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Introduction

CollaFix products are composed of high-strength, absorbable, biocompatible, cross-linked collagen fibers. The fibers can be woven, knitted, spun, braided, etc into various geometries tailored for various surgical procedures and native tissues. Two different cross-linking technologies (CD, NDGA) allow MiMedx to design products for differential absorption rates for different applications. In either cross-linking case, the fibers are approximately twice as strong as native tendon fibers of the same diameter.

Numerous applications are possible for these technologies and this poster will examine the applicability of using CollaFix fibers as suture material, both from a cosmetic aspect and from an ease-of-use approach, in several applications.



Figure 1. CollaFix braided suture (432 fibers) subject to 100 lbs of load

Materials and Methods

For the cosmesis study a total of four female Hanford minipigs were used. On Day 0, nine (9) 1-inch incisional wounds were created on the designated areas. For each pig, one suture material was utilized per wound. The animals were then euthanized on study Day 21. For the 21 days termination animal, the wound was scored macroscopically for inflammation, healing, scar formation, and cosmesis with digital imaging of the wounds daily until fully healed. Scoring was performed by an independent plastic surgeon not affiliated with MiMedx Group. Histology will be presented at a later date.

For the nerve repair and soft tissue closure investigation, pig feet were used with mono-filament and 8-fiber CollaFix sutures. For the tendon repair investigation, human cadaver feet were used with a 16-fiber CollaFix suture.

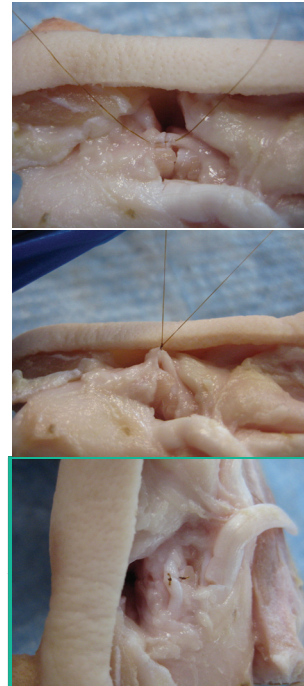


Figure 2. CollaFix suture

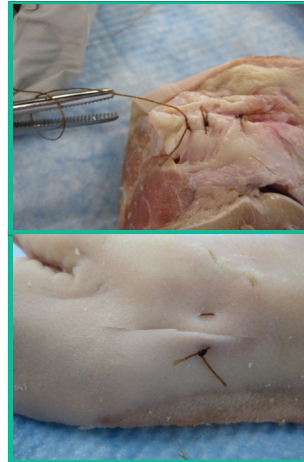
Results 21 day Cosmesis of CollaFix Suture

Suture	Cosmesis	Notes	Pictures
Ethicon PDS 6-0	Average	Edges raised Flat scar Suture material present	
Ethicon Chromic gut 7-0	Excellent	Sutures resorbed Barely detectable incision; fine line Nice flat scar	
MiMedx NDGA single fiber (equiv. to 7-0)	Average	Fine line scar Raised scar around edges Suture material present	
MiMedx CD single fiber (equiv. to 7-0)	Excellent Best in show	Incision line difficult to visualize Excellent cosmesis No scar visualized All redness gone	
Ethicon PDS 4-0	Good	Fine lined scar Suture still present Raised scar	
Ethicon Chromic gut 4-0	Excellent	Fine lined scar Flat and well healed Suture material still present	
MiMedx NDGA 8-fiber (equiv. to 3-0)	Average	Suture present Fine lined scar Raised scar	
MiMedx CD 8-fiber (equiv. to 3-0)	Excellent	Fine lined scar Flat scar Suture material present without elevated tissue surrounding sutures	
Plain gut 4-0	Good	Suture present Fine lined flat scar without inflammation	

Nerve Repair, Mono-filament



Soft Tissue Closure, 8-fiber



Tendon Repair / Augmentation 16-fiber



Conclusions

CollaFix CD fibers provided excellent cosmesis in this model, both in a mono-filament (7-0 equivalent) and 8-fiber construct (3-0 equivalent). The CollaFix CD suture held the wound closed for the duration of healing, and was scored highest for cosmesis over standard PDS and gut sutures. CollaFix NDGA fibers are more long-lived in-vivo than equivalent CD fibers and have a brown coloration due to the cross-linking agent. This resulted in average cosmesis scores being assigned to the NDGA fiber suture. However the NDGA fiber was still an effective suture and held the wound closed until healing.

CollaFix fibers were easily handled and were effective both in very fine suturing applications (nerve repair), to more demanding applications in tendon repair and augmentation. Since the CollaFix fiber is strong, scalable to various suture sizes, and composed of bioabsorbable purified collagen this material has great promise for numerous applications.

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.