Barefoot versus Shod Training: Effects on Navicular Drop and Foot Pressure Analysis

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BAREFOOT VERSUS SHOD TRAINING: EFFECTS ON NAVICULAR DROP AND

FOOT PRESSURE ANALYSIS

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A Scholarly Project Submitted to the Graduate Faculty of the

Department of Physical Therapy
School of Medicine
University of North Dakota

In partial fulfillment of the requirements for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota

May, 2017
This Scholarly Project, submitted by Evan Condry, Daniel Himmerick, and Tiffany VanHaaften in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Gary Schindler, PT, DPT, PhD OCS, SCS, LATC, CSCS

David Relling, PT, PhD, Department Chair
PERMISSION

Title: Barefoot Versus SHOD Training: Effects on Navicular Drop and Foot Pressure Analysis

Department: Physical Therapy

Degree: Doctor of Physical Therapy

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Date 10/31/16
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Abstract

Background and Purpose: Running is a popular form of exercise around the world. The running population generally runs in a rear-foot strike pattern (RFSP), yet there is questioning on the possible benefits of running in a forefoot strike pattern (FFSP). The main goal of FFSP is the possible reduction of running related injuries by reducing the stress on the medial longitudinal arch. The purpose of this research study is to determine if a barefoot running retraining program will have an effect on navicular drop height, plantar pressure area, and peak plantar pressure of the medial aspect of the foot.

Material/Methods: Eleven first and second year physical therapy students participated in this study. Each subject was randomly assigned to a barefoot running group (N = 6) and shod running group (N =5). Measurements of foot pronation were taken using the navicular drop test. Spatiotemporal foot pressures and area were evaluated through the GAITRite® system to measure plantar pressure area and peak plantar pressure. Each subject completed pre-testing a week prior to beginning a 5-week retraining program designed from relevant literature. Post-testing was completed one week following the retraining program to assess changes in arch dynamics. The data collected from the pre- and post-testing was processed and analyzed using the Statistical Package for Social Sciences (SPSS) software. An alpha (α) level <0.05 was used to determine statistical significance. Following the completion of the study, a post survey was used to determine subject’s perception of this study.

Results: The statistically significant result came from the barefoot running group, in which peak plantar pressure decreased in foot division 6 from 0.70 to 0.2920 (p=0.035). There were no other statistically significant changes to note from the plantar pressure area or navicular drop
examinations. The post survey results included the perceived adverse effects of pain along the heads of metatarsals, blisters and, muscle tightness.

**Discussion:** There may be clinical relevance for barefoot running versus shod running despite the lack of statistically significant results from this study. Due to the one statistically significant result coming from a dynamic assessment, it may be possible that barefoot running has more of an effect on foot pronation during dynamic activities as opposed to static activities. This increase in dynamic stability may lead to a decrease in running related injuries thus possibly making barefoot running a clinically relevant intervention. Limitations of this study included: a small sample size, narrow population, too rapid of running progression, running on treadmills with socks on, researcher did not remain blinded to subject group, length of the study was too short, inability to directly measure dynamic navicular drop, and GAITRite® mapping system provided occasionally inconsistent measurements with additional running/walking trials needed. Future research could address these limitations through creation of an ongoing study and/or open it to the public to improve subject population.
CHAPTER I

Introduction

During the past decade, a trend developed among the running population which involved the conversion from conventional shoes to barefoot running or the use of a minimalist style running shoe. In conventional running shoes, there is increased cushion in the sole and heel of the foot; however, barefoot or minimalist running shoes lack this cushion, which encourages the individual to convert from a rear-foot strike (RFSP) running pattern to more of a forefoot strike (FFSP) running pattern.\textsuperscript{1,2} RFSP occurs when the heel of the runner makes the initial contact with the ground, whereas FFSP occurs when the ball of the foot, or the forefoot, makes initial contact with the ground.\textsuperscript{1,2} Thus, it is important to understand changes which may occur when converting from RFSP to FFSP with respect to kinematics, kinetics, lower leg muscle activity, and foot dynamics. In regards to foot dynamics, navicular drop is an important risk factor and has been speculated as a significant factor in many running related injuries. Since increased navicular drop may lead to additional overuse injuries it must be studied further to identify any role that FFSP may have in altering the height of navicular drop.\textsuperscript{3–5} The goal of this research study is to determine if a barefoot running retraining program will have an effect on navicular drop height, along with plantar pressure of the medial aspect of the foot.

With the change from RFSP to FFSP, researchers have shown a decreased incidence of running related injuries.\textsuperscript{6,7} To our knowledge, only two studies identified a decrease in pain from a running related injury. Diebal et al\textsuperscript{6} found that barefoot running could be used as an intervention in Chronic Exertional Compartment Syndrome (CECS). Diebal et al\textsuperscript{6} conducted a barefoot retraining program for ten military recruits who were scheduled for a fasciotomy to relieve
pressure in the anterior compartment due to CECS. Following the study, recruits did not require the scheduled fasciotomy due to abolishment of symptoms. In a separate case series involving three female runners who were experiencing unilateral patellofemoral pain, Cheung and Davis utilized audio biofeedback to convert their running gait from a RFSP to a FFSP. Following eight sessions of audio biofeedback and gait retraining, all three individuals were able to maintain the converted running gait three-months post-training. They reported a decrease in pain and improvements in function. In addition, Barton et al conducted interviews with 16 international experts on their recommendations for gait retraining. The 16 experts recommended running retraining for a variety of running related injuries including: iliotibial band syndrome, plantar fasciopathy, lower extremity tendinopathies, calf pain, and medial tibial stress syndrome. As shown by these studies, healthcare professionals may optimize therapeutic outcomes for running related injuries by retraining an individual’s running pattern.

As healthcare professionals see a need for running retraining, additional evidence is needed to support barefoot running and subsequently FFSP running as a therapeutic or preventative measure. This evidence must start with an understanding of kinetic and kinematic differences between FFSP and RFSP. Upon immediate investigation of FFSP and RFSP, FFSP includes a greater ankle plantarflexion, knee flexion, and knee internal rotation upon initial contact. Biomechanical studies identified a greater eccentric contraction of the gastrocnemius and soleus muscles during barefoot running, which led to a decreased axial force transmitted through the tibia, fibula, and ultimately the knee. Research also found decreased peak forces through the rectus femoris, vastus lateralis, and vastus medialis. It was theorized, the incidence of running related injuries may be minimalized if the axial force transmitted through the lower extremity was reduced.

In addition to increased gastrocnemius and soleus activity during barefoot running, Sinclair et al revealed a significant reduction in quadriceps and tibialis anterior muscle activity
during barefoot running. The authors of the study concluded barefoot running caused a decrease in stride length, and did not require a larger force output to control the knee. This decrease in force output also decreased the peak force transmitted through the knee, which may reduce the amount of wear and tear the knee experiences.9

**Kinetic, Kinematic, and Muscle Activity**

Not only has converting from a RFSP to FFSP shown to have changes in running biomechanics and muscle activity, it has also revealed a change in joint loading. Rooney and Derrick11 found that FFSP runners had increased ankle joint loading compared to RFSP runners. This increase in joint loading is thought to be from an increase in plantarflexor muscle activity. Rooney and Derrick11 state that it has yet to be proven if this enhanced muscle activity caused increased compression to the tibia due to the additional axial compression, or caused a decrease in compression to the tibia due to decreased bending moments. An additional study investigated the muscle activity in natural FFSP versus natural RFSP, particularly of the tibialis anterior and plantarflexor musculature.12 This study12 supported Rooney and Derrick11 by establishing FFSP increased gastrocnemius and soleus muscle activity. Furthermore, Cooper, Leissring, and Kernozek13 studied the force distribution throughout the foot in shod and barefoot runners. Cooper et al13 found those who converted to a forefoot or midfoot strike pattern demonstrate lower total forces and a more uniform distribution of forces along the metatarsal region than those who continue to run with a RFSP. Based on the above studies, FFSP has an effect on force distribution and an overall decrease in risk of running related injury.11,13

In addition to differences in kinetic, kinematic, and muscle activity between FFSP and RFSP, there are also spatiotemporal differences. Running with a FFSP, gait patterns typically demonstrate an increased step cadence, decreased step length, and decreased vertical ground reaction force (vGRF).2,14–16 Studies revealed several benefits for runners who utilized a FFSP running pattern. Increased step cadence and decreased stride length as seen with a FFSP are two
benefits and provide for an increase in knee flexion angle. By increasing the knee flexion angle at initial contact, there is a decrease in force impact at the knee and hip. Increased step cadence and decreased stride length also decreased the overall peak hip adduction and hip internal rotation angles. In addition, researchers found reduced stride length had significantly decreased vGRF and sagittal plane joint moments. Therefore, FFSP may decrease the load on the knee and hip joints which may reduce the risk of running related injuries.

As seen with changes to the leg, there should also be kinetic, kinematic, and muscle activity changes in the foot. These changes are likely observed in high mobility areas of the foot, such as the navicular bone and the medial longitudinal arch of the foot. The degree of mobility in these areas is important for the health of a runner. Thus, it is important to understand the dynamics of the navicular bone and the arch of the foot as runners change from a RFSP to a FFSP. This understanding would also help healthcare professionals in utilizing gait transitions to optimize therapeutic outcomes in foot related running injuries.

**Foot Anatomy and Dynamics**

The arch of the foot is a complex formation with three supporting structures including the medial longitudinal arch, lateral longitudinal arch, and transverse arch. The medial, lateral, and transverse arches act to support the weight of the body during lower extremity physical activity. The metatarsal bones play a role in the structure of the arch while ligaments aid in overall stability. A variety of muscles serve to allow proper foot function with tibialis posterior playing a significant role in maintaining the medial longitudinal arch.

The medial longitudinal arch of the foot is a compound structure made up of several different tissues interacting to produce functional stability with optimal mobility. It is comprised of nine small bones and the joints between them: the calcaneus, talus, navicular, medial cuneiform, intermediate cuneiform, lateral cuneiform, first metatarsal, second metatarsal, and third metatarsal. The soft tissue structures are comprised of ligaments, muscles, and tendons. The
primary ligament supporting these bones on the plantar surface is the plantar calcaneonavicular ligament which is also referred to as the “spring” ligament. Laxity in the calcaneonavicular ligament can cause flattening of the arch during weight bearing which may lead to pain in the foot and ankle as well as problems going up the kinetic chain. There are also two main muscles and associated tendons that provide stability in the joint during weight bearing activities. Tendons of both tibialis anterior and tibialis posterior cross the plantar surface of the medial longitudinal arch running posterior to anterior. Tibialis anterior inserts onto the plantar surface of the first metatarsal, and tibialis posterior tendon inserts onto the navicular and medial cuneiform. Both of these muscles support the medial longitudinal arch, but tibialis posterior has a more direct effect due to its insertion site. Damage or weakness of the tibialis posterior could result in the collapse of the medial longitudinal arch. Olin et al, using EMG on lower extremity musculature, indicated the average muscular activity in barefoot runners is greater than shod runners while peak EMG between barefoot and shod runners is similar. The increased average lower extremity muscular activity along with similar peak EMG suggested the plantar flexor muscles were firing longer with a greater use of quadriceps musculature. Therefore, transitioning to barefoot running too quickly may lead to development of overuse injuries due to increased muscle fatigue. The dynamic interactions of the bones and soft tissue structures of the foot determine the stability and mobility of the medial longitudinal arch.

Within the medial longitudinal arch, the navicular bone is the most mobile bone. Given the posterior tibialis inserts directly on to the navicular bone, it will directly control pronation of the foot. The navicular bone is a marker used to determine if an individual’s foot is considered pronated, normal, or supinated. A certain amount of pronation is a normal motion during the stance phase of gait. It consists of three actions including eversion, abduction, and dorsiflexion. An increase in pronation, also known as hyper-pronation, can be detrimental to an athlete. Hyper-pronated pes planus arches can be labeled as fixed or flexible in nature. Fixed arches occur when
the degree of pronation does not change when transitioning from weight bearing to non-weight bearing. Flexible arches are defined as a medial longitudinal arch which flattens during weight bearing and reappears when non-weight bearing or when pressure is taken off of the arch. Laxity in the calcaneonavicular ligament, structural abnormalities, and the length and activity of the tibialis posterior and anterior all play a role in arch height. The average navicular drop in males is 6mm and in females is 4mm as determined by Adhikari et al. Additional studies indicate hyper-pronation as a navicular drop greater than 8-10 mm. Nielsen et al found the effect of foot length on navicular drop to be significant in both genders with the drop increasing by 0.40mm in males and 0.31mm in females for every 10 mm increase in foot length. These studies provided a standard range for determining hyper-pronation, thus aiding in the determination of appropriate of foot pronation levels for subjects in this study.

Having either an abnormally supinated or pronated foot may cause injuries. For runners in particular, high-arches have been associated with a greater incidence of ankle injuries, bony injuries and lateral injuries including stress fractures and plantar fasciitis, while low arches have been associated with more knee injuries, soft tissue injuries and medial injuries including ankle sprains and tendinitis. Hyper-pronation or flexible arches have also been reported to have a significantly higher prevalence in people diagnosed with Patellofemoral Pain Syndrome (PFPS). Hyper-pronation may be a risk factor associated with Iliotibial Band Friction Syndrome (ITBS), Medial Tibial Stress Syndrome, Plantar Fasciitis, and Tibial Stress Fractures.

Arch Dynamics and Injury

Although research identified foot pronation as a potential cause of LE injury, current evidence is controversial on the efficacy of barefoot running in controlling foot pronation. Hoffman et al conducted a study that assessed the dynamic navicular drop in barefoot, minimalist shoe, and motion-controlled shoe conditions. Hoffman et al concluded motion controlled shoes have a slower navicular drop than barefoot and minimalist shoes. These results
contradicted previous theories in which foot pronation was better controlled via barefoot running. However, the results were obtained by having the subjects run in all three conditions without conducting a gait retraining program. A separate study identified the opposite affect: an increased barefoot weight-bearing activity increased strength of the intrinsic muscles of the feet which led to a decrease in the span of the medial arch. This shortening of the medial arch span coincided with a reduced navicular drop height which reinforced the importance of barefoot running in potentially limiting the risk of running related injuries. Navicular drop measurement and pressure mapping analysis can be used for assessing arch dynamics. When analyzing spatiotemporal foot patterns, it is important to detect where the person’s foot is striking. If pressure is decreased on the medial longitudinal arch, the navicular drop height may be decreased. Therefore, indicating the subject may be striking more on the lateral longitudinal arch. Understanding the arch dynamics through assessing gait patterns will aid in discovering how injuries occur.

**Gait Patterns in Barefoot and Shod Running**

In a typical gait pattern, there are two different phases: stance and swing phase. A substantial amount of research has involved the stance phase, which occurs when the foot comes in contact with the ground. The reason for emphasis on the stance phase is to better understand different foot striking patterns relevant to spatial and temporal pressure mapping. The stance phase is approximately 60% of walking time, yet decreases while running due to the increased velocity or distance traveled per unit of time. Included in the stance phase is heel strike, midstance, heel off, and toe off which all can be measured through ground reaction forces. Whereas swing phase has no connection with surface or what is considered the float phase. Each stance phase component provides a unique assessment of the foot strike patterns; therefore, evaluating the dynamics of the arch structures. Robbins et al. analyzed the adaptive patterns of the medial longitudinal arch of 17 recreational runners. Robbins et al. hypothesized, with increased weight bearing, barefoot activity acted as a mechanism to which reduced shock absorption. In this
experiment, using X-ray analysis, the effects showed a positive impact in shortening the medial longitudinal arch with an increase in weight bearing activity, thus potentially decreasing injuries. Recent research continues to question whether arch dynamics play a role in lower extremity injuries. Lieberman et al theorized through five different subject groups of varying ages that barefoot runners were better suited to utilize the eccentric contractions of gastrocnemius and soleus and arch of the foot mechanics as compared to shod runners. Furthermore, Titianova et al assessed the depth and width of medial and lateral longitudinal arches through pressure distribution on the runner’s foot. Although there is limited research on pressure mapping in runners, Titianova et al found peak active areas having occurred on heel strike and toe off in stance phase during normal walking. Therefore, footprint analysis and in particular, the forefoot peak pressure, may help in the clinical assessment of rehabilitation strategies. Despite proposed negative effects of rear foot striking there are no studies directly examining the efficiency of forefoot or midfoot strike patterns on running injuries as compared to rear foot contact.

**GAITRite Pressure Mapping**

The GAITRite® is a computer based instrumented walkway which measures spatial and temporal gait characteristics. It includes a roll-up walkway available in various lengths with embedded pressure sensors. This GAITRite® system will assist in measuring the area and pressure of plantar surface contact in barefoot runners following the 5-week running retraining program. There is a lack of evidence on the effects of a gait retraining program focused on converting from a RFSP to a FFSP and the changes of navicular drop and plantar pressure. This study utilized a 5-week gait retraining program to convert from RFSP to FFSP in a small sample group of healthy young adults. This study hypothesized that runners who convert from a RFSP to a FFSP will reduce the height of the navicular drop most likely due to the strengthening of the tibialis posterior muscle. Given the insertion of the tibialis posterior on the navicular bone, by strengthening the tibialis posterior there should be a decrease in navicular drop height. In theory,
the navicular drop may lead to a decrease in hyper-pronation and running related pain and injury. We will be measuring the navicular drop before and after the retraining period. The GAITRite® system will be utilized to evaluate the plantar pressure of the foot during the stance phase of gait in walking and running. The GAITRite® will allow us to measure any change along the medial aspect of the longitudinal arch to assess a change in plantar pressure. A decrease in the plantar pressure of the medial longitudinal arch may suggest a reduction of hyper-pronation, further supporting barefoot running as a way to decrease running related pain and injury.
CHAPTER II

Methods

Outlined in this chapter is information regarding how this study was organized and includes: information regarding the subjects and recruitment, informed consent, measurements/instruments, the study’s retraining program, post-survey, data analysis, and ensuring internal validity.

Subjects

To ensure that the rights and welfare of human subjects in social behavioral and biomedical research were protected, the investigators in this study obtained approval from the Institutional Review Board of the University of North Dakota (UND). See Appendix A for the approval letter. After approval, recruitment of subjects commenced. Subjects were recruited from the first and second year physical therapy classes at the University of North Dakota. All students received an email describing the study and inclusion/exclusion criteria for them to evaluate their own interest and ability to participate. The inclusion criteria included: no pain in the lower extremities in the past 3-months, age between 20-30, greater than 7 mm navicular drop, must run with a rear foot striking pattern, no current use of NSAIDs, no cardiopulmonary pathologies or significant medical history, and must currently complete a minimum of 2-10 miles of running per week, not exceeding 25 miles over the past month. If any student was interested and qualified, they attended the pre-testing to affirm that their navicular drop was greater than 7 mm, and if so went through the entire pre-testing. Eleven subjects were interested in participating and met the inclusion criteria. See Table 1 for subject demographics. The eleven subjects were randomly assigned into either the shod running group or the barefoot running group by using small pieces
of paper with each one containing the name of subject, being put into a hat. The pieces of paper were then randomly chosen with the first subject drawn being placed in the barefoot group and the second subject being placed in the shod group with the alternating pattern continuing. Six subjects were selected for the barefoot group and five for the shod group. Each subject was informed of their assignment via email.

Table 1: Subject Demographics

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Informed Consent

Prior to the pre-testing, each subject filled out and signed an informed consent form. The informed consent explained the details of the study to the subjects. See Appendix B for the consent form in its entirety. The consent form described the purpose of the study as well as the testing and training program protocols. Subjects were educated on the risks of taking part in the study which included the chance of muscle strains, fatigue, tendinitis, stress fractures, delayed onset muscle soreness (DOMS), and/or a general pain response. The benefits of participation were also included and consisted of a potential decrease in navicular drop possibly leading to injury prevention, improved cardiorespiratory fitness, decreased BMI, evidence that may impact
how physical therapists practice, and information that may alter how people train and exercise. Subjects were informed there were no financial factors in this study leading to biases as there was no funding for the study and there would be no cost or compensation for those taking part. It was reiterated that this was a voluntary study and that each subject could leave at any time for any reason, but it was requested that they inform the head researcher before doing so. The process of maintaining patient confidentiality was described which included the five-digit code that would be used to identify each subject. The code consisted of the first two digits being the subject’s mother’s birth day, while the last three were the last three digits of the zip code of their residence while attending high school.

**Measurements/Instruments**

**Navicular Drop**

The navicular drop test is a tool for measuring the height of the navicular bone in both non-weight bearing and weight bearing scenarios and determining the difference. Navicular drop is measured by palpating the navicular tuberosity and measuring the height from the floor with the ankle in sub-talar neutral during sitting and again measured in natural stance. An analysis by Menz and Munteanu assessment found navicular drop assessment to be a useful clinical measure and valid test due to its accurate representation of the anatomical structure, compared to their radiographic findings, of the medial longitudinal arch. Studies on the reliability of the navicular drop test are contradictory. Picciano et al assessed the intra-tester and inter-tester reliabilities of the navicular drop test with two inexperienced physiotherapy students and found them both to be poor (intra-tester: 0.61 & 0.79, inter-tester: 0.57). The authors concluded the navicular drop test could be a useful tool, but should be used by clinicians that are experienced with the examination procedure to improve their reliability of the measurements. Another study included low experienced physiotherapy students and experienced clinicians to assess the reliability of the navicular drop test and deemed it reliable in both inter-tester (0.94) and intra-
tester (0.91) parameters.\textsuperscript{32} The difference in experience between the studies conducted by Sporndly-Nees et al.\textsuperscript{32} and Picciano et al.\textsuperscript{31} appeared to have an impact on intra-tester reliability. By receiving standardized training and practicing the particular method, the use of the navicular drop test can be a reliable tool to assess the level of foot pronation.

**Reliability Testing**

The researcher assessing navicular drop, in this study, was blinded to subject assignment throughout the study, and thus did not attend training sessions. Prior to pre-testing, the tester assessed their reliability with navicular drop and foot length by recruiting twelve second year physical therapy students to volunteer as subjects in an assessment whom were not involved in the study. These student’s navicular drop and foot length were measured twice with one day off between measurements. The same protocol was used for foot length measurements and navicular drop testing as were performed in the pre- and post-testing protocols. The tester’s intra-rater reliability was determined to be 0.97 for right foot length, 0.98 for left foot length, 0.91 for right navicular drop height, and 0.85 for left navicular drop height. These results compared favorably with a study by Vauhnik et al.\textsuperscript{33} They found their intra-rater reliability to be .78 for the dominant leg and .88 for the non-dominant leg, which they considered moderate to good results for the use of the navicular drop test in a clinical setting.\textsuperscript{33}

During pre-testing, the subjects first entered the pre-testing room and provided a security code to protect their privacy which consisted of a five-digit code where the first two digits were their mother’s day of birth and the final three digits were the last three digits of the zip code of their residence while attending high school. This was written on their 3”x5” pre-testing notecard. Subjects filled out an informed consent form before proceeding. Subjects then removed their shoes and sock and their height and weight were taken respectively using a Detecto\textsuperscript{TM} Scale and both were recorded on the notecard.
Next, each subject’s navicular drop was assessed bilaterally. The protocol performed in this study was modeled off of Anthony Redmond’s Foot Posture Index©. They sat in a chair in approximately 90 degrees of hip and knee flexion with their feet on the floor. In this position, their foot length was measured using a segmometer from the right side of each foot, and this was recorded on their notecard. The subject moved to a different chair and assumed the 90 degrees of hip and knee flexion as before while sitting up tall with their feet on the ground. Their navicular drop measurements were taken by the tester first palpating the most prominent portion of the navicular bone on the right and marking it with a dot using a black fine point Sharpie permanent marker, and the same step was repeated on the left foot. The tester then palpated the talus of the right foot on the subject and put the ankle into sub-talar neutral. Participants were directed to maintain that position as best as possible during the initial marking of the notecard. The subject’s card was placed perpendicular to and touching the floor as well as the ankle. The height of the navicular was measured by making a mark on the index card at the location of the center of the dot. See Figure 1 for an illustration of this procedure. The same step was repeated on the left foot. The subject was told to stand without moving their feet and stand in a relaxed foot posture. The navicular height was measured in millimeters by measuring the distance between the two tick marks for the right foot and then the two for the left foot using a McCoy Medical™ retractable fiberglass tape measure. Subjects were directed out of the room to complete the active portion of testing with the GAITRite®.

The post-testing procedure was similar to the pre-testing with a few exceptions. First, the height of the subjects and their foot length were not measured as it was assumed that they would not have changed from the training program and were thus deemed an insignificant factor in our study. Second, each subject completed a paper based post-survey regarding their perceptions of the study and of barefoot running.
The GAITRite® system provided measurements of spatial and temporal parameters and identified striking patterns and medial and lateral arch pressures of subjects during walking and jogging. The GAITRite® system consists of a portable walkway embedded with pressure-activated sensors which is pictured in Figure 2. The walkway detects the timing of sensor activation distances between the activated sensors, and feeds this information into application software that calculates spatial and temporal gait parameters for individual footfalls.

Prior to initiation of the study, the GAITRite® system was tested appropriately by researchers through multiple runs and walks on the embedded walkway in order to confirm accurate measurements of walking and jogging speed. Each subject completed pre-testing a week prior to beginning a 5-week retraining program. Post-testing was completed one week following the retraining program. Pre and post testing procedures lasted approximately 2 hours in conjunction with height, weight, and navicular drop measurements.
With use of this system, each of the subjects walked and jogged barefoot on the GAITRite® in the UND physical therapy hallway. Each subject walked across the 16-foot walkway at a comfortable pace three times. Taped lines were utilized to indicate the starting point, which were placed three feet from the walkway to ensure consistent starting and ending points during post-testing. The subjects were cued to engage in walking through verbal commands to allow enough time for the computer to process information before beginning another trial. Therefore, each subject walked barefoot 22 feet on the GAITRite® system for each of the three trials. The GAITRite® system has proven to be reliable and valid while walking barefoot through a number of different studies.\textsuperscript{29,35–37} McDonough et al\textsuperscript{36} concluded the GAITRite® system to be a valid and reliable tool for measuring selected gait components: spatial and temporal parameters. The analysis of our data will be strengthened secondary to using a valid and reliable instrument.

Following the three walking trials, the subjects jogged barefoot at a comfortable rate five times across the GAITRite®. Taped lines were placed 55 feet in front of and three feet beyond the GAITRite® to indicate when to begin and end jogging. Subjects were asked to jog through the final taped line at a normal jogging speed. The total amount of jogging was approximately 75 feet. Following each trial, the subjects walked back to the starting position. Subjects were cued...
with verbal commands and hand demonstrations of a thumbs up to begin jogging again. The increase of speed created variability and uncertainty due to the system difficulties of detecting the separation of right and left foot markings. Therefore, each of the trials were suspended allowing time for researchers to process accurate correct data. The suspension mode in the GAITRite® software enabled the researchers to save the walks in order to separate the footfalls at a later time. Therefore, this aspect was useful for time management since the subjects were performing multiple walks throughout pre and post testing. The three most accurate spatiotemporal patterns of the five trials were used in data collection. Completing multiple trials allowed for walkway malfunctions, computer glitches, and the best representation of the spatiotemporal patterns of each subject. Although the GAITRite® system is valid and reliable when using step and stride lengths while walking, there has been little to no documented research in measuring spatial and temporal parameters while running at higher speeds. One study assessed the walk to run transition using the GAITRite® system. The small sample size of three participants and methodology of participants only asked to step at least one time on the GAITRite® mat while running showed this study was not applicable. To accommodate the unreliable measures of running on the GAITRite®, part of the retraining program included slower speeds including 4.0 mph for one minute and 5.0 mph for one minute.

**Post Survey**

At the post-testing, subjects began filling out the post-survey by writing their five-digit code at the top of the form. Then, they answered demographics questions including gender, age, height, and weight. Subjects were asked about their running activities prior to taking part in the study such as weekly running mileage, use of orthotics, and their interest in barefoot running. After this point, the subjects were asked if they were in the shod or barefoot running group and directed to different portions of the survey accordingly. The remainder of post-survey included opinionated questions on how subjects felt about the program including appropriateness of
intensity, structure, time to complete the program, and their opinions on barefoot running. The post survey finished with a question that allowed subjects to report any and all injuries that they incurred throughout the running program. See Appendix C for the post-survey in its entirety.

**Retraining Program**

All of the subjects were part of the retraining program designed by researchers based on relevant literature. A common fear and risk with converting to an FFSP of running is doing too much too soon. Utilizing a retraining program is vital to the success of converting as well as staying injury free. Research conducted by Hart and Smith\(^9\) provided some general guidelines for habituation programs. They suggested that during weeks 1-2 of the program, runners should only run barefoot for 30 minutes total each week and use multiple sessions to reach that goal as needed. Then during weeks 3-16, the athletes should be doing 1 session a week for 1 hour.\(^9\) Increasing to FFSP quickly should be reserved for more experienced runners. In a study involving military personnel and with significant running experience and barefoot habituation programs, weeks 1-3 involved 15-20 minutes of FFSP training drills and a 0.25 Km run with a 2-minute walking interval between. During weeks 4-6, they progressed both the speed and endurance of the program gradually.\(^6\) When working with novice runners, the progression should be more cautious and slow. A study by Warne and Warrington\(^4\) used a 4 week program that gradually retrained the runners into an FFSP. The runners performed two 15 minute runs in the first week and progressed gradually to 3-4, 30 minutes runs in the 4th week.\(^4\) Despite the variation, caution and a slow progression is safest when retraining to prevent injuries and optimize the benefits.

The subjects were randomly assigned to either the barefoot or shod group. Six subjects were selected to run barefoot and five were selected to run in their preferred workout shoes. All individuals engaged in an identical 5-week running programs on Tuesday and Thursday mornings at the UND Wellness Center despite designated group. The routine consisted of an identical
warm-up, running program, and cool-down procedures in order to maintain consistent and reliable measures.

Prior to the warm-up, subjects were asked how they were feeling and if any adverse effects were present. The warm-up consisted of biking, dynamic stretching, and three minutes of treadmill walking at 3.0 miles per hour (mph). Barefoot subjects wore socks on the treadmill to comply with the UND Wellness health code while shod runners utilized their preferred footwear. Each subject biked five minutes on either LifeFitness 95R Lifecycle® recumbent bike or LifeCycle GX® upright exercise bike followed by dynamic stretches. The dynamic stretches included: flexion/extension leg swings, abduction/adduction leg swings, lunge with a twist, knee to chest, and hip stretch with a twist. Demonstrations of these exercises can be found in Figure 3. Ten repetitions of leg swing stretches were performed on each leg while 5-repetitions of the remaining three stretches were performed on individual legs. Following the stretches, each of the subjects began walking at 3.0 mph for three minutes on a Precor TRM® 885 treadmill. A total of three-minutes of the warm-up phase of the retraining program. Therefore, the total warm-up consisted of 10-15 minutes.
Figure 3. Dynamic Stretches. (a) Flexion/Extension leg swings (b) Knee to chest (c) Lunge with a twist (d) Abduction/Adduction leg swings (e) Hip stretch with a twist
Following the warm-up, the subjects began the retraining program designed by researchers (see Appendix D). All subjects completed identical training speeds and time. After three minutes of walking during the warm-up phase, the treadmill speed was increased to 4.0 mph for one-minute then 5.0 mph for an additional minute progressing to 6.0 mph at the three-minute mark. The subjects were asked to jog at these elevated speeds. Subjects in the barefoot group, were instructed to run on their toes when the training program began. During the first week of the retraining program, the subjects ran a total of 8-12 minutes on both days. Therefore, the runners engaged in 6-10 minutes of running at 6.0 mph. The subjects were instructed to run to the suggested time of 8 minutes but if they felt capable, they could continue toward the full training schedule of 12 minutes. Following each run, the researchers recorded the amount of minutes each subject ran on the exercise log sheet. Due to the intensity of the retraining program, if subjects felt they were unable to complete the 8 minutes they were told to stop and perform cool down immediately. Allowing the subjects the ability to terminate their daily training due to increased symptoms was consistent throughout each week despite the increase of total time running. The second week the subjects engaged in 12-16 minutes of running therefore, resulting in an increase of four minutes from the previous week. The retraining program stayed consistent throughout the process with a gradual increase of 4 minutes per week therefore, week three the subjects ran 16 to 20 minutes and week four 20 to 24 minutes. Finally, during the fifth week, the subjects were running a total of 24 to 28 minutes. Subjects were reminded if they felt the mileage was too much due to pain or discomfort, they could terminate the training for the day and begin the cool-down process.

Following the retraining program, subjects walked for three minutes at 3.0 mph on the Precor TRM® 885 treadmill to encourage adequate decrease in heart rate and provide adequate recovery time cool-down. Subsequently, static stretches were performed 30 seconds on each leg for two repetitions. These stretches, in order of performance, included: standing gastrocnemius
stretch leg straight, standing soleus stretch with knee bent, standing quadriceps stretch, seated hamstring stretch by reaching hand toward toes while other leg is in butterfly position, standing hip flexors stretch in lunge positioning with knee in contact with the floor, and supine piriformis stretch of one leg straight and other knee bent and brought toward chest. Demonstrations of the above seven stretches can be found in Figure 4. Following static stretching, the subjects had concluded the cool-down and completed the retraining program for the day.
Figure 4. Static Stretches. (a) Gastrocnemius (b) Soleus (c) Quadriceps (d) Hip Flexors (e) Hamstring (f) Piriformis
Data Analysis

Data collected from the pre- and post-testing was processed and analyzed using the Statistical Package for Social Sciences (SPSS) software. Independent variables included whether the subject was placed in the shod or barefoot running group. Dependent variables included: navicular drop height, heel-to-heel base of support, toe in/out angle peak pressure and pressure area of foot divisions 6 and 8 from the GAITRite® system. Other dependent variables that may considered for analysis include: BMI and weight change. All dependent variables were taken bilaterally. Confounding variables include adverse effects during the study, subject running outside of study, running surface, and efficacy of retraining program. The GAITRite® divides the foot into twelve trapezoidal divisions in order to map the pressure to certain areas of the foot. These twelve trapezoidal foot divisions were numbered starting from posterior-lateral at the heel of the foot, running lateral to medial. Foot divisions 6 and 8 were used as these correlate with the medial longitudinal arch, and will show any changes in foot pronation. According to the GAITRite® Electronic Technical Reference41, pressure is represented by a switching level. Each sensor along the GAITRite® pressure mat is activated when pressure is applied. Peak pressure for a given foot division is the “maximal sectional switching level expressed as a percent of the overall maximum switching level.” Sectional switching levels occur at the peak time of the section. Further changes in pressure were not analyzed as these data were not pertinent to our research question. Repeated measures paired sample t-tests were used to measure significance of the change in navicular drop height and pressure changes along the medial longitudinal arch with an α level of less than 0.05.

Ensuring Internal Validity

In order to ensure internal validity, the following steps were taken: all subjects completed identical warm-up, retraining protocol, cool-down, pre- and post-testing were conducted in the same order, fashion, time of day, and setting. Warm-up, retraining protocol, cool-down, pre- and
post-testing were discussed above. Navicular drop intra-rater reliability was assessed along with testing of the GAITRite equipment prior to pre- and post-testing procedures.
CHAPTER III

Results

This chapter contains the results of this research as it pertains to the study’s three research questions: Does a barefoot running retraining program reduce navicular drop height, decrease the plantar area, and reduce the plantar pressure on the medial longitudinal arch of the foot? Each of the three research questions were analyzed using repeated measures paired sample t-tests to determine clinical significance (p < 0.05). The pre- and post-test results for navicular drop and GAITRite® assessment from one subject in the shod running group were dropped leaving results from four subjects to be analyzed in the shod group (N=4). The post-test GAITRite® results from one subject in the barefoot running group were not included leading to pre-test GAITRite® results from six subjects (N=6) being analyzed and post-test GAITRite® results from 5 subjects being analyzed (N=5).

Question One: Navicular Drop Changes

The first research question intended to assess if a barefoot running retraining program could decrease navicular drop. After Navicular Drop Testing was completed for post-testing, the pre- and post-testing results were computed using paired sample T-tests to evaluate for statistically significant change. The statistical analysis showed that there were no statistically significant changes in either the barefoot running group or shod running group for navicular drop height following the retraining program. Despite the lack of statistically significant results, the barefoot group did show an overall reduction in navicular drop height bilaterally. The shod running group displayed an overall reduction in left foot navicular drop height; however, the shod group displayed an increase in right navicular drop height. Results are displayed in Table 2.
Question Two: Plantar Area Changes

The second research question proposed the gait retraining program will have an effect on the plantar area resulting in a decrease of pressure on the medial arch. Following data collection from the GAITRite®, paired sample t-tests were analyzed comparing pre- and post-test in order to find statistical significance on plantar pressure area during walking and running. The barefoot and shod running groups did not result in any significant differences for plantar pressure area during walking or running. However, trends were found on pressure area which may lead to clinical significance.

When analyzing the data, it is important to discuss the tendencies occurring in foot pressure area despite the lack of statistical significance. Following the retraining program, the barefoot running group displayed an overall decrease of pressure area in foot division six on both right and left feet during walking and running. The barefoot group also demonstrated a decrease in plantar area pressure in foot division eight on the left foot only while walking and running. Interestingly, the right foot showed an increase in pressure area in foot division eight which contradicts this hypothesis. The shod group results presented with an increase of area pressure in foot divisions six and eight on the right foot while walking and running which supports the research question of shod runners striking more on their medial arch due to increase of pronation. All the other results for the shod group show a decrease in plantar pressure area while walking and running. Results are shown in Table 3.
<table>
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<tr>
<th>Running Group</th>
<th>Walking/Running</th>
<th>Foot</th>
<th>Foot Division</th>
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Table 3: Plantar Pressure Area
Question Three: Plantar Pressure Changes

The third research question speculated that a gait retraining program will have a decrease in plantar pressure in the medial longitudinal arch of the foot. After the data from the GAITRite® was collected during post-testing, paired-sample t-tests were conducted to compare pre- and post-test data in order to measure significant differences. In the barefoot group, the peak plantar pressure of foot division six had a statistically significant decrease of 0.70 to 0.2920 (p=0.035). No other statistically significant changes in peak plantar pressure were noted in the barefoot group during running or walking. No statistically significant changes in peak plantar pressure were noted in the shod running group during running or walking. Results are shown in table 4.

Although there was only one statistically significant change in the peak plantar pressure, it is important to note any trends that a retraining program may have on peak plantar pressure. After the completion of the retraining program, the barefoot group displayed an overall decrease in peak plantar pressure of foot division 6 during walking on both the right and the left foot. Foot division 8 showed an overall decrease during walking on the left and no change on the right foot. During running, foot division 6 demonstrated an overall decrease in peak plantar pressure in both right and left feet. Foot division 8 had no change on the right and a decrease on the left foot. When comparing the barefoot running group to the shod running group there was an increase in foot division eight while walking, and all other results show a decrease in peak plantar pressure while walking and running.
<table>
<thead>
<tr>
<th>Running Group</th>
<th>Walking/Running</th>
<th>Foot</th>
<th>Foot Division</th>
<th>Mean</th>
<th>Mean Difference</th>
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<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>Significance</th>
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Post Survey Results

Other data noted concern the survey given to the subjects after the completion of the gait retraining program. The subjects answered questions regarding interest in barefoot running, retraining program structure, intensity, and time to complete, any adverse effects obtained during the program, whether they would continue with barefoot running after the conclusion of the study, and any other comments they have regarding the retraining program. Six subjects agreed or were neutral to interest in barefoot running prior to the study. One subject strongly agreed with the intensity of the program, eight subjects agreed with the intensity of the program, and one subject was neutral to the intensity of the program. All eleven subjects either agreed or strongly agreed with the structure of the program. All eleven subjects agreed or strongly agreed that the program allowed an appropriate amount of time to complete the program. Five of the subjects had adverse effects during the running program, most notably pain along the heads of the metatarsals and blisters developing while running. Nine of the subjects felt supervised instruction from a professional would be the most helpful when transitioning to barefoot running. Ten subjects reported not being interested in transitioning to barefoot running after the study if given the proper resources, with one stating they would transition to barefoot running. Four subjects stated a fear of injury would be the most prevalent barrier to beginning a retraining program, whereas five subjects stated a lack of adequate training surfaces would be the most prevalent barrier to starting a retraining program. Some comments the subject had after the completion of the retraining program included allowing the runner to choose their own running speed. Results of the survey can be seen in Table 5. Overall, this study showed statistically significant changes only in foot division six in regards to peak plantar pressure. There were no other statistically significant changes to note from the results of this study. What these results mean to the clinician, limitations to the study, and future research will be discussed in the next section.
Table 5: Post-Survey Results

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tr>
<td>I was interested in barefoot running prior to this study?</td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>0</td>
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<td>I felt the training intensity was appropriate?</td>
<td>1</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td>0</td>
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<td>I felt the program was well structured?</td>
<td>6</td>
<td>5</td>
<td>0</td>
<td>0</td>
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</tr>
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<td>I felt there was sufficient time to complete the program?</td>
<td>4</td>
<td>7</td>
<td>0</td>
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<td>I would start barefoot running if given the proper resources</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>4</td>
<td>0</td>
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</tbody>
</table>

N: 5

Adverse Effects

What do you feel is the most prevalent barrier to barefoot running?

- Fear of injury: 4
- Lack of adequate instruction: 1
- Lack of adequate training surfaces: 5
- Fear of decline in performance: 1
- Other: 0

Which resource would be most helpful when transitioning to barefoot running?

- Supervised instruction from a reputable coach or running professional: 9
- Internet: 1
- Book on barefoot running: 1
- Other: book available online: 1

Which of the following apply to your experience with barefoot running?

- I felt great while barefoot running: 3
- I will continue to barefoot run: 0
- I would recommend barefoot running to friends: 1
- I would not recommend barefoot running to friends: 4
- I never want to barefoot run again: 3
CHAPTER IV
Discussion

This research study proposed that barefoot running may promote a decreased navicular drop height, plantar pressure area, and plantar pressure along the medial longitudinal arch. This study investigated changes by utilizing the navicular drop height in standing and the GAITRite® system to measure plantar pressure of the foot during walking and running. Habitual shod runners will be conditioned to perform a heel-to-toe running gait pattern and may have difficulty transitioning to a toe to heel pattern since approximately 75% of shod runners heel strike.40 This led the researchers to question the effects barefoot running may have on navicular drop and plantar pressure of the foot while walking and running. The results of the study indicate that there was no statistical significance between the barefoot group and the shod group in the navicular drop height and plantar pressure area. However, the barefoot group showed a significant change in plantar pressure along cell six of the right foot while running when compared to the shod running group.

Since this study found no statistically significant changes in navicular drop height or plantar pressure area, the benefits of barefoot running may not have occurred due to the limited amount of changes noted in navicular drop height and plantar pressure area. There may, however, be benefits from a decreased plantar pressure in cell six of the foot which correlates with the navicular bone. Therefore, barefoot running may assist the runner during pronation. This is especially important because dynamic navicular drop is a more significant factor of pronation as opposed to static navicular drop. Since dynamic navicular drop is related to the level of pronation, we can utilize barefoot running to create adaptations in the running in order to reduce hyper-
pronation. This is relevant because researchers have shown that reducing hyper-pronation can reduce the risk of running related injuries.\textsuperscript{5-7,24}

**Adverse Effects**

While conducting a retraining program, there is an increased chance of acquiring any adverse effects from a change in stress to the feet. This study found a high incidence of adverse effects from the retraining program, most notably pain located at the heads of the metatarsals. These adverse effects may be attributed to the running surface or to a rapid progression of the retraining program. Other adverse effects to this study occurred, however, they are not attributable to any injuries acquired during the retraining program.

**Limitations**

Limitations were noted while conducting this study that could have affected the results of the retraining program. The small sample size (N=11) and narrow population of only physical therapy students did not allow for a diverse patient population. Having a more diverse group of subjects brings more relevance to the clinical setting. Also, the navicular drop tester did not remain blinded to subject group assignments which may have hindered unbiased results. This was partially due to the close interaction of the researchers and subjects on a daily basis, but it could be corrected by opening up the subject population to a more public audience.

Time constraints were a significant factor in the results of this study. Due to the deadlines for completing the research, the training program was shorter than ideal which lead to a progression that was too aggressive. This vigorous advancement may have been a contributing factor causing the adverse side effects that were reported in the post survey. Also, the short time duration may have not allowed sufficient time for the training program to induce sufficient results. Allowing more time for a longer training program with a slower progression could lead to less adverse effects while also enhancing the benefits of barefoot running.
The running surface on the treadmill may have contributed to adverse effects specifically pain on metatarsal heads and blisters because of the friction of the socks and landing on a hard surface. A more natural way to begin barefoot running would be starting on a softer surface such as grass; therefore, subjects would be able to absorb the initial impact of barefoot running. The reason for treadmill use in this study was to keep the same variables for all subjects. Also, researchers were present and available while runner's performed the retraining program to subjectively assess the adverse effects of each subject. Another factor contributing to the poor running surface was the need for subjects in the barefoot running group to wear socks while running on the treadmills. This was a requirement by the UND Wellness Center to maintain their sanitation standards. The socks could have caused slight slipping on the treadmill surface which could have caused some adverse forces on the structures of the foot and ankle. Having the subjects run in a true barefoot fashion could have avoided some of the adverse effects noted in the post survey results.

Due to limited resources, researchers were unable to directly measure dynamic navicular drop. The incapability of doing a dynamic navicular drop was addressed with use of the static navicular drop test therefore, this study still obtained relevant data related to the navicular drop height. Along with only providing static measurements of navicular drop, the GAITRite® mapping system providing occasionally inconsistent spatiotemporal and area measurements. This may be the result of the increase of subject's speed on the embedded walkway and glitches within the actual mat. The GAITRite® is not accustomed to accurately measure jogging speed because the system's software is created for measuring walking speeds therefore, the data acquired from the GAITRite® often times had to be edited based on accuracy of subject's footfalls.

**Future Research**

In order to address some of these limitations, future researchers can create an ongoing study throughout the year to increase our sample size and open our sample population to more
students or to the public. Opening the study to the public may also assist in maintaining the assessor’s blindness to the study. Future researchers may also change the running surface, such as running on grass in barefoot rather than in socks on a treadmill or concrete. By utilizing a softer surface, the runners will be able to tolerate the changes from RFSP to FFSP. This may decrease the incidence of adverse effects during the retraining program.

Future research may also investigate correlations between pressure mapping systems and dynamic navicular drop, increased length in the retraining program with a slower progression, or utilize more specialized research tools. We propose a study that investigates the use a treadmill mapping system to assess dynamic navicular drop. Also, future research ventures could look at the optimal time length and intensity of a barefoot retraining program to assess running adaptations. A more clinically relevant study could be performed as well on injured runners to determine the efficacy of a barefoot retraining program being used in a clinical setting.

The results of the current study showed only one statistically significant change in the pressure area of the foot. Other improvements were made in all areas assessed but did not reach statistical significance. This illustrates that adaptations may occur from barefoot running and may be used in a clinical setting. It is up to future research to expand on the knowledge of the clinical use of barefoot running retraining programs.
**APPENDIX A**

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<thead>
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<th>Principal Investigator:</th>
<th>Gary Schindler, DPT</th>
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<tr>
<td>IRB Project Number:</td>
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The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your original consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. **You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

Prior to implementation, submit any changes to or departures from the protocol or consent form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: [http://und.edu/research/resources/human-subjects/](http://und.edu/research/resources/human-subjects/)

Sincerely,

Michelle L. Bowles, M.P.A., CIP  
IRB Coordinator
MLB/sb  
Enclosures
Cc: Chair, Physical Therapy
INSTRUCTIONS:

- This consent document template is recommended for non-medical studies because it contains all required elements of consent.

- The text in bold throughout this document offers suggestions and guidance. It should be deleted and replaced with information specific to your study. The headers and footers are not meant to be edited and should remain on your consent document.

CONSENT DOCUMENT INSTRUCTIONS:

- Consent documents should be written in the second person (e.g., “You are invited to participate”). Use of the first person (e.g., “I understand that…”) can be interpreted as suggestive and can constitute coercive influence over a subject.

- The consent form should be written at about an eighth grade reading level. Clearly define complicated terms and put technical jargon in lay terms.

- The consent form must be signed and dated by the subject or the subject’s legally authorized representative. The signed consent from each subject must be retained by the investigator and a copy of the consent form must be provided to the subject.

CONSENT DOCUMENT FORMAT:

- To facilitate the IRB review process, the sample format below is recommended for consent forms.

- Prepare the entire document in 12 point type, with no blank pages or large blank spaces/paragraphs, except for a 2 inch by 2 1/2 inch blank space on the bottom of each page of the consent form for the IRB approval stamp.

- Multiple page consent documents should contain page numbers and a place for the subject to initial each page.

ASSISTANCE

- If you have questions about or need assistance with writing an informed consent please call the Institutional Review Board office at 701 777-4279.
THE UNIVERSITY OF NORTH DAKOTA
CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Barefoot versus Shod Running: Training Effects on Navicular Drop and Foot Pressure Analysis

PROJECT DIRECTOR: Gary Schindler

PHONE # 701-777-6081

DEPARTMENT: Physical Therapy

STATEMENT OF RESEARCH

A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to be in a research study that is interested in investigating how training barefoot running versus shod (shoe) running effects navicular drop (the amount that the navicular bone drops to the ground with weight bearing activities) and foot pressure. Literature identifies the barefoot runners complete more of a forefoot strike than shod runners (rear foot) which can lead to more gastrocnemius (calf) and quadriceps (thigh) activation creating more supinated (walking/running more on the outside of the foot) foot mechanics. This study aims to investigate whether training in barefoot running versus shod running reduces the amount of navicular drop and reduces the amount of medial arch pressure during walking and running activities. You have been identified as a potential participant because you are a first or second year physical therapy student at the University of North Dakota, a novice runner, and meet this study’s inclusion criterion.

The purpose of this research study is to understand what effect barefoot training has on navicular motion during walking and running activities, which may assist in future injury prevention.

HOW MANY PEOPLE WILL PARTICIPATE?

A minimum of 6 participants will be take part in this study at the University of North Dakota. Each participant will be randomly placed in either the shoe running group or barefoot running group with each group having a minimum of 3 participants. Each group will complete pre- and post-test navicular drop, walking/running pressure analysis utilizing the GAITRite® system, and complete a post-survey analysis to determine compliance and training schedule. The GAITRite® system is an instrument to measure the foot pressure along the bottom of your foot during walking and running activities and will be used to determine if changes occur between training groups. In between the pre- and post-tests each individual will complete a 6-week training schedule involving running on a treadmill with a gradual progression of distance and time per week as symptoms allow. Surveys will be completed at the time of the post-testing at the School of Medicine and Health Sciences in the Physical Therapy Department on the campus of the University of North Dakota.
HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last approximately 8 weeks. Each participant will complete a pre-test navicular drop test and a walking/running pressure analysis utilizing the GAITRite ® system. Following the pre-testing, each participant will complete a 6-week training program in either the barefoot running or shod running groups with a gradual progression of both distance and time per week as symptoms allow. Following the 6-week training period, each participant will complete a post-test navicular drop test and a walking/running pressure analysis utilizing the GAITRite ® system and complete a post-survey analysis to determine compliance and training schedule.

WHAT WILL HAPPEN DURING THIS STUDY?

Those who choose to participate will be screened to determine qualification to participate in the study according to the inclusion criteria which includes: no pain in the lower extremities in the past 3-months, age between 20-30, greater than 7 mm navicular drop, must be a rear foot striker, no current use of NSAIDs, no cardiopulmonary pathologies or significant medical history, and must currently complete between 2-10 miles of running per week. If you are included in this research, this study will take place over approximately an 8-week period. A bilateral navicular drop test and foot pressure analysis will be performed on you prior to beginning the program. Then you will be randomly placed into either the barefoot or shod group. Each group will complete the same 6-week training program. You will run 2 mornings per week (Monday and Thursday) progressing from 8-12 minutes per session during the first week in 4 minute increments to 28-32 per session during the sixth week as tolerated. After completing the program, a navicular drop test and foot pressure analysis will be performed again, and each participant will complete a survey. No personal identifications are used on any written document and all descriptions of participants are anonymous. Participants are allowed to skip any questions in the survey that he/she would prefer not to answer.

WHAT ARE THE RISKS OF THE STUDY?

There are no foreseeable risks of physical, emotional, or financial risks to the participants with this study; however, since physical activity is taking place there may be a chance of muscle strains, fatigue, tendinitis, stress fractures, delayed onset muscle soreness (DOMS), or a general pain response, but minimal risk is anticipated. A certified athletic trainer, licensed physical therapist, sports/orthopedic specialist, and certified strength and conditioning specialist will be on site for all training sessions to answer any questions and to direct activity progression to limit adverse reactions. If adverse reactions occur the participant will be evaluated by the primary investigator and will be referred for further medical evaluation if deemed necessary.

WHAT ARE THE BENEFITS OF THIS STUDY?

Each participant may not benefit personally from being in this study. It is possible that the participants may see a decrease in their navicular drop and decreased medial arch pressure which may aid in injury prevention. Participants may also see improved cardiorespiratory fitness and a decrease in BMI. Also, we hope that in the future other people might benefit because a better understanding of how barefoot running training may affect navicular placement and movement and alter foot pressure, which may assist in reduced pain, improved function, and prevention of future overuse injuries for some patients. It will also provide evidence supporting or refuting the impact barefoot running training may have on arch dynamics. This research may impact how physical therapists practice clinically, therefore impacting the lives of their patients and their
families. This research may lead to alterations in exercise training that may lead to less future injuries.

**WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

You will not have any costs for participating in this research study.

**WILL I BE PAID FOR PARTICIPATING?**

You will not be paid for participating in this research study.

**WHO IS FUNDING THE STUDY?**

No funding is needed for this study. The University of North Dakota and the research team are receiving no payments from any agencies, organizations, or companies to conduct this research study. Treadmills at the Wellness Center on the campus of the University of North Dakota will be utilized for this study.

**CONFIDENTIALITY**

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else. Confidentiality will be maintained with anonymous surveys conducted. All data collections will be kept anonymous by means of a 5-digit code that will include the participant’s mother’s or father’s day of birth and the last three digits of their zip code while in high school. Consent forms will be kept in a locked and secure location for a minimum of three years, with only Gary Schindler having access to the consent forms and personal data.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

**IS THIS STUDY VOLUNTARY?**

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota.

If you decide to leave the study early, we ask that you inform Gary Schindler that you would like to withdraw.
CONTACTS AND QUESTIONS?

The researchers conducting this study are Gary Schindler. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Gary Schindler at 701-777-6081 or at gary.schindler@med.und.edu.

If you have questions regarding your rights as a research subject, you may contact The University of North Dakota Institutional Review Board at (701) 777-4279 or UND.irb@research.UND.edu.

- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
- General information about being a research subject can be found by clicking “Information for Research Participants” on the web site: http://und.edu/research/resources/human-subjects/research-participants.cfm

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subjects Name: ________________________________________________________________

_____________________________  ______________________________
Signature of Subject                  Date

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative.

_____________________________  ______________________________
Signature of Person Who Obtained Consent       Date
Q1 Gender
○ Male (1)
○ Female (2)

Q2 Age in years _____

Q3 What ethnicity do you most associate with?
○ Caucasian (1)
○ Hispanic (2)
○ African American (3)
○ Asian (4)
○ Native American (5)
○ Pacific Islander (6)

Q4 Weekly running mileage prior to this study
○ I did not run (1)
○ 0-2 miles (2)
○ 2-4 miles (3)
○ 4-6 miles (4)
○ 6-8 miles (5)
○ 8-10 miles (6)
○ 10+ miles (7)

Q5 Do you currently use orthotics?
○ Yes, while running (1)
○ Yes, while walking (2)
○ Yes, during running and walking (3)
○ No (4)

Q6 I was interested in barefoot running prior to this study?
○ Strongly Agree (1)
○ Agree (2)
○ Neutral (3)
○ Disagree (4)
○ Strongly Disagree (5)
Q7 I felt the training intensity was appropriate?
- Strongly Agree (1)
- Agree (2)
- Neutral (3)
- Disagree (4)
- Strongly Disagree (5)

Q8 I felt the program was well structured?
- Strongly Agree (1)
- Agree (2)
- Neutral (3)
- Disagree (4)
- Strongly Disagree (5)

Q9 I felt there was sufficient amount of time to complete the program?
- Strongly Agree (1)
- Agree (2)
- Neutral (3)
- Disagree (4)
- Strongly Disagree (5)

Q10 Did you have any adverse effects from this study? If yes, please describe the injury and where it occurred.
- Yes (1) ____________________
- No (2)

Q11 Did you abide by the study's protocol? If no, please describe what you did outside of the program (i.e. run additional miles, started resistance training program, etc.).
- Yes (1)
- No (2) ____________________

Q12 What do you feel is the most prevalent barrier to starting barefoot running?
- Fear of possible injury (1)
- Lack of adequate instruction (2)
- Lack of adequate training surfaces (3)
- Fear of decline in performance (4)
- Other (5) ____________________

Q13 Which resource would be the most helpful when transitioning to barefoot running?
- Supervised instruction by a reputable coach or running professional (1)
- Internet (2)
- Book on barefoot running (3)
- Other (4) ____________________
Q14 I would start or continue barefoot running if given the proper resources?
☑️ Strongly Agree (1)
☑️ Agree (2)
☐ Neutral (3)
☑️ Disagree (4)
☐ Strongly Disagree (5)

Q15 Which of the following best describes your perception of barefoot running? (Click all that apply)
☐ I felt great while running barefoot (1)
☐ I will continue to always run barefoot (2)
☐ I would recommend barefoot running to my friends (3)
☐ I would not recommend barefoot running to my friends (4)
☐ I never want to run barefoot again (5)
☐ **I was placed in the shod running group (6)

Q16 Is there anything else you would like to comment on regarding this study?
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References


30. Menz HB, Hons B, Munteanu SE, Hons B. Validity of 3 Clinical Techniques for the Measurement of Static Foot Posture in Older People.


