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# A Device for Zone-II Flexor Tendon Repair

## Surgical Technique

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### INTRODUCTION

Many multiple-stranded suture configurations proposed for repairing zone-II flexor digitorum profundus lacerations in the hand are high in tensile strength but are technically demanding, require excessive tendon manipulation, and increase the work of flexion<sup>1-4</sup>. The stainless steel Teno Fix implant (Ortheon Medical, Winter Park, Florida) is a United States Food and Drug Administration-approved device that was developed to take advantage of the strength of stainless steel suture while avoiding difficulties with handling and knotting. The Teno Fix device has increased gapping strength and energy compared with suture repair<sup>5</sup> and was well tolerated in an in vivo canine model<sup>6</sup>. We recently reported the results of a multicenter, randomized, blinded, clinical trial comparing the results of the Teno Fix repair with those of a four-stranded suture repair<sup>7</sup>. The most notable finding was that nine of the fifty-one suture repairs ruptured, whereas none of the Teno Fix repairs ruptured. Five of the nine ruptures in the control group were caused by active gripping against medical advice in the early passive motion rehabilitation protocol. The Teno Fix repair did not fail in the group of patients managed with the standard passive rehabilitation protocol. This advantage is important when patient compliance with a program may be inadequate.

One important observation, made after completion of that study, was that in nine of eighty-five digits there was a lack of adequate surgical exposure secondary to very distal lacerations, which precluded placement of the distal anchor 1 cm from the lacerated tendon edge. To address this, we have developed a new technique utilizing the Teno Fix anchor in conjunction with a pullout suture through the distal phalanx; this technique is similar to that employed

### ABSTRACT

#### 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 leinert rehabilitation technique was employed, with active flexion starting at four weeks post-operatively. Patients were followed for six months by

*continued*

**ABSTRACT** | continued**METHODS (CONTINUED):**

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:**

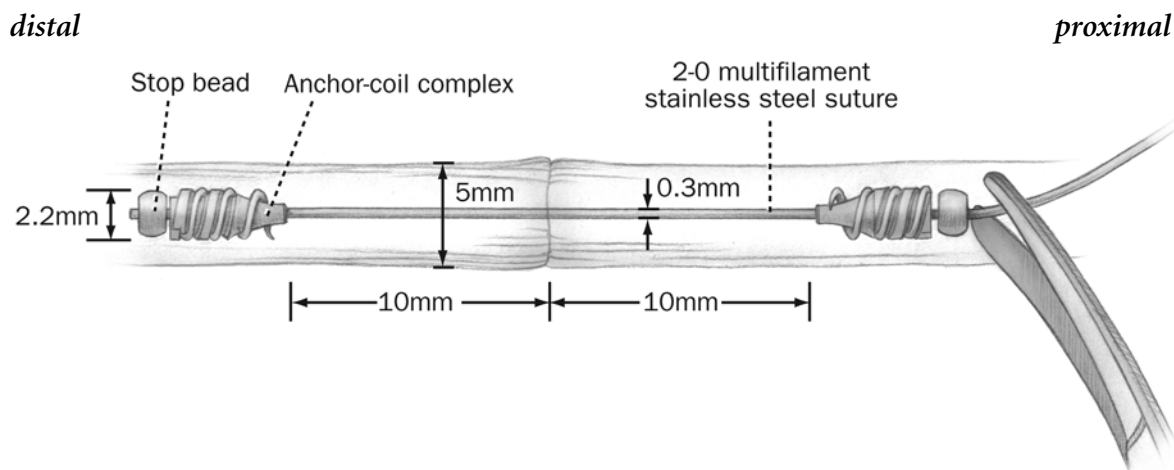
The Teno Fix is safe and effective for flexor tendon repair if the tendon size and exposure are sufficient. Tendon repairs with the Teno Fix have lower rupture rates and similar functional outcomes when compared with conventional repair, particularly in patients who are non-compliant with the rehabilitation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

for flexor digitorum profundus avulsions.

This synopsis reviews the steps of the standard method for implanting the Teno Fix device and outlines clinical tips for accessing and delivering the proximal and distal tendon stumps while preserving the critical pulleys. The new technique for repairing distal zone-II and zone-I injuries through a transosseous pullout stainless steel suture will also be reviewed.

**SURGICAL TECHNIQUE***Basic Technique Description*

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). The device is currently available in one size; each anchor is 2.2 mm in diameter and 4.0 mm in length, and the suture is 0.3 mm in diameter. Each kit contains two obturators (each

**FIG. 1**

Schematic diagram of the Teno Fix device.

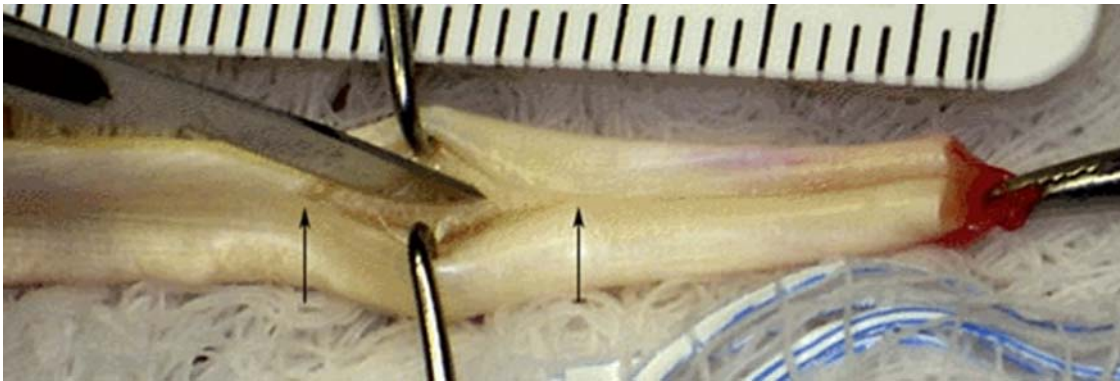
**FIG. 2**

A Teno Fix kit contains two obturators (each preloaded with an anchor), a suture with stop-bead attached, and a crimper preloaded with a stop-bead.

preloaded with an anchor), a suture with a stop-bead attached, and a crimper preloaded with a stop-bead (Fig. 2).

The patient is placed supine. A standard arm table and an arm tourniquet set to 250 mm Hg are used. Regional anesthesia

(usually in the form of an axillary block) is used for this procedure. We routinely give a single dose of intravenous antibiotics

**FIG. 3**

A longitudinal tenotomy is made halfway through each tendon, starting 1 cm from the cut edge. The arrows denote the beginning and end of the tenotomy.

**CRITICAL CONCEPTS****INDICATIONS:**

- Zone-II flexor digitorum profundus lacerations in which the tendon is at least 5 mm in width to accommodate the device anchor.
- Zone-I lacerations and flexor digitorum profundus avulsions utilizing a transosseous pull-through technique, crimping over a sterile button distally.

**CONTRAINDICATIONS:**

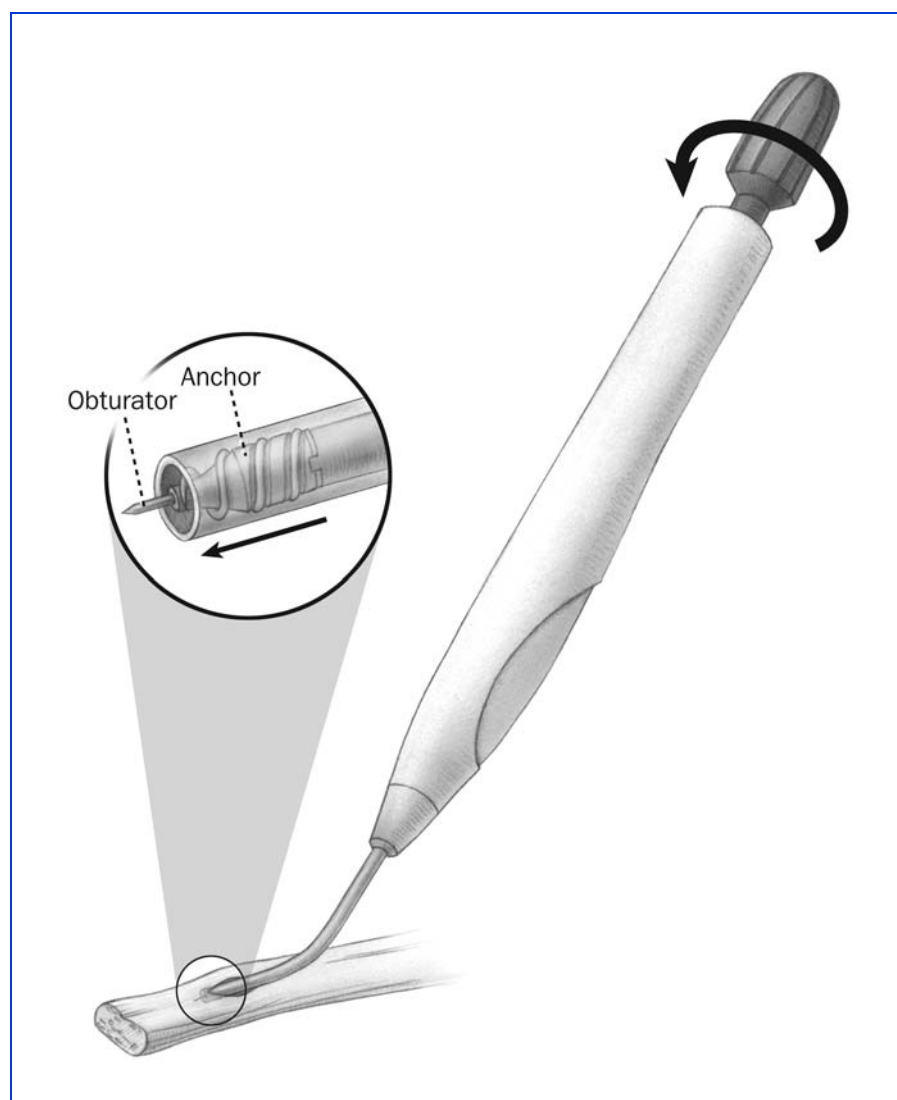
- An important observation from our clinical study relates to the size of the tendon relative to the implant, which prevents its use in smaller flexor digitorum profundus tendons. Four of the digits in the study were thought to have tendons of inadequate size to accommodate the anchor. Although direct measurements of the tendon diameter were not made, data collected from our published biomechanical study<sup>5</sup> indicate that most flexor digitorum profundus tendons have a 5-mm width, making placement of the 2.2-mm-diameter anchor possible.
- Patients with known sensitivity or allergy to the metals contained in the ASTM (American Society for Testing and Materials) F138-00 stainless steel (chromium, nickel, copper, cobalt, and/or iron) used to manufacture the Teno Fix device should not receive the device.

*continued*

(cephazolin) prior to incision. The laceration is respected and is incorporated into an extensile zig-zag or Bruner incision to allow for visualization of the injured tendon.

In the case of a typical zone-II injury, the proximal stump of the flexor digitorum profundus is retracted back to the mid-palm at the lumbrical attachment. It

can be instrumented at that location with placement of the first anchor. After the cut end of the proximal tendon stump is visualized, a longitudinal intratendinous split is made through half of the tendon substance. This incision starts 1 cm from the cut edge and is extended proximally several millimeters away from that edge to accommodate the

**FIG. 4**

After ensuring that the delivery tube is parallel to the longitudinal axis of the tendon, the anchor is screwed into the tendon by turning the knob at the top of the obturator.



FIG. 5

After anchor implantation, the anchor should sit comfortably within the longitudinal tenotomy.

obturator tip and delivery tube (Fig. 3). After ensuring that the delivery tube is sited properly and parallel to the longitudinal axis within the tendon substance, the anchor is advanced into the tendon by turning the knob at

the top of the obturator (Fig. 4). The anchor engages the tendon substance by capturing collagen fibers between the core and the corkscrew-like coil and should sit comfortably within the longitudinal tenotomy (Fig. 5). In a sim-

ilar manner, an anchor is then placed into the distal stump. The distal stump is usually lying near or under the proximal edge of the A4 pulley. It should be noted that the tenotomy for the distal anchor is made either proximal



FIG. 6

The needle, with the suture and stop-bead attached, is threaded into one anchor and is pulled through the center of the cut end.

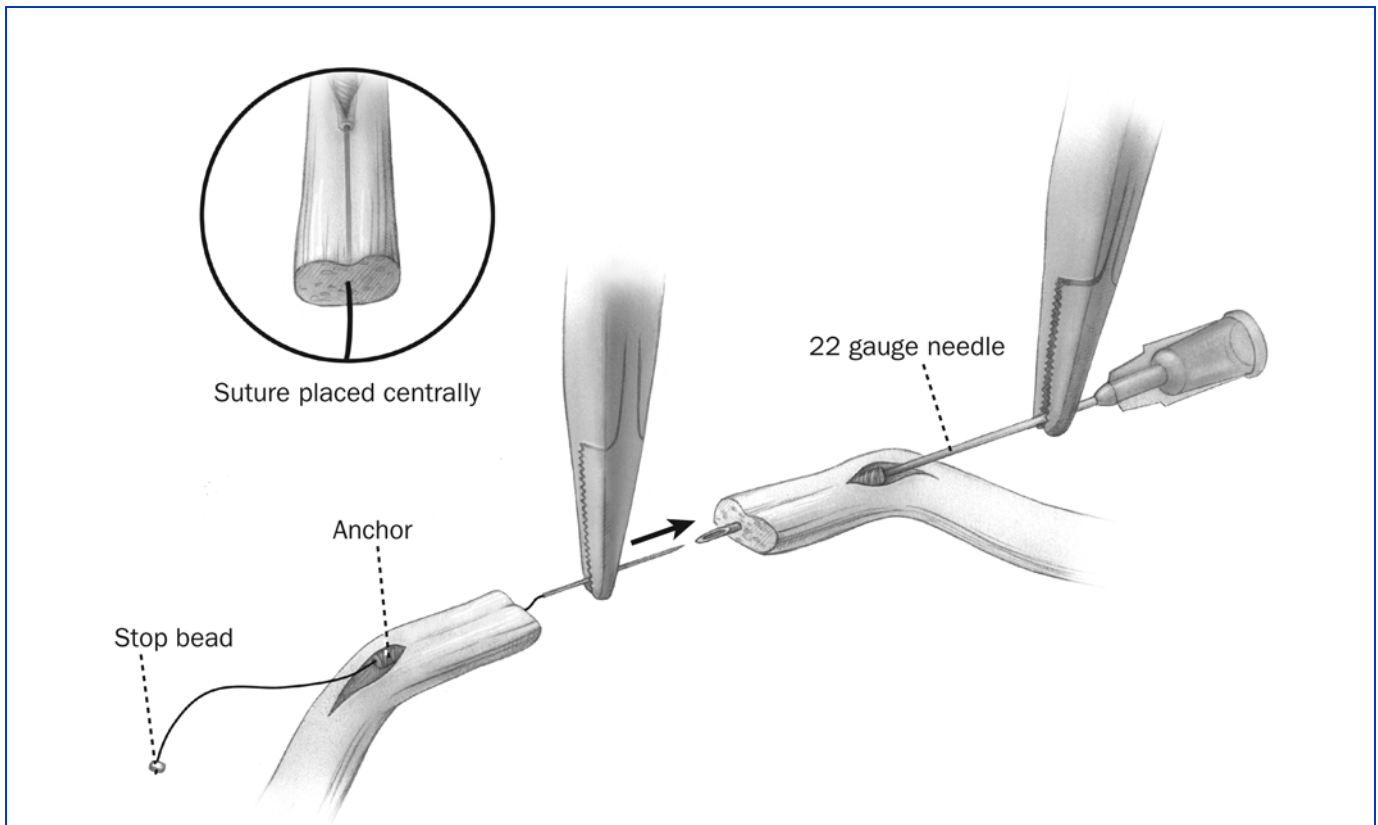


FIG. 7-A

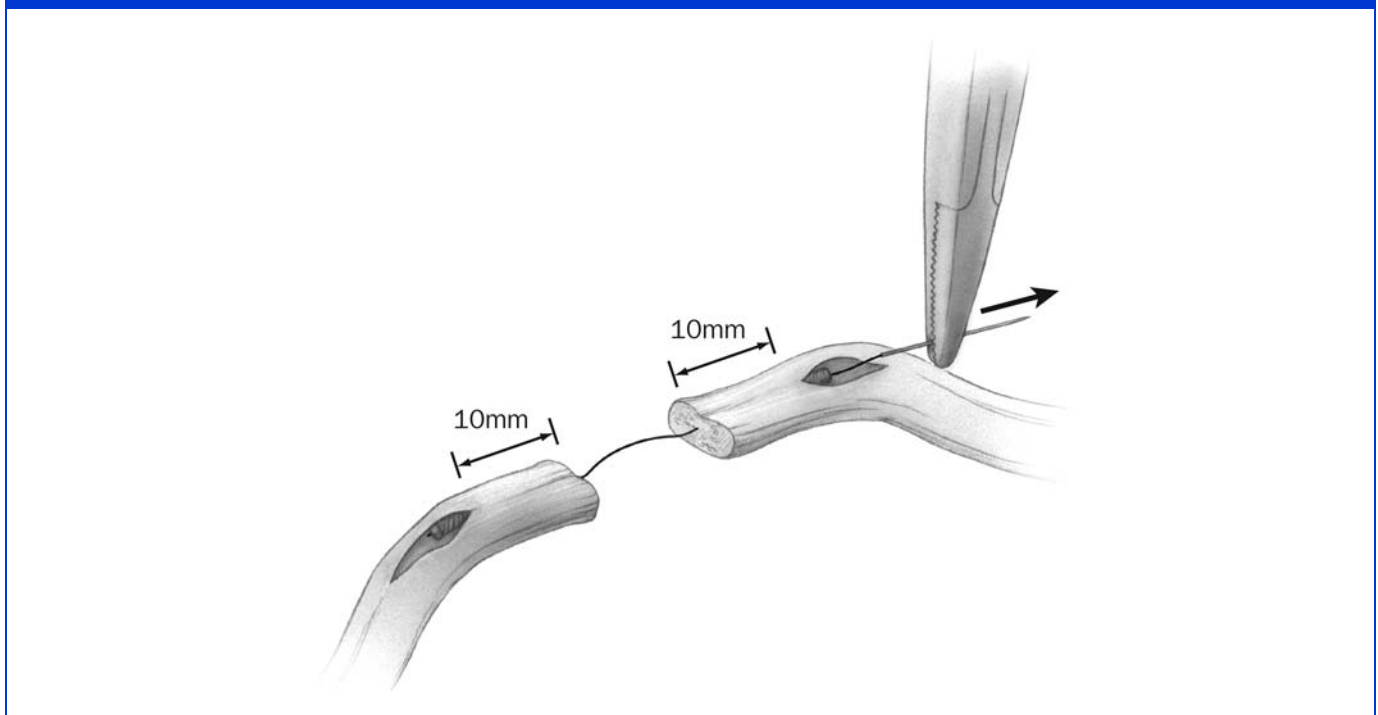


FIG. 7-B

**Figs. 7-A and 7-B** The needle is then threaded through the center of the opposite tendon and anchor with the aid of a 22-gauge needle.

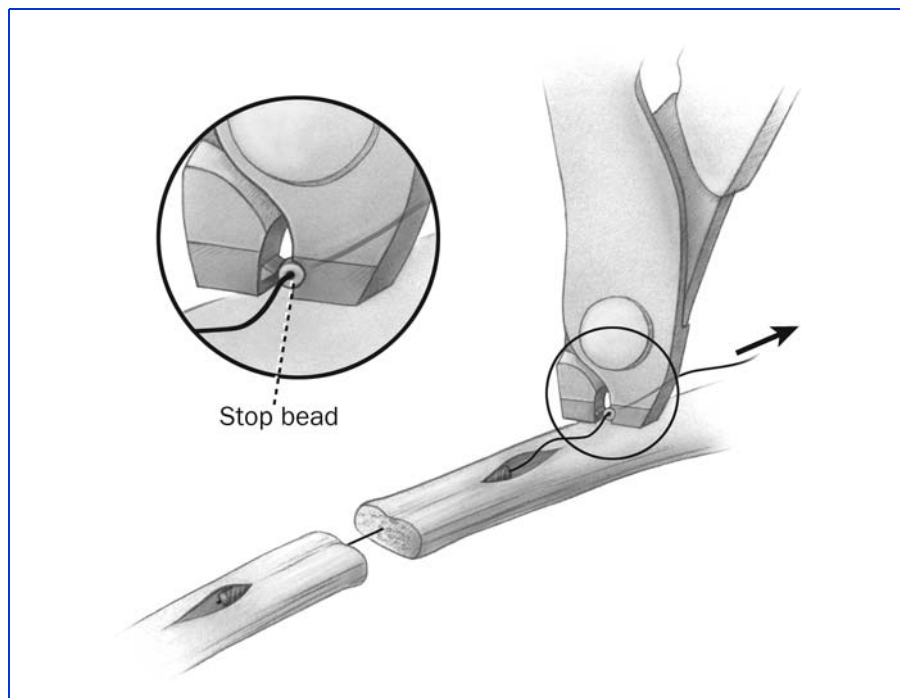


FIG. 8-A

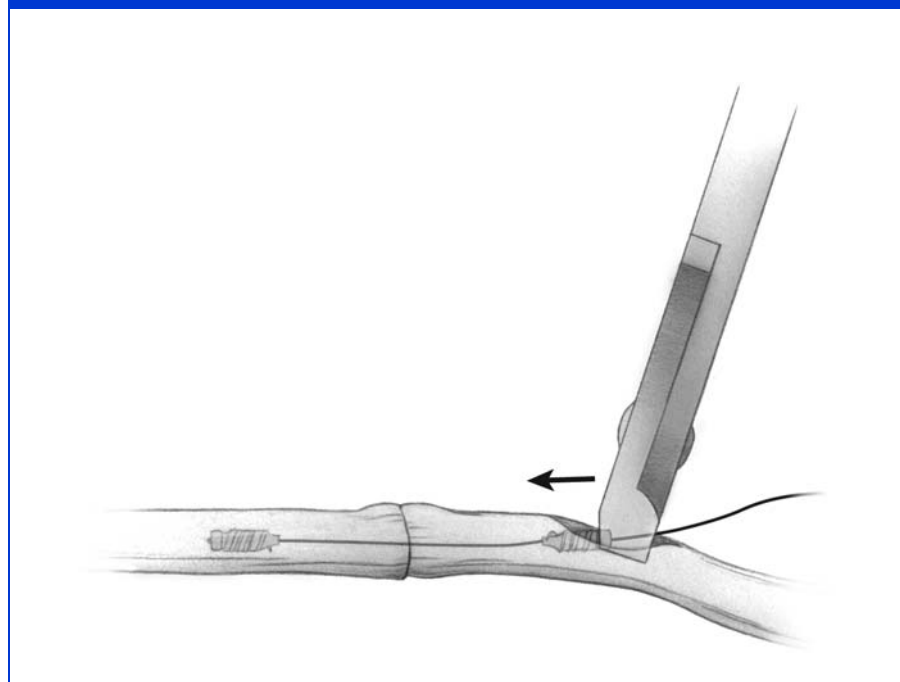


FIG. 8-B

**Figs 8-A and 8-B** The tendons are pulled together until the tendon is approximated and tensioned; a stop-bead is crimped onto the suture.

to the A4 pulley by maximally flexing the distal interphalangeal joint and delivering the tendon

or by pulling the distal stump out from under the A4 pulley and then placing the anchor. If there

### CRITICAL CONCEPTS | continued

#### PITFALLS:

- The tenotomy must be made starting at least 1 cm from the cut edge, extending away from the lacerated end. This will ensure that there is sufficient tendon between the anchor and the repair site after the anchor is twisted into the tendon.
- After placement of the anchor, the dorsal side of the tendon should be visualized to ensure that the anchor did not exit dorsally during implantation.
- Prior to positioning the 22-gauge needle that is used to guide the needle/suture construct through the proximal stump, it may be useful to place a slight bend in the hypodermic needle so that it can be accurately directed through the center of the tendon end.
- It is critical to note that the stop-bead is preloaded flush to only one side of the crimping instrument. The suture should be threaded through the stop-bead such that the flush side of the instrument comes directly into contact with the proximal anchor.
- After closure of the tenotomy, the anchors should be completely buried within the tendon to avoid catching on the pulley system.

*continued*

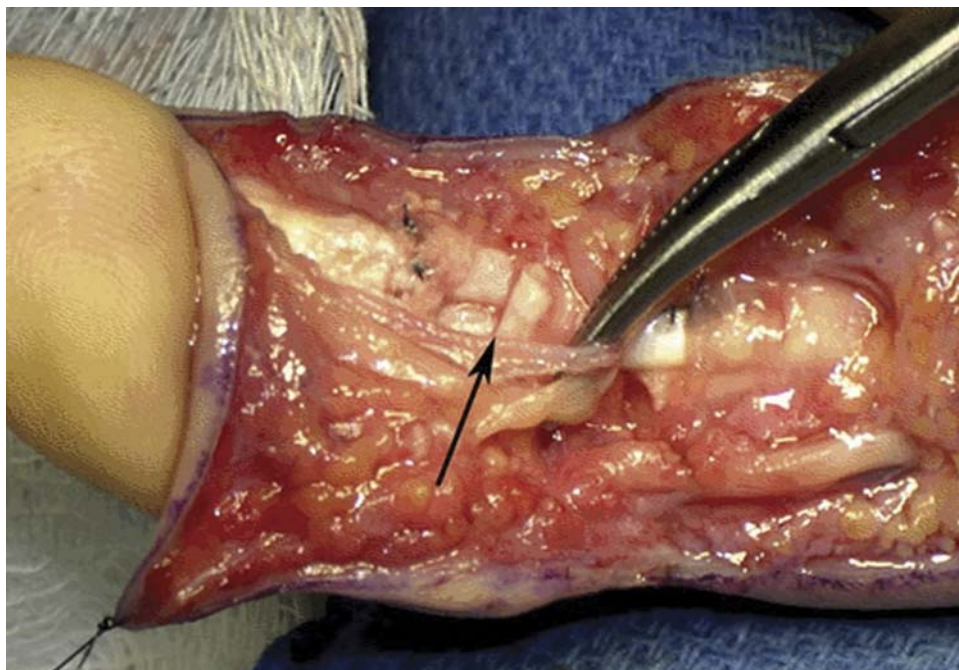


FIG. 9

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

is inadequate palmar surface to place the anchor in the ventral aspect of the tendon, then the anchor can be placed in the lateral side of the tendon by means of a similar sequence of steps through a lateral tenotomy.

A straight needle with a 2-0 multifilament stainless-steel suture and an attached stop-bead is then threaded into one of the cannulated anchors and is pulled through the center of the cut surface of the tendon until the stop-bead comes into contact with the anchor (Fig. 6). This is usually done through the distal anchor so that the device ultimately can be crimped proximally. At this point, if the distal anchor was implanted with the tendon extracted distal to the A4 pulley, the tendon should be replaced

underneath the A4 pulley with use of the needle-suture construct as a tendon passer. We prefer to do the final tensioning and tendon apposition with crimping on the proximal stump because distal zone-II injuries often have the tenorrhaphy site hidden under the middle portion of the A4 pulley, which would require maximal distal interphalangeal joint flexion to visualize the repair site during the crimping process if it were done at the distal stump.

A standard 22-gauge needle used as a retriever is then threaded through the proximal anchor exiting at the center of the tendon substance of the proximal stump. The needle suture is engaged into the 22-gauge needle and then is guided

through the anchor into the proximal stump, where it is readied for the preloaded crimping tool and stop-bead for final tensioning. (Figs. 7-A and 7-B). The suture is then threaded through a stop-bead in a preloaded crimping instrument. The proximal part of the tendon is advanced until there is a slight overlap with the distal stump to allow for creep. Unlike many multiple-stranded suture configurations that involve the use of braided suture, the Teno Fix system allows for precise control of repair tension with the single-stranded suture and stop-bead. When the appropriate alignment and tension is obtained, the stop-bead is crimped onto the stainless-steel suture (Figs. 8-A and 8-B).

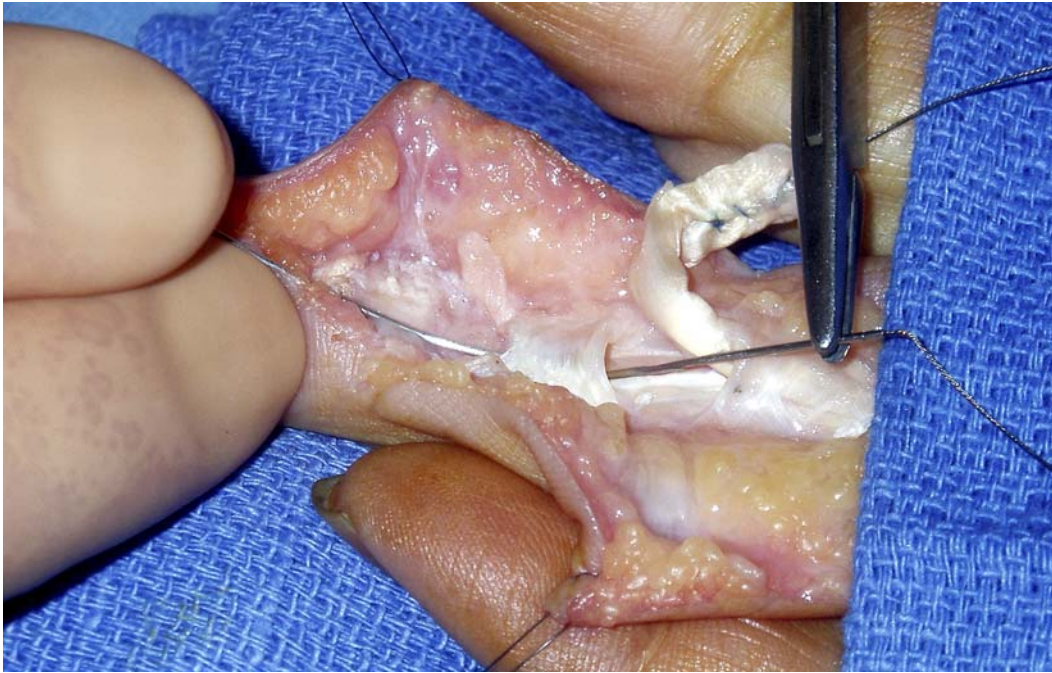
The excess suture is cut so

**FIG. 10-A**

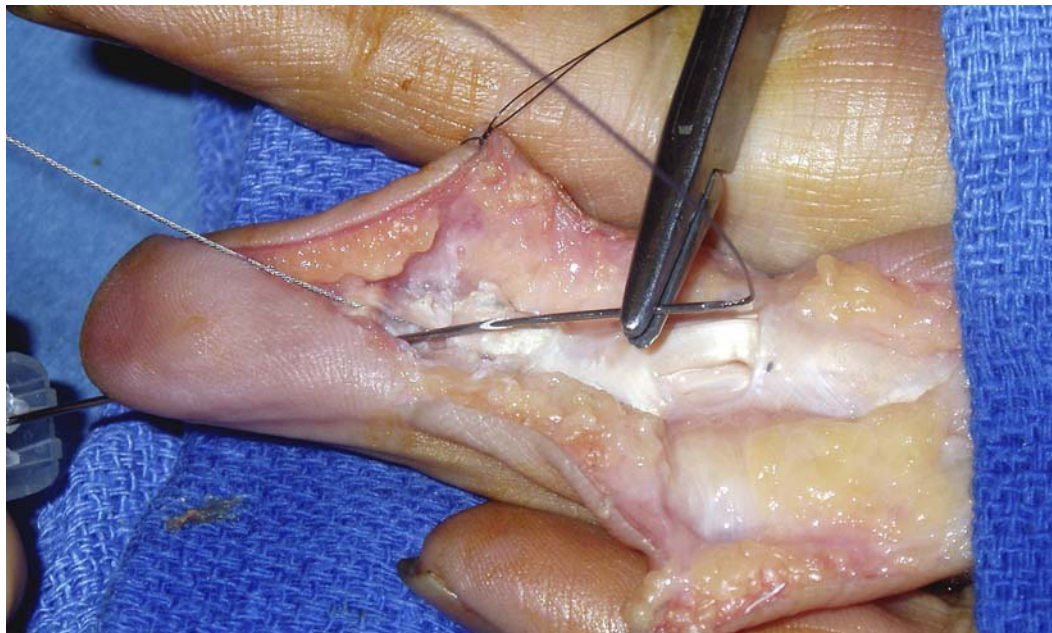
The needle/suture construct can be used as a tendon passer to deliver the proximal stump into the finger for the remainder of the repair.

**FIG. 10-B**

We ensure proper placement of the anchor within the tendon substance by assessing the dorsal surface prior to passing the tendon through the tendon sheath. The use of the anchor suture construct obviates the need for a tendon-passer instrument. After the tendon has been positioned, the suture/stop-bead construct is removed from the proximal anchor and is reused for the final repair. The final tensioning and crimping is usually done on the proximal stump, and so the distal part of the tendon must be engaged with the precrimped suture first.

**FIG. 11**

A 22-gauge needle distal to the A4 pulley is used to guide the needle/suture construct through the distal tendon segment and under the A4 pulley.

**FIG. 12**

After a hole is predrilled through the distal phalanx and nail bed, a 22-gauge needle is passed in a retrograde fashion to engage the tendon suture-needle construct and ease its passage through the distal phalanx.

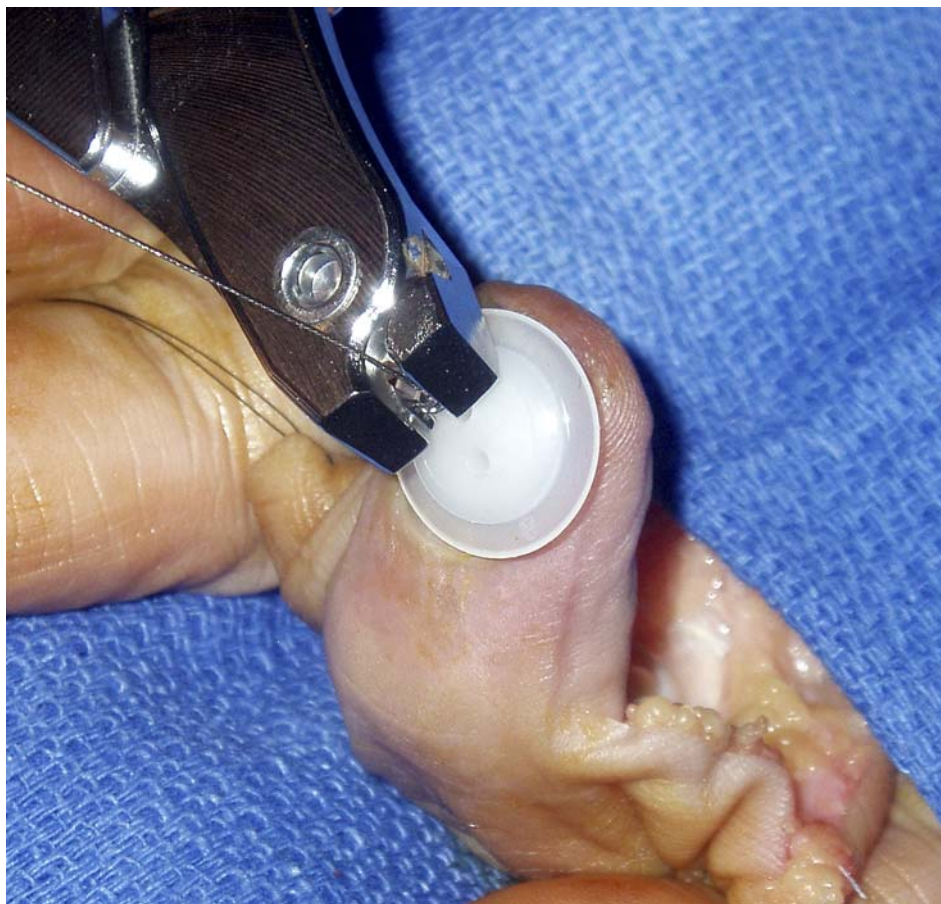


FIG. 13

The repair is tensioned, and the stop-bead is crimped onto a properly sized endobutton over the fingernail.

that the suture end is flush with the crimped bead. At this point, the repair is stressed with passive extension of the digit to allow for creep of the anchor within the tendon. An example of an in situ repair prior to placement of the circumferential suture is seen in Figure 9. The proximal and distal tenotomy sites are closed with 5-0 nylon buried interrupted sutures. After repair of the tenotomy sites, the anchors should no longer be visible on the tendon surface. An epitendinous stitch in a locked configuration with use of 5-0 nylon suture is placed

to complete the repair.

#### *Retrieval of the Proximal Tendon Stump*

An advantage of the Teno Fix device is the ability to use the proximal anchor with a stop-bead and suture attached as a tendon passer in lieu of other techniques such as a feeding tube or tendon-grasping forceps. This technique delivers the flexor digitorum profundus tendon from the palm and redirects it through the fibro-osseous sheath in an atraumatic fashion. This technique has been previously employed

with the two-stranded modified Kessler repair but is not possible with the four-stranded cruciate repair as the nature of the suture configuration requires both ends of the tendon to be in close proximity prior to repair.

To perform this technique, the needle/suture construct is first threaded through the proximal anchor until the stop-bead catches against the anchor. The needle/suture construct is then used to deliver the proximal stump into the finger for the remainder of the repair (Figs. 10-A and 10-B). The core suture is

**CRITICAL CONCEPTS** | continued**AUTHOR UPDATE:**

Since the original report on the clinical outcomes associated with this device, there have been no substantive changes to the surgical technique other than the development of the transosseous technique for distal repairs.

then removed from the proximal stump, and the tendon is held in place with a hypodermic needle at the level of the palm or with a restraining suture. The core suture with stop-bead attached should be reused for the final repair. The core suture needs to be removed from the proximal anchor after tendon retrieval because in most instances the final tensioning and crimping is done on the proximal stump and so the distal part of the tendon must be engaged with the precrimped suture first.

### *Transosseous Repair for Distal Injuries*

In the original clinical study<sup>7</sup>, injuries that were too distal in zone II could not be repaired with the Teno Fix device secondary to an inadequate amount of distal tendon to implant the device. We have since developed techniques to repair very distal zone-II injuries as well as zone-I avulsions with a transosseous stainless steel core suture, which is crimped over an endobutton.

The technique begins with retrieval of the flexor digitorum

profundus and implantation of the proximal anchor as described above. The straight needle with suture and an attached stop-bead is threaded into the proximal anchor and is pulled through the center of the tendon stump until the stop-bead comes into contact with the anchor. The tenotomy is then closed with a 5-0 monofilament suture in a buried interrupted fashion. A 22-gauge needle is then placed under and distal to the A4 pulley to guide the needle/suture construct through the distal tendon segment and under the A4 pulley (Fig. 11). The distal phalanx is then drilled with a 0.045-in (1.1-mm) Kirschner wire in an antegrade manner. The stainless steel suture with attached needle is guided through the predrilled hole by a 22-gauge needle that is used as a suture-passer (Fig. 12). The repair is then appropriately tensioned, and the stop-bead is crimped onto a properly sized endobutton over the fingernail (Fig. 13). The suture is cut flush with the bead. An epitendinous suture is then placed in a standard fashion to complete the repair. Since the stainless steel suture is not retrievable like most pullout sutures, there is a potential for hardware irritation or protrusion. It is critical that, after tendon healing, the suture and crimp bead are grasped and advanced distally so the suture can be cut flush with the nail and will then retract several mm below the nail plate. Since we have been using this technique, we

have not observed nail deformities or hardware prominence.

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