

Comparison of Extracorporeal Shockwave and High-Intensity Laser in Treating Chronic Plantar Fasciitis - A single-blinded Randomized controlled trial

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ABSTRACT

Background: Plantar fasciitis (PF), an inflammation of the plantar fascia. This study compared the effects of the extracorporeal shockwave and high-intensity laser in reducing pain and enhancing function in chronic plantar fasciitis patients, who have failed to achieve results by the conservative treatment.

Aim: To explore the best non-invasive treatment option for chronic PF within the scope of physical therapy.

Method: After registry of trial the data collection was started. A total of 45 chronic PF patients were divided, randomly into three groups. Group 1 received BTL-6000 Shockwave therapy (ESWT), group 2 received Diowave 60W Class IV hot Laser (HILT) and group 3 (the control group) was not given any electrotherapy treatment. All groups were given some exercises for the home plan. The groups were assessed with the Visual Analogue scale (VAS) and foot functional index (FFI) at baseline, post-treatment, and follow-up of 2 months.

Result: The mean age of participants was 39.66±10.05, 38.06 ±12.64 and 37.40±13.18 for ESWT, HILT group and control groups respectively. There was significant difference in VAS and FFI score $p < 0.001$ across the time. Pre-treatment and post-treatment scores were significantly different but post treatment and follow-up scores were not significantly different for both VAS and FFI score ($p = 1.00$).

Practical implication: This study will help us to find out chronic Plantar fasciitis treatment within physical therapy and electrotherapy domain. As both these modalities are non-invasive, cost effective and proved as effective treatment for reduction of pain and improvement of pain in chronic plantar fasciitis patients.

Conclusion: Extracorporeal shockwave have been promising treatment for chronic plantar fasciitis but High intensity LASER therapy effectiveness was not explored a lot in previous literature. The study concluded that both ESWT and HILT are effective in reducing pain and improving function on VAS and FFI, though the ESWT group was found better than both groups in FFI score and VAS across time on the basis of the mean differences across time.

Keywords: Exercise, Extra-corporeal shockwave therapy, heel pain, High-intensity Laser therapy, Plantar fasciitis

INTRODUCTION

Plantar fasciitis, an inflammation of the plantar fascia, affects 10% of the general population and is most prevalent in the age between 40 and 60 years. The typical presentation is a sharp, achy, burning pain in the heel after stepping down out of bed in the morning or after a period of inactivity. The primary cause is known to be musculoskeletal in origin¹. It is associated with marked morbidity, which results in the limitation of activities in affected patients. The biomechanical overuse and overstress of the plantar fascia's insertion on the tuberosity of calcaneus is the cause of plantar fasciitis. Plantar fascia's biomechanical cause usually has windlass mechanism and rise in the stress of plantar fascia during overload, gait, irrespective of whether it is caused by biomechanical abnormalities, work habits that include prolonged running and standing or obesity can lead to the disease symptoms. Due to this, it's more likely a chronic degenerative process rather than an acute one².

Plantar fasciitis is common but chronic cases are not common. These patients do not have a good response to common treatment options like exercises, stretches, healing modalities, and therapeutic ultrasounds. Plantar fasciotomy, corticosteroid injection, and platelet-rich plasma was common in practice to treat chronic plantar fasciitis. In the past, common treatments have a 90% success rate in treating plantar fasciitis and the remaining cases were treated with invasive treatment options³.

Over the past decade minimally, invasive procedures have shown drastic results, and these have become more available.

Previous literature has shown that minimally invasive that are non-surgical interventions such as platelet-rich plasma injection, extracorporeal shockwave therapy, percutaneous electrolysis dry needling, and botulinum toxin A type injection showed the same or sometimes even better outcomes as compared to corticosteroids injections. Even at present days, there is no decisive option for treating chronic plantar fasciitis. However non-invasive treatment options are supported by literature and are widely accepted as good treatment options with better outcomes⁴. Low Level Laser Therapy was reported more effective than Ultrasound Therapy in improvement of function and reduction in pain in PF patients⁵.

Extracorporeal shockwave therapy (ESWT) is a secure therapy for patients with plantar fasciitis. And even no complication was reported with follow-up up to 1 year. However, according to recent studies, long-term side effects still need more reports to prove the safety of treatment. Better descriptions of patient registration and characteristics of adverse side effects, treatment protocols, and complications, especially discomfort during the session, were recommended². ESWT is an effective as well as a safe treatment of chronic plantar fasciitis. ESWT can provide symptomatic relief in plantar fasciitis patients, with minimal and no side effects⁶.

According to a previous study conducted on 8 different types of treatment options for plantar fasciitis patients, including ultrasound therapy (US), nonsteroidal anti-inflammatory medications, corticosteroid injections, extracorporeal shockwave therapy (ESWT), autologous whole blood, botulinum toxin A (BTX-A), platelet-rich plasma (PRP) and dry needling (DN). ESWT ranked the first for all eight outcomes⁷.

Sports physical therapist also recommends the treatment of sports-related injuries with extracorporeal shockwave therapy and research evidence also prove its effectiveness. In Sports various

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conditions can be treated with the help of ESWT i.e. Rotator cuff tendinopathy, pain in the greater trochanter, hamstring tendinopathy, tennis elbow, and patellar and Achilles tendon degenerative conditions also in bone stress syndromes. ESWT should be used in combination with physical therapy exercises and a home-based plan to facilitate longer-term gains in recovery and to optimize healing and functional status.

In the field of physical therapy high-intensity laser therapy (HILT) has recently emerged and shown its effectiveness in a wide range of musculoskeletal disorders that are commonly frozen shoulder, back pain, tennis elbow, fractures, and plantar fasciitis^{8,9}.

According to a previous study, high-intensity laser therapy reported more reduction of symptoms in all outcome parameters than Low-level laser therapy. Although both treatments improved the quality of life, function, and pain levels in patients with plantar fasciitis, HILT had better outcomes than LLLT¹⁰. Not only in plantar fasciitis, is HILT a successful therapeutic modality in treating patients with knee osteoarthritis⁹.

This study aimed to compare the effects of an extracorporeal shockwave and high-intensity Laser in enhancing the foot function and reduction of pain in the patients with chronic plantar fasciitis. This study could help in spreading awareness of using these non-invasive modalities, in curing chronic plantar fasciitis within the scope of physical therapy.

MATERIAL AND METHOD

Study Design: A single-blinded, randomized clinical trial was performed at physiotherapy clinic from 11th May 2020 to 20th July 2020. Informed consent was taken from participants. The study was approved from BASR (Board of Advanced Studies and Research), Faculty of Rehabilitation and Allied Health Sciences, reference number RCRS-RE-MS-OMP/2019/033 on 14th December 2019. After approval from committee the study was registered in the Iranian registry of clinical trials, IRCT ID IRCT20200317046798N1.

Participants: A total of 45 patients with chronic plantar fasciitis, of both genders (age range 20–60 years) were enrolled in the study and randomly divided into three groups by lottery method. To conceal randomization sequentially numbered sealed opaque envelopes were prepared in advance and opened in sequence.

Inclusion Criteria: Patients suffering from chronic plantar fasciitis, minimum age 18 and maximum up to 70 years were included. Patients having a Visual analogue scale of more than 5 on the first step in the morning were included, having a duration of symptoms of more than 6 months. Both genders were included¹¹.

Exclusion Criteria: Patients with previous surgery of plantar fasciitis, pregnancy, pacemaker fitted, Bleeding disorder, Any tumor of the treatment site, calcaneus stress fracture checked by squeeze test were excluded¹¹.

Treatment Approach: Patients have randomly allocated to three groups of 15 subjects in each group, an assessor took demographic data and baseline readings of each patient with the help of the Foot functional index revised (FFI R) short version and visual analogue scale. Group 1 was treated with BTL-6000 Shockwave therapy Intensity= 2.0 Bar, Frequency =10Hz, Number

of Shocks=2000. The ESWT was applied on the heel, the insertion region of the fascia in a circular manner (1,000 shocks) and along the fascia (1,000 shocks)¹². Twice a week, for 3 weeks. Group 2 received Diowave 60W Class IV Laser three times per week for 3 weeks for a total of 9 sessions at a wavelength of 980nm, a laser output of 30 Watts, and an energy dose of 10,000 Joules. The scanning method was used. Group 3 was a control group; no electrotherapy treatment was given to this group. (Figure 1) All three groups were given some exercises to follow for the home plan and given some postural correction guidelines. After completion of their treatment session, the post-treatment outcomes were taken with the help of an outcome assessor. The assessor used Foot Function Index Short Version and Visual Analogue scale to access post-treatment outcomes. After 2 months follow-up readings were taken by using FFI and VAS again. No dropout patients were reported.

Figure 1 a) Application of High-intensity Laser therapy b) Application of Extracorporeal shockwave therapy in chronic plantar fasciitis patient.



RESULTS

SPSS version 25 was used for the analysis of the data. The Shapiro-Wilk test was used to assess the data distribution before statistical analyses. Parametric tests were used for statistical analyses as the data was normally distributed. Two way repeated measure (ANOVA) was used to assess overall differences in groups across time. An alpha level of 0.05 was established for all statistical tests. After analysis of the socio-demographic data at baseline, the results showed that all 3 groups were comparable at baseline on basis of mean \pm Standard Deviation. In the population 17(37.8%) were male and 28 (62.2%) were females. 19(42.2%) had plantar fasciitis in right foot and 26(57.8%) had plantar fasciitis in left foot. The mean age of participants of the ESWT group was 39.66 \pm 10.05 and the mean age HILT group and control groups were 38.06 \pm 12.64 and 37.40 \pm 13.18, the p=0.869. The mean Body mass index of the ESWT group was 26.70 kg/m², the mean BMI in the HILT group was 25.77 kg/m² and the mean BMI in the control group was 24.80 kg/m², p=0.262

Table 1: Between and within Groups Comparison of Visual Analogue scale and Foot Functional Index Total Score.

Variables		ESWT Group	HILT Group	Control Group	Between Groups
		Mean \pm SD	Mean \pm SD	Mean \pm SD	P value
Visual Analogue Scale	Pre-treatment	6.93 \pm 1.38	7.60 \pm 1.24	6.93 \pm 1.33	<0.001
	Post-treatment	1.33 \pm 1.39	2.80 \pm 1.74	4.86 \pm 1.24	
	Follow-Up	1.33 \pm 1.04	2.67 \pm 1.87	5.33 \pm 1.49	
	P Value	<0.001	<0.001	<0.001	
Foot Functional Index (FFI) Score	Pre-treatment	95.00 \pm 12.81	98.07 \pm 17.65	97.33 \pm 17.49	<0.001
	Post-treatment	43.60 \pm 11.72	57.46 \pm 18.76	65.80 \pm 14.53	
	Follow-Up	40.80 \pm 6.50	58.87 \pm 21.41	68.00 \pm 13.78	
	P value	<0.001	<0.001	<0.001	

Figure 2: Profile plot for estimation of means of Visual analogue scale across time in 3 groups

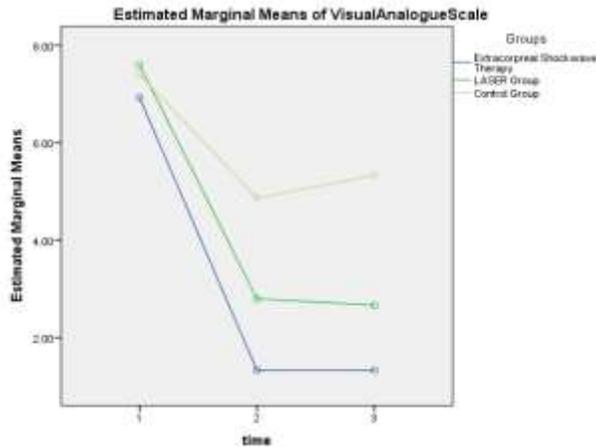
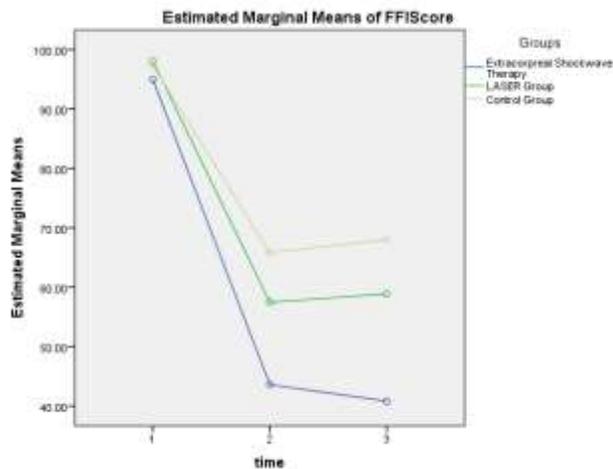


Figure 3 Profile plot for estimation of means of Foot functional Index total score across time in groups.



There was no significant difference in VAS across the time, which was $p = <0.001$ ($p > 0.05$). Pairwise comparison showed there was a highly significant difference between pre-treatment and post-treatment scores and between pre-treatment and Follow-up scores of VAS i.e. ($p < 0.001$) and there was no significant difference between post-treatment and follow-up scores of VAS ($p = 1.00$) (Table 1).

There was a highly significant difference in Foot functional index (FFI) total score with time in the 3 groups $p < 0.001$, and there was a significant difference in groups in FFI total score across the time, which was $p = <0.001$ ($p < 0.05$). Pairwise comparison showed there was a significant difference between pre-treatment and post-treatment score of FFI total score ($p < 0.05$), There was a highly significant difference between pre-treatment and Follow-up score of FFI total score ($p < 0.001$) and there was no significant difference between post-treatment and follow-up score of FFI total score ($p = 1.00$) (Table 1).

Figure 2 shows the means of baseline, post, and follow-up readings of Visual analogue score. Shockwave therapy proved to be clinically more effective than HILT for reducing pain (VAS) in patients with chronic plantar fasciitis.

Figure 3 shows the means of pre, post, and follow-up readings of FFI score. According to the present study, ESWT was clinically more effective than HILT for the treatment of chronic plantar fasciitis.

DISCUSSION

This study reported HILT as a promising treatment for reducing pain and improving functions in chronic plantar fasciitis patients. Previous research reported that the high-intensity laser group showed better improvement in the given scales as compared to low intensity laser therapy group (LLLT). Although both modalities enhanced the function and reduced pain in plantar fasciitis patients, HILT showed more reduction in symptoms than the LLLT group¹⁰.

Previous studies also concluded that HILT is a promising treatment option for other musculoskeletal conditions that are myofascial pain syndrome of the trapezius muscle, Achilles tendinopathy, and knee osteoarthritis^{9,13,14}. Combination of both ESWT and platelet-rich plasma injection can be helpful to manage recalcitrant cases of PF without adverse effects¹⁵.

In this study when across time readings were seen, there was a significant difference between baseline and post-treatment and between baseline and follow-up readings in VAS and FFI scores in all three groups (ESWT, HILT and control), and all 3 groups were given some home exercises too. Previous studies also showed that ESWT and home exercise therapy combined are effective for decreasing fatigue, and pain and improving foot performance and walking distance in patients suffering from plantar fasciitis¹⁶.

ESWT group showed significant differences across time in all readings of VAS and FFI total scores. ESWT proved to be more effective than HILT and control group based on mean differences. Previous studies also showed ESWT as a promising and safe non-invasive treatment option for treating patients suffering from chronic plantar fasciitis. (2) ESWT also showed long-term (12 months) effectiveness for the treatment of chronic plantar fasciitis¹⁷. In previous studies the comparison of Both ESWT and local corticosteroid injection treatments also proved to improve pain and functional ability in patients with chronic PF in the ESWT group more¹⁸. The present study reported slight difference in means of LASER and Control group (home exercises) in both variables (VAS and FFI score) as compare to significantly more improvement in ESWT group according to mean differences. Some previous studies also reported that home plan exercises and traditional physiotherapy improved PF symptoms as much as HILT along with exercises does. So traditional physiotherapy treatments should be part of treatment plan for calcaneus spurs and PF¹⁹. The present study reported slight difference in means of LASER and Control group (home exercises) in both variables (VAS and FFI score) as compare to significantly more improvement in ESWT group according to mean differences.

ESWT is reported to be a good treatment option for musculoskeletal disorders. It was reported to be good recommendation for treating PF, also a good evidence for calcifying tendinopathy of the shoulder. Grade B recommendation was found for patellar tendinopathy, greater trochanter pain syndrome, Achilles tendinopathy, lateral epicondylopathy of the elbow and bone non-union²⁰.

In the present study follow-up readings of ESWT showed more improvement than HILT and control group according to the mean differences between VAS and FFI scores. Previous studies on ESWT showed improvement even at 1-year follow-up in plantar fasciitis patients^{21,22}.

HILT combined with therapeutic exercise seems to be clinically effective in the treatment of patients with hemiplegic shoulder pain²³.

A previous study was conducted to compare HILT and ESWT for the therapy of chronic knee osteoarthritis. The success rate in the HILT group was reported more compared with ESWT on pain, physical function, and disability²⁴. But the present study concluded that ESWT is a better treatment option than HILT for the cure of chronic plantar fasciitis based on FFI score readings across time and mean differences of the variables.

All three groups in our study were given home exercises for

PF. Along with home exercises ESWT group showed better results. According to previous study conventional physical therapy and LLLT when combined gives better results than conventional physical therapy alone in patients having pain and trigger points of upper trapezius muscle²⁵.

The lack of ultrasonography findings to check improvement of chronic plantar fasciitis can be considered a limitation of this study too. We recommend researchers explore more about this promising technological trend, High-intensity Laser therapy. More research is needed to explore the effectiveness of these two modalities working together for developing the most successful and best-tolerated non-invasive treatment protocols for chronic plantar fasciitis in physical therapy.

CONCLUSION

The study concluded that both ESWT and HILT are effective in reducing pain and improving function on VAS and FFI. The results were statistically significant for all 3 groups ($p < 0.05$) including the control group, though the ESWT group was found better than both groups in FFI total score and VAS across time on the basis of the mean differences across time.

Ethical Consideration: Ethical approval of all procedures performed in studies involving human participants was per the ethical standards. Written Informed consent was obtained from all individual participants included in the study. The study was approved from BASR (Board of Advanced Studies and Research), Faculty of Rehabilitation and Allied Health Sciences, reference number RCRS-RE-MS-OMPT/Spring2019/033 on 14th December 2019. After approval from committee the study was registered in the Iranian registry of clinical trials, IRCT ID IRCT20200317046798N1.

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

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