

Guilhem Denoziere MS, Rebecca Brown PhD, Thomas Koob 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 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. This poster will focus on CD fiber, and NDGA fiber study is underway.

Numerous applications are possible for these technologies and this poster will examine the applicability of using CollaFix fibers as a tendon protector in tendon repair surgery. Degradation data will also be presented on the life-span of the tendon protector construct in-vivo.

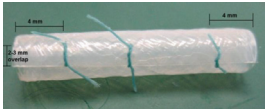


Figure 1. CollaFix Tendon Protector

## Materials and Methods

The aim of the study was to determine the rate of degradation of the product when used as a tendon protector around a surgically defected Achilles tendon. The implanted product encircled the entire Achilles after a surgical defect was created in the tendon and repaired per standard surgical repair with suture. 16 rabbits were used in this study. Each animal received two devices, one per rear leg. The device implanted in the right leg was analyzed at termination for burst strength to assess mechanical degradation. The device implanted in the left leg was analyzed histologically for efficacy of the tendon protector in preventing adhesions to damaged tissue. 30, 60, 90 and 150 day time points were assessed.

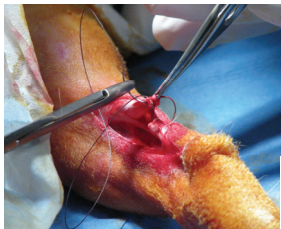


Figure 2. Tendon Repair with Suture

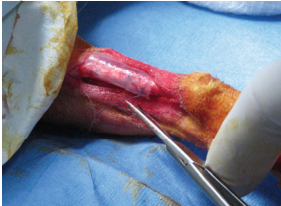
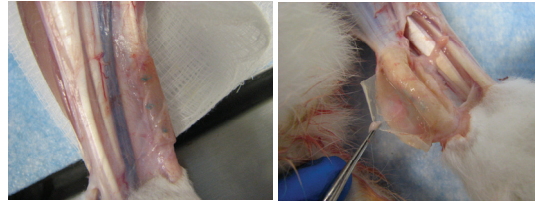
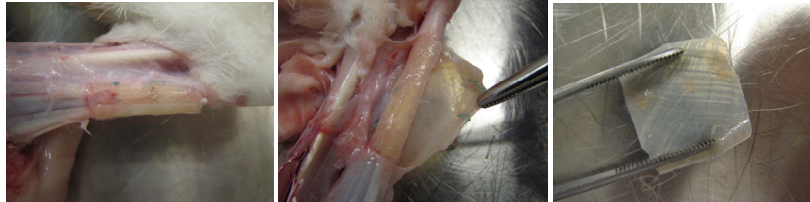


Figure 3. CollaFix Tendon Protector Implantation  
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## Results



30 day CollaFix CD Tendon Protector



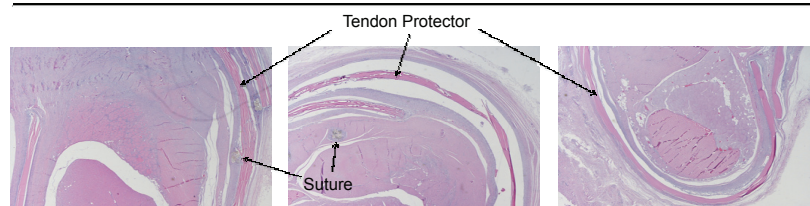
60 day CollaFix CD Tendon Protector



90 day CollaFix CD Tendon Protector



150 day CollaFix CD Tendon Protector



30 Day Histology

60 Day Histology

90 Day Histology

## Ball Burst Strength Data and Degradation Rates

Time (days)	0	30	60	90	150
Average (N)	28.24	14.39	14.28	12.54	7.50

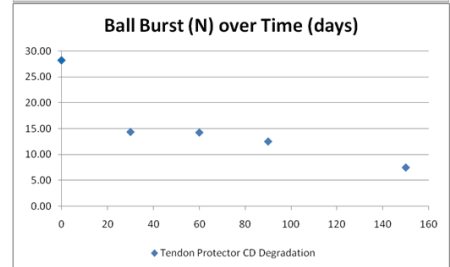


Figure 4. CollaFix CD Tendon Protector Degradation Data

## Conclusions

All tendon protectors remained in place throughout the study duration. Tendon protectors were easily removed during sacrifice, up to the 150 day animal. No substantial adhesions were visible in the interface between the healing tendon and tendon protector, or between the tendon protector and surrounding soft-tissue.

The devices were effective at providing an environment that allowed the damaged tendon to heal, and no substantial adhesions that could limit recovery to full pre-injury motion were observed.

Based on ball burst strength testing data, the estimated degradation time for the CollaFix CD tendon protector is around 199 days. Consequently the device will remain a protective barrier for the approximate 12 week healing time for this tendon.

30, 60, and 90 day histological examinations confirmed no adhesions between the CollaFix Tendon Protector and the repaired tendon. 150 day histology is pending.

## For further information

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

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