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# An Electromyographic Study of Hip Muscle Activity in Varying Subtalar Joint Positions: Implications for Anterior Cruciate Ligament Injury Risk

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# AN ELECTROMYOGRAPHIC STUDY OF HIP MUSCLE ACTIVITY IN VARYING SUBTALAR JOINT POSITIONS: IMPLICATIONS FOR ANTERIOR CRUCIATE LIGAMENT INJURY RISK

by

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A Scholarly Project

Submitted to the Graduate Faculty

of the

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota May 2008



This scholarly project, submitted by Holly Augustine, Allison Biwer, Greg Jorgensen, and Mitch Kary 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 Faculty Advisor under whom the work has been done and is hereby approved.

Graduate Advisor

Chairperson

#### PERMISSION

- Title An Electromyographic Study of Hip Muscle Activity in Varying Subtalar Joint Positions: Implications for Anterior Cruciate Ligament Injury Risk
- Department Physical Therapy

Degree Doctor of Physical Therapy

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#### ABSTRACT

**Purpose:** The purpose of this study is to determine if subtalar joint position affects the activity of hip musculature in static standing, and by those results imply a correlation between foot position and ACL injury risk.

**Methods:** Thirty participants took part in this randomized study in which EMG data were collected during 3 trials of 3 subtalar joint positions on the right lower extremity. Subtalar joint positions included a flat surface to represent a neutral subtalar position, a 5-degree incline rising from lateral to medial, promoting a supinated attitude of the foot, and the third position was on a 5degree incline rising from medial to lateral promoting a pronated attitude of the foot. EMG activity was monitored in the gluteus maximus, gluteus medius, rectus femoris, biceps femoris, tibialis anterior, and gastrocnemius during static standing.

**Results:** All 30 subjects were tested individually and able to complete all of the trials required for data collection. Repeated analysis of variance (ANOVA) was utilized in each of the six muscle groups tested within the three different subtalar conditions. There was no significant difference found in the EMG activity of gluteus maximus, gluteus medius, biceps femoris, rectus femoris, and gastrocnemius. There was a significant difference found in the EMG activity of the tibialis anterior muscle demonstrating a higher EMG activity in subtalar flat

and pronated positions as compared to the subtalar supination position. The EMG results from subject 12 had an unusually high amount of interference in the muscle activity of the rectus femoris and tibialis anterior. For this reason, readings in all three conditions for rectus femoris and tibialis anterior were discarded for subject 12.

**Conclusion:** There was no significant difference found in hip muscle activity with varying subtalar joint positions. Even though our results showed no significant differences, future studies including more functional positions and kinetics throughout the lower extremity might produce results that demonstrate a relationship between the two areas and, therefore, possibly identify this relationship as a determinant for anterior cruciate ligament injury risk.

## CHAPTER I

## INTRODUCTION

## **Problem Statement**

Recent findings have connected hip musculature activity to anterior cruciate ligament (ACL) injury. Currently, there is limited literature regarding subtalar position and its effect on hip muscle activity, potentially connecting subtalar joint position with ACL injury risk.

## Purpose of the Study

The purpose of ths study is to determine if subtalar joint position affects the activity of hip musculature in static standing, and by those results imply a correlation between foot position and ACL injury risk.

## Significance

This study is significant to the field of physical therapy and physical therapy research due to the fact that ACL injuries are a common occurrence in active, young adults. According to the National Center for Injury Prevention and Control, the cost of ACL reconstruction in the U.S.A. is just under \$1 billion per year.<sup>1,2</sup> The results of this study will provide a better understanding of subtalar position and its implication for ACL injury. An effective alternative subtalar position could provide physical therapists and their clients with an effective preventative method that will minimize ACL injuries. While hip muscle activity

has been correlated with ACL injuries, there is little research investigating the effect of varying subtalar positions will have on the activity of hip musculature and its possible implications for ACL injury risk.

### Research Questions

1. Is there a significant difference on the activity of hip musculature based on the position of the subtalar joint?

2. Which muscles of the lower extremity are affected the most by varying positions of the subtalar joint?

## Hypothesis

Null Hypothesis: There is no significant difference on the activity of hip musculature based on the position of the subtalar joint.

Alternative Hypothesis: There is a significant difference on the activity of hip musculature based on the position of the subtalar joint.

### CHAPTER II

## LITERATURE REVIEW

The commonality of the ACL injury, especially in athletics, has warranted much research in order to develop a greater understanding of predisposing factors that may put an individual at risk for injury. Each year, an estimated 80 000 to more than 250 000 anterior cruciate ligament (ACL) injuries occur, many in young athletes 15 to 25 years of age.<sup>3</sup> The Centers for Disease Control and Prevention has reported that about 100 000 ACL reconstructions are performed annually at a estimated cost of about \$1 billion per year.<sup>1,2</sup> Due to these high numbers, there has been a considerable amount of research done regarding the causes and prevention of ACL injuries. In 1999, a meeting was held in Hunt Valley, Maryland, and again in 2005, in Atlanta, Georgia, looking to review and summarize the information on ACL risk factors, injury biomechanics, and injury prevention programs. This group included physicians, physical therapists, athletic trainers, and biomechanists who were engaged in ACL research. As a result of this meeting, four categories of ACL risk factors were identified to be environmental, hormonal, neuromuscular, and anatomical.<sup>4</sup> Each category can be broken down into different components to try to locate potential problems.

In the environmental category, the predominant schools of thought are meteorological conditions, surfacing, footwear, and bracing. Meteorological conditions focus on weather and its effect on high-evaporation and low-rainfall periods creating harder ground conditions, in turn increasing shoe-surface traction which can increase the risk of ACL injurv.<sup>5,6</sup> Surfacing also looks at the shoe-surface relationship, focusing more on artificial surfaces like field turfs reduction of injuries compared to natural grass<sup>7</sup> and increase in injuries due to artificial flooring compared to natural hardwood floors.<sup>8</sup> Footing focuses on the shoe-surface interaction by increasing the traction between footwear and playing surface<sup>9</sup> or by indirectly altering human neuromuscular and biomechanical movement patterns to adapt to variations in shoe and surface factors.<sup>10</sup> In bracing, the focus shifts to prevention of knee injury by offering support to the knee and, in turn, its effect on lowering the numbers of injuries.<sup>11</sup> Bracing, however, does not prevent the increased anterior displacement of the tibia on the femur in knees with ACL deficiency.<sup>12</sup>

For the hormonal component, research focuses on why there is a higher incidence of ACL tears in women. This idea picked up in intensity after Liu and Sciore<sup>13</sup> found receptors for sex hormones in ACL tissue obtained in male and female subjects. The first aspect they looked at was hormones and animal ACL tissue. This found a mix of results. One study showed a decreased load to failure in the ACL of rabbits,<sup>14</sup> while others found no difference in studies involving sheep<sup>15</sup> and goat<sup>16</sup> ACL tissue. The next area of focus was hormones and human ACL tissue. In a pair of studies by Yu et al,<sup>17,18</sup> they found results

that suggest acute increases in sex hormone concentration across the menstrual cycle may influence ACL metabolism and collagen synthesis in a time-dependent and dose-dependent interactive manner. These findings led researchers to look at hormones and knee laxity across the menstrual cycle. Researchers have found significant increases in anterior-posterior knee laxity using a knee arthrometer during the periovulatory and luteal phases of menstruation.<sup>19-21</sup> Other cohort studies did not detect variable laxity with any phase of the menstrual cycle<sup>22-24</sup>; however, these later studies did not measure hormone concentrations to determine the actual phase of the menstrual cycle<sup>25</sup> and due to the inherent variability among women in the timing of hormone changes, it creates challenges comparing groups of women in the same stage of menstruation. The implications of menstruation's cyclical increases in laxity on the knee joint and ACL injury risk have yet to be determined. In examining the menstrual cycle phase and actual ACL non-contact injury, only three studies have measured actual hormone levels to confirm cycle phase at the time of injury.<sup>26-28</sup> These studies do not show a consistent time during the menstrual cycle that a non-contact injury is likely to occur. However, they do document hormone concentrations in the days preceding the injury as well as the day the injury happened which might play a role. More research into the time during the menstrual cycle when the most injuries occur is warranted.

The next area of focus looks at the neuromuscular system as the cause of injury. The neuromuscular risk factors can be broken down into three groups consisting of altered movement patterns, altered activation patterns, and

inadequate muscle stiffness. First, looking at altered movement patterns, they focused on how women differ from men. There have been multiple findings that women appear to land a jump, cut, and pivot with less knee and hip flexion, increased knee valgus, increased internal rotation of the hip, increased external rotation of the tibia, less knee joint stiffness, and high quadriceps activity relative to hamstring activity; that is, quadriceps-dominant contraction.<sup>29-33</sup> This aggressive guadriceps contraction has been found to result in significant anterior translation of the tibia relative to the femur, and has been proposed as a potential mechanism of injury.<sup>34</sup> Other findings have found that women have "leg dominance" that is an imbalance between muscular strength, flexibility, and coordination between their lower extremities, and that these imbalances are associated with increased risk of injury.<sup>35-38</sup> Yu et al<sup>39</sup> found that after 13 years of age, girls have decreased knee flexion angles at ground contact. Hewett et al<sup>40</sup> theorized that, unlike boys, girls do not have a neuromuscular spurt to match their growth spurt and this can lead to ACL injury. Fatigue also appears to be a factor that can lead to ACL injury. Chappell et al<sup>41</sup> found that men and women both had a decreased knee flexion angle and increased proximal tibial anterior shear force while performing jump stop tasks. Next, researchers looked at altered muscle activation patterns. As mentioned above, many studies have found that guadriceps-dominant contractions in landing and cutting activities may produce significant anterior displacement of the tibia. Three well-designed controlled laboratory studies found that female athletes have greater quadriceps activation than hamstring and decreased knee stiffness resulting in anterior tibial

translation compared to their male counterparts.<sup>42-44</sup> In looking at inadequate muscle stiffness, research found that non-injured female athletes had a significant decrease in muscle stiffness (quad and hamstrings) resulting in decreased knee joint stiffness.<sup>45-48</sup>

The last area that researchers investigated as a possible cause of ACL injury was anatomical risk factors. They started by looking at the Q angle (quadriceps angle) which is typically 15°. An altered Q angle has been proposed as a contributing factor in injuries by altering the knee kinematics.<sup>49</sup> It has been consistently found that young adult women have an increased Q angle compared to young adult men which could explain their greater susceptibility to injury.<sup>50-52</sup> A study by Shambaugh et al<sup>53</sup> found that recreational basketball players who sustained injury had a larger mean Q angle compared to the mean of those who did not experience an injury. Q angle has also been shown to affect knee valgus/varus position during single-leg landings showing females maintain a valgus position post-pubescent while men move into a more varus position at this time.<sup>54</sup> When looking at knee valgus, it has commonly been listed as a factor for a non-contact knee injury based on observations.<sup>55</sup> biomechanical studies,<sup>56</sup> and video analysis.<sup>57</sup> In recent work, it has been found that female subjects landed with significantly greater total valgus knee motion and greater maximum valgus knee angle than did the male subjects.<sup>36</sup> Using 3D kinematics and joint kinetics during a jump-landing task, researchers found that dynamic knee valgus measures were predictive of future ACL injury risk.<sup>37,40</sup> Body mass index (BMI) has also been looked at as an anatomical risk factor. In one study,

the U.S. Military Academy found women with a higher than average BMI were at an increased risk of injury.<sup>58</sup> Brown et al<sup>59</sup> added support for this finding; however, Knapik et al<sup>60</sup> and Ostenberg and Roos<sup>61</sup> did not find an association with BMI and ACL injury. The data on BMi is inconsistent, making it had to come to a reliable conclusion. Another area of focus has been on the intercondylar notch size as a cause of injury. Many studies have found that a decreased notch width when measured radiographically puts subjects at an increased risk for noncontact ACL injury.<sup>62-64</sup> On the other hand, a number of studies have found that comparing ACL injury to notch size does not have sufficient power to make definitive conclusions.<sup>65-67</sup> ACL size has also been researched, finding that in females the length, cross-sectional area, volume, and mass were less than in men.<sup>68</sup> Research has also looked at foot position and its effect on ACL injury through alignment and biomechanical changes of the lower leg. Research suggest that excessive pronation may lead to ACL injuries by increasing internal tibial rotation and having a greater navicular drop.<sup>69,70</sup> Loudon et al<sup>71</sup> researched 40 female athletes, 20 of whom had prior ACL injuries, focusing on several variables of static posture. The areas examined were standing pelvic position, hip position, standing sagittal knee position, standing frontal knee position, hamstring length, prone subtalar joint position, and navicular drop test. They found that knee recurvatum, excessive navicular drop, and excessive subtalar joint pronation were significant discriminators between the ACL-injured and the non-injured group. However, some controversy exists whether this structural variable is a significant predictor.<sup>70,72</sup> Smith et al<sup>72</sup> were unable to predict injury

risk by using the navicular drop score and concluded that hyperpronation, as measured by the navicular drop test, may not be a predisposing factor to noncontact ACL injury. This area has mixed results making it hard to draw a definite conclusion on foot position's direct effect at the knee.

Recent studies have returned to the fact that female athletes have greater knee valgus than their male counterparts.<sup>37,40</sup> However, the focus of the research is now on poor proximal control (i.e., hip weakness) and its effect on the knee. Pollard et al<sup>73</sup> demonstrated that gender differences in knee valgus moments exist. They then went on, in another study, to show that those female athletes with greater knee valgus employed different movement patterns at the hip.<sup>74</sup> These movements were greater hip internal rotation and decreased hip flexion exhibited by female athletes during the early deceleration phase of cutting. In addition, females showed greater hip adductor movements and decreased hip extensor movements during this phase.<sup>74</sup> As mentioned before and back by Leetun et al,<sup>75</sup> internal rotation during functional activities may result in altered alignment of the lower extremity leading to a predisposition to ACL injury. The decreased hip extensor moments in females show that they were less able to engage the hip extensors in order to control the deceleration phase of the cutting maneuver. Since the hip extensor (i.e., gluteus maximus) are also external rotators, the female's weakness in this area could allow them to go into further internal rotation. In a study by Shimokochi et al,<sup>76</sup> they show a relationship between ankle eversion motion and isokinetic thigh strength with knee internal rotation motion during a single leg squat. In two studies, Petal et

al<sup>77,78</sup> found evidence that suggested that the lateral trunk orientation observed during cutting tasks might be associated with medial rotation of the lower extremity at the subtalar joint, inducing medial translation of the hip joint. However, in another study, Houck et al<sup>79</sup> concluded that this was not correct due to the fact that lateral trunk orientation increased in their study. They found that the decreased hip joint angle is likely a failure of the lower extremity to medially rotate around the subtalar joint during cutting tasks. This led us to wonder if foot position (i.e., excessive pronation or supination) had any effect on the hip or hip musculature. Would allowing the foot to go into excessive pronation or supination be enough to get a response from the hip musculature? Very little research has been performed in this area. The majority of the older research is all on foot position and its effect directly at the knee. No one has looked to see if foot position affects hip musculature indirectly affecting knee kinematics. This led us to examine foot position and its effect on lower extremity hip biomechanics including muscle activity and the effect it has on the anterior cruciate ligament (ACL) of the knee.

## CHAPTER III

## METHODS

### Subjects

Participants in this study were volunteers from the community and student population at the University of North Dakota. All subjects were required to sign an informed consent form (Appendix A) prior to participating, with each participant receiving a copy of the consent form. Thirty volunteers comprised of 18 females and 12 males participated.

Inclusion criteria for this study included both male and female subjects between the ages of 18 and 30 with no previous knee ligament surgeries on the right lower extremity. Inclusion and exclusion criteria were determined by a questionnaire that was completed prior to subject testing (see Appendix B).

All research was conducted in the University of North Dakota Department of Physical Therapy and was approved by the Institutional Review Board at the University of North Dakota (see Appendix C).

## Instrumentation

Electromyography (EMG) was used to assess the activity levels of the muscles being measured. The EMG data were collected using a Noraxon Telemyo 900 telemetry unit (Noraxon USA, Scottsdale, AZ). Information was

collected, transmitted, and converted to a digital form by an analog to digital interface board installed in the computer.

#### Procedure

Prior to testing, a history was obtained from each subject via the use of a questionnaire to determine eligibility (see Appendix B). Each eligible subject was required to read and sign the informed consent form prior to continuing (see Appendix A). Two stations were established in the testing room, with two researchers at each station. Each researcher performed the same duty throughout data collection to ensure consistency. At the first station, the subjects were prepared for and completed the electrode placement phase. The subjects were then sent to the second station where they were connected to the telemetry unit in preparation for EMG data collection.

#### Electrode Preparation and Placement

The six muscles of interest in this study included the gluteus maximus, gluteus medius, biceps femoris, tibialis anterior, rectus femoris, and gastrocnemius. The fibular head was used as a reference point for the ground electrode. Electrode placement points were found using a standard tape measure.<sup>80</sup> The motor point position of the gluteus maximus as defined as ½ the distance between the inferior lateral angle of the sacrum and the greater trochanter. The gluteus medius motor point was defined as 1/3 the distance between the iliac crest and the greater trochanter. The motor point of the biceps femoris was defined as ½ the distance between the iliac crest and the greater trochanter. The motor point of the biceps femoris was defined as ½ the distance between the ischial tuberosity and the lateral femoral condyle. The anterior tibialis motor point was defined as being

directly over the muscle belly, 1/3 the distance between the inferior patellar pole and the superior portion of the lateral malleolus. The motor point of the rectus femoris was defined as ½ the distance between the anterior superior iliac spine (ASIS) and the superior patellar pole. The gastrocnemius motor point was defined as being directly over the muscle belly, 1/4 the distance between the fibular head and the calcaneus. The ground electrode was placed directly over the fibular head. All motor points were marked with a washable marker. The motor points on the skin were prepared for greatest conductivity by shaving any excess hair from the area (if necessary), lightly abrading the skin with eight passes of fine sandpaper, and finally cleaning the area with isopropyl alcohol. Two adult-sized, pre-gelled, self-adhesive electrodes (Ambu/Blue Sensor, Model: M-00-S, Denmark) were placed at each motor point, parallel to the long axis of the muscle. An impedance analyzer was utilized to determine whether the amount of conductivity was adequate (Figure 1).

### EMG Data Collection

A lead was connected to electrodes over each of the six muscles and the ground electrode. Each lead was connected to a telemetry unit that was eventually belted around the subject's waist to measure the amount of activity of each muscle. Each subject began the data collection phase by performing a maximal voluntary contraction (MVC) for each muscle. The MVC for each muscle would serve as baseline against which muscle activity during the testing would be compared. The MVC of the gluteus medius, gluteus maximus, rectus femoris, and biceps femoris were measured in similar ways. Each position for



Figure 1. Test equipment, including a washable marker, fine sandpaper, isopropyl alcohol, self-adhesive electrodes, tape measure, and an impedance analyzer.

MVC assessment used a belt that was secure at one end and as wrapped around the subject's ankle at the opposite end. Each subject was asked to hold the position for five seconds, and three trials were performed for each muscle. The gluteus medius was measured with the subject standing and maximally contracting into hip abduction, against the belt. Gluteus maximus was measured with the subject standing and extending the hip against the resistance of the belt. The maximal contraction of rectus femoris was measured with the subject sitting unsupported on a plinth and resisting the belt while extending the leg into leg extension. The biceps femoris muscle was tested with the subject in a standing position and flexing the knee, performing a leg curl against the belt resistance. The maximal contraction of the gastrocnemius and anterior tibialis were measured with the subject in a standing position. For the gastrocnemius, the subject rose up on toes three times consecutively. This was performed three times. Similar to the measurement of the gastrocnemius, the anterior tibialis was measured by instructing the patient to roll back on the heels three times consecutively.

Each subject was asked to perform static, single-leg standing on three different surfaces on the right leg (Figures 2-4). The first was done on a flat



Figure 2. (*Top*) 5-degree incline, representing subtalar supination and pronation. (*Bottom*) Flat surface, representing subtalar neutral position.



## Figure 3. 5-degree incline

surface to represent a neutral subtalar position, the second on a 5-degree incline rising from lateral to medial, promoting a supinated attitude of the foot (Figures 5 and 6), and the third position was on a 5-degree incline rising from medial to lateral promoting a pronated attitude of the foot. Each position was held for five seconds and was performed three times.

## EMG Data

All electrodes and equipment were removed upon completion of the testing and the subject's skin was cleaned with isopropyl alcohol. The raw EMG signals were full wave rectified and smoothed using RMS averaging with a 50-



Figure 4. Flat surface representing subtalar neutral.

msec window. The EMG data were exported to MyoResearch XP software (Noraxon USA, Scottsdale, AZ) for analysis of mean activity levels. The level of EMG activity during each subtalar condition was compared to the EMG activity during the MVCs for each subject.

## Statistical Analysis

Data analysis of mean activity of the gluteus maximus, gluteus medius, biceps femoris, tibialis anterior, rectus femoris, and gastrocnemius was performed on the EMG activity during each of the three subtalar conditions using the Statistical Package for Social Sciences (SPSS) software program (Version 11.0.1, SPSS Inc., Chicago, IL). The means were compared and interpreted



Figure 5. 5-degree incline representing subtalar supination. using the statistical analysis of repeated measures ANOVA and a significance level (alpha level) of .05.



Figure 6. Subject demonstrating subtalar supination.

#### CHAPTER IV

#### RESULTS

All 30 subjects were tested individually and able to complete all of the trials required for data collection. The mean age of the subjects was 22.9 years old, with 18 female subjects and 12 male subjects. Characteristics of the subjects are summarized in Table 1.

Repeated analysis of variance (ANOVA) was utilized in each of the six muscle groups tested within the three different subtalar conditions. There was no significance difference found in the EMG activity of gluteus maximus, gluteus medius, biceps femoris, rectus femoris, and gastrocnemius (Table 2).

There was a significant difference found in the EMG activity of the tibialis anterior muscle within the three subtalar conditions (Table 2). Post hoc analysis (Boneferoni) demonstrated a higher EMG activity in subtalar flat and pronated positions as compared to subtalar supination position. This demonstrates that subtalar supination is the least desirable position for muscle activation of the tibialis anterior (Table 3).

The EMG results from subject 12 had an unusually high amount of interference in the muscle activity of the rectus femoris and tibialis anterior. For this reason, readings in all three conditions for rectus femoris and tibialis anterior

Subject	Age (years)	Gender	Subject	Age (years)	Gender
1	23	F	16	18	F
2	23	F	17	21	М
3	23	F	18	18	F
4	23	F	19	23	F
5	24	F	20	24	М
6	25	Μ	21	22	М
7	23	F	22	24	М
8	24	М	23	25	F
9	23	М	24	23	F
10	23	F	25	23	М
11	24	М	26	23	М
12	22	F	27	22	F
13	26	F	28	22	М
14	24	F	29	24	F
15	23	F	30	22	Μ

Table 1. Characteristics of Subjects Participating in Research Study

Muscle	Condition	η	Mean	SD	F	df	Sig.	Partial Eta Squared	Observed Power
	Flat	30	19.8	10.5	0.252	(1,29)	0.619	0.009	0.077
Gluteus Maximus*	Supinated	30	20.3	11.1	0.252	(1,29)	0.619	0.009	0.077
	Pronated	30	19.8	10.9	0.252	(1,29)	0.619	0.009	0.077
	Flat	30	22.1	10.2	1.700	(2,58)	0.192	0.055	0.343
Medius	Supinated	30	21.7	10.7	1.700	(2,58)	0.192	0.055	0.343
	Pronated	30	20.3	10.7	1.700	(2,58)	0.192	0.055	0.343
	Flat	30	7.9	7.5	0.553	(2,58)	0.578	0.019	0.137
Biceps Femoris	Supinated	30	7.2	7.4	0.553	(2,58)	0.578	0.019	0.137
	Pronated	30	7.7	6.3	0.553	(2,58)	0.578	0.019	0.137

# Table 2. Repeated Measures Analysis of Variance Between Conditions

	Flat	29	28.0	15.6	6.113	(2,54)	0.004**	0.185	0.870
Anterior	Supinated	29	23.2	12.8	6.113	(2,65)	0.004**	0.185	0.870
	Pronated	29	28.5	13.8	6.113	(2,54)	0.004**	0.185	0.870
Destus	Flat	29	13.2	9.9	1.429	(2,56)	0.248	0.049	0.294
Rectus Femoris	Supinated	29	13.0	10.4	1.429	(2,56)	0.248	0.049	0.294
	Pronated	29	11.8	8.9	1.429	(2,56)	0.248	0.049	0.294
Castros	Flat	30	23.7	11.2	1.894	(1,29)	0.179	0.061	0.265
Gastroc- nemius*	Supinated	30	22.0	9.1	1.894	(1,29)	0.179	0.061	0.265
	Pronated	30	22.2	10.4	1.894	(1,29)	0.179	0.061	0.265

Table 2. Repeated Measures Analysis of Variance Between Conditions (cont.)

\* If sphericity assumption was violated, lower bound analysis is reported. \*\* Significance at p < .05.

Condition of Tibialis Anterior		Mean Difference	Standard Error	Significance	95% Confidenc for Differ	e Interval ence
					Lower	Upper
F	S	4.8	1.750	.033	.319	9.253
	Ρ	-0.5	1.802	1.000	-5.047	4.154
S	F	-4.8	1.750	.033	-9.253	319
	Ρ	-5.3	1.395	.003	-8.793	-1.671
Р	F	0.5	1.802	1.000	-4.154	5.047
	S	5.3	1.395	.003	1.671	8.793

Table 3. Tibialis Anterior Post Hoc Analysis

F = Flat subtalar position S = Supinated subtalar position P = Pronated subtalar position

were discarded for subject 12. Therefore, the n for these two muscles was 29 rather than 30.

## CHAPTER V

### DISCUSSION

### **Tibialis Anterior**

A significant difference was found in the EMG activity of the tibialis anterior (TA) within the three testing positions of the subtalar joint. The increase of EMG activity of TA was greater in subtalar neutral and pronated positions as compared to the subtalar supinated position. We feel this is due to the actions of the TA, which are to dorsiflex and invert the ankle. TA was least active in the subtalar supinated position due to the fact that the ankle was acting to return to neutral by everting or pronating which is not an action the TA is able to perform.

Research suggests that excessive pronation may lead to ACL injuries by increasing internal tibial rotation and having a greater navicular drop.<sup>70-71</sup> The significant difference in EMG activity of TA related to foot position suggests that it may be important to prevent the foot from being in an overly pronated position in order to allow for the activation of the TA for greater stabilization at the subtalar joint.

Gluteus Maximus, Gluteus Medius, Biceps Femoris, Rectus Femoris, and Gastrocnemius

There was no significant difference found in the EMG activity of the gluteus maximus, gluteus medius, biceps femoris, rectus femoris, or

gastrocnemius among the three different foot positions. We feel that this may be due to the degree of pronation and supination in which the foot was placed during testing. Each subject was placed on a 5-degree wedge in order to pronate and supinate the foot. If this incline or decline was increased, the subjects would have to rely more on hip strategies to remain balanced, a position which would cause more activity in the hip musculature. By doing this, we would be able to see which hip muscles are most responsible for this stabilization; however, it is unlikely that an individual would bear weight in such a high degree of pronation or supination during activity. Another possible reason may be that the tests were performed statically, resulting in an insufficient amount of force through the lower extremity. In a more dynamic test, such as jumping, more force will be passed through the lower extremity, requiring leg and hip musculature to be more active. Greater lower extremity muscle activation may have a greater influence on the positioning of the subtalar joint. EMG activity might also have been impacted due to the subjects being tested in full or near full knee extension, a position that perhaps would not be as functional as what might be seen in everyday activities.

There have been multiple findings that support the idea that individuals with certain biomechanical characteristics are at greater risk of ACL injury. These characteristics are found more often in females and include attempting to land a jump, cut, and pivot with less knee and hip flexion, an increased knee valgus, internal rotation of the hip, and external rotation of the tibia along with high quadriceps activity relative to hamstring activity; that is, a quadricepsdominant contraction.<sup>29-33</sup> This aggressive quadriceps contraction results in significant anterior translation of the tibia relative to the femur and is thought to be a potential mechanism of injury.<sup>34</sup> We were anticipating significant change in the activity of the gluteus maximus, gluteus medius, biceps femoris, rectus femoris, and gastrocnemius muscles in the different foot positions due to the distribution of ground reaction forces throughout the lower extremity. However, these values were not found to be significant. The reason for this lack of significance is unknown, other than the aforementioned standardized wedge, lack of dynamic testing, and positioning of the knee.

## Limitations and Future Recommendations

There were several limitations to our study. We obtained our subjects through the method of convenience sampling rather than random sampling. Therefore, the sample we used was made up of healthy, young adults between the ages of 18 and 26. We understand that by using random sampling, we would have obtained a more accurate representation of the population for statistical analysis.

The accuracy of our statistical analysis could have been increased by using a larger sample size. We originally tested 30 subjects; however, one subject was not able to be included in the analysis of the rectus femoris and tibialis anterior due to an unusually high amount of interference in muscle activity. It would have been beneficial to have a larger sample size in order to provide a more accurate representation.

Another limitation to our study involved the way in which we manipulated the angle of the subtalar joint. By using the same standardized wedge for each subject, we were able to assume a relatively equal amount of pronation and supination in the foot. However, each individual is structurally different in the amount of natural pronation or supination in the foot. However, each individual is structurally different in the amount of natural pronation or supination at rest. With a normal subtalar joint axis location, the foot is more likely to function normally because there are neither excessive subtalar joint pronation moments nor excessive subtalar joint supination moments acting on the foot during weightbearing activities. In addition, the subtalar joint supination moments caused by ground reaction force acting medial to the subtalar joint axis and the subtalar joint pronation moments caused by ground reaction force acting lateral to the subtalar joint axis counterbalance each other to create a state of rotational equilibrium.<sup>81-83</sup> By using a standardized wedge for each person, we were unable to accurately manipulate exactly how much the subtalar joint was inverted or everted. It was assumed that when each subject was standing on the wedge, they were no longer in subtalar neutral, but instead in some degree of pronation or supination. The exact amount of subtalar pronation and supination achieved by each subject in the various test positions was relatively unknown. One way to gain more accurate results would be to individualize the pronation and supination surface to each subject so that each would be in a specifically measured position of inversion and eversion using a standardized goniometric measurement technique performed by the same researcher.

#### **Clinical Implications**

ACL injury is the most common traumatic knee injury among active young adults. Understanding the mechanisms of how this injury occurs is important in developing preventative measures to help protect individuals from ACL injury. It is now believed that a number of different anatomical, hormonal, biomechanical, and environmental factors may contribute to injuries involving the ACL. Examining all of these different areas collectively is perhaps the key to evaluating an individual who may be at risk for injury as well as taking steps to prevent these injuries from occurring.

Traditionally, research has concentrated on the effects the hip and ankle have on the knee joint and its ligaments separately. Our study attempted to examine the effect the ankle may have on the hip and how that then affects the knee. This study did not generate sufficient evidence to support the idea that hip musculature activation is significantly affected by foot position. This may have been due to the way in which the foot was positioned during testing, the amount of stress that was placed on the lower extremity, or that the foot position might not influence hip muscle activity. Although our study did not yield significant results of foot position affecting the hip musculature, it is important to understand as a clinician that the entire lower extremity works collectively as a single unit and that problems at the hip and ankle as well as the knee must be addressed when working to prevent ACL injuries. The limitations of the study may have prevented fully accounting for the influence of foot position on hip muscle activation.

# Conclusion

Although hip muscle activity did not appear to be influenced by subtalar position in this study, including more functional positions and kinetics throughout the lower extremity might produce results that demonstrate a relationship between the two areas and, therefore, possibly identify this relationship as a determinant for anterior cruciate ligament injury risk. APPENDIX A

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#### INFORMED CONSENT FORM

Title: Hip Muscle Activity in Varying Subtalar Joint Postitions: Implications for Anterior Cruciate Ligament Injury

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

Before you learn about the study, it is important that you know the following:

- Your participation is entirely voluntary.
- You may choose not to take part or to withdraw from this study at any time

#### Purpose:

1.14 2

You are invited to take part in a research study conducted by Dr. Mark Romanaick. and colleagues The overall purpose of the study is to better understand the effect that foot position has on hip musculature and the resulting correlation with the anterior cruciate ligament of the knee, a commonly injured knee occurrence.

The study expects to enroll up to 40 people, being open for a period of 6 months,. The length of your participation will be 1 session taking up approximately 1 hour of your time.

#### Participation:

This is an experimental study, for research purposes, meaning that there will be no drug treatment given to you as part of the study. Records of the results will then be shared with the study leaders to understand them further.

You will be asked questions about your medical history, your current symptoms, and your medications.

Electromyography (EMG), which measures the muscles electrical activity using electrodes placed over the muscle, will be performed as a measuring tool.

#### Cost and Payments to Participants

Research Related: You will not have to pay anything for participating in the study. Payment: You will not receive monetary reimbursement for participating in this research study.

#### Risks

There is a small risk of mild skin irritation at the sight of the electrode that reads the muscle activity, a common transient occurrence in studies using EMG. There is a small risk of embarrassment due to the placement of the electrodes over muscles of the buttocks; however, steps will be taken to ensure subject's modesty will be preserved by draping over this area for electrode application. You may refuse to answer any questions or perform any activity with which you are uncomfortable.

University of North Dakota Institutional Review Board Approved on <u>MAY -8 2007</u> Expires on <u>MAY -7 2008</u> <u>EMG</u>: What is electromyography? Electromyography (ee-lek-troh-meye-OG-rah-fee) is a test that is also called an electromyogram (ee-lek-troh-MEYE-oh-gram) or EMG. It measures electrical activity of the muscles at rest and when they are used. Electrodes are placed over the muscles to read their activity. No shock is administered to the patient.

#### Benefits

There will be no direct benefit to you from being in the study. However, the study will help further the research and knowledge in the area of the ACL.

#### Alternatives

Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time.

#### Confidentiality

Your results will only be shared with those involved in interpreting the results.

#### Contacts

If you have any questions regarding this study, or if any problems arise, you may call the Principal Investigator, Dr. Mark Romanick, at (701)777-3668. You may also ask questions, state concerns regarding your rights as a research subject.

Reasons Why You May be Withdrawn From the Study Without Your Consent:

You do not follow the study requirements. You have a prior history of knee injury.

I have read this consent form and have been given the opportunity to ask questions. I will also be given a copy of this consent form for my records. I hereby give my permission to participate in the research described above, titled:

Hip Muscle Activity in Varying Subtalar Joint Postitions: Implications for Anterior Cruciate Ligament Injury

Participant's Signature

Date

2

University of North Dakota Institutional Review Board Approved on <u>MAY -8 2007</u> Expires on <u>MAY -7 2008</u> APPENDIX B

# Questionnaire

Subject #\_\_\_\_\_ Gender\_\_\_\_\_

Please list and explain any previous injuries to the **right** lower extremity: Ankle Injuries:

Knee Injuries:

Hip Injuries:

APPENDIX C

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# University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below:

Principal Investigator	: Mark Romanick, Holly Augustine, Allison Biwer, Greg Jorgenson, Mitch Kary				
Telephone: 701-777-3	E-mail Address: mromanick@medicine.nodak.edu				
Complete Mailing Add	ress: School of Medicine & Health Services, 501 North Columbia Road, Box 9037				
School/College: Univer	sity of North Dakota Department: Physical Therapy				
Student Adviser (if ap	plicable): Mark Romanick				
Telephone: 701-777-3	668 E-mail Address: mromanick@medicine.nodak.edu				
Address or Box #: 9037	7				
School/College: Univer	sity of North Dakota Department: Physical Therapy				
Project Title: Hip Mus	cle Activity in Varying Subtalar Joint Positions: Implications for Anterior Cruciate Ligament Injury				
<u>.</u>					
Proposed Project Date	es: Beginning Date: May 20,2007 Completion Date: December 31,2007				
Funding agencies supp	porting this research: NONE				
Did the contract with the Attach a copy of the conductor without a copy of the conductor between the conductors.	the funding entity go through UND Grants and Contracts Administration? $n/a \square$ YES or $\boxtimes$ NO ntact. Do not include the any budgetary information. The IRB will not be able to review the study ontract with the funding agency.				
- YES or 🛛 NO	Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.				
YES or NO	Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?				
If yes, list all institutio	ns:				
Letters from each or their involvement in individual signing th	ganization must accompany this proposal. Each letter must illustrate that the organization understands that study, and agrees to participate in the study. Letters must include the name and title of the he letter and should be printed on letterhead.				
Does any external site where the research will be conducted have its own IRB? 🗌 YES 🔲 NO 🔀 N/A					
f yes, does the external site plan to rely on UND's IRB for approval of this study?  YES NO X N/A (If yes, contact the UND IRB at 701 777-4279 for additional requirements)					

	·	39			
If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.					
	N/A	Date submitted:	Status: 🗌 Approved 🗌 Pending		
		Date submitted:	Status: Approved Pending		
(include the par	me and address of the IRR contact pe	arson at the IDB and a phot	ne number for that person)		
(include the har	he and address of the first, contact pe	and a pho	ne number for that person)		
Type of Projec	t: Check "Yes" or "No" for each of th	ne following.			
YES or	NO New Project	🗌 YES or 🛛	NO Dissertation/Thesis/Independent Study		
🗌 YES or 🛛	NO Continuation/Renewal	YES or	] NO Student Research Project		
□ YES or ⊠	Is this a Protocol Change for p NO the changes bolded or highligh	reviously approved project	t? If yes, submit a signed copy of this form with		
	Does your project involve abst	tracting medical record info	ormation? If yes, complete the HIPAA		
☐ YES or ⊠	NO Compliance Application and s	ubmit it with this form.			
☐ YES or ⊠	NO Does your project include Gen	etic Research?			
☐ YES or ⊠	NO Does your project include Inte	rnet Research?			
Subject Classif	fication: This study will involve subje	ects who are in the followin	g special populations: Check all that apply.		
Chil	ldren (< 18 years)		UND Students		
D Pris	oners		Pregnant Women/Fetuses		
Pers	sons with impaired ability to understar	nd their involvement and/or	r consequences of participation in this research		
Othe	er				
Please use a involve	appropriate checklist when children, p. d in the research.	risoners, pregnant women,	or people who are unable to consent will be		
This study will	involve: Check all that apply.				
Dec	eption (Attach Waiver or Alteration o	f Informed			
	Consent Requirements)		Stem Cells		
Rad	liation		Discarded Tissue		
 New	v Drugs (IND) IND # Attach Appro	oval	Fetal Tissue		
Inve	estigational Device Exemption (IDE) #	# Attach Approval	Human Blood or Fluids		
☐ Non	1-approved Use of Drug(s)		Other		
Non	ne of the above will be involved in this	study	_		
I Project Over	view				

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

The purpose of this study is to determine if foot position affects the activity of hip musculature in static standing and, if so, perhaps imply that foot position may influence susceptibility toward anterior cruciate ligament (ACL) injuries. Previous studies have shown that hip musculature plays a role in ACL injuries; this study is trying to determine if foot position affects hip muscles ultimately providing implications for the ACL. The subjects used will be between the ages of 18 and 30. These subjects are being used because this age group has a high prevalence of ACL injuries.

#### **II.** Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories.

#### 1. Subject Selection.

a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

Researchers involved will recruit subjects by word of mouth. Recruitment will take place on the UND campus and will last throughout the length of the study.

b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.

Subjects involved will be both male and females between the ages of 18 and 30. Subjects must not have any previous knee ligament repairs on the tested extremity.

c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

The exclusionary criteria include previous knee ligament repairs to the tested extremity. Individuals with knee ligament repairs may confound research results. All subjects will be asked to complete a questionnaire prior to participation inquiring about previous lower extremity injuries/surgeries.

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

We will include up to 40 subjects for this study. This number will decrease our chances of statistical error and will allow for a more normal distribution of samples and more accurate statistically analysis. A relatively equal distribution of males and females will assist in determining influence of gender.

e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

Larger groups of subjects will maximize the validity and reliability of our data allowing increased carryover to clinical practice.

#### 2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.

Prior to participation in this study, subjects will be required to read, understand, and sign the provided consent form (see attached). At least one of the principal investigators will be available to address any questions or concerns subjects may have at that time.

b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

All research will be conducted in the Physical Therapy Department located in the UND School of Medicine & Health Sciences. Permission for use of the facility will be obtained from the proper officials prior to use. Five researchers, including the student advisor will be conducting the research.

c) Indicate who will carry out the research procedures.

The five researchers, including the student advisor will be conducting the research. They are as follows: Holly Augustine, Allison Biwer, Greg Jorgenson, Mitch Kary, and Mark Romanick (student advisor).

d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

The study will consist of 2 parts, preparing the subjects and measuring muscle activity. In the first part each subject will have the researchers place electrodes on the muscles surrounding the hip. The skin will be prepared by shaving hair from the area (if necessary), lightly abrading the skin with fine sandpaper, and finally, cleaning the area with rubbing alcohol. This skin preparation is all done to ensure best electrical conveyance from muscle to interpretive equipment. The electrodes will then be placed over the hip muscles being tested. The second part of the study involves measuring the hip activity of the hip with electromyography (EMG) equipment. EMG measures the electrical activity of the muscles during a contraction, it is important to remember that no electrical shock is given to the subject involved. EMG is only a measure of the muscle activity. Three different foot positions will be tested: flat ground, standing on a slight incline with the foot pronated, and standing on a slight incline with the foot supinated. Each position will be measured three times, with 1 practice trial allowed. The total time will be about 1 hour per subject.

e) Describe audio/visual procedures and proper disposal of tapes.

There will be no audio or video material in this study.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

Holly Augustine, Allison Biwer, Greg Jorgenson, & Mitch Kary are graduate students in the Physical Therapy program. Mark Romanick is an assistant professor faculty member in the Physical Therapy Department. All principle investigators are EMG trained.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

No compensation will be provided. Subject participation will be on a voluntary basis.

<u>Attachments Necessary:</u> Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

#### 3. Risk Identification.

a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

Although minimal, risk of injury is possible with any type of activity. This risk will be minimized through proper instruction prior to and during the study. The EMG equipment that will be used with each participant poses very little, if any risk to the participant. Keep in mind with EMG, there is no electrical shock administered to the subject. The incline the participants will be standing on is very low to the ground, resembling walking on an uneven surface. Walking on uneven surfaces is an everyday, functional activity for most individuals, posing a minimal chance for injury.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

All subjects will be linked to a consent form by a random number. This information will only be available to the principle investigators. This link will be necessary so the investigators can match each participant to their questionnaire involving lower extremity injuries that may affect the results.

c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.

There is minimal risk to subjects in this study, thus there is no need for a data monitoring plan.

d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multicenter study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.

Not applicable to our research study.

- 4. Subject Protection.
  - a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

The precautions that will be taken to ensure subject protection include using very finegraded sandpaper to abrade the areas where the electrodes will be placed. Numerous studies using EMG have lightly abraded the surface of the skin showing minimal adverse effects. The incline the subjects will be standing on will be very low to the ground, resembling walking on an uneven surface. Also, with EMG, it is important to remember that there is no electrical shock administered to the subject. The electrodes are only reading the amount of electrical activity a muscle produces.

b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

Subject confidentiality will be protected by assigning each subject a random number. All information will be linked only to this number with no identifying factors included.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

All subjects will be provided with a copy of the consent form before the subject will participate in the study.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study. Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)

2) who will have access to the data

3) how the data will be destroyed

4) the storage location of consent forms and personal data (separate from research data)5) how the consent forms will be destroyed

All records and research data will be saved for three years in locked separate locations.

- 1. All research data will be stored separately from the consent forms within the Physical Therapy Department.
- 2. Only the principle investigators will have access to this information.
- 3. All research data will be destroyed through means of shredding after three years.
- 4. All consent forms will be stored in locked cabinets within the Physical Therapy Department separate from the research data.
- 5. Consent forms will be destroyed through means of shredding after three years.
- e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

Although risk is minimal, in the unlikely chance of an injury occurring, all subjects will receive immediate attention. The researchers present will assist the injured participant in receiving emergency care in the city of Grand Forks, ND.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

By signing the consent form, subjects become liable for all medical expenses involved in any injury associated with participation in our study. If necessary, medical attention is available through various medical providers in the Grand Forks area.

#### III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

Subjects who participate will receive greater understanding of the hip muscles that are affected with altered foot position. This research will benefit the field of Physical Therapy by providing clinicians with information on how foot position affects the muscles of the hip and its possible implications on anterior cruciate ligament injuries.

#### IV. Consent Form

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. Please note: All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. The consent form should be written at no higher than an 8<sup>th</sup> grade reading level, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

#### -See Appendix A

#### Necessary attachments:

Signed Student Consent to Release of Educational Record Form (students only);

- Investigator Letter of Assurance of Compliance;
- Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- Surveys, interview questions, etc. (if applicable);
- Printed web screens (if survey is over the Internet); and
- Advertisements.

#### By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate, and that the project will be completed as indicated

#### Signatures:

(Principal Investigator)	Date:	
(Student Adviser)	Date:	
Requirements for submitting proposals: Additional information can be found on the IRB web site at www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html.		

Original Proposals and all attachments should be submitted to Research Development and Compliance, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to http:// http://www.und.edu/dept/rdc/regucomm/IRB/IRBEducation.htm for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the RD&C website regarding required copies and IRB review categories, or you may call the RD&C office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

## INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS

I (Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

- 1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)
- 2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.
- 3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Investigator Signature

Date

**STUDENT RESEARCHERS:** As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

# STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD<sup>1</sup>

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

NAID #

Printed Name

Date

Signature of Student Researcher

<sup>1</sup>Consent required by 20 U.S.C. 1232g.

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