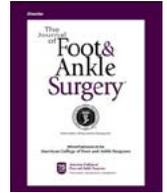




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# Magnetic Resonance Imaging and Clinical Outcomes of Laser Therapy, Ultrasound Therapy, and Extracorporeal Shock Wave Therapy for Treatment of Plantar Fasciitis: A Randomized Controlled Trial

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## ABSTRACT

We determined and compared the effectiveness of low-level laser therapy (LLLT), therapeutic ultrasound (US) therapy, and extracorporeal shock wave therapy (ESWT) using magnetic resonance imaging (MRI). We performed a randomized, prospective, comparative clinical study. A total of 60 patients with a diagnosis of chronic plantar fasciitis were divided randomly into 3 treatment groups: group 1 underwent 15 sessions of LLLT (8 J/cm<sup>2</sup>; 830 nm); group 2 underwent 15 sessions of continuous US (1 mHz; 2 W/cm<sup>2</sup>); and group 3 underwent 3 sessions of ESWT (2000 shocks). All patients were assessed using the visual analog scale (VAS), heel tenderness index (HTI), American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale, Roles-Maudsley score, and MRI before and 1 month after treatment. The primary efficacy success criterion was the percentage of decrease in heel pain of >60% from baseline at 1 month after treatment for  $\geq 2$  of the 3 heel pain (VAS) measurements. Significant improvement was measured using the mean VAS, AOFAS scale, and HTI scores for all 3 groups. The thickness of the plantar fascia had decreased significantly on MRI in all 3 groups. The treatment success rate was 70.6% in the LLLT group, 65% in the ESWT group, and 23.5% in the US group. LLLT and ESWT proved significantly superior to US therapy using the primary efficacy criterion ( $p = .006$  and  $p = .012$ , respectively), with no significant difference between the LLLT and ESWT groups ( $p > .05$ ). The treatment of chronic plantar fasciitis with LLLT and ESWT resulted in similar outcomes and both were more successful than US therapy in pain improvement and functional outcomes.

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Plantar fasciitis is the most common diagnosis (10% to 15%) for patients with foot and ankle pain (1). Plantar fasciitis has a multifactorial etiology. It was previously thought to be an inflammatory syndrome; however, recent studies have emphasized that a degenerative process is more dominant (2–4). The factors thought to be associated with the disease include biomechanical dysfunction, mechanical overload, obesity, overuse, Achilles tendon strain, decreased ankle dorsiflexion, atrophy of the intrinsic muscles, and a pronated foot type (5,6). The patient's history and physical examination findings are usually sufficient to diagnose plantar fasciitis. Patients

typically present with a throbbing, burning, or piercing type of inferior heel pain, especially with the first few steps in the morning. However, the pain will decrease after a few steps but will return during the day with prolonged weightbearing activity. Sometimes, the pain will persist for months or even years (4).

Although not routinely necessary, imaging can be used to verify recalcitrant plantar fasciitis or to rule out other foot pathology. Magnetic resonance imaging (MRI), although expensive, is very sensitive and has been accepted as the standard imaging method to evaluate plantar fascia morphology and bone marrow edema. The MRI findings of plantar fasciitis include thickening of the plantar fascia, perifascial and intrafascial edema pattern at T<sub>2</sub>-weighted images, intrafascial T<sub>1</sub>-weighted signal enhancement, and a limited bone marrow edema pattern at the calcaneal tuberosity (7,8).

The treatment options include numerous methods focusing on the anatomic and biomechanical problems and pain management. The recommended first-tier treatment options are nonsteroidal anti-inflammatory drugs, therapeutic orthotic insoles, limitations of extended physical activities, and Achilles and plantar fascia stretching

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exercises (4,9). Patients will usually have a clinical response within 6 weeks. However, if the symptoms persist, second-tier treatment, including physical therapy, orthotic devices, steroid injections, and night splints be added to the ongoing first-tier treatment. Extracorporeal shock wave therapy (ESWT) and surgery are recommended as the third tier of treatment for patients with chronic (6-month) plantar fasciitis recalcitrant to treatment (4).

Low-level laser therapy (LLLT) can be used to accelerate wound healing and reduce pain and inflammation (10). The studies investigating the molecular effects of LLLT have focused on the photobiomodulation and photobiostimulation phenomena, which promote cell proliferation and tissue regeneration (11). An important factor associated with the effectiveness of LLLT is tissue penetration capability and the optimum dosage of energy. Therefore, standardization of the treatment protocols and dosages according to the disease directly affects the success of the treatment (12). In that context, the World Association for Laser Therapy group published disease-specific dosage recommendations for LLLT (13). Another treatment modality used for >60 years extensively in the treatment of acute and chronic pain is therapeutic ultrasound (US). Therapeutic US is used to produce thermal or nonthermal effects by high-frequency acoustic energy (14). US therapy is usually used in combination with the other conventional therapies for the treatment of the plantar fasciitis in daily practice. ESWT is another treatment recommendation for chronic plantar fasciitis approved in 2000 by the Food and Drug Administration. The possible effect of ESWT is stimulation of the wound healing cascade, allowing chronic damage to become acute damage and initiate the normal wound healing process by application of high-intensity pressure waves into the body. Previous studies reported a success rate for ESWT for plantar fasciitis ranging from 34% to 88% (15).

Despite the increasing popularity of LLLT and ESWT, randomized controlled trials comparing the efficacy of the treatment modalities are lacking. The aims of the present study were to determine and compare the clinical effects of LLLT, ESWT, and therapeutic US objectively using MRI at 1 month of follow-up for patients with chronic recalcitrant plantar fasciitis.

## Patients and Methods

### Participants

From December 2012 to December 2014, the present study included 60 patients with chronic recalcitrant plantar fasciitis. All patients agreed to participate in the study and freely signed an informed consent statement after being informed about the purpose of the study, examination, and treatment application. The local medical ethics committee approved the present study, which was supported by University Scientific Research Project Coordination.

The inclusion criteria were the presence of symptoms of a chronic recalcitrant plantar painful heel of  $\geq 6$  months duration that was unresponsive to 6 weeks of first-tier conservative treatment (nonsteroidal anti-inflammatory drug, home exercise program, and standard insoles). The diagnosis was confirmed clinically by the physical examination finding of tenderness to palpation with local pressure at the origin of the plantar fascia on the medial tubercle of the calcaneus and an indication of significant pain by a score of  $\geq 5$  for  $\geq 1$  of 3 visual analog scales (VASs; intensity of pain measured by the VAS for the first few steps in the morning, during daily activities, and during exercise) before treatment.

The exclusion criteria were previous local trauma, foot surgery, local steroid injection within the previous 3 months, local infection, abnormalities in the knees or ankles, vascular disease, diabetes mellitus, malignancy, peripheral neuropathy, pacemaker, metal implants, rheumatic inflammatory disease, and plantar fascial rupture.

The trial design was a prospective, randomized, comparative, clinical study with the investigators kept unaware of the treatment groups. The patients were advised to continue their standard home exercise program (plantar fascia stretching, calf muscle stretching, Achilles tendon stretching, and strengthening of the intrinsic muscles of the foot) previously implemented during the treatment course (2,4). Sixty patients were randomized into 3 treatment groups using the stratified block randomization method according to gender and body mass index by one of us (A.U.). The 3 groups were the LLLT group, US therapy group, and ESWT group. All patients were assessed using the VAS for heel pain (first steps in the morning, during daily activities, and during exercise), foot functionality (pain and range of motion domains) using the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale and Roles-Maudsley score (RMS; patient-administered scoring system regarding activity limitations), and the sensitivity of the heel using the heel tenderness index (HTI) before and after 1 month of treatment. The same investigator (L.C.) administered these measures and was kept unaware of the treatment groups. MRI was performed using a SIGNA™ HDXT 1.5 Tesla MRI system (GE Healthcare, Chicago, IL) before and 1 month after treatment. The maximum thickness of the proximal plantar fascia where it attaches to the calcaneus was measured using electronic calipers on fluid-sensitive MRI sequences in the sagittal and coronal planes (Fig. 1). The intrafascial and perifascial soft tissue edema and calcaneal bone marrow edema were assessed in the sagittal plane on short tau inversion recovery sequences, and the presence of the calcaneal spurs was evaluated on T<sub>1</sub>-weighted sequences. After all the patients had completed therapy, the pre- and post-treatment MRI scans were interpreted simultaneously by a radiologist (S.O.), who was unaware of the treatment groups.

LLLT, US therapy, and ESWT were performed by the same investigator (A.U.) using the BTL-5000 SWT combined device (BTL Turkey, Ankara, Turkey). All subjects were placed in the prone position during treatment.

Group 1 underwent LLLT. All patients in group 1 received a total of 15 LLLT sessions (5 sessions each week during a consecutive 3-week period). All patients were treated with a gallium-aluminum-arsenide (GaAlAs) laser, with 830 nm of laser light with 50 mW. The laser probe was scanned into the areas of the painful heel, insertion of the plantar fascia on the medial calcaneal area, and the myofascial junction at the dorsum of the heel, for a total dose of 8 J/cm<sup>2</sup> for 200 seconds.

Group 2 underwent US therapy. All the patients in group 2 received a total of 15 US sessions (5 sessions each week during a consecutive 3-week period). US therapy was applied using the following parameters: continuous mode, base frequency of 1 MHz to produce a deeper penetration, power of 2 W/cm<sup>2</sup> into the areas of the painful heel, insertion of the plantar fascia on the medial calcaneal area, and the myofascial junction at the dorsum of the heel for 5 minutes using an ultrasound gel.

Group 3 underwent ESWT. All the subjects in the ESWT group received 3 sessions of ESWT weekly for 3 weeks. Ultrasound gel was applied for better transmission between the ESWT head and the skin. The patients received 2000 shock waves with a 2.5-bar

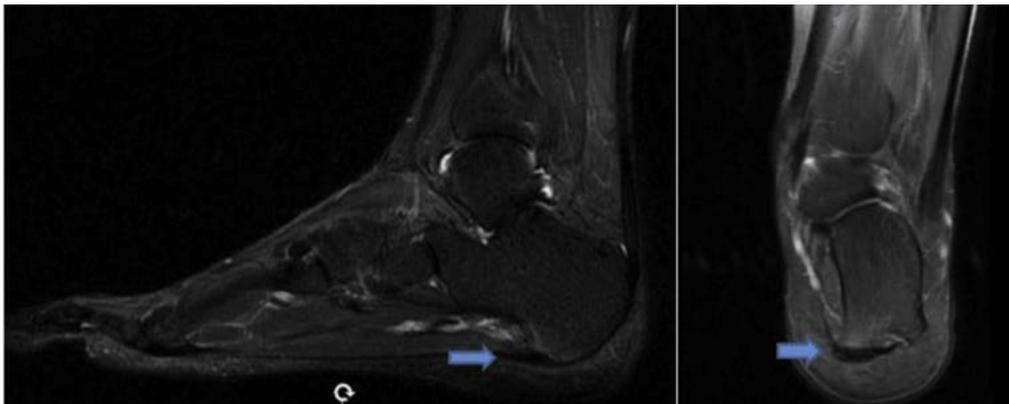


Fig. 1. Evaluation of the plantar fascia thickness by magnetic resonance imaging on sagittal (5.4 mm) and coronal (5.6 mm) planes. Arrows indicate measurement location.

pressure, 10-Hz frequency during sessions into the areas of the painful heel, insertion of the plantar fascia on the medial calcaneal area, and myofascial junction at the dorsum of the heel.

#### Outcome Measures

The primary efficacy success criterion was defined as a  $\geq 60\%$  decrease in heel pain for  $\geq 2$  VAS measurements (16,17). The secondary outcome measures were a functional response to treatment as defined by the RMS (1 indicating excellent; 2, good; 3, fair; and 4, a poor response), HTI (0 indicating excellent; 1, good; 2, fair; and 3, a poor response), and improvement in the AOFAS scale score and a reduction in plantar fascial thickness on MRI.

#### Statistical Analysis

In the present study, we calculated that the required minimum number of patients would be 45 for 3 groups, with an effect size of 0.48, an  $\alpha$  of 0.05, and power of 0.80. Allowing for withdrawals, we determined that the number of participants should be 60. Statistical analyses were performed using the SPSS for Windows, version 15.0, software (IBM Corp., Armonk, NY). Descriptive statistics and frequency analysis were performed for categorical variables using counts and percentages, and the minimum, maximum, mean, and standard deviation are presented for the numerical variables. We performed the Wilcoxon test to compare the pretreatment and post-treatment findings within the groups; the McNemar test was used for categorical data. The Kruskal-Wallis test was used to assess the differences among the 3 groups and the crosstab chi-square test for categorical data. The Mann-Whitney *U* test used for pairwise comparisons. Correlations between continuous variables were analyzed using the Pearson correlation test. A *p* value of  $< .05$  was considered statistically significant.

## Results

Sixty patients fulfilled the inclusion criteria and were included in the present study. Of the 60 patients, 2 withdrew from the study during the treatment period (both from group 2), 4 were unable to complete the follow-up examination by 1 month after treatment (3 from group 1 and 1 from group 2), and 2 patients refused the second MRI examination at the follow-up visit because they reported their symptoms had completely improved (1 from group 1 and 1 from group 3; Fig. 2). Thus, the data from 54 patients were analyzed for the primary outcome and 52 for the MRI evaluations. Side effects were not observed in any patient. No significant differences were found in age, body mass index, or symptom duration in months among the 3 groups ( $p > .05$ ) before treatment (Table 1). Also, no significant differences were found in the initial clinical parameters as determined using the VAS (pain intensity), HTI, AOFAS scale, and RMS among the 3 groups ( $p > .05$ ).

In all 3 groups, significant differences were found between the pre- and post-treatment clinical values. The VAS score had significantly decreased and the AOFAS scale scores had significantly improved after treatment in all 3 groups ( $p < .05$ ; Table 2).

The primary efficacy measure of success (decreasing heel pain  $> 60\%$  for  $\geq 2$  of the 3 heel pain VAS measurements) was detected in 70.6% of the LLLT group, 65% of the ESWT group, and 23.5% of the US

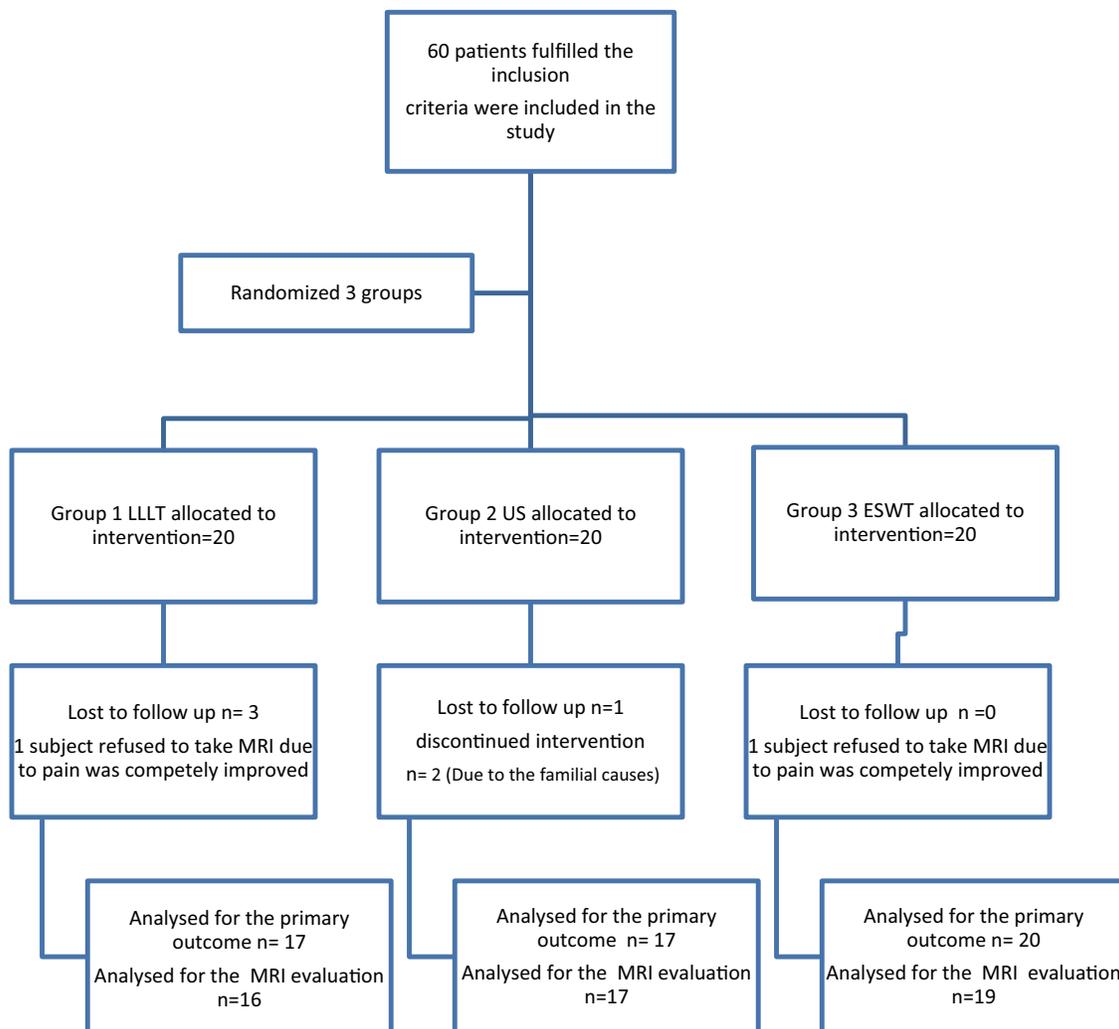


Fig. 2. Flowchart of the study design. Abbreviations: ESWT, extracorporeal shock wave therapy; LLLT, low-level laser therapy; MRI, magnetic resonance imaging; US, ultrasound.

**Table 1**  
Patient characteristics at enrollment stratified by treatment group

Characteristic	LLLT (n = 20)	US Therapy (n = 20)	ESWT (n = 20)	p Value
Age (y)				.388
Mean ± SD	53.40 ± 14.71	50.95 ± 9.62	54.45 ± 6.90	
Range	19–75	34–75	43–66	
Gender				.895
Female	16	17	16	
Male	4	3	4	
Pain duration (mo)				.389
Mean ± SD	14.40 ± 9.00	17.30 ± 14.71	27.00 ± 29.79	
Range	6–36	6–60	6–120	
BMI (kg/m <sup>2</sup> )	31.94 ± 5.55	30.20 ± 4.45	32.01 ± 4.06	.353

Abbreviations: BMI, body mass index; ESWT, extracorporeal shock wave therapy; LLLT, low-level laser therapy; SD, standard deviation; US, ultrasound.

group (Table 3). In the comparison of the 3 groups, LLLT and ESWT were found to be more effective than US therapy, with no significant difference found between LLLT and ESWT (group 1 versus 2,  $p = .006$ ; group 2 versus 3,  $p = .012$ ; group 1 versus 3,  $p = .717$ ) in the success rate (VAS score 60%).

The RMSs for the functional responses are listed in Table 4. The RMSs improved in all 3 groups. The comparison showed that 2 treatment modalities (LLLT,  $p = .03$ ; ESWT,  $p = .014$ ) were more effective than US therapy, with no significant differences found between LLLT and ESWT ( $p = .82$ ).

The HTI score changes before and after treatment are listed in Table 5. In the comparison of the 2 groups, ESWT was found to be more effective than US therapy ( $p = .004$ ). No significant difference was found between LLLT and ESWT ( $p = .115$ ) or between LLLT and US therapy ( $p = .106$ ).

The initial MRI findings and measurements are listed in Table 6. Soft tissue edema was present in 88.3% and bone marrow edema in 36.7%. The fascia thickness was  $\geq 4$  mm in 86.7% on  $\geq 1$  plane. A significant decrease was revealed in the thickness of the fascia in all 3 groups after treatment (LLLT,  $p = .001$ ; US,  $p < .001$ ; ESWT,  $p < .001$ ; Table 7). No statistically significant difference was found between the groups in the reduction of the fascia thickness measured on MRI. The reduction in plantar fascia thickness correlated moderately with the reduction in the pain with the first steps in the morning after treatment ( $p = .027$ ;  $r = 0.306$ ). Soft tissue edema persisted in 32 of the 52 patients at the 1-month follow-up MRI. Also, in these patients, the

**Table 2**  
Results for mean values of American Orthopaedic Foot and Ankle Society scale and visual analog scale scores before and after treatment

Variable	Before Treatment	After Treatment	p Value
AOFAS scale score			
LLLT (n = 17)	60.85 ± 15.90	85.70 ± 14.51	<.001*
US therapy (n = 17)	58.90 ± 13.33	82.00 ± 10.71	<.001*
ESWT (n = 20)	63.60 ± 15.74	83.70 ± 8.37	<.001*
VAS score, daily activities			
LLLT (n = 17)	6.87 ± 1.25	2.93 ± 1.84	<.001*
US therapy (n = 17)	6.66 ± 1.11	3.56 ± 1.68	<.001*
ESWT (n = 20)	6.60 ± 1.12	2.74 ± 1.41	<.001*
VAS score, first steps in morning			
LLLT (n = 17)	7.09 ± 1.34	2.75 ± 1.91	<.001*
US therapy (n = 17)	7.14 ± 1.74	3.77 ± 2.38	<.001*
ESWT (n = 20)	7.12 ± 1.12	2.81 ± 1.27	<.001*
VAS score, exercise			
LLLT (n = 17)	6.95 ± 1.45	2.90 ± 1.93	<.001*
US therapy (n = 17)	7.26 ± 0.88	4.20 ± 1.64	<.001*
ESWT (n = 20)	6.69 ± 1.47	2.41 ± 1.58	<.001*

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; ESWT, extracorporeal shock wave therapy; LLLT, low-level laser therapy; US, ultrasound; VAS, visual analog scale.

\* Statistically significant.

**Table 3**  
Primary efficacy success rate\* for the 3 groups

Variable	LLLT	US Therapy	ESWT	p Value
Primary efficacy success rate	12 (70.6)	4 (23.5)	13 (65)	.01
Failure rate	5 (29.4)	13 (76.5)	7 (35)	
p Value	<.001	.125	<.001	

Abbreviations: ESWT, extracorporeal shock wave therapy; LLLT, low-level laser therapy; US, ultrasound.

Data presented as n (%).

\* Decreasing in heel pain of  $>60\%$  for  $\geq 2$  of the 3 heel pain (visual analog scale) measurements.

reduction in the VAS score for morning first step pain ( $p = .040$ ) and VAS score for pain with daily activity ( $p = .037$ ) was lower than that of the patients with complete regression of soft tissue edema. However, no significant differences were found in pain reduction with ( $n = 13$ ) or without ( $n = 39$ ) ongoing bone marrow edema after treatment ( $p > .05$ ). The reduction in plantar fascia thickness in the excellent-good group using the RMS score was significantly greater than that in the fair-poor group on the sagittal ( $p = .042$ ) and coronal ( $p = .023$ ) planes.

When the patients were invited to attend the follow-up clinic at the first year, they reported no serious symptoms that would require the patients to undergo physical therapy again.

## Discussion

Plantar fasciitis is the most common cause of plantar heel pain in adults. The goals of treatment are pain relief and restoration of function (17). However, many different treatment strategies have been recommended, and limited evidence are available to support any of the common treatments (18). The findings from the present investigation showed that LLLT, US therapy, and ESWT all significantly reduced the pain with no side effects and provided an objective reduction in fascial thickness on MRI. However when we evaluated the effectiveness and functionality of the 3 treatment modalities, we found that ESWT and LLLT were more effective than US therapy at 1 month after the intervention.

LLLT has gained popularity in recent years and has been supported by new evidence resulting from the standardization of dosing recommendations according to the disease being treated. The first study of the effectiveness of LLLT in plantar fasciitis was reported in 1998 by Basford et al (19). In their study, 28 subjects underwent irradiation with 830-nm GaAlAs laser in 12 sessions, for 1 month, with a dosage of 1 J to the origin of the plantar fascia and 2 J to the medial side of the fascia. They detected no clinically significant differences between the LLLT and placebo groups. The investigators concluded that laser therapy is ineffective in the treatment of plantar fasciitis (19). However, this failed result likely resulted from the low therapeutic dosage they used, because the World Association for Laser Therapy recommended a treatment dose of a minimum of 8 J for LLLT for plantar fasciitis (13). Kiritsi et al (10) applied GaAlAs (904 nm) LLLT at 8.4 J to

**Table 4**  
Roles–Maudsley scores after treatment

Functional Response	LLLT (n = 17)		US Therapy (n = 17)		ESWT (n = 20)	
	Before	After	Before	After	Before	After
Excellent-good (1–2)	0 (0)	14 (82.4)	0 (0)	8 (47.1)	0 (0)	17 (65)
Fair-poor (3–4)	17 (100)	3 (17.6)	17 (100)	9 (52.9)	20 (100)	3 (35)

Abbreviations: ESWT, extracorporeal shock wave therapy; LLLT, low-level laser therapy; US, ultrasound.

Data presented as n (%).

**Table 5**  
Heel tenderness index scores after treatment

Heel Tenderness Index Score	LLLT (n = 17)		US Therapy (n = 17)		ESWT (n = 20)	
	Before	After	Before	After	Before	After
Excellent–good (0–1)	4 (17.6)	15 (88.2)	1 (5.9)	11 (64.7)	8 (40)	20 (100)
Fair–poor (2–3)	13 (82.4)	2 (11.8)	16 (94.1)	6 (35.3)	12 (60)	0 (0)

Abbreviations: ESWT, extracorporeal shock wave therapy; LLLT, low-level laser therapy; US, ultrasound.

Data presented as n (%).

the tendon insertion and 8.4 J to the medial side of the fascia or placebo to 30 individuals, recorded the pain on the VAS, and used US to measure the plantar fascia thickness before and after treatment. Pain had improved significantly in the LLLT group compared with the placebo group; however, the plantar fascia thickness was similar in both groups that showed significant changes (10). In a 2015 study, Macias et al (20) reported on a randomized placebo-controlled study of LLLT in 69 subjects were treated with a wavelength of 635 nm and 17 MW output for 6 sessions. The patients experienced an improvement in pain and the plantar fascial thickness decreased significantly with LLLT compared with the placebo group (20). In the present study, the clinical parameters improved and the plantar fascia thickness decreased significantly in the LLLT group, similar to the findings from Macias et al (20). We used the BTL GaAlAs laser for the present study, which has a wavelength of 830 nm and 50 MW output, with the recommended dose of 8 J/cm<sup>2</sup>, 5 times per week for 3 weeks. The treatment success rate was 70.6% in the LLLT group. These data have demonstrated that LLLT is an efficient and reliable treatment method for chronic plantar fasciitis.

Therapeutic US treatment is one of the most commonly used physical therapy modalities; however, conflicting results have been reported regarding its effectiveness in the treatment of plantar fasciitis. Both Crawford and Snaith (21) and Zanon et al (22) reported that therapeutic US was not superior to placebo in plantar fasciitis treatment. In addition, the 2014 plantar fasciitis treatment guidelines did not include therapeutic US among the recommendations (9). In contrast, Aydoğ et al (23) compared US therapy (10 sessions, 2 W/cm<sup>2</sup>, for 10 minutes) plus infrared therapy versus infrared therapy alone. They showed increased effectiveness in the US therapy plus infrared therapy group (23). Cheing et al (24) applied US treatment in continuous mode for 5 minutes at 1 MHz, 1 W/cm<sup>2</sup> for 3 days each week for 3 weeks and showed significant improvements in the VAS pain scores after treatment. These conflicting findings resulted from the lack of standardization of dosages, sessions, and implementation

**Table 6**  
Initial magnetic resonance imaging findings and measurements (n = 60)

Variable	Value
Plantar fascia thickness, coronal (mm)	
Mean ± SD	4.75 ± 0.813
Range	3.40–6.50
Plantar fascia thickness sagittal	
Mean ± SD	4.75 ± 0.867
Range	3.40–6.60
Soft tissue edema (intrafacial, perifacial)	
Yes	53 (88.3)
No	7 (11.7)
Bone marrow edema	
Yes	22 (36.7)
No	38 (63.3)
Calcaneal spur	
Yes	50 (83.3)
No	10 (16.7)

Abbreviation: SD, standard deviation.

Data presented as n (%), unless noted otherwise.

**Table 7**  
Fascial thickness measured on magnetic resonance imaging scans before and after treatment

Group	Fascial Thickness (mm)	
	Coronal Plane	Sagittal Plane
LLLT		
Before	4.33 ± 0.59	4.31 ± 0.68
After	3.75 ± 0.69	3.76 ± 0.73
US therapy		
Before	4.76 ± 0.72	4.79 ± 0.68
After	3.99 ± 0.62	4.03 ± 0.65
ESWT		
Before	5.17 ± 0.89	5.16 ± 1.00
After	4.31 ± 0.82	4.31 ± 0.87

Abbreviations: ESWT, extracorporeal shock wave therapy; LLLT, low-level laser therapy; US, ultrasound.

Data presented as mean ± standard deviation.

periods, making it difficult to compare the results of clinical trials. In our investigation, we found statistically significant improvements in the clinical parameters and VAS pain scores in the US treatment group (1 MHz, 2 W/cm<sup>2</sup>, 5 minutes, 15 sessions), which also experienced significant reductions in the thickness of the plantar fascia. However, when we evaluated the effectiveness of treatment, the success rate in the US therapy group was 23.5%, and 47.1% of patients had functional improvement according to the RMS. These data suggest that therapeutic US alone for plantar fasciitis treatment is unable to provide sufficient success in the short term.

A large number of randomized controlled trials were conducted to investigate ESWT efficacy in the treatment of plantar fasciitis. In the present study, the ESWT group showed significant improvement in all clinical parameters after treatment, and the functional and success rate was 65%. In 2013, a meta-analysis investigated the effect of ESWT compared with placebo to treat chronic plantar fasciitis and reported a >60% reduction in pain scores and improvement in RMSs. In the 5 of the 6 studies, ESWT was significantly superior to placebo (25). However, some studies could not show the superiority of ESWT to placebo. The trial by Haake et al (26) randomized 272 patients to 3 sessions of ESWT or sham ESWT. Treatment success was defined as achieving an RMS of 1 or 2. The success rate did not differ between groups at 12 weeks (34% for ESWT versus 30% for placebo) or at 1 year (81% for ESWT versus 76% for placebo) of follow-up (26).

Studies of the effectiveness of plantar fasciitis treatment have often been designed as placebo-controlled trials, and the number of studies comparing different treatments have been quite limited. Also, the comparison of these studies is often difficult owing to differences in the methods used. The design of the present study was scientifically rigorous, comparative, randomized, and prospective and included blinding of the investigator. To the best of our knowledge, the present study is the first to evaluate LLLT, US therapy, and ESWT and compare the results objectively using MRI. In the present study, each of the 3 treatments improved the pain VAS scores, heel sensitivity, RMS, and AOFAS scale scores compared with before treatment. However, ESWT and LLLT resulted in greater success rates than therapeutic US.

The measurement of the plantar fascia thickness provide an objective finding regarding the effect of the treatment used. MRI also allowed for the assessment of bone marrow edema and facial and perifacial edema. Grasel et al (27) showed that perifacial edema was the most common feature of plantar fasciitis. Zhu et al (28) reported a similar incidence in both facial thickening and soft tissue edema. Also, in our study, soft tissue edema was the most frequent MRI sign (increased facial and perifacial signal in 88.3%), and facial thickening (86.7% with fascia thickness >4 mm) was the second. The least common MRI feature in our series was limited bone marrow edema in the calcaneal region at 36%.

We detected significantly greater pain scores for daily activities and the first steps in the morning for the subjects with persistent soft tissue edema at the follow-up examination compared with those without soft tissue edema. These results suggest that the pain is associated with soft tissue edema persistence after treatment. Despite this, we could not demonstrate this association between pain and the presence of bone marrow edema at 1 month after the intervention. Probably owing to the short follow-up period, we failed to show any MRI change, because the expected time for visible regression of bone marrow edema on MRI is  $\geq 6$  weeks (29).

Fabrikant and Park (30) measured the plantar fascia thickness before and after treatment but found no correlation between a reduction in thickness and clinical improvement. However, Mahowald et al (31) showed statistically significant correlations between the reduction in fascial thickness ( $0.82 \pm 1.04$  mm) and improvement in pain VAS scores ( $3.64 \pm 2.7$ ). In the present study, we have confirmed their findings by showing a correlation between the fascial thickness reduction and decreased first step in the morning pain. Also, the fascial thickness reduction was greater for patients with a good functional response (according to the RMS) after treatment. These results suggest that the changing thickness on MRI of the plantar fascia is associated with clinical success and is a valid objective measure to assess the effectiveness of treatment. MRI is a valid, but expensive, tool. However, the cost/benefit ratio for MRI in standard practice has shown that clinical improvement will be sufficient during follow-up.

#### Study Limitations

The present study had several limitations. The first and most important limitation was the short follow-up period. Second, the sample size of the study was relatively limited. Also, we could not include a control group because we included patients who had been experiencing pain for  $\geq 6$  months that had been unresponsive to first-line treatment for 6 weeks. Thus, we could not include a placebo group because of ethical concerns.

In conclusion, we found that LLLT, US therapy, and ESWT significantly reduced the pain experienced with plantar fasciitis, providing clinical and radiologic improvement. However, when we evaluated the success rates, LLLT and ESWT were more successful in providing pain improvement and functional outcomes compared with US therapy at 1 month after treatment.

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