SCIENTIFIC ARTICLE

Proximal Tendon-Prosthesis Junction for Active Tendon Implants of the Hand: A Biomechanical Comparison of 2 Techniques

Matthew J. Thompson, MD, John R. Owen, MS, Charles L. McDowell, MD, Jennifer S. Wayne, PhD

Purpose To study the biomechanical characteristics (percent stretch, stiffness, and ultimate load) of 2 tendon-prosthesis techniques used to connect the proximal tendon stump to silicone active tendon implants used in reconstruction of flexor tendons.

Methods We evaluated percent stretch following cyclic loading and at failure, stiffness during load to failure, and ultimate load of 16 tendon-prosthesis junctions using cadaveric canine flexor digitorum profundus tendons to re-create 2 junction techniques: the tendon loop (TL) and the polyester weave (PW).

Results The TL junction showed greater percent stretch at a static load of 2 N, following 500 cycles of loading between 2 N and 50 N, and at peak load. The PW junction displayed greater stiffness from 50 to 150 N during load to failure. Both junctions failed at a mean ultimate load greater than 220 N.

Conclusions The described proximal junction techniques for active tendon implants were strong enough to resist early active motion in the immediate postoperative period without significant elongation. The PW technique displayed greater stiffness and ultimate load compared with the TL.

Clinical relevance Data on tendon-prosthesis characteristics of these 2 methods may aid the surgeon in choosing which junction technique to use, during surgical tensioning decisions, and in considering activity protocols after surgery. These data may also serve as a baseline for further investigations regarding active tendon implants. *(J Hand Surg Am. 2015;40(1):109–114. Copyright © 2015 by the American Society for Surgery of the Hand. All rights reserved.)*

Key words Active tendon implant, Hunter technique, percent stretch, staged-tendon reconstruction, structural performance.

From the Orthopaedic Research Laboratory, Departments of Orthopaedic Surgery & Biomedical Engineering, Virginia Commonwealth University, Richmond, VA.

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Corresponding author: Jennifer S. Wayne, PhD, Orthopaedic Research Laboratory, Departments of Orthopaedic Surgery & Biomedical Engineering, Virginia Commonwealth University, P.O. Box 980694, Richmond, VA 23298-0694; e-mail: jwayne@vcu.edu.

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STAGED FLEXOR TENDON RECONSTRUCTION is an established method for addressing flexor tendon injuries when direct primary or secondary reconstruction is unlikely to be successful and a reasonable likelihood of functional recovery exists in adults[1–15] and children.[16] During the first stage, a silicone implant is inserted into the native tendon bed allowing passive motion to prevent joint stiffness and to stimulate the production of a pseudosheath prior to inserting a tendon graft.[17–19] After soft tissue equilibrium has returned, tendon grafting is performed through the pseudosheath.[1,3,19,20]

Historical innovations in implant design and application led to the use of active tendon prostheses in staged reconstructions.[20,21] Hunter et al[22] published promising results using active tendon implants in staged reconstructions in humans. In Hunter et al's cohort,[22] patients initiated passive flexion and active extension immediately. Active flexion was delayed 3 to 6 weeks and resisted flexion 8 weeks. Second-stage reconstruction was undertaken only when host tissues ruptured at the sites of the tendon-prosthesis junction. At 14 months, 72% (13 of 18) of implants remained functional with a mean increase in total active motion of 72°, which fell to 62° following second-stage grafting. Implants have remained functional up to 25 years after reconstruction,[23] second-stage grafting has been successful up to 18 years following implantation,[24] and improvements in range of motion may occur with increased time between stages.[25] The importance of motion is underscored by investigations identifying the quality of joint motion prior to tendon grafting as the most reliable predictor of a successful outcome, as adhesions are observed following insertion of a tendon graft in spite of passing it through a pseudosheath.[18] Based on these considerations and the opportunity to avoid the complications of muscle atrophy and stiffness of the digit and those incurred from second-stage reconstruction, the use of active prostheses has been proposed as a permanent one-stage procedure for severe injuries or in those whose medical comorbidities, social constraints, or functional status preclude from successful second-stage reconstruction.[22,25]

Based on direct communication with the manufacturer regarding unit sales and donation for instructional use, the tendon implant is currently used by many surgeons. Although having potential, concern exists regarding the implant's ability to survive the loading environment during active motion. When used in 2-staged reconstruction, experimental findings might also support use of early active motion protocols following stage I in order to maximize strength and range of motion prior to second-stage grafting. Finally, such information may be useful in the creation of durable permanent tendon prostheses. The purpose of this study was to examine the mechanical behavior of 2 recommended techniques for tendon-prosthesis junction under tensile loads during cyclic and load-to-failure testing. The null hypothesis was that there would be no difference between the 2 techniques in the biomechanical parameters.

MATERIALS AND METHODS

Cadaveric digits (n = 16) from 4 forelimbs of separate dogs with an average adult weight of 22.7 kg bred for medical research were donated from an unrelated physiology experiment at necropsy (after achieving adult weight and at younger than 1 y) and kept frozen in a moist wrapping within an airtight specimen bag. The forelimbs were thawed and the flexor digitorum profundus (FDP) tendons of the second through the fifth digits were isolated by open dissection and then refrozen separately. Where the FDP tendons form a common tendon in the foreleg, each individual tendon was transected sharply immediately distal to the common tendon. The flexor tendon sheath/pulley system and flexor digitorum superficialis were dissected free of the FDP tendon, which was explanted with its attachment to the distal phalanx left undisturbed. Specimens were designated for junction technique such that each technique would be equally represented on each forelimb and on each numbered digit[2–5]; thus, both junctions would be performed twice per forelimb and twice per digit number.

At the time of testing, each individual specimen was removed from the freezer and allowed to thaw. Prior to creation of the tendon-prosthesis junctions, the cross-sectional dimensions of each tendon were measured using a digital caliper at 1 and 3 cm from the end of the tendon destined to form the tendon-prosthesis interface and area calculated assuming an elliptical shape of tendon specimens. Each specimen was then individually prepared immediately prior to testing and kept moist using saline mist. The junctions were connected as described in the active tendon implant manufacturer's product guide[26] using donated implants from the manufacturer. For the tendon loop (TL) technique, the tendon was passed through the Hunter prosthesis loop (Model AT HUNTER Active Tendon Implant, Wright Medical Technology, Inc., Arlington, TN) and 2 simple 4-0 braided nonabsorbable sutures were used to reinforce each pass of the tendon with 3 horizontal mattress sutures used to secure the tail to the proximal tendon limb (Fig. 1). For the polyester weave (PW) technique, each pass of each Hunter prosthesis polyester cord (Model ATPC HUNTER Active Tendon Implant, Wright Medical Technology, Inc., Arlington, TN) was reinforced with a single simple 4-0 braided nonabsorbable suture. Three total passes of each cord were made in a crossed pattern and the remaining tails of the polyester cords were then tied with a square knot, divided, and the ends cauterized as described in the manufacturer's guide.

The native tendon attachment to the distal phalanx was preserved and the phalanx was mounted in in a 45-mm-long section of 2-inch polyvinyl chloride tube using a 1.6-mm K-wire passed through the tube, which was then filled with polymethylmethacrylate.

FIGURE 1: Schematic representation of the PW and TL junction techniques.

Then, to allow digital measurement of stretch, small black glass bead markers were glued onto each specimen (Fig. 1). The polyvinyl chloride section was then mounted in a rigid fixture on an Instron1321 biaxial servohydraulic testing machine (Instron Corp., Canton, MA) retrofitted with MTS TestStarII digital controls (MTS Systems, Eden Prairie, MN) and the free end of the Hunter prosthesis was secured in a custom-designed clamp without loading the specimen.

The specimen was then cycled between 2 and 50 N at 0.192 Hz for 500 cycles to match the equivalent cyclic frequency of Latendresse et al[27] but with the peak cyclic load increased to represent maximal reported values of active tendon flexion in the rehabilitation period[28–33] with a safety margin of 10 N. The specimens were then loaded to failure at a rate of 20 mm/min.

Test images were captured with a video camera (Panasonic PV-GS35 Digital Palmcorder, Panasonic Corporation of North America, Secaucus, NJ), analyzed at select intervals during cycling (eg, start, 100 cycle intervals, and end), and continuously during load to failure. Cyclic and load-to-failure video images were processed using NIH ImageJ freeware (National Institutes of Health, Bethesda, MD) to measure separation between bead pairs for intervals of interest. The distance from the most proximal tendon to the second most proximal prosthesis bead represented stretching of the tendon-prosthesis junction (Fig. 1). Bead separations were tabulated and synchronized with corresponding Instron load data. Percent stretch for each data point during cycling and load to failure was calculated as the percent change in bead separation relative to the starting bead distances at 2 N of load during the first cycle.

The mode of failure for each test was noted by gross observation and later verified by review of digital recording. Load-elongation curves were created and the peak load identified for each sample. Linear regression was used to identify stiffness, defined as load/percent stretch (N/(mm/mm) $\times$ 100), from 50 to 150 N.

A mixed model analysis of variance followed by Tukey-Kramer post hoc pairwise comparison was conducted with statistical significance set at P of .05 or less to assess for differences between junction techniques.

RESULTS

No significant difference in tendon cross-sectional areas between groups was observed at 10 mm (P = .22) or 30 mm (P = .39) from the free end of the tendon, representing the region wherein junctions were performed (Table 1). Stretch of the straight sections of prosthesis was negligible (data not shown).

Representative load versus percent stretch curves during load-to-failure testing were found to approximate linearity across all samples in the load range used to determine stiffness (Fig. 2). Data for some specimen parameters were missing owing to missing beads or for failures occurring outside of the junction within the substance of the free tendon, at the bone-tendon junction, or at the bone-polymethylmethacrylate interface. These are noted subsequently in the sample sizes indicated on Figures 3 and 4.

Mean elongation after cycling and at peak load for the 2 junction techniques showed the TL elongated more than the PW, despite having a smaller starting distance between beads (Table 1). No failures were observed during cyclic testing. Percent stretch of the tendon-prosthesis junction after cyclic loading (P = .003) and at peak load (P = .003) was significantly greater for TL than for PW (Fig. 3).

During load to failure, tendon-prosthesis junction stiffness was significantly greater for the PW than for the TL (P < .001) (Fig. 4). No statistically significant difference was detected in peak load (P = .20) between the 2 junction techniques. Constructs failed at peak load. For the PW, the polyester cords remained knotted proximally and shredded through the tendon with failure of sutures at weave sites. For the TL weave, sutures at the weave sites and at the distal tail of the tendon failed in a variable pattern before the

TABLE 1. Comparison Between the PW and TL Tendon-Prosthesis Junction Techniques of Various Biomechanical Parameters*

	PW	TL	*P* Value
Tendon cross-sectional area, 10 mm	4.1 mm^2 (0.8); 8	4.7 mm^2 (1.0); 8	Not significant (.22)
Tendon cross-sectional area, 30 mm	9.1 mm^2 (1.9); 8	8.2 mm^2 (2.0); 8	Not significant (.39)
Junction length at 2 N precycling	56.1 mm (1.3); 8	52.4 mm (4.4); 8	.03
Junction elongation at 2 N postcycling	3.8 mm (1.6); 8	6.6 mm (1.6); 8	< .01
Junction elongation at peak load	10.2 mm (3.1); 6	15.9 mm (2.9); 5	.01

*Means (SD); sample size.

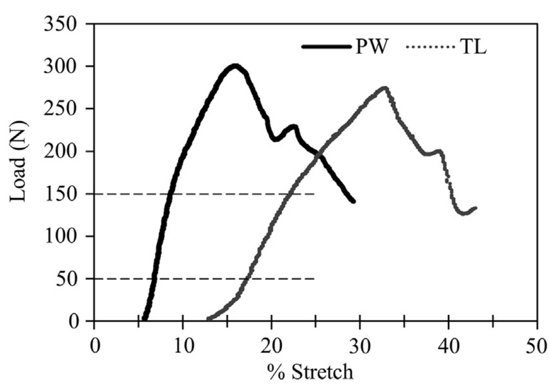

FIGURE 2: Example load versus percent stretch curve during load-to-failure testing. Between load ranges of 50 N to 150 N, the curve was found to approximate linearity across all samples. Thus, this region was used for linear regressions to calculate stiffness (N/[mm/mm] × 100) during load to failure.

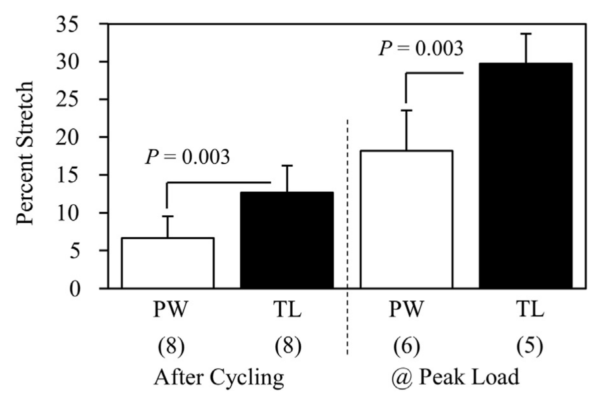

FIGURE 3: Percent stretch after cycling (at 2 N of load) and at peak load during load-to-failure testing for the PW and TL tendon-prosthesis junction techniques (mean, SD). Sample size is indicated by the numbers in parentheses below each technique identifier on the X axis.

distal limb was pulled through the proximal limb weave points and through the silicone loop.

DISCUSSION

The use of silicone prostheses is an established method for the staged reconstruction of large flexor tendon defects in the setting of severe soft tissue injury, infection, or joint contracture or following failed early repairs when a reasonable likelihood of functional recovery exists.[2,4,10,11,14,15,20,21] The prosthesis can be used passively[1–15] or as an active implant with or without planned second-stage reconstruction.[16,20,22–25,34] It may be especially useful in settings where devastating injuries occur in patients unwilling or medically unfit for second-stage reconstruction.[22,23,25,34]

In scenarios involving second-stage tendon grafting, preoperative motion has been identified as the most important predictor of success.[18] Thus, every effort should be made to preserve range of motion and prevent joint contractures by using rehabilitation protocols that maximize motion without compromising implant function or healing of concomitant injuries. If an active implant is used, the second-stage reconstruction may be delayed for more than 2 years with improved motor strength, range of motion, and pliability of soft tissues with time.[25]

In this *ex vivo* study using cadaveric canine FDP tendons, the biomechanical characteristics of 2 recommended styles of proximal tendon-prosthesis junction were evaluated.[26] Experimental groups showed no significant difference in tendon size between groups. Using measures of elongation and stiffness corrected for tendon-prosthesis junction length compensated for a difference in mean junction length between the techniques. The synthetic prosthesis did not appear to affect the observed differences in repair groups.

The tendon-prosthesis junction was chosen as the primary means of comparison between groups because it represents a composite of the individual intervals and was felt to best reflect the clinical characteristics

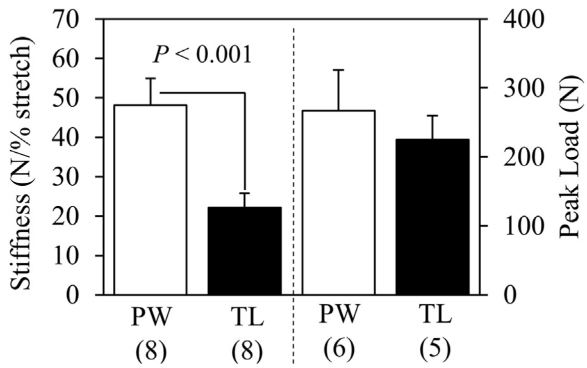

FIGURE 4: Stiffness (N/% stretch) and peak load (N) during load-to-failure testing for the PW and TL tendon-prosthesis junction techniques (mean, SD). Sample size is indicated by the numbers in parentheses below each technique identifier on the X axis.

of each style of junction. No statistical difference in peak load was detected between techniques, supporting the null hypothesis with regard to ultimate load. Failures occurred at the junctions at ultimate loads greater than 220 N. Forces experienced by flexor tendons have been extensively studied with some variability in results; however, tendon-prosthesis junctions able to withstand 15 to 40 N should be able to withstand passive motion and unresisted active flexion, respectively, taking into account the effects of increased friction from inflammation and other potential barriers to smooth tendon gliding during the healing process.[28–32] Resisted flexion is associated with forces as high as 120 N for firm tip pinch and 200 N for power grip.[33] Recognizing that active tendon implants may not experience the same forces as an anatomical 2-tendon, 3-joint system,[25] it would appear that the proximal junctions may be able to withstand early active motion protocols with active flexion beginning immediately after surgery. This may not only improve motion and prevent muscle atrophy but also aid in tendon-tendon and tendon-prosthesis healing.[10] The strength of the proximal tendon-prosthesis junction is at least comparable with tendon-tendon repair techniques currently exposed to early active motion in flexor tendon repair.[31,34]

With regard to elongation (percent stretch), the TL showed greater elongation after cyclic loading and at failure compared with the PW, correlating with a greater stiffness in the PW. This finding rejected the null hypothesis with regard to elongation and stiffness. The observed elongation of the 2-junction techniques (which were representative of repair lengths used *in vivo*) of less than 10 mm after cycling is unlikely to have a significant effect on long-term function of the active unit; however, it may be useful information when surgically tensioning the myotendinous unit during surgery. Mean elongation at peak load less than 16 mm may be considered as reassurance that elongation capable of compromising the function of the motor unit is unlikely to occur in the submaximal load range.

Absolute values for the tested parameters performed in an *ex vivo* canine model may not be precisely applicable to human tendons. However, canine models of human flexor tendons are a common means by which meaningful conclusions with regard to human flexor tendon surgery have been drawn,[21,35–37] and the relative value of a biomechanical comparison of 2 tendon-prosthesis junction techniques may be less affected by the use of a representative model. Conclusions regarding rehabilitation protocols may only be applied to the durability of the proximal junction and more may be learned with a more extensive fatigue protocol. However, such a protocol would be limited *ex vivo* owing to the absence of biological factors important to biomechanical properties of tendons and tendon healing in this regard. Although care was taken to apply only enough glue to the referencing beads necessary to achieve adhesion, it is possible that the glue could have local effects on tendon elasticity. Prior models have used a similar technique.[38–41] Further work investigating the biomechanical characteristics of the distal interface is needed. Based on data obtained in this experiment coupled with experience from surgeons using tendon prostheses for extended durations, indications for use of the active tendon implant may be expanded. The ultimate objective of this and future investigations is to use a prosthesis as a permanent replacement; thus, reliable junctions at the bone and soft tissue interfaces are critical to success.

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