The Journal of Foot & Ankle Surgery 57 (2018) 60–64

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

Fixation Strength of Polyetheretherketone Sheath-and-Bullet Device for Soft Tissue Repair in the Foot and Ankle

Jay Christensen, DPM, FACFAS [1], Brian Fischer, DPM, AACFAS [2], Michael Nute, DPM [3], Robert Rizza, PhD [4]

[1]*Second-Year Resident, Podiatric Medicine and Surgery Program, Wheaton Franciscan Healthcare, Milwaukee, WI*
[2]*First-Year Resident, Podiatric Medicine and Surgery Program, Wheaton Franciscan Healthcare, Milwaukee, WI*
[3]*Attending Physician, Podiatric Medicine and Surgery Program, Wheaton Franciscan Healthcare, Milwaukee, WI*
[4]*Associate Professor, Milwaukee School of Engineering, Milwaukee, WI*

ARTICLE INFO

Level of Clinical Evidence: 5

Keywords:
bone model
fixation strength
interference device
soft tissue anchor
tendon transfer

ABSTRACT

Tendon transfers are often performed in the foot and ankle. Recently, interference screws have been a popular choice owing to their ease of use and fixation strength. Considering the benefits, one disadvantage of such devices is laceration of the soft tissues by the implant threads during placement that potentially weaken the structural integrity of the grafts. A shape memory polyetheretherketone bullet-in-sheath tenodesis device uses circumferential compression, eliminating potential damage from thread rotation and maintaining the soft tissue orientation of the graft. The aim of this study was to determine the pullout strength and failure mode for this device in both a synthetic bone analogue and porcine bone models. Thirteen mature bovine extensor tendons were secured into ten $4.0 \times 4.0 \times 4.0$-cm cubes of 15-pound per cubic foot solid rigid polyurethane foam bone analogue models or 3 porcine femoral condyles using the 5×20-mm polyetheretherketone soft tissue anchor. The bullet-in-sheath device demonstrated a mean pullout of 280.84 N in the bone analog models and 419.47 N in the porcine bone models. ($p = .001$). The bullet-in-sheath design preserved the integrity of the tendon graft, and none of the implants dislodged from their original position.

Tendon transfers and allograft soft tissue fixation have played very important roles in the correction of deformities from multiple etiologies. Traditionally, tendon graft fixation was achieved through the use of buttons sutured externally to hold grafts within bone tunnels. Newer techniques using suture anchors have been adopted owing to their ease of use. However, this approach results in less tendon-to-bone contact, because the graft only lies on top of the cortices and can be compromised if the anchor migrates or a knot loosens under cyclic loading. Previous studies have suggested suture button and tunnels could lead to low graft stiffness and allow micromotion within the tunnel. This micromotion has been termed the "bungee cord" effect and can cause tunnel enlargement and possible graft failure (1). More recently, the use of tenodesis interference screws to fixate and compress a tendon graft in a tunnel have gained acceptance to address the shortcomings of using buttons and suture anchors. The use of interference screws reduces the length of tendon graft necessary within the tunnel compared with placing a tendon through a bone tunnel and either suturing it onto itself or using a button (2).

Tenodesis screws have their own set of limitations related to the device material and design. Previous studies have shown titanium screws can lacerate the soft tissue graft, causing damage and contributing to graft failure at the screw–graft interface (3). The use of bioabsorbable screws will lessen this effect to some degree owing to the blunted edges of the threads (4). Additionally, bioabsorbable polymers have differing degradation profiles, contributing to multiple unwanted side effects. The degradation products cause reactions such as foreign body reactions, osteolysis, synovitis, intraosseous cyst formation, intraarticular inflammatory reactions, systemic allergic reactions, and loose intraarticular foreign bodies (5). The introduction of polyetheretherketone (PEEK) as an implant material has diminished or eliminated these adverse reactions. PEEK is a rigid, highly unreactive, biostable thermoplastic polymer that is radiolucent and able to provide stable, rigid fixation (5). Previous animal studies have shown no acute inflammatory responses to PEEK implants (6).

Sheath-based interference devices have gained much attention in anterior cruciate ligament reconstructions for their ability to protect

Financial Disclosure: Implants provided by Medshape, Inc., in addition to funding for bone models.

Conflict of Interest: M.N. was a previous advisor to Medshape, Inc., for an unrelated product.

Address correspondence to: Jay Christensen, DPM, FACFAS, Podiatric Medicine and Surgery Department, Prevea Healthcare, 1411 N. Taylor Dr., Sheboygan, WI 53081.
E-mail address: jay.christensendpm@gmail.com (J. Christensen).

1067-2516/$ - see front matter © 2017 by the American College of Foot and Ankle Surgeons. All rights reserved.
https://doi.org/10.1053/j.jfas.2017.08.004

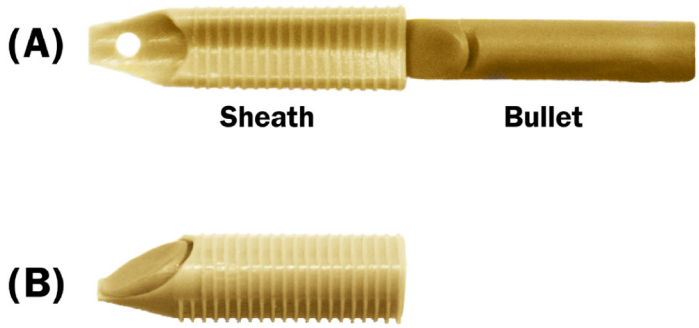

Fig. 1. *(A)* The Eclipse™ implant (Medshape, Inc., Atlanta, GA) before deployment showing the individual bullet and sheath components. *(B)* The implant after deployment showing the bullet in the sheath and the sheath fully expanded circumferentially. Modified figure used with permission of manufacturer.

the graft from damage during implantation. Recently, this implant design has been specifically adapted for use in foot and ankle procedures. The basic design incorporates a concavity within the sheath component of the implant to aid in graft placement and orientation within a bone tunnel. This allows movement of the soft tissue without placing a stress on the graft (Fig. 1). Once the bullet has been deployed, the shape memory properties of the PEEK Altera® material (Medshape, Inc., Atlanta, GA) allows the tendon graft to be securely compressed and fixated to the bone interface, maintaining the precise orientation and structural integrity of the graft. In 1 previous study, a sheath-based interference device was shown to generate superior compressive force and achieve greater pullout strength compared with interference screws (7). Additionally, the use of the sheath allows the surgeon to place the graft in the proper orientation relative to the implant, preventing the inevitable rotation of the graft or breakage of the implant, which has been associated with insertion of a biotenodesis screw (8). These sheath-based devices allow more anatomic placement of the tendon graft within the bone tunnel and reduced the shear stresses that can lead to enlargement of the tunnel (9). They also create friction through a press fit among the implant, graft, and bone to prevent graft movement (10).

To date, the use of sheath-based interference devices in tendon transfer procedures has yet to be reported (7). In particular, it is important to understand their biomechanical performance as it pertains to securely fixating a tendon graft without inducing any soft tissue damage. Thus, the purpose of the present study was to evaluate the pullout strength of a shape memory PEEK sheath-based interference device (Eclipse™ Soft Tissue Anchor; Medshape, Inc., Atlanta, GA) when securing bovine extensor tendons to both bone analogue and porcine bone models.

Materials and Methods

Specimen Preparation

Thirteen mature bovine extensor tendons, each 10 cm long, and 3 porcine femoral condyles were obtained from Animal Technologies, Inc. (Tyler, TX) and stored at –20°C on arrival. Bovine extensor tendons have been shown to exhibit similar mechanical properties to cadaver tendons when used in biomechanical studies (11). We used 15-pound per cubic foot (PCF) polyurethane synthetic bone (Pacific Research Laboratories, Vashon, WA) to represent healthy bone with an average-quality bone density and to eliminate intraspecimen variability (12,13). The density of porcine bone has been shown to be comparable to that of young human bone and allows for control of variability related to cadaveric bone (1,14–16). Before testing, the tendons were thawed in a warm water bath for a minimum of 15 minutes and trimmed to appropriate diameters 5 mm in width and measured using the enclosed tendon sizer (7). A no. 2 Fiberwire® suture (Arthrex, Inc., Naples, FL) was then used in a whipstitch with 4 loops at the proximal 4 cm of extensor tendon. The 3 porcine femoral condyles were allowed to thaw for 12 hours and excess connective tissue was removed before testing. The 15-PCF solid rigid polyurethane foam bone analogues were fashioned into 10 individual 4.0 × 4.0 × 4.0-cm cubes representing the density of the calcaneus. A 5-mm pilot hole was placed in the center of the bone analogue block and in the center of the lateral aspect of the femoral condyles. The sutured end of the tendon was placed within the pilot hole and advanced 2.5 cm. Each model had one 5.0 × 20-mm Eclipse™ Soft Tissue Anchor (Medshape, Inc.) inserted using the manufacturer's recommended procedures (Fig. 2). In brief, the sheath component was inserted such that the tendon was properly aligned within the concavity of the sheath and facing upward toward the testing aperture. Once the sheath had been placed slightly deep to the outer cortical edge, the bullet was deployed into the sheath using the deployment gun, facilitating the radial expansion of the sheath and subsequent tendon fixation. The no. 2 Fiberwire® suture (Arthrex, Inc.) was looped 3 times around the moving arm of the MTS Alliance RT/50 machine (MTS Systems, Eden Prairie, MN) and securely fastened onto itself.

Fig. 2. Placement of the implant within the bone analogue tunnel with the tendon graft. The implant was placed flush to the surface with all suture material completely inserted within the tunnel.

Mechanical Testing

The bone analogue cubes and femoral condyles were secured to the testing frame of the MTS Alliance RT/50 machine (MTS Systems) with a combination of Dentsply™ (York, PA) cementation and 4 screws within the fixture, entering the specimens at 90° to each other in the bottom 2.0 cm of the specimen. MTS TestWorks® software (MTS Systems) was used to control the load frame and acquire the load and displacement data. The length of the tendon was maintained at 6.0 cm from the aperture to the anchor (Fig. 3).

The tendon was then pulled once at a 2-mm/sec rate until failure of the specimen at 90° to the pilot hole straight vertical (1). The direction of the pull was anatomic, away from the anchor (17). The load versus time data were collected at 1 kHz with a 5-kN load cell. The load versus extension data were recorded, and the pullout strength was defined as the maximum load on the load–extension curve. All tendons were pulled until failure, as defined by visual analysis, correlating with the peak force/displacement curve values recorded in the TestWorks® software (MTS Systems). Failure using visual analysis was defined as exposure of the suture material with movement of the tendon within the predrilled tunnel. A total of 10 and 3 tests were performed in the bone analogues and porcine bone models, respectively.

The mean ± standard deviation was calculated for each test group (synthetic bone and porcine model). The mean pullout strength was compared between the 2 groups using Student's *t* test to assess the statistical significance between the comparative specimens. Statistical significance was defined at the 5% level ($p \leq .05$).

Results

The mean pullout force for the 5.0-mm bullet-in-sheath device in the bone analogue was 281.8 ± 91.7 N, and that for the porcine bone