

Ultrasonographic Evaluation of Low Energy Extracorporeal Pulse Activated Therapy (EPAT) for Chronic Plantar Fasciitis

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ABSTRACT

Background: Ultrasonographic measurement of the plantar fascia can be used to objectively diagnose plantar fasciitis. The purpose of this study was to determine the long-term effectiveness of Extracorporeal Pulse Activated Therapy (EPAT) for the treatment of plantar fasciitis using ultrasonographic measurement as an objective outcome measure, with a minimum followup of 12 months. **Methods:** Patients with chronic recalcitrant plantar fasciitis were prospectively recruited and underwent EPAT. Ultrasound measurement of the plantar fascia and patient-rated pain scores were collected before treatment and at followup (minimum of 12 months post-treatment). Twenty-five subjects (35 feet) met the inclusion criteria. The average followup time was 29.4 ± 13.1 (M \pm SD; range, 12 to 54) months. **Results:** The average thickness of the plantar fascia of the symptomatic heels was 7.3 ± 2.0 mm before treatment and 6.0 ± 1.3 mm after treatment ($p < 0.001$). The average change in thickness of the treated heels was -1.3 mm (-0.8 to -1.8 mm; 95% CI, $p < 0.0001$). No correlation was found between length of followup and change in ultrasound measured plantar fascia thickness ($r = -0.04$, $p = 0.818$). **Conclusion:** For patients with a greater than 12-month history of heel pain, EPAT can effectively decrease plantar fascia thickness as demonstrated objectively by ultrasound evaluation and reduce patient-reported pain. No relationship between length of followup and change in plantar fascia thickness was found after 12 months.

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INTRODUCTION

Plantar fasciitis (PF) is the most common cause of inferior heel pain in North America, accounting for 11% to 15% of all foot symptoms requiring professional care.² Contrary to conventional belief, some have found plantar fasciitis not to be caused by inflammation, but by hyaline degeneration of the plantar fascia.³ It is found most commonly in middle-aged people, with other predisposing factors including obesity, excessive pronation, reduced ankle dorsiflexion, inferior calcaneal spurs, improper footwear, or occupations which require extensive standing or walking.^{12,16} Upon palpation, heel pain is usually most intense at the point of the medial tubercle of the calcaneus, where the plantar fascia originates.

As the progression of the disorder can be self-limiting, the majority of patients (90%) recover without treatment or through conventional treatment within 1 year.⁴ These may include ice, ultrasound treatment, stretching or massage.^{4,10,22} However, 10% of patients do not heal and develop chronic hyaline degeneration of their plantar fascia, requiring further medical intervention.⁴

The medical use of sound waves (also called shockwaves or radial shockwaves) has been documented since the 1970s as an option for treating kidney, urinary, and salivary calculi.^{3,19} More recently, the effects of treating orthopaedic pathologies such as bone non-unions and tendinopathies with shockwaves have been investigated. The exact mechanism of Extracorporeal Pulse Activated Therapy (EPAT), also known as radial shockwave, remains unclear. Current evidence suggests that its action is mediated by both inflammatory and growth factors, which affect the long-term healing and remodelling of vascular tissue.^{8,21} Randomized, placebo-controlled, double-blinded clinical trials have demonstrated the effectiveness of EPAT on chronic recalcitrant PF as

an alternative to surgery, allowing patients less loss of work, quicker recovery times and the ability to continue sports.^{4,7,9,11,17,23} Gerdesmeyer et al. showed that radial shockwave therapy is effective and almost painless in treating plantar fasciitis, with an 84% success rate after 1 year, with success defined as a 60% decrease in pain.⁴

Ultrasound imaging of the thickness of the plantar fascia is a readily available, non-invasive and inexpensive diagnostic tool for plantar fasciitis. Numerous studies have demonstrated that degeneration of the plantar fascia is correlated with an increase in pain, as well as an increase in the thickness of the plantar fascia.^{6,9,10} A conclusive diagnosis can therefore be made by history, physical exam and when the large medial band of the plantar fascia is thicker than 4 mm.²⁰

The existing literature on this treatment modality is limited by the fact that the majority of the available literature has thus far relied upon subjective, patient-reported pain measures or general measures of function such as the Roles and Maudsley, or Short Form-36. As well, the majority of the evidence includes patients with mostly a short history of PF (less than 6 months) and short followup (6 weeks to 6 months), and are therefore limited to measuring the short-term effects of shockwave treatment.

This study hypothesized that for cases of chronic recalcitrant plantar fasciitis (clinical symptoms for greater than 12 months), shockwave treatment would reduce objectively measured plantar fascia thickness by ultrasound measurement, and subjectively rated patient pain scores.

The purpose of this study was to show the effectiveness of EPAT in treating PF in a population of patients with chronic recalcitrant PF by using ultrasonographic measurement of plantar fascia thickness as an objective outcome measure and to observe the long-term effect of EPAT on patient reported pain, with a minimum followup of 12 months.

MATERIALS AND METHODS

Patients

Patients were recruited prospectively from a university- and community-based orthopaedic practice in Toronto, Ontario from January 2005 to May 2008. This research study was approved by the Institutional Research Ethics Board. Inclusion criteria required: 1) diagnosis of chronic plantar fasciitis by an orthopaedic surgeon, including at least 1 year of clinically significant pain, 2) ultrasonographic diagnosis of PF (plantar fascia ≥ 4 mm); 3) no history of surgery on the plantar fascia, and 4) failed conservative treatment (Table 1). Patients were excluded if there was local cancer of the involved foot or ankle, systemic inflammatory disease, neurological pain, fractures of the foot, or if a steroid injection was performed within 6 weeks prior to consultation. Patients were not excluded by age, sex, race or occupation. Patients meeting the inclusion criteria were approached to participate in the study. All 25 patients who were approached agreed to participate in the study, providing written, informed consent.

Twenty-five patients (10 male) and 35 symptomatic feet were included in the study. Patient demographic data is displayed in Table 2.

Treatment protocol

Using the Masterpuls® MP50 (Storz Medical AG, Switzerland), patients received a standardized EPAT treatment, which consisted of three treatment sessions at 1-week intervals. Patients received 2000 pulses per treatment session at 11 Hz and 2.6 barr (0.11 mJ/mm²). Treatment was patient-guided, targeting the point of maximal tenderness, and was administered by the same healthcare professional. Anesthetic was not administered (Figure 1).

Outcome measures and followup

For each patient, bilateral ultrasound measurements (Philips HD II; L12/5 probe) of the large medial band of the plantar fascia were performed by a single ultrasound technician at baseline (before EPAT treatment) and at a single followup time at least 12 months after treatment. The technician was blinded to both the patient diagnosis, as well as their treatment status. To examine the large medial band of the plantar fascia, the transducer was longitudinally positioned over the medial tubercle of the calcaneus and oriented to follow the medial band of the ball of the foot where it thinned out (Figure 2). The plantar fascia thickness was measured 1 cm distal to the origin on the medial tubercle, unless this was not the thickest part of the plantar fascia, in

Table 1: Patient Demographics (*n* = 35 Feet)

| | <i>n</i> (%) |
|----------------------------|-----------------------|
| Age, years (M ± SD, Range) | 52.6 ± 10.5, 29 to 71 |
| Sex | |
| Male | 10 (40%) |
| Female | 15 (60%) |
| Side | |
| Right | 7 (28%) |
| Left | 8 (32%) |
| Bilateral | 10 (40%) |

Table 2: Failed Conservative Measures

| |
|---------------------|
| Ultrasound |
| Laser Therapy |
| Chiropractics |
| Night Splints |
| Physiotherapy |
| Stretching |
| Cortisone Injection |
| Icing |



The hand piece was applied with coupling gel to the patient's skin over the site of maximal tenderness to palpation and 2000 pulses were applied. Photograph by Jane Southey.

Fig. 1: EPAT Technique. Photograph displaying the administration of EPAT to the plantar fascia.

To examine and measure the thickness of the large medial band of the plantar fascia, the transducer is longitudinally positioned over the medial tubercle of the calcaneus and oriented to follow the medial band of the ball of the foot where it thins out. Photograph by Jane Southey.



Fig. 2: Plantar Fascia Ultrasound Measurement Technique. Photograph of plantar fascia ultrasound technique.

which case the thickest part was measured and its distance from the medial tubercle was recorded. In all patients, post-treatment measurement was taken at the same location as their before treatment measurement, as recorded by the ultrasonographer (Figure 3). The ultrasound characteristic of plantar fasciitis was a hypoechoic fusiform swelling of the normally hyperechoic plantar fascia, especially at the calcaneal insertion. A calcaneal spur may or may not have been present. The ultrasound examiner would also look for other pathology of the plantar fascia and heel. Patients were also asked to rate their pain on a visual analogue scale (VAS) from zero (no pain) to 10 (maximum pain) at the time of each ultrasound. The time of followup varied for individual patients according to their availability, but all followups



The plantar fascia thickness (6.58mm) is the length between the two markers 'x,' which were placed to measure the thickest portion of the plantar fascia. The thickest portion of the plantar fascia was found to be 1.05cm (length between '+' markers) from the medial tubercle (MED TUB) in this patient. Image courtesy of Jag Dhanju.

Fig. 3: Ultrasound Measurement of the Plantar Fascia. Ultrasound image of plantar fasciitis with labels and markers used for measurement of plantar fascia thickness.

occurred at a minimum of 12 months after their EPAT treatment. The average time between initial and followup ultrasound and VAS measurement was 29.4 ± 13.1 (range, 12 to 54) months (Figure 4).

Statistical analysis

Statistical analysis was performed using SPSS 15.0 (IBM, Chicago, IL). Results were calculated as means and standard deviations ($M \pm SD$) for continuous data or counts and percentages for categorical data. To avoid making assumptions about the underlying distribution of the data, both parametric (Student's t-test and paired t-test) and equivalent non-parametric tests (Mann-Whitney and Wilcoxin signed-ranks test) were performed to detect differences between groups and paired data. No discrepancies in probabilities between parametric and non-parametric tests were observed. P values for non-parametric tests are displayed unless otherwise noted. Pearson correlation coefficient was used to test for an association between variables. Statistical significance was defined as $p < 0.05$.

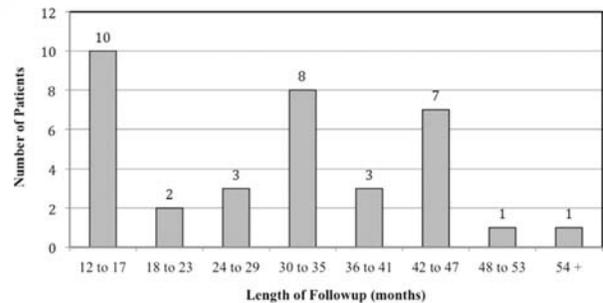


Fig. 4: Length of Followup Varied by Patient. This histogram displays the count of patients per category by length of followup.

RESULTS

Ultrasound measured plantar fascia thickness

The average thickness of the plantar fascia of the symptomatic heel was 7.3 ± 2.0 mm before treatment and 6.0 ± 1.3 mm after treatment ($p < 0.001$). The average change in thickness of the treated heels was -1.3 mm (-0.8 to -1.8 mm; 95% CI, $p < 0.0001$; paired t-test), representing a 17.7% decrease in thickness.

Overall at followup, 26 feet (74%) showed a decrease in plantar fascia thickness, six feet (17%) showed an increase, and three feet (9%) showed no change. Heels that decreased in thickness did so by an average decrease of 2.0 ± 1.1 mm. No correlation was found between length of followup and change in ultrasound measured plantar fascia thickness ($r = -0.04$, $p = 0.818$) (Figure 5). Additionally, a median split was performed by length of followup. Change in plantar fascia thickness did not differ ($p = 0.42$) between those with a followup time less than 32 months (-1.5 ± 1.7 mm) and patients with a followup at 32 months or greater (-1.1 ± 1.3 mm).

Self-reported pain (VAS)

Table 3 demonstrates that both pain described at rest and with activity significantly decreased at followup. Using a

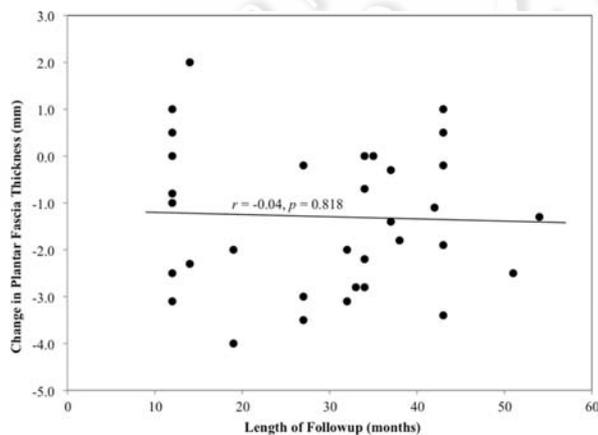


Fig. 5: Change in ultrasound measured plantar fascia thickness and length of followup. This scatterplot displays the change in plantar fascia thickness versus the length of followup in months.

60% decrease in pain to define clinical success, 32 feet (91.4%) and 29 feet (82.9%) out of the total 35 feet achieved clinical success at rest and with activity, respectively.

No correlation was found between change in plantar fascia thickness and change in pain at rest ($r = 0.273$, $p = 0.11$). The association between length of followup and change in pain at rest was found to have borderline significance ($r = 0.334$, $p = 0.05$) (Figure 5).

DISCUSSION

Evidence supporting the effectiveness of EPAT has resulted in it becoming a treatment for PF as an alternative to surgical intervention. It is currently thought that EPAT promotes the healing process in PF by causing microtrauma within the affected tissue and signalling for the healing process to commence via neovascularization.²¹ Low energy EPAT is readily tolerated, administered without anesthesia and can be repeated as needed.

The thickness of the plantar fascia was found to decrease an average of 2.0 ± 1.1 mm in 74% of treated patients, with clinically significant pain improvement in 91.4% of feet at rest, and 82.9% of feet with activity. Six feet (17%) showed an increase in thickness, and three feet (9%) showed no change. The clinical success rate, with respect to VAS pain scores, found in this study is in accordance with the 84% success rate found by the double-blind, randomized control trial by Gerdesmeyer et al., who also defined clinical success as a 60% decrease in pain.⁴ Interestingly, patients with a significant decrease in plantar fascia thickness did not regress to within normal limits (under 4 mm) despite vast improvements in patient-reported pain scores. In fact, no correlation was found for change in plantar fascia thickness and change in patient-reported pain at rest ($r = 0.273$, $p = 0.112$). Although plantar fascia thickness greater than 4mm is associated with clinical symptoms, further investigation is warranted to understand the relationship between changes in the plantar fascia thickness in response to treatment and patient-reported pain.

Length of followup was shown to have no correlation to change in plantar fascia thickness. Although not statistically significant ($p = 0.418$), patients with a followup less than 32 months had a greater change in plantar fascia thickness

Table 3: Changes in VAS Pain Score (M \pm SD)

| | Before Treatment | Post-Treatment | p^* |
|------------------|------------------|------------------|-----------|
| Pain at Rest | 7.1 ± 2.6 mm | 0.7 ± 1.4 mm | <0.0001 |
| Pain in Activity | 8.4 ± 1.9 mm | 1.4 ± 2.0 mm | <0.0001 |

*, Results of Wilcoxin-signed-ranks tests; equal probabilities were reported for paired t-test.

compared to those with a followup at or beyond 32 months (-1.5 ± 1.7 mm versus -1.1 ± 1.3 mm, respectively). A moderate positive correlation ($r = 0.334$) existed between length of followup and change in pain at rest, although this relationship had borderline statistical significance ($p = 0.05$).

To our knowledge, only two other studies have been published that report the use of objective ultrasound measurement for patients undergoing EPAT for PF.^{6,14} Both of these studies recruited patients with a 6-month history of heel pain and were limited to a 6-month followup. The decrease in plantar fascia thickness in these two studies at followup were 0.8 ± 2.5 mm ($p < 0.05$)⁶ and 0.4 ± 2.5 mm ($p < 0.05$, for low intensity treatment group) / 0.1 ± 2.3 mm (not significant, high-intensity treatment group),¹⁴ compared to the average decrease of 1.3 mm (-0.8 to -1.8 mm; 95% CI, $p < 0.0001$) reported in this study. In consideration of this disparity, we note that the initial average plantar fascia thickness in these previously published studies were 5.2 ± 1.5 mm⁶ and 4.6 ± 1.2 mm (low-intensity treatment group) / 4.7 ± 1.3 mm (high intensity treatment group),¹⁴ compared to an average initial thickness of 7.3 ± 2.0 mm reported in this study.

The present study of 35 feet is the first that we are aware of to report on a population of patients with chronic recalcitrant plantar fasciitis with greater than 12-months duration of symptoms, and a followup of at least 12 months after treatment. The increased thickness of the plantar fascia for patients in this study relative to those reported in the literature suggests that an increase in duration of symptoms may lead to increase in plantar fascia thickness. Additionally, patients with a longer clinical history of PF are just as likely to respond to EPAT, and greater absolute reductions in plantar fascia thickness may be observed.

The strengths of this study include the use of an objective and reproducible outcome measure, use of a single treating professional, blinding of the ultrasound technician to both treatment status and patient diagnosis, and a longer followup period. This study is limited by the lack of prospective randomization, the absence of a control group, the absence of patient blinding and variable length of patient followup (12 to 54 months). Future investigations should measure outcomes (plantar fascia thickness and patient-reported pain) at multiple time points after initial treatment to determine the relationships between time, plantar fascia thickness and patient reported pain.

CONCLUSION

Direct anatomical measurement of the plantar fascia using ultrasound is not only useful for comparative purposes in research, but may serve as a useful clinical monitoring tool for both clinicians and patients. This study showed that for patients with chronic heel pain, in general, significant

improvements in both plantar fascia thickness and patient-rated pain score can be achieved with EPAT.

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