TITLE: Effectiveness of Intense Therapeutic Ultrasound in the Management of Patients with Plantar Fasciitis

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Sponsor: Guided Therapy
33 S Sycamore
Mesa, Arizona 85202-1150 USA

Principal Investigator: Dan Latt, MD, Ph.D.
University of Arizona

Statistical Approach

- Pain Reduction:

Pain level at the plantar fascia was self-reported by subjects at pre-treatment (used as baseline measurement) and again at each follow-up - 4, 8, 12, and 26 weeks - after initial treatment. The pain scale subjects used to identify their level of pain was a 10-point pain scale range, where 0 = no pain, 1 = slight pain through 10 which equates to the patient's worst imaginable pain. The goal for all subjects in the treatment group was to reduce pain by at least 25%. Pain scores reported at follow-up timepoints were compared to baseline score for each subject to determine if the goal was met by dividing the difference in the follow-up and baseline pain score by the baseline pain score. The percentage of subjects that met the pain reduction goal was calculated at each timepoint for both control/sham-treated and treatment groups by dividing the number of subjects that achieved the pain reduction goal at each timepoint by the total number of patients that gave a pain score for that time point.

- Plantar Fascia Hypoechoic Lesion Size:

A large proportion of patients suffering from chronic plantar fasciitis present with hypoechoic lesions in or around the proximal plantar fascia, as viewed by diagnostic ultrasound imaging[7].

Hypoechoic lesions were imaged and 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:

$$\text{Volume} = (4/3)\pi * r1 * r2 * r3$$

With r1, r2, and r3 representing the three radii detailed above. Changes to lesion volumes were recorded at each follow-up timepoint and compared to baseline by dividing the volume of the lesion at that timepoint with the volume of the same lesion at pre-treatment baseline.

- Foot Function Index Score Reduction:

In addition to the 11-point VAS pain scale, patients self-reported answers to questions from the Foot Function Index (FFI) pain subscale questionnaire, which has been standardized in a number of PF-focused publications [8-10]. Scores range from 0-90, 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 timepoint. The average score for each timepoint were calculated, and follow-up averages were compared to baseline to calculated the percentage reduction in score.

- Statistical Calculations

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.