



Comparison of effects of low-level laser therapy and extracorporeal shock wave therapy in plantar fasciitis treatment: A randomized, prospective, single-blind clinical study

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ABSTRACT

Objectives: The aim of this study is to compare the efficacy of extracorporeal shock wave therapy (ESWT) and low-level laser therapy (LLLT) in terms of fascia thickness, heel pain, and foot functions in patients with plantar fasciitis (PF).

Patients and methods: Between April 2015 and October 2015, a total of 34 patients (5 males, 29 females; mean age 51.5±10.8 years; range, 18 to 65 years) with PF were randomized into two treatment groups to receive either ESWT or LLLT using closed envelope method. The patients were evaluated before and after treatment and one month after treatment using the Visual Analog Scale (VAS)-pain, Foot Function Index (FFI), and plantar fascia thickness measured by ultrasonography.

Results: A significant improvement in the VAS-pain and FFI scores and plantar fascia thickness was observed in both groups after treatment and one month after treatment, compared to pre-treatment values ($p<0.05$). Changes over time in these outcome parameters were not different between study groups ($p>0.05$).

Conclusion: Our study results suggest that both ESWT and LLLT seem to be effective on pain, foot functions, and fascia thickness in the treatment of PF.

Keywords: Extracorporeal shock wave therapy; low-level laser therapy; plantar fasciitis; ultrasonography.

Plantar fascia is a strong aponeurosis located at the base of the foot, starting from the anterior edge of the medial calcaneal tubercle and extending to the metatarsophalangeal joint. Plantar fasciitis (PF) may be idiopathic or associated with inflammatory rheumatic disorders. Idiopathic PF is the most common cause of heel pain.^[1,2] Mechanical overload has been considered as the major factor involved in the development of PF.^[2] The most frequent complaint of affected patients is pain, particularly during the first few steps in the morning which worsens with increased weight bearing throughout the day. The diagnosis of the condition is clinical; it is diagnosed on the basis of patient history and tenderness at the insertion site of the plantar fascia on the medial calcaneal tubercle elicited by palpation.^[1,2]

Ultrasonography (USG) is a non-invasive, inexpensive, and easily accessible imaging tool which is useful in the differential diagnosis of heel pain. It provides guidance to physicians in making the most appropriate treatment decision. In most of the studies on PF treatments, the plantar fascia thickness has been most widely used as the outcome parameter for USG assessment of the plantar fascia. As a general rule, a plantar fascia thickness of ≥ 4 mm would be consistent with the diagnosis of PF. In addition, echogenicity, the presence of tear, inflammation and epine calcanei can be also evaluated by USG.^[3] Conservative treatments such as rest, cold application, stretching exercises, non-steroidal anti-inflammatory drugs, splint use, footwear modification, extracorporeal shock wave therapy (ESWT), low-level laser therapy (LLLT), and

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therapeutic USG are preferred for the treatment of PF. Additionally, steroid injections and platelet-rich plasma can be administered.^[4,5] Numerous studies are available in the literature investigating the effectiveness of different treatment modalities for the treatment of PF. In particular, there are several studies demonstrating superiority of ESWT to placebo.^[6] However, there are only two studies comparing the efficacy of ESWT with other treatment modalities in the treatment of PF. One of them is the comparative study with corticosteroid injection.^[7] The other is the comparative study of ESWT, therapeutic USG and LLLT, recently carried out by Ulusoy et al.^[8]

In the present study, we aimed to compare the effects of ESWT and LLLT on pain, functional status, and plantar fascia thickness in the treatment of PF.

PATIENTS AND METHODS

This randomized, prospective, single-blind study included a total of 46 patients who were admitted to our Physical Medicine and Rehabilitation outpatient clinic with heel pain and were diagnosed with PF between April 2015 and October 2015. The study protocol was approved by the local Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Inclusion criteria were as follows: being between 18 and 65 years, presence of heel pain, tenderness at the insertion site of the plantar fascia on the anteromedial aspect of the calcaneal tubercle elicited by palpation, and unresponsiveness to medical treatment. Exclusion criteria were as follows: being younger than 18 years of age, a history of inflammatory rheumatic disease, trauma of the foot or foot surgery, local dermatological lesion or infection, impaired peripheral circulation, a neurological disorder such as radiculopathy and neuropathy, patients with sequelae of lower extremity fracture, a congenital or acquired deformity, malignancy, cardiac pacemaker, metal implant at the application site, pregnancy, anticoagulant use for coagulopathy, and inflammation within or around plantar fascia identified by USG.

A total of 40 patients who met the inclusion criteria were randomized into two groups using the closed envelope method. Randomization was performed by an independent individual who did not participate in the study. The first group received ESWT (Group 1, n=17) and the second group received LLLT (Group 2, n=17). None of the patients received medical treatment, did not do exercises, or used a splint during the treatment

period. The treatment plan was thoroughly explained to each patient in detail before the initiation of the study, and a written informed consent was obtained from each patient.

Group 1 received three sessions of ESWT (Elmed Vibrolith ESWT, Elmed Medikal/Ankara, Turkey) at an energy density of 2 bar with a frequency of 2,000 shocks/min at 10 Hz with each session given once per week for three weeks. The ESWT was applied in a circular motion on the insertion site of the plantar fascia (1,000 shocks) and along the fascia (1,000 shocks). Group 2 received LLLT (BTL 4000 Lazer Topliner, BTL Industries Ltd., Cleveland, UK) three times per week for four weeks for a total of 12 sessions at a wavelength of 685 nm, a laser output of 30 mW, and a dose of 2 J/cm². Similar to the ESWT application, LLLT was applied in a circular motion on the insertion site of the plantar fascia for one min and along the fascia for another one min, perpendicularly. Seventeen patients from each group completed the study. The study flow chart is presented in Figure 1.

Outcome measures

USG evaluation

The USG imaging was conducted using a 7.5 MHz linear probe (Mindray DC-T6, probe model 7L4A, Shenzhen Mindray, Shenzhen, China). During the procedure, the patients lay on the examination table in the prone position with their knees fully extended and ankles in a neutral position. The calcaneus was set as the bone landmark and scanned up to the calcaneal attachment of the plantar fascia. The thickness of the plantar fascia was measured in the sagittal plane at the insertion site of the plantar fascia on medial calcaneal tubercle (Figure 2). The USG images were also assessed for fluid collections around the plantar fascia and epine calcanei formation.

Visual Analog Scale (VAS)

The VAS-pain is the most widely used scale for rating the intensity of pain. The VAS-pain consists of a horizontal line of 10 cm in length and is anchored by “no pain” on one end and “the most severe/unbearable pain you ever felt in your lifetime” on the other. Patients are asked to mark the point that best represents their pain severity along the line and that point is measured on the 10-cm line using a ruler and assigned a score between 0 and 10.^[9]

Foot Function Index (FFI)

The FFI is a tool to measure the impact of foot pathology on pain, disability, and activity restriction. It

can be used at any age in various foot and ankle problems such as congenital, acute, and chronic diseases and injuries and to evaluate the effectiveness of treatment following surgical interventions or use of orthoses.^[10]

The FFI questionnaire is divided into three subcategories; pain, disability, and activity restriction. It consists of 23 items including nine items for the pain subcategory, nine items for the disability subcategory, and five items for the activity restriction subcategory. For the evaluation of 23 items, patients have to score their pain, disability and activity limitation over the past week on a VAS. The scores for each item are summed, divided by the total maximum score of all items, and multiplied by 100 to obtain the final FFI score. If the patient does not perform activities such as walking barefoot or using a foot orthosis, this item is, then, marked as inapplicable and deleted from the total score.^[11] The reliability and validity of the Turkish version of the FFI were conducted by Yaliman et al.^[12]

All measurements and assessments were performed at baseline, immediately after the treatment, and after one month by a physician who was blind to the treatment allocation.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 25 (IBM Corp., Armonk, NY, USA) and NCSS version 11 statistical software (NCSS, LLC, Kaysville, Utah, USA). The post-hoc power analysis of the study was estimated using the G*Power V.3.1.5 (Heinrich Heine University, Dusseldorf, Germany). Descriptive statistics were expressed in mean, standard deviation, median, minimum, maximum. The Shapiro-Wilk test was used to check whether the study groups were normally distributed. Since data did not show a normal distribution, non-parametric tests were conducted using the Fisher's exact probability test and quantitative data were analyzed using the Mann-Whitney U test. The Friedman's two-way analysis of variance was used to compare the interaction with changes over time by each group. The significance of changes in time for each group was assessed using the Friedman's test. The Wilcoxon test with the Bonferroni correction was used to identify the timepoints at which significant changes occurred. A *p* value less than 0.05 was considered statistically significant.

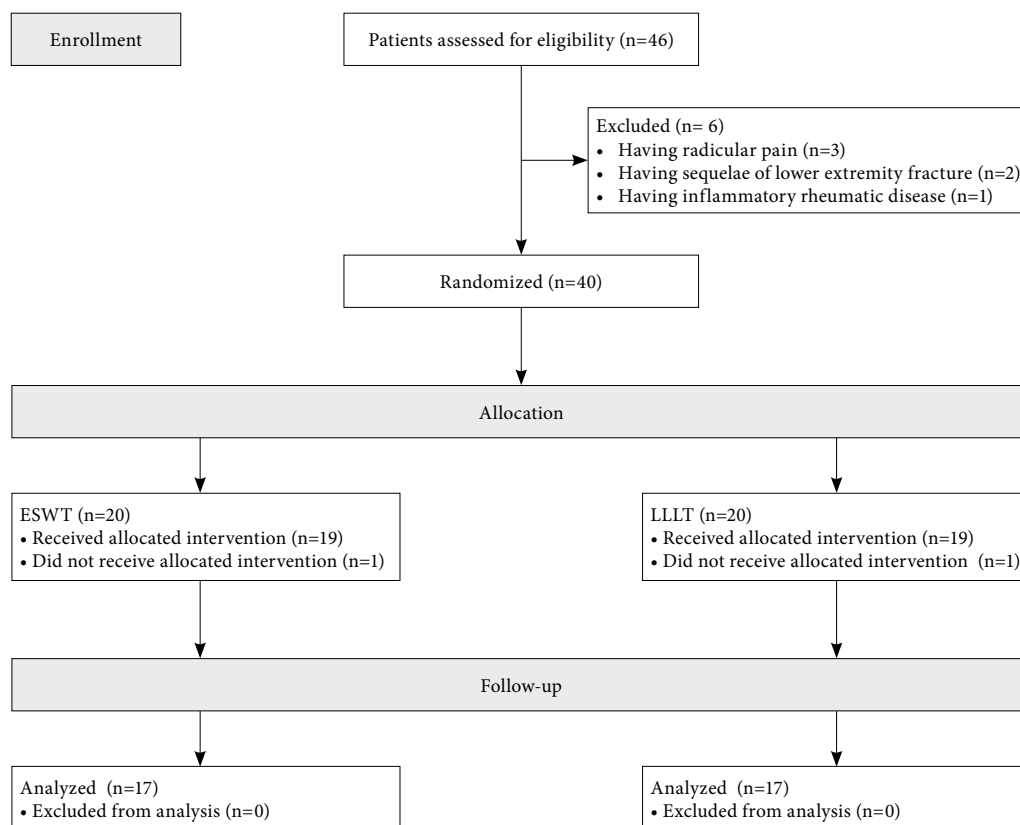


Figure 1. Flow diagram. ESWT: Extracorporeal shock wave therapy; LLLT: Low-level laser therapy.

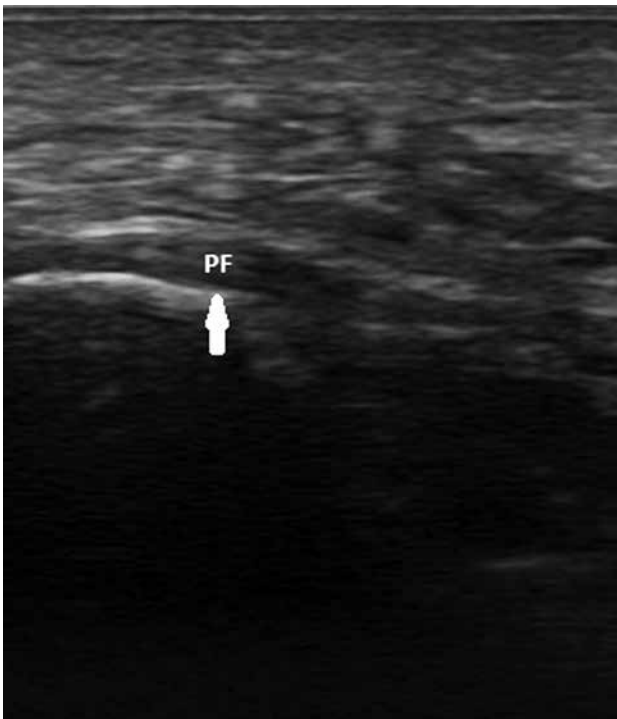


Figure 1. An ultrasound image of plantar fascia.

RESULTS

Of the study population, the mean Body Mass Index (BMI) was $30.4 \pm 4.64 \text{ kg/m}^2$. Baseline and demographic characteristics of the patients are shown in Table 1.

ESWT group

The plantar fascia thickness significantly decreased ($p=0.012$). The post-hoc tests for significance revealed

that the statistical significance resulted from reductions achieved at one month after the treatment. The plantar fascial thickness at one month after the treatment decreased compared to the pre-treatment values ($p<0.001$) and immediately after treatment ($p=0.011$).

The FFI scores significantly decreased ($p=0.001$). The post-hoc tests showed that the statistical significance resulted from reductions achieved at one month after the treatment. The FFI scores at one month after the treatment decreased compared to the pre-treatment FFI scores ($p<0.001$) and immediately after treatment ($p=0.030$).

The VAS-pain scores significantly decreased ($p=0.002$). The post-hoc tests for significance showed that statistical significance resulted from reductions at one month after the treatment. The VAS-pain scores at one month after the treatment decreased compared to the pre-treatment VAS-pain scores ($p<0.001$).

LLLT group

The plantar fascia thickness significantly decreased ($p<0.001$). The post-hoc tests showed that both fascial thickness values obtained immediately after the treatment ($p=0.030$) and at one month after the treatment ($p<0.001$) were lower compared to the pre-treatment values. The difference between the fascial thickness values obtained immediately after treatment and one month after the treatment was not statistically significant.

The FFI scores significantly reduced ($p=0.011$). The post-hoc tests for significance showed that statistical significance resulted from reductions at one month

Table 1. Baseline demographic and clinical characteristics of patients

| | ESWT (n=17) | | | LLLT (n=17) | | | p |
|----------------------------|-------------|--------|-------------|-------------|--------|-------------|--------|
| | n | Median | Min-Max | n | Median | Min-Max | |
| Age (year) | | 49 | 32-67 | | 53 | 32-67 | 0.409* |
| BMI (kg/m^2) | | 29.64 | 25.34-36.44 | | 30.22 | 20.82-44.20 | 0.446* |
| Heel pain duration (month) | | 12 | 2-84 | | 5 | 3-120 | 0.532* |
| Heel pain side | | | | | | | 0.821* |
| Right | 9 | | | 9 | | | |
| Left | 8 | | | 8 | | | |
| Gender | | | | | | | 0.500† |
| Female | 14 | | | 15 | | | |
| Male | 3 | | | 2 | | | |
| PF thickness (mm) | | 4.7 | 3.8-6.8 | | 4.6 | 3.4-6.0 | 0.946* |
| FFI | | 61.73 | 16.01-92.41 | | 61.32 | 25.65-90.24 | 0.946* |
| VAS-pain | | 8 | 2-10 | | 7 | 4-10 | 0.357* |

ESWT: Extracorporeal shock wave therapy; LLLT: Low-level laser therapy; Min: Minimum; Max: Maximum; BMI: Body Mass Index; PF: Plantar fascia; FFI: Food function index; VAS: Visual Analog Scale; * Mann-Whitney U test p value; † Fisher's Exact probability test p value.

Table 2. Comparison of outcome parameters within groups and between changes in groups over time

| | ESWT | | | | LLLT | | | | <i>p</i> † |
|-----------------------------|-------|--------|-------------|----------|-------|-------------|---------|----------|------------|
| | % | Median | Min-Max | <i>p</i> | % | Median | Min-Max | <i>p</i> | |
| PF thickness (mm) | | | | | | | | | |
| Pretreatment | | 4.7 | 3.8-6.8 | | 4.6 | 3.4-6.0 | | | |
| Immediately after treatment | | 4.5 | 3.2-5.3 | | 4.3 | 3.0-5.9 | | | 0.963 |
| 1 month posttreatment | | 3.8 | 3.1-5.0 | | 4.0 | 3.0-6.3 | | | |
| <i>p</i> * | | | | 0.012 | | | | <0.0001 | |
| Post-hoc power | 92.1 | | | | 87.8 | | | | |
| FFI | | | | | | | | | |
| Pretreatment | | 61.73 | 16.01-92.41 | | 61.32 | 25.65-90.24 | | | |
| Immediately after treatment | | 53.31 | 20.71-82.47 | | 56.98 | 21.73-93.91 | | | 0.533 |
| 1 month posttreatment | | 31.13 | 10.87-61.38 | | 38.24 | 19.13-80.43 | | | |
| <i>p</i> * | | | | 0.001 | | | | 0.011 | |
| Post-hoc power | 99.8 | | | | 95.92 | | | | |
| VAS-pain | | | | | | | | | |
| Pretreatment | | 8 | 2-10 | | 7 | 4-10 | | | |
| Immediately after treatment | | 7 | 2-10 | | 6 | 3-10 | | | 0.917 |
| 1 month posttreatment | | 5 | 1-10 | | 5 | 1-8 | | | |
| <i>p</i> * | | | | 0.002 | | | | 0.001 | |
| Post-hoc power | 89.62 | | | | 96.68 | | | | |

ESWT: Extracorporeal shock wave therapy; LLLT: Low-level laser therapy; Min: Minimum; Max: Maximum; PF: Plantar fascia; FFI: Foot function index; VAS: Visual Analog Scale; * In-group difference (Friedman's test); † Between groups interaction (Friedman's two-way analysis of variance).

after the treatment. The FFI scores at one month after the treatment was lower compared to the pre-treatment scores ($p < 0.001$).

The VAS-pain scores significantly decreased ($p = 0.001$). The post-hoc tests for significance showed that statistical significance resulted from reductions at one month after the treatment. The VAS-pain scores at one month after the treatment were lower compared to the pre-treatment scores ($p < 0.001$) and immediately after treatment ($p = 0.039$).

Changes over time in these outcome parameters were not significantly different between the study groups (Table 2). A post-hoc power analysis was conducted for all study data, yielding $\geq 80\%$ power (Table 2).

DISCUSSION

In the present study comparing the efficacy of ESWT and LLLT in the treatment of PF, we found that both treatment modalities were effective and not superior to one another in terms of pain and the plantar fascia thickness reduction and improvement of functional status.

General consensus for plantar fascia thickness at the insertion site on the medial calcaneal tubercle is 4 mm

on average for healthy individuals.^[13-15] Therefore, a cut-off value of 4 mm has been generally accepted, and our results are consistent with literature.

In addition to thickness, USG is useful to evaluate the plantar fascia in terms of echogenicity, biconvexity, perifascial fluid collections, intrafascial calcification, and subcalcaneal spur. In addition, USG is valuable for the assessment of PF, as it is a simple, widely accessible, and inexpensive method using no radiation. It may provide guidance for diagnosis and therapeutic decisions.^[3] The presence of enthesitis or perifascial fluid collection eliciting a Doppler signal may suggest spondyloarthropathy. In this case, further investigations in conjunction with a more detailed history and physical examination would assist in making a correct diagnosis. In the presence of a heel spur, ESWT may be more appropriate, since it diminishes the size of calcific deposits.^[6] Additionally, treatment efficacy may be more objectively evaluated with the USG images during follow-up by checking whether there was a decrease in fluid collection, heel spur formation, or fascial thickness. In our study, we excluded patients with perifascial fluid collection at baseline and calcaneal spurs were identified in two patients each in two groups.

The ESWT has been widely used in the last decade for the treatment of PF. Recent treatment guidelines recommend ESWT or surgery for patients with PF who have failed to respond to conservative therapies for at least six months. For the treatment of PF, ESWT has been used as an alternative to surgery due to its efficacy, safety, non-invasive nature and association with few side effects.^[6] The ESWT was shown to exert its effects by stimulating neovascularization, increasing the expression of angiogenic factor, decreasing calcification, reducing the concentrations of inflammatory mediators and substance P in tendinopathies.^[16] In a meta-analysis involving seven double-blind, randomized-controlled trials with 553 patients, Yin et al.^[6] reported that ESWT provided favorable short-term effects in PF treatment and further studies were needed to establish its long-term effects. They concluded that ESWT was an effective treatment for evidence-based medicine in the treatment of PF.

According to our literature search, there are two studies comparing the ESWT treatment with other treatment methods in patients with PF. Yucel et al.^[7] compared the efficacy of ESWT with that of corticosteroid injection. In the study of Yucel et al.,^[7] corticosteroid injection yielded improved short-term treatment outcomes of PF, although ESWT yielded improved long-term results. In a recent study, Ulusoy et al.^[8] compared the effectiveness of three modalities: therapeutic USG, ESWT, and LLLT in patients with PF. They evaluated pain level, functional level, and plantar fascia thickness using magnetic resonance imaging (MRI) before and after one month. They found a significant decrease in terms of the fascia thickness in all groups. They found that the LLLT and ESWT resulted in similar outcomes and both were more successful than USG in pain improvement and functional outcomes. Their results are similar to our results.

However, to the best of our knowledge, there are only two studies in the literature examining the effects of ESWT on PF using USG. Cosentino et al.^[17] evaluated the plantar fascia thickness at baseline, immediately after ESWT, and after one month using USG in patients diagnosed with PF. They found a significant reduction in the fascial thickness measurements after one month, compared to the control group. Hammer et al.^[18] evaluated the effect of ESWT treatment on the plantar fascia thickness using USG at baseline and at six, 12, and 24 weeks after the treatment in patients with PF. They found a significant reduction in the plantar fascia thickness at 24 weeks after the treatment. In our study,

we found that a significant reduction in terms of the plantar fascia thickness values in the ESWT group one month after treatment.

Furthermore, LLLT is another conservative treatment approach. It induces analgesic effects by modulating pain regulation mechanisms, and this analgesic action is used for the treatment of musculoskeletal disorders. Low-level laser therapy acts on the metabolism of serotonin, which is a potent suppressor of pain. It stimulates fibrous tissue regeneration and repairs process. In the past decade, laser therapy has been employed for the treatment of musculoskeletal conditions due to its tissue repairing and biostimulatory effects.^[19-23] To date, two studies examined the effects of LLLT in PF using USG. In a double-blind, placebo-controlled study involving 25 patients, Kiritsi et al.^[24] used gallium-arsenide (GaAs) laser with an infrared wavelength of 904 nm using energy densities of 0.16 W/cm² and 0.08 W/cm². The patients received LLLT three times weekly for six weeks. Calcaneal spur was identified in two cases at baseline. The plantar fascia thickness was examined with USG and pain severity was rated using VAS at baseline and after the completion of treatment. A significant difference was observed in the VAS-pain scores between the treatment and placebo groups at six weeks after LLLT with a pain reduction of 59% in the treatment group and 26% in the placebo group. Lower plantar fascia thickness values were observed six weeks after LLLT with a more significant change in the treatment group.^[24] Similarly, in the current study, we applied low-level laser therapy for a total of 12 sessions (three sessions per week for four weeks) at a wavelength of 685 nm, a laser output of 30 mW, and a dose of 1-2 J/cm². We found that both VAS-pain scores and the fascial thickness measurements were significantly improved in the LLLT group and the improvement persisted at one month after the treatment.

The second study which examined the impact of LLLT on PF by USG was conducted by Macias et al.^[25] At the end of the study, the VAS-pain scores and plantar fascia thickness measurements significantly decreased in the treatment group, compared to placebo, and these results are consistent with our findings. In a long-term follow-up study, Jastifer et al.^[26] examined the effectiveness of LLLT in patients with PF in terms of pain and FFI scores and demonstrated that treatment efficacy persisted at six and 12 months after the treatment. However, since we did not follow the patients for more than one month after the treatment, we were unable to evaluate long-term effects of treatment.

A limitation of the present study is the lack of long-term follow-up results. Yet, we believe that our study is valuable, since this is the second study in the literature to compare ESWT and LLLT in patients with PF. Additionally, this study suggests that USG imaging is feasible and provides valuable objective data, allowing monitoring of treatment efficacy.

In conclusion, based on our study results, both ESWT and LLLT are effective treatments for PF in short-term and are not superior to each other. Both treatment modalities should be preferred in routine clinical practice, not only because they are effective treatments, but also non-invasive, cost-effective, easy-to-use methods with few side effects.

Declaration of conflicting interests

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