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Efficacy of Shock Wave and Laser in Treatment of Planter Fasciitis

Maian W. Farag[1*], Soheir S. Rezk Allah[2], Mary N Takla[3]. Ahmed H. Azzam[4]

[1]*Department of Basic science, Faculty of physical therapy, Cairo University, Egypt.*
[2] *Department of Basic science, Faculty of Physical Therapy, Cairo University, Egypt.*
[3]*Department of Basic science, Faculty of physical therapy, Cairo University, Egypt.*
[4]*Department of Orthopedic Surgery and Traumatology Kasr Al Aini, Faculty of Medicine, Cairo University, Egypt.*

***Correspondence to:**
Maian W. Farag, Department of Basic science, Faculty of Physical Therapy, Cairo University, Egypt.

Tel:01000383334

Email:
marian.william411@gmail.com

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Abstract:

Objective: This study was conducted to assess the efficacy of shockwave and laser therapy for plantar fasciitis.

Methods: A randomized controlled clinical trial was conducted on 80 patients with chronic planter fasciitis, plus calcaneal spur, their ages range is 40-60 years old. They were randomly divided into four equal groups. *Group A* received ESWT and LLLT in addition to selected physical therapy program received treatment with ESWT with parameter 2000 impulses, 15 Hz, 2 bar twice a week for 3 weeks and LLLT with a wave length of 905 nm, mean power output of 400 mWatt, frequency of 10000 Hz and dose of 300 J/cm² , *Group B* received ESWT with parameter 2000 impulses, 15 Hz, 2 bar twice a week for 3 weeks in addition to selected physical therapy program , *Group C* received LLLT, its wave length is 905 nm, mean power output of 400 mWatt, frequency of 10000 Hz and dose of 300 J/cm² in addition to selected physical therapy program and *Group D* received selected physical therapy program which consist of stretching planter fascia and ice massage only, all groups schedule was twice a week for three weeks. All participants were evaluated before and after the treatment sessions by visual analogue scale (VAS) to assess pain intensity, foot functional index (FFI) for measure the impact of foot pathology on function in terms of pain, disability and activity restriction.

Results: All groups showed significant reductions in pain and FFI scores ($p<0.001$). Group A had the highest improvement, while Group D had the lowest. Group A also showed significant differences compared to Groups B, C, and D ($p<0.001$), but no differences were observed among Groups B, C, and D ($p>0.05$). Significant changes in plantar fascia abnormalities were seen in Group A and Group B ($p<0.01$), but not in Group C and Group D ($p>0.05$).

Conclusion: Shockwave, unlike laser alone or in combination with stretching exercise and ice massage, were effective in reducing foot pain and improving foot function in plantar fasciitis patients. Shockwave showed the highest efficacy. Further research with larger sample sizes and longer follow-up is needed for confirmation.

Keywords: Plantar fasciitis, Shockwave Therapy, Laser Therapy, Efficacy, Randomized controlled trial.

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Introduction:

Plantar fasciitis (PF) is a thickened fibrous aponeurosis that is defined by t inflammation of the plantar fascia causing significant discomfort and disability (1). PF estimates nearly one million patients seek treatment annually and approximately 1 in 10 individuals are predicted to develop such heel pain during their lifetime (2). Etiologies of PF are not fully understood and seem to be multifactorial including obesity, occupational requiring prolonged.

Weight-bearing positions (i.e. standing) believed to be largely mechanic-based (3), thus frequent overload on plantar fascia and calcaneal tuberosity could enhance persistent micro tears and repair procedures. Calcaneal spur considered additional pathology of PF based on inflammation of aponeurosis that is developing in attachment of plantar fascia (4).

Planter fasciitis is characterized by an intensive, sharp heel pain during first walking steps in the morning and moderate cases experience morning pain after prolonged walking or standing, as well many patients might complain of concomitant foot stiffness and localized heel swelling (5). Clinically, PF might present with heel pain with first steps in the morning or after prolonged sitting, also sharp pain while palpating medial plantar calcaneal region (6).

PF treatment ranged from rest to surgical intervention. Conservative treatments have always been the first approach for treating PF and are actually used in 85 to 90% of the cases (7). Conservative modalities could range from as rest even with application of immobilizing cast for 4-6 weeks (8) foot orthotics, night splinting, stretching, modifying of physical activities, physical therapy and non-steroidal anti- inflammatory, as well a single dexamethasone injection or platelet-rich plasma injections (9, 10). In addition, both conservative and surgical interventions (recommended for those who have failed managed through conservative approaches with incidence 2% to 35%), there is only limited evidence for a short-term management (9).

More recently, ESWT is a transient sequence of acoustic impulses with elevated peak pressure (100 Mpa) accompanied by a negative pressure about of 5-10 Mpa and energy density between 0.003–0.89 mJ/mm^2 (11. 12). ESWT is categorized into focused ESWT and defocused radial ESWT based on shape of reflector, which is less penetrative depth, less focusing energy to a targeted spot and subsequently lower intensity compared with focused ESWT (13).

LLLT is a painless, is noninvasive therapeutic modality that has shown short-term efficacy in PF, it contributes to PF healing, serving as a cell stimulator and possibly increase in number of epithelial cells, providing sufficient mitochondrial respiration and required circulation based on its photo biomodulation, also induces regulatory protein and ATP synthesis of collagen by fibroblast using photo biomodulation in injured site (14.15).

According to our knowledge conservative treatments have always been the first approach for PF treating thus actually used in 85 to 90% of cases (7). That raises the need of further studies to clarify the effect of shockwave and laser on pain in treatment of planter fasciitis when combined with stretching and ice massage. So, this study was conducted to assess the efficacy of shockwave and laser therapy for plantar fasciitis.

Participants, Materials & Methods:

After ethical approval was obtained from the institutional review board at Faculty of Physical Therapy, Cairo University **[**P.T.REC/012/001601**]**. The study followed the Guidelines of Declaration of Helsinki on the conduct of human research. It was conducted between April 2020 to August 2021.

Study design:

This study was designed as a randomized, experimental, pre-post-test, controlled trial study.

Participants:

This study was conducted on eighty participants suffering from PF they were selected from the outpatient clinic in physical therapy department at El Sahel teaching hospital Cairo, Egypt as shown in **Figure (1).**

a. Inclusion criteria:

To be included in the study; all patients with chronic planter fasciitis, who suffering from pain for at least 3 months with history of unsuccessful treatment of NSAID, plus calcaneal spur confirmed by X-ray, their ages range is 40-60 years old.

b. Exclusion criteria:

They were excluded if they have other musculoskeletal injuries at foot area, diabetic foot, pregnant women, who received local corticosteroid injection within last two months or whom have anemia, hypertension, diabetes mellitus, malignancies or underwent X-ray therapies any chest surgeries or have internal fixations or peripheral circulatory abnormalities including peripheral arterial diseases or deep venous thrombosis (16).

Sample size calculation:

G*Power software (version 3.0.10) was used for sample size calculation. F-test MANOVA within and between interaction effects was selected with 80% power at α 0.05 level, number of measurements 2 for 4 groups and effect size 0.463. The minimum proper sample size is 80 patients, 20 one in each group.

Randomization:

All the patients had signed a consent form for their agreement to participate in the study. The aim of the study and their right to withdraw from the study at any time. Participants were divided sporadically into four groups by computer generation methods. *Group A* received ESWT and LLLT with stretching exercise and ice massage, *Group B* received ESWT with stretching exercise and ice massage, *Group C* received LLLT with stretching exercise and ice massage and *Group D* received stretching exercise and ice massage only, all groups schedule was twice a week for three weeks.

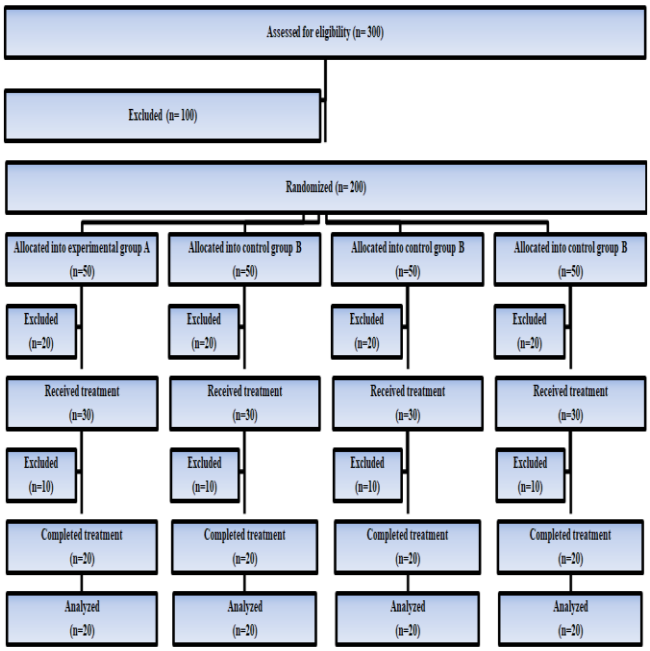

Figure (1): Flow chart of the study.

Instruments:

A. Measurement instrument

i. Visual analogue scale: VAS

It was used to evaluate foot pain severity for each participant in all groups. The VAS is usually presented as horizontal line with a length of 10 cm. Each participants' foot pain intensity is represented by a mark between extremes of 'no pain' and 'unbearable pain'. It is a very simple, reliable and valid tool, in addition its ratio scale features make the VAS is the most permissive tool for describing pain severity (17).

ii. Foot functional index: FFI

It is a self-administrative reasonable index used to measure the effect of foot etiology on function in the form of pain, disability and functional activity limitations. The total number of items is 23 items divided into 3 sub-scales. Both total and sub-scale scores are produced. Overall FFI test-retest reliability and subscale scores range from 0.87 to 0.69, while internal consistency ranged from 0.96 to 0.73, plus it has moderate construct and criterion validity and strong correlation between FFI total and sub-scale scores, thus could be efficiently used for clinical and research tasks (18).

B. Treatment instrument

i.Ice pack gel

Blitz Hot / Cold Pack is 230mm x 130mm dimensions fully reusable gel pack, easy to use and cool in freezer helps to reduce swelling, alleviate pain (19).

ii.Shockwave device

Intellect RPW Chattanooga device has two 2 hand pieces for quick and efficient use of integrative applicator transmitters, it is a form of art navigation and unique optimal energy level justification, also it includes a full suite of accessible references with additional features 'colour LCD touch screen interface and patient data cards record. It has compressed Air Output of 1.4-5 bar with power Increment Settings 0.2 bar and comes with single shock / continuous shock modes.

iii.LLLT device

Chattanooga Vectra Genisys Laser Therapy System 2784 'class 3b' fully functional device is an easy-to-use cold laser system. It has a cluster probe having 13 diodes with wavelength 3*850nm with power 200 mw and 7*670nm with power 10mw LED and 3*950nm with power 15mw SLD and total power 715mw.

Procedures

a-Evaluating Procedures:

- All information regarding name, age, address, job and all measuring variables were registered on the data sheet.
- Before starting the treatment procedure, body weight and height for each participant were measured by traditional weight height scale to calculate their BMI (weight (kg)/height (m^2) (kg/m^2)
- Initially, a careful history including present, past, medical examination was taken from each participant in all groups (A, B, C and D).
- Firstly, before starting the application of the LLLT and the HLLT for group (A) and group (B) respectively, the nature, aim of the producers and the benefits of each treatment modality were explained toall participants to gain their cooperation during the treatment sessions.
- Pain inweresity assessment: Each patient in all groups was asked to grade their pain in relation to VAS from 1 to 10, so pain intensity level was assessed before then after three weeks (17).
- Foot Functional Index test: Each patient has to score each item on a scale from 0 (no pain or difficulty) to 10 (worst unbearable pain), that best

characterizes their foot over the previous week. Both total and subcategory scores are calculated **(**18**)**.

b-Therapeutic procedures:

• **ESWT**: Each patient in groups (A& B) received treatment with ESWT with parameter 2000 impulses, 15 Hz, 2 bar twice a week for 3 weeks. Patient lied in supine, barefoot, by ink was marked localized spot then had received 2000 shot per session using Probe (Omnispec ED1000, Medi spec Ltd, Yehud, with 160Hz along 4 minutes without analgesia, done twice a week for 3 weeks (20).

• **LLLT**: Each patient in groups (A& C) received treatment with LLLT a pulsed diode low intensity laser device (Endo laser 422 Cp 400, Enraf– Nonius apparatus) (Enraf, Rootterdam, Netherlands), with a wavelength of 905 nm, mean power output of 400 mWatt, frequency of 10000 Hz and dose of 300 J/cm². Laser probe was applied directly and perpendicularly on prelocalized spot, done twice a week for 3 weeks ().

• Ice massage: Each patient in all groups had received two minutes done twice a week for 3 weeks (19).

• Stretching exercise: Each patient in all groups had received planter fascia stretching by placing clinician` fingers across toes` base distal to MTP then pulled toes toward patient` shin tell patient felt foot arch stretch confirmed with palpable tension in planter fascia along 10 counts repeated 10 sets twice a week for three weeks (21).

Statistical analysis:

Data were expressed as mean± SD. ANOVA test was used to compare between subjects' demographic data of the four groups, chi square for sex distribution. The Kruskal Wallis test for between group comparison and Wilcoxon test for within group and chi square nominal variables. The statistical package for the social sciences computer program (version 20 for Windows; SPSS Inc., Chicago, Illinois, USA) was used for data analysis. P less than or equal to 0.05 was considered significant.

Results:

Participants` demographic data:

As shown in **table (1)** and **figures (1-5)**; the mean values of age of groups A, B, C and D were (47±5.9), (49±5.3), (47±5.5) and (48.8±6.4) years, the mean values of height were (163.5±7.4), (166.2±9), (164.4±7.9) and (166±9.5) cm. The mean values of weight were (77.5±8.2), (78.7±9.7), (77.3±7) and (81±9.7) kg and the mean values of BMI were (29±2.4), (28.4±1.9), (28.6±1.9) and (29.3±1.7) kg/m^2 respectively. There was no significant difference between groups of mean values of age, height, weight and BMI (p> 0.0.05). The number (%) of females of groups A, B, C and D were 12 (70.5%), 10 (59%), 10 (59%) and 13(76.5%) and the number (%) of males 5 (29.5%), 7 (41%), 7 (41%) and 4 (23.5%) respectively. There was no significant difference in sex distribution, between the four groups (p >0.05).

Table (1): subjects' characteristics of four groups

	Group A	Group B	Group C	Group D	f-value	p-value
Age (years)	47±5.9	49±5.3	47±5.5	48.8±6.4	0.757	0.522
Height (cm)	163.5±7.4	166.2±9	164.4±7.9	166±9.5	0.719	0.544
Weight (kg)	77.5±8.2	78.7±9.7	77.3±7	81±9.7	0.469	0.705
BMI (kg/m^2)	29±2.4	28.4±1.9	28.6±1.9	29.3±1.7	0.828	0.483
Sex Females	15 (75%)	14 (70%)	15 (75%)	14 (70%)	χ^2 = 0.251	0.969
Males	5 (25%)	6 (30%)	5 (25%)	6 (30%)		

Comparison between shockwave and laser on pain and FFI (Table 2):

a- Within groups

Group A: The median values (interquartile range) of pain pre and post study of group A were 7 (6-8) and 1.5 (1-2.75) cm respectively. The percentage of change was 79%. There was a statistically significant decrease in pain in group A post-study compared with that of pre-study (p 0.001). The median values (interquartile range) of FFI pre and post study of group A were 55.5 (41-76) and 3.6 (2-10.5) % respectively. The percentage of change was 93.5%. There was a statistically significant decrease in FFI in group A post-study compared with that of pre-study (p 0.001)**.**

Group B: The median values (interquartile range) of pain pre and post study of group B were 7.5 (7-8) and 2 (1.25-3) cm respectively. The percentage of change was 73.3%. There was a statistically significant decrease in pain in group B post-study compared with that of pre-study (p 0.001). The median values (interquartile range) of FFI pre and post study of group B were 64 (50-71) and 7.4 (3.4-14) % respectively. The percentage of change was 88.4%. There was a statistically significant decrease in FFI in group B post-study compared with that of pre-study (p 0.001)**.**

Group C: The median values (interquartile range) of pain pre and post study of group C were 7 (6-8) and 5 (4.25-6) cm respectively. The percentage of change was 28.6%. There was a statistically significant decrease in pain in group C post-study compared with that of pre-study (p 0.001)**.** The median values (interquartile range) of FFI pre and post study of group C were 57 (44-74) and 35 (26-45) % respectively. The

percentage of change was 38.6%. There was a statistically significant decrease in FFI in group C post-study compared with that of pre-study (p 0.001).

Group D: The median values (interquartile range) of pain pre and post study of group D were 7 (7-8) and 6 (5-7.75) cm respectively. The percentage of change was 14.3%. There was a statistically significant decrease in pain in group D post-study compared with that of pre-study (p 0.001). The median values (interquartile range) of FFI pre and post study of group D were 59 (51-74) and 45 (27-57) % respectively. The percentage of change was 23.7%. There was a statistically significant decrease in FFI in group D post-study compared with that of pre-study (p 0.001).

b- Comparison between groups: There was no significant difference in the median values of pain pre-study between the four groups (p 0.814), while there were significant differences post study (p 0.001). There was no significant difference in the median values of FFI pre-study between the four groups (p 0.664), while there were significant differences post study (p 0.001).

Table (2): Comparing pre and post study median values of pain/ FFI between and within groups

Variables	Group A	Group B	Group C	Group D	P value
Pain (cm)					
Pre-study	7 (6-8)	7.5 (7-8)	7 (6-8)	7 (7-8)	0.814
Post-study	1.5 (1-2.75)	2 (1.25-3)	5 (4.25-6)	6 (5-7.75)	0.001*
% of change (P-value)	79% 0.001*	73.3% 0.001*	28.6% 0.001*	14.3% 0.001*	
FFI (%)					
Pre-study	55.5 (41-76)	64 (50-71)	57 (44-74)	59 (51-74)	0.664
Post-study	3.6 (2-10.5)	7.4 (3.4-14)	35 (26-45)	45 (27-57)	0.001*
% of change (P-value)	93.5% 0.001*	88.4% 0.001*	38.6% 0.001*	23.7% 0.001*	

Data is represented as median (interquartile range), p-value: probability value, *: significant

Post-hoc test between groups for pain post study:

Post hoc test for pain post study revealed that; there was no significant difference between groups A and B (P 0.432) and between Groups C and D (p 0.374) **Table (3).** While there was significant difference between groups A and C (P 0.001) in favor to group A, between groups A and D (p 0.001) in favor to group A, between groups B and C (p 0.001) in favor to group B and between groups B and D (P 0.001) in favor to group B. Post hoc test for FFI post study revealed that; there was no significant difference between groups A and B (P = 0.341) and between Groups C and D (p=0.496). While there was significant difference between groups A and C (P = 0.001) in favor to group A, between groups A and D (p=0.001) in favor to group A, between groups B and C (p=0.001) in favor to group B and between groups B and D (P = 0.001) in favor to group B.

Table (3): post hoc test between groups of pain post-study

Post hoc between groups	Pain P-value	FFI P-value
Group A vs. B	0.432	0.341
Group A vs. C	0.001*	0.001*
Group A vs. D	0.001*	0.001*
Group B vs. C	0.001*	0.001*
Group B vs. D	0.001*	0.001*
Group C vs. D	0.374	0.496

Discussion:

Plantar fasciitis is the most prominent cause of heel pain and foot dysfunction. Treatments such as ESWT and LLLT are used, but their efficacy is unclear (22). This study's aim was to assess the efficacy of shockwave and laser therapy for plantar fasciitis.

The results of the study exhibited that there were significant reductions in pain levels and FFI scores in all groups after the study ($p < 0.001$). The percentage of change in pain and FFI scores varied among the groups, with Group A showing the highest percentage of change (79% for pain and 93.5% for FFI) and Group D showing the lowest percentage of change (14.3% for pain and 23.7% for FFI). The post hoc analysis revealed significant differences in pain and FFI scores between Group A and Groups B, C and D ($p < 0.001$), but no significant differences among Groups B, C and D ($p > 0.05$).

This study results were confirmed a recent retrospective cohort study that has investigated effects of different forms of shockwave therapy (Radial and focused) in compare with foot intrinsic strengthening exercise program and has reported functional improvement with minimal clinically important difference between radial and combined groups using the foot and Ankle Ability Measure (23).

This study came in agreement with prior systematic review and meta-analysis that has stated that shockwave therapy was effective in reducing pain and improving functional outcomes in patients with plantar fasciitis (24).

Our findings came in same line with a recent randomized controlled trial that demonstrated shockwave therapy was superior to conservative treatment in terms of pain reduction and functional improvement in patients with plantar fasciitis (25).

However, other studies conflicted with our findings. Earlier study has concluded that the evidence for efficacy of shockwave therapy for plantar fasciitis is equal to eccentric loading but superior to wait and

see strategy with positive effects over pain and VISA-A scores (26).

Our findings were agreed with a recent systematic review that has investigated effects LLLT on pain and disability in patients with PF and neglect any significant difference in short-term disability was found for participants in LLLT group compared to the placebo ones. Also, it concluded that LLLT might improve pain in the short term and could be considered as a component of care of patients with PF. However, this superiority disappeared compared to ESWT (27).

In the same line with our findings, a recent systematic review involved eleven randomized controlled trials with 658 patients has reported that ESWT exhibited a moderate confirmation to better pain and foot function of individuals with chronic plantar fasciitis. So, they recommended ESWT as a promising rehabilitation intervention that could improve both pain and foot function in who complained of chronic plantar fasciitis (28).

Earlier clinical trials stated that laser therapy, although statistically effective in reducing pain, might not be clinically meaningful due to small effect sizes those came in agreement with the current study (29). These findings highlight the importance of considering both statistical and clinical significance in interpreting research results.

Our findings agreed with earlier clinical trial concluded that ESWT conducted for one session per week along six consecutive weeks resulted in statistically significant pain reduction and function improvement in PF patients using VAS and mobility subscale of plantar fasciitis pain and disability scale (30).

On the other hand, a recent trial has compared efficacy of ESWT and LLLT in terms of fascia thickness, heel pain and foot functions in PF patients has concluded that both ESWT and LLLT seem to be effective on pain, foot functions and fascia thickness in PF treatment that might be explained by difference in laser wavelengths used as that study used only red wavelength (685 nm), (31). Where, in our trial use infrared wavelength which might not be suitable for ankle area as it is superficial, also, it used a wider age of only 34 patient that is a small sample to draw conclusion that could be generalized.

On the other hand, a recent clinical trial has compared the effects of Laser Therapy and ESWT with clinical parameters and Magnetic Resonance Imaging for managing PF Patients with spondylarthritis. They had ensured their efficiency in pain management and functional outcomes (32).

Another clinical trial has estimated the degree to which an accompanying therapy of LLLT with exercise and orthotic support ‘usual care’ improves functional ability in PF patient when compared to usual care alone. Both groups showed significant reduction in pain over 3 months; however, LLLT group had lower pain than control group at 3 months (p 0.03). Such combination therapy of LLLT with usual care is more effective to improve functional outcomes and activity-related pain when compared to traditional care alone (22). They attribute their result to different LLLT application that was applied on 5 points along heel and planter fascia, while in our trial it is applied on heel only.

In contrast to our study, a contemporary clinical trial comparing combination therapy of ESWT with exercise and orthotic support ‘usual care’ in PF patient when compared to usual care alone has revealed that ESWT did not have an additive benefit over usual care to improve foot function and walking performance over three months post-treatment (33). Absence of ESWT effect might be explained by distribution of the 2000 pulse as 1000 pulse was given to planter fascia and not the heel.

On the other hand, a recent clinical trial disagreed with our finding, they compared efficacies of ESWT and LLLT on forty patients suffering from chronic PF, their aged range 18-70 years, they did not use oral and/or parenteral corticosteroids in the last 6 months based on clinical outcome measures “VAS, Roles and Maudsley Score (RMS), American Orthopedic Foot and Ankle Association Score (AOFAS) and FFI”. This recent trial has revealed significant improvements in terms of pain, functional status and daily life activities following administration of both treatments. Furthermore, LLLT was found to be significantly more effective for alleviating pain than ESWT in treatment of PF (34). Such contradictions might be hard to explain due to lack of published paper from numerous items i.e., sampling, randomization, Shockwave used parameters, even detailed exercise description.

In disagreement of our findings, a recent randomized controlled trial has compared the short-term effectiveness of ESWT and LLLT on pain and function in PF patients and revealed significant main effects of time, interaction effects between both modalities and time on pain, disability and activity limitation. LLLT was found to be superior to ESWT as an effective approach in short-term PF management (35). This contradiction might be due to different control interventions, did not involve a control group, in addition unlike our study no ice application and/ or stretching beside laser and shockwave therapy, as well our trial was verified ESWT once a week unlike their trial it was applied twice per week.

There are several limitations to our study that should be considered when interpreting our results. First, this study evaluated short-term outcomes, with pain and function assessed immediately after the intervention. Longer-term follow-up would be needed to determine the sustainability of treatment effects and

whether there are any potential delayed effects or recurrence of symptoms.

Lastly, this study did not assess potential adverse effects or safety concerns associated with shockwave and laser therapies. While these interventions are generally considered safe, there may be potential risks, such as skin burns, nerve damage or other adverse effects that were not evaluated in the present study.

Conclusion:

Based on current clinical trial findings could ensure that Shockwave unlike laser alone or in combination with stretching exercise and ice massage, were effective in reducing foot pain and improving foot function in plantar fasciitis patients. Shockwave showed the highest efficacy

Limitation of this study:

This study did not investigate long-term effects, as well limited generalizability to other populations.

Recommendations:

Further research with larger sample sizes and longer follow-up is needed for confirmation. As well real need to conduct further trial on different subpopulations of patients with plantar fasciitis, such as patients with different disease durations, severity levels and comorbidities

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Conflict of interest:

The authors confirmed that this article content has no conflict of interest.

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