A Prospective, Randomized Evaluation of Acellular Human Dermal Matrix Augmentation for Arthroscopic Rotator Cuff Repair

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Purpose: To prospectively evaluate the safety and effectiveness of arthroscopic acellular human dermal matrix augmentation of large rotator cuff tear repairs. **Methods:** A prospective, institutional review board–approved, multicenter series of patients undergoing arthroscopic repair of 2-tendon rotator cuff tears measuring greater than 3 cm were randomized by sealed envelopes opened at the time of surgery to arthroscopic single-row rotator cuff repair with GraftJacket acellular human dermal matrix (Wright Medical Technology, Arlington, TN) augmentation (group 1) or without augmentation (group 2). Preoperative and postoperative functional outcome assessments were obtained by use of the American Shoulder and Elbow Surgeons (ASES), Constant, and University of California, Los Angeles scales. Gadolinium-enhanced magnetic resonance imaging (MRI) evaluation of these repairs was obtained at a mean of 14.5 months (range, 12 to 24 months). Adverse events were recorded. **Results:** There were 22 patients in group 1 and 20 in group 2 with a mean age of 56 years. The mean follow-up was 24 months (range, 12 to 38 months). The ASES score improved from 48.5 to 98.9 in group 1 and from 46.0 to 94.8 in group 2. The scores in group 1 were statistically better than those in group 2 ($P = .035$). The Constant score improved from 41.0 to 91.9 in group 1 and from 45.8 to 85.3 in group 2. The scores in group 1 were statistically better than those in group 2 ($P = .008$). The University of California, Los Angeles score improved from 13.3 to 28.2 in group 1 and from 15.9 to 28.3 in group 2 ($P = .43$). Gadolinium-enhanced MRI scans showed intact cuffs in 85% of repairs in group 1 and 40% in group 2 ($P < .01$). No adverse events were attributed to the presence of the matrix grafts. **Conclusions:** Acellular human dermal matrix augmentation of large (>3 cm) cuff tears involving 2 tendons showed better ASES and Constant scores and more frequent intact cuffs as determined by gadolinium-enhanced MRI. Intact repairs were found in 85% of the augmented group and 40% of the nonaugmented group ($P < .01$). No adverse events related to the acellular human dermal matrix were observed. **Level of Evidence:** Level II, lesser-quality randomized controlled trial.

Rotator cuff tears are increasingly common with advancing age and lead to both pain and disability. Surgery is an option for patients who do not respond to a nonoperative program. Neither open nor arthroscopic rotator cuff repairs have uniform success in preventing retears.

Arthroscopic repair offers advantages of decreased morbidity, better visualization, and patient acceptance. However, a significant percentage of tears fail to completely heal or are found to have persistent defects in the tendon at follow-up. The degenerative nature of the rotator cuff tendon may contribute to this finding. In addition, the tension on the repaired tendon after it is reattached to the greater tuberosity for a "double-row" repair or even a basic single-row repair may reduce the likelihood of complete healing.

Every effort should be made to enhance the potential for complete healing after rotator cuff repair. However, despite the use of the best technique, the quality of cuff tissue is often so poor that biologic healing is compromised, resulting in rotator cuff tissue retearing or incomplete healing at rates ranging from 40% to over 90%.[1-4] There is no uniformly accepted surgical solution to this problem because even the most advanced biomechanical constructs have been unable to improve what is usually a compromised biologic environment. Many techniques have been devised to enhance the repair of large and degenerative tears including the recent emphasis on biologic healing enhancements, such as platelet-rich plasma and marrow aspirates.

The incorporation of biologic tissue scaffolds into the rotator cuff is another biologic approach. Both autograft and allograft materials have been used to augment or replace irreparable portions of the rotator cuff tendon. An acellular human dermal matrix allograft (GraftJacket; Wright Medical Technology, Arlington, TN) is currently available for tendon augmentation. This graft tissue is processed to render it acellular and therefore less immunogenic while the collagen extracellular matrix is left intact to provide strength and a scaffold into which new host tissue can regenerate. GraftJacket matrix is a human skin allograft processed to remove the epidermis and dermal cells and was chosen for this study because these properties facilitate incorporation of the matrix and reduce any rejection response. The 3-dimensional human dermal tissue forms a scaffold from native collagen structure that contains blood vessel channels and essential biochemical components that enhance cellular repopulation and revascularization during healing. Biomechanical testing has shown GraftJacket's superior strength to xenograft and synthetic alternatives,[5,6] and clinical reports support its use in the shoulder.[7-9]

The purpose of this study was to prospectively evaluate the safety and effectiveness of arthroscopic acellular human dermal matrix augmentation of large rotator cuff tear repairs. The hypothesis was that an arthroscopically applied soft-tissue allograft augmentation would both reinforce and enhance the healing of a significant rotator cuff repair, resulting in fewer retears.

METHODS

A randomized, prospective, multicenter clinical study of a consecutive series of patients undergoing large (>3 cm), 2-tendon arthroscopic rotator cuff repair was undertaken. Patients were prospectively randomized into 2 groups by means of sealed envelopes opened at the time of surgery after assessment of the size and reparability of the rotator cuff tendon: group 1 included rotator cuff repairs with an acellular human dermal matrix augmentation, and group 2 (control group) comprised repairs without any augmentation. Patients were excluded at the time of surgery if any of the exclusion criteria were found to be present or if the inclusion criteria were not met. This was determined before the envelope was opened. This multicenter study was conducted in accordance with the approved research protocol, good clinical practice guidelines, and applicable local regulatory requirements and laws, and institutional review board approval was obtained. Preoperative and postoperative functional outcome assessments were obtained with the Constant, American Shoulder and Elbow Surgeons (ASES), and University of California, Los Angeles (UCLA) scores. Postoperative patient evaluations including range of motion, strength, and standard shoulder tests were obtained in conjunction with the subjective questions associated with the functional outcome scores mentioned previously at 6 and 12 months after surgery and annually thereafter.

Magnetic resonance imaging (MRI) arthrogram evaluations with gadolinium enhancement of these repairs were obtained at 12 or 24 months in 1.5-T scanners. The MRI interpretations were performed at 4 separate study sites by an independent radiologist at each site who was blinded to the patients' treatment assignments. The method of MRI setup and amount and brand of gadolinium injected were left to the discretion of the radiologists and not controlled.

Inclusion criteria were patients aged between 18 and 75 years with large rotator cuff tears measuring at least 3 cm in width and with 2-tendon involvement that could be repaired arthroscopically (Fig 1). Good preoperative movement of the nonoperative arm (defined as shoulder elevation >90°), the ability to perform postoperative exercises, and the ability to read, understand, and complete the patient-reported outcome forms in English were required. Workers' Compensation patients were allowed.

Exclusion criteria were irreparable massive rotator cuff tears measuring more than 5 cm; subscapularis tendon disruptions; revision surgery; inflammatory or autoimmune diseases; evidence of active infection, cancer, or highly communicable diseases; smokers; and patients for whom there was no reasonable expectation that they would be able to participate in the protocol-required postoperative follow-up examina-
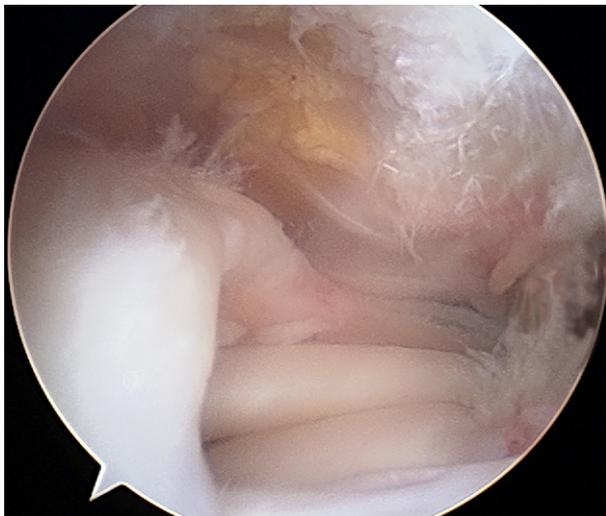
FIGURE 1. Large, 2-tendon rotator cuff tears measuring at least 3 cm that could be arthroscopically repaired were included in the study. © Dr. F. Alan Barber.

tions. Smoking was an initial exclusion criterion because of the effect smoking has on cuff microvascularity. It has been established that smokers do not heal as well as nonsmokers, and we wanted to eliminate this as a confounding variable.

Group 1 patients' rotator cuff repairs were augmented with GraftJacket acellular human dermal matrix, and group 2 patients did not receive the acellular human dermal matrix augmentation and served as controls. The native tendon underwent reattachment to the area adjacent to the articular cartilage or a slightly more lateral area as tendon tension and excursion permitted. A watertight repair was not required. A residual defect of less than or equal to 1 cm was permitted at any site associated with the repair.

In those tendons with augmentation, the surgeon's standard repair was performed first, just as was done in the nonaugmented patients. A single-row arthroscopic suture anchor repair using 2 double- or triple-loaded anchors with either an arthroscopic modified Mason-Allen stitch or simple stitches from triple-loaded suture anchors was used for the cuff attachment to the abraded bone surface of the greater tuberosity by use of established techniques.[10-12] After the primary repair, the group 1 repairs were augmented by an onlay graft at the repair site.[10] The GraftJacket onlay technique was rehearsed at a prestudy closed investigators meeting using models. It was previously published by 1 of the authors (M.R.L.), who reviewed the technique with the other

investigators.[10] Medial cuff sutures were placed at the anterior medial and posterior medial musculotendinous area. These were used in conjunction with 1 suture from both laterally placed suture anchors to fix the 4 corners of the graft. The distances between these 4 suture points were carefully measured and recorded to clearly define the dimensions of the cuff tendon to be augmented. The graft was cut to a size that would extend from the medially placed sutures near the musculotendinous junction across the bone-tendon interface to then cover the entire tuberosity footprint laterally (Fig 2). Orientation guide marks were placed along the edges of the graft with a marking pen. The graft was fixed arthroscopically with sutures placed through the native cuff tissue at the graft corners anteromedially and posteromedially and then secured to the bone with 1 suture from each anchor laterally.[10,13] All sutures were brought out of the lateral cannula, and corresponding ends of each suture were held together by a clamp. The sutures were maintained in their respective orientations once outside the cannula to facilitate suture orientation and management. A standard round-ended knot pusher was used to ensure that the sutures had no twists and were not wrapped around other sutures. Short-tailed interference knots were placed in these sutures after being passed through the graft by use of a free needle in the respective corners to facilitate graft control and simplify suture management (Fig 3). The rubber dam on the cannula was removed to facilitate graft passage. The folded graft was then grasped on its medial edge

FIGURE 2. The acellular human dermal matrix graft is cut to a size that will extend at least 1 cm medial to the bone-tendon interface and also cover the entire tuberosity footprint laterally. © Dr. F. Alan Barber.

FIGURE 3. Short-tailed interference knots are tied at the ends of the anchoring sutures after they are passed through the graft to facilitate graft control and simplify suture management. © Dr. F. Alan Barber.

by a smooth grasper and passed through the operative cannula into the subacromial space and to the surgical site (Fig 4) by a combination of pulling the free ends of the 4 sutures and pushing with the smooth grasper. Once in the bursa, the graft is opened by pulling the various sutures, oriented appropriately, and each short-tailed interference knot is retrieved and tied to its corresponding suture to secure the graft augmentation in place (Fig 5). Tying the lateral sutures first facilitates this process. Other than the normal freeing

FIGURE 4. The graft is delivered through an operative cannula to the surgical site. © Dr. F. Alan Barber.
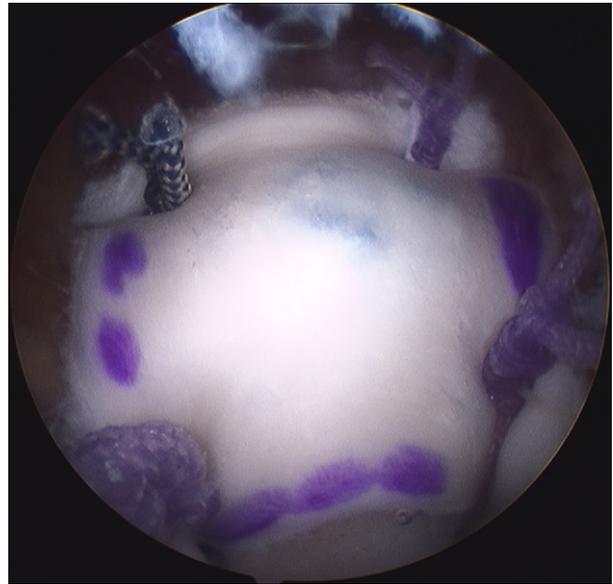

FIGURE 5. Once in place, the augmenting graft is secured by tying each short-tailed interference knot to the corresponding suture. © Dr. F. Alan Barber.

up of the tendons associated with a cuff repair, no extensive releases or interval slides were performed.

Postoperatively, patients' extremities were placed in an abduction sling for 4 to 6 weeks, allowing daily pendulum motion exercises. Supervised physical therapy was started at 4 weeks, with strengthening allowed starting at 12 weeks.

All adverse events occurring both in the first 30 days after the procedure and long-term were reported and analyzed. An adverse event form was created as part of this study. Bursitis was diagnosed independently by each investigator using his clinical skills (positive impingement test, tenderness on the anterior shoulder inferior to the acromion, and so on). No subsequent or revision procedures have been performed. The primary endpoint was to evaluate the presence of residual tendon defects on MRI at 1 year. Healing was defined as complete excursion of the repaired tendon to the greater tuberosity with attachment to bone and no leakage of the gadolinium. The secondary endpoints were to measure the graft's effectiveness by clinical outcome measures and to determine the incidence of acute or late adverse events for the 2 groups.

Statistical Methods

On the basis of the literature previously referenced,[1-4] a retear rate of at least 40% can be antici-

TABLE 1. *Patient Data in Groups 1 and 2*

	Group 1 (Augmented)	Group 2 (Nonaugmented)
Mean age (range) (yr)	56 (43-69)	56 (34-72)
Sex	18 men and 4 women	13 men and 7 women
Mean anteroposterior length (cm)	3.1 ± 1.4	2.4 ± 1.0
Mean retraction (cm)	3.2 ± 1.3	2.5 ± 1.1
Mean atrophy classification	1.7 ± 0.7	1.7 ± 0.9
Interval slides	1	0
Retear rate	15%	60%
Operative side	17 right and 5 left	13 right and 7 left
Dominant hand	91%	90%
Mean body mass index (range)	29 (21-44)	29.7 (20-44)
Mean height (in)	70 ± 4	68 ± 4
Mean weight (lb)	200 ± 31	194 ± 47
Mean no. of sutures (range)	9.5 (6-16)	5.4 (2-9)
Platelet-rich plasma	7 of 22	4 of 20
Mean no. of anchors (range)	3.3 (2-5)	1.9 (1-3)
Margin convergence	8 of 22 (36%)	5 of 20 (25%)

pated for single-row repairs. Reducing this rate by half would be clinically meaningful. An SD of 15% within groups was allowed. Power analysis indicated that 20 patients in each group would provide sufficient power to identify statistical significance in healing rates between the 2 groups. Preoperative and postoperative clinical outcome measures as well the presence of persistent cuff defects between groups were evaluated by use of Student t tests. Statistical significance was placed at $P \leq .05$.

RESULTS

There were 22 patients in group 1 (augmented) and 20 in group 2 (nonaugmented) with a mean age of 56 years (range, 34 to 72 years). Of the patients, 31 were men and 11 were women. The mean follow-up was 24 months (range, 12 to 38 months). Clinical outcome scores were obtained both preoperatively and postoperatively. The ASES score improved from 48.5 to 98.9 (SD, ± 4.2) in group 1 and from 46.0 to 94.8 (SD, ± 14.2) in group 2 ($P = .035$). The Constant score improved from 41.0 to 91.9 (SD, ± 9.2) in group 1 and from 45.8 to 85.3 (SD, ± 11.0) in group 2 ($P = .008$). The UCLA score improved from 13.3 to 28.2 (SD, ± 2.1) in group 1 and from 15.9 to 28.3 (SD, ± 3.0) in group 2 ($P = .43$). Details of the 2 groups are listed in Table 1.

Of those patients who were willing to undergo gadolinium-enhanced MRI at either 12 months or 24 months after surgery (mean, 14.5 months), intact cuffs were shown on MRI in 17 of 20 (85%) in group 1 and 6 of 15 (40%) in group 2 ($P < .01$). Seven patients in this study group had gadolinium-enhanced MRI per-

formed at 24 months instead of 12 months. No correlation between MRI findings and clinical outcomes was found.

Adverse events in group 1 included recurrent shoulder bursitis in 1 patient and 3 rotator cuff retears. Group 2 adverse events included cellulitis in 2 patients, shoulder bursitis in 1 patient, post-traumatic fibrosis in 1 patient, 9 rotator cuff retears, and 1 biceps tendon rupture. No adverse events were attributed to the presence of the dermal matrix grafts. Associated procedures are listed in Table 2.

DISCUSSION

Rotator cuff repair attempts to create a strong biomechanical construct that promotes secure and enduring healing to the bone. Healing occurs by reactive scar formation rather than the re-creation of a histologically normal tendon-bone insertion site. Inadequate cuff healing is probably multifactorial but on the

TABLE 2. *Associated Procedures*

Associated Procedure	Group 1 (Augmented) (n = 22)	Group 2 (Nonaugmented) (n = 20)
Subacromial decompression	20	18
Mumford	0	6
Biceps tenodesis	4	5
Biceps debridement	1	2
Biceps tenotomy	1	1
Labral debridement	3	3
SLAP repair	1	0

histologic level is caused by reduced cellularity, decreased vascularity, increased disorganization, and lower collagen concentration in the abnormal tendon.[14] Larger cuff tears are often chronic, retracted, and fibrotic and present a challenge because of the lack of sufficient tissue for a complete repair. Little detailed information exists regarding the healing cuff including the timing, size, and type of the mechanical load seen at the tendon-bone healing site over time. This is especially important because a rotator cuff tear can increase in size over time and become associated with muscle atrophy and fatty infiltration if not successfully repaired.[15,16]

Efforts to improve healing and achieve an anatomic, tension-free repair in these large cuff tears include various techniques to decrease the load on the healing tendon-bone interface. Because the tendon repair–suture interface is the weakest portion of the repair, different suturing approaches have been advocated, including the arthroscopic creation of a modified Mason-Allen stitch, triply loaded suture anchors, various combinations of simple and horizontal stitches, and margin convergence techniques.[17] Other approaches in addition to these suturing techniques include the use of dual-row fixation, "transosseous-equivalent" repairs, muscle interval slides/releases, changes in the anchoring systems, and mechanical reinforcement of the repair tissue by tissue augmentation materials. Even with an "ideal" mechanical fixation, the biologic aspects of tendon healing may play the most significant role in determining the ultimate clinical outcome.

Although most patients improve clinically after cuff repair and show good or excellent clinical outcomes, these may deteriorate long-term because of the presence of retears or of repaired defects that never healed. Whereas smaller cuff tears have better healing rates,[18] in a series of rotator cuff tears larger than 2 cm repaired arthroscopically, recurrent tears were observed on 1-year ultrasounds in 94% despite significant improvements in the clinical outcome scores.[2] That is not to say that outcomes are not linked to complete tendon healing. Intact rotator cuff repairs have been shown to yield better strength,[19] better active forward elevation,[20,21] and significantly lower pain scores[22] when compared with those repairs that fail to heal. Double-row repairs also show a relation between clinical outcomes and complete healing. A prospective study of arthroscopic double-row repairs noted a 40% retear rate for large and massive tears with reduced strength and poorer outcome scores for incompletely healed repairs.[23]

The mechanical reinforcement of a cuff repair using tissue augmentation materials holds the promise of better healing and improved results. Various allograft, xenograft, and synthetic augmentation materials are available for clinical use in conjunction with rotator cuff repair. Available xenografts include porcine dermal collagen and small intestinal submucosa (SIS). However, there are limited clinical data to support the use of these materials for rotator cuff augmentation in humans.[24,25] In fact, despite encouraging preliminary reports, SIS xenografting does not appear to improve clinical outcomes and was reported to be ineffective in reinforcing large and massive rotator cuff tears. At 6 months postoperatively, 91% of 11 cases had MRI-documented retears, and 45% were actually worse.[26] Cuff repairs augmented with SIS have been reported to have more weakness in liftoff, internal rotation, and adduction; more impingement in external rotation; and a higher incidence of postoperative reactions requiring surgical treatment.[27] Other authors have recommended against the use of SIS for cuff repair augmentation.[28]

Allograft augmentations have been used in a variety of applications including the shoulder. Again, the data on their effectiveness are preliminary.[7-9,29] In a canine model, the use of this acellular human dermal matrix in controlled rotator cuff reconstructions showed equivalent tissue strength by 12 weeks, with both control and grafted tissue mimicking normal tendon grossly and histologically by 6 months.[13] Koh et al.[30] investigated the use of a poly-levo-lactide scaffold to augment infraspinatus rotator cuff repairs in sheep, finding that the augmentation increased repair strength by 25% over unreinforced repairs. Subsequently, biomechanical evaluation of the strength of a human cadaveric supraspinatus repair augmented with human dermal matrix showed a significant 19% improvement in strength in those tendons that were augmented while also changing the mode of failure to where fewer repairs failed at the suture-tendon interface.[5]

This prospective, randomized, multicenter study examined the use of acellular human dermal matrix to augment large, 2-tendon rotator cuff tears measuring at least 3-cm wide using an onlay grafting technique. The primary endpoint for this study was the presence of retears independently verified by radiologists using gadolinium-enhanced MRI at least 12 months after surgery. These MRI scans showed intact cuffs in 85% of the augmented group but only 40% of the nonaugmented repairs ($P < .01$).

The secondary endpoint was the clinical outcome. Clinical outcomes measured by ASES and Constant

scores were statistically better for the augmented group than the nonaugmented group ($P = .035$ and $P = .008$, respectively) at a mean follow-up of 24 months. No clinical difference was measured by use of the UCLA score. It should be noted that although the UCLA score is frequently used and can provide a useful outcome measure for historical comparison, it was developed before the advent of modern measurement methodology. Its validity and responsiveness for measuring rotator cuff surgery are questionable, and it may not be an appropriate choice for evaluating patients' shoulder outcomes.[31]

Although operative time was increased by between 30 and 60 minutes in cases requiring augmentation, the arthroscopic nature of the procedure avoided open incisions, increased pain, and the potential for hospital stays. No adverse events related to the acellular human dermal matrix were observed. Cuff repair coupled with a biologic augmentation using acellular human dermal matrix offers an effective treatment for large rotator cuff tears, does not become irreparable, and enhances the likelihood of complete healing.

Weaknesses of this study include the limited number of patients and the short follow-up. No pattern of complication occurred. In addition, the number of complications was so small that the power was not sufficient to draw any meaningful data from them. Repeat arthroscopic examinations were not performed to confirm healing, but the use of gadolinium-enhanced MRI obviates this concern. The MRI scans were performed at different sites by independent radiologists, and variations in gadolinium techniques could represent an uncontrolled variable. Because of patient preference, some studies were performed in open units and some in closed units. It is doubtful, however, that this would alter the accuracy of a gadolinium-enhanced MRI evaluation. In addition, whereas the ASES and Constant scores are validated research tools, the UCLA score may not be an effective assessment tool in this patient population especially when comparing preoperative with postoperative states.[31]

CONCLUSIONS

Acellular human dermal matrix augmentation of large (>3 cm) cuff tears involving 2 tendons showed better ASES and Constant scores and more frequent intact cuffs as determined by gadolinium-enhanced MRI. Intact repairs were found in 85% of the augmented group and 40% of the nonaugmented group ($P < .01$). No adverse events related to the acellular human dermal matrix were observed.

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