Superior Capsule Reconstruction using ArthroFLEX®

CASE STUDY

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Superior Capsular Reconstruction (SCR) is a surgery intended to restore normal joint biomechanics and stability to the glenohumeral joint. The surgery is used to treat large and irreparable rotator cuff tears and provides an alternative to other treatments, such as reverse total shoulder arthroscopy.[1] Patients with massive rotator cuff tears lose the space between the humeral head and acromion process, which can cause pain and dysfunction when the humeral head displaces superiorly.[1] SCR includes use of a supplemental covering, such as ArthroFlex, to the glenohumeral joint. The supplemental covering helps the humeral head stay centered on the glenoid, restoring the acromial-humeral distance, relieving pain 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 in which the patient's cells can infiltrate and proliferate.[2] Donor cells and DNA are removed during the process, reducing the possibility of an immunogenic response.[3] 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 use of SCR using ArthroFlex for repair of an irreparable rotator cuff tear.

Patient

- 67-year-old, active male
- No previous surgeries
- Goutallier Stage: 2
- Hamada Grade: 2
- Existing Comorbidities: None
- Concomitant Medication: Prostate meds

Procedure

- ArthroFlex 301 – 3.5 mm thickness
- SCR, Biceps Tenodesis, Extensive Debridement, PRP
- Lateral Fixation: 6 – 4.75 mm Vented SwiveLock® SpeedBridge™
- Medial Fixation: 2 – 3.0 mm SutureTak®
- Graft Dimensions: 2.2 (M) x 3.5 (L) x 5.0 (A) x 5.0 (P)
- Anterior & Posterior Margin Convergence

Outcome

At final follow up, the patient is completely satisfied with the outcome. Patient reports no pain and full range of motion. See table on the next page for reported outcome measures.

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	Pre-op	6 months	12 months	24 months
Visual Analogue Scale (VAS)	3	2	2	0
American Shoulder and Elbow Surgeon Score (ASES)	84	80	94	97
Acromial-Humeral Distance (mm)	5.0	6.0	9.0	8.1
Ultrasound - Thickness at Greater Tuberosity (mm)	-	3.71	3.43	5.43
ROM	Full	Full	Full	Full

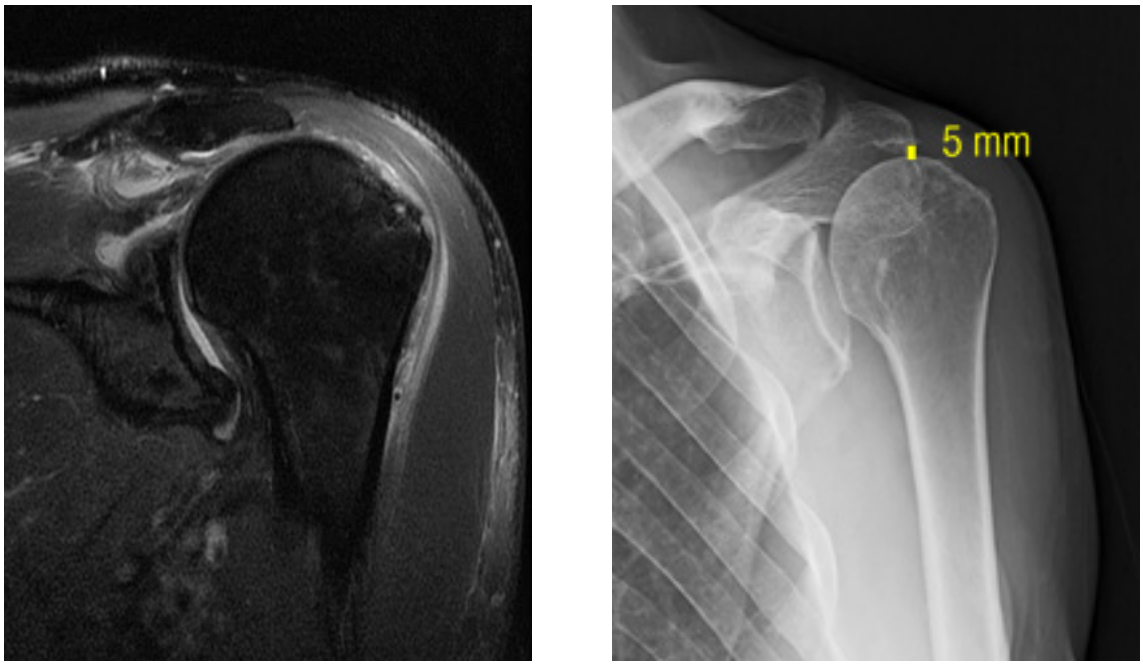

Figure 1. Pre-operative images

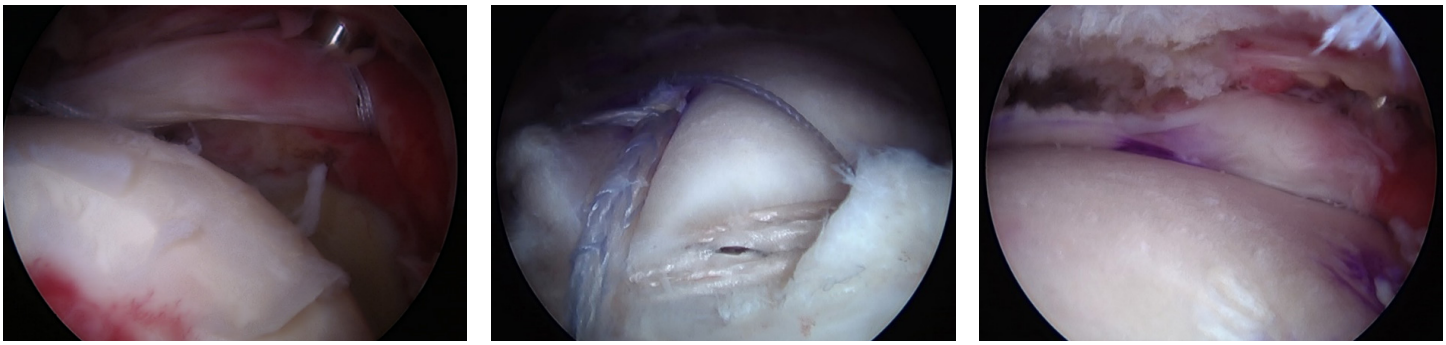

Figure 2. Intra-operative images

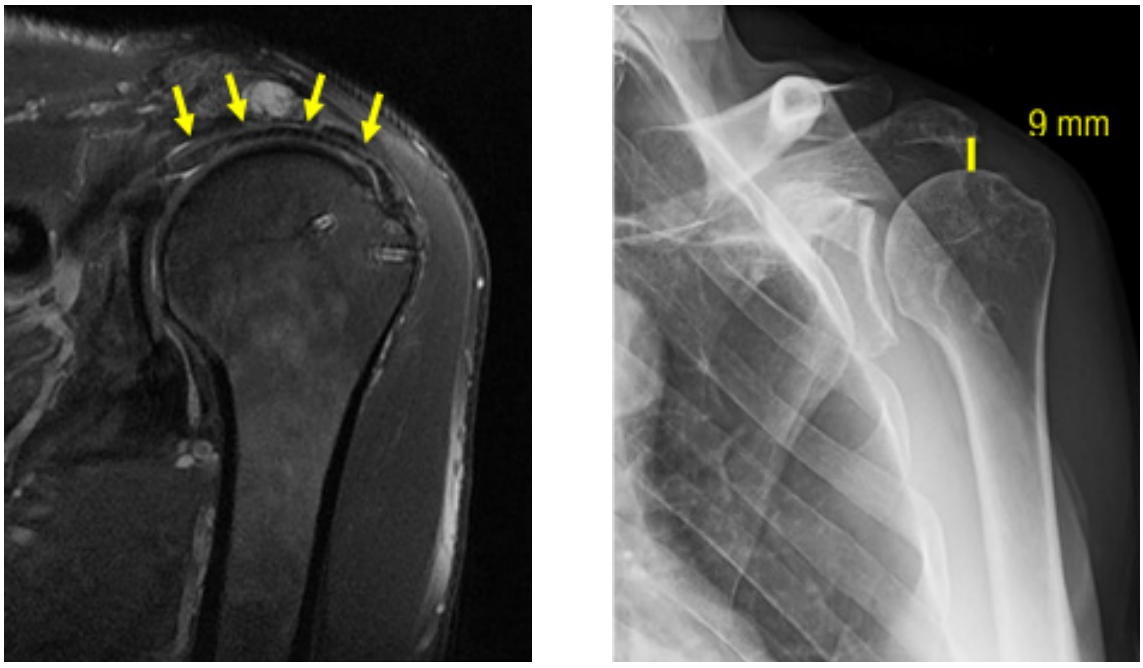

Figure 1. Post-operative imaging at 12 months

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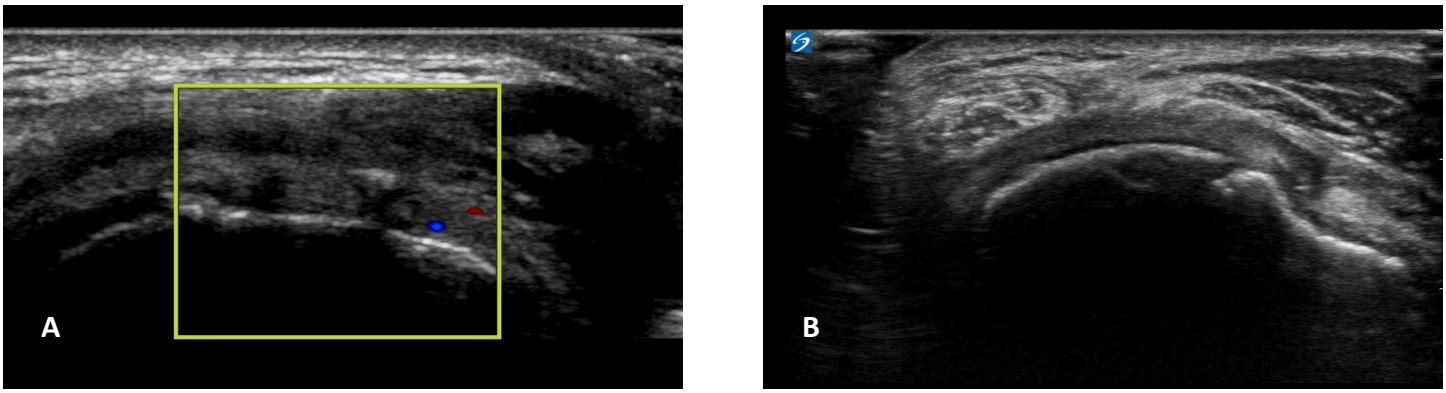

Figure 1. Pulsatile vessels observed in post-operative ultrasound A) 6 months B) 24 months

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

References

1. Hirahara AM, Andersen WJ, Panero AJ. Superior capsular reconstruction: clinical outcomes after minimum 2-Year follow-up. Am J Orthop (Belle Mead NJ). 2017;46(6):266-278.
2. 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.
3. 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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