Intense Therapeutic Ultrasound for Treatment of Chronic Plantar Fasciitis: A Pivotal Study Exploring Efficacy, Safety and Patient Tolerance

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Statement of Purpose

The purpose of this study is to assess the effectiveness of Intense Therapeutic Ultrasound (ITU) in the treatment of Chronic Plantar Fasciitis/Fasciosis (CPF) by assessing pain, function, and change in perifascial lesions treated with ITU in addition to standard of care.

Methodology & Hypothesis

This study was conducted at University Foot and Ankle Institute, Santa Monica, California, USA. Western Institutional Review Board approved the study #20160753. Verbal and written informed consent was obtained from all subjects.

Selection of Subjects

Patient recruitment was restricted to adults of either gender diagnosed with chronic pain (>90 days) where standard of care treatments had failed to reduce pain. This is a single-blinded, pivotal study, where the Principal Investigator and study personnel were blinded to the patient's identity and timing of where the subject was in the course of the study.

Inclusion Criteria

Male and female adults (18 to 85 years) with unilateral plantar heel pain and point tenderness near the medial calcaneal insertion of the plantar fascia for at least three months without improvement were considered for inclusion into the study. Subjects were willing and able to follow post treatment regimen including immobilization boot for 2 - 4 weeks after each treatment, along with massage therapy.

Exclusion Criteria

Subjects with diabetes or other circulatory issues that might impede healing, bilateral plantar heel pain, current systemic or local infection (within the last 30 days), previous foot or ankle surgeries, other previous or currently diagnosed foot/ankle pathologies (inflammatory arthritis, gout, neurologic disorders, connective tissue disorders, bone spurs and fragments and malignancy), unwilling or unable to complete post regimen follow up, and pregnancy were excluded. Patients who have received other previous non-conservative treatment in the symptomatic limb were excluded, as were subjects with thick calluses on their heel, making ultrasound imaging and treatment of the plantar fascia difficult.

Interventions

Standard of care treatment included appropriate footwear selection, orthotic use, and physical therapy stretching instruction along with massage 5 minutes daily. These continued while in the study and after treatment with intense therapeutic ultrasound. Additionally, all subjects used an immobilization boot along with an orthotic insert for 2 to 4 weeks after each treatment. Subjects massaged the region twice a day for 2 ½ minutes per each session for a total of 5 minutes/day.

During Visit 2 (4 weeks after the first treatment), subjects received a second treatment. The use of the boot and orthotic resumed as defined after the first treatment. ITU treatments were performed using a Actisound™ (Guided Therapy Systems, Mesa, AZ,). Trained study personnel conducted the treatments. The treatment session lasted 15 – 20 minutes. The subjects were reclined supine on an exam table with their feet hanging over the end of the table. An average energy up to 5 joules / thermal zone, administered to the plantar fascia in a matrix pattern (Figure 1) with up to 1000 thermal zones distributed along the length and width of the proximal plantar fascia (~5cm^2). Each thermal zone was less than 1 mm^3 in volume, centered at 10 - 15 mm depth, and formed a matrix of lesions along the plantar fascia.

Hypothesis

It is hypothesized that patients receiving ITU in addition to standard of care will have a rapid resolution of their pain, return to activities, and a decrease in perifascial lesions.

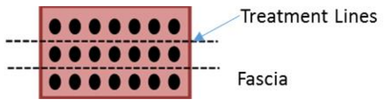


Figure 1: Treatment pattern transverse across the Plantar Fascia

Procedures

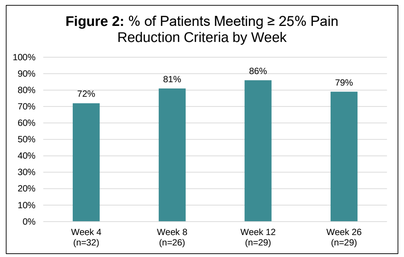
Treatment Regimen

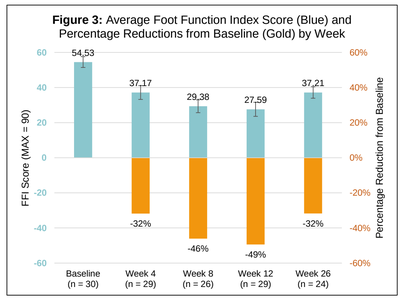
Treatments were administered with an Actisound™ (Guided Therapy Systems) intense therapeutic ultrasound system. The device delivered a matrix of micro coagulation zones along the PF from the insertion, just distal to the calcaneus, to mid-foot region utilizing a 3.3MHz probe capable of up to75 Watts at ≤ 100msec duration, and 5Hz pulse repetition frequency. The energy applied per zone was up to 5 Joules as selected by the technician.

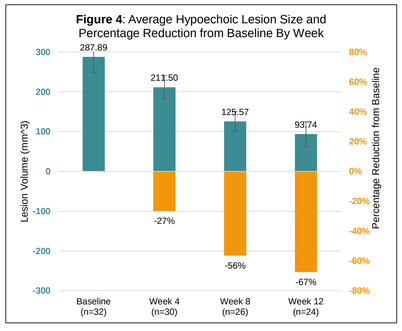
Statistical Analysis

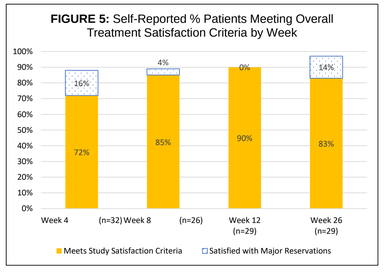
Data was assessed for variance homogeneity and normality. Foot Function Index Pain Subscale (FFI-P) scores and Foot and Ankle Ability Measure (FAAM) scores before and after interventions were compared using a Student t-test. Perifascial lesion volume was measured before and at each post treatment clinical visit using diagnostic ultrasound imaging. Paired student T-tests were utilized to determine statistically significant differences between baseline and subsequent follow-up measurements for self-reported and lesion size measurements. The level of significance (α) was set to 0.05 prior to data analysis.

Results









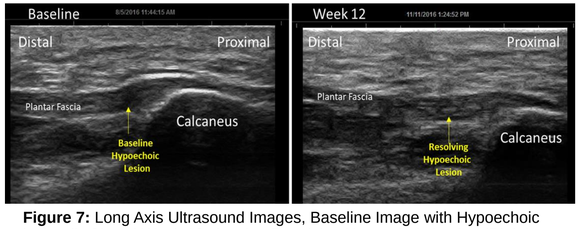
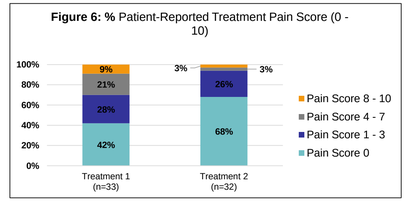


Figure 7: Long Axis Ultrasound Images, Baseline Image with Hypoechoic lesion (Left) and Week 12 showing Resolving Hypoechoic Lesion (Right)



Literature Review

Various types of ultrasound have been used to treat soft tissue injuries since the 1930s (1). The majority of such conventional ultrasound treatments (Diathermy) involves diffuse, low energy, long duration pulses resulting in the warming of tissues under the ultrasound beam. Intense therapeutic ultrasound (ITU) is a recently developed ultrasound based therapy in which sound waves are concentrated to produce selective thermal coagulative change over a small area while leaving the remaining regions unaffected (2,3). ITU has been used clinically for treating the facial skin for the past decade and it has received CE Mark and United States FDA approvals for non-surgical brow and submental tissue lifting. Over 3,000,000 patients worldwide have been treated using this technology. Clinical studies have shown that 85% of subjects receiving this treatment on facial skin tissue showed an improvement in facial lifting with no significant pain, erythema, inflammation or scarring (4). Histologically, it has been shown that ITU induces the production of dermal collagen with thickening of the dermis and straightening of the elastic fibers in the reticular dermis (2, 5-7). Laboratory research has shown that ITU can improve healing of damaged Achilles tendon in a rabbit model. Preliminary results showed an increase in markers for wound healing and a decrease in markers for scar tissue formation in injured rabbit tendon treated with ITU compared to injured, untreated rabbit tendons (8,9).

Analysis & Discussion

In this pivotal clinical trial, the study objectives were met. After failing conservative therapy, ITU was administered and the reduction in pain scores of 25% or more occurred in 72%, 81%, 86% and 79% at the time points of 4,8,12 and 26 weeks following treatment (Figure 2). Similarly, mean pain scores at each visit were significantly different from baseline ($p<0.001$) at -39%, -49%, -57%, and -44% . As hypothesized, Foot Function Index scores declined favorably from baseline ($p<0.001$) at all time points evaluated (Figure 3). Most patients had hypoechoic lesions (>90%) and they decreased in size significantly ($p<0.05$) at weeks 8 and 12, with -56%, and -67% on average (Figure 4). The very encouraging sign was the subjects meeting satisfaction criteria of 72%, 85% 90% and 83% at subsequent time points (Figure 5). No adverse events occurred. This procedure was well tolerated with early attrition of one patient in the study (Figure 6) .

Our study found a reduction in size of hypoechoic lesions on diagnostic ultrasound and a correlation of size deduction to pain reduction to be significant (Figure 7). The clinical meaning of this finding is uncertain, but may propose a relationship of hypoechoic lesions in heel pain. Diagnostic ultrasound in plantar fasciitis was evaluated systematic review that identified 34 relevant quality studies. The review concludes that diagnostic ultrasound is a reliable technique for assessing plantar fascia thickness, monitoring the effect of therapeutic interventions, and for guiding therapeutic interventions in patients with plantar fasciitis (10).

Our study has several limitations. The comparator was prior conservative therapy that was continued, not a sham or active alternative therapy comparator control group. The trial is small with 29 patients successfully completing the two treatments and follow up. Small trials like these are necessary to develop larger studies and fine-tune research questions. In this pivotal clinical trial, Intense Therapeutic Ultrasound for Chronic Plantar Fasciitis musculoskeletal tissue pain reduction was effective, safe and well tolerated. In addition to having less pain and clinical improvement, the subjects were highly satisfied with the therapy. Based on this preliminary information, larger studies to clarify the possible role of intense therapeutic ultrasound in the treatment of chronic plantar fasciitis are warranted.

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