Cyclic Testing of Pullout Sutures and Micro-Mitek Suture Anchors in Flexor Digitorum Profundus Tendon Distal Fixation

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Purpose: Little data exist comparing the strength of traditional methods of fixation in a flexor digitorum profundus tendon with the use of a suture anchor. In vitro cyclic testing simulating a passive mobilization protocol was used to compare the repair of a flexor digitorum profundus tendon using a single micro-Mitek anchor (Mitek, Westwood, MA) or a modified Bunnell 2-strand pullout technique using a monofilament or a braided polyester suture.

Methods: Twenty-four fresh-frozen cadaveric fingers were divided randomly into 4 repair groups (n = 6 each): a micro-Mitek with a 3-0 braided polyester suture or a 3-0 monofilament suture, or a modified Bunnell technique with a 3-0 braided polyester suture or a 3-0 monofilament suture. After repair the specimens were loaded cyclically from 2 to 15 N at 5 N/s, for a total of 500 cycles. Gap formation at the tendon–bone interface was assessed every 100 cycles. Samples were tested to failure at the completion of 500 cycles.

Results: No specimens failed catastrophically during cyclic testing. A significantly greater gap formed using the monofilament sutures compared with the braided polyester sutures with both repair techniques. Load to failure in the modified Bunnell technique was superior to the micro-Mitek with both suture types. The modified Bunnell technique using a braided polyester suture was superior to the monofilament suture whereas the suture type did not alter the properties of the micro-Mitek repair.

Conclusions: Significant gap formation with the use of a monofilament suture may be of concern. The use of a braided polyester suture when removal of the pullout suture is required as in the Bunnell technique also needs to be considered. (J Hand Surg 2005;30A:471–478. Copyright © 2005 by the American Society for Surgery of the Hand.)

Key words: Bunnell, suture anchors, suture, tendon, flexor digitorum profundus tendon.
Distal zone 1 flexor digitorum profundus (FDP) lacerations and avulsions require fixation of the tendon end to the volar base of the distal phalanx. A widely accepted method uses a modification of the Bunnell pullout suture tied dorsally over a button on the nail plate (Figs. 1A, 1B). \(^1\)–\(^6\) Clinical results published for this zone of injury show a 75% fair to poor outcome. \(^7\),\(^8\) The reasons for the poor results may reflect issues relating to the fixation, suture choice, and rehabilitation programs. Studies reviewing flexor tendon repairs in zone 2 have shown that results are influenced by gap formation at the repair site, with gap formation as low as 3 mm causing decreased repair strength and poorer outcomes. \(^9\)–\(^12\) We hypothesized that some of the poor results reported may be explained in part by gap formation at the tendon–bone interface, which can form under a single loading event (static testing) or repeated loading (dynamic testing). Many studies of zone 2 repairs have shown improved outcomes if patients are subject to an early postoperative mobilization protocol. \(^13\)–\(^17\) The same benefits may apply after zone 1 tendon repairs but only if the loads encountered early in the postoperative period and rehabilitation can be sustained by the chosen method of fixation.

The external dorsal button is often a source of inconvenience for the patient. Potential risks associated with its use include nail-plate deformities, nailfold necrosis, and infections tracking along the sutures. Buried fixation avoids these complications. Micro-Mitek suture anchors (1.3 × 3.7 mm; Mitek, Westwood, MA) are easy to use and short enough to be embedded completely within the distal phalanx (Fig. 2). The use of small suture anchors provides an attractive alternative to the traditional modified Bunnell\(^4\),\(^5\) pullout technique for FDP tendon fixation to the distal phalanx (Fig. 1C). \(^4\),\(^5\),\(^18\),\(^19\)

The application of a single tensile loading profile (static testing) on the in vitro properties of various FDP tendon-to-bone techniques has been reported. \(^4\),\(^5\),\(^19\),\(^20\) Skoff et al\(^20\) reported a static failure load of approximately 40 N for the Bunnell technique using 3-0 braided polyester sutures in a human cadaver model. Similarly Silva et al\(^4\) examined the effect of different suturing patterns (Bunnell, Kessler, Kleinert) on the static tensile properties for the Bunnell technique by using 3-0 monofilament (Prolene; Ethicon, Somerville, NJ) in human cadavers. They reported a static tensile failure load for the Bunnell technique of 30 N using the Kessler repair whereas the Bunnell and Kleinert patterns achieved loads of 39 N. \(^4\) The deformation at a load of 20 N was reported to be 8 mm, which was considered a considerable amount of displacement. \(^4\) Silva et al\(^5\) went on to study the effects of multiple-strand suture techniques on the tensile properties of FDP tendon-to-bone repairs in human cadavers by using suture anchors or the Bunnell technique. Static testing to failure of repairs consisting of 4- or 8-strand proximal grasping sutures that were secured to the distal phalanx using a suture anchor or a dorsally placed button were examined. Although no difference in elongation at 20 N was detected in the 4 groups, the load to failure in the Bunnell technique with 8 strands

**Figure 1.** (A) Bunnell technique of suture insertion into the tendon. (B) Pullout suture tied over a button on the nail plate. (C) Fixation using a suture anchor.

**Figure 2.** Close-up of a micro-Mitek anchor loaded with 3-0 Ethibond.
was significantly different compared with the other groups (p > .05). More recently Brustein et al\textsuperscript{19} reported the static tensile properties of the Bunnell technique in human cadavers using 3-0 monofilament nylon in a 2-strand Bunnell suture pattern, a 1.8-mm Mini-QuickAnchor (Mitek Products, Westwood, MA) using 3-0 braided polyester in a 2-strand Bunnell suture pattern, and the Mitek micro-anchor using 3-0 braided polyester with a modified 4-strand Becker suture pattern. The ultimate tensile load using the Bunnell technique was reported to be similar to the Becker technique. The ultimate tensile load using a modified Bunnell suture pattern, and the Mitek micro-anchor using 3-0 braided polyester with a modified 4-strand Becker suture pattern. The ultimate tensile load using the Bunnell technique was reported to be similar to the Mini-QuickAnchor (43.3 ± 4.8 N vs 44.6 ± 12.7 N) whereas the 1.3-mm Micro-QuickAnchor (Mitek) technique achieved the greatest loads (69.6 ± 10.8 N) in static testing. These investigators suggested that the micro–bone suture anchor with the modified Becker technique is worth consideration as an alternative method to repair distal FDP avulsions.

The studies noted earlier provide an extensive characterization of the in vitro properties of FDP repairs from a single application of the load. Although this provides a reasonable way to compare the properties of different repair techniques, the static nature of the testing is a limiting factor. A dynamic or cyclic loading profile applies a load and then removes it and applies it again. This differs from a single 1-time (static) loading case in which the development of a gap under dynamic conditions cannot be assessed. To date the biomechanical fixation properties using anchors with a braided polyester or monofilament in dynamic or cyclic protocols have not been examined. Our in vitro biomechanical study was performed to compare FDP tendon fixation using a modified Bunnell pullout technique with fixation using a single micro-Mitek anchor immediately after the repair at time zero. This study was limited because we did not explore the biology of healing and we did not study the biomechanical properties in a curvilinear manner. We also did not examine comprehensively all variations of suture patterns that potentially can be used in this type of repair. Our aim was to examine the ability of the techniques performed in our study to withstand a simulated passive mobilization protocol by the development of any gap formation at the tendon–bone interface and ultimate load to failure of these constructs in a dynamic uniaxial testing protocol. Considering the micro-Mitek devices are provided with 3-0 braided polyester (Ethibond; Ethicon, Sommerville, NJ) whereas the modified Bunnell technique traditionally uses a monofilament such as 3-0 Prolene, both techniques were examined with both suture types to cover all possible combinations.

Materials and Methods

Twenty-four nonrandomized fresh-frozen human cadaveric fingers (mean age, 73 y) were used in this study. Specimens from the ring, middle, and index fingers were harvested through the level of the proximal interphalangeal joint, preserving a maximum length of the FDP tendon (all >15 cm). The volar skin and subcutaneous tissue were excised to expose the flexor sheath. The A5 pulley was cut and the FDP insertion was dissected sharply from the base of the distal phalanx. The flexor digitorum superficialis tendon was removed and any adhesions between the FDP tendon and the surrounding tissues were liberated to allow free excursion of the FDP in the remaining flexor sheath. The distal edge of the A4 pulley was vented to allow visual measurement of a 6-0 Prolene marker suture used to monitor the gap formation with the point of fixation of the testing rig.

Four experimental groups were examined in this study. The FDP insertion was repaired using 1 of the 2 methods (Fig. 1) using a monofilament or a braided polyester suture. A sample size of n = 6 was determined based on a power analysis of previous testing in our laboratory. Six repairs were performed with a modified Bunnell pullout suture of 3-0 Prolene or 3-0 Ethibond. The suture ends were passed extraosseously on either side of the distal phalanx and tied over a button at the midportion of the nail plate. Six repairs were performed using a micro-Mitek suture anchor loaded with 3-0 Ethibond or 3-0 Prolene. The micro-Mitek anchor was inserted at 45° to the surface of the distal phalanx in a retrograde fashion (Fig. 1C) in accordance with the deadman theory of suture anchors.\textsuperscript{20} The deadman theory refers to the analogy made by Burkhart\textsuperscript{21} in which the suture anchor is analogous to a rock placed in the ground when installing a fence. The angle of 45° represents the angle for equilibrium of the system.\textsuperscript{21} The suture was woven into the tendon using the same Bunnell pattern in all repairs.

Each specimen was prepared for mounting with an anteroposterior 1.6-mm K-wire through the tuft of the distal phalanx. Marker sutures of 6-0 Prolene were placed superficially at the most proximal extent of the suture repair to allow measurement of gap formation in the most consistent manner (Fig. 2). X-rays of specimens with suture anchors were taken before testing in the anteroposterior and lateral planes (Fig. 3) to confirm proper placement using a
Faxitron (Faxitron; Whelling, IL) and high-resolution mammography film.

The repaired fingers were mounted on a servohydraulic material testing machine using pneumatic clamps and a 100-N load cell (MTS 858 Mini Bionix; MTS Systems Corp., Eden Prairie, MN). A preload to 2 N was used to determine the baseline measurement from the K-wire to our tendon marker using a caliper (Series 500 Digimatic Absolute Caliper; Mitutoyo UK Ltd., Andover, Hampshire, UK). All samples were irrigated carefully with a phosphate-buffered saline mist periodically throughout preparation and testing. Specimens were loaded and unloaded cyclically from 2 to 15 N at a rate of 5 N/s for a total of 500 cycles. Testing was paused every 100 cycles for 10 seconds at the initial 2 N preload to measure gap formation between the markers. Specimens were loaded to failure at 20 mm/min at the completion of the cyclic testing. Load and displacement and the mechanism of failure were recorded using a personal computer. X-rays of the suture anchor specimens were taken after testing to failure to determine if any migration of the anchors in the bone had occurred. The tensile stiffness of 6 samples of 3-0 Prolene and 3-0 Ethibond was measured using a testing machine (Mach 1 Micromechanical Testing Machine; Biosyn-tech, Montreal, Canada) immersed in phosphate-buffered saline at room temperature using a gauge length of 10 mm and a displacement of 0.1 mm/s. The linear stiffness in the initial part of the load versus the displacement graph was used to determine the stiffness based on a linear regression analysis. Mechanical data from the cadaveric testing were analyzed using a 2-way analysis of variance followed by a Tukey honest significant difference post hoc test using statistical software (SPSS for Windows; SPSS Inc., Chicago, IL). An unpaired Student t test was used to determine any differences in the properties of the sutures using statistical software (SPSS for Windows). Data were considered significant at a p value of less than .05.

Results

No cadaver specimens failed during cyclic testing. Anchor failure or retraction, joint penetration, and suture-anchor junction failure were not encountered. Table 1 and Figures 5 and 6 summarize the mechanical data for the cadaver testing. Suture type had a significant effect on the properties measured. Gap

Figure 3. Specimen mounted on the testing unit. Gap formation distance (arrow) was measured with a digital caliper (not shown) from the base of the K-wire to the 6-0 Prolene marking suture knot.

Figure 4. X-rays showing lateral and anteroposterior views of the micro-Mitek anchor position.
formation was significantly greater using 3-0 Prolene compared with 3-0 Ethibond in both fixation methods. Mean gap formation (Fig. 5) after 500 cycles was 6.8 mm (SD, 1.24) in the modified Bunnell pullout group with 3-0 Prolene and decreased to 1.66 mm (SD, 1.67) using 3-0 Ethibond (p < .05). Similarly the gap formation in the micro-Mitek group using 3-0 Prolene was 4.81 mm (SD, 0.91) and decreased to 2.00 (SD, 0.36) using 3-0 Ethibond (p < .05).

Load to failure (Fig. 6) was greater in the modified Bunnell method compared with the micro-Mitek suture anchors with both suture types (p < .05) (Table 1). The load to failure in the modified Bunnell technique using 3-0 Ethibond (47.11 N; SD, 4.51) was superior to all groups (p < .05). The modified Bunnell technique using 3-0 Prolene (37.63; SD, 4.70) was greater than both groups using the micro-Mitek (p < .05), whereas the suture type did not influence the load to failure in the micro-Mitek group (p < .05). This difference was statistically significant (p < .05).

Suture failure over the plastic button in the modified Bunnell group or over the Mitek anchor eyelet was observed in all specimens with 3-0 Prolene or Ethibond. One micro-Mitek anchor partially pulled out from the bone when tested with 3-0 Ethibond.

The stiffness of 3-0 Ethibond (7.51 N/mm; SD, 0.40) was statistically greater compared with 3-0 Prolene (4.90 N/mm; SD, 0.05)(p < .05).

**Discussion**

Gap formation at the repair site in zone 2 is related adversely to the outcome of FDP tendon repairs, although there is still some disagreement as to how much gap is detrimental. 

Ejeskär et al used metallic markers in 63 repaired digits and found a strong correlation between gap formation and a poor outcome. Seradge related the incidence of tenolysis to gap formation in a prospective study of 91 patients, concluding that the incidence of tenolysis increased to 100% if there was a gap formation of 4 mm or more. Silfverskiold et al found that gap formation up to 10 mm was compatible with good function in 34 digits when evaluating proximal interphalangeal and distal interphalangeal range of motion. Gelberman et al in a canine model found that tendons with a gap of more than 3 mm had a small margin of safety compared with the upper limit of tendon force required for active unopposed digital flexion at 21 and 42 days.

Although we could not find similar data for repairs in zone 1, the limited published data report a high level of poor outcomes. Moiemen and Elliot evalu-

<table>
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<th>Group</th>
<th>Gap Formation (mm)</th>
<th>SD</th>
<th>Load to Failure (N)</th>
<th>SD</th>
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</thead>
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<tr>
<td>Bunnell Ethibond</td>
<td>1.66</td>
<td>1.67</td>
<td>47.11</td>
<td>4.51</td>
</tr>
<tr>
<td>Bunnell Prolene</td>
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<td>1.24</td>
<td>37.63</td>
<td>4.70</td>
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<tr>
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<td>0.36</td>
<td>28.50</td>
<td>4.03</td>
</tr>
<tr>
<td>Mitek Prolene</td>
<td>4.81</td>
<td>0.91</td>
<td>29.52</td>
<td>4.23</td>
</tr>
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**Figure 5.** Gap formation in the Bunnell technique using 3-0 Prolene was significantly greater (p < .05) than all other groups. Gap formation in the Mitek technique using 3-0 Prolene also was greater than both repair techniques with 3-0 Ethibond (*), which did not differ.

**Figure 6.** The failure load was greater using the Bunnell technique using 3-0 Ethibond compared with all techniques (p < .05). The Bunnell technique using 3-0 Prolene also was greater than the 2 Mitek groups (**p < .05), which did not differ.
ated the results of 102 primary flexor tendon repairs in zone 1. Fourteen of the 102 repairs required reinsertion with a similar 3-0 or 4-0 Prolene modified-Bunnell pullout technique. When evaluated with the original Strickland criteria 6 were excellent, 3 were good, and 5 were fair. When evaluated with the distal interphalangeal range of motion alone, however, approximately 50% had poor results. In a similar clinical study Hartmann et al found that when using a similar pullout technique with 3-0 monofilament, 9 of 13 patients had moderate to severe losses of distal interphalangeal and proximal interphalangeal joint range of motion. Although the reasons for these poor results are not clear we hypothesized that some of it may be caused by excessive gap formation at the repair site.

Considering early postoperative mobilization is beneficial to clinical outcomes in flexor tendon injuries we believed it was important to establish whether such protocols would lead to gap formation. The loading protocol used in this study was established based on the following considerations. In vivo loading along the FDP during passive flexion has been reported to be 9 N. An increase in loads of up to 50% can be expected from friction and edema, generating an expected force of 15 N with passive-motion rehabilitation protocols. The rate of approximately 10 cycles per minute and the total of 500 cycles in this study are based on a patient flexing and extending 10 times per minute, 1 minute an hour, 10 hours a day, for 5 days. The time period of 5 days was chosen because it represents the amount of time before any significant reduction in tendon repair strength occurs.

Abboud et al investigated cyclic loading of various suture anchors in human cadaveric carpal bones. The rate of loading and frequency were different from the current study and thus make any comparison difficult. The investigators showed, however, that threaded or screw-type anchors were stronger than pronged anchors. We selected the micro-Mitek suture anchor because it was the smallest anchor with a 3-0 nonresorbable braided polyester suture (Ethibond) that was available commercially. The anchors were inserted at an angle of 45° in a retrograde fashion in accordance with the deadman theory of suture anchors as proposed by Burkhart. Both suture types were examined with both fixation techniques to examine also the role of the suture.

Gap formation can arise because of a number of factors including the level of loading, suture properties, length of suture, suturing technique, and point of fixation. The length of the suture used in the pullout repair is considerably greater than that used with an anchor. The 3-0 Prolene is significantly less stiff than the 3-0 Ethibond and as a result will deform more under the same applied load. The reduced stiffness of 3-0 Prolene and the greater length required for the pullout suture may contribute to the development of a significant tendon–bone interface gap formation using this technique.

The pullout repair technique necessitates the use of a monofilament suture to facilitate later removal. We used 3-0 Prolene because this is a commonly used monofilament suture for this repair. In contrast suture anchors often are supplied preloaded with braided polyester sutures such as Ethibond. Because both methods are used to address the same pathology and are expected to withstand the same postoperative treatment we believe that subjecting them to the same testing protocol was appropriate. We did, however, examine both techniques with both suture types to examine the role of the suture. The results reflect the increased strength and stiffness of the 3-0 Ethibond compared with the 3-0 Prolene in reducing the gap formation and increasing the strength of the modified Bunnell repair. The micro-Mitek anchor eyelet, however, presented a stress riser to both suture types and resulted in the failure of both repairs at similar loads. Excessive gap formation in the pullout technique may be a contributing factor to the poor results reported in studies using this method. The minimal gap formation in the micro-Mitek group is encouraging.

A number of studies have examined the failure properties as well as the deformation after FDP repairs using the Bunnell technique with different sutures, different suture patterns, and different anchors. The failure loads in the current study agree with reported values in the literature with respect to the Bunnell repair technique.

Silva et al compared 3 suture methods to reinsert FDP tendons by a pullout method with 3-0 Prolene and obtained load-to-failure values between 33.4 and 39.9 N depending on the suture pattern. Their study also measured an average elongation of 8 mm at a load of 20 N. Our gap formation of 6.8 mm after 500 cycles is a concern similar to the one raised in the study by Silva et al, although our measurements reflect a permanent deformation at the repair site. Brustein et al compared the mini-Mitek and the 2 micro-Mitek 4-strand techniques and the Bunnell technique for FDP repairs. The ultimate fixation properties using the Bunnell technique were reported.
to be similar to the mini-anchor (43.3 ± 4.8 N vs 44.6 ± 12.7 N) whereas the 1.3-mm micro-Quick-
Anchor technique achieved the greatest loads (69.6 ± 10.8 N) in static testing. Differences in implant size and technique in the anchor groups precludes a direct comparison with our study. Failure load after cyclic loading in the anchor group in our study was significantly lower in the anchor groups compared with the Bunnell technique.

The failure loads of both techniques in our study suggest that neither would be suitable for a postoperative active mobilization protocol. The reason for this is the loads encountered during the active protocol may exceed the strength of fixation based on our failure data. This conclusion agrees with the data from Silva et al[4] based on static testing. This is not that surprising given that the trend in zone 2 injuries is for multistrand repairs and that such repairs also are reinforced with a peripheral suture. Thus one could not expect that a simple 2-strand FDP fixation technique, regardless of whether it is a pullout or anchor fixation method, would provide sufficient biomechanical integrity to withstand an aggressive rehabilitation protocol.

Our data also suggest that both methods of fixation may be sufficient to resist failure in the first 5 days of a passive mobilization rehabilitation protocol. This belief is based on the reported loads during passive flexion to be 9 N in the FDP.22 Furthermore even with an increase in loads of up to 50%, which may be experienced and generate a load of approximately 15 N as reported by Strickland,6 the repairs should be able to withstand these forces. Significant gap formation at the tendon–bone interface in the modified Bunnell technique using the micro-Mitek with 3-0 Prolene is of concern and some may consider this as a form of failure. Minimal gap formation in the micro-Mitek group using 3-0 Ethibond would suggest this might be a better method of fixation for patients undergoing a passive mobilization protocol. The lower load to failure using the micro-Mitek highlights the importance of the anchor eyelet design and also leaves a narrow margin of safety for rehabilitation. Further developments in suture materials, suture anchors, eyelet design, and multistrand techniques may offer improvements in this type of repair.

This study has limitations related to the age of the cadaver specimens. The mean age of our samples was 73 years old; however, suture failure occurred in all samples, showing the bone density was not a limiting factor. The suture anchor group represents a worst-case scenario with regard to bone density and quality. The suture in the modified Bunnell pullout technique is fixed to the nail plate; thus the properties of the bone density are not relevant. The sample size in the current study, although small, was adequate to detect differences between the testing techniques.

References