# Effect of Monophasic Pulsed Current on Heel Pain and Functional Activities caused by Plantar Fasciitis

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Data Collection B
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**Background:**   Plantar fasciitis (PF) is a soft tissue disorder considered to be one of the most common causes of inferior heel pain. The aim of this study was to investigate the effect of monophasic pulsed current (MPC) and MPC coupled with plantar fascia-specific stretching exercises (SE) on the treatment of PF.

**Material/Methods:**   Forty-four participants (22 women and 22 men, with a mean age of 49 years) diagnosed with PF were randomly assigned to receive MPC (n=22) or MPC coupled with plantar fascia-specific SE (n=22). Prior to and after 4 weeks of treatment, participants underwent baseline evaluation; heel pain was evaluated using a visual analogue scale (VAS), heel tenderness threshold was quantified using a handheld pressure algometer (PA), and functional activities level was assessed using the Activities of Daily Living subscale of the Foot and Ankle Ability Measure (ADL/FAAM).

**Results:**   Heel pain scores showed a significant reduction in both groups compared to baseline VAS scores (P<0.001). Heel tenderness improved significantly in both groups compared with baseline PA scores (P<0.001). Functional activity level improved significantly in both groups compared with baseline (ADL/FAAM) scores (P<0.001). However, no significant differences existed between the 2 treatment groups in all post-intervention outcome measures.

**Conclusions:**   This trial showed that MPC is useful in treating inferior heel symptoms caused by PF.

**MeSH Keywords:**   **Electric Stimulation Therapy • Exercise Therapy • Fasciitis, Plantar**

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## Background

Plantar fasciitis (PF) is a soft tissue disorder first described by William Wood in 1812 [1] and is known by many pseudonyms such as jogger's heel, heel spur syndrome, plantar fascial insertitis, calcaneal enthesopathy, subcalcaneal bursitis, subcalcaneal pain, stone bruise, calcaneal periostitis, neuritis and calcaneodynia [1–3]. PF can be defined as a localized inflammation of perifascial structures and plantar fascia at the proximal attachment on the medial tuberosity of the calcaneus resulting from chronic repetitive microtears and degeneration secondary to overuse or mechanical and congenital disorders [4–9]. It can cause other foot disorders such as Baxter's neuropathy[10]. PF is a common diagnostic entity affecting more than 2 million Americans every year [11]. PF constitutes approximately 15% of foot dysfunctions in the United States and accounts for more than 1 million outpatient visits each year [4,7,8]. Symptoms are resolved in approximately 90% of cases and resolution of symptoms occurs in the majority of patients within 10 months of conservative treatment [5,9,12].

The onset of inferior heel pain is insidious and may worsen over time. The sharp pain is usually localized to the plantar-medial aspect of the heel or over a small area near the proximal insertion of the plantar fascia at the medial tuberosity of the calcaneus [4,13]. Many physical therapy regimens are available that may mitigate and relieve heel pain associated with PF. These modalities include iontophoresis, manual therapy, night splinting, prefabricated and customized inserts, shoe modification, stretching exercises of calf muscles and plantar fascia, taping, and orthotic devices, which can be used to suit patient needs [7,8].

Electrical stimulation (MPC) is used to promote wound and pressure ulcer healing processes. Delivery of electrical current using electrodes to the wound bed is presumed to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis and adenosine triphosphate production, as well as increasing the number of growth factor receptors and enhancing calcium influx [14–21]. The plantar fascia is a connective tissue, and the main function of fibroblast cells is to maintain structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts make the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix [15,18,19,22].

Therefore, the hypothesis to be tested here is that electrical stimulation may also help reduce pain and promote healing in people with plantar fasciitis. Two groups of subjects were tested – 1 with electrical stimulation alone and 1 with electrical stimulation and stretching – to see if the 2 therapy modalities were synergistic.

## Material and Methods

### Subjects

This prospective randomized clinical trial was approved by the Institutional Review Board (IRB) at Loma Linda University (LLU) and conducted in the Physical Fitness Laboratory at the School of Allied Health Professions (SAHP), Department of Physical Therapy between March and September 2013. The following inclusion/exclusion criteria were used to determine eligibility for enrollment in this clinical trial. Inclusion criteria were: (1) participants of both sexes diagnosed with PF, (2) participant age range was 18–65 years; and (3) the diagnosis was made upon the finding of tenderness to pressure at the origin of the plantar fascia on the medial tubercle of the calcaneus, as well as complaint of heel pain greater than or equal to 3 on a 1–10 VAS scale. Exclusion criteria were: (1) previous fracture or surgery of the foot and (2) specific metabolic and connective tissue disorders associated with or contributing to the diagnosis of PF (e.g., rheumatoid arthritis, gout, and lupus).

Forty-eight participants with a clinical diagnosis of plantar fasciitis met the inclusion criteria of this randomized clinical trial and underwent baseline evaluation. Four participants never retuned beyond the baseline evaluation session due to scheduling conflicts. Data analysis was based on the remaining 44 patients who provided written consent to continue with the study. All subjects were instructed to not use NSAIDS or other analgesics during the 4 weeks the study was conducted. No follow-up was conducted after the study was over.

### Methods

#### Visual analogue scale

A visual analogue scale (VAS) was used to measure heel pain. VAS is a numerical scale with marked points at 0 and 10 in which 0 indicates no pain and10 indicates the highest level of pain. The scale was 10-cm long and was on a single piece of white paper. Patients were requested to rate their heel pain based on their initial steps in the morning, by putting a vertical mark on the scale representing the level of heel pain. The subject was only shown a single scale on each visit to avoid prejudice. This scale has been established as a reliable and valid subjective outcome measure to assess acute and chronic pain [23–25].

#### Pressure algometer

A handheld pressure algometer (PA) was used to measure each patient's heel tenderness threshold. The threshold is defined as the minimum force required to produce the sensation of pain. The PA is a force gauge equipped with a rubber tip and

calibrated in kg/cm² (Model FDX, Algometer, WAGNER instruments, Greenwich, CT). To assess heel tenderness, the investigator directed the patient to recline in a supine position with the affected leg fully extended. The investigator then palpated and marked the tender point over the origin of the plantar fascia at the medial tuberosity of the calcareous. Finally, the investigator passively dorsiflexed the ankle and toes, applying the algometer over the mark placed on the medial tuberosity of the calcaneus. The algometer contact head was aligned perpendicularly to the tender point, with the investigator gradually increasing the algometer force until the patient reported pain. The algometer reading, which represents the force needed to stimulate pain, was recorded in newtons. Higher algometer scores indicated greater force tolerance and, thus, less tenderness. Lower algometer readings indicated less force tolerance and, thus, greater heel tenderness. The reliability and validity of the algometer as a subjective outcome measure of tenderness has been supported in various studies [26–28].

### Foot and ankle ability measure

To assess functional activity levels, the participants were asked to record their ability to perform daily activities using the Activities of Daily Living subscale of the Foot and Ankle Ability Measure (ADL/FAAM). The ADL/FAAM identifies 21 daily activities, and participants rated their ability to complete each activity based on a scale ranging from no difficulty to inability to complete. Individual responses to the ADL/FAAM questions were converted to numerical scores using a 5-point scale ranging from 0 (no difficulty doing) to 4 (unable to do) that particular daily activity. A lower ADL/FAAM score indicated a higher functional activity level. ADL/FAAM is a self-reported instrument specific to lower leg musculoskeletal disorders, and is known to be a reliable, valid, and responsive self-reported instrument for assessing the activity and function level for patients with lower leg musculoskeletal disorders [29–31].

### Monophasic pulsed current

MPC involved delivery of pulsed, twin-peak, monophasic pulses, each pulse having a duration of 100 µsec, and employed voltage that was too weak to elicit a visible muscle contraction [14,16]. The frequency was 100 pulses per second, and an amplitude at submotor level, too weak to elicit a visible muscle contraction [14–16].

### Plantar fascia stretching exercise

Plantar fascia stretching exercises (SE) are often considered an integral component of the physical therapy treatment plan for the treatment of PF, used to decrease pain and improve functional limitations. In this study, plantar fascia specific SE were utilized as demonstrated by DiGiovanni et al.

[7]. Patients were directed to cross the affected leg over the other leg while in a sitting position, and using a hand to apply metatarsophalangeal joint dorsiflexion (pull the toes back toward the shin until the patient feels a stretch in the arch of the foot), while holding each stretch for a count of 10, and repeating each stretch 10 times. All patients were required to perform the SE program 3 times per day. The first stretch was to be completed before getting up in the morning and exiting the bed. Patients were provided a written protocol of the stretching program and asked to keep a daily log of exercise completion for 4 weeks.

### Procedure

After obtaining participant informed consent, the investigator recorded demographic information (age, sex, height, weight, body mass index, and duration of symptoms) and determining whether the patient engaged in athletics and on which side the affected area presented. A baseline evaluation was performed on eligible participants, including measurement of: (1) heel pain using the Visual Analogue Scale (VAS); (2) heel tenderness with pressure algometer (PA); and (3) functional activities level with Activities of Daily Living Subscale of the Foot and Ankle Ability Measure (ADL/ FAAM).

The investigator then randomly assigned the participants to 1 of 2 treatment groups. Group I (STIM group) received MPC and Group II (STIMSTRECH) received MPC coupled with plantar fascia SE, using a computer-generated random 2-digit number. Each participant received 3 sessions of MPC per week for 4 weeks, for a total of 12 sessions. Each session lasted 60 minutes. Participants in Group II were instructed to perform home-based stretching exercises as described by DiGiovanni [7]. After completing the assigned treatments, the investigator performed a post-intervention evaluation that included the same subjective outcome measures used in the baseline evaluation. No follow-up was done after the study. All subjects were instructed not to use nsaids or other pain medications unless directed to by a physician. If they did need pain medications, they were dropped from the study, but this was not necessary for this group of subjects.

### Data analysis

### Sample size estimation

SAS statistical analysis software was used to calculate the sample size required so that there was a reasonable expectation to detect a moderate effect size of 0.4 between the 2 study groups using a level of significance 0.05 and power of 0.8. A sample size of 40, with 20 participants per group with 0% attrition rate was needed in the study. Forty participants were required to show statistical significance when clinically significant
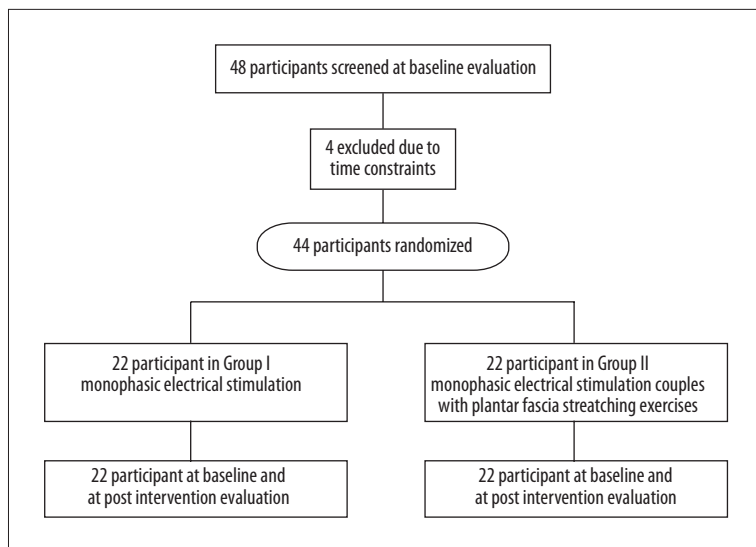
**Figure 1.** The progression of participants through clinical trial.

**Table 1.** General characteristics of subjects (N= 44).

| | | STIM (n=22) | | STIMSTRECH (n=22) | | p-value |
|---|---|---|---|---|---|---|
| Age, mean (SD) year | | 49.7 | (11.7) | 49.0 | (9.7) | 0.60* |
| Height, mean (SD) cm | | 171.5 | (12.0) | 171.0 | (13.5) | 0.91* |
| Weight, mean (SD) kg | | 96.4 | (22.9) | 87.4 | (22.9) | 0.20* |
| BMI, mean (SD) kg/m$^2$ | | 32.8 | (7.2) | 30.0 | (7.4) | 0.21* |
| Standing hours, mean (SD) | | 8.8 | (3.2) | 9.6 | (2.48) | 0.31* |
| Duration of symptom, median (IQR) months | | 12.0 | (154.0) | 12.0 | (149.0) | 0.12** |
| Gender | Male,% (n) | 36.4 | (8.0) | 31.8 | (7.0) | 0.75# |
| | Female,% (n) | 63.6 | (14.0) | 68.2 | (15.0) | |
| Athletic status | Athletic,% (n) | 9.1 | (2.0) | 13.6 | (3.0) | 0.50## |
| | Non-athletic,% (n) | 90.9 | (20.0) | 86.4 | (19.0) | |
| Involved side | RT,% (n) | 27.3 | (6.0) | 50.0 | (11.0) | 0.12# |
| | LT,% (n) | 72.7 | (16.0) | 50.0 | (11.0) | |

SD – standard deviation; BMI – body mass index; IQR – interquartile range; RT – right; LT – left. * Independent t-test;
** Mann Whitney U- test; # Pearson chi square; ## Fisher's exact test.

differences between the groups were present. Additional participants were recruited to provide for attrition.

### Description of statistical procedures

IBM SPSS Statistics Grad Pack 22.0 PREMIUM was used to analyze the data. Participants' demographic data for each group was summarized using means and standard deviations (SD) for continuous variables and frequencies and percentages for categorical variables. The assumption of normality of the continuous variables was examined using the Kolmogorov-Smirnov test and the assumption of homogeneity was examined by Levene's test.

The 2 groups were compared at baseline using an independent t-test. Differences were calculated between before and after measurements for heel pain, heel tenderness, and functional activities level. A mixed 2×2 factorial Analysis of Variance (ANOVA) was conducted to examine the effect of the 2 interventions – monophasic pulsed current and combination of monophasic pulsed current and plantar fascia stretching exercises – on heel pain, heel tenderness, and functional activities level. To explore if changes in outcome measures over time were consistent across treatment groups, we examined whether there was an interaction between time and treatment group. The level of significance was set at p value <0.05.

**Table 2.** Mean (SD) of outcome measurements by treatment group at baseline (N=44).

|  | STIM (n=22) | STIMSTRECH (n=22) | Difference | p-value* |
|---|---|---|---|---|
| VAS | 7.39 (1.75) | 6.84 (2.14) | 0.55 | 0.38 |
| PA, N | 17.41 (6.69) | 14.47 (5.41) | 2.94 | 0.12 |
| ADL/FAAM | 34.14 (11.33) | 30.64 (12.65) | 3.50 | 0.34 |

SD – standard deviation; VAS – visual analog scale; PA – pressure algometer; ADL – activity of daily living; FAAM – foot and ankle ability measure. * Independent t-test.

**Table 3.** Mean (SD) of outcome measures by treatment group over time (N=44).

|  | Pre Mean (SD) | Post Mean (SD) | p-value* | p-value# | Pre-post by-group interaction |
|---|---|---|---|---|---|
| VAS |  |  |  |  |  |
| STIM (n=22) | 7.4 (1.8) | 3.4 (2.0) | <0.001 | 0.67 | 0.28 |
| STIMSTRETCH (n=22) | 6.8 (2.1) | 3.6 (1.9) |  |  |  |
| PA, Newton |  |  |  |  |  |
| STIM (n=22) | 17.41 (6.69) | 36.74 (9.11) | <0.001 | 0.21 | 0.75 |
| STIMSTRETCH (n=22) | 14.47 (5.41) | 34.55 (8.88) |  |  |  |
| ADL/FAAM |  |  |  |  |  |
| STIM (n=22) | 34.14 (11.33) | 15.27 (12.31) | <0.001 | 0.86 | 0.07 |
| STIMSTRETCH (n=22) | 30.64 (12.65) | 17.55 (14.00) |  |  |  |

SD – standard deviation; VAS – visual analog scale; PA – pressure algometer; ADL – activity of daily living; FAAM – foot and ankle ability measure. * Significant differences between pre- and post-intervention within each group; # significant differences between two groups.

**Table 4.** Mean (SD) of outcome measurements by treatment group at post intervention (N=44).

|  | STIM (n=22) | STIMSTRECH (n=22) | Difference | p-value |
|---|---|---|---|---|
| VAS | 3.43 (1.95) | 3.55 (1.95) | −0.11 | 0.84* |
| PA, N | 36.74 (9.11) | 34.55 (8.88) | 2.18 | 0.43 |
| ADL/FAAM | 15.3 (12.3) | 17.6 (14.0) | −2.27 | 0.57* |

SD – standard deviation; VAS – visual analog scale; PA – pressure algometer; ADL – activity of daily living; FAAM – foot and ankle ability measure. * Independent t-test.

## Results

Of the 44 participants completing the study, 22 were women and 22 were men (Figure 1). The right foot was involved in 22 participants and the left foot in 22. There were no significant differences between the STIM group managed with MPC and group II managed with MPC coupled with plantar fascia SE (STIMSTRECH group) in regards to age, sex, height, weight, body of mass index (BMI), athletic status, and affected side (Table 1).

At baseline evaluation, no significant differences existed between STIM and STIMSTRETCH groups with regard to VAS scores (p=0.36, Table 2). The 2 groups experienced improvement in heel pain after completing the assigned treatments compared with baseline VAS scores (p<0.001), but differences between the 2 groups were small and statistically insignificant (p=0.85, Table 3).

The results of post-intervention evaluation showed that the STIM group had a reduction in heel pain on the analog visual

scales by –3.96/10 (95% confidence interval (CI), compared to a mean reduction of –3.30/10 in the 10-cm analog visual scale scores (95% CI –4.19 to –2.40) for the STIMSTRECH group. The mean difference for heel pain between the 2 groups was insignificant, with mean reduction or difference of –0.11; (95% CI, –1.30 to –1.07; Tables 3, 4).

At the baseline evaluation, no significant differences existed between the 2 subject groups with regard to their tolerance for pressure applied with the pressure algometer (p=0.12, Table 2). The 2 groups experienced improvement in heel tenderness after completing the assigned treatments compared with baseline scores (p<0.001), but no significant differences between the 2 groups were detected (p=0.21, Table 3, 4). The STIM group had an improvement in heel tenderness of 19.33N (95% CI 16.12 to 22.53) of additional force that could be applied to the plantar fascia before they reported pain from the beginning to the end of the study compared to an improvement of 20.08 N (95% CI 16.51 to 23.65) for the STIMSTRECH group.

Concerning the 2 questionnaire instruments for evaluation of foot disability, at baseline, no significant differences existed between the 2 groups with regard to ADL/FAAM scores (p=0.34, Table 2). The 2 groups experienced improvements in functional activities of daily living after completing the assigned treatments compared with baseline ADL/FAAM scores (p<0.001), but differences between the 2 groups were insignificant (p=0.57, Table 3).

## Discussion

The primary focus of this prospective clinical trial was to examine the effect of MPC and MPC coupled with plantar fascia SE on recovery in activities of daily living and pain scores in people diagnosed with plantar fasciitis. To the best of our knowledge no prior studies have been conducted to examine the effect of MPC on patients with PF.

We hypothesized that the use of MPC would promote and accelerate the healing processes, especially the proliferation phase associated with plantar fasciitis. The results of this prospective clinical trial were consistent with results of other clinical studies that concluded that physical therapy interventions and the use of modalities may mitigate and improve functional difficulties caused by plantar fasciitis[8,13,32–39].

In this study, there were no significant differences between the 2 treatment groups in terms of age, sex, height, weight, BMI, duration of heel symptoms, athletic status, and involved side. Participants' characteristics in the two treatment groups appeared to be well matched and did not appear to affect the subjective outcome measures used to determine the effect of monophasic pulsed current on the treatment of plantar fasciitis.

Findings from the post-intervention evaluation showed that both groups experienced significant reductions in VAS scores, pressure tolerance, and in questionnaires showing impairment in activities of daily living compared to baseline. Improvement in the pressure algometer scores in both groups was large enough to be clinically important [26–28] and the reduction in ADL/FAAM scores was also large enough to be clinically important [29–31].

The results of this prospective study were consistent with other physical therapy studies indicating that physical therapy interventions and modalities were efficient in improving inferior heel pain symptoms resulting from plantar fasciitis [8,13,32–39]. However, stretching and stimulation was not better than stimulation alone. Therefore, the 2 modalities were not synergistic as predicted. However, the fact that 3 electrical stimulations per week were equivalent to stretching indicate that electrical stimulation may be a far more efficient therapeutic modality since it requires less time for the patient to accomplish than stretching.

The results of this trial need to be viewed in light of two limitations: First, the assessor and patients were not blinded to treatment allocation and outcome assessment. This is a potential source of bias. Nevertheless, the outcome measures were subjectively self-reported by participant and ultrasound was used as an objective outcome measure. Second, more meticulous inclusion and exclusion criteria would be required to be able to make sound inferences about the effect of treatment. For instance, the participants exhibited chronic symptoms with varying duration of symptoms. Future research should target symptoms of a limited duration (i.e., less than 12 months). Third, because the sample of convenience was insufficiently large, we were unable to have the plantar fascia-specific stretching exercise group reach a more reliable inference about the additive effect of the monophasic pulsed current effect.

While the addition of electrical stimulation to stretching was not different in terms of patient outcomes than stretching alone, it does seem to be a good therapeutic modality since it was only applied once every 3 days compared to 3 times per day for stretching. Further studies should look at electrical stimulation alone.

## Conclusions

This prospective controlled trial supports the efficiency of MPC in reducing inferior heel pain and tenderness, and improving functional activities levels associated with PF.

### Conflict of interest

The authors declare no conflicts of interest.

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