TITLE: Preliminary Protocol for Intense Therapeutic Ultrasound for the Treatment of Chronic Plantar Fasciitis

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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%. For patients reporting an initial (baseline) score ranging 6-10, this reflects a VAS pain score reduction ≥ a 2 point drop; for initial scores ranging 2-5, this reflects a VAS pain score reduction ≥ a 1 point drop. 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 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:

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 10-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.

- Hypoechoic Lesion Size – Pain/Function Correlation:

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

- 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. All error bars displayed in graphs are standard error. The level of significance (α) was set to 0.05.