Arthroscopic Rotator Cuff Repair with Bioinductive Patch Achieves Equivalent Patient-Reported Outcomes At 1 Year

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INTRODUCTION:

The purpose of this study is to compare patient-reported outcomes, range of motion (ROM), and complications of patients undergoing arthroscopic rotator cuff repair (RCR) augmented with a bovine bioinductive patch compared to standard repair.

METHODS:

A retrospective review of patients undergoing primary arthroscopic rotator cuff repair with and without bioinductive bovine collagen patch augmentation for supraspinatus/infraspinatus tears from 2016 to 2021 at a single institution was performed. Patients were excluded based on the following criteria: age <18 years, open or mini-open rotator cuff repair, prior surgery of the affected shoulder (except diagnostic arthroscopy), rheumatological disease, active infection, or cancer. Patients who underwent rotator cuff repair augmented with collagen patch were matched 1:1 to patients who underwent standard rotator cuff repair based on tear thickness and size. The electronic medical record was used to obtain patient demographics, range of motion (ROM), and assess for complications. MRI or ultrasound was used to confirm tear size and classified using the DeOrio and Cofield classification of small (< 1 cm), medium (1 - 3 cm), large (3 - 5 cm), and massive (> 5 cm). In addition, Patient-Reported Outcome Information System (PROMIS) scores were recorded at preoperative, 6 weeks, 3 months, 6 months, and 1 year postoperative timepoints. These outcomes were compared between the collagen patch and control groups.

RESULTS:

Eighty-one patients underwent RCR with bioinductive patch augmentation and were matched to 162 controls. No significant differences were found between groups in terms of age (57.7 ± 7.9 patch vs. 58.3 ± 9.5 years control; P = 0.63), sex, smoking, diabetes, degenerative vs. traumatic tears, partial vs. full thickness (91.4% vs. 91.4%; P = 1), as well as tear size. Preoperatively, the patch group had increased forward flexion (FF, 143.3 ± 39.2 vs. 127.6 ± 43.1; P < 0.01) and abduction (ABD, 123.0 ± 41.6 vs. 107.0 ± 43.8; P = 0.04), as well as increased FF (156.8 ± 21.6 vs. 148.1 ± 23.2; P < 0.01) and ABD (133.1 ± 33.2 vs. 114.1 ± 36.5; P = 0.01) at 6 months. There were no differences observed in ROM at 1 year. Aside from lower PROMIS-Pain Interference (PI) at 1 year (54.3 ± 8.8 vs. 60.1 ± 9.4; P = 0.049), there were no significant differences observed for PROMIS-Upper Extremity, Depression, or Pain Interference. The patch group had 4 (4.9%) retears compared to 11 (6.8%) controls, P = 0.57. There were 6 (7.4%) patients in the patch augment with adhesive capsulitis compared to 4 (2.5%) control patients, P = 0.07.

DISCUSSION AND CONCLUSION:

Bioinductive patch augmentation for arthroscopic RCR demonstrated equivalent ROM, patient-reported outcomes in terms of pain and function, without differences in retear rate.

Table I. Demographics and tear characteristics

	Control (n = 162)	Patch (n = 81)	*P* - Value
Age	58.3 ± 9.5	57.7 ± 7.9	0.63
Sex			1.0
Male	90 (55.6)	45 (55.6)	
Female	72 (44.4)	36 (44.4)	
Comorbidities			
DM	16 (9.9)	9 (11.1)	0.74
ID-DM	8 (4.9)	1 (1.2)	
Tear Characteristics			
Degenerative	50 (30.9)	34 (42.0)	
Traumatic	62 (38.2)	41 (50.6)	
Unspecified	50 (30.9)	6 (7.4)	
Partial thickness	14 (8.6)	7 (8.6)	1.0
Full thickness	148 (91.4)	74 (91.4)	1.0
Small	12 (8.1)	7 (9.5)	
Medium	55 (37.2)	27 (36.5)	
Large	16 (10.8)	7 (9.5)	
Massive	65 (43.9)	33 (44.5)	

Abbreviations: DM = diabetes mellitus; ID-DM = insulin dependent-diabetes mellitus.
Data depicted as mean ± standard deviation or n (%).

Table II. Active Range of motion

		Control (n = 162)	Patch (n = 81)	*P* – Value
Preoperative				
	FF	128 ± 3.6	143 ± 4.9	**0.002***
	ABD	107 ± 4.8	123 ± 6.1	**0.037***
	ER	51 ± 1.6	53 ± 2.0	0.761
6-week				
	FF	97 ± 5.0	103 ± 8.0	0.931
	ABD	84 ± 7.5	89 ± 8.7	0.721
	ER	35 ± 2.9	33 ± 4.0	0.992
3-month				
	FF	131 ± 2.8	141 ± 3.8	**0.029***
	ABD	110 ± 4.9	122 ± 5.5	0.138
	ER	45 ± 1.6	38 ± 2.3	**0.004***
6-month				
	FF	148 ± 2.5	157 ± 3.2	**0.007***
	ABD	114 ± 4.7	133 ± 6.0	**0.019***
	ER	49 ± 1.9	49 ± 2.5	0.915
1-year				
	FF	152 ± 4.8	158 ± 5.8	0.127
	ABD	125 ± 9.5	140 ± 9.9	0.310
	ER	44 ± 2.8	47 ± 3.1	0.615

Abbreviations: FF = forward flexion; ABD = abduction; ER = external rotation
Data reported as mean ± standard error.
* Indicates P < 0.05.

Table III. Patient Reported Outcomes Up to 1 Year.

		Control (n = 162)	Patch (n = 81)	*P* – Value
Preoperative				
	PROMIS-UE	29.8 ± 0.9	29.0 ± 0.8	0.734
	PROMIS-PI	63.7 ± 1.0	61.7 ± 1.0	0.374
	PROMIS-D	49.2 ± 1.8	46.4 ± 1.6	0.333
10-day				
	VAS score	4.7 ± 0.2	3.8 ± 0.3	**0.013***
6-week				
	VAS score	3.8 ± 0.2	2.7 ± 0.3	**0.006***
	PROMIS-UE	28.5 ± 1.2	27.6 ± 1.0	0.736
	PROMIS-PI	62.0 ± 1.0	61.2 ± 0.8	0.683
	PROMIS-D	47.3 ± 2.5	44.4 ± 1.9	0.791
3-month				
	VAS score	2.8 ± 0.2	2.5 ± 0.3	0.695
	PROMIS-UE	32.7 ± 1.4	34.0 ± 1.2	0.267
	PROMIS-PI	58.2 ± 1.1	58.2 ± 1.0	0.855
	PROMIS-D	48.3 ± 2.4	43.9 ± 1.9	0.428
6-month				
	VAS score	2.1 ± 0.2	2.2 ± 0.3	0.590
	PROMIS-UE	40.1 ± 1.9	39.7 ± 1.6	0.697
	PROMIS-PI	56.1 ± 1.4	56.2 ± 1.1	0.712
	PROMIS-D	42.4 ± 2.5	45.5 ± 1.7	0.304
1-year				
	VAS score	2.9 ± 0.4	1.6 ± 0.5	0.124
	PROMIS-UE	37.1 ± 2.8	38.6 ± 2.3	0.699
	PROMIS-PI	60.1 ± 2.2	54.3 ± 1.9	**0.049***
	PROMIS-D	48.9 ± 5.0	47.0 ± 3.5	0.705

Abbreviations: PROMIS = Patient Reported Outcome Measure Information System; UE = upper extremity; PI = pain interference; D = depression; VAS = visual analog scale.
Data reported as mean ± standard error.
* indicates P < 0.05

Table IV. Complications

	Control (n = 162)	Patch (n = 81)	*P* – Value
Total Complications	20 (12.4)	10 (12.4)	1.0
Re-tear	11 (6.8)	4 (4.9)	0.57
Required Revision RCR	8 (4.9)	3 (3.7)	
Adhesive Capsulitis	4 (2.5)	6 (7.4)	0.07
During 2020-2021	1 (0.6)	5 (6.2)	
CRPS	1 (0.6)	0 (0)	
Persistent pain	1 (0.6)	0 (0)	
Impingement syndrome	1 (0.6)	0 (0)	

Abbreviations: CRPS = complex regional pain syndrome.
Data presented as number (%).