The Effects of Extracorporeal Shockwave Therapy on Pain, Function, Range of Motion, and Strength in Patients with Insertional Achilles Tendinosis

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Abstract-Increased physical fitness participation has been paralleled by increasedoveruse injuries such as insertional Achilles tendinosis (AT). Treatment has provided inconsistentresults. The use of extracorporeal shockwave therapy (ECSWT) offers a new treatment consideration. The purpose of this study was to assess the effects of ECSWTon pain, function, range of motion (ROM), joint mobility and strength in patients with AT. Thirty subjects were treated with ECSWT and measures were takenbefore and three months after treatment. There was significant differences in visual analog scale (VAS) scores for pain at rest (p=0.002); after activity (p= 0.0001); overall improvement(p=0.0001); Lower Extremity Functional Scale (LEFS) scores (p=0.002); dorsiflexion range of motion (ROM) (p=0.0001); plantarflexion strength (p=0.025); talocrural joint anterior glide (p=0.046); and subtalar joint medial and lateral glide (p=0.025).ECSWT offers a new intervention that may limit the progression of the disorder and the long term healthcare costs associated with AT.

Keywords—Extracorporeal shockwave therapy, shockwave therapy, Achilles tendinosis, range of motion, strength, joint mobility.

I. INTRODUCTION

VER the past few decades, there has been an increase in physical fitness participation but this has been paralleled by an increase in the incidence of overuse injuries such as insertional Achilles tendinosis. Depending upon the activity, the rate of injuries may be as high as ten times that in agematched controls [1]. The Achilles tendon is the largest and strongest tendon in the human body and it is named after the seemingly indestructible Greek mythological warrior, Achilles [1]. This is somewhat of a misnomer as injury to the Achilles tendon can occur and may encompass a wide range of injuries including inflammation, degeneration or tendon rupture. The incidence of AT is unknown but is reported to range from 6.5 to 18% in runners [1]. During running, forces equaling 10 times the body weight have been measured within the tendon and this may explain the higher incidence within this sport [1]. Through extensive study of AT, it has been determined that prostaglandin mediated inflammation may not be the primary source of the problem but rather the presence of neuropeptides such as substance P and calcitonin gene related peptide suggesting more of a neurogenic mediated cause rather than inflammatory [1]. Insertional AT involves the lower portion of the Achilles tendon and the calcaneous where the tendon attaches. Insertional AT can occur at any time or age and even in patients who are not active [2].

The causes for the development of this condition are multifactorial including overuse and repetitive stress from jumping and running sports; deconditioning; muscle imbalances such as weakness, length tension and flexibility issues; sudden changes in training or exercise patterns; use of inappropriate footwear or; inappropriate training surfaces or regimes [3], [4], [5], [6], [7].Other risk factors that may contribute to the development of AT include increased age and structural foot deformities such as pes cavus, tibial varum and heel or forefoot varum [1], [8].

AT often does not respond to typical treatments that are used for acute inflammatory conditions [9], [10]. This may be partly due to the lack of inflammatory mediators but also due to the anatomy of the region and the relative lack of blood supply to the tendon [9]. As a result, the tendon is less resilient to repetitive micro trauma and has a higher tendency for irritation, degeneration and possible rupture [10], [11].

The treatment of AT ranges from conservative measures, to immobilization in a cast or brace, to surgical interventions and procedures. Conservative treatment includes the use of heat, ice, stretching exercises, eccentric heel drop strengthening exercises and therapeutic modalities such as ultrasound therapy, laser and interferential current [9], [11]-[13], [14]-[18].In patients with AT, the success of reducing heel pain with treatment can be quite variable [19]. With the ever increasing cost of treatment in healthcare, it is imperative that healthcare providers make accurate choices for the treatment of the patient and, at the same time, consider the economic impact of the treatment decision.

Recently, the use of ECSWT has been demonstrated to be safe and effective in the treatment of a variety of musculoskeletal disorders including tendinopathy [20]-[22].Shockwaves are acoustic waves that can be generated by electrohydraulic, electromagnetic, piezoelectric or radial generators [21], [23]-[25]. Radial shockwaves are generated

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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[21], [26]. The unit used for this study produced radial shockwaves.

ECSWT offers an exciting and relatively new intervention for the treatment of AT. At the present time there are limited high quality studies on the use of ECSWT with AT. The studies that are available have reported findings in which the success of treatment is quite variable [19], [27]-[35].

II. OBJECTIVES AND HYPOTHESIS

The purpose of this study was to assess the effects of ECSWT on heel pain and function measured with the VAS and LEFS, ROM, joint mobility and strength in patients with AT. It was hypothesized that ECSWT would have a positive effect on function and heel pain and that subjects would demonstrate a higher LEFS score and a lower VAS score with treatment. It was also hypothesized that there would be no change in ROM, strength and joint mobility 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 and swelling localized to the posterior aspect of the heel over the Achilles tendon and; (2) reported Achilles tendon pain that was within two centimeters of the insertion point on the calcaneous. Participants who met the following were excluded from the study: (1) had heel pain that was more than two centimeters proximal to the insertion point; (2) had bilateral heel pain; (3) had previous surgery to the Achilles tendon or ankle region; (4) used an assistive device such as an ankle foot orthoses; (5) had vascular or neurological disorders of the feet; (6) were pregnant; (7) had implanted metal in the region or; (8) 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, strength, active and passive ROM, accessory movement and stability testing of the foot was assessed. Active and passive ROM for the ankle and first metatarsophalangeal (MTP) joint was measured and recorded in degrees using a goniometer. Accessory movement testing was performed examining the joint mobility of the anterior and posterior glide of the talocrural joint, medial and lateral glide of the anterior and posterior subtalar joints and anterior and posterior glide of the first MTP joint. Accessory movements were measured and recorded as normal, hypomobile or hypermobile. 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) level of heel pain at rest; (2) level of heel pain following activity; (3) how much better the heel pain was at that time. Subjects marked the VAS at the point that corresponded to 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 [36], [37]. It has been reported that the LEFS has an internal consistency ranging from α =0.90-0.96 and a test-retest reliability ranging from 0.88-0.94 [38]-[40].

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 Achilles tendon. Subjects received three treatments in total spaced one week apart over a three week period. 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, strength and joint mobility 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 Wilcoxen Signed Rank Test was used to analyze and compare the pre-test and post-test differences in VAS and LEFS scores, strength and passive accessory joint movement differences. A Paired Samples t-Test was used to analyze and compare the pre-test and post-test differences in ROM.

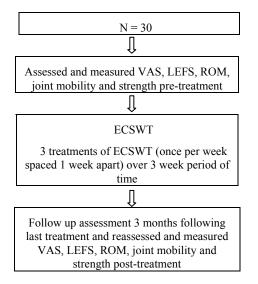


Fig. 1 Study design flow chart

IV. RESULTS

The sample consisted of 30 subjects (14 males and 16 females) with a mean age of 53 years. Descriptive data for height, weight and body mass index is summarized in Table I.

There was a significant difference from pre-treatment to post-treatment for VAS scores for heel pain at rest (p=0.002), heel pain after activity (p=0.0001) and overall improvement in heel pain (p=0.0001). There was also a significant improvement in function as noted in the LEFS scores (p=0.002). 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.

TABLE I DEMOGRAPHIC INFORMATION		
Age (years)	53±7.2	
Gender	14 M, 16 F	
Height (cm)	163.4±19.6	
Weight (kg)	87.3±25.9	
Body Mass Index (kg/m ²)	32.7	

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.

Active plantarflexion ROM was decreased both pretreatment (45.5°) and post-treatment (46.6°). Active dorsiflexion was decreased both pre-treatment (16.9°) and post-treatment (19.1°). Active inversion and eversion ROM was normal both pre-treatment and post-treatment. Decreased active flexion was evident both pre-treatment (40.9°) and post-treatment (38.4°) for the first MTP joint. The ROMfor flexion of the first MTP was decreased post-treatment. Decreased extension was evident both pre-treatment (52.5°) and post-treatment (54.8°) for the first MTP.

The ROM findings are summarized in Table II. There was a significant improvement in dorsiflexion active ROM from pretreatment to post-treatment (p=0.0001). With resisted isometric testing, 23% had weakness with plantarflexion; 10% weakness with dorsiflexion and inversion; and 6% weakness with eversion pre-treatment. Post-treatment 10% of the subjects still presented with weakness in plantarflexion with resisted isometric testing. There was, however, a significant improvement in resisted isometric plantarflexion strength from pre-treatment to post-treatment (p=0.025).

With accessory movement biomechanical assessment of joint glide, 20% demonstrated hypomobility with an anterior glide and 13% demonstrated hypomobility with a posterior glide of the talocrural joint. Post-treatment 6% still had hypomobility with the

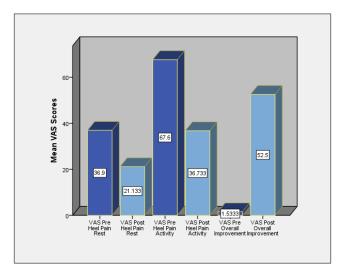


Fig. 2 VAS scores for heel pain at rest, heel pain after activity and for overall improvement in heel pain

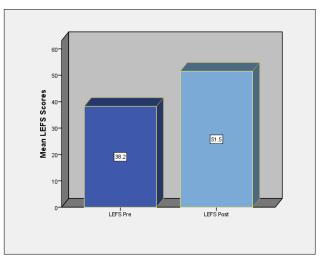


Fig. 3 LEFS scores

anterior and posterior glide of the talocrural joint. There was a significant improvement in talocrural joint mobility for anterior glide from pre-treatment to post-treatment (p=0.046).

With accessory movement biomechanical analysis of the subtalar joint, 16% demonstrated hypomobility with a medial and lateral glide at the anterior and posterior subtalar joints. No hypomobility was evident post-treatment in the subtalar joint anterior or posterior joints. There was a significant improvement in subtalar joint mobility for medial and lateral glide at the anterior and posterior joints from pre-treatment to post-treatment (p=0.025).

Accessory movement biomechanical analysis of the first MTP joint was normal bilaterally pre and post-treatment. No significant joint hypomobility was evident.

TABLE II			
SUMMARY OF MEAN ROM PRE-TREATMENT AND POST-TREATMENT			
Ankle ROM ^a	Pre-Treatment	Post-Treatment	
Plantarflexion	45.5°±6.3	46.6°±7.7	
(50°)	16.9°±3.0	19.1°±1.6	
Dorsiflexion (20°)	57.3°±5.5	58.6°±4.1	
Inversion (60°)	29.2°±2.2	29.5°±1.8	
Eversion (30°)			
First MTP ROM ^a	40.9°±6.5	38.4°±8.5	
Flexion (45°)	52.5°±17.1	54.8°±17.3	
Extension (70°)			

^aNormal ROM values listed in parentheses.

V.DISCUSSION

This study demonstrated that all subjects experienced improvements in function and heel pain with ECSWT. The reduction in heel pain is consistent with other reported research findings that found that ECSWT decreased heel pain in patients with AT [19], [27]-[34]. 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 used 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 the treatment in these 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 AT in the sample or the type of AT present (insertional versus non insertional). Many studies have primarily looked at the treatment of chronic AT while others did not specify the length of the problem [28], [32], [33]. The mean length of time that subjects in this sample had pain was 20 months (chronic AT).

An increased hydroxyproline level in the Achilles tendon of rats following ECSWT treatment was found in reference [22]. The histopathological findings were consistent with increased tendon healing. They also found increased angiogenesis and an increased number of capillaries in the Achilles tendon with less adhesions following the use of ECSWT [22]. Although we did not biopsy the tissue in our study post-treatment, these animal studies may help to explain some of the positive findings evident post-treatment at a physiological level following ECSWT in insertional AT patients. Improved American Orthopaedic Foot and Ankle Society pain, function and alignment scores were reported following the use of ECSWT in chronic AT compared to placebo [31]. The improvement in function and pain in this study is consistent with the findings of our study and the significant improvements in LEFS and VAS scores.

Significant improvement in VAS scores for heel pain was also reported in 23 chronic cases of insertional and non insertional AT patients [28]. Overall improvement in morning heel pain and activity pain was reported following the use of ECSWT with the majority of subjects reporting that they would have the treatment procedure again if given the choice. The current study found improved heel pain following activity and an overall improvement in heel pain and this is consistent with the findings reported by reference [28]. Our study, however, focused solely on insertional AT whereas the location of the AT was not controlled in the previous reported study.

Improvement in chronic non-insertional AT with a single dose of high energy ECSWT in combination with the use of regional anesthesia to the Achilles tendon was reported compared to the use of non-operative treatment [30]. Self report Roles and Maudsley and VAS scores were significantly improved post-treatment. Satisfactory improvements were also reported in VAS scores in patients with AT at 6 to 12 month follow up and at 13 to 24 month follow up after three to five treatments with ECSWT using an electromagnetic generator [35]. Again, the improvement in heel pain on VAS in these studies is consistent with our findings despite the use of a different type of ECSWT generator, the use of a different treatment protocol with only one treatment being used and with the use of a regional anesthetic.

Significant improvement was reported in mid portion AT and in chronic insertional AT with ECSWT when using a 6point Likert scale measuring level of improvement, Victorian Institute of Sport Assessment Achilles (VISA-A) questionnaire score measuring functional improvement and an 11-point numerical rating scale for level of pain [32], [33]. The effect of cointerventions such as the use of medications or other treatments was not controlled for and may have affected the outcomes of these studies. These findings are consistent with the improvement noted on LEFS scores and on VAS scores for heel pain at rest, after activity and level of overall improvement. They compared the use of ECSWT to ECSWT and eccentric loading exercises. The study design included two groups that received ECSWT or ECSWT and eccentric loading exercises. There was no group that just received eccentric loading. Future study designs examining the effects of combined treatments should include a third group that examines the effects of eccentric loading in isolation.

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 and dorsiflexion pre-treatment. Significant improvement was noted post-treatment in dorsiflexion ROM. No direct benefit can be attributed to the ECSWT directly but it is hypothesized that the reduction in pain may have reduced some of the protective muscle tone in the region as the subject moved towards end range dorsiflexion placing tension on the Achilles tendon. The consistent finding of reduced ROM in the talocrural joint makes it prudent for the examining healthcare provider to consider the use of active or passive stretching exercises to address plantarflexion and dorsiflexion ROM restrictions. Future studies examining the effects of ECSWT should be designed looking at the effects of combined treatment interventions including stretching exercises to see if this produces better results and improvements in range.

Resisted isometric strength findings pre-treatment revealed weakness in plantarflexion and dorsiflexion. Plantarflexion strength was improved post-treatment but weakness was still present. Again, the reason for the improvement in strength cannot be attributed directly to the effects of the ECSWT. The reduction in pain may have resulted inless neural inhibition. The decreased neural inhibition may have resulted in improved motor control and recruitment and the ability of the muscle to actively generate power resulting in improved plantarflexion strength post-treatment. The consistent finding of reduced ankle strength makes it prudent for the examining healthcare provider to also consider the use of strengthening exercises to address strength issues. Future studies examining the effects of ECSWT should also look at the effects of combined treatment interventions including strengthening exercises to see if this produces better results and improvements when also combined with ECSWT. The use of the combination of treatments will also be beneficial in that it will add to the limited body of research currently available looking at combined treatments for AT.

Hypomobility was also evident in the talocrural and subtalar joints for accessory movement analysis. Significant improvement was noted in the talocrural and subtalar joints with accessory movement findings post treatment. Again, the reason for this improvement cannot be attributed directly to the use of ECSWT directly. If a reduction in pain and protective muscle spasm was produced then this may have contributed to the improvement in joint mobility. The consistent finding of reduced talocrural and subtalar joint glide with accessory movement analysis also makes it prudent for the examining healthcare provider to consider the use of joint mobilizations or joint manipulation to these joints to address the joint hypomobility issues. Clinically, the healthcare provider should assess the patient and conclude whether joint mobilizations or manipulations are appropriate. This would be based upon the assessment findings and clinical reasoning that manual therapy is indicated. The treating physiotherapist should, therefore, consider the use of joint mobilizations especially if restrictions are noted during the assessment of the patient's ROM and accessory glides. This may, in turn, produce the greatest reduction in heel pain. Future studies should examine joint mobilizations or joint manipulations to the talocrural or anterior and posterior subtalar joints to see if this produces better results and improvements when used in isolation or when combined with ECSWT. The use of the combination of treatments will also be beneficial in that it will add to the limited body of research currently available looking at combined treatment for AT.

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 small number of patients treated. The sample also was a relatively sedentary and overweight group making it difficult to extrapolate our conclusions to more of an athletic population. Future studies should include a larger sample size and possibly more of an athletic 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 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 between group 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 measure such as the four item pain intensity measure known as the P4 or the use of an alternate functional measure such as the VISA-A functional questionnaire. 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. 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. Healthcare providers normally do not treat with only one modality or treatment approach 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 ormanual therapy used alone or when combined, for example, may provide further information on how to best manage and guide the optimal treatment for AT.

ECSWT offers an exciting and new intervention for the treatment of AT. In the future, we may see this treatment utilized earlier and in more clinical facilities. These findings

may also assist healthcare providers in making treatment decisions that may impact on overall healthcare costs and demonstrate fiscal responsibility that we must have when choosing optimal treatments for patients. Future studies looking at ECSWT combined with either stretching or strengthening exercises or the use of manual therapy to the talocrural or subtalar joints may also provide valuable information to the treating healthcare provider and to the limited body of research available examining combinations of treatments. By using the most effective treatment or combinations of treatment we may also impact on the length of recovery, length of treatment time and lost time in sport, work or other functional tasks.

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