

The Biomechanical Analysis of a Tendon Fixation Device for Flexor Tendon Repair

Brian W. Su, MD, Themistocles S. Protopsaltis, MD,
Matthew F. Koff, PhD, Ketharin P. Chang, BA, Robert J. Strauch, MD,
Scott A. Crow, BA, Melvin P. Rosenwasser, MD, New York, NY

Purpose: Stainless steel suture is high in tensile strength but is not widely used in flexor tendon repair because of difficulty with handling and knot tying. The purpose of this study was to examine the biomechanical characteristics of the single-strand multifilament stainless steel Teno Fix device (Ortheon Medical, Winter Park, FL) designed for zone II flexor digitorum profundus (FDP) tendon repair.

Methods: Sixty cadaveric flexor tendons were transected and randomized to receive a Teno Fix or 4-stranded (3-0 or 4-0 braided polyester) suture repair; all repairs were tested with and without a 5-0 monofilament polypropylene circumferential epitendinous suture. By using a material testing system all tendons were tested to failure in tension using a linear model with a loading rate of 1 mm/s. Stiffness, force, and energy at both 2-mm gap and peak force were calculated from the resulting force-displacement curves.

Results: The 2-mm gapping force was significantly greater for the Teno Fix and the 3-0 repairs than for the 4-0 repairs. The energy absorbed up to 2-mm gap was significantly greater for the Teno Fix, however, than for all suture repairs both with and without a circumferential suture. There was no statistically significant difference in peak force or energy absorbed at peak force between the Teno Fix and suture repairs; the average gap at peak force for all repairs was 5.2 mm. The addition of a circumferential suture increased the 2-mm gapping and peak forces of the Teno Fix repair to 54.5 N and 66.7 N, respectively.

Conclusions: Increased strength and energy absorbed at 2-mm gap and ease of installation makes the Teno Fix a promising repair method. (*J Hand Surg* 2005;30A:237–245. Copyright © 2005 by the American Society for Surgery of the Hand.)

Key words: Flexor tendon repair, tendon biomechanics, stainless steel.

From the Trauma Training Center, New York Orthopaedic Hospital, Columbia University Medical Center; and the Department of Biomedical Engineering, Columbia University, College of Physicians and Surgeons, New York, NY.

Received for publication October 16, 2002; accepted July 26, 2004.

No benefits in any form have been received or will be received by a commercial party related directly or indirectly to the subject of this article.

Supported by an educational grant from Ortheon Medical, LLC (Orlando, FL).

Reprint requests: Melvin P. Rosenwasser, MD, New York Orthopaedic Hospital, 622 W. 168th St, PH-11, Room 1164, New York, NY 10032
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0363-5023/05/30A02-0004\$30.00/0
doi:10.1016/j.jhsa.2004.07.020

In 1960 Verdan¹ suggested that gentle passive motion after flexor tendon repair at 4 weeks could rupture adhesions and improve digit function. Subsequent studies established the importance of passive or active mobilization immediately after repair to prevent adhesions and the need for tenolysis.^{2–9} Modern multistrand repairs and the addition of circumferential sutures have increased the tensile strength of repairs,^{10–13} suggesting that they are adequate to sustain forces in early active mobilization.^{8,9,14,15} Many of these biomechanical tests have used the study of forces in FDP tendons during carpal tunnel release by Schuind et al¹⁶ as a benchmark. Several investigators, however, feel that measure-

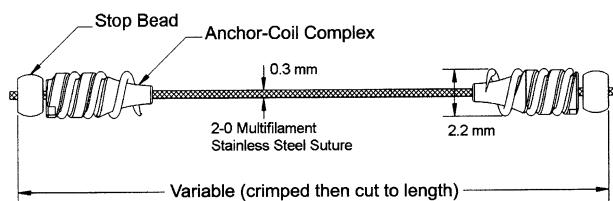


Figure 1. The Teno Fix device.

ment of forces in tendons without prior trauma overlooks increases in work of flexion from postsurgical edema and adhesion formation.^{16–19} In the clinical setting underestimation of forces after trauma and noncompliance during rehabilitation²⁰ may explain rupture rates up to 46% of the time,⁹ with most between 5% and 10%.^{3–8,14,15,21–25} In addition to rupture early mobilization may lead to gapping with adhesion formation and diminished tendon glide and function.

New suture configurations have been devised based on Strickland's²⁶ concept of an ideal repair: sufficient strength throughout healing to permit early motion stress, minimal interference with vascularity, minimal gapping, smooth juncture at tendon ends with minimal bulk, secure knots, and sutures easily placed in the tendon. A good tendon–suture interface is essential to decrease gapping and suture pull out, which usually are related to softening of tendon bundles.^{27–30} Although many of the proposed suture configurations are high in tensile strength they are technically demanding, require excessive tendon manipulation, and increase the work of flexion.^{12,29,31} To meet idealized repair requirements the Teno Fix (Ortheon Medical, Winter Park, FL) has been developed.

The purpose of this study was to examine the biomechanical characteristics of the stainless steel Teno Fix implant intended for use in flexor tendon repair. We hypothesized that the Teno Fix device would sustain greater peak force, greater 2-mm gap resistance, and greater energy than either the 3-0 and 4-0 four-strand suture repair.

Methods and Materials

Teno Fix Device Description and Surgical Technique

The device is composed of 2 intratendinous stainless steel anchors (coil–core combination) that are joined by a single multifilament 2-0 stainless steel suture (Fig. 1). The diameter of the suture is 0.3 mm. After exposure a longitudinal slit is made through half the

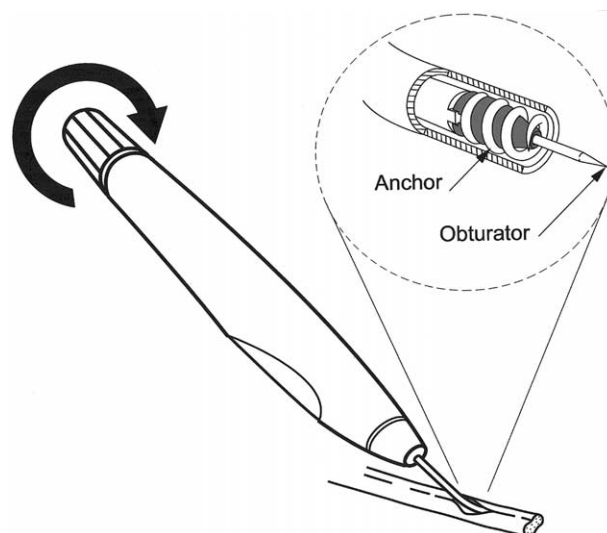


Figure 2. Anchor implantation. Anchors are twisted into the tendon after a longitudinal slit halfway through each tendon starting 1.0 cm from the cut edge is made.

tendon substance. This incision starts 1.0 cm from the cut edge and extends approximately 5 mm to accommodate the obturator tip and delivery tube. After ensuring that the delivery tube is well aligned the anchors are twisted into the tendon (Fig. 2). The anchor engages the tendon substance by capturing fibers between the core and the corkscrew-like coil. A straight needle with a 2-0 multifilament stainless steel suture and an attached stop bead is threaded into one of the anchors and pulled through the center of the tendon's cut end until the end of the bead docks against the anchor. The needle then is threaded through the center of the opposite tendon and its anchor and captured with a 22-gauge needle (Fig. 3).

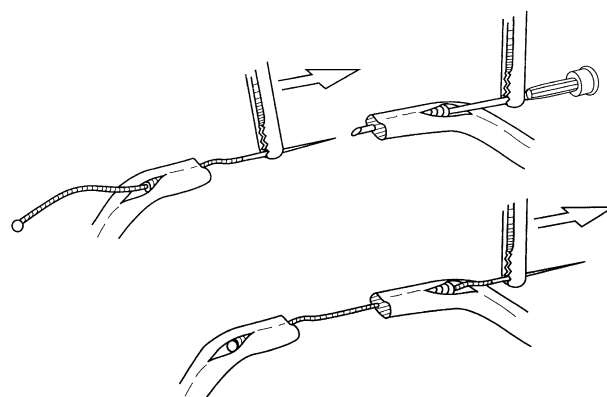


Figure 3. Alignment of tendon sections. A needle with suture and stop bead attached is threaded into one anchor and pulled through the center of the cut end. The needle then is threaded through the center of the opposite tendon and anchor.

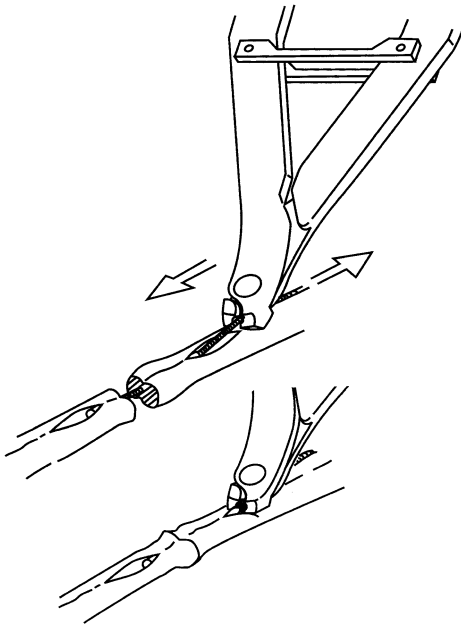


Figure 4. Approximation of tendon. Cut ends are pulled together until the tendon is approximated and tensioned; a stop bead is crimped onto the suture.

The suture is threaded through a stop bead in a preloaded crimping instrument. The tendon is approximated and properly tensioned with a slight overlap. The stop bead then is crimped onto the stainless steel suture (Fig. 4). The excess suture is cut so that the suture end is flush with the crimped bead. The longitudinal slits are closed with 5-0 monofilament polypropylene buried suture (Surgi-Pro; US Surgical, Norwalk, CT) that covers the intratendinous anchor.

Sixty flexor digitorum profundus (FDP) tendons were dissected in the zone II region of fresh-frozen human cadaver hands. Only index, middle, and ring fingers were used to ensure that the device would fit every tendon. Tendons with evidence of synovitis or degeneration were excluded. Each tendon was transected sharply at the distal end of the A2 pulley with the fingers in full extension. Each tendon was repaired *in situ* with either the 4-strand locked cruciate¹² technique or the Teno Fix device. Thirty of the tendons were randomized to 3 core-only repair groups: cruciate with 3-0 braided polyester (3-0_C), cruciate with 4-0 braided polyester (4-0_C), and Teno Fix repair (Teno Fix). The 30 remaining tendons were repaired similarly with the core technique but then augmented with a running locked circumferential epitendinous suture (3-0_C+E, 4-0_C+E, and Teno Fix+E) using 5.0 monofilament polypropylene suture. (All braided polyester suture was

Surgi-Dac and all polypropylene suture was Surgi-Pro, both from US Surgical.) After repair the FDP tendon was removed from the digit between the regions bound by the proximal A1 pulley and the insertion of the FDP at the distal phalanx. All tendons were kept moist with physiologic saline solution and were tested within 1 hour of repair.

The tendon ends were fixed with cyanoacrylate glue and emory cloth before being clamped in a set of parallel soft-tissue grips on a testing system (Bionics 858 Material Testing System [MTS]; MTS Corporation, Eden Prairie, MN) with a 125-N load cell. Each repair was preloaded to a force of 7 N before testing. The tendon width was recorded with a millimeter reference ruler placed next to the repair. Two 26-gauge pins were placed on either side of the repair so that the amount of gap could be monitored. The tendons then were distracted using a linear model at 1 mm/s while force and cross-head displacement data were obtained at 100 samples/s. Each trial was recorded with digital video (Sony DCR-TRV20; Sony Corporation, Tokyo, Japan) synchronized with the MTS. The time to 2-mm gap between the pin entry sites was determined by inspection of the digital video data with a software package (MGI Videowave III; Roxio, Santa Clara, CA) at minimum intervals of .01 seconds. The force corresponding to the time when 2-mm gap was reached was obtained from the force versus time data.

Energy absorbed by the repair (area under force-displacement curve) was calculated by using the trapezoidal integration function on a mathematic software program (MATLAB; Mathworks, Natick, MA)

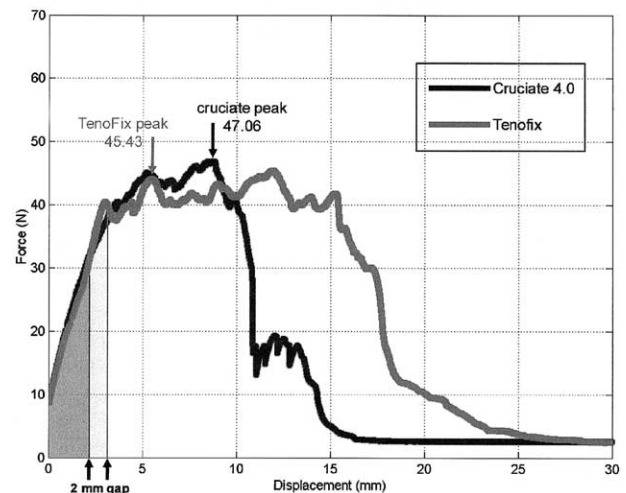


Figure 5. Representative force versus tensiometer cross-head displacement curve of 2 core repairs (arrows mark the point of 2-mm gap): 4-0_C versus Teno Fix.

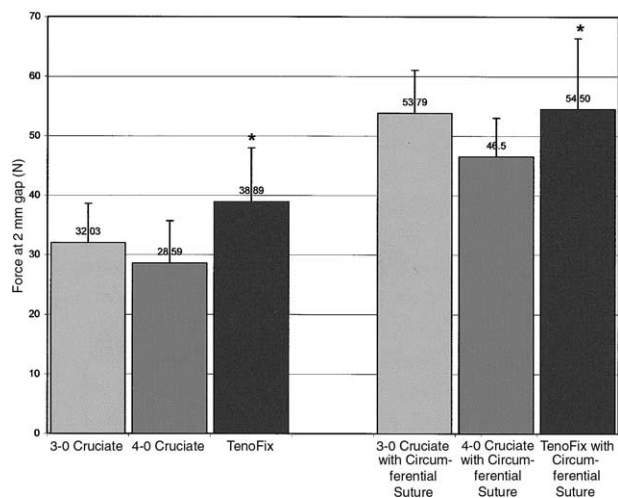


Figure 6. Force at 2-mm gap for all repairs. Teno Fix significantly greater force than 4-0 but not 3-0 cruciate repair both with and without a circumferential suture.

(Fig. 5). Stiffness (force per unit of distraction) was calculated as the slope of the best-fit line on the linear region of the force-displacement curve on the software (MATLAB). The following structural properties were calculated for each repair: force at 2-mm gap, energy absorbed to 2-mm gap, peak force (largest force on the linear region of the force-displacement curve), energy absorbed to peak force, gap at peak force, and stiffness of repair. Based on the video data the gap at peak force also was obtained for each repair. The mechanism of failure (suture breakage, knot breakage, suture pull-out, crimp slippage, or anchor pull-out) was noted for each trial. The results of the different repairs were analyzed with a 1-way analysis of variance with a statistical software package (SPSS 11.0 for Windows; SPSS, Chicago, IL). Statistical significance was achieved at $p \leq .05$. A post hoc least significant difference method was used when significance was found.

Results

There were no significant differences among the average widths of the index, middle, and ring finger flexor tendons; the average tendon width was 5.9 mm (SD 9 mm). All tendons randomized to a Teno Fix repair were wide enough to accommodate the Teno Fix anchor easily. The 2-mm gapping force of the Teno Fix core repair was 38.9 N (SD 9.1 N). This was significantly greater than the 2-mm gapping force of the 4-0_C (28.59 N) but not the 3-0_C (32.03 N) repairs (Fig. 6). When a circumferential suture was added, the 2-mm gapping force of the Teno Fix + E remained significantly greater than

only the 4-0_C+E repair. The energy absorbed up to 2 mm, however, was significantly greater for the Teno Fix than for either the 3-0 or 4-0 suture repairs with and without a circumferential suture (Fig. 7).

There were no differences in peak force or energy absorbed at peak force between the Teno Fix and suture core repairs when analyzed as separate groups with and without circumferential sutures (Table 1). Although not statistically significant the peak force of the Teno Fix repairs was smaller than both the 4-0 and 3-0 repairs; however, the average gap when peak force was reached was 6.3 mm (SD 2.1 mm) when all core-only repairs were evaluated and 4.1 mm (SD 1.3 mm) for repairs using circumferential sutures (Table 1). The stiffness of the Teno Fix core was significantly greater than the 4-0_C but not the 3-0_C (Table 1). When a circumferential suture was added there were no differences in stiffness between the Teno Fix + E and suture repairs (3-0_C+E, 4-0_C+E).

The addition of the circumferential suture for the Teno Fix repair altered the structural properties of the tendon test specimens. The additional suture increased the 2-mm gapping force by 40% and the peak force by 48%. The stiffness of the Teno Fix repair increased from 10.5 N/mm to 16.1 N/mm with the circumferential suture.

The mechanisms of failure are summarized in Table 2. For all cruciate core repairs 25% (5 of 20) failed by suture or knot breakage and the remainder failed by pull-out. With the addition of a circumferential suture the proportion of cruciate repairs failing by suture or knot breakage increased to 60% (12 of 20) whereas failures by suture pull-out decreased.

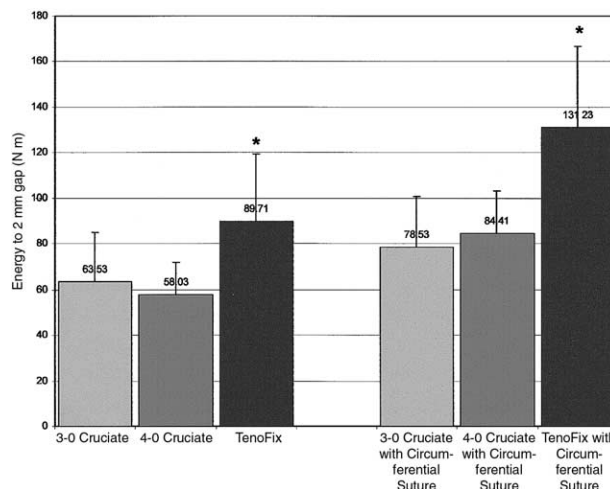


Figure 7. Energy (N·mm) up to 2-mm gap for all repairs. Teno Fix significantly greater energy than 4-0 and 3-0 cruciate repairs both with and without a circumferential suture.

Table 1. Peak Force, Gap at Peak Force, Energy Absorbed to Peak Force, and Stiffness for All Repairs

Repair	Peak Force* N (SD)	Gap at Peak Force† mm (SD)	Energy Absorbed to Peak Force‡ N-mm (SD)	Stiffness§ N/ mm (SD)
3-0_C	50.4 (8.9)	6.6 (1.0)	273.5 (65.5)	9.2 (1.8)
4-0_C	45.4 (9.8)	6.8 (2.5)	250.6 (97.3)	8.5 (1.5)
Teno Fix	45.0 (8.6)	5.6 (2.5)	231.2 (100.7)	10.5 (1.9)
3-0_C + E	73.8 (6.6)	4.6 (1.5)	266.1 (88.4)	17.8 (2.4)
4-0_C + E	70.0 (11.8)	4.2 (1.3)	232.0 (77.5)	14.8 (2.4)
Teno Fix + E	66.7 (10.9)	3.7 (.9)	213.4 (73.8)	16.0 (2.3)

*No differences in peak force when core and core and circumferential repairs are considered separately.

†No differences in gap at peak force when core and core and circumferential repairs are considered separately.

‡No differences in energy absorbed to peak force and core and circumferential repairs are considered separately.

§Greater stiffness for Teno Fix repair when compared with 4-0 cruciate repair in core-only repairs. With the addition of the circumferential suture the 3-0_C + E was stiffer than the 4-0_C + E but not Teno Fix + E.

One of the Teno Fix repairs failed by crimp slippage; none failed by stainless steel suture breakage. The remaining Teno Fix failures were secondary to evisceration of the anchors from the tendon substance (19 of 20) regardless of whether or not a circumferential suture was used. We observed that when the anchor was avulsed from the tendon a large portion of the tendon substance was embedded between the coil and core of the anchor complex.

Discussion

Although stainless steel sutures are used widely in surgery there have been few reports of their use as a core suture for flexor tendon repair,^{27,32,33} likely because of the difficulty in handling and knot tying.²⁷ Moneim et al³⁴ recently investigated the strength of a shape memory alloy suture that is superelastic in its cold state, allowing for suturing and knotting, and that contracts as the thread gains body temperature. Wade et al³² and Cieslik et al,³³ using stainless steel sutures, reported in vitro ultimate failure strengths of up to approximately 80 N; these studies suggest that stainless steel sutures have higher resistive loads to failure than conventional suture techniques.^{13,34,35} Urbaniak et al²⁷ observed that stainless steel suture

was stronger than polyester in a canine model until day 5, when all repairs failed by pulling out of the tendon substance owing to tenomalacia at the suture interface. The Teno Fix device was designed to use the superior material properties of stainless steel suture with an improved mechanism of knotless tendon anchoring. The Teno Fix anchors interdigitate with collagen fibers and the single-stranded multifilament repair does not weave throughout the damaged tendon segments, reducing the bulk of suture material at the repair site.

We elected to test the repairs both with and without a circumferential suture. Several other investigators have tested core repairs independent of circumferential sutures^{29,36–38} because small variability in depth and the technique of circumferential suture placement also has a profound effect on tensile strength.^{39,40} Although this variability did not appear to effect the conclusions of this study significantly, testing with a circumferential suture was necessary because it is indicative of what can be tolerated when each repair is used in a clinical setting. The addition of the circumferential suture increased the 2-mm gapping strength of the 4-0 and 3-0 suture repairs by 63% and 68%, respectively. This is in agreement

Table 2. Failure Modes of All Repairs

Repair	Knot Breakage	Suture Breakage	Suture/Anchor Pullout	Crimp Slippage
3-0_C	1	1	8	NA
4-0_C	1	2	7	NA
Teno Fix	NA	0	9	1
3-0_C + E	2	3	5	NA
4-0_C + E	2	5	3	NA
Teno Fix + E	NA	0	10	0

Table 3. Review of In Vitro Studies on Gapping and Ultimate Strengths of Repair Techniques

Repair	Study	Material	Gapping Force (gap)	Ultimate Force, N
Modified Kessler (2 strand)	Stein et al ⁴⁷	4-0 braided polyester, 6-0 nylon epitendinous	23.6 N (2 mm)	28.9
	Gordon et al ³⁶	4-0 nylon, no epitendinous	Not recorded	22.2
	McLarney et al ¹²	4-0 braided polyester, 6-0 polypropylene epitendinous	22 N (2 mm)	28
	Tang et al ⁴⁶	3-0 nylon, 5-0 nylon epitendinous	23.4 (2 mm)	28.2
Modified Savage (4 strand)	McLarney et al ¹²	4-0 braided polyester, 6-0 polypropylene epitendinous	21 N (2 mm)	32
Cruciate (4 strand)	McLarney et al ¹²	4-0 braided polyester, 6-0 polypropylene epitendinous	44 N (2 mm)	56
	Tang et al ⁴²	4-0 nylon, 6-0 nylon epitendinous	37.4 N (2 mm)	46.3
	Moneim et al ³⁴	4-0 braided polyester, 6-0 polypropylene epitendinous	35.5 N (2 mm)	44.3
	This study	4-0 braided polyester, 5-0 polypropylene epitendinous	46.5 (2 mm)	70
Savage (6 strand)	Savage ³⁸	4-0 braided polyester, no epitendinous	58.9 N (2.7 mm)	67.2
	Wagner et al ²⁹	4-0 braided nylon, no epitendinous	Not recorded	40
	Gordon et al ³⁶	4-0 nylon, no epitendinous	Not recorded	50.4
Tang (6 strand)	Tang et al ⁴²	3 × 4-0 looped nylon, 6-0 nylon epitendinous	43 N (2 mm)	53.6
Nonsuture Repairs	Gordon et al ³⁶	Stainless steel internal anchor	Not recorded	75.2
	Gordon et al ³⁷	Stainless steel external splint	Not recorded	60.6
	Moneim et al ³⁴	Shape memory alloy (nickel and titanium) suture	50.8 N (2 mm)	61.9
Teno Fix	This study	See text	54.5 N (2 mm)	66.7

with studies that showed that the addition of circumferential sutures as well as multistrand repairs increase the *in vitro* tensile strength of a repair.^{10–13,41} It is well known that circumferential sutures can increase the strength of core repairs by up to 88%.³² The 2-mm gapping strength for the 4-0 suture repair of 46.5 N in this study was higher than in others that have reported 2-mm gapping strengths of 35.5 to 44 N for the same repair with a similar caliber suture (Table 3).^{12,34,42} Although we used a running locked circumferential suture technique, using an interlocking horizontal mattress suture as recommended by Dona et al⁴³ may increase the tensile strength of the repairs further.

There was no difference between the peak force to failure of the Teno Fix repair and the suture repairs. Several studies have looked at peak forces with some of the strongest being the 6-strand repairs^{29,36,38,42,44–46} such as those by Savage³⁸ and

Tang et al.⁴² Although seldom mentioned, it is imperative to report the gap developed at peak force because a large gap leads to poor outcomes by allowing intrusion of dense adhesions, leading to decreased tendon excursion. Gapping at peak forces ranged from 3.7 to 6.8 mm for all repairs with no significant differences when core and circumferential groups were analyzed separately. Thus although peak force is a good measure of general strength characteristics it may not be the most clinically relevant.³² There was no difference between groups in energy absorbed up to peak force. This may have been related to our methodology of calculating energy as the area under the force-displacement curve when the peak force was first reached. In many of the Teno Fix cases, because of the characteristic plateau on the force-displacement curve, values near the peak force were maintained even after this force was reached. Because failure did not occur until well after peak

force this may have led to an underestimation of the total energy absorbed by the repair.

The addition of the circumferential suture for the Teno Fix repair increased the 2-mm gapping force by 40% to 54.5 N and the peak force by 48% to 66.7 N. There was less contribution of the circumferential suture to the gapping strength of the repair for the Teno Fix than for the suture repair. The high gapping forces already seen with the device as a core-only repair may explain this finding. The average 2-mm gapping force of the Teno Fix with circumferential suture (54.50 N) is higher than previously reported gapping forces of the techniques such as the modified Kessler^{12,37,47,48}, Kessler, modified Savage,¹² cruciate^{12,35,43} and Tang et al⁴³ repair techniques, but not the technique by Savage³⁸ (Table 3). Notably the gapping strength also is higher than the cruciate repair tested with the 4-0 memory shape alloy suture composed of nickel and titanium.³⁴ The 2-mm gapping force of the Teno Fix and suture repairs were well above the 19N force in active distal interphalangeal joint flexion as reported by both Schuind et al¹⁶ and Urbaniak et al.²⁷ The use of braided stainless steel wire as the core of the repair was likely a large part of the increased strength of the Teno Fix. The use of a larger caliber suture in the Teno Fix system is possible because only 1 strand crosses the repair site in contrast to 4 strands for the cruciate configuration.

We elected to evaluate 2 calibers of braided polyester for the 4-strand cruciate repair. Although the use of 3-0 caliber suture has been advocated for increased tensile strengths,^{48,49} most surgeons use sutures of 4-0 caliber for flexor tendon repair,⁵⁰ and 4-0 suture is what is used most often in biomechanical evaluation of suture configurations (Table 3). Larger suture caliber may increase the bulk of the repair and increase the work of flexion; we currently use 3-0 suture only for the repair of flexor tendons of larger widths. The higher 2-mm gapping force of the Teno Fix compared with the 4-0 suture repair may be clinically helpful because most surgeons feel that a gap greater than 1 to 3 mm is incompatible with a good result because it causes gap-associated adhesions to form.⁵¹⁻⁵⁶ The energy absorbed by the repair to 2-mm gap was significantly greater for the Teno Fix repair than for both the 3-0 and 4-0 suture repairs. We attribute this to the increased surface area of the coil in contact with tendinous fibrils; this may explain why at ultimate failure the anchor eviscerates a central portion of tendon.

The differences between the peak forces sustained

using 4-0 versus 3-0 sutures in this study were not as apparent as the 50% increase that has been reported previously.^{48,49} The failure mode when suture caliber was increased shifted from suture and knot breakage with 4-0 suture to suture pullout with 3-0 suture with the tensile strengths increased. This is in agreement with Taras et al⁴⁹ who found that failure is ultimately through the grasping of the suture configuration rather than by strength of the suture. Failure of 95% of the Teno Fix by pullout rather than suture rupture at high strengths is indicative not only of the strength of a single strand of 2-0 suture but also of the ability of the anchors to grasp the tendon fibrils.

The need to minimize bulk underneath the pulley system necessitates control of the number of strands crossing the repair and the bulk of the tendon at the repair site.^{17,18} Angeles et al⁵⁷ reported an increase in work of flexion secondary to the amount of suture exposed at the tendon surface when comparing the locked cruciate configuration with other 4-strand core repairs. The crimping tool and stop bead-anchor interface allows for precise control of approximation of the tendon ends with a slight overlap. For many surgeons the use of braided polyester suture in the 4-strand cruciate technique often can lead to difficulties in controlling the amount of tendon approximation because of friction between the braided suture and the tendon.

Gordon et al^{36,37} developed devices that use stainless steel either as the core of the repair or as reinforcement to a standard suture repair. Both devices were found to be superior biomechanically to the conventional core suture but likely would have limited use in a clinical setting. The suture anchor was a stiff 1-mm thick device that may cause decreased flexibility when placed over the interphalangeal joints.³⁶ The stainless steel splint was sutured onto the exterior of the tendon to reinforce a standard repair and may cause a decrease in gliding through the fibro-osseous tunnel.³⁷ Olivier et al⁵⁸ recently published a clinical study on the motion stable wire suture of Towfigh, a steel device that anchors on the exterior of the tendon with 2 steel hooks. Because of local irritation, likely caused by the superficial extratendinous anchoring, the device was removed in 29% of patients. The flexibility of the multifilament core suture and intratendinous anchoring of the Teno Fix avoids potential complications seen in these other stainless steel devices. This is supported by use of the Teno Fix device in a clinical setting, which showed that the device has a low complication rate and does not restrict motion around the pulleys and joints.⁵⁹

Nineteen of 20 failures in the Teno Fix group were a result of anchor pullout from the tendon substance whether a circumferential suture was used or not. In the clinical setting the revision of a ruptured repair would be possible without removing the remaining intact anchor. It is important to note, however, that revision may require up to 1 cm of tendon advancement as in FDP avulsion repair. On the contrary, the majority of failures in the suture repair when subjected to high loads with the addition of a circumferential suture were from suture or knot breakage. The use of a stainless steel suture and the anchoring mechanism precluded failure at the suture or knot.

The Teno Fix device is currently only available in one size (2.2-mm diameter) and although the device readily was placed in the index, middle, and ring fingers, its size limitation may preclude its use in lacerations of the fifth digit. The use of the Teno Fix for repairs of concomitant flexor digitorum superficialis injuries is limited to more proximal zone II injuries in which the caliber of the flexor digitorum superficialis can accommodate the device anchor.

This study showed that the clinically relevant 2-mm gapping strength was significantly greater for the Teno Fix device when tested against a 4-0 but not a 3-0 cruciate repair. The energy absorbed by the repair to 2-mm gap was greater than for all suture repairs. We believe energy absorbed to 2-mm gap is one of the most important biomechanical characteristics of a repair because it best quantifies the amount of force the repair is able to absorb throughout the first 2 mm of gap. In addition the ease of device placement and controlled approximation of tendon ends may make the Teno Fix a potentially superior technique for flexor tendon repairs. Testing this device against other suture configurations is necessary as is evaluation of its use in a curvilinear physiologic model.

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