

Percutaneous Ultrasonic Fasciotomy: A Novel Approach to Treat Chronic Plantar Fasciitis

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Abstract

Purpose: Evaluate percutaneous ultrasonic fasciotomy as a safe and definitive treatment for chronic, refractory plantar fasciopathy.

Methods: Prospectively gathered and retrospectively analyzed the data from 100 consecutive procedures performed between August 2013 through May 2014 was assessed. Inclusion criteria included symptomatic plantar fasciitis for a minimum of 4 months' duration and failure of at least one conservative treatment measure. Patients were treated with the Tenex-Health TX1™ device with a standardized procedure. Time of TX1 activation was at the discretion of the operator. All patients completed a standardized postprocedure rehabilitation program. Foot and Ankle Disability Index (FADI) score was assessed preprocedure, 2 weeks, 6 weeks and 6 months' postprocedure.

Results: FADI scores indicated symptomatic improvement at each assessed time point ($P < 0.05$). At 6 months after the procedure 51 of 53 patients (96%) indicated they would recommend the procedure to a friend. There were no procedure related complications. Plantar thickness, BMI and age showed no statistical correlation with treatment outcomes. However, TX1 activation times did demonstrate a correlation with improved FADI scores.

Conclusion: Percutaneous ultrasonic fasciotomy is a safe and highly effective treatment for chronic refractory plantar fasciopathy. Statically improved FADI scores occurred at all measurement periods. Longer term controlled studies are required to validate the long-term durability.

Level of evidence: Level 2. Prospective, non-randomized.

Keywords: Percutaneous ultrasonic fasciotomy; Chronic refractory plantar fasciopathy; Chronic plantar fasciitis

Introduction

Chronic plantar fasciitis, or fasciopathy, is the most common debilitating foot complaint, affecting approximately 10% of the population and accounting for over one million office visits and nearly \$300,000,000 per year [19]. This condition most commonly affects women age 40 -60 years [16]. Risk factors include excessive running, limited ankle dorsiflexion, flatfoot deformity, obesity, and prolonged work-or activity-related weight bearing [16].

Plantar fasciitis is a condition characterized by degeneration of the plantar fascia and perifascial structures with isolated inferior heel pain, particularly with the first steps of the day and after prolonged sitting [9]. Diagnosis of chronic plantar fasciitis is predicated on clinical history of tenderness over the medial tubercle of the calcaneus (the plantar fascial insertion site) with weight bearing of at least 3 months' duration, first-step pain in the morning and pain relief and pain reproduced with manual palpation over the medial calcaneal tubercle [22]. Imaging techniques can be employed to aid in diagnosis of plantar fasciitis. Plantar calcaneal heel spur is visible on lateral foot x-ray in 38.3% of cases [22]. Ultrasound imaging has been demonstrated to be both sensitive and specific for diagnosis of plantar fasciitis (Figure. 1).



Figure 1. An ultrasound image of normal plantar fascia (left). Chronic fasciitis is associated with hypoechoic thickening of the attachment site at the medial tubercle of the calcaneus (right).

Ultrasound features of plantar fasciitis include plantar fascial thickness $>4\text{mm}$, hypoechoic appearance of the plantar fascia and loss of fascia edge sharpness [17]. MRI has also been shown to be an effective diagnostic tool in the evaluation of plantar fasciitis [2].

The plantar fascia connects the medial calcaneal tuberosity to the proximal aspect of the phalanges, plays a major role in supporting the medial longitudinal arch, and aids in dynamic shock absorption [7]. The term plantar fascia is actually a misnomer since this structure is not a fascial layer, but a tendinous aponeurosis that shares histological and mechanical traits with tendons and ligaments [3]. Currently the most commonly offered treatment for chronic plantar fasciitis is open surgical plantar fasciotomy which results in only moderate patient success rates, extended recovery times, and potential complications such as plantar fascial rupture, medial longitudinal arch destabilization and altered loading patterns [12]. Percutaneous ultrasonic fasciotomy is a minimally invasive ultrasound guided method of cutting and removing tendinopathic tissue. Percutaneous ultrasonic plantar fasciotomy has been previously described. However these procedures do not remove the diseased tissue and the available literature reports only small patient cohorts and limited duration of follow up.

The purpose of this study was to assess the safety, efficacy and durability of ultrasound guided percutaneous ultrasonic fasciotomy as a definitive treatment for chronic plantar fasciitis in a relatively large patient cohort.

Materials and Methods

This is a prospective non randomized study of 100 consecutive patients who were enrolled between August 2013 and May 2014. Evaluation and treatment was performed by one of two different interventional radiologists in a single outpatient surgery center. All patients provided verbal consent to allow their depersonalized clinical and imaging data to be used in this study. This study was approved by the internal review board of Catholic Health Institute.

Inclusion criteria included: duration of symptoms >4 months and failure of at least one conservative treatment including but not limited to, analgesics, activity modification, physical therapy and arch supports. Patient sex, age, Body Mass Index (BMI), TX1 device activation time and plantar fascia thickness were recorded along with individual clinical features (Table 1).

	Average Value (± 1 SD)
Female gender	72%
Age (y)	50.4 ± 12.8
Body Mass Index (BMI)	29.8 ± 5.5
Treatment Time (seconds)	103 ± 24
Plantar Fascia Thickness	6.1 ± 1.2

Table 1: Summary of patient, disease and treatment characteristics

The Foot and Ankle Disability Index (FADI) score (Figure.2) was collected preprocedure, 2 weeks, 6 weeks and 6 months postprocedure. This index recognizes 5 levels of pain from none (0) to unbearable (4) for 4 activity levels [10].



Figure 3: The TX1 ultrasonic treatment device: note the hollow probe that allows aspiration of the diseased tissue. The probe is cooled by a continuous flow of saline that is activated by the ultrasonic energy.

Local anesthetic (1% lidocaine) was administered from the plantar surface under ultrasound guidance along the anticipated access tract. A 3 to 5 mm skin incision was made along the plantar aspect of the foot approximately 1 cm distal to the medial calcaneal tubercle. The TX1 hand piece was directed into the pathologic portion of the plantar fascia under direct ultrasound guidance. (Terason t3200 L15-4 MHz (Terason, Burlington, ME) or a Phillips iU22 L12-5 MHz probe (Philips Ultrasound Inc, Reedsville, PA) (Figure. 4).

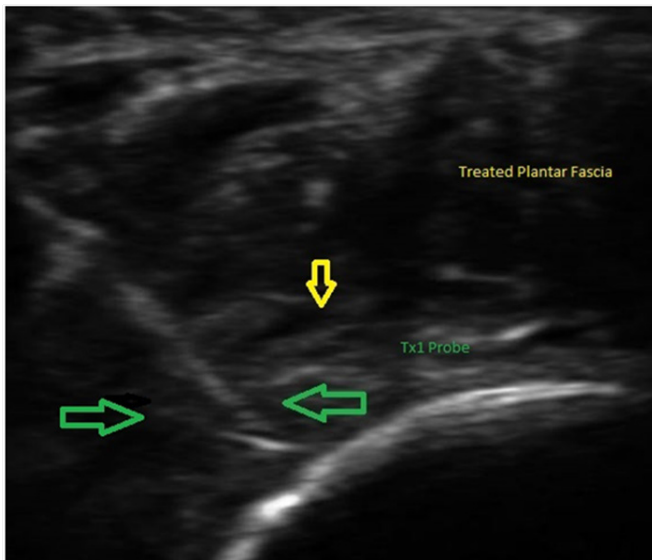


Figure 4: TX1 probe inserted into the lesion under ultrasonic visualization.

The duration of activation was at the discretion of the operator and ranged from 46 to 185 seconds. Technical success was defined as the ability to place and activate TX1 hand piece into pathologic portion of the plantar fascia. A standardized postprocedure rehabilitation program consisted of placing the treated foot in a pneumatic cam walker boot for 2 weeks' duration. A physical therapy program was initiated on post op day 3 consisting of education on stretching and exercise, evaluation for shoe inserts and gait evaluation.

Results

Technical success, identifying and entering the lesion, was achieved in 100% of patients. As noted Foot and Ankle Disability Index (FADI) scores were assessed preprocedure, 2 weeks, 6 weeks, and 6 months postprocedure. Patient follow up was 100% (100 patients) at 2 weeks, 94% (94 patients) at 6 weeks and 82% (82 patients) at 24 weeks post procedure. Average FADI scores were 59 preprocedure, 71 at 2 weeks, 83 at 6 weeks and 90 at 24 weeks post procedures ($P < 0.05$) (Figure. 5). At 6 months, 51 of 53 (98%) indicated they were pleased enough with the procedure to recommend it to a friend.

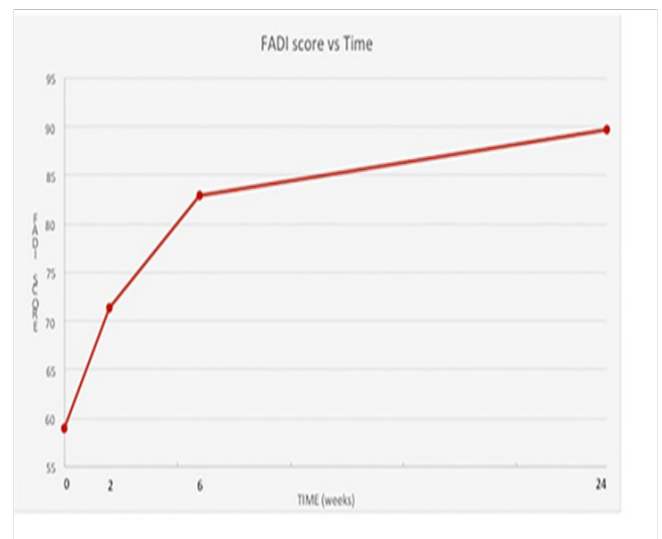


Figure 5: Average Foot and Ankle Disability Index (FADI) score across all patients immediately prior to procedure (0) and each subsequent follow-up time point (2,6, and 24 weeks) ($P < 0.05$).

TX1 hand piece activation times averaged 115 secs (range 46 to 185). There was a correlation with longer activation times and higher FADI scores at 24 weeks ($P < 0.05$) (Figure. 6). Plantar fascia thickness, BMI and age did not have a statistical correlation with outcomes.

Complications

Our study protocol stratified potential complications as minor or major based on Society of Interventional Radiologists consensus criteria. (www.sirweb.org; practice guidelines) However, there was only one minor complication of a patient who experienced moderate post procedure related pain which resolved with a 3 day course of tramadol. No additional procedure related complications were encountered. Specifically, there were no post procedure infections, plantar fascia rupture, or nerve injury.

Discussion

Plantar fasciitis when diagnosed in its acute stage (<3 months duration) has a favorable prognosis, with 80% of patients achieving symptom resolution within 1 year if timely institution of traditional nonsurgical treatments including activity modification, gastrocnemius and plantar fascia-specific stretching, anti-inflammatory medications, and/or shoe inserts [4,11,21]. However, plantar fasciitis symptoms fail to resolve with conservative measures in 10 to 20% of cases. When conservative measures fail, plantar fasciitis becomes a debilitating lifestyle limiting condition. The precise etiology of chronic plantar fasciitis is unclear, but the chronic state is histologically defined by collagen degeneration rather than an inflammatory process [7]. Conventional nonsurgical treatments in chronic plantar fasciitis may be misdirected, while therapies which augment local hemodynamics, thereby initiating a regenerative tissue healing cascade, have the greatest potential to resolve long-standing symptoms [12]. Current surgical treatment options have a variable success rate, are invasive and require prolonged recovery time which is not conducive to maintain an active patient lifestyle. Ultrasonic debridement of tendinopathic tissue has been demonstrated at the histologic level to remove tendinopathic debris while stimulating a normalized physiologic tendon healing response (collagen type I, II I, and X profile) [6].

The cohort described in this study demonstrates percutaneous ultrasonic fasciotomy with the Tenex TX1 hand-piece to significantly and safely reduce symptoms of chronic plantar fasciitis. Symptomatic relief was found to be durable to at least 24 weeks. We are in the process of recalling this cohort of patients to determine if the early success is maintained long term. These results are consistent with those shown in a small pilot study for the treatment of plantar fasciitis and plantar fibromas [1,14]. Patel et al reported on their experience in 12 patients with recalcitrant plantar fasciitis who underwent percutaneous ultrasonic plantar fasciotomy. They noted 11/12 of the treated patients were symptom free by 3 months [15]. Of interest, 4 of the 12 had failed prior surgical intervention. Additional studies currently available in the literature have reported on the use of percutaneous ultrasonic tenotomy/fasciotomy in patients with refractory tendonosis / fasciosis in other areas of the body; primarily lateral epicondylitis, medial epicondylitis, achilles tendon, and patellar tendon. The mean satisfactory outcome in these patients is 88% [5,8,20].

The documented outcomes reveal an excellent safety profile with no reportable minor or major complications. This is consistent with several reports utilizing the TX1 device for treatment of elbow tendinopathy [1,13,18].

The high procedural success rate appears to be independent of plantar fascial thickness, BMI or patients' age. Currently the optimal activation time for plantar fascial treatment cannot be defined based on the existing clinical evidence. However, this study suggests that longer treatment times may result in better outcomes. This experience suggests the most effective treatment time is between 2 and 3 minutes. Further study is warranted in regards to length of activation time. Importantly, additional treatment time does not appear to subject the patient to additional risk of complications.

This study has several limitations. First, is the inherent bias of a single arm non-randomized design. Second, a single institution experience limits the generalizability of these results to a more heterogeneous patient and operator population. Third, outcomes based on a patient survey scoring system while providing numerical data is truly subjective and limited by the patient's interpretation their own symptoms at the time of survey. Yet such is the current direction of the requirements for clinical treatment studies.

Conclusion

In conclusion, the high prevalence and the considerable economic burden of refractory plantar fasciitis make this treatment attractive in several ways. The described experience demonstrates percutaneous ultrasonic fasciotomy with the TenexHealth TX1™ device to be safe and highly effective in the treatment of chronic plantar fasciopathy. The results are durable to a minimum of 6 months. The excellent safety profile, fast recovery time, and limited resource requirement make percutaneous ultrasonic fasciotomy an attractive and effective therapeutic option for the treatment of chronic plantar fasciitis. Long-term outcome studies are under way and will be helpful to clarify late term durability and incidence of recurrence if any. Further investigation as to the optimal procedural end points, activation times and post procedure treatment regimen would be beneficial.

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