

## Randomized Controlled Trial of Intense Therapeutic Ultrasound for the Treatment of Chronic Plantar Fasciitis

L. Daniel Latt, MD, PhD, Dallin N. Christensen, Ashley L. McNelly, Michael H. Slayton, PhD, Richard C. Amodei, Cindy D. Fastje, BS

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**Introduction/Purpose:** Initial treatment of plantar fasciitis (PF), consisting of anti-inflammatories, stretching and in-shoe orthosis (heel pad, heel wedge, or arch support), leads to symptomatic resolution in over 90% of patients but takes 3-6 months. This study was conducted to test the effectiveness of a minimally invasive modality, intense therapeutic ultrasound (ITU), in accelerating the healing of chronic plantar fasciitis (PF). ITU uses high-frequency high-intensity focused ultrasound to create small thermal injury zones inside soft tissue without damage to surrounding structures. ITU has been shown to initiate a tissue repair cascade and promote collagen generation in dermal and musculoskeletal tissue and is FDA approved for use in non-surgical brow lifts [1,2]. The goal of this study was to determine if ITU when combined with standard therapy could speed the healing of chronic PF.

**Methods:** 47 patients with chronic (greater than 3 months) heel pain due to PF were randomized to standard therapy (anti-inflammatory pills, stretching, and gel heel cups) plus ITU ("ITU", n=33) or standard therapy plus sham ITU ("control", n=14) groups. ITU treatments were administered at enrollment and two-weeks later using a custom 3.3 MHz therapeutic ultrasound system (Guided Therapy Systems, Mesa, AZ). Sham treatment utilized the same protocol but with the energy set to 0 Joules. Treatment effect was assessed at 2, 4, 6, and 12 weeks after the initiation of treatment using diagnostic ultrasound and patient reported outcomes (PROMIS physical function computer adaptive test, PROMIS global health, Foot Function Index pain subscale, and a non-validated heel pain specific questionnaire). Ultrasound images were analyzed to determine the size of lesions within the PF. Both the sonographer and the study coordinator administering the patient reported outcome instruments were blinded to group assignment.

**Results:** 38 patients completed the 12 week study (ITU: n=37, Control: n=11). The ITU group reported a significantly greater reduction in heel pain scores [Mean 8.27, SD 4.69, P=0.027] compared to the control group [Mean 2.25, SD 5.92] (Figure 1). Ultrasound imaging showed an 81% decrease in perifascial lesion size in the treatment group, compared to a 26% increase in lesion size in the control group (Figure 2).

**Conclusion:** Preliminary results of this clinical study of noninvasive ITU for the treatment of chronic PF showed that ITU treatment as compared to sham control lead to a larger and more rapid reduction of heel pain and perifascial lesion size. ITU holds promise as a potential therapy to accelerate the healing of chronic plantar fasciitis

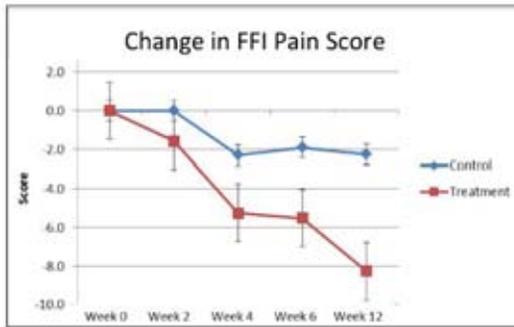


Figure 1

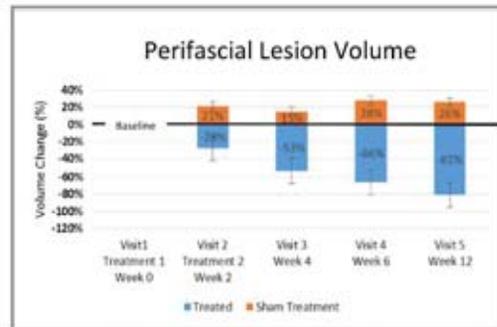


Figure 2