

Effectiveness and tolerability of focal *versus* radial extracorporeal shock wave therapy in patients affected by plantar fascia enthesopathy

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Abstract

Plantar fascia enthesopathy is the most common cause of heel pain. Extracorporeal shock wave therapy (ESWT) is widely used in patients affected by this condition. The aim of this study was to compare efficacy and tolerability of ESWT modalities in the treatment of plantar fasciitis.

We included 42 patients receiving 1 session of focused ESWT (f-ESWT group) or radial ESWT (r-ESWT group) per week for 3 weeks. Pain assessment was performed at baseline, before each session, and 1 month after the last session using brief pain inventory (BPI) severity index, and interference index (II). Tolerability was defined in terms of patient discomfort after treatment assessed by numeric rating scale at baseline and after each session. Plantar fascia changes in ultrasonography were further investigated.

A significant reduction of BPI-II ($P < 0.001$) was reported in both groups, although no between-group differences were found. Plantar fascia thickness showed significant reduction only in the f-ESWT group ($P = 0.028$). Patient's tolerability was significantly better in the r-ESWT group ($P < 0.05$).

Our study confirms that ESWT is effective for reducing pain and disability in patients affected by plantar fasciitis, although r-ESWT seems to be better tolerated.

Introduction

Plantar fascia enthesopathy is a common foot disorder in adult population characterized by heel pain,¹ particularly at the insertion of plantar fascia on the medial calcaneal tubercle. The pathophysiology of this condition is unclear, but it seems to be related to poor foot biomechanics along with overloading of the plantar fascia.² High body mass index (BMI), female gender, ageing, running and jumping sports as well as foot deformities are well-known risk factors for plantar fasciitis.³ This condition is characterized by chronic degeneration of the plantar fascia that may be associated with microtears, inflammation or fibrosis.⁴ Diagnosis is usually based on clinical examination including patient's history, and localized pain at the anteromedial side of the heel. However, currently no objective and reliable clinical test for plantar fasciitis is available.⁵

Ultrasonography (US) is a noninvasive and cost-effective diagnostic tool to evaluate the thickening of the plantar fascia and perifascial fluid collection. Plantar fascia thickening is the most widely reported imaging finding in patients affected by plantar fascia enthesopathy.⁶ It is generally accepted that a plantar fascia thickness of more than 4 mm is consistent with plantar fasciitis.⁷

Nonsurgical management of plantar fasciitis is successful in 90% of cases.⁸ Conservative options include rest, plantar fascia and gastrocnemius-soleus muscle stretching, cushioned sole footwear, anti-inflammatory medications, therapeutic US and low-level laser therapy (LLLT).⁹

Corticosteroid injections are effective to treat this condition because of their rapid pain relief effect and low cost,¹⁰ although side effects, such as plantar fascia rupture, have been reported.¹¹ Surgery is indicated when conservative approaches fail.

Over the last few years, the development of extracorporeal shock wave therapy (ESWT) for treating musculoskeletal conditions has become a new, safe and effective treatment option also for plantar fascia enthesopathy. This intervention, originally applied for breaking kidney stones,¹² consists of pulsed acoustic waves with high-peak pressure amplitude and short duration that induce mechanical effects on target tissues.

The biological mechanism of ESWT is not completely understood. However, it has been reported that shock waves can induce several effects on tissues and cells. Repetitive ESWT applied to the fibrotic tissues might be able to induce a local remodeling, by modulating the expression of metalloproteinases and proinflammatory cytokines, stimulating collagen synthesis, and up-regulating the expression of *TGFβ1* genes. Moreover, shock waves may induce neo-vascularization and nitric oxide production, which have a key role in the modulation of the inflammatory process.¹³

Extracorporeal shock wave therapy can be classified into two main modalities based on the propagation of acoustic waves: fo-

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cused (f-ESWT) and radial (r-ESWT). Focused shock waves are generated from the probe and converge to the target area. In contrast, radial shock waves disperse eccentrically from the applicator tip and distribute radially to the tissue.

A recent systematic review suggested that both focused and radial shock wave therapy compared to placebo are effective in reducing pain and disability in patients with plantar fascia enthesopathy.¹⁴

Moreover, plantar fascia thickness increases significantly in this condition and ESWT is effective in counteracting fascial thickening,¹⁵ although it is not yet clear if a thickening of the plantar fascia is correlated with the clinical impact, such as pain, functional outcomes and health-related quality of life (HRQoL) during the disease course.¹⁶

However, no research has directly compared the effectiveness of f-ESWT and r-ESWT in the treatment of plantar fasciitis. Therefore, the aim of our study is to evaluate and compare the effectiveness and tolerability of these ESWT modalities in reducing pain and disability in patients with plantar fascia enthesopathy.

As secondary outcome we assessed structural changes of plantar fascia using US.

Materials and Methods

We carried out a longitudinal prospective study on eligible subjects who met the following criteria: patients with clinical diagnosis of plantar fascia enthesopathy aged 18 years and older; US plantar fascia thickness >4 mm.

Exclusion criteria included previous treatment of the affected foot with therapeutic exercise, physical therapy, corticosteroid injections or surgical procedures in the previous 6 months, cognitive impairment, skin breakdown, sensitive and vascular impairments, malignant tumor in the treatment area, pregnancy and severe coagulopathy. All patients provided an informed written consent to participate in the study.

The primary outcome measure was the change of pain and pain-related disability scores from baseline (T0) to 1-month after the last session (T3). We carried out a multidimensional assessment of pain, including its interference in performing the activities of daily life (ADL), using the brief pain inventory (BPI), an evaluation tool in which the patient reports the intensity of his/her pain on a numeric rating scale (NRS scale, from 0 to 10, where 0 corresponds to *absence of pain* and 10 to *maximum perceived pain*). BPI scoring consists of two indexes: the severity index (BPI-SI) and the interference index (BPI-II).

The secondary outcome measures included treatment tolerability and the changes of fascia thickness on US examination. The treatment tolerability was defined as patient pain and discomfort

after treatment assessed by an NRS score after each session (T0-T1-T2). US examination of the proximal plantar fascia was assessed with a 7 to 16 MHz linear array US transducer (Samsung HM70A) before (T0) and 1 month (T3) after the last session of ESWT. The plantar fascia thickness was measured at its proximal end near its insertion into the calcaneus.

Focused Shock wave treatment was applied with the Duolith SD1 device (Storz Medical, Switzerland) and radial extracorporeal shock waves with the BTL-6000 SWT TOPLINE (BTL, Italy). Treatment was administered directly to the heel at the point of maximal intensity of pain. All patients received a total of 3 sessions once a week with a 1-week interval between each treatment.

In the f-ESWT group, we applied the following parameters: energy flux density (EFD) 0.20 mJ/mm²; frequency 4 Hz; number of shots 1500. Patients in the r-ESWT group received this treatment protocol: pressure 2.5 bar; frequency 10 Hz; number of shots 2000.

All patients were treated lying in prone position. Before starting each single session, the most painful point of plantar fascia was localized by the physician and marked with a sign. Gel was applied between the probe and the patient skin to ensure best conductivity.

Adverse events were monitored during the study and documented during treatment and at follow-up visits.

Statistical analysis was performed using the IBM SPSS statistics V21.0 software. Continuous variables are presented as means \pm standard deviations (SD), categorical data as absolute values and percentages. As statistical method we performed a Mann-Whitney test for independent sample to calculate the between-group differences. Moreover, we performed Wilcoxon test for paired samples to compare means at different times. All tests were considered statistically significant, if P values were <0.05 .

Results

Forty-two patients (21 males and 21 females) with plantar fascia enthesopathy, diagnosed according both to clinical and US evaluation were enrolled. The demographic and clinical data of the study population are reported in Table 1. The population was divided into 2 groups: f-ESWT and r-ESWT. No statistically significant between-group difference was found at baseline in terms of BMI, BPI-SI, BPI-II, and plantar fascia thickness. No adverse events, such local edema, hematoma, and skin ecchymoses were reported during the study period.

The outcome measures assessed at baseline and at 1-month follow-up assessment in f-ESWT and r-ESWT group are reported in Table 2. A statistically significant reduction of the BPI-SI and BPI-II between T0 and T3 was observed in both groups (in f-ESWT,

Table 1. Demographic and clinical data in our population at baseline.

Variables	f-ESWT (n=21)	r-ESWT (n=21)	P-value
Age	51.45 \pm 9.15	60.9 \pm 12.75	0.0007*
BMI (kg/m ²)	28.37 \pm 4.55	28.93 \pm 4.88	0.753
Plantar fascia thickness	5.67 \pm 0.9	5.9 \pm 1.44	0.639
BPI severity index	5.03 \pm 1.73	4.59 \pm 1.69	0.413
BPI interference index	5.29 \pm 1.97	5.16 \pm 1.83	0.762

Values are expressed as means (SD) for continuous data and counts (percentages) for categorical data. BMI, body mass index; BPI, brief pain inventory.

BPI-SI $P=0.036$ and BPI-II $P<0.001$; in r-ESWT, BPI-SI $P=0.001$ and BPI-II $P<0.001$).

However, the r-ESWT group showed better mean differences between T0 and T3 scores for BPI SI (Δ BPI-SI r-ESWT -2.37 vs Δ BPI-SI f-ESWT -1.27) and for BPI II (Δ BPI-II r-ESWT -2.84 vs Δ BPI-II f-ESWT -2.30) compared to f-ESWT group.

Compared with the baseline, both groups reported significantly greater treatment tolerability after each session. Moreover, the r-ESWT group showed significantly lower NRS values at T0 ($P<0.01$), T1 ($P<0.20$) and T2 ($P<0.01$) compared to the f-ESWT group (Table 3). Both groups showed reduction of plantar fascia thickness at follow-up (T3). One example of each is reported in Figure 1. Reduction was not significant in r-ESWT: 5.9 ± 1.44 mm and 5.4 ± 1.06 mm, at T0 and T3, respectively. Conversely, a significant reduction of plantar fascia thickness was detected in f-ESWT: 5.67 ± 0.9 mm and 5.1 ± 1.0 mm ($p=0.028$) at T0 and T3, respectively (Figure 2).

Discussion

Our study found that both focused and radial shock wave therapy can lead to a significant reduction of pain and improvement in pain-related disability in the affected foot in patients with plantar fascia enthesopathy after one month of treatment.

Moreover, on US evaluation, plantar fascia thickness was reduced in both groups, although the reduction was statistically significant only in patients treated with f-ESWT. Several studies confirmed that US is an effective diagnostic imaging tool, even if it is uncertain if ultrasonographic findings may be associated with patient's pain or disability.¹⁷

The lack of a well-defined relationship maybe explained by the disease course; plantar fascia seems to swollen in an overload con-

dition, particularly during early inflammation. This process can still be reversed by conservative treatments, including ESWT. On the other hand, in chronic plantar fasciitis a degenerated *fasciosis* with multiple ultrastructural changes may occur.¹⁷

The current study also suggests that radial shock wave therapy might be more tolerable than the focused shock wave for treated patients.

Plantar fascia enthesopathy is a common and disabling disease. Current management of this condition generally consists of conservative approaches. Extracorporeal shock wave therapy has been suggested to be an effective physical modality for reducing pain in patients with plantar fasciitis. In a recent meta-analysis, Sun J et al. have also demonstrated that either focused or radial shock wave therapy result in favorable effects for patients affected by this condition.¹⁸

Clinical benefits of this intervention might be related to the biological effect of shock wave pressure on the treated target, which consists of both an increase of local nitric oxide production and a release of angiogenetic factors.¹⁹ This biological signaling cascade might result in improvement of symptoms by initiating an inflammatory response, thus enhancing the physiological healing process of the tissues. Furthermore, shock waves might influence even nervous system and pain modulation, by inhibiting small unmyelinated sensory nerve fibers transmission as well as substance P and Calcitonin Gene Related Peptide (CGRP) release.^{20,21}

Based on the propagation pattern of the wave, ESWT can be classified as focused and radial shock wave therapy. Radial extracorporeal shock waves differ from focused extracorporeal shock waves in penetration depth and certain physical properties. Moreover, radial shock waves have a more superficial area of effect compared with focused shock waves, that usually target deeper tissue layers. However, the differences between radial and focused ESWT in terms of efficacy and effectiveness in the treatment of patients affected by plantar fascia enthesopathy remain still unclear.

Table 2. Outcome measures at baseline and at 1-month follow-up in both groups.

r-ESWT	T0	T3	P-value
US Plantar fascia thickness	5.9 ± 1.44	5.4 ± 1.06	0.109
BPI severity index	4.59 ± 1.69	2.22 ± 1.77	0.001*
BPI interference index	5.16 ± 1.83	2.32 ± 1.68	0.0001*
f-ESWT			
US Plantar fascia thickness	5.67 ± 0.9	5.1 ± 1	0.028*
BPI severity index	5.03 ± 1.73	3.76 ± 2.62	0.036*
BPI interference index	5.29 ± 1.97	2.99 ± 2.23	0.0001*

Continuous variables are expressed as means (SD). Wilcoxon matched-paired signed-rank test was used for the statistical analysis. BMI, body mass index; US, ultrasound; BPI, brief pain inventory.

Table 3. Tolerability at each session in both groups.

NRS	Mean \pm SD	P-value
f-ESWT T0	6.40 ± 1.50	0.001*
r-ESWT T0	3.47 ± 1.50	
f-ESWT T1	4.33 ± 2.25	0.020*
r-ESWT T1	2.47 ± 1.88	
f-ESWT T2	4.00 ± 1.92	0.001*
r-ESWT T2	1.47 ± 0.99	

Continuous variables are expressed as means (SD). Mann-Whitney test was used for the statistical analysis. NRS, numeral rating scale; f-ESWT, focused extracorporeal shock wave therapy; r-ESWT, radial extracorporeal shock wave therapy.

Although both ESWT modalities showed a significant pain relief in our study, no significant between-group difference was observed. Our results, in accordance with previous studies, confirm that both focused and radial shock wave therapy might be an effective approach for these patients, because of their significant benefits in terms of pain relief, and both reduced pain-related disability and plantar fascia thickness.^{22,23}

Furthermore, we found that r-ESWT is less painful and more tolerable for patients than f-ESWT. A putative explanation for this effect might be that radial shock waves have a broader and superficial therapeutic area as opposed to focused shock waves.

Our study has several limitations, in particular the study design, due to lack of a sham or non-intervention control group, considering that plantar fasciitis is a self-limiting disease with time to resolution of 6-18 months.²⁴

Another limitation is the short follow-up. Indeed, some studies have a 12 to 24 weeks follow-up period for pain and disability assessment in the management of plantar fascia enthesopathy.^{25,26} Therefore, the beneficial effect of either focused or radial shock wave therapy simply due to natural recovery cannot be excluded. However, it should be underlined that the magnitude of the effect

in terms of pain relief is unlikely to be justified only by spontaneous recovery. Indeed, Malay *et al.* in a randomized controlled trial have already demonstrated that ESWT is more effective than placebo in the treatment of plantar fascia enthesopathy.²⁷ Finally, the treatment parameters and quantity of energies may vary, influencing the outcomes, as stated by National Institute for Health and Care Excellence (NICE) guidelines on ESWT for refractory plantar fasciitis.²⁸ In our study, the treatment protocols, including energy, frequency, number of shots and sessions, were based on available literature about this topic.²⁹ However, it is unclear if a greater number of sessions or different ESWT parameters would have resulted in different findings. Other two important limitations of study are the lack of randomization and blindness of examiners.

Despite these limitations, to our knowledge, this study is the first direct estimation of the effectiveness of radial and focused ESWT for the treatment of patients with plantar fascia enthesopathy. Current results add to the growing evidence that both the ESWT modalities are effective and safe for these patients. On the other hand, r-ESWT might be considered the appropriate treatment option because of its cost-effectiveness, and probably better tolerability. Future studies might further elucidate if structural changes

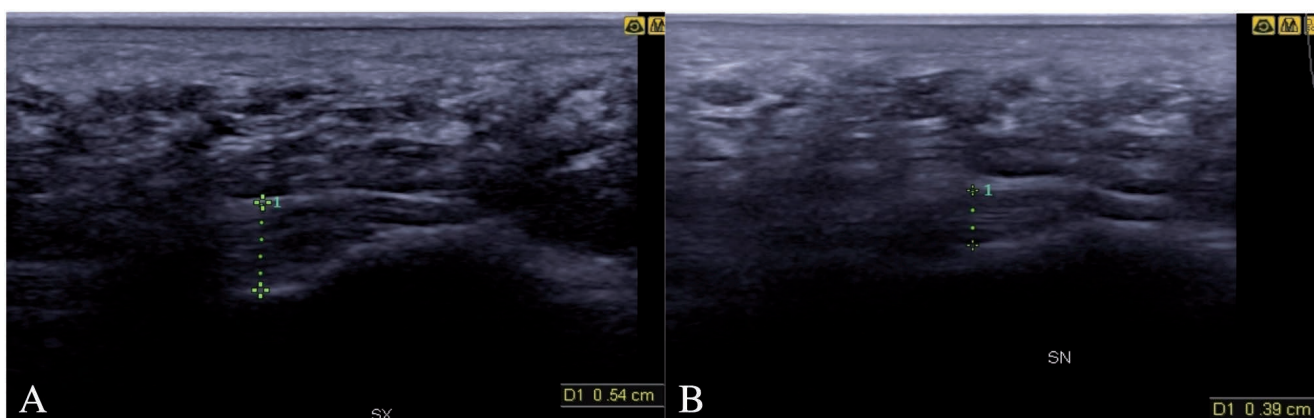


Figure 1. Ultrasound evaluation of illustrative patient at baseline (left) and 1 month after focused extracorporeal shock wave therapy (ESWT) (A) and after radial ESWT (B).

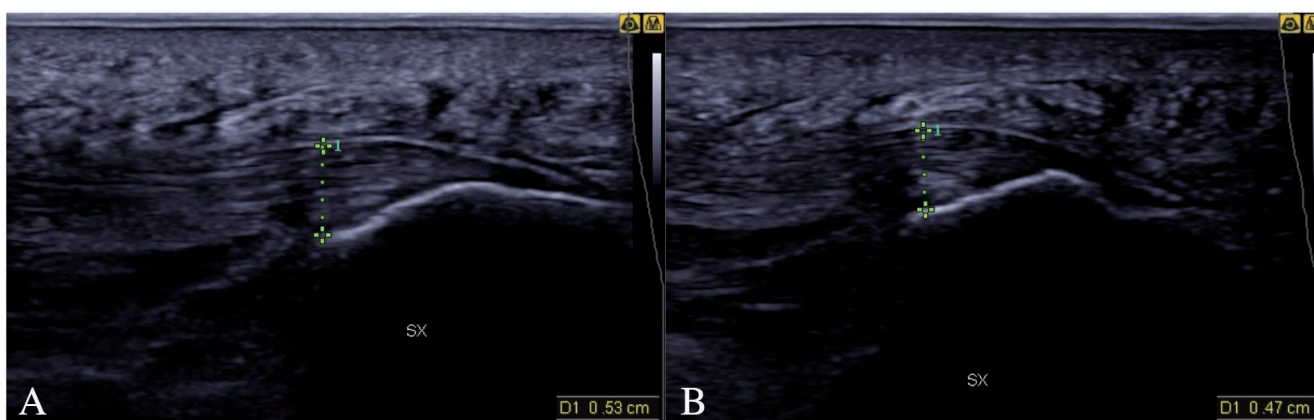


Figure 2. Ultrasound thickness at baseline (A) and 1 month after radial extracorporeal shock wave therapy treatment (B).

affecting plantar fascia are associated with clinical findings, particularly pain and disability, in order to better define the role of imaging approaches in the work-up of patients with plantar fasciitis. We also believe that these results might facilitate stakeholders in providing specific recommendations regarding the use of r-ESWT or f-ESWT in patients affected by this condition.

Conclusions

This study provides evidence supporting the effectiveness and feasibility of ESWT for plantar fascia enthesopathy in the clinical practice. According to literature, we found that both f-ESWT and r-ESWT might be effective in alleviating symptoms and reducing plantar fascia thickness in affected patients.

In particular, our data suggest that r-ESWT seems to be more tolerable, with a comparable effectiveness to f-ESWT. Finally, future well-designed studies with long-term follow-up time should be planned to confirm our findings.

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