Effect of radial shock wave and ultrasound therapy combined with traditional physical therapy exercises on foot function and dorsiflexion range in plantar fasciitis: a prospective randomized clinical trial

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Abstract. – OBJECTIVE: This study aimed to assess the effect of radial shock wave and ultrasound therapy combined with traditional physical therapy on foot function and range of motion in chronic plantar fasciitis.

PATIENTS AND METHODS: Sixty-nine participants with chronic plantar fasciitis (25-56 years) were allocated randomly into three groups. Group (A) received ultrasound (US) therapy plus conventional physical therapy exercises (in the form of stretching, strengthening exercise, and deep friction massage), Group (B) received a radial shock wave (RSW) therapy plus conventional physical therapy exercises, and Group (C) received a combination of both RSW and US therapy in addition to conventional physical therapy exercises, with 3 sessions per week for US therapy and one session for RSW therapy, in addition to 45 minutes of exercises for all groups for 4 consecutive weeks. Foot function was assessed using the foot function index (FFI), and ankle dorsiflexion range of motion was measured using the Baseline® bubble inclinometer at baseline and 4 weeks following treatment.

RESULTS: ANOVA revealed significant differences (p<0.05) in the measured outcomes among the groups after treatment. Tukey’s honest significant difference post-hoc test demonstrated a highly statistically significant (p<0.001) improvement in the assessed outcomes of group C in the post-intervention settings when compared to the other groups. After 4 weeks of intervention, the mean (SD) of FFI in groups A, B, and C were (64.54±4.91, 61.93±4.17, and 45.16±4.57) respectively, and the active range of motion (ROM) of the ankle dorsiflexion were (35.27±3.22, 36.59±2.91, and 41.85±3.04) respectively.

CONCLUSIONS: The addition of RSW to US with the conventional physical therapy program improved foot function and ankle dorsiflexion range of motion significantly for patients with chronic plantar fasciitis.

Key Words: Plantar fasciitis, Radial shock wave, Ultrasound, Foot function index.

Introduction

Plantar fasciitis (PF) is the most prevalent foot pain issue handled by healthcare experts and one of the leading reasons of heel pain, accounting for 11% to 15% of all foot issues. Millions of people suffer from PF discomfort. It affects people of all ages and can be seen in both sedentary and physically active individuals¹.

The major complaints of patients with PF are stinging and burning pain sensed inside the heel. Pain is excessive at the first steps after getting up in the morning, or after a period of inactivity. It alleviates after a few steps, however, it becomes severe towards the end of the day based on activity².

The plantar fascia is a dense, fibrous membrane that supports and stabilizes the foot’s medial longitudinal arch³. The most common cause of PF identified in literatures is degeneration and chronic inflammation of the plantar fascia and its surrounding perifascial structures⁴,⁵.
Numerous factors, classified as intrinsic and extrinsic, contribute to PF. Obesity, rapid weight gain, flat feet, high arched feet, limited ankle dorsiflexion, and short calf muscles are among the patient's intrinsic variables. Inadequate footwear, running on hard surfaces, instantly increased activity level, barefoot walking, a fast increase in running volume and/or intensity, and prolonged walking/standing are environmental and exercise issues.

Previous studies used a variety of physical therapy procedures to treat chronic PF, such as stretching exercises, taping, night splinting, silicone heel pads, manual therapy techniques, and various electrotherapy modalities such as laser, ultrasound, and shock wave therapy. However, the scientific findings that support their use are conflicting.

Therapeutic ultrasound (US) is one of the most often utilized therapy techniques that is beneficial as an adjuvant to expedite recovery in patients with chronic PF. Furthermore, radial shock wave therapy (SWT) has been established as a viable therapeutic approach for individuals with chronic PF that does not require local anesthetic or weight bearing cessation. There is much debate on whether ultrasound or shockwaves are superior in the treatment of individuals with chronic PF, and whether combining the two therapy methods would provide a better treatment benefit.

Plantar fasciitis treatment approaches vary, and the findings that support their use can be conflicting. According to the literature, PF can be handled conservatively. Unfortunately, PF is frequently reluctant to respond to standard treatments because many traditional approaches solely focus on increasing foot flexibility or strength. Stretching and strengthening the tissue on their own are sometimes limited because they do not address the scar tissue and lesions that really tighten and weaken the tissue first.

Previous studies evaluated the effect of RSW or US on plantar fasciitis, indicating RSW and US as effective treatment methods but not adequate in the rehabilitation of multiple factors such as pain and functionality. Moreover, using RSW and US in combination with other physical therapy modalities might be more useful in the treatment of the PF. To be successful, these modalities need to be combined depending on the patient’s condition.

To the best of the authors’ knowledge, there has been no such research on chronic PF where the integral therapeutic effect of adding shock wave therapy and ultrasound to the conventional physical therapy program has been studied.

As a result, the authors hypothesized that the radial shock wave and ultrasound therapy combined with traditional physical therapy program improves foot function and dorsiflexion range, than RSW with the traditional physical therapy program or US with traditional physical therapy alone in patients with chronic plantar fasciitis.

**Patients and Methods**

This study was a pre-test/post-test, single-blinded (assessor), prospective randomized clinical trial. The patients were recruited from outpatient clinics from Al-Qurayyat General Hospital in Al-Jouf Region, Saudi Arabia, from May 2021 to March 2022. The National Committee for Bio and Medical Ethics (NCBE) approved the study [approval No.: H-13-S-071(068)] and it was prospectively recorded in the Clinical Trial Registry (NCT04967703). All participants involved in this study provided informed consent, with the promise that their data would be kept confidential and utilized anonymously in the analysis for the purpose of the study only. The participants had been knowledgeable about the objective, study benefits, were free to leave the study at any moment. This study was reported according to CONSORT guidelines.

**Participants**

Sixty-nine patients, who had been clinically diagnosed with unilateral chronic plantar fasciitis of more than 3 months, were invited to participate in this study. The patients were composed of 25 men (36.23%) and 44 women (63.77%), ranging in age from 25 to 56 years and a mean body mass index (BMI) of 27.65 kg/m². Patients with chronic PF were referred by community-based referring physicians (orthopedic surgeons, orthopedists and primary care physicians) based on their history and physical examination, which included heel pain and local tenderness over the plantar-medial aspect of the calcaneal tuberosity close the plantar fascia insertion.

The following were the inclusion criteria: patients with plantar fasciitis for more than three months, with greatest soreness near the medial calcaneal insertion and pain greater than four on the visual analogue scale (VAS) during the first steps in the morning.

Patients were excluded if they had bilateral PF, previous ankle or foot surgery or pathology, or a history of shock wave therapy or topical corticosteroid injections to the ankle or foot, circulatory...
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abnormalities in the lower extremities, neuropathic or radicular pain in the lower limbs. Participants with systemic diseases that cause foot discomfort, such as ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, and gout, as well as those with type I or type II diabetes and pregnancy, were also excluded from the study.

Sample Size Calculation

To eliminate type II error, the sample size was estimated before the experiment. The computations were conducted using G*Power software ver.3.1.9.7. (Heinrich-Heine, Düsseldorf, Germany) at $\alpha=0.05$, $\beta=0.2$, effect size =0.40. Based on the earlier work of Akinoğlu et al, the effect size for the foot function index was established. The required sample size was determined to be $N=66$. To account for the drop-off, the sample size was expanded to 69 participants.

Randomization

Sixty-nine subjects with chronic plantar fasciitis were randomly assigned to one of the three groups: ultrasound therapy plus conventional physical therapy (Group A), radial shock wave therapy plus conventional physical therapy (Group B), or a combination of both radial shock wave and ultrasound therapy plus conventional physical therapy (Group C). A statistician who was not involved in the data collection performed the randomization using a computer-generated random number list. Sealable, sequentially numbered opaque envelopes were used to ensure the secret allocation. According to the group assignment, the first author opened the envelopes and proceeded to the treatment. The second author, who was not aware of the group assignment, obtained the outcome measures.

Intervention

The patients were allocated into three equal groups at random ($n=23$). All groups received the traditional physical therapy exercise program, three days a week for four weeks. The program comprised 45 minutes of a supervised and customized exercise, which included calf muscle and plantar fascia stretching and strengthening exercises. A demonstration session was used to provide patients with a full description of the manual therapy procedure which included: (1) passive stretching exercises for the calf muscle and plantar fascia followed by self-stretching, (2) strengthening training for the ankle and foot muscles, hip muscular strengthening, involving abductor and lateral rotator muscles, and (3) transverse friction massage given over the area of trauma or inflammation, first manually and then with Graston devices. To ensure that the results were not influenced, all participants in the trial were instructed not to conduct any exercise other than the exercise program and not to use any orthotic support during therapy.

Appendix I shows the specifics of the conventional physical therapy program.

Group (A) received ultrasound therapy utilizing an Enraf-Nonius Sonoplus 490 (Vareseweg, Rotterdam, Netherlands), the patient lies in prone position with the corresponding feet outside the bed, with the following parameters: (1) the energy level was 0.12 mJ/mm$^2$ (equal to 2.5 bar intensity), (2) the number of shots was 2,000, and (3) the frequency was 8 Hz. The patient shifted to a side-lying position, with the affected foot supported near the bed’s edge. The location of maximal tenderness around the medial calcaneal insertion is identified and marked with a marker before being stimulated with an Evo Blue hand piece of the RSW device, gel was used between the cap and skin during the applications for ensuring conductivity conductivity [Aquasonic gel (Parker Inc., Fairfield, NJ, USA) for 1 session per week for 4 weeks. The applicator was placed perpendicular to the insertion of the plantar fascia into the calcaneus.

Group (B) got radial shock wave therapy (RSWT) protocol utilizing the Swiss DolorClast® Master, Electro Medical Systems, (SA, Nyon, Switzerland), with the following parameters: (1) the energy level was 0.12 mJ/mm$^2$ (equal to 2.5 bar intensity), (2) the number of shots was 2,000, and (3) the frequency was 8 Hz. The patient shifted to a side-lying position, with the affected foot supported near the bed’s edge. The location of maximal tenderness around the medial calcaneal insertion is identified and marked with a marker before being stimulated with an Evo Blue hand piece of the RSW device, gel was used between the cap and skin during the applications for ensuring conductivity conductivity [Aquasonic gel (Parker Inc., Fairfield, NJ, USA) for 1 session per week for 4 weeks. The applicator was placed perpendicular to the insertion of the plantar fascia into the calcaneus.

Group (C) got both ultrasound therapy (3 sessions per week, for 4 weeks) and RSWT (1 session per week for 4 weeks) plus the conventional physical therapy exercise program 3 days a week for four weeks. The session starts with US that is followed immediately by the physical therapy exercise program then rest for 10 minutes followed by the RSW at the specific day of the week.

Treatment-Related Side Effects on Patients

There were no negative impacts reported in the US therapy (Group A). Three patients in the
used to analyze the data. Subjects’ demographic characteristics and outcome variables were described using the mean and standard deviation. To analyze the differences in the mean values of the variables under investigation among the three groups, an analysis of variance (ANOVA) with Tukey’s honest significant difference (HSD) posthoc test was performed. The level of significance between groups was fixed at alpha<0.05.

Results

The flow diagram of the study participants is shown in Figure 1. Eighty participants were enrolled in the current study; eight did not match the inclusion criteria, and three subjects declined to participate; thus, 69 participants were eligible to participate, and they were divided into three equal groups at random. The patients comprised 25 men (36.23%) and 44 women (63.77%) with a mean age of 41.22±4.42 years and a body mass index of 27.65±2.57 Kg/m². As indicated by ANOVA there were no significant differences (p>0.05) among the groups regarding patients’ demographic characteristics as shown in Table I.

According to the dependent t-test, the comparison of pre-test vs. post-test mean values for each dependent variable in the examined groups revealed statistically significant differences (p<0.001) in all of the groups under investigation. The percentage of improvement in foot function was 49.69% for group A, 52.02% for group B, and 64.75% for group C. While, the percentage of improvement in active range of motion (ROM) of the ankle DF was 25.02% for group A, 31.24% for group B, and 47.30% for group C as shown in Table II.

ANOVA revealed no significant differences (p>0.05) among the groups when the mean values of the measured outcomes were compared in the pre-test condition. While it indicated significant differences (p<0.001) among the groups when comparing the mean values for the measured outcomes in the post-test condition as shown in Table III.

Tukey’s HSD post hoc test revealed statistically significant variations in foot function between groups A and C after treatment (p<0.001) and active ROM of the ankle DF (p<0.001). There were also statistically significant variations in foot function (p<0.001) and active ROM of the ankle DF (p<0.001) between groups B and C after therapy. While, there were no significant differences in foot function (p=0.135) or active

Outcome Measures

One author, who was blinded to the allocation, evaluated the measured outcomes at baseline and at the end of the fourth week of the treatment program. The foot function index was the primary outcome measure, and the ankle dorsiflexion range of motion was the secondary outcome measure.

Foot Function

The modified foot function index (FFI) consists of 17 items scored on a VAS scale with a straight line of 10-cm. It was split into three subscales: pain (5 items), disability (9 items), and activity limitation (3 items). It was utilized to measure the changes in foot function from the beginning of treatment to four weeks later. It has been reported to be a valid and reliable (Cronbach’s α=0.95) assessment of illness impact on foot and ankle function³²,³³.

Ankle Dorsiflexion Range of Motion

The active range of motion (ROM) of the ankle dorsiflexion (DF) in the weight-bearing lunge position was evaluated using a Baseline® bubble inclinometer (Fabrication Enterprises Inc., White Plains, NY, USA) from baseline to 4 weeks after treatment. To standardize the measurement, the patient established a standing lunge position against the wall, with the measured leg in front, toes facing toward the wall, and the big toe 30 cm away from the wall. The inclinometer was fastened to the tibial tuberosity along the anterior tibial crest, and the patient bent the knee maximally toward the big toe without lifting the heel off the ground. The measured angle to the vertical is recorded as the ankle DF value. This measurement method has previously been reported in the literature to have higher reliability (intraclass correlation coefficient=0.96-0.99) than the goniometer³⁴,³⁵.

Statistical Analysis

The statistical package for social sciences (SPSS) for Windows, Version 22.0 (Chicago, IL, USA) was prescribed using the mean and standard deviation. As indicated by ANOVA there were no significant differences (p>0.05) among the groups when the mean values of the measured outcomes were compared in the pre-test condition. While it indicated significant differences (p<0.001) among the groups when comparing the mean values for the measured outcomes in the post-test condition as shown in Table III.

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RSWT (Group B) reported pain and/or discomfort, but all patients were able to complete their treatments without anesthesia. Aside from that, two patients noticed slight skin reddening for a short period after treatment. Other negative events were not observed. The maximal duration of discomfort was 15 minutes, and therefore no participant needed local anesthetic during RSWT, despite the fact that it was supplied to all patients. These adverse reactions had no effect on the treatment outcomes.

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ROM of the ankle DF ($p=0.315$) between groups A and B after treatment as in Table IV.

**Discussion**

The current study findings supported the authors’ hypothesis that RSW and US combined with supervised conventional physical therapy program can improve foot function and ankle dorsiflexion more than RSW with traditional physical therapy or US with traditional physical therapy alone in patients with chronic PF, as evidenced by significant ($p<0.001$) improvements in both foot function and active ROM of the ankle DF in all groups after 4 weeks of treatment. These results correlates with the minimal clinical importance difference of foot function index which valued 6.5° decrease$^{16}$. The results also indicated that the treatment protocol that used RSW and US in addition to the conventional physical therapy program exhibited a highly statistically significant ($p<0.001$) improvement in the measured outcomes after 4 weeks of treatment when compared to other protocols that used only ultrasound therapy or RSWT in conjunction with the same traditional physical therapy program. Furthermore, after 4 weeks of treatment, there was no significant ($p>0.05$) difference between the ultrasound therapy protocol and the RSWT protocol employed in this study in treating patients with chronic PF. However, the percentages of improvement in assessed outcomes obtained from the RSWT treatment protocol were larger than those obtained from the ultrasound therapy protocol.

The current study’s findings are consistent with earlier studies$^{19,37,39}$ that found a significant

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**Figure 1.** Flowchart for participants recruitment and allocation.
improvement in measured outcomes after treating PF cases with ultrasound therapy or RSWT in conjunction with a traditional physical therapy regimen. To the best of the authors' knowledge, no previous research has attempted to explore the combined efficacy of RSWT therapy with ultrasound associated with the conventional physical therapy exercise program for the treatment of chronic plantar fasciitis.

Greve et al. conducted a study on patients with chronic plantar fasciitis utilizing RSW on one
group and US plus the traditional physical therapy program on the other. The authors reported that both treatments were beneficial for pain relief and improved functional abilities of patients with PF. The authors did remark, however, that the effects of RSW occurred sooner than the effects of physiotherapy after the start of treatment.

The therapeutic effects of ultrasound, which can accelerate tissue repair, increase collagen fibres extensibility, and reduce pain and muscular spasms, could be linked to the improvement in measurable outcomes that occurred with ultrasound therapy. The extent of these therapeutic activities varies depending on tissue absorption properties and application parameters.

Ultrasound was found to be significantly more beneficial than RSW for pain and impairment as measured by the foot function index scale. On the other hand, when comparing the effect of RSW with US in a meta-analysis, four studies out of five (using the VAS to determine the improved condition after pain treatment) concluded that RSW was superior to US when calculating the pooled effect size of VAS.

In contrast, Katzap et al. observed that adding active therapeutic US therapy to plantar fasciitis treatment does not improve its efficacy. The study population got 8 minutes of therapeutic US at a frequency of 1 MHz and a pulse intensity of 1.8 W/cm² in continuous mode, whereas the control group received 8 minutes of negligible intensity. The frequency was set to 3 MHz, the pulse intensity was set to 0.1 W/cm², and the duty cycle was set to 1:4. However, because their study only included a control group that did not receive therapy, it is impossible to rule out the possibility that the improvement seen in both groups was due to the natural course of recovery.

Radial SWT has powerful analgesic and anti-inflammatory properties. It induces anabolic responses in tendon and ligament tissues, which promote tissue repair. It promotes vascularization in the bone tendon articulation by releasing growth factors. These factors could explain the RSWT-induced improvement in the measured outcomes.

Konjen et al. conducted a randomized controlled trial to compare the efficacy of RSW therapy vs. US therapy in the treatment of chronic PF. For six weeks, the RSW group received 2,000 impulses at 10 Hz frequency and 2 bar pressure once a week, whereas the ultrasound group received 3 MHz frequency and 0.5-1 watt/cm² on continuous mode three times a week. The VAS scale was used to assess pain before therapy, as well as at 1, 3, 6, 12, and 24 weeks after treatment, while the mobility subscale of the plantar fasciitis pain and disability scale was utilized to assess foot mobility function before and after treatment. Both RSW and US were shown to be effective in reducing pain and increasing mobility.

Radial shock wave provided relatively more effective and stable pain relief than other interventions in a systematic review and meta-analysis of extracorporeal shock wave, ultrasound, low-level laser therapy, noninvasive interactive neurostimulation, and pulsed radiofrequency for the treatment of plantar fasciitis, making it a promising candidate for clinical applications. This is consistent with our findings. Radial shock wave treatment has the advantage of not requiring patients to restrict weight bearing or return to work for an extended length of time. Rather, RSW allows patients to resume daily activities in 1 or 2 days, with most jobs and ordinary daily shoe wear returning immediately.

Concerning the amount of RSW sessions that appeared to be useful for patients with chronic PF, it is suggested that symptoms improved after only two sessions, another study showed that three sessions were required for patients to reduce symptoms, however the sample size of the 2 session study was substantially less than that of the 3 session study.
On the other hand, Speed et al. observed no treatment effect of RSW on patients with PF; the authors attributed their results to the machine type and treatment protocols. They used a sham protocol for the control group with minimal energy pulses (0.04 mJ/mm²) but no contact with the site of inflammation. Another difference between our study and Speed’s is that the authors only evaluated pain, night pain, and start-up pain.

Plantar fasciitis causes lateral body weight support on the foot or forefoot (supported on the toes) during gait due to pain in the calcaneus’s medial region or at the plantar fascia’s proximal insertion. This results in chronic shortening of the achillea tendon and painful feeling at the medial portion of the gastrocnemius. Stretching the Achilles tendon and plantar fascia can enhance ankle dorsiflexion ROM and foot function by increasing muscle length and lowering passive stiffness of the muscle-tendon unit.

The plantar fascia is made up of collagen type I fibers. This type of collagen appears to respond to high-load conditions by boosting collagen synthesis. Increased collagen production may assist restore tendon structure and improve patient outcome in individuals with plantar fasciitis who have degenerative abnormalities at the plantar fascia insertion. According to earlier research, patients with low ankle dorsiflexion strength may benefit from high-load strength training.

Friction massage has considerable impacts, such as the release of adhesions (scar tissue), the stimulation of controlled inflammation, increased blood supply to the tissue, which allows healing to accelerate, and the parallel formation of new fibroblasts. Adhesions are produced as a result of previously uncontrolled inflammation, eventually leading to controllable inflammation and more structured regeneration of previously inflamed tissues. Transverse friction massage can thus be used to treat chronic inflammation by raising inflammation to the point where the inflammatory reaction is complete and the injury can progress to the later stages of healing.

Previous research on PF patients revealed that a single therapeutic modality for PF treatment was often insufficient, so more than one therapy modality should be utilized in combination. In our study, we found that the combination of RSW and US paired with a conventional physical therapy program improved foot function and ankle dorsiflexion range of motion more than US applied in combination or RSW coupled with exercise alone.

**Limitations**

The current study has some limitations, including the inability to blind the patients due to the nature of the investigation. Another issue was the lack of follow-up for participants in all groups. As a result, future research should be conducted to investigate the long-term effect of RSW and US combined with traditional physical therapy programs on patient outcomes.

**Conclusions**

According to the findings of this study, RSW and US coupled with a traditional physical therapy exercise program had a notable efficacy in improving foot function and active ROM of the ankle dorsiflexion in patients with chronic Plantar Fasciitis.
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