Original Article

Focused Extracorporeal Shockwave Therapy versus Prefabricated Insoles for Treatment of Plantar Fasciitis: A Randomized Trial

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ABSTRACT

Objectives: To compare the clinical effectiveness of focused extracorporeal shockwave therapy (fESWT) and prefabricated insoles among patients suffering from plantar fasciitis (PF).

Study design: Pragmatic randomized open-label trial.

Setting: Rehabilitation Medicine outpatient clinic at a medical school hospital in Bangkok, Thailand.

Subjects: Patients suffering from subacute or chronic PF.

Methods: Participants were randomly allocated (1:1) to receive either 3 weekly sessions of fESWT (2,000 shocks/session of at least 0.2 mJ/mm^2) or to wearing prefabricated insoles. All participants were advised to perform stretching of the plantar fascia and gastrocnemius muscle. The clinical outcome measured was an improvement in Foot Function Index (FFI) at 12 weeks. An analysis was done based on the intention-to-treat principle.

Results: Twenty-nine participants were enrolled and randomly assigned to either the fESWT (n = 14) or the insole group (n = 15). A mean and standard deviation (SD) of the improvement in total FFI at 12 weeks was 65 (25.8) points for fESWT and 65.2 (39.2) points for prefabricated insoles with an adjusted mean difference between two interventions of 14.9 (95%CI: -15.4 to 45.2).

Conclusions: The fESWT did not improve FFI compared with prefabricated insoles among patients with subacute and chronic plantar fasciitis. However, the results should be interpreted with caution because of inadequate statistical power.

Keywords: plantar fasciitis, focused extracorporeal shockwave therapy, prefabricated insole, foot function index

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Introduction

Plantar fasciitis (PF) is one of the most common causes of heel pain. Statistically, its prevalence in the American population is approximately 10 percent. An estimated one million American patients visit a doctor for treatment of this condition annually,[1] and the cost of treating this disease in the US is approximately $192-376 million per year.[2]

It is believed that the cause of PF is the degeneration of collagen tissue of the plantar fascia resulting from repetitive microtrauma of the plantar fascia.[3] The classic symptom is the worst pain at the heel during the first few steps after waking.[3] However, some patients may experience more pain in their heels after walking a long distance.[4] For treatment of PF, stretching of the plantar fascia and gastro-soleus muscles plus strengthening of the intrinsic foot muscles are recommended.[5-7] The use of customized and prefabricated insoles is also common.[8] Other management methods include topical steroid injections, ultrasound, acupuncture,[9-11] and extracorporeal shock wave therapy (ESWT).[10,12-14]

ESWT is widely used in management of plantar fasciitis. The principle of ESWT is to stimulate blood supply flow to the injured area and to promote the release of growth factors for tissue regeneration and vascularization to reduce inflammation.[13] Previous studies have shown this to be effective in reducing pain by up to 60% and approximately 70% of patients experiencing great to excellent in pain relief.[14,15] A meta-analyses by Chang and colleagues reported that high- and moderate-intensity focused ESWT (fESWT) had reliably greater effectiveness than both low-intensity fESWT and radial ESWT (rESWT). They concluded that moderate-intensity fESWT (0.12 to 0.25 mJ/mm^2) with mostly tolerable energy is the best option when using ESWT for PF.[16] Although fESWT seems to be a preferable treatment option, its use is limited due to the high cost of the devices which can be about 2 million baht (60,000 USD) in Thailand. Interestingly, no economic evaluation studies of fESWT for lower extremity musculoskeletal pain were found in a literature search.

Prefabricated insoles are commonly used as a non-invasive treatment for individuals with subacute to chronic PF. It is believed that insoles can support the medial longitudinal arch of the foot, prevent foot pronation, and decrease the strain on the plantar fascia.[17] Moreover, prefabricated insoles are much cheaper and less time is spent fitting them than customized insoles, although the effectiveness of both types has been reported to be similar.[18]

Both fESWT and prefabricated insoles have been proven to be an effective treatment for PF, but there have been no studies comparing the effectiveness of these 2 treatments.

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The current research primarily aimed to compare improvement in foot function index between fESWT and the use of prefabricated insoles among patients suffering from subacute and chronic plantar fasciitis, including an economic evaluation of these two interventions.

Methods

Study design

This study was a pragmatic randomized open-label trial conducted at Phramongkutklao Hospital in Bangkok, Thailand from September 2019 to August 2020. The trial protocol was approved by the Institutional Review Board of the Royal Thai Army Medical Department (Number R082h/62) and was registered in the Thai Clinical Trials Registry (TCTR20210608002).

Participants

Study participants were adults (age ≥ 18 years) presenting with significant pain (Numeric Rating Scale at least 4) and tenderness at the medial heel at for least 1 month before enrollment and who were able to communicate and to complete the questionnaires.[19] Exclusion criteria were a history of steroid injection at the heel and sole within 6 months before enrollment; a previous surgery at the heel and/or sole; midfoot deformities; diabetic neuropathy; arthritis at the ankle joint or the foot; polyneuropathy and entrapment disorder at the foot and ankle; a history of calcaneus fracture and retrocalcaneal bursitis; a previous wound at the heel; pregnancy; or bleeding disorders. All participants provided written informed consent.

Sample size

The sample size calculation was based on a study by Traijeewornporn et al. (2016).[20] The sample size was determined using the clinical superiority design formula to compare the two independent groups in terms of mean difference of foot function. For an alpha level of 0.05, a power of 80%, and with an estimated drop-out rate of 20%, the target sample size was 76 participants (38 participants per group).

Randomization

Randomization was performed by an independent researcher with the use of a computer-generated randomization list for a block of four randomization stratified by the onset of disease: subacute (1-3 months) and chronic (> 3 months).[21] The random allocation sequence was concealed by an opaque envelope. Participants were randomly allocated 1:1 into 2 groups: focused shock wave therapy (fESWT) and prefabricated insole groups.

Intervention

The fESWT group was treated with a Duolith SD1 T-top (Storz Medical, Switzerland) and received a total of 2,000 pulses at a rate of 4 Hz at each treatment session, once a week for 3 consecutive weeks.[22] A stimulator head with stand-off II (long) which provides a penetration depth of 15 mm was placed on the maximal pain site of the infra-calcaneal heel and ultrasound gel was applied as the coupling media. The energy influx density started at 0.20 mJ/mm^2 and was then gradually raised to the highest level that the patient could tolerate.

The insole group received a pair of full-length prefabricated insoles with heel cup and medial arch support (Care Step®) to be placed inside any indoor and outdoor shoes they used for daily living. Additionally, both groups were advised to perform stretching of the calf muscle and plantar fascia, 10 sets/session for at least 3 sessions every day.[23,24]

Outcomes

The clinical outcome measure was the level of improvement of the Foot Function Index (FFI) at week 12. The FFI is a self-administered questionnaire consisting of 23 items divided into 3 categories: pain (9 items), disability (9 items), and activity limitation (5 items).[25] A higher FFI score indicates a higher level of impairment. The Thai FFI has a high test-retest reliability (ICC of 0.92) and excellent internal consistency (Cronbach's alpha of 0.96).[25] Measurement of FFI was conducted at baseline, week 6, and week 12. The improvement of total FFI score at week 12 was considered as the primary outcome of this study. For the cost-effectiveness analysis from the healthcare provider perspective, costs incurred were calculated based on the labor cost, material cost, and capital cost.

Statistical analysis

The intention-to-treat principle was used for the statistical analysis. Baseline and clinical characteristics of both groups are shown as mean (standard deviation, SD) for continuous data and number (%) for categorical data. Normality of distribution and equality of variance of FFI scores were assessed to confirm that parametric tests could be used. The comparison of mean values of FFI between the 2 groups at three periods (baseline, week 6, week 12) was performed using repeated measure ANOVA. The improvement of FFI at week 12 between the two groups was compared using an unpaired t-test or linear regression model. A p-value < 0.05 was considered to be statistically significant. The cost-effectiveness ratio of both groups was also calculated and compared.

Results

Between September 1, 2019 and August 31, 2020, 29 participants were enrolled, with 14 participants randomly assigned to the fESWT group and 15 to the insole group. No participants were withdrawn from the study. All participants' data were included in the analysis (Figure 1). Some baseline characteristics, including age, sex, and body mass index (BMI), were unbalanced between the groups. The fESWT group had a higher mean age (59.5 vs. 50.5) and percentage

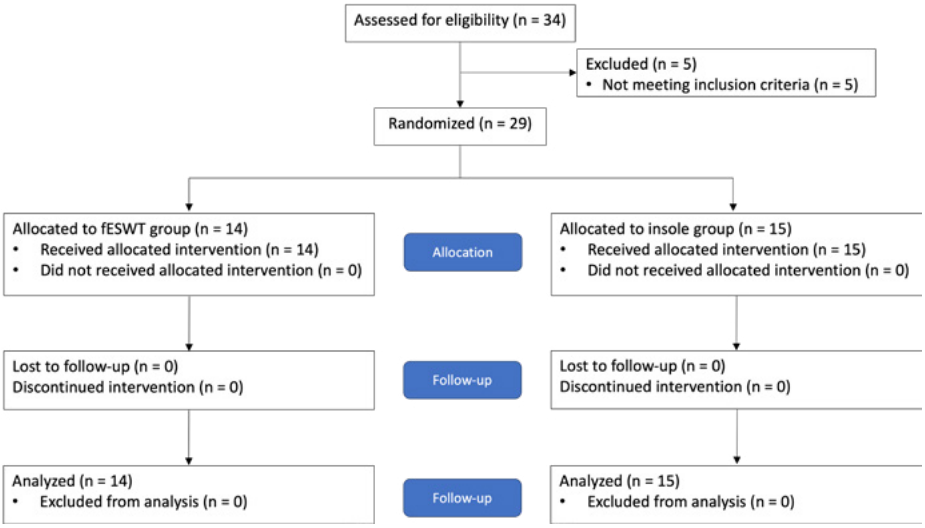

Figure 1. CONSORT diagram of the study

Table 1. Baseline and clinical characteristics by treatment group

	fESWT (n = 14)	Insole (n = 15)
Age (years)[1]	59.5 (15.2)	50.5 (13.8)
Sex, female[2]	13 (92.86)	10 (66.67)
BMI[1]	23.85 (4.34)	26.73 (3.30)
DM, Yes[2]	1 (7.14)	1 (6.67)
Affected foot, bilateral[2]	5 (35.71)	6 (40.00)
Onset, chronic[2]	10 (71.43)	10 (66.67)
Arch of foot[2]		
Normal	12 (85.71)	11 (73.33)
Low	2 (14.29)	3 (20.00)
High	-	1 (6.67)
Hours spent standing per day[1]	3.89 (1.68)	3.73 (2.15)
Hours spent walking per day[1]	3.57 (1.45)	3.73 (2.02)
Hours spent running per day[1]	0.07 (0.18)	0.13 (0.29)
Pretreatment FFI score[1]		
Pain	42.71 (8.88)	41.53 (9.96)
Disability	43.64 (12.19)	44.13 (19.09)
Activity limitation	0.5 (1.28)	1.2 (3.17)
Total	86.86 (19.36)	86.86 (28.57)

[1]Mean (SD), [2]n (%)

BMI, body mass index; DM, diabetes mellitus; FFI, Foot Function Index; fESWT, focused extracorporeal shock wave therapy

of females (92.9% vs. 66.7%) but had a lower mean BMI than the insole group (23.9 vs. 26.7). However, the mean total score of FFI at baseline was comparable between groups (Table 1).

The FFI scores of both groups showed normal distribution and equal standard deviation. There was no statistically significant difference in the mean FFI scores between the two groups over the 3 measures (p = 0.85) (Figure 2). The crude and adjusted mean differences (fESWT minus Insole) of the total improvement of FFI at week 12 were 0.2 (95%CI: -25.3 to 25.7) and 14.9 (95%CI: -15.4 to 45.2), respectively. Additionally, no statistically significant difference was found for each subscale of FFI as shown in Table 2.

The total cost for fESWT and for insoles was 2,043 and 897 baht per participant, respectively. The incremental cost

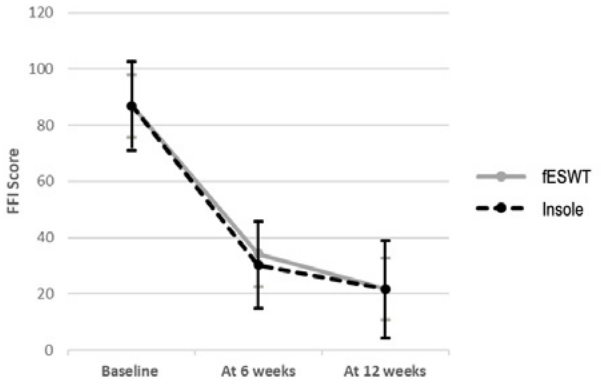

Figure 2. Mean (95%CI) FFI score at baseline, 6 and 12 weeks by treatment group

CI, confidence interval; FFI, Foot Function Index; fESWT, focused extracorporeal shock wave therapy

of fESWT over the insole was 1,146 baht, and the incremental cost per effectiveness ratio (ICER) of fESWT compared with the insole was 1,146 baht/14.9 FFI score or 77 baht/FFI score.

All participants in the fESWT group were able to complete all treatment sessions, and those in the insole group reported using the insoles for the entire study period. Regarding the use of non-steroidal anti-inflammatory drugs (NSAIDs) as a rescue analgesic during 12 weeks of the study, one participant in the fESWT group used a single tablet of NSAIDs, while one participant in the insole group used five tablets of NSAIDs. No adverse effects were reported or identified in any of the participants.

Discussion

To the best of our knowledge, this study is the first to evaluate the effectiveness of fESWT compared with prefabricated insoles among patients with subacute to chronic plantar fasciitis. The main results showed no statistically significant difference in FFI improvement at week 12 between the two groups in either crude or adjusted analysis. However, the adjusted mean difference of total FFI score (14.9 points)

was greater than the minimal important change (7 points).[26] Hence, if the sample size of the present study had been larger, the difference might have been statistically significant.

The findings of this study are similar to a study by Çağlar, which found that rESWT and customized insoles were effective modalities in pain reduction and foot function improvement in the treatment of plantar fasciitis, but that study found no difference in the short (4-week post-treatment) and midterm (12-week and 24-week post-treatment) effects between the two treatments.[27] It should be noted the Çağlar study used rESWT which might have been less effective than moderate-intensity fESWT. Additionally, the present study used prefabricated insoles which differs from the study by Çağlar, but there has been evidence that the effectiveness of prefabricated and customized insoles to treat PF is similar.[18,28]

It is important to consider whether fESWT has a beneficial carryover effect for PF because the participants in this study received fESWT only once a week for 3 weeks, while the prefabricated insoles were used for 12 weeks. A study by Wang reported that participants in the fESWT group had a better clinical outcome and lower recurrence rate than those in the control group who had received other conservative treatment at the long-term follow-up (60-72 months).[29] Another randomized clinical trial which compared rESWT with a sham in 50 patients with chronic PF reported a positive effect of ESWT on reduction of pain score and improvement of quality of life at 1, 3, 6, 12, and 24 weeks after treatment.[29] Importantly, no long-term complications were reported in either of these two studies.[29,30]

In the cost-effectiveness analysis, fESWT was approximately 2 to 3 times more costly compared to using prefabricated insoles. When an adjusted mean difference was calculated, the cost of ICER of fESWT compared to insoles was 77 baht per FFI score, i.e., an additional cost of 77 baht was incurred for each one point in the FFI score. However, there is no consensus about the use of ICER to determine whether fESWT is less cost effective than insoles or not. Hence, choice of treatment option for PF might depend on the financial status and human resources of each individual hospital.

Strengths of the present study include that the outcome measure was FFI, a valid and reliable clinical measurement widely used in the study of foot problems. Additionally, no participants withdrew from the study, so there was no missing data. Finally, the cost-effectiveness analysis reported might help physiatrists or other specialists in selecting treatment options for patients with PF.

Several limitations of the present study do, however, need to be noted. Due to COVID-19-related measures by the Thai government (e.g., lockdowns, inter-provincial travel restrictions) and the hospital's controls during the COVID-19 outbreak in 2020, the present study was not able to achieve the targeted sample size within the time available (one fiscal year of funding). Therefore, this study had only 40% statistical power to establish the statistical significance of the difference between the 2 interventions. In addition, the unequal baseline in age, sex, and BMI, requiring the use of linear regression in the statistical analysis, might have affected the clinical outcome. Extra physiotherapy sessions from other hospitals, level of compliance with stretching exercise recommendations, and time spent using the insoles were not monitored because this trial was designed as an effectiveness study (real-world practice), not an efficacy study (ideal and controlled circumstances). Additionally, the present study was not able to blind the participants regarding the treatments and FFI is a self-reported questionnaire that provides a subjective outcome. As a result, measurement bias probably occurred. Finally, all costs were calculated for a tertiary-care government hospital, so the results from this study might not be representative of other hospital settings in Thailand or elsewhere in the world.

Conclusions

The present study found no evidence that fESWT improved foot function index compared with prefabricated insoles among patients suffering from subacute and chronic plantar fasciitis. However, due to the small sample size, the study findings should be interpreted cautiously.

Disclosure

The authors declare that they have no conflicts of interest related to the materials and equipment used in this study.

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