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Effect of Orthotics on Dynamic Balance in Participants with Pes Planus and Subacute Lateral Ankle Sprains

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THE EFFECT OF ORTHOTICS ON DYNAMIC BALANCE IN PARTICIPANTS WITH PES PLANUS AND SUBACUTE LATERAL ANKLE SPRAINS

by

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(Under the Direction of Jim McMillan, Ed.D, CSCS)

ABSTRACT

Lateral ankle sprains are common athletic injuries which lead to a decrease in balance via proprioceptive damage around the joint. Orthotics have been shown to help increase balance following acute ankle sprains. This research focused on the effect of orthotics on balance in participants with unilateral, subacute lateral ankle sprains and pes planus. Ten participants (half randomly assigned to orthotics group) performed balance testing twice (pre- and 5 minute-post) on each leg on the Biodex Balance System. A 2 x 2 ANOVA with Repeated Measures was used to evaluate the treatment (orthotics, no orthotics) over time (pre-orthotic, post-orthotic). The results revealed no treatment effects, interactions, or time effects for the dependant variables of overall stability index, anterior-posterior stability index, medial-lateral stability index for the injured and the uninjured ankles. In conclusion, for this time frame orthotics did not improve balance in participants with subacute lateral ankle sprains and pes planus.

KEY WORDS: Orthotics, Subacute, Ankle sprain, Dynamic balance, Biodex Balance System, Pes Planus

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DEDICATION

This thesis is dedicated to my parents, Glen & Eileen Wheeler, and my husband, Christopher Antinori. Thank you for your love and support.

Table of Contents

The Effect of Orthotics on Dynamic Balance in Participants with Pes Planus and Subacute Lateral Ankle Sprains

Most athletes experience an ankle sprain some time during their career. Lateral ankle sprains are the most frequently occurring injury among athletes and the physically active.[1,2,4,5] When a lateral ankle sprain occurs there may be structural and neurological damage to the lateral ligaments, muscles, and joint capsule. Balance is affected because a decrease in proprioception results from damage to the mechanoreceptors found in the ligaments, muscle, and capsule.[3,7,22,23]

The assessment of balance has often been used as a tool to help determine an athlete's progress,[25] capability of returning to participation,[3,4,25] and their susceptibility to ankle sprains.[6,24,25] The majority of studies evaluating balance have focused on static balance.[4,18,19,23-28] However, static balance does not resemble real-life, dynamic activities. It is suggested that balance be measured dynamically to more closely resemble functional, dynamic, athletic activity.[4,5,25,29] Fewer dynamic balance studies have been published.[4,5,10-12,29] The majority of these studies focus on the reliability of the dynamic balancing tool.[10-12,29] Only a couple of studies have focused on the effect of orthotics on dynamic balance.[4,5]

Orthotics have been shown to help increase balance after an acute ankle injury.[4,5] Orthotics may help increase balance by positioning the foot in its most mechanically efficient structural alignment, resulting in minimal stress on the joint, ligaments, and joint capsule.[4,5] The position of the ankle when the foot is in the orthotic also may allow the joint mechanoreceptors to detect perturbations to balance, thus enhancing somatosensory

feedback necessary for balance control.[4] This early foot and ankle manipulation from the orthotic may allow for a quicker return to participation.

The two studies that evaluated the effect of orthotics on balance were good starting points for research in this area.[4,5] Acute ankle sprains were compared to uninjured ankles with no distinction in foot type. No published literature discusses how long it will take an individual to obtain the benefits of orthotics could be located.

This study attempted to describe a more specific population to utilize orthotics following an ankle sprain. The purpose of this study was twofold. The first was to examine the effect of orthotics on dynamic balance in an active sample with pes planus in the subacute phase of a lateral ankle sprain. The second was to describe balance over the course of time to support an allotted adjustment period for the effect of orthotics on balance.

The significance of this study was to help support a rehabilitation specialist's decision to utilize orthotics after an ankle sprain. Currently, the literature focuses on theoretically how orthotics correct a problem,[6,9,10] the different types of orthotics available,[6,9,10] and orthotics on special populations.[9] There exists very little research on orthotics and athletes or orthotics and active people. Most specifically there is little research on how orthotics affect balance in active populations. This study brought attention to some of these concerns and encouraged further research to explore other areas of orthotics in relation to balance after an injury.

Methods

Participants

Ten (6 males, 4 females) active, college-aged, participants were recruited for this study. The inclusion criteria identified participants who had a subacute ankle sprain, defined as occurring within the last three to fifty-two weeks, to only one ankle. The participants had pes planus quantified by a navicular drop of greater than 10mm. The participants did not use orthotics or had prior orthotic experience. The participants had no previous or current professionally guided rehabilitation for the injured ankle. The participants did not have any balance disorders or vestibular disturbances and had no other lower extremity injury.

Materials

The materials used for the study included a small ruler, one index card per participant and a thin, black marker which were used to take measurements of navicular drop as described by Brody.[17] The Biodex Balance System (Biodex Medical Systems, Inc., Shirley, New York) was used to quantify balance as the dependent variables of overall stability index (OSI), anterior-posterior stability index (APSI), and medial-lateral stability index (MLSI). Each participant's information was stored in a file with access limited to the principle investigator and faculty advisor. Orthotic materials were purchased from Foot Management, Inc. (Pittsville, MD) and molded according to the manufacturer's instructions (See Appendix F). All testing was performed in the same place under the same conditions by the principle investigator.

Instrumentation

The Biodex Balance System (BBS) assessed neuromuscular control in a closed-chain, multi-plane test by quantifying the ability of the subject to maintain dynamic unilateral postural stability on an unstable surface.[9] The platform allowed movements in a 360 degree range and up to 20 degrees of tilt at any point in the range.[3,9]

The least stable level on the BBS is Level 1 and the most stable level is Level 8. The testing for this study was performed on Level 6 which is consistent with the literature resulting in a moderately unstable platform.[3] When properly calibrated, the BBS is a reliable tool for measuring balance.[10-12,29] The BBS reported the dependent variables of the overall stability index (OSI, r= 0.91[29]), the anterior-posterior stability index (APSI, r=0.89[29]), and the medial-lateral stability index (MLSI, r=0.92[29]). These numbers represented the variance of the platform from level in degrees caused by balance perturbations. A high number indicated a poor stability index.

Procedures

Participants were actively sought through strategically placed flyers, school newspaper advertisements, and were physically recruited from club sports, intramural sports, and activity classes. Once the participant expressed interest, he/she read and signed the consent form (Appendix D), then were asked a series of questions regarding demographics, medical history, ankle sprain history, and rehabilitation history (Appendix D). The answers to these questions were grounds for inclusion for the remainder of the study. Those participants that met the profile of the desired sample made an appointment

to meet individually with the principle investigator and a physical therapist in the testing area.

During the appointment, the physical therapist assessed navicular drop. Navicular drop was defined as the distance between the original height of the navicular in the subtalar joint neutral position to the final weight-bearing position of the navicular in relaxed, bilateral stance.[8,13-16] The measurement of navicular drop was performed as described by Brody.[17] The measurement must have exceeded 10mm[13,14] to be considered abnormal and thus allow the participant to qualify for the study. According to data gathered from pilot testing the intratester reliability of the physical therapist for navicular drop was 0.87 for a one trial reliability and 0.93 for a two trial reliability.

After the navicular drop measurement, the participant received an explanation on how to use the Biodex Balance System and was given the opportunity to ask any questions about the study. After the participant's concerns and questions were addressed each participant completed three practice trials[9,11] for each foot for a total of six practice trials.

The participant's position was uniform during the data collection. The participant had their navicular tuberosity aligned with the division representing the coronal plane on the platform while the second ray was aligned with the division representing the sagittal plane. The participant balanced unilaterally with the contralateral hip and knee flexed comfortably to ensure no contact with the platform or any other structures. The participant faced straight ahead, held his/her arms either at his/her side or abducted, and focused on one spot on the wall.[2,5,20] Each testing session required two acceptable tests:

one for the involved ankle and one for the uninvolved ankle. A test trial was accepted when the participant was able to balance unassisted, without touching down for the duration of the thirty second test. If a participant lost balance during a testing trial, the trial was discarded and an uninterrupted trial recorded.[29] Ninety seconds of rest was completed between each testing trial.

Five of the ten participants were randomly assigned orthotics. Those that were issued orthotics were given proper instruction for the orthotics in verbal and written form (Appendix G). The orthotics were heated in warm water during the practice and testing trials to prepare them for molding. The participants that were randomly assigned orthotics were fitted for them after the completion of the baseline, or first, test. Between each trial the BBS was reset and following each setup the BBS unit should show the cursor balanced at the intersection of the center medial-lateral line and the center anterior-posterior line. All participants performed another testing trial, or second test, after the completion of the baseline testing trial. The participants that were not assigned orthotics were tested five minutes after the completion of the baseline trial. The participants that were randomly assigned orthotics were tested immediately after the fitting of their orthotics. It was found through pilot testing that the orthotic fitting would take five minutes. The same testing procedure was executed as before: two thirty-second tests, one on each leg. This initial testing period lasted approximately thirty minutes.

Statistical Analysis

The dependent variables for this study were the overall stability index (OSI), anterior-posterior stability index (APSI), and medial-lateral stability index (MLSI). Each

of these dependent variables was calculated by the Biodex Balance System. A 2 x 2 Analysis of Variance (ANOVA) with Repeated Measures was used to analyze the data. SPSS version 10.0 was used to interpret the data. The probability (p) and alpha (α) level was set at 0.05.

Results

The sample demographic consisted of 10 participants. Six males and four females (mean age of 22.30 ± 2.75 years, mean height of 175.50 ± 9.95cm, mean weight of 82.68 ± 17.68kg, mean shoe size 9.95 ± 2.59). Five participants received the orthotic treatment and five participants did not receive orthotics. Seven participants injured their right foot and three participants injured their left foot. The mean navicular drop for the injured ankle was 15.30 ± 3.13mm with a minimum navicular drop of 11mm and a maximum navicular drop of 20mm. The mean navicular drop for the uninjured ankle was 12.40 ± 3.84mm with a minimum navicular drop of 6mm and a maximum navicular drop of 16mm.

In the injured group, there was no significant difference over time for OSI, APSI, or MLSI ($p>0.05$). No interaction was found between time and treatment for the injured group in OSI, APSI, or MLSI ($p>0.05$). And no treatment effect was found in the injured group for OSI, APSI, or MLSI ($p>0.05$). In the uninjured group, no time effect was found for OSI, APSI, or MLSI ($p>0.05$). No interaction between time and treatment was found for OSI, APSI, or MLSI ($p>0.05$). And no treatment effect was found for OSI, APSI, or MLSI ($p>0.05$). Results are illustrated in Tables 1-4, located in Appendix C.

Discussion

According to the results of this study, it seemed that orthotics did not improve balance in subjects with subacute lateral ankle sprains. This result is in contrast to Orteza et al[5] and Guskiewicz & Perrin[4] who both found orthotics to improve balance in subjects with ankle sprains. Both Orteza et al[5] and Guskiewicz & Perrin[4] studied subjects with acute ankle sprains where this study focused on subacute ankle sprains. Orteza et al[5] limited his subjects' ankle sprain to within three weeks of testing and Guskiewicz & Perrin[4] limited their subject's ankle sprain to within six weeks of testing. This study, in contrast, limited its subject's ankle sprains to no less than three weeks and no greater than fifty-two weeks during the duration of testing. This time frame for a definition of subacute is extremely large. Having this large of a time frame may allow participants to be in very different points of healing based on the severity of the sprain and how recently it occurred.

Another difference in criteria between this study and Orteza et al[5] and Guskiewicz & Perrin[4] was that the previous two studies made no consideration for foot type. This study was limited to participants who had pes planus. The criteria to having pes planus was a navicular drop of 10mm or greater on the injured foot. The distinction in foot type was made to attempt to look at a distinct population which already places an excessive amount of stress on their lower extremity, especially their foot and ankle. An attempt was made to take this sample and manipulate their foot to improve and correct their faulty mechanics which may lead to a decrease in healing time from less stress on the

surrounding structures and lead to an increase in balance secondary to improved foot and ankle mechanics.

The last major difference between this study and the previous studies performed by Orteza et al[5] and Guskiewicz & Perrin[4] was that the previous studies had half of their participants with acute ankle sprains where as the other half had no history of an ankle sprain. This study, in contrast, had all participants in the subacute phase of an ankle injury. Having all subjects in the same phase of healing was hoping to illustrate the sole effect of the orthotics without coupling the results with two variables such as a sprain and the orthotic. It was attempted that the ankle injury not be a factor in determining one's ability to balance.

One challenge that was faced during the testing procedure that had not been identified in literature was foot placement on the BBS.[3,4,10-12,21,29] In the studies that involved the BBS a standardized foot position was not described. Arnold and Schmitz[10] give the most thorough attempt stating "the subjects were instructed to adjust the supporting foot's position until they found a position at which they could maintain platform stability (p 324)." An attempt was made in this study to standardize foot placement by aligning the second metatarsal with the center anterior-posterior line and the navicular tuberosity with the center medial-lateral line. This lack of standardized procedure calls for the detail of foot placement to be studied specifically to find the optimal placement so that single leg balance testing on the BBS can be reliably replicated.

Another challenge was the small sample size which may have been too small to

have any power and support significance. Orteza et al[5] used 24 participants and Guskiewicz & Perrin[4] used 25 participants whereas this study had 10 participants complete the data collection. The small sample size may be attributed to the timing of data collection. Testing was limited to the month of June when a traditional school schedule was not in session thus resulting in less potential recruits. In addition some recruits were unable to continue with the study secondary to a newly acquired injury, lack of commitment, and/or truancy.

Conclusion

According to the results obtained, orthotics did not significantly improve balance in subjects with pes planus in the subacute phase of healing from a lateral ankle sprain. But these results indicate that there needs to be further study in this area. First, it is suggested that a study be performed that will standardize foot placement of the Biodex Balance System. After a standard position is supported, this study should be performed again using a larger sample size, and an increased number of testing trials over time, and a definition of subacute which allows for greater consistency of stage of healing. These suggestions may lead to more accurate results.

Secondarily, it also may be most beneficial to use orthotics after an acute lateral ankle sprain to allow for optimal alignment and mechanically efficient alignment of the subtalar and talocrual joints which should theoretically put the least amount of stress on the injured tissues.

These results may also indicate the resiliency and the ability for the body to adapt. After spending a lifetime adjusting to faulty mechanics with pes planus, potentially introducing the orthotic to correct the foot and ankle mechanics may not actually help improve balance for two reasons. The allotted time frame may not have been long enough for the foot and ankle to adjust and result in an improvement in balance. Or balance would not specifically improve in the orthotic without implementing a specific proprioceptive and balance rehabilitation program. Therefore it may be beneficial to orchestrate another study which an orthotic intervention coupled with a proprioceptive

rehabilitation regimen would be compared to only the orthotic intervention and only the proprioceptive rehabilitation intervention as they are applied to participants who have experienced a lateral ankle sprain. This may support that in addition to the orthotic treatment, a challenging, progressive proprioceptive rehabilitation program should be implemented promptly after the injury occurs to help expedite return to normal activity.

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APPENDIX A

Hypotheses

The research hypothesis of this study was that orthotics would increase dynamic balance of participants with pes planus and a history of a subacute, lateral ankle sprain. In addition, a description of balance over the course of time will be assessed to support an allotted adjustment period for the effect of orthotics on balance.

Definition of Terms

Balance - The ability to control and maintain the center of the body mass within the support base of the feet. Balance requires visual, vestibular, and somatosensory senses for postural orientation and the appropriate movements to control the motion of the body.[1]

Kinesthesia - The conscious awareness of joint position and movement resulting from proprioceptive input to the central nervous system (CNS).[2]

Navicular Drop - Distance between the original height of the navicular in the subtalar joint

neutral position to the final weight bearing position of the navicular in relaxed stance.[3]

Neutral or Subtalar Joint Neutral - The position in which the foot is neither pronated nor supinated.[4] Position in which the foot functions most efficiently and causes the least stress to the surrounding joints, ligaments, and tendons.[5]

Orthotic, orthosis - Any device used to support, align, or protect joints or body segments, thus improving function.[6]

Pes planus/flatfoot - Absence of the arching of the foot, so that the sole lies flat on the

ground.[1]

Postural balance - The ability to maintain the body center of mass within the area of support provided by the feet.[2]

Pronation (closed kinetic chain) - Calcaneal eversion with talar plantarflexion and adduction.[7]

Proprioception - The cumulative neural input to the CNS from mechanoreceptors in the joint capsules, ligaments, muscles, tendons, and skin.[2]

Assumptions

The assumption is made that the participants were honest with the principle investigator about the time period in which they last injured their ankle, their use of orthotics, their rehabilitation history, and their unilateral ankle injury.

Limitations

Limitations for this study have attempted to be minimized. The BBS is a relatively new tool to measure balance. Previously balance had been measured using a force platform that is mounted in the ground. The Biodex Balance System was a dynamic measuring tool that allowed movements in all three cardinal planes which allowed the foot to function in a more realistic and common situation, especially in sports, as opposed to standing on a still, unmoving surface. Because this stability system was relatively new there was not a great deal of normative data using the BBS. In addition, the amount of literature on the force platform exceeded the amount of literature on the dynamic platform. The transfer of data from a static measuring tool is limited when compared to a dynamic measuring tool.

Another limitation is that this study used an active population as opposed to an athletic population. Athletes may have better neuromuscular control than active, recreational persons due to their intensity and duration of training. Therefore, this study is limited to describing an active, college-aged population. The ability to generalize this data to an athletic population or a different age group may be limited.

The last limitation is the timing of the data collection. The data was collected during the summer after the traditional semesters were terminated. This circumstance limited the contact with potential participants thus affecting the population size for this study.

Delimitations

Participants chosen for this study had an ankle injury within the last year. This time frame was chosen to allow uniformity of participants. With the time frame controlled as it was, the participants were in the subacute phase of the healing process. This time period from 21 days up to one year was considered sub-acute for this study. Previous research defined acute ankle sprains as the time period from date of injury to 21 days post injury.[8] This time frame allowed some healing to occur to the ankle. The participants were full weight bearing without a limp.

Temporary orthotics were used in this study due to the ease and convenience of participant fitting and limited finances. Clinically, temporary orthotics were given as treatment prior to permanent orthotics. The expertise of the physical therapist ensured that the quality of the fitting was exceptional.

Significance of Study

The significance of this study was to help support a rehabilitation specialist's decision to utilize orthotics after an ankle sprain. Currently, the literature focuses on theoretically how orthotics correct a problem,[6,9,10] the different types of orthotics available,[6,9,10] and orthotics in special populations.[9] There is very little research on orthotics and athletes or orthotics and active people. Most specifically there is little research on how orthotics affect balance in active populations.

In addition, no published studies looked at the time frame to adjust to orthotics. Anecdotally clinicians claim it takes approximately two weeks to accommodate to orthotics and become comfortable wearing them. This study also described a time frame, termed an adjustment period, where desired results from the use of the orthotic is expected. This study called attention to some of these concerns and encouraged further research to explore other areas of orthotics in relation to balance and balance over time following an injury.

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APPENDIX B

Review of Literature

Most athletes experience an ankle sprain some time during their career. After an ankle sprain, no matter the severity, a decrease in balance is typically observed.[8-10,36,37,38] This decrease in balance has been shown to lead to further injury to the ankle, or possibly secondary injury elsewhere in the body.[27]

The decrease in balance presents a challenge for the rehabilitation specialist. When an injury occurs proprioception, a component of balance, is altered and must be addressed.[1-7] Proprioceptive rehabilitation is an effective way to improve decreased proprioception.[8] Other options in addition to proprioceptive rehabilitation need to be explored to see if they will enhance proprioception. Very few studies have addressed the use of orthotics after an ankle sprain to see how they would affect balance.[9,10]

Mechanical

Lateral ankle sprains are the most frequently occurring injury among athletes and the physically active.[4,5,9,10] Injury generally occurs from an inversion force[9,11,12,30] that places excessive stress on the lateral complex. For example, stepping in a hole and rolling over the ankle. When a lateral ankle injury occurs there is common local mechanical damage to the anterior talofibular ligament, the calcaneofibular ligament, and the posterior talofibular ligament, as well as the capsule, and the peroneal muscles. Trauma to the mechanoreceptors located in the surrounding area of the injury, including the muscles, ligament, and joint capsule may lead to neurological damage such as partial deafferentation and decreased proprioception.[2,7,9,10]

Movement of the ankle occurs at the talocrual joint and the subtalar joint predominantly. The talocrual joint is made up of the tibia, fibula, and talus. The talocrual joint is responsible for the largest degree of motion occurring at the ankle. Plantarflexion and dorsiflexion occur at the talocrual joint. The subtalar joint is responsible for the conversion of the rotatory forces of the lower extremity and dictates the movements of the midtarsal joints and forefoot.[13] The subtalar joint is a synovial joint which is formed by three separate plane articulations between the talus superiorly and the calcaneus inferiorly called the tarsal canal.[13-16] Together, the bones provide a triplanar movement around a single joint axis.[13-15] The posterior talocalcaneal articulation is the largest of the three articulations and is formed by a concave facet on the undersurface of the body of the talus and a convex facet on the body of the calcaneus.[14,15] The anterior and middle articulations are formed by a convex facet on the undersurface of the body of the talus and a concave facet on the body of the calcaneus.[14] Between the posterior articulation and the anterior and middle articulations there is a canal formed by concave grooves in the inferior talus and superior calcaneus.[14] The tarsal canal runs obliquely across the foot, providing a path for ligaments to run, and divides the posterior articulation and the anterior and middle articulations into two separate joint cavities.[14] The posterior articulation has its own fibrous capsule and synovial membrane, while the anterior and middle articulations share a capsule with the talonavicular joint.[14]

Though the subtalar joint is comprised of three articulations, the orientation of the facets limit joint mobility. Mobility is described according to the concave-convex rule.[14] When the talus moves on the posterior facet of the calcaneus, the articular surface of the

talus should slide in the same direction as the bone moves (concave surface moving on a fixed convex surface). When the middle and anterior joints move, the talar surfaces should glide in a direction opposite to movement of the bone (convex surface moving on a fixed concave surface). This results in the talus moving in a twisting, screwlike, triplanar motion around a single oblique axis.[13,14] The axis of subtalar joint motion is reported in the range from 20° - 68° in the transverse plane[17,18] and 4° - 47° in the sagittal plane[17,18] but is most commonly thought of at 42° from the transverse plane and 16° from the sagittal plane through the heel to the space between the first and second toes.[18] Movement along this axis creates the motion of supination and pronation.

Supination and pronation are best defined by describing motion that occurs in each of the three cardinal planes separately but it must be understood that the motion of pronation and supination cannot and do not occur independently.[14] The components of this motion occur simultaneously as the talus twists across its three articular surfaces and cannot be separated.[14] For the purposes of this review, supination and pronation will be described in weight-bearing. When the foot is fixed on the ground, the calcaneus is limited to inversion and eversion causing the talus to move according to the concave-convex rule.[14] Pronation of the subtalar joint in weight-bearing permits calcaneal eversion and plantarflexion and adduction of the talus, and internal rotation of the tibia.

Pronation is a normal phenomenon of gait and pronation is necessary to have a normal gait pattern. It is when there is an excess of pronation that problems begin to occur. One of the most common foot abnormalities is pes planus which is an abnormally low-arched, excessively pronated foot.[16] Hyperpronation results in a laterally positioned

calcaneus which describes a valgus rearfoot deformity.[16] Excessive pronation causes undue stress on the ligaments, and muscles surrounding the ankle from excessive movement of the talus. One way to possibly decrease or ideally eliminate this stress from hyperpronation is to put the foot in its optimal alignment.

Theoretically, the "ideal foot position"[19] will allow optimal function with minimum risk of injury. This gold standard is based on the assumption that the weight-bearing foot in a particular orientation will be more efficient and less prone to injury.[19] The ideal foot position is also known as subtalar neutral.[19] The subtalar neutral position is used to provide a point of reference for measurement so that deviations from neutral can be observed, evaluated, and quantified.[14] Root et al[16] describes subtalar neutral as the position of the subtalar joint that is neither supinated nor pronated based on the palpation of the talus as described by Wernick & Langer[14,20] where the protrusion of the talus is felt equally on the lateral and medial sides of the calcaneus. This neutral position should allow for maximum congruency of the talus and the calcaneus. The subtalar neutral position is used to provide consistency in the positioning of the foot before assessing structural or bony deformities of the foot.[16,21,22]

When the foot pronates in weight-bearing there is eversion of the calcaneus, adduction and plantarflexion of the talus, and abduction of the forefoot.[14,22] These movements result in the lowering of the medial longitudinal arch and internal rotation of the tibia. [12,22] Greater subtalar motion in pronation requires more muscle work, specifically eccentrically from the posterior tibialis, than is necessary in the supinated foot.[12] When maximum pronation occurs in weight-bearing, torque conversion and shock

absorption are significantly reduced.[13,23-25] Treatment focuses on the prevention of excessive pronation when the foot is loaded, in weight-bearing, by controlling hyperpronation.

Foot orthoses are used to control undesirable motion in the subtalar joint and ultimately limit the extent of hyperpronation[23,24] and correct faulty stance phase mechanics.[14] An orthosis is defined as any device used to support, align, or protect joints or body segments, thus improving function.[23] The theoretical idea behind orthotics is that they put the foot, specifically the subtalar joint, in its neutral position in order to control abnormal and potentially harmful movements. The neutral position will put the foot in the position in which the foot functions most efficiently. In this study, the orthotic will be used to correct the foot deformity of pes planus which may result from excessive subtalar joint pronation.

Pes planus tends to make the foot less rigid because of its lack of supination. This causes the foot to be insufficient in forming a rigid lever during the push-off phase in gait.[19] A rigid or semi-rigid orthotic may be used to support the foot and allow it to resupinate.[14]

Neurological

The presence of a capsular lesion caused by trauma may interfere with the transmission of afferent impulses from the joint and alter the afferent neural code that is conveyed to the central nervous system (CNS).[7,26] Structural joint damage may adversely affect protective neuromuscular mechanisms, resulting in greater susceptibility to reinjury and progressively greater ligament laxity.[2-5,7,9-10] It is believed that ankle injuries

causing partial deafferentation and functional instability result in altered postural sway due to a proprioceptive deficit.[9]

When an injury occurs, there is usually a decrease in proprioception and balance.[9,10] This decrease in balance is described by the proprioception paradigm.[27] Once a ligamentous injury occurs it may result in ligamentous laxity. This laxity results in mechanoreceptor damage which in turn results in proprioceptive deficits. If these deficits are left untreated, functional instability of that joint will occur. Functional instability leads to repetitive injury where the paradigm comes full circle and results in greater ligamentous injury (see Appendix E).

Proprioception is defined as the cumulative neural input to the CNS from mechanoreceptors in the joint capsules, ligaments, muscles, tendons, and skin.[7] Muscle spindles are the proprioceptors in muscles which monitor the degree of stretch within that muscle and golgi tendon organs are proprioceptors typically found in muscle-tendon junctions that monitor the tension within the tendons. Joint kinesthetic receptors are proprioceptors found in the joint capsule that monitor stretch in the synovial capsule. The Pacinian corpuscles monitor acceleration and rapid movements of the joints. During an inversion ankle sprain the muscle spindles and golgi tendon organs fire in the peroneal muscles which attempt to minimize the extent of stretch that is occurring to the muscle and its tendon. The joint kinesthetic receptors fire letting the brain know that the joint capsule is experiencing a greater stretch than what is normal for the joint. And the Pacinian corpuscles fire as well to relay that the joint is rapidly going into a compromising position.[2,3,26,28,45]

Proprioceptors only provide sensory feedback to the CNS. Proprioceptors take the sensory stimulus through the afferent neurons and bring it to the CNS and the brain. The brain makes the decision to alter behavior based on the proprioceptive sensory feedback. The brain then sends a signal down the efferent pathway that results in the modified behavior. Proprioceptors send the information but they do not perform the resulting movement.[2,3,26,28,45]

Subconscious lower extremity proprioceptive information is carried in the sensory motor pathway two ways. The first way is when the sensory information occurs and the impulses are carried through the peripheral nervous system (PNS) to the CNS and the impulse remains on the stimulated side up to the thalamus. The dorsal column pathway of the fasciculus gracilis carries its impulse this way which results in the localization of the sensation of touch, pressure, and body sense of kinesthetic awareness. An example of this is the tactile feedback and stimulation that the foot receives from the orthotic. The second way for the proprioceptive information to be relayed is when the stimulus occurs, and along the way up the spinal cord to the brain the impulse crosses the dorsal pathway twice on the way to the cerebellum. The spinocerebellar pathways carry their information in this fashion which causes the cerebellum on the same side of the stimulus to interpret the stimulus and results in subconscious proprioception.[26,28] This is how the peroneal muscles are fired in attempt to evert and dorsiflex the foot when an inversion mechanism for an ankle sprain is occurring.

When an injury occurs it results in structural joint damage of the ligaments, tendons, and joint capsule. This, in turn, adversely affects the protective neuromuscular

mechanisms possibly leading to a greater susceptibility to injury. Damage to the ligaments and/or disrupted integrity of the joint capsule may interfere with the transmission of afferent impulses at the site of the injury resulting in altered neural input to the CNS.[7] Ankle injuries cause partial deafferentation, a deficit in proprioception, and an increased postural sway.[9,10,29]

Instrumentation

Traditionally, balance has been measured on a force platform.[9,31,32,39-43] However, the transfer from the force platform to functional activity may be less than desired.[9] Therefore the use of a dynamic measuring tool is highly desired and more closely resembles functional, dynamic activities.[9,10,41,44]

In the two studies that look at the effect of orthotics on balance, balance was measured two different ways using a digital balance evaluator and a dynamic balance system. A digital balance evaluator is a uniaxial board that measures only inversion and eversion.[10] This instrument does not take the other motions that occur at the foot into consideration. The Balance System (Chattex Corporation, Chattonooga, TN) uses four force transducers under the medial and lateral aspects of the forefoot and rearfoot that results in measurements in the medial-lateral, plantarflexion-dorsiflexion, and inversion-eversion directions. The dynamic conditions of the Biodex Balance System more closely resemble functional activity and may be more valuable in considering athletic activity.[9]

The Biodex Balance System (BBS) assesses neuromuscular control in a closed-chain, multi-plane test by quantifying the ability of the subject to maintain dynamic

unilateral postural stability on an unstable surface.[33] The platform allows movements in a 360° range and up to 20° of tilt at any point in the range.[8,33]

The least stable level is Level 1 and the most stable is Level 8. The BBS will report the dependent variables of the overall stability index (OSI), the anterior-posterior stability index (APSI), and the medial-lateral stability index (MLSI). These numbers represent the variance of the platform from level in degrees. A high number indicates poor stability index. The BBS is a reliable tool for measuring balance.[34-36,44] Reliability is reported as 0.91 for OSI and as 0.89 for APSI, and 0.92 for MLSI.[44]

The literature is inconsistent with the suggestion of the number of practice sessions needed for accommodation of the learning effect to the testing environment. One, two, and as many as five practice trials have been recommended.[34-36,44] The Biodex manual suggests three practice trials and one study[35] found that there was no significant difference in the results of trials three through six. Therefore the consensus seems to indicate that three practice trials is adequate.

The Effect of Orthotics on Balance

An orthotic restores proper biomechanical alignment to the ankle joint. It relieves excessive stress on the injured peripheral mechanoreceptors that lay within the injured capsulo-ligamentous structures of the ankle resulting in an enhanced functioning of the ankle joint.[10] Putting the subtalar joint in optimal alignment with the use of an orthotic may allow joint mechanoreceptors to detect disruptions to postural sway[9] and improve afferent feedback. Very few articles specifically looked at the affect of orthotics on balance.[9,10]

Orteza et al[10] looked at the effect of a molded orthotic, unmolded orthotic, or no orthotic on the balance of 24 young adults. Fifteen of her participants had no history of an ankle sprain. The remaining nine subjects had an acute ankle sprain at the time of testing and had received physical therapy. Her instrument for measuring balance was a single axis board that allowed movement in the plane of inversion-eversion which measured the time out of balance and the number of times time out of balance occurred. She defined acute as an ankle sprain occurring within six weeks of testing. Her results suggested that participants with an ankle sprain spent significantly more time out of balance than her uninjured subjects. She also found that molded orthotics significantly improved balance over no orthotics in those who suffered a lateral ankle sprain. In those who were uninjured there was no significant difference between no orthotics, unmolded orthotics nor molded orthotics. Based on her results, Orteza et al[10] believes that molded orthotics are primarily responsible for the reestablishment of balance from a lateral ankle sprain.

Guskiewicz and Perrin[9] also examined the effect of orthotics on postural sway. They looked at 13 subjects with acute lateral ankle sprains and 12 subjects with no history of ankle sprains. Their definition of an acute ankle sprain was having the sprain occur within 21 days of testing. Each subject was fitted for custom orthotics using a foam impression and was tested randomly in both orthotic and non-orthotic conditions. The subject's balance was measured on a multidirectional platform giving feedback in the medial-lateral, plantarflexion-dorsiflexion, and inversion-eversion planes. The study

revealed that subjects with acute ankle sprains had significantly more postural sway than the uninjured subjects when not wearing orthotics. This study also showed that injured subjects significantly improved their balance using orthotics over the uninjured subjects. And, orthotics significantly reduced postural sway in the medial-lateral and inversion-eversion planes. Based on the results of their study, Guskiewicz and Perrin[9] believe that orthotic intervention puts the ankle in a neutral position, which improves alignment and helps control postural sway by decreasing stress on the injured structures in those with acute lateral ankle injuries. They hypothesize that orthotics enhance tactile stimulation to the surrounding surface of the foot which stimulates and improves the somatosensory feedback from the skin that is necessary for balance control.[9]

In this study, a three-quarter, semi-rigid temporary orthotic will be used to accomplish two things. The first thing it will do is create a rigid lever, which is lost with excessively pronating feet, to help improve the push-off phase of gait. Next, the orthotic will also create a medial longitudinal arch which will put the participant in subtalar neutral and allow them to stand without hyperpronation. The orthotics will reestablish the proper foot alignment. When a properly fitted orthotic is introduced, the externally created arch should correct the calcaneus and place it in a more upright or neutral position. This will cause the talus to abduct and dorsiflex to its ideal alignment, which should in turn allow the tibia to externally rotate until it reaches neutral as well. Due to the correction of the faulty alignment, there should be less stress on the surrounding ligaments, capsule, and muscles thus leading to improved afferent feedback.

Existing literature supports that orthotics may be useful in treating post traumatic

ankle sprains. Utilization of orthotics allows the foot and ankle to be in the most mechanically efficient position which results in the least amount of stress to the foot and ankle. The tactile feedback elicited from the orthotic coupled with efficient positioning may lead to improved afferent feedback resulting in improved proprioception and balance.

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APPENDIX C

Table 1. OSI Comparisons

	OSI, Injured		OSI, Uninjured	
	Trial 1	Trial 2	Trial 1	Trial 2
Orthotic	4.04 ± 0.34	3.44 ± 0.49	4.02 ± 2.25	3.50 ± 1.07
No Orthotic	3.80 ± 1.28	3.22 ± 0.54	3.66 ± 0.56	3.48 ± 0.89

Table 2. APSI Comparisons

	APSI, Injured		APSI, Uninjured	
	Trial 1	Trial 2	Trial 1	Trial 2
Orthotic	3.46 ± 0.41	3.08 ± 0.40	3.26 ± 2.01	2.88 ± 1.06
No Orthotic	3.28 ± 1.09	2.56 ± 0.35	3.30 ± 0.75	3.26 ± 0.86

Table 3. MLSI Comparisons

	MLSI, Injured		MLSI, Uninjured	
	Trial 1	Trial 2	Trial 1	Trial 2
Orthotic	2.24 ± 0.76	1.66 ± 0.48	2.50 ± 1.28	2.06 ± 0.79
No Orthotic	2.08 ± 0.86	1.94 ± 0.89	1.60 ± 0.68	1.60 ± 0.37

Table 4. P-value Comparisons

	P-value, Injured			P-value, Uninjured		
	OSI	APSI	MLSI	OSI	APSI	MLSI
Time effect	0.16	0.14	0.19	0.38	0.61	0.31
Time * Treatment	0.98	0.63	0.41	0.66	0.68	0.31
Treatment effect	0.45	0.17	0.89	0.81	0.77	0.21

APPENDIX D

INSTITUTIONAL REVIEW BOARD
GEORGIA SOUTHERN UNIVERSITY

APPROVAL FORM

1. Department Health and Kinesiology Request # ____ Date Submitted ____

2. Principle Investigator (PI) if student, include Faculty Advisor (FA).
Amanda Dawn Wheeler (PI) Dr. Jim McMillan, EdD, CSCS (FA)
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Dr. Jim McMillan, EdD, CSCS (FA) jmcmillan@GeorgiaSouthern.edu

3. Title of Research or Thesis Project
The Effect of Orthotics on Dynamic Balance in Participants with Pes Planus and a History of SubacuteLateral Ankle Sprains

4. If Grant Proposal, list agencies to which it is being submitted:
None

5. PI or FA Recommendations
_____ Exempt _____ Expedited Review _____Full Review

6. DIRB Recommendations
_____ Exempt _____ Expedited Review _____ Full Review

PI Signature _____ Date_____
FA Signature_____ Date_____
DIRB Chair_____ Date_____
Department Chair_____ Date_____

DETERMINATION OF INSTITUTIONAL REVIEW BOARD

Human Participants: _____ At Risk _____ Not at Risk

Action: _____ Approved _____ Not Approved _____ Reapproved

_____ Exempt - Department Approved _____ Returned for Revisions

Signed:_____Date: _____
Chair, Institutional Review Board

GEORGIA SOUTHERN UNIVERSITY
Department of Health & Kinesiology
College of Health & Professional Studies

Departmental Approval Form

Researcher

I have read the University IRB Policies and Procedures on the use of human participants in research and agree to abide by them. I agree to report any significant and relevant changes in procedures and instruments as they relate to participants to the review committee for consideration. I also understand the feedback containing information that infers a participant is at risk should be provided to the participant by an individual with faculty status. I understand that any questions I have regarding the use of Human Participants should be referred to the Chair of the DIRB committee.

DATE_____ Signed (PI) _____
DATE_____ Advisor's Signature_____

DIRB & Department Chair

_____ A. The research using human participants described on this form involves no significant issues of human rights or participant welfare. The department approves this proposal in its present form and requests that it be **exempt** from University IRB review.

_____ _____ _____ _____
DIRB Committee Initials

_____ B. The research using human participants described in this proposal has the department's approval. The study proposed does not involved any obvious violations of human rights or participant welfare but before activation of the department research requests an **expedited review** from the University IRB.

_____ _____ _____ _____
DIRB Committee Initials

_____ C. The research using human participants described in this proposal has the department's approval. Since the study proposed involved significant issues of human rights and participant welfare, the department requests a **full review** of the proposal by the University IRB.

_____ _____ _____ _____
DIRB Committee Initials

_____ _____
Signature of DIRB Chair Date

_____ _____
Signature of Department Chair Date

INSTITUTIONAL REVIEW BOARD
RESEARCH PROPOSAL FORM FOR
RESEARCH INVOLVING HUMAN PARTICIPANTS

I. Statement of the problem to be studied.

Ankle sprains are the most prevalent of all athletic injuries. Once an athlete injures his ankle a decrease in balance is typically observed. The aim of this study is to see if temporary orthotics affect balance in an active sample with a history of uni-lateral ankle sprains.

II. Describe your research design.

Participants of this study will be active, college-aged, males and females. A person will be defined as active if they participate in activity at least three time per week for a minimum of thirty minutes. Contact will be made with the participants by advertisement with posted flyers around the Recreation Activity Center (RAC) and campus, advertisements in the school newspaper (George-Anne), and through personal contact in activity classes as well as recruiting from club sports and intramurals. Please see attached flyers and newspaper advertisement.

Once the participants have read and signed the consent form they will be asked a series of questions regarding demographics, medical history, ankle sprain history, and rehabilitation history. Please see attached *History and Record Sheet*. The answers to these questions will be grounds for inclusion or exclusion from the remainder of the study. Those that are excluded will be thanked for their time while those that are included will progress to the next level of inclusion criteria.

An appointment will be made with these participants to meet individually with the principle investigator, a physical therapist, and a student assistant in the rehabilitation room in the Hanner Fieldhouse. Initial measurements will be taken of the participant's feet to see if they will meet the final qualifications for the study. Navicular drop will be measured in stance as an indicator of pes planus. This will be done by quantifying the extent of reduction in the longitudinal arch height indicating flat feet. The measurement must be equal to or exceed 10mm in order for the participant to qualify for the study. Rearfoot and forefoot angles will be measured with the participant's foot placed in subtalar neutral as indicators of additional hyperpronation in stance. After these measurements, the participant will receive an explanation on how to use the Biodex Stability System. All questions the participant may have will be answered before he/she begins his/her practice trials. The participant will be allowed three (3) practice trials for each foot.

Twenty of the forty participants will be randomly assigned orthotics. Those that are issued orthotics will be given proper instruction for the orthotics, both verbally and written. The orthotics will be heated in warm water during the practice and testing trials to prepare them for molding. For each testing session two (2) acceptable tests will be performed; one for the leg with a history of ankle problems and one for the uninvolved leg. A test trial will be accepted when the participant is able to balance unassisted and without touching down for the entire thirty (30) seconds of each test with his or her eyes open, focusing on one spot on the wall. If a participant were to lose balance during a testing trial, the trial would be discarded and an uninterrupted trial recorded. A minimum of ninety (90) seconds rest will be completed between the testing trials.

The participants that are randomly assigned orthotics, will be fitted for them after the completion of the baseline test. These subjects will be given both written and verbal instructions on how to wear the orthotics (please see attached sheet). All participants will perform another testing trial after the completion of the baseline testing trial. The participants that are not assigned orthotics will be tested immediately after the completion of the baseline trial. The participants that are randomly assigned orthotics will be tested immediately after the fitting of their orthotics. The same testing procedure will be executed as before: two thirty-second tests on each leg. This initial testing period will last approximately thirty (30) to forty-five (45) minutes, depending on if the participant is randomly chosen for orthotics. After these two tests are completed, an appointment will be made to re-test seven and fourteen days after the initial baseline testing.

The third (7 days post-baseline) and fourth (14 days post-baseline) testing trials will be run in a similar fashion as the second trial. Those participants who are randomly assigned orthotics will wear them in all succeeding trials while those who were not assigned orthotics will test in athletic shoes only. When the participants arrive they will be asked if any changes in their medical history or ankle-injury history have been made. If they are wearing orthotics, they will be given the opportunity to make any adjustments, if necessary. It will also be confirmed that those who are wearing orthotics are wearing them properly. Next, it will be verified that they are wearing the proper shoes. At this point, they will be ready for testing. The same 30-second balance test will be done on each leg. The third and fourth testing sessions should last approximately fifteen (15) to twenty (20) minutes each.

During the testing sessions, a digital camcorder (Cannon, XLI) will be used to capture testing trials and still pictures will be taken of the testing and measurement procedures with a digital camera (Sony, Digital Mavica) and the shoes that each participant is wearing. E-mails will be sent out to the participants confirming the information for the next testing session and with a picture of their shoes as a reminder to wear the same pair for subsequent testing. The email will be sent two days prior to their third and fourth

testing session. The participants will not be allowed to re-test unless they are wearing the

same shoes.

The dependent variables for this study are the Overall Stability Index (OSI), Anterior-Posterior Stability Index (APSI), and Medial-Lateral Stability Index (MLSI). Each of these dependent variables will be calculated by the software accompanying the Biodex Stability System and printed out after each test trial. A 2 x 4 Analysis of Variance (ANOVA) with Repeated Measures will be used to analyze the data. SPSS version 10.0 will be used to interpret the data. A Scheffe post hoc test will be performed if there are any significant differences. If none are found, then the Newman-Keuls post hoc test will be performed. If still no differences are found, then a Fisher's LSD post hoc test will be performed. The probability (p) and alpha (α) level will be set at 0.05.

III. Description of possible risk to human participants.

The participation in this study exposes the participant to potential mild ankle joint injury. This study requires balancing on an unstable, dynamic surface which may induce mild ankle sprains from high-velocity and/or excessive range of motion. The risk is minimal for the following reasons: 1) the stability level will be set at level 6 which is on the more stable levels (the most stable is level 8 and the least stable is level 1), 2) if the participant were to lose balance, safety rails are in place to allow the participant to regain balance before the point of injury, and lastly 3) the literature shows that the ankle typically experiences injury if there is greater than twenty (20) degrees of tilt and the Biodex Stability System only allows a maximum of twenty degrees of tilt in all three cardinal planes.

Another potential risk to the participants is a possibility of mild muscle soreness due to a sudden increase of work experienced by the muscles of the lower leg. It is assumed that because of the active status of these participants that they will be able to manage the increased muscular demands of balancing for two thirty-second balance tests.

The last potential risk is limited to the participants that are assigned orthotics. These participants may experience mild discomfort due to the firm, unyielding orthotic material. This should be minimal because the participants are gradually progressing the length of time that they spend in the temporary orthotics (please refer to the orthotics instruction sheet). The participants will be informed to contact the principle investigator if the orthotics are causing them discomfort. Upon report of discomfort, the principle investigator will promptly make an appointment with the participant and the physical therapist to adjust the orthotic to a position of comfort yet still complying with the manufacturer's instructions.

IV. Description of possible benefits to human participants and society in general.

The individual benefit of participation is notable and greatly outweighs its risk. In order to participate in the study, the participant must meet minimal requirements which ultimately indicates that the subject is still feeling the effects of his previous ankle injury. This study will allow the volunteer to have a complete lower extremity evaluation to assess his gait, joint integrity (back, hip, knee, ankle, foot), rearfoot angle, forefoot angle, and extent of hyperpronation during gait. The subject that qualifies for the study also receives multiple assessments of balance. If the volunteer qualifies for the study, he becomes a participant which may allow him to be given a pair of temporary orthotics that will be custom made by an experienced physical therapist.

If a participant is injured during the study, rehabilitation services will be provided for him by the athletic training staff at St. Joseph's/Candler Health Systems whose service is furnished out of the Recreation Activity Center (RAC) on the Georgia Southern University campus. All of these services will be provided to the participant free of charge.

This is an important study for society at large because the results will help support the decision for the use of orthotics after an ankle sprain. Currently, the literature indicates who should afford the benefit of orthotics and focuses on what occurs, theoretically, to the alignment of the lower extremity. Literature also describes the different types of orthotics and orthotic materials. What seems to be neglected is a lack of hard research on how an orthotic effects the athletic or active population, how long an orthotic must be worn to effect balance, and if there is an immediate change in balance after exposure to an orthotic or if an accommodation period of a certain length is required.

Also, in the literature, there are no studies that measure balance immediately after the issuance of orthotics. This allows the study to make a new and unique contribution to literature in the fields of athletic training, physical therapy, podiatry, and rehabilitation in general. This study hopes to call attention to some of these concerns, support what it may, and encourage further research to explore other areas of orthotics in relation to balance after an injury.

V. Information on participants to be utilized in the research.

The sample for this study will be forty (40) participants that must meet a series of requirements. These participants will be both male and female, must be active, and must have suffered a previous ankle sprain to only one leg sometime in the last twelve (12) months but not in the last month (21 days). These participants must also have a Navicular Drop of at least 10mm, no experience with orthotics, and not have had any rehabilitation for the ankle injury. Rehabilitation is functionally defined for this study as any professionally guided external physical modality such as ultrasound, electrical stimulation, assigned exercises, etc. This functional definition of rehabilitation does not

include general ice application and/or the use of over the counter (OTC) non-steroidal anti-inflammatories (NSAIDs), which for this case are considered injury management and generic first aid. A general history will also be obtained to rule out any balance disorders, medications that may effect balance, or head injuries.

The sample population will be recruited through flyers posted in and around the Georgia Southern University Recreation Activity Center, advertisements in the university newspaper, and physical recruiting from activity classes and the university club sports and intramural program. Please see additional handouts for examples of each flyer and advertisement.

VI. Materials and procedures to be used.

The materials to be used for the study are a small metal goniometer, flexible ruler, one index card per participant and marker to be used to take measurements of the rearfoot angle, forefoot angle, and extent of Navicular Drop. The Biodex Stability System and its included software will be used to examine balance and report the dependent variables of overall stability index, anterior-posterior stability index, and medial-lateral stability index. All of the participant's information will be stored in a file with limited access restricted only to the principle investigator and the faculty advisor. Orthotic materials will be purchased from Foot Management, Inc. and molded according to manufacturer's instructions. A digital camera (Sony, Digital Mavica) and camcorder (Cannon, XLI) will be utilized to take pictures of the participants, testing procedures, and measurements. All testing will be performed in the Georgia Southern University Athletics Rehabilitation Room in Hanner Fieldhouse.

Please see attached forms for subject history and record sheet, orthotic instructions, advertising flyers, and newspaper advertisement.

VII. Procedures to secure informed consent.

Informed consent will be obtained by having the volunteer read and sign the consent form before the initial inclusion questions have been answered and before the history questions will be asked. Please see the attached copy of the informed consent form.

VIII. Procedures to gain consent and utilize minors in research.

No minors will be used in this study.

IX. Please provide an explanation, if any of the data collected will relate to illegal

activities.

No data collected will be related to illegal activities.

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

1. Title of Project: The Effect of Orthotics on Dynamic Balance in Participants with Pes Planus and a History of Subacute Lateral Ankle Sprains.

   Investigator's Name Amanda Dawn Wheeler Phone # (912) 681-7661

   Participant's Name _____ Date _____

   Data Location _____ Georgia Southern University Campus
   _____ Other _____

2. I hereby authorize Amanda D. Wheeler and such assistants as may be selected by her to perform on me the following procedures:

   I will be asked a series of questions regarding demographics (name, address, phone number, email), my history of ankle sprains including the care that was given, and general medical history to see if I can be included as a participant in the study. If my history indicates that I may be further investigated, I will remove my shoes and socks in order to have measurements taken of my foot as the final inclusion phase.

   If my measurements allow my participation in the study, I will put my shoes and socks on and then perform balance testing on the Biodex Stability System. I will be instructed on the proper testing procedure and given three practice trials with each leg before the actual testing begins. During the balance test I will stand on one leg at a time, with my eyes open, for the duration of the test of thirty (30) seconds. I understand that if my non-contact foot or any other part of me makes contact with another object then that trial will be discarded.

   After the initial balance test, I may be a randomly chosen participant whom will be assigned a pair of temporary orthotics for which I will wear in all possible shoes, at least eight (8) hours per day, for the duration of the study lasting fourteen (14) days. I am aware that if the orthotics cause me discomfort that I must make an effort to contact the principle investigator, Amanda D. Wheeler, immediately to have the problem corrected. A second balance test will be administered in the same fashion immediately after the issuance of orthotics or the conclusion of my participation in the control group.

   I will schedule an appointment for the first retest session seven (7) days following the initial balance testing. I will wear the exact same shoes and similar socks for the remainder of the testing sessions. A digital picture will be taken of my lower legs and shoes that will be sent to me by email so that I will remember

which shoes to wear. I will also receive a call from the principle investigator the day before the testing session as a reminder. When I arrive for testing I will be asked a series of questions that will allow the investigators to monitor my activity and detect any changes in my medical history and ability to participate in this study. The same balance testing will be administered.

The final testing session will take place fourteen (14) days after the initial testing. I will be contacted in the same manner previously mentioned. The same series of questions and the same balance testing protocol will be administered. After this testing session, my obligations for this study will have been concluded.

3. The procedures and/or investigations listed in paragraph have been explained to me by Amanda D. Wheeler and/or her assistant:

The procedures described previously may involve the following risks and discomforts:

> My participation in this study potentially exposes me to mild ligamentous, capsular, or bone injury to my ankle(s) from balancing on an unstable surface. I may also experience mild muscle soreness from challenging my body to balance on an unstable surface.

These risks and discomforts will be minimized in the following manner:

> The Biodex Stability System will be set at the third most stable level (Level 6 of 8) for both testing and practice. I will be given complete instructions on how to execute the physical aspect of practice and testing on the Biodex Stability System. I will be given the opportunity to ask questions and have a demonstration performed if I desire. My history reports that I am an active participant, therefore I and the principle investigator assume that I will have adequate muscular strength and endurance to participate in minimal balance testing without experiencing excessive muscle soreness.
>
> If an injury were to occur to me during the testing session, there will be a certified athletic trainer present to provide immediate first aid care. I will also have the opportunity to get a complete evaluation and rehabilitate the injury on campus with the athletic training services provided by St. Joseph's/Candler Health System.

4. There is also the rare possibility that a physical injury or latent illness may become evident from the exercise. This possibility is hoped to be minimized by assessment of my physical condition prior to participation in this project.

5. The following benefits from participation in this investigation have been explained to me:

   I will receive a complete lower extremity evaluation including visual gait analysis, and measurements of the rearfoot and forefoot. I may be issued, free of charge, temporary orthotics to help correct my excessive pronation. I will be given the opportunity to ask as many questions as I like about how to properly recover from an ankle injury. I may experience a decrease in discomfort and occurrence of ankle injury as a result in receiving orthotics.

6. I understand that Amanda D. Wheeler and/or appropriate assistants may be selected by her will answer any inquiries I may have at anytime concerning these procedures and/or investigations.

7. I understand that all data concerning myself will be kept confidential and available only upon my written request to Dr. Jim McMillan, EdD, CSCS. I further understand that in the event of publication, no association will be made between the reported data and myself.

8. I understand that I may terminate participation in this study at anytime without prejudice or consequence. The investigator may in her absolute discretion terminate the procedures and/or the investigation for any individual at any time.

9. If I have any questions about this research project, I may call Amanda D. Wheeler at (912) 681-7661. If I have a question or concern about my rights as a research participant, I understand that I may contact the Chairperson of the Departmental Internal Review Board, at (912) 681-0200, or the IRB Coordinator at the Office of Research Services and Sponsored Programs at (912) 681-5465.

10. I understand and am aware that still photographs may be taken of my lower extremities to aid in identification. Additionally a brief video may be taken from behind, during the balance test, and will be used only during the thesis defense and then erased.

Initial and date *one* of the following:

_____ I give my permission for the principle investigator to obtain and use the photos and videos as described above.

_____ I do not give my permission for the principle investigator to obtain and use the photos and videos as described above.

PARTICIPANT'S SIGNATURE_____

DATE

_____

WITNESS_____ DATE_____

History & Record Sheet

DEMOGRAPHICS

Name _____ Participant #

Address _____ Phone Number _____

_____ Email _____

Shoe Size _____ Age _____

Height_____ Weight _____

ORTHOTIC **NO ORTHOTIC**

INCLUSION QUESTIONS

1. Have you had an ankle sprain during the last year? Yes No
2. Have you had an ankle sprain during the last month (21 days)? Yes No
3. Do you have flat feet? Yes No
4. Have you ever used orthotic before? Yes No
5. Have you had any rehabilitation for you ankle injury in the last year? Yes No

HISTORY

1. Have you sprained both ankles during the past year? Yes No
2. Which ankle has been sprained? Left Right
    a. How many times?
3. Was rehabilitation performed? Yes No
4. Have you ever worn orthotics? Yes No
    a. Custom or Over the Counter (OTC)?
    B. Do you still?
5. Do you have a known balance disorder? Yes No
    a. Vertigo? Yes No
    b. Inner ear problems? Yes No
    c. Current ear infection? Yes No
    d. Balance problems? Yes No
    e. History of concussions? Yes No
        1. When was the most recent? _____

2. How severe? _____
3. Loss of consciousness (LOC)? _____

f. Are you currently taking any medication? Yes No
   a. What? _____
   b. Are any of the above known to effect balance? Which?

_____

g. Do you wear corrective lenses? Yes No
   a. Contacts or Glasses?
   B. Are they in right now?

H. Do you, or have you, had an injury to the:
   a. ACL? Yes (L/R) No
   b. Hip? Yes (L/R) No

MEASUREMENTS PERFORMED

Subtalar Neutral (prone) Rearfoot

Right_____ Left_____

Subtalar Neutral (prone) Forefoot

Right_____ Left_____

Navicular Drop

Right_____ Left_____

Explanation and instruction of the Biodex Stability System _____ (Initials)

Practice Biodex Stability System

Right _____ _____ _____
Left _____ _____ _____

Balance Testing

Baseline_____ Trial 2_____ Date_____

Trial 3_____ Date_____

Trial 4_____ Date_____

Photographs

I allow my photograph and possibly a video of me to be used for illustrative purposes of this study only.

_____ (Initials)

_____ (Navicular Drop) _____ (STN-Rearfoot) _____ (STN-Forefoot)
_____ (Testing Video)

Additional Information and Notes

TEST TRIAL 3
FOLLOW UP QUESTIONS

1. Have you had any changes in your medical history since we have last seen you?

2. Have you had any injuries to either ankle since we have last seen you?

3. Have you had any injuries at all since we have last seen you?

4. If you are wearing orthotics, have you been wearing them as instructed?

5. Do you have any questions or comments about the study thus far?

TEST TRIAL 4
FOLLOW UP QUESTIONS

1. Have you had any changes in your medical history since we have last seen you?

2. Have you had any injuries to either ankle since we have last seen you?

3. Have you had any injuries at all since we have last seen you?

4. If you are wearing orthotics, have you been wearing them as instructed?

5. Do you have any questions or comments about the study thus far?

ORTHOTIC INSTRUCTIONS

1. Ease into the use of your orthotics.
    Day 1- Wear orthotics 2 hours
    Day 2- Wear orthotics 4 hours
    Day 3- Wear orthotics 6 hours
    Day 4- Wear orthotics 8 hours
    Days 5 - 14 Wear orthotics at least 8 hours per day

If you can wear the orthotics comfortably for eight (8) hours before the fourth day, please do so.

2. ***Once you have reached day four (4), wear orthotics all day (minimum of 8 hours), every day until the completion of the study*** (14 days from random assignment).

3. ***Wear orthotics in all possible shoes that will be worn between now and the termination of the study***.

4. If you are wearing shoes, you should have your orthotics in them.

5. If you find that your orthotics are causing blisters or you are getting a "hot" or sore spot from them, please contact Amanda Wheeler at (912)
681-7661 to have your orthotic modified immediately.

6. It is imperative that you wear these orthotics according to these instructions. If you do not think you will be able to coincide with these directions please speak up now.

Do you have flat feet?

Do you suffer from
ankle sprains?

Sounds like you could benefit
from orthotics.

Please contact Mandy
Wheeler
at 681-7661

HELP ME

I need active people who have sprained their ankles and have flat feet. If this sounds like you and you want a **FREE** pair of orthotics please be a participant in my thesis.

Contact Mandy Wheeler at 681-7661

Have you done anything important or significant with your life yet?

If not, **START NOW**.

Volunteer to be a participant in my thesis.
Volunteers must be active, have flat feet, and have sprained his ankle in the last 12 months.

Contact Mandy Wheeler at 681-7661

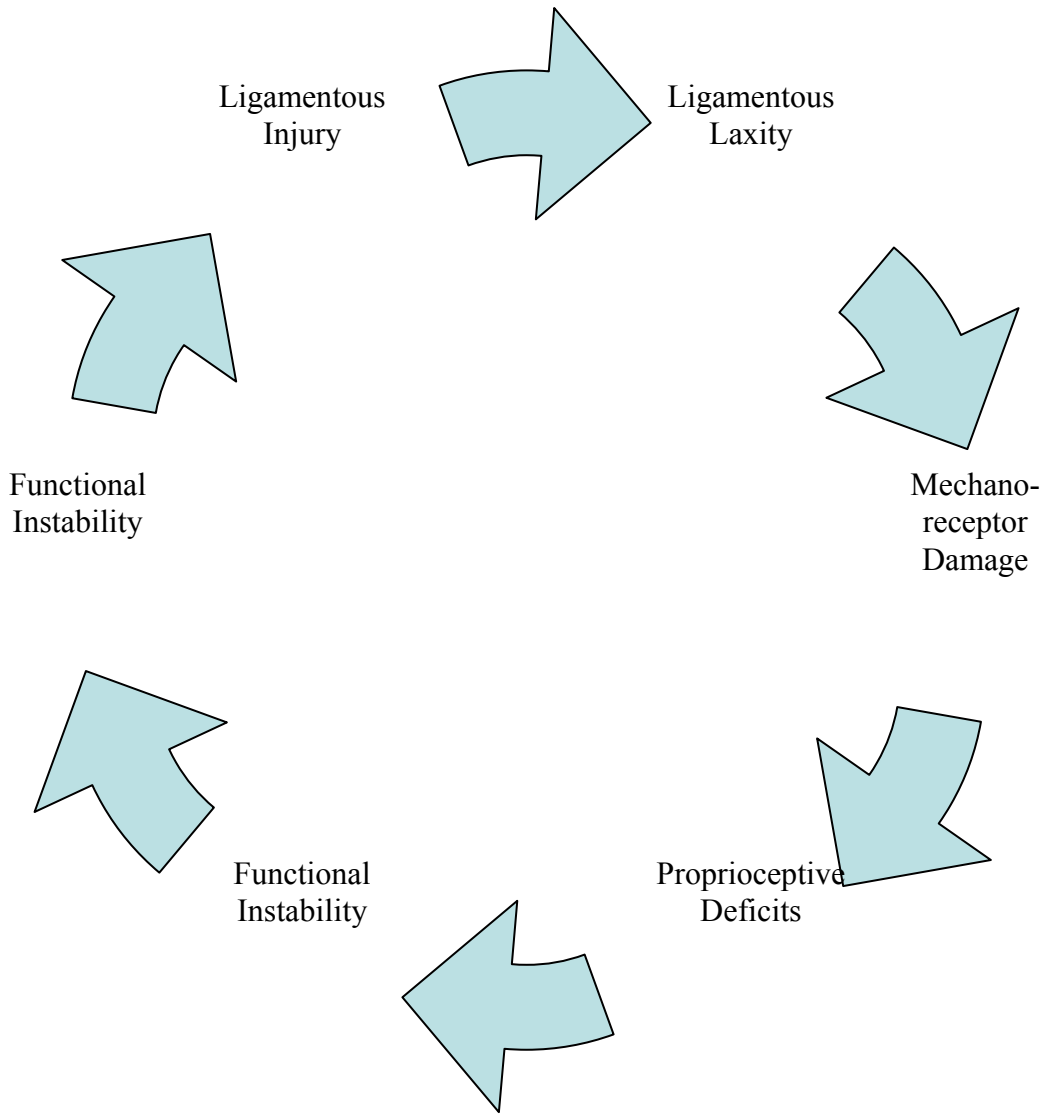
Newspaper Advertisement for the George-Anne

DESPERATE & PRESSED FOR TIME

I am looking for volunteers to participate
in a thesis studying the effect of orthotics
on balance in subjects with a history of
ankle sprains. If you are interested, please
contact Mandy Wheeler, 681-7661.

APPENDIX E

Proprioceptive Paradigm



APPENDIX F

AQUATEMPS

(Custom Splinting Material)

AQUATEMPS ARE AVAILABLE IN *SMALL – MEDIUM – LAREGE & EXTRA LARGE*

HEATING

- Place plastic mesh pan guard in bottom of heat pan or electric frypan. If using a hydrocollator, lay pan line over racks, with at least 1" of water above the racks. Plastic pan liner is available upon request.
- Water temperature must be over 140 degree F. Recommended temperature range is between 160-180 degrees F.
- Heat **Aquaplast-T Splinting Material** until it becomes transparent, which indicates that it is softened and ready to mold. Make sure to blot perforated material dry on a towel prior to placing it on the patient's extremity.
- "Elastic memory" allows for easy splint revisions. Re-soften splint and it will return to original size and shape.

MOLDING

Position patient prone on table with opposite let in a figure 4 position. Place heated Aquatemp on the foot with the curved front portion just proximal to the met heads. Pull the back of the Aquatemp over the heel and smooth to conform. Hold the patient's foot in sub-talar neurtral while the material cools and sets.

Trim

as necessary around the heel.

COOLING

- For faster cooling, use cold spray, ice pack or dip splint in cold water.
- Accommodate for up to 2% shrinkage by molding over stockinet, padding over bony prominences prior to molding and spreading the splint shell once cooled.

BONDING

- Just press together for self-bond rolled edges, reinforcements, etc.
- For more durable and permanent bonds (i.e. areas under high stress), use a splint solvent on both surfaces to be bonded or abrade both surfaces to be bonded. Heat one or both surfaces (at least one surface must be softened to produce a solid bond) then adhere. A heat gun may be used to spot heat both surfaces to be bonded; heat surfaces until shiny.

CLEANING

- **Aquaplast-T Splinting Materials** can be easily cleaned with soap and lukewarm water, however, do not immerse in hot water over 135 degrees F.

FOOT MANAGEMENT, INC. 410-835-3668

APPENDIX G

ORTHOTIC INSTRUCTIONS

1. Ease into the use of your orthotics.
    Day 1- Wear orthotics 2 hours
    Day 2- Wear orthotics 4 hours
    Day 3- Wear orthotics 6 hours
    Day 4- Wear orthotics 8 hours
    Days 5 - 14 Wear orthotics at least 8 hours per day

If you can wear the orthotics comfortably for eight (8) hours before the fourth day, please do so.

2. ***Once you have reached day four (4), wear orthotics all day (minimum of 8 hours), every day until the completion of the study*** (14 days from random assignment).

3. ***Wear orthotics in all possible shoes that will be worn between now and the termination of the study***.

4. If you are wearing shoes, you should have your orthotics in them.

5. If you find that your orthotics are causing blisters or you are getting a "hot" or sore spot from them, please contact Amanda Wheeler at (912)
681-7661 to have your orthotic modified immediately.

6. It is imperative that you wear these orthotics according to these instructions. If you do not think you will be able to coincide with these directions please speak up now.