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Supplementary material

Commentary and Perspective, data tables, additional images, video clips and/or translated abstracts are available for this article. This information can be accessed at <http://www.ejbjs.org/cgi/content/full/87/5/923/DC1>

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DEVICE FOR ZONE-II FLEXOR TENDON REPAIR

A MULTICENTER, RANDOMIZED, BLINDED, CLINICAL TRIAL

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Background: The stainless-steel Teno Fix tendon-repair device has improved biomechanical characteristics compared with those of suture repair, and it was well tolerated in a canine model. The purpose of this study was to compare the Teno Fix with suture repair in a clinical setting.

Methods: Sixty-seven patients with isolated zone-II flexor tendon injury were randomized to be treated with a Teno Fix or a four-stranded cruciate suture repair. There were eighty-five injured digits: thirty-four were treated with the Teno Fix, and fifty-one served as controls. A modified Kleinert rehabilitation technique was employed, with active flexion starting at four weeks postoperatively. Patients were followed for six months by blinded observers who determined the range of motion, Disabilities of the Arm, Shoulder and Hand (DASH) score, pinch and grip strength, and pain score on a verbal scale and assessed swelling and neurologic recovery. Adverse outcomes, including device migration and rupture, were monitored at frequent intervals.

Results: Nine of the fifty-one suture repairs ruptured, whereas none of the Teno Fix repairs ruptured ($p < 0.01$). Five of the nine ruptures were caused by resistive motion against medical advice. There were no differences between the two groups in terms of range of motion, DASH score, pinch and grip strength, pain, swelling, or neurologic recovery. The Teno Fix group had slightly slower resolution of pain and swelling compared with the control group. Of the patients who were available for follow-up at six months, sixteen of the twenty-four treated with a Teno Fix repair and nineteen of the twenty-seven treated with a control repair had a good or excellent result. One Teno Fix device migrated and extruded secondary to a wound infection. Of all eighty-five digits that were operated on, four were thought to have tendons of inadequate size to accommodate the device and nine were deemed to have inadequate exposure to allow placement of the anchors.

Conclusions: The Teno Fix is safe and effective for flexor tendon repair if the tendon size and exposure are sufficient. Tendon repairs with the Teno Fix have lower rupture rates and similar functional outcomes when compared with conventional repair, particularly in patients who are noncompliant with the rehabilitation protocol.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

In 1960, Verdan suggested that gentle passive mobilization at four weeks could rupture fresh adhesions and improve the end result of flexor tendon repairs¹. In the 1970s, Kleinert et al.² and Lister et al.³ reported the results of flexor tendon repair with the Bunnell suture technique followed by immediate active extension and passive flexion with Young's rubber-band contraction⁴ to prevent active flexion and rupture. Subsequent studies shaped the now widely accepted be-

lief that the tendon should be mobilized with either passive or active flexion soon after repair to prevent contractures and the need for tenolysis^{3,5-13}.

Modern four or six-stranded repairs and the addition of circumferential sutures have increased the tensile strength of repairs¹⁴⁻¹⁷, suggesting that they are adequate to sustain forces of early active mobilization^{5,6,9,18}. However, several investigators have proposed that measurement of forces in tendons without prior trauma does not account for increases in work of flexion from postoperative edema and adhesion formation¹⁹⁻²². Underestimation of forces after trauma and patients' noncompliance with instructions to avoid resistive active motion during



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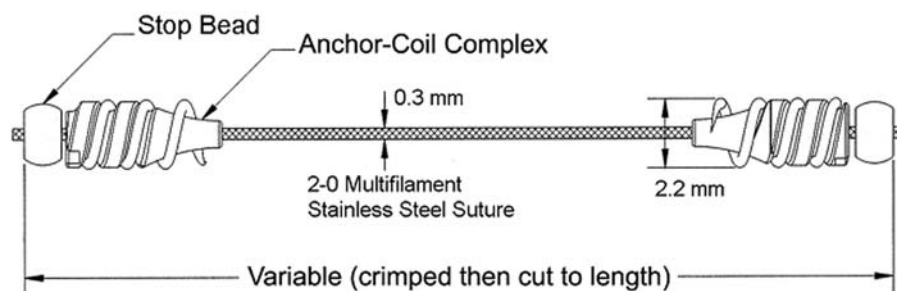


Fig. 1
Schematic of the Teno Fix device.

rehabilitation²³ may explain rupture rates of up to 46% in patients treated with early-active-motion protocols⁹. In addition to rupture, gapping with adhesion formation and diminished tendon glide and function may result from early mobilization.

While many of the proposed suture configurations result in high tensile strength, they are technically demanding, require excessive tendon manipulation, and increase the work of flexion^{16,24-26}. Strickland's repair requirements were based on the concept of sufficient strength throughout the healing period to permit early motion stress, minimal interference with vascularity, minimal gapping, a smooth juncture at the tendon ends, secure knots, and easy placement of sutures in the tendon²⁵. Another criterion may be ease of application and reproducibility of the repair technique across a range of surgeons. The Teno Fix device (Ortheon Medical, Winter Park, Florida) was developed for zone-II flexor tendon repairs to meet these ideal repair requirements.

We previously demonstrated that the Teno Fix device withstands greater force and energy at a 2-mm gap than does a 4-0 four-stranded cruciate repair²⁷. In addition, we showed that the device was well tolerated in a canine model, with successful repairs progressing with normal tendon-healing as documented histologically²⁸. The purpose of the present prospective, blinded, randomized clinical study was to evaluate the safety and effectiveness of the Teno Fix device compared with the locked four-stranded cruciate¹⁶ suture repair.

Materials and Methods

Patients with flexor tendon injury, seen at one of three separate centers over a one-year period, were randomized to

be managed with either a locked four-stranded cruciate¹⁶ repair (control group) or a Teno Fix repair. A separate blocked randomization procedure, based on random numbers generated by the SAS statistical package (SAS Institute, Cary, North Carolina), was used to assign the patients at each center to one of the two treatment groups. Each series of assignments was blocked in groups of eight, so that, of every eight surgical procedures, four were Teno Fix repairs and four were control repairs. Single and multiple-digit injuries were subdivided into two stratifications and randomized separately to ensure an approximately equal number of repaired digits in each treatment group. Digits that were eligible for the study were those that had a laceration of the flexor digitorum profundus tendon, with or without a concomitant injury of the flexor digitorum superficialis, in zone II of the index, long, ring, and/or small fingers that had occurred within the fourteen days prior to the study. Fourteen days was used as the cutoff, as studies have demonstrated no differences in outcome between tendons repaired immediately after injury and those repaired up to four weeks after injury^{29,30}. Randomization was performed after it had been determined that the inclusion criteria had been met but before the patient was taken to the operating room. Ethics committee/institutional review board approval was obtained at each site prior to the initiation of the trial and was in accordance with the Food and Drug Administration's good clinical practices guidelines and the declaration of Helsinki ethical principles for medical research involving human subjects. All patients enrolled in the study signed an informed-consent form and were willing to return for the required postoperative follow-up visits.

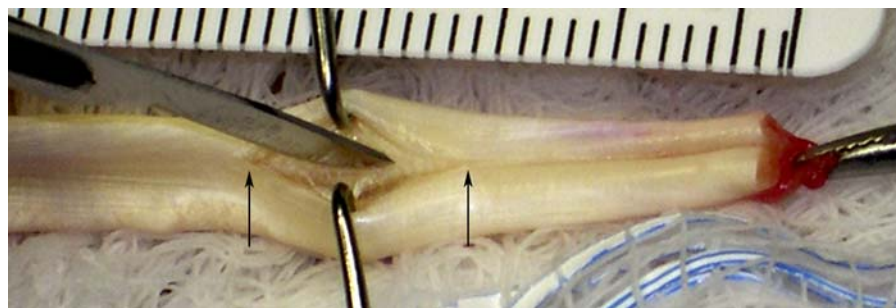


Fig. 2
A longitudinal tenotomy is performed halfway through each tendon, starting 1.0 cm from the cut edge. The arrows denote the beginning and end of the tenotomy.

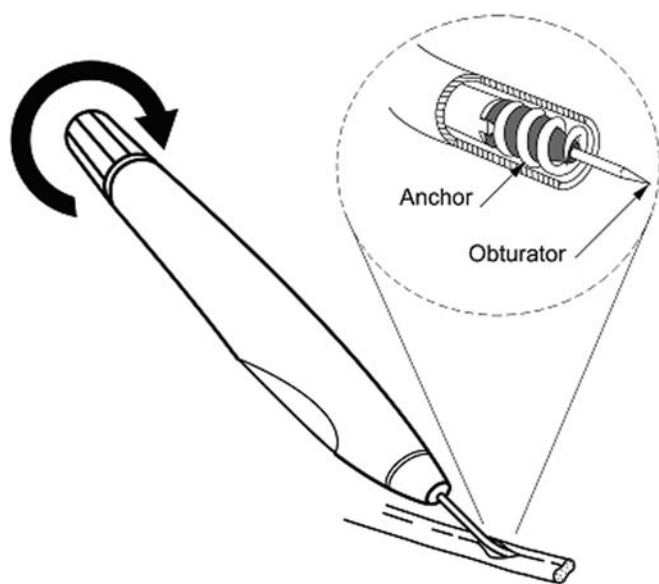


Fig. 3-A
The anchors are twisted into the tendon with the delivery device.

All patients were at least eighteen years of age at the time of the repair. Exclusion criteria included known pregnancy, diabetes mellitus, an autoimmune disorder, documented acquired immunodeficiency syndrome, chronic infection, or another condition or use of a medication that could affect postoperative wound-healing. To avoid complications related to the wound site or that could confound outcome measurements, patients were excluded if they had a history of keloid formation, a lack of adequate cutaneous coverage at the repair site, a concomitant fracture, an amputated digit, arthritis of the hand, prior hand trauma, a congenital hand defect, or another condition that would affect comparative measurements in the contralateral hand. Patients with a crush injury were also excluded, as were those with prior sensory impairment in digits of either hand. However, patients with digital nerve injuries associated with the

trauma that had caused the flexor tendon injury were eligible. Patients with known sensitivity or allergy to the metals contained in the ASTM F138-00 stainless steel (chromium, nickel, copper, cobalt, and/or iron) used to manufacture the Teno Fix device were excluded from the study.

At each of the three sites, one experienced senior surgeon who was adept at standard four-stranded cruciate repairs performed both the control and the Teno Fix repairs. All procedures were performed with use of either axillary or Bier block anesthesia and with a similar surgical technique. Tendons were approached through a modified Bruner incision with windowing of the tendon sheath. Once exposed, all tendons were subjectively evaluated to determine if their size and the exposure were adequate for implantation of the Teno Fix device. Specific criteria included a tendon that was wide enough for approximately 1 mm of tendon to remain on each side of the anchor following implantation; also, it had to be possible to expose at least 10 mm of tendon from the severed end of each injured segment. The tendons that had been preoperatively randomized to be repaired with the Teno Fix device but did not meet the intraoperative criteria for implantation were switched into the control group and were followed as members of that group.

The Teno Fix device is composed of two intratendinous, stainless-steel anchors (a coil around a core) joined by a single multifilament 2-0 stainless-steel suture (Fig. 1). Each anchor is 2.2 mm in diameter and 4.0 mm in length, and the suture is 0.3 mm in diameter. After exposure, a longitudinal intratendinous split is made through half of the tendon substance. This incision starts 1.0 cm from the cut edge and is extended proximally several millimeters away from that edge to accommodate the obturator tip and delivery tube (Fig. 2). After ensuring that the delivery tube is sitting comfortably within the tendon substance, the anchors are twisted into the tendon (Figs. 3-A and 3-B). The anchor engages the tendon substance by capturing fibers between the core and the cork-screw-like coil. A straight needle with a 2-0 multifilament



Fig. 3-B
The proximal anchor after implantation.

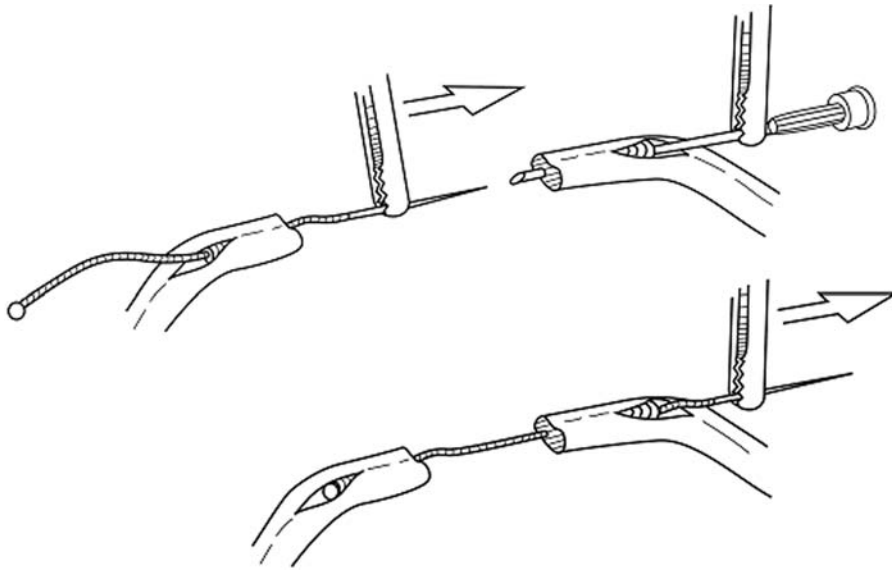


Fig. 4-A

A needle with a suture and a stop-bead attached is threaded into one anchor and pulled through the center of the cut end. The needle is then threaded through the center of the opposite tendon segment and anchor.

stainless-steel suture and an attached stop-bead is threaded into one of the cannulated anchors and is pulled through the center of the tendon's cut end until the end of the stop-bead comes into contact with the anchor. The needle is then threaded through the center of the opposite tendon segment and its anchor with the assistance of a 22-gauge needle (Figs. 4-A and 4-B). The suture is then threaded through a stop-bead in a preloaded crimping instrument. The cut ends of the tendon are pulled together until they are approximated and properly tensioned by ensuring that the two tendon ends overlap slightly, in a fashion equivalent to a suture repair. The stop-bead is then crimped onto the stainless-steel suture (Fig. 5). The excess suture is cut so that the suture end is flush with the crimped bead. Finally, the two tenotomies are closed with 6-0 monofilament suture in a buried configuration, and the

repair site is closed with a running circumferential 6-0 suture. An example of an in situ repair prior to placement of the circumferential suture is seen in Figure 6.

The operative technique for the cruciate suture repair has been previously described¹⁶. All cruciate repairs were performed with a single 4-0 or 3-0 monofilament polypropylene (Prolene; Ethicon, Somerville, New Jersey) suture, depending on tendon size.

Both the control and the Teno Fix repairs were finished with a single epitendinous 6-0 monofilament nylon suture (Ethilon; Ethicon) in a running circumferential configuration.

Concomitant injury to the flexor digitorum superficialis tendon did not preclude the digit from being included in the study and did not affect randomization. In digits with a proximal zone-II injury with transection of the flexor digi-



Fig. 4-B

The needle being delivered through the proximal anchor.

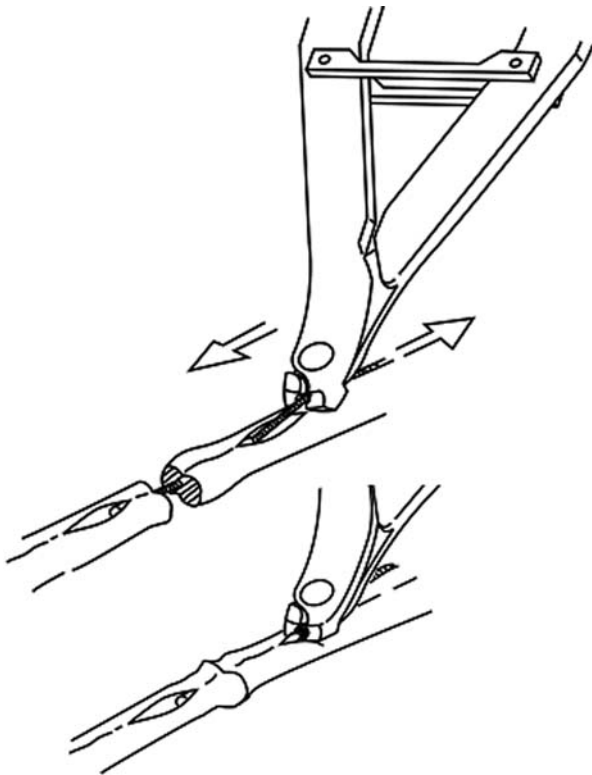


Fig. 5

The tendon ends are pulled together until the tendon is approximated and tensioned. A stop-bead is then crimped onto the suture.

torum superficialis tendon, the flexor digitorum superficialis tendon was repaired with an interrupted suture technique. In other cases, the decision was made to repair only the flexor digitorum profundus tendon and to leave the distal flexor digitorum superficialis tendon stump as a gliding bed for the ten-

orrhaphy and to maintain the vascular supply to the flexor digitorum profundus tendon. Except for jagged injuries, lacerated digital nerves were isolated and were repaired with 8-0 or 9-0 monofilament nylon (Ethilon) under loupe magnification. The flexor sheath was replaced over the tendon but was not closed. Repairs under the A2 or A4 pulley that impeded gliding led to pulley narrowing. After the procedure, the hand was immobilized in a dorsal plaster splint with the wrist in 30° of flexion, the metacarpophalangeal joints in 60° of flexion, and the interphalangeal joints in 0° of flexion.

Rehabilitation was started on the first postoperative day with a passive flexion and active extension protocol. The Kleinert method was utilized for the first three weeks of rehabilitation³. Starting at four weeks, an active flexion protocol that was a modification to the Coventry-Kleinert²⁹ regimen was implemented. The protocol required patients to exercise the injured digit or digits with the prescribed regimen five times a day, with the goals of achieving 25% of flexion during the fourth week, 50% of flexion during the fifth week, and 100% of flexion during the sixth week. Each patient was seen by a therapist twice a week for the first twelve weeks and then once at six months. Each visit included visual inspection and physical examination of the repaired digit or digits, assessment for signs of wound dehiscence or infection of the wound or surrounding area, a pain rating, and a review of home exercise regimens and limitations of activity. In addition, complications such as tendon rupture (as reported by the patient and confirmed through physical examination), triggering, and flexion contractures were monitored weekly. Pain was rated with use of a verbal scale ranging from 0 to 10, with 10 being the "worst pain imaginable." Verbal reports of pain show good correlation with the visual analogue pain scale described by Huskisson³¹. Other outcome measures were assessed at one or two days postoperatively and at three, six, twelve, and twenty-

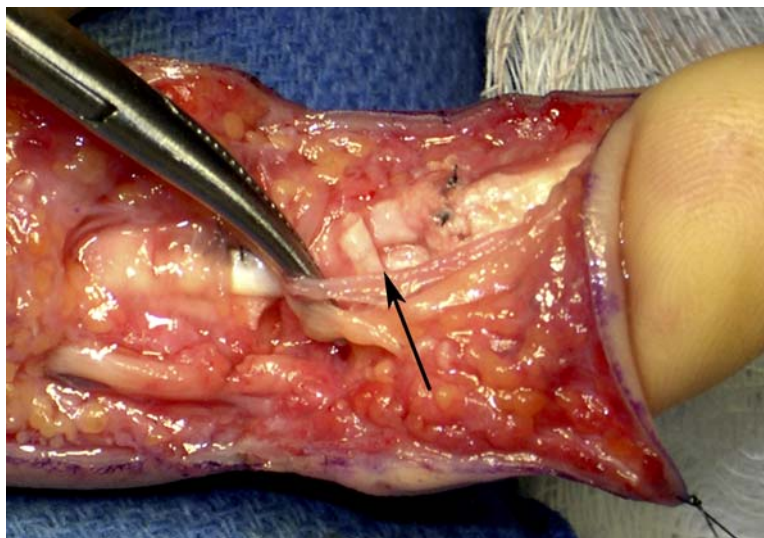


Fig. 6

The final repair prior to the completion of the circumferential suture. The arrow denotes the area of tendon approximation.

four weeks postoperatively. The patients, hand therapists, and clinical personnel who performed the postoperative evaluations were blinded to the type of repair for the duration of the study. Surgeons did not perform the outcome assessments as they obviously knew what type of repair had been done. Data were recorded on case report forms and then were transferred to an electronic web-based data-collection system; all data were verified and analyzed by blinded research personnel and remained confidential.

The mobility of the distal interphalangeal and proximal interphalangeal joints were evaluated with use of Strickland's³² revised score at twelve and twenty-four weeks. This score is calculated as: $\frac{[(\text{proximal interphalangeal} + \text{distal interphalangeal flexion}) - (\text{proximal interphalangeal} + \text{distal interphalangeal extension deficit})]/175^\circ}{100} \times 100$. Repairs are then classified as excellent (75% to 100%), good (50% to 74%), fair (25% to 49%), or poor (<25%). The number and percentage of repairs within each group were used for statistical analysis.

Grip strength and pinch strength were measured at twelve and twenty-four weeks with use of a Jamar hydraulic grip dynamometer and a Jamar hydraulic pinch gauge (Sammons Preston Rolyan, Bolingbrook, Illinois), respectively. Grip strength was measured according to the recommendations by the American Society for Surgery of the Hand, with the elbow in 90° of flexion and the wrist in the neutral position³³. Tip pinch was measured with the thumb and injured digit in a tip-pinching position. Both grip and tip-pinch strength were calculated as a percentage of the strength of the contralateral, uninjured hand. Swelling (an increase in the circumference of the injured digit relative to the contralateral, uninjured digit) was measured in millimeters with use of a finger-circumference gauge (Sammons Preston Rolyan) placed over the approximate area of repair at three, six, twelve, and twenty-four weeks postoperatively.

Functional outcome was assessed with use of the validated Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire³⁴. This survey contains thirty questions on activities of daily living and pain and is intended to be used to evaluate disability and symptoms in patients with a single disorder or multiple disorders of the upper limb at one point or many points in time. A higher score on the DASH reflects greater disability, with 100 representing the highest level of disability. The baseline DASH score was calculated on the first postoperative day to estimate the patient's preinjury level of disability and was compared with the DASH scores at six, twelve, and twenty-four weeks postoperatively.

Semmes-Weinstein monofilament testing³⁵ was performed with the five standard calibrated monofilament sizes (Sammons Preston Rolyan). The sensory threshold of the ulnar and radial side of each injured digit was recorded on the first postoperative day and at twelve weeks postoperatively.

Statistical Methods

All analyses were based on the repair that was performed on the injured digit rather than on the group to which it had been initially randomized. Differences between the control and treatment groups with respect to swelling, grip strength, pinch

TABLE I Patient Demographics*

	Teno Fix	Control
Total	29	38
Gender		
Male	21	26
Female	8	12
Mean age and stand. dev. (yr)	31 ± 13	29 ± 10
Smoker		
Yes	11	19
No	18	19
Dominant hand		
Right	28	36
Left	1	2
Injured hand		
Right	15	18
Left	14	20
Cause of injury		
Knife	18	18
Glass	5	9
Stab	3	6
Metal cut	0	5
Other	3	0
Single or multiple digit injury		
Single	22	29
Multiple	7	9
No. of injured digits		
Index	3	8
Long	7	14
Ring	13	14
Small	11	15
Total	34	51
No. of digits with nerve injury		
Injured	14	34
Repaired	14	28

*The values represent the number of patients, unless otherwise indicated.

strength, and DASH score were analyzed with a repeated one-way analysis of variance; a post hoc least-significant-difference method was used when significance was found. The percentage of patients within range-of-motion and demographic categories was analyzed with a chi-square test or Fisher exact test when expected values were less than five. All statistical testing was done with the SAS statistical package (SAS Institute). The level of significance for all tests was $p \leq 0.05$.

Results

Sixty-seven patients with a total of eighty-five injured digits met the inclusion criteria; forty-one digits were initially randomized to the Teno Fix repair group and forty-four, to

TABLE II Outcome Measures

	Teno Fix	Control	Significance
Duration of op.* (min)			
Single digit	91 ± 23	86 ± 34	P > 0.05
Multiple digits	164 ± 53	148 ± 52	P > 0.05
Ruptures (no. of digits)	0/34 (0%)	9/51 (18%)	P = 0.01†
Infections (no. of patients)	3/29 (10%)	4/38 (11%)	P > 0.05
Swelling* (% of circumference of uninjured digit)			
3 wk	115 ± 11	115 ± 9	P > 0.05
6 wk	116 ± 10	109 ± 7	P > 0.05
12 wk	110 ± 7	106 ± 7	P > 0.05
6 mo	107 ± 7	103 ± 6	P > 0.05
Pain* (verbal scale) (points)			
1 day	2.9 ± 2.5	2.7 ± 1.8	P > 0.05
3 wk	1.4 ± 2.6	0.9 ± 1.5	P > 0.05
6 wk	1.6 ± 2.3	0.8 ± 1.2	P > 0.05
12 wk	0.6 ± 0.9	0.5 ± 0.9	P > 0.05
6 mo	0.6 ± 1.6	0.4 ± 1.2	P > 0.05
Strickland's revised score at 6 mo (no. of digits)			
Excellent	7 (29%)	8 (30%)	
Good	9 (38%)	11 (41%)	
Fair	5 (21%)	5 (19%)	
Poor	3 (13%)	3 (11%)	
Excellent/good	16 (67%)	19 (70%)	P > 0.05
Fair/poor	8 (33%)	8 (30%)	
Grip strength at 6 mo* (% of that of uninjured hand)	88 ± 38	84 ± 20	P > 0.05
Pinch strength at 6 mo* (% of that of uninjured digit)	81 ± 32	78 ± 42	P > 0.05
Mean DASH score* (points)			
Baseline	1.3 ± 4.7	0.8 ± 2.2	P > 0.05
6 wk	27.2 ± 22.7	22.7 ± 19.8	P > 0.05
12 wk	7.4 ± 8.6	8.1 ± 13.8	P > 0.05
6 mo	2.5 ± 3.8	2.0 ± 4.2	P > 0.05

*The values are given as the mean and standard deviation. †A significant difference.

the control group. However, seven digits that had been randomized to the Teno Fix group were switched into the control group because there was inadequate surgical exposure to implant the device. Ultimately, thirty-four digits were repaired with the Teno Fix device and fifty-one, with the control technique. With the exception of one patient, all patients had involvement of only one or two digits. All injuries were associated with a concomitant injury to the flexor digitorum superficialis tendon, but only one patient had a repair of that tendon. Specific characteristics of the patients, including hand dominance, mechanism of injury, involved digit or digits, and presence of digital nerve injury are summarized in Table I. Sixty (90%) of the sixty-seven patients were available for follow-up at twelve weeks, and fifty-two (78%) were available at six months. One patient (the one who had the repair of the flexor digitorum superficialis tendon) in the control group died from a cerebrovascular event four weeks postoperatively.

Nine (18%) of the fifty-one tendons that were repaired with the cruciate technique ruptured, whereas none of the tendons repaired with the Teno Fix device ruptured ($p < 0.01$). The cause and course of all ruptures are presented in the Appendix. With the exception of those in two patients (Cases 4 and 6; see Appendix), all ruptures occurred within six weeks after the primary repair. One patient (Case 4; see Appendix) missed all of the visits between the sixth and twelfth weeks after the operation, and the repair may have ruptured earlier than the twelve-week visit. Three ruptures (Cases 7, 8, and 9; see Appendix) occurred in patients who had two digital injuries, but the other repair remained unruptured. Two ruptures (Cases 1 and 9; see Appendix) occurred after a wound infection. Five of the nine ruptures occurred while the patient was being noncompliant with therapy by prematurely using the hand for active or resisted flexion earlier than healing dictated. Three of the nine ruptures occurred during the active-motion

phase of rehabilitation of patients who were compliant with therapy. Seven of the ruptured repairs were treated with suture repair or tendon-grafting. Intraoperative findings revealed that five of those repairs had failed by suture rake-out and one, by suture breakage. The failure mode was not recorded for the seventh repair. None of the ruptures for which the failure mode was recorded were due to failure at the knot. Regardless of the final outcome of the repair of a rupture, all ruptured digits were excluded from the final range-of-motion measurements.

Pain and swelling decreased six weeks after the Teno Fix repairs and three weeks after the control repairs; both decreased over time over six months (Table II). There was no significant difference in the percentage of digits with an excellent or good result, based on Strickland's revised score³², at twelve weeks between the Teno Fix group (44%; twelve of twenty-seven digits) and the control group (59%; seventeen of twenty-nine digits). This percentage was increased at six months in both the Teno Fix group (67%; sixteen of twenty-four) and the control group (70%; nineteen of twenty-seven), and again there was no difference between the groups ($p > 0.05$) (Table II). Grip and pinch strength relative to that of the contralateral hand or digit increased over time, to approximately 80% of that on the contralateral side at six months, with no significant differences between the two groups at any time-point (Table II). At six months, the mean functional DASH scores (and standard deviation) for the Teno Fix and control groups were 2.5 ± 3.8 and 2.0 ± 4.2 points, respectively ($p > 0.05$), which approached baseline preinjury scores (Table II). There were no significant differences in the DASH scores between the two groups at baseline or at six, twelve, or twenty-four weeks.

In the Teno Fix group, a nerve laceration was repaired in fourteen digits, and at twelve weeks eleven of them were available for testing of neurologic recovery with the Semmes-Weinstein monofilaments. In the cruciate-repair group, a nerve laceration was repaired in twenty-eight digits, and at twelve weeks twenty-three were available for testing. The majority of the patients in the series had diminished protective sensation (purple monofilament) or better neurologic function, regardless of whether the digital nerve had never been injured or had been transected and repaired. With the numbers available, the proportion of patients with a digital nerve repair who had diminished protective sensation or better neurologic function did not differ significantly between the Teno Fix and control groups, and there were no differences in the remaining outcome measures between the patients who had had a digital nerve repair and those who had not.

An infection developed in three patients in the Teno Fix group and four patients in the control group; details of those cases are summarized in the Appendix. The infection in one patient (Case 10; see Appendix) led to extrusion of the Teno Fix device, which was subsequently removed. That patient was a sixteen-year-old boy who had sustained a single-digit injury—a laceration of the flexor tendon of the ring finger on the dominant, right hand from broken glass. The wound was in-

jured at the time of presentation and was treated with irrigation and antibiotics for eleven days until the infection resolved clinically. At nine days after the primary repair with the Teno Fix device, *Staphylococcus aureus* cellulitis developed in the wound and was treated with antibiotics. The infection resolved three weeks postoperatively. At four weeks postoperatively, a flexion contracture of the proximal interphalangeal joint developed, and the ring finger was splinted in extension. At eleven weeks postoperatively, a pressure area developed on the volar aspect of the proximal interphalangeal joint, presumably from a tight-fitting dorsal extension splint. At twelve weeks, despite the flexion contracture, the range of motion was categorized as good. At sixteen weeks, a small piece of the Teno Fix suture became visible over the volar sore. The patient was taken to the operating room, where an intact repair site surrounded by dense adhesions and an extruded Teno Fix device were found. The device was removed. Pus drained from the wound three days later, and the skin was surgically débrided. Antibiotics were administered, and the infection resolved twelve days later. This patient ended up with a poor result. At the end of the study, no other Teno Fix devices had migrated or had been removed after a primary repair.

Regardless of the initial randomization, all digits were subjectively evaluated to determine the feasibility of placement of the Teno Fix device. Four digits (three ring fingers and one small finger) were deemed, on the basis of visual inspection, to have tendons that were too small to accommodate the tendon anchors for all randomized digits. Nine (11%) of the digits (one index finger, two long fingers, two ring fingers, and four small fingers) were deemed to have inadequate exposure or an injury too distal in zone II for placement of both anchors. Of the forty-one digits that had been initially randomized to be treated with a Teno Fix repair, seven were reassigned intraoperatively to be managed with a cruciate repair because the surgical exposure was perceived to be inadequate for implantation of the Teno Fix. Three of the digits for which it was decided intraoperatively that it was necessary to change to a control repair were in patients who did not complete the study and were lost to follow-up. Another of the repairs (of the index finger in Case 9; see Appendix) ruptured at 1.5 weeks, in a patient who was noncompliant with therapy. In a subset analysis, there were no significant differences between the outcomes of the remaining three digits that were switched into the control group and those of the digits that had been originally randomized to the control group.

Discussion

Since the advent of primary repair of flexor tendon lacerations in Bunnell's "no man's land," there has been an abundance of biomechanical and animal studies on flexor tendon repair^{16,17,36-50}. The aim of those studies was to reduce gapping and rupture secondary to forces encountered during rehabilitation. Clinical studies of flexor tendon repair have focused less on comparing repair techniques and more on methods of rehabilitation (Table III). With the exception of studies by Savage and Risitano, who used a six-stranded technique⁵¹,

TABLE III Clinical Studies on Zone II Flexor Tendon Repair

Study	Repair	Mobilization*	Mean Duration of Follow-up (mo)	Rate of Exc./Good Results (%)	Rupture Rate (%)
Duran and Houser, 1975 ⁵³	Modified Bunnell (two-strand)	Duran Houser	NA	74†	16
Lister et al., 1977 ³	Modified Bunnell (two-strand)	Kleinert	5.3	75	7
Becker et al., 1979 ⁷	Becker repair (beveled ends secured by three sutures on each side)	Active	2	70	10
Strickland and Glogovac, 1980 ¹³	Modified Bunnell or modified Kessler (two-strand)	Immobilized	5.1	12	16
		Duran Houser	4	56	4
Strickland, 1985 ³²	Modified Bunnell or modified Kessler (two-strand)	Duran Houser	NA	56	4
Gault, 1987 ⁶⁵	Kessler (two-strand)	Kleinert	26.4	72	4‡
Singer and Maloon, 1988 ⁵⁴	Kessler-Mason-Allen (two-strand)	Kleinert	10	49	3‡
Chow et al., 1988 ⁵²	Modified Kessler or Tajima (two-strand)	Kleinert with Duran Houser component	6 (minimum)	98	4
Small et al., 1989 ⁶⁶	Kessler (two-strand)	Active	6 (minimum)	75	9
Cullen et al., 1989 ⁶⁷	Modified Kessler (two-strand)	Active	10.2	78	7
Savage and Risitano, 1989 ⁵¹	Savage (six-strand)	Active	3 (minimum)	70	4
May et al., 1992 ⁸	Kessler (two-strand)	Kleinert	12	72	4
		Kleinert modification§		62	2
		Kleinert modification#		83	4
Silfverskiold and May, 1994 ¹⁰	Kessler (two-strand)	Modified active**	6	100	4
Bainbridge et al., 1994 ⁵	Modified Kessler (two-strand)	Kleinert	2.5 (minimum)	54	4
		Active		94	8
Elliot et al., 1994 ¹⁸	Modified Kessler (two-strand)	Active	6.1	79	5
Baktir et al., 1996 ⁶	Kessler (two-strand)	Kleinert	12	78	5
		Active		85	4
Peck et al., 1998 ⁹	Modified Kessler (two-strand)	Kleinert	3	85	8
		Active		69	46
Kitsis et al., 1998 ²⁹	Kessler (two-strand)	Active	12	89	6
Harris et al., 1999 ²³	Kessler (two-strand)	Active	7.5	NA	4

*Active = active flexion and extension, Kleinert = passive flexion and active extension, Duran Houser = passive flexion and passive extension, and Immobilized = immobilization for three weeks. †Average percentage of the range of motion, compared with the contralateral side, based on distal interphalangeal, proximal interphalangeal, and metacarpophalangeal motion. ‡Includes injuries in other zones. §Passive flexion with active extension with the addition of increased passive flexion. #Passive flexion of all fingers with active extension. **Active flexion after full passive flexion.

and Becker et al., who used a beveled tendon technique⁷, all of the clinical investigations that we reviewed were of two-stranded core repairs. Of the studies on rehabilitation techniques, few involved more than one cohort within the same population, which makes it difficult to draw conclusions on the advantages of one technique over another^{5,6,8,9,13}. Comparisons are also difficult because the results of flexor tendon repairs are influenced by many factors, such as patient age, cause and severity of injury, case selection, preoperative delay, postoperative rehabilitation, methods of measurements, and technique of repair^{3,13}. To our knowledge, we performed the first randomized, blinded study in which more than one repair

technique was investigated in a series of patients treated with the same rehabilitation protocol.

While some authors have advocated early active flexion over passive flexion⁵, others have reported high proportions of excellent and good results of protocols involving passive flexion with either the Kleinert or the Duran-Houser technique^{3,6,8,9,52,53}. We elected to use the Kleinert technique because it is the gold standard worldwide. Others who have used the Kleinert method of rehabilitation have reported rates of good to excellent results ranging between 49% (nineteen of thirty-nine)⁵⁴ and 85% (twenty-two of twenty-six)⁹. The rates of good to excellent results in the present study (67% in the Teno Fix repair



Fig. 7
Radiograph of a hand with a tendon repaired with the Teno Fix device, which conforms to the fibro-osseous tunnel across the interphalangeal joints.

group and 70% in the control group) is thus within the range reported for historical controls. Comparison of the range-of-motion results in this study with those in other reports may be of limited value because of differences in patient compliance with the rehabilitation protocol and in the rehabilitation regimens themselves. In addition, the method used to score the range of motion^{55,56} is a confounding factor between studies, which share only the categorization of results into excellent, good, fair, or poor categories. Other investigators have commented that many uncontrolled variables make it extremely difficult to meaningfully compare results between different centers^{13,54}. Notably, Singer and Maloon⁵⁴ studied a cohort of patients that was similar to ours in terms of socioeconomic variables and found that, at ten months, only 49% of digits in which a zone-II injury had been repaired with a two-stranded suture technique had a good or excellent outcome.

We did not anticipate differences between our two study groups with respect to range of motion, as the same rehabilitation protocol was used in both groups. As other investigators have reported^{13,52}, the Kleinert technique potentiated flexion deformities early on, as a result of the flexed position of the in-

terphalangeal joints from the rubber band traction. We employed an established method of passive extension exercises and extension splinting at night starting at nine weeks after the surgery. This increased the number of good to excellent results between the twelve and twenty-four-week time-points in both groups.

Clinical studies of patients treated with flexor tendon repair and various rehabilitation protocols have demonstrated rupture rates ranging from 2%⁸ to 46%⁹ (Table III). While the trade-off for the benefits of aggressive mobilization may be an increased risk of gapping and rupture, there has been no clearly defined increase in rupture rates with the progression from early passive to early active mobilization. We agree with other authors²³ that it is likely that variations in patient population, rather than the method of mobilization, produces the variations in rupture rates among studies. The 18% rate of ruptures of the four-stranded cruciate repairs in our study is within the range for historic controls but is higher than the typical rate of between 4% and 10%. We think that a randomized trial is an ideal method for controlling for patient characteristics. Two ruptures (Cases 1 and 9; see Appendix) in our study likely occurred because of infection, which may have disrupted the fixation of the suture to the tendon substance. As has been reported by others, the majority of the ruptures occurred when the patients were noncompliant with therapy by prematurely using the hand for active or resistive flexion earlier than the protocol dictated⁵⁷. None of the thirty-four digits with the Teno Fix repair ruptured. To our knowledge, no other clinical study has demonstrated a 0% rupture rate with zone-II repair. Notably, Savage and Risitano⁵¹ reported a 4% rupture rate following use of a six-stranded suture configuration in twenty-three zone-II repairs. Almost all of the ruptures in our study occurred within the first six weeks after the primary repair, a finding that is in agreement with those in other studies that we reviewed. Assuming that the control and study groups were equally matched cohorts, it is likely that the Teno Fix device increased the threshold for rupture either during the active-motion phase of therapy or when the patient used the hand prematurely.

We are not aware of any previous studies in which a validated hand and upper-extremity questionnaire was used to evaluate functional outcome following flexor tendon repair. We found no differences in the DASH scores between the two groups at any time-point in our study. There was a reduction in disability from the six-week to the three-month time-point, and function approached the baseline level at six months following the repair. This finding was supported by grip and pinch-strength measurements. Grip strength at six months (88% of that on the contralateral side in the Teno Fix group and 84% in the control group) was similar to that reported by others who measured grip strength at one year^{6,58}. Finally, with the numbers available, our analysis showed that the Teno Fix device did not interfere with recovery of digital nerve function compared with that following the control repairs.

As anticipated, the patients in both groups reported the greatest pain on the first postoperative day. The pain rapidly

decreased after the three-week time-point in the control group and after the six-week time-point in the Teno Fix group. Overall, the pain ratings were relatively low because of a lack of concomitant injuries and the assessment of pain at rest rather than during movement. Digital swelling followed a similar pattern, with the Teno Fix group having slightly more swelling than the control group at most time points. The surgeons performing the repairs noted that the exposure needed to implant the Teno Fix anchors was greater than that needed for the cruciate repairs. This might explain the prolonged increase in swelling and pain after the Teno Fix repairs.


In vitro studies have suggested that stainless-steel sutures have high resistive loads to failure^{17,45,59,60}. However, they are not typically used in flexor tendon repair, probably because of the difficulty in handling them and in knot-tying⁶¹. The Teno Fix device was designed to take advantage of the properties of stainless-steel sutures while providing a knotless anchoring device, thus preventing both suture and knot-related failures. Gordon et al.⁶² developed a flat, stiff, stainless-steel device that was biomechanically superior to two and six-stranded suture repairs; however, they did not perform clinical studies to demonstrate efficacy or equivalence. The Teno Fix device did not limit interphalangeal joint flexion, as evidenced on radiographs and by clinical examinations (Fig. 7). Olivier et al.⁶³ reported the results following use of a stainless-steel device anchored on the exterior of the tendon surface; the device had to be removed from 29% of patients secondary to local irritation. Foreign material placed on the outside of tendons was shown to cause adhesions in a canine study⁶⁴. In our study of a canine model, we observed that the Teno Fix device remains embedded in the tendon substance with little reaction on the tendon surface in successful primary repairs²⁸. Similarities between the ranges of motion in the two groups in the present clinical study suggest that the device does not increase extratendinous adhesions when compared with suture repair. The single strand of braided stainless-steel suture that crosses the repair site did not lead to clinically reported triggering, and none of the patients complained of a foreign-body sensation or bulkiness along the volar aspect of the digit.

There was no significant difference in the duration of surgery between the two groups, and all three surgeons reported that they had easily mastered the technique of implanting the Teno Fix device. An advantage of the device was the ability to use the proximal anchor with a stop-bead and suture attached as a tendon passer to retrieve the flexor digitorum profundus and flexor digitorum superficialis tendons from the palm and to redirect them through the fibro-osseous sheath. This technique has been previously employed with the two-stranded modified Kessler repair. The Teno Fix device is currently available in one size and, as a result, mandates that tendon size and exposure be adequate for placement of both anchors while pulley anatomy is respected. Throughout the study, techniques for negotiating repairs of distal zone-II injuries in which the repair site lay under the A4 pulley were developed. The repair sequence requires retrieval of the distal stump out of the sheath to allow anchor placement with deliv-

ery of the tendon through the pulley with use of the wire suture of the device. This is followed by crimping at the proximal end of the repair and windowing the pulley to complete the repair.

The results of this study showed that, compared with a conventional repair, the Teno Fix repair has a lower rupture rate and a similar outcome in patients treated with a conservative rehabilitation protocol. The Teno Fix repair may be particularly useful in noncompliant patients by raising the threshold for rupture early after the repair. We are presently studying this device in the setting of a more aggressive, early-active-motion protocol, where gap-associated adhesions may emphasize differences in the range of motion while maintaining a low rupture rate.

Appendix

 Tables presenting the details on all tendon repair ruptures and the course of all infections that occurred in the series are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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