



Comparative Effectiveness of Radial Extracorporeal Shock Wave Therapy Versus Physiotherapy for Chronic Plantar Fasciitis

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Abstract: Background: Plantar fasciitis (PF) is a common and potentially debilitating cause of chronic plantar heel pain involving the plantar fascia and its surrounding structures. Radial extracorporeal shock wave therapy (rESWT) is widely accepted as a non-invasive treatment modality. **Aim of Study:** To determine the effectiveness of rESWT compared with physiotherapy in controlling pain intensity and functional stability in people with chronic PF. **Methods:** Patients who suffered from unilateral chronic PF and met the inclusion criteria were recruited to participate in this prospective randomized controlled trial (November 2022–November 2025). Patients were randomly assigned to two groups: group A (GA) received rESWT, and group B (GB) received physiotherapy. Pain intensity was the primary outcome measured by the visual analogue scale (VAS), and the American Orthopedic Foot and Ankle Society (AOFAS) score was the secondary functional outcome. Data were collected based on the AOFAS clinical classification system and VAS. These data were then statistically analyzed using SPSS version 27.0 (IBM Inc., Chicago, IL, USA). **Results:** In total, 296 patients who fulfilled the inclusion criteria remained for the final assessment; allocated equally, with 148 patients in each group. Their mean age was 46.3 years, with female predominance (77%). Both treatment groups showed significant within-group improvements in VAS and AOFAS scores from baseline to post-treatment ($p < 0.0001$). The mean VAS decreased from 8.6 to 3.6 in GA and from 9.1 to 4.1 in GB, showing an equal average decrease of 5.0 points in both groups. AOFAS scores also improved considerably within-group in both groups, improving from 42.2 to 85.6 in GA and from 42.9 to 84.8 in GB. On the other hand, there was no significant difference in the between-group change in VAS ($p = 0.637$) and AOFAS scores ($p = 0.663$). **Conclusion:** Both rESWT and PT showed considerable improvements in pain and foot function among patients with chronic PF. Neither one had a better outcome than the other.

Key Words: American Orthopedic Foot and Ankle Society Score (AOFAS), Radial Extracorporeal shock wave therapy (rESWT), physiotherapy, Plantar fasciitis, Visual Analog Scale (VAS)

INTRODUCTION

Plantar fasciitis (PF) affects approximately 10% of the general population, and it is a common cause of chronic heel pain, involving degenerative changes that may occur concurrently with local inflammatory and mechanical processes [1]. Studies have indicated that it is most common among those ages spanning between 40 and 60,

with a female-to-male ratio of 2:1. [2]. Some believe this condition is caused by microscopic tears from the stress of standing and repetitive weight-bearing, followed by altered biomechanics and a delay in collagen healing within the fascia which can lead to chronic pain even at rest [1-2]. Although the exact cause behind this phenomenon is still uncertain, it is believed that the

causation may be multifactorial [2]. It has been suggested to use conservative treatment strategies, such as rest, moderate activity, ice massage, and acetaminophen or nonsteroidal anti-inflammatory drugs, which can be somewhat satisfactory [3-4].

Currently, the most frequently employed treatment options are physiotherapy (PT), ESWT [4-5], the use of plantar orthotics, stretching of the calf muscle, and steroid injections [6]. For those who do not respond to these methods, surgery is regarded as an acceptable option, with numerous minimally invasive techniques [7], other regenerative therapies have shown encouraging outcomes [8]. The diagnosis of PF is mainly made by clinical evaluation [3,9,10], imaging studies are often unnecessary in those who meet clinical criteria until conservative treatment has failed [1]. The rESWT has been used as a non-invasive approach to manage chronic PF. It induces fast pain relief by stimulating soft tissue repair, reducing calcification, and suppressing pain receptors. Nevertheless, its actual effects are still a subject of debate [11], and doses and protocols can vary [4,12-14]. It is advised to administer rESWT without using local anesthesia, and it has been shown to result in clinical improvement within 3 to 12 weeks after treatment [15]. Despite the widespread use of rESWT for patients with chronic PF, its benefits remain controversial, with several studies showing statistically significant improvement but not clinically evident [16].

However, the question of whether rESWT is superior to PT—or vice versa—for treating chronic PF remains a subject of debate. Differences in treatment protocols, outcome measures, and follow-up periods have contributed to the discrepancies observed in the results of previous studies [17-18,24]. Accordingly, it remains necessary to conduct clinical research comparing these two treatment modalities to determine which one leads to the greatest improvement in pain and functional outcomes. This study aimed to determine the efficiency of rESWT versus PT in patients with chronic PF. Improvement in pain intensity, assessed using the VAS score, and foot function, assessed using the AOFAS score, were the primary and secondary outcomes, respectively.

METHODS

Research Design and Cohort

A prospective randomized controlled trial was conducted to assess the treatment outcomes at King Khalid Hospital's Outpatient Clinic in Hail, Saudi Arabia, from November 2022–November 2025. Patients were diagnosed by the same 3 orthopedic consultant surgeons. The participants were divided into 2 groups: Group A (GA), which received rESWT, and Group B (GB), which received PT. Participants were assigned to respective groups by a simple random selection technique utilizing a computer-generated sequence created by an independent biostatistician.

A computer-generated randomization sequence was used for allocation. It was independent of the clinical assessment and treatment procedures.

Inclusion Criteria

Patients should have unilateral chronic PF, clinically confirmed by typical focal pain originating from the medial plantar fascia, load-dependent plantar pain with a VAS score greater than 5, and morning pain characterized by discomfort with first steps after getting up.

In addition, participants must have a medical treatment history of more than three months and have been refractory to conventional treatment methods, such as systemic NSAIDs and regional cortisone injections. The 4-point Maudsley score was used as a measure of persistent symptomatic PF despite medical treatment. The presence or absence of a heel spur was assessed radiographically as a standard routine procedure. It was neither a criterion for eligibility nor a factor in determining the type of treatment. Participants must be at least 18 years old and must provide signed informed consent after being fully informed about the study. They must also be willing to waive additional therapeutic measures throughout the study period, apart from wearing orthotic shoes for more than two months.

Exclusion Criteria

Exclusion criteria include local and systemic neurological disorders, for example, sciatica, rheumatic diseases, and malignant diseases. Individuals with lower limb bone diseases such as osteomyelitis or Paget's disease are not eligible to participate in the study. In addition, patients with axial deformity following lower limb trauma, such as heel fractures, are excluded. Individuals on systemic corticosteroid therapy, or having diabetes, and those with coagulopathies are also not eligible to participate in the study. Pregnant women and those with bilateral heel pain are excluded from participation in the study. Likewise, participants who had previously been treated with ESWT or PT were excluded.

Baseline and Follow-Up

After obtaining written informed consent, the treating orthopedic surgeon conducted a baseline assessment. Follow-up assessments were performed at 1, 6, and 12 months after the last treatment session. During the follow-up of patients over the first six months, their adherence to the treatment regimen was confirmed. Whereas, for statistical data analysis, the change in VAS and AOFAS scores is calculated only between baseline and the final 12-month assessment.

Sample Size

The required sample size for comparing two groups with a 1:1 allocation ratio was determined based on a significance level (alpha) of 0.05 and a statistical power of 80% aiming to detect a clinically meaningful reduction

in VAS scores of 4 points (e.g., from 9 to 5) [10]. Accordingly, the calculated minimum sample size was 140 participants per group. To account for potential withdrawals or loss to follow-up during the study, the sample size was increased by 5%, resulting in a minimum of 147 participants per group. Each group was assigned 150 participants to ensure a sample size of at least 143 participants per group, accounting for potential contingencies.

Procedure

In GA, a single therapist who is a certified health professional trained in the application of rESWT provided ultrasound-guided rESWT throughout the treatment sessions; DUOLITH SD1 »ultra« shock wave equipment manufactured by Storz Medical AG in Switzerland (2009) was used with a low-intensity applicator. The therapist was not involved in any other aspect of the study and engaged with participants in a consistent manner, irrespective of their treatment assignment. During the procedure, the applicator was held perpendicular to the plantar fascia on the calcaneus, and ultrasonic gel was employed to ensure its contact with the skin. Patients received four treatment sessions at a frequency of 1000 beats per minute for 2 minutes (2000 impulses per session) and a power density of 0.25 mJ/mm², with weekly rest periods in between, without the need for anesthesia during the therapy. These parameters were applied to all patients in this group, as they are the rESWT protocol parameters used for chronic PF at the study center.

In GB, patients were engaged in eight weeks of PT in two sessions weekly. It included ultrasound, stretching, and strengthening exercises. They were subjected to ultrasound for 7 minutes at a frequency of 3 MHz and a power intensity of 1.5 W/cm². The stretching and strengthening process is made up of 10 cycles of stretching exercises for the plantar fascia, soleus muscle, gastrocnemius muscle, plantar flexors, and the intrinsic muscles of the foot. Participants were given verbal and written instructions to ensure correct technique. Stretches for each muscle were held for 10 seconds and repeated 6 times, for a total of 3 minutes per session. Patients underwent plantar fascia-specific stretching by dorsiflexing the ankle and toes while seated. For gastrocnemius stretching, standing calf stretches were carried out with the knee extended while the heel was maintained on the ground to target the gastrocnemius muscle. For soleus stretching, a similar stretch was done with the knee slightly flexed to stress the soleus muscle. Patients were instructed to carry out the activity on a daily basis during the treatment period. As this is the protocol used at the study center for treating chronic PF, it was administered to the patients in this group throughout the eight-week treatment period.

Co-interventions and Adherence

Patients were advised against seeking any additional treatments for PF during the study period, such as

analgesics, NSAIDs, stretching exercises at home, or any other kind of treatment.

In both groups, patients underwent in-person assessments of their pain and foot function. Further, between follow-up visits, they were regularly contacted by mobile phone to ensure they did not receive an out-of-scope treatment. This contact was maintained throughout the follow-up period to ensure close tracking of their progress and adherence to treatment protocols. However, patients in both groups were allowed to keep wearing orthopedic shoes.

Outcome Measures

The basic outcome measures included pain intensity evaluated using the Visual Analogue Scale (VAS), and foot function utilizing the American Orthopedic Foot and Ankle Society score (AOFAS). The primary and secondary outcome measures were the change in VAS and AOFAS scores between baseline and the post-treatment phase, respectively. Follow-up assessments were conducted one month and six months after the completion of treatment sessions to monitor adherence to the treatment protocol and ensure that no additional treatments were used. The effects of the treatment were evaluated after 12 months. The VAS was calculated by having the patient indicate their pain level on a 10-centimeter horizontal graded line marked in one-centimeter intervals, with the distance measured from the left zero end to the marked point; the lower indicates the better. According to AOFAS, 50% is allocated for function, 40% for pain, and 10% for alignment; a higher cumulative score designates higher levels of function. Weight-bearing X-rays of the foot were obtained to evaluate foot alignment.

Statistical Analysis

The study data were analyzed using the Statistical Package for Social Sciences (SPSS) version 27 program (IBM Inc., Chicago, IL, USA). Continuous variables were presented as mean±standard deviation (SD), while categorical variables were presented as frequencies and percentages. An independent-samples t-test was used to examine differences in continuous variables between the two treatment groups, whereas the chi-square test or Fisher's exact test, as appropriate, was employed for categorical variables. Changes in VAS and AOFAS scores from baseline to post-treatment at 12 months were compared within-group and between-groups. Statistical significance was set at a two-tailed p-value of less than 0.05 with 95% CI.

RESULTS

Participant Flow

The study initially enrolled 300 patients (150 in each group). During follow-up, two participants from GA were lost, while one from GB was lost to follow-up, and another withdrew from the study. A total of 296 patients with chronic unilateral PF remained for the final assessment,

Table 1: Baseline Variables, Demographics, And Outcome Measures

Variables (demographics, outcomes measures)	GA (rESWT)	GB (Physiotherapy)
Age/year	45.8±7.9	46.9±8.3
Female sex, n (%)	120 (81.1%)	108 (73.0%)
Baseline VAS (0-10, lower is better), mean±SD	8.6±1.7	9.1±0.7
Baseline AOFAS (0-100, higher is better), mean±SD	42.2±14.7	42.6±13.7

Table 2: Changes in VAS Scores from Baseline to Post-Treatment

Treatment group	Baseline VAS, Mean±SD	Post-treatment VAS, Mean±SD	Within-group p-value	Mean change
rESWT (GA)	8.6±1.7	3.6±2.8	<0.0001	-5.0
Physiotherapy (GB)	9.1±0.7	4.1±2.7	<0.0001	-5.0
Between-group comparison of change	p= 0.637			

p<0.0001 represents the within-group pre/post comparison; p = 0.637 represents the reported between-group comparison and does not support superiority of either intervention

Table 3: Changes in AOFAS Components from Baseline to Post-Treatment

Treatment	AOFAS components	Baseline, Mean±SD	Post-treatment, Mean±SD	Within-group p -value
rESWT (GA)	Function (50 points)	28.1±2.2	45.3±11.5	<0.0001
	Pain (40 points)	4.3±9.3	30.5±12.7	<0.0001
	Alignment (10 points)	9.8±2.7	9.8±2.7	1.000
	Total AOFAS (100 points)	42.2±14.7	85.6±15.6	<0.0001
Physiotherapy (GB)	Function (50 points)	28.9±1.6	45.9±11.6	<0.0001
	Pain (40 points)	4.0±6.2	28.9±11.2	<0.0001
	Alignment (10 points)	10.0±0.0	10.0±0.0	1.000
	Total AOFAS (100 points)	42.9±12.6	84.8±17.6	<0.0001
Between-group comparison of change	Between-group comparison of AOFAS change: p = 0.663			

p<0.0001 represents the within-group pre/post comparison; the between-group comparison of AOFAS change: p = 0.663 and does not support superiority of either intervention

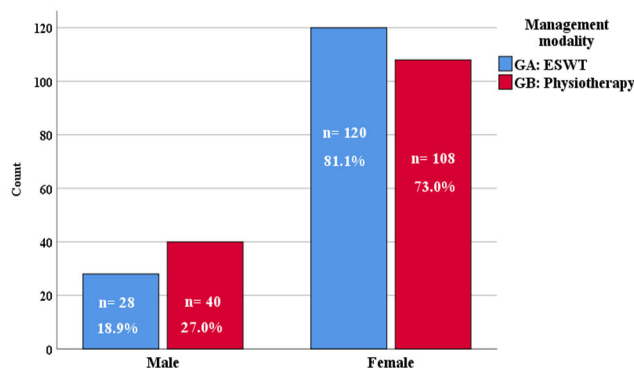


Figure 1: Gender Distribution in Patients with Chronic PF

148 patients in each group. None of the patients required additional treatment throughout the follow-up period.

Baseline Characteristics

The average age of the participants was 46.3±8.1 years (range: 32–63 years), with the mean age of GA being 45.8±7.9 years and GB being 46.9±8.3 years (p = 0.241). The majority were female (77.0%, n = 228), with a female-to-male ratio of 3.4:1; in Group A, females constituted 81.1% (n = 120), and in Group B, females constituted 73.0% (n = 108) (p = 0.097). Baseline demographic characteristics were comparable between the two treatment groups (Table 1 and Figure 1).

VAS Results

Table 2 shows a significant improvement in mean within-group pain intensity in both groups (VAS, P<0.0001). The mean VAS score decreased from 8.6±1.7 to 3.6±2.8 in the GA, a decrease of 5.0 points. It decreased from 9.1±0.7 to 4.1±2.7 in the GB, a 5.0-point decrease. Therefore, the absolute within-group reduction in VAS was identical in both groups. The reported between-group comparison was also not significant (p = 0.637).

AOFAS Results

Both groups showed improvement from baseline to post-treatment in AOFAS scores (p<0.0001). In GA, it increased from 42.2±14.7 at baseline to 85.6±15.6 post-treatment, with a mean increase of 43.4 points. Likewise, it increased from 42.9±12.6 to 84.8±17.6 in GB, with a mean increase of 41.9 points. Despite the slightly greater numerical improvement in the GA group—by approximately 1.5 points—this does not indicate superiority, given that the comparison between the two groups was not statistically significant (p = 0.637). Limb alignment remained unchanged in both groups (p = 1.000). The general improvement in the AOFAS score is therefore primarily attributable to improvements in function and pain symptoms, rather than changes in limb alignment (Table 3).

Interpretation of AOFAS Components

The baseline and post-treatment analysis revealed significant differences in functional outcomes, assessed

Table 4: Baseline and Post-Treatment Changes in VAS and AOFAS Scores

Variables	Pairwise comparisons					
	GA (Mean±SD)			GB (Mean±SD)		
	Baseline	Post-treatment	p-value	Baseline	Post-treatment	p-value
VAS (0-10, lower is better)	8.6±1.7	3.6±2.8	<0.0001	9.1±0.7	4.1± 2.7	<0.0001
AOFAS (0-100, higher is better)	42.2±14.7	85.6±15.6	<0.0001	42.9±12.6	84.8±17.6	<0.0001

Between-group comparison of VAS change: $p = 0.637$, Between-group comparison of AOFAS change: $p = 0.663$

through the AOFAS score. Both groups showed substantial improvement in the function and pain components of the AOFAS score.

The alignment component remained unchanged in both groups ($p = 1.00$). This indicates that the overall improvement in total AOFAS score was not attributed to changes in structural alignment.

The PT group also demonstrated substantial improvement in pain and function. Although the numerical increase in total AOFAS was slightly greater in GA, the current results do not establish a statistically significant difference between the interventions.

Baseline and Post-Treatment Comparison

The baseline and post-treatment analysis demonstrated statistically significant improvements in VAS and AOFAS scores in both treatment groups. The VAS score decreased by 5.0 points in each group. The total AOFAS score increased by 43.4 points in GA and 41.9 points in GB.

The magnitude of improvement in VAS analysis ($p = 0.637$), indicated no statistically significant difference between treatments (Table 4). Notably, no recurrences of plantar heel pain after initial improvement, no treatment failure, and no adverse events were observed, and no additional treatment was required during follow-up.

DISCUSSION

Inferior heel pain is a common condition that affects many people, with PF being the most frequent cause, and remains a significant challenge in orthopedic practice, impacting the quality of life for many individuals [12]. The gender disparity in prevalence, with females being more frequently affected [2,13,17], raises questions about potential biological, hormonal, or lifestyle factors that may contribute to this trend. The predominance of female patients in the current study (77%) and in the research by Greve *et al.* (81%) [18] highlights the need for targeted approaches in understanding and treating this condition, especially considering the main age of the affected individuals is around 46 years, a demographic that may be partly susceptible due to factors such as weight changes, footwear choices, and physical activity levels. The demographic distribution in this study is consistent with some previous studies [17-19]. The higher number of female participants and reliance on a single hospital may limit the generalizability of the findings to other populations and different healthcare settings.

Despite the high incidence of PF, advancements in treatment methodologies have been slow. Current conservative management strategies lack a standardized protocol, leading to variability in patient outcomes and satisfaction [20]. rESWT has emerged as a promising intervention, utilizing high-energy sound waves to stimulate healing. Its parameters, including intensity, pulse frequency, and the specific type of shockwave applied, are critical in determining its effectiveness. Research indicates that these factors can significantly influence treatment outcomes, suggesting that a more tailored approach to rESWT could enhance its efficacy [21]. The comparison of rESWT with PT has yielded mixed results in various studies. The results demonstrated that both treatment methods were significantly and comparably effective in alleviating pain. This was reflected by the marked improvement in Visual Analog Scale (VAS) scores in both groups. The reported between-group comparison was not statistically significant. Therefore, neither treatment modality is superior to the other in terms of pain relief. Additionally, the assessment of AOFAS scores showed consistent improvement in both groups. The total AOFAS score increased by 43.4 points in GA and by 41.9 points in GB. Even though the increase was slightly greater in GA, it was not statistically significant. Moreover, the absence of changes in the axial alignment component in both groups suggests that the improvement in the total AOFAS score was driven by changes in pain and function rather than structural alignment. This aligns with previous studies that have emphasized the advantages of rESWT in treating chronic musculoskeletal conditions, particularly those involving soft tissue [16,22].

Previous studies have yielded inconclusive results, including evidence supporting PT, studies demonstrating comparable effects, and other research reporting only minimal differences between rESWT and placebo. These discrepancies may be due to differences in patient characteristics, treatment protocols, the interventions compared, and outcome assessment methods [14,19,22,24].

The present findings support the effectiveness of both treatment approaches. However, the contention that PT might be equally effective as rESWT, as advocated by Abdoli and Roohi, highlights the need for further investigation into the mechanisms of both treatments [23]. The conflicting results, particularly those from Rompe *et al.*, asserting PT's superiority [24], contrast with other studies that paired rESWT with PT and found

that this approach was more efficient than using isolated PT or frequent rESWT [19,22]. Such findings underscore the importance of study design, patient selection, and treatment protocols in deriving conclusive evidence. Moreover, the debate surrounding the effectiveness of rESWT is further complicated by contrasting findings, such as those from studies that report no significant difference between rESWT and Placebo treatments in treating chronic PF [14]. These inconsistencies introduce skepticism about the universal applicability of rESWT as a treatment modality, warranting a cautious interpretation of its effectiveness in the management of chronic PF.

Interestingly, the current study reported no recurrences of PF during the follow-up period, which is an encouraging finding. In contrast, other studies have reported recurrence rates as high as 8% [25]. This discrepancy may be attributed to variations in patient demographics, treatment adherence, or follow-up methodologies. Such differences reinforce the necessity for long-term studies to better understand the durability of treatment effects and recurrence patterns in PF patients.

Limitations

The current study, like other studies, has several limitations:

- **First:** Given the nature of the interventions, blinding of participants or therapists was not possible. Consequently, subjective outcomes—such as VAS and AOFAS scores—could have been influenced by expectations or assessor bias
- **Secondly:** The study was only carried out at a single hospital, which may affect the applicability of the results to other populations and healthcare settings
- **Thirdly:** Factors—such as obesity/body mass index, standing while working, physical activity, or foot biomechanics—were not evaluated. Finally, although patients underwent follow-ups at one, six, and twelve months, the assessments during the first six months served solely to verify adherence to treatment constraints

Treatment outcomes and effects were recorded only at one year, which limits the ability to interpret the progression of the treatment's effects.

CONCLUSIONS

The study compared the efficacy of rESWT with physiotherapy (PT) for chronic PF. Both methods significantly reduced pain severity and improved foot function, as shown by VAS and AOFAS scores. Changes in the VAS as well as AOFAS scores within and between groups were not statistically significant. Therefore, both modalities may be considered effective treatment options for chronic PF. While rESWT is an effective non-surgical option for treating chronic PF, the decision to

use this or PT for a patient with chronic PF must be based on patient characteristics, treatment availability, and the extent of their adherence to the treatment plan. Future research with larger sample sizes and diverse populations should focus on exploring treatment progress and long-term outcomes.

DECLARATIONS

Declaration of Conflict of Interest

The authors do NOT have any potential conflicts of interest for this manuscript.

Declaration of Funding

The authors received NO financial support for the preparation, research, authorship, and publication of this manuscript.

Declaration of Ethical Approval for Study: The research was approved by the research ethics committee at the University of Hail (H-2022-362).

Declaration of Informed Consent

Written informed consent was obtained from the participant prior to enrollment into study.

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Availability of Data and Materials

The study's data and materials are available upon request.

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