THE ACUTE EFFECTS OF SUBTALAR NEUTRAL ON PRE-ACTIVATION LEVELS OF THE PERONEUS LONGUS, TIME TO STABILIZATION, AND STIFFNESS IN UNSTABLE AND STABLE ANKLES

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ABSTRACT

SARAH M. ALLARD: The Acute Effects of Subtalar Neutral on Pre-Activation Levels of the Peroneus Longus, Time to Stabilization, and Stiffness in Unstable and Stable Ankles
(Under the direction of Michael D. Lewek, PT, PhD)

The purpose of this study was to examine if a more affordable over the counter orthotic can be used by the public to assist people with unstable ankles with ankle joint stiffness, pre-activation levels of the peroneus longus (PL), and time to stabilization (TTS). Forty individuals (20 unstable ankles and 20 stable ankles) repeated three randomized tasks with and without orthotics in a pretest-posttest design. The tasks included: 1) A single leg drop landing task in a) frontal and b) sagittal planes and 2) ankle joint stiffness utilizing an ankle cradle with inversion perturbation. Results revealed no interaction effects on ankle joint stiffness, pre-activation levels of the PL, and TTS in both the sagittal and frontal planes. We observed the unstable ankle group took longer to stabilize in both the sagittal and frontal planes. We also noted that ankle joint stiffness decreased in both groups in the orthotic condition.

List of Abbreviations

AJFAT	Ankle Joint Functional Assessment Tool
Avg	Average
BW	Bodyweight
CAI	Chronic ankle instability
EMG	Electromyography
FADI scale	Foot and Ankle Disability Index
FAI	Functional ankle instability
GRF	Ground reaction force
HS	Heel strike
LG	Lateral gastroconemius
MAI	Mechanical ankle instability
MOI	Mechanism of Injury
MVIC	Maximum voluntary isometric contraction
OTC	Over the counter
PL	Peroneus longus
SEBT	Star excursion balance test
STJ	Subtalar joint
TA	Tibialis anterior
TTS	Time to Stabilization

List of Tables

List of Figures

Figure Page

Table of Contents

CHAPTER I

INTRODUCTION

Medical professionals have prescribed custom made orthotics for different lower extremity conditions for nearly 40 years. (Bates, Osternig, Mason, & James, 1979; Richie & Olson, 1993) Orthotics are often prescribed to individuals with chronic ankle instability (CAI) in an effort to bring the foot into a neutral position and decrease stress on the subtalar and talocrural joints. (Hertel, 2002; Richie, 2007; Richie & Olson, 1993) Chronic ankle instability can be defined in one of two ways; the first is mechanical instability, which involves trauma to the soft tissue structures of the ankle. Such trauma results in greater laxity in the subtalar joint which can be observed upon examination by a positive anterior drawer and/or talar tilt.(Hertel, Denegar, Buckley, Sharkey, & Stokes, 2001b; Monaghan, Delahunt, & Caulfield, 2006) The second type of ankle instability is functional instability which has been described subjectively as a feeling of “giving way” but upon examination may or may not display a positive anterior drawer and/or talar tilt. (Hertel, et al., 2001b; Monaghan, et al., 2006) Mechanical instability has been suggested to lead to functional instability over time. (Hertel, 2002; Richie & Olson, 1993)

Orthotics have been found to reduce pain, decrease postural sway, and decrease the peroneal latency time in individuals with CAI.(Hertel, et al., 2001b; Ochsendorf, Mattacola, & Arnold, 2000; Richie & Olson, 1993) Many studies investigate the advantages of custom-made orthotics as it relates to balance, pain, and peroneal latency, but few studies have investigated the use of over the counter orthotics on the same testing factors. Custom-made orthotics require time and money to produce, whereas an over the counter orthotic is more affordable for the general population. If custom made orthotics could produce gains in impairment level outcome measures, then substantial savings to healthcare costs might be possible for individuals with CAI. It remains unclear, however, whether orthotics could be used be used as a preventative measure against future ankle sprains in the functionally unstable ankle.

Normal gait involves triplanar motion of the ankle joint and therefore changes the position of the talus as it relates to the calcaneous during the different stages of gait. During heel strike the ankle is supinated, which means that the foot is inverted, adducted, and plantarflexed. After heel strike, the midstance phase begins as the foot and ankle pronate, which means that the foot is everted, abducted, and dorsiflexed. (Prentice, 2004) The ankle is thought to be most stable when the talus is most congruent in the mortise (formed by the tibia, and fibula) in maximum dorsiflexion. The peroneus longus muscle, an important active stabilizer for the lateral aspect of the ankle, begins at the head of the fibula and attaches at the first metatarsal and medial cuneiform in the foot. The peroneus brevis muscle begins at the distal two-thirds of the fibula and attaches to the base of the fifth metatarsal and functions to evert the foot, which has the potential to be used as protection against lateral (inversion) ankle sprains. (Hertel, 2002; Richie & Olson, 1993) Orthotics aim to place the ankle into subtalar neutral thereby placing the joint its most biomechanically correct position. (Hunter, 2000; Prentice, 2004) In subtalar neutral a more advantageous gait may be possible because the stresses placed on the bones, ligaments, and muscles have been shown to decrease. (Monaghan, et al., 2006)

Ankle injuries account for 14% of all injuries to the body, with 80% of those ankle injuries representing sprains, and 85% of the sprains occurring on the lateral side of the ankle.(Garrick, 1977) Lateral ankle sprains are more common than medial ankle sprains as a direct function of the anatomy of the foot and ankle.(Ferran & Maffulli, 2006) Due to the anatomy of the ankle/foot complex, lateral ankle sprains typically occur with inversion, internal rotation, and a plantarflexion mechanism of injury. (Ferran & Maffulli, 2006) If an ankle sprain is left untreated it can lead to chronic pain and instability. This cycle of instability can contribute to a high cost of medical care. (Ferran & Maffulli, 2006) The rehabilitation of one ankle sprain can range from $318 to $914, which costs $2 billion a year in total medical costs in the United States. This high cost can be attributed to the successive pathologies that may develop following ankle instability. Specifically, it is thought that the chronic unstable ankle may lead to articular degeneration requiring treatment later on in life. (Ferran & Maffulli, 2006) About 80% of lateral ankle sprains result in re-injury. (Hertel, et al., 2001b)

In order to offset the high cost of future injuries, preventative techniques have been established. The use of ankle taping or bracing prior to activity, for example, may increase sensory input and therefore increase proprioceptive feedback to prevent further ankle injuries.(Ferran & Maffulli, 2006; Mohammadi, 2007) Another strategy thought to prevent future re-injury of the ankle is the use of orthotics in daily life and during exercise. The concept behind orthotics is to bring the “floor to the foot” in order to control for compensatory foot movements. (Prentice, 2004) Forefoot varus and rearfoot valgus are associated with excessive pronation, whereas forefoot valgus is associated with excessive supination. Excessive pronation can lead to overuse stress injuries, and excessive supination can lead to a rigid foot and predisposition to inversion ankle. (D'Amico, 1984; Hertel, et al., 2001b; Prentice, 2004)

Time to stabilization (TTS) has been investigated to determine differences between healthy (stable) ankles and subjects with unstable ankles. Healthy subjects on average have been shown to have a decreased TTS in the sagittal plane when compared to subjects with unstable ankles. (Guskiewicz & Ross, 2003; Hertel, et al., 2001b; S. E. Ross & Guskiewicz, 2004) Healthy individuals tend to control their sway using an ankle strategy, which involves the delicate combination of pronation and supination. Alternatively, individuals with chronic ankle instability have been shown to use a hip strategy due to a loss of functional support in the ankle. (Hertel, 2002) It has been theorized that the use of a hip strategy can increase the center of pressure changes as the control of balance comes from higher up in the kinetic chain. (Hertel, 2002) In a healthy population, the hip and ankle strategies are therefore the primary means of controlling balance; however, an ankle strategy may allow for an increase in fine motor control because the control is coming from closer to the ground. (Hertel, 2002) The use of orthotics may improve subtalar joint alignment to promote the re-appearance of an 'ankle strategy'. We hypothesize that the use of orthotics will decrease the TTS in individuals with unstable ankles.

Control of balance is performed, in part, by the peroneal complex, particularly when the foot becomes supinated. (Hertel, 2002) The peroneal muscle complex assists in protecting the lateral ligaments of the ankle by increasing joint stiffness while everting the foot. Increasing muscle activation may increase the dynamic protection around a given joint.(Hertel, 2002; Percy & Menz, 2001) The protective component of the peroneal reflex has been studied in order to determine if there is a correlation between its function and the possible protective component that can be used to decrease the incidence of lateral ankle sprains. In addition to the amplitude of the response, the latency may also be an important factor. Normally, the peroneal reflex is elicited approximately 54msec after inversion onset with a 72msec electromechanical delay, suggesting that protection cannot occur until 126msec, therefore leaving time for an ankle injury to occur. (Hertel, 2002) This would suggest that the peroneus longus may not protect against ankle injury unless the muscle is activated prior to an ankle perturbation in anticipation of passive ankle inversion. It remains unknown, however, if orthotic intervention can increase pre-activation levels of the peroneus longus. An increase in peroneus longus pre-activation levels would increase ankle joint stiffness to ultimately reduce the risk of lateral ankle sprain re-injury.

Statement of the Problem

Although studies have examined the effect of custom-made orthotics on chronic ankle instability, there has been limited work to address the role of over the counter orthotics on ankle joint stiffness, pre-activation levels of the peroneus longus, and time to stabilization (TTS) in the frontal and sagittal planes. This is important, because orthotics place the subtalar joint into a neutral position, which encourages correct biomechanics of the foot and ankle and may therefore decrease the risk of an ankle injury. Therefore the purpose of this study was to determine if altering STJ alignment with more affordable over the counter orthotics would influence factors purported to minimize chronic ankle instability.

Research Questions

1) Does the addition of an over the counter orthotic into the shoe decrease ankle joint stiffness?

2) Does the addition of an over the counter orthotic into the shoe increase preparatory, pre-activation levels of the peroneus longus?

3) Does the addition of an over the counter orthotic into the shoe decrease time to stabilization after a drop landing task in the frontal plane in the anterior/posterior direction?

4) Does the addition of an over the counter orthotic into the shoe decrease time to stabilization after a drop landing task in the frontal plane in the medial/lateral direction?

5) Does the addition of an over the counter orthotic into the shoe decrease time to stabilization after a drop landing task in the sagittal plane in the anterior/posterior direction?

6) Does the addition of an over the counter orthotic into the shoe decrease time to stabilization after a drop landing task in the sagittal plane in the medial/lateral direction?

Research Hypothesis

We hypothesized that ankle joint stiffness would decrease with the use of over the counter orthotics. We also hypothesized that pre-activation levels of the peroneals would increase with orthotics. Lastly, we hypothesized that over the counter orthotics would decrease time to stabilization in the frontal and sagittal planes.

Null Hypotheses

1) $\mathbf{H_o}$**:** There will be no statistically significant difference in ankle stiffness between the unstable ankle and stable ankle groups with and without orthotics

2) $\mathbf{H_o}$**:** There will be no statistically significant difference in pre-activation of the peroneus longus prior to an ankle perturbation between the unstable ankle and stable ankle groups with and without orthotics

3) $\mathbf{H_o}$**:** There will be no statistically significant difference in the time to stabilization after a sagittal plane drop landing task in the anterior/posterior direction between the unstable ankle and stable ankle groups with and without orthotics

4) $\mathbf{H_o}$**:** There will be no statistically significant difference in the time to stabilization after a sagittal plane drop landing task in the medial/lateral direction between the unstable ankle and stable ankle groups with and without orthotics

5) $\mathbf{H_o}$**:** There will be no statistically significant difference in the time to stabilization after a frontal plane drop landing task in the anterior/posterior direction between the unstable ankle and stable ankle groups with and without orthotics

6) **H_o:** There will be no statistically significant difference in the time to stabilization after a frontal plane drop landing task in the medial/lateral direction between the unstable ankle and stable ankle groups with and without orthotics

Alternate Hypotheses

1) **H_a:** There will be a statistically significant difference in ankle stiffness between the unstable and stable ankle groups with and without orthotics

2) **H_a:** There will be a statistically significant difference in pre-activation levels of the peroneus longus during ankle perturbation between the unstable and stable ankle groups with and without orthotics

3) **H_a:** There will be a statistically significant difference in the time to stabilization after a sagittal plane drop landing task in the anterior/posterior direction between the unstable and stable ankle groups with and without orthotics

4) **H_a:** There will be a statistically significant difference in the time to stabilization after a sagittal plane drop landing task in the medial/lateral direction between the unstable and stable ankle groups with and without orthotics

5) **H_a:** There will be a statistically significant difference in the time to stabilization after a frontal plane drop landing task in the anterior/posterior direction between the unstable and stable ankle groups with and without orthotics

6) **H_a:** There will be a statistically significant difference in the time to stabilization after a frontal plane drop landing task in the medial/lateral direction between the unstable and stable ankle groups with and without orthotics

Definition of terms

a) **Ankle perturbation**- passive movement of the ankle. In this study, we define the ankle perturbation as an inversion movement intended to mimic the most common mechanism of injury (MOI) for lateral ankle sprains.

b) **Orthotics**- over the counter foot device intended to support the ankle into a subtalar neutral position

c) **Functional Ankle Instability**- subjective feeling of "giving way" in ADL with or without negative talar tilt and ant drawer test (Freeman, 1965)

d) **Proprioception**- refers to the inborn kinesthetic awareness of body posture including movement (Mohammadi, 2007)

e) **Somatosensory**- refers to signals coming from the periphery (e.g., plantar aspect of the foot) that can provide feedback to the CNS (e.g., to assist in postural stability) (Jerosch & Prymka, 1996)

f) **Chronic Ankle Instability (CAI)**- condition of repetitive bouts of lateral ankle instability or the feeling of "giving way" which may or may not result in an ankle sprains (Hertel, 2002; Monaghan, et al., 2006). This study defined CAI as those subjects that score less than a 94 on the functional ankle disability index (FADI) test. (Hale & Hertel, 2005)

g) **Pronation-** those subjects that possess "flat feet" (navicular drop score of ≥10mm) (Cote, Brunet, Gansneder, & Shultz, 2005; Hunter, 2000; Kelly, 2003)

h) **Stiffness-** The force response that is a product of and resistant to mechanical stress. (Rack & Westbury, 1969)

i) **Time to Stabilization-** Time (in seconds) it takes during a dynamic task to mimic the range of variance during a static single leg balance trial (S. E. Ross, Guskiewicz, Gross, & Yu, 2009)

j) **Subtalar Joint Neutral-** position at which the medial and lateral aspects of the talus are palpated to be congruent with the navicular when the patient is in a prone position (Hunter, 2000)

k) **Range of Variance-** the amount of variability from the mean during a balance task during a pre-set 2 second window of data

Variables

a) Dependent Variables: PL pre-activation levels, ankle joint stiffness, and sagittal and frontal plane time to stabilization (TTS)

b) Independent Variables: Orthotic and no orthotic, unstable and stable ankle groups

Delimitations

1) The subjects consisted of 20 mixed male and female subjects in each group (CAI and control), collegiate aged recreation athletes with the exclusion of having a diagnosed ankle sprain within the last 6 months of the study

2) Subjects in unstable and stable ankle groups were matched in demographic characteristics

3) Each subject was counterbalanced with task order

4) Each subject received over the counter orthotics (i.e., Superfeet®)

5) Each subject was allowed to rest between tasks to accommodate for fatigue

Limitations

1) Foot type (only used pronators due to ease of recruiting)

2) Subjects used their own athletic shoes

3) Orthotics may not have been potent enough to produce change

4) Did not measure change in foot position with orthotics (i.e. navicular drop)

5) Self-report FADI score

6) EMG crosstalk

Assumptions

1) Orthotics would be potent enough to produce change
2) Electrode placement were consistent across subjects
3) EMG accurately measures muscle activity
4) Subjects responded truthfully to the FADI scale
5) Each subject performed to his or her best effort
6) The ankle perturbation was uniform between the subjects because of the ankle cradle being used for each subject

Significance of the study

The significance of this study was to determine whether the insertion of over the counter orthotics into the shoes can increase pre-activation levels of the peroneus longus, decrease ankle joint stiffness, and decrease the time to stabilization in order to react quicker and preserve ankle integrity. This study aimed to discover if over the counter orthotics can assist the general population in the rehabilitation of ankle injuries by preventing possible re-injury. There have been a limited number of studies that have investigated the relationship between ankle instability and orthotic use. There are numerous studies that look at the relationship between chronic ankle sprains and bracing, but more research should be done to see if orthotics may have a positive influential effect on the peroneal pre-activation, and time to stabilization in order to prevent future episodes of giving way. However, previous research with braces suggests that orthotics will decrease ankle joint stiffness.

CHAPTER II

LITERATURE REVIEW

Introduction

Epidemiologic research has shown that lateral ankle sprains are one of the most common injuries in both the general population, as well as the athletic population. (Richie, 2007) A lateral ankle sprain is defined as a disruption of the lateral ligaments in the ankle. (Hertel, et al., 2001b) The NCAA has reported that lateral ankle sprains are the top lower extremity injury for men and women who participate in volleyball, basketball, and soccer. (Brown & Mynark, 2007) Research has shown that the rehabilitation of one ankle sprain can range from $318 to $914, which contributes to the United States $2 billion a year medical costs. (Morrison & Kaminski, 2007) It has been reported that women have an increased incidence of grade 1 lateral ankle sprains than men with no explanation for differences between sexes. (Hertel, 2002) A prospective study done by Ferran and Maffulli indicated that lateral ankle sprains were the most common injury over a 2 year period, as well as the most undertreated injury in the general UK population. (Ferran & Maffulli, 2006) The lack of treatment regarding ankle sprains often leads to chronic increased joint laxity, pain, early articular degenerative changes, and an increased chance of subsequent ankle sprains. There are two types of ankle instability. The first type is mechanical, which involves the disruption of ligaments in the ankle. The second type of instability is functional; although unrelated to joint laxity, it can be subjectively described as a feeling of “giving way” on a frequent basis.

(Freeman, 1965; Richie, 2007) The recurrence rate for lateral ankle sprains has been reported to be as high as 80% in athletics, which can be due to either mechanical or functional instability. (Hertel, et al., 2001b)

With the relatively high recurrence rate, the medical community has attempted to decrease the incidence of ankle sprains using various methods of protection and/or rehabilitation. Foot orthotics have been used over the past 40 years to help control joint stability. (Bates, et al., 1979; Richie & Olson, 1993) The concept of "bringing the floor to the foot" allows orthotics to be made for various foot types, and is thought to align the ankle into a subtalar neutral position. (Hunter, 2000; Prentice, 2004) The subtalar neutral position may be more biomechanically advantageous for gait by decreasing tension on ligaments, tendons, and bones of the ankle and foot. (M. T. Gross, 1995; Henry, 2000) Orthotics can decrease pain during activity, postural sway (e.g., center of pressure changes), and time to stabilization during a balance task. (Brown & Mynark, 2007; Richie, 2007; Willems, Witvrouw, Verstuyft, Vaes, & De Clercq, 2002) It remains unknown, however, whether or not orthotics are beneficial for athletes with a history of unstable ankles in decreasing the prevalence of subsequent ankle injuries.

Anatomy and Biomechanics of the Foot and Ankle

In order to have a better understanding of how custom made orthotics are fabricated, the function of the peroneal reflex, and the mechanism of injury for lateral ankle sprains it is important to become familiar with the pertinent anatomy of the foot and ankle. The most common mechanism of injury for a lateral ankle sprain is inversion of the foot in a plantarflexed position. (Ferran & Maffulli, 2006) A primary function of the ankle and foot is to absorb forces coming from the ground and to absorb forces from the closed kinetic chain during dynamic movements. (Dayakidis & Boudolos, 2006; Hertel, 2002; Monaghan, et al., 2006) The ankle joint consists of the talocrural joint which acts as a hinge joint between the lateral malleolus, the talus, and the medial malleolus to form the talar mortise. (Prentice, 2004) The ankle allows approximately 10 degrees of dorsiflexion and 20 degrees of plantarflexion, during normal gait. Dorsiflexion is considered the closed packed position of that talocrural joint and is protective against lateral ankle sprains due to a decrease in ligamentous joint laxity.(Hertel, 2002)

Inferior to the talocrural joint is the subtalar joint, which allows for eversion and inversion of the foot. (Hertel, 2002) The subtalar joint is used when assessing gait and when fabricating orthotics by observing the calcaneous' position relative to the talocrural joint. (M. T. Gross, Byers, Krafft, Lackey, & Melton, 2002; Hunter, 2000; Spaulding, Livingston, & Hartsell, 2003) The talocrural joint contains the ligaments that attach the foot bones to the ankle bones. The ligaments located on the lateral side of the ankle are the anterior talofibular (ATF) ligament, the posterior talofibular (PTF) ligament, and the calcaneofibular (CF) ligament, which function to protect the foot from hyper-inversion.(Ferran & Maffulli, 2006; Hertel, 2002; Richie, 2007) The ATF ligament is the most common ligament injured in lateral ankle sprains. The CF ligament is injured about 50-75% of the time and the PTF ligament is only injured about 10% of the time. (Ferran & Maffulli, 2006) Along with the ligaments located on the lateral side of the ankle additional mechanical protection is provided by the peroneal complex.

The peroneal complex is composed of two main muscles, the peroneus longus and the peroneus brevis. The peroneus longus muscle, which is widely studied in ankle instability studies, begins at the head of the fibula and attaches at the first metatarsal and medial cuneiform in the foot. The peroneus brevis muscle begins at the distal two-thirds of the fibula and attaches to the base of the fifth metatarsal and functions to evert the foot. The peroneals function together to provide protection against lateral ankle sprains that generally occur with an inversion mechanism.(Hertel, 2002; Richie, 2007)

The anatomy of the foot and ankle play a crucial role in gait patterns and postural control. In the healthy population, gait patterns involve a heel strike to toe off pattern that occurs in about 500 ms from HS to toe off. During gait the foot supinates, then pronates, and finally returns to supination. Gait analysis has indicated that frontal plane velocity that is taken around 50 ms after the heel strike reveals a normal foot will go into eversion. (Dayakidis & Boudolos, 2006; Monaghan, et al., 2006) Studies have shown important differences during gait between healthy and unstable ankles. These studies have found that people with CAI will remain in an inverted position for a longer period of time, will have a greater inversion velocity, and will accept more bodyweight early on in the gait cycle when compared to the healthy population. (Dayakidis & Boudolos, 2006; Monaghan, et al., 2006) Most differences in gait patterns were noted during the time period of 100ms pre-heel strike and 200ms post-heel strike, which studies have shown to be the time when the ankle and the shank are most vulnerable to injury. (Monaghan, et al., 2006) A better understanding of the ankle anatomy and gait patterns can help to enhance future research focused on correcting and preventing chronic ankle instability in the future.

Chronic Ankle Instability

Chronic ankle instability has been studied in order to better understand injury rehabilitation, how to protect against instability, and how to properly define what constitutes chronic ankle instability. Reports have shown that 10% to 30% of lateral ankle sprains develop into chronic ankle instability. (Docherty, Arnold, & Hurwitz, 2006; Hale & Hertel, 2005) A leading debate about CAI has been how to define it. Many authors now define CAI as a feeling of "giving way" and a perception of weakness in the ankle because of numerous ankle sprains without a history of fractures. (Hale & Hertel, 2005; Monaghan, et al., 2006; Richie, 2007) Chronic ankle instability can involve mechanical and/or functional instability. Mechanical instability is best described as ligamentous disruption with a positive talar tilt and anterior drawer test, whereas functional instability is best defined as subjective feeling of "giving way" during activities of daily living (ADL) with or without a positive talar tilt and anterior drawer test. (Monaghan, et al., 2006; Richie, 2007) A recent study by Ross et. al. in 2008 examined the Ankle Joint Functional Assessment Tool test (AJFAT), which measures subjective ankle joint stability through a series of 12 questions on which the subjects rate their pain, function levels, ankle strength, etc. of the healthy side against the side with instability, as well as a single leg jump task to define functional ankle instability. Fifteen healthy subjects and 15 subjects with functional ankle instability were examined and it was reported that the AJFAT was accurate in finding functional deficiencies in all subjects with functional ankle instability. (S. E. e. a. Ross, 2008)

In order to understand current concepts, it is important to examine past research and implications for future research. To our knowledge, the first chronic ankle instability study was performed by Freeman et. al. in 1965 and examined CAI as it related to 3 different treatments (6 week cast immobilization, surgical fixation and immobilization, and strapping and immobilization) after varying degrees of lateral ligamentous rupture. Freeman followed 42 subjects with severe ankle sprains and 20 subjects with mild ankle sprains over a period of one year to see who reported signs and symptoms related to chronic ankle instability. This groundbreaking study had several limitations, most notably, the lack of a universal definition of what constitutes CAI. Additionally, Freeman and colleagues used varying degrees of ankle injuries without explaining who was in which treatment group, did not perform any statistical analyses, and sprains were diagnosed via radiographs as opposed to using an MRI. The results stated that those subjects that used the orthotic device had decreased symptoms and less people re-injured their ankle. (Freeman, 1965)

More recently, Hertel in 2002 investigated the pathomechanics of chronic ankle instability. Hertel discussed how subjects with CAI tended to use more of a “hip strategy” for balance when compared to healthy subjects who use more “ankle strategy.” Hip strategy is best defined as the torque that is placed around the hip joint in order to maintain balance and the center of mass. Ankle strategy, on the other hand, is best defined as the torque around the ankle joint that is used to keep the body in a stable and upright posture. (Mahboobin, et al., 2008) The ankle strategy is seen as being advantageous because it involves less movement of the body due to increased fine motor control, whereas the hip strategy involves use of the full kinetic chain. (Beckman & Buchanan, 1995; Hertel, 2002)

Functional ankle instability may also lead to joint position sense or neuromuscular deficits. Docherty et. al. examined 60 subjects (47 with unilateral ankle instability and 13 healthy subjects with no prior history of ankle sprains) and studied whether or not subjects could reproduce joint angles at the ankle and a reproduction of force. The study was done during a single testing session in which the subjects first performed a maximum voluntary isometric contraction (MVIC) in eversion and then the active joint reposition and force sense were done in a counterbalanced order. The study found that subjects with functional ankle instability had a high correlation with force reproduction, but a low correlation with joint reposition sense. Some of the strengths in this study are the use of both healthy and unhealthy ankles, counterbalanced tasks, and that averages were taken for each task for analysis. Some of the weaknesses in this study are that they did not match for subjects demographically in either group and that the subjects were mainly female.(Docherty, et al., 2006)

In 2007, Richie performed a meta-analysis and noted that subjects with CAI tended to have deficits in joint position sense as it relates to proprioception. Proprioception is often defined as being able to sense the body's position in space as it relates to neighboring body parts via feedback in the affected joint or joints. (Konradsen, 2002; Willems, et al., 2002) Proprioception as it relates to neuromuscular control has been measured in various ways, such as time to stabilization tasks, displacement of center of pressure in the anterior/posterior and the medial/lateral directions, and velocity of postural sway as it relates to center of pressure changes. (Konradsen, 2002; Willems, et al., 2002) The information received from proprioception can be used as a protective mechanism against injuries in the ankle because it allows for internal sensors to detect changes in joint angle, which can assist the body's reaction to perturbation. (Jerosch & Prymka, 1996; Willems, et al., 2002)

One of the largest problems that may interfere with proprioceptive information is effusion or swelling in the joint. In 2008 Palmeri et. al. investigated the effects of fluid (or swelling) in the ankle in 8 neurologically healthy men and women. Each subject's ankle joint capsule was injected with 10ml of saline solution to mimic joint effusion. Upon injection of fluid the H-reflex (the reflex response reaction in which the muscle contracts during stimulation) increased, indicating a protective mechanism against further ankle "injury" or swelling. The investigators stimulated the H-reflex of the peroneals by using surface EMG to percutaneously stimulate the sciatic nerve as it branches off into the common peroneal and posterior tibial nerves after joint effusion. Co-contraction of agonist and antagonist musculature of the lower leg also increases with joint effusion when compared to the absence of swelling.(Palmieri, et al., 2004) Some limitations with this study are the lack of exact methodology on how they collected the H-reflex and M-wave data, they injected saline solution into healthy subjects rather than using subjects with a history of ankle sprains, all tests were done in the same non-functional position, and the saline solution was kept at room temperature (which is cooler than the body temperature). Although this study dealt with injected effusion, which is more comparable to an acute injury, many people with chronic ankle instability have elevated levels of joint effusion, so these findings could apply to the population with CAI. (Hertel, 2002; Richie, 2007) The gaps in the literature allow for future research to be conducted comparing acute ankle sprains with chronic ankle instability to distinguish if the two groups have any similarities in musculature reflexes that help protect against further injury.

Fabrication of Orthotics

One strategy that has been used to prevent ankle sprains is the use of orthotics in daily life and during exercise. The foot is largely responsible for motion control of the ankle and body, as well as shock absorption, and lowering the rate of load to avoid injury to the lower extremities. (Morrison & Kaminski, 2007) This is why the concept behind orthotics is to bring the "floor to the foot" in order to control for compensatory movements in the foot and allow for more fluidity of motion. (Hunter, 2000; Prentice, 2004) The different foot types are forefoot varus, rearfoot valgus, and forefoot valgus. Forefoot varus and rearfoot valgus are associated with excessive pronation, whereas forefoot valgus is associated with excessive supination. Excessive pronation can lead to overuse stress injuries and excessive supination can lead to a rigid foot and predisposition to inversion ankle sprains. (D'Amico, 1984; Hertel, et al., 2001b; Prentice, 2004) Studies have shown that the most common types of foot characteristics with lateral ankle sprains are cavovarus foot (also known as forefoot varus), excessive eversion of the calcaneus, and increased foot width. (Morrison & Kaminski, 2007)

The fabrication of orthotics is a skill that requires the knowledge of different foot types, gait, activities the person participates in, and shoe type (such as running shoes or running spikes). When fabricating orthotics, it is important to consider the playing surfaces that the athlete will be on, the foot type, and the type of sport that the athlete plays. For example, a rigid orthotic tends to be contraindicated in most sports because it does not allow for mid-foot movement that is required to run and cut effectively. A rigid orthotic is usually made from hard plastic or casting material. (D'Amico, 1984; Percy & Menz, 2001; Prentice, 2004) The most common type of orthotic made is a semi-rigid orthotic which is a combination of flexible and rigid materials because it allows for comfort and movement control without being too rigid. (Percy & Menz, 2001) A semi-rigid orthotic also allows for support and movement between the foot and ankle joints as it is made from flexible thermoplastics, rubber, or leather. (D'Amico, 1984; Percy & Menz, 2001; Prentice, 2004) When fabricating orthotics it is important to find subtalar neutral in order to effectively create the mold for custom orthotics. This is because subtalar neutral is the position of the least amount of stress on the ankle and is most conducive to proper biomechanics. (Hunter, 2000; Prentice, 2004)

Finding subtalar neutral is especially important when fitting orthotics particularly for athletes that perform dynamic movements, such as running, jumping, cutting, or quick changes in direction. Subtalar neutral is best defined as the position in which the athletic trainer or therapist is able to equally palpate both the medial and lateral aspects of the talus and the talus is congruent with the navicular when the patient is in a prone position. (Hunter, 2000) After inspecting various foot types, Mundermann et. al. found that molding custom made orthotics had a greater advantage in reducing pain and providing motion control in runners when compared to postings that are only added to inserts to bring the “floor to the foot.” (Mundermann, Nigg, Humble, & Stefanyshyn, 2003)

Cote et. al. found that orthotics placed 32 subjects with either supinated or pronated feet into a neutral position and this was advantageous because those 16 subjects with neutral feet without orthotics had an increase in changes in position as it relates to balance. (Cote, et al., 2005) Studies that investigate pronated feet often describe its association with navicular drop, which is associated with increased stress on the foot. Navicular drop is measured by marking the position of the navicular tubercle when the subject is seated. While seated, the talus is placed into subtalar neutral and a mark is placed on the index card, then the subject marches in place and stands in a bipedal stance in order to make a second mark on the index card. The navicular drop is then measured by comparing the distances between the 2 marks in millimeters (pronated (≥10 mm), neutral (5–9 mm), or supinated (≤4 mm)). (Cote, et al., 2005; Hunter, 2000; Kelly, 2003) In order to help correct this problem the foot should be placed into a subtalar joint neutral position which is the most important component of fitting orthotics. A neutral position is seen as the best fit because it is the most comfortable and biomechanically advantageous position for dynamic movement. This advantageous position can be used in people with CAI in order to give them the biomechanical position that is best suited to protect the ankle.

Chronic Ankle Instability and Orthotics

Lateral ankle sprains occur in about 1 out of every 10,000 people. (Hale & Hertel, 2005) Although there are different techniques that attempt to prevent an ankle sprain from becoming a chronic issue, the use of orthotics represents an intriguing possibility. There are many different types of orthotics that exist from over the counter arch supports that the general public can purchase to the custom made orthotics formatted at a clinic. (M. T. Gross, et al., 2002; Hunter, 2000) The general public tends to be uninformed as to what type of orthotic would best fit their foot type and provide the proper support during activity; they either read the side of the box and try to judge what is best for them or attempt to find a store in which the employees receive training in orthotics fitting. Without proper control of the foot and ankle, a mild ankle sprain (where the lateral ligaments are overstretched, but do not have full substance tears) occurring early in life can end up being a lifetime problem. (Hertel, et al., 2001b; Richie, 2007) Freeman et. al. investigate the effects of Elastoplast (which is an early form of orthotics) on chronic ankle instability in 1965. Subjects who used the Elastoplast had fewer cases of chronic ankle instability reported one year post-treatment. This study was the first of its kind and therefore had a few weaknesses. The subjects used in this study had no previous history of ankle sprains prior to the one being studied, so they were dealing with acute ankle sprains, the investigators did not define what mechanical instability meant in terms of the study, functional instability was defined as the feeling of "giving way" but there were no tests designed to collect this data, and the kind of orthotic that they created was a crude and hard form of what is used today (practically you would not use this type of orthotic today because it is too stiff). Some of the positive aspects of this study is that they used 50 subjects and radiographed each one prior to the orthotics use and then again one year afterwards to see if there was a significant difference between pre and post testing, they waited one year until re-collecting data in order for the subjects to have enough time in the orthotics for a change to occur, and they had a high compliance rate with the orthotic use. (Freeman, 1965)

The Functional Ankle Disability Index (FADI) scale is the most common method of defining CAI for examining the effects of orthotics on CAI.(Hale & Hertel, 2005; S. E. e. a. Ross, 2008) The use of 50 subjects with CAI allowed the FADI scale to be found a reliable and valid means of identifying subjects with chronic ankle instability. The FADI scale is composed of 26 questions that deal with various tasks (such as walking, running, sleeping, squatting, etc.) that are rated from a 0 (unable to perform) to a 4 (no difficultly) and the lower the score the more significant the instability. The scale that has been shown to be best used with athletes is the FADI sport scale that consists of 8 sport specific questions that are rated in the same manner as the FADI scale. (Hale & Hertel, 2005) Hertel et. al. have conducted various studies that have examined the use of different types of orthotics in subjects with CAI, as well as healthy subjects. In order to understand the effects orthotics have on those with CAI, one must first examine their effects on the population that is free of ankle injury as done by Hertel et. al. in 2001. Hertel took 15 collegiate athletes with unilateral acute grade one or grade two lateral ankle sprains and had each subject perform a single leg balance test for 3 trials of 5 seconds during the 6 conditions: 1) shoe only, 2) molded Aquaplast orthotic, 3) lateral heel wedge, 4) 7 degree medially posted orthotic, 5) 4 degree laterally posted orthotic, and 6) a neutral orthotic. The subjects were tested during 3 different sessions: 1) 72 hours post injury, 2) 2 weeks after the first session, and 3) 4 weeks after the first session. Results demonstrated that that rearfoot orthotics did not decrease postural sway after an acute ankle sprain and that the shoe-only condition had the best results in reducing sway. (Hertel, et al., 2001b)

Although most orthotics have a positive effect on postural sway, it was found that people with CAI did not decrease postural sway in over the counter orthotics made by Superfeet®, a generic orthotic. (Hertel, et al., 2001b; Ochsendorf, et al., 2000) However, the studies that have investigated the use of Superfeet ® or other generic orthotics tend to use them without the use of shoes. The subjects stand on the orthotics, which is not their intended purpose. (Guskiewicz & Perrin, 1996; Hals, Sitler, & Mattacola, 2000; Ochsendorf, et al., 2000; Percy & Menz, 2001) This strengthens the case for individuals with CAI to have custom-made orthotics. (Hertel, et al., 2001b) Baier conducted a study in 1996 revealing that postural sway velocity in the medial and lateral direction in subjects with CAI improved the most when they wore both rigid and flexible orthotics. (Baier & Hopf, 1998) The custom-made flexible orthotics were found to not only decrease the velocity of sway, but also the total sway displacement when compared to the rigid orthotic. (Baier & Hopf, 1998) Molded orthotics have also been found to increase balance scores in control subjects that are free of CAI which may be due to an increase of somatosensory feedback. (Richie & Olson, 1993) Studies such as Richie's, explain why custom-made orthotics have postings that are fabricated to the specific foot type for which they are being formed and this will help to decrease sway and thereby increase control.

Many different types of athletic teams have used orthotics from distance runners to basketball players. After wearing custom orthotics 64-95% of subjects with CAI reported a decreased level of pain during activity. (Richie & Olson, 1993; Stefanyshyn, 2006) A decrease in pain levels could help make the population with CAI more comfortable which may allow them to participate in their activities for a longer period of time. In populations with CAI it has been found that there is a 40-80% satisfaction rate in those that wear orthotics. (M. L. Gross, Davlin, & Evanski, 1991; James, Bates, & Osternig, 1978)

Ankle Rehabilitation

Since medical costs are on the rise, it is important that we, as health care providers, do all that we can to keep the general population healthy and active. The trouble with chronic ankle instability is that it can persist for many years and interfere with an active lifestyle. Many people that report CAI symptoms have had at least one grade 1 lateral ankle sprain. (Richie, 2007) With a high incidence of ankle sprains in both the general and athletic populations, various preventative strategies have been created in an effort to avoid future ankle sprains from occurring. One technique that has received a lot of attention is taping or bracing the ankle prior to activity. It is thought that this technique will increase sensory input and therefore improve proprioceptive feedback in order to prevent injury at the ankle. (Ferran & Maffulli, 2006; Mohammadi, 2007) Another way to increase feedback is the aforementioned custom-made orthotics that helps to decrease pain and increase postural control. (Hertel, et al., 2001b; Richie & Olson, 1993; Stuber & Kristmanson, 2006)

There has been varied success in the different types of rehabilitation for the prevention of ankle sprains (Mohammadi, 2007; Richie, 2007). Included in the preventative strategies is rehabilitation which can range from strengthening programs, balance programs, or a combination of the two. Hale et. al. created a 4 week comprehensive rehabilitation program that involved stretching, balance exercises, strengthening, and functional rehabilitation for individuals with CAI and control groups (CAI=16 subjects and control=13 subjects). The CAI group made the greatest amount of improvements in the star excursion balance test (SEBT) when compared to pre-test levels of balance. (Hale, Hertel, & Olmsted-Kramer, 2007) Another study that found improvements in stability was conducted by Mattacola et. al. in 2002 in which they investigated various aspects of rehabilitation in subjects with acute ankle sprains. They found that as long as the program addressed the deficiencies caused by the ankle sprain it was deemed effective, meaning that if they worked on improving strength then those deficiencies were diminished. The most important aspects of rehabilitation that were addressed in almost all subjects were proprioception training, neuromuscular facilitation, balance training and functional rehabilitation. (Mattacola & Dwyer, 2002)

Coughlan and Caulfield investigated the effectiveness of a 4 week neuromuscular training program in CAI subjects. They took 10 recreational athletes (3 subjects with CAI and 7 healthy subjects) and had them follow a neuromuscular training program; they had a matched control group that did not perform the training program. Each subject came in for a pre and post intervention testing session in which they walked and jogged on a treadmill while ankle position and velocity were measured in the frontal and sagittal planes prior to heel strike, during heel strike, and 100miliseconds after heel strike. The intervention was unable to improve ankle position or velocity during gait in all subjects. (Coughlan & Caulfield, 2007) Although orthotics and rehabilitation alone have been studied, no study to date has addressed the effects of orthotics on rehabilitation of the ankle and whether the combination of the two has positive effects on reducing sway and pain. This leaves the window of opportunity open for further research to be conducted on how to best treat patients with CAI in the future.

Postural Sway

A component of ankle instability that has been frequently studied is that of postural sway as it relates to center of pressure (COP) changes in displacement and velocity. (Bernier, Perrin, & Rijke, 1997; Guskiewicz & Perrin, 1996) The center of pressure is not equivalent to the center of gravity, but rather is best described as when the body weight remains stable above the foot and ankle during a balance task. (Bernier, et al., 1997; Wikstrom, Tillman, & Borsa, 2005) Center of pressure movement is often measured on a forceplate in the anterior and posterior direction, as well as the medial and lateral direction. Specifically, sway is often analyzed by assessing how far in centimeters from the starting point a person's center of pressure changes. Velocity measurements take into account the time in which the data is collected and then divides the displacement by time. (Bernier, et al., 1997; Wikstrom, Tillman, & Borsa, 2005) When collecting postural sway data it is important to note that generally both limbs in the lower extremity are used; however, they are not labeled right and left, but rather dominant and non-dominant. A problem in the literature is that each study will define the dominant leg differently. Some studies will define the dominant leg as being the leg you would use to kick a ball for distance, whereas other studies would define the dominant leg as being the leg you plant when you kick a ball. (Guskiewicz & Perrin, 1996; Hertel, et al., 2001b; Wikstrom, Tillman, & Borsa, 2005)

When analyzing the literature there have been various findings that are different from each other. Studies have shown that a chronically injured ankle often displays an increased sway in the medial and lateral direction, as this is the direction of sway that most relates to the inversion mechanism of injury that is associated with ankle sprains. (Bernier, et al., 1997; Hertel, et al., 2001b) A similar study conducted in 1996 by Guskiewicz and Perrin examined postural sway and the use of orthotics in subjects with acute ankle sprains that occurred within the last 21 days (13 subjects and 12 matched control subjects). The balance system had the subjects perform under 4 different conditions: 1) stable, 2) medial/lateral, 3) inversion/eversion, and 4) plantarflexion/dorsiflexion. Postural sway (deviation from the center in centimeters) was measured in the medial/lateral direction, as well as the anterior/posterior direction during a single leg balance test. Subjects were tested in a randomized order of orthotic and non-orthotic conditions. Results showed that the center of pressure displacement measurements were greater in the medial and lateral direction, as well as the anterior and posterior direction when compared to non-orthotic condition. (Guskiewicz & Perrin, 1996) After comparing the effects of ankle instability on postural sway it was shown that whether the instability was caused by an acute sprain or chronic ankle instability, the two conditions demonstrate similar findings, meaning that there is a deficit present in both conditions that should be addressed.

Although postural sway and ankle instability are frequently studied together, it is important to note that sway has also been studied in healthy subjects, as well as in groups that wear orthotics. On average, healthy subjects demonstrate minimal sway in any direction, which establishes a baseline for comparison with unstable ankles. (Hertel, et al., 2001b) Healthy subjects and subjects with CAI have been used in studies that place orthotics in the shoes of both groups. When comparing sway between the two groups, both the CAI and the acute ankle sprain groups, tended to have the greatest decrease in postural sway when orthotics were placed in the shoes. (Guskiewicz & Perrin, 1996; Hertel, et al., 2001b; Ochsendorf, et al., 2000; Wikstrom, Tillman, & Borsa, 2005) Although sway increases in subjects with ankle instability, whether from an acute or chronic condition, sway has not been found to improve in healthy subjects in any direction or in velocity changes. (Guskiewicz & Perrin, 1996; Hertel, et al., 2001b; Wikstrom, Tillman, & Borsa, 2005)

Overall, an established baseline sets the standard for the CAI and acute ankle sprain groups to strive towards.

In order to simulate ankle instability in CAI and healthy subjects, Ochsendorf et. al. looked at postural sway after an ankle fatigue protocol and found that both groups had a decrease in sway when placed in orthotics. (Ochsendorf, et al., 2000) There are very few studies that look at fatigue protocols in the ankle and orthotics as it relates to sway. The studies aim to find whether the healthy group will display similar characteristics that subjects with CAI display. Although differences between healthy and unstable ankles have been found, studies vary in the type of orthotic that they are testing (ranging from an over the counter orthotic to a custom-made orthotic) and the time in which data is being collected (ranging from 5 seconds to 30 seconds). Without a universal timeframe or a baseline orthotic to compare to, it is difficult to ascertain where the differences are truly coming from.

Time to Stabilization

Similar to postural sway studies, researchers have also investigated time to stabilization after a dynamic task. We operationally define the time to stabilization as the time it takes after a single hop task in order for center of pressure changes to resemble the sway that is seen when balancing on one leg prior to the hop task. (S. E. Ross, Guskiewicz, & Yu, 2005; Wikstrom, Arrigenna, Tillman, & Borsa, 2006) Subjects with functional ankle instability will often require a greater amount of time to stabilize after a single leg hop test. (S. E. Ross & Guskiewicz, 2006; S. E. Ross, et al., 2005; Wikstrom, et al., 2006) Similar to the hop task, some researchers have investigated the time to stabilization after a single leg drop landing task. (Wikstrom, et al., 2006) The results from these studies are similar to those that use the single leg hop task. Each of these studies investigated the differences between subjects with ankle instability and compared them to a healthy set of subjects. In general, a healthy subject swayed less and took less time to return back to baseline. (Hertel, et al., 2001b; S. E. Ross & Guskiewicz, 2006; S. E. Ross, et al., 2005; Wikstrom, et al., 2006)

There have been a limited number of studies that have investigated the differences between stable and unstable ankles in various balance measurements. One study that investigated the accuracy of different balance tasks was conducted in 2009 by Scott Ross et. al. in which they investigated various static and dynamic balancing tasks on a forceplate. They compared the difference in COP changes in the A/P and M/L direction, the ground reaction force (GRF), and time to stabilization (TTS) in a single leg balance task using the dominant (leg you would kick a ball for distance) or non-dominant leg matched leg between the stable and unstable ankle groups. This study found that the M/L GRF SD and A/P time to stabilization were the most accurate in discriminating between ankle groups. On average, the unstable ankle group exhibited higher values in COP and TTS when compared to the stable ankle group. (S. E. Ross, et al., 2009)

Not only have the effects of orthotics been studied, but so have the effects of ankle braces. Ankle braces have been investigated with the same types of CAI subjects in order to find out if receiving more external support will decrease the time it takes to stabilize after a dynamic task. Although not many studies have examined this theory, in 2006 Wikstrom et. al. examined the effects of two different types of ankle braces (semi-rigid and rigid) on stabilization after a single leg hop task. They found that neither brace decreased the stabilization time, but instead helped produce greater ground reaction force for take-off during the hop task.(Wikstrom, et al., 2006) Although this seems counterintuitive, further investigation needs to be done in order to find more conclusive results. Also, the effects of orthotics in the shoe should be a part of this investigation in order to better understand the function of orthotics during dynamic movement.

Peroneus Reflex

One of the key components in the prevention of inversion ankle sprains is the peroneus longus stretch reflex. This reflex acts to evert the foot once the lateral musculature has been placed on a strain, thereby protecting the lateral ligaments of the ankle from further damage. (Cordova & Ingersoll, 2003) A reflex is an innate response that is thought to help protect the body from damage, the presence of ankle instability may affect the latency time of the peroneus longus muscle creating increased potential for ankle injury. (Ebig, Lephart, Burdett, Miller, & Pincivero, 1997) Reflexes can be altered with injury or disease and can be trained to be modifiable. (Konradsen, 2002) At the ankle, the peroneal muscle response is assessed as the EMG output of peroneus longus latency, as well as pre-activation levels during different tasks. A rapid foot inversion has been used to simulate the mechanism of injury (MOI) that is often associated with lateral ankle sprains. Normal ankles that are free of injury have been found to elicit the peroneal reflex 49-90ms after an inversion mechanism has occurred, precluding a short-loop reflex with medium latency. (Konradsen, 2002) Some research has shown that healthy subjects tend to have an increased deceleration after initial inversion perturbation when compared to subjects with CAI. Clinically, the initial deceleration time serves to decrease the speed of the foot moving into inversion. Subjects with CAI tend to have decreased control and this can lead to further complications in the ankle because the protective mechanism of the peroneal reflex is diminished. (Beckman & Buchanan, 1995; Cordova & Ingersoll, 2003; Lynch, Eklund, Gottlieb, Renstrom, & Beynnon, 1996; Vaes, Duquet, & Van Gheluwe, 2002)

Although initial deceleration differs between the two groups, many studies have found that the actual peroneal latency time does not differ between the CAI and those with healthy ankles. (Beckman & Buchanan, 1995; Cordova & Ingersoll, 2003; Ebig, et al., 1997; Vaes, et al., 2002) Although the peroneus longus latency has been found to be fairly comparable between the CAI and the healthy ankle groups, Beckman et. al found that those subjects with CAI tended to have a decrease in gluteus medius latency when compared to healthy subjects, therefore, emphasizing the theory that people with CAI tend to use more hip strategy than ankle strategy when balancing. (Beckman & Buchanan, 1995) Not only has hip activation been studied, but so have dynamic tasks on the peroneus longus latency time. Hip strategy is when the control for balance comes from the hip and not the ankle, which is a problem because the control is coming farther away in the kinetic chain making balance corrections more difficult. Another study in agreement with Beckman was that of Lynch et. al. found that with an inversion moment at increased plantarflexion the peroneal reflex decreased significantly in subjects with CAI. The CAI group also had a greater peroneal reflex delay at neutral when compared to matched controls. (Lynch, et al., 1996)

In 1997 Fu et. al. investigated the role of the peroneus longus after a landing task. They found that the peroneus longus functions to protect the ankle prior to landing in subjects with CAI especially in the expected drop landing task; however, the healthy subjects did not have any changes in either the unexpected or the expected drop landing tasks. (Fu & Hui-Chan, 2007) Investigators have also looked at the effect of gait on the peroneals in people with CAI. Results show that the injured side has less EMG output (indicating activation) of the peroneals during gait. (Santilli, et al., 2005) Thus it remains unknown whether rehabilitation or early sensory feedback via orthotics can help decrease the peroneal latency to protect against future ankle sprains.

Stiffness

Overall, stiffness has been found to decrease joint translation during perturbation, thereby decreasing the likelihood of injury. One factor that contributes to joint stiffness is that of muscle stiffness; this is an innate mechanism that combines both passive and active activation of muscles. Muscle stiffness has been described as being either intrinsic or a reflex mediated response. (Rack & Westbury, 1969) Intrinsic muscle stiffness is what exists during the time of muscle lengthening due to actin-myosin bonds. (Nichols & Houk, 1976) The intrinsic property of muscle stiffness can be used to describe how active a muscle is at the time of use. The reflex mediated response is the stiffness acquired after the feedback system has been activated. (Hoffer & Andreassen, 1981) Stiffness can best be summarized as the force response that is a product of and resistant to mechanical stress. (Rack & Westbury, 1969) Stiffness is useful in that it is believed that the stiffer a joint is during perturbation, the more likely the muscle will protect a given joint against injury. (Docherty, Arnold, Zinder, Granata, & Gansneder, 2004) Overall, increased stiffness may help to protect against joint translation and therefore will decrease the likelihood of injury. (Docherty, et al., 2004; Duan, Allen, & Sun, 1997; Kaminski, Perrin, & Gansneder, 1999) Studies have shown that subjects who are able to perceive when the perturbation of the ankle had an increase in muscle stiffness, specifically in the peroneals. (Fitzpatrick, Taylor, & McCloskey, 1992; Kaminski, et al., 1999)

Similar to perception and muscle stiffness, the concept of joint reposition sense and the concept of strength reproduction have also been studied. In 2004 Docherty et. al. examined subjects with CAI and compared them to healthy subjects and found no significant difference between groups for joint position sense. However, when they studied muscle stiffness and force production they did find a significant difference between the two groups. This meant that subjects with CAI were not able to reproduce forces in the ankle to the same extent as those with healthy ankles. It is unclear if this deficit was present prior to injury or developed as a result of ankle injury. (Docherty, et al., 2004) Other studies have found similar findings regarding eversion forces and muscle stiffness, specifically subjects with CAI tend to have a decrease in force reproduction with eversion. (Arnold & Docherty, 2006; Kaminski, et al., 1999)

There is limited research investigating gait and the function of muscle stiffness. One of the few studies was conducted by Duan et. al., in which they investigated the effects of ankle muscle stiffness in healthy subjects as it relates to stride length and cadence (or speed) during gait. The researchers found that stride length does not affect ankle muscle stiffness from subject to subject, but rather the differences in muscle stiffness were observed during different cadences. The fastest cadence leads to the most muscle stiffness in order to stabilize the body during increased motion.(Duan, et al., 1997) Although gait was analyzed in healthy subjects, it has yet to be investigated on how a subject with CAI would compare to this muscle stiffness gait pattern found in healthy ankles.

Neuromuscular Control and Joint Position

Limited research has been done to relate subtalar neutral to neuromuscular control in the ankle for both healthy and CAI subjects. Some theories that exist about the possible causes of sensorimotor and neuromuscular control deficits include: 1) damage to the afferent fibers in the ligament and joint capsule, 2) deficits in the Tibialis anterior and peroneal musculature, 3) loss of motorneuron pool excitability, 4) decreased muscle strength, 5) loss of postural control, and 6) hyporeflexive peroneals (variable results). (Sojka, Sjolander, Johansson, & Djupsjobacka, 1991; Solomonow & Krogsgaard, 2001) Most of these theories have been found to hold true in subjects with CAI; however, results are variable when it comes to acute ankle sprains because of the severity of injury and the ability to test these theories in a timely manner. (Andreassen & Rosenfalck, 1981; Benesch, Putz, Rosenbaum, & Becker, 2000; Fitzpatrick, et al., 1992)

Hertel and McKeon investigated joint position sense in CAI and matched healthy subjects. (Hertel, 2008) Each subject performed 3 single leg balance trials for 10 seconds each on a forceplate with their eyes open and then again with their eyes closed. They analyzed the time to boundaries (TTB) or the time it takes for the subject to sway towards the border of his or her foot in both the medial/lateral and anterior/posterior directions. They found that the CAI group had larger deficits with their eyes closed than the healthy group.

Neither group had significant differences during the eyes open condition. This study demonstrates that subjects with CAI lose some of the neuromuscular control with an ankle injury.

Although limited research has been done on sensorimotor control in the ankle, Solomonow et. al. investigated sensorimotor control in knee stability. (Solomonow & Krogsgaard, 2001) They found that the most important factor in sensorimotor and neuromuscular control is that of the mechanoreceptors (i.e. the muscle spindles, Golgi tendon organs, Ruffini endings, etc.) which sense joint velocity, joint position sense, or deformation. They also noted the importance of co-activation of the surrounding musculature around a joint in order to provide more stability. The investigation discussed injuries to the knee and how they affect joint stability; however, the overall findings can be applied to any joint and the importance of regaining strength and neuromuscular control for increased joint stability. When a joint is placed in its most stable position (one with more joint congruency) then the mechanoreceptors can sense changes at a more optimal rate. This is the theory behind placing the ankle into a subtalar neutral position because this is the most biomechanically advantageous position and will therefore allow for the afferent fibers to fire properly in order to make proper reflexive changes to the joint to encourage more stability in the joint.

Reliability and Validity of Equipment

FADI and AJFAT tests

Although there are varying definitions of what constitutes functional ankle instability as it relates to chronic ankle instability, there have been a few studies that have verified the best tests that are used to define FAI. The Ankle Joint Functional Assessment Tool (AJFAT) consists of 12 questions that compares the healthy ankle side to the injured ankle side and the subjects grade various daily tasks that are rated from a 0 (unable to perform) to a 4 (no difficultly) and the lower the score the more significant the instability. The AJFAT has been found to have a sensitivity and specificity score of 1 when compared to other functional ankle instability tests assessing the TTS in subjects that reported having FAI. (S. E. e. a. Ross, 2008) The AJFAT test is similar to the FADI test and the FADI sport test that have been shown to be reliable and valid in past studies.(Hale & Hertel, 2005)

Ankle Cradle

Related to the difficulty in defining FAI, is how to test the inversion MOI without injuring subjects. An ankle cradle has been used to assess ankle stability by having a subject stand or be seated with 90 degrees at the hip and knee with 50% of their bodyweight placed over the tibia over the ankle cradle prior to an inversion perturbation taking place. The in vivo ankle cradle has been shown to have an ICC (2,1) reliability of .96 from trial to trial and an ICC (2,k) reliability of .93 from day to day, which means that it is fairly accurate at predicting ankle muscle stiffness during ankle perturbation. Muscle stiffness is measured via spring-mass oscillators located on the underside of the ankle cradle. Perturbation is achieved by dropping a weighted ball in a target tube with an electronic trigger. Stiffness data is taken for 5 seconds after the ball is dropped and the transient motion is analyzed. (Zinder, Granata, Padua, & Gansneder, 2007)

Electromyography

When it comes to measuring ankle muscle stiffness with EMG, studies have demonstrated the importance of proper electrode placement on the subjects. It has been shown that the optimal location for obtaining peroneus longus EMG measurements is to place the electrodes between the innervation zone and the tendon. (Isabelle, 2003; Rainoldi, Melchiorri, & Caruso, 2004) Many researchers establish this position via a manual muscle test that allows for the palpation of the correct muscle. The position of the electrode is then checked by moving the foot and ankle joint into positions that would activate the muscle you are attempting to measure. (Isabelle, 2003; Rainoldi, et al., 2004)

Forceplates

Not only do the electrodes have to be properly positioned, but the placement of the foot upon landing on a forceplate is just as important. In order to properly assess postural control or time to stabilization, it has been found that the reliability of the test is around .96 with 10 seconds worth of data collection following a single leg hop. (Wikstrom, Tillman, Smith, & Borsa, 2005) Postural control data collected on a forceplate has been found to have a range of .06 (poor) to .90 (excellent) intertester reliability. (Mattacola, Lebsack, & Perrin, 1995) Whereas, another study found a day to day reliability of .97. (Bauer, Cauraugh, & Tillman, 2000)

CHAPTER III

METHODOLOGY

Purpose

The overall goal of this project was to examine the effects of over the counter foot orthotics on subjects with pronated feet on time to stabilization, ankle joint stiffness, and pre-activation levels of the peroneus longus. The main group that we investigated was a group of individuals known to have a history of unstable ankles.

Subjects

An *a priori* power analysis gave a power level of 0.80 with 20 subjects per group. Power was investigated using previous ankle instability and orthotics studies on postural sway. (Baier & Hopf, 1998; Guskiewicz & Perrin, 1996) We tested 43 subjects divided into a stable ankle group and an unstable ankle group. We excluded one subject from the unstable group and two subjects from the stable group as a result of incomplete data resulting in only 20 subjects per group being included in all analyses. The subjects were divided into 2 groups, each consisting of 20 qualified participants. The unstable ankle group consisted of 10 female and 10 male subjects who scored less than 94 on the functional ankle disability index (FADI) test for functional ankle instability and were free from injury at the time of testing, as well as for the past 6 months. (Hale & Hertel, 2005) The stable ankle group (11 females and 9 males) had pronated feet, with no history of ankle sprains. Subjects in the stable ankle group were matched to those in the unstable ankle group by height and weight. Subject demographic data are presented in Table 1. The only statistically significant difference between the two groups was the navicular drop score ($t(38) = -2.685$, $p = .011$), with the unstable ankle group having the greater mean value. Subject navicular drop data are presented in Table 2.

Subjects were recruited from the University of North Carolina-Chapel Hill population with the inclusion criteria of: 1) being between the ages of 18 and 25 years old, 2) student, faculty, or staff member, and 3) a recreational athlete, who exercised at least 3 days per week for at least 30 minutes at a time. The exclusion criteria for this study included: 1) documented lower extremity injury in the past 6 months, 2) lower extremity surgery in the past year, 3) currently using orthotics, 4) currently rehabilitating a lower extremity injury, 5) do not meet the criteria for a recreationally active athlete, 6) any neurological disorder (vertigo, etc) that affected balance, or 7) had a neutral or supinated foot. Subjects were recruited on a volunteer basis via email and flyers. Each subject signed an informed consent form approved by the University of North Carolina–Chapel Hill Institutional Review Board committee prior to beginning the study.

Procedures and Instrumentation

This study involved two sessions in the Sports Medicine Research Lab (SMRL). The first was a pre-screening session for all interested potential subjects and a second session consisted of testing for qualified participants. The second session used a pre-test/post-test format in which subjects performed the same tasks first without and then with foot orthotics.

Screening for subjects and foot type

Potential subjects who answered the flyer, email, or in class announcement were screened prior to participation to evaluate for current lower extremity injuries, a history of surgery within the past year, lower extremity injury in the past 6 months, and to evaluate navicular drop (amount of pronation). During this screening exam, potential subjects filled out the informed consent and demographic data information forms. After filling out the forms the navicular drop test was performed by having the subject sit in a chair with their back supported, with a 90 degree angle at the hip and knee and the feet placed flat on the floor. The medial and lateral borders of the talus were palpated while inverting and everting the foot until both prominences were felt equally, achieving subtalar neutral. Once subtalar neutral was established, a mark was made on the navicular tubercle and also on an index card held next to the foot that extended to the floor. The subject then stood up, marched in place 5 times, and finally stood still with his or her feet shoulder width apart to be re-measured. This process was repeated 3 times for each subject and the average difference (e.g., between sitting and standing measurement) was taken as the subject's navicular drop score (pronated (≥10 mm), neutral (5–9 mm), or supinated (≤4 mm)). (Cote, et al., 2005; Hunter, 2000; Kelly, 2003) Only individuals with pronated feet qualified for participation in the study, as people with pronated or flat feet have the highest frequency amongst this age population. (McManus, et al., 2004)

Potential subjects filled out the FADI scale questionnaire to determine the presence of CAI. (Hale & Hertel, 2005) The questionnaire consists of 12 questions that compare the most frequently injured ankle to the contralateral ankle in a scaled range from 0=much more than the other ankle, and 4= much less than the other ankle (Appendix B). Those subjects that scored under 90% or 94 out of 104 possible points were considered to possess chronic functional ankle instability. (Hale & Hertel, 2005) Once the unstable ankle group had been established, a control group was formed in order to match the unstable ankle group according to the criteria previously stated.

Pre-testing

Qualified subjects returned to the lab shortly after the arrival of his or her orthotics (around 7-10 days after the pre-screening session), to receive the orthotics and undergo testing. Superfeet Inc® donated their green orthotic with a medial post designed for people with pronated feet. The orthotics were intended to help correct for pronation by positioning the ankle in subtalar neutral during the post-testing data collection. Each subject wore his or her self-owned pair of athletic shorts, shirt, and athletic shoes throughout both the pre-testing (no orthotics) and post-testing (with orthotics) sessions.

Collection of electromyographic (EMG) data involved electrode placement over the peroneus longus (PL), tibialis anterior (TA), and lateral gastrocnemius (LG) musculature. A manual muscle test (MMT) was used in order to find the muscle bellies of the PL, LG, and TA. Electrodes were placed parallel to the muscle fiber orientation and over a flat part of the mid-belly of the PL, TA, and LG as established by the manual muscle test done prior to placement. (Benesch, Putz, Rosenbaum, & Becker, 2000; Mora, Quinteiro-Blondin, & Perot, 2003; Rainoldi, et al., 2004) Subjects had their skin prepared using a disposable razor to remove hair from the area and were cleaned with alcohol wipes in order to ensure good contact with the skin. Each electrode was secured with pre-wrap and tape in order to stabilize the placement of the Ag/AgCl surface EMG electrode (Delsys Inc.,Boston, MA) on the skin. Electrodes were then connected to a transmitter on a belt attached around the waist, which was worn for each task. A maximum voluntary isometric contraction (MVIC) was recorded from each muscle group for each subject by performing 3 trials for 5 seconds each. The electrodes remained in the same testing locations as during the post-testing session.

Performed Tasks

Each subject performed the following 3 tasks: 1) ankle joint stiffness using a custom-built ankle cradle with unanticipated inversion perturbation and 2) drop landing from a 30cm box in the frontal plane and sagittal plane. The order of these tasks was counterbalanced between each subject. Each task was performed 5 times and an average was taken for analysis.

Ankle Joint Stiffness Assessment

The ankle joint stiffness assessment was performed with a custom-built ankle cradle that perturbed the foot with transient oscillations (Figure 1). (Zinder, et al., 2007) The in vivo ankle cradle has been shown to have an ICC (2,1) reliability of .96 from trial to trial and an ICC (2,k) reliability of .93 from day to day, which means that it is fairly accurate at predicting ankle joint stiffness during ankle perturbation. (Zinder, et al., 2007) Prior to the initiation of the ankle oscillation, we measured the pre-activation level of the affected PL muscle.

Each subject was placed in a seated position with 90 degrees of hip and knee flexion with 50% of their bodyweight placed above his or her tibia. EMG electrodes remained placed over the TA, PL, and LG of the testing leg. The data acquisition began 5 seconds after the subject was seated in the unperturbed position with their eyes closed. A weighted ball was placed down a tube placed on a stand to the wing of interest; once the ball passed a photoelectric eye, the data collection began and then ended 3 seconds after the perturbation occurred. The subtalar joint was free to move because the foot rested on top of the wooden plate.

Testing was repeated to complete three external inertial conditions (0.000, 0.065 and 0.131 kg/cm2) which were achieved by adding weights to the sides of the cradle. (Zinder, et al., 2007) As the ankle cradle moved in response to the dropped ball, we collected the frequency and decay of oscillations measured by the ankle cradle to compute ankle joint stiffness. EMG data was collected 250ms prior to the photoelectric eye trigger being switched on to determine pre-activation levels of the peroneus longus.

Drop Landing Task

Prior to beginning the drop landing task a static single leg balance trial was collected for 10 seconds in order to have a baseline of comparison for the drop landing task. The static trial involved subjects walking onto a forceplate (Bertec Corp, Columbus, OH) to assume a single limb stance, with hands on hips, and the eyes open and focused on the wall straight ahead. Subjects then performed a single leg jump off a 30cm box, for a horizontal distance equal to 50% of their body height, to land on the same leg that they jumped off of. During the drop landing task, subjects landed on a forceplate, and held a static position for 10 seconds. A rest period of 30 seconds was used between each trial. Testing was done in both the frontal (jump towards the tested side) and sagittal (jump forwards) planes (Figures 2 and 3). Recording for the drop landing task began when the subject landed on the forceplate (Fz >10N) and ended 10 seconds after the subject landed. If the subject placed his or her non-tested foot down on the forceplate or did not land correctly, then that trial was deleted and a new one was performed.

Tested Side

The unstable ankle group used the side which possessed the greatest amount of instability based on the FADI scale. This side was then defined as either being the subject's dominant or non-dominant side according to our definition of the dominant foot was the foot that the subject would use to kick a ball for distance. The stable ankle group was then matched for foot dominance of the unstable ankle group.

Post-testing

After performing each task without orthotics, subjects were provided with their orthotics. The orthotics were trimmed to fit the shoes that the subject wore during the pre-testing session, and subjects then wore the orthotics for a 10 minute acclimatization period. All testing (ankle joint stiffness assessment and time to stabilization) was then repeated in the same order as the pre-testing session.

Data Collection

All EMG, ankle joint stiffness, and kinetic forceplate data were collected using the DataPac 2K2 software program (Run Technologies, Mission Viejo, CA). There were 6 channels used to collect kinetic data from the forceplate (forces in the X, Y, and Z direction, as well as moments in the X, Y, and Z direction). Only forces in the Fx and Fy direction were used for analysis. For the sagittal plane jumps, Fx represented the medial/lateral direction and Fy represented the anterior/posterior direction. In the frontal plane jumps, Fx represented the anterior/posterior direction and Fy represented the medial/lateral direction. One channel was used to collect data from the potentiometer and another was linked to the trigger on the ankle cradle. Three additional channels were used for each of the muscles investigated in this study (PL, TA, and LG).

Data Reduction

Pre-activation levels of the peroneus longus (PL), and ankle joint stiffness values were reduced using custom-made MabLab programs (Mathworks, Natick, MA). EMG data (MVIC and pre-activation levels of the PL) were corrected for DC bias, bandpass filtered using 20-350Hz 4^{th} order Butterworth filter, and smoothed using a 20ms root-mean-square sliding window function. The raw data from DataPac were exported in text format and MVIC values for each muscle were calculated using a custom MabLab program in which the MVIC value was calculated by taking an average of the acquired 3 trials. Pre-activation of the PL was determined by taking the average level of activation during the 250ms preceding trigger activation of the ankle cradle. This value was then normalized to each subject's MVIC value.

Ankle joint stiffness was reduced by measuring the transient motion oscillations that were recorded using a single turn potentiometer (Clarostat, Mexico City, Mexico) aligned with the axis of rotation of the cradle. Raw ankle motion data in text format were exported from DataPac to be used in a custom MatLab program helped to find the decay in the oscillations and frequency of oscillations that occurred during the ankle stiffness task. The processed data from the MatLab program was then placed into an excel spreadsheet and utilized the following equation to plot and assess the ankle's inertial value: $I_{\mathrm{EXT}} = ((\mathrm{k} + \mathrm{MgL})/ w^2_n) - I_{\mathrm{o}}$. The I_{EXT} represents the added external inertia versus the inverse square of natural frequency ($1/ w^2_n$). The pendulum behavior was represented by MgL and k represented the stiffness value of the regression line. Lastly, the I_{o} value represented inertia of the ankle and cradle, which was extracted by using the intercept of the regression line produced.

The time to stabilization was calculated by comparing the range of variance (ROV) of sway in the medial/lateral direction and anterior/posterior direction during the static trial of each orthotic condition to the drop landing task variance of sway. Raw data from DataPac was exported in Excel format and made tab delimited in an excel spreadsheet. This data was then used to find the ROV value from the 4^{th}-6^{th} seconds of the static trials. The ROV average was taken for both stable and unstable subjects in both the orthotic and no orthotic condition during the static trials. (S. E. Ross, et al., 2009; S. E. Ross, et al., 2005) This ROV value was used to compare the TTS data to each testing condition for each subject. Time to stabilization data were reduced and calculated using customized LabVIEW program (National Instruments; Austin, TX).

Data Analysis

All data was analyzed using SPSS version 16 statistical software (Chicago, IL) using an a priori alpha level of 0.05. The independent variables for this study included: 1) orthotics and no orthotics and 2) unstable and stable ankle subjects. The dependent variables for this study included: 1) ankle joint stiffness, 2) pre-activation levels of the PL, and 3) Time to Stabilization (TTS) after drop landing task performed in the a) frontal plane (anterior/posterior and medial/lateral direction) and b) sagittal plane (anterior/posterior and medial/lateral direction). Six separate 2X2 mixed model ANOVAs were used to analyze the data.

Figure 1: Ankle Cradle for Ankle Joint Stiffness

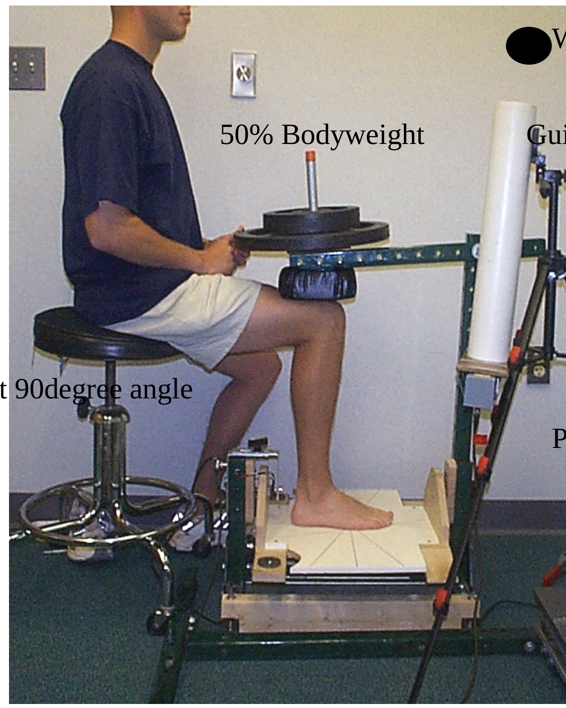
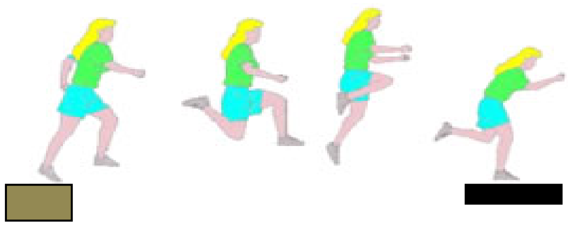


Figure 2: TTS in Sagittal Plane



Start Finish

Figure 3: TTS in Frontal Plane

Finish Start

Table 1 Demographic Data

Group	Sex		Age(years)	Height (cm)	Weight (kg)
	Male	Female	Mean SD	Mean SD	Mean SD
Stable (n=20)	9	11	20.60 ± 1.10	173.10 ± 7.47	70.32 ± 9.03
Unstable (n=20)	10	10	20.35 ± 1.87	174.37 ± 13.01	80.38 ± 20.84

* Denotes significance at p <.05 level

Table 2 Navicular Drop (mm)

Group	**Navicular Drop***	**Range of Values**		**Independent t-test**	
	Mean SD	Min	Max	t	p
Stable (n=20)	14.20 ± 3.56	10	25	-2.685	.011
Unstable (n=20)	16.69 ± 3.86	11	29		

* Denotes significance at p <.05 level

CHAPTER IV

RESULTS

Ankle joint stiffness

Means and standard deviations for ankle joint stiffness data are represented in Table 3 and Graph 1. For ankle joint stiffness there was no statistically significant orthotic x group interaction effect ($F_{1,38}$= .219, p= .642). There was also no statistically significant group difference ($F_{1,38}$=1.245, p=.272). There was a statistically significant difference of orthotics on stiffness ($F_{1,38}$=8.117, p=.007); whereby, stiffness decreased in both groups when wearing orthotics.

Pre-Activation Levels of Peroneus Longus

Means and standard deviations for pre-activation of the peroneus longus (PL) data are presented in Table 4 and Graph 2. No statistically significant group x orthotic interaction was observed for pre-activation levels of the PL ($F_{1,38}$= . 1.513, p= .226). There also was not a significant effect of group ($F_{1,38}$=3.932, p=.055) or orthotic condition ($F_{1,38}$=1.661, p=.205) on pre-activation levels of the PL .

Time to Stabilization

Frontal Plane Anterior/Posterior

Means and standard deviations for time to stabilization (TTS) in the frontal plane in the anterior/posterior direction are represented in Table 5 and Graph 3. No group x orthotic interaction was observed for TTS in frontal plane in the anterior/posterior direction ($F_{1,38}$=1.044, p= .313). There also was not a significant effect of orthotic ($F_{1,38}$=.728, p=.399). There was a statistically significant difference in the effect of group ($F_{1,38}$=4.370, p=.043) observed for TTS in frontal plane in the anterior/posterior direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Frontal Plane Medial/Lateral

Means and standard deviations for time to stabilization (TTS) in the frontal plane in the medial/lateral direction are represented in Table 6 and Graph 4. No group x orthotic interaction was observed for TTS in frontal plane in the medial/lateral direction ($F_{1,38}$=2.157, p=.150). There also was not a significant effect of orthotic ($F_{1,38}$=1.683, p=.202). There was a statistically significant difference in the effect of group ($F_{1,38}$=6.442, p=.015) observed for TTS in frontal plane in the medial/lateral direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Sagittal Plane Anterior/Posterior

Means and standard deviations for time to stabilization (TTS) in the sagittal plane in the anterior/posterior direction are represented in Table 7 and Graph 5. No group x orthotic interaction was observed for TTS in sagittal plane in the anterior/posterior direction

($F_{1,38}$=.616, p=.437). There also was not a significant effect of orthotic ($F_{1,38}$=1.876, p=.179). There was a statistically significant difference in the effect of group ($F_{1,38}$=4.947, p=.032) observed for TTS in sagittal plane in the anterior/posterior direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Sagittal Plane Medial/Lateral

Means and standard deviations for time to stabilization (TTS) in the sagittal plane in the medial/lateral direction are represented in Table 8 and Graph 6. No group x orthotic interaction was observed for TTS in sagittal plane in the medial/lateral direction ($F_{1,38}$=.017, p=.898). There also was not a significant effect of orthotic ($F_{1,38}$=.005, p=.945). There was a statistically significant difference in the effect of group ($F_{1,38}$=5.674, p=.022) observed for TTS in sagittal plane in the medial/lateral direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Table 3 Ankle joint stiffness (Nm/rad)

Group	Condition		Interaction Effect		Orthotic Effect		Group Effect	
	No Orthotic	**Orthotic**	**F**	**p**	**F**	**p**	**F**	**p**
Stable (n=20)	30.58 ±18.24	26.22 ±21.80	.219	.642	8.117	.007*	1.245	.272
Unstable (n=20)	38.85 ±18.40	32.77 ±27.43						

* Denotes significance at p <.05 level

Figure 4 Ankle joint stiffness (Nm/rad)

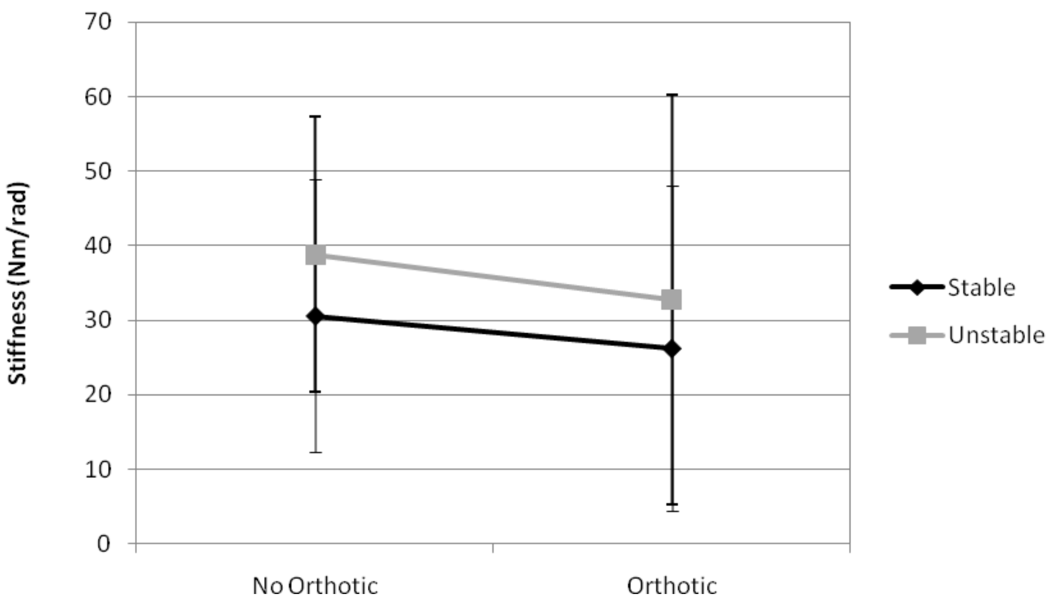


Table 4 Pre-activation Levels of the Peroneus Longus (%MVIC)

Group	Condition		Interaction Effect		Orthotic Effect		Group Effect	
	No Orthotic	Orthotic	F	p	F	p	F	p
Stable (n=20)	5.6 ± 5.0	5.7 ± 2.0	1.513	.226	1.661	.205	3.932	.055
Unstable (n=20)	7.2 ± 5.0	9.4 ± 6.8						

* Denotes significance at p <.05 level

Figure 5 Pre-activation Levels of the Peroneus Longus (%MVIC)

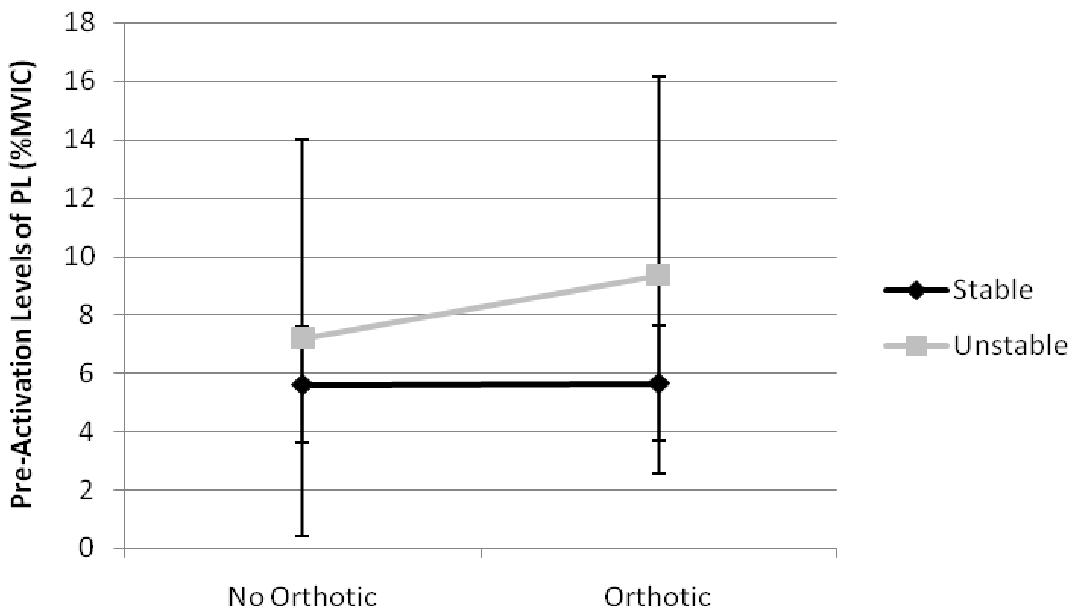


Table 5 Time to Stabilization Frontal Plane Anterior/Posterior (seconds)

Group	Condition		Interaction Effect		Orthotic Effect		Group Effect	
	No Orthotic	Orthotic	F	p	F	p	F	p
Stable (n=20)	1.69 ± 0.2	1.68 ± 0.21	1.044	.313	.728	.399	4.370	.043*
Unstable (n=20)	1.97 ± 0.57	2.05 ± 0.79						

* Denotes significance at p <.05 level

Figure 6 Time to Stabilization Frontal Plane Anterior/Posterior (seconds)

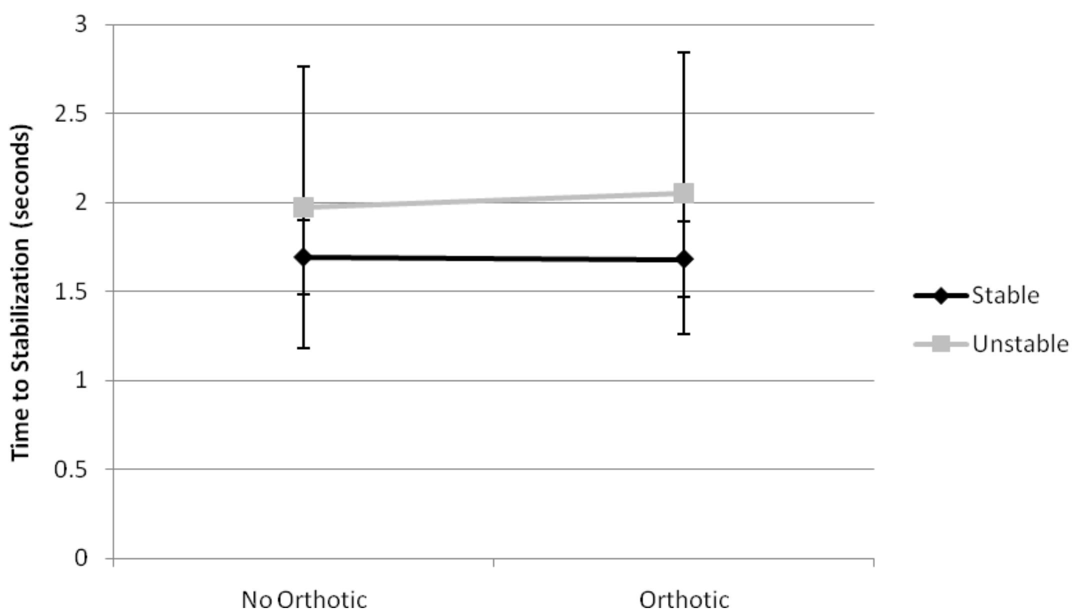


Table 6 Time to Stabilization Frontal Plane Medial/Lateral (seconds)

Group	Condition		Interaction Effect		Orthotic Effect		Group Effect	
	No Orthotic	Orthotic	F	p	F	p	F	p
Stable (n=20)	1.15 ± 0.05	1.15 ± 0.04	2.157	.150	1.683	.202	6.442	.015*
Unstable (n=20)	1.25 ± 0.15	1.28 ± 0.24						

* Denotes significance at p <.05 level

Figure 7 Time to Stabilization Frontal Plane Medial/Lateral (seconds)

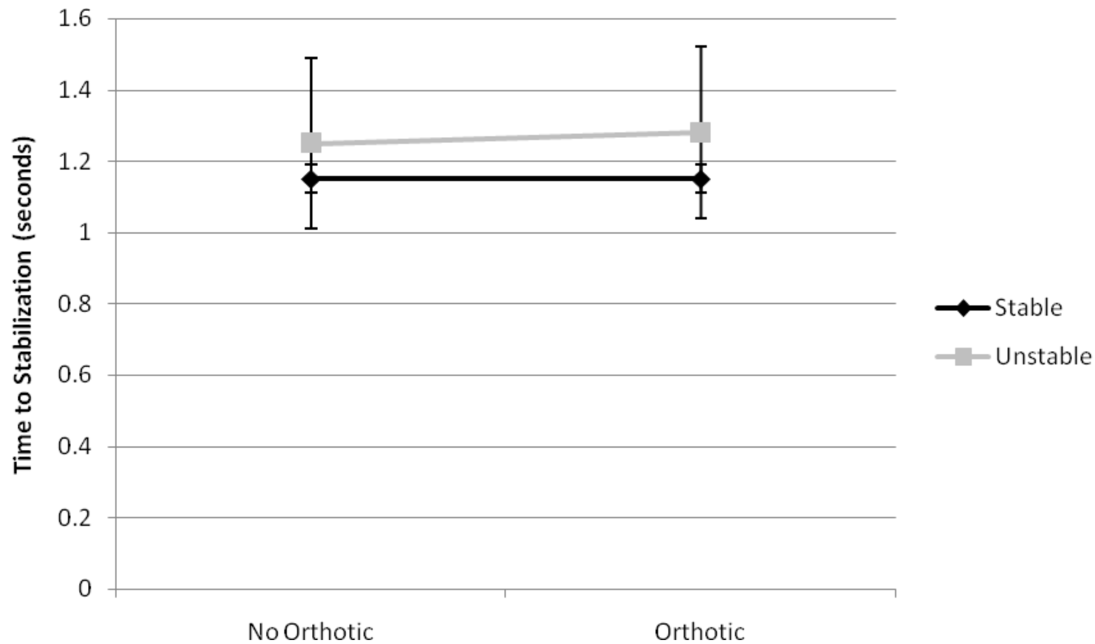


Table 7 Time to Stabilization Sagittal Plane Anterior/Posterior (seconds)

Group	Condition		Interaction Effect		Orthotic Effect		Group Effect	
	No Orthotic	Orthotic	F	p	F	p	F	p
Stable (n=20)	1.63 ± 0.11	1.65 ± 0.14	.616	.437	1.876	.179	4.947	.032*
Unstable (n=20)	1.90 ± 0.46	2.00 ± 0.78						

* Denotes significance at p <.05 level

Figure 8 Time to Stabilization Sagittal Plane Anterior/Posterior (seconds)

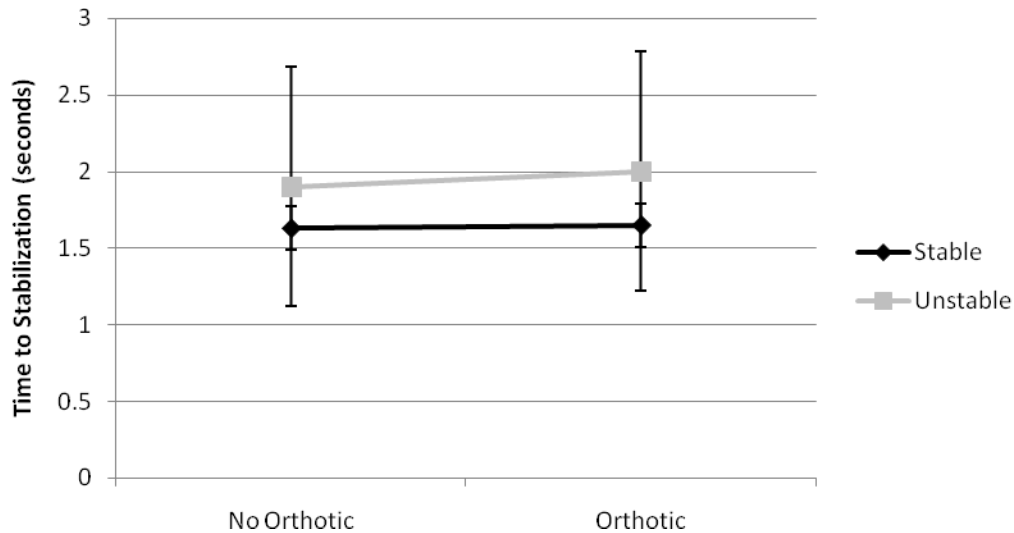
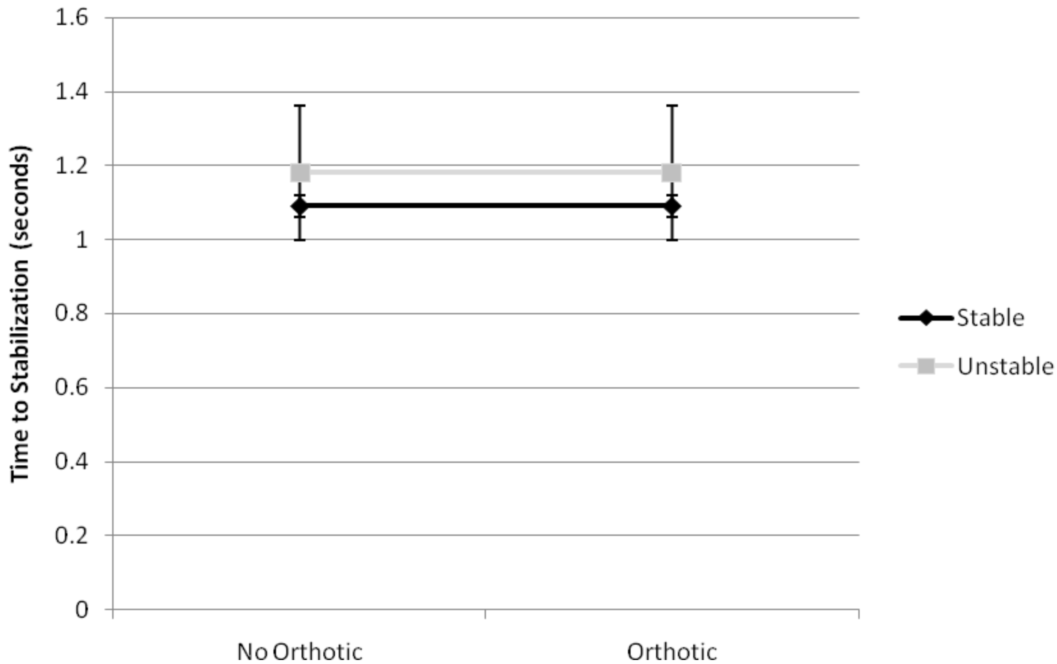


Table 8 Time to Stabilization Sagittal Plane Medial/Lateral (seconds)

Group	Condition		Interaction Effect		Orthotic Effect		Group Effect	
	No Orthotic	Orthotic	F	p	F	p	F	p
Stable (n=20)	1.09 ± 0.02	1.09 ± 0.03	.017	.898	.005	.945	5.674	.022*
Unstable (n=20)	1.18 ± 0.2	1.18 ± 0.18						

* Denotes significance at p <.05 level

Figure 9 Time to Stabilization Sagittal Plane Medial/Lateral (seconds)



CHAPTER V

DISCUSSION

The principle findings of this study are that over the counter orthotics do not acutely alter balance, pre-activation levels of the peroneus longus, or ankle joint stiffness. An over the counter orthotic with a medial post was placed into each subject's shoes to change the position of the calcaneous into a neutral position when weight bearing. (Prentice, 2004) These results indicate that there is significantly less ankle joint stiffness with the orthotics compared to without. We also observed that the unstable group exhibited a trend towards greater pre-activation levels than the stable group. Furthermore, the unstable group exhibited a greater anterior/posterior and medial/lateral TTS when compared to the stable group in both frontal and the sagittal plane jumps. Although few changes were observed as a result of orthotic placement, this could be explained by the possibility that foot position may not have been substantially altered by the presence of the orthotic in the shoes.

Stiffness

An orthotic with a medial post positions the calcaneous into a more neutral position, which can increase the joint space on the lateral side of the ankle in a person with a pronated foot. This new position, which is comparable to the subtalar neutral position will change the length of the muscles that surround the ankle. The length-tension relationship of muscle dictates the change in force generation at this new length. In addition, the length of the ligaments within the ankle joint is altered when the foot is re-aligned into subtalar neutral. For example, when a person with pronated feet is in a weight bearing position the peroneals are shortened as the fifth metatarsal is in a raised position above the 1st ray of the foot (pronation). Once a medial post orthotic is placed into the shoe the fifth metatarsal lies below the 1st ray of the foot and lengthens the peroneals. This new position should allow for a decrease in relative inversion compared to no orthotics, and therefore an increase in joint stiffness due to a change in ankle joint position into subtalar neutral. (M. T. Gross, 1995; M. T. Gross, et al., 2002; Prentice, 2004) We did not observe this phenomena in our study, nor did we observe an increase in muscle activation levels that would assist in increasing ankle joint stiffness. However, we did observe a decrease in ankle joint stiffness that may be explained by the medial post in the orthotic raising the calcaneous above the axis of rotation on the platform when compared to the no orthotics condition.

In addition to repositioning the ankle joint, it is possible that the addition of orthotics provided increased cutaneous stimulation to the sole of the foot. Others have previously assessed the effect of cutaneous stimulation on ankle joint stiffness. A study done by You et. al. applied circumferential ankle pressure (via a blood pressure cuff) to the lower 1/3 of the tibia in subjects with stable ankles and with chronic ankle instability. They found that this cutaneous pressure increased active ankle joint stiffness. They hypothesized that ankle joint stiffness and proprioception would increase with circumferential ankle pressure and would therefore increase postural stability during a monopedal stance. This study varied from ours in that they stimulated cutaneous receptors in the lower leg, whereas we used orthotics to stimulate cutaneous receptors in the foot. This study was similar to ours in that both of the studies used the same ankle cradle; however, You et al. investigated passive stiffness (ratio of applied static moment versus joint angular displacement) and active stiffness (biomechanical analyses of ankle joint motion after mediolateral perturbation), whereas our study only investigated the active ankle joint stiffness after perturbation. (You, Granata, & Bunker, 2004)

Another similar study to ours investigated ankle joint stiffness in elderly patients that have a history of falling, stable elderly patients, and young adults during an unperceived perturbation while standing. Ho and Bendrups found that the stable elderly patients and the young adults had similar ankle joint stiffness values, whereas the elderly patients with a history of falling had a greater ankle joint stiffness value. (Ho & Bendrups, 2002) This suggests that greater ankle stiffness may be detrimental in certain populations. Originally, we had anticipated that orthotics would decrease joint stiffness in patients with unstable ankles due to the change in the subtalar joint when the calcaneous is placed in a more inverted position. Our observation that orthotics decrease ankle stiffness may not benefit individuals with chronic ankle instability, but may have important implications for elderly patients at risk for falling.

Pre-activation Levels of the Peroneus Longus

Research would suggest that people would benefit from the activation of the peroneals prior to a perturbation because the peroneals would be in a preparatory state and would be more prone to react. When a person with a pronated foot is given an orthotic with a medial post to use in his or her shoe, the peroneals are placed in a more lengthened position.

Clinically, when the foot is passively perturbed into inversion, the peroneal muscles act eccentrically to decelerate the foot and ankle's movement into inversion. The peroneal muscles therefore play an important role in protecting the ankle joint from an inversion ankle sprain. A longer time to deceleration in people with unstable ankles may indicate decreased control, leading to further complications in the ankle because the protective role of the peroneals is diminished. (Beckman & Buchanan, 1995; Cordova & Ingersoll, 2003; Lynch, et al., 1996; Vaes, et al., 2002) Other studies have investigated the role of the peroneus longus in various tasks, such as a drop landing task. A study done by Fu and Hui-Chan found that subjects with unstable ankle had an increase in peroneal/TA co-activation levels during drop landing tasks. (Fu & Hui-Chan, 2007) Another study found an increase in peroneal activation (when normalized to each subject's MVIC) during walking with a sudden inversion mechanism in subjects with unstable ankles. (Ty Hopkins, McLoda, & McCaw, 2007) An increase in peroneal activity prior to inversion perturbation allows the ankle joint to become more active and therefore stiffer. Nevertheless, the tendency for subjects with unstable ankles to increase preactivation levels of the PL did not translate to increased joint stiffness.

Many studies have investigated the effects of an inversion perturbation on the peroneus longus reflex, but do not investigate the pre-activation levels. Muscle pre-activation may be an indicator of the neuromuscular systems preparatory state. The more prepared a system is for perturbation, the more primed the muscles are to react and protect the joint. Previous studies have investigated the initial reflexive response to imposed ankle inversion perturbation in both healthy subjects and unstable ankle subjects. Overall, these studies have found that inversion perturbation does not affect initial deceleration reflexive levels between the unstable and stable ankle groups. (Beckman & Buchanan, 1995; Cordova & Ingersoll, 2003; Ebig, et al., 1997; Vaes, et al., 2002) Unstable ankles would benefit the most from pre-activation of the peroneals, but no studies to date have shown an increase with any intervention. These findings were similar to those found in our study because both of the groups in our study did not demonstrate a significant difference in activation levels prior to an inversion perturbation. Our study demonstrated a trend that would suggest that people with unstable ankles have an increase in pre-activation levels when compared to stable ankles, but it is hard to state whether people with unstable ankles have developed this as a protective mechanism or if they have possessed this prior to injury. In our study, the orthotics possibly changed the position of the calcaneous, so that the peroneals were placed in a more lengthened position, but may not have affected the activation levels due to a low potency of the over the counter orthotics. This would suggest that reflexes and activation levels are not affected by orthotics. The pre-activation levels set-up the peroneals for reflexive activation; without early feedback from pre-activation, the reflexive response is diminished.

Time to Stabilization

Our study found that the unstable ankle group exhibited a longer TTS in each task when compared to the stable ankle group. The findings of my study agree with previous work suggesting that the unstable ankle group possesses a higher mean value for TTS in the M/L and A/P direction when compared to a stable ankle group. (Bernier, et al., 1997; Guskiewicz & Perrin, 1996; Hertel, et al., 2001b; S. E. Ross, et al., 2009) Each of these studies investigated the differences between stable and unstable ankles as defined by either acute ankle sprain (mild to moderate diagnosed ankle sprain within the past 6 weeks) or chronic, recently recurring ankle instability. Our study differed from previous studies in that we investigated the differences between stable and chronically unstable ankles, with each group being injury-free for the 6 months prior to testing. It is interesting that our subjects, despite the lack of a recent injury, continue to show deficits in TTS, similar to individuals with a more acute injury. Our unstable ankle group may take longer to stabilize due to reduced motor control because people with unstable ankles tend to use a hip strategy, rather than ankle strategy to assist with balance. If the muscular source for stability is coming from farther up the kinetic chain, it is harder to stabilize quickly because of the multiple joints and muscle groups involved. (Hertel, 2002)

Several studies have investigated the acute use of orthotics on COP changes during a postural sway test in subjects with unstable ankles. These studies found that orthotics did not alter COP sway in subjects with unstable ankles.(Guskiewicz & Perrin, 1996; Hertel, et al., 2001b) Each of these studies used various types of orthotics, ranging from rearfoot orthotics to custom-made orthotics, with each attempting to place the ankle into subtalar neutral. Studies have shown that subjects with stable ankles do not exhibit any significant changes in COP with the use of orthotics. (Guskiewicz & Perrin, 1996; Hertel, Denegar, Buckley, Sharkey, & Stokes, 2001a) Although TTS has been investigated in studies, there have been no studies to date that look at unstable versus stable ankles with orthotics. It is likely that the stable subjects in our group didn’t improve TTS significantly due to a floor effect, meaning that subjects were performing so well on the task, that little improvement was possible. If a floor effect was seen in the stable ankle group, than statistical significance might be underestimated because in both orthotic conditions the stable ankle group would exhibit similar TTS values.

Clinical Significance

The clinical significance related to the orthotic intervention may be limited due to few statistical differences. However, our statistically significant findings between unstable and stable ankles are supported by previous literature. This study suggests that the acute use of orthotics may have a negative influence on ankle joint stiffness. An orthotic with a medial post changes the position of the calcaneous and talus, which therefore changes the length of the lateral ankle ligaments and the peroneals. This new position raises the calcaneous above the axis of rotation when compared to no orthotics. This can allow for a larger torque to occur at the ankle joint. Importantly, our study suggests that over the counter orthotics for pronators may not provide enough change in foot position to produce a response that aids in protection from lateral ankle sprains. Clinically, it appears difficult to recommend over the counter orthotics for the treatment or prevention of lateral ankle sprains. However, over the counter orthotics may be used for other foot and ankle pathologies that were not investigated in this study. Also, there may be a case to be made for the benefits of a custom-made orthotic in that the clinician will ensure proper alignment of the foot and ankle in order to correct for the biomechanical abnormality specific to the patient.

Limitations

We feel that this research thesis possessed some limitations that need to be addressed in order to improve future research. First, this study only investigated the acute effects of orthotics, which means that given more time with the orthotics we may have seen more significant results. Second, this study only used subjects that possessed pronated feet, which is a group that does not typically see many inversion ankle sprains, especially when compared to people with supinated feet. Pronated feet are more common to find in the overall population, but supinated feet are more prone to ankle sprains. We had to assume that orthotics place these subjects into subtalar neutral, but we did not investigate if this phenomenon was truly observed. Lastly, we may not have seen significant findings with our TTS data due to possible over sampling at a rate of 1000Hz, rather than 180Hz as seen in other TTS research. (S. E. Ross, et al., 2009; S. E. Ross, et al., 2005; S. E. e. a. Ross, 2008)

Future Research Considerations

There have been a limited number of studies done investigating the effects of orthotics on the many different aspects that may affect the integrity of the ankle joint. Future research should investigate the effects of orthotics on different foot types, especially with those people that possess a supinated foot or high arch as this is the group that is most prone to lateral ankle sprains. Another place for future research is to investigate the effects of chronic use of orthotics on the same variables investigated in this study. This study investigated pre-activation levels of the peroneus longus, but other musculature that could be investigated are the gluteus medius (GM), the tibialis anterior, or the tibialis posterior, as they each serve in either protecting the ankle joint or can be used in a hip strategy for protecting the ankle (GM).

In addition to looking at other musculature, future research could investigate the reflexes that help to protect the ankle joint from injury and whether or not orthotics have an influence. Reflexes, balance, and muscle activation in a similar study would best be measured on subjects that participate in volleyball, basketball, and soccer, as these are the most at risk sports for lateral ankle sprains.

APPENDIX A

MANUSCRIPT

The Acute Effects of Subtalar Neutral on Pre-Activation Levels of the Peroneus Longus, Time to Stabilization, and Stiffness in Unstable and Stable Ankles

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The Acute Effects of Subtalar Neutral on Pre-Activation Levels of the Peroneus Longus, Time to Stabilization, and Stiffness in Unstable and Stable Ankles

Context: Excessive subtalar joint pronation can lead to numerous overuse injuries in the lower extremity. For years orthotics have been used to being the ankle into subtalar joint neutral. This study investigated the effects of over the counter orthotics on ankle joint stiffness, pre-activation levels of the peroneus longus, and time to stabilization in unstable and stable ankles in order to better understand if orthotics is an effective form of prevention against ankle sprains.

Objective: The purpose of this study was to examine the effects of over the counter orthotics on pre-activation levels of the peroneus longus, muscle stiffness, and time to stabilization. Limited studies to date have been conducted investigating the effects of orthotics on ankle joint stiffness, balance, and the pre-activation levels of the peroneus longus.

Design: A pretest, posttest design was used. Subjects reported for a total of two sessions, a pre-screening session and a testing session. The testing tasks included: 1) A single leg drop landing task from a 30cm box in the a) frontal and b) sagittal planes and 2) ankle stiffness testing using a custom-built ankle cradle with inversion perturbation. All trials were done 5 times each and an average value was taken for data reduction and analysis. Separate 2X2 Repeated Measures ANOVAs were used for each dependent variable.

Setting: Sports Medicine Research Laboratory at the University of North Carolina, Chapel Hill

Patients/Participants: Forty healthy active adult volunteers participated in this study (20 unstable ankles and 20 stable ankles)

Intervention(s): Subjects were fitted with a green medial post Superfeet® orthotic for pronated feet.

Results: Results of the statistical analyses revealed no interaction effects of orthotics and group on stiffness or pre-activation levels of the PL. No group differences were observed concerning pre-activation levels, TTS, or ankle joint stiffness; however, there was a significant effect of orthotic condition on stiffness, with ankle joint stiffness decreasing in both groups when wearing orthotics. There was also a significant effect of group on TTS, with the unstable ankle group taking longer to stabilize than the stable ankle group.

Conclusion: In conclusion this study indicated that there was significantly less ankle joint stiffness with the orthotics compared to without. This was evident in both stable and unstable ankles. The unstable group exhibited trends towards a larger increase in mean values from the no orthotic condition to the orthotic condition regarding pre-activation levels, suggesting the orthotics may have a clinically significant impact on unstable ankles pre-activation levels of the peroneus longus. The TTS data indicated that in each task the unstable group exhibited a greater mean value in TTS when compared to the stable group.

Introduction:

Medical professionals have prescribed custom made orthotics for different lower extremity conditions for nearly 40 years (Bates, et al., 1979; Richie & Olson, 1993). Orthotics are often prescribed to individuals with chronic ankle instability (CAI) in an effort to bring the foot into a neutral position or restoring proper ankle alignment (called subtalar neutral) which allows the foot and ankle to function in the most advantageous way (Hertel, 2002; Richie, 2007; Richie & Olson, 1993). If a person has a flat foot (pronator) or a high arch (supinator) then an orthotic can be used to correct for this foot abnormality and allow for more comfort and stability. Chronic ankle instability can be defined in one of two ways; the first is mechanical instability which involves trauma to the soft tissue structures of the ankle resulting in greater laxity in the subtalar joint which can be explained upon examination by a positive anterior drawer and/or talar tilt (Hertel, et al., 2001b; Monaghan, et al., 2006). The second type of instability is functional instability which can be described subjectively as a feeling of “giving way” but upon examination may not display a positive anterior drawer and/or talar tilt (Hertel, et al., 2001b; Monaghan, et al., 2006). Studies suggest an association between mechanical and functional instability as mechanical instability may lead to functional instability over time (Hertel, 2002; Richie & Olson, 1993). Studies have also suggested a strong effect from the use of orthotics in populations affected by chronic ankle instability. Specifically, orthotics may reduce pain, postural sway, and decrease the time in which reflexes in the peroneal muscles occur in individuals with CAI (Hertel, et al., 2001b; Ochsendorf, et al., 2000; Richie & Olson, 1993).

Although studies have examined the effect of orthotics on diminishing the symptoms of chronic ankle instability, there are a limited number of studies that address the role of orthotics on biomechanical and muscle activity measures (e.g., peroneal latency, peroneal pre-activation, and center of pressure displacement in the medial and lateral direction). This is important, because orthotics return the subtalar joint into a neutral position, which theoretically will encourage correct biomechanics of the foot and ankle and may therefore decrease the risk of an ankle injury.

Time to stabilization (TTS) is best described as the time it takes a subject to completely regain balance after landing from a height.. (S. E. Ross, et al., 2005; Wikstrom, et al., 2006) Subjects with functional ankle instability will often require a greater amount of time to stabilize after a single leg hop test. (S. E. Ross & Guskiewicz, 2006; S. E. Ross, et al., 2005; Wikstrom, et al., 2006) Similar to the hop task, some researchers have investigated the time to stabilization after a single leg drop landing task. The results from these studies are similar to those researchers who use the single leg hop task. (Wikstrom, et al., 2006) Each of these studies investigated the differences between subjects with ankle instability and compared them to a healthy set of subjects. In general, a healthy subject swayed less and took less time to return back to baseline. (Hertel, et al., 2001b; S. E. Ross & Guskiewicz, 2006; S. E. Ross, et al., 2005; Wikstrom, et al., 2006)

Muscle stiffness is an innate mechanism that combines both passive and active activation of muscles. Muscle stiffness has been described as being either intrinsic or reflex mediated (Rack & Westbury, 1969). Intrinsic muscle stiffness is what exists during the time of muscle lengthening due to actin-myosin bonds of the muscle fibers (Nichols & Houk, 1976). The intrinsic property of muscle stiffness describes how active a muscle is at the time of use. The reflex mediated response is the stiffness acquired after the feedback system has been activated (Hoffer & Andreassen, 1981). Joint stability is affected by several factors, including joint stiffness. Stiffness is described as the ratio of force response that results from and resists mechanical stretch (Zinder, et al., 2007). The stiffness of the active and passive structures surrounding a joint contributes to the biomechanical stability of a joint, especially at the end ranges. A measurement of the stiffness of the ankle joint could therefore be considered a direct measurement of ankle joint stability. When the ankle is placed into a more biomechanical advantageous position (i.e. subtalar neutral via orthotics) then the peroneals will be placed at an optimal length, as opposed to an elongated position with excessive pronation. When a joint is placed into a more biomechanical advantageous position, studies have shown that this can increase muscular and joint stiffness.

Statement of the Problem:

Although studies have examined the effect of custom-made orthotics on chronic ankle instability, there has been limited work to address the role of over the counter orthotics on ankle joint stiffness, pre-activation levels of the peroneus longus, and time to stabilization (TTS) in the frontal and sagittal planes. This is important, because orthotics place the subtalar joint into a neutral position, which encourages correct biomechanics of the foot and ankle and may therefore decrease the risk of an ankle injury. Therefore the purpose of this study was to determine if altering STJ alignment with more affordable over the counter orthotics would influence factors purported to minimize chronic ankle instability.

Methods:

Subjects

An *a priori* power analysis gave a power level of 0.80 with 20 subjects per group. Power was investigated using previous ankle instability and orthotics studies on postural sway. (Baier & Hopf, 1998; Guskiewicz & Perrin, 1996) We tested 43 subjects divided into a stable ankle group and an unstable ankle group. We excluded one subject from the unstable group and two subjects from the stable group as a result of incomplete data resulting in only 20 subjects per group being included in all analyses. The subjects were divided into 2 groups, each consisting of 20 qualified participants. The unstable ankle group consisted of 10 female and 10 male subjects who scored less than 94 on the functional ankle disability index (FADI) test for functional ankle instability and were free from injury at the time of testing, as well as for the past 6 months. (Hale & Hertel, 2005) The stable ankle group (11 females and 9 males) had pronated feet, with no history of ankle sprains. Subjects in the stable ankle group were matched to those in the unstable ankle group by height and weight. Subject demographic data are presented in Table 1. The only statistically significant difference between the two groups was the navicular drop score ($t(38) = -2.685$, $p = .011$), with the unstable ankle group having the greater mean value. Subject navicular drop data are presented in Table 2.

Subjects were recruited from the University of North Carolina-Chapel Hill population with the inclusion criteria of: 1) being between the ages of 18 and 25 years old, 2) student, faculty, or staff member, and 3) a recreational athlete, who exercised at least 3 days per week for at least 30 minutes at a time. The exclusion criteria for this study included: 1) documented lower extremity injury in the past 6 months, 2) lower extremity surgery in the past year, 3) currently using orthotics, 4) currently rehabilitating a lower extremity injury, 5) do not meet the criteria for a recreationally active athlete, 6) any neurological disorder (vertigo, etc) that affected balance, or 7) had a neutral or supinated foot. Subjects were recruited on a volunteer basis via email and flyers. Each subject signed an informed consent form approved by the University of North Carolina–Chapel Hill Institutional Review Board committee prior to beginning the study.

Procedures and Instrumentation

This study involved two sessions in the Sports Medicine Research Lab (SMRL). The first was a pre-screening session for all interested potential subjects and a second session consisted of testing for qualified participants. The second session used a pre-test/post-test format in which subjects performed the same tasks first without and then with foot orthotics.

Screening for subjects and foot type

Potential subjects who answered the flyer, email, or in class announcement were screened prior to participation to evaluate for current lower extremity injuries, a history of surgery within the past year, lower extremity injury in the past 6 months, and to evaluate navicular drop (amount of pronation). During this screening exam, potential subjects filled out the informed consent and demographic data information forms. After filling out the forms the navicular drop test was performed by having the subject sit in a chair with their back supported, with a 90 degree angle at the hip and knee and the feet placed flat on the floor.

The medial and lateral borders of the talus were palpated while inverting and everting the foot until both prominences were felt equally, achieving subtalar neutral. Once subtalar neutral was established, a mark was made on the navicular tubercle and also on an index card held next to the foot that extended to the floor. The subject then stood up, marched in place 5 times, and finally stood still with his or her feet shoulder width apart to be re-measured. This process was repeated 3 times for each subject and the average difference (e.g., between sitting and standing measurement) was taken as the subject's navicular drop score (pronated (≥10 mm), neutral (5–9 mm), or supinated (≤4 mm)). (Cote, et al., 2005; Hunter, 2000; Kelly, 2003) Only individuals with pronated feet qualified for participation in the study, as people with pronated or flat feet have the highest frequency amongst this age population. (McManus, et al., 2004)

Potential subjects filled out the FADI scale questionnaire to determine the presence of CAI. (Hale & Hertel, 2005) The questionnaire consists of 12 questions that compare the most frequently injured ankle to the contralateral ankle in a scaled range from 0=much more than the other ankle, and 4= much less than the other ankle (Appendix B). Those subjects that scored under 90% or 94 out of 104 possible points were considered to possess chronic functional ankle instability. (Hale & Hertel, 2005) Once the unstable ankle group had been established, a control group was formed in order to match the unstable ankle group according to the criteria previously stated.

Pre-testing

Qualified subjects returned to the lab shortly after the arrival of his or her orthotics (around 7-10 days after the pre-screening session), to receive the orthotics and undergo testing. Superfeet Inc® donated their green orthotic with a medial post designed for people with pronated feet. The orthotics were intended to help correct for pronation by positioning the ankle in subtalar neutral during the post-testing data collection. Each subject wore his or her self-owned pair of athletic shorts, shirt, and athletic shoes throughout both the pre-testing (no orthotics) and post-testing (with orthotics) sessions.

Collection of electromyographic (EMG) data involved electrode placement over the peroneus longus (PL), tibialis anterior (TA), and lateral gastrocnemius (LG) musculature. A manual muscle test (MMT) was used in order to find the muscle bellies of the PL, LG, and TA. Electrodes were placed parallel to the muscle fiber orientation and over a flat part of the mid-belly of the PL, TA, and LG as established by the manual muscle test done prior to placement. (Benesch, et al., 2000; Mora, et al., 2003; Rainoldi, et al., 2004) Subjects had their skin prepared using a disposable razor to remove hair from the area and were cleaned with alcohol wipes in order to ensure good contact with the skin. Each electrode was secured with pre-wrap and tape in order to stabilize the placement of the Ag/AgCl surface EMG electrode (Delsys Inc.,Boston, MA) on the skin. Electrodes were then connected to a transmitter on a belt attached around the waist, which was worn for each task. A maximum voluntary isometric contraction (MVIC) was recorded from each muscle group for each subject by performing 3 trials for 5 seconds each. The electrodes remained in the same testing locations as during the post-testing session.

Performed Tasks

Each subject performed the following 3 tasks: 1) ankle joint stiffness using a custom-built ankle cradle with unanticipated inversion perturbation and 2) drop landing from a 30cm box in the frontal plane and sagittal plane. The order of these tasks was counterbalanced between each subject. Each task was performed 5 times and an average was taken for analysis.

Ankle Joint Stiffness Assessment

The ankle joint stiffness assessment was performed with a custom-built ankle cradle that perturbed the foot with transient oscillations (Figure 1). (Zinder, et al., 2007) The in vivo ankle cradle has been shown to have an ICC (2,1) reliability of .96 from trial to trial and an ICC (2,k) reliability of .93 from day to day, which means that it is fairly accurate at predicting ankle joint stiffness during ankle perturbation. (Zinder, et al., 2007) Prior to the initiation of the ankle oscillation, we measured the pre-activation level of the affected PL muscle.

Each subject was placed in a seated position with 90 degrees of hip and knee flexion with 50% of their bodyweight placed above his or her tibia. EMG electrodes remained placed over the TA, PL, and LG of the testing leg. The data acquisition began 5 seconds after the subject was seated in the unperturbed position with their eyes closed. A weighted ball was placed down a tube placed on a stand to the wing of interest; once the ball passed a photoelectric eye, the data collection began and then ended 3 seconds after the perturbation occurred. The subtalar joint was free to move because the foot rested on top of the wooden plate.

Testing was repeated to complete three external inertial conditions (0.000, 0.065 and 0.131 kg/cm2) which were achieved by adding weights to the sides of the cradle. (Zinder, et al., 2007) As the ankle cradle moved in response to the dropped ball, we collected the frequency and decay of oscillations measured by the ankle cradle to compute ankle joint stiffness. EMG data was collected 250ms prior to the photoelectric eye trigger being switched on to determine pre-activation levels of the peroneus longus.

Drop Landing Task

Prior to beginning the drop landing task a static single leg balance trial was collected for 10 seconds in order to have a baseline of comparison for the drop landing task. The static trial involved subjects walking onto a forceplate (Bertec Corp, Columbus, OH) to assume a single limb stance, with hands on hips, and the eyes open and focused on the wall straight ahead. Subjects then performed a single leg jump off a 30cm box, for a horizontal distance equal to 50% of their body height, to land on the same leg that they jumped off of. During the drop landing task, subjects landed on a forceplate, and held a static position for 10 seconds. A rest period of 30 seconds was used between each trial. Testing was done in both the frontal (jump towards the tested side) and sagittal (jump forwards) planes (Figures 2 and 3). Recording for the drop landing task began when the subject landed on the forceplate (Fz >10N) and ended 10 seconds after the subject landed. If the subject placed his or her non-tested foot down on the forceplate or did not land correctly, then that trial was deleted and a new one was performed.

Tested Side

The unstable ankle group used the side which possessed the greatest amount of instability based on the FADI scale. This side was then defined as either being the subject's dominant or non-dominant side according to our definition of the dominant foot was the foot that the subject would use to kick a ball for distance. The stable ankle group was then matched for foot dominance of the unstable ankle group.

Post-testing

After performing each task without orthotics, subjects were provided with their orthotics. The orthotics were trimmed to fit the shoes that the subject wore during the pre-testing session, and subjects then wore the orthotics for a 10 minute acclimatization period. All testing (ankle joint stiffness assessment and time to stabilization) was then repeated in the same order as the pre-testing session.

Data Collection

All EMG, ankle joint stiffness, and kinetic forceplate data were collected using the DataPac 2K2 software program (Run Technologies, Mission Viejo, CA). There were 6 channels used to collect kinetic data from the forceplate (forces in the X, Y, and Z direction, as well as moments in the X, Y, and Z direction). Only forces in the Fx and Fy direction were used for analysis. For the sagittal plane jumps, Fx represented the medial/lateral direction and

Fy represented the anterior/posterior direction. In the frontal plane jumps, Fx represented the anterior/posterior direction and Fy represented the medial/lateral direction. One channel was used to collect data from the potentiometer and another was linked to the trigger on the ankle cradle. Three additional channels were used for each of the muscles investigated in this study (PL, TA, and LG).

Data Reduction

Pre-activation levels of the peroneus longus (PL), and ankle joint stiffness values were reduced using custom-made MabLab programs (Mathworks, Natick, MA). EMG data (MVIC and pre-activation levels of the PL) were corrected for DC bias, bandpass filtered using 20-350Hz 4^{th} order Butterworth filter, and smoothed using a 20ms root-mean-square sliding window function. The raw data from DataPac were exported in text format and MVIC values for each muscle were calculated using a custom MabLab program in which the MVIC value was calculated by taking an average of the acquired 3 trials. Pre-activation of the PL was determined by taking the average level of activation during the 250ms preceding trigger activation of the ankle cradle. This value was then normalized to each subject's MVIC value.

Ankle joint stiffness was reduced by measuring the transient motion oscillations that were recorded using a single turn potentiometer (Clarostat, Mexico City, Mexico) aligned with the axis of rotation of the cradle. Raw ankle motion data in text format were exported from DataPac to be used in a custom MatLab program helped to find the decay in the oscillations and frequency of oscillations that occurred during the ankle stiffness task. The processed data from the MatLab program was then placed into an excel spreadsheet and utilized the following equation to plot and assess the ankle's inertial value: $I_{EXT} = ((k + MgL)/ w^2_n) - I_o$. The I_{EXT} represents the added external inertia versus the inverse square of natural frequency ($1/ w^2_n$). The pendulum behavior was represented by MgL and k represented the stiffness value of the regression line. Lastly, the I_o value represented inertia of the ankle and cradle, which was extracted by using the intercept of the regression line produced.

The time to stabilization was calculated by comparing the range of variance (ROV) of sway in the medial/lateral direction and anterior/posterior direction during the static trial of each orthotic condition to the drop landing task variance of sway. Raw data from DataPac was exported in Excel format and made tab delimited in an excel spreadsheet. This data was then used to find the ROV value from the 4^{th}-6^{th} seconds of the static trials. The ROV average was taken for both stable and unstable subjects in both the orthotic and no orthotic condition during the static trials. (S. E. Ross, et al., 2009; S. E. Ross, et al., 2005) This ROV value was used to compare the TTS data to each testing condition for each subject. Time to stabilization data were reduced and calculated using customized LabVIEW program (National Instruments; Austin, TX).

Data Analysis

All data was analyzed using SPSS version 16 statistical software (Chicago, IL) using an a priori alpha level of 0.05. The independent variables for this study included: 1) orthotics and no orthotics and 2) unstable and stable ankle subjects. The dependent variables for this study included: 1) ankle joint stiffness, 2) pre-activation levels of the PL, and 3) Time to

Stabilization (TTS) after drop landing task performed in the a) frontal plane (anterior/posterior and medial/lateral direction) and b) sagittal plane (anterior/posterior and medial/lateral direction). Six separate 2X2 mixed model ANOVAs were used to analyze the data.

Results:

Ankle joint stiffness

Means and standard deviations for ankle joint stiffness data are represented in Table 3 and Graph 1. For ankle joint stiffness there was no statistically significant orthotic x group interaction effect ($F_{1,38}$= .219, p= .642). There was also no statistically significant group difference ($F_{1,38}$=1.245, p=.272). There was a statistically significant difference of orthotics on stiffness ($F_{1,38}$=8.117, p=.007); whereby, stiffness decreased in both groups when wearing orthotics.

Pre-Activation Levels of Peroneus Longus

Means and standard deviations for pre-activation of the peroneus longus (PL) data are presented in Table 4 and Graph 2. No statistically significant group x orthotic interaction was observed for pre-activation levels of the PL ($F_{1,38}$= . 1.513, p= .226). There also was not a significant effect of group ($F_{1,38}$=3.932, p=.055) or orthotic condition ($F_{1,38}$=1.661, p=.205) on pre-activation levels of the PL .

Time to Stabilization

Frontal Plane Anterior/Posterior

Means and standard deviations for time to stabilization (TTS) in the frontal plane in the anterior/posterior direction are represented in Table 5 and Graph 3. No group x orthotic interaction was observed for TTS in frontal plane in the anterior/posterior direction ($F_{1,38}$=1.044, p= .313). There also was not a significant effect of orthotic ($F_{1,38}$=.728, p=.399). There was a statistically significant difference in the effect of group ($F_{1,38}$=4.370, p=.043) observed for TTS in frontal plane in the anterior/posterior direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Frontal Plane Medial/Lateral

Means and standard deviations for time to stabilization (TTS) in the frontal plane in the medial/lateral direction are represented in Table 6 and Graph 4. No group x orthotic interaction was observed for TTS in frontal plane in the medial/lateral direction ($F_{1,38}$=2.157, p=.150). There also was not a significant effect of orthotic ($F_{1,38}$=1.683, p=.202). There was a statistically significant difference in the effect of group ($F_{1,38}$=6.442, p=.015) observed for TTS in frontal plane in the medial/lateral direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Sagittal Plane Anterior/Posterior

Means and standard deviations for time to stabilization (TTS) in the sagittal plane in the anterior/posterior direction are represented in Table 7 and Graph 5. No group x orthotic interaction was observed for TTS in sagittal plane in the anterior/posterior direction

($F_{1,38}$=.616, p=.437). There also was not a significant effect of orthotic ($F_{1,38}$=1.876, p=.179). There was a statistically significant difference in the effect of group ($F_{1,38}$=4.947, p=.032) observed for TTS in sagittal plane in the anterior/posterior direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Sagittal Plane Medial/Lateral

Means and standard deviations for time to stabilization (TTS) in the sagittal plane in the medial/lateral direction are represented in Table 8 and Graph 6. No group x orthotic interaction was observed for TTS in sagittal plane in the medial/lateral direction ($F_{1,38}$=.017, p=.898). There also was not a significant effect of orthotic ($F_{1,38}$=.005, p=.945). There was a statistically significant difference in the effect of group ($F_{1,38}$=5.674, p=.022) observed for TTS in sagittal plane in the medial/lateral direction such that the unstable ankle group took longer to stabilize across orthotic conditions.

Discussion:

The principle findings of this study are that over the counter orthotics do not acutely alter balance, pre-activation levels of the peroneus longus, or ankle joint stiffness. An over the counter orthotic with a medial post was placed into each subject's shoes to change the position of the calcaneous into a more inverted position when weight bearing. (Prentice, 2004) The altered position of the calcaneous changes its relationship with the talus to a more neutral position. These results indicate that there is significantly less ankle joint stiffness with the orthotics compared to without. We also observed that the unstable group exhibited a trend towards greater pre-activation levels than the stable group. Furthermore, the unstable group exhibited a greater anterior/posterior and medial/lateral TTS when compared to the stable group in both frontal and the sagittal plane jumps. Although few changes were observed as a result of orthotic placement, this could be explained by the possibility that foot position was not altered by the presence of the orthotic in the shoes.

Stiffness

An orthotic with a medial post changes the calcaneous into a more inverted position, which can increase the joint space on the lateral side of the ankle in a person with a pronated foot. This new position, which is comparable to the subtalar neutral position will change the length of the muscles that surround the ankle. The length-tension relationship of muscle dictates the change in force generation at this new length. In addition, the length of the ligaments within the ankle joint is altered when the foot is re-aligned into subtalar neutral. For example, when a person with pronated feet is in a weight bearing position the peroneals are shortened as the fifth metatarsal is in a raised position above the 1st ray of the foot (pronation). Once a medial post orthotic is placed into the shoe the fifth metatarsal lies below the 1st ray of the foot and lengthens the peroneals. This new position can allow for more a decrease in relative joint motion compared to no orthotics, and therefore an increase in joint stiffness due to a change in ankle joint position into subtalar neutral. (M. T. Gross, 1995; M. T. Gross, et al., 2002; Prentice, 2004) We did not observe this phenomena in our study, nor did we observe an increase in muscle activation levels that would assist in increasing ankle joint stiffness. However, we did observe a decrease in ankle joint stiffness that may be explained by the medial post in the orthotic raising the calcaneous above the axis of rotation on the platform when compared to the no orthotics condition. This increase in distance from the axis of rotation allows for a larger torque to occur at the ankle joint.

In addition to repositioning the ankle joint, it is possible that the addition of orthotics provided increased cutaneous stimulation to the sole of the foot. Others have previously assessed the effect of cutaneous stimulation on ankle joint stiffness. A study done by You et. al. applied circumferential ankle pressure (via a blood pressure cuff) to the lower 1/3 of the tibia in subjects with stable ankles and with chronic ankle instability. They found that this cutaneous pressure increased active ankle joint stiffness. They hypothesized that ankle joint stiffness and proprioception would increase with circumferential ankle pressure and would therefore increase postural stability during a monopedal stance. This study varied from ours in that they stimulated cutaneous receptors in the lower leg, whereas we used orthotics to stimulate cutaneous receptors in the foot. This study was similar to ours in that both of the studies used the same ankle cradle; however, You et al. investigated passive stiffness (ratio of applied static moment versus joint angular displacement) and active stiffness (biomechanical analyses of ankle joint motion after mediolateral perturbation), whereas our study only investigated the active ankle joint stiffness after perturbation. (You, et al., 2004)

Another similar study to ours investigated ankle joint stiffness in elderly patients that have a history of falling, stable elderly patients, and young adults during an unperceived perturbation while standing. Ho and Bendrups found that the stable elderly patients and the young adults had similar ankle joint stiffness values, whereas the elderly patients with a history of falling had a greater ankle joint stiffness value. (Ho & Bendrups, 2002) This suggests that greater ankle stiffness may be detrimental in certain populations. Originally, we had anticipated that orthotics would decrease joint stiffness in patients with unstable ankles due to the change in the subtalar joint when the calcaneous is placed in a more inverted position. Our observation that orthotics decrease ankle stiffness may not benefit individuals with chronic ankle instability, but may have important implications for elderly patients at risk for falling.

Pre-activation Levels of the Peroneus Longus

Research would suggest that people would benefit from the activation of the peroneals prior to a perturbation because the peroneals would be a preparatory state and would be more prone to react. When a person with a pronated foot is given an orthotic with a medial post to use in his or her shoe, the peroneals are placed in a lengthened position. Clinically, when the foot is passively perturbed into inversion, the peroneal muscles act eccentrically to decelerate the foot and ankle's movement into inversion. The peroneal muscles therefore play an important role in protecting the ankle joint from an inversion ankle sprain. A longer time to deceleration in people with unstable ankles may indicate decreased control, leading to further complications in the ankle because the protective role of the peroneals is diminished. (Beckman & Buchanan, 1995; Cordova & Ingersoll, 2003; Lynch, et al., 1996; Vaes, et al., 2002)   Other studies have investigated the role of the peroneus longus in various tasks, such as a drop landing task. A study done by Fu and Hui-Chan found that subjects with unstable ankle had an increase in peroneal/TA co-activation levels during drop landing tasks. (Fu & Hui-Chan, 2007) Another study found an increase in peroneal activation (when normalized to each subject's MVIC) during walking with a sudden inversion mechanism in subjects with unstable ankles. (Ty Hopkins, et al., 2007) An increase in peroneal activity prior to inversion perturbation allows the ankle joint to become more active and therefore stiffer. This stiffness can be used to protect the ankle joint against injury.

Many studies have investigated the effects of an inversion perturbation on the peroneus longus reflex, but do not investigate the pre-activation levels. Muscle pre-activation may be an indicator of the neuromuscular systems preparatory state. The more prepared a system is for perturbation, the more primed the muscles are to react and protect the joint. Previous studies have investigated the initial reflexive response to imposed ankle inversion perturbation in both healthy subjects and unstable ankle subjects. Overall, these studies have found that inversion perturbation does not affect initial deceleration reflexive levels between the unstable and stable ankle groups. (Beckman & Buchanan, 1995; Cordova & Ingersoll, 2003; Ebig, et al., 1997; Vaes, et al., 2002) Unstable ankles would benefit the most from pre-activation of the peroneals, but no studies to date have shown an increase with any intervention. These findings were similar to those found in our study because both of the groups in our study did not demonstrate a significant difference in activation levels prior to an inversion perturbation. Our study demonstrated a trend that would suggest that people with unstable ankles have an increase in pre-activation levels when compared to stable ankles, but it is hard to state whether people with unstable ankles have developed this as a protective mechanism or if they have possessed this prior to injury. In our study, the orthotics possibly changed the position of the calcaneous, so that the peroneals were placed in a more shortened position, but did not affect the activation levels due to a low potency of the over the counter orthotics. This would suggest that reflexes and activation levels are not affected by orthotics. The pre-activation levels set-up the peroneals for reflexive activation; without early feedback from pre-activation, the reflexive response is diminished.

Time to Stabilization

Our study found that the unstable ankle group exhibited a longer TTS in each task when compared to the stable ankle group. The findings of my study agree with previous work suggesting that the unstable ankle group possesses a higher mean value for TTS in the M/L and A/P direction when compared to a stable ankle group. (Bernier, et al., 1997; Guskiewicz & Perrin, 1996; Hertel, et al., 2001b; S. E. Ross, et al., 2009) Each of these studies investigated the differences between stable and unstable ankles as defined by either acute ankle sprain (mild to moderate diagnosed ankle sprain within the past 6 weeks) or chronic, recently recurring ankle instability. Our study differed from previous studies in that we investigated the differences between stable and chronically unstable ankles, with each group being injury-free for the 6 months prior to testing. It is interesting that our subjects, despite the lack of a recent injury, continue to show deficits in TTS, similar to individuals with a more acute injury. Our unstable ankle group may take longer to stabilize due to reduced motor control because people with unstable ankles tend to use a hip strategy, rather than ankle strategy to assist with balance. If the muscular source for stability is coming from farther up the kinetic chain, it is harder to stabilize quickly because of the multiple joints and muscle groups involved. (Hertel, 2002)

Several studies have investigated the acute use of orthotics on COP changes during a postural sway test in subjects with unstable ankles. These studies found that orthotics did not alter COP sway in subjects with unstable ankles.(Guskiewicz & Perrin, 1996; Hertel, et al., 2001b) Each of these studies used various types of orthotics, ranging from rearfoot orthotics to custom-made orthotics, with each attempting to place the ankle into subtalar neutral. Studies have shown that subjects with stable ankles do not exhibit any significant changes in COP with the use of orthotics. (Guskiewicz & Perrin, 1996; Hertel, et al., 2001a) Although TTS has been investigated in studies, there have been no studies to date that look at unstable versus stable ankles with orthotics. It is likely that the stable subjects in our group didn't improve TTS significantly due to a floor effect, meaning that subjects were performing so well on the task, that little improvement was possible. If a floor effect was seen in the stable ankle group, than statistical significance might be underestimated because in both orthotic conditions the stable ankle group would exhibit similar TTS values.

Clinical Significance

The clinical significance related to the orthotic intervention may be limited due to few statistical differences. However, our statistically significant findings between unstable and stable ankles are supported by previous literature. This study suggests that the acute use of orthotics may have a negative influence on ankle joint stiffness. An orthotic with a medial post changes the position of the calcaneous and talus, which therefore changes the length of the lateral ankle ligaments and the peroneals. This new position allows raises the calcaneous above the axis of rotation when compared to no orthotics. This can allow for a larger torque to occur at the ankle joint. Importantly, our study suggests that over the counter orthotics for pronators may not provide enough change in foot position to produce a response that aids in protection from lateral ankle sprains. Clinically, it appears difficult to recommend over the counter orthotics for the treatment or prevention of lateral ankle sprains. However, over the counter orthotics may be used for other foot and ankle pathologies that were not investigated in this study. Also, there may be a case to be made for the benefits of a custom-made orthotic in that the clinician will ensure proper alignment of the foot and ankle in order to correct for the biomechanical abnormality specific to the patient.

Limitations

We feel that this research thesis possessed some limitations that need to be addressed in order to improve future research. First, this study only investigated the acute effects of orthotics, which means that given more time with the orthotics we may have seen more significant results. Second, this study only used subjects that possessed pronated feet, which is a group that does not typically see many inversion ankle sprains, especially when compared to people with supinated feet. Pronated feet are more common to find in the overall population, but supinated feet are more prone to ankle sprains. We had to assume that orthotics place these subjects into subtalar neutral, but we did not investigate if this phenomenon was truly observed. Lastly, we may not have seen significant findings with our TTS data due to possible over sampling at a rate of 1000Hz, rather than 180Hz as seen in other TTS research. (S. E. Ross, et al., 2009; S. E. Ross, et al., 2005; S. E. e. a. Ross, 2008)

Future Research Considerations

There have been a limited number of studies done investigating the effects of orthotics on the many different aspects that may affect the integrity of the ankle joint. Future research should investigate the effects of orthotics on different foot types, especially with those people that possess a supinated foot or high arch as this is the group that is most prone to lateral ankle sprains. Another place for future research is to investigate the effects of chronic use of orthotics on the same variables investigated in this study. This study investigated pre-activation levels of the peroneus longus, but other musculature that could be investigated are the gluteus medius (GM), the tibialis anterior, or the tibialis posterior, as they each serve in either protecting the ankle joint or can be used in a hip strategy for protecting the ankle (GM).

In addition to looking at other musculature, future research could investigate the reflexes that help to protect the ankle joint from injury and whether or not orthotics have an influence. Reflexes, balance, and muscle activation in a similar study would best be measured on subjects that participate in volleyball, basketball, and soccer, as these are the most at risk sports for lateral ankle sprains.

APPENDIX B

FADI SCALE

Table 1. Foot and Ankle Disability Index and Foot and Ankle Disability Index Sport Items*

Foot and Ankle Disability Index Items	Foot and Ankle Disability Index Sport Items
Standing	Running
Walking on even ground	Jumping
Walking on even ground without shoes	Landing
Walking up hills	Squatting and stopping quickly
Walking down hills	Cutting, lateral movements
Going up stairs	Low-impact activities
Going down stairs	Ability to perform activity with your normal technique
Walking on uneven ground	
Stepping up and down curves	Ability to participate in your desired sport as long as you would like
Squatting	
Sleeping	
Coming up on your toes	
Walking initially	
Walking 5 minutes or less	
Walking approximately 10 minutes	
Walking 15 minutes or greater	
Home responsibilities	
Activities of daily living	
Personal care	
Light to moderate work (standing, walking)	
Heavy work (push/pulling, climbing, carrying)	
Recreational activities	
General level of pain	
Pain at rest	
Pain during your normal activity	
Pain first thing in the morning	

*Subjects were given the following instructions: "Please answer every question with one response that most closely describes your condition within the past week. If the activity in question is limited by something other than your foot or ankle, mark N/A." Subjects rate the activity as no difficulty at all (4 points), slight difficulty (3 points), moderate difficulty (2 points), extreme difficulty (1 point), unable to do (0 points), or N/A (not applicable). For pain related to the foot and ankle, subjects select no pain (4 points), mild (3 points), moderate (2 points), severe (1 point), or unbearable (0 points). The Foot and Ankle Disability Index scores are recorded as a percentage of 104 points. The Foot and Ankle Disability Index Sport scores are recorded as a percentage of 32 points.

(Hale & Hertel, 2005)

APPENDIX C

IRB MATERIAL

OFFICE OF HUMAN RESEARCH ETHICS

Institutional Review Board

APPLICATION FOR IRB APPROVAL OF
HUMAN SUBJECTS RESEARCH

Version 23-Apr-2008

Part A.1. Contact Information, Agreements, and Signatures

Date: 12/03/2008

IRB Study #: 08-1674

Title of Study: The Acute Effects of Subtalar Neutral on Center of Pressure, Reflex Latency, Pain, Balance, and Stiffness in Unstable and Healthy Ankles

Name and degrees of Principal Investigator: Sarah Allard, ATC

Department: EXSS-Athletic Training Mailing address/CB #:

UNC-CH PID: 713-599-439 Pager:

Phone #: 414-520-3174 Fax #: Email Address: sallard@email.unc.edu

For trainee-led projects: __ undergraduate X graduate __ postdoc __ resident __ other

Name of faculty advisor: Michael Lewek, PT, PhD

Department: Allied Health Sciences Mailing address/CB #: 7135

Phone #: (919) 966-9732 Fax #: (919) 966-3678 Email Address: mlewek@med.unc.edu

Center, institute, or department in which research is based if other than department(s) listed above: Research will be completed in the Sports Medicine Research Laboratory in Fetzer Gymnasium (Department of Exercise and Sport Science)

Name of Project Manager or Study Coordinator (if any): N/A

Department: Mailing address/CB #:

Phone #: Fax #: Email Address:

List **all other project personnel** including co-investigators, and anyone else who has contact with subjects or identifiable data from subjects. **Include email address for each person who should receive electronic copies of IRB correspondence to PI:**

Steven M. Zinder PhD, ATC szinder@unc.edu

Johna Register-Mihalik, MA, ATC johnakay@email.unc.edu

Shana Harrington, MPT shanapt@nc.rr.com

Name of funding source or sponsor (*please do not abbreviate*):

_X_ not funded __ Federal __ State __ industry __ foundation __ UNC-CH

__ other (specify):

Include the following items with your submission, where applicable.

- Check the relevant items below and include one copy of all checked items 1-11 in the order listed.
- Also include two additional collated sets of copies (sorted in the order listed) for items 1-7.

→ **Applications will be returned if these instructions are not followed.**

Check	Item	Total No. of Copies
□	1. This application. One copy must have original PI signatures.	3
□	2. Consent and assent forms, fact or information sheets; include phone and verbal consent scripts.	3
□	3. HIPAA authorization addendum to consent form.	3
□	4. All recruitment materials including scripts, flyers and advertising, letters, emails.	3
□	5. Questionnaires, focus group guides, scripts used to guide phone or in-person interviews, etc.	3
□	6. Documentation of reviews from any other committees (e.g., GCRC, Oncology Protocol Review Committee, or local review committees in Academic Affairs).	3
□	7. Protocol, grant application or proposal supporting this submission, if any (e.g., extramural grant application to NIH or foundation, industry protocol, student proposal). This must be submitted if an external funding source or sponsor is checked on the previous page.	1
□	8. Addendum for Multi-Site Studies where UNC-CH is the Lead Coordinating Center.	1

□	9. Data use agreements (may be required for use of existing data from third parties).	1
□	10. Only for those study personnel *not* in the online UNC-CH human research ethics training database (http://cfx3.research.unc.edu/training_comp/): Documentation of required training in human research ethics.	1
□	11. Investigator Brochure if a drug study.	1

Principal Investigator: I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

____ _______________

Signature of Principal Investigator Date

Faculty Advisor if PI is a Student or Trainee Investigator: I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

____ _______________

Signature of Faculty Advisor Date

Note: The following signature is not required for applications with a student PI.

Department or Division Chair, Center Director (or counterpart) of PI: (or Vice-Chair or Chair's designee if Chair is investigator or otherwise unable to review): I certify that this research is appropriate for this Principal Investigator, that the investigators are qualified to conduct the research, and that there are adequate resources (including financial, support and facilities) available. If my unit has a local review committee for pre-IRB review, this requirement has been satisfied. I support this application, and hereby submit it for further review.

____ ______________

Signature of Department Chair or designee Date

____ ______________

Print Name of Department Chair or designee Department

Part A.2. Summary Checklist *Are the following involved?*

	Yes	No
A.2.1. Existing data, research records, patient records, and/or human biological specimens?	__	x
A.2.2. Surveys, questionnaires, interviews, or focus groups with subjects?	x	__
A.2.3. Videotaping, audiotaping, filming of subjects, or analysis of existing tapes?	__	x
A.2.4. Do you plan to enroll subjects from these vulnerable or select populations:		
a. UNC-CH students or UNC-CH employees?	x	__
b. Non-English-speaking?	__	x
c. Decisionally impaired?	__	x
d. Patients?	__	x
e. Prisoners, others involuntarily detained or incarcerated, or parolees?	__	x
f. Pregnant women?	__	x
g. Minors (less than 18 years)? ***If yes***, give age range: to years	__	__
A.2.5. a. Are sites outside UNC-CH engaged in the research?	__	x
b. Is UNC-CH the sponsor or lead coordinating center for a multi-site study?	__	x
If yes, include the ***Addendum for Multi-site Studies***.		
If yes, will any of these sites be outside the United States?	__	x
If yes, is there a local ethics review committee agency with jurisdiction? (provide contact information)	__	x
A.2.6. Will this study use a data and safety monitoring board or committee?	__	x
If yes: UNC-CH School of Medicine DSMB? (must apply separately)	__	x
Lineberger Cancer Center DSMC?	__	x
Other? Specify:	__	x

A.2.7. a. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc? b. Do you plan to obtain a federal Certificate of Confidentiality for this study?	__ __	x x
A.2.8. a. Investigational drugs? (provide **IND #**) b. Approved drugs for "non-FDA-approved" conditions? *All studies testing substances in humans must provide a letter of acknowledgement from the UNC Health Care Investigational Drug Service (IDS).*	__ __	x x
A.2.9. Placebo(s)?	__	x
A.2.10. Investigational devices, instruments, machines, software? (provide **IDE #**)	__	x
A.2.11. Fetal tissue?	__	x
A.2.12. Genetic studies on subjects' specimens?	__	x
A.2.13. Storage of subjects' specimens for future research? ***If yes***, *see instructions for* ***Consent for Stored Samples***.	__	x
A.2.14. Diagnostic or therapeutic ionizing radiation, or radioactive isotopes, which subjects would not receive otherwise? ***If yes***, *approval by the* ***UNC-CH Radiation Safety Committee*** *is required.*	__	x
A.2.15. Recombinant DNA or gene transfer to human subjects? ***If yes***, *approval by the* ***UNC-CH Institutional Biosafety Committee*** *is required.*	__	x
A.2.16. Does this study involve UNC-CH cancer patients? ***If yes***, *submit this application directly to the* ***Oncology Protocol Review Committee***.	__	x
A.2.17. Will subjects be studied in the General Clinical Research Center (GCRC)? ***If yes***, *obtain the* ***GCRC Addendum*** *from the GCRC and submit complete*	__	x

application (IRB application and Addendum) to the GCRC.		
A.2.18. Will gadolinium be administered as a contrast agent?	..__	x

Part A.3. Conflict of Interest Questions and Certification

The following questions apply to **all investigators and study staff** engaged in the design, conduct, or reporting results of this project **and/or their immediate family members.** For these purposes, "family" includes the individual's spouse and dependent children. "Spouse" includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other's welfare and shares financial obligations.

A.3.1. Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have: (a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study? (b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project? (c) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes __ yes __ yes	x no x no x no
A.3.2. Has the University or has a University-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team?	__ yes	x no

A.3.3. Has the University or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes	x no

If the answer to ANY of the questions above is *yes*, the affected research team member(s) must complete and submit to the Office of the University Counsel the form accessible at http://coi.unc.edu. List name(s) of all research team members for whom any answer to the questions above is *yes*:

____

<u>Certification by Principal Investigator</u>: By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of every UNC-Chapel Hill employee or trainee who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above, and that I have instructed any such person who has answered "yes" to any of these questions to complete and submit for approval a Conflict of Interest Evaluation Form. I understand that as Principal Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by University policy.

____ __________________

Signature of Principal Investigator Date

<u>Faculty Advisor if PI is a Student or Trainee Investigator</u>: I accept ultimate responsibility for ensuring that the PI complies with the University's conflict of interest policies and procedures.

Signature of Faculty Advisor Date

Part A.4. Questions Common to All Studies

For all questions, if the study involves only secondary data analysis, focus on your proposed design, methods and procedures, and not those of the original study that produced the data you plan to use.

A.4.1. **Brief Summary**. Provide a *brief* non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. *Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content.*

Purpose: To investigate the effects of restoring ankle alignment by use of a foot orthotic on biomechanical and reflex measures

Participants: Subjects will be male and female recreational athletes from UNC-Chapel Hill between the ages of 18-25 years old. There will be 2 groups of subjects: 1) Chronically unstable and 2) matched controls subjects (normal/uninjured ankles)

Procedures (methods): 200 potential subjects will be pre-screened to determine group and foot-type prior to the study testing session. From the potential subjects there will be 20 qualified subjects in the CAI group and 20 in the healthy ankle group. During the study test session, each subject will perform the following 3 randomly ordered tasks: 1) test of ankle stiffness and 2) single leg drop landing from a 30cm box at 50% of the subject's body height away from the forceplate in both forward and sideways directions. Each task will be done 5 times each and an average will be taken for analysis. All tasks will be done first without an orthotic and then with a pre-ordered orthotic which is placed in the shoe.

A.4.2. **Purpose and Rationale**. Provide a summary of the background information, state the research question(s), and tell why the study is needed. If a complete rationale and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive rationale and literature review, including references.

Medical professionals have prescribed custom made orthotics for different lower extremity conditions for nearly 40 years. (Bates, et al., 1979; Richie & Olson, 1993) Orthotics are often prescribed to individuals with chronic ankle instability (CAI) in an effort to bring the foot into a neutral position or restoring proper ankle alignment (called subtalar neutral) which allows the foot and ankle to function in the most advantageous way. (Hertel, 2002; Richie, 2007; Richie & Olson, 1993) If a person has a flat foot (pronator) or a high arch (supinator) then an orthotic can be used to correct for this foot abnormality and allow for more comfort and stability. Chronic ankle instability can be defined in one of two ways; the first is mechanical instability which involves trauma to the soft tissue structures of the ankle resulting in greater laxity in the subtalar joint which can be explained upon examination by a positive anterior drawer and/or talar tilt (Hertel, et al., 2001b; Monaghan, et al., 2006). The second type of instability is functional instability which can be described subjectively as a feeling of "giving way" but upon examination may not display a positive anterior drawer and/or talar tilt (Hertel, et al., 2001b; Monaghan, et al., 2006). Studies suggest an association between mechanical and functional instability as mechanical instability may lead to functional instability over time (Hertel, 2002; Richie & Olson, 1993). Studies have also suggested a strong effect from the use of orthotics in populations affected by chronic ankle instability. Specifically, orthotics may reduce pain, postural sway, and decrease the time in which reflexes in the peroneal muscles occur in individuals with CAI (Hertel, et al., 2001b; Ochsendorf, et al., 2000; Richie & Olson, 1993).

Although studies have examined the effect of orthotics on diminishing the symptoms of chronic ankle instability, there are a limited number of studies that address the role of orthotics on biomechanical and muscle activity measures (e.g., peroneal latency, peroneal pre-activation, and center of pressure displacement in the medial and lateral direction). This is important, because orthotics return the subtalar joint into a neutral position, which theoretically will encourage correct biomechanics of the foot and ankle and may therefore decrease the risk of an ankle injury.

Time to stabilization (TTS) is best described as the time it takes a subject to completely regain balance after landing from a height.. (S. E. Ross, et al., 2005; Wikstrom, et al., 2006) Subjects with functional ankle instability will often require a greater amount of time to stabilize after a single leg hop test. (S. E. Ross & Guskiewicz, 2006; S. E. Ross, et al., 2005; Wikstrom, et al., 2006) Similar to the hop task, some researchers have investigated the time to stabilization after a single leg drop landing task. The results from these studies are similar to those researchers who use the single leg hop task. (Wikstrom, et al., 2006) Each of these studies investigated the differences between subjects with ankle instability and compared them to a healthy set of subjects. In general, a healthy subject swayed less and took less time to return back to baseline. (Hertel, et al., 2001b; S. E. Ross & Guskiewicz, 2006; S. E. Ross, et al., 2005; Wikstrom, et al., 2006)

Muscle stiffness is an innate mechanism that combines both passive and active activation of muscles. Muscle stiffness has been described as being either intrinsic or reflex mediated (Rack & Westbury, 1969). Intrinsic muscle stiffness is what exists during the time of muscle lengthening due to actin-myosin bonds of the muscle fibers (Nichols & Houk, 1976). The intrinsic property of muscle stiffness describes how active a muscle is at the time of use. The reflex mediated response is the stiffness acquired after the feedback system has been activated (Hoffer & Andreassen, 1981). Joint stability is affected by several factors, including joint stiffness. Stiffness is described as the ratio of force response that results from and resists mechanical stretch (Zinder, et al., 2007). The stiffness of the active and passive structures surrounding a joint contributes to the biomechanical stability of a joint, especially at the end ranges. A measurement of the stiffness of the ankle joint could therefore be considered a direct measurement of ankle joint stability. When the ankle is placed into a more biomechanical advantageous position (i.e. subtalar neutral via orthotics) then the peroneals will be placed at an optimal length, as opposed to an elongated position with excessive pronation. When a joint is placed into a more biomechanical advantageous position, studies have shown that this can increase muscular and joint stiffness. Therefore, the purpose of this study is to determine if restoring subtalar joint alignment with an over-the-counter orthotic will influence ankle stability, such as reaction time, time to stabilization, and ankle muscle stiffness, purported to contribute to chronic ankle instability.

The following research questions will guide this study:

- Will placing the ankle joint into subtalar neutral decrease the reaction time of ankle musculature?
- Will placing the ankle joint into subtalar neutral decrease time to stabilization after a drop landing task?
- Will placing the ankle into subtalar neutral increase ankle muscle stiffness?

A.4.3. **Subjects.** *You should describe the subject population even if your study does not involve direct interaction (e.g., existing records).* Specify number, gender, ethnicity, race, and age. Specify whether subjects are healthy volunteers or patients. If patients, specify any relevant disease or condition and indicate how potential subjects will be identified.

A total of 40 volunteer subjects (20 male and 20 female) will be recruited from the University of North Carolina-Chapel Hill population with the inclusion criteria of: 1) between the ages of 18 and 25 years old, 2) faculty, staff, or students, and 3) meet the criteria for a recreational athlete, in which the subject exercises at least 3 days per week for at least 30 minutes at a time, and 4) has a low arch (pronated) foot. Subjects will be categorized into 2 groups (ankle instability and control). To identify qualified subjects a pre-screening session will take place. The chronic ankle instability (CAI, N=20) group will consist of 10 females and 10 males. The CAI group will be identified as those subjects that test positive according to the Functional Ankle Disability Index (FADI) (Appendix Ia and Ib) and are free from injury at the time of testing, as well as in the past 6 months. The Control group will consist of an equal number of females and males that do not have a history of ankle sprains. Subjects in the Control group (N=20) will be matched to those in the CAI group by gender, physical activity level, height, and weight. The exclusion criteria for this study will include: 1) a physician documented lower extremity injury in the past 6 months, 2) lower extremity surgery in the past year, 3) currently using orthotics, 4) currently rehabilitating a lower extremity injury, and 5) any neurological disorder (vertigo, etc) that affects your balance. Individuals will be enrolled without restriction in regard to ethnicity, race, or socioeconomic status.

A.4.4. **Inclusion/exclusion criteria.** List required characteristics of potential subjects, and those that preclude enrollment or involvement of subjects or their data. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race, or age. If pregnant women are excluded, or if women who become pregnant are withdrawn, specific justification must be provided.

Inclusion criteria: 1) between the ages of 18 and 25 years, 2) faculty, staff, or students, 3) meet the criteria for a recreational athlete, in which the subject exercised at least 3 days per week for at least 30 minutes at a time, 4) have a pronated (low arch) foot and 5) for the CAI group must have sustained ankle sprain and score ≤94 on the FADI screening test.

Exclusion criteria: 1) documented lower extremity injury in the past 6 months, 2) lower extremity surgery in the past year, 3) currently using orthotics, 4) currently rehabilitating a lower extremity injury, and 5) any neurological disorder (vertigo, etc) that affects balance.

A.4.5. **Full description of the study design, methods and procedures.** Describe the research study. Discuss the study design; study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; doses; frequency and route of administration of medication and other medical treatment if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject; outcome measurements; and follow-up procedures. If the study involves medical treatment, distinguish standard care procedures from those that are research. If the study is a clinical trial involving patients as subjects and use of placebo control is involved, provide justification for the use of placebo controls.

Pre-screening

Prior to testing, informed consent will be collected from potential subjects who answer the flyer and report to the Sports Medicine Research Laboratory (SMRL).We expect to screen close to 200 potential subjects in order to narrow down the subject pool to 20 in the CAI group and 20 in the healthy ankle group. In the SMRL potential subjects will be screened by the principal investigator, a certified athletic trainer, prior to full study participation to evaluate for current lower extremity injuries, a history of surgery within the past year, lower extremity injury in the past 6 months, and assess arch height (foot type) using a test called “navicular drop”. The navicular drop test is described below. The pre-screening (Appendix II) will determine the foot type that a subject possesses between a pronator or any other foot type (neutral or supinator). This session will also be used to assign potential subjects to the appropriate study group based on their general questionnaire answers, FADI score, and navicular drop score.

Navicular drop will be measured by:

1) Having the subject sit in a chair with their back supported with a 90-degree angle at the hip and knee and the feet placed on flat on the floor

2) The next step will be to palpate the medial and lateral borders of the talus (a bone above the ankle) while inverting and everting the foot until both prominences are felt equally, achieving subtalar neutral

3) Once subtalar neutral is established a skin marker will be used to make a mark on the navicular tubercle and also on an index card

4) The subject will then be asked to stand up and march in place 5 times and then stand still with his or her feet shoulder width apart to be re-measured

5) This process will be repeated 3 times for each subject and the average difference between the sitting and standing measurement will be taken as the subject's navicular drop score. Pronation is defined as having a score of ≥10mm, a neutral foot has a score of 5-9 mm and supination has a score of ≤4mm.

(Figure 1: Navicular Drop)

(Cote, et al., 2005; Hunter, 2000; Kelly, 2003)

Pre-screening will also include both groups filling out the FADI ankle stability scale questionnaire to determine the presence of CAI. (Hale & Hertel, 2005) The questionnaire involves 12 questions that compare the most frequently injured ankle to the contralateral ankle in a scaled range from 0=much more than the other ankle to 4= much less than the other ankle. Those subjects who score less than 94 out of 104 possible points will be considered to possess chronic functional ankle instability.

Once the CAI group has been established a control group will be formed in order to match the CAI group according to the criteria that were previously stated (i.e. foot type, age, foot dominance, etc.). The orthotics that will be used in this study will be obtained from Superfeet Inc®. Those subjects who qualify for the study will be contacted by the principal investigator in order to schedule testing and the fitting of the orthotics. The orthotics will help correct each subject's foot abnormality by positioning the subject in subtalar neutral during the time of data collection. Once a subject receives his or her orthotics they will be required to wear the orthotics in the same athletic shoes that they arrived in during the orthotic fitting. Subjects will wear the orthotics that will correct for his or her foot type for 10 minutes in order for the ankle and lower leg musculature to adjust to the orthotics during the post-testing phase.

Baseline/Pre-testing

Those subjects who qualify based on the pre-screening data for the CAI and control groups will report to the Sports Medicine Research Laboratory (SMRL) for a single testing session at the University of North Carolina-Chapel Hill. The subjects will have their demographic data collected for testing. The subjects will be tested without orthotics during the baseline testing, and they will be instructed to wear the same athletic shoes that can be laced closed during the baseline and post-testing sessions. Subjects will also be instructed to dress comfortably in their own athletic shorts at the time of testing. Each subject will perform the following 2 tasks: 1) ankle stiffness testing, and 2) single leg drop landing from 30cm in the forward and sideways direction. The order of these tasks will be counterbalanced. Each task will be done 5 times each and an average will be taken for analysis.

The electromyography (EMG) collection will be used to measure muscle activity during the series of tasks. The EMG electrodes will be placed over the peroneus longus (PL), tibialis anterior (TA), and lateral (or outer) gastrocnemius (LG) musculature of the testing leg (see Figure 2). Prior to placing the surface EMG electrodes to the skin, it must be prepared via shaving, lightly abrading, and cleaning the area with isopropyl alcohol in order to have good contact with the skin. The EMG electrodes will be secured with pre-wrap and tape in order to stabilize the placement of the surface EMG electrodes (Delsys Inc.,Boston, MA) to the skin. The electrodes will then be connected to a transmitter on a belt attached around the waist and will be worn for each task. A maximum voluntary isometric contraction (MVIC) will be recorded from each muscle group for each subject by performing 3 maximal 5 second trials. The average maximum voluntary isometric contraction (MVIC) value will then be calculated to normalize the muscle pre-activation levels.

(Figure 2: Electrode Placement)

<u>Drop Landing Task</u>

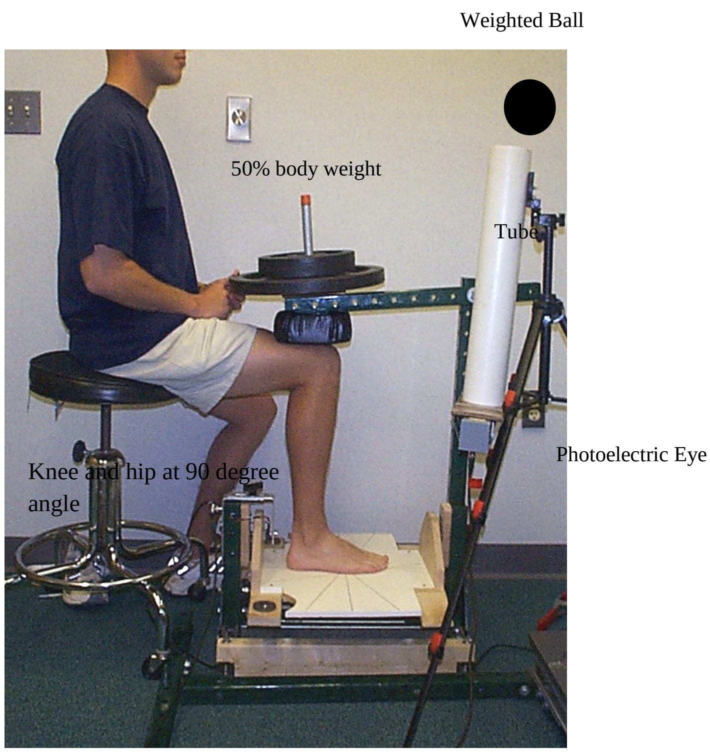
*****These procedures have been approved for previous investigations conducted in our laboratories (IRB# 05-EXSS-1184 and IRB# 07-0810) with no adverse events.*****

The drop landing into a single leg balance test will be performed off of a 30cm box. The subject will then jump a horizontal distance equal to 50% of their body height and land on the testing foot on the forceplate and hold this position for 10 seconds. Recording for the drop landing task begins when the subject lands on the forceplate and will end 10 seconds after the subject lands. This task will be done in 2 planes of motion (the frontal plane or a side jump and in the sagittal plane or a front jump). There will be a resting period of 1 minute between each trial to account for fatigue. Trials will be repeated until the subject is able to complete 5 successful trials (e.g., they were able to maintain balance for the full 10 seconds after landing) in both the forwards and sideways position.

<u>Ankle Cradle Task</u>

*****These procedures have been approved for previous investigations conducted in our laboratories (IRB# 08-EXSS0877) with no adverse events.*****

While seated, the knees and hips of the subject will be kept at 90°, and a weight equaling 50% of the subject's body mass will be placed on a pad over the test knee (Figure 3) to simulate a bipedal stance. A weighted ball will be dropped on the edge of the cradle platform causing the cradle to oscillate back and forth. The total movement is less than one inch in each direction, which is well within the physiologic limits of ankle motion. A potentiometer attached to the cradle's axis of rotation will record the oscillations for ankle stiffness calculation. An example of a typical potentiometer tracing is seen in Figure 4. These procedures have been performed on both stable and unstable ankles in previous investigations with no ill effects. Five cradle oscillations (ball drops) will be measured in a neutral position. The data collection will include measurement of pre-activation levels and peroneal reflex latency.



(Figure 3: Ankle Cradle)

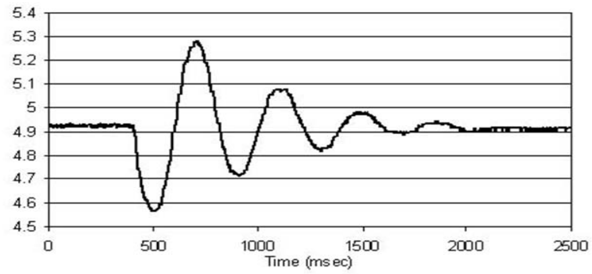


Figure 4. Typical potentiometer tracing

(Figure 4: Potentiometer Output)

Post-testing

Upon completion of the pre-testing tasks, the subjects will then be issued their orthotics. The appropriate orthotics will then be trimmed to fit the subject's same shoes that were worn during the pre-testing session. The subjects will then be allowed 10 minutes to walk around the lab in the orthotics. The subjects will then perform the same 2 tasks in the same order from the pre-test. Each procedure will be done in the exact same manner as the pre-testing session. The electrodes will remain in the same testing locations as during the pre-testing session. We had considered counterbalancing the order of testing, but we don't know if (or how long) of a washout period would be necessary following exposure to the orthotics. In other words, because there is the possibility (although admittedly small) that there may be a lasting effect after the exposure to the orthotics, we are reluctant to test with orthotics first.

A.4.6. **Benefits to subjects and/or society.** Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form). Do not list monetary payment or other compensation as a benefit.

The qualified subjects will receive a pair of Superfeet ® orthotics as a benefit for participating in this study as all subjects will have abnormal foot alignment, this will be beneficial. The value of these orthotics is approximately $30. It is expected that this information will be used to develop more effective rehabilitation protocols. Despite the minimal risks involved to the research subjects (as described below), the potential benefits to this research includes important information regarding how over-the-counter orthotics may influence biomechanical, and reflex measures about the ankle for the prevention and rehabilitation of ankle injuries.

A.4.7. **Full description of risks and measures to minimize risks.** Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

Participation in this study may involve minimal inherent risks. One risk is a breach of confidentiality with respect to a subject's participation in the study, which will be minimized by keeping all identifying information in a locked office, while test data is coded to correspond with an individual person. There is a risk of ankle muscle soreness following testing, although this will be minimized using adequate rest breaks. In addition, a licensed athletic trainer will be on hand to supervise the testing.

Subjects may feel slight discomfort with the addition of the 50% body mass load, but this weight is less than what subjects would experience if they were stand on one leg and previous testing on the apparatus has caused no ill effects. There is also a small risk of ankle injury while on the testing cradle. The movement of the cradle is well within the physiologic limits of the ankle joint, and this device has been used on several other studies at other institutions with no adverse effects, so this risk is minimal. Additionally, minor skin abrasions and discomfort will be possible during and following skin preparation for EMG electrodes. (Ankle cradle ***(IRB# 08-EXSS0877))***

Subjects will be instructed that they may discontinue participation at any time for any reason without penalty. All participants will indicate that they understand that they will be financially responsible for any medical costs incurred through their participation in this study. There is the possible risk of an ankle sprain occurring during the drop landing task.(Drop landing ***(IRB# 05-EXSS-1184 and IRB# 07-0810)***) In case of injury, medical personnel (certified athletic trainers) will be located in the same building as the testing session. If further medical assistance is required, the principal investigator will assist subjects in acquiring the necessary care.

A.4.8. **Data analysis.** Tell how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies).

Number of Subjects: An *a priori* power analysis suggested that 20 subjects per group (for a total of 40 subjects) will be required in order to have power of at least 0.80. Statistical power was investigated using previous ankle instability and orthotics studies, as well as the data collected during pilot testing. (Baier & Hopf, 1998; Guskiewicz & Perrin, 1996)

Data Analysis: All data will be analyzed using the SPSS 16.0 statistical software (Chicago, IL) using a pre-set alpha level of 0.05. The independent variables for this study include: 1) orthotics and no orthotics and 2) CAI and healthy subjects. The dependent variables for this study include: 1) Time to Stabilization (TTS) after drop landing task, 2) EMG of peroneus longus reflex latency, and 3) ankle stiffness. A 2 x2 Mixed Model ANOVA will be run for each dependent measure.

A.4.9. **Will you collect or receive any of the following identifiers?** Does not apply to consent forms.

__ No **_X_** Yes *If yes, check all that apply*:

a. _X_ Names
b. _X_ Telephone numbers
c. __ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
d. ___ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
e. __ Fax numbers
f. _X_ Electronic mail addresses
g. __ Social security numbers
h. __ Medical record numbers
i. __ Health plan beneficiary numbers
j. __ Account numbers
k. __ Certificate/license numbers
l. __ Vehicle identifiers and serial numbers (VIN), including license plate numbers
m. __ Device identifiers and serial numbers (e.g., implanted medical device)
n. __ Web universal resource locators (URLs)
o. __ Internet protocol (IP) address numbers
p. __ Biometric identifiers, including finger and voice prints
q. __ Full face photographic images and any comparable images
r. __ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

A.4.10. **Identifiers in research data**. Are the identifiers in A.4.9 above linked or maintained with the research data?

_X_ yes __ no

A.4.11. **Confidentiality of the data**. Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

A subject identification number will be used to identify each subject. The code is a unique number assigned by one of the investigators and has no relationship to any other information that may be linked to the subject. When reporting the data these will be presented as group means and standard deviations rather than individual data. The results from this research study will be collected and stored in a password protected computer. Access to these records is restricted to study personnel. All written data will be stored in locked cabinets. Following completion of data collection end entry, all identifiers will be removed.

A.4.12. **Data sharing.** With whom will *identifiable* (contains any of the 18 identifiers listed in question A.4.9 above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.

_X_ No one
__ Coordinating Center:
__ Statisticians:
__ Consultants:
__ Other researchers:
__ Registries:
__ Sponsors:

__ External labs for additional testing:

__ Journals:

__ Publicly available dataset:

__ Other:

A.4.13. **Data security for storage and transmission**. Please check all that apply.

For electronic data:

__ Secure network x Password access __ Encryption

__ Other (describe):

_x Portable storage (e.g., laptop computer, flash drive)

Describe how data will be protected for any portable device:

The flash drive will only be in the hands of the researcher and the subjects will be coded with no identifiable information on the flash drive. Furthermore, the spreadsheet with any identifiable information will be password protected.

For hardcopy data (including human biological specimens, CDs, tapes, etc.):

_X_ Data de-identified by research team (stripped of the 18 identifiers listed in question A.4.9 above)

_X_ Locked suite or office

__ Locked cabinet

_X_ Data coded by research team with a master list secured and kept separately

__ Other (describe):

A.4.14. **Post-study disposition of identifiable data or human biological materials**. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.

Identifiable data will be destroyed following data collection and entry. The code linking subject ID numbers and personal information will remain in a locked filing cabinet and password secured computer for 3 years following the completion of the study and then it will be destroyed after this time.

Part A.5. The Consent Process and Consent Documentation (including Waivers)

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances.

- If you will obtain consent in any manner, complete **section A.5.1**.
- If you are obtaining consent, but requesting a waiver of the requirement for a signed consent document, complete **section A.5.2**.
- If you are requesting a waiver of any or all of the elements of consent, complete **section A.5.3**.
- If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *limited waiver of HIPAA authorization*. This is addressed in section B.2.

You may need to complete more than one section. For example, if you are conducting a phone survey with verbal consent, complete sections A.5.1, A.5.2, and possibly A.5.3.

A.5.1. **Describe the process of obtaining informed consent from subjects**. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child. If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). If non-English speaking people will be enrolled, explain how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. *After you have completed this part A.5.1, if you are not requesting a waiver of any type, you are done with Part A.5.; proceed to Part B.*

Each subject participating in the pre-screening and/or the total study will be required to read and sign an informed consent document detailing the nature of the study and the risks involved, and indicating that they have the right to leave the study at any point. All subjects will complete the consent form prior to the pre-screen test session. Subjects will be recruited via fliers and verbally in classes in the Department of Exercise and Sports Science.

A.5.2. **Justification for a waiver of *written* (i.e., signed) consent**. *The default is for subjects to sign a written document that contains all the elements of informed consent.* Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true.
Chose only one:

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). __ yes x no

Explain.

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey). __ yes x no

Explain.

If you checked "yes" to either (and you are not requesting a waiver in section A.5.3) consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated document.

→ If you have justified a waiver of written (signed) consent (A.5.2), you should complete A.5.3 *only* if your consent process will not include all the other elements of consent.

A.5.3. **Justification for a full or partial waiver of consent.** *The default is for subjects to give informed consent.* A waiver might be requested for research involving only existing data or human biological specimens (see also Part C). More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

__ Requesting **waiver of some elements** (specify; see SOP 28 on the IRB web site):

__ Requesting **waiver of consent entirely**

If you check either of the boxes above, answer items a-f.. To justify a full waiver of the requirement for informed consent, you must be able to answer “yes” (or “not applicable” for question c) to items a-f. **Insert brief explanations that support your answers.**

a. Will the research involve no greater than minimal risk to subjects or to their privacy? __ yes __ no

Explain.

b. Is it true that the waiver will *not* adversely affect the rights and welfare of subjects? *(Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)* __ yes __ no

Explain.

c. When applicable to your study, do you have plans to provide subjects with pertinent information after their participation is over? *(e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)* __ yes __not applicable

Explain.

d. Would the research be impracticable without the waiver? *(If you checked “yes,” explain how the requirement to obtain consent would make the research impracticable, e.g., are most of the subjects lost to follow-up or deceased?).* **Explain.** __ yes __ no

e. Is the risk to privacy reasonable in relation to benefits to be gained or the importance of the knowledge to be gained? __ yes __ no

Explain.

If you are accessing patient records for this research, you must also be able to answer "yes" to item f to justify a waiver of HIPAA authorization from the subjects.

f. Would the research be impracticable if you could not record (or use) Protected Health Information (PHI)? *(If you checked "yes," explain how* not *recording or using PHI would make the research impracticable).* __ yes __ no

Explain.

Part B. Questions for Studies that Involve Direct Interaction with Human Subjects

→ ***If this does not apply to your study, do not submit this section.***

B.1. **Methods of recruiting.** Describe how and where subjects will be identified and recruited. Indicate who will do the recruiting, and tell how subjects will be contacted. Describe efforts to ensure equal access to participation among women and minorities. Describe how you will protect the privacy of potential subjects during recruitment. *For prospective subjects whose status (e.g., as patient or client), condition, or contact information is not publicly available (e.g., from a phone book or public web site), the initial contact should be made with legitimate knowledge of the subjects' circumstances. Ideally, the individual with such knowledge should seek prospective subjects' permission to release names to the PI for recruitment. Alternatively, the knowledgeable individual could provide information about the study, including contact information for the investigator, so that interested prospective subjects can contact the investigator.* Provide the IRB with a copy of any document or script that will be used to obtain the patients' permission for release of names or to introduce the study. Check with the IRB for further guidance.

Subjects will be recruited via fliers (Appendix III), an informational email (Appendix IV) and verbally in classes in the Department of Exercise and Sports Science via a standard script (Appendix V). The fliers will be placed around campus (especially in gymnasiums, work out facilities and recreational playing fields) in order to recruit a recreationally active population. Each subject interested in the study will first go through a pre-screening process in which they will fill out a FADI in order to identify those subjects that qualify as having stable or unstable ankles. During the pre-screening session potential subjects will also have their foot screened to ensure that they have a pronated foot. After a subject is placed into a group, he or she will then be fitted for orthotics, and an order will be placed for their orthotics. Once the orthotics arrive and the qualified subjects have been contacted via email and/or phone, data collection will begin.

B.2. **Protected Health Information (PHI).** If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *limited waiver of HIPAA authorization*. If this applies to your study, please provide the following information.

a. Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. What information are you planning to collect for this purpose?

b. How will confidentiality/privacy be protected prior to ascertaining desire to participate?

c. When and how will you destroy the contact information if an individual declines participation?

B.3. **Duration of entire study and duration of an individual subject's participation, including follow-up evaluation if applicable.** Include the number of required contacts and approximate duration of each contact.

Each subject will have 3 required contacts during the study. The first contact will be when the interested volunteers contact the principal investigator their interest in participating in the study. The second contact will be the pre-screening to fill out the FADI ankle stability questionnaire and assess foot type for the orthotics fitting (total time of 45 minutes). This could all be done on one day, but for matched controls, it may take 2 contact days to first identify the group in which the person falls into and then screen for orthotics. Once the orthotics arrive, then the day of data collection will be the last contact day (total study time of 45-60 minutes).

B.4. **Where will the subjects be studied?** Describe locations where subjects will be studied, both on and off the UNC-CH campus.

The subjects will be screened and tested in the Sports Medicine Research Laboratory.

B.5. **Privacy.** Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope).

Each subject will read and sign an informed consent form. Data collection sheets will identify subjects using ID numbers and not names. There will be a compiled list of names, email, and orthotics sizing that will be kept password protected in the research laboratory in order to email the subjects once the orthotics have arrived so data collection can begin. At the end of the study all identifiers will be deleted from the computer or if applicable will be shredded.

B.6. **Inducements for participation.** Describe all inducements to participate, monetary or non-monetary. If monetary, specify the amount and schedule for payments and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it. For compensation in foreign currency, provide a US$ equivalent. Provide evidence that the amount is not coercive (e.g., describe purchasing power for foreign countries). Be aware that payment over a certain amount may require the collection of the subjects' Social Security Numbers. If a subject is paid more than $200.00 per year, collection of subjects' Social Security Number is required (University policy—see SSN Guidance) using the Social Security Number collection consent addendum found under forms on the IRB website (look for Study Subject Reimbursement Form).

Each subject will receive a new pair of Superfeet orthotics for completing the study. Each pair of Superfeet costs approximately $30.

B.7. **Costs to be borne by subjects.** Include child care, travel, parking, clinic fees, diagnostic and laboratory studies, drugs, devices, all professional fees, etc. If there are no costs to subjects other than their time to participate, indicate this.

The only cost for the subjects is their time during the duration of the study.

APPENDIX D

SPSS OUTPUT

DEMOGRAPHIC T-TEST AND DESCRIPTIVE STATISTICS

Group Statistics

	Stability	N	Mean	Std. Deviation	Std. Error Mean
Age	Stable	20	20.6000	1.09545	.24495
	Unstable	20	20.3500	1.87153	.41849
Sex	Stable	20	1.5500	.51042	.11413
	Unstable	20	1.5000	.51299	.11471
Height	Stable	20	173.1010	7.47491	1.67144
	Unstable	20	174.3710	13.01102	2.90935
Weight	Stable	20	70.3246	9.03437	2.02015
	Unstable	20	80.3807	20.84057	4.66009
Navicular_Drop	Stable	20	13.9250	3.24149	.72482
	Unstable	20	16.9250	3.80192	.85014

Independent t-test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
		Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower
Age	Equal variances assumed	5.078	.030	.516	38	.609	.25000	.48490	-.73164	1.23164
	Equal variances not assumed			.516	30.651	.610	.25000	.48490	-.73942	1.23942
Sex	Equal variances assumed	.192	.664	.309	38	.759	.05000	.16182	-.27758	.37758
	Equal variances not assumed			.309	37.999	.759	.05000	.16182	-.27758	.37758
Height	Equal variances assumed	8.950	.005	-.379	38	.707	-1.27000	3.35530	-8.06245	5.52245

	Equal variances not assumed			-.379	30.310	.708	-1.27000	3.35530	-8.11950	5.57950
Weight	Equal variances assumed	6.459	.015	-1.980	38	.055	-10.05610	5.07912	-20.33824	.22604
	Equal variances not assumed			-1.980	25.897	.058	-10.05610	5.07912	-20.49839	.38619
Navicular_ Drop	Equal variances assumed	.247	.622	-2.685	38	.011	-3.00000	1.11718	-5.26161	-.73839
	Equal variances not assumed			-2.685	37.073	.011	-3.00000	1.11718	-5.26347	-.73653

STIFFNESS ANOVA

Descriptive Statistics

	Stability	Mean	Std. Deviation	N
Stiff_N	Stable	30.5795	18.23618	20
	Unstable	38.8475	18.40477	20
	Total	34.7135	18.56256	40
Stiff_O	Stable	26.2159	21.79230	20
	Unstable	32.7679	27.43155	20
	Total	29.4919	24.67729	40

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Orthotics	Sphericity Assumed	545.301	1	545.301	8.117	.007	.176	8.117	.793
	Greenhouse-Geisser	545.301	1.000	545.301	8.117	.007	.176	8.117	.793
	Huynh-Feldt	545.301	1.000	545.301	8.117	.007	.176	8.117	.793
	Lower-bound	545.301	1.000	545.301	8.117	.007	.176	8.117	.793
Orthotics * Stability	Sphericity Assumed	14.724	1	14.724	.219	.642	.006	.219	.074
	Greenhouse-Geisser	14.724	1.000	14.724	.219	.642	.006	.219	.074
	Huynh-Feldt	14.724	1.000	14.724	.219	.642	.006	.219	.074
	Lower-bound	14.724	1.000	14.724	.219	.642	.006	.219	.074
Error(Orthotics)	Sphericity Assumed	2552.754	38	67.178					
	Greenhouse-Geisser	2552.754	38.000	67.178					
	Huynh-Feldt	2552.754	38.000	67.178					
	Lower-bound	2552.754	38.000	67.178					

a Computed using alpha = .05

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	82446.681	1	82446.681	93.459	.000	.711	93.459	1.000
Stability	1098.159	1	1098.159	1.245	.272	.032	1.245	.193
Error	33522.317	38	882.166					

a Computed using alpha = .05

PRE-ACTIVATION LEVELS OF THE PERONEUS LONGUS

Descriptive Statistics

	Stability	Mean	Std. Deviation	N
NormPrePL_N	Stable	.0560	.05041	20
	Unstable	.0720	.05022	20
	Total	.0640	.05032	40
NormPrePL_O	Stable	.0565	.01981	20
	Unstable	.0935	.06784	20
	Total	.0750	.05277	40

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Orthotics	Sphericity Assumed	.002	1	.002	1.661	.205	.042	1.661	.241
	Greenhouse-Geisser	.002	1.000	.002	1.661	.205	.042	1.661	.241
	Huynh-Feldt	.002	1.000	.002	1.661	.205	.042	1.661	.241
	Lower-bound	.002	1.000	.002	1.661	.205	.042	1.661	.241
Orthotics * Stability	Sphericity Assumed	.002	1	.002	1.513	.226	.038	1.513	.224
	Greenhouse-Geisser	.002	1.000	.002	1.513	.226	.038	1.513	.224
	Huynh-Feldt	.002	1.000	.002	1.513	.226	.038	1.513	.224
	Lower-bound	.002	1.000	.002	1.513	.226	.038	1.513	.224
Error(Orthotics)	Sphericity Assumed	.055	38	.001					
	Greenhouse-Geisser	.055	38.000	.001					
	Huynh-Feldt	.055	38.000	.001					
	Lower-bound	.055	38.000	.001					

a Computed using alpha = .05

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	.386	1	.386	108.181	.000	.740	108.181	1.000
Stability	.014	1	.014	3.932	.055	.094	3.932	.489
Error	.136	38	.004					

a Computed using alpha = .05

TTS FRONTAL PLANE A/P

Descriptive Statistics

	Stability	Mean	Std. Deviation	N
TTS_NF_AP	Stable	1.6889	.20305	20
	Unstable	1.9672	.56551	20
	Total	1.8280	.44243	40
TTS_OF_AP	Stable	1.6815	.21092	20
	Unstable	2.0493	.79169	20
	Total	1.8654	.60143	40

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Orthotics	Sphericity Assumed	.028	1	.028	.728	.399	.019	.728	.132
	Greenhouse-Geisser	.028	1.000	.028	.728	.399	.019	.728	.132
	Huynh-Feldt	.028	1.000	.028	.728	.399	.019	.728	.132
	Lower-bound	.028	1.000	.028	.728	.399	.019	.728	.132
Orthotics * Stability	Sphericity Assumed	.040	1	.040	1.044	.313	.027	1.044	.169
	Greenhouse-Geisser	.040	1.000	.040	1.044	.313	.027	1.044	.169
	Huynh-Feldt	.040	1.000	.040	1.044	.313	.027	1.044	.169
	Lower-bound	.040	1.000	.040	1.044	.313	.027	1.044	.169
Error(Orthotics)	Sphericity Assumed	1.459	38	.038					
	Greenhouse-Geisser	1.459	38.000	.038					
	Huynh-Feldt	1.459	38.000	.038					
	Lower-bound	1.459	38.000	.038					

a Computed using alpha = .05

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	272.827	1	272.827	571.069	.000	.938	571.069	1.000
Stability	2.088	1	2.088	4.370	.043	.103	4.370	.531
Error	18.154	38	.478					

a Computed using alpha = .05

TTS FRONTAL PLANE M/L

Descriptive Statistics

	Stability	Mean	Std. Deviation	N
TTS_NF_ML	Stable	1.1539	.04737	20
	Unstable	1.2459	.14812	20
	Total	1.1999	.11812	40
TTS_OF_ML	Stable	1.1517	.04033	20
	Unstable	1.2826	.24154	20
	Total	1.2171	.18333	40

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Orthotics	Sphericity Assumed	.006	1	.006	1.683	.202	.042	1.683	.244
	Greenhouse-Geisser	.006	1.000	.006	1.683	.202	.042	1.683	.244
	Huynh-Feldt	.006	1.000	.006	1.683	.202	.042	1.683	.244
	Lower-bound	.006	1.000	.006	1.683	.202	.042	1.683	.244
Orthotics * Stability	Sphericity Assumed	.008	1	.008	2.157	.150	.054	2.157	.299
	Greenhouse-Geisser	.008	1.000	.008	2.157	.150	.054	2.157	.299
	Huynh-Feldt	.008	1.000	.008	2.157	.150	.054	2.157	.299
	Lower-bound	.008	1.000	.008	2.157	.150	.054	2.157	.299
Error(Orthotics)	Sphericity Assumed	.134	38	.004					
	Greenhouse-Geisser	.134	38.000	.004					
	Huynh-Feldt	.134	38.000	.004					
	Lower-bound	.134	38.000	.004					

a Computed using alpha = .05

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	116.842	1	116.842	3029.999	.000	.988	3029.999	1.000
Stability	.248	1	.248	6.442	.015	.145	6.442	.696
Error	1.465	38	.039					

a Computed using alpha = .05

TTS SAGITTAL PLANE A/P

Descriptive Statistics

	Stability	Mean	Std. Deviation	N
TTS_NS_AP	Stable	1.6261	.11431	20
	Unstable	1.8984	.45795	20
	Total	1.7623	.35713	40
TTS_OS_AP	Stable	1.6526	.13929	20
	Unstable	1.9961	.77862	20
	Total	1.8243	.57883	40

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Orthotics	Sphericity Assumed	.077	1	.077	1.876	.179	.047	1.876	.267
	Greenhouse-Geisser	.077	1.000	.077	1.876	.179	.047	1.876	.267
	Huynh-Feldt	.077	1.000	.077	1.876	.179	.047	1.876	.267
	Lower-bound	.077	1.000	.077	1.876	.179	.047	1.876	.267
Orthotics * Stability	Sphericity Assumed	.025	1	.025	.616	.437	.016	.616	.119
	Greenhouse-Geisser	.025	1.000	.025	.616	.437	.016	.616	.119
	Huynh-Feldt	.025	1.000	.025	.616	.437	.016	.616	.119
	Lower-bound	.025	1.000	.025	.616	.437	.016	.616	.119
Error(Orthotics)	Sphericity Assumed	1.560	38	.041					
	Greenhouse-Geisser	1.560	38.000	.041					
	Huynh-Feldt	1.560	38.000	.041					
	Lower-bound	1.560	38.000	.041					

a Computed using alpha = .05

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	257.275	1	257.275	671.460	.000	.946	671.460	1.000
Stability	1.896	1	1.896	4.947	.032	.115	4.947	.582
Error	14.560	38	.383					

a Computed using alpha = .05

TTS SAGITTAL PLANE M/L

Descriptive Statistics

	Stability	Mean	Std. Deviation	N
TTS_NS_ML	Stable	1.0860	.01783	20
	Unstable	1.1797	.20017	20
	Total	1.1328	.14808	40
TTS_OS_ML	Stable	1.0871	.02500	20
	Unstable	1.1759	.17915	20
	Total	1.1315	.13402	40

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Orthotics	Sphericity Assumed	3.45E-005	1	3.45E-005	.005	.945	.000	.005	.051
	Greenhouse-Geisser	3.45E-005	1.000	3.45E-005	.005	.945	.000	.005	.051
	Huynh-Feldt	3.45E-005	1.000	3.45E-005	.005	.945	.000	.005	.051
	Lower-bound	3.45E-005	1.000	3.45E-005	.005	.945	.000	.005	.051
Orthotics * Stability	Sphericity Assumed	.000	1	.000	.017	.898	.000	.017	.052
	Greenhouse-Geisser	.000	1.000	.000	.017	.898	.000	.017	.052
	Huynh-Feldt	.000	1.000	.000	.017	.898	.000	.017	.052
	Lower-bound	.000	1.000	.000	.017	.898	.000	.017	.052
Error(Orthotics)	Sphericity Assumed	.274	38	.007					
	Greenhouse-Geisser	.274	38.000	.007					
	Huynh-Feldt	.274	38.000	.007					
	Lower-bound	.274	38.000	.007					

a Computed using alpha = .05

Tests of Between-Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power(a)
Intercept	102.546	1	102.546	3494.403	.000	.989	3494.403	1.000
Stability	.167	1	.167	5.674	.022	.130	5.674	.641
Error	1.115	38	.029					

a Computed using alpha = .05

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