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Revolutionizing Tendon Repair®

Biomechanical Comparison of Soft Tissue Fixation Strength of Coronet™ Soft Tissue Fixation System and Suture

CoNextions Research & Development

Objective

The purpose of this study was to compare the ultimate pull out strength of Coronet Soft Tissue Fixation System with that of a traditional suture repair in cadaveric tendons of the foot using a laterally applied load.

Background

The current standard of care uses knotted suture to achieve soft tissue fixation during tenodesis procedures. Accordingly, the most common source of failure for these types of repair is suture pulling through tendon (1). The Coronet Soft Tissue Fixation System was designed to address this limitation inherent in many tenodesis devices by using an electropolished stainless steel washer (8.7 mm outer diameter, 0.5 mm thickness) with six tines spaced equidistance around the circumference of the washer to fixate to the underlying soft tissue at the repair site. The soft tissue washer is secured to a 3.5 mm diameter PEEK bone anchor via a continuous loop of #2 suture (Figure 1). The device is provided pre-assembled to an inserter to allow for simultaneous placement of the bone anchor and soft tissue washer during implantation.

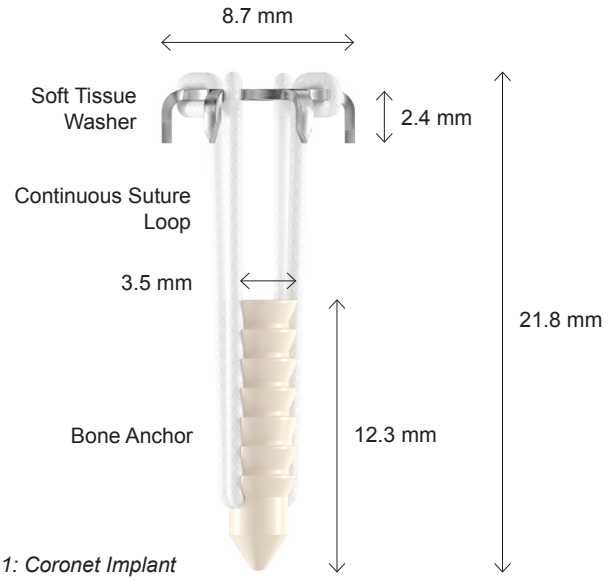

Figure 1: Coronet Implant

Sample Preparation

A total of 10 tendons were harvested from the feet of 4 adult cadaveric specimens. Peroneus Brevis (PB), Peroneus Longus (PL), Posterior Tibial (PT), and Anterior Tibialis (AT) tendons were selected due to the propensity for these tendons to be reattached to bone in surgical settings. Harvested tendons were sectioned along their transverse axis creating proximal and distal tendon sections. To reduce the impact of variable tissue quality on the testing, one section of each tendon sample was used to test the Coronet, with the other section of the same tendon sample used to test suture.

Coronet **Suture**

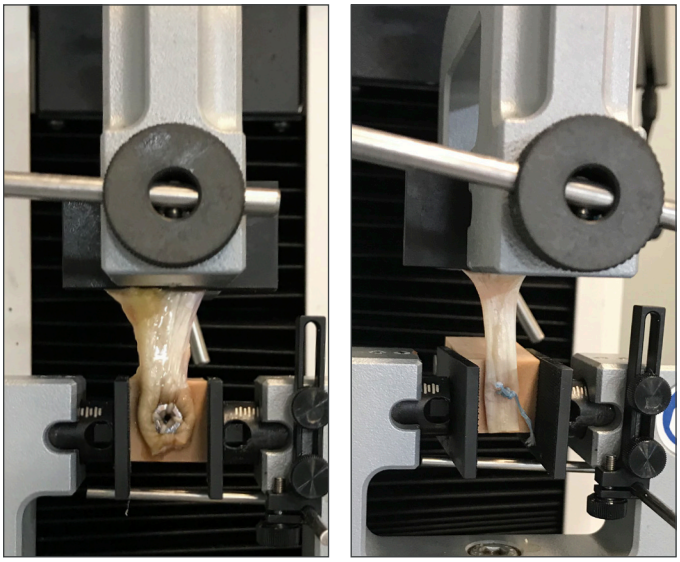

Figure 2: Tensile Test Set-up

To reduce the impact of variable bone quality and ensure the failure of the soft tissue connection during testing, synthetic test blocks were used to represent bone for the study (40 PCF density Sawbones, Pacific Laboratories, Inc).

Coronet Samples: Coronet samples were prepared by attaching the tendon sections to the test blocks following the device's Instructions for Use (IFU Ref. PK01024).

Suture Samples: A single stitch pattern commonly used in clinical practice was placed on the tendon using #2 suture (FiberWire® Suture, Arthrex, Inc) (2). Suture from the tendon sections was threaded down a Ø2.8mm through hole in the test block, wrapped around a steel dowel pin, and threaded back up through the hole in the test block where it was secured with 3 square knots creating a simple interrupted stitch.

Tensile Testing

Pull tests were completed using an Instron® test frame (Instron 3342 Series Universal Testing Device, Instron Corporation) Figure 2 shows the test setup for the Coronet and Suture samples. The tensile load was applied laterally to the simulated soft-tissue bone fixation in order to be representative of the loading conditions seen clinically following various soft tissue to bone repairs performed in the foot and ankle (2). The pull rate of the applied load was set at 12.5mm/s.

Results

The failure mode for all test samples was pull-through at the soft tissue. All Coronet specimens were stronger than the corresponding suture repairs in the same cadaveric tissue. The average load at failure for the Coronet specimens was 130.6N, the average repair strength for the suture repairs was 65.5N (Table 1).

Force	Coronet (n=10)	Suture (n=10)
Max (N)	182.0	75.4
Min (N)	79.4	48.4
Avg (N)	130.6	65.5

Table 1: Summary of Pull Test Results

Conclusion

Coronet Soft Tissue Fixation System holds tissue at an average maximum applied load almost 2 times greater than a standard of care suture technique under lateral loading conditions in cadaveric tendon samples.

References

1. Cummins, Craig A. et al. Mode of failure for rotator cuff repair with suture anchors identified at revision surgery. Journal of Shoulder and Elbow Surgery 2003;12(2):128-133.

2. Dawson, David M. et al. Modified Kidner Procedure Utilizing a Mitek Bone Anchor. JFAS 1998;37(2):115-121.

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