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A Randomized Clinical Trial on the Effects of Extracorporeal Shockwave Therapy, Joint Mobilizations and Exercise on Plantar Heel Pain in Patients with Plantar Fasciitis

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Abstract Plantar fasciitis (PF) is the most common cause of heel pain today impacting on the patient's walking ability, work tolerance, and ability to participate in active sport. Two million people in the United States (US) are treated for PF yearly with heel pain accounting for 11 to 15% of visits to medical professionals. It is estimated that 10% of the US population will develop PF during their lifetime. Treatment for PF may include a variety of interventions ranging from conservative treatment to surgical interventions. One of the suggested treatments for PF is the use of extracorporeal shockwave therapy (ECSWT). ECSWT is a relatively new therapeutic modality that has been used in the treatment of PF and a variety of other musculoskeletal disorders with some success reported. Normally healthcare providers do not treat with the use of only one modality or treatment approach but rather a combination of treatments in an attempt to obtain a desired positive effect on the patient. The research available on the use of ECSWT is limited in that it has not been determined whether this modality used in isolation, or in combination is the most effective. Research has been conducted comparing ECSWT to placebo and a variety of controls but the effectiveness of combinations of treatment has not been studied. Therefore, the purpose of this study was to compare the effects of ECSWT alone, to ECSWT and joint mobilization, and ECSWT and exercise, on heel pain in patients with PF, as measured by the visual analog scale (VAS) and Lower Extremity Functional Scale (LEFS). Subjects (N=75) were randomly assigned into 3 groups: ECSWT, ECSWT and joint mobilizations to the talocrural, subtalar, and first metatarsophalangeal (MTP) joint, or ECSWT and stretching for the gastrocnemius, soleus, and plantar fascia and strengthening for the ankle. Subjects received three treatments in total spaced one week apart. A VAS for pain and LEFS were measured pre-treatment and three months post-treatment. All groups demonstrated statistically significant improvement over time in all VAS scores and in the LEFS ($P<.05$). There was a statistically significant difference in VAS for heel pain following activity between the ECSWT and joint mobilization group and ECSWT and exercise group ($F= 3.577$, $p= .033$) with a greater reduction in pain in the ECSWT and joint mobilization group. Further research is required using an alternative study design to compare the combinations of treatment to a control or placebo group. The findings of this study, however, indicate that if ECSWT is going to be combined with another treatment, then the combination of ECSWT and joint mobilization may be more effective than combining ECSWT with exercise.

Keywords Extracorporeal shockwave therapy, Plantar fasciitis, Joint mobilizations, Exercise

1. Introduction

Plantar fasciitis (PF) is the most common cause of heel pain today with 10% of the population in the United States (US) developing it in their lifetime[11, 20, 43]. The functional implications of this disorder result in decreased walking tolerance, the inability to complete daily functional and work related tasks and the inability to participate in active exercise and sport. Two million people are treated for PF in the US yearly with heel pain accounting for 11 to 15% of visits to medical professionals (physicians, physiotherapists, chiropractors and athletic therapists)[11, 20, 43]. Although the exact causes of PF are unknown, it is felt that PF may be associated with several factors including overuse, poor intrinsic muscle strength, over pronation and various foot deformities[7, 10, 27, 48]. Other risk factors also include increased age, increased body mass index (BMI) greater than 30kg/m^2, increased height and weight, decreased ankle dorsiflexion and decreased first metatarsophalangeal

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(MTP) joint range of motion (ROM)[29, 53, 56, 58].

Questions regarding whether PF is an inflammatory condition with prostaglandin mediated inflammation, or rather a degenerative condition have arisen and may impact on treatment decisions[23]. PF often does not respond to typical treatments that are used for acute inflammatory conditions and this may be partly due to the lack of inflammatory mediators present. Typical treatments for PF include interventions ranging from conservative to surgical. The use of non-steroidal anti-inflammatory medications (NSAIDS), therapeutic modalities such as ultrasound therapy, laser and interferential current, orthotics, nights splints and a variety of taping techniques have been proposed with mixed results reported[33]. Short term relief has been reported with the combination of NSAIDS delivered via iontophoresis or with the use of custom or pre-fabricated orthotics or night splints[33, 61]. Other proposed treatments include the use of manual therapy and stretching and strengthening exercises[3, 9, 12, 15, 23, 26, 30, 33, 36, 44, 45, 59]. Stretching exercises for the gastrocnemius, soleus and plantar fascia have been shown to provide short term pain relief lasting only a few hours to a few days[18, 31, 39, 40, 47, 49]. It has been recommended that the calf muscle stretches should be held for 30 second holds and performed for 3-5 repetitions per day[18, 40, 49]. Longer relief has been reported in patients treated with fascial specific stretching exercises[13, 16, 52]. Stretching and mobilizations of the first MTP into dorsiflexion as well, may be beneficial[14]. There has been limited, high quality studies performed on the use of manual therapy as an intervention for PF. Suggested mobilizations to the talocrural, subtalar and first MTP joints have been recommended but the evidence to support the use of manual therapy to these articulations is contradictory[33, 34, 60]. Some studies have reported that combinations of treatment may be the optimal treatment choice for patients with PF. For example, combining manual therapy with exercise may be more effective than combining electrotherapeutic modalities and exercise[9].

Drake et al[16] examined the effects of stretching compared to custom foot orthotics in 15 patients with PF. Stretches consisted of plantar fascial, gastrocnemius and soleus stretches and general ROM exercises first thing in the morning. Significant improvement was demonstrated with both the use of orthotics and stretching[16]. Renan Ordine et al[40] also examined the effect of myofascial trigger point therapy versus stretching exercises on patients with plantar heel pain. Sixty patients were randomly assigned to either the stretching group or the stretching and manual therapy group. Self-stretching exercises consisted of gastrocnemius, soleus and plantar fascial stretches while the manual therapy group consisted of trigger point pressure and longitudinal stroking over the gastrocnemius muscle. Clinically significant improvement was evident with the combination of stretching and manual soft tissue techniques[40].

Extracorporeal shockwave therapy (ECSWT) is a new therapeutic modality that has been used in the treatment of acute and chronic PF and a variety of other musculoskeletal conditions with varied success reported[5, 6, 50]. The exact physiological affect and mechanism on healing is unknown but several hypotheses exist. A shockwave unit generates soundwaves at a frequency of 10-15 Hz causing cavitation bubbles and a water jet effect which creates microscopic holes and hemorrhaging in the plantar fascia. This initiates a local inflammatory reaction and chemical changes[41]. These physiological effects have been proposed to be beneficial in the treatment of the chronic and degenerative changes present in the tissue of the plantar fascia[7, 21]. Other hypotheses on the affects of ECSWT include the degeneration of axons and sensory nerves, the activation of the Gate Control Theory, the chemical alteration of receptor neurotransmitters and cell mediums and reduced production of inflammatory mediators, calcitonin gene related peptide and substance P[21, 22, 32, 37, 46]. Once again, these proposed benefits may help reduce pain and initiate healing in the plantar fascia.

Studies examining the effectiveness of ECSWT in patients with PF have reported positive treatment effects in decreasing pain and improving function with success ranging from 50 to 90% with a low recurrence rate of 5 to 7%[14, 29]. A systematic review and meta-analysis on the effectiveness of ECSWT in the treatment of plantar heel pain, however, has reported mixed findings and the studies that did find positive results had a small effect size[54].

Gollwitzer et al[21] examined the effects of ECSWT on 40 patients with PF. Patients were randomly assigned to either the ECSWT group or the sham group. The ECSWT treatment protocol consisted of three sessions of 2000 electromagnetic generated shockwaves spaced one week apart. A visual analog scale (VAS) was used to compare the effects of the treatments. Significant improvement was noted in the ECSWT group as compared to the sham treatment group[21]. Gerdesmeyer et al[20] also examined the effects of radially generated ECSWT versus placebo in a very large study with 245 patients with chronic PF. Clinically significant improvement in the VAS scores and in the functional scale scores was evident in the ECSWT group compared to the placebo group. Overall success rate was 61% compared to 42% in the placebo group[20].

In another large retrospective study of 225 patients with chronic PF who were treated with ECSWT, Chuckpaiwong et al[7] reported success rates of 71% at three months post treatment and 77% at twelve months post treatment. Similar positive findings were reported in Cheing's study comparing ECSWT and ultrasound therapy on plantar heel pain as measured with the VAS and functional tolerances for standing and walking[6]. Several authors have summarized the use of ECSWT in the treatment of PF and have described the common use of the VAS in combination with other functional measures to analyse the effects of the treatment. Common parameters used in the treatment protocols cited was 2000 shockwaves applied to the painful region and treated three times per week, spaced one week apart[6, 12].

Wang et al[55] examined the long term effects of ECSWT on 168 patients with chronic PF compared to patients having

NSAIDS, orthotics, physical therapy and exercise using a 100 point scoring system for pain and a VAS. The ECSWT group demonstrated excellent results in 69.1% of the cases compared to 0% in the control group. Malay et al[32] examined the effects of ECSWT on 172 patients compared to a placebo group with a single treatment. VAS scores were significantly improved in the shockwave group in comparison to the placebo group at three months and 12 months post treatment. Rompe et al[44] compared the effects of plantar fascial specific stretching to ECSWT on 102 patients with PF. They reported that patients that received plantar fascial specific stretching demonstrated significant improvement in acute pain and symptoms when compared to the ECSWT group alone. Looney et al[31] compared the combined effects of a home stretching program for the calf muscles and plantar fascia and the use of soft tissue mobilization using a Graston Instrument on the numerical pain rating scale, Lower Extremity Functional Scale (LEFS) and Global Rating of Change Scale in 10 patients with PF. All patients demonstrated a significant improvement at the eight week follow up with the combined treatment interventions[37].

1.1. Clinical Justification and Purpose

The use of ECSWT continues to expand clinically. As highlighted previously, several studies have examined the effects of ECSWT in isolation for PF, or in comparison to placebo and sham treatments, but rarely in combination with other treatments. Healthcare providers (physiotherapists, athletic therapists, chiropractors) normally do not treat with only one modality or treatment approach but rather a combination of treatments. Therefore, the purpose of this study was to assess the effects of ECSWT in isolation compared to ECSWT combined with either joint mobilizations or exercise on plantar heel pain in patients with PF as measured by the VAS and LEFS. It was hypothesized that ECSWT combined with either exercise or joint mobilizations would have a more positive effect on function and heel pain than ECSWT alone as measured by the LEFS and VAS.

2. Methods

2.1. Subjects

This randomized clinical trial pre-test post-test design included 75 subjects divided into three treatment groups. The treatment groups consisted of either ECSWT, ECSWT and joint mobilizations to the talocrural, subtalar, and first MTP joint, or ECSWT and stretching exercises for the gastrocnemius, soleus and plantar fascia and strengthening for the ankle. Prior to recruiting subjects, ethical approval for the study was obtained by the university Research Ethics Board.

The sample of convenience was recruited over a one year period of time from an urban, private, outpatient physiotherapy clinic. Eighty-five patients diagnosed with PF were referred by their physician into the study. The primary investigator, a registered physiotherapist, screened each patient for inclusion and exclusion criteria. Three participants did not meet the inclusion criteria and seven did not consent to participate in the study.

All participants were between the ages of 22 and 68 years. All participants met the following inclusion criteria: (1) had unilateral foot pain localized to the heel, anteromedial calcaneal tubercle, body of the fascia or medial arch; (2) had heel pain in the morning with the first few steps and; (3) had heel pain after getting up after prolonged sitting, walking or running. Participants were excluded from the study if they met the following exclusion criteria: (1) had previous surgery to the plantar fascia; (2) had any other form of treatment during the study period excluding the intervention assigned; (3) had a history of foot fracture or congenital deformity of the foot; (4) used an assistive device such as an ankle foot orthoses; (5) had bilateral heel pain; (6) had any contraindications such as vascular or neurological disorders of the feet, pregnancy, implanted metal, or were taking NSAIDS, aspirin or coumadin.

2.2. Outcome Measures

The primary outcome measure commonly used in studies examining the effectiveness of various treatments for PF include the VAS and the LEFS[6, 7, 8, 9, 20, 21, 31, 32, 55]. Thus, the intensity of heel pain at rest, after activity, and overall improvement in heel pain, were assessed using a 100 mm horizontal linear VAS. The self-report VAS has evidence of good validity, reliability and psychometric properties, and has been validated as a reliable measure for pain in musculoskeletal disorders[25, 51]. The pooled coefficients for the VAS ranges from .73-.80 for test-retest reliability and the pooled value for construct validity from .82-.94[25, 51]. The minimally clinically significant difference for the VAS score is a change of 30 millimeters on a 100 millimeter VAS[25, 51]. Pain, however, is a complex, subjective and multi-dimensional sensation. As highlighted previously, this dependent variable is commonly used in the analysis of pain but we must also consider the practical difficulties of its use. This outcome measure must be administered electronically or on paper; when using paper scales it must be insured that the length of the line is in fact not distorted in length by copying or printing; and lastly, the orientation of the scale (horizontal versus vertical) may produce varied results among different users[28, 57]. As a result, a horizontal VAS scale was used in the current study and we insured that no distortion was present and that the scale was in fact 100 mm in length. Subjects filled out the VAS and were asked to consider the following questions: (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 compared to the initial onset. The amount of pain was estimated by measuring in millimeters the distance from the “no pain” marker to the mark provided by the

subject.

Secondary outcomes in this study included overall functional abilities. Functional ability was assessed using the LEFS. The LEFS has evidence of good psychometric properties, validity and reliability. The LEFS has an internal consistency ranging from α = .90-.96, test–retest reliability ranging from .88-.94, and minimal detectable change and minimally clinical significant differences of nine[4, 8, 58]. The LEFS is useful with either acute or chronic impairment, is sensitive to change over time, and can be used in subjects of all ages and functional levels[4, 8, 58].

2.3. Data Collection and Test Procedures

The principal investigator, who was a student completing this study in partial fulfillment of his doctoral degree, obtained voluntary consent from subjects, assessed, and randomly assigned each subject to a treatment group; thus, there was no blinding to group or treatment of the principal investigator. Once the randomization process was completed, anthropometric measures, strength, ROM, accessory movement and stability testing of the foot was performed.

Subjects in group one received only 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[8]. The applicator was positioned over the painful site and plantar fascia. Subjects received three treatments in total spaced one week apart over a three week period.

Subjects in group two received ECSWT as described previously and joint mobilizations. Mobilizations included posterior glides of the talus on the tibia to increase talocrural dorsiflexion, lateral glides of the calcaneous on the talus at the posterior subtalar to increase supination, and dorsal glides of the first proximal phalanx on the first metatarsal to increase MTP extension of the first ray. Mobilizations consisted of three sets of grade II and three sets of III oscillations as described by Maitland, performed for 30 seconds[24]. These mobilizations were chosen as over pronation, decreased ankle dorsiflexion and decreased first MTP joint ROM have been described as contributing risk factors for PF[7, 10, 11, 27, 29, 44, 48, 53, 56]. The goal of these mobilization techniques was to increase ROM, thereby, reducing stress on the plantar fascia. Each subject received three treatments in total spaced one week apart over a three week period of time and included both ECSWT and mobilizations. Subjects in group two were not prescribed any therapeutic exercises (stretching or strengthening).

Subjects in group three received ECSWT as described previously and stretching exercises for the gastrocnemius, soleus and plantar fascia, and ankle strengthening. Calf muscle and plantar fascial stretches were held for 30 seconds with three repetitions performed three times per day[31, 47]. Three sets of ten repetitions of strengthening exercises for the ankle with theraband and towel exercises for the intrinsic foot muscles were performed three times per day. Exercise parameters including frequency, repetitions and sets were based upon Rhea et al[42] and the American College of Sports Medicine guidelines[1,2]. These stretches were chosen as decreased dorsiflexion has been identified as a possible cause of PF[7, 11, 27, 29, 56]. When these stretching exercises have been used, good relief in heel pain has been reported[18, 31, 39, 40, 47, 49]. Longer term relief has been reported in patients that were also treated with plantar fascial stretching[13, 16, 52]. As a result, the combination of these exercises were used. Subjects received three treatments in total spaced one week apart over a three week period of time. During each treatment subjects received ECSWT. The exercises were performed independently at home but the exercise details were reviewed each week at the treatment session to formally check and review compliance with the exercise and encourage the participants to complete the program appropriately. No other form of exercise compliance was monitored and no level of non-compliance was established to disqualify participants from the study (figure 1).

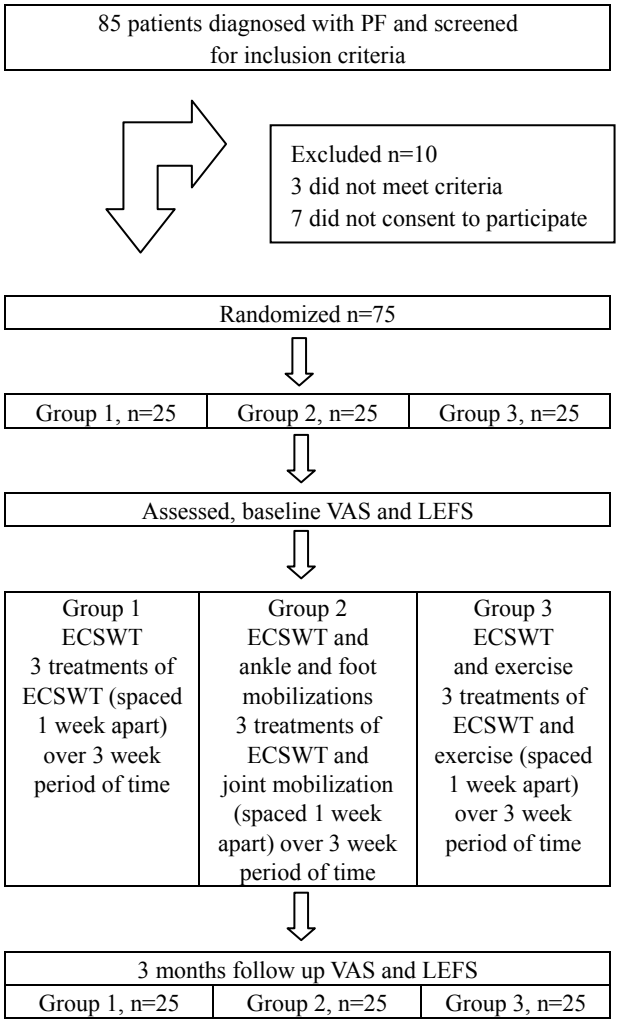

Figure 1. Study design flowchart

All subjects were treated individually by the principal investigator, a physiotherapist with 20 years of clinical

experience and a Fellow of the Canadian Academy of Manual Physiotherapists. Subjects had no contact or knowledge of the identity of any other participants. Each session lasted approximately 30-60 minutes. All baseline and follow-up measurements and treatment sessions were carried out by the principal investigator. All subjects were also instructed to avoid NSAIDS or aspirin products for the duration of the study.

Pre-test measures for the LEFS and VAS were taken prior to the initial assessment. These variables were also reassessed during each individual treatment session and then reassessed at three months post-treatment. For analysis, only the pre and 3 months post measures were used. All subjects participated in each treatment and testing session and no adverse events or dropouts occurred in the study.

2.4. Sample-Size Calculation

The sample-size calculation for analysis of variance (df_b=2) for VAS score utilized a change of 30 mm as the minimal clinically significant difference (MCSD) on a 100 mm scale. A study by Williamson and Hoggart[57] found that repeat measures with the VAS could vary by 20%. Thus, with the significance level set at .05, a standard deviation (SD) of 20 mm was used to achieve a power level of 85% for an estimated 21 subjects per group.

The sample-size calculation for a 2-tailed test for VAS score utilized a change of 30 mm as the minimal clinically significant difference (MCSD) on a 100 mm scale with a standard deviation (SD) of 20 mm. To achieve a power level of 90% with the significance level set at .05, 25 subjects per group were needed.

2.5. Statistical Analysis

SPSS Version 20.0 (SPSS Inc., Chicago, IL) was utilized to analyze means, SD and 95% confidence interval (CI) for the descriptive characteristics of the cohort and for pre and post changes within and between treatment groups. The Kolmogorov-Smirnov test for normality was used and was not significant revealing a normal distribution of the data. A One-way ANOVA was used to determine if there was a difference between treatment groups for the VAS and LEFS. If significance was found a Tukey post-hoc test was used to identify where the difference lies. Cohen's d was used to calculate effect size with .8 being large, .5 medium, and .2 small. A dependent T-test was used to determine if there was a significant change from pre to post scores for the VAS and LEFS scores within each group. For all analyses the alpha level was set at .05.

3. Results

The sample consisted of 75 subjects (22 males and 53 females) with a mean age of 47 years with each subject randomized into one of three groups, ECSWT (n=25), ECSWT and joint mobilizations (n=25), and ECSWT and exercise (n=25). Descriptive data for height, weight, and BMI is summarized in Table 1. All groups improved over time in all VAS scores and in the LEFS (Table 2).

The baseline score was subtracted from the final score to obtain a change value for each appropriate dependent variable. A One-way ANOVA was run to determine if there was a statistically significant difference in the pain levels between treatment groups for the LEFS score and VAS of pain at rest, with activity, and pain improvement (see Figures 2-5). There was a statistically significant difference between groups for pain levels with activity (F (2, 72)= 3.577, p= .033). Effect size was calculated using Cohen's d =.655 which demonstrated a large effect size, yielding a 99% power. The Tukey post hoc test identified a difference between the ECSWT and mobilization and ECSWT and exercise group. The mean VAS score for pain after activity was significantly lower for ECSWT and mobilization compared to ECSWT and exercise (Table 2). No other statistical significance was found between groups for any of the other dependent variables.

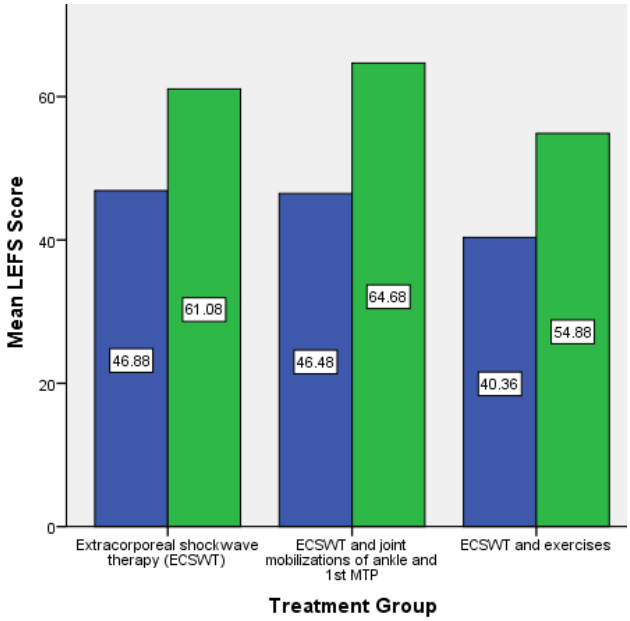

Figure 2. LEFS scores by treatment group pre-treatment and post-treatment (mean pre and post LEFS scores contained in text box within columns; pre-treatment LEFS score ■; post-treatment LEFS score ■;)

Table 1. Demographic Information for all Subjects

Treatment Group	ECSWT	ECSWT and Joint Mobs	ECSWT and Exercise
Age (years)	48 ± 10.9	47 ± 6.0	48 ± 8.8
Gender	9 M, 16 FM	8 M, 17 FM	5 M, 20 FM
Height (inches)	65.8 ± 4.5	67.0 ± 4.4	66.1 ± 3.1
Weight (pounds)	192.8 ± 26.2	187.2 ± 24.0	190.5 ± 22.8
BMI (kg/meter^2)	31.3	29.3	30.7

Abbreviations: BMI, Body Mass Index; M,male;FM,female.

Table 2. Group Outcome Data for Pain (VAS) and Function (LEFS)

	ECSWT (n=25)	ECSWT and Jt Mobs (n=25)	ECSWT and Exer (n=25)
VAS At Rest			
Pre-treatment	34.8 ± 29.0	29.4 ± 33.6	45.8 ± 29.4
Post-treatment	18.2 ± 24.4	9.5 ± 12.9	25.0 ± 27.4
Within group change score	16.56 (7.6, 25.6)	19.76 (9.0, 30.5)	20.68 (6.2, 35.1)
Within	[b]T= 3.79, P= .001	[b]T=3.84, P= .001	[b]T=2.97, P=.007
Between	F= .147, P=.863		
VAS After Activity			
Pre-treatment	79.6 ± 13.5	78.7 ± 6.8	73.6 ± 18.5
Post-treatment	31.5 ± 23.2	25.64 ± 22.7	42.4 ± 34.0
Within group change score	48.0 (39.3, 56.7)	[a]51.7 (40.9, 62.5)	[a]33.0 (20.3, 45.6)
Within	[b]T = 11.39, P < .001	[b]T=11.46, P < .001	[b]T=4.81, P < .001
Between	[a]F=3.57, P=.033		
VAS Overall Improvement			
Pre-Treatment	.00 ± .00	.00 ± .00	.00 ± .00
Post-Treatment	63.4 ± 23.5	72.3 ± 30.7	52.2 ± 34.8
Within	[b]T= -13.46, P < .001	[b]T= -11.76, P< .001	[b]T=-7.48, P < .001
Between	F=2.81, P=.067		
LEFS (0-100)			
Pre-Treatment	46.9 ± 12.3	46.5 ± 15.0	40.4 ± 16.6
Post-Treatment	61.1 ± 14.9	64.7 ± 16.5	54.9 ± 20.0
Within group change score	13.6 (7.3, 20.0)	18.7 (12.26, 25.1)	14.5 (6.64, 22.4)
Within	[b]T= -4.76, P < .001	[b]T= -5.75, P < .001	[b]T=-3.80, P= .001
Between	F=.643, P=.529		

Abbreviations: VAS, Visual Analog Scale; LEFS, Lower Extremity Function Scale; ECSWT, Extracorporeal Shock Wave Therapy; Jt Mobs, joint mobilization; Exer, Exercise.
[a] One-Way ANOVA Significant at P ≤ .05.
[b] Independent T-test significant at P ≤ .05. Upper and lower bound means in parentheses at 95% confidence interval.

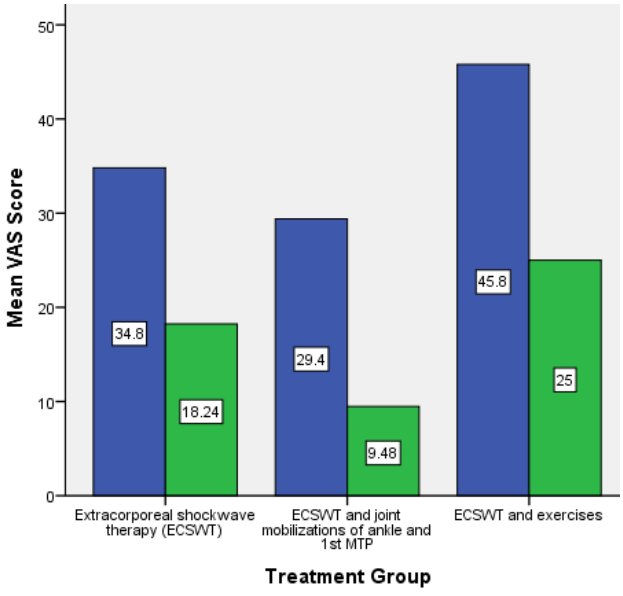

Figure 3. VAS scores for heel pain at rest by treatment group pre-treatment and post-treatment (mean pre and post VAS scores contained in text box within columns; pre-treatment VAS score ■; post-treatment VAS score ■;)

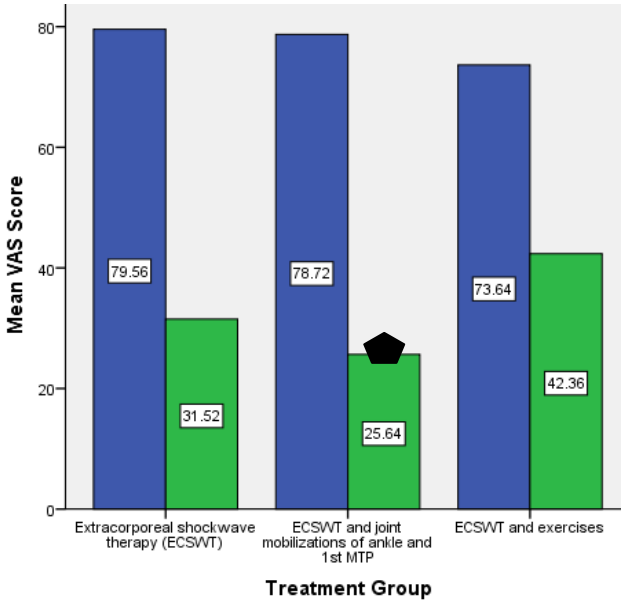

Figure 4. VAS scores for heel pain following activity by treatment group pre-treatment and post-treatment (mean pre and post VAS scores contained in text box within columns; pre-treatment VAS score ■; post-treatment VAS score ■; ⬟ significant between groups P<.05)

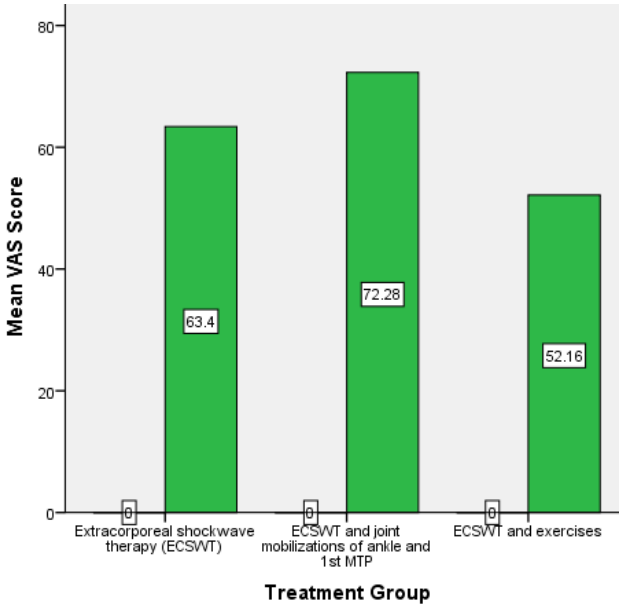

Figure 5. VAS scores for overall improvement in heel pain by treatment group pre-treatment and post-treatment (mean pre and post VAS scores contained in text box within columns; pre-treatment VAS score ; post-treatment VAS score ;)

4. Discussion

It was hypothesized that ECSWT in combination with mobilization and exercise would have a greater effect on heel pain and function compared to ECSWT alone. All three groups had a clinically significant change in the VAS score for pain after activity, but the combination of ECSWT and joint mobilizations resulted in a statistically (p=.033) and clinically significant improvement when compared to the combination of ECSWT and exercise. This finding demonstrated a large effect size (d=.7) suggesting that there is a strong relationship between this treatment and the resulting reduction in pain. Joint mobilizations of the talocrural, subtalar, and first MTP joints when combined with ECSWT may be an effective treatment option in improving heel pain. Furthermore, all three groups improved in function as measured by the LEFS. Although this improvement was not statistically significant, each group demonstrated a clinically significant change in LEFS scores (post-treatment score changed by more than 9 points).

Although not statistically significant, the greatest improvement in VAS and LEFS scores was consistently found in the ECSWT and joint mobilizations group. Subjects that were randomly allocated to this treatment group all received joint mobilizations whether or not it was necessary and joint stiffness was present. In the clinical setting, the healthcare provider would assess the patient and conclude whether joint mobilizations are appropriate. This would be based upon the assessment and clinical reasoning findings, and the healthcare provider's determination that joint mobilizations were indicated. Therefore, the healthcare provider that is using ECSWT for the treatment of the PF patient should consider combining this with joint mobilizations to the talocrural, subtalar, and first MTP joints especially if ROM and accessory glide restrictions are noted during the assessment. This may, in turn, produce the most effective and greatest reduction in the patient's heel pain.

It should be highlighted that the inferences made above from the results of this study are limited by the fact that a control group was not used. The initial intent of this study, however, was to assess whether the use of ECSWT used in isolation would have the same effects as if ECSWT was combined with joint mobilizations or exercise. Based on the current results the consistent trends described above definitely suggests some positive findings and warrants further study examining the combinations of treatment using a different study design and control group.

Studies examining the effects of mobilizations alone or compared to ECSWT are very limited. Cleland et al[9] reported that mobilizations directed to the hip, knee, and ankle combined with exercises were superior to the use of therapeutic modalities and exercise in improving heel pain and function in patients with PF. Cleland et al[9] used similar joint mobilizations to the talocrural and subtalar joints but did not include mobilizations of the first MTP joint. They mobilized several other joints including the hip, knee, inferior tibiofibular, and calcaneocuboid joints and also performed several soft tissue techniques. The different manual therapy techniques used by Cleland et al[9] varied from subject to subject with the treating practitioner using an impairments based manual therapy approach deciding what treatment to use based upon the assessment findings. 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 studies looking at ECSWT in combination with other interventions such as exercise or joint mobilizations should incorporate this impairment based treatment progression. This would allow the healthcare provider to use clinical reasoning to progress or modify the treatment regime according to the patient's clinical presentation.

It is possible that in the current study the combination of ECSWT and joint mobilizations to the talocrural, subtalar, and first MTP joints may have increased the joint mobility, improved the efficiency of the windlass mechanism, or had a segmental anti-nociceptive effect via stimulation of local mechanoreceptors thereby reducing strain on the plantar fascia. These treatments may have also improved the blood flow to the region, increased the elasticity of the tissue and stimulated connective tissue remodeling[21, 22, 24, 32, 37, 41, 46]. These hypotheses may explain some of the benefits noted in our study with this combination of treatments but due to the current study design and the lack of a control group we must make this conclusion cautiously.

Overall, the ECSWT treatment group and the ECSWT and exercise treatment group improved similarly suggesting that the addition of exercise was not consequential. A possible reason for this may have been due to a lack of compliance by subjects with the prescribed exercise program, or due to the actual exercises that were used as part of the intervention.

The therapeutic benefits, optimal exercise, intensity, speed, load and frequency of any stretching or strengthening program used in patients with PF is unclear, and there is no explicit explanation as to why or why not exercise may or may not help. The lack of improvement with exercise combined with ECSWT may also have been due to the lack of treatment and the possibility that three treatment sessions were not sufficient. Rompe et al[45] compared the effects of ECSWT to exercise and reported a greater improvement in acute heel pain with plantar fascial stretching compared to ECSWT. Rompe et al[44] also reported improved function and greater overall satisfaction in another study in patients who received therapeutic exercises compared to ECSWT. The contrasting findings from the current study may be attributed to the slightly different stretching parameters used (type of exercise and dosage). The stretches used by Rompe et al[44, 45] consisted of a static self-manual stretch to the plantar fascia completed in a sitting position compared to stretches for the gastrocnemius and soleus muscles and the plantar fascia completed in standing used in the current study. The use of the combination of stretching exercises for the plantar fascia and calf muscles in our study is consistent with what has been described in several previous studies[16, 19, 22, 45, 54]. The length of time that the stretch was held also differed and was longer in our study (30 second holds, for three repetitions and repeated three times per day compared to 10 second holds, for 10 repetitions and repeated twice per day). The exercise program also differed in our study because the stretching exercises were also combined with strengthening exercises and this may have somehow impacted on the results.

Other possible factors that may have influenced the results of this study is the treatment process. The ECSWT and joint mobilization group had the most direct hands on care. Rompe et al[44] raised this question in his study and whether the improved satisfaction of patients was related to the outcome of treatment or the process in which the treatment was carried out. The process of treatment can be described as the type and way in which the treatment is performed. The outcome of treatment can be described as the effectiveness of the intervention and the post-treatment effect. The greater improvement noted in our study with ECSWT and mobilizations may have been influenced by the process of treatment. With regards to the joint mobilizations, the patient may have reported benefit and positive feedback because of the touch and tactile stimulation used by the treating physiotherapist and the effect on the mechanoreceptors in the region.

Lastly, while all groups improved from pre to post treatment, neither group achieved complete pain relief or restoration of function at three months post-treatment. This may be due to the fact that insufficient treatment was provided. Three treatments of ECSWT, manual therapy, or exercise may not have been sufficient and patients may have continued to improve if more treatment was provided. The frequency of ECSWT treatment in our study is consistent with the number of treatments proposed and used in most treatment protocols.

Several studies have highlighted the long term benefit of ECSWT in the treatment of plantar heel pain. Our results are similar to these studies with the overall improvement at the three month follow up ranging from 52-72%. Gerdesmeyer et al[20] reported a significant improvement in VAS pain scores and functional scale scores at 4 months and 12 months follow up when compared to placebo. Two hundred and forty five subjects with chronic PF were randomly assigned either into the ECSWT treatment group or the placebo treatment group. The ECSWT treatment group received three treatments of 2000 shockwaves applied to the painful heel spaced two weeks apart. The placebo treatment group received ECSWT using the same parameters described but a placebo hand piece was used that prevented the actual transmission of the shockwaves. The overall success rates ranged from 61% in the ECSWT group as compared to 42.2% in the control group. Similarly, we found a 63% improvement in our study for the ECSWT group when using the same number of shockwaves but spacing the treatment apart by one week. Chuckpaiwong et al[7] also reported similar success rates to those of the current study. At the three month follow up, they found a 70.7% reduction and at 12 months a 77.2% improvement in VAS scores for pain with the first few steps in the morning, pain during daily activities and exercise, and an in functional scale outcome scores.

Although different treatment parameters and different ECSWT generators have been used in the studies highlighted, the long term benefit and success rates of ECSWT appear to be consistent with the findings of our study. In several of the studies highlighted, despite the use of different ECSWT treatment parameters most patients improved over time. Some variability in the amount of improvement, however, has been reported in the literature regarding the success of ECSWT in patients with PF. This once again supports the use of this intervention in the treatment of heel pain but also reinforces the need for further research.

As mentioned previously, a limitation to this study was the lack of a true control group. In order to determine the influence of ECSWT on the outcomes in this study, a group that received only joint mobilizations or exercise was needed. Future study designs that examine the effects of combinations of treatment with ECSWT must include appropriate controls in which the alternate intervention is used in isolation. Another limitation of the current study was the number of treatments used for the exercise group and not including a method for encouraging or monitoring compliance with exercise. Future studies should incorporate greater treatment frequency, a method of monitoring patient compliance, and a cut off whereby patients will not be included in the statistical analysis if a certain degree of compliance is not obtained. Finally, the number of treatments for the joint mobilization group and an impairments based progression should be implemented so

that only patients that require joint mobilizations receive this treatment in future studies.

5. Conclusions

All patients experienced improvements in function and heel pain with the use of ECSWT alone or in combination with joint mobilization or exercise. It appears that this modality has positive effects in the treatment of pain and function. The combination of ECSWT with joint mobilizations appears to be more effective than the combination of ECSWT with stretching and strengthening exercises to improve heel pain following activity. Treating practitioners may want to consider this treatment combination if the primary aggravating factor for heel pain is activity or post exercise. Further research is required that integrate the examination of combinations of treatments with ECSWT as this modality continues to be used more frequently clinically. Most healthcare providers do not treat solely with one modality or treatment approach so more research is required such as this study that examines combinations of treatments to simulate the actual clinical combinations used in the practical settings. Future studies must incorporate alternate designs to control for the limitations described in the current study.

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