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Ultrasound and patient-reported outcomes of rotator cuff repair with new acellular human allograft at 6 months and 1 year post surgery

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Background: Determine the effect of a novel acellular cannulated dermal allograft on tendon-to-bone healing, retear rates, and clinical outcomes over a 12-month period.

Methods: This was a single surgeon prospective nonrandomized case series. Patients with medium sized full-thickness superior and posterosuperior rotator cuff tears, as confirmed by magnetic resonance imaging, were consented. Patients were excluded if they had fatty atrophy indicative of Goutallier grade III or IV. The allograft is a cannulated rectangular prism that has a 5-year shelf life, does not require prehydration, and does not need to be trimmed to size. Outcome metrics included ultrasound assessment at 1-year as well as 6-month patient-reported outcomes (PROs) scores.

Results: 31 patients consented and enrolled in this consecutive cohort series. 9 patients were excluded, and statistical analysis was performed on the remaining 22 patients. There were 9 females and 13 males. The average age was 59.27 ± 7.48 year old. The average supraspinatus short axis measurement in males was 0.56 ± 0.12 cm and 0.52 ± 0.09 cm in females ($P = .44$). The average supraspinatus long axis measurement in males was 0.61 ± 0.18 cm and 0.55 ± 0.14 cm in females ($P = .46$). The average infraspinatus short axis measurement in males was 0.48 ± 0.10 cm and 0.50 ± 0.13 in females ($P = .74$). The average infraspinatus long axis measurement in males was 0.44 ± 0.12 cm and 0.43 ± 0.08 cm in females ($P = .84$). Of the 19 patients who completed baseline and 6-month PRO's, 17 achieved the minimal clinical important difference for American Shoulder and Elbow Surgeons and Patient-Reported Outcomes Measurement Information SystemUE 7a. Retear occurred in 2 cases. The remaining 20 cases have all demonstrated healing or fully healed repairs at their most recent clinical visits with no additional cases of retears.

Conclusion: This study is the first to report the results of a novel acellular dermal allograft for rotator cuff repair augmentation. Satisfactory PRO measures and robust tendon healing at 1 year, as measured by ultrasound, demonstrate the utility of a cannulated human acellular dermal allograft as a viable biologic augmentation device for rotator cuff repair.

Rotator cuff repair (RCR) is one of the most commonly performed orthopedic procedures, with an estimated incidence of 98 per 100,000 people undergoing RCR per year for a total of 200,000 to 300,000 surgically repaired rotator cuffs per year.[9,30] RCR is considered the gold standard treatment for those tears that have failed conservative management due to the high level of patient satisfaction and reliable pain relief following the procedure.[15] Despite the overall success of this procedure; however, the historically cited retear rate is reported to be as high as 94%.[12] Although more recent estimates cite lower retear rates of 11%-57%, the incidence of this complication remains a significant issue.[24,26]

Recently, biologic augmentation in RCR has gained significant interest as a method to reduce retear rates. One such option for biologic augmentation is dermal allografts. Dermal allografts, otherwise known as acellular dermal matrices (ADMs), are acellular extracellular matrices composed primarily of type 1 collagen. Biomechanical and cadaveric studies have demonstrated superior pullout strength and increased load to failure of dermal allografts, therefore presenting dermal allografts as a promising tool for increasing time zero repair integrity.[1,4,5] Furthermore, the extracellular matrix and collagen provide an optimal biologic environment and scaffolding for organized tendon healing. The favorable

University of Cincinnati Institutional Review Board approved this study, IRB ID: 2021-0274.

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outcomes published in biomechanical and cadaveric studies have been replicated in clinical studies, which have demonstrated decreased retear rates and satisfactory patient-reported outcomes (PROs).[2,3]

Classically, the dermal allograft is offered as a sheet of acellular tissue that must be cut to size prior to fixation. This requires accurate measurement prior to application and the placement of multiple anchors for fixation, leading to significant implant waste, longer surgical times, and the placement of separate implants within the graft.[19,29] To address these shortcomings, a new cannulated human acellular dermal allograft has emerged as an alternate iteration to previously used ADM's. This cannulated dermal allograft improves upon previous ADM's in the following ways: 1) it does not need to be trimmed to size, resulting in no wasted tissue, and 2) it is scalable, meaning multiple units can be added in tandem depending on the size of the repair. Additionally, the graft is stored at room temperature, has a 5-year shelf life, and comes ready-to-use as it does not require prehydration. The purpose of this study is to report the results of a consecutive case series of 22 patients who underwent RCR augmentation with a novel cannulated allograft.

Materials and methods

This was a single surgeon prospective nonrandomized case series. Following institutional review board approval, patients with medium sized superior and posterosuperior rotator cuff tears, as confirmed by magnetic resonance imaging (MRI), were recruited for a clinical study to determine the effect of a novel acellular dermal allograft on tendon-to-bone healing, retear rates, and clinical outcomes over a 12-month period. All patients signed informed consent. The inclusion criteria were as follows: patients aged 18 years or older at the time of surgery, repairable medium sized full-thickness superior or posterosuperior rotator cuff tears, as confirmed by MRI, and Goutallier grade I and II. The exclusion criteria included patients who had previous RCR failure, subscapularis disease, fatty atrophy (Goutallier III or IV), tear of the teres minor, tendon retraction >22.2 cm, inflammatory or autoimmune diseases, or signs and symptoms of rotator cuff tear arthropathy. Patients who did not receive successful coverage with the graft intraoperatively were removed from the study. Furthermore, tear properties that were not amendable to transosseous equivalent knotless repair at the time of operation were removed from the study. Outcome metrics included ultrasound (US) assessment of tissue induction (change in tendon thickness), structural changes of the tendon-bone interface, and fatty-infiltration of the muscle belly of the injured tendon as well as 6-month PRO scores.

Dermal scaffold

Dermis-on-Demand (DePuy Synthes, Raynham, MA, USA) is an acellular dermal allograft that promotes ingrowth of fibrous tissue, angiogenesis, and mesenchymal integration. Dermis-on-Demand has a 5-year stable shelf life and can hydrate in vivo and be arthroscopically incorporated into the repair constructs rapidly (30 seconds vs. 1-2 hours with traditional grafts). Multiple allografts of this type can be used to "build" a custom patch that maximizes biological and biomechanical properties based on patients' anatomy.

Surgical technique

The surgical procedures were performed under regional anesthesia in the beach chair position, as described by Gardner et al.[13]

Postoperative care

The use of the dermal implant did not alter the standardized postoperative protocol used for patients undergoing RCRs. Patients followed a standardized physical therapy protocol involving abduction sling for 4 weeks, with supervised rehabilitation commencing two weeks after surgery with formal strengthening allowed at 12 weeks.

Ultrasound assessment

Patients underwent US assessment 12 months postoperatively to evaluate tendon thickness at the repair site, distance between suture anchors, signal intensity of the repaired tendon, and the disappearance of a tear or defect using a Sonosite MTurbo (FUJIFILM Sonosite Inc., Bothell, WA, USA) with 12 Mhz linear transducer. The US was performed by a board-certified physical medicine and rehabilitation physician with a fellowship in sports medicine. US and US-guided procedures are a routine part of his practice. The infraspinatus was evaluated in both the axial and longitudinal views with the shoulder abducted and forearm on the lap (Fig. 1, *A* and *B*). The supraspinatus tendon was evaluated in both axial and longitudinal views with the patients placed in the modified crass position (Fig. 2, *A* and *B*).

Clinical assessment

Clinical assessments and PRO measures included use of the American Shoulder and Elbow Surgeons standardized shoulder assessment form (ASES), Patient-Reported Outcomes Measurement Information System (PROMIS) Upper Extremity[7] (UE7), and RAND Short Form 12 (SF-12), which were administered preoperatively and 6 months postoperatively. The minimal clinical important difference (MCID) used in this study for ASES was 11.1.[10] The MCID used in this study for PROMIS UE7 was 4.87.[17]

Statistical analysis and reporting of data

Each patient from this cohort will be referred to using a case number. There will be a total of 22 cases. Statistical analyses were performed using SPSS (IBM SPSS Statistics for Windows, version 28.0; IBM, Armonk, NY, USA). Paired Student's t-tests were used to compare pre and postoperative PRO scores. Independent samples t-test were used to compare continuous variables between male and female participants. Statistical significance was set as P value <.05.

Results

31 patients consented and were enrolled in this consecutive case series. 8 patients were withdrawn due to not meeting the inclusion criteria upon further review of their imaging, and one patient was withdrawn due to having no baseline or follow-up PRO data collected as well as no US scan performed. A statistical analysis of the remaining 22 patients is summarized below. There were 9 females and 13 males. The average age of this cohort was 59.27 ± 7.48 year old. The average body mass index was 30.99 ± 6.51 kg/m^2. The average time from surgery to US scan was 11.44 ± 2.68 months. The average time from surgery to the most recent clinical follow-up was 11.34 ± 3.42 months.

Ultrasound findings

Ultrasound scans were performed on 18 of the 22 patients at an average of 11.44 ± 2.68 months postoperatively. US was unable to be performed for case 18, 19, 20, and 21. Case 18 moved to a new

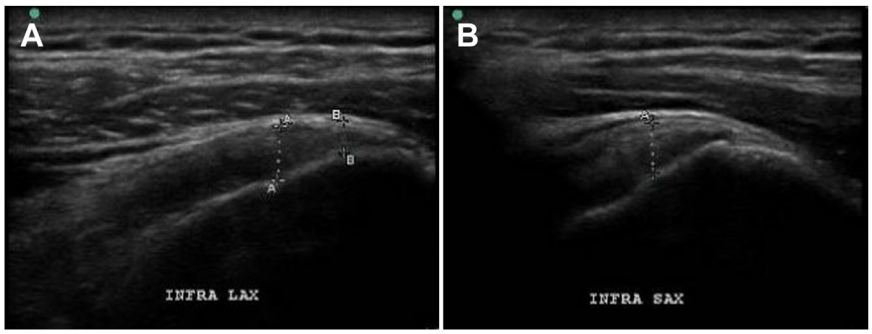

Figure 1 (**A** and **B**) Ultrasound (US) images of the infraspinatus from Case 1. (**A**) US images of the infraspinatus long-axis measurement view from Case 1. (**B**) US images of the infraspinatus short-axis measurement view from Case 1.

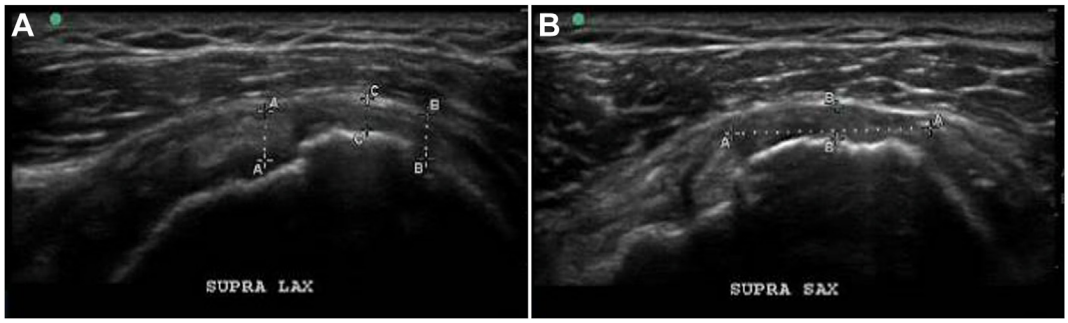

Figure 2 (**A** and **B**) US images of the supraspinatus from Case 1. (**A**) US images of the supraspinatus long-axis measurement view from Case 1. (**B**) US images of the supraspinatus short-axis measurement view from Case 1. *US*, ultrasound.

city. Cases 19 and 20 had a retear prior to the US. Case 21 refused to return to the clinic for a formal study sponsored US.

The following data is for cases 1-17 and case 22. The average supraspinatus short-axis measurement in males was 0.56 ± 0.12 cm and 0.52 ± 0.09 cm in females ($P = .44$). The average supraspinatus long-axis measurement in males was 0.61 ± 0.18 cm and 0.55 ± 0.14 cm in females ($P = .46$). (Table I) 2 of the 18 supraspinatus tendons showed no signs of tendinosis, tendon tear, or fluid collection. 16 supraspinatus tendons demonstrated thickening (Fig. 3, *A* and *B*).

The average infraspinatus short-axis measurement in males was 0.48 ± 0.10 cm and 0.50 ± 0.13 in females ($P = .74$). The average infraspinatus long-axis measurement in males was 0.44 ± 0.12 cm and 0.43 ± 0.08 cm in females ($P = .84$). (Table I) 15 of the 18 infraspinatus tendons showed no signs of tendinosis, tendon tear, or fluid collection. 1 tendon showed signs of slight bursal distention, 1 tendon was associated with superficial fluid collection, and 2 tendons demonstrated thickening.

Table I
Average US measurements of supraspinatus and infraspinatus tendons repaired with dermal allograft.

	Male	Female	*P* value
Supraspinatus average measurement (cm)			
Short axis	0.56 ± 0.12	0.52 ± 0.09	.44
Long axis	0.61 ± 0.18	0.55 ± 0.14	.46
Infraspinatus average measurement (cm)			
Short axis	0.48 ± 0.10	0.50 ± 0.13	.74
Long axis	0.44 ± 0.12	0.43 ± 0.08	.84

US, ultrasound.

Clinical improvement and patient reported outcome scores

Individual patient reported outcome measures (PROMs) are available for cases 1-19. (Table II) The average baseline ASES, PROMIS UE 7a, and SF-12 physical component score (PCS) and mental component score (MCS) were 40.5 ± 17.5, 28.8 ± 7.0, 34.6 ± 6.3, and 52.7 ± 10.3, respectively. The average 6-month ASES, PROMIS UE 7a, and SF-12 PCS and MCS were 80.1 ± 16.3, 45.3 ± 10.5, 48.6 ± 7.5, and 55.8 ± 6.6, respectively. The average difference between the 6-month and baseline ASES scores was 39.6 ± 20.6 ($P < .001$). The average difference between the 6-month and baseline PROMIS UE 7a scores was 16.7 ± 11.0 ($P < .001$). The average difference between the 6-month SF-12 PCS scores was 14.0 ± 10.1 ($P < .001$). The average difference between the 6-month SF-12 MCS scores 3.2 ± 13.5 ($P = .317$). (Table II) 17 of the 19 patients with completed PROs achieved the MCID for ASES. After the removal of ASES scores for the 2 patients who did not achieve the MCID, the average improvement in ASES was 43.2 ± 18.7. 17 of 19 patients with completed PROs achieved the MCID for PROMIS UE 7. After removal of the PROMIS UE 7 scores for the 2 patients who did not achieve the MCID, the average improvement in PROMIS UE 7 was 18.6 ± 10.1 (Table II).

Graft complications

Retear occurred in 2 cases. Case 19 was progressing as planned following the RCR, but at the 5-month postoperative visit the patient reported continued pain and shoulder disability. An MRI was performed on the operative shoulder that revealed a retear of the supraspinatus. The patient then underwent a reverse shoulder arthroplasty. At the most recent follow-up (6 months after the reverse shoulder arthroplasty), the patient was doing well clinically with full range of motion. Case 20 was progressing as planned following the RCR, but at the 4 month-postoperative follow-up, the patient presented to the clinic with acute shoulder pain and disability following a traumatic event. The patient reported having

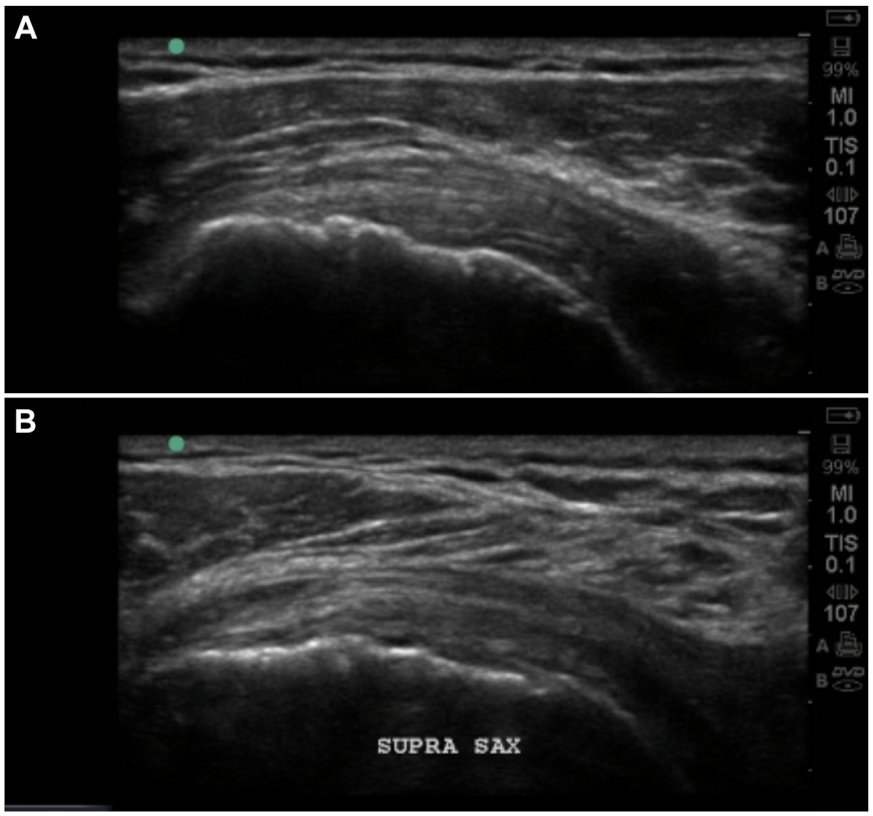

Figure 3 (**A** and **B**) US measurements of supraspinatus tendon demonstrated thickening from Case 13. (**A**) supraspinatus long-axis. (**B**) supraspinatus short-axis. *US*, ultrasound.

the dog leash yanked from the hand on his operative side while walking his dogs. The patient then underwent rotator cuff revision surgery and has had no complications since the revision. The remaining 20 cases have all demonstrated healing or fully healed repairs at their most recent clinic visits with no additional cases of retears.

Discussion

This study is the first to report the results of RCR augmentation with a novel cannulated dermal allograft. The results of this study demonstrate that augmentation of RCR with this allograft results in reconstructed tendon dimensions consistent with physiologically normal literature reported ranges, along with significant improvements in PROMs at 6 months postoperatively. These positive outcomes within this series of patients support the utility of this dermal allograft augment for patients with large rotator cuff tears.

Using US, Kyeongwon et al reported US-derived measurements of the rotator cuff in healthy adults between the ages of 20 and 70. The average supraspinatus thickness in the dominant arm was 5.1 ± 0.8 mm in males and 4.6 ± 0.9 mm in females ($P = .005$), and the average thickness of the infraspinatus tendon in the dominant arm was 4.7 ± 0.6 mm in males and 4.0 ± 0.7 mm in females ($P = .001$).[22] Karthikeyan et al performed a similar study and reported the average supraspinatus thickness to be 5.6 mm in males and 4.9 mm in females, whereas the average infraspinatus thickness was 4.9 mm in males and 4.4 mm in females.[21] Using these values as a reference, our US measurements of the supra and infraspinatus tendons demonstrate that physiologically normal tendon thickness can be expected at roughly 1 year following RCR augmentation with this novel allograft. Furthermore, 16 of the patients demonstrated increased thickening of the supraspinatus tendon, and 2 showed increased thickening of the infraspinatus, therefore suggesting that this allograft promotes an optimal environment for more robust tendon healing. This is consistent with prior clinical and biologic studies published in the literature. For example, studies examining biologic augmentation using a porous bovine collagen implant that showed increased tendon thickness can be expected as early as 3 months postoperatively and persist for up to 2 years.[6,7] This can be explained mechanistically by previous research that has shown revascularization, host cell infiltration, organized collagen fibers, incorporation with surrounding tissue, and minimal inflammatory response following the use of acellular dermal allografts.[16,28]

The PROMs assessed in this cohort reveal robust and significant improvements in clinical outcomes. The average improvement in this cohort's ASES scores (39.6 ± 20.06) at 6 months is well above the MCID (11.1). Only 2 patients within this study cohort did not achieve the ASES MCID; however, these patients still experienced improvement in their ASES scores and met the MCID established in other previously reported literature.[25] Similarly, both the mean improvement in PROMIS UE 7 scores and the number of patients who achieved the MCID for PROMIS UE 7 further underscore the clinical utility of this graft. Furthermore, patients are estimated to have achieved 75%-85% of the ultimate recovery at 6 months post RCR; therefore, it is reasonable to assume continued improvements past the 6-month postoperative visit.[8,14,23]

Our retear rate of 9% after an average follow-up time of roughly 1 year is below the rate of 26.6% reported in a recent meta-analysis, which assessed the retear rate at 2 years.[26] Although the short duration of follow-up and a 29% rate of patients lost to follow-up limit the ability to make definitive conclusions regarding the durability of this graft, our outcomes are promising when considering the fact that the most likely timing for retear is within the first 6 months postoperatively.[18,20,27] One of the retears occurred in a 71-year-old male and was presented as a nontraumatic retear at 5

Table II
Patient-reported outcomes (PROs) (ASES, PROMIS upper extremity 7a, SF-12) at baseline and 6 months post-surgery.

Case	Baseline			6-months			Δ		
	ASES	PROMIS UE 7a	SF-12	ASES	PROMIS UE 7a	SF-12	ASES	PROMIS UE 7a	SF-12
1	43	28.9	PCS: 36.1 MCS: 27.4	93	58.2	PCS: 44.5 MCS: 64.8	50	29.3	PCS: 8.4 MCS: 37.4
2	43	36.4	PCS: 37.8 MCS: 62.6	58	34.8	PCS: 46.2 MCS: 51.0	17	−1.6	PCS: 8.4 MCS: −11.6
3	30	26.8	PCS: 38.1 MCS: 48.4	85	47	PCS: 55.5 MCS: 57.8	55	20.2	PCS: 17.4 MCS: 9.4
4	25	23.8	PCS: 29.2 MCS: 61.3	93	51.1	PCS: 56.6 MCS: 60.8	68	27.3	PCS: 27.4 MCS: −0.5
5	23	23.0	PCS: 29.8 MCS: 66.6	95	58.2	PCS: 56.6 MCS: 57.9	72	35.2	PCS: 26.8 MCS: −8.7
6	53	26.7	PCS: 34.5 MCS: 45.1	78	37.5	PCS: 41.4 MCS: 57.5	25	10.8	PCS: 6.9 MCS: 12.4
7	32	38.2	PCS: 35.4 MCS: 48.0	63	49.7	PCS: 52.4 MCS: 59.1	31	11.5	PCS: 17 MCS: 11.1
8	68	34.8	PCS: 42.4 MCS: 47.6	78	42.4	PCS: 47.4 MCS: 41.3	10	7.6	PCS: 5 MCS: −6.3
9	50	24.6	PCS: 38.8 MCS: 44.2	78	42.7	PCS: 54.2 MCS: 58.8	28	18.1	PCS: 15.4 MCS: 14.6
10	45	19.6	PCS: 35.1 MCS: 36.5	67	27.7	PCS: 28 MCS: 58.5	22	8.1	PCS: −7.1 MCS: 22
11	38	23.5	PCS: 43.5 MCS: 56.7	95	58.2	PCS: 54.2 MCS: 56.0	57	34.7	PCS: 10.7 MCS: −0.7
12	5	23.8	PCS: 37.8 MCS: 62.6	48	31.9	PCS: 46.2 MCS: 51.0	43	8.1	PCS: 8.4 MCS: −11.6
13	58	46.9	PCS: 35.5 MCS: 61.2	85	50.3	PCS: 49.4 MCS: 55.0	27	3.4	PCS: 13.9 MCS: −6.2
14	37	31.4	PCS: 28.7 MCS: 52.0	97	47	PCS: 59.0 MCS: 49.0	60	15.6	PCS: 30.3 MCS: −3
15	35	27.1	PCS: 35.2 MCS: 64.9	90	58.2	PCS: 54.8 MCS: 60.0	55	31.1	PCS: 19.6 MCS: −4.9
16	65	31.2	PCS: 34.1 MCS: 52.1	98	58.2	PCS: 43.7 MCS: 61.0	33	27	PCS: 9.6 MCS: 8.9
17	23	23.4	PCS: 15.1 MCS: 61.7	92	36.3	PCS: 47.5 MCS: 56.3	69	12.9	PCS: 32.4 MCS: −5.4
18	72	32.2	PCS: 40.3 MCS: 47.6	82	42.9	PCS: 44.6 MCS: 64.3	10	10.7	PCS: 4.3 MCS: 16.7
19	25	19.6	PCS: 30.5 MCS: 54.0	47	27.6	PCS: 40.6 MCS: 41.0	22	8.0	PCS: 10.1 MCS: −13.0
Average	*40.5 ± 17.5*	*28.8 ± 7.0*	*PCS: 34.6 ± 6.3* *MCS: 52.7 ± 10.3*	*80.1 ± 16.3*	*45.3 ± 10.5*	*PCS: 48.6 ± 7.5* *MCS: 55.8 ± 6.6*	*39.6 ± 20.6* *(P < .001)*	*16.7 ± 11.0* *(P < .001)*	*PCS: 14.0 ± 10.1 (P < .001)* *MCS: 3.2 ± 13.5 (P = .317)*

ASES, American Shoulder and Elbow Surgeons; *UE*, upper extremity; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *SF*, short form; *PCS*, physical component score; *MCS*, mental component score. Italic values represent the significance is set for $P < .05$.

months post-RCR with persistent pain and disability. Age has been shown to be an independent risk factor for retear following RCR and 1 study of 1600 patients found the retear rate to be 25% in patients aged 70-79 year old.[11] The second case of retear occurred at 4 months following an accidental traumatic event. Following a revision RCR, this patient is doing well clinically and radiographically at 1-year status post-revision RCR.

There are several limitations to this study and the subsequent conclusions. First, the study included a limited number of patients and no control group. This study was designed as a pilot study to determine the safety and feasibility of this graft prior to initiating a larger randomized control clinical trial. Follow-up studies with larger sample sizes and the presence of a control group will be required in order to draw stronger conclusions regarding the efficacy and durability of this graft. Secondly, we only report US findings at 6 months and PROMs at 1 year. Additional US measurements and PROM data up to 2 years would be ideal in order to draw more definitive conclusions.

Conclusions

This study represents the first report of a novel graft for augmentation of RCR. These results demonstrate satisfactory PROMs and robust tendon healing at 1 year as measured by an US. Therefore, this novel acellular cannulated dermal allograft may represent a viable biologic augmentation device for RCR, but additional studies with larger cohorts and longer follow up will be helpful to further define the results of this new graft.

Disclaimers:

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Conflicts of interest: Brian M. Grawe MD is a consultant for DePuy Synthes MITEK. The other authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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