ORIGINAl Article

Extracorporeal Shock Wave Therapy Versus Low Level Laser Therapy in The Treatment of Plantar Fasciitis: A Randomized Controlled Trial

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Background: Plantar fasciitis (PF) is predominantly treated conservatively through some modalities such as extracorporeal shock wave therapy (ESWT) and low-level laser therapy (LLLT), yet the short effect of these modalities on pain and function is still ambiguous. This study aims to compare the short-term effectiveness of ESWT and LLLT on pain and function in patients with PF.

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Methods: Participants (n=47) were randomly assigned into 2 groups as ESWT (n=27) and LLLT (n=20). ESWT (once a week) and LLLT (three times a week) were administered to the participants for 3 weeks. Foot function index (FFI) including pain, disability, and activity limitation subscales was administered at baseline and post-treatment. A reduction of one point in total scores was considered as a minimum clinically important difference. Repeated measures of ANOVA were used to analyze the changes in outcomes and compare the groups.

Results: There were significant main effects of time, and significant interaction effects between group and time on pain (P<0.001), disability (P<0.001), and activity limitation (P<0.05). The main effect of the group was not significant for all subscales (P=0.811, P=0.481, P=0.865, respectively). The LLLT group showed a significant decline in pain (P<0.001), disability (P<0.001), and activity limitation (P<0.001) while there was no change in the ESWT group over time (P=0.319, P=0.711, P=1.0 respectively). Consistently, 95% of participants in the LLLT had CID in the pain subscale whereas 48% of the ESWT group had.

Conclusions: LLLT was found to be superior to ESWT as an effective approach in the short-term management of PF.

Plantar fasciitis (PF) is a condition that represents the chronic degenerative process of plantar fascia [2] affecting 10% of the adult population at some point in their lives [3, 4, 5]. Considering the long-term disability caused by the disorders and its significant impact on productivity [6].

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and medical expenses, addressing complaints in the short term is vital to reducing the economic and health-related issues begotten by the disorder.

The PF is predominantly treated conservatively, which mostly resolves the symptoms in the majority of the patients [7]. The conservative treatment includes a vast array of modalities such as extracorporeal shock wave therapy (ESWT) and low-level laser therapy (LLLT) [8]. ESWT and LLLT are both contemporary treatments in the management of PF using a different mechanisms of action. ESWT, for example, causes micro-trauma with a subsequent minor inflammatory reaction that leads to remodeling of the plantar fascia and initiates healing [9, 10]. LLLT, on the other hand, uses photons to stimulate cell proliferation, microcirculation, and vascular neoformation which increases the healing of plantar fascia and collagen formation [1, 11].

ESWT has been extensively used in the care of patients with PF [12, 13] and has shown to be safe and effective in improving pain in PF [10, 14, 15]. However, there is an ongoing debate regarding the short-term effects of ESWT, particularly whether there is an increase in pain during and immediately after ESWT due to micro-trauma caused by the shock waves. [16] On the other hand, LLLT is considered to follow a more compliant approach to reduce pain, and reported to be effective in the treatment of various musculoskeletal disorders [17, 18], and has the potential to reduce pain in patients with PF in the short and long term [19]; yet, further evidence is needed to support its effectiveness [17]. Therefore, in this study, our objective is to
investigate and compare the short-term effectiveness of ESWT and LLLT on pain and function in patients with plantar fasciitis.

MATERIALS AND METHODS

This study was approved by the Ethics Committee of Marmara University (Approval number: 2021-36) and was carried out in accordance with the Declaration of Helsinki. The clinical trial registration number is NCT04826263. The participants were informed about the study and their consent was obtained.

An experimental study was conducted to assess the changes in the pain, disability, and activity limitation of participants with PF in an outpatient physiotherapy department. Assessments were performed at baseline and at the end of treatment (3rd week).

Participants

Fifty participants diagnosed with PF were invited to participate in the study from multiple outpatient clinics at public hospitals. The participants that experienced pain on the medial tuberosity or medial process of plantar fascia within the past month, felt pain in the morning at the first step, and agreed to participate in the study were included. Participants were excluded if they had arthritis in the foot or ankle, cardiac arrhythmia or pacemaker, previous foot or ankle surgery, cancer or tumor, acute trauma, Body Mass Index (BMI) over 40 kg/m², participated in any other therapy or had corticosteroid injection in the last 6 months.

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A total of 47 participants were consented and included in the study (38 females and 9 males). Table 1 shows the characteristics of the participants. The mean age of the participant was 46.9 ± 10.9 years in the ESWT group and 46.8 ± 10.2 years in the LLLT group. The flow diagram of the study is presented in Figure 1.

Randomization

Participants were randomly assigned to either the intervention ESWT or the LLLT group after the baseline evaluation. A simple randomization method, which is flipping a coin (i.e., heads - ESWT, tails - LLLT), was used to assign the participants to the groups. 27 participants were allocated to the ESWT and 20 to the LLLT group.

Assessments

Foot function index (FFI)

FFI is a valid and reliable self-administered questionnaire that can measure pain, activity limitation, and disability caused by foot and ankle disorders [20]. A modified version of the Foot Function Index developed by Venditto et al. was used in this study, which comprises 17 items separated into three subscales: pain (5 items), disability (9 items), and activity limitation (3 items) [21]. The VAS in the original version has been substituted with the Numerical Rating Scale (NRS) which is an 11-point scale from 0 to 10 [21]. The modified version of FFI has been reported to be a reliable and valid scale and its use has been recommended for musculoskeletal

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foot and ankle disorders including plantar fasciitis [21]. A between-group difference of a minimum 1-point change in the numeric pain rating scale (NRPS) was considered clinically important [22].

Interventions

Extracorporeal shockwave therapy (ESWT)

Participants in the ESWT group received treatment with a radial ESWT system (EMS Swiss Dolor Clast), which transforms kinetic energy into a shock wave, applied to the target tissue with pressure varying from 1 to 10 bar and penetrating up to 40 mm. The ESWT treatment was administered to the participants once a week for three weeks, for a total dose of 0.2 mJ/mm2 pulse per application. ESWT application was performed in prone position with participants’ foot inverted. The area of tenderness was palpated, 1000 shock wave impulses were applied to this area, and 1000 pulses were applied over the plantar fascia.

Low level laser therapy (LLLT)

Participants in the LLLT group received gallium-aluminum-arsenide (Ga-Al-As) low level laser treatment with Chattanooga Vectra Genisys Transport model (Chattanooga Group) with a wavelength of 850 nm and a power of 100 mW. The LLLT treatment was applied 3 times a week for three weeks. A maximum energy density of 5.6 j/cm2 was reached by delivering a continuously increasing dose of energy to each tender spot for one minute. The LLLT was

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performed on participants in the prone position and was applied to 5 points on the plantar fascia by positioning the laser head perpendicular to the treatment area.

Home exercise program

All participants were instructed to follow a home exercise program for 3 weeks. Participants were informed about the exercises by giving an exercise sheet describing the exercises and an exercise diary prepared to mark the days they exercise. The home exercise program included previously recommended exercises such as Achilles tendon and plantar fascia stretching and toe curl exercises [23, 24]. Participants were instructed to perform these exercises 10 repetitions for each and 3 times per day for three weeks.

Statistical methods

Descriptive analyses were presented using mean and standard deviations (SD) or a table of frequencies where appropriate. Repeated measures ANOVA was used to analyze the effect of time and group factors on the outcomes and their interactions. The outcome measures were pain, disability, and activity limitation from modified FFI. The exposure was the ESWT or LLLT groups. When applicable, pairwise comparisons were used to ascertain group differences by time. The level of significance was set at P<.05 for all the analyses. All analyses were done using IBM SPSS Statistics version 22.
Posteriori power analysis was performed using the G*Power 3 application. Considering our study’s total sample size of 47 individuals, 5% type I error, an effect size of 0.69, the statistical power was calculated to be 99% [25].

RESULTS

Foot function index

Pain subscale

Repeated measures ANOVA revealed significant main effects of time, and significant interaction between group and time in total score (P<0.001) (Table 2); but the group effect was not significant (P=0.811). (Table 2) According to pairwise comparison, the LLLT group showed a significant decline in pain (P<0.001) after treatment whereas no change in the ESWT group (P=0.319) (Table 3). The mean scores of each item under the pain subscale were presented in Figure 2.

Disability subscale

There was a significant main effect of time, and significant interaction between group and time in total score (P<0.001); but no significant group effect (P=0.481) (Table 2). The LLLT group showed significant improvement in disability after treatment (P<0.001); however, there was no change in the ESWT group (P=0.711) (Table 3).

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Activity limitation subscale

The analysis showed a significant effect of time and significant interaction between group and time in activity limitation total score (P<0.050); yet group effect was not significant (p=0.865) (Table 2). The LLLT group showed improvement in the activity limitation (P<0.001) while there was no change in the ESWT group (P=1.0) (Table 3).

Clinically important difference in pain, disability, and activity limitation

Between baseline and posttreatment in the ESWT and LLLT groups, 48% (n = 13) and 95% (n = 19) of the participants showed a CID in the total pain score, respectively. The percentage of participant having CID in the total disability score was 33% (n= 9) in ESWT group and 80% (n= 16) in LLLT group which were 19% (n= 5) in ESWT group and 60% (n= 12) in the LLLT group in the activity limitation total score.

DISCUSSION

The results of the current study provide evidence suggesting that three weeks of treatment with LLLT in combination with home exercises provided pain relief and improvement in function and activity in patients suffering from PF immediately after the treatment. In other words, LLLT indicated statistically significant improvements in measured parameters at the third week of treatment whereas ESWT did not.

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ESWT modality is one of the commonly recommended treatment approaches by
clinicians and researchers in physiotherapy clinics for PF management due to its stimulant
effects on the tissue healing process at cellular level [19]. However, there is no announced
consensus regarding the optimal ESWT intensity in PF treatment yet [13]. After all, most of the
studies have been carried out with moderate intensity ESWT. Evidence suggested that both
high and moderate-intensity ESWT was found to be effective in functional outcomes while
moderate-intensity was more effective in overall and activity pain relief [12]. Wang et al.
supported previous findings in favor of moderate-intensity by investigating the efficiency of
different energy levels of ESWT in PF [26]. Therefore, in the present study, we chose to use a
total dose of 0.20 mJ/mm² pulse per application for ESWT which is determined as moderate
intensity. Another popular modality, LLLT, has two common types used for PF treatment: Ga-As
and He-Ne type. The Ga-As type, which was performed in our study, was found to be more
effective in PF due to its deeper penetrating ability [27]. We also did include therapeutic home
exercise in both treatment programs since it is considered as a fundamental approach in PF
treatment with strong evidence obtained from high-quality studies [28].

Although ESWT and LLLT interventions in PF have been widely researched in PF owing to
their ability to enable fast recovery without the necessity of activity modification, the results in
the literature are controversial. Moreover, related studies have different follow-up time
windows varying from two weeks (short-term) to one year (long-term) [29]. In the current

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study, we searched for a better modality resulting in pain relief and functional improvement in a short period, just after accomplishment of the treatment.

One of the main results of the current study was substantial pain relief and functional improvement in the LLLT group compared to ESWT at the end of three weeks treatment. The short-term efficacy of LLLT in the treatment of PF has also been proven by several studies [30-32]. Kiritsi et al. used Ga-As LLLT three times weekly for 6 weeks treatment period. They reported significant improvement in pain levels of the LLLT group with a reduction of 59% compared to placebo [31]. Marcias et al. performed 6 sessions of LLLT for 3 weeks and suggested that LLLT was a promising treatment approach for pain relief in PF. However, they did not find any significant difference in FFI score after treatment between LLLT and placebo groups [33]. A metanalysis study by Wei et al. demonstrated that LLLT has an effect on pain relief in PF in short-term which is consistent with the results of the current study [27]. We have substantiated LLLT as a successful approach to providing relief from the symptoms of pain and functional & activity limitations at the end of the 3 weeks treatment. It may be considered that LLLT has the capability to deal with the symptoms that keep individuals from attending work and participating in functional activities in a short-time period [34]. Unfortunately, we did not ask any questions regarding functional return to daily living. Further studies may include this aspect into their study design for empirical evidence.

The results of our study supported the notion that ESWT is not beneficial for the treatment of PF in the short-term. The study of Speed et al. indicated no significant benefit with
the use of moderate-intensity ESWT applied monthly for 3 months over a placebo in overall pain, morning pain, and night pain [35]. In addition, Çinar et al. stated that ESWT had no additive improvement in pain levels over exercise and orthotic support at up to three months [19]. In contrast to our results, the ESWT was found to be an effective method in reduction of morning and activity pain compared to control or placebo groups even in the short-term by some previous studies [36-38]. Ibrahim et al. investigated the effects of two sessions of ESWT (moderate-intensity) on plantar heel pain from baseline to 4, 12 and 24 weeks follow up. Their findings showed that ESWT for plantar fasciitis resulted in pain reduction even in the short-time period. They reported short-term treatment success of ESWT 92% and long-term treatment success 100% compared to 4% short-term and 16% long-term treatment success in the placebo group [37]. Gerdesmeyer et al. performed totally three session of moderate-intensity ESWT as each session in one week similar to ESWT protocol used in our study. They proved that ESWT significantly superior to placebo with a reduction of overall pain at 12th week [36]. The treatment efficiency of ESWT in PF seems to be highly dependent on treatment protocol. It is worth noting that we just discuss our results with the studies that performed moderate-intensity ESWT in PF treatment. In addition, we took into consideration the studies investigating the short-term effects since we searched for the effectiveness of the modalities in the similar time period.

Even though ESWT and LLLT become increasingly popular in PF treatment, there is limited number of studies on the comparison of the effectiveness of these two modalities on...
pain, function and activity. Ulusoy et.al. used 3 sessions of moderate ESWT, 15 sessions of LLLT and ultrasound therapy in PF treatment and compared the results at one month after treatment. They found that ESWT and LLLT were significantly superior to ultrasound therapy while there were no significant differences between ESWT and LLLT in pain and functional outcomes [39]. Sanmak et al. performed moderate 3 ESWT sessions (as one session per week for 3 weeks) and 12 LLLT sessions (as three sessions per week for 4 weeks). They assessed the pain intensity and function at baseline and just after treatment similar to our study, but they also included a follow-up evaluation one month after treatment. Their results showed that both ESWT and LLLT were effective on pain and foot functions in a short-time period. The concern related to immediately after treatment evaluation results of the study of Sanmak et al. is the possible time difference in assessments since LLLT treatment was completed in the fourth week while ESWT at the third week. They compared the third-week results of ESWT and fourth-week results of LLLT which were in different time periods [40]. Another previous study compared 2 sessions of ESWT and 6 sessions of LLLT in the management of PF by means of pain, foot function, and fascia thickness. A significant improvement in all measured parameters was observed in both modality groups one month after treatment. However, their LLLT results were significantly superior to ESWT in pain relief while it is not valid for foot function improvement (FFI) [41]. Çınar et al. investigated the effectiveness of ESWT and LLLT combined with exercise and orthotic support in PF patients. They chose similar treatment protocols for LLLT and ESWT to our study. They performed pain assessment by numeric pain scale and pain subscale of FFI at

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baseline, third week, and third month after treatment. Parallel to our results, they indicated that LLLT was more effective than ESWT in pain relief at short-term follow-up. They did not include the other subscales of FFI so there was no data to compare our results in the context of function and activity [19]. Unfortunately, we did not perform any follow-up assessment since we aimed to investigate the immediate effect of both modalities in PF treatment.

We also further investigated our data to reveal clinically important changes in outcomes. Our results indicated that 95% of participants in the LLLT had clinically important differences in the pain subscale whereas 48% of the ESWT group had. Çınar et al. showed that a substantial percentage of their patients such as 79% in the LLLT group showed significant improvement in pain compared to 61% in the ESWT group [19]. LLLT in the current study showed clinically important improvement in 80% of group participants while ESWT ratio was 33% for the disability subscale. There was a similar trend, with 60% of participants in LLLT and 19% of participants in ESWT showing clinically important differences in the activity limitation subscale. Unfortunately, we could not compare our results except pain with the literature since there is no data on the clinically important changes regarding these parameters.

Our results showed that LLLT is an effective modality providing pain relief, functional improvement, and elimination of barriers to physical activity limitation in patients with PF immediately after treatment compared to ESWT. Besides its effectiveness, LLLT is considered a better tolerated, less painful, easier to use, and cheaper modality than ESWT in clinics [31]. Although the present study showed the immediate efficiency of LLLT in PF, studies utilizing

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long-term follow-up data are needed to see its clinical benefit over a longer period. However, we aimed to ascertain the short-term effects of both modalities in PF management. Also, we did not track the participant’s compliance with the home exercise program which can be considered a potential limitation. Another possible limitation of our study may be the absence of a nontreatment group to follow the symptoms of PF in its natural healing process.

CONCLUSIONS

In conclusion, the short-term efficiency of LLLT in the treatment of PF, which has become increasingly popular in the last ten years due to its non-invasive and painless nature [27], has been proven, by the current study. We can also state that LLLT was found to be superior to ESWT as an effective approach in the short-term management of PF. Also, a larger proportion (47% higher compared to the ESWT group) of participants with PF treated with LLLT showed clinically important changes in pain. Therefore, further studies regarding optimal treatment parameters of LLLT in short- and long-term periods are warranted. The present study has shown its efficiency on pain and function in patients with PF in the short-term, but well-designed studies are needed to clarify its health-related impact on economics.
References


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Table 1. Demographic and Clinical Characteristics by Group.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>ESWT Group (n=27)</th>
<th>LLLT Group (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>46.9 (10.9)</td>
<td>46.8 (10.2)</td>
</tr>
<tr>
<td>Gender, % (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>96.3 (26)</td>
<td>60.0 (12)</td>
</tr>
<tr>
<td>Male</td>
<td>3.7 (1)</td>
<td>40.0 (8)</td>
</tr>
<tr>
<td>BMI, mean (SD)</td>
<td>31.6 (4.3)</td>
<td>33.1 (10.0)</td>
</tr>
<tr>
<td>Affected Side, % (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>44.4 (12)</td>
<td>40.0 (8)</td>
</tr>
<tr>
<td>Left</td>
<td>37.1 (10)</td>
<td>35.0 (7)</td>
</tr>
<tr>
<td>Both</td>
<td>18.5 (5)</td>
<td>25.0 (5)</td>
</tr>
</tbody>
</table>

Abbreviations: BMI: Body Mass Index; SD: Standard deviation; ESWT: Extracorporeal Shockwave Therapy; LLLT: Low Level Laser Therapy

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Table 2. Mean and Confidence Intervals of Total Scores of FFI Subscales at Baseline and Post-Treatment and Results of Repeated Measures of ANOVA

<table>
<thead>
<tr>
<th>Variables</th>
<th>Groups</th>
<th>Original Data</th>
<th>Mean (CI)</th>
<th>Repeated Measure</th>
<th>Time</th>
<th>Time</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline</td>
<td>3. Week</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot Function Index</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>ESWT</td>
<td>7.0 (6.1-7.9)</td>
<td>6.5 (5.3-7.7)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.811</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LLLT</td>
<td>8.7 (8.2-9.2)</td>
<td>4.9 (4.0-5.9)</td>
<td>.68</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td>ESWT</td>
<td>5.0 (4.0-6.0)</td>
<td>4.9 (3.4-6.3)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.481</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LLLT</td>
<td>6.8 (6.0-7.6)</td>
<td>3.7 (2.8-4.7)</td>
<td>.76</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity Limitation</td>
<td>ESWT</td>
<td>1.5 (1.1-1.8)</td>
<td>1.5 (1.0-1.9)</td>
<td>.002</td>
<td>.008</td>
<td>.865</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LLLT</td>
<td>1.8 (1.5-2.1)</td>
<td>1.1 (0.7-1.4)</td>
<td>.26</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The level of significance was set at p<.05 for all the analyses.

Abbreviations: CI: Confidence Intervals; ESWT: Extracorporeal Shockwave Therapy; LLLT: Low Level Laser Therapy
Table 3: Mean Changes in Outcome Measures between Baseline and Post-Treatment and Confidence Intervals

<table>
<thead>
<tr>
<th>Variables</th>
<th>Groups</th>
<th>Mean (CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot Function Index</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>ESWT</td>
<td>0.5 (-0.6-1.6)</td>
<td>.319</td>
</tr>
<tr>
<td></td>
<td>LLLT</td>
<td>3.8 (2.8-4.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ESWT</td>
<td>0.2 (-0.7-1.0)</td>
<td>.711</td>
</tr>
<tr>
<td></td>
<td>LLLT</td>
<td>3.1 (2.0-4.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Activity Limitation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ESWT</td>
<td>0.0 (-0.3-0.3)</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>LLLT</td>
<td>0.8 (0.4-1.1)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

The level of significance was set at p<.05 for all the analyses.

Abbreviations: CI: Confidence Intervals; ESWT: Extracorporeal Shockwave Therapy; LLLT: Low Level Laser Therapy

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Figure 1. Study Flow Diagram
Figure 2. The mean scores on the five items of pain subscale at baseline and post-treatment

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