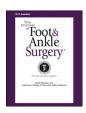


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Evaluating Plantar Fascia Strain in Hyperpronating Cadaveric Feet Following an Extra-osseous Talotarsal Stabilization Procedure

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ABSTRACT

Abnormal talotarsal joint mechanics leading to hyperpronation is implicated as one of the most common causes of plantar fasciopathy. In patients with hyperpronating feet, the plantar fascia experiences excessive tensile forces during static and dynamic weight-bearing activities because of excessive medial longitudinal arch depression. For the purposes of this study, we hypothesized that plantar fascia strain in hyperpronating cadaveric feet would decrease after intervention with an extra-osseous talotarsal stabilization (EOTTS) device. A miniature differential variable reluctance transducer was used to quantify the plantar fascia strain in 6 freshfrozen cadaver foot specimens exhibiting flexible instability of the talotarsal joint complex (i.e., hyperpronation). The strain was measured as the foot was moved from its neutral to maximally pronated position, before and after intervention using the HyProCure® EOTTS device. The mean plantar fascia elongation was 0.83 \pm 0.27 mm (strain 3.62% \pm 1.17%) and 0.56 \pm 0.2 mm (strain 2.42% \pm 0.88%) before and after intervention, respectively (N = 18, variation reported is \pm 1 SD). The average plantar fascia strain decreased by 33%, and the difference was statistically significant with p < .001. From this cadaveric experiment, the reduction in plantar fascia strain suggests that an EOTTS device might be effective in stabilizing the pathologic talotarsal joint complex and the medial longitudinal arch and in eliminating hyperpronation. An EOTTS procedure might offer a possible treatment option for plantar fasciopathy in cases in which the underlying etiology is abnormal talotarsal biomechanics.

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Plantar fasciitis, or plantar fasciopathy, is one of the most common causes of pain along the plantar aspect of the foot. The etiology of plantar fasciopathy is broadly classified under the following 3 categories: mechanical, degenerative, and systemic (1–5). It is generally accepted by the medical community that plantar fasciopathy is most often caused by an underlying mechanical etiology (1,2). However, this remains open to debate, as mentioned by Wearing et al (6). Theoretically, abnormal talotarsal joint mechanics leading to hyperpronation results in lowering of the medial longitudinal arch, which places excessive tensile strain on the plantar fascia, eventually leading to microscopic tears and inflammation (7–14). Thus, patients with

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Conflict of Interest: Michael E. Graham is the inventor of HyProCure[®]. He is the Founder and President of GraMedica, LLC, the company that manufactures and distributes HyProCure[®]. He is also the Founder of Graham International Implant Institute

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hyperpronating feet are at a high risk of acquiring plantar fasciopathy because with each weight-bearing step the plantar fascia experiences excessive abnormal tensile strain (2,15–22).

Depending on the underlying etiology, different treatment options have been suggested for managing plantar fasciopathy. In cases in which mechanical etiology is identified as the main cause, it is recommended that the treatment should focus on both a short- and long-term solution (2). The short-term goals should primarily focus on reducing plantar fascia inflammation and the long-term goals should focus on reducing excessive plantar fascia strain caused by hyperpronation, considered 1 of the most common causes of plantar fasciopathy (1,2). Nonoperative treatment modalities such as modified footwear, foot orthoses, foot strapping, orthotic wedges, and so forth have been used to reduce the amount of hyperpronation and have been indicated for the long-term treatment of plantar fasciopathy (2,10,12,23–26). The basic premise for the use of these modalities has been that they provide support to the medial longitudinal arch in the hyperpronated foot and hence reduce plantar fascia strain during static and dynamic weight-bearing activities (27). To evaluate the efficacy of various types of foot orthoses and orthotic wedge combinations for the treatment of plantar fasciitis, Kogler et al (28–30) measured plantar fascia strain in human adult cadaver foot specimens before and after treatment with various combinations of orthotic support devices and under different load bearing conditions. They concluded that certain types of foot orthoses and orthotic wedge combinations were more effective than others in supporting the foot's medial longitudinal arch and reducing plantar fascia strain (28–30).

The extra-osseous talotarsal stabilization (EOTTS) procedure involves the placement of a device into the sinus tarsi for the treatment of hyperpronation and its associated pathologic features. Clinical research studies, in the pediatric and adult population, have shown that EOTTS devices are successful in the treatment of flatfeet and posterior tibial tendon dysfunction, both of which are associated with hyperpronation (31-35). However, limited scientific studies have been conducted to evaluate the biomechanical effects of these devices on the soft tissue structures supporting the foot and ankle joint complex. Because hyperpronation causes excessive tensile strain to the plantar fascia, and EOTTS devices are indicated for the treatment of hyperpronation, our goal was to experimentally evaluate the efficacy of such devices in reducing plantar fascia strain. For the purposes of this study, we hypothesized that strain on the plantar fascia in hyperpronating cadaveric feet would decrease after placement of the HyProCure® (GraMedica, Macomb, MI) EOTTS device. It is our ultimate goal to understand the biomechanics of EOTTS devices in the treatment of pathologies related to flexible talotarsal joint instability and hyperpronation. A complete understanding of the biomechanical functioning of these devices is required to appreciate their advantages and understand any possible adverse effects.

Materials and Methods

Plantar fascia elongation (strain) was measured in 6 fresh-frozen human adult cadaver foot specimens (all female). Each specimen consisted of the foot, ankle, and distal segment of the leg (approximately 20 cm proximal to the ankle joint). All specimens were inspected for their range of motion at the ankle joint complex. The investigating surgeon clinically determined that each of these specimens exhibited hyperpronation (i.e., flexible instability of the talotarsal joint complex). The exclusion criteria for the specimens included previous operative intervention, fracture or pathologic conditions in the ankle-hindfoot complex such as tarsal coalition, or arthritic degeneration of the midfoot and hindfoot joints. The specimens were adequately thawed to room temperature before testing. Each specimen was dissected free of the soft tissue at the proximal tibial and fibular segment. The proximal segment of the leg was potted using polymethylmethacryalte for mounting in the testing fixture. Care was taken to avoid damage to the soft tissue structures of the foot and ankle joint complex. The plantar fascia was exposed by blunt dissection on the medial plantar aspect of the foot for placement of an elongation measuring device (Fig. 1).

The technique and instrumentation described previously by Kogler et al (28) and Alshami et al (36) were used in the present study to measure elongation of the plantar fascia. A differential variable reluctance transducer (DVRT®, Microstrain, Williston, VT) with a 9-mm linear stroke range and a resolution of 1.5 μm was used. The output voltage of the DVRT® was amplified using a DEMOD-DVRT signal processor (Microstrain) and recorded using the MB-SMT 4 motherboard with data acquisition software (Microstrain). Using the calibration equation provided by the manufacturer, the output voltage (in volts) was converted to displacement (in millimeters). With the foot in the neutral position (neither pronated nor supinated), the DVRT® was inserted in the plantar fascia with the help of a needle and barbed pins (Fig. 1). In contrast to the study by Kogler et al (28–30) in which the DVRT® was placed in the central band of the plantar fascia, in the present investigation, we placed the DVRT® just distal to the origin of the plantar fascia (i.e., the medial calcaneal tuberosity). We chose this setup because the most frequently reported site of pain and failure is the origin of the plantar fascia on the calcaneus (1,2). With the foot held in a neutral position, the DVRT® output voltage was recorded to calculate the length between the needle and barbed pin; this was denoted as the reference or the initial length (Lo). Next, the investigator pronated the foot maximally by applying a vertical and abductory force under the fourth and fifth metatarsal head. The foot was held in this position, and the change in the DVRT® voltage was recorded after allowing the reading to equilibrate for approximately 15 seconds. This voltage change was converted to a change in length (ΔL , elongation of the plantar fascia) to yield the final length between the 2 pins (L = $L_0 + \Delta L$). The percentage of strain was calculated as ($\Delta L/L_0 \times 100$). The foot was then unloaded



Fig. 1. Plantar fascia with differential variable reluctance transducer. Image of left footed specimen mounted on the materials testing system (not shown) with foot in neutral position and differential variable reluctance transducer mounted on plantar fascia, as described in "Materials and Methods" section. Output of differential variable reluctance transducer was recorded in this position to give initial or reference length, after which the foot was maximally pronated and the differential variable reluctance transducer output was recorded to calculate the elongation (strain) of the plantar fascia.

back to its neutral position, and the procedure was repeated 3 times (i.e., N=3 for each foot without intervention). Note, that the strain or elongation measured is a relative value (i.e., relative with respect to the foot in a neutral position, neither pronated nor supinated).

After these measurements, the appropriate size EOTTS device was placed into the sinus tarsi of the cadaveric foot to stabilize the talus on the tarsal mechanism while also ensuring that the normal range of pronation and supination was possible. Trial sizing was performed to determine which size would give the best correction. The 5-mm trial sizer (smallest) was inserted into both the canalis and the sinus portions of the sinus tarsi. The talotarsal joint was then placed through a full range of motion to determine the amount of correction achieved. The goal was to restore the normal range of hindfoot pronation (i.e., 3° to 5°). If excessive hindfoot motion was present with the 5-mm size, the next incremental trial sizer (available in 1-mm increments ≤ 10 mm) was used, and the new range of hindfoot motion was determined. This procedure was repeated until the desired trial sizer achieved the required amount of correction, after which the corresponding size EOTTS device was implanted. Next, elongation of the plantar fascia was measured after maximally pronating the foot, as described (again, N=3 for each foot with intervention). Throughout the experiment, the investigator was unaware of the output of the DVRT®.

Statistical Analysis

The data are reported as the mean, median, range, standard deviation (\pm 1 SD), and 95% confidence interval of the mean of the elongation (in millimeters) and strain (in percentages) for each experimental condition (i.e., without and with intervention) and for each of the 6 foot specimens. The hypothesis tested was that in cadaveric feet exhibiting flexible talotarsal joint instability, elongation (strain) of the plantar fascia would decrease after an EOTTS procedure (H_a : $\mu_{EOTTS\,Device} < \mu_{NO\,Treatment}$). Because of the small sample size and assuming a non-normally distributed data set, a one-tailed Wilcoxon signed rank test for 2 groups was computed to test for significance at the 95% confidence level. The null hypothesis of no difference was rejected for p values \leq .05.

Results

As previously reported, a consistent load was applied by the investigator under the fourth and fifth metatarsal head while maximally pronating the foot (37). For each of the 6 foot specimens, the relative elongation measured in the plantar fascia as the foot was moved from its neutral to its maximally pronated position, without and with intervention, is listed in the Table 1. The mean elongation of the plantar fascia was 0.83 ± 0.27 mm (strain 3.62%) and 0.56 ± 0.2 mm (strain 2.42%) without and with intervention, respectively (N = 18). The corresponding median values of plantar fascia elongation were 0.78 (range 0.41 to 1.4) mm and 0.51 (range 0.17 to 0.85) mm, without and with intervention, respectively. The 2 groups were significantly different statistically, with p < .001 (Fig. 2).

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