Faculty Of physical Therapy
Cairo University

Cairo University

Comparison between Radial Extracorporeal Shockwave Therapy and Traditional Physical Therapy for treating Plantar Fasciitis: Randomized Controlled Clinical Trial

Ahmed Z Hussein[1],Mahmoud I Ibrahim[2], Robert Donatelli[3]

[1] Faculty of Physical Therapy, Pharos University, Egypt
[2] Faculty of Physical Therapy, Cairo University, Egypt
[3] Rocky Mountain University of Health Professions, USA

Abstract

Background: Plantar fasciitis is estimated to account for up to 15% of foot disorders in adults. There are different treatment options and the success rate of the non-surgical treatment is between 44 and 90%. Relevant clinical studies have produced contradictory results about the efficacy of radial extracorporeal shockwave therapy (RSWT) and the clinical significance of its effect compared with traditional physical therapy remains controversial. **Objective:** The purpose of the present study was to compare RSWT with traditional physical therapy for treatment of plantar fasciitis. **Design:** Prospective comparative randomized controlled clinical study. **Participants and intervention:** Sixty patients with a diagnosis of chronic plantar fasciitis participated in the study. The mean age was 49.6 ± 11.8 years (25-68 years), 65% were female, 75% were overweight, and 70% used analgesics regularly. Patients were randomly divided into 2 groups. Group 1 no=30 subjects received 10 traditional physical therapy sessions comprising ultrasound, therapeutic exercises, and guidance for home-based stretching. Group 2 no=30 subjects received 2 applications of RSWT, once a week for only 2 weeks (2,000 impulses with energy flux density = 0.16 mJ/mm2 per session), and guidance for home-based stretching. **Main outcome measures**: Pain and functional abilities were assessed before the treatment, immediately after the end of the treatment, at 3 months, and at 12 months later. **Results:** At the 12-month follow-up, both treatments were found to have been effective for pain relief, increasing functional abilities, improving quality of life, and heightening satisfaction among the patients with plantar fasciitis, statistical analysis showed no significant difference between the 2 groups (P > 0.05). Nevertheless, the improvement with RSWT occurred relatively faster. **Conclusion:** Although both treatments were effective, RSWT was not seen to be more effective than traditional physical therapy program at the assessment done 12 months after the end of the treatment.

Keywords:*Plantar fasciitis, Shockwave therapy, Physical therapy, Radial extracorporeal shockwave therapy*

Corresponding Author*: Dr. Mahmoud Ibrahim, imahmoud@nova.edu, Department of Orthopedic, Musculoskeletal Disorder, and Surgery, Faculty of Physical Therapy, Cairo University, Egypt.*

INTRODUCTION

Shockwave is a high amplitude sound wave causing transient pressure disturbance that propagates rapidly in three-dimensional space.[1,2] It is associated with a sudden rise from ambient pressure to its maximum pressure at the wave front.[2]

A significant tissue effect is cavitation consequent to the negative phase of the wave propagation.[1-3]It has been used for more than 15 years for treating musculoskeletal conditions.[2] Its biological effect is produced through the mechanical action of the ultrasonic vibrations on tissues.[2-4] It can be focal or radial. Focal shockwaves have great tissue penetration power (10 cm) and impact force (0.28-0.6 mJ/mm²). They produce mechanical and biological effects such as destruction of fibrosis and stimulation of neovascularization in treated tissues.[1-3,5,6]

The radial shockwaves are pneumatic waves generated by air compressors, which are transmitted radially with shorter penetration (3cm), lower impact (0.02-0.08 mJ/mm²) and limited biological effect.[5,6]They have been shown to be effective in treating musculoskeletal conditions that are more superficial, with clinical results similar to those of focal shockwaves. The effect of radial shockwaves is less intense, but they cause disintegration of fibroses and calcifications and increase the blood circulation at the treated site.[6-9]

Plantar fasciitis is a degenerative alteration of the plantar fascia that affects up to 15% of the population.[10-12]The preferred

treatment is physical therapy, which has the aims of suppressing pain, restoring the mechanical function of the plantar fascia and improving gait. Use of ultrasound to promote analgesia, in association with stretching of the plantar fascia and the posterior muscles of the lower limb, is one of the most indicated therapeutic alternatives for plantar fasciitis.[10,13-16]

Treatment of plantar fasciitis using a small number of focal and radial shockwave therapy applications has shown good results in terms of pain relief and enhancement of functional outcomes.[1,3,6-9,11,17-19]

The purpose of the present study was to compare theeffectsof RSWTwith traditional physical therapy on pain and functional outcomes in patients with chronic plantar fasciitis.

METHODS

Design

This was a randomized prospective comparative clinical study. The research project was approved by the Ethics Committee for Research Project Analysis at Nova Southeastern University (NSU), Florida, USA.

Participants

Sixty patients with plantar fasciitis were treated at Health Check Center in Brooklyn, NY, USA between 2010 and 2012. All the patients came from the institution's emergency service. There was no deception or incomplete disclosure to the recruited subjects, and the subjects did not receive any compensation or incentives for participating in the study. Patient names or other identifying data were not included in the research files. The only person with access to the study data files was the principle investigators.
The cases were diagnosed by means of anamnesis, physical examination and ultrasonography. All the patients agreed to participate in the study and signed the free and informed consent statement. Randomization was performed by a computerized random number generator created by an independent bio-statistician to draw up groups' allocation. The study follow diagram is shown in Figure 1.

The inclusion criteria were:

• Diagnosis of plantar fasciitis, with plantar fascia thickness greater than 4 millimeters, as assessed using ultrasonography.
• Age between 20 and 68 years.
• Painful symptoms for 3 months or more.
• Not illiterate.
• Not using a heart pacemaker or anticoagulant medication.
• Absence of coagulopathy, other musculoskeletal conditions of any etiology with clinical manifestations in the lower limbs and spine.
• Absence of central or peripheral neuropathy, systemic inflammatory disease, associated metabolic and endocrine diseases or psychiatric disorders.
• Ability to coming to the hospital for evaluation and treatment.

The exclusion criteria were:

• Reception of any other therapeutic intervention for the current plantar fasciitis prior to and/or during the study.
• Painful Symptoms for less than 3 months.

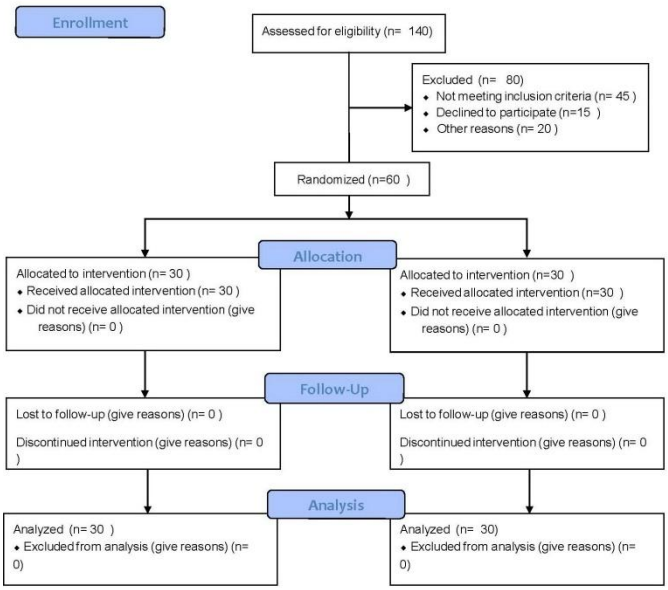

Figure 1. Follow diagram of the study

Evaluation protocol

The same evaluation was made before and immediately after treatment, at 3 and 12 months after the end of the treatment. The same therapist performed the evaluation in all the occasions that consisted of comprehensive pain and functional abilities assessment specifically as follows:

Pain assessment

• Periodicity of the pain: number of times per week that pain was experienced.
• Duration of the pain: number of hours per day with pain.
• Visual analogue scale (VAS) for morning and gait pain.
• Fischer's algometer: to quantify the painful pressure at the insertion of the plantar fascia in the calcaneus and the middle third of the medial gastrocnemius.
• Use of analgesics before and during the participation of the study.
The Visual Analog Scale (VAS) is a horizontal, 10 cm-long line with the phrase "no pain" on the left side (score: 0) and the phrase "pain as bad as it could be" on the right side of the line (score: 10). Patients were asked to place a hatch mark on the line that corresponded to their current level of pain. The distance between the phrase "no pain" and the hatch mark was used as linear measure of the VAS score. All patients scored

substantial morning and gait pain greater than 5 on the VAS at baseline.

Functional abilities assessment

The modified Roles and Maudsley (R&M) score was used to quantify changes in patients' quality of life, functional abilities, and satisfaction. Score 1 (excellent quality of life) represented unlimited walking ability without pain, no symptoms, patient satisfied with the treatment outcome. Score 2 (good quality of life) represented ability to walk more than 1 hour without pain, symptoms substantially decreased after treatment, patient satisfied with the treatment outcome. Score 3 (acceptable quality of life) represented inability to walk more than 1 hour without pain, symptoms somewhat better and pain more tolerable than before treatment, patient slightly satisfied with the treatment outcome. Score 4 (poor quality of life) represented inability to walk without severe pain, symptoms not better or even worse after treatment, patient not satisfied with the treatment outcome. All patients scored higher than 3 at baseline indicating marked decline in functional abilities, and close to poor quality of life and satisfaction.

Treatment protocol

Group 1 – traditional physical therapy

These subjects n=30 were treated with continuous ultrasound at a frequency of 1.0 Hz and intensity of 1.2 watt/cm², for 5 minutes in a dynamic application mode. Ten sessions were provided, at a frequency of twice a week. All the subjects performed therapeutic exercises after the ultrasound application, in order to stretch all the posterior muscles of the involved lower limb (3 sets of 30 seconds for each exercise) and strengthen the anterior tibial group muscles (4 sets of 10 repetitions, with weights of 3 to 5 kg for each exercise). All the subjects were guided and monitored by the same physical therapist in all the sessions. All the subjects were also advised to do active stretching of the gastrocnemius and plantar fascia at home.

Group 2 – Radial extracorporeal shockwave therapy

These subjects n=30 were treated with 2 applications of RSWT, always administered by the same physical therapist. The Swiss Dolorclast® equipment was used, with a low-intensity applicator. Two thousand impulses with energy flux density = 0.16 mJ/mm^2 per session were applied, at a frequency of 8 Hz and a pressure of 3 bars. The patients were positioned in ventral decubitus, with the dorsum of the foot supported on the edge of the bed. The applicator was placed perpendicularly over the insertion of the plantar fascia in the calcaneus, and gel was used to keep the applicator in contact with the skin. A total of 2 sessions were given, each was 1 week apart. All the patients were also advised to do active stretching of the gastrocnemius and plantar fascia at home, and this advice was given by the same physical therapist as in group 1.

The stretching exercises that the physical therapist advised the patients to perform at home were the same for both groups. The patients were allowed to use analgesics during the participation in the study as needed but they were instructed to report type, dosage, and frequency to their physical therapist during the scheduled assessment.

The therapist responsible for the evaluation not only made pain and function abilities assessment in person before and after treatment sessions, but also followed up all the patients by conducting over the phone assessment once a month, in order to ensure that the patients were not undergoing other treatments, a reason for immediate exclusion of the study. These contacts were maintained through the entire follow-up year.

Sample Size Determination

The sample size and power calculations were performed using PASS 11 (Power Analysis and Sample Size Software, NCSS, LLC. Kaysville, Utah, USA). The calculations were based on detecting a 10 % group difference in the R& M score at fallow-up, assuming a standard deviation of 13%, a 2- tailed test, an alpha level of .05, and a desired power of 80%. These assumptions generated a sample size of 28 subjects per group.

Statistical analysis

Firstly, descriptive statistics were used to evaluate the patients' characteristics. The quantitative data were presented as means and standard deviations (Table 1-3;Figure 2,3), andthe categorical data were presented as frequencies and percentages (Table 4-7).

The variables of sex, medical diagnosis, previous treatments, physical activity and use of analgesics were compared between the groups by means of Fisher's exact test. The continuous variables of age and body mass index were tested by means of the non-paired t-test.

Comparisons between the 2 treatment groups for morning pain, gait pain and functional abilities performed using two-way repeated measures analyses of variance (ANOVA), followed by Bonferroni post-tests to compare replicate means by the investigated time points(Table 1-3;Figure 2,3).

Thedistribution of weekly periodicity of pain symptoms (Table 4) and the distribution of patients according to Fischer's algometer (Table 5,6) variables were classified as categories that were represented as frequencies and percentages (%).

Intragroup comparisons between the results of the 4 evaluations (baseline, immediately after treatment, 3 and 12 months later) were made by means of the nonparametric Friedman test and the comparisons between the 2 groups were made by the nonparametric Mann-Whitney test (Table 4-6).

Frequencies and percentages of patients who ceased to use analgesics within one year after treatment were compared between the 2 groups by means of Fisher's exact test (Table7).

All the tests were performed taking a hypothesis of bilaterality and assuming a significance level of $\alpha = 5\%$. Calculations were performed using IBM SPSS 22.0 for Windows (SPSS, Chicago, IL, USA) and GraphPad Prism (Version 6.01 for Windows; GraphPad Software, San Diego, CA, USA). Codes were not broken, i.e., the study clinical outcome assessors did not have access to the patients' group allocation until all patients had completed the 12-month follow-up evaluation.

RESULTS

Thirty patients were treated in group 1 and 30 patients in group 2, no patient was lost or needed to receive other kind of treatment procedure during the entire follow-up time. There was no difference between group 1 and group 2 with regard to distribution of gender, age, physical activity practices or body mass index. The subjects' mean age was 49.6 ± 11.8 years (range: 25-68); 39 subjects (65%) were women and 21 (35%) were men; 42 subjects (70%) were using analgesic medication; and 45 subjects (75%) were above the ideal weight and only 36 subjects (60%) practiced any physical activity regularly.

The analysis of the data showed statistically significant ($\rho < 0.001$) decrease in mean morning and gait pain scores(Table 1,2) obtained immediately after treatment, at 3 and 12 months later in comparison with baseline scores in both groups (Figure 2).

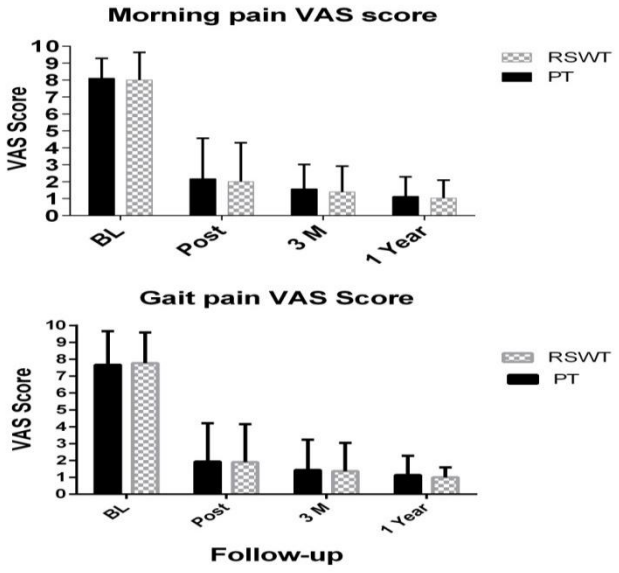

Figure 2. Mean and standard deviation of the mean of Visual Analog Scale (VAS) scores of patients with chronic plantar fasciitis after treatment with radial extracorporeal shockwave therapy (RSWT; n=30) or traditional physical therapy treatment (n=30) at baseline (BL) as well as immediately after treatment (Post), 3 months (3M) and 12 months (1 Year) after the treatment with RSWT or traditional physical therapy, respectively.

Both groups also showed increased functional abilities, improved quality of life, and heightened satisfaction (Figure 3). The modified Roles and Maudsley scores showed statistically significant ($\rho < 0.001$) improvement in quality of life immediately after treatment, at 3 and 12 months later in both groups (Table 3). In the traditional physical therapy group, 87% of patients presented with poor quality of life at baseline, which was improved to excellent quality of life in 70% of patients immediately after treatment, 60% at 3 months, and 53% at 12 months later ($\rho < 0.001$). In the RSWT group, 83% of patients presented with poor quality of life at baseline, which was improved to excellent quality of life in 77% immediately after treatment, 67% at 3 months, and 60% at 12 months later ($\rho < 0.001$).

Figure 3. Mean and standard deviation of the mean of modified Roles and Maudsley (R&M) scores of patients with chronic plantar fasciitis after treatment with radial extracorporeal shockwave therapy (RSWT; n=30) or traditional physical therapy treatment (n=30) at baseline (BL) as well as immediately after treatment (Post), 3 months (3M) and 12 months (1 Year) after the first RSWT or traditional physical therapy treatment, respectively.

The RSWT had a significant and lasting impact on the mean morning painVAS, gait pain VAS, and R&M scores of the patients. Specifically, the mean morning pain VAS scores were reduced after RSWT from 8.00 ± 1.64 (mean ± SD) at baseline to 2.00 ± 2.30 immediately after treatment, 1.40 ± 1.52 at 3 months and 1.03 ± 1.07 at 12 months later (Table 1). Likewise, the mean gait pain VAS scores were reduced after RSWT from 7.77 ± 1.81 (mean ± SD) at baseline to 1.90 ± 2.25 immediately after treatment, 1.37 ± 1.67 at 3 months and 1.00 ± 0.59 at 12 months later (Table 2).

The mean R&M scores were reduced after RSWT from 3.83 ± 0.38 at baseline to 1.27 ± 0.52 immediately after treatment, 1.33 ± 0.48 at 3 months and 1.40 ± 0.49 at 12 months later (Table 3).

These changes in the mean morning painVAS, gait pain VAS, and R&M scores of the patients were also observed after traditional physical therapy treatment.Specifically, the mean morning pain VAS scores were reducedafter traditional physical therapy from 8.10 ± 1.18 (mean ± SD) at baseline to 2.17 ± 2.39 immediately after treatment, 1.57 ± 1.45 at 3 months and 1.13 ± 1.17 at 12 months later (Table 1).

Likewise, the mean gait pain VAS scores were reduced aftertraditional physical therapy from 7.67 ± 1.99 (mean ± SD) at baseline

Table 1.
Morning pain intensity VAS Scores [Points] Mean ± SD (n = 30 per group

	Group 1 Mean ± SD	Group 2 Mean ± SD	Difference	95% CI of diff.	t	*P* value
Evaluation1	8.10± 1.18	8.00 ± 1.64	0.10	-1.18 to 0.98	0.27	P =0.79
Evaluation2	2.17± 2.39	2.00± 2.30	0.17	-1.25 to 0.91	0.27	P =0.78
Evaluation3	1.57± 1.45	1.40± 1.52	0.17	-1.25 to 0.91	0.43	P =0.67
Evaluation4	1.13± 1.17	1.03± 1.07	0.10	-1.18 to 0.98	0.35	P =0.73

SD: Standard Deviation; CI: Confidence Interval; VAS: Visual Analog Score; Group 1 = 10 physical therapy sessions (ultrasound and exercise); Group 2 = 2 RSWT sessions; Evaluation 1 = before treatment; Evaluation 2 = immediately after treatment; Evaluation 3 = 3 months after treatment; Evaluation 4 = 12 months after treatment.

Table 2.
Gait pain intensity VAS Scores [Points] Mean ± SD (n = 30 per group)

	Group 1 Mean ± SD	Group 2 Mean ± SD	Difference	95% CI of diff.	t	*P* value
Evaluation1	7.67± 1.99	7.77 ± 1.81	0.10	-1.05 to 1.25	0.20	P =0.84
Evaluation2	1.93± 2.27	1.90± 2.25	0.03	-1.19 to 1.12	0.06	P =0.95
Evaluation3	1.43± 1.79	1.37± 1.67	0.06	-1.22 to 1.09	0.15	P =0.88
Evaluation4	1.13± 1.14	1.00± 0.59	0.13	-1.29 to 1.02	0.57	P =0.57

SD: Standard Deviation; CI: Confidence Interval; VAS: Visual Analog Score; Group 1 = 10 physical therapy sessions (ultrasound and exercise); Group 2 = 2 RSWT sessions; Evaluation 1 = before treatment; Evaluation 2 = immediately after treatment; Evaluation 3 = 3 months after treatment; Evaluation 4 = 12 months after treatment.

Table 3.
The modified Roles &Maudsley (R&M) score [Points] Mean ± SD (n = 30 per group)

	Group 1 Mean ± SD	Group 2 Mean ± SD	Difference	95% CI of diff.	t	*P* value
Evaluation1	3.87 ± 0.35	3.83 ± 0.38	0.03	-0.28 to 0.34	0.35	P =0.72
Evaluation2	1.33 ± 0.55	1.27± 0.52	0.07	-0.24 to 0.38	0.48	P =0.63
Evaluation3	1.40 ± 0.49	1.33± 0.48	0.07	-0.24 to 0.38	0.53	P =0.59
Evaluation4	1.47± 0.51	1.40± 0.49	0.07	-0.24 to 0.38	0.51	P =0.61

SD: Standard Deviation; CI: Confidence Interval; R&M: The modified Roles and Maudsley scores; Group 1 = 10 physical therapy sessions (ultrasound and exercise); Group 2 = 2 RSWT sessions; Evaluation 1 = before treatment; Evaluation 2 = immediately after treatment; Evaluation 3 = 3 months after treatment; Evaluation 4 = 12 months after treatment.

to 1.93 ± 2.27 immediately after treatment, 1.43 ± 1.79 at 3 months and 1.13 ± 1.14 at 12 months later (Table 2).

The mean R&M scores were reduced after traditional physical therapy from 3.87 ± 0.35 at baseline to 1.33 ± 0.55 immediately after treatment, 1.40 ± 0.49 at 3 months and 1.47 ± 0.51 at 12 months later (Table 3).

Post-hoc Bonferroni test demonstrated no statistically significant differences in the mean morning and gait pain VAS scores (Table1,2; Fig 2), and in the mean R&M scores (Table 3;Figure 3) between the RSWT-treated patients and the traditional physical therapy-treated patients immediately after treatment (morning pain VAS score: t = 0.27 and p = 0.78; gait pain VAS score: t = 0.06 and p = 0.95; R&M score: t = 0.48 and p = 0.63), 3 months (morning pain VAS score: t = 0.43 and p = 0.67; gait pain VAS score: t = 0.15 and p = 0.88; R&M score: t = 0.53 and p = 0.59) and 12 months (morning pain VAS score: t = 0.35 and p = 0.73; gait pain VAS score: t = 0.57 and p = 0.57; R&M score: t = 0.51 and p = 0.61) later, and at baseline itself (morning pain VAS score: t = 0.27 and p = 0.79; gait pain VAS score: t = 0.20 and p = 0.84; R&M score: t = 0.35 and p = 0.72).

Both groups showed improvements in pain symptoms.Numbers of episodes of pain per week and numbers of hours of pain per daywere decreased (Table 4). At the first evaluation, intense pain (up to 4 kg in Fischer's algometer) was found in the calcaneus in 34 % of all the patients treated,

and in in the gastrocnemius in 73% of them. Post-test, there was a statistically significant ($\rho < 0.001$) decrease in the intensity of pain in the calcaneus region (Table 5) and in the gastrocnemius (Table 6) in both groups immediately after treatment, at 3 and 12 months later. Most of the patients were found to have reduced their intake of analgesic medication at the evaluation conducted 12 months after the end of the treatment (Table 7).

Table 4.
Distribution of weekly periodicity of pain symptoms in groups 1 and 2 (n = 30 per group) before and after the treatment (immediately, 3 months and 12 months after the treatment)

Weekly frequency of pain	Group 1				
	Evaluation 1	Evaluation 2	Evaluation 3	Evaluation 4	P*
No pain	0 (0%)	19 (63%)	20 (67%)	19 (63%)	
Pain once a week	0 (0%)	6 (20%)	3 (10%)	3 (10%)	P <0.001
Pain twice a week or more	30 (100%)	5 (17%)	7 (23%)	8 (27%)	

	Group 2				
	Evaluation 1	Evaluation 2	Evaluation 3	Evaluation 4	P*
No pain	0 (0%)	20 (67%)	19 (63%)	24 (80%)	
Pain once a week	0 (0%)	6 (20%)	3 (10%)	3 (10%)	P <0.001
Pain twice a week or more	30 (100%)	4 (13%)	8 (27%)	3 (10%)	

No significant difference was detected (Mann-Whitney test) between the two groups (p > 0.05).
* Friedman test comparing the 4 evaluations within each group.
Group 1 = 10 physical therapy sessions (ultrasound and exercises); Group 2 = 2 RSWT sessions
Evaluation 1 = before treatment; Evaluation 2 = immediately after treatment; Evaluation 3 = 3months after treatment;
Evaluation 4 = 12 months after treatment.

DISCUSSION

The plantar fascia is one of the most important static support structures of the medial longitudinal arch. Plantar fasciitis is inflammation of this structure and occurs through repeated microtrauma at the origin of the medial tuberosity of the calcaneus. The traction forces during weight-bearing lead to an inflammatory process that results in fibrosis and degeneration.[11,14] Calcaneal spurs and plantar nerve incarceration may be associated with the inflammatory process.[15,16,18,20] Women are affected more than men. Plantar fasciitis is associated with obesity and the climacteric.[11,16,21,22] In thepresent study too, women were more affected, 39 female subjects (65%), versus 21 male subjects included,mean age of the group was 49.6 ± 11.8 years. Forty-two subjects (70%) were using analgesics prior to the study.

Presence of plantar fasciitis is related to professional and leisure activities that require weight-bearing, without any relationship with loss of strength, muscle atrophy or range of motion.[16] The majority of the subjects in the present study (66%) worked standing up, and 60% of them were doing some type of physical activity impact, therefor, demonstrating the importance of mechanical factors in the etiopathogenesis of this disease. None of the subjects in this study group presented any loss of strength or diminished range of motion. Ninety-six percent of the subjects reported having

Table 5.
Distribution of patients according to Fischer's algometer (calcaneus) in groups 1 and 2 (n = 30 per group) before and after the treatment (immediately, 3 months and 12 months after the treatment)

	Group 1				
	Evaluation 1	Evaluation 2	Evaluation 3	Evaluation 4	P*
Up to 4 kg	5 (16%)	0 (0%)	0 (0%)	0 (0%)	
More than 4 and up to 6 kg	8 (25%)	1 (3%)	0 (0%)	0 (0%)	
More than 6 and up to 8 kg	14 (44%)	5 (16%)	3 (9%)	2 (6%)	P <0.001
More than 8 and up to 10 kg	3 (9%)	9 (28%)	1 (3%)	5 (16%)	
No pain	2 (6%)	17 (53%)	28 (88%)	25 (78%)	

	Group 2				
	Evaluation 1	Evaluation 2	Evaluation 3	Evaluation 4	P*
Up to 4 kg	6 (18%)	1 (3%)	0 (0%)	0 (0%)	
More than 4 and up to 6 kg	14 (42%)	0 (0%)	0 (0%)	0 (0%)	
More than 6 and up to 8 kg	10 (30%)	4 (12%)	0 (0%)	1 (3%)	P <0.001
More than 8 and up to 10 kg	3 (9%)	6 (18%)	5 (15%)	5 (15%)	
No pain	0 (0%)	22 (67%)	28 (85%)	27 (82%)	

No significant difference was detected (Mann-Whitney test) between the two groups (p > 0.05).
* Friedman test comparing the 4 evaluations within each group.
Group 1 = 10 physical therapy sessions (ultrasound and exercises); Group 2 = 2 RSWT sessions
Evaluation 1 = before treatment; Evaluation 2 = immediately after treatment; Evaluation 3 = 3 months after treatment;
Evaluation 4 = 12 months after treatment.

Table 6.
Distribution of patients according to Fischer's algometer (gastrocnemius) in groups 1 and 2 (n = 30 per group) before and after the treatment (immediately, 3 months and 12 months after the treatment)

	Group 1				
	Evaluation 1	Evaluation 2	Evaluation 3	Evaluation 4	P*
Up to 4 kg	10 (33%)	0 (0%)	0 (0%)	0 (0%)	
More than 4 and up to 6 kg	8 (27%)	4 (13%)	5 (17%)	0 (0%)	
More than 6 and up to 8 kg	2 (7%)	8 (27%)	6 (20%)	9 (30%)	P <0.001
More than 8 and up to 10 kg	0 (0%)	3 (10%)	3 (10%)	3 (10%)	
No pain	10 (33%)	15 (50%)	16 (53%)	18 (60%)	

	Group 2				
	Evaluation 1	Evaluation 2	Evaluation 3	Evaluation 4	P*
Up to 4 kg	12 (40%)	0 (0%)	0 (0%)	0 (0%)	
More than 4 and up to 6 kg	8 (27%)	6 (20%)	3 (10%)	0 (0%)	
More than 6 and up to 8 kg	1 (3%)	3 (10%)	5 (17%)	8 (27%)	P <0.001
More than 8 and up to 10 kg	0 (0%)	2 (7%)	6 (20%)	3 (10%)	
No pain	9 (30%)	19 (63%)	16 (53%)	19 (63%)	

No significant difference was detected (Mann-Whitney test) between the two groups (p > 0.05).
* Friedman test comparing the four evaluations within each group.
Group 1 = 10 physical therapy sessions (ultrasound and exercises); Group 2 = 2 RSWT sessions
Evaluation 1 = before treatment; Evaluation 2 = immediately after treatment; Evaluation 3 = 3 months after treatment;
Evaluation 4 =12 months after treatment.

Table 7.
Frequencies and percentages of patients who had ceased using analgesics within one year after the treatment.

	Patients who ceased using analgesics within one year after the treatment		Patients who were using analgesics before the treatment†	P*
	Yes	No		
Group 1	14 (51.9%)	13 (48.1%)	27 (100%)	P <0.001
Group 2	8 (30.8%)	18 (69.2%)	26 (100%)	

† Three patients in group 1 and four in group 2 were not using analgesics before the treatment.
* Fisher's exact test.

morning pain, and 93% had pain during gait. Morning pain is an important assessment criterion.[6,7,17] In the present study, morning pain measured using a VAS before the treatment showed scores greater than 5 for all the patients. After the treatment, 53 of the 60 patients in the present study had VAS scores of less than 2, thus showing that treatment given to the 2 study groups was effective for pain reduction.

Plantar fasciitis leads to gait in which weight is borne on the outer side of the foot or on the forefoot (toes) because of pain in the medial region of the calcaneus or at the proximal insertion of the plantar fascia. This causes shortening of the achilles tendon and pain in the medial portion of the calcaneus and gastrocnemius.[11,14,15] Use of Fischer's algometer provided a simple and reproducible mean of quantifying the pain in the medial tuberosity of the calcaneus and medial portion of the gastrocnemius. Thirty-four percent of all the patients treated presented intense pain in the calcaneus (up to 4 kg in Fischer's algometer) compared to 73% in the gastrocnemius at the first evaluation. These findings differed from data in the literature, which reported intense pain at these 2 sites in the majority of patients.[11,14] In the present study, it was seen that the patients had greater pain in the gastrocnemius than in the calcaneus, thus revealing the role of muscle shortening in maintaining the pain vicious circle and the need for therapeutic exercise either in clinic or home-based to eliminate the pain.

Thickening of the plantar fascia beyond 4 mm has been reported to be related to intense pain and limitation of the ankle joint range of motion,[20-22-24] but this relationship was not observed in the present study sample. The thickness of the plantar fascia ranged from 4 to 9 mm in our study sample; ,however, decrease in the range of motion of the ankle joint was neither reported nor detected.

Surgical treatment for plantar fasciitis is exceptional and does not always produce good results, with recurrence possible in 30% of the cases.[24-26] Conservative treatment is always the first-choice treatment.[10,11,14] Application of therapeutic ultrasound, accompanied by stretching exercises, is one of the physical therapeutic procedures most indicated for plantar fasciitis.[10,13,27-29]

In the present study, the continuous ultrasound form was used, with constant wave intensity at a dose of 1.2 W/cm2. The doses that have been used and described in the literature ranged from 0.1 to 4.0 W/cm.[30,31] Use of higher doses in cases of plantar fasciitis is justified by the thickness of the corneal layer in the calcaneal region.[30,31] We chose to use a lower dose with continuous flow, for greater safety. The present study showed that there was no need for high doses of ultrasound in order to achieve statistically significant pain reduction and functional improvement.

Radial extracorporeal shockwave therapy has shown good results, without side effects, but it is still relatively new technology, with a high cost, and it needs to be evaluated comparatively with other types of conservative treatment.[6-12,19] In the present comparative study, no complications from the use of RSWT were observed. Shockwave differs from ultrasound wave that is typically biphasic and has a peak pressure of 0.5 bar.[5,8,19] In essence, the peak pressure of shock wave is approximately 1000 times that of ultrasound wave.[6,10,26] Shock wave changes its physical properties through attenuation and steepening when traveling through a medium and through reflection and refraction at the boundaries when subsequently moving into another medium.[6,9,12] Shock waves, which are pneumatic in origin (air compressor), are administered through contact with the skin and penetrate the tissue to a depth of 3to 4 cms.[8,9,25]

All the subjects were advised to do active stretching exercises on the gastrocnemius and plantar fascia twice a day; in order to improve their soft tissues extensibility and flexibility, under the guidance of the same physical therapist, during the treatment sessions. The consistency of the repeated advice in all the sessions may have been one of the factors that contributed most towards adherence to the home exercise program and change of subjects' habits. When exercise program is applied with care and commitment, it brings good results.[11]

In group 2, the subjects were advised individually to do active stretching of the gastrocnemius and plantar fascia, but they did not receive any therapeutic exercises program in clinic, as did the subjects in group 1, during the treatment sessions.

The present study showed faster effects of RSWT (after only 2 applications, 1 week apart) than a traditional physical therapy program. However, a more cost effective traditional physical therapy program carried out carefully and in a well-guided manner was capableof promoting similar pain relief, increased functional abilities, improved quality of life, and heightened satisfaction among subjects with plantar fasciitis, but in a relatively slightly longer time (after 10 sessions given in 5 weeks).

After 12 months of follow-up, both groups maintained their alleviation of morning and gait pain. The number of hours per day with pain and number of pain crises per week decreased, and the use of analgesics likewise decreased. Similarly, increased functional abilities, improved quality of life, and heightened satisfaction were maintained throughout the 12-month follow-up period following the end of the treatment. There was no difference in the efficacy of the 2 treatments, but RSWT provided relatively faster results.

Adherence to active stretching of the gastrocnemius muscle and the plantar fascia may improve the painful symptoms of plantar fasciitis.[11,28,29,32] This advice, given in all the treatment sessions, may have been decisive in maintaining the improvement in the 2 groups. Restoration of the resting normal length of the gastrocnemius muscle and the plantar fascia will result in improvement in foot and ankle functional ability, and correction of gait deviations.[1,11,14]

Correctly making a clinical diagnosis of plantar fasciitis, combined with the provision of a simple but well-implemented rehabilitation program was the determining factor in achieving good results, thus demonstrating that sophisticated resources or technologies are not always necessary.[32-34] Some study results[4,21,35] did not agree with Ogden et al.[36] who concluded that RSWT was superior for treating plantar fasciitis, with disappearance of the symptoms in 90% of the treated cases.The superiority of RSWT was not

proven in the present comparative study either.

The present study on chronic cases did not show any difference between the compared 2 treatment methods used, therefor, indicating that good physical therapy program and therapeutic guidance, even if very simple, may be as equally effective as RSWT treatment. Consequently, traditional physical therapy associated with appropriate guidance for stretching exercises should be considered in early cases, especially those that have not received any previous treatment. Nevertheless, there are indications that RSWT might be better than other treatments in some cases of plantar fasciitis, where despite of completing traditional physical therapy program, they remain with increasing pain and incapacity that may persist for many months or even years. This treatment failure could be attributed to the long clinical evolution of plantar fasciitis, together with difficulties in changing patients' habits (weight loss, use of appropriate footwear and adherence to an exercise program). Use of RSWT in these specific cases may produce better results because of the needed type of therapeutic physiological effect on the thick tissues of the plantar fascia and calcaneal tendon.[36,37] In these instances, use of RSWT should be considered in treating plantar fasciitis[7,36,37] to diminish the evolution time of the disease. Accordingly, the best indication for RSWT use would possibly be in cases with more chronic nature that have not responded to traditional physical therapy interventions.

Study Limitations

Among the limitations of the present study, no assessment was made to reveal any possible correlation between the thickness of the plantar fascia and the parameters of the existing pain. Unfortunately, we could not provide a standardized shoe/footbed for the patients included in our study, although it might be important to control this variable in future studies since it could contribute to the changes in patients symptoms. The direct correlation between pain and functional limitation is evident. In cases with planter fasciitis, the functional limitations in our opinion are best demonstrated in gait deviations and alteration in weight bearing activities. In our study, although we assessed morning and gait pain, and used R&M scores to quantify pain related functional activities, quality of life, and satisfaction, hopefully, in future studies more gold standard measure will be considered, e.g., force platform gait analysis. We acknowledge the fact that the relatively small sample size in our study might limit the study results generalization.

CONCLUSION

The 2 treatment methods evaluated here were effective for maintaining the achieved improvement in pain, functional abilities, quality of life, and satisfaction among the patients with plantar fasciitis during the 12-month follow-up commenced after the end of treatment.

Funding: None declared.

*Ethical approval:*This study was approved by Institutional Review Board of Nova Southeastern University.

Conflict of interest: The authors declare there are no conflicts of interest in the undertaking of the study and preparation of this manuscript.

REFERENCES

1- Rompe JD. Plantar fasciopathy. *Sport Med Arthrosc Rev* 2009; 17(2):100-4.

2- Ogden JA, Alvarez RG, Levitt R, Marlow M. Shock wave therapy in musculoskeletal disorders. *ClinOrthopRelat Res*. 2001; 387:22-40.

3 -Ogden JA, Tóth-Kischkat A, Schultheiss R. Principles of shock wave therapy. *ClinOrthopRelat Res*. 2001; 387:8-17.

4 -Haake M, Buch M, Schollner C, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. *BMJ*. 2003; 327:75-9.

5 - Rompe JD, Kirkpatrick CJ, Kullmer K, Schwitalle M, Krischek O. Dose related effects of shock wave on rabbit tendon Achilles. *J Bone joint Surg*. 1998; 80B:546-52.

6- Haupt G, Diesch R, Straub T, et al. Radial Shock Wave Therapy in Heel Spurs. *Der NiederGelasseneChirurg*. 2002; 6(4):1-6.

7- Gerdesmeyer L, Weil L, Maier M, et al. Treatement of Painful Heel . Swiss Dolor Clast: Summary of Clinics Study Results-FDA/PMA Approval. May 2007.

8- Gerdesmeyer L, Gollwitzer H, Diehl P, Wagner K. Radial Extracorporeal Shock Wave Therapy in Orthopaedics. *J Miner Stoffwechs*. 2004; 11(4): 36-9.

9-Gerdesmeyer L, Frey C, Vester J, et al. Radial shock wave therapy is safe and effective in the treatment of chronic racalcitrant plantar fasciitis. *Am J Sports Med*. 2008; 36(11):2100-9.

10 -Zanon RG, Kundrat A, Imamura M. Ultra-somcontínuo no tratamento da fasciite plantar crônica. *ActaOrtop Bras*. 2006; 14(3):137-40.

11 -Roxas M. Plantar Fasciitis: diagnosis and therapeutic considerations. *Alt Med Rev*. 2005; 10: 83-93.

12 -Dyck DD. Plantar Fasciitis.*Clin J Sport Med*. 2004; 14: 305-9.

13 - Neufeld SK, Cerrato R. Plantar Fasciitis: evaluation and treatment. *J Am AcaOrthop Surg*. 2008; 16(6):338-46.

14 - League AC. Current Concepts Review: Plantar Fasciitis. *Foot and Ankle Int*. 2008; 29(3):358-66.

15 -Alshami AM, Sourbis T, Coppieters MW. A review of plantar heel pain of neural origin: differential diagnosis and management. *Man Ther.* 2008; 13(2):103-11.

16 Irving DB, Cook JL, Meng HB. Factors associated with chronic plantar heel pain: a systematic review. *J Sci Med Sport*. 2006; 9(2):11-22.

17- Chuckpaiwog B, Theodore GH. ESWT for chronic proximal plantar fasciitis:225 patients with results and outcomes predictors. *J Foot and Ankle Surg*. 2009; 48(2):148-55.

18 -Helbig K, Herbert C, Schostok T, Brown M, Thiele R. Correlation Between the Duration of Pain and the Success of Shock Wave Therapy. *ClinOrthopRelat Res*. 2001; 387: 68-71.

19- Hofling L, Joukainer A. Preliminary experience of a single session of low-energy ESWT for chronic plantar fasciitis. *Foot and Ankle Inte*. 2008; 19(2): 150-4.

20 - Hammer DS, Adam F, Kreutz A, Rupp S, Kohn D, Seil R. Ultrasonographic evaluation at 6-month follow-up of plantar fasciitis after ESWT. *Arch Orthop Trauma Surg*. 2005; 125(1):6-9.

21 - Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabaharan V, Forbes A. Ultrasound-guided extracorporeal shockwave therapy for plantar fasciitis: a randomized controlled trial. *JAMA*. 2002; 288(11):1364-72.

22- Liang WH, Wang TG, Chen WS, Hou SM. Thinner Plantar Fascia Predicts Decreased Pain after Shock Wave Therapy. *ClinOrthop and Relat Res*. 2007; 460: 219-25.

23- Mulligan EP. Reabilitação da Perna, do Tornozelo e do Pé. In: Andrews JR, Wilk KE, Harrelson GL. ReabilitaçãoFísica das LesõesDesportivas. 2end ed. Rio de Janeiro: Guanabara Koogan; 2000. p.224.

24- WeilJr LS, Roukis TS, Borrelli AH. Extracorporeal shockwave treatment of chronic plantar fasciitis: indication, protocol intermediate results and comparison of results to fascitomy. *JFAS*. 2002; 41(3).

25- Chen HS, Chen LM, Huang TW. Shockwave therapy for patients with plantar fasciitis: a one-year follow-up study. *ClinOrthopRelat Res*. 2001; 387:41-6.

26- Hammer DS, Rupp S, Kreutz A, Pape D, Kohn D, Seil R. Extracorporeal shockwave therapy in patients with chronic proximal plantar fasciitis. *Foot Ankle Int*. 2002; 23(4):309-13.

27- Rompe JD, Fúria J, Weil L, MaffulliN.Shock Wave Therapy for chronic plantar fasciopathy. *British Medical Bulletin*. 2007; 82(1):183-208.

28- Radford JA. Effectiveness of calf muscle stretching for the short-term treatment of plantar heel pain: a randomized trial. *BMC Musculoskeletal Disord*. 2007; 8:36.

29 - DiGiovanni BF, Nawoczenski DA, Lintal ME, et al. Tissue-specific plantar fascia-stretching exercise enhances outcomes in patients with chronics heel pain. *J Bone Joint Surg*. 2003; 85-A (7):1270-77.

30- terHaar G. Therapeutic application of ultrasound. *ProgBiophysMol Bio*. 2007; 93:111-29.

31- Robertson VJ. Dosage and treatment response in randomized clinical trials of therapeutic ultrasound. *PhysTher in Sport*. 2002; 3:124-33.

32- Harris SR. Plantar Fasciitis: What's an evidence-Informed consumer to do? *Physiother Can*. 2008; 60(1):3-5.

33 - Marabha T, Al-Amani M, Dahmashe Z, Rashdan K, Hadid A. The relation between conservative treatment and heel pain duration in plantar fasciitis. *Kuwait medical Journal*. 2008; 40(2):130-132.

34- Stuber K, Kristmanson K. Conservative therapy for plantar fasciitis: a narrative review of randomized controlled trials. *J Can Chiropr Assoc*. 2006; 50(2): 118-33.

35 - Speed CA, Nichols D, Wies J, Humphreys H, Richards C, Burnet S, et al. Extracorporeal shock wave therapy for plantar fasciitis: a double blind randomized controlled trial. *J Orthop Res*. 2003; 21:937-40.

36- Ogden J A, Alvarez RG, Marlow M. Shockwave Therapy in Plantar Fasciitis: A meta-analysis. *Foot and Ankle Int*. 2002; 23(4): 301-8.

37- Rompe JD. Repetitive Low Energy Shock Wave Treatment is Effective for Chronic Simptomatic Plantar Fasciitis. *Knee Surg Sports TraumatoArthrosc*. 2007; 15:107.

الملخص العربى

مقارنة بين الموجات الشعاعية ذات الصدمات العالية والعلاج الطبيعىالتقليدى لعلاج التهاب اللفافة الأخمصية

بحث سريرى بتحكم لعينة عشوائية

الهدف من البحث:- إجراء مقارنة بين الموجات الشعاعية ذات الصدمات العاليه والعلاج الطبيعىالتقليدى لعلاج التهاب اللفافة الأخمصية. **تصميم البحث:-** سريرىمستقبلى مقارن لعينة عشوائية بتحكم **.المشاركون والعلاج:-** شارك بالبحث 60 مريضا يعانون من التهاب اللفافة الأخمصية المزمن تراوحت اعمارهم من 25 – 68 سنة ، 65% منهم أناث و75% عانى من زيادة بالوزن، و70% تناول مسكنات بانتظام . تم تقسيم المرضى بطريقة عشوائية غير انتقائية إلى مجموعتين. تلقت المجموعة الأولى المكونة من 30 مريضا 10 جلسات علاج طبيعى تقليدية اشتملت على العلاج بالموجات فوق الصوتية والتمارين العلاجية، وتوجيهم لإجراء تمارين اطالة بالمنزل، وتلقت المجموعة الثانية المكونه من 30 مريض علاجاً بالموجات الشعاعية ذات الصدمات العالية مرة واحدة اسبوعياً لمدة اسبوعين فقط بواسطة 2000 نبضة بكثافة تدفق طاقة = 16. ميلى جول / مم ^{2} فى كل جلسة مع توجيهم لإجراء تمارين اطالة بالمنزل. **مقاييس النتائج الرئيسية:-** تم تقييم جميع المرضىالمشاركين بالبحث فيما يتعلق بشكواهم من الألم وقدرتهم الحركية الوظيفية قبل العلاج، مباشرة بعد نهاية العلاج، وبعد مرور 3 أشهر ثم 12 شهر لاحقاً . **النتائج:-** عند المتابعة بعد مرور 12 شهر من انتهاء العلاج ثبت فاعلية كلا الطريقتين، لتحسن المرضى بالمجموعتين بصورة ملحوظة اتضحت بانخفاض الألم، وزيادة القدرة الوظيفية، وتحسين نوعية الحياة، والارتياح والرضا للمرضى الذين عانوا من التهاب اللفافة الأخمصية، ومع ذلك تلاحظ أن التحسن الحادث بجلستين من الموجات الشعاعية ذات الصدماتالعالية حدث اسرع نسبياً من التحسن بعشر جلسات من العلاج الطبيعىالتقليدى . **الخلاصة:-** على الرغم من فاعلية كلا الطريقتين إلا أنه لم يثبت أن العلاج بالموجات الشعاعية ذات الصدمات العالية اكثر فاعلية من العلاج الطبيعىالتقليدى عند التقييم بعد 12 شهر من نهاية العلاج .

مفتاح كلمات البحث:- التهاب اللفافة الأخمصية – العلاج بالموجات ذات الصدمات العالية ، العلاج الطبيعى،ا العلاج بالموجات الشعاعية ذات الصدمات العالية.