

# Analgesic Effect of Low Energy Extracorporeal Shockwave Therapy on Chronic Plantar Fasciitis: A Randomized, Placebo-Controlled, Clinical Trial

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**Submitted:** 2017-06-23; **Accepted:** 2017-09-27

## Abstract

**Introduction:** Plantar fasciitis is the most prevalent cause of pain in heels and widely treated using the shockwave therapy. **Materials and Methods:** Thirty patients (12 males and 18 females) randomly participated in this single blind clinical trial study that aimed to evaluate the effects of low energy extracorporeal shockwave therapy on pain in patients with chronic plantar fasciitis. Group 1 patients were treated with low energy shockwave and stretch, and group 2 control patients were treated by stretch and a placebo shockwave. The groups were demographically similar with respect to age, gender, and BMI. The patients were assessed for pain using the visual analog scale (VAS). **Results:** After 2 weeks of treatment, a significant difference in pain was observed between the two groups. The VAS results showed 76% reduction of pain in group 1 and 46% in group 2. **Discussion:** The use of low energy radial shockwave has significant short-term effects on pain relief in chronic plantar fasciitis and is, thus, recommended as a relatively painless and safe therapy prior to surgery.

**Keywords:** Extracorporeal Shockwave, Low Energy, Plantar Fasciitis

**Please cite this paper as:** Aftabi A, Sarrafzadeh J, Mohsenifar H, Moghaddam N. Analgesic Effect of Low Energy Extracorporeal Shockwave Therapy on Chronic Plantar Fasciitis: A Randomized, Placebo-Controlled, Clinical Trial. J Clin Physio Res. 2017; 2(4): 152-156.

## Introduction

Plantar fasciitis is the most prevalent cause of heel pain and accounts for 11%–15% of foot pain in adults that require treatment (1). It is associated with pain and morning stiffness that increases with walking (2). In 2000, the American Food and Drug Administration declared shockwave therapy as a safe and effective treatment for plantar fasciitis. This therapy reportedly has a long-time regenerative effect on tendons and short-time analgesic and anti-inflammatory effect (3).

In recent studies, the shockwave energy used is set at more than 0.08 mJ/mm<sup>2</sup> or 2.5 bar (1, 4-11). Usually, patients suffer from pain 2 days after the administration of this energy on the affected area. In patients with low levels of tolerance against the intensity of shockwave, it is possible that they may abandon

treatment or cause problems for the operator during the therapy through sudden movements due to pain and discomfort.

Thus, this study aimed to evaluate the effects of low energy extracorporeal shockwave therapy (energy level lower than 1.4 bar) on pain in patients with chronic plantar fasciitis.

### Participants and methods:

The current study was performed as a single blind clinical trial.

### Participants

Thirty patients (18 women and 12 men) suffering from chronic plantar fasciitis as diagnosed by physicians participated through university medical centers, orthopedic surgeons, sports medicine specialists, and direct attendance. The average age of the participants was 38.06 years (SD=6.76) with a median of 37 years and a range of 26–50 years.

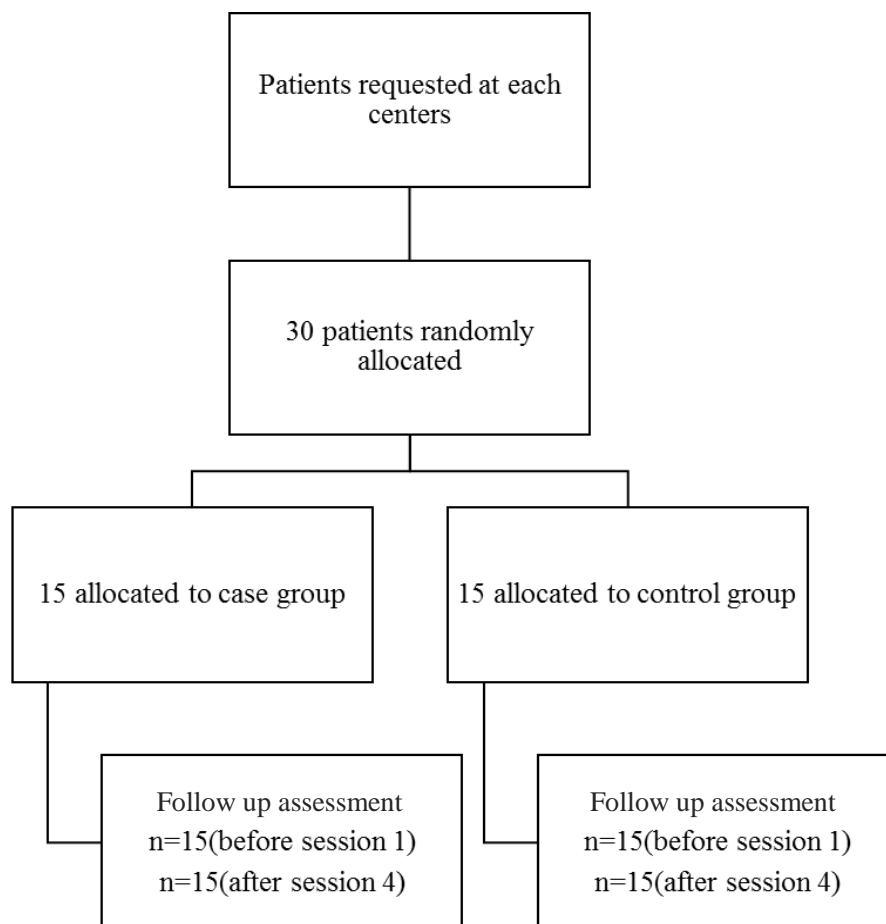


Figure 1. Study flow diagram

**Inclusion criteria**

1) The patients should be suffering for at least 4 months from chronic plantar fasciitis, non-responsive to all non-surgical methods. 2) Their visual analog scale (VAS) score at the beginning of walking in the morning should be more than 5. 3) All patients should have experienced maximum pain with direct palpation and when direct force was applied to the anteromedial tuberosity of the calcaneus bone. 4) None of the patients should have any apparent deformity in their lower extremities or spinal cord, any discrepancies in length of lower extremities or any problems in the foot that could prevent the administration of shockwave therapy.

**Exclusion criteria**

During the treatment and follow-up, we controlled the use of any local anesthetics, anti-inflammatory drugs or the injection of any corticosteroids. The exclusion criteria included any foot injuries, diabetes, tumors, pregnancy, general infections, and use of pacemakers.

**Groups 1 and 2**

The participants were randomly divided into two groups. The group 1 patients (n=15) were treated with low energy shockwaves and stretch while the group 2 patients (n=15) were considered as controls and treated with stretch and a placebo shockwave (Figure 1).

**Evaluation**

The VAS was used to evaluate pain in all patients. It is a commonly used scale in studies on plantar fasciitis treatment using shockwave therapy(4). VAS includes a horizontal line of length 10 cm on which the patient is asked to rate his or her pain using a pen(4). This was followed before and after each treatment session, and the VAS sheets were separated without the patient's knowledge of his or her previous pain.

**Treatment**

The group 1 patients were asked to lie down in the prone position. After rubbing the ultrasound gel on the treatment

**Table 1.** Characteristics at baseline (N=15)

Characteristics at baseline	Case group	Control group	P-value
Gender (Male/Female)	6.9	6.9	<b>1.00</b>
Mean (SD) Age (Years)	38.40 (7.59)	37/73 (6.07)	<b>0.31</b>
Mean (SD) BMI	27% (0.04)	26% (0.04)	<b>0.66</b>

**Table 2.** Mean VAS and SD before session 1 and session 4 in group 1(CASE) and group 2 (Control)

Group	VAS mean(SD) Before session 1	VAS mean (SD) After session 4	P-value (Trend)	P-value (between groups)
<b>Case</b>	6.67 (2.09)	1.68 (1.94)	<0.001	0.01
<b>Control</b>	6.68 (1.92)	3.45 (1.61)	<0.001	

**Table 3.** Mean VAS difference and SD during therapy in group 1(CASE) and group 2 (Control)

Groups	N	VAS Diff Mean (SD)	P-value
<b>VAS diff</b>	case	15	-0.76 (0.21)
	control	15	-.46 (0.23)

area, *i.e.*, foot, the shockwave was administered at 1.2 bar, 2000 beats, and 8 Hz. After two sessions, the intensity was increased from 1.2 bar in the first week to 1.4 bar in the second week (Figure 2). At the end of the treatment therapy, the therapist taught the patients to perform gastrocnemius and plantar fascia stretch for 3 repetitions per day, each set lasting 30 seconds.

In group 2, all methods were similar to group 1 except for a layer of dry cotton foam of 15mm thickness and having the same diameter as the shockwave probe being placed on its head in order to prevent the sonic waves from passing on to the patient's foot.

The repeated measurement statistical test was used for statistical analysis of the dependent variable, VAS, in each group and between the two groups. The sample t test was used to study VAS difference and to compare independent variables such as age, gender and BMI. Normality of the data of the groups was initially confirmed using K-S statistical test.

## Results

There was no significant difference between the groups with respect to age ( $P=0.79$ ) and gender of the participants ( $P=1.0$ ). The average BMI in the two groups was 27 (SD=0.04), and there was no significant difference between the groups ( $P=0.66$ ) with respect to BMI (Table 1).

### Primary outcome

The average VAS for the first group prior to treatment was 6.67 (SD=2.09) and for the second group was 6.68 (SD=1.92), and

there was no significant difference among the groups with respect to average VAS ( $P=0.99$ ). No significant difference was observed between the two groups with respect to the VAS score after the treatment sessions ( $P=0.01$ ).

### Secondary outcome:

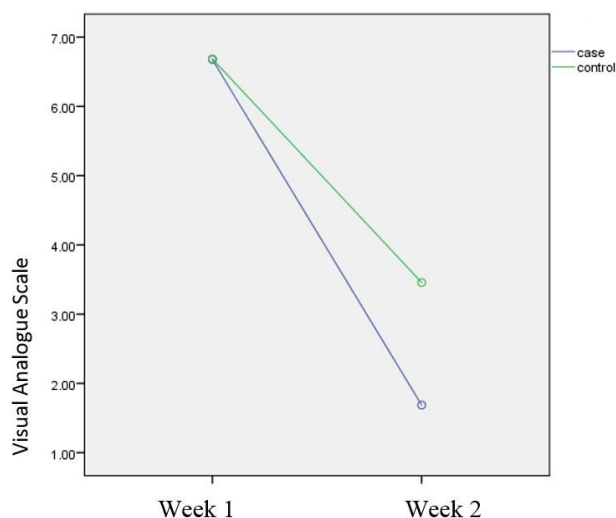
In addition to the results regarding the variables mentioned above, another variable "VAS Difference" was defined for both groups using the equation (Start – End)/(start) as an index of change in the amount of pain at the start and end of the study. The results showed a 76% mean decrease in visual pain in the first group and 46% in the second group. There was a significant difference among the two groups with respect to this VAS Difference ( $P=0.001$ ). These changes are shown in Table 3 and Figure 4.

## Discussion

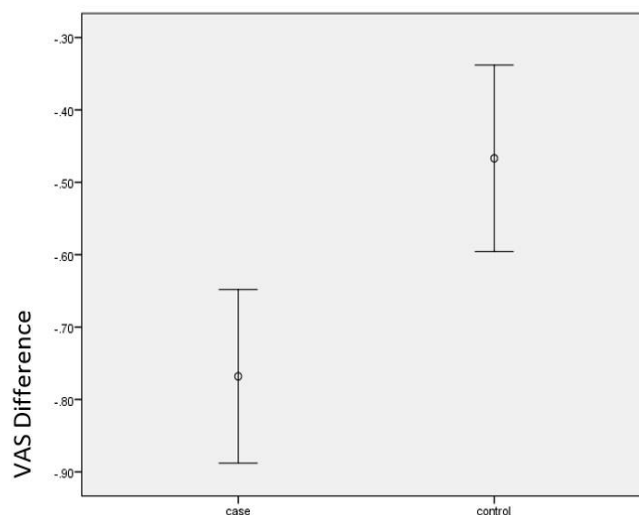
In this study, we found that low energy shockwave has a therapeutic effect on the symptoms of chronic plantar fasciitis. The use of low energy in shockwave therapy along with stretch exercises of the calf muscles relieved pain in people suffering from plantar fasciitis. Our study showed that using high intensity of shockwave is not necessary and that even with the lower bar, we can have the same effect of pain relief. Thus, the shockwave therapy can become a comfortable and non-painful treatment for chronic plantar fasciitis. The analgesic effect of shockwave is attributed to enzymes that affect pain receptors, just like TENS (12).



**Figure 2.** Method of application



**Figure 3.** VAS changes in group 1(case) and group 2 (Control)



**Figure 4.** Mean VAS difference changes during

Our study confirmed the existence of this effect of shockwave therapy even when low energy is used, indicating that this effect is related to the nature of the shockwaves.

Similar to our study, Di Giovanni *et al.* (13) reported that regular stretching exercises of the calf muscles and the Achilles tendon were an effective non-surgical method of decreasing acute plantar fasciitis symptoms.

In 2007, Gollwitzer *et al.* (5) performed a random double blind research on 40 patients in which the control group received placebo therapy and the other group received electromagnetic focused shockwave therapy. Both groups received 3 sessions of treatment, 1 week apart with 2000 beats in each session. The

results were studied at 12 weeks, and the shockwave group showed 73.2% pain relief, which was more than that of the placebo group by a margin of 32.7% (5). In our study, the shockwave group showed 76% pain relief.

Ibrahim *et al.* studied the effect of pain relief after two sessions of radial shockwave (2000 beats with 0.016 mj/mm<sup>2</sup> energy each session) on 50 chronic plantar fasciitis patients (6). Their goal was to compare the short term effects of 2 sessions of radial shockwave therapy with the placebo group in chronic plantar fasciitis, and our study confirmed the same effect but with a lower energy of shockwave therapy.

In another similar study by Shaheen *et al.*, which was done in the form of 3 sessions, 2000 beats, frequency of 8 Hz and an

energy of 2 bars (8), significant pain relief was observed after 3 weeks in both groups with the shockwave group showing more significant pain relief in weeks 3 and 6. We also found the same result in 2 weeks but without follow-up.

## Conclusion

The use of low energy radial shockwave has significant short-term analgesic effects on pain relief chronic plantar fasciitis and is recommended as a relatively painless and safe therapy method before surgery. However, future studies should focus on comparison with other methods and long-term follow-up.

### Conflict of interest:

None

### Funding support:

This project had no external funding, and no financial or other relationships pose a conflict of interest

### Authors' contributions:

All authors made substantial contributions to conception, design, acquisition, analysis and interpretation of data.

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