The Effects of Early Active Motion Rehabilitation after Teno Fixrm Tendon Repair in Zone 11 Flexor Tendon Lacerations of the Hand

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A. Study purpose and Rationale

The purpose of this study is to evaluate the advantages of an early active motion rehabilitation protocol after flexor tendon repair of the hand with the Teno Fix system. Patients with Zone II flexor tendon lacerations repaired with the Teno Fix system will undergo a rigorous early active motion protocol developed at the New York Orthopedic Hospital, starting post-op day 3. Each patient will be followed and our analysis will focus on range of motion, grip and pinch strength, pain, swelling, and a ftinctional assessment with the DASH (Disabilities of the Arm, Shoulder, and Head) questionnaire. Given that the Teno Fix system offers a stronger and more stable tendon repair construct which allows for earlier mobilization, our hypothesis is that early active motion rehabilitation will lead to a better range of motion of the affected finger while maintaining a low rupture rate.

a. Background

Repair of flexor tendon injuries of the hand represent a challenge for even the most experienced hand surgeon. Prior to the 1960's, severed tendons were not repaired, instead surgeons chose to graft in tendons as replacements for those injured. Over the last 25 years, an enormous amount of basic research has expanded our knowledge of tendon structure, biomechanics and their response to injury, repair, and rehabilitation, thereby allowing the advent of primary tendon suture methods. The desired outcome is a strong repair that is resistant to rupture and the formation of adhesions. A strong repair permits early mobilization of the digit, a factor that has been correlated with eventual range of motion and functionality.

The flexor tendons of the hand are enclosed by a tendon sheath lined by synoviocytes in a parietal and visceral layer that provide a smooth gliding surface for the tendon. Anatomically, the flexor tendons are divided into five zones, with Zone I being the most distal and Zone V the most proximal to the wrist. Overlying the synovial sheath are annular and cruciate pulleys (A I -A5, and C 1 -0) that surround the tendon and bring it next to the phalanges for efficient gliding. Loss of portions of these particular digital pulleys may significantly alter the normal integrated balance between the flexor, intrinsic, and extensor tendons and result in diminished digital motion, power, and flexion contrwtures of the interphalangeal (1P) j ointS . 2

The degree of difficulty in repairing tendon lacerations differs for each of the zones. Zone 11 lacerations are the most difficult to repair because of their involvement of the sheath and pulleys. The essential contribution to tendon healing and gliding is provided by the sheath's vascular and synovial systems. It is therefore important that the surgeon recognizes their integrity during repair. 3 Flexor lacerations in the finger were once found to perform so poorly after primary 4 repair that the Zone H digital sheath was referred to as a surgical no-mans-land. The historically poor results with Zone II repairs has made it the one that most clinical studies focus on. Small commented that tendon repairs in Zone 11 is widely accepted as the yardstick by which 5 techniques of flexor tendon repairs should be assessed.

Restoring ftinction after flexor tendon injuries is one of the greatest challenges to hand surgeons and therapists. Historically, repaired flexor tendons were treated with immobilization. Immobilization reduced suture breakage and protected the repair site because tendon healing had already occurred by the time the subject was allowed to move. However, immobilization led to the formation of adhesions that took away all gliding function of the tendon, leading to contractures and functional disability. 6

While mobilization is the key to preventing adhesions and achieving maximum ROM, it is at the risk of rupture. In vivo and in vitro studies confirm that mobilization with cyclic tension delivers nutrients more efficiently and promotes better and faster healing7-16 . Early motion also decreases the number of adhesions and joint contractures that develop secondary to the formation of scar tissue 17 . However, observational studies have shown that most traditional suture techniques do not provide enough strength to allow for safe, early active mobilization. The rupture rate is proportional to the postoperative mobilization regimen for the repaired digit and has been reported in the literature to vary between 3% and 9.4%, depending upon the mobilization scheme used. [18,19]

The newly **FDA approved** Teno Fix tendon repair system was developed to specifically address these difficulties with Zone R flexor tendon repairs. The Teno Fix uses a stainless steel braided suture to approximate the severed tendon edges, and in a randomized controlled clinical trial by B. Su et al, it was shown to have a significantly decreased rupture rate when compared to the traditional suture method (unpublished data). In summary, the Teno Fix produces a stronger and more stable tendon repair construct with the potential to allow for early active mobilization of the repaired digit while minimizing trauma to the vascular and synovial sheath. This translates into minimized adhesions, gap formation, and rupture of the initial repair while allowing fuller, quicker recovery while obviating the need for additional surgeries. Earlier return to ftinction and fewer complications would present a significant advance in the field of flexor tendon surgery.

B. Study Design and Statistical Analysis

This is a prospective, single arm, blinded study to evaluate the functional outcome of an early active motion rehabilitation protocol after flexor tendon repair of the hand using the newly FDA approved Teno Fix tendon repair system. Eligible patients with single digit or multiple digit flexor tendon lacerations in Zone II of the hand will undergo tendon repair with the Teno Fix system. Occupational/hand therapists and clinical personnel taking post-operative outcome measures (physicians, nurses, etc) will be blinded to the type of rehabilitation program the patient is undergoing.

a. Power Analysis

The primary outcome measure will be range of motion. The analysis will compare the average range of motion after early active motion rehabilitation using the Teno Fix repair with historical data of 34 cases of Teno Fix flexor tendon repair using a traditional passive motion protocol for the first 3 weeks followed by active flexion at four weeks. Published literature by Silfverskiold et al. indicates that the average range of motion 24 weeks post-surgery for standard passive/active motion rehabilitation is about 157' with a standard deviation of 17'. We estimate that the early active motion protocol will result in a clinically significant 10% increase in the range of motion at six months. Based on this data, a total of 19 digits are needed in the early active motion group to yield a power of 80% at an alpha of 0.05.

Secondary outcome measurements will include pain and swelling, grip and pinch strength, and the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire for upper extremity functional ability. Pain in the injured digit(s) will be assessed via a verbal numerical scales designed as an alternative or complement to the categorical and visual analogue scales. Swelling and grip/pinch strength will be clinically measured and compared with an uninjured digit and contralateral hand, respectively.

b. Outcome Analysis

Range of motion is a continuous variable and it will be assumed that it is normally distributed. Our hypothesis that early active motion rehabilitation will. yield a 10% increase in ROM at 24 weeks when compared to the traditional passive/active rehabilitation, will be tested using the usual two-sample t-test.

Range of motion data will also be translated into the Strickland Original Scores at 12 and 24 weeks. The score is calculated as: % of normal active PIP and DIP motion = [(arch of motion at both the PIP and DIPjoint) / 175*] x 100. 175' is assumed to the normal combined ROM for the PIP and DIP joints. The percentage scores will be classified into the following categories:

Classification	Score
Excellent	85%-100%
Good	70%-84%
Fair	50%-69%
Poor	< 50%

For the 12 and 24 weeks range of motion assessment, a Fisher's exact test will be performed to determine if the distribution of subjects in the treatment and historical control groups are the same across these classifications.

C. Study Procedure

1) Baseline examination: After obtaining informed consent, all patients will undergo a baseline exam that includes a medical and orthopedic history and physical examination.
2) Surgical procedure: The surgical procedure will utilize the same anesthesia and surgical approach as in a traditional suture repair of the tendon. The tendon repair will be performed using the standard surgical method for insertion of the Teno Fix device. First, two stainless steel coil anchors will be inserted in the tendon tissue, approximately I cm from the proximal and distal cut ends of the tendon. Next, a multifilament braided stainless steel suture will be passed through the anchors, starting with the distal. anchor. A crimp on the end of the suture will stop the suture from completely passing through the anchor. The tendon edges will be reapproximated, and the suture will be crimped on the proximal side, maintaining the correct length. A single circumferential suture will be used to smooth the reapproximated edges. The placement of this epitendonous suture is a step used in traditional tendon repair to restore contour to the tendon, thus facilitating gliding through the flexor pulley system. Should the investigator determine during the surgery that there is not enough tend on exposure or the tendon is too small in size for use of the Teno FiXTm device, the subject will undergo a standard repair using fourstrand suture technique. Such subjects would be classified as an intraoperative screening failure and would not enter in the study.
3) Postoperative management: After the operation, the hand will be immobilized in a dorsal plaster splint with the wrist and hand in neutral position. On postoperative day 3, patients will be taken out of the splint and started on the New York Orthopedic Hospital Early Active Motion Protocol. They will be asked to hold an appropriate sized dowel allowing for active flexion and extension at the MP joint. VVhile at home patients will do 10 reps of dowel exercise four times per day. Between the exercises, patients' will be in a hand splint and encouraged to perform passive flexion and extension. Each week, the hand therapist will see the patient to evaluate their progress. This regiment will continue for six weeks with progressively decreasing dowel size.
4) Postopgrative evaluation: Patients will be evaluated starting at postoperative day I with the DASH questionnaird to establish a baseline fimctional status of their upper extremity. Outcome measurements will also be taken at week 3, 6, 12, and 24.

Outcome measurements will include range of motion and grip/pinch strength at weeks 12 and 24, pain and swelling assessment at postoperative day 1, week 3, 6, 12, and 24, and fimetional assessment with the DASH questionnaires at week 6, 12, and 24 compared to baseline. Safety monitoring throughout the study will include evaluating subjects at each visit for signs and symptoms of tendon rupture, infection, contractures, nerve injury and wound dehiscence.

The total follow-up time for each patient is 6 months. Based on prior experience at the New York Orthopedic Hospital, approximately 2 patients with flexor tendon laceration are expected per month. The study is expected to take approximately I year for completion of patient recruitment.

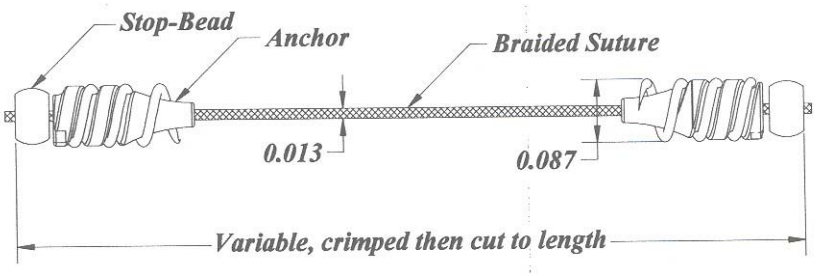
D. Study Drugs

none

E. Medical Device

The Teno FiXTm Tendon Repair System from Ortheon Medical is a surgical anchoring system for soft tissue repair. It received its FDA approval as an implantable device in June 2003 and is currently a commercially available implant intended for the repair of lacerated or severed digital flexor tendons. The device comes as a sterile, preloaded instrument that, when used as directed, implants a stainless steel suture across the area of tendon injury. This core suture is held in place by anchors at its proximal and distal ends. The implantable components (suture, stop beads and anchors) are composed of stainless steel alloy ASTM, similar to suture materials already used in human surgery. The device remains embedded in the tendon substance with little reaction on the tendon surfaces and in successful primary repairs, provides a stronger and more stable repair construct than conventional suture repairs with less rupture and gapping rates, and does not limit interphalangeal joint flexion.

The Teno Fix device is well toleirated, does not elicit an inflammatory response, and allows normal histologic tendon healing. It is currently considered an improved alternative to conventional stranded cruciate suture repair. The device is currently available in one size and limits its use in tendons of large enough width to accommodate the stop beads and anchors.



F. Study Questionnaires

For this study, we will use the Disabilities of the Arm, Shoulder, and Hand (DASH) Survey as a means to measure functional outcome. DASH was created as a joint effort by the American Academy of Orthopedic Surgeons (AAOS), the Council of Musculoskeletal. Specialty Societies, and the Institute for Work and Health.20 The survey contains 30 questions on activities of daily living and pain and is intended to be used to evaluate disability and symptoms in single or multiple disorders of the upper limb at one point or at many points in time. A higher score reflects greater disability. Preliminary work on the DASH showed that it was both reliable and valid. The DASH questionnaire will be used in this study at different points after tendon repair as an assessment of improvement in functional outcome.

A suitable measurement of pain for the Teno-FiXTMstudy is a group of verbal numerical scales designed as an alternative or complement to the categorical and visual analogue scales. With these scales, the patient is asked to express numerically the magnitude of the pain. A scale of 0 (no pain) to 10 (worst pain imaginable) showed good correlation with the conventional 10 cm. unmarked horizontal visual analogue scale developed by Huskisson. 21,22 For this study, patients will be asked to assess their own pain on a scale of 0- 10 immediately after the operation and at each visit to the therapist up till 6 weeks, and then at 12 and 24 weeks follow-up.

G. Study Subjects

Subjects can be male or female, of any race, at least 18 years old, with a lacerated or severed digital flexor digitorum. profimdus tendon with or without concomitant flexor digitorum superficialis injury in Zone 11 of the index, middle, ring, and small finger. The laceration must have occurred within the previous fourteen days, as studies have shown, after 14 days, histologic changes in the tendon appear which can impair tendon healing. Subjects must also have an uninjured contralateral hand and digits that can be used for comparison to the injured hand and injured digits.

Exclusion criteria include pregnancy, diabetes mellitus, autoirnmune disorders, documented acquired immunodeficiency complex (AIDS), chronic immunosupressive medications or other conditions that could affect postoperative wound healing.: To minimize confounding outcome measures, subjects with a lack of adequate cutaneous coverage at repair site, concomitant fractures, amputated digits, arthritis of hand, prior hand injury or trauma, congenital hand defects, or other condition(s) that will impair comparative, measurements in the treated hand or the contralateral. control hand, will be excluded. The presence of infected, necrotic or ischemic tissue in the injured hand will also be excluded, along with subjects with known sensitivity or allergy to the metals contained in Teno Fix stainless steel rod: chromium, nickel, copper, cobalt, and iron. If it is determined intraoperatively that the Teno Fix cannot be completed (e.g., insufficient tendon for placement of the Teno FiXTm anchor), the patient will also be excluded.

H. Recruitment of Subjects

Subjects will be identified and referred by the patient's primary orthopedic surgeon, Dr. Melvin Rosenwasser, after confirmation that the Teno Fix tendon repair system is appropriate for the patient.

I. Confidentiality of Study Data

Study data will be coded and a unique identifier will be assigned to each subject. All study data will be stored in a locked cabinet in the Department of Orthopedics Trauma Training Center, accessible only to the investigators of the study.

J. Potential Conflict of Interest

none

K. Location of Study

The study is a single site study and will be conducted through the Department of Orthopedic Surgery at CPMC. During the postoperative rehabilitation period, patients will be followed by the occupational therapist at CPMC and will return for to CPMC for each subsequent follow-up visit.

L. Potential Risks

Adverse events in the Teno Fix treatment group include, but are not limited to: rupture of the tendon repair, infection, secondary surgical intervention, adhesions and/or contractures, wound dehiscence, nerve injury, and allergic reaction to the stainless steel suture material. Patient may also experience minimally increased pain and swelling when compared to patients with a less strong, traditional suture repair.

M. Potential Benefits

Enrollment in the study may be beneficial by assuring close follow-up of patients through their rehabilitation period. By adhering closely to the early active motion protocol, patients may experience early movement of their fingers, as well as an accelerated return to per-operative function and normal activity levels. In addition, future patients may benefit from the results of this early active motion rehabilitation technique after Teno Fix tendon repair.

N. Alternative Therapies

The Teno Fix tendon repair system is a FDA approved device designed to give improved outcomes of flexor tendon lacerations of the hand when compared to more traditional methods. These alternative methods include other more complicated suturing techniques, which are technically challenging requiring more time in the operating room while necessitating more holes be made in the tendon to repair it. When this occurs, more time may be needed for healing.

O. Compensation to Subjects

none

P. Costs to Subjects

Patients will not incur and additional costs due to their participation in the study.

Q. Minors as Research Subjects

N/A

R. Rtadiation or Radioactive Substances

Aside from the conventional radiographic imaging to follow the stability of the tendon repair construct and to ascertain the absence of the Teno Fix device migration, no additional radiation exposures are required.

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