The Journal of Foot & Ankle Surgery 58 (2019) 519–527

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

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

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ARTICLE INFO

*Level of Clinical Evidence:* 3

*Keywords:*
heel pain
hypoechoic lesions
intense therapeutic ultrasound
plantar fasciitis
plantar fasciosis
therapeutic ultrasound
ultrasound

ABSTRACT

Intense therapeutic ultrasound for chronic plantar fasciitis musculoskeletal tissue pain reduction was evaluated in a pivotal clinical trial examining effectiveness, safety, and patient tolerance. In this single-blinded study, 33 patients received 2 treatments that were 4 weeks apart on plantar fascia tissue along with conservative standard of care. Patients were followed for up to 6 months after the first treatment, receiving a physical examination and diagnostic ultrasound at each follow-up visit and completing patient-/subject-reported outcome measure and Foot Function Index surveys. The goal was to reduce overall pain by ≥25% on average and >25% individually. Hypoechoic area changes on diagnostic ultrasound and adverse events were measured. The percentage meeting pain reduction criteria at weeks 4, 8, 12, and 26 were 72%, 81%, 86%, and 79%, respectively. Mean pain scores at each visit were significantly different from baseline ($p < .001$) at −39%, −49%, −51%, and −44%. Hypoechoic lesions were found in all patients and decreased in size significantly ($p < .05$) at weeks 8 and 12 (−56% and −67%). Foot Function Index scores declined favorably from baseline ($p < .001$) at all time points (−32%, −46%, −49%, and −32%). The percentages of patients meeting satisfaction criteria were 72%, 85%, 90%, and 83%. The mean pain score during treatment 1 was 3.4, and during treatment 2, 2.9. Attrition of only 1 patient owing to pain occurred, after treatment 1. No adverse events occurred. Intense therapeutic ultrasound for chronic plantar fasciitis is shown to be effective, safe, and well tolerated in this pivotal clinical trial.



Plantar fasciitis is one of the most common clinical conditions encountered in the practice of medicine and represents 11% to 15% of all visits (1). Plantar fasciitis is responsible for ~1 million patient visits per year in the United States (2). Chronic plantar fasciitis (CPF) results from a degenerative process of the plantar fascia and its surrounding perifascial structures. The condition may be more appropriately called *plantar fasciosis* (3,4). Although the exact etiology of CPF is unclear, some evidence indicates that it is the combination of age and overuse that leads to degenerative changes within the fascia, resulting in symptoms (4).

The diagnosis of CPF is made clinically based on history and physical examination (5). Confirmation with diagnostic imaging may be helpful when the symptoms are atypical or refractory to treatment. Magnetic resonance imaging (MRI) is a useful diagnostic tool to evaluate for plantar fascia thickening and edema in and around the fascia, findings often associated with the diagnosis of CPF (6). Diagnostic ultrasound can also be used to quantify the thickness of the plantar fascia. Several studies have shown that patients with CPF have an associated increased thickness of the fascia compared with asymptomatic individuals (7–11). Mean thickness in these studies for subjects with CPF range from 4.8 to 6.5 mm, as opposed to 2.3 to 4.0 mm for subjects without the disease (7–12). In addition to the evidence of inflammation (8), the presence of a hypoechoic lesion in the plantar fascia was noted in 68% to 84% of

**Financial Disclosure:** Study sponsor with unrestricted research grant that facilitated the conduct of the study: Guided Therapy Systems, Inc.; medical device: Actisound System–Intense Therapeutic Ultrasound by Guided Therapy Systems, Inc., Mesa, AZ.

**Conflict of Interest:** E.H., L.B., G.B., and B.B report research funding from Guided Therapy Systems, Inc. M.S. reports a leadership position with and stock ownership in Guided Therapy Systems, Inc. R.A. and K.C. have nothing to report.

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https://doi.org/10.1053/j.jfas.2018.10.002

patients with CPF (7,9). Diagnostic ultrasound has been used to quantify the effectiveness of various treatments for patients with CPF, including extracorporeal shock wave therapy, nonsteroidal antiinflammatory drugs, and Botox injections (10,12). Another use of diagnostic ultrasound may be to examine the plantar fascia to predict response to different foot supports. Patients with CPF who have bioconvexity of the plantar fascia may be less responsive to treatment focused on mechanical support of the plantar fascia (13).

Conservative therapy for plantar fasciitis usually consists of rigid supportive shoes, the use of functional orthotics, and physical therapy with stretching and massage, which have been shown to effectively treat symptoms in 90% of patients in <12 months (5). However, ~10% of patients fail conservative management and continue to have symptoms beyond 12 months (4,5,14). Other commonly used therapies include glucocorticoid injection, shock wave therapy, human tissue injection therapies with platelet-rich plasma or cryopreserved human amniotic membrane, minimally invasive surgical microdebridement procedures, or formal fasciotomy (15,16). Intense therapeutic ultrasound (ITU) may be a noninvasive treatment that can be used as an adjunct to speed healing in patients with CPF and as an alternative to other advanced therapies in those with plantar fasciitis.

ITU is an established ultrasound-based therapy in which sound waves are concentrated and focused into a well-defined specific area of musculoskeletal tissue. The therapeutic ultrasound energy produces selective thermal coagulative changes over a small controlled area. The surrounding tissue is left unaffected, without impacting the integrity of the dermis (17–20). The coagulative changes induced are known to begin the body's tissue response cascade and promote collagen generation in the targeted anatomy, resulting in pain reduction (21,22). For the past decade, ITU has been used in the United States and around the world for facial aesthetic purposes to induce subcutaneous collagen formation to improve submental and brow appearance without surgery (17,20). Preliminary evidence from other studies suggests there may be a role for ITU in plantar fasciitis (23). At 12 weeks, for the treatment group compared with baseline, pain was reduced by 30%, and hypoechoic lesion size was reduced by 80%. In the control/sham treatment group at 12 weeks, pain and lesion size were not significantly different from baseline data (23).

The primary objective of this study was to evaluate the efficacy of combining ITU with standard conservative care, including posttreatment therapy, exercises, and boot immobilization for patients who had already failed standard conservative care alone and, in most cases, failed additional, more aggressive treatment options. A secondary objective was to evaluate the tolerability and safety of ITU in the treatment of CPF.

It was hypothesized that patients receiving ITU in addition to the standard of care would have a more rapid resolution of pain, faster return to activities, and a decrease in intra- and perifascial lesions. This investigation was designed as a pivotal study to potentially supply information that would lead to device clearance to market by the U.S. Food and Drug Administration (FDA).

## Patients, Materials, and Methods

This study was conducted at University Foot and Ankle Institute, Santa Monica, CA, a private group practice of podiatric medicine and surgery. The Western Institutional Review Board approved the study (IRB 20160753), and verbal and written informed consent was obtained from all subjects.

### *Selection of Subjects*

Patient recruitment was limited to adults diagnosed with chronic heel pain (>90 days) for which standard-of-care treatments had failed to reduce pain. This was a single-blinded, pivotal study, assessing the safety and efficacy of a new device for treatment of refractory plantar fasciitis.

### *Inclusion Criteria*

Male and female adults (18 to 85 years old) with unilateral plantar heel pain and point tenderness near the medial calcaneal insertion of the plantar fascia for ≥3 months without improvement were considered for inclusion into the study. Subjects were willing and able to follow the posttreatment regimen, including an immobilization boot, for 2 to 4 weeks after each treatment, along with massage therapy.

### *Exclusion Criteria*

Subjects were excluded if they had diabetes or other circulatory issues that might impede healing, bilateral plantar heel pain, current systemic or local infection (within the past 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, bone fragments, or malignancy); were unwilling or unable to complete the post regimen follow-up; were pregnant; or had thick calluses on the heel (making ultrasound imaging and treatment of the plantar fascia difficult). Patients who had received other previous nonconservative treatment (extracorporeal shock wave therapy, biologic injection therapy, surgery) in the symptomatic limb were also excluded.

### *Interventions*

Patients presenting with CPF were treated, before the study, with standard-of-care modalities that included appropriate footwear selection, orthotic use, and physical therapy stretching instruction, along with massage for 5 minutes daily. These standard-of-care measures continued while in the study and after treatment with ITU. Additionally, once the study began, all subjects used an immobilization boot for 2 to 4 weeks after each treatment. Although refractory to therapeutic use in the past, previously prescribed orthotic inserts were allowed to be used within the boot. The decision to continue or discontinue the boot was made during the follow-up telephone call 2 weeks after each treatment. Subjects massaged the region twice a day for 2.5 minutes per session for a total of 5 minutes per day.

Treatments were administered by specially trained podiatrists and ultrasound technologists. The treatment session lasted 15 to 20 minutes. The subjects reclined supine on an examination table with feet hanging over the end of the table. An average energy ≤5 joules/thermal zone was administered to the plantar fascia in a matrix pattern with ≤1000 thermal zones distributed along the length and width of the proximal plantar fascia (~5 $cm^2$) (Fig. 2). Each thermal zone was <1 $mm^3$ in volume, centered at 10- to 15-mm depth, and formed a matrix of lesions along the plantar fascia. Patients received an initial treatment at visit 1; 4 weeks later, at visit 2, subjects received a second treatment. The use of the boot and orthotic resumed as defined after the first treatment. ITU treatments were performed using an Actisound (Guided Therapy Systems, Mesa, AZ).

Diagnostic ultrasound imaging was performed with an FDA 510(k)-cleared ultrasound scanner (Spark System, Ardent Sound, Inc., Mesa, AZ) using a coupling gel (Polysonic; Parker Laboratories, Inc., Fairfield, NJ). Probes of 10 and 12 MHz were used with a high-resolution imaging system (Fig. 2). Diagnostic ultrasound imaging was performed by podiatrists and ultrasound technologists. All were blinded to the patient clinical and treatment status.

### *Details of ITU Treatment*

Treatments were administered with an Actisound ITU system. The device delivered a matrix of microcoagulation zones along the plantar fascia from the insertion (Fig. 3), just distal to the calcaneus, to the mid-foot region, using a 3.3-MHz probe capable of ≤75 W at 100-ms duration and 5-Hz pulse repetition frequency. The energy applied per zone was ≤5 joules as selected by the technician. Prior research with the device system included simulation, verified intensity, and high focal pressure (1200 to 1500 W/$cm^2$, 17.3 MPa at a focal distance of 13 to 15 mm) (23).

### *Outcome Measures*

Subjects completed subject-reported outcome measures (SROMs) and had a focused physical examination and diagnostic ultrasound at 0, 4, 8, and 12 weeks. At 26 weeks, the clinical coordinator, using the same SROM questionnaire, administered a telephone survey. Adverse events, if any, and treatment tolerability were recorded at each visit and 2 to 3 days after each treatment.

### *Subject-Reported Outcomes and Structured Physical Examination*

Subjects completed validated SROM questionnaires assessing pain, function, and level of activity before initiating treatment and at 4, 8, 12, and 26 weeks (26-week surveys were completed by a telephone interview) after starting treatment on scales of overall improvement, pain, and percentage improvement in activities of daily living (24,25). Subjects were also contacted 2 to 3 days after each treatment to assess treatment tolerability and document and address adverse effects (if any), as well as 2 weeks after treatment to assess progress and determine whether the boot could be discontinued. SROM

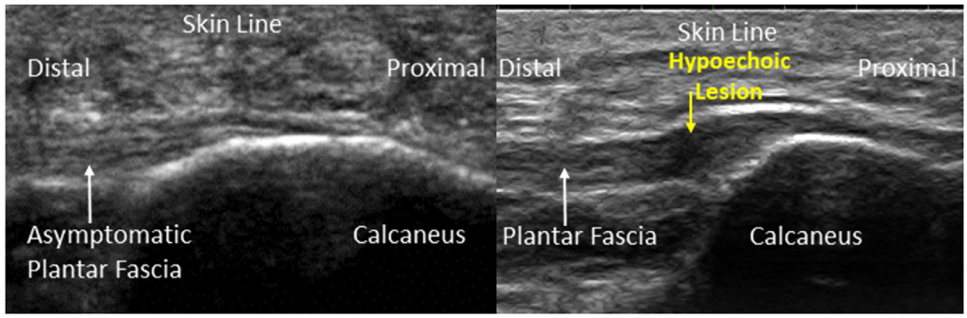


**Fig. 1.** Representative long-axis ultrasound images of the proximal plantar fascia. Normal appearance of asymptomatic plantar fascia (left) and diagnosed chronic plantar fasciitis with hypoechoic lesion, indicating a lack of fascia integrity at the point of pain (right).

questionnaires assessing each patient's progress were completed during each follow-up time point.

Pain was assessed using the universal visual analog scale (VAS), the Foot Function Index Pain (FFI-P) subscale, and the SROMs. These assessments have been used for pain measurement in previous studies of plantar fascia treatments (25–28). On commencement of the study, patients were provided with study documentation that included a VAS so that data could be collected by telephone. The 10-point VAS was used for assessment of tolerability and safety. Patient self-reported answers to questions from the FFI-P subscale questionnaire have been standardized in several plantar fasciitis–focused publications (24,26,29). Scores range from 0 to 90, with 0 indicating no pain and 90 indicating the worst pain imaginable in a variety of daily activities involving use of the plantar fascia. Self-reported scores were taken at baseline and each follow-up time point. The average score for each time point was calculated, and follow-up averages were compared with baseline to calculate the percentage of reduction in score.

The Foot and Ankle Ability Measure (FAAM) has been shown to be a reliable, responsive, and valid measure of physical function for individuals with a broad range of musculoskeletal disorders of the lower leg, foot, and ankle (30). Level of activity was assessed using the activity subscale of the FAAM. This subscale scores quantitatively the level of difficulty that subjects face when they perform basic activities of daily living. It has been shown to be an accurate and reliable predictor of the activity level while performing day-to-day activities (30). Overall patient satisfaction was also tracked using a patient-reported 4-point scale (26,29).

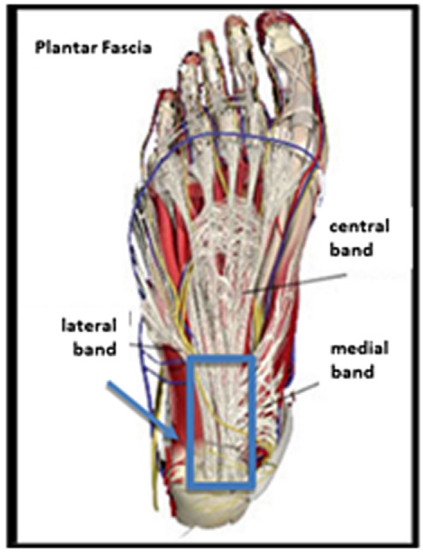


**Fig. 2.** Treatment zone (blue box).

*Assessment of Intra- and Perifascial Hypoechoic Lesions*

Hypoechoic lesions were imaged using diagnostic ultrasound (Figs. 1 and 3). Volumes were calculated at the baseline visit and each follow-up visit by measuring the inferior-to-superior and posterior-to-anterior radii in the long axis and the medial-to-lateral radius of the transverse axis and applying the following formula for the volume of an ellipse: volume = $(4/3)\pi * r1 * r2 * r3$, with $r1$, $r2$, and $r3$ representing the 3 radii above. Changes to lesion volumes were recorded at each follow-up time point (4, 8, and 12 weeks) and compared with baseline by dividing the volume of the lesion at that time point with the volume of the same lesion at pretreatment baseline.

*Hypoechoic Lesion Size and Pain/Function Correlation*

To determine the strength of a linear relationship between pain/function score reduction and lesion size reduction, linear regression analysis was performed. Patient data related to pain/function score reduction at each follow-up time point compared with baseline were matched with corresponding data related to lesion size reduction. The average pain reduction percentage for each follow-up time point was paired with the average lesion size reduction percentage for the same follow-up time point to generate a data point for linear regression and the Pearson-correlation coefficient ($r$) calculation. The $r$ values between 0.6 and 0.8 were considered strong, and those >0.8 were considered very strong.

*Assessment of Safety and Tolerability*

Subject self-assessments of treatment tolerability were recorded during and immediately after each treatment, again 2 to 3 days later (via telephone survey), and 2 weeks after treatment (via telephone survey) using a 10-point VAS where 0 = no pain, 1 = slight pain, and 10 = the patient's worst imaginable pain. Subjects were asked to report their current level of pain and the maximum level of pain experienced over the prior few days. The VAS is the standard for assessing pain for both clinical and research purposes (27).

The study assistants completed telephone surveys, and any adverse effects were noted and addressed during these telephone calls. Recording of adverse events also took place at all clinic visits and follow-up telephone calls. Adverse events and serious adverse events were monitored throughout the study.

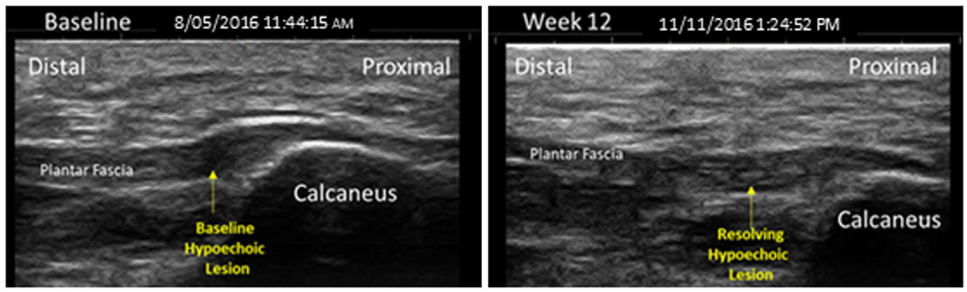


**Fig. 3.** Long-axis ultrasound images of the proximal plantar fascia. Baseline image with hypoechoic lesion (left) and week 12 showing resolving hypoechoic lesion (right).

*Statistical Analysis*

Data were assessed for variance homogeneity and normality. FFI-P scores and FAAM scores before and after interventions were compared using Student's *t* test. Intra- and perifascial lesion volume was measured before and at each posttreatment clinical visit using diagnostic ultrasound imaging. Paired Student's *t* tests were used to determine statistically significant differences between baseline and subsequent follow-up measurements for self-reported and lesion size measurements. All error bars displayed in graphs are standard error. The level of significance ($\alpha$) was set to 0.05 before data analysis.

## Results

*Patients*

This study was conducted on 33 patients (20 female and 13 male) with chronic symptoms lasting for an average of 19 (range 4 to 48) months. The age range was from 31 to 73 years, with a median age of 56 years. One patient withdrew after treatment 1 because she requested analgesia for treatment 2, and analgesia for pain relief was not part of the investigational plan. Three other patients did not respond to telephone follow-up or return for repeat appointments, eliminating them from the study per the exclusion criteria. Table 1 depicts the patient population.

**Table 1**
Patient demographics

| | |
|---|---|
| Mean age, y (range) | 56 (31–73) |
| Mean length of reported symptoms, mo (range) | 19 (4–48) |
| M/F sex, n (%) | 13 (39.4)/20 (60.6) |

*Pain Reduction*

Patients self-reported pain using the VAS at baseline and at each follow-up time point. Table 2 depicts the number of patients at each baseline pain score (1 to 10) and the number and percentage of patients who met the 25% pain reduction goal at each follow-up time point (week 4, 72%; week 8, 81%; week 12, 86%; and week 26, 79%). The percentage of patients meeting pain reduction criteria ranged from 72% to 86% (Fig. 4). The average pain score for each follow-up assessment was significantly different from baseline for all follow-up assessments ($p < .001$) and demonstrated a 49% (±17) and 51% (±17) reduction at weeks 8 and 12, respectively, as seen in Fig. 5.

*Plantar Fascia Hypoechoic Lesion Size*

Perifascial or intrafascial hypoechoic lesions were noted on all patients. After treatment, the size of the hypoechoic lesions significantly decreased. The size of the hypoechoic lesions was measured over time and progressively decreased in size to week 12, the last diagnostic ultrasound of the study (Fig. 6). The percentage decrease in lesion size from baseline was statistically significant at weeks 8 and 12 ($p < .005$), reducing by 56% (±20) and 67% (±33), respectively. When a correlation of average reduction in pain score (using the VAS) with average lesion size reduction was analyzed for follow-up time points 4, 8, and 12, a strong

**Table 2**
Patient-reported pain scores by visit and percentage meeting pain reduction criteria

| | Baseline Pain Scores | Baseline n Value | Total Responses at Week 4 | No. Meeting Pain Reduction Criteria at Week 4 | Total Responses at Week 8 | No. Meeting Pain Reduction Criteria at Week 8 | Total Responses at Week 12 | No. Meeting Pain Reduction Criteria at Week 12 | Total Responses at Week 26 | No. Meeting Pain Reduction Criteria at Week 26 |
|---|---|---|---|---|---|---|---|---|---|---|
| No. and Percentage of Patients Reporting at Least 25% Pain Reduction | 10 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 9 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 |
| | 8 | 9 | 9 | 6 | 7 | 5 | 8 | 6 | 8 | 5 |
| | 7 | 3 | 2 | 1 | 2 | 2 | 3 | 2 | 3 | 3 |
| | 6 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 5 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 4 | 4 | 4 | 3 | 3 | 1 | 4 | 3 | 4 | 3 |
| | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 2 |
| | 2 | 6 | 6 | 4 | 3 | 3 | 3 | 3 | 3 | 2 |
| | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Total | 33 | 32 | 23 | 26 | 21 | 29 | 25 | 29 | 23 |
| | Responses Meeting Pain Reduction Criteria | | | 72% | | 81% | | 86% | | 79% |

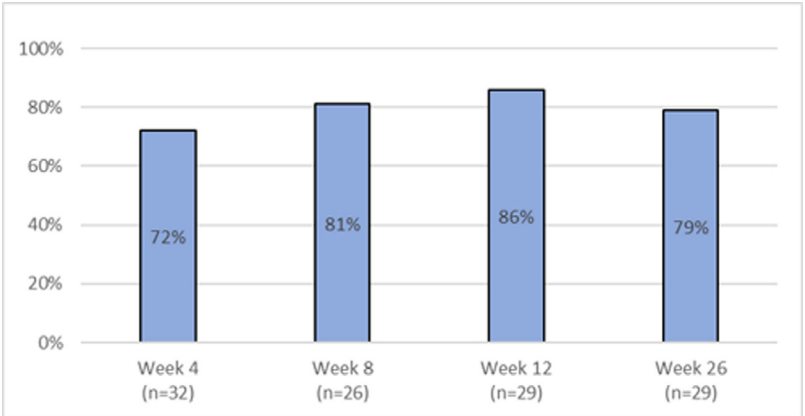


**Fig. 4.** Percentage of patients meeting 25% pain reduction criteria.

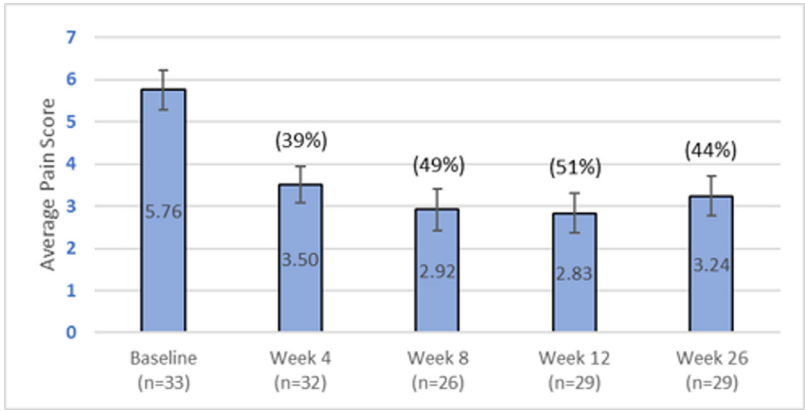


**Fig. 5.** Average visual analog scale pain score by visit (standard error noted). Average pain score reduction compared with baseline: week 4, 39%; week 8, −49%; week 12, −51%; week 26, −44%.

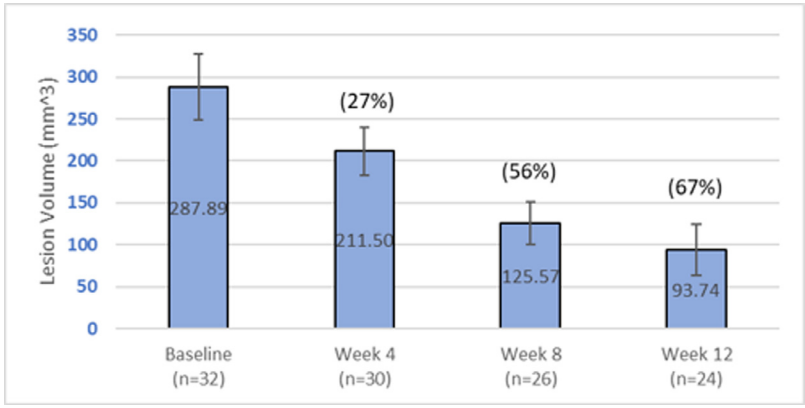


**Fig. 6.** Average lesion size by visit (standard error noted). Average lesion size reduction compared with baseline: week 4, −27%; week 8, −56%; week 12, −67%.

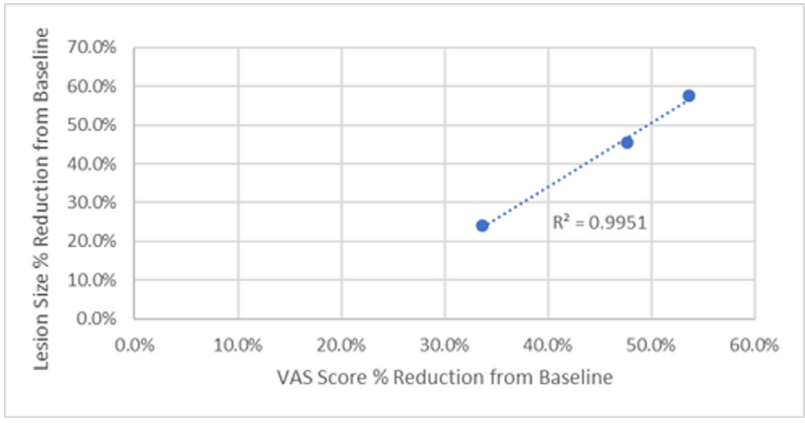


**Fig. 7.** Correlations between lesion size and visual analog scale pain score.

correlation was identified (Fig. 7). For weeks 8 and 12, patients had a strong positive correlation between these 2 measures on an individual basis ($r = 0.84$ and 0.64, respectively).

*Additional Parameters*

A decline in the Foot Function Index (FFI) score from baseline showed favorable clinical improvement, and this was seen for each follow-up visit, as depicted in Fig. 8. A highly significant difference ($p < .001$) for all follow-up time points was found compared with baseline. An increase in FAAM (Fig. 9) scores and FAAM Daily Activity scores (Fig. 10) beginning at the first follow-up visit continued throughout the 6-month follow-up period. SROMs of how patients felt and how much pain they had at each time point in the study are depicted in Table 3. At every time point, most patients felt better and experienced at least a 25% improvement in pain and daily activities. The proportion of

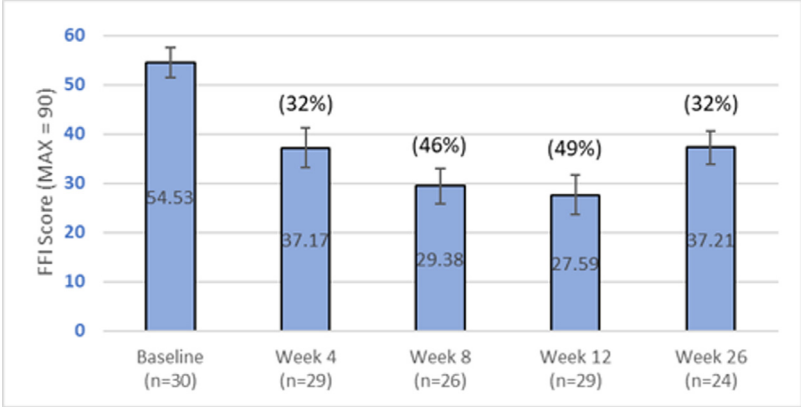


**Fig. 8.** Average Foot Function Index score by visit (standard error noted). Average Foot Function Index score compared with baseline: week 4, −32%; week 8, −46%; week 12, −49%; week 26, −32%.

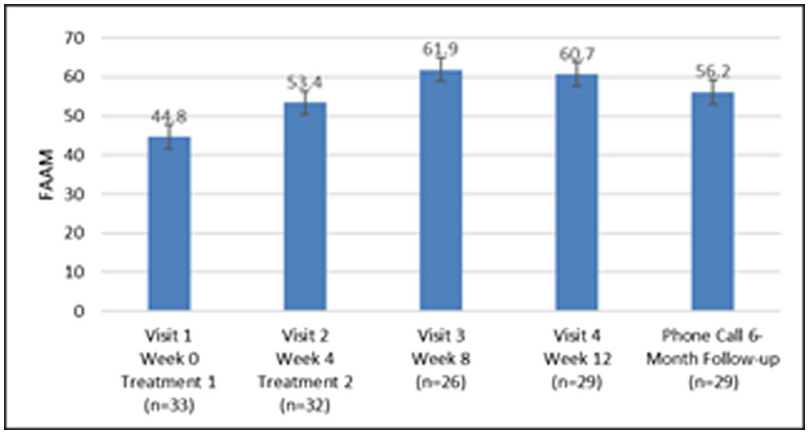


**Fig. 9.** Average Foot and Ankle Ability Measure score by visit (standard error noted).

patients who felt improvement in these categories increased at each subsequent time point.

Patient satisfaction on an overall basis was tracked at each of the follow-up time points using a 4-point scale. Subjects had the options of choosing dissatisfied, satisfied with major reservations, satisfied with minor reservations, and totally satisfied. At each time point, patient satisfaction based on these criteria was between 72% and 90% (Fig. 11).

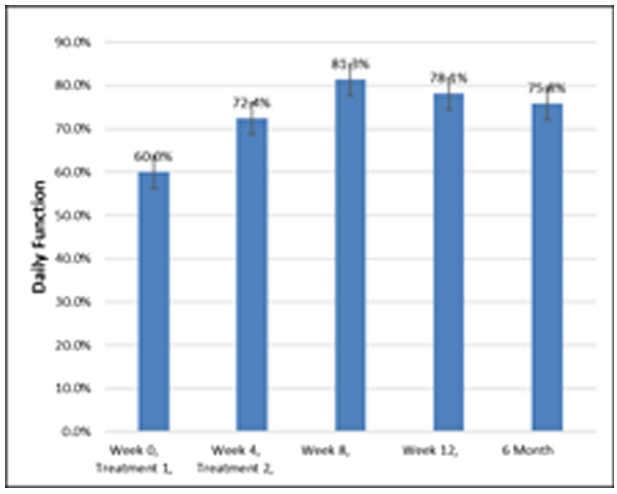


**Fig. 10.** Average Daily Activity score by visit (standard error noted).

Additionally, patients reporting satisfaction with major reservations were tracked. This same figure also shows that with that category added, patient satisfaction was recorded as between 88% and 97%.

### *Patient Tolerance and Safety*

No anesthetic was provided during the ITU treatments. Treatment tolerance was tracked via a patient-reported VAS pain score 10 to 20 times during each treatment. Fig. 12 shows the percentage of patients reporting no pain and minor, moderate, or severe momentary pain during treatment. For treatment 1, the average pain score was 3.4; for treatment 2, the average pain score was 2.9. No adverse events were recorded over the 9-month trial duration.

## Discussion

Plantar fasciitis is very common. Unfortunately, conservative therapy does not render all patients pain free, and chronic pain leaves many searching for relief (1,2). Currently, if nonprocedural therapy is insufficient to resolve symptoms, a stepwise progression of therapies frequently includes corticosteroid injections, shock wave therapy, human tissue injections with plasma-rich platelets or cryopreserved human amniotic membrane, microdebridement surgery, or fasciotomy (4,5,14–16,24). Conceivably, if an additional effective therapy were available, pain could be reduced, and the journey of progressive and more invasive therapies could be halted. ITU may fulfill this goal.

**Table 3**
Patient self-reported outcome measures questionnaire results by week and percentage of patients meeting criteria

| Week | "Compared to My Initial Visit. . . | | | | |
|---|---|---|---|---|---|
| | . . .I Feel Better" | . . .I Have No/ Less Pain" | . . .I Have >25% Improvement in Heel Pain" | . . .Heel Pain Is Much/All Better" | . . .I Have >25% Improvement in Daily Activities" |
| 4 | 66% | 75% | 56% | 47% | 53% |
| 8 | 85% | 85% | 73% | 58% | 73% |
| 12 | 79% | 83% | 76% | 62% | 72% |
| 26 | 86% | 93% | 86% | 79% | 86% |

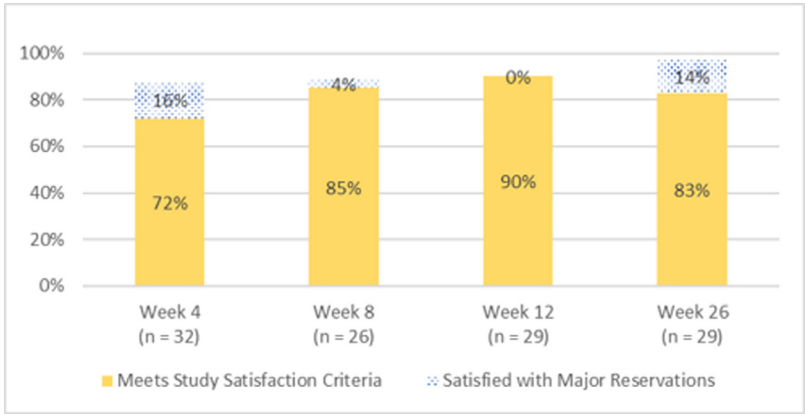


**Fig. 11.** Percentage of patients meeting overall treatment satisfaction criteria.

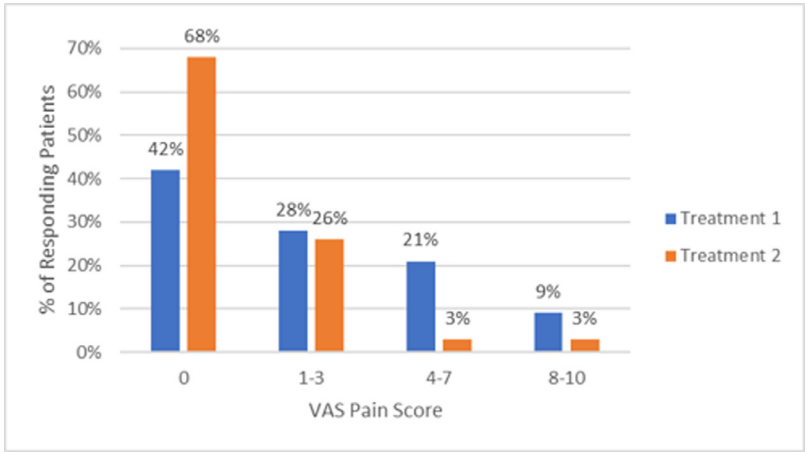


**Fig. 12.** Patient-reported treatment pain scores by percentage of patients.

Various types of ultrasound have been used to treat soft tissue injuries since the 1930s (31). Most of such conventional ultrasound treatments (diathermy) involve diffuse, low-energy, long-duration pulses resulting in the warming of tissues under the ultrasound beam. 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 (19). ITU has been used clinically for treating the facial skin for the past decade, and it has received CE mark and U.S. FDA clearance to market (32) for nonsurgical brow and submental tissue lifting. More than 3 million patients worldwide have been treated using this technology (33). 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 (34). 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 (17–20). Laboratory research has shown that ITU can improve healing of a damaged Achilles tendon in a rabbit model. Preliminary results showed an increase in markers for wound healing (eg, Vascular Endothelial Growth Factor A, Tumor Necrosis Factor Alpha, Interleukin-1 Beta, and Transforming Growth Factor Beta 1) and a decrease in markers for scar tissue formation (eg, Collagen Type I Alpha, Collagen Type I Alpha 2, Collagen Type II Alpha 1) in injured rabbit tendon treated with ITU compared with untreated rabbit tendons (21,22). These results have led us to explore the possibility of using ITU to treat patients with CPF.

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% occurred in 72%, 81%, 86%, and 79% at the time points of 4, 8, 12, and 26 weeks after treatment, respectively (Fig. 4). Similarly, mean pain scores at each visit were significantly different

from baseline ($p < .001$) at −39%, −49%, −51%, and −44% (Fig. 5). As hypothesized, FFI scores declined favorably from baseline ($p < .001$) at all time points evaluated (Fig. 8). All patients had hypoechoic lesions, and they decreased in size significantly ($p < .05$) at weeks 8 and 12, −56% and −67% on average (Fig. 6). These findings are consistent with the original feasibility study (23). The very encouraging sign was the subjects meeting satisfaction criteria of 72%, 85%, 90%, and 83% at subsequent time points (Fig. 11). No adverse events occurred. The procedure was well tolerated, with early attrition of only 1 patient in the study.

Comparing trials and the results of ITU is difficult because even if the patients enrolled are similar, the details of treatment may differ. Conventional therapeutic ultrasound (diathermy) treatment trials may differ by the specific device used, the dose applied (delivered pulses of energy intensity, frequency, depth of penetration, or duration), diagnostic ultrasound monitoring, the systematic approach to the plantar fascia field specifically treated, the number of sessions energy is applied, and recovery time between treatments.

Despite some potential variables between treatment trials, it is possible to compare this trial with another study (23) with the same patient selection criteria, an identical device, identical depth of penetration, and identical energy application. This trial differed in that the second application of therapy was at 2 weeks after initial treatment rather than our 4 weeks, and the patient-reported monitoring used the FFI-P outcome measure. The trial also compared results with a sham treatment session in a double-blind fashion. In the 41-patient study, the 29 patients being actively treated had a significant reduction in the pain score and 100% satisfaction. In the treated group, there was statistically significant reduction in hypoechoic area size (−81%) and a 54% decrease in the FFI score at 12 weeks compared with baseline metrics. In contrast, the control/sham treatment group had average hypoechoic lesions increase (+26%), and average FFI-P scores were slightly reduced (23).

When examined by diagnostic ultrasound, a large portion of patients with CPF are found to have hypoechoic lesions in or around the proximal plantar fascia (35). This study found a reduction in size of these lesions and the correlation of size deduction to pain reduction to be significant. The clinical meaning of this finding is uncertain but may propose a possible association of hypoechoic lesions in heel pain. MRI has been used to study the plantar fascia in plantar fasciitis, and typical findings include plantar fascial thickening, intrafascial edema and edema surrounding on the fascia on T2 weighted images (primarily the proximal aspect of the fascia is edematous), and increased intrafascial T1 signal. Fascial thickening is defined as >3 mm, with some cases having thickening up to 7 and 8 mm. The thickening is usually fusiform and not nodular. Sometimes marrow edema of the calcaneal tuberosity is present on MRI (36,37). Diagnostic ultrasound in plantar fasciitis was evaluated in a systematic review that identified 34 relevant quality studies. The review concluded that diagnostic ultrasound is a reliable technique for assessing plantar fascia thickness, monitoring the effect of therapeutic interventions, and guiding therapeutic interventions in patients with plantar fasciitis (38). With further development of high-resolution diagnostic ultrasound, it is hopeful that better understanding of the plantar fascia, its pathology, and the natural history of changes in treated and untreated plantar fasciitis will emerge.

Using diathermy ultrasound therapeutically to try to help patients with foot and heel pain has been reported since the mid-1970s (39). Clinical studies have shown varying treatment programs and response rates. In a 2006 study of 19 patients with heel pain, some bilateral, 13 patients received therapy with an ultrasound device and 13 received placebo. Although more patients had pain relief in the treated group than with placebo, there was no statistical difference. This type of ultrasound treatment (diathermy) involves diffuse, low-energy, long-duration pulses resulting in the warming of tissues under the ultrasound beam (0.5 W/cm$^2$, 3 MHz, pulsed 1:4 for 8 minutes) performed twice a week for 8 weeks. A specific mapping of the area treated was not performed, and validation of the specific depth of tissue treated with the device was not reported. The authors specifically noted that ultrasound doses of differing parameters might produce different conclusions (40). Other diathermy studies have been conducted with similar results (41).

Overall, although several studies on diathermy ultrasound in plantar fasciitis have been reported, differences in patient characteristics, the dose of energy applied, the mode of administration (pulse or continuous), the presence or absence of a standardized treatment protocol, confirmed localization of energy delivery to the plantar fascia, and other details between the studies make comparisons difficult.

In a 37-patient study in 2007 comparing extracorporeal shock wave to diathermy ultrasound therapy for heel pain, the authors found that 37% had a decline in pain (using the VAS score) in the shock wave group and 24% in the ultrasound group, and the pain increased 3% in the control group ($p = .002$). Ultrasound therapy was administered 3 times a week at a frequency of 1 MHz with an intensity of 1 W/cm$^2$ (Phyaction 190i, Uniphy, Netherlands) for 5 minutes each session, and an ankle splint post therapy was used. A detailed energy application location strategy was not reported. The authors noted improvement with ultrasound and different results from other studies owing to treatment parameters or outcome parameters (42).

A recent 60-patient study in CPF of at least 6 months' duration explored the efficacy of shock wave therapy and compared it with low-level laser therapy and therapeutic diathermy ultrasound. Patients receiving shock wave therapy had a 65% improvement on MRI findings or clinical response that was comparable to low-level laser therapy (70.6% improvement) and more effective than diathermy ultrasound, which had only 23.5% improvement. The ultrasound portion of the study evaluated therapy by a device that delivered 2 W/cm$^2$ and was used at 5 sessions a week for 3 consecutive weeks (BTL-5000 SWT combination device, BTL, Ankara, Turkey). A frequency of 1 MHz was used at a power of 2 W/cm$^2$ to the painful heel area and the myofascial junction at the dorsum of the heel for 5 minutes a session. This differed from our study in the dose of energy applied (intensity of acoustic waves delivered at each session, total energy delivered) and systematic application of therapy (43).

Our study had several limitations. By design, it is a pivotal clinical trial to explore the effectiveness and safety of a new device and new approach to treating CPF. This was a descriptive treatment study of an intervention without a concomitant sham or active alternate therapy comparator control group. The trial was small, with 29 patients successfully completing the 2 treatments and follow-up assessments. Small trials such as these are necessary to develop larger studies and fine-tune research questions.

In conclusion, in this pivotal clinical trial, ITU for CPF musculoskeletal tissue pain reduction was effective, safe, and well tolerated. In addition to having reduced 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 ITU in the treatment of CPF are warranted.

## Acknowledgments

The authors thank the study sponsor, Guided Therapy Systems, Inc., for an unrestricted research grant that facilitated the conduct of this study. The authors recognize the entire University Foot and Ankle Institute team for their excellent patient care and assistance in conducting this clinical trial.

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