Early Radiologic and Clinical Outcomes After Arthroscopic Rotator Cuff Repair Augmented with Demineralized Bone Fiber Implant

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Disclosures

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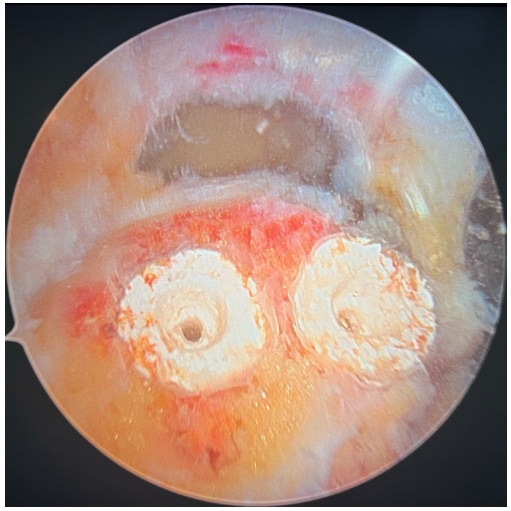
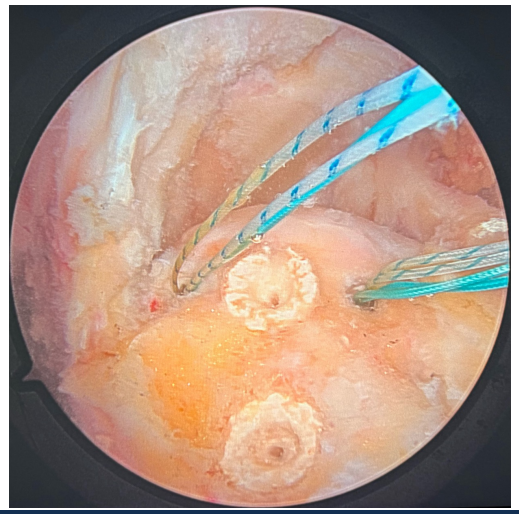
Introduction

- Healing at the enthesis after rotator cuff repair: weak link
- Re-tear rate after repair: can be as high as 94% in massive cuff tears
- **Aim:** To present the early radiological and clinical outcomes after arthroscopic repair of rotator cuff tears augmented with a novel demineralized bone fiber (DBF) implant (Enfix RC™, Tetrous Inc, Los Asngeles, CA) at the footprint





Methods

- Patients who underwent arthroscopic rotator cuff repair with DBF augmentation
- **Comparison group:** patients who did not receive augmentation (matched according to age, sex, tendons involved, degree of retraction, follow-up period)
- **Outcomes**
  - Clinical Outcomes (preop, 6 months, 12 months)
    - Pain
    - Active range of motion
    - Isometric strength of rotator cuff measured by dynamometer
    - PROMs (ASES, Constant score, UCLA)
  - Radiologic outcomes (MRI at 6 months postop)
    - Tendon thickness at footprint
    - Sugaya classification
    - Healing

Results

- 31 patients in each group
- **Mean age:** 54.8 years
- **Mean follow-up:** 8 months
- Majority of patients with **at least 2-tendon tears** with **Patte 2-3 retraction** and **low-grade fatty infiltration** (comparable distribution between the 2 groups)

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Table 1. Preoperative Patient and Rotator Cuff Tear Characteristics

Variables	Augmented Group	Control Group	*p-value*
n	31	31	
Age at surgery, y Mean (SD, range)	54.8 (6.1, 40-65)	54.8 (6.2, 42-64)	p=1.000
Sex (Male : Female)	24 (77.4%) : 7 (22.6%)	23 (74.2%) : 8 (25.8%)	p=0.767
Follow-up time, months Mean (SD, range)	7.8 (3.4, 6-14)	8.4 (3.4, 6-18)	p=0.388
Affected tendons based on Collin Classification			
Type A	1 (3.2%)	1 (3.2%)	p=0.617
Type B	2 (6.5%)	1 (3.2%)	
Type C	6 (19.4%)	4 (12.9%)	
Type D	15 (48.4%)	12 (38.7)	
Type E	2 (6.5%)	6 (19.4%)	
Type B+D§	3 (9.7%)	2 (6.5%)	
Type C+E§	0 (0%)	1 (3.2%)	
Type B+E§	0 (0%)	2 (6.5%)	
Isolated supraspinatus	2 (6.5%)	2 (6.5%)	
Fatty Degeneration*			
SSC			
Goutallier 0-2	10/12 (83.3%)	11/11 (100%)	p=0.478
Goutallier 3-4	2/12 (16.7%)	0/11 (0%)	
SSP			
Goutallier 0-2	27/31 (87.1%)	27/31 (87.1%)	p=1.000
Goutallier 3-4	4/31 (12.9%)	4/31 (12.9%)	
ISP			
Goutallier 0-2	24/26 (92.3%)	25/27 (92.6%)	p=1.000
Goutallier 3-4	2/26 (7.7%)	2/27 (7.4%)	
TM			
Goutallier 0-2	2/2 (100%)	9/9 (100%)	N/A
Goutallier 3-4	0/2 (0%)	0/9 (0%)	
Tendon Retraction			
Patte 1	13 (41.9%)	10 (32.3%)	p=0.662
Patte 2	4 (12.9%)	6 (19.4%)	
Patte 3	14 (45.2%)	15 (48.4%)	

SD, standard deviation; *SSC*, subscapularis; *SSP*, supraspinatus; *ISP*, infraspinatus; *TM*, teres minor.
§Not in the original Collin classification but the types have been combined to depict involved tendons.
*Only includes the ones with tears

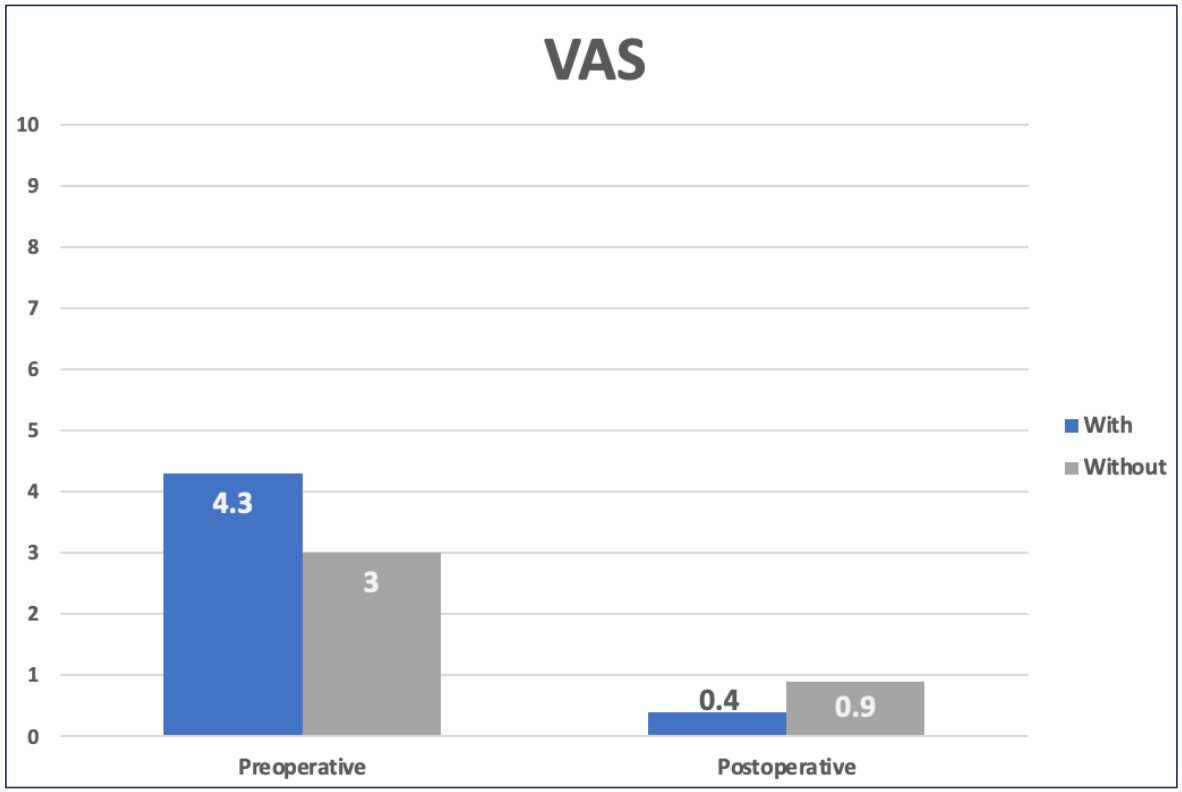
Results

VAS

- Preop and postop pain scores were comparable between the 2 groups

Satisfaction rate

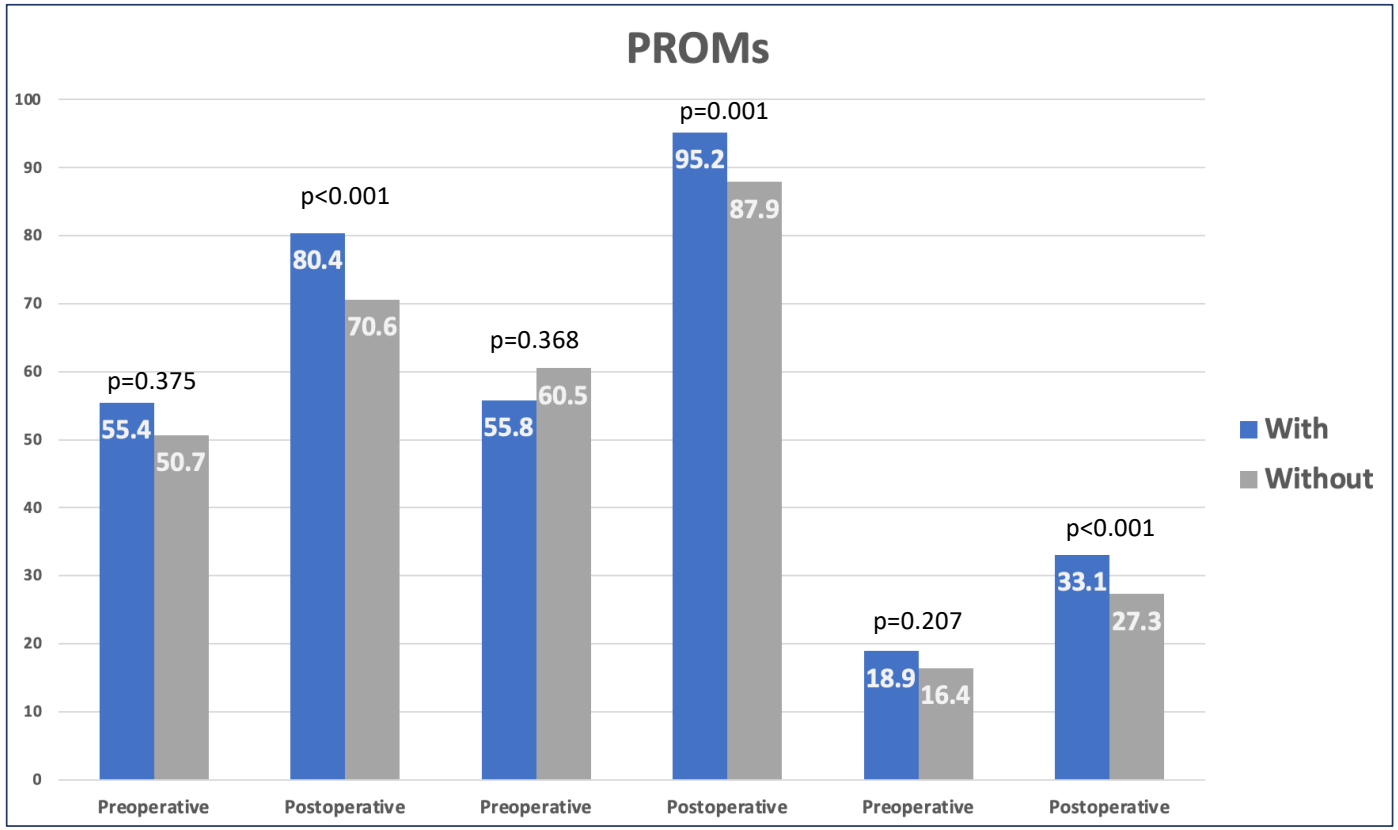
- Comparable between the 2 groups
- 96.8% in augmented group, 90.3% in control group, p=0.612)



*mean f/u = 8 months

Results

- Both groups improved from preop to postop
- **Augmented group** had **significantly higher Constant, ASES, and UCLA scores postoperatively**

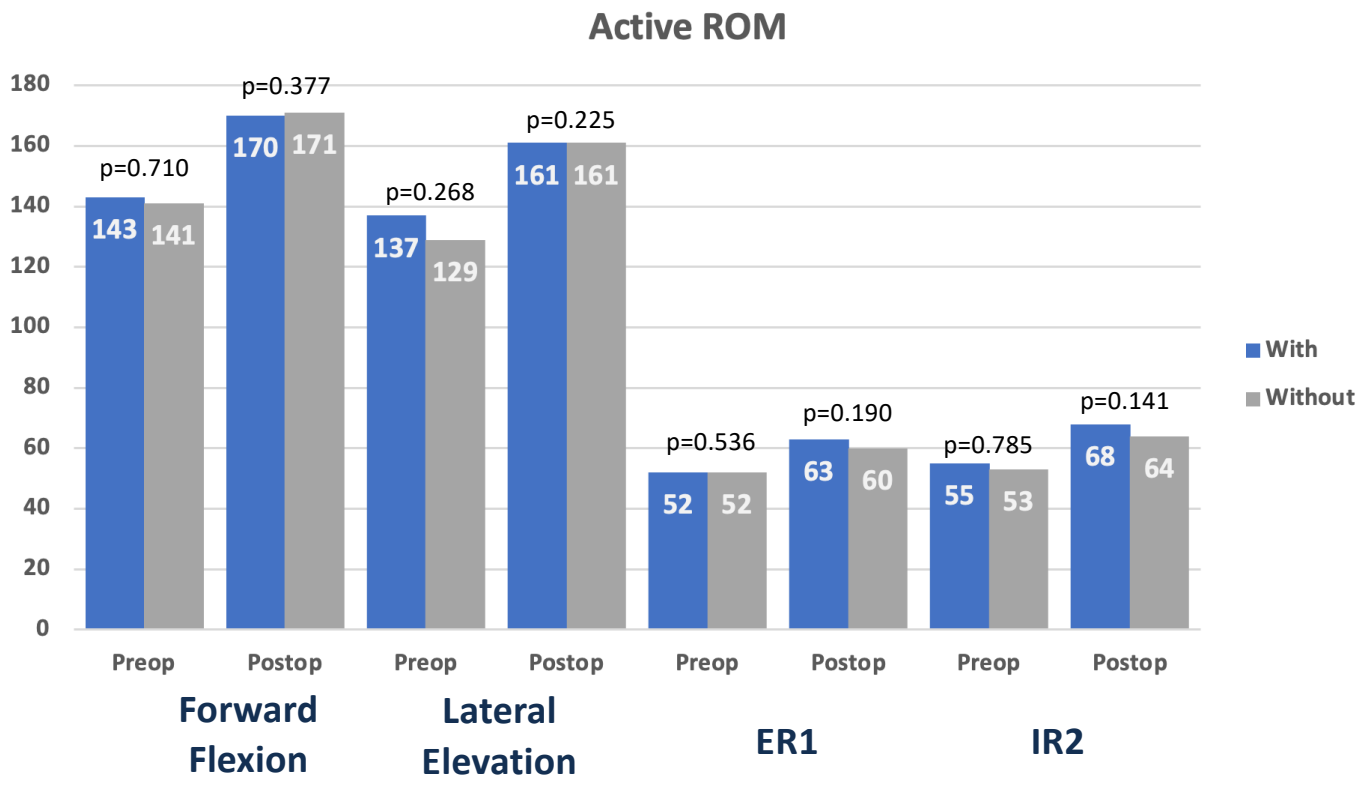


*mean f/u = 8 months

Results

Active ROM

- Both groups had improvement in ROM in all planes
- Preop and postop ROM were comparable in both groups

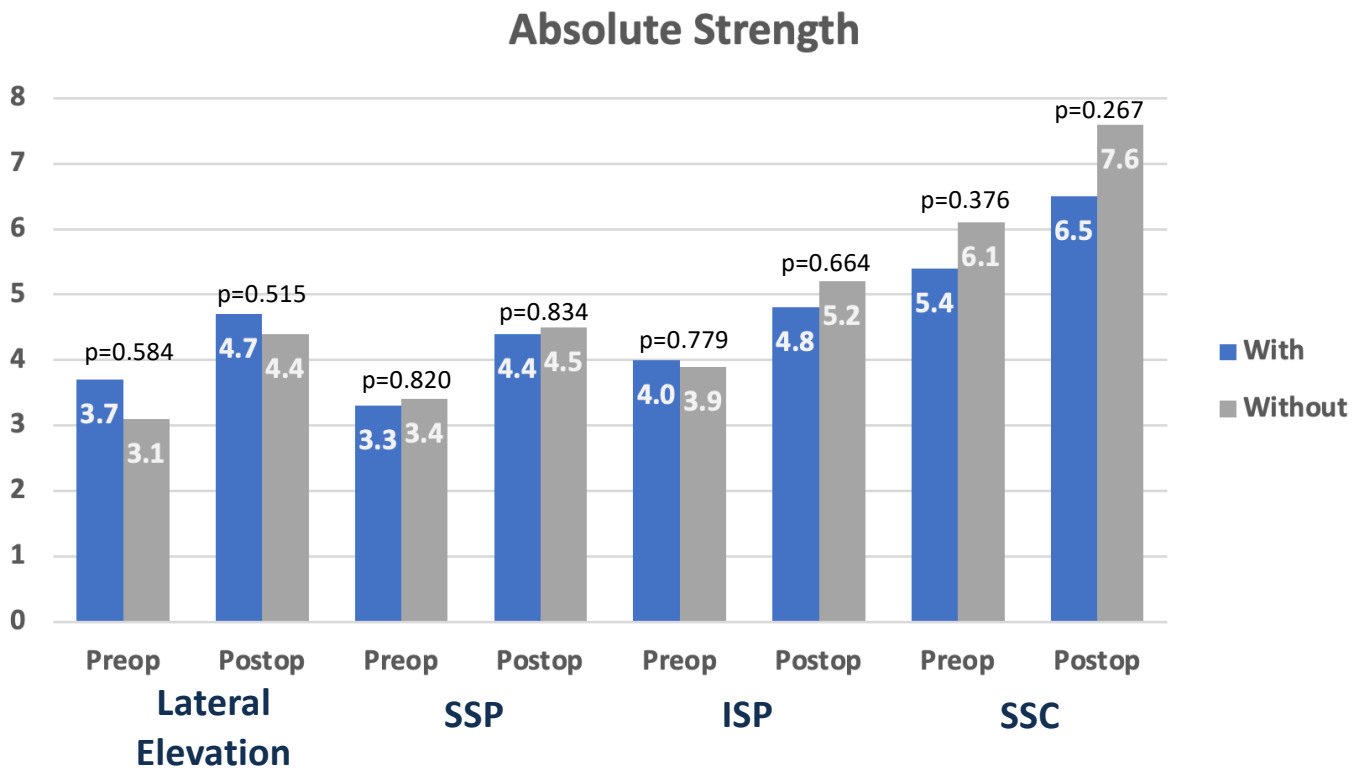


*mean f/u = 8 months

Results

Absolute Strength

- Both groups had improvement strength
- Comparable preop and postop strengths

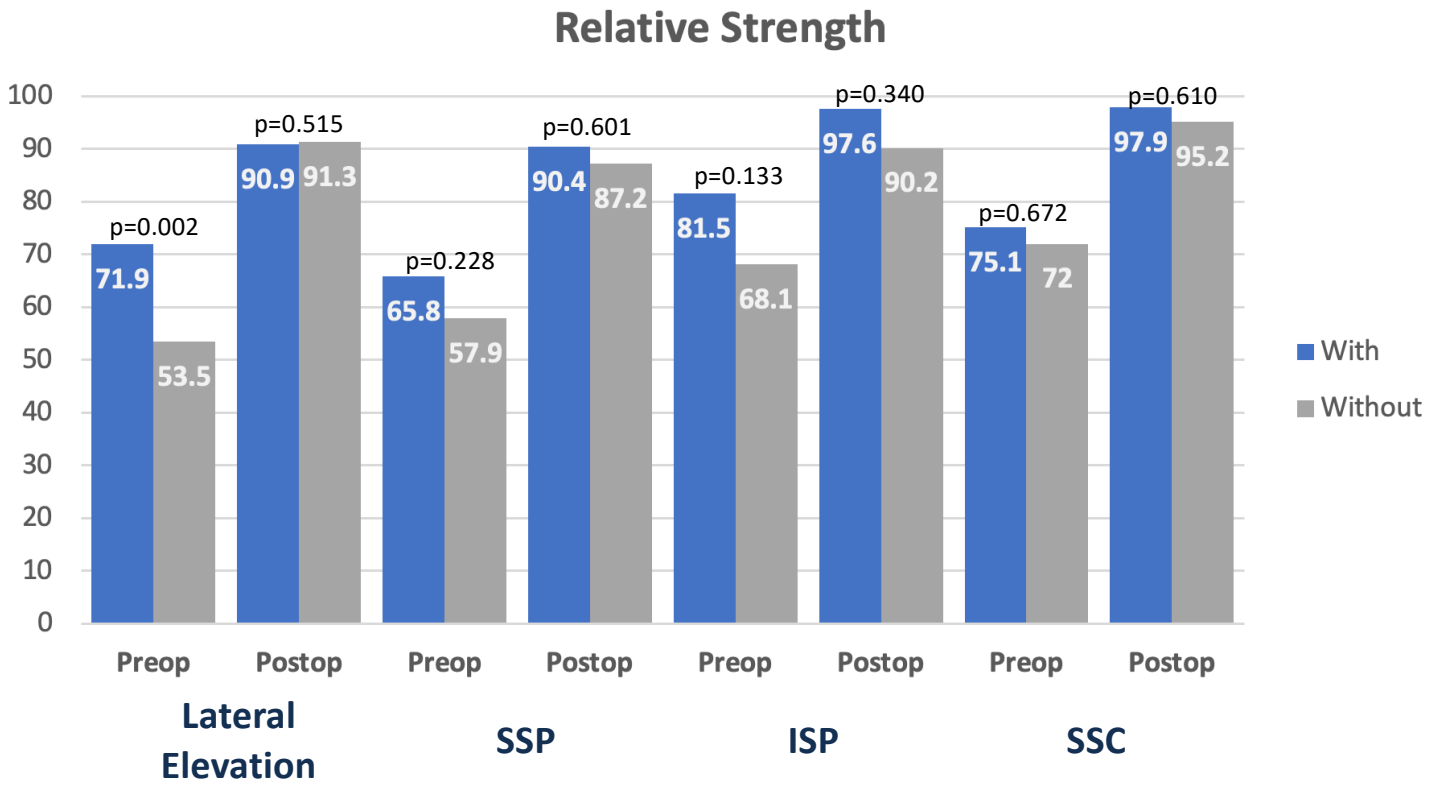


*mean f/u = 8 months

Results

Relative Strength

- Both groups achieved at least 90% strength of contralateral shoulder (except for supra strength in control group)
- Greater improvement in relative strength in augmented group but this was not statistically significant

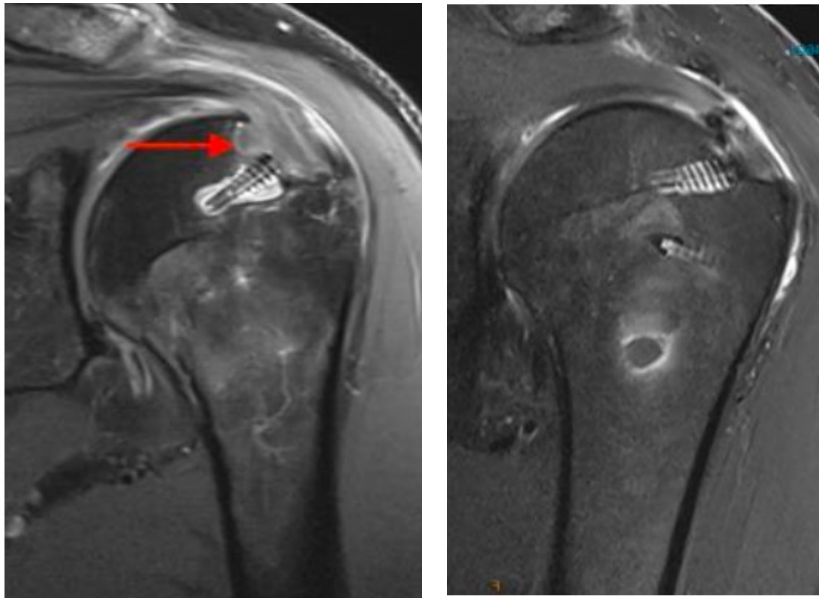


*mean f/u = 8 months

Results

	With	Without	p value
Mean tendon thickness	5.3 mm	4.9mm	p=0.464
Healing	100%	100%	p=0.985
Tendon integrity			
Sugaya 1	3.7%	3.4%	
Sugaya 2	74.1%	72.4%	
Sugaya 3	22.2%	24.1%	
Sugaya 4	0%	0%	
Sugaya 5	0%	0%	

With augmentation **Without augmentation**

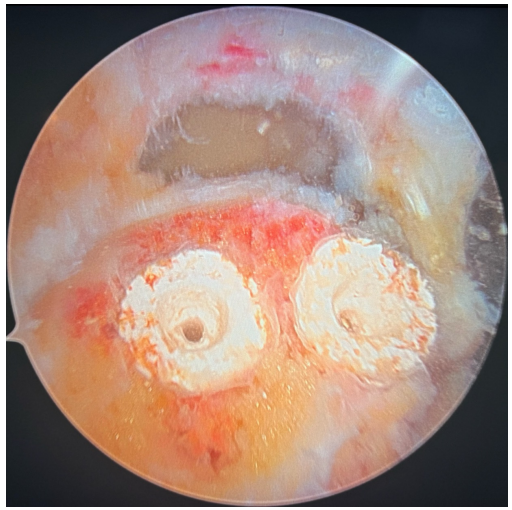


*MRI at 6 months

Discussion

Demineralized Bone Fiber Implant

- Utilizes the biologic potential of DBM but in a form that has better handling characteristics and osteoconductivity, providing ease of use during arthroscopic rotator cuff repairs
- promotes healing and integration at the enthesis following rotator cuff repair through both osteoconductive and osteoinductive properties, and leads to development of a more functional four-zone enthesis with better histological and biomechanical properties



Conclusion

- Although both cohorts demonstrated comparable postoperative outcomes across most variables, the augmented group showed superior postoperative Constant, ASES, and UCLA scores and a trend toward rotator cuff strengths more closely resembling that of the non-operated shoulder at mean follow-up of 9 months
- The findings of this study demonstrates promising early results.
- However, extended follow-up and larger patient cohort is warranted to confirm these short-term outcomes presented in this study.