Title: Clinical and Radiographic Outcomes of Rotator Cuff Repair with Bovine-Derived Scaffolds vs Decellularized Dermal Allografts: A Comparative Retrospective Cohort Study at a Mean Follow-up of 1-Year

Author(s): Kassem Ghayyad MD[1], Roya Khorram MD[1], Jamal Zahir BS[1], Allison Williams MD[1], Olamide Oshikoya MD Pharm D, Daniel Goltz MD, G. Russell Huffman, MD, MPH, FAAOS[1]

Institution(s): [1]Rothman Orthopaedics Florida at AdventHealth, Orlando, FL

Introduction: Rotator Cuff Repair (RCR) failure rates remain high, ranging from 20%-90% depending on tear size and repair technique. To improve healing and reduce retear rates, augmentation strategies have become mainstream, with various biological and synthetic options available. Bovine Derived Collagen Scaffolds (BDS) and Decellularized Dermal Allografts (DDA) are two commonly used augments, however comparative data on their clinical and radiographic outcomes remain limited. The study aims to compare the outcomes of RCR with BDS and DDA. The null hypothesis is that there will no difference in complication and reoperation rates between BDA and DDA cohorts.

Material & Methods: This retrospective cohort study was conducted at a single institution from February 2022 to September 2024. Patients ≥ 18 years old undergoing rotator cuff augmentation using BDS or DDA were included. One hundred thirty-six patients were included in this study (72 BDS and 64 DDA). The mean patient age was approximately 61 ± 10 years with a preponderance of females (51.5%). The mean follow-up time was 20.3 ± 8.9 months. Primary outcome measures, including retear rate, reoperation rate, need for repeat MRI, and need for a postoperative steroid injection, were assessed. Secondary outcomes included patient-reported outcome measures (PROMs), such as the American Shoulder and Elbow Score (ASES), Single Assessment Numeric Evaluation (SANE), and Visual Analog Scale (VAS) pain score. Demographic, clinical, operative, and radiographic data was collected from the electronic medical record (EMR). An a priori power analysis was performed, and the minimum sample size needed to detect a 10% absolute difference in reoperation rates between groups (alpha 0.05; power at 80%), was 40 patients per group. $P \leq 0.05$ was considered significant.

Results & Discussion: Retears occurred exclusively in the BDS group as compared to the DDA group (15.3% vs 0%; p = 0.001). The reoperation rate was also significantly higher in the BDS group compared to the DDA group (20.8% vs 1.6%; p =.001). The need for repeat MRI was significantly greater in the BDS group than in the DDA group (33.3% vs 9.4%; p=.001). The need for postoperative steroid injection was not significantly different between the groups (p = 0.07). Both postoperative ASES and SANE scores indicated good function with no statistically significant differences between the groups (p = 0.17 and p = 0.08, respectively). VAS pain scores were reduced postoperatively in both the BDS and DDA cohorts; however, only the BDS group had statistically significant reductions (p<.001). RCR with DDA results in lower complications and reoperation rates compared to BDS at a mean follow-up of 1-year. However, PROMs were not significantly different between the groups (i.e., ASES, SANE, and VAS). Future research should focus on larger cohorts with longer follow-up times and prospectively collected data.

Table 1. Patient Demographics

Variable	Overall	BDS	DDA	p-value
	(n=136)	(n=72)	(n=64)	0.47
Age (y) (mean ± SD)	61.3 ± 11.0	61.6 ± 10.7	60.9 ± 11.4	0.72
Sex: male (n, %)	66 (48.5)	39 (54.2)	27 (42.2)	0.16
Follow-up (months) (mean ± SD)	20.3 ± 8.9	27.2 ± 4.7	12.6 ± 5.6	**<.001**
BMI: Kg/m^2 (mean ± SD)	29.1 ± 5.8	29.4 ± 5.8	28.8 ± 5.8	0.56
Diabetes (n, %)	22 (16.2)	10 (13.9)	12 (18.8)	0.44
Smoker (n, %)	5 (3.7)	1 (1.4)	4 (6.3)	0.18
Alcohol (n, %)	62 (45.6)	31 (43.1)	31 (48.4)	0.42
Laterality (n, %):				
left	57 (41.9)	30 (41.7)	27 (42.2)	
right	79 (58.1)	42 (58.3)	37 (57.8)	
Traumatic tear (n, %)	73 (53.7)	35 (48.6)	38 (59.4)	0.17
Prior cuff repair (n, %)	27 (19.9)	17 (23.6)	10 (15.6)	0.33
Full Thickness Tear (n, %)	74 (54.4)	39 (54.2)	35 (54.7)	0.86
Partial Thickness Tear (n, %)	58 (42.6)	32 (44.4)	26 (40.6)	0.77
Significant Intratendinous Tendinopathy (n, %)	74 (54.4)	47 (65.3)	27 (42.2)	**<.001**

BMI, Body Mass Index; SD, Standard Deviation; BDS, Bovine-Derived Scaffolds; DDA, Decellularized Dermal Allograft.

Table 2. Postoperative Outcome Data

Variable	Overall	BDS	DDA	p-value
Retear (n, %)	11 (8.1)	11 (15.3)	0 (0)	**0.001**
Reoperation (n, %)	15 (11.0)	14 (19.4)	1 (1.6)	**0.001**
Repeat MRI Required (n, %)	30 (22.1)	24 (33.3)	6 (9.4)	**0.001**
Postoperative Steroid Injection (n, %)	21 (15.4)	15 (20.8)	6 (9.4)	0.07
ASES (mean ± SD)	89.6 ± 13.1	91.9 ± 11.4	86.6 ± 14.80	0.17
SANE (mean ± SD)	82.0 ± 15.5	85.4 ± 13.5	77.4 ± 17.04	0.08

Abbreviations: ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; BDS, Bovine-Derived Scaffolds; DDA, Decellularized Dermal Allograft.

Table 3. Average Time to Reoperation in the BDS Group

Overall (mean ± SD)	8.3 ± 3.2 months
Patch related (mean ± SD)	7.7 ± 3.0 months
Non-patch related (mean ± SD)	9.75 ± 3.59 months

Abbreviations: BDS, Bovine-Derived Scaffolds

Table 4. Average Preoperative vs Postoperative VAS Scores

	Preopoperative	Postoperative	p-value
BDS (mean ± SD)	7.00 ± 2.97	0.49 ± 1.35	**<.001**
DDA (mean ± SD)	6.50 ± 4.95	0.54 ± 1.54	0.31

Abbreviations: VAS, Visual Analog Scale; BDS, Bovine-Derived Scaffolds; DDA, Decellularized Dermal Allograft.

Table 5. Augmentation Types and Augmentation-Related Versus Non-Augmentation-Related Reoperations

Patient Number	Augmentation Type	Reason for Reoperation	Reoperation Related to Augmentation?	Percentage of Reoperations Related to Augmentation
1	BDS	Patch overgrowth	yes	71.40%
2	BDS	Patch migration	yes	
3	BDS	Patch overgrowth	yes	
4	BDS	Patch overgrowth	yes	
5	BDS	Patch overgrowth	yes	
6	BDS	Patch overgrowth	yes	
7	BDS	Patch overgrowth	yes	
8	BDS	Patch migration	yes	
9	BDS	Patch overgrowth	yes	
10	BDS	Patch migration	yes	
11	BDS	Traumatic rotator cuff injury	no	
12	BDS	Worsening rotator cuff arthropathy	no	
13	BDS	Worsening rotator cuff arthropathy	no	
14	BDS	Worsening rotator cuff arthropathy	no	

15	DDA	Distal clavicle excision due to traumatic injury	no	0%

Abbreviations: BDS, Bovine-Derived Scaffolds; DDA, Decellularized Dermal Allograft.

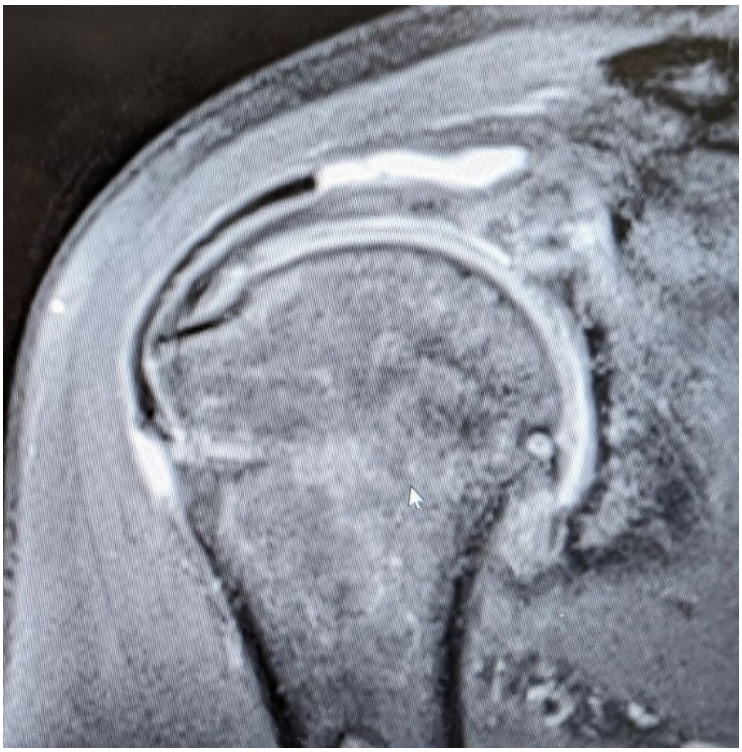

Figure 1. MRI of a patient post RCR with DDA augmentation. After a subsequent fall, imaging demonstrates an AC joint sprain. The graft appears well-incorporated without evidence of tear, retraction, or other complications.

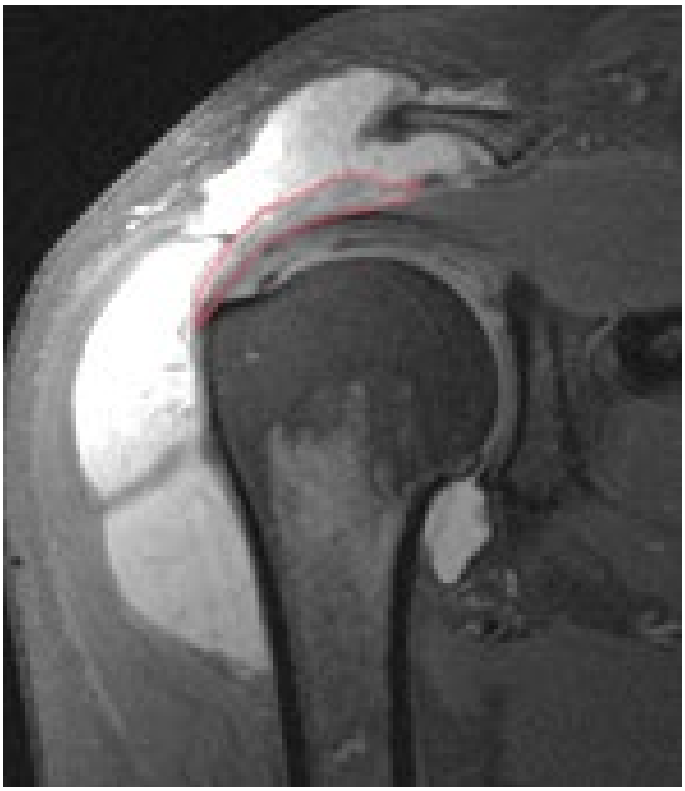

Figure 2. MRI of a patient post RCR with BDS augmentation. Imaging demonstrating markedly reactive subacromial-subdeltoid bursitis. The patient underwent subsequent bursectomy.