

Introduction

CollaFix products are composed of high-strength, absorbable, biocompatible, cross-linked collagen fibers. The fiber can be woven, knitted, spun, braided, etc into various geometries tailored for various surgical procedures and native tissues. There are numerous potential applications for these constructs in complex foot and ankle reconstructions; including:

- Achilles rupture, re-attachment to bone
- Lateral ankle reconstruction/Instability
- Tendonopathy

This poster will display several applications in cadaver foot and ankle repair/reconstruction that have been performed with CollaFix constructs.

Materials and Methods

Human cadaver feet were utilized for technique development. CollaFix BioBraid (432 fibers per device) and Suture (16 fibers per device) were chosen for investigation. A basic braid passer was also developed and used in the technique development.



Figure 1. CollaFix BioBraid and Suture constructs

1. Achilles Repair:

The cadaveric Achilles tendon was exposed through a medial midline incision using standard surgical technique. The tendon was then transected at the mid substance approximately 2-4cm from it's insertion. The tendon was repaired using CollaFix BioBraid on a prototype braid passer to construct a single Kessler stitch with 2 strands of CollaFix BioBraid crossing the transection site. The knot was tied at the proximal medial limb of the stitch to bury the knot deep to the tendon. A standard 2-0 suture was then used to construct a single Krakow stitch that interdigitated the CollaFix BioBraid.

2. Achilles Reattachment:

The insertion portion of cadaveric Achilles tendon was exposed through a medial midline incision using standard surgical technique. The tendon was then dissected off its bony insertion and split longitudinally to allow resection of a Haglunds deformity often associated with insertional Achilles tendonitis. The tendon was reattached using CollaFix BioBraid on a prototype braid passer to allow a double row construct anchoring the Achilles tendon back to the calcaneus with bone anchors (Morphix 4.5mm suture anchors, MedShape Solutions).

3. Lateral Ankle Ligament Reconstruction:

The lateral portion of the cadaveric ankle was exposed through a direct lateral approach. The Anterior Talofibular Ligament (ATFL) and the Calcaneofibular Ligament (CFL) were exposed and then resected to allow reconstruction. The reconstruction was performed using CollaFix BioBraid anchored first at the insertion point of the previously resected CFL and then passed through a 4 mm bone tunnel drilled transversely across the fibula entering just proximal to the CFL origin site and exiting at the ATFL origin site. After passing the CollaFix BioBraid through this bone tunnel it was anchored to the talus at the ATFL insertion site using a bone anchor (Morphix 4.5mm suture anchors, MedShape Solutions).

4. Tibialis Posterior Tendon Debridement:

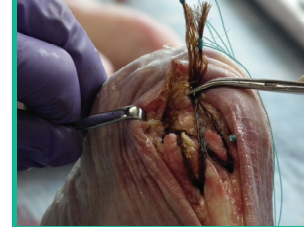
The Tibialis Posterior tendon of the cadaveric ankle was exposed through a direct medial approach. The tendon was then debrided through a standard midline splitting approach. The tendon was then repaired using a CollaFix BioBraid to "bulk up" the tendon which was sutured in place using a CollaFix suture on a standard mayo needle.

Results

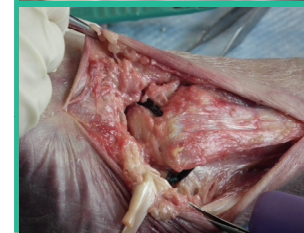
1. Achilles Repair



2. Achilles Reattachment



3. Lateral Ankle Reconstruction



4. Tendon Debridement & Repair



Conclusions

The BioBraid device handled easily and was passed through soft tissue with minimal effort using the BioBraid passer. The BioBraid held a knot without fraying or snapping. The device was usable with suture anchors (Morphix 4.5mm suture anchors, MedShape Solutions) in an Achilles suture bridge technique; however, we did have one anchor failure and the interference fit between this anchor and the BioBraid device was not optimal. CollaFix Suture was also used successfully to suture a CollaFix BioBraid to a deficient tendon in a simulated tendonopathy. The Suture was attached to a spring-loaded Mayo needle and worked as intended to affix the tendon/BioBraid construct together. It appears that CollaFix devices (BioBraid and Suture) have potential in complex foot and ankle reconstructions.

Mechanical testing on the Achilles repair with BioBraid resulted in a load to failure of 570N. However this result was based on a sample size of one, so additional testing is required to validate this result. Additionally the prototype braid passer worked as intended in these investigations, but will require more refinement to increase ease-of-use in actual surgery. Additional exploratory work under appropriate ethical boards and regulatory authorities will be required to further develop these products and techniques.

Table 1. Potential Applications of Techniques in Foot & Ankle for CollaFix

| | |
|--|------------------|
| Achilles Repair | |
| Achilles Reattachment | |
| Lateral Ankle Ligament Reconstruction | |
| Tibialis Posterior Tendon Debridement | |
| Ankle Syndesmosis repair (acute) | Not trialed here |
| Ankle Syndesmosis reconstruction (chronic) | Not trialed here |
| Peroneal Tendon Debridement Repair | Not trialed here |
| Achilles Tendonopathy Debridement Repair | Not trialed here |
| Hallux Valgus with Increased Intermetatarsal Angle | Not trialed here |

For further information

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