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Effect of Monophasic Pulsed Current on the Treatment of Plantar Fasciitis

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School of Allied Health Professions
in conjunction with the
Faculty of Graduate Studies

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Effect of Monophasic Pulsed Current on the Treatment of Plantar Fasciitis

by

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A Dissertation submitted in partial satisfaction of
the requirements for the degree
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Each person whose signature appears below certifies that this dissertation in his/her opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Science.

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ABBREVIATIONS

MPC	Monophasic Pulsed Current
PF	Plantar Fasciitis
ES	Eelectrical Stimulation
VAS	Visual Analogue Scale
PA	Pressure Algometer
ST	Sagittal Thickness
ADL	Activities of Daily Living Subscale
FAAM	Foot and Ankle Ability Measure
MSK US	Musculoskeletal Ultrasound
SE	Stretching Exercises
ES	Electrical Stimulation
SD	Standard Deviation
ANOVA	Analysis of Variance

ABSTRACT OF THE DISSERTATION

Effect of Monophasic Pulsed Current on the Treatment of Plantar Fasciitis

by

Abdullah Alotaibi

Doctor of Science, Graduate Program in Physical Therapy
Loma Linda University, June 2014
Dr. Jerrold Petrofsky, Chairperson

Background: Plantar fasciitis (PF) is one of the most common soft tissue disorders that causes inferior heel and rear foot pain. Monophasic pulsed current (MPC) is a method of electrical stimulation (ES) clinically used to promote and accelerate wound healing processes. The aim of this prospective clinical trial was to investigate the effect of MPC and MPC coupled with plantar fascia specific stretching exercises (SE) in the treatment of PF.

Methods: Forty four participants (twenty- two subjects were women; 22 were men with a mean age of 49 ± 10.6 years) diagnosed with PF were randomly allocated to receive MPC (n=22) or MPC coupled with plantar fascia specific SE (n=22). Prior to treatment, participants underwent a baseline evaluation. Heel pain was evaluated using the visual analogue scale (VAS), heel tenderness threshold was quantified using a handheld pressure algometer (PA), the functional activities level was assessed using the Activities of Daily Living subscale of the Foot and Ankle Ability Measure (ADL/FAAM), and the sagittal thickness (ST) of the proximal insertion of the plantar fascia was measured with musculoskeletal ultrasound (MSK US). Following treatment, post intervention evaluation was performed using the same outcome measures.

Results: The findings of this study demonstrated that the two groups of subjects experienced significant improvements in all outcome measures after treatment. First, heel pain scores showed statistically significant reduction in both groups compared with baseline VAS scores ($P < 0.001$). Second, heel tenderness decreased significantly in both groups compared with baseline PA scores ($P < 0.001$). Third, the functional activities level improved significantly in both groups of subjects compared with baseline (ADL/FAAM) scores ($P < 0.001$).). Lastly, the ST of the proximal insertion of the plantar fascia decreased significantly in both groups compared with baseline MSK US measurements ($P < 0.001$). However, no statistically significant differences between the two treatment groups were exhibited in all post intervention outcome measures.

Conclusion: This trial showed the ability of MPC and MPC coupled with plantar SE to produce benefits for patients diagnosed with PF in terms of reducing heel pain and tenderness, improving the function activities level, and decreasing the ST of plantar fascia. Both MPC and MPC coupled with plantar fascia SE had similar effectiveness on the treatment of PF.

Keywords: plantar fasciitis, monophasic pulsed current, plantar fascia specific stretching exercises.

CHAPTER ONE

INTRODUCTION

Plantar fasciitis (PF) was first described by William Wood in 1812 and he attributed its presentation to tuberculosis[1-3]. PF as a clinical diagnosis is known by many pseudonyms: Jogger's heel, heel spur syndrome, plantar fascial insertitis, calcaneal enthesopathy, subcalcaneal bursitis, subcalcaneal pain, stone bruise, calcaneal periostitis, neuritis and calcaneodynia[4-6]. Proximal PF or plantar heel pain is the most common soft tissue disorder that causes inferior heel and rear foot pain in athletes as well as those not involved in sport activities[7,8]. Proximal PF is a common clinical diagnostic entity usually affecting more than two million Americans every year. It constitutes approximately 15 % of foot dysfunction conditions in the United States, affects two million individuals, and accounts for more one million outpatient visits annually[3,9,10].

PF is considered to be a self-limited condition and symptoms settle in 80% to 90% of conditions. The resolution of symptoms occurs in majority of patients within ten months with conservative treatment[2,7,11]. PF can be a painful, debilitating, and disabling condition that often frustrates not only the patient but also the physician because its etiology is still equivocal[3,8,12,13]. PF is also considered to be an overuse syndrome and an inflammatory reaction from chronic irritation or microtears of proximal plantar fascia at its attachment at the medial tuberosity of the calcaneus[2,14].

PF is defined as a localized inflammation of perifascial anatomical structures and plantar fascia at its proximal insertion on the medial tuberosity of the calcaneus resulting

from chronic repetitive microtears and degeneration secondary to overuse, mechanical and congenital disorders[3,7-10,15]. PF is also clinically defined as inferior heel pain and tenderness of gradual onset, localized to the medial tuberosity of the calcaneus and exacerbated by weight bearing[11,16]. It can affect patients from childhood to older ages, but is most common in middle aged women and young athletes. Inflammation of the plantar fascia is prevalent in joggers, long distance runners and tennis players as well as soccer players, gymnasts, volleyball and basketball players[7,8,17]. PF is also common in overweight individuals with occupations that require extensive standing or weight bearing[8,18,19].

Plantar fascia or plantar aponeurosis is a thick and strong fibrous connective tissue which originates at the medial tuberosity of the calcaneus and fans out distally into three bands to attach into the bases of proximal phalanges or at the metatarsophalangeal joints to form the medial longitudinal arch of the foot[11,18]. Plantar fascia lies superficial to the muscles of the plantar surface of the foot and divides into three portions: central or middle, lateral, and medial. The central or middle portion is considered to be the thickest component of the plantar fascia, and originates from the posterior aspect of the medial tuberosity of the calcaneus posterior to the origin of the flexor digitorum brevis tendon, and is its width is between 1.5 to 2.0 cm. Distally, at the level of the metatarsophalangeal joints, the central portion of the plantar aponeurosis divides in to five bands, one for each of the toes[3,20-24].

The lateral component of the plantar aponeurosis originates from the lateral aspect of the medial tuberosity of the calcaneus with its distal medial and lateral bands connecting to the plantar plate of the fourth toe and to the base of the fifth metatarsal

bones, respectively. The medial component of the plantar aponeurosis is thin and lies superficial to the abductor hallucis muscle and connected medially with the dorsal fascia and laterally with the central component of the plantar aponeurosis[3,18,20,21,23,25].

Histological examination of biopsy samples of the irritated and inflamed plantar fascia reveal granulation tissue, fibroblast proliferation, and fibrosis, collagen necrosis, chondroid metaplasia, and matrix calcification, all of which are suggestive of a repetitive strain and fascia degenerative process[26,27].

The windlass mechanism is a term used to explain the responsibility of the plantar fascia dynamic function during a manner of walking[28]. The plantar fascia functions through the windlass mechanism which was described first by Hicks as a mechanical model[29,30]. The plantar fascia plays an important role in providing support for the foot through the stance phase of gait cycle. During the toe off of phase the gait cycle, the extension of the toes at the metatarsophalangeal joints tightens the planter fascia and elevates the medial longitudinal arch, thus forming a solid pivot of the foot for push off[30,31]. The foot and its ligaments can be thought of as a truss or arch-like triangular structure, with the calcaneus, midtarsal joint, and metatarsals forming the medial longitudinal arch[28,29].

The etiology of PF remains unclear and is poorly understood and is still debated among medical fraternity despite its high prevalence[3,7,11]. Even the etiology of PF is poorly established in previous research literature, it is thought to be caused by intrinsic and extrinsic predisposing factors[11,32]. Intrinsic precipitating factors that may make an individual vulnerable for the development of PF may include obesity and a body mass index of more than 30. Being overweight can increase stress upon plantar fascia during

normal walking. Secondly, advanced age can predispose an individual to PF. After the age of 40 years, the fat pad begins to degenerate, with loss of water content and collagen component that affects it elasticity. When sagittal thickness of the fat pad decreases, it may result in minimizing shock absorbency of that anatomical structure and reduced protection of the calcaneal tuberosity and plantar fascia. Thirdly, Achilles tendon tightness and inadequate ankle dorsiflexion may lead to excessive subtalar pronation and thus contributes to plantar fascia elongation and irritation. Fourthly, excessive pronation (pes planus) is caused by plantar flexion and adduction of talus and can cause the height of the longitudinal arch of the foot to decrease and create strain on the plantar aponeurosis which can result in the development of plantar fasciitis[7,10,11,33]. Other intrinsic potential risk factors may include leg length discrepancy, excessive lateral tibial torsion, and excessive femoral anteversion, pes cavus and equinus, and sudden weight gain[7,8,11]

Potential extrinsic potential predisposing factors that may make someone susceptible for the development of plantar fasciitis may include high intensity sport activities or training that require repetitive plantar flexion of the ankle joint and extension of the metatarsophalangeal joints and that mechanical overload and excessive tensile load produce microtears within the plantar fascia, which eventually incites a chronic inflammatory response followed by degeneration[8,33,34]. Other extrinsic potential risk factors include the use of poor or worn footwear, occupational and recreational activities that require prolonged standing or weight bearing, and improper training techniques[7,11,32].

The classic feature and presentation of PF are mechanical symptoms of pain on the sole of the foot at the inferior region of the heel[32,33]. The onset of the inferior heel

pain is insidious and may worsen over time. Heel pain may interfere with walking, particularly when first taking the first few steps in the morning after getting out of the bed, or weightbearing after prolonged sitting or inactivity. The intense and shooting inferior heel pain can be so terrible that the patient may limp around with the affected heel off the ground. By the end of the day, a dull aching pain typically occurs and may extend to the midfoot and forefoot. The sharp pain is usually localized to the plantarmedial aspect of the heel or over a small area near the proximal insertion of the plantar fascia at the medial tuberosity of the calcaneus[3,18,19,26,32,33,35].

The diagnosis of PF can be made through a thorough and comprehensive history taking and physical examinations. Heel pain, while taking first steps in the morning, is typical of plantar fasciitis and presents differently from other inferior heel pain dysfunctions. Inferior heel pain imposed by plantar fasciitis is associated with paresthesia or nocturnal pain. Localized tenderness to palpation of plantar fascia at its origin on the anteromedial aspect of the calcaneal tuberosity may be elicited by slight passive dorsiflexion of the toes or having the patient stand on the tips of the toes. A windlass test is considered to be positive when passive dorsiflexion of the hallux reproduces pain and discomfort at the proximal plantar fascia. The evaluation of range of motion may reveal or demonstrate a restriction of ankle dorsiflexion by 5 degrees or more which indicates contracture of the Achilles tendon[3,8,11,25,36].

A plain radiograph does not support the diagnosis of PF but can be used to look for bony lesions of the foot. Diagnostic ultrasonography is inexpensive and useful in ruling out soft tissue pathology of the heel. Findings of diagnostic ultrasound that verify the presence of PF fasciitis include proximal plantar fascia thickness greater than 4 mm

and areas of hypoechogenicity. Magnetic resonance imaging, although expensive, is also a valuable tool for assessing causes of recalcitrant heel pain[11,18,21,37,38]. Diagnostic findings include increased proximal plantar fascia thickening with increased signal intensity on T2-weighted imaging[11,18,26,39]. Differential diagnosis of plantar fasciitis includes calcaneal stress fractures, osteomyelitis, tumor, sacral radiculopathy, Reiter's syndrome, Sever's disease, psoriatic arthritis, ankylosing spondylitis, tarsal tunnel syndrome, foreign body, and nerve entrapments[7,8,11,34].

The treatment of PF is primarily conservative. It is commonly treated with nonsteroidal anti-inflammatory medications, physical therapy, and corticosteroid injections. If conservative treatment fails, surgical option may be indicated[1,3,7,11].

Physical therapy plays a significant role in the treatment of PF[32]. Many physical therapy treatment options are available which may mitigate and allay the heel pain symptoms associated with PF besides rest and avoiding any strenuous and arduous activities that place strain on the inflamed and irritated proximal insertion of plantar fascia[9,10,40,41].

In 2008, the orthopedic section of the American Physical Therapy Association (APTA) began issuing a series of evidence based clinical practice guidelines linked to the international classification of function, disability, and health that gives recommendations about assessment, prognosis, diagnosis, and treatment for common musculoskeletal dysfunctions. In terms of plantar fasciitis, there are many physical therapy interventions or means that can be used to alleviate and attenuate the inferior heel symptoms that are associated with PF,[42]. These modalities include iontophoresis, manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises of

calf muscles and plantar fascia, taping, orthotic devices, which can be used to suit patient needs[9-11,32,33,40-49]. Other physical therapy techniques may include soft tissue mobilization, heel padding, icing, contrast baths, ultrasound, and rest[34,50,51].

Monophasic pulsed current (MPC) is utilized clinically to promote wound and pressure ulcer healing processes. Delivering of electrical current using electrodes to wound bed seems to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, increase the number of growth factor receptor, and calcium influx. Vitro studies showed that key tissue cells such epithelial and fibroblast cells have been attracted to wound site when electrically stimulated resulting in promoting collagen deposition, angiogenesis and wound tensile strength. Many studies inferred that wounds treated with MPC demonstrated 1.5 times greater rate of healing when compared to normal wound healing rates[52-59]. MPC is defined as percutaneous delivery of pulsed, twin-peak, monophasic pulses, each pulse having very short phase duration of less than 100 μsec, which employs voltage up to 500 volts [52-54]. Galvanotaxis is one of the MCP features and is defined as the process of attracting charged cells to an electric field of opposite polarity. Clinically in treating wounds or decubitus ulcers, a positively charged electrode (anode) is placed over a wound or ulcer, to attract negatively charged cells such as neutrophils and macrophages to facilitate the inflammatory phase of wound healing. Plantar fascia is a connective tissue. The fibroblast cells' main function in connective tissue is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts make the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60]. Because polarity selection is

based on the healing phase the practitioner wishes to facilitate and accelerate, we used the negatively charged cathode to attract the positively charged fibroblast cells to promote and accelerate proliferation phase of plantar fascia.

The primary focus of this study was to examine the effect of MPC and MPC coupled with plantar fascia-stretching exercises (SE) on inferior heel symptoms caused by PF. Chapter two evaluated the effect of MPC and MPC coupled with plantar fascia SE on the subjective reporting of heel pain, tenderness, and functional activities level caused by PF. Chapter three examined the effect of MPC and MPC coupled with plantar fascia SE on the change of the sagittal thickness of proximal insertion of plantar fascia on patients diagnosed with PF. Chapter four investigated the correlation between the change of heel pain scores using visual analogue scale (VAS) as a subjective outcome measure and the change in the sagittal thickness proximal insertion of plantar fascia using musculoskeletal ultrasound (MSK US) as an objective measure when investigating the effect of MPC and MPC coupled with plantar fascia specific SE in the treatment of PF.

CHAPTER TWO

EFFECT OF MONOPASHIC PULSED CURRENT ON HEEL PAIN, TENDERNESS, AND FUNCTIONAL ACTIVITIES LEVEL CAUSED BY PLANTAR FASCIITIS

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Abstract

Background: Plantar fasciitis (PF) is one of the most common causes of heel and foot pain, affecting up to 2 million Americans each year and accounting for 15% of all foot pathologies. Monophasic pulsed current (MPC) is a method of electrical stimulation (ES) clinically used to promote and accelerate wound healing processes. The aim of this prospective clinical trial was to investigate the effect of MPC and MPC coupled with plantar fascia specific stretching exercises (SE) in the treatment of plantar fasciitis

Methods: Forty four participants (22 were women; 22 were men, with a mean age of 49 ± 10.6 years) diagnosed with PF were randomly allocated to receive MPC (n=22) or MPC coupled with plantar fascia specific stretching exercises (SE) (n=22). Prior to each treatment, participants underwent baseline evaluation, heel pain was evaluated using the visual analogue scale (VAS), heel tenderness threshold was quantified using a handheld pressure algometer (PA), and the function activities level was assessed using the Activities of Daily Living subscale of the Foot and Ankle Ability Measure (ADL/FAAM). Following treatment, post intervention evaluation was performed using the same outcome measures.

Results: This study demonstrated that the two groups experienced significant improvement in all outcome measures after treatment. First, heel pain scores showed a significant reduction in both groups compared with baseline VAS scores ($P < 0.001$). Second, heel tenderness decreased significantly in both groups compared with baseline PA scores ($P < 0.001$). Lastly, functional activities levels improved significantly in both groups compared with baseline (ADL/FAAM) scores ($P< 0.001$). However, no significant differences existed between the two treatment groups in all post intervention outcome measures.

Conclusion: This trial showed the capacity of MPC to reduce heel pain and tenderness, while improving functional activities levels associated with PF. Both MPC and MPC coupled with plantar fascia SE had similar effectiveness on the treatment of PF.
Keywords: plantar fasciitis, monophasic pulsed current, plantar fascia specific stretching exercise

Introduction

Plantar fasciitis (PF) is a soft tissue disorder first described by William Wood in 1812 and he linked its presentation to infectious diseases such as tuberculosis[1-3]. PF is often misdiagnosed under the auspices of jogger's heel, heel spur syndrome, plantar fascial insertitis, calcaneal enthesopathy, subcalcaneal bursitis, subcalcaneal pain, stone bruise, calcaneal periostitis, neuritis and calcaneodynia[4,5 6]. PF is the most common soft tissue dysfunction that causes inferior heel pain in athletes as well as sedentary adults[7,8]. PF is a common diagnostic entity affecting more than two million Americans every year[1-3]. It constitutes approximately 15 % of foot dysfunctions in the United States and accounts for more than one million outpatient visits each year[3,9,10].

PF symptoms resolve in 90% of cases and resolution of symptoms occurs in the majority of patients within ten months of conservative treatment[7,11,12]. PF can be a painful and disabling disorder that often frustrates not only the patient but also the physician because its etiology is still equivocal[3,8,13,14].

PF is presumed to be an inflammatory reaction from chronic irritation or microtears of proximal plantar fascia at its attachment at the medial tuberosity of the calcaneus[2,15]. It can be defined as a localized inflammation of perifascial structures and plantar fascia at proximal attachment on the medial tuberosity of the calcaneus resulting from chronic repetitive microtears and degeneration secondary to overuse, mechanical and congenital disorders [3,7-10,12].

PF is also clinically defined as inferior heel pain and tenderness of gradual onset, localized to medial tuberosity of the calcaneus and exacerbated by weight bearing [11,16]. It can affect patients from childhood to older adults, but is most common in middle aged women and young athletes. Inflammation of the plantar fascia is prevalent in athletes

such as joggers, long distance runners and tennis players as well as soccer players, gymnasts, volleyball and basketball players [7,8,17]. PF is also common in overweight individuals with occupations which require extensive standing[8,18 19].

Plantar fascia or plantar aponeurosis is a thick and strong fibrous connective tissue which originates at the medial tuberosity of the calcaneus and fans out distally into three bands to attach into the bases of proximal phalanges or at the metatarsophalangeal joints to form the medial longitudinal arch of the foot [11,18]. Plantar fascia lies superficial to the muscles of the plantar surface of the foot and divides into three portions: central or middle, lateral, and medial. The central or middle portion is considered to be the thickest component of the plantar fascia, and originates from the posterior aspect of the medial tuberosity of the calcaneus posterior to the origin of the flexor digitorum brevis tendon, and is its width is between 1.5 to 2.0 cm. Distally, at the level of the metatarsophalangeal joints, the central portion of the plantar aponeurosis divides in to five bands, one for each of the toes[3,20-24].

The lateral component of the plantar aponeurosis originates from the lateral aspect of the medial tuberosity of the calcaneus with its distal medial and lateral bands connecting to the plantar plate of the fourth toe and to the base of the fifth metatarsal bones respectively. The medial component of the plantar aponeurosis is thin and lies superficial to the abductor hallucis muscle and connected medially with the dorsal fascia and laterally with the central component of the plantar aponeurosis [3,10,18,20,21,23].

Histological examination of the irritated and inflamed plantar fascia reveal granulation tissue, fibroblast proliferation, and fibrosis , collagen necrosis, chondroid

metaplasia, and matrix calcification, all of which are suggestive of repetitive strain and fascia degeneration[25,26].

The windlass mechanism model is a term used to explain the responsibility of the plantar fascia dynamic function during a manner of walking[27]. The plantar fascia functions through the windlass mechanism which was described first by Hicks as a mechanical model[25,28]. The plantar fascia plays an important role in providing support for the foot through the stance phase of gait cycle. During the toe off of the gait cycle, the extension of the toes at the metatarsophalangeal joints tightens the planter fascia and elevates the medial longitudinal arch thus forming a solid pivot of foot for the push off [28,29]. The foot and its ligaments can be thought of as a truss or arch-like triangular structure, with the calcaneus, midtarsal joint, and metatarsals forming the medial longitudinal arch[25,27].

The etiology of PF is unclear. It is poorly understood and still debated among medical fraternity[3,7,11]. Even the etiology of plantar fasciitis is poorly established in previous research; it is thought to be caused by intrinsic and extrinsic predisposing risk factors[11,30]. Intrinsic precipitating factors that may make an individual vulnerable for the development of plantar fasciitis include obesity and a body mass index of more than 30. Being overweight can increase stress upon plantar fascia during normal walking. Secondly, advanced age can predispose an individual to plantar fasciitis. After the age of 40 years, the fat pad begins to degenerate, with loss of water content and collagen component that affects it elasticity. When sagittal thickness of the fat pad decreases, it minimizes shock absorbency of that anatomical structure and reduced protection of the calcaneal tuberosity and plantar fascia. Thirdly, Achilles tendon tightness and inadequate

ankle dorsiflexion can lead to excessive subtalar pronation to compensate for that dysfunction and over pronation contributes to plantar fascia elongation and overstretch. Fourthly, excessive foot pronation (pes planus) is caused by plantar flexion and adduction of talus and can cause the height longitudinal arch of the foot to decrease and create strain on the plantar aponeurosis which can result in the development of plantar fasciitis[7,10,11,31]. Other intrinsic potential risk factors may include leg length discrepancy, excessive lateral tibial torsion, and excessive femoral anteversion, pes cavus and equinus, and sudden weight gain[7,8,11].

Extrinsic potential predisposing factors that may make someone susceptible to developing plantar fasciitis include high intensity sport activities or training that require repetitive plantar flexion of the ankle joint and extension of the metatarsophalangeal joints and that mechanical overload and excessive tensile load that produce microtears within the plantar fascia, which eventually incites a chronic inflammatory response followed by degeneration[8,31,32].

Other extrinsic potential risk factors include use poor or worn footwear, occupational and recreational activities which require prolonged weight bearing, and improper training techniques[7,11,30].

The classic feature and presentation of PF are mechanical symptoms of pain on the sole of the foot at the inferior region of the heel[30,31]. The onset of the inferior heel pain is insidious and may worsen over time. Pain may interfere with walking, particularly when taking the first few steps in the morning after getting out of the bed, or weightbearing after a period of prolonged sitting or inactivity. The intense and shooting inferior heel pain can be so intense that the patient may limp around with the affected

heel off the ground. By the end of the day, a dull aching pain typically occurs and may extend to the midfoot and forefoot. The sharp pain is usually localized to the plantarmedial aspect of the heel or over a small area near the proximal insertion of the plantar fascia at the medial tuberosity of the calcaneus[3,18,26,30,31,33].

The diagnosis of PF can be made through a comprehensive history taking and physical examination. Heel pain, while taking first steps in the morning, is typical of plantar fasciitis and will reveal differences from other inferior heel pain dysfunctions. Inferior heel pain imposed by PF does not accompany paresthesia or nocturnal pain. Localized tenderness of plantar fascia at its origin on anteromedial aspect of the calcaneal tuberosity may be elicited by slight passive dorsiflexion of the toes or having the patient stands on the tips of the toes. A windlass test is considered to be positive when passive dorsiflexion of the hallux reproduces pain and discomfort at the proximal plantar fascia. Range of motion assessment may demonstrate a restriction of ankle dorsiflexion by 5 degrees or more which indicates contracture of the Achilles tendon[3,8,11,34,35].

A plain radiograph does not support the diagnosis of PF but can be used to look for bony lesions of the foot. Diagnostic ultrasonography is inexpensive and useful in ruling out soft tissue pathology of the heel. Findings of diagnostic ultrasound that support the presence of PF include proximal plantar fascia thickness greater than 4 mm and areas of hypoechogenicity. Magnetic resonance imaging, although expensive, is a valuable tool for assessing causes of recalcitrant heel pain[11,18,21,36,37]. Diagnostic findings include abnormal proximal plantar fascia thickening with increased signal intensity on T2-weighted imaging[11,18,26,38].

PF needs to be differentiated from diagnoses and diseases that cause inferior heel pain such as calcaneal stress fractures, osteomyelitis, tumor, sacral radiculopathy, Reiter's syndrome, Sever's disease, psoriatic arthritis, ankylosing spondylitis, tarsal tunnel syndrome, foreign body, and nerve entrapments[7,8,11,39].

The treatment of PF is primarily conservative. It is commonly treated with nonsteroidal anti-inflammatory medications, physical therapy, and corticosteroid injections. If conservative treatment fails, surgical option may be indicated[1,3,7,11].

Physical therapy interventions are considered an integral portion of treatment of PF. Many physical therapy regimens are available which may mitigate and relieve heel pain associated with PF. In addition, rest and avoiding strenuous activities that place strain on the inflamed and irritated proximal insertion of plantar fascia may also allay inferior heel symptoms [9,10,40,41].

In 2008, the orthopedic section of the American Physical Therapy Association (APTA) began issuing a series of evidence based clinical practice guidelines linked to the international classification of function, disability, and health which provide recommendations regarding assessment, prognosis, diagnosis, and treatment for common musculoskeletal dysfunctions. In terms of PF, many physical therapy interventions can be used to attenuate inferior heel symptoms associated with its presence[,42]. These modalities include iontophoresis, manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises of calf muscles and plantar fascia, taping, orthotic devices, which can be used to suit patient needs[9-11,30,31,40-49]. Other physical therapy techniques may include soft tissue mobilization, heel padding, icing, contrast baths, ultrasound, and rest[39,50,51].

Monophasic pulsed current (MPC) is utilized to promote wound and pressure ulcer healing processes. MPC is defined as percutaneous delivery of pulsed, twin-peak, monophasic pulses, each having very short phase duration of less than 100 μsec, which employs a voltage of up to 500 volts [52-54]. Delivery of electrical current using electrodes to the wound bed is presumed to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, as well as increasing the number of growth factor receptors , and enhancing calcium influx [52-59]. Vitro studies revealed that key tissue cells such epithelial and fibroblast cells have been attracted to wound site when electrically stimulated resulting in promoting collagen deposition, angiogenesis and wound tensile strength. Many studies inferred that wounds treated with MPC demonstrated 1.5 times greater rate of healing when compared to normal wound healing rates [52-59].

Galvanotaxis is one of the features of MPC and is defined as the process of attracting charged cells to an electric field of opposite polarity. In treating wounds or decubitus ulcers, a positively charged electrode (anode) is placed over a wound or ulcer, to attract negatively charged cells such as neutrophils and macrophages to facilitate the inflammatory phase of wound healing. Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts make the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60]. Because polarity selection is based on the healing phase, we used the negatively charged cathode to attract the positively charged fibroblast cells to promote and accelerate proliferation phase of plantar fascia.

The primary focus of this study was to examine the effect of MPC and MPC coupled with plantar fascia stretching exercises on subjective reporting of heel pain, heel tenderness, and functional activities level on patients diagnosed with PF.

We hypothesized that MPC would promote and precipitate the plantar fascia healing process thus mitigating inferior heel symptoms associated with PF.

Materials and Methods

Research Design

This study is a prospective randomized clinical trial to compare the effectiveness of two interventions on the treatment of PF. Participants were randomly assigned to one of two treatment groups. Group I was treated with MPC and Group II was treated with a combination of MPC and plantar fascia SE.

Participants

This prospective randomized clinical trial was approved by the Institutional Review Board (IRB) at Loma Linda University (LLU) and conducted at the Physical Fitness Laboratory at the School of Allied Health Professions (SAHP), Department of Physical Therapy between March and September, 2013.

The following inclusion/exclusion criteria were used to determine eligibility for enrollment in this clinical trial. Inclusion criteria included: (1) participants of both genders were diagnosed with PF; and (2) the diagnosis was made upon the finding of tenderness to pressure at the origin of plantar fascia on the medial tubercle of the calcaneus, as well as complaint of heel pain greater than or equal to 3 on a 1 to 10 VAS scale. Exclusion criteria included: (1) previous fracture or surgery to the foot; and (2)

specific metabolic and connective tissue disorders associated with or contributing to the diagnosis of PF (i.e., rheumatoid arthritis, gout, lupus).

The recruitment of the participants was assisted by referrals from the Loma Linda Medical Center's orthopedists, podiatrists, and primary care physicians (APPENDEX A). Additional recruitment was sourced via advertisements in Loma Linda Trading Post and online and weekly newspapers in area cities (APPENDEX B). Also, study fliers were placed on bulletin boards of the Drayson Fitness Center of Loma Linda University as well as the School of Allied Health Professions (APPENDEX C), with electronic versions of the study flier having been sent to the School of Allied Health Professions students.

If the referring physician felt patients would qualify for or benefit from participation in the clinical trial and ascertained patient interest, the patient was contacted with details about the study. Participant permission was obtained by provision of Authorization for Use of Protected Health Information (PHI) (APPENDEX D). This form allowed the patient's name, diagnosis, telephone number, date of birth, and gender to be forwarded to the study investigator (APPENDEX E). The investigator contacted the patient by telephone to provide additional information regarding the study, address questions, and schedule a baseline evaluation session (APPENDEX F).

A convenience sample of 48 patients with a clinical diagnosis of plantar fasciitis met this randomized clinical trial's inclusion criteria and underwent the baseline evaluation. Four participants never retuned beyond the baseline evaluation session due to scheduling conflicts. Data analysis was based on the remaining 44 patients who provided written consent to continue with the study.

During the baseline evaluation, the investigator first explained the study to the patient, including its overall purpose, the procedures that would be performed, and potential benefits and risks of the interventions. If the patient decided to proceed, the investigator provided him/her a copy of the informed consent as approved by the IRB (APPENDEX G). If the patient chose to enroll in the study, he/she signed the consent form and California Experimental Subject's Bill of Right Form (APPENDEX H).

Procedure

Following procurement of patient informed consent, the investigator obtained the patient's demographic information (age, sex, height, weight, body mass index, duration of symptoms) as well as determining whether the patient was athletic or not, and on which side the affected area presented. A baseline evaluation was performed on the eligible participant and included the measurement of: (1) heel pain using the Visual Analogue Scale (VAS); (2) heel tenderness with pressure algometer (PA); and (3) functional activities level with Activities of Daily Living Subscale of the Foot and Ankle Ability Measure (ADL/ FAAM).

The investigator then randomly assigned the participants to one of two treatment groups. Group I received MPC and Group II received MPC coupled with plantar fascia SE, using a computer-generated random two-digit number. Each patient received three sessions of MPC per week for four weeks, for a total of twelve sessions. Each session lasted 60 minutes. Patients in Group II were instructed to perform home based stretching exercises as described by Digiovanni[8] (APPENDEX I).

The investigator instructed the patients on how to perform the plantar fascia SE and told them the number of daily sets to complete during the four week treatment. (APPENDEX J)

After completing the assigned treatments, the investigator performed a post-intervention evaluation. The post-intervention evaluation included the measurement of: (1) heel pain using the VAS; (2) heel tenderness with PA; and (3) functional activities level using ADL/FAAM.

Outcome Measures

Visual Analogue Scale

The visual analogue scale (VAS) was utilized to measure heel pain. VAS is a numerical scale with marked points at 0 and 10 while 0 indicates no pain, and10 indicates the highest level of pain (Figure 1). The patient was requested to rate his/her heel pain based on his/her initial steps in the morning, by putting a mark on the scale representing his/her level of heel pain. This scale has been established as a reliable and valid subjective outcome measure to assess acute and chronic pain[61-63].

Figure 1. Visual Analogue Scale (VAS)

Pressure Algometer

A handheld pressure algometer (PA) was used to measure each patient's heel tenderness threshold. The threshold is defined as the minimum pressure force or pressure required to produce the sensation of pain. PA is a force gauge equipped with a rubber tip and calibrated in newton **(**WAGNER, compact digital Force Gauge) (Figure 2). To assess heel tenderness, the investigator directed the patient to recline in a supine position with affected leg fully extended. The investigator then palpated and marked the tender point over the origin of the plantar fascia at the medial tuberosity of calcareous. Finally, the investigator passively dorsiflexed the ankle and toes, applying the algometer over the marked placed on the medial tuberosity of the calcaneus. The algometer contact head was aligned perpendicularly to the tender point with the investigator gradually increasing the algometer pressure until the patient reported pain. The algometer reading, which represents the pressure needed to stimulate pain, was recorded in kilograms (Figure 3). Higher algometer scores indicated greater pressure tolerance and, hence, less tenderness. Lower algometer readings indicated less pressure tolerance and, thus, greater heel tenderness. The reliability and validity of the pressure algometer as a subjective outcome measure of tenderness has been supported in the literature [64-66] .

Figure 2. Handheld Pressure Algometer (PA)

Figure 3. Heel Tenderness Measurement Technique

Foot and Ankle Ability Measure

To assess functional activity levels, the participants were asked to record their ability to perform daily activities using the Activities of Daily Living subscale of the Foot and Ankle Ability Measure (ADL/FAAM). The ADL/FAAM identifies 21 daily activities, and participants rated their ability to complete each activity based on a scale ranging from no difficulty to inability to complete (APPENDEX K). Individual participant responses to the ADL/FAAM questions were converted to numerical cores using a 5-point scale, with scale ranging from 0 " no difficulty" to 4 "unable to do," that particular daily activity. A lower ADL/FAAM score indicated a higher functional activity level. ADL/FAAM is a self-reported instrument specific to those with lower leg

musculoskeletal disorders, known to be a reliable, valid, and responsive self-reported instrument for assessing the activity and function level for patients with lower leg musculoskeletal disorders[67-69].

Interventions

Monophasic Pulsed Current

MPC is utilized clinically to promote wound and pressure ulcer healing processes. MPC is defined as percutaneous delivery of pulsed, twin-peak, monophasic pulses, each pulse having very short phase duration of less than 100 μsec, which employs voltage up to 500 volts [52-54]. Delivering of electrical current using electrodes to wound bed seems to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, increase the number of growth factor receptor , and calcium influx, and. Vitro studies showed that key tissue cells such epithelial and fibroblast cells have been attracted to wound site when electrically stimulated resulting in promoting collagen deposition, angiogenesis and wound tensile strength. Many studies inferred that wounds treated with MPC demonstrated 1.5 times greater rate of healing when compared to normal wound healing rates[52-59].

Galvanotaxis is one of the MPC features and is defined as the process of attracting charged cells to an electric field of opposite polarity. Clinically in treating wounds or decubitus ulcers, a positively charged electrode (anode) is placed over a wound or ulcer, to attract negatively charged cells such as neutrophils and macrophages to facilitate the inflammatory phase of wound healing. Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts make the collagens,

glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60].

Because polarity selection is based on the healing phase the practitioner wishes to facilitate and accelerate, we used the negatively charged cathode to attract the positively charged fibroblast cells to promote and accelerate proliferation phase plantar fascia healing process (GV 350 Galvanic High-Volt Pulsed Stimulator) (Figure 4, 5). MPC has been shown to increase fibroblast proliferation and DNA and protein synthesis essential for the production of granulation tissue. The therapeutic parameters included: current type (pulsed current), pulse type (twin peaked), electrode polarity cathode (negative), frequency (100 pulse per second), pulse duration (100 milliseconds), and mplitude (at submotor level, too weak to elicit a visible muscle contraction) [52-54].

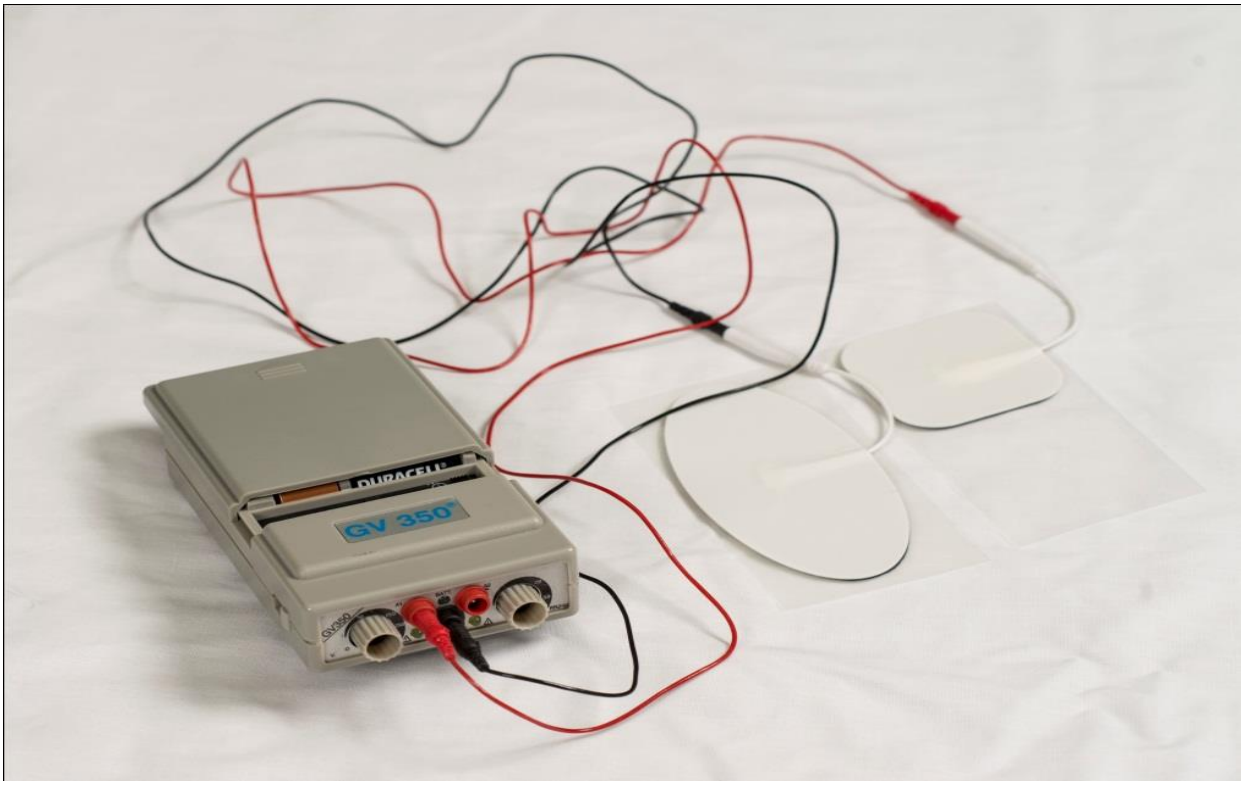

Figure 4. GV 350 Galvanic High-Volt Pulsed Stimulator

Figure 5. Monopolar Application of Monophasic Pulsed Current

Plantar Fascia Stretching Exercise

Plantar fascia stretching exercises (SE) are often considered an integral component of the physical therapy treatment plan for the treatment of PF, used to decrease pain and functional limitations. In this study, plantar fascia specific SE were utilized as demonstrated by DiGiovanni and his colleagues[9]. The patient was directed to cross the affected leg over the other leg while in a sitting position, and using his/her hand, apply metatarso-phalangeal joint dorsiflexion (or pull the toes back toward the shin until the patient feels a stretch in the arch of the foot), while holding each stretch for a count of 10, and repeating each stretch 10 times (Figure 6). All patients were required to perform the SE program three times per day. The first stretch was to be completed before rising

and exiting the bed. Patients were provided a written protocol of the stretching program and asked to keep a daily log of exercise completion for 4 weeks. (APPENDEX J)

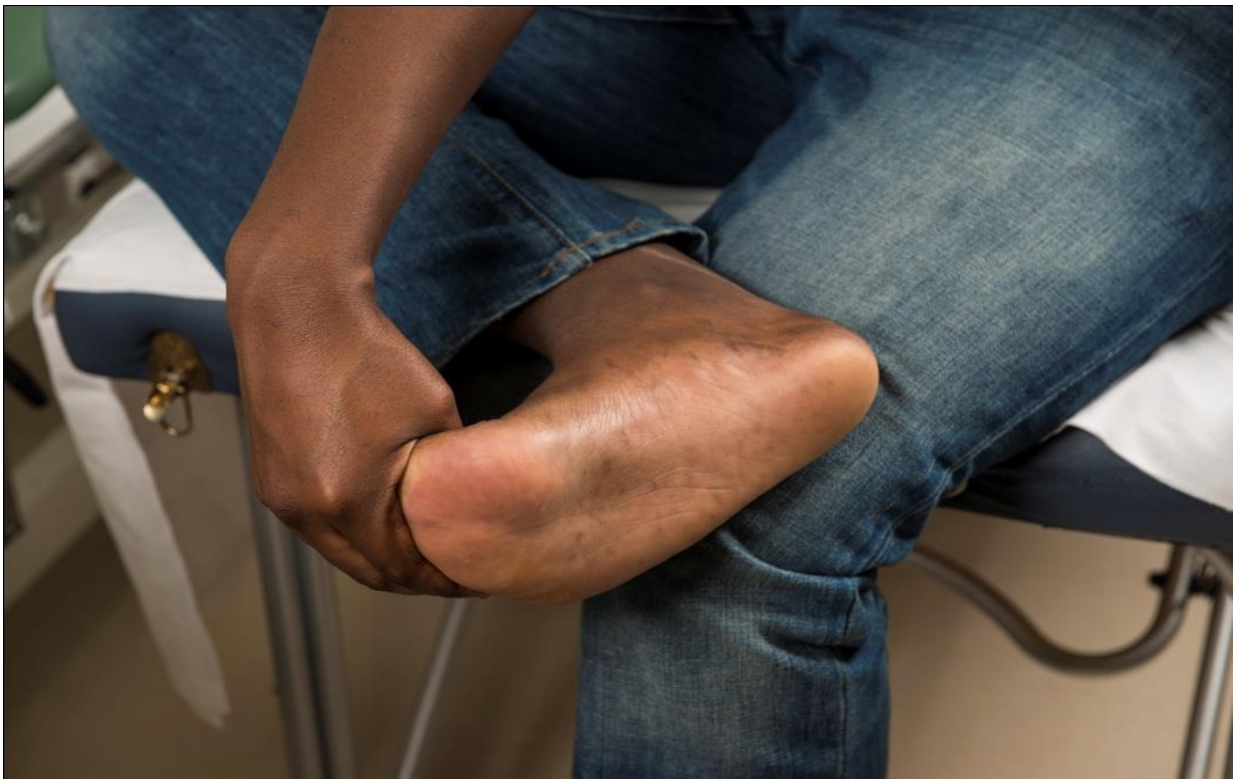

Figure 6. Plantar Fascia Stretching Exercise

Data Analysis

Sample Size Estimation

SAS statistical analysis software was used to calculate the sample size required so that a reasonable expectation would be likely to detect an expected effect size of 0.4 between the two study groups. A sample size of 40, with 20 participants per group with 0% attrition rate was utilized in the study. Forty participants were required to show statistical significance when clinically significant differences between the groups were present. Additional participants were recruited to provide for unanticipated attrition.

Description of Statistical Procedures

IBM SPSS Statistics Grad Pack 22.0 PREMIUM was used to analyze the data. Participants' demographic data for each group was summarized using means and SDs for continuous variables and frequencies and percentages for categorical variables to determine if significant differences between the two the groups existed. The assumption of normality of the continuous variables was examined using the Kolmogorov- Smirnov test. Also, the assumption of homogeneity was examined by Levene's test.

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

Results

Of the 44 participants completing the study, 22 subjects were women, and 22 were men (Figure 7). The right foot was involved in 22 participants and the left foot in 22. The mean age of Group I (received MPC) was 49.7 ± 11.7 years, and the mean age of Group II (received MPC couples with plantar fascia SE) was 49.0 ± 9.7 years. The mean height of Group I was 171.5 ± 12.0 cm and the mean height of Group II was 171.0 ± 13.5 cm. The mean weight of Group I was 96.4 ± 22.9 kg and the mean height of Group II

was 87.4 ± 22.9 kg. The median duration of symptoms in Group I was 12 months with Interquartile Range (IQR) of 154, and for Group II was 12 months with IQR of 154, hence, the sample consisted primarily of participants with relatively chronic symptoms. All participants in the two treatment groups appeared to be generally well matched. No significant differences between group I managed with MPC and group II managed with MPC coupled with plantar fascia SE were found in regards to age, gender, height, weight, body of mass index (BMI), athletic status, and affected side (Table 1).

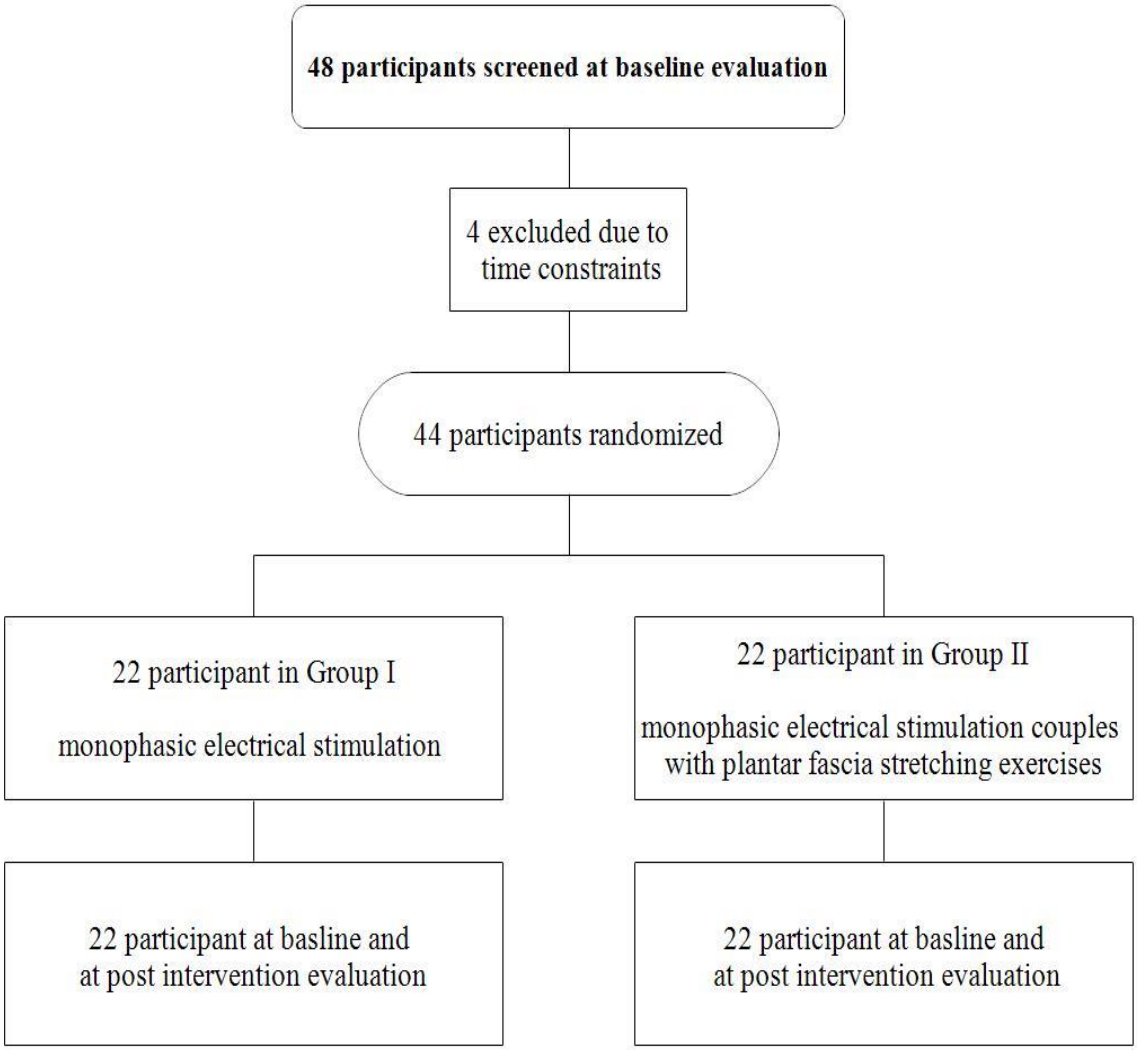

Figure 7. The Progression of Participants through the Clinical the Trial

Table 1. General Characteristics of Subjects (N= 44)

		Group I (n=22)	Group II (n=22)	p-value
Age, mean (SD) year		49.7(11.7)	49.0(9.7)	0.60 *
Height, mean (SD) cm		171.5 (12.0)	171.0 (13.5)	0.91*
Weight, mean (SD) kg		96.4 (22.9)	87.4 (22.9)	0.20*
BMI, mean (SD) kg/m^2		32.8 (7.2)	30.0 (7.4)	0.21*
Standing hours, mean (SD)		8.8 (3.2)	9.6(2.48)	0.31*
Duration of symptom, median (IQR) months		12 (154)	12 (149)	0.12^
Gender	Male, % (n)	36.4 (8)	31.8 (7)	0.75#
	Female, % (n)	63.6 (14)	68.2 (15)	
Athletic status	Athletic, % (n)	9.1 (2)	13.6 (3)	0.50$
	Non-Athletic, % (n)	90.9 (20)	86.4 (19)	
Involved side	RT, % (n)	27.3 (6)	50.0 (11)	0.12#
	LT, % (n)	72.7 (16)	50.0 (11)	

Abbreviations: SD, Standard deviation; BMI, Body mass index; IQR, Interquartile range; RT, Right; LT, Left
*Independent t-test; ^ Mann Whitney U- test; # Pearson chi square; $Fisher's exact test

Table 2. Mean (SD) of Outcome Measurements by Treatment Group at Baseline (N=44)

	Group I (n=22)	Group II (n=22)	Difference	p-value*
VAS	7.39 (1.75)	6.84 (2.14)	0.55	0.36
PA, N	17.41 (6.69)	14.47 (5.41)	2.94	0.12
ADL/FAAM	34.14 (11.33)	30.64 (12.65)	3.50	0.34

Abbreviations: SD, Standard deviation; VAS, Visual analog scale; PA, Pressure algometer; ADL, Activity of daily living; FAAM, Foot and ankle ability measure
*Independent t-test

Table 3. Mean (SD) of Outcome Measures by Treatment Group over time (N = 44)

	Pre Mean(SD)	**Post** Mean(SD)	**p-value***	**p-value#**	**Pre-post by-group interaction**
VAS					
Group I (n=22)	7.39 (1.75)	3.43 (1.95)	< 0.001	0.67	0.28
Group II (n=22)	6.84 (2.14)	3.55 (1.95)			
PA, N					
Group I (n=22)	17.41 (6.69)	36.74 (9.11)	< 0.001	0.21	0.75
Group II (n=22)	14.47 (5.41)	34.55 (8.88)			
ADL/FAAM					
Group I (n=22)	34.14 (11.33)	15.27 (12.31)	< 0.001	0.86	0.07
Group II (n=22)	30.64 (12.65)	17.55 (14.00)			

Abbreviations: SD, Standard deviation; VAS, Visual analog scale; PA, Pressure algometer; ADL, Activity of daily living; FAAM, Foot and ankle ability measure

* Significant differences between pre- and post-intervention between two groups

Significant differences between two groups at post-intervention

Table 4. Mean (SD) of Outcome Measurements by Treatment Group at Post Intervention (N = 44)

	Group I (n=22)	**Group II** (n=22)	**Difference**	**p-value***
VAS	3.43 (1.95)	3.55 (1.95)	- 0.11	0.85
PA, kg/cm^2	36.74 (9.11)	34.55 (8.88)	2.18	0.43
ADL/FAAM	15.27 (12.31)	17.55 (14.00)	-2.27	0.57

Abbreviations: SD, Standard deviation; VAS, Visual analog scale; PA, Pressure algometer; ADL, Activity of daily living; FAAM, Foot and ankle ability measure

*Independent t-test

At baseline evaluation, no significant differences existed between Group I and Group II with regard to VAS scores ($p = 0.36$, Table 2). The two groups experienced improvement in heel pain after completing the assigned treatments compared with baseline VAS scores ($p < 0.001$), but differences between the two groups were small and statically insignificant ($p = 0.85$, Table 3; Figures 8,9).

The results of post intervention evaluation showed that Group I managed with MPC had reduction in heel pain by -3.96 scores (95% confidence interval (CI), −4.81 to -3.10) compared to mean reduction of -3.30 scores (95% CI, −4.19 to - 2.40) for Group II managed with MPC coupled with plantar fascia SE. The mean difference for heel pain between the two groups was insignificant, mean reduction or difference of -.11; (95% CI, −1.30 to −1.07; Tables 3, 4).

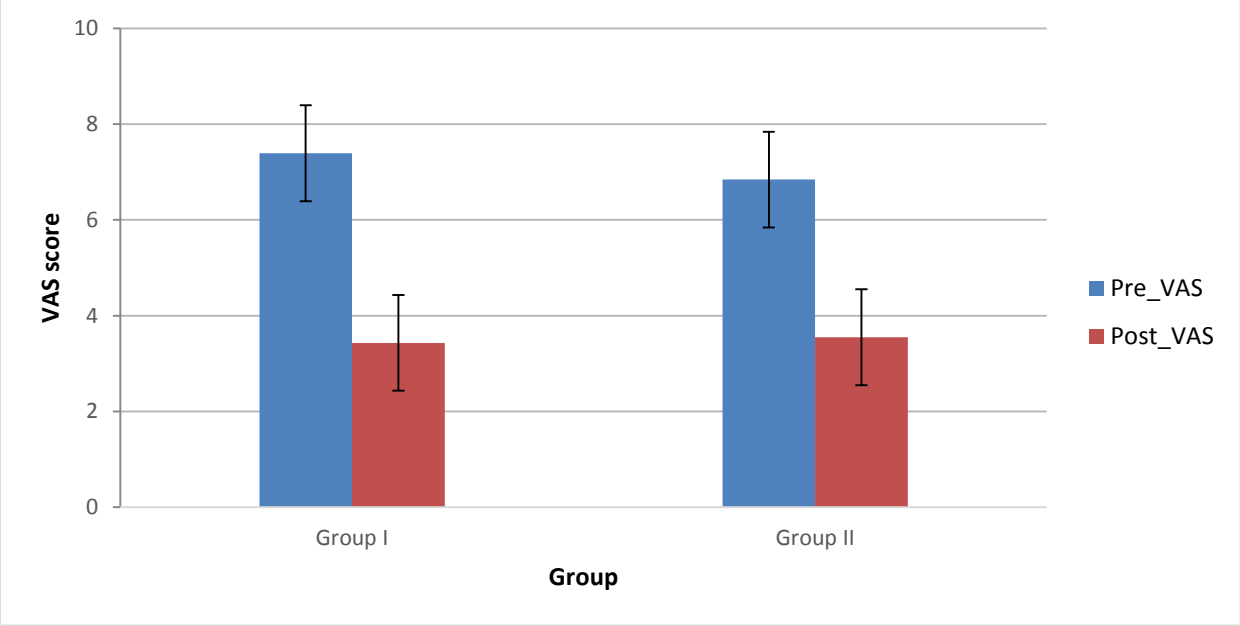

Figure 8. Mean ± SD of Visual Analogue Scale Scores between the Two Groups over time

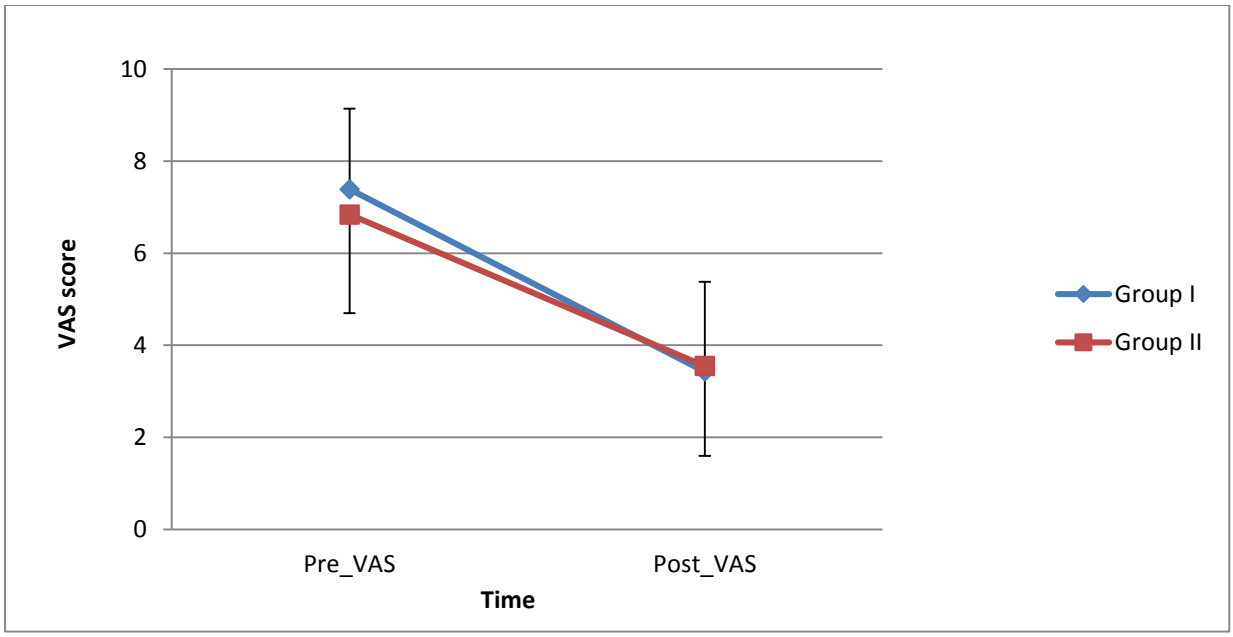

Figure 9. Mean ± SD of Visual Analogue Scale Scores by Treatment Group over time.

At baseline evaluation, no significant differences existed between Group I managed with MPC and Group II managed with MPC coupled with plantar fascia SE with regard to PA scores ($p = 0.12$, Table 2). The two groups experienced improvement in heel tenderness after completing the assigned treatments compared with baseline PA cores ($p < 0.001$), but no significant differences between the two groups were detected ($p= 0.21$, Table 3; Figure 10).

Findings of post intervention evaluation showed that Group I managed with MPC had an improvement in heel tenderness of 19.33N (95% confidence interval (CI), 16.12 to 22.53) compared to an improvement of 20.08 N (95% CI, 16.51 to 23.65) for Group II managed with MPC coupled with plantar fascia SE. The mean difference for PA scores between the two groups was not significant, mean reduction or difference of 0.75 (95% CI, −5.4 to 3.90; Tables 3, 4).

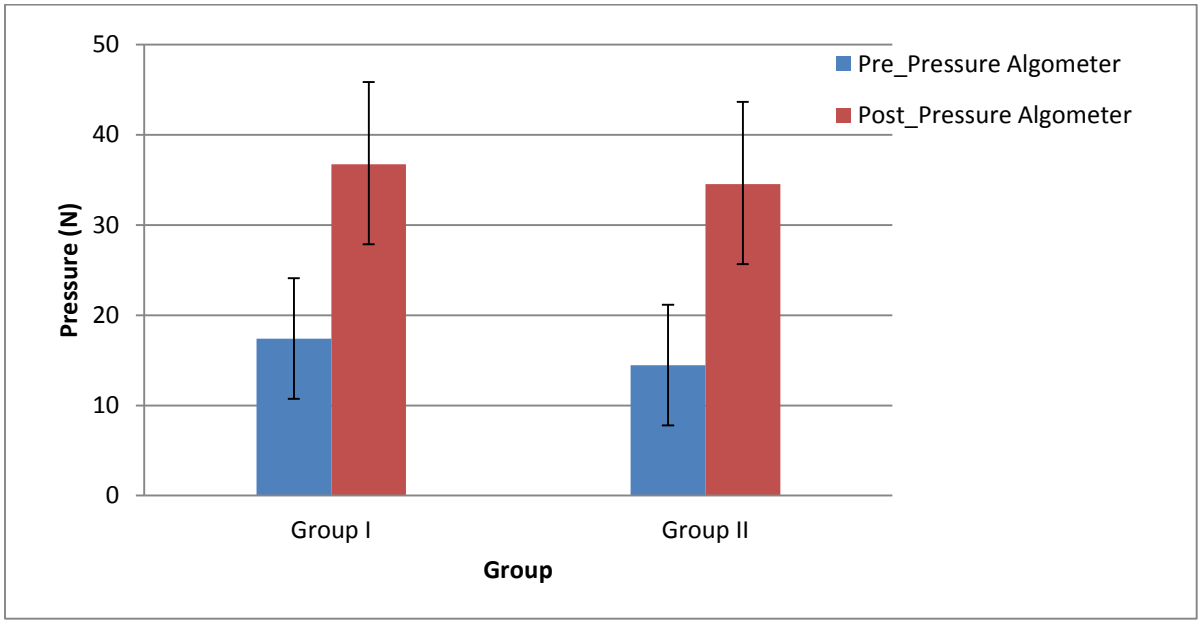

Figure 10. Mean ± SD of Pressure Algometer scores between the Two Groups over time

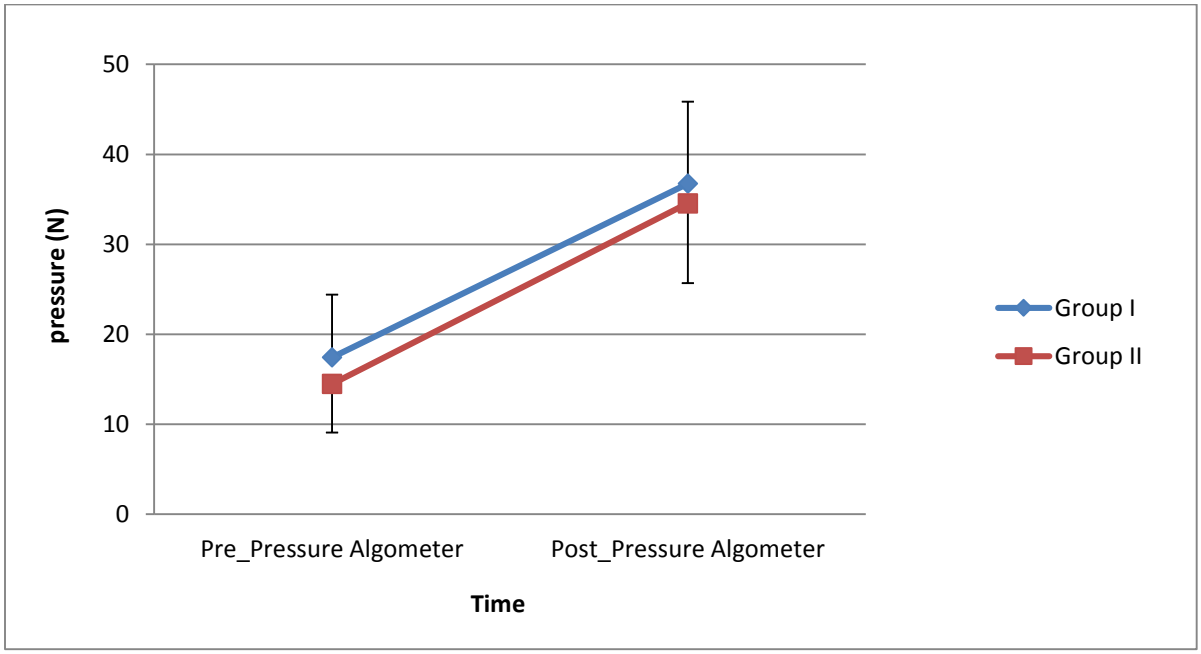

Figure 11. Mean ± SD of Pressure Algometer Scores by Treatment Group over time

At baseline, no significant differences existed between the two groups with regard to ADL/FAAM scores ($p = 0.34$, Table 2). The two groups experienced improvements in functional activities of daily living after completing the assigned treatments compared with baseline ADL/FAAM scores ($p < 0.001$), but differences between the two groups were insignificant ($p = 0.57$, Table 3; Figures 12, 13).

Results of post intervention evaluation showed that Group I managed with MPC had an improvement in the ADL/FAAM of -18.90 scores (95% confidence interval (CI), −23.85 to -13.87) compared to mean reduction of -13.09 scores (95% CI, −17.31to −8.85) for Group II managed with MPC coupled with plantar fascia SE .The mean difference for ADL/FAAM scores between the two groups was not significant, mean reduction or difference of -2.30 (95% CI, −10.29 to 5.74; Tables 3,4).

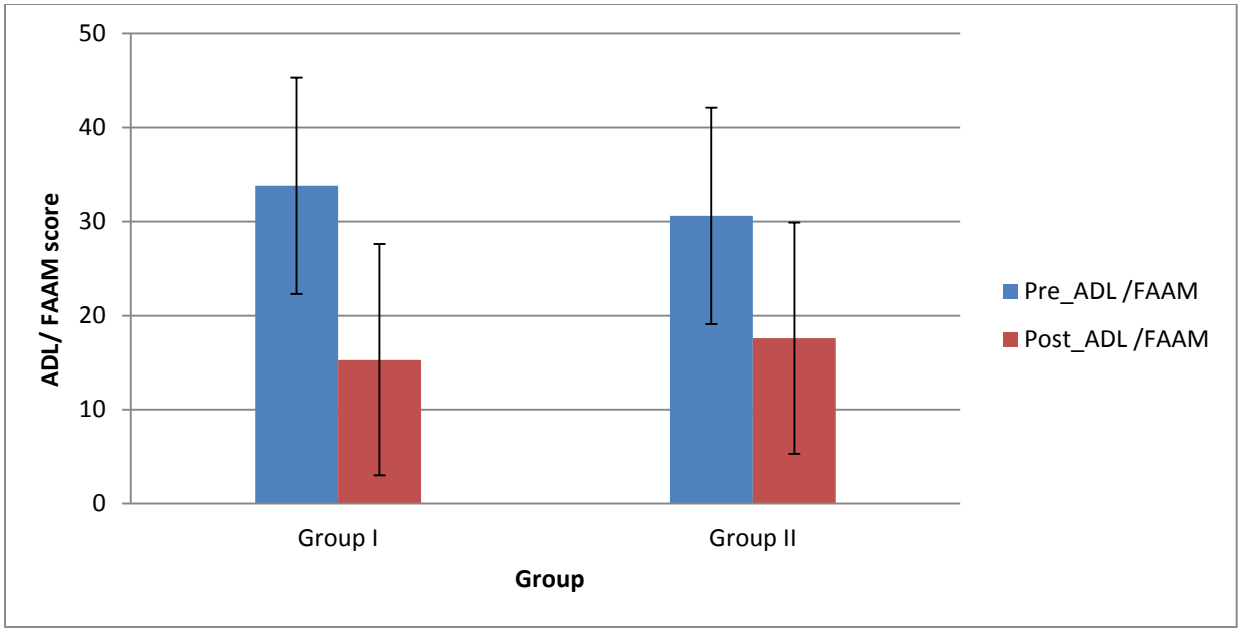

Figure 12. Mean ± SD of Active Daily Living /Foot Ankle Ability Measure Scores between the Two Groups

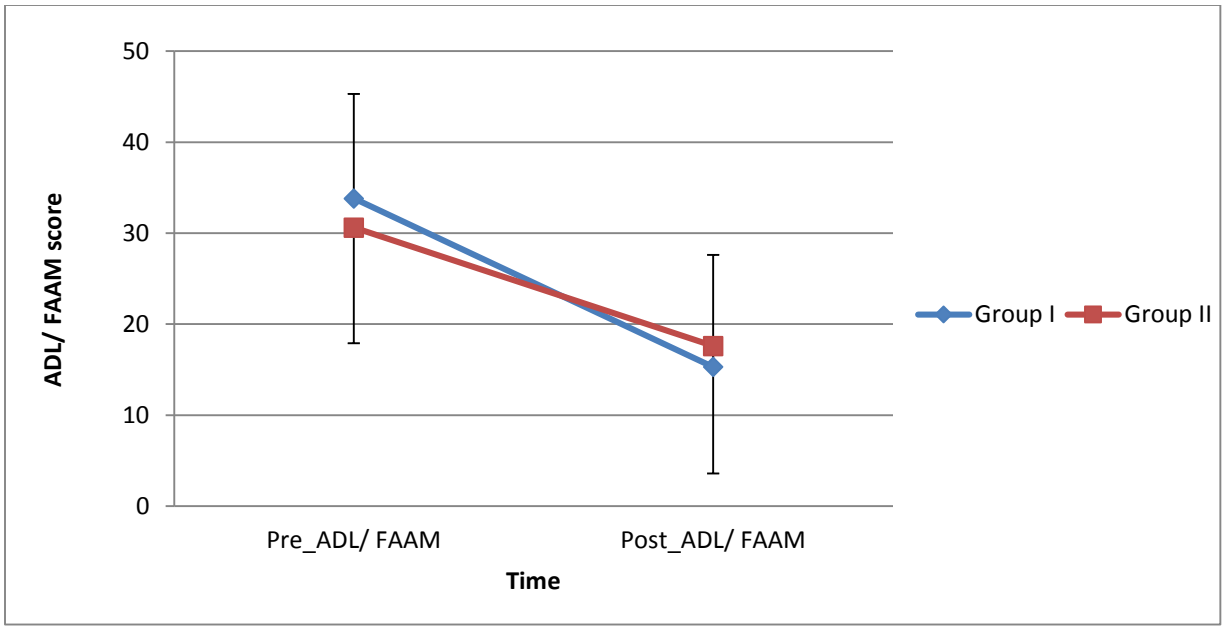

Figure 13. Mean ± SD of Active Daily Living /Foot Ankle Ability Measure Scores by Treatment Group over time

Discussion

PF is the most common cause of heel pain. For the vast majority of conditions, most experience resolution of symptoms within 10 months[3,7,19]. Disagreement exists regarding the etiology of PF. Its causes are still debated among histologists, pathologists and different healthcare professionals[7,11,31]. PF is presumed to be associated with overuse, training errors, improper or worn footwear, sudden increase in weight bearing activity, weak intrinsic foot muscles, and obesity[8,10,11]. PF appears to result from an inflammatory reaction which occurs in conjunction with microtears within the plantar fascia[9-11]. The majority of non-operative treatments for PF have demonstrated encouraging results[9-11,30,31,40-49].

Many physical therapy interventions can be used to alleviate inferior heel symptoms associated with plantar fasciitis[30]. These modalities include iontophoresis,

manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises of calf muscles and plantar fascia, taping, and orthotic devices[10,30,31,40-42,44-46,48].

MPC is utilized clinically to promote wound and pressure ulcer healing processes. It appears to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, and increase the number of growth factor receptors, and aid in calcium influx[52-59].

The primary focus of this prospective clinical trial was to examine the effect of MPC and MPC coupled with plantar fascia SE on subjective reporting of heel pain, heel tenderness, and functional activities level on patients diagnosed with PF. To our knowledge no prior studies have been conducted to examine the effect of MPC on patients with PF.

We hypothesized that the use of MPC would promote and accelerate healing processes, especially the proliferation phase associated with plantar fasciitis. Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain the structural integrity of connective tissue. Fibroblasts make collagen, glycosaminoglycans, reticular and elastin fibers, and glycoproteins found in the extracellular matrix. The promotion and acceleration of healing processes of the inflamed plantar fascia may decrease heel pain, tenderness, disability level, and thickness of plantar fascia imposed by PF. We utilized plantar fascia SE in our study because such exercises are considered central to most conservative treatment plans for heel pain associated with PF. DiGiovanni reported a significant reduction in pain and improvement in the level of activities[9].

The results of this prospective clinical trial are consistent with results of other clinical studies which have concluded that physical therapy interventions and the use of modalities may mitigate inferior heel and improve patients' functional difficulties caused by plantar fasciitis[10,30,31,40-42,44-46,48].

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

Findings from the post intervention evaluation determined that both Group I managed with MPC and Group II managed with MPC coupled with plantar fascia SE experienced significant reduction in VAS scores compared to baseline, with a mean effect of -3.95 for Group I and -3.29 for Group II. The differences between the two groups were not significant. The reduction in VAS scores in either group was clinically significant[61-63].

Comparison of the baseline pressure algometer scores revealed significant improvements in heel tenderness in both groups. Group I managed with MPC and Group II managed with MPC coupled with plantar fascia SE displayed a mean effect of 19.33 N and 20.88 N on the PA scores, respectively. However, no significant difference existed between the two treatment groups. Improvement in the pressure algometer scores was large enough to be clinically important[64-66].

This study showed significant improvement in the functional activities level for both groups. Group I managed with MPC and Group II managed with MPC coupled with plantar fascia SE showed a mean effect of -18.9 and - 13.1 scores on the ADL/FAAM, respectively; however, no significant difference between the two treatment groups was revealed. This reduction in ADL/FAAM scores was large enough to be clinically important[67-69].

The results of this prospective study are consistent with other physical therapy studies indicating that physical therapy interventions and modalities were efficient in improving inferior heel pain symptoms resulting from plantar fasciitis [10,30,31,40-42,44-46,48].

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

The strengths of this study were based on its prospective randomized design. Additionally, the attrition rate was not high. Finally, the number and duration of

treatments were based on clinical expertise and considered adequate to draw sound conclusions about the efficacy of the MPC.

Based on this study's findings, physical therapists are urged to use MPC as an effective treatment for patients clinically diagnosed with PF. However, it is suggested that clinicians combine MPC with plantar fascia SE to promote and accelerate the healing process as well as regain and maintain the flexibility of the plantar fascia, even though this study did not support conclusively the additive effect of using plantar fascia SE on inferior heel symptoms associated with PF.

Further studies are encouraged to address the limitations of this study, issues of plantar skin resistance on the treatment with MPC, and long-term effects of MPC on treatment of PF.

Conclusion

In conclusion, this prospective controlled trial supports the efficiency of MPC in reducing inferior heel pain and tenderness, and improving functional activities levels associated with PF. MPC can be effective for treatment of patients with chronic PF and is considered a low risk and low cost alternative to costly and more invasive medical and surgical treatments. This study yielded notable improvements in both groups in different subjective outcome measures. Further explanatory prospective controlled clinical trials are needed to draw more conclusive inferences about the efficacy and ability of MPC on patients with PF.

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CHAPTER THREE

THE EFFECT OF MONOPASHIC PULSED CURRENT ON THE SAGITAL THICKNESS OF PLANTAR FASCIA IN PATIENTS WITH PLANTAR FASCIITIS

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Abstract

Background: Plantar fasciitis (PF) is one of the most common causes of heel and foot pain, affecting up to 2 million Americans each year. Monophasic pulsed current (MPC) is a method of electrical stimulation clinically used to promote and accelerate wound and decubitus ulcers healing processes. The aim of this prospective clinical trial was to investigate the effect of MPC and MPC coupled with plantar fascia specific stretching exercises (SE) on the plantar fascia sagittal thickness (ST) in patients with PF.

Methods: Forty four participants (22 were women; 22 were men, with a mean age of 49 $\pm$ 10.6 years) diagnosed with plantar fasciitis were randomly allocated to receive MPC (n=22) or MPC coupled with plantar fascia SE (n=22). All participants were clinically diagnosed with PF. The ST of the proximal insertion of the plantar fascia was measured with musculoskeletal ultrasound (MSK US) using a linear array transducer.

Results: This study showed that the two treatment groups, Group I managed with MPC, and Group II received MPC coupled with plantar fascia SE, experienced a significant reduction in the sagittal thickness of the proximal insertion of plantar fascia, ($P < 0.001$). Although the differences between the two groups in the ST of plantar fascia were small and not statistically significant.

Conclusion: This trial revealed the ability of MPC to reduce the ST of proximal plantar fascia caused by PF. Both MPC and MPC coupled with plantar fascia SE exhibited a similar reduction in the ST of plantar fascia.

Keywords: plantar fasciitis, plantar fascia sagittal thickness, ultrasound, monophasic pulsed current, plantar fascia specific stretching exercises.

Introduction

Plantar fasciitis (PF) was first described by William Wood in 1812 and he regarded its presentation to tuberculosis[1-3]. PF as a clinical diagnosis is known by many pseudonyms: jogger's heel, heel spur syndrome, plantar fascial insertitis, calcaneal enthesopathy, subcalcaneal bursitis, subcalcaneal pain, stone bruise, calcaneal periostitis, neuritis and calcaneodynia[4-6]. Proximal PF or plantar heel pain is the most common soft tissue disorder that causes inferior heel and rear foot pain in athletes as well as those not involved in sport activities[7,8]. Proximal PF is a common clinical diagnostic entity usually affecting more than two million Americans every year. It constitutes approximately 15 % of foot dysfunction conditions in the United States, affects two million individuals, and accounts for more one million outpatient visits annually[3,9,10].

PF symptoms settle in 80% to 90% of conditions and resolution of symptoms occurs in majority of patients within ten months with conservative treatment[2,7,11]. PF can be a painful, debilitating, and disabling condition that often frustrates not only the patient but also the physician because its etiology is still equivocal[3,8,12,13].

PF is considered to be an overuse syndrome and an inflammatory reaction from chronic irritation or microtears of proximal plantar fascia at its attachment at the medial tuberosity of the calcaneus[2,14]. PF is defined as a localized inflammation of perifascial anatomical structures and plantar fascia at its proximal insertion on the medial tuberosity of the calcaneus resulting from chronic repetitive microtears and degeneration secondary to overuse, mechanical and congenital disorders[3,7-10,15].

PF is also clinically defined as inferior heel pain and tenderness of gradual onset, localized to the medial tuberosity of the calcaneus and exacerbated by weight bearing[11,16]. It can affect patients from childhood to older ages, but is most common in middle aged

women and young athletes. Inflammation of the plantar fascia is prevalent in joggers, long distance runners and tennis players as well as athletes, soccer players, gymnasts, volleyball and basketball players[7,8,17]. PF is also common in overweight individuals with occupations that require extensive standing or weight bearing[8,18,19].

Plantar fascia or plantar aponeurosis is a thick and strong fibrous connective tissue which originates at the medial tuberosity of the calcaneus and fans out distally into three bands to attach into the bases of proximal phalanges or at the metatarsophalangeal joints to form the medial longitudinal arch of the foot[11,18]. Plantar fascia lies superficial to the muscles of the plantar surface of the foot and divides into three portions: central or middle, lateral, and medial .The central or middle portion is considered to be the thickest component of the plantar fascia, and originates from the posterior aspect of the medial tuberosity of the calcaneus posterior to the origin of the flexor digitorum brevis tendon, and is its width is between 1.5 to 2.0 cm. Distally, at the level of the metatarsophalangeal joints, the central portion of the plantar aponeurosis divides in to five bands, one for each of the toes[3,20-24].

The lateral component of the plantar aponeurosis originates from the lateral aspect of the medial tuberosity of the calcaneus with its distal medial and lateral bands connecting to the plantar plate of the fourth toe and to the base of the fifth metatarsal bones respectively. The medial component of the plantar aponeurosis is thin and lies superficial to the abductor hallucis muscle and connected medially with the dorsal fascia and laterally with the central component of the plantar aponeurosis[3,18,20,21,23,25].

Histological examination of biopsy samples of the irritated and inflamed plantar fascia reveal granulation tissue, fibroblast proliferation, and fibrosis , collagen necrosis,

chondroid metaplasia, and matrix calcification, all of which are suggestive of a repetitive strain and fascia degenerative process[26,27].

The windlass mechanism model is a term used to explain the responsibility of the plantar fascia dynamic function during a manner of walking[28]. The plantar fascia functions through the windlass mechanism which was described first by Hicks as a mechanical model[29,30]. The plantar fascia plays an important role in providing support for the foot through the stance phase of gait cycle. During the toe off of the gait cycle, the extension of the toes at the metatarsophalangeal joints tightens the planter fascia and elevates the medial longitudinal arch thus forming a solid pivot of foot for push off[30,31]. The foot and its ligaments can be thought of as a truss or arch-like triangular structure, with the calcaneus, midtarsal joint, and metatarsals forming the medial longitudinal arch[28,29].

The etiology of PF remains unclear and is poorly understood and still debated among medical fraternity despite its high prevalence[3,7,11]. Even the etiology of plantar fasciitis is poorly established in previous research literature, it is thought to be caused by intrinsic and extrinsic predisposing factors[11,32]. Intrinsic precipitating factors that may make an individual vulnerable for the development of PF may include obesity and a body mass index of more than 30. Being overweight can increase stress upon plantar fascia during normal walking. Secondly, advanced age can predispose an individual to PF. After the age of 40 years, the fat pad begins to degenerate, with loss of water content and collagen component that affects it elasticity. When sagittal the thickness of the fat pad decreases, it may result in minimizing shock absorbency of that anatomical structure and reduced protection of the calcaneal tuberosity and plantar fascia. Thirdly, Achilles

tendon tightness and inadequate ankle dorsiflexion may lead to excessive subtalar pronation to compensate for that dysfunction and that over pronation contributes to plantar fascia elongation, overstretch and irritation. Fourthly, excessive pronation (pes planus) is caused by plantar flexion and adduction of talus and can cause the height longitudinal arch of the foot to decrease and create strain on the plantar aponeurosis which can result in the development of PF [10,11,33]. Other intrinsic potential risk factors may include leg length discrepancy, excessive lateral tibial torsion, and excessive femoral anteversion, pes cavus and equinus, and sudden weight gain[7,8,11]

Extrinsic potential predisposing factors that may make someone susceptible for the development of plantar fasciitis may include high intensity sport activities or training that require repetitive plantar flexion of the ankle joint and extension of the metatarsophalangeal joints and that mechanical overload and excessive tensile load that produce microtears within the plantar fascia, which eventually incites a chronic inflammatory response followed by degeneration[8,33,34]. Other extrinsic potential risk factors include the use of poor or worn footwear, occupational and recreational activities that require prolonged standing or weight bearing, and improper training techniques[7,11,32].

The classic feature and presentation of plantar fasciitis are mechanical symptoms of pain on the sole of the foot at the inferior region of the heel[32,33]. The onset of the inferior heel pain is insidious and may worsen over time. Pain may interfere with walking, particularly when taking the first few steps in the morning after getting out of the bed, or arising from a seat after prolonged sitting or inactivity. The intense and shooting inferior heel pain can be so terrible that the patient may limp around with the affected heel off the ground. By the end of the day, a dull aching pain typically happens

and may extend the midfoot and forefoot. The sharp pain is usually localized to the plantarmedial aspect of the heel or over a small area near the proximal insertion of the plantar fascia at the medial tuberosity of the calcaneus[3,18,19,26,32,33,35].

The diagnosis of PF can be made through a thorough and comprehensive history taking and physical examination. Heel pain, while taking first steps in the morning, is typical of PF and will reveal differences from other inferior heel pain dysfunctions. Inferior heel pain imposed by plantar fasciitis is not associated with paresthesia or nocturnal pain. Localized tenderness to palpation of plantar fascia at its origin on anteromedial aspect of the calcaneal tuberosity may be elicited by slight passive dorsiflexion movement of the toes or having the patient stands on the tips of the toes. A windlass test is considered to be positive when passive dorsiflexion of the hallux reproduces pain and discomfort at the proximal plantar fascia. The evaluation of range of motion may reveal or demonstrate a restriction of ankle dorsiflexion by 5 degrees or more which indicates contracture of the Achilles tendon[3,8,11,25,36].

A plain radiograph does not support the diagnosis of plantar fasciitis but can be used to look for bony lesions of the foot. Diagnostic ultrasonography is inexpensive and useful in ruling out soft tissue pathology of the heel. Findings of diagnostic ultrasound that support the presence of plantar fasciitis include proximal plantar fascia thickness greater than 4 mm and areas of hypoechogenicity. Magnetic resonance imaging, although expensive, is a valuable tool for assessing causes of recalcitrant heel pain[11,18,21,37,38]. Diagnostic findings include increased proximal plantar fascia thickening with increased signal intensity on T2-weighted imaging[11,18,26,39]. Differential diagnosis of plantar fasciitis includes calcaneal stress fractures, osteomyelitis, tumor, sacral

radiculopathy, Reiter's syndrome, Sever's disease, psoriatic arthritis, ankylosing spondylitis, tarsal tunnel syndrome, foreign body, and nerve entrapments[7,8,11,34].

The treatment of PF is primarily conservative. It is commonly treated with nonsteroidal anti-inflammatory medications, physical therapy, and corticosteroid injections. If conservative treatment fails, surgical option may be indicated[1,3,7,11].

Physical therapy plays a significant role in the treatment of plantar fasciitis[32]. Many physical therapy treatment options are available which may mitigate and allay the heel pain symptoms associated with PF. Patient with PF is instructed to have rest and avoid any strenuous and arduous activities that place strain on the inflamed and irritated proximal insertion of plantar fascia[9,10,40,41].

In 2008, the orthopedic section of the American Physical Therapy Association began issuing a series of evidence based clinical practice guidelines linked to the international classification of function, disability, and health that provide recommendations about assessment, prognosis, diagnosis, and treatment for common musculoskeletal dysfunctions. In terms of plantar fasciitis, there are many physical therapy interventions or means that can be used to alleviate and attenuate the inferior heel symptoms that are associated with plantar fasciitis[32,42].

These modalities include iontophoresis, manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises of calf muscles and plantar fascia, taping, orthotic devices, which can be used to suit patient needs[9-11,32,33,40-49]. Other physical therapy techniques may include soft tissue mobilization, heel padding, icing, contrast baths, ultrasound, and rest[34,50,51].

MPC is utilized clinically to promote wound and pressure ulcers healing processes. Delivering of electrical current using electrodes to wound bed appears to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, increase the number of growth factor receptor, and calcium influx[52-59]. Vitro studies showed that key tissue cells such epithelial and fibroblast cells have been attracted to wound site when electrically stimulated resulting in promoting collagen deposition, angiogenesis and wound tensile strength. Many studies inferred that wounds treated with monophasic pulsed current demonstrated 1.5 times greater rate of healing when compared to normal wound healing rates[52-59]. MPC is defined as percutaneous delivery of pulsed, twin-peak, monophasic pulses, each pulse having very short phase duration of less than 100 μsec, which employs voltage up to 500 volts [52-54]. Galvanotaxis is one of the monophasic pulsed current features and is defined as the process of attracting charged cells to an electric field of opposite polarity. Clinically in treating wounds or decubitus ulcers, a positively charged electrode (anode) is placed over a wound or pressure ulcer, to attract negatively charged cells such as neutrophils and macrophages to facilitate the inflammatory phase of wound healing. Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts make the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60]. Because polarity selection is based on the healing phase the practitioner wishes to facilitate and accelerate, we used the negatively charged cathode to attract the positively charged fibroblast cells to promote and accelerate proliferation phase of plantar fascia.

Musculoskeletal Ultrasound (MSK US) can be utilized as a diagnostic tool to corroborate or verify a clinical diagnosis of plantar fasciitis[21,37,38]. Numerous diagnostic sonography studies showed that abnormal thickening of plantar fascia greater than 4 mm and reduced echogenicity are associated with plantar fasciitis[23,25,36,49,61,62]. Many clinical trials have been conducted to measure the sagittal proximal thickness of the plantar fascia before and after a given treatment regimen to prove that treatment's efficacy[17,20,27,37,38,61,62].

The primary focus of this study was to examine the effect of MPC and MPC coupled with plantar fascia SE on the ST of proximal plantar fascia on patients diagnosed with PF.

Materials and Methods

Research Design

This study is a prospective randomized clinical trial to compare the effectiveness of two interventions on the treatment of plantar fasciitis. Participants were randomly assigned to one of two treatment groups. Group I was treated with MPC and Group II was treated with a combination of MPC and plantar fascia SE.

Participants

This prospective randomized clinical trial was approved by the Institutional Review Board (IRB) at Loma Linda University and conducted at the Physical Fitness Laboratory at the School of Allied Health Professions, Department of Physical Therapy between March and September, 2013.

The following inclusion/exclusion criteria were used to determine eligibility of the participants for enrollment in this clinical trial. Inclusion criteria included: (1) subjects of both genders were diagnosed with plantar fasciitis; and (2) the diagnosis was made upon the finding of tenderness to pressure at the origin of plantar fascia on the medial tubercle of the calcaneus, as well as complaint of heel pain greater than or equal to 3 on a 1 to 10 VAS scale. Exclusion criteria included: (1) previous fracture or surgery to the foot; and (2) specific metabolic and connective tissue disorders associated with or contributing to the diagnosis of PF (i.e., rheumatoid arthritis, gout, lupus).

The recruitment of the subjects was assisted by referrals from Loma Linda Medical Center's orthopedists, podiatrists, and primary care physicians (APPENDEX A). Additional recruitment was sourced via advertisements in Loma Linda Trading Post and online and weekly newspapers in area cities (APPENDEX B). Also, study fliers were placed on bulletin boards of the Draysen Fitness Center of Loma Linda University as well as the School of Allied Health Professions (APPENDEX C), with electronic versions of the study flier having been sent to the School of Allied Health Professions students.

If the referring physician felt patients would qualify for or benefit from participation in the clinical trial and ascertained patient interest, the patient was contacted with details about the study. Participant permission was obtained by provision of Authorization for Use of Protected Health Information (PHI) (APPENDEX D). This form allowed the patient's name, diagnosis, telephone number, date of birth, and gender to be forwarded to the study investigator (APPENDEX E). The investigator contacted the patient by telephone to provide additional information regarding the study, address questions, and schedule a baseline evaluation session (APPENDEX F).

A convenience sample of 48 patients with a clinical diagnosis of plantar fasciitis met this randomized clinical trial's inclusion criteria and underwent the baseline evaluation. Four subjects never retuned beyond the baseline evaluation session due to scheduling conflicts. Data analysis was based on the remaining 44 patients who provided written consent to continue with the study.

During the baseline evaluation, the investigator first explained the study to the patient, including its overall purpose, the procedures that would be performed, and potential benefits and risks of the interventions. If the patient decided to proceed, the investigator provided him/her a copy of the informed consent as approved by the IRB (APPENDEX G). If the patient chose to enroll in the study, he/she signed the consent form and California Experimental Subject's Bill of Right Form (APPENDEX H).

Procedure

Following procurement of patient informed consent, the investigator obtained information regarding age, gender, height, weight, body mass index (BMI), duration of symptoms as well as determining whether the patient was athletic or not, and on which side the affected area presented. A baseline evaluation was performed which included the measurement of ST of proximal plantar fascia with MSK US.

The investigator then randomly assigned the participants to one of two treatment groups. Group I received MPC and Group II received MPC coupled with plantar fascia SE, using a computer-generated random two-digit number. Each patient received three sessions of MPC per week for four weeks, for a total of twelve sessions. Each session lasted 60 minutes. Patients in Group II were instructed to perform home based SE as described by Digiovanni and his colleagues[9] (APPENDEX I).

The investigator instructed the patients on how to perform the plantar fascia SE and told them the number of daily sets to complete during the four week treatment. (APPENDEX J). After completing the assigned treatments, the investigator performed a post-intervention evaluation which included the measurement of ST of proximal plantar fascia with MSK US.

Outcome Measures

Musculoskeletal Ultrasound

Musculoskeletal ultrasound (MSK US) is an imaging tool utilized for confirming a diagnosis of plantar fasciitis and differentiating its occurrence from other inferior heel pain conditions[63]. MSK US is a valid and valuable diagnostic tool which measures changes in plantar fascia thickness before and after a given treatment regimen to gauge the treatment's efficacy. According to musculoskeletal ultrasound investigation, the standard normal or asymptomatic thickness value reported for the plantar fascia is 2.3 to 4.0 mm[36,54,62,64]. It is accepted that a thickness greater than 4 mm would be consistent with presentation of plantar fasciitis[25,36]. Each involved foot was evaluated sonographically with an L14-6 MHz linear array transducer, using Mindray-M7 Diagnostic Ultrasound System (Figure 14), and a coupling gel was applied to the plantar surface of the foot. The plantar fascia is most effectively assessed with the patient in the prone position, with the affected foot hanging over the edge of the examination table and the ankle in neutral position. The ultrasound transducer was placed vertically in relation to the plantar aspect of the heel. Finally, the sagittal thickness of the proximal insertion of the plantar fascia was measured, at a reference point 5 mm from the proximal insertion at the anterior aspect of the inferior border of the calcaneus[21,22,37,38,61,62,65] (Figure 15).

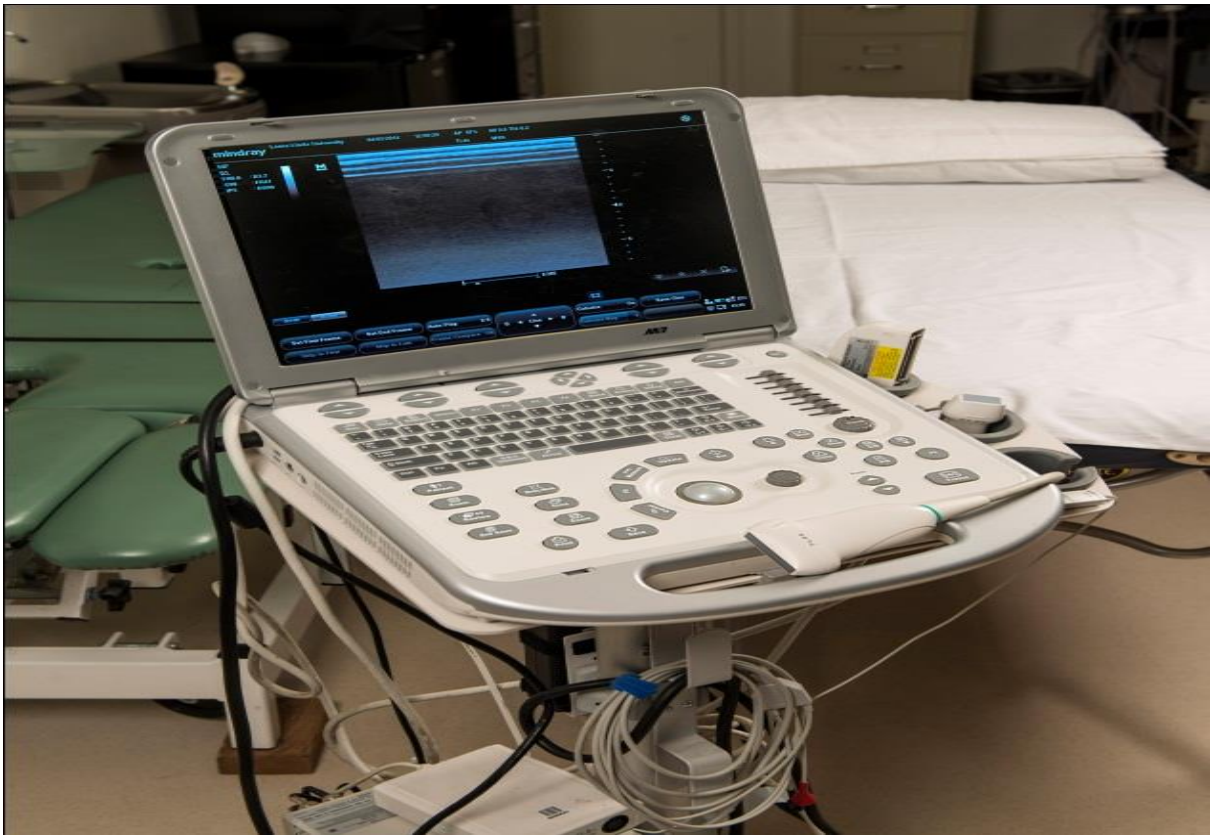

Figure 14. Mindray-M7 Diagnostic Ultrasound System

Figure 15. Measurements of the Sagittal Thickness of Plantar Fascia Technique

Interventions

Monophasic Pulsed Current

MPC is utilized clinically to promote wound and pressure ulcer healing processes. MPC is defined as percutaneous delivery of pulsed, twin-peak, monophasic pulses, each pulse having very short phase duration of less than 100 μsec, which employs voltage up to 500 volts [52-54]. Delivering of electrical current using electrodes to wound bed seems to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, increase the number of growth factor receptor, and calcium influx[52-59]. Vitro studies showed that key tissue cells such epithelial and fibroblast cells have been attracted to wound site when electrically stimulated resulting in promoting collagen deposition, angiogenesis and wound tensile strength. Many studies inferred that wounds treated with MPC demonstrated 1.5 times greater rate of healing when compared to normal wound healing rates[52-59].

Galvanotaxis is one of the MPC features and is defined as the process of attracting charged cells to an electric field of opposite polarity. Clinically in treating wounds or decubitus ulcers, a positively charged electrode (anode) is placed over a wound or ulcer, to attract negatively charged cells such as neutrophils and macrophages to facilitate the inflammatory phase of wound healing. Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts make the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60]. Because polarity selection is based on the healing phase the practitioner wishes to facilitate and accelerate, we used the negatively charged cathode to attract the positively charged fibroblast cells to promote and accelerate proliferation phase plantar

fascia healing process (GV 350 Galvanic High-Volt Pulsed Stimulator, Figure 4, 5). MPC has been shown to increase fibroblast proliferation and DNA and protein synthesis essential for the production of granulation tissue. The therapeutic parameters included: current type (pulsed current), pulse type (twin peaked), electrode polarity cathode (negative), frequency (100 pulse per second), pulse duration (100 milliseconds), and amplitude (at submotor level, too weak to elicit a visible muscle contraction) [52-54].

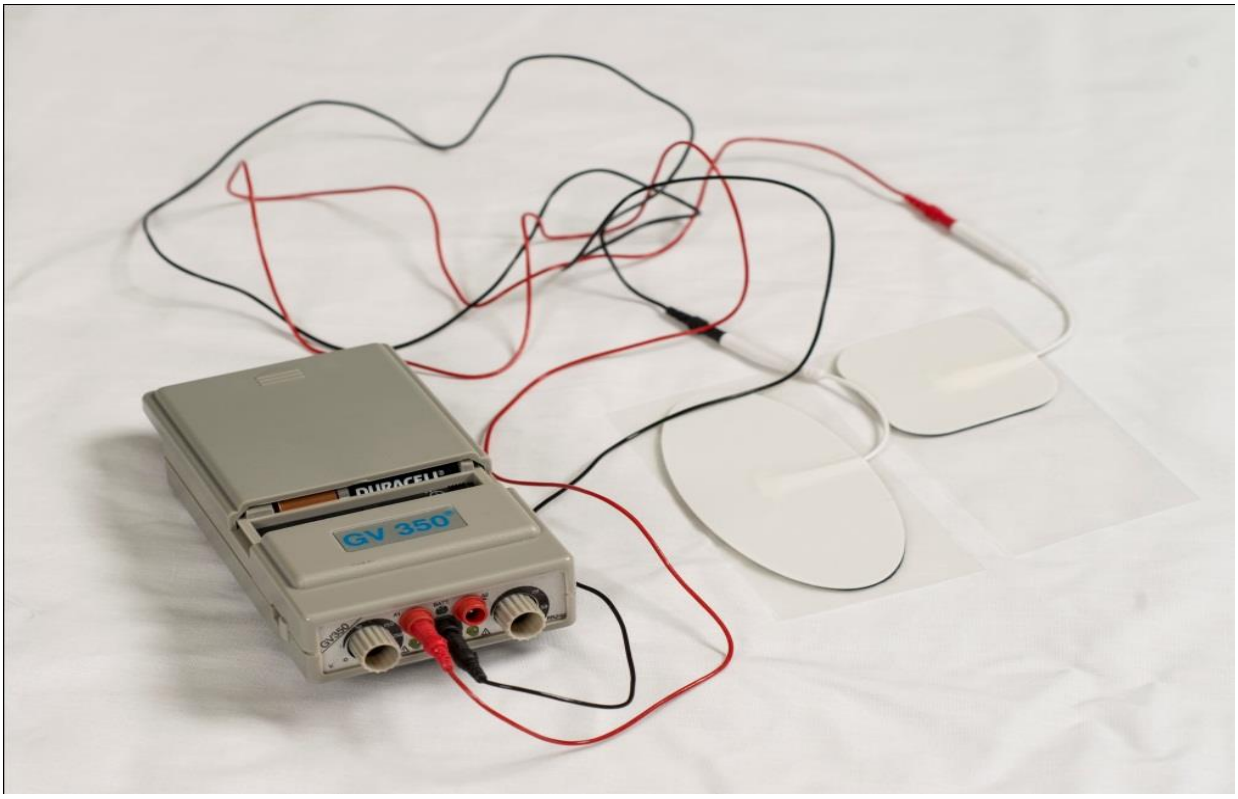

Figure 4. GV 350 Galvanic High-Volt Pulsed Stimulator

Figure 5. Monopolar Application of Monophasic Pulsed Current

Plantar Fascia Stretching Exercise

Plantar fascia stretching exercises (SE) are an integral component of the physical therapy treatment plan for the treatment of PF, used to decrease pain and functional limitations. In this study, plantar fascia SE was utilized as described by DiGiovanni and his colleagues[9]. The patient was directed to cross the affected leg over the other leg while in a sitting position, and using his/her hand, apply metatarso-phalangeal joint dorsiflexion (or pull the toes back toward the shin until the patient feels a stretch in the

arch of the foot), while holding each stretch for a count of 10, and repeating each stretch 10 times (Figure 6). All patients were required to perform the stretching program three times per day. The first stretch was to be completed before rising and exiting the bed. Patients were provided a written protocol of the home based SE program and asked to keep a daily log of exercise completion for 4 weeks. (APPENDEX J)

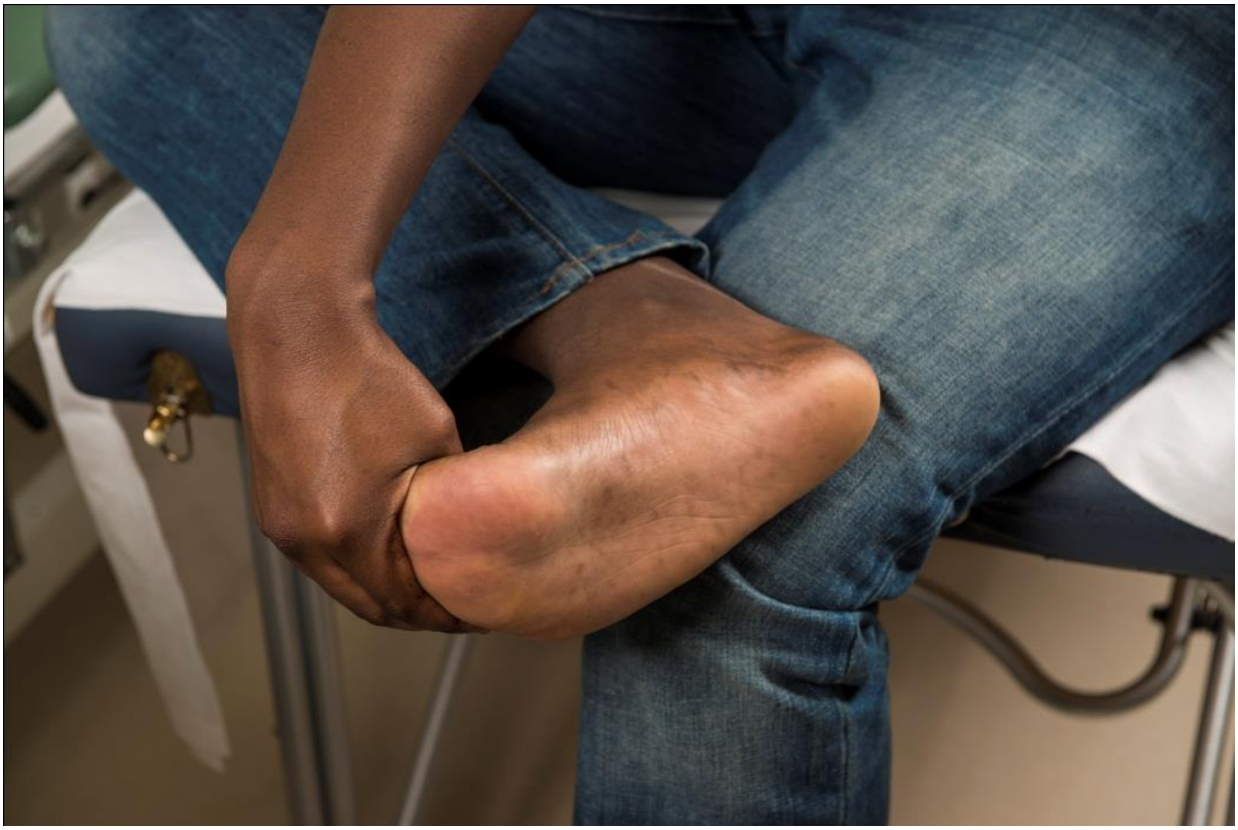

Figure 6. Plantar Fascia Stretching Exercise

Data Analysis

Sample Size Estimation

SAS statistical analysis software was used to calculate the sample size required so that a reasonable expectation would be likely to detect an expected effect size of 0.4 between the two study groups. A sample size of 40, with 20 participants per group with 0% attrition rate was utilized in the study. Forty participants were required to show statistical significance when clinically significant differences between the groups were present. Additional participants were recruited to provide for unanticipated attrition.

Description of Statistical Procedures

IBM SPSS Statistics Grad Pack 22.0 PREMIUM was used to analyze the data. Participants' demographic data for each group was summarized using descriptive statistics using means and SDs for continuous variables and frequencies and percentages for categorical variables to determine if significant differences between the two the groups existed. The assumption of normality of the continuous variables was examined using the Kolmogorov- Smirnov test. Also, the assumption of homogeneity was examined by Levene's test.

The two groups were compared at baseline using independent t-test. Differences were calculated between pre and post measurements for heel pain, heel tenderness, and functional activities level. A mixed 2×2 factorial Analysis of Variance (ANOVA) was conducted to examine the effect of the two interventions MPC and combination of MPC and plantar fascia SE on heel pain, heel tenderness, and functional activities level. To explore if changes in outcome measures over time were consistent across treatment

groups, researchers examined whether there was an interaction between treatment group and time. The level of significance was set at P value ≤ 0.05.

Results

Of the 44 participants completing the study, 22 were women, and 22 were men (Figure 7). The right foot was involved in 22 participants and the left foot in 22. The mean age of Group I (received monophasic electrical stimulation) was 49.7 ± 11.7 years, and the mean age of Group II (received monophasic electrical stimulation couples with plantar fascia stretching exercises) was 49.0 ± 9.7 years. The mean height of Group I was 171.5 ± 12.0 cm, and the mean height of Group II was 171.0 ± 13.5 cm. The mean weight of Group I was 96.4 ± 22.9 kg, and the mean height of Group II was 87.4 ± 22.9 kg. The median duration of symptoms in Group I was 12 months with interquartile range (IQR) of 154, and for Group II was 12 months with IQR of 154, hence, the sample consisted primarily of participants with relatively chronic symptoms. All participants in the two treatment groups appeared to be generally well matched. No significant differences between group I managed monophasic electrical stimulation and group II managed monophasic electrical stimulation coupled with plantar fascia stretching exercises were found in regards to height, weight, BMI age, gender, athletic status, and affected side (Table 1).

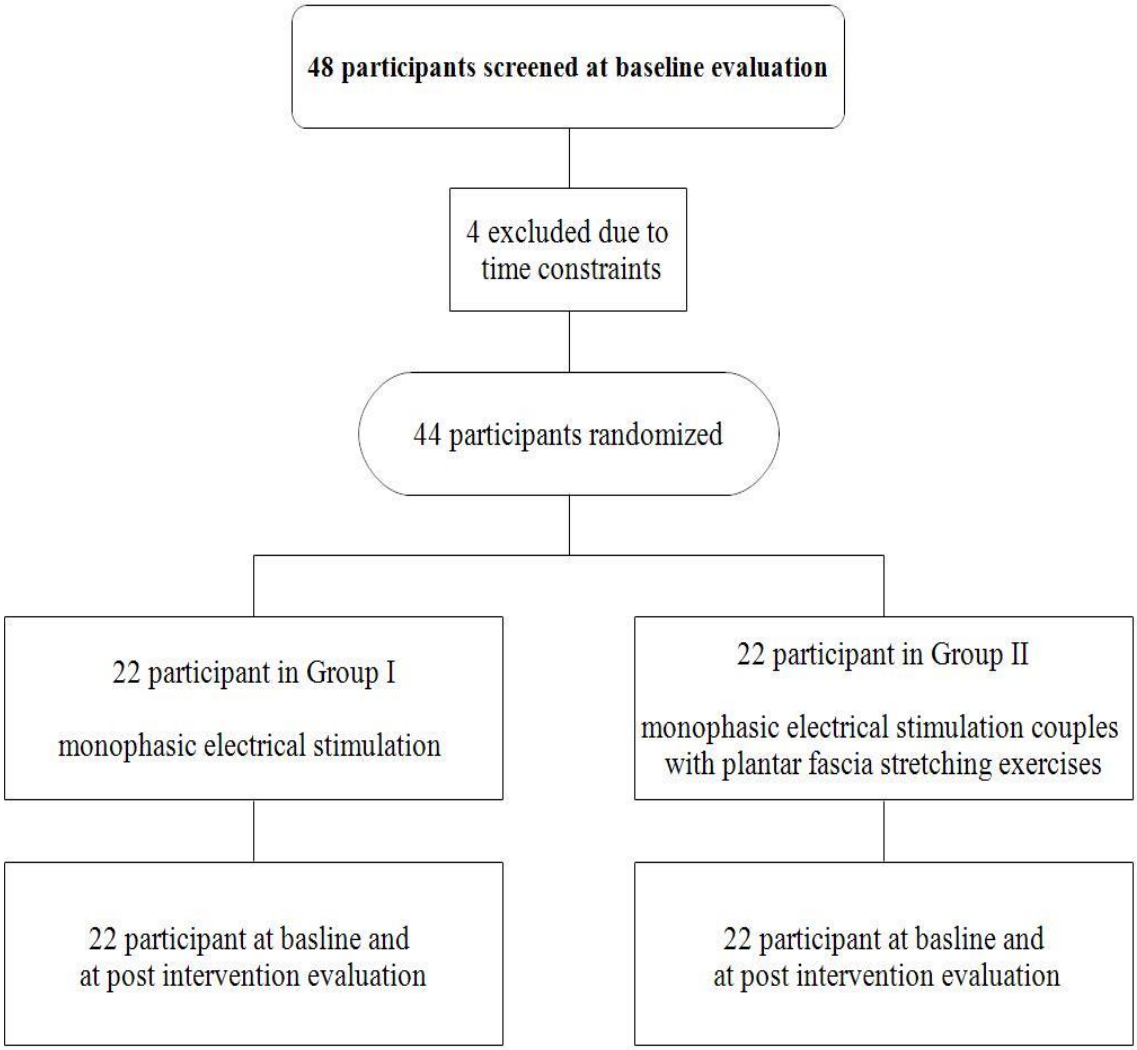

Figure 7. The Progression of Participants through the Clinical the Trial

Table 1. General Characteristics of Subjects (N= 44)

		Group I (n=22)	**Group II** (n=22)	**p-value**
Age, mean (SD) year		49.7 (11.7)	49.0 (9.7)	0.60 *
Height, mean (SD) cm		171.5 (12.0)	171.0 (13.5)	0.91*
Weight, mean (SD) kg		96.4 (22.9)	87.4 (22.9)	0.20*
BMI, mean (SD) kg/m^2		32.8 (7.2)	30.0 (7.4)	0.21*
Standing hours, mean (SD)		8.8 (3.2)	9.6 (2.48)	0.31*
Duration of symptom, median (IQR) months		12 (154)	12 (149)	0.12^
Gender	Male, % (n)	36.4 (8)	31.8 (7)	0.75#
	Female, % (n)	63.6 (14)	68.2% (15)	
Athletic status	Athletic, % (n)	9.1 (2)	13.6 (3)	0.50$
	Non-Athletic, % (n)	90.9 (20)	86.4 (19)	
Involved side	RT, % (n)	27.3 (6)	50.0 (11)	0.12#
	LT, % (n)	72.716)	50.0 (11)	

Abbreviations: SD, Standard deviation; BMI, Body mass index; IQR, Interquartile range; RT, Right; LT, Left
*Independent t-test; ^ Mann Whitney U- test; # Pearson chi square; $Fisher's exact test

Table 5. Mean (SD) of Sagittal Thickness of Plantar Fascia by Treatment Group at Baseline (N=44)

	Group I Mean (SD)	Group II Mean (SD)	**Difference**	**p-value***
ST (mm)	4.61 (1.19)	4.11 (0.99)	0.50	0.14

Abbreviations: SD, Standard deviation; ST, Sagittal thickness.
*Independent t-test

Table 6. Mean (SD) of Sagittal Thickness of Plantar Fascia by Treatment Group over Time (N=44)

	Pre Mean(SD)	**Post** Mean(SD)	**p-value***	**p-value#**	**Pre-post by-group interaction**
ST (mm)					
Group I (n=22)	4.61 (1.19)	3.87 (1.19)	< 0.001	0.23	0.49
Group II (n=22)	4.11 (0.99)	3.45 (1.06)			

Abbreviations: SD, Standard deviation; ST, Sagittal thickness.

* Significant differences between pre- and post-intervention between two groups

Significant differences between two groups at post-intervention

Table 7. Mean (SD) of Sagittal Thickness by Treatment Group at Post Intervention (N=44)

	group I Mean (SD)	group II Mean (SD)	**Difference**	**p-value***
ST (mm)	3.87(1.19)	3.45 (1.06)	0.4	0.23

Abbreviations: SD, Standard deviation; ST, Sagittal thickness.

*Independent t-test

At baseline evaluation, no significant differences existed between group I and group II with regard to MSK US measurement of the ST of proximal insertion of plantar fascia, (P = 0.14) (Table 5, Figure 16). The two groups experienced significant reduction in the ST of plantar fascia after completing the assigned treatments compared with baseline evaluation (p < 0.001), but differences between the two groups were small and statistically insignificant (P = 0.23) (Table 3, Figure 17).

Post intervention evaluation showed that group I managed with MPC had a mean reduction of the proximal thickness of plantar fascia by -0.74 mm (95% confidence interval (CI), −0.93 to -0.55mm) compared to mean reduction of -0.66 mm (95% CI, −0.81 to −0.51 mm) for group II managed with MPC coupled with plantar fascia SE.

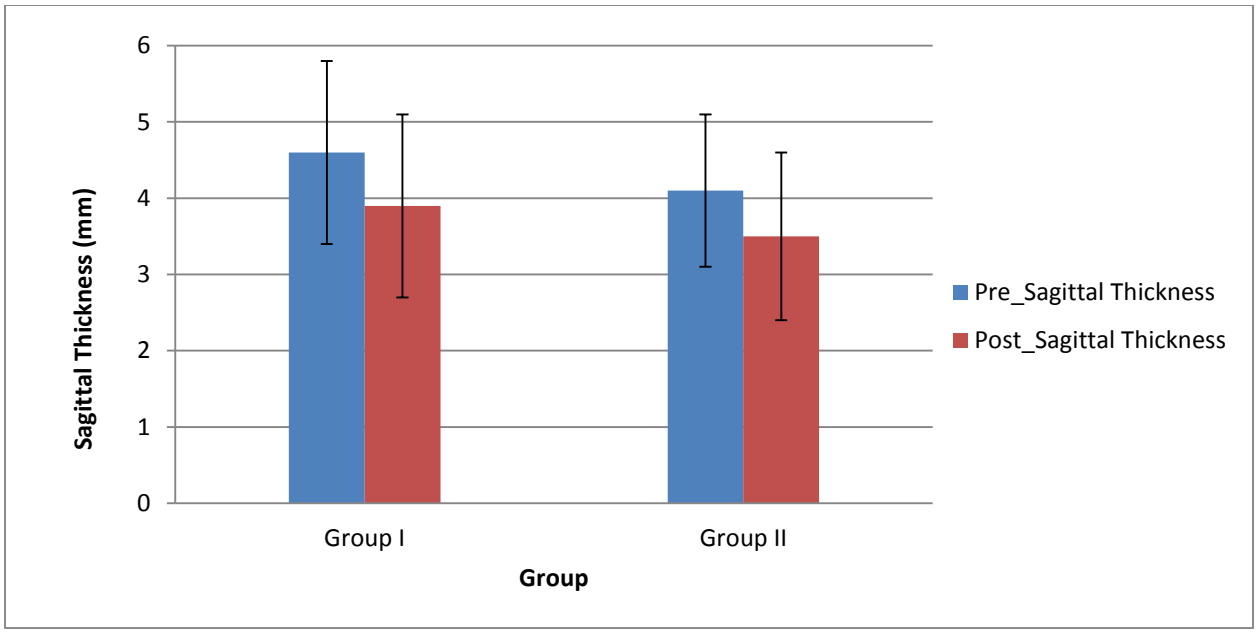

Figure 16. Mean ± SD of Sagittal Thickness by between the Two Groups

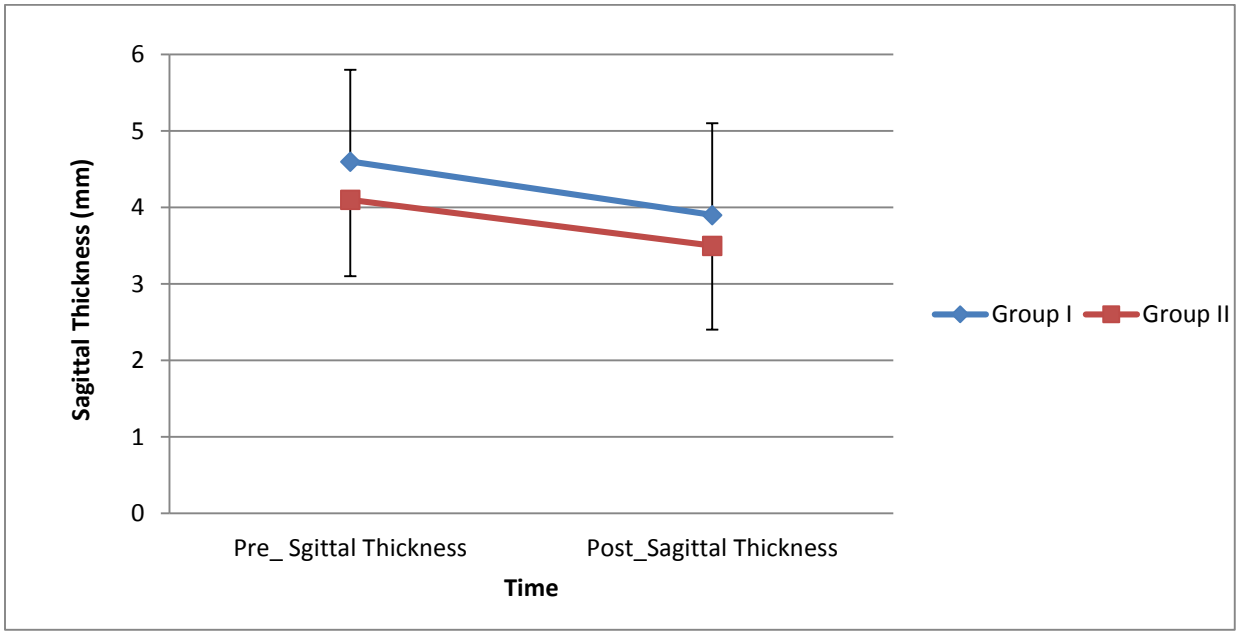

Figure 17. Mean ± SD of Sagittal Thickness by Treatment Group over time

Discussion

The most common cause of inferior heel pain is plantar fasciits. Vast majority of the conditions experienced resolution of symptoms within 10 months [8,5,38]. It is related to overuse, training errors, improper or worn footwear, sudden increase in weight bearing activity, weak intrinsic foot muscles, and/or obesity[8,10,11]. The majority of physical therapy interventions and modalities for PF have demonstrated positive and encouraging results[9-11,32,40,41,43,44]. These interventions include iontophoresis, manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises of calf muscles and plantar fascia, taping, and orthotic devices[9-11,32,33,40-43,45-49].

MPC is utilized clinically to promote wound and pressure ulcer healing processes. MPC seems to induce cellular and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, increase the number of growth factor receptors, and enhance calcium influx[52-59].

Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts create the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60]. Negatively charged cathodes were used to attract positively charged fibroblast cells which promote and accelerate the proliferation phase of plantar fascia[52-54].

Plantar fascia stretching exercises were utilized in this study because they are considered central to most conservative treatment and viable therapeutic techniques for inferior heel pain associated with PF. DiGiovanni et al reported that plantar fascia specific stretching exercises showed significant reduction in heel pain and improvement in the functional activities level in patients with PF[9].

Musculoskeletal Ultrasound MSK US can be utilized as a diagnostic tool to corroborate or verify a clinical diagnosis of plantar fasciitis, although initially, it is not routinely required[21,37,38]. It is often used to effectively evaluate plantar fascia pathology and rule out other heel dysfunctions. Also, it can be useful as an objective outcome measure in evaluating the effectiveness of new or existing intervention for different musculoskeletal conditions[22,63].

Many clinical trials have been conducted to measure the sagittal proximal thickness of the plantar fascia before and after a given treatment regimen to prove that treatment's efficacy[17,20,27,37,38,61,62]. Diagnostic sonography studies showed that abnormal thickening of plantar fascia greater than 4 mm and reduced echogenicity and loss of delineation of the borders of the plantar fascia distal to its proximal attachment on the medial tuberosity of the calcaneus of the fascia would be consistent with the presence of plantar fasciitis[23,25,36,49,61,62].

The primary focus of this study was to examine the effect of monophasic pulsed current and monophasic pulsed current coupled with plantar fascia-stretching exercises on abnormal change in sagittal thickness of proximal insertion of plantar fascia on patients diagnosed with plantar fasciitis. To our knowledge no prior studies have been conducted to examine the effect of monophasic pulsed current as a physical therapy modality on patients diagnosed clinically with plantar fasciitis using Musculoskeletal Sonography.

Each involved foot was evaluated sonographically with a L14-6 MHz linear array transducer (Mindray-M7 Diagnostic Ultrasound System) and acoustic coupling gel was applied to the plantar surface of the foot. All plantar fascia measurements were taken by

the investigator, who received individualized practical training sessions regarding using diagnostic ultrasound to measure the sagittal thickness of the proximal plantar fascia by two musculoskeletal radiology faculty and a chiropractor who is a registered diagnostic medical sonographer. Each participant was examined while lying in a prone position with knee extended and ankle in the neutral position with the affected foot hanging over the edge of the examination table. The ultrasound probe was applied vertically to the plantar aspect of the heel. The sagittal thickness of the proximal insertion of the plantar fascia was measured to the nearest tenth of a millimeter at a reference point 5 mm from the proximal insertion at the anterior aspect of the inferior border of the calcaneus[61,62].

Data analysis of the of indicated there were no significant differences the participants' characteristics between the two treatment groups in terms of age, gender, height, weight, BMI, duration of heel symptoms, athletic status, and involved side. Participants' characteristics in the two treatment groups appeared to be generally well matched with each other and would not affect the objective outcome measure utilized to determine the effect of monophasic pulsed current on the treatment of plantar fasciitis.

At baseline evaluation, no significant differences existed between Group I and Group II with regard to MSK US measurement of the ST of plantar fascia.

The two groups experienced significant reduction in the ST of plantar fascia after completing the assigned treatments compared with baseline MSK US measurement but differences between the two groups were small and insignificant.

After treatment, Group I managed MPC experienced a mean decrease in the sagittal thickness of plantar fascia by -0.74 mm (95% confidence interval (Cl), −0.93to -

0.55 mm) compared to mean reduction of -0.66 mm (95% CI, −0.80 to −0.51 mm) for Group II which managed with MPC coupled with plantar fascia SE.

This study showed significant decrease in the sagittal thickness of proximal plantar fascia after the use of MPC. Findings of this clinical trial agreed with previous studies results about the efficacy of nonoperative treatment options in reducing abnormal proximal thickening of planter fascia caused by plantar fasciitis[21-23,25,36,38,49,63].

MSK US is a cost- and time-effective and useful imaging modality in ruling out soft tissue pathology of inferior heel dysfunction. Based on the study's findings, we recommend to use MSK US as an objective assessment tool in physical therapy outpatient settings to confirm a diagnosis of PF and to examine the efficiency of different physical therapy interventions and modalities. Furthermore, physical therapists need to enroll in different levels of MSK US training courses and obtain professional certification in diagnostic sonography. This professional skill will be crucial in exploring the effectiveness of current and novel physical therapy treatments.

Conclusion

MPC is an effective physical therapy intervention in decreasing the abnormal thickening of proximal planter fascia imposed by plantar fasciitis. MSK US is noninvasive, cost- and time-effective, and capable of confirming or excluding a diagnosis of plantar fasciitis. It can be utilized in physical therapy practice in diagnosing and gauging the effectiveness of physical therapy interventions and modalities on the treatment of orthopedic conditions.

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CHAPTER FOUR

THE CORRELATION BETWEEN THE CAHNGE IN THE SAGITAL THICKNESS OF PLANTAR FASCIA AND HEEL PAIN IN EVALUATING THE EFFICACY OF MONOPAHSIC PULSED CURRENT ON THE TREATMENT OF PLANTAR FASCIITIS

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Abstract

Background: Plantar fasciitis (PF) is one of the most common causes of foot complaints. The purpose of this prospective clinical trial was to investigate the correlation between the visual analogue scale (VAS) scores as a subjective outcome measure and Musculoskeletal Ultrasound (MSK US) as an objective measure when investigating the effect of monophasic pulsed current (MPC) and MPC coupled with plantar fascia stretching exercises (SE) on the treatment of PF.

Methods: Forty four participants (22 were women; 22 were men, with a mean age of 49 $\pm$ 10.6 years) diagnosed with PF were randomly allocated to receive MPC (n=22) or MPC coupled with plantar fascia SE (n=22). Prior to each treatment, participants underwent a baseline evaluation. Heel pain was evaluated using the visual analogue scale (VAS) as subjective measure. The sagittal thickness (ST) of the plantar fascia was measured with MSK US as an objective measure. Following treatment, post intervention evaluation was performed using the same subjective and objective outcome measures.

Results: This study showed that the two groups experienced significant reduction in heel pain and in ST of the plantar fascia compared with baseline evaluation, ($P < 0.001$) although the differences between the two groups in the reduction of heel pain and the sagittal thickness of plantar fascia were small and not statistically significant. The average reduction in heel pain did not correlate with the average reduction in the ST of the plantar fascia, ($r = -.006$, $P = 0.97$).

Conclusion: This trial displayed the efficiency of MPC and MPC coupled with plantar fascia SE to reduce heel pain and sagittal thickness of the plantar fascia associated with PF, although no significant correlation existed between the average reduction in heel pain and ST of the plantar fascia.

Keywords: plantar fasciitis, musculoskeletal ultrasound, visual analogue scale, monophasic pulsed current, plantar fascia specific stretching exercise

Introduction

Plantar fasciitis is (PF) is a common diagnostic entity and was first described by William Wood in 1812 and he attributed its presentation to tuberculosis[1-3]. PF as a clinical diagnosis is known by many pseudonyms: jogger's heel, heel spur syndrome, plantar fascial insertitis, calcaneal enthesopathy, subcalcaneal bursitis, subcalcaneal pain, stone bruise, calcaneal periostitis, neuritis and calcaneodynia[4-6]. Proximal PF or plantar heel pain is the most common soft tissue disorder that causes inferior heel and rear foot pain in athletes as well as those not involved in sport activities[7,8]. Proximal PF is a common clinical diagnostic condition usually affecting more than two million Americans every year. It constitutes approximately 15 %of foot dysfunction conditions in the United States, affects two million individuals, and accounts for more one million outpatient visits annually[3,9,10].

PF is symptoms settle in 80% to 90% of conditions and the resolution of symptoms occurs in majority of patients within ten months with conservative treatment[2,7,11]. PF can be a painful, debilitating, and disabling condition that often frustrates not only the patient but also the physician because its etiology is still equivocal[3,8,12,13].

PF is considered to be an overuse syndrome and an inflammatory reaction from chronic irritation or microtears of proximal plantar fascia at its attachment at the medial tuberosity of the calcaneus[2,14]. PF is defined as a localized inflammation of perifascial anatomical structures and plantar fascia at its proximal insertion on the medial tuberosity of the calcaneus resulting from chronic repetitive microtears and degeneration secondary to overuse, mechanical and congenital disorders[3,7-10,15].

PF is also clinically defined as inferior heel pain and tenderness of gradual onset, localized to the medial tuberosity of the calcaneus and exacerbated by weight bearing[11,16]. It can affect patients from childhood to older ages, but is most common in middle aged women and young athletes. Inflammation of the plantar fascia is prevalent in joggers, long distance runners and tennis players as well as soccer players, gymnasts, volleyball and basketball players[7,8,17]. PF is also common in overweight individuals with occupations that require extensive standing or weight bearing[8,18,19].

Plantar fascia or plantar aponeurosis is a thick and strong fibrous connective tissue which originates at the medial tuberosity of the calcaneus and fans out distally into three bands to attach into the bases of proximal phalanges or at the metatarsophalangeal joints to form the medial longitudinal arch of the foot[11,18]. Plantar fascia lies superficial to the muscles of the plantar surface of the foot and divides into three portions: central or middle, lateral, and medial .The central or middle portion is considered to be the thickest component of the plantar fascia, and originates from the posterior aspect of the medial tuberosity of the calcaneus posterior to the origin of the flexor digitorum brevis tendon, and is its width is between 1.5 to 2.0 cm. Distally, at the level of the metatarsophalangeal joints, the central portion of the plantar aponeurosis divides in to five bands, one for each of the toes[3,20-24].

The lateral component of the plantar aponeurosis originates from the lateral aspect of the medial tuberosity of the calcaneus with its distal medial and lateral bands connecting to the plantar plate of the fourth toe and to the base of the fifth metatarsal bones respectively. The medial component of the plantar aponeurosis is thin and lies

superficial to the abductor hallucis muscle and connected medially with the dorsal fascia and laterally with the central component of the plantar aponeurosis[3,18,20,21,23,25].

Histological examination of biopsy samples of the irritated and inflamed plantar fascia reveal granulation tissue, fibroblast proliferation, and fibrosis , collagen necrosis, chondroid metaplasia, and matrix calcification, all of which are suggestive of a repetitive strain and fascia degenerative process[26,27].

The windlass mechanism model is a term used to explain the responsibility of the plantar fascia dynamic function during a manner of walking[28]. The plantar fascia functions through the windlass mechanism which was described first by Hicks as a mechanical model[29,30]. The plantar fascia plays an important role in providing support for the foot through the stance phase of gait cycle. During the toe off phase of the gait cycle, the extension of the toes at the metatarsophalangeal joints tightens the planter fascia and elevates the medial longitudinal arch thus forming a solid pivot of foot for push off [30,31]. The foot and its ligaments can be thought of as a truss or arch-like triangular structure, with the calcaneus, midtarsal joint, and metatarsals forming the medial longitudinal arch[28,29].

The etiology of plantar fasciitis remains unclear and is poorly understood and is still debated among medical fraternity despite its high prevalence[3,7,11]. Even the etiology of plantar fasciitis is poorly established in previous research literature, it is thought to be caused by intrinsic and extrinsic predisposing factors[11,32]. Intrinsic precipitating factors that may make an individual vulnerable for the development of plantar fasciitis may include obesity and a body mass index of more than 30. Being overweight can increase stress upon plantar fascia during normal walking. Secondly, advanced age can

predispose an individual to plantar fasciitis. After the age of 40 years, the fat pad begins to degenerate, with loss of water content and collagen component that affects it elasticity. When the sagittal thickness of the fat pad decreases, it may result in minimizing shock absorbency of that anatomical structure and reduced protection of the calcaneal tuberosity and plantar fascia. Thirdly, Achilles tendon tightness and inadequate ankle dorsiflexion may lead to excessive subtalar pronation to compensate for that dysfunction and that over pronation contributes to plantar fascia elongation, overstretch and irritation. Fourthly, excessive pronation (pes planus) is caused by plantar flexion and adduction of talus and can cause the height longitudinal arch of the foot to decrease and create strain on the plantar aponeurosis which can result in the development of plantar fasciitis[7,10,11,33]. Other intrinsic potential risk factors may include leg length discrepancy, excessive lateral tibial torsion, and excessive femoral anteversion, pes cavus and equinus, and sudden weight gain[7,8,11]

Potential extrinsic predisposing factors that may make someone susceptible for the development of plantar fasciitis may include high intensity sport activities or training that require repetitive plantar flexion of the ankle joint and extension of the metatarsophalangeal joints and that mechanical overload and excessive tensile load that produce microtears within the plantar fascia, which eventually incites a chronic inflammatory response followed by degeneration[8,33,34]. Other extrinsic potential risk factors include the use of poor or worn footwear, occupational and recreational activities that require prolonged standing or weight bearing, and improper training techniques[7,11,32].

The classic feature and presentation of plantar fasciitis are mechanical symptoms of pain on the sole of the foot at the inferior region of the heel[32,33]. The onset of the

inferior heel pain is insidious and may worsen over time. Pain may interfere with walking, particularly when taking the first few steps in the morning after getting out of the bed, or arising from a seat after prolonged sitting or inactivity. The intense and shooting inferior heel pain can be so terrible that the patient may limp around with the affected heel off the ground. By the end of the day, a dull aching pain typically happens and may extend the midfoot and forefoot. The sharp pain is usually localized to the plantarmedial aspect of the heel or over a small area near the proximal insertion of the plantar fascia at the medial tuberosity of the calcaneus[3,18,19,26,32,33,35].

The diagnosis of plantar fasciitis can be made through a thorough and comprehensive history taking and physical examinations. Heel pain, while taking first steps in the morning, is typical of plantar fasciitis and will reveal differences from other inferior heel pain dysfunctions. Inferior heel pain imposed by plantar fasciitis is not associated with paresthesia or nocturnal pain. Localized tenderness to palpation of plantar fascia at its origin on anteromedial aspect of the calcaneal tuberosity may be elicited by slight passive dorsiflexion of the toes or having the patient stands on the tips of the toes. A windlass test is considered to be positive when passive dorsiflexion of the hallux reproduces pain and discomfort at the proximal plantar fascia. The evaluation of range of motion may reveal or demonstrate a restriction of ankle dorsiflexion by 5 degrees or more which indicates contracture of the Achilles tendon[3,8,11,25,36].

A plain radiograph does not support the diagnosis of plantar fasciitis but can be used to look for bony lesions of the foot. Diagnostic ultrasonography is inexpensive and useful in ruling out soft tissue pathology of the heel. Findings of diagnostic ultrasound that support the presence of plantar fasciitis include proximal plantar fascia thickness

greater than 4 mm and areas of hypoechogenicity. Magnetic resonance imaging, although expensive, is a valuable tool for assessing causes of recalcitrant heel pain[11,18,21,37,38]. Diagnostic findings include increased proximal plantar fascia thickening with increased signal intensity on T2-weighted imaging[11,18,26,39]. Differential diagnosis of plantar fasciitis includes calcaneal stress fractures, osteomyelitis, tumor, sacral radiculopathy, Reiter's syndrome, Sever's disease, psoriatic arthritis, ankylosing spondylitis, tarsal tunnel syndrome, foreign body, and nerve entrapments[7,8,11,34].

The treatment of plantar fasciitis is primarily conservative. It is commonly treated with nonsteroidal anti-inflammatory medications, physical therapy, and corticosteroid injections. If conservative treatment fails, surgical option may be indicated[1,3,7,11].

Physical therapy plays a significant role in the treatment of plantar fasciitis[32]. Many physical therapy treatment options are available which may mitigate and allay the heel pain symptoms associated with plantar fasciitis besides rest and avoiding any strenuous and arduous activities that place strain on the inflamed and irritated proximal insertion of plantar fascia[9,10,40,41].

In 2008, the orthopedic section of the American Physical Therapy Association began issuing a series of evidence based clinical practice guidelines linked to the international classification of function, disability, and health that gives recommendations about assessment, prognosis, diagnosis, and treatment for common musculoskeletal dysfunctions. In terms of plantar fasciitis, there are many physical therapy interventions or means that can be used to alleviate and attenuate the inferior heel symptoms that are associated with plantar fasciitis[32,42].

These modalities include iontophoresis, manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises of calf muscles and plantar fascia, taping, orthotic devices, which can be used to suit patient needs[9-11,32,33,40-49]. Other physical therapy techniques may include soft tissue mobilization, heel padding, icing, contrast baths, ultrasound, and rest[34,50,51].

Monophasic pulsed current (MPC) is utilized clinically to promote wound and pressure ulcer healing processes. Monophasic pulsed current is defined as percutaneous delivery of pulsed, twin-peak, monophasic pulses, each pulse having very short phase duration of less than 100 μsec, which employs voltage up to 500 volts [52-54]. Delivering of electrical current using electrodes to wound bed seems to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, increase the number of growth factor receptor, and calcium influx [52-59].Vitro studies showed that key tissue cells such epithelial and fibroblast cells have been attracted to wound site when electrically stimulated resulting in promoting collagen deposition, angiogenesis and wound tensile strength. Many studies inferred that wounds treated with monophasic pulsed current demonstrated 1.5 times greater rate of healing when compared to normal wound healing rates[52-59]. Galvanotaxis is one of the MPC features and is defined as the process of attracting charged cells to an electric field of opposite polarity. Clinically in treating wounds or decubitus ulcers, a positively charged electrode (anode) is placed over a wound or ulcer, to attract negatively charged cells such as neutrophils and macrophages to facilitate the inflammatory phase of wound healing. Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation

phase of fascia healing. Fibroblasts make the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60]. Because polarity selection is based on the healing phase the practitioner wishes to facilitate and accelerate, we used the negatively charged cathode to attract the positively charged fibroblast cells to promote and accelerate proliferation phase of plantar fascia.

Musculoskeletal Ultrasound MSK US can be utilized as a diagnostic tool to corroborate or verify a clinical diagnosis of plantar fasciitis[21,37,38]. Numerous diagnostic sonography studies showed that abnormal thickening of plantar fascia greater than 4 mm and reduced echogenicity are associated with plantar fasciitis[23,25,36,49,61,62]. Many clinical trials have been conducted to measure the sagittal proximal thickness of the plantar fascia before and after a given treatment regimen to prove that treatment's efficacy[17,20,27,37,38,61,62].

In previous physical therapy studies, the effect of the interventions and modalities on the treatment of plantar fasciitis was investigated mainly using subjective self-reported outcome measures. Even the psychometric or clinimetric properties of those outcomes measured have been documented in the literature[63-65,67-72]. It is important to employ reliable, valid and responsive subjective outcome measures such as ultrasound in physical therapy research on examining the capacity of physical therapy treatments[21,22,37,38,61,62].

The purpose of this prospective clinical trial was to investigate the correlation between the change of heel pain scores using visual analogue scale VAS as a subjective outcome measure and the change in the sagittal thickness of plantar fascia using

musculoskeletal ultrasound MSK US as an objective measure when investigating the effect of MPC and MPC coupled with plantar fascia specific SE in the treatment of PF.

\Materials and Methods

Research Design

This study is a prospective randomized clinical trial to compare the effectiveness of two interventions on the treatment of plantar fasciitis. Participants were randomly assigned to one of two treatment groups. Group I was treated with MPC and Group II was treated with a combination of MPC and plantar fascia SE.

Participants

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

The recruitment of the participants was assisted by referrals from the Loma Linda Medical Center's orthopedists, podiatrists, and primary care physicians (APPENDEX A). Additional recruitment was sourced via advertisements in Loma Linda Trading Post and online and weekly newspapers in area cities (APPENDEX B). Finally, study fliers were placed on bulletin boards of the Draysen Fitness Center of Loma Linda University as well as the School of Allied Health Professions (APPENDEX C), with electronic versions of the study flier having been sent to the School of Allied Health Professions students.

If the referring physician felt patients would qualify for or benefit from participation in the clinical trial and ascertained patient interest, the patient was contacted with details about the study. Participant permission was obtained by provision of Authorization for Use of Protected Health Information (PHI) (APPENDEX D) for the patient to read and sign. This form allowed the patient's name, diagnosis, phone number, date of birth, and gender to be forwarded to the study investigator (APPENDEX E). The investigator contacted the patient by telephone to provide additional information regarding the study, address questions, and schedule a baseline evaluation session (APPENDEX F).

A convenience sample of forty-eight patients with a clinical diagnosis of plantar fasciitis met this randomized clinical trial's inclusion criteria and underwent the baseline evaluation. Four subjects never retuned beyond the baseline evaluation session due to scheduling conflicts. Data analysis was based on the remaining 44 patients and who provided written consent to continue with the study.

During the baseline evaluation, the investigator first explained the study to the patient, including its overall purpose, the procedures that would be performed, and

potential benefits and risks of the interventions. If the patient decided to proceed, the investigator provided him/her a copy of the informed consent as approved by the IRB (APPENDEX G). If the patient chose to enroll in the study, he/she signed the consent form and California Experimental Subject's Bill of Right Form (APPENDEX H).

Procedure

Following procurement of patient informed consent, the investigator obtained information regarding age, gender, height, weight, body mass index (BMI), duration of symptoms as well as determining whether the patient was athletic or not, and on which side the affected area presented. A baseline evaluation was performed which included the measurement of: (1) heel pain using the Visual Analogue Scale (VAS); (2) the measurement of sagittal thickness of proximal plantar fascia with Musculoskeletal Ultrasound MSK US.

The investigator then randomly assigned the participants to one of two treatment groups. Group I received MPC and Group II received MPC coupled with plantar fascia SE, using a computer-generated random two-digit number. Each patient received three sessions of MPC per week for four weeks, for a total of twelve sessions. Each session lasted 60 minutes. Patients in Group II were instructed to perform home based SE as described by DiGiovanni et al [9] (APPENDEX I).

The investigator instructed the patients on how to perform the plantar fascia SE and told them the number of daily sets to complete during the four week treatment. (APPENDEX J)

After completing the assigned treatments, the investigator performed a post-intervention evaluation which included the measurement of: (1) heel pain using the VAS); (2) the measurement of ST of proximal plantar fascia with MSK US.

Outcome Measures

Visual Analogue Scale

The visual analogue scale (VAS) was utilized to measure heel pain. VAS is a numerical scale with marked points at 0 and 10, while 0 indicating no pain, and 10 indicating the highest level of pain. (Figure1). The patient was requested to rate his/her heel pain based on his/her initial steps in the morning, by putting a mark on the scale representing his/her level of heel pain. This scale has been established as a reliable and valid subjective outcome measure to assess acute and chronic pain[63-65].

Figure 1. Visual Analogue Scale (VAS)

Musculoskeletal Ultrasound

Musculoskeletal ultrasound (MSK US) is an imaging tool utilized for confirming a diagnosis of plantar fasciitis and differentiating its occurrence from other inferior heel pain conditions[66]. MSK US is a valid and valuable diagnostic tool which measures changes in plantar fascia thickness before and after a given treatment regimen to gauge

the treatment's efficacy. According to musculoskeletal ultrasound investigation, the standard normal or asymptomatic thickness value reported for the plantar fascia is 2.3 to 4.0 mm[23,36,61,62]. It is accepted that a thickness greater than 4 mm would be consistent with presentation of plantar fasciitis[25,36]. Each involved foot was evaluated sonographically with an L14-6 MHz linear array transducer, using Mindray-M7 Diagnostic Ultrasound System (Figure 14), and a coupling gel was applied to the plantar surface of the foot. The plantar fascia is most effectively assessed with the patient in the prone position, with the affected foot hanging over the edge of the examination table and the ankle in neutral position. The ultrasound probe was placed vertically in relation to the plantar aspect of the heel. Finally, the sagittal thickness of the proximal insertion of the plantar fascia was measured, at a standard reference point 5 mm from the proximal insertion at the anterior aspect of the inferior border of the calcaneus[21,22,37,38,61,62] (Figure 15).

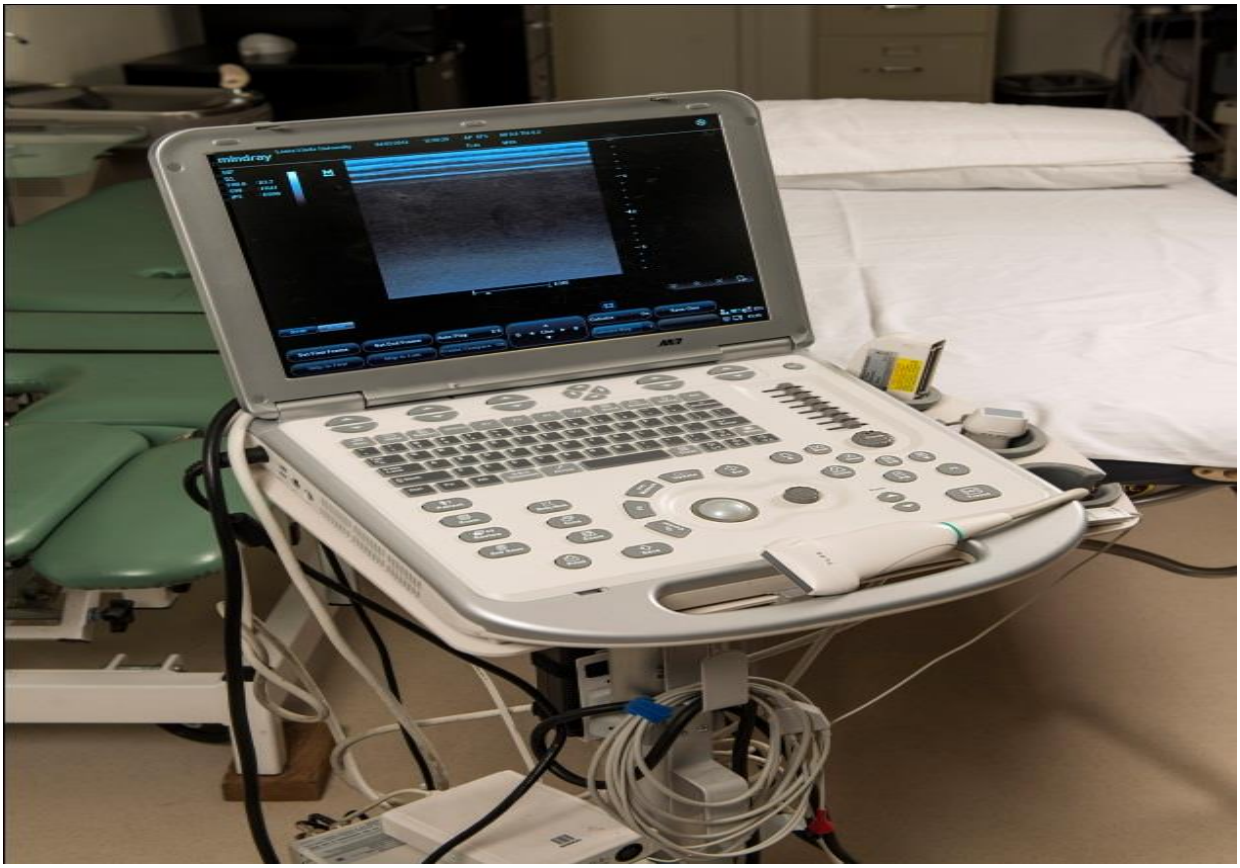

Figure 14. Mindray-M7 Diagnostic Ultrasound System

Figure 15. Measurements of the Sagittal Thickness of Plantar Fascia Technique

Monophasic Pulsed Current (MPC)

MPC is utilized clinically to promote wound and pressure ulcers healing processes. MPC is defined as percutaneous delivery of pulsed, twin-peak, monophasic pulses, each pulse having very short phase duration of less than 100 μsec, which employs voltage up to 500 volts [52-54.]

Delivering of electrical current using electrodes to wound bed seems to induce cellular actions and histological responses such as collagen and deoxyribonucleic acid synthesis, adenosine triphosphate production, increase the number of growth factor receptor, and calcium influx[52-59]. Vitro studies showed that key tissue cells such epithelial and fibroblast cells have been attracted to wound site when electrically stimulated resulting in promoting collagen deposition, angiogenesis and wound tensile strength. Many studies inferred that wounds treated with monophasic pulsed current demonstrated 1.5 times greater rate of healing when compared to normal wound healing rates[52-59].

Galvanotaxis is one of the MPC features and is defined as the process of attracting charged cells to an electric field of opposite polarity. Clinically in treating wounds or decubitus ulcers, a positively charged electrode (anode) is placed over a wound or ulcer, to attract negatively charged cells such as neutrophils and macrophages to facilitate the inflammatory phase of wound healing. Plantar fascia is a connective tissue, and the fibroblast cells' main function is to maintain its structural integrity. Fibroblasts are the key cells during the proliferation phase of fascia healing. Fibroblasts make the collagens, glycosaminoglycans, elastin fibers, and glycoproteins found in the extracellular matrix[53,56,57,60]. Because polarity selection is based on the healing phase the practitioner wishes to facilitate and accelerate, we used the negatively charged cathode to attract the

positively charged fibroblast cells to promote and accelerate proliferation phase plantar fascia healing process (GV 350 Galvanic High-Volt Pulsed Stimulator, Figures 4, 5).

MPC has been shown to increase fibroblast proliferation and DNA and protein synthesis essential for the production of granulation tissue. The therapeutic parameters included: current type (pulsed current), pulse type (twin peaked), electrode polarity cathode (negative), frequency (100 pulse per second), pulse duration (100 milliseconds), and amplitude (at submotor level, too weak to elicit a visible muscle contraction) [53,54,57].

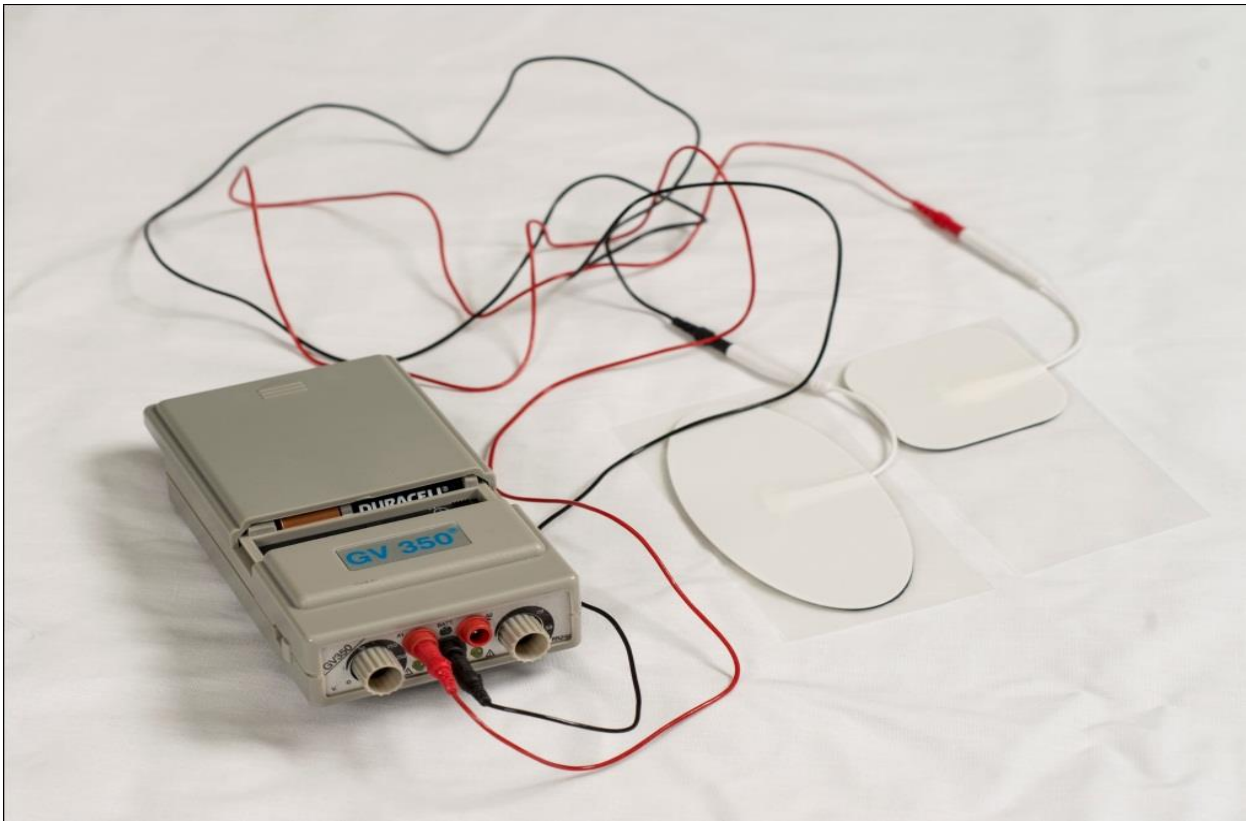

Figure 4. GV 350 Galvanic High-Volt Pulsed Stimulator

Figure 5. Monopolar Application of Monophasic Pulsed Current

Plantar Fascia Stretching Exercise

Plantar fascia stretching exercises (SE) are an integral component of the physical therapy treatment plan for the treatment of plantar fasciitis, used to decrease pain and functional limitations. In this study, plantar fascia specific stretching exercises were utilized as described by DiGiovanni and his colleagues[9]. The patient was directed to cross the affected leg over the other leg while in a sitting position, and using his/her hand, apply metatarso-phalangeal joint dorsiflexion (or pull the toes back toward the shin until the patient feels a stretch in the arch of the foot), while holding each stretch for a count of

10, and repeating each stretch 10 times (Figure 6). All patients were required to perform the stretching program three times per day. The first stretch was to be completed before rising and exiting the bed. Patients were provided a written protocol of the stretching program and asked to keep a daily log of exercise completion for 4 weeks. (APPENDEX J)

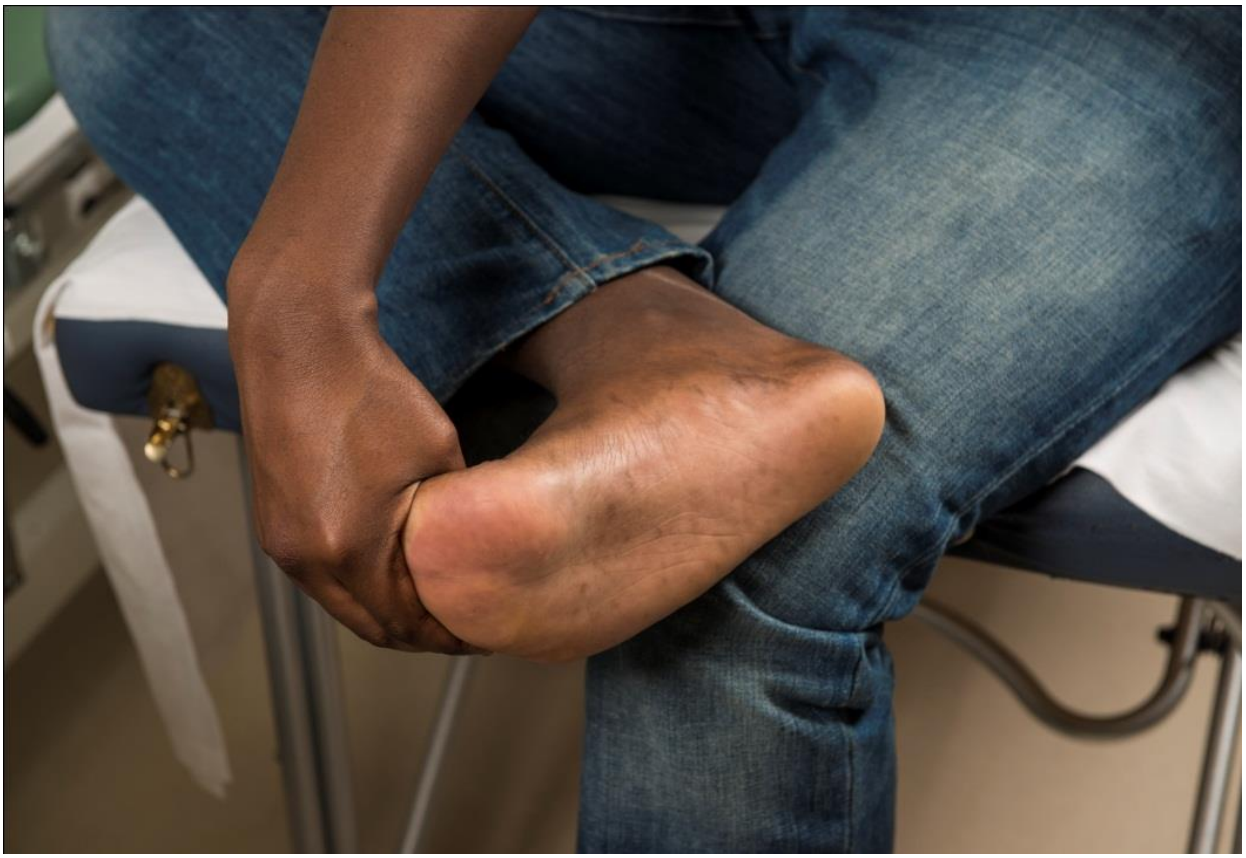

Figure 6. Plantar Fascia Stretching Exercise

Data Analysis

Sample Size Estimation

SAS statistical analysis software was used to calculate the sample size required so that a reasonable expectation would be likely to detect an expected effect size of 0.4 between the two study groups. A sample size of 40, with 20 participants per group with 0% attrition rate was utilized in the study. Forty participants were required to show statistical significance when clinically significant differences between the groups were present. Additional participants were recruited to provide for unanticipated attrition.

Description of Statistical Procedures

IBM SPSS Statistics Grad Pack 22.0 PREMIUM was used to analyze the data. Participants' demographic data for each group was summarized using descriptive statistics using means and SDs for continuous variables and frequencies and percentages for categorical variables to determine if significant differences between the two the groups existed. The assumption of normality of the continuous variables was examined using the Kolmogorov- Smirnov test. Also, the assumption of homogeneity was examined by Levene's test.

The two groups were compared at baseline using independent t-test. Differences were calculated between pre and post measurements for heel pain, heel tenderness, and functional activities level. A mixed 2×2 factorial Analysis of Variance (ANOVA) was conducted to examine the effect of the two interventions monophasic pulsed current and combination of monophasic pulsed current and plantar fascia stretching exercises on heel pain, heel tenderness, and functional activities level. To explore if changes in outcome measures over time were consistent across treatment groups, researchers examined

whether there was an interaction in between treatment group and time. The level of significance was set at P value ≤ 0.05.

Results

Of the 44 participants completing the study, 22 were women, and 22 were men (Figure 7). The right foot was involved in 22 participants and the left foot in 22. The mean age of Group I (received monophasic electrical stimulation) was 49.7 ± 11.7 years, and the mean age of Group II (received monophasic electrical stimulation couples with plantar fascia stretching exercises) was 49.0 ± 9.7 years. The mean height of Group I was 171.5 ± 12.0 cm, and the mean height of Group II was 170.98 ± 13.54cm. The mean weight of Group I was 96.4 ± 22.9 kg, and the mean height of Group II was 87.4 ± 22.9 kg. The median duration of symptoms in Group I was 12 months with interquartile range (IQR) of 154, and for Group II was 12 months with IQR of 154, hence, the sample consisted primarily of participants with relatively chronic symptoms. All participants in the two treatment groups appeared to be generally well matched. No significant differences between group I managed monophasic electrical stimulation and group II managed monophasic electrical stimulation coupled with plantar fascia stretching exercises were found in regards to age, gender, height, weight, body mass index (BMI), athletic status and involved side (Table 1).

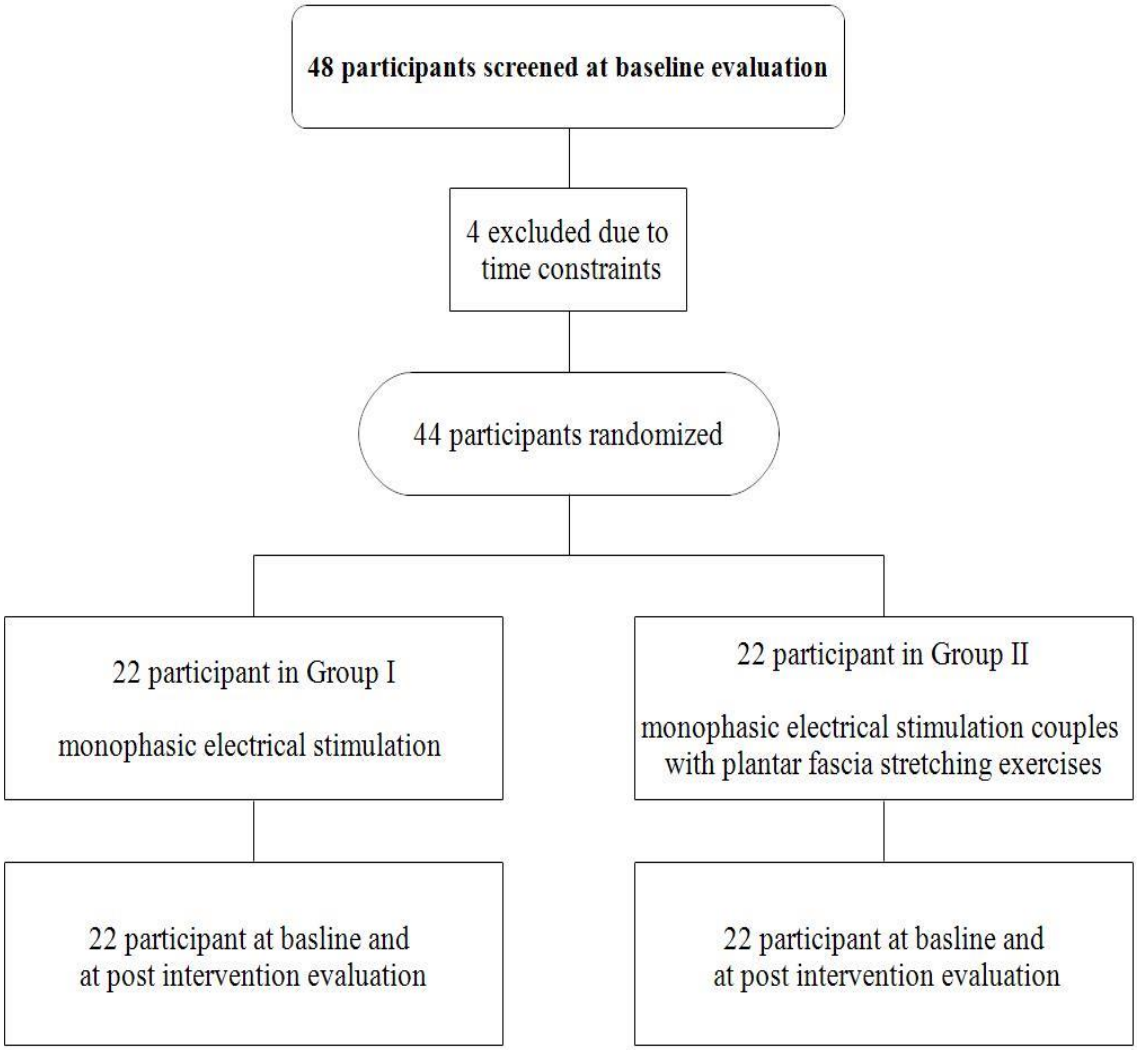

Figure 7. The Progression of Participants through the Clinical the Trial

Table 1. General Characteristics of Subjects (N= 44)

		Group I (n=22)	Group II (n=22)	p-value
Age, mean (SD) year		49.7 (11.7)	49.0 (9.7)	0.60 *
Height, mean (SD) cm		171.5 (12.0)	171.0 (13.5)	0.91*
Weight, mean (SD) kg		96.4 (22.9)	87.4 (22.9)	0.20*
BMI, mean (SD) kg/m^2		32.8 (7.2)	30.0 (7.4)	0.21*
Standing hours, mean (SD)		8.8 (3.2)	9.6 (2.48)	0.31*
Duration of symptom, median (IQR) months		12 (154)	12 (149)	0.12^
Gender	Male, % (n)	36.4 (8)	31.8 (7)	0.75#
	Female, % (n)	63.6 (14)	68.2 (15)	
Athletic status	Athletic, % (n)	9.1 (2)	13.6 (3)	0.50$
	Non-Athletic, % (n)	90.9 (20)	86.4 (19)	
Involved side	RT, % (n)	27.3 (6)	50.0 (11)	0.12#
	LT, % (n)	72.7 (16)	50.0 (11)	

Abbreviations: SD, Standard deviation; BMI, Body mass index; IQR, Interquartile range; RT, Right; LT, Left
*Independent t-test; ^ Mann Whitney U- test; # Pearson chi square; $Fisher's exact test

Table 8. Mean (SD) of Visual Analogue Scale and Sagittal Thickness by Treatment Group at baseline (N=44)

	group I Mean (SD)	group II Mean (SD)	Difference	p-value*
VAS	7.39 (1.75)	6.84 (2.14)	0.55	0.36
ST	4.61 (1.19)	4.11 (0.99)	0.50	0.14

Abbreviations: SD, Standard deviation; VAS, Visual Analogue Scale; ST, Sagittal thickness
*Independent t-test

Table 9. Mean (SD) of Visual Analogue Scale and Sagittal Thickness by Treatment Group over Time

	Pre Mean(SD)	**Post** Mean(SD)	**p-value***	**p-value#**	**Pre-post by-group interaction**
VAS					
Group I (n=22)	7.39 (1.75)	3.43 (1.95)	< 0.001	0.85	0.28
Group II (n=22)	6.84 (2.14)	3.55 (1.95)			
ST					
Group I (n=22)	4.61 (1.19)	3.87 (1.19)	< 0.001	0.23	0.49
Group II (n=22)	4.11 (0.99)	3.45 (1.06)			

Abbreviations: SD, Standard deviation; VAS, Visual analog scale; ST, Sagittal thickness.

* Significant differences between pre- and post-intervention between two groups

Significant differences between two groups at post-intervention

Table 10. Mean (SD) of Visual Analogue Scale and Sagittal Thickness by Treatment Group at Post Intervention (N=44)

	Group I Mean (SD)	Group II Mean (SD)	**Difference**	**p-value***
VAS	3.43 (1.95)	3.55 (1.95)	- 0.11	0.85
ST	3.87 (1.19)	3.45 (1.06)	0.40	0.23

Abbreviations: SD, Standard deviation; VAS, Visual analog scale; ST, Sagittal thickness.

*Independent t-test

At baseline evaluation, no significant differences existed between group I and group II with regard to VAS scores, ($p = 0.36$, Table 8). The two groups experienced improvements in heel pain after completing the assigned treatments compared with baseline VAS scores ($p < 0.001$), but differences between the two groups were small and statistically insignificant ($p = 0.85$, Tables 9,10; Figure 8).

The results of post intervention evaluation showed that group I managed with MPC had improvement and reduction in heel pain of -3.96 scores (95% confidence

interval (CI), −4.81 to -3.10) compared to mean reduction of -3.30 scores (95% CI, −4.19 to -2.40) for group II managed with MPC coupled with plantar fascia SE). The mean difference for heel pain between the two groups was insignificant, mean difference of -0.11 (95% CI, −1.30 to −1.07; Tables 9, 10)

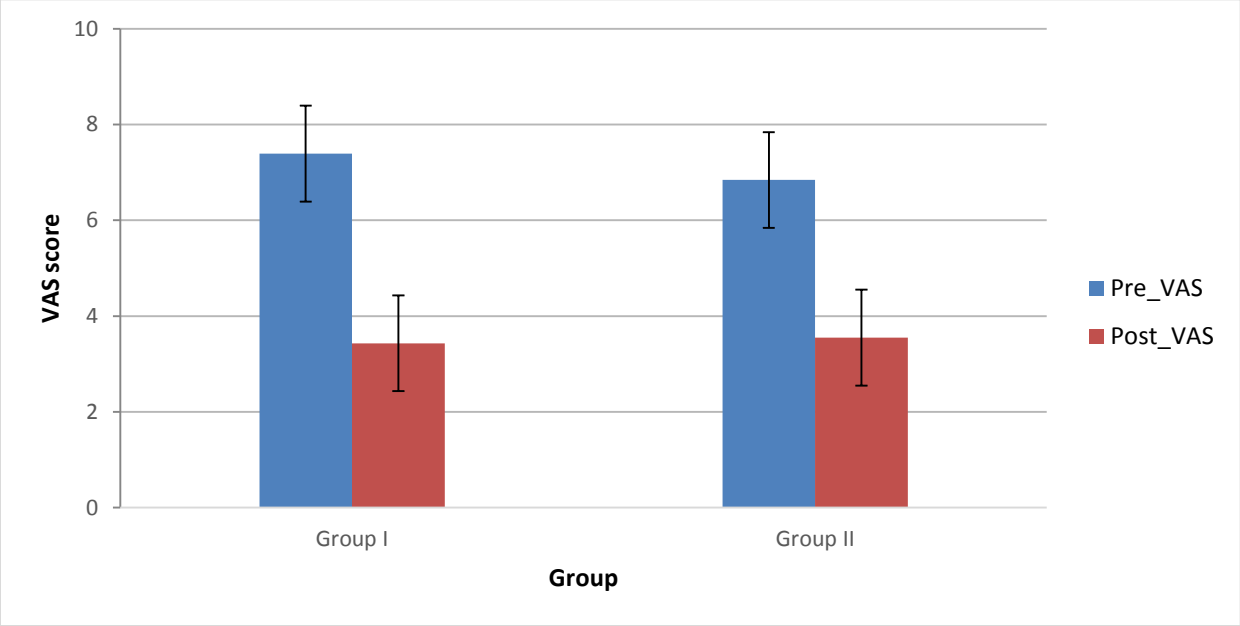

Figure 8. Mean ± SD of Visual Analogue Scale Scores between the Two Groups over time

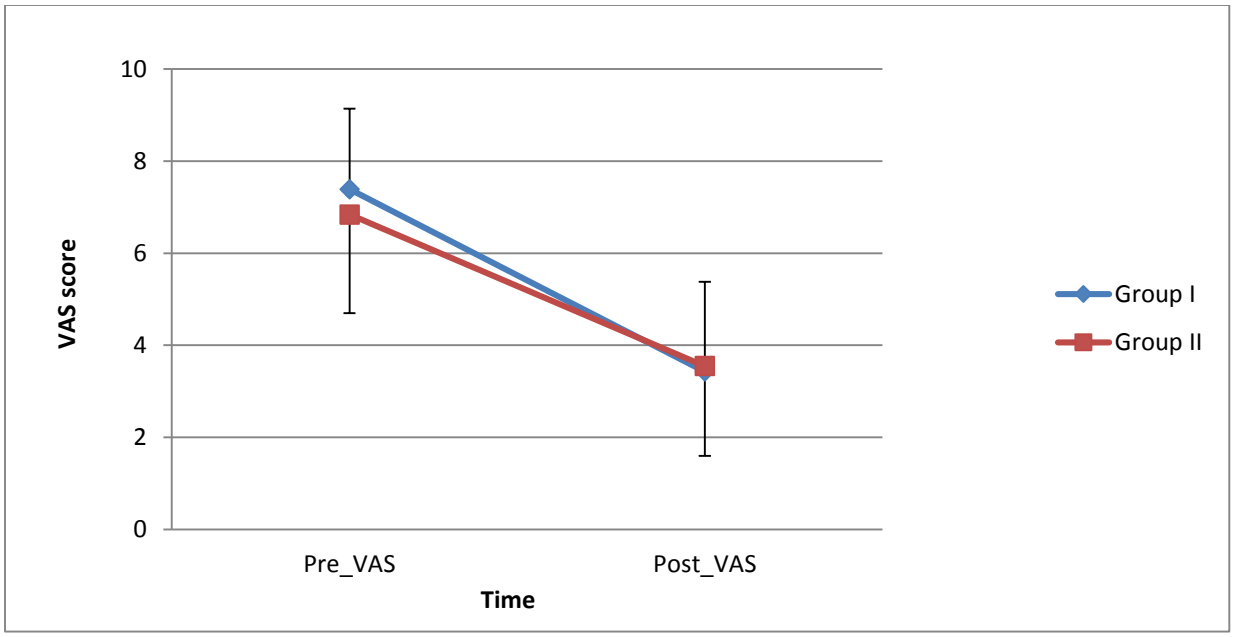

Figure 9. Mean ± SD of Visual Analogue Scale Scores by Treatment Group over time

At baseline evaluation, no significant difference between group I and group II with regard to MSK US measurement was detected, ($p = 0.14$, Table 8; Figure 16) The two groups experienced significant reduction in the ST of plantar fascia after completing the assigned treatments compared with baseline MSK US measurements ($p < 0.001$), but differences between the two groups were insignificant ($p = 0.23$, Table 9; Figures12,16)

After treatment, group I managed with MPC had a mean reduction in ST of plantar fascia of -0.74 mm (95% confidence interval (Cl), −0.93to -0.55 mm) compared to mean reduction of -0.66 mm (95% CI, −0.80 to −0.51 mm) for group II managed with MPC coupled with plantar fascia SE. (Tables 9, 10).

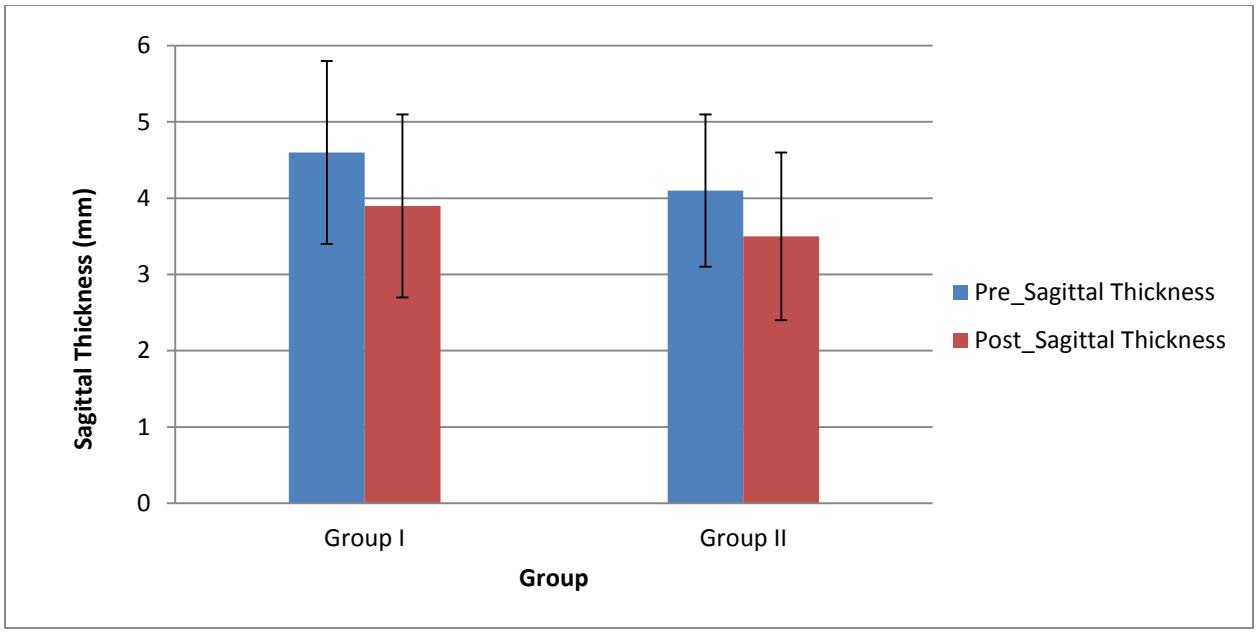

Figure 16. Mean ± SD of Sagittal Thickness by between the Two Groups

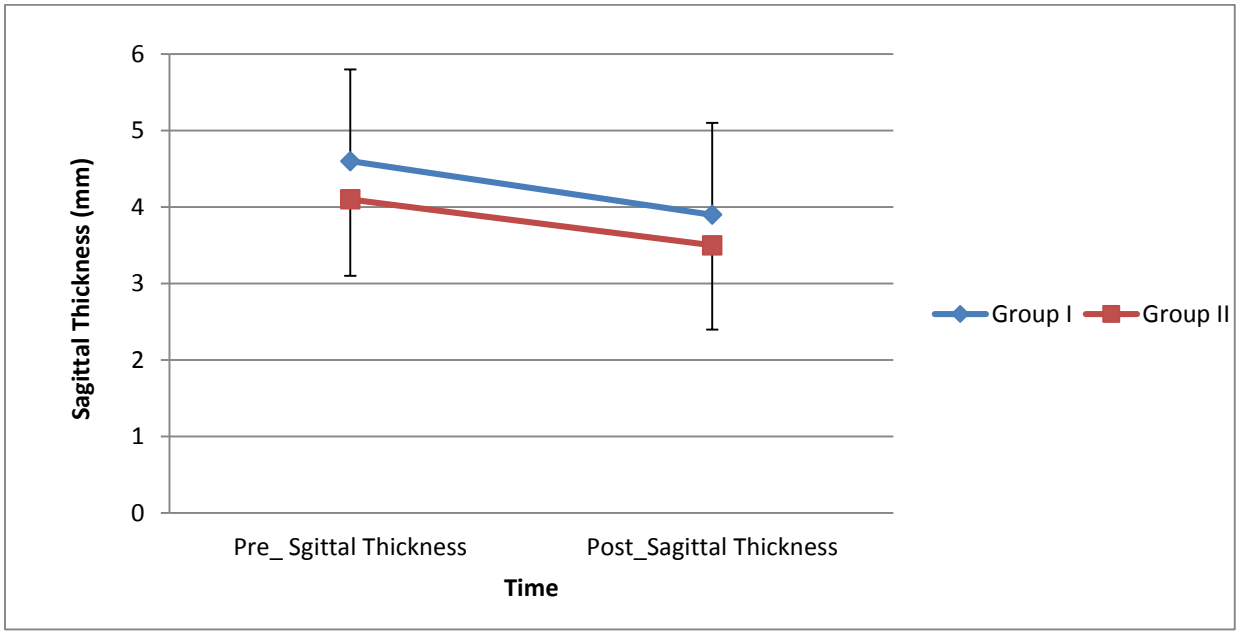

Figure 17. Mean ± SD of Sagittal Thickness by Treatment Group over time

After treatment, the average reduction in heel pain using VAS as a subjective measure was -3.63 ± 1.98 and the average reduction in the ST of plantar fascia using

MSK US as an objective outcome measure was -0.70 mm ± 0.37 mm. There was no significant correlation between the mean reduction in heel pain scores and the ST of proximal insertion of plantar fascia measurement, (r = -0.006, p = 0.97).

Table 11. Mean (SD) Reduction in Outcome Measures (N=44)

	Mean (SD)	**Min, Max**
VAS	-3.63 (1.98)	-9.50, -1.00
ST	-0.70 (0.37)	-0.22, 0.00

Abbreviations: SD, Standard deviation; Min, Minimum; Max, Maximum; Visual Analog Scale VAS; Sagittal thickness
ST,

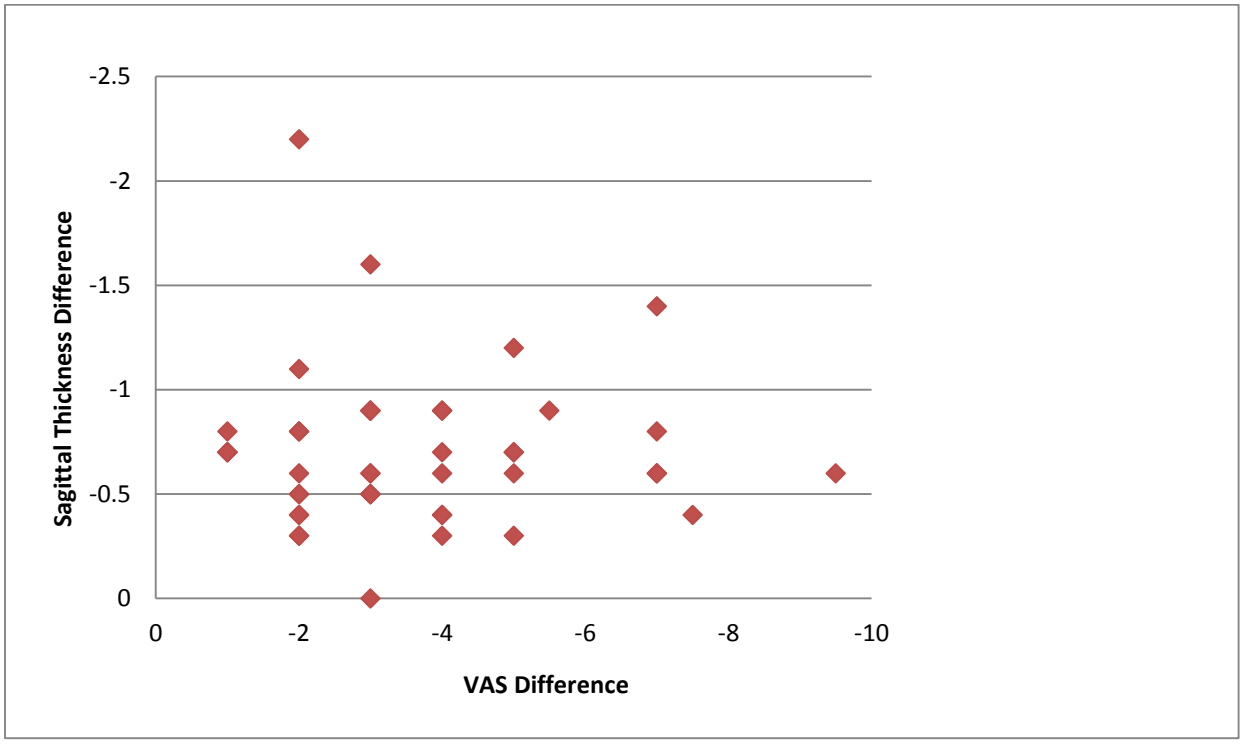

Figure 18. Scatter Plot of the Relationship between Average Reduction in Visual Analogue Scale and Sagittal Thickness

Discussion

Plantar fasciitis is one of the most common musculoskeletal conditions seen in outpatient orthopedic settings [2,3]. It is associated with morning inferior heel pain especially when taking first few steps upon rising [2, 3, 4]. It is further associated with abnormal thickening of the proximal plantar fascia. Many clinical studies found that plantar fascia thickening decreased and inferior heel pain improved with the use of different nonoperative treatments including steroid injections, nonsteroidal anti-inflammatory drugs, and Botulinum toxin[7,16,17,62,66].

many research studies has revealed that physical therapy interventions and modalities such as iontophoresis, manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises of calf muscles and plantar fascia, taping, and orthotic devices have proven to be effective in alleviating and relieving inferior heel symptoms associated with plantar fasciitis[9-11,22,32,33,40-48].

In previous physical therapy studies, the effect of the interventions and modalities on the treatment of plantar fasciitis was investigated mainly using subjective patient reported outcome measures. Even the psychometric or clinimetric properties of those outcomes measures have been documented in the literature[63-65,67-72]. It is important to employ reliable, valid and responsive objective outcome measures such as ultrasound on examining the capacity of new or current physical therapy treatments[21,22,37,38,61,62].

Studies that investigated the effect of nonoperative treatments on plantar fasciitis assumed an intimate relationship between the decrease in proximal plantar fascia sagittal thickness and inferior heel pain. While direct correlation was indicated and documented when exploring the effectiveness of nonoperative treatments such as the steroid injections , the precise relationship between the change in sagittal thicknesses of plantar fascia and

changes in inferior heel pain was not examined when assessing the effectiveness of physical therapy interventions or modalities , especially MPC on the treatment of PF.

The primary focus of this study was to examine if the relationship existed between changes in plantar fascia proximal ST of plantar fascia and changes in inferior heel pain while evaluating the effectiveness of MPC and MPC coupled with plantar fascia SE on the treatment of PF.

According to diagnostic sonography studies, PF is considered present when the ST of the proximal attachment of the plantar fascia is greater than 4 mm with reduced echogenicity, and loss of delineation of the borders of the plantar fascia distal to its proximal attachment on the medial tuberosity of the calcaneus[11,21,33,73].

In this study, there were no significant differences in the participants' characteristics indicated between the two treatment groups in terms of age, gender, height, weight, BMI, duration of heel symptoms, athletic status, and involved side. Participants' characteristics in the two treatment groups appeared to be well matched with each other and would not affect the VAS and MSK US that have been utilized as outcomes measures to determine the effect of MPC on the treatment of PF.

This prospective clinical trial showed average reduction in inferior heel pain scores of -3.6 ± 2.0 and average reduction in the sagittal proximal insertion of thickness of plantar fascia of -0.7 mm ± 0.4 mm. No significant relationship between the change in heel pain and the sagittal thickness of proximal insertion of plantar fascia was observed ($r = -0.006$, $P = 0.97$) , even though this study demonstrated significant statistical reduction in inferior heel pain and also in the sagittal thickness of the proximal insertion of plantar fascia compared to baseline evaluation.

Sometimes the relationship between two variables may be affected by the presence of extreme or influential outliers. The Boxplot is a useful tool in illustrating the distribution of data, and it did not reveal the presence of extreme or influential outliers in mean reduction in VAS scores as a subjective outcome measure and MSK US as an objective outcome measure. The convenience sample of 44 participants may not be adequate to detect the correlation between self-reported inferior heel pain scores and objectively measured proximal sagittal thickness of plantar fascia. Further studies with larger sample sizes of participants is encouraged to be able to infer conclusions about the magnitude of the relationship between VAS scores and MSK US measurement when examining the effect of MPC on the treatment of PF.

Conclusion

Using VAS as a subjective outcome measure of inferior heel pain and MSK US as an objective outcome measure are vital in assessing the effectiveness of different physical therapy interventions and modalities on the treatment of PF. This study showed no significant correlation existed between the change in ST of proximal plantar fascia and heel pain scores when evaluating the effect of MPC on the treatment PF. However, we found significant statistical reduction in the ST measurement of plantar fascia and heel pain scores after treatment.

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CHAPTER FIVE

DISCUSSION

Plantar fasciitis as a self-limiting condition is the most common cause of inferior heel pain. The vast majority of patients experienced resolution of symptoms within 10 months[1,7,19]. The etiology and clinical course of PF is equivocal and still debated among medical fraternity[7,11,33]. PF is associated with overuse, training errors, improper or worn footwear, sudden increase in weight bearing activity, weak intrinsic foot muscles, and obesity [8,10,11]. PF appears to be associated with an inflammatory reaction as a result of microtears and irritations within the proximal insertion of the plantar fascia. The majority of non-operative treatments for PF have demonstrated positive and encouraging results but no single treatment is considered best for treating that specific musculoskeletal dysfunction [9-11,32,33,40-49].

Many physical therapy interventions can be utilized to mitigate, alleviate and attenuate inferior heel symptoms associated with plantar fasciitis[17]. These modalities include iontophoresis, manual therapy, night splinting, prefabricated and customized insets, shoe modification, stretching exercises for calf muscles and plantar fascia, taping, and orthotic devices[10,32,40,41,44-48].

Monophasic pulsed current is utilized clinically to promote wound and pressure ulcer healing. It appears to induce cellular action and histological responses such as enhancing production of collagen and deoxyribonucleic acid synthesis, supporting

adenosine triphosphate production, as well as increasing the number of growth factor receptors and calcium influx[52-59].

The primary focus of this prospective clinical trial was to examine the effect of MPC and MPC coupled with plantar fascia SE on heel pain, heel tenderness, functional activities level, and ST of plantar fascia on patients diagnosed with PF. No prior studies appear to have been conducted in examining the effect of MPC on patients diagnosed clinically with PF.

We hypothesized that the use of monophasic pulsed current would promote and accelerate the proximal plantar fascia healing process, especially the proliferation phase associated with plantar fasciitis. Plantar fascia is a connective tissue and the fibroblast cells whose main function is to maintain the structural integrity of the plantar fascia. Fibroblasts produce collagen, glycosaminoglycans, reticular and elastin fibers, and glycoproteins found in the extracellular matrix. The promotion and acceleration of healing processes of the inflamed proximal plantar fascia may decrease heel pain, tenderness, improve functional activities level, and reduce abnormal thickening of plantar fascia associated with PF. We utilized plantar fascia SE as demonstrated by DiGiovanni in our study because they are considered central to most conservative treatment protocols and viable treatment techniques for inferior heel symptoms associated with PF, especially in reducing heel pain, heel tenderness and improving functional activities level[9].

The results of this prospective clinical trial were consistent with results of other clinical studies which have concluded that physical therapy interventions and modalities may alleviate and mitigate inferior heel symptoms and improve patients's functional activities level imposed by plantar fasciitis[9-11,32,33,40-49].

Data analysis of the of the participants' characteristics indicated that no significant differences between the two treatment groups in terms of age, sex height, weight, BMI, duration of heel symptoms, athletic status, and involved side. Participants' characteristics in the two treatment groups appeared to be generally well matched with each other and would not affect the subjective and objective outcome measures utilized to determine the effect of MPC on the treatment of PF.

In post intervention evaluation, both groups indicated statistically significant reduction in heel pain compared to baseline evaluation of VAS scores, with a mean effect of -3.95 scores on VAS for Group I and -3.29 scores for Group II. The differences between the two groups were negligible. The reduction in VAS scores was clinically significant[61-63].

Post intervention evaluation revealed significant statistical improvements in heel tenderness in both groups. Group I and Group II displayed a mean effect of 1.9 and 2.0 kg on the PA scores respectively. However, no significant difference existed between the two treatment groups. This improvement in the PA scores is large enough to be clinically important [64-66].

This study showed significant improvement in functional activities level for both groups. Group I and Group II exhibited a mean effect of -18.87 and - 13.09 scores on the ADL/ FAAM, respectively. However, no significant difference between the two treatment groups was revealed. This reduction in ADL/FAAM scores is large enough to be clinically important[67-69].

Many clinical studies have concluded that plantar fascia thickening has decreased and inferior heel pain improved with the use of nonoperative treatments including steroid injections, nonsteroidal anti-inflammatory drugs, and Botulinum toxin[7,16,17,21-23,38,49,70,71].

Post intervention evaluation showed that Group I experienced a mean decrease in the ST of plantar fascia of -0.7 mm compared to mean reduction of -0.7 mm for Group II. However, no significant difference existed between the two treatment groups.

This study revealed a significant decrease in the sagittal thickness of the proximal plantar fascia after the use of MPC. Findings of this clinical trial agreed with previous studies about the efficacy of medical treatment options in reducing abnormal proximal thickening of planter fascia caused by plantar fasciitis[7,16,17,21-23,25,36,38,49,70,71].

This study further sought to examine whether a statistically significant correlation existed between changes in plantar fascia proximal sagittal thickness and changes in inferior heel pain while simultaneously evaluating the effectiveness of MPC and MPC coupled with plantar fascia SE on the treatment of PF.

This prospective clinical trial detected an average reduction in inferior heel pain of -3.6 ± 1.9 scores and an average reduction in sagittal proximal thickness of the plantar fascia of -0.7 mm ± 0.4 mm. No statistically significant correlation between the mean reduction in heel pain and the sagittal thickness of the plantar fascia existed. However, this study demonstrated significant statistical reduction in inferior heel pain and in the sagittal thickness of the proximal insertion of plantar fascia on patients diagnosed with PF compared to baseline evaluation.

The relationship between two variables may be affected by the presence of extreme or influential outliers. The Boxplot is a useful tool in illustrating the distribution

of data, and it did not reveal the presence of extreme or influential outliers in average difference in VAS scores as a subjective outcome measure and MSK US as an objective outcome measure.

The results of this trial need to be viewed in light of two limitations: first, the assessor was not blinded to treatment allocation and outcome assessment. This is a potential source of bias. Nevertheless, outcome measures were subjective and self-reported by participant and MSK US was used as an objective outcome measure. Second, more meticulous inclusion and exclusion criteria would be needed to draw sound inferences about the effect of MPC. For instance, the participants exhibited chronic symptoms with varying duration of symptoms. Future research should target symptoms of a limited duration, i.e., less than 12 months.

Third, the sample of convenience was insufficiently large, thus we were unable infer a more reliable conclusion about the additive effect of plantar fascia SE on the treatment of PF.

The strengths of this study were based on its prospective randomized design. Additionally, its attrition rate was not abnormally high.

Based on this study's findings, physical therapists are urged to use MPC as an effective treatment for patients clinically diagnosed with PF. However, it is suggested that physical therapists combine MPC with plantar fascia specific SE to promote and accelerate healing processes as well as regaining and maintaining the flexibility of the plantar fascia, even though this study did not demonstrate additive effect of using plantar fascia SE on inferior heel symptoms caused by PF.

Further research is encouraged to address the limitations of this study, issues of plantar skin resistance on the treatment with MPC, and the long-term effect of MPC on treatment of PF.

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APPENDIX A

LETTER FOR PATIENT REFERRAL

LOMA LINDA UNIVERSITY

School of Allied Health Professions

Letter for Patient Referral

Dr. _____

My name is Jerrold Petrofsky, Ph.D. JD., and I am on the faculty of the Department of Physical Therapy at the Loma Linda University School of Allied Health. My investigative team, including my doctoral graduate student, Abdullah Alotaibi, will conduct a prospective clinical trial in conjunction with his doctoral studies. The purpose of the study is to examine the effectiveness of electrical stimulation (ES) on plantar fasciitis. The inclusion criteria for the study are as follows: (1) men and women who have been diagnosed with unilateral plantar fasciitis; and (2) who are between 18-65 years. The exclusion criteria are: (1) previous fracture or surgery to the foot; (2) specific metabolic and connective tissue disorders associated with or contributing to the diagnosis of plantar fasciitis (i.e., rheumatoid arthritis, gout, lupus); and (3) bilateral plantar fasciitis.

If you have patients whom you feel would qualify for or may benefit from participation in the study, we would appreciate it if you would inform them about the existence of this study and ascertain if they are interested in learning more about it. If the patient expresses interest, we will contact them with details about the study. However we need the patient's permission to do so. Thus, would you please provide him/her with enclosed Authorization for Use of Protected Health Information (PHI) form to read and sign. This form will allow his or her name, diagnosis, phone number (home, cellular), date of birth, and gender to be forwarded to the study investigator. After the form is signed please contact Abdullah Alotaibi, MSPT, the study

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Adventist Health Sciences Center
Institutional Review Board
Approved 4/10/2013
#5130018 Chair R. L. Rigsbee

A Seventh-day Adventist Institution
DEPARTMENT OF PHYSICAL THERAPY | Nichol Hall, Loma Linda, California 92350
(909) 558-4632 · (800) 422-4558 · *fax* (909) 558-0459 · www.llu.edu/llu/sahp/pt

investigator at (909) 358-3875 or e-mail address, akalotaibi@llu.edu) and arrangement will be made to obtain the signed PHI form and the enclosed patient information form for our files.

Thank you for referring prospective eligible subjects for participation in our study.

Sincerely,

Jerrold Petrofsky Ph.D, JD

24951 North Circle Drive, Nichol Hall

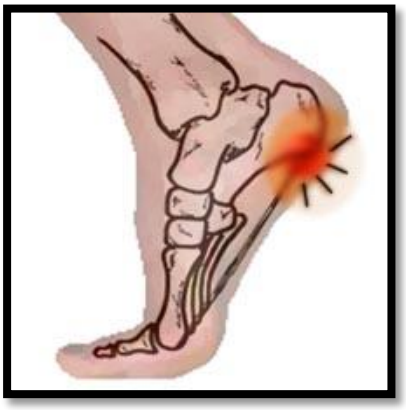
Loma Linda, CA 92350

Phone: (909) 651-5921 Ext. 87274

E- mail: jpetrofsky@llu.edu

APPENDIX B

NEWS PAPERS ADVERTISEMENT



RESEARCH PARTICIPANTS NEEDED

The Department of Physical Therapy in the School of Allied Health Professions at Loma Linda University is currently conducting a student dissertation project to examine **the effect of Electrical Stimulation in the treatment of plantar fasciitis (heel pain)**.

You may qualify to take part in this four week study if:

- You have been diagnosed with **PLANTAR FASCIITIS**
- You are at between **18 and 65** years of age

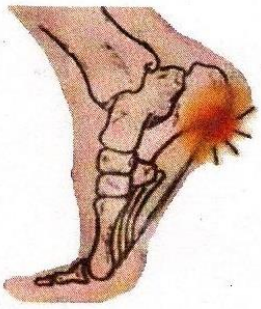
If you are interested in participating or would like further information concerning the study, please contact **Abdullah Alotaibi at 909-358-3875** or **akalotaibi@llu.edu**

APPENDIX C

STUDY FLIER

PUBLIC ADVERTISEMENT

RESEARCH PARTICIPANTS NEEDED



The Department of Physical Therapy in the School of Allied Health Professions at Loma Linda University is currently conducting a student dissertation project to examine **the effect of Electrical Stimulation in the treatment of plantar fasciitis (heel pain)**.

You may qualify to take part in this four week study if:

- You have been diagnosed with **PLANTAR FASCIITIS**
- You are at between 18 and 65 years of age

If you are eligible for participation you will undergo baseline and post intervention evaluations that include the measurement of:

- Heel pain
- Heel tenderness
- Activity level
- Plantar fascia thickness

Neither you nor your health insurance provider will be charged for costs of any assessment performed or treatment provided for the purposes of this study. After completing the four-week study, you will receive a gift card for a modest amount as an expression of our thanks for your participation.

If you are interested in participating or would like further information concerning the study, please contact **Abdullah Alotaibi** at **909-358-3875** or **akalotaibi@llu.edu**

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APPENDIX D

AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI)

Per 45 CFR §164.508(b)

OFFICE OF SPONSORED RESEARCH
Loma Linda University • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)

TITLE OF STUDY: **The effect of monophasic pulsed current on Plantar Fasciitis**

PRINCIPAL INVESTIGATOR: Jerrold Petrofsky

Others who will use, collect, or share PHI: Abdullah Alotaibi

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: name, diagnosis, gender, telephone number, date of birth.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not need to follow the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

- This authorization does not expire, and will continue indefinitely unless you notify the researchers that you wish to revoke it.

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IRB 12/07/2011

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at 909-358-3875.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

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S13 0018 Chair R L Rigsby MD

APPENDIX E

PATIENT'S INFROMATION FORM

PATIENT'S INFORMATION FORM

Name: .....

Diagnosis: .....

Gender: .....

Phone numbers:

Home: .....

Cellular: .....

Date of birth (MM/DD/YYYY): .....

APPENDIX F

PHONE SCRIPT FOR REFERRED PERSONS

Phone Script for Referred Persons

- Hello. My name is Abdullah Alotaibi. I am a doctor of science in physical therapy student at Loma Linda University. May I speak to (name of the eligible participant)?
- You name has been given to me by your physician----------
- I would like to tell you about our research study that will be conducted by a number of investigators from the physical therapy department of Loma Linda University.
- Would it be convenient for me to talk to you about this study right now? (If not, I will set time for re-call.)
- The purpose of this study is to examine the effectiveness of electrical stimulation on plantar fasciitis.
- You are being invited to participate in our study based on your eligibility of having been diagnosed with plantar fasciitis, your age being between 18-65 years, and you have experienced symptoms for less than 12 months.
- If you agree to participate, you will undergo a baseline evaluation which will include the measurement of heel pain, heel tenderness, activity level and the thickness of plantar fascia. You will then be placed in one of three treatment groups which will receive treatment for four weeks: one group will receive electrical stimulation, one group will be given plantar fascia stretching exercises to be completed at home and, one group will receive the electrical stimulation and plantar fascia stretching exercises. After finishing the assigned treatment, you will asked to participate in a post intervention evaluation which will include the

Phone Script for Referred Persons

- Hello. My name is Abdullah Alotaibi. I am a doctor of science in physical therapy student at Loma Linda University. May I speak to (name of the eligible participant)?
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- Do you have any questions?
- Would you like to participate in our study? If yes, is it convenient to schedule an appointment for baseline evaluation?
- You can contact the study's principal investigator Dr. Jerrold Petrofsky during regular office hours at: (909) 558 4300 ext. 82186 or e-mail him at jpetrofsky@llu.edu.
- Participation in this study is voluntary. Your decision whether or not to participate or deciding to terminate your participation at any time will not affect the quality of care you receive.
- If you would like to contact me, don't hesitate to call my cellphone number (909) 3583875 or e-mail me at akalotaibi@llu.edu
- Thank you for your time.

APPENDIX G

INFORMED CONSENT FORM

LOMA LINDA UNIVERSITY
School of Allied Health Professions

Effect of Monophasic Pulsed current on Plantar Fasciitis

Informed Consent to Participate in Research

1. WHY IS THIS STUDY BEING DONE?

Plantar fasciitis is an overuse injury causing inflammation at the origin of the plantar fascia (the muscles and tendons on the bottom of the foot) and is characterized by plantar heel pain that is provoked by taking first steps in the morning and by prolonged standing. No previous study, to the best of our knowledge, has been conducted to examine the effect of electrical stimulation in the treatment of plantar fasciitis. The purpose of this study is to investigate the effect of electrical stimulation (using small amount of electricity passing through the study participant foot) on heel pain, tenderness, activities level, and plantar fascia thickness. You are being asked to participate in this study because you have been diagnosed with, or have symptoms of plantar fasciitis.

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Initial: _____

Date: _____

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DEPARTMENT OF PHYSICAL THERAPY | Nichol Hall, Loma Linda, California 92350
(909) 558-4632 · (800) 422-4558 · fax (909) 558-0459 · www.llu.edu/llu/sahp/pt

2. HOW WILL I BE INVOLVED?

If you decide to participate in this student dissertation study, you will undergo the following procedures:

- The investigator will first obtain background information about you such as age, sex, height (in), weight (lb), body mass index, duration of symptoms, status (athletic, nonathletic), involved side (Rt, Lt), average number of hours per day during which you are on your feet, number of previous corticosteroid injections, and current medications (Will require about 5 minutes of your time).
- Then, you will undergo a baseline evaluation which will include the measurement of:
    - Heel pain with numerical scale ranging from 0 to 10 where you place a mark on the line representing your heel the level of pain.
    - Heel tenderness with a tool that determine the minimum pressure that produces heel pain.
    - Activity level by completing a questionnaire regarding the difficulty you have performing everyday activities because of your heel pain.
    - Plantar fascia thickness with ultrasound (imaging tool). (Will require about 30 minutes of your time).
- Once the measurements are completed, the investigator will assign you to one of three four-week intervention groups: electrical stimulation group, home based plantar fascia stretching exercises group, or the electrical stimulation and home based plantar fascia

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stretching exercises group. The investigator will then provide you with clarification about the use and application of the assigned treatment.

- If you are going to receive home based stretching exercises, the investigator will instruct you how to perform the plantar fascia stretching exercises. Additionally, the investigator will tell you the number of daily sets to complete during the four week treatment.
- If you are going to receive electrical stimulation, the investigator will tell you about the nature of the treatment and the benefits and possible risks associated with the application procedure. You will receive three sessions per week for four weeks, or a total of twelve sessions. Each session will last 60 minutes.
- After you finish the four week treatment, you will undergo the post intervention evaluation which will include the same measurements of baseline evaluation. (Will require about 30 minutes of your time).
- Baseline and post intervention evaluations, and the electrical stimulation treatment will take place at room A640, Nichol hall, Loma Linda University.

3. WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MAY EXPERIENCE DURING TREATMENT?

Very few potential adverse effects from the clinical application of electrical stimulation have been noted. The study participant will be monitored throughout the initial treatment for any adverse effects. Skin irritation may occur in the area where electrical stimulation electrodes are applied. Some individuals find electrical stimulation to be painful. In our study, the intensity of

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the electrical stimulation will be limited to a feeling of tapping and tingling. No adverse effect of using plantar fascia stretching exercises is known.

4. WILL THERE BE ANY BENEFIT TO ME OR OTHERS?

Participation in this study may lead to decreased heel tenderness and pain, along with improved ability to perform daily activities. However, these benefits cannot be guaranteed. Information gained from this study may also lead to a more effective treatment plan of plantar fasciitis, which could benefit future patients.

5. WHAT ARE MY RIGHTS AS A SUBJECT?

Participation in this study is voluntary. You may leave the study at any time. Your decision whether or not to participate or stop at any time will NOT affect your present or future relationship with those conducting the study at Loma Linda University Department of Physical Therapy and will not involve any penalty or loss of benefits to which you are otherwise entitled.

6. WILL I BE INFORMED OF SIGNIFICANT NEW FINDINGS?

You will be promptly notified if any new information emerges during the research phase of this study which may cause you to change your mind about continuing your participation in the study.

Initial: _____

Date:_____

7. HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

To ensure that confidentiality of any information obtained about you during this research study is maintained, data associated with your participation in this study will be passcode protected. Your identity on these records will be indicated by a unique three-digit code assigned to your name. Information linking your code to your identity will be accessible only to the investigator and will be stored in separate file which will be passcode protected.

8. WHAT COSTS ARE INVOLVED?

Neither you nor your insurance provider will be charged for costs associated with procedures performed for purposes of this research study.

9. WILL I BE PAID IF I TAKE PART IN THIS RESEARCH STUDY?

A one-time gift card of $25 will be given upon completion of study participation in this study.

10. WHO DO I CALL IF I HAVE QUESTIONS?

If you wish to contact an impartial third party not associated with this study regarding questions about your rights in conjunction with the study, or to report a complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, (909) 558-4647, or e-mail patientrelations@llu.edu for information and assistance.

Initial: _____

Date:_____

Effect of Monophasic Pulsed current on Plantar Fasciitis

11. SUBJECT'S STATEMENT OF CONSENT

I have read the contents of the consent form and have listened to the verbal explanation provided by the investigators. My questions concerning this study have been answered to my satisfaction.

I hereby give voluntary consent to participate in this study. I have been given a copy of the consent form. Signing this consent document does not waive my rights nor does it release the investigators, institution, or sponsors from their responsibilities associated with the study. I may call and leave a voice message for Dr. Jerrold Petrofsky during routine office hours at (909) 558 4300 ext. 82186 or e-mail him at jpetrofsky@llu.edu, if I have additional questions or concerns.

By signing this form I agree to participate in this research study.

SIGNATURES

_____ _____

Signature of Subject **Date**

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of this study to the participant.

_____ _____

Investigator **Date**

APPENDIX H

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental clinical procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of any signed and dated written consent form used in relation to the experiment.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I have carefully read the information contained above in the "California Experimental Subject's Bill of Rights" and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

Date	Patient
For inpatient studies, add: Time	Parent/Legal Guardian

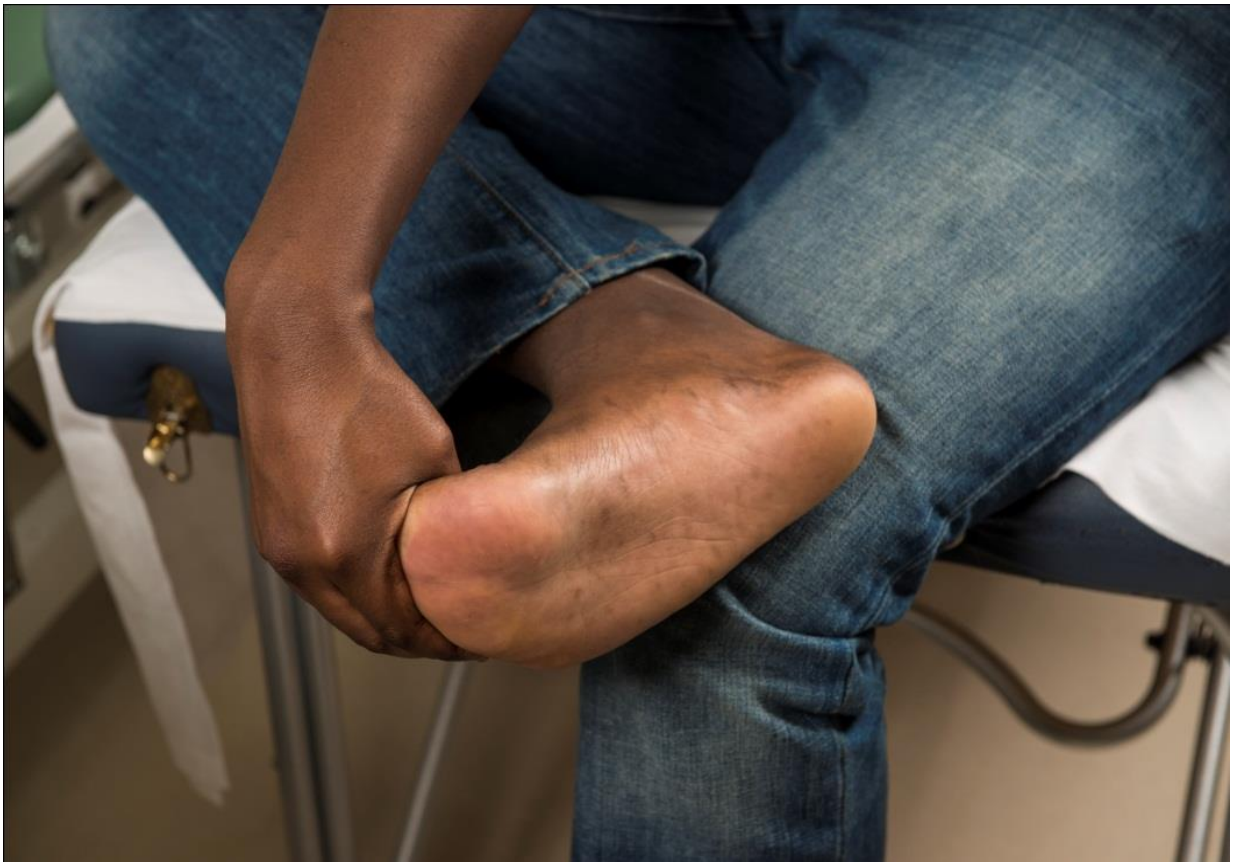
If signed by other than the patient, indicate relationship:

Relationship	Witness

APPENDIX I

HOME BASED PLANTAR FASCIA STRETCHING EXERCISES

- The patient will be instructed to cross the affected leg over the sound leg while seated, and using his/her hand, applying metatarso-phalangeal joint dorsiflexion (pulling the toes back toward the shin until the patient feels a stretch in the arch of the foot).
- Hold each stretch for a count of 10 (or 10 seconds), and repeating 10 times (DONOT OVER STRETCH).
- All patients will be asked to perform the stretching program three times per day.
- Keep a daily log of stretching exercise for 4 weeks.
- The first stretch will be done before taking the first step in the morning.



APPENDIX J

HOME BASED PLANTAR FASCIA STRETCHING EXERCISES LOG

Plantar Fascia stretching exercises log

Day / Week	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1							
Week 2							
Week 3							
Week 4							

Name: ----------

APPENDIX K

FOOT AND ANKLE ABILITY MEASURE (FAAM)

ACTIVITIES OF DAILY LIVING SUBSCALE

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living subscale

Please answer **every question** with one response that most closely describes to your condition within the past week.
If the activity in question is limited by something other than your foot or ankle mark not applicable (N/A).

	No difficulty	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
Standing	❑	❑	❑	❑	❑	❑
Walking on even ground	❑	❑	❑	❑	❑	❑
Walking on even ground without shoes	❑	❑	❑	❑	❑	❑
Walking up hills	❑	❑	❑	❑	❑	❑
Walking down hills	❑	❑	❑	❑	❑	❑
Going up stairs	❑	❑	❑	❑	❑	❑
Going down stairs	❑	❑	❑	❑	❑	❑
Walking on uneven ground	❑	❑	❑	❑	❑	❑
Stepping up and down curbs	❑	❑	❑	❑	❑	❑
Squatting	❑	❑	❑	❑	❑	❑
Coming up on your toes	❑	❑	❑	❑	❑	❑
Walking initially	❑	❑	❑	❑	❑	❑
Walking 5 minutes or less						
Walking approximately 10 minutes	❑	❑	❑	❑	❑	❑
Walking 15 minutes or greater	❑	❑	❑	❑	❑	❑

Because of your **foot and ankle** how much difficulty do you have with:

	No difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
Home Responsibilities	❑	❑	❑	❑	❑	❑
Activities of daily living	❑	❑	❑	❑	❑	❑
Personal care	❑	❑	❑	❑	❑	❑
Light to moderate work (standing, walking)	❑	❑	❑	❑	❑	❑
Heavy work (push/pulling, climbing, carrying)	❑	❑	❑	❑	❑	❑
Recreational activities	❑	❑	❑	❑	❑	❑

How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

❑❑❑.0 %