AN ABSTRACT OF THE THESIS OF

Stephanie M. Cohen for the degree of Honors Baccalaureate of Science in Exercise and Sport Science presented on June 1, 2010. Title: Digit Span Ratio, Joint Laxity, and Muscular Strength as Predisposing Factors for Female ACL Injuries.

 Mark Hoffman

Abstract Body

Abstract approved:

Females more commonly injure their anterior cruciate ligament (ACL) in athletics than do males. Despite many studies researching anatomical, neuromuscular, and hormonal causes, the predisposing risk factors behind this occurrence are currently unknown. This study compared 5 females who had injured their ACL to 15 healthy females concentrating on three dependent variables. The first variable measured was digit span ratio of the second and fourth digits because previous studies suggest that this ratio is related to prenatal sex hormones that affect visual-spatial abilities. The next variable was knee joint laxity using an arthrometer to measure the stiffness of the ACL. The last variable tested was the muscular strength of the quadriceps and hamstrings using the Biodex dynamometer. The strength of these muscle groups is suggested in the literature to be a risk factor for ACL injuries because they protect the knee joint. After analysis, the three variables were not shown to be significantly different between the two female populations. Further research is needed to determine what factors predispose females to ACL injuries. Knowing these factors may allow for prediction of group membership for females who have torn their ACL and for females who have not.

Key Words: anterior cruciate ligament, digit span ratio, knee laxity, quadriceps-hamstring strength

Corresponding e-mail address: cohenst@onid.orst.edu

©Copyright by Stephanie M. Cohen June 1, 2010 All Rights Reserved

Digit Span Ratio, Knee Joint Laxity, and Muscular Strength as Predisposing Factors for Female Anterior Cruciate Ligament Injuries

by Stephanie M. Cohen

A PROJECT

submitted to

Oregon State University

University Honors College

in partial fulfillment of the requirements for the degree of

Honors Baccalaureate of Science in Exercise and Sport Science (Honors Scholar)

Presented June 1, 2010 Commencement June 2010

Stephanie M. Cohen, Author
I understand that my project will become part of the permanent collection of Oregon State University, University Honors College. My signature below authorizes release of my project to any reader upon request.
Dean, University Honors College
Chair, Department of Nutrition and Exercise Sciences
Committee Member, representing Exercise and Sport Science
Committee Member, representing Exercise and Sport Science
Committee Member, representing Exercise and Sport Science
Mentor, representing Exercise and Sport Science
APPROVED:
Honors Baccalaureate of Science in Exercise and Sport Science project of Stephanie M. Cohen presented on June 1, 2010.
Honors Baccalaureate of Science in Exercise and Sport Science project of Stephanie M.

TABLE OF CONTENTS

	Page
INTRODUCTION	1
Statement of Problem	2
Statement of Purpose	2
Statement of Hypothesis	3
Significance	3
REVIEW OF LITERATURE	4
Digit span ratio	5
Knee joint laxity	6
Hormones	7
Neuromuscular Control	7
METHODS	10
Subjects	10
Experimental Protocol	10
Statistical Analysis	13
RESULTS	14
DISCUSSION	16
BIBLIOGRAPHY	18
APPENDICES	
Appendix A Institutional Review Board Protocol	19
Appendix B Informed Consent	
Appendix C Health History Questionnaire	33

LIST OF FIGURES

1.	Digit span ratio.	age 11
2.	LigMaster	12
3.	Biodex dynamometer	13
4.	Female control results	15
5.	Female ACL results	15

Introduction

The anterior cruciate ligament (ACL) is the most commonly injured ligament of the knee. It is one of the four ligaments located in the knee that stabilize the joint. The ACL originates on the lateral condyle of the femur and inserts in the front of the intercondyloid eminence of the tibia. Specifically, it prevents the tibia from moving anterior to the femur and rotates the tibia on the femur. The understanding of how the stresses placed on the ACL cause it to rupture during noncontact movements, especially in the female athlete is currently unknown.

More females than males injure their ACL in athletics, despite the fact that there is a greater prevalence in men. ^{2, 3, 4, 5, 6} This difference in injury rates between the sexes has prompted researchers to examine intrinsic and extrinsic factors that may explain the discrepancy. There have been numerous studies investigating anatomical, hormonal, and neuromuscular factors in order to find an explanation for this difference. Many studies have also researched anatomic and neuromuscular sex differences, but there has not been sufficient evidence that the differences are contributing factors to female ACL injuries.

This study involved the testing of variables that are either known or suspected to be risk factors for ACL injury. The variables were tested in females who have sustained an ACL injury and the findings were compared to a control group of healthy females. The three dependent variables explored were digit span ratio, knee joint laxity, and muscular strength of the quadriceps and hamstrings.

Digit span ratio has been suggested to be related to prenatal testosterone and androgen levels, which play a role in visual-spatial abilities.^{7,8} Having good visual-spatial abilities is important for athletes to play sports with safer movements, because 70% of

ACL injuries are noncontact and occur from deceleration, anticipation of lateral movements, changing directions, or landing from a jump.^{2, 3, 4, 5, 9, 10}

The second variable, knee joint laxity, is the measurement of the stiffness of the ligaments between the femur and the tibia. More stiffness in the ligaments and muscles of the knee contribute to increased knee joint stability. Female muscle stiffness has been shown to be less than in males.¹

The last variable tested was the quadriceps-to-hamstrings strength ratio. The hamstrings are thought to stabilize the knee joint and reduce the stress put on the ACL because contraction of the quadriceps pulls the tibia anterior to the femur. Greater strength of the hamstrings could then better stabilize this movement. ¹⁰ The outcome of the tibia moving forward puts strain on the ACL since it resists that motion. Ideal hamstring strength would theoretically be greater or equal to the strength of the quadriceps. ¹¹

Statement of Problem

It remains unknown as to why females have a higher incidence of ACL injury than males. ²

Statement of Purpose

While the reason females injure their ACL more commonly than males is unknown, the factors of digit span ratio, joint laxity, and strength of the quadricep and hamstring muscle groups may be influencing factors on female ACL injuries. The purpose of this study is to determine if the three variables being measured are different in groups of women who have torn their ACL and those who have not.

Statement of Hypothesis

We hypothesize that the variables measured in this study will be different between female subjects who have previously injured their ACL and those who have not. Significance

Understanding whether the measurements of potential risk factors are different between groups of injured and uninjured females may be helpful in the development of ACL injury prevention programs. Females competing in athletics could be tested to find anatomical risk factors. Also, knowledge of neuromuscular risk factors can assist in prevention programs to decrease the likelihood of an ACL injury in those who have a risk factor. Knowledge of risk factors for ACL injuries may help prevent injuries from happening in the future.

Review of Literature

More men injure their ACL than women, yet females are 2-8 times more likely to injure their ACL than males in athletics. ^{4,5,6,9,11} Over 80,000 people injure their ACL each year in the United States, meaning that one in every 1,750 people injure their ACL, with more than 10,000 ACL injuries occurring in female collegiate athletes each year. ACL injuries primarily occur in individuals 15-25 years old. ⁴ The cost of ACL reconstruction is approximately \$17,000 for the patient and approximately 50,000 reconstructive surgeries are performed each year. ^{4,5,6}

Females were found to injure their ACL 3.5 times more than males in basketball and 2.8 times more than males in soccer.² There are over 15,000 knee injuries in female collegiate athletes each year.⁴ After studying the injuries from three NCAA conferences during the 1988-1989 and 1989-1990 seasons, female basketball players were found to be 6.1 times more likely to injure their ACL than males.⁹

These statistical differences between men and women have created a need to find the risk factors which predispose women to ACL injuries. There are most likely many risk factors for noncontact ACL injuries.² Potential risk factors for noncontact injuries may be anatomical, environmental, hormonal, and biomechanical (which includes muscular strength, neuromuscular control, skill level).^{3, 6, 10}

Anatomical sex differences between men and women include the size differences in the femoral notch and ACL. Females also have increased femoral anteversion and Q angle, and excessive tibial torsion and foot pronation. A study comparing healthy and injured females found that femoral anteversion does not affect ACL injuries, but the

thigh-foot angle may. These anatomical differences between sexes have not been found to have a significant impact on ACL injuries. 9

Digit Span Ratio

Previous research has shown that a greater digit span ratio may be related to a greater visual-spatial abilities, which males perform better at than women. ^{7,8} It is also theorized to be related to numerical ability, perception of dominance, improved performance of the left hand, and increased masculinity. ⁷ Masculine qualities of aggressiveness and competitiveness thought to be associated with the digit span ratio are common qualities of athletes. ⁸ The way prenatal testosterone levels actually affect athletic performance is unknown. Prenatal testosterone is also thought to affect the formation of the cardiovascular system, explaining why there had been reports of a relationship between digit span ratio and physical fitness. ⁷

Performance in athletics has been shown to possibly have a relationship with prenatal testosterone levels. Tester and Campbell⁷ researched four personality traits and one cognitive ability that are related to athletes in order to determine if a relationship exists between digit span ratio and athletic performance. The four personality variables were social potency (persuasiveness, leadership, social personality, and decisiveness), harm avoidance (not participating in risky or dangerous activities), achievement (hardworking, perfectionist, and motivated), and control (cautious, rational, anticipation, and planning). These variables were seen as important because men have been found to have a more dominant and assertive personality than women, contact sports involve some dangerous situations, and elite athletes were found to have significantly high motivation, females being higher than males. Mental rotation was a variable to measure visual-spatial ability. Males have higher levels of visual-spatial ability in accuracy and speed. Males

tend to have longer ring fingers than index fingers, therefore having a lower digit span ratio. This study expanded on previous research to compare sex differences with the five variables compared to digit ratio. The four personality traits did not show any relationship to digit span ratio. There was no association between digit span ratio and visual-spatial abilities, despite a previous study's findings of a relationship. They also determined that using more than one digit ratio has been shown to be unreliable (using the left, right, and both) in the same study.⁷

Studies looking at the prenatal androgen levels in female rats have found that increased levels lead to increased aggressiveness. It is suggested that female athletes may have had high prenatal androgen levels leading to their competitiveness. In contrast to the study by Tester and Campbell, they found lower 2D:4D ratios in elite female athletes compared to non-elite athletes. These results were found in the left hand only. Athletic performance is determined, not only by visual-spatial abilities, but by multiple factors including height and weight, intensity of training, experience, and practice. The second of training is determined.

Knee Joint Laxity

Joint laxity is the measurement of stiffness of the ligaments in the joint. When a force from an arthrometer is applied to the back of the tibia, the end segments of the joint move apart. The displacement from the force of the tibia moving anterior to the femur measures the apparent stiffness of the ACL. Females tend to have more laxity in their knees than males. Yet, hypermobility of the knee as a potential risk factor still needs to be further researched.⁶ There is conflicting evidence that knee laxity causes ACL injuries. Some studies have found a relationship between increased laxity and increased ACL injuries, while others have not.¹¹ Knee laxity has been shown to increase 18-20% after 30

minutes of jogging and playing basketball.⁶ It then returns to normal after 60 minutes. Laxity was shown to decrease with age and maturity more significantly in males.¹¹ Females did not show a decrease in knee laxity with age.¹¹ There is not sufficient evidence yet that knee joint laxity is a predisposing factor of female ACL injuries.⁶ *Hormones*

Hormones have been suggested to cause neuromuscular and musculoskeletal changes. Studies have researched the effect of estrogen receptors located in the ACL to determine if they cause a change in knee joint laxity with changing estrogen levels. A relationship between sex hormone concentrations and anterior tibial displacement was not found, and the correlation was near zero. This reinforces the findings of many previous studies on hormones and knee laxity.³

In contrast, Park and colleagues observed an increase in knee joint laxity in healthy female participants during ovulation. ¹² They believe hormones do influence knee joint laxity, but further research is required. There is currently no significant evidence that fluctuating hormones or hormone interventions decrease the risk of ACL injuries. ⁶ Neuromuscular Control

Griffin and colleagues believe the primary goal of knowing the risk factors involved in female ACL injuries is to develop prevention programs. These programs train neuromuscular patterns in individuals. Neuromuscular training is currently thought to decrease the incidence of ACL injuries. Hewett and colleagues researched neuromuscular variables, knee joint angles, and joint loads during a jump landing with female athletes in soccer, basketball, and volleyball. They found significant differences in

knee abduction angles between ACL injured and healthy individuals, yet leg dominance did not prove to be a risk factor. ¹⁰

In a different study, Hewett and colleagues sent instructional videos and training manuals to coaches for a neuromuscular training program during 6-weeks in the preseason. The videos focused on flexibility, plyometics, weight training to increase muscular strength and prepare for landings, and using proper body mechanics. The three groups studied consisted of trained females, untrained females, and untrained males. The trained females and untrained males who obtained a knee injury were not significantly different. The untrained females were injured 3.6 times more than the trained females and 4.8-5.8 times more than the untrained males, while the trained females were injured 1.3-2.4 times more than untrained males. The effect of training in females was statistically significant. The training could have been successful because it improves the quadricephamstring strength ratio and because it decreases abduction and adduction at the knee, but both factors still need to be further researched.⁵

Integrating ideas used for treatment programs, such as landing safely, into physical education classes could be beneficial in neuromuscular programming. As children get older, emphasizing improved performance is important for treatment programs because most athletes feel immune to injuries and may not take part just for injury prevention.²

Prevention programs involving proprioception and neuromuscular control seem to have an influence on decreasing the risk of injuring the ACL, but they still need to be continually improved. They should be sport-specific and may simultaneously increase athletic performance.⁶ They should also be fast-paced, sport-specific, teach proper

biomechanics, control of center of mass, sport-specific balance drills, consistent analysis and feedback from an athletic professional, plyometics, increase muscular strength, and control over deceleration of center of mass. ^{4,6} Previous studies have also shown that neuromuscular training can decrease the incidence of ACL injuries in male athletes. More understanding of the prevention programs can make these programs even more effective than they already appear to be. ⁹

Methods

Subjects

The two groups of females tested were 15 females who have not had a previous ACL injury and 15 who have. The participants needed to be between the ages of 18 and 35. The ACL injury must have occurred in the last 10 years and surgery for the reconstruction of the injury must have taken place at least one year before.

Experimental Protocol

The study's protocol was submitted to the Institutional Review Board of Oregon State University to gain approval for testing human subjects. One testing session took place for each participant in the Sports Medicine Laboratory. Each participant signed an informed consent form and filled out a questionnaire about her health history. Leg dominance was then tested by performing three activities: kicking a soccer ball, taking a step up, and balance recovery. Whichever leg they used two times in these three activities was recorded as their dominant leg.

A coin toss determined the order of the hand measured first for the digit span ratio, the leg measured first for knee joint laxity, and the leg and the muscle group (the quadriceps or the hamstrings) tested first for isometric muscular strength. To measure digit span ratio, the experimenter sat across the table from the participant. The participants rested their arm on a bolster, with their palm up. Their fingers were marked with a pen where the measurements were to be taken from the first crease to the tip of the finger and were immediately measured (Fig. 1). Three consecutive measurements were taken on each finger using veneer calipers, starting with the second digit. The

measurements taken from each finger were averaged. The same person measured the digit span in a single session.



Fig. 1 Digit span ratio

Knee joint laxity was measured next using a LigMaster to measure the apparent stiffness of the ACL. The subject was placed on the side that was being measured and rested their opposite leg directly anterior. A pillow supported the opposite leg in order to keep the hips straight on top of each other. The LigMaster was adjusted to fit the participant. The top bar was placed two finger widths above the knee and the bottom bar was placed anterior to the ankle joint. The device that puts force on the tibia was placed directly above the belly of the gastrocnemius. The experimenter gradually applied 130 Newtons of force to the tibia via the LigMaster. This pushes the inferior portion of the joint forward, moving the tibia anterior to the femur. Three trials were obtained for both the right and left legs. Only the second and third trials were averaged and used for analysis.

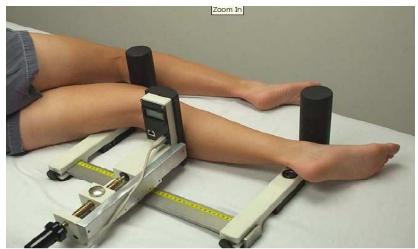


Fig. 2 LigMaster

The subject then warmed-up on a stationary bike for five minutes. Each participant sat on a Biodex System 3 dynamometer and was secured with straps to prevent movement from other muscles from assisting the strength of the quadriceps or the hamstrings (Fig. 3). The Biodex knee attachment was positioned at 60 degrees of knee flexion for isometric contractions. The knee joint was lined up with the fulcrum of the Biodex attachment by adjusting the position of the chair. The participant was instructed to either flex their knee joint to measure the strength of the hamstrings or extend their knee to measure the strength of their quadriceps after a cue from a light stimulus directly in front of them. They also kept their arms crossed on their chest. The first three isometric contractions were performed as hard and as fast as possible. There was a series of three trials with at least 60 seconds of rest in between. Then the participant was instructed to perform a maximal contraction at her own pace, without using a light stimulus. The opposite muscle group was then tested, using the same instructions. After all the strength measurements were taken on one leg, the next leg was tested. The Biodex needed to be

readjusted to line up with the knee joint of the opposite leg, and the same steps were taken.



Fig. 3 Biodex dynamometer

Statistical Analysis

Four of the five females who injured their ACL, injured their dominant leg, therefore analysis of the data focused on the results from the dependent variables on the nondominant and uninjured leg for the ACL stiffness and muscular strength ratio. The nondominant hand was analyzed for digit span ratio. The ACL stiffness was found from the slope of the ACL load-displacement curve. T-tests were used to evaluate mean differences for each dependant variable and the alpha level was set at 0.05.

The data from control number 9 was not used. Control number 9 was considered an outlier because her hamstring strength was significantly larger than her quadricep strength, which is atypical. Because of this outlier, a sixteenth control was recruited to make a total of 15 healthy female participants for the analysis of data.

Results

The data for all the control participants are in figure 4, and the data for the ACL injured participants are in figure 5. The ratio between the lengths of the second and fourth digits in the nondominant or uninjured hand did not differ between females who inured their ACL and did not (p = 0.76). The mean ratios of the two groups were the same (x = 0.99). The ACL stiffness in the nondominant or uninjured leg did not vary between the two groups of females (p = 0.30). The mean ACL stiffness of the control females (x = 16.65) was slightly lower than the ACL injured females (x = 17.68). The last variable, the ratio of the maximal isometric strength of the quadriceps and hamstrings in the nondominant or uninjured leg also did not differ between the groups (p = 0.15). The mean quadriceps to hamstring strength ratio of the control females (x = 0.65) was slightly higher than the ACL injured females (x = 0.52).

	Height (cm)	Weight (kg)	Age	Leg Dom	ND Digit Ratio	ND ACL Stiffness	ND Q:H
Con_01	168.28	63.10	22	R	0.93	20.25	0.53
Con_02	168.40	61.80	26	R	1.00	16.49	0.68
Con_03	174.30	65.30	20	R	0.95	14.36	0.47
Con_04	158.10	51.70	22	R	1.01	16.59	0.68
Con_05	171.00	61.60	22	L	0.99	15.00	0.57
Con_06	174.00	80.00	22	L	1.05	17.99	0.67
Con_07	174.00	91.90	22	R	1.06	14.71	0.41
Con_08	164.00	80.50	24	R	1.01	16.61	0.75
Con_09							
Con_10	173.50	67.50	19	R	0.99	18.14	0.88
Con_11	168.00	49.30	21	R	0.99	16.79	0.58
Con_12	169.20	57.30	21	R	0.98	17.67	0.93
Con_13	167.00	78.00	19	R	0.99	16.81	0.64
Con_14	163.80	61.30	20	R	0.97	15.06	0.65
Con_15	172.20	64.00	23	R	0.98	17.23	0.48
Con_16	165.60	48.90	22	R	0.98	17.23	0.45
Mean	168.74	66.87	21.54		0.99	16.65	0.65
Stdev	4.72	11.92	1.91		0.024	1.58	0.15

Fig. 4 Female control results

	Height	Weight	Age	ACL Leg	Leg Dom	Uninj Digit Ratio	Uninj ACL Stiffness	Uninj Q:H
ACL_01	161.30	57.60	19	L	R	0.98	16.10	0.61
ACL_02	168.20	73.50	22	R	R	0.96	20.20	0.45
ACL_03	164.30	72.70	22	R	R	1.02	17.22	0.47
ACL_04	173.40	66.30	26	R	R	0.99	17.22	0.55
ACL_05	158.60	53.90	21	R	R	0.88	18.73	0.55
Mean	166.80	67.53	22.25			0.99	17.68	0.52
Stdev	5.23	7.36	2.87			0.03	1.76	0.07
t test	0.44	0.89	0.62			0.76	0.30	0.15

Fig. 5 Female ACL results

Discussion

There is a need to research females who have already injured their ACL because of the lack of previous research on this population in order to find possible risk factors for ACL injuries. This study measured digit span ratio, ACL stiffness, and quadriceps to hamstring strength ratio to determine if these variables differ between females who have injured their ACL and females who had not.

None of the p-values were below the alpha level of 0.05. The p values of the nondominant ACL stiffness and muscular strength ratio were lower than that of the digit span ratio. The digit span ratio between the control and injured groups appeared to be very similar. The slight difference between the p values suggests that ACL stiffness and the muscular strength ratio are more likely to be contributing factors of female ACL injuries. There was no significant difference for the digit span ratio, ACL stiffness, and strength ratio between the control and ACL injured group.

Digit span ratio did not differ between the two groups, but ACL stiffness and the quadriceps to hamstring strength ratio did. The control females had less ACL stiffness than the ACL injured females. These results were not expected because if ACL stiffness is a risk factor for ACL injuries, the ACL stiffness is thought to be less. The results for the quadriceps to hamstring muscular strength were also unexpected. The ACL injured females had a lower ratio, suggesting that their hamstrings are stronger than their quadriceps when compared to the control group. Having strong hamstrings are thought to be ideal in order to stabilize the knee joint. The results from the quadriceps to hamstring strength ratio show there needs to be research on other factors related to hamstring strength. The rate of force development of the hamstrings is a variable that needs to be

further researched in order to determine if rapid contraction of the hamstrings is more beneficial than the muscular strength of the hamstrings.

The sample size of ACL injured participants was small. Further research is necessary to determine if these variables are risk factors for female ACL injuries and need to recruit more participants in order to gain more knowledge about the larger population. Future research should explore the relationship between the muscular strength ratio and ACL injuries in healthy and ACL injured females.

Knowledge of risk factors for female ACL injuries will not only increase understanding of the mechanisms behind the injuries, but also assist in prevention of future injuries. Patients incur significant financial, emotional, and physical burdens from ACL injuries, therefore understanding the mechanisms behind ACL injuries is important. 6

Bibliography

- 1. Hurd, W, Axe, M, and Snyder-Macker, L. Influence of age, gender, and injury mechanism on the development of dynamic knee stability after acute acl rupture. Journal of Orthopedic Sports Physical Therapy 2008; 38: 36-41.
- 2. Ireland, M. The female ACL: why is it more prone to injury? Orthopedic Clinics of North America 2002; 33: 637-651.
- 3. Hoffman, M. et al. The interrelationships among sex hormone concentrations, motoneuron excitability, and anterior tibial displacement in women and men. Journal of Athletic Training 2008; 43: 364-372.
- 4. Hewett, T. et al. Dynamic neuromuscular analysis training for preventing anterior cruciate ligament injury in female athletes. Instructional Course Lectures 2007; 56: 397-406.
- 5. Hewett, T. et al. The effect of neuromuscular training on the incidence of knee injury in female athletes. American Journal of Sports Medicine 1999; 27: 699-706.
- 6. Griffin, L. et al. Noncontact anterior cruciate ligament injuries: risk factors and prevention strategies. Journal of the American Academy of Orthopaedic Surgeons 2000; 8: 141-150.
- 7. Tester, N, Campbell, A. Sporting achievement: what is the contribution of digit ratio? Journal of Personality 2007; 75: 663-667.
- 8. Pokrywka L, Rachon D. The second to fourth digit ratio in elite and non-elite female athletes. American Journal of Human Biology 2005; 17: 796-800.
- 9. Ireland, M. Anterior cruciate ligament injury in female athletes: epidemiology. Journal of Athletic Training 1999; 34: 150-154.
- 10. Hewett, T. et al. Biomechanical measures of neuromuscular control and valgus loading of the knee predict anterior cruciate ligament injury risk in female athletes. American Journal of Sports Medicine 2005; 33: 492-501.
- 11. Ahmad C. Effect of gender on maturity on quadriceps-to-hamstring strength ratio and acl laxity. American Journal of Sports Medicine 2006; 34: 370-374.
- 12. Park, S. et al. Changing hormone levels during the menstrual cycle affect knee laxity and stiffness in healthy female subjects. The American Journal of Sports Medicine 2009; 37: 588-98.

APPENDIX A

Institutional Review Board Protocol

RESEARCH PROTOCOL

2-25-2010

1. Protocol Title Comparison of women who have and have not torn their ACL

PERSONNEL

2. Principal Investigator Mark Hoffman, PhD, ATC

3. Student Researcher(s)

4. Co-investigator(s) Sam Johnson, PhD, ATC

5. Study Staff Erica Perrier, Jeff Doeringer, Marie Zidek, Allison Fisher,

Stephanie Cohen

6. Investigator Qualifications:

Drs Hoffman and Johnson are published scholars in the area of neuromuscular control with expertise in all data collection techniques. Graduate students: Perrier, Doeringer, and Zidek, have all conducted studies in the Sports Medicine Laboratory under the supervision of Dr Hoffman. Each of these students will assist in: recruiting, consenting, and data collecting as well as data analysis. At no time will they collect data using a technique in which they have not been trained. The undergraduate students (Fisher and Cohen) will be involved in recruiting and subject preparation but at no time will be the primary person responsible for collection of any data.

7. Student Training and Oversight:

The PI will ensure that all data collected is being collected by an individual specifically trained for that technique. In the absence of the PI, the co-investigator, Dr. Johnson will be responsible for oversight of all issues related to the project including the protection of human subjects.

DESCRIPTION OF RESEARCH

8. Description of Research:

In very general terms, we wish to determine if the variables being measured in this study in both an injured and an un-injured population can serve as predictors for who has sustained a rupture to the anterior cruciate ligament (ACL) of the knee. To date, several potential risk factors for this injury have been identified but many of them have not been investigated in an injured population in an attempt to determine their strength in prediction of injury. We plan to obtain consent and test a group of females that have sustained a rupture to the ACL and a group that has not sustained the injury. The sample will be representative of the population demographic that most often suffers this type of injury. The data collection will require a single testing session in the Sports Medicine Laboratory on the campus of Oregon State University.

At the conclusion of this study we plan to analyze the data and submit it for publication as well as utilize it as support in grant applications. The aim of this study is to:

Determine to what extent the neuromuscular and skeletal variables measured in this study are able to predict group membership for females who have torn their ACL and for females who have not torn their ACL.

We hypothesize that the variables chosen for this study will be predictive of ACL injury group membership.

9. Background Justification: For several years it has been known that females experience more ruptures of the anterior cruciate ligament (ACL) than do comparison males. However, research has yet to clearly identify the predisposing factors responsible for this injury rate discrepancy. We believe that one major shortcoming of the past and current research has been the lack of investigations of individuals who have sustained the injury. Typically healthy individuals have been tested in an effort to determine if a sex difference can be identified with the expectation that any identified sex difference could be a precipitating factor for this injury. We believe a paradigm shift is required in that females who have sustained the injury should be evaluated to determine if any existing characteristics can serve as predictive factors.

10. Subject Population and Recruitment

- In this study we plan to test **females** who have and who have not sustained a non-contact ACL rupture. Due to natural progression of joint degeneration after the injury and changes over time with age, the age range of participants will be between 18 and 35 years of age. Participation in the study will not be restricted to any ethnic group.
- For inclusion in the injury group the injury must have occurred in **the past 10 years and the reconstruction of the injury cannot be more recent than one year**. A non-contact injury will be defined as an ACL injury that occurred due to a cutting or landing maneuver and is not the result of being hit by another person or object.
- For inclusion in the non-injured group the subject must have no history of a serious knee injury that has required the use of crutches for more than 3 days.
- The total number of subjects to be recruited for this study will not exceed 50 participants.
- The exclusion criteria are:

Having neurological or musculoskeletal condition that prevents participation in activities of daily living.

INJURY GROUP: have a history of ACL injury on more than one leg

NON-INJURED GROUP: have a history of any knee injury requiring the use of crutches for more than 3 days.

- The following steps will be taken during the study in the order presented:
 - o Subjects will be recruited.
 - Subject will provide informed consent in the laboratory (Rm 8 of the Women's Building) upon arrival for their single day of testing.
 - o Assessment of Digit Span Ratio.

- o Assessment of Knee Joint Laxity.
- Assessment of Strength and Muscle Activation.
- During the conversations related to recruitment, subjects will be informed that they will not be
 able to participate in data collection if they have exercised within the past 12 hours and/or if
 they have any lingering muscle soreness related to physical activity.
- The following text will be utilized in an informational flyer to be posted on the OSU campus, health and fitness facilities in Corvallis, and possibly on social advertising sites such as Craigslist.
 This information is for recruitment of subjects in the injured cohort only and subjects in the control cohort will be recruited by word of mouth in the OSU and Corvallis community.
 - Comparison of women who have and have not torn their Anterior Cruciate Ligament
 - We are recruiting Females who have had ACL reconstruction surgery
 - If you have had ACL reconstruction surgery and:
 - The injury occurred no longer than 10 years ago.
 - The reconstruction of the ACL is not more recent than 1 year.
 - Have injured only one of your ACLs.
 - Are between the ages of 18 and 35.
 - You may qualify for this study.
 - Please contact Mark Hoffman PhD or a member of the research team in the Sports Medicine Laboratory at 541 737 7899
- The word of mouth recruitment will take place by research study team members and individuals
 that have participated in the study. During word of mouth recruitment the information
 presented will be the information provided in the recruitment flyer.

11. Consent Process

The consent process will be as follows:

During the first conversation related to the study, the participants will be asked if they generally believe they meet the inclusion criteria as posted or explained to them during word of mouth recruitment. No personal or sensitive data will be collected or recorded prior to screening. If they believe they qualify, an appointment will be scheduled.

Subjects will arrive at the Sports Medicine Laboratory and be greeted by one of the study team members. They will be given a copy of the informed consent document and be seated in a quiet area where they can read and consider the information on the form. A study team member will be available during this process to answer questions.

During the process, the study team member will be available to answer questions but also to have a conversation with the subject to ensure they understand the scope of the study and the details of the procedures.

If the subject signs the informed consent document, they will be offered a copy of the signed

document. If they choose not to enroll they will be asked if they have other questions and then be dismissed. (Estimated maximum time 10 minutes)

12. Eligibility Screening:

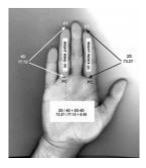
Comprehensive screening for inclusion and exclusion criteria will take place after the consent process. A screening document will be completed jointly by a study team member and the subject (attached). If an individual screen fails, their file will be closed and the information will be retained with all study documents, but their individual data will not be used for study purposes. (Estimated maximum time 5 minutes)

13. Methods and Procedures:

Methods for Digit Span Ratio Assessment

In general, the digit span ratio is believed to be influenced by prenatal sex hormones and may be related to the following: athletic performance, visual spatial awareness.

- The subject will be seated next to the examiner at a conference type table.
- 2 to 4 measurements will taken on the 2nd and 4th digit of both hands.
- The measurement locations (tip of finger 2 and 4 and crease of finger 2 and 4) will be marked by a small dot with a permanent marker.
- A veneer caliper will be used to directly measure digit length.
- The veneer caliper tips will be placed at the base of the digit (at the first crease) and at the finger tip.
- Each measurement will be recorded immediately after it is taken.
- (Estimated maximum time 10 minutes).

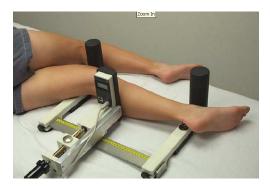


Method for Knee Joint Laxity Assessment

Every joint of the body has some laxity (looseness between the bones of the joint). It is suspected that knee joint laxity may vary across the menstrual cycle and may play a role in ACL injury. Laxity is measured by a device called an arthrometer that applies a safe level of the force across the joint and then measures the magnitude of the movement that occurs between the bones. In the case of the knee, the force is applied to the back of the calf resulting in forward movement of the tibia (shin bone). To perform this measurement the following steps

will be followed:

- The subject will be asked to change into shorts if they are not currently wearing them.
- The subject will have the laxity (amount of movement between the bones of the knee)
 assessed on both legs. Between 3 to 5 assessment trials will be conducted on both legs.
 The name of the device used in this assessment is the LigMaster
 (http://www.sporttech.com/).
- Subject will be placed in a side-lying position on an examination table with leg closest to the table positioned in the testing apparatus.
- A force not exceeding 130 Newtons will be gradually applied to the back of the leg to tighten the ligaments of the knee while the amount of displacement of the bones is being measured. This is an instrumented approach that mimics a commonly used clinical test called the Lachman's test.



- Following the completion of the test on one leg, the opposite leg will be tested.
- (Estimated maximum time 20 minutes).

• Method for Strength Assessment

The strength assessment will be completed on the Biodex dynamometer. The maximal strength will be assessed on the quadriceps (front of the thigh) and the hamstrings (back of the thigh) of both legs. Prior to strength testing, the participant will warm-up on a stationary bike for 5 to 10 minutes at a light resistance. Next, participants will be positioned in a seated position on the Biodex dynamometer with the test leg's hip at ~90 degrees of flexion and knee at ~60 degrees. The subject will be secured in the device with a series of straps.



The testing will consist of having the subject provide a maximal strength effort as quickly as possible in response to a light stimulus. This will happen 3 to 5 times for each muscle group with at least 60 seconds of rest between contractions. The order of muscle group testing will vary between subjects. In addition to the rapid response trials, the subject will be asked to provide a slow-ramped maximal effort 2 times for each muscle. Again there will be at least 60 seconds rest between trials. A sample testing order is provided here:

<u>First Test Leg</u>			
1	3 to 5 rapid QUADRICEPS contractions with rest between contractions		
2	2 slow ramped QUADRICEPS contractions with rest between contractions		
3	3 to 5 rapid HAMSTRINGS contractions with rest between contractions		
4	2 slow ramped HAMSTRINGS contractions with rest between contractions		
Second Test Leg			
1	3 to 5 rapid QUADRICEPS contractions with rest between contractions		
2	2 slow ramped QUADRICEPS contractions with rest between contractions		
3	3 to 5 rapid HAMSTRINGS contractions with rest between contractions		
4	2 slow ramped HAMSTRINGS contractions with rest between contractions		

(Estimated maximum time 30 minutes)

- General Method Considerations
 - Following data collection small amount of data processing will be conducted prior to the data being subjected to statistical analysis. The time commitment for the subject is not expected to exceed 90 minutes.
- 14. Compensation: There will be no compensation for participation.
- 15. Cost: There are no foreseeable costs.
- 16. Anonymity or Confidentiality:
 - All information stored on Data Collection Systems (Knee Laxity and Strength), will be subject coded and not individually identifiable.
 - All identifiable subject data (name, email address, phone number, etc.) will be kept in a locked office where access will be limited to sports medicine laboratory researchers. The data will be kept for a minimum of 3 years after the close of the IRB file.

17. Risks:

- The risks associated with the testing in this study do not exceed those experienced in routine
 examination of the musculoskeletal system. The strength testing is commonly conducted in the
 rehabilitation setting and the knee ligament assessment is commonly done in the orthopedic
 setting. Specifically, the strength testing and the laxity testing are techniques commonly used in
 the post operative assessment of individuals who have undergone reconstruction of the ACL.
 Multiple study members (Hoffman, Johnson, and Doeringer) are certified athletic trainers and
 licensed in the state of Oregon to practice athletic training.
- The laxity testing device used in this protocol was designed for the assessment of individuals who have sustained an acute ACL injury or have had a reconstruction of the ACL. As far as the

strength testing, typically individuals with an ACL reconstruction are cleared after 3 months to have a strength assessment. As clinicians of sports medicine, we are not aware of any limitations that would prevent this type of testing on a post surgical patient that is 1 year post.

- Part of the information to be gained from this study is to compare the individuals in the groups but also to have information related to the injured limb in order to assess changes that may have resulted due to the injury. We contend that none of the procedures in this study extend beyond the low risk that patients with this condition would experience in the rehabilitation of this condition.
- There is an additional risk of breach of confidentiality that will be minimized through our data storage procedures. All data will be securely stored on campus.
- Subjects will be informed during the consent process as to whom to contact if they experience study related problems. Additionally, the study team members will report to the PI who will in turn notify the IRB office if an adverse event or unexpected problem occurs.
- 18. Benefits: There are no direct benefits to the subjects participating in this study, but the potential contribution of these findings to the body of literature of ACL injuries could impact the understanding of the injury that all in the injured group has experienced.
- 19. Assessment of Risk: Benefit ratio: The risk to the subjects is minimal and the potential benefit to society is great.

APPENDIX B

Informed consent

INFORMED CONSENT FORM

Project Title: Comparison of women who have and have not torn their Anterior

Cruciate Ligament (ACL)

Principal Investigator: Mark Hoffman, PhD, ATC

Student Researcher:

Co-Investigator(s): Sam Johnson, PhD, ATC

Sponsor: None

1. WHAT IS THE PURPOSE OF THIS FORM?

This form contains information you need to help you decide whether to be in this study or not. Please read the form carefully and ask the study team member(s) questions about anything that is not clear.

2. WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if we can identify variables that will help us predict who is susceptible to anterior cruciate ligament (ACL) injury, one of the major ligaments of the knee. We plan to take measurements on females who have torn their ACL and females who have not torn their ACL to see if these measurements are predictive of who has a history of ACL injury. If we are able to identify who might tear their ACL, we may be able to prevent the injury.

Up to 50 women will be invited to take part in this study.

3. WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?

You are being invited to take part in this study because you are a female between the age of 18 and 35 and have sustained an ACL rupture or you meet the criteria for being a subject in the control group, which includes being between the age of 18 and 35 and have not sustained an injury to your ACL.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you decide to participate in this study after reading and signing the form, you will be tested on a variety of measures we have identified as potentially related to tearing the ACL. We don't expect that the testing (including this consent process) will exceed 90 minutes. The testing procedures (3) are as follows:

Assessment of Digit Span Ratio

In general, the digit span ratio is believed to be influenced by prenatal sex hormones and may be related to things such as: athletic performance, visual spatial awareness.

- You will be seated next to the examiner at a conference type table.
- 2 to 4 measurements will be taken on the 2nd and 4th digit of both hands.
- The measurement locations (tip of finger 2 and 4 and crease of finger 2 and 4) will be marked by a small dot with a permanent marker.
- A measuring caliper will be used to directly measure your finger length.
- The caliper tips will be placed at the base of the digit (at the first crease) and at the finger tip.

Assessment of Knee Joint Laxity

Every joint of the body has some laxity (looseness between the bones of the joint). It is suspected that knee joint laxity may vary across the menstrual cycle and may play a role in ACL injury. We measure laxity with a device called an arthrometer, that applies a safe level of force across the joint and then measures the amount of movement between the bones. This device has been designed to test people who have injured their knee and for the exam of people after they have had surgery to measure the strength of the knee ligaments. During this study, the force will be applied to the back of the calf resulting in forward movement of the tibia (shin bone). To perform this measurement the following steps will be followed:

- You will be asked to change into shorts if not currently wearing them.
- You will be placed in a side-lying position on an examination table with leg closest to the table positioned in the testing apparatus.
- You will have the laxity (amount of movement between the bones of the knee) assessed on both legs. Between 3 to 5 trials will be conducted on both legs.

• Assessment of Leg Strength

The strength assessment will be completed on a machine called the Biodex Dynamometer. This device is similar to strength training machines found in exercise gyms. Your maximal strength will be assessed on the Quadriceps (front of the thigh) and the Hamstrings (back of the thigh) of both legs. This type of testing is also commonly used for people who have had knee injuries and in rehabilitation for that injury. Prior to strength testing, you will warm-up

on a stationary bike for 5 to 10 minutes at a light resistance. Next, you will be positioned in a seated position on the Biodex dynamometer and secured in the device with a series of straps.

This test will consist of having you provide a maximal strength effort as quickly as possible in response to a light. This will happen 3 to 5 times for each muscle group with at least 60 seconds of rest between trials. In addition to the rapid response trials, you will be asked to provide a slow-ramped maximal effort 2 times for each muscle. Again, there will be at least 60 seconds rest between trials.

Storage and Future use of data or samples:

Information from this study may be used in published reports. At no time will any of your individually identifiable data be used in those reports. All study related information will be kept in a secure location for a minimum of 3 years after the completion of the study.

Future contact: We may contact you in the future for another similar study. You may ask us to stop contacting you at any time.

Study Results: There is no plan for formal reporting of study findings to each of the subjects in this study, but we will be happy to discuss any relevant findings with you at the end of the data collection. .

5. WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?

The possible risks and/or discomforts associated with being in the study are minimal and include and do not exceed those experienced in routine examination of the musculoskeletal system.

- Slight chance for muscle soreness due to the strength testing and muscle ligament testing.
 This soreness should resolve within 24 hours and can be lessened by light physical
 activity and stretching. Additionally the possibility exists that you may feel fatigued
 during the strength testing although this will be minimized by the rest between trials of
 the testing.
- Potential breach of confidentiality of the personal information you provide.

6. WHAT HAPPENS IF I AM INJURED?

Oregon State University has no program or plan to pay for research-related injuries. If you think that you have been injured as a result of being in this study, please contact Dr. Hoffman at 541-737-6787.

6. WHAT ARE THE BENEFITS OF THIS STUDY?

This study is not designed to benefit you directly but the potential contribution of these findings to active people in the future is substantial.

7. WILL I BE PAID FOR BEING IN THIS STUDY?

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

9. WHO WILL SEE THE INFORMATION I GIVE?

The information you provide during this research study will be kept confidential to the extent permitted by law. Research records will be stored securely and only researchers will have access to the records. Federal regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

If the results of this project are published your identity will not be made public.

10. WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this research project, please contact: Mark Hoffman, 541-737-6787.

If you have questions about your rights or welfare as a participant, please contact the Oregon State University Institutional Review Board (IRB) Office, at (541) 737-8008 or by email at IRB@oregonstate.edu

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.

12. WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Participant's ID code:	
Participant's Name (printed):	
(Signature of Participant)	(Date)
(Signature of Person Obtaining Consent)	(Date)

Your signature indicates that this 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.

APPENDIX C

Health History Questionnaire

Comparison of women who have and have not torn their ACL Screening Tool

Please answer the following questions:						
1)	Date of Birt	h:				
2)	Are you cur	rently being treated for any neurological disorder? Yes / No				
3)	Have you ever had a leg injury (strain, sprain, fracture) requiring the use of crutches for 3 or more days? Yes /					
	No					
4)	Do you exe	rcise at least 30 minutes/day, 3 days/week? Yes / No				
5)	Have you p	reviously torn your ACL? Yes / No				
	a.	Estimated date of injury:				
	b. Estimated date/method of surgical repair:					
	c. How did the injury happen?					
If a	If all criteria above are met, assign a subject ID number:					