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The Effect of Barefoot Running on Navicular and Pelvic Drop: A Randomized Controlled Trial

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THE EFFECT OF BAREFOOT RUNNING ON NAVICULAR AND PELVIC DROP: A RANDOMIZED CONTROLLED TRIAL

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This Scholarly Project, submitted by Sarah Bunde, Kathryn West, and Christopher James 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.

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David Relling, PT, PhD, Department Chair

Permission

Title THE EFFECT OF BAREFOOT RUNNING ON NAVICULAR DROP: A RANDOMIZED CONTROLLED TRIAL

Department Physical Therapy

Degree Doctor of Physical Therapy

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Signature Sarah Brude

Signature Kathryn West

Signature ________________

Date: 10/15/19

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ABSTRACT

Background and Purpose: Gaining knowledge of the change in navicular drop of the foot and pelvic movement in response to barefoot running training may allow sports medicine professionals, coaches, athletes, and others in the healthcare field to decrease the amount of injuries that may be caused by these motions. The effects of rearfoot strike pattern (RFSP) versus a forefoot strike pattern (FFSP) in determining the impact on navicular drop and pelvic movement is lacking in literature. Due to the increased correlation of hip movement and lower extremity injuries, the purpose of this study was to determine if barefoot running with a FFSP compared to shod running using a RFSP would affect the amount of drop during walking and running activities.

Material/Methods: Navicular and pelvic movement was analyzed between shod and barefoot running groups by utilizing the VICON motion analysis system and the static navicular drop test. This study implemented a one-day session of five different gait analysis: walking barefoot, running normal (RFSP) barefoot, running on toes (FFSP) barefoot, walking shot, and running shod. The VICON was specifically used to evaluate the pelvic movement and navicular drop of the foot during the stance phase of gait in walking and running. A decrease in navicular distance traveled from pre- to post-test, may suggest a decrease in dynamic foot over-pronation. This result could support the effects of barefoot running with a FFSP, as a method for reducing pain and injuries associated with running. Decreased pelvic drop could support the effects of walking or running barefoot to reduce the amount of injuries to the hip, knee, and down the kinematic chain.

Results: The data collected from the VICON motion analysis indicated minimal statistical significant evidence supporting that the navicular and pelvis move less with barefoot running and walking in comparison to shod walking. Statistically significant data was found when comparing navicular drop in walking barefoot to running barefoot on the right foot only. Walking barefoot compared to walking shod showed to be statistically significant for pelvic drop on the right.

Discussion: Although not all of the data was statistically significant, the trend with the data does support that navicular and pelvic drop is reduced with barefoot motions in comparison to shod. The clinical significance associated with these results identify the potential to reduce running injuries by correcting overpronation and creating a proper force distribution through the lower extremity. Due to the limitations of this study (small sample size, narrow population, and the specifics of the VICON motion analysis process) future research could address these limitations through conducting an ongoing study and/or open it to the public to improve subject population.

Chapter I

Background and Purpose

Interests and studies conducted in the biomechanics, kinetics, and kinematics of running have become more prevalent within the last decade; specifically, the effects of barefoot versus shod running. Forefoot strike pattern (FFSP) among barefoot runners as opposed to rear foot strike pattern (RFSP) is one significant aspect differentiating the two running styles. According to a study done by Hashish et al,[1] without the impact absorption that a supportive shoe sole provides, a barefoot runner changes their dynamics by relying on lower leg posterior musculature (gastrocnemius, soleus, tibialis posterior, and Achilles tendon) and a forefoot striking pattern to reduce load.

Due to the lack of research found in literature, we hope to further investigate barefoot versus shod running and the effect on pelvic and navicular drop in healthy subjects. The hypothesis of this study is that barefoot running will decrease the amount of pelvic drop and the distance traveled of the navicular within the medial longitudinal arch of the foot compared to shod running. Reduced navicular movement may be due to the muscular attachment of the tibialis posterior (TP) tendon. The TP is the primary stabilizer during dynamic activity of the rearfoot and medial longitudinal arch due to its multiple attachments. These include: the navicular tuberosity, tarsal bones, 2nd, 3rd, and 4th metatarsals, and the flexor hallucis brevis muscle.[2] Additional medial longitudinal arch support includes the contribution of the flexor hallucis longus (FHL) and flexor digitorum longus (FDL) muscles.[3,4] The FHL arises from the posterior fibula and attaches to the distal phalanx of the great toe on the plantar surface.[3] The

FDL arises from the posterior tibia and continues on the plantar surface to then insert on the distal phalanx of the second through fifth toes.[4] Together these muscles act as toe flexors and assist in plantar flexion of the ankle. Functionally, FHL and FDL are strong during toe-off and propulsion phases of gait prior to the swing phase; great toe flexion necessary for final propulsion (FHL) and toe flexion necessary for gripping and balance during running, walking, and jumping.[3,4] Barefoot running may accentuate this phase of gait while utilizing the forefoot striking method and therefore recruiting necessary musculature to enhance the support of the medial longitudinal arch and decrease the navicular drop.

Common causes of injuries in runners are due to anatomical factors such as excessive pronation or supination of the foot or an increased hip Q-angle (a line representing the force of the quadriceps, made by connecting a point near the anterior superior iliac spine [ASIS] of the pelvis to the midpoint of the patella). With the repetitive stress on these maligned structures and forces generated from running, injuries including plantar fasciitis and stress fractures commonly occur.[5,6] By reducing the distance in which the navicular travels, in theory, should reduce the amount of over-pronation. In turn, this may indirectly reduce the Q angle at the knee and prevent subsequent injuries. In a study by Khamis et al,[7] a translation effect of hyper pronation of the foot cause a kinematic chain reaction, finding that the shank has a great effect on the alignment of the foot and pelvis-translating to the lumbar spine. Thus, adjusting the foot alignment may create proper distributions of forces during running, decreasing the likelihood of injury.

Although there is increased interest on the impacts of barefoot running, there is a paucity of research pertaining to the impact barefoot running may have on navicular drop. Because the literature is so scarce, there is a great need for research in this area. The purpose of this study is to investigate the pelvic and navicular movements during barefoot and shod walking and running.

Biomechanics of the Lower Extremity

The biomechanics of the lower extremity joints are identified further in this section. Anatomical joints identified for discussion include forefoot, ankle, knee, and hip. In addition, common links to biomechanical related injuries were identified and discussed.

Forefoot

It has been hypothesized that some of the benefits of barefoot running are due to an acquired forefoot strike pattern as opposed to a rearfoot strike pattern, most often seen in shod running. Forefoot strike pattern is believed to decrease the ground reaction forces experienced during barefoot running, which may decrease the risk of injury to the lower extremity. Hashish et al,[1] evaluated 22 recreational runners transitioning to barefoot running to determine carry-over into forefoot running. It was concluded that not all runners adopted a forefoot strike pattern. Without instruction, 8 runners maintained rearfoot strike pattern, 9 runners adopted a midfoot strike pattern, and 5 runners adopted the desired forefoot strike pattern.

Ankle

Ankle kinematics has significant implications in relation to barefoot running. Ankle plantar flexion and dorsiflexion are often hypothesized to be affected in various time frames of the gait cycle during barefoot vs. shod running. It has been thought that during foot strike there is a reduction of ankle dorsiflexion and an increase in plantar flexion during barefoot running. A study conducted by Fredericks et al,[31] evaluated 26 recreational runners either barefoot or shod in their own personal shoes, standardized shoes, or minimalist shoes, concluded that barefoot and minimalist runners had significantly greater plantar flexion moments during foot strike than the other two groups. Divert et al[40] also suggests that there is a pre-activation of the gastrocnemius muscles to maintain plantarflexion in barefoot running in comparison to shod running. Hollander et al,[8] concluded that there is limited evidence to support the hypothesis of reduced ankle dorsiflexion at foot strike when compared to shod runners. In addition to plantarflexion/dorsiflexion moments, barefoot running is also hypothesized to have an effect on ankle eversion.

Perkins et al,[9] suggests there is a decreased tendency for barefoot forefoot strike runners to evert their foot during running compared to shod rearfoot strike runners. This running position may support the hypothesis that barefoot runners experience less navicular drop than shod runners. It was concluded that barefoot runners display an increase in power generation and absorption of ground reaction forces at the ankle, illustrating the significance of the position of the ankle during foot strike in producing good biomechanics while running.[9] In addition, Hashish et al,[1] concluded the finding that midfoot and forefoot strike runners showed increased ankle energy absorption rates. The increase in ground reaction forces at the ankle helps support the claim that barefoot runners experience less ground reaction force at the knee, which may decrease the stress to the knee, thus preserving soft tissues.

Knee

Due to the high incidence of knee injuries in runners, the biomechanics of the knee has a significant level of interest in barefoot running. Barefoot running has been hypothesized to prevent certain type of running related knee injuries. One aspect of study during barefoot running is Q angle. Increased Q angle at the knee has been correlated with numerous pathologies at the knee. A study conducted by Fredericks et al,[31] concluded that type of footwear had no significant effect on the knee Q angle during running. Although evidence suggests that barefoot running has little effect on Q angle at the knee, it may have an effect of knee flexion moments during running.[2] A systematic analysis conducted by Perkins et al[9] identified an increase in knee flexion at contact in barefoot/minimalist runners and increased knee flexion angle in stance phase of barefoot or minimalist running. This increased knee flexion at contact is hypothesized to reduce the knee extension moment arm and lessen the stress across the patellofemoral joint. In addition to increased knee flexion, barefoot runners also exhibited earlier knee flexion moments in a study conducted by Sinclair et al,[11] who evaluated female recreational runners. The loading rates at the knee have a significant effect on the kinetic chain during barefoot running, therefore, possibly improving injury prevention.

Hashish et al,[1] found that loading rates in the knee increased in runners that maintained RFSP while barefoot running, while forefoot strike runners showed significantly decreased loading rates in the knee. Sinclair et al,[11] supported this claim as barefoot running showed significant reductions in patellofemoral loads.

Hip/Pelvis

The biomechanical effects of barefoot running at the hip contribute to the mechanics of the kinetic chain above and below this joint. Inadequate strength and muscle activation at the hip have been correlated with a variety of hip and knee pathologies. Sinclair et al,[11] evaluated 20 experienced male runners performing either barefoot running or shod running and concluded that the shod group displayed significantly more hip flexion while the barefoot group exhibited significantly more knee flexion and plantar flexion at the ankle. The shod group displayed greater peak force in their quadriceps and tibialis anterior. The barefoot group showed significantly higher peak forces in the gastrocnemius. Another study, performed on female recreational runners, concluded that when comparing the kinematics of barefoot running versus shod running, barefoot runners had significant reduction in hip adduction, hip internal rotation, and contralateral pelvic drop at initial contact. At 10% stance, they remained significantly lower than the shod group; however, there was no significant difference observed in peak stance.[15] The gluteus medius (GM) acts as stabilizer at foot strike, preventing the knee from moving into genu valgum. During single leg stance, the force of gravity pulls the pelvis into relative adduction. The ipsilateral hip abductors provide a counter-force to stabilize the pelvis and control the magnitude of pelvic drop.[26] GM activation has been well documented for shod running and weight bearing activities. The GM has the largest mean peak muscle force of all hip muscles during running. This peak mean muscle force occurs during the initial stance phase of running to help control lateral pelvic tilt.[27] The shape and size of the GM is favorable for a large abduction moment arm which is a key component to proper hip alignment and stability when performing weight bearing activities.[28] The stance phase of running recruits the GM to prevent excessive pelvic drop. Without sufficient GM activation during the stance phase of gait, excessive pelvic motion can result and may cause injury.[29]

Injuries of the Lower Extremity

Due to the altered biomechanics barefoot running may have on the lower extremity kinetic chain, it has been hypothesized that barefoot running may serve as a method of prevention of many lower extremity orthopedic pathologies. Hollander et al,[8] concluded that there was no difference in injury rates between shod and barefoot runners and walkers. A review by Perkins et al,[9] then supported this conclusion, stating there is not enough evidence to ascertain specific risks and benefits related to barefoot running versus shod running.

A hypothetical risk of barefoot running is found with the increased plantar flexion moment seen. This may put the Achilles tendon and plantar fascia at increased risk for injury. A study conducted by Chen et al[38], found that a forefoot strike pattern when barefoot running increases the plantar fascia stress and tensile force, creating a greater vulnerability for developing plantar fasciitis.

Another study conducted by Sinclair et al[39], found that limb stiffness is larger when running barefoot in comparison to wearing conventional footwear. The increase in limb stiffness relates to a decrease in limb compression when running barefoot because of a decrease in stance time during the gait cycle. Decreased stance time is associated with increased limb stiffness. This study suggests that increased limb stiffness may protect the body from soft tissue injuries. However, it also suggests that this increase in stiffness may increase the risk of bone injuries. This particular study also claims that barefoot running may reduce the risk of knee injuries, while increasing the risk of attaining an ankle injury.

A potential benefit to barefoot running shows moderate evidence to support the claim that it helps to decrease ground reaction forces in the lower extremity which could decrease forefoot and knee injuries.[1,9] This transfer of ground reaction forces is further explained in a study conducted by Bergstra et al[10] in which an increase in forefoot pressure was observed in female endurance runners who transitioned to a minimalist running shoe. This increase in pressure is thought to play a role in metatarsal stress fractures. A decrease in knee injuries via barefoot running could also be explained by the decrease in hip internal rotation at contact according to Sinclair et al.[11] It is important to note the authors attribute this decrease in ground reaction force to a forefoot strike pattern rather than the barefoot running itself.

Rearfoot eversion, tibial rotation, knee adduction, and ankle inversion are biomechanical gait measures which have been identified as potential risk factors for lower limb injuries.[12,13,14] Eslami et al[15] found navicular drop having had significant positive correlations between peak knee adduction moment and peak ankle inversion moment in participants during barefoot running. Their findings suggested a low navicular drop could be associated with increasing tibial rotation excursion, while a high navicular drop could be associated with increased peak ankle inversion and knee adduction moments. Although not finding a correlation with rearfoot eversion excursion, Cornwall and McPoil[16] did find a correlation with rearfoot eversion and navicular drop. These moments (rearfoot eversion, tibial rotation, knee adduction, and ankle inversion) in return could potentially lead to injury over time such as shin and knee injuries.[17,18,19] Which is why this study was conducted, in order to investigate whether barefoot running decreases navicular and pelvic movement compared to shod running.

Recent studies indicate an omnipotent association of hip flexor and abduction weakness with lower extremity running injuries.[26] In one study, they analyzed thirty injured runners with overuse injuries to thirty non-injured runners.[29] Muscle testing of all six hip muscle groups revealed that hip abductors and hip flexors were significantly weaker in the injured group in comparison to the non-injured control. Further, the hip rotators also have been found to uphold greater stress and discomfort when gluteus medius weakness is present, therefore, eccentric strengthening has been emphasized as a successful treatment method to restore ideal biomechanics of gait.[26] By strengthening the gluteus medius, the amount of pelvic drop may be reduced, encouraging ideal mechanics of gait and reducing abnormal repetitive stress due to excessive motion of the pelvis.

Navicular Drop

The measurement of the navicular drop movement was managed utilizing the Navicular Drop Test (NDT). The reliability of the NDT will be discussed below along with the rate of drop that occurs during running.

Measurement Using the Navicular Drop Test (NDT)

The NDT was developed by Brody[20] to help determine the measurement of pronation in the foot. In the majority of the studies, the NDT protocol was used to determine the measurement of the navicular drop and will also be used in the current study. To perform the test, the participant was placed in a sitting position with their feet flat on a firm surface with hips and knees in 90 degrees and ankles in neutral position. Subtalar neutral was found when there were equal depressions on both the medial and lateral side of the ankle. The most prominent point of the navicular tubercle was identified and marked, to be referred to during the NDT. One assessor maintained subtalar neutral and the other marked the height of the navicular tubercle on an index card. Without changing the position of the foot, the participant then stood up and bared weight equal through both feet. Using the same mark on the navicular tubercle, the height was measured on the same index card. The difference in height between the two markings was measured in millimeters. The same procedure was performed to calculate the measurements on the opposite foot as well. For normal values of navicular height drop, Brody described values of 10mm and under to be normal, and 15mm and over to be abnormal.

McPoil et al[21] proposed that there are issues in performing the traditional navicular drop test involving lower levels of inter-rater reliability, including the identification of the navicular tuberosity bony landmark and the consistency of placing the subtalar joint in a neutral position using palpation while the patient is in a seated position. To overcome these issues, the authors of this study developed an alternative method for assessing foot mobility during the sit to stand portion of the navicular drop test by utilizing digital images to measure the change in dorsal arch height measured at 50% of the foot. In this method, the location of subtalar joint neutral was not performed due to the alternative method.

Van der Worp et al[25] investigated NDT assessment in runners in order to identify whether hyper pronation of the foot along with decreased ankle joint dorsiflexion and the degree of the first metatarsophalangeal joint extension are risk factors for running injuries and to determine if there are differences between males and females. The cohort study performed the NDT using modified procedures by both Vinicombe et al[22] and McPoil et al[21] using a stance and single limb-stance measurement. Inter- and intrarater ICCs were low for both NDT stance and single limb-stance. However, the authors did not determine subtalar joint neutral before taking measurements during this study and determined that this was one of their limitations in the study when comparing to ICC data from other literature. Sell et al,[23] suggests that subtalar neutral position can be measured reliably by palpating the talus equally between the thumb and the index finger of the examiner. Along with this, they also explained finding the navicular tuberosity in prone instead of sitting which proved to be reliable.

NDT Reliability

The inter- and intra-rater reliability of the navicular drop test has only been proven to be moderate. In a study performed by Vinicombe et al,[22] two methods two methods of quantifying foot posture were evaluated: navicular drop and navicular drift. Navicular drop is how much the navicular moves when it is measured in a relaxed state and when the foot is put into subtalar neutral. Navicular drift is how much the navicular moves medially when the foot is in subtalar neutral and then is in a relaxed position. Five clinicians measured twenty nonpathological participants on two occasions, using both methods. The authors found intratester reliability having been slightly higher than intertester reliability for both measurements, but intraclass correlation coefficients and standard error of measurement findings for navicular drop (0.33 to 0.76 and +/- 1.5mm to +/-3.5, respectively) were only slightly higher than navicular drift (0.31 to

0.62 and +/- 3mm to +/-5mm, respectively). This indicates that both techniques are only moderately reliable.

In comparison, Sell et al[23] found good interrater and intrarater reliability when evaluating and measuring the navicular drop in 30 healthy participants. These authors reported a mean navicular drop value of 0.6 cm and an ICC for intra- and inter-rater reliability of 0.73 and 0.83 respectively.

Rate of Drop

Previous studies have suggested that an increase of pronation of the foot may contribute to running-related injuries. Hoffman et al[24] conducted a study using dynamic, biplane X-ray imaging to address the effects of three different footwear conditions (barefoot, minimalist shoes, motion control shoes) on the impact of navicular drop during running. The purpose of the study was to determine the association between dynamic and static measures of navicular drop. The motion control shoes had a slower navicular drop rate than running barefoot or minimalist shoes but there was no effect on magnitude comparing the difference in shoes. Static assessment was found to be a poor predictor of dynamic navicular drop in all footwear conditions.

Pelvic Drop

The amount of pelvic drop was analyzed by using the 10 camera VICON system, which is addressed in more detail in the following section. Subjects had a sensor on each ASIS and were analyzed during barefoot walking, barefoot jogging, barefoot jogging on their toes, shod walking, and shod jogging. The amount of pelvic drop was measured for each target hip along with the amount of pelvic drop on the contralateral. Measurement of pelvic drop was taken from heel strike to toe off of the target leg. Two steps were analyzed for each subject with measurements of the target hip and the contralateral hip being assessed. On some subjects only one step had data that was read by the VICON system due to poor recognition of sensors with two steps. The averages of the amount of pelvic drop for the two steps was taken and those are the data that is included in the final results.

Motion analysis

Development of a stretch-sensor that allowed for in-shoe measurement of navicular drop was investigated for its reliability for measuring navicular drop and concurrent validity of the stretch-sensor compared to the static navicular drop test.[32] Twenty-seven participants were tested by walking on a treadmill on two separate days for six minutes before navicular drop was measured. Placement of the stretch-sensor was 20 mm posterior to the tip of the medial malleolus and 20 mm posterior to the navicular tuberosity. Results showed acceptable reliability for dynamic barefoot measurement of navicular drop and also showed concurrent validity compared with the static navicular drop test. Conclusions drawn from this research article on the development of stretch-sensors to measure navicular drop is very new and needs more research before it can be recommended, but it holds promise for future assessments. In another study by Barton et al,[33] stretch sensors were used to evaluate dynamic navicular motion difference between walking and running and between over ground and treadmill conditions. The authors' conclusion was that the presence of footwear has minimal impact on navicular motion during walking.[11]

Differences in navicular motion between walking and running, and treadmill and over ground conditions highlight the importance of task specificity during gait analysis. Therefore, task specificity should be taken into consideration when deciding what conditions to run.

An alternate use of sensors to detect motion was conducted in a study by Klein and Dehaven,[34] these authors investigated the accuracy of three-dimensional linear and angular estimates obtained with the Ariel Performance Analysis System. This system is a method of evaluating human kinematics using computer-assisted motion analysis. This instrument was shown to be valid and reliable to the degree required in most clinical applications. Suggestions for using marker placement and marker movement on human subjects were given to decrease the amount of error.

Although this was a reliable source, the 3D motion analysis tool, VICON, has been used as a gold standard for many studies analyzing human movement.[35] VICON was utilized in a study which investigated the reliability and validity of the Stride Analyzer in persons with knee osteoarthritis.[36] The VICON used a 16 camera-infrared optoelectronic motion capturing system. When comparing the Stride Analyzer to the VICON system it was found to be valid and reliable. By using the sensor and motion analysis instruments, navicular drop. may be measured at a much higher level (greater evidence of validity and reliability). Pelvic drop may also be measured at this greater level of validity and reliability using the VICON system. The VICON system in the current study will be using 10 cameras to capture the distance and rate of navicular movement and the distance of pelvic drop during walking and jogging activities.

Summary

By utilizing the navicular drop test and the VICON motion analysis system, navicular drop and pelvic movement of the barefoot and shod participants can be analyzed. The intention of this study is to determine whether a significant difference in pelvic and navicular movement in noted during barefoot and shod running and walking.

The VICON was specifically used to evaluate the navicular drop of the foot and the lateral pelvic tilt during the stance phase of gait in walking and running. Results could support the effects of barefoot running with a FFSP as a method for reducing pain and injuries associated with running. Because of high increases in injury rate due to over-pronation of the foot, the current study will investigate differences in pelvic and navicular movement during barefoot and shod walking and running.

Chapter II

Methods

The following chapter includes information regarding the subjects and recruitment, informed consent, measurements/instruments, data analysis, and measuring internal validity. Study design for this research utilized VICON video analytics for dynamic monitoring of navicular and pelvis movement during barefoot and shod walking and running trials.

Prior to testing being completed, information was gathered from the participants which was completed in a semi private room. Subjects filled out the informed consent form before being allowed to proceed with testing. Each subject entered the room and provided their unique five-digit confidentiality code that was written on their 4"x6" pre-testing note card. Subjects sex, height, weight, and foot length were also added to the notecard. Participants then had sensors placed at specific bony landmarks on their feet and pelvis. Once placed, two trial runs each of barefoot walking (BW), barefoot running with normal footstrike, barefoot running with forefoot striking (BR), shod walking (SW), and shod running (SR) were recorded by the VICON system.

Subjects

To ensure the rights and welfare of human subjects in this study were protected, this study's investigators obtained prior approval from the Institutional Review Board (see Appendix A) of the University of North Dakota (UND). Following approval, recruitment of subjects was initiated verbally and via email to all first- and second-year physical therapy students at UND. This email included a description of the study along with inclusion/exclusion criteria so that each recipient was able to independently assess their ability to participate. The inclusion criteria included: no pain or injury to the lower extremities in the past 6 months, age between 18-30 years old, must run with a rear foot striking pattern, must be a habitual shod runner, no current use of NSAIDs, no cardiopulmonary pathologies or significant medical history, and must currently complete a minimum of 0-20 miles of running per week.

Once their inclusion/exclusion criteria were confirmed, participants were evaluated dynamically for navicular drop and pelvic movement during walking and running using VICON video analytics software. Subjects were also evaluated using a standardized, static Navicular Drop Test. Twenty-six subjects were recruited; no participants were excluded from this study. The mean age of participants was 22.85 years old. There were 20 female participants and 6 male participants that were eligible for the study. Subject selection was based on inclusion and exclusion criteria are depicted on Figure 1.

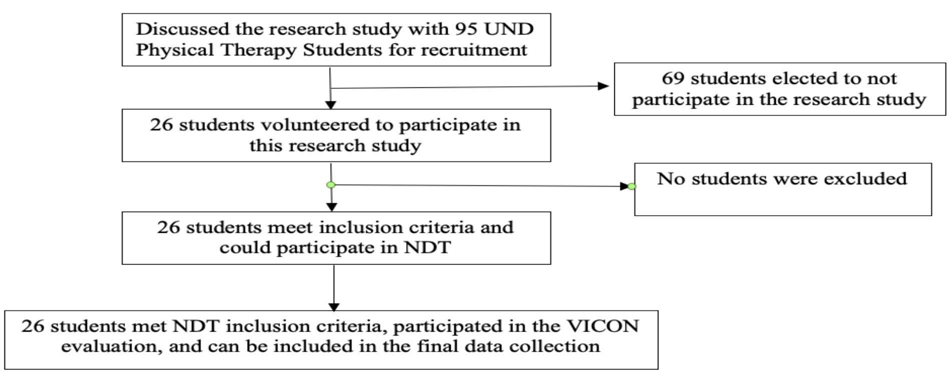

Figure 1. Subject Selection Process & Inclusion Criteria
NDT = Navicular Drop Test
**Inclusion Criteria:*

- *No pain or injury to the lower extremities in the past 6 months*
- *Age between 18-30 years old*
- *Must run with a rear foot striking pattern*
- *No current use of NSAIDs*
- *No cardiopulmonary pathologies or significant medical history*
- *Must currently complete a minimum of 0-20 miles of running per week*

Informed Consent

Prior to testing, each subject completed and signed an informed consent for detailing the study design, risks, and benefits of taking part in the study (see Appendix B). The consent form described the purpose of the study and the risks/benefits that could occur as a result of participation in the study. Subjects were informed that they would receive no financial compensation for their participation, and that there was no funding attached to this study. Subjects were reminded that their participation in this study was completely voluntary and would be permitted to terminate their participation at will. The process of participant confidentiality included a unique 5-digit code that would be assigned to each participant. This code was constructed using the two digits of their mother's day of birth, and the last three digits of the zip code where they attended high school. Two participants, coincidentally, had the same code. This was resolved by using the father's day of birth instead for the second subject.

Measurements/Instruments

Reliability Testing for the Navicular Drop Test

A single researcher was utilized to assess navicular drop in this study. Prior to testing, the reliability of this researcher was confirmed via evaluation of navicular drop in first and second year physical therapy students. Previous training of intra-rater reliability was performed until instrumentation results reached 0.90 reliability as recommended by Portney and Watkins. The final reliability results yielded an intraclass correlation equals 0.90 for the right foot and 0.95 for the left foot. The process of measuring navicular drop was the same that was used in the current study. Overall, the researcher continued to practice and improve testing skills throughout these intra-rater reliability studies prior to pre-testing.

Navicular Drop Test

Navicular drop was assessed in each participant during pre-testing using the standardized sit to stand test developed originally by Brody. Charlesworth and Johansen,[20] describe this method in detail and was used for this study. Only one researcher was in charge of performing this test. Prior to beginning the test, identification of the most prominent point of the navicular tubercle was marked using a fine tip Sharpie marker (Figure 2a). The researcher then placed the participant in an upright sitting position with feet flat on the floor and hips and knees flexed to 90 degrees with the ankle in a neutral position. Subtalar neutral was found when depressions were equal on both sides of the ankle (Figure 2b). The participant was asked to maintain this subtalar neutral position and while the researcher used a notecard to mark the height of the navicular tubercle. The patient was asked to relax the foot but not remove it from the ground, the participant then stood up without changing the position of the feet but to allow distribution of equal weight between both feet and to be in a relaxed position, marking the height of the navicular on the notecard; the opposite foot was then put in subtalar neutral and marked as well, repeating the stand without moving the foot from the ground. Again, the most prominent point of the navicular was measured for height on the notecard (Figure 2c). The difference between the two markings for both right and left were measured in millimeters.

Figure 2(a)

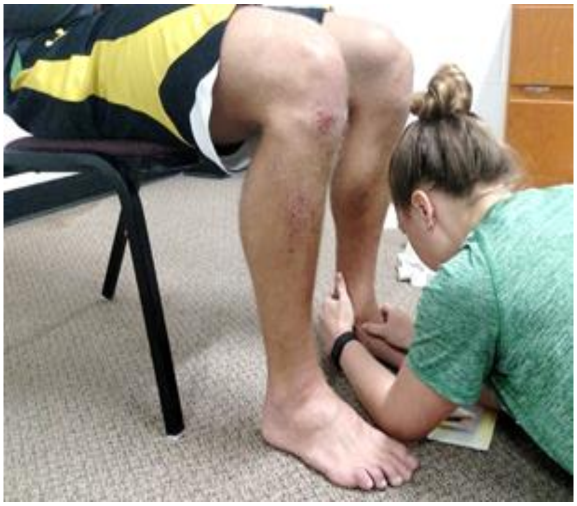

Figure 2(b)

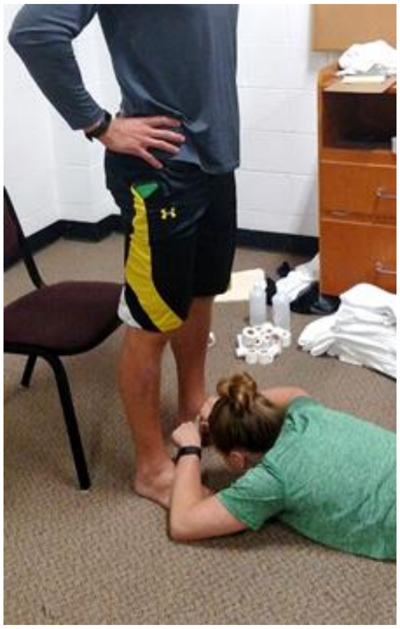

Figure 2(c)

Figure 2: Manual Measurement of Navicular Drop. *(a-above left) Navicular tubercle marking in sitting, (b-above right) Finding subtalar neutral with feet shoulder-width apart, relaxed position, and hips/knees/ankles at 90 degrees of flexion, (c-above center) Measuring the difference in navicular tubercle height between sitting and standing Instructions were given to stand up without moving feet, equal weight-bearing, and in a relaxed position.*

VICON Background

VICON, a video analysis software, was utilized in this study to assess dynamic navicular drop and pelvic movement during walking and running. This system uses a series of 10 cameras (Figure 3) recording infrared data from sensors placed on the subject to determine the positions of specific points on the body during dynamic activity. The full testing process that was utilized is explained below.

Figure 3: VICON Testing Facility

VICON Pre-Testing

Prior to placement of the sensors, calibration of the VICON system was completed using a wand with multiple sensors being waved in random manner in front of each camera to orient the system to the 3D environment. In order to calibrate the exact position of the floor, the sensors were placed in a straight line 12 inches apart running the length 10 feet in the center of the testing area. This sensor placement allows the cameras to measure the exact height of the floor to compensate for any deviations in floor height of the testing area.

Each area where the sensor was placed was cleaned and prepped by a towel with rubbing alcohol solution to remove dirt and sweat prior to sensor application. This helped ensure the sensors on each foot, and hips would not move or fall off during running and walking. Small reflective sensors were then placed on each participant's bilateral feet and hips by one researcher to maintain consistency and reliability. Four sensors were placed per foot as follows: one on the most prominent portion of the navicular bone, a second on the posterior portion of the calcaneus, a third on the lateral border of the fifth metatarsal head, and the final sensor on the medial aspect of the first metatarsal head (Figure 4). One sensor placed on the anterior superior iliac spine (ASIS) of the hip. The same process was then repeated on the opposite foot and hip. This process was completed for each participant prior to beginning the VICON analysis procedure.

Figure 4: Sensor Placement
Markers were positioned on the following anatomical landmarks: (1) base of the first metatarsal head (2) most prominent part of navicular tuberosity (3) inferior portion of the posterior-medial aspect of the base of the calcaneus (4) lateral border of the fifth metatarsal head

VICON Testing

After the sensor placement process, each participant's sensors were calibrated to the system in order to orient the system to the 3D environment before testing. This was completed by having the participant stand with their feet shoulder width apart and shoulders abducted to 90 degrees and a snapshot was taken by the VICON cameras (Figure 5). Each participant was then placed in subtalar neutral position in the center of the testing area for the right foot by the same researcher who conducted the static NDT reliability testing. Once set, a static frame shot was taken using the VICON system to determine each participant's navicular height in standing. This was completed on the opposite foot as well. Frames were also taken after the subjects were instructed to perform one smooth motion of their ankle in all planes of movement; plantarflexion, dorsiflexion, eversion, and inversion. The same frames were captured on the opposite foot. These frames will also be analyzed to find subtalar neutral using the VICON. The participants then completed 2 trials of each of the following categories of their normal pace: barefoot walking (BW), barefoot running with normal foot-strike, barefoot running with forefoot striking (BR), shod walking (SW), and shod running (SR) while being recorded by the VICON system.

Once each participant's trials were recorded, the data was evaluated using the VICON system to determine the amount of navicular drop of the navicular sensor from heel strike to toe off. Three steps on each foot that took place in the center of the testing area while walking and running were analyzed during each trial using the VICON system software. This data was compared to the subtalar neutral navicular height previously recorded. Navicular drop was calculated using trigonometry equations created by Dr. Jesse Rhoades in Microsoft Excel with the calcaneus, navicular, and forefoot sensors each making up one vertex of a scalene triangle. This equation provided the maximum navicular travel for each step which will be referred to as navicular drop from this point forward. The amount of navicular drop in each step was inputted into an Excel file that compared the total distance of the navicular sensor drop to the static subtalar neutral navicular sensor height, then averaged over the three steps and two trials in both walking and running. The same procedure was then performed to determine the amount of pelvic drop during the two trials using the ASIS sensors.

Figure 5: VICON Participant Sensor Calibration. *Each participant stood with their feet shoulder width apart and shoulder abducted to 90 degrees; snapshots were taken by the VICON.*

Data Analysis

Data collected for the standard navicular drop test reliability studies were analyzed using the ICC Model 3 Two-Way Mixed method per Portney and Watkins. This test looked at the intraclass correlation of the left and right navicular drop that was measured during pre- and post-tests. The current study will use the Statistical Package for Social Sciences to interpret difference in groups for the standard navicular drop test. Two researchers analyzed the data that was collected using the VICON system. This VICON analysis data was analyzed by the Statistical Package for Social Sciences (SPSS) software. Independent variables were barefoot or shod running and walking. Dependent variables included the following: pelvic drop height, navicular drop height, and navicular drop rate from the VICON system. All dependent variables were taken bilaterally. Other dependent variables that may be considered for analysis include subject BMI. Confounding variables that were identified in this study involved, running surface, and subjects' ability to maintain subtalar neutral in VICON data collection.

Ensuring Internal Validity

Steps to ensure internal validity were taken by performing identical protocols for collecting data for both the static Navicular Drop Test and the dynamic VICON walking and running series. Navicular drop intra-rater reliability was determined prior to testing to increase the validity of this study. In addition, a pilot study was conducted to ensure the validity of the Vicon Motion Analysis System in regard to this study.

Chapter III

Results

The hypothesis of this study is that barefoot running will decrease the amount of pelvic drop and the distance traveled of the navicular compared to shod running. This data collection followed the appropriate preparation of the participants and VICON motion analysis system. By utilizing the navicular drop test and the VICON motion analysis system, navicular drop and pelvic movement of the barefoot and shod participants were analyzed using Statistical Package for Social Sciences (SPSS) software.

VICON Motion Analysis

The results of the VICON testing for navicular drop and pelvic movement showed a trend for decreased movement with barefoot walking compared to barefoot running. Statistically significant data was found when comparing navicular drop when walking barefoot to running barefoot on the right foot only (Table 1). This identified that the navicular moved less with barefoot walking (2.60) compared to barefoot running (4.10). Table 1 summarizes the data collected for the VICON motion analysis for navicular drop. Although there was no other statistically, a common trend was found throughout the data for both the left and right foot barefoot trials. Both feet showed an increase in navicular motion, with most motion occurring during barefoot running on the toes, in comparison to barefoot walking.

Table 1. Summarized Statistics of Navicular Drop during Barefoot Trials vs. Shod Trials. **Bolded numbers show statistically significant data when comparing walking barefoot to running barefoot on the right foot only*

	N	Mean	Standard Deviation
Right BW	9	**2.5989***	2.21662
Left BW	10	4.4380	2.10435
Right BR	9	**4.1011***	2.75345
Left BR	10	4.7950	3.02426
Right BRT	9	4.4956	2.81589
Left BRT	10	5.0330	2.98786

Further research is recommended to establish statistical significance for decreasing navicular drop during running barefoot and running barefoot on toes. Limitations are discussed in the following chapter.

In comparison, Table 2 summarizes the data collected from the VICON motion analysis for the pelvic movement. Results identified in Table 4 display trends in which barefoot walking, running, and running on toes cause the pelvis to drop less than walking or running shod. Walking barefoot compared to walking shod were identified to be statistically significant for pelvic drop on the right (Table 2). Although the left may not have been statistically significant, it followed the same trend.

Table 2. Summarized Statistics of Pelvic Movement during Barefoot Trials vs. Shod Trials. **Bolded numbers show statistically significant data when comparing walking barefoot to walking shod on the right side only.*

	N	Mean	Standard Deviation
Right BW	25	**1.6880***	1.23333
Left BW	24	2.9208	2.41804
Right SW	25	**2.7080***	1.65905
Left SW	24	2.4792	1.21045
Right SR	25	5.4720	2.47799
Left SR	24	5.2583	2.54659
Right BR	25	4.6120	1.82627
Left BR	24	4.5458	2.13602
Right BRT	25	4.0080	2.27283
Left BRT	24	2.7083	1.28466

As shown in the means, decreased pelvic drop is associated with the barefoot trials as compared to the shod trials. Running shod (R= 5.47; L= 5.26) had the most pelvic movement followed by running normal barefoot (R= 4.61; L= 4.56). Walking barefoot (R= 1.69; L=2.92) had the least amount of pelvic movement followed by walking shod (R= 2.71; L= 2.48). Data in Table 3 and Table 4 may identify a valid hypothesis since pelvic and navicular movement were reduced with barefoot waking and running compared to shod walking and running. Due to certain limitations discussed in the next chapter, further research should be done in order to strengthen our hypothesis.

Chapter IV

Discussion

Overall, the data collected from the trial testing showed minimal statistical significant evidence supporting that the navicular and pelvis move less with barefoot running and walking in comparison to shod walking. Although not all of the data was statistically significant, the trend with the data does support the navicular and pelvic drop is reduced with barefoot motions in comparison to shod. The clinical significance associated with these results identify barefoot running and walking possibly as having the ability to lessen navicular and pelvic movement compared to shod running and walking. Reduced motion of the navicular may have a role in decreasing the amount of over-pronation. This may indirectly reduce the Q angle at the knee and prevent subsequent injuries. Correcting foot alignment may also reduce forces placed on the pelvis and lumbar spine via the kinematic chain reaction. Therefore, by adjusting the foot alignment, the potential for running injuries decreases through proper force distribution.

Limitations

Navicular Drop Test

While there has been research that indicates the reliability of this test, there is also research that suggests parts of the test to be inadequate. The placement of the foot in subtalar neutral can be difficult to find and be consistent in placing the foot in this position.

Along with these limitations includes the inexperience of the examiner which could have produced error in the assessment of both locating the navicular tuberosity and finding the placement of the foot in subtalar neutral; these errors could have skewed the data results. Picciano et al[37] found that both open and closed kinetic chain subtalar joint neutral positions yield poor intra- and inter-tester reliability and the NDT does poor to moderate intra-tester and poor inter-tester reliability. Their research recommends that the examiner for static navicular drop testing would benefit the results with increased practice and experience. In addition, this test is limited to the participant holding their foot in the subtalar neutral position while the examiner marks the point of the navicular tuberosity. While making the mark, it is possible that some participants might have moved their foot out of the assigned placement which could have caused error in our measurements.

VICON Motion Analysis

The VICON system, while highly reliable and accurate, did have a few inherit issues. One of the issues related to the VICON system had to do with the amount of error. While there are no concrete measures of error related to the VICON system, it is reasonable to infer that the amount of error would be in relation to the size of the sensor used. The VICON system maps sensors in three-dimensional space by marking the center of each sensor. It can be assumed that during any point of the gait cycle this exact center of the circular sensor could be in a slightly different location as the angle of the camera to the sensor has changed as the gait cycle progressed. This issue may not be a problem when dealing with large movements such as when calculating hip and knee angles during gait but presents a unique obstacle when calculating small movements such as navicular drop which is measured in millimeters. The error of the system may be partially to blame for the inconclusive data obtained in the study. Another issue with the

VICON system was related to the filters used after data collection. These filters were applied to the data in order to prevent interference and mislabeling of points due to reflections picked up by the cameras that were not caused by the applied sensors. They also aided in smoothing out the trajectories of the sensors during the gait cycle that may have been caused by the system mislabeling points as a result of poor sensor reflection, or extra reflections picked up by the system. This smoothing may have also introduced an amount of error in the system. Since this study was concerned with millimeters of change even small changes caused by the filters could have had significant negative effects on the final results of the study. These limitations ended up affecting our final numbers for navicular drop, only having nine and ten reliable navicular measurements for the right and left feet respectively.

Another limitation of this study was during data collection to find navicular height at subtalar neutral for each subject. One researcher placed one of the subjects' feet in subtalar neutral and instructed the subject to hold this position while data was collected. Then was completed the same way on the opposite side. While this entire process from placement of subtalar neutral to data collection only lasted a few seconds, it is possible that the participant could have moved during the collection process- thus, altering their subtalar neutral navicular height. It is important to note that, although the VICON system has been used previously to assess navicular drop, this study is the first study to use it dynamically during walking and running.

Sample Size

Because the smaller sample size of participants (n = 26) included in this study involved only physical therapy students younger than age 35, our results may not be correlated or generalizable to most of the adult population. A majority of the participants represented an overall healthy sample population based on BMI, age, and non-significant past medical histories. Many of the participants only met the navicular drop criteria by a few millimeters, so a larger sample size may have yielded more significant results for improvement in navicular drop height with barefoot running.

Future Research

Based on the results and limitations discovered in this randomized controlled trial, future researchers may want to consider the following recommendations. Increasing the sample size to allow for a more diverse participant population in order to make correlations of the results with the general adult population. A second recommendation would be to increase the number of VICON cameras to increase accuracy of the sensor readings from additional angles.

Conclusion

In conclusion, the data showed that navicular and pelvic drop presented a trend towards having less movement during barefoot running and barefoot walking in comparison to shod walking and running. It should be taken into consideration the limitations in this study such as the small sample size, the population of only student physical therapists, the limited amount of cameras in the VICON system, and the number of reliable data.

APPENDIX A

Informed Consent

INFORMED CONSENT DOCUMENT TEMPLATE: NON-MEDICAL PROJECTS

IC 701-B 04/18/2013

THE UNIVERSITY of NORTH DAKOTA
INSTRUCTIONS FOR WRITING AN INFORMED CONSENT DOCUMENT
NON-MEDICAL CONSENT TEMPLATE

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 ½ 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 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 running and walking barefoot versus shod (shoe) effects navicular and pelvic movements (the amount that the navicular bone drops to the ground with weight bearing activities) and surface Electromyography (EMG) activity of the Tensor Fasciae Latae (TFL) and Gluteus Medius (GM) during walking and running activities. Literature identifies the barefoot runners complete more of a forefoot strike than shod runners (rear foot) which can lead to more gastrocnemius (calf) activation creating more supinated (walking/running more on the outside of the foot) foot mechanics. In addition, literature has not investigated the EMG activity of GM and TFL musculature during barefoot walking and running. This study aims to investigate whether barefoot running and walking versus shod walking and running reduces the amount of navicular and pelvic movements and surface EMG activity of the TFL muscle while increasing EMG activity of the GM muscle during walking and running activities. You have been identified as a potential participant because you are a first, second, or third-year physical therapy, athletic training, or occupational therapy student at the University of North Dakota, a novice runner (0-20 miles per week), and meet this study's inclusion criterion.

The purpose of this research study is to understand what effect barefoot walking and running has on navicular/pelvic motion and EMG activity of the TFL and GM muscles compared to shod walking and running, which may assist in future injury prevention.

Approval Date: MAR 7 2019
Expiration Date: MAR 6 2020
University of North Dakota IRB

Date: __________
Subject Initials: __________

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 complete a one-time navicular/pelvic movement assessment during walking and running utilizing the VICON motion analysis system, and complete a one-time surface EMG of the TFL/GM muscles during shod/barefoot walking and running activities. The Vicon Motion Analysis system utilizes 10 separate cameras in order to obtain a 3D motion analysis image of lever arms and joints. This system will assist in detecting the amount and speed of navicular drop and measure changes in pelvis and knee angles during barefoot walking/running activities between training groups. Testing will take place at the Hyslop Sports Center on the campus of the University of North Dakota.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will include a one-day testing. Each participant will complete a one-time navicular/pelvic movement assessment during walking/running utilizing the Vicon Motion Analysis system, and surface EMG analysis of the TFL and GM during shod and barefoot walking/running.

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 significant injury in the lower extremities in the past 6-months, age between 18-35, 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 0-20 miles of running per week. If you are included in this research, this study will take place over approximately a one-day testing requirement. A bilateral navicular drop test, foot/pelvis motion analysis utilizing the Vicon Motion Analysis system, and surface EMG of your TFL and GM musculature will be performed on you during shod/barefoot walking and running.. No personal identifications are used on any written document and all descriptions of participants are anonymous.

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.

Date: ________
Subject Initials: ________

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 static/dynamic navicular drop, decreased TFL EMG activity, and increased GM EMG activity, 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 walking and running 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. 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. The 6-week training will take place at the High Performance Center on the campus of the University of North Dakota.

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

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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

Approval Date: MAR 7 2019
Expiration Date: MAR 6 2020
University of North Dakota IRB

Date: ________
Subject Initials: ________

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

Approval Date: MAR 7 2019
Expiration Date: MAR 6 2020
University of North Dakota IRB

Date: ________
Subject Initials: ________

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