

# Biological Incorporation of ArthroFlex® in Superior Capsular Reconstruction for Irreparable Rotator Cuff Repair

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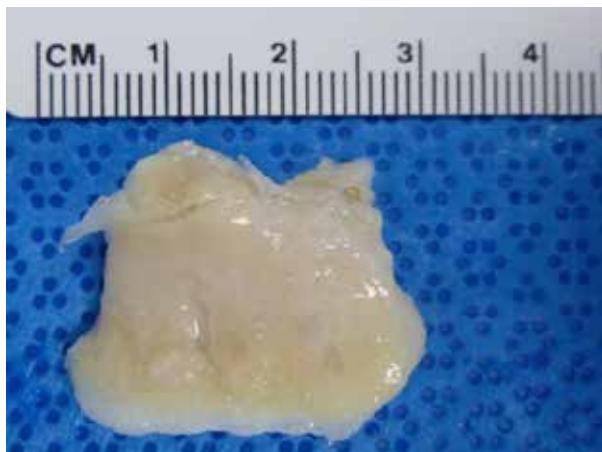
BIO-IMPLANT BRIEF

## Introduction

Tendon augmentation using human acellular dermal matrix (ADM) has become an attractive option for the repair of difficult to heal rotator cuff tears, especially massive tears ( $> 5$  cm) and revision procedures. ADMs are decellularized using a process that eliminates potentially immunogenic components and offers a biocompatible scaffold which allows integration by host cells.<sup>1</sup> One ADM, ArthroFlex, has demonstrated previous success in rotator cuff repair (RCR) studies<sup>2,3</sup> and is now being used in a new technique for massive, irreparable RCRs called superior capsular reconstruction (SCR). The Matracell® process effectively decellularizes the dermal tissue scaffold, as demonstrated by removal of  $\geq 97\%$  of the host residual DNA and the ADM is also provided fully hydrated and shelf-stable at ambient temperature via Preservon®.<sup>4</sup> Additionally, ArthroFlex is terminally sterilized using low dose gamma irradiation to a sterility assurance level (SAL) of  $10^{-6}$ ,<sup>4</sup> the level recommended by the CDC for products that come in contact with compromised tissue such as in a surgical site.<sup>5</sup>

While ArthroFlex has demonstrated an excellent record of successful RCRs<sup>3</sup>, there is a lack of detailed histology from human implants covering the mechanism of incorporation. This case study provides a histology analysis of an ArthroFlex explant from a patient who underwent the SCR technique.

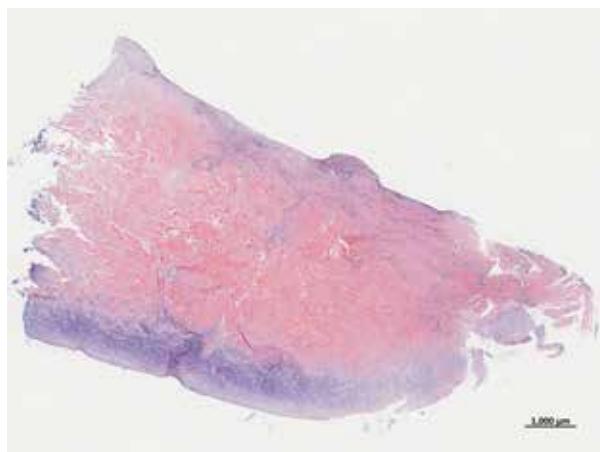
**Figure 1:** View of bursal (superior) surface of explanted ArthroFlex. Glenoid attachment is closest to ruler.



## Case Notes

After four failed shoulder surgeries, including one failed revision RCR in 2009, this patient underwent SCR with ArthroFlex augmentation in 2015. They sustained a shoulder injury during a fall 10 weeks post-operative, and MRIs showed repair failure — suspected to be a result of the fall — at six months and 12 months post-operative. The graft was explanted during a debridement surgery 13 months post-op, sent to LifeNet Health courtesy of Dr. Lederman and prepared for histological analysis (Figure 1).

**Figure 2:** Cross-sectional view of quarter 1. Medial glenoid attachment is to the right, articular side is at the bottom of the image.



## Histological Analysis

The explant sample was dissected to four quarters via the mid-line, formalin-fixed, paraffin-embedded, cross-sectioned, and stained with hematoxylin and eosin (H&E) for analysis. Histological analysis showed that ArthroFlex maintained the acellular dermal matrix structure for about 80% of explanted tissue (Figure 2). Infiltrated fibroblast-like cells and neovascularization were most located at the edges (Figure 3 and Figure 4). The center of the ArthroFlex tissue remained acellular and avascular, while no signs of necrosis or calcification were observed. Tendon-like tissue structure was found near the glenoid attachment point (Figure 5). Fibrocartilage-like tissue was observed at the edges of the explanted graft on the articular side towards the patient's own cartilage (Figure 6).

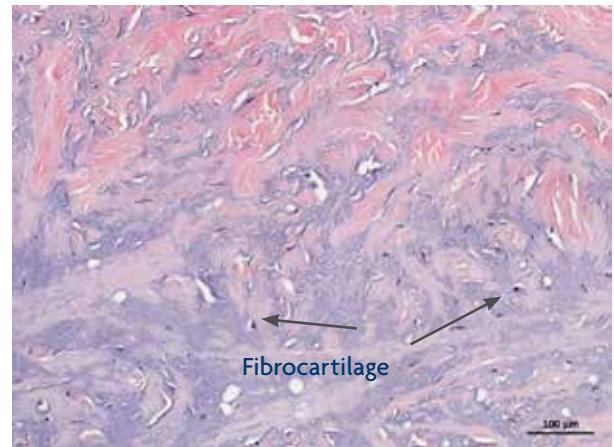
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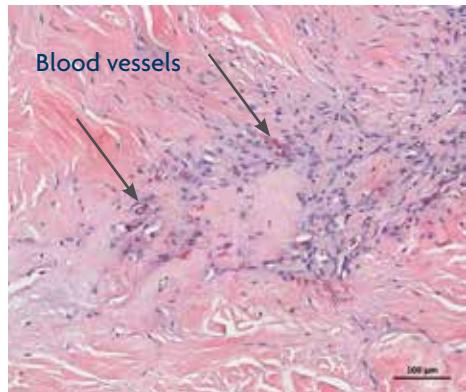
## Discussion

Published studies, using a rodent implant model, show that Matracell-treated dermis has greater cellular infiltration and blood vessel counts at the 7, 21, and 42 day time points compared to other commercially available ADMs.<sup>6</sup> Additionally, a more favorable M1/M2 ratio was found in the Matracell-treated dermis suggesting a more constructive tissue remodeling ability.<sup>7</sup> Although arthroscopic SCR has the advantage of restoring the force couples required for active shoulder function, this technique is relatively new and outcome information is helpful in further evaluating its effectiveness.<sup>8</sup> The fibroblast infiltration, neovascularization and tissue remodeling seen here demonstrated that ArthroFlex can adapt to the local environment and have good incorporation following SCR.

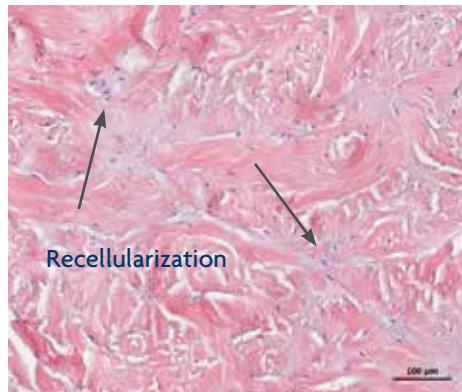
**Figure 6: Identified fibrocartilage on explanted ArthroFlex.**



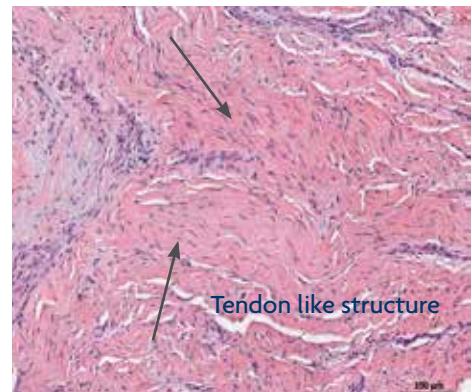
**Figure 3: Abundant blood vessel formation on explanted ArthroFlex.**



**Figure 4: Recellularization observed on explanted ArthroFlex.**



**Figure 5: Tendon-like structures noted on explanted ArthroFlex.**



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\* Dr. Evan Lederman is a paid consultant of Arthrex, Inc.