Ultrasound and Outcomes of Rotator Cuff Repair with New Acellular Human Allograft at 6-Months Post-Surgery

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INTRODUCTION: It is known that the repair rate of rotator cuff tears decreases with increasing tear size. Efforts are being made to improve upon the repair rate and produce more consistent results for patients. A new option is to use an acellular human allograft to supplement rotator cuff repair (RCR). This is an FDA-approved implant for use in primary rotator cuff repair, though it is not the standard of practice for orthopaedic surgeons. This allograft is an acellular dermal allograft: a soft tissue allograft developed from donated human tissue that has had all epidermal and dermal cells removed but the remaining bioactive dermal matrix is preserved. By 6-months post-surgery, the allograft is completely absorbed by the body ideally leaving behind a repaired rotator cuff. The study aim is to observe the patient-reported outcomes and level of tendon repair after RCR with this allograft, and in the future compare these to patients undergoing RCR without the allograft through a randomized controlled trial.

METHODS: This is a prospective single-center study aiming to observe the patient-reported outcomes and level of tendon repair after RCR with this allograft. Twenty-six patients with a large rotator cuff tear undergoing rotator cuff repair (RCR) were enrolled in this study. Patient-reported outcomes (via ASES, PROMIS upper extremity 7a, and SF-12 scores) were prospectively collected at baseline and 6 weeks, 3 months, 6 months post-surgery. Within this initial cohort, 10 patients that were 6 months post-surgery had an ultrasound performed of their operative shoulder to visualize the level of repair and integration of allograft. The ultrasound was completed by a board-certified and fellowship-trained physical medicine and rehabilitation physician. Measurements of the supraspinatus and infraspinatus tendons included short axis (both vertical and horizontal measurements) and long axis (both vertical and horizontal). The vertical measurement was the thickest point of the tendon between anchors and the horizontal measurement was the distance between anchors. Measurements were averaged for the cohort. Two sample independent t-tests were conducted to determine if there was a significant improvement from baseline to 6-months post-surgery with the allograft.

RESULTS: Twenty-six total patients had a rotator cuff repair with the acellular human allograft. Ten patients were 6 months post-surgery and had an ultrasound of their operative shoulder performed. Of the patients who underwent ultrasound, the average age was 57.5 ± 7.4 years and 30% were male. The cohort's average supraspinatus and infraspinatus tendon ultrasound measurements were calculated (Table 1). A full 100% of patients had intact supraspinatus and infraspinatus tendons; 40% of patients had minimal distention of subacromial bursa and minimal tendinosis of the supraspinatus. Individual patient-reported outcomes (baseline and 6 months post-surgery) and cohort averages are listed in Table 2. The improvement between baseline and 6-month ASES, PROMIS upper extremity 7a, and SF-12 physical component score (PCS) values were significant; while SF-12 mental component score (MCS) improvement was not significant (Table 2).

DISCUSSION AND CONCLUSION: Our preliminary data of the 10 patients that are 6-months from rotator cuff repair with the acellular human allograft is the beginning of uncovering the utility of this graft in improving rotator tear repair rate. The results thus far are promising, demonstrated by the ultrasound findings and the improvement in patient-reported outcomes compared to pre-surgery. This allograft will be further understood as more patients hit the 6-month post-surgery milestone and undergo ultrasound. These ultrasound measurements can be compared to patients without rotator cuff pathology to uncover how well the allograft aids in restoring a tear to its uninjured state. The future randomized controlled trial will compare the allograft to current standard of practice RCR techniques. The new allograft is a potential resource to improve the repair rate of large rotator cuff tears.

	Supraspinatus				*Infraspinatus*			
	Short Axis – Horizontal	*Short Axis – Vertical*	*Long Axis – Horizontal*	*Long Axis – Vertical*	*Short Axis – Horizontal*	*Short Axis – Vertical*	*Long Axis – Horizontal*	*Long Axis – Vertical*
Average Measurement (cm)	2.48	0.50	2.08	0.49	1.04	0.52	*not measured	0.42

Table 1: Average Ultrasound Measurements of Supraspinatus and Infraspinatus Tendons Repaired with Allograft

Case	*ASES baseline*	*PROMIS UE 7a baseline*	*SF-12 baseline*	*ASES 6-months*	*PROMIS UE 7a 6-months*	*SF-12 6-months*	*Δ ASES*	*Δ PROMIS UE 7a*	*Δ 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	42	36.4	PCS: 37.8 MCS: 62.6	62	34.8	PCS: 46.2 MCS: 51.0	20	-1.6	PCS: 8.4 MCS: -11.6
3	33	26.8	PCS: 38.1 MCS: 48.4	85	47	PCS: 55.5 MCS: 57.8	52	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
Average	*41.4 ± 13.7*	*28.3 ± 6.2*	*PCS: 35.7 ± 4.0* *MCS: 48.8 ± 12.1*	*79.2 ± 12.4*	*44.9 ± 9.9*	*PCS: 48.3 ± 8.9* *MCS: 56.8 ± 6.4*	*37.8 ($p < .00001$)*	*16.6 ($p = 0.0003$)*	*PCS: 12.56 ($p = 0.0007$)* *MCS: 7.98 ($p = 0.0811$)*

Table 2: Patient-Reported Outcomes (ASES, PROMIS upper extremity 7a, SF-12) at Baseline and 6-Months Post-Surgery

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