CONSERVATIVE TREATMENT OF PLANTAR FASCIITIS WITH DORSIFLEXION NIGHT SPLINTS AND MEDIAL ARCH SUPPORTS: A PROSPECTIVE RANDOMIZED STUDY

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Background: Plantar fasciitis is an overuse injury causing inflammation at the origin of the plantar fascia and is characterized by plantar heel pain that is provoked by taking the first few steps in the morning and by prolonged standing. Dorsiflexion night splints are used to address early morning pain by preventing contracture of the plantar fascia and Achilles tendon overnight. Medial arch supports, on the other hand, address the end of the day pain by preventing overstretch of the plantar fascia during prolonged weight bearing. Therefore, both night splints and arch supports may be necessary to treat plantar fasciitis as they complement each other by both controlling nocturnal contracture of the plantar fascia and Achilles tendon and reducing stresses imposed on the plantar fascia during the day, respectively. **Hypotheses:** We hypothesized that the night splint and arch support together would be more effective in the treatment of plantar fasciitis than a night splint or arch support alone in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis. A secondary hypothesis of this study was that those with less passive dorsiflexion of the ankle would benefit from a night splint more than those with greater passive dorsiflexion of the ankle and those with a lower medial longitudinal arch would benefit from an arch support more than those with a higher medial longitudinal arch in terms of the previously mentioned outcome measures. **Methodology:** Subjects of this study were randomly assigned to one of three treatment groups. Group I was treated with night splints,

group II with arch supports, and group III with a combination of night splints and arch supports. Range of motion was measured with a goniometer; heel tenderness was measured with a pressure algometer; and pain and disability were measured by the Foot Function Index before and after six weeks of treatment. **Results:** Ninety patients with plantar fasciitis (23 men and 67 women) were enrolled in the study, 30 in each group. Demographic, compliance and baseline evaluation data showed no significant differences between the groups. Analysis of the post-intervention evaluation data demonstrated significant differences between group I and III and group II and III, but not between group I and II, for all outcome measures. The range of pain-free passive ankle joint dorsiflexion and medial longitudinal arch height were not useful predictors of the success of treatment with a night splint and arch support for all outcome measures. **Discussion:** Using night splints and arch supports together may speed time to recovery by accelerating the healing process. Limitations of the study include observer's bias, subjects' bias, and short follow-up period. **Conclusion:** It was concluded that a night splint and arch support together may be more effective in the treatment of plantar fasciitis than either a night splint or arch support alone. Patients with plantar fasciitis who have less passive dorsiflexion of the ankle joint do not benefit from a night splint more than those with greater passive dorsiflexion of the ankle joint. Patients with plantar fasciitis who have a lower medial longitudinal arch do not benefit from an arch support more than those with a higher medial longitudinal arch.

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PREFACE

The opportunity to live in Pittsburgh and to study at the School of Health and Rehabilitation Sciences of the University of Pittsburgh has been one of the most exciting and enriching experiences of my life, that I will treasure its memories forever. I have been so lucky to be surrounded by a group of worldwide respected and highly prestigious pioneers in the field of physical therapy who have facilitated my academic and professional growth and molded me into a better scientist and person.

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1.0 INTRODUCTION

Plantar fasciitis is a common pathological condition affecting the hindfoot, and can often be a challenge for clinicians to successfully treat.[1,2] It is an overuse injury causing inflammation at the origin of the plantar fascia and surrounding perifascial structures, such as the calcaneal periosteum.[3-6] It is the most common clinical problem that causes inferomedial heel pain in adults.[3,7-10] Lapidus and Guidotti, in 1965, found that the number of patients in their foot clinic with plantar fasciitis was greater than those with any other recorded foot lesion.[11] It is estimated that more than two million people receive treatment for plantar fasciitis in the United States each year.[12]

This overuse syndrome has been recognized for almost two hundred years.[8,10] In 1812, Wood described this condition, which has been referred to by various synonyms, including plantar fasciitis, heel pain syndrome, subcalcaneal pain syndrome, calcaneodynia, subcalcaneal bursitis, calcaneal periostitis, neuritis, heel spur syndrome, subcalcaneal spur syndrome, stone bruise, medial arch sprain, runner's heel, jogger's heel, and policeman's heel.[2,8,9,12-18] This confusion in terminology reflects the poor understanding of the etiology of the plantar fasciitis.[13,19]

Successful treatment of plantar fasciitis usually requires a combination of treatment modalities, rather than administering only one treatment at a time.[4,14,19,20] Although many authors agree that mechanical treatment should be considered a cornerstone of any plan of treatment,

some debate remains regarding the most effective form of mechanical intervention.[14,20-22] The aim of mechanical treatment modalities is to reduce the load and stress applied to inflamed plantar fascia during activity to a tolerable level. These modalities may include foot orthoses, foot taping, footwear, night splints, rest, and walking casts.[1,22,23]

Plantar fasciitis is typically characterized by pain in the inferior heel region, which is aggravated by weight bearing after a long period of non-weight bearing and by prolonged weight bearing.[1,4,9,14,19,21,24,25] Night splints have been proven to be effective in relieving the pain associated with the first step in the morning by preventing nocturnal contracture of the plantar fascia and Achilles tendon.[4,5,7,15,19,23,24,26-32] On the other hand, arch supports have been found to relieve the end of the day pain by supporting the medial longitudinal arch and, thus, preventing overstretch of plantar fascia during prolonged weight bearing.[1,7,21,24,33-37] Therefore, the combination of both night splints and arch supports may be a more effective treatment for plantar fasciitis than either of these interventions alone because together these interventions would control nocturnal contracture of the plantar fascia and Achilles tendon and reduce stress imposed on the plantar fascia during the day. Although the isolated effectiveness of night splints and arch supports in relieving symptoms of plantar fasciitis is well-established in the literature, no previous study, to the best of our knowledge, has been conducted to evaluate the combined effect of these treatment modalities.

2.0 SPECIFIC AIMS/RESEARCH QUESTIONS/HYPOTHESES

2.1 SPECIFIC AIM/RESEARCH QUESTION/HYPOTHESIS 1

2.1.1 Specific aim 1

To examine whether there will be any difference between the efficacy of three different treatment regimens: (1) dorsiflexion night splints; (2) medial arch supports; and (3) dorsiflexion night splints and medial arch supports together, in the management of plantar fasciitis in terms of: (1) the range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis.

2.1.2 Research question 1

In patients with plantar fasciitis, will a dorsiflexion night splint and medial arch support together, compared to a dorsiflexion night splint or medial arch support each by itself, increase the range of pain-free passive ankle dorsiflexion, relieve heel tenderness and pain, and reduce disability imposed by the heel pain/plantar fasciitis?

2.1.3 Hypothesis 1

A dorsiflexion night splint and medial arch support together will be more effective in the treatment of plantar fasciitis than a dorsiflexion night splint or medial arch support each by itself in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis because, together, they address both the early morning pain and the end of the day pain, respectively.

2.2 SPECIFIC AIM/RESEARCH QUESTION/HYPOTHESIS 2

2.2.1 Specific aim 2

To investigate whether patients with plantar fasciitis who have less passive dorsiflexion of the ankle joint will benefit from a dorsiflexion night splint more than those with greater passive dorsiflexion of the ankle joint in terms of: (1) the range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis.

2.2.2 Research question 2

In patients with plantar fasciitis, will the range of pain-free passive ankle joint dorsiflexion be a useful predictor of the success of treatment with a dorsiflexion night splint in terms of increasing

the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis?

2.2.3 Hypothesis 2

Patients with plantar fasciitis who have less passive dorsiflexion of the ankle joint will benefit from a dorsiflexion night splint more than those with greater passive dorsiflexion of the ankle joint in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis.

2.3 SPECIFIC AIM/RESEARCH QUESTION/HYPOTHESIS 3

2.3.1 Specific aim 3

To investigate whether patients with plantar fasciitis who have a lower medial longitudinal arch will benefit from a medial arch support more than those with a higher medial longitudinal arch in terms of: (1) the range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis.

2.3.2 Research question 3

In patients with plantar fasciitis, will medial longitudinal arch height be a useful predictor of the success of treatment with a medial arch support in terms of increasing the range of pain-free

passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis?

2.3.3 Hypothesis 3

Patients with plantar fasciitis who have a lower medial longitudinal arch will benefit from a medial arch support more than those with a higher medial longitudinal arch in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis.

3.0 REVIEW OF THE LITERATURE/STATEMENT OF PROBLEM

3.1 ANATOMY

The plantar fascia is an extremely strong structure composed of a thin multi-layered fibrous aponeurosis.[3,7,19,38-40] The fascia divides into medial, central and lateral components. The central portion is the most dominant and the usual site of pathologic disorders.[3,38] It originates on the plantar surface of the posteromedial calcaneal tuberosity and runs forward to form the medial longitudinal arch.[3,7,15,19,28,38-41] Distally, five tracts are formed with superficial and deep components.[3,19] The superficial portion anchors the skin, providing support from shear forces.[3] The deep portion of the plantar fascia attaches to the plantar plates of the metatarsophalangeal joints and the bases of the proximal phalanges of the toes by connections to the flexor tendon sheaths.[3,19,38-40] The medial component is the fascial covering of the abductor hallucis. The lateral component originates from the lateral margin of the medial calcaneal tubercle. It may be rudimentary or a fully developed fascial structure with distal bands to the plantar plates of the metatarsophalangeal joints of the fourth and fifth toes.[3]

The medial process of the calcaneal tubercle serves as the point of origin of the abductor hallucis, flexor digitorum brevis and abductor digiti minimi muscles.[3,15,41] The plantar fascia is innervated by the medial calcaneal nerve, a branch of the posterior tibial nerve.[28] The posterior tibial nerve bifurcates into the medial and lateral plantar nerves, which course deep to the

abductor hallucis muscle. The lateral plantar nerve gives off the nerve to the abductor digiti minimi before coursing deep to the abductor hallucis muscle. The nerve to the abductor digiti minimi travels adjacent to the medial calcaneal tubercle in close proximity to the plantar fascia and the fascia of the abductor hallucis where it may be compressed.[13,41] A variety of bursae are present in the foot. A subcutaneous plantar calcaneal bursa is a perifascial structure often involved with plantar fasciitis.[3]

Histologically, the extracellular matrix within the plantar fascia is comprised of collagenous and elastic fibers. The elastic fibers are present in longitudinal strands and in wavy, bundled networks. These elastic fibers may alter orientation from wavy to straight under increasing amount of acute and chronic loading, leading to stiffening of the fascia.[38]

3.2 PATHOMECHANICS

The function of the plantar fascia is to support the medial longitudinal arch during static and dynamic loading of the foot, and to provide midfoot stability. It also assists the heel pad in dynamic shock absorption.[7,9,19,25,38,39,42-45] Just after heel strike during the first half of the stance phase of the gait cycle, the tibia turns inward and the foot pronates to allow flattening of the foot. This stretches the plantar fascia. The flattening of the medial longitudinal arch allows the foot to accommodate to irregularities in the walking surface and also to absorb shock.[3,19]

The plantar fascia functions through the windlass mechanism to limit the flattening of the foot and to elevate and stabilize the medial longitudinal arch. This occurs when the toes are dorsiflexed, passively pulling the plantar fascia under the metatarsal heads. Thus, each time the

foot passes from heel rise to toe off in the stance phase of the gait cycle, the plantar fascia is placed under increased tension.[3,5,21,23,45]

Mechanistically, Hicks appears to be the first to describe the windlass mechanism by which passive dorsiflexion of the toes causes the medial longitudinal arch to rise, the hindfoot to supinate, the leg to externally rotate, and the plantar fascia to become more tense than when the foot and toes are in neutral. He stated that the plantar fascia acts as a cable that is wound around the metatarsal head, which acts as a drum, with the proximal phalanx acting as a handle to provide the winding.[45]

The plantar fascia is prone to repetitive injury at the posterior insertion due to its role in maintaining the medial longitudinal arch and through the stress placed on it by the shock absorbency function of the heel.[16,40] If there is a predisposing or aggravating factor, the repetitive traction placed on the plantar fascia during walking or running may lead to micro- and macro-tears, which induce a reparative inflammatory response.[1-6,10,12-17,19,21,25,39,44,46,47] The healing response is then interrupted by the continued stress produced by weight bearing, resulting in chronic degenerative changes.[5,6,12,21,40]

Histologically, these changes include collagen necrosis, angiofibroblastic hyperplasia, chondroid metaplasia and matrix calcification.[3,4,6,9,13,17,21,24,25,39,48] A single histologic study of specimens obtained from cases with inflamed plantar fascia revealed mucinoid degeneration or fibrous degeneration in 34 of 35 specimens.[2] Pathologically, prolonged inflammatory changes in the tissue are seen initially as edema, and are seen later as thickening of the plantar fascia.[21,25,38,40] In one study, the dorsoplantar thickness of the plantar fascia was 3 mm in normal subjects and 15 mm in patients with plantar fasciitis.[19]

Indeed, the specific pathologic features responsible for any patient's symptoms are not well understood.[38] However, it is suggested that the normally resilient fascia becomes stiffened and prone to reinjury, thus setting up a vicious circle of persistent pain.[4] In addition, thickening of the plantar fascia, decreased vascularity, peritendinous inflammation, and alteration of nocioceptor physiology all may play roles in the onset and persistence of the heel pain.[38]

3.3 ETIOLOGY

Despite its familiarity to physicians, the exact etiology of plantar fasciitis remains obscure.[8,9,13,14,19] The variety of treatments noted in the literature attests to the uncertainty of the etiology and pathogenesis of plantar fasciitis.[24] Snook and Chrisman wrote, "It is reasonably certain that a condition which has so many different theories of etiology and treatment does not have valid proof of any one cause."[49] This thinking has been reiterated by other authors.[11,24]

Several factors may contribute to the development of plantar fasciitis. The underlying factors that have been said to precipitate the condition can be divided into anatomical, biomechanical, and environmental factors.[1,3,14,21] Anatomical factors include low arch or pes planus, high arch or pes cavus, sudden gain in body weight or obesity, unequal leg length, and fat pad atrophy.[3-5,7,8,11,13,16-19,21,24,28,40,47,50-53] Biomechanical factors include tight Achilles tendon or equinus, weak plantar flexor muscles, weak intrinsic musculature, excessive subtalar joint pronation, and externally rotated lower extremity.[3-5,7,11,13,16,18,19,47,50-53] Environmental factors include trauma, an increase in activity, unyielding surfaces, going barefoot, improper or excessively worn footwear, occupation involving prolonged weight bearing, and inadequate

stretching.[1,4-6,11-13,16,18,19,21,24,28,40,46,52,53] In most cases, a combination of these factors leads to the development of plantar fasciitis.[1,6,21]

Many authors have noted that specific anatomic foot configurations are associated with the development of plantar fasciitis.[3,47,51] Pes planus with excessive pronation is the most common mechanical cause of structural strain on the plantar fascia resulting in plantar fasciitis.[1,3,28] Between 81 and 86% of individuals with symptoms consistent with plantar fasciitis have been classified on examination as having pes planus with excessive pronation.[1] The theoretical basis for this finding is the increased tension placed on the plantar fascia as a result of a lower arch during standing and walking.[7,13,19,42,54] In addition, increased pronation results in decreased stability of the hindfoot, which produces additional stress on the origin of the central band of the plantar fascia and may ultimately lead to plantar fasciitis.[1,15,28]

Excessive pronation results in an inability of the foot to supinate from mid to terminal stance.[3,51] Consequently, little load is conveyed through the lateral portion of the midfoot and normal loading forces are inadequately supported by the bones and ligaments. The vertical impulse is thus shifted away from the midfoot, and secondary structures, such as the plantar fascia, must assume a greater load.[6] Mann and Inman confirmed this by noting that heel pronation increased the tension along the medial aspect of the heel.[54]

It has been reported that most cases of plantar fasciitis are the result of different factors that cause abnormal pronation.[15] These include leg length discrepancy, ankle equinus, excessive tibial torsion, worn shoes, loose heel counters, inadequate arch support, and tight shoebox construction.[3,15,28,46,50] However, research studies have not demonstrated that foot pronation is a primary factor in the cause of plantar fasciitis.[1]

The cavus foot is also commonly associated with the occurrence of plantar fasciitis.[6] It has been suggested that the intrinsically tight plantar fascia develops fasciitis secondary to its inability to dissipate force during stance phase.[3,13,16,19,47] The result is similar to the stretching of a bowstring with increased tension generated within the fascia.[3,6] Notably, a cavus foot by itself, without concurrent fasciitis, has been shown to load the midfoot to a lesser extent, and the forefoot to a greater extent than in the normal foot. The shifting of the vertical impulse to the forefoot and, more particularly, away from the midfoot is certainly consistent with the theory of intrinsically tight fascia.[6] While some authors have noted an association between pes cavus and plantar fasciitis, another study of 323 patients (364 feet) with plantar fasciitis could find no causal relationship.[11]

A tight Achilles tendon is found in 78% of patients with plantar fasciitis.[4,13,16,17,24,39] It limits ankle joint dorsiflexion, which increases the load on the intrinsic muscles of the foot and results in abnormal compensatory pronation of the subtalar joint as ankle dorsiflexion progresses during the stance phase of gait.[3,16,19,46,47,55]

The externally rotated lower extremity resulting from excessive femoral or tibial torsion is another significant pathomechanical factor for plantar fasciitis. The stance foot is not capable of supination from mid to terminal stance, and instead pronation occurs, because the medial portion of the midfoot assumes a greater load.[3]

Obesity occurs in 40% of men and 90% of women with plantar fasciitis, compared to 20% of both men and women without plantar fasciitis.[13,19,56] Hill and Cutting found a statistically significant correlation between plantar fasciitis and increased body weight, and concluded that increased body weight is an associated factor in many patients with plantar fasciitis.[52] This

finding is consistent with other studies reporting a strong correlation between obesity and the incidence and severity of plantar fasciitis.[10,12,15,24,53]

Overuse, rather than anatomy, is the most common cause of plantar fasciitis in athletes. A history of an increase in weight bearing activities is common, especially those involving running, which causes micro-trauma to the plantar fascia and exceeds the body's capacity to recover.[7] One study found a significant correlation between activity level and plantar fasciitis. Specifically, the plantar fasciitis group was more active than the control group.[10]

Most patients with plantar fasciitis work on hard floors. Indeed, there is an association between plantar fasciitis and the type of floor on which individuals work.[10] Other associations have been proposed, such as occupations involving prolonged weight bearing, wearing shoes with poor cushioning or inadequate arch support, and walking barefoot. With the exception of prolonged weight bearing, these associations have not been substantiated.[19,53]

3.4 DIAGNOSIS

Even in this age of modern technology, the diagnosis of plantar fasciitis is based mainly on the patient history and physical examination.[5,15,19] A detailed history will often provide enough information to make the diagnosis of plantar fasciitis, and physical examination will confirm it. A complete description of the pain is essential.[4] Further investigations, such as radiographs, electrophysiological studies, and blood tests, are used only to rule out other disorders that cause inferior heel pain.[19]

The most common symptom associated with plantar fasciitis is pain and discomfort in the inferior heel region, which is aggravated on weight bearing after a period of non-weight

bearing.[1,4,9,14,19,21,24] Patients will often note that they have excruciating pain when arising from bed in the morning. This is typical of plantar fasciitis because the foot tends to remain in an equinus position during the night and the fascial tissues contract. In the morning, putting weight on the foot puts the plantar fascia under tension, aggravating the pain. The pain may become so incapacitating that the patient limps to the bathroom or hobbles around with the heel off the ground. However, the acute discomfort will slowly subside during the next 30 to 45 minutes.[1,4,7,9,14,15,19,21,24,38,42] If the patient has a long commute to work, he/she can also report that his/her heel was not painful during the commute but that the pain commenced immediately as he/she attempted to weight bear again on the involved extremity.[1] Once at work, depending on whether the patient's job requires sitting or extended periods of weight bearing throughout the day, he/she might be able to undertake various activities for 3 to 4 hours before the return of his/her heel pain.[1,4,7,21,24,38,42] The duration of activity before the onset of heel pain can serve as an excellent indicator of the degree of irritability of the involved tissues.[1] In general, the pain is brought on by weight bearing activities, such as standing, walking, jogging, or running, and relieved with rest.[1,4,9,19,25]

The source of pain is believed to be inflammation of the plantar fascia that results from excessive tension.[3,5] In its acute stage, the discomfort most often is localized to the origin of the medial and central bands of the plantar fascia at the medial tubercle of the calcaneus and is characterized as a sharp or knife-like intermittent pain. However, patients who present with chronic complaints indicate that the pain may become dull or achy and constant, and the discomfort may progress distally along the entire course of the central band in the region of the medial longitudinal arch.[1,3,5,14,15,19,21,24]

The pain is usually insidious.[4,5,9,15,19] It is not unusual for a patient to endure the symptoms and try to relive them with home remedies for many years before seeking medical treatment. Acute trauma is not common; however, further questioning may indicate a recent increase in either the amount or intensity of physical activity or a change of shoe wear before the onset of the symptoms.[1,4,15,24]

The condition is usually not completely disabling; however, patients frequently report limitations in their routine daily activities.[24,26] Using the Physical Activity sub-scales of the Health Status Questionnaire Short Form 36, a recent study showed that, on average, physical activity of patients with plantar fasciitis was inferior to that of patients with diabetes and equivalent to that of patients with acute sciatica.[26]

Physical examination of patients with plantar fasciitis most often yields few objective findings.[26] Careful palpation is required in the physical examination to determine the exact location of the patient's discomfort and to ensure a correct diagnosis of plantar fasciitis.[1] On deep palpation, the patient usually has localized tenderness at the anteromedial aspect of the heel with no significant pain on compression of the calcaneus from a medial to a lateral direction; firm finger pressure is often necessary to localize the point of maximum tenderness.[4,5,7,15,19,27] The patient may also have tenderness along the entire plantar fascia. Passive dorsiflexion of the toes or ankle stretches the fascia, reproducing the pain of weight bearing, and facilitates palpation of the plantar fascia.[4,5,7] The pain may also be exacerbated by having the patient stand on the tips of the toes.[7] Tightness of the Achilles tendon, as noted by limited ankle dorsiflexion with the knee in extension, is usually found in patients with this condition.[4,13,16,17,24,39] Although localized swelling is usually absent, nodules or thickening of the plantar fascia may be noted when the condition is chronic.[3-5]

The clinical diagnosis of plantar fasciitis is relatively easy; however, when patients present with atypical or chronic symptoms, differential diagnostic testing may provide useful information.[4,38] In a recent study, both ultrasonography and bone scintigraphy confirmed the clinical diagnosis in a total of 25 of 27 heels, highlighting the accuracy of clinical diagnosis. This suggests that clinical examination is sufficient to establish the initial diagnosis of plantar fasciitis and that the diagnostic role of ultrasonography and scintigraphy should be limited to the evaluation of persistent heel pain in order to rule out rare, alternative pathologies.[40]

Ultrasonography and bone scintigraphy are equally effective in the diagnosis of plantar fasciitis.[40] Ultrasound examination may show increased thickness of the plantar fascia and appearance of inflammatory changes.[6,19] On the other hand, bone scintigraphy confirms plantar fasciitis by uptake at the origin of the fascia.[4,16] MRI is rarely indicated but may show thickening and inflammation of the medial bundle of the plantar fascia.[19,27] Radiographically, a heel spur on the inferior surface of the calcaneus frequently is evident but is not considered pathognomonic of the disorder.[38] In addition, standard weight bearing radiographs demonstrate the biomechanical character of the hindfoot and forefoot; however, they usually serve only as an aid to confirm the clinical diagnosis.[15]

3.5 DIFFERENTIAL DIAGNOSIS

Plantar fasciitis is often called “heel spur syndrome,” although this terminology is somewhat of a misnomer because 15 to 25% of the general population without symptoms have heel spurs and half of patients with plantar fasciitis do not.[1,2,4,7,19,29] A heel spur is a bony osteophyte located at the medial process of the calcaneal tubercle.[1,2,7] The greater pull of the plantar fascia was thought

to lead to periosteal hemorrhage and inflammatory reaction, and to laying down of new bone and heel spur formation, but the heel spur is more often associated with the flexor digitorum brevis muscle than the plantar fascia.[2,16,17,19,24,28,29,39,47,48] The spur has no diagnostic value and should not be considered the cause of symptoms.[1-4,19,29]

Differential diagnosis includes rupture of the plantar fascia, inflammatory rheumatologic conditions, tumors, nerve entrapment, tarsal tunnel syndrome, stress fracture of the calcaneus, fat pad atrophy, subcalcaneal bursitis and calcaneal periostitis.[2,8,11,16,39,50,52] Acute heel or arch pain suggests rupture of the plantar fascia, especially following athletic activity. Bilateral symptoms could represent a manifestation of an inflammatory disorder.[4,5,15,24] The etiology in younger patients, particularly when the symptoms are bilateral and are unresponsive to the usual conservative modalities, may be juvenile or adult rheumatoid arthritis, spondylitis, or Reiter's syndrome.[3,8,13,15-17,19,24,40] The older patient with bilateral plantar fasciitis may have gout or osteomalacia.[3,15] Nocturnal pain should raise the suspicion of several causes of heel pain such as inflammatory disorders, tumors, and neuropathic pain including nerve entrapment and tarsal tunnel syndrome.[15,19,38] Heel pain was recently reported to involve the nerve to abductor digiti minimi, which supplies a motor branch to the abductor digiti minimi and sensory branches to the periosteum and plantar fascia. In 20% of the cases of inferior heel pain, the pain may be caused by this nerve being trapped, or affected by inflammation of the plantar fascia.[2,4,15,19,42] Tenderness on mediolateral compression of the heel (squeeze test) should lead to a suspicion of a stress fracture of the calcaneus. Tenderness in the center of the posterior part of the heel may be due to atrophy of the heel pad, subcalcaneal bursitis or calcaneal periostitis.[4,13,15,19]

Differential diagnostic testing is indicated in cases of atypical plantar fasciitis, in patients with heel pain that is suspicious for other causes or in patients who are not responding to

appropriate treatment.[4,7,38] Standard weight bearing radiographs in the lateral and anteroposterior projection are usually taken to rule out rheumatoid arthritis in the calcaneus, tumors, a stress fracture of the calcaneus, or erosions due to subcalcaneal bursitis. Positive percussion (Tinel's sign) on the medial aspect of the heel should lead to a suspicion of entrapment of the nerve to abductor digiti minimi or a tarsal tunnel syndrome.[4,5,15,19] Electrophysiological studies may be performed to confirm the nerve entrapment and tarsal tunnel syndrome.[4,5,9,13,15,19,38] A full blood count and erythrocyte sedimentation rate (ESR) are recommended in patients with bilateral disease or an atypical clinical picture to rule out inflammatory disorders.[4,5,13,15,19]

3.6 CONSERVATIVE TREATMENT

Despite the lack of understanding of the causes of plantar fasciitis, most authors agree that it is a self-limiting condition in the vast majority of cases and that surgery is not the treatment of choice.[2,7,8,10,19,24,27,38,57] Approximately 95% of those with plantar fasciitis will have resolution of their symptoms in six to eighteen months.[2,4,5,7,8,10,40,57] Although the natural history may be associated with symptomatic improvement in the absence of any intervention, most patients have sufficient pain and incapacitation that they eventually seek medical evaluation and treatment.[38] The mainstay of treatment for acute and chronic plantar fasciitis remains non-operative because conservative techniques are successful in over 90% of patients.[2,4,8-14,23,24,27,29,30,32,38,48,58-60] However, there is no consensus about which treatments are the best or the most cost-effective, and there is inconsistency in the treatments provided by various practitioners.[10,12,14,27,38]

The success of conservative care for the treatment of patients with plantar fasciitis requires a combination of treatment modalities.[4,14,19,20] Such modalities should address the

inflammatory component that causes the discomfort and the biomechanical factors that produce the disorder.[1,5,7,15,50] Patient education is imperative. Patients must understand the etiology of their pain, including the biomechanical factors that caused their symptoms.[4,15] In addition, it is important, but difficult, to make the patient understand that treatment consists of several methods and that a total, not a fragmented, effort is necessary.[4,14,19]

Non-surgical management for the treatment of the symptoms and discomfort associated with plantar fasciitis can be classified into three broad categories: reducing pain and inflammation; reducing tissue stress to a tolerable level; and restoring muscle strength and flexibility of involved tissues.[1,5]

3.6.1 Reduce pain and inflammation

Anti-inflammatory medications are frequently used to reduce pain and assist the natural healing process of the involved tissues.[1] Non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injections into the region of pain are the two most commonly prescribed medications used in the treatment of plantar fasciitis.[1,3,7,9,46,58] The use of such medications is based on the premise that plantar fasciitis is an inflammatory disorder.[38] Oral NSAIDs provide pain relief and are useful in temporarily decreasing the inflammation, but without correction or modification of the structural changes within the plantar fascia that are manifested as marked thickening on the MRI scan, the inflammation can readily recur.[4,13,29,38]

Corticosteroid injection remains a popular treatment method in most studies.[24] If other measures fail, a corticosteroid injection near the plantar fascia origin may provide adequate pain relief.[4,5,19] Despite its common use, there is minimal evidence for its effectiveness. One randomized controlled trial found corticosteroid injection had a success rate of 70% or better,

and a second randomized trial indicated that corticosteroid injection relieved symptoms for four weeks.[61-63] Corticosteroid injections are not without complications. Potential risks of multiple corticosteroid injections include osteomyelitis of the calcaneus, loss of cushioning through atrophy of the fat pad beneath the calcaneus, collagen degeneration and calcification, and weakness and rupture of the plantar fascia. In addition, corticosteroid injections are often followed by a recurrence of symptoms.[4,5,9,14-16,19,28,38,39,64,65]

In addition to medications, a variety of physical agents, including iontophoresis, phonophoresis, ultrasound, cryotherapy, and hydrotherapy, have been described as effective in the management of plantar fasciitis.[1,3,5,7,13,15,16,44] Although all these modalities have been recommended for the management of pain and inflammation, no studies have been conducted on patients with plantar fasciitis to determine their actual effectiveness.[1,58]

Because of the recognized risks and delayed healing often associated with surgery, alternative non-operative therapeutic methods have been assessed. Particularly in Europe, since 1992, the use of shock waves for various musculoskeletal conditions has been investigated. This includes use of shock waves to treat chronic conditions such as calcific tendonitis of the shoulder, tennis elbow, and plantar fasciitis.[38,66,67] Shock waves used to treat musculoskeletal conditions are comparable with those currently in widespread clinical use for the fragmentation of renal and ureteral stones.[38] Although several studies found shock waves to be a safe and effective therapy for chronic plantar fasciitis, the exact mechanism of action of this modality is unclear.[38,66,67]

3.6.2 Reduce tissue stress

The most common interventions to reduce tissue stress to a tolerable level include foot orthoses, strapping the foot with adhesive tape, and footwear. The primary reason for the selection of these interventions has been the suggested association between foot pronation and the development of plantar fasciitis.[1,22] Foot orthoses, foot taping, and footwear have thus been used to reduce the amount of foot pronation and redistribute load to the lateral portion of the foot during activity and, thus, decrease the stresses applied to inflamed tissues.[1,3,5-7,15,16,22,24,28,68] Other mechanical treatment modalities include night splints, rest, and walking casts.[23] Although many authors have stated that mechanical therapy is important in treating plantar fasciitis, some debate remains regarding the most effective form of mechanical treatment.[14,20-22]

Orthotic devices are the mainstay of ongoing conservative treatment for patients with plantar fasciitis.[15] The three most commonly used orthoses are over-the-counter arch supports, custom orthotics, and heel pads. Over-the-counter arch supports may be useful in patients with acute plantar fasciitis and mild pes planus. They are especially useful in the treatment of adolescents whose rapid foot growth may require a new pair of arch supports once or more per season.[7,44] The support provided by over-the-counter arch supports is highly variable and depends on the material used to make the support.[7] Various rigid, semi-rigid, and soft arch supports are available commercially. Rigid plastic arch supports rarely alleviate the symptoms and often aggravate the heel pain.[13,19] Arch supports made of softer materials provide cushioning by reducing the shock when walking by up to 42%.[19] In general, patients should try to find the most dense material that is soft enough to be comfortable to walk on.[7]

Custom orthotics are usually designed to control biomechanical risk factors such as pes planus, pes cavus, valgus heel alignment, and discrepancies in leg length.[7] For patients with

plantar fasciitis, the most common prescription is for semi-rigid orthotics that support the longitudinal arch, take some of the weight bearing load away from the plantar surface of the calcaneus, and absorb weight bearing stresses.[4,7,15,19] Two important characteristics for successful treatment of plantar fasciitis with custom orthotics are the need to control pronation and metatarsal head motion, especially of the first metatarsal head.[3,7] However, only few patients with plantar fasciitis require custom orthotics.[4,12] The main disadvantage of custom orthotics is the cost, which is frequently not covered by health insurance.[7]

Campbell and Inman, in 1974, were the first authors to describe success with mechanical therapy using arch supports. They treated 33 patients with University of California Biomechanics Laboratory (UC-BL) inserts and retrospectively reported a 94% success rate.[37] In 1985, O'Brien and Martin performed a retrospective telephone survey of 41 patients with plantar fasciitis. Excellent and good results were recorded for 96.7% of the patients, most of whom received multiple therapies. Subjectively, the patients stated that orthoses were the most successful treatment modality.[36] Recently, Kogler and colleagues reported that foot orthoses designed to provide total contact to the plantar surface of the foot in combination with proper footwear significantly decreased the strain on the plantar fascia during weight bearing.[34] It was suggested that the primary role of footwear and foot orthoses in the treatment of plantar fasciitis is not controlling foot motion but rather providing total contact and, thus, support of the plantar structures of the foot to reduce stress.[1] In another study, orthotics were cited by 27% of patients as the best treatment.[24]

Several studies have demonstrated that soft over-the-counter foot orthoses are just as effective as custom-made foot orthoses.[33,35] The reason for this may be that over-the-counter orthotics provide total contact with the plantar surface of the foot.[1] Another study conducted by

Martin and associates found that over-the-counter arch supports, custom-made orthoses, and dorsiflexion night splints were all equally effective as initial treatments for plantar fasciitis.[21] Pfeffer et al., in a recent multi-center prospective study of 236 patients, compared five treatment modalities: stretching alone; a silicon heel cup; a rubber heel cup; a felt pad; and a custom-made orthosis. The silicon insert was the most shock absorbent; followed by the rubber insert, felt insert, and plastic orthosis. They concluded that, when used in conjunction with a stretching program, a prefabricated shoe insert was more likely than a custom-made orthotic device to produce improvement in symptoms as part of the initial treatment of plantar fasciitis. However, the authors did state that orthoses with more shock absorptive characteristics may be beneficial in the treatment of plantar fasciitis.[12]

Recently, Lynch et al. conducted a randomized, prospective study to compare the individual effectiveness of three types of conservative therapy in the treatment of plantar fasciitis. One hundred three subjects were randomly assigned to one of three treatment categories: anti-inflammatory therapy with NSAIDs in combination with injections; accommodative therapy with visco-elastic heel cups; or mechanical control of the foot with taping and custom-made orthoses. Overall, 70% of the patients in the mechanical group had an excellent or fair outcome, significantly better than the 33% and 30% rates for the anti-inflammatory and accommodative groups, respectively. Also, only 4% of the mechanical control group had treatment failure, as opposed to 23% for the anti-inflammatory group and 42% for the accommodative group. An “excellent” outcome was defined as a visual analogue scale score of 0 to 2, minimal to no first step pain, and minimal to no effect on activities. A “fair” outcome was defined as a visual analogue scale score of 3 to 5, occasional first step pain, and occasional effect on activities. A “poor” outcome was defined as a visual analogue scale score of more than 5,

constant first step pain, and constant effect on activities. It was concluded that mechanical control of the foot was the most important non-surgical treatment modality for plantar fasciitis.[14]

Shock absorbing heel pads are used to decrease the impact on the calcaneus and to theoretically decrease the tension on the plantar fascia.[5,7] If the cause of plantar fasciitis is atrophy of the calcaneal fat pad or prolonged standing, then an effective use of a heel pad shaped to fit the shoe to prevent slippage may be indicated.[28,50] The material needs to have good shock absorbing properties which will compress under body weight and cushion the "jar" of heel strike without elevating the heel, and have a "memory" that allows it to spring back to original thickness during the swing phase of gait.[3,4,50,55] Using a material which is incompressible will elevate the heel and hold the ankle joint in a slight plantar flexed position, thereby shortening the Achilles tendon.[50]

Heel pads have been found to be a successful treatment, with an 83% success rate in 100 patients.[24] A small study noted "immediate improvement in comfort" in all of 9 patients.[60] However, in another study, only 2% of 184 patients who had been using heel pads rated them excellent, and 34% said they provided no improvement.[10]

If a patient has significant plantar fasciitis pain secondary to a limb length inequality or unilateral ankle equinus, a simple heel lift in the shoe of the affected foot may provide temporal relief.[4,15]

Before resorting to corticosteroid injections, physicians should consider using night splints to hold the patient's ankle and metatarsophalangeal joints in a dorsiflexed position overnight.[5,7,19,28,29] Most individuals naturally sleep with the feet plantar flexed, a position that causes nocturnal contracture of the plantar fascia and gastro-soleus complex, which is thought to be detrimental to plantar fascia healing.[7,15,19,23,26,28,29,32] A dorsiflexion night splint allows passive

stretching of the plantar fascia and Achilles tendon during sleep.[4,7,19,23,28,29] Theoretically, it also allows any healing to take place while the plantar fascia is in an elongated position, thus creating less tension with the first step of the day.[7] Therefore, patients usually note decreased morning pain with use of the night splint.[4,19,21,23,29] A night splint can be molded from plaster or fiberglass casting material or may be a prefabricated, commercially produced plastic brace.[5,7,28]

The successful use of dorsiflexion night splints for prolonged or recalcitrant cases of plantar fasciitis has been reported.[1] Wapner and Sharkey were one of the first to report that a molded ankle foot orthosis used at night to maintain the foot in either neutral or dorsiflexion was a useful adjunct in the treatment of prolonged cases of plantar fasciitis. They had a 79% cure rate after patients used the splint for an average of four months.[32] In a later study, 14 patients with plantar fasciitis who had had pain for longer than a year were treated with night splints. In less than four months, 11 of the 14 had relief of symptoms.[31] Most recently, Powell et al. reported that the use of a dorsiflexion night splint for one month, without the use of any other treatment, resulted in decreases symptoms for 29 of 37 patients with chronic plantar fasciitis. They also noted that the response to use of dorsiflexion night splints did not correlate with foot type, degree of obesity, or presence of heel spur on radiographs; however, patients with bilateral involvement had less relief of their symptoms. They suggested that adding stretching and strengthening exercises may provide greater improvement. It was concluded that dorsiflexion night splints were a low-risk alternative to surgical release of plantar fascia for patients with chronic plantar fasciitis.[29]

Night splints were cited as the best treatment by approximately one third of patients with plantar fasciitis who tried them.[24,27] However, the use of night splints in acute cases of plantar fasciitis is controversial. Batt and colleagues, in one study found the use of night splints to be

effective when combined with a visco-elastic heel pad, Achilles tendon stretching program, and NSAIDs.[30] In another study, Mizel et al. showed that use of night splints to prevent plantar fascia contracture and shoe modification consisting of a steel shank and anterior rocker bottom to limit plantar fascia tension from heel rise to toe off during ambulation resulted in improvement in approximately 80% of patients with acute plantar fasciitis.[23] On the other hand, Probe and associates found no statistically significant improvement when dorsiflexion night splints were added to a standard non-operative protocol in patients with acute plantar fasciitis.[26] However, the authors continued to recommend use of dorsiflexion night splints in recalcitrant cases based on findings of other studies on patients with chronic plantar fasciitis.[29,32]

Disadvantages of night splints include mild discomfort, which may interfere with the patient's or a bed partner's ability to sleep.[7,29,69] Other possible side effects of dorsiflexion night splints include transient numbness of the toes and nocturnal leg cramps. However, refitting the splint so that there is less dorsiflexion and gradually increasing the amount of dorsiflexion as the plantar fasciitis abates may be helpful.[29,69] Also, preformed adjustable posterior splints specifically designed for the treatment of plantar fasciitis are available and may be of benefit. Another alternative is the use of an elastic band that applies a steady traction throughout the night.[69]

Taping the foot during weight bearing stabilizes the head of the first metatarsal during plantar flexion, prevents excessive pronation, reduces stress on the origin of the plantar fascia, and provides rapid pain relief.[5,19,28] However, it provides only transient support, with studies showing that as little as 24 minutes of activity can decrease the effectiveness of taping significantly.[7] A figure of eight taping applied in a lateral to medial direction using a non-stretch one inch adhesive tape is recommended.[44,57]

A single taping treatment is much less expensive than an over-the-counter arch support or an orthotic. Arch taping can be used as definitive treatment or as a trial to determine if the expense of arch supports or orthotics is worth the benefit. Taping may be more cost-effective for acute cases of plantar fasciitis, and over the counter arch supports and orthotics may be more cost-effective for chronic or recurrent cases of plantar fasciitis and for prevention of injuries.[7]

Arch taping was cited by 2% of patients as the treatment that worked best for plantar fasciitis in one study.[24] Scherer and the Biomechanics Graduate Research Group for 1988 performed a prospective study in which they treated 73 patients with 118 painful heels with taping, NSAIDs, corticosteroid injections, and rigid orthoses. The study showed that, within six weeks, approximately 84% of the patients had at least 80% relief of symptoms. This study also identified a sub-group of 27 patients with 43 painful heels who received only mechanical therapy with taping and rigid orthoses because of contraindications in their physical condition and medical history, including sensitivity to NSAIDs and systemic pathology restricting the use of corticosteroid injections. Of this group, 90% had more than 80% relief of symptoms. The authors concluded that mechanical therapy was the most successful treatment modality for plantar fasciitis.[22]

The most logical first line of non-surgical treatment should be rest, because plantar fasciitis is viewed as an overuse syndrome.[5,10] Indeed, protecting the patient from weight bearing for several weeks may reduce inflammation of the plantar fascia and lead to complete relief of symptoms.[3,4,15,42] However, athletes, active adults, and persons whose occupations require lots of walking may not be compliant if instructed to stop all activity.[7] Many sports medicine physicians have found that outlining a plan of "relative rest" that substitutes alternative forms of non-weight bearing activities, such as walking or running in a pool, cycling, and swimming, for weight

bearing activities that aggravate the symptoms, such as walking, jogging, running, and tennis, will increase the chance of compliance with the treatment plan.[4,5,7,15] Rest was cited by 25% of patients with plantar fasciitis in one study as the treatment that worked best.[24]

In very severe cases, a limited period of non-weight bearing with crutches can be beneficial. However, during use of crutches, the foot is constantly in a plantar flexed position, which may make the eventual rehabilitation of plantar fasciitis more difficult. The return to activity is guided by the patient's symptoms and can range from a few days to a few weeks.[69] If the patient is on his/her feet all day, placement of padding on the floor where the patient stands or having the patient sit down instead of stand may be helpful.[5,69] In one study, standing for 8 hours or more per day was the only factor that appeared to influence the relative effectiveness of the different treatment modalities for plantar fasciitis.[12] The patient should also be advised not to walk barefoot or in slippers on hard surfaces.[4,19] If the patient is obese, weight loss may reduce stress on the plantar fascia.[5]

A change to properly fitting, appropriate shoes may be useful in some patients.[7] Appropriate shoes have arch support, a firm posterior counter, and soft heels.[1,3,5,19] Patients often find that wearing shoes with thicker, well-cushioned midsoles decreases the pain associated with long periods of walking or standing.[4,7,15,19] In addition, studies have shown that with age, running shoes lose a significant portion of their shock absorption, which may aggravate plantar fasciitis. Thus, simply getting a new pair of shoes may be helpful in decreasing pain.[7,19] For patients with excessive foot pronation, motion-control shoes or shoes with a better longitudinal arch support may decrease the pain associated with long periods of walking or standing. Motion-control shoes usually have a straight last, board or combination lasted construction, an external heel counter, a

wider flare, and extra medial support.[1,7] A change in shoes was cited by 14% of patients with plantar fasciitis as the treatment that worked best for them.[24]

Patients with severe pain and marked limitation of activity are best treated with a molded, below knee, walking cast for three to six weeks.[4,19] It provides relative rest, reduces pressure on the heel at heel strike, provides support for the arch, and prevents tightening of the Achilles tendon.[19] However, because of its expense and inconvenience, clinicians usually advocate the use of the walking cast as the final conservative step in the treatment of plantar fasciitis.[10,15] Although it is the most expensive conservative treatment, many of the less expensive treatments may involve multiple visits and higher overall cost. For this reason, if the condition seems to be recalcitrant, casting is recommended with the hope of minimizing repeated visits. In one study, a short leg cast worn for a minimum of three weeks was found to be an effective form of treatment for chronic plantar fasciitis. In addition, in a survey of 411 patients with plantar fasciitis, treatment with a cast was ranked as the most effective of eleven different treatments.[10]

3.6.3 Restore muscle strength and flexibility

Most patients with plantar fasciitis have tightness of the Achilles tendon.[4,13,16,17,24,39,53] In addition, research has shown that the plantar fascia becomes shortened as a result of pain.[1] A tight Achilles tendon or contracted plantar fascia places increased stress on the inflamed fascia during gait.[12] This cycle of tightness and plantar fasciitis should be interrupted as soon as possible by exercises to stretch the Achilles tendon and plantar fascia.[13,16,17,19]

A stretching program of the Achilles tendon and plantar fascia should be considered a cornerstone of any effective treatment plan.[1,3,4,7,12,15,24,28,47,68,70] Most authors on the subject of treating plantar fasciitis agree that the use of a stretching protocol alleviates the condition in most

patients.[12,26] Boyd, in 1992, stated, "Stretching results in almost complete restoration of comfort."[55] Regularly stretching the Achilles tendon and plantar fascia allows the calcaneus to assume a more midline or supinated position in mid- to terminal stance, reducing strain on the plantar fascia, which in turn decreases symptoms.[3] In addition, gentle stretching exercises help ease pain and improve flexibility of the Achilles tendon and plantar fascia.[4,5]

Davis et al. conducted a retrospective study of 105 patients via a follow-up questionnaire to assess long-term results of non-operative treatment for 132 symptomatic heels. They stated, "Stretching was rated as the most effective treatment."[59] In another study, 83% of patients involved in stretching programs were successfully treated, and 29% of patients in the study cited stretching as the treatment that had helped the most compared with use of orthotics, NSAIDs, ice, corticosteroid injection, heat, heel cups, night splints, taping, and shoe changes.[24] More recently, Pfeffer and associates investigated the efficacy of muscle stretching on reducing the symptoms associated with plantar fasciitis in 236 individuals. They found that 72% of the subjects who performed only stretching for an eight-week treatment period had decreased symptoms. If, however, the treatment included a combination of stretching and a silicon heel cup, the success rate increased to 95%.[12]

Strengthening programs play an important role in the treatment of plantar fasciitis and can correct functional risk factors such as weakness of the extrinsic and intrinsic foot muscles.[1,7] Strengthening exercises for the extrinsic muscles should emphasize the inverter and plantar flexor muscle groups.[28,46,47] Exercises used to strengthen the intrinsic muscles include towel curls and toe taps. Exercises such as picking up marbles and coins with the toes are also useful.[7] In one study, strengthening programs were cited as the most helpful treatment by 34.9% of the subjects,

compared with stretching exercises, night splints, orthotics, heel cups, NSAIDs, corticosteroid injection, or surgery.[27]

3.7 SURGICAL INTERVENTION

Surgical management of plantar fasciitis should be reserved for the small percentage of patients who have intractable heel pain that interferes with their normal life style.[5,15,19] It is generally agreed that surgical intervention should not be considered until all conservative measures have been tried.[1,2,4,5,8,15,19,39] No time limit is placed on this decision, but surgery is typically indicated if symptoms do not significantly decrease within twelve months.[2,4,5,8,19] However, Cornwall and McPoil suggested that four to six months of symptoms is an appropriate length of time before considering a surgical option.[1] On the other hand, Howell found that it took an average of nine months to have no morning pain and an average of eleven months to have no pain with activities of daily living. He collected data on 96 patients with plantar fasciitis over a seven year period. Ninety five of the 96 patients were free of pain in the morning and with activity by two years. He suggested twelve to twenty four months of symptoms as an appropriate amount of time before considering surgical options for plantar fasciitis.[71]

There have been more than 30 surgical series reported on the treatment of plantar fasciitis in the literature.[2,48,72,73] The operations have included drilling decompression of the calcaneus, Steindler stripping, plantar fasciotomy, excision of a heel spur, neurolysis of the nerve to abductor digiti minimi, neurolysis of the calcaneal nerve, and calcaneal neurectomy.[2,4,8,19] What is surprising is that almost all of these interventions have been associated with a high success rate.[2,4,16,17,25,48,72] With respect to rehabilitation and recovery times, eight months has been

reported in the literature as being necessary for complete resolution of heel pain following surgery.[2,8,38]

The biomechanical consequences of sectioning the plantar fascia have been described in several studies.[43,48,74] Huang et al. showed the importance of the plantar fascia in maintaining stability of the medial longitudinal arch and suggested a significant deleterious effect after plantar fasciotomy.[43] Arangio et al. evaluated the effect of dividing the plantar fascia on the mechanical properties of the foot. They concluded that plantar fasciotomy, although clinically satisfactory in cases of recalcitrant heel pain, decreases the stiffness of the foot and creates a less rigid and more deformable arch.[75] Moreover, Wolgin et al. stated, "If the disorder has a generally self-limiting course, then some of the patients who became surgical candidates might have improved regardless if given more time. Alternatively, those who are recovering from a surgical procedure may be improving from an enforced rest period which may have been the key to recovery if their condition were due to a chronic overuse situation."[24]

3.8 SIGNIFICANCE

Plantar fasciitis is the most common clinical problem that causes inferomedial heel pain in adults.[3,7-10] Lapidus and Guidotti, in 1965, found that the number of patients in their foot clinic with plantar fasciitis was greater than those with any other recorded foot lesion.[11] Approximately 11% to 15% of adult patients who seek treatment from a podiatric physician present with a chief complaint of heel pain.[76,77] It is estimated that more than two million people receive treatment for plantar fasciitis in the United States each year.[12]

The variety of treatment options noted in the literature reflects the poor understanding of the etiology of this condition.[11,13,19,24,49] Therefore, successful treatment usually requires a combination of treatment modalities, rather than administering only one treatment at a time.[4,14,19,20] Many authors agree that mechanical treatment is the mainstay of the conservative treatment of plantar fasciitis and should be considered a cornerstone of any plan of treatment. However, some debate remains regarding the most effective form of mechanical intervention.[14,20-22]

Plantar fasciitis is typically characterized by pain in the inferior heel region, which is aggravated by weight bearing after a long period of non-weight bearing and by prolonged weight bearing.[1,4,9,14,19,21,24,25] Night splints have been proven to be effective in relieving the pain associated with the first step in the morning by preventing nocturnal contracture of the plantar fascia and Achilles tendon.[4,5,7,15,19,23,24,26-32] On the other hand, arch supports have been found to relieve the end of the day pain by supporting the medial longitudinal arch and, thus, preventing overstretch of plantar fascia during prolonged weight bearing.[1,7,21,24,33-37] Therefore, the combination of both night splints and arch supports may be a more effective treatment for plantar fasciitis than either of these interventions alone because together these interventions would control nocturnal contracture of the plantar fascia and Achilles tendon and reduce stress imposed on the plantar fascia during the day. Although the isolated effectiveness of night splints and arch supports in relieving symptoms of plantar fasciitis is well-established in the literature, no previous study, to the best of our knowledge, has been conducted to evaluate the combined effect of these treatment modalities.

4.0 RESEARCH DESIGN AND METHODS

4.1 STUDY DESIGN

This study was a prospective randomized clinical trial to compare three interventions for plantar fasciitis. Subjects were randomly assigned to one of three treatment groups. Group I was treated with dorsiflexion night splints, group II with over-the-counter medial arch supports, and group III with a combination of dorsiflexion night splints and over-the-counter medial arch supports. Outcome measures were recorded before and after six weeks of treatment (Figure 1).

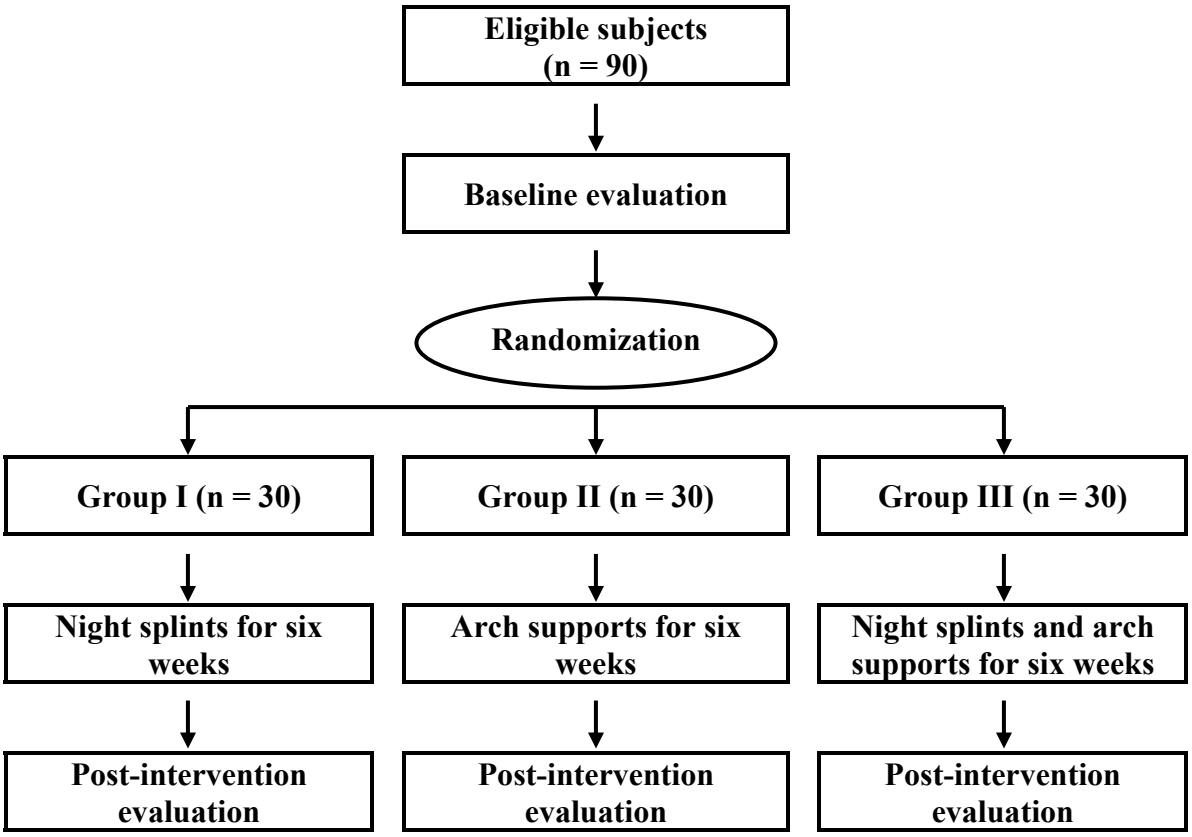

Figure 1: Study design

4.2 INCLUSION/EXCLUSION CRITERIA

All subjects were referred by physicians with a clinical diagnosis of plantar fasciitis or directly recruited by the principal investigator based on the presence/absence of the inclusion/exclusion criteria. Eligible patients were required to meet all the following inclusion criteria: (1) plantar heel pain; (2) pain provoked by taking the first few steps in the morning, by standing after prolonged sitting, and/or by prolonged standing; and (3) tenderness localized to the origin of the plantar fascia on the medial calcaneal tubercle.[21,29]

Exclusion criteria included: (1) previous foot surgery; (2) foot trauma within the previous three months; (3) tarsal tunnel syndrome; (4) loss of plantar foot sensation; (5) foot pathology other than plantar fasciitis including tendonitis, bursitis, or calcaneus fracture; (6) generalized inflammatory disorders associated with the diagnosis of plantar fasciitis including rheumatoid arthritis, ankylosing spondylitis, Reiter's disease, gout, or lupus; (7) previous treatment of plantar fasciitis with dorsiflexion night splints and/or medial arch supports; (8) inability or unwillingness to discontinue current treatment modalities that are used for the purpose of plantar fasciitis; (9) participation in a worker's compensation program; and (10) age of less than eighteen years (Appendix A).[21,29]

4.3 RECRUITMENT PROCEDURES

A convenience sample of 90 subjects was recruited through physician offices at the University of Pittsburgh Medical Center (UPMC) and through direct advertisements to the public.

The principal investigator targeted physicians who treat a high volume of patients with impairments of the foot and ankle. The treating physician informed the patient about the study. If the patient expressed an interest in learning more about the study, the physician would give him/her a copy of the "HIPAA Authorization for Sharing Health Information" form to read and sign so that the physician could release his/her name and phone number(s) to the principal investigator. The principal investigator then contacted the patient by phone to schedule him/her for the initial visit within one week of the recruitment date (Appendixes B and C).

Additionally, the principal investigator directly recruited subjects to the study via public advertisements in terms of notices or flyers posted in public places, on the internet, and/or in local newspapers (Appendix D).

During the initial visit, the principal investigator first explained the study to the patient including the overall purpose of the study, the experimental procedures that would be performed, and the potential benefits and risks of the interventions. However, the patient was blinded to the research questions and hypotheses. If the patient decided to proceed, the principal investigator gave him/her a copy of the informed consent, as approved by the University of Pittsburgh Institutional Review Board (IRB), to read at his/her own desired speed, and encouraged him/her to ask any questions or raise any concerns. If the patient chose to enroll in the study, he/she signed the consent form (Appendix E).

4.4 STUDY PROTOCOL

After informed consent had been obtained, the principal investigator assigned the subject a unique three-digit code, obtained demographic information, and performed the baseline evaluation. The baseline evaluation included: (1) height; (2) weight; (3) medial longitudinal arch height; (4) range of pain-free passive ankle joint dorsiflexion; (5) plantar heel tenderness; (6) plantar heel pain; and (7) disability imposed by the heel pain/plantar fasciitis. The principal investigator then randomly assigned the subject to one of three six-week intervention groups using a computer-generated randomization schedule. Subjects were randomized in blocks of 15 so that, after every 15 subjects, there was an equal number of subjects in each group. The random group assignments were placed in sealed opaque envelopes. The randomization had been

concealed to the investigator until an opaque envelope containing the group assignment was opened. The principal investigator opened the next envelope in the series and informed the subject of the treatment he/she would receive only after the baseline information had been collected. The principal investigator then provided the treatment modality that corresponds with the group assignment to the subject and instructed him/her on its use. The initial visit required about 30 minutes of the subject's time. At the end of the initial visit, the principal investigator scheduled the subject for the six-week follow-up visit (Appendix F).

At three weeks, the principal investigator contacted the subject by phone to answer any questions, discuss any concerns, encourage continued participation, and record compliance. The phone call required about 5 minutes of the subject's time (Appendix G).

During the follow-up visit, the principal investigator performed the post-intervention evaluation, recorded compliance, and discharged the subject. The post-intervention evaluation included: (1) range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis. The follow-up visit required about 15 minutes of the subject's time. The principal investigator was blinded to the baseline evaluation data and the group assignment of the subject during the follow-up visit. If the subject did not return for the follow-up visit, the principal investigator contacted him/her by phone to encourage continued participation and reschedule the appointment. Both the initial and follow-up visits took place at the UPMC Center for Sports Medicine (Appendix H).

Group I wore dorsiflexion night splints (Healwell Plantar Fasciitis Night Splints) for six weeks. Each participant in this group received a dorsiflexion night splint made of polypropylene, which holds the ankle in about 5° of dorsiflexion.[29,32] A firm foam wedge was anchored to the distal aspect of the foot plate of the splint with Velcro. The wedge was positioned such that its

apex was at the level of the metatarsophalangeal joints to provide approximately 30° of extension at these joints. The Velcro allows easy adjustment of the wedge for different foot sizes. A washable foam liner, one-quarter inch thick, was placed inside the splint for comfort. The splint was applied to the lower leg and foot with Velcro straps.[29] The principal investigator instructed the subjects of this group on proper application of the splint and to wear it only while sleeping. He advised them of possible symptoms and/or problems associated with use of the night splints including transient numbness of the toes, nocturnal leg cramps, and difficulty sleeping.[7,29,69,78] The principal investigator also advised the subjects to slide the wedge distally along the foot plate to decrease the extension angle of the metatarsophalangeal joints if they experienced these symptoms (Figure 2).[29,69]

Figure 2: Dorsiflexion night splint

All subjects in group II received a pair of over-the-counter medial arch supports (Tulis Gaitors ¾ Length Arch Supports) that are made of semi-rigid material. The selection of these orthoses was based on the results of several studies that showed over-the-counter foot orthoses to be more effective than or just as effective as custom-made orthoses.[12,21,33,35] In addition, rigid plastic arch supports rarely alleviate the symptoms and often aggravate the heel pain.[13,19] Arch supports made of softer materials provide cushioning by reducing the shock on walking by up to 42%.[19] The reason for this may be that they provide total contact with the plantar surface of the foot.[1] On the other hand, very soft foot inserts may not provide adequate support to the medial longitudinal arch. The principal investigator instructed group II subjects to use the arch supports whenever they are on their feet. He also advised them that they may feel general leg discomfort or soreness until they get used to wearing the arch supports. To minimize this discomfort, the principal investigator advised the subjects to use a deep pair of shoes to accommodate the arch supports (Figure 3).

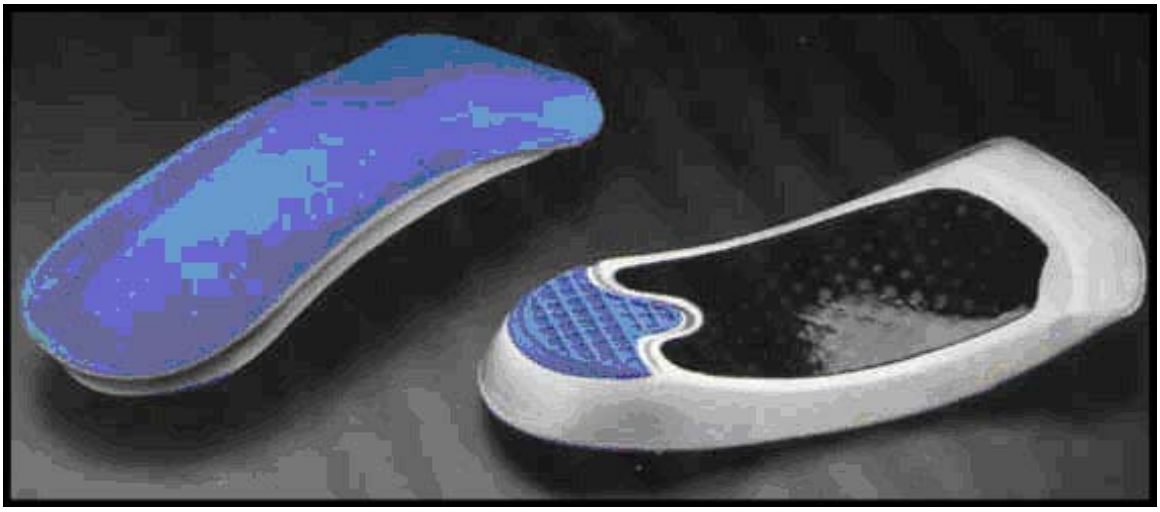

Figure 3: Medial arch support

Group III subjects received both night splints and arch supports as described above. The principal investigator advised the subjects of all groups of the potential risk of developing

pressure sores or ulcers from the use of night splints and/or arch supports. However, he provided them with well-padded night splints and/or arch supports to minimize this risk. In addition, the fact that those with decreased plantar foot sensation were excluded from the study, would also minimize this risk. No other medications, stretching, or strengthening exercises were prescribed to all groups. In addition, all subjects were instructed to discontinue use of any other intervention modalities, except medications that are used for reasons other than plantar fasciitis, at least three days before the initial visit, and were encouraged not to change their activity level during the six-week enrollment in the study because these confounding factors would threaten the internal validity of the study and could potentially mask the differences between the groups. Night splints and arch supports were free of charge to all subjects.

4.5 MEASUREMENTS/INSTRUMENTATION

Each patient provided demographic information at the initial visit by completing questions pertaining to age, gender, unilateral or bilateral involvement, involved side (if both feet were involved, only the most symptomatic foot, as identified by the patient, was evaluated and treated, with the exception that patients in group II and group III received a pair of the arch supports to prevent any imbalances during weight bearing), duration of symptoms prior to treatment (in months), average number of hours per day during which the patient is on his/her feet, number of previous corticosteroid injections, and current medication use.

In addition, the principal investigator measured the height (in centimeters) and weight (in kilograms) of each patient. He also measured medial longitudinal arch height as the arch index. To do so, he positioned the patient in standing and measured both the navicular height and foot

length with a ruler.[79,80] The navicular height was measured by marking the navicular tuberosity on the medial side of the foot and measuring the perpendicular distance (in centimeters) from the marked point to the floor.[79-82] Foot length was measured by marking the medial side of the first metatarsophalangeal joint and measuring the distance (in centimeters) from the marked point to the most posterior point of the calcaneus.[79,80] The arch index was then calculated, as described by Cowan et al., by dividing the navicular height by the foot length.[80]

In 1997, McCrory and colleagues conducted a study to evaluate the validity of the arch index as a predictor of the medial longitudinal arch height. They found a correlation coefficient of $r = 0.71$ between normalized navicular height measured from weight bearing radiographs and the arch index. It was concluded that the arch index provides a simple quantitative means of assessing height of the medial longitudinal arch.[83]

Medial longitudinal arch height was also measured using the navicular drop test. The principal investigator positioned the patient in standing and placed his/her foot in subtalar neutral position by palpating the medial and lateral heads of the talus. The subtalar joint is in neutral position when there is equal prominence of the talar head medially and laterally. The patient was instructed to hold this position and navicular height was assessed by measuring the perpendicular distance (in millimeters) from the previously marked navicular tuberosity to the floor, using a ruler. The patient was then instructed to relax his/her foot and the navicular height was reassessed. The difference between these two measurements is the navicular drop.[84]

Sell et al. found acceptable intra- and inter-tester reliability for measuring navicular height in the subtalar neutral position (intra-class correlation coefficients of 0.92 and 0.87, respectively) and in resting stance (intra-class correlation coefficients of 0.96 and 0.95, respectively). Additionally, Sell et al. reported acceptable levels of intra- and inter-tester

reliability of the navicular drop (intra-class correlation coefficients of 0.83 and 0.73, respectively).[84]

At the three-week phone call and the six-week follow-up visit, each patient answered question(s), according to his/her group assignment, about the average percentage of sleeping hours wearing the night splint and/or the average percentage of weight bearing hours using the arch support during the last three weeks.[78]

Outcome measures included: (1) the range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis.

The principal investigator tested the range of pain-free passive ankle joint dorsiflexion in two positions: supine, with the legs fully extended, and sitting. He placed the patient's foot in subtalar neutral position by palpating the medial and lateral heads of the talus while supinating and pronating the subtalar joint. The position between pronation and supination when there is equal prominence of the talar head medially and laterally was defined as the subtalar neutral position. From the subtalar neutral position, the principal investigator passively dorsiflexed the patient's ankle through the maximum pain-free range of ankle dorsiflexion. He aligned the stationary arm of the goniometer with the fibular head and the moving arm parallel to the lateral border of the calcaneus. Range of motion (ROM) value was recorded as positive (+) when the ROM is beyond neutral (0°). The value was recorded as negative (-) when the ROM does not reach neutral. Several studies have been conducted to examine the validity and intra- and inter-tester reliability of the goniometer. The results of these studies indicated that goniometric measurements are both valid and reliable, with the intra-tester reliability being strong (intra-class

correlation coefficients ranging from 0.825 to 0.997) and the inter-tester reliability being moderate (intra-class correlation coefficients ranging from 0.43 to 0.99).[85-91]

Evaluation also included plantar heel tenderness, which was measured using a pressure algometer. To assess tenderness, the principal investigator first positioned the patient in supine with the legs fully extended and palpated and marked the origin of the plantar fascia at the medial calcaneal tubercle. He then dorsiflexed the ankle and toes passively and applied the algometer over the mark placed on the medial calcaneal tubercle.[4,5,7,92] The algometer contact head was aligned perpendicularly to the skin and the principal investigator gradually increased the algometer pressure until the patient reported pain. The algometer reading, which represents the pressure needed to elicit pain (in Newton per square centimeter), was recorded. Higher algometer scores indicated greater pressure tolerance and, hence, less tenderness. Lower algometer scores indicated less pressure tolerance and, thus, greater tenderness.[92] The reliability and validity of pressure algometer as a measure of tenderness have been documented in the literature.[93-97]

Plantar heel pain and disability imposed by the heel pain/plantar fasciitis were measured using the Pain and Disability sub-scales of the Foot Function Index (FFI), respectively. Each of these sub-scales consists of nine items. All items are rated using a visual analogue scale that consists of a horizontal 100 millimeter line, to which, no numbers or divisions are attached. Verbal anchors, representing opposite extremes of the dimension being measured, were placed at either end of the line. The principal investigator instructed the patient to place a mark on the line in a position which best represented his/her experience in the past week, or to answer the question as not applicable (NA) if he/she did not perform or was not involved in the activity in question, which removes that question from scoring. The principal investigator then assigned a

score between 0 and 100 to the item by measuring the distance (in millimeters) from the anchor on the left hand side of the line to the mark placed by the patient. He then obtained the sub-scale score by adding the scores of the items and dividing by the number of the applicable items in that sub-scale. Thus, the score for each sub-scale ranged from 0 to 100, with 0 representing the best and 100 representing the worst possible scenario.[98]

The Pain sub-scale measures the level of foot pain in a variety of situations. The dimension of measurement used for this sub-scale was severity of pain, and the anchors for the visual analogue scale were "no pain" and "worst pain imaginable." The Disability sub-scale describes the difficulty in performing various activities due to foot problems. The measurement dimension employed by this sub-scale was the degree of difficulty, and the visual analogue scale anchors were "no difficulty" and "so difficult unable."[98]

The FFI is a validated short and simple measure of foot pain and disability.[98] Although it was originally designed to assess the effect of foot orthoses on foot pathology in patients with rheumatoid arthritis, it has been suggested by its developers that it is not limited to this group of patients.[99] Recently, several studies have used the FFI in research relating to different foot pathologies, including plantar fasciitis, unrelated to rheumatoid arthritis.[12,100,101] The FFI has been examined for test-retest reliability, internal consistency, validity, and responsiveness on 87 patients with rheumatoid arthritis. It had good test-retest reliability (intra-class correlation coefficients ranging from 0.69 to 0.87) with a one-week interval between the two tests. It also had a high degree of internal consistency (Cronbach's alpha ranging from 0.73 to 0.96) and validity. In addition, the FFI was sensitive enough to detect changes in clinical status over a period of six months.[98]

4.6 DATA MANAGEMENT

Only the patient's ID code was used to identify patients on all data recording forms. The principal investigator kept patient information, including his/her name, phone number(s), ID linkage code, consent form, and "HIPAA Authorization for Sharing Health Information" form in a file that was separate from the data recording forms. He kept this file and the IRB and data recording forms in two locked drawers located in a locked office in the Department of Physical Therapy in the School of Health and Rehabilitation Sciences at the University of Pittsburgh. The principal investigator entered available data and verified the entered data once per week on his own laptop computer, which has a password not known to anyone other than him. It was the responsibility of the principal investigator to keep the data secured at all times. The data were entered twice to insure accuracy and were coded into SPSS software. The principal investigator then reviewed the entered data and backed-up the file. He evaluated the data periodically. For missing data points, the "worst case scenario" was used (the least difference in each outcome measure of each group between the post-intervention and baseline evaluation data was added to the baseline evaluation data) in order to adhere with the principle of intention-to-treat analysis.

4.7 DATA ANALYSIS

4.7.1 Power analysis

Power estimates based on a standard deviation (SD) of 2.3, which was obtained from a recent study with a similar design, revealed that a sample size of 30 subjects per group, taking into

account a 30% drop-out rate, would result in greater than 80% power to detect a 2 centimeter mean difference on the Pain sub-scale of the FFI between group I and III and group II and III.[102]

4.7.2 Description of statistical procedures

Using SPSS software, the principal investigator first described the demographic, compliance, baseline and post-intervention evaluation data of each group using means and SDs for continuous variables and frequencies and percentages for categorical variables. He also tested the normality and homogeneity of variances of the data. Then, he compared the demographic, compliance, and baseline evaluation data of the three groups using analysis of variance (ANOVA) test for each continuous variable and the chi-square test for each categorical variable to determine if there were significant differences among the groups. Kruskal-Wallis non-parametric test was used if the data showed significant skewness and/or heterogeneity of variances. An overall significance level was maintained at p-value less than 0.05.

4.7.2.1 Analysis of specific aim 1: To examine whether there will be any difference between the efficacy of three different treatment regimens: (1) dorsiflexion night splints; (2) medial arch supports; and (3) dorsiflexion night splints and medial arch supports together, in the management of plantar fasciitis in terms of: (1) the range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis.

Specific aim 1 was analyzed using analysis of covariance (ANCOVA) test to compare the post-intervention scores of each outcome measure between the treatment groups in order to examine if there was a significant difference. The baseline scores of the outcome measure being

tested as well as any other demographic and/or compliance variables that were significantly different among the groups and were significantly correlated with the outcome measure being tested were entered as covariates to "statistically equate" the groups.

If the post-intervention scores of any outcome measure showed a significant difference between the groups, post-hoc analyses were explored to determine if there were significant differences between group I and III and/or group II and III. Kruskal-Wallis non-parametric test was used if the data had significant skewness and/or heterogeneity of variances.

4.7.2.2 Analysis of specific aim 2: To investigate whether patients with plantar fasciitis who have less passive dorsiflexion of the ankle joint will benefit from a dorsiflexion night splint more than those with greater passive dorsiflexion of the ankle joint in terms of: (1) the range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis.

Specific aim 2 was analyzed using multiple regression analysis with the post-intervention scores of each outcome measure being the criterion and the baseline range of pain-free passive ankle joint dorsiflexion being the predictor after controlling for the effect of baseline scores of the outcome measure being tested, with the exception that simple regression analysis was used with the difference between the post-intervention and baseline scores being the criterion to analyze the range of pain-free passive ankle joint dorsiflexion because it is not possible to control for the effect of baseline score of the range of pain-free passive ankle joint dorsiflexion and then use it as a predictor or to use two predictors (the baseline range of pain-free passive ankle joint dorsiflexion with the knee straight and bent) that are highly correlated ($r = 0.78$, p-value < 0.001). This analysis was applied to group I only.

4.7.2.3 Analysis of specific aim 3: To investigate whether patients with plantar fasciitis who have a lower medial longitudinal arch will benefit from a medial arch support more than those with a higher medial longitudinal arch in terms of: (1) the range of pain-free passive ankle joint dorsiflexion; (2) plantar heel tenderness; (3) plantar heel pain; and (4) disability imposed by the heel pain/plantar fasciitis.

Specific aim 3 was analyzed using multiple regression analysis with the post-intervention scores of each outcome measure being the criterion and the medial longitudinal arch height being the predictor after controlling for the effect of baseline scores of the outcome measure being tested. This analysis was applied to group II only.

5.0 RESULTS

5.1 PROFILE OF PROSPECTIVE RANDOMIZED STUDY

Between August 2005 and July 2006, 91 patients with plantar fasciitis who met the inclusion/exclusion criteria of the study were identified and recruited. One patient declined to be randomized, leaving 90 patients enrolled in the study, 30 in each group. The first 18 patients were referred to the study by physicians at the UPMC over a period of eight months. Because patient recruitment through physician offices had been too slow, the principal investigator started to directly recruit patients via public advertisements, and he successfully recruited the rest of the patients (72 patients) during the next three months. Demographic, compliance, baseline and post-intervention evaluation data demonstrated no significant differences between patients who were recruited through physician offices and those recruited via public advertisements, with the exception that patients who were recruited through physician offices had significantly shorter duration of symptoms prior to treatment, fewer number of previous corticosteroid injections, and greater tenderness than those recruited via public advertisements (p-value < 0.05).

Nine subjects (10%) dropped-out of the study, 2 from group I and 7 from group II. Seven drop-outs were lost to follow-up, and 2 chose to withdraw their consent for participation in the study, one because she felt that the intervention was ineffective, while the other because he moved. The study sample consisted of 23 men (25.6%) and 67 women (74.4%) (Figure 4).

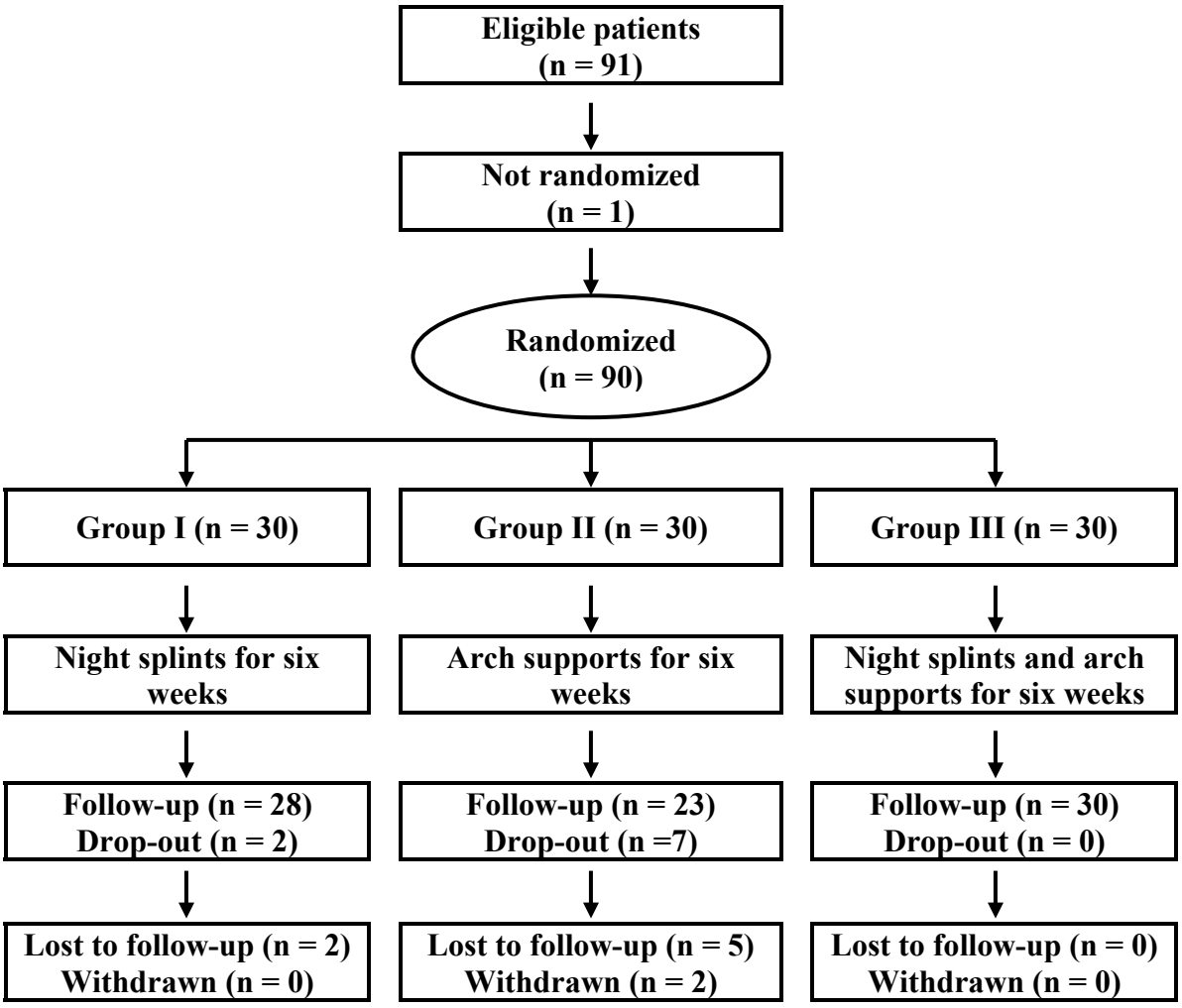

Figure 4: Profile of prospective randomized study

5.2 DESCRIPTION OF DEMOGRAPHIC, COMPLIANCE, BASELINE AND POST-INTERVENTION EVALUATION DATA

The demographic, compliance, baseline and post-intervention evaluation data of each group were described using mean, median, SD, minimum, maximum, skewness, and kurtosis for continuous variables, and frequency and percentage for categorical variables.

5.2.1 Subjects' characteristics (Table 1)

Table 1: Subjects' characteristics

Group / Demographic variable		Group I mean / median (SD) minimum / maximum skewness (kurtosis) or frequency (percentage)	Group II mean / median (SD) minimum / maximum skewness (kurtosis) or frequency (percentage)	Group III mean / median (SD) minimum / maximum skewness (kurtosis) or frequency (percentage)
Age		50.23 / 50.00 (11.37) 27.00 / 74.00 -0.124 (-0.245)	48.24 / 51.00 (12.73) 24.00 / 74.00 -0.313 (-0.293)	49.07 / 52.00 (10.13) 26.00 / 67.00 -1.028 (0.549)
Gender	Male	11 (36.70)	5 (16.70)	7 (23.30)
	Female	19 (63.30)	25 (83.30)	23 (76.70)
Unilateral or bilateral involvement	Unilateral	13 (43.30)	15 (50.00)	9 (30.00)
	Bilateral	17 (56.70)	15 (50.00)	21 (70.00)
Involved side	Right	14 (46.70)	16 (53.30)	17 (56.70)
	Left	16 (53.30)	14 (46.70)	13 (43.30)
Duration of symptoms prior to treatment (in months)		16.88 / 9.50 (18.29) 1.00 / 60.00 1.307 (0.356)	18.26 / 6.00 (25.04) 0.50 / 120.00 2.731 (9.268)	8.78 / 6.00 (8.08) 1.00 / 36.00 1.823 (3.534)
Average number of hours per day during which the patient is on his/her feet		7.25 / 5.50 (4.26) 1.00 / 17.00 0.658 (-0.636)	7.29 / 7.00 (3.74) 1.50 / 14.00 0.313 (-0.861)	7.47 / 7.00 (3.51) 2.00 / 15.00 0.423 (-0.679)
Number of previous corticosteroid injections		0.30 / 0.00 (0.79) 0.00 / 3.00 2.927 (8.083)	0.38 / 0.00 (0.78) 0.00 / 3.00 2.163 (4.249)	0.43 / 0.00 (1.04) 0.00 / 4.00 2.555 (5.720)
Height (in centimeters)		171.63 / 170.60 (10.65) 156.20 / 199.40 0.606 (0.144)	168.33 / 167.80 (9.33) 144.10 / 188.50 -0.069 (1.279)	169.29 / 168.80 (8.74) 151.20 / 194.20 0.825 (1.778)
Weight (in kilograms)		93.38 / 92.10 (22.06) 59.40 / 137.30 0.259 (-0.927)	87.10 / 85.60 (20.19) 54.50 / 135.70 0.545 (-0.139)	88.20 / 86.55 (22.93) 51.50 / 179.10 2.063 (7.798)

Arch index	0.25 / 0.24 (0.05) 0.15 / 0.36 0.435 (-0.379)	0.26 / 0.25 (0.04) 0.20 / 0.38 0.667 (0.759)	0.27 / 0.27 (0.03) 0.21 / 0.35 0.369 (-0.044)
Navicular drop (in millimeters)	7.10 / 6.00 (5.20) 1.00 / 21.00 0.933 (0.292)	5.14 / 4.00 (3.42) 1.00 / 13.00 0.933 (0.135)	4.93 / 5.00 (2.41) 0.00 / 10.00 0.227 (-0.200)

5.2.2 Compliance (Table 2)

Table 2: Compliance

Group / Compliance (in percentage)	Group I mean / median (SD) minimum / maximum skewness (kurtosis)	Group II mean / median (SD) minimum / maximum skewness (kurtosis)	Group III mean / median (SD) minimum / maximum skewness (kurtosis)
At three weeks	79.60 / 87.50 (23.50) 10.00 / 100.00 -1.329 (1.413)	76.10 / 80.00 (26.02) 10.00 / 100.00 -1.353 (1.381)	81.92 / 85.00 (17.38) 22.50 / 100.00 -1.635 (3.445)
At six weeks	75.90 / 80.00 (25.68) 0.00 / 100.00 -1.328 (1.532)	78.24 / 90.00 (27.71) 10.00 / 100.00 -1.462 (1.149)	78.97 / 88.75 (22.22) 25.00 / 100.00 -1.186 (0.432)
Average	77.75 / 86.25 (23.99) 5.00 / 100.00 -1.383 (1.610)	77.17 / 82.50 (25.63) 10.00 / 100.00 -1.515 (1.883)	80.44 / 83.13 (16.39) 38.75 / 98.75 -1.052 (0.716)

5.2.3 Scores of outcome measures at baseline (Table 3)

Table 3: Scores of outcome measures at baseline

Group / Outcome measure	Group I mean / median (SD) minimum / maximum skewness (kurtosis)	Group II mean / median (SD) minimum / maximum skewness (kurtosis)	Group III mean / median (SD) minimum / maximum skewness (kurtosis)
Passive ROM of ankle dorsiflexion with straight knee	5.63 / 5.00 (3.22) -2.00 / 11.00 -0.115 (-0.533)	5.55 / 6.00 (3.32) 0.00 / 13.00 0.248 (-0.255)	4.47 / 3.00 (3.48) 0.00 / 15.00 1.113 (1.375)
Passive ROM of ankle dorsiflexion with bent knee	7.07 / 7.00 (3.97) 0.00 / 15.00 0.381 (-0.530)	7.45 / 7.00 (3.92) 2.00 / 15.00 0.370 (-1.064)	5.40 / 6.00 (4.07) -5.00 / 15.00 -0.040 (0.629)
Difference between passive ROM of ankle dorsiflexion with straight and bent knee	-1.43 / -1.00 (2.47) -7.00 / 2.00 -0.606 (-0.497)	-1.83 / -1.50 (3.33) -14.00 / 2.00 -1.784 (5.043)	-0.93 / 0.00 (3.02) -10.00 / 5.00 -0.989 (1.752)
Plantar heel tenderness (in N/cm²)	43.87 / 41.27 (18.56) 7.13 / 83.23 0.345 (0.041)	42.20 / 42.23 (15.00) 6.27 / 71.07 -0.159 (-0.153)	36.75 / 32.43 (18.24) 7.17 / 79.93 1.135 (0.710)
Plantar heel pain	56.13 / 57.78 (16.37) 25.43 / 92.14 -0.063 (-0.440)	54.70 / 58.11 (20.47) 12.00 / 86.43 -0.467 (-0.490)	61.99 / 64.23 (16.38) 17.67 / 87.57 -0.521 (0.303)
Disability imposed by the heel pain/plantar fasciitis	41.37 / 32.97 (24.36) 0.00 / 89.67 0.338 (-1.038)	44.22 / 46.89 (23.71) 8.00 / 81.33 -0.146 (-1.332)	54.60 / 59.94 (23.05) 11.63 / 82.56 -0.515 (-1.061)

5.2.4 Scores of outcome measures at six weeks (Table 4)

Table 4: Scores of outcome measures at six weeks

Group / Outcome measure	Group I mean / median (SD) minimum / maximum skewness (kurtosis)	Group II mean / median (SD) minimum / maximum skewness (kurtosis)	Group III mean / median (SD) minimum / maximum skewness (kurtosis)
Passive ROM of ankle dorsiflexion with straight knee	6.13 / 6.00 (4.08) -6.00 / 14.00 -0.581 (1.570)	4.86 / 5.00 (5.17) -5.00 / 15.00 0.020 (-0.648)	9.10 / 9.00 (2.72) 4.00 / 15.00 0.239 (-0.305)
Passive ROM of ankle dorsiflexion with bent knee	7.87 / 7.50 (5.22) -7.00 / 17.00 -0.727 (1.827)	7.41 / 8.00 (5.48) -2.00 / 21.00 0.121 (-0.020)	11.17 / 10.50 (4.23) 3.00 / 18.00 0.119 (-0.934)
Plantar heel tenderness (in N/cm²)	46.98 / 43.87 (19.52) 12.73 / 94.27 0.413 (-0.510)	41.89 / 46.60 (21.75) -0.03 / 93.57 -0.081 (-0.071)	68.20 / 69.48 (19.50) 25.50 / 104.43 -0.269 (-0.496)
Plantar heel pain	41.19 / 40.43 (26.56) 1.00 / 85.44 0.122 (-1.284)	45.72 / 42.33 (32.88) 1.00 / 113.44 0.371 (-0.873)	24.22 / 16.28 (20.31) 0.00 / 68.56 0.747 (-0.545)
Disability imposed by the heel pain/plantar fasciitis	35.85 / 31.83 (27.00) 0.00 / 104.50 0.667 (-0.151)	37.94 / 33.78 (28.12) 0.33 / 91.02 0.311 (-1.122)	13.92 / 8.39 (15.87) 0.00 / 52.78 1.025 (-0.119)

5.2.5 Change in scores of outcome measures (Table 5)

Table 5: Change in scores of outcome measures

Group / Outcome measure	Group I mean / median (SD) minimum / maximum skewness (kurtosis)	Group II mean / median (SD) minimum / maximum skewness (kurtosis)	Group III mean / median (SD) minimum / maximum skewness (kurtosis)
Passive ROM of ankle dorsiflexion with straight knee	0.50 / 0.00 (3.12) -4.00 / 11.00 1.352 (3.455)	-0.69 / 0.00 (3.79) -5.00 / 7.00 0.351 (-0.908)	4.63 / 5.00 (2.51) -1.00 / 12.00 0.251 (2.064)
Passive ROM of ankle dorsiflexion with bent knee	0.80 / 1.00 (3.35) -7.00 / 6.00 -1.056 (1.124)	-0.03 / 0.00 (3.09) -4.00 / 6.00 0.128 (-1.018)	5.77 / 5.00 (4.53) -4.00 / 15.00 0.130 (-0.399)
Plantar heel tenderness (in N/cm²)	3.11 / 6.17 (16.18) -26.10 / 42.47 -0.089 (0.210)	-0.31 / 4.47 (23.73) -33.73 / 47.67 -0.067 (-0.669)	31.45 / 30.80 (19.57) 2.70 / 68.03 0.126 (-1.272)
Plantar heel pain	-14.94 / -10.39 (20.56) -54.86 / 10.44 -0.448 (-0.995)	-8.99 / -5.78 (31.05) -75.30 / 29.44 -0.428 (-0.667)	-37.77 / -37.69 (22.27) -79.71 / 16.45 0.349 (-0.049)
Disability imposed by the heel pain/plantar fasciitis	-5.52 / -1.00 (28.38) -57.45 / 39.83 -0.171 (-0.729)	-6.28 / -3.13 (24.65) -71.00 / 19.27 -1.345 (1.507)	-40.69 / -44.54 (22.20) -78.44 / 1.60 0.150 (-0.886)

5.3 ASSESSMENT OF STATISTICAL ASSUMPTIONS

The assumptions of normality and homogeneity of variances were tested to determine whether or not the data had significant skewness and/or heterogeneity of variances and, thus, if use of the Kruskal-Wallis test was necessary.

5.3.1 Normality test of demographic, compliance, baseline and post-intervention evaluation data

The assumption of normality was assessed by testing skewness and kurtosis of the demographic, compliance, baseline and post-intervention evaluation data of the three groups.

5.3.1.1 Normality test of subjects' characteristics

The assumption of normality was not met for all demographic continuous variables (-1.96 > t > 1.96) except average number of hours per day during which the patient is on his/her feet and arch index (-1.96 < t < 1.96) (Table 6).

Table 6: Normality test of subjects' characteristics

Demographic variable \ Group		Group I t	Group II t	Group III t
Age*	Skewness	-0.290	-0.721	-2.407*
	Kurtosis	-0.294	-0.347	0.659
Duration of symptoms prior to treatment*	Skewness	3.061*	6.293*	4.269*
	Kurtosis	0.427	10.968*	4.242*
Average number of hours per day during which the patient is on his/her feet	Skewness	1.541	0.721	0.991
	Kurtosis	-0.764	-1.019	-0.815
Number of previous corticosteroid injections*	Skewness	6.855*	4.984*	5.984*
	Kurtosis	9.703*	5.028*	6.867*
Height*	Skewness	1.419	-0.159	1.932
	Kurtosis	0.173	1.514	2.134*
Weight*	Skewness	0.607	1.256	4.831*
	Kurtosis	-1.113	-0.164	9.361*
Arch index	Skewness	1.019	1.537	0.864
	Kurtosis	-0.455	0.898	-0.053
Navicular drop*	Skewness	2.185*	2.150*	0.532
	Kurtosis	0.351	0.160	-0.240

* -1.96 > t > 1.96

5.3.1.2 Normality test of compliance

The assumption of normality was not met for compliance (-1.96 > t > 1.96) (Table 7).

Table 7: Normality test of compliance

Compliance \ Group		Group I t	Group II t	Group III t
At three weeks*	Skewness	-3.112*	-3.118*	-3.829*
	Kurtosis	1.696	1.634	4.136*
At six weeks*	Skewness	-3.110*	-3.369*	-2.778*
	Kurtosis	1.839	1.360	0.519
Average*	Skewness	-3.239*	-3.491*	-2.464*
	Kurtosis	1.933	2.228*	0.860

* -1.96 > t > 1.96

5.3.1.3 Normality test of outcome measures at baseline

The assumption of normality was met for all outcome measures at baseline (-1.96 < t < 1.96) except passive ROM of ankle dorsiflexion with straight knee and plantar heel tenderness (-1.96 > t > 1.96) (Table 8).

Table 8: Normality test of outcome measures at baseline

Outcome measure / Group		Group I t	Group II t	Group III t
Passive ROM of ankle dorsiflexion with straight knee*	Skewness	-0.269	0.571	2.607*
	Kurtosis	-0.640	-0.302	1.651
Passive ROM of ankle dorsiflexion with bent knee	Skewness	0.892	0.853	-0.094
	Kurtosis	-0.636	-1.259	0.755
Plantar heel tenderness*	Skewness	0.808	-0.366	2.658*
	Kurtosis	0.049	-0.181	0.852
Plantar heel pain	Skewness	-0.148	-1.076	-1.220
	Kurtosis	-0.528	-0.580	0.364
Disability imposed by the heel pain/plantar fasciitis	Skewness	0.792	-0.336	-1.206
	Kurtosis	-1.246	-1.576	-1.274

* -1.96 > t > 1.96

5.3.1.4 Normality test of outcome measures at six weeks

The assumption of normality was met for all outcome measures at six weeks (-1.96 < t < 1.96) except passive ROM of ankle dorsiflexion with bent knee and disability imposed by the heel pain/plantar fasciitis (-1.96 > t > 1.96) (Table 9).

Table 9: Normality test of outcome measures at six weeks

Outcome measure / Group		Group I t	Group II t	Group III t
Passive ROM of ankle dorsiflexion with straight knee	Skewness	-1.361	0.046	0.560
	Kurtosis	1.885	-0.767	-0.366
Passive ROM of ankle dorsiflexion with bent knee*	Skewness	-1.703	0.279	0.279
	Kurtosis	2.193*	-0.024	-1.121
Plantar heel tenderness	Skewness	0.967	-0.187	-0.630
	Kurtosis	-0.612	-0.084	-0.595
Plantar heel pain	Skewness	0.286	0.855	1.749
	Kurtosis	-1.541	-1.033	-0.654
Disability imposed by the heel pain/plantar fasciitis*	Skewness	1.562	0.717	2.400*
	Kurtosis	-0.181	-1.328	-0.143

* -1.96 > t > 1.96

5.3.2 Test of homogeneity of variances of demographic, compliance, baseline and post-intervention evaluation data

The assumption of homogeneity of variances of the demographic, compliance, baseline and post-intervention evaluation data among the groups was assessed using Levene's test.

5.3.2.1 Test of homogeneity of variances of subjects' characteristics

The assumption of homogeneity of variances was met for all continuous demographic variables (p-value > 0.05) except duration of symptoms prior to treatment and navicular drop (p-value < 0.05) (Table 10).

Table 10: Test of homogeneity of variances of subjects' characteristics

Levene's test / Demographic variable	F	p-value
Age	0.726	0.487
Duration of symptoms prior to treatment*	6.797	0.002*
Average number of hours per day during which the patient is on his/her feet	1.297	0.279
Number of previous corticosteroid injections	0.722	0.489
Height	0.814	0.447
Weight	0.648	0.525
Arch index	2.965	0.057
Navicular drop*	8.805	< 0.001*

* p-value < 0.05

5.3.2.2 Test of homogeneity of variances of compliance

The assumption of homogeneity of variances was met for compliance (p-value > 0.05) (Table 11).

Table 11: Test of homogeneity of variances of compliance

Levene's test / Compliance	F	p-value
At three weeks	1.569	0.214
At six weeks	0.254	0.776
Average	1.680	0.192

5.3.2.3 Test of homogeneity of variances of outcome measures at baseline

The assumption of homogeneity of variances was met for all outcome measures at baseline (p-value > 0.05) (Table 12).

Table 12: Test of homogeneity of variances of outcome measures at baseline

Levene's test / Outcome measure	F	p-value
Passive ROM of ankle dorsiflexion with straight knee	0.041	0.960
Passive ROM of ankle dorsiflexion with bent knee	0.036	0.965
Plantar heel tenderness	0.464	0.630
Plantar heel pain	0.882	0.418
Disability imposed by the heel pain/plantar fasciitis	0.078	0.925

5.3.2.4 Test of homogeneity of variances of outcome measures at six weeks

The assumption of homogeneity of variances was not met for all outcome measures at six weeks (p-value < 0.05) except passive ROM of ankle dorsiflexion with bent knee and plantar heel tenderness (p-value > 0.05) (Table 13).

Table 13: Test of homogeneity of variances of outcome measures at six weeks

Levene's test / Outcome measure	F	p-value
Passive ROM of ankle dorsiflexion with straight knee*	5.921	0.004*
Passive ROM of ankle dorsiflexion with bent knee	0.735	0.483
Plantar heel tenderness	0.209	0.812
Plantar heel pain*	3.871	0.025*
Disability imposed by the heel pain/plantar fasciitis*	6.508	0.002*

* p-value < 0.05

5.4 COMPARING DEMOGRAPHIC, COMPLIANCE, AND BASELINE EVALUATION DATA

The demographic, compliance, and baseline evaluation data were compared between the treatment groups using ANOVA test for each continuous variable and chi-square test for each categorical variable to determine if there was a significant difference among the groups. Kruskal-Wallis test was used for the continuous variables that showed significant skewness and/or heterogeneity of variances.

5.4.1 Comparing means of subjects' characteristics

There were no significant differences between the groups for all demographic variables (p-value > 0.05) (Table 14).

Table 14: Comparing means of subjects' characteristics

ANOVA, Kruskal-Wallis, or chi-square test / Demographic variable	F, (Kruskal-Wallis), or [χ^2]	p-value
Age	(0.114)	0.944
Gender	[3.271]	0.195
Unilateral or bilateral involvement	[2.570]	0.277
Involved side	[0.623]	0.732
Duration of symptoms prior to treatment	(2.036)	0.361
Average number of hours per day during which the patient is on his/her feet	0.025	0.975
Number of previous corticosteroid injections	(0.367)	0.832
Height	(1.019)	0.601

Weight	(1.488)	0.475
Arch index	1.670	0.194
Navicular drop	(2.421)	0.298

5.4.2 Comparing means of compliance

There was no significant difference between the groups for compliance (p-value > 0.05) (Table 15).

Table 15: Comparing means of compliance

Kruskal-Wallis test / Compliance	Test statistic	p-value
At three weeks	0.246	0.884
At six weeks	0.639	0.727
Average	0.208	0.901

5.4.3 Comparing means of outcome measures at baseline

There were no significant differences between the groups for all outcome measures at baseline (p-value > 0.05) (Table 16).

Table 16: Comparing means of outcome measures at baseline

ANOVA or Kruskal-Wallis test / Outcome measure	F or (Kruskal-Wallis)	p-value
Passive ROM of ankle dorsiflexion with straight knee	(3.243)	0.198
Passive ROM of ankle dorsiflexion with bent knee	2.083	0.131
Plantar heel tenderness	(5.368)	0.068
Plantar heel pain	1.394	0.254
Disability imposed by the heel pain/plantar fasciitis	2.623	0.078

5.5 RESULTS OF SPECIFIC AIM 1

The post-intervention evaluation data were compared between the treatment groups using ANCOVA test to examine if there was a significant difference among the groups. Kruskal-Wallis test was used for the outcome measures that showed significant skewness and/or heterogeneity of

variances (passive ROM of ankle dorsiflexion with the knee straight and bent, plantar heel pain, and disability imposed by the heel pain/plantar fasciitis). Bonferroni and Mann-Whitney post-hoc analyses were explored to determine if there were significant differences between group I and III and/or group II and III.

5.5.1 Comparing means of outcome measures at six weeks

There were significant differences in all outcome measures between the groups at six weeks (p-value < 0.05) (Table 17).

Table 17: Comparing means of outcome measures at six weeks

ANCOVA or Kruskal-Wallis test / Outcome measure	F or (Kruskal-Wallis)	p-value
Passive ROM of ankle dorsiflexion with straight knee*	(15.771)	< 0.001*
Passive ROM of ankle dorsiflexion with bent knee*	(9.045)	0.011*
Plantar heel tenderness*	22.097	< 0.001*
Plantar heel pain*	(8.485)	0.014*
Disability imposed by the heel pain/plantar fasciitis*	(18.107)	< 0.001*

* p-value < 0.05

5.5.2 Post-hoc analyses of outcome measures at six weeks

Post-hoc analyses showed no significant difference between group I and II for all outcome measures at six weeks (p-value > 0.05). However, all outcome measures showed significant differences between group I and III and group II and III at six weeks (p-value < 0.017). In other words, a dorsiflexion night splint and medial arch support together were more effective in the treatment of plantar fasciitis than a dorsiflexion night splint or medial arch support each by itself in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis (Table 18).

Table 18: Post-hoc analyses of outcome measures at six weeks

Group / Outcome measure	Group I & II p-value (2-tailed) Bonferroni or (Mann-Whitney)	Group I & III p-value (1-tailed) Bonferroni or (Mann-Whitney)	Group II & III p-value (1-tailed) Bonferroni or (Mann-Whitney)
Passive ROM of ankle dorsiflexion with straight knee*	(0.232)	(0.001**)	(< 0.001**)
Passive ROM of ankle dorsiflexion with bent knee*	(0.711)	(0.007**)	(0.004**)
Plantar heel tenderness*	0.836	< 0.001*	< 0.001*
Plantar heel pain*	(0.773)	(0.006**)	(0.007**)
Disability imposed by the heel pain/plantar fasciitis*	(0.574)	(< 0.001**)	(< 0.001**)

* p-value < 0.05
** p-value < 0.017 (0.05/3)

5.6 RESULTS OF SPECIFIC AIM 2

The post-intervention evaluation data of group I were regressed on the baseline passive ROM of ankle dorsiflexion with the knee straight and bent after controlling for the baseline evaluation data.

5.6.1 Regression of group I outcome measures on baseline passive ROM of ankle dorsiflexion with straight knee

Baseline passive ROM of ankle dorsiflexion with the knee straight was not a useful predictor of the success of treatment with a dorsiflexion night splint for all outcome measures (p-value > 0.05). In other words, patients with plantar fasciitis who had less passive dorsiflexion of the ankle joint with straight knee did not benefit from a dorsiflexion night splint more than those with greater passive dorsiflexion of the ankle joint with straight knee in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis (Table 19).

Table 19: Regression of group I outcome measures on baseline passive ROM of ankle dorsiflexion with straight knee

Outcome measure \ Regression		b_0	b_1	b_1^*	R^2	ΔR^2	p-value
Change in scores of passive ROM of ankle dorsiflexion with straight knee		1.445	-0.168	-0.173	0.030		0.359
Change in scores of passive ROM of ankle dorsiflexion with bent knee		-0.207	0.179	0.172	0.030		0.363
Plantar heel tenderness at six weeks	Block 1 (baseline tenderness)	12.058	0.598	0.569	0.409		0.001
	Block 2 (baseline ROM S.)		1.542	0.254	0.469	0.060	0.093
Plantar heel pain at six weeks	Block 1 (baseline pain)	-19.696	1.034	0.637	0.401		< 0.001
	Block 2 (baseline ROM S.)		0.509	0.062	0.405	0.004	0.682
Disability imposed by the heel pain/plantar fasciitis at six weeks	Block 1 (baseline disability)	18.079	0.436	0.393	0.155		0.035
	Block 2 (baseline ROM S.)		-0.045	-0.005	0.155	< 0.001	0.976

5.6.2 Regression of group I outcome measures on baseline passive ROM of ankle dorsiflexion with bent knee

Baseline passive ROM of ankle dorsiflexion with the knee bent was not a useful predictor of the success of treatment with a dorsiflexion night splint for all outcome measures (p-value > 0.05). In other words, patients with plantar fasciitis who had less passive dorsiflexion of the ankle joint with bent knee did not benefit from a dorsiflexion night splint more than those with greater passive dorsiflexion of the ankle joint with bent knee in terms of increasing the range of pain-

free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis (Table 20).

Table 20: Regression of group I outcome measures on baseline passive ROM of ankle dorsiflexion with bent knee

Outcome measure \ Regression		b_0	b_1	b_1^*	R^2	ΔR^2	p-value
Change in scores of passive ROM of ankle dorsiflexion with straight knee		0.097	0.057	0.073	0.005		0.703
Change in scores of passive ROM of ankle dorsiflexion with bent knee		0.716	0.012	0.014	< 0.001		0.941
Plantar heel tenderness at six weeks	Block 1 (baseline tenderness)	12.362	0.644	0.612	0.409		< 0.001
	Block 2 (baseline ROM B.)		0.904	0.184	0.442	0.033	0.218
Plantar heel pain at six weeks	Block 1 (baseline pain)	-22.070	1.042	0.642	0.401		< 0.001
	Block 2 (baseline ROM B.)		0.679	0.101	0.411	0.010	0.500
Disability imposed by the heel pain/plantar fasciitis at six weeks	Block 1 (baseline disability)	15.509	0.444	0.401	0.155		0.034
	Block 2 (baseline ROM B.)		0.277	0.041	0.156	0.002	0.823

5.6.3 Regression of group I outcome measures on difference between baseline passive ROM of ankle dorsiflexion with straight and bent knee

Difference between baseline passive ROM of ankle dorsiflexion with straight and bent knee was not a useful predictor of the success of treatment with a dorsiflexion night splint for plantar heel tenderness, plantar heel pain, and disability imposed by the heel pain/plantar fasciitis (p-value > 0.05) (Table 21).

Table 21: Regression of group I outcome measures on difference between baseline passive ROM of ankle dorsiflexion with straight and bent knee

Outcome measure \ Regression		b_0	b_1	b_1^*	R^2	ΔR^2	p-value
Plantar heel tenderness at six weeks	Block 1 (baseline tenderness)	17.777	0.670	0.638	0.409		< 0.001
	Block 2 (baseline ROM S-B)		0.145	0.018	0.410	0.001	0.903
Plantar heel pain at six weeks	Block 1 (baseline pain)	-18.169	1.035	0.638	0.401		< 0.001
	Block 2 (baseline ROM S-B)		-0.875	-0.082	0.408	0.007	0.587
Disability imposed by the heel pain/plantar fasciitis at six weeks	Block 1 (baseline disability)	15.735	0.458	0.413	0.155		0.032
	Block 2 (baseline ROM S-B)		-0.821	-0.075	0.160	0.005	0.684

5.6.4 Regression of group I outcome measures on change in scores of passive ROM of ankle dorsiflexion with straight knee

Change in scores of passive ROM of ankle dorsiflexion with the knee straight was a useful predictor of the success of treatment with a dorsiflexion night splint for disability imposed by the heel pain/plantar fasciitis (p-value < 0.05) but not for plantar heel tenderness and plantar heel pain (p-value > 0.05). In other words, greater change in scores of passive ROM of ankle dorsiflexion with the knee straight was associated with less disability imposed by the heel pain/plantar fasciitis (Table 22).

Table 22: Regression of group I outcome measures on change in scores of passive ROM of ankle dorsiflexion with straight knee

Outcome measure \ Regression		b_0	b_1	b_1^*	R^2	ΔR^2	p-value
Plantar heel tenderness at six weeks	Block 1 (baseline tenderness)	17.829	0.667	0.635	0.409		< 0.001
	Block 2 (change in ROM S.)		-0.256	-0.041	0.411	0.002	0.786
Plantar heel pain at six weeks	Block 1 (baseline pain)	-15.148	1.017	0.627	0.401		< 0.001
	Block 2 (change in ROM S.)		-1.530	-0.179	0.433	0.032	0.226
Disability imposed by the heel pain/plantar fasciitis at six weeks	Block 1 (baseline disability)	19.727	0.431	0.389	0.155		0.022
	Block 2 (change in ROM S.)		-3.409	-0.393	0.309	0.154	0.021*

* p-value < 0.05

5.6.5 Regression of group I outcome measures on change in scores of passive ROM of ankle dorsiflexion with bent knee

Change in scores of passive ROM of ankle dorsiflexion with the knee bent was a useful predictor of the success of treatment with a dorsiflexion night splint for plantar heel tenderness and disability imposed by the heel pain/plantar fasciitis (p-value < 0.05) but not for plantar heel pain (p-value > 0.05). In other words, greater change in scores of passive ROM of ankle dorsiflexion with the knee bent was associated with less plantar heel tenderness and disability imposed by the heel pain/plantar fasciitis (Table 23).

Table 23: Regression of group I outcome measures on change in scores of passive ROM of ankle dorsiflexion with bent knee

Outcome measure \ Regression		b_0	b_1	b_1^*	R^2	ΔR^2	p-value
Plantar heel tenderness at six weeks	Block 1 (baseline tenderness)	17.049	0.642	0.611	0.409		< 0.001
	Block 2 (change in ROM B.)		2.204	0.378	0.551	0.142	0.007*
Plantar heel pain at six weeks	Block 1 (baseline pain)	-8.075	0.906	0.558	0.401		0.001
	Block 2 (change in ROM B.)		-1.989	-0.251	0.458	0.057	0.103
Disability imposed by the heel pain/plantar fasciitis at six weeks	Block 1 (baseline disability)	20.271	0.446	0.402	0.155		0.015
	Block 2 (change in ROM B.)		-3.575	-0.443	0.351	0.196	0.008*

* p-value < 0.05

5.7 RESULTS OF SPECIFIC AIM 3

The post-intervention evaluation data of group II were regressed on the arch index and navicular drop after controlling for the baseline evaluation data.

5.7.1 Regression of group II outcome measures on arch index

The arch index was not a useful predictor of the success of treatment with a medial arch support for all outcome measures (p-value > 0.05). In other words, patients with plantar fasciitis who had a lower arch index did not benefit from a medial arch support more than those with a higher arch index in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis (Table 24).

Table 24: Regression of group II outcome measures on arch index

Outcome measure \ Regression		b_0	b_1	b_1^*	R^2	ΔR^2	p-value
Passive ROM of ankle dorsiflexion with straight knee at six weeks	Block 1 (baseline ROM S.)	-1.622	1.076	0.680	0.464		< 0.001
	Block 2 (arch index)		1.405	0.011	0.464	< 0.001	0.937
Passive ROM of ankle dorsiflexion with bent knee at six weeks	Block 1 (baseline ROM B.)	-1.944	1.194	0.838	0.703		< 0.001
	Block 2 (arch index)		1.336	0.010	0.703	< 0.001	0.924
Plantar heel tenderness at six weeks	Block 1 (baseline tenderness)	36.238	0.249	0.170	0.031		0.383
	Block 2 (arch index)		-21.656	-0.042	0.033	0.002	0.830
Plantar heel pain at six weeks	Block 1 (baseline pain)	23.711	0.627	0.391	0.159		0.040
	Block 2 (arch index)		-46.816	-0.060	0.162	0.004	0.741
Disability imposed by the heel pain/plantar fasciitis at six weeks	Block 1 (baseline disability)	9.690	0.661	0.550	0.303		0.002
	Block 2 (arch index)		-0.603	-0.001	0.303	< 0.001	0.996

5.7.2 Regression of group II outcome measures on navicular drop

Navicular drop was not a useful predictor of the success of treatment with a medial arch support for all outcome measures (p-value > 0.05). In other words, patients with plantar fasciitis who had a greater navicular drop did not benefit from a medial arch support more than those with a smaller navicular drop in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis (Table 25).

Table 25: Regression of group II outcome measures on navicular drop

Outcome measure \ Regression		b_0	b_1	b_1^*	R^2	ΔR^2	p-value
Passive ROM of ankle dorsiflexion with straight knee at six weeks	Block 1 (baseline ROM S.)	-1.733	1.091	0.689	0.464		< 0.001
	Block 2 (navicular drop)		0.079	0.051	0.467	0.003	0.721
Passive ROM of ankle dorsiflexion with bent knee at six weeks	Block 1 (baseline ROM B.)	-2.178	1.205	0.846	0.703		< 0.001
	Block 2 (navicular drop)		0.101	0.061	0.707	0.004	0.563
Plantar heel tenderness at six weeks	Block 1 (baseline tenderness)	28.666	0.253	0.173	0.031		0.371
	Block 2 (navicular drop)		0.338	0.052	0.034	0.003	0.784
Plantar heel pain at six weeks	Block 1 (baseline pain)	11.602	0.635	0.396	0.159		0.040
	Block 2 (navicular drop)		-0.126	-0.013	0.159	< 0.001	0.944
Disability imposed by the heel pain/plantar fasciitis at six weeks	Block 1 (baseline disability)	17.203	0.627	0.522	0.303		0.003
	Block 2 (navicular drop)		-1.219	-0.147	0.324	0.021	0.369

6.0 DISCUSSION

6.1 DISCUSSION OF SPECIFIC AIM 1

Plantar fasciitis is an overuse injury causing inflammation at the origin of the plantar fascia and is typically characterized by pain in the inferior heel region that is provoked by weight bearing after a long period of non-weight bearing and by prolonged weight bearing.[1,4,9,14,19,21,24,25] A dorsiflexion night splint is used to relieve the pain associated with the first step in the morning by preventing contracture of the plantar fascia and Achilles tendon overnight.[4,5,7,15,19,23,24,26-32] A medial arch support, on the other hand, relieves the end of the day pain by supporting the medial longitudinal arch and, thus, preventing overstretch of plantar fascia during prolonged weight bearing.[1,7,21,24,33-37] Therefore, both night splints and arch supports may be necessary to treat plantar fasciitis as they complement each other by both controlling nocturnal contracture of the plantar fascia and Achilles tendon and reducing stresses imposed on the plantar fascia during the day, respectively. In fact, many authors agree that the success of conservative treatment of plantar fasciitis usually requires a combination of treatment modalities, rather than administering only one treatment at a time.[4,14,19,20] Although the isolated effectiveness of night splints and arch supports in relieving symptoms of plantar fasciitis is well-established in the literature, no previous study, to the best of our knowledge, has been conducted to evaluate the combined effect of these treatment modalities.

The results of this study demonstrated that the combination of a night splint and arch support resulted in a greater increase in the range of passive ankle dorsiflexion and decreased heel tenderness, pain, and disability compared to either a night splint or arch support alone. This might be because the night splint and arch support complement each other in addressing both the early morning pain and the end of the day pain by preventing contracture of the plantar fascia and Achilles tendon overnight and by preventing overstretch of the plantar fascia and reducing stresses imposed on it during prolonged weight bearing, respectively. Also, these findings supported the suggestion reported by some researchers that treatment of plantar fasciitis should consist of several modalities and that a total, not a fragmented, effort is necessary.[4,14,19] However, this finding cannot be generalized to the use of custom-made foot orthoses.

The treatment period for this study was six weeks which is relatively short compared to most previous studies that suggested that three to four months of continued use of night splints or arch supports was necessary to have significant improvement.[14,21,30-32] This means that the use of both night splints and arch supports might have speeded the time to recovery by accelerating the healing process. However, we do not know if the differences between group I and III and group II and III would remain significant after three or four months of treatment.

It is well-established in the literature that early recognition and treatment of plantar fasciitis usually leads to a shorter course of treatment as well as increased probability of success with conservative treatment measures.[1,7,10,13,19,24,27] It may be that acute cases have few permanent changes and, therefore, respond well to non-operative treatment.[27] Wolgin felt that subjects who had symptoms for a prolonged time before treatment were at a higher risk for continued symptoms.[24] They may have such thickened and degenerated plantar fascia bundles that non-operative treatment becomes less successful.[1,27] In this study, the means of duration of

symptoms prior to treatment of group I, II, and III were 16.88, 18.26, and 8.78 months, respectively. Therefore, one can argue that the significant differences between group I and III and group II and III might be due, in part, to the fact that cases of group III were less chronic than those of group I and II. However, this is very unlikely because, from a statistical point of view, duration of symptoms prior to treatment did not differ significantly between the groups (p-value = 0.361 > 0.05) and, more importantly, it did not correlate significantly with any of the outcome measures (p-value > 0.05).

Unlike subjects in group I and II who received only one treatment modality, those in group III received two different treatments; therefore, an alternative explanation of the significant differences between group I and III and group II and III may be that subjects in group III had a second chance that if one treatment was ineffective or intolerable the other treatment might contribute to the healing process because what works for some patients may not work for others.

All missing data points were replaced using the "worst case scenario" (the least difference in each outcome measure of each group between the post-intervention and baseline evaluation data was added to the baseline evaluation data). This was a decision that we made prior to data collection as it is the most conservative way to adhere with the principle of intention-to-treat analysis. However, since all drop-outs were from group I and II, but not from group III, using the "worst case scenario" increased the differences between group I and II on one side and group III on the other side. In other words, it can be argued that part of the significant differences between group I and III and group II and III might be due to the way we replaced the missing data points. Therefore, to be more conservative in interpreting these findings, the data analyses were repeated using two other methods of replacing the missing data

points. One of these methods used the “average” (the average difference in each outcome measure of each group between the post-intervention and baseline evaluation data was added to the baseline evaluation data), while the other assumed “no change” (the baseline evaluation data were used to replace the missing post-intervention evaluation data). However, these methods of replacement still resulted in significant differences between group I and III and group II and III for all outcome measures, with the exception that the difference in plantar heel pain between group II and III using the “average” method was no longer significant (p-value = 0.040 > 0.017).

Finally, it should be mentioned that there is a chance that we have committed a type I error. The type I error, also known as an α error or a "false positive," is the error of rejecting a null hypothesis when it is true. For example, the term “false positive” can be used when we detect a significant difference in tenderness between group I and III when there is actually no difference. In other words, this is the error of accepting an alternative hypothesis when an observation is due to chance. To control for type I errors, α was divided by the number of comparisons when the Mann-Whitney post-hoc analysis was used for multiple comparisons.

In order to explore the dose-response effect of night splints, we ran a correlation between the compliance of night splint wear and the change in scores of the range of pain-free passive ankle joint dorsiflexion; however, the correlation was not statistically significant (p-value > 0.05). The lack of a correlation between the compliance and the change in scores of the ROM might be due to a restriction in the range of the values of the compliance that had suppressed the regression because most subjects reported a compliance rate of 80% or higher. Therefore, we continue to recommend use of night splints during all sleeping hours. This is illustrated in the scatter plots of the compliance data points (Figure 5).

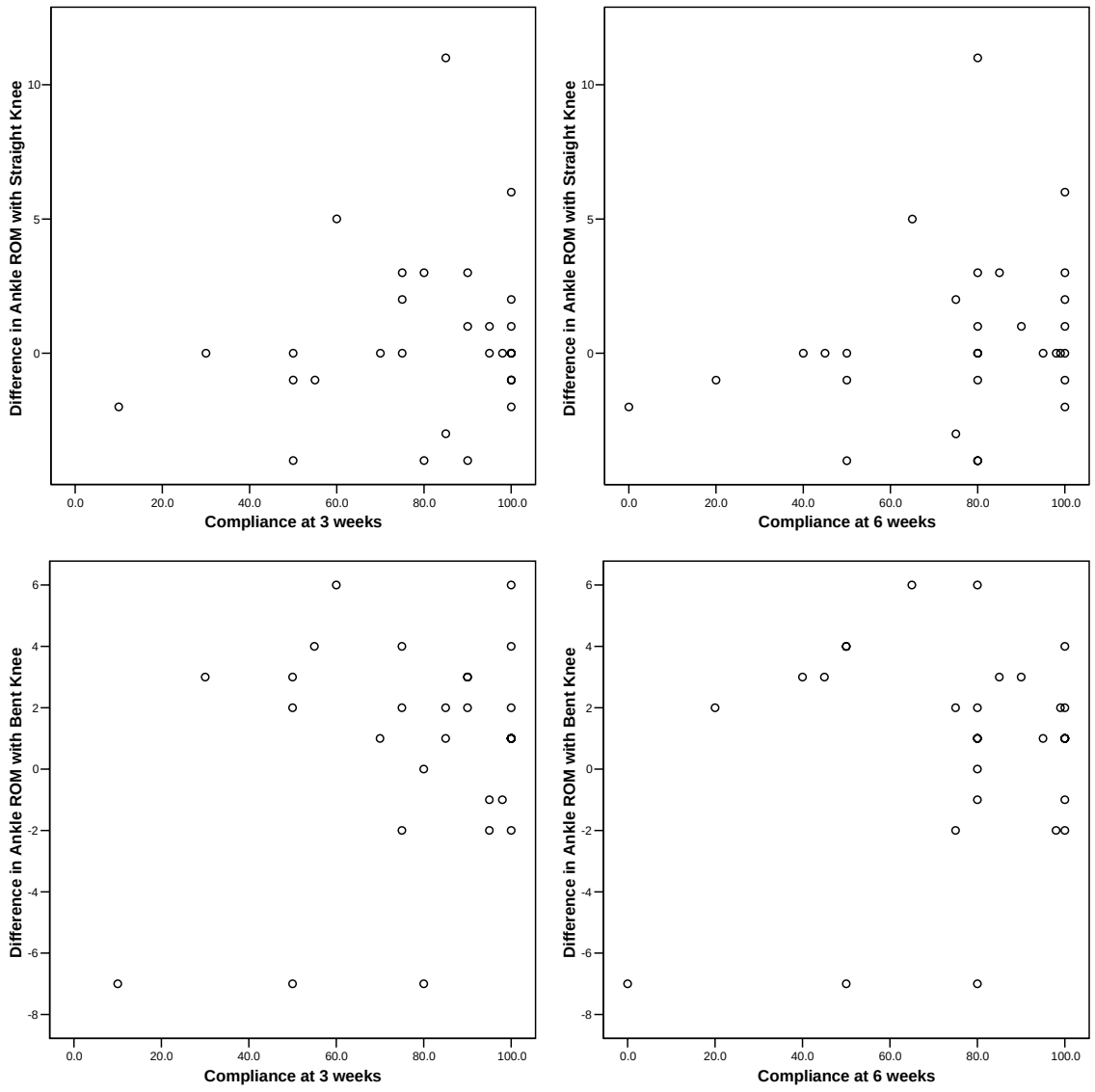

Figure 5: Scatter plots of group I compliance data points

All complaints in this study came from night splints. They included difficulty sleeping, difficulty applying the splint, lack of comfort, and transient numbness of the toes. There were no complaints from arch supports. Indeed, many subjects reported that they were very comfortable.

6.1.1 Limitations of prospective randomized study

Limitations of the study include observer's bias, subjects' bias, and short follow-up period.

6.1.1.1 Observer's bias

In order to eliminate observer's bias, we should, ideally, have blinded the principal investigator from the group assignment of the subject by letting him perform the assessment himself and hiring another physical therapist to do the randomization and provide the corresponding treatment to the subject. However, we were unable to do that because of the limited funds for the study. Therefore, we decided that the principal investigator should perform the assessment before the randomization at the initial visit to be completely blinded to the group assignment of the subject and, thus, to eliminate his bias toward any treatment group. We also decided that he should have no access to the data recording form of the initial visit at the time of the follow-up visit, and to record compliance, which would tell him to which treatment group the subject belonged, only after finishing the follow-up assessment, with the hope that he would forget the group assignment of the subject after six weeks of the subject's participation in the study. Although the principal investigator might not have been completely blinded to the group assignment of the subject during the follow-up visit, he would be completely blinded to the baseline measurements. In other words, even if he still could remember the subject's assigned group at the time of the follow-up visit, there would be no way that he could recall his/her baseline measurements. In addition, the fact that most of the outcome measures of the study were questionnaires that were completed by the subject (pain and disability) or tests that were subjective in nature (tenderness), would minimize the effect of the principal investigator's bias on the follow-up assessment. In other words, ROM was the only objective outcome measure that could be affected by the observer's bias. We understand that the principal investigator might not be completely blinded during the follow-up visit, and that his bias toward any treatment group was not fully eliminated, but this was the best we could do to try to minimize the observer's bias,

and we felt that it would result in a non-biased follow-up assessment and an acceptable level of validity of the results.

6.1.1.2 Subjects' bias

Subjects of the study were not blinded to their group assignment and, thus, their bias toward any treatment group was not eliminated. In other words, those who were assigned to group III might be psychologically affected by the fact they were in the combination group that received two treatment modalities compared to group I and II that received only one treatment. This is particularly important since all outcome measures, except ROM, were subjective in nature. Therefore, one can argue that the significant differences between group I and III and group II and III might be due, in part, to the subjects' bias. However, the subjects were blinded to the research questions and hypotheses of the study, which might minimize, but did not completely eliminate, their bias. In addition, there was no possible way to blind the subjects from their group assignment.

6.1.1.3 Short follow-up period

The follow-up period of this study was six weeks which is relatively short compared to most previous studies on plantar fasciitis.[14,21,30-32] Therefore, we do not have enough information about the long-term benefits of the treatment measures used in this study. In other words, it is unknown whether or not the improvement in the outcome measures would be retained for a long period of time and whether or not a recurrence of symptoms would occur after discontinuing treatment.

6.2 DISCUSSION OF SPECIFIC AIM 2 AND 3

The secondary hypotheses of this study were based on the suggested association between tightness of the Achilles tendon and pes planus and their consequent excessive pronation with the development of plantar fasciitis.[1,22] A tight Achilles tendon is found in 78% of patients with plantar fasciitis.[4,13,16,17,24,39] It limits ankle joint dorsiflexion, which increases the load on the intrinsic muscles of the foot and results in abnormal compensatory pronation of the subtalar joint as ankle dorsiflexion progresses during the stance phase of gait.[3,16,19,46,47,55]

Between 81 and 86% of individuals with symptoms consistent with plantar fasciitis have been classified on examination as having pes planus with excessive pronation.[1] The theoretical basis for this finding is the increased tension placed on the plantar fascia as a result of a lower arch during standing and walking.[7,13,19,42,54] In addition, increased pronation results in decreased stability of the hindfoot, which produces additional stress on the origin of the central band of the plantar fascia and may ultimately lead to plantar fasciitis.[1,15,28]

Excessive pronation results in an inability of the foot to supinate from mid to terminal stance.[3,51] Consequently, little load is conveyed through the lateral portion of the midfoot and normal loading forces are inadequately supported by the bones and ligaments. The vertical impulse is thus shifted away from the midfoot, and secondary structures, such as the plantar fascia, must assume a greater load.[6] Mann and Inman confirmed this by noting that heel pronation increased the tension along the medial aspect of the heel.[54]

However, despite the wide acceptance of the association between these factors and plantar fasciitis, research studies have not demonstrated that they are primary factors in the cause of plantar fasciitis.[1] Snook and Chrisman wrote, “It is reasonably certain that a condition which

has so many different theories of etiology and treatment does not have valid proof of any one cause."[49] This thinking has been reiterated by other authors.[11,24]

The questionable validity of tightness of the Achilles tendon and pes planus as factors that cause plantar fasciitis might be the reason behind the findings of this study that the range of pain-free passive ankle joint dorsiflexion and medial longitudinal arch height were not useful predictors of the success of treatment with a night splint and arch support in terms of all outcome measures, respectively. However, greater change in the range of pain-free passive ankle joint dorsiflexion following treatment with a night splint was associated with less plantar heel tenderness and disability imposed by the heel pain/plantar fasciitis.

An alternative explanation may be that we have committed a type II error. The type II error, often denoted as a β error or a "false negative," is the error of not rejecting a null hypothesis when it is false. In other words, this is the error of failing to accept an alternative hypothesis because of inadequate power.

In addition, it can be argued that the range of pain-free passive ankle joint dorsiflexion and medial longitudinal arch height were not useful predictors of the success of treatment with a night splint and arch support because there was a restriction in the range of the values of the ROM and arch height that had suppressed the regression. However, this is very unlikely because the ROM and arch height data points were randomly scattered through all the ranges of their scatter plots (Figure 6 and 7). Figure 7 also shows that neither high nor low values of the medial longitudinal arch height were useful predictors of the success of treatment with an arch support since the arch height data points did not follow a curved pattern.

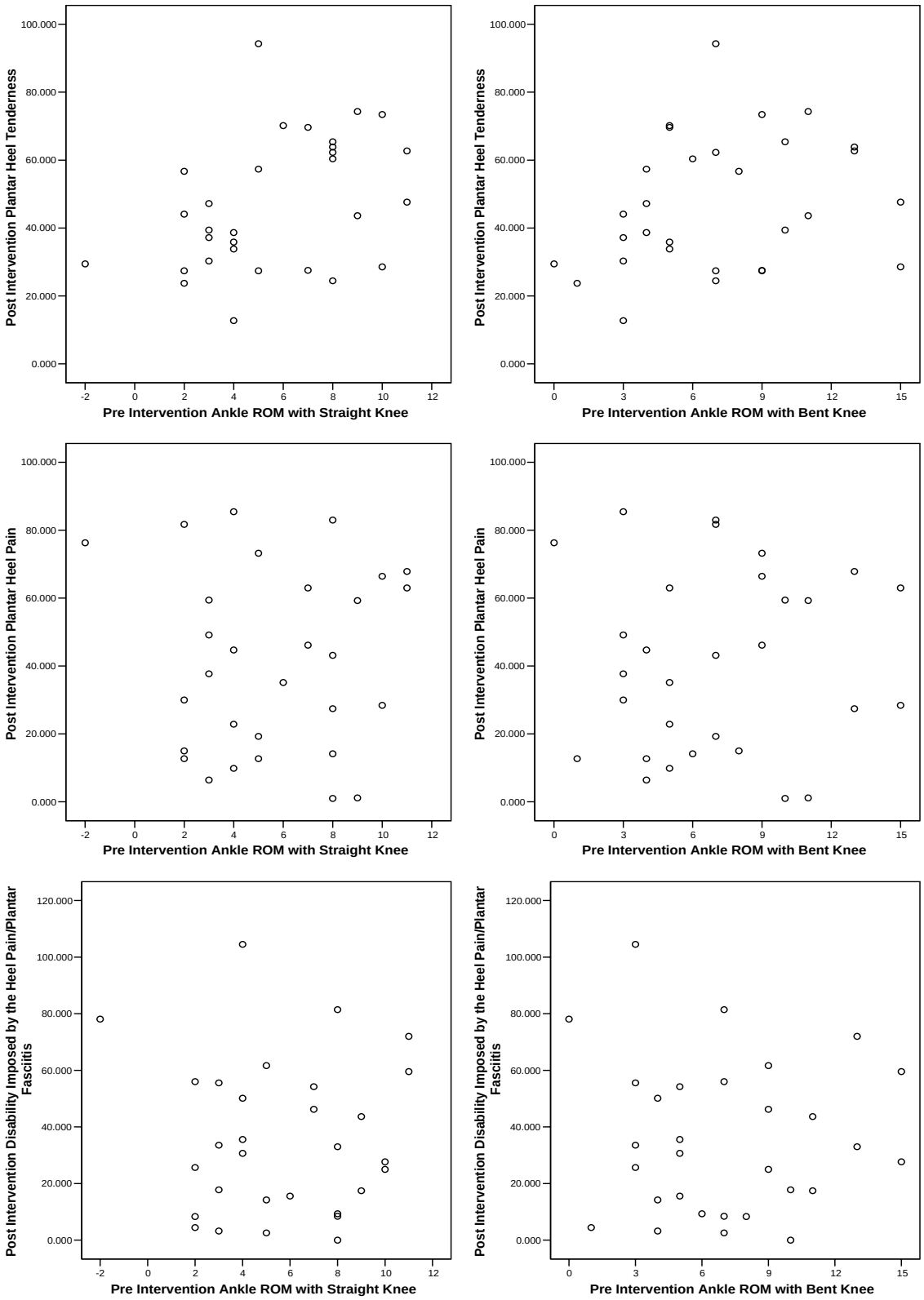

Figure 6: Scatter plots of group I range of pain-free passive ankle joint dorsiflexion data points

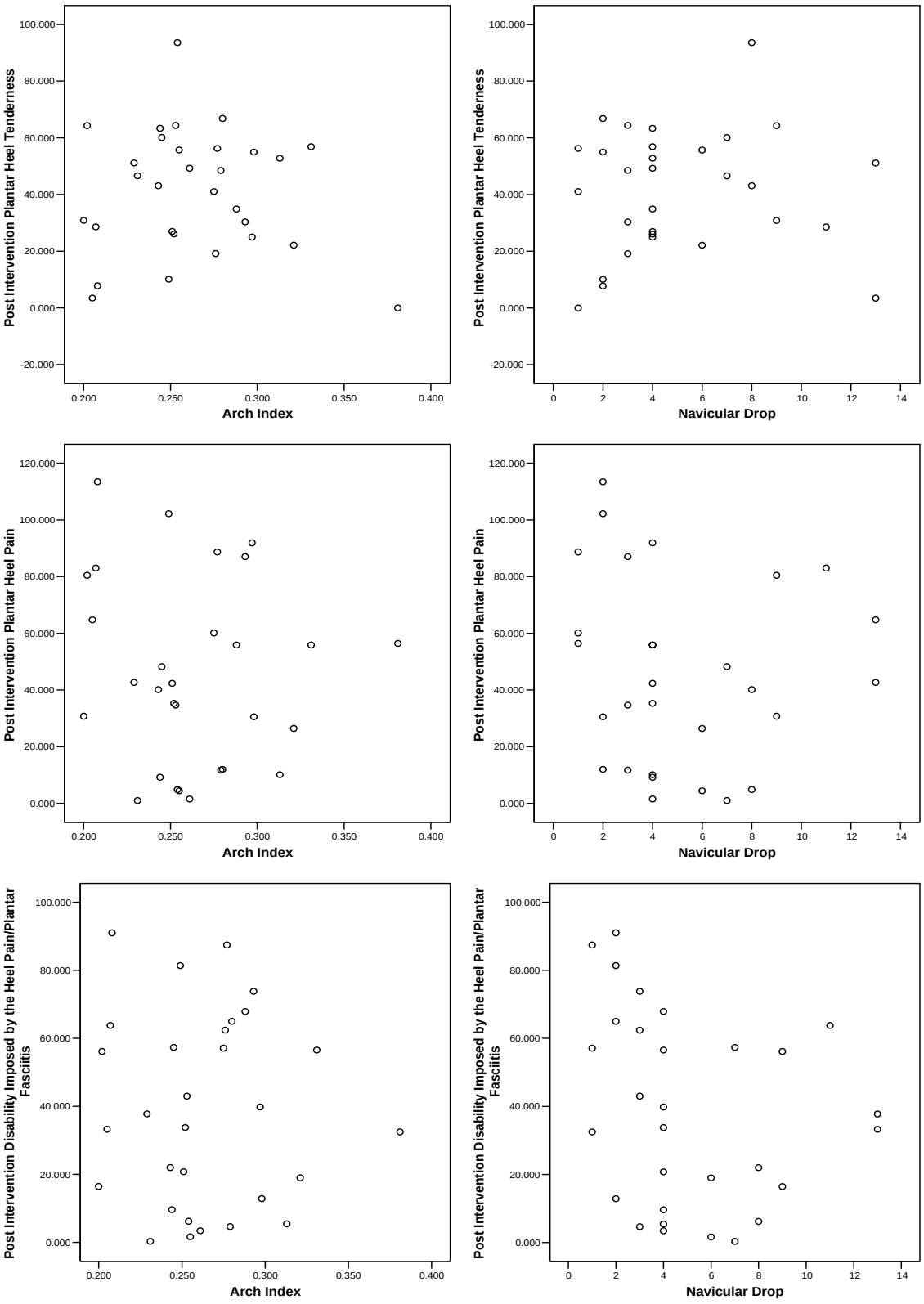

Figure 7: Scatter plots of group II medial longitudinal arch height data points

Also, the reason that patients with plantar fasciitis who had a lower medial longitudinal arch did not benefit from a medial arch support more than those with a higher medial longitudinal arch might be that the primary role of the arch supports in the treatment of plantar fasciitis is not just controlling foot motion and abnormal pronation but also providing total contact with the plantar surface of the foot and, thus, distributing plantar pressures and reducing contact stresses imposed on the plantar fascia during weight bearing.[1,3,5-7,15,16,22,24,28,68] Kogler and colleagues reported that foot orthoses designed to provide total contact to the plantar surface of the foot in combination with proper footwear significantly decreased the strain on the plantar fascia during weight bearing.[34] As a result of this effect, the arch supports may also be beneficial to those with normal and high arches. Alternatively, the arch supports may provide cushioning that reduces pain and disability associated with plantar fasciitis. In one study, arch supports made of softer materials provided cushioning by reducing the shock on walking by up to 42%.[19]

It may also be worth mentioning that because the predictors were continuous variables, they did not control for the individual variations in the range of pain-free passive ankle joint dorsiflexion and medial longitudinal arch height and, here, side-to-side comparison becomes handy.

Both body mass index (BMI) and average number of hours per day during which the patient is on his/her feet were also not useful predictors of the success of treatment with a night splint and arch support in terms of all outcome measures.

7.0 CONCLUSION

Based on the results of this study, it was concluded that a dorsiflexion night splint and medial arch support together may be more effective in the treatment of plantar fasciitis than a dorsiflexion night splint or medial arch support each by itself in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis because, together, they address both the early morning pain and the end of the day pain, respectively.

Patients with plantar fasciitis who have less passive dorsiflexion of the ankle joint do not benefit from a dorsiflexion night splint more than those with greater passive dorsiflexion of the ankle joint in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis. However, greater change in the passive dorsiflexion of the ankle joint is associated with less plantar heel tenderness and disability imposed by the heel pain/plantar fasciitis.

Patients with plantar fasciitis who have a lower medial longitudinal arch do not benefit from a medial arch support more than those with a higher medial longitudinal arch in terms of increasing the range of pain-free passive ankle dorsiflexion, relieving heel tenderness and pain, and reducing disability imposed by the heel pain/plantar fasciitis.

Further studies may include, but are not limited to, evaluation of the effectiveness of dorsiflexion night splints and medial arch supports in the treatment of plantar fasciitis for a

longer follow-up period. These studies may also compare the effects of different models and brands of night splints and arch supports. For instance, comparing the effects of adjustable versus non-adjustable night splints, and full length versus ¾ length arch supports. They may also investigate whether foot taping is a useful predictor of the success of treatment with an arch support.

In addition, the efficacy of different modalities of physical therapy such as cryotherapy and hydrotherapy needs to be assessed. Although these modalities have been described as effective in the management of plantar fasciitis, no studies have been conducted on patients with plantar fasciitis to determine their actual effectiveness. Future studies may also examine the effects of different combinations of treatment modalities. Despite the wide agreement that the success of conservative care for the treatment of patients with plantar fasciitis requires a combination of treatment modalities, there is no consensus about which treatments are the best or the most cost-effective, and there is inconsistency in the treatments provided by various practitioners.

APPENDIX A

INCLUSION/EXCLUSION CRITERIA CHECK-LIST

A.1 INCLUSION CRITERIA

[ ] Plantar heel pain.
[ ] Pain is provoked by taking the first few steps in the morning, by standing after prolonged sitting, and/or by prolonged standing.
[ ] Tenderness localized to the origin of the plantar fascia on the medial calcaneal tubercle.

A.2 EXCLUSION CRITERIA

[ ] Previous foot surgery.
[ ] Foot trauma within the previous three months.
[ ] Tarsal tunnel syndrome.
[ ] Loss of plantar foot sensation.
[ ] Foot pathology other than plantar fasciitis including tendonitis, bursitis, or calcaneus fracture.
[ ] Generalized inflammatory disorders associated with the diagnosis of plantar fasciitis including rheumatoid arthritis, ankylosing spondylitis, Reiter's disease, gout, or lupus.
[ ] Previous treatment of plantar fasciitis with dorsiflexion night splint and/or medial arch support.
[ ] Inability or unwillingness to discontinue current treatment modalities that are used for the purpose of plantar fasciitis.
[ ] Participation in a worker's compensation program.
[ ] Age of less than eighteen years.

APPENDIX B

HIPAA AUTHORIZATION FOR SHARING HEALTH INFORMATION

University of Pittsburgh Physicians
Department of Orthopaedic Surgery

Part of
UPMC Health System

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Pittsburgh, PA 15213-3221
Appointments: 412-687-3900
Fax: 412-687-3724
www.orthonet.upmc.edu

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Constance R. Chu, MD
Joint Reconstruction
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Peter Z. Cohen, MD
Joint Reconstruction / Orthopaedic Surgery
412-802-4100
Stephen F. Conti, MD
Foot and Ankle Surgery
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Lawrence S. Crossett, MD
Joint Reconstruction
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Pediatric Orthopaedic / Scoliosis
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Bruce H. Ziran, MD
Orthopaedic Trauma
412-605-3327

AUTHORIZATION FOR THE SHARING OF HEALTH INFORMATION RELATED TO POSSIBLE PARTICIPATION IN A RESEARCH STUDY

Title of Research Study:

Conservative Treatment of Plantar Fasciitis with Dorsiflexion Night Splint and Medial Arch Supports: a Prospective Randomized Study

Research Study Investigators:

Principal Investigator:

Ahmad Al-Ghadir, MS, PT, PhD Candidate, Department of Physical Therapy, Room 6010A Forbes Tower, Pittsburgh, PA 15260. Telephone: 412-726-1826

Co-Investigators:

Anthony Delitto, PhD, PT, FAPTA, Associate Professor and Chair, Department of Physical Therapy, Room 6036 Forbes Tower, Pittsburgh, PA 15260. Telephone: 412-383-6631

Dane Wukich, MD, Assistant Professor, Department of Orthopaedic Surgery, Suite 1010 Kaufmann Medical Building, Pittsburgh, PA 15213. Telephone: 412-687-3900

James Irrgang, PhD, PT, ATC, Associate Professor and Vice Chair of Clinical Services, Department of Physical Therapy, Room 6010A Forbes Tower, Pittsburgh, PA 15260. Telephone: 412-647-1237

Ray Burdett, PhD, PT, CPed, Associate Professor and Assistant Dean of Undergraduate Programs, Department of Physical Therapy, Room 6022 Forbes Tower, Pittsburgh, PA 15260. Telephone: 412-383-6704

Patient's Initials: _____

B.1 WHAT IS THE PURPOSE OF THIS AUTHORIZATION?

Your doctor or a member of your doctor's health care staff has discussed with you that you may be eligible to take part in the above-named research study. You have indicated an interest in learning more about this research study from the researchers who are involved in conducting the study. Thus, your authorization (permission) is being requested to:

- share the fact that you are interested in participating in this study with the involved researchers;
- share only your medical diagnosis which suggests you may be eligible to take part in this study with the involved researchers; and
- allow the involved researchers to contact you so as to permit additional discussions of this study with you and/or to provide you with information on how you may take part in this study.

B.2 WHAT INFORMATION ABOUT ME WILL BE SHARED WITH THE RESEARCHERS?

If you give your permission, the following information about you will be shared (for example, by telephone or FAX) with the researchers involved in the conduct of the above-named research study:

- your name, address, and telephone number
- only your medical diagnosis which suggests you may be eligible for this research study
- your interest in being contacted for the research
- a copy of this signed document

B.3 TO WHOM WILL THE ABOVE INFORMATION BE GIVEN?

We will share this information with one of the researchers listed above or a member of their research staff. This information will be used by the researchers to evaluate if you are eligible to participate in this research study and/or to contact you to further discuss this research study with you.

These researchers recognize the importance of maintaining the confidentiality (privacy) of your health information; however, it is not possible for us to guarantee its confidentiality after we have provided it to them.

Patient's Initials: _____

B.4 FOR HOW LONG IS AUTHORIZATION VALID?

Once this information has been shared with the researchers, this authorization form will expire. We will not continue to share your future health information with these researchers, nor will we share your health information with any other researchers unless you sign a separate authorization form that permits us to do so.

B.5 IS MY PERMISSION TO PROVIDE THIS INFORMATION TO THE RESEARCHERS VOLUNTARY?

Your permission to provide this information to the researchers is completely voluntary. Whether or not you provide your permission will have no affect on your current or future medical care or your relationship with your doctor or health care provider. Whether or not you provide your permission will have no affect on your current or future relationship with the University of Pittsburgh or University of Pittsburgh Medical Center.

B.6 MAY I WITHDRAW, AT A FUTURE DATE, MY PERMISSION TO PROVIDE THIS INFORMATION TO THE RESEARCHERS?

You may withdraw, at any time, your permission to provide this information to the researchers. However, once this information has been shared with the researchers, the information will be in their possession. Hence, should you decide to withdraw your permission after your information has been given to the researchers you should send a written and dated notice of this decision to the principal investigator of this research study at the address listed above. Upon receipt of this request, the researchers will destroy your information that was provided to them. If you wish to withdraw your permission to provide this information to the researchers before it is given to them, you should contact, by telephone, your doctor or a member of your doctor's health care staff. With receipt of this request, your information will not be shared with the researchers.

Your decision to withdraw your permission to provide this information to the researchers will have no effect on your current or future medical care or your relationship with your doctor or health care provider. Your decision to withdraw your permission will have no affect on your current or future relationship with the University of Pittsburgh or University of Pittsburgh Medical Center.

****

VOLUNTARY AUTHORIZATION

Patient's Initials: _____

All of the above has been explained to me. By signing below I give my permission to share the information, specified above, with the researchers, identified above, for the purposes described.

_____
Printed Name of Patient

_____ _____
Signature of Patient Date

APPENDIX C

PATIENT'S INFORMATION CHART

-Name: ……
-Phone numbers:
    home: ……
    work: ……
    cellular: ……
-Date (MM/DD/YYYY): ……
-Gender: ……
-Foot size: ……

APPENDIX D

PUBLIC ADVERTISEMENT

University of Pittsburgh

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Department of Physical Therapy

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Pittsburgh, Pennsylvania 15260
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Fax: 412-383-6629
http://www.shrs.pitt.edu/physicaltherapy/

RESEARCH PARTICIPANTS NEEDED

The Department of Physical Therapy in the School of Health and Rehabilitation Sciences at the University of Pittsburgh is currently conducting a study to examine the combined effect of night splints and arch supports in the treatment of plantar fasciitis.

If you are at least eighteen years of age and have inferior **HEEL PAIN** that is provoked by taking the first few steps in the morning or by prolonged standing, you may qualify to take part in this study.

Participation in this study will require you to attend two visits at the University of Pittsburgh Medical Center (UPMC) Center for Sports Medicine. The initial visit will last for approximately 30 minutes. The follow-up visit will take place after six weeks of treatment with a night splint, an arch support, or a combination of both, and will last for approximately 15 minutes. During these visits, your heel tenderness will be measured and you will be asked to complete several questionnaires regarding the pain and difficulty you have performing everyday activities because of your heel pain.

Neither you nor your health insurance provider will be charged for the costs of any assessment performed or treatment provided for the purpose of this study.

If you are interested in participating or would like further information concerning this study, please contact **AHMAD** at **412-726-1826** or **aha31@pitt.edu**

APPENDIX E

CONSENT FORM

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CONSENT TO ACT AS AN EXPERIMENTAL PARTICIPANT IN A RESEARCH STUDY

TITLE: Conservative Treatment of Plantar Fasciitis with Dorsiflexion Night Splints and Medial Arch Supports: a Prospective Randomized Study

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SOURCE OF SUPPORT: Saudi Arabian Cultural Mission

Patient's Initials: _____

E.1 WHY IS THIS RESEARCH 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 the first few steps in the morning and by prolonged standing. The literature provides evidence to support the use of dorsiflexion night splints (splints that hold the foot and toes in extended position during sleep to stretch and, thus, prevent tightness of the plantar fascia and Achilles tendon) and medial arch supports in the treatment of plantar fasciitis. A night splint is used to address early morning pain by preventing tightness of the plantar fascia and Achilles tendon overnight. An arch support, on the other hand, addresses the end of the day pain by preventing overstretch of the plantar fascia during prolonged standing. Therefore, both night splints and arch supports may be necessary to treat plantar fasciitis as they complement each other by controlling tightness of the plantar fascia and Achilles tendon that develops overnight and reducing stresses imposed on the plantar fascia during the day, respectively. No previous study, to the best of our knowledge has been conducted to examine the combined effect of night splints and arch supports in the treatment of plantar fasciitis. The purpose of this study is to compare the effect of combining a night splint and arch support to the effect of either a night splint or arch support alone on heel tenderness, pain, and disability.

E.2 WHO IS BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to participate in this study because you have been diagnosed with or have symptoms of plantar fasciitis. You are also being asked to participate in this study because you have no previous foot surgery, traumatic foot injury, other conditions affecting the foot such as arthritis, or prior treatment for your plantar fasciitis with a night splint or arch support. In addition, you are not being treated for a work-related injury and you are at least eighteen years of age.

Patient's Initials: _____

E.3 WHAT PROCEDURES WILL BE PERFORMED FOR RESEARCH PURPOSES?

If you decide to take part in this research study, you will undergo the following procedures:

- In order to participate in this study, you will be required to discontinue use of current treatment modalities, except medications that are used for reasons other than plantar fasciitis, at least three days before the initial visit.
- During the initial visit, the principal investigator will first obtain background information about you such as your age, sex, involved side, duration of symptoms prior to treatment, average number of hours per day during which you are on your feet, number of previous corticosteroid injections, and current medication use (will require about 5 minutes of your time). You will then be asked to complete several questionnaires regarding the pain and difficulty you have performing everyday activities because of your heel pain (will require about 10 minutes of your time), and the investigator will measure your height, weight, arch height, range of motion, and heel tenderness (will require about 10 minutes of your time). Once the measurements are completed, the investigator will randomly assign you (for example, by flip of a coin) to one of three six-week intervention groups. The investigator will then provide you with either the night splint and/or arch support (you may receive the night splint alone, the arch support alone, or a combination of both) and will give you instructions for its use (will require about 5 minutes of your time). If you are given the night splint, you will be instructed to wear it only while sleeping; and if you are given the arch support, you will be instructed to use it whenever you are on your feet. At the end of the initial visit, the investigator will schedule you for the follow-up visit in six weeks.
- At three weeks, the investigator will contact you by phone to answer any questions, discuss any concerns, encourage continued participation, and record compliance (will require about 5 minutes of your time).
- During the follow-up visit, you will complete questionnaires regarding your pain and ability to perform daily activities (will require about 10 minutes of your time), and the investigator will measure your range of motion and heel tenderness and will record your compliance (will require about 5 minutes of your time). If you do not return for the follow-up visit, the investigator will contact you by phone to encourage continued participation and reschedule the appointment. You will be permitted to keep the night splint and/or arch support after the study is completed.
- Both the initial and follow-up visits will take place at the University of Pittsburgh Medical Center (UPMC) Center for Sports Medicine.

Patient's Initials: _____

E.4 WHAT ARE THE POSSIBLE RISKS, SIDE EFFECTS, AND DISCOMFORTS OF THIS RESEARCH STUDY?

Possible symptoms and/or problems associated with the use of night splints may include transient numbness of the toes, leg cramps, and difficulty sleeping. These risks are common, that is, they occur in 10 to 25% (10 to 25 out of 100 individuals) of the people who use the night splints. To minimize these risks, the principal investigator will advise you to adjust the wedge placed under your toes. Some patients may feel general leg discomfort or soreness until they get used to wearing the arch supports. Development of general leg discomfort with the use of arch supports occurs infrequently, that is, it occurs in 1 to 10% (1 to 10 out of 100 individuals) of the people who use the arch supports. To minimize this, the principal investigator will advise you to use a deep pair of shoes to accommodate the arch supports. In addition, some patients may develop pressure sores or ulcers from the use of night splints and/or arch supports. However, the principal investigator will provide you with a well-padded night splint and/or arch support to minimize these risks. With such well-cushioned night splints and arch supports, these risks become rare, that is, they occur in less than 1% (less than 1 out of 100 individuals) of the people who use well-padded night splints and/or arch supports. Moreover, the fact that those with decreased plantar foot sensation will be excluded from the study will also minimize these risks. All these risks are mild in severity.

E.5 WHAT ARE THE POSSIBLE BENEFITS FROM TAKING PART IN THIS RESEARCH STUDY?

Participation in this study may lead to decreased heel tenderness and pain and 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.

Patient's Initials: _____

E.6 WHAT TREATMENTS OR PROCEDURES ARE AVAILABLE IF I DECIDE NOT TO TAKE PART IN THIS RESEARCH STUDY?

If you decide not to participate in this research study, you will still receive the medical care and/or physical therapy as prescribed by your physician, which may or may not include the use of a night splint and/or arch support. Alternative treatments may include non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, ice massage, footwear, foot taping, heel pads, walking casts, stretching and strengthening exercises, and/or surgical intervention.

E.7 IF I AGREE TO TAKE PART IN THIS RESEARCH STUDY, WILL I BE TOLD OF ANY NEW RISKS THAT MAY BE FOUND DURING THE COURSE OF THE STUDY?

You will be promptly notified if any new information develops during the conduct of this research study that may cause you to change your mind about continuing to participate.

E.8 WILL I OR MY INSURANCE PROVIDER BE CHARGED FOR THE COSTS OF ANY PROCEDURES PERFORMED AS PART OF THIS RESEARCH STUDY?

Neither you nor your insurance provider will be charged for the costs of any of the research procedures performed for the purpose of this research study. Funds from the Saudi Arabian Cultural Mission will cover the costs of all services associated with this study including night splints and arch supports. You or your insurer will be billed for any standard care services not done for the purpose of the research study and will be responsible for any co-pays, co-insurances, or deductibles.

Patient's Initials: _____

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

You will not be paid for participation in this study.

E.10 WHO WILL PAY IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH STUDY?

University of Pittsburgh researchers and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of your participation in this study. If you believe that you are injured as a result of the research procedures being performed, please contact the principal investigator or one of the co-investigators listed on the first page of this form immediately. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. You will not receive any monetary payment for, or associated with, any injury that you suffer in relation to this research.

E.11 WHO WILL KNOW ABOUT MY PARTICIPATION IN THIS RESEARCH STUDY?

To ensure that the confidentiality of any information obtained about you from this research study is maintained, records associated with your participation in this study will be stored in a locked file cabinet. Your identity on these records will be indicated by a unique three-digit code rather than by your name. Information linking your code to your identity will be accessible only to the investigators and their research team and will be stored in a locked file separate from the research records. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

E.12 WILL THIS RESEARCH STUDY INVOLVE THE USE OR DISCLOSURE OF MY IDENTIFIABLE MEDICAL INFORMATION?

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will include information concerning diagnosis and treatment of plantar fasciitis. This information will be used to help describe the general characteristics of people who participated in the study.

This research study will not result in any identifiable information that will be placed into your medical records.

E.13 WHO WILL HAVE ACCESS TO IDENTIFIABLE INFORMATION RELATED TO MY PARTICIPATION IN THIS RESEARCH STUDY?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.
- In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law.

Patient's Initials: _____

- If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

E.14 FOR HOW LONG WILL THE INVESTIGATORS BE PERMITTED TO USE AND DISCLOSE IDENTIFIABLE INFORMATION RELATED TO MY PARTICIPATION IN THIS RESEARCH STUDY?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period of time. It is a University policy that all research records must be maintained for at least five years following study completion.

E.15 MAY I HAVE ACCESS TO MY MEDICAL INFORMATION THAT RESULTS FROM MY PARTICIPATION IN THIS RESEARCH STUDY?

In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

E.16 IS MY PARTICIPATION IN THIS RESEARCH STUDY VOLUNTARY?

Your participation in this research study, to include the use and disclosure of your identifiable medical information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable medical information for the purposes described above, you will not be allowed, in general, to participate in the research study). Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated healthcare provider or your current or future relationship with a health care insurance provider.

Your physician may be involved as an investigator in this research study. As both your physician and a research investigator, he/she is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another physician who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

E.17 MAY I WITHDRAW, AT A FUTURE DATE, MY CONSENT FOR PARTICIPATION IN THIS RESEARCH STUDY?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable medical information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study). Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Patient's Initials: _____

E.18 IF I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY, CAN I BE REMOVED FROM THE STUDY WITHOUT MY CONSENT?

The investigators may withdraw your participation if for example you are unable to tolerate or comply with the use of the night splint or arch support. Any identifiable research or medical information recorded for, or resulting from your participation in this research study prior to the date that you are withdrawn from participation may continue to be used and disclosed by the investigators for the purposes described.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my questions have been answered. Any future questions I have about this research study will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions be answered by a listed investigator. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate, Institutional Review Board Office, University of Pittsburgh (866-212-2668). A copy of this consent form will be given to me.

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

_____ _____

Signature of Patient Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

APPENDIX F

INITIAL VISIT DATA RECORDING FORM

-Patient's ID code: ……
-Date (MM/DD/YYYY): ……
-Participation status: ……..

F.1 DEMOGRAPHIC INFORMATION

-Age: ……
-Gender: ……
-Unilateral or bilateral involvement: ……
-Involved side: ……
-Duration of symptoms prior to treatment (in months): ……
-Average number of hours per day for which the patient is on his/her feet: ……
-Number of previous corticosteroid injections: ……
-Medications currently used:

1 ……	6 ……..
2 ……	7 ……..
3 ……	8 ……..
4 ……	9 ……..
5 ……	10 ……..

-Height (in centimeters): ……
-Weight (in kilograms): ……
-Arch index from standing: ……
    navicular height (in centimeters): ……
    foot length (in centimeters): ……
-Navicular drop (in millimeters): ……
    navicular height from subtalar neutral position (in millimeters): ……
    navicular height from relaxed standing (in millimeters): ……

F.2 BASELINE EVALUATION

-Range of pain-free passive ankle joint dorsiflexion with straight knee: ……
-Range of pain-free passive ankle joint dorsiflexion with bent knee: ……
-Plantar heel tenderness: ……

-Plantar heel pain (place a mark on the line in a position which best represents your experience in the **past week**, or answer the question **not applicable** (NA) if you did not perform or were not involved in the activity in question): ……

How severe is your heel pain:		**NA**
1. At its worst?		
No pain _____	Worst pain imaginable	_____
2. After you get up in the morning with the first few steps?		
No pain _____	Worst pain imaginable	_____
3. At the end of the day?		
No pain _____	Worst pain imaginable	_____
4. When you walk barefoot?		
No pain _____	Worst pain imaginable	_____
5. When you stand barefoot?		
No pain _____	Worst pain imaginable	_____
6. When you walk wearing shoes?		
No pain _____	Worst pain imaginable	_____
7. When you stand wearing shoes?		
No pain _____	Worst pain imaginable	_____
8. When you walk wearing orthotics?		
No pain _____	Worst pain imaginable	_____
9. When you stand wearing orthotics?		
No pain _____	Worst pain imaginable	_____

-Disability imposed by the heel pain/plantar fasciitis (place a mark on the line in a position which best represents your experience in the **past week**, or answer the question **not applicable** (NA) if you did not perform or were not involved in the activity in question): ……

How much difficulty do you have:		**NA**
1. Walking in house?		
No difficulty	_____	So difficult unable _____
2. Walking outside?		
No difficulty	_____	So difficult unable _____
3. Walking four blocks?		
No difficulty	_____	So difficult unable _____
4. Running or walking fast?		
No difficulty	_____	So difficult unable _____
5. Climbing stairs?		
No difficulty	_____	So difficult unable _____
6. Descending stairs?		
No difficulty	_____	So difficult unable _____
7. Climbing curbs?		
No difficulty	_____	So difficult unable _____
8. Standing on tip toe?		
No difficulty	_____	So difficult unable _____
9. Getting up from chair?		
No difficulty	_____	So difficult unable _____

F.3 RANDOMIZATION

-Assigned group: ……

F.4 TREATMENT

-Provide the treatment modality that corresponds with the group assignment to the patient and instruct him/her on its use: ……
-Instruct the patient to discontinue use of any other intervention modalities, except medications that are used for reasons other than plantar fasciitis, at least three days before the initial visit, and encourage him/her not to change his/her activity level during the six-week enrollment in the study: ……

APPENDIX G

PHONE CALL DATA RECORDING FORM

-Patient's ID code: ……
-Date (MM/DD/YYYY): ……
-Participation status: ……..

G.1 COMPLIANCE

-What is the average percentage of sleeping hours wearing the night splint during the last three weeks: ……
-What is the average percentage of weight bearing hours using the arch support during the last three weeks: ……

G.2 QUESTIONS AND CONCERNS

-Questions:
1 ……
2 ……
3 ……
4 ……
5 ……
-Concerns:
1 ……
2 ……
3 ……
4 ……
5 ……

APPENDIX H

FOLLOW-UP VISIT DATA RECORDING FORM

-Patient's ID code: ……
-Date (MM/DD/YYYY): ……
-Participation status: ……..

H.1 POST-INTERVENTION EVALUATION

-Range of pain-free passive ankle joint dorsiflexion with straight knee: ……
-Range of pain-free passive ankle joint dorsiflexion with bent knee: ……
-Plantar heel tenderness: ……

-Plantar heel pain (place a mark on the line in a position which best represents your experience in the **past week**, or answer the question **not applicable** (NA) if you did not perform or were not involved in the activity in question): ……

How severe is your heel pain:		**NA**
1. At its worst?		
No pain _____	Worst pain imaginable	_____
2. After you get up in the morning with the first few steps?		
No pain _____	Worst pain imaginable	_____
3. At the end of the day?		
No pain _____	Worst pain imaginable	_____
4. When you walk barefoot?		
No pain _____	Worst pain imaginable	_____
5. When you stand barefoot?		
No pain _____	Worst pain imaginable	_____
6. When you walk wearing shoes?		
No pain _____	Worst pain imaginable	_____
7. When you stand wearing shoes?		
No pain _____	Worst pain imaginable	_____
8. When you walk wearing orthotics?		
No pain _____	Worst pain imaginable	_____
9. When you stand wearing orthotics?		
No pain _____	Worst pain imaginable	_____

-Disability imposed by the heel pain/plantar fasciitis (place a mark on the line in a position which best represents your experience in the **past week**, or answer the question **not applicable** (NA) if you did not perform or were not involved in the activity in question): ……

How much difficulty do you have:		**NA**
1. Walking in house?		
No difficulty	_____	So difficult unable _____
2. Walking outside?		
No difficulty	_____	So difficult unable _____
3. Walking four blocks?		
No difficulty	_____	So difficult unable _____
4. Running or walking fast?		
No difficulty	_____	So difficult unable _____
5. Climbing stairs?		
No difficulty	_____	So difficult unable _____
6. Descending stairs?		
No difficulty	_____	So difficult unable _____
7. Climbing curbs?		
No difficulty	_____	So difficult unable _____
8. Standing on tip toe?		
No difficulty	_____	So difficult unable _____
9. Getting up from chair?		
No difficulty	_____	So difficult unable _____

H.2 COMPLIANCE

-What is the average percentage of sleeping hours wearing the night splint during the last three weeks: ……
-What is the average percentage of weight bearing hours using the arch support during the last three weeks: ……

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