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## Introduction

Over 400,000 surgeries are performed each year in the United States to repair the torn rotator cuff tendon in the shoulder<sup>1</sup>. The impact of a torn rotator cuff is pain, weakness and the inability to lift and rotate the arm. Thirteen percent of individuals aged 50-59 years and 51% of people over the age of 80 years suffer from rotator cuff injury. Currently, permanent synthetic suture is the only device used to repair the torn rotator cuff. Failure rates for arthroscopic rotator cuff repair with suture range anywhere from 18%<sup>2</sup> in younger patients up to 57%<sup>3</sup> in older patients with large tears. If the rotator cuff is not repaired or the repair fails, arthritis ensues. An unmet need in rotator cuff repair is a construct that has sufficient strength to hold the tendon in place during the regenerative phase, distributes force evenly over the surface of the tendon, and is of a material that actually becomes part of the tendon as it heals, for instance a pure collagen or collagen containing tape.

## Materials and Methods

Live sheep were utilized as the model for the rotator cuff surgeries. The infraspinatus was excised from the humeral head and re-attached using several different techniques. The initial technique excised the complete tendon, later techniques created a 50% tear. Suture anchors (Lupine, Mitek) and CollaFix constructs (432-fiber BioBraid, 432-fiber BioRibbon, and a BioRibbon/high strength suture combination product) were used in the repairs. The sheep infraspinatus is anatomically similar to the human supraspinatus, and therefore, this model is a good human analog<sup>4</sup>.

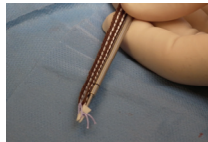


Figure 1. CollaFix BioRibbon/Suture hybrid loaded on a Lupine anchor



Figure 2. CollaFix BioRibbon



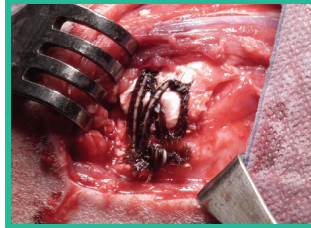
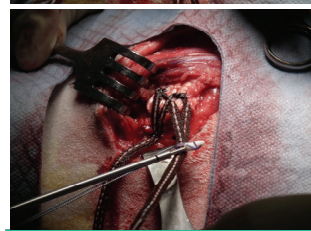
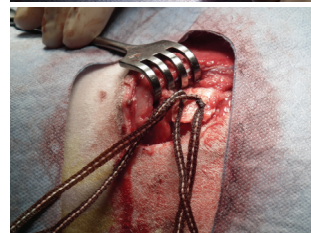
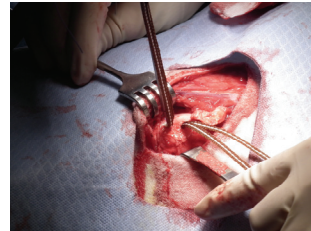
Figure 3. CollaFix BioBraid



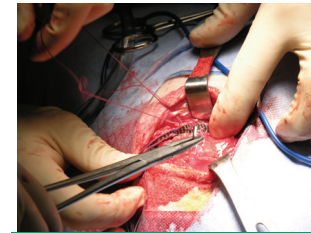
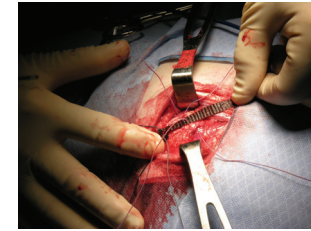
Figure 4. Animal model

## Results

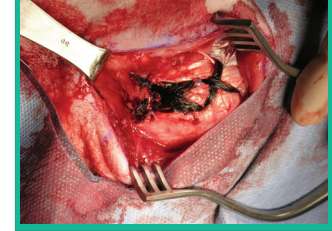
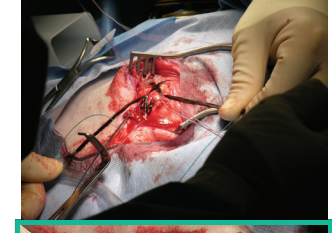
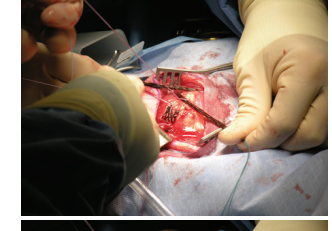
### Double Row Recon. with BioRibbon/Suture Hybrid



### Primary Suture Reconstruction with BioRibbon Augmentation



### Double Row Reconstruction with BioBraid Augmentation



## Conclusions

An unmet need in rotator cuff surgery is a construct that has sufficient strength to hold the tendon in place, distributes force evenly over the surface of the tendon, and is of a material that actually becomes part of the tendon as it heals (for instance a pure collagen or collagen containing tape). This would result in less volume of foreign material remaining in the joint and the construct would also become part of the tendon thus the repair would have a “self-reinforcement” effect. In these early studies looking at material handling, and ease-of-use as part of standard techniques, the CollaFix constructs performed well. The constructs held the repair in a stable fashion during surgery and were usable with off-the-shelf suture anchors. Further research into the mechanical effectiveness of these repairs will be reported at a later date.

## References

1. iData (2009) US markets for orthopedic soft tissue and sports medicine
2. Boileau P, B. N. (2005). Arthroscopic repair of full-thickness tears of the supraspinatus: does the tendon really heal? J Bone Joint Surg Am , 1229-40
3. Levy O, V. B. (2008). Mid-term clinical and sonographic outcome of arthroscopic repair of the rotator cuff . J Bone Joint Surg Br , 1341-7
4. Turner AS, (2007) Experiences with sheep as an animal model for shoulder surgery: strengths and shortcomings, J Shoulder Elbow Surg. Sep-Oct;16(5 Suppl):S158-63. Epub, May 15

## 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.