Rotator Cuff Repair with ArthroFLEX® Augmentation

CASE STUDY

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Rotator Cuff Repair (RCR) has been successfully used to treat massive rotator cuff tears associated with shoulder instability, loss of function, and pain.[1] The procedure involves debriding the damaged tissue and reattaching the tendon to the greater tuberosity of the humerus. However, poor tissue quality of the native tendon can cause repair failures at the suture-tendon junction, and thus requiring revision surgery.[2] In cases of massive rotator cuff tears augmenting the repair with biological patches, such as ArthroFlex, reinforces the suture-tendon interface, increasing the repair strength and restoring function.[1]

ArthroFlex is an acellular dermal extracellular matrix processed with LifeNet Health's patented and validated decellularization technology, Matracell®. The process leaves a biomechanically intact extracellular matrix on which the patient's cells can infiltrate and proliferate.[3] Donor cells and DNA are removed during the process, reducing the possibility of an immunogenic response.[4] ArthroFlex is provided at medical device level sterility, SAL 10^{-6}, and can be stored at room temperature (15°C-30°C).

The following case study presents the use of ArthroFlex to augment the repair of a rotator cuff tear.

Patient

- 71-year-old, female
- No previous surgeries
- No specific injury, progressive pain for one year
- Difficulty reaching out and overhead
- Existing comorbidities: None
- Concomitant Medications: Thyroid hormone replacements and Hydroxychloroquine

Procedure

- Massive RCR with augmentation and extensive debridement
- Massive rotator cuff identified with thinned tissue
- Tissue able to be mobilized to the tuberosity
- ArthroFlex 201: 27 mm A-P, 15 mm M-L
- 4 – 4.75 mm Vented SwiveLock® SpeedBridge® at tuberosity

Outcome

At one year post-op, patient report zero pain and significant improvements in function and range of motion.

See table on the next page for reported outcome measures.

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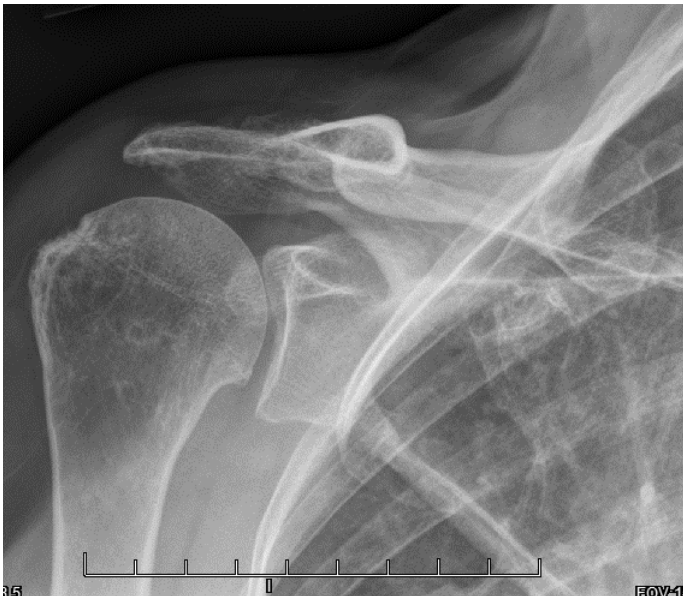
	Pre-op	6 months	12 months
Visual Analogue Scale (VAS)	6	0	0
American Shoulder and Elbow Surgeon Score (ASES)	48	88	83
Flexion active Range of Motion (ROM)	90	110	135



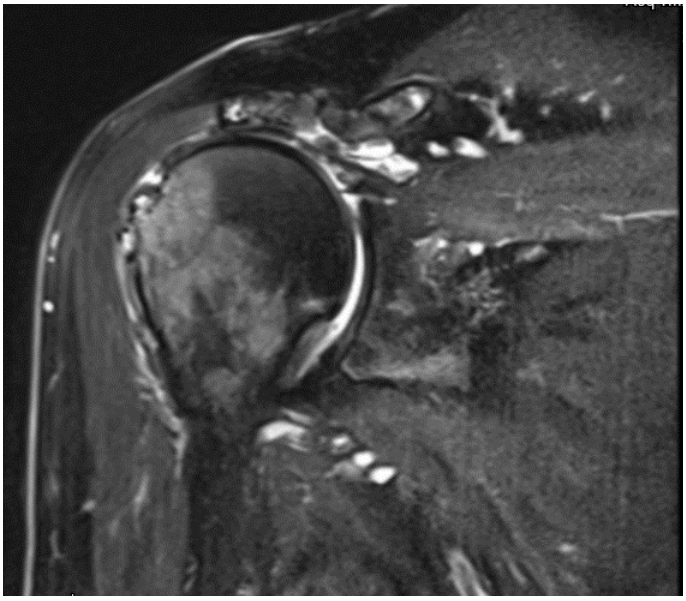


Figure 1. Pre-operative images

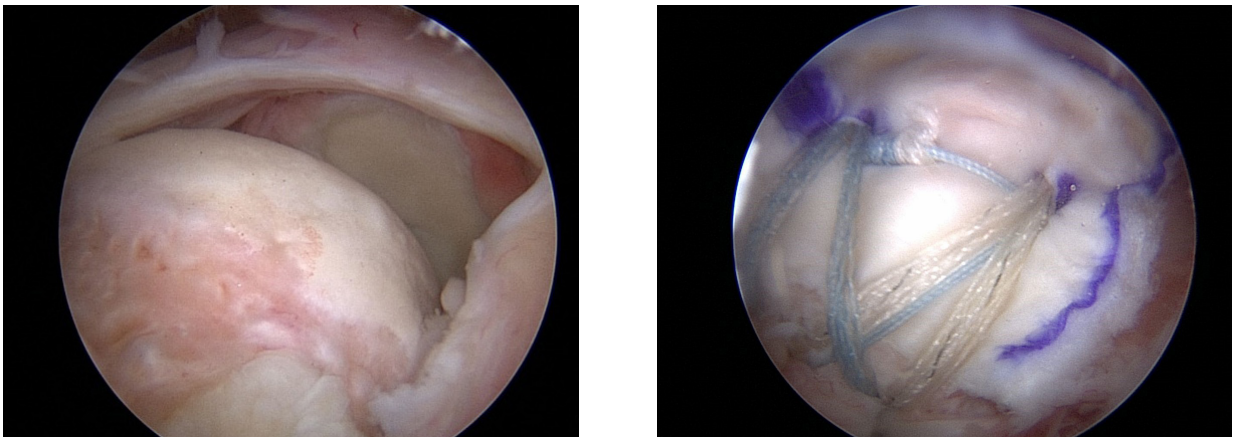


Figure 2. Surgery pictures

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

References

1. Petri M, Warth RJ, Horan MP, Greenspoon JA, Millet PJ. Outcomes after open revision of massive rotator cuff tears with biologic patch augmentation. Arthroscopy. 2016;32(9):1752-1760.
2. Gilot GJ, Alvarez-Pinzon AM, Barcksdale L, Westerdahl D, Krill M, Peck E. Outcomes of large to massive rotator cuff tears repaired with and without extracellular matrix augmentation: a prospective comparative study. Arthroscopy. 2015;31(8):1459-1465.
3. Capito AE, Tholpady SS, Agrawal H, Drake DB, Katz AJ. Evaluation of host tissue integration, revascularization, and cellular infiltration within various dermal substrates. Ann Plast Surg. 2012;68(5):495-500.
4. Crapo PM, Gilbert TW, Badylak SF. An overview of tissue and whole organ decellularization processes. Biomaterials. 2011;32(12):3233-3243.

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