

Exploratory Analysis of Pain and Function Improvement after Radial Pressure Wave Therapy in Plantar Fasciitis

Armando Tonatiuh Ávila García¹, Ana Lilia Villagrana Rodríguez¹, Cinthia Citlalli Domínguez Navarrete¹, Karen Chacón Morales¹, Marco Antonio González López¹

Abstract

Background: Plantar fasciitis (PF) is a common cause of heel pain, impairing functionality and quality of life. Radial pressure wave therapy (RPWT) is a well-known non-invasive option to treat PF, but evidence on factors influencing outcomes is limited.

Objectives: The objectives of the study are to explore associations between baseline patient characteristics and clinical outcomes and to evaluate the impact of RPWT on pain and functionality in PF patients.

Materials and Methods: This exploratory, pilot study included 19 PF patients treated with three RPWT sessions. Pain intensity (numerical pain rating scale [NPRS]) and functionality (World Health Organization Disability Assessment Schedule 2.0 [WHODAS 2.0]) were assessed pre- and post-treatment. Retrospective data on age, body mass index (BMI), and PF chronicity were analyzed. Statistical tests included Wilcoxon signed rank for outcome comparisons and Spearman's correlation for associations.

Results: NPRS scores decreased significantly from 6.89 ± 1.88 to 4.42 ± 2.36 ($P = 0.001$), while WHODAS 2.0 scores improved from 47.60 ± 21.85 to 21.34 ± 20.30 ($P = 0.001$). Baseline NPRS scores showed a moderate, positive correlation with post-treatment NPRS scores ($\rho = 0.561$, $P = 0.01$). No significant correlations were found between post-treatment outcomes and BMI, age, or PF chronicity.

Conclusion: RPWT significantly reduced pain and improved functionality in PF patients, with baseline pain levels emerging as a factor associated with outcomes. These preliminary findings support RPWT as a promising treatment and highlight the need for larger, controlled studies to validate and expand these results.

Keywords: Plantar fasciitis, Radial pressure wave therapy, Rehabilitation outcomes

Introduction

Plantar fasciitis (PF) is one of the most common foot conditions in adults, affecting 10% of the general population and limiting individuals' ability to perform daily activities. Its incidence has increased alongside the rise in physical activity, becoming a significant challenge for treatment. The condition has an incidence of 3.83 cases/1,000 persons/year, predominantly affecting individuals aged 40–60, with a peak prevalence in younger runners [1].

The plantar fascia is a dense, inelastic fibrous band that extends from the medial calcaneal tuberosity to the toes. PF is an inflammatory condition characterized by pain at the medial insertion of the plantar aponeurosis, particularly at the calcaneus, which worsens with the first steps in the morning or after a period of inactivity and gradually improves with activity and rest. Diagnosis is clinical and based on the

presence of heel pain and tenderness at the origin of the plantar fascia [2-5].

Standard treatment for PF includes conservative measures such as lifestyle changes, physical therapy, orthotics, non-steroidal anti-inflammatory drugs, corticosteroids, footwear modifications, and, in some cases, surgical treatment. However, these approaches do not always result in significant improvement [1, 2]. Radial pressure wave therapy (RPWT) is a therapeutic option applied to the medial calcaneal tuberosity. These acoustic waves, characterized by pressure changes that propagate through tissues in a divergent pattern, stimulate repair through an inflammatory response, potentially providing long-lasting analgesia, especially in chronic conditions. Determining the most effective treatment intensity is critical to achieving optimal outcomes [6-8].

¹Department of Physical Medicine and Rehabilitation, Hospital Civil de Guadalajara Fray Antonio Alcalde, Jalisco, México, 44280

Address of Correspondence

Dr. Armando Tonatiuh Ávila García,
Department of Physical Medicine and Rehabilitation, Hospital Civil de Guadalajara Fray Antonio Alcalde, Coronel Calderón 777, Guadalajara, Jalisco, México, 44280
E-mail: atavila@hcg.gob.mx



Dr. Armando
Tonatiuh Ávila
García



Dr. Ana Lilia
Villagrana
Rodríguez



Dr. Cinthia Citlalli
Domínguez
Navarrete



Dr. Karen
Chacón
Morales



Dr. Marco Antonio
González López

Submitted Date: 07 Mar 2025, Review Date: 30 Apr 2025, Accepted Date: 10 May 2025 & Published: 30 Jun 2025

Journal of Regenerative Science | Available on www.jrsonweb.com | DOI:10.13107/jrs.2025.v05.i01.159

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The American College of Foot and Ankle Surgery published guidelines on PF management, recommending extracorporeal shockwave therapy (ESWT) with a grade B level of evidence. Several meta-analyses have concluded that RPWT is an effective and safe technique for treating PF, achieving pain relief and improved functionality. This condition represents a public health problem that significantly affects the quality of life, emphasizing the need to standardize optimal management, including radial shockwave therapy [9-11].

Given the preliminary nature of the evidence and the variability in RPWT outcomes, this study was designed as an exploratory analysis of a pilot sample to identify potential factors associated with pain and functional improvement in patients with PF treated with this therapy, based on pre- and post-treatment measurements. The findings aim to provide a basis for future larger-scale research with long-term follow-up and to contribute to evidence-based treatment for this population.

Materials and Methods

Study design, setting, and participants

This study was designed as an exploratory, cross-sectional, pilot study aimed at identifying factors associated with improvements in pain and functionality following RPWT in patients with PF. The study was conducted at a tertiary care hospital. Data collection was retrospective and included patients treated with RPWT for PF between January 2022 and June 2024.

Patients were eligible for inclusion if they had a documented diagnosis of PF confirmed by clinical evaluation and, if applicable, radiographic evidence of calcaneal spur; aged 18–60 years; had experienced symptoms for more than 3 months before treatment; completed three sessions of RPWT following a standardized protocol (2,000 impulses/session, 10 Hz, and 3.5 bar); and had complete medical records and follow-up data at 3-month post-treatment. Patients were excluded if they had undergone surgery or corticosteroid injection in the affected foot within the previous 6 months; were pregnant at the time of treatment; had concomitant conditions such as fractures, active infections, or sprains in the affected limb; or were diagnosed with systemic conditions such as cancer, osteoporosis, or autoimmune diseases. Additional exclusion criteria included incomplete or missing medical records and failure to attend follow-up appointments or complete the RPWT sessions.

No formal sample size calculation was performed, given the exploratory nature of the study. Instead, the sample consisted of all patients meeting the inclusion criteria and with complete follow-up data at 3-month post-treatment, resulting in a total of 18 participants. This approach was intended to provide preliminary insights and guide the development of future research with larger and more robust samples.

Outcome measures

The primary outcomes of this study were pain intensity and functionality, assessed using the numerical pain rating scale (NPRS) and the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) scale, respectively. The NPRS is a 10-cm horizontal line, where 0 represents “no pain” and 10 represents “the worst pain imaginable.” It is a widely used, reliable, and validated tool for measuring subjective pain intensity. The WHODAS 2.0,

developed by the World Health Organization, evaluates functionality and disability across six domains: Cognition, mobility, self-care, interpersonal relationships, life activities, and community participation. The 12-item version of the WHODAS 2.0 was used, with each item rated on a scale from 1 (none) to 5 (extreme or cannot do). Higher scores indicate greater disability or functional impairment.

In addition, a simple internal questionnaire was used to collect sociodemographic and lifestyle information, including age, gender, body mass index (BMI), level of education, and physical activity participation.

Outcome measures were collected retrospectively at two points: Baseline (before RPWT treatment) and immediately after completing the treatment sessions. These measures were used to evaluate changes in pain and functionality and to explore potential associations between patient characteristics and treatment outcomes.

Data collection and procedures

Data collection was conducted retrospectively using electronic medical records from the physical medicine and rehabilitation department of a public tertiary care hospital. Patients with a documented diagnosis of PF who underwent RPWT between January 2022 and June 2024 were identified and screened for eligibility based on the inclusion and exclusion criteria. Data included patient demographics, clinical characteristics, and outcome measures such as pain intensity and functionality.

For sociodemographic and lifestyle variables, a simple internal questionnaire was administered during routine clinical evaluations at baseline. Data related to the RPWT intervention, such as the number of sessions and treatment parameters, was also obtained from medical records. Outcome measures were recorded at 2 times: Baseline (before treatment) and immediately after completing the RPWT sessions.

During the RPWT sessions, therapy was applied to the most painful area of the foot, following a standardized protocol consisting of three weekly sessions, with each session delivering 2,000 impulses at a frequency of 10 Hz and a pressure of 3.5 bar with the device BTL-6000 radial shockwave therapy (BTL Industries, Ltd.). Consistency in the administration of the therapy and the collection of post-treatment data was ensured through adherence to this protocol.

Statistical analysis

The statistical analysis was performed using the Statistical Package for the Social Sciences software. Descriptive statistics were calculated for all variables. For quantitative variables, measures of central tendency and dispersion were used, including median and interquartile range for non-normally distributed data and mean and standard deviation for normally distributed data. Frequencies and percentages were calculated for categorical variables. The normality of data distribution was assessed using the Shapiro–Wilk test.

Inferential analyses were conducted to explore differences in pain intensity and functionality scores (NPRS and WHODAS 2.0) between baseline and immediate post-treatment. Paired t-tests were applied for normally distributed data, and Wilcoxon signed-rank tests for non-normally distributed data. Statistical significance was set at a $P < 0.05$.

Bivariate correlations between pain intensity, age, BMI, and baseline disability were analyzed. Pearson's correlation coefficient was used for normally distributed variables, while Spearman's rank correlation was applied for non-normally distributed variables. Correlation strength was interpreted as follows: No correlation (0.00), very weak (0.01–0.20), weak (0.21–0.40), moderate (0.41–0.60), strong (0.61–0.80), very strong (0.81–0.99), and perfect (1.00). Statistical significance was also considered at a $P < 0.05$.

Given the exploratory and pilot nature of this study, the results were interpreted as preliminary patterns intended to generate hypotheses and guide the design of future studies with larger sample sizes and greater statistical power.

Ethics

This pre- and post-test study was conducted in the physical medicine and rehabilitation department of a public tertiary care hospital. The research adhered to the ethical guidelines set forth by the World Medical Association's Declaration of Helsinki and was approved by the hospital's institutional ethics committee (approval number: CEI 255/24). The study is registered in ClinicalTrials.gov (identifier: NCT06813105). As this study utilized a retrospective analysis of medical records, informed consent was not required. Confidentiality and anonymity of patient data were maintained throughout the study, in compliance with ethical and regulatory standards.

Results

Sample characteristics

The study included a total of 19 patients with a mean age of 46.58 ± 7.07 years, reflecting a middle-aged population typically affected by PF. The mean BMI was 29.61 ± 5.04 kg/m², with 57.9% of participants classified as having normal weight or overweight and 42.1% classified as obese, consistent with known risk factors for PF. Regarding physical activity, 89.5% of patients reported not engaging in

Table 1: Baseline characteristics of the study population	
Characteristic	Value (%)
Number of patients	19
Age (years)	46.58 ± 7.07
BMI (kg/m ²)	26.61 ± 5.04
Weight status	
Normal weight/overweight	57.9
Obesity	42.1
Physical activity	
Irregular (<3/week)	89.5
Regular (3/week or more)	10.5
Duration of PF	
<6 months	63.2
>6 months	36.8
Prior physical therapy	
Received	68.4
Not received	31.6
BMI: Body mass index, PF: Plantar fasciitis	

regular exercise (defined as physical activity at least 3 times/week), while only 10.5% engaged in regular physical activity. The duration of PF was <6 months for 63.2% of participants, while 36.8% had chronic PF (≥ 6 months). In addition, 68.4% of patients had undergone prior conventional physical therapy, while RPWT was the first therapeutic approach for 31.6%. Further details are summarized in Table 1.

Changes in outcome measures

The Wilcoxon signed-rank test revealed significant reductions in both pain intensity and functionality scores following RPWT. The NPRS score decreased from 6.89 ± 1.88 at baseline to 4.42 ± 2.36 post-treatment ($P = 0.001$), indicating substantial pain relief. Similarly, the WHODAS 2.0 score decreased from 47.60 ± 21.85 to 21.34 ± 20.30 (P

Table 2: Differences in pain intensity and functionality pre and post-treatment

Outcome measure	Pre-treatment (Mean \pm SD)	Post-treatment (Mean \pm SD)	P-value*
NPRS	6.89 ± 1.88	4.42 ± 2.36	<0.01
WHODAS 2.0	47.60 ± 21.85	21.34 ± 20.30	<0.01

NPRS: Numeric pain rating scale, WHODAS 2.0: World Health Organization Disability Assessment Schedule 2.0, SD: Standard deviation. *Wilcoxon signed-rank test

= 0.001), reflecting notable improvement in functionality. These findings suggest that RPWT effectively reduced pain and improved functionality in patients with PF after three treatment sessions. Further details are summarized in Table 2.

Exploration of associations between variables

Spearman's bivariate correlation analysis showed a moderate, positive, and statistically significant correlation between post-treatment NPRS scores and baseline NPRS scores ($\rho = 0.561$, $P = 0.01$), indicating that patients with higher baseline pain tended to retain higher post-treatment scores. In contrast, the correlations between post-treatment NPRS scores and age or BMI were weak and not statistically significant.

For WHODAS 2.0 post-treatment scores, weak-positive correlations were observed with both baseline WHODAS 2.0 scores and BMI, but these were not statistically significant. A very weak, negative, and non-significant correlation was found between post-treatment WHODAS 2.0 scores and age. These findings suggest limited associations

Table 3: Relationship between patient characteristics and post-treatment outcomes

Variable	NPRS post-treatment (ρ *, P-value)	WHODAS 2.0 post-treatment (ρ , P-value)
Baseline NPRS	0.561, 0.01	0.517, 0.02
Baseline WHODAS 2.0	0.429, 0.06	0.381, 0.10
Age	0.226, 0.35	-0.124, 0.61
BMI	0.265, 0.27	0.304, 0.20

*Spearman's correlation coefficient, NPRS: Numeric pain rating scale, WHODAS 2.0: World Health Organization Disability Assessment Schedule 2.0, BMI: Body mass index

between patient demographics or clinical characteristics and the observed improvements, warranting further research with larger sample sizes to validate these patterns. Further details are summarized

in Table 3.

Discussion

This study demonstrated significant improvements in pain intensity and functionality following RPWT in patients with PF, as evidenced by reductions in NPRS and WHODAS 2.0 scores. A moderate positive correlation between baseline and post-treatment NPRS scores suggests that initial pain levels may influence treatment outcomes. However, other variables, such as age and BMI, showed weak or non-significant correlations with post-treatment results. These findings are consistent with the effectiveness of ESWT reported in prior studies, including the work by Lee et al. [12], which identified ESWT as a successful long-term treatment for chronic refractory tendinopathy. Similar to Lee et al. [12], who highlighted the importance of specific clinical and imaging characteristics in predicting treatment success, our study underscores the potential role of baseline pain levels in influencing outcomes. These findings align with previous evidence, including Guimarães et al., who identified ESWT as one of the most effective interventions for reducing pain in PF, particularly in sustained outcomes over the medium and long term [13]. However, additional factors, such as imaging findings or enthesopathic changes, were not assessed in this study and may warrant consideration in future research.

The observed improvements in NPRS and WHODAS 2.0 scores are consistent with prior studies that have reported the efficacy of RPWT in reducing pain and improving functionality in PF patients [14, 15]. For instance, Melese et al. conducted a systematic review of randomized controlled trials and highlighted that ESWT, which includes radial pressure wave RPWT, is a promising intervention for alleviating pain and improving foot function in chronic PF patients [16]. Similarly, Guimarães et al. demonstrated that while multiple therapies may offer short-term pain relief, ESWT stands out as one of the few interventions with sustained benefits over time [13]. These findings align with the reductions in NPRS scores observed in our study after three treatment sessions. However, the lack of significant correlations with demographic variables, such as BMI and age, contrasts with findings from studies like Lee et al. [12], where higher BMI was associated with reduced treatment efficacy. Interestingly, Notarnicola et al. reported that elevated BMI was linked to greater therapeutic success in their study of prognostic factors for ESWT across various tendinopathies, including PF. These discrepancies may be attributed to differences in sample size, treatment protocols, or patient populations, such as the inclusion of multiple tendinopathies in Notarnicola et al.'s analysis [17]. This variability highlights the need for further research to identify patient-specific characteristics that predict optimal responses to RPWT in PF and related conditions.

These findings suggest that RPWT can be a valuable non-invasive treatment for PF, offering significant reductions in pain and disability after just three sessions. The standardized protocol used in this study, which involved three weekly sessions with defined parameters (2,000 impulses, 10 Hz, 3.5 bar), demonstrates both its feasibility and its potential for broader clinical implementation in routine rehabilitation settings. Evidence from prior studies, including the meta-analysis by Li et al., supports the superiority of ESWT over other modalities, such as ultrasound therapy, in reducing pain in PF patients [13, 18]. However, similar to the findings of Li et al., improvements in functionality

observed in our study were notable but less pronounced compared to pain relief, indicating that ESWT primary benefit may lie in its analgesic effects. In addition, the findings of Vahdatpour et al. suggest that ESWT may not only alleviate pain but also promote structural healing of the plantar fascia, as evidenced by ultrasonographic changes [19]. These results further highlight the potential of ESWT, including RPWT, to address both the symptomatic and structural aspects of PF. The variability in individual responses observed in this study underscores the importance of identifying patient-specific characteristics, such as baseline pain levels or chronicity of PF, to optimize treatment outcomes. Personalized therapeutic approaches could enhance the clinical efficacy of RPWT and improve the overall management of PF.

This study has limitations inherent to its exploratory and pilot nature. The small sample size ($n = 19$) and the absence of a control group restrict the generalizability of the findings, as the lack of comparison with alternative treatments or placebo hinders definitive conclusions about the relative efficacy of RPWT. In addition, the retrospective data collection and the reliance on short-term outcomes preclude a comprehensive understanding of the long-term sustainability of the observed improvements in pain and functionality. While previous studies, such as Guimarães et al., have highlighted the sustained benefits of shockwave therapy, our study lacked follow-up assessments beyond the immediate post-treatment phase, which limits our ability to contextualize the results within broader therapeutic timelines [13]. Another notable limitation is the exclusion of imaging assessments, such as ultrasonography, which could have provided objective measures of structural changes in the plantar fascia, as demonstrated in studies like Vahdatpour et al. Incorporating such measures in future studies could enhance the understanding of the mechanistic effects of RPWT [19-21]. Furthermore, potential confounding factors, such as psychosocial variables, comorbidities, and adherence to post-treatment recommendations, were not assessed but could influence treatment outcomes. Future research should address these limitations by employing larger, more diverse samples and randomized controlled designs to validate these preliminary findings. Including a placebo or active comparator group would be critical for establishing the relative efficacy of RPWT. In addition, longitudinal studies with extended follow-up periods and the incorporation of imaging and patient-reported outcomes could provide deeper insights into the efficacy, mechanisms of action, and durability of RPWT effects [22, 23]. Such efforts would not only strengthen the evidence base for RPWT but also contribute to the development of personalized treatment strategies for PF.

Conclusion

This exploratory analysis identified baseline pain intensity as a potential factor associated with post-treatment outcomes in patients with PF undergoing RPWT. While no significant associations were found between outcomes and other demographic variables, such as age or BMI, the findings highlight the importance of considering individual patient characteristics when evaluating responses to RPWT.

In addition, the study observed significant improvements in pain intensity and functionality following RPWT, suggesting its potential as a non-invasive treatment option for PF. However, these results

should be interpreted cautiously given the descriptive nature of the study, the small sample size, and the absence of a control group. Future research should prioritize validating these associations and clinical outcomes through larger, more robust studies, incorporating diverse patient populations, and including additional measures such as

imaging and long-term follow-up. These efforts will be crucial for advancing the understanding of RPWT's role in managing PF and for developing evidence-based, personalized treatment strategies.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: Nil **Source of support:** None

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Conflict of Interest: NIL
Source of Support: NIL

How to Cite this Article

Ávila García AT, Rodríguez ALV, Navarrete CCD, Morales KC, López MAG | Exploratory analysis of pain and function improvement after radial pressure wave therapy in plantar fasciitis. | Journal of Regenerative Science | Jan-Jun 2025; 5(1): 08-13.