



CLINICAL EXPERIENCE WITH A NEW TENDON FIXATION DEVICE USING AN ACCELERATED ACTIVE MOTION PROTOCOL

Dr. MW Solomons¹, Dr. SJ Carter¹, Ms. A Catchpole¹, Dr. M Rosenwasser², Dr. E Diao³

¹Martin Singer Hand Unit; Department of Orthopaedics, Groote Schuur Hospital in Cape Town, South Africa

²Columbia University, New York, New York; ³University of California, San Francisco

INTRODUCTION

The two most important complications of flexor tendon surgery are adhesions and dehiscence at the repair site. Adhesion and thereby tenolysis can be limited by increasing the excursion of the repaired tendon throughout the healing period.

Suture techniques continue to be developed and described to match more aggressive rehabilitation techniques. Despite this, rupture rates of up to 25% continue to be reported. In our study, 19 FDP tendons were repaired in Zone 2 using a new tendon fixation device - the Teno Fix™ Tendon Repair System. The device utilizes two intratendonous anchors joined by a 2-0 multifilament stainless steel suture and held with two stop beads. An accelerated active motion protocol was used for active flexion and extension from post-operative day one in an effort to demonstrate 3500 cycles of active motion within the first two-week post-operative time period.

METHODS

Prospectively, patients with complete transections of both FDP and FDS tendons within Zone II were included in the study; those with concomitant joint injuries or fractures were excluded. Follow up was for a minimum of 3 months. Clinical end points assessed included comparison ROM (Strickland Score) of all joints of the affected digits with those of the uninjured contralateral digits, as well as recording of the linear measurements of pulp-to-distal-palmar crease distances. Patients after repair were placed in a splint with both the wrist and MP joints flexed 30°. Using an immediate active motion protocol (shown as Figure 1), active digital flexion and extension maximal attainable to the palm were started on the first day, with the goal of full flexion at 2 weeks post-operatively. All digits were assessed using the Strickland (TAM), Buck-Gramko and ASSH scoring systems. Gap and tendon excursion will be evaluated radiographically by utilizing stainless steel markers placed both proximal and distal to the intratendonous anchors during the procedure.

Only risk is: -
1: - forced passive extension, or
2: - resisted flexion

Post op splintage
Wrist 30° flexed
MPJ's 30° flexed
IPJ's straight

Day 1 to 4 post op - respect soft tissues
5 active flexions and extensions every hour
Between exercises and at night, thermoplastic insert to keep IPJ's extended
Aim for PDPC of 3 cm

Day 5 - 14
Debulk dressings
5 Active flexions and extensions every hour
Increase to maximum unresisted flexion i.e. PDPC 0 cm.
If developing FFD of PIPJ then work harder on active extension with MP flexed.
Between exercises and at night, thermoplastic insert to keep IPJ's extended
If not achieving full flexion then do place and hold exercises

Day 14 - 28
Plaster removed. Sutures removed.
Splint applied - wrist 30°, MPJ's 30°, IPJ's 0°
Flexion: Unrestricted active flexion (no resistance)
Aggressive passive flexion with place and hold
Extension: Active extension with and without MPJ flexed
Thermoplastic insert at night only

Day 29 to 3 months
Leave splint off
Scar massage
Do flexion as above with wrist flexed, neutral and extended
Treat FFD's accordingly
Note: If patient unreliable then leave splint on to 6/52

NOTE : ONLY RISKS ARE FORCED PASSIVE FLEXION ESPECIALLY OF BOTH WRIST AND FINGER (e.g. fall on outstretched hand) AND RESISTED FLEXION

Day 1 or 2 - consider wrist block

Physio - Day 1, 2, 5
- Week 2 - 3x
- Week 3 to 4 - 2x
- Week 4 to 12 - 1x

RESULTS

At an average follow-up of 4.6 months (range 3 - 8) 2 digits had ruptured. Both these cases were due to hyper-physiologic loads (One fall and one forced hyperextension in an assault). In the remaining digits the results were as follows:

	Excellent	Good	Good / Excellent
Strickland	47%	23%	70%
Buck-Gramko	31%	31%	62%
ASSH	15%	54%	69%
Linear Scale	46%	38%	84%

Fig. 1.

Unsatisfactory results were invariably due to poor compliance with therapy. One patient with multiple digit involvement failed to attend therapy appointments diligently. He ended up with poor pull through and a marked flexion contracture. In a small cohort this skews the results negatively. One patient required removal of a TenoFix™ device due to persistent pain and suspected low grade sepsis. Despite surgery this patient remains in the good / excellent category.

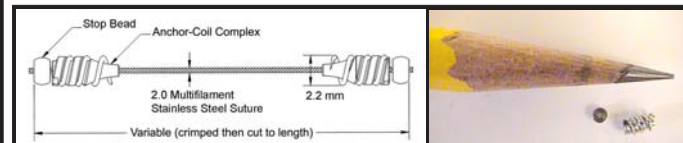


Fig. 2a. Schematic drawing of device.

Fig. 2b. Anchor & stop bead to show relative size.

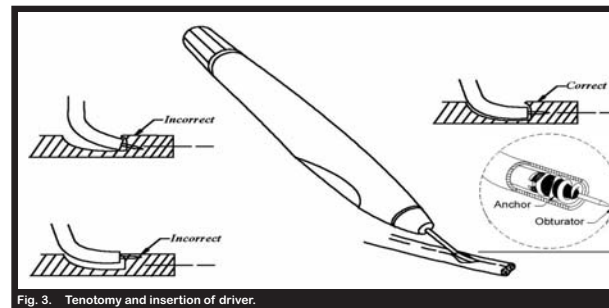


Fig. 3. Tenotomy and insertion of driver.

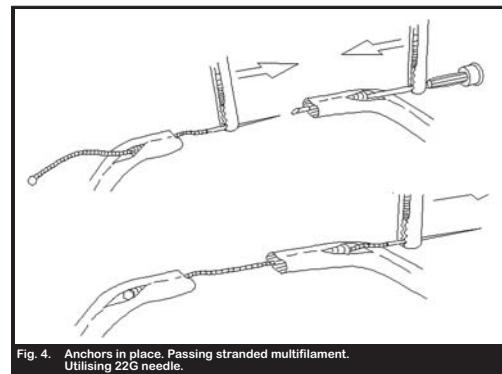


Fig. 4. Anchors in place. Passing stranded multifilament. Utilising 22G needle.

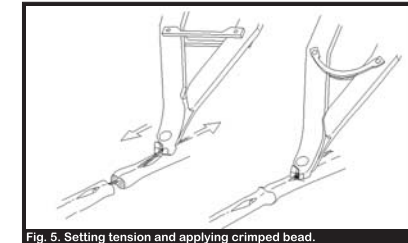


Fig. 5. Setting tension and applying crimped bead.



Fig. 6. PA X-ray of devices in-situ also showing intra-tendonous markers. (See Arrows)



Fig. 7. Little finger repair showing excellent result.



Fig. 8. Placement of proximal anchor in proximal window. TenoFix™ used to pass tendon deep to A2 pulley.

CONCLUSIONS

This clinical study confirms that the Teno Fix™ Tendon Repair system has sufficient pull out strength to resist the cyclic forces (3680 cycles over a 2 week time period) of an immediate, full range, active motion protocol (within physiological loads) without rupture and gap formation. However, as is mostly appreciated, patient insight and commitment are vital for achieving good results. Larger and longer-term studies will be necessary to confirm the efficacy of this combination of tendon repair system and rehabilitation protocol in improving clinical results.