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The effect of high-intensity versus low-level laser therapy in the management of plantar fasciitis: randomized participant blind controlled trial

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Abstract

Objectives: To evaluate and compare the efficacy of high-intensity laser therapy (HILT) and low-level laser therapy (LLLT) for plantar fasciitis.

Design: A participant blind randomized controlled trial with parallel group design and an active comparator with follow-up at four weeks.

Settings: Outpatient, University hospital.

Subjects: Unilateral plantar fasciitis participants ($n = 102$) were randomly assigned into two groups. Recruitment period was from January 2017 to April 2019.

Interventions: Interventions included eight sessions of laser therapy over three weeks and single session of patient education. The HILT group ($n = 51$) received HILT and the LLLT group ($n = 51$) received LLLT.

Main measures: Primary outcomes: visual analogue scale; secondary outcomes: pressure algometry, sonography of plantar fascia thickness (time frame: baseline to three-week and four-week follow-up) and numeric rating scale (0%–100%) for opinion of participants on effect of treatment (time frame: three weeks). Data presented: mean (SD) or *n* (%).

Results: There was no statistically significant difference between the groups according to visual analogue scale (pain in general reduction in three weeks: 2.57(3.45) vs. 2.88(3.28) cm), pressure algometry (pain threshold difference between healthy and affected heel reduction in three weeks: 1.80(6.39) vs. 1.77(2.85) kg) and sonography measurements (plantar fascia thickness difference between healthy and affected heel reduction in three weeks: 0.19(0.56) vs. 0.30(0.57) mm). There was a statistically significant difference between the groups in participants' opinion in favor to HILT group (efficacy of treatment better than 50%: 26(51%) vs. 37(73%)).

Conclusion: No statistically significant difference between groups was observed.

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Introduction

Conservative therapy provides significant relief in approximately 90% of patients with plantar fasciitis,[1] but there is neither golden standard nor unified algorithm for the treatment of plantar fasciitis. Clinical studies conclude that the low-level laser therapy (LLLT) is a promising treatment of chronic plantar fasciitis.[2,3] In 2019, a systematic review with meta-analysis of six studies concluded that the LLLT in patients with plantar fasciitis significantly relieves heel pain and the excellent efficacy lasts for three months after treatment.[4]

To the best of our knowledge, to date, only one clinical trial has evaluated the effectiveness of different laser therapies in plantar fasciitis treatment. The conclusions were made that both high-intensity laser therapy (HILT) and LLLT improve pain levels, function and quality of life in individuals with plantar fasciitis, but HILT has a more significant treatment effect than LLLT on plantar fasciitis.[5] Another recent randomized placebo-controlled study that aimed to evaluate the efficacy of HILT on pain, quality of life, foot function and plantar pressure in the treatment of patients with plantar heel pain with calcaneal spur found that all evaluated parameters, except dynamic pedographic measurements, have improved in both groups and results showed no superiority of HILT over placebo.[6] However, it was recommended to add laser treatment along with exercise in case who have documented gait disorder with concurrent pain complaint.[6]

LLLT seems to be an appropriate treatment of plantar fasciitis. There is very little data on the use of HILT to treat plantar fasciitis and the conclusions are controversial. The main aim of this study was to evaluate and compare the efficacy of HILT and LLLT for plantar fasciitis. The secondary objective was to evaluate and compare opinion of participants on effect of treatment using HILT and LLLT.

Methods

The study was a single-centered single (participant) blinded randomized controlled trial with parallel group design with follow-up at four weeks conducted at The Hospital of Lithuanian University of Health Sciences Kaunas clinics, Department of Rehabilitation (Kaunas, Lithuania). This study was carried out in accordance with the World Medical Association Declaration of Helsinki.[7] It was approved by the local ethical board (Kaunas Regional Biomedical Research Ethics Committee No. BE-2-32), registered at ClinicalTrials.gov (NCT03873961) and drawn up in accordance with the CONSORT statement guideline. The Lithuanian University of Health Sciences was responsible for oversight of study conduct and governance. Patients were recruited consecutively from the waiting list of the outpatient care unit. Recruitment period was January 2017 to April 2019. Patients were assessed and enrolled in this study, if they fit the criteria and gave consent to participate.

Inclusion criteria:

- Unilateral plantar heel pain lasting for at least one month, mainly during the first few steps upon rising in the morning, which worsens with increased weight-bearing activity through the day;
- Tenderness at the insertion site of the plantar fascia on the calcaneus;
- Patients aged from 18 to 85 years.

Exclusion criteria:

- Bilateral heel pain;
- History of laser therapy already applied for this heel pain episode;
- Diagnosis of other heel pathology (calcaneal stress fracture, osteomyelitis, plantar fascia neoplasm, plantar fascia rupture, etc.);

- History of recent trauma or foot surgery;
- Wounds, infections in the treatment area;
- Impaired sensation in the treatment area;
- Pigmentation changes on the skin in the treatment area (tattoo, birthmarks);
- Implanted metal constructions in the treatment area;
- Received oral or injected corticosteroids within the last six weeks;
- Diagnosis of neurological heel pain (radiculopathy);
- Diagnosis of systemic inflammatory arthritis (goat, rheumatoid arthritis, etc.);
- Other acute pathology (febrile fever, cold. etc.) that require treatment;
- Other painful conditions that require painkillers (tooth pain, back pain, etc.);
- Pregnancy;
- Oncology.

Following screening, enrollment and baseline assessment, participants were randomized to HILT or LLLT group. Randomization sequence was created using SPSS statistical software and was stratified by center with a 1:1 allocation using random block sizes of four. The group allocations were kept secret using sealed opaque envelopes. After the initial evaluation, the allocation scheme was revealed to the physical medicine and rehabilitation physician who applied the treatment. The design of the single blind study where only the physical medicine and rehabilitation physician, who performed the intervention and carried out the evaluations, knew which laser was chosen for treatment. Participants were informed that they will receive treatment with laser. Participants were not informed which laser (HILT or LLLT) was administered.

Pain evaluation according to visual analogue scale was considered to be the primary outcome, other measurements were considered to be secondary outcomes. The following measurements were taken by physical medicine and rehabilitation physician before, immediately after eight procedures and one month after treatment was finished (time frame: baseline to three-week and four-week follow-up).

- Visual analogue scale (cm). Heel pain in general and in specific day time (first morning step, several minutes after first step, first step after prolonged sitting in the middle of the day and in the evening) was evaluated by measuring pain intensity using visual analogue scale from 0 to 10.0 cm ("0" = no pain and "10.0" = the most intense pain).[8,9]
- Pressure algometry (kg/cm^2). Pressure algometry was performed on both affected and healthy feet. Algometry measurements were done in standardized prone position with the feet hanging from the examination table. Pressure pain threshold was measured with algometer (Pain Test FPX 25) using 1-cm² rubber tip on the middle of anatomical site of enthesis zone of plantar fascia to the heel.[10,11] Pressure was applied slowly until the participant first felt the pain and responded by saying "stop." In each heel, there were three measurements taken with 30 seconds break after each measurement. The average of all three measurements in each heel was recorded as a final value.
- Sonography (mm). Ultrasound measurements were done in standardized prone position with the feet hanging from the examination table.[12] Acoustic gel was applied to the plantar surface of the heel. The focus was adjusted to the depth of plantar fascia. The plantar fascia thickness was measured at the point of plantar fascial insertion into the calcaneus with ultrasound machine in longitudinal view of tendon in both affected and healthy feet (mm).[13,14] The quantitative measurement was achieved by recording the thickest part measured.
- Anti-inflammatory drug intake. Participants were actively asked if they take anti-inflammatory drugs to reduce the pain. We did not allow the use of pharmacological pain therapies during the study.[15,16]

The opinion of participants on the effect of treatment was evaluated once immediately after the treatment (time frame: three weeks).

- Numeric rating scale (0%–100%). Subjects were asked to evaluate their satisfaction and the

Table 1. Interventions used in clinical trial.

Group	LLLT group	HILT group
Laser therapy parameters	LAS-expert (PHYSIOMED)	BTL-6000 high intensity laser 12 W (BTL)
Light source type	Infrared	Infrared
Laser class	3B	4
Wavelength	785 nm	1064 nm
Applicator	Shower applicator	10-mm pen applicator
Power per diode	50 MW	7 W
Number of diodes	14	1
Mode	Pulsed (50%); 50–60 Hz	Continuous
Energy density	4.0 J/cm²	120 J/cm²
Total energy per session	140 J	3000 J
Beam area	35 cm²	25 cm²
Treatment time	6 minutes 40 seconds	7 minutes 8 seconds
Session number	Procedures done three times per week (Monday, Wednesday and Friday), in total of eight procedures	
Patient education	Self-help strategies at home: shoes with soft pad, foot sole massage, exercise and icing	

HILT: high-intensity laser therapy; LLLT: low-level laser therapy.

effect of treatment with the laser on a scale of 0%–100% ("0" = no effect; very dissatisfied and "100" = cured; very satisfied).

Interventions were provided by trained physical medicine and rehabilitation physicians individually to each participants. Interventions included eight sessions of laser therapy over three-week period and a single session of patient education immediately after the first laser therapy session. The HILT group received patient education and HILT. The LLLT group received patient education and LLLT.

HILT was applied to plantar fascia with the parameters that are described in Table 1. A handpiece endowed with fixed spacer was used to provide the same distance to the skin and perpendicularity to the zone to be treated with laser beam. Two phases of treatment were performed for every session. The first phase involved manual slow scanning over medial border of plantar fascia for 2 minutes (840 J). The second phase involved fast scanning of anatomical site of enthesis zone of plantar fascia to the heel and whole heel scanning for 5 minutes 8 seconds (2160 J).

LLLT was applied to plantar fascia with the parameters that are described in Table 1. A shower applicator was applied touching the skin perpendicularly to the zone to be treated with laser beam. Two phases of treatment were performed for every session. The first phase involved manual slow scanning over medial border of plantar fascia for 1 minute (21 J). The second phase involved slow scanning of anatomical site of enthesis zone of plantar fascia to the heel and whole heel scanning for 5 minutes 40 seconds (119 J).

Patient education was carried out on the first day of participation in the trial. All participants were informed to avoid using anti-inflammatory drugs. In the case of anti-inflammatory drug use during the study, participants were excluded from study. In the case of increase in pain, icing was recommended to relieve the pain instead of anti-inflammatory drugs.[17,18] The smashed ice wrapped in towel should be applied on the plantar heel area for 10 minutes. If necessary, the procedure should be repeated after 10 minutes. All participants were recommended to wear shoes with soft pad or wear a silicone insole under the heel,[19,20] to increase heel height from 0 to 5.08 cm,[21] and were discouraged

to walk with bare foot on firm surfaces. Foot sole massage for both feet was recommended to relax plantar fascia and tense sole muscles.[22] Exercises to increase the range of motion in the first metatarsal and ankle joints were recommended.[23–25] Participants were given a leaflet with the information to remind them what must be done at home.

The number of participants included in this study was determined based on a visual analogue scale and algometry. The minimal important difference for the visual analogue scale was −1.9 cm for first-step pain on the 10-cm visual analogue scale.[26] Differences in pressure pain threshold measurements of more than 17.39 N/cm (1.77 kg/cm) are likely to exceed the magnitude of measurement error and could be used to indicate true change.[27] The sample size was based on a power of 80% (beta 0.2), a dropout rate 10% and a statistical significance (alpha 0.05) of 95% ($P = 0.05$). Therefore, 51 patients were required in each group with a total of 102 patients.

The IBM SPSS version 25 for Windows software package and Excel were used for statistical analysis. Chi-square test was used to analyze categorical variables. The Jarque–Bera test was used to test whether the sample data have the skewness and kurtosis matching a normal distribution. Between-group differences were investigated using Mann–Whitney *U*-test for non-parametric data and *t*-test for parametric data. An ANOVA was used to evaluate changes within-group over time. Outcomes were expressed as mean with standard deviation (SD) and 95% confidence intervals (95% CI) or *n* (%). A *P*-value less than 0.05 was considered statistically significant and a difference between groups exists.

Results

After signing informed consent, the 109 participants were randomly allocated to two groups. We recruited seven more participants than initially planned for their willingness to participate, meeting requirements of the studies protocol, our technical ability to include them and mainly due to anticipating possible dropouts. Seven participants did not finish the intervention protocol: three in HILT group and four in LLLT group (Figure 1). The reasons for leaving the study were not related with treatment or study protocol. The dropouts happened due to personal reasons or other unrelated health problems that occurred. The data of the lost patients were not included in the analysis. The baseline characteristics of 102 participants included and analyzed in the study, as presented in Table 2. There was no significant difference in baseline demographics such as age, gender, affected side and duration of pain from the onset.

The data of pain evaluations in given situations according to visual analogue scale; pressure pain threshold difference between healthy and affected heels according to algometry; and plantar fascia thickness difference between healthy and affected heels according to sonography are shown in Table 3. There was no statistically significant difference between the groups in given situations. In both groups, participants were actively asked about the use of anti-inflammatory drugs and in both groups, participants stated that they did not take anti-inflammatory drugs during the treatment. According to the subjects' ratings, the effect of treatment was 58.75 (27.79)% (individual ratings ranging from 0% to 100%, 95% CI 50.30%–67.20%) in LLLT group and 67.20 (19.22)% (individual ratings ranging from 20% to 98 %, 95% CI 61.68%–72.72%) in HILT group; the mean difference between groups was not significant, $P = 0.096$. But it was noticed that in HILT group statistically significantly more participants evaluated the efficacy of treatment was 50% and better (between the groups, $P < 0.05$). The data of participants' opinion on treatment are presented in Table 4.

The possible harms were evaluated during the treatment. The treatment we used in this study had neither adverse events nor complications. However, some people noticed the temporary increase in pain for short period of time in the middle of the treatment in HILT group.

Discussion

In this randomized study, we compared two different laser therapy methods in plantar fasciitis treatment. To the best of our knowledge, this is the first

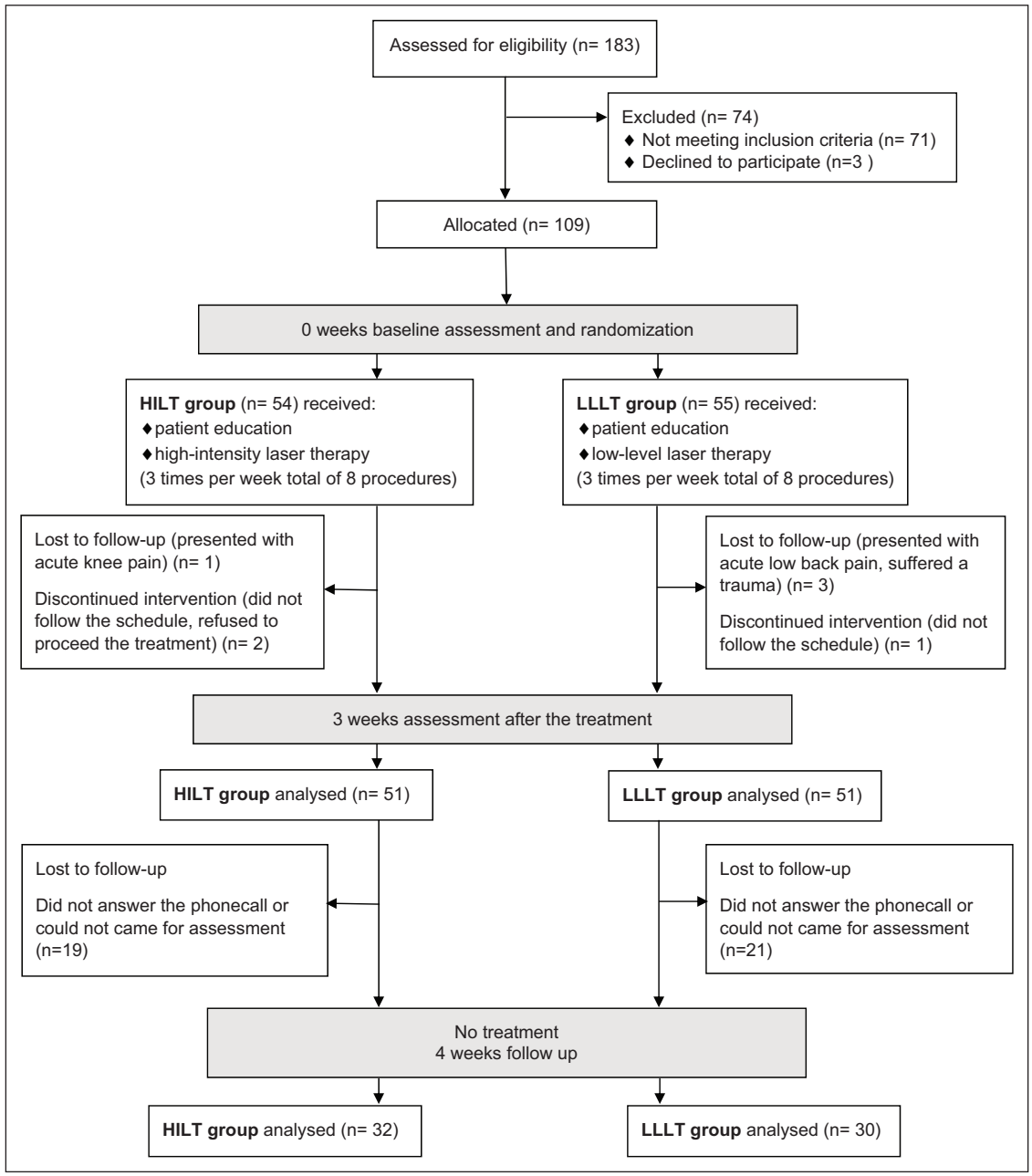

Figure 1. Flow diagram.

study that evaluates the efficacy of the laser therapy in combination with patient education about self-help strategies. In this study, there was no statistically significant difference between the groups according to visual analogue scale, pressure algometry and sonography measurements. However, there was a statistically significant difference between the groups in participants' opinion in favor to HILT.

Table 2. Baseline demographic and clinical characteristics for each group.

Group	LLLT group ($n=51$)	HILT group ($n=51$)
Age	58.2 (10.2)	54.2 (11.0)
Gender		
Male	13 (26%)	8 (16%)
Female	38 (75%)	43 (84%)
Duration of pain (month)	3.75 (4.75)[a]	3.00 (4.00)[a]
First time PF	37 (73%)	38 (75%)
Side affected		
Left	20 (39%)	28 (55%)
Right	31 (61%)	23 (45%)

HILT: high-intensity laser therapy; LLLT: low-level laser therapy; PF: plantar fasciitis.
Data presented as mean (SD) for parametric data and median (interquartile range (IQR)) or *n* (%).
[a]Non-parametric data.
Difference between the groups, $P > 0.05$.

Table 3. Measurement at baseline and pain reduction after the treatment and in the follow-up to the specific day time using visual analogue scale, pressure algometry and plantar fascia thickness difference between healthy and affected side reduction.

Group	LLLT group			HILT group		
	Mean	Difference		Mean	Difference	
	Baseline	0–3 weeks	3–4 weeks	Baseline	0–3 weeks	3–4 weeks
	$n=51$	$n=51$	$n=30$	$n=51$	$n=51$	$n=32$
Visual analogue scale (cm)						
Pain in general	5.99 (2.33)	2.57 (3.45)	0.18 (2.59)	6.78 (2.12)[a]	2.88 (3.28)[b]	1.69 (3.37)[a]
First morning step	6.93 (2.61)[a]	4.70 (3.66)[a,b]	0.68 (2.85)[a]	6.69 (2.88)[a]	4.44 (2.67)[b]	0.75 (1.37)[a]
Several minutes after first step	4.52 (2.13)	3.08 (2.14)[a,b]	0.45 (1.99)[a]	5.63 (2.73)	3.85 (3.11)[a,b]	0.51 (1.55)[a]
First step after prolonged sitting in the middle of the day	6.18 (2.11)	3.78 (2.94)[a,b]	0.15 (2.57)	6.35 (2.49)	3.73 (3.01)[a,b]	0.29 (1.73)
In the evening	7.02 (2.61)[a]	3.11 (3.52)[b]	0.23 (3.04)	7.63 (2.12)[a]	4.15 (2.56)[b]	0.05 (2.88)
Algometry (kg/cm^2)						
Pain threshold difference	3.03 (2.57)	1.80 (6.39)[a]	0.27 (0.51)	4.05 (3.41)[a]	1.77 (2.85)[a]	0.77 (2.35)[a]
Sonography (mm)						
US difference	1.51 (0.80)[a]	0.19 (0.56)	0.18 (0.51)	1.46 (0.79)	0.30 (0.57)[a,b]	0.059 (0.54)

HILT: high-intensity laser therapy; LLLT: low-level laser therapy; US: ultrasound.
Data presented as mean (SD)
[a]Non-parametric data.
[b]Significant at $P < 0.05$ for difference within groups 0–3 weeks.
Difference within groups 3–4 weeks, $P > 0.05$; difference within groups 0–4 weeks, $P < 0.05$; difference between the groups, $P > 0.05$.

Table 4. Efficacy of laser therapy according to the subjects' ratings shown in percentages from the number of participant in each group.

Group	LLLT group	HILT group	*P*-value
	n = 51	*n* = 51	
Efficacy of laser			
More than 50%	26 (51%)	37 (73%)	0.041
More than 75%	16 (31%)	25 (49%)	0.106

HILT: high-intensity laser therapy; LLLT: low-level laser therapy.
Data presented as *n* (%).

The pain was chosen as main outcome measure, because all patients with plantar fasciitis experience pain. Patients report that the pain is the worst in their first steps after rising from bed or after prolonged sitting.[5] We found that after the intervention the pain according to visual analogue scale was reduced statistically significant in both groups. However, there was no difference between the groups. These results are consistent with the findings of previous studies, suggesting benefits of LLLT in heel pain caused by plantar fasciitis.[28] In the systematic review with meta-analysis done by Wang et al.,[4] it was admitted that LLLT intervention indeed alleviated pain as indicated by the decreased visual analogue scale score. But our results differ from those of Ordahan et al.[5] where it was stated that both high-intensity and low-level laser treatments improved the pain levels, but HILT had a more significant effect than LLLT. In the study published by Ordahan et al.,[5] the device used for HILT was the same as ours, but different protocol was applied. At first, there were three sessions of laser therapy in pulsed mode applied (this device has a frequency of 50–60 Hz) and later six sessions in continuous mode.[5] Furthermore, the device used for LLLT was different from ours and had super pulsed irradiation of 5000 Hz. In comparison, we used the continuous mode when applying HILT, while LLLT was applied in pulsed mode with a duty cycle of 50% and frequency of 50–60 Hz. The literature has not yet made clear which frequencies are particularly suited to which treatment. It is suggested that frequency range from 1 to 100 Hz is suitable for pain reduction and neuralgia treatment despite the general recommendation to use continuous mode.[29] Other studies used continuous mode for LLLT and concluded that LLLT is effective in pain reduction[30,31] and improves functional outcomes.[32] Based on previous studies conclusions that LLLT reduces the heel pain caused by plantar fasciitis, we believe that, in this study, both laser therapies were effective. However, our study had no control group, unlike the study published by Yesil et al.[6] According to Yesil et al.,[6] there were no difference between the HILT and placebo groups in terms of pain, quality of life and functionality found. Yesil et al.[6] used a different HILT device that had very high peak power (3000 W) and pulsed mode with a low frequency of 10–40 Hz. However, Yesil H. et al.[6] found a significant difference in favor of HILT in terms of dynamic pedographic measurements. We expected similar results in pressure algometry. The increase in pressure pain threshold and decrease in pressure pain threshold difference between the healthy and affected heels after treatment would suggest that participants can stand on affected leg with less pain. However, in our study, such results were not achieved after treatment. Nevertheless, in this study, there was a tendency observed that HILT is better in reducing plantar fascia thickness, but no statistically significant difference between groups was observed. Plantar fascia thickness is one of the indicators of plantar fasciitis, and more than 4 mm thickness is considered as a sign of plantar fasciitis.[32] Previously, Kiritsi et al.[33] applied LLLT and concluded that immediately after treatment (six weeks), ultrasound imaging is able to depict the morphological changes related to plantar fasciitis. Later, similar results were presented by Macias et al.,[2]

who measured plantar fascia thickness with ultrasound and found that between the baseline and final measurement (eight weeks), the thickness decreased statistically significant only in LLLT group and no significant changes in placebo group. Ulusoy et al.[34] measured plantar fascia thickness with magnetic resonance imaging after treatment (four weeks) and found that plantar fascia thickness decreased significantly in LLLT group. In this study, we did not find the statistically significant difference of plantar fascia thickness in three weeks from baseline in LLLT group. In the HILT group, significant plantar fascia thickness reduction was detected in three weeks from baseline, but no statistically significant difference between groups was observed. It is possible that HILT reduces plantar fascia thickness faster than LLLT.

Due to possible negative effect of non-steroidal anti-inflammatory drugs, we chose not to allow non-steroidal anti-inflammatory drugs during the study. Oral non-steroidal anti-inflammatory drugs are recommended as initial treatment for patients with plantar fasciitis,[35] but there is little evidence about their effect on tendon healing. However, there are data in literature available that non-steroidal anti-inflammatory drugs can delay tendon healing and decrease the biomechanical strength of repaired tendon.[36,37] Recently, Naterstad et al.[15] found that diclofenac reduce inflammatory signs during the first two days, although there is prolongation of the inflammatory phase and slower normalization of tendon quality. Furthermore, it was demonstrated that laser therapy can interact with pharmaceuticals, such as steroids and anti-inflammatory drugs.[29] Also, Marcos et al.[16] found that LLLT may have potential to become a new and safer non-drug alternative to the highly selective COX-2 inhibitors, because LLLT seems to act on inflammation through a selective inhibition of the COX-2 isoform in collagenase-induced tendinitis.

There are some limitations of this study. First, the lack of a control group. Therefore, it is not possible to evaluate the isolated effect of laser in patients with plantar fasciitis. Second, relevant limitation of the study is lack of assessor blindness, which could have resulted to a less accurate results. Third, there was a high loss to follow-up, but the loss was equally distributed between groups. Fourth, a short follow-up duration does not show the long-term effect of the chosen rehabilitation protocol. Follow-up of six months or longer should present the long-term effects of chosen rehabilitation protocol better.

In conclusion, both groups improved, but there was no statistically significant difference between HILT and LLLT observed. Most of the participants considered treatment to be effective. Further studies should be done to determine the efficacy of different lasers and to evaluate cost-effectiveness of laser therapy in combination with patient education. It is important to focus on how the laser therapy procedure should be applied. Also, more objective outcome measures should be used to evaluate pressure pain threshold, gait and the ability to bear weight on affected side.

Clinical messages

- There is no statistical difference between HILT or LLLT groups according to visual analogue scale, pressure algometry and sonography measurements in participants with plantar fasciitis.
- Statistically significantly more participants considered the treatment to be effective in more than 50% in HILT group.

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Author contributions

Dovile Naruseviciute collected and organized the data, performed the statistical analysis and wrote the article. Raimondas Kubilius supervised the research, advised in all steps of the research and reviewed the article.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Trial registration

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