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The Effects of a Rigid Shoe Midsole on Plantar Fasciitis in Runners

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THE EFFECTS OF A RIGID SHOE MIDSOLE ON PLANTAR FASCIITIS IN RUNNERS

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ABSTRACT

Plantar fasciitis is a common overuse injury in runners accounting for almost 10% of all injuries. (45) An excessively flexible shoe midsole or shank may be at fault for the development of plantar fasciitis in runners because of the unnecessary stretching of the plantar fascia ligament. (9;12;48) The main **purpose** of the study was to assess whether a change in shoe midsole flexibility would influence gait behavior and/or accelerate recovery time from plantar fasciitis. **Method:** Eighteen male and female (M= 10: F= 8) subjects participated for 3-months performing their normal exercise activities and either wearing shoes prescribed by the study (> 27 N/mm in stiffness) or remained in their current shoes. Mean age, mass, height and years running for the experimental group were 41.9 yrs, 147.3 lbs, 167.1 cm and 13.7 yrs and the control group were 45.3 yrs, 199.7 lbs, 180 cm and 15.3 yrs, respectively. Participants attended 3-separate sessions (initial, 45 & 90 days post initial visit). Pre and post kinematic parameters were collected for rear foot, ankle, knee and hip angles (degrees) while running at a speed of 3.0m/s. Shoe shank-midsole motion (mm) was also evaluated to determine dynamic flexibility of the shoe. **Results:** Significant differences were found between groups for range of motion (ROM) of the rear foot angle and mid shoe shank compression motion as well as pain level ($p<0.05$). The experimental group increased rear foot ROM, slightly decreased mid shoe shank ROM motion and decreased pain level. The control group decreased rear foot angle, decreased mid shoe shank ROM and maintained pain level. No significant differences were found for ankle, knee and hip angles. **Conclusion:** A stiffer shoe could potentially dissipate or transfer forces exerted on the foot away from the plantar fascia to alleviate strain during stance phase of running. Significant relief from the symptoms of plantar fasciitis can be attained with the use of a stiffer shoe. No generalizations can be drawn for ankle, knee and hip ROM because too many adaptations patterns exist among runners.

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LIST OF ABBREVIATIONS

CCF	The Cleveland Clinic Foundation
EVA	Ethylene vinyl acetate
GRF	Ground reaction force
PF	Plantar fasciitis
PU	Polyurethane
ROM	Range of Motion

CHAPTER 1

1.1 INTRODUCTION

Over the years, the popularity of the sport of running has risen exponentially. Albeit, at the cost of corresponding running injuries, which have also risen simultaneously. As such, plantar fasciitis and its associated symptoms have been increasingly reported in small case podiatric offices nationwide and has become one of the most common foot injuries amongst the running population. (17) Plantar fasciitis is the inflammation of the plantar fascia ligament, which spans the posterior side of the foot. It is associated with acute symptoms such as heel pain, inflammation and swelling.(17) If this condition is not treated appropriately, micro tears may arise, followed by calcification of the soft tissue, which can ultimately form bone spurs and result in immense and chronic pain. (40) In extreme conditions, the plantar fascia can be pulled from the point of insertion on the medial calcaneal tuberosity. (17) In addition, when the plantar fascia ligament is stiff, strain is transferred to the supporting tissues resulting in further injury. (6)

The treatment for plantar fasciitis is quite variable and ranges from more conservative approaches to more invasive ones. Conservative modifications include: shoe adjustments, custom inserts, stretching exercises, physical therapy, nonsteroidal anti-inflammatory medications, and night splints. (11; 22) More invasive approaches include: cortisone injections, surgery and extracorpeal shock wave therapy. (22; 43) If plantar fasciitis is treated in the early stages, conservative treatments have been shown to be effective in alleviating symptoms in 80 % of cases. (22)

The role of the plantar fascia is to maintain flexibility under tension as it anchors both the proximal and distal structures of the arch. It prevents the medial and longitudinal arch from collapsing by limiting subtalar joint pronation, provides forefoot/rear foot stability against the supporting surfaces and resupinates the foot synergistically with the Achilles tendon to add power in midstance to the initiation of swing. Any mechanical factor disrupting this sequence for forward progression disturbs the function of the plantar fascia and can lead to fasciitis.

Although, medical experts do not entirely agree on the specific cause of plantar fasciitis, most health practitioners and investigators include the following etiologies: overuse, biomechanical/ anatomical abnormalities, uneven training surfaces, shape and structure of the foot, quality of shoe gear, tight calf muscles and/or achilles tendons, and limited dorsiflexion of the ankle joint. (2; 16; 17; 40) Reports have also associated plantar fasciitis with other health ailments such as obesity. (37)

Past research has alluded to the idea that an excessively flexible midsole or shank, the portion of the shoe that extends from the heel to the ball of the foot and sits above the outer sole, (41) may be a factor to consider for the development of plantar fasciitis in runners. This is because of the unnecessary stretching of the plantar fascia ligament. (9;12;17;48) This said, the midsole region of the shoe has the potential in reducing or preventing injury because this region determines the overall cushioning properties of the shoe. (12;18) To date, no scientific research has investigated the correlation between varying midsole stiffness and injury, in particular, plantar fasciitis.

The midsole acts as the shoes cushioning system by protecting the foot from the ground, decreasing shock impact, and evenly distributing foot pressure. (41) As well, the midsole functions to reduce the amount of twisting that takes place in front of the shoe.(27) The midsole region is mainly compromised of polyurethane (PU) and/or ethylene vinyl acetate (EVA) materials and the density of these materials determine the overall stiffness of the shoe. (41)

Researchers have examined the role of varying shoe stiffness on runners overall mechanics but this has only been done on injury free participants. Outcome variables such as vertical impact forces, ankle movement, and internal loading have been evaluated. Although it is important to evaluate healthy individuals, it is equally important to look at injured participants as their biomechanics are altered due to injury.

A review of the available literature reveals that further research is warranted in order to better understand the full extent of the effects of shoe midsole flexibility on the development and subsequent recurrence of plantar fasciitis. Hence, the main purpose of the study was to assess whether a change in shoe midsole flexibility would influence gait behavior and/or accelerate recovery time from plantar fasciitis. Indeed, by controlling participants shoe gear, the corresponding response (recurrence of plantar fasciitis) will be monitored and outcome of treatment evaluated.

1.2 Justification for Research

Over the years, plantar fasciitis has become one of the most common foot injuries amongst the running population. (17) It has been speculated that running shoes that have a flexible midsole can be at fault for the development of this condition because of the unnecessary stretching of the plantar fascia ligament. To date, no scientific research has investigated the effects of varying midsole hardness on those diagnosed with plantar fasciitis. Since this condition can lead to an unbearable outcome, such as chronic pain, it is only logical to find means to alleviate those symptomatic of plantar fasciitis by exploring all aspects such as the shoe design.

1.3 Primary research question

The identification of different kinematics in plantar fasciitis runners running in different shoes.

1.4 Specific research question

The main purpose of the study was to assess whether a change in shoe midsole flexibility would influence gait behavior and/or accelerate recovery time from plantar fasciitis. By controlling the subject's shoe gear, the corresponding response (resolution or recurrence of plantar fasciitis) will be monitored and outcome of treatment evaluated.

1.5 Research hypotheses

***Hypothesis 1*:** The use of shoes whose stiffness characteristics fall above the threshold of 27 N/mm will accelerate the recovery of plantar fasciitis due to a change in the structural properties of the shoe.

***Hypothesis 2*:** The change to a stiffer shoe will reduce rear foot angle, as less movement will take place in the subtalar joint.

Hypothesis 3: A change to a stiffer shoe will decrease ankle motion in the sagittal plane.

***Hypothesis 4*:** A stiffer shoe will reduce range of motion at the knee.

Hypothesis 5: A stiffer shoe will reduce range of motion at the hip.

1.6 Limitations

The sample population was limited to those that had symptoms of uni- or bilateral plantar fasciitis within the last six months, were active runners – ran at least 10 miles per week, agreed to perform stretching exercises once a day and ice after running if necessary for 90 days and had shoe stiffness values greater than 27 N/mm. The original number of participants to be recruited was thirty. The results on eighteen subjects are presented. Twenty-four participants were tested and eighteen remained in the study. This drop in number was due to that some subjects developed other foot ailments other than plantar fasciitis and some participants did not qualify for the study at the initial session because their current running shoes were above the desired shoe stiffness threshold (>27Nm) when subjected to mechanical testing. The study did not reach the goal of testing thirty participants because of difficulty recruiting participants coupled with time constraints. All testing sessions were performed on a standardized treadmill.

1.7 Delimitations

There were several variables the study was unable to maximally control. It was assumed participants complied with the requirements of the study away from the testing sessions. The study relied on honesty of the participants. As such, participants may not have run the minimum amount of running required to take part in the study, which was 10 miles per week. Though, at each testing session, participants were asked to indicate via participant history questionnaire their estimated average mileage run per week. Examining the recorded data, large differences were not seen between groups.

Participants may not have performed stretching exercises before and after each run. Also, it was out of the studies control if participants sought other treatment for their condition. However, subjects were asked via participant history questionnaire if they sought other treatment or developed any other condition. In addition, the assessment of the Podiatrist at 45 days was used to address the above questions and was documented.

Precision of marker placement for the measurement of kinematics from pre and post assessments may not have been 100 % accurate. However, intra-reliability and validity was controlled by having the same person perform pre and post marker placements. Also, because the participants were runners and thus had reduced fat tissue, it was easy for the tester to find landmarks for marker placement.

CHAPTER 2

REVIEW OF LITERATURE

2.1 Overview

Key components that surround plantar fasciitis must be outlined for a better understanding of this foot ailment. As such, pertinent concepts include: the context of running as a sport, biomechanics of the foot, current athletic shoe design, pathology of plantar fasciitis, shoe design and runners, plantar fasciitis and runners and finally plantar fasciitis, runners and shoe design as a whole.

2.2 Running as a Sport

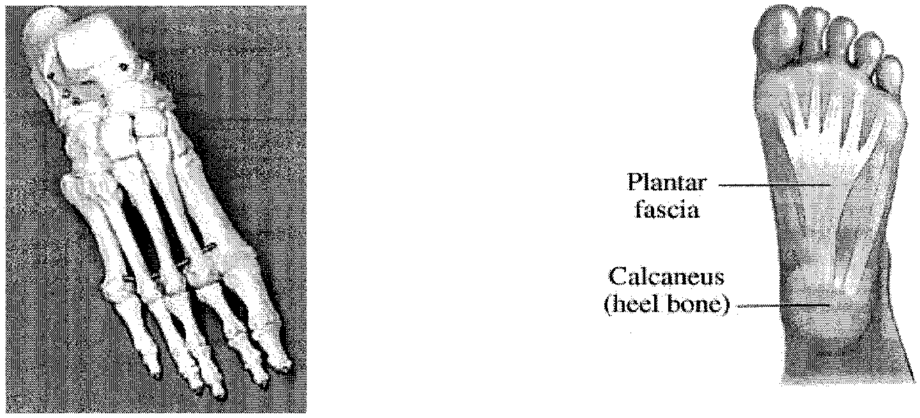
During moderate speed running, 3.0- 3.5 m/s, on flat surface, ground reaction forces reach two to three times body weight on the lower extremities.(47) During a marathon, the body is impacted with 25,000 heel strikes. (14) Moreover, between 27 and 70% of runners or joggers are injured in a period of 1 year.(33) Indeed, a review conducted by McClay (24) indicated that 50% to 75% of running injuries are attributed to overuse. Of these injuries, plantar fasciitis has become the most common foot condition in podiatric offices. (17) Clearly, running has a significant impact on the body and subsequent corresponding injuries. Seemingly, it is logical to address running related injuries as they have such an effect on the running population.

2.3 Biomechanics of the Foot

In order to understand foot problems associated with running, one has to consider the function of the foot, its anatomy, the different types of feet among individuals and associated biomechanics.

2.3.1 Anatomy of the Foot

The foot provides shock absorption, support and locomotion for the body. Main bones that comprise the foot unit include: talus, calcaneus, navicular, cuboid, cuneiforms, metartarsal, and phalanx bones (Figure 1a). Collectively, these bones act together to form joints that allow the body to be propelled forward. The organizations of these bones form the intricate concave longitudinal and transverse arches, which act as a unit to distribute weight of the body. This concave shape allows the body to absorb varying degrees of shock and allows the foot to adapt to different terrains. The bony network of the arches is maintained by the strength of the supporting plantar fascia ligament, and muscles. The remaining details of the foot unit are beyond the scope of this research; thus, the proceeding literature review will focus mainly on the plantar fascia ligament, as this ligament has a direct association with the foot condition plantar fasciitis.



a. Superior view of foot **b. Dorsal view of plantar fascia**

Figure 1. Foot structure

In isolation, the plantar fascia runs from the medial tubercle of the calcaneus and spans out to the proximal phalanges of the toes (Figure 1b). It acts to support as well as protect the transverse and longitudinal arches of the foot, absorbs shock and assists in propelling the body forward. This ligament is anatomically described as a thick white band of fibrous connective tissue. Ultimately, the predominant role of the plantar fascia is to prevent the foot from spreading out.(17)

The plantar fascia plays a predominant role in locomotion. If this ligamentous soft tissue is injured, its function deteriorates and results in subsequent invasive damage. This provides evidence regarding the importance of exploring the cause of the corresponding foot condition, plantar fasciitis and to determine the most effective preventative as well as curative means to accommodate those diagnosed with this condition.

2.3.2 Foot Types

Foot types are classified according to alignment of the forefoot to rear foot and the corresponding shape of the arch. Root, Orien and Weed (39) established three main foot types: *pes cavus*, *pes planus* and *rectus* foot. A *pes cavus* foot is characterized by a high arched foot and is linked with excessive rearfoot varus. This can lead to uneven distribution of foot pressures, abnormal weight bearing during contact and decreased foot mobility.(47) A *pes planus* foot can be recognized by a low arch/ flat foot and associated with rearfoot valgus and excessive forefoot varus. This type of foot has been linked to abnormal loading, rotational stresses, hypermobility and increased susceptibility to pronation. (28;44) A *rectus* foot is characterized by a medium arched foot and is not associated with forefoot or rearfoot misalignment because it is considered the "normal" type of foot. Therefore, being able to discern between foot types is imperative due to the relevance it has in determining the underlying biomechanical significance of a foot injury.

2.3.3 Kinematics of Walking

Before one can understand the kinematics behind running, it is imperative to grasp the kinematics of walking (Figure 2). As described by Tylkowski, (46) the gait cycle is divided into two main phases: the *stance* phase and the *swing* phase. The stance phase is the weight bearing of one or two limbs that begins with heel contact and ends with toe-off of the same foot. The swing phase is the period of time in which the foot is off the ground and swinging in the forward direction. During the gait cycle, the majority of time, approximately 51-62%, is spent in the stance phase, whereas, the remainder of the time, approximately 38-42 %, is spent in swing phase.(47)

As outlined in a pathological gait syllabus by Ranchos Los Amigos Hospital, (36) the *stance* phase can further subdivide into: first double limb stance, single limb stance and second double limb stance. The first occurrence of double limb phase begins when the swinging limb contacts the ground. Subsequent to contact, the same limb moves forward and begins to bear more weight as the opposite foot lifts off the ground. The point at which the opposite foot is completely off the ground and body weight shifts to one limb, single limb stance begins. This stage is classified as the initial or early contact of single limb stance. It is at this point that the limb absorbs body weight. Subsequent to contact, two other phases are involved in the single limb stance: middle and terminal. Middle phase, the body moves forward over the support limb while the foot is flat on the ground. Terminal stance, the body continues to move forward ahead of the supporting foot. Fundamentally, each phase progresses into the next phase as the body moves forward and weight shifts from the heel to the toe over the supporting limb. The second period of double limb phase begins when the opposite foot contacts the ground causing weight transfer from the initial contact limb.

Swing phase begins with toe off and can further be subdivided into: early, middle and late phases. As with the second double limb contact, each of these stages progresses into subsequent phases as the body moves forward and the position of the swinging limb shifts forward. Early or initial swing, the thigh advances to attain toe clearance. Mid swing, the limb advances to achieve vertical tibial position. Terminal swing, tibial position is continued to full knee extension until desired step length is reached. In essence, this stage prepares for thigh deceleration and foot position for heel contact.

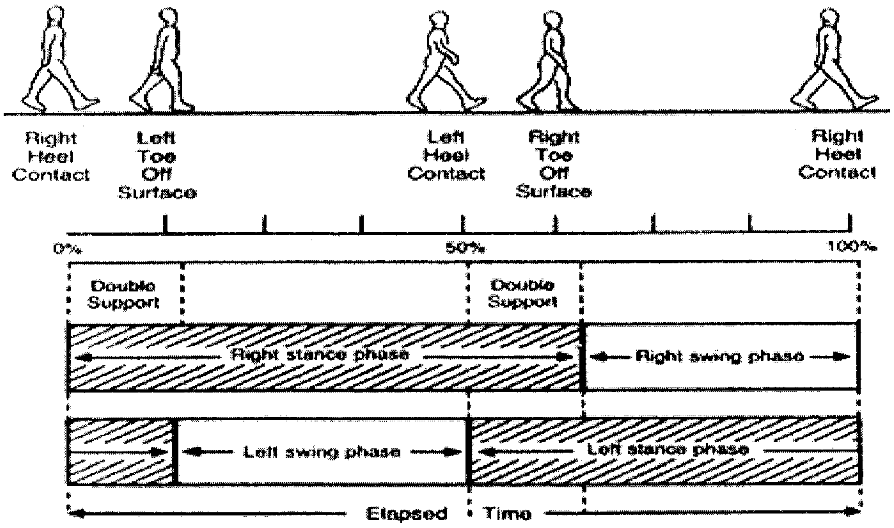


Figure 2. Gait cycle during walking

In effect, the body follows a sequence of steps in order to propel and move the body in a forward direction. If one of these steps is altered in any capacity, then a negative sequence can be easily set off. Thus, understanding these cyclical phases and corresponding biomechanical movements will guide researchers in further understanding the underlying cause of foot related injuries such as plantar fasciitis.

2.3.4 Kinematics of Running

The proportions of each phase change as the speed increases, such as in running because of the changing ground forces. Accordingly, as running speed increases, the proportion of time spent in the stance phase decreases, while the time spent in swing phase increases. Thus, an inverse relationship exists between the stance and swing phase.(3;35;47) Another distinct marking from walking to running is when two periods of double limb stance turn into two periods of double float, as both feet spend more time in the air opposed to the ground.(35)

Since running produces higher impact forces, compared to walking, more damage can occur. An understanding of the differing characteristics between walking and running will help in exploring foot related injuries.

In relation to internal rotary movements, the following sequence is generally followed: calcaneous contacts the ground and everts until midstance, then the tibia internally rotates. Simultaneously, as calcaneal eversion is transferred to tibial rotation, the pelvis externally rotates which is followed by femoral external rotation.(16)

In accordance with the above mentioned, it has been found that an offset of this sequence can lead to injury. This is because runners follow a particular timing sequence and if there is any degree of a delay, subsequent events are thrown off balance. If this abnormal timing is repeated on a continual basis it will result in injury. Also, rear foot movement about the subtalar joint axis coupled with delayed timing, has been indicated to have the same negative affect.(10) Evidently, the sequence of events is crucial for biomechanical purposes, as an alteration could potentially cause harm.

2.3.5 Ankle Deviations

The kinematics of walking and running previously mentioned was an outline of a normal gait sequence. However, there are many deviations that can arise at any point during the cyclical process. Please refer to appendix C for an outline of the classical examples of ankle segment deviations.

2.4 Running Shoe Design

The function of the running shoe is to protect the foot from the stresses of running while simultaneously allowing the athlete to perform at their maximum potential.(9;41) With the increased numbers of individuals participating in the sport of running, running shoe companies are constantly required to produce and accommodate the comfort level of their clients while minimizing the risk of injury.

Nonetheless, there are questions as to which shoe type, motion control, cushioned or stability is the most appropriate for individuals with plantar fasciitis. Wernick and Volpe (47) suggested that mechanics of the movements involved in each specific sport, recurring injuries, playing terrain, and equipment used plays an intricate role and must be taken into consideration. Therefore, long distance runners should generally purchase athletics shoes that help control excessive motion and ease shock forces, as well as select a shoe relevant to their foot type and biomechanics. Novacheck (35) advocated that as long as the forefoot is in a neutral position within the shoe, it has the capability in reducing the amount of stress exerted on the plantar fascia ligament.

Hence, if appropriate shoes are not chosen, a person may offset their running biomechanics by forcing unnecessary loads on the lower extremities resulting in injury.(10;33) This suggests that running shoes play an important role as they have the potential to affect a person's mechanics. However, many of these suggestions are simply speculative and have not been experimentally tested.

The athletic shoe can be divided into two main sections: the upper and lower portions. Each respective section can be subdivided; the upper part is broken down into the vamp, quarter, toe box, throat, insole board and topline. Whereas, the lower section consists of the: outsole, shank/midsole and heel.(27) Due to the complex nature of a shoe design and its corresponding parts, the scope of this paper will focus on the shank or midsole of the shoe. As such, relative to the foot, the shoe shank or midsole extends from the heel to the ball of the foot and sits above the outer sole.(41) It acts as the shoes cushioning system by protecting the foot from the ground, decreasing shock impact and evenly distributing foot pressure.(41) As well, the midsole functions to reduce the amount of twisting that takes place in front of the shoe.(27) Two main types of material compromise the midsole: polyurethane (PU) and/or ethylene vinyl acetate (EVA) and the density of these materials determine the overall stiffness of the shoe.(41)

Studies, as early as the late 1980's, have indicated that the midsole has the potential capability in reducing or preventing injury because this region determines the overall cushioning properties of the shoe.(12;18) As a result, since this time, researchers have examined the role of varying shoe stiffness on injury free participants. Though, there has been no direct link made between running related injuries and the effect of shoe stiffness.

It has been suggested, however, in relation to plantar fasciitis, shoes that are too flexible in the midsole region alter forces exerted on the foot, which, in turn, cause an unnecessary stretch in the plantar fascia ligament.(16;17) The effects of instability in the midsole region, where the shoe flexes the most during motion, are transferred in both the transverse and longitudinal planes. Since both planes are affected, a two-fold outcome on the effectiveness of the running shoe is evident.(17)

The midsole region of the shoe plays an integral role in relation to foot control and protection of the foot. Perhaps, providing a stiffer midsole shoe will, in effect, provide incidences as to the role of the running shoe with regard to foot injuries. In other words, by investigating this aspect, shoe stiffness modification could potentially be used as an indicator when treating running injuries and thus clarify the uncertainty currently present in literature.

Three types of running shoes are currently available: cushioned, motion control and stability. Each respective shoe type has a specific role and function in relation to protection of the foot. A cushioned shoe is characterized as having extra cushioning in the midsole region and acts to reduce impact loads.(33) This shoe type is best suited for individuals that have a high arch foot (pes cavus foot). A motion control shoe is geared for cushion and maximum stability and is appropriate for low arch/ flat foot individuals (pes planus foot). A stability shoe is designed for cushion and moderate stability and is allocated for those that have a medium arch (rectus foot).(38)

2.5 Pathology of Plantar Fasciitis

In 85% of cases in which a person is diagnosed with plantar fasciitis, the etiology is unknown.(37) This is because plantar fasciitis is multi-factorial and cannot be narrowed to one exact cause. Indeed, many researchers have established that this condition can be caused by: health ailments such as obesity, overuse, biomechanical/ anatomical abnormalities, uneven training surfaces, shape and structure of the foot, quality of shoe gear, tight calf muscles and /or achilles tendons, and limited dorsiflexion of the ankle joint (i.e., (2;16;37;40))

The available literature suggests that the etiology of plantar fasciitis stems from over stretching of the thick ligament at this structure and subsequent inflammation and swelling. If this condition is not treated appropriately, micro tears may arise, followed by calcification of the soft tissue, which can ultimately form bone spurs and result in immense pain.(40) In extreme conditions, the plantar fascia can be pulled from the point of insertion on the medial calcaneal tuberosity.(17) Also, plantar fasciitis has been associated with pain in the heel, which is most intense with the first step in the morning but gradually improves with walking.

While running, pain is worse in the first portion of the run then resides during the run and peaks after the run.(2) Tenderness is usually located on the insertion of the plantar fascia located on the medial tubercle of the calcaneous.(2) In general, this injury is not caused by a single traumatic event; it is caused from repetitive stress loads such as in running.

In addition, when the plantar fascia ligament is stiff, strain is diffused to the supporting tissues resulting in further injury.(6) Since the plantar fascia ligament plays a crucial role in stabilizing the foot during weight bearing, when this ligament is impaired, it causes a lot of subsequent problems.

It is apparent that this condition can range from moderate symptoms such as inflammation and swelling, yet it can be as insidious as developing bones spurs. Since this condition can lead to an unbearable outcome such as chronic pain, it is only logical to find means to alleviate plantar fasciitis by exploring all aspects such of the shoe design.

2.6 Synopsis of Running and Midsole

A large spectrum of evidence outlining the effects of differing midsole shoe stiffness has been established on healthy participants while running. Outcome variables such as vertical impact forces, ankle movement, internal loading and performance have been evaluated. Though ankle movement research is most pertinent to the topic at hand, a brief overview of the remaining outcome variables indicated above will be mentioned. Surrounding outcome variables may help further understand possible influences on the relationship between the foot-ground-shoe. As such, the following will review existing literature.

A review conducted by Shorten (42) outlined the controversies that exist in relation to the effects of shoe cushioning on damping impact ground forces at heel strike. It was revealed that there is conflicting evidence to support this notion. Indeed, some researchers found no significant differences of heel peak forces (F_z) between shoes, while others deduced that heel peak forces (F_z) were increased with softer shoes. A study conducted by Nigg, Bahhlsen, Luethi, and Stokes (31) concluded that midsole hardness of shoes did not alter impact load but rather redistributed the load. Similarly, Cavanagh, Valiant and Misevich (5) reported that net forces of the shoe, foot and ground cannot be manipulated by shoe material because the forces must equal ground forces. However, they did suggest that different shoe material could affect the applied force by redistributing pressures exerted on the foot which would in turn change running patterns.

In addition, Kersting and Bruggemann, (19) in a longitudinal study (20 weeks), reported that external ground reaction forces (GRF) and internal impact loads (m/s) in the heel region as well as rear foot motion (degrees) were not statistically influenced by midsole hardness. Though, no significant results were found, tendencies were observed and explained. It was such that external forces underneath the foot had a tendency to increase with a softer shoe (45 shore C). This could have been due to the shoe giving out on impact because of the soft characteristics of the shoe. In their study they compared Asics brand name running shoes that differed in misdole hardness, 45°, 53° and 61° shore C, respectively. Another tendency noted was there were small differences between shoes for maximum impact force. It was suggested that impact forces cannot be altered by running shoes because too many adaptation patterns exist between runners.

A study conducted by McNair and Marshall (26) found similar findings such that no significant differences were found in peak acceleration (g) and time to peak acceleration (m/s) of the tibia at heel strike in four pairs of running shoes that differed in midsole hardness. Material tests using a mechanical release system revealed that there was a 17%, 30% and 4 % range for mean peak acceleration (g), time to peak acceleration (m/s) and kinetic energy absorbed (%), respectively across shoes. McNair and Marshall (26) pointed out that the time to peak acceleration (g) adopted from shoe material tests may have not been realistic to the "human-shoe interaction" because the times were below the recorded jogging test values (p.259). Accordingly, this may have influenced the final results of the study.

Conversely, Nigg and Liu $^{(32)}$ discovered using a simulated "lumped-mass-spring-damper" model of the foot that vertical peak forces (N) and maximal loading rates (N/m/s) were indeed higher in a hard midsole shoe compared to a soft shoe (p.850). They found that vertical peak force and maximal loading rate for the hard shoe were 1339 N and 90.7 N/m/s and for the soft shoe 1187 N and 54.4 N/m/s, respectively. These results were explained by the change in muscle tuning in that the harder shoe increased loading rate. The parameters of the hard and soft shoes were modeled from a previous study using a least square fit procedure.

In relation to foot movement, Clarke, Frederick and Hamill $^{(7)}$ examined rear foot movement while wearing increasingly stiffer shoes. Ten subjects ($N = 10$) ran at a speed of 3.8 m/s wearing shoes with 25, 35 and 45 durometer Shore A, respectively. Significant differences ($p < 0.05$) were found between shoes such that maximum pronation (degrees), total rear foot movement (ROM; degrees) and time to maximum velocity (m/s) increased with the softer shoe.

Moreover, a study conducted by Kurz and Stergiou $^{(21)}$ outlined the effects of differing footwear densities on the peripheral sensory system by examining ankle movement in the sagittal plane (plantarflexion and dorsiflexion) (degrees) while running. They ascertained that as mechanoreceptors, located on the plantar side of the foot, are activated, the variability in ankle joint movement will increase and along with corresponding muscle activation. This said, in the event that a softer shoe would be worn, the above sequence would be reversed causing a decrease in sensory perception, which may result in further injury.

Athletic footwear compared to bare feet, changed variability of ankle movement such that the amount of motion at the ankle was reduced. Nevertheless, when two different types of shoe densities were compared with respect to ankle movement variability, no significant difference was found. The softer midsole shoe, 10.5 ± 1.0 g, indicated a 2.5 ±0.9 degree change in ankle movement, whereas the stiffer midsole shoe, 15.1 ± 0.3 g, showed to have a 2.9± 10.0 degree change. Though results were not significant, subjects wearing the stiffer shoes had higher ankle movement variability. This suggests that more mechanoreceptors were recruited which in turn increased muscle activation. Running shoes themselves have an impact on limiting ankle joint variability and corresponding muscle activity but do not have a significant impact on ankle movement.

Hardin, Van Den Bogert and Hamill (13) purported that when runners are exposed to new shoes that differ in midsole hardness, kinematics change. They found when comparing a soft shoe, 40 shore A, to a hard shoe, 70 shore A, that running in harder shoes increased ankle dorsiflexion velocity (m/s) ($p < 0.0005$). Further to these results, runners had a tendency to increase knee flexion velocity (m/s), however not at the significance level ($p = 0.099$). It was determined that these results occurred due to passive rather than active mechanical reactions to first contact. In other words, these results were attributed to a more subtle change in the sequence of running gait.

Milani, Hennig, and Lafortune (29) conducted a study looking at rear foot movement while running in shoes that differed minimally in midsole stiffness. Vertical impact forces were simultaneously evaluated to provide further insight of the results. Impacter tests conducted on eight pairs of shoes used for this study indicated a sole deformation and acceleration range of 7.4 to 11.5 mm and 9.6 to 13 g, respectively. A stiffer shoe significantly decreased peak vertical force (bw), increased vertical force loading rate (bw/s), decreased maximum rear foot pronation (degrees), and increased maximum rear foot pronation velocity (degrees/s) ($p<0.005$).

In addition to these variables, regression analyses were conducted to distinguish if subjects were able to perceive differences in impact loads and movement between shoes using a 15-point categorical Borg scale. Subjects were in fact able to differentiate between shoes at the significant level. Further regression analyses comparing initial impact of the subject to impact testing of the shoes alone ($r=0.82$) revealed that runners shift their rear foot at contact as a defense mechanism to stiffer shoes. This is because runners are attempting to limit the amount of force exerted on the body.

Evidently, based on these findings, running in stiffer shoes affects foot mobility and runners are able to discern between differing midsole hardness using their own perceptual judgment.

Similar results were found in another study performed by Hennig, Valiant and Liu.(15) They found using three different pairs of running shoes that runners had a tendency to change rear foot motion to reduce the amount of impact force that occurred when wearing increasingly stiffer shoes. The only difference between studies was that larger stiffness ranges of the shoes were used.

With respect to the internal loading, Cole, Nigg, Fick and Morlock (8) examined the rate of internal loading in the foot and ankle while running in shoes with different midsoles--shore C 35, 54 and 75, respectively. A 3-D model of the foot and ankle was created using Morlock's six rigid body segment model to investigate internal forces.

Kinetic, kinematic and plantar pressure data were collected from live participants (N = 7 males) and anatomical information was retrieved from cadaver feet. Foot size (± 0.4 mm) and leg configuration were matched between subjects and cadaver feet to quantify the model. It was concluded that there was no statistically significant difference of the rate of internal loading for shoe stiffness. Though, there was higher rate in barefoot running compared to shod running.

Cole *et al.,* (8) pointed out several variables that could have accounted for the results of their study. Accordingly, even though statistically significant results were not achieved for subtalar joint loading rate, the tendency for this variable was approaching significance (p= 0.07) for the stiffer shoe (shore C 75). Such that when looking at subjects individually, subtalar joint loading rate seemed to increase. Perhaps, a larger sample size would have changed the significance value. In addition, it was indicated that limited warm-up time might have played a role in not finding significant results. In the study, subjects were allowed to perform warm-up runs but minimal runs were taken. It was suggested that a longer warm-up time would have allowed the subjects to acclimatize to differing midsole hardness. This recommended that warm-up time is a key factor when testing for shoe-foot interaction.

In relation to performance, Nigg, Stefanyshyn, Cole, Stergious, and Miller (34) conducted a study evaluating oxygen consumption while running in two differing shoe midsole harnesses. It was concluded that oxygen consumption (VO_2) was not significantly affected by altering shoe midsole hardness. Shoe A was classified as mainly elastic and having a stiffness value of 45 shore C and shoe B was classified as more viscous and having a stiffness value of 26 shore C. The results indicated that subjects wearing shoe A (elastic) consumed 39.4± 3.4ml/kg/min, whereas subjects wearing shoe B (viscous) consumed 39.4 ± 3.7 ml/kg/min.

A review of the available literature reveals that many researchers have evaluated the effects of differing midsole stiffness on several variables. Such variables include: vertical force, ankle movement, internal loading, and performance. The conclusions drawn provide insight with regard to running in different midsole stiffness; however, there are conflicting results that exist. The following will address potential issues and suggest possible remedies.

One factor could be the limited numbers of shoes used across studies coupled with varying and inconsistent stiffness values. There seems to be no uniformity as to how hard and soft shoes are classified into their respective categories. A threshold or range must be established to differentiate hard shoes from soft shoes. This study will attempt to devise a standard stiffness threshold. Also, if there is a small sample of shoes used along with a wide range of shoe stiffness then no wonder results vary between studies. This can be seen when comparing Kersting and Bruggemann (19) study which used three pairs of shoes ranging in stiffness from 45° to 61° Shore C to Milani *et al.,* (29) study which used eight pairs of shoes that indicated a sole deformation and acceleration range of 7.4 to 11.5 mm and 9.6 to 13 g, respectively. Evidently between these studies, a wide range of shoe samples were used, as well as different measurement tools to distinguish hard from soft shoes.

Also, varying measurement techniques and protocols were used across studies. As such, kinematic variables were tested either: by one footfall at a time on a short runway or on a treadmill for a span of time. Seemingly, it would be more appropriate for subjects to be tested on a treadmill because this would allow subjects a sufficient amount of time to adopt their own running pattern. In turn, outcome variables would be more representative of the subject's running behavior. Also, this would allow the subjects to acclimatize to the new shoes. Because of this reason, this study will have participants run on a treadmill until a comfortable running pattern has been reached.

Many studies tested kinematic variables having subjects run in shoes provided by the study but not one study tested subjects in their original shoes that they have been running in previously. Runners have a tendency to adapt their running pattern to the shoes they wear; perhaps taking the above into consideration would limit the amount of discrepancy in the literature.

With respect to evaluation of kinematic variables, the number of camera's used for each study ranged from a 2-camera set-up to an 8-camaera set-up. Depending on the number of camera's used; different angles can be seen through the frontal, sagittal and tranverse planes. This could lead to misrepresentation of movement occurring at the angle. Perhaps, this could account for the varying results between studies.

Furthermore, the duration of the study design spanned from a few hours to a 4-month protocol. Perhaps, a more consistent time frame should be established to measure certain parameters and/or variables.

Running speeds were not consistent between subjects. Running speeds ranged from 3.0 to 4.0 m/s. Running speeds should fall within this range to be classified as recreational runner, the extremes of the range can affect impact forces. This is because impact forces exerted on the body change with the time spent in the stance and subsequent swing phases.(18) Perhaps, taking these aforementioned variables into perspective would clarify the available literature.

2.7 Synopsis of Running and Plantar Fasciitis

Plantar fasciitis is indicative of having microruptures at the insertion of the calcaneous. Doctors and podiatrists prescribe treatments that target the insertion point such as injections, heel pads and heel cups. However, James and Jones (18) have pointed out that the problem for runners is not located at the injured site but rather transposed from secondary biomechanical abnormalities. For example, while running, tension of the plantar fascia ligament is increased by compensatory pronation, excess friction is exerted on the calcaneous when body weight is concentrated on the forefoot during heel lift and ground reaction forces are increased during downward acceleration.(18) These aforementioned secondary causal relationships to plantar fasciitis suggest that other treatments are needed to alleviate this problem.

Functional deficits are associated with symptomatic runners with plantar fasciitis. Kibler, Goldberg, and Chandler (20) reported that a negative feedback process exists when strength and flexibility of the supporting foot structures are altered. As such, the efficiency of force absorption is decreased because of the altered biomechanics of the foot. This suggests flexibility and strength ailments are linked with plantar fasciitis. Kibler *et al.,* (20) found using a Cybex dynamometer (Cybex, Ronkonkoma, NY), that 41 out of 43 symptomatic feet showed deficits in the plantar flexor muscles at 60 deg/sec and 37 were found to have deficits at 180 deg/sec. In relation to flexibility, it was found that 38 out of the 43 feet, demonstrated deficits in dynamic range of motion during dorsiflexion.

Excessive pronation in runners has been attributed to sport related injuries such as plantar fasciitis. Hintermann and Nigg (16) outlined in a review article that biomechanical abnormalities contribute to over compensatory foot pronation, which can be altered by midsole support from athletic shoes. It was suggested that midsole support provides stability and limits the degree of maximal foot pronation. However, this support may increase external rotation of the tibia. Subsequently, this increased external rotation is speculated to cause an undesirable rotary force through the tibia. Similarly, McClay and Manal (25) found that over pronators had a tendency to be in a more everted (rear foot motion) position compared to normal runners that are more inverted during ground contact. Also, greater mean peak velocities were consistently higher in all three ankle motions.

It has been advocated by some researchers that excessive rear foot motion and high impact forces are influenced by running shoe construction, in particular, the midsole region.(7;29;32;42) Based on these findings, other researchers have suggested that shoe material can be manipulated to prevent running injuries.(9;12;17) Since the midsole of the shoe underlies a large portion of the sole of the shoe and acts as the shoes cushioning system(4) it seems logical to alter this particular area. Limited research has been conducted on specific running related injuries; in particular, plantar fasciitis and the effects of shoe design. This provides ample reason to conduct a research study that examines the effects of midsole shoe stiffness in the resolution or recurrence of plantar fasciitis in runners.

Also, due to the fact that the popularity running as a sport has risen along with its corresponding running related injuries, it seems logical to determine means to minimize these injuries, as it has the capability in reducing cost in healthcare.(24) Furthermore, it is important to point out that most of the studies were conducted on healthy participants. Although, it is important to evaluate healthy individuals; it is equally important to look at injured participants as their biomechanics are altered due to injury. Thus, it is necessary to take one step further and evaluate shoe stiffness as a potential conservative treatment in alleviating those with plantar fasciitis.

CHAPTER 3

METHODOLOGY & MATERIALS

3.1 Description of study

Participants were informed that the study involved identifying the effects of a rigid shoe midsole on plantar fasciitis in runners. Candidates that accepted to participate in this study were asked to actively participate for three months by performing their normal exercise activities and either wearing shoes prescribed by the study or remain in their current shoes. Within the three-month time frame, participants were expected to attend three separate sessions (initial, 45 & 90 days post initial visit) conducted at The Cleveland Clinic Foundation in Biomechanics Laboratory. A written informed consent was signed before participation in the study (see appendix D). The protocol of this study received approval from both the University of Ottawa and The Cleveland Clinic Foundation ethics review boards (see appendix E).

3.2 Selection of participants

Twenty-four participants were recruited and eighteen remained in the study (Males = 10: Females = 8). All subjects had symptoms of uni-or bi-lateral plantar fasciitis within the last six months, ran at least 10 miles per week, performed stretching exercises once a day and ice after running if it was necessary for 90 days and had shoe stiffness values greater than 27 N/mm. Twelve of these participants were quasi-randomly assigned to the experimental group (Male = 6: Females = 6; Uni-PF = 10 : Bi-PF = 2) and six to the control group (Males = 4: Females = 2; Uni-PF = 4 : Bi-PF = 2). Mean age, mass, height and years running for the experimental group were 41.9 yrs (SD: 12.7), 147.3 lbs

(SD: 22.6), 167.1 cm (SD: 7.9) and 13.7 yrs (SD: 9.9) and the control group were 45.3 yrs (SD: 10.0), 199.7 lbs (SD: 46.3), 180 cm (SD: 10.5) and 15.3 yrs (SD: 11.0), respectively.

Participants were recruited by flyers posted (see appendix D). Information was obtained by phone from those that responded to the flyer. Participants that satisfied the inclusion criteria from the phone screen were asked to present themselves to the laboratory for the first initial visit (see appendix D).

3.3 Research design

This study was a repeated research design.

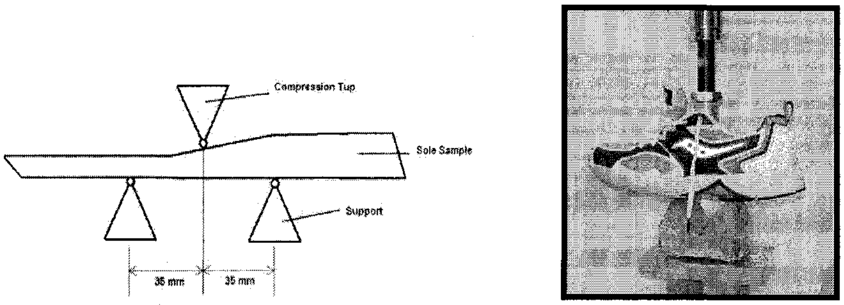
3.4 Protocol and procedure for data collection

Participants were asked to attend three separate sessions: initial, 45 & 90 days post initial visit.

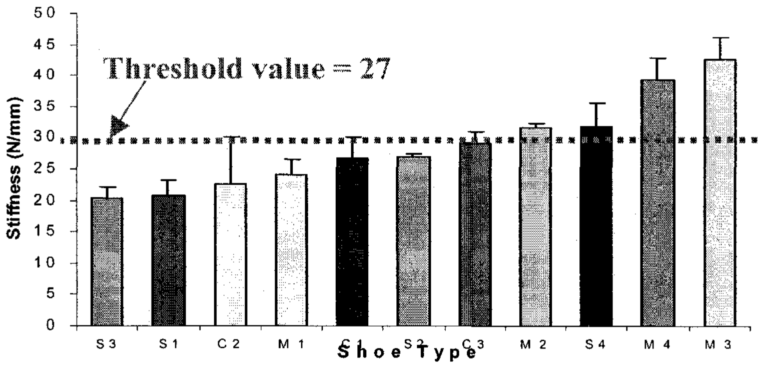
3.4.1 Shoe Selection Process

A select number of running shoes were previously tested in another study using three point bending tests in a MTS™ Servo Hydraulic Testing machine (858 Bionix Test System, Mechanical Testing Systems, Minneapolis, MN, Figure 1a,b). Tests followed closely to the American Society for Testing and Materials (West Conshohocken, PA) standards for testing running shoes. The shoes were placed in the jig with the supports centered on the shank with a distance of 70 mm between supports. The compression arm of the jig was centered on the two supports. All inserts were removed from the shoes.

Prior to bending, a 10N preload force was applied by a compression arm perpendicular to the mid region of the shoe midsole. The compression arm was displaced 5 mm/s to a maximum of 30 mm. This procedure was repeated for 5 consecutive trials with a 30 second relaxation period in between each trial. Stiffness values were calculated from the force-deformation data in the steepest region of the linear elastic portion of the curve using a LabVIEW program (National Instruments, Austin, TX). Cycle 1 was omitted for the purpose of preconditioning and cycle 2 to 5 were used. A threshold value of 27 N/mm was selected based upon the statistical analyses of the stiffness data. Shoe types (stability, motion control and cushioned) were grouped accordingly and the average stiffness of each shoe was evaluated in comparison to each other. Shoes above the threshold value were shown to have statistically higher stiffness compared to the majority of shoe groups below the cut-off of 27 N/mm (Figure 1c).



a. Schematic of MTS Testing Apparatus **b.** Experimental Setup



c. Stiffness of Select Shoes

Figure 1. MTS Testing Apparatus and Results

3.4.2 Characteristics of shoes selected

Eight pairs of shoes were chosen from the above-mentioned procedures and re-tested to ensure all shoes had a shoe stiffness value above 27 N/mm (Table 1). From these eight pairs of shoes, participants were allowed to pick which shoes they wanted to wear for the length of the study. This allowed participants to wear shoes that met their desired comfort level. Precautions were taken to ensure each participant remained in their initial shoe type (e.g. motion control, cushioned or stability). This was done to preserve foot structure.

Table 1. Characteristics of shoes.

Shoe name	Shoe type	Shoe stiffness values (N/mm)
S1	Stability	29.5
M1	Motion control	53.3
C1	Cushioned	27
S2	Stability	28.5
M2	Motion control	34.1
S3	Stability	29.1
S4	Stability	45.1
M3	Motion control	34.1

3.4.3 Testing Sessions

Three testing sessions took place. The initial visit involved completion of a questionnaire in relation to recent running practices (e.g., mileage per week) and symptoms experienced with plantar fasciitis using a 10-point pain ranking scale . A CCF podiatrist assessed the participants for plantar fasciitis ailments using a standard medical exam.

This assessment involved: (1) ruling out other medical ailments such as achilles tendinitis, stress fractures, posterior tibial tendinitis and nerve entrapment; (2) determining the foot type (flat, cavus or rectus) of the participant using gross observation method; (3) examining the plantar fascia ligament to see if the etiology of the participants plantar fasciitis was due to tight ligamentous structures, specifically the achilles tendon complex; (4) using the information gathered, the proper shoe type was recommended; and (5) educating about plantar fasciitis and given recommendations about proper stretching exercises and use of ice therapy for severe exacerbations. If tight ligaments were the most reasonable explanation for the plantar fascia, participants remained in the study and it was reasonable to conclude that once the ligament is stretched a supportive shoe would keep it from tightening during the normal gait cycle. Participants were excluded if Podiatrist identified major reasons other than tight ligamentous structures for plantar fasciitis such as achilles tendinitis and stress fractures.

Subsequent to the assessessment, the current shoes of the participants were subjected to mechanical testing using the procedure indicated above. If the shoes stiffness values were below a predetermined treshold of 27N/mm, subjects were either assigned to the control or experimental group.

Those assigned to the control group were asked to remain in their current running shoes, resume normal activity, perform stretching exercises once a day and ice after running if necessary and be evaluated in the clinic after 45 and 90 days. Upon completion of the initial visit, participants in this category, were given a check and at the end of the third visit received a voucher to purchase new shoes at the local running shoe store.

Participants assigned to the experimental group were given a voucher to purchase a new pair of shoes (within days of their first test visit) that are more rigid in the midsole region than their previous athletic shoes. This voucher was given at the end of the first visit. Over a course of 90 days, they were expected to resume normal activity, perform stretching exercises once a day and ice after running if necessary, as well as be evaluated in the clinic after 45 and 90 days. At the end of the third visit, participants received $75.00 in the form of a check.

Also, during the initial visit, an Eva 6.0 motion analysis system (Motion Analysis Corp., Santa Rosa, CA, US) was used to test gait on the participants in both groups while wearing their current shoes to determine rear foot range of motion (ROM), dynamic flexibility of the midsole and dynamic ROM of ankle, knee and hip motion.

An anatomical marker set to define each segment in three dimensions was used. Thirty three reflective markers were placed on both legs of the participants at specific locations in order to define the variables of interest (Figure 2). Strategic placements of three markers were placed on lower limb segments to allow analysis of movement in all planes. As such, 3 reflective markers were placed in a triangle formation around the shoe midsole area on the lateral side, 4 markers were linearly aligned starting on the heel counter of the shoe and ending on the posterior distal end of the tibia spacing 1 cm apart, 1 marker was placed on the 5th metatarsal head on the outsole of the shoe, and

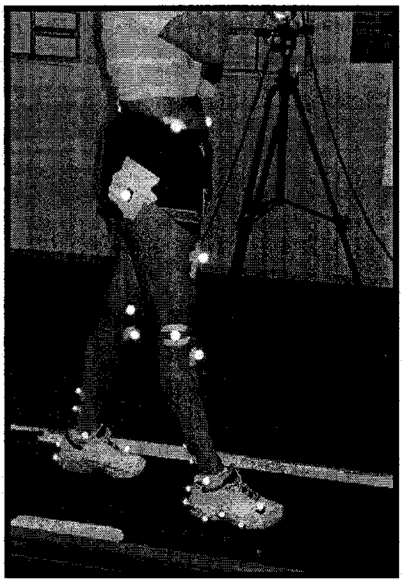


Figure 2. Marker Position

on the medial and lateral malleolus, tibial tubercle, medial and lateral femoral epicondyls, greater tronchanter, left and right anterior superior iliac spine and the site of the sacrum.

Rear foot angle was defined between the tibial (2) and rearfoot markers (2). Shoe shank displacement (mm) was defined by the motion-taking place at the apex of the triangle. Ankle angle was defined between the 5th metatarsal head on the outsole of the shoe, lateral malleolus and lateral femoral epicondyls markers. Knee angle was defined between the greater tronchanter, lateral femoral epicondyls and lateral malleolus markers. Hip angle was defined between the anterior superior iliac spine, greater tronchanter and lateral femoral epicondyls markers.

Motion analysis was performed on an instrumented treadmill (Quinton 65, US) in which participants were expected to run at a speed of 3.0 m/s. This speed was selected to accommodate runners with plantar fasciitis and to control the amount of time spent in the stance phase for pre and post evaluations.

A weight bearing trial (standing trial) was collected for one second in a staggered position. This was completed to retrieve a marker reference position when body weight was applied to calculate joint ROM. After this trial, the medial reflective markers on the malleolus were removed. A non-weight bearing trial (sitting trial) was collected for one second in the same staggered position as in the standing trial. This was completed to retrieve a reference point for the midsole markers when no body weight was applied to calculate midsole height ROM. While running, two ten second trials were collected after a warm-up period of two minutes or until the participant felt comfortable running at the selected speed (3.0 m/s).

The second session (after 45 days) involved the same questionnaire as previously outlined during the intial visit, followed by an assessment performed by a CCF podiatrist and mechanical testing of the current running shoes of the participant. The purpose of the second assessment by a CCF podiatrist was to follow up on the participants. The assessment involved: (1) asking the participants if their symptoms were getting better or worse and if they were being compliant with the shoes they were given, as well as using ice and stretching as directed; (2) re-educating on stretching as needed; and (3) evaluating for other podiatric heel pain issues as needed.

The third session (after 90 days), the participants filled out the same questionnaire as previously mentioned followed by a post motion analysis test and mechanical testing of the participants most current shoes, as outlined in the first session.

3.5 Subject Shoe Assignment

Shoe construction affects movement in the foot (i.e., pronation, supination, inversion, eversion, plantarflexion and dorsiflexion). Increasing shoe stiffness could potentially decrease joint motion and therefore alter running mechanics, which will, in turn, lead to less strain in plantar fascia. In order to preserve the structural alignment of the lower extremity, subjects were accommodated with a shoe that fit their shape and orientation of foot. For example, a planus foot was assigned a motion control shoe, a cavus foot was assigned a cushioned shoes and a rectus foot was assigned a stability shoe.

3.6 Measurement of Variables

From the kinematics retrieved from motion analysis, rear foot, ankle, knee and hip angles as well as shoe midsole displacement, were measured and used as the dependent variables. Each respective angle was normalized over a time-based series to calculate the average movement taken place during the gait cycle, more specifically, the stance phase. Pre (initial) and post (after 90 days) evaluations were compared. Shoe type was used as the independent variable. Moreover, questionnaires were completed at pre (initial), mid (45 days) and post (90days) to assess the amount of pain experienced during daily activities and direct pain in the heels/arches. Also, from the same questionnaire, estimated running mileage (miles/week) for pre, mid and post visits were recorded and compared to assess if runners changed running mileage (see appendix F). Furthermore, shoe stiffness (N/mm) was recorded pre, mid and post visits to assess shoe midsole breakdown (see appendix F).

3.7 Statistical Analysis

A 3-way repeated measure ANOVA comparing Group (controls versus subjects wearing new shoes), Affected foot (affected versus non-affected foot) and Session (pre versus post) was used to determine the effect of treatment (new shoes) on those diagnosed with plantar fasciitis. The above statistical analysis was used to assess the effect on rear foot, ankle, knee, hip angles (degrees) as well as midsole-shank compression (mm). When interactions were significant, a post hoc Scheffe was used. Also, a 2-way repeated measure ANOVA (Group X Session) was used to determine the amount of pain participants experienced during daily activities and direct pain in the heels/arches of one or both feet. Statistica software package (STAT Soft Inc., Tulsa, USA) was used for all analyses. $P < 0.05$ was considered statistically significant.

Statistical analyses were not performed on running mileage and shoe stiffness. These variables were used to monitor changes, if applicable.

3.8 Description of mearsures

3.8.1 Kinematic motion capture

An Eva 6.0 motion analysis system (Motion Analysis Corp., Santa Rosa, CA, US) with six non-colinear camera pixels were posiontioned around the parameter of a treadmill with three cameras on each side to collect kinematic data (Figure 3). Data was collected at 240 Hz. Two different sizes of adhesive retro reflective markers were used to collect data such that 19mm markers were used on all joints and 12 mm markers were used for the shoe shank triangle. Joint angles (degrees) and displacement motion (mm) were digitized for rear foot, ankle, knee, hip angles and shoe shank, respectively, using Midas computer software. A Butterworth 6.0 Hz cut-off frequency was used post digitization. Motion capture reliability was less than 1 mm for marker movement.

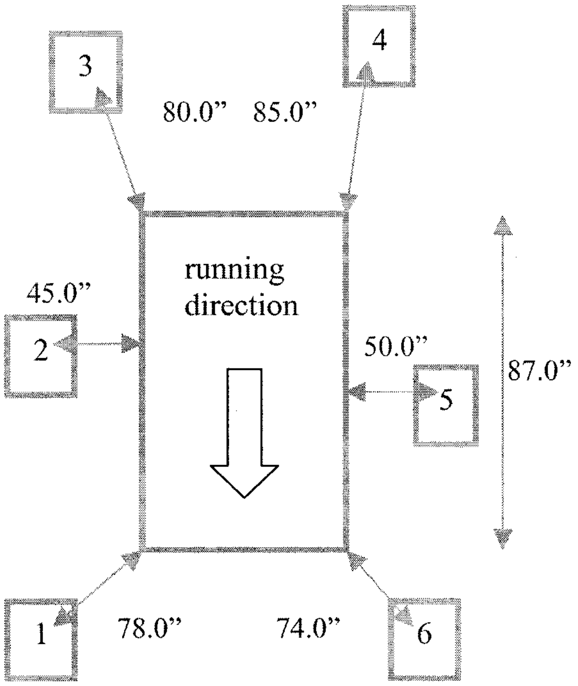


Figure 3. Schematic view of camera set-up

This system is validated by the calibration of the Falcon analog cameras using a dynamic linearization technique, which produces precise, accurate, and efficient measurements for motion capture. These cameras have an accuracy of pixel-locked digitizing systems.

3.8.2 Mechanical testing of shoes

A three point bending test using an MTS™ Servo Hydraulic Testing machine (858 Bionix Test System, Mechanical Testing Systems, Minneapolis, MN) was used to evaluate shoe stiffness. Test star computer software was used to capture and store data. Stiffness values were calculated from force-deformation (N/mm) curves using a custom designed LabVIEW program (National Instruments, Austin, TX). The steepest region of the most linear elastic portion of the curve was used to compute shoe stiffness. MTS machinery must be calibrated on a regular basis to comply with ISO/IEC 17025 standards by an accredited vendor. Calibration tests can be traced back to the National Institute of Standards and Technology. The Cleveland Clinic Foundation MTS 858 Bionix received a calibration certificate in August 2003. This certificate credits the MTS machine to a 99% accuracy and repeatability for force-deformation tests. MTS equipment or related machinery has been used by many researchers to test for shoe stiffness.(i.e.,(1;19;21;26;29;41))

3.8.3 Questionnaire

A questionnaire in relation to recent running practices and symptoms experienced with plantar fasciitis was admimistered for all three sessions (initial, 45 and 90 post initial visit) (see appendix D). The goal of this questionnaire was to evaluate change in symptoms (i.e., pain level) experienced by the participant. The questionnaire was designed by two qualified and experienced CCF podiatrists to ensure appropriate questions were being asked to assess the level of symptoms experienced with those diagnosed with plantar fasciitis. Questions were similar to that of what a podiatrist would ask during patient assessments. For instance, using a pain scale (with 10 being the most severe pain & 0 being no pain), [are you] experiencing pain of one or both of [your] heels/arches?

CHAPTER 4

RESULTS

4.1 Overview

A custom LabVIEW (National Instruments, Austin, TX) program was used to process rear foot, ankle, knee and hip angles (degrees) as well as shoe midsole displacement (mm). Each respective angle was segmented into separate strides and normalized over a time-based series to calculate the average movement taken place during the gait cycle, more specifically, the stance phase. The range of motion (ROM) (max value – min value) was computed for all variables listed above to determine the amount of motion taking place at each joint or within the shoe midsole.

4.2 Rear foot angle

The dynamic range of motion of the rear foot was evaluated by the change of motion in the frontal plane--inversion and eversion during running. The average range was determined during stance and averaged for each trial. A 3-way repeated measure ANOVA (Group X Affected foot X Session) was used for analysis. No significant differences were discovered for group ($F(1, 11) = 0.95$, $p > 0.05$), affected foot ($F(1, 11) = 0.61$, $p > 0.05$) and session ($F(1, 11) = 0.89$, $p > 0.05$). However, the ANOVA revealed a significant triple interaction ($F(1, 11) = 5.03$, $p < 0.05$). A post hoc follow up using a Scheffe decomposition into main effect revealed that the control group decreased rear foot angle significantly ($p < 0.05$) and the experimental group increased rear foot angle significantly ($p < 0.05$). Figure 1 illustrates pre and post assessments of the a) non-affected foot and b) affected foot of the experimental versus control groups.

4.3 Shoe shank

The dynamic range of the shoe was evaluated by the change of the shoe shank compression during running (mm). Average range of motion of the shoe shank during stance was determined for all strides and averaged for each trial. Separate 3-way repeated measure ANOVA's (Group X Affected foot X Session) were completed for all compressions in the shoe shank triangle formation and were anatomically described as mid, posterior, anterior.

For mid shank motion, a significant difference was found for pre-post sessions (F (1, 14) = 12.2, $p < 0.05$) but no significant differences were found for group (F (1, 14) = 1.01, $p > 0.05$) and affected foot (F (1, 14) = 0.01, $p > 0.05$). A significant interaction between group and pre-post sessions was found (F (1, 14) = 5.19, $p < 0.05$). Figure 2 illustrates pre and post assessments of the a) non-affected foot and b) affected foot of the experimental versus control groups.

A 2-way interaction decomposition using Scheffe's model revealed that the control group significantly decreased shoe shank motion ($p < 0.05$) and the experimental group slightly decreased but no significance was revealed ($p > 0.05$).

For the post shank motion, a significant difference was revealed for pre-post sessions (F (1, 14) = 5.66, $p < 0.05$) but no significant differences were revealed for group (F (1, 14) = 0. 28, $p > 0.05$) and affected foot (F (1, 14) = 1.07, $p > 0.05$). Two-way interaction between group and session indicated to have an almost significant value (F (1, 14) = 3.31, $p = 0.09$). The trend was that the control group decreased more in post shank motion compared to the experimental who only decreased slightly.

For the anterior shank motion, no significant differences were revealed for pre-post sessions (F (1, 14) = 0.85, $p > 0.05$), group (F (1, 14) = 1.61, $p > 0.05$) and affected foot (F (1, 14) = 0.003, $p > 0.05$). Though, similar trends to the mid and post shank motion were observed in that the control group decreased more in anterior shank motion compared to the experimental who only decreased slightly.

4.4 Ankle, Knee and Hip angles

The dynamic ranges of motion of the ankle, knee and hip angles were evaluated by the change of motion in the sagittal plane -positive (flexion) and negative direction (extension) during running. Average joint range of motion was determined for all strides and averaged for each trial.

Separate 3-way repeated measure ANOVA's (Group X Affected foot X Session) were completed for ankle, knee and hip angles. For ankle angle, no significant differences were observed for affected foot (F (1, 22) = 1.73, $p > 0.05$) and session (F (1, 22) = 2.61, $p > 0.05$). Though, an almost significant difference was observed for group (F (1, 22) = 3.04, $p = 0.095297$). Similarly, a 2-way interaction between group and affected foot revealed an almost significant difference (F (1, 22) = 3.05, $p = 0.09$). Figure 3 illustrates pre and post assessments of the a) non-affected foot and b) affected foot of the experimental versus control groups.

For knee angle, no significant differences were seen for group (F (1, 19) = 0.26, $p > 0.05$), affected foot (F (1, 19) = 0.32, $p > 0.05$) and session (F (1, 19) = 1.68, $p > 0.05$). Figure 4 illustrates pre and post assessments of the a) non-affected foot and b) affected foot of the experimental versus control groups.

For hip angle, no significant differences were seen for group (F (1, 19) = 0.28, $p > 0.05$) and affected foot (F (1, 19) = 0.98, $p > 0.05$) but a significant difference was observed for session (F (1, 19) = 6.002, $p < 0.05$). Figure 5 illustrates pre and post assessments of the a) non-affected foot and b) affected foot of the experimental versus control groups.

4.5 Pain level

A 10-point pain scale (e.g. with 10 being the most severe pain & 0 being no pain) was used to determine pain level experienced during the course of the study (initial, 45 & 90 days) during daily activities and pain directly associated with the heels/arches. Separate 2-way repeated measure ANOVA's (group X visit) were used for analysis.

For daily activities, the amount of pain experienced in one or both feet while standing, walking, lifting, stair-climbing, stepping sideways, sitting and standing on toes were averaged and compared between groups. Significant differences were revealed for group (F (1, 16) = 7.89, $p < 0.05$) and visit (F (1, 32) = 17.5, $p < 0.05$). A post hoc Scheffe test revealed that the experimental group decreased significantly the amount of pain experienced during daily activities at 90 days ($p < 0.05$). Figure 6 illustrates pre and post assessments of the a) non-affected foot and b) affected foot of the experimental versus control groups.

For direct pain, the overall amount of pain experienced at each visit in one or both feet of heels/arches was evaluated. A significant differences was revealed for session (F (1, 17) = 5.42, $p < 0.05$) but no significant difference was observed for group (F (1, 17) = 0.01, $p > 0.05$). A post hoc Scheffe test revealed that the experimental group decreased significantly the amount of direct pain experienced with the heels/arches (p <

0.05) at 90 days. Figure 7 illustrates pre and post assessments of the a) non-affected foot and b) affected foot of the experimental versus control groups.

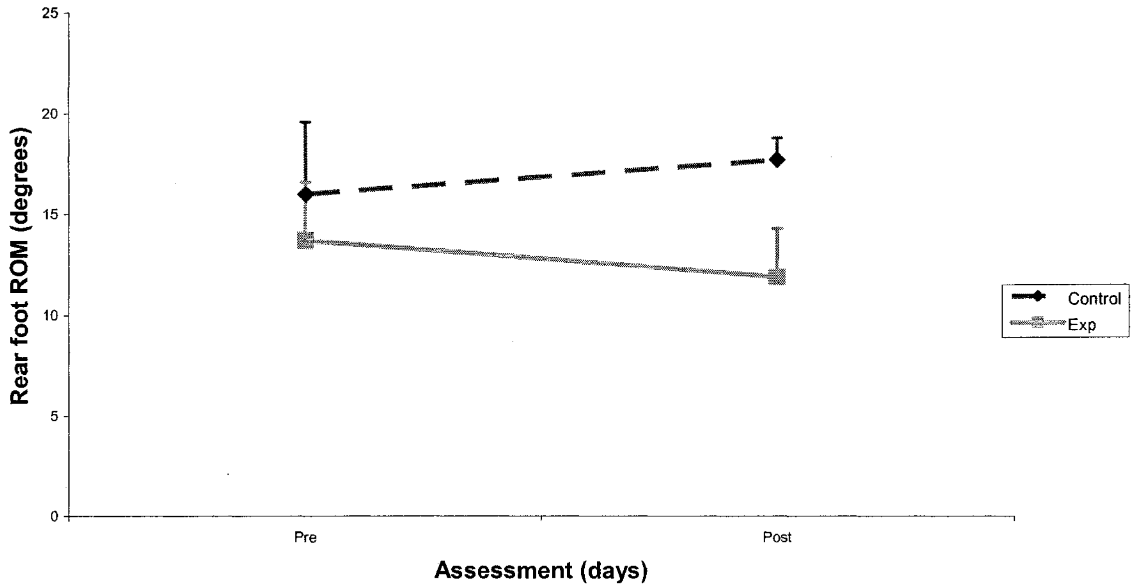


Figure 1a. Mean (X) and standard deviation (sd) pre and post assessments (days) of the non-affected foot during rear foot motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

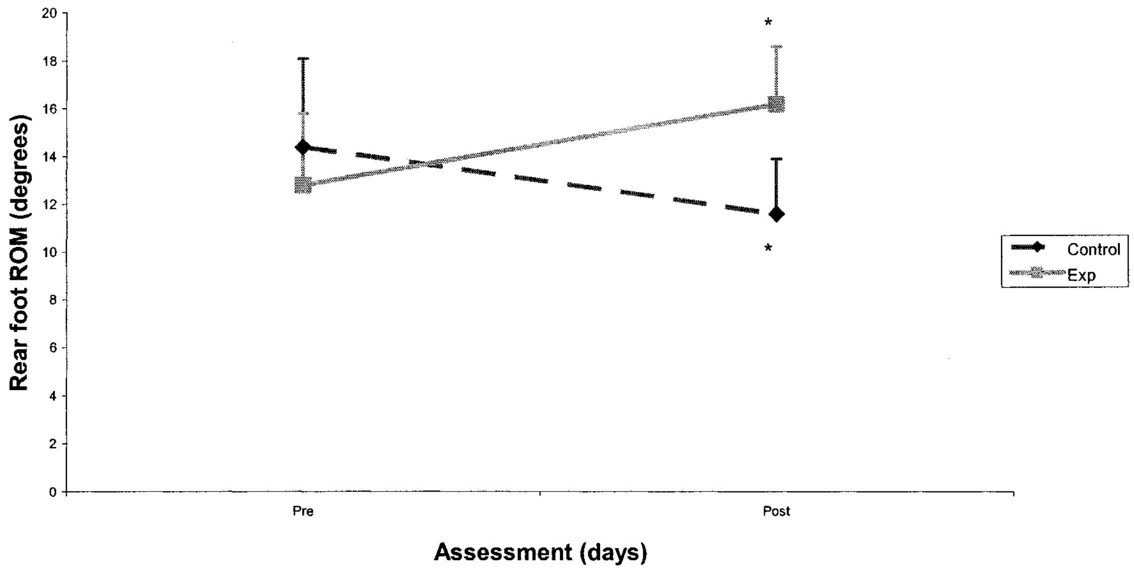


Figure 1b. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during rear foot motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

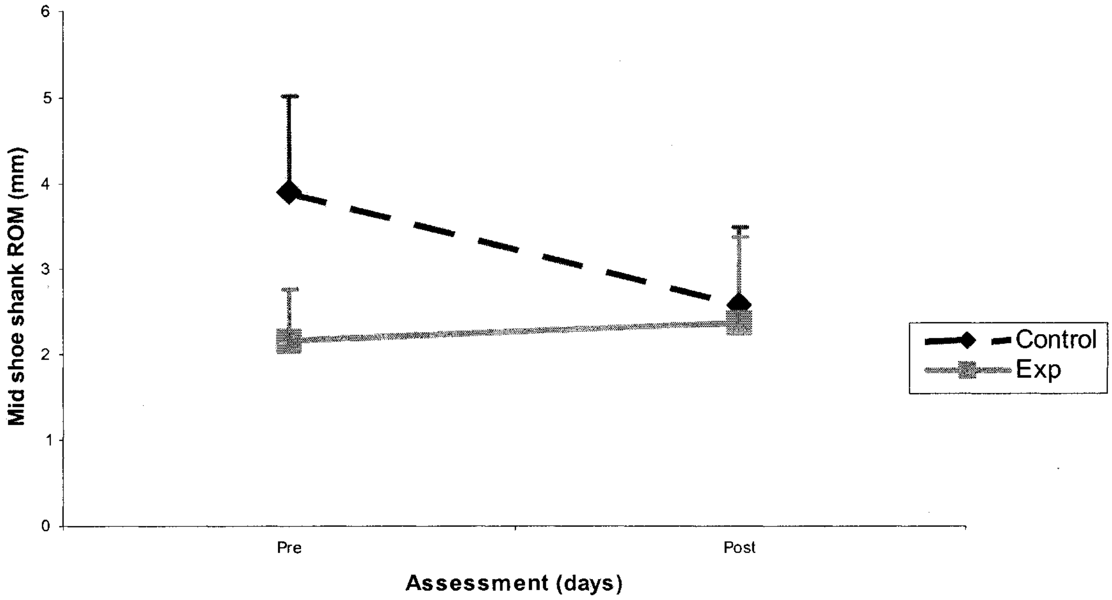


Figure 2a. Mean (X) and standard deviation (sd) pre and post assessments (days) of the non-affected foot during mid shoe shank motion (ROM; mm) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

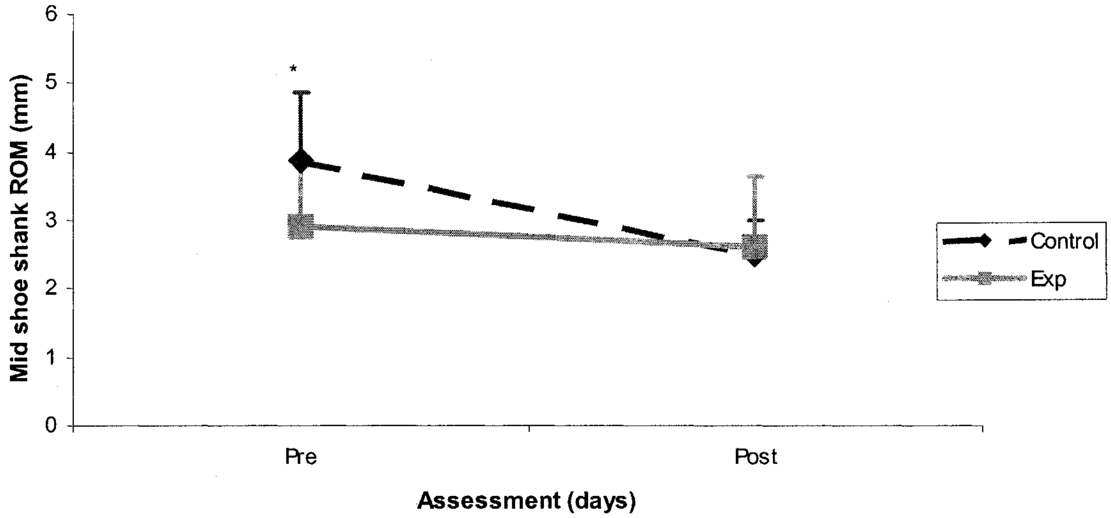


Figure 2b. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during mid shoe shank motion (ROM; mm) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

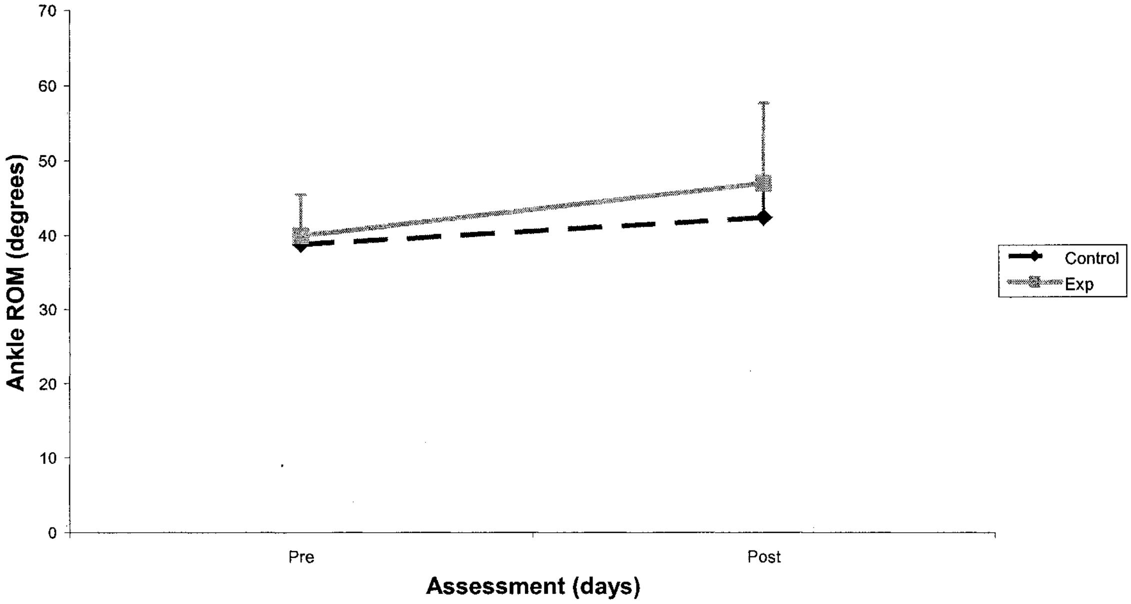


Figure 3a. Mean (X) and standard deviation (sd) pre and post assessments (days) of the non-affected foot during ankle motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

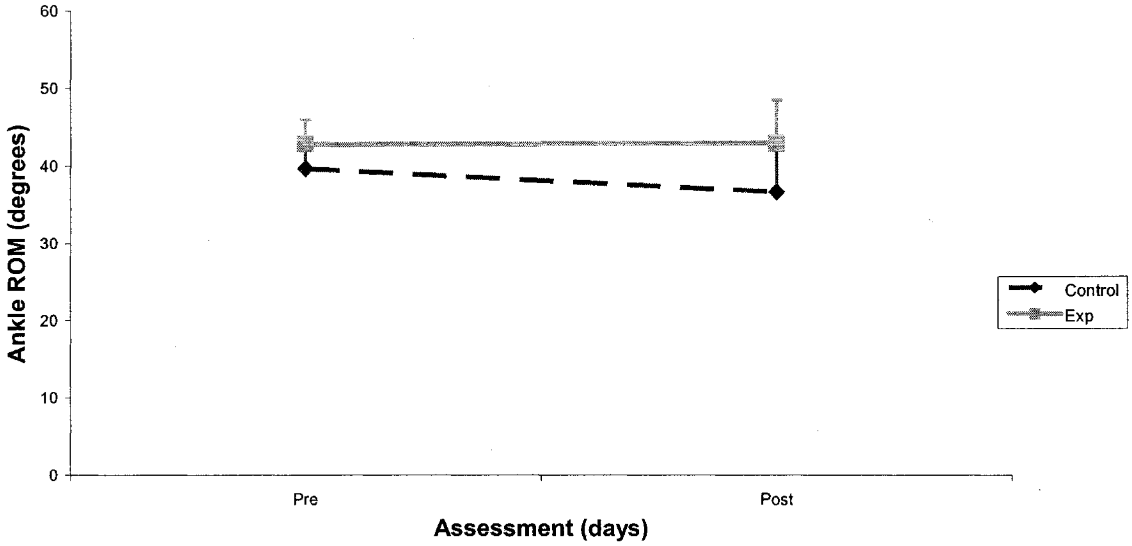


Figure 3b. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during ankle motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

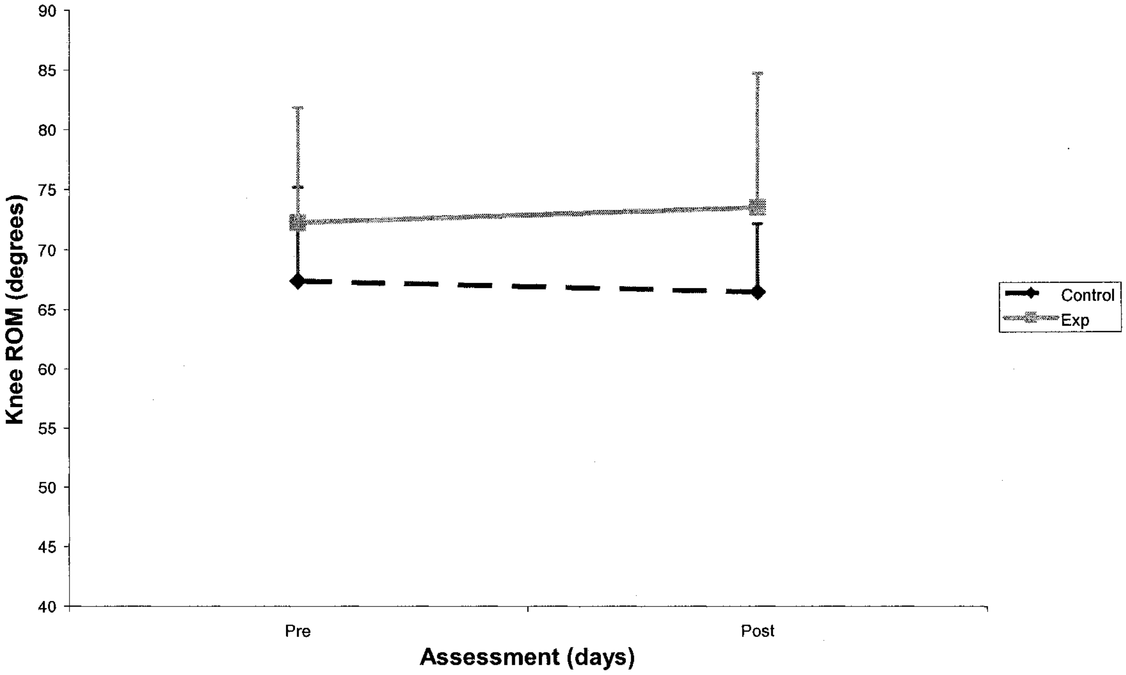


Figure 4a. Mean (X) and standard deviation (sd) pre and post assessments (days) of the non-affected foot during knee motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

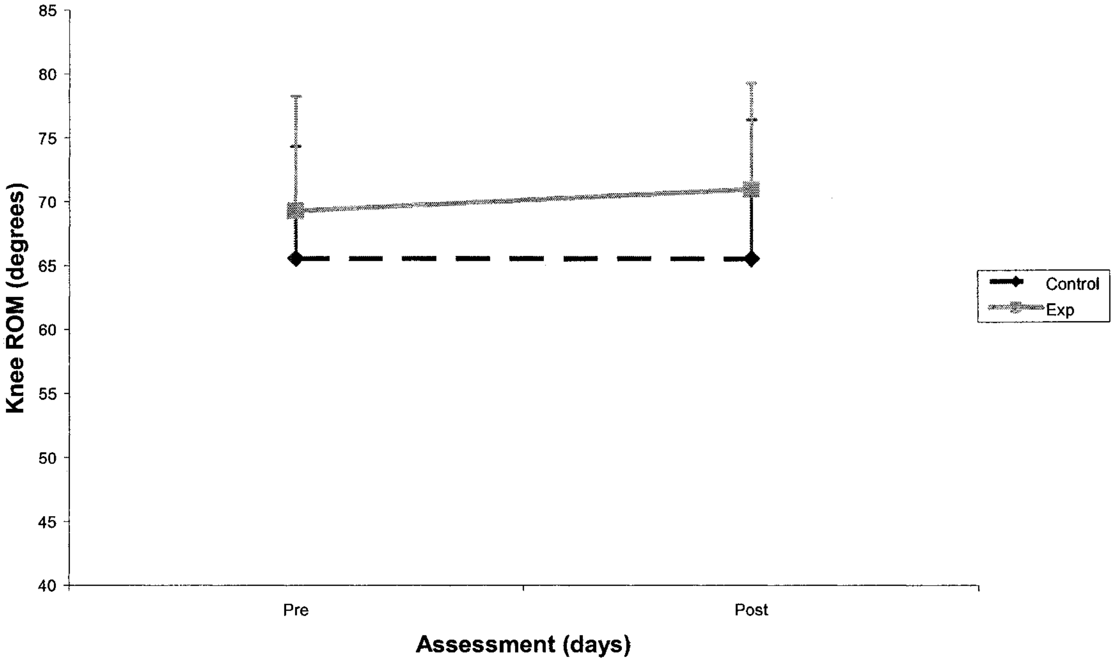


Figure 4b. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during knee motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

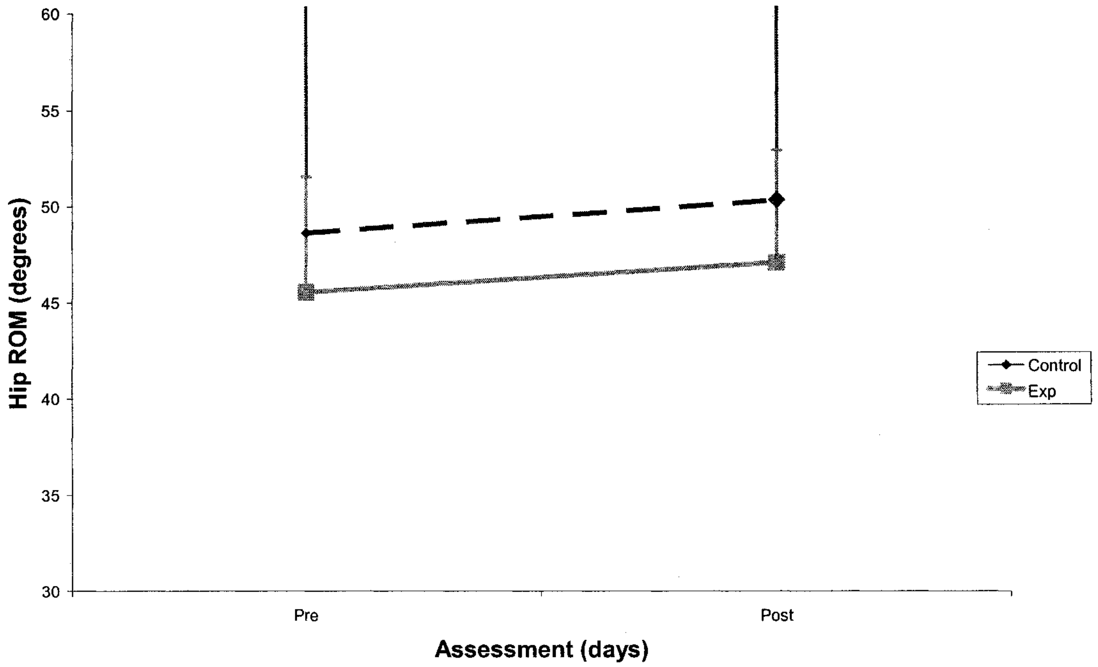


Figure 5a. Mean (X) and standard deviation (sd) pre and post assessments (days) of the non-affected foot during hip motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

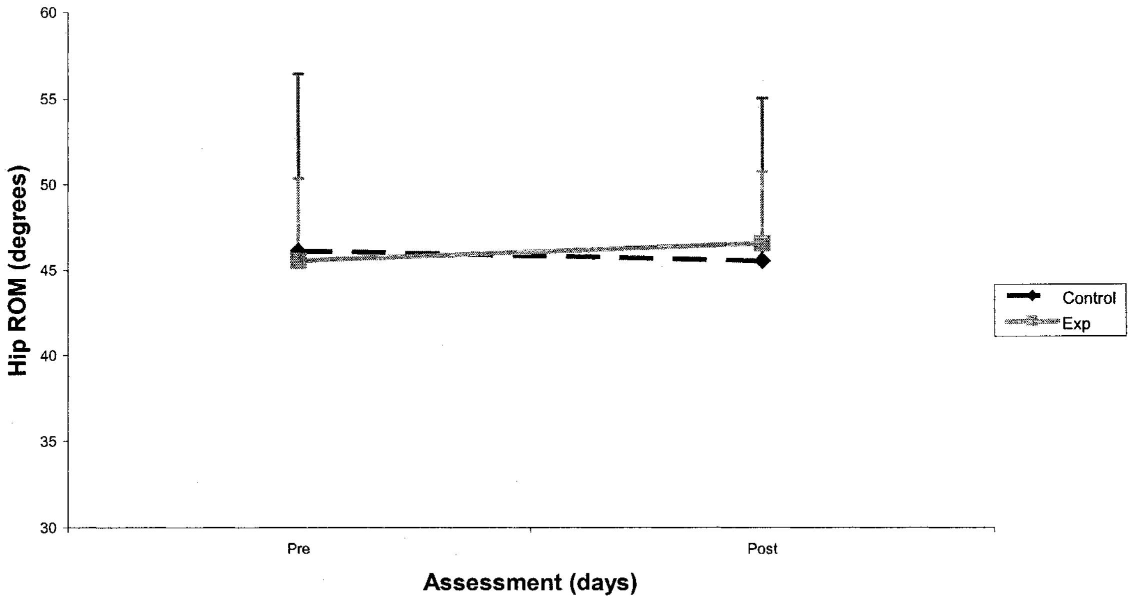


Figure 5b. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during hip motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

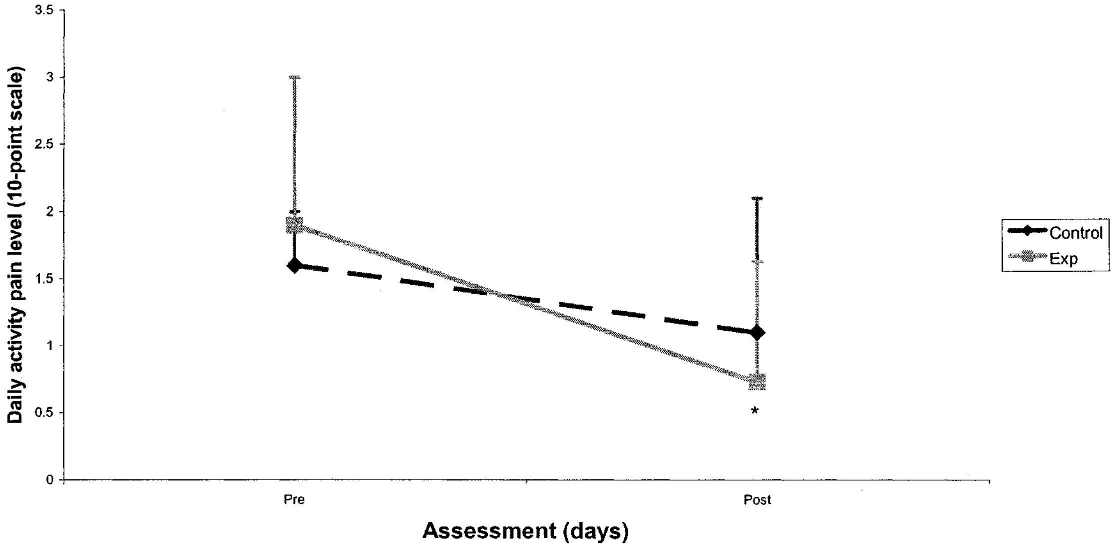


Figure 6. Mean (X) and standard deviation (sd) pre and post assessments (days) of daily activity pain (10-point pain scale, 10 being most severe & 0 being no pain) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

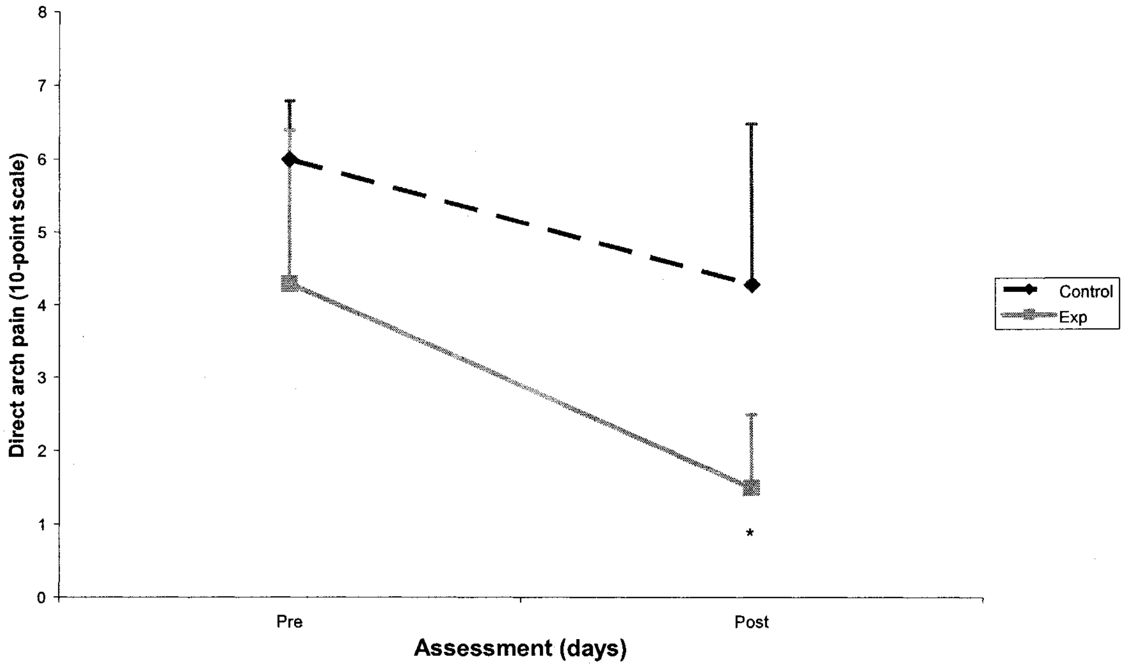


Figure 7. Mean (X) and standard deviation (sd) pre and post assessments (days) of direct pain (10-point pain scale, 10 being most severe & 0 being no pain) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

CHAPTER 5
DISCUSSION

Running shoes can be instrumental in reducing the risk of injury by modulating impact forces and excessive pronation. Cushioning, wedges and mechanical stiffening elements added to the shank region of the shoe address the issue of over pronation. However, little has been done to objectively quantify this effect, particularly with respect to running injuries like plantar fasciitis. Traditional thinking dictates that the cushioning characteristics play a critical role in the motion control of the shoe. There is not, however, consensus in the literature. The main focus of this study was to determine if the stiffness of the shoe plays a role in the functional outcome in plantar fasciitis. This study represents one of the first attempts to measure the characteristics of the shoe shank and correlate it to the dynamic response of the shoe during running and injury.

Subjects who remained in their current shoes, with stiffness values below the acceptable level (less than 27 N/mm), showed a decrease in height (mm) for mid shoe shank range of motion over the test period. Conversely, subjects who were given new shoes immediately following the initial visit maintained a more constant mid shoe shank range of motion over time with only a slight decrease apparent in the data. The latter result was expected, as new shoes should remain at a steady height range. The decrease in mid shoe shank height ROM seen in the control group (those that remained in their shoes) can be explained by examining the shoe stiffness (N/mm) data collected over the three testing sessions-initial, 45 & 90 days post initial visit. After 90 days, participants shoe stiffness values decreased suggesting that the midsole compressed to the point in which there was no material deformation left to absorb. This would be in sync with the decreased and therefore flattened height in the motion of the mid shoe shank for the control group who did not change their current shoes. With the decrease in motion, the plantar fascia is further stretched and the condition potentially aggravated.

The rear foot motion, a factor thought to be a large contributor to the motion in arch region of the foot,(10) increased over time in the experimental group and decreased for the control group. Interestingly, this finding was contrary to our hypothesis that a stiffer shoe would reduce rear foot motion. Rear foot motion seems to be related to the shoe fitting, design of the shoe and stiffness of the midsole

Perhaps the stiffer shoe reduced the motion taking place at the plantar fascia ligament but simultaneously altered rotary movements of the lower leg. This would partially fit the speculation of Hintermann and Nigg (16) that midsole support may increase external rotation of the tibia causing an undesirable rotary force through the tibia. Another possible explanation for the increase in rear foot movement could be that more appropriate loading is being dissipated away from the plantar fascia causing movement shifts within the foot. This would be in sync with Cavanagh *et al.,*(5) theory that running behavior (movement) is affected by shoe material because of pressure re-distribution.

Kurz and Stergiou (21) suggested that a stiffer midsole may increase joint variability (movement) causing joint forces to spread across surrounding tissues opposed to being localized in one tissue such as the plantar fascia ligament. On the other hand, McClay and Manal (25) suggested that excessive pronation could potentially lower the arch and cause instability throughout the rest of the foot.

Milani, *et al.*, (29) have indicated that runners have a tendency to change rear foot motion as a defense mechanism to reduce the amount of impact force that occurs when wearing increasingly stiffer shoes. Our results seem to be consistent with these findings in that the experimental group increased rear foot motion to accommodate their new shoes, whereas the control group decreased rear foot motion to accommodate remaining in shoes that are deteriorating in material deformation.

Furthermore, the increased range of motion seen at the rear foot in the experimental group may indicate a more balanced range of inversion-eversion opposed to being more restricted. Plantar fasciitis patients have been shown to have a deficient range of motion in the ankle.(20) Conceivably, a stiffer shoe loosened the surrounding tissues allowing for an increase in the range of motion at the rear.

The results of the rear foot motion and mid shoe shank motion are reinforced by the data from the subjective questionnaire. Although both groups started at a moderately high level of direct pain to one or both arches/heels and pain during daily activities, after 90 days, subjects with stiffer shoes reduced their pain level in the arches/heels of their foot/feet significantly. Control group subjects still had moderate pain scores after the same period of time. This finding would reiterate Luke's (22) finding that conservative treatments such as a shoe adjustment alleviate symptoms of plantar fasciitis in 80 % of cases. Another possible explanation for the results could be that the participants may have altered their behavior because they knew they were being studied-- Hawthorn Effect. In other words, one may have received new shoes and automatically felt better versus one that did not receive new shoes expected their pain symptoms to remain the same or deteriorate. Though, the fact that the control group maintained moderate pain symptoms suggests this did not occur.

The range of motion of lower extremity kinematics was evaluated over the course of the study to see if stiffer shoes could in fact alter mechanics. Ankle, knee and hip angles were within the normative values found in the literature for running (23;24;35) despite the fact that they were injured.

Although no significant differences were found, small changes were noticed. Ankle ROM seemed to have increased slightly in the experimental group compared to the control group and the hip ROM seemed to have increased for both the experimental and control group but the experimental group seemed to have decreased less. Slight modifications in gait have been suggested by many researchers to potentially offset timing (ms) of joint mechanics resulting in further injury.(33) While generalizations cannot be drawn from these particular results, it is important to note any degree of change as it may affect biomechanics.

McNair and Marshall (26) have suggested that runner's respond more with kinetic parameters opposed to motion taking place at the joints when observing shoe changes. Conceivably it would be interesting to examine the applied force, pressure distribution patterns and/or even electromyography activity-taking place at the foot shoe interface. Examining forces exerted on the foot such as loading rates (Fz) throughout stance and maximum vertical loading rates (m/s) could be useful in determining the influence of midsole construction on damping impact forces.(31) Pressure variables such as peak pressures (kPa) and relative loads (%) would useful in determining if stiffer shoes dissipate or transfer pressure to supporting tissues.(30) Observing electromyography activity in the supporting tissue of the foot could determine the amount of activity taking within each respective tissue. All the above variables would provide insight as to precisely what is taking place when patients with plantar fasciitis wear stiffer shoes.

Another explanation for the results from above could be that a wide range of adaptation patterns among runners.(19) For instance, any change to the lower extremity such as a change in footwear could offset timing sequences resulting in movement shifts. Perhaps too many variation patterns exist to detect a noteworthy mechanical difference. The above would suggest that the same trend exists in runners symptomatic of plantar fasciitis.

CONCLUSION

To date, little documentation is available regarding the correlation of shoe construction and the incidence of injury. Many researchers have alluded to the idea that a modification in shoe midsole stiffness may alleviate tension within the plantar fascia ligament but nothing concrete has been established. Hence, the main purpose of this study was to assess whether a change in shoe midsole flexibility would influence gait behavior and/or accelerate recovery time from plantar fasciitis.

The current study attempted to bridge this gap by objectively quantifying the shoe shank stiffness and correlating it to the dynamic range of the shoe motion during running in an attempt to alleviate the symptoms of plantar fasciitis. This investigation has demonstrated that significant relief from symptoms of plantar fasciitis (i.e., pain level) can be attained with the use of shoes stiffer than 27 N/mm. Further research is necessary to develop a means to implement the data for the prescription and everyday use of running shoes. Though, it can be said that runners with plantar fasciitis should generally be advised to select a shoe that is firm in the midsole region.

Another hypothesis of this study was that range of rear motion would be reduced with a stiffer shoe resulting in a reduction of plantar fasciitis symptoms. Interestingly, rear foot movement was increased with those wearing stiffer shoes but simultaneously the pain level of the participants decreased. This result could indicate that more appropriate loading is being dissipated or transferred away from the plantar fascia causing movement shifts within the foot and thus alleviating the amount of pain. It would be interesting to see a study correlating a relationship between rear foot and plantar fascia movements.

In addition, it was thought that ROM of the ankle, hip and knee would decrease with a stiffer shoe causing more stability throughout the lower extremity. This study found no significant differences but rather small changes were noticed. Ankle ROM seemed to have increased slightly in the experimental group compared to the control group and the hip ROM seemed to have increased for both the experimental and control group but the experimental group seemed to have decreased less. Slight modifications in gait have been suggested by many researchers to potentially offset timing of joint mechanics resulting in further injury.(33) While generalizations cannot be drawn from these particular results, it is important to note any degree of change as it may affect biomechanics.

Conceivably it would be interesting to examine the applied force, pressure distribution patterns and/or even electromyography activity-taking place at the foot shoe interface. These variables would provide more insight as to precisely what is taking place when patients with plantar fasciitis wear stiffer shoes.

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APPENDIX A: Article in submission

Article to be submitted to Clinical Biomechanics

The effects of a rigid shoe midsole on plantar fasciitis in runners.

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Running head: Plantar fasciitis, rigid shoe midsole & runners

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Key words: Plantar fasciitis, rigid shoe midsole & runners

ABSTRACT

Background. Plantar fasciitis is a common overuse injury in runners accounting for almost 10% of all injuries. (45) An excessively flexible shoe midsole or shank may be at fault for the development of plantar fasciitis in runners because of the unnecessary stretching of the plantar fascia ligament. (9;12;17;48) The main purpose of the study was to assess whether a change in shoe midsole flexibility would influence gait behaviour and/or accelerate recovery time from plantar fasciitis. ***Methods.*** Eighteen male and female (M= 10: F= 8) subjects actively participated for 3-months and attended 3-separate testing sessions (initial, 45 & 90 days post initial visit). Twelve (n=12) were quasi-assigned to the experimental (given new shoes) and six (n=6) to the control group (remained in shoes). Pre and post rearfoot, ankle, knee and hip parameters (degrees) were collected while running. Shoe shank-midsole motion (mm) was also evaluated to determine dynamic flexibility of the shoe. ***Findings*:** Significant differences were found between groups for range of motion (ROM) of the rear foot angle and mid shoe shank motion as well as pain level ($p<0.05$). The experimental group increased rear foot ROM, slightly decreased mid shoe shank ROM motion and decreased pain level. The control group decreased rear foot angle, decreased mid shoe shank ROM and maintained pain level. No significant differences were found for ankle, knee and hip angles.

Interpretation: A stiffer shoe could potentially dissipate or transfer forces exerted on the foot away from the plantar fascia to alleviate strain during stance phase of running. Significant relief from the symptoms of plantar fasciitis can be attained with the use of a stiffer shoe. No generalizations can be drawn for ankle, knee and hip ROM because too many adaptations patterns exist among runners.

1. INTRODUCTION

Plantar fasciitis is a common overuse injury in runners accounting for almost 10% of all injuries.(45) It is associated with acute symptoms such as heel pain, inflammation and swelling.(17) If this condition is not treated appropriately, micro tears may arise, followed by calcification of the soft tissue, which can ultimately form bone spurs and result in immense and chronic pain.(40) In extreme conditions, the plantar fascia can be pulled from the point of insertion of the medial calcaneal tuberosity.(17) When the plantar fascia ligament is stiff, strain is transferred to the supporting tissues resulting in further injury. (6)

The treatment for plantar fasciitis is quite variable and ranges from more conservative approaches to more invasive ones. Conservative modifications include: shoe adjustments, custom inserts, stretching exercises, physical therapy, nonsteroidal anti-inflammatory medications, and night splints.(11;22) More invasive approaches include: cortisone injections, surgery and extracorpeal shock wave therapy.(22;43) If plantar fasciitis is treated in the early stages, 80 % of cases conservative treatments have been shown to alleviate symptoms.(22)

The midsole or shank, the portion of the shoe that extends from the heel to the ball of the foot and sits above the outer sole, (41) acts as the shoes cushioning system by protecting the foot from the ground, decreasing shock impact, and evenly distributing foot pressure.(41) Simultaneously, it functions to reduce the amount of twisting that takes place in front of the shoe.(27) The midsole region is mainly compromised of polyurethane (PU) and/or ethylene vinyl acetate (EVA) materials and the density of these materials determine the overall stiffness of the shoe.(41)

An excessively flexible shoe midsole or shank, may be at fault for the development of plantar fasciitis in runners because of the unnecessary stretching of the plantar fascia ligament.(9;12;17;48) To date, no scientific research has investigated the correlation between varying midsole stiffness and injury, in particular, plantar fasciitis. Injury free runners have been evaluated but no concrete evidence exists identifying the effects on injured runners.

Clarke, Frederick and Hamill (7) examined rear foot movement while runners ($N = 10$) wore increasingly stiffer shoes-25, 35 and 45 durometer Shore A, respectively and found that maximum pronation (degrees), total rear foot movement (ROM; degrees) and time to maximum velocity (m/s) increased significantly ($p < 0.05$).

Hennig, Valiant and Liu (15) found using three different pairs of running shoes which differed in stiffness, that runners had a tendency to change rear foot motion to reduce the amount of force impact. Similarly, Milani, Hennig, and Lafortune (29) studied running shoes that differed minimally opposed to a wider spectrum of midsole stiffness. Impacter tests on eight pairs of shoes revealed sole deformation and acceleration range of 7.4 to 11.5 mm and 9.6 to 13 g, respectively. A stiffer shoe significantly decreased maximum rear foot pronation (degrees) and increased maximum rear foot pronation velocity (degrees/s) ($p<0.005$).

Hardin, Van Den Bogert and Hamill (13) reported that when runners are exposed to new shoes that differ in midsole hardness, kinematics change. They found comparing a soft shoe, 40 shore A, to a hard shoe, 70 shore A, that running in harder shoes increased ankle dorsiflexion velocity (m/s) ($p < 0.0005$). Further to these results, runners had a tendency to increase knee flexion velocity (m/s), however not at the significance level (p

= 0.099). These results were suggested to be due to passive rather than active mechanical reactions to first contact. In other words, these results were attributed to a more subtle change in the sequence of running gait.

This said, the main purpose of the study was to assess whether a change in shoe midsole flexibility would influence gait behavior and/or accelerate recovery time from plantar fasciitis.

2. METHODS

2.1 Description of study

Participants were informed that the study involved identifying the effects of a rigid shoe midsole on plantar fasciitis in runners. Candidates that accepted to participate in this study were asked to actively participate for three months by performing their normal exercise activities and either wearing shoes prescribed by the study or remain in their current shoes. Within the three-month time frame, participants were expected to attend three separate sessions (initial, 45 & 90 days post initial visit) conducted at The Cleveland Clinic Foundation in Biomechanics Laboratory. A written informed consent was signed before participation in the study. The protocol of this study received approval from both the University of Ottawa and The Cleveland Clinic Foundation ethics review boards.

2.2 Selection of participants

Eighteen participants were recruited and remained in the study (Males = 10: Females = 8). All subjects had symptoms of uni-or bi-lateral plantar fasciitis within the last six months, ran at least 10 miles per week, performed stretching exercises once a day and ice after running if it was necessary for 90 days and had shoe stiffness values greater than 27 N/mm. Twelve participants were quasi-randomly assigned to the experimental group (Male = 6: Females = 6; Uni-PF = 10: Bi-PF = 2) and six to the control group (Males = 4: Females = 2; Uni-PF = 4: Bi-PF = 2). Mean age, mass, height and years running for the experimental group were 41.9 yrs (SD: 12.7), 147.3 lbs (SD: 22.6), 167.1 cm (SD: 7.9) and 13.7 yrs (SD: 9.9) and the control group were 45.3 yrs (SD: 10.0), 199.7 lbs (SD: 46.3), 180 cm (SD: 10.5) and 15.3 yrs (SD: 11.0), respectively.

Participants were recruited by flyers posted. Information was obtained by phone from those that responded to the flyer. Participants that satisfied the inclusion criteria from the phone screen were asked to present themselves to the laboratory for the first initial visit.

2.3 Shoe Selection Process

A select number of running shoes were previously tested in another study using three point bending tests in a MTS™ Servo Hydraulic Testing machine (858 Bionix Test System, Mechanical Testing Systems, Minneapolis, MN, Figure 1a,b). Tests followed closely to the American Society for Testing and Materials (West Conshohocken, PA) standards for testing running shoes. Stiffness values were calculated from the force-deformation data in the steepest region of the linear elastic portion of the curve using a LabVIEW program (National Instruments, Austin, TX). A threshold value of 27 N/mm was selected based upon the statistical analyses of the stiffness data. Shoe types (stability, motion control and cushioned) were grouped accordingly and the average stiffness of each shoe was evaluated in comparison to each other. Shoes above the threshold value were shown to have statistically higher stiffness compared to the majority of shoe groups below the cut-off of 27 N/mm (Figure 1c).

Insert Figure 1

2.4 Characteristics of shoes selected

Eight pairs of shoes were chosen from the above-mentioned procedures and re-tested to ensure all shoes had a shoe stiffness value above 27 N/mm (Table 1). From these eight pairs of shoes, participants were allowed to pick which shoes they wanted to wear for the length of the study. This allowed participants to wear shoes that met their desired comfort level. Precautions were taken to ensure each participant remained in their initial shoe type (e.g. motion control, cushioned or stability). This was done to preserve foot structure.

Insert Table 1

2. 5 Testing Sessions

Three testing sessions took place. The initial visit involved completion of a questionnaire in relation to recent running practices (e.g., mileage per week) and symptoms experienced with plantar fasciitis using a 10-point pain ranking scale . A CCF podiatrist assessed the participants for plantar fasciitis ailments using a standard medical exam.

If the podiatrist deduced tight ligaments as the most reasonable explanation for the plantar fascia, participants remained in the study and it was reasonable to conclude that once the ligament is stretched a supportive shoe would keep it from tightening during the normal gait cycle. Participants were excluded if Podiatrist identified major reasons other than tight ligamentous structures for plantar fasciitis such as achilles tendinitis and stress fractures.

Subsequent to the assessessment, the current shoes of the participants were subjected to mechanical testing using the procedure indicated above. If the shoes stiffness values were below a predetermined treshold of 27N/mm, subjects were either assigned to the control or experimental group.

Those assigned to the control group were asked to remain in their current running shoes, resume normal activity, perform stretching exercises once a day and ice after running if necessary and be evaluated in the clinic after 45 and 90 days.

Participants assigned to the experimental group were given a voucher to purchase a new pair of shoes (within days of their first test visit) that are more rigid in the midsole region than their previous athletic shoes. This voucher was given at the end of the first visit. Over a course of 90 days, they were expected to resume normal activity, perform stretching exercises once a day and ice after running if necessary, as well as be evaluated in the clinic after 45 and 90 days.

Also, during the initial visit, an Eva 6.0 motion analysis system (Santa Rosa, CA, US) was used to test gait on the participants in both groups while wearing their current shoes to determine rear foot range of motion (ROM), dynamic flexibility of the midsole and dynamic ROM of ankle, knee and hip motion.

An anatomical marker set to define each segment in three dimensions was used. Thirty three reflective markers were placed on both legs of the participants at specific locations in order to define the variables of interest.. Strategic placements of three markers were placed on lower limb segments to allow analysis of movement in all planes.

As such, 3 reflective markers were placed in a triangle formation around the shoe midsole area on the lateral side, 4 markers were linearly aligned starting on the heel counter of the shoe and ending on the posterior distal end of the tibia spacing 1 inch apart, 1 marker was placed on the 5th metatarsal head on the outsole of the shoe, and on the medial and lateral malleolus, tibial tubercle, medial and lateral femoral epicondyls, greater tronchanter, left and right anterior superior iliac spine and the site of the sacrum.

Motion analysis was performed on an instrumented treadmill (Quinton 65, US) in which participants were expected to run at a speed of 3.0 m/s. This speed was selected to accommodate runners with plantar fasciitis and to control the amount of time spent in the stance phase for pre and post evaluations.

A weight bearing trial (standing trial) was collected for one second in a staggered position. This was completed to retrieve a marker reference position when body weight was applied to calculate joint ROM. After this trial, the medial reflective markers on the malleolus were removed. A non-weight bearing trial (sitting trial) was collected for one second in the same staggered position as in the standing trial. This was completed to retrieve a reference point for the midsole markers when no body weight was applied to calculate midsole height ROM. While running, two ten second trials were collected after a warm-up period of two minutes or until the participant felt comfortable running at the selected speed (3.0 m/s).

The second session (after 45 days) involved the same questionnaire as previously outlined during the intial visit, followed by an assessment performed by a CCF podiatrist and mechanical testing of the current running shoes of the participant. The purpose of the second assessment by a CCF podiatrist was to follow up on the participants. The assessment involved: (1) asking the participants if their symptoms were getting better or worse and if they were being compliant with the shoes they were given, as well as using ice and stretching as directed; (2) re-educating on stretching as needed; and (3) evaluating for other podiatric heel pain issues as needed.

The third session (after 90 days), the participants filled out the same questionnaire as previously mentioned followed by a post motion analysis test and mechanical testing of the participants most current shoes, as outlined in the first session.

2. 6 Statistical Analysis

A 3-way repeated measure ANOVA comparing Group (controls versus subjects wearing new shoes), Affected foot (affected versus non-affected foot) and Session (pre versus post) was used to determine the effect of treatment (new shoes) on those diagnosed with plantar fasciitis. The above statistical analysis was used to assess the effect on rear foot, ankle, knee, hip angles (degrees) as well as midsole-shank compression (mm). When interactions were significant, a post hoc Scheffe was used. Also, a 2-way repeated measure ANOVA (Group X Session) was used to determine the amount of pain participants experienced during daily activities and direct pain in the heels/arches of one or both feet. Statistica software package (STAT Soft Inc., Tulsa, USA) was used for all analyses. $P < 0.05$ was considered statistically significant.

Statistical analyses were not performed on running mileage and shoe stiffness. These variables were used to monitor changes, if applicable.

3. RESULTS

A custom LabVIEW (National Instruments, Austin, TX) program was used to process rear foot, ankle, knee and hip angles (degrees) as well as shoe midsole displacement (mm). Each respective angle was segmented into separate strides and normalized over a time-based series to calculate the average movement taken place during the gait cycle, more specifically, the stance phase. The range of motion (ROM) (max value – min value) was computed for all variables listed above to determine the amount of motion taking place at each joint or within the shoe midsole.

3.1 Rear foot angle

The dynamic range of motion of the rear foot was evaluated by the change of motion in the frontal plane--inversion and eversion during running. The average range was determined during stance and averaged for each trial. A 3-way repeated measure ANOVA (Group X Affected foot X Session) was used for analysis. No significant differences were discovered for group ($F(1, 11) = 0.95$, $p > 0.05$), affected foot ($F(1, 11) = 0.61$, $p > 0.05$) and session ($F(1, 11) = 0.89$, $p > 0.05$). However, the ANOVA revealed a significant triple interaction ($F(1, 11) = 5.03$, $p < 0.05$). A post hoc follow up using a Scheffe decomposition into main effect revealed that the control group decreased rear foot angle significantly ($p < 0.05$) and the experimental group increased rear foot angle significantly ($p < 0.05$). Figure 2 illustrates pre and post assessments of the affected foot of the experimental versus control groups.

Insert Figure 2

3.2 Shoe shank

The dynamic range of the shoe was evaluated by the change of the shoe shank compression during running (mm). Average range of motion of the shoe shank during stance was determined for all strides and averaged for each trial. Separate 3-way repeated measure ANOVA's (Group X Affected foot X Session) were completed for all compressions in the shoe shank triangle formation and were anatomically described as mid, posterior, anterior.

For mid shank motion, a significant difference was found for pre-post sessions (F (1, 14) = 12.2, $p < 0.05$) but no significant differences were found for group (F (1, 14) = 1.01, $p > 0.05$) and affected foot (F (1, 14) = 0.01, $p > 0.05$). A significant interaction between group and pre-post sessions was found (F (1, 14) = 5.19, $p < 0.05$). Figure 3 illustrates pre and post assessments of the affected foot of the experimental versus control groups.

A 2-way interaction decomposition using Scheffe's model revealed that the control group significantly decreased shoe shank motion ($p < 0.05$) and the experimental group slightly decreased but no significance was revealed ($p > 0.05$).

For the post shank motion, a significant difference was revealed for pre-post sessions (F (1, 14) = 5.66, $p < 0.05$) but no significant differences were revealed for group (F (1, 14) = 0. 28, $p > 0.05$) and affected foot (F (1, 14) = 1.07, $p > 0.05$). Two-way interaction between group and session indicated to have an almost significant value (F (1, 14) = 3.31, $p = 0.09$). The trend was that the control group decreased more in post shank motion compared to the experimental who only decreased slightly.

For the anterior shank motion, no significant differences were revealed for pre-post sessions (F (1, 14) = 0.85, $p > 0.05$), group (F (1, 14) = 1.61, $p > 0.05$) and affected foot (F (1, 14) = 0.003, $p > 0.05$). Though, similar trends to the mid and post shank motion were observed in that the control group decreased more in anterior shank motion compared to the experimental who only decreased slightly.

Insert Figure 3

3.3 Ankle, Knee and Hip angles

The dynamic ranges of motion of the ankle, knee and hip angles were evaluated by the change of motion in the sagittal plane -positive (flexion) and negative direction (extension) during running. Average joint range of motion was determined for all strides and averaged for each trial.

Separate 3-way repeated measure ANOVA's (Group X Affected foot X Session) were completed for ankle, knee and hip angles. For ankle angle, no significant differences were observed for affected foot ($F (1, 22) = 1.73$, $p > 0.05$) and session ($F (1, 22) = 2.61$, $p > 0.05$). Though, an almost significant difference was observed for group ($F (1, 22) = 3.04$, $p = 0.095297$). Similarly, a 2-way interaction between group and affected foot revealed an almost significant difference ($F (1, 22) = 3.05$, $p = 0.09$).

For knee angle, no significant differences were seen for group ($F (1, 19) = 0.26$, $p > 0.05$), affected foot ($F (1, 19) = 0.32$, $p > 0.05$) and session ($F (1, 19) = 1.68$, $p > 0.05$).

For hip angle, no significant differences were seen for group ($F (1, 19) = 0.28$, $p > 0.05$) and affected foot ($F (1, 19) = 0.98$, $p > 0.05$) but a significant difference was observed for session ($F (1, 19) = 6.002$, $p < 0.05$).

3. 4 Pain level

A 10-point pain scale (e.g. with 10 being the most severe pain & 0 being no pain) was used to determine pain level experienced during the course of the study (initial, 45 & 90 days) during daily activities and pain directly associated with the heels/arches. Separate 2-way repeated measure ANOVA's (group X visit) were used for analysis.

For daily activities, the amount of pain experienced in one or both feet while standing, walking, lifting, stair-climbing, stepping sideways, sitting and standing on toes were averaged and compared between groups. Significant differences were revealed for group ($F(1, 16) = 7.89$, $p < 0.05$) and visit ($F(1, 32) = 17.5$, $p < 0.05$). A post hoc Scheffe test revealed that the experimental group decreased significantly the amount of pain experienced during daily activities at 90 days ($p < 0.05$). Figure 4 illustrates pre and post assessments of the experimental versus control groups.

Insert Figure 4

For direct pain, the overall amount of pain experienced at each visit in one or both feet of heels/arches was evaluated. A significant difference was revealed for session ($F(1, 17) = 5.42$, $p < 0.05$) but no significant difference was observed for group ($F(1, 17) = 0.01$, $p > 0.05$). A post hoc Scheffe test revealed that the experimental group decreased significantly the amount of direct pain experienced with the heels/arches ($p < 0.05$) at 90 days. Figure 5 illustrates pre and post assessments of the experimental versus control groups.

Insert Figure 5

Figure 6 illustrates mean and standard deviation of shoe stiffness (N/mm) monitored over the three testing sessions-initial, 45 & 90 days post initial visit.

Insert Figure 6

4. DISCUSSION

Running shoes can be instrumental in reducing the risk of injury by modulating impact forces and excessive pronation. Cushioning, wedges and mechanical stiffening elements added to the shank region of the shoe address the issue of over pronation. However, little has been done to objectively quantify this effect, particularly with respect to running injuries like plantar fasciitis. Traditional thinking dictates that the cushioning characteristics play a critical role in the motion control of the shoe. There is not, however, consensus in the literature. The main focus of this study was to determine if the stiffness of the shoe plays a role in the functional outcome in plantar fasciitis. This study represents one of the first attempts to measure the characteristics of the shoe shank and correlate it to the dynamic response of the shoe during running and injury.

Subjects who remained in their current shoes, with stiffness values below the acceptable level (less than 27 N/mm), showed a decrease in height (mm) for mid shoe shank range of motion over the test period. Conversely, subjects who were given new shoes immediately following the initial visit maintained a more constant mid shoe shank range of motion over time with only a slight decrease apparent in the data. The latter result was expected, as new shoes should remain at a steady height range. The decrease in mid shoe shank height ROM seen in the control group (those that remained in their shoes) can be explained by examining the shoe stiffness (N/mm) data collected over the three testing sessions-initial, 45 & 90 days post initial visit. After 90 days, participants shoe stiffness values decreased suggesting that the midsole compressed to the point in which there was no material deformation left to absorb. This would be in sync with the decreased and therefore flattened height in the motion of the mid shoe shank for the control group who did not change their current shoes. With the decrease in motion, the plantar fascia is further stretched and the condition potentially aggravated.

The rear foot motion, a factor thought to be a large contributor to the motion in arch region of the foot,(10) increased over time in the experimental group and decreased for the control group. Interestingly, this finding was contrary to our hypothesis that a stiffer shoe would reduce rear foot motion. Perhaps the stiffer shoe reduced the motion taking place at the plantar fascia ligament but simultaneously altered rotary movements of the lower leg. This would partially fit the speculation of Hintermann and Nigg (16) that midsole support may increase external rotation of the tibia causing an undesirable rotary force through the tibia. Another possible explanation for the increase in rear foot movement could be that more appropriate loading is being dissipated away from the plantar fascia causing movement shifts within the foot. This would be in sync with Cavanagh *et al.,*(5) theory that running behavior (movement) is affected by shoe material because of pressure re-distribution.

Kurz and Stergiou (21) suggested that a stiffer midsole may increase joint variability (movement) causing joint forces to spread across surrounding tissues opposed to being localized in one tissue such as the plantar fascia ligament. On the other hand, McClay and Manal (25) suggested that excessive pronation could potentially lower the arch and cause instability throughout the rest of the foot.

Milani, *et al.,* (29) have indicated that runners have a tendency to change rear foot motion as a defense mechanism to reduce the amount of impact force that occurs when wearing increasingly stiffer shoes. Our results seem to be consistent with these findings in that the experimental group increased rear foot motion to accommodate their new shoes, whereas the control group decreased rear foot motion to accommodate remaining in shoes that are deteriorating in material deformation.

Furthermore, the increased range of motion seen at the rear foot in the experimental group may indicate a more balanced range of inversion-eversion opposed to being more restricted. Plantar fasciitis patients have been shown to have a deficient range of motion in the ankle.(20) Conceivably, a stiffer shoe loosened the surrounding tissues allowing for an increase in the range of motion at the rear.

The results of the rear foot motion and mid shoe shank motion are reinforced by the data from the subjective questionnaire. Although both groups started at a moderately high level of direct pain to one or both arches/heels and pain during daily activities, after 90 days, subjects with stiffer shoes reduced their pain level in the arches/heels of their foot/feet significantly. Control group subjects still had moderate pain scores after the same period of time. This finding would reiterate Luke's (22) finding that conservative treatments such as a shoe adjustment alleviate symptoms of plantar fasciitis in 80 % of cases. Another possible explanation for the results could be that the participants may have altered their behavior because they knew they were being studied-- Hawthorn Effect. In other words, one may have received new shoes and automatically felt better versus one that did not receive new shoes expected their pain symptoms to remain the same or deteriorate. Though, the fact that the control group maintained moderate pain symptoms suggests this did not occur.

The range of motion of lower extremity kinematics was evaluated over the course of the study to see if stiffer shoes could in fact alter mechanics. Ankle, knee and hip angles were within the normative values found in the literature for running(23;24;35) despite the fact that they were injured.

Although no significant differences were found, small changes were noticed. Ankle ROM seemed to have increased slightly in the experimental group compared to the control group and the hip ROM seemed to have increased for both the experimental and control group but the experimental group seemed to have decreased less. Slight modifications in gait have been suggested by many researchers to potentially offset timing (ms) of joint mechanics resulting in further injury.(33) While generalizations cannot be drawn from these particular results, it is important to note any degree of change as it may affect biomechanics.

McNair and Marshall (26) have suggested that runner's respond more with kinetic parameters opposed to motion taking place at the joints when observing shoe changes. Conceivably it would be interesting to examine the applied force, pressure distribution patterns and/or even electromyography activity-taking place at the foot shoe interface. Examining forces exerted on the foot such as loading rates (Fz) throughout stance and maximum vertical loading rates (m/s) could be useful in determining the influence of midsole construction on damping impact forces.(31) Pressure variables such as peak pressures (kPa) and relative loads (%) would useful in determining if stiffer shoes dissipate or transfer pressure to supporting tissues.(30) Observing electromyography activity in the supporting tissue of the foot could determine the amount of activity taking within each respective tissue. All the above variables would provide insight as to precisely what is taking place when patients with plantar fasciitis wear stiffer shoes.

Another explanation for the results could be that a wide range of adaptation patterns among runners.(19) For instance, any change to the lower extremity such as a change in footwear could offset timing sequences resulting in movement shifts. Perhaps too many variation patterns exist to detect a noteworthy mechanical difference. The above would suggest that the same trend exists in runners symptomatic of plantar fasciitis.

5. CONCLUSION

To date, little documentation is available regarding the correlation of shoe construction and the incidence of injury. Many researchers have alluded to the idea that a modification in shoe midsole stiffness may alleviate tension within the plantar fascia ligament but nothing concrete has been established. Hence, the main purpose of this study was to assess whether a change in shoe midsole flexibility would influence gait behavior and/or accelerate recovery time from plantar fasciitis.

The current study attempted to bridge this gap by objectively quantifying the shoe shank stiffness and correlating it to the dynamic range of the shoe motion during running in an attempt to alleviate the symptoms of plantar fasciitis. This investigation has demonstrated that significant relief from symptoms of plantar fasciitis (i.e., pain level) can be attained with the use of shoes stiffer than 27 N/mm. Further research is necessary to develop a means to implement the data for the prescription and everyday use of running shoes. Though, it can be said that runners with plantar fasciitis should generally be advised to select a shoe that is firm in the midsole region.

Another hypothesis of this study was that range of rear motion would be reduced with a stiffer shoe resulting in a reduction of plantar fasciitis symptoms. Interestingly, rear foot movement was increased with those wearing stiffer shoes but simultaneously the pain level of the participants decreased. This result could indicate that more appropriate loading is being dissipated or transferred away from the plantar fascia causing movement shifts within the foot and thus alleviating the amount of pain. It would be interesting to see a study correlating a relationship between rear foot and plantar fascia movements.

In addition, it was thought that ROM of the ankle, hip and knee would decrease with a stiffer shoe causing more stability throughout the lower extremity. This study found no significant differences but rather small changes were noticed. Ankle ROM seemed to have increased slightly in the experimental group compared to the control group and the hip ROM seemed to have increased for both the experimental and control group but the experimental group seemed to have decreased less. Slight modifications in gait have been suggested by many researchers to potentially offset timing of joint mechanics resulting in further injury.(33) While generalizations cannot be drawn from these particular results, it is important to note any degree of change as it may affect biomechanics.

Conceivably it would be interesting to examine the applied force, pressure distribution patterns and/or even electromyography activity-taking place at the foot shoe interface. These variables would provide more insight as to precisely what is taking place when patients with plantar fasciitis wear stiffer shoes.

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Figure captions

Figure 1a) b) c). (a) Schematic of MTS testing apparatus (b) experimental setup and (c) stiffness of select shoes.

Figure 2. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during rear foot motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill. X-axis = assessments (days), Y-axis = range of motion (ROM; degrees).

Figure 3.Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during mid shoe shank motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill. X-axis = assessments (days), Y-axis = range of motion (ROM; millimeters).

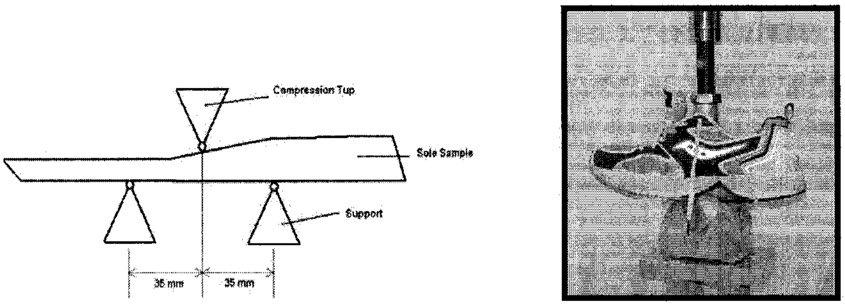
Figure 4. Mean (X) and standard deviation (sd) pre and post assessments (days) of daily activity pain (10-point pain scale, 10 being most severe & 0 being no pain) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill. X-axis = assessments (days), Y-axis = pain level (10-point scale).

Figure 5. Mean (X) and standard deviation (sd) pre and post assessments (days) of direct pain (10-point pain scale, 10 being most severe & 0 being no pain) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill. X-axis = assessments (days), Y-axis = pain level (10-point scale).

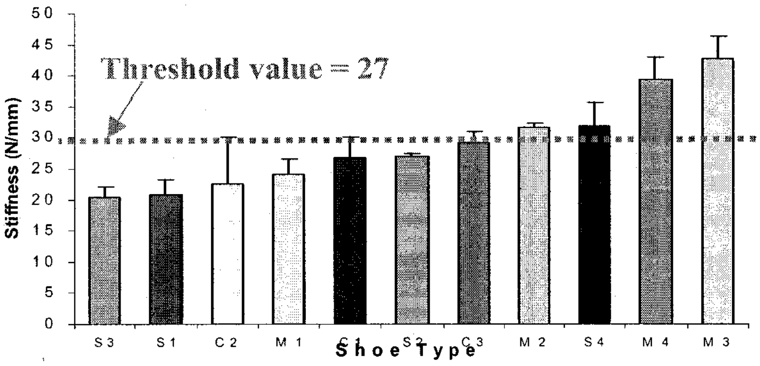
Figure 6. Mean (X) and standard deviation (sd) pre, mid and post assessments (days) of shoe stiffness (27 N/mm) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill. X-axis = assessments (days), Y-axis = shoe stiffness (N/mm).

Table 1. Characteristics of shoes used for the study.

Shoe name	Shoe type	Shoe stiffness values (N/mm)
S1	Stability	29.5
M1	Motion control	53.3
C1	Cushioned	27
S2	Stability	28.5
M2	Motion control	34.1
S3	Stability	29.1
S4	Stability	45.1
M3	Motion control	34.1

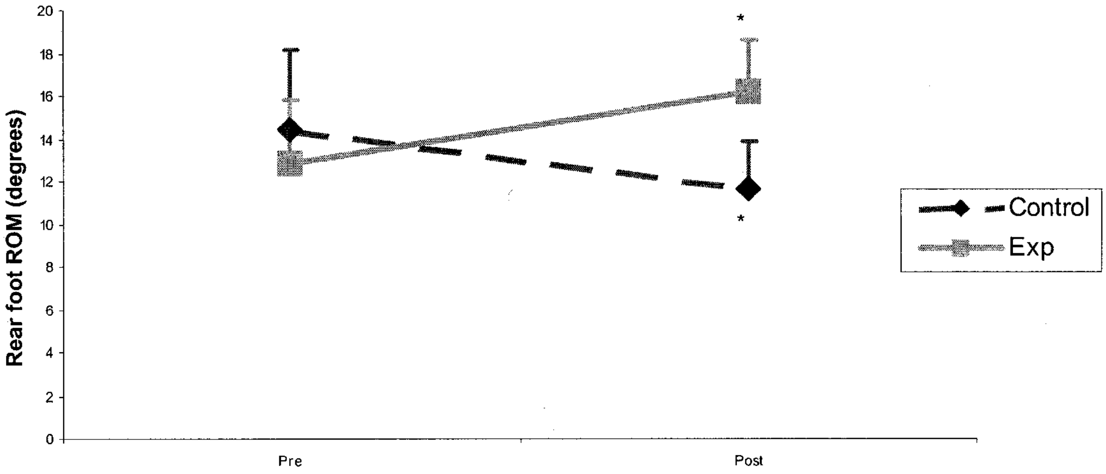


a. Schematic of MTS Testing Apparatus **b.** Experimental Setup



c. Stiffness of Select Shoes

Figure 1. **MTS Testing Apparatus and Results**



Assessment (days)

Figure 2. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during rear foot motion (ROM; degrees) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

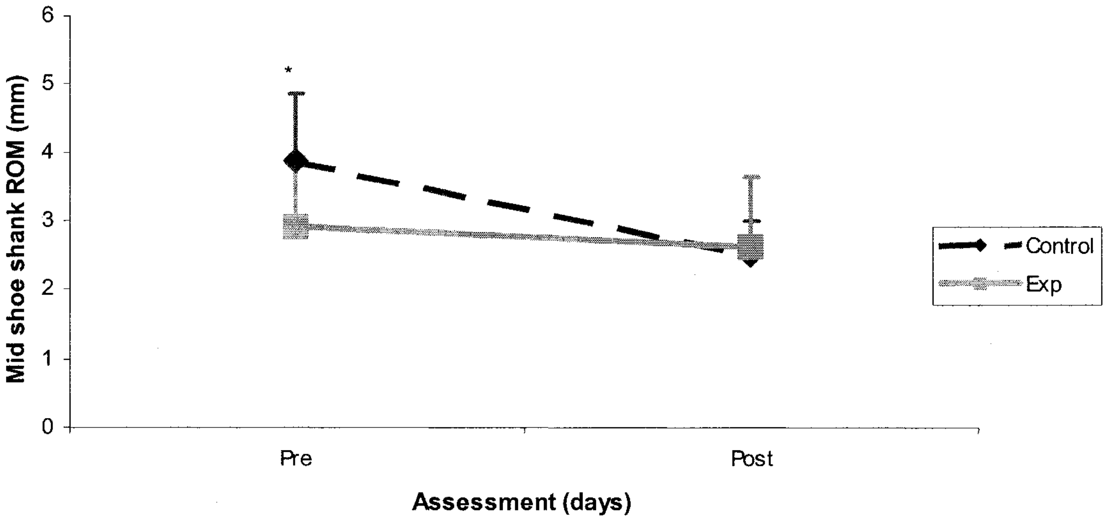


Figure 3. Mean (X) and standard deviation (sd) pre and post assessments (days) of the affected foot during mid shoe shank motion (ROM; mm) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

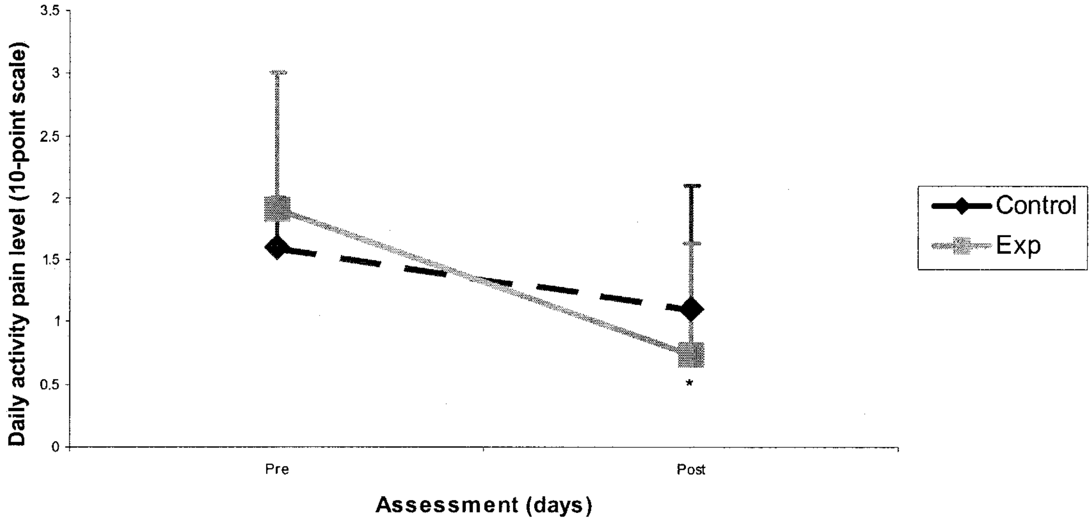


Figure 4. Mean (X) and standard deviation (sd) pre and post assessments (days) of daily activity pain (10-point pain scale, 10 being most severe & 0 being no pain) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

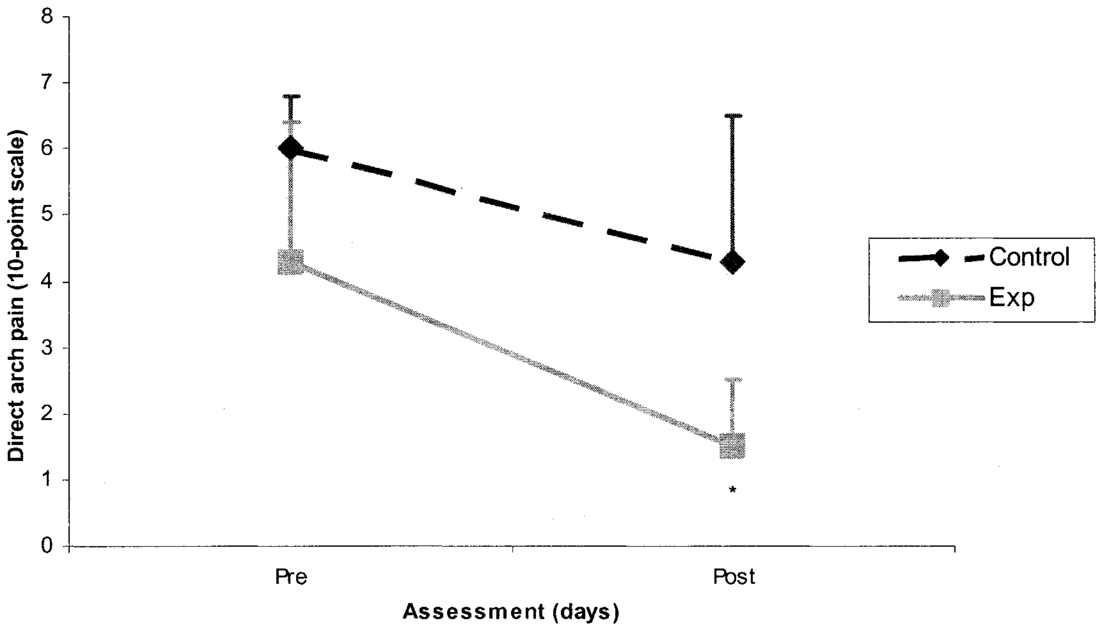


Figure 5. Mean (X) and standard deviation (sd) pre and post assessments (days) of direct pain (10-point pain scale, 10 being most severe & 0 being no pain) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

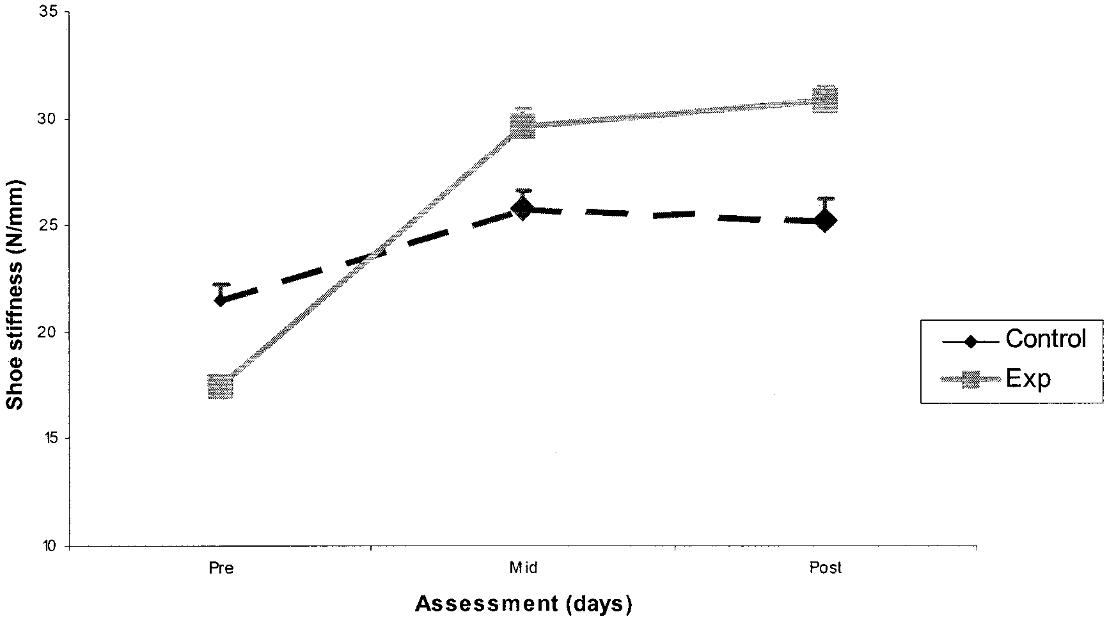


Figure 6. Mean (X) and standard deviation (sd) pre, mid and post assessments (days) of shoe stiffness (27 N/mm) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

APPENDIX B: Statement of contribution of collaborators

Kasey Parker:

I was the Master's student of Dr. Yves Lajoie. I was the first author of my thesis, and journal article submission associated with completing the requirements for the Master's of Science program at the University of Ottawa. All corrections and feedback came from my supervisor, Dr. Yves Lajoie and special collaborator, Dr. Susan D'Andrea. I was responsible for collecting all the data in the laboratory at the Cleveland Clinic Foundation. I, with the help of Dr. Susan D'Andrea, was responsible for processing and analyzing the data.

Yves Lajoie:

Dr. Yves Lajoie was my supervisor for my Master's project. He helped me interpret and analyze the data. He further provided me with feedback on my thesis and journal article submission.

Susan D'Andrea:

Dr. Susan D'Andrea acted as a special collaborator on this project. Her and I designed the protocol together prior to participation. She further supervised me in laboratory data collection, designed software packages to process data and provided feedback on my thesis paper.

APPENDIX C: Ankle Deviations

ANKLE:

1. FOREFOOT CONTACT- initial contact with the floor made with the forefoot
2. FOOT FLAT CONTACT- initial contact with the floor made with the entire foot
3. FOOT SLAP-uncontrolled plantar flexion at the ankle joint occurring at initial contact (usually accompanied by a slapping sound)
4. EXCESSIVE PLANTAR FLEXION- plantar flexion greater than normal for the specific phase
5. EXCESSIVE DORSIFLEXION- dorsiflexion greater than normal for the specific phase
6. VARUS- inversion occurring at the subtalar joint
7. VALGUS- eversion occurring at the subtalar joint
8. WOBBLES- alternating position of the ankle or foot occurring in a single phase
9. HEEL OFF- heel not in contact with floor
10. NO HEEL OFF- absence of heel rise during terminal stance
11. DRAG- contact of the toes or forefoot with the floor during swing
12. CONTRALATERAL VAULTING- rising on the forefoot of the stance limb during swing of the reference limb

(Rancho Los Amigos Hospital, 14, 1981)

APPENDIX D: Supporting documentation

D1 Advertisement flyers

D2 Phone screening

D3 Informed consent form

D4 Questionnaire

D5 Stretch exercices and ice participant information flyer

D6 Payment form

D1 Advertisement flyers

THE CLEVELAND CLINIC

AAPSM
American Academy of Podiatric Sports Medicine

RECRUITING PARTICIPANTS...

The Cleveland Clinic Foundation is looking for people interested in participating in a research study investigating the effects of athletic shoes on plantar fasciitis in runners.

Objective:

- To determine the effect of a flexible versus non-flexible shoe on the incidence and recovery of plantar fasciitis.

What is plantar fasciitis?

- Plantar Fasciitis is an inflammatory condition affecting the connective tissue on the arch of the foot. This condition is generally caused by overuse and can be debilitating to the athlete as well as the non-athlete.
- Symptoms include:
  - Pain on the sole of the foot, often localized to the front of the heel
  - Pain is most severe when you first stand on the foot in the morning.
  - Pain often aggravated by standing, walking or running, with running being the most painful.

What type of requirements do I have to meet to participate?

- Must be recovering from plantar fasciitis
- Must be an "active" runner:
  - Run at least 3 times per week
  - Run at least 10 miles per week
  - Maintained running schedule for at least 6 months

What will I have to do?

- Be an active participant for 3 months;
- Visit The Cleveland Clinic Foundation on 3 separate occasions during the 3 month period; and
- Be willing to run in a pair of shoes provided to you by the study for three months.

What do I get for my participation in this study?

- $75.00 upon completion of the study; and
- If you qualify (meet desired requirements) and are accepted into the study, a free pair of running shoes!

If interested, please contact:

Principal Investigator:	Dr. Susan D'Andrea
Phone:	(216) 444-5347
E-mail:	dandreas@bme.ri.ccf.org
OR	
Research Assistant:	Kasey Parker
E-mail:	

CCF IRB # 6445
Approval Date 8-13-03
Expiration Date 7-31-04

Runners with Heel Pain

Subjects are needed for an American Academy of Podiatric Sports Medicine sponsored study investigating the effects of athletic shoes on runners diagnosed with plantar fasciitis. This research is intended to find preventative and curative means to alleviate symptoms from this condition.

- Male or Female.
- Age 18+.
- Diagnosed with plantar fasciitis.
- Experiment time commitment:
  - 3 months of active participation; and
  - 3 visits to The Cleveland Clinic Foundation

Compensation of cash and a pair of athletic shoes, if you qualify and are accepted as a participant

THE CLEVELAND CLINIC

Department of Biomedical Engineering
The Lerner Research Institute
If interested:

Runners with Heel Pain
Call Dr. Susan D'Andrea
(216) 444-5347 or
E-mail
dandreas@bme.ri.ccf.org

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CCF IRB # 6445
Approval Date 8-13-03
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D2 Phone screening

"Hello, my name is Kasey Parker and I am responsible for investigating this particular research project that you are potentially interested in participating. Before I ask you some questions, I would like to indicate the goals and purpose of this study."

"The goal of this study will be to determine the effect of a flexible versus non-flexible shoe on the incidence and recovery of plantar fasciitis. Researchers and clinicians have recognized that a flexible shank, the portion of the shoe between the heel and the metatarsal heads, may be at fault for the great abundance of plantar fasciitis patients. Further analysis is required to grasp a better understanding of the full extent of the effects shoe shank flexibility has on plantar fasciitis. Therefore, one of the main purposes of this study is to assess the conservative treatment of a change in shoe and corresponding shoe flexibility. By controlling shoe gear, we can monitor the onset, resolution or recurrence of plantar fasciitis."

"If you choose to participate, you will be asked to do the following."

The research project will require participants to actively participate for three months by performing their normal exercise activities wearing shoes prescribed by the study. Within the three-month time frame, participants will also be expected to attend three separate sessions (initial, 45 & 90 days post initial visit) conducted at The Cleveland Clinic Foundation in Biomechanics Laboratory.

The initial visit will involve completion of a questionnaire in relation to recent running practices and symptoms experienced with plantar fasciitis. A CCF podiatrist will assess the participant for plantar fasciitis ailments. Subsequent to the assessessment, the current shoes of the participants will be subjected to mechanical testing. Based upon this information, the shoe will be categorized as rigid or flexible and therefore having properties above/below a predetermined threshold.

If the shoes are considered rigid, the participant will be given prescribed shoes that are equivelent to there current running shoe stiffness. Thereafter, they will be asked to resume normal activity, perform stretching exercises once a day and ice after running if and be evaluated in the clinic after 45 and 90 days. Participants will be given a voucher to purchase shoes at the local running shoe store, Second Sole. These participants will serve as the controls for the study.

A second group of participants will be placed in the experimental group if the participant's current shoe is deemed too flexible as a result of the biomechanical analyses. These participants will be given a new pair of shoes that are more rigid in the midsole region than their previous athletic shoes. Over a course of 90 days, they will also be expected to resume normal activity, perform stretching exercises once a day and ice after running if necessary, as well as be evaluated in the clinic after 45 and 90 days.

A select set of shoes previously tested will be chosen for their ability to provide good rigidity in the shank region. Participants will be given choices of shoes and a voucher to purchase them at a local running shoe store, Second Sole. Care will be taken to assure that the participant chooses a similar heel counter as the shoes previously worn. The participant will be asked to wear these shoes with the same frequency at which they wore their previous pair – on all runs and during any other high level activity for the next 90 days.

Also during the initial visit, motion analysis will be done on the participants in both groups while wearing their current shoes to determine the dynamic flexibility of the shoes. The motion analysis will be performed on an instrumented treadmill in which participants will be expected to run at a speed of 10 km/hr . Reflective markers will be placed on the lateral side of the right shoe forming a triangle on the rear of the heel counter. Marker position data will be collected for ten seconds after a period of two minutes of running.

The second session (after 45 days) will involve the same questionnaire as previously outlined during the intial visit, followed by an assessment performed by a CCF podiatrist and mechanical testing of the current running shoes by the participant.

The third session (after 90 days), the participants will fill out the same questionnaire as previously mentioned followed by a post motion analysis test and mechanical testing of the participants most current shoes, as outlined in the first session.

"That said, I will now ask you some questions in relation to your current running practices and symptoms related to plantar fasciitis to see if you meet all the necessary requirements to participate in this research study".

The following is a list of questions that will be asked of the potential candidate. At this point the candidate will be reminded that they are not obligated to answer any questions that make them feel uncomfortable.

Candidate Questionnaire

AGE________ Weight___________ (lbs) Height____________ (cm)

JOB ____

____

____

Summary of Running Activities

YEARS RUNNING	____________________	YEARS
MILEAGE PER WEEK	____________________	MILES
I CHANGE SHOES EVERY OR	____________________	MILES
ABOUT EVERY	____________________	MONTH(S)

Injury Status

Please answer the following.

1. A medical professional has diagnosed me as having plantar fasciitis in the last 12 months

   YES ________, NO__________.

2. Have you recently purchased new shoes?

   YES ________, NO__________.

3. Have you changed training locations or your training regimen?

YES ________, NO__________.

4. Have you tried any devices (e.g., orthotics) to accommodate your current condition?

YES ________, NO__________.

5. Have you tried any type medical relief to alleviate or minimize the pain?

YES ________, NO__________.

Using a pain scale (e.g. with 10 being the most severe pain & 0 being no pain) circle the value that most represents your experience (Circle one).

6. I currently am experiencing pain of one or both of my heels/ arches at a level of

0 1 2 3 4 5 6 7 8 9 10

No Pain At All Severe Pain

7. Does the pain occur with activities of daily living?
Please check all activities that apply and indicate the severity of pain on a scale of 1(no pain at all) to 10 (severe pain)

Activity	**Yes or No**	**Pain Level**
Standing	________	________
Lifting	________	________
Stair climbing	________	________
Stepping Sideways	________	________
Sitting	________	________
Walking	________	________
Standing on your toes	________	________

8. Does the pain occur with sporting activities other than running?

YES ________, NO__________.
If yes, what level of pain do you experience?

0 1 2 3 4 5 6 7 8 9 10

No Pain At All Severe Pain

9. Do you experience swelling/ inflammation at the end of the day or running or the next day?

YES ________, NO__________.
If yes, to what extent does the swelling affect your mobility?

0 1 2 3 4 5 6 7 8 9 10

Not at all   Cannot move

Please check and answer additional questions if applicable.

10. Currently or in the last 12 months, I have had pain of one or both of my heels / arches when I get out of bed?

YES ________, NO__________.
If yes, how long does the pain last (min)? ______.
Would you describe your pain as sharp, burning, dull aching or a pulling sensation?
____.

11. Currently or in the last 12 months, I have had pain of one or both of my heels/ arches when I sit for a while & then stand up?

YES ________, NO__________.
If yes, how long does the pain last (min)? ______.
Would you describe your pain as sharp, burning, dull aching or a pulling sensation?
____.

12. Currently or in the last 12 months, I have had pain of one or both of my heels/ arches

A.	At the end of my runs	YES	NO
B.	At the end of my "work day"	YES	NO
C.	The next day?	YES	NO

How long does the pain last (min)?

D. At the end of my runs __________ minutes
E. At the end of my "work day" __________ minutes
F. The next day? __________ minutes

Would you describe your pain as sharp, burning, dull aching or a pulling sensation?

____.

"Lastly, if you choose to participate in the study, will you agree to perform stretching exercises and ice after running if necessarry and not follow any other treatment for your current foot condition? Based on the information that you have provided me, you are an excellent candidate to participate in the study. Do you have any questions? When are you available to schedule an intial visit?" Great! Thanks for expressing interest in the study, and I will see you at the initial visit. If you have any future questions or concerns, please do not hesitate to contact me."

Because you have answered “no” to one or more of the following questions:

(a) having symptoms of plantar fasciitis within the last six months;

(b) being an active runner – run at least three times a week;

(c) agreeing to perform stretching exercises and ice after running if necessarry;

unfortunetaly you do not qualify for the research study. All these previously outlined criteria are necessary to participate. Thank-you for expressing interest in the study. I’ll be happy to answer any questions or concerns that you may have.

D3 Informed consent form

The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: The Effects of a Rigid Shank Shoe on Plantar Fasciitis in Runner

You are being asked to participate in a research study. The purpose of this document is to provide you with information to consider in deciding whether to participate in this research study. Consent must be based on an understanding of the nature and risks of the treatment, device or procedure. Please ask questions if there is anything you do not understand. Your participation is voluntary and will have no effect on the quality of your medical care if you choose not to participate.

1. Information on the Research

The purpose of the research study is to study whether changes in the running shoe flexibility improves plantar fasciitis (pain in the foot) symptoms. Thirty subjects will be recruited for the study. Your participation in this study may last up to three months with three sessions on campus at The Cleveland Clinic Foundation in the Biomechanics Laboratory. You will only be selected as a participant if you meet all of the following criteria: (a) have had symptoms of plantar fasciitis within the last six months; (b) are an active runner – run at least three times a week; and (c) agree to stretching exercises once a day and icing after running if necessary for 90 days.

You will be expected to complete a questionnaire in relation to your recent running practices and symptoms that you have experienced with regard to plantar fasciitis . You will also be expected to fill out this questionnaire during the second and third visit which will occur 45 and 90 days after the first visit, respectively. A CCF podiatrist will perform a biomechanical evaluation. Therafter, a gait analysis will be completed wearing your current athletic shoes. You will then be expected to remove your shoes, which will be subjected to mechanical testing. Based on the gathered information from the mechanical testing, your shoes will be categorized as rigid or flexible. If your shoes are considered rigid, you will be asked to remain in your current shoes, perform stretching exercises and ice after running if necessary and be evaluated in the clinic after 45 and 90 days. You can then resume your normal running activity level. At the end of the study, you will be given a voucher to purchase shoes at the local running shoe store. In the event that your shoes will be considered too flexible, as a result of the biomechanical analyses, you will be given a new pair of running shoes to wear over the next 90 days. You will be given a choice of select shoes and a voucher to purchase them at a local running shoe store. The podiatrist will advise you on your shoe selection. You will be asked to wear these shoes with the same frequency at which you wore your previous pair – on all runs and during any other high level activity for the next 90 days.

Regardless of which category you fall under, you will be asked to return to the Biomechanics Laboratory 45 and 90 days after the initial visit for further assessment. On your second visit (after 45 days), you will be expected to fill out the same questionnaire as previously outlined during the intial visit followed by an assessment performed by a CCF podiatrist for the purpose of a follow-up. This particular session will endure approximately 1 hour.

The third session (after 90 days), you will be asked to fill out the same questionnaire as in previously mentioned in visit 1 and 2, followed by a gait assessment on a treadmill. This session will endure approximately 1 hour. After completetion of the study, you will receive a compensation equivalent to $75.00 in the form of a check.

CCF IRB # 6445
Approval Date 8-20-04
Expiration Date 7-31-05

2. Risks and Discomforts

Anticipated risks for this study is inherent to exercise and may include muscle fatigue, muscle soreness, and/or falling from a treadmill due to loss of balance. Therefore, you will be given an opportunity to get familiar with the treadmill. All of the measurements will be conducted by a qualified personnel and a spotter will be ready at all times in case you lose your balance. You will be attached to a harness to prevent any risk of injury due to the loss of balance. The handrails on the treadmill may also be used to prevent loss of balance. A potential risk of embarrassment exists from performing a skill in front of an audience (e.g., principal researcher and/or research assistant). Further, because you are expected not to receive any treatment for 90 days while participating in the study, you may risk aggravating your current foot condition. Although there are no direct benefits to you, the research may provide knowledge and understanding of how an athletic shoe can inherently affect plantar fasciitis in runners.

3. Benefits

Although there are no direct benefits to you, the research may give insight to Clinicians regarding the effects shoe rigidity or flexibility on plantar fasciitis. Also, the outcome of this study could potentially contribute to a better understanding of shoe design for researchers in the biomechanics field.

4. Alternatives

The alternative is not to participate in this research study.

5. Privacy and Confidentiality

The medical and research information recorded about you will be used within the Cleveland Clinic and/or disclosed outside the Cleveland Clinic as part of this research. Some of the tests and procedures done solely for this research study also may be placed in your medical record so your other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in the medical chart.

Your access to research information about you will be limited while the study is in progress. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study. This information will be available should an emergency arise that would require your treating physician to know this information to treat you best.

Your research information may be disclosed to the Principal Investigator (Dr. Susan D'Andrea), the American Academy of Podiatric Sports Medicine and its agents, the Cleveland Clinic research review staff, and other outside collaborators or laboratories that are participating in this study, if any. The Cleveland Clinic also may use and disclose this information for treatment and payment reasons. The Cleveland Clinic must comply with legal requirements that mandate disclosure in unusual situations. Otherwise, the information recorded about you as part of this research will be maintained in a confidential manner. It is possible that information disclosed about you outside the Cleveland Clinic could be re-disclosed and no longer protected by federal privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to The Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio 44195. If you do so, any information previously disclosed cannot be withdrawn. The Cleveland Clinic will not use or disclose the information collected in this study for another research purpose without your written permission, unless the Cleveland Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects.

If you choose not to sign this consent form, you will not be permitted to participate in this research study.

6. Research-Related Injuries

If physical injury occurs due to your involvement in this research, medical treatment is available by The Cleveland Clinic Foundation, but your medical insurance must pay the cost of treatment. Such medical treatments that are not covered by your medical insurance shall not be paid by The Cleveland Clinic Foundation. Compensation for lost wages and /or direct or indirect losses are not available. The Cleveland Clinic will not voluntarily provide compensation for medical expenses or any other compensation for research-related injuries. Further information about research-related injuries is available by contacting the Institutional Review Board at (216) 444-2924.

7. Costs

There will be no charge to participate in this study. Participants will be issued $75.00 in the form of a check upon completion of the entire study for their participation. The sponsor, the American Academy of Podiatric Sports Medicine, will pay for the cost of a pair of running shoes that will be given upon qualification and acceptance into the study. Also, The Cleveland Clinic will not pay for the costs of procedures, tests, visits and hospitalizations in connection with this research.

8. Questions

If you have any questions about the research or develop a research-related problem, you should contact Dr. Susan D'Andrea (216) 444-5347. You can contact the on call orthopedic resident for after hours at the following pager number (216) 464-8410 ext. 23360. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

9. Voluntary Participation

Your participation in this study is completely voluntary. You can choose not to participate, or stop participating at any time without fear of penalty or loss of medical care. You will be informed of any significant new findings recognized during the course of the research that may relate to your willingness to continue participating in the study.

10. Signature

I have read the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. A copy of this consent will be provided to you. By signing below, I agree to take part in this research study.

Subject Signature: ______________________________ Date: __________

Witness/Person Obtaining Consent Signature: ______________________ Date: __________

CCF IRB # 1446

Approval Date 2-20-04

Expiration Date 1-31-05

D4 Questionnaire

Subject Questionnaire

NAME____

AGE________ Weight__________ (lbs) Height__________ (cm)

JOB ____
____
____

Summary of Running Activities

YEARS RUNNING ________________ YEARS

MILEAGE PER WEEK ________________ MILES

I CHANGE SHOES EVERY ________________ MILES
OR
ABOUT EVERY ________________ MONTH(S)

Injury Status

Please answer the following.

1. A medical professional has diagnosed me as having plantar fasciitis in the last 12 months

   YES ________, NO__________.

2. Have you recently purchased new shoes?

   YES ________, NO__________.

3. Have you changed training locations or your training regimen?

   YES ________, NO__________.

4. Have you tried any devices (e.g., orthotics) to accommodate your current condition?

   YES ________, NO__________.

5. Have you tried any type medical relief to alleviate or minimize the pain?

   YES ________, NO__________.

Using a pain scale (e.g. with 10 being the most severe pain & 0 being no pain) circle the value that most represents your experience (Circle one).

6. I currently am experiencing pain of one or both of my heels/ arches at a level of

0 1 2 3 4 5 6 7 8 9 10
No Pain At All Severe Pain

CCF IRB # 6445
Approval Date 8-13-03
Expiration Date 7-31-04

7. Does the pain occur with activities of daily living?
Please check all activities that apply and indicate the severity of pain on a scale of 1(no pain at all) to 10 (severe pain)

Activity	**Yes or No**	**Pain Level**
Standing	________	________
Lifting	________	________
Stair climbing	________	________
Stepping Sideways	________	________
Sitting	________	________
Walking	________	________
Standing on your toes	________	________

8. Does the pain occur with sporting activities other than running?

YES ________, NO__________.
If yes, what level of pain do you experience?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
No Pain At All										Severe Pain

9. Do you experience swelling/ inflammation at the end of the day or running or the next day?

YES ________, NO__________.
If yes, to what extent does the swelling affect your mobility?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Not at all										Cannot move

Please check and answer additional questions if applicable.

10. Currently or in the last 12 months, I have had pain of one or both of my heels / arches when I get out of bed?

YES ________, NO__________.
If yes, how long does the pain last (min)? ______.
Would you describe your pain as sharp, burning, dull aching or a pulling sensation?
____.

11. Currently or in the last 12 months, I have had pain of one or both of my heels/ arches when I sit for a while & then stand up?

YES ________, NO__________.
If yes, how long does the pain last (min)? ______.
Would you describe your pain as sharp, burning, dull aching or a pulling sensation?
____.

CCF IRB # 6445
Approval Date 8-13-03
Expiration Date

12. Currently or in the last 12 months, I have had pain of one or both of my heels/ arches

A.	At the end of my runs	YES	NO
B.	At the end of my "work day"	YES	NO
C.	The next day?	YES	NO

How long does the pain last (min)?

D. At the end of my runs __________ minutes

E. At the end of my "work day" __________ minutes

F. The next day? __________ minutes

Would you describe your pain as sharp, burning, dull aching or a pulling sensation?

____.

CCF IRB # 6445
Approval Date 8-13-03
Expiration Date 7-31-04

Objective Clinical Examination

	Left heel/foot	Right heel/foot	Comments
Location of pain			
Intensity of pain			
Structure of foot (planus, rectus, or cavus)			
STJ position & axis of motion			
AJ dorsi-flexion (knee extended & flexed)			
FF to RF relationship			
Limb length discrepancy			
Tibial varum or valgum			
1st MPJ motion			

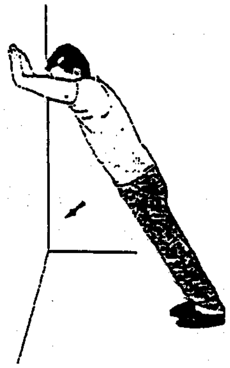
**Patients will be excluded (initially) if the examiner re-produces more pain upon side-to-side compression of the heel vs. the above-mentioned areas of the heel or if the predominant location of pain is found to be at the attachment of the Achilles tendon or along the Achilles tendon

** If the patients have pain in the above-mentioned areas of the heel/arch at the times mentioned and there is no evidence in the patient's history of any other suspicious systemic condition (independent of x-ray findings), then a diagnosis of plantar fascitis is achieved (via a process of elimination).

CCF IRB # 6445
Approval Date 8-13-03
Expiration Date 7-31-04

D5 Stretch exercices and ice participant information flyer

Stretch Exercises and Ice

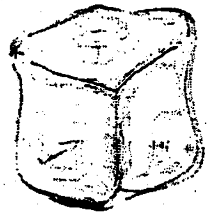


Achilles tendon stretch

- **Keep heels flat on floor, back and knees straight, and lean forward on wall.**
- **Hold for 20 seconds, rest briefly and repeat 3X.**
- **Perform task 1X daily.**

Calf stretch

- **Sit with knee straight and leg extended @ 90°.**
- **Hold a towel, belt or band in both hands and sling it over the ball of the foot.**
- **Lean forward and pull foot toward the nose.**
- **Hold for 20 second, rest briefly and repeat 3X.**
- **Perform task 1X daily.**



Ice

- **Take a Styrofoam cup with water and place it in the freezer.**
- **Take the cup out of the freezer and apply the ice directly on the heel.**
- **Massage the ice in the area of tenderness for 20 minutes every evening.**
- **Alternative: a bag of frozen peas.**

CCF IRB # 6445
Approval Date 8-13-03
Expiration Date 7-31-04

D6 Payment form

THE CLEVELAND CLINIC

Date: ______________

This serves as verification that ________________________ has participated in the Plantar Fasciitis and Athletic Shoe study sponsored by the American Academy of Sports Medicine (AASM). Reimbursement for participating is $_______ and should be charged to account number 015356670102.

Name: ______________________ Address: ____________________

SS#: ______________________ ____________________

Signature: ______________________

Administrator: ______________________

Signature: ______________________

APPENDIX E: Ethical approval letters

E1 Ottawa University ethics approval letter

E2 The Cleveland Clinic Foundation ethics approval letter

E1 Ottawa University ethics approval letter

Université d'Ottawa · University of Ottawa

Cabinet du vice-recteur
à la recherche

Office of the Vice-Rector,
Research

HEALTH SCIENCES AND SCIENCES RESEARCH ETHICS BOARD

CERTIFICATE OF ETHICAL APPROVAL

This is to certify that the University of Ottawa Health Sciences and Sciences Research Ethics Board has examined the application for ethical approval for the research project **The Effects of a Rigid Shank Shoe on Plantar Fasciitis in Runners (our file: H 10-03-08)** submitted by Kasey Parker and supervised by Dr. Yves Lajoie, of the School of Human Kinetics, University of Ottawa, and Dr. Susan D'Andrea, of the Department of Biomedical Engineering of The Cleveland Clinic. The Board found that this research project met appropriate ethical standards as outlined in the Tri-Council Policy Statement and in the Procedures of the University of Ottawa Research Ethics Boards, and accordingly gave it a Category 1a (approval). This certification is valid for one year from the date indicated below.

Rita D'Alessandro
Protocol Officer for Ethics in Research,
For the Chairperson of the Health
Sciences and Sciences REB
Daniel Lagarec

November 7, 2003
Date

550, rue Cumberland
Ottawa (Ontario) K1N 6N5 Canada

550 Cumberland Street
Ottawa, Ontario K1N 6N5 Canada

(613) 562-5270 • Téléc./Fax (613) 562-5271

E2 The Cleveland Clinic Foundation ethics approval letter

FOUNDATION

August 26, 2003

Office of the Institutional
Review Board / Wb2
Office: 216/444-2924
Fax: 216/445-4094
E-mail: IRB@ccf.org

Susan D'Andrea, Ph.D.
ND 20

RE: IRB 6445: The Effects of a Rigid Shank Shoe on Plantar Fascitis in Runners (American Academy of Podiatric Sports Medicine)

Dear Dr. D'Andrea:

Thank you for your response dated August 6, 2003 to requests from a prior full Board review of your application for the new study listed above. This study was reviewed on August 13, 2003 through the expedited review process. This activity will be reported to the Institutional Review Board.

This is to confirm that your application is now fully approved inclusive of the following: The Application (dated July 16, 2003) includes the Clinical Study Protocol (not dated), the revised Informed Consent Document dated August 6, 2003, two Advertisements, one Questionnaire and a "Stretch Exercises and Ice" Informational Sheet.

The consent form as most recently revised dated August 6, 2003 and the Advertisements, Questionnaire and Information Sheet have been stamp approved by the IRB for the period 8/13/03 through 7/31/04. You must obtain signed written consent from all subjects with the attached consent form.

You are granted permission to conduct your study according to the proposal that was most recently described. The study is subject to continuing review and requires the submission of a renewal or completion report before July 31, 2004.

Any changes to the protocol or consent must be approved by the IRB. Any unanticipated problems, unexpected adverse events that are related or possibly related, and all deaths and serious adverse events related or possibly related must be promptly reported to the IRB.

Please contact the IRB office, if you have any questions or require further information.

Sincerely,

Daniel Beyer, MS, MHA, CIP
Executive Director
Institutional Review Board

DB:jk
Attachment: Informed Consent Document/Advertisements/Questionnaire/Information Sheet

EXPIRATION DATE: July 31, 2004

APPENDIX F: Secondary data

F1 Shoe stiffness

F2 Running mileage

F1 Shoe stiffness

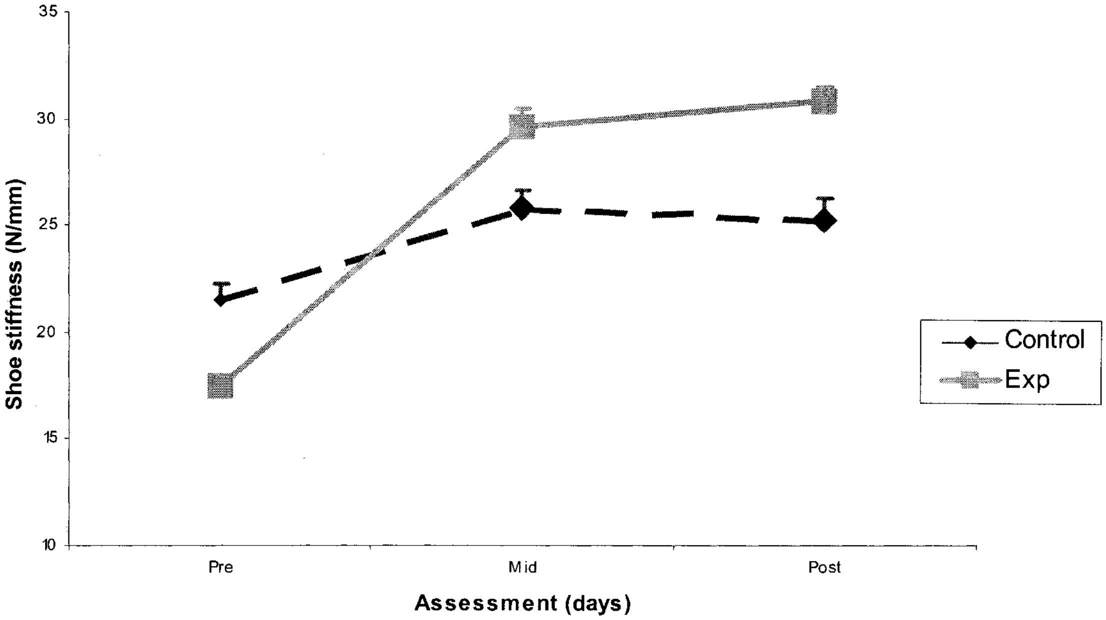


Figure 1. Mean (X) and standard deviation (sd) pre, mid and post assessments (days) of shoe stiffness (27 N/mm) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.

F2 Running mileage

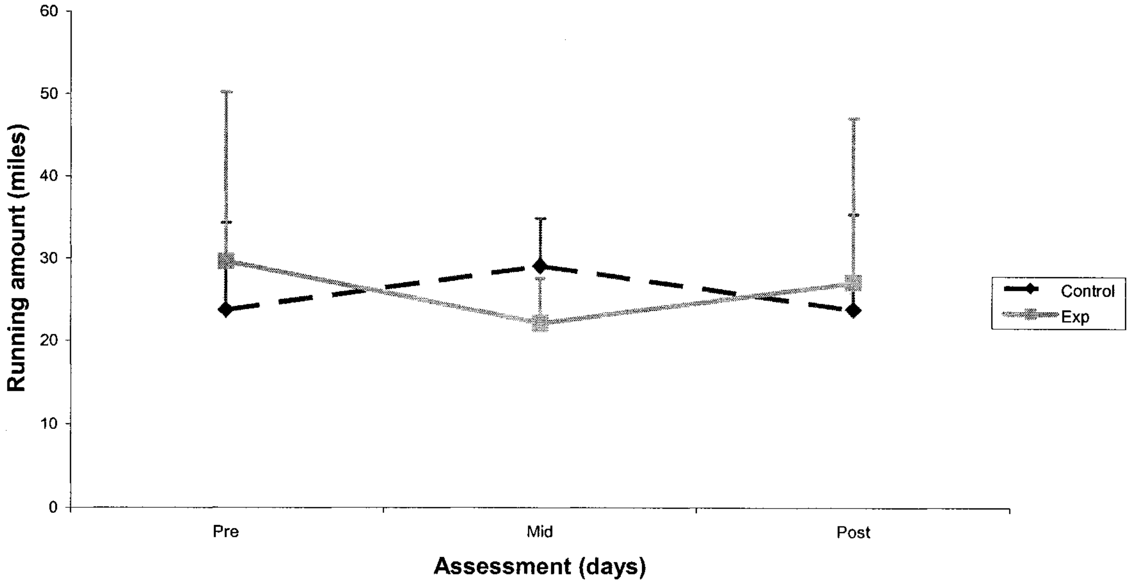


Figure 2.Mean (X) and standard deviation (sd) pre, mid and post assessments (days) of running mileage (miles/week) of eighteen participants (C=6; E=12 : M=10; F= 8) while running on a treadmill.