

## Effectiveness of Extracorporeal Shock Wave Therapy in Treatment of Chronic Plantar Fasciitis: A Comparative Prospective Study

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### Abstract:

**Background:** Plantar fasciitis; is a self-limited condition, and a common cause of heel pain in adults. There are different risk factors for developing plantar fasciitis such as obesity, excessive foot pronation, excessive running, and prolonged standing/walking. Almost 90% percent of patients improved with conservative treatment, nonetheless, extracorporeal shock wave therapy (ESWT) is an important options in some patients but there still little evidence supporting its use.

**Objective:** To assess the effectiveness of Extracorporeal Shock Wave Therapy in treating chronic plantar Fasciitis in comparison to conventional conservative treatment.

**Patients and Methods:** A prospective comparative non-blinded randomized controlled clinical trial conducted at Alhussain Medical City in Kerbalaa province, Iraq. During a period of one year. Included 60 patients assigned randomly into two groups (30 patients in each) to be managed either with Extracorporeal Shock Wave Therapy or conventional conservative treatment, and they were followed up for three months at scheduled visits.

**Results:** Both treatment groups were almost matched for age, gender, duration of illness, standing/working hours, and smoking history. We found that both treatment groups got clinical improvement over time. Better improvement reported in Extracorporeal Shock Wave Therapy group, regarding reduction in heel pain, less use of NSAID, more satisfied for their treatment modality.

**Conclusions:** Extracorporeal Shock Wave Therapy was an effective and safe treatment for chronic Plantar Fasciitis and was better than conventional conservative treatment.

**Keywords:** Plantar Fasciitis, Diagnosis, Treatment, Extracorporeal Shock Wave Therapy

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## **1. INTRODUCTION**

Plantar fasciitis is an inflammatory process in the area of the fascia, which is located along the lower surface of the foot and is the connecting link between the metatarsal and calcaneus (1,2). The pathogenesis of plantar fasciitis is unknown. The most common causes of pathology are degenerative changes of varying degrees, accompanied by microtrauma of the sole and the growth of vascular fibroblasts. Degenerative changes lead to chronic inflammatory processes. Signs of plantar fasciitis increase with each step and load on the foot, which complicates the treatment. Over time, the intensity of pain decreases. Prolonged plantar fasciitis can lead to the growth of bone directed toward the anterior foot (3–5). The main etiological and risk factors of plantar fasciitis include loss of fat in the heel; flat feet, which is characterized by flattening of the foot (6), resulting in a fascia stretched on it formed tears; overweight and obesity, prolonged walking on a hard surface; sedentary lifestyle; wearing uncomfortable tight shoes or shoes with high heels; sports that overload the aponeurosis, high or low arch of the foot, inflammation, excessive tension or contracture of the Achilles tendon and triceps (7–12). The main symptoms of plantar fasciitis are quite characteristic and can easily be recognized. Patients with this disease experience constant pain. More pronounced in the morning when getting out of bed. The pain is localized in the plantar area and intensifies with prolonged upright position, after a step load and training (13). Diagnosis based on clinical examination and radiographic imaging. Timely diagnosis will allow to begin treatment at an early stage of the disease and will help to do without surgery, which is inevitable with a heel spur (14,15). Ultrasonography (16), Bone Scintigraphy and Magnetic resonance imaging (in complicated cases) are useful diagnostic modalities. There is no clear classification of plantar fasciitis, however, X-rays can determine the absence (only inflammation - fasciitis) or the presence of osteophytes (heel spurs). Therapeutic tactics aimed at eliminating plantar fasciitis are largely based on the results of X-ray examination, taking into account the intensity of the pain (17–21). Plantar fasciitis has the following negative consequences; marginal bone growths (osteophytes), fracture of the heel spur, Achilles tendonitis and it may be accompanied by reactive and psoriatic arthritis (22). There are different methods used in the treatment of plantar fasciitis: Therapeutic exercise and stretching exercises aimed at reducing the severity of the inflammatory process; night immobilization with an orthosis; soft tissue massage aimed at both the sole and calf muscles, Physiotherapy, surgery, and

others in addition to medications and conservative treatment, (23–26). Extracorporeal shock wave therapy or ESWT; Shock wave therapy is a non-invasive method that is successfully used to treat orthopedic diseases. The method is based on the effect of low-frequency pulse waves in the focus of the pathological process, which stimulates metabolism, increases blood circulation, restores damaged tissues, accelerates their healing, and, as a consequence, eliminates plantar fascia tension and shortens calf muscles. Shock wave therapy is carried out with the help of special nozzles, through which the point or diffuse pulse wave is transmitted. The frequency, number and strength of strokes are selected individually depending on the severity of the pathological process and the patient's pain sensitivity. The SWT procedure is performed both at the site of pain (plantar surface of the heel) and adjacent regions of the foot. At the beginning of treatment, the procedure can be painful; with subsequent sessions, the pain gradually goes away, which is one of the criteria for the effectiveness of therapy. At a heel spur (heel spur) SWT appoint a course of 5-8 procedures with a frequency of 4-7 days for a sick extremity; in some cases, a final procedure is possible for another. Before the course of SWT, during the examination the root cause of tension of the plantar fascia have to be determined and shortening of the calf muscles. In some cases, before the procedure, recommend X-rays or ultrasound of the foot, or other methods of examination, if necessary. No special preparation for SWT is required. During the course of treatment, exercise therapy may recommended, osteopathic (manual) correction or drug therapy. In advanced cases and ineffectiveness of conservative treatment, surgical removal of bone growth by surgery (endoscopic or open method) is used (25,27–31). However, orthopedic surgeons still debating the effectiveness of ESWT in treatment of plantar fasciitis and no strong evidence about its use, hence we aimed to compare this treatment modality to conservative treatment among group of Iraqi patients.

## **2. PATIENTS AND METHODS**

A non-blinded randomized controlled clinical trial conducted at our medical city, , in the orthopedic consultation clinic, and the physiotherapy and rehabilitation unit.

Included patients attended the orthopedic consultation clinic during a period of one year 2020-2021. A total of 60 patients assigned into two groups (30) patients in each group namely, ESWT group and Conservative group. Patients were assigned randomly to each group to be treated either with ESWT or conservatively.

Randomization was, according to attendance number of patients to the orthopedic clinic (odd numbers assigned for ESWT and the even numbers assigned for the conventional conservative treatment group), keeping in mind to have a comparable or equal numbers of patients in each treatment group at the end of the study.

The diagnosis of chronic planter fasciitis in each case was made through proper history taking, physical examination, laboratory tests (according the case), and conventional x ray to the foot.

**Inclusion criteria:**

1. Patient had heel pain and diagnosed as chronic plantar fasciitis (with duration of symptoms for more than 6 months), with temporal or mild response to the conservative treatment and recurrence of the symptoms.
2. Patient age is from 20 years to 50 years.
3. Accept to be included in the study.

**Exclusion criteria:**

1. Pregnant female.
2. Having previous trauma or operation in the heel or ankle.
3. Having diabetes mellitus.
4. Having peripheral neuropathy.
5. Having peripheral vascular disease or coagulation problem.
6. Having rheumatoid disease or other inflammatory disorders.
7. History of local steroid injection to the heel for the last 6 weeks before the study.
8. Concurrent bacterial infection or chronic osteomyelitis in ankle or foot.
9. Those who took less than 4 sessions of ESWT, in the ESWT group.
10. Those that didn't attend the follow up visits and/or lost contact with them.

**Data collection:**

Data collected through direct interviewing, using data collection sheet. One month and three months follow up and data collection after the intervention was done through either direct interviewing or through phone calls with the patients.

At The first visit-pretreatment data include full history taking, demographic characteristics , clinical examination, laboratory and imaging findings. Presence of calcaneal spur and its length in millimeter(calcaneal spur considered present when its length is more than 2 millimeter in standard conventional lateral X ray to the foot); patient symptoms regarding

pain in the heel assessed at different times during the day using the Visual Analogue Scale (VAS) as following:

1. Patient's assessment of heel pain during first steps in the morning.
2. Patient's assessment of heel pain during daily activity.
3. Patient's assessment of pressure induced pain at the heel at the medial side of the calcaneus (at maximum pain site). The pressure induced pain is elicited by direct pressure using the thumb.
4. Patient's assessment of heel pain at night before sleep.

During the first visit, the patients got full explanation on how to use VAS, how to describe and express their pain on the scale, and how to express pain elicited in the heel by direct pressure by the thumb on the heel at planter fascia attachment point.

When the patient had bilateral planter fasciitis and he or she was assigned for ESWT, the ESWT was directed for the more painful site.

After one month of treatment of ESWT the collected data include:

1. Assessment of pain during the same different times mentioned above;
2. Assessment of the need/use of NSAID;
3. Any side effect of ESWT and how it was dealt with;
4. Commitment for stretching exercises.

After 3 months , in addition to the same assessment of one month visit, patient's satisfaction was assessed with his/her treatment and does he/she recommend it for other patients having the same heel problem. The satisfaction with the treatment modality assessed using Five-points Likert scale, ranged from strongly agree to strongly disagree on the questionnaire item.

#### **Intervention protocol and procedure:**

We used focused shock waves therapy (using the focused large head probe), with frequency of 4 Hz, 800 shocks per session, and with intensity of 3.2 Bars. This would deliver low energy ESWT for 6 sessions over three weeks (two sessions per week), with no need for anesthesia.

During the first visit, the ESWT group received some basic information about the principle of ESWT, some analgesic medication to be used on need. Also we informed the patients to contact us if there were any side effects of ESWT treatment. The patient sits comfortable

on the couch. The ESWT probe applied directly at the maximum pain point for treatment session duration.

For the conventional conservative treatment group, the patients got NSAID medication, advised for activity modification and how to avoid long standing hours, advised for use of heel pad orthotics, and taught some stretching exercises to be practiced daily, three times a day, for at least one month, and to continue it to prevent the recurrence of the symptoms. Also, they were informed to contact us if there were any concerns or need for further treatment.

The stretching exercises were as follow: (each exercise should create a pulling- stretching feeling but should not cause pain)

1. Stretches to the Planter Fascia: use a plastic bottle of water (volume 0.5 litter) as a roller, and he/she roll his/her feet over it for stretching and messaging the planter fascia and the sole, for both feet, for 5 minutes, three times per day. Originally, this exercises designed to use freeze ice bottle, to apply cold, and stretching. Here we used water bottle for stretching only.

2. Static stretches to the Planter Fascia: cross the affected leg over his/her other leg, using the hand on the affected side, take hold of his/her affected foot and pull his/her toes back towards shin. This creates tension-stretch in the arch of the foot plantar fascia. Check for the appropriate stretch position by gently rubbing the thumb of his/her unaffected side left to right over the arch of the affected foot. The plantar fascia should feel firm, like a guitar string. Hold the stretch for a count of 10. A set is 10 repetitions. Perform at least 3 sets of stretches per day. The most important times to stretch are before taking the first step in the morning and before standing after a period of prolonged sitting. Towel curls, or toe curls: this test designed for strengthening the intrinsic muscles of the foot. It is done while sitting, place his/her foot on a towel on the floor and scrunch the towel toward him/her with his/her toes, then, also using his/her toes, push the towel away from him/her.

3. Towel Stretch: sit on the floor with his/her legs stretched out in front of him/her. Loop a towel around the top of the injured foot. Slowly pull the towel towards to keeping His/her body straight so that the foot stretches toward him/her. Hold for 15 to 30 seconds then relax - repeat 10 times.

Treatment response assessment:

The response to the treatment with ESWT or the conservative treatment was assessed depending on:

1. The improvement of heel pain measured by the VAS;
2. The reduction in use and need for NSAID medication;
3. The patient's satisfaction with the treatment results, and his/ her recommendation for the treatment modality to the others.

**Statistical analysis:**

The data were analyzed using statistical package for social science (SPSS) version 25. Data were expressed in as frequencies, percentage, means, and standard deviations. Student t test used to compare means. Pearson Chi-square and Fisher's Exact Test used to analyze qualitative data. P value of less than 0.05 considered statistically significant.

### **3. RESULTS**

In this study, Females were dominant in both ESWT and conservative treatment groups, they represented 76.7% and 80%, respectively. However, all baseline characteristics of the studied groups are shown in (Tables 1 & 2). Comparison of pain scores at different follow-up times revealed better improvement in ESWT at the end of follow up period , after three months, where the mean Pain during early morning and first steps reduced from 6.9 at baseline to 3.35 after three months with a 3.55 points reduction and 51.4% overall improvement while the corresponding values for this pain scores were 2 points and 30.1% only in the conservative group, similar trend in change in Pain during the active working and standing during the day, Pain elicited by direct pressure in the heel at plantar fascia insertion, Pain at night and before sleep and Composite pain, (Tables 3 & 4).

The non-steroidal anti-inflammatory medications had been prescribed for the ESWT and conventional conservative treatment groups to be used on need for their heel pain. (Table 5) Need and duration of NSAID use during the study period in both studied groups .

Regarding patients' satisfaction and recommendations, in ESWT group, 5 patients (16.7%) were strongly agree with their treatment results, 15 patients (50%) agree, 3 patients (10%) were equivocal, and 8 patients (26.7%) were disagree on the treatment and none were strongly disagree. On the other hand, 20patients (66.7%) would recommend ESWT for others who had the same heel problem, while 10 patients (33.3%) would not. In the conventional conservative group, none were strongly agree, 11 patients (36.7%) agree on

their treatment results, 6 patients (20%) were equivocal, while 13 patients (43.3%) were disagree on it and none strongly disagree. Moreover, 11 patients (36.7%) would recommend this treatment for those who had the same heel problem, while 19 patients (63.3%) would not, (Table 5 & 6).

**Table 1. Baseline characteristics of the studied groups (categorical variables)**

Variable	ESWT group		Conservative group		P. value
	No.	%	No.	%	
Gender					
Female	23	76.7	24	80.0	0.754
Male	7	23.3	6	20.0	
Smoking	5	16.7	6	20.0	0.817
Calcaneus Spur present	24		23	76.7	0.996
Previous treatment					
• NSAID	30	100.0	30	100.0	1.000
• Corticosteroid injection	12	40.0	13	43.3	0.982
• Heel pad orthotics	6	20.0	5	16.7	0.992
ESWT: extracorporeal shock wave therapy					

**Table 2. Baseline characteristics of the studied groups (Scale variables)**

Variable	ESWT group		Conservative group		P. value
	Mean	SD	Mean	SD	
Age (year)	44.1	6.7	43.6	5.9	0.760
BMI (kg/m)	27.8	3.9	28.6	4.3	0.453
Duration of illness (month)	10.3	4.9	9.6	3.3	0.519
Standing/working hours in the day	3.6	0.8	3.4	0.9	0.366
SD: standard deviation					



**Table 3. Comparison of mean pain scales at different times of follow up in both groups.**

	ESWT group (n = 30)	Conservative group (n = 30)	P value
Pain during early morning and first steps			
Baseline	6.9 (0.9)	6.63 (0.7)	0.403
After one month	4.9 (1.1)	5.0 (0.6)	0.824
After 3 months	3.35 (1.5)	4.63 (2.1)	0.035
Pain during active working and standing during the day			
Baseline	5.80 (1.2)	5.74 (0.8)	0.856
After one month	3.9 (1.4)	4.37 (1.2)	0.293
After 3 months	2.70 (1.3)	3.84 (1.3)	0.024
Pain elicited by direct pressure in the heel at plantar fascia insertion			
Baseline	5.80 (1.6)	5.53 (0.8)	0.538
After one month	3.75 (1.2)	3.95 (1.5)	0.702
After 3 months	2.50 (1.6)	3.16 (1.8)	0.276
Pain at night and before sleep			
Baseline	2.90 (1.1)	3.00 (1.374)	0.804
After one month	1.15 (0.9)	1.68 (1.7)	0.229
After 3 months	0.30 (0.42)	1.16 (1.4)	0.017
Composite pain			
Baseline	6.16 (0.9)	5.91 (0.6)	0.416
After one month	4.20 (1.1)	4.43 (1.3)	0.541
After 3 months	2.85 (1.4)	3.87 (1.4)	0.047
All values are mean (standard deviation)			

**Table 4. Pain reduction points and improvement percentage at after one and three months of follow up compared to baseline levels in both studied groups**

	ESWT group (n = 30)	Conservative group (n = 30)
Pain during early morning and first steps		
After one month	2 points (28.9%)	1.63 points (24.5%)
After three month	3.55 points (51.4%)	2 points (30.1%)
Pain during the active working and standing during the day		
After one month	1.85 points (31.9%)	1.37 points (23.9%)
After three month	3.1 points (53.4%)	1.89 points (33.0%)
Pain elicited by direct pressure in the heel at plantar fascia insertion		
After one month	2.05 points (35.3%)	1.58 points (28.6%)
After three month	3.3 points (56.9%)	2.37 pints (42.9%)
Pain at night and before sleep		
After one month	1.75 points (60.3%)	1.32 points (44.0%)
After three month	2.6 points (89.6%)	1.85 points (61.6%)
Composite pain		
After one month	1.96 points (31.8%)	1.53 points (25.6%)
After three month	3.31 points (53.7%)	2.09 points (35.0%)

**Table 5. Need and duration of NSAID use during the study period in both studied groups**

Item	ESWT group (n = 30)		Conservative group (n = 30)	
	No.	%	No.	%
Didn't took NSAID	3	10.0	0	0.0
Took NSAID for 1 week	14	46.7	3	10.0
Took NSAID for 2-3 weeks	11	36.7	16	53.3
Took NSAID for more than 3 weeks	3	10.0	11	36.7
P. value = 0.127 , not significant				

**Table 6. Degree of patients' satisfaction and recommendations in each treatment group,**

Item	ESWT group (n = 30)		Conservative group (n = 30)	
	No.	%	No.	%
Strongly agree	5	16.7%	0	0.0%
Agree	15	50.0%	11	36.7%
Equivocal (neither agree nor disagree)	3	10.0%	6	20.0%
Disagree	8	26.7%	13	43.3%
Strongly disagree	0	0.0%	0	0.0%
Recommend it to others	20	66.7%	11	36.7%
Do not recommend it to others	10	33.3%	19	63.3%

#### 4. DISCUSSION

There are many modalities for treatment of planter fasciitis have been suggested including surgical methods; heel spur resection, open planter fasciotomy, percutaneous planter fasciotomy, and endoscopic planter fasciotomy. Many studies have confirmed that transecting the planter fascia alters the integrity of the foot such that the stability of the foot decreases, the arch lowers, and digital instability or claw toe deformity occurs. This results in transfer of pressure to the metatarsal heads, creating significant pathology in the area(32,33). From other point of view, conservative treatment failed in many cases (34,35) therefore, there still a need for other options of treatment with lower invasiveness and good outcomes (31,36–38), hence, this study designed to assess the effectiveness of treating chronic planter fasciitis with ESWT in comparison with the conventional conservative treatment.

The two treatment groups were comparable in many variables, with insignificant statistical differences regarding their baseline characteristics which may affect the study and treatment outcomes, we almost matched both groups in their baseline characteristics, matching and stratifications applied in our study are among the successful methods to control confounders and prevent bias (39). The diagnosis of planter fasciitis in this study was determined clinically. According to the results of this study, there was clinical improvement (pain reduction) in both treatment groups, with better improvement seen in the ESWT group, after one month and after three months from the baseline. Although the difference in the clinical improvement and pain reduction between the two groups was statistically not significant after one month from the baseline in all occasions (pain in early morning, pain during the active working and standing during the day, pain elicited by direct pressure in the heel at plantar fascia insertion, pain at night before sleep, and the composite pain), but it was statistically significant difference after three months from the base line for early morning pain, pain during the active working and standing during the day, pain at night before sleep, and the composite pain.

In the ESWT group, the pain reduction was more than (50%) after three months from base line in all occasions (pain in the early morning, pain during work, pain elicited by direct pressure, pain at night, and composite pain), while in the conventional conservative treatment group, the pain reduction was more than (50%) only in pain at night after three months from the base line.

Some studies like Ogden JA et al. (40) defined the successful treatment as pain reduction more than (50%) from the base line. According to this, we can consider the treatment of plantar fasciitis using ESWT as a successful treatment in comparison with the use of conventional conservative treatment. There were differences in the use of NSAID between the two treatment groups during the study period, with less use of NSAID seen in ESWT group. According to the results of this study, only 3 patients (15%) complained from exaggeration of heel pain for 1-2 days after ESWT, which was relieved using NSAID. Apart from that, no other side effects were reported using the low energy ESWT. So, we can recommend that the use of low energy ESWT is a safe procedure for treating chronic plantar fasciitis.

In the ESWT group some patients not completing the whole protocol and this because some patients claimed they couldn't find the time or being busy, some said they didn't feel

immediate improvement, and some complained from the difficulty to reach the hospital each time however, we used the Likert scale for assessment of patient satisfaction regarding the results of their treatment modality. The ESWT group patients were more satisfied with their treatment modality than the conventional conservative treatment group. The ESWT group patients would recommend their treatment modalities for others more than those of the conventional conservative treatment. There are many studies done in assessing the effectiveness of use of ESWT in treating chronic plantar fasciitis, and with different results. Most of the studies compare ESWT with placebo or sham ESWT (30,31,38,41–43) In a RCT study, done by Wang CJ, et al. comparing ESWT with conservative treatment reported that (69%) of ESWT had a good result (> 50% reduction in baseline pain) (44). These results go with the conclusion that the ESWT is more effective than the conventional conservative treatment in treating plantar fasciitis, and it agrees with the results of our study(30,41–43).

The limitations and weak points in our study were:

We couldn't include the assessment of functional improvement in the design of this study, because it was difficult to be interpreted or expressed by our patients, so we couldn't use other assessment and scoring tools in our study, like the Maryland Foot Score (which is a disability index that in account pain and function of the foot) or Short- Form- 36 Health Survey (SF-36). The sample size is relatively small. The three months duration of the study and follow up is not a long period, although many relevant studies on the same subject use the same three months period for follow up. In this study design, we didn't include corticosteroid injection in the heel at the insertion of plantar fascia within the conventional conservative treatment items. The reason for that we tried to avoid its complications especially for those who already took it previously. In assessing the heel pain elicited by direct pressure at the plantar fascia insertion, we did direct pressure using the thumb with certain amount of pressure, while in other studies, they used special instruments (like Dolorimeter, a pressure sensor) to do that. We couldn't get and use one of these instruments in our study.

## 5. CONCLUSION

ESWT can provide better clinical improvement, less use of NSAID, and more patient satisfaction when used in treating chronic plantar fasciitis in comparison to the continuation on the conventional conservative treatment. Using low energy ESWT for treating chronic plantar fasciitis is a safe procedure. ESWT can provide a treatment option for the treating physician; and for the patients who have chronic plantar fasciitis, tired from the conventional conservative treatment, and reluctant to have surgery for it

**Ethical Issues:** All ethical issues were approved by the authors. Verbal and signed informed consents were obtained from all patients who included in the study during their first visit.

**Conflict of interest:** None

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