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ORIGINAL ARTICLE

Effects of radial extracorporeal shockwave therapy versus high intensity laser therapy in individuals with plantar fasciitis: A randomised clinical trial

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Abstract

This study aimed to compare the effects of radial extracorporeal shockwave therapy (rESWT) to the effects of high-intensity laser therapy (HILT) in the treatment of individuals with plantar fasciitis. Thirty-two individuals with unilateral plantar fasciitis were randomized into two groups: rESWT and HILT. In each group, the individuals underwent the intervention two sessions per week, for three weeks. Outcome measures included morning pain, resting pain, pain at 80 newtons (N) pressure, skin blood flow and temperature, plantar fascia (PF) and flexor digitorum brevis (FDB) thickness, and Foot Function Index (FFI). There was no significant difference in baseline characteristics of the individuals in both groups. All outcome measures, except skin blood flow and temperature, and FDB thickness, were significantly different ($p < 0.05$) over time. Skin blood flow was significantly different between groups at the end of the program. Either HILT or rESWT could alleviate pain in individuals with plantar fasciitis significantly. However, HILT was better at reducing FFI (functional limitation domain) rather than rESWT. This study was a randomized clinical trial and was approved by Mahidol University-Central Institutional Review Board (MU-CIRB) following the Declaration of Helsinki, COA no. MU_CIRB 2020/207.0412, the Thai Clinical Trials Registry (TDTR) numbered TCTR2021012500.

Keywords Plantar fasciitis · High-intensity laser · Radial extracorporeal shockwave · Physiotherapy

Introduction

Plantar fasciitis is a common heel pain that accounted for 10–15% of all foot conditions [1]. The most common complaints, sharp and stabbing pain, are usually found at the first step in the morning or after prolonged resting or by palpation of the inferomedial part of the calcaneus [2–4]. The burdens caused by plantar fasciitis were reported in terms of its high prevalence and economic impacts [5]. The management of plantar fasciitis includes pain alleviation and improvement of foot-related functional outcomes [6]. For conservative treatments, several treatments are commonly used such as physical therapy, calf and plantar fascia stretching, anti-inflammatory medicine, and corticosteroid injection [7]. However, the most effective approach is yet unanswered.

Either radial extracorporeal shockwave therapy (rESWT) or high-intensity laser therapy (HILT) has been used for plantar fasciitis. Due to its mechanical effect, previous rESWT studies were promising for pain reduction in treating plantar fasciitis [8–10]. Also, HILT has been reported its therapeutic benefits such as analgesic, anti-inflammatory, and anti-edematous effects owing to its photobiomodulation effect [11]. Even though those two interventions generate therapeutic ingredients based on different mechanisms, the objective of using rESWT and HILT is the same for clinicians in alleviating pain in individuals with plantar fasciitis.

Besides plantar fasciitis, rESWT and HILT were reported to be effective modalities for the management of other musculoskeletal disorders as well [1, 12–17]. Although numerous studies are showing the effectiveness of rESWT and HILT for the treatment of musculoskeletal disorders including plantar fasciitis, the decision making for selecting either

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rESWT or HILT for managing plantar fasciitis is still unclear since the study to directly compare the effectiveness of rESWT versus HILT in terms of pain, foot function, and other clinical outcomes await formal comparative investigation. For clinicians' decision making, there are some limitations, for example, time, human resource, and the effectiveness concerning selecting each modality for plantar fasciitis management. Therefore, this study aimed to compare the effects of rESWT to the effects of HILT in the treatment of individuals with plantar fasciitis.

Methods

This study was a randomized clinical trial and was approved by Mahidol University-Central Institutional Review Board (MU-CIRB) following the Declaration of Helsinki, COA no. MU_CIRB 2020/207.0412, the Thai Clinical Trials Registry (TDTR) numbered TCTR2021012500. For eligibility assessment, 193 individuals were recruited, however, 128 individuals were excluded because of unmet inclusion criteria, and 33 individuals declined to participate. The 32 individuals with unilateral plantar fasciitis were eligible in accordance with the power analysis and recruited at XXX from May 2021 until December 2021, Fig. 1. The inclusion criteria were pain at medial calcaneal tuberosity, unilateral (VAS $\geq$ 2/10), pain at the first step in the morning (VAS $\geq$ 2/10), and age $\geq$ 18. The exclusion criteria were musculoskeletal disorders such as Tendo Achilles (TA) rupture, ankle osteoarthritis, prior surgery or metal implant in the lower back and lower limb, acute plantar fasciitis or having severe pain (P10/10), or unable to bear weight or positive result of Ottawa's rule, pain medication within one week before participation, red flags, precautions/contra-indications, and systemic diseases such as cancer, autoimmune disease, vascular disease or observable skin change, infected area, coagulation disorders, diabetes-related, steroid (injection and oral), tattoo at plantar area, nerve or neurologic impairments, pregnancy, BMI $\geq$ 30, physical or mental disorders. All individuals provided informed written consent. The case managers had roles in interviewing the individuals and assigning them after concealed block randomization technique regarding age- and gender-matched into two groups. The physical therapist performed a physical examination to detect the plantar fascia tenderness in the medial tubercle of the calcaneus. Sample size calculation, based on the data of pain intensity when taking the first steps from the previous study, Aqil et al., 2013 [8]. The alpha level was set 5%, power 90%, and effect size 1.5, and then the calculated sample size of 22 subjects in total was needed to see the

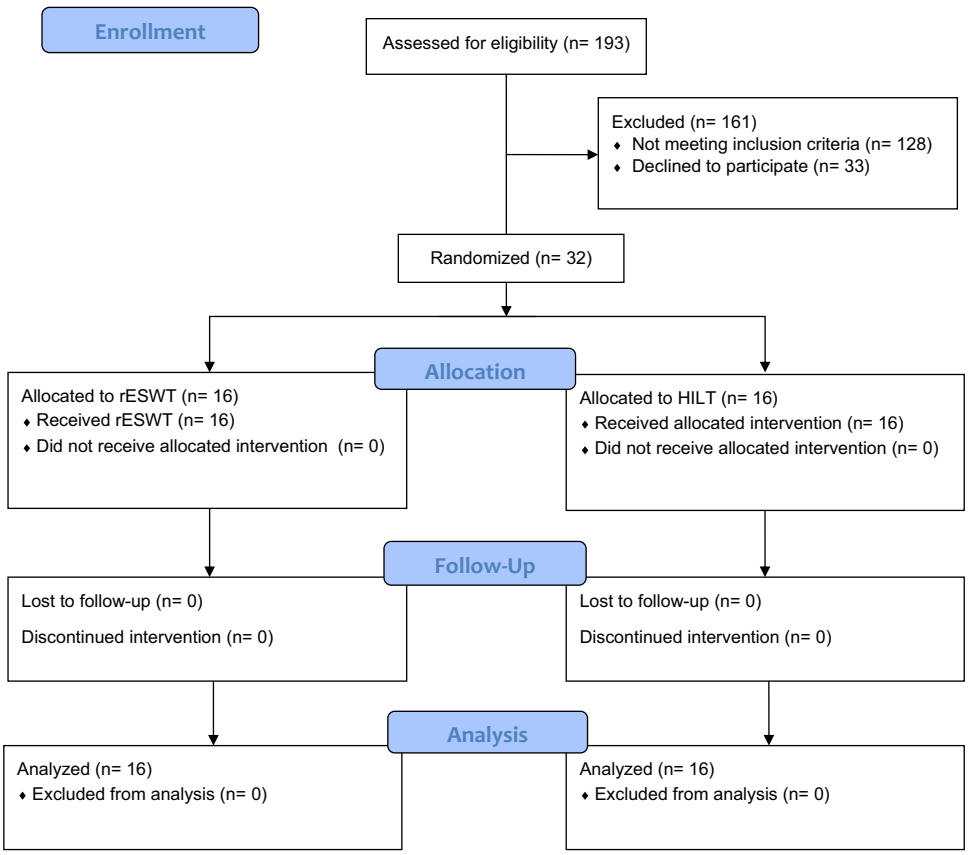

Fig. 1 Flow chart of the study

difference between groups. However, 10 individuals were recruited additionally to cover all possible missing values that might happen. Therefore, 32 subjects in total, or 16 subjects per group participated this study.

Random assignment and blinding

The case managers randomized the individuals into two groups by using the concealed block randomization technique considering age-, and gender-matched. The assessor and the individuals were blinded to intervention allocation. The therapists were blinded to the measured values.

Outcome measurement tools

Primary outcomes

The primary outcomes in this study was pain in three aspects: morning pain, resting pain, and pan at 80 newtons (N) pressure. Visual analog scale (VAS) which is a valid and reliable outcome measure was used for pain assessment [18].

Morning pain and resting pain The individuals rated the pain scores at the first step in the morning (morning pain) and after prolonged resting (resting pain), of which 0 represents no pain and 10 is the worst pain imaginable by using the 10-cm VAS.

Pain at 80 N pressure The individuals were prone lying with their feet on the edge of a couch. The assessor placed the probe of the handheld algometer [19] on the most painful spot perpendicularly, which was at the medial calcaneal tuberosity. The measurement researcher applied the pressure at 80 N/cm2 at a speed of 10 N/s (pain at 80 N). Then the individuals rated the VAS scores.

Secondary outcomes

Skin blood flow and temperature assessment An assessor who has been trained in assessing skin blood flow and temperature using a Laser Doppler flowmetry (LDF) (Moor Instruments Ltd, Devon, UK) measured blood flow in perfusion unit (PU) and temperature in degrees Celsius (^{o}C). The data was calculated mathematically by using moorVMS-PC software. The individuals were prone with their feet at the edge of a plinth. The probe was placed on the most painful spot. The data were recorded for 10 s, and the average value was calculated to minimize the variability of data and used for data analysis [20]. The intra-tester reliability from the pilot study represented with ICC3,1 (95% CI); blood flow was 0.867 (0.556—0.965) and the temperature was 0.866 (0.551—0.965).

Thickness assessment An assessor who is experienced in musculoskeletal imaging used a B-mode ultrasound imaging device (USI; model CX50, Philips, NV, USA) with a broadband linear array (model L12-3) transducer for measuring the thickness of plantar fascia (PF) and flexor digitorum brevis (FDB) in the sagittal plane. FDB thickness was also measured because *FDB* plays an important role in distributing pressure away from the *plantar* fascia [21]. The individuals were positioned prone lying with their feet at the edge of a plinth. The transducer was placed perpendicularly over the PF on the medial tubercle of the calcaneus (insertion of the plantar fascia) and repeated three times. The average value was used for data analysis. In terms of assessing FDB thickness, the probe was placed perpendicularly at the center of the foot on the cross-sectional area (CSA) line and repeated 3 times. The average value was used for data analysis. The intra-tester reliability pilot study represented with ICC3,1 (95% CI); PF thickness was 0.920 (0.787—0.977) and FDB was 0.961 (0.891—0.989).

Foot function index (FFI) questionnaire, Thai version The individuals filled in the questionnaire comprising three domains. The previous study about the Thai version of FFI showed that the internal consistency and test–retest reliability were at a good to an excellent level, also the correlations with pain level and criterion validity with EuroQol (5-dimension) questionnaire were at moderate to a strong level [22].

Intervention procedures

Radial extracorporeal shockwave therapy (rESWT)

The radial extracorporeal shockwave (BTL-6000 SWT, BTL Corporate, United Kingdom) was used by the experienced physical therapist with the protocol were following: pressure 2–3 bars, frequency 10 Hz, 2000 shocks each session in a total of six sessions (two sessions/week). The individuals were prone and their ankle was at the edge of the couch. The physical therapist localized the most painful spot and applied the probe around the painful spot for 500 shocks. Then, 1000 shocks were applied at the most painful spot in a circular motion and the last 500 shocks were applied along plantar aponeurosis.

High-intensity laser therapy (HILT)

The high-intensity laser (SH1, ASA Srl, Italy) was used by the experienced physical therapist for a total of six sessions, three weeks (two sessions/week). The individuals in this group received pulsed Nd: YAG with a wavelength of 1064 nm, maximum average power of 6 W, energy density (fluence) of 5 J/cm^2, and a pulse duration was up to 250 µs. The diameter of the probe is 5 mm. In this study, HILT was performed in three phases. The initial phase was

a fast manual scanning along the tenderness area of plantar aponeurosis, 12 cm^2 approximately, with a total energy of 60 J, two minutes. In the intermediate phase, HILT was applied on the most painful spots from palpation, six times separately,one minute approximately, with a total energy of 30 J. The final phase was considered as a slow manual scanning, yet applied on the plantar aponeurosis as the initial phase with a total energy of 60 J, two minutes. The total energy in one session was 150 J., which took approximately five minutes. During these three phases, the probe was vertical to the treatment area and individuals were prone with their ankles at the edge of the couch. During the treatment, the individuals wore safety goggles for eye protection.

Study procedure

Baseline assessments were performed by an experienced physical therapist including pain assessment, which is pain at the first step in the morning (morning pain), pain after prolonged resting (resting pain), and pain at constant load pressure of 80 N (pain at 80 N), skin blood flow and skin temperature, PF and FDB thickness, and FFI. The individuals were randomly allocated into 2 groups and underwent the randomly-assigned interventions, either rESWT or HILT, two visits per week, three weeks, and six visits total. The assessments for primary outcomes were performed four times: baseline (T0), immediately after the first session (T1), at the end of the first week (T2), at the end of the second week (T3), and at the end of the program (T4), except for morning pain that was measured at T0, T2, T3, and T4. All secondary outcomes were measured at T0 and T4. According to the data collection, there were no drop-outs in this study, by which the intention-to-treat analysis has been planned, therefore, the data from all individuals were analyzed. The flow chart of the study is shown in Fig. 1.

Statistical analysis

The demographic data was presented in mean and standard deviation, except for the gender, of the individuals. Data analysis was performed using the SPSS program version 23.0 (IBM Corp., Armonk, NY, USA), and the significant p-value was set at < 0.05 for all comparisons. Data distribution was checked with the Shapiro–Wilk test, which was normally distributed. Two-way mixed analysis of variance (ANOVA) with repeated measures was used to analyze the effect of time, group, and interaction effect of time x group. If the effect was significant, the multiple comparisons by using repeated measures and Bonferroni post-hoc test were done for within-group comparisons and an independent t-test for comparing between groups.

Results

Baseline characteristics of the individuals between the two groups in terms of age, gender, weight, height, BMI, and duration of symptoms had no significant difference ($p > 0.05$), as shown in Table 1.

Comparisons of the outcomes

Primary outcomes

Main effect of group: no main effect of group was found on morning pain [F (1, 30) = 1.482, $p = 0.233$], resting pain [F (1, 30) = 1.767, $p = 0.194$], pain at 80 N [F (1, 30) = 0.100, $p = 0.755$], as shown in Table 2.

Main effect of time: there was a significant main effect of time on morning pain [F (3, 90) = 30.477, $p < 0.001$], resting pain [F (4, 120) = 20.658, $p < 0.001$], and pain at 80 N [F (4, 120) = 22.604, $p < 0.001$], as shown in Table 2.

Interaction effect of time x group: no interaction effect of time x group was found in morning pain [F (3, 90) = 0.790, $p = 0.503$], resting pain [F (4, 120) = 0.756, $p = 0.556$], pain at 80 N [F (4, 120) = 0.225, $p = 0.924$], as shown in Table 2. Pairwise comparison for post-hoc test of the mean of primary outcomes: morning pain, resting pain, and pain at 80 N has been shown in Table 3.

Secondary outcomes

Main effect of group: skin blood flow [F (1, 30) = 4.476, $p = 0.043$], skin temperature [F (1, 30) = 0.029, $p = 0.865$], PF thickness [F (1, 30) = 0.739, $p = 0.397$], FDB thickness [F (1, 30) = 0.051, $p = 0.822$], FFI pain [F (1, 30) = 4.865, $p = 0.050$], FFI activity [F (1, 30) = 1.476, $p = 0.051$], FFI

Table 1 Characteristics of the individuals ($n = 32$)

Characteristics	rESWT ($n = 16$)	HILT ($n = 16$)
Age (years)	48.12 (11.96)	46.06 (8.55)
Gender (Female/Male)	8/8	8/8
Weight (kg.)	65.96 (11.01)	64.36 (9.03)
Height (cm.)	164.31 (6.33)	164.68 (9.70)
BMI	24.00 (3.01)	23.69 (1.91)
Duration of symptoms (months)$^{\beta}$	12.00 (11.25)	8.00 (21.00)

rESWT radial extracorporal shockwave therapy group, *HILT* high-intensity laser therapy group.

$^{\beta}$ reported in median (interquartile range).

Table 2 Mean (standard deviation) of primary outcomes; morning pain, resting pain, and pain at 80 N and within-group comparison ($n=32$)

Time of measurement Variables	Group	T0	T1	T2	T3	T4	Within-group *p*
Pain intensity (cm.)							
- Morning pain	rESWT	5.57 (2.44)	-	5.20 (2.79)	3.23 (2.58)	2.79 (2.65)	**< 0.001***
	HILT	5.11 (2.51)	-	3.68 (2.36)	2.48 (2.06)	1.90 (2.02)	**< 0.001***
- Resting pain	rESWT	4.75 (2.26)	3.65 (2.72)	4.65 (2.72)	3.11 (2.39)	2.60 (2.70)	**< 0.001***
	HILT	4.58 (2.45)	2.57 (1.44)	3.55 (2.87)	2.02 (1.46)	1.55 (1.55)	**< 0.001***
- Pain at 80 N	rESWT	5.19 (3.24)	4.34 (2.87)	3.96 (3.02)	2.64 (2.79)	2.33 (2.46)	**< 0.001***
	HILT	5.13 (2.39)	4.27 (2.18)	3.80 (2.23)	2.44 (1.95)	1.65 (1.92)	**< 0.001***

rESWT radial extracorporal shockwave therapy group, *HILT* high-intensity laser therapy group, *T0* baseline, *T1* immediately after the 1st session, *T2* end of the 1st week, *T3* end of the 2nd week, *T4* end of the program, significance tested at $p<0.05$., * denotes significant difference.

Table 3 Pairwise comparison of the mean of primary outcomes; morning pain, resting pain, and pain at 80 N (n = 32)

Time of measurement Variables	Group	T0 vs T1 *p*	T0 vs T2 *p*	T0 vs T3 *p*	T0 vs T4 *p*	T1 vs T2 *p*	T1 vs T3 *p*	T1 vs T4 *p*	T2 vs T3 *p*	T2 vs T4 *p*	T3 vs T4 *p*
Pain intensity (cm.)											
- Morning pain	rESWT	N/A	1.000	**0.005***	**0.003***	N/A	N/A	N/A	**0.005***	**0.003***	1.000
	HILT	N/A	0.111	**0.004***	**0.001***	N/A	N/A	N/A	**0.011***	**0.006***	0.077
- Resting pain	rESWT	0.231	1.000	0.055	**0.014***	0.715	1.000	0.738	**0.029***	**0.018***	1.000
	HILT	**0.007***	0.514	**0.004***	**0.002***	0.277	1.000	0.054	**0.033***	**0.005***	0.452
- Pain at 80 N	rESWT	0.567	0.367	**0.015***	**0.012***	1.000	0.060	**0.023***	0.065	**0.017***	1.000
	HILT	1.000	0.575	**0.009***	**0.007***	1.000	**0.025***	**0.013***	0.071	**0.008***	0.957

rESWT radial extracorporal shockwave therapy group, *HILT* high-intensity laser therapy group, *T0* baseline, *T1* immediately after the 1st session, *T2* end of the 1st week, *T3*: end of the 2nd week, *T4* end of the program, significance tested at $p<0.05$.

* denotes significant difference.

functional limitation [F (1, 30) = 3.495, $p=0.071$], FFI total score [F (1, 30) = 1.610, $p=0.051$], as shown in Table 4.

Main effect of time: skin blood flow [F (1, 30) = 0.739, $p=0.397$], skin temperature [F (1, 30) = 0.474, $p=0.496$], PF thickness [F (1, 30) = 13.262, $p<0.001$], FDB thickness [F (1, 30) = 1.506, $p=0.229$], FFI pain [F (1, 30) = 33.816, $p<0.001$], FFI activity [F (1, 30) = 40.044, $p<0.001$], FFI functional limitation [F (1, 30) = 8.591, $p=0.006$], FFI total score [F (1, 30) = 39.172, $p<0.001$], as shown in Table 4.

Interaction effect of the time x group: skin blood flow [F (1, 30) = 2.721, $p=0.109$], skin temperature [F (1, 30) = 0.055, $p=0.816$], PF thickness [F (1, 30) = 0.637, $p=0.431$], FDB thickness [F (1, 30) = 0.055, $p=0.816$], FFI pain [F (1, 30) = 0.068, $p=0.796$], FFI activity [F (1, 30) = 0.005, $p=0.944$], FFI functional limitation [F (1, 30) = 0.010, $p=0.922$], FFI total score [F (1, 30) = 0.030, $p=0.863$], as shown in Table 4.

T0 baseline, *T4* end of the program, significance tested at $p<0.05$. * denotes significant difference.

Discussion

This study has found that the average age of individuals with PF was 46 years, which was similar to the previous study indicating that middle-aged people were the most prevalent group in this condition [23]. Regarding the between-group difference of gender and age, there were no differences between the two groups due to age and gender match.

Pain, this study investigated three aspects of pain comprising morning pain, resting pain, and pain at 80 N representing pain aggravated from palpation. The results found that there were statistically significant differences within the group in all three aspects of pain, while the between-group difference was not found. This study indicated that either rESWT or HILT was able to decrease pain effectively in individuals with plantar fasciitis after the end of the

Table 4 Mean (standard deviation) and pairwise comparison of secondary outcomes; skin blood flow, skin temperature, thickness, and FFI ($n=32$)

Time of measurement Variables	Group	T0	T4	T0 vs T4 *p*
Skin blood flow (PU)	rESWT	53.84 (70.74)	74.16 (50.70)	N/A
	HILT	37.11 (22.86)	30.72 (21.67)	N/A
	p	0.375	**0.005***	
Skin temperature (°C)	rESWT	24.77 (2.17)	24.59 (1.43)	N/A
	HILT	24.79 (1.76)	24.42 (1.17)	N/A
Thickness (cm.)				
- PF	rESWT	0.38 (0.11)	0.35 (0.10)	**0.007***
	HILT	0.41 (0.11)	0.39 (0.12)	**0.046***
- FDB	rESWT	0.60 (0.13)	0.61 (0.11)	N/A
	HILT	0.59 (0.12)	0.61 (0.11)	N/A
FFI				
- Pain	rESWT	39.08 (10.32)	20.07 (18.87)	**0.002***
	HILT	32.15 (13.17)	11.37(11.85)	**< 0.001***
- Activity	rESWT	43.15 (15.67)	21.66 (21.79)	**0.001***
	HILT	31.86 (14.39)	9.89 (10.30)	**< 0.001***
- Functional limitation	rESWT	6.64 (5.84)	4.05 (6.33)	0.105
	HILT	3.84 (5.11)	1.07 (1.73)	**0.018***
- Total scores	rESWT	88.87 (27.39)	45.78 (45.08)	**0.001***
	HILT	67.87 (27.70)	22.32 (21.16)	**< 0.001***

rESWT radial extracorporal shockwave therapy group, *HILT* high-intensity laser therapy group, *PF* plantar fascia, *FDB* flexor digitorum brevis, *FFI* Foot Function Index, *N/A* not available, [a b]: different labels represent significant pairwise difference within group (time effect).

program, while HILT could alleviate all three aspects of pain after second week. In addition, it has been found clinically significant differences due to the reduction of VAS, which is over two cm. greater than the previous study that proposed 0.8 cm [24]. Therefore, these two interventions could effectively decrease pain for the management of plantar fasciitis regarding pain at the first step in the morning, pain after prolonged resting, and pain under the constant pressure of 80 N. For pain reduction, the plausible mechanism of rESWT is related to acoustic mechanical waves inducing neovascularization, the release of angiogenetic factors, and the reduction of inflammatory mediators [7]. Thus, pain relief and functional improvement have been found beneficial in treating plantar fasciitis [15, 29]. For HILT, it provides slow light absorption by chromophores, resulting in ATP synthesis enhancing tissue healing [15, 17, 25–27].

Skin blood flow which was considered a parameter for investigating the mechanism of the interventions, there were statistically significant differences between rESWT and HILT at the end of the program. The HILT group had a significantly lower skin blood flow compared to the rESWT group. These results demonstrated the different physiological effects of the two interventions. HILT has played an important role in reducing inflammatory processes as anti-inflammatory via photochemical effects [16]. While, rESWT has a significant role in neovascularization [9]. The higher skin blood flow was therefore observed in the rESWT group.

In another parameter, skin temperature, there was no difference within the group or between groups. This result reflected a small effect size of skin temperature in the heel area. This might be because of the small amount of blood over the heel area that insufficiently makes an obvious change in skin temperature.

PF thickness was reported to be associated with foot dysfunction [28]. In this study, a significant reduction has been found over time in both groups, while the difference between groups was not detected. There were several studies indicating the reduction of PF thickness after using rESWT. The previous studies have found that plantar fascia thickness decreased significantly after using rESWT at a one-month follow-up assessment [29, 30]. Also, there was a previous study reporting the effectiveness of rESWT in reducing PF thickness after a six-month follow-up assessment [31]. However, to recent literature, there was no previous study investigating HILT in reducing PF thickness, this study found a significant reduction in PF thickness from HILT. Since the average thickness of plantar fascia to be considered as plantar fasciitis is up to 4 mm [32], Both rESWT and HILT interventions can penetrate deeper more than 4 cm [33–35], which can be confirmed in reaching the area of treatment.

However, for FDB thickness, there was no difference within and between groups. The hypothesis was about the increase of FDB thickness after the treatment program because of the increase of FDB activation after pain alleviation, anyhow, the FDB thickness increase was not detected, this might represent that the recovery from pain is not sufficient, and strengthening exercise is perhaps needed.

Considering the three scales of the FFI questionnaire: pain scale, disability scale, and functional limitation scale. There were significant differences over time in all three scales and total scores, except for the functional limitation scale in the rESWT group. While there was no difference between groups. These findings suggested that rESWT and HILT reduced disability and improved quality of life in individuals with plantar fasciitis.

This study reported no adverse events during or after the applications of rESWT and HILT. The results of this study could be generalized to the individuals with plantar fasciitis who undergo the intervention program either rESWT or HILT.

Limitations of the study

This study was limited by sample size, lack of control group and follow-up period. Also, this study found pain reduction in both rESWT and HILT groups without significant difference between groups. The future study might investigate cost effectiveness between those two interventions, or add other clinical outcomes or physiological outcomes to detect the difference according to their different therapeutic mechanisms for clinical decision making.

Conclusion

This study proved that either rESWT or HILT can successfully reduce all three aspects of pain within six sessions of the interventions, no intervention was superior to the other regarding pain management. However, HILT seemed to be better in reducing FFI (functional limitation) after six sessions of the intervention program. It was found that either rESWT or HILT can alleviate pain and other clinical variables. Therefore, clinicians can select either rESWT or HILT for managing pain and disability according to their expertise and the availability of the instruments.

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Draft manuscript preparation: Chutiporn Thammajaree, Montartip Theapthong, Prasert Sakulsriprasert.
All authors reviewed the results and approved the final version of the manuscript.

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Data availability The data that support the findings of this study are available on request from the corresponding author.

Declarations

Conflict of interest All authors in this study declare no conflict of interest.

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