Clinical Outcomes in Patients Undergoing Revision Rotator Cuff Repair With Extracellular Matrix Augmentation

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abstract

Outcomes following revision surgery for failed rotator cuff repairs are far less predictable than and are associated with decreased patient satisfaction compared with primary repairs. Extracellular matrix augmentation (ECM) may improve the biologic potential for healing during revision repair. The authors examined clinical outcomes and healing rates based on postoperative imaging of patients who underwent revision open rotator cuff repair with an ECM patch for symptomatic recurrent rotator cuff tear. Twenty-four (77%) of 31 patients with a mean follow-up of 50 months (range, 30-112 months) completed post-revision surgery outcome questionnaires at a mean of 5.3 years after revision surgery, and 16 patients (67%) underwent a physical examination and repeat imaging (ultrasound or magnetic resonance imaging) at a mean of 4.2 years after revision surgery. Ten (63%) of those 16 patients were found to have failed revision rotator cuff repair on imaging, with American Shoulder and Elbow Surgeons (ASES) outcome measures that were significantly (*P*=.04) better in patients with confirmed intact repairs than those with confirmed failed revision repair. Outcome measures for all patients (n=24) included a mean ASES score of 67.2 (SD, 27.9) and a mean Single Assessment Numeric Evaluation (SANE) score of 66.9 (SD, 26.0). Based on these scores, excellent results were achieved in 24% of patients, good in 13%, fair in 21%, and poor in 42%. Results of this investigation demonstrated that augmentation of revision rotator cuff repair with an ECM patch through an open approach showed no significant improvement in outcomes when compared to historical reports without augmentation. [*Orthopedics*. 2015; 38(4):e292-e296.]

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Rotator cuff injuries are common, leading to 30,000 to 75,000 surgical repairs annually in the United States.[1] In general, repair of symptomatic rotator cuff tears demonstrate good results in both pain relief and function.[2-4] However, the incidence of recurrent rotator cuff tear following repair has been estimated to be as high as 20% to 40%, with some authors reporting rates of recurrent tear in up to 94% in patients with chronic and large tears.[5-8] Outcomes following revision surgery for failed repairs are far less predictable and are associated with decreased patient satisfaction compared to primary repairs.[9-15]

The utility of scaffold devices, derived from allograft or xenograft extracellular matrix (ECM) or synthetic matrices, has been increasingly investigated as an adjunct for improving the healing potential with rotator cuff repair.[16-18] Scaffold devices are thought to augment postoperative healing through biological and biomechanical mechanisms,[18,19] although their utility in the clinical setting has had mixed results.[20-22] Along with unproven clinical benefits, concerns regarding the implantation and cost of allograft tissue have resulted in some hesitancy to use ECM patches without improved understanding of outcomes within the clinical setting.

Despite these concerns, use of ECM patches for revision cuff repair may theoretically be beneficial because these patients commonly have a biological predisposition toward poor healing. The authors examined clinical outcomes and healing rates based on postoperative imaging in patients who underwent revision open rotator cuff repair with an ECM patch for symptomatic recurrent rotator cuff tear. The authors' hypothesis is that ECM augmentation will improve the biologic potential for revision rotator cuff repair healing and improve patient perceived outcomes.

Materials and Methods

Patient Selection and Surgical Fixation

This investigation was reviewed and approved by the Thomas Jefferson Medical Center institutional review board. From 2003-2009, thirty-one shoulders in 30 patients, with an average age of 50.5 years (range, 37-70 years), underwent open revision rotator cuff repair from by the senior author (M.D.L.) for symptomatic, full-thickness recurrent rotator cuff tears. All repairs were augmented with an ECM patch, and no defect was bridged with a graft. The type of ECM augmentation included Conexa (Tornier, Bloomington, Minnesota), Graft Jacket (Wright Medical, Memphis, Tennessee), and Tissuemend (Stryker, Kalamazoo, Michigan). The choice of augmentation was based on graft availability, as well as an evolving understanding of advantages and disadvantages of the various patches.

Operative Technique

Patients were positioned in the beach chair position and underwent initial diagnostic arthroscopic evaluation of the shoulder. Antibiotics were withheld until cultures were obtained. When a decision was made to revise the rotator cuff tear and augment the fixation, the surgery was converted to an open procedure. A 5-cm incision was made along Langer's lines just lateral to the anterior aspect of the lateral acromion. The anterior deltoid and anterior half of the middle deltoid were then reflected off of their acromial insertion and the underlying rotator cuff was evaluated. If the rotator cuff appeared amenable to repair, the coracoacromial ligament was released from its insertion on the acromion and any residual suture or debris was removed.

Multiple tissue cultures were collected and held at the microbiologic laboratory for an average of 14 days. Appropriate releases were made to maximize cuff excursion and minimize tension on the planned repair. The greater tuberosity was then lightly decorticated to bleeding bone. All repairs were made using interosseous tunnels with a No. 2, nonabsorbable braided suture (Arthrex, Naples, Florida). For patients with extremely retracted tendons, the repair was medialized and may not have covered the entire footprint to minimize tension on the repaired tendon. Following fixation of the cuff tear, the ECM patch was then secured over the bursal side of the repair with tension on the patch (**Figure 1**). Laterally, the graft was secured directly to bone via transosseous tunnel sutures. Finally, the deltoid was repaired with nonabsorbable sutures to the acromion through bone tunnels.

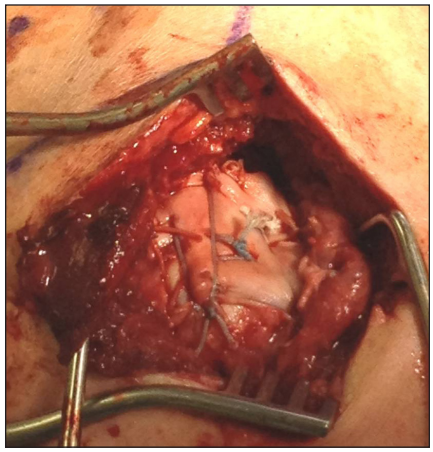

Figure 1: Photograph showing the extracellular matrix patch secured over the bursal side of the rotator cuff repair through an open approach.

Postoperatively, all operative arms were kept in a sling for 4 weeks before passive motion exercises were initiated. No active motion was allowed before 12 weeks postoperatively. Progressive weight bearing was increased until 6 months postoperatively.

Data Collection

Twenty-four (77%) of 31 patients with a mean follow-up of 50 months (range, 30-112 months) completed post-revision surgery outcome questionnaires over the phone consisting of American Shoulder and Elbow Surgeons (ASES) and Single Assessment Numeric Evaluation (SANE) scores at a mean of 5.3 years after revision surgery. Sixteen patients underwent physical examination and repeat imaging (ultrasound or magnetic resonance image) at a mean of 4.2 years after revision

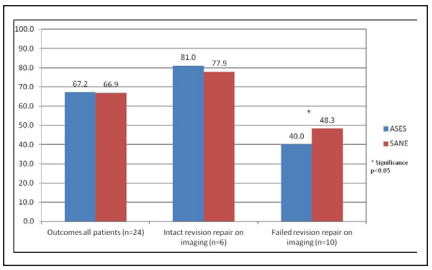

Figure 2: Bar graph showing patient outcome measures including American Shoulder and Elbow Surgeons (ASES) and Single Assessment Numeric Evaluation (SANE) scores.

surgery. Assessment of magnetic resonance imaging (MRI) was completed by both reading radiologists and the senior author (M.D.L.). Ultrasonography for all patients was performed by a single physician (A.G.) with outcomes blinded prior to interaction with the patient. Physical examination included strength and motion analysis, as well as evaluation of cuff integrity.

Statistical Analysis

Clinical outcome data were compared between patients with the use of paired Student's *t* tests. Significance was placed at a *P* value less than .05.

Results

Patients were divided into 2 groups. Group A consisted of patients with postoperative imaging and physical examination. Group B consisted of patients who completed a postoperative phone outcome questionnaire.

Group A

Sixteen patients underwent postoperative imaging and clinical evaluation following revision rotator cuff repair with ECM augmentation. Eight (50%) patients underwent MRI following revision cuff repair for persistent pain and weakness (clinical failure). Of these, all (100%) had a recurrent tear. For patients who did not have a clinical failure, 8 shoulders were available for outcome measures, physical examination, and postoperative ultrasound analysis. Of these, 2 (25%) shoulders were found to have a recurrent cuff tear. Of all patients who underwent post-revision imaging (MRI or ultrasound), 10 (63%) of 16 had recurrent rotator cuff tears.

Nine patients underwent revision surgery for a large preoperative re-tear (>1 tendon tear). Six (67%) of these patients had not healed on post-revision imaging, and 3 (33%) were confirmed healed. Of the 7 patients who underwent revision surgery with a single tendon tear, 3 (43%) had a healed repair on imaging, whereas 4 (57%) were confirmed not healed. Of shoulders with confirmed healed repair, 4 (67%) of 6 were workers' compensation (WC) patients. However, of the shoulders with confirmed nonhealed repairs, 9 (90%) of 10 were WC patients. In addition, 5 (45%) of 11 nonsmokers were found to have healed revision cuff repairs, but only 1 (20%) of 5 smokers demonstrated a healed repair. None of these results demonstrated significance, but outcomes for non-WC patients or nonsmokers demonstrated a trend toward improved outcome measures when compared to WC patients or smokers ($P<.22$) (**Figure 2**).

In addition, 2 patients were found to have positive intraoperative cultures for *Propionibacterium acnes*. These patients were treated with intravenous antibiotics for 6 weeks, with an additional 6 weeks of oral antibiotics following revision repair. Both patients had an intact rotator cuff tendon on reimaging. Finally, 1 patient underwent repair of a deltoid dehiscence at time of revision. This patient was found to have an ASES outcome score of 70.9 and a SANE score of 70.

Outcome measures for patients with an intact repair on postoperative imaging demonstrated a mean ASES score of 81 (SD, 18.4) and a mean SANE score of 77.5 (SD, 21.6), with full active motion and strength equal to the contralateral shoulder in each patient as measured by manual muscle testing. Patients with a recurrent tear demonstrated a mean ASES score of 40 (SD, 40.7) and a mean SANE score of 48.3 (SD, 36.1), and all had clinical weakness by functional cuff testing (**Figure 2**). ASES outcome measures were found to be significantly ($P=.04$) better in patients with intact repairs compared to those with a re-tear confirmed on imaging.

Group B

Twenty-four patients who underwent revision rotator cuff repair with ECM augmentation completed a postoperative outcome questionnaire via the telephone (consisting of ASES and SANE scores). Outcome measurements for this group included a mean ASES score of 67.2 (SD, 27.9) and a mean SANE score of 66.9 (SD, 26.0) (**Figure 2**). Based on these scores, excellent results were achieved in 24% of patients, good in 13%, fair in 21%, and poor in 42%.

No significant differences were found in outcome measures based on ECM patch type (Conexa, Graft Jacket, or Tissuemend), tear size (1 or more than 1 tendon tear) (**Figure 3**), or associated deltoid dehiscence. Outcome measures were better for nonsmokers when compared to smokers; however, this was not significant. Outcome measures were also better for non-WC patients compared to WC patients. Again, this was not significant but did demonstrate a trend ($P=.22$).

Discussion

Recurrent rotator cuff tears are relatively common following primary repair.[5-8] When symptomatic, these failures present a challenging problem because revision repair is historically associated with significantly worse outcomes when compared to primary repair.[9-15] Commonly, patients who fail primary repair have biological barriers that influence potential repair success, including poor tissue quality, deltoid dehiscence, or medical comorbidities.[9-15] The current investigation is the first to examine the clinical utility of augmenting revision rotator cuff repair with scaffold devices, or ECM patches, in

an effort to improve outcome by optimizing the biology of repair tissue.

Extracellular matrix patches are scaffold devices designed to create a cellular reaction that leads to an inflammatory response, host cell infiltration, and tendon-like remodeling.[18,19] In addition, ECM patches provide mechanical and suture retention properties that augment rotator cuff repair, increasing load to failure and reducing gap formation under cyclic loading when compared with nonaugmented repairs.[23-25] In the clinical setting, several investigations, consisting mostly of case series (level 4 evidence), have evaluated the use of these patches during primary rotator cuff repair with inconsistent results.[26-28] Barber et al[22] published the only current prospective, randomized control trial examining the use of the ECM patch as augmentation for repair of chronic, large (>3 cm) tears. These authors found that augmentation significantly improved outcome scores and healing rate on postoperative magnetic resonance arthrogram imaging when compared with the nonaugmented group.[22]

In the current study, patient-reported outcomes following revision rotator cuff repair with an ECM patch were excellent or good in only 37% of patients, whereas 63% of patients reported fair or poor results. These results are comparable to reported historical outcomes in populations undergoing open revision repair without the use of ECM patches. Durasovic et al[11] evaluated 80 patients undergoing revision open rotator cuff repair, with 31% having an unsatisfactory outcome. Ma et al[14] reported an unsatisfactory rate of 45% in 20 patients who underwent revision cuff repair. Bigliani et al[9] also reported 31 patients undergoing repeat repairs of rotator cuff tendons, finding that although 81% had satisfactory pain relief, 45% reported persistent weakness that led to an unsatisfactory result.

Arthroscopic revision rotator cuff repair has demonstrated improved patient outcomes compared to those results presented in the literature following open repair in 2 smaller studies. Lo and Burkhart[29] reported that 13 (93%) of 14 patients were satisfied following arthroscopic revision repair. Keener et al[12] retrospectively reviewed 21 shoulders following revision arthroscopic rotator cuff repair. They found that revision repair resulted in reliable pain relief and improved shoulder function; however, only 48% of revision shoulders had an intact repair on ultrasonography at a mean of 25 months postoperatively.[12] Currently, there are no investigations evaluating arthroscopic revision rotator cuff repair with augmentation.

Investigations evaluating revision rotator cuff repair report worse outcomes in patients with advanced age, poor tissue quality, deltoid dehiscence, or medical comorbidities.[9-15] In theory, the use of ECM patches for revision rotator cuff repair should improve the biological potential of these repairs allowing for tendon-like remodeling. However, results of the current study demonstrate no improvement in subjective outcomes for patients undergoing revision cuff repair with augmentation when compared with nonaugmented results reported in the literature.[9-11,14] In addition, in the current study, the use of an ECM patch for open revision rotator cuff repair actually demonstrated higher re-tear rates (63%) than historical reports, although the significance of this is unknown. It is likely that augmentation of the repair simply did not provide any advantage to healing of the revision repair in this difficult patient population.

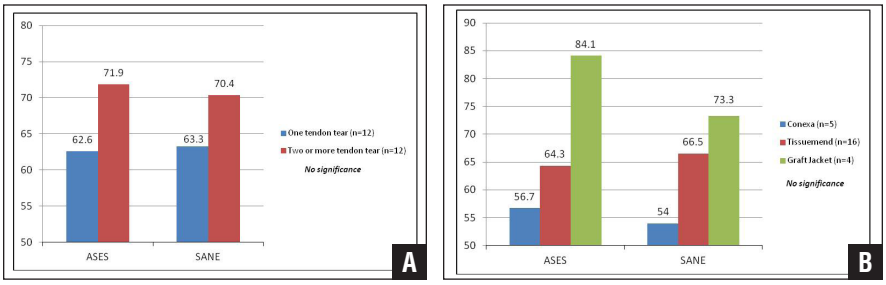

Figure 3: Bar graph showing patient outcome measures based on size of rotator cuff tear (1 tendon tear or 2 or more tendon tears), including American Shoulder and Elbow Surgeons (ASES) and Single Assessment Numeric Evaluation (SANE) scores (A). Bar graph showing patient outcome measures based on type of extracellular matrix patch, including ASES and SANE scores (B).

In the current study population, no significant differences were found in outcomes based on size of primary tear or re-tear (according to the number of tendons torn), type of ECM patch used, age, previous infection, or deltoid dehiscence. Patients who were nonsmokers and non-WC patients showed a trend toward better outcomes; however, this difference was not significant. Notably, patients with a confirmed re-tear demonstrated significantly worse outcome measures when compared to patients with confirmed intact repairs.

There are several limitations to this study. First, this is a retrospective review in which 6 patients were lost during follow-up or unavailable for inclusion into evaluation of outcome measures. Second, the authors' sample of 24 patients available for outcome measures and 16 patients available for imaging is a relatively small sample size compared to some other reports in the literature. Finally, the authors were only able to obtain postoperative imaging in a subset of patients, including those patients with clinical failure. It is possible that the rate of failed revision repairs would be diminished if asymptomatic patients were available to undergo imaging.

Conclusion

Recurrent symptomatic rotator cuff tears present a challenging problem. Outcomes, both historically and in the current

study, are substantially worse and less predictable when compared to primary repairs. Augmentation of the repair with an ECM patch using an open approach demonstrated no significant improvement in outcomes when compared to historical reports without augmentation. In addition, patients in the current study with clinical failures following revision repair demonstrated significantly worse outcomes compared with those patients with confirmed intact revision repairs.

REFERENCES

1. Vitale MA, Vitale MG, Zivin JG, Braman JP, Bigliani LU, Flatow EL. Rotator cuff repair: an analysis of utility scores and cost-effectiveness. *J Shoulder Elbow Surg*. 2007; 16(2):181-187.
2. Russell RD, Knight JR, Mulligan E, Khazzam MS. Structural integrity after rotator cuff repair does not correlate with patient function and pain: a meta-analysis. *J Bone Joint Surg Am*. 2014; 19:96(4):265-271.
3. Mather RC III, Koenig L, Acevedo D, et al. The societal and economic value of rotator cuff repair. *J Bone Joint Surg Am*. 2013; 20:95(22):1993-2000.
4. Flurin PH, Hardy P, Abadie P, et al. Rotator cuff tears after 70 years of age: a prospective, randomized, comparative study between decompression and arthroscopic repair in 154 patients. *Orthop Traumatol Surg Res*. 2013; 99(8 suppl):S371-S378.
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(3):290-299.
6. Björnsson HC, Norlin R, Johansson K, Adolfsson LE. The influence of age, delay of repair, and tendon involvement in acute rotator cuff tears: structural and clinical outcomes after repair of 42 shoulders. *Acta Orthop*. 2011; 82(2):187-192.
7. Boileau P, Brassart N, Watkinson DJ, Carles M, Hatzidakis AM, Krishnan SG. Arthroscopic repair of full-thickness tears of the supraspinatus: does the tendon really heal? *J Bone Joint Surg Am*. 2005; 87(6):1229-1240.
8. 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(2):219-224.
9. Bigliani LU, Cordasco FA, McIlveen SJ, Musso ES. Operative treatment of failed repairs of the rotator cuff. *J Bone Joint Surg Am*. 1992; 74(10):1505-1515.
10. Cordasco FA, Bigliani LU. The treatment of failed rotator cuff repairs. *Instr Course Lect*. 1998; 47:77-86.
11. Djurasovic M, Marra G, Arroyo JS, Pollock RG, Flatow EL, Bigliani LU. Revision rotator cuff repair: factors influencing results. *J Bone Joint Surg Am*. 2001; 83(12):1849-1855.
12. Keener JD, Wei AS, Kim HM, et al. Revision arthroscopic rotator cuff repair: repair integrity and clinical outcome. *J Bone Joint Surg Am*. 2010; 92(3):590-598.
13. Kim HM, Caldwell JM, Buza JA, et al. Factors affecting satisfaction and shoulder function in patients with a recurrent rotator cuff tear. *J Bone Joint Surg Am*. 2014; 15:96(2):106-112.
14. Ma HL, Hung SC, Wang ST, Chen TH. The reoperation of failed rotator cuff repairs. *J Chin Med Assoc*. 2003; 66(2):96-102.
15. Namdari S, Donegan RP, Chamberlain AM, Galatz LM, Yamaguchi K, Keener JD. Factors affecting outcome after structural failure of repaired rotator cuff tears. *J Bone Joint Surg Am*. 2014; 15:96(2):99-105.
16. Aurora A, McCarron J, Iannotti JP, Derwin K. Commercially available extracellular matrix materials for rotator cuff repairs: state of the art and future trends. *J Shoulder Elbow Surg*. 2007; 16(5 suppl):S171-S178.
17. Derwin KA, Badylak SF, Steinmann SP, Iannotti JP. Extracellular matrix scaffold devices for rotator cuff repair. *J Shoulder Elbow Surg*. 2010; 19(3):467-476.
18. Ricchetti ET, Aurora A, Iannotti JP, Derwin KA. Scaffold devices for rotator cuff repair. *J Shoulder Elbow Surg*. 2012; 21(2):251-265.
19. Leigh DR, Baker AR, Mesiha M, et al. Effect of implantation site and injury condition on host response to human-derived fascia lata ECM in a rat model. *J Orthop Res*. 2012; 30(3):461-467.
20. 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(6):1238-1244.
21. 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(4):786-791.
22. 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(1):8-15.
23. McCarron JA, Milks RA, Chen X, Iannotti JP, Derwin KA. Improved time-zero biomechanical properties using poly-L-lactic acid graft augmentation in a cadaveric rotator cuff repair model. *J Shoulder Elbow Surg*. 2010; 19(5):688-696.
24. MacGillivray JD, Fealy S, Terry MA, Koh JL, Nixon AJ, Warren RF. Biomechanical evaluation of a rotator cuff defect model augmented with a bioresorbable scaffold in goats. *J Shoulder Elbow Surg*. 2006; 15(5):639-644.
25. 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(8):1072-1079.
26. 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.
27. Encalada-Diaz I, Cole BJ, Macgillivray JD, et al. Rotator cuff repair augmentation using a novel polycarbonate polyurethane patch: preliminary results at 12 months' follow-up. *J Shoulder Elbow Surg*. 2011; 20(5):788-794.
28. Rotini R, Marinelli A, Guerra E, et al. Human dermal matrix scaffold augmentation for large and massive rotator cuff repairs: preliminary clinical and MRI results at 1-year follow-up. *Musculoskelet Surg*. 2011; 95(suppl 1):S13-S23.
29. Lo IK, Burkhart SS. Arthroscopic revision of failed rotator cuff repairs: technique and results. *Arthroscopy*. 2004; 20(3):250-267.