2005

The Effectiveness of Semi-Rigid Custom Made Foot Orthotics in Correcting Abnormal Foot Positions

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THE EFFECTIVENESS OF SEMI-RIGID CUSTOM MADE FOOT ORTHOTICS IN CORRECTING ABNORMAL FOOT POSITIONS

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A Scholarly Project Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota

in partial fulfillment of the requirements for the degree of
Doctor of Physical Therapy

Grand Forks, North Dakota
May, 2005
This Scholarly Project, submitted by Kimberly Austin, Chris Gietzen, Bonnie Nostdahl, and John Sayler in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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Title The Effectiveness of Semi-Rigid Custom Made Foot Orthotics in Correcting Abnormal Foot Positions

Department Physical Therapy

Degree Doctor of Physical Therapy

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ACKNOWLEDGEMENTS

We would like to thank Meridee Danks, MPT, NCS and Craig Hahn, MPT for the time and effort they have put forth on this project. Their hard work and support helped greatly with the completion of this study.
ABSTRACT

Researchers have been trying to understand the complexity of foot biomechanics for over 100 years, and this has lead to an increase in more sensitive technology. Abnormal foot biomechanics are commonly corrected using orthotics. Pressure mapping systems, such as the Force Sensitive Application (FSA) and Teckscan, are becoming more prevalent in both clinical settings and in research to assist clinicians in making proper fitting orthotics. FSA allows clinicians the ability to measure the amount of pressure on patients' feet with and without orthotics. The purpose of this study is to determine the effectiveness of semi-rigid custom foot orthotics in correcting abnormal foot positions.

The fourteen subjects in this study were past or present patients of a local physical therapist's. Subjects stood on the FSA pressure mapping system with and without their orthotics to record visual pressure distribution. They were also asked to complete a subjective questionnaire and consent to a chart review.

The foot was divided into five regions: medial/lateral heel, lateral midfoot, and medial/lateral forefoot. Data was analyzed using the SPSS program for the statistical data from the pressure mapping system. Significance of pressure changes with and without orthotics was determined by paired t-tests. A two-tailed alpha level of 0.05 was used to determine significance. There was a significant difference found in all sections of the feet. Pressure decreased with orthotics in the lateral/medial forefoot ($t(13)=-4.256$, $p=.001$) and rearfoot ($t(13)=-3.313$, $p=.001$ respectively) and rearfoot ($t(13)=-3.749$, $p=.002$).
respectively) sections, while pressure increased in the lateral midfoot section (t(13)=2.632, p=.021). Questionnaire data was reviewed for subjective data patterns.

The results demonstrated that orthotics reduce peak pressure by distributing pressure throughout the foot. Clinical researchers were able to identify positive outcomes in 13/14 feet. Pressure mapping systems can be functional in clinical settings when used for visual description of pressure distribution.

Findings suggest orthotics do decrease pressure from the foot. The pressure mapping system is a helpful tool in evaluating if pressure change is relevant to the goal of the orthotic. Additional research is needed to determine if pressure mapping systems can decrease costs associated with multiple orthotic fittings.
CHAPTER I
INTRODUCTION/LITERATURE REVIEW

The foot and ankle form a very complex structure that provides a dynamic relationship between the body and the ground. These two structures must coincide without any abnormalities to cause efficient and normal movement. A misaligned foot may not only cause foot pain but may also be the cause of knee, hip or back pain due to lower extremity’s shift out of true anatomical position.¹ Foot orthosis are widely used to treat foot and lower limb pathology, although it is not fully understood how foot function is affected by the orthosis. Foot orthosis are designed to realign the foot in relation to the supporting surface it is on, in order to establish a normal propulsive order. Orthotics are designed to control the amount, rate, and temporal sequence of subtalar joint movement and restore normal biomechanical relationships in the lower extremity during stance.²

There are certain contributing factors that cause this uncertainty such as the complex anatomy of the human foot which contains 26 bones, 33 joints, 107 ligaments, 19 muscles and tendons which hold the structure together and allow it to move in a variety of ways.³ Not only are there many different pieces that make up the intricacies of the foot and ankle but the anatomy also differ between gender, age, person’s weight, and a person’s height.⁴

The purpose of the orthosis is to decrease any abnormal pressures on the plantar surface of the foot that may be the result of abnormal foot alignment.² ⁴ By evening out
the pressures and bringing the foot back into its true anatomical position, in
to the body, the desired effect is to diminish any existing foot pain along with
any knee, hip, back, and any pain that may be a direct result from the misaligned foot.
The problem lies with constructing the proper orthotic for each individual person and
his/her own complex foot.

Biomechanics

Biomechanical abnormality has been widely considered as an important
predisposing factor in lower extremity injuries. A difference in foot type, which is
usually determined by changes in arch height, has been shown to render individuals with
painful feet. It is believed that a low arched foot tends to be more flexible and, thus, is
subject to increased pronation. In contrast, a high arched foot is more rigid and
consequently exhibits increased supination. A high arched foot is often associated with a
higher incidence of stress fractures; whereas, a low arched foot is often associated with
shin splints, bunions, knee pain, hip pain, and Achilles tendonitis. The successful
management of many lower extremity injuries by the use of orthotics has been believed
to be beneficial to help redistribute abnormal pressures of a misaligned foot, which in
turn will influence the function of the lower limb. Foot orthosis are designed to realign
the foot in relation to the supporting surface it is on, in order to establish a normal
propulsive order. Orthotics are designed to control the amount, rate, and temporal
sequence of subtalar joint movement and restore normal biomechanical relationships in
the lower extremity during stance. Despite apparent relief of symptoms following the
use of orthotics up to 40% of people gain little or no benefit, which results in increased
symptoms and newly developing complaints during orthotic usage. This has been
attributed to poorly fitted or fabricated orthotics and/or an incorrect diagnosis. With the technology of this day in age, such as a pressure mapping system, there is hope that the number of poorly fitted orthotics will decrease on the first try of fabrication.

The pressure mapping system is a clinical tool that allows users to evaluate interface pressures between a person’s foot and the support surface that is being stood on. The idea is that a clinician or researcher will receive a computer picture of the individual’s feet, which shows where there is the greatest peak pressure and this information will allow the orthotic maker to construct orthotics that will even out that pressure over the entire plantar surface of the foot.

Anatomy

The human foot functions in synchrony to allow for a variety of movement. The foot is able to accomplish these diverse activities by a series of complex and balanced interactions occurring between the various articulations and their supporting soft tissues. There are numerous articulations in the foot and ankle including the talocrural joint, the subtalar joint, the midtarsal joint, the tarsometatarsal joints and the metatarsophalangeal joints. Each joint has a specific responsibility and must combine its capabilities with the abilities of the other joints in order to produce a functional foot.

Subtalar Joint

The subtalar joint is composed of the talus and the calcaneus. The calcaneus is the largest bone in the foot and plays a controlling role in the movement that occurs in the functional joints of the foot. The superoanterior portion of the calcaneus is concave in shape and articulates with the convex inferior portion of the talus. The two congruent articulations then form the subtalar joint. This joint is referred to as a ginglymus joint,
which has motion occurring around one axis; however, the motion does not occur in one
pure cardinal plane and is ultimately described as triplanar motion.\textsuperscript{13} Therefore due
to the structural mechanics of this joint, two possible motions could occur within the
subtalar joint. The first possibility is a combination of inversion, plantarflexion, and
adduction of the calcaneus. This overall motion is called supination.\textsuperscript{14} Secondly, there
could be a combination of eversion, dorsiflexion and abduction of the calcaneus. The
summation of these motions is called pronation.\textsuperscript{14} During supination the most
measurable movement that occurs is calcaneal inversion. Calcaneal eversion is the most
measurable movement occurring with pronation. Therefore calcaneal inversion and
eversion are often used clinically to measure supination and pronation of the subtalar
joint.

The talocalcaneal, also called the interosseus, ligament divides the subtalar joint
into anterior and posterior halves that serves to hold the calcaneus and talus together.
This ligament will become taut during supination and slack during pronation.\textsuperscript{15} The
ligament is located within the sinus tarsi, which is tunnel like in shape. By being located
in this tunnel, the ligament is then protected from weightbearing forces between the
calcaneus and the talus.\textsuperscript{16}

Talocrural Joint

The talocrural joint is the articulation between the talar trochlea and the distal
tibia and fibula.\textsuperscript{2,17} The joint axis runs in a distal and posterolateral direction from the
medial malleolus to the lateral malleolus. The distal tibia and fibula come together to
form a concave socket into which the convex superior portion of the talus articulates.\textsuperscript{17}
Talocrural supination combines ankle plantarflexion with adduction and inversion, while
talocrural pronation combines ankle dorsiflexion with abduction and eversion, which due to the orientation, makes dorsiflexion and plantarflexion the primary movements of this joint.\textsuperscript{17}

Medial to the talocrural joint is the deltoid ligament. This ligament is very broad and strong. Its primary function is to connect the talus, tibia, calcaneus and navicular to limit valgus stress to the talocrural joint along with pronation of the subtalar joint.\textsuperscript{18}

Lateral to the ankle lay three primary ligaments that limit varus stress to the talocrural joint and supination to the subtalar joint. The first of these ligaments is called the anterior talofibular ligament, which runs from the anterolateral talus to the lateral side to the fibular. The next ligament is the posterior talofibular ligament, which runs from the posterolateral talus to the lateral side to the fibula. The third of these ligaments is called the calcaneofibular ligament, which is found between the lateral calcaneus and the lateral fibula.\textsuperscript{19}

Midtarsal Joint

Anterior to the talus and calcaneus is the midtarsal joint, which acts as a divider for the forefoot and rearfoot.\textsuperscript{10} This joint separates the talus and calcaneus from the navicular and cuboid, which allows for gliding in conjunction with rotation to occur. It would seem easier to visualize this joint as a single articulation dividing the talus and calcaneus from the navicular and the cuboid; however, it is actually two separate articulations. There is one articulation between the talus and navicular and the second occurs between the calcaneus and the cuboid. Due to the congruency of the tarsal bones and the abundance of connective tissue in the midfoot, only a small amount of movement
is normally available between the navicular and cuboid, which causes this joint to move functionally as a single articulation.\textsuperscript{13}

Tarsometatarsal Joint

The tarsometatarsal joint divides the cuneiforms and cuboid from the metatarsals. This joint allows flexion and extension of the metatarsal bones and a small amount of supination and pronation of the first and fifth rays.\textsuperscript{20} In the midfoot, including the midtarsal and tarsometatarsal joints, there are many ligaments that serve to limit range of motion. Movement in the midfoot is also limited by the tight fit of the bones in this area of the foot. For this reason trauma to specific ligaments of the midfoot is rare.

The role of the ligaments of the midfoot, along with the plantar aponeurosis, should be discussed in maintaining the arches of the foot. The arches of the foot provide structural form for the foot and ensure proper biomechanical and weightbearing patterns. There are three arches of the foot whose primary purpose is to prevent the collapse of the foot while supporting the body during weight bearing activities. The individual arches of the foot are the medial longitudinal arch, the lateral longitudinal arch and the transverse arch. Connective tissue running along the base of each arch ties the anterior portion of the arch to the posterior portion and locks the bones into a tightly bound structure that will support the body’s weight without collapsing. This mechanism is the means by which the arches of the foot derive their primary support. In addition, limited support for the arch is also given by the way the bones of the arch fit together and by muscular suspension coming superiorly.
Medial Longitudinal Arch

The bones of the medial longitudinal arch are the calcaneus, talus, navicular, the three cuneiforms and the first three metatarsals. The primary purpose of this arch is support of the talus, which bears the full weight of the body during ambulation. The plantar fascia or plantar aponeurosis provides primary support of both this arch and the talus. The plantar fascia is a strong, thick band of longitudinally arranged collagen fibers designed to resist tensile forces. It provides strong support for the whole medial arch by connecting the calcaneus and metatarsals; therefore, locking the bones between these structures in the arched shape.

Lateral Longitudinal Arch

The lateral longitudinal arch is made up of the calcaneus, cuboid and the fourth and fifth metatarsals. This arch is more stable and less adjustable than the medial longitudinal arch. The long and short plantar ligaments help maintain this arch by connecting the inferior surfaces of the bones of the arch. The long plantar ligament runs from the inferior surface of the calcaneus to the inferior surface of the cuboid and third, fourth and fifth metatarsals. The short plantar ligament is a wide, strong ligament that connects the cuboid to the anterior tubercle on the inferior surface of the calcaneus. The plantar aponeurosis also helps maintain the arch by connecting the ends of the arch together to form a tight bond between these structures.

Transverse Arch

The transverse arch is made up of the navicular, cuneiforms, cuboid, and metatarsals. This arch is given support by the wedging of the cuneiforms and metatarsal
bases as well as the deep tarsal, metatarsal and plantar ligaments that tie the arch into a tightly bound structure.23

Structural Foot Deformities

Structural or positional changes in one part of the body may lead to a change in the biomechanical function of another part of the body, which is termed compensation. In the lower extremity, the subtalar joint often compensates to adjust for changes in terrain or to adjust for changes in the position of the trunk or lower extremity. Due to the subtalar joint’s ability to move in all three planes of the body, this joint has the capability to adjust to lower extremity deviations in any direction.24

While changes in the position of the lower extremity or trunk occur only on occasion, subtalar joint compensation is a normal function of the foot, providing the trunk or lower extremity are transmitted inferiorly to the subtalar joint. This joint may pronate or supinate to absorb these transverse plane motions that, without subtalar joint compensation, would cause the foot to rotate on the ground, compromising the body’s stability. When subtalar joint compensation must take place because of a permanent structural abnormality, such as hip anteversion, genu valgum, or forefoot varus, the subtalar joint is forced to compensate on a continued basis.25 The compensation is usually required in just one place of the body. If compensation in this joint were ideal, compensatory motion would occur in only that plane that caused the demand for compensation; however, because the subtalar joint is a triplanar joint, motion must occur in the other two planes as well. Constant compensatory motion in the two planes that do not require compensation frequently leads to abnormal function and pathology.26 Therefore, although subtalar joint compensation is useful in that it can adjust for
structural abnormalities in the lower extremity, it may also lead to faulty biomechanics and lower extremity injuries due to foot malalignment.

Foot malalignment is defined as a deviation of the rearfoot or the forefoot from the body planes when the foot is in subtalar neutral. The neutral position of the subtalar joint is used because this is the position in which there is the least amount of stress to the joint and the soft tissues of the foot. In the neutral position of this joint the vertical bisection of the posterior calcaneus should be parallel to the vertical bisection of the lower one-third of the tibia and the plane of the metatarsals should be perpendicular to the vertical bisection of the posterior calcaneus (see Figure 1).27 Although there are various methods used to determine the neutral position of this joint, congruency of the talar head with the talonavicular joint line appears to be the most useful and operational technique for assessing subtalar joint neutral.27,28

The basic biomechanical role of the foot is to achieve a flat-on-the-ground position during weightbearing activities. Assessing the orientation of the calcaneus and metatarsal heads in subtalar joint neutral provides information about how the foot will respond to ground reaction forces and the weight of the body so that it may achieve this flat-on-the-ground position. If the foot does not line up with the vertical bisection of the calcaneus perpendicular to the ground and the plane of the metatarsal heads parallel to the ground in subtalar joint neutral, compensation may occur in the subtalar joint to allow the foot to rest flat on the ground during stance.

The fact that subtalar joint compensation usually occurs to help the foot attain a more flat-on-the-ground position means that the compensations for specific positional deviations of the calcaneus or metatarsal heads are predictable. To be able to understand
how subtalar compensation may lead to injuries in the lower extremities, it is helpful to have some knowledge of common structural deformities of the foot and the compensations that often occur with these deformities. The following paragraphs are descriptions of common structural foot malalignments, compensation and pathomechanics that occur with these malalignments (see Table 1).

Figure 1. Normal calcaneal position.
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**Calcaneal Varus**

Calcaneal varus is a deformity of the calcaneus on the talus. The calcaneus is inverted relative to the vertical bisection of the posterior one-third of the tibia when the foot is in subtalar neutral (see Figure 2). This deformity is caused by a failure of the calcaneus to fully derotate from its infantile position.\(^\text{29}\) The mechanism for compensation, achieving a stable, flat-on-the-ground position, is pronation of the foot. Pronation takes place primarily at the subtalar joint, although pronation can also occur at the midtarsal joint if the subtalar joint does not have enough range of motion available to allow the forefoot to reach the ground. In addition, supination of the tarsometatarsal joint
or plantarflexion of the first ray may take place to compensate for calcaneal varus if the subtalar joint does not have enough range of motion to fully compensate for this deformity.\textsuperscript{30}

![Calcaneal varus](image)

Figure 2. Calcaneal varus.

**Forefoot Varus**

Forefoot varus is a fixed osseous deformity of the forefoot in which the plane of the metatarsal heads is inverted relative to the bisection of the posterior calcaneus with the foot in subtalar joint neutral (see Figure 3). It is caused by insufficient development rotation of the head of the talus.\textsuperscript{29} The resulting weight-bearing compensation of this deformity is also pronation commonly at the subtalar joint. If enough range of motion does not exist at the subtalar joint to allow the forefoot to reach the ground, pronation can
occur at the midtarsal joint. Tarsometatarsal supination or first ray plantarflexion may also occur as a compensation for this deformity.

Figure 3. Forefoot varus.

Forefoot Equinus

A forefoot equinus deformity can be defined as a condition in which the forefoot is in a more plantarflexed plane than the rearfoot or calcaneus (see Figure 4). With this foot type, the ankle must dorsiflex greater than normal to allow the tibial to advance forward during late stance phase. If the ankle does not have enough dorsiflexion range of motion, compensation must occur somewhere in the lower extremity. Because the oblique axis of the midtarsal allows this joint to function like a little ankle joint. The midtarsal joint is capable of becoming an effective dorsiflexor of the forefoot when the
midtarsal joint is unlocked; however, since foot dorsiflexion is needed at midstance and terminal stance during gait, if the midtarsal joint is going to compensate for lack of ankle dorsiflexion, the subtalar joint must remain pronated throughout this time frame so that the midtarsal joint stays unlocked and is able to dorsiflex.\textsuperscript{31}

![Figure 4. Forefoot equinus.](image)

**Forefoot Valgus/Rigid Plantarflexed First Ray**

Forefoot valgus is an osseous deformity of the forefoot in which the plane of the metatarsal heads is everted relative to the bisection of the posterior aspect of the calcaneus in the subtalar joint neutral. A rigid plantarflexed first ray is described by the neutral position of the first metatarsal head remaining below the level of the second through fifth metatarsal heads despite pressure from an outside source. Causes of this deformity include congenital torsion of the head of the talus, which results in an eversion deformity of the forefoot, post cerebrovascular accident, congenital plantarflexion of the first ray or trauma.\textsuperscript{30,32}
With this foot type the medial side of the forefoot contacts the ground before the lateral side, causing the subtalar joint to supinate, which brings the forefoot evenly to the ground. This compensation occurs early in the stance phase, during loading response. Since full, normal position does not occur, the foot cannot complete its role as a mobile adaptor and the foot has a difficult time adjusting to uneven terrain, causing postural instability at the ankle.\textsuperscript{26,30}

The lack of full pronation also compromises the shock adsorbing mechanisms of the lower extremity during gait by falling to shorten the lower extremity and by falling to unlock the knees through tibial internal rotation. Also, producing stress to the soft tissues of the lateral knee and altering knee alignment.\textsuperscript{33}

Figure 5. Forefoot valgus.
Combined Rearfoot and Forefoot Varus

With the structural deformity both the calcaneus and plane of the metatarsal heads assume an abnormally inverted position in subtalar joint neutral. This foot type causes the compensations of rearfoot varus to be combined the compensations of forefoot varus. Subtalar joint pronation occurs too rapidly and to too great an extreme at initial contact due to the varus position of the calcaneus, and the pronation lasts too long through stance position that occurs too fast, to too great an extreme, and at the wrong time are the same as those described for the rearfoot varus and forefoot varus deformities.

Rearfoot Varus with Rigid Forefoot Valgus

This deformity consists of a calcaneus that is inverted in subtalar joint neutral, combined with a forefoot that is everted (see Figure 6). Compensations with this foot type again work to bring the foot flat onto the ground. At heelstrike the ground reaction and weightbearing forces acting on the rearfoot varus causes subtalar joint pronation to occur. Then, as the valgus forefoot contacts the ground, the subtalar joint supinates to bring the front of the foot evenly to the ground. Due to this valgus, problems can with lateral ankle instability and an excessive varus movement at the knee can also occur.\(^{30}\)

Rearfoot Varus with Flexible Forefoot Valgus

In this type the calcaneus is inverted with a neutral subtalar joint. The forefoot is everted in relationship to the posterior calcaneus. This deformity will usually develop when the subtalar joint is not able to fully compensate through subtalar pronation for the varus position of the calcaneus during initial contact and loading response. This will then cause the midtarsal joint to pronate, which further brings the medial forefoot flat onto the ground.\(^{30}\)
From the information presented earlier on the biomechanics, it is apparent that there is a complex relationship between the foot and the lower extremity. Due to the triplanar axis of the subtalar joint, all subtalar motions in the closed kinetic chain are converted to motion or forces in the tibia, femur and pelvis. Subtalar joint supination leads to external rotation forces transmitted superiorly to the lower extremity chain and subtalar pronation leads to internal rotation forces are transmitted superiorly. The opposite is then also true. The pelvis, femur and tibia are able to influence the closed kinetic chain motion of the subtalar joint. External rotation of these structures will lead to subtalar joint supination whereas internal rotation will cause subtalar joint pronation.6

When the biomechanics of the foot do not coincide with the biomechanics of the pelvis, femur or tibia, lower extremity injuries can result. If motions at the subtalar joint are out of phase with motions in the lower extremity, such as subtalar joint pronation
occurring when the pelvis is externally rotating, internal rotation forces transmitted up the lower extremity chain from subtalar joint pronation will conflict with the external rotation forces transmitted down the lower extremity chain from the pelvis. This will result in torsional stresses to soft tissues and bone where these conflicting forces meet. In repetitive situations, these conflicting forces can lead to injury of the tissues being stressed.

Patellofemoral Pain

Insufficient and excessive subtalar joint pronation can lead to patellofemoral pain for a multitude of reasons. A foot that lacks pronation can cause a varus moment at the knee with each step. As the foot is put into supination, a lateral force is transferred to the tibia, which would then produce a force at the knee in a varus direction. This position causes the quadriceps and patellar tendon to be pulled medially relative to the patella, which moves laterally with the proximal tibia and distal femur. When the quadriceps contracts, irritation is a resultant between the patella and its opposing joint on the femur.

Iliotibial Band Syndrome

Iliotibial Band Syndrome (ITBS) is inflammation of the iliotibial band either at its insertion into the lateral tubercle or over the lateral femoral epicondyle. This injury can be related to the abnormal biomechanics of a foot that pronates for too long or from the abnormal biomechanics of a foot that lacks pronation. The reason prolonged pronation can cause ITBS is because the tibia is forced to internally rotate and the pelvis and femur are externally rotating. This would then cause increased stress at the insertion of the ITB on the lateral tibial tubercle.
A supinated foot may lead to another mechanism of ITB injury. This type of foot may cause the knee to move into a varus alignment due to ground reaction forces. Since the ITB runs over the lateral knee, varus stresses may strain this structure as it is pulled against the lateral epicondyle. When this stress is repeated enough, injury over the ITB insertion site or lateral femoral epicondyle may result.³⁴,³⁵

Knee Collateral Ligament Sprains

As with patellofemoral pain and ITBS, collateral ligament sprains of the knee can be produced by frontal place forces at the knee joint resulting from abnormal biomechanics of the foot. With a foot that remains supinated throughout the gait cycle, ground reaction forces which cause the foot to supinate also creates a lateral force, which is directed to the knee with each step. When every step an individual takes results in a varus stress to the knee, cumulative trauma to the lateral collateral ligament may occur.³⁴ With a foot that pronates excessively ground reaction forces are directed medially to the knee, which produces a valgus stress with each step.

Plantar Fascitis

This foot pathology is most often associated with excessive subtalar joint pronation. Overpronation of the foot causes a flattened and stretched arch. If the foot remains pronated, the midtarsal joint cannot become locked. The plantar fascia’s role in maintaining the arch of the foot increases dramatically as there is little support from inherent bony stability when the midtarsal joint is not locked. This places a large amount of stress on the plantar fascia, which will then cause microtrauma and tearing. A foot that does not pronate enough can also cause plantar fascitis.³⁷ Without sufficient subtalar pronation there is little subtalar joint shock absorption, which causes the tibia to not
internally rotate enough to unlock the knee during gait. Here the plantar fascia absorbs most of the shock caused by ground reaction forces. This excessive shock could lead to microtrauma and plantar fascitis.\textsuperscript{38}

Achilles Tendonitis

This injury can also be attributed to both excessive and insufficient pronation. For those individuals who pronate excessively, the foot may still be in a pronated position when the knee begins to extend during terminal stance. As this happens, the tibia externally rotates, which causes conflicting forces on the Achilles tendon. This twisting motion is similar to wringing out of a towel, which will cause vascular impairment, degenerative changes and possibly microtearing and/or inflammation of this tendon.\textsuperscript{39}

With a foot that remains supinated, the shock from ground reaction forces is not absorbed by appropriate structures in the lower extremity and is transferred to the Achilles tendon. This additional shock can cause damage to tissues carrying the tendon’s blood supply and lead to tendonitis.\textsuperscript{40}

Stress Fracture

Stress fractures are microfractures of bone due to inability of the bone to adapt to slow rhythmic stress applied in an abnormal manner.\textsuperscript{41} This can occur in individuals who overpronate and those who lack pronation of the subtalar joint. Torsional force can result in tibial stress when due to external rotation of lower extremity and pronation of the foot.

A foot type that combines a rigid forefoot valgus with a rearfoot varus also increases the stress to bones of the foot. This type of foot undergoes rapid pronation followed by rapid supination, especially in midstance. The quick change between pronation and supination, combined with the fact that the foot does not fully pronate to
allow for adequate shock absorption, which leads to a significant amount to torsion in the bones of the foot and lower leg.42

Recurrent Ankle Sprains and Peroneal Tendonitis

Recurrent ankle sprains and peroneal tendonitis are due to the weight to the body causing the foot to assume a flat on the ground position. Forefoot valgus types cause the foot to assume a position in which the ankle is inverted excessively and the peroneal musculature is called on to control the abnormal ankle inversion.42 A foot that demonstrates increased range of motion for midtarsal joint pronation will allow the subtalar joint to supinated past vertical with the forefoot still remaining flat on the ground. This excessive subtalar supination results in lateral postural instability and predisposes an individual to inversion ankle sprains. The foot may respond to this instability by supination the midtarsal joint to bring the subtalar joint back to a more vertical, stable position. If the midtarsal joint would not supinate enough to bring the calcaneus to a more vertical position, then the subtalar joint may pronate to achieve a vertical calcaneal position.33

If the midtarsal joint fails to supinated or the subtalar joint fails to pronate, or if the combined midtarsal joint supination and subtalar joint pronation is not enough to combat forefoot valgus, then lateral postural instability can only be prevented by a powerful sustained contraction of the peroneal musculature. Excessive subtalar joint supination associated with forefoot valgus causes marked external rotation of the tibia, which results in added stress to the peroneals since they are responsible for decelerating external rotation of the tibia. This increased stress can lead to tendonitis of the peroneals.44
Cuboid Syndrome

This condition involves dislocation or subluxation of the cuboid and may be seen as a result of trauma or as an insidious onset from an athletic overuse injury. Newell and Woodie found that most cuboid subluxations occurred in a pronated foot. Pronation unlocks the midtarsal joint and allows the peroneus longus to rotate the cuboid. It then uses this bone as a pulley, pulling the lateral aspect in a dorsal direction and the medial aspect in a plantar direction.

Hallux Valgus

This type of foot pathology can result from a foot that pronates excessively. The rigidity of a supinated foot and contraction of the peroneus longus normally allow the first ray to be stable enough to support the weight of the body; however, if the foot isn’t unlocked due to prolonged pronation, the normal rigidity of the foot is vanished. In addition, a pronated foot’s mechanical advantage of the peroneus longus is lost, as this muscle no longer has a downward pull on the first metatarsal. Since the normal rigidity and mechanical advantage is lost, the first ray is not stable enough to support the body’s weight and is pushed into a dorsiflexed and abducted position. As the body passes over the unstable first metatarsal, the hallux is forced into a valgus position from the weight of the body. Eventually, subluxation of the first metatarsophalangeal may occur.

Tibialis Posterior Tendonitis

Overpronation at the subtalar joint is a frequent cause of this lower extremity injury. The tibialis posterior is active in gait from shortly after initial contact until early preswing. When a foot continues to pronate past loading response into midstance and terminal stance, the tibialis posterior can undergo excessive stress. The insertion of the
tibialis posterior on the navicular will be pulled away from its origin as the foot pronates. The internal tibial rotation that accompanies closed kinetic chain subtalar joint pronation will also increase the strain to the tibialis posterior by lengthening the distance between the origin and insertion of this muscle. The result of prolonged pronation at the subtalar joint is that the origin and insertion of this muscle are brought pulled away from each other at a time when the muscle is contracting in an attempt to supinate. This will create an increase in tension and eccentric stress to the tibialis posterior, which could cause microtearing of the muscle.47

Shin Splints

Shin splints can be defined as regular, long lasting pain at the medial distal 2/3 of the tibia without diagnosis of a stress fracture or specific tendonitis.34 Strain to the tibialis posterior has been cited as a possible cause of this pathology. This muscle plays a major role in controlling subtalar joint pronation and would therefore suggest that shin splints can result from excessive subtalar joint pronation. When the effects of stress to the tibialis posterior are manifested at its origin, symptoms of pain can easily result.48

Soleus is another possible mechanism of this pathology. As dorsiflexion is a component of subtalar pronation, a foot that pronates excessively may stress the soleus. If the insertion of the soleus on the medial 1/3 of the calcaneus were considered, it would seem that pronation of the subtalar joint could indeed cause stress to this muscle and symptoms of shin splints could be present.

With proper knowledge of the biomechanics of the foot, it becomes clearer to understand why a certain lower extremity injury may occur as a result of a structural deformity in the foot; however, lower extremity injuries can not be predicted by assessing
the structure of the foot. Any injuries that occur in the lower extremity as a result of structural foot deformities depend on how and where the compensation for the deformity takes place.49

Orthotic Fitting

Orthotics can be custom made or they can be purchased over the counter. Rigid, semi-rigid, soft and over the counter orthotics are commonly used to correct abnormal foot positions. Rigid, semi-rigid and soft orthotics are widely prescribed by orthotists, physicians, and physical therapists to treat foot and lower limb pathologies.

Rigid orthotics are fabricated from a plaster of paris mold of the individual foot and can be made from firm material such as plastic or carbon fiber. The finished product normally extends along the sole of the heel to the ball or toes of the foot. It is worn mostly in closed shoes with a heel height under two inches. Due to the nature of the materials involved, very little if any, alteration in shoe size is necessary.

Rigid orthotics are chiefly designed to control motion in two major foot joints, which lie directly below the ankle joint. These devices are long lasting, do not change shape, and are usually difficult to break; however, they weigh more and do not contain a protective soft layering. Strains, aches, and pains in the legs, thighs, and lower back may be due to abnormal function of the foot, or a slight difference in the length of the legs. In such cases, orthotics may improve or eliminate these symptoms, which may seem only remotely connected to foot function.50

Semi-rigid orthotics are made out of thermal plastics, leather and cork and their main use is to provide motion and some cushion. This functional dynamic orthotic helps guide the foot through proper functions, allowing the muscles and tendons to perform
more efficiently. The classic, semi-rigid orthotic is constructed of layers of soft material, reinforced with more rigid materials such as firm density alcoplast allowing them to be light weight. They have a high resilience, but do not have the longevity of a pair of rigid orthotics.

Soft orthotics are primarily used to provide cushioning and to a lesser extent motion control and materials used are pliable substances. These orthotics help to absorb shock, increase balance, and take pressure off uncomfortable or sore spots and are usually constructed of soft, compressible materials, and may be molded by the action of the foot in walking or fashioned over a plaster impression of the foot. Also worn against the sole of the foot, it usually extends from the heel past the ball of the foot to include the toes. The advantage of any soft orthotic device is that it may be easily adjusted to changing weight-bearing forces. The disadvantage is that it must be periodically replaced or refurbished. Often they must be replaced yearly due to the wearing pattern that occurs. It is particularly effective for arthritic and grossly deformed feet when there is a loss of protective fatty tissue on the side of the foot and is also widely used in the care of the diabetic foot. The soft orthotic is usually bulkier and may well require extra room in shoes, or prescription footwear because it is compressible.

The use of pressure mapping systems has become an integral part of prescription of pressure relieving devices as of recent. In the matter of foot orthotics it can be used to determine the areas of peak pressures on the planter surface of an individual’s foot. Cavanagh et al states that the foot can be divided into ten areas that should all have a mean peak pressure within them. These areas and their mean peak pressures are: Medial heel (20.141 psi), Lateral heel (19.227 psi), Medial midfoot (2.784 psi), Lateral midfoot
(4.031 psi), First metatarsal (5.568 psi), Second metatarsal (7.511 psi), Lateral metatarsals (7.743 psi), Great toe (2.958 psi), Second toe (1.261 psi), and the Lateral toes (2.334 psi). These pressures show that most of a person's weight is centered at the heel region of the foot, and then the forefoot. The heel has approximately 2.6 times higher pressure compared to the forefoot and most of the forefoot pressure is located under the 2nd and 3rd metatarsal heads. By measuring a person's pressure distribution and knowing what the mean averages should be, an orthotist can then construct an orthotic that may shape the foot to mimic these normal mean peak pressures.

Casting Techniques

The number one common cause for a failed orthotic is the incorrect positioning of the foot during the casting process. There are many different types of casting techniques used for fitting orthotics. The four main casting techniques are: full weight-bearing polystyrene foam step-in, neutral position semi-weight-bearing polystyrene foam step-in, neutral position off-weight bearing plaster casts, hang technique plaster cast, and the in-shoe vacuum techniques.

Full weight-bearing polystyrene foam step-in the subject is instructed to stand with equal weight bearing on each leg in a tray of polystyrene foam. The benefit of this technique is that it captures bony, ligamentous, and soft tissue deformities associated with stance. This type of casting does not allow for navicular bone movement that occurs during a neutral to stance position. It also may allow for the same pathologies to become present in the orthotic that the patient is trying to treat. Full weight bearing casts are with the goal of medial arch support are outdated and inappropriate as it reportedly allows for
no effective control of abnormal foot function. An effective orthotic must treat more than just the medial arch.

Neutral position semi-weight-bearing polystyrene foam step is a technique where the subject gains the proper angle and base of gait needed while standing and then sits down while still maintaining talonavicular congruency. The caster then will place a tray with the polystyrene foam under the feet and give a downward pressure at both the knee first then the top of the metatarsal heads and the toes. The impression is then filled with plaster to obtain an imprint of the feet. This technique benefits from maintaining the subtalar joint in neutral position and avoids any need to fill out the impression around the boarders, which is necessary with non-weightbearing techniques. The drawback to this technique is that it does not allow for flexible forefoot deformities i.e. flexible forefoot valgus and plantarflexed first ray.\(^{54}\) Recently, this technique has also had scrutiny about accurately capturing forefoot/rearfoot relationships.

Neutral position off-weight-bearing plaster casts techniques are casted while the subject’s foot is in a neutral position. This procedure can be done in supine or prone as long as the subject’s foot rests in a vertical position. Subtalar neutral is then found by placing the foot in dorsiflexion around the 4\(^{th}\) and 5\(^{th}\) metatarsal heads. The subject then maintains that position. One of four extra-fast-setting plaster splints is folded in half and submerged in warm water and mixed with plaster if Paris thoroughly. The upper ¼ inch of the strip is folded creating an upper ledge. This plaster cast is then wrapped around the foot and tacked down to the top of the first and fifth metatarsal heads, and then the medial arch and the heel are smoothed. Another piece of plaster is also submerged in water and then draped over the forefoot. This position is held for approximately 2 minutes while
the plaster hardens. The benefit of this technique is that it maintains the most stable foot position of subtalar neutral. The pitfall of this casting method is that it requires practice to establish a reliable technique for the neutral foot position.

Hang technique plaster cast the subject is supine with their foot and leg resting comfortably. In this technique there is not any positioning of subtalar neutral or loading of the forefoot. The benefit of this technique is that it provides a negative impression that closely copies the contours of a neutrally positioned foot. This has been found to allow inverted forefoot and a supinated rearfoot, and then substantial modifications of the impression are needed, thus making it an inaccurate technique.

In-shoe vacuum technique allows the foot to form to a specific shoe. The foot is wrapped in plaster and placed in a plastic bag then placed into a shoe. Then cast is then vacuum-molded while the subject is wearing the shoe. The benefits of this technique are that if takes into account the orthotic, foot, and shoe for a properly aligned foot. This works best when the shoes contain extreme heels and curved shanks. Vacuum-molding in these specific types of shoes often will find the feet in a pathological position where the forefoot is adducted and the midtarsal joint is supinated. This also might allow injuries to develop from overcorrecting the initial pathology.

Purpose

The purpose of this particular study is to use the FSA pressure mapping system in the process of fitting custom semi-rigid orthotics, along with making sure the final product is performing as it is intended. It was expected that with the use of semi-rigid foot orthosis there would be a change in pressure distribution under the foot and a
decrease in peak pressure in the areas. In the clinic the pressure mapping system could be used to save money and time associated with fitting orthotics multiple times.

Research Questions

The purpose of this paper is to address these four questions. 1) Do orthotics change the average pressure in pathological feet? 2) Is the biomechanical change that occurs with orthotics optimal to what the physical therapist intended? 3) Are pressure mapping systems supported by administered subjective data questionnaires? 4) Can a pressure mapping tool be utilized to decrease time needed to correctly fit orthotics in a clinical setting?

Clinical Significance

A clinical goal is to correct abnormal foot alignment using orthotics. This can be attained using FSA along with current orthotic knowledge. Pressure mapping systems can help physical therapists in the properly fitting orthotics during the initial visit which can decrease time, money and resources used by performing multiple orthotic fittings.
CHAPTER II

METHODOLOGY

Prior to the start of this study, approval for the use of human subjects was obtained from the IRB at Altru Health Systems and the University of North Dakota (see Appendix A). During the recruitment process and participation, each subject was informed that participation was voluntary. The study was explained in detail to each individual and an explanation of the pressure mapping system used for the study was also included. Individuals who wished to participate signed a consent form and a copy was provided at the time of participation (see Appendix A). The consent form granted the permission of the subject to participate in the study. The individuals also signed a HIPPA form informing the participant of how privacy will be maintained. A review of the subject’s medical records was performed to identify any possible foot abnormalities or other structural concerns.

Subjects

The volunteers included 12 females and 2 males (mean age 32.14, age range 11-69). There were a wide variety of foot types and diagnoses reflected in this study such as pronation, forefoot and rearfoot varus (see Table 2). Recruited subjects were the past and present patients of a practicing physical therapist at a local outpatient clinic, who had received custom made semi-rigid orthotics. Subjects were recruited by the physical therapist via verbal and written invitation. All subjects had semi-rigid foot orthoses prescribed to correct an abnormal biomechanical dysfunction.
Table 2: Subjects Profile.

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Gender</th>
<th>Age</th>
<th>Height</th>
<th>Diagnosis</th>
<th>Abnormal Foot Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>69</td>
<td>62&quot;</td>
<td>Plantar Fasciitis</td>
<td>pronation with large forefoot varus</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>32</td>
<td>66&quot;</td>
<td>Plantar Fasciitis</td>
<td>Rearfoot varus and pronation</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>49</td>
<td>71&quot;</td>
<td>Pes planus</td>
<td>pronation</td>
</tr>
<tr>
<td>4</td>
<td>Female</td>
<td>18</td>
<td>63&quot;</td>
<td>Patellar tendonitis</td>
<td>over pronation</td>
</tr>
<tr>
<td>5</td>
<td>Female</td>
<td>11</td>
<td>60&quot;</td>
<td>Pes planus</td>
<td>pronation with large forefoot varus</td>
</tr>
<tr>
<td>6</td>
<td>Female</td>
<td>21</td>
<td>67&quot;</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>7</td>
<td>Male</td>
<td>59</td>
<td>72&quot;</td>
<td>back &amp; midfoot pain</td>
<td>over pronation</td>
</tr>
<tr>
<td>8</td>
<td>Female</td>
<td>16</td>
<td>66&quot;</td>
<td>shin splints</td>
<td>over pronation with rearfoot varus</td>
</tr>
<tr>
<td>9</td>
<td>Female</td>
<td>53</td>
<td>64&quot;</td>
<td>Pes planus</td>
<td>over pronation</td>
</tr>
<tr>
<td>10</td>
<td>Female</td>
<td>15</td>
<td>72&quot;</td>
<td>medial knee pain</td>
<td>over pronation</td>
</tr>
<tr>
<td>11</td>
<td>Female</td>
<td>18</td>
<td>66&quot;</td>
<td>posterior tibial pain</td>
<td>over pronation</td>
</tr>
<tr>
<td>12</td>
<td>Female</td>
<td>23</td>
<td>66&quot;</td>
<td>medial knee pain</td>
<td>forefoot varus</td>
</tr>
<tr>
<td>13</td>
<td>Female</td>
<td>23</td>
<td>63&quot;</td>
<td>Pes planus</td>
<td>over pronation</td>
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<tr>
<td>14</td>
<td>Female</td>
<td>43</td>
<td>66&quot;</td>
<td>peroneal pain</td>
<td>over pronation</td>
</tr>
</tbody>
</table>

NA = chart review unavailable
Instrumentation

This study used the FSA (Vista Medical Ltd., Unit # 3 - 55 Henlow Bay, Winnipeg, Manitoba, R3Y 1G4) pressure mapping floor pad to measure the pressure of each participant’s feet with or without orthotics.\textsuperscript{9} The device consists of a tactile sensor pad connected to a personal computer through an interface board. The FSA floor pad is $30 \times 30$ cm and uses over 900 sensors that continually gather pressure data in pressure per square inch (psi). The software program installed on the laptop computer interprets the information from the pressure pad. The laptop computer then produces a visual pressure distribution display of the foot.

Both UND Department of Physical Therapy and Altru Health Systems have access to a FSA pressure mapping system. To keep reliability and validity, the same system was used throughout the study. All five researchers were considered competent following an instrumentation course. Intra-class correlation coefficients (ICC) were used to determine reliability and validity through an instrumentation class consisting of 11 UND PT students who wore orthotics. It was established that the ICC $>.98$ in all cases for reliability in a two-way random as concluded by the SPSS program.

A questionnaire was developed to obtain nominal and ordinal data about the subjects that would be complimentary to the pressure mapping system data. The questionnaire was verbally administered to all subjects prior to pressure mapping evaluation (see Appendix A).

Procedure

Subjects were instructed to stand on FSA floor pad with feet 10 cm apart measured from medial malleoli. Subjects were instructed to focus on an object 10 ft
away while keeping their arms at their side, knees extended and equal weight bearing on each leg. Subjects stood still for 10 seconds while each measurement was taken for a total of three measurements with and without orthotics. The first trial consisted of the subject standing barefoot on the floor pad without custom orthotics. Marks were used to identify feet placement so that subjects could be consistent in their stance. Subjects then stood on the floor pad with the orthotics underneath the pad to obtain the second set of measurements. Subjects were withdrawn from the study if their orthotics were over two years old or if it experienced any malformation since initial construction. Also, only semi-rigid custom-made orthotics were used in this study.

Figure 7. FSA Pressure Mapping System.
Chart reviews were performed for each participant in the study. Charts were reviewed for the following information: foot pathology, date of receiving orthotics and orthotics prescription. During chart review it was determined that the largest biomechanical dysfunction was caused by overpronation of the subtalar joint (n=11). In addition, some participants also displayed both forefoot (n=3) and rearfoot varus (n=2).

Following the completion of the participant questionnaire, the most common reason for receiving the orthotics by the participants was pain in joints (n=9). Other reasons included: stress fractures/shin splints (n=2), recommendations by doctors (n=2), and plantarfascitis (n=1).

Data Analysis

The foot was divided into five sections: medial/lateral heel, lateral midfoot, and the medial/lateral forefoot. Average peak pressure was determined for each area using the techniques described in Cavanagh et al.\textsuperscript{52} Data was analyzed using the SPSS program for both the questionnaire data and statistical data from the FSA pressure mapping system. A paired t-test with a two-tailed alpha level of .05 was used to determine significance.

Reporting of Results

Upon completion of this study, a summary of the results will be completed and will be given to both the preceptor of this research project and the University of North Dakota Health Sciences Library. This study was completed to partially fulfill the requirements for the University of North Dakota School of Medicine and Health Sciences Doctor of Physical Therapy Program.
Figure 8. Correct Stance During Pressure Mapping Measurements.
Figure 9. FSA pressure without orthotics.

Figure 10. FSA pressure with orthotics.
CHAPTER III

RESULTS/DISCUSSION

The data from this study was collected from an FSA pressure mapping system. A paired t-test was used to determine if there were significant differences in foot pressure with and without semi-rigid orthotics while static standing. The means and standard deviations for the five sections are reported in Table 3.

Table 3: Results for Pressure Changes Within the Five Sections of the Foot: Mean, Standard Deviation, t-score, Degrees of Freedom, and Significance

<table>
<thead>
<tr>
<th>Section</th>
<th>Conditions</th>
<th>M</th>
<th>SD</th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>with orthotic</td>
<td>1.2143</td>
<td>0.61823</td>
<td>-4.256</td>
<td>13</td>
<td>.001</td>
</tr>
<tr>
<td></td>
<td>without orthotic</td>
<td>3.1914</td>
<td>1.89971</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>with orthotic</td>
<td>1.7493</td>
<td>1.30861</td>
<td>-3.313</td>
<td>13</td>
<td>.006</td>
</tr>
<tr>
<td></td>
<td>without orthotic</td>
<td>3.2171</td>
<td>2.33434</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>with orthotic</td>
<td>2.9121</td>
<td>2.62322</td>
<td>2.632</td>
<td>13</td>
<td>.021</td>
</tr>
<tr>
<td></td>
<td>without orthotic</td>
<td>1.9686</td>
<td>1.58420</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>without orthotic</td>
<td>7.4521</td>
<td>4.30563</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>with orthotic</td>
<td>3.2300</td>
<td>3.56828</td>
<td>-3.774</td>
<td>13</td>
<td>.002</td>
</tr>
<tr>
<td></td>
<td>without orthotic</td>
<td>8.7521</td>
<td>5.70846</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

M = mean, SD = standard deviation, t = paired samples t-test, Sig. = significance, df = degrees of freedom

* = All tests showed a significant change in pressure between with and without orthotics
Pressure in each section showed a significant change between the two groups with and without orthotics during static standing (see Figure 11). Regions one, two, four, and five all show significant decrease in pressure when the individual is standing on his/her orthotics. Region three shows a significant increase in pressure when the individual is standing on his/her orthotics (Table 3).

![Figure 11. Results of change in peak PSI with and without orthotics.](image)

Also given to the participants in this study was a questionnaire that asked them how many pairs of orthotics they owned, how often they wore their orthotics, if they were satisfied with the orthotics, how much effect they thought the orthotics had. These results are displayed in Table 4.

The results from the questionnaire showed that an average of the participants owned 2.5 pairs of orthotics through out their life time. Participants reported that 10 (75%) wear them everyday, 2 (16.6%) wear them five times per week, and 1 (8.4%) wear
them three times per week. The participants average level of satisfaction was a 3.58 on a scale of 1-5 (1 = low satisfaction, 5 = high satisfaction). The effect was measured on a scale of 0-3 (0-no effect, 1-small effect, 2-medium effect, and 3-large effect) with an average of 2.16 meaning a medium effect. Two participants were not included in questionnaire statistics due to inability to contact for follow up.

Table 4: Results from Questionnaire. n = 12

<table>
<thead>
<tr>
<th>Subjects</th>
<th>How many pairs of orthotics have you owned?</th>
<th>How long have you owned your current pair?</th>
<th>How often do you wear your orthotics?</th>
<th>How satisfied are you with your orthotics?[^a]</th>
<th>How much of an effect do your orthotics provide?</th>
<th>Clinical effects of orthotics.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>3 weeks</td>
<td>7x/week</td>
<td>3</td>
<td>Small</td>
<td>+</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2 years</td>
<td>3x/week</td>
<td>1</td>
<td>None</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>5 months</td>
<td>7x/week</td>
<td>5</td>
<td>Large</td>
<td>+</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>2 days</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>+</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>1 week</td>
<td>7x/week</td>
<td>5</td>
<td>Large</td>
<td>+</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>1 day</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>+</td>
</tr>
<tr>
<td>7</td>
<td>12</td>
<td>2 months</td>
<td>7x/week</td>
<td>1</td>
<td>None</td>
<td>+</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>4 months</td>
<td>7x/week</td>
<td>3</td>
<td>Medium</td>
<td>+</td>
</tr>
<tr>
<td>9</td>
<td>3</td>
<td>5 months</td>
<td>7x/week</td>
<td>2</td>
<td>Large</td>
<td>+</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>2 months</td>
<td>7x/week</td>
<td>5</td>
<td>Large</td>
<td>+</td>
</tr>
<tr>
<td>11</td>
<td>1</td>
<td>1 year</td>
<td>7x/week</td>
<td>4</td>
<td>Medium</td>
<td>+</td>
</tr>
<tr>
<td>12</td>
<td>2</td>
<td>3 months</td>
<td>5x/week</td>
<td>4</td>
<td>Large</td>
<td>+</td>
</tr>
<tr>
<td>13</td>
<td>1</td>
<td>9 months</td>
<td>5x/week</td>
<td>5</td>
<td>Large</td>
<td>+</td>
</tr>
<tr>
<td>14</td>
<td>2</td>
<td>2 months</td>
<td>7x/week</td>
<td>5</td>
<td>Large</td>
<td>+</td>
</tr>
</tbody>
</table>

[^a]: scale of 1-5: 5 = very satisfied, 4 = satisfied, 3 = neutral, 2 = dissatisfied, 1 = very dissatisfied.

NA = Subject unable to be contacted for follow-up.

+ = Noticeable difference with and without orthotics and decreased pressure with orthotic use.

- = No noticeable difference with and without orthotics and increased pressure with orthotic use.

This study addressed three research questions. 1) Do orthotics change the average pressure in pathological feet? 2) Is FSA data supported by the subjective questionnaire information? 3) Can this FSA tool be utilized to help fit orthotics?
Questions one was answered through collected data from the FSA pressure mapping system and the average pressures taken from each section. Question two was answered by looking at the subject reports of satisfaction and effect from orthotics. Question three was answered by a verbal interview given to the physical therapist at a local hospital assisting with this study. The results from each test and how they answer the research questions are further discussed.

Research question 1) In symptom free feet Cavenagh et al found that about 60% of the load being carried is by the rearfoot, 8% of the load is in the midfoot, and 28% by the ball of the foot. Although the feet are divided into five sections instead of three, overall similar results were found. Average medial heel pressure without orthotics carried 35.6% of the total average, the lateral heel pressure with orthotics carried 30.3% total heel pressure would have, the average lateral midfoot without orthotics carried 8%, average lateral forefoot without orthotics carried 13.1%, and the average medial forefoot without orthotics carried 13% by the midfoot. Pressure distribution is similar in both studies the rearfoot accepts the majority of pressure, the midfoot carries the least pressure, and the forefoot accepts the second highest amount of pressure.

It is not understood why the subjects that were symptom free in Cavenagh et al study and had pressure that was similar to study where the subjects received orthotics to decrease biomechanical abnormalities. The questionnaire found that 64.2% of the participants experienced pain as a primary complaint for receiving orthotics. Pain in itself is subjective and many times people with the same biomechanical abnormality report different pain levels or no pain at all. Another concept is given by Sahramann, "when movements are faulty or strength and flexibility are compromised, negative
changes occur in soft tissue and in bony structures. The eventual result of injury to these tissues is musculoskeletal pain or a movement impairment syndrome". Participants’ feet were measured in static standing position; therefore, it does not take into account how movement affects the pressure and symptoms.

The pressure was changed when subjects statically stood on orthotics. There were significant pressure changes that happened in each region. The medial, lateral forefoot and the medial, lateral rearfoot had significant decrease in average pressure. The lateral midfoot significantly increased in the average pressure as the orthotic distributed the pressure throughout the foot. The percentages of load carried in each section changed with orthotics. These changes were as follows average medial heel pressure was 25.5% of the total pressure, lateral heel pressure was 28% of the total average, lateral midfoot was 23% of the total pressure, lateral forefoot was 13.8% of the total pressure, and the medial forefoot was 9.5% of the total pressure. These changes are contributed to the effects of the orthotic distributing pressure over the entire plantar surface of the foot.

Research question 2) In answering question two the subjective data from the questionnaire was analyzed. It was found that although the FSA pressure in each section changed significantly the questionnaire did not reflect this difference in pressure change as a positive effect. Subject number two had unwanted changes when wearing orthotics due to increased pressure in the heel (see Appendix B). This finding can be matched to his report of being unsatisfied with the orthotics and describing them as having no effect. In exception to subject number two, there is no discernable pattern found within the subjective questions asked on the questionnaire. This leads to the conclusion that subjective data is often inconsistent with objective data.
Research question 3) FSA can be a useful tool in the physical therapy setting. Images are effortlessly printed off and added to patient charts and can be easily reviewed over time. Semi-rigid custom made orthotics significantly changed pressure in all regions of the foot in static standing position. The forefoot and medial/lateral hindfoot had significant decrease in pressure while the midfoot had increased pressure with orthotics. It is believed that the orthotic distributed the pressure evenly over the whole foot explaining the increased pressure in the mid foot region. Although our statistics showed significant in pressure distribution the questionnaire results showed that participants were neutral to satisfied with their orthotics and thought they only had a medium effect.

Using a pressure mapping system in the clinic can be cost effective when taking into consideration that the system costs approximately $10,000. To make one pair of orthotics, it costs $300. If the clinician utilizes this system often enough, the benefits outweigh the costs. Potentially, the pressure mapping system could decrease the number of attempts to correctly fit the patient.

Upon completion of this study, an exit interview was performed on the physical therapist who oversaw the referrals of participants. He felt that FSA pressure mapping could help him in a clinical setting. It was able to give instant and visual feedback about the patient’s pressure areas. He believed that he could use this system for future evaluations to make a complete and thorough inspection of the patient’s foot. Setup time may limit the use of FSA system in a clinical setting and he believes that a greater number of participants in this study would lead to a population that is more representative of the clientele he regularly sees.
There were many strengths of this study. There was extremely significant reliability and validity formed by a pilot study. The system itself was very user friendly and setup took less than five minutes. The administration of the study averaged less than ten minutes from beginning to end. The visual feedback was shown and explained to the participant at the end of the study. This provided the participant with increased education on what is causing discomfort in the feet and the usefulness of the orthotics.

In hindsight, there were areas that can be improved in this study. The most challenging task of this study was finding subjects to participate. In the future, it would be beneficial to have at least 30 participants to help achieve normalized data. More participants may have been reached through a more aggressive mailing course. It would have been beneficial if the FSA system could divide the foot into quadrants and determine the average pressure in each quadrant. There is an increased risk of human error when dividing quadrants and adding pressures. There was not a standardization of charts while performing chart reviews. This inconsistencies lead to increased difficulty in finding biomechanical abnormality information. There were also many challenges in time restrictions for a full-time physical therapist, student schedules and participants availability.
Orthotics are used to treat many abnormal foot biomechanics. In this study the most common structural deformities found in participants were pronation and large forefoot varus. Based on the literature review, it can be demonstrated that many things lead to pathologies. This often leads to improper pressure distribution and/or increased peak pressure in the feet. In attempt to correct these abnormalities orthotics are provided.

When reflecting on the research questions, it can be stated that orthotics do change the average pressure in pathological feet as demonstrated by FSA. Subjective data does agree with the objective data provided by the pressure mapping system. If clinicians are performing many orthotic evaluations, this tool may be beneficial for them by reducing the number of times it takes to properly fit the orthotic.

Semi-rigid orthotics reduce peak pressure by distributing weight and pressure throughout the foot. When wearing semi-rigid orthotics pressure decreased in the medial/lateral forefoot and rearfoot and increased in the lateral midfoot. This pressure shift was easily observed by the researchers in all but one of the subjects’ feet. Subjectively, this participant reported being unsatisfied with his orthotics and them having no effect. This unintended change in pressure can be observed using the pressure
mapping system, making it a functional tool to be used in clinical settings. Orthotic goal attainment is easier to achieve if the clinician can visualize the distribution of pressure. Additional research is needed to determine if pressure mapping systems can decrease costs associated with multiple orthotic fittings.
ALTRU HEALTH SYSTEM

APPROVAL TO CONDUCT RESEARCH STUDY
AT ALTRU HEALTH SYSTEM

Name: John Sayler, Chris Gietzen, Kin Austin, Bonnie Nostdahl, Meridee Danks, & Craig Hahn
Date: 05/25/04

Address: UND Physical Therapy Dept Grand Forks, ND 58201

Telephone Numbers: (work) 777-2831 (home) 218-791-4514

Department/College UND Department of Pathology

Project: The effectiveness of semi-rigid custom make foot orthotics in correcting abnormal foot positions

Your request to conduct the above named study at an Altru Health System facility involving employees or patients as participants, and/or requiring facility resources has been reviewed. The following action has been taken:

_____ Permission to conduct the study is granted

_____ Permission to conduct the study will be granted upon completion of the following:


_____ Permission to conduct the study is denied for the following reason(s):


RECOMMENDATIONS/REMARKS:

Signature Administrative Director Medical Specialty Care Title 07/24/04 Date

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Institutional Review Board
Research Project Action Report

Date: May 27, 2004
IRB #: UND-39

Principal Investigator: John Sayler, Chris Gietzen, Kim Austin, Bonnie Noetdahl, Meridee Danks and Craig Hahn

Department: Physical Therapy

Address to which notice of approval should be sent: P.O. Box 9037 - Grand Forks, ND 58202

Research Coordinator: Meridee Danks

Phone #: 777-2831

Project Title: Effectiveness of semi-rigid custom made foot orthotics in correcting abnormal foot positions.

The above referenced project protocol and informed consent was reviewed by the Altru Health System Institutional Review Board on and the following action was taken:

CONDITIONAL APPROVAL:
☐ Project conditionally approved on pending modifications. This study cannot be started until revisions have been made and submitted, and final approval has been granted.

FINAL APPROVAL:
☐ Final project approval granted on Next scheduled review is on
☐ If no date is given, then review will be required in 12 months. (See REMARKS SECTION for any special conditions.
☐ Project approved. EXPEDITED REVIEW NO. 4 Next scheduled reviewed is on
☐ Project approved. EXEMPT CATEGORY NO. No periodic review scheduled unless so stated in REMARKS SECTION.
☐ Project approval deferred. (See REMARKS SECTION for further information)
☐ Project approval denied. (see REMARKS SECTION for further information)
☐ Amendment approved
☐ Administrative change approved
☐ Protocol revision approved
☐ Revised consent form approved
☐ Other

REMARKS:
Any changes in protocol, adverse occurrences or deaths in the course of the research project must be reported immediately to the IRB chairperson or the IRB office (780-6161).

Signature of Chairperson or Designated IRB Member
Altru Health System Institutional Review Board

Date 5/27/04
INFORMATION AND CONSENT FORM

The effectiveness of semi-rigid custom made foot orthotics in correcting abnormal foot positions.

Principal Investigators: Kim Austin, Chris Gietzen, Bonnie Nostdahl, John Sayler, Craig Hahn and Meridee Danks from the Department of Physical Therapy at the University of North Dakota and Altru Health Systems

You are being invited to participate in this study of orthotic fitting and pressure mapping. The purpose of this study is to determine if the use of semi-rigid custom made foot orthotics corrects abnormal foot positions. We hope that the results of this study will help physical therapists in properly fitting orthotics during the initial visit. We also hope to further decrease time, money and resources used by performing multiple orthotic fittings.

You were chosen for this study because you have been a past patient of Craig Hahn, PT, and fitted with semi-rigid custom made foot orthotics. As a subject for this study, you will be asked to report to Altru Rehabilitation Outpatient Physical Therapy Facility. Mr. Hahn will be the individual administering the pressure mapping data with assistance from the rest of the names listed above, which will allow Mr. Hahn to visually view the areas of your foot that have increased pressure areas. A questionnaire will then be completed, which will include such information as age, how long orthotics have been used, satisfaction level, number of fittings required, etc. Following this, shoes and socks will be removed to obtain valid pressure recordings from the FSA pressure mapping system. It will be randomly determined whether a subject will start by using bare feet or with the use of orthotics; however, both sets of data will be collected during the study and three recordings will be taken from each variable. The testing should take no longer than 15 minutes to complete and overall time for participation for this study would be less than 30 minutes. Although the process of physical performance testing always involves some degree of risk, the investigators in this study feel that, because of our prior training, the risk of injury or discomfort is minimal to none.

With your authorization, chart reviews will be obtained to identify pathological foot mechanics. An authorization form will be available prior to and chart reviews will occur at the time of assessment. A randomized number will be used to link your questionnaire to FSA recordings. Your name will not be used in any reports of the results of this study; therefore, confidentiality will be maintained throughout the study. The data will be identified by a number, which will be known only to the investigators. Once data has been analyzed, the link will be destroyed. Only the researchers, the advisor, and people who audit the IRB procedures will have access to the data. The investigators or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his/her health. Participation in this study is voluntary and your decision whether or not to participate will not prejudice your future relationship with the Physical Therapy Department at the University of North Dakota or with Altru Health Systems. If you
decide to participate, you are free to discontinue participation at any time without prejudice. Consent forms and data from study will be kept in separate locked files in the UND PT Department for 3 years following completion of this study.

The investigators involved are available to answer any questions you have concerning this study. In addition, you are encouraged to ask any questions concerning this study that you may have in the future. If you have any questions about the research, please call Meridee Danks at (701) 777-2831 or Craig Hahn at (701) 780-2462. If you have any other questions or concerns, please call the Office of Research and Program Development at 777-4279. You will be given a copy of this form for future reference at the time of participation.

In the event that this research activity results in physical injury, which is highly unlikely, medical treatment will be as available as it is to a member of the general public in similar circumstances. You and your third party payer must provide payment for any such treatment.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all of the above and willingly agree to participate in this study as Kim Austin, Chris Gietzen, Bonnie Nostdahl, or John Sayler has explained it to me.

Subject's signature Date

Please take the time to place an X on the line that applies.

_______ I will be able to participate in the study on foot orthotics using a pressure mapping system at Altru Rehabilitation Health System on a date to be determined later.

_______ I would not like to participate in this study.

Please place an “X” in either of the first two spaces provided. If you chose to place an “X” in the first space, please provide your name, phone number, best day and time of day to reach you so we may contact you to set up a time to meet.

_________________________ (Name) __________________ (Phone- work/home)

_________________________ (Most convenient day to meet) _________________ (Best hours to reach)
Questionnaire

1. What is your age? ________ years old.

2. What is your height? _____ feet _____ inches

3. What is your weight? ________ pounds

4. What is your gender? (Circle one)   Male   Female

5. What was the reason you decided to receive custom made orthotic(s)? (Pain in joints, discomfort, blisters, shin splints, recommendation, etc)

6. How many orthotic(s) have you owned in your life? ________

7. How long have you owned your current pair of current orthotic(s)?
   __________ years ________ months

8. How often do you wear your orthotic(s)?
   Everyday
   5 Times a week
   3 Times a week
   1 Time a week
   Less than 1 time a week

9. On 1-5 scale, if 5 is very satisfied and 1 is not satisfied, how satisfied are you with your current orthotic(s)? Please briefly explain.

10. How many times did it take to properly fit your current orthotic(s)? ________

11. How much of an effect do your orthotic(s) provide? Please explain.
   Large effect
   Medium effect
   Small effect
   No effect

12. In how many pairs of shoes do you use your orthotic(s)? ________
   Also please indicate the type/style of shoes

13. Do different shoes cause increased/decreased comfort while using your orthotics?
   Type of shoe that causes increased comfort with orthotic(s)? ________
   Type of shoe that causes decreased comfort with orthotic(s)? ________
FSA Pressure Mapping – Example of standing barefoot without orthotic
FSA Pressure Mapping – Example of Poor Orthotic Fitting
REFERENCES


50. [http://www.apma.org/topics/orthotics.htm](http://www.apma.org/topics/orthotics.htm) American Podiatry medical association. Accessed 7/1


