CollaFix™ BioBraid – Gapped Achilles Tendon Sheep Study
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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

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 calcaneum 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 reports. 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.

Results
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.

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.

References

For further information
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Figure 1. CollaFix Fiber & CollaFix BioBraid
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Figure 2. Achilles Repair Technique

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

Figure 4. Strength of different configurations of CollaFix BioBraid

Figure 5. CollaFix BioBraid strength versus human tendons and ligaments

The data provided on CollaFix™ is from our research efforts, including feasibility studies in animals. NOT AVAILABLE FOR HUMAN IMPLANTATION

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