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AN ANALYSIS OF PRESSURE DISTRIBUTION WITH A PREFABRICATED FOOT ORTHOTIC ON A SYMPTOMATIC POPULATION

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AN ANALYSIS OF PRESSURE DISTRIBUTION WITH A PREFABRICATED FOOT ORTHOTIC ON A SYMPTOMATIC POPULATION

By

William J. Vascik

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ABSTRACT

AN ANALYSIS OF PRESSURE DISTRIBUTION WITH A PREFABRICATED FOOT ORTHOTIC ON A SYMPTOMATIC POPULATION

By

William J. Vascik

The purpose of this study was to study the effect of a locally manufactured prefabricated foot orthotic on the role of force distribution through the plantar forefoot. It is theorized that an equal distribution of plantar pressures is desired, to reduce the incidence of forefoot overuse injuries. Plantar pressures were analyzed with an in-shoe device called the Parotec-System. Plantar pressure distribution was calculated by averaging plantar pressures and calculating a lateral:medial ratio. Results indicated that plantar pressures were significantly reduced in the lateral forefoot, as well as a significant medial deviation in plantar pressure ratios, with use of the orthotic. It was concluded that although pressure deviated medially in the midfoot, it should not be seen as a negative outcome. This was due to a significant reduction in lateral pressures due to the high arch support in the orthotic. Additionally, the orthotic appears to be an effective tool in reducing lateral forefoot pressures, potentially reducing the incidence of fifth metatarsal stress fractures.

ACKNOWLEDGEMENTS

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To the people who I met as classmates in 2004 when I moved to Michigan, whom I now call my family. I've truly enjoyed the past 2 years here. I especially have to acknowledge my roommates Kyle & Leigh which represented "G" the way it should have.

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Chapter 1: Introduction

Optimal function of the body depends on the ability to maintain proper biomechanics through static and dynamic motions. These structures must be capable of adapting to a variety of internal and external influences to function properly. If there is a disturbance in the body's natural function, performance may be affected, leading to injury.

A variety of factors may affect the body's ability to maintain proper mechanics to achieve optimal performance. For example, improper mechanics may create abnormal pressure across the plantar surface of the foot. If a small area of the foot absorbs repetitive, abnormal pressure, then that area may be susceptible to developing minor injuries, such as blisters or corns. More severe injuries include stress fractures and lesions in diabetic patients. It is theorized that an equal distribution in forefoot plantar pressure is desired to limit forefoot overuse injury.

Due to the extensive number of structures, proper mechanics and function of the foot may be more critical for optimal performance than any other structure in the lower extremity. When mechanics are not synchronous, techniques may be used to "fix" the problem, such as orthotic intervention. Today, foot orthotics are being prescribed very frequently for lower-extremity ailments. Often, custom-molded orthotics are tailored to each patient to correct structural abnormalities in the lower extremity. Although pain relief often comes with introduction of the device, outcomes are unpredictable. Numerous studies have shown both positive outcomes and neutral outcomes from custom orthotic intervention (Bratta, 2004; Denegar & Miller, 2002; Ekenman, Milgrom, Finestone, Begin, Olin, Arndt & Burr, 2002; Fish, 1998; Franco, 1987; Gross, Davlin & Evanski, 1991; Guskiewicz & Perrin, 1996; Hertel, Denegar, Monroe & Stokes, 1999; Hertel & Olmsted, 2004; Hertel, Sloss & Earl, 2005; Hockenbury, 1999; Janisse, 1998; Kupperman, 2005; Mattacola, 2005; Mattacola & Dwyer, 2002; Mundermann, Nigg, Humble & Stefanyshyn, 2003; Nigg Nurse & Stefanyshyn, 1999; Nigg, Stergiou, Cole, Stefanyshyn, Mundermann & Humble, 2003; Ochsendorf, Mattacola & Arnold, 2000; Williams, McClay-Davis & Baitch, 2003). Unfortunately, relief comes with a hefty price tag when purchasing custom orthotics.

One potential alternative to expensive, custom-molded orthotics is using generic, prefabricated orthotics. Numerous shapes, sizes, and brands are available to customers in pharmacies, grocery stores, and shoe stores. Sometimes, clinicians will suggest using a prefabricated orthotic prior to prescribing a custom-molded orthotic. If the patient's problem has not subsided, it may warrant using a custom-molded device. Surprisingly, little clinical research has been conducted on the effectiveness of prefabricated orthotics. This is perplexing due to the wide assortment of prefabricated orthotics on the market and the plethora of ailments they are designed to alleviate.

One such device, the Stabil Lite, is frequently used to alleviate foot pain. It is produced by Playmakers (East, Lansing, MI). Many testimonials have praised its effectiveness in the reduction of foot pain resulting from plantar fasciitis, metatarsal stress fractures, and hyperpronation. Because this device is used frequently in sports medicine in the Mid-Michigan area, it is advantageous to analyze why it is clinically effective.

This study examined the effectiveness of the Stabil Lites in creating uniform plantar pressures across the forefoot. It is theorized that the Stabil Lite is clinically effective in injury management because of its ability to offset or redistribute plantar pressures equally in the forefoot.

Chapter 2: Literature Review

Anatomy & Physiology

The ankle and foot are complex segments in the body, due to the number of bones (26) and joints (over 30 synovial joints) and neurological anatomy that can control motion (Yuk San Tsung, Zhang, Fan & Boone, 2003). These structures must work together to achieve optimal performance. If the structures are abnormal or injured, altered gait may result.

The "true ankle joint", or talocrural joint, is made up of the distal portions of the tibia and fibula and the superior surface of the talus. It is responsible for ankle plantar flexion and dorsiflexion. The subtalar joint is comprised of the inferior surface of the talus and the superior aspect of the calcaneous. The subtalar joint is responsible for ankle inversion and eversion (Arnheim & Prentice, 1999). These joints work together to control the ankle in coordinated movements.

The foot is divided into two distinct areas based on function and mechanics. Twenty-one bones make up the forefoot's structure. These bones are the 5 metatarsals, 14 phalanges, and 2 sesamoids. The rearfoot is comprised of the talus and calcaneous. The navicular, cuboid, and three cuneiforms make up the midfoot. These areas of the body can exhibit a variety of malalignments, which will be discussed further in the "Foot Mechanics" section in this chapter.

The medial longitudinal arch is a very important structure for proper biomechanics of the lower extremity. The medial longitudinal arch is found in the medial aspect of the foot and spans from the anterior surface of the calcaneous to the head of the first metatarsal. In podiatry, the medial longitudinal arch height is measured to classify foot type. Foot type classification according to the medial longitudinal arch will be covered in detail in the "Foot Mechanics" section of this chapter.

At a standing-at-ease posture, very little muscle activity occurs to maintain the arch height. Instead, static structures, such as the plantar fascia, plantar ligaments, and spring ligament maintain the arch's height (Kaufman, Brodine, Shaffer, Johnson & Cullison 1999; Wearing, Smeathers, Yates, Sullivan, Urry, & DuBois, 2004). During dynamic movements, the medial longitudinal arch acts to store elastic strain energy and react as elastic recoil (Kaufman, et al., 1999). The medial longitudinal arch is also responsible for dissipating forces during weight bearing prior to reaching the long bones of the leg and thigh (Franco, 1987). Dynamic movements in the medial longitudinal arch are also aided by the posterior tibialis muscle (Kaufman, et al., 1999; Kulig, Burnfield, Requenjo, Sperry & Terk, 2004; Wearing, et al., 2004).

The muscles of the lower extremity are very complex and aid in both static and dynamic stability, while also creating coordinated movements. Three muscles are oriented laterally for concentric ankle eversion and resist ankle inversion and moments in the lateral direction. These are the peroneus longus, peroneus brevis, and peroneus tertius. The peroneus longus muscle acts as the primary defense mechanism against an inversion perturbation targeted at the ankle (Cordova, Cardona, Ingersoll & Sandrey, 2000).

Medially, the posterior tibialis muscle acts to concentrically invert the ankle and resist eversion and moments in the medial direction. The posterior tibialis is also important to aid in shock absorption (Kulig, et al., 2004) and maintain dynamic arch height. Chronic weakening of this muscle can lead to development of acquired adult flatfoot deformity (Kitaoka, Kura, Luo & An, 2000; Kitaoka & Patzer, 1997; Kulig, et al., 2004).

Two muscles are found anteriorly to concentrically dorsiflex the ankle and resist ankle plantar flexion and deviations in the anterior direction. These muscles are the tibialis anterior and extensor digitorum longus (Krell, Cinelli & Patla, 1998). The extensor digitorum longus also concentrically extends the phalanges.

Posteriorly, the gastrocnemius and the soleus act as the main propulsive force in gait by concentrically plantar flexing the foot, while resisting forces from the posterior direction during standing. The flexor digitorum, also oriented posteriorly, acts to plantar flex the foot and flex the phalanges. These muscles collectively act together to resist deviations in the posterior direction (Krell, et al., 1998; Schepsis, Jones & Haas, 2002). Activation of all the lower extremity muscles (particularly in the A/P direction) maintains stability. This is called the ankle strategy (Krell, et al., 1998).

Central and peripheral components of the central nervous system constantly process information to influence the maintenance of the postural-control system (PCS). Peripheral components include somatosensory, visual, and vestibular systems (Cote, Brunet, Gansneder & Shultz, 2005; Riemann, 2002; Riemann & Lephart, Part I, 2002; Willems, Witvrouw, Verstuyft, Vaes & De Clerq, 2002). The central nervous system processes stimuli from these systems and adjusts muscle tension around the affected joint to maintain homeostasis. The phenomenon with the PCS is that even when one peripheral component is restricted (example, shutting the eyes), stability typically is not compensated (Riemann, 2002).

The postural-control system must function properly for optimum balance. Balance is defined as the process of maintaining the center of gravity within the body's base of support (Cote, et al., 2005). Any joint can alter balance in the lower extremity, due to the fact that the foot is fixed in the closed kinetic chain. One component of balancing is postural stability. Riemann and Lephart (Part I, 2002) define stability as "state of a joint remaining or promptly returning to proper alignment through an equalization of forces". It has also been defined as a function requiring the coordinated activation of joint, muscle, visual, and vestibular receptors to maintain the body's center of mass (Harkins, Mattacola, Uhl, Malone & McCrory, 2005).

Postural stability is influenced by homeostasis of the body. Homeostasis is constantly regulated in the body by two processes: feedback controls and feedforward controls. Feedback (reactive) controls are initiated following a sensory detection and correct the organism following the perturbation (Riemann, 2002; Riemann & Lephart, Part I, 2002). This constant processing by the body is regulated by afferent information (Riemann, 2002; Riemann & Lephart, Part I, 2002). Feedforward (preparatory) controls are actions initiated by the body to maintain homeostasis when anticipating a disruption (Riemann, 2002; Riemann & Lephart, Part I, 2002). Unlike feedback control, feedforward controls are inactive until feedback controls are initiated (Riemann & Lephart, Part I, 2002).

As previously stated, postural stability is important because it keeps the structures in the lower extremity in proper alignment. When the body is in proper alignment, plantar pressures should equally be distributed across the foot to prevent overuse injuries. When postural stability is compromised, the foot may be susceptible to increased pressures at specific anatomic landmarks in the forefoot. This may predispose individuals to injuries at that site.

Postural stability depends on the body having optimal stability over the center of pressure and optimal activity from mechanoreceptors (Harkins, et al., 2005). Mechanoreceptors are joint afferents within ligaments, muscles, and cutaneous tissue that are mostly influenced by gamma motor neurons (Hertel, Buckley & Denegar, 2001; Riemann & Lephart, Part II, 2002; Riemann, Myers, & Lephart, 2002). Specifically, these mechanoreceptors are responsible for a sense called proprioception. It is defined as the conscious awareness of limb movement and position (Pincivero & Coelho, 2001).

Proprioception is enhanced by visual and auditory signals (Riemann, Myers, & Lephart, 2002). The mechanoreceptors that act predominantly on proprioception are Ruffini-type receptors, Pacinian corpuscles, and Golgi tendon organ receptors (Riemann & Lephart, Part I, 2002). These structures are maintained by spinal level reflexes (Pincivero & Coelho, 2001). These specialized structures are important to maintain a proprioceptive role in ankle joint dynamic stability and coordinated motor patterns. Additionally, stimulation of these mechanoreceptors affects sensitivity and activation of gamma motor neurons in the muscle spindles in the surrounding musculature (Myers, Riemann, Hwang, Fu & Lephart, 2003).

Specifically, cutaneous afferent mechanoreceptors in the glabrous skin of the foot, Merkel cell complexes under the epidermis, Meissner corpuscles in the superficial epidermis, and Pacinian corpuscles in deep dermal layers all work in conjunction to provide sensory input from a variety of force thresholds in the plantar aspect of the foot, which arise from gamma motor neurons (Nigg, et al., 1999, Riemann & Lephart, Part II, 2002). These cutaneous afferents have been shown to be very important in the role of maintaining postural stability and joint stability, due to an increase in the gamma motor neuron activation, which is a theory why orthotics are effective (Gribble, Hertel, Denegar & Buckley, 2004; Mattacola, 2005; Riemann & Lephart, Part II, 2002).

Gait Mechanics

Gait mechanics vary from individual to individual. The smallest abnormality in any part of the biomechanical chain can greatly alter proper gait mechanics. Although gait may appear to vary from individual to individual, general patterns and phases exist in average adults.

Independent motions occur in both the rearfoot and forefoot. Rearfoot motions that occur are plantar flexion/dorsiflexion (sagittal-plane motions), inversion/eversion (frontal-plane motions), and internal/external rotation or abduction/adduction (transverse-plane motions). A natural combination of these motions allows for movement about an axis of rotation oblique to the long axis of the lower leg called pronation and supination (Hertel, 2002). While the foot is in contact with the ground, also called the closed kinetic chain, pronation is the combination of eversion, external rotation/abduction of the foot, and plantar flexion of the talus (Hertel, 2002). Normal range of motion of pronation has been listed at 4-8° (Neely, 1998). In the closed kinetic chain, supination is the combination inversion, dorsiflexion of the talus, and internal rotation/adduction (Hertel, 2002). Figure 2.1 displays pronation and supination of the foot around the foot axis.

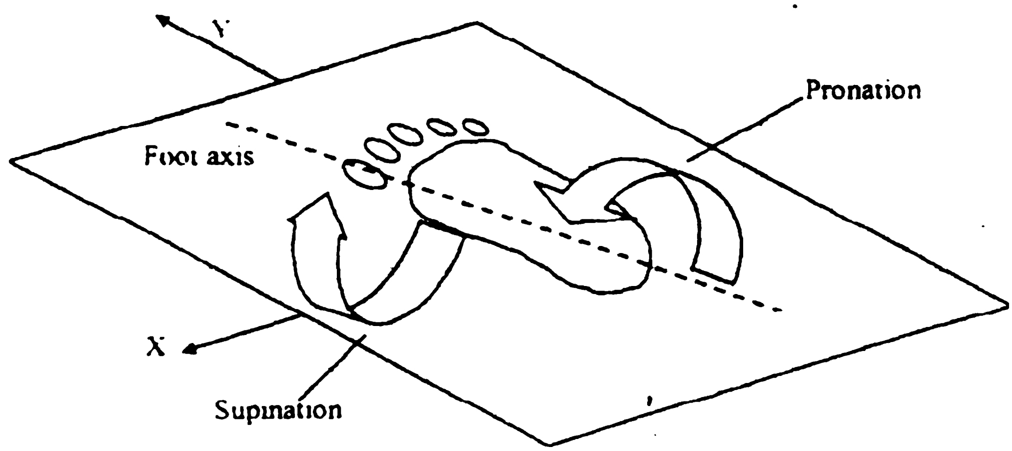


Figure 2.1. Pronation and supination of the foot around the foot axis (Bratta, 2004)

Research has found that females demonstrate a higher degree of pronation compared to males (Zeller, McCrory & Uhl, 2003). Using EMG and kinematic analysis, Zeller and colleagues (2003) found an inability to maintain a knee varus position in a single-legged squat. The increase in valgus angle results in hyperpronation (Zeller, et al., 2003). Anatomically, females should demonstrate a higher degree of pronation compared to males. Generally, females tend to have a wider pelvis. This creates a greater knee valgus angle, which results in increases in rearfoot pronation.

There are two forms of gait terminology: the Traditional terminology and the Rancho Los Amigos (RLA) terminology. The Rancho Los Amigos terminology will be used throughout this study. The RLA method is divided in the stance phase and swing phase. The stance phase (closed-kinetic chain) occurs when the initial contact of the heel is on the ground and ends as the toe leaves the ground. It is further divided into initial contact, loading response, midstance, terminal stance, and preswing.

The swing phase (open-kinetic chain) occurs between toe-off and the next contact by the heel (Starkey & Ryan, 2002). The stance phase is of interest, due to the research being concentrated on ground reaction forces. Figures 2.2-2.6 depict the position of the leg in the closed-kinetic chain, while also displaying the movement of the center of pressure during gait (Starkey & Ryan, 2002). It should be noted that the center of pressure locations in the figures are seen in a pes rectus (anatomically correct) foot. Structural abnormalities of the foot will alter the center of pressure position and is discussed in the "Foot Mechanics" section.

Normal gait mechanics begin at initial contact. The subtalar joint is supinated prior to initial contact. Typically, the joint everts quickly 4°-5° at initial contact by the lateral aspect of the plantar surface of the heel (Manoli, 2001; Neely, 1998; Starkey & Ryan, 2002). This allows for a maximal amount of energy to be absorbed at heel strike. Energy absorption is possible due to pronation unlocking the structures of the midtarsal joints and metatarsals (Franco, 1987; Neely, 1998; Starkey & Ryan, 2002). The subtalar joint unlocking also aids in maintaining balance, improving efficiency of muscle contraction and assist in distribution of forces through the lower kinetic chain (Neely, 1998).

During this period, both feet are in contact with the ground at the same time. This period represents approximately 20% of the total gait cycle (Starkey & Ryan, 2002). Figure 2.2 depicts where the leg is positioned and where the center of pressure is located during initial contact.

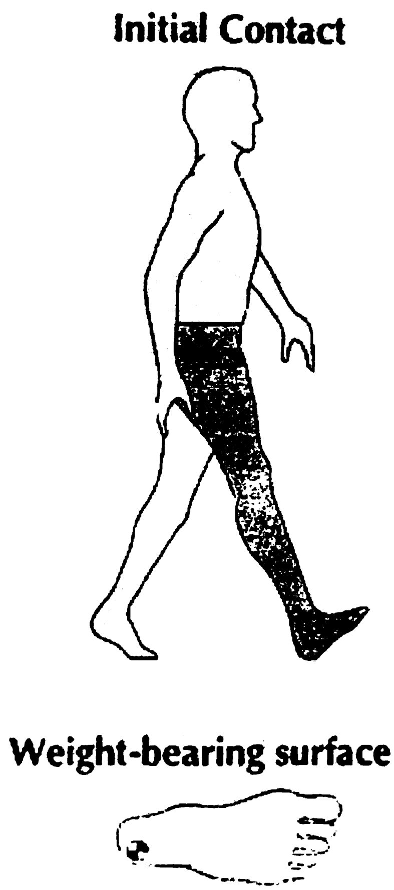


Figure 2.2. Initial contact in gait mechanics (Starkey & Ryan, 2002)

The next phase in the RLA terminology is the loading response. As the foot transfers to the loading response, the body's weight and center of pressure is transferred to the supple lateral border of the foot (Manoli, 2001; Starkey & Ryan, 2002). The foot flattening due to the unlocking of the midtarsal joints and metatarsals allows the foot further absorbs energy from the initial contact phase (Franco, 1987; Starkey & Ryan, 2002). Additionally, the tibialis posterior eccentrically contracts, which attempts to decelerate the rate of pronation (Starkey &

Ryan, 2002). Figure 2.3 depicts where the leg is positioned and where the center of pressure is located during the loading response. Note the center of pressure moving anteriorly along the lateral border of the foot.

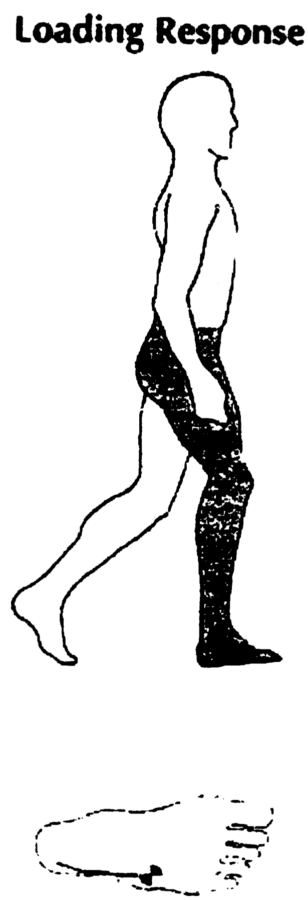


Figure 2.3. Loading response in gait mechanics (Starkey & Ryan, 2002)

Midstance is defined as the period when the body weight moves directly over the support limb and concludes when the center of gravity is directly over the foot (Starkey & Ryan, 2002). The forefoot and rearfoot is seen being evenly distributed on the ground (Starkey & Ryan, 2002). As the talocrural joint initiates dorsiflexion, the subtalar joint begins to supinate, resulting in calcaneal inversion (Franco, 1987; Starkey & Ryan, 2002). Approximately 10° of supination will lock the midtarsal joints, which makes the foot more rigid (Franco, 1987; Konradsen, 2002; Starkey & Ryan, 2002). This is advantageous, so the foot can prepare to act as a lever during propulsion at toe-off (Franco, 1987; Neely, 1998; Starkey & Ryan, 2002).

Beginning in this phase, the posterior shank musculature contracts to prevent the anterior movement of the tibia over the planted foot (Schepsis, Jones & Haas, 2002). Figure 2.4 depicts where the leg is positioned and where the center of pressure is located during midstance. Note the center of pressure moving anteromedial towards the first ray as the foot prepares for toe-off.

Figure 2.4. Midstance in gait mechanics (Starkey & Ryan, 2002)

As the foot prepares for terminal stance, the center of gravity passes over the foot and ends before the contralateral foot strikes the ground (Starkey & Ryan, 2002). The center of gravity begins to transfer to the forefoot, where the metatarsal heads and sesamoids of the first metatarsal equally distribute the weight (Manoli, 2001; Starkey & Ryan, 2002).

The posterior shank musculature continues to contract to prevent anterior movement of the tibia over the planted foot (Schepsis, Jones & Haas, 2002). Lastly, the posterior tibialis lock the transverse tarsal joints, which aids in creating a rigid foot for propulsion (Kulig, et al., 2004). Figure 2.5 depicts where the leg is positioned and where the center of pressure is located during terminal stance. Note the center of pressure moving to the head of the first metatarsal as the foot prepares for toe-off.

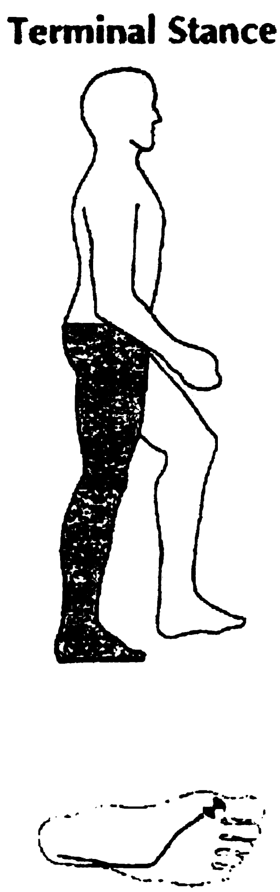


Figure 2.5. Terminal stance in gait mechanics (Starkey & Ryan, 2002)

Preswing is the final period in the stance phase. This is a transitional period of double support and ending in toe-off. In this phase the ankle is maximally dorsiflexed, then the ankle quickly plantar flexes to 20°-

30° at toe-off (Mullin, 2003; Starkey & Ryan, 2002). Further supination occurs in the subtalar joint and the transverse tarsal joint becomes locked prior to toe-off (Franco, 1987; Hockenbury, 1999). This is where most of the forefoot's stresses occur, which can lead to overuse injuries (Hockenbury, 1999).

Finally, the first metatarsal ends ground contact at toe-off to heel lift and the subtalar joint is positioned at approximately 4° of inversion (Franco, 1987; Mullin, 2003; Starkey & Ryan, 2002). The triceps surae complex contracts concentrically to initiate propulsion (Schepsis, Jones & Haas, 2002). The phalanges reach maximum dorsiflexion, especially the first phalange. This places strain on the plantar fascia, which aids in elevating the medial longitudinal arch. This is termed the windlass mechanism (Franco, 1987; Hockenbury, 1999). Figure 2.6 depicts where the leg is positioned and where the center of pressure is located during pre-swing. Note the center of pressure is at the distal portion of the first metatarsal at toe-off.

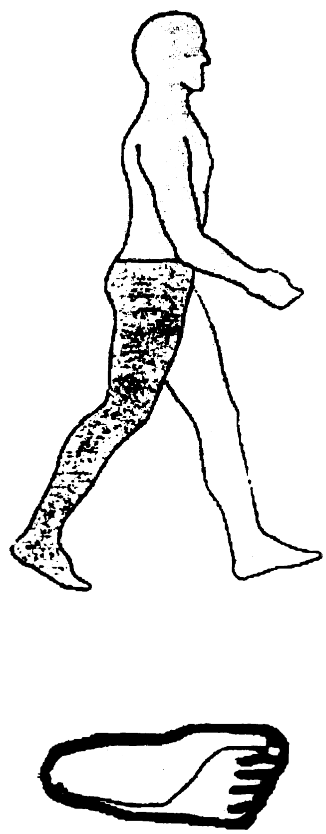


Figure 2.6. Preswing in gait mechanics (Starkey & Ryan, 2002)

Foot Mechanics

Foot mechanics, size, shape, and mobility vary in all individuals. Because of the variety of feet a clinician will encounter in a given day, analyzing structural abnormalities can be a difficult task.

The foot tends to reshape during weightbearing conditions compared to non-weightbearing conditions. Yuk San Tsung and colleagues (2003) found using a 3-dimensional analysis machine, foot length will increase up to 3.4% and foot width will increase up to 6.0 % under weight-bearing conditions. Additionally, weightbearing conditions typically demonstrate a decrease in arch height, which is why it is necessary to analyze foot mechanics dynamically.

Because the foot's ground contact is relatively small in area, the tiniest amount of skeletal malalignment in the foot and ankle complex can alter the body's biomechanics. Skeletal malalignments can be defined as abnormal joint alignment or a deformity within a particular bone (Riegger-Krugh & Keysor, 1996). Skeletal malalignments can alter the joint's load distribution, adjacent or distal joint's contact pressure distribution, excessive joint contact pressures, inability of joints to shock absorb properly, or reduced joint surface contact areas (Riegger-Krugh & Keysor, 1996). This can result in abnormal plantar pressures being seen across the foot and can result in injury.

A number of structural abnormalities throughout the foot are indicators for foot types. Abnormalities occur both in the forefoot and rearfoot. Forefoot deformities are more common due to more bones potentially creating more problems (Bratta, 2004). Deformities in the forefoot are categorized as either forefoot varus or forefoot valgus and are analyzed by looking at the alignment of the metatarsal heads. Forefoot varus is defined as an inward tipping (inversion) of the forefoot on the rearfoot with the subtalar joint in neutral (Neely, 1998). Forefoot varus is clinically the most common intrinsic deformity seen in the lower extremity (Neely, 1998). Compensation for a forefoot varus deformity often includes eversion of the subtalar joint, hyperpronation, and a hypermobile forefoot (Neely, 1998). Forefoot valgus is defined as having an outward tipping (eversion) of the forefoot on the rearfoot with the subtalar joint in neutral. Because this abnormality is fairly uncommon and has many causes of its occurance (Michaud, 1997), little research is devoted to study it further.

Similar names are given in the rearfoot, termed rearfoot valgus and rearfoot varus. Rearfoot deformities are analyzed by the alignment of the calcaneous and Achilles tendon. Rearfoot valgus is more common than rearfoot varus and is defined when there is excessive subtalar valgum and the subtalar joint rotates medially (Bratta, 2004). Conversely, rearfoot varus is defined as excessive subtalar varum, which allows the subtalar joint to rotate laterally (Bratta, 2004).

Numerous methods have been developed to evaluate and classify the foot at the subtalar joint, rearfoot, and forefoot. The main tool to assess foot alignment is through a theoretical position called subtalar neutral, developed by Merton Root, DPM. This position is when all the bones in the subtalar joint and talocrural joint line up equally in the open packed positions. This position is important because optimal foot alignment theoretically occurs in the subtalar neutral position. The clinician finds this position by having the patient lie prone on an exam table with their opposite hip flexed, abducted and externally rotated. The examiner uses the hand of the contralateral side of the foot being tested to feel the motion of the anterior talus and the ipsilateral hand moves the foot in inversion and eversion. The clinician feels for an equal protrusion of the talus on the medial and lateral sides. Once subtalar neutral is found, custom orthotics can be created to maintain subtalar neutral during gait (Mullin, 2003).

Research sited by Groner (2005) has since found that Root's work may be partially incorrect. In their study, only 17% of the 58 subjects they analyzed had "normal" foot alignment according to Root's standards and definitions. This error by Root was concluded to be the result of a misinterpretation of earlier work in podiatry. Additionally, Song and colleagues (1996) state that there is low intertester reliability seen when finding subtalar neutral. Although some clinicians discount Root's work, it still is the primary assessment tool in foot alignment evaluation.

Measuring the arch height is often used to classify foot types and analyze motions of the foot. A variety of methods have been developed to do this. One method is measuring the arch height by navicular drop. This is done by the most prominent part of the navicular being marked, then having the affected foot placed in subtalar neutral. A card is placed next to the navicular and the position of the navicular from the ground is marked on the card. The patient is then instructed to stand in a relaxed position and the new position of the navicular is marked on the card. Excessive pronation is classified as the distance between the marks on the card exceeding 7 mm (Mullin, 2003).

Other authors have suggested that individuals with a navicular drop less than 5 mm as being supinators, 5-10 mm being neutral, and greater than 10 mm as being pronators (Bratta, 2004; Hargrave, Carcia, Gansneder & Shultz, 2003; Neely, 1998). Figure 2.7 shows a schematic of how the navicular drops inferiorly when the foot is weightbearing.

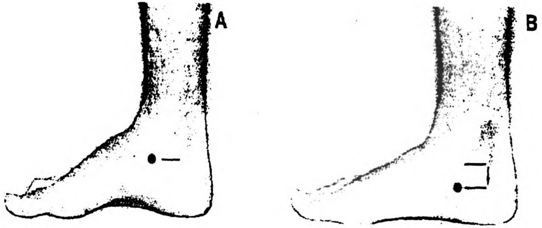


Figure 2.7. Navicular drop non-weightbearing (A) and weightbearing (B) (Bratta, 2004)

Arch height can also be measured using calipers. Neely (1998) suggests this measurement to be the most reliable versus calculation by footprint parameters. Average arch heights are said to fall between 2.12 ± 0.67 mm and 2.83 ± 0.44 mm.

A more technical method has been developed to measure arch height. This calculation is called the arch index. This calculates a ratio of the area of the middle third of the footprint to the entire footprint area. The developers of this method classify a high arch as an arch index < 0.21, a normal arch as 0.21 < arch index < 0.26, and a flat arch as arch index ≥ 0.26 (Cavanaugh & Rodgers, 1987).

The bony arch index is an alternative method to classify arch height. This is calculated as the ratio of navicular height to foot length (Kaufman, et al., 1999; Wen, Puffer & Schmalzried, 1997) or truncated foot length (posterior calcaneous to the first metatarsophalangeal joint) (Bratta, 2004; Kulig, et al., 2004). Although these are good numerical methods of classifying the arches, factors such as height, body weight, subcutaneous fat, and soft tissue motion can provide false calculations by clinicians (Hargrave, et al., 2003).

Recently, three-dimensional analysis of foot structure through computed tomography has been suggested (Edwards, 2004). Researchers at the Rehabilitation Research and Development Center of Excellence for Limb Loss Prevention and Prosthetic Engineering at the VA Puget Sound (WA) and the departments of orthopedics, sports medicine, and mechanical engineering at the University of Washington in Seattle developed a computer program, which classify foot types using Euler angles. This process was developed due to structural differences in feet being three-dimensional. A strong correlation was found with this computer program by verification of foot classification types versus orthopedic surgeons in their classification of foot type (Edwards, 2004).

Typically, there are three general shapes to feet, determined by the medial longitudinal arch and rearfoot and forefoot positioning. The classifications are pes cavus, or arched feet, pes planus, or flat feet, and pes rectus, or "anatomically correct" feet. It has been noted that individuals with feet regarded as either pes cavus or pes planus have an increased incidence of overuse injuries compared to individuals with average arch height (Kaufman, et al., 1999; Korpelainen, Orava, Karpakka, Siira & Hulkko, 2001; Neely, 1998; Seligman, 2004).

Pes cavus feet typically are associated with excessively high arches, a hypersupinated foot, and hypomobile midfoot (Cote, et al., 2005; Kaufman, et al., 1999). "Flexible" pes cavus feet do exist, but they are not as prominent as rigid pes cavus feet (Franco, 1987). Additional anatomic signs that are related to pes cavus are rearfoot varus, forefoot valgus, and a plantar flexed first metatarsal (Hertel, Sloss & Earl, 2005; Manoli, 2001). Feet classified as pes cavus tend to distribute pressures abnormally over the metatarsal heads and lateral border of the foot (Franco, 1987).

Gait mechanics are altered due to the pes cavus malalignment. The heel typically strikes in supinated position, causing the center of pressure of the foot to be medial to the subtalar joint axis (Olmsted-Kramer & Hertel, 2004). Because rearfoot eversion is limited, shock-absorbing capacity is decreased in the subtalar joint (Bratta, 2004; Neely, 1998; Song, Hillstrom, Secord & Levitt, 1996). During mid-stance, the lateral border of the foot, which is typically supple, is fairly rigid. This is due to the increase height of the medial longitudinal arch. As the weight of the body is transferred to the forefoot, the plantar flexed first metatarsal strikes the ground first, which tips the entire foot in an everted position (Manoli, 2001). The supinated position of the subtalar joint also reduces propulsion efficiency in the pre-swing phase (Song, et al., 1996).

The abnormal pressure distribution due to the high arch can cause a variety of overuse injuries, such as callus formation/contusions under the first and fifth metatarsal heads (Franco, 1987), sesmoiditis (Manoli, 2001), and stress fractures to the metatarsals (Franco, 1987; Kaufman, et al., 1999; Manoli, 2001; Neely, 1998; Omey & Micheli, 1999; Weist, Eils & Rosenbaum, 2004). Other injuries that are common with pes cavus feet are inversion ankle sprains (Manoli, 2001; Neely, 1998; Olmsted-Kramer & Hertel, 2004; Song, et al., 1996), peroneal tendonosis/subluxations (Bratta, 2004; Manoli, 2001; Neely, 1998), Achilles tendon tendonitis and ruptures (Neely, 1998; Schepsis, Jones, Haas, 2002), Jones fractures

(Manoli, 2001), stress fractures to the tibia (Franco, 1987; Kaufman, et al., 1999; Manoli, 2001; Neely, 1998; Omey & Micheli, 1999), plantar fasciitis (Manoli, 2001; Neely, 1998; Wearing, et al., 2004), and varus joint strain to the knee (Manoli, 2001).

The converse to a pes cavus foot is a pes planus foot. This structural abnormality is characterized by excessively flat arches caused by a medially displaced talus. Other signs associated with pes planus are a pronated foot, rearfoot valgus, inverted forefoot, and hypermobile midfoot, resulting in the structural abnormality being termed "flexible flatfoot" (Chen, Chen, Lew, Hsieh, Yang & Tang, 2003; Franco, 1987; Hertel, Sloss & Earl, 2005; Kitaoka & Patzer, 1997). This condition has been reported to occur in 15% of the general population (Omey & Micheli, 1999).

Another characteristic of pes planus feet is the "too-many-toes" sign, which was described in the 1980's by Ken A. Johnson, MD. The "too-many-toes" sign can be seen from a posterior view of the weightbearing foot. The clinician will see excessive heel valgus and more toes laterally due to an abducted forefoot (Manoli, 2001).

Pes planus is often developed over one's lifespan as a result of weakness in the posterior tibialis. This is termed posterior tibial tendon dysfunction and results in acquired flatfoot deformity in adults (Kitaoka & Patzer, 1997; Kitaoka, et al., 2000; Kulig, et al., 2004). Acquired adult flatfoot deformity can also result from weak flexor digitorum longus and flexor hallucis longus muscles, diabetes mellitus, obesity, and hypertension (Kitaoka & Patzer, 1997). Pronation can result from compensation of another structural deformity from soft tissues, osseous deformities, limitations of muscular flexibility, leg length discrepancies, forefoot varus, subtalar varus, lack of ankle dorsiflexion, femoral neck anteversion, tibial torsion, or tibial/genu varum (Neely, 1998).

Like the pes cavus foot, foot mechanics are greatly altered in the pes planus foot. Due to the medial longitudinal arch being flatter, an angle greater than 90° between the rearfoot and forefoot is created. Static equilibrium then is not achieved, due to the center of mass and ground reaction force not counteracting each other. If an imbalance exists with the tensile strain of the passive plantar mechanism, the soft tissues in the sole will deform, causing plantar hypermobility and instability.

With a decrease in the medial longitudinal arch height, the head and neck of the talus will plantar flex, adduct, and internally rotate abnormally. Forefoot varus and pes planus will increase due to the calcaneous becoming abnormally everted, abducted, and dorsiflexed. As a result, over-pronation and tibial internal rotation will occur during gait. Over time, the peroneus brevis will assume a mechanical advantage over the posterior tibialis, resulting in an even more drastic pronation action during toe-off (Maurer, 2003). With all this motion occurring in the foot, ligamentous structures become weakened due to the foot relying on them for stability. This decreases stability, resulting in the foot relying on intrinsic and extrinsic musculature, specifically the anterior and posterior tibialis to aid in stability (Franco, 1987; Neely, 1998).

Overpronation is typically seen with a pes planus deformity. The amount of pronation can be fairly severe (reported as high as 10-12° (Neely, 1998)), causing a plethora of issues in the biomechanical chain. Some suggest that a mild degree of pronation may be protective against lower extremity injuries (Neely, 1998). Hreljac (2004) notes that the majority of clinical studies conducted find that injured runners tended to exhibit hyperpronation. Abnormal plantar pressures resulting from hyperpronation deformities can predispose individuals to metatarsal stress fractures (Franco, 1987; Kitaoka &

Patzer, 1997; Neely, 1998). Other overuse injuries associated with hyperpronation include medial tibial stress syndrome (Franco, 1987; Hreljac, 2004; Neely, 1998), plantar fasciitis (Bratta, 2004; Seligman, 2004; Song, et al., 1996; Wearing, et al., 2004), heel spur development as a result of chronic plantar fasciitis (Song, et al., 1996), patellofemoral syndrome (Franco, 1987), anterior cruciate ligament injuries (Hargrave, et al., 2003), tibialis posterior tendon and Achilles tendon tendonitis (Bratta, 2004; Omey & Micheli, 1999), and Achilles tendon ruptures (Schepsis, Jones & Haas, 2002). As severe as the injuries that may develop with a pes planus abnormality, the majority of these individuals experience no pain or discomfort (Omey & Micheli, 1999).

Although the base of support is greater with pes planus malalignments, muscle activity is altered at the ankle, knee, and hip, which may compromise balancing capabilities (Cote, et al., 2005). This may be due to an overload of plantar sensory information, which the body cannot process thoroughly. Regardless of the structural malalignments, joint mechanics are altered significantly during dynamic activities.

Plantar Pressures

During gait, plantar pressures are seen as being the highest in the heel during heel strike and under the metatarsal heads during toe-off. This can be very problematic for diabetic patients. It has been demonstrated that sensations on the plantar surface of feet in diabetics become reduced compared to healthy feet. As demonstrated by Nurse and Nigg (2001), when normal feet had an acute loss of sensation, plantar pressures increased at the metatarsal heads and decreased pressures around the periphery. Thus, it should not be surprising that diabetics frequently have problems with ulceration at the metatarsal heads (Blackwell, et al., 2002; Nurse & Nigg, 2001).

Excessive plantar pressures are also detrimental to athletes in developing stress fractures in the metatarsals. It has been suggested that increased pressures in the feet increase risk for developing stress fractures, especially in the second and third metatarsals (Boden, Osbahr & Jiminez, 2001; Eils, Streyl, Linnenbecker, Thorwesten, Volker & Rosenbaum, 2004; Gross & Bunch, 1989; Weist, et al., 2004). It has been reported that metatarsal stress fractures make up between 9-18% of all reported stress fractures (Boden, et al., 2001, Gross & Bunch, 1989). The second metatarsal is most prone to developing stress fractures due to it being more firmly secured at the base than other metatarsals, thereby transmitting more force through the bone (Boden, et al., 2001).

A study conducted by Eils and colleagues (2004) utilizing an in-sole pressure measuring device, peak pressures were greatest in the heel and metatarsal heads (first and second ray) for running and in the forefoot (especially the medial forefoot) during soccer-specific movements. It is not surprising that the majority of stress fractures in the foot occur along the second metatarsal, approximately where the greatest peak pressures were located during movements. Similarly, Weist and colleagues (2004) found significant increases in the peak pressures under the second and third metatarsal heads during a fatiguing protocol on a treadmill. Additionally, Gross and Bunch (1989) estimated using biomechanical models and force transducers that the second and first metatarsal heads experienced the highest forces and were as high as 340 N and 280 N, respectively, during a running protocol.

Orthotics

Kitaoka, Luo, and An (1997) estimate that between six and ten million individuals use custom orthotics for a variety of problems. The "success rates" of custom orthotics in studies have ranged from 50% to 90% (Hunter, 1997; Mundermann, et al., 2003; Nigg, et al., 1999). Satisfaction of the orthotic will depend on factors, such as foot shape, skeletal alignment, joint motion, foot sensitivity, forces acting on the musculoskeletal system, and muscle activity (Mundermann, et al., 2003).

A questionnaire developed by Gross and colleagues (1991) analyzed the use of inserts for symptomatic relief of lower extremity complaints in long-distance runners. Among the 347 participants, 31.1% used an insert for excessive pronation, 13.5% used an insert for a leg length discrepancy, 12.6% used an insert for patellofemoral disorders, 20.7% used an insert for plantar fasciitis, 18.5% used an insert for Achilles tendonitis, 7.2% used an insert for shin splints, and 4.9% used an insert for miscellaneous reasons. Over 75% of the respondents reported complete resolution or great improvements of their symptoms. A high degree of satisfaction was seen because 90% of the runners continued to wear the insert even after resolution of their symptoms.

Orthotics are classified as prefabricated or custom-molded models and vary in stiffness. Stiffness levels are classified as flexible, semi-rigid, or rigid (Hertel & Olmsted, 2004). The more rigid an orthotic is, the more control and support can be influenced in motion (Hertel & Olmsted, 2004; Janisse, 1998; Seligman, 2004). Conversely, the more flexible the orthotic is, the less motion can be controlled while offering more shock absorption and cushioning (Hertel & Olmsted, 2004; Janisse, 1998; Seligman, 2004). Often, a semirigid orthotic is used, which offer more cushioning than a rigid orthotic, but more support than a soft orthotic (Janisse, 1998). This is often preferred in athletics where pivoting is involved (Franco, 1987). A post is a wedge added into an orthotic to decrease a particular motion or "bring the ground up to the foot" (Franco, 1987). In hyperpronation, medial wedges may be utilized (Janisse, 1998; Seligman, 2004). A lateral wedge may be utilized for ankle instabilities or varus heel deformity (Janisse, 1998).

Currently, the literature is filled with studies looking at the benefits of custom-molded orthotics. Clinicians primarily prescribe orthotics to prevent developing an overuse injury or to avoid a common movement-related injury (Gross, et al., 1991; Mundermann, et al., 2003; Nigg, et al., 1999; Nigg, et al., 2003; Williams, et al., 2003) and to properly align the skeleton due to structural abnormalities (notably in the lower extremity) (Bratta, 2004; Denegar & Miller, 2002; Fish, 1998; Gross, et al., 1991; Hertel, et al., 1999; Hertel & Olmsted, 2004; Hockenbury, 1999; Janisse, 1998; Mattacola, 2005; Mattacola & Dwyer, 2002; Nigg, et al., 1999; Nigg, et al., 2003; Williams, et al., 2003). Other reasons orthotics are used are to provide additional impact cushioning (Bratta, 2004; Ekenman, et al., 2002; Hertel & Olmsted, 2004; Janisse, 1998; Kupperman, 2005; Nigg, et al., 1999), reduce stress fractures (Ekenman, et al., 2002; Hertel, et al., 1999), improve sensory feedback (Kupperman, 2005; Mattacola, 2005; Nigg, et al., 1999; Nigg, et al., 2003; Ochsendorf, et al., 2000), alter neuromuscular control (Franco, 1987; Guskiewicz & Perrin, 1996; Hertel & Olmsted, 2004; Hertel, Sloss & Earl, 2005; Kupperman, 2005), improve healing following a lateral ankle sprain (Denegar & Miller, 2002; Guskiewicz & Perrin, 1996; Hertel & Olmsted, 2004; Mattacola, 2005; Mattacola & Dwyer, 2002; Ochsendorf, et al., 2000), reduce stabilizing muscle activity (Kupperman, 2005; Hertel & Olmsted, 2004; Nigg, et al., 2003), improving balance in healthy and unhealthy ankles (Denegar & Miller, 2002; Mattacola, 2005; Mattacola & Dwyer, 2002; Nigg, et al., 2003; Ochsendorf, et al., 2000), improve performance (Mundermann, et al., 2003), and improve comfort (Ekenman, et al., 2002; Hertel & Olmsted, 2004; Hockenbury, 1999; Janisse, 1998; Mundermann, et al., 2003; Nigg, et al., 1999; Nigg, et al., 2003).

So why do orthotics work? Traditional thinking has focused on a reduction in deviation and velocity of motion of the foot and proximal segments of the lower extremity, especially in the clinical population (Kupperman, 2005; Nigg, et al., 2003). This is due to a reduction in rearfoot pronation or supination and tibial rotation and a decrease in knee abduction and adduction movements (Hertel & Olmsted, 2004; Williams, et al., 2003). Hertel and Olmstead (2004) use the example with a forefoot varus foot. To control this motion, a medial post is placed at the metatarsal heads. This is in attempt to provide a block and reduce excessive forefoot pronation and reduce strain on the posterior tibialis and soleus muscle origins on the posterior aspect of the tibial shaft.

Additionally, orthotics may properly align the skeleton, notably in the subtalar joint. Structural malalignments predispose individuals to a variety of problems. Ottaviani, Ashton-Miller, and Wojtys (2001) quote, "…osteological risk factors...are thought to include excessive talar tilt". A variety of studies cited by Nigg and colleagues (1999) reported a reduction in rearfoot eversion position between 1-3° with the introduction of orthotics and reduction in tibial internal rotation by 2°. If talar tilt is maintained in a neutral position and unnecessary muscle strain is reduced, then these orthopedic injuries may be lessened.

In a study by Ochsendorf and colleagues (2000), the authors concluded that center of pressure deviations were reduced in individuals wearing custom orthotics due to the cradle effect. The first part of the cradle effect says that the talocrural joint alignment will be improved and the ankle mortise will be in more of a neutral position. This results in neuromuscular alterations that will be discussed shortly.

The theory of the skeletal realignment has been challenged recently, due to research showing little variations in individual responses to orthotic intervention. In a study by Wen and colleagues (1997) and prospective study by Nigg and colleagues (1999) analyzing lower extremity alignment and risk of overuse injuries in marathon runners, both studies concluded that lower extremity alignment was not considered a major predisposing factor or predictor for overuse running injuries. Another study by Nigg and colleagues (2003) hypothesized that in the normal, healthy population, the skeleton cannot be realigned. This is due to the skeletal movement being "preprogrammed", thus not being able to alter mechanics.

Chen and colleagues (2003) also state that the literature is limited for support of orthotics to correct flexible flatfoot abnormalities. Factors that compound the problem of flexible flatfoot are the need for a precise correction of forefoot pronation, which is difficult to do with a goniometer and clinicians thinking that only a medial longitudinal arch support is suffice to correct the problem.

The new theory on why orthotics work is due to alterations in neurological information processing. Examples are increases in plantar cutaneous receptor activation, changing the afferent input, and neuromuscular activation from the somatosensory system (Hertel & Olmsted, 2004; Ochsendorf, et al., 2000). Kupperman (2005) cites a few studies in which orthotic intervention resulted in increased muscle EMG intensities, notably in the peroneus longus, hamstrings, and tibialis anterior. Hertel, Sloss and Earl (2005) reported an increase in vastus medialis and gluteus medius EMG levels with the use of prefabricated orthotics in patients with all three foot-type classifications (pes planus, pes cavus, and pes rectus) during dynamic motions. This increase in muscle activity can possibly reduce tibial rotation, which in turn may reduce hyperpronation, dampen soft tissue vibration in the lower extremities, or increase activity in the hip strategy to maintain postural control.

Another theory behind the effectiveness of orthotics is the increased comfort of individual's feet. How can comfort be described physiologically when this is a fairly subjective concept? As pointed out by Nigg and colleagues (1999), comfort can be related to dynamic stability. A comfortable orthotic will have a direct relationship with reducing muscle tension and theoretically, equally distribute plantar pressures due to altering a biomechanical abnormality. If the individual is uncomfortable with their feet due to a biomechanical abnormality, increased plantar pressures should be evident in certain areas of the foot. Also, a reduction in muscle activity would stabilize joints and minimize soft tissue vibration (Nigg, et al., 1999).

A few articles have been devoted to the effect of orthotics on plantar pressures. Results have found reduction in plantar pressures (Cobb, Limroongreungrat, Tis & Higbie, 2003; Hacker, Walsh, Bokser, Grogers, Walden & Walsh, 2005; Higbie, Tis, Lichty, Dupont & McCarty, 1998; Hodgson, Tis & Cobb, 2005) and conversely studies have found increases in plantar pressures (Donahue, Higbie, Simpson & Wisenbaker, 1996; Willis, McCurdie, Jones & Bain, 2005), especially in the medial forefoot. According to the authors, the reasoning for increases in plantar pressures can be attributed to the stiffness of the material comprising the orthotic.

As previously mentioned, literature is very limited analyzing the use of prefabricated orthotics on foot pathology. Researchers appear to be analyzing their effectiveness more extensively. There are three reasons that prefabricated orthotics should be used. First, they possibly can prevent overuse injury. Second, they help to determine if a patient's pathology is mechanically related, or from another source. Third, they provide temporary relief while a custom orthotic is made (Groner, 2005). There are two types of prefabricated orthotics: accommodative and functional. Accommodative prefabricated orthotics are shaped to offload a particular area of the foot and used mostly for patients with arthritis and diabetes. Functional prefabricated orthotics alters the foot's mechanics in attempt to correct some malalignments (Groner, 2005).

Typically, prefabricated orthotics are designed for a variety of foot variations, but Arthur Manoli, MD has developed a prefabricated orthotic that is designed specifically for pes cavus feet called the "cavus foot orthosis" (CFO). The CFO is constructed of ethylvinylacetate that is heated to be custom molded to the foot. Fitting of the orthotic is done by arch height, not foot length. Many features make this insert specific for the cavus foot. First, the elevated heel cushion increase shock absorption and aid with the tight triceps surae complex. Second, an intrinsic lateral heel wedge induces inversion and redistributes pressures to a larger area of the foot. The arch support is generally less pronounced than a generic prefabricated orthotic. This, combined with a recess under the first metatarsal allows for some rearfoot pronation, by aiding in the plantar flexed first ray. Lastly, a forefoot wedge is incorporated laterally to the first metatarsal ray to accommodate the forefoot valgus (Manoli, 2001).

Only three articles have been found that analyzed the effectiveness of prefabricated orthotics directly on the foot or ankle. The first study was conducted by Finestone, Novack, Farfel, Berg, Amir and Milgrom (2004). They compared a prefabricated orthotic versus custom-molded orthotics that were soft or semi-rigid, in the incidence of stress fractures, ankle sprains, foot problems, and comfort levels in a military population. The authors conducted a single-blinded clinical trial among 874 Israeli infantry recruits during basic training. The authors introduced either custom or prefabricated soft or semi-rigid orthotics to the recruits for 14 weeks during basic training. Every three weeks, the recruits were screened for foot problems by orthopedists. Results indicated that there was no significant difference documented in incidence of stress fractures, ankle sprains, or foot problems using all types of orthotics. Additionally, it was discovered that the recruits who wore the "soft custom" orthotics wore the devices significantly fewer times than the soft prefabricated orthotics. As a result, the authors suggest that there is no reason to prescribe expensive, semirigid orthotics when similar preventative measures can be made by a simple, inexpensive prefabricated orthotic.

The second study relating to prefabricated orthotics was performed by Kitaoka and colleagues (1997). In their study, they analyzed arch support efficacy using two commonly prescribed prefabricated orthotic devices on 14 fresh cadaveric feet and shanks. Using a loading frame, axial loads of 222, 445, or 667 Newtons were applied while a magnetic tracking system performed three-dimensional analysis on the talus, calcaneous, navicular, and first metatarsal. They found that the arch supports had an immediate effect on foot alignment throughout a variety of axial loads versus axial loads without the orthotics. It was observed that foot alignment had been maintained because the arch supports had effectively increased the arch heights.

The last study on prefabricated orthotics was conducted by Landorf, Keenan, and Herbert (2004). It was a thorough evidence-based review on different types of foot orthotics for the treatment of plantar fasciitis. They concluded throughout all the studies they analyzed, both custom-molded and prefabricated orthotics offer benefits to reduce pain stemming from plantar fasciitis. Due to the problems seen in random control trials, one device cannot be seen as being more beneficial than the other.

Only one study has been found in the literature which stated that prefabricated orthotics were inferior to custom orthotics. Using a F-Scan in-shoe pressure system, Hacker, et al., (2005) concluded that plantar pressures in the forefoot and heel were reduced by a significant amount with the use of a custom orthotic versus a prefabricated orthotic. The authors did not analyze the reduction of plantar pressures of the custom or prefabricated orthotics compared to baseline readings, so it is unknown what role the prefabricated orthotics have against a baseline reading. Additionally, the analysis was on a normal adult population, so it is unsure what the results would be on an injured or malaligned population.

Research is beginning to show that prefabricated orthotics may also have benefits in the knees and hips. Two studies showed that prefabricated orthotics might be useful in treating osteoarthritis of the knee (Groner, 2005). Additionally, research is being shown that prefabricated orthotics may increase muscle activity further up the biomechanical chain. In a study by Hertel, Sloss, and Earl (2005), EMG levels in the vastus medialis and gluteus medius muscles during squat and step-down exercises, regardless of the posting that was introduced to the orthotic or the subject's foot type, were higher than under the control conditions. It was theorized that prefabricated orthotics showed beneficial results due to the increased cutaneous activation in the plantar aspect of the foot, rather than altering the position of the joints of the feet.

The general consensus in the studies is that prefabricated orthotics can have a positive effect on symptomatic patient's feet or show no difference in performance versus custom orthotics, despite their generic design. Like custom-molded orthotics, prefabricated orthotics can possibly offer benefits in injury reduction and pain maintenance.

Orthotics may alter plantar pressures via three processes: alteration in neuromuscular activation, proper alignment of the skeleton, and an increase in plantar cutaneous sensory activity. Research has shown evidence that an increase in muscle activity is achieved with the introduction of an orthotic in the hips and thigh (Hertel, Sloss & Earl, 2005). This increase in muscular activation distally allows for a decrease in muscle activation in the foot, since these muscles now do not have to strain themselves to keep the structures stable in the foot. This decrease in muscle tension in the foot can be advantageous in physically active individuals. If the foot's musculature is constantly active to keep the structures stable, fatigue is inherent. As Boden and colleagues (2001) state, muscular fatigue at intrinsic muscles in the feet may predispose individuals to excessively high plantar pressures, leading to metatarsal stress fractures. If the orthotic can reduce some muscular activation, then fatigue can be staved off for a longer period of time, reducing the chance of developing a stress fracture.

Secondly, the proper alignment of the skeleton results in a more stable joint structure. The orthotic may create the body's preferred alignment, resulting in an increase in joint stability. If the joint structure is more stable, then the subtalar joint should not deviate in great distances from subtalar neutral (Cote, et al., 2004; Fish, 1998; Denegar & Miller, 2002; Gross, et al., 1991; Hertel, et al., 1999; Hertel & Olmsted, 2004; Hockenbury, 1999; Janisse, 1998; Mattacola, 2005, Mattacola & Dwyer, 2002; Nigg et al., 1999; Nigg, et al., 2003; Williams, et al., 2003). This should again result in an equal pressure distribution across the foot.

Lastly, it has been hypothesized that having an increase in cutaneous sensation allows the body to be more aware of its proprioception, resulting in a more stable base of support (Kupperman, 2005; Mattacola, 2005; Nigg, et al., 1999; Nigg, et al., 2003; Ochsendorf, et al., 2000) and have more control in gait patterns (Nurse & Nigg, 2001). In a study by Hertel, Gay, and Denegar (2002), individuals who had a pes cavus deformity had a significant reduction in postural stability compared to individuals with pes rectus or pes planus feet. To test the effective of orthotics on these individuals, Hertel and Olmsted (2004) found that orthotic intervention improved dynamic stability in individuals with pes cavus feet. They attributed this to an increase in mechanical support, leading to enhanced sensory receptor activity and neuromuscular function. Nurse and Nigg (2001) also demonstrated that when a reduction in plantar sensation was initiated by ice, the participants tended to increase their plantar pressures at areas that had a normal sensation. These studies demonstrate that increased and equal plantar pressures are advantageous to individuals.

The intervention that will be introduced to the groups are Stabil Lite insoles, manufactured by Playmakers (East Lansing, MI). This device is manufactured from closed-cell foam molded from a pes rectus foot. It has a high arch for support and deep heel cup to control rear-foot motion. Figures 2.8-2.11 shows different views of the ¾ length Stabil Lites for a right foot.

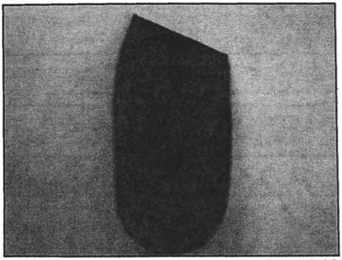


Figure 2.8. Superior view of Stabil Lite for right foot

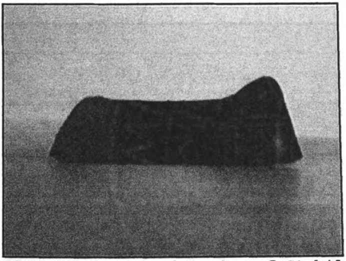


Figure 2.9. Anterior view of Stabil Lite for right foot

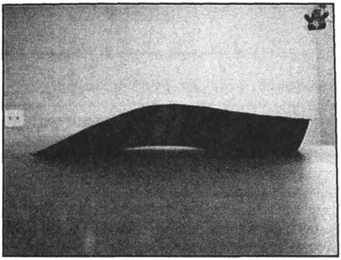


Figure 2.10. Medial view of Stabil Lite for right foot

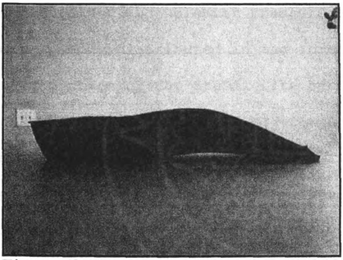


Figure 2.11. Lateral view of Stabil Lite for right foot

Chapter 3: Methods

Objective

The objective of this study was to determine the role of the Stabil Lite orthotics on plantar pressure distribution at the forefoot during a dynamic protocol on a "clinical population". Research has demonstrated equivalent results in multiple studies using prefabricated orthotics versus custom-molded orthotics. This equivalency has not been studied in pressure distribution. It is hypothesized that plantar pressure distribution will be more evenly distributed in the forefoot with the introduction of the Stabil Lite orthotics versus baseline control measurements. As previously mentioned, a foot with minimal structural abnormalities will demonstrate equal plantar pressures across the metatarsal heads. The Stabil Lite should either 1) support the foot's natural mechanics, creating equal pressure across the forefoot or 2) increase plantar cutaneous mechanoreceptor activation, which would encourage optimal biomechanics of the forefoot.

Research Design

The set-up of this study was an A-B counterbalanced design. The dependent variable was the Stabil Lite orthotic intervention. The independent variable was the plantar pressure distribution across the forefoot measured with the Parotec-System.

Subjects

This study consisted of 20 subjects (10 female, 10 male), who voluntarily participated at the testing site. The tests were conducted at a local athletic shoe store, which has a free, weekly injury clinic. Because each subject acted as their own control, there were 20 participants in the control group and 20 participants in the experimental group.

At this clinic, local physicians, physical therapists, and massage therapists offer free evaluations of orthopedic injuries. Often, the clinicians suggest purchasing an orthotic to alleviate the patient's ailment. If an insert was suggested, then the individual was asked if they would be interested in participating in the study.

Inclusion criteria were: 1) between the ages of 18 and 35 years old, 2) no previous lower extremity orthopedic surgery, 3) no uncorrectable visual or balancing problems, and 4) had not used an orthotic device or insert for the past six months. The participants were of varying heights, weights, shoe sizes, pain location, and activity level.

Instrumentation

To conduct this study, a mobile pressure device, called the Parotec-System (Paromed Medizintechnik GmbH, Neubeuern, Germany) was used. This portable pressure insole system has 24 pressure-measuring sensors, called hydrocells, which slip into any shoe under the plantar aspect of the foot. There are corresponding insoles to fit a variety of shoe sizes, according to European measurements. The hydrocells cover 46% of the insole, which have been arranged to record pressures that Paromed believes to be the most clinically relevant areas of the foot. The insole itself is a 2.5 mm-thick sheet of polyvinyl chloride with the conductive transducers planted in hydrocells filled with silicon. The hydrocells collect pressure data and calculate the shoe reaction forces based on surface area of the sensors. Regardless of where the hydrocell sensor is compressed, the sensor cell will record the same measurement. Figures 3.1-3.2 shows the Parotec-System insoles.

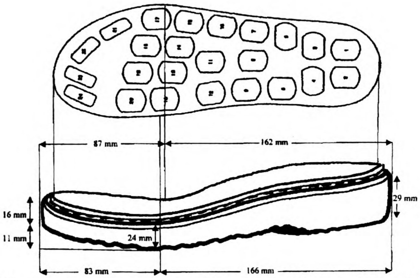


Figure 3.1. A schematic of the Parotec-System insole (Hsi, Chai & Lai, 2004)

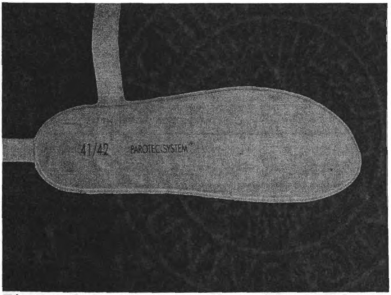


Figure 3.2. The Parotec-System insole

Two wires are stabilized to the shank (Figure 3.3) and a controller unit is stabilized around the torso, which collects the data (Figure 3.4).

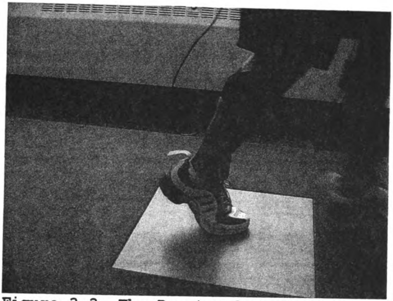


Figure 3.3. The Parotec-System wiring stabilized **to the** shank

Figure 3.4. The Parotec-System computer **stabilized to torso**

The controller unit can store and collect foot pressure data on a removable PCMCIA compatible memory card. The insole has a resolution of 2.5 kPa and a range of 600 kPa. Data is recorded between 10-300 Hz. Following data collection, information collected by the controller unit can be downloaded into a computer using a serial connection and viewed with the Parotec-System data acquisition and analysis software.

Although the Parotec-System is a fairly new device, a variety of studies have been conducted which utilized the Parotec-System to analyze foot pressures (Arampatzis, Bruggemann & Klapsing, 2002; Blackwell, et al., 2002; Chesnin, Selby-Silverstein & Besser, 2000; Goldberg, Besser, & Selby-Silverstein, ND; Hsi, et al., 2002; Hsi, Chai, & Lai, 2004; Tillman, Fiolkowski, Bauer & Reisinger, 2002).

Testing Procedures

The control and experimental testing was conducted on the same day, within a 20-minute time frame. The only clothing requirement was that the participant had to wear an athletic shoe, so the Parotec-System insole and Stabil Lite orthotic could be inserted.

Once written consent was given, a participant demographics questionnaire was administered. (See Appendix E). Answers given on the participant demographics questionnaire can be found in Table 4.2. The following topics were asked on the demographics questionnaire:

- Age
- Weight

- Height
- Shoe Size
- Sex
- Body part that is painful (multiple answers could be given)
- Physical activities the participant participated in (multiple answers could be given)
- Hours per week in those activities
- Pain during day-to-day activity
- Pain during physical activity
- Pain at pre-test
- Pain at post-test

Once the survey was completed, the proper insoles of the Parotec-System were fitted to French shoe size and inserted in the shoe. Next, the computer was stabilized to the torso, the shoes were placed on the participant, the sensors were connected to the computer on the torso, and the wires were stabilized to the shank via Velcro straps.

Prior to the calibration of the Parotec-System in both the control and experimental conditions, the participant was instructed to walk around for a few steps to make sure the insoles were positioned correctly inside the shoe. Calibration was accomplished by the participant sitting on a chair and lifting their feet off the ground, so they were non-weightbearing. Additionally, the computer was set to a dynamic setting at a sampling rate of 60 Hz.

In the non-orthotic (control) condition, the participant was placed on a straight path and instructed to walk down the path at normal walking pace. Data collection began with the right foot. The participant was instructed to start walking with their right foot. The first two steps with the right foot were necessary for the participant to accelerate to their normal gait speed. Prior to the third heel strike with the right foot, the researcher used the remote control to begin data recording. Data was collected for a total of seven steps in the right foot. Following the last toe-off of the right foot, the researcher paused the computer with the remote control. The participant was instructed to walk back to the starting point, beginning with their left foot. Again, the first two steps with the left foot were necessary for the participant's normal gait speed to occur. Prior to the heel contact with the third left step, the computer was unpaused and data collection resumed. Another seven steps were recorded, to conclude data collection for that trial. These procedures occurred five times, resulting in 35 steps recorded for each foot to be analyzed. Following each trial, the card was taken out of the computer on the torso and placed into a reader on a laptop, where the data were saved.

The Stabil Lite orthotic was introduced for the experimental condition. For this condition, the Parotec-System insole was placed directly over the Stabil Lite orthotic to measure the effects the orthotic had on plantar pressure. Once the orthotic was inserted and the Parotec-System was placed on the participant and calibrated, the same walking protocol from the control condition occurred. The participant walked down the path beginning with the right foot. After the first two steps, the researcher began data collection. Data collection occurred in steps 3-9. Next, the participant turned around and walked back to the starting point, starting with the left foot. After the first two steps with the left foot, data collection began in steps 3-9. This concluded one trial. A total of five trials occurred, resulting in 35 steps recorded for each foot.

Data Analysis

From the five trials, data were taken from predetermined sensors via the Parotec-System for Windows version 4.02.18. The areas that were analyzed were the metatarsal heads. The cells that were analyzed were cells

13-20. The cells that were under the heel were not analyzed due to 1) the high error rate in cells 1-4 and 2) low incidence of chronic injury as a result of abnormal plantar pressures. The medial longitudinal arch (cells 5-12) and toes (cells 21-24) were not examined also because of the low incidence of chronic injury as a result of abnormal plantar pressures.

This group of cells at the metatarsals was divided equally so there was a lateral half and medial half. Cells 13, 14, 17, and 18 were defined as the "lateral forefoot" and cells 15, 16, 19, and 20 were defined as the "medial forefoot". Figure 3.5 demonstrates the location of the sensors on the Parotec-System insole.

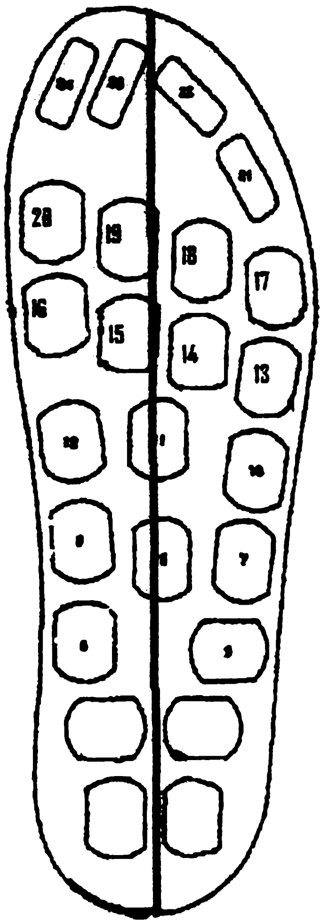


Figure 3.5. Parotec-System insole numbering for a right foot

The Parotec-System data analysis program automatically computed the mean pressures for each cell for the seven steps. From each trial, the sum was calculated for each region of the pressures (ie, cells 15, 16, 19, and 20 were summed and cells 13, 14, 17, and 18 were summed). The summed pressures over the five trials in each condition were averaged and were defined as the average plantar pressures. (See Appendix A). These data were analyzed for statistical significance. The average plantar pressures in each condition were used to calculate a lateral forefoot plantar pressures:medial forefoot plantar pressures ratio to quantify plantar pressure distribution during the control trial and experimental trial. (See Appendix B). This method of analyzing plantar pressures was derived from a study by Willis and colleagues (2002). A 1.00:1.00 ratio demonstrated an even distribution of pressures across the forefoot. A ratio of less than 1.00 demonstrated increased pressures on the medial portion of the forefoot. A ratio of greater than 1.00 demonstrated greater pressures on the lateral portion of the forefoot.

Chapter 4: Analysis of Results

Twenty participants (10 male and 10 female) between the ages of 18-35 (mean age: 26.8 years, mean height: 1.8 m., mean mass: 79.1 kg, mean BMI: 24.9, mean French shoe size: 42.4) were used for this study. French shoe size was used in this study so a common shoe measuring system could be used between both sexes. Body mass index (BMI) was calculated as [mass (kg) / height $(m)^2$]. (See Table 4.1).

Table 4.1. Participant Demographic Information

Subject	Age (yrs)	Height (m)	Mass (kg)	BMI	Shoe Size (Fr)	Sex
1	20	1.8	56.7	18.5	38.5	F
2	18	1.5	63.5	26.5	37.5	F
3	30	1.9	79.4	22.5	46.0	M
4	35	1.7	97.5	33.7	40.5	F
5	23	1.7	65.8	22.0	40.0	F
6	23	1.8	63.5	19.5	40.5	F
7	25	1.9	74.8	21.2	46.0	M
8	28	1.9	142.9	38.9	49.5	M
9	34	1.7	56.7	19.6	37.0	F
10	24	1.9	79.4	21.9	48.5	M
11	24	1.8	108.9	34.4	44.5	M
12	23	1.8	72.6	23.6	41.0	F
13	25	1.8	90.7	29.5	40.5	F
14	28	1.7	62.6	23.0	40.0	F
15	35	1.9	83.9	23.8	44.0	M
16	27	1.8	68.0	22.2	41.0	M
17	33	1.7	61.2	22.4	36.0	F
18	22	1.9	113.4	33.0	46.0	M
19	24	1.8	74.8	22.4	44.5	M
20	35	1.9	65.8	19.1	46.0	M

Specific questions were asked about the participant's injury and training regimen. The participants were asked in the questionnaire about area of pain (1-foot, 2-arch, 3-

ankle, 4-shin, 5-knee, 6-thigh, 7-spine), activities participating in (1-run, 2-walk, 3-bike, 4-swim, 5-weight lifting, 6-aerobics, 7-other), hours per week participating in the activities, pain day-to-day (Pain D-D), pain during physical activity (Pain P.A.), pain pre-test (Pain Pre), and pain post-test (Pain Post) The answers given are displayed in Table 4.2.

Table 4.2. Participant Characteristic Information

Subject	Area of Pain	Activities	Hours/ Week	Pain D-D	Pain P.A.	Pain Pre	Pain Post
1	2	1,7	4	3	5	1	0
2	4	1,6	12	2	6	2	2
3	1,5	3,4,7	6	1	2	2	2
4	1,5	1,2,7	8	2	4	0	0
5	2,5	1,7	7	4	7	1	1
6	3	1,6,7	8	2	4	3	3
7	4	2	4	4	4	3	3
8	1	1,2,3	6	7	9	6	3
9	1	1	10	0	2	0	0
10	5	7	10	2	3	0	0
11	3,7	1,4,5	10	0	3	0	0
12	1,4	1,4	6	0	3	0	0
13	1	1,2,4	5	4	4	2	2
14	2,6	1,3,5	10	1	4	1	1
15	2,4	2	2	1	3	0	0
16	5	1	3	1	3	0	0
17	5	2	5	1	4	1	1
18	6	2,7	3	4	6	5	5
19	1	1,2	7	1	2	0	0
20	1	1	12	7	9	7	7

Statistical Analysis

Statistical Analysis Between Pressure Measurements in Control and Experimental Conditions

All statistical analyses were performed using the SPSS statistical software package (version 14.0; SPSS, Inc., Chicago, IL). Descriptive statistics were analyzed between the right and left foot's recorded medial plantar pressures with and without the Stabil Lite orthotic (See Table 4.3). A 2(without) x 2 (with) repeated measures ANOVA was conducted to determine the effect Stabil Lite orthotics had on plantar pressures in the right and left medial forefoot compared to baseline readings. Results indicated that there were no statistical changes in the right medial forefoot with insertion of the Stabil Lite orthotic versus baseline measurements ($F = 0.022$, $p = 0.884$). There were also no statistical changes in the left medial forefoot with insertion of the Stabil Lite orthotic versus baseline measurements ($F = 0.580$, $p = 0.456$). (See Table 4.4).

Table 4.3. Descriptive Statistics for Plantar Pressures Means Without and With Stabil Lite Orthotic In Medial Forefoot

Time	N	Mean (kPa)	Std. Deviation
Without Orthotic			
Right	20	484.33	149.90
Left	20	513.31	125.62
With Orthotic			
Right	20	482.26	141.58
Left	20	524.00	163.45

Table 4.4. Individual 2x2 Repeated Measures ANOVAs Comparing Medial Forefoot Without and With Use of Stabil Lite Orthotic

Foot	SS	df	MS	F	P
Right	42.539	1	42.539	0.022	0.884
Left	1142.013	1	1142.013	0.580	0.456

*(significance at the p = 0.05 level)

Descriptive statistics were analyzed between the right and left foot's recorded medial plantar pressures with and without the Stabil Lite orthotic (See Table 4.5). A 2(without) x 2 (with) repeated measures ANOVA was conducted to determine the effect Stabil Lite orthotics had on plantar pressures in the right and left lateral forefoot compared to baseline readings. Results indicated that there were reductions in the right lateral forefoot pressures with insertion of the Stabil Lite orthotic versus baseline measurements ($F = 23.822$, $p = 0.000$). There were also reductions in the left lateral forefoot with insertion of the Stabil Lite orthotic versus baseline measurements ($F = 25.699$, $p = 0.000$). (See Table 4.6).

Table 4.5. Descriptive Statistics for Plantar Pressures Means Without and With Stabil Lite Orthotic In Lateral Forefoot

Time	N	Mean (kPa)	Std. Deviation
Without Orthotic			
Right	20	501.05	161.41
Left	20	499.64	120.40
With Orthotic			
Right	20	449.33	158.49
Left	20	447.48	122.40

Table 4.6. Individual 2x2 Repeated Measures ANOVAs Comparing Lateral Forefoot Without and With Use of Stabil Lite Orthotic

Foot	SS	df	MS	F	P
Right	26747.515	1	26747.515	23.822	0.000*
Left	27199.354	1	27199.354	25.699	0.000*

*(significance at the p = 0.05 level)

Statistical Analysis Between Right and Left Foot's Plantar Pressure Ratios

Descriptive statistics were analyzed between the right and left foot's plantar pressure ratios with and without the Stabil Lite orthotic. (See Table 4.7). A 2 (right) x 2 (left) repeated measures ANOVA was conducted to determine the relationship of the Stabil Lite orthotics in the right and left foot. Results indicated that medial shifts occurred in the right foot (F = 4.393, p = 0.050) and left foot (F = 9.593, p = 0.006) compared to baseline readings, but not for the interaction between the right and left foot (F = 0.937, p = 0.345). (See Table 4.8).

Table 4.7. Descriptive Statistics for Plantar Pressure Ratio Means Between R/L Foot

Time	N	Mean	Std. Deviation
Without Orthotic			
Right	20	1.12	0.42520
Left	20	1.01	0.28873
With Orthotic			
Right	20	0.99	0.32337
Left	20	0.93	0.28785

Table 4.8. Individual 2x2 Repeated Measures ANOVAs Comparing Right and Left Foot With Use of Stabil Lite Orthotic

Foot	SS	df	MS	F	P
Right	0.154	1	0.154	4.393	0.050*
Left	0.250	1	0.250	9.593	0.006*
Right & Left	9.977 E-3	1	9.977 E-3	0.937	0.345

*(significance at the p = 0.05 level)

Statistical Analysis Between Genders' Plantar Pressure Ratios

Descriptive statistics were analyzed between the genders' plantar pressure ratios with and without the Stabil Lite orthotic. (See Table 4.9). A 2 (right) x 2 (left) x 2 (gender) repeated measures ANOVA was conducted to determine the interaction of the Stabil Lite orthotics in gender compared to baseline readings. Results demonstrated no significant differences between genders following insertion of the Stabil Lite between genders ($F = 3.497$, $p = 0.078$). The Observed Power for this analysis was calculated as 0.425. (See Table 4.10).

Table 4.9. **Descriptive Statistics for Plantar Pressure Ratio Means Between Gender**

Time	N	Mean	Std. Deviation
Without Orthotic			
Right			
Male	10	1.27	0.33115
Female	10	0.98	0.47412
Total	20	1.12	0.42520
Left			
Male	10	1.13	0.29027
Female	10	0.90	0.24477
Total	20	1.01	0.28873
With Orthotic			
Right			
Male	10	1.12	0.29752
Female	10	0.98	0.30441
Total	20	0.99	0.32337
Left			
Male	10	1.01	0.28371
Female	10	0.84	0.27953
Total	20	0.93	0.28785

Table 4.10. **Individual 2x2x2 Repeated Measures ANOVAs Comparing Mean Pressure Ratios Without/With Orthotic and Gender**

	SS	df	MS	F	p	OP
Gender	1.174	1	1.174	3.497	0.078	0.425

Statistical Analysis Between Age Groups' Plantar Pressure Ratios

Two age groups were created to analyze the effects the Stabil Lite orthotic had on age. The median was calculated from the participants' ages and was found to be 25 years old. Participants who were younger than the median age was placed in the "young group" and participants who were either the median age and older were placed in the "old group".

Descriptive statistics were analyzed between the age groups' plantar pressure ratios with and without the Stabil Lite orthotic. (See Table 4.11). A 2 (right) x 2 (left) x 2 (age) repeated measures ANOVA was conducted to determine significance with the use of the Stabil Lite orthotics on age compared to baseline readings. Results demonstrated no significant differences among the age groups ($F = 0.154$, $p = 0.699$) with use of the Stabil Lite orthotics. The Observed Power for this analysis was calculated as 0.066 (See Table 4.12).

Table 4.11. Descriptive Statistics for Plantar Pressure Ratio Means Between Age Group

Time	N	Mean	Std. Deviation
Without Orthotic			
Right			
Young	10	1.06	0.31817
Old	10	1.18	0.50468
Total	20	1.12	0.42520
Left			
Young	10	0.94	0.16449
Old	10	1.07	0.35875
Total	20	1.07	0.28873
With Orthotic			
Right			
Young	10	1.03	0.30993
Old	10	1.18	0.34610
Total	20	1.12	0.32337
Left			
Young	10	0.91	0.29732
Old	10	0.94	0.29353
Total	20	0.93	0.28785

Table 4.12. Individual 2x2x2 Repeated Measures ANOVAs Comparing Mean Pressure Ratios Without/With Orthotic and Age

	SS	df	MS	F	p	OP
Age	6.119 E-2	1	6.119 E-2	0.154	0.699	0.066

Chapter 5: Discussion

Analysis of Plantar Pressure Data

Each participant had their mean plantar pressures recorded over each trial. The effect the Stabil Lite had on pressure alteration could be compared from the control trials to the experimental trials. In this study, 19 right feet and 17 left feet had reduced lateral pressure with the use of the Stabil Lite orthotic. Statistical analysis revealed a significant reduction in lateral plantar pressure in both the right and left foot with insertion of the Stabil Lite orthotic. These findings of reduced pressures in the lateral forefoot are consistent with previous literature (Donahue et al., 1996; Higbie, et al., 1998; Hodgson, et al., 2005).

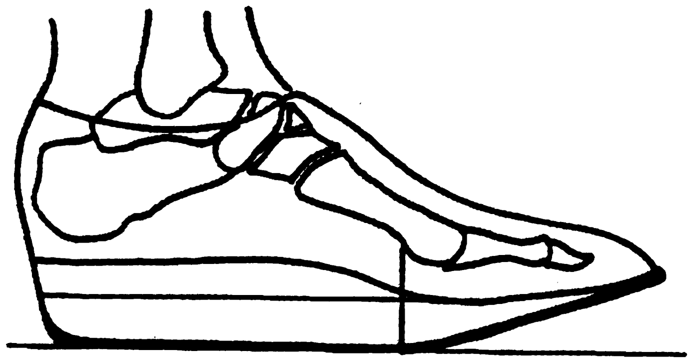
In the medial forefoot, alterations of plantar pressure were mixed. For the right foot, 14 participants had their medial pressures decreased and only 9 had medial pressures reduced in the left foot. Statistical analysis revealed there was no significant change in medial plantar pressure with the insertion of the Stabil Lite orthotic. These results are inconclusive compared to studies by Donahue and colleagues (1996), Higbie and colleagues (1998), and Willis and colleagues (2002). Higbie and colleagues (1998) found that there was a reduction in medial plantar pressures with the use of an orthotic. Donahue and colleagues (1996) and Willis and colleagues (2002) found increases in medial forefoot plantar pressures with use of an orthotic. They attribute this increase in medial forefoot pressures for two reasons. One, the composition of the orthotic was harder than the insole of the shoe, thus reducing shock-absorbing capabilities. Secondly, the increased arch support in the medial longitudinal arch resulted in more contact with the foot, resulting in more forces being absorbed along the first and second metatarsal.

Decreases in plantar pressures in the midfoot, can be very advantageous to physically active individuals. Research has shown that plantar pressures can increase up to 12% in the midfoot during a fatiguing protocol, which replicated a bout of exercise (Weist, et al., 2004). This increase in plantar pressures can predispose individuals to metatarsal stress fractures if these forces are repetitive (Boden, et al., 2001; Eils, et al., 2004; Gross & Bunch, 1989; Weist, et al., 2004). According to Boden and colleagues (2001), there is a high risk for stress fractures in the second and fifth metatrsals. Thus, an external device that can offload plantar pressures in these areas should be desirable to physically active individuals.

This study demonstrated that plantar pressures in the area of the fourth and fifth metatarsals were significantly reduced with the use of the Stabil Lite orthotic. As a result, active individuals who experience repetitive high forces in feet, such as runners, would benefit from using this device.

Multiple theories can be formulated to why forefoot pressures were reduced. The first theory is because of the medial arch support of the Stabil Lite supporting the medial longitudinal arch. The high arch support would create an increase in ground contact in the medial longitudinal arch. The arch support also would act like a fulcrum proximal to the metatarsal heads.

This aspect of the Stabil Lite mimics the design of a metatarsal head (met-head) rocker sole. This device is an addition on a shoe's sole, which adds a fulcrum proximally to the metatarsal heads. Its goal is to offload plantar pressures across the forefoot. Figure 5.1 shows a schematic of a met-head rocker.



<u>Figure 5.1.</u> Met-head rocker sole (Custom Footwear Inc., 2002).

Although the Stabil Lite is not structurally similar to the rocker sole, it is possible that the high arch support of the Stabil Lite acted in a similar manner. If the high arch support functioned like a fulcrum, then the reduction in lateral plantar pressures would be explained.

Another possibility of why lateral plantar pressures were reduced in the forefoot is due to a reduction in intrinsic musculature activity. If an orthotic supports a joints' preferred movement path, then a reduction in muscle activation will result (Hertel & Olmsted, 2004; Kuppermann, 2005; Nigg, et al., 1999). Less muscle tension results in a less rigid foot. A less rigid foot should be able to absorb more forces throughout the structures of the foot. If the Stabil Lite is encouraging the structures in the foot to work in their preferred movement path and muscle tension is reduced, then there should be a reduction in plantar pressures. This would explain the reduction in plantar pressures laterally, but does not explain the lack of change in medial plantar pressures.

Muscle activity could have also been altered in the proximal tissues surrounding the knee and hip. Previous research found increased EMG levels in the quadriceps, hamstrings, and gluteus medius with the introduction of orthotics (Hertel & Olmsted, 2004; Kuppermann, 2005). This increase in muscle activity around the hip is called the hip strategy in stability. It results in the stabilizing musculature around the ankle and foot to be reduced during activity. Again, reduced musculature in the foot will result in a more supple foot, which allows for forces to be absorbed more in the structures of the foot.

The Stabil Lite also could have been effective in reducing lateral forefoot plantar pressures because of the deep heel cup acting as a cradle around the calcaneous. In a study by Ochsendorf and colleagues (2000), they theorize that the ankle mortise is in a neutral position when using the orthotics they were testing, due to the orthotic cradeling the calcaneous. This neutral position in the ankle mortise results in a reduction in the reliance of supporting musculature in the ankle and foot for stability. As previously stated, this reduced muscle activity in the foot will result in a more supple foot, which allows for more force absorption in the structures of the foot.

Analysis of Pressure Ratios in Control & Experimental Conditions

Plantar pressure ratio calculations demonstrated almost every participant shifting their pressure distribution medially with the insertion of the Stabil Lite. With the insertion of the Stabil Lite orthotics, 19 participants had a significant medial shift of their plantar pressure ratios in the right foot from 1.12 to 0.99. This change in the ratios signified that the Stabil Lite was effective in creating almost uniform plantar pressures across the forefoot.

With the insertion of the Stabil Lite orthotics, 18 participants had their plantar pressure ratios significantly shifted medially in their left foot from 1.01 to 0.93. This change in the ratios resulted in plantar pressures being concentrated medially, beyond the desired 1.00 ratio. It is unknown why there was a disparity in ratios between the two feet.

This shifting of pressure ratios was not caused by a change in medial plantar pressures. Results did indicate that there was a significant reduction in lateral plantar pressures. This reduction laterally would in effect reduce the total ratio, resulting in the plantar pressures to be concentrated medially.

Similar results of a medial shift in plantar pressure ratios were found in a study by Willis and colleagues (2002). In this study, the authors analyzed the plantar pressure distribution of a medial orthotic using a medial:lateral ratio. The authors found a 0.76 M:L ratio for the control condition (or 1.316 L:M ratio) and a 0.84 M:L ratio (or 1.190 L:M ratio) for the experimental condition. The authors concluded that the orthotic was effective in increasing peak medial load in the patients, which also created a more uniform plantar pressure. The one aspect that the authors did not mention in their study was the effect that the orthotics had on the actual plantar pressures. Their increase in peak medial load could have also been the result of a reduction in lateral plantar pressures.

Analysis Among Genders

Analysis between males and females revealed interesting findings. In analyzing the mean pressure ratios, the data showed both males and females shifted their plantar pressures medially with the insertion of the Stabil Lite. In addition, the left foot demonstrated plantar pressure ratios more medial than the right foot.

Lastly, it was found that females had overall higher medial pressure ratios compared to males in both the control and experimental conditions.

Males had reduced pressures medially in seven right forefeet and five left forefeet, as well as reduced pressures laterally in all ten right forefeet and nine left forefeet. Females did not exhibit a reduction in pressures as frequently as males. Females had reduced pressures medially in six right forefeet and five left forefeet, as well as reduced pressures laterally in nine right forefeet and eight left forefeet.

Although there seemed to be a difference between males and females when looking at L:M plantar pressure ratios, statistical analysis revealed no significant differences between the genders. When considering anatomic differences between genders, it would not be surprising if there were statistical differences. Females anatomically tend to have wider pelvises, to allow for childbirth. This widened pelvis results in a higher Q-angle at the knees. An increase in Q-angle places the calcaneous in an everted position, which results in the foot having more contact with the ground medially. It would then appear that females could have a greater concentration of plantar pressures medially then males. Is possible that the low observed power altered the significance, due to a low sample of participants. If a greater number of participants were used, then the changes between males and females could possibly have been significant.

Analysis Among Age Groups

The next analysis was between the two age groups. Again, groups were formed as being either younger than the median or older than the median. First, it was seen that the Stabil Lite orthotics shifted the plantar pressure ratios medially in both groups. Second, the younger group was more medially dominant with their plantar pressures compared to the older group. Lastly, the left forefoot showed more plantar pressures medially oriented compared to the right forefoot.

Data analysis revealed there was no significant interaction with the insertion of the Stabil Lites between age groups. This can be attributed to the participants being very comparable in age. There are not a lot of anatomical and physiological differences among individuals between the ages of 18-35 years old, especially since this was a physically active population. It can only be speculated what kinds of changes may have been seen with the comparison of participants in a wider spectrum of age.

Clinical Implications

The data and statistics demonstrate that the Stabil Lites significantly shifted the plantar pressures of the forefoot medially compared to baseline conditions. The Stabil Lites were also effective in reducing lateral forefoot plantar pressures. This should be seen as a potential prevention/treatment for active individuals who may be at risk for metatarsal stress fractures, especially in the fifth metatarsal. Research has demonstrated that increased plantar pressures predispose individuals for metatarsal stress fractures (Boden, et al., 2001; Eils, et al., 2004; Gross & Bunch, 1989; Weist, et al., 2004). If there is a reduction in the lateral plantar pressures with the use of the Stabil Lite orthotic, then less force will be absorbed in the metatarsals, thus potentially decreasing injury rate.

Another aspect of the Stabil Lite that is clinically relevant is the high arch support could increase plantar cutaneous receptor activity and potentially reduce injury. As concluded by Hertel, Gay, and Denegar (2002), individuals with pes cavus feet have a reduced degree of postural stability, creating an instable base of support and potentially predisposing individuals for lateral ankle sprains. They theorized that this was due to a lack of cutaneous sensation from reduced surface area on the plantar surface. If individuals with pes cavus are making more contact with the ground through the Stabil Lite, then plantar cutaneous receptors should process more information to keep the base of support more stable, thus reducing injury.

Sources of Measurement Error

It was attempted to record 7 full steps for each trial. This was done by having a testing protocol that analyzed one foot at a time. If the researcher was too quick or too slow in starting the remote to the Parotec-System, then part of a step would not be completely recorded or an extra part of a step could be recorded. This should not alter the data too significantly, since averages are being calculated over multiple steps.

Also, because the testing was done in the middle of the store, customers were free to walk through the testing site. This often would skew the participant from walking in a completely straight line. If the participant had to veer severely to avoid a customer, then the trial was nixed and a new one was started.

It was observed in participant 10 that sensor 16 in the right foot gave a reading of 0 kPa for every trial. This was an unexpected finding, since the Stabil Lite clearly covered this sensor, which should give a pressure reading. As a result, it is theorized that that sensor has some defectiveness in it. There were no other participants who used this insole, since the size was rather large, so this theory cannot be compared to any other test. The participant's data was not omitted, due to their resultant data being comparable to the other participants.

Considerations for the Future

The main suggestion for future research would be to study exactly what constitutes "good pressure distributions" and "bad pressure distributions". Although this study did not find equal distributions of pressures across the forefoot, it may not be a negative thing. Clarity is necessary to determine what calculated ratio increases individuals' chances of developing an injury. At this point, it is only hypothesized that an equal distribution of pressures would be considered optimal, since no part of the foot would receive higher stresses compared to another (Franco, 1987; Kaufman, et al., 1999; Kitaoka & Patzer, 1997; Manoli, 2001; Neely, 1998; Omey & Micheli, 1999; Weist, Eils & Rosenbaum, 2004). But, the pressure ratios tended to shift to a medial dominance with the Stabil Lite intervention in this study. It would be erroneous to think that the Stabil Lite negatively affect feet. To analyze this puzzle, long-term studies are necessary to track injury rates. Through a population of healthy individuals, it would be beneficial to track any lower extremity injuries and see if any correlations exist with laterally/medially dominant plantar pressures.

As previously stated, biomechanical changes that orthotics induce is debated. Digital imaging techniques, such as MRI and CT scan should be performed to determine if structural changes occur with the use of prefabricated orthotics during static stance and dynamic movements. Another method of analyzing biomechanical alterations is videography analysis. Anatomical markings can be digitally tracked to see biomechanical changes in the body. It would be especially effective to compare changes made among individuals who clinically are hyperpronators and hypersupinators.

Research should continue analyzing the effectiveness of not only the Stabil Lite orthotic, but also the effectiveness of other prefabricated orthotics. Currently, there is limited research on prefabricated orthotics, so contributions to the literature can be beneficial. If more studies find comparable outcomes of prefabricated orthotics to custom-molded orthotics, then health care costs to manage lower-extremity injuries should be decreased.

As the study progressed, the manufacturer released a full-length Stabil Lite orthotic. Instead of the Stabil Lite being cut off at the metatarsal heads, it stretched the full length of the shoe. It would be beneficial to compare the two types of Stabil Lites, analyzing if there are any differences between the models.

Additionally, it would be beneficial to see whether or not the Stabil Lites are an effective treatment to reduce plantar pressures in individuals with a high body mass index (BMI). It has been suggested that individuals with a higher body mass exhibit higher plantar pressures under the metatarsal heads and medial longitudinal arch (Dowling, Steele & Baur, 2004). Because our society is continuing to increase in obesity levels, it is important to develop devices that can reduce injuries that these individuals may develop.

The last consideration for future research would be to use a greater number of participants. Previous literature utilized between 6-20 participants when using the Parotec-System, which influenced the decision to collect data from 20 participants in this study. This low number of participants resulted in a lower observed power. To increase the observed power score, it would be wise to use more participants in future studies.

Limitations to the Study

Although the Parotec-Device has been proven to be an effective method to analyze plantar pressures in previous research, some limitations exist in the study. Although the method of analyzing the data was adapted from previous studies, the detail in which they were analyzed were not given. Thus, the effectiveness of how the data was analyzed can be debated.

One factor that was decided not to control was the shoe selection of the participant. The only requirement was that the participant had to wear an athletic shoe during the study. Although this eliminated boots and dress shoes from the study, certain shoes are designed to limit/enhance pronation or supination through stiffness in the soles. This in effect would lead to some biomechanical correction without even using an orthotic. Additionally, older shoes lose shock-absorbing capabilities. This could possibly increase plantar pressures at areas of excessive wear in the soles.

Conclusions

- The Stabil Lite orthotics were effective in reducing lateral forefoot plantar pressures. This could be an effective device in reducing stress fractures in the fifth metatarsal.

- The Stabil Lite orthotics did not equally distribute the plantar pressures as was hypothesized. The pressures that were concentrated medially in the forefoot may not necessarily be a negative outcome from the orthotic, since some individuals had a decrease in medial plantar pressures.
- The significant increase in plantar pressure ratios medially can be a result from a significant reduction in lateral plantar pressures.
- There were no significant differences in changes with plantar pressure ratios among males and females.
- There were no significant differences in changes with plantar pressure ratios among the two age groups. This can be attributed to the two groups being similar anatomically and in physical activity.

APPENDIX A

Participant Mean Pressure Data

Raw Data for Medial Forefoot Plantar Pressure Means

Subject	Right Medial Forefoot Without Orthotic (kPa)	Right Medial Forefoot With Orthotic (kPa)	Net Change (kPa)	Left Medial Forefoot Without Orthotic (kPa)	Left Medial Forefoot With Orthotic (kPa)	Net Change (kPa)
1	622.82	588.60	**-34.22**	595.86	589.65	**-6.21**
2	630.57	629.32	**-1.25**	649.50	642.72	**-6.78**
3	446.07	442.43	**-3.64**	394.57	398.78	**-4.21**
4	280.14	450.65	**+170.51**	479.87	506.38	**+26.51**
5	549.17	452.58	**-96.59**	549.12	426.72	**-122.40**
6	424.50	421.50	**-3.00**	439.95	473.79	**+33.84**
7	394.82	365.68	**-29.14**	416.29	392.51	**-23.78**
8	614.59	590.46	**-24.13**	574.09	538.57	**-35.52**
9	565.94	559.53	**-6.41**	590.17	597.58	**+7.41**
10	309.26	263.00	**-46.26**	387.05	330.25	**-56.80**
11	784.25	773.47	**-10.78**	829.63	953.65	**+124.02**
12	297.90	306.46	**+8.56**	301.40	227.59	**-73.81**
13	622.53	628.32	**+5.79**	678.50	724.56	**+46.06**
14	469.45	492.96	**+23.51**	481.07	439.09	**-41.98**
15	421.30	526.64	**+105.34**	561.48	607.92	**+46.44**
16	477.40	558.92	**+81.52**	390.64	454.50	**+63.86**
17	680.65	621.74	**-58.91**	572.71	682.31	**+109.60**
18	481.00	391.57	**-89.43**	525.66	623.57	**+97.91**
19	415.86	378.29	**-37.57**	485.29	530.14	**+44.85**
20	198.28	203.13	**+4.85**	363.36	339.66	**-23.70**

Raw Data for Lateral Forefoot Plantar Pressure Means

Subject	Right Lateral Forefoot Without Orthotic (kPa)	Right Lateral Forefoot With Orthotic (kPa)	Right Lateral Forefoot Net Change (kPa)	Left Lateral Forefoot Without Orthotic (kPa)	Left Lateral Forefoot With Orthotic (kPa)	Left Lateral Forefoot Net Change (kPa)
1	324.93	278.35	**-46.58**	426.18	283.64	**-142.54**
2	458.72	451.49	**-7.23**	475.89	442.22	**-33.67**
3	571.35	561.00	**-10.35**	534.93	511.28	**-23.65**
4	563.76	592.77	**+29.01**	682.97	678.14	**-4.83**
5	486.55	455.91	**-30.64**	439.13	419.29	**-19.84**
6	484.59	451.71	**-32.88**	473.18	485.50	**+12.32**
7	287.93	230.00	**-57.93**	382.72	294.06	**-88.66**
8	701.39	511.14	**-190.25**	606.44	509.48	**-96.96**
9	454.68	388.59	**-66.09**	459.59	394.52	**-65.07**
10	386.44	327.50	**-58.94**	406.53	289.63	**-116.90**
11	971.11	918.59	**-52.52**	808.05	731.23	**-76.82**
12	454.77	401.18	**-53.59**	338.87	309.64	**-29.23**
13	492.51	469.78	**-22.73**	534.71	485.59	**-49.12**
14	387.83	344.51	**-43.32**	419.71	391.86	**-27.85**
15	565.56	534.54	**-31.02**	463.89	467.83	**+3.94**
16	715.12	668.64	**-46.48**	677.53	546.38	**-131.15**
17	347.28	316.84	**-30.44**	353.72	357.90	**+4.18**
18	610.34	459.39	**-150.95**	584.97	564.00	**-20.97**
19	368.00	308.71	**-59.29**	430.57	366.01	**-64.56**
20	388.14	316.00	**-72.14**	493.14	421.46	**-71.68**

APPENDIX B

Participant Mean Ratio Data

Descriptive Statistics for Mean Right & Left Forefoot Plantar Lateral:Medial (L:M) Pressure Ratios Without and With Orthotic

Subject	Right Forefoot Without Orthotic	Right Forefoot With Orthotic	Pressure Shift	Left Forefoot Without Orthotic	Left Forefoot With Orthotic	Pressure Shift
1	0.52	0.47	*	0.72	0.48	*
2	0.73	0.72	*	0.73	0.69	*
3	1.29	1.27	*	1.36	1.28	*
4	2.03	1.32	*	1.43	1.35	*
5	0.89	1.01	**	0.80	0.98	**
6	1.14	1.07	*	1.09	1.09	*
7	0.74	0.63	*	0.92	0.75	*
8	1.15	0.87	*	1.06	0.95	*
9	0.81	0.70	*	0.78	0.66	*
10	1.27	1.26	*	1.05	0.89	*
11	1.24	1.19	*	0.98	0.77	*
12	1.54	1.31	*	1.13	1.12	*
13	0.80	0.75	*	0.79	0.67	*
14	0.83	0.71	*	0.87	0.89	**
15	1.35	1.02	*	0.83	0.77	*
16	1.53	1.20	*	1.78	1.25	*
17	0.51	0.51	=	0.62	0.53	*
18	1.27	1.17	*	1.12	0.91	*
19	0.90	0.82	*	0.89	0.69	*
20	1.96	1.61	*	1.36	1.24	*
MEAN	**1.13**	**0.99**	*	**1.02**	**0.93**	*

Key: * (Medial Pressure Shift)
** (Lateral Pressure Shift)
= (No Pressure Shift)

APPENDIX C

University Committee for Research Involving Human Subjects (UCRIHS) Approval Form

MICHIGAN STATE UNIVERSITY

Initial IRB Application Approval

March 23, 2006

To: John POWELL
105 IM Sports Circle
MSU

Re: **IRB # 06-194** Category: EXPEDITED 2-4, 2-6
Approval Date: **March 23, 2006**
Expiration Date: **March 22, 2007**

Title: AN ANALYSIS OF PRESSURE DISTRIBUTION WITH A PREFABRICATED FOOT ORTHOTIC

The Institutional Review Board has completed their review of your project. I am pleased to advise you that **your project has been approved.**

The committee has found that your research project is appropriate in design, protects the rights and welfare of human subjects, and meets the requirements of MSU's Federal Wide Assurance and the Federal Guidelines (45 CFR 46 and 21 CFR Part 50). The protection of human subjects in research is a partnership between the IRB and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: IRB approval is valid until the expiration date listed above. If you are continuing your project, you must submit an ***Application for Renewal*** application at least one month before expiration. If the project is completed, please submit an ***Application for Permanent Closure.***

Revisions: The IRB must review any changes in the project, prior to initiation of the change. Please submit an ***Application for Revision*** to have your changes reviewed. If changes are made at the time of renewal, please include an ***Application for Revision*** with the renewal application.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects, notify the IRB office promptly. Forms are available to report these issues.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

Good luck in your research. If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

Sincerely,

Peter Vasilenko, Ph.D.
BIRB Chair

c: William Vascik
4326 Dell Rd.
Apt. G
Lansing, MI 48911

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Fax: 517-432-4503

www.humanresearch.msu.edu
SIRB & BIRB: IRB@msu.edu
CRIRB: crirb@msu.edu

APPENDIX D

Human Subjects Consent Form

An Analysis of Pressure Distribution With A Prefabricated Foot Orthotic

Informed Consent

For questions regarding this study, please contact:
Dr. John Powell, ATC
Michigan State University
Phone: (517) 432-5018
E-mail: powellj4@msu.edu or

William J. Vascik, ATC
Graduate Assistant
Michigan State University
E-mail: vascikwi@msu.edu
Phone: (814) 360-0186
Work: (517) 490-2645

For questions regarding your rights as a research participant, please contact:
Peter Vasilenko, Ph.D.
Committee on Research Involving Humans
Michigan State University
202 Olds Hall
East Lansing, MI 48824
E-mail: uchrihs@msu.edu
Phone: (517) 355-2180
Fax: (517) 432-4503

The purpose of this study is to examine the pressure distribution across the sole of the foot while using an insert in your shoe. The orthotic that will be introduced is called a Stabil-Lite and is produced by Playmakers Athletic Footwear & Apparel in East Lansing, MI. To measure the pressure distribution, a portable pressure insole system, called the Parotec-System (Paromed Medizintechnik GmbH, Neubeuern, Germany), will be used inside your shoe.

You have agreed to the following criteria to be a potential participant in the study: 1) having no lower extremity injury within the past year, 2) no previous surgery in the lower extremity, 3) no uncorrectable-visual or balancing problems, 4) are between the ages of 18 and 35 years-old, and 5) have not used an orthotic device or insert for the past six months. If you are willing to participate, you will be asked a few demographical questions, as well as questions relating to your injury. Next, your navicular drop will be measured, which classifies your foot type. This is done by the most prominent part of your navicular bone in your foot being marked. The height of this mark is recorded on an index card while you are partial weightbearing. You will stand normally and the mark will be rerecorded. The distance will be measured to determine the total navicular drop. Navicular drop <5 mm is considered a high arched foot, navicular drop between 5-10 mm is considered a "normal foot", and a navicular drop >10 mm is considered a flat foot, as defined in the literature.

Your participation in this study will consist of one 30-minute testing period to be conducted in Playmakers Shoe Store. Professionals who are familiar with the equipment being used will supervise the study. Additionally, there will be a certified athletic trainer

This consent form was approved by the Biomedical and Health Institutional Review Board (BIRB) at Michigan State University Approved 03/23/06 – valid though 03/22/07. This version supersedes all previous versions. IRB # 06-194.

(ATC) on site in case of a medical emergency or injury. We will use connection wires that are directly plugged into a portable computer around your waist and Velcro straps on your leg will stabilize the wires. Once the insoles have been selected according to your shoe size, they are placed inside your shoe. There are 24 hydrocells imbedded in the insole system, which directly record pressures from your feet throughout the experiment. The computer is then stabilized around the torso with a belt. Once the computer is stabilized, the wires from the leg are connected to the computer.

Prior to data recording, you will have two minutes to walk around with the insole from the Parotec-System in your shoe. You will feel some cushioning under your foot. This walking around is for the insole to conform under your foot. The control protocol will have you walk down a runway 8 steps with each foot at your normal walking pace, turn around and walk 8 steps with each foot back. The first three steps are necessary for your walking speed to become normal. The other 5 steps will be recorded via the Parotec-System. There will a total of 5 cycles of this for the control protocol. Once these cycles have ended, we will begin testing your pressure distribution with the introduction of Playmakers Stabil-Lite orthotic. This device looks like a harder variation of the insole in your shoe, with an increased heel cup depth, lateral wall, and increased arch support. During these trials, you will feel the Stabil-Lite under your foot. Although the orthotic may feel slightly uncomfortable, it should not be painful. You may feel an increase in lift in your arch and/or cradling around your heel. Once the orthotic is inserted, the same procedures will take place as before. Following these trials, you will be asked to evaluate your pain while wearing the Stabil Lites and provide any comments on the study or inserts.

It is impossible for the risk of injury to be completely eliminated during the trials. Although you should not feel any pain as a result of the insertion of the insole or orthotic or the computer stabilized around the torso, it is possible to get your legs tangled in the wiring that emits from the computer. This risk is minimized with the wiring being stabilized around your leg. In case of injury, a certified athletic trainer (ATC) will be on site to manage the injury.

The benefits that come from your participation will help further advancements in understanding the effect that prefabricated orthotics have on an injured population as it relates to plantar pressure distribution. Following the conclusion of the testing, your results will be provided for you in a printout, as well as impressions from the printout. Additionally, it will give the medical community more information on the Parotec-System, which is a relatively new device for research.

Participation in this study is voluntary. Your identity and information recorded during the study will remain confidential. Confidentiality will be protected by; (a) results will be presented in aggregate form in any presentations and publications; and (b) all data will be stored in a computer that has a password necessary to see confidential data. Your privacy will be protected to the maximum extent allowable by law. You may also discontinue participation at any time without penalty. Your participation in this research project will not involve any additional costs to you or your health care insurer.

This consent form was approved by the Biomedical and Health Institutional Review Board (BIRB) at Michigan State University. Approved 03/23/06 – valid though 03/22/07. This version supersedes all previous versions. IRB # 06-194

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean you are giving up any legal rights you may have. You may also contact Dr. John Powell at 517-432-5018 with any questions or to report an injury.

Any questions concerning participation in this study should be directed to William J. Vascik at 814-360-0186 or Dr. John Powell at 517-432-5018. If you have questions or concerns about your rights as a research participant, please feel free to contact Peter Vasilenko, Ph.D., Director of the Human Subject Protection Programs at Michigan State University: (517) 355-2180, fax: (517) 432-4503, email: irb@msu.edu, or regular mail: 202 Olds Hall, East Lansing, MI 48824.

INFORMED CONSENT

Your signature below indicates your voluntary agreement to participate in this study.

I, ______________________________ have read and agree to participate in this study as
(Please Print Your Name)
described above.

____
(Please Print Your Name)

______________________________ ____/____/____
(Please Sign Your Name) *(Date)*

Witness

____
(Please Print Your Name)

______________________________ ____/____/____
(Please Sign Your Name) *(Date)*

This consent form was approved by the Biomedical and Health Institutional Review Board (BIRB) at Michigan State University. Approved 03/23/06 – valid though 03/22/07. This version supersedes all previous versions. IRB # 06-194.

APPENDIX E

Participant Demographics Form

Participant ______

An Analysis of Pressure Distribution With A Prefabricated Foot Orthotic

Participant Intake Questionnaire\

Circle "yes" if the following questions apply:

Are you between the ages of 18 and 35 years old? Yes No

Have you ever had an orthopedic surgery in the lower extremity? Yes No

Do you have any non-correctable visual and/or balancing problems? Yes No

Have you previously used any type of orthotic (custom or store bought), arch support, or other type of insert in your shoe? Yes No

If you answered "yes" to number 4, please answer questions 5-8:

Are you wearing them currently? Yes No

If not, when did you stop wearing them? <1 month ago 1-6 months ago >6 months ago

How often do you wear them? 1-2 days/week 3-5 days/week 6-7 days/week

What kind are they? Custom Off-the-Shelf Brand:____________

FOR OFFICE USE ONLY

Eligible for Participation? Yes No

Participant ______

An Analysis of Pressure Distribution With A Prefabricated Foot Orthotic

Participant Demographics

Age:______________________________
Weight:____________________________
Height:____________________________
Shoe Size:_________________________
Sex: Male Female

What area of the body has been painful?

Hip	Thigh	Knee	Shin	Calf
Ankle	Arch	Foot	Toes	Low Back

Other____

What physical activities do you participate in during a normal week?

Running	Walking	Basketball	Volleyball	Wrestling	Soccer	Tennis
Swimming	Ice Hockey	None	Other:______________________			

How many hours do you participate in the activity a week?______________________________

Rate your pain, 0 being no pain and 10 being extreme pain during day-to-day activity:

1 2 3 4 5 6 7 8 9 10

Rate your pain, 0 being no pain and 10 being extreme pain during physical activity:
1 2 3 4 5 6 7 8 9 10

Pre-Test
Rate your pain, 0 being no pain and 10 being extreme pain now:
1 2 3 4 5 6 7 8 9 10

Post-Test
Rate your pain, 0 being no pain and 10 being extreme pain while using the Stabil Lites:
1 2 3 4 5 6 7 8 9 10

What comments do you have relating to the testing procedure or Stabil Lite orthotics?

____

____

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