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Barefoot Training: Effect on Lateral Pelvic Drop and EMG Activity of Gluteus Medius and TFL

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BAREFOOT TRAINING: EFFECT ON LATERAL PELVIC DROP AND EMG ACTIVITY OF GLUTEUS MEDIUS AND TFL

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This Scholarly Project, submitted by Hailey Brinkman, Anna Yanchek and Esley Thorton 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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PERMISSION

Title: Barefoot Training: Effect on Lateral Pelvic Drop and EMG Activity of Gluteus Medius and TFL

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Abstract

Purpose/Hypothesis: Exercise has been widely accepted for its key role in disease prevention and promotion of healthy lifestyle. Due to its relative ease and low cost, running continues to be one of the most popular forms of exercise today. Although running can have a significant impact on disease prevention, injury prevalence in running is high. Barefoot running is a relatively new form of exercise that has gained popularity amongst the running community. However, enhancing muscular activity at the hip is a rehabilitation strategy, which may reduce lower extremity injury. Research investigating the hip muscle activity and movement with barefoot running is lacking in literature; thus, giving rise to the purpose of this study. This multifactorial study was performed to explore the effect of barefoot training on the muscular activity of the gluteus medius (GM) and tensor fascia latae (TFL) in addition to the degree of lateral pelvic drop. Three hypotheses are being investigated: (1) Does running barefoot increase the activity of the GM, (2) decrease the activity of the TFL (3) decrease the amount of lateral pelvic drop. These hypotheses are being examined by comparing the EMG intensity during running trials both barefoot and shod, in addition to using the VICON, a three-dimensional motion analysis system, to assess lateral pelvic tilt.

Materials/Methods: Fourteen subjects, 8 females and 6 males, with a mean age of 23.2 (1.41) completed the pre-testing electromyography (EMG) and VICON motion analyses. EMG muscle activity was recorded during a maximal isometric contraction, barefoot running and walking trial and shod running and walking trial. Lateral pelvic drop was analyzed during pre-testing with the

VICON system. Subjects were randomly assigned to a barefoot running group (N=7) and shod running group (N=7). Participants completed a 6-week training program consisting of running twice a week. The first week of training will include 10 minutes of running followed by a 2-minute increase each week totaling 18 minutes of running during the final week. Following the training program, post-test EMG and VICON was performed and analyzed.

Results: No significant change in EMG activity of the GM and TFL was found between running barefoot and running shod during pre-testing and post-testing data collection. No significant training effect was found with the amount of lateral pelvic drop comparing pre- and post-testing VICON analyses.

Conclusions: Due to no statistically significant change in EMG activity of the GM and TFL during pre- and post-test trials, further research is recommended to explore the impact of a training protocol on GM and TFL muscle activity and lateral pelvic drop.

Clinical Relevance: This study provides insight to the muscle activity occurring at the hip when foot attire is altered during initial running trials. No statistically significant change was found between barefoot or shod walking and running which may indicate six weeks of training twice a week may not provide a great enough stimulus to impart significant change in muscle strength and activity. In addition, foot attire may not be a significant factor for altering the muscle activity patterns at the hip. Therefore, a greater impact may be found elsewhere, such as strike pattern rather than foot attire. Furtheresearch is recommended to study the impact of strike pattern on activity of the GM and TFL.

Chapter I

INTRODUCTION

The movement pattern termed "running" has been present from the beginning of human creation. From hunting and gathering, to the first foot race in the ancient Olympic games in 776 B.C. signifying the evolution of competitive sport, running has been considered a high value to the species.[1] Currently, running has transformed into a primary method for achieving fitness and long-term exercise habits. Per the National Sporting Goods Association, 35.5 million Americans participated in running or jogging in 2010.[1] The desire for health and wellness is on the verge of explosion as prevention becomes a rising revolution.[2] The American Center for Sports Medicine recommends healthy adults ages 18 to 65 to partake in moderate physical activity for at least 30 minutes, five days per week, or high intensity physical activity for at least 20 minutes, three days per week. For adults over the age of 65, intensity is modified per individual health status and a greater emphasis is placed on balance and flexibility.[3] Exercise has been proven to have a positive impact on one's fitness and reduce the incidence of cardiovascular disease, obesity, hypertension and many other chronic health problems.[4,5] Running has become an exercise favorite due to its relative ease in performance and accessibility. Barefoot running has recently increased in popularity; therefore, our purpose of this study is to explore the effects of barefoot training on proximal hip musculature and biomechanics.

Although running can have a significant impact on disease prevention, it comes at a price. Rates may vary across studies; however, all yield uncomfortably high results. The low back, hip, knee and ankle all become sources of abnormal stress when non-optimal biomechanical patterns are utilized.[5,6] A systematic review published in the British Medical Journal analyzed 17 studies and found the overall incidence of reported lower extremity injuries was as high as 79%.[5] The knee which is intended to be a relatively stable joint, takes the brunt of the force with an injury rate of 7.2-50%.[5] Common injuries of the knee include patellofemoral pain syndrome, patellar tendonitis and meniscal injuries.[7] A study performed by Cheng & Davis[8] found, an alteration of foot strike pattern from rearfoot to forefoot, reduced symptoms and functional limitations related to patellofemoral pain. Moving distally, the injury rate to the lower leg (Achilles tendon, calf, and heel) was found to be 9.0-32%.[5] In a study[9] analyzing more than 2000 running injuries, the most common injuries to the lower leg included tibial stress fracture, medial tibial stress syndrome, Achilles tendinopathy and medial tibial stress syndrome. Injuries to the foot (also toes) were found to be 5.7%-39.3%, with metatarsal fractures and plantar fasciitis being the most prevalent.[5,6] As for the proximal lower extremity (hamstring, thigh, and quadriceps) the injury rate was 3.4%-38.1%.[5] IT band syndrome and hamstring strains are commonly reported findings proximally.[6]

The injury rate tied to running is uncomfortably high and in need of a solution. Recent studies indicate an omnipotent association of hip flexor and abduction weakness with lower extremity running injuries.[7] In one study[10] analyzing thirty injured runners with overuse injuries to thirty non-injured runners, 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. The gluteus medius acts as stabilizer at foot strike, preventing the knee from moving into genu valgum.[7] Proximally, the hip rotators also have been found to uphold greater stress and discomfort when gluteus medius weakness is present.[7] During single leg stance, the force of gravity pulls the pelvis into relative adduction. The ipsilateral hip abductors provide a counterforce to stabilize the pelvis and control the magnitude of pelvic drop.[11] Eccentric strength has been emphasized as a successful treatment method to restore ideal biomechanics of gait.[7] By strengthening the gluteus medius, one of the primary hip abductors, the amount of pelvic drop will be reduced, ultimately encouraging ideal mechanics of gait and reducing abnormal repetitive stress due to excessive motion of the pelvis.

The mission to reduce the injury rate of runners has led to the recent trends and exploration of minimalist running instead of the typical conventional shoe style. Forty-two experts from eleven countries, primarily consisting of researchers and health care practitioners, came to a consensus on a definition for minimalist shoes to clarify this term.[12] Minimalist footwear was defined as "Footwear providing minimal interference with the natural movement of the foot due to its high flexibility, low heel to toe drop, weight and stack height, and absence of motion control and stability devices."[12] In shod (wearing shoes) running conditions, it is common to perform a rearfoot strike pattern where the heal contacts prior to the forefoot.[13] To clarify, when discussing the foot complex the areas of the foot are commonly divided into three categories, the hindfoot or rearfoot (talus and calcaneus), midfoot (navicular, cuboid and cuneiforms) and forefoot (metatarsals and phalanges).[11] Several studies [14,15,16,17] have found the foot strike position at initial contact to be the greatest difference between barefoot and shod runners. During this initial phase, barefoot runners strike the ground with a forefoot or midfoot strike and shod runners perform a rearfoot strike.[18] Current literature has found that those who perform barefoot running, commonly adopt a forefoot strike pattern.[19] With a forefoot strike pattern, the body absorbs the ground reaction forces with eccentric control as the ball of the foot strikes before the heel.[20] Due to a smaller base of support, greater kinematic changes must be made proximally up the chain to stabilize the body against gravity when the foot strikes the ground with the forefoot rather than rearfoot. This creates the potential for greater stabilization and activation of the hip musculature following a forefoot strike. This alteration would lead to an ideal adaptation that may enhance the bodies biomechanics with every step.

When it comes to the rehabilitation of an injury, no runner wants to be told to stop training. In all reality, many will completely disregard this recommendation. What if changing the pattern of running could alter the pain and activation of muscles proximally and be used as a source of rehabilitation and prevention? A profound theory that would add, not take away. The purpose of the study is to explore the effects of a barefoot training protocol on the EMG activity of the gluteus medius and TFL in conjunction with a biomechanical assessment of lateral pelvic drop.

Chapter II

LITERATURE REVIEW

Kinematics

Throughout the literature different strike patterns are discussed. The two most common strike patterns researched are forefoot strike pattern (FFS) and rearfoot strike pattern (RFS). Some literature also discusses a midfoot strike to describe a contact not clearly defined as forefoot or rearfoot. In shod distance running, approximately 75% of runners show a RFS, 20% a MFS and 5% a FFS.[13] Forefoot strike and rearfoot strike have been found to engage different kinematic adaptions as methods to reduce impact.[13] FFS adopts a plantar flexion strategy to absorb vertical ground reaction forces with eccentric contraction gastrocnemius and soleus.[19] RFS has been shown to fire the biceps femoris prior to the tibialis anterior to stabilize the body at contact.[8]

Angular Displacement of Joints

A study[21] published in the Journal of Sports Medicine analyzed the immediate kinematic adaptations throughout a 30-minute barefoot training period broken down into three 10-minute intervals. They found anterior pelvic tilt and hip flexion significantly decreased by 3° and 4°, respectively. This change initiated at contact, continued through the barefoot training intervals and was retained during post-testing shod trials. Maintenance of change in degree of pelvic tilt indicate carryover of learning. This study provides insight to acute adaptations, however the carryover of learning over a period of time is lacking. Thus, supporting the need for analyzing the impact of a training period of sufficient duration to impart lasting change.

Kinetics

Ground Reaction Forces (GRF) & Joint Forces

Studies [8,17,19] have found there to be a reduced peak vertical impact ground reaction force and knee extension moment when running barefoot in comparison to running shod. In addition, average vertical loading rate (AVLR), and instantaneous vertical loading rate (IVLR) have also been found to be lower in runners with midfoot and forefoot strike patterns than those with a rearfoot strike pattern.[8] As ground reaction forces react up the chain, the force transferred through knee has also been studied. An article[18] comparing minimalist and maximalist shoe attire found the peak patellofemoral force to be significantly larger in maximalist shoes (4.74 ± 0.88 BW, 13.59 ± 2.63 MPa), in comparison to minimalist attire (3.87 ± 1.00 BW, 11.59 ± 2.63 MPa). Patellofemoral force per mile was also found to be significantly larger in maximalist (251.94 ± 59.17 BW) in relation to minimalist (227.77 ± 58.60 BW) shoe attire.[18] Thus, clarifying that even though more steps may be taken when shifting to a forefoot strike utilized in minimalist running, the summation of force at the patellofemoral joint remained lower than the rearfoot strike pattern.

Muscle activation

Thus far, studies have been performed to analyze the EMG activity of vastus lateralis, biceps femoris, tibialis anterior, gastrocnemius and soleus; however, there is a lack of research studying the EMG of proximal hip musculature such as the gluteus medius and tensor fascia latae. With a modification of foot strike position, different patterns of muscle activation are used to accept the load through the lower extremity. The force vector of the ground reaction force in relation to the joint center will lead to the recruitment of the appropriate musculature necessary to stabilize the body to keep the body erect and propel one forward for locomotion. Thus, changes in muscle activity throughout the lower extremity are expected in response to a shift in the joint centers in relation to the ground reaction force.[11]

Prior to initial contact muscle activation patterns are changed. A study[19] published in the Journal of Sports Sciences in 2016 found the tibialis anterior was active prior to the bicep femoris during a forefoot strike and the reverse was found during a rearfoot strike. The activation of vastus lateralis was not changed between techniques. However, following initial contact, changes were seen in intensity rather than activation order. EMG intensities differed throughout the movement pattern for forefoot and rearfoot strike patterns. In a study[22] performed by Olin and Gutierrez, decreased activity of tibialis anterior and increased activity of gastrocnemius was documented during forefoot running. Barefoot and shod running do not lead to different muscle activation time patterns after foot strike, but they do change EMG intensity before foot strike.[22]

Gluteus Medius Function

Barefoot running has become an increasingly prevalent form of exercise over the past 15 years. Electromyography (EMG) studies have been widely used to assess the muscle activation differences between shod and barefoot running. The muscles that have been studied through EMG analysis include medial gastrocnemius and lateral gastrocnemius, soleus, rectus femoris, vastus medialis and lateralis, fibularis longus, tibialis anterior, and biceps femoris.[19, 21, 23-25] Two muscles that have not appeared in the EMG studies for barefoot running are gluteus medius (GM) and tensor fascia latae (TFL). 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.[26] 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. [27] 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. [28] Sufficient control and activation of the GM may have a role in minimizing the risk of acquiring musculoskeletal syndromes such as patellofemoral pain syndrome, low back pain, and Achilles and gluteal tendinopathy.

Gluteus Medius and Injury

Patellofemoral Pain Syndrome

Patellofemoral pain (PFP) is very common in sports medicine. A study of 2519 patients found that 5.4% sports medicine patients had PFP which accounted for ¼ of the knee injuries. [29] In addition, females may be more susceptible to PFP during running. [9, 30] A study by Herrington [31] found that females with patellofemoral pain had increased knee valgus during single leg squats and single leg hop landing. This increased injury prevalence may be due to decreased hip strength which can contribute to increased pelvic drop and knee valgus in the stance phase of gait.[32] Increased proximal control at the hip from the GM may be a key factor in preventing excessive pelvic drop and knee valgus, thus resulting in the reduction and prevention of patellofemoral pain.

Low Back Pain

Low back pain (LBP) has been cited as the single most common cause of disability in the world. This may be due to the aging population since the highest prevalence of low back pain is seen in the elderly.[33] Eighty percent of people will experience low back pain at some point in their life and 1 in 10 recreational runners will have low back pain within their first year of running.[34] Simons and Travell [35] found that myofascial pain of the GM has been associated with LBP. A study by Cooper [36] found GM to be significantly weaker and have increased tenderness to the gluteal and greater trochanter area in patients with chronic LBP. One of the most common interventions for LBP is strengthening and stabilization exercises which has been proven to be effective in terms of pain and functional improvement.[37] Although core stabilization exercises have proven to be successful initially, 70% of people report having a recurrence of low back pain within a year. Since a correlation with low back pain and gluteus medius weakness has been shown, supplementing core stabilization exercise with pelvic stabilization and GM strengthening may result in better outcomes and a reduction of recurrent low back pain.[36, 38]

Achilles Tendinopathy

Achilles tendinopathy is a general term used to describe Achilles injuries that present with symptoms of morning stiffness, pain, tenderness, and changes noted on imaging.[39] Tendinopathy is associated with chronic pain and potential swelling that is made worse with activity. The highest incidence of non-insertional Achilles tendinopathy is seen in runners and presents with pain above the insertion of the Achilles.[40] The relation between GM control during running has been examined as a risk factor for Achilles tendinopathy. A study by Azevedo and Lambert [41] found that GM activity was significantly reduced following heel strike in the Achilles tendinopathy group when compared to the control group. Based on the study findings, increasing GM activity through a barefoot running program could potentially reduce the risk of developing Achilles tendinopathy. These results warrant further investigation into a correlation between GM EMG activity and risk of acquiring Achilles tendinopathy.

Hip Osteoarthritis

Osteoarthritis (OA) can be defined clinically or radiographically. A clinical diagnosis is made through symptom analysis and physical examination.[42] A radiographic diagnosis is made when osteophytes, or bone growths, are found in the joint.[43] Almost 27 million people are affected by OA in the United States, making it one of the most prevalent pathologies in medicine. In fact, about 25% of people over the age of 45 have radiographically diagnosed OA.[44] Muscle weakness has been shown to be a risk factor for hip OA. Studies by Dwyer [45] and Sims both found that GM surface electromyography (sEMG) activity was higher in the hip OA patients as compared to the healthy control group when performing weight bearing activities. In the hip OA groups, the involved and uninvolved leg demonstrated higher GM sEMG activity**.** The increased GM activity is most likely not a causative factor of hip OA, but more so a compensatory strategy for general weakness when weight bearing. Patient's with insufficient GM strength may require increased central nervous system input to the muscle in order to maintain proper pelvic position in stance, thus resulting in higher sEMG activity.[46] Although running is one activity which can be used to improve one's overall health, studies have found that running may cause an increased incidence of hip osteoarthritis (OA). A study of 27 elite runners, 9 bobsledders, and 23 sedentary patients found that the runners showed more hip OA compared to the bobsledders and sedentary group when viewed through radiographs.[47] A further review of the literature does not support a link between running and hip OA. For example, Sohn and Micheli [48] compared the incidence of severe hip or knee pain 2-55 years following graduation in 504 collegiate cross-country runners and 287 collegiate swimmers. Two percent of the runners were symptomatic compared to 2.4% of the swimmers. 0.8% of the runners required surgical treatment for OA as compared to 2.1% of the swimmers. For the symptomatic runners, there was no correlation found between mileage volume and joint pain.

Surface Electromyography

Surface EMG (sEMG) is the topical application of electrodes onto the skin that cover the muscle(s) to be analyzed.[49] SEMG is used to measure the activation and muscle force contractions during static or dynamic activities.[50] It is important to understand that SEMG is measures the electrical activity given off by a muscle and is not a strength or force measure. There are three types of electrode placements that represent how accurate electrodes can pick up EMG signals from a muscle. The three types of placements are general, specific, and quasi-specific placement. The muscles examined by SEMG in this study are the gluteus medius and tensor fascia latae. Their placements are considered "specific" meaning they are superficial muscles that are easy to isolate, thus increasing the accuracy of the SEMG readings.[51] A study performed by Czaprowski [52] examined the intra and inter-session reliability of using sEMG for the trunk extension-flexion ratio. The study found that sEMG had good reliability with a intraclass correlation range of .90 to .68 when measuring paraspinal activity during trunk extension and flexion. It should also be noted that experience between examiners plays a role in intra and inter-session reliability of sEMG. SEMG reliability and validity for GM during running was not examined in the literature.

Tensor Fascia Latae

Studies investigating TFL activity (via sEMG) during running and walking were not found during the literature review. The TFL is a pelvic muscle with actions including hip flexion, hip abduction, and hip internal rotation movements. The TFL muscle belly joins with the iliotibial band (IT band) which acts as the insertion for the muscle crossing and attaching to the lateral knee. Although TFL activity has not been researched in runners, the IT band has been identified as problematic for runners. ITBS is the number one cause of lateral knee pain in runners and is the second most common injury in runners.[53] For example, a study of 2002 runners found IT band syndrome (ITBS) to be the second most common injury in runners**,** which occurs due to overuse and biomechanical abnormalities that can occur during repetitive motions like running. [9]

Studies have found that ITBS in runners can be related to reduced hip adduction and knee flexion during running.[54, 55] Barefoot running alters biomechanics by promoting a fore foot strike, thus resulting in increased knee flexion and a shorter stride length.[56] It is possible that these biomechanical differences with barefoot running could result in a reduced risk of acquiring ITBS.

Biomechanics

Ideal Running Mechanics

It is unrealistic to have a definitive set of rules to define ideal mechanics for running. Every individual varies in body size and structure and uses different techniques in order to attempt to be the most efficient in their running form. However, attempting to return to the desired running form may assist in injury prevention. Supination is when the foot rolls outward in the gait cycle, it is a combination of inversion, plantarflexion and adduction. Pronation is when the foot rolls inward during the gait cycle is a combination of eversion, dorsiflexion and abduction. Ideally, at heel strike the foot is in a supinated position and transitions into foot pronation during stance phase. During pronation, the arch height drops in order to provide natural shock absorption and allows the great toe to approximate the ground. Great toe approximation is significant because the great toe provides 80-85% of the foot's primary support and is used as a ridged lever to push off during supination. [57] When the foot contacts the ground in front of the body elastic energy is stored. Ground reaction force is at its greatest once the runner hits mid-stance and the foot is directly under the body. The release of the stored elastic energy occurs from mid stance to push off. This requires dynamic control of the hip stabilizers.[57]

Undesirable Running Mechanics

Eighty-two percent of runners will sustain a running related injury at some point in their life, which may be attributed to faulty running biomechanics.[57] Many runners are told that they either over-supinate or over-pronate. These foot positions can have great impacts on a runner's biomechanics. Runners who over-supinate tend to land on the outside of the foot, which reduces their natural shock absorption attributes and may increase the prevalence of a tibial stress fracture. Alternatively, overpronator's may have too much shock absorption when landing which may cause high forces to be transmitted through unstable lever arms. Overpronation may lead to genu valgus or "knock-knees" which in turn may lead to an increased Q-angle. The Q-angle is the intersection of two lines that cross at the patella. Proximal line landmarks include the anterior superior iliac spine (ASIS) and the center of the patella, while the distal line landmarks includes the center of the patella and the tibial tuberosity. It is hypothesized that the greater the Q-angle the greater the lateralization force on the patella which may cause compression of structures and breakdown of cartilage leading to osteoarthritis.[58] According to Huberti and Hayes,[59] with every 10% increase in Q-angle there is a 45% increase in patellofemoral stress. Increasing hip abductor strength and activation may reduce the Q-angle and prevent osteoarthritis. For example, gluteus medius activation reduces pelvic drop and hip adduction, which may reduce the Q-angle. If our hypothesis is correct and barefoot running increases the activation of gluteus medius, barefoot running would be a good intervention technique to reduce Q-angle and its associated knee pain. In addition, a common problem many runners have is overstriding. Overstriding is where the runner's foot contacts the ground too far forward and the foot stays on the ground longer than it should. This causes increased vertical motion, which in turn leads to more energy expended and a greater chance of injury due to the increased forces when re-contacting the ground. A runner's optimal vertical translation is 1.5-2.3 inches for most efficient running.[57] A study by Francis et el,[60] compared stride length and lower extremity kinematics in trained distance runners during barefoot and shod running. This study found that barefoot running decreases stride length by 6-8% which may reduce the likelihood of lower extremity injuries.

Barefoot Running Mechanics

Approximately 80% of shod runners have a rear foot strike.[61] Barefoot running promotes a forefoot strike along with a more plantarflexed ankle.[62] Forefoot strike runners have lower loading rates of the ground reaction force than rear foot strike runners. However, due to highly cushioned heels in standard running shoes most runners adopt the rear foot strike pattern. Forefoot strike runner allows for overall more efficient biomechanics. It increases stride frequency and may allow for shorter contact time with the ground. Forefoot strike runners also have a greater bend at the knee and a more plantarflexed ankle when landing which helps to shorten the stride length.[56] Barefoot running has become increasingly popular in the last decade. Many studies have been published, both supporting and not supporting, the effects of barefoot running. For example, Sinclair et al[63] compared the effects of barefoot running, barefoot inspired footwear and conventional running footwear on joint stiffness. Joint stiffness has been correlated with an increased risk of injury, therefore, is an undesirable effect. Sinclair et al[63] identified 15 male subjects who were analyzed with an 8 camera motion analysis system running over a force plate at 4 meters per second. Running barefoot identified a higher rate of overall joint stiffness, especially knee stiffness. However, conventional shoes showed greater ankle stiffness compared to barefoot running. The authors of this study theorized that the increased joint stiffness in barefoot running is due to the decreased stance time that typically occurs. Therefore, decreased limb compression occurs in conjunction with similar ground reaction force values between footwear and this may lead to the increased joint stiffness. De Wit et al[62] preformed a study comparing barefoot running mechanics with shod running mechanics with nine trained male distance runners. Video analysis and ground reaction force were measured, in addition, a pressure mat was using during barefoot running. De Wit et al[62] found that barefoot running has been shown to shorten stride length, shorten foot-ground contact time and increase stride frequency, which may improve overall efficiency and decreases injury risk.

Shoe Mechanics

For years, shoe mechanics have been on the forefront of running injury prevention. However, new technology may hinder a runner's biomechanics and may increase the risk of injury. For example, some shoe manufacturers develop shoes with a medial post or medial cushioning. This medial post may cause the point of contact to shift to the medial foot. This shift to the medial foot may increase medial knee force and require stronger hip stabilizers to overcome the genu valgus. In addition, most standard running shoes have higher heels, the heel is usually two times higher than the forefoot, this forces the soleus and gastrocnemius to work in a shortened position, which may lead to injury. Furthermore, standard running shoes generally have a fair amount of cushioning. Excess cushioning may compromise the foot’s proprioception and muscle firing patterns. Decreased proprioception may lead to decreased stability which may cause injury. Often, standard running shoes have a narrow toe box. A narrow toe box may decrease leverage during push off because the great toe has an increased lateral angle. With barefoot running the foot and toes land with a wider base of support which allows for more leverage and stability.[57]

Vicon

Quantitative gait analysis is most accurately measured by three-dimensional motion analysis systems.[64] The motion analysis system used in this study is the VICON system. The VICON system uses 10 cameras to assess the 3D movement of the retroreflective markers that are placed on predetermined anatomical landmarks. A study by Collins et al[64] analyzed the intra-rater reliability and inter-rater reliability of the VICON system. Gait analysis of eight subjects with no gait altering injuries was preformed twice a day on two separate days. Two different raters preformed separate gait analysis's each day. As a result, the VICON system was reliable in both intra and inter-rater reliability. The repeatability was shown to be higher in the hip assessment and lowest in the knee most likely due to the subjects' knees not being locked when the markers were being placed. The VICON system is often used as the gold standard to compare other 3D motion analysis systems. For example, in a study by Bouillod et al[65] a 3D motion analyzer used for bike fitting was compared to the VICON system. Three cyclists participated in the study and cycled at three different cadences (60, 90 and120 rpm) for ten seconds each. Kinematic measurements were taken simultaneously from the two systems. Measurements were taken five times at each pedaling cadence. The two devices demonstrated a high reliability with no significant differences. The minor differences were attributed to the altered alignment of the VICON system's retroreflective markers during dynamic movement.

Chapter III

METHODS

Participant Selection

Participants were recruited via an in-class presentation outlining the study. Study details were shared with the University of North Dakota first and second year physical therapy students. Inclusion criteria and study information was distributed through email communication. In order to participate individuals must be (1) a rearfoot striker, (2) currently complete between 2-15 miles of running per week, (3) age 20-30. Those with (1) a significant injury to the lower extremity in the past 6 months, (2) use of NSAIDS, (3) cardiopulmonary pathologies or significant medical history were excluded.

Protocol

Prior to training, participants completed a pre-test data collection consisting of VICON movement analysis and EMG recordings. The VICON system was used to analyze lateral pelvic drop and pelvic tilt. The EMG recordings included gluteus medius and TFL activity. Participants ran in the morning two days a week for a six-week training period, which took place at the UND Wellness Center. They began with a warm-up for three minutes on a stationary bicycle and then completed a dynamic stretching warm-up (Figure 1). The running protocol began with a three-minute warm up walk, then transitioned into a one-minute warm-up at a four-mph pace followed by one minute at five-mph. The speed was then increased to six-mph for the remainder of the run.

A three-minute walk followed the running period to ensure adequate cool down. The session was then completed with a series of static stretches (Figure 2). The first week of training included ten minutes of running, followed by a two-minute increase each week totaling 18 minutes of running during the final week. Following the six-week training period, runners performed post-test VICON and EMG data collection followed by a brief post-survey.

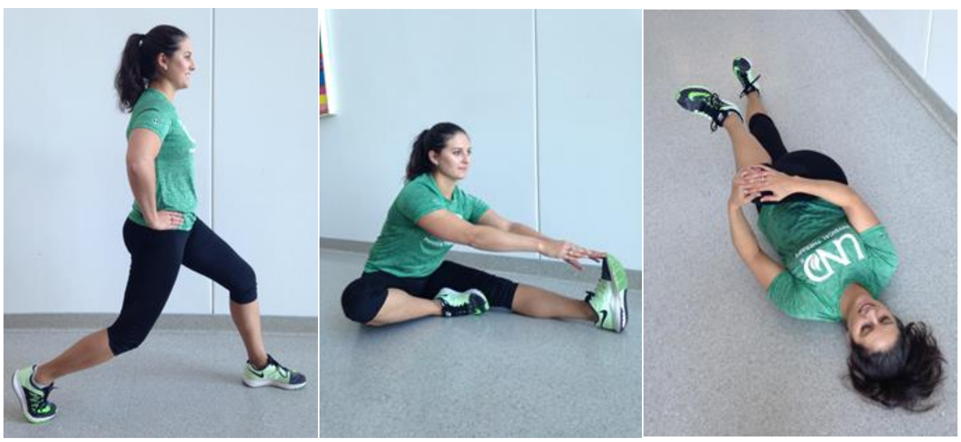
Figure 1. Dynamic Stretches (a) hip abduction/adduction leg swings, (b) hip flexion/extension leg swings (c) lunge with a twist, (d) knee to chest hug, (e) lunge with a twist toward ceiling

(a) (b)

(c) (d) (e)

Figure 2. Static Stretches (a) gastrocnemius, (b) soleus, (c) quadricep (d) hip flexor (e) hamstring, (f) piriformis

(a) (b) (c)



(d) (e) (f)

EMG

Procedure

All participants completed an informed consent. Height and weight were measured, BMI was calculated, and foot dominance was recorded. Barefoot and shod running and walking were investigated with participants randomly selected to begin with shoes or barefoot first. The following section will describe the electrode placement utilized to assess GM and TFL firing, as well as MVC process and data collection.

Electrode Placement

Each electrode skin placement area was prepped by brushing sandpaper over the area five times and thoroughly cleaning the area with alcohol. Once electrodes were placed over each muscle, the electrical impedance was tested using the NORAXON Electrode Impedance Checker. If electrode impedance was greater than 50k, the electrodes were removed and the procedure repeated. A ground electrode was placed over the left iliac crest and shared a lead with the left TFL. Foot contact sensors were applied to each participant's right foot. Sensors were placed on the first metatarsal head, fifth metatarsal head and the heel, to identify ground contact. This allowed for correct distinction between stance and swing phases of gait.

- Lead one- Left TFL and ground electrode
- Lead two- Right TFL
- Lead three- Left Gluteus Medius
- Lead four- Right Gluteus Medius

Gluteus Medius

The greater trochanter and iliac crest were palpated and the distance between was measured in centimeters. A mark was made one-third of the total distance from the iliac crest inferiorly. This process was performed bilaterally. The skin was then prepped by swiping each landmark five times with sandpaper and then vigorously wiping with a towel and alcohol. Two electrodes were placed at each gluteus medius marking bilaterally and placed as close as possible so the center of each electrode was about 2 cm apart.[51]

TFL

The ASIS was located bilaterally and a dot was placed 2 cm distally. The skin was prepped in the same manner as the gluteus medius with the sandpaper and towel with alcohol. Two electrodes were placed at each TFL marking bilaterally and placed as close as possible so the center of each electrode was about two cm apart. A ground electrode was also placed on the left iliac crest for a total of nine electrodes on each subject.[51]

Maximum Voluntary Contraction

Following electrodes placement, participants completed bilateral Gluteus Medius and TFL maximum voluntary contractions (MVC). In order to assess participant's MVC of the gluteus medius muscle, participants were positioned in sidelying, with 30 degrees of hip abduction, neutral hip rotation, and zero degrees of hip extension (Figure 3). Two trials were performed in this position. A similar position was utilized to assess the MVC of the TFL muscle, which included 30 of abduction, neutral hip rotation, and 45 degrees of hip flexion (Figure 4). Two trials were performed in each position. Participants were asked to slowly lift leg until contacting support belt and push maximally for five seconds. The process was repeated on both lower extremities. A goniometer was used for each patient to ensure proper hip positioning. Prior to EMG testing, participants were randomly selected, via a random number generator, to start the pre- and post-test with or without shoes. Each participant walked on the treadmill at three-mph for 40 seconds and progressed to running at six-mph for 40 seconds. The first 20 seconds of walking and running was used to normalize each subjects gait and the final 20 seconds was recorded for data collection. The participant then donned or doffed their shoes depending on their random selection, and repeated the walking and running trials.

Figure 3. MVC of Gluteus Medius

Subjects were tested in a position with 30 degrees of hip abduction, neutral hip rotation, and zero degrees of hip extension.

Figure 4. MVC of TFL

Subjects were tested in a position with 30 of abduction, neutral hip rotation, and 45 degrees of hip flexion.

Data Collection

Surface EMG electrodes were placed over the GM and TFL bilaterally through a standardized method. EMG data was collected using an eight channel Noraxon Telemyo 2400 system. The EMG signals were rectified, smoothed (RMS 50), and then normalized to the respective maximal voluntary contraction prior to analysis.

Vicon

Procedure

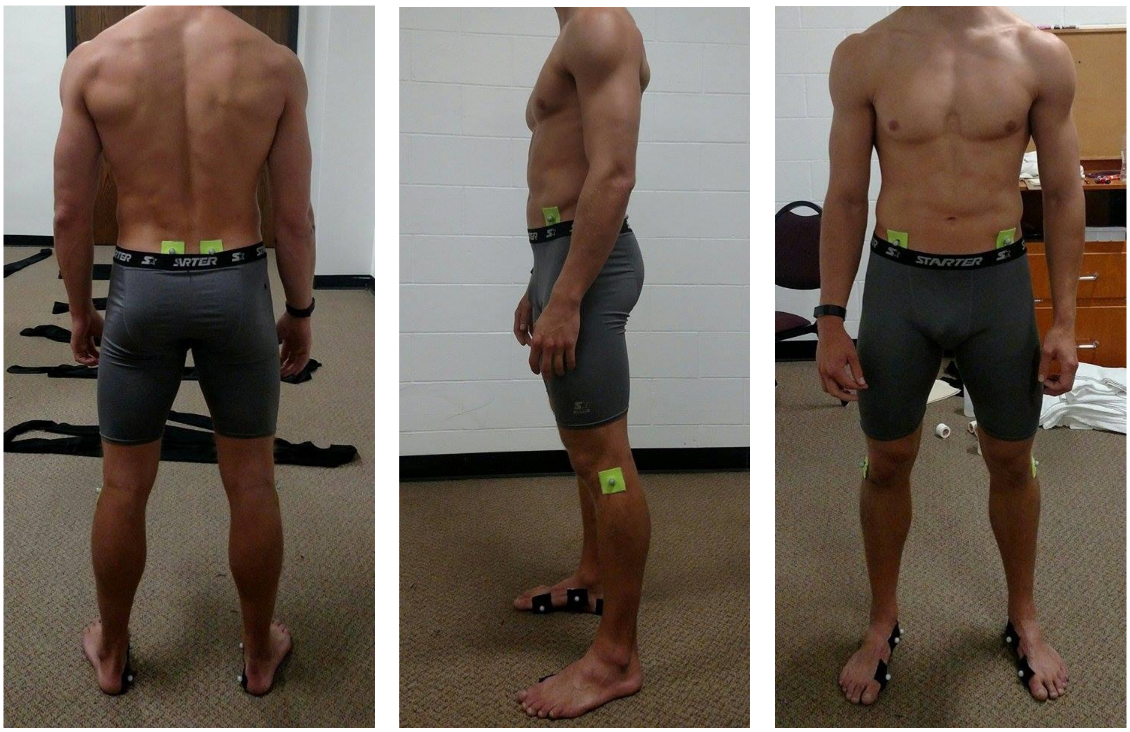
One static and five dynamic trials were recorded. The static frame consisted of a calibration frame necessary to collect reference points. Three trials were performed for each of the five different dynamic trials. These included walking barefoot, running barefoot normal, running barefoot with forefoot strike, walking with shoes, and running with shoes. Participants were instructed to keep normal stride and pace as comfortable. Cues for forefoot strike included run on your toes and avoid allowing your heel to contact the ground.

Placement

Prior to sensor application, participants skin was cleansed with alcohol. Sensors, one-centimeter in diameter were applied to participant's ASIS, PSIS, lateral joint line of knee, calcaneus, navicular tuberosity and first metatarsal head (Figure 5). One researcher, an experienced physical therapist applied the ASIS, PSIS and lateral joint line of the knee. A second researcher checked each sensor placement to assure accuracy. A third researcher applied the sensors to the calcaneus, navicular tuberosity and first metatarsal head. A fourth researcher checked each sensor placement to assure accuracy. This check-recheck method was enforced to increase reliability of sensor placement. Sensors were applied with carpet tape to ensure adherence. All sensors were applied directly to the skin and spandex clothing was worn to avoid interference with sensors.

Figure 5. Sensor Placement for Pelvis

Sensors were applied to participant's ASIS, PSIS, lateral joint line of knee, calcaneus, navicular tuberosity and first metatarsal head.



Data Collection

Data was extracted by a team of two researchers using the VICON system for analysis. In order to calculate the degree of lateral pelvic drop, the path of the ASIS was observed on an X, Y, Z graph on the VICON system. The lowest point in the Z plane was found for each step. The X, Y, Z coordinates of each hip was recorded at this exact point. The coordinate points were recorded into a trigonometric function to produce the total degrees of drop in a 3-dimensional plane.

Each participant performed three trials of each dynamic condition. The last two trials were used for data analysis avoid data inconsistencies due to novelty of the first trial. For each trial, lateral pelvic drop was calculated for 3 steps on each limb. An average of all steps recorded in the two trials was computed for statistical analysis.

Statistical Analysis

Data collected from pre- and post-testing was analyzed using the Statistical Package for Social Sciences (SPSS) software. Independent variables included whether the subject was placed in barefoot or shod running group. Dependent variables included lateral pelvic drop and EMG activity of TFL and gluteus medius. All dependent measures were considered bilaterally. Confounding variables include adverse effects during the study, subject running outside of the study, running surface, and efficacy of retraining program. Independent sample t-tests were used to measure significance of change in lateral pelvic drop and EMG activity of gluteus medius and TFL between barefoot and shod training groups, with an α level of less than 0.05.

Chapter IV

RESULTS

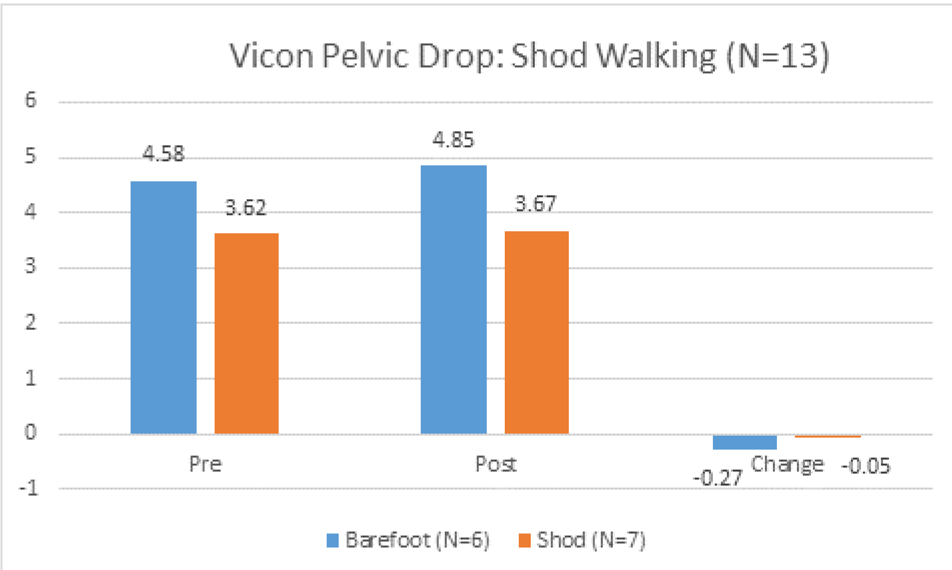
This chapter includes the results of this research in regard to the two primary questions of this research: Does a barefoot training program reduce degree of lateral pelvic drop height, and Does barefoot training alter EMG activity of the gluteus medius and TFL? Each of the research questions were analyzed using independent sample t-tests to determine clinical significance ($p<0.5$). The pre- and post-test results for one subject in the barefoot group were dropped for both the VICON and EMG assessment, reducing the group to six subjects (N=6).

Question One: Does a barefoot raining program reduce degree of lateral pelvic drop height?

When analyzing the degree of lateral pelvic drop, during walking trials the greatest amount of drop was observed during push off on the measured hip. As for the running trials, the most significant drop occurred during single leg stance of the contralateral limb. When investigating the impact of training on pelvic drop comparing pre- and post-testing, no statistically meaningful change in amount of pelvic drop was identified. Upon first glance, it appears as if shod has a lesser degree of pelvic drop both pre- and post. However, this may be misleading. After randomization, those with a lesser degree of pelvic drop ended up being designated to the shod group, thus making it appear as if shod consistently had a lesser degree of pelvic drop. A focus of this study was to identify the impact of training on everyday functional life. Therefore, we chose to analyze the shod walking trials since majority of an individual's day is spent walking in shoes. As you can see in Table 1 below, the degree of pelvic drop remained relatively consistent from pre- to post testing.'

Table 1. Vicon Pelvic Drop

This table depicts the average degree of lateral pelvic drop in millimeters.



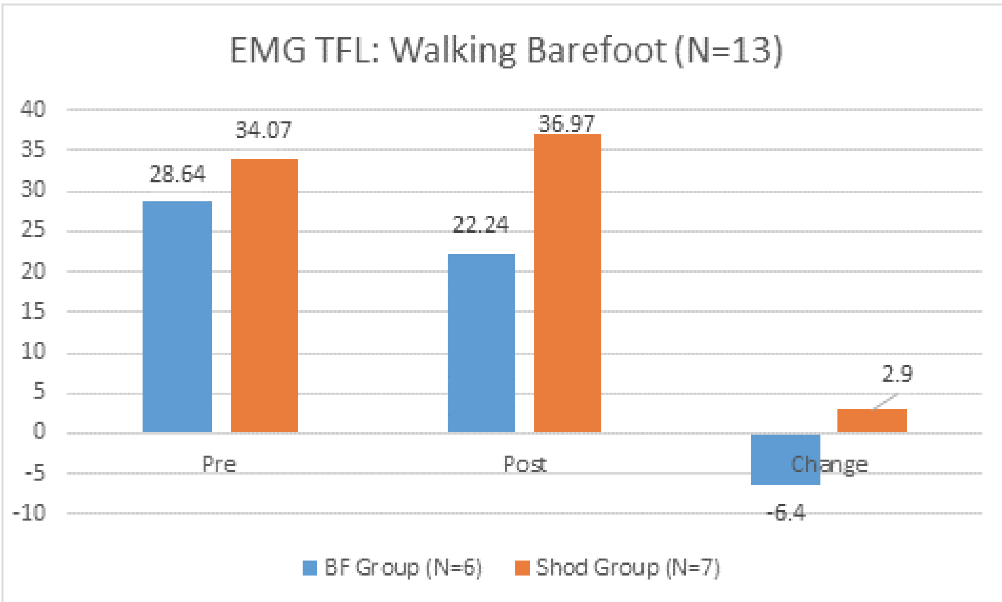
Question Two: Does barefoot training alter EMG activity of the gluteus medius and TFL?

When comparing the training effect of barefoot vs shod running on the activation of Gluteus Medius and Tensor Fascia Latae, no statistically significant results were noted. A depiction of results is demonstrated on the graphs included in Table 2. Gluteus medius activation decreased in the shod training group's walking and running post-test, however, this included both barefoot and shod post-test results. Interestingly, the barefoot training group increased gluteus medius activation in both barefoot and shod post-testing. This may be clinically significant in that barefoot running training may increase the activation and utilization of the gluteus medius.

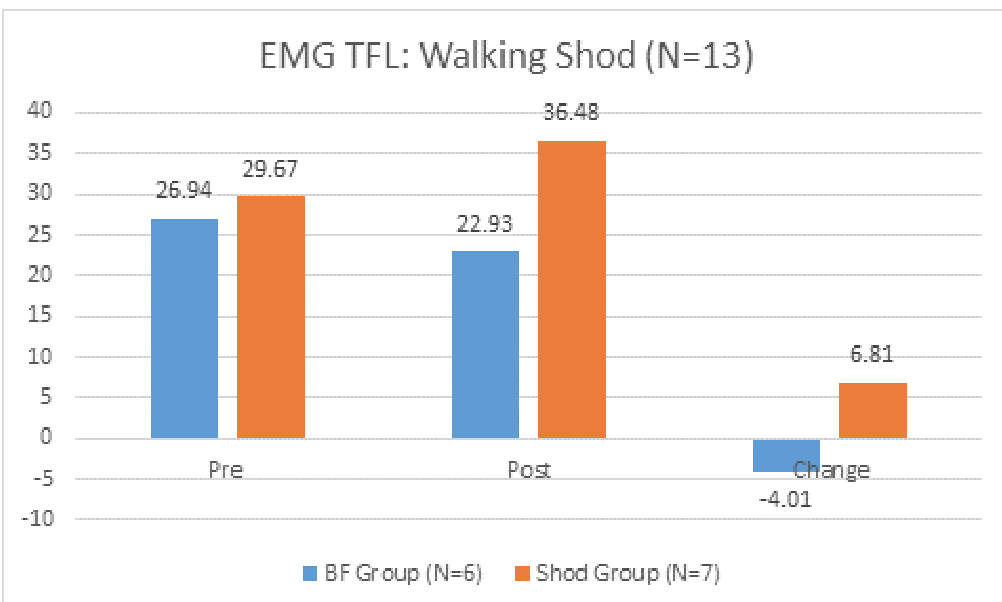
Tensor fascia latae activation increased for both the barefoot and shod training groups when running shod. In addition, the barefoot training group had a decrease in TFL activation when walking and running barefoot and walking shod. The shod training group saw increases in TFL activation for walking and running whether barefoot or shod. Activation of the TFL when running shod was the greatest change from pre-testing to post-testing for both the barefoot and shod training groups.

Table 2. EMG Results TFL

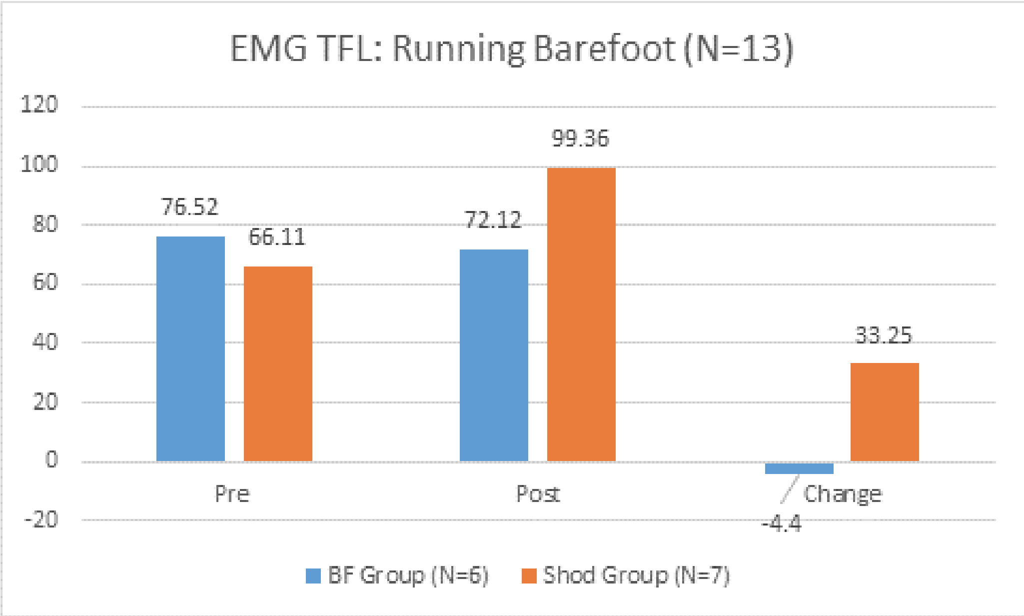
(a) Walking Barefoot, (b) Walking Shod, (c) Running Barefoot, (d) Running Shod



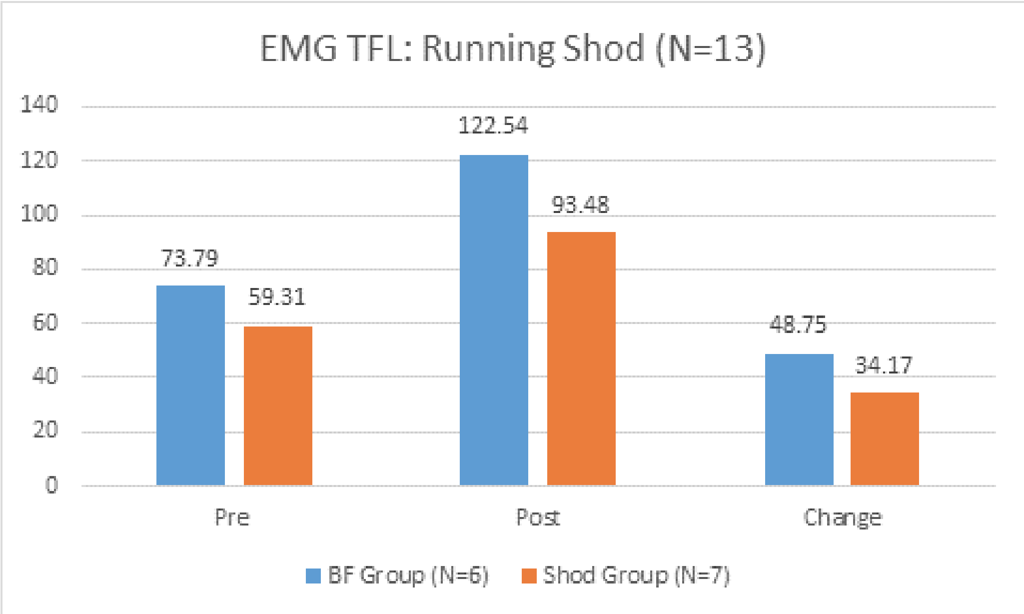
(a)



(b)


EMG TFL: Running Barefoot (N=13)
120
100
80
60
40
20
0
-20
76.52
66.11
72.12
99.36
-4.4
33.25
Pre
Post
Change
BF Group (N=6)
Shod Group (N=7)

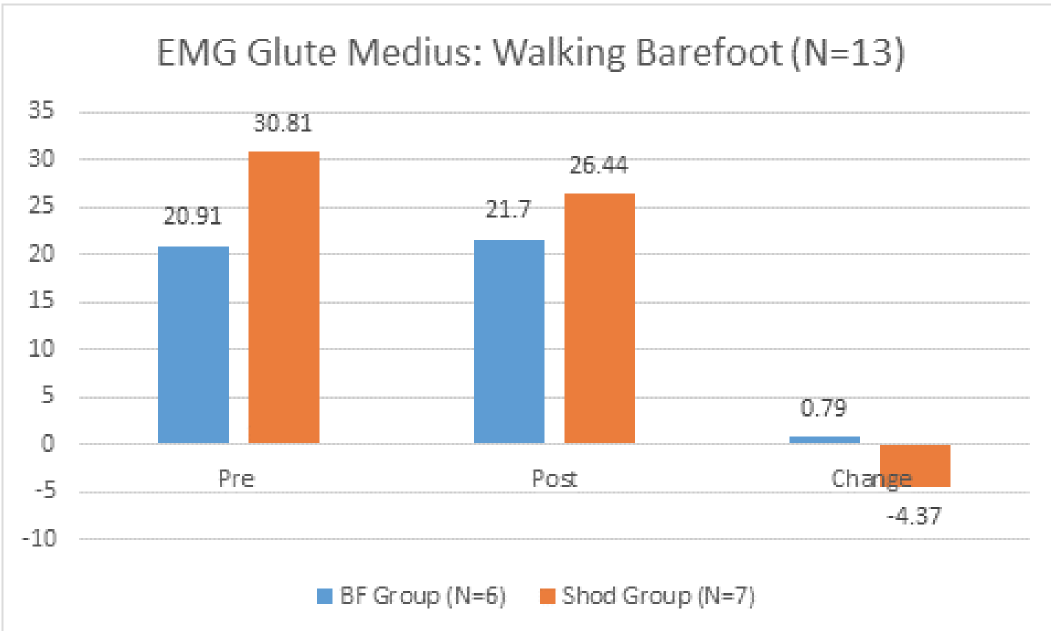
(c)


EMG TFL: Running Shod (N=13)
140
120
100
80
60
40
20
0
73.79
59.31
122.54
93.48
48.75
34.17
Pre
Post
Change
BF Group (N=6)
Shod Group (N=7)

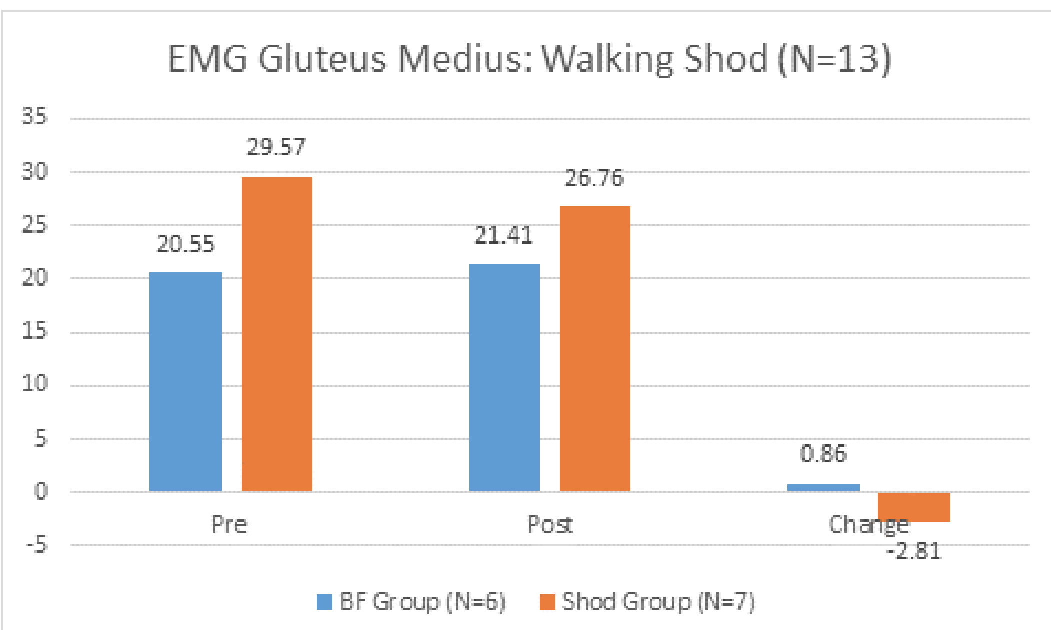
(d)

Table 3. EMG Results Gluteus Medius

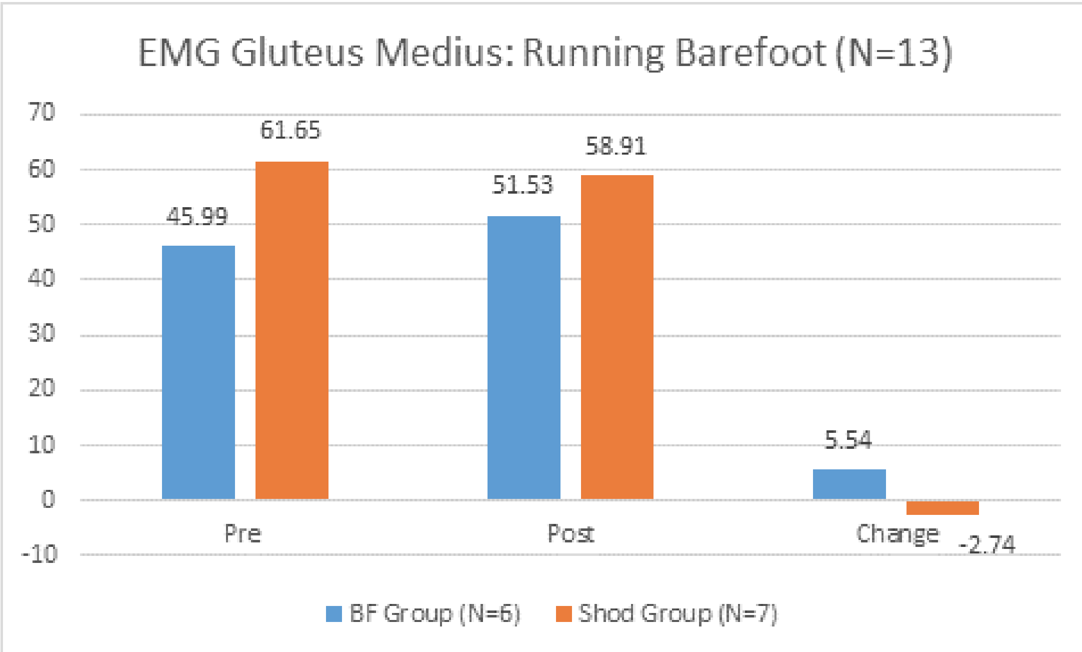
(a) Walking Barefoot, (b) Walking Shod, (c) Walking Barefoot, (d) Walking Shod



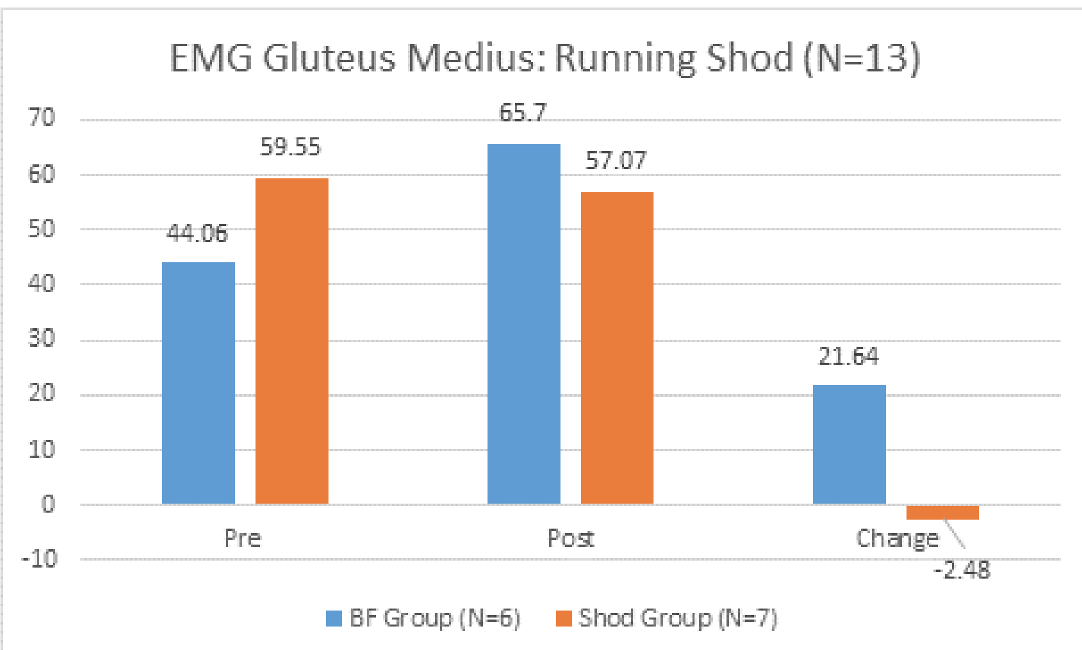
(a)



(b)


EMG Gluteus Medius: Running Barefoot (N=13)
70
60
50
40
30
20
10
0
-10
61.65
45.99
58.91
51.53
5.54
-2.74
Pre
Post
Change
BF Group (N=6)
Shod Group (N=7)

(c)


EMG Gluteus Medius: Running Shod (N=13)
70
60
50
40
30
20
10
0
-10
59.55
44.06
65.7
57.07
21.64
-2.48
Pre
Post
Change
BF Group (N=6)
Shod Group (N=7)

(d)

Chapter V

DISCUSSION

Conclusion

This study proposed barefoot training would decrease the degree of lateral pelvic drop, as a result of an increase in gluteus medius activity and decrease in TFL activity. However, this proposal was not found to be statistically significant upon statistical analysis following the six-week training period. Overall, a general training effect was exhibited, but no statistically significant differentiation was able to be made between barefoot and shod running.

Limitations

There were limitations that affected this study. The pre-test and post-test EMG data of the gluteus medius and TFL cannot be directly compared to each other, due to the fact that the post-test electrodes may not have been placed in the exact same spot as the pre-test. Therefore, the identical muscle fibers may not have been tested for their amount of activation during pre- and post-testing. In addition, the machine used to measure electrical impedance between the electrodes was used for pre-testing, but malfunctioned during the post-testing. Therefore, it was not used. One subject missed five training sessions due to foot pain. Another subject missed one training session due illness. In addition, in week five and six the study participants had only one training session to allow their legs to rest. These inconsistencies in training participation and training sessions per week are additional limitations to the study. Furthermore, all study participants had different fitness levels and training regimens that may have impacted the degree of treatment effect across the group.

Furthermore, the power of this study was limited due to the small sample size (n=14). This sample size was limited to physical therapy students which did not allow for a diverse sample. Due to time constraints, the training period was only six weeks. A longer training period may have allowed a more significant progression of intensity and an increased treatment effect.

Adverse Effects

When starting any training program there is a risk for adverse events. Metatarsal pain was the main complaint from many of the study participants. One participant dropped out of the training program due to metatarsal pain, the participant completed 5 out of 10 training sessions. In addition, certain participants selected for barefoot running had blisters throughout the study. This may be attributed to the facility requiring the barefoot runners to wear socks when on the treadmill. None of the subjects had prior experience barefoot running, so their feet were not accustomed to this type of running thus potentially adding to increased risk of acquiring foot blisters.

Recommendations for Future Research

It may be useful in the future to analyze the immediate impacts for muscle activity performing barefoot running versus shod running rather than looking at a training effect. This would eliminate the inevitable placement errors for electrodes when measuring EMG activity. It would also be easier to recruit more subjects from multiple academic disciplines for this study format since the study is less time intensive due to no post-testing or training. The previous study compared the training effect for many variables which were as follows: TFL and GM shod and barefoot walking for shod training group, TFL and GM shod and barefoot running for shod training group, TFL and GM shod and barefoot walking for barefoot training group, TFL and GM shod and barefoot running for barefoot training group. This made the results analysis more difficult and limited the strength of our results since we compared so many different areas. By studying the immediate impacts of barefoot versus shod running, the only variables to analyze are walking and running barefoot versus walking and running shod.

Appendix A: IRB Approval & Informed Consent

UNIVERSITY OF NORTH DAKOTA.

UND.edu

Institutional Review Board
Twamley Hall, Room 106
264 Centennial Drive Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.6708

April 6, 2017

Principal Investigator:	Gary Schindler, PT, DPT, Ph.D.
Project Title:	Barefoot Versus Shod Running: Training Effects on Navicular Drop and Foot Pressure Analysis
IRB Project Number:	IRB-201605-389
Project Review Level:	Expedited 4
Date of IRB Approval:	04/04/2017
Expiration Date of This Approval:	04/03/2018
Consent Form Approval Date:	04/04/2017

The Protocol Change 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 revised 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.

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/

Sincerely,

Michelle L. Bowles

Michelle L. Bowles, M.P.A., CIP
IRB Coordinator

MLB/sb

Enclosures

Cc: Chair, Physical Therapy

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 surface Electromyography (EMG) activity of the Tensor Fasciae Latae (TFL) and Gluteus Medius (GM) during waling 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 training in barefoot running versus shod running reduces the amount of navicular drop 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 (2-15 miles per week), and meet this study's inclusion criterion.

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

HOW MANY PEOPLE WILL PARTICIPATE?

Approval Date: APR 3 2017
Expiration Date: APR 3 2018
University of North Dakota IRB

Date: ________
Subject Initials: ________

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 analysis utilizing the VICON motion analysis system, and surface EMG of the TFL/GM muscles during shod/barefoot walking and running and complete a post-survey analysis to determine compliance and training schedule. 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. 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 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 last approximately 8 weeks. Each participant will complete a pre-test navicular drop test, a walking/running analysis utilizing the Vicon Motion Analysis system, and surface EMG analysis of the TFL and GM during shod and barefoot walking/running. 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, a walking/running analysis utilizing the Vicon Motion Analysis system, and surface EMG analysis of the TFL and GM during shod and barefoot walking/running 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 injury in the lower extremities in the past 6-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 2-15 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, 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 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 (Tuesday and Thursday) progressing from 10 minutes per session during the first week to 20 minutes per session upon week 6 resulting in 2-minute increment increases per week. After completing the program, a navicular drop test, foot/pelvis motion analysis, and surface EMG of TFL/GM musculature will be performed again. In addition, each

Date: ________
Subject Initials: ________

participant will complete a post-program 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 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 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, while TFL/GM EMG activity between shod runners and barefoot runners. 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.

Approval Date: APR 4 2017
Expiration Date: APR 3 2018
University of North Dakota IRB

Date: ____
Subject Initials: ____

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

Approval Date: APR 4 2017
Expiration Date: APR 3 2018
University of North Dakota IRB

Date: ________
Subject Initials: ________

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