

The Effects of Extracorporeal Shockwave Therapy on Pain, Function, Range of Motion and Strength in Patients with Plantar Fasciitis

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Abstract—Ten percent of the population will develop plantar fasciitis (PF) during their lifetime. Two million people are treated yearly accounting for 11-15% of visits to medical professionals. Treatment ranges from conservative to surgical intervention. The purpose of this study was to assess the effects of extracorporeal shockwave therapy (ECSWT) on heel pain, function, range of motion (ROM), and strength in patients with PF. One hundred subjects were treated with ECSWT and measures were taken before and three months after treatment. There was significant differences in visual analog scale scores for pain at rest ($p=0.0001$); after activity ($p=0.0001$) and; overall improvement ($p=0.0001$). There was also significant improvement in Lower Extremity Functional Scale scores ($p=0.0001$); ankle plantarflexion ($p=0.0001$), dorsiflexion ($p=0.001$), and eversion ($p=0.017$), and first metatarsophalangeal joint flexion ($p=0.002$) and extension ($p=0.003$) ROM. ECSWT is an effective treatment improving heel pain, function and ROM in patients with PF.

Keywords—Extracorporeal shockwave therapy, shockwave therapy, plantar fasciitis, heel pain, function, range of motion, strength.

I. INTRODUCTION

PLANTAR FASCIITIS (PF), inflammation and degeneration of the plantar fascia, is the most common cause of heel pain today [1]-[5]. Two million people are treated in the United States (USA) yearly and 10% of the population will go on to develop PF during the course of their lifetime [1]-[5]. PF accounts for 11-15% of visits to medical professionals yearly [1]-[5]. The economic costs associated with musculoskeletal disorders are rising reaching 149 billion dollars per year in the USA [6]. In Europe, musculoskeletal disorders are the most expensive of all disease categories and in Australia, it is second only to cardiovascular disease [6]. There has been an emphasis promoting physical activity levels in the general population in an attempt to improve overall fitness levels, decrease obesity and prevent many chronic disorders and diseases. Unfortunately, we have also seen a dramatic increase in the number of overuse musculoskeletal injuries such as PF. With the ever increasing cost of treatment in healthcare it is imperative that the healthcare provider make accurate choices for the treatment of the patient complaining

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of overuse injuries such as PF and, at the same time, consider the economic impact of the treatment decision.

The treatment of PF ranges from conservative measures to surgery. Treatments may include soft tissue massage, heat or cold application, electrotherapeutic modalities such as ultrasound, laser or interferential current, custom or pre-fabricated orthotics, heel pads and cups, specialized footwear, or the use of taping and bracing [1], [4], [5], [7]-[11]. Patients may also be treated with non-steroidal anti-inflammatory medications (NSAIDs), stretching and strengthening exercises, joint mobilizations, corticosteroid or Botox injections, and endoscopic or open surgical release techniques [1], [4], [5], [7]-[11]. The success of reducing heel pain with treatment, however, can be quite variable.

The use of extracorporeal shockwave therapy (ECSWT) has been demonstrated to be safe and effective in the treatment of a variety of musculoskeletal disorders including PF. Shockwaves are acoustic waves that can be generated by electrohydraulic, electromagnetic, piezoelectric or radial generators [12]-[14], [16], [22]. Radial shockwaves are generated by the acceleration of a bullet that hits an applicator. They have a larger focus area, do not penetrate as deep and do not have as high intensity as the shockwaves generated by the other devices [2], [13], [14]. The unit that will be used for this study produces radial shockwaves.

II. OBJECTIVES AND HYPOTHESIS

The purpose of this study was to assess the effects of ECSWT on heel pain, function, range of motion (ROM), and strength in patients with PF. It was hypothesized that ECSWT would have a positive effect on function and heel pain and that subjects would demonstrate a higher Lower Extremity Functional Scale (LEFS) score, and a lower visual analog scale (VAS) score with treatment. It was also hypothesized that there would be no effect, or change in ROM, and strength with treatment.

III. RESEARCH DESIGN AND METHODOLOGY

The design for this study was a pre-test post-test design. Participants for this study included both men and women between the ages of 18 to 70 years who were able to complete the questionnaires, give informed consent and met the following inclusion criteria: (1) reported unilateral heel pain localized to the heel and plantar fascial region of the foot, anteromedial calcaneal tubercle, or medial longitudinal arch;

(2) reported heel pain first thing in the morning with the first few steps; (3) reported heel pain after getting up after prolonged sitting, with running, or walking. Participants who met the following criteria were excluded from the study: (1) had bilateral heel pain; (2) had previous surgery to the plantar fascia, or ankle region; (3) were receiving any other form of treatment during the study period; (4) had a history of ankle or foot fracture; (5) had a congenital foot deformity; (6) used an assistive device such as an ankle foot orthoses; (7) had vascular, or neurological disorders of the feet; (8) were pregnant; (9) had implanted metal in the region or; (10) were taking non-steroidal anti-inflammatory drugs (NSAIDs), Aspirin, or Coumadin.

Once the purpose and methodology of the study was explained and consent to participate was obtained, a detailed initial assessment and anthropometric measures were performed. Height, weight, active and passive ROM, and strength of the foot were assessed. Active and passive ROM for the ankle and first metatarsophalangeal (MTP) joint was measured and recorded in degrees using a goniometer. Resisted isometric strength of the ankle was measured, recorded and graded using the 5-point Oxford scale (grade 5 - movement against gravity with full resistance; grade 4 - movement against gravity with some resistance; grade 3 - movement against gravity only; grade 2 - movement with gravity eliminated; grade 1 - visible and palpable muscle contraction but no movement and; grade 0 - no contraction).

During the initial assessment, subjects also filled out the LEFS and a horizontal 100 millimeter VAS. The subject was asked to consider the following questions when filling out the linear scales: (1) their level of heel pain at rest; (2) their level of heel pain following activity and; (3) how much better their heel pain was at that time. Subjects marked the VAS at the point that corresponded with their pain intensity. The amount of pain was estimated by measuring in millimeters the distance from the "no pain" marker to the mark provided by the subject for each question.

The outcome measures chosen have been shown to have good validity, reliability, and psychometric properties. The pooled coefficients for the VAS ranged from 0.73-0.80 for test-retest reliability, and the pooled value for construct validity ranged from 0.82-0.94 [17], [18]. It has been reported that the LEFS has an internal consistency ranging from $\alpha = 0.90-0.96$, and a test-retest reliability ranging from 0.88-0.94 [19]-[21].

After the initial assessment, the subject was treated with ECSWT. Treatment consisted of 2000 shockwaves at an intensity of 2.5 bars, 10-15 Hz and 11.5 Mp using a D Actor 100 Radial Shockwave Unit developed by Storz Medical. The applicator was positioned over the painful site on the calcaneous and plantar fascial region. Subjects received three treatments in total spaced one week apart over a three week period of time. Participants were clearly advised to continue with their normal daily routines and patterns in between each treatment. A three month follow up assessment was performed with each subject. All subjects filled out the LEFS and VAS at the three month follow up once again. A detailed subjective

assessment and objective assessment of ROM and strength was also performed again and the findings documented at follow up. Fig. 1 illustrates the study design flow chart.

Demographic and anthropometric measures were summarized. A Wilcoxon Signed Rank Test was used to analyze and compare the pre-test and post-test VAS, LEFS and strength measures and a Paired Samples t-Test was used to analyze and compare the pre-test and post-test differences in ROM.

IV. RESULTS

The sample consisted of 97 subjects (27 males and 70 females) with a mean age of 48 years. Descriptive data for height, weight and body mass index (BMI) is summarized in Table I.

There was a significant decrease in heel pain from pre-treatment to post-treatment for VAS scores for heel pain at rest ($p=0.0001$), heel pain after activity ($p=0.0001$), and for overall improvement in heel pain ($p=0.0001$). There was also a significant improvement in function as noted in the LEFS scores ($p=0.0001$). Fig. 2 illustrates the VAS findings for heel pain at rest, heel pain after activity, and for overall improvement in heel pain. Fig. 3 illustrates the findings for the LEFS scores.

Active ankle plantarflexion ROM was decreased pre-treatment (46.8°) and improved post-treatment (48.9°). Active ankle dorsiflexion was decreased pre-treatment (17.2°) and improved post-treatment (18.9°). Active ankle inversion was decreased pre-treatment (57.3°) and improved slightly post-treatment (57.8°). Active ankle eversion was decreased pre-treatment (28.9°) and improved post-treatment (29.6°). Decreased active flexion was evident both pre-treatment (40.9°) and post-treatment (37.9°) for the first MTP joint. The ROM for flexion of the first MTP decreased post-treatment. Active first MTP joint extension was decreased pre-treatment (45.3°) and improved post-treatment (50.0°).

TABLE I
 DEMOGRAPHIC INFORMATION

Age (years)	48±9.2
Gender	27 M, 70 F
Height (cm)	168.9±10.7
Weight (kg)	86.8±26.5
Body Mass Index (kg/m ²)	30.4

M=males, F=females, cm=centimeters, kg=kilograms, kg/m² =kilogram per meter squared, Body Mass Index Weight Status Categories: Less than 18.5=Underweight; 18.5-24.9=Normal; 25-29.9=Overweight; Greater than 30= Obese.

The ROM findings are summarized in TABLE II. There was a significant increase in ankle plantarflexion ($p=0.0001$), dorsiflexion ($p=0.001$), and eversion ($p=0.017$), and in first MTP joint extension ($p=0.003$) from pre-treatment to post-treatment. There was a significant decrease in first MTP joint flexion ($p=0.002$) following treatment.

With resisted isometric strength testing, 7% had weakness with plantarflexion; 3% had weakness with dorsiflexion; 8% had weakness with inversion; and 4% had weakness with

eversion pre-treatment. Post-treatment 2% of the subjects still presented with weakness in plantarflexion, dorsiflexion and eversion strength, and 3% with inversion strength with resisted isometric testing. There was no significant change in resisted isometric strength from pre-treatment to post-treatment for all strength measures.

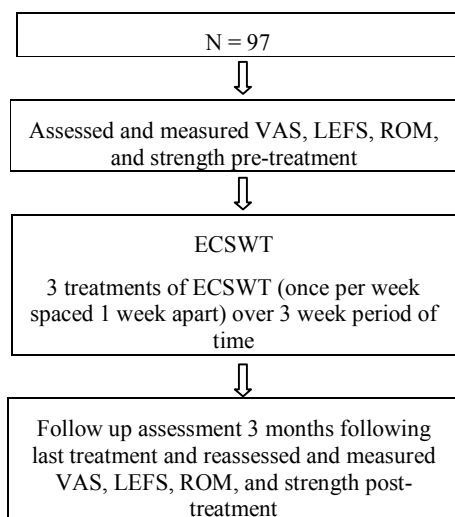


Fig. 1 Study design flow chart

TABLE II
 SUMMARY OF MEAN ROM PRE-TREATMENT AND POST-TREATMENT

	Pre-Treatment	Post-Treatment
Ankle ROM ^a		
Plantarflexion (50°)	46.8°±6.3	48.9°±4.6
Dorsiflexion (20°)	17.2°±3.6	18.9°±2.8
Inversion (60°)	57.3°±7.9	57.8°±6.9
Eversion (30°)	28.9°±3.6	29.6°±2.3
First MTP ROM ^a		
Flexion (45°)	40.9°±8.7	37.9°±9.1
Extension (70°)	45.3°±15.9	50.0°±15.6

^aNormal ROM values listed in parentheses.

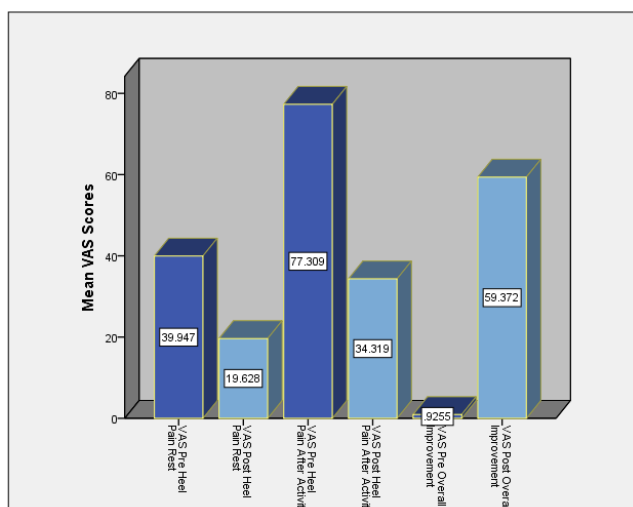


Fig. 2 VAS scores for heel pain at rest, heel pain after activity and for overall improvement in heel pain

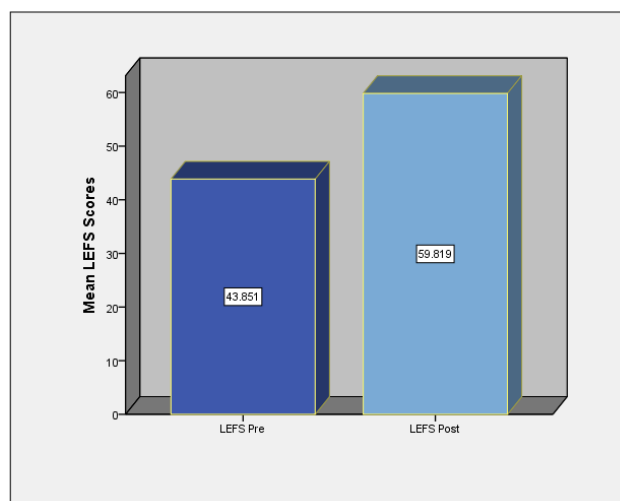


Fig. 3 LEFS scores

V. DISCUSSION

This study demonstrated that all subjects experienced improvements in heel pain and function with ECSWT. The reduction in heel pain at rest over time is consistent with other reported research findings [2], [6], [11], [15], [18], [23]-[32]. Studies have reported positive treatment effects when using ECSWT with success ranging from 50 to 90% with a low recurrence rate of 5 to 7% in patients with PF [4], [33], [34].

Significant improvement has been reported in heel pain and VAS scores with treatment consisting of electromagnetically generated ECSWT as compared to placebo [24]. Clinically significant improvement in VAS and functional scale scores was also reported with the use of radially generated ECSWT compared to placebo [2]. Overall success rate was 61% compared to 42% in the placebo group [2]. The effect of a single ECSWT treatment compared to placebo has also been compared [11]. VAS scores were significantly improved with ECSWT in comparison to placebo at three and 12 months post-treatment [11]. The success rates reported in these studies is consistent with our positive treatment findings.

The fact that placebo was reported to have a positive effect is an interesting finding in the fact that even this produced a dramatic change in heel pain. The concept of using placebo when analyzing the efficacy of a new treatment seems to be imperative especially when uncertainty arises over its initial use. In light of the number of studies available on the use of ECSWT and the difficulty in using a true placebo makes it difficult to integrate in such a study design. Some authors have even gone so far as to argue that the use of placebo when treatment efficacy has already been shown may be unethical and not necessary [35].

In another large retrospective study of chronic PF patients, success rates of 71% at three months and 77% at 12 months post-treatment with ECSWT was reported [9]. In our study, we found that 71% had very good improvement with treatment and 29% reporting less than 50% improvement in their heel

pain. Our findings are consistent with the reported findings in the previously cited studies.

Some of the variability in the research available on treatment outcomes, however, can be attributed to the different parameters used, the different types of shockwave generators, and the different study designs. This variability makes it difficult to compare the findings of each study as well. A consistent measure of the success of treatment in many studies was the use of self-report measures or functional outcome questionnaires. Variability in the findings of the available studies may also be due to the acuteness or chronicity of the heel pain in the participants included in the studies. Many studies have primarily looked at the treatment of chronic PF while others did not control for the length of the problem [3], [5], [9], [11], [23]-[25], [27], [29], [36]. The mean length of time that subjects in our sample had pain was 10 months and can be classified as chronic. We did not control for the acuteness or chronicity of the problem but rather were more concerned on the effects of the treatment on pain, function, ROM and strength. Variability in the amount of improvement has been reported regarding the actual success of ECSWT in patients with PF. The range of improvement and success rates has been controversial with some questions raised as to how successful this treatment truly is. These questions and inconsistent findings, however, may be partially attributed to the variability described in treatment parameters, dosages, different shockwave generators and research designs used in the studies.

Positive findings have also been reported when comparing ECSWT and ultrasound therapy on heel pain measured with the VAS and functional tolerances for standing and walking [15]. The use of a self-report pain measure was combined in this study with more of an objective functional test. This may be more of an optimal combination when looking at treatment effects. Most studies have consistently used self-report pain or functional questionnaires or outcome measures but not tested functional abilities, ROM or strength effects.

Negative and positive predictors to the use of ECSWT in PF patients have been described in the available literature [9]. Negative predictors may include the presence of diabetes mellitus, psychological issues, increased age or an increased number of hours walking per day [9]. These predictors should be screened for clinically if ECSWT is going to be used to treat PF. In our study, the presence of vascular and neurological disorders such as diabetes mellitus was used as an exclusion criteria as were other variables reported to adversely affect the treatment outcome or put into question the validity of the diagnosis. Clinicians using ECSWT should consider the possible positive and negative predictors and the above information to optimize treatment results. Clinicians should be selective in order to choose the most appropriate patients to treat with ECSWT thereby decreasing some of the wide range of effects reported in treatment and insure an optimal outcome.

Contradictory findings have been reported with the use of ECSWT and PF and whether the satisfaction of patients having ECSWT was related to the outcome of treatment or to

the process of treatment [29]. This is definitely a factor that may explain the wide range of success rates reported. Certain patients may have certain expectations for treatment and prefer hands on treatments or exercise based active treatments as compared to a passive therapeutic modality. This must be considered by the clinician who is using evidence based practice and sound clinical reasoning and trying to balance and integrate the information and research available with the expectations of the patient in deciding what treatment to use. If the patient has uncertainty about using ECSWT or is expecting some other form of treatment then this may impact on the success of the treatment and outcome. The clinician should then consider combining ECSWT with other forms of treatment in these cases.

A BMI of greater than 30 kg/m² has also been identified as an associated risk factor for developing PF [1], [3], [4], [6], [9]. The mean BMI for the current sample was 30.4 kg/m² placing the subjects in the obese category and this is consistent with this reported risk factor. The healthcare provider should educate the patient on the importance of exercise, dietary modifications and the possible contribution of increased body weight to heel pain. ECSWT can be considered as a treatment option for both the sedentary and athletic population. Good to excellent results have been reported in 71% of runners receiving treatment with ECSWT with the treatment effects lasting up to 24 months post-treatment [28]. In the current study, VAS scores for heel pain following activity were improved with all groups at three months post-treatment. As a result, the use of ECSWT may be an appropriate treatment consideration to use in the physically active population allowing the individual to continue or return to their sport, occupation or functional activity with less heel pain. We may assume that our subjects were not very active due to the high calculated BMI in our sample. As a result, it is difficult then to assume that the findings can be generalized and applied to the more active or athletic population. A question that can be raised for future study also is whether the use of ECSWT in combination with other forms of treatment such as active exercises or diet modification may produce even better results in the sedentary or active populations.

It is thought that PF is a self-limiting disorder that will usually resolve in 12 months, 80% of the time regardless of the intervention [2], [4], [5]. Conversely, 10 to 20% of patients may not respond to any form of conservative treatment [1], [5], [11]. The mean length of time that subjects had heel pain in our study was 10 months. Only 12% of our sample had acute PF (heel pain that was present for less than 6 weeks) while 88% had chronic PF (heel pain that was present for greater than six weeks). In our study, 60% of individuals reported a decrease in heel pain and good overall improvement with treatment. Heel pain may be decreased and recovery time shortened if ECSWT is used earlier in the course of treatment. Further study, however, comparing the use of ECSWT or combined treatments in both the acute versus chronic PF patient may be beneficial.

Pain is a subjective, complex and multi-dimensional sensation. As a result, using pain as a measure of treatment

effectiveness may be considered to be a potential weakness. The current study also used the LEFS to monitor improvement in overall function. The improved function may also indirectly reflect an improvement in heel pain. Indeed, all groups reported improved functional outcomes measured by the LEFS. The LEFS is also limited in that it is a self-report measure that is not based on actual testing, observation or objective assessment of the patient's functional ability. The psychometric properties of the LEFS has been completed with good results reported but future study combining the use of the LEFS with an objective functional assessment measure may be a better study. Objective functional assessment of walking, standing or running tolerance, for example, can be measured and compared to the commonly used functional outcome scales. The future development and validation of a PF specific outcome measurement tool may also be beneficial to combine with other pain or functional scales.

Most studies examining the effects of ECSWT have looked at the effects on pain or function. No studies have examined or reported effects on ROM, strength, or accessory movement findings pre or post-treatments. Subjects in the present study demonstrated decreased ROM for plantarflexion, dorsiflexion, inversion, and eversion and first MTP flexion, and extension prior to having treatment. Significant improvement was noted post-treatment in plantarflexion, dorsiflexion, and eversion and first MTP flexion ROM. Although no direct benefit can be attributed to the ECSWT directly, it can be hypothesized that the reduction in pain may have reduced some of the protective muscle tone in the musculature of the lower leg and ankle region as the subject moved towards end range positions. The consistent finding of reduced ROM in the ankle and first MTP joints makes it prudent for the examining healthcare provider to consider the use of active or passive stretching exercises to address these ROM restrictions.

The healthcare provider must also consider that talocrural, subtalar and first MTP joint hypomobility may also contribute to the reduced ROM. The assessment of the joint biomechanics and accessory glide may also be beneficial. Future studies examining the effects of ECSWT should be designed looking at the effects of ECSWT combined with other interventions including stretching exercises, joint mobilizations or joint manipulations to see if this produces better results and improvements in ROM.

Studies examining the effects of specific joint mobilizations alone or compared to ECSWT for the treatment of plantar heel pain is very limited. No such studies have been performed looking at the effects of ECSWT and joint mobilizations together. If manual therapy is reported in the literature as part of the treatment intervention used for patients with PF, often a variety of techniques to a wide range of joints were used [21], [30], [33], [34], [37], [38]. The treatments used were not consistent for all subjects making comparison of findings extremely difficult. Some subjects had joint mobilizations, massage or passive stretching to the foot while others had a variety of these treatment techniques to the more proximal joints. In many cases, the techniques were all classified and

described as joint mobilizations but lacked specific details regarding frequency, grade and the type of technique used.

In one such example, joint mobilizations directed to the hip, knee and ankle combined with exercises were reported to be superior to the use of electrical therapeutic modalities and exercise in the treatment of plantar heel pain [37]. VAS, LEFS and Foot and Ankle Ability Measure (FAAM) scores improved with joint mobilizations to the hip, knee, inferior tibiofibular, talocrural, subtalar, or calcaneocuboid joints and with the use of several soft tissue techniques [37]. The many different techniques used varied from subject to subject. The treating practitioner used an impairments based manual therapy approach and decided what treatment to use based upon the assessment findings. Thus, each subject in the mobilization and exercise group did not receive the same treatment technique making it difficult to conclude what produced the treatment effect. Future research that clearly defines and examines accessory joint glide involvement and uses combinations of treatments will also be beneficial in that it will add to the limited body of research currently available examining the treatment of PF.

Slight weakness was evident with resisted isometric strength findings pre-treatment for all movements with the greatest weakness being present with plantarflexion and inversion. There was no significant difference in resisted isometric ankle strength before or after treatment. This may highlight the fact that PF may not necessarily be associated with strength issues but rather mobility issues. This is consistent with the findings that decreased first MTP ROM, and decreased dorsiflexion may be a potential cause to the development of PF. It has been reported that decreased intrinsic muscle strength may be a cause for the development of PF [1], [4], [5], [7]-[11]. Intrinsic muscle strength was not measured in our study but this may be something for researchers to consider for the design of future studies examining the strength findings for patients with PF.

Another consideration may be assessing strength with the use of a more objective measurement device such as a strength dynamometer. This was not used in the current study and is considered a limitation of the study. Future studies should also examine the strength of the intrinsic muscles of the sole of the foot and also other specific muscles directly involved in the gait cycle such as the peroneus longus, tibialis anterior, and tibialis posterior muscles. The strength of these muscles should be examined using combined movements to see if there is weakness present, and if this is a contributing factor to the development of PF. One of the limitations of the current study is the fact that a true control group was not used in the study design. A group that did not receive any intervention was not included and monitored. Also all patients were aware of the intervention that they were receiving. No blinding or placebo control was used. It is difficult to have a group that does not receive any intervention or to produce a placebo effect with this type of therapeutic modality in a clinical environment.

Another limitation of the present study is the relatively short follow up period lasting three months that was used to monitor

post-treatment effects and changes. With a longer follow up assessment period, the true long term success may be clarified.

Our sample also was a relatively sedentary and overweight group making it difficult to extrapolate our conclusions to more of an active and athletic population. Future studies should include a more active or athletic population so that the findings can be applied to this sport specific population. The use of ECSWT should also be examined in more of an acute population with future studies as most studies, including the current study, have examined ECSWT in the chronic population.

Another limitation that must be considered is the fact that the VAS and the LEFS are self-report measures for function and pain that are not based on actual testing, observation or objective assessment of the patient. Future study combining the use of the VAS or LEFS with an objective functional assessment may be beneficial in identifying significant treatment effects and differences. Pressure pain threshold may also be monitored with the use of a dolorimeter to measure pain on palpation rather than with the use of a self report measure. This provides a more objective measure of pain. Another consideration might be the use of an alternate pain questionnaire or measure such as the four item pain intensity measure known as the P4[39]. Several studies have used the VAS to monitor change and the effects of ECSWT but this may not be sensitive enough to monitor changes over time in some patients. For example, if a subject presented with a very low score on the VAS at baseline, the measure chosen may not allow for clinically significant change over time. Consideration of alternate pain or functional measures should be considered.

Another consideration for future study should also look at the fact that rarely has the research examined the effects of ECSWT in combination with other treatments. Health care providers normally do not treat with only one modality or treatment approach alone but rather a combination of treatments in an attempt to obtain the desired positive effect for the patient. It is thus important to examine how treatments work in combination. Future studies designed to examine the effect of ECSWT, exercise or manual therapy used alone or when combined, for example, may provide further information on how to best manage and treat PF.

The results of our study found that subjects experienced improvements in heel pain, function and ROM and this supports the use of ECSWT in the treatment of patients with PF. ECSWT is an effective treatment consideration for patients with PF and is a modality that seems to present with little complications. With only three treatments, patients may experience decreased heel pain and recovery time, improved function and ROM, and may be able to return to normal functional activities, gainful employment and sporting activities quicker.

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