



The effect of high-intensity versus low-level laser therapy in the management of plantar fasciitis: a randomized clinical trial

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Abstract

We aimed to compare the efficacy of low-level laser therapy (LLLT) and high-intensity laser therapy (HILT) in the treatment of plantar fasciitis (PF). Seventy patients were randomized into either the LLLT (8 men, 27 women; mean age 48.65 ± 10.81 years) or HILT (7 men, 28 women; mean age 48.73 ± 11.41 years) groups. LLLT (904 nm) and HILT (1064 nm) were performed three times per week, over a period of 3 weeks. Each treatment combined with silicone insole and stretching exercises. Patients' pain and functional status were evaluated with Visual Analog Scale, Heel Tenderness Index, and Foot and Ankle Outcome Score before and after treatment. A chi-square test was performed to compare demographic and clinical characteristics. Within-group and between-group differences were also investigated. Paired samples *t* test was used to analyze the differences between baseline and after treatment values, while independent samples *t* test was used to compare the two groups. Both groups contained similar demographic characteristics including age, sex, and body mass index (all $p > 0.05$). Three and two patients in the HILT and LLLT group, respectively, were lost to follow-up. At the study onset, there were no statistically significant differences between the two groups in the Visual Analog Scale, Heel Tenderness Index, and Foot And Ankle Outcome Scores. Three weeks later, both groups showed significant improvement in all parameters ($p < 0.05$). The HILT group demonstrated better improvement in all parameters than the LLLT group. Although both treatments improved the pain levels, function, and quality of life in patients with PF, HILT had a more significant effect than LLLT.

Keywords Low-level laser therapy · High-intensity laser therapy · Plantar fasciitis · Visual Analog Scale · Heel Tenderness Index

Introduction

Plantar fasciitis (PF) is the most common cause of heel pain in adults. Although the exact cause is unknown, risk factors include middle age, obesity, excessive foot pronation, pes cavus, excessive running, pes planus, and prolonged standing [1, 2]. The pathological process, often called “calcaneal spur,” with severe pain syndrome, is caused by degenerative-dystrophic

changes in the plantar aponeurosis; this occurs at the place of attachment to the calcaneus [1, 2]. Most patients with PF experience pain in their first steps after rising from bed or after prolonged sitting. After the first few steps, pain and stiffness may decrease, but the former may intensify throughout the day, most often when climbing stairs or after standing for long durations [3, 4]. Stretching the plantar fascia and weight bearing on the heel may trigger symptoms [4].

Conservative therapy provides significant relief in approximately 90% of patients with PF [1]. Numerous methods have been used to treat PF, including nonsteroidal anti-inflammatory drugs, cortisone injections, foot orthoses, physical therapy, stretching exercises, night splints, and extracorporeal shockwave therapy (ESWT) [5–9]. A small number of patients undergo surgery, including spur resection and release of all parts of the fascial band [9]. Another method for treating PF is via low-level laser therapy (LLLT). Laser therapy presents a non-invasive and painless method of treatment for patients with PF [10, 11]. Recently, the pulsed neodymium-doped yttrium aluminum garnet (Nd: YAG) laser, a form of

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high-intensity laser therapy (HILT), was introduced as a new treatment option. HILT is able to reach and stimulate the larger and deeper areas of the fascia. In addition, during a HILT session, a significantly greater amount of energy may be transferred into the issue compared to LLLT [12]. The effectiveness of HILT in PF remains unclear. To the best of our knowledge, to date, no clinical trial or study has evaluated the effectiveness of different laser therapies in PF treatment. Therefore, the aim of this study was to compare the effectiveness of HILT and LLLT for PF treatment.

Materials and methods

Design

This study was designed as a randomized clinical trial with a follow-up of 3 weeks. A total of 75 patients with unilateral plantar heel pain at the outpatient clinic of the Physical Medicine and Rehabilitation Department, were screened for enrollment in the study. The study was approved by the local research ethics committees of Selçuk University's Medical Faculty (No: 288/2017). The diagnosis of PF was based on tenderness localized to the medial tubercle of the calcaneus and pain that began with the first step in the morning and worsened with weight-bearing activities. Data were collected before the procedure and at three-week follow-up. The following inclusion criteria were used: Pain was (1) reproduced with palpation of the plantar fascia, (2) localized and sharp but not radiating, (3) worse in the initial step after and an extended period of rest, and (4) decreased initially after the first steps but exacerbated with increased activity at least 6 weeks, (5) unresponsive conservative form of plantar fasciitis care (ie, rest, stretching, full-length silicone insole, prescription NSAIDs when taken for a period of 2 weeks) [8]. The exclusion criteria included (1) history of previous steroid injections, (2) previous surgery of the foot, lumbar spine disc herniation or back injury, and (3) patients with rheumatic diseases (e.g., rheumatoid arthritis, spondyloarthropathy, gout disease, enthesopathy, Sjogren's syndrome, and systemic lupus erythematosus). Also, patients with peripheral joint stiffness, redness, warmth, swelling, deformities, and skin changes including erythema were excluded from the study. In the HILT group, three patients did not participate in the program regularly, while in the LLLT group, two patients did not participate regularly in the program Fig. 1.

Sample size

The number of participants included in this study was determined based on Foot And Ankle Outcome Score (FAOS). A pain subscale of FAOS was selected as the main data source. According to the results of Ordahan et al. [8], the mean score

of FAOS pain of a kinesio-tape group was 44.8 with standard deviation of 17.5. The mean score in the Extracorporeal Shock Wave Therapy (ESWT) treatment group after treatment was 55.8 [13]. The sample size was based on a power of 80% (beta 0.2), a dropout rate of 10%, and a statistical significance (alpha 0.05) of 95% ($p = 0.05$). Therefore, 35 patients were required in each group with a total of 70 patients.

Randomization

Patients were randomized into two groups. Concealed allocation was performed prior to the initiation of the study using a computer-generated (SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc.) randomized table of numbers. This program was used to generate block sizes and randomization schedules. Physicians remained blinded to these schedules and all outcome measures were collected by the same researcher.

Blinding and masking

According to study design, only physiotherapists who performed the interventions and the physician who carried out the evaluations of the patients were blinded to the study design and the treatment groups.

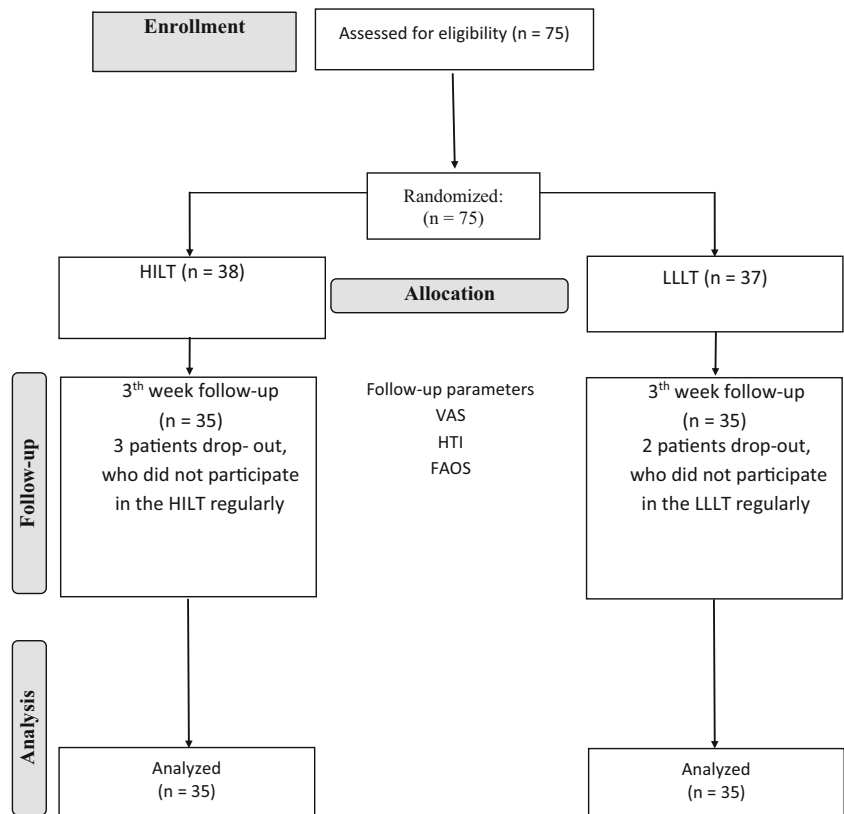
Pain evaluation

Pain levels were assessed using a 100-mm horizontal Visual Analog Scale (VAS) and Heel tenderness index (HTI). HTI was an index that physician used to assess heel pain on palpation. It was defined as 0 point = no pain, 1 point = painful, 2 points = painful and winces, and 3 points = painful, winces, and withdraws. Pain levels were assessed before and after the treatment period.

FAOS

Function and quality of life were measured using the FAOS [13]. The FAOS is a 42-item questionnaire divided into five subscales: pain, other symptoms, activities of daily living, sport, and recreation function and foot and ankle-related quality of life. The pain subscale contains nine items, the other symptoms' subscale contains seven items, the activities of daily living subscale contains 17 items, the sports and recreation function subscale contains five items, and the foot, and ankle-related quality of life subscale contains four items. Each question is scored on a 5-point Likert scale (from 0 to 4), and each of the five subscale scores is calculated by adding the included subscale items. The raw scores are then transformed into a final score ranging from 0 to 100 (from worst to best outcomes) score. The reliability of the Turkish FAOS—which was translated into Turkish and culturally adapted from the

Fig. 1 Flow diagram



original FAOS—was previously verified in a study by Karatepe et al. [13].

Low-level laser therapy (LLLT)

Laser treatment was administered at a wavelength of (904 nm, output power of 240 Mw, and frequency of 5000 Hz) using a gallium-aluminum-arsenide (GaAIAs, infrared laser) diode laser (Chattanooga, Mexico, USA). Standard treatment was provided, which consisted of super pulsed irradiation over the origin of the plantar fascia on the medial calcaneal tubercle, followed by two continuous sweeps of the probe along the proximal medial border of the fascia. The spot area was approximately 1.5 cm² over the tendon insertion, and 3 cm² along the medial border of the fascia, administering a power density of 0.16 W/cm² and 0.08 W/cm² respectively. Each patient was treated for 157.5 s per session, and the dose of active treatment was 8.4 J over the tendon insertion site followed by 8.4 J along the medial border of the fascia. The total energy delivered to the patient during one session was 680.4 J. Laser treatment was performed for three sessions per each week, over a period of 3 weeks [11].

High-intensity laser therapy (HILT)

HILT was performed using a BTL-6000 high-intensity laser, 12 W (watt), 1064 nm device was a hot laser with Nd: YAG

LASER source [12]. In the HILT group, we applied the device on the plantar fascia area in two phases: phase I and phase II. In both phase I and phase II, the application was made by using continuous circular movements. The first three sessions were analgesic effect at an intermittent phase, applying a 75 s, 8 W 6 J/cm², for a total of 150 J of energy. The subsequent six sessions were bio-stimulation effect at a continuous phase, applying a 30s, 6 W 120 J-150/cm² dose. HILT was applied for a total nine treatment sessions over a period of 3 consecutive weeks.

Additional treatments

Patients in both groups were given a full-length silicone insole. Patients were instructed to wear the insole in their daily lives for 3 weeks, both indoors and outdoors as much as possible. Plantar facial stretching exercises were described by an experienced physiotherapist. A brochure containing exercise recommendations was given to patients and they were asked to do these home exercises twice daily.

Statistical analysis

The SPSS 11.0 for Windows software package (SPSS Inc. Released 2007. SPSS for Windows, Version 11.0. Chicago, SPSS Inc.) was used for the analysis. The Kolmogorov-Smirnov test was used for conformity of continuous variables

with a normal distribution. All variables were normally distributed. Descriptive data were presented as the mean \pm standard deviation. A chi-square test was performed to compare the demographic and clinical characteristics. Within-group and between-group differences were investigated. The paired samples *t* test was used to analyze the differences between the baseline and after treatment values. The independent samples *t*-test was used to compare the two groups. A *p* value less than 0.05 was considered statistically significant and a difference between groups exists.

Results

Baseline characteristics of the patients are given in (Table 1). At the study onset, there were no statistically significant differences between the two groups in their VAS and HTI scores, and FAOS (*p* > 0.05). Both HILT and LLLT groups revealed significant improvement for all evaluated parameters including VAS and HTI scores, and FAOS after 3 weeks of the treatment (*p* < 0.05). The improvement in all parameters in the HILT group was greater than the improvement in LLLT group (*p* < 0.05) (Tables 2 and 3).

Discussion

In this randomized study, we compared two different laser therapy methods in PF treatment. To the best of our knowledge, this is the first study to compare HILT with LLLT. We observed significant improvement in the VAS and HTI scores, and FAOS in both groups.

LLLT is a conservative treatment choice for patients with PF. Trials on the effectiveness of LLLT in PF have shown conflicting results. Basford et al. [14], using a subjective pain scale, had evaluated the effectiveness of LLLT in the treatment of PF. The authors found that laser therapy is ineffective in the treatment of PF. However, according to the results of other studies, LLLT may contribute to healing and pain reduction in PF [11, 15]. In a study by Kiritsi et al., 30 subjects were super pulsed irradiated with 904-nm GaAIs laser three times per week, for 6 weeks for 18 total treatment sessions. A

placebo-irradiated group was used as the control group. They investigated the efficacy of LLLT in PF using ultrasonography and VAS. They reported a statistically significant difference in the VAS pain score between the study groups. However, the ultrasonographic findings did not reveal a statistically significant difference between the study groups. Similarly, Macias et al. [15] reported relief of chronic pain with 635 nm laser irradiation. A recent study by Cinar et al. [16] showed positive effect of LLLT on pain, foot function, and walking performance in patients with PF.

Despite the many applications in humans, the biomodulatory effects of laser treatment remain poorly understood. Tam [17] revealed that LLLT dilates arterial and capillary vessels, thereby increasing microcirculation, activating angiogenesis, and stimulating nerve regeneration and immunological processes. LLLT is able to increase cell numbers, DNA, and RNA synthesis and collagen production, and in addition is able to initiate mitosis in cultured cells. LLLT stimulates the photoreceptors present on the mitochondrial and cell membranes to convert light energy into chemical energy in the form of ATP within the cell, which enhances cellular functions and cell proliferation rate [18–20]

Furthermore, laser treatment has been shown to exert an anti-inflammatory effect by decreasing the level of pro-inflammatory cytokines such as interleukin-1 alpha and interleukin-1 beta, and by increasing the level of other cytokines and anti-inflammatory growth factors such as fibroblast growth factor [21]. It may also have inhibitory effects on the release of prostaglandins, cytokine levels, and cyclooxygenase, and has been shown to accelerate cell proliferation, collagen synthesis, and tissue repair [22, 23]

On the other hand, HILT, pulsed Nd: YAG laser therapy, has been used for a wide range of disorders, including knee osteoarthritis [24], low back pain [25], facial paralysis [26], subacromial impingement syndrome [27], and lateral epicondylitis [28]. Some studies have shown that HILT was more effective than LLLT due to its ability to reach and stimulate the larger and deeper fascial areas [12, 24, 26].

HILT, which uses high-intensity laser radiation, leads to minor and slow light absorption by melanin and chromophores [12]. This absorption increases the mitochondrial

Table 1 Demographic and clinical characteristics of the patients

	HILT (<i>n</i> :35)	LLLT (<i>n</i> :35)	<i>p</i>
Age (years)	48.73 \pm 11.41	48.65 \pm 10.81	0.822
Gender (F/M)	28/7	27/8	0.912
BMI (kg/m ²)	31.16 \pm 3.66	31.22 \pm 4.21	0.841
Duration of pain (week)	8 \pm 1.5	8 \pm 1.6	0.97

Data are given as mean \pm SD or ratio

F female, M male, chi-square test; BMI body mass index, HILT high-intensity laser therapy, LLLT low-level laser therapy

Table 2 Assessment of functional parameters

	HILT (<i>n</i> :35) Mean ± SD	LLLT (<i>n</i> :35) Mean ± SD	HILT vs. LLLT <i>p</i>
VAS			
Baseline	8.87 ± 1.54	8.35 ± 1.78	0.660
After treatment	2.75 ± 1.84	5.56 ± 2.11	0.048
<i>p</i>	0.017 †	0.036 †	
HTI			
Baseline	2.05 ± 0.89	2.11 ± 1.21	0.731
After treatment	0.37 ± 0.48	0.98 ± 0.51	0.043
<i>p</i>	0.021 †	0.038 †	

† Baseline versus after treatment. Samples *t* test, paired-samples *t* test; *p* < 0.05

VAS Visual Analogue Scale, HTI Heel Tenderness Index; HILT high-intensity laser therapy, LLLT low-level laser therapy

oxidative reaction and adenosine triphosphate, RNA and DNA production (photochemistry effects) resulting in the phenomenon of tissue stimulation (photobiology effects) [29].

Moreover, the photochemical and photothermic effects of HILT may simulate collagen production within tendons and increase blood flow, vascular permeability and has an anti-inflammatory effect. Thus, HILT may help to repair damaged tissue and remove the pain stimulus [24, 25].

On the other hand, a recent clinical practice guideline recommends that both corticosteroid injection and over-the-counter arch support/heel cups should be considered as part of initial treatment options [9].

However, corticosteroid injection may have side-effects such as tendon rupture, local skin atrophy, facial flushing, post-injection pain, hyperglycemia, sepsis, and hypersensitivity reactions [30–32]. Specifically, injections of corticosteroid

Table 3 Comparison of the Foot and Ankle Outcome Score (FAOS)

	HILT (<i>n</i> :35) Mean ± SD	LLLT (<i>n</i> :35) Mean ± SD	HILT vs. LLLT <i>p</i>
FAOS pain			
Baseline	46.84 ± 16.22	45.93 ± 18.45	0.811
After treatment	54.7 ± 10.22	49.9 ± 10.77	0.023
<i>p</i>	0.019 †	0.038 †	
FAOS symp			
Baseline	56.50 ± 23.72	56.89 ± 23.87	0.921
After treatment	68.30 ± 25.04	60.75 ± 21.25	0.023
<i>p</i>	0.014 †	0.037 †	
FAOS ADL			
Baseline	45.6 ± 18.10	46.51 ± 18.26	0.630
After treatment	58.8 ± 20.5	51.63 ± 20.24	0.033
<i>p</i>	0.010 †	0.028 †	
FAOS SPORT			
Baseline	42.34 ± 21.1	42.82 ± 20.51	0.641
After treatment	56.93 ± 25.9	49.17 ± 25.14	0.022
<i>p</i>	0.011 †	0.022 †	
FAOS QOL			
Baseline	45.53 ± 9.4	45.77 ± 11	0.856
After treatment	57.62 ± 14.6	52.79 ± 22	0.034
<i>p</i>	0.018 †	0.020 †	

† Baseline versus after treatment. Samples *t* test, paired-samples *t* test; *p* < 0.05

HILT high-intensity laser therapy, LLLT low-level laser therapy, FAOS Foot and Ankle Outcome Score, FAOS pain Foot and Ankle Outcome Score pain, FAOS symp Foot and Ankle Outcome Score symptoms, FAOS ADL Foot and Ankle Outcome Score function, daily living, FAOS SPORT Foot and Ankle Outcome Score, function, sports and recreational activities, FAOS QOL Foot and Ankle Outcome Score, quality of life

into the medial lobe of the calcaneus can lead to irreversible atrophy of the fat pad of the heel, which, in turn, leads to patient disability [30, 31, 33]. Therefore, the laser therapy may present a painless physical therapy option, that allows recovery from PF and decreases the possibility of side effects due to corticosteroid injection. Silicone insoles and stretching of the plantar fascia are considered to be one of the hallmark treatments in the management of plantar fasciitis [33]. Recalcitrant cases even after adequate conservative treatment are may be the appropriate patient group for laser combination therapies.

There were some limitations to this study. The lack of a control group was the main limitation of our study. Second, a short follow-up duration may be a limitation. However, a systematic review with meta-analysis that evaluated the effectiveness of conservative treatments of PF, demonstrated that follow-up durations change from 1 week to 6 months in different studies [33]. Third, the lack of ultra-sonographic findings of PF could also be considered a limitation. Fourth, the optimal frequency, dose, and wavelength of LLLT and HILT are not known. We have conducted a pilot study of the duration, dose, and wavelength of laser applications; further studies may be needed in the future to determine optimal treatment.

In conclusion, both HILT and LLLT improved pain levels, function, and quality of life in individuals with PF. HILT has a more significant treatment effect than LLLT on PF.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

Ethical approval All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration.

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