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Investigation of The Effectiveness of Extracorporeal Shock Wave Therapy in Patients Diagnosed with Plantar Fasciitis: Comparison of Radial and Focus Applications

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ABSTRACT

The aim of the study was to investigate the effectiveness of radial and focus (extracorporeal shock wave therapy) ESWT treatment on pain, function and size of the calcaneal spur in patients with clinical and radiological diagnosis of plantar fasciitis. A total of 112 patients aged between 18 and 95 years, were divided into 2 groups; group 1, rESWT (2.4 bar 12 hz 2000 beats), group 2 received fESWT (0.14 bar 14 hz 1000 beats) 3 times a week for 3 weeks. All patients were evaluated using the Visual Analog Scale (VAS)-pain and Foot Function Index before and after the treatment, at 4 week and 12 weeks. Calcaneal spur size was measured radiographically in the patients before and after the treatment at the 12th week follow-up. According to our records, VAS scores were found to be similar between the groups before treatment and at follow-ups (all $p > .05$). In both groups, a significant decrease in VAS scores was found in the follow-ups compared to before treatment ($p < .001$). FFI total, pain, activity and disability scores were found to be similar between the groups before treatment and at follow-up (all $p > .05$). In both groups, a significant decrease in Foot Function Index scores was found in the follow-ups compared to before treatment ($p < .001$). Both of rESWT and fESWT were effective in plantar fasciitis treatment there were no significant difference between 2 modalities in long term.

Heel pain is a symptom that is common in the community, can be seen in up to 10% of the population, and can affect the daily life of the individual (1). Plantar fasciitis is one of the most common causes of localized heel pain, can cause serious discomfort and limitations in daily life (2). While it can be seen any age, usually seen in women between the ages of 40-50 years (3), and the incidence increases in obesity (4).

In the pathophysiology of plantar fasciitis, plantar calcification follows inflammation of the plantar fascia caused by exposure to repeated microtraumas under the influence of predisposing factors (5). Foot deformities, obesity, and extreme sports exercise exacerbate this injury.

The main complaint is pain that increases gradually inside of the heel. The pain is especially burning and stinging in the medial heel. It is more severe when the first step is taken in the morning and gets lighter after a few steps but intensifies towards the end of the day depending on the load and activity (6). Rest reduces pain and provides relief, but pain is felt again on the first step after sitting. The duration of symptoms can range from a few weeks to many years.

The medical history and clinical examination findings are essential in diagnosis, and it is confirmed by radiography. Conservative approaches are the first choice in treatment. Wearing orthopedic shoes, reducing the load with insoles or heels, rest, losing weight, cold application, stretching exercises, shoe modification, organization of activities of daily living are the basic principles of the treatment. In addition, nonsteroidal anti-inflammatory drugs, local corticosteroid and anesthetic injections, kinesiotherapy, physical therapy modalities such as iontophoresis, microwave, low-energy laser therapy (LLLT) and ultrasound are common treatment methods (7). Recently, the use of extracorporeal

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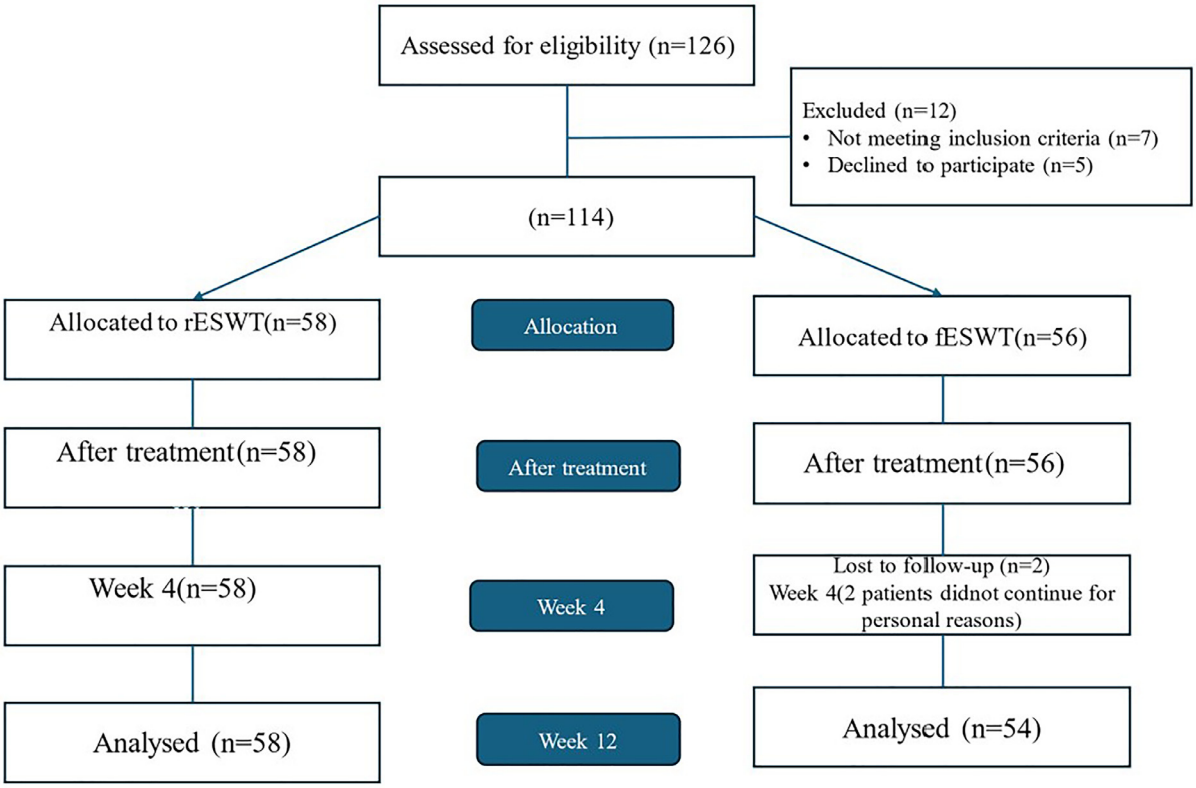

Fig. 1. Flowchart of the study.

shock wave therapy (ESWT) has increased in the treatment of plantar fasciitis (8). There are many studies in the literature investigating the efficacy of different treatment modalities for plantar fasciitis treatment; however, the most effective method is still unclear (9).

ESWT is a noninvasive method used in different musculoskeletal system pathologies. It has taken its place among nonsurgical methods based on the principle that high amplitude sound waves focus on the desired area of the body and provide treatment there (10). There are studies in the literature showing that ESWT reduces pain associated with plantar fasciitis (11,12). There are 2 main types to generate ESWT: focused ESWT (fESWT) and radial ESWT (rESWT). These 2 types differ, not only in their physical properties and mode of generation, but also in the magnitude of the standard parameters used and the penetration depths. fESWT utilizes electromagnetic, electrohydraulic, or piezoelectric sources to create shockwaves. These waves have a rapid pressure increase and can penetrate deep into tissues, reaching up to 12 cm. The delivered energy is relatively low, minimizing the risk of damage to the skin and underlying soft tissues. In contrast, rESWT relies on a pneumatic system to generate the shockwaves. The peak energy is concentrated at the probe tip and disperses outward (radially) into the tissue. The pressure increase is much slower, and the effective depth of treatment is shallower, typically only reaching 3-4 cm (13).

To the best of our knowledge, there are research on the efficacy of ESWT in the conservative treatment of plantar fasciitis in the literature, but studies that compare the effects of radial and focus waves, which have different mechanisms of action, on plantar fasciitis are insufficient. There is no consensus on which type of application is more effective in plantar fasciitis.

The aim of the study was to investigate the effectiveness of radial and focus ESWT treatment on pain, function and size of the calcaneal spur in patients with clinical and radiological diagnosis of plantar fasciitis.

Patients and Methods

Study Design and Participant

This prospective, clinical study was carried out Ankara City Hospital Physical Therapy and Rehabilitation Hospital, outpatient clinic between May 2023 and September 2023. A total of 112 patients aged between 18 and 95 years, who were diagnosed with a plantar fasciitis based on clinical examination and plain radiography were recruited. Inclusion criteria were as follows: Presence of heel pain for at least 4 weeks, receiving no medical treatment, injection, physical or surgical treatment for the last 4 weeks and agreed to participate in the study. Exclusion criteria were as follows; patient who cannot follow up, history of fracture or surgery, polyneuropathy, rheumatological diseases, coagulation disorders, tumor, thrombosis, soft tissue or bone infection, pregnancy, lactation, epilepsy, presence of a pacemaker. The patients were informed about the procedure to be performed and their informed consent was obtained. The study was carried out in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the Ankara City Hospital Ethics Committee 10.05.2023, E2-23-3834.

Demographic data (age, gender, occupation), the location of pain, the duration of the symptoms, and previous treatments were questioned. Height and weight measurements of all patients were taken and body mass index (BMI) was calculated.

The patients were divided into 2 groups according to the order in which they applied to the outpatient clinic. Odd numbers of applications apply to Group 1, and even numbers to Group 2. Our study flowchart is Fig. 1.

Treatment Protocols

Patients in both groups**,** shockwave therapy was applied without anesthesia while patients were placed in prone position lying face down on a table. After the most tender point on the patient's heel was located by manual palpation, patients in the first group, rESWT (2.4 bar 12 hz 2000 beats), while patients in the second group received fESWT (0.14 bar 14 hz 1000 beats) 3 times a week for 3 weeks using the Modus ESWT device (Modus Radial and Focused Combined Extracorporeal Shockwave Therapy Device, Turkey) (Figs. 2 and 3). Plantar fascia stretching exercises were given to both groups. Detailed written and visual templates were given to the patients to remind them how and how much the movements should be done.

The patients were informed not to use muscle relaxants and pain relievers during the application period and not to take any other treatment from the heel area.

Fig. 2. Radial extracorporeal shock wave therapy.

Clinical and Radiological Assessments

The patients who applied to the outpatient clinic were diagnosed with plantar fasciitis by a specialist and were divided in to 2 groups. ESWT treatment was administered by a different physician trained in this field. Before and after-treatment evaluations were made by a single investigator, and the investigator was blinded for the treatment groups. All patients were evaluated using the Visual Analog Scale (VAS)-pain and Foot Function Index (FFI) before and after the treatment, at 4 week and 12 weeks. Calcaneal spur size was measured radiographically in the patients before and after the treatment at the 12th week follow-up.

The VAS consisted of a 10-centimeter horizontal line anchored on one end with "no pain" (score: 0) and on the other end with "the worst pain imaginable" (score: 10). During data collection, participants weren't just asked to mark a point on the line. They were also asked to verbally describe their current pain intensity using specific terms: "no pain," "mild pain," "moderate pain," "severe pain," or "the worst pain imaginable." These descriptive terms were then converted to numerical scores (0-10) for analysis purposes (14).

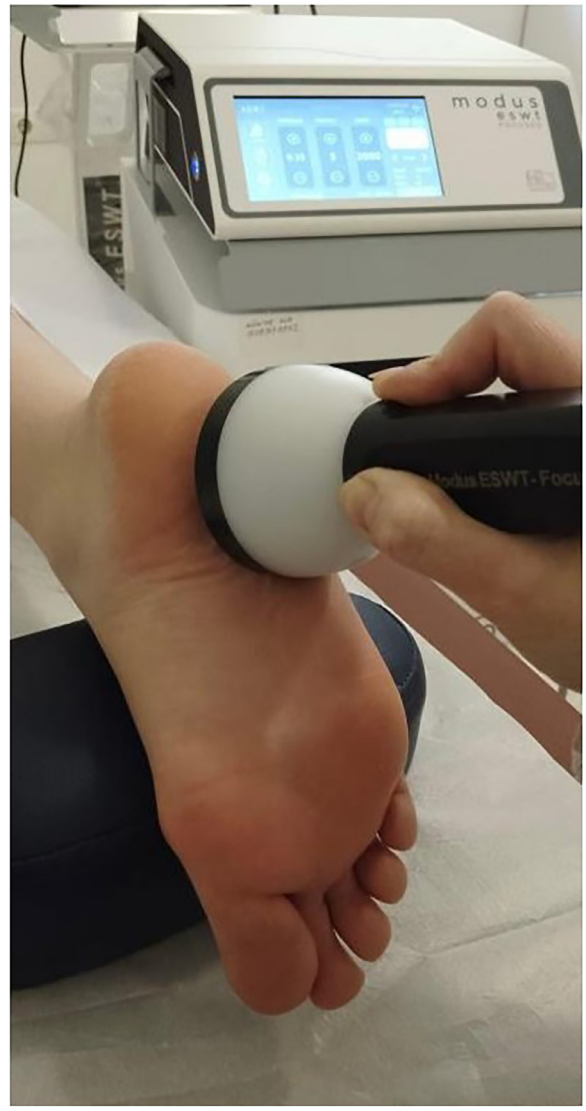

Fig. 3. Focus extracorporeal shock wave therapy.

The FFI was originally developed to assess foot pain, disability and activity limitation, and its Turkish validity and reliability studies were performed by Anaforoğlu Külünkoğlu et al. It consists of 23 items including 9 items for the pain, 9 items for the disability, and 5 items for the activity restriction. Each item is scored on a 10-point scale. Higher scores indicate weak foot health (15).

For radiographic assessment, the presence of the calcaneal spur was seen on the direct/lateral X-ray. Size of the calcaneal spur was evaluated in mm by measuring the lowest point of the medial calcaneal tubercule and the lowest point of the calcaneal spur. One line demarcating the calcaneal border and another line from the calcaneal border to calcaneal tip (16) (Fig. 4).

Statistical Analysis

Statistical analysis was done using Statistical Package for Social Sciences version 22.0 (SPSS Inc., Chicago, IL). Continuous data were shown as median (minimum-maximum) and categorical data were shown as number and percentage. The normality of data distribution was evaluated using the Kolmogorov-Smirnov test. Mann Whitney-U test was used to compare continuous variables between groups and Pearson chi-square test was used to compare categorical variables between groups. Wilcoxon test was used to compare within group differences. p-value <.05 was considered significant.

Results

A total of 112 patients were included in our study, 88 women and 24 men. There were 58 patients in Group 1 (rESWT) and 54 patients in

Fig. 4. Two reference lines are used for measurement. The first line marks the border of the calcaneus, and the second line runs from this point to the tip of the calcaneal spur.

Table 1
Clinical and demographic parameters of the patients

	Radial ESWT group (n = 58)		Focus ESWT group (n = 54)		*p*
	Median	Min-max	Median	Min-max	
Age (years)	49	32-69	50	28-95	.130
Symptom duration (months)	12	2-120	12	1-120	.736
BMI (kg/m^2)	30.9	22.5-42.6	31.15	22.3-51.3	.793
	n	%	n	%	
Gender					.469
Female	44	75.9	44	81.5	
Male	14	24.1	10	18.5	
Painful foot					.173
Right	30	51.7	21	38.9	
Left	28	48.3	33	61.1	
Profession					.701
Active worker	20	34.5	15	27.8	
Retired	7	12.1	6	11.1	
Housewife	31	53.4	33	61.1	
Comorbidity					.752
Yes	23	39.7	23	42.6	
No	35	60.3	31	57.4	

Abbreviation: BMI, body mass index.

Table 2
Statistical analysis foot the VAS

	Radial ESWT group n = 58		Focus ESWT group n = 54		*p*
	Median	Min-max	Median	Min-max	
VAS maximum (0-10)					
Before treatment	9^a	5-10	9^a	5-10	.649
After treatment	5^b	0-10	6^b	1-10	.803
Week 4	5^c	0-10	4^c	0-10	.401
Week 12	3^d	0-10	3^d	0-8	.376
	***p* < .001**		***p* < .001**		

Abbreviation: VAS, Visual Analog Scale.
The uppercase a,b,c,d letters are the post hoc test results and give the difference among time points ($p < .008$). The same letters represent similar groups, while different letters indicate statistically different groups. Bold values indicate statistically significance.
Analysis of the difference in change of treatments compared to the beginning was made with the Wilcoxon test. $p < .01$ was considered significant. Letters shown differently in the column are statistically significant.

Group 2 (fESWT). The clinical and demographic characteristics of the groups are shown in Table 1. The groups were similar in terms of age, gender, BMI, and symptom duration (all $p > .05$).

VAS scores were found to be similar between the groups before treatment and at follow-ups (all $p > .05$). In both groups, a significant decrease in VAS scores was found in the follow-ups compared to before treatment ($p < .001$) (Table 2).

FFI total, pain, activity and disability scores were found to be similar between the groups before treatment and at follow-up (all $p > .05$). In both groups, a significant decrease in FFI scores was found in the follow-ups compared to before treatment ($p < .001$). When the difference in FFI activity scores was compared between the groups, the differences were similar in the before - after treatment and before - 12th week, but the change difference between before treatment and fourth week was higher in fESWT group than rESWT group (7[0-14] and 5[0-13], respectively) ($p = .037$). There was no difference between the changes in other assessments (all $p > .05$) (Table 3).

Calcaneal spur size was found to be similar in both groups before treatment and at 12-week follow-up (all $p > .05$). There was no significant difference in spur size measurement after treatment compared to before treatment between the 2 groups ($p > .05$) (Table 4).

Discussion

Plantar fasciitis is a clinical condition that causes chronic plantar heel pain characterized by inflammation of the plantar fascia after chronic microtraumas and calcification proximal to the plantar fascia after this inflammation. One of the conservative treatment methods is ESWT applications, which have been increasingly used in recent years (5,6). The aim of this study was to evaluate and compare the effects of radial and focused ESWT with different wavelengths on foot pain, disability, activity, and calcaneal spur size in the treatment of plantar fasciitis.

Unfortunately, the mechanism of shockwave effects has not yet been fully explained. The analgesic effect of shockwave is probably largely related to the reduction of the concentration of substance P in

Table 3
Statistical analysis foot the FFI

	Radial ESWT group (n = 58)		Focus ESWT group (n = 54)		
	Median	Min-max	Median	Min-max	*p*
FFI total					
Before treatment	158.0[a]	81.0-200.0	166.0[a]	90.0-196.0	.425
After treatment	104.5[b]	9.0-200.0	107.0[b]	20.0-196.0	.800
Week 4	92.5[c]	9.0-200.0	85.5[c]	12.0-182.0	.499
Week 12	63.0[d]	9.0-200.0	66.5[d]	10.0-172.0	.850
	***p* < .001**		***p* < .001**		
Pain					
Before treatment	73.5[a]	42.0-90.0	73.5[a]	42.0-90.0	.351
After treatment	53.0[b]	2.0-90.0	54.0[b]	9.0-90.0	.944
Week 4	38.0[c]	5.0-90.0	37.5[c]	5.0-78.0	.444
Week 12	32.0[d]	5.0-5.90	28.5[d]	2.0-75.0	.542
	***p* < .001**		***p* < .001**		
Activity					
Before treatment	12.0[a]	4.0-20.0	13.0[a]	4.0-18.0	.412
After treatment	8.0[b]	1.0-20.0	7.5[b]	1.0-16.0	.806
Week 4	5.0[c]	0.0-20.0	5.0[c]	0.0-16.0	.414
Week 12	3.0[d]	0.0-20.0	3.0[d]	0.0-16.0	.575
	***p* < .001**		***p* < .001**		
Disability					
Before treatment	79.0[a]	21.0-90.0	81.5[a]	14.0-90.0	.571
After treatment	46.5[b]	4.0-95.0	54.0[b]	7.0-90.0	.758
Week 4	43.5[c]	2.0-90.0	40.5[c]	2.0-88.0	.629
Week 12	30.0[d]	4.0-90.0	33.0[d]	2.0-81.0	.963
	***p* < .001**		***p* < .001**		

Abbreviation: FFI, Foot Function Index.
The uppercase a,b,c,d letters are the post hoc test results and give the difference among time points ($p < .008$). The same letters represent similar groups, while different letters indicate statistically different groups. Bold values indicate statistically significance.
Analysis of the difference in change of treatments compared to the beginning was made with the Wilcoxon test. $p < .01$ was considered significant. Letters shown differently in the column are statistically significant.

Table 4
Statistical analysis calcaneal spur size

	Radial ESWT groups (n = 58)		Focus ESWT groups (n = 54)		
	Median	Min-max	Median	Min-max	*p*
Calcaneal spur size (mm)					
Before treatment	4.76	1.42-11.58	5.53	1.20-11.32	.427
After treatment (week 12)	4.79	1.35-11.64	5.47	1.20-11.34	.435
	$p < .218$		$p < .623$		

the stimulated site (17) and of the calcitonin gene-related peptide in the dorsal root ganglion, as the experiments with shockwave-treated rats have demonstrated (18). Calcaneal spurs are a recognized symptom of underlying degenerative and inflammatory processes that cause heel pain. The effectiveness of ESWT on calcaneal spur may be via multiple functions, resulting in functional improvement and pain relief, such as inhibition of nociceptors, suppression of inflammatory responses by regulating effector cytokines, stimulation of neovascularization, activation of cellular proliferation, and acceleration of injured tissue regeneration (19).

Studies investigating the effectiveness of ESWT in the treatment of calcaneal spur have reported positive results (20,21,22). Similarly, our analysis indicates that focused and radial shock wave therapies induce a significant improvement of the patient's symptoms; and they initiate reparative processes within injured tissues.

Although there are many studies in literature showing that ESWT is effective in the treatment of plantar fasciitis, to the best of our knowledge, there have been limited studies comparing the therapeutic efficacy of radial and focused shock. Ninety-nine patients were included in a study that evaluated the efficacy of radial and focused ESWT in the treatment of plantar calcaneal spur and found a significant decrease in FFI scores in both groups. Additionally, in that study, the radial group was significantly superior to focused group based on the changes in the FFI scores (19). Similar to previous study, in our study, we also found a significant decrease in FFI scores in both radial and focused ESWT follow-ups in the treatment of calcaneal spur. However, while improvement in foot function related to activity level was more significant in the focused ESWT group in the short term, there was no significant difference between the 2 groups in the long term. Although a difference between their mechanism of action is not known, the superior of fESWT on rESWT in the treatment of plantar calcaneal spur in terms of FFI activity level in the short term may be related to the differences in their electrophysical characteristics in the tissues. In fESWT, the energy reaches deeper tissues due to the rapidly rising pressure, while in rESWT, the energy is transmitted radially from the probe tip to the surrounding tissues. The pressure rises much more slowly and the distance the energy can reach is quite shallow (23,24).

Hayta et al. conducted a study on rESWT in obese patients with symptomatic calcaneal spur. They found that both VAS scores and calcaneal spur size significantly improved after treatment compared to baseline (20). In another study, Öztürk et al. (25) a statistically significant difference was observed in the ESWT + PEMFT (pulsed electromagnetic field therapy) group compared to the ESWT alone group in terms of the functions and pain level of the foot before and after treatment evaluation. According to our research, the VAS scores significantly improved for both ESWT modalities at every evaluation point. Both groups were similar in terms of improvement in VAS scores. However, we did not find a statistically significant difference in calcaneal spur size compared to before treatment.

Studies using different types of ESWT devices that generate different shock waves have shown that in focused shock waves, obstacles (such as bones or calcifications) in the path of the shock wave can weaken the energy of the wave and reduce treatment efficacy by preventing acoustic energy from reaching the target tissue. However, radial shock waves are not affected by such obstacles and their energy transmission remains unaffected. Kiessling et al. emphasized that the maximum energy density is concentrated at the tip of the applicator in rESWT, while in fESWT, the maximum energy density is located in a focal zone within the treated tissue. Another study stated that there is no definitive answer to the question of which method is more effective (radial or focused). These studies suggest that the clinical efficacy of focused and radial waves may also be different (26-28).

Okçu et al. (29) found a significant correlation between spur size and pain level, and symptom duration. In another study, it was reported that ESWT application in patients with symptomatic calcaneal spur reduced the size of the calcaneal spur and pain (20). In our study, no significant changes were detected in the measurement of calcaneal spur size both between and within groups after treatment compared to before treatment.

The study has a few limitations. First, there is no sham group. This makes it difficult to definitively conclude that the observed improvements were actually due to the applied treatment. The 3-month follow-up period does not provide information on long-term impacts. Longer-term follow-up studies are needed to evaluate the effect of ESWT on pain relief and calcaneal spur size in the long term.

The limited number of studies comparing different ESWT types with different wavelengths in the literature for the treatment of calcaneal spur and the lack of consensus on the most effective ESWT type for treatment prompted this study. We believe that this study will make a significant contribution to the evaluation of the effectiveness of ESWT with different wavelengths in the treatment of calcaneal spur. Our study will contribute to the literature in terms of the large number of participants included. It is also important because it evaluates foot pain, disability, activity, and calcaneal spur size together.

Ethics Committee Approval

Ankara City Hospital Ethics Committee 10.05.2023, E2-23-3834.

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