

Thomas Koob PhD, Rebecca Brown PhD  
 MiMedx Group, 811 Livingston Ct. SE, Suite B, Marietta, GA 30067

## Introduction

CollaFix products are composed of high-strength, absorbable, biocompatible, cross-linked collagen fibers. The fiber can be woven, knit, spun, braided, etc into various geometries tailored for various surgical procedures and native tissues. Animal studies have shown that a braided collagen-fiber construct would provide an ideal product for the repair of gapped tendons due to the nature of the collagen fibers:

- Strength (approx 2x that of equivalent human tendon of same cross-sectional area)
- Provides a scaffold for native tenocyte proliferation
- Shares the repair load so fibrous repair will re-model into true tendon
- Biocompatible
- Cross-linking ensures CollaFix fibers remain in-vivo throughout the tissue repair process

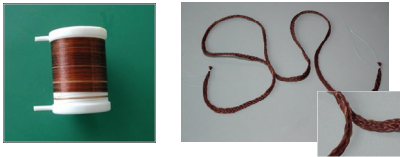


Figure 1. CollaFix Fiber & CollaFix BioBraid

The objective of this study is to provide a “proof of concept” for the CollaFix BioBraid products as a tendon repair augment in a gap Achilles tendon in a sheep model. Tissue in-growth into the device will be assessed by gross visual assessment and cellular in-growth histologically in the defect area.

## Materials and Methods

Seven skeletally mature sheep were used in the study, with endpoints of 1 week and 1 day (pilot animal – 1 sheep), 3 weeks (2 sheep), 6 weeks (2 sheep) and 12 weeks (2 sheep). An approximately 1 cm section at the midpoint of the calcaneon tendon was marked and removed. The BioBraid device was implanted as shown in Figure 2 while the left leg was in flexion. A 1 cm gap was left between the two ends of the tendon. All study sheep recovered for 3 weeks with the left leg casted, before cast removal. The right leg of all animals had no injury or treatment. All sheep were observed at least once daily. At sacrifice, gross necropsy included a routine exam of any abnormalities, photographs, and collection of tissues for histopathology. Tissue in-growth was documented photographically and observations were recorded on the necropsy records. Cross-sectional and transverse histology sections on the implanted area were taken using standard H&E staining. Cellular in-growth was evaluated in the defect area and documented in the pathology report.

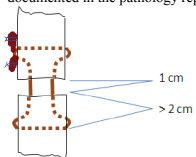
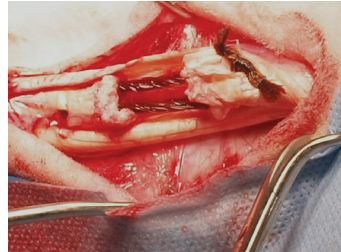
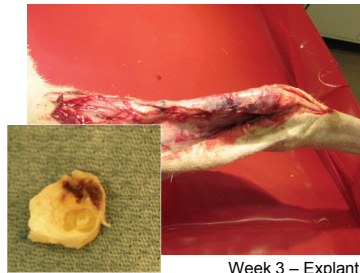


Figure 2. Achilles Repair Technique

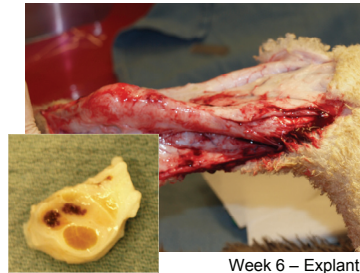
## Results



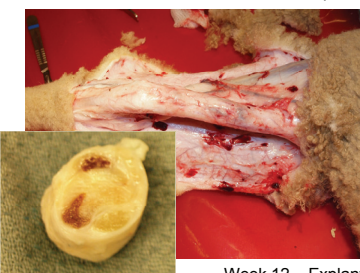
Initial Implantation



Week 3 – Explant



Week 6 – Explant



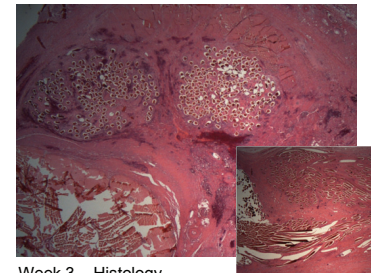
Week 12 – Explant

None of the BioBraid repaired tendons failed during this study, the animals were fully ambulatory after the casts were removed at three weeks.

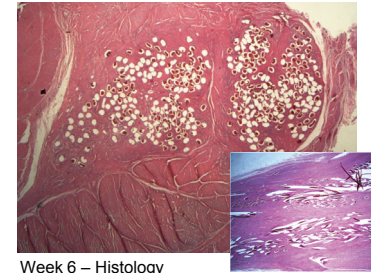
**Week 3:** Visual inspection showed new tissue growth over the entire repair site with implant visible through the tissue. Histology showed some tendon in-growth, no substantial foreign body response.

**Week 6:** Visual inspection showed substantial tendon-like tissue growth over the repair site. Histology showed substantial tendon in-growth into the BioBraid device, no substantial foreign body response.

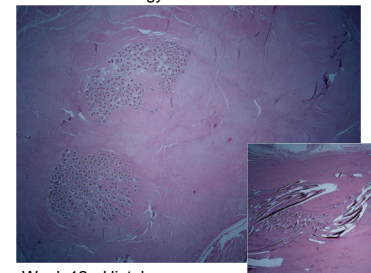
**Week 12:** Visual inspection showed a normal looking tendon. Histology showed complete tendon in-growth and some CollaFix BioBraid degradation, no substantial foreign body response.



Week 3 – Histology



Week 6 – Histology



Week 12 – Histology

## Conclusions

The gapped tendon showed complete healing at 12 weeks. There were no obvious tissue defects or signs of tissue reaction or infection. Histology confirmed that there was no substantial foreign body response and that the regenerated tissue at 12 weeks was composed of new tenocyte cells. The CollaFix BioBraid exhibited excellent performance in this Achilles gap tendon model.

Previous mechanical work on the CollaFix BioBraid device (not part of this study) has demonstrated robust strength data as outlined in the below charts:

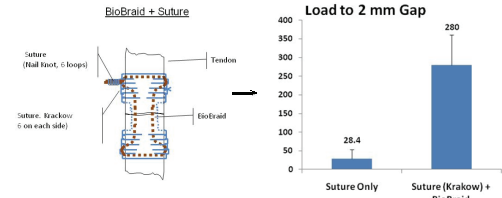


Figure 3. Strength of bovine flexor tendon repaired with CollaFix BioBraid (432 fiber) and suture (#2, Ticon)

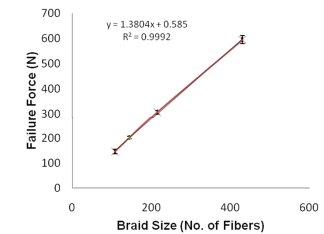


Figure 4. Strength of different configurations of CollaFix BioBraid

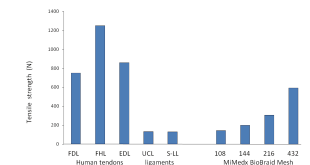


Figure 5. CollaFix BioBraid strength versus human tendons and ligaments

## References

1. The splice variants 120 and 164 of the angiogenic peptide vascular endothelial cell growth factor (VEGF) are expressed during Achilles tendon healing. Petersen W, et al. Arch Orthop Trauma Surg. 2003. Nov; 123(9):475-80. Epub 2003 May 15.
2. Early Achilles tendon healing. Virchenko O, et al. Arch Orthop Trauma Surg. 2008; 128:1001-1006.
3. Zimmer® Collagen Repair Patch and Platelet-Rich Plasma Fibrin Matrix for Achilles Tendon Repair in Sheep. Tiffany L. Sarrafian, et al. Paper No. 322 • 54th Annual Meeting of the Orthopaedic Research Society

## For further information

MiMedx Group, 811 Livingston Ct. SE, Suite B, Marietta, GA 30067  
 Toll Free: (866) 477-4219 www.mimedx.com