Outcomes After Open Revision Repair of Massive Rotator Cuff Tears With Biologic Patch Augmentation

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Purpose: To assess minimum 2-year clinical outcomes after open revision biologic patch augmentation in patients with massive rotator cuff retears who had deficient rotator cuff tendons with healthy rotator cuff muscles. **Methods:** Patients with massive posterosuperior rotator cuff retears who underwent open revision rotator cuff repair with patch augmentation were identified from a surgical registry. Outcomes data collected included American Shoulder and Elbow Surgeons; Quick Disabilities of the Arm, Shoulder and Hand; Single Assessment Numeric Evaluation; and Short Form-12 Physical Component Summary scores along with postoperative patient satisfaction, and activity modification. **Results:** There were 10 men and 2 women (13 shoulders, 1 bilateral) with a mean age of 57 years (range, 26 to 68 years). All patients had at least one prior arthroscopic rotator cuff repair. After patch augmentation, there were no complications, no adverse reactions to the patch, and no patients required further surgery. One patient (7.7%) with 4 prior cuff repairs had a documented posterosuperior retear on magnetic resonance imaging 2 months after repair. Minimum 2-year outcome scores were available for 12 of 13 (92.3%) shoulders after a mean follow-up period of 2.5 years (range, 2.0 to 4.0 years). The ASES score improved by 21.5 points. Although the pain component of the ASES score and the total ASES score did not improve significantly, the function component of the ASES score improved significantly when compared with their preoperative baselines ($P < .05$). Median patient satisfaction at final follow-up was 9/10 (range, 2 to 10). **Conclusions:** Biologic patch augmentation with human acellular dermal allograft was a safe and effective treatment method for patients with massive rotator cuff retears with deficient posterosuperior rotator cuff tendons in the presence of healthy rotator cuff muscles. **Level of Evidence:** Level IV, therapeutic study.

The surgical management of rotator cuff tears has been successful in reducing symptoms and improving shoulder function in the most affected patients.[1-4] However, there are several surgical factors that have been found to negatively affect patient outcomes. These include large tear size, poor tendon quality, increased degree of tendon retraction, and the presence of fatty degeneration, among many other factors.[5,6] Therefore, patients with massive, retracted rotator cuff tears are less likely to achieve an optimal outcome using standard rotator cuff repair constructs, particularly in a revision situation. As a result, new methods of tendon repair have been developed to improve outcomes in this subgroup of patients. Specifically, rotator cuff augmentation using biological patches has been proposed as a method to improve repair integrity, particularly when tendon quality is less than optimal.

Patch augmentation can be performed using open, mini-open, or arthroscopic techniques. A variety of biological patch materials have been used with favorable results, including autologous fascia lata,[7] human acellular dermis,[8] and porcine dermal collagen[9,10] in addition to various synthetic grafts composed of poly-L-lactic acid,[11] polyester,[12] polypropylene,[13] polytetrafluoroethylene,[14] or polyurethane.[15] Some studies, however, have not reported good results with biological patches.[16,17]

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Although the most appropriate materials for the augmentation of rotator cuff repairs has not yet been defined, preliminary biomechanical and clinical evidence suggest that rotator cuff augmentation may be a safe and effective method for the treatment of massive, retracted rotator cuff tears.[7,8,15,18-20] However, limited data exist regarding minimum 2-year clinical outcomes after rotator cuff augmentation using acellular dermal matrix allografts in this group of patients.[10,11,13,21-23] In addition, the treatment of rotator cuff tendon deficiency in the setting of otherwise healthy rotator cuff muscles has not been well studied. Finally, data regarding the use of biological patch augmentation in revision rotator cuff repair are currently lacking. The purpose of this study was to assess minimum 2-year clinical outcomes after open revision biologic patch augmentation in patients with massive rotator cuff retears who had deficient rotator cuff tendons with healthy rotator cuff muscles. We hypothesized that revision rotator cuff repair with biologic patch augmentation using human acellular dermal allograft would be safe, effective, and would result in significant improvement in clinical outcomes scores when compared with preoperative baselines in patients with massive rotator cuff tears.

Methods

Study Design

Institutional Review Board approval was obtained before the initiation of this study. Between January 2010 and January 2013, all patients who underwent open revision repair of large to massive rotator cuff tears with biological patch augmentation by a single surgeon (P.J.M.) were identified from a surgical registry. All patients were assessed by the senior surgeon (P.J.M.) both pre- and postoperatively. Minimal subjective follow-up was set at 2 years. Patients with concomitant pathologies such as SLAP tears, osteoarthritis, and biceps pathology were included. Patients with concomitant tears of the subscapularis (SSC) tendon were also included. One patient underwent arthroscopic repair of a retracted full-thickness SSC tear, whereas 2 patients underwent debridement for smaller partial-thickness SSC tears. In all 3 of these cases, the SSC tears were considered subordinate to the more clinically relevant posterosuperior tears. Patients who underwent primary repair of the rotator cuff with patch augmentation, who underwent arthroscopic patch augmentation surgery, or who underwent re-revision of a prior allograft patch were excluded. Figure 1 provides information on patients who were included and excluded. Minimum 2-year subjective follow-up data were obtained using validated shoulder questionnaires.

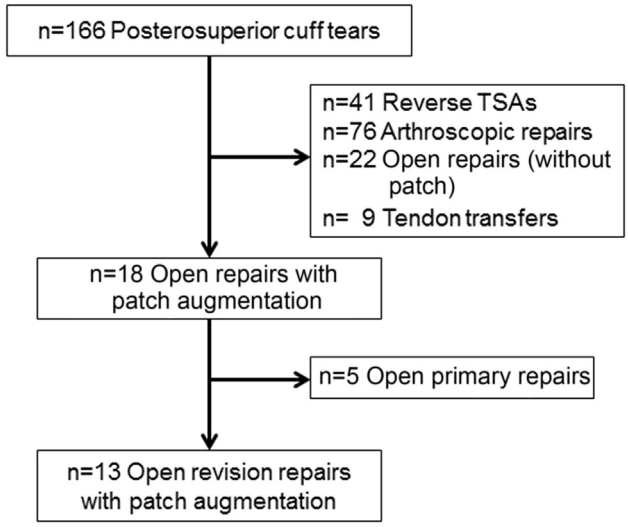

Fig 1. Flow diagram depicting the included and excluded patients. (TSA, total shoulder arthroplasty.)

Surgical Treatments

The decision to perform rotator cuff repair with patch augmentation was based on preoperative evaluations, magnetic resonance imaging (MRI) appearance, and intraoperative tendon quality and mobility. Rotator cuff repair with human acellular dermis biological patch augmentation was indicated for patients with massive, retracted posterosuperior rotator cuff tears with poor tendon quality and good muscle quality (Goutallier < 3) (Fig 2). If the cuff tendon could not be sufficiently mobilized, other options such as debridement, partial repair, tendon transfer, and reverse total shoulder arthroplasty (rTSA) were considered. For all cases included in this series, the patch was used for augmentation (not bridging) where the native rotator cuff tendon was secured to the medial footprint on the greater tuberosity. The allograft patch was placed over the top of the cuff tendon and secured medially to the remaining rotator cuff tissue and laterally to the greater tuberosity as described in a biomechanical study by van der Meijden et al.[21]

Surgical Technique

After the administration of a regional interscalene block and the induction of general anesthesia, the patient was placed in the modified beach-chair position. The operative arm of the affected shoulder was placed in a pneumatic arm holder and the operative field was prepared and draped using sterile techniques. Standard posterior and anterosuperior portals were established, diagnostic arthroscopy was performed, and all intra-articular pathologies were addressed as necessary. An accessory lateral portal was established to allow for access to the subacromial space. Mobility of the torn cuff tendons was assessed and intra- and extra-articular

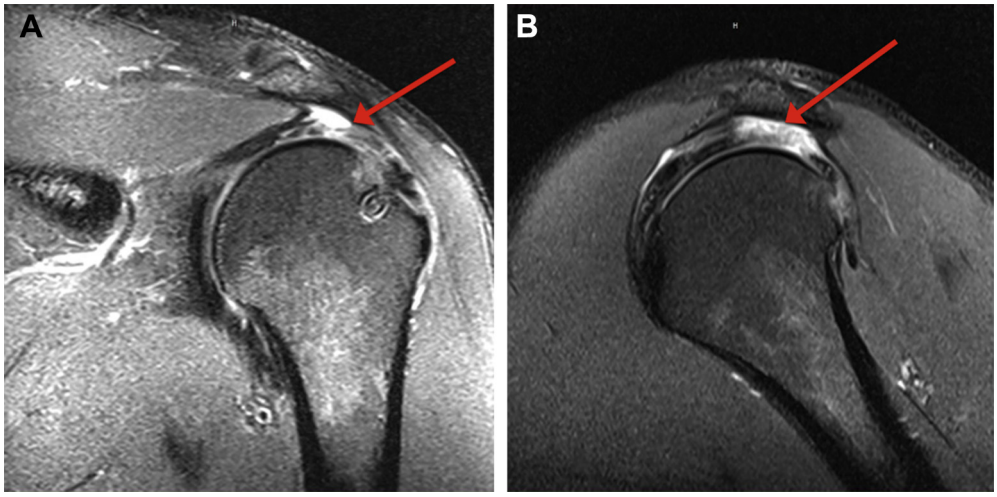

Fig 2. (A) A coronal T2 slice of magnetic resonance imaging (MRI) showing a massive rotator cuff tear after previous double-row rotator cuff repair in a left shoulder. The red arrow depicts the rotator cuff tear. (B) A sagittal T2 slice of MRI showing a massive rotator cuff tear after previous double-row rotator cuff repair in a left shoulder. The red arrow depicts the rotator cuff tear. Note that the rotator cuff muscle is healthy, but the tendon quality is poor given the medial tendon failure.

releases were performed using an elevator and radiofrequency probe where necessary. At this point, the decision was made whether to perform rotator cuff repair with or without patch augmentation. Retained hardware, including sutures and suture anchors that were placed during previous surgeries, were removed as indicated. If the prior fixation was unlikely to interfere with the new repair, or if its removal was likely to result in substantial destruction of the tuberosity, then the prior hardware was retained. Typically, we tried to remove as much foreign material as possible to optimize the biological site of healing. If subacromial or subcoracoid impingement was identified, the subacromial and subcoracoid motion interfaces were re-established via acromioplasty and coracoplasty, respectively.

Rotator cuff repair with patch augmentation was then performed using an open deltoid-splitting approach. An anterolateral approach between the anterior and middle heads of the deltoid was performed, extending approximately 4 cm distally from the acromial tip. The deltoid was partially taken down anteriorly from the acromion, and acromial osteotomy was avoided. In all cases, human acellular dermal extracellular matrix patches impregnated with growth factors, glycosaminoglycans, and proteoglycans were used (Arthroflex, Arthrex, Naples, FL). The dermal allografts were used as tendon augments to reinforce the native rotator cuff tissue and were not used to bridge tendon defects. The greater tuberosity footprint was debrided to a bleeding surface using a motorized shaver. For U-shaped tears, margin convergence techniques were used to close the defects in the cuff tendons in a side-to-side fashion, followed by repair of the remaining host rotator cuff tendons to the medial aspect of the footprint. L-shaped and reverse L-shaped tears were repaired using a combination of margin convergence and direct repair to the tuberosity. The native cuff was secured by the medial row of anchors. Suture tapes and mattress sutures were passed through the native tissues and they were secured at the medial footprint. Aluminum foil was used as a template to measure the area to be augmented. The allograft patch was trimmed to match the planned area of augmentation. In most cases, the augmentation was performed using an extended, linked double-row technique with suture tapes according to the method described by van der Meijden et al.[21]

The planned sites for the medial suture anchors were prepared with a punch and each anchor was loaded with No. 2 suture (Fiberwire, Arthrex) and 2-mm suture tape (Fibertape, Arthrex). Suture anchors (Speedbridge Kit, Arthrex) were placed to ensure a bone bridge of approximately 1 cm anterior to posterior and 1.5 cm medial to lateral. One strand of both the suture and the suture tape was passed through the native rotator cuff approximately 1 to 2 mm lateral to the musculotendinous junction using a standard shuttling device. These strands were then passed through the medial aspect of the patch. The sutures were tied using horizontal mattress stitches that anchored the medial suture anchors to the remaining native host cuff tissue and additionally stabilized the patch.

Once the native cuff was repaired, the patch was draped over the top and tensioned. To tension the patch, it was sewn into the native cuff medially and then 2 or 3 additional No. 2 continuous braided polyester and/or polyethylene suture loops (Fiberlink, Arthrex) were passed through the anterolateral and posterolateral aspects of the allograft patch. Additional tagging sutures were placed in the lateral aspect of the patch. The planned sites for the lateral row anchors were then prepared with a punch. The patch was then incorporated into the double-row repair using linked suture tapes that traveled from the medial row of anchors to the lateral row of anchors over the top of the entire construct. This technique stretched and

compressed the patch on the bursal side of the native tendon, completely covering the greater tuberosity footprint (Fig 3). For smaller tears, we used fewer anchors, but larger tears needed more anchors. Typically, anchors were placed at 1 cm intervals in the sagittal plane and 20 mm intervals in the coronal plane. In 2 of 13 cuff repairs, the size of the tuberosity only allowed for the placement of a total of 4 anchors where 2 anchors were placed medially and 2 anchors were placed laterally. For the remaining 11 repairs, larger double-row constructs were created using 6 to 8 anchors. The mean number of anchors used was 6 (range, 4 to 9). An additional running suture (3-0 Vicryl) was placed at the patch-tendon interface to prevent edge instability. Early in the series, 2 repairs were performed using a knotted suture bridge technique because pending cadaveric lab experiments were still being conducted.[21]

Application of platelet-rich plasma (PRP) into the rotator cuff repair site at the end of the procedure was recommended to all patients in the early phase of the study; however, the decision to undergo PRP treatment depended on practical limitations and the patients' willingness to pay for this treatment. As the study progressed and we learned more about its effectiveness, PRP treatment was no longer routinely recommended.

If the long head of the biceps tendon (LHBT) had not been tenodesed during a prior surgery, open suprapectoral (n = 1) or subpectoral (n = 6) tenodesis was performed. Suprapectoral tenodesis was performed using the same deltoid splitting approach that was used for rotator cuff repair (this method was chosen in 1 case because of prior scarring in the subpectoral region). The proximal portion of the LHBT was resected and the tendon was whipstitched. It was then secured to the upper border of the pectoralis major tendon and the inferior border of the bicipital tendon sheath using No. 2 nonabsorbable sutures.

For subpectoral tenodesis, the arm was abducted and slightly internally rotated, and the skin was incised along the axillary crease from 1 cm superior to 3 cm inferior to the inferior border of the pectoralis major tendon. Using the interval between the pectoralis major tendon superiorly and the short head of the biceps inferiorly, the LHBT was retrieved in the bicipital groove, externalized and whipstitched. A unicortical bone tunnel was reamed at the inferior aspect of the bicipital groove and the tendon was inserted using an interference screw. The sutures were tied as well to enhance the fixation.[24]

Postoperative rehabilitation was influenced by intraoperative findings, concomitant treatments, and tissue quality. In general, patients were protected in a sling for 6 to 8 weeks. Shoulders were immobilized for 2 weeks followed by the initiation of passive motion exercises. To gradually increase shoulder range of motion, a limitation of 30° of external rotation, 90° of abduction, and 120° of forward flexion was typically implemented from weeks 2 through 6. At 6 weeks after surgery, active and active-assisted range of motion was allowed with stepwise strengthening exercises started at 8 weeks. Active motion of the elbow, wrist, and hand was allowed immediately after surgery. However, flexion of the elbow against resistance was not allowed for 6 weeks in those who underwent biceps tenodesis.

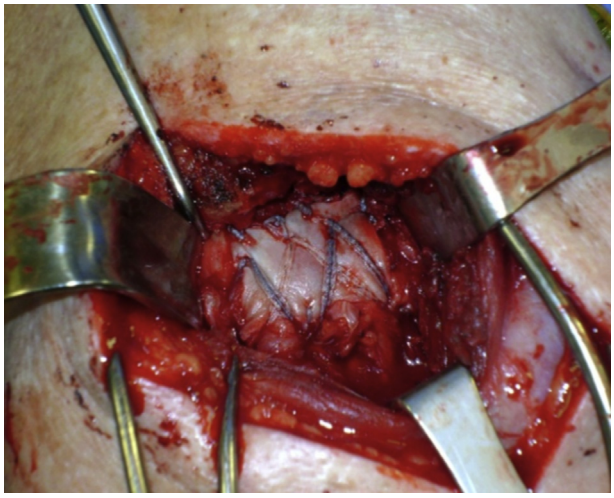

Fig 3. A photograph of an extended, linked double-row construct showing the integration of a human acellular dermal patch into the rotator cuff repair in a left shoulder. The rotator cuff tendon was repaired medially onto the native tendon footprint of the tuberosity, the graft was placed on top of the native tendon, and the graft was secured by sutures and suture tapes, thus completing the double-row construct.

Data Collection

All data were prospectively collected, stored in a surgical registry, and retrospectively retrieved for analysis. Demographic data (age, gender, body mass index [kg/m^2]), surgical history (previous rotator cuff repairs or other surgeries on the index shoulder), intraoperative data (surgical techniques, concomitant pathologies), and perioperative complications were collected for analysis (Table 1). In this study, treatment failure was declared when subsequent revision cuff repair or rTSA was performed after the index surgery. Postoperative MRI was performed in patients who were able to return to our referral clinic for follow-up assessment (Fig 4). All MRIs were obtained using a 3.0-Tesla scanner (Siemens Magnetom, Erlangen, Germany) and were interpreted by a single, nonblinded, board-certified musculoskeletal radiologist with more than 20 years of experience.

Clinical outcomes scores were collected both pre- and postoperatively and included American Shoulder and Elbow Surgeons (ASES),[25] Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH),[26] Single

Table 1. Patient Demographic Data

	Data
Patient Factors	
Mean age, yr (95% CI)	57 (50-64)
Mean body mass index, kg/m^2 (95% CI)	26.9 (24.7-29.1)
Gender, n, male/female	11/2
Former smoker, n (%)	3 (23.1)
Diabetes mellitus, n (%)	1 (7.7)
Surgical Factors	
Median no. of prior cuff repairs, n (range)	1 (1-4)
Surgery on dominant shoulder, n (%)	8 (61.5)
Subscapularis tears, n (%)	3 (23.1)
PRP injection, n (%)	10 (76.9)
Biceps tenodesis, n (%)	7 (53.8) (the remaining 6 patients underwent tenodesis at the previous rotator cuff repair)

CI, confidence interval; PRP, platelet-rich plasma.

Assessment Numeric Evaluation (SANE),[27] and Short Form-12 Physical Component Summary (SF-12 PCS) scores. Data regarding patient satisfaction and activity modification were also collected postoperatively. Short of rotator cuff revision surgery, functional failures were defined as patients with satisfaction scores of 6 or less.

Statistical Analyses

Statistical analyses were performed using SPSS version 11.0 (SPSS, Chicago, IL). Because of the limited number of patients included, a formal post hoc power analysis was not appropriate (because more patients could not be included to increase power). Instead the effect size of our study was generated directly from our sample size. Therefore, assuming 80% power, with α equal to 0.05, the effect size of our study was calculated to be 0.94. The current study was powered to detect between 7- and 16-point differences in the outcome scores. In this data set, continuous variables were normally distributed. Univariate analyses were performed using an independent *t*-test, bivariate data were analyzed using χ^2 tests, and continuous variables were analyzed using Spearman's rho coefficient. The paired 2-tailed Student *t*-test was used to detect differences between pre- and postoperative outcomes scores. Preoperative and postoperative categorical variables were analyzed using the Wilcoxon signed-rank test. *P* values of less than .05 indicated statistical significance.

Results

Open revision rotator cuff repair with allograft patch augmentation was performed in 13 shoulders (10 men, 2 women, 1 bilateral) with a mean age of 57 years (range, 26 to 68 years). All shoulders underwent at least 1 prior rotator cuff repair. Seven shoulders (53.8%) underwent biceps tenodesis, whereas 6 shoulders (46.1%) had already undergone biceps tenodesis in their previous surgery, all of which were effectively tenodesed. Three shoulders (23.1%) were noted to have Outerbridge grade III or IV chondral defects. Eight shoulders (61.5%) received PRP injections into the rotator cuff repair site at the end of the procedure. There were no complications related to the surgical procedures and no patients required further surgery at the time of study completion. There were no adverse effects as a result of the human acellular dermal allografts.

Of the 13 shoulders, 6 (46.2%) underwent MRIs at a mean of 9.9 months postoperatively (range, 11 days to 26.3 months). Five of these 6 shoulders (83.3%) showed intact repair constructs, whereas 1 patient with 4 prior cuff repairs had a documented posterosuperior retear on MRI 2 months after repair.

Minimum 2-year outcomes scores were available for 12 of 13 (92.3%) shoulders after a mean follow-up period of 2.5 years (range, 2.0 to 4.0 years). Although the pain component of the ASES score and the total ASES score did not improve significantly, the function

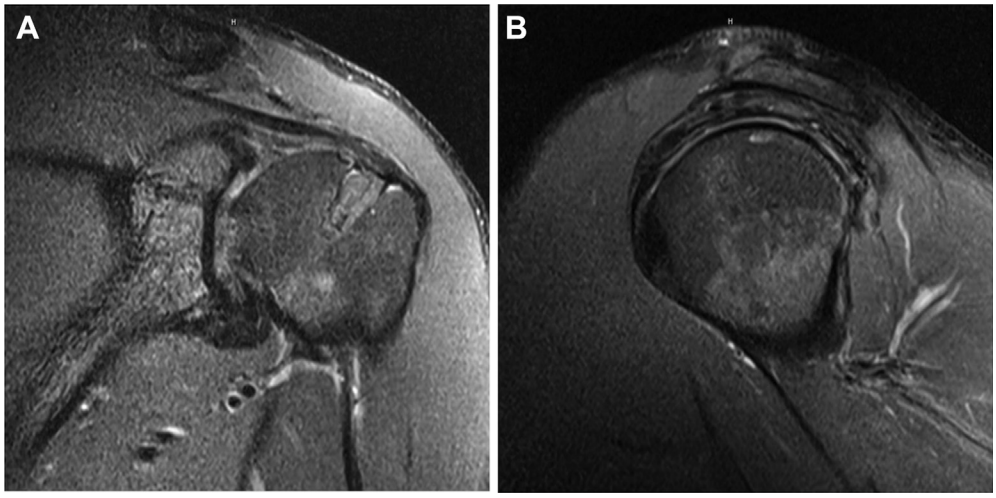

Fig 4. (A) A coronal T2 slice of magnetic resonance imaging (MRI) 2 years after patch-augmented rotator cuff repair in a left shoulder. Note that the repair is intact (same patient as shown in Fig 2). (B) A sagittal T2 slice of MRI 2 years after patch-augmented rotator cuff repair in a left shoulder, showing an intact repair and closure of the rotator cuff (same patient as shown in Fig 2).

component of the ASES score improved significantly when compared with its preoperative baseline. The physical component of the SF-12 score, the SANE score, and the QuickDASH score each showed statistically significant improvements when compared with their preoperative baselines ($P < .05$) (Table 2). Median patient satisfaction at final follow-up was also high at 9/10 (range, 2 to 10).

Three patients with median satisfaction scores of 4 (range, 3 to 5) were deemed to be functional failures when compared with the rest of the cohort that showed higher median satisfaction scores of 10 (range, 8 to 10). One of these 3 patients had a postoperative MRI that showed a retear. Patients with functional failure of their repairs had preoperative scores that were similar to the rest of the cohort, but they exhibited significantly lower postoperative SF-12 PCS (48.5 *v* 54.6; $P = .009$) and ASES scores (64.4 *v* 94.2; $P = .043$). No differences were observed in postoperative SANE (47.7 *v* 86.4; $P = .157$) or QuickDASH scores (11.3 *v* 11.3; $P = .997$) between these groups.

Discussion

The most important finding in this study was that open revision rotator cuff repair with patch augmentation using human acellular dermal allograft was a safe and effective treatment method for patients with massive, retracted rotator cuff tears. Patient satisfaction was high at 9/10, and there were no complications or problems associated with the graft itself. After a minimum of 2 years and a mean follow-up period of 2.5 years, the SF-12 PCS score, the function component of the ASES score, the SANE score, and the QuickDASH score each showed statistically significant improvements when compared with their preoperative baseline. Although the pain component of the ASES score and the total ASES score did not improve significantly, the function component of the ASES score improved significantly when compared with its preoperative baseline.

Table 2. Pre- and Postoperative Clinical Outcomes Scores After Open Revision Rotator Cuff Repair With Patch Augmentation

	Preop Scores, Mean −41 d (range, −110 to 0 d)	Postop Scores, Mean 2.8 yr (range, 2.0 to 3.9 yr)	*P* Value
ASES pain	38.6 95% CI (33.1-44.0)	44.6 95% CI (36.5-50)	.506
ASES function	25.0 95% CI (17.0-33.0)	41.7 95% CI (36.7-46.7)	.008*
ASES total score	64.5 95% CI (52.0-77.1)	86.0 95% CI (75.8-96.3)	.094
SF-12 PCS	44.5 95% CI (39.6-49.3)	52.9 95% CI (49.8-56.0)	.005*
SANE	54.3 95% CI (33.8-74.9)	74.8 95% CI (57.3-92.3)	.011*
QuickDASH	36.5 95% CI (22.1-51.0)	11.3 95% CI (92.7-20.0)	.006*
Median satisfaction with surgical outcomes	NA	9 (range, 2-10)	—

NOTE. All data were normally distributed according to the Kolmogorov-Simirnov test; therefore, the parametric independent paired *t*-test was performed.

ASES, American Shoulder and Elbow Surgeons; ASES function scale: 0-50, 50 = best; ASES pain scale: 0-50, 50 = best; ASES total scale: 0-100, 100 = best; CI, confidence interval; NA, not applicable; Postop, postoperative; Preop, preoperative; QuickDASH, Quick Disabilities of the Arm, Shoulder and Hand, scale: 0-100, 0 = best; SANE, Single Assessment Numeric Evaluation, scale: 0-100, 100 = best; SF-12 PCS, Short Form-12 Physical Component Summary.

*P value is significant.

Several studies have reported the clinical outcomes after cuff augmentation using a variety of patch materials (Table 3).[8-11,13,15,18,22,23] Three studies investigated clinical outcomes after cuff augmentation with an acellular human dermal matrix patch, each of which reported favorable clinical outcomes in agreement with the current study.[8,18,23] Bond et al.[8] showed satisfactory clinical outcomes in 16 patients after a minimum 12-month follow-up period. The mean Constant score was 84.0 and the University of California Los Angeles (UCLA) shoulder score was 30.4 at final follow-up. Evidence of graft failure was observed on MRI in 3 patients; however, these patients were satisfied with their clinical outcome as a result of decreased pain and improved function. Wong et al.[23] evaluated the clinical outcomes in 45 patients after a minimum 2-year follow-up period. In that study, the mean postoperative ASES score was 84.1 and the mean postoperative Western Ontario Rotator Cuff score was 75.2. Barber et al.[18] evaluated the clinical outcomes in 22 patients who underwent rotator cuff patch augmentation. After a minimum 1-year follow-up period, the mean ASES score was 98.9 and the mean Constant score was 91.9. In that study, 3 of the 20 patients who returned for postoperative MRI showed recurrent cuff tendon defects. The difference between our mean ASES score of 86.0 and that which was reported by Barber et al.[18] may be attributable to several factors. Barber et al.[18] excluded patients who underwent revision procedures, those with cuff tears measuring more than 5 cm in length, and patients who had SSC tendon involvement. It is possible that these variables may negatively affect the clinical outcomes after rotator cuff patch augmentation.[5,6]

The repair of massive cuff tears with biodegradable or synthetic patches has been used for many years—the first of these clinical studies was published by Ozaki et al.[28] in 1986. Since then, the materials used for these patches have undergone significant changes. Nonbiodegradable constructs were initially used; however, substantial concerns such as the gradual loss of structural integrity and the elevated risk of infection led to the development of biodegradable extracellular matrix patches from various sources. Gupta et al.[10] reported

Table 3. Summary of Studies That Have Evaluated the Clinical Outcomes After Rotator Cuff Repair With Patch Augmentation

Authors and Year	N	Mean Age, yr (range)	Technique	Patch Materials	Revisions and Complications	Mean Follow-up, mo (range)	Preoperative Status	Postoperative Results
Bond et al.[8] 2008	16	54.4 (39-74)	Arthroscopic	Acellular human dermal matrix	NR	26.7 (12-38)	UCLA: 18.4 Constant: 53.8	UCLA: 30.4 Constant: 84.0
Wong et al.[23] 2010	45	53.6 (39-67)	Arthroscopic	Acellular human dermal matrix	NR	NR (24-68)	UCLA: 18.4 ASES: NR WORC: NR	UCLA: 27.5 ASES: 84.1 WORC: 75.2
Encalada-Diaz et al.[15] 2011	10	56.2 (44-65)	Open	Polycarbonate polyurethane patch	NR	12	UCLA: NR ASES: 44	UCLA: 29.2 ASES: 73.3
Barber et al.[18] 2012	22	56 (34-72)	Arthroscopic	Acellular human dermal matrix	1 recurrent shoulder bursitis	24 (12-38)	UCLA: 13.3 ASES: 48.5 Constant: 41.0	UCLA: 28.2 ASES: 98.9 Constant: 91.9
Gupta et al.[10] 2013	27	60 (45-77)	Mini-open	Porcine dermal tissue matrix xenograft	2 reoperations	32 (24-40)	ASES: 62.7 SF-12: 48.4	ASES: 91.8 SF-12: 56.6
Mori et al.[22] 2013	24	65.9 (NR)	Arthroscopic	Fascia lata autograft	NR	Minimum 24	UCLA: 14.3 ASES: 40.8 Constant: 37.4 VAS: 7.0	UCLA: 32.6 ASES: 94.1 Constant: 81.1 VAS: 0.3
Giannotti et al.[9] 2014	9	66.9 (50-88)	Mini-open	Porcine dermal tissue matrix xenograft	None	36 (30-45)	ASES: 38 Constant: 42	ASES: 79 Constant: 73
Ciampi et al.[13] 2014	152	66.5 (57-77)	Open	Open repair only (n = 51) *v* polypropylene patch (n = 52) *v* collagen patch (n = 49)	None	36	UCLA: NR VAS: NR	UCLA: 24.6 (polyprop) *v* 14.7 (collagen) VAS: 3.3 (polyprop) *v* 4.1 (collagen)
Proctor[11] 2014	18	66 (52-89)	Arthroscopic	Poly-L-lactic acid bioabsorbable patch	NR	42 (35-47)	ASES: 26	ASES: 70

ASES, American Shoulder and Elbow Surgeons; NR, not reported; SF-12, Short Form-12; UCLA, University of California Los Angeles score; VAS, visual analog scale for pain; WORC, Western Ontario Rotator Cuff Score.

results using a porcine dermal tissue matrix xenograft similar to those for studies involving an acellular human dermal matrix patch. In their series of 27 shoulders, the mean postoperative ASES score was 91.8 after a minimum 2-year follow-up period. It has been shown that clinical outcomes after rotator cuff augmentation with xenografts have been less favorable due to concerns regarding infection transmission and the possibility of inciting unacceptable immunogenic responses to foreign materials.[16,17,28,29]

Recently, a new generation of synthetic, biomimetic, and biodegradable rotator cuff patches has been developed. These patches are composed of resorbable polyesters including poly-L-lactic acid,[11] polyester,[12] polypropylene,[13] polytetrafluoroethylene,[14] and polyurethane.[15] Ciampi et al.[13] evaluated the clinical outcomes after the repair of massive posterosuperior cuff tears with either an open repair, open repair plus a collagen patch, or open repair plus a polypropylene patch. There were no differences in clinical outcomes between open cuff repair and open cuff repair plus the additional collagen patch. However, the authors suggested that the collagen patch may resorb too quickly and, therefore, may be less capable of protecting the repaired tendon during the early postoperative period. Patients who underwent repair with the polypropylene patch showed statistically significant improvements in outcomes when compared with the other 2 groups with regard to retear rates, University of California Los Angeles scores, and elevation strength. The authors concluded that the polypropylene patch protected the repair construct, promoted healing, and improved clinical outcomes when compared with the collagen patch.

Our data show that rotator cuff repair with biologic patch augmentation with human acellular dermal allografts is a viable and safe method by which good clinical results, high patient satisfaction, and low retear rates can be achieved for selected patients with massive posterosuperior retears of the rotator cuff. We believe that this technique is particularly indicated for young and active patients with poor cuff tendon quality, sufficient muscle quality (Goutallier < 3), and adequate mobility of the native host rotator cuff tendon to allow for reapproximation to the medial aspect of the greater tuberosity footprint. This study did not specifically study bridging grafts, although other studies have explored these techniques.[10,30] In revision rotator cuff tear cases in which the muscle quality is also poor (Goutalier > 3), other procedures such as tendon transfers, superior capsule reconstruction, or rTSA should be considered.[10,30-32]

Limitations

This study has several limitations. First, this study may have been underpowered to detect differences or variables affecting clinical outcomes due to low patient numbers. We attempted to include all patients needing revision rotator cuff repairs who had deficient tendons but healthy muscles. Second, postoperative MRIs were not available for all patients. Although postoperative MRIs were desired from all patients, some patients did not return for repeated follow-up, particularly if they were satisfied with their result. Third, intraobserver reliability of the musculoskeletal radiologist was not investigated in this study. Fourth, 8 of 13 patients (61.5%) underwent additional PRP injections into the repair site at the time of surgery. The influence of PRP on the outcomes after rotator cuff repair is currently unclear; however, a recent meta-analysis performed by Warth et al.[33] did not show any differences in clinical outcomes after rotator cuff repair with and without PRP supplementation. Fifth, although the potential for selection bias exists, all patients who had recurrent tears suitable for patch augmentation and who presented for treatment during the study period were advised to undergo this treatment strategy. Because of the retrospective study design and the relative scarcity of patients with the specific clinical and anatomic criteria required for enrollment in this study, it is possible that the improved results may be due to chance, a confounding variable, or a placebo effect. Certainly, it would be more advantageous to compare due to clinical outcomes between those who underwent open revision repair with patch augmentation and other indicated treatments; however, this would likely require a multicenter or multisurgeon study. Finally, there were slight variations in surgical techniques with respect to patient-specific tear patterns and tendon quality, although the patch was always placed on top of the native tendon and was always used to augment the repair of native tissue rather than to bridge a gap.

Conclusions

Biologic patch augmentation with human acellular dermal allograft was a safe and effective treatment method for patients with massive rotator cuff retears with deficient posterosuperior rotator cuff tendons in the presence of healthy rotator cuff muscles.

References

1. Franceschi F, Papalia R, Del Buono A, et al. Articular-sided rotator cuff tears: Which is the best repair? A three-year randomized controlled trial. *Int Orthop* 2013;37:1487-1493.
2. Lafosse L, Brozska R, Toussaint B, Gobezie R. The outcome and structural integrity of arthroscopic rotator cuff repair with use of the double-row suture anchor technique. *J Bone Joint Surg Am* 2007;89:1533-1541.
3. Peters KS, McCallum S, Briggs L, Murrell GA. A comparison of outcomes after arthroscopic repair of partial versus small or medium-sized full-thickness rotator cuff tears. *J Bone Joint Surg Am* 2012;94:1078-1085.

4. Sugaya H, Maeda K, Matsuki K, Moriishi J. Repair integrity and functional outcome after arthroscopic double-row rotator cuff repair: A prospective outcome study. *J Bone Joint Surg Am* 2007;89:953-960.
5. Gerber C, Fuchs B, Hodler J. The results of repair of massive tears of the rotator cuff. *J Bone Joint Surg Am* 2000;82:505-515.
6. Le BT, Wu XL, Lam PH, Murrell GA. Factors predicting rotator cuff retears: An analysis of 1000 consecutive rotator cuff repairs. *Am J Sports Med* 2014;42:1134-1142.
7. Baker AR, McCarron JA, Tan CD, Iannotti JP, Derwin KA. Does augmentation with a reinforced fascia patch improve rotator cuff repair outcomes? *Clin Orthop Rel Res* 2012;470:2513-2521.
8. Bond JL, Dopirak RM, Higgins J, Burns J, Snyder SJ. Arthroscopic replacement of massive, irreparable rotator cuff tears using a GraftJacket allograft: Technique and preliminary results. *Arthroscopy* 2008;24:403-409.
9. Giannotti S, Ghilardi M, Dell'osso G, et al. Study of the porcine dermal collagen repair patch in morpho-functional recovery of the rotator cuff after minimum follow-up of 2.5 years. *Surg Technol Int* 2014;24:348-352.
10. Gupta AK, Hug K, Boggess B, Gavigan M, Toth AP. Massive or 2-tendon rotator cuff tears in active patients with minimal glenohumeral arthritis: Clinical and radiographic outcomes of reconstruction using dermal tissue matrix xenograft. *Am J Sports Med* 2013;41:872-879.
11. Proctor CS. Long-term successful arthroscopic repair of large and massive rotator cuff tears with a functional and degradable reinforcement device. *J Shoulder Elbow Surg* 2014;23:1508-1513.
12. Petrie MJ, Ismaiel AH. Treatment of massive rotator-cuff tears with a polyester ligament (LARS) patch. *Acta Orthop Belg* 2013;79:620-625.
13. Ciampi P, Scotti C, Nonis A, et al. The benefit of synthetic versus biological patch augmentation in the repair of posterosuperior massive rotator cuff tears: A 3-year follow-up study. *Am J Sports Med* 2014;42:1169-1175.
14. Kanbe K, Chiba J, Nakamura A. Histological evaluation after arthroscopic reconstruction of the shoulder using a polytetrafluoroethylene patch for massive rotator cuff tears. *Eur J Orthop Surg Traumatol* 2013;23:S183-S187.
15. Encalada-Diaz I, Cole BJ, Macgillivray JD, et al. Rotator cuff repair augmentations using a novel polycarbonate polyurethane patch: Preliminary results at 12 months' follow-up. *J Shoulder Elbow Surg* 2011;20:788-794.
16. Walton JR, Bowman NK, Khatib Y, Linklater J, Murrell GA. Restore orthobiologic implant: Not recommended for augmentation of rotator cuff repairs. *J Bone Joint Surg Am* 2007;89:786-791.
17. Phipatanakul WP, Petersen SA. Porcine small intestine submucosa xenograft augmentation in repair of massive rotator cuff tears. *Am J Orthop* 2009;38:572-575.
18. Barber FA, Burns JP, Deutsch A, Labbe MR, Litchfield RB. A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. *Arthroscopy* 2012;28:8-15.
19. Beitzel K, Chowaniec DM, McCarthy MB, et al. Stability of double-row rotator cuff repair is not adversely affected by scaffold interposition between tendon and bone. *Am J Sports Med* 2012;40:1148-1154.
20. Shea KP, Obopilwe E, Sperling JW, Iannotti JP. A biomechanical analysis of gap formation and failure mechanics of a xenograft-reinforced rotator cuff repair in a cadaveric model. *J Shoulder Elbow Surg* 2012;21:1072-1079.
21. van der Meijden OA, Wijdicks CA, Gaskill TR, Jansson KS, Millett PJ. Biomechanical analysis of two-tendon posterosuperior rotator cuff tear repairs: Extended linked repairs and augmented repairs. *Arthroscopy* 2013;29:37-45.
22. Mori D, Funakoshi N, Yamashita F. Arthroscopic surgery of irreparable large or massive rotator cuff tears with low-grade fatty degeneration of the infraspinatus: Patch autograft procedure versus partial repair procedure. *Arthroscopy* 2013;29:1911-1921.
23. Wong I, Burns J, Snyder S. Arthroscopic GraftJacket repair of rotator cuff tears. *J Shoulder Elbow Surg* 2010;19:104-109.
24. Millett PJ, Rios D, Martetschläger F, Horan MP. Complication after biceps tenodesis. *Obere Extremität* 2014;9:276-279.
25. Richards RR, An KN, Bigliani LU, Friedman RJ, Gartsman GM, Gristina AG. A standardized method for the assessment of shoulder function. *J Shoulder Elbow Surg* 1994;1:347-352.
26. Beaton DE, Wright JG, Katz JN. Development of the QuickDASH: Comparison of three item-reduction approaches. *J Bone Joint Surg Am* 2005;87:1038-1046.
27. Williams GN, Gangel TJ, Arciero RA, Uhorchak JM, Taylor DC. Comparison of the single assessment numeric evaluation method and two shoulder rating scales. Outcomes measures after shoulder surgery. *Am J Sports Med* 1999;27:214-221.
28. Ozaki J, Fujimoto S, Masuhara K, Tamai S, Yoshimoto S. Reconstruction of chronic massive rotator cuff tears with synthetic materials. *Clin Orthop Relat Res* 1986;202:173-183.
29. Iannotti JP, Codsi MJ, Kwon YW, Derwin K, Ciccone J, Brems JJ. Porcine small intestine submucosa augmentation of surgical repair of chronic two-tendon rotator cuff tears. A randomized, controlled trial. *J Bone Joint Surg Am* 2006;88:1238-1244.
30. Mihata T, Lee TQ, Watanabe C, et al. Clinical results of arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. *Arthroscopy* 2013;29:459-470.
31. Petri M, Greenspoon JA, Millett PJ. Arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. *Arth Tech* 2015;4:e583-e587.
32. Gerber C, Rahm SA, Catanzaro S, Farshad M, Moor BK. Latissimus dorsi tendon transfer for treatment of irreparable posterosuperior rotator cuff tears: Long-term results at a minimum follow-up of ten years. *J Bone Joint Surg Am* 2013;95:1920-1926.
33. Warth RJ, Dornan GJ, James EW, Millett PJ. Clinical and structural outcomes following arthroscopic repair of full-thickness rotator cuff tears with and without platelet-rich product supplementation: A systematic review, meta-analysis, and meta-regression. *Arthroscopy* 2015;31:306-320.