J Shoulder Elbow Surg (2016) 25, 1961–1970

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

A prospective, multicenter study to evaluate clinical and radiographic outcomes in primary rotator cuff repair reinforced with a xenograft dermal matrix

Evan S. Lederman, MD[a,*], Alison P. Toth, MD[b], Gregory P. Nicholson, MD[c], Robert J. Nowinski, DO[d], George K. Bal, MD[e], Gerald R. Williams, MD[f], Joseph P. Iannotti, MD, PhD[g]

[a]*The Orthopedic Clinic Association, Phoenix, AZ, USA*
[b]*Duke University Medical Center, Durham, NC, USA*
[c]*Midwest Orthopedics at Rush, Chicago, IL, USA*
[d]*OrthoNeuro, New Albany, OH, USA*
[e]*West Virginia University, Morgantown, WV, USA*
[f]*Department of Orthopaedic Surgery, The Rothman Institute, Jefferson Medical College, Philadelphia, PA, USA*
[g]*Orthopaedic and Rheumatology Institute, Cleveland Clinic, Cleveland, OH, USA*

Background: Minimal information is currently available on the outcome of rotator cuff repair reinforced with an extracellular matrix (ECM) graft. Therefore, the purpose of this study was to determine the clinical and radiographic outcome of repair of large rotator cuff tears with ECM graft reinforcement.
Methods: This was a prospective study of 61 shoulders with large repairable rotator cuff tears (3 to 5 cm). The rotator cuff tears were surgically repaired and reinforced with a xenograft ECM graft. The average patient age was 56 years (range, 40-69 years). The average tear size was 3.8 cm.
Results: Follow-up was obtained at 6, 12, and 24 months in 58, 54, and 50 of the 61 patients, respectively. Functional outcome scores, isometric muscle strength, and active range of motion were significantly improved compared with baseline. Magnetic resonance imaging at 12 months showed retorn rotator cuff repairs in 33.9% of shoulders, using the criteria of a tear of at least 1 cm, and tears in 14.5% of the shoulders using the criteria of retear >80% of the original tear size. Three patients underwent surgical revision. Complications included 1 deep infection.
Conclusions: Repair of large rotator cuff tears structurally reinforced with xenograft ECM resulted in improved functional outcomes scores and strength. Adverse events were uncommon, and the rate of revision surgery was low.

This study was approved by the Western Institutional Review Board (PRO Number 20090049, Study #1105872), and the Institutional Review Boards of Duke University (IRB Pro00015984), Rush University (IRB 09051202IRB01), Mount Carmel (IRB 090127-4), West Virginia University (IRB H-22417), and Thomas Jefferson University (IRB #10C.89). Institutional Review Board approval was not required for Cleveland Clinic because no patients were enrolled.
*Reprint requests: Evan S. Lederman, MD, The Orthopedic Clinic Association, 2222 E Highland Ave, Ste 300, Phoenix, AZ 85253, USA.
E-mail address: elederman@tocamd.com (E.S. Lederman).

http://dx.doi.org/10.1016/j.jse.2016.02.029

Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Prospective; rotator cuff; xenograft; extracellular matrix; repair; augmentation

Rotator cuff repair can result in improved clinical outcome; however, recurrent tears of large to massive rotator cuff repairs are still reported to be 34% to 94%.[3,5,11,12,17,25]

In an effort to improve the healing rates of large tears, extracellular matrix (ECM) grafts derived from human or animal tissues have been used to surgically augment the repaired rotator cuff by reinforcing the repair.

The use of porcine xenograft noncrosslinked ECM grafts in rotator cuff repairs has yielded variable results. In addition, several series have reported high rates of complications. Iannotti et al[15] evaluated Restore (DePuy Orthopedics, Richmond, VA), a collagen-based material made from porcine small intestinal submucosa (SIS), in a randomized controlled trial. The results demonstrated no improvement with the patch use over patients without xenograft addition, and there were complications related to hypersensitivity reactions associated with this ECM graft. Others have reported complications, reactions, and clinical failure with porcine SIS ECM.[18,22,26]

The purpose of this study was to evaluate the clinical and radiographic outcomes of patients undergoing reinforcement of primary rotator cuff repair with the Conexa (Tornier, Edina, MN, USA) porcine dermal xenograft ECM.

Materials and methods

Study design

This prospective multicenter study was conducted in accordance with the approved research protocol and good clinical practice guidelines. The surgeons assessed and counseled the patients and obtained informed consent for enrollment.

Six participating sites enrolled 68 patients undergoing unilateral primary rotator cuff repair by a minimally invasive open repair technique. Inclusion and exclusion criteria are listed in Table I. Seven patients failed to meet screening criteria upon surgical evaluation. The tears were larger or smaller than 3 to 5 cm. Sixty-one patients (38 men and 23 women) underwent surgical repair of the rotator cuff. Average age was 56 years (range 40-69 years).

All patients received the Conexa graft repair reinforcement. Conexa is a terminally sterilized noncrosslinked porcine dermis surgical mesh intended for the reinforcement of soft tissues during tendon repair. It is available in 2 thicknesses and several sizes.

At the 6-, 12- and 24-month follow-up, 58, 54, and 50 of the 61 patients, respectively, were available for evaluation.

Surgical technique

The surgical technique was agreed upon and used by all sites. All patients were evaluated arthroscopically. Qualifying tear size was confirmed at surgery and measured in the sagittal plane before the repair. Rotator cuff repair was performed by minimally invasive open technique. Mobility and reparability of the rotator cuff were assessed to confirm that the rotator cuff could be repaired to the greater tuberosity by a double-row technique. Medial sutures (#2 Force Fiber; Tornier) for the graft were placed before repair of the rotator cuff 1 cm lateral to the musculotendinous junction of the supraspinatus and infraspinatus tendons in an inverted mattress and spaced 1 cm apart. Double-row repair using Insite suture anchors (Tornier) and high-strength #2 Force Fiber was performed. The medial anchors were placed at the medial edge of the greater tuberosity, and medial sutures were passed in a mattress configuration. The lateral anchors were placed in the lateral aspect of the greater tuberosity, and lateral sutures were passed with the modified Mason-Allen technique.[21]

The Conexa 200 graft was cut to overlap the completed repair of the rotator cuff covering the entire repair and was attached medially using a modified Mason-Allen technique. The graft was stretched over the repair applying mild tension and attached laterally with 2 suture anchors on the greater tuberosity distal to the native rotator cuff lateral anchors, and lateral sutures in the graft were placed with the modified Mason-Allen technique. Simple or figure-of-eight sutures were used anteriorly and posteriorly to complete the augmentation attaching the graft to the repaired rotator cuff.

Rehabilitation procedure

All patients were instructed on a standardized postoperative protocol. The patient was required to wear an abduction sling with a pillow that provided 15° to 20° abduction for 8 to 10 weeks. They also performed passive motion (external rotation and elevation with range of motion determined at time of repair) for up to 6 weeks. At 6 weeks, the surgeon allowed the patient to perform active assisted pulley and wand exercises. Then at 8 to 10 weeks, the abduction sling was removed and the patient began isometric strength exercises. Active range of motion was permitted at 3 months, and patients were allowed to resume normal activities at 6 months.

Clinical assessment

Clinical assessments were performed at baseline (preoperatively), on postoperative day 10, and at 3, 6, 12, and 24 months. Shoulder outcome scores were evaluated preoperatively and postoperatively using 3 shoulder surveys: American Shoulder and Elbow Score (ASES),[20] Constant-Murley Score,[7] and Simple Shoulder Test (SST).[10] Range of motion was measured in abduction in the scapular plane, forward elevation, external rotation at 0° and 90° of abduction, and adduction at 90° of flexion. All measurements were made with a goniometer. Strength testing was standardized using the IsoForce Control Dynamometer (MDS Medical Device Solutions AG, Oberburg, Switzerland). The dynamometer was attached to a table,

Table I Inclusion and exclusion criteria

Inclusion criteria
• aged 40-70 years old
• has repairable primary large retracted 2-tendon rotator cuff tears of the supraspinatus and infraspinatus measuring from 3 cm to 5 cm
• has movement of the nonoperative arm, defined as shoulder elevation of ≥90°
• is able to perform postoperative exercises
• is able to return for all scheduled and required study visits
• is able to provide written informed consent for study participation
Exclusion criteria
• has irreparable large rotator cuff tears that are found intraoperatively, defined by the inability to approximate the tendon to the tuberosity without tension
• has a rotator cuff tear >5 cm or <3 cm (measured intraoperatively)
• has a rotator cuff tear where the subscapularis tendon is disrupted/requires repair
• has grade 3 or 4 fatty infiltration of the rotator cuff
• has had prior surgical repair to the affected shoulder
• is American Society of Anesthesiologists class 4 or 5
• is a tobacco user; unless tobacco free for 6 months and willing to remain tobacco free for the duration of the study
• requires walking assist devices such as crutches and walkers
• has a known collagen disorder, including systemic lupus erythematosus, rheumatoid arthritis, polymyositis, scleroderma, ankylosing spondylitis, dermatomyositis, or osteogenesis imperfecta, or Sjögren, Larsen, Raynaud, Ehlers-Danlos, or Marfan syndromes
• has comorbid factors that predispose to postoperative infection, such as insulin-dependent diabetes, chronic steroid use, malnourishment, cancer, or coexistent infection
• has a history of alcohol abuse, illicit drug use, significant mental illness, physical dependence to any opioid, or drug abuse or addiction
• is enrolled or plans to enroll in another clinical trial during this study that would affect the patient's safety or results of this trial
• has any of the conditions identified within the labeled contraindications (ie, sensitivity to porcine-derived products or polysorbate)
• has an inability to have a closed magnetic resonance imaging conducted

and measurements were conducted at 90° of abduction in the scapular plane. Each measurement was conducted for 5 seconds. The maximum force was recorded in Newtons for 3 trials, and the average was reported.

Patients were assessed for signs and symptoms of inflammation, erythema, edema, heat and pain, seroma/hematoma formation, infection, hypersensitivity reactions (defined as an exaggerated immune response[15]), and other abnormal conditions associated with the surgical site. Magnetic resonance imaging (MRI) evaluations were obtained preoperatively within 3 months of surgery and postoperatively at 6 and 12 months.

MRI assessments

A 1.5 Tesla or stronger closed magnet was used. Positioning was standardized. Combined sagittal measurements were collected for all full-thickness tears. Two fellowship-trained musculoskeletal radiologists reviewed the images independently. If there was a discrepancy, the radiologists reached a consensus on interpretation. A repair was graded as retorn if there was a discontinuity on more than 1 slice of the MRI series.

Full-thickness tear ≥1 cm, which included all retears. This group included all retears. Retears were further classified as a defect ≥80% of the size of the original tear as measured in the sagittal plane (≥80% tear). These are felt to represent complete retears. Tears between 1 cm and 80% of the original size were felt to represent partial retears. Differences in outcome were analyzed. The MRI retear definition is consistent with that as described by Sugaya et al.[24]

Fatty infiltration of the supraspinatus and infraspinatus was determined on preoperative and postoperative MRI as described by Goutallier et al.[13]

Statistical methods

Preoperative and postoperative clinical outcome measures were evaluated by use of 2-sided, paired *t* test. Statistical significance was placed at $P \leq .05$. Analysis of variance was used to determine effect of retears or defects on muscle strength and outcome scores.

Results

Of the 61 patients who entered the study and underwent rotator cuff repair with Conexa augmentation, 58 patients completed the 6-month visit, 54 patients completed the 12-month, and 50 (82%) completed the 24-month evaluation. All results are reported in the intent-to-treat cohort. Average tear size was 3.8 cm (range, 3-5 cm) on direct surgical measurement. Six surgical sites enrolled patients in the study: Site 1 (R.J.N.), 20 (32%); site 2 (G.K.B.), 13 (22%); site 3 (A.P.T.), 12 (19%); site 4 (E.S.L.), 6 (10%); site 5 (G.R.W.), 6 (10%); and site 6 (G.P.N.), 4 (7%). Eleven patients did not complete the 24-month evaluation: 2 withdrew due to a complication (infection, retear, and reverse shoulder replacement), 1 had a cervical disc herniation unrelated to the study, 1 withdrew, and 7 were lost to follow-up.

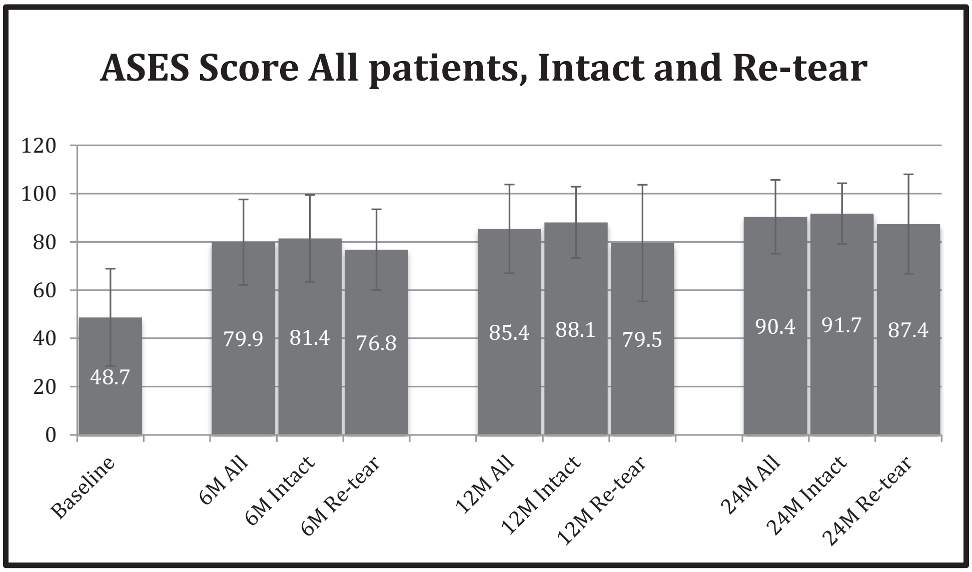

Figure 1 American Shoulder and Elbow Surgeons (*ASES*) Score compared with baseline for all patients, intact repairs, and retears. Data are shown as average with the standard deviation (*error bars*).

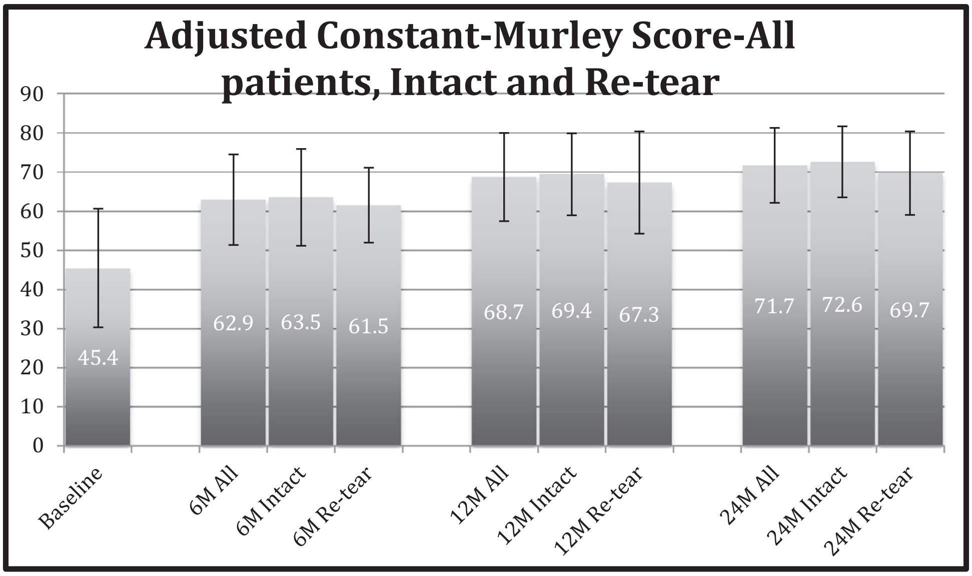

Figure 2 Adjusted Constant-Murley Score compared with baseline for all patients, intact repairs. and retears. Data are shown as the average with the standard deviation (*error bars*).

Clinical outcome

Outcome scores for ASES, Constant-Morley, SST and Strength scores at baseline and at 6, 12, and 24 months postoperatively are shown in Figs, 1-3. Statistically significant differences between preoperative and postoperative follow-up were observed for all functional outcome measurements.

ASES scores improved from 48.7 points at baseline to 90.4 points at 24 months postoperatively ($P < .0001$, Fig. 1). There was no statistical difference in the ASES outcome score between intact repairs and retears by definition compared with baseline at 24 months.

The adjusted Constant-Morley scores improved from 45.4 at baseline to 71.7 at 24 months postoperatively ($P < .0001$; Fig. 2). There was no statistical difference in the raw or adjusted Constant-Morley[16] outcome score between retears of 80% compared with baseline at 24 months. Intact repairs and retears of 1 cm had a statistical difference between baseline Constant-Morley scores at 24 months.

SST scores improved from 5 points at baseline to 10.6 points at 24 months postoperatively ($P < .0001$; Fig. 3). There was no statistical difference in the SST outcome score between intact repairs and retears by definition compared with baseline at 24 months.

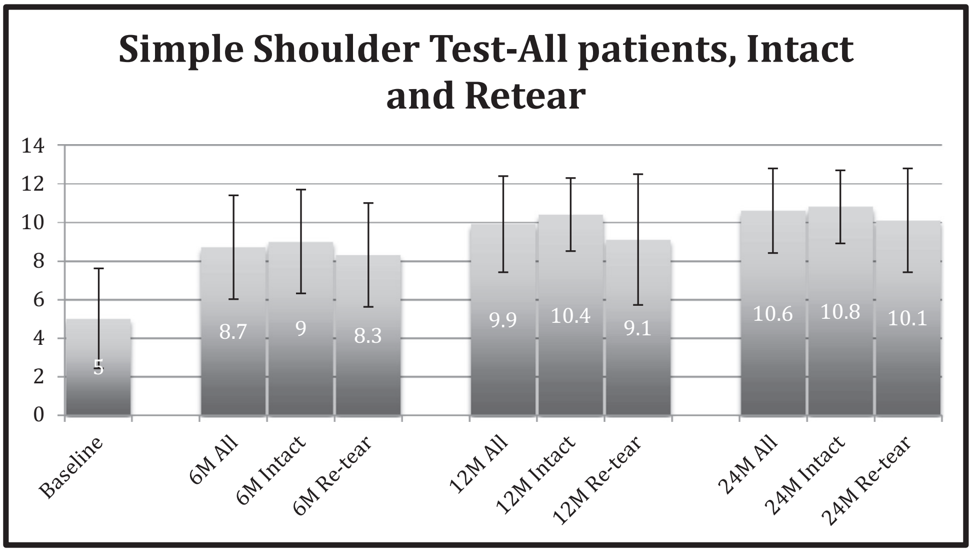

Figure 3 Simple Shoulder Test (SST) Score compared with baseline for all patients, intact repairs, and retears. Data are shown as the average with the standard deviation (*error bars*).

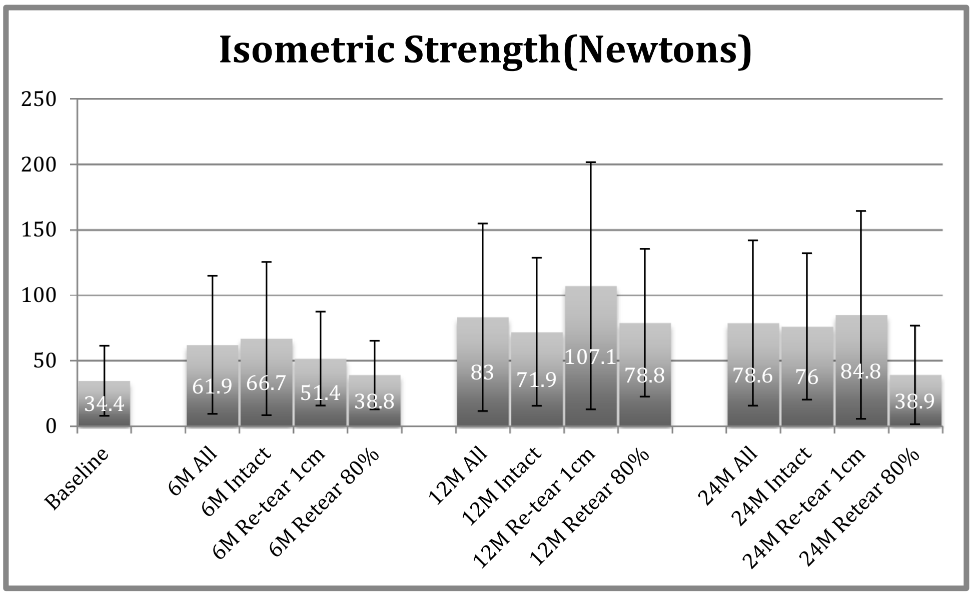

Figure 4 Isometric strength (Newtons) at baseline for all patients, retears of <1 cm, and retears >80%. Data are shown as the average with the standard deviation (*error bars*).

Muscle strength of all patients was significantly increased at 6, 12, and 24 months compared with baseline ($P < .0001$; Fig. 4). Strength measurements for comparison between intact repairs and retears are reported in Table II. There was no statistical difference in strength measurements between intact repairs and 1-cm retears at 24 months. There was a significant difference in strength between the intact repair and retears ≥80% at 24 months.

Active range of motion significantly improved at 12 months compared with baseline for 4 of 5 (forward flexion, abduction, external rotation at 90° flexion and adduction) measures and for all 5 measures at 24 months (Table II and Fig. 5).

MRI assessment

All patients had a preoperative MRI, 59 patients had an MRI at 6 months, and 56 patients had an MRI at 12 months of follow-up. Retears were reported in the intent-to-treat cohort, and all retears are reported. A retear of ≥80% the original tear was present in 8 of 55 (14.5%) at 12 months. There were 11 of 56 with tears between 1 cm and 80% of the original tear size. A retear of ≥1 cm was present in 19 of 56 (33.9%) at 12 months. Four patients were lost to follow-up between 6 and 12 months, 3 of whom had intact repairs and 1 had a 1-cm tear. Two patients had intact repairs at 6 months and were

Table II Outcome scores, strength, and range of motion compared with baseline

Outcome scores and isometric strength	Baseline (Mean ± SD)	12 months (Mean ± SD)	*P* value*	24 months (Mean ± SD)	*P* value†
ASES score					
All patients	48.7 ± 20.2	85.4 ± 18.4	<.0001	90.4 ± 15.3	<.0001
1 cm	–	79.5 ± 24.2	<.0001	87.4 ± 20.6	<.0001
80% MRI	–	75.3 ± 25.5	.0447	86.0 ± 22.3	.0107
Constant-Murley adjusted					
All patients	45.4 ± 15.2	68.7 ± 11.3	<.0001	71.7 ± 9.6	<.0001
1 cm	–	67.3 ± 13.1	<.0001	69.7 ± 10.7	<.0001
80% MRI	–	66.9 ± 18.0	.0597	72.3 ± 11.9	.0505
SST					
All patients	5.0 ± 2.6	9.9 ± 2.7	<.0001	10.6 ± 2.2	<.0001
1 cm	–	9.1 ± 3.4	<.0001	10.1 ± 2.7	<.0001
80% MRI	–	8.8 ± 3.5	.0212	10.0 ± 2.9	.0062
Isometric strength					
All patients	34.4 ± 26.8	83.0 ± 71.7	<.0001	78.6 ± 63.2	<.0001
1 cm	–	107.1 ± 94.5	.006	84.8 ± 79.5	.0261
80% MRI	–	78.8 ± 56.5	.148	38.9 ± 37.7	.2285
Forward elevation,°	123 ± 12	161 ± 6	<.0001	165 ± 4	<.0001
Abduction,°	101 ± 10	132 ± 9	<.0001	134 ± 11	<.0001
External rotation (0°),°	42 ± 6	47 ± 5	.19	53 ± 4	.004
External rotation (90°),°	45 ± 9	64 ± 7	.0001	67 ± 7	.0011
Adduction,°	48 ± 11	66 ± 14	.0011	67 ± 15	.0013

ASES, American Shoulder and Elbow Surgeons; *MRI*, magnetic resonance imaging; *SD*, standard deviation; *SST*, Simple Shoulder Test.
* 12 months compared with baseline.
† 24 months compared with baseline.

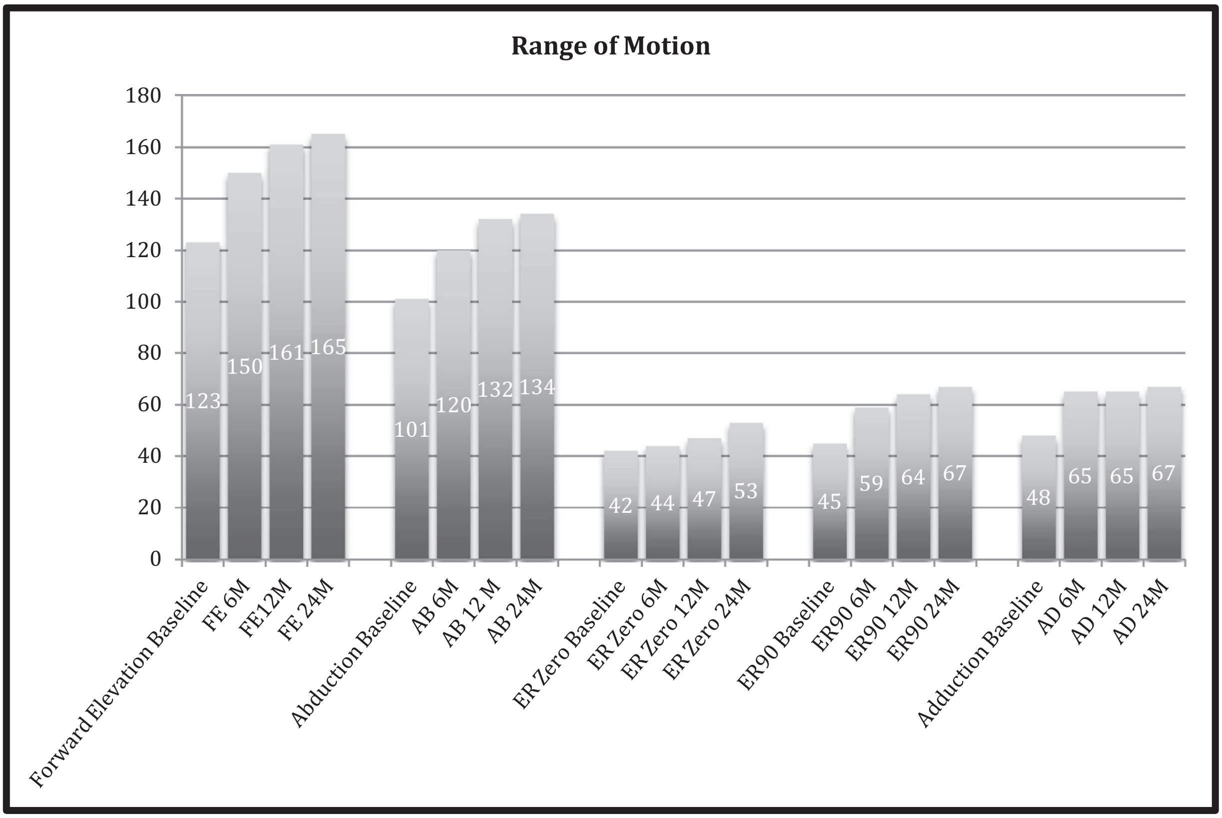

Figure 5 Range of motion. *AB*, abduction; *AD*, adduction; *ER*, external rotation; *FE*, forward elevation.

Table III Retear rates by magnetic resonance imaging evaluation

MRI definition	Retear rate % (n/N)
Retear 80%	
6-month visit	16.9 (10/59)
12-month visit	14.5 (8/55)
Retear 1 cm	
6-month visit	32.2 (19/59)
12-month visit	33.9 (19/56)

MRI, magnetic resonance imaging.

found to have tears at 12 months. Both were ≥1 cm and <80% of original tear size. One patient had a ≥1 cm tear at 6 months that progressed to a ≥80% tear at 12 months. No patient had a full-thickness retear of <1 cm. All participating sites had retears with an incidence of 25% to 38% (Table III).

Fatty infiltration

Baseline MRI supraspinatus fatty infiltration was 0.62 ± 0.6 (range, 0-2) and at the 12-month evaluation was 0.80 ± 0.9 (range, 0-4). The difference between these groups was not significant ($P = .094$). Intact repairs had an average supraspinatus fatty infiltration score of 0.57 ± 0.7 (range, 0-3) and retears of 1.18 ± 1.1 (range, 0-4). Fatty infiltration of the supraspinatus significantly increased when there was a retear ($P < .0015$).

Baseline MRI infraspinatus fatty infiltration was 0.69 ± 0.8 (range 0-4) and at the 12-month evaluation was 0.89 ± 0.9 (range 0-4). The difference between these groups was not significant ($P = .08$). Intact repairs had an average infraspinatus fatty infiltration score of 0.67 ± 0.8 (range 0-4), and retears of 1.61 ± 1.0 (range 0-4). Fatty infiltration of the infraspinatus significantly increased when there was a retear ($P < .0001$). In the patients who had grade 3 or 4 fatty infiltration at the 12-month follow-up, 4 patients had intact repairs and 3 had retears. Fatty infiltration did not change at the 12-month evaluation in 9 patients with retears, and progressed 1 grade in 9 patients and 2 grades in 1 patient.

Complications and adverse events

Three patients had revision rotator cuff repair. Revisions in 2 patients occurred before their 12-month follow-up visit and in 1 patient between 12 and 24 months. One of these patients experienced a deep wound infection and retear, resulting in reoperation. Cultures were positive for *Propionibacterium acnes* and *Staphylococcus epidermidis*. One patient was diagnosed with a mild superficial infection at 3 months postoperatively and was prescribed oral antibiotics, with no further adverse event reported. This patient had an intact rotator cuff on the 12-month postoperative MRI. The treating physician diagnosed another patient with a fluid collection described as a mild seroma without erythema at ~6 weeks postoperatively. This patient did not require intervention and was stable at the 24-month follow-up, with an intact rotator cuff on MRI at 12 months. A small superficial hematoma, which did not require intervention, was diagnosed at the operative site in another patient 10 days postoperatively.

There were no hypersensitivity reactions that were felt to be related to the implant as assessed by the investigators. An event responsible for retear occurred in 4 of 19 patients with retears. There were 3 major falls resulting in retear and the patient discussed above with infection.

Discussion

There has been discussion that the use of ECM could improve healing of rotator cuff repairs. However, prior studies have been limited due to small patient size, limited follow-up, retrospective design, and lack of clear inclusion and exclusion criteria.

In this study, patients had rotator cuff tears defined as large, between 3 and 5 cm, and involved the supraspinatus and infraspinatus tendons.[8] Clinical results demonstrated statistically significant improvement in assessment scores and strength at all study assessments. There were no hypersensitivity reactions or safety concerns with the porcine dermis ECM graft.

Several studies have looked at rotator cuff retears. Galatz et al[11] reviewed 18 patients after arthroscopic repair of tears >2 cm using a single-row technique and ultrasound evaluation after 12 months and found 17 of 18 retears. Lee et al[17] reported retear after arthroscopic double-row repair in 30 of 62 (48.4%). In patients aged >60 years, the retear rate was 62.5%, and medium to large tears retore in 27 of 51 (53%). Tashjian et al[25] reported arthroscopic repair of 2-tendon tears evaluated by ultrasound imaging and found 64% retears after double-row repair. Bishop et al[5] evaluated open and arthroscopic rotator cuff repair by MRI. Large rotator cuff tears had a retear rate of 38% in the open group and 76% in the arthroscopic group.

In the present study, MRI assessment demonstrated intact repairs in 66.1% of shoulders at 12 months using the criteria of retear as ≥1 cm and in 85.5% at 12 months using the criteria of retear of ≥80% of the original tear. This compares favorably with historical controls.[5] Retears of the rotator cuff detected on MRI at ≥1-cm criteria had no statistically significant difference in outcome scores or strength compared with repairs that were intact. Retears that were ≥80% of the original tear size had strength deficits. Fatty replacement progressed when there was a retear of the rotator cuff.

Augmentation of rotator cuff repair may increase mechanical strength at initial fixation. Shea et al[23] evaluated rotator cuff repair reinforced with Conexa augmentation in a human cadaveric model that was tensioned over the repair as performed in this clinical study. The gap formation under cyclic loading was reduced by 40% for the reinforced specimens compared with the control. The ultimate load to failure was significantly higher for the ECM-reinforced group, and the ECM graft was estimated to share 35% of the load. McCarron et al[19] evaluated rotator cuff repair reinforced with a lyophilized poly-L-lactide fiber-reinforced fascia lata graft (Musculoskeletal Transplant Foundation, Edison, NJ, USA) that was tensioned over this repair as performed in this clinical study. Augmentation significantly decreased the amount of gap formation. All augmented repairs were able to complete the 1000-cycle loading protocol, whereas 3 of 9 nonaugmented repairs failed.

Barber et al[2] evaluated rotator cuff repair augmented with human dermal allograft (GraftJacket; Wright Medical Technology, Arlington, TN, USA) in a human cadaveric model. No differences were found under cyclic loading. Ely et al[9] studied rotator cuff repair, with and without, augmentation using a double-row transosseous equivalent repair technique and ECM human dermis allograft. The authors found decreased cyclic displacement of 2.2 mm vs. 2.8 mm and increased load to failure of 551 N vs. 643 N in the control vs. the augmented group. Results did not reach statistical significance. Beitzel et al[4] studied several different augmentation techniques with a transosseous equivalent repair and found human dermal ECM augmentation on top of the repair increased the load to failure from 348 to 575 N ($P = .025$).

Although structural augmentation of rotator cuff repair has been demonstrated in vitro and may be conceptually beneficial, clinical evidence of higher healing rates is limited, as is evidence of biologic augmentation of repair.

Clinical results for augmented rotator cuff repair have had mixed results. Iannotti et al[15] completed a randomized controlled study repairing large and massive tears in which 30 patients underwent standard rotator cuff repair or repair and augmentation with porcine SIS Restore. The control group had 5 large and 10 massive tears, and the SIS group had 4 large and 11 massive tears. Repair was achieved in 4 of 15 in the SIS group and in 9 of 15 in the control group ($P = .11$).

Sclamberg et al[22] documented that augmented rotator cuff repair with SIS failed in 10 of 11 patients. These were described as large to massive tears; 4 of 11 were completely repairable, and 7 were described as partially repairable. Walton et al[26] identified 6 of 10 failures after augmentation with Restore and 7 of 12 in their control group. Four of their patients who received Restore had severe postoperative reactions requiring surgical management. The authors stated they no longer used or recommended use of the porcine SIS xenograft.

Arthroscopic rotator cuff repair of 3-cm tears, with and without augmentation with GraftJacket, demonstrated improved healing rates by MRI in a randomized prospective study.[1] The authors reported the healing of augmented repairs by MRI of 85% and 40% in nonaugmented repairs.

Ciampi et al[6] retrospectively reviewed 152 patients with massive 2-tendon supraspinatus and infraspinatus rotator cuff tears treated by open repair and single-row fixation. The control group comprised 51 patients who had a primary repair. Forty-nine were augmented with bovine pericardium and 52 with a polypropylene patch. Retears were assessed by ultrasound imaging and occurred in 21 of 51 (41%) of the control group, in 25 of 49 (51%) in the bovine pericardium group, and in 9 of 52 (17%) in the polypropylene group.

One prior clinical study involved the Conexa graft. Gupta et al[14] reviewed 27 shoulders with minimum 2-year follow-up. Massive rotator cuff tears were treated with Conexa interposition graft. Twenty-two shoulders returned for ultrasound examination, and 16 (73%) demonstrated a fully intact tendon-graft reconstruction, 5 (22%) had a partially intact reconstruction, and 1 (5%) had a complete tear at the graft-bone interface caused by suture anchor pullout as a result of a fall. There were no cases of infection or tissue rejection.

In the present study, 3 patients underwent revision rotator cuff repair. Three patients had complications, including 1 deep infection requiring surgery, 1 superficial infection that did not require surgery, and 1 fluid collection (seroma) that resolved without treatment. It is not possible to determine whether complications that were identified would be considered a consequence of the graft reinforcement procedure or material. No inflammatory reactions were encountered.

The main weakness of this study is the lack of a control group. This study represents a large series of ECM-augmented rotator cuff repairs to establish a healing rate of this augmentation technique and analysis of results. Many prior publications have documented the challenges in obtaining structural healing of the rotator cuff, and healing rates have been documented. Inclusion criteria were strict and eliminated many common disorders that patients encountered in an orthopedic practice may have. Eleven patients withdrew from the study before completion.

The strengths of this study included multiple surgeons and sites, the prospective study design, rigid inclusion criteria, consistent protocol and surgical technique, and MRI imaging for repair integrity evaluated by independent musculoskeletal radiologists. A more detailed analysis of rotator cuff failures may assist in deciding when revision surgery is indicated and beneficial.

Conclusion

Repair of large rotator cuff tears structurally reinforced with xenograft ECM (Conexa) resulted in improved functional outcomes scores and strength. Structurally augmented rotator cuff repair of large 3- to 5-cm rotator cuff tears had a 66% healing rate by MRI evaluation at 12 months by ≥1 cm retear criteria and an 85% healing rate at 12 months by ≥80% of original tear size criteria.

Disclaimer

Funding and research support for this study to include Institutional Review Board fees, logistics, database maintenance, and statistical analysis was received from Tornier, Edina, MN, USA and LifeCell Corporation, Branchburg, NJ, USA.

Evan S. Lederman is a consultant for and receives royalties from Arthrex, and receives Sport Medicine Fellowship support from Arthrex, Tornier, Ossur, Smith and Nephew. Alison P. Toth is an education consultant for Tornier and receives research support (institution) from Active Implants and Sports Medicine Fellowship Support from Arthrex, Smith and Nephew, Mitek-DePuy, and Breg. Gregory P. Nicholson is a consultant for Tornier and receives fellowship support from Arthrex, Smith and Nephew, Ossur, and Tornier and royalties from Innomed Inc. Robert J. Nowinski receives research support from Tornier and LifeCell and is a speaker for Tornier. George K. Bal is a consultant for DePuy. Gerald R. Williams, Jr receives stock or stock options from CrossCurrent Business Analytics, Force Therapeutics, ForMD, In Vivo Therapeutics, and OBERD; receives IP royalties from DePuy and IMDS; receives research support from DePuy, Synthasome, and Tornier; and receives publishing royalties, financial, or material support from Wolters Kluwer Health, Lippincott Williams & Wilkins. Joseph P. Iannotti receives royalties from Tornier, DePuy-Synthes, Zimmer, Integra, and Lippincott and is a consultant for DePuy-Synthes, DJO, Arthrex, and Custom Orthopaedic Solutions.

References

1. Barber FA, Burns JP, Deutsch A, Labbé MR, Litchfield RB. A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. Arthroscopy 2012;28:8-15. http://dx.doi.org/10.1016/j.arthro.2011.06.038
2. Barber FA, Herbert MA, Boothby MH. Ultimate tensile failure loads of a human dermal allograft rotator cuff augmentation. Arthroscopy 2008;24:20-4. http://dx.doi.org/10.1016/j.arthro.2007.07.013
3. Bartl C, Kouloumentas P, Holzapfel K, Eichhorn S, Wörtler K, Imhoff A, et al. Long-term outcome and structural integrity following open repair of massive rotator cuff tears. Int J Shoulder Surg 2012;6:1-8. http://dx.doi.org/10.4103/0973-6042.94304
4. Beitzel K, Chowaniec DM, McCarthy MB, Cote MP, Russell RP, Obopilwe E, 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;40:1148-54. http://dx.doi.org/10.1177/0363546512437835
5. Bishop J, Klepps S, Lo IK, Bird J, Gladstone JN, Flatow EL. Cuff integrity after arthroscopic versus open rotator cuff repair: a prospective study. J Shoulder Elbow Surg 2006;15:290-9. http://dx.doi.org/10.1016/j.jse.2005.09.017
6. Ciampi P, Scotti C, Nonis A, Vitali M, Di Serio C, Peretti GM, 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;42:1169-75. http://dx.doi.org/10.1177/0363546514525592
7. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214:160-4.
8. DeOrio JK, Cofield RH. Results of a second attempt at surgical repair of a failed initial rotator-cuff repair. J Bone Joint Surg Am 1984;66:563-7.
9. Ely EE, Figueroa NM, Gilot GJ. Biomechanical analysis of rotator cuff repairs with extracellular matrix graft augmentation. Orthopedics 2014;37:608-14. http://dx.doi.org/10.3928/01477447-20140825-05
10. Fehringer EV, Kopjar B, Boorman RS, Churchill RS, Smith KL, Matsen FA. Characterizing the functional improvement after total shoulder arthroplasty for osteoarthritis. J Bone Joint Surg Am 2002;84-A:1349-53.
11. Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. J Bone Joint Surg Am 2004;86-A:219-24.
12. Gerber C, Fuchs B, Hodler J. The results of repair of massive tears of the rotator cuff. J Bone Joint Surg Am 2000;82:505-15.
13. Goutallier D, Postel JM, Bernageau J, Lavau L, Voisin MC. Fatty muscle degeneration in cuff ruptures. Pre- and postoperative evaluation by CT scan. Clin Orthop Relat Res 1994;304:78-83.
14. 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;41:872-9. http://dx.doi.org/10.1177/0363546512475204
15. 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;88:1238-44. http://dx.doi.org/10.2106/JBJS.E.00524
16. Katolik LI, Romeo AA, Cole BJ, Verma NN, Hayden JK, Bach BR. Normalization of the Constant score. J Shoulder Elbow Surg 2005;14:279-85. http://dx.doi.org/10.1016/j.jse.2004.10.009
17. Lee KW, Seo DW, Bae KW, Choy WS. Clinical and radiological evaluation after arthroscopic rotator cuff repair using suture bridge technique. Clin Orthop Surg 2013;5:306-13. http://dx.doi.org/10.4055/cios.2013.5.4.306
18. Malcarney HL, Bonar F, Murrell GA. Early inflammatory reaction after rotator cuff repair with a porcine small intestine submucosal implant: a report of 4 cases. Am J Sports Med 2005;33:907-11. http://dx.doi.org/10.1177/0363546504271500
19. McCarron JA, Milks RA, Mesiha M, Aurora A, Walker E, Iannotti JP, et al. Reinforced fascia patch limits cyclic gapping of rotator cuff repairs in a human cadaveric model. J Shoulder Elbow Surg 2012;21:1680-6. http://dx.doi.org/10.1016/j.jse.2011.11.039
20. Richards RR, An KN, Bigliani LU, Friedman RJ, Gartsman GM, Gristina AG, et al. A standardized method for the assessment of shoulder function. J Shoulder Elbow Surg 1994;3:347-52.
21. Scheibel MT, Habermeyer P. A modified Mason-Allen technique for rotator cuff repair using suture anchors. Arthroscopy 2003;19:330-3. http://dx.doi.org/10.1053/jars.2003.50079
22. Sclamberg SG, Tibone JE, Itamura JM, Kasraeian S. Six-month magnetic resonance imaging follow-up of large and massive rotator cuff repairs reinforced with porcine small intestinal submucosa. J Shoulder Elbow Surg 2004;13:538-41. http://dx.doi.org/10.1016/j.jse.2004.03.005
23. 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;21:1072-9. http://dx.doi.org/10.1016/j.jse.2011.07.024
24. 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;89:953-60. http://dx.doi.org/10.2106/JBJS.F.00512

25. Tashjian RZ, Hollins AM, Kim H-M, Teefey SA, Middleton WD, Steger-May K, et al. Factors affecting healing rates after arthroscopic double-row rotator cuff repair. Am J Sports Med 2010;38:2435-42. http://dx.doi.org/10.1177/0363546510382835

26. Walton JR, Bowman NK, Khatib Y, Linklater J, Murrell GAC. Restore orthobiologic implant: not recommended for augmentation of rotator cuff repairs. J Bone Joint Surg Am 2007;89:786-91. http://dx.doi.org/10.2106/JBJS.F.00315