The Effect of Semi-Rigid Foot Orthotics on Subtalar Joint Subluxation and Pain during Three Gait Velocities

Lynnelle A. Gelinske

University of North Dakota

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THE EFFECT OF SEMI-RIGID FOOT ORTHOTICS
ON SUBTALAR JOINT SUBLUXATION AND PAIN
DURING THREE GAIT VELOCITIES

by

Lynnette A. Gelinske
Bachelor of Science in Physical Therapy
University of North Dakota, 1993

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May
1994
This Independent Study, submitted by Lynnelle A. Gelinske in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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PERMISSION

Title The Effect of Semi-rigid Foot Orthotics on Subtalar Joint Subluxation and Pain During Three Gait Velocities

Department Physical Therapy

Degree Master of Physical Therapy

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ABSTRACT

It has been established that foot orthotics can effectively control the amount of maximal calcaneal eversion while walking. However, there are conflicting studies about the successfulness of foot orthotics in regulating rearfoot motion during running. The purpose of this study was to determine the effectiveness of standard vertical semi-rigid foot orthotics in controlling subtalar joint subluxation (STJS) and pain during three gait velocities. The study was also completed to ascertain whether any correlations existed between STJS and the static lower extremity measurements of tibio-fibular varum, gastrocnemius flexibility, and navicular drop. The results of this study revealed that pain increased significantly across the three test speeds; however, STJS did not. No strong correlations were found to exist between STJS and the three lower extremity measurements for any test velocity. The current methods of prescribing, creating, and evaluating foot orthotics are not always adequate to control biomechanical alignment and shock dissipation through a large spectrum of gait velocities.
INTRODUCTION

Foot orthotics are frequently used in sports medicine to help restore biomechanical alignment and to attenuate shock in the lower extremities. James et al\textsuperscript{1} examined records of 180 patients with running injuries and found that 58\% of the subjects (104 individuals) exhibited pronated feet in the static weightbearing position. Forty-six percent of all the runners (83 individuals) were prescribed orthotics as the form of treatment. Seventy-eight percent of those runners (65 individuals) were able to return to their previous running programs with orthotic correction only.

Foot orthotics are worn to support, align, and/or correct deformities of the lower extremity.\textsuperscript{2} They attempt to restore dynamic stability by controlling the velocity and the degree of abnormal movement of the subtalar joint (STJ) during the stance phase of gait. Rigid orthotics, created from heat moldable plastic, are primarily designed to control motion. Semi-rigid orthotics, molded from a combination of leather, cork, and thermoplastic substances, provide motion control and some cushioning. Soft orthotics are comprised of pliable substances which allow less motion control, but provide greater cushioning.\textsuperscript{3,4}

Expected benefits from foot orthotics include any combination of the following: 1) biomechanical support, 2) restriction of joint range of motion (ROM),
3) redistribution of body weight, 4) dissipation of weightbearing forces, 
5) reduction of contact on tender areas, and 6) reduction of shear forces on the 
plantar aspect of the foot.\textsuperscript{5}

Normal Biomechanics for the Stance Phase of Gait

An understanding of normal foot and ankle biomechanics is essential for 
physical therapists treating patients with pathological gait deviations. In a 
closed kinetic chain, motions at the foot and ankle are dependent upon the 
position of the STJ. Initial contact with the ground occurs on the lateral 
calcaneus while the rearfoot is inverted approximately three to four degrees.\textsuperscript{6-9} As the leg moves over the talus, the cone-shaped trochlea (medial apex) 
causes a larger anterolateral displacement of the lower leg resulting in internal 
rotation of the tibia. The internal rotation of the tibia elicits pronation of the STJ 
which in turn induces midtarsal joint (MTJ) pronation, thereby allowing the 
calcaneocuboid and the talonavicular joint axes to become parallel. Parallel 
alignment of the axes allows the foot the greatest flexibility in adapting to 
uneven terrain and shock absorption.\textsuperscript{6,10,11}

Midstance begins with the completion of STJ pronation.\textsuperscript{3} The tibia 
continues to move anteriorly over the talus causing closed kinetic chain 
dorsiflexion and the subtalar and midtarsal joints initiate supination. The 
metatarsal heads also become full weightbearing as body weight is transmitted 
from the rearfoot to the forefoot.\textsuperscript{10}
During terminal stance, the orientation of the metatarsal break (functional axis connecting the distal heads of the 2nd-5th metatarsals) causes the tibia to externally rotate to distribute body weight uniformly, further inducing supination of the STJ and MTJ. A rigid lever for preswing is created as the MTJ axes become oblique.\textsuperscript{6,10,11} Body weight is also shifted from the lateral to the medial side of the foot and the first ray plantarflexes for toe-off.\textsuperscript{6,10}

Biomechanics of Walking vs. Running

The same biomechanics and stabilization mechanisms are employed for both walking and running; however, the gait cycle is somewhat varied.\textsuperscript{12} In walking, the stance phase comprises 60\% of the gait cycle and the swing phase makes up the remaining 40\%. As speed increases, there is a decrease in the percentage of time spent in stance and an increase in the percentage of time spent in swing. In running, the stance phase is roughly 45\% and the swing phase is approximately 55\% of the gait cycle.\textsuperscript{13} In terms of duration, the running cycle constitutes 60\% of the walking cycle. The absence of double support during running, the period when both feet are simultaneously in contact with the ground, distinguishes walking from running.

As indicated by Baitch et al,\textsuperscript{9} numerous studies have shown a greater tendency for excessive pronation in running compared to walking. Theories used to explain this occurrence include: 1) the foot is generally pronated for a greater percentage of the stance phase during running and 2) running increases tibial varum which accentuates calcaneal inversion relative to the
ground. The STJ compensates by pronating to allow the calcaneus to fully contact the supporting surface.\textsuperscript{9}

Baitch and associates\textsuperscript{9} reported two factors which contribute to increased injuries among runners who are rearfoot strikers (person whose rearfoot has initial contact with the ground). The first factor was STJ subluxation (STJS), which the researchers defined as occurring when the degree of calcaneal eversion measured dynamically exceeds the degree of calcaneal eversion measured statically. The second contributor was abnormal STJ pronation relative to the ground, consisting of calcaneal eversion beyond a line perpendicular to the ground.

Injuries to the foot, achilles tendon, knee, and hip can all be linked to abnormal pronation of the foot during the stance phase of gait.\textsuperscript{14} Orthotic prescription is a common treatment used to correct biomechanical faults such as STJS and abnormal pronation in the foot and ankle during walking and running.

Orthotic Intervention

Walking

Several studies have shown reduced maximum pronation with the use of both semi-rigid and rigid orthotics during walking.\textsuperscript{15,16} McCulloch et al\textsuperscript{15} examined the effect of foot orthotics on maximal calcaneal eversion at walking speeds of 2 and 3 mph. Ten subjects, all with excessive subtalar joint pronation, participated in the study. Seven individuals wore rigid foot orthotics
and three subjects used semi-rigid orthotics. The results showed maximal calcaneal eversion was reduced from 10.40 degrees to 6.40 degrees at 2 mph and from 10.20 degrees to 7.50 degrees at 3 mph. No distinction was made between rigid and semi-rigid orthotics in the reduction of maximal calcaneal eversion. The results were found to be statistically significant.

Novick and Kelley\textsuperscript{16} also performed a study that evaluated the effect of foot orthotics on maximum calcaneal eversion during walking. Twenty subjects, all with rigid foot orthotics, were evaluated at their casual walking speed. This research also showed a statistically significant decrease in the maximal calcaneal eversion angle between orthotic (8.54 degrees) and non-orthotic (4.30 degrees) conditions. Both McCulloch et al\textsuperscript{15} and Novick and Kelley\textsuperscript{16} found an average reduction of three to four degrees in maximal calcaneal eversion using orthotic devices while walking.

Running

Numerous studies have investigated the effect of foot orthotics on maximal calcaneal eversion during running.\textsuperscript{4,9,17,18} In contrast to the literature on walking, the data from these studies show conflicting results.

In a study performed by Rodgers et al\textsuperscript{17} 29 male runners using semi-rigid foot orthotics were evaluated while jogging/running at a comfortable pace (ranging from 7.5 to 8.6 mph). The maximal calcaneal eversion decreased when wearing orthotics. Insertion of the orthotics significantly controlled maximum pronation in the left foot (8.89 to 7.96 degrees), but not in the right
foot (7.98 to 7.58 degrees). Therefore, the authors concluded that overall reduction in maximal pronation was insignificant.

Bates and associates\textsuperscript{18} conducted a similar study in which six joggers/runners wearing rigid foot orthotics were examined while jogging/running at a comfortable pace (ranging from 6.3 to 10 mph). Maximal calcaneal eversion decreased from 11.0 degrees with only shoes to 7.0 degrees with shoes and orthotics, but the authors concluded the reduction was not significant. Possible reasons for non-significance in this study may be hypothesized to include small subject size and research methodology.

While these previous studies allowed the subjects to select a comfortable jogging/running pace, Smith et al\textsuperscript{4} selected a single velocity condition. Nine subjects using semi-rigid foot orthotics were evaluated while running at 8.6 mph on a treadmill. Maximum pronation was decreased from 11.3 degrees with shoes to 10.1 degrees with shoes and orthotics. This decrease in maximal calcaneal eversion was found to be statistically significant.

A study performed by Baitch and colleagues\textsuperscript{9} evaluated the effectiveness of two different rigid foot orthotic devices in controlling STJ subluxation (STJS) and abnormal pronation. The authors reported that functional STJS occurs when the degree of dynamic calcaneal eversion exceeds the degree of static calcaneal eversion. Seven subjects were instructed to run at a comfortable pace (approximately 9.2 mph). They were examined in four different conditions: 1) barefoot, 2) shoes only, 3) shoes with vertical orthotics, and 4) shoes
containing 25 degree inverted orthotics. (Inverted orthotics were molded into 25 degrees of calcaneal inversion compared to standard vertical orthotic casting in subtalar joint neutral.) The inverted orthotic was designed to counter the increased tibial varum that occurs with running. The study demonstrated that functional STJS can occur during running and also revealed that the 25 degree inverted orthotic was the most effective in controlling abnormal pronation and functional subluxation of the STJ in running when compared to the other three test conditions. The researchers feel the traditional criteria for evaluating orthotics used during the walking cycle may not be applicable for those used during running.

It has been established that foot orthotics can successfully control the amount of maximal calcaneal eversion while walking. However, there are conflicting studies about the effectiveness of foot orthotics in regulating rearfoot motion during running. Also, none of these studies evaluated the effectiveness of foot orthotics in controlling calcaneal eversion during walking, jogging, and running speeds. Since the amount of maximal pronation increases as the speed of gait increases,9,18 functional STJS may not occur in an individual until a fast speed is reached. It is possible that the current techniques of prescribing, creating, and evaluating foot orthotics are inadequate to control biomechanical alignment and shock dissipation through a large spectrum of gait velocities. Therefore, the purpose of this study is to determine the
effectiveness of standard vertical semi-rigid foot orthotics in controlling STJS and pain during three gait velocities.
METHODS

Subjects

Eight subjects (four males and four females) between the ages of 17 and 43 years volunteered to participate in the study (mean age=23.4, SD=10.3). All individuals had previously received standard vertical semi-rigid foot orthotics from the Institute of Sports Medicine in Bismarck, ND.

Each subject demonstrated either a pronating gait pattern in which there was excessive calcaneal valgus at initial contact, midfoot collapse at loading response, and medial forefoot pushoff or a cross-over gait pattern defined as excessive calcaneal varus at initial contact, midfoot pronation at loading response, and medial forefoot pushoff. All subjects were rearfoot strikers and only feet with a flexible first ray were included in the data analysis. Each subject signed a consent form before participation in the study in accordance with policies and procedures outlined by the Institutional Review Board at the University of North Dakota (Appendix A).

Instrumentation

Passive range of motion for calcaneal eversion was measured in prone with the foot positioned over the edge of a plinth. The contralateral lower extremity was placed in hip flexion, abduction, and external rotation with knee
flexion to stabilize the ipsilateral lower leg and calcaneus in the frontal plane. Reference markings were made on the distal one-third of the subject’s posterior leg and the calcaneus with a felt-tip marker. A caliper was used to determine the midpoint of the lower leg. One dot was made on the posterior leg below the definition of the gastrocnemius and the second was placed slightly superior to the malleoli, excluding the angulation of the achilles tendon. The two dots were connected with a straight line. To bisect the posterior calcaneus, markings were made visually at its proximal and distal aspect and connected with a line.

A seven-inch universal plastic goniometer with two-degree increments was used for all calcaneal measurements. The stationary arm of the goniometer was placed along the bisection of the distal lower leg and the moveable arm was aligned with the calcaneal bisection. The axis of the goniometer was positioned between the malleoli (Figure 1). Passive range of motion (PROM) was measured to the nearest degree by everting the calcaneus until a firm endfeel was acquired. Subtalar joint PROM is shown to have fair (ICC=.75) intratester reliability.\textsuperscript{19,22}

Tibio-fibular varum, which has high (ICC=.96) intratester reliability,\textsuperscript{21,22} was measured as each subject stood barefoot with their heels at the edge of an elevated platform. Each subject stood in a resting calcaneal stance position (RCSP) on a footprint template made of their dynamic angle and base of gait. The technique utilized for determining the dynamic angle and base of walking
Figure 1. Measurement of static maximal calcaneal eversion with the subject lying prone.
has been previously described by McPoil et al.\textsuperscript{21} The bisection of the lower one-third of the leg was used to align the moveable arm of the goniometer and the stationary arm was positioned parallel to the horizontal platform surface (Figure 2).

Gastrocnemius flexibility was measured with the subject in long sitting using a towel roll placed under the distal lower leg. The stationary arm of the goniometer was aligned parallel to the fibula, the axis was placed at the distal lateral aspect of the calcaneus, and the moveable arm positioned parallel to the distal portion of the lateral calcaneus (Figure 3). Intratester reliability has been found to be high (ICC=.90) for ankle dorsiflexion.\textsuperscript{19,22} Measurements for both tibio-fibular varum and gastrocnemius flexibility were performed using a nine-inch goniometer with one-degree intervals and recorded to the nearest degree.

For the navicular drop test, a dot was placed with a felt-tip marker over the most prominent aspect of each navicular tuberosity while the subject was in a non-weightbearing position. The participant was then instructed to stand barefoot on his/her footprint template with both heels along the edge of the elevated platform with equal weightbearing bilaterally. The researcher positioned each foot in subtalar joint neutral as described by Root et al.\textsuperscript{23} An index card was then placed between the medial malleoli and marked at the height of the most prominent point on each navicular tuberosity. The same procedure was repeated with the subject in a RCSP. The distance between the two dots on the index card was measured in millimeters, representing the
Figure 2. Measurement of tibio-fibular varum in the resting calcaneal stance position (RCSP).
Figure 3. Measurement of gastrocnemius flexibility.
distance the navicular tuberosity dropped from the neutral calcaneal stance position (NCSP) to the RCSP. The navicular drop test has been found to yield poor to fair (ICC=.61-.79) intratester reliability.\textsuperscript{20,22}

A visual analogue scale (VAS) and pain diagram were used to evaluate and locate pain experienced by the subjects (Appendix B). The VAS is a 10 cm line illustrating the spectrum of the perception of pain. One boundary of the line represents "pain as bad as it could be," and the other signifies "no pain at all." The subject rated the degree of pain by marking a line across the VAS. The distance between zero and the mark was measured in millimeters, corresponding to the value of perceived pain. The VAS has been found to be a highly reliable and valid instrument for the evaluation of pain.\textsuperscript{24,25}

Subjects walked, jogged, and ran on an Acceleration Treadmill developed by Standard Industries (Acceleration Products, Inc, 2301 25th St S, Suite E, Fargo, ND) which had speed capabilities of 0-26 mph. Action was recorded by an 8 mm Sony video camera Model CCD870 (Sony Corp, PO Box 704, Park Ridge, NJ 07656) at a shutter speed of 1000 frames per second. Additional lighting was provided to enhance the video cinematography. The video tape was played in a Sony Super 8 player and viewed on a Sony Trinitron video monitor. Through frame by frame advancement, the principle investigator selected maximal calcaneal eversion during the stance phase of each gait velocity. A Sony digital video adapter XV-D30 stopped the action and the picture was reproduced through a Sony videographic printer UP-850 (Figure 4).
Figure 4. Printed videographic picture of dynamic maximal calcaneal eversion with the subject running on a treadmill.
The angle formed between the bisection of the distal lower leg and the bisection of the calcaneus was measured off of the print with a 3.5 inch plastic protractor.

Because one of the subjects exhibited an inflexible first ray, only fifteen individual feet received analysis in this study. Three gait cycle recordings were measured at all velocities for a total of nine prints of each foot. Of the 135 pictures, 30 were randomly selected to be measured by a second investigator. Intertester reliability of the calcaneal eversion measurements from the printed videographic picture was found to be highly reliable ($r=.92$).

Procedure

Each participant received a static lower extremity musculoskeletal exam which evaluated PROM for calcaneal eversion, tibio-fibular varum, gastrocnemius flexibility, and navicular drop bilaterally (Appendix C).

Next, orthotics were placed on the footprint template on the raised platform. Subjects were then instructed to stand barefoot in a RCSP on the orthotics. The position of the calcaneus was measured bilaterally with a goniometer. The goniometer was aligned with the same reference markings used during passive calcaneal eversion measurements. The orthotics were then placed in the subject's shoes and each subject stood with his/her shoes and orthotics over his/her footprint template on the elevated platform. A piece of tape representing the bisection of the posterior calcaneus was placed on the posterior aspect of each shoe. The tape was positioned to replicate the calcaneal angle measured in the barefoot/orthotic condition described above.
Studies indicate that movements of the calcaneus and the shoe are well correlated.\textsuperscript{4,26}

The video camera was positioned five feet, six inches from the rear of the treadmill to capture each subject's maximal calcaneal eversion during the three test velocities. Trial sessions were performed by the subject before each speed to familiarize himself/herself with the treadmill and testing procedures. Each subject also completed a visual analogue scale (VAS) and pain diagram before the initial testing speed and after each of the three test speeds. Subjects walked (3.5 mph), jogged (7 mph), and ran (10 mph) on the treadmill for 20 seconds at each velocity. A two-minute interval was allowed between test conditions so the subject could rest and complete the VAS and pain diagram.

Data Analysis

An average of three gait cycle recordings was used for data analysis to determine dynamic calcaneal eversion for each foot across all three gait velocities. STJS was then computed by subtracting the static maximal calcaneal eversion measurement from the average dynamic measurement. An ANOVA was performed on the information to determine if statistical variance existed between 1) STJS and the three test speeds and 2) between the VAS and the three test speeds. Statistical analysis also included correlation coefficients to determine if a relationship existed between 1) STJS at each test
speed and tibial varum, 2) STJS at each test speed and gastrocnemius flexibility, and 3) STJS at each test speed and navicular drop.
RESULTS

The results of the analysis revealed that pain increased significantly across the test speeds (p=0.02). The mean level of pain before testing was 0.75 millimeters on the VAS and increased to 17.13 millimeters after running. A Tukey B analysis demonstrated a significant difference at the 0.05 level between the pre-test and the post-running conditions and also between the post-walking (0.63 mm) and post-running conditions.

In contrast to pain, STJS was not significant between the three test speeds. Mean STJS was as follows: walking, 4.04 degrees; jogging, 6.27 degrees; and running, 6.20 degrees. Of the 15 individual feet analyzed, however, 12 (80%) demonstrated STJS at the walking and jogging speeds and 13 (87%) were subluxed during running. While most subjects did not vary significantly in STJS between the velocities, two participants exhibited a greater than five degrees difference in STJS between the walking and jogging speeds.

Correlation coefficients for STJS at each velocity and the static lower extremity measurements are listed in Table 1. No strong correlations existed between STJS and tibio-fibular varum, gastrocnemius flexibility, and navicular drop for any test speed.
Table 1.--Correlation Coefficients for Subtalar Joint Subluxation During Three Gait Velocities with Static Lower Extremity Measurements (N=15)

<table>
<thead>
<tr>
<th>Velocity</th>
<th>Tibio-fibular Varum</th>
<th>Navicular Drop</th>
<th>Gastrocnemius Flexibility</th>
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<tr>
<td>3.5 mph</td>
<td>0.2806</td>
<td>-0.1783</td>
<td>-0.1621</td>
</tr>
<tr>
<td>7 mph</td>
<td>0.0715</td>
<td>-0.1979</td>
<td>-0.2017</td>
</tr>
<tr>
<td>10 mph</td>
<td>0.0362</td>
<td>-0.2023</td>
<td>-0.1947</td>
</tr>
</tbody>
</table>
DISCUSSION

The results of this study showed that pain significantly increased across the three test velocities. All test speeds were performed in the identical sequence, making it impossible to conclusively determine whether the pain magnification was caused by the changes in treadmill velocity, the duration of gait, or a combination of factors. However, since each subject ambulated for a total of only 60 seconds, it can be hypothesized that velocity, rather than duration, had a greater impact on pain.

James and associates\(^1\) stated, in their opinion, pain is associated with "accumulated impact loading" of the lower extremity. This study corroborated James et al.'s\(^1\) findings that pain is affiliated with "impact loading" by demonstrating that as speed and thus ground reaction force increase, so does pain. Clinical statements from physical therapists and orthotic users reveal that high impact, continuous duration activities (i.e., jogging and running) escalate pain to a greater extent than either low impact, continuous duration (i.e., walking) or high impact, intermittent duration (i.e., basketball and volleyball) activities.\(^2\)

A survey was sent to 43 individuals who had previously received standard vertical semi-rigid foot orthotics from the Institute of Sports Medicine in
Bismarck, ND (Appendix D). Twenty-five (58%) fully completed questionnaires were returned. The surveys supported James and associates' research revealing that pain was the greatest in high impact, continuous duration activities and was reduced least often with orthotic correction during those activities. Sixty-eight percent of the people (17 individuals) reported that the orthotics decreased pain in some or all of their physical activities, 24% (6 individuals) described no reduction in pain, and 8% (2 individuals) revealed an increase in pain while wearing the orthotics.

In contrast, Donatelli and colleagues reported that 90% of their subjects surveyed indicated that the orthotics were effective in relieving pain. Variance between the two studies may be due to the fact that the subjects in Donatelli et al.'s study received temporary orthotics for an average of six to eight weeks. During that time, adjustments were made to the orthotics according to the pain reported by the patient. The individuals who received orthotics from the Institute of Sports Medicine in Bismarck, ND, were fitted with orthotics initially and occasional corrections were performed on an individual basis. The temporary orthotics allowed for changes to be made that achieved both symptom relief and proper biomechanical alignment before the permanent orthotics were fabricated.

STJS was not significant between the three test speeds. However, 87% of the individual feet analyzed in this study were subluxed while using semi-rigid foot orthotics at a speed of 10 mph. In a study completed by Baitch et al., only
29% of the feet examined demonstrated STJS with rigid vertical orthotics at a velocity of approximately 9.2 mph. Possible reasons for discrepancy in the frequency of STJS between the two studies include the use of different types of orthotics, different test speeds, and small sample sizes.

This study demonstrated that standard vertical semi-rigid foot orthotics are not controlling STJS through a spectrum of gait velocities. Since subjects were not tested in either a shoes only or barefoot condition, it is impossible to determine the amount of STJS that would have occurred without the use of orthotics. However, it is likely that without the orthotics, the individuals would have had greater maximal calcaneal eversion and STJS. The orthotic correction may have been enough to reduce symptoms in the majority of participants, but not fully achieve an optimal biomechanical alignment. Blake\textsuperscript{28} indicated that inverted functional orthotics are recommended for patients who demonstrate biomechanical symptomology and abnormal STJ pronation with the use of standard vertical orthotics. It is possible that some of the subjects in this study would be candidates for inverted orthotics.

No strong correlations existed between STJS and the three static lower extremity measurements at any test velocity. Magee\textsuperscript{29} indicated that 10 degrees of dorsiflexion is required for normal locomotion. Thirteen out of the fifteen lower extremities examined possessed gastrocnemius flexibility greater than 10 degrees. For the navicular drop test, a difference greater than 15 millimeters between the NCSP and the RCSP is considered to be abnormal.\textsuperscript{30}
None of the subjects exhibited a navicular drop larger than 11 millimeters. Therefore, most subjects were within the normal limits for both navicular drop and gastrocnemius flexibility, possibly making it difficult to establish a correlation between the clinical measures and STJS. In bilateral stance, normal tibial varum occurs when the tibia is aligned vertically with respect to the floor. None of the individuals studied demonstrated a tibial varum measurement of zero. Perhaps the orthotics controlled enough calcaneal eversion, eliminating correlations that might have existed between any of the three lower extremity measurements and STJS.

Limitations of this research include small subject size and the use of two dimensional videographic information rather than data produced from a three dimensional motion analysis system. Error could have also been introduced during the placement of the tape representing the calcaneal bisection on the posterior aspect of the shoe. Additionally, subjects were only evaluated while wearing shoes and orthotics.

One positive aspect of this study is that it is easily reproducible. The equipment used in this research is readily available at many physical therapy facilities. Also, intertester reliability of the calcaneal eversion measurements from the printed videographic picture was found to be highly reliable.

If this study were to be repeated, it would be beneficial to include the following conditions: 1) shoes only, 2) barefoot, and 3) shoes with orthotics. Instead of placing tape on the posterior aspect of the shoe, a shoe with a
translucent heel counter could be used to more accurately evaluate the movement of the calcaneus. Finally, a larger sample size would enhance the statistical analysis.
CONCLUSION

Subtalar joint subluxation did not increase significantly between the three test speeds; however, the semi-rigid orthotics were unable to adequately control biomechanical alignment at any test velocity. Pain was found to be significantly increased across the speeds, demonstrating that shock dissipation was not controlled as well at the faster velocities.

Oftentimes orthotics are molded with the foot in a STJN position and the permanent orthotics are created from the initial casting. Orthotics are frequently evaluated by a therapist as the patient stands in a static position and also ambulates for a short distance. These methods of prescribing, creating, and evaluating foot orthotics are not always adequate to control biomechanical alignment and shock dissipation through a large spectrum of gait velocities.

It might be beneficial if all initial orthotics created were temporary. Temporary orthotics allow for changes to be made that achieve biomechanical alignment and symptom relief before the permanent orthotics are fabricated. Therefore, not all orthotics would be permanently cast into subtalar joint neutral, instead orthotics could be inverted, everted, or neutral depending on the patient's needs. With the use of a video camera, orthotics could then be evaluated as the patient performs the activities in which he/she participates.
Analysis of the video will reveal whether the proper biomechanical alignment has been achieved. In addition, the patient's subjective reporting enables the clinician to determine if symptom relief has been obtained. Therefore, the orthotics would be custom designed both for the patient's biomechanical uniqueness and the activities in which he/she participates. This should improve both the patient compliance and overall satisfaction with orthotics.
DATE: October 18, 1993

NAME: Lynnelle Gelinske

DEPARTMENT/COLLEGE: Physical Therapy

PROJECT TITLE: The Effect of Standard Semi-Rigid Foot Orthotics on Subtalar Joint Subluxation and Pain During Three Gait Velocities

The above referenced project was reviewed by the University's Institutional Review Board on October 18, 1993 and the following action was taken:

☐ Project approved. Next scheduled review is on October 1994.
If no date is given then review will be required in 12 months. (See REMARKS SECTION for any special condition.)

☐ Project approval deferred. (See REMARKS SECTION for further information.)

☐ Project denied. (See REMARKS SECTION for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairman or ORPD.

E. Simunds, Adviser
Dean, Graduate School

Signature of Chairperson or designated IRB Member: Gloria Ayers

Date: 10/18/93

UND's Institutional Review Board

the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 596 Form may be required. Contact ORPD to obtain the required documents. (9/87)
MEMORANDUM

TO: Independent Review Board Members

FROM: Keith House, PT/LATC

RE: Foot Orthotic Study by Lynelle Gelinski

DATE: August 4, 1993

Lynelle Gelinski is a physical therapy student at the University of North Dakota who we have been working with here at the Institute of Sports Medicine at St. Alexius Medical Center in Bismarck, North Dakota, to assist with development and coordination of this study. We have thoroughly reviewed the contents of the study and are in complete cooperation with this project.

If there are any questions as to the involvement of our Medical Center, feel free to contact me at 1-800-222-7858. Thank you.
Foot orthotics are frequently used in sports medicine to help restore proper biomechanical alignment and to attenuate shock in the lower extremities. Smith, et al. state that studies on the effectiveness of foot orthotics controlling rearfoot motion, however, have produced mixed results. It is possible that the current techniques of prescribing, creating, and evaluating foot orthotics are inadequate to control biomechanical alignment and shock absorption through a large spectrum of gait velocities. Therefore, the purpose of this study is to determine the effectiveness of standard vertical semi-rigid foot orthotics in controlling subtalar joint subluxation and pain during three gait velocities.

Individuals who have previously received standard vertical semi-rigid foot orthotics from the Institute of Sports Medicine in Bismarck, ND, will be invited to participate in the study. Kinetic data will be recorded for the lower legs bilaterally as each subject walks/runs on a treadmill for 30 seconds at speeds of 3.5, 7, and 10 mph while wearing their own walking/running shoes and orthotics. Pain will also be documented using a visual analogue scale.

Statistical analysis of these data will be conducted to determine if standard vertical orthotics significantly control subtalar joint subluxation and pain during various gait velocities. Human subjects are required because proposed benefits resulting from the study will be used clinically.
A survey will be sent to approximately 75 people who have previously received standard semi-rigid foot orthotics from the Institute of Sports Medicine in Bismarck, ND. Many individuals will be invited to participate in a study about the effect of semi-rigid orthotics on subtalar joint subluxation and pain during three gait velocities. The approximate age range for these subjects may vary from 15 to 45 years of age. Criteria for inclusion in the study are normal and symmetrical muscle strength, flexibility, and range of motion (ROM) in both legs (McCulloch, et al.); pronating gait pattern; the heel striking the ground first while walking; and participation in moderate aerobic exercise 3 to 5 days per week.

If the subject agrees to participate, he/she will receive a consent form to sign, and any questions will be answered. Subjects under the age of 18 must have one parent or guardian in the consent form.

Equipment

The treadmill to be used in the study is custom built by Acceleration Products Inc. out of Fargo, ND. The video camera is an 8 mm Sony video cam-caddie cam with a maximum shutter speed of 4000 frames per second.

Procedure

The survey will gather the following information from each subject: which sport(s) he/she participates in and how many hours/week are spent participating in each sport; which sports orthotics worn for; rating of pain experienced during each sport, the effect of orthotics on pain, length of time pain persists after the activity has ended; and overall satisfaction with orthotics (See Appendix A).

Each subject will schedule two appointments. During the first appointment, the subject will receive a static lower extremity (LE) musculoskeletal exam. In addition, he/she will complete a training session on a treadmill at the three test speeds (3.5, 7, and 10 mph). Subjects must feel comfortable with the treadmill and testing procedures before the actual testing begins. The first appointment will last no longer than one hour.

The static lower extremity (LE) musculoskeletal exam will include evaluation of the following: Subtalar joint (STJ) ROM, first metatarsophalangeal (MTP) extension, ankle dorsiflexion, tibial varum (Smith, et al.), and navicular drop and calcaneal position when standing on one leg (Mueller, et al.). Navicular drop and calcaneal position in one leg standing will be recorded for both barefoot and orthotics only conditions. A generalized LE flexibility and strength evaluation will also be performed (See Appendix B).

Two separate appointments for each subject are necessary because the practice and testing sessions must occur on different days. This will ensure that any pain recorded through the visual analogue scale (VAS) is due to the testing session and not the trial session. During the second appointment, each subject will be asked to walk/run for 30 seconds at each test speed while wearing their own personal walking/running shoes with orthotics. Video camera will be used to record the movement of reference markings placed on the subject’s lower legs. Each subject will also complete a VAS before the initial testing speed and after each of the three testing speeds in order to evaluate his/her pain. This method for rating pain has been proven both reliable and valid (Wallenstein, et al. & Revill, et al.). There will be a four-minute interval between test speeds so the subject may rest and complete the VAS (See Appendix C). The second appointment will last no longer than 30 minutes.

The therapist will make marking bilaterally on the subject’s lower legs with a felt-tip marker. The markings will represent the axes of the lower legs and will act as reference points for STJ movement (McCulloch, et al. & Baitch, et al.). The markings will be made at the posterior bisection of the lower 1/3 of the leg. In addition, a strip of tape will be placed on the back of the shoes to represent bisection of the posterior heel (See Appendix D).

One video camera will be positioned at the rear of the treadmill in order to record the movement of the subject’s lower legs. Maximum calcaneal eversion, between heelstrike and toe off, will be calculated for each subject bilaterally. This kinetic data, along with information from the static LE exam and VAS, will be statistically analyzed, and the results sorted in aggregate form. An average of five gait cycle recordings for each test speed will be used for analysis.

To maintain confidentiality, the subject’s name will not be included anywhere in the report or mentioned to anyone not involved with the study.
Statistical analyses will be performed on the data to determine if there are any relations between (1) joint subluxation at each speed and navicular drop and (2) joint subluxation at each speed and tibial varum. An ANOVA will also be performed on the formation to determine if statistical variance exists (1) between the VAS and the three test speeds and (2) between maximum eversion and the three test speeds.
**BENEFITS:** (Describe the benefits to the individual or society.)

Possible benefits to each subject include, but are not limited to, discovering if his/her orthotics properly controls his/her foot motion at varying speeds of gait. Subjects may gain an interpretation of the results as it relates to his/her own personal function. Possible benefits to society are (1) research examining the effectiveness of a current treatment technique that is very prevalent in our society and (2) stimulation of further search on this topic.

**RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional, or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

Possible risks in this study are minimal. The treadmill speeds used in this study are comparable to walking at a comfortable pace, a slow jog, and a moderate jogging speed. Any fatigue or increase in pain would be equivalent to walking/running for 30 seconds at each of three test conditions. There is a slight possibility of injury while walking/running on the treadmill. However, the practice session should decrease the possibility of injury by enhancing each subject's kinesthetic awareness and proprioception on the treadmill. In the event that a physical injury is incurred during the study, medical treatment will be available as it is to any member of the general public.

Participation in this study is completely voluntary. Subjects may withdraw from the study any time without fear of retribution. To maintain confidentiality, subject's names will not appear in the study or be shared with anyone not involved in the study.
CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

Consent forms will be kept in Erin Simunds' office, Room 146, Medical Science North building for a two-year period.

For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Box 8138, University Station
Grand Forks, North Dakota 58202

On campus, mail to: Office of Research & Program Development, Box 134, or drop it off at Room 101 Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

For policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SATURES:

Principal Investigator

DATE: __________________________

Project Director or Student Adviser

DATE: __________________________

Gr Group or Center Grant Director

DATE: __________________________

(Revised 8/1992)
You are invited to participate in a research project conducted by Lynnelle Gelinske, a graduate student in Physical Therapy working in affiliation with the Institute of Sports Medicine in Bismarck, ND. The research project is intended to study the effects of foot orthotics on ankle movement (subtalar joint subluxation) and pain during three treadmill speeds.

You were selected because you have previously received semi-rigid foot orthotics from the Institute of Sports Medicine in Bismarck, ND. You will be asked to schedule two appointments at your convenience. It is requested that you bring shorts and your walking/running shoes with orthotics in them to both appointments. You will be asked to report to The Human Performance Center located at 941 Basin Ave, Bismarck, ND. The first appointment will last no longer than one hour and the second appointment will last no longer than 30 minutes.

The study will be conducted as follows: During the first appointment, you will receive (1) a musculoskeletal exam which evaluates muscle strength, flexibility, and joint range of motion in your legs. (2) You will also be asked to complete a training session on a treadmill at the three test speeds (3.5, 7, and 10 mph) to familiarize yourself with the treadmill and testing procedures.

During the second appointment, (3) markings with a felt-tip marker will be applied to your lower legs and a small piece of tape will be placed on the back of your shoes. The markings act as reference points to help evaluate and record ankle motion. (4) Prior to the initial test speed, you will be asked to rate the amount of pain you are experiencing (if any) and location you are experiencing pain. (5) You will then be asked to walk/run for 30 seconds during each test speed while wearing your own walking/running shoes and orthotics. (6) Between test speeds, you will be given a 4 minute break in which you may rest and rate your pain after completing the previous test speed. The above measures are all common techniques used in Physical Therapy clinics. Total time for both appointments should not exceed 1 1/2 hours.

Possible risks in this study are minimal. The treadmill speeds used in this study are comparable to walking at a comfortable pace, a slow jog, and a moderate jogging speed. Any increase in pain or fatigue would be equivalent to walking/running for 30 seconds at each of the three test conditions. There is a very slight possibility of injuring yourself while walking/running on the treadmill. However, the practice session should decrease the possibility of injury by helping your body become familiar with the treadmill.

In the event that a physical injury is incurred during the study, medical treatment will be available as it is to any member of the general public. Payment for treatment required must be paid for by you or your third party payor. If the orthotics are damaged during the study, the Institute of Sports Medicine will replace them.

Possible benefits to you include, but are not limited to, discovering if your orthotics properly control your foot motion at
varying speeds of walking/running. You may request an interpretation of the results as it relates to your own personal function. Possible benefits to society are (1) research examining the effectiveness of a treatment technique that is very prevalent in our society today and (2) stimulation of further research on this topic.

If you decide to participate, you are free to discontinue participation at any time without any negative affect to your relationship with the Institute of Sports Medicine. Any questions concerning the study can be answered by contacting Lynnelle Gelinske at _________ (work).

Information obtained in this study will be reported in aggregate form. To maintain confidentiality, your name will not appear in the study or be shared with anyone not involved in the study.

(subject’s signature) (date)

(signature of parent/guardian if the subject is under the age of 18.) (date)


Reference markings bisect the lower 1/3 of the leg and heel
APPENDIX B
Pain as Bad
As it Could Be

Name: __________________
Date: __________________
Test Condition: ________

No Pain At All

LOCATION OF PAIN
APPENDIX C
EVALUATION FORM

Name:____________________
Age:____________________
Date:____________________

I. Calcaneal eversion  Left ____  Right ____

II. Tibio-fibular varum  Left ____  Right ____

III. Gastrocnemius flexibility  Left ____  Right ____

IV. Flexible foot  Left yes/no  Right yes/no

V. Navicular drop
   a) Bilateral NCSP (mark index card)
   b) Bilateral RCSP (mark index card)
   c) NCSP-RCSP  Left ____  Right____

VI. Calcaneal measurements when standing barefeet on the orthotics.
   Left ____  Right ____

VII. Place tape for calcaneal bisection on the shoe at the position measured in VI.
Dear

I would like to ask for your help with a research project I will be conducting in order to receive a Masters degree in Physical Therapy from the University of North Dakota this Spring. I'm working in affiliation with the Institute of Sports Medicine in Bismarck, ND.

The purpose of the project is to study the effects of foot orthotics on ankle joint movement and pain during various walking and running speeds. The basis of my research project is the assumption that orthotics aren't always fitted properly for the individual's intended use. Before I begin the actual study, however, I need background information about the relationship between orthotics, pain, and athletic participation in individuals who wear orthotics.

You were selected to complete the background survey because you have previously received foot orthotics from the Institute of Sports Medicine in Bismarck, ND.

Participation in this survey is completely voluntary. All information obtained from the survey will be kept confidential. The survey will take less than 5 minutes to complete. Your time and effort is greatly appreciated!

Thank-you very much for your time.

Sincerely,

Lynnelle Gelinske
1. Please follow these directions.

A. Check the blank if you participate in the sport at any time during the year.

B. Estimate how many hours/week you participate (games and practice) in each sport during that season.

C. Check the blank if you wear orthotics while participating in the sport.

D. How much pain do you experience during the sport?
Rate pain from 0-5. 0=no pain, 1=not very painful, 2=somewhat painful, 3=moderately painful, 4=quite painful, 5=extremely painful

E. If you wear orthotics while participating in a sport, do they increase (+), decrease (-), or have no effect on pain (0).

F. If you experience pain, how long does it persist after the activity has ended?

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2. If you experience pain, please shade in the appropriate areas of the body where pain is located.

3. Overall, how satisfied are you with your orthotics? Check One
   _____ Not satisfied (please answer question # 4)
   _____ Slightly satisfied (please answer question # 4)
   _____ Somewhat satisfied (please answer question # 4)
   _____ Satisfied
   _____ Very satisfied

4. Please indicate why you are less than satisfied with your orthotics.
REFERENCES


