

Clinical Summary

Augmentation of a rotator cuff tendon repair using a bioinductive biocomposite scaffold in an ovine infraspinatus model

Authors: William R. Walsh, PhD, Joaquin Batista, MS, Vedran Lovric, PhD, James D. Crowley, BVS, Dan Wills, BVSc, PhD, Andrew J. Carter, PhD, Tian Wang, PhD, Robert Stanton, MD, Kevin Rocco, MS, and Robert Arciero, MD

Journal: Journal of Shoulder and Elbow Surgery



Aim:

To assess the short- and long-term performance of the BioBrace® Reinforced Bioinductive Implant in supporting rapid proliferation, maturation and remodeling of new host tissue in a large-animal rotator cuff repair model.

Method:

- **Model:** Full-thickness infraspinatus tears were surgically created and repaired in 25 sheep
- **Repair technique:** Double-row suture bridge technique with scaffold augmentation
- **Assessments:**
 - » Scaffold Characterization: SEM, MIP, and tensile testing at time zero (n=3, n=3, and n=6, respectively)
 - » Histology & MRI: Performed at 6, 12, 26, and 52 weeks (n=3 per timepoint)
 - » Mechanical Testing: Conducted at 6 and 12 weeks (n=7 and n=6, respectively)

Results:

- **Scaffold Characterization:**
 - » SEM showed a continuous, highly porous collagen matrix integrated with PLLA microfilaments
 - » Mercury intrusion porosimetry revealed $81\% \pm 3\%$ porosity, an average pore diameter of $\sim 20 \mu\text{m}$, and pore metrics consistent with a well-defined, interconnected pore network optimized for tissue ingrowth
 - » Tensile testing revealed $516 \pm 10.2 \text{ N}$ strength and $75.5 \pm 5.7 \text{ N/mm}$ stiffness for the 23mm wide implant when hydrated, demonstrating robust handling characteristics
- **Histological Analysis:**
 - » The BioBrace implant facilitated new tissue growth within, above, and below the scaffold as early as 6 weeks, confirming BioBrace is bioinductive
 - » Continued tissue remodeling and maturation was observed through 52 weeks (1 year post-op), with no adverse reactions.
 - » Enthesis healing improved over time, demonstrating tendon-to-bone integration with the appearance of Sharpey-like fibers at the entheses

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- **MRI Analysis:**
 - » BioBrace-augmented repairs exhibited a 180% increase in tendon thickness at all time points, compared with the nonoperative control, further confirming bioinductivity
 - No evidence of inflammation or adverse reaction to the BioBrace implant at any timepoint
- **Mechanical Analysis:**
 - » Mechanical strength of the BioBrace-augmented repairs increased significantly between 0, 6 and 12 weeks indicating that the new tissue is functional tissue
 - » At 12 weeks, augmented repairs reached strength levels comparable to non-operated controls

Key Takeaways:

- The BioBrace implant delivers both mechanical reinforcement and biologic augmentation through the induction of new, thicker, regularly oriented connective tissue
- The BioBrace implant has a functional porosity that enables cellular ingrowth and tissue regeneration within the scaffold
- The BioBrace implant is bioinductive, it induces new tissue generation, resulting in an increase in tendon thickness. Thicker tendon tissue is thought to lead to a reduction in retear rates.
- BioBrace augmented repairs demonstrated significant strength improvements over time and achieved native-tendon-level
- No long term inflammatory response or adverse reaction to the BioBrace implant was observed. strength by 12 weeks. This indicates that the new tissue induced by BioBrace is functional and aligned tissue.