Tissue-Engineered Augmentation of a Rotator Cuff Tendon Using a Novel Reinforced Bioinductive Implant: A Preliminary Study In Sheep

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Introduction

Surgical repair of torn rotator cuff tendons has been associated with a high degree of re-tears. Recent studies have shown that augmenting the repair through the induction of new host tissue can prevent gapping or re-tears by increasing the thickness of the tendon. This study investigated the ability of a novel, reinforced bioinductive (high porosity collagen with PLLA microfilaments) implant to support the rapid proliferation, maturation, and remodeling of new host tissue in an animal model of rotator cuff tendon repair. The reinforced bioinductive implant was hypothesized to rapidly increase the thickness of the repaired tendon through the addition of functional host tissue.

Methods

The porosity of the reinforced bioinductive (collagen-PLLA) implant (BioBrace®, CONMED) was measured using mercury porosimetry. Arthroscopic surgical technique of an augmented rotator cuff repair was evaluated using human cadaveric shoulders. Following Institutional Animal Care and Use Committee approval, a mid-portion detachment of the infraspinatus tendon (IST) was created and repaired in 18 sheep using a double row suture bridge, and augmented using the reinforced bioinductive implant, mimicking human cadaveric technique. Nine animals were humanely euthanized at either 6 or 12 weeks for radiography, micro-computed tomography, MRI, histology, or biomechanical testing.

Results

Mercury Porosimetry: The reinforced bioinductive implant had an average porosity of 80%, median pore diameter of 19.4 micron, and pore volume of 4.2 cm3/gram. *Surgical Technique:* The BioBrace® could be introduced into the joint arthroscopically and incorporated using a double row suture bridge (**Fig. 1A**). *Imaging* (T2 MRI): The mean thickness in the IST (**Fig. 1B** arrow) of non-operated animals was 3.5 mm while the mean thickness of the repaired ISTs was 10.0 mm at six weeks and 9.8 mm at twelve weeks (**Fig. 1C/D**). *Histology:* At six weeks the BioBrace® was infiltrated by host fibroblasts and fibrovascular tissue. Dense, regularly oriented connective tissue was also observed on the superior and inferior surfaces of the BioBrace® which added to the overall thickness of the healing tendon (**Fig. 2A**). By 12 weeks there was maturation and remodeling of the fibrovascular connective tissue within the BioBrace® as well as on its inferior and superior surfaces (**Fig. 2B**). Scattered foreign body giant cells (arrows) were observed at both 6 and 12 weeks and were associated with the PLLA fibers (**Fig. 2C**). *Mechanical testing:* The ultimate tensile strength (UTS) of the repaired IST construct significantly increased between 0 (1163 ± 303N) and 6 weeks (1740 ± 338N) (p=0.01), and 6 (1740 ± 338N) and 12 weeks (2463 ±484N) (p=0.01) (**Fig. 2D**). There was no significant

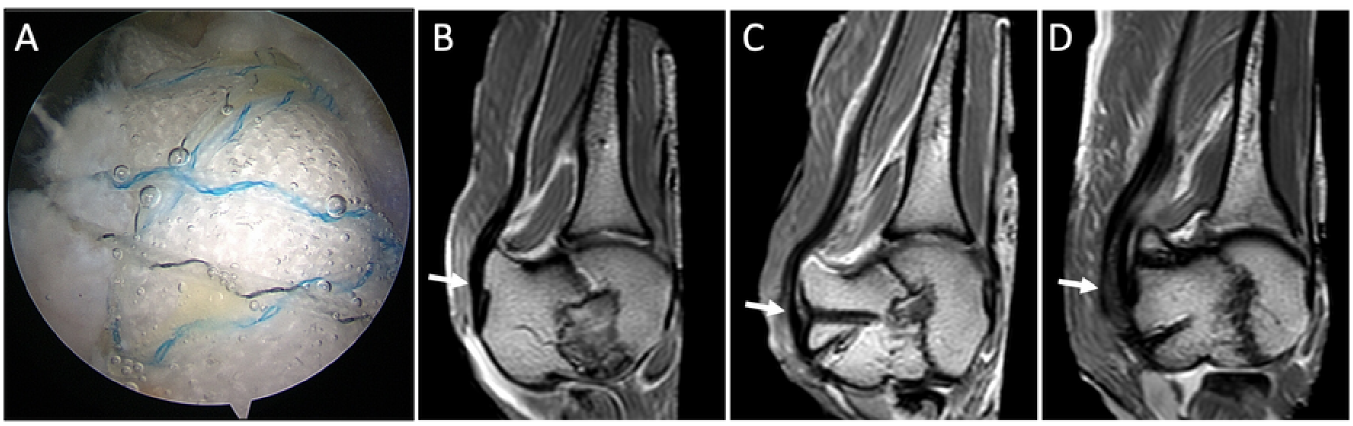

Figure 1. *Arthroscopic image of augmented repair (**A**), T2 MRI imaging of ISTs (arrows) on non-operated (**B**), 6 weeks post-op (**C**), 12 weeks post-op (**D**).*

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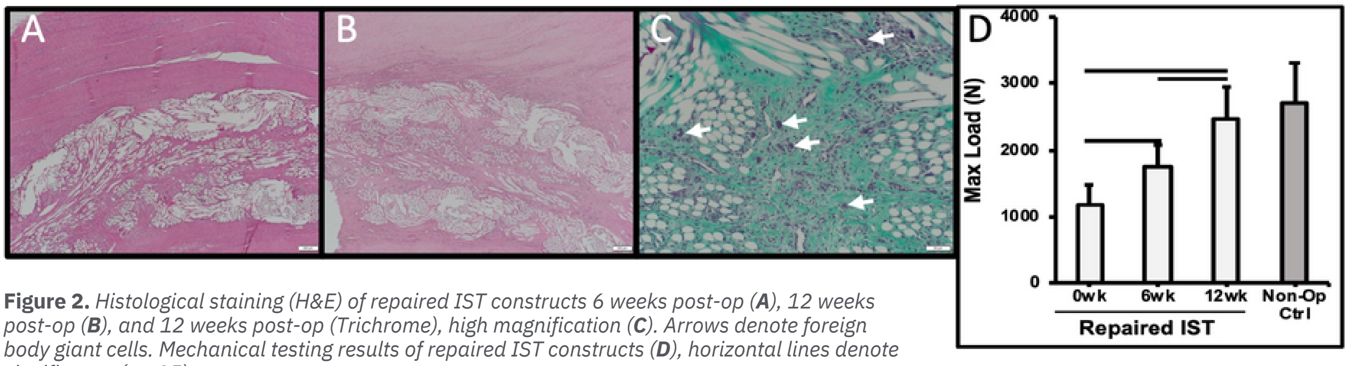

Figure 2. *Histological staining (H&E) of repaired IST constructs 6 weeks post-op (**A**), 12 weeks post-op (**B**), and 12 weeks post-op (Trichrome), high magnification (**C**). Arrows denote foreign body giant cells. Mechanical testing results of repaired IST constructs (**D**), horizontal lines denote significance (p<.05)*

difference in UTS between repaired (2463 ± 484N) and contralateral control tendons (2707 ± 605N) at 12 weeks (p=0.35) (**Fig. 2D**).

Discussion

The collagen-PLLA reinforced bioinductive implant increased the thickness of a repaired rotator cuff tendon through the rapid induction of host-generated dense, regularly-oriented connective tissue. The new host tissue demonstrated functional remodeling over time resulting in a repair that was as strong as the unoperated control by 12 weeks.

Significance/Clinical Relevance

Healing of rotator cuff repairs has been a challenging clinical problem. In addition, functional outcomes are improved with integrity of the rotator cuff after repair. This study shows that a reinforced bioinductive implant induced a proliferative healing response that improved the thickness of the repair tissue, and was as strong as controls. This has strong potential as an adjunct for rotator cuff repair.

This abstract or variations thereof was or will be presented at the following conferences: Rocco et al. Biologic Scaffolds for Regenerative Medicine 11th Symposium 2021 (Podium)
Kanski et al. OSET 2020 (Podium, Awarded Best *Science Paper*)
Walsh et al. ORS 2021 (Podium)
Carter et al. AAOS 2021 (Accepted, Poster)
Rocco et al. Military Health System Research Symposium 2021 (Accepted, Poster)

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