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MUSCULOSEKELTAL SECTION

Original Research Article

Comparison of the Acute Effect of Radial Shock Wave Therapy and Ultrasound Therapy in the Treatment of Plantar Fasciitis: A Randomized Controlled Study

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Abstract

Objective. This study compared the effectiveness of radial extracorporeal shock wave therapy (r-ESWT) with ultrasound (US) therapy in the treatment of plantar fasciitis (PF).

Study Design. Level II, randomized controlled study.

Design. A total of 54 female patients with unilateral PF were randomly assigned to two study groups and one control group. All groups performed home exercises. In addition, the first study group received three sessions of r-ESWT treatment and the second study group received seven sessions of US treatment. The Foot Function Index (FFI) and the American Orthopedic Foot and Ankle Association (AOFAS) hind foot score were determined. Static and dynamic equilibrium were evaluated with the single leg standing test and the functional reach test. Ankle proprioception sense was determined with the Biodex III isokinetic device. Patients were evaluated before and four weeks after the first treatment.

Results. According to the evaluation results, there was a decrease in FFI values in all groups and these decreases were more prominent in the US group than the other groups ($P < 0.05$). It was observed that the hind foot AOFAS scores increased in all groups, but this increase was less in the control group ($P < 0.05$). Static and dynamic balance increased in all groups ($P < 0.05$). Ankle proprioception sense increased only in the r-ESWT group ($P < 0.05$).

Conclusions. All groups and particularly the r-ESWT and US groups' symptoms were decreased after treatment. However; FFI parameters were reduced more in the US groups than the other two groups, the ankle proprioception sense increased in the r-ESWT group, and there was no change in the other groups.

Key Words. Plantar Fasciitis; Radial Extracorporeal Shock Wave Therapy; Ultrasound Therapy; Physiotherapy; Exercise

Introduction

Plantar fasciitis (PF) is one of the most common foot problems in adults. It occurs in approximately 10% of the population throughout life and is bilateral in about

20% to 30% of the patients [1–3]. PF occurs due to factors that can be anatomical (such as pes planus, pes cavus, the size difference of the lower limbs) [3,4], biomechanical (such as more external rotation in the lower extremities, pronation increase in the subtalar joint, shortening of the Achilles tendon, weakness of plantar flexors) [4,5], or environmental (such as obesity, improper shoes) [6–10]. The most important symptom is pain that increases especially in the morning while getting out of bed and that can appear after standing inactive for a long time. It is often described as at the heel, over the proximal medial longitudinal arc, around the medial tubercle, and at the plantar fascia adhesion site [3,10,11]. Approximately 28% to 66% of patients with PF have also signs of a heel spur [10].

Treatment modalities for PF can be surgical or conservative. The success rate of conservative treatments such as splints, ultrasound therapy, iontophoresis, laser therapy, extracorporeal shock wave therapy, exercise therapy, steroid injection, etc., is 90% to 95% [12,13]. Surgery should therefore only be a last resort [14–17].

Some studies have compared different treatment modalities to find the most effective treatment for PF [18–20]. However, we do not have precise information about the most effective conservative treatment method. It has also been stated that combining treatment modalities is needed for successful treatment [21–24].

There are no studies comparing the acute and chronic effects of radial extracorporeal shock wave therapy (r-ESWT) and ultrasound (US) treatment in the treatment of PF, and it has been stated that more detailed studies are required [4]. Therefore, this study was designed to compare the acute effects of r-ESWT and US treatment in the treatment of PF.

Methods

Patients

This prospective, single-blinded, randomized controlled study was performed in a physical therapy and rehabilitation clinic. Patients diagnosed with PF by a physician and meeting the study criteria were invited to participate. Patients who agreed to participate in the study signed a written informed consent form that had been approved by the ethics committee.

The sample size of this study was evaluated, and power calculations were performed using an instant sample size calculator. The alpha level used was 0.05, and the β level 20% at a desired power of 80%. These parameters generated a sample size of at least 16 patients per group. In the beginning of the study, we included 24 patients in the r-ESWT and exercise group, 26 patients in the US and exercise group, and 28 patients in the exercise group, for a total of 78 patients, but 24 patients dropped out. The study was therefore completed with a total of 54 patients meeting the inclusion criteria and study rules (Figure 1). Fifty-four (average age = 50 years, range = 39 to 59 years) female patients with PF were randomly assigned to the r-ESWT (N = 18) group, US (N = 18) group, and control (N = 18) group. Randomization was provided with a sealed envelope including cards with the modalities written on them. Randomization was performed after the first assessment.

The inclusion criteria were tenderness on palpation of the heel, presence of pain in the plantar region for at least three months, presence of a calcaneal spur in lateral radiographs of the foot, and unilateral PF. Exclusion criteria consisted of a history of surgery or trauma of the lower extremities, low back surgery (that may affect the proprioception sense result), limitation of lower extremity joints, neurological and vestibular system disorder, systemic inflammatory disease, steroid injections in the last six months, pacemakers, coagulation problems, using anticoagulant medication, and body mass index greater than 30 kg/m^2 or less than 20 kg/m^2 as they could influence the effectiveness of the applied treatment. In addition, patients who exercised regularly (stretching, aerobic exercises such as walking, running, swimming, etc., for at least half an hour a day, three days a week) were also excluded from the study as it could change the effectiveness of home exercises. We first considered including both genders at the beginning of the study, but when analyzing the variation of the patients coming to the clinic, we observed that there were many more female patients than male patients. This could affect the homogeneity of the study, and the study was therefore performed only on female patients.

Outcome Measurements

The first evaluation was performed before the first treatment for all groups. The last evaluation was performed one week after the last r-ESWT treatment for the r-ESWT group, three days after the last US treatment for the US group, and four weeks after the teaching exercises for the control group.

The individual's personal information was filled in the form for demographic information.

The patients' pain, disability, and activity limitation were determined with the Foot Function Index (FFI), and they were asked to show their pain level, disability, and activity limitations on a 10 cm visual analog scale (VAS) with measurements made using a ruler. Pain, disability, and activity limitation scores were collected and the category considered separately. Similarly, foot functioning was determined by the American Orthopedic Foot and Ankle Association (AOFAS) hind foot score [13]. Static equilibrium was determined by the one leg stand test, and dynamic equilibrium was determined by the forward functional reach test. Ankle proprioception sense was evaluated with plantar flexion passive joint position sense using the Biodex III isokinetic device, and the

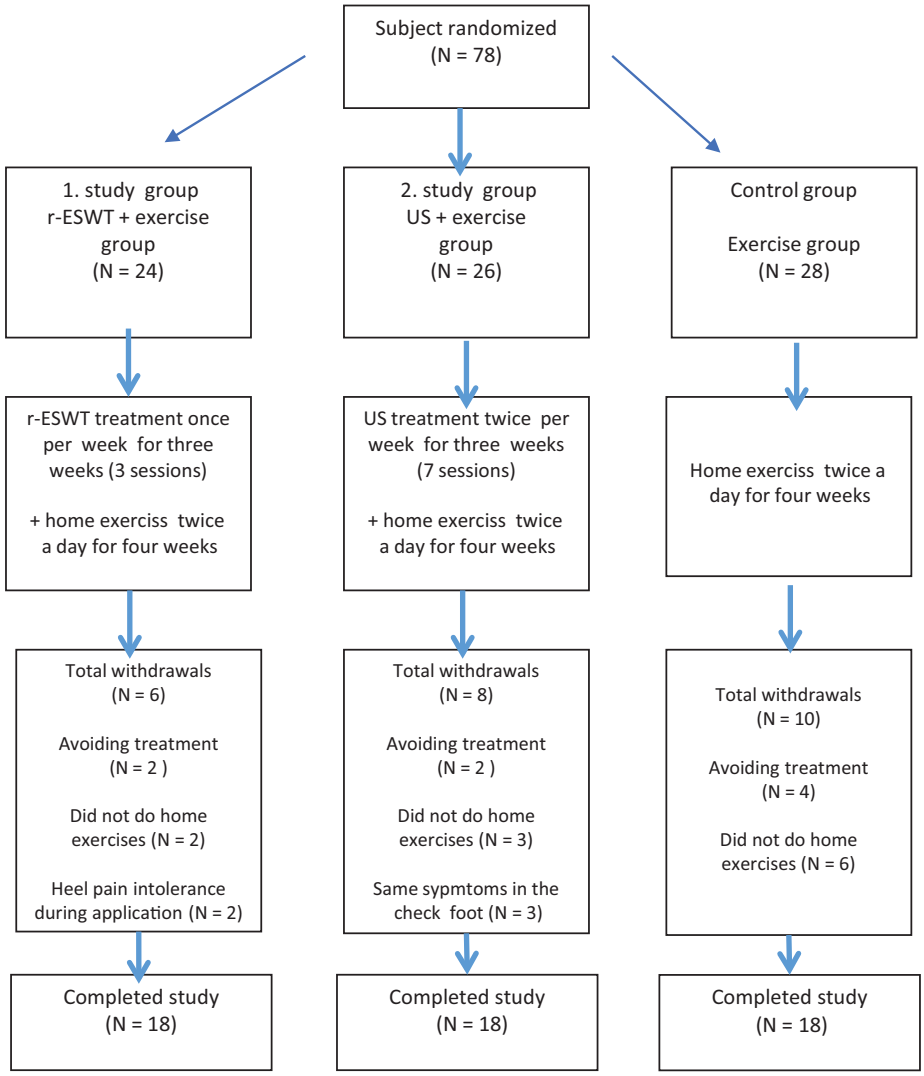

Figure 1 Shematic presentation of the study flow. r-ESWT = radial extracorporeal shock wave therapy; US = ultrasound therapy.

angle of the test was defined as 15°. These evaluations were made before and after the treatment.

Interventions

Individuals were randomly divided into three groups. Each group was given a home exercise program. In addition to the home exercises, the first study group received a total of three sessions of r-ESWT treatments administered once a week, and the second study group received a total of seven sessions of US treatment administered two days a week. The third group was used as the control group and did not receive a treatment modality other than home exercises.

All individuals in the study were asked not to perform any exercise other than the home exercise program provided and not to use any orthotic support during the treatment so that the results would not be affected. We gave the patients a schedule for them to note the exercise sessions including the date, the start and end times of the exercise, and the times of the day. We also told the patients to note whether they used any support or performed any exercise other than the ones recommended. Incompliant subjects were dropped out of the study.

r-ESWT Treatment

Individuals in the first group were treated with Swiss Dolor Clast devices by Electro Medical Systems SA (EMS). The treatment was performed in the prone position. The most painful point was determined with palpation and marked with a pencil (Figure 2A) before starting each treatment. The treatment began with a dose of

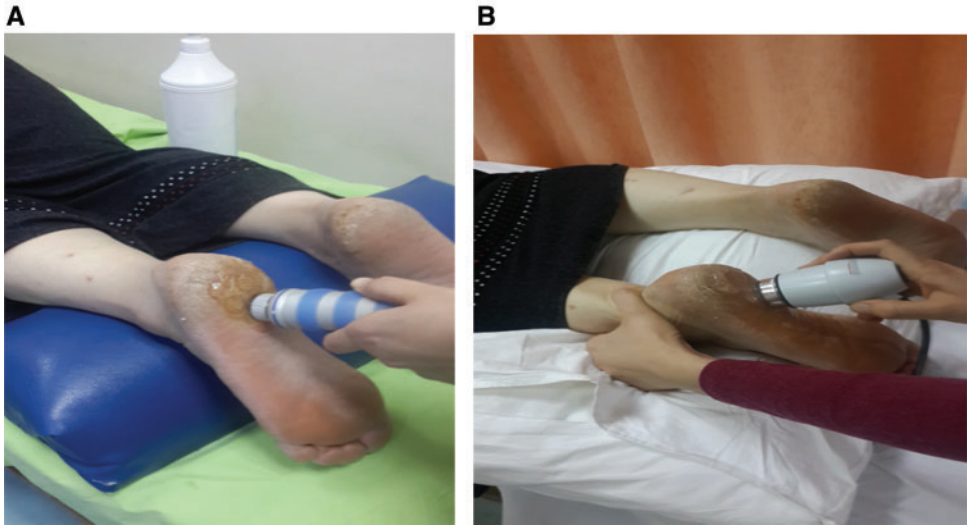

Figure 2 Application of the treatment modalities. **A)** Radial extracorporeal shock wave therapy application. **B)** Ultrasound application.

500 pulses, 3 Hz, 0.2 mJ/mm^2 applied to the whole heel area. Then, a dose of 1,500 pulses, 8 Hz, 0.3 mJ/mm^2 was applied to the specified tender point palpated before the treatment. Thus, a total of 2,000 pulses of r-ESWT treatment was applied in each session. A gel was used to provide conductivity between the probe and the skin during the application. A total of three sessions of r-ESWT treatment were administered once a week [25].

US Treatment

Individuals in the second group were treated with the Gymna Pulson 200 US therapy device. The treatment was performed with longitudinal movements in the prone position using the full-contact technique all along the plantar fascia. US treatment was applied with 3.0 MHz frequency, power density 1 W/cm^2, and a pulsed wave duty cycle of 1/4 (impulse time/interval) for eight minutes. During the application, a gel was used to provide conductivity between the US probe and the skin (Figure 2B). The patients were treated two days per week for a total of seven sessions [21,26,27].

Home Exercise Program

This program was prescribed to all patients and included stretching of the gastrocnemius and gastro soleus muscles by standing (standing calf stretch exercise, standing soleus muscle stretch exercise) (Figure 3, A and B), the Achilles tendon by sitting (towel stretch exercise) (Figure 3C), and the plantar fascia on a step (plantar fascia stretch exercise) (Figure 3D) [20,28]. Patients were asked to do the exercises for four weeks, 10 times each morning and evening by counting up to 30. In addition, a chart was provided to the patients for them to mark the exercise days and sessions apart from the exercise form, and the patients received a call from the therapist once a week for stimulation and to check whether the exercises were being done.

Statistical Analysis

The data were evaluated using the Statistical Package for the Social Science 15.0 program for Windows and via descriptive statistics analysis (frequency, mean, minimum and maximum, and standard deviation). Before starting the study, a power analysis was performed to determine the number of patients required. The Kolmogorov-Smirnov test was used to determine whether data distribution was normal, and it was determined that the data did not have a normal distribution. We therefore used the Wilcoxon signed rank test to compare the treatment groups' data before and after the treatment. The Kruskal-Wallis test was used to determine the group causing the differences between the three groups. The Mann-Whitney U test was used to make comparisons between the two groups. The statistical significance level was a P value of less than 0.05, and we used 95% confidence intervals.

Results

The patients' characteristics are shown in Table 1. There was no significant difference between the three groups ($P > 0.05$).

Pretreatment evaluation results are presented in Table 2. Pretreatment values of the AOFAS score and FFI results were similar in all three groups ($P > 0.05$). There was also no difference between the pretreatment

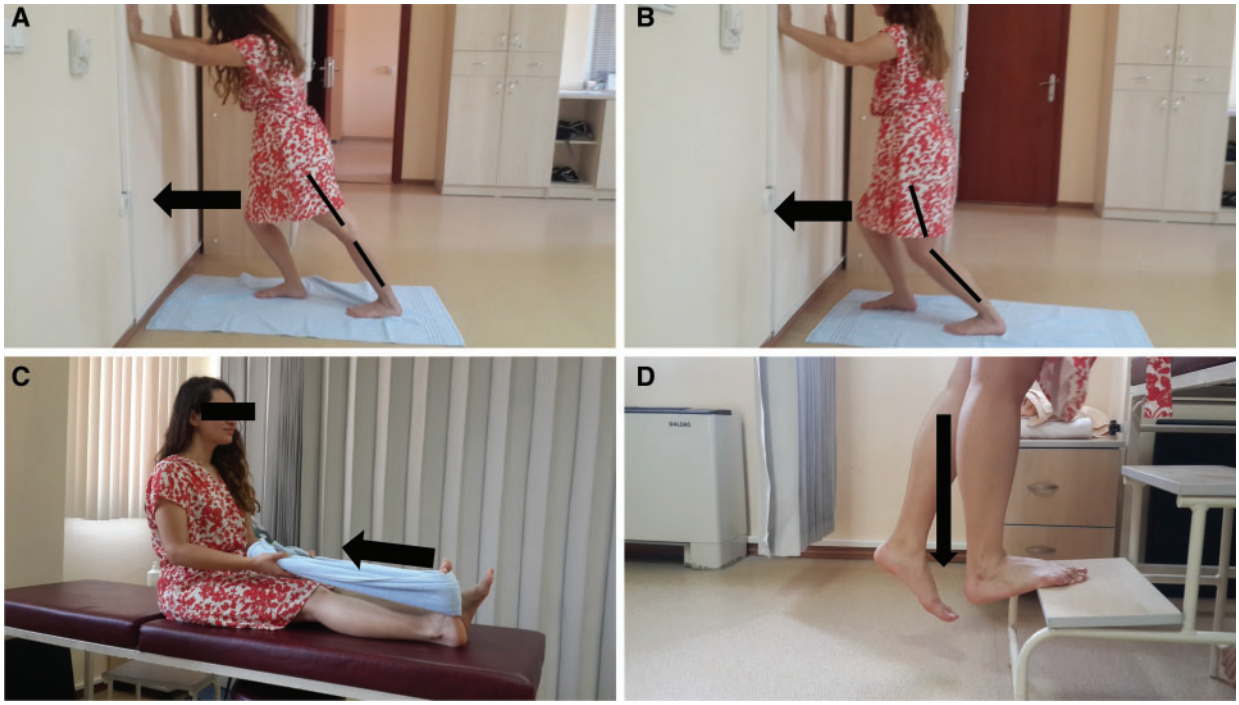

Figure 3 Home exercises program. **A)** Standing calf stretch exercise. **B)** Standing soleus muscle standing exercise. **C)** Towel stretch exercise. **D)** Plantar fascia stretch exercise.

Table 1 Patient demographics*

	r-ESWT Group (N = 18)	US Group (N = 18)	Control Group (N = 18)	$\chi^{2\dagger}$	*P*
Age, y	50.00±6.54(39–59)	50.11±9.29(32–65)	45.22±7.64(32–62)	4.596	0.100
Education level, y	3.94±3.75(1–11)	3.22±4.04(0–11)	3.78±4.02(0–11)	3.281	0.703
BMI, kg/m^2	28.58±1.67(23.51–29.94)	28.48±2.15(21.97–29.94)	28.03±2.04(22.95–29.97)	1.299	0.522

r-ESWT = radial extracorporeal shock wave therapy; US = ultrasound therapy.
*Values are expressed as mean ± SD and minimum – maximum value.
†Kruskal-Wallis test.

values of the one leg stance test, functional reach tests, and passive ankle proprioception sense between the groups ($P > 0.05$). These results indicated that our groups were distributed homogeneously before the treatment.

After treatment, there was a reduction in the FFI's pain, disability, and activity limitations subtitles in all three groups ($P < 0.05$), but these were most marked in the US group compared with the two other groups ($P < 0.05$). The AOFAS score of hind legs increased in all groups, but the end value was less in the control group than in the other groups ($P < 0.05$). An improvement was recorded in the one leg stance and functional reach tests ($P < 0.05$) with no difference between the groups ($P > 0.05$). The ankle proprioception sense increased in the r-ESWT group after the treatment compared with the values before treatment ($P < 0.05$), but there was no difference in the other groups ($P > 0.05$) (Tables 3 and 4).

Discussion

In this study, a total of 54 female patients with unilateral PF were randomly assigned to two study groups and one control group. All groups performed home exercises. In addition, the first study group received three sessions of r-ESWT treatment and the second study group received seven sessions of US treatment. At the end of the study, all groups got better. However, FFI parameters were reduced more in the US group than the other two groups, while the ankle proprioception sense increased in the r-ESWT group but there was no change in the other groups.

Table 2 Comparison of pre-treatment evaluation results of patients*

Pretreatment		r-ESWT Group	US Group	Control Group	$\chi^{2\dagger}$	*P*
FFI	Pain	62.94±9.00	59.06±11.86	54.61±13.17	4.558	0.102
	Disability	75.61±19.05	74.61±18.78	63.06±17.64	5.927	0.052
	Activity limitation	20.61±6.48	16.22±9.52	17.28±8.57	2.242	0.326
AOFAS hind foot score		30.11±12.49	33.94±14.02	37.50±15.88	2.451	0.294
Single leg stance test, sec		19.94±11.27	17.78±11.37	17.72±9.32	0.491	0.782
Functional reach test, cm		25.06±5.82	24.94±7.96	26.39±6.92	1.517	0.468
Ankle proprioception sense, degrees		17.86±2.11	16.19±1.80	16.99±2.10	5.546	0.062

AOFAS = American Orthopedic Foot and Ankle Association; FFI = Foot Function Index; r-ESWT = radial extracorporeal shock wave therapy; US = ultrasound therapy.
*Values are expressed as mean ± SD.
†Kruskal Wallis test.

Table 3 Comparison of pre- and post-treatment evaluation results of patients*

		Pretreatment	Post-treatment	z†	*P*
r-ESWT group					
AOFAS hind foot score		30.11±12.49	74.72±13.55	−3.729	0.001‡
FFI	Pain	62.94±9.00	43.28±18.52	−3.553	0.001‡
	Disability	75.61±19.05	47.67±23.72	−3.595	0.001‡
	Activity limitation	20.61±6.48	8.83±7.02	−3.504	0.001‡
Single leg stance test, sec		19.94±11.27	23.56±8.39	−2.449	0.014‡
Functional reach test, cm		25.06±5.82	30.78±5.96	−3.306	0.001‡
Ankle proprioception sense, degrees		17.86±2.11	14.91±2.25	−3.202	0.001‡
US group					
AOFAS hind foot score		33.94±14.02	68.39±12.91	−3.725	0.001‡
FFI	Pain	59.06±11.86	28.56±12.44	−3.724	0.001‡
	Disability	74.61±18.78	30.78±15.01	−3.724	0.001‡
	Activity limitation	16.22±9.52	4.28±4.53	−3.353	0.001‡
Single leg stance test, sec		17.78±11.37	24.56±8.66	−2.087	0.042‡
Functional reach test, cm		24.94±7.96	31.17±4.64	−3.317	0.001‡
Ankle proprioception sense, degrees		16.19±1.80	16.50±1.57	−1.450	0.147
Control group					
AOFAS hind foot score		37.50±15.88	59.50±9.34	−3.550	0.001‡
FFI	Pain	54.61±13.17	38.89±16.52	−2.897	0.004‡
	Disability	63.06±17.64	46.78±21.05	−2.275	0.023‡
	Activity limitation	17.28±8.57	11.89±8.61	−1.967	0.049‡
Single leg stance test, sec		17.72±9.32	25.67±6.94	−3.110	0.002‡
Functional reach test, cm		26.39±6.92	30.50±3.49	−2.942	0.003‡
Ankle proprioception sense, degrees		16.99±2.10	16.48±1.51	−1.279	0.201

AOFAS = American Orthopedic Foot and Ankle Association; FFI = Foot Function Index; r-ESWT = radial extracorporeal shock wave therapy; US = ultrasound therapy.
*Values are expressed as mean ± SD.
†Wilcoxon signed ranks test.
‡$P < 0.05$.

In our study, FFI's pain, disability, and activity limitations subtitles were reduced in all three groups after the treatment. This reduction occurred more in the US group than the other groups. The inflammatory process in PF causes pain due to thickening of the plantar fascia and affects the patient's activities in daily living. Unlike the r-ESWT treatment, the US treatment increases the cellular activity level and the circulation with its thermal,

Table 4 Comparison of post-treatment evaluation results of patients between groups*

		r-ESWT Group	US Group	Control Group	$\chi^{2\dagger}$	*P*
FFI	Pain	43.28±18.52‡	28.56±12.44‡,§	38.89±16.52§	7.743	0.021‖
	Disability	47.67±23.72‡	30.78±15.01‡,§	46.78±21.05§	7.330	0.026‖
	Activity limitation	8.83±7.02‡	4.28±4.53‡,§	11.89±8.61§	8.621	0.013‖
AOFAS hind foot score		74.72±13.55¶	68.39±12.91§	59.50±9.34§,¶	10.536	0.005‖
Single leg stance test, sec		23.56±8.39	24.56±8.66	25.67±6.94	1.003	0.606
Functional reach test, cm		30.78±5.96	31.17±4.64	30.50±3.49	0.485	0.785
Ankle proprioception sense, degrees		14.91±2.25‡,¶	16.50±1.57‡	16.48±1.51¶	7.520	0.023‖

AOFAS = American Orthopedic Foot and Ankle Association; FFI = Foot Function Index; r-ESWT = radial extracorporeal shock wave therapy; US = ultrasound therapy.
*Values are expressed as mean ± SD.
†Kruskal-Wallis test.
‡According to the Mann-Whitney U test, there is a difference between the r-ESWT and US groups.
§According to the Mann-Whitney U test, there is a difference between the US and control groups.
¶According to the Mann-Whitney U test, there is a difference between the r-ESWT and control groups.
‖$P < 0.05$.

nonthermal, mechanical, and micro-massage effects and heals the inflammatory process while creating an analgesic effect [29]. We believe US treatment caused a more significant reduction in pain and decreased activity limitations and disability because of these effects. Similar to our study, Greve at al. compared US and r-ESWT treatments in PF, but unlike our study they also administered kinesiotherapy to the US group. They did not have a control group. They randomly divided 32 patients with PF into two groups. The first group received 1.0 Hz, 1.2 W/cm^2 US treatment, kinesiotherapy, and home exercises for a total of 10 treatment sessions administered two days a week. The second group received r-ESWT treatment with 2,000 pulse, 6 Hz frequency, 3 MPa pressure and home exercises with a total of three treatment sessions administered one day a week. Treatment results revealed that r-ESWT showed its pain reducing effect faster but there was no difference between the groups three months later. We found US treatment to be as effective as ESWT when combined with other physiotherapy modalities [18].

Gerdesmeyer at al. investigated the safety and effectiveness of r-ESWT in the treatment of recalcitrant plantar fasciitis after 12 weeks and 12 months in a placebo-controlled study. They compared three interventions of r-ESWT (0.16 mJ/mm^2, 2,000 impulses) with placebo in 245 patients with chronic plantar fasciitis and found that r-ESWT was significantly superior to placebo, with r-ESWT significantly improving pain, function, and quality of life compared with placebo in patients with recalcitrant PF [30]. All three groups in our study and especially the r-ESWT and US groups similarly had a significant improvement in all parameters. We did not have a placebo group, but we had a control group that only used a home exercise program, and the r-ESWT group improved more than the control group, in line with the Gerdesmeyer at al. study. However, our study has only shown short-term effects. The long-term effects could have been different, and the effects of r-ESWT could have been found to be more significant than the other modalities.

The AOFAS scores increased in all groups after treatment in our study. Our study is also in line with the relevant literature. Ilieva at al. investigated the effects of ESWT treatment on 21 patients with PF. The patients were evaluated with the visual analog scale and AOFAS in the third, sixth, and 12th months. Pain decreased in all patients, and their AOFAS scores increased with time [31].

We compared the AOFAS scores of the groups among themselves after the treatment and found the AOFAS scores of the groups treated with r-ESWT and US with a combination of exercise to have increased more than the group treated only with exercise. The AOFAS clinical evaluation system evaluates pain, functionality, and sequence. Our result indicates that exercise is an effective treatment method but is not adequate in the rehabilitation of multiple factors such as pain and functionality and that using exercise in combination with other physical therapy modalities might be more useful in the treatment of the PF. There is not much reported on the effectiveness of only one of treatment modality in PF, but it is generally stated that these modalities need to be combined depending on the condition of the patient to achieve success [21,22,24,32]. Different kinds of exercise protocols such as stretching, strengthening, or combinations of the two have been used in PF patients, and they have been shown to be effective in reducing pain [33]. Sweeting et al. investigated the effect of stretching exercises on PF in their review. They found low levels of evidence showing that stretching exercises are as effective as the other treatment modalities [28]. This information is also supplemented with our study.

We found the one leg stance test values to increase in all groups after treatment, indicating an improvement in one leg stance balance. When all three groups were compared with each other, there was no difference between the one leg stance test values. In addition, the values of the forward functional reach test were found to increase. This could be due to the increased time of balance while standing on one leg and the decrease in pain. There are no studies comparing US and r-ESWT treatments and evaluating one leg stance balance in PF patients. In a single case study, a 61-year-old patient suffering from PF for 10 years was reported to obtain relief in functional activity with increased standing on one leg duration after eight sessions of iontophoresis therapy and a home exercise program [32].

We found no difference between pre- and post-treatment ankle proprioception values in the US and control groups, but an increase was recorded in the r-ESWT group. Although there was no difference between the three groups for the before-treatment values, the r-ESWT group was closer to the target angle when comparing after-treatment values. This showed us that the sense of ankle proprioception increased in the group receiving r-ESWT. There are no previous studies on ankle proprioception sense in PF. However, patients with functional ankle instability have been shown to suffer partial afferent transmission loss in the joint mechanoreceptors after injury [34–36] with joint position sense [37,38] and kinesthesia errors [38,39] and prolonged peroneal muscle reaction time [35,40,41]. The vibrations during the application are thought to affect the ankle and thus perhaps increase the proprioception of ankle due to the fact that the ESWT consists of high-intensity pressure waves while r-ESWT has the ability to affect a wide area [25] without focusing on one point. Based on our work, patients need to be evaluated well and r-ESWT treatment may be preferred if there are contraindications such as ankle instability or factors that impair biomechanics, which could affect the proprioception of the ankle.

Reviews of other studies in patients with PF generally indicate that a single treatment modality is inadequate in PF treatment and a combination of multiple treatment modalities should be used. It has also been determined a single type of exercise therapy is not enough in the treatment of PF. In parallel with this knowledge, we found that pain intensity decreased more in the US and exercise group, the proprioception sense increased only in the r-ESWT and exercise group, and there was less improvement in the group that received only exercise treatment.

This study has several limitations. The biggest limitation was the duration of the study. The study needs to be longer to determine the long-term effects of US and r-ESWT treatment and to compare them in a better way. The other limitation is that we could not make a control group without treatment as it would not be ethical. This caused us to apply these exercises in the study groups in order to prevent a difference, and we were therefore unable to evaluate the effectiveness of the r-ESWT and US treatments by themselves. The other limitation is that we performed the study solely on female subjects. Participation of male patients in the study will make the results more variable.

Conclusion

In conclusion, the results of this study provide evidence that US treatment and r-ESWT treatment are effective methods to reduce pain and increase functionality in PF when combined with exercises. We determined that only a combination of r-ESWT and exercise therapy is effective in increasing the sense of ankle proprioception in PF, but a combination of US therapy with exercise and also only exercise therapy were inadequate in this regard. On the other hand, US therapy was found to be superior to r-ESWT treatment in reducing pain in PF. There was less improvement in the group receiving only exercise therapy when compared with the two other groups.

If the patient's complaints about pain are at the forefront, treatment could consist of a combination of US and exercise therapy. If there is a pain together with pathologies that disrupt the patient's biomechanical sequence, the combination of r-ESWT and exercise therapy could be preferred. Our results could be useful in the management of PF. However, mixed-gender studies on larger series comparing r-ESWT and US treatment with longer follow-up are needed.

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