought to neutral. We define neutral as where the arm rests at the patient's side, which may vary based on body habitus and may not necessarily be zero degrees of abduction.

Biomechanical data from Scheiderer and Mihata have suggested that thicker grafts for SCR (6-8 mm compared with 3-4 mm) better restore glenohumeral joint position and improve contact pressures.^{22,23} In the present study, SCR was performed using a 3.0 mm acellular dermal allograft, which was associated with a mean AH distance increase from 6.0 mm preoperatively to 8.0 mm at 6 months. The AH distance decreased to 7.4 mm at 1 year. The decreasing AH distance from 6 months to 1 year correlated with our MRI data showing an average graft thickness of 3.0 mm at 6 months and 2.6 mm at 1 year. Our ultrasound data demonstrated an increase in graft thickness from 4.0 mm at 6 months to 4.3 mm at 1 year, followed by a decrease to 3.7 mm at 2 years. Possible reasons for these differences include measurements taken at different parts of the graft, operator error, and measurement error. The patients in our study continued to show improvements in shoulder pain and function at 2 years despite these changes observed on diagnostic imaging.

Ultrasonography of SCR grafts in this study demonstrated vascularity detectable by color Doppler in the majority of patients at 6 months (83%) postoperatively that decreased to 67% at 1-year postoperatively. Hirahara et al. reported similar findings with 56% of SCR dermal allografts having vascularity detectable by color Doppler during the initial 12 months after surgery, with the minimum time from surgery for evidence of blood flow being 4.0 months. Ultrasonographic evidence for pulsatile vessels disappeared in their series of patients by 8.7 months except in 1 instance, which had persistent vasculature 25 months postoperatively. The findings of their study, combined with their previous histologic analysis of an explanted SCR dermal allograft at 13 months postoperatively demonstrating an abundance of capillary vessels, suggested that the graft vascularity transforms from larger vessels to smaller vessels over time.^{21,24} Hartzler and et al.²⁵ also evaluated an explanted SCR allograft histologically at 7 months after surgery. The graft demonstrated gross and microscopic incorporation with the host, including a tendon-like structure, aligned collagen fibers, fibroblast-like cells, and no clear graft-host distinction. Neovascularization and active graft remodeling were confirmed histologically in their report. Samade et al.²⁶ confirmed vascularity of the SCR dermal allograft visually during a diagnostic arthroscopy at 1-year postoperatively.

Overall, there was a 14.3% complication rate and a 7.1% revision surgery rate in the present study. These rates are lower than other SCR studies including graft integrity rate reported at 50% and revision surgery rate as high as 18.6%.^{12,27}

One of the 2 graft complications in the present study occurred at 5 months' postoperatively in a laborer who was required to lift weight in excess of 50 pounds (22.7 kg) repetitively. The 6-month MRI demonstrated graft detachment from the medial aspect of the repair site representing incomplete healing or tear of the graft from the glenoid. The patient continued to improve with conservative treatments, including a single corticosteroid injection and oral anti-inflammatories. At 1year postoperatively, the patient reported pain relief compared with before surgery with VAS pain scores ranging from 0 to 2 of 10 between the 6-month and 1year time points. This patient's active FE was 170° and ASES index score was 68.3. The 1-year MRI demonstrated that the graft did not heal over the medial aspect of the construct, but it remained over the posterior aspect of the humeral head, seemingly protecting the humeral head by interposition to some extent. The patient reported a VAS pain score of 1 of 10 at the 2-year visit with ASES index score of 76.7.

The second graft complication occurred in a farmer involved in heavy labor. The 6-month MRI showed the graft as partially attached medially and laterally, but torn in the midsubstance. The graft was found to be completely unattached from the glenoid but attached at the humerus at 12-months. Ultrasonography performed at the same timepoints indicated that the graft was attached to the humerus laterally, with signs of pulsatile vessels present at the 12-month time point but not at 6-months. There was no specific incident during these time points that would indicate a definitive cause for failure. Interestingly, the patient reported doing well and being satisfied with the outcome of SCR at these time points. This patient reported a fall at 18 months after SCR and subsequent MRI after the fall showed that the graft had failed. The patient opted for rTSA.

The mechanisms of graft complications in the present study are consistent with the previous report by Emerson et al.²⁸ These authors reported that the most common mode of failure was loss of fixation on the glenoid, followed closely by midsubstance rupture. They reported no instances of isolated fixation failure on the humeral head. Our study had 2 additional patient's that had 6-month and 1-year MRI findings of graft detachment from the glenoid. These patients were asymptomatic and the corresponding ultrasounds showed only partial graft detachment. These findings indicate the glenoid fixation technique with the SCR is critical.

Limitations

There are several limitations to our study. First, only 14 patients were included in the study. While these patients were comprehensively assessed before and after surgery, broad application of these data is limited by the number of patients. Second, the study included follow up to only 2 years after surgery. Even though the data showed continued improvements from year 1 to year 2, long-term outcomes after SCR were not determined. Third, the generalizability of these results may be somewhat limited since both surgeons in this study have extensive training and experience with shoulder surgery. Lastly, the experimental design did not permit inclusion of a control group or cohort such as rotator cuff repair, partial repairs, tendon transfers, SCR with fascia lata autograft, or SCR with different dermal allograft thicknesses for comparison of results.

Conclusions

Arthroscopic SCR using dermal allograft can be a safe and effective treatment option for patients with massive irreparable rotator cuff tears with statistically significant improvements in VAS pain, ASES, SANE, and active FE at 2-years postoperatively, with 93% of grafts demonstrating vascularity at 1-year postoperatively. Neutral abduction of the arm at the time of implantation resulted in positive clinical outcomes and may decrease graft failure rate.

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8

T. D. PASHUCK ET AL.

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SCR WITH DERMAL ALLOGRAFT

Appendix Table 1. SCR Inclusion and Exclusion Criteria

Inclusion

- Subjects who have consented to implantation of allograft tissue
- Adult patients (≥18 y)
- Subjects who are candidates and planning to undergo arthroscopic SCR for irreparable supraspinatus tears
- Preoperative MRI obtained within 26 weeks before surgery
- Must have 3 of 5 external rotation
- Must have teres minor
- Preoperative exclusion
- Pregnant or planning to become pregnant
- Persons with a mental or cognitive disability deemed significant enough that they would not be capable of completing the outcome measures
- Patients with known contraindications to MRI
- Greater than 20° loss of passive ROM compared with the contralateral side
- Grade 4 or 5 Hamada classification
- Radiograph greater than 4 weeks
- Pec, deltoid, or latissimus dorsi dysfunction
- Acute fractures of humerus, clavicle, scapula
- Intra-articular injections (steroids) within 1 month of surgery
- Inability to speak and understand English
- Intraoperative exclusion
- Damaged coracoacromial ligament
- Unable to fixate the graft on the humeral side utilizing a double row SpeedBridge repair
- Inability to address subscapularis pathology
- Diffuse bipolar cartilage loss
- CA, coracoacromial; MRI, magnetic resonance imaging; ROM, range of motion; SCR, superior capsular reconstruction.