

A Randomized, Double Blind, Clinical Trial of Teno Fix™; A Novel Device for Flexor Tendon Repair

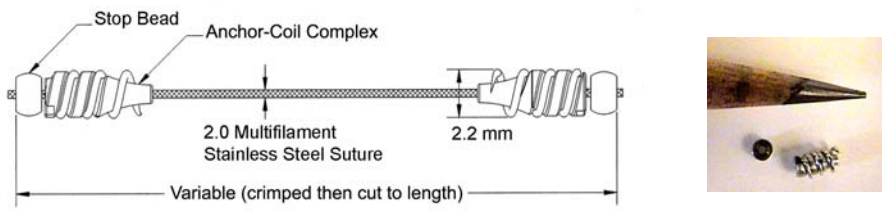
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Purpose

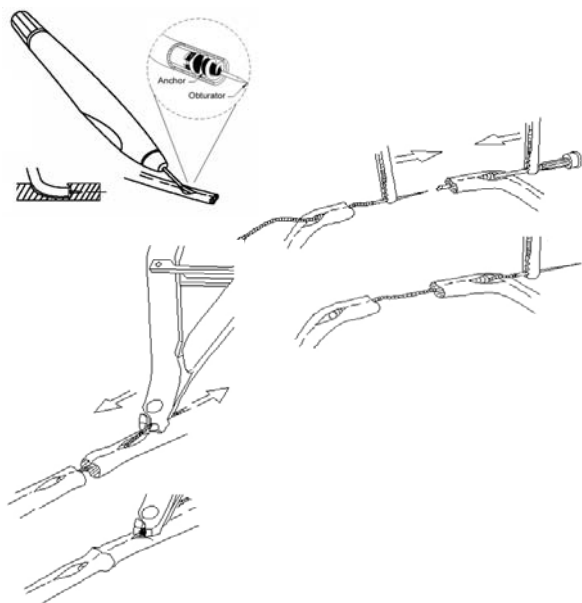
Compare the safety and effectiveness of the Teno Fix™ tendon repair system to the conventional four-stranded Cruciate repair for the repair of lacerated Zone II flexor tendons. This trial was designed to be an equivalency study to support an FDA submission.

Methods

The Teno Fix™ system is a novel intra-tendinous soft tissue anchoring device that has CE Mark approval and is currently being sold in Europe, Australia, Middle East, and South Africa.



Zone II flexor tendon injuries less than 14 days old were randomized to a Cruciate or Teno Fix™ repair. The follow-up duration lasted 6 months with both patient and therapist blinded. The post-op therapy consisted of modified Kleinert technique with active flexion starting at 3 weeks. Stainless steel markers were placed at each end of the tendon so that gapping and excursion could be radiographically assessed.



Surgical Technique

- The system works by placing one anchor on each side of the repair site through a tenotomy 1.0 cm away from the cut edge. The tip of the pre-loaded installation instrument is placed into the tenotomy and the anchors are turned into tendon, in turn capturing collagen fibers.
- The stainless steel core suture having a pre-placed stop bead on one end is placed through the distal anchor. Using a 22g cannulated needle as a guide, the suture is placed through the remaining proximal anchor.
- Approximate the tendon ends and fix the distance between the soft tissue anchors by placing a second stop bead.
- The tenotomies are closed, preferably with a buried knot, and the epitendinous stitch is placed.

Results

Enrollment

In the Teno Fix™ group there were a total of 29 subjects with 34 repaired digits and in the Control group there were a total of 38 subjects with 51 repaired digits.

Repair	Number of single digit subjects	Number of multi-digit subjects	Number of Subjects	Number of Digits
Teno Fix™	22	7	29	34
Control	29	9	38	51
Total	51	16	67	85

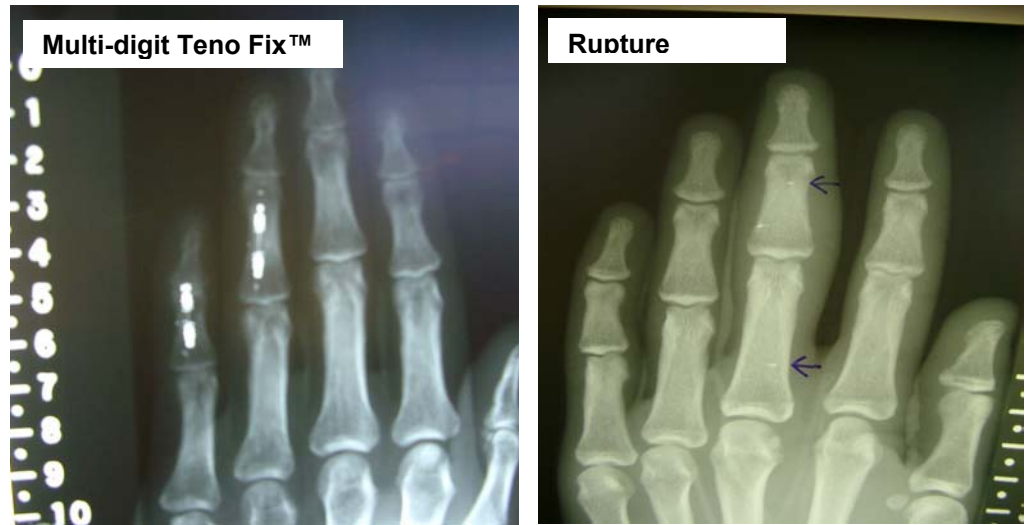
Primary Safety Results

Rupture rate is calculated on a per digit basis the Control rupture rate is 17.6%. All but 2 of the 9 ruptures presented in the first 6 weeks of the study. One rupture was determined radiographically at 9 weeks, and the second was suspected ruptured at week 7 due to a lack of improvement in ROM, confirmed at week 12.

Principal Safety Parameters	Teno Fix™	Control	Statistically Significant
Rupture Rate (digits)	0/34 (0.0%)	9/51 (17.6%)	Yes (p=0.010)
Secondary Surgical Procedures (patients)	3/29 (10.4%)	12/38 (31.6%)	Yes (p=0.045)

Radiographic Markers

This method of rupture detection is more sensitive than evaluation by physical evaluation, particularly if scar tissue formation bridging the gap masks the rupture. In fact, the patient on the right was originally categorized as a contracture, with a poor Strickland score. Upon looking at the radiograph, the markers indicate that this repair has actually ruptured.



Primary Efficacy Results

The range of motion was shown to improve not decline between 6, 12, 24 weeks post-repair.

Visit	Device	Strickland "Excellent"	Strickland "Good"	Total Success
Week 12	Teno Fix™	6/27 (22.2%)	6/27 (22.2%)	12/27 (44.4%)
	Control	8/31 (25.8%)	10/31 (32.3%)	18/31 (58.1%)
Week 24	Teno Fix™	7/24 (29.2%)	9/24 (37.5%)	16/24 (66.7%)
	Control	8/27 (29.6%)	11/27 (40.7%)	19/27 (70.4%)

Conclusions

The device is both **SAFE** and **EFFICACIOUS** in a clinical setting for flexor tendon repair. The trial was designed to be an equivalency study; therefore, all measured outcomes showed equivalency to the control except for the rupture rates, which showed Teno Fix™ to be superior.