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Bone - Prosthesis Junction for Active Tendon Implants: A Biomechanical Comparison of Two Fixation Techniques

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INTRODUCTION

End-to-end repair of damaged tendon is not possible in many instances of injury. Staged flexor tendon reconstruction has been proven to be a valuable method of addressing complex flexor tendon injuries when the patient presents late, has failed primary repair, or the injury mandates it (1). Silicone implants have been used for two-stage flexor tendon reconstructions with reports of long-term use as active implants (2,3). Implants have been reported functional approximately one year post-surgery with some still in use up to 25 years after reconstruction (4). This suggests the potential of the implant serving as a permanent prosthesis. The biomechanical strength of two proximal junction methods using a commercially available active tendon implant has been studied with a reported mean ultimate failure load of 220N (5). Biomechanical investigation of distal fixation has yet to be studied, but combined with the proximal results could lead to changes in two-staged flexor tendon reconstruction protocols allowing for earlier active range of motion, delayed Stage II surgeries, and perhaps permanent implantation.

Purpose: This study investigates two distal fixation techniques, Screw versus Knot fixation, using an active tendon implant in a canine model.

METHODS

- Cadaveric canine middle phalanges in matched fashion from 3rd and 4th toes of 14 forepaws
- Cleat and cord ends of tendon implant (Model ATPC Hunter Active Tendon Implant, Wright Medical Technology, Inc., Arlington, TN) applied (6) alternately to matched 3rd and 4th phalanges
- **Screw:** cleat end attached with 2.0mm bicortical screw (TriMed, Inc., Santa Clara, CA)
- **Knot:** cords through 2.0mm transverse bone tunnel and wrapped dorsal to volar around bone then tied in surgeon's knot
- Two 1.6mm K-wires through bone distal to fixation in U-shape for load application
- Bone painted white for contrast; one black mark on bone; two black marks on implant
- Constructs mounted via custom-designed clamp in a biaxial servohydraulic testing machine (Model 1321, Instron Corp., Canton, MA) retrofitted with MTS TestStar™ II digital controller (MTS Corp., Eden Prairie MN) (Figure 1)
- Constructs were loaded 2 and 50 N at 0.192 Hz for 500 cycles then load-to-failure at 20mm/min (5)
- Video recording at start, every 100 cycles, at end of cycling, and for entire failure test; digitally processed (NIH ImageJ freeware, Bethesda, MD) for stretch between distal bone and rod black marks (5)
 - % stretch defined as percent change relative to marker distances start of cycling 2N load
 - Stiffness: load/% stretch in $N/(mm/mm) \times 100$ defined by linear regression of load-elongation data from 50 to 150N
 - Peak load and failure mode noted for each test
- Cyclic data analyzed via mixed model ANOVA followed by Tukey-Kramer post hoc pairwise comparisons; Failure data analyzed by paired t-test; Statistical significance set at P = 0.05

DISCUSSION

Problematic flexor tendon injuries are often treated with staged flexor tendon reconstruction (1). The silicone implant has been used passively (1) but also as an active tendon implant (3,4,7) in the hopes of functional outcome after one surgery and allowing earlier resumption of normal activities. Implant biomechanical characteristics must be understood to ensure repair survival during loads associated with normal activities. Implants must survive forces up to 9N during passive finger movement and 35N with active flexion (8), and up to 120N during firm tip pinch of the index finger (9). Two types of proximal tendinous attachments for the implant have been shown to exceed these values by surviving average loads greater than 220N (5).

The current study investigated bony attachment methods using a Screw or a Knot. The majority of the Screw constructs failed with the screw pulling through the bone and creating an intraarticular fracture suggesting that bone would have to be repaired in addition to Stage II tendon grafting. In contrast, the Knot construct cords failed leaving little damage to the bone during cycling or load-to-failure testing. However, both the Screw and Knot methods survived average loads greater than 340N suggesting that the proximal tendinous attachment would be more likely to fail first. Thus, distal bony failure might not occur for the Screw at these lower loads.

The higher failure loads at distal and proximal ends of the implant than those required for normal activities suggests survival under early active motion. This should be considered in rehabilitation protocols following stage I of reconstruction. Further, the potential use of the implant as a permanent tendon prosthesis may be considered. When using the Knot method of distal attachment, stretching of the Knot construct was greater than the Screw which should be accounted for during implantation.

Significance: This study suggests that tendinous and bony connections of tendon implants can survive loads typical of active rehabilitation protocols with failure likely occurring at the tendinous attachment. Potential use of the implant as a permanent prosthesis is suggested and should be investigated further.

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RESULTS

- No constructs failed during cycling
- Cyclic stretch between bone and distal rod not detected different from 0 for Screw constructs ($p > 0.54$); but significantly greater after 1st cycle, 500th cycle, and 500th vs 1st cycle for Knot constructs ($p < 0.001$) (Figure 2)
- Significantly greater stiffness for Screw construct vs Knot ($p < 0.001$) during load to failure (Figure 3a)
- Significantly more stretch at peak load for Knot construct than Screw ($p < 0.001$) (Figure 3b)
- No significant difference detected between Screw and Knot peak loads ($p = 0.234$) (Figure 3c)
- 11 out of 14 (79%) of Screw constructs failed as screw pulled through bone tunnel resulting in intraarticular fractures
- 10 out of 14 (71%) Knot constructs failed at bone tunnel but with cords fraying at bone-cord interface
- Peak load excluded from analysis for 1 Screw construct which failed in bone at K-wire without failure of Screw fixation

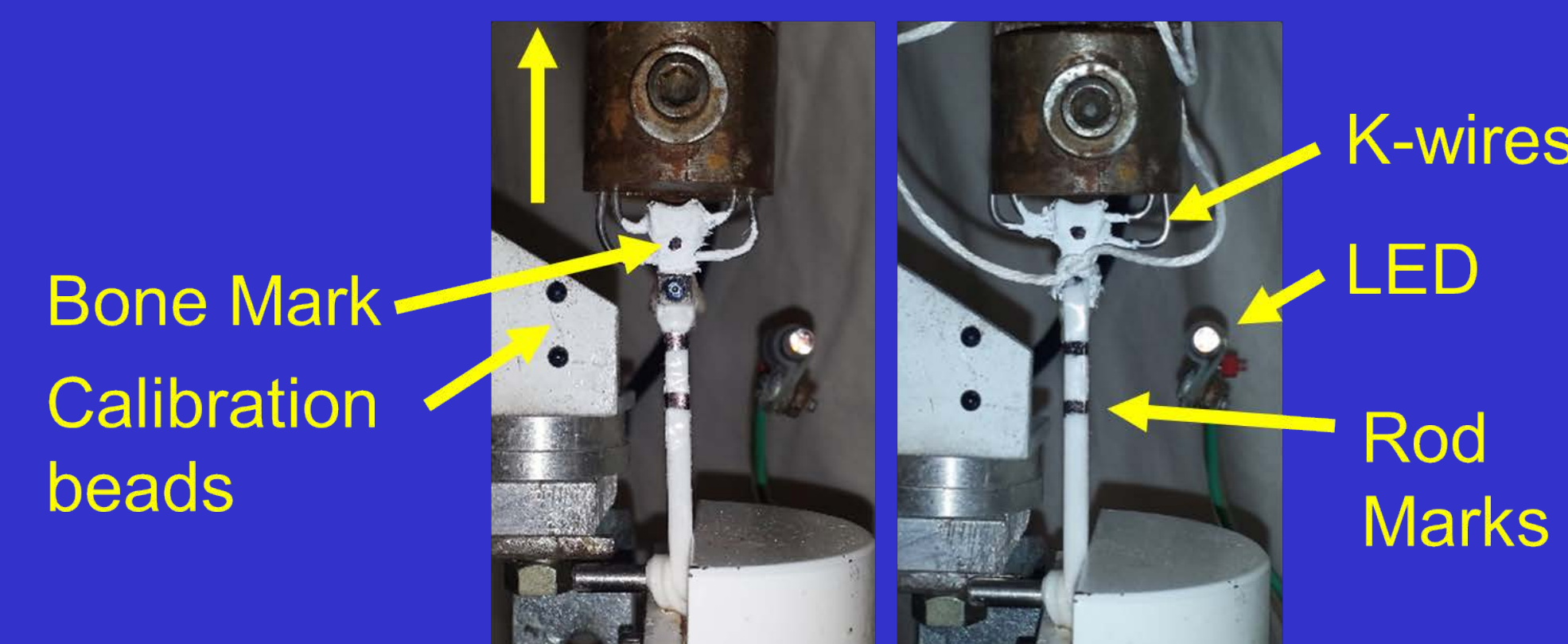


Figure 1: Typical setup for testing of constructs, Screw (left) and Knot (right). Calibration beads and LED are for digital image processing.

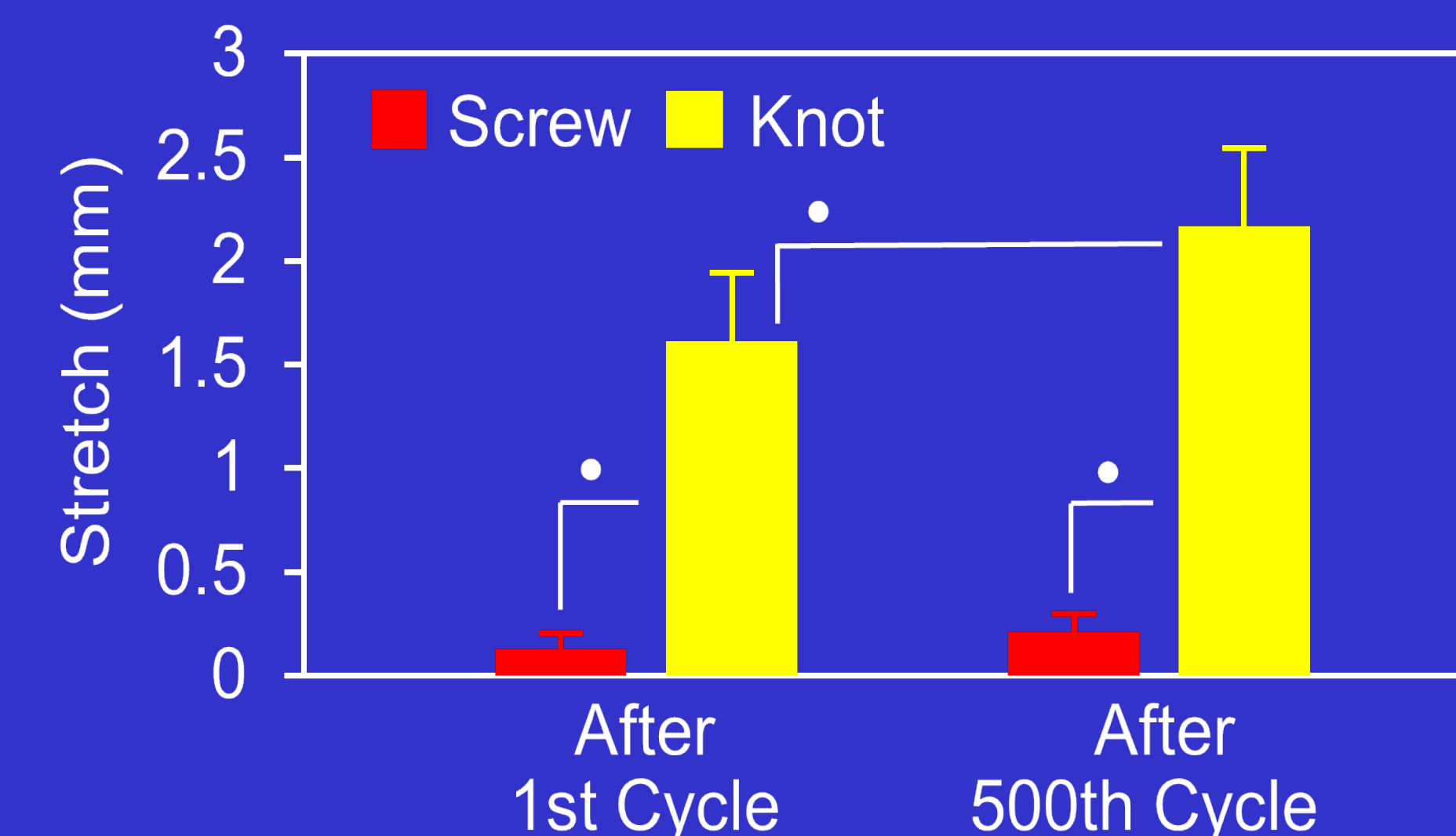


Figure 2: Stretch of constructs after 1st and 500th cycles. • denotes $p < 0.001$

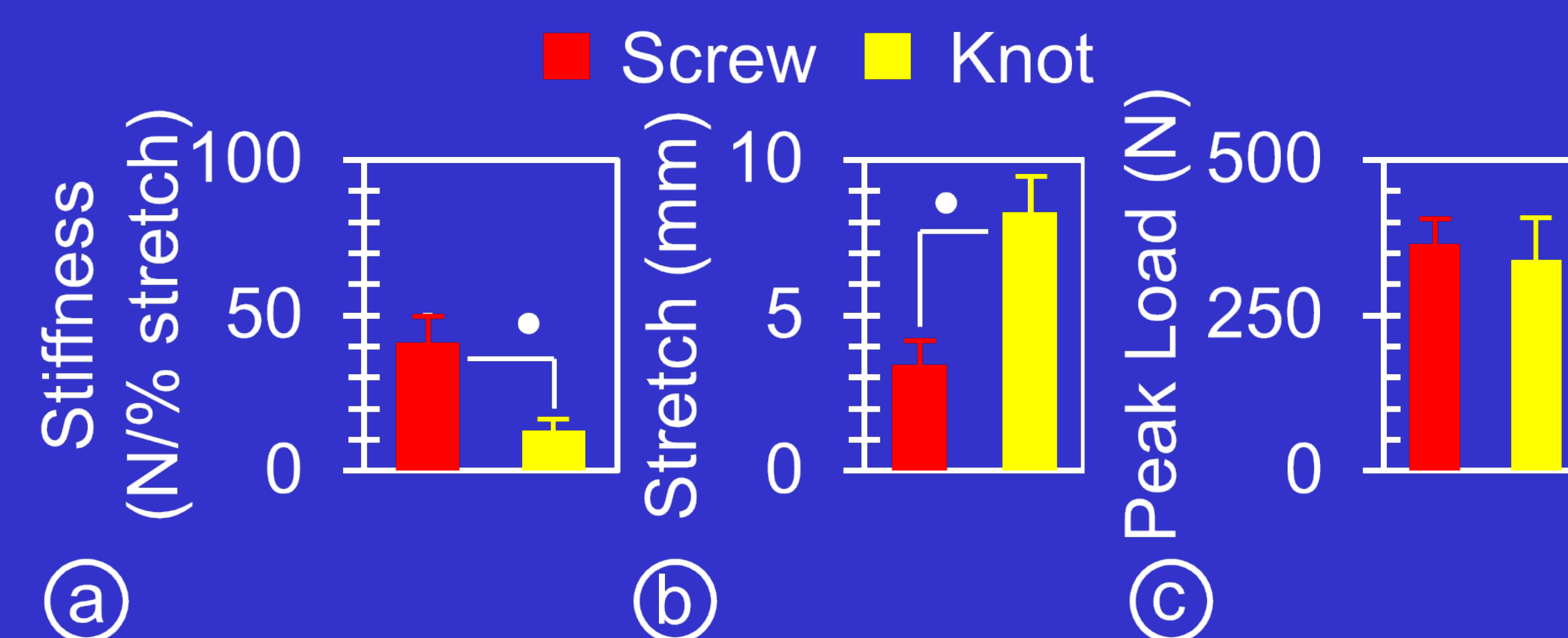


Figure 3: a) Stiffness of the constructs from 50N to 150N, b) Stretch at peak load during failure, c) Peak load during failure. • denotes $p < 0.001$