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ORIGINAL ARTICLE

Comparison of Plantar Pressure Distribution, Ultrasonographic and Clinical Features Following the Application of Different Energy Levels of Extracorporeal Shock Wave Therapy in Patients with Plantar Fasciitis: A Randomized, Prospective, Double-Blind Clinical Trial

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Background: The effectiveness of different energy levels used in extracorporeal shockwave therapy (ESWT) have been investigated in previous studies, but controversy remains regarding which energy levels should be used in the treatment of plantar fasciitis. The objective of this study was to compare the efficacy of different energy levels used in ESWT in the treatment of plantar fasciitis through comparisons of plantar fascia thickness and pressure distribution.

Methods: Between July 2020 and September 2020, a total of 51 patients (71 feet) with plantar fasciitis were randomized into three treatment groups using the sealed envelope method.

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Group 1 (n = 25) received low energy density (0.09 mJ/mm²), Group 2 (n = 25) received medium energy density (0.18 mJ/mm²), and Group 3 (n = 21) received high energy density (0.38 mJ/mm²). All groups received three sessions of ESWT with a frequency of 2,000 shocks/min at one week intervals. The patients were evaluated before and after treatment using a visual analog scale (VAS) for pain, the Foot Function Index (FFI), and plantar fascia thickness measured by ultrasonography, and plantar pressure distribution.

Results: The posttreatment VAS and FFI scores were determined to be statistically significantly lower than the pretreatment values in all three groups ($p < 0.001$). There was no significant difference between the groups in terms of the pre and post treatment values of VAS, FFI scores, plantar fascia thickness and pressure distribution ($p > 0.05$). No statistically significant difference was found between the groups in terms of percentage changes in all the outcome parameters ($p > 0.05$).

Conclusions: The results of the study suggest that neither low, medium, or high levels of ESWT were superior to one another in terms of pain, foot functions, fascia thickness and pressure distribution in the treatment of plantar fasciitis.

Plantar fasciitis is one of the most common causes of heel pain in adults. Patients present with pain in the heel, which characteristically worsens on arising in the morning and after periods of prolonged sitting. The tender points are located on the plantar side of the foot, often near the medial side of the calcaneal tuberosity. Although the exact etiology is unknown, it is probably

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multifactorial, including chronic inflammation, degeneration, and microtrauma of the plantar fascia, entrapment of the lateral planter nerve, overuse syndrome, heel spurs, heel pad atrophy, and seronegative arthritis induced inflammation (1).

The diagnosis of plantar fasciitis is based on patient history and physical examination findings (2). The general therapy of choice is conservative, which is effective in approximately 90% of patients. Treatment modalities include heel cups, orthotics and/or shoe modifications, surgical release, nonsteroidal anti-inflammatory drugs, extracorporeal shockwave therapy (ESWT), local corticosteroid injection and physiotherapy with stretching exercises (3,4).

ESWT has been used for approximately twenty years in the treatment of refractory plantar fasciitis (5). The effectiveness of ESWT has been established in large randomized clinical trials and several meta-analyses (6).

ESWT energy levels are categorized as high (> 0.28 mJ / mm²), medium (0.08-0.28 mJ / mm²) and low (< 0.08 mJ / mm²) (7). Although previous meta-analyses have investigated the effectiveness of different energy levels used in ESWT, it is not yet clear which energy level is most effective in the clinical recovery and pain relief of plantar fasciitis after ESWT treatment. Ultrasonography (USG) is a non-invasive, inexpensive, and easily accessible imaging tool, which is useful in the differential diagnosis of heel pain. In studies of plantar fasciitis treatments, USG evaluation of the plantar fascia thickness is widely used as the outcome parameter. Plantar fascia thickness of ≥ 4 mm is compatible with a diagnosis of plantar fasciitis (8).

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Plantar pressure distribution is considered to provide valuable information in the study of specific foot pathologies (9). It has also been shown to be useful in the evaluation of foot function by comparing the loads between pre and posttreatment (10). There are various studies in the literature regarding foot loading during walking in patients with plantar fasciitis (11), but knowledge about the effect of ESWT on plantar pressure distribution is scarce.

There are few studies in the literature that have compared different treatment energy levels of ESWT. Consequently, there are no clear guidelines for which energy level is most effective, when implementing ESWT, for the treatment of plantar fasciitis. The aim of this single center, prospective, double-blind, randomized controlled study was to compare the effects of low, medium and high energy ESWT on pain, functional status, plantar fascia thickness, and plantar pressure distribution in the treatment of plantar fasciitis.

Materials and Methods

This study was included a total of 71 feet of 51 participants who presented at the Physical Medicine and Rehabilitation Clinic and the Orthopedics and Traumatology Outpatient Clinic with heel pain and were diagnosed with plantar fasciitis between July 2021 and September 2021.

The diagnosis of plantar fasciitis was made based on clinical evidence, such as the presence of plantar heel pain with the first step taken in the morning, or after a period of rest,

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and positive physical examination findings (pain on palpation of the site of plantar fascial insertion to the heel bone).

The subjects were informed about the study and written informed consent was obtained at the beginning of the study. The study protocol was approved by the Local Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki. The trial was registered on the ClinicalTrials.gov register.

The study inclusion criteria were defined as 1) Age 18-85 years, 2) Presence of heel pain, 3) Tenderness at the insertion site of the plantar fascia on the anteromedial aspect of the calcaneal tubercle on palpation, and 4) Nonresponse to conservative treatment for three months. The study exclusion criteria included: 1) History of inflammatory rheumatic disease 2) Local dermatological lesion or infection 3) Peripheral circulatory disorder 4) Neurological disorder such as radiculopathy or polyneuropathy 5) Congenital or acquired foot deformity 6) Malignancy 7) Cardiac pacemaker 8) Metal implant at the application site, and 9) Pregnancy.

The 51 participants (71 feet) who met the inclusion criteria were randomly separated into three groups using the sealed envelope method, by an independent person who did not participate in the study. All groups received three sessions of ESWT (StorzMedical, Masterplus MP100, Germany) with a frequency of 2,000 shocks/min at 10 Hz with each session given once a week for three weeks. The ESWT target area was set as the area of maximum tenderness in the medial calcaneus, in the proximal fourth of the foot. No local anesthesia was administered. The

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ESWT was applied in a circular motion over the insertion site of the plantar fascia (1,000 shocks) and along the fascia (1,000 shocks). Group 1 received low energy ESWT (n=25, 2000 shocks/session, energy density per shock 0.09 mj/mm²), Group 2 received medium energy ESWT (n=25, 2000 shocks/session, energy density per shock 0.18 mj/mm²) and Group 3 received high energy ESWT (n=21, 2000 shocks/session, energy density per shock 0.38 mj/mm²). All ESWT sessions were performed by a single orthopedist.

During the course of the treatment, none of the participants received any additional treatment, such as physical therapy, acupuncture, steroid injection, or anti-inflammatory drugs.

Outcome Measurements

All the pre (at baseline) and posttreatment (at 1 month) measurements were evaluated by a physiatrist.

A Visual Analog Scale (VAS) was used for the evaluation of pain. The score ranges from 0 to 10, where 0 indicates no pain and 10 indicates intolerable pain (12).

The Foot Functional Index (FFI) was developed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction. The FFI is a self administered index consisting of 23 items including nine items in the pain subcategory, nine items in the disability subcategory, and five items in the activity restriction subcategory (13).

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Ultrasonographic evaluations

High resolution ultrasound (frequency transducers: 13-6 MHz linear transducer, Sonosite Micromaxx, USA) was used to measure plantar fascia thickness. During the procedure, the participants were positioned prone with the knees fully extended and ankles in a neutral position. The thickness was measured vertically from the hyperechogenic border of the calcaneus bone to the inferior hyperechogenic rim of the plantar fascia in the longitudinal view (Figure 1). In order to minimize potential errors, an average of three measurements of plantar fascia thickness were taken at each assessment session.

The thickness of the plantar fascia was evaluated with USG before (at baseline) and after (at 1 month) ESWT by a physiatrist blinded to the treatment groups. The physiatrist also checked the hypoechogenicity, partial rupture, and calcification of the fascia.

Plantar Fascia Pressure

All participant underwent an assessment of plantar pressure distribution with a static baropodometry. In the baropodometric test, each participant was in a standing position on the platform (freeMed Base; Sensor Medica; Guidonia Montecelio, Roma, Italia) for 5 seconds, looking straight ahead, barefoot, with feet placed side by side and arms held along the trunk. The parameters examined were total plantar pressure (%), rearfoot plantar pressure (%), and forefoot plantar pressure (%). Physiologically, in the barometric test, the plantar pressure

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should be divided as 50% on the right foot and 50% on the left foot, and normal distribution of the plantar pressure percentage for each foot should be 60% on the rearfoot and 40% on the forefoot (Figure 2) (14).

The plantar pressure distribution was evaluated before and after ESWT by a physiatrist who was blinded to the treatment groups.

Statistical Analysis

The power of the study was calculated using the G Power Statistical Program version 3.1.9.4 (Universität Düsseldorf, Germany) based on the study by Ulusoy et al. (15,16) A total of 26 participants per group were deemed necessary for a study power of 80% with a 5% type 1 error and $f=0.36$ effect size.

Continuous variables were expressed as means \pm standard deviation or median(minimum-maximum) values, and categorical variables as number (n) and percentage (%). The conformity of continuous variables to normal distribution was evaluated using the Kolmogorov-Smirnov test. Intergroup comparisons of normally distributed qualitative variables were performed using the One way ANOVA Test (Post hoc: LSD), and within group analysis of normally distributed data using the Paired Samples T Test. Intergroup analysis of data not showing normal distribution was performed using the Kruskal Wallis test (Bonferroni corrected Mann Whitney U test), and the Wilcoxon Signed Rank Test was used in within group analyses. The Chi-

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square test was used in the comparisons of categorical data. Data were analyzed statistically using the IBM Statistical Package for Social Sciences (SPSS) version 22.0 software (IBM Corporation, Armonk, NY, USA). A value of $p < 0.05$ was considered statistically significant.

Results

No statistically significant difference was found between the groups in terms of body mass index, gender, marital status, occupation and duration of symptoms. Age and education level were seen to be different between the groups (Table 1). The posttreatment VAS scores and all FFI subgroup scores were determined to be statistically significantly lower than the pretreatment values in all three groups ($p < 0.001$). There was no significant difference between the groups in terms of the pre and posttreatment values of VAS and all FFI subgroups ($p > 0.05$) (Table 2).

Posttreatment plantar fascia thickness values were statistically significantly higher than the pretreatment values in the low level group ($p = 0.037$). The posttreatment values were statistically significantly lower than the pretreatment values in the high level group ($p = 0.008$). There was no significant difference between the groups in terms of pre and posttreatment median values of plantar fascia thickness and pressure distribution ($p > 0.05$) (Table 3). No statistically significant difference was found between the groups in terms of percentage

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changes in VAS, FFI (all subgroups), plantar fascia thickness, and pressure distribution ($p>0.05$) (Table 4).

Discussion

In this study, evaluations were made of the efficacy of ESWT applied at different energy levels in the treatment of plantar fasciitis using the outcome measurements of plantar fascia thickness and pressure distribution. The study results demonstrated no superiority of the different ESWT energy levels over each other in respect of the shortterm VAS, FFI and plantar pressure distribution values. In addition, although there was no significant difference between the groups in plantar fascia thickness, success was not obtained in the low and medium level ESWT after the treatment, but there was a significant improvement in the high level ESWT after the treatment. To the best of our knowledge, this is the first study to have investigated the efficacy of different energy levels of ESWT in the treatment of plantar fasciitis using the outcome measures of plantar fascia thickness and plantar pressure distribution.

Although the effects of ESWT on plantar fasciitis have been reported, no treatment protocol for ESWT has been established. There is controversy in particular about the proper amount of energy to be applied. Previous studies have shown that high energy ESWT reduced symptoms of painful heel in significantly more patients than a placebo (17,18). The same result has been demonstrated using low energy ESWT (19,20) and medium energy ESWT (21). In the

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current study, all the groups exhibited a statistically significant decline in pain and an improvement in functional status over time, consistent with the findings of previous studies. A few meta-analyses have compared the efficacy of different energy levels used in ESWT in the treatment of plantar fasciitis. Yin et al. stated that low intensity ESWT was superior to high intensity treatment in respect of shortterm pain relief and functional outcomes (22). These results contradict those of the systematic review conducted by Dizon et al., in which it was shown that high and moderate intensity ESWT applications were more effective in pain and functional outcomes than low intensity ESWT in the management of chronic plantar fasciitis (23). Likewise, Chang et al suggested that setting the highest and most tolerable energy efflux densities in the range of medium intensity was the preferable option(24).

In another meta-analysis which investigated the efficacy of ESWT with different energy levels and follow ups in the treatment of plantar fasciitis, medium energy ESWT was shown to be more effective in the long term compared with the control group. However, in that meta-analysis, the efficacy of low and high energy ESWTs with the control groups provided inconsistent results due to the limited number of articles in the subgroup analysis and the lack of longer follow up periods (25).

Except for these meta-analyses, there are no randomized controlled studies in literature that have investigated three energy level groups. In this respect, the current study is the first in

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the literature. Unlike the results of all the meta-analyses mentioned above, in the current study no energy level was found to be superior to the others in terms of pain and functionality. Plantar fasciitis has previously been evaluated mostly with outcome parameters such as pain and functionality, but recently, the measurement of plantar fascia thickness with ultrasonography has been used as an outcome parameter. There are very few studies in literature that have evaluated the effectiveness of different energy levels of ESWT on plantar fascia thickness.

In a randomized controlled pilot study evaluating the effects of low level versus high level ESWT in patients with chronic plantar fasciitis, Liang et al. reported no difference in plantar fascia thickness, pain and function level between the two groups at 3 and 6 months. It was recommended that low intensity ESWT be used as it was not associated with lower outcomes and caused less discomfort during treatment (26).

Lee et al found that medium energy level was more efficient in terms of relieving pain, and restoring functional activity and thickness of the plantar fascia than low energy level applied in the same session. However, when the sessions were applied at different times to provide the same total energy influx, different therapeutic effects in the different energy groups no longer occurred. It was therefore suggested that the therapeutic effect might disclose a dose related relationship and the energy density and times of sessions are factors to be considered when treating with ESWT(27).

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In the current study, no difference was observed between all groups in respect of plantar fascia thickness before and after treatment. After treatment, plantar fascia thickness increased in the low level ESWT treatment group, no change was detected in the medium level ESWT group, only a significant improvement in plantar fascia thickness was observed in the high level ESWT group. This result suggested that if total energy influx were provided as in the study by Lee et al., similar effects on the plantar fascia thickness may be seen in all the groups (27). Similarly, Gollitzwer et al. reported that the total energy applied significantly influences the final outcome and it was suggested that lower energy flux densities can be partly compensated by higher impulse numbers and repeated treatment (28).

In contrast, in a study to investigate the effect of density and number of sessions of ESWT in patients with plantar fasciitis, 3 groups were formed (Group 1: 7 sessions of high energy ESWT, Group 2: 3 sessions of high energy ESWT, and Group 3: 7 sessions of low energy ESWT) and the results demonstrated that high energy has a more important role than the number of sessions in ESWT (29).

There are various reports which have observed that plantar fasciitis alters the plantar load distribution. Patients with plantar fasciitis have been shown to have reduced force under the rearfoot and forefoot of the symptomatic and asymptomatic foot by approximately 8% and 6% bodyweight, respectively (11). Similarly, other studies have reported reduced loading of the rearfoot (30,31) or forefoot (32,33) in the symptomatic foot when compared to control subjects.

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A few studies have investigated the effects of ESWT on plantar pressure distribution in patients with plantar fasciitis. Brachman et al found that plantar pressure distribution, which had decreased before treatment, increased after ESWT (34). In contrast, Hsu et al. stated that ESWT did not influence the rearfoot pressure, the pressure over the forefoot increased and the total foot pressure also decreased (35).

The current study is the first in literature to have compared the effects of different energy levels of ESWT on plantar pressure distribution. However, according to the results obtained, the distribution of total, fore and rear foot pressure did not change in any group after ESWT. Although the effect of ESWT on plantar pressure distribution is controversial, this result can be considered to be due to the short follow up period and the evaluation of only static plantar pressure.

There were some limitations to this study, primarily the low number of patients and the short follow up period. The lack of longer follow up periods may have caused uncertainty about the efficacy of different energy levels of ESWT in this study. There is a need for further studies with larger samples and longer follow up to compare these methods. Another limitation was that only static weightbearing biomechanical inferences were considered, and the forces in dynamic situations such as gait were not taken into account.

In conclusion, the results of this study demonstrated that the three different levels of ESWT significantly reduced the pain experienced with plantar fasciitis and provided functional

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improvement. However, when the success rates were evaluated, no level of ESWT was found to be superior to the others in terms of reducing pain and plantar fascia thickness, and improving functional status and plantar pressure distribution. Further studies are required to confirm the

Financial Disclosure: None reported.

Conflict of Interest: None reported.

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Table 1: Comparison of socio-demographic and clinical characteristics

	Low level ESWT (n=25)	Medium level ESWT (n=25)	High level ESWT (n=21)	<i>p</i>
Age (years) (mean±SD)	54,92±8,66 ^a	51,88±12,79	46,38±10,23 ^a	0.031*
BMI (kg/m²) (mean±SD)	29,08±4,22	27,56±3,77	27,75±4,17	0.306*
Symptom duration (months) [median(min-max)]	18 (1-36)	6 (2-120)	12 (1-60)	0.880**
Gender (n, %)				
Female	21 (%84,0)	16 (%64,0)	13 (%61,9)	0.179***
Male	4 (%16,0)	9 (%36,0)	8 (%38,1)	
Education (n, %)				
Primary school	9 (%36,0)	8 (%32,0)	4 (%19,0)	0.031***
High school	9 (%36,0)	7 (%28,0)	15 (%71,4)	
University	7 (%28,0)	10 (%40,0)	2 (%9,5)	
Marital status (n, %)				
Married	25 (%100,0)	22 (%88,0)	20 (%95,2)	0.180***
Single	0 (%0,0)	3 (%12,0)	1 (%4,8)	
Job (n, %)				
Housewife	11 (%44,0)	8 (%32,0)	5 (%23,8)	0.108***
Retired	5 (%20,0)	3 (%12,0)	3 (%14,3)	
Worker	0 (%0,0)	3 (%12,0)	6 (%28,6)	
Officer	5 (%20,0)	10 (%40,0)	5 (%23,8)	
Private Job	4 (%16,0)	1 (%4,0)	2 (%9,5)	

* One way ANOVA Test (Posthoc:^aLSD) ** Kruskal Wallis Test *** Chi-square Test

SD: standart deviation, ESWT: Extracorporeal Shock Wave Therapy, BMI: Body Mass Index

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Table 2: Comparison of the outcome parameters of the groups

	Low level ESWT (n=25)	Median level ESWT (n=25)	High level ESWT (n=21)	<i>p</i>
VAS pretreatment[med(min-max)]	8 (5-9)	8 (5-10)	8 (5-9)	0.998*
VAS posttreatment[med(min-max)]	5 (0-7)	5 (0-9)	4 (0-8)	0.472*
	p<0.001**	p<0.001**	p<0.001**	
FFI activity limitation pretreatment [med(min-max)]	26 (2-46) ^a	20 (0-34) ^a	22 (6-42)	0.033*
FFI activity limitation posttreatment [med(min-max)]	12 (0-36)	8 (0-46)	10 (0-24)	0.810*
	p<0.001**	p<0.001**	p<0.001**	
FFI pain pretreatment (mean±SD)	64,48±15,48	62,96±15,62	62,52±16,37	0.905***
FFI pain posttreatment (mean±SD)	38,12±20,79	39,68±28,10	33,61±21,42	0.678***
	p<0.001****	p<0.001****	p<0.001****	
FFI disability pretreatment (mean±SD)	61,76±16,05	60,32±16,70	60,28±19,27	0.944***
FFI disability posttreatment (mean±SD)	33,08±19,57	34,76±26,32	32,09±22,05	0.922***
	p<0.001****	p<0.001****	p<0.001****	

* Kruskal Wallis test (^aBonferroni corrected Mann Whitney U test)

** Wilcoxon Signed Ranks Test

*** One way ANOVA Test (Post hoc:LSD)

**** Paired Samples T Test

SD: standart deviation, ESWT: Extracorporeal Shock Wave Therapy, VAS: Visual analog scale, FFI: Foot function index, med: median, min: minmum, max: maximum

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Table 3: Comparison of the groups in terms of median values of plantar fascia thickness and pressure distribution

	Low Level ESWT [median(min- max)] (n=25)	Medium level ESWT [median(min- max)] (n=25)	High Level ESWT [median(min- max)] (n=21)	<i>p</i>
PF thickness pretreatment	0.40 (0.28-0.71)	0.42 (0.29-0.65)	0.45 (0.24-0.65)	0.636*
PF thickness posttreatment	0.42 (0.25-0.64)	0.39 (0.32-0.66)	0.43 (0.19-0.60)	0.932*
	p=0.037**	p=0.987**	p=0.008**	
Fore foot (%) pretreatment	0.47 (0.33-0.60)	0.50 (0.25-0.67)	0.45 (0.28-0.68)	0.577*
Fore foot (%) posttreatment	0.47 (0.34-0.65)	0.49 (0.25-0.68)	0.45 (0.27-0.61)	0.266*
	p=0.886**	p=0.435**	p=0.872**	
Rear foot (%) pretreatment	0.53 (0.40-0.67)	0.50 (0.33-0.75)	0.55 (0.32-0.72)	0.577*
Rear foot (%) posttreatment	0.53 (0.35-0.66)	0.51 (0.32-0.75)	0.55 (0.39-0.73)	0.266*
	p=0.886**	p=0.435**	p=0.872**	
Total foot pretreatment (%)	0.50 (0.38-0.62)	0.49 (0.40-0.60)	0.49 (0.39-0.57)	0.872*
Total foot posttreatment (%)	0.50 (0.34-0.66)	0.49 (0.39-0.56)	0.50 (0.38-0.55)	0.557*
	p=0.787**	p=0.419**	p=0.764**	

* Kruskal Wallis test (^aBonferroni corrected Mann Whitney U test)

** Wilcoxon Signed Ranks Test

min-max: minimum-maximum, PF: Plantar fascia, ESWT: Extracorporeal Shock Wave Therapy

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Table 4: Comparison of the percentage changes of VAS, FFI, plantar fascia thickness and pressure distribution of the groups

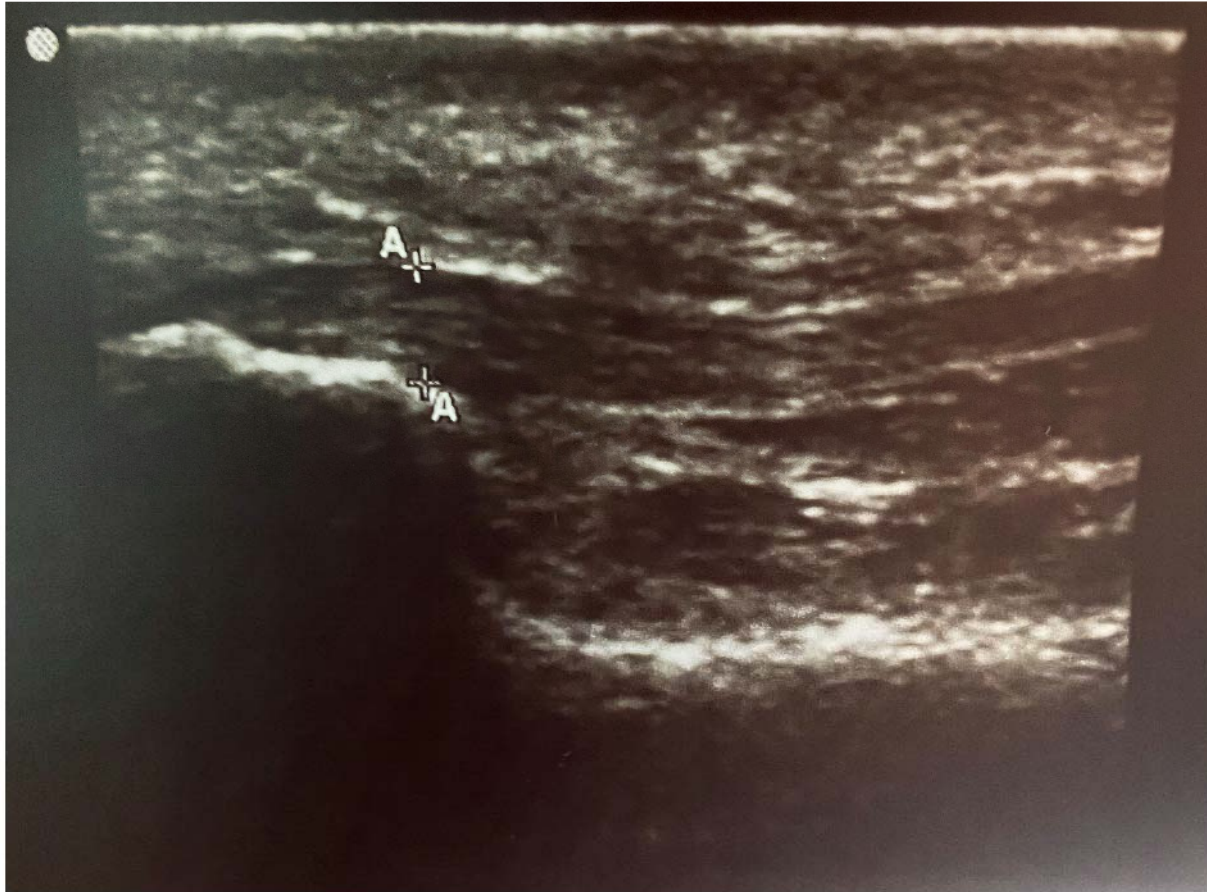
Percentage of changes (%Δ)	Low Level ESWT [med(min- max)] (n=25)	Medium Level ESWT [med(min- max)] (n=25)	High Level ESWT [med(min- max)] (n=21)	<i>p</i>
VAS	-37.5 (-100 - 0)	-25 (-100 - 0)	-42.8 (-100 - 0)	0.575*
FFI pain	-47.5 (-95.5 - 0)	-51.5 (-100 - 14.9)	-46.6 (-100 - 3.4)	0.744*
FFI disability	-50.9 (-96 - 5)	-41.1 (-97 - 18.6)	-44.7 (-100 - 3.6)	0.964*
FFI activity limitation	-59 (-100 - 36.3)	-22.5 (-100 - 109)	-54.5 (-100 - 0)	0.370*
Plantar fascia thickness	-5.1 (-26.4 - 16.6)	-1.5 (-43.3 - 18.1)	-3.9 (-25.8 - 11.1)	0.062*
Forefoot (%)	-1.7 (-30.6 - 31.7)	-0.0 (-22.2 - 59.5)	-0.0 (-25 - 29.4)	0.833*
Rare foot (%)	-2.2 (-22.3 - 29.4)	-0.0 (-43.1 - 26)	-0.0 (-15.1 - 37.5)	0.748*
Total foot (%)	-1.8 (-33.3 - 34.6)	-1.8 (-18.3 - 27.5)	-0.0 (-23.6 - 13.6)	0.680*

* Kruskal Wallis Test

ESWT: Extracorporeal Shock Wave Therapy, VAS: Visual analog scale, FFI: Foot function index, med: median, min: minimum, max: maximum

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Figure 1: An ultrasound image of plantar fascia



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Figure 2: Pressure baropodometric analyses of plantar areas

