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Use of Acellular Dermal Matrix for Reconstruction of Massive Rotator Cuff Tears in an Older Population

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Abstract

Introduction: Massive cuff tears can prove especially challenging to treat. Although these types of tears are often considered inoperable, augmented repair using an acellular dermal matrix may improve success rates. One acellular dermal matrix, AF-ADM, has shown encouraging results in an earlier case series which prompted this prospective study in an older population.

Methods: After screening and evaluation for repair using traditional arthroscopic techniques, thirteen subjects with irreparable rotator cuff tears underwent a mini-open approach with AF-ADM augmentation. An MRI was performed for each subject preoperatively, at 3 months post-operative, and at 12 months post-operative. Clinical outcomes were assessed at 3 months, 12 months, and 24 months postoperative using the Constant-Murley Shoulder Scoring Scale, the Modified ASES, and patient satisfaction scores.

Results: At 24 months follow-up, subjects demonstrated a significant 32.3 (64.4%) mean improvement in the Constant-Murley score (p=0.0001), a significant 32.5 (60.4%) mean improvement in the ASES score (p=0.0009), and a significant 31.8 mean in VAS (p=0.0011) with scores of 82.5, 86.3, and 7.4, respectively. Patient satisfaction was high at 24 months with a reported mean score of 3.4 and a median of 4.0 (out of 4). There were no complications related to graft use. Only two subjects exhibited radiographic graft failures with MRIs revealing tears in the native tissue but fully intact graft material. However, these subjects also showed excellent clinical outcome scores.

Conclusion: The assessments and patient satisfaction scores indicate that significant improvements can be achieved as early as three months with AF-ADM augmentation, despite the severity of these tears and age of the patients. The high success rate was especially notable as the subject group was older patients, who may have greater difficulty healing. The results presented here demonstrate that AF-ADM can be used successfully to treat massive and recurrent rotator cuff tears.

Keywords: Rotator cuff repair; Massive tear; Recurrent tear; Acellular dermal matrix; ArthroFlex

Introduction

Rotator cuff damage is one of the most prevalent of musculoskeletal disorders. Approximately 300,000 Americans require shoulder surgery related to rotator cuff repair each year [1]. The surgery rate is particularly high amongst older individuals with a rate of 28.3 procedures per 10,000 patients aged 65-74 years [2]. Massive rotator cuff tears are especially problematic and considered significantly more challenging to repair than smaller tears [3]. Massive rotator cuff tears are often considered irreparable and revision rates are high due to poor tissue quality and wide gap [4]. The manifestation of symptoms and tear patterns can vary across individuals, further increasing the complexity of treatment [5]. Recurrent rotator cuff tears present another challenge for surgeons: patients experience high retear rates after surgery because tendons have an intrinsically poor healing potential. This is exacerbated in tendons that have been chronically ruptured.

Tissue augmentation using an Acellular Dermal Matrix (ADM) can reinforce massive rotator cuff repairs and may result in higher success rates. These ADMs provide structural collagen, which functions as a scaffold, allowing host tissue to integrate with the goal of enhancing the healing response [6]. Studies using human ADM to augment massive rotator cuff tears reported success and safety [4,6,7]. AF-ADM is one human ADM that has previously shown success in treating rotator cuff tears [8-10]. Dermis from a deceased donor undergoes a decellularization process to thoroughly remove donor DNA content [11] while maintaining the biochemical and biomechanical properties of the graft [12]. Advantages of AF-ADM include medical-device grade sterilization using low-dose gamma irradiation [13,14] and storage at ambient temperature using a glycerol-based solution that eliminates the need for thawing or rehydration [11]. The earlier published successes of AF-ADM combined with these benefits prompted the prospective study in a challenging population.

The purpose of this study is to report the outcomes through two years of follow-up using AF-ADM to augment the repair of massive rotator cuff tears in an older population.

Methods

Subject population

The Andrews Research and Education Institute (AREI, Gulf Breeze, FL) obtained institutional review board approval for this single-arm, prospective study. All potential subjects were educated about the use of allograft tissue, and informed consent was obtained. Inclusion criteria allowed enrollment of skeletally mature subjects over the age of 18 with MRI evidence of a massive tear or recurrent with a sagittal component tear of the rotator cuff. A massive tear was defined as a tear >5 cm or a tear that involved at least two tendons per ICD-10 code M75.120 [15]. Subjects were excluded if an active local or systemic infection was present, the rotator cuff tear was considered irreparable, concomitant glenohumeral joint arthritis was severe enough to contraindicate rotator cuff repair, or if the subject was concurrently participating in another research study. Preoperatively, subjects who met all the inclusion criteria and none of the exclusion criteria were eligible for treatment with AF-ADM. Ineligible patients, preoperative evaluation by magnetic resonance imaging (MRI) identified a massive tear or recurrent rotator cuff tear with a sagittal component. The degree of retraction and trophicity of the involved rotator cuff musculature was determined intraoperatively. If the surgeon believed that augmentation was necessary, AF-ADM (ArthroFlex®, LifeNet Health, Virginia Beach, Virginia, USA) was utilized.

Surgical technique and post-operative care

In all patients, the shoulder was first arthroscopically evaluated through a posterior and lateral portal, and all necessary procedures prior to rotator cuff repair were performed. For example, bicep tenotomy, sub-acromial decompression with acromioplasty, intra-articular debridement, etc., were first completed arthroscopically. Once the rotator cuff tear was evaluated and determined to be irreparable by traditional arthroscopic techniques, a mini-open approach with augmentation was performed.

Open augmentation with AF-ADM was utilized for massive cuff tears that were unable to be fully mobilized after releases and margin convergence or after the failure of a prior arthroscopic rotator cuff repair with sutures alone. The open approach used was an anterior deltoid-splitting approach after the arthroscopic portals had been closed. In the cases of revision rotator cuff repair, the rotator cuff was repaired with double row technique first, and then the ADM was sewn into the rotator cuff medially and stretched over the repair site and enthesis in a trampoline-like fashion and anchored into the tuberosity. For the case in which where the rotator cuff was irreparable due to chronicity and size margin convergence, sutures were first placed and then the ADM was sewn into the periphery of the rotator cuff defect first so the tissue augmentation and the far anterior and posterior rotator cuff margins moved as a unit. Next, the ADM augmentation and rotator cuff were repaired over the humeral head into the tuberosity. Last, the deep and superficial deltoid fascia was closed, followed by the skin, in standard fashion. Postoperative immobilization consisted of an abduction pillow at 45 degrees with no motion for 3 weeks, followed by passive motion above the pillow for an additional three weeks or conversion to a sling with a gentle passive range of motion. The active assisted range of motion was initiated at 6 weeks and slowly progressed. Strengthening exercises were delayed for at least 12 weeks.

Clinical evaluations

Subjects with AF-ADM augmentation were evaluated preoperatively and at visits scheduled at 3 months, 12 months, and 24 months postoperatively.

Preoperatively, subjects underwent the following assessments:

- Constant-Murley Shoulder Scoring Scale
- Visual Analog Score (VAS) for pain (Scale 0 to 100)
- American Shoulder and Elbow Surgeons Assessment (Modified ASES)
- Patient Satisfaction survey (Scale 1 to 4)
- MRI

Postoperatively, subjects underwent the following assessments at 3 months, 12 months and 24 months:

- Constant-Murley Shoulder Scoring Scale
- Visual Analog Score (VAS) for pain (Scale 0 to 100)
- American Shoulder and Elbow Surgeons Assessment (Modified ASES)
- Patient Satisfaction survey (Scale 1 to 4)

A repeat MRI was performed postoperatively at 3 months and 12 months.

Results

Forty-nine subjects underwent the informed consent process. During surgery, the surgeon determined that thirty-three did not need augmentation. One subject postponed surgery indefinitely for personal reasons, and two subjects withdrew from the study early, leaving thirteen subjects who received augmentation and completed the study duration of 24 months. One subject experienced severe neck pain that was unrelated to either the reconstruction procedure or the graft; however, she mistakenly included this pain in the VAS section of the 12-month outcome scores. Due to this significant breach of protocol, her 12-month VAS score and any associated tests (e.g., ASES) were removed from the analysis. Demographic variables and baseline information about the tears can be found in Table 1. Although still in relatively good health, this patient group tended to be older (mean 64.5 years) and overweight (mean BMI of 27.9). Three patients had comorbidities of obesity, one had neuropathy, and one had both obesity and neuropathy. Twelve out of thirteen exhibited a massive tear. The remaining patient displayed a 5.0 cm full-thickness tear of the supraspinatus tendon with retraction to the glenoid that was not mobile for arthroscopic repair. Seven patients had undergone previous surgical procedures on the index shoulder, four of which were rotator cuff tear repair. The Constant-Murley, ASES, and VAS scores at baseline were 50.2 ± 21.3, 53.8 ± 26.6, and 39.2 ± 26.7, respectively.

Subject demographics and tear characteristics		
Subjects (n)	13	
Age (years)	Mean	64.5 ± 8.5
	Median	65
	Range	52.0-78.0
BMI (kg/m2)	Mean	27.9 ± 4.0
	Median	27.1

	Range	22.0-35.5
Tear Location	Supraspinatus Tendons	8
	Supra And Infra Spinatus Tendons	5
Grade	1	1
	2	1
	3	11

Table 1: Subject demographics and tear characteristics.

At 3 months follow-up, subjects demonstrated a 9.4 ± 19.6 (18.7%) mean improvement in the Constant-Murley score (p=0.2457), a significant 30.3 ± 27.3 (36.7%) mean improvement in the ASES score (p= 0.0314), and a significant 24.7 ± 34.1 mean improvement in VAS (p=0.0108) with scores of 59.6 ± 18.8, 73.5 ± 15.2, and 14.5 ± 17.3, respectively (Figure 1). Patient satisfaction was high at 3 months with a reported mean score of 3.5 ± 0.5 and a median of 4.0 (out of 4). At 12 months follow-up, subjects demonstrated a significant 27.0 ± 18.2 (53.9%) mean improvement in the Constant-Murley score (p=0.0008), a significant 30.3 ± 26.5 (56.4%) mean improvement in the ASES score (p=0.0059), and a significant 28.6 ± 28.9 mean improvement in VAS (p=0.0103) with scores of 77.2 ± 11.9, 84.1 ± 16.7, and 10.6 ± 17.9, respectively (Figure 1). Patient satisfaction was high at 12 months with a reported mean score of 3.4 ± 0.8 and a median of 4.0 (out of 4). At 24 months follow-up, subjects demonstrated a significant 32.3 ± 16.6 (64.4%) mean improvement in the Constant-Murley score (p=0.0001), a significant 32.5 ± 26.7 (60.4%) mean improvement in the ASES score (p=0.0009), and a significant 31.8 mean in VAS ± 25.5 (p=0.0011) with scores of 82.5 ± 10.4, 86.3 ± 11.9, and 7.4 ± 10.2, respectively (Figure 1). Patient satisfaction was high at 24 months with a reported mean score of 3.4 ± 0.6 and a median of 4.0 (out of 4).

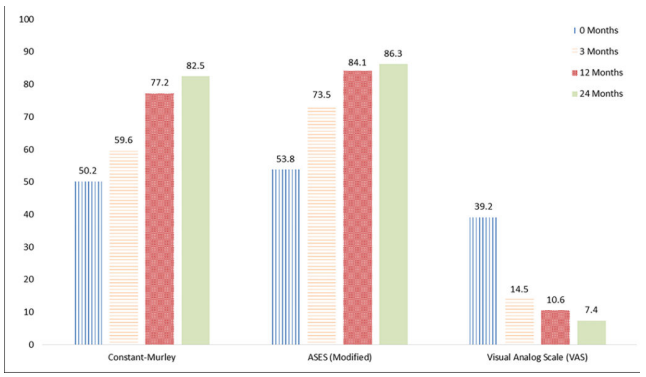


Figure 1: Constant-Murley, modified ASES, and VAS scores through 24 months. All scores showed significant improvement ($p<0.05$) over the corresponding baseline score with the single exception of the Constant-Murley score at 3 months follow-up.

Adverse events were minimal. Two subjects exhibited radiographic graft failures, and MRI imaging showed these tears occurred solely within the native tissue and not in the graft material. One of these subjects had been non-compliant regarding the return to a work schedule that was recommended. The other subject reported successful clinical outcomes, but the MRI showed that the tear had not entirely healed and was therefore considered a failure. Nonetheless, both of these subjects showed excellent clinical outcome scores at 24 months with 65 and 83 for Constant-Murley, 88 and 84 for ASES, and 0 and 2 (out of 100) for VAS. Finally, one patient reported an occasional clicking noise at 12 months but had no pain and this noise disappeared by the 24 months follow-up visit. No infection or rejection of the graft in any of the subjects was reported.

One patient's result showed a typical history of rotator cuff disease as well the utility of AF-ADM in an older patient. The patient was a right-hand dominant male, aged 78 at the time of rotator cuff AF-ADM augmentation. Radiographs taken when the patient was age 73 were on file. The coronal view of the shoulder demonstrated no rotator cuff pathology at that time (Figure 2). The patient presented again with pain at age 77, and an MRI showed tendonosis but no atrophy (Figures 3A and 3B). After nonoperative treatment followed by a fall, the patient presented 6 months later with a musculotendon junction tear and stage 1 supraspinatus atrophy (Figures 4A and 4B). He underwent arthroscopic repair and had an all-suture margin convergence technique to close the rotator cuff defect. Four months later the patient fell again and had recurrent rotator cuff tear (Figures 5A and 5B). The decision was then made to augment his repair using AF-ADM using the technique described above. At three months postoperative, his cuff and graft were intact (Figure 6). At his one year follow up visit, the patient had mild pain with overhead activities but could perform all activities of daily living. He had full shoulder flexion and abduction, internal rotation to L2, and he could place his hand behind his head. His maximum strength at 30 degrees of shoulder abduction was 9 pounds. The one year postoperative MRI showed that his AF-ADM graft augmented rotator cuff repair was intact with no further atrophy (Figures 7A-D).

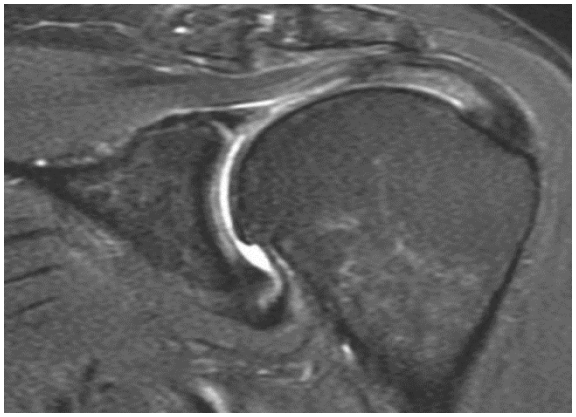
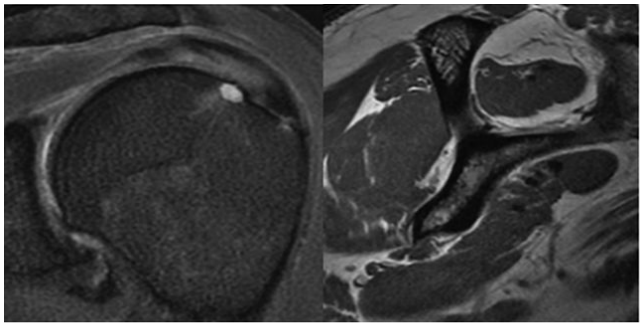
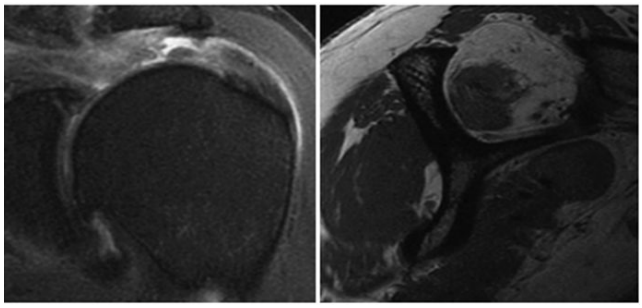


Figure 2: Coronal view of a rotator cuff tear of the patient at 73 years old.



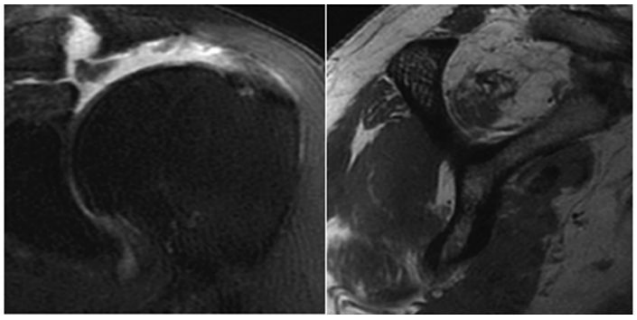
3A 3B

Figures 3A and 3B: MRI image showing tendonosis but no atrophy of the same patient at 77 years old who presented with pain.



4A 4B

Figures 4A and 4B: MRI image displaying a musculotendon junction tear and stage 1 supraspinatus atrophy.



5A 5B

Figures 5A and 5B: MRI images of a recurrent rotator cuff tear sustained after a patient fall.

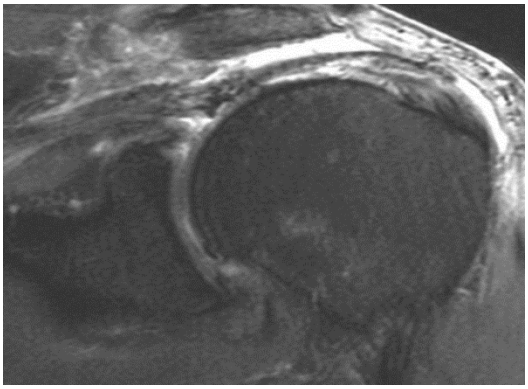
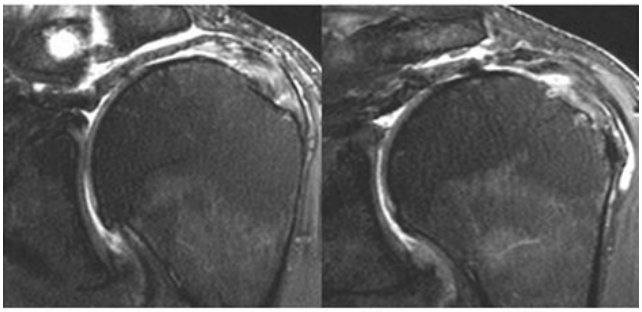
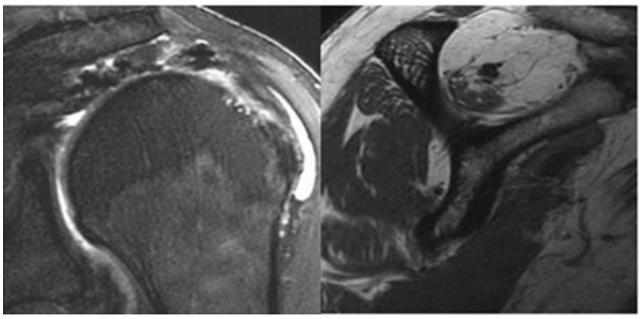


Figure 6: MRI image of the intact cuff and graft 3 months post-operative following repair with AF-ADM.



7A 7B



7C 7D

Figures 7(A-D): One-year post-operative images show an intact, augmented repair with no further atrophy.

Discussion

Rotator cuff repair augmented with AF-ADM demonstrated excellent results at 24 months follow-up across all metrics evaluated, including functional outcome, pain, patient satisfaction, and radiographic imaging. The high success rate was especially notable as the subject group was older patients, mainly consisted of massive tears, and several patients had revision surgeries. Massive rotator cuff tears can be difficult to treat even in younger patients. Obtaining successful outcomes in older patients, who sometimes have difficulty healing,

shows the power of using AF-ADM for these challenging repairs. As the baby boomers age and our older population grow, it is important to identify techniques that lead to successful outcomes in this population. Despite the massive and recurrent tears, statistically significant improvements were seen in each of the three outcome scores, and subjects also reported high rates of satisfaction. Two subjects in this study did show evidence of tear failure in the native tendon on MRI images, notably with both grafts still intact, but these patients also had high clinical outcome scores with extremely low VAS scores and good patient satisfaction. The assessments and patient satisfaction scores indicate that significant improvements can be achieved as early as three months, despite the severity of these tears and the age of the patients.

Although the radiograph failures seemed to contradict the good clinical outcome scores, Barber et al. [16] observed that there may not be any correlation between MRI results and clinical outcomes. Other studies, not using AF-ADM, have also reported patients who were satisfied with their rotator cuff repair and had low pain, yet still experienced radiographic failure [17-19]. Galatz et al. [18] reported 17 out of 18 (94.4%) patients had recurrent tears visualized through ultrasound at a minimum 24 months follow-up, yet all patients stated they were satisfied with the procedure and would undergo it again. More recently, Crim et al. [20] explored the correlation between functional outcome and MRI appearance at one year post-operative in 40 patients who underwent arthroscopic repair for rotator cuff tears. The authors found the appearance of the rotator cuff varies considerably and that apparently did not correlate with clinical outcome as assessed by Constant-Murley scores. Reported retear rates in the literature range from 10%-27% [6,16,21] for augmented repair, and from 10%-47% [16,20,22] for repair without augmentation. The retear rate in our population was 15.4%, which is very favorable for a group comprised of massive and recurrent tears.

Prior reports [8-10] on the use of AF-ADM in the repair of rotator cuff tears corroborate the good clinical outcomes presented here. Levenda et al. [8] first published on this use of AF-ADM in a technical paper that also included a case series subsection. Although the patients in Levenda et al. were similar in age to those in this study, the rotator cuff tears were smaller (2-4 cm), and radiographic evaluation was not performed; however, the authors considered every repair a success due to improvements in pain and strength. The authors excluded two patients due to retears sustained in falls. Similar to our findings, the authors noted the graft and footprint were intact in both cases. Petri et al. [9] recently published a retrospective study that explored augmented repair of large to massive recurrent tears using AF-ADM in patients aged 50-64. After a mean 2.8 years follow-up, subjects scored a mean 44.6 on the ASES pain subsection, a mean 41.7 on the ASES function subsection, and an average of 86 for the ASES total score. The improvement in total score was not significant due to the non-significant improvement in the pain subsection. Although the tears were similar in size and our population was older, our study saw statistical significance in improvements for both ASES subsections as well as for the average ASES total score. This divergence may be attributed to the different surgical techniques as arthroscopic repair has shown to improve patient outcomes over open repairs for small tears, but there is conflicting evidence regarding large tears [22,23]. Finally, in a blinded, prospective study recently published by Gilot et al. [10], the authors compared the use of AF-ADM in 20 subjects to a control group of 15 subjects in for the arthroscopic repair of large to massive rotator cuff tears. At a mean 24.9 months follow-up, the AF-ADM group had a significantly higher ASES score of 88.9 compared to the 72.6 reported for the control group. This study had a younger population (oldest patient in mid-60s for both groups) and the average tear size was smaller. Regardless, this study corroborates our findings of ASES score of 86.3 at 24 months, which is particularly notable because our subjects started with a lower baseline ASES score (53.8 vs. 63.8).

One limitation of this study is the lack of a control group. Given the abundance of historical data from other studies using older or alternative techniques, we felt that the documented radiographic and functional outcomes scores could be used by clinicians for comparison. Another limitation is the small subject population. However, this investigation does have the strength of a prospective study, and the subject population is similar enough to that of other studies to be comparable, yet different enough to add to the literature [4,6,24,25]. Finally, in support of transparency, some authors were affiliated with LifeNet Health, the non-profit organization that processes AF-ADM. However, potential bias was minimized by permitting only the clinician investigators to decide whether augmentation was necessary as well as to determine if repairs were successful.

Conclusion

This study supported the findings of previous research on AF-ADM, provided Constant-Murley scores at key time points that have not been previously published, and presented evidence that AF-ADM can successfully repair massive and recurrent rotator cuff tears in older patients. ADM was successfully used in the setting of massive rotator cuff tears to augment rotator cuff defects that remained after margin convergence or in the setting of revision surgery for a failed all suture repair. The results presented here support the use of AF-ADM as a safe and effective option for the treatment of massive and recurrent rotator cuff tears.

Author disclosures

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