KEEPING ATHLETES ON THE FIELD;

AN EXAMINATION OF PRIMARY AND SECONDARY ANTERIOR CRUCIATE LIGAMENT PREVENTION OUTCOMES

by

Amelia J.H. Arundale

A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biomechanics and Movement Science

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ABSTRACT

Very few injuries have the household recognition or receive the media attention of anterior cruciate ligament (ACL) injuries. Soccer has a high incidence of ACL injuries and once an athlete has sustained an ACL injury they are at a high risk for a second; making primary and secondary prevention programs important. This project explored the outcomes of a primary prevention program, rehabilitation and return to sport after ACL reconstruction, and a secondary ACL injury prevention program. The FIFA11+ is a primary prevention program that reduces knee injuries in men's collegiate soccer, however has not been examined in women's collegiate soccer and it remains unknown if the program is effective in changing movement patterns associated with ACL injuries. In its first aim this dissertation established smallest detectable change and minimal important difference values for motion analysis of a vertical drop jump landing task. Then using these values to provide clinical context, this study found that although effective in reducing non-contact lower extremity injuries, the FIFA11+ did not reduce knee injuries or change biomechanical risk factors, such as valgus collapse. In the second aim this dissertation explored if professional male athletes in Major League Soccer (MLS) after ACL reconstruction were at an increased risk for injuries, beyond their known increased risk for a new knee injury, and how returning to play after ACL reconstruction affected their career length. This study found that although not at an increased risk for lower extremity injury, MLS athletes had shorter careers compared to age matched controls. Seemingly these athletes made a return to sport but not a return to their preinjury level of performance. In its third aim this study explored the outcomes of the Anterior Cruciate Ligament-Specialized Post-Operative Return to Sports (ACL-SPORTS) program, a secondary prevention program designed to help bridge the gap between physical therapy discharge and return to sport. This study found that both men and women had increases in objective and self-reported outcome measures over the course of the training program, with the exception of quadriceps strength limb symmetry. Men had an increase in quadriceps strength limb symmetry with the program, where women's strength symmetry remained the same. Further examination of the men found that 95% returned to their preinjury level of sport and only one had a second ACL injury (incidence 2.5%) in the two years following ACL reconstruction. The results of this dissertation set out future research goals to optimize primary and secondary prevention and return to sport, however also provides recommendations for clinicians on primary and secondary prevention programs that may benefit their athletes and encourages attention to the return to performance phase of ACL reconstruction rehabilitation.

Chapter 1

KEEPING ATHLETES ON THE FIELD

Introduction

Soccer is the most popular sport worldwide.[1] With an estimated 265 million players globally,[1] the Census Bureau estimates more than 13.6 million people play soccer regularly in the United States.[2] Soccer dominates American youth sports, with 3.5 million youth players registered with clubs in 2014.[3] For comparison there are only 2.5 million registered little league baseball and softball players worldwide.[4] Unfortunately, cutting and pivoting sports, such as soccer, carry a high risk for anterior cruciate ligament (ACL) injuries. Women's soccer, in particular, has one of the highest ACL injury risks of any women's collegiate or high school sport.[5-7] High school women's soccer has an ACL injury rate of 0.42/1000 athletic exposures (AEs).[8] For a team of 22 athletes this rate is equivalent to one ACL injury every three years. But there are two important factors this rate excludes: 1) the risk associated with playing for a club or travel team, outside of high school soccer, which we know many girls do,[8] and 2) the risk for second ACL injuries. The rate of primary ACL injuries is also quite high in National Collegiate Athletics Association (NCAA) women's soccer at 0.38/1000AEs.[8] This is equivalent to one ACL injury every other season.

Over all sports and activities there are an estimated 250,000 ACL injuries per year.[9] ACL reconstruction is often recommended to young active individuals, to help them regain knee stability and return to sport after ACL injury.[10] Ninety one percent of patients about to undergo an ACL reconstruction expect to return to their same level of sport after surgery and 98% expect no or only a slight increase in their risk of developing osteoarthritis.[11] However, ACL reconstruction does not guarantee an athlete will return to sport.[12] Only approximately 65% of athletes after ACL reconstruction return to their preinjury level of activity, and even fewer, 55%, return to their preinjury level of competition.[12] Further, ACL reconstruction actually increases the risk for osteoarthritis development,[13-16] with the majority of individuals after ACL reconstruction having some degree of osteoarthritis development within 10 years.[14-16]

Second ACL injuries (graft ruptures or contralateral ACL injuries) are a large problem in athletes who return to sport, particularly athletes in high risk groups such as athletes under 20 years old,[17] and women athletes.[17-19] The highest risk for a second ACL injury is in the first 72 athletic exposures (AE) after returning to sport.[18] In the first year after returning to sport athletes are fifteen times more likely to sustain a second ACL injury compared to athletes with no history of ACL injury.[19] Women are at a higher risk compared to both men with a history of ACL injury and their uninjured female peers.[19] To make matters worse, outcomes after ACL reconstruction revisions are not as good as after primary ACL reconstructions.[20-23] Meta-analyses indicate that after ACL reconstruction revision individuals have lower self-reported outcome measure scores, lower scores on objective measures of knee function, and increased risk for radiographic osteoarthritis compared to after primary ACL reconstruction. [20-23]

It is clear that efforts to prevent both primary and secondary ACL injuries are essential. This dissertation aims to examine the outcomes of primary and secondary ACL injury prevention programs (0) with the hope that its results will benefit future athletes and improve future outcomes. Starting with primary prevention in the first aim, preventing the injury from occurring in the first place, moving through the injury, and in the second and third aims examining the outcomes of rehabilitation, return to sport, and secondary ACL prevention.

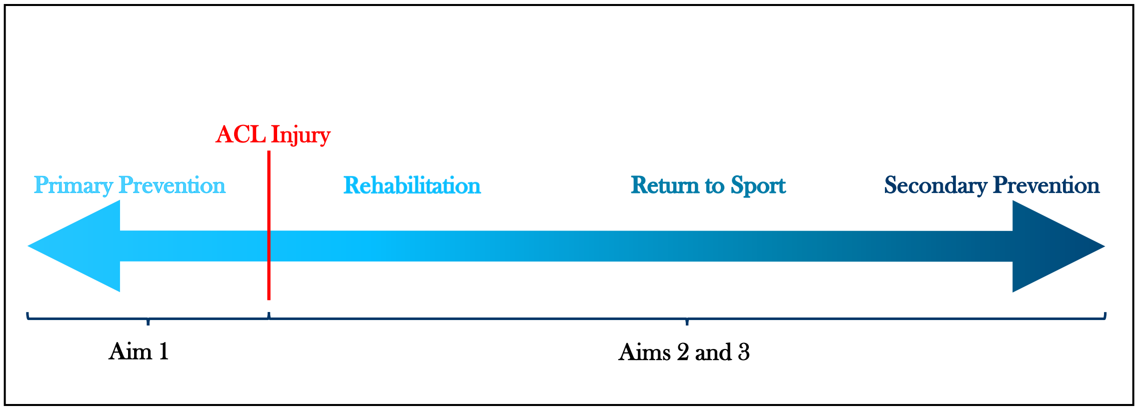

Figure 1 Diagram of ACL injury prevention and study aims

Aim 1: Primary Prevention (Chapters 2-3)

Women's collegiate soccer has an overall injury rate of 8.44/1000 AEs.[24] Although ACL injuries account for only 0.7% of all injuries, they cause the longest median time off due to injury.[25] To prevent ACL injuries, research has examined the risk factors and mechanisms of injury. Non-modifiable risk factors for ACL injuries include age, with younger athletes being at a higher risk, and sex, with women being at a higher risk.[9] Modifiable risk factors include faulty biomechanics and altered neuromuscular control.[9 26] Hewett et al. identified high peak knee abduction angles and moments during a vertical drop jump landing task as risk factors for ACL injuries in high school age female athletes.[26] Video analysis studies have identified common mechanisms of injury in soccer,[27] handball,[28] and basketball.[29] These mechanistic studies indicate that, particularly in women, valgus collapse (hip adduction, hip internal rotation, and knee abduction) may place the ACL in a position of high risk.[26]

In response to risk factor and mechanistic studies, primary injury prevention programs were developed. One of the first well known programs was the Prevent Injuries and Enhance Performance Program (PEP).[30] From the PEP program, the FIFA11, and subsequently the FIFA11+ programs were developed by the Medical and Research Committee of the Fédération Internationale de Football Associations (FIFA). The FIFA11+ was designed to be used as a dynamic warm-up prior to sports training sessions or games. The program involves active stretching of the lower extremities, core and leg strengthening, balance, plyometric, and agility exercises. Each exercise has three levels to facilitate progression in difficulty.[31] The primary focus of the FIFA11+ is on correct performance of each exercise, particularly proper alignment during single leg activities and proper form during jump landings.

To date much of the research surrounding the FIFA11+ has been on its efficacy in reducing injuries. Two large scale efficacy studies have been performed. In high school women's soccer the FIFA11+ reduced all injuries by 34%,[32] and in collegiate men's soccer the FIFA11+ reduced lower extremity injuries by 92%,[31] and ACL injuries by 76%.[33] Other smaller scale efficacy studies have been performed,[34 35] as well as studies examining implementation, compliance,[36-38] and the program's effects on physiological preparation of the body for sport,[39 40] lower extremity strength[41-43] and functional performance measures.[42] Given the FIFA11+ focus on proper alignment during single leg and jump landing tasks, however, there is currently no evidence on whether the program changes movement patterns.

Very few studies have examined the efficacy of injury prevention programs over multiple seasons.[30 44] Myklebust et al.[44] examined the use of an injury prevention program over two handball seasons, however the program was changed from the 1st to the 2nd seasons, so results of each season are in essence the results of two different programs. Mandelbaum et al.[30] explored the efficacy of the PEP program in reducing injuries over two soccer seasons. They found an 88% decrease in injuries in the first season and a 74% in the second season.[30] To the author's knowledge there are no studies on the effects of the FIFA11+ over multiple seasons, and no studies on the biomechanical changes over multiple seasons with use of any injury prevention program.

Aim: Determine kinetic and kinematic changes that occur with FIFA11+ utilization over two soccer seasons in collegiate women soccer players.

Hypothesis 1.1 Smallest detectable change and minimal important difference scores can be calculated for the vertical drop jump landing task, so that meaningful and clinically meaningful change can be established.

Hypothesis 1.2 After using the FIFA11+ for one season athletes will have a lower non-contact lower extremity injury incidence rate, particularly a lower knee injury incidence rate, than athletes in the control group.

Hypothesis 1.3 After using the FIFA11+ for a second season athletes will have a lower non-contact lower extremity injury incidence rate, particularly a lower knee injury incidence rate, than after the first season of FIFA11+ use.

Hypothesis 1.4 After using the FIFA11+ for one season athletes will have smaller peak knee abduction, hip adduction, and hip internal rotation angles and moments than athletes in the control group.

Hypothesis 1.5 After using the FIFA11+ for a second season athletes will have smaller peak knee abduction, hip adduction, and hip internal rotation angles and moments compared to after the first season of FIFA11+ use.

Aim 2: Return to Sport, Subsequent Injuries, and Secondary Prevention (Chapters 4)

Injuries cost athletes physically and emotionally, as well as costing teams financially and in teams' performance.[45] In professional European men's soccer, players incur, on average, two injuries per year or approximately 50 injuries per team per year.[46] Proportionally, eight of each team's injuries will be severe, causing players to miss ≥28 days of training and competition.[46] Muscle injuries account for one third of all time-loss injuries in European men's professional soccer, with hamstring and quadriceps injuries accounting for almost 20% of all time-loss injuries.[46 47] Work by Hagglund et al.[48] in European men's professional soccer found that a previous muscle injury was a risk factor for a future injury in that same muscle group. But more importantly, injury to any muscle group increased risk for a lower extremity injury in the subsequent season.[49]

ACL injuries occur at a rate of 0.07/1000AEs in European men's professional soccer.[50] While these injuries aren't common, ACL injuries are still of grave concern due to the impact on a player's career, the long time-loss, and the high risk of second ACL injury.[50] Second ACL injuries have been a common outcome measure used to assess ACL reconstruction and rehabilitation.[17-19 51-53] A recent meta-analysis found that approximately 20% of all athletes returning to sport after ACL reconstruction incurred second ACL injuries (8% ipsilateral/12% contralateral).[53] Although the reinjury rate may be lower in men's professional soccer than amateur level play, with 6.7% of male European professional players requiring subsequent knee surgery after ACL reconstruction,[54] these elite athletes are still at risk. Walden et al.[55] found that male Swedish professional soccer players after ACL reconstruction were at 7.9 times greater risk for a new knee injury and 4.8 times greater risk for a knee overuse injury compared to athletes with no history of ACL reconstruction. This high risk for a new knee injury after ACL reconstruction prompts questions as to whether the knee is the only joint at increased risk. For a clinician to fully educate their athletes on the risks of returning to sport, more knowledge is needed on the type and severity of injuries that athletes incur after ACL reconstruction, rehabilitation, and return to sport. Further, it is important to explore if there is a relationship between graft type and injury. For example, if athletes with a hamstring autografts are at greater risk for hamstring injuries compared to athletes with other graft types.

Currently only one study has examined ACL injuries in Major League Soccer (MLS),[56] the highest men's professional soccer league in the United States. However, this study only used publically available online data. The study found no significant difference in career length between athletes after ACL reconstruction and matched controls;[56] a contrasting finding to European men's professional soccer where only two-thirds of athletes were still playing at the highest level three years after ACL reconstruction.[50] Research in other professional sports, such as the NBA and NFL, indicates that ACL reconstruction may negatively affect performance and career longevity,[57-59] however accurate analysis of return to play and career length is still needed in MLS. Thus, this study will explore the impact of ACL reconstruction on return to play, career length, and injury incidence in MLS athletes.

Aim: Establish the incidence of lower extremity injuries, time loss, and career duration after ACL reconstruction, rehabilitation, and return to sport in Major League Soccer (MLS).

Hypothesis 2.1 From the time of their return to play, athletes after ACL reconstruction will have shorter careers in the MLS than athletes with no history of ACL injury

Hypothesis 2.2 In the first two years after ACL reconstruction and return to play athletes will have a higher incidence of lower extremity time-loss injuries than athletes with no history of ACL injury.

Hypothesis 2.3 In the first two years after ACL reconstruction and return to play athletes will have a higher incidence of time-loss injuries to the thigh muscles than athletes with no history of ACL injury

Hypothesis 2.4 In the first two years after ACL reconstruction and return to play athletes will have a higher number of severe lower extremity time-loss injuries than athletes with no history of ACL injury

Hypothesis 2.5 Injury incidence in the first two years after ACL reconstruction and return to play will differ between athletes who received different graft types

Aim 3: Rehabilitation, Return to Sport, and Secondary Prevention (Chapters 5-6)

Rehabilitation and return to sport criteria used after ACL reconstruction are not standardized. Slight differences are necessary in order to tailor treatments to athletes' specific needs and progress, however a 2011 systematic review found that of 264 studies identifying factors used in return to sport decision-making, 40% provided no return to sport criteria, 32% used time from surgery, and only 13% used objective return to sport criteria.[60] More recently, a 2016 study found that only 19% of ACL reconstruction protocols available online recommended passing strength and activity criteria prior to return to sport.[61] Although peer reviewed literature on rehabilitation following ACL reconstruction exists, much of it is level five evidence.[62] Particularly in the return to sport phases of ACL reconstruction rehabilitation, a large portion of the literature consists of clinical commentaries.[63-66] There are very few studies examining the outcomes of specific physical therapy interventions during the return to sport phase of ACL reconstruction rehabilitation.

With the low return to sport rates and high second ACL injury risk there is clearly room for improvement in ACL reconstruction outcomes. Over the first two years after ACL reconstruction strength imbalances, influenced by graft type, have been observed.[67] These imbalances are seen to effect functional performance[68 69] and self-reported outcomes.[70] Resolution of strength asymmetries are crucial, as symmetrical quadriceps strength upon return to sport has been seen to reduce the risk of reinjury.[71] Improvements in self-reported outcomes may also be needed. Twelve months after ACL reconstruction almost 22% of an international cohort still rated their knee function as below age-matched norms, using the International Knee Documentation Committee 2000 Subjective Knee Form.[72] Thus, there are clear reasons to examine the outcomes of interventions used during ACL reconstruction rehabilitation.

In addition to exploring effects on function, return to sport, and second ACL injury, the differential effects of sex must also be taken into consideration when studying ACL reconstruction rehabilitation interventions. Beyond being at a higher risk for a second ACL injury,[18 19] women have lower odds of returning to their preinjury level of sport than men.[12] The impact of ACL reconstruction on activity may be long term, as even six years after reconstruction women are more likely to be less active than their male counterparts.[73] Women tend to have lower IKDC scores in the 1st year after ACL reconstruction, [70] and have greater deficits in knee extensor strength at the same time point. [74] These results could indicate that men and women rehabilitate and recover from ACL reconstruction differently and that their outcomes after specific interventions may need to be examined separately.

Aim: Quantify the effects of a specialized return to sport training and second injury prevention program on function, return to sport, and second ACL injury incidence in athletes after ACL reconstruction.

Hypothesis 3.1 The Anterior Cruciate Ligament Specialized Post-Operative Training (ACL-SPORTS) program will improve functional and self-reported outcomes from pre-training to post-training.

Hypothesis 3.2 Men and women who undergo the ACL-SPORTS program will have different changes in functional and self-reported outcomes from pre-training to post-training.

Hypothesis 3.3 Men who undergo the ACL-SPORTS program will return to sport at higher rates and have a lower second ACL injury incidence in the first two years after ACL reconstruction, when compared to the previously reported data.

Summary

Few injuries have the household recognition or receive the media coverage of ACL injuries. With approximately 250,000 ACL injuries,[9] an estimated 130,000 ACL reconstructions,[75 76] and around 19,500 second ACL injuries each year in the United States,[53] implementing and optimizing primary and secondary prevention strategies is paramount. Although the scope is quite broad, the information gained from this study and its three aims will directly impact primary and secondary prevention practices. Examining the biomechanical changes that occur with use of a primary prevention program will help clinicians and researchers understand the mechanism by which the program protects athletes and its efficacy when used over multiple seasons. Examining the types and severity of injuries that athletes incur after ACL reconstruction, rehabilitation, and return to sport will help clinicians accurately educate their athletes on the risks they face in returning to sport. Additionally, this research may identify injuries that could be prevented through interventions integrated into ACL reconstruction rehabilitation or additional return to sport criteria. Examining the outcomes of a return to sport training and second injury prevention program in men and women as well as its return to sport and second ACL injury outcomes, will help clinicians understand the specific benefits of the training program. The results will also serve as some of the first evidence-based intervention recommendations for the return to sport phase of ACL reconstruction rehabilitation. Primary and secondary ACL injury prevention are necessary, and this assessment of outcomes aims will help improve their efficacy. The findings of this dissertation will be immediately clinically applicable, and have the potential to help decrease the number of ACL injuries, ACL reconstructions, and second ACL injuries that occur each year.

Chapter 2

SMALLEST DETECTABLE CHANGE AND MINIMAL IMPORTANT DIFFERENCE VALUES FOR BIOMECHANICAL TESTING OF A DROP JUMP LANDING TASK IN COLLEGIATE WOMEN SOCCER PLAYERS

Introduction

Biomechanics of ACL injury and ACL injury prevention is of great interest to athletes, coaches, clinicians, and researchers. In 2005 Hewett et al.[26] examined biomechanical risk factors for ACL injury using a vertical drop jump landing task (drop jump). Subsequently the drop jump has been used as a screening tool for risky biomechanics. Myer et al.[77] used 3D motion analysis of a drop jump to classify athletes with a knee abduction moment ≥25.25 Nm as having high ACL injury risk with 73% sensitivity and 70% specificity. The Landing Error Scoring System (LESS) used 2D cameras recording in the sagittal and frontal planes to assess drop jump biomechanics and identify athletes at risk for ACL injury in a clinical setting.[78] In addition to being used as a screening tool, the drop jump has been employed to assess changes in movement patterns. Barber-Westin et al.[79] used 2D analysis of the drop jump to assess changes in knee separation distance after an injury prevention program. Several other studies have examined changes in drop jump kinematics and kinetics with 3D motion analysis.[77 80 81]

Previous work has established that 3D motion analysis of a drop jump is reliable.[82-84] These reliability studies found higher within-session than between-session reliability,[82-84] with both Mok et al.[85] and Ford et al.[84] finding good to excellent intraclass correlation coefficients (ICCs) for knee angles and moments. Ford et al.[84] also found good to excellent ICCs for hip angles and moments.

These reliability studies suggest that the drop jump may have the necessary measurement properties to serve as a valuable screening tool.[82-84] Literature reporting on use of the drop jump to assess change indicates that modifications to movement patterns occur,[77 80 81] but there are no published smallest detectable change (SDC) or minimal important difference (MID) values for the drop jump to give clinical meaning to the size of these reported changes. The SDC (also known as the minimal detectable change) represents the smallest change that can be considered 'real,' given the error of a measurement.[86 87] Lower extremity joint angle and moment SDCs have been published for walking gait, but not for the drop jump.[88 89] The MID represents the smallest improvement that a patient or clinician would consider worthwhile, and is also known as the minimal clinically important difference.[90] MIDs are used frequently in patient-reported outcome measures,[91 92] but have also been established in walking gait after ACL injury.[89] SDC and MID values for the drop jump would help clinicians and researchers assess if changes in biomechanical variables are meaningful. In particular, SDC and MID values could help clinicians and researchers assess if an intervention, such as an injury prevention program, has actually changed risk factors for ACL injury.

The purpose of this study was to calculate SDC and MID values for knee and hip angles and moments during a drop jump in collegiate women soccer players. This study was performed using the baseline data from a cohort study examining the effects of the FIFA11+ injury prevention program. Thus, this study is an exploration into whether establishing SDCs and MIDs is feasible for the drop jump.

Methods

Athletes from two NCAA Division I and one NCAA Division II women's soccer teams participated in this study. All athletes gave written informed consent prior to participating, and the study was approved by the institution's human subjects review board. Athletes were included regardless of position, academic year, or injury/surgery history. Athletes were excluded if they were unable to perform the drop jump. Motion analysis data collection occurred during preseason.

Motion analysis of a drop jump was performed using an eight camera motion system (VICON; Oxford Metrics Ltd, London, England) sampled at 240Hz, and two 6 component embedded force plates (Bertec, Worthington, Ohio, USA) sampled simultaneously at 1080Hz. Athletes wore their own athletic shoes and clothes. Twenty two retro-reflective markers were affixed, using double sided tape, to identify joint centers and six rigid shells were affixed using elastic wraps to track segment positions (Figure 2). Previous research, including a reliability study that calculated SDC and MID values for walking gait,[89] has used this maker set.[93 94]All markers were placed by one researcher (AA) who had excellent inter-rater (against others who regularly use this marker set, ICC >0.95) and intra-rater reliability (ICC >0.97).

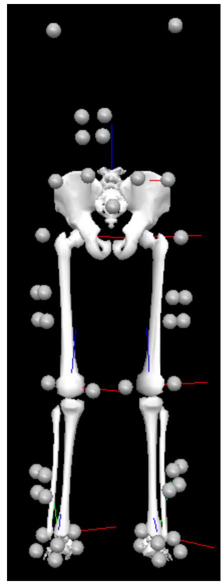

Figure 2 Marker set used for study. Individual markers affixed medially and laterally to identify joint centers (medial and lateral metatarsal heads, medial and lateral malleoli, medial and lateral femoral condyles, the greater trochanters of each hip, and each acromion). Six rigid shells were affixed to the trunk, pelvis, thighs, and shanks, to track each segment.

The drop jump was performed similar to Hewett et al.[26] Athletes dropped from a 40 cm box, landing with one foot on each force plate. Upon landing they immediately jumped up and again landed with one foot on each force plate. Analysis focused on the first landing, with initial contact defined by when the vertical force exceeded 5N. Athletes were given verbal instructions and allowed to practice the drop jump. Three trials of the drop jump were then performed with no standardization of the time between jumps.

Markers were labeled using Vicon Nexus software (v 1.8.5, VICON, Oxford Metrics Ltd, London, England) and gaps in the signal caused by marker drop out were filled using the program's spline filling algorithm. Trials with gaps too large for the algorithm to fill were excluded from analysis. Rigid-body analysis and inverse dynamics post-processing was performed using Visual 3D (C-Motion Inc., Germantown, Maryland, USA). Kinematic and kinetic data were low pass filtered at 6 Hz and 40 Hz respectively.[95] External moments were calculated and hip flexion, hip adduction, hip internal rotation, knee extension, and knee adduction, were presented as positive values. Variables of interest were the peak hip angles and external moments in the sagittal, frontal, and transverse planes, as well as peak knee angles and external moments in the sagittal and frontal planes.

Statistical analyses were performed in SPSS version 24 (Microsoft, Redmond, Washington, USA) and Microsoft Excel 2013 (Redmond, Washington, USA). In order to determine if SDCs could be applied bilaterally, paired t-tests were performed to examine if there were differences between the right and left limbs. Where no significant difference was found, the limbs were collapsed for reliability analyses, but where differences were present, the limbs were analyzed separately. ICC(2,1) was selected for analysis.[86 96] The standard error of the mean (SEM) was calculated using the equation $SEM = \text{Standard Deviation} \times \sqrt{(1-ICC)}$. The SDC was calculated using the equation $SDC = SEM \times 1.96 \times \sqrt{(2)}$. [86] ICC analyses were performed on all three drop jump trials for each variable (data not shown), but there were significant inter-trial differences for peak hip flexion angle ($p<0.01$), left peak hip adduction moment (p=0.02), right peak hip internal rotation angle (p=0.01), and left peak knee flexion angle (p=0.02). As a result the analyses were repeated using only the second and third trials. ICCs were classified as either excellent (>0.75), good (0.60-0.75), fair (0.40-0.59), or poor (<0.40).[97] Effect sizes (Cohen's D) were classified as small (0.2), medium (0.5), and large (0.8).[98]

Two teams participated in the intervention arm of this study, performing the FIFA11+. The third team served as a control group (N=20) who participated in biomechanical motion analysis but did not participate in any intervention. Control group athletes were monitored throughout the soccer season by a certified athletic trainer and all injuries/complaints reported to the athletic trainer were recorded. At the conclusion of the season control group athletes were categorized as to whether they experienced a non-contact lower extremity injury[99] (Injured) or not (Uninjured). All non-contact lower extremity injuries were included, as they are the target of injury prevention programs. A MANOVA was used to assess if there were differences between the Injured and Uninjured groups in the variables of interest at preseason. The mean difference between the Injured and Uninjured groups was compared to the SDC. Where the mean difference between the Injured and Uninjured groups was greater than the SDC it was chosen as the MID.[90] Power calculations were performed similar to Mok et al.[82] using sample size calculations specifically designed for reliability studies.[100] Using a confidence interval width of 0.2, a mean ICC value of 0.80, p=0.05, with two trials of the drop jump a minimum sample size of 50 was needed.

Results

Sixty eight players participated in preseason motion analysis testing of the drop jump (Table 1). Of those 54 had usable drop jump trials (FIFA11+ = 34, Control = 20

). The primary reason for exclusion of trials was marker drop out. Marker drop out was caused by athlete's arms swinging and obstructing the thigh shells from camera view.

Table 1 Demographics and anthropometrics

Demographics and Anthropometric Variables (N=68)	Mean ± Standard Deviation
Age	19.4 ± 1.2 years
Height	1.7 ± 0.1 meters
Weight	63.9 ± 6.6 kg
Positions	Forwards: 13 Midfielders: 24 Defense: 21 Goalkeepers: 8

There were significant differences between limbs in hip adduction angle ($p<0.01$) and moment ($p=0.02$), hip internal rotation angle (<0.01) and moment ($p<0.01$), knee flexion angle ($p<0.01$) and knee abduction moment ($p=0.05$) (Table 2). As a result the separate right and left ICCs, SEMs, and SDCs were calculated for these variables.

Table 2	Results of paired t-tests comparing limbs (N=54)

Variable	Left (Mean ± Standard Deviation)	Right (Mean ± Standard Deviation)	p-value	Cohen's D
Peak Hip Flexion Angle	88.83 ± 13.75°	88.68 ± 13.24°	0.77	0.03
Peak Hip Flexion Moment	1.08 ± 0.27 Nm/kgm	1.09 ± 0.25 Nm/kgm	0.87	0.12
Peak Hip Adduction Angle*	-4.70 ± 4.40°	-2.01 ± 5.04°	<0.01	0.57
Peak Hip Adduction Moment	0.14 ± 0.10 Nm/kgm	0.17 ± 0.1 Nm/kgm	0.02	0.38
Peak Hip Internal Rotation Angle**	-8.68 ± 5.91°	-4.88 ± 6.32°	<0.01	0.62
Peak Hip Internal Rotation Moment	0.16 ± 0.08 Nm/kgm	0.19 ± 0.08 Nm/kgm	<0.01	0.38
Peak Knee Flexion Angle	-107.49 ± 12.20°	-105.90 ± 12.12°	0.02	0.13
Peak Knee Flexion Moment	-0.96 ± 0.15 Nm/kgm	-0.98 ± 0.17 Nm/kgm	0.31	0.12
Peak Knee Abduction Angle	-1.87 ± 4.70°	-1.76 ± 3.80°	0.81	0.03
Peak Knee Abduction Moment	-0.17 ± 0.10 Nm/kgm	-0.26 ± 0.12 Nm/kgm	<0.01	0.81

In accordance with the right hand rule, hip flexion, adduction, internal rotation, knee extension, and adduction are presented as positive.
* Some athletes performed the drop jump in hip adduction (+) others in hip abduction (-). As a result the mean peak hip adduction angle was negative, and actually represents a small hip abduction angle.

** Similar to the peak hip adduction angle, some athletes performed the drop jump in hip internal rotation (+) some in hip external rotation (-). As a result the mean peak hip internal rotation angle was negative, and actually represents a small hip external rotation angle.

There was a significant difference between trials in right peak hip internal rotation angle, however, the effect size for this inter-trial difference was small (Cohen's D = 0.13). All variables except peak knee flexion moment (ICC 0.43, 95% confidence interval 0.22-0.58, SEM 0.16, SDC 0.44 Nm/kgm) had good or excellent ICCs (Table 4). To explore the reason for this low reliability in the knee flexion moment, the reliability analysis was run again, this time separating the right and left. The results of this subsequent analysis of peak knee flexion moment found that the ICCs improved to excellent and SDCs decreased (Table 3).

Table 3 Reliability analysis (N=54)

	p-value	**ICC** (95% Confidence Interval)	ICC Classification	**SEM**	**SDC**
Peak Hip Flexion Angle	0.97	0.93 (0.89 to 0.95)	Excellent	1.80°	4.99°
Peak Hip Flexion Moment	0.21	0.63 (0.51 to 0.74)	Good	0.18 Nm/kgm	0.51 Nm/kgm

Table 3 Continued

	p-value	**ICC** (95% Confidence Interval)	ICC Classification	**SEM**	**SDC**
Peak Left Hip Adduction Angle	0.83	0.82 (0.71 to 0.89)	Excellent	0.80°	2.23°
Peak Right Hip Adduction Angle	0.29	0.92 (0.86 to 0.95)	Excellent	0.45°	1.25°
Peak Left Hip Adduction Moment	0.08	0.82 (0.70 to 0.89)	Excellent	0.02 Nm/kgm	0.05 Nm/kgm
Peak Right Hip Adduction Moment	0.78	0.78 (0.66 to 0.88)	Excellent	0.02 Nm/kgm	0.06 Nm/kgm
Peak Left Hip Internal Rotation Angle	0.51	0.86 (0.77 to 0.92)	Excellent	0.79°	2.19°
Peak Right Hip Internal Rotation Angle	0.03	0.92 (0.86 to 0.95)	Excellent	0.55°	1.53°
Peak Left Hip Internal Rotation Moment	0.65	0.76 (0.61 to 0.85)	Excellent	0.02 Nm/kgm	0.06 Nm/kgm
Peak Right Hip Internal Rotation Moment	0.33	0.63 (0.44 to 0.77)	Good	0.03 Nm/kgm	0.09 Nm/kgm
Peak Left Knee Flexion Angle	0.53	0.86 (0.76 to 0.91)	Excellent	1.73°	4.79°
Peak Right Knee Flexion Angle	0.24	0.86 (0.77-0.92)	Excellent	1.77°	4.92°
Peak Left Knee Flexion Moment	0.52	0.82 (0.70 to 0.89)	Excellent	0.03 Nm/kgm	0.08 Nm/kgm
Peak Right Knee Flexion Moment	0.12	0.82 (0.70 to 0.89)	Excellent	0.03 Nm/kgm	0.07 Nm/kgm

Table 3 Continued.

	p-value	**ICC** (95% Confidence Interval)	ICC Classification	**SEM**	**SDC**
Peak Knee Abduction Angle	0.78	0.73 (0.62 to 0.81)	Good	2.08°	5.78°
Peak Left Knee Abduction Moment	0.81	0.72 (0.56 to 0.83)	Excellent	0.03 Nm/kgm	0.09 Nm/kgm
Peak Right Knee Abduction Moment	0.34	0.75 (0.60 to 0.85)	Excellent	0.03 Nm/kgm	0.09 Nm/kgm

The p-value presented is that of the two-way ANOVA used in the ICC calculation, and represents if there were significant differences between trials. ICCs were classified as either excellent (>0.75), good (0.60-0.75), fair (0.40-0.59), or poor (<0.40).[97]

In the Control group, 11 of 20 athletes experienced non-contact lower extremity injuries (Injured group), six athletes with multiple injuries. Injuries included: Achilles pain/calf tightness, lateral ankle sprains, groin, hamstring and quadriceps strains, patellofemoral pain, peroneal tendonitis, and iliotibial band syndrome. There were no statistically significant differences between the Injured (N=11) and Uninjured groups (N=9) at preseason (Table 4), but there were four measures where the mean differences between groups exceeded the SDC. The Injured group landed in more hip flexion (86.46 ± 11.08° vs Uninjured 80.64 ± 17.48), less right hip external rotation (-3.62 ± 3.33° vs Uninjured -7.95 ± 9.06°), and less knee flexion on both the right (-103.95 ± 12.09° vs Uninjured -110.77 ± 14.57°) and left (-104.21 ± 11.81° vs Uninjured -110.70 ± 13.45°) compared to the Uninjured group.

Thus, MID values of 5.82° for peak hip flexion angle, 4.33° for peak hip internal rotation angle, and 6.82° for peak knee flexion angle were proposed.

Table 4 Results of MANOVA comparing Injured and Uninjured groups (N=54)

	Smallest Detectable Change (from Table 3)	Mean Difference between Injured and Uninjured groups	p-value	Effect size (Cohen's D)
Peak Hip Flexion Angle	4.99°	5.82° *	0.39	0.41
Peak Hip Flexion Moment	0.51 Nm/kgm	0.10 Nm/kgm	0.35	0.46
Peak Left Hip Adduction Angle	2.23°	0.67°	0.73	0.20
Peak Right Hip Adduction Angle	1.25°	0.71°	0.74	0.20
Peak Left Hip Adduction Moment	0.05 Nm/kgm	0.01 Nm/kgm	0.70	0.20
Peak Right Hip Adduction Moment	0.06 Nm/kgm	0.004 Nm/kgm	0.93	0.00
Peak Left Hip Internal Rotation Angle	2.19°	0.58°	0.81	0.10

Table 4 Continued

	Smallest Detectable Change (from Table 3)	Mean Difference between Injured and Uninjured groups	p-value	Effect size (Cohen's D)
Peak Right Hip Internal Rotation Angle	1.53°	4.33° *	0.18	0.70
Peak Left Hip Internal Rotation Moment	0.06 Nm/kgm	0.03 Nm/kgm	0.17	0.70
Peak Right Hip Internal Rotation Moment	0.09 Nm/kgm	0.01 Nm/kgm	0.79	0.13
Peak Left Knee Flexion Angle	4.92°	6.49° *	0.28	0.55
Peak Right Knee Flexion Angle	4.79°	6.82° *	0.28	0.55
Peak Left Knee Flexion Moment	0.08 Nm/kgm	0.04 Nm/kgm	0.48	0.35
Peak Right Knee Flexion Moment	0.07 Nm/kgm	0.06 Nm/kgm	0.47	0.35
Peak Knee Abduction Angle	5.78°	0.98°	0.66	0.20
Peak Left Knee Abduction Moment	0.09 Nm/kgm	0.06 Nm/kgm	0.12	0.81
Peak Right Knee Abduction Moment	0.09 Nm/kgm	0.01 Nm/kgm	0.83	0.11

*Mean difference between Injured and Uninjured group was larger than the SDC. MID values: Peak hip flexion angle (5.82°), peak hip internal rotation angle (4.33°), and peak knee flexion (6.82°). As the mean differences between the Injured and Uninjured groups in the right peak hip internal rotation angle (4.33°) was greater than both the right (1.53°) and left (2.19°) SDC values, 4.33° was considered the MID bilaterally. Similar for the peak knee flexion angle, the mean difference between groups in right knee flexion angle (6.82°), was greater than both the right (4.79°) and left (4.92°) SDC values, thus 6.82° was made the MID bilaterally.

Discussion

The results of this study indicate that the drop jump is a reliable task for motion analysis and calculations of SDC and MID values are feasible. There were significant differences between limbs in six variables, indicating that even in a healthy collegiate women soccer population, asymmetries are present. There were no statistically significant differences between Control group athletes who went on to incur a non-contact lower extremity injury and those who did not, but four variables had between group mean differences greater than the SDC. As a result, this study proposes potential MIDs for hip flexion, hip internal rotation, and knee flexion angles. The results of this study may enable clinicians and researchers to assess changes in biomechanics, and within the context of ACL injury prevention determine if there has been a meaningful change in injury risk factors.

The most important results of this study are the SDC and MID calculations for the peak hip and knee angles and moments during a drop jump. Thirteen of the seventeen measures in this study had excellent reliability with good reliability in the remaining four. Mok et al.[82] and Ford et al.[84] also found good to excellent reliability, and although they found slightly higher ICC values than in this study, the slight differences are likely due to the ICC calculations used. This study used ICC (2,1), meaning the analysis used a two-way model (keeping variability between trials and error separate), that assessed single scores from each athlete for each trial, and assumed the rater used was a random sample of a population of raters was used.[86] In other words, the person who placed the markers was considered to be one of many people who could have placed the markers. In this study even though only one researcher placed all of the makers, that researcher was highly reliable to a larger group of investigators, and thus could have been replaced by any other reliable researcher. In contrast, both Mok et al.[82] and Ford et al.[84] used ICC (3,k), a two-way model, that uses an average score across trials from each subject, and assumes that the rater(s) is/are the only rater(s) of interest.[86] In other words, the results are only applicable to the raters or researchers who placed the markers in the study.[86] Therefore, although the differences in ICCs are minimal and all studies indicate good to excellent reliability, the implications of the ICC models used means the results of this study are more generalizable. By using the ICC (2,1) the SDCs produced from this study can be used outside our institution. Clinicians and researchers anywhere can apply similar methods and evaluate athlete’s movement to determine if meaningful changes have occurred.

This study was performed as part of a wider cohort study examining the effects of the FIFA11+ injury prevention program. One team served as a control and did not participate in any intervention. As a result of the cohort study design, only the control athletes (20 of the 66 athletes) could be used in the MID calculations. Only non-contact lower extremity injuries were assessed in the calculation of MID values, as these injuries were targeted by the FIFA11+ and had the potential to be influenced by faulty lower extremity biomechanics. There are numerous methods for establishing MIDs.[90] Anchor-based methods compare a change in the outcome score to an external criteria, such as a global rating of change.[90] Distribution-based methods compare the score to a measure of variability such as the SEM or SDC.[90] In establishing MID values for gait biomechanics after ACL reconstruction, Di Stasi et al.[89] used a hybrid of these approaches by comparing the knee extension range of motion loss known to effect patient function as a clinical anchor, and comparing this clinical anchor to a distribution measure, the SDC.[89] The present study aimed to be conservative in proposing preliminary MID values, and thus used a similar hybrid method. As in an anchor-based method where a global rating of change score is used to dichotomize athletes and then the differences between groups in the variable of interest is used as an MID,[90] this study categorized Control group athletes as Injured or Uninjured and examined the mean difference in each variable of interest between groups. This anchor-based approach was taken one step further. The mean difference between the Injured and Uninjured groups was compared to both the SEM and SDC, distribution-based methods. MID values were proposed only where the mean difference between the Injured and Uninjured groups exceeded the SEM and SDC. The mean differences between the groups for hip flexion angle, right hip internal rotation angle, right and left knee flexion angles were two times greater than their respective SEMs and SDCs. Thus, the authors felt these mean differences were appropriate MID values. The mean difference in right peak hip internal rotation angle (4.33°) was greater than both the right (1.53°) and left (2.19°) SDC values, thus 4.33° was considered the MID bilaterally. Similar reasoning was applied to the knee flexion angles. These MID values should not be considered definitive, and future research should examine SDC and MID values more rigorously in the drop jump, however, this study provides preliminary MID values for peak hip flexion angle (5.82°), peak hip internal rotation angle (4.33°), and peak knee flexion angle (6.82°).

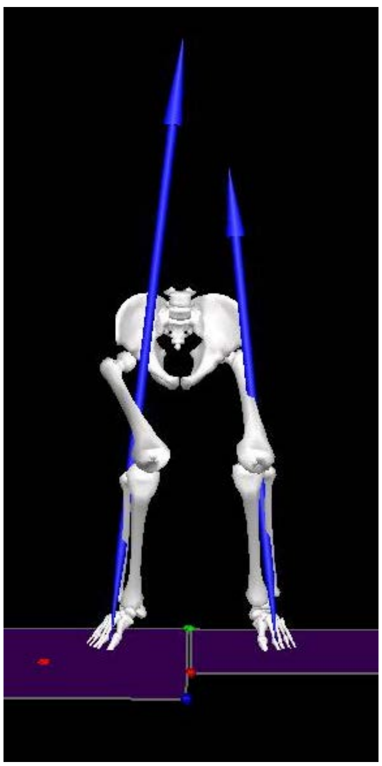

Figure 3 Example of asymmetry during drop jump task

There were significant differences between limbs in six of the ten peak hip and knee angles and moments examined in this study (Figure 3). Previous reliability studies have either averaged the right and left limbs together,[84] or examined only the right[82] or the dominant limb[83], making this the first study to explore these limb differences in the context of reliability. Asymmetries are found elsewhere in the drop jump biomechanics literature. Hewett et al.[26] found that high school women athletes who went on to incur an ACL injury had 6.4 times greater asymmetry between limbs in knee abduction moment than athletes who remained uninjured. Other studies have found asymmetries in athletes after ACL reconstruction,[101] and associations between drop jump landing asymmetry and quadriceps strength in this ACL reconstructed population.[68] Further research is needed to investigate the implications of these asymmetries, particularly on injury risk, in the collegiate women's soccer population. Based on clinical experience and the previous literature, the authors hypothesize that these asymmetries may place an athlete at risk for a lower extremity injury. This study indicates that clinicians should be aware that biomechanical asymmetries are present in the collegiate women's soccer population, and by calculating SDCs for each limb this study makes it possible to assess changes in movement and progress towards asymmetry resolution, an assumed improvement in movement pattern.

An argument could be made that higher reliability was found assessing two trials as opposed to three because variability was reduced by removing a trial. The authors acknowledge this possibility, and hope that further research designed specifically to assess and calculate SDC and MID values may clarify the exact methods needed to perform and analyze a drop jump assessment. The authors specifically chose an ICC (2,1) rather than an ICC (2,k), to try and address the concern of the number of trials. An ICC (2,1) uses each individual trial, where an ICC (2,k) uses the average of the trials for each subject. Thus, even though an ICC (2,k) would have produced higher ICCs, an ICC(2,1) was more appropriate in this study. Further, although recording three drop jump trials is common in the literature,[26 82-84 102] more research may be needed to explore if there is a learning effect and the impact of performing more than three trials.

In conclusion, this study provides SDC and MID values for peak hip and knee angles and moments during a drop jump. Significant differences were found between limbs for peak hip adduction angle and moment, peak hip internal rotation angle and moment, peak knee flexion angle and peak knee abduction moment indicating that even in a healthy collegiate women's soccer population kinematic and kinetic asymmetries are present. The results of this study are important for injury prevention research in proposing values to define a meaningful biomechanical change, and thus facilitating better assessment of athletes' movement and the impact of injury prevention programs.

Chapter 3

INJURIES AND CHANGES IN BIOMECHANICAL KNEE INJURY RISK FACTORS ACROSS TWO COLLEGIATE SOCCER SEASONS USING THE FIFA11+ PREVENTION PROGRAM IN WOMEN

Introduction

ACL injuries cause a median of 159 days absence from sport, the longest time off due to any injury in NCAA women's soccer.[25] The ACL injury rate in collegiate women soccer players is quite high, approximately one primary ACL injury per team every other season.[8] This rate only encompasses the risk for primary ACL injuries; it does not include of the high risk for second ACL injuries.[18 19] The risk of second ACL injury is particularly high in collegiate athletes who have sustained an ACL injury during high school or before.[52]

Neuromuscular injury prevention programs, designed as dynamic warm-ups prior to athletic activities effectively reduce lower extremity injuries in college soccer players.[31 103] The FIFA11+ injury prevention program reduced lower extremity injuries by 92%,[31] ACL injuries by 76%,[33] and the time loss due to injury,[31] in male collegiate soccer players. The FIFA11+ has not been examined in women collegiate soccer players, but in high school women's soccer the FIFA11+ reduced the overall risk of injury, the risk of severe injuries (injuries that cause >28 days absence), and the risk of overuse injuries.[32] These and other smaller scale efficacy studies of the FIFA11+ have explored the program's impact over one soccer season.[34 35] No studies of the FIFA11+ have examined injury incidence over multiple seasons. Understanding the program's effects over multiple seasons is important to optimizing the FIFA11+ and building recommendations for its use. For example, if the FIFA11+ was less effective in its second season of use compared to its first, program changes could be needed so athletes continue to benefit from the program when it is used over multiple seasons.

The FIFA11+ involves running, strengthening, balance, and plyometric exercises, all focused on proper lower extremity alignment and landing technique, emphasizing avoidance of valgus collapse (knee abduction, hip adduction, and hip internal rotation). Given this focus, however, it is unknown whether the FIFA11+ actually changes athletes' movement patterns.

The FIFA11+ was designed to be implemented by coaches, parents, or athletes with limited or no knowledge of exercise progression. Most teams do not have access to medical or strength and conditioning staff who can tailor exercise progressions for athletes as they develop from season to season, so the FIFA11+ was developed with the intention it would be used over multiple seasons. Thus, examining whether the FIFA11+ changes movement patterns over one season is insufficient. It is important to know if the FIFA11+ changes movement patterns over multiple seasons. The mechanism by which the FIFA11+ prevents injuries is unknown. Understanding if the FIFA11+ changes movement patterns, particularly over multiple seasons, is important to determining the underlying mechanism of the program, and informs how improvements can be made.

Previous studies indicate that neuromuscular injury prevention programs may change movement patterns.[77 80 81 104 105] None of these sources have given any clinical context for the size of the observed changes. Smallest detectable change (SDC, also known as the minimal detectable change) and minimal important difference (MID, also known as the minimal clinically important difference) values give changes clinical context. In the case of ACL injury prevention programs SDC and MID values gauge whether a program has made a meaningful impact on known ACL injury risk factors and help build the link between injury prevention efficacy and the underlying mechanism of the program. High peak knee abduction moments and knee valgus collapse are known ACL injury risk factors that have been identified using a vertical drop jump landing task (drop jump)[26] and mechanistic studies.[27 29 106] Previous studies have found that motion analysis of a drop jump is reliable,[82-84] and Arundale et al. (Chapter 2) proposed SDC and MID values for the drop jump, providing context for the amount of change needed to exceed the measurement error (SDC) and be clinically meaningful (MID).

The purpose of this study was to report the injury incidence and explore the changes in hip and knee biomechanics with use of the FIFA11+ injury prevention program over two soccer seasons. Our injury incidence hypotheses were that: 1) after using the FIFA11+ for one season athletes in the intervention group would have a lower non-contact lower extremity injury incidence rate, particularly a lower knee injury incidence rate, than athletes in the control group, 2) after using the FIFA11+ for a second season athletes in the intervention group would have a lower non-contact lower extremity injury incidence rate, especially knee injury incidence rate, than after the first season of FIFA11+ use. Our biomechanical hypotheses were that: 1) after using the FIFA11+ for one season athletes in the intervention group would have smaller peak knee abduction, hip adduction, and hip internal rotation angles and moments than athletes in the control group, 2) after using the FIFA11+ for a second season athletes in the intervention group would have smaller peak knee abduction, hip adduction, and hip internal rotation angles and moments compared to after the first season of FIFA11+ use. This study aimed to place biomechanical changes in the context of clinically meaningful alterations in movement patterns through comparisons to SDC and MID values.

Methods

Three women's soccer teams (NCAA Division I and II) participated in this study. All athletes gave written informed consent prior to participating and the study was approved by the institution's human subjects review board. Teams were selected based on location relative to the study site and willingness to attend testing sessions. Two teams served as intervention teams and were selected based on their willingness to implement the FIFA11+ injury prevention program. The third team served as a control. Athletes in all positions and all academic years were included. Athletes were included regardless of injury and surgery history, but were excluded if they were unable to perform the drop jump.

The intervention teams (FIFA11+ group) performed the FIFA11+ for two consecutive soccer seasons (Figure 4). The teams instituted the FIFA11+ during preseason and continued to perform the program prior training sessions or games at least three times per week throughout both soccer seasons. Details of the exercises and progressions involved in the FIFA11+ injury prevention program are publically available (www.f-marc.com/11plus/home/). The FIFA11+ takes approximately 15-20 minutes to perform and involves running, flexibility, strengthening, balance, and plyometric exercises. No interventions were performed during the off-season. The Control team was followed for one soccer season (Figure 4). The team performed their standard warm-up prior to training sessions and games. Researchers only interacted with the team staff to organize testing sessions and arrange receipt of the injury report after the season. Athletic trainers working with all three teams recorded any injuries as well as the number of training sessions and games during each season they participated in the study (i.e. the Control group team for one season and the FIFA11+ group teams for two season). Injury definitions followed the UEFA consensus statement.[99] Only non-contact lower extremity injuries were analyzed, as these are the target of the FIFA11+.

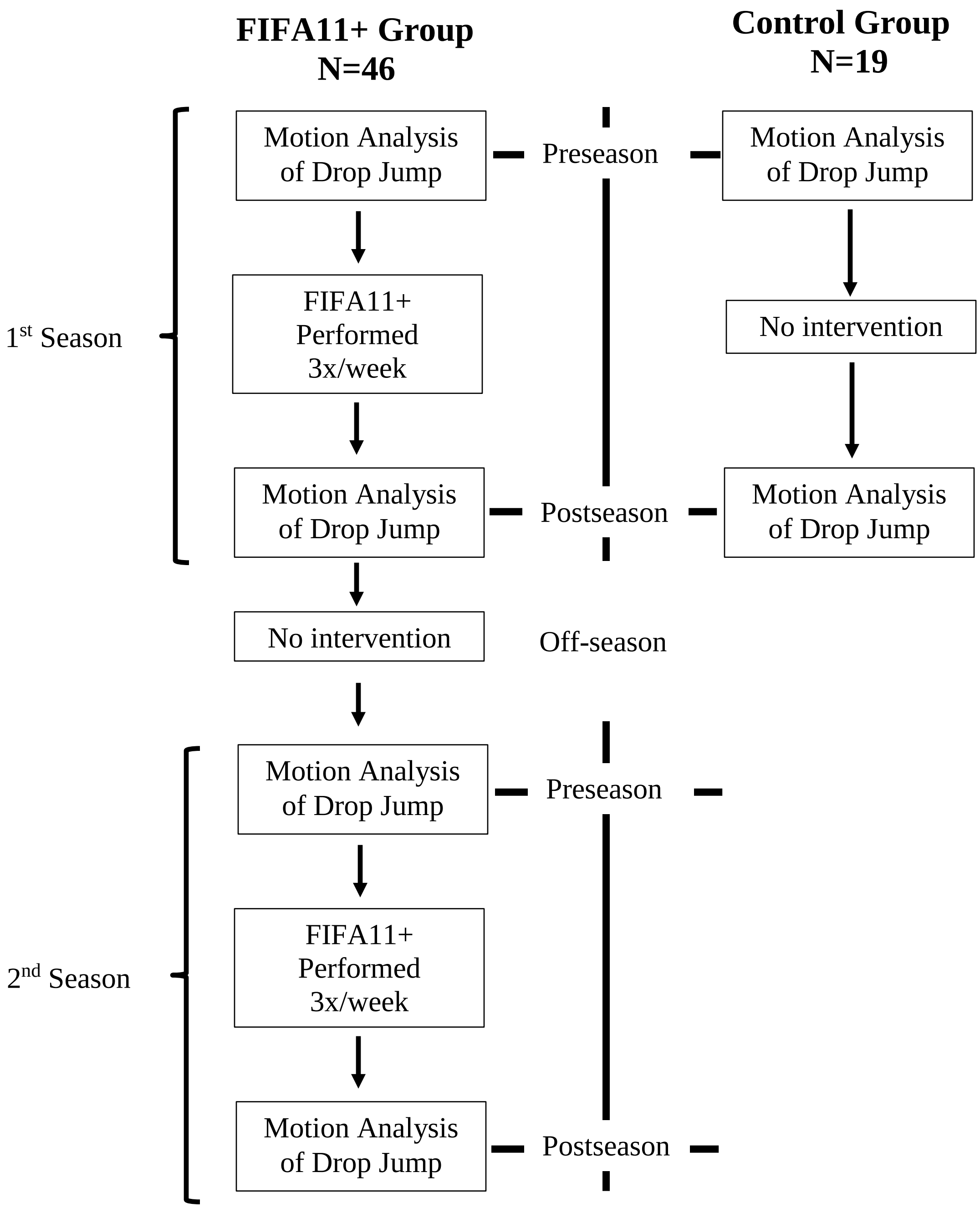

Figure 4 Flow diagram of study, including testing time points and intervention.

Motion analysis of a drop jump was performed in preseason and postseason (Figure 4). Motion analysis used an eight camera motion system (VICON; Oxford Metrics Ltd, London, England) sampling at 240Hz, and two 6 component embedded force plates (Bertec, Worthington, Ohio, USA) sampling simultaneously at 1080Hz. Twenty two retro-reflective markers were affixed to the acromion, pelvis, and lower extremities (medial and lateral metatarsal heads, medial and lateral malleoli, medial and lateral femoral condyles, the greater trochanters of each hip, and each acromion). Six rigid shells were affixed to the trunk, pelvis, thighs, and shanks. All markers were placed by one researcher (AA). Details of the drop jump, motion analysis, and post-processing methods are described in Arundale et al. (Chapter 2).

The drop jump was performed similar to Hewett et al..[26] Athletes dropped from a 40 cm box, landing with one foot on each force plate. Upon landing athletes immediately jumped up and landed again with one foot on each force plates. Analysis focused on the first jump, with initial contact defined as when the vertical force exceeded 5N. Athletes were given verbal instructions and allowed to practice the drop jump before three trials were recorded. Only the second and third trials were analyzed in accordance with Arundale et al. (Chapter 2).

Rigid-body analysis and inverse dynamics post-processing was performed using Visual 3D (C-Motion Inc., Germantown, Maryland, USA). Kinematic and kinetic data were low pass filtered at 6 Hz and 40 Hz respectively.[95] External moments were calculated and hip flexion, adduction, and internal rotation, as well as knee extension and adduction, were represented as positive values. Variables of interest were the peak hip angles and external moments in the sagittal, frontal, and transverse planes, as well as peak knee angles and external moments in the sagittal and frontal planes. The peak hip adduction and internal rotation angles and moments, the peak knee flexion angles and moments, and the peak knee abduction moments were analyzed separately on the right and left in order to compare directly to the SDC and MID values calculated in Arundale et al. (Chapter 2).

Valgus collapse is often studied by looking at its components (hip adduction, hip internal rotation, and knee abduction) individually. However, none of these motions occur in isolation, so to look at change in these variables together, a measure of valgus collapse was created. The hip adduction, hip internal rotation, and knee abduction angles were calculated at the time of peak knee flexion and the following equation was used: Valgus Collapse = hip adduction angle + hip internal rotation angle + (knee abduction angle x -1). Thus, negative valgus collapse values indicate an athlete is in more hip abduction, external rotation and knee adduction, where as positive valgus collapse values indicate hip adduction, internal rotation and knee abduction.

Statistical Analysis: The number of non-contact lower extremity injuries was reported both as the raw number of injuries and as the incidence per 1000 athletic exposures (AE). The number and incidence of non-contact knee injuries was also reported. Any game or training session was considered an AE. Relative rate ratios with their associated 95% confidence intervals were calculated using the incidence for each group.

To examine change in biomechanics over the first season, 2x2 (time x group) repeated measures ANOVAs with planned least squared comparisons assessed if the Control group and the FIFA11+ group changed differently over the first season. Planned comparisons were the interaction effect and change over the season for each variable of interest in the Control and FIFA11+ groups. Each groups' mean change over the season was compared to the SDC value (Chapter 2) and the changes in peak hip flexion, hip internal rotation, and knee flexion angles were also compared to the MID values (Chapter 2). Only changes greater than the SDC were considered meaningful, and changes greater than the MID considered clinically meaningful. A similar 2x2 ANOVA was used to determine if the FIFA11+ and Control groups' valgus collapse value changed differently across the first season.

To examine change in biomechanics over the second season, 2x2 (time x season) repeated measures ANOVAs with planned least squared comparisons assessed if the changes over the second season of FIFA11+ use were different from the changes over the first season of FIFA11+. Planned comparisons were the interaction effect and the change over the second season for each variable of interest. Again, mean differences were compared to the proposed SDC and MID values. A similar 2x2 ANOVA was used to examine if the change in valgus collapse value was different in the first season compared to the second in the FIFA11+ groups. Effect sizes were calculated as Cohen's D and categorized as small (d=0.2), medium (d=0.5), or large (d=0.8).[98]

Power Analysis: An a priori power analysis was performed using G*Power software v 3.1.0 (Universität Düsseldorf, Düsseldorf, Germany). The preseason mean right peak hip internal rotation angle was used to establish the effect size needed to detect a change larger than the SDC as it was one of the variables with the largest variance and related to the hypotheses of this study. These calculations indicated that an effect size of f=1.08 was needed. Thus, using a repeated measures ANOVA, with alpha set at p=0.05, and power = 0.80, two groups each with ten would be necessary.

Results

Sixty-eight athletes were enrolled and participated in at least one testing time point. The Control group had 15 athletes with biomechanical data at both time points (Figure 5). The FIFA11+ group had 39 athletes with complete biomechanical data across the first season, and 22 with complete biomechanical data across the second season. There were no differences between groups in age (p=0.85), height (p=0.15), or weight (p=0.30) (Table 5).

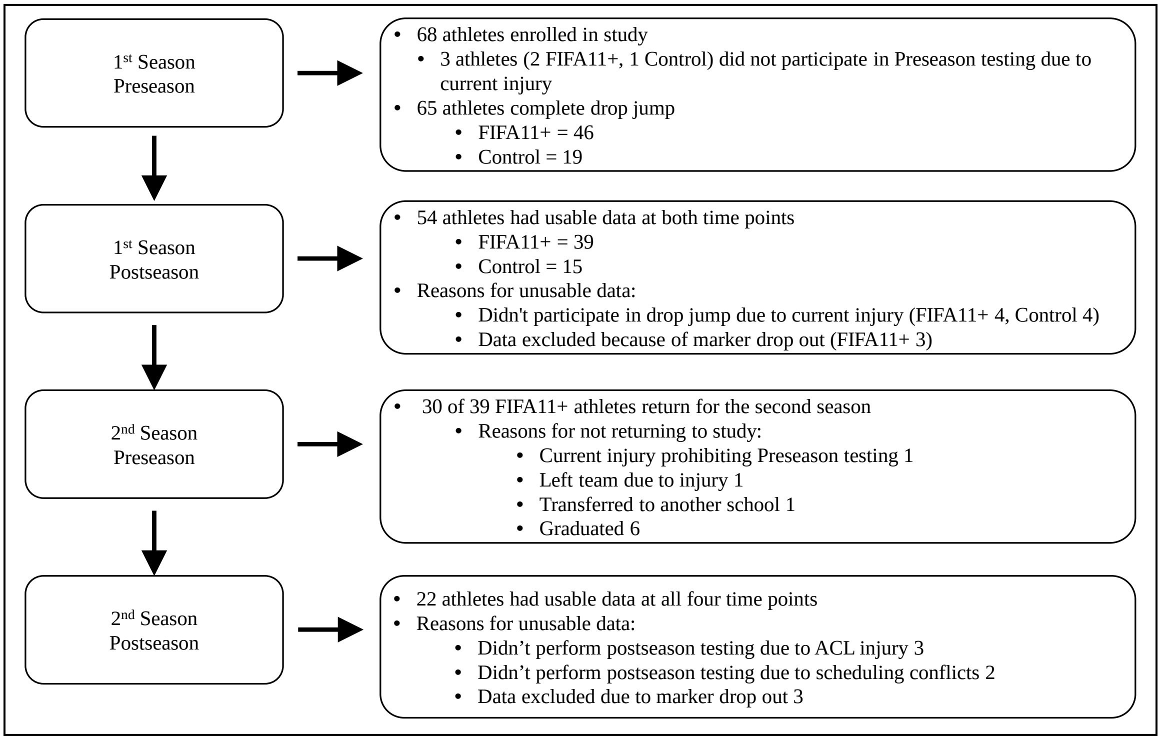

Figure 5 Number of athletes with biomechanical data at each time point and reasons for loss to follow-up.

Table 5 Anthropometrics and demographics of athletes

Variable	FIFA11+ Group (N=46)	Control Group (N=19)	p-value
Age (years)	19.4 ± 1.3	19.4 ± 1.2	0.85
Height (m)	1.7 ± 0.1	1.6 ± 0.1	0.15
Weight (kg)	60.9 ± 10.6	63.8 ± 8.5	0.30
Positions	Forward 9 Midfield 18 Defense 12 Goalkeeper 7	Forward 6 Midfield 5 Defense 7 Goalkeeper 1	
Year*	Freshmen 16 Sophomore 14 Junior 8 Senior 8	Freshmen 7 Sophomore 1 Junior 7 Senior 4	
Leg Dominance	Right 39 Left 7	Right 18 Left 1	

*In the US Freshmen = 1st year, Sophomore = 2nd year, Junior = 3rd year, Senior = 4th year. These years represent the athlete's playing years, not necessarily their year in college as sometimes athletes 'red shirt' their first year in college, meaning they practice with the team but do not compete.[107]

Injuries: In the first season 15 FIFA11+ group athletes had 20 injuries (Incidence rate = 8.0/1000 AE). Twelve Control group athletes had 19 injuries (Incidence rate = 11.0/1000 AE). This resulted in a 27% smaller non-contact lower extremity injury incidence rate in the FIFA11+ group compared to the Control group (relative rate ratio = 0.73, 95% CI 0.39 to 1.37, p=0.33). Table 6 shows the distribution of injuries by location of injury and injury type. Although the raw number of knee injuries was higher in the FIFA11+ group (6 knee injuries) than the control group (4 knee injuries) the injury incidence was similar for the two groups (FIFA11+ group knee injury incidence =2.4/1000AEs, Control group knee injury incidence = 2.4/1000AEs, relative risk 1.04, 95% CI 0.29 to 3.69, p=0.95).

In the second season 12 FIFA11+ group athletes had 13 injuries (Incidence = 6.9/1000 AE). Compared the first FIFA11+ season, there was a 13% smaller non-contact lower extremity injury incidence rate in the second season (relative rate ratio = 0.87, 95% confidence interval 0.43 to 1.74, p=0.69). However, there were more knee injuries in the second season (incidence 3.2/1000AEs) compared to the first (Table 6) (relative risk = 1.33, 95% CI 0.43 to 4.13, p=0.62), including three ACL injuries. There were no ACL injuries in the first season in either the Control or the FIFA11+ group.

Table 6 Body parts effected and injury types observed over study period

	Control Group (N=19) (%)	1st FIFA11+ Season (N=46) (%)	2nd FIFA11+ Season (N=30) (%)
Location of Injury			
Hip/Groin	0 (0)	2 (10)	0 (0)
Thigh	6 (32)	5 (25)	1 (8)
Knee	4 (21)	6 (30)	6 (46)
Lower Leg	0 (0)	1 (5)	1 (8)

Table 7 Continued

Ankle	8 (42)	4 (20)	4 (30)
Foot/Toes	1 (5)	2 (10)	1 (8)
Injury Type			
Muscle/Tendon	12 (63)	8 (40)	1 (8)
Ligament/Joint	7 (37)	9 (45)	11 (85)
Contusion	0	1 (5)	1 (8)
Bone	0	2 (10)	0

Percentages rounded up to whole integers.

First season: There were five variables that had significant time x group interactions, in other words, the change in the Control group was different from the change in the FIFA11+ group across the first season. However, only one interaction, right peak knee flexion angle (p=0.01, d=0.74) involved a meaningful change for either team (Table 8). The FIFA11+ group had no change in right knee flexion angle (Preseason = -105.60 ± 12.32°, Postseason = -104.69 ± 9.36°, p=0.56), however, the Control group had a statistically significant decrease (Preseason = -107.51 ± 12.62°, Postseason = -98.89 ± 11.03°, p<0.01), that was greater than both the SDC and MID. This significant and clinically meaningful decrease in the Control group's peak knee flexion angle on the right was somewhat mirrored on the left. There was no time x group interaction (p=0.20, d=0.47), and again no significant change in the FIFA11+ group (Preseason = -107.32 ± 12.65°, Postseason = -105.91 ± 10.70°, p=0.35) but the Control group had a significant decrease in left peak knee flexion angle exceeding the SDC (Preseason = -107.53 ± 12.23°, Postseason = -101.39 ± 10.18°, p=0.01).

Although no interaction effects were present, indicating the change in the Control group was not different from the change in the FIFA11+ group; the FIFA11+ group had a meaningful decrease in left peak hip adduction angle, meaning athletes landed in more hip abduction after the season (Preseason = -4.10 ± 0.72°, Postseason = -6.59 ± 0.67°, $p<0.01$) (Table 8). The FIFA11+ group did not have a significant or meaningful decrease in right peak hip adduction angle, but the Control group did (Preseason = -2.58 ± 4.79°, Postseason = -4.21 ± 4.95°). A similar pattern was seen for left and right peak hip internal rotation angles. The FIFA11+ group had a significant and meaningful decrease in left peak hip internal rotation angle, meaning the athletes landed in more hip external rotation after season (Preseason = -8.6 ± 3.7°, Postseason = -11.80 ± 6.50°, $p<0.01$), and the Control group had a non-significant but meaningful decrease in right peak hip internal rotation angle (Preseason = -5.84 ± 7.53°, Postseason= -8.03 ± 6.16°, $p=0.16$).

Table 8 Results of repeated measures ANOVA comparing the Control (N = 15) and FIFA11+ (N = 39) groups change over the first season

Peak Hip and Knee Angles and Moments	Time x Group Interaction p-value	Effect Size (Cohen's D)	Control Group Mean Change Across Season	p-value	FIFA11+ Group Mean Change Across Season	p-value	SDC
Hip Flexion Angle	0.65	0.13	-3.47°	0.23	-1.92°	0.28	4.99° (MID 5.82°)

Table 8 Continued

Peak Hip and Knee Angles and Moments	Time x Group Interaction p-value	Effect Size (Cohen's D)	Control Group Mean Change Across Season	p-value	FIFA11 + Group Mean Change Across Season	p-value	SDC
Hip Flexion Moment	<0.01*	0.82	-0.15 Nm/kgm	0.02	0.06 Nm/kgm	0.12	0.51 Nm/kgm
Left Hip Adduction Angle^	0.32	0.28	-1.12°	0.34	-2.49° **	<0.01	2.23°
Right Hip Adduction Angle^	0.37	0.26	-1.63° **	0.18	-0.35°	0.64	1.25°
Left Hip Adduction Moment	0.03*	0.60	-0.02 Nm/kgm	0.31	0.03 Nm/kgm	0.02	0.05 Nm/kgm
Right Hip Adduction Moment	0.60	0.14	0.03 Nm/kgm	0.27	0.05 Nm/kgm	0.02	0.06 Nm/kgm
Left Hip Internal Rotation Angle ^^	0.10	0.47	-0.81°	0.57	-3.66° **	<0.01	2.19° (MID 4.33°)
Right Hip Internal Rotation Angle ^^	0.26	0.32	-2.19° **	0.16	-0.15°	0.88	1.53° (MID 4.33°)
Left Hip Internal Rotation Moment	0.67	0.13	0.02 Nm/kgm	0.34	0.01 Nm/kgm	0.47	0.06 Nm/kgm
Right Hip Internal Rotation Moment	0.01*	0.71	-0.04 Nm/kgm	0.02	0.01 Nm/kgm	0.38	0.09 Nm/kgm
Left Knee Flexion Angle	0.10	0.47	-6.14° **	0.01	-1.41°	0.35	4.92° (MID 6.82°)
Right Knee Flexion Angle	0.01*	0.74	-8.62° **	<0.01	-0.90°	0.56	4.79° (MID 6.82°)
Left Knee Flexion Moment	0.03*	0.63	-0.07 Nm/kgm	.15	0.06 Nm/kgm	0.06	0.08 Nm/kgm

Table 8 Continued

Peak Hip and Knee Angles and Moments	Time x Group Interaction p-value	Effect Size (Cohen's D)	Control Group Mean Change Across Season	p-value	FIFA11 + Group Mean Change Across Season	p-value	SDC
Right Knee Flexion Moment	0.12	0.44	-0.09 Nm/kgm	0.13	0.02 Nm/kgm	0.58	0.07 Nm/kgm
Knee Abduction Angle	0.68	0.11	1.99°	0.02	2.37°	<0.01	5.78°
Left Knee Abduction Moment	0.20	0.36	-0.02 Nm/kgm	0.41	0.02 Nm/kgm	0.26	0.09 Nm/kgm
Right Knee Abduction Moment	0.34	0.27	-0.03 Nm/kgm	0.28	0.002 Nm/kgm	0.93	0.09 Nm/kgm

Positive values in the mean change across season columns indicate an increase over the course of the season. Negative values in the mean change across the season columns indicate a decrease over the course of the season. ^ The mean peak hip adduction angle at both time points was negative, meaning the athletes were landing in hip abduction. A negative change over the season indicates that over the season the athletes landed in more hip abduction. ^^ The mean peak hip internal rotation angle at both time points was negative, meaning the athletes were landing in hip external rotation. A negative change over the season indicates that over the season the athletes landed in more hip external rotation. * Significant Time x Group interaction. ** Mean change across the season greater than SDC or MID

The changes observed in the individual frontal and transverse plane hip variables were similar to the changes observed in the valgus collapse values. There was no interaction effect for left valgus collapse ($p=0.93$, $d=0.0$). Both groups had a decrease in valgus collapse (valgus collapse value becoming more negative), but only the FIFA11+ group had a significant decrease ($p=0.01$) (Figure 6). There was a significant interaction effect for the right valgus collapse ($p=0.02$, $d=0.63$), with the Control group having a significant decrease in their valgus collapse value ($p=0.01$) (Figure 6), and the FIFA11+ group having no change ($p=0.80$)

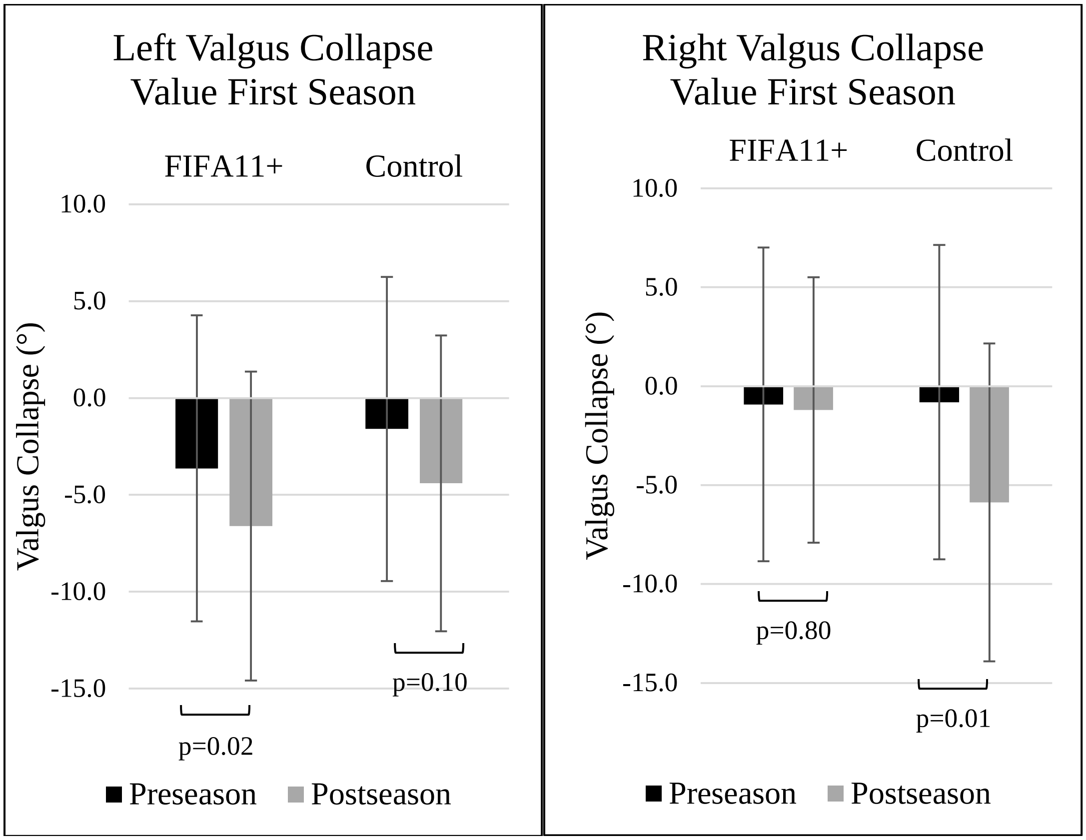

Figure 6 Change in valgus collapse values on the left and right over the first season for the FIFA11+ (N = 39) and Control groups (N=15).

Second season: Four measures had significant time x season interaction effects, in other words the change across the first season was different from the change across the second season (Table 9), however only two involved meaningful changes. There was a time x season interaction for left peak hip adduction angle (p=0.02, d=1.15). This interaction was driven by the meaningful decrease in peak hip adduction that occurred in the first season, as there was no significant change during the second season (Preseason = -5.91 ± 4.28 Nm/kgm, Postseason = -5.18 ± 4.39 Nm/kgm, p=0.19). There was also a significant time x season interaction (p<0.01, d= 1.53) for left peak hip internal rotation angle. Again this interaction was driven by the meaningful decrease in peak hip internal rotation that occurred in the first season, with no significant or meaningful change in the second season (Preseason = -10.13 ± 6.01°, Postseason = -9.36 ± 5.92°, p=0.33).

Table 9 Results of repeated measures ANOVA examining changes in biomechanics over the first FIFA11+ season (N=39) compared to the second FIFA11+ season (N=22)

Peak Hip and Knee Angles and Moments	Time x Season Interaction p-value	Effect Size (Cohen's D)	Mean Change Across 2nd Season of FIFA11+ use	p-value	Smallest Detectable Change
Hip Flexion Angle	0.14	0.66	3.23°	0.29	4.99° (MID 5.82°)

Table 9 Continued

Peak Hip and Knee Angles and Moments	Time x Season Interaction p-value	Effect Size (Cohen's D)	Mean Change Across 2nd Season of FIFA11+ use	p-value	Smallest Detectable Change
Hip Flexion Moment	0.33	0.44	0.05 Nm/kgm	0.18	0.51 Nm/kgm
Left Hip Adduction Angle^	0.02*	1.15	0.73°	-0.19	2.23°
Right Hip Adduction Angle^	0.69	0.18	0.76°	-0.32	1.25°
Left Hip Adduction Moment	0.07	0.85	-0.02 Nm/kgm	-0.15	0.05 Nm/kgm
Right Hip Adduction Moment	0.41	0.38	0.11** Nm/kgm	-0.30	0.06 Nm/kgm
Left Hip Internal Rotation Angle^^	<0.01*	1.53	0.77°	-0.33	2.19° (MID 4.33°)
Right Hip Internal Rotation Angle^^	0.98	0.00	1.53° **	-0.12	1.53° (MID 4.33°)
Left Hip Internal Rotation Moment	0.86	0.09	0.01 Nm/kgm	-0.57	0.06 Nm/kgm
Right Hip Internal Rotation Moment	0.66	0.20	0.01 Nm/kgm	-0.60	0.09 Nm/kgm
Left Knee Flexion Angle	0.87	0.06	-1.25°	0.36	4.92° (MID 6.82°)
Right Knee Flexion Angle	0.90	0.06	-1.46°	0.34	4.79° (MID 6.82°)

Table 9 Continued

Peak Hip and Knee Angles and Moments	Time x Season Interaction p-value	Effect Size (Cohen's D)	Mean Change Across 2nd Season of FIFA11+ use	p-value	Smallest Detectable Change
Left Knee Flexion Moment	0.03*	1.02	-0.05 Nm/kgm	0.06	0.08 Nm/kgm
Right Knee Flexion Moment	0.52	0.09	-0.01 Nm/kgm	0.76	0.07 Nm/kgm
Knee Abduction Angle	0.03*	1.04	0.53°	0.30	5.78°
Left Knee Abduction Moment	0.66	0.19	0.01 Nm/kgm	063	0.09 Nm/kgm
Right Knee Abduction Moment	0.76	0.14	0.03 Nm/kgm	0.47	0.09 Nm/kgm

Positive values in the mean change across season column indicates an increase over the course of the season. Negative values in the mean change across the season column indicates a decrease over the course of the season. ^ The mean peak hip adduction angle at both time points was negative, meaning the athletes were landing in hip abduction. A positive change over the season indicates that over the season the athletes landed in less hip abduction. ^^ The mean peak hip internal rotation angle at both time points was negative, meaning the athletes were landing in hip external rotation. A positive change over the season indicates that over the season the athletes landed in less hip external rotation. * Significant Time x Season Interaction, indicating the change over the 1st season of FIFA11+ use was different from the change over the 2nd season. **Mean change across the season was greater than the SDC; MID= minimal important difference. SDC and MID values from Arundale et al. (Chapter 2)

There were two variables that had meaningful changes across the second season. Right peak hip adduction moment (Preseason = -0.19 ± 0.08 Nm/kgm, Postseason = -0.30 ± 0.47 Nm/kgm, p=0.30) had a meaningful but not statistically significant increase (meaning athletes landed in less hip abduction), and right peak hip internal rotation angle (Preseason = -5.33 ± 5.03°, Postseason = -3.80 ± 4.10°, p=0.12) had a non-significant but meaningful increase (meaning they landed in less hip external rotation).

There was a large effect size for the time x season interaction (p=0.06, d= 0.87) comparing the change in left valgus collapse value over the first season to the second. This interaction was driven by the significant decrease in valgus collapse value in the first season, as there was no significant change in left valgus collapse value in the second season (preseason = -6.52 ±7.66°, postseason = -5.70 ± 8.49°, p=0.43). There was no interaction effect for right valgus collapse (p=0.70, d=0.17). There was no significant change in right valgus collapse over either season (second season preseason -4.03 ± 7.09°, postseason = -2.05°, p=0.14).

Discussion

This study aimed to describe the injuries and explore the changes in biomechanics, particularly those related to knee and ACL injuries, that occurred over two season of FIFA11+ use. There was a 27% decrease in non-contact lower extremity injuries in the first season of FIFA11+ use compared to controls, but no reduction in knee injury incidence. In the second FIFA11+ season there was a 13% decrease in non-contact lower extremity injury incidence, but a higher incidence of knee injuries, including three ACL injuries. Even though the FIFA11+ encourages proper lower extremity alignment and jump landing technique this study did not find consistent bilateral changes in valgus collapse or frontal and transverse plane movements over either season. These results indicate that the mechanism by which the FIFA11+ reduces non-contact lower extremity injuries may not be by changing movement patterns, and that in collegiate women the program may need to be modified so that it can make a greater impact preventing knee injuries and modifying potentially risky biomechanics.

This is the first study to examine injury incidence over two seasons of FIFA11+ use. Compared to controls, this study found there was a 27% decrease in non-contact lower extremity injury incidence during the first season of FIFA11+ use, in comparison in collegiate men there was a 19.5% rate reduction.[31] Unlike the men who had a 58% decrease in knee injuries, though, this study found no difference in knee injury incidence in the FIFA11+ group compared to the Control group. These results could indicate that although the FIFA11+ program may have influenced overall lower extremity injuries, it did not seem to protect against knee injuries in its first season of use. This trend was mirrored in the second season. There was also a 13% decrease in non-contact lower extremity injury incidence in the second FIFA11+ season compared to the first. But, there was a higher knee injury incidence in the second compared to the first, including three non-contact ACL injuries (two primary ACL injuries, one second ACL injury) on one FIFA11+ team. A larger scale efficacy study examining one season of FIFA11+ use by high school women soccer players found non-significant reductions in lower extremity injuries (rate ratio 0.71, p=0.07) and knee injuries (rate ratio 0.62, p=0.08).[32] Combined these studies together could potentially indicate that changes may need to be made to the FIFA11+ in order to increase the program's impact on knee injury reduction in women. And further that changes may be necessary to ensure the program is effective over multiple seasons.

This study found no consistent bilateral change in knee abduction, hip adduction, or hip internal rotation, variables associated with higher risk for knee injuries. Even when these variables were combined into a measure of valgus collapse, still only unilateral changes were observed and only in the first season. The FIFA11+ group had meaningful increases in hip abduction and external rotation, and a significant decrease in their valgus collapse value over the first season. Theoretically these are positive changes, however these changes were only unilateral. The Control group experienced the same changes, just on the opposite side, the right side. In the second season the FIFA11+ group had no meaningful changes on the left, and although not significant, actually had an increase in valgus collapse value, indicating their changes could actually be placing them in a position of higher risk. The biomechanical results of this study seem to indicate that in collegiate women the FIFA11+ may not change movement patterns associated with a high risk for knee injuries, and potentially link the absence of knee injury prevention to the absence of bilateral changes in hip and knee frontal and transverse plane biomechanics.

This study did observe clinically meaningful decreases in knee flexion on the right and meaningful decreases in knee flexion on the left in the Control group. The FIFA11+ encourages "soft landings" and jump landings in greater hip and knee flexion. Although the FIFA11+ group did not have increased knee flexion angles over either season, they did not have any meaningful decreases. Sagittal plane forces alone do not cause ACL injuries, but a more extended knee position in combination with transverse and frontal plane forces may place the ACL at greater risk for injury.[108]

Thus the FIFA11+ may have successfully mitigated decreases in knee flexion, however such changes may be less important than influencing knee and hip frontal and transverse plane mechanics when it comes to preventing knee injuries.

Biomechanical studies examining the effects of other injury prevention programs have reported changes in movement patterns. Similar to this study, two studies have found no change in knee flexion angles,[104 105] after use of an injury prevention program. But two other studies found increases in knee flexion.[80 81] The changes in knee flexion observed in only one of these studies, however, would be considered meaningful when compared to the SDC values (Chapter 2). One study examining the Prevent Injury and Enhance Performance (PEP) program, a predecessor to the FIFA11+, in high school age women athletes (mean age 14.9 years old) found meaningful increases in hip abduction and external rotation angles,[105] when compared to the SDC values (Chapter 2). However, the study only examined the dominant limb,[105] defined as their preferred kicking limb, in a cohort of 18 athletes. Asymmetries are common between limbs in women soccer players (Chapter 2),[109] so having information on the non-dominant limb would be very helpful for comparison. In this cohort, using the same definition, the majority of the athletes (86%) were right foot dominant. Thus, the results of this study finding meaningful increases in hip abduction and external rotation on the left, with no meaningful changes on the right, may stand in contrast to their results. Unfortunately, differences in the way external moments were calculated, particularly with regard to if and how moments were normalized, makes it difficult to compare the results of previous studies reporting changes in frontal and transverse plane movements[77 80 81 104] to the SDC/MID values (Chapter 2). But outcome studies of the Sportsmetrics program, a 90-120 minute 6-

week long injury prevention program, have consistently reported changes frontal plane knee mechanics.[77 81 104] Future research is needed investigate if the longer duration and higher intensity, particularly the higher dosage of plyometric exercises and close supervision, involved in the Sportsmetrics program as compared to the FIFA11+, may be necessary to change biomechanical knee injury risk factors and preventing knee injuries in women.

Overall, the results of this study may indicate that the mechanism by which the FIFA11+ prevents non-contact lower extremity injuries is not by changing biomechanics. The FIFA11+ has been shown to improve dynamic balance and agility in soccer players.[40] Thus, it seems plausible that the FIFA11+ changes neuromuscular control, without changing an athlete’s biomechanics as captured by a traditional kinematic and kinetic viewpoint. This study took a close look at the injury incidence and biomechanical risk factors for knee injuries in particular, because knee injuries, especially ACL injuries, are common, severe,[5 6 8 25] and carry long term consequence.[15] When the FIFA11+ was developed its creators wanted to develop a program that prevented all lower extremity injuries and had a large focus on the hip and core musculature. The results of this study indicated that the FIFA11+ group had more meaningful changes at the hip than at the knee, potentially reflecting that hip/core focus during the program’s development. The results of this study could help support that exercises specifically targeting the knee and knee biomechanics may need to be added to the FIFA11+, particularly for women, in order to broaden its original hip/core focus and to improve its efficacy.

This study was unique in creating a valgus collapse measure. Hip adduction, hip internal rotation, and knee abduction do not occur in isolation. From a clinical standpoint knowing specifically if a change is occurring in hip abduction versus external rotation is less important than knowing whether the overall movement pattern is improving. Thus, use of this measure seems to both help summarize the results of the individual joint measures, but also help frame a bigger picture for the change, or lack thereof, in movement these athletes are experiencing.

Each exercise in the FIFA11+ has three progressively more difficult stages, unfortunately neither progression through the FIFA11+, nor the number of times each player performed the FIFA11+ were recorded. The program was run and progressed by the team athletic trainers, and the researchers received verbal confirmation from the coaching staff that the program was being performed in full. Previous research has shown that compliance influences the outcomes of the FIFA11+.[32] However, the researchers have no reason to believe that the lack of significant bilateral changes in valgus collapse were a result of non-compliance. The FIFA11+ group teams were chosen because their coaching staff was enthusiastic about participating, team athletic trainers agreed to assist with the study, and both wanted to see a decrease in lower extremity injury incidence. Future work could examine if there is a relationship between compliance/dosage, program intensity, injuries, and changes in biomechanics. This study was adequately powered, but injuries, graduation, scheduling conflicts, transferring to other universities, and marker drop out meant that data on all athletes was not available at all time points. Marker drop out primarily occurred as a result of the athletes' arm swing obstructing the cameras' view of the thigh shells. The researchers chose not to limit arm motion in order to preserve the sport-like quality of the task.

In conclusion, the FIFA11+ seems to decrease lower extremity injury risk in collegiate women soccer players, but not knee injury over two seasons of use. The program may mitigate bilateral decreases in knee flexion over the course of two soccer seasons, but it does not seem to create bilateral changes in valgus collapse. The results of this study seem to reflect the program's creator's focus on the hip and core, raising the possibility that more may be needed for women in order to address the knee. This study should not dissuade clinicians, coaches, or athletes from implementing the program. Rather, this study stands as one of the first in many investigating the program's mechanism, so that researchers and clinicians can continue to optimize the FIFA11+; keeping future generations of athletes healthy and on the field.

Chapter 4

CAREER LENGTH AND INJURY INCIDENCE IN MAJOR LEAGUE SOCCER AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

Introduction

Injuries are unfortunately a common occurrence in soccer. Approximately eight severe injuries, or injuries that cause an athlete to miss more than 28 days of soccer, occur per team per season in men's European professional soccer.[110] Anterior cruciate ligament (ACL) injuries are one of the more common severe injuries seen in soccer, with an incidence of approximately 0.07 per 1,000 hours or 0.43 injuries per team per season.[50]

Returning to play and career longevity is of great concern to professional athletes as sport is their primary occupation and a source of income. An athlete's return to sport after injury is also of great concern to a club, as the athlete's return effects the coach's staffing options, the team's financial interests and the win-loss record.[45] Career length after ACL injury has been explored in some professional sports. In the National Basketball Association, athletes play for approximately 4 ± 2-3 years after ACL reconstruction.[57,111] This is similar in length to athletes in the National Hockey League (4.5 ± 3.3 years)[112] and quarterbacks in National Football League (NFL, 4.9 ± 2.7 years).[58] Another study of NFL athletes found that offensive linemen with a history of ACL reconstruction were 2.2 times more likely to have a shorter career than offensive linemen with no history of ACL injury.[113]

Return to sport in European men's professional soccer is very high, with 97% of athletes playing for Union of European Football Associations (UEFA) Champions League teams returning to game play after ACL reconstruction. However, only 65% of these athletes continue to play at the same level three years later.[50] The truncated career length information seems startling, however it is difficult to interpret without reference for the mean career length in European men's professional soccer. Injury trends and return to sport may be different in American and European men's professional soccer. A study of United States professional men's soccer players participating in Major League Soccer (MLS) found that 77% were able to return to the highest league with a mean career length after reconstruction of 4 ± 3 years.[56] The study found no significant difference in career survival in the first five years after return to play between athletes after ACL reconstruction and healthy controls, but unfortunately, this study was based only on online and publically available data.

In men's professional soccer a musculoskeletal injury increases an athletes' risk three fold for a new musculoskeletal injury in the subsequent season.[48] Hägglund et al.,[48] found that hamstring, groin, and knee injuries, in particular, increased the risk for an identical injury in the subsequent season by two to three times. A history of knee injury increasing the risk for a new knee injury is also found in athletes with a history of ACL reconstruction[55]. Athletes after ACL reconstruction have been reported to be at six times higher risk for a second ACL injury (ipsilateral or contralateral) compared to athletes with no history of an ACL injury.[18] In men's soccer a history of ACL injury, reconstruction, and return to play doesn't just increase the risk for a second ACL injury, but in fact may increase the risk for all new knee injuries, especially overuse knee injuries.[55] Risks for other lower extremity injuries, outside the knee joint, upon return to sport after ACL reconstruction or any differentiation of risk by graft type have not been reported. ACL graft type has also been implicated in ACL graft rupture (allograft),[114-116] and anterior knee pain (bone-patellar-tendon-bone [BPTB] autograft).[117]

The purpose of this study was to examine the careers of athletes returning to MLS after ACL reconstruction, and specifically explore career length and lower extremity injury incidence in comparison to age-matched control athletes. This study involved four hypotheses. First, we hypothesized that athletes with a history of ACL reconstruction and successful return to play in MLS would have shorter careers when measured both in years and athletic exposures, and would participate in fewer games compared to age-matched control athletes with no history of ACL injury. Second, we hypothesized that athletes after ACL reconstruction and return to play in MLS would have a higher lower extremity injury incidence, particularly higher incidences of non-contact injuries, muscle injuries, thigh injuries, hamstring injuries, knee injuries, and overuse injuries compared to MLS athletes with no history of ACL injury. Third, we hypothesized that athletes after ACL reconstruction would miss more days due to injury upon their return to MLS and would experience more severe injuries than their counterparts with no history of ACL injury. And finally, we hypothesized that there would be no difference in injury risk based on the type of graft used for ACL reconstruction.

Methods

This study was a matched cohort study approved by the University of Delaware Institutional Review Board and the MLS Medical and Research Committee (M-MARC). Data were collected prospectively by the certified athletic trainers of each MLS team and were entered into the HealtheAthlete™ database used by MLS to track injuries. Demographic, injury, and exposure data for all MLS athletes from January 1, 2011 to March 8, 2016 were then extracted from the database. All athletes who had sustained an ACL injury were identified. Athletes were excluded if they had a partial ACL injury, grade III ligamentous injury, chondral defect ≥1cm^2, or history of an ACL injury prior to the study period. Athletes identified as having an ACL injury and returned to play but then sustained a second ACL injury (both ipsilateral graft ruptures) within the study period were included, however for injury incidence calculations the date of their second ACL injury was used as the end of their career.

The ACL reconstructed athletes were matched with controls based on age. Age served as a proxy for playing experience. Control athletes were identified through participation records in the HealtheAthlete™ database. Control athletes were identified as the athlete closest in age to their respective ACL group athlete who participated in a training session or game on the same day that the ACL group athlete returned to MLS training. This date, for both groups, was referred to as the "return to play date."

Career length was defined as the period between the return to play date and the date the player left or retired from MLS. Career length was measured in years, athletic exposures (AEs, any game or training session), number of games, and a games-to-training sessions ratio. Games included pre-season, reserve team, regular season and post-season games. The games-to-training session ratio was used rather than the raw number of training sessions to capture the amount of training the athlete was performing relative to the number of games they played. For example, a small games: training session ratio would indicate that an athlete was training quite a bit but not playing in games.

In addition to career length, a matched period was also defined to capture the window of time after the athlete's return to sport when participation or subsequent injuries could be related to their ACL reconstruction. The matched period extended from the return to play date for two years or until the ACL group athlete left MLS, whichever occurred first. The matched period was measured in AEs, games, and games-to-training sessions ratio, as well as the percentage of regular/post-season games the athlete started, substituted, or was not selected. The percentage of regular/post-season games each player started, substituted, or was unused, was calculated using both the HealtheAthlete™ database and publically available data (www.mlssoccer.com). The MLS website provided the information on whether the athlete started, substituted, or was unused for each game. For each game that an athlete was unused, the HealtheAthlete™ database clarified if they were unused because they were unavailable due to injury or if they were available for selection (i.e. healthy) but not chosen as a starter or substitute. The percentage of regular/post-season games started was calculated by dividing the number of regular/post-season games started by the total number of regular/post-season games in the matched period that the athlete was available for selection. A similar calculation was performed for the percentage of regular/post-season games substituted and unused.

The UEFA consensus statement injury definitions were used.[99] A lower extremity injury was defined as any complaint related to the hip/groin, thigh, knee, lower leg, ankle, or foot, sustained by a player during a soccer game or training session and caused the athlete to seek medical attention.[99] A time-loss injury was defined as an injury which caused an athlete to miss a subsequent training session or game. A non-contact injury was defined as an injury that was not the result of a collision with another player or object. Injury severity was defined by the number of days away from soccer; minimal (1-3 days), mild (4-7 days), moderate (8-28 days), or severe (>28 days).[99] Injury incidence of each group during the matched period was calculated by dividing the total number of injuries by the number of exposures and then multiplying by 1,000 AEs. The total number of days missed due to injury by each player was calculated, and each athlete's injuries were categorized by severity. Athletes in the ACL group were then categorized by graft type (BPTB autograft, BPTB allograft, and hamstring autograft) and injury incidence and severity was calculated for each graft type group.

All statistical analyses were performed in SPSS v. 24 (IBM, Armonk, NY, USA). Demographics were compared between the ACL and Control groups using t tests. A MANOVA was used to determine if there were differences between groups in career length measured in years, AEs, games, and games-to-training sessions ratio. All athletes, including those still playing in MLS, were included in the analysis. Career length for those athletes still playing in MLS was calculated using the last day of the study as the last day of their career. A second MANOVA was used to determine if there were differences between groups in the number of AEs, games, and games-to-training sessions ratio in the matched period. A third MANOVA was used to determine if there were differences between groups in the percentage of games started, substituted, or unused.

The percentage of an athlete's potential career that they played was calculated by dividing the athlete's career length by their time in the study (from return to sport date to the last day of the study). To measure survival in MLS, a cumulative survival curve was graphed as well as athletes' percentage of potential career played. A chi squared was used to determine if there was a difference between the two groups in the number of athletes who played 100% of their potential careers.

Generalized linear model regressions with Tweedie distributions and logit link functions were used to calculate the relative risks and 95% confidence intervals for lower extremity injuries, time-loss lower extremity injuries, non-contact injuries, muscle injuries, thigh injuries, hamstring injuries, knee injuries, and overuse injuries. The percentage of regular/post-season games unused were included in all models as a covariate. An ANCOVA was used to determine if there were differences between groups in the number of days missed due to injury, including the percentage of regular/post-season games unused as a covariate. Generalized linear model regressions with Tweedie distributions and logit link functions were also used to determine the relative risks and 95% confidence intervals for each category of injury severity (minimal, minor, moderate, severe). The control group was used as the reference group in all models.

Generalized linear model regressions with Tweedie distributions and logit link functions were used to calculate the relative risk based on graft type and 95% confidence intervals for lower extremity injuries, time-loss lower extremity injuries, non-contact injuries, muscle injuries, thigh injuries, hamstring injuries, knee injuries, and overuse injuries as well as for each category of injury severity. The BPTB autograft group was used as the comparison group in all models.

Alpha was set a priori at p=0.05 and Cohen's d effect sizes were calculated and compared to small d=0.20, medium d=0.5, and large d=0.8.[118] Power calculations were performed a priori using preliminary data and G*Power software v 3.1.0 (Universität Düsseldorf, Düsseldorf, Germany). The Control group had a preliminary knee injury incidence of 0.9 per 1,000AEs, using a generalized linear model with

Tweedie distribution and logit link function, with p=0.05 and power=0.80, it was determined that a relative risk of 1.4 could be detected with a total sample size of 73.

Results

Between January 1, 2011 and March 8, 2016, 64 athletes sustained 66 ACL injuries (Figure 7). Three athletes were excluded because they had ACL injuries with concomitant lateral collateral ligament avulsions, and one due to only a partial ACL injury. Two additional athletes were excluded because they had a history of an ACL injury prior to the study period, and four were still in rehabilitation at the end of the study period. This left 54 athletes (54 primary ACL injuries) with the potential to return to MLS within the study period. Of these 54 athletes, 40 returned to MLS (74%) and were included in the analysis. Two athletes returned to play, however sustained graft ruptures (BPTB autograft 1, BPTB allograft 1). Table 10 includes the anthropometrics and demographics of the included athletes in each group.

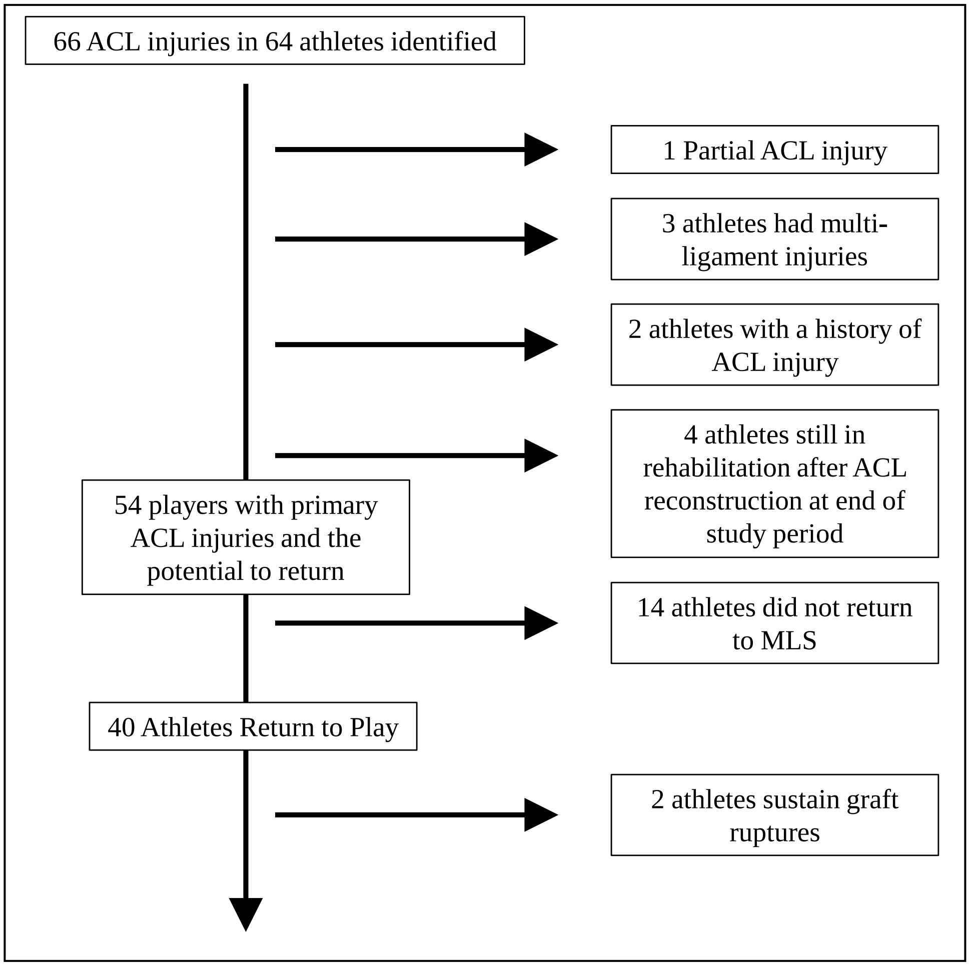

Figure 7 Flow diagram showing inclusion of athletes in study

Table 10 Anthropometrics and demographics of the ACL and Control groups

	ACL Group (N=40)	**Control Group** (N=40)	**p-value**
Height (m)	1.83 ± 0.06	1.80 ± 0.07	0.06
Weight (kg)	79.2 ± 8.3	77.4 ± 9.7	0.38
Age at Beginning of MLS Career (years)	24.1 ± 4.3	24.9 ± 3.8	0.42
Age at Date of Return to Play (years)	26.8 ± 4.1	26.7 ± 3.8	0.85
Graft Type	BPTB Autograft: 25 BPTB Allograft: 6 Hamstring Autograft: 6 Graft Type Information Missing: 3	-	-

Of the 40 athletes in each group, 12 ACL group athletes and all 40 Control group athletes were still actively playing in MLS at the end of the study period. There was a significant difference between groups in career length (Table 11A) when measured in years ($p<0.01$, $d=0.94$), AEs ($p<0.01$, $d=0.97$), and games ($p<0.01$, $d=0.79$). However, there was no difference in games-to-training sessions ratio ($p=0.54$, $d=0.14$). There were no differences between groups in AEs ($p=0.95$, $d=0.00$), games ($p=0.44$, $d=0.18$), or games-to-training sessions ratio ($p=0.87$, $d=0.00$) during the matched period (Table 11B).

Table 11 Differences between groups in career length and matched period exposures

A) Career Length				
	ACL Group (N=38)	**Control Group (N=38)**	**p-value**	**Effect size**
Years	1.3 ±1.3	2.5 ± 1.3	<0.01	0.94
Athletic Exposures	209.0 ± 199.7	421.4 ± 255.5	<0.01	0.97
Games	49.2 ± 51.8	92.2 ± 58.5	<0.01	0.79
Games-to-Training Sessions Ratio	0.30 ± 0.2	0.27 ± 0.1	0.54	0.14
B) Matched Period				
	ACL Group (N=38)	**Control Group (N=38)**	**p-value**	**Effect size**
Athletic Exposures	169.9 ± 129.	171.6 ± 124.9	0.95	0.00
Games	36.8 ± 28.7	42.4 ± 34.7	0.44	0.18
Games-to-Training Sessions Ratio	0.31 ± 0.22	0.30 ± 0.12	0.87	0.00

Four ACL group athletes returned to training and participated in reserve team and/or pre-season matches, however did not return to regular/post-season games. As a result these ACL group athletes and their matched Control group athletes were not included in the analysis of the percentage regular/post-season games started, substituted, or unused. Athletes in the Control group had a significantly higher percentage of regular/post-season games started (60.1 ± 33.8%, ACL group 36.7 ± 34.3%, $p<0.01$, $d=0.76$). The ACL group had a significantly higher percentage of regular/post-season games unused (31.0 ± 34.4%, ACL group 47.4 ± 35.5%, $p=0.03$, $d=0.54$) and seemingly higher percentage substituted as well (8.9 ± 17.5%, ACL group 15.9 ± 15.4%, $p=0.08$, $d=0.43$) compared to Control group athletes (Figure 8). Figure 9 shows the cumulative survival of athletes still playing at each year after the return to play date. There was a significant difference between groups in the number of athletes who played 100% of their potential careers (i.e. athletes who played the entire duration of time they were in the study) in the ACL group (12 of 40) compared to the Control group (40 of 40, $p<0.01$) (Figure 10).

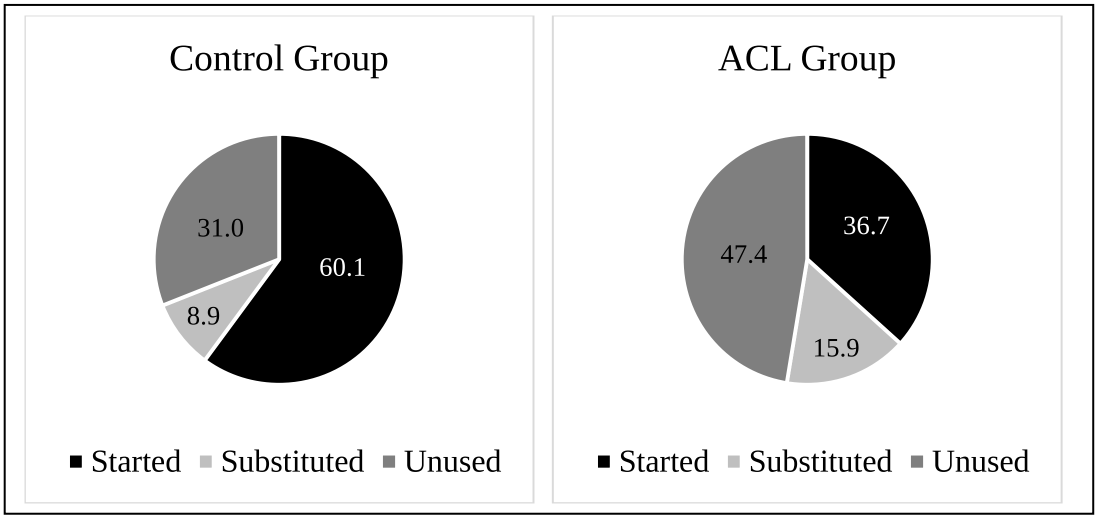

Figure 8 Pie charts representing the mean percentage of regular/post-season games started, substituted, or were unused for each group

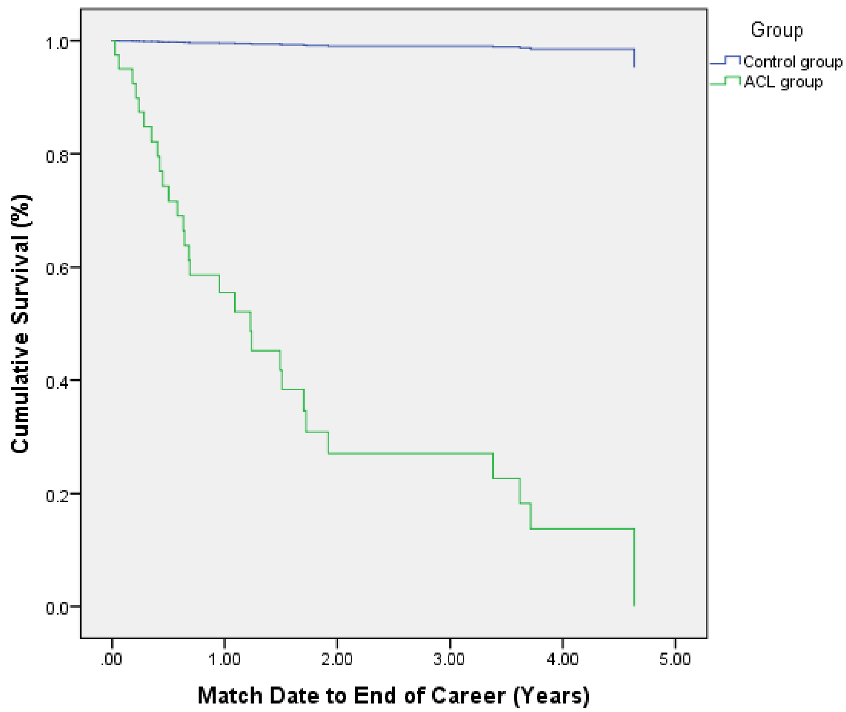

Figure 9 Cumulative number of athletes still playing for each year after the return to play date

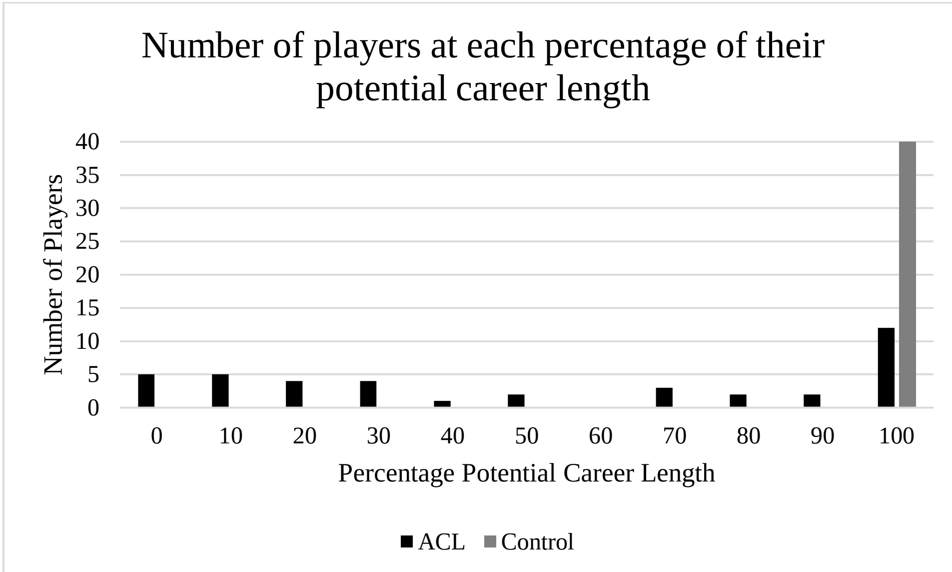

Figure 10 The number of athletes who played each percentage of their potential careers

In the matched period the ACL group had 114 lower extremity injuries in 6,798 AEs (lower extremity injury incidence rate of 16.8/1,000 AEs). The Control group had 132 lower extremity injuries in 6,868 AEs (lower extremity injury incidence rate 19.2/1,000 AEs). Table 12 details the number of injuries, incidence rate, and relative risk for each category of injury studied. The ACL group seemed to have a lower risk for hamstring injuries compared to the Control group (relative risk 0.32, 95% confidence interval 0.09-1.13, p=0.07). The risk for thigh injuries (relative risk

0.37, 95% confidence interval 0.12-1.11, p=0.08) also appeared to be lower in the ACL group compared to the Control group (Table 12). The only category of injury where the ACL group seemed to have a higher risk than the Control group was knee injuries (relative risk 2.59, 95% confidence interval 0.69-9.69, p=0.16).

Table 12 Number of injuries, incidence, relative risk, and significance for injuries during the matched period in the ACL and Control groups

	ACL group Raw Number of injuries (Rate per 1,000 AEs)	**Control group Raw Number of injuries** (Rate per 1,000 AEs)	**Relative Risk** (95% confidence interval)	**p-value**
Lower Extremity Injuries	114 (16.77)	132 (19.23)	0.87 (0.55-1.37)	0.55
Time-loss Lower Extremity Injuries	62 (9.12)	55 (8.01)	0.98 (0.50-1.93)	0.96
Non-Contact Lower Extremity Injuries	28 (4.12)	14 (2.04)	1.37 (0.51-3.72)	0.54
Muscle/Tendon Injuries	30 (4.41)	34 (4.95)	0.55 (0.22-1.42)	0.22
Thigh Injuries	22 (3.23)	26 (3.79)	0.37 (0.12-1.11)	0.08
Hamstring Injuries	8 (1.17)	18 (2.62)	0.32 (0.09-1.13)	0.07
Knee Injuries	17 (2.50)	10 (1.46)	2.59 (0.69-9.69)	0.16

Table 12 Continued

	ACL group Raw Number of injuries (Rate per 1,000 AEs)	**Control group Raw Number of injuries** (Rate per 1,000 AEs)	**Relative Risk** (95% confidence interval)	**p-value**
Overuse Injuries	5 (0.74)	6 (0.87)	0.36 (0.09-1.40)	0.14

There was no significant difference between groups in the mean number of days missed due to injury (p=0.19, d=0.38), with the ACL group missing on average 39.8 ± 55.1 days, and the Control group missing 26.5 ± 61.2 days. The ACL group had a relative risk of 2.17 for severe injuries (95% confidence interval 0.86-5.48, p=0.10) (Table 13).

Table 13 Number of time loss injuries according to injury severity in each group, relative risk, and significance

	ACL Group	**Control Group**	**Relative Risk**	**p-value**
Minimal (1-3 days)	7	9	0.84 (0.29-2.45)	0.75

Table 13 Continued

	ACL Group	Control Group	Relative Risk	p-value
Mild (4-7 days)*	14	12	1.64 (0.73-3.70)	0.23
Moderate (8-28 days)**	29	24	1.32 (0.70-2.49)	0.39
Severe (>28 days)	17	9	2.17 (0.86-5.48)	0.10

* The percent of regular/post-season games unused was a significant covariate indicating that as the percentage of regular/postseason games unused increased the risk for minor injuries decreased (relative risk 0.08, 95% confidence interval 0.02-0.32, p<0.01) ** The percent of regular/post-season games unused was also a significant covariate indicating that as the percentage of regular/postseason games unused increased the risk for moderate injuries decreased (relative risk 0.35, 95% confidence interval 0.14-0.89, p=0.03)

The majority of ACL reconstructed athletes had BPTB autografts (68%) (Table 10). There were no differences in risk between graft type groups for lower extremity injuries or time loss lower extremity injury rates (Appendix A), however the hamstring autograft group had a significantly lower risk for muscle/tendon injuries compared to the BPTB autograft group (relative risk 0.11, 95% confidence interval 0.02-0.77, p=0.03). The risk of a new knee injury (Appendix A) was approximately the same in each graft type group. The BPTB allograft group had approximately 19 times higher risk for overuse injuries compared to the BPTB autograft group (relative risk 18.85, 95% CI 2.73-130.13, p<0.01).

Comparing the graft type groups by injury severity, the hamstring autograft group had almost a 6 times higher risk for minimal injuries compared to the BPTB autograft group (relative risk 5.56, 95% confidence interval 1.39-22.27, p=0.02) (Appendix B). The hamstring autograft group may have also had a higher risk for severe injuries (relative risk 2.32, 95% confidence interval 0.95-5.67, p=0.07). The number of days missed due to injury were as follows: BPTB autograft 35 ± 50 days, BPTB allograft 42 ± 72 days, and hamstring autograft 73 ± 69 days.

Discussion

Seventy-four percent of athletes returned to MLS after primary ACL reconstruction. Athletes who returned to play in MLS had significantly shorter playing careers than their counterparts with no history of ACL injury, by approximately half. Interestingly, during the matched period (the two years after return to play or until the ACL group athlete left MLS, whichever occurred first) there were no differences in athletic exposures, indicating athletes were participating to the same extent. However, ACL group athletes started significantly fewer games and were unused in significantly more games than Control group athletes. There were no differences between groups in lower extremity injury risk, however the ACL group may have had a lower risk for hamstring and thigh injuries compared to the Control group. The ACL group may have also been at higher risk for more severe injuries. The results of this study indicate that more work may be needed to assist MLS athletes after ACL reconstruction return to performance once they have returned to play.

In 2016, Waldén et al.[50] reported that 100% of athletes playing for UEFA Champions League teams returned to training, 97% returned to game play after ACL reconstruction, but only 65% were still playing after three years. This study found that return to MLS was lower than what was reported from UEFA, with only 74% of players returning to MLS training, and 69% returning to game play. However, the findings of this study are similar to rate previously reported in the MLS of 77%.[56]

The striking finding of this study was that athletes in the ACL group had careers approximately half as long as those in the Control group. This study found that only 5 of the 40 ACL group athletes (12.5%) played ≥3 years after their ACL reconstruction. This is a startling statistic particularly given the comparison to the 65% of athletes after ACL reconstruction still playing for UEFA Champions League teams after the same period of time.[50] The results of this study are also in contrast to those of Erickson et al.[56] who found a mean career length for ACL group athletes of 4.0 ± 2.8 years and that approximately 52% were still playing after three years. Erickson et al.[56] also reported no difference between their ACL group and Control group in MLS survival. The decision to include athletes in both groups who were still active in MLS influenced the findings of this study. If the results of this study had been held until all of these players had concluded their MLS careers, the Control group mean career length would be even longer than the 2.5 ±1.3 years, and making the contrast to the ACL group mean career length (1.3 ± 1.3 years) even greater.

Although the ACL group athletes had shorter careers, they participated in a similar number of athletic exposures while they were playing. There were no significant differences between groups in the number of athletic exposures or games, nor was there a difference in the games-to-training sessions ratio during the matched period. These findings support a view of return to sport not as one specific time point, but rather as a continuum.[119] The similarities between groups in participation indicates that these athletes after ACL reconstruction made a return to participation and return to sport. However, athletes did not make a full return to their prior level of performance[119] demonstrated by the differences between groups in the percentage regular/post-season games started and unused. The ACL group athletes started significantly fewer and were unused significantly more than the Control group. An athlete being unused means that they were available and selected to the game day roster, but did not start the game or get substituted onto the field. For a professional athlete not playing frequently may have negative impacts on their leverage during contract negotiations, potentially leading to a premature ending of their MLS career. Such findings may indicate a greater need for return to performance training. Increased emphasis on transitioning athletes from rehabilitation to the field, followed by field play back to their prior level of performance, requires numerous resources and extensive collaboration between the medical team, strength and conditioning staff, and coaching staff.

Athletes in the ACL group were potentially at a lower risk for hamstring and thigh injuries, compared to their Control group peers. Deficits in quadriceps and hamstring muscle strength, dependent on graft type, have been observed after ACL reconstruction.[67] Furthermore, quadriceps strength asymmetries after ACL reconstruction have negative functional and biomechanical repercussions.[68 69] As a result, quadriceps and hamstring strengthening are a primary focus of many ACL reconstruction rehabilitation protocols. It is possible that the decreased risk for thigh and hamstring injuries seen in the ACL group could be a result of this focused training and effort. Further studies are needed to examine if there is a direct link between quadriceps and hamstring exercises performed during ACL reconstruction rehabilitation and decreased thigh and hamstring injury rates upon return to sport, however this study seems to support that the continued focus on these two muscle groups during rehabilitation may positively impact quadriceps and hamstring risk upon returning to the field.

This study found that athletes in the ACL group were at a 2.6 times higher risk for a new knee injury. Although this relative risk was not significant, a higher risk for a new knee injury is not surprising given the known high risk for second ACL injuries.[18 19] What was interesting about this result was how small the observed increased risk was compared to findings of Waldén et al.[55] in Swedish professional men's soccer. In the Swedish cohort players returning to sport after ACL reconstruction were at 7.9 times higher risk for a new knee injury. One reason for the risk difference between the two studies may be the time period after ACL reconstruction used. This study only examined the risk of injuries within the first two years after returning, where Waldén et al.[55] analyzed all athletes who had a history of ACL injury. Therefore, some athletes in the Waldén et al.[55] cohort were analyzed 9-10 years after their ACL reconstruction.

Many studies have found that there is an increased risk for musculoskeletal injury during games compared to training sessions.[31 47 110 120 121] Although injury risk during games was not a focus of this study, it was a secondary finding. Given that the ACL group athletes were utilized less during regular/post-season games compared to the Control group athletes, the percentage of regular/post-season season games was included in the regression models as a covariate to control for the amount of time when an athlete was exposed to that high risk for injury. Despite the fact there was no difference between the ACL and Control groups in injury risk, the percentage of regular/post-season games unused was a significant covariate in the regression models exploring the risk for mild and moderate injuries. These findings can be interpreted as, regardless of group, for every one percent increase in unused regular/post-season games an athlete's risk for a mild severity injury decreases approximately 82% and his risk for a moderate severity injury decreased 65%. In other words, as a player's match exposure decreases so too does his injury risk.

This study did find differences in injury risk based on graft type. The BPTB allograft group was at approximately a 19 times higher risk for overuse injuries compared to the BPTB autograft group, and the hamstring autograft group was at a 89% lower risk for muscle/tendon injuries compared to the BPTB autograft group. The hamstring autograft group was also at a higher risk for minimal severity injuries, and potentially severe injuries, compared to the BPTB autograft group. Although these differences were present, clinically it is difficult to find reasons for these relationships. Previously it was reported that MLS surgeons favored BPTB autografts,[122] and this was reflected in the majority (68%) of the ACL group athletes having BPTB autografts. But it is possible that the differences in risk between graft type groups may be due to the small ACL reconstruction sample and lop-sided graft type groups. These results indicate that future work in other larger cohorts may be needed to fully examine risks of injury, beyond just the knee joint, based on graft type after ACL reconstruction.

This study is not without limitations. A matched cohort design was chosen for this study as it is the most appropriate when a condition is rare. As the ACL group athletes played for varying amounts of time and their Control group matches were followed for the same periods, large standard deviations in career length and exposures were observed. Regardless of these large standard deviations though, significance was still found in career length and regular/post-season percentage of games started, truly highlighting the contrast between the groups and the importance of these results. Furthermore, as this study examined only one professional league, MLS (18 teams in 2011, 19 teams in 2012-2014, 20 teams in 2015-2016), it is smaller in size than other studies. For example, Waldén et al.[50] included 78 clubs. However, in using the injury surveillance data from MLS, this study was able to capture all ACL injuries that occurred during the study period, and a priori calculations indicated the study was adequately powered. Future studies with larger populations could allow for an examination of the influence of previous lower extremity injuries or history of knee injuries on the incidence of injury upon return to sport after ACL reconstruction.

In conclusion, athletes who return to MLS after ACL reconstruction have significantly shorter careers, by approximately half, compared to age-matched healthy peers. Although the injured athletes had the same number of athletic exposures as their matched control athletes in the two years after their return to play, they started in a smaller percentage and were unused in a larger percentage of regular and post-season games. ACL group athletes trended towards fewer hamstring and thigh injuries compared to Control group athletes and although they did not miss more days due to injury or may have had a higher risk for more severe injuries. These results highlight the importance of viewing return to sport as a continuum and continuing to focus on the athlete’s needs even upon return to play to maximize their potential to return to prior level of performance.

Chapter 5

FUNCTIONAL OUTCOMES WITH PERFORMANCE OF THE ACL-SPORTS TRAINING PROGRAM IN MEN AND WOMEN

Introduction

Approximately 130,000 anterior cruciate ligament (ACL) reconstructions are performed each year in the United States.[76] Prior to ACL reconstruction the majority of athletes expect to return to their preinjury level of sport,[11] however only approximately 65% of athletes achieve their goal, and an even smaller percentage, 55% return to competition at their preinjury level.[12] Further, a return to preinjury sport after ACL reconstruction places athletes at a significantly higher risk for a second ACL injury, especially younger athletes.[17 18]

Improving functional outcomes after ACL reconstruction is also needed. Quadriceps strength is an important factor in function and ACL reconstruction rehabilitation. Grindem et al.[71] found that athletes with stronger quadriceps muscles had less risk for a subsequent knee injury upon return to sport. They found a 3% reduction in reinjury rate for every 1% increase in quadriceps strength limb symmetry index (QI). Other studies have found similar importance of quadriceps strength.[68 69 123] QI was found to be a better predictor of performance of single legged hop test score than graft type, presence of meniscal injury, knee pain, and knee symptoms.[68] QI is also associated with higher self-reported knee function, particularly with higher scores on the International Knee Documentation Committee 2000 Subjective Knee form (IKDC).[123]

Patient-reported outcome measures are crucial to consider in evaluating the success of ACL reconstruction rehabilitation.[124] Several large scale studies have reported patient-reported outcomes at one and two years after ACL reconstruction.[73]

[125] The Multicenter Orthopedic Outcomes Network (MOON) was a large study that provided participants with high quality criterion-based ACL reconstruction rehabilitation in the United States.[126] Two year MOON outcomes were a median IKDC score of 75, Knee Injury and Osteoarthritis Outcomes Score (KOOS)-Sport/recreation subscale score of 85, and KOOS-Quality of Life subscale score of 75.[73] The Scandinavian ACL registries have also reported KOOS subscale scores at one and two years after ACL reconstruction. At one year they found mean KOOS-Sport/recreation scores of 63-64 and KOOS-Quality of Life subscale scores of 60. Two years after ACL reconstruction they found KOOS-Sport/recreation scores of 66-70 and KOOS-Quality of Life scores of 62-69.[125] These studies on self-report measures indicate that there is still room to improve patient-reported outcomes.

After ACL reconstruction women have a higher risk of second ACL injury than men,[18 19] are less likely to return to sport by one year after ACL reconstruction,[127] and overall have lower odds of returning to their preinjury levels of sport.[12] Further, the impact of ACL reconstruction on activity for women may extend beyond the first few years. Six years after reconstruction women were likely to be less active than their male counterparts.[73] Men and women may rehabilitate or recover from ACL reconstruction differently. Women tend to have lower IKDC scores,[70] and greater deficits in knee extensor strength in the 1st year after ACL reconstruction.[74] Perhaps indicating the outcomes of men and women need to be considered separately after ACL reconstruction and rehabilitation.

Much of the current literature on the return to sport phase of rehabilitation after ACL reconstruction is level 5 evidence or expert opinion.[63 128] The Anterior Cruciate Ligament Specialized Post-Operative Return to Sports (ACL-SPORTS) single-blinded randomized control trial was designed to help fill that gap. The trial tested the ACL-SPORTS training program, a secondary injury prevention program developed to optimize the outcomes after ACL reconstruction and improve functional performance. The program was based on the primary ACL injury prevention literature, which has shown that successful programs are multi-modal, involving both strengthening and plyometric components,[129] are performed multiple times per week, and have a weekly duration greater than 30 minutes.[130] Using these guidelines and the model of previously successful protocols,[104 131] the ACL-SPORTS training program incorporated secondary prevention, strengthening, agility, and plyometric exercises to help athletes transition from rehabilitation back to sport specific movements.[132]

The purpose of this report was to examine the primary functional outcomes of the ACL-SPORTS trial; to investigate the changes in quadriceps strength limb symmetry, single-legged hop test limb symmetry, and patient reported outcomes scores with performance of the ACL-SPORTS training program and determine if these changes were different in men and women. We hypothesized that the ACL-SPORTS training program would improve functional and self-reported outcomes, but that the outcome scores of men and women would change differently from Pre-training to Post-training.

Methods

The methods of the ACL-SPORTS program have been previously published in detail by White et al.[132] and are briefly described here. Forty men and 40 women (N=80) participated in this study. The study was approved by the institutions human subjects review board and registered at clinicaltrials.gov (NCT01773317). Athletes were between the ages of 13-54 (median 18.7), regularly participated in Level I or II sports[133] (cutting, pivoting, and jumping type sports) >50 hours per year prior to the ACL injury, and intended to return to their preinjury levels of activity. Athletes were recruited from the local community. It is common in the United States for athletes to be discharged from formal physical therapy when they have achieved activities of daily living goals and begun basic athletic tasks, such as running.[134] The ACL-SPORTS program was developed as a secondary prevention and return to sport program to bridge the gap between when physical therapy generally concludes and return to sport. ACL reconstructions were performed by 31 different experienced sports orthopedic surgeons and patients participated in post-operative rehabilitation in a number of different community physical therapy clinics. Rehabilitation prior to enrollment was not controlled in order to allow for a more generalizable sample. Strict enrollment criteria were applied to ensure a homogenous entry level. Enrollment criteria were; no more than 9 months after isolated, unilateral ACL reconstruction (no grade III concomitant ligamentous injuries or chondral injuries >1cm^2), ≥80% QI, minimal effusion, no pain, full range of motion, and successful completion of a running progression (Figure 11).[132 134]

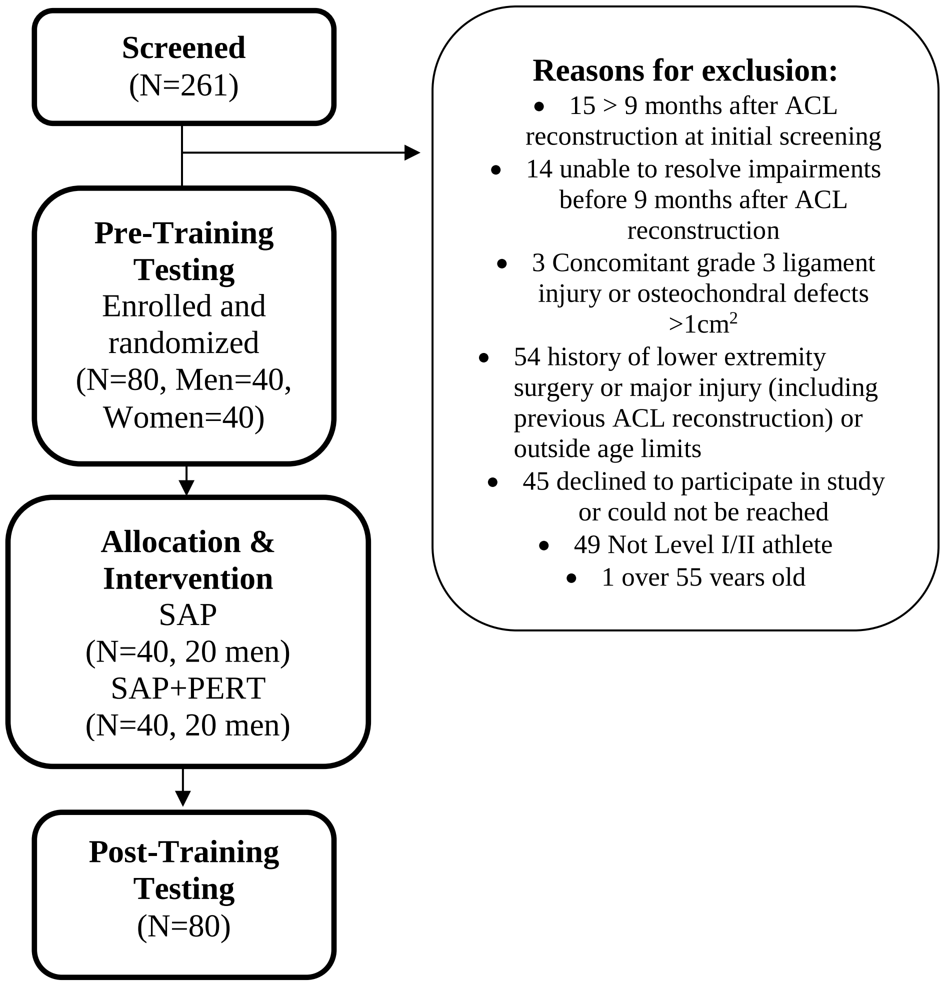

Figure 11 Flow of athletes through study. SAP = secondary prevention, agilities, and plyometrics, SAP+PERT = secondary prevention, agilities, and plyometrics with the addition of perturbation training

Upon enrollment into the ACL-SPORTS randomized control trial, athletes were randomized into either the secondary prevention, agilities and plyometrics (SAP, N=40, 20 women and 20 men) group, or the SAP+PERT group that received these exercises with the addition of a neuromuscular reeducation technique called perturbation training.[135] Randomization and allocation was performed using a random number generator by a research coordinator (MC) who had no contact with the athletes beyond scheduling. Researchers and physical therapist performing data collections were blinded to group.

All athletes in the study received secondary prevention, strengthening, agility, and plyometric exercises (Appendix C). The ACL-SPORTS training program was performed twice a week for five weeks, a total of ten sessions. Sessions progressively increased in difficulty following soreness and effusion guidelines to monitor athlete's response to treatment and ensure a safe progression through the protocol. Session were supervised by a physical therapist, and education was given on correct landing technique and lower extremity alignment during exercises. Procedural reliability was performed (AS), to ensure that all athletes received all exercises in the protocol. Training sessions from each athlete were randomly selected and the number of the ACL-SPORTS protocol exercises performed during that training session was assessed. A minimum of 85% was considered acceptable. Three training sessions from the first 10 athletes enrolled into the ACL-SPORTS trail, and then one session from the remaining 70 athletes, for a total of 100 procedural reliability checks were performed.

Upon enrollment (Pre-training) and again upon completion of the ACL-SPORTS training protocol (Post-training) athletes participated in quadriceps strength testing, single-legged hop testing, and completed patient reported outcome measures.

Quadriceps strength testing was assessed using an electromechanical dynamometer (Kin-com; DJO Global, Chula Vista, CA, USA; or System 3, Biodex, Shirley, NY, USA) to measure maximal volitional isometric contractions. Athletes were seated on the machine with their hips and knees positioned at 90° and the machine's lever arm axis of rotation aligned with the axis of rotation of the athlete's knee. Straps held the athletes pelvis, thigh, and shank in place. Maximal volitional contractions were performed on the uninvolved limb then the involved limb, with two submaximal contractions performed as practice prior to the recording of a maximal contraction. QI was calculated by dividing the maximum torque of the involved limb by the maximum torque of the uninvolved limb and multiplying by 100%. The single, crossover, and triple hops for distance and the 6-m timed hop tests[136] were also performed bilaterally. Athletes performed the tests on the uninvolved limb followed by the involved limb performing two practice trials of each hop followed by two trials that were recorded. The tests were always performed in the same order; single, crossover, and triple hops for distance and then the 6-m timed hop. Limb symmetry indices were calculated for the three distance hops by dividing the mean of the two recorded trials on the involved limb by the mean of the two recorded trials on the uninvolved limb and multiplied by 100%. Limb symmetry indices for the 6-m timed hop were calculated by dividing the mean of the two recorded trials on the uninvolved limb by the mean of the two recorded trials on the involved limb and multiplied by 100%.

Patient-reported outcome measures included the Knee Outcomes Survey-Activities of Daily Living (KOS-ADLs), the Global Rating of Perceived Knee Function (GR), the IKDC, and the KOOS-Sport/recreation and KOOS-Quality of Life (QoL) subscales. The KOS-ADLs is a 14 item questionnaire asking the athlete about their symptoms and function during tasks related to daily living.[137] The questionnaire is valid in an active population[138] and has been used frequently as a tool to help determine when athletes are ready to progress to more advanced tasks as well as in return to sport criteria.[71 134] The GR is a single question asking the athlete to rate on a scale from 0-100 their current knee function (0 being unable to perform any activity, 100 being preinjury level of activity including sports). The IKDC is a 10 item questionnaire that enquires about an athlete's symptoms, function, and activity particularly with regards to pain, swelling, stiffness, and giving-way.[91 139] Scored on a 0-100% scale the IKDC has a minimal clinically important difference (MCID) of 11.5%.[91] The KOOS-Sport/recreation and KOOS-QoL are two of the five subscales that make up the KOOS and are useful in differentiating athletes at higher levels of function after ACL reconstruction.[132] The KOOS-Sport/recreation subscale asks athletes about difficulty they have with tasks such as squatting, running, jumping, and kneeling. The KOOS-QoL enquires about the athlete's awareness of their knee and lifestyle modifications they have made as a result of their knee. Both subscales are scored as a percentage from 0-100% and have MCIDs of 8%.[92]

Statistical analyses were performed in SPSS version 24 (Microsoft, Redmond, Washington, USA). Primary variables of interest were QI, single-legged hop test limb symmetry on all four hop tests, KOS-ADLs, GR, IKDC, KOOS-Sport/recreation, and KOOS-QoL scores. Independent t-tests were used to determine if there were differences in any of the variables of interest between the SAP and SAP+PERT groups at Post-training. As there were no differences between the SAP and SAP+PERT groups the groups were collapsed. Independent t-tests and chi-squared tests were used to examine differences between men and women in demographic and surgical variables. Repeated measures ANOVAs (Time x Sex) with planned least squared comparisons were used to determine if there were changes in functional measures between the Pre-training and Post-training time points and if this change was different for men and women. Planned comparisons were the interaction effect, and the change in outcome measures over time for each sex. Alpha was set a prior at $p \leq 0.05$.

Power calculations were performed in G*Power software v 3.1.0 (Universität Düsseldorf, Düsseldorf, Germany). To remain consistent with the sample size calculations performed for the grant funding the ACL-SPORTS randomized control trial as well as previous studies, power calculations performed for this study used the IKDC. Calculations used Pre-Training group means and the IKDC MCID, 11.5%,[91] to determine the effect size that needed to be detected. These calculations indicated that using a 2x2 (time x sex) ANOVA, with power = 0.80, alpha = 0.05, an effect size of f(V)=12.9, a sample 5 of each sex would be needed.

Results

Eighty athletes (40 women) were enrolled and completed all 10 sessions of the ACL-SPORTS training protocol. There were no adverse events and 93 of the 100 procedural reliability checks showed >85% adherence to the ACL-SPORTS protocol. There were no significant differences between the SAP and SAP+PERT groups for any variable, thus the two groups were collapsed. There were differences between men and women in age ($p<0.01$), time from surgery to enrollment ($p=0.02$), and potentially graft type ($p=0.06$) (Table 14). The men were older, had a shorter period time from surgery to enrollment, and had more allografts. There was no difference in the mechanism of injury between men and women.

Table 14 Demographics, injury mechanism, graft type, and time from surgery to enrollment between men and women

	Women (N=40)	Men (N=40)	p-value
Age	18.8 ± 7.2	23.3 ± 7.3	<0.01
Weeks from Surgery to enrollment/Pre-training	25.8 ± 8.3	21.5 ± 7.4	0.02
Mechanism of Injury	Non-Contact: 29 Contact: 11	Non-Contact: 22 Contact: 18	0.16
Graft Type	Autograft: 35 Allograft: 5	Autograft: 27 Allograft: 13	0.06
Injured Limb	Right: 22 Left: 18	Right: 23 Left: 17	
Sports	American Football: 8 Soccer: 8 Basketball: 7 Lacrosse: 5 Flag Football: 3 Ultimate Frisbee: 3 Ice Hockey: 2 Baseball: 1 Beach Volleyball: 1 Cheerleading: 1 Rugby: 1	Soccer: 14 Basketball: 8 Field Hockey: 5 Cheerleading: 3 Softball: 2 Volleyball: 2 Flag Football: 1 Ice Hockey: 1 Lacrosse: 1 Track (Hurdles): 1 Tennis: 1 Ultimate Frisbee: 1	

There was no significant time x sex interaction for QI (p = 0.07), but the men had a significant increase in QI after training (p=0.02), while the women did not (p=0.82) (Table 15). There were also no significant time x sex interactions for any of the four single-legged hop tests (Table 15). Both men and women had significant increases in limb symmetry on all four hop tests.

Table 15 Results of repeated measures ANOVA for QI and single-legged hop tests

Measure	Sex	Pre-Training Mean	Post-Training Mean	Change Over Time p-value	Time x Sex Interaction p-value
QI (%)	Women	91.6 ± 9.7	91.1 ± 11.2	0.82	0.07
	Men	91.0 ± 8.2	95.9 ± 12.3	0.02	
Single Hop for Distance (%)	Women	79.4 ± 15.8	93.1 ± 9.9	<0.01	0.74
	Men	79.2 ± 15.0	94.0 ± 12.8	<0.01	
Cross-over Hop for Distance (%)	Women	87.2 ± 15.9	96.7 ± 6.6	<0.01	0.68
	Men	86.0 ± 14.0	96.8 ± 8.1	<0.01	
Triple Hop for Distance (%)	Women	87.1 ± 12.4	95.9 ± 5.5	<0.01	0.49
	Men	86.4 ± 12.1	97.0 ± 7.2	<0.01	

Table 15 Continued

Measure	Sex	Pre-Training Mean	Post-Training Mean	Change Over Time p-value	Time x Sex Interaction p-value
Six Meter Timed Hop (%)	Women	92.6 ± 7.7	99.9 ± 7.7	<0.01	0.66
	Men	91.1 ± 10.6	99.4 ± 6.5	<0.01	

There were no time x sex interactions for any of the self-reported measures (Table 16). Both men and women had significant increases in scores on all patient-reported outcomes, including increases in KOOS-Sport/recreation larger than MCID of 8%.[92] Although both men and women had increases in KOOS-QoL scores, only men had increases in score greater than the MCID.

Table 16 Results of repeated measures ANOVA for patient-reported outcome measures

Measure	Sex	Pre-Training	Post-Training	Change Over Time p-value	Time x Sex Interaction p-value
KOS-ADLS	Women	93.4 ± 5.8	95.2 ± 5.1	0.02	0.42
	Men	92.5 ± 6.7	95.1 ± 5.8	<0.01	

Table 16 Continued

Measure	Sex	Pre-Training	Post-Training	Change Over Time p-value	Time x Sex Interaction p-value
GR	Women	80 ± 8	87 ± 9	<0.01	0.32
	Men	78 ± 10	87 ± 8	<0.01	
IKDC	Women	78.3 ± 10.1	85.3 ± 9.8	<0.01	0.30
	Men	77.1 ±8.9	86.3 ± 9.5	<0.01	
KOOS-Sport/ recreation	Women	80.0 ± 14.9	90.0 ± 10.6*	<0.01	0.66
	Men	79.1 ± 14.5	87.9 ± 10.6*	<0.01	
KOOS-QoL	Women	58.4 ± 15.9	66.1 ± 19.1	<0.01	0.58
	Men	58.6 ± 16.2	68.4 ± 18.4*	<0.01	

*Change greater than MCID

Discussion

The men and women who underwent the ACL-SPORTS training protocol had significant improvements in limb symmetry on all four single-legged hop tests, and in KOS-ADLS, GR, IKDC, KOOS-Sport/rec, and KOOS-QoL scores. Interestingly, men had a significant increase in QI with the ACL-SPORTS training program, but women did not. These results indicate that the ACL-SPORTS program may be beneficial and may help serve as a bridge between discharge from physical therapy and return to sport.

On average, the men in this study were older than the women. The range of ages was similar between the two groups with the men ranging in age from 15-54 and the women 13-54, however the women had a younger median (16.7 years old) and mean (18.8 years old) age than the men (median 21.5, mean 23.3). All athletes were recruited from the community and local physical therapy clinics so the younger female sample is likely a reflection of the high risk for ACL injury risk in adolescent women athletes.[18]

One of the interesting findings of this study was that men had a significant increase in QI over the course of the ACL-SPORTS training program, while women did not. The two groups were very similar at Pre-trining (women 91.3 ± 9.7%, men 91.0 ± 8.2%); the men increased to a QI of 95.1 ±12.3% after the training program while women remained at 91.4 ±12.3%. Examining the sample as individuals, 20 women had decreases in QI (7 had bilateral decreases in quadriceps strength, 4 had decreased in quadriceps strength on their involved limb but increased on their uninvolved, and 9 had increases in strength bilaterally but greater on the uninvolved side) over the course of the training. In contrast, only 11 men had QI decreases (3 had bilateral decreases in quadriceps strength, three had decreased strength on their involved and increased on their uninvolved, and the remaining five had increases in strength bilaterally but greater on the uninvolved limb). All athletes during the ACL-SPORTS program were encouraged to continue performing strengthening on their own outside of the training program, and athletes who were between 80-90% QI at enrollment were given additional quadriceps strengthening exercises within the program for the first six sessions.[132] However, even with these additional exercises it seems that women may require additional focus and continued quadriceps strengthening. Given the importance of quadriceps strengthening in ACL reconstruction rehabilitation, and the implications of higher QI on risk of reinjury,[68 70 71] these results are clinically important. Focus during the return to sport phases of rehabilitation is generally shifted away from strengthening and towards sport specific movements, higher level athletic tasks and gradual return to sport. These results indicate that, especially in women, quadriceps strengthening needs to remain part of an athletes training program in order to prevent decreases quadriceps strength and strength asymmetries.

Both men and women had significant increases in all patient-reported outcomes after undergoing the ACL-SPORTS training program. Of particular note, both sexes had increases greater than the MCID of 8%[92] in the KOOS-Sport/recreation subscale, and men had increases greater than the MCID in the KOOS-QoL subscale. Improvements larger than an MCID indicate that changes are identifiable and important to a patient. As the ACL-SPORT training program focuses on introducing and returning athletes to higher level sport-related tasks and activities, the improvements greater than the MCID in the KOOS-Sport/recreation scores likely indicates success in this regard. The improvements in the men in KOOS-QoL would indicate that the training program could also help in decreasing the lifestyle modifications and general awareness of their knee during everyday life. The women in this study made a significant improvement in KOOS-QoL score, however the 7.2% change in score the women experienced did not quite equal the MCID of 8%. Future studies will examine the self-reported outcomes of this cohort at one and two years after ACL reconstruction. It seems likely that once these women returned to sport that their KOOS-QoL scores would increase further, exceeding the MCID.

The results of this study are most easily compared to the patient-reported outcomes of the Scandinavian ACL registries at one year.[125] Both the men and women in this study had mean KOOS-Sport/rec and KOOS-QoL scores at Post-training greater than the Scandinavian ACL registries means at one year.[125] In fact the men and women in this study had KOOS-Sport/recreation scores almost three times the MCID[92] greater than those in the Scandinavian ACL registry. It is important to acknowledge, though, in making the comparison of sport related patient-reported outcome scores, that not all of the individuals in the Scandinavian ACL registries were athletes. The mean KOOS-QoL score for the men in this study was 8% greater than the Scandinavian ACL registries at one year, the same value as the MCID for the measure.[92] The men reached the Post-training time point at a mean of 28.9 ± 7.9 weeks (about 7 months) after ACL reconstruction, indicating the men in this study reached a point where their knee made less of an impact on their lives earlier after surgery compared to those in the Scandinavian ACL registry.

There are some limitations to this study. There was no comparison to a control group that was tested at similar time points but had been discharged from physical therapy. ACL reconstructions were performed by a number of different surgeons and athletes did their post-operative rehabilitation in many community-based physical therapy clinics. Given these variations, the sample was standardized at enrollment as all athletes met strict inclusion criteria.[132 134] Pain, effusion, and range of motion were used as indicators that the athlete's knee was quiet and not aggravated, and the ≥80% QI criteria ensured that athletes were strong enough to safely to participate in the higher level athletic tasks introduced in the ACL-SPORTS training program. Athletes took differing amounts of time to meet these criteria, and such variation is also a reflection of a typical ACL reconstruction rehabilitation population, as not all athletes are discharged from physical therapy or return to sport at the same time after surgery.

In conclusion, this study found that both men and women improved in single-legged hop test limb symmetry, KOS-ADLS, GR, IKDC, KOOS-Sport/recreation, and KOOS-QoL scores with performance of the ACL-SPORTS training program. Men had a significant increase in QI with performance of the program, however women did not, potentially indicating that women may require more quadriceps strengthening even during the return to sport phase of ACL reconstruction rehabilitation. The results of this study indicate that the ACL-SPORTS program is beneficial in improving functional and clinical outcomes after ACL reconstruction, and may be a good clinical tool in return to sport rehabilitation. More studies are needed on the short and long term outcomes of ACL-SPORTS program, however this study indicates that the program may be beneficial for both men and women, and is one more step towards filling a gap in the literature on rehabilitation protocols during return to sport after ACL reconstruction.

Chapter 6

ACL-SPORTS PROGRAM RESULTS IN 95% RETURN TO PREINJURY LEVEL OF SPORT AND 2.5% SECOND ACL INJURY INCIDENCE IN MALE ATHLETES

Introduction

The majority of athletes aim to return to sport after an anterior cruciate ligament (ACL) injury, and 91% believe that they will be able to return to their preinjury level of sports and activity after ACL reconstruction.[11] Unfortunately, not all athletes will achieve this goal. Eighty one percent of athletes return to activity at some level, but only approximately 65% of athletes return to their preinjury level of sport after ACL reconstruction. An even smaller percentage, 55%, return to competition.[12]

Athletes who do return, are at higher risk for a second ACL injury to either their graft or contralateral ACL compared to those who do not return to their preinjury level.[17 71 85] Returning to any cutting and pivoting sports increases an athlete's odds for an ipsilateral second ACL injury by 3.9 times and for a contralateral injury by five times.[17] Returning to Level I sports (sports with frequent cutting/pivoting such as soccer, handball, or basketball)[133] increases an athlete's risk for any subsequent knee injury by 4.3 times compared athletes returning to Level II sports (sports with less frequent cutting/pivoting such as martial arts, baseball, or racquet sports).[71]
The first year after ACL reconstruction, particularly the first 72 athletic exposures (games or training sessions) after an athlete returns to sport, is a high risk period for second ACL injuries.[19] A recent study found a 51% decrease in the risk of a subsequent knee injury for every month delay in returning to sport, up to nine months after ACL reconstruction. This same study found that 40% of athletes who returned

within nine months of their ACL reconstruction had a knee reinjury, compared to only 19% of those who returned after nine months.[71]

The Anterior Cruciate Ligament Specialized Post-Operative Return to Sports (ACL-SPORTS) program was developed as part of a singled blinded randomized control trial to be a sport-specific training used in the return to sport phases of ACL reconstruction rehabilitation.[132] All athletes in the program received an evidence-based secondary prevention exercise progression, progressive strengthening, plyometric, and agility exercises developed to address the functional deficits, low return to sport rates, and high second ACL injury risk observed in the literature. The program utilized best practices from the primary ACL injury prevention literature, making sure to employ multiple exercise modalities during training,[129] have a total training duration ≥30 minutes per week,[130] over multiple sessions, and with high compliance.[140] The ACL-SPORTS training program was designed and optimized from previous injury prevention programs effective in improving landing biomechanics in young female athletes[104] and reducing primary ACL injuries.[131]

The primary outcomes of the ACL-SPORTS randomized control trial have examined the programs' effects on knee function, patient self-report,[141] and gait biomechanics[142] in men. These primary outcomes indicated that there was no difference in functional outcomes or patient self-report measures between athletes who received the ACL-SPORTS program involving progressive strengthening, agility, and secondary prevention exercises, (SAP group), and athletes who received the same program with the addition of perturbation training (SAP+PERT).[141] Rather, these results demonstrated that both groups score higher than participants in the Multicenter Orthopaedic Outcomes Network (MOON) group in the United States, as well as the

Scandinavian ACL registries (baseline data from the Norwegian, Danish, and Swedish Knee Ligament Registries[125]).[141] These primary outcome results suggest the ACL-SPORTS program is a valuable rehabilitation intervention after ACL reconstruction. The purpose of this study was to explore the secondary outcomes of the men in the ACL-SPORTS randomized control trial, particularly the return to sport rates, return to preinjury level of sport rates, and second ACL injury rates.

Methods

The ACL-SPORTS randomized control trial was approved by the University of Delaware Institutional Review Board and registered at clinicaltrials.gov (NCT01773317). All athletes gave written informed consent prior to participation and parents/guardians gave written informed consent for athletes under 18 years old. This study reports on only the men in the ACL-SPORTS randomized control trial. Data collection and analysis is still in progress on the women in the sample and will be published in future work.

The men in the ACL-SPORTS randomized control trial were between the ages of 15-54 years old (median 21.5) and regular participants (≥50 hours per year) in Level I or II[133] cutting and pivoting sports prior to their ACL injury.[132] At the time athletes were enrolled into the ACL-SPORTS program they intended to return to their preinjury level of activity. Athletes were recruited through local physical therapy clinics, surgeon referrals, newspaper advertisements, and word of mouth. ACL reconstructions were performed by 21 experienced orthopedic surgeons. Rehabilitation prior to ACL-SPORTS enrollment was not standardized and was performed in multiple community physical therapy clinics. Often in the United States athletes after ACL reconstruction are discharged when they achieve activities of daily living and basic athletic task goals. Thus, in an attempt to capture a generalizable cohort athletes were enrolled in the ACL-SPORTS program athletes when they were 3-9 months after ACL reconstruction had no pain, minimal effusion, full range of motion, ≥80% quadriceps strength limb symmetry, and had completed a running progression.[134] Athletes were excluded if they had a concomitant >1cm^2 full thickness chondral defect, grade three ligamentous injury, previous ACL reconstruction, or a history of major lower extremity injury or surgery to either limb. The methods and procedures of the ACL-SPORTS program have been published previously.[132] Figure 12 shows a diagram of flow through the program and follow-up.

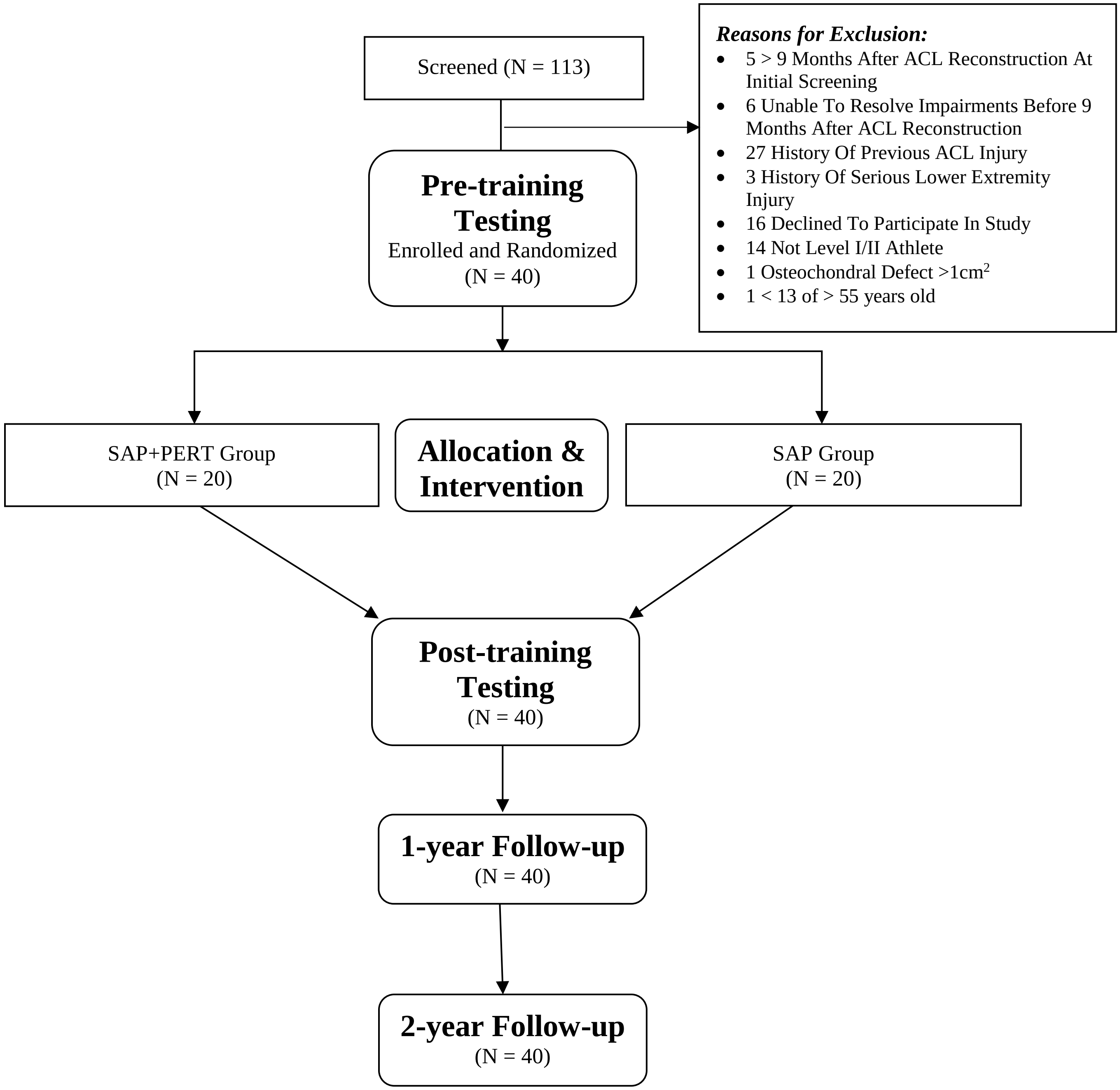

Figure 12 Flow diagram of athletes through study

The ACL-SPORTS program was performed twice a week over five weeks, for a total of ten sessions. All athletes in the ACL-SPORTS program performed five exercises specifically derived from published primary prevention programs[104 131 143 144]: Nordic hamstrings, standing squats, drop jumps, triple single leg hopping, and tuck jumps. These exercises were progressed through the sessions (Table 17) in accordance with soreness and effusion rules.[132] Athletes performed agility drills including forward/backward running, side shuffling, cariocas, figure eight's, circles, and 90 degree turns starting at 50% maximum effort and progressing to 100% maximum effort and speed by the final session. At each session the physical therapist choose three to four of the agility drills, progressing the difficulty as the sessions advanced by eliminating linear drills, adding the more advanced multi-directional drills, and making the drill sport-specific for the athlete, such as by adding a ball. Athletes in the SAP group performed a single leg balance with hip flexor resistance task, while athletes in the SAP+PERT group performed perturbation training (Appendix C).[132 135] In addition, athletes enrolled with a quadriceps strength index between 80% and 90% performed progressive quadriceps strengthening exercises. Exercises such as lateral step downs, leg press, long arc quads, or isokinetic strengthening were performed during training sessions for the first six sessions. After the 6th training session, these strengthening exercises were transitioned to a progressive home exercise program. Athletes enrolled with a quadriceps strength index >90% were encouraged to continue any gym strengthening programs they had previously been performing.

Table 17 Exercises involved in the ACL-SPORTS training program

	Sessions 1-3	Sessions 4-6	Sessions 7-10
Nordic Hamstrings	2x5 (~30-45°)	3x5 (~30-45°)	3x5 (~60°)
Standing Squat (Bilateral to 90°)	Session 1: 3x10 focusing on proper technique Session 2 and 3: Add theraband around knees	3x10 progression to black theraband around knees	Not performed
Drop Jump	3x10 Taking off and landing bilaterally Step height progresses as appropriate for the athlete from 4 to 6 to 8 inches tall	3x10 Taking off bilaterally, landing on the involved limb Step height progresses as appropriate for the athlete from 4 to 6 to 8 inches tall	3x10 Taking off and landing on the involved limb Step height progressing as appropriate for the athlete from 4 to 6 to 8 inches tall
Triple Single Leg hopping	Forward/backwards (3 hops forward, 3 hops backwards) x10 Side to Side (3 consecutive hops laterally) x10 Overground	Forward/backwards (3 hops forward, 3 hops backwards) x15 Side to Side (3 consecutive hops laterally) x15 Over a low object approximately 2 inches high (such as cup or low cone)	Forward/backwards (3 hops forward, 3 hops backwards) x15 Side to Side (3 consecutive hops laterally) x15 Over an object the height appropriate for the patient such as 4 in cones or 6 in hurdles
Tuck Jumps	Not performed	Not performed	2 sets for 10-20 seconds Progressing to 3 sets for 20-30 seconds

Upon completion of the program all athletes were required to pass return to sports criteria for clearance to begin to return to sport/activity. These criteria were ≥90% quadriceps strength limb symmetry index, ≥90% limb symmetry index on four single-legged hop tests (single, cross-over, and triple hops for distance and the six meter timed hop tests),[136] and ≥90% scores on the Knee Outcomes Survey-Activities of Daily Living Scale (KOS-ADLS)[137] and the global rating of perceived knee function (global rating). The date each athlete passed the return to sport criteria was recorded.

As part of a comprehensive one and two year follow-up after ACL reconstruction athletes answered the questions "Have you returned to sports or recreational activities?" and "Have you returned to the same level of sports or recreational activities as before your injury?" Athletes also reported if they had incurred a second ACL injury.

Demographic and anthropometric data, such as age, height, weight, mechanism of initial injury, and graft type were compiled, and return to sport and return to preinjury level of sport rates were calculated. The mean time to passing the return to sport criteria and incidence proportion of second ACL injuries was also calculated. Means and standard deviations were calculated using Microsoft Excel (Redmond, Washington, USA).

Results

Forty men were enrolled and completed the 10 sessions of the ACL-SPORTS training program. The mean age, height, weight, mechanism of injury, and graft types are listed in Table 18. The most common sports were soccer, basketball, American football, lacrosse, ultimate frisbee, flag football, and ice hockey.

Table 18 Demographics and anthropometrics

Age (years)	Mean: 23.3 Median: 21.5 Range: 15-54
Height (meters)	Mean ± Standard Deviation: 1.79 ± 0.07
Weight (kg)	Mean ± Standard Deviation: 85.39 ± 9.32
Mechanism of Injury	Contact 18 Non-Contact 22
Graft Type	Allograft: 13 Hamstring Autograft: 19 BPTB Autograft: 8

One year after ACL reconstruction all but two (95%) athletes had returned to sport at some level (Table 19). One of these two athletes had not yet passed the return to sport criteria, and the other cited changes in lifestyle and not enough time. Logically, these two athletes had also not returned to their preinjury level of sport. In addition, seven other athletes had not returned to their preinjury level of sport at one year. Three cited fear of reinjury as their reasoning for not returning. Two of the three athletes citing fear had returned to Level III activities (low level jogging and weight lifting) but had not been cleared to return to their preinjury level as they had not yet passed the return to sport criteria. One athlete cited swelling as their reason for not returning to preinjury level of sport and shortly after had a meniscectomy and scar tissue debridement. Two athletes cited not enough time as their reason for not returning to preinjury level of sport, one due to a change in lifestyle, the other due to joining a military reserve officer training corps. And one athlete was waiting on final clearance from his surgeon to return.

Table 19 Number of athletes who returned to sport and preinjury level of activity at each time point

	Number of athletes (%)
1 year	
Return to Sport (N=40)	38 (95%)
Return to Preinjury Level (N=40)	31 (78%)
2 years	
Return to Sport (N=40)	40 (100%)
Return to Preinjury Level (N=40)	38 (95%)

At two years all athletes had returned to sport (Table 19), and only two athletes had not returned to their preinjury level. One of these athletes at one year had cited not enough time to return to any activity, and while he had returned to some activity at two years, he reported that at two years he still did not have enough time to participate at his preinjury level. The other athlete had cited fear of reinjury and lack of confidence as his reasoning for not returning to sport at one year but had not yet passed return to sport criteria. Again at two years he cited the same reasons and was still unable to pass the return to sport criteria.

The mean time to passing return to sport criteria was 232 ± 99 days (~7.5 months) after ACL reconstruction. Only one athlete had a second ACL injury. This athlete incurred an ipsilateral second ACL injury, two days before to the two year anniversary after his ACL reconstruction. The incidence proportion of second ACL injuries was 0.025 injuries/athlete.

Discussion

This study indicates that in the first two years after ACL reconstruction 100% of men who participated in the ACL-SPORTS training program returned to sport, 95% returned to their preinjury level of sport, and only one experienced a second ACL injury. The findings of this study indicate that the ACL-SPORTS training program may be beneficial in men athletes who want to return to sport after ACL reconstruction.

There is very little literature on the outcomes of specific interventions used during rehabilitation after ACL reconstruction. There are a number of clinical commentaries making recommendations for exercises and programs to be used during the return to sport phase of rehabilitation,[63 143] however, none have published outcomes. One meta-analysis reported that 77% of athletes attempt to return to play in the first year after ACL reconstruction.[127] Overall 81% of athletes return to some level activity, but only 65% ever return to their preinjury level.[12] In this study 95% of athletes returned to sport at some level by one year, and 78% had returned to their preinjury level. A cohort similar in demographics and athletic participation to the one in this study is a subgroup of MOON cohort, identified by Failla et al.[145] The return to preinjury level of sport rate in that MOON subgroup at two years was 63%. In contrast, by two years after ACL reconstruction 100% of athletes in this study had returned to sport, and 95% had returned to their preinjury level. Similar return to preinjury level of sport rates have been published, however are rare. Walden et al.[120] reported that in elite level soccer 94% of athletes returned to training and 89% returned to match play within one year of their ACL reconstruction. The study was criticized because the high return to preinjury level of sport rates were attributed to the fact that the athletes in the Walden et al. cohort were elite level players. Elite athletes return to play at higher rates than athletes at lower levels[12] and in some cases receive higher quality of medical care as well as have more frequent access to physical therapy.[146] This study demonstrates that high return to sport rates are not limited to elite level athletes who have frequent access to physical therapy. The athletes included in the ACL-SPORTS program ranged from NCAA Division I athletes to high school level players and recreational level adult league participants, there was no control for quality of athlete. Further, these athletes ranged in age from 15 to 54 years old (median 21.5), came from 21 different orthopedic surgeons, with different graft types, and performed their postoperative rehabilitation prior to the ACL-SPORTS training in a range of different community clinics. The unifying attribute of these athletes was they all met enrollment criteria and participated in the ten sessions of progressive strengthening, agilities, plyometric, and prevention exercises involved in the ACL-SPORTS program. The diverse population of Level I and II male athletes included in this study make these results generalizable. More importantly though, these results indicate that high return to sport rates are achievable in cohorts outside of elite athletes.

Second ACL injury rates in young athletes after ACL reconstruction have been reported to be between 23-36%[17 18 53 147] In comparison, this study found a second ACL injury incidence of 2.5%. No second ACL injuries occurred in the first year after ACL reconstruction, the known high risk window, and the one injury that did occur happened late in the second post-operative year. The athlete who had the second ACL injury had an ipsilateral allograft injury. Allografts are known to have a higher risk for graft ruptures compared to autografts.[148] This second injury was a non-contact injury, and the athlete attributed the injury to the uneven surface of the soccer field. The athlete had no episodes of giving way following this second injury and pursued a course of non-operative treatment, suggesting that neuromuscular control was not at fault for this injury. This athlete returned to his preinjury level of sport within one year of his second injury and remains at this level, non-operatively managed, three years later. The results of this study indicate that the ACL-SPORTS training program may be beneficial in secondary ACL injury prevention in men.

There are multiple factors which could be contributing to the success of the ACL-SPORTS program. The strict return to sport criteria could be one. All athletes were required to pass these criteria before returning to their Level I and II sports. By including strength, neuromuscular control, and patient-reported outcomes in the return to sport criteria, scores reflect a broad view of the athletes' function. The quadriceps and single-legged hop tests confirmed that athletes were symmetrical in performance. The KOS-ADLS shed light on any limitations in activities of daily living. Ensuring basic function is important because in order to safely perform higher level athletic tasks an athlete must be able to perform lower level activities of daily living without difficulty or knee symptoms. And the global rating score allowed for an overall view of how the athlete viewed their knee. Putting the ACL-SPORTS training aside, it is possible that by requiring scores ≥90% on all return to sport criteria, prior to returning to sport, meant that athletes were more symmetrical, functioning at a higher level, and potentially psychologically more ready than if they had they been cleared without passing these criteria. Recent findings from Grindem et al.[71] bolsters the importance of the return to sport criteria. Athletes who passed these same return to sport criteria were at an 84% lower risk for a future knee injury. And where 40% of those who failed the return to sport criteria went on to have another knee injury, only one athlete (6%) of those who passed the criteria went on to experience a subsequent knee injury. Future research could help elucidate the benefits of strict return to sports criteria from benefits of the ACL-SPORTS program, but for now, the results of this study indicate that together the ACL-SPORTS program and strict adherence to return to sport criteria are beneficial to return to sport and second ACL injuries.

Another factor contributing to the success of the ACL-SPORTS program could be that athletes' return to sport was generally between 8-10 months after ACL reconstruction, later than many athletes in the literature.[127] Although the exact date each athlete returned to their preinjury level of activity was not known, the date each athlete passed the return to sport criteria was used as a proxy. This proxy is in fact a liberal estimate of an athlete's return date. Once athletes were cleared they were given instructions on how to gradually acclimatize to sport, starting with returning to practice without contact, then introducing contact in controlled small groups, progressing to full contact during training sessions and eventually full participation in games. Thus, an athlete's return to sport date is likely weeks, to potentially a few months, after the date they passed the return to sport criteria. This delay in return to sport may contribute to the higher return to sport rates, but more likely may contribute to the lower second ACL injury rates. Although many athletes are told that they can return to sport in 6-9 months, recently there has been more support in delaying an athlete's return in order to align more with biological tissue healing.[71 149] Depending on the graft type, healing can take 12-24 months[150] with hamstring autografts having a delayed remodeling phase, occurring more in the second year after surgery,[150] and patella tendon autografts still changing and remodeling up to 24 months after ACL reconstruction.[151] In addition to the graft healing, depending on the presence and extent, bone bruise healing may take as many as 12-16 months to resolve.[152 153] These biological time frames are just one component of the arguments to delay athletes' return to sport,[149] but in the case of this study with athletes passing return to sport criteria on average ~7.5 months after surgery and returning to sport in the weeks to months after, this delayed return to sport may have helped protect them from a second ACL injury. Further study is needed on the contributions of rehabilitation and biological tissue healing towards preventing second ACL injuries, however as there is little other outcomes research related to specific rehabilitation interventions, this study provides a contribution to the current knowledge base.

The ACL-SPORTS program was designed by integrating the evidence-based best practices of primary ACL injury prevention into a secondary prevention program. The progressive strengthening, gradual and guided introduction to agilities, and the focused plyometric training involved in the ACL-SPORTS training program may be important to its outcomes. Meta-analyses have shown that primary injury prevention programs which use a combination of different exercise modalities, particularly programs that use both strengthening and plyometric exercises, are more effective than programs using just one modality or programs that do not include strengthening.[129] The ACL-SPORTS program combines progressive strengthening, plyometric exercises, and agilities, with therapist supervision providing feedback on performance and form throughout. Training volume is also an important component of primary prevention, with programs that are performed multiple times per week, for a total training time exceeding 30 minutes each week, being more effective in reducing ACL injuries.[130] The ACL-SPORTS program takes approximately 60-90 minutes per session and is performed twice per week, closely monitoring an athlete's response and adjusting progression based on soreness and effusion.[132] In this study the ACL-SPORTS program was implemented in a clinic, however it could easily be transferred to a gym, field, or court allowing therapists more latitude to make the program sport-specific. The results of this study indicate best practices from the primary ACL injury prevention literature are applicable in secondary ACL injury prevention. These results indicate that the specific progressive strengthening, agility, plyometric, and prevention exercises involved in the ACL-SPORTS program, combined with the tailoring of progression to an athlete's response and the appropriate training volume are beneficial in reducing secondary ACL injury rates to below published values in men. These results advocate for use of the ACL-SPORTS program in male athletes hoping to safely return to cutting and pivoting sports.

This study has some limitations. The ACL-SPORTS program study is on-going. This paper examined the secondary outcomes of the ACL-SPORTS program in 40 men, however data on 40 women is still being collected and analyzed. Examination of the ACL-SPORTS program in both sexes will allow for a broader picture of the program benefits and if it impacts the sexes differently. This study also relies on self-report data for return to activity and second injury data. It also does not include exposure data. Without exposure data, only an incidence proportion could be calculated, not an incidence rate. However, an incidence proportion still reflects an estimation of risk, and with only one second ACL injury occurring we believe this is a moot point.

In conclusion, this study supports the use of the ACL-SPORTS program in male athletes during the return to sport phase of ACL reconstruction rehabilitation. All athletes who participated in the ACL-SPORTS program returned to sport and 95% returned to their preinjury level with only one athlete incurring a second ACL injury in the two years following ACL reconstruction. The ACL-SPORTS program is a clinically feasible training program, based on primary ACL injury prevention best practices. The results of this study can be implemented immediately with benefits to male athletes who hope to safely return to sport after ACL reconstruction.

Chapter 7

AN EXAMINATION OF PRIMARY AND SECONDARY ACL INJURY PREVENTION PROGRAMS OUTCOMES

Purpose

Primary and secondary ACL injury prevention are important to athletes at all levels of play. From youth recreational athletes to adult professional players, ACL injuries carry heavy implications for athletes at any point in their careers. This dissertation has a large scope, reporting on the outcomes of both primary and secondary ACL injury prevention, with the intent that these results can make an immediate clinical impact and serve to help guide clinicians in their decision making and patient education.

Aim 1

Aim: Determine kinetic and kinematic changes that occur with FIFA11+ utilization over two soccer seasons in collegiate women soccer players

Hypothesis 1.1 Smallest detectable change and minimal important difference scores can be calculated for the vertical drop jump landing task, so that meaningful and clinically meaningful change can be established.

Hypothesis 1.2 After using the FIFA11+ for one season athletes will have a lower non-contact lower extremity injury incidence rate, particularly a lower knee injury incidence rate, than athletes in the control group.

Hypothesis 1.3 After using the FIFA11+ for a second season athletes will have a lower non-contact lower extremity injury incidence rate, particularly a lower knee injury incidence rate, than after the first season of FIFA11+ use.

Hypothesis 1.4 After using the FIFA11+ for one season athletes will have smaller peak knee abduction, hip adduction, and hip internal rotation angles and moments than athletes in the control group.

Hypothesis 1.5 After using the FIFA11+ for a second season athletes will have smaller peak knee abduction, hip adduction, and hip internal rotation angles and moments compared to after the first season of FIFA11+ use.

Neuromuscular injury prevention programs have been effective in reducing lower extremity injuries and some have reported changes in movement patterns. However, this study was the first to calculate SDC and MID values for peak hip and knee angles and moments during a drop jump, so that changes in biomechanics could be placed in clinical context. Chapter 2 found good to excellent ICC values for peak hip angles and moments in all three planes and for peak knee angles and moments in the sagittal and frontal planes. Significant differences were found between limbs for peak hip adduction angle and moment, peak hip internal rotation angle and moment, peak knee flexion angle and peak knee abduction moment indicating that even in a healthy collegiate women's soccer population kinematic and kinetic asymmetries are present. Supporting hypothesis 1.1, the SDC and MID values proposed in Chapter 2 serve to define meaningful and clinically meaningful biomechanical changes, and thus facilitate better assessment of athletes' movement and the impact of injury prevention programs.

Using the SDC and MID values proposed in Chapter 2, Chapter 3 examined the injury incidence outcomes and biomechanical changes that occurred with two seasons of FIFA11+ utilization. The results indicated that the FIFA11+ may decrease lower extremity injury risk in collegiate women soccer players, but not knee injury risk over two seasons of use, only partially supporting hypotheses 1.2 and 1.3. The program may mitigate bilateral decreases in knee flexion over the course of two soccer seasons, but it does not seem to create bilateral changes in valgus collapse. This lack of support for hypotheses 1.4 and 1.5, possibly reflects the core and hip focus that the FIFA11+ creators had when designing the program, and thus suggesting that changes to the program may be needed for women in order to address knee injuries and biomechanics, particularly when the program is used over multiple seasons.

The results from Aim 1 impact both research and clinical practice. Using the methodology laid out in Chapter 2, researchers and clinicians with access to motion analysis can use the SDC and MID values to determine if meaningful or clinically meaningful changes have occurred in an athlete's movement pattern. Such context will help gauge the impact of an intervention, particularly prevention interventions. The results of Chapter 3 indicate that the FIFA11+ holds value in reducing lower extremity injury incidence in collegiate women. These results may also encourage clinicians or strength and conditioning staff working with women's soccer teams to supplement the FIFA11+ with further exercises focused on the knees and proper landing technique, avoiding valgus collapse.

Aim 2

Aim: Establish the incidence of lower extremity injuries, time loss, and career duration after ACL reconstruction, rehabilitation, and return to sport in Major League Soccer (MLS).

Hypothesis 2.1 From the time of their return to play, athletes after ACL reconstruction will have shorter careers in the MLS than athletes with no history of ACL injury

Hypothesis 2.2 In the first two years after ACL reconstruction and return to play athletes will have a higher incidence of lower extremity time-loss injuries than athletes with no history of ACL injury.

Hypothesis 2.3 In the first two years after ACL reconstruction and return to play athletes will have a higher incidence of time-loss injuries to the thigh muscles than athletes with no history of ACL injury

Hypothesis 2.4 In the first two years after ACL reconstruction and return to play athletes will have a higher number of severe lower extremity time-loss injuries than athletes with no history of ACL injury

Hypothesis 2.5 Injury incidence in the first two years after ACL reconstruction and return to play will differ between athletes who received different graft types

Return to play and athlete career length are very important in professional sports particularly given the financial implications associated with injury. Although ACL injuries are not common in professional men's soccer, they have serious consequences on athlete's careers.[50] After ACL reconstruction professional male soccer players are at a high risk for a new knee injury after ACL reconstruction,[55] but it was unknown if they were at risk for other lower extremity injuries. Further, it was unknown the impact that ACL reconstruction had on career length, as the available literature was based only on publically available online sources.[56] This study found that athletes who returned to MLS after ACL reconstruction had significantly shorter careers, by approximately half, compared to age-matched healthy peers. Although these athletes had the same number of athletic exposures in the two years after their return to play, they started significantly fewer and were unused for significantly more regular and post-season games. Thus, the results of this study supported hypothesis 2.1.

There was no difference between ACL group and Control group athletes in lower extremity injury risk, but ACL group athletes may have had a lower risk for hamstring and thigh injuries compared to Control group athletes. Thus, hypotheses 2.2 and 2.3 were not supported. There may be some support for hypothesis 2.4. Although the ACL group athletes did not miss more any days due to injury than the Control group athletes, they may have been at a higher risk for severe injuries than Control group athletes. There were differences in injury rates between athletes in the ACL group who had different graft types, supporting hypothesis 2.5. Further work in a larger cohort with a more even distribution of graft types is needed to explore the injury risks that could be associated with different graft types after ACL reconstruction and return to play.

These results highlight the importance of viewing return to sport as a continuum from return to participation, to return to play, to return to prior level of performance.[119] An athlete's rehabilitation and return to sport does not end when they get back on the field, and these results draw attention to the return to performance phase of rehabilitation. Athlete education and close collaboration within the medical team, strength and conditioning staff, and coaching staff is integral to helping athletes safely return to performance, and hopefully play the duration of their career to the best of their capabilities.

Aim 3

Aim: Quantify the effects of a specialized return to sport training and second injury prevention program on function, return to sport, and second ACL injury incidence in athletes after ACL reconstruction.

Hypothesis 3.1 The Anterior Cruciate Ligament Specialized Post-Operative Training (ACL-SPORTS) program will improve functional and self-reported outcomes from pre-training to post-training.

Hypothesis 3.2 Men and women who undergo the ACL-SPORTS program will have different changes in functional and self-reported outcomes from pre-training to post-training.

Hypothesis 3.3 Men who undergo the ACL-SPORTS program will return to sport at higher rates and have a lower second ACL injury incidence in the first two years after ACL reconstruction, when descriptively compared to the published literature.

Once athletes in the United States have achieved activities of daily living goals and begun basic athletic tasks such as running, they are generally discharged from physical therapy. The ACL-SPORTS program was designed to fill the gap between an athletes' discharge from physical therapy and their return to sport, as well as to improve functional and return to sport outcomes after ACL injury, serving as a secondary ACL injury prevention program. The results of Chapter 5 partially supported hypothesis 3.1. This study found both men and women improved in single-legged hop test limb symmetry, KOS-ADLS, GR, IKDC, KOOS-Sport/recreation, and KOOS-QoL scores with performance of the ACL-SPORTS training program. However, men had a significant increase in QI with performance of the program, but women did not. Thus, with regards to QI hypothesis 3.2 was supported, finding differences in the changes that men and women experienced with the ACL-SPORTS program. Although QI was the only functional measure where this difference was present, it is very important as QI is related to both functional and self-reported outcomes.[68-70] These results indicate that women may require more quadriceps strengthening even during the return to sport phase of ACL reconstruction rehabilitation.

The most commonly cited meta-analysis on return to play reports that return to sport at any level after ACL reconstruction is approximately 81%, return to preinjury level of sport is 65%.[12] All of the men who participated in the ACL-SPORTS program returned to sport and 95% returned to their preinjury level in the two years following their ACL reconstruction. Only one male athlete sustained a second ACL injury. This non-contact injury was likely a result of the playing surface not faulty mechanics as the athletes was able to return to preinjury level of sport non-operatively managed for the 2+ years following his second ACL injury. Thus, these results support hypothesis 3.3 and indicate that the ACL-SPORTS program is a clinically feasible training program can be implemented immediately with benefits to men who hope to safely return to sport after ACL reconstruction.

Future Research

Each aim of this study provides a platform for building future primary and secondary ACL injury prevention research. In finding that the FIFA11+ did not cause meaningful changes in frontal plane knee mechanics; the first aim of this study indicates that future research is needed to draw increased focus onto the knee. This future research will need to be multipronged as examining the specific exercises needed is important, but so too is examining the overall design of the program.

Especially for women, (Chapter 3,Chapter 5) [31-33] investigations into whether the program needs to be a higher intensity, longer duration, and potentially involve more individualized feedback, will give clinicians and researchers information on how to make the FIFA11+ more effective. Further, once changes are made to the FIFA11+ research on its use over multiple seasons is necessary to ensure the program's continued benefit, particularly for teams who do not have medical or strength and conditioning support staff.

The second aim of this study examined the outcomes of ACL reconstruction rehabilitation and return to play in the MLS, but was not able to investigate the specific interventions that comprised that rehabilitation. Future studies within MLS could examine the rehabilitation protocols and return to sport criteria to draw more concrete links between rehabilitation and outcomes. This dissertation highlights an apparent gap in return to preinjury level of performance in MLS. Most teams collect preseason screening and daily workload data, opening the route for future investigations into how many athletes achieve their preinjury objective measures, before returning to play and the subsequent impact on career length and injuries in athletes. Such work could help create return to sport recommendations for surgeons and clinicians within the league. Further, this study served as a pilot data, for examining injury incidence based on graft type after ACL reconstruction and return to play. Given the small sample size and uneven graft type groups it is hard to draw conclusions from study's results, but future research in a larger cohort could help advise surgeons on the impacts of various graft types as well as help clinicians further individualize rehabilitation and prevention.

Finally, the larger study behind the third aim, the ACL-SPORTS randomized clinical trial, is still on-going. This dissertation reported on the two year return to sport and second ACL injury outcomes in the 40 men involved in the trial. There are still women who have yet to reach their two year time point, though. Thus, analysis of the functional, self-report, return to sport, and second ACL injury outcomes in these 40 women will be forthcoming. Future research is also needed to investigate how to assist women in gaining and maintaining quadriceps strength during the return to sport phase of rehabilitation. Similar to the investigations related to the FIFA11+, future studies related to the ACL-SPORTS program should examine the intensity, duration, and specific exercises involved in the program as this will help researchers and clinicians build an effective sex-specific secondary prevention programs.

Prevention research is ongoing. Van Mechlen et al. [154] framed prevention research as a four step cycle starting with identifying the problem by establishing the incidence and severity, assessing the mechanism of injury, developing an intervention, and finally assessing outcomes by returning to the beginning to reassess incidence and severity. This dissertation contributes to the body of knowledge regarding primary and secondary ACL injury prevention. The results presented here feed new information into the cycle of prevention as we strive to improve prevention interventions; all with the goal of keeping our athletes on the field, playing not rehabilitating.

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Appendix

Appendix A

RAW INCIDENCE RATES AND RELATIVE RISK RATIOS FOR THE BPTB AUTOGRAFT, BPTB ALLOGRAFT, AND HAMSTRING AUTOGRAFT GROUPS

Injury Type	Graft Type Group	Number of Injuries (Injury Incidence /1000AEs)	Relative Risk Ratio*	Lower Bound 95% CI	Upper Bound 95% CI	p-value
Lower Extremity Injuries	*Hamstring Tendon Autograft*	13 (11.0)	0.55	0.22	1.34	0.18
	BPTB Autograft	74 (17.6)	-	-	-	-
	BPTB Allograft	22 (24.1)	0.97	0.46	2.07	0.94
Time-loss Lower Extremity Injuries	*Hamstring Tendon Autograft*	10 (8.6)	0.63	0.26	2.26	0.63
	BPTB Autograft	40 (9.5)	-	-	-	-
	BPTB Allograft	9 (9.8)	0.66	0.27	1.57	0.34
Non-Contact Lower Extremity Injuries	*Hamstring Tendon Autograft*	3 (3.1)	0.33	0.09	1.21	0.09
	BPTB Autograft	19 (4.5)	-	-	-	-
	BPTB Allograft	4 (4.4)	0.58	0.17	1.95	0.38
Muscle/Tendon Injuries	*Hamstring Tendon Autograft*	1 (0.8)	0.11	0.02	0.77	0.03
	BPTB Autograft	23 (5.5)	-	-	-	-
	BPTB Allograft	4 (4.4)	0.55	0.13	2.40	0.43

Thigh Injuries	*Hamstring Tendon Autograft*	0	-	-	-	-
	BPTB Autograft	18 (4.3)	-	-	-	-
	BPTB Allograft	3 (3.3)	0.67	0.14	3.13	0.61
Hamstring Injuries	*Hamstring Tendon Autograft*	0	-	-	-	-
	BPTB Autograft	7 (1.7)	-	-	-	-
	BPTB Allograft	1 (1.1)	1.20	0.14	10.0	0.87
Knee Injuries	*Hamstring Tendon Autograft*	6 (5.5)	1.27	0.23	7.05	0.78
	BPTB Autograft	8 (1.9)	-	-	-	-
	BPTB Allograft	3 (3.3)	0.69	0.13	3.81	0.68
Overuse Injuries	*Hamstring Tendon Autograft*	0	-	-	-	-
	BPTB Autograft	2 (0.5)	-	-	-	-
	BPTB Allograft	3 (3.3)	18.85	2.73	130.13	<0.01

Appendix B

NUMBER OF INJURIES, INJURY INCIDENCE, AND RELATIVE RISK OF INJURIES BY SEVERITY FOR BPTB AUTOGRAFT, BPTB ALLOGRAFT, AND HAMSTRING AUTOGRAFT GROUPS

	Graft Type Group	Number of Injuries (Injury Incidence per 1000 AEs)	Relative Risk Ratio	Lower Bound 95% CI	Upper Bound 95% CI	p-value
Minimal Injuries	*Hamstring Autograft*	4 (3.3)	5.56	1.39	22.27	0.02
	BPTB Autograft	3 (0.7)	-	-	-	-
	BPTB Allograft	0 (0)	-	-	-	-
Mild Injuries	*Hamstring Autograft*	1 (4.2)	0.46	0.07	3.30	0.44
	BPTB Autograft	9 (2.1)	-	-	-	-
	BPTB Allograft	2 (2.2)	0.93	0.23	3.72	0.91
Moderate Injuries	*Hamstring Autograft*	4 (4.2)	0.88	0.21	3.61	0.86
	BPTB Autograft	19 (4.5)	-	-	-	-
	BPTB Allograft	5 (5.5)	1.10	0.41	2.96	0.86
Severe Injuries	*Hamstring Autograft*	5 (7.5)	2.32	0.95	5.67	0.07
	BPTB Autograft	9 (2.1)	-	-	-	-
	BPTB Allograft	3 (3.3)	1.39	0.36	5.44	0.64

Appendix C

EXERCISES PERFORMED AS PART OF THE ACL-SPORTS TRAINING PROGRAM

Group(s) performing		Sessions 1-3	Sessions 4-6	Sessions 7-10
SAP and SAP+PERT[132]	**Nordic Hamstrings**	2x5 (~30-45°)	3x5 (~30-45°)	3x5 (~60°)
	Standing Squat (Bilateral to 90°)	Session 1: 3x10 focusing on proper technique Session 2 and 3: Add theraband around knees	3x10 progression to black theraband around knees	Not performed
	Drop Jump	3x10 Taking off and landing bilaterally Step height progresses as appropriate for the athlete from 4 to 6 to 8 inches tall	3x10 Taking off bilaterally, landing on the involved limb Step height progresses as appropriate for the athlete from 4 to 6 to 8 inches tall	3x10 Taking off and landing on the involved limb Step height progressing as appropriate for the athlete from 4 to 6 to 8 inches tall
	Triple Single Leg hopping	Forward/backwards (3 hops forward, 3 hops backwards) x10 Side to Side (3 consecutive hops laterally) x10 Overground	Forward/backwards (3 hops forward, 3 hops backwards) x15 Side to Side (3 consecutive hops laterally) x15 Over a low object approximately 2 inches high (such as cup or low cone)	Forward/backwards (3 hops forward, 3 hops backwards) x15 Side to Side (3 consecutive hops laterally) x15 Over an object the height appropriate for the patient such as 4 in cones or 6 in hurdles
	Tuck Jumps	Not performed	Not performed	2 sets for 10-20 seconds Progressing to 3 sets for 20-30 seconds
SAP Only	**Single-leg balance with hip**	3 x 30 seconds	3 x 45 seconds	3 x 1 minute

<table>
<tr><td></td><td>flexor resistance</td><td></td><td></td><td></td></tr>
<tr><td rowspan="4">SAP+PERT Only</td><td colspan="4">Perturbation Training[132 135]
Progressed according to athlete response not by treatment session number
-As athlete progresses the speed of perturbations is increased
-Perturbations begin in anterior/posterior and medial/lateral and are advanced to including rotations</td></tr>
<tr><td>Roller board</td><td colspan="3">Double limb support
Single limb support in parallel bars
Single limb support out of parallel bars</td></tr>
<tr><td>Roller board and stationary platform (one foot on roller board one foot on platform)</td><td colspan="3">Perturbations with feet parallel to each other in a straddle stance
Add perturbations with feet in a diagonal stance
Add functional task during perturbations</td></tr>
<tr><td>Tilt board</td><td colspan="3">Double limb support
Single limb support
Add functional task during perturbation</td></tr>
</table>

Appendix D

IRB APPROVAL AND CONSENT FORMS AIM 1

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Fax: 302/831-2828

DATE:	June 21, 2016
TO:	Holly Silvers, MPT
FROM:	University of Delaware IRB
STUDY TITLE:	[617078-4] Biomechanical analysis of the FIFA 11+ injury prevention program
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	June 21, 2016
EXPIRATION DATE:	July 6, 2017
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *(4,6)*

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

University of Delaware
Informed Consent Form

Title of Project: *Biomechanical Analysis of the FIFA 11+ Injury Prevention Program*

Principal Investigator (s): Holly J. Silvers, PT

Other Investigators: Amelia Arundale, PT, Ryan Zarzycki, PT, Adam Marmon, PhD, Lynn Snyder-Mackler, PT, ScD, Adam Marmon, PhD

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will be asked to do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn more about the effectiveness of an injury prevention program (The FIFA 11+ program) developed specifically for competitive soccer players. The program has been studied in females and in male NCAA soccer players and has been shown to reduce injury by 52%. Your coach has agreed to utilize the FIFA 11+ program as your warm-up throughout the course of the season. We now would like to understand how it works by analyzing it biomechanically.

- *The study will be conducted in the NCAA using men's and women's soccer players.*
- *We will analyze your movements in the motion analysis lab (Star Campus, University of Delaware). These movements are soccer specific and will include cutting, pivoting, deceleration, a lateral shuffle, a triple hop and a single leg squat.*
- *Your team will utilize the FIFA 11+ warm-up program twice a week throughout the course of the 2014 fall, 2015, and 2016 spring and fall seasons.*
- *Your injuries will be tracked throughout the course of the season. This information will be kept confidential and your name and any unique identifying information will never be disclosed.*
- *This study will be utilized towards completion of a PhD dissertation.*

You are being asked to take part in this study because…

- *You are a soccer player competing as a member of an NCAA Men's or Women's soccer team.*

Participant Initials ________

- *Every player on your team will be invited to participate. You have the option not to participate in the study.*
- *The testing will take approximately 2 hours. The testing will occur once during preseason and again at the conclusion of the fall (men) and spring seasons (mend and women) for a total of 4-6 hours. In addition, your team may utilize the FIFA 11+ Program as a dynamic warm-up twice a week. This will replace your traditional warm-up and will require no additional time from you as a player.*

WHAT WILL YOU BE ASKED TO DO?

- *Upon your approval, a member of the research team will schedule you for a session in the motion analysis lab to be tested at your convenience. A follow-up testing will be scheduled at the end of the fall and spring seasons.*
- *During the season, you will perform the FIFA 11+ warm-up program twice a week. This will replace your traditional warm-up program and will require no additional time from you. You can view the program in its' entirety here: http://f-marc.com/11plus/home/*
- *Any injury that you incur during the course of the season will be collected.*
- *The number of completed FIFA 11+ warm-ups throughout the course of the season will also be collected.*
- *The movement testing will take place in the motion analysis laboratory on the Star Campus, University of Delaware. The testing will occur once in August, 2014 (men), once during December, 2014 – February, 2015 (men and women), in May, 2015 (men and women), August, 2015 and December, 2015 (for men and women), and August, 2016 and December, 2016 (men and women) . Each testing session will take approximately 1 hour.*

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- *There are no foreseeable risks from participating in the study. The FIFA 11+ warm-up is a well-researched program and has been shown to decrease the number of soccer related injuries and time loss associated with injury.*
- *There is always a small risk associated with movement analysis or participating in an injury prevention program. However, we expect these risks to be minimal or non-existent.*
- *There are no financial risks associated with your participation. The only foreseeable discomfort may be associated with the time devoted to the actual testing process (2 hours for 3 sessions – one in August, one in December, 2014 – February, 2015, once in May, 2015, and once in August and December, 2016).*

WHAT ARE THE POTENTIAL BENEFITS?

- *The potential benefit for participating in the research project is that your risk of soccer related injury may potentially be decreased.*

Participant Initials ________

- *The other potential benefits include a more thorough understanding of how the FIFA 11+ program helps to reduce injury in soccer players.*
- *The future benefits include a better scientific understanding of how the FIFA 11+ program helps to decrease injury by slight changes to movement patterns in competitive soccer players. This knowledge is very important to the medical community that works directly with soccer players.*

HOW WILL CONFIDENTIALITY BE MAINTAINED?

- *Your identity will be protected during the course of the study. You will be assigned a unique identifying code number and your name will not be associated with any data that the research team collects. A list will be created to link the code number to the participant. Only the primary investigator (Holly Silvers) will have access to this and this will be kept in a secured file (password protected).*
- *The data that we collect in the lab and the injury data collected throughout the course of the season will be stored in an excel worksheet and will be password secured. Any data that we collect on paper will be stored in a locked filing cabinet in the BIOMS office on the Star Campus, University of Delaware. The records will be stored for three years.*
- *Only the research team will have access to the video recordings of your movement analysis. This data will be stored on a secured hard drive and will be password protected. Your file will be saved with a unique identifier and will not include your name or date of birth. This data will be stored for seven years and will only be used for research purposes. Recordings will be permanently destroyed at this time.*
- *The data will be reported in a manuscript form and will not include your name, age, date of birth or any unique identifier. The data will be grouped together and analyzed. Upon completion, the data will be submitted to a scientific journal for publication.*
- *There is always a risk that confidentiality may be breached. However, the research team will do everything possible to ensure that this in minimized; including the removal of your name, date of birth, position and jersey number from every file, assigning you with a unique identifying code, keeping all of the files password secured, and keeping any written documentation in a locked-secured cabinet.*

"We will make every effort to keep all research records that identify you confidential to the extent permitted by law. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. "

Your research records may be viewed by the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

- *No other research organization will have access to these records.*

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?

- *There are no financial costs associated with your participation*

Participant Initials ________

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?

- *There is no compensation associated with your participation, in accordance with NCAA rules and regulations.*

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, you will be offered first aid and medical treatment at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not influence current or future relationships with the institution that you attend or are employed by, or the Women's or Men's soccer program at the NCAA member institution.

As a student-athlete, if you decide not to take part in this research, your choice will have no effect on your academic status or with your status as a player on the Men's soccer team.

- *If you are indeed injured during the course of the study, you have the option to have your medical care provided by the University of Delaware's Athletic Department. You may also see private treatment through your private insurance.*
- *In the event you incur a season ending injury during the course of the season, your participation in the study will end.*

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Holly Silvers at 310 871-2823 or via email: hollys@udel.edu.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at 302-831-2137.

Participant Initials ________

Your signature below indicates that you are voluntarily agreeing to take part in this research study. You have been informed about the study's purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep.

______________________________ ____________

Signature of Participant Date

____

Printed Name of Participant

Participant Initials _______

WILMINGTON UNIVERSITY
HUMAN SUBJECTS REVIEW COMMITTEE (HSRC)
PROTOCOL REVIEW

This section is to be completed by the HSR Committee Person.

Principal Investigator: Holly Silvers

Date submitted: 7/28/16

The protocol and attachments were reviewed:

The proposed research is approved as:

____ Exempt X Expedited ____ Full Committee

The proposed research was approved pending the following changes:

____ See attached letter

____ Resubmit changes to the HSRC chairperson

The proposed research was disapproved:

____ See attached letter for more information.

HSRC Chair or Representative: Ruth Norman
Print name

Ruth T. Norman
Signature Date: 7/28/16

HSRC Chair Or Representative: Stephanie A. Battis
Print name

SA Battis
Signature Date: 7/28/16

Wilmington University
Informed Consent Form

Title of Project: *Biomechanical Analysis of the FIFA 11+ Injury Prevention Program*

Principal Investigator (s): Holly J. Silvers, PT

Other Investigators: Amelia Arundale, PT, Ryan Zarzycki, PT, Adam Marmon, PhD, Lynn Snyder-Mackler, PT, ScD, Adam Marmon, PhD

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will be asked to do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn more about the effectiveness of an injury prevention program (The FIFA 11+ program) developed specifically for competitive soccer players. The program has been studied in females and in male NCAA soccer players and has been shown to reduce injury by 52%. Your coach has agreed to utilize the FIFA 11+ program as your warm-up throughout the course of the season. We now would like to understand how it works by analyzing it biomechanically.

- *The study will be conducted in the NCAA using men's and women's soccer players.*
- *We will analyze your movements in the motion analysis lab (Star Campus, University of Delaware). These movements are soccer specific and will include cutting, pivoting, deceleration, a lateral shuffle, a triple hop and a single leg squat.*
- *Your team may or may not utilize the FIFA 11+ warm-up program twice a week throughout the course of the 2014 fall, 2015, and 2016 spring and fall seasons.*
- *Your injuries will be tracked throughout the course of the season. This information will be kept confidential and your name and any unique identifying information will never be disclosed.*
- *This study will be utilized towards completion of a PhD dissertation.*

You are being asked to take part in this study because…

- *You are a soccer player competing as a member of an NCAA Men's or Women's soccer team.*

Participant Initials ________

- *Every player on your team will be invited to participate. You have the option not to participate in the study.*
- *The testing will take approximately 1 hour. The testing will occur once during preseason and again at the conclusion of the fall (men) and spring seasons (men and women) for a total of 4-6 hours. In addition, your team may utilize the FIFA 11+ Program as a dynamic warm-up twice a week. This will replace your traditional warm-up and will require no additional time from you as a player.*

WHAT WILL YOU BE ASKED TO DO?

- *Upon your approval, a member of the research team will schedule you for a session in the motion analysis lab to be tested at your convenience. A follow-up testing will be scheduled at the end of the fall and spring seasons.*
- *During the season, if you are selected as an intervention team, you may or may not perform the FIFA 11+ warm-up program twice a week. This will replace your traditional warm-up program and will require no additional time from you. You can view the program in its' entirety here: http://f-marc.com/11plus/home/*
- *Any injury that you incur during the course of the season will be collected.*
- *The number of completed FIFA 11+ warm-ups throughout the course of the season will also be collected.*
- *The movement testing will take place in the motion analysis laboratory on the Star Campus, University of Delaware. The testing will occur once in August, 2014 (men), once during December, 2014 – February, 2015 (men and women), in May, 2015 (men and women), August, 2015 and December, 2015 (for men and women), and August, 2016 and December, 2016 (men and women) . Each testing session will take approximately less than 1 hour.*

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- *There are no foreseeable risks from participating in the study. The FIFA 11+ warm-up is a well-researched program and has been shown to decrease the number of soccer related injuries and time loss associated with injury.*
- *There is always a small risk associated with movement analysis or participating in an injury prevention program. However, we expect these risks to be minimal or non-existent.*
- *There are no financial risks associated with your participation. The only foreseeable discomfort may be associated with the time devoted to the actual testing process (2 hours for 3 sessions – one in August, one in December, 2014 – February, 2015, once in May, 2015, and once in August and December, 2016).*

WHAT ARE THE POTENTIAL BENEFITS?

Participant Initials ________

- *The potential benefit for participating in the research project is that your risk of soccer related injury may potentially be decreased.*
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- *The data will be reported in a manuscript form and will not include your name, age, date of birth or any unique identifier. The data will be grouped together and analyzed. Upon completion, the data will be submitted to a scientific journal for publication.*
- *There is always a risk that confidentiality may be breached. However, the research team will do everything possible to ensure that this in minimized; including the removal of your name, date of birth, position and jersey number from every file, assigning you with a unique identifying code, keeping all of the files password secured, and keeping any written documentation in a locked-secured cabinet.*

"We will make every effort to keep all research records that identify you confidential to the extent permitted by law. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. "

Your research records may be viewed by the Wilmington University and the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

- *No other research organization will have access to these records.*

Page 3 of 5

Participant Initials ________

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?

- *There are no financial costs associated with your participation*

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?

- *There is no compensation associated with your participation, in accordance with NCAA rules and regulations.*

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, you will be offered first aid and medical treatment at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not influence current or future relationships with the institution that you attend or are employed by, or the Women's or Men's soccer program at the NCAA member institution.

As a student-athlete, if you decide not to take part in this research, your choice will have no effect on your academic status or with your status as a player on the Men's soccer team.

- *If you are indeed injured during the course of the study, you have the option to have your medical care provided by the University of Delaware's Athletic Department. You may also see private treatment through your private insurance.*
- *In the event you incur a season ending injury during the course of the season, your participation in the study will end.*

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Holly Silvers at 310 871-2823 or via email: hollys@udel.edu or hollysilverspt@gmail.com.

If you have any questions or concerns about your rights as a research participant, you may contact the Wilmington University Institutional Review Board at University of Delaware Institutional Review Board at 302-831-2137.

Participant Initials ________

Your signature below indicates that you are voluntarily agreeing to take part in this research study. You have been informed about the study's purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep.

______________________________ ______________

Signature of Participant Date

____

Printed Name of Participant

Participant Initials ________

Appendix E

IRB APPROVAL FOR AIM 2

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	November 11, 2014
TO:	Amelia Arundale, DPT,
FROM:	University of Delaware IRB
STUDY TITLE:	[681115-1] Lower extremity injury risk following anterior cruciate ligament reconstruction and return to major League Soccer
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF EXEMPT STATUS
DECISION DATE:	November 11, 2014
REVIEW CATEGORY:	Exemption Category # : 45 CFR 46.101(b) 4

Thank you for your submission of New Project materials for this research study. The University of Delaware IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will put a copy of this correspondence on file in our office. Please remember to notify us if you make any substantial changes to the project.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

Appendix F

IRB APPROVAL AND CONSENT FORMS AIM 3

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	February 27, 2017
TO:	Lynn Snyder-Mackler, PT, ScD, FAPTA
FROM:	University of Delaware IRB (HUMANS)
STUDY TITLE:	[225014-15] Can Neuromuscular Training Alter Movement Patterns? (Renewal Period)
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	February 27, 2017
EXPIRATION DATE:	March 14, 2018
REVIEW TYPE:	Full Committee Review

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

UNIVERSITY OF DELAWARE
DEPARTMENT OF PHYSICAL THERAPY
INFORMED CONSENT FORM

Study Title: Can Neuromuscular Training Alter Movement Patterns? (Renewal Period), Experiment 2 (Aim 3), new randomized controlled trial.

Principal Investigators: Lynn Snyder-Mackler, ScD, PT

Co-investigators: Thomas Buchanan, PhD, Kurt Manal, PhD, Gregory Hicks, PT, PhD, Paul Kolm, PhD, Stephanie Di Stasi, PT, MSPT, PhD, David Logerstedt, PT, MPT, PhD, Andrew Lynch, PT,DPT, Michael J. Axe, M.D., Emily Gardinier, MS, Kathleen White, PT, DPT, Amelia Arundale, PT, DPT, Ryan Zarzycki, PT, DPT, Jacob Capin, PT, DPT, MS,

PURPOSE AND BACKGROUND

You are being asked to participate in a study that will investigate the effect of post-operative rehabilitation on the movement patterns and functional abilities in patients who have had a complete anterior cruciate ligament (ACL) rupture. You have been referred to this study because you have completed a functional screening examination and have decided to undergo ACL reconstruction.

Participation in this research study is voluntary. Your treatment will not be affected by whether or not you participate and you may withdraw from the study at any time without penalty. This program will include treatment activities we currently use in our clinic to treat patients with ACL injury. Your surgeon and physical therapist have agreed that this treatment regimen and all of the testing procedures included in the study are acceptable. Your surgeon has agreed that the tests are being conducted at appropriate intervals following your surgery. In addition to the physical therapy treatment, the study includes strength testing and analysis of your knee movement during walking. There will be a total of four (4) testing sessions: 1) pre-intervention, 2) immediately after completing intervention, 3) 12 months after surgery, and 4) 24 months after surgery. This research study will involve approximately eighty (80) subjects with ACL injury between the ages of 13-55 years. Persons of all sexes, races, and ethnic origins may serve as subjects for this study.

A description of each procedure and the approximate time it takes for each test and the study procedure are outlined below.

Subject's Initials_______

PROCEDURES

ACL Functional Test

Functional testing will take place in the Physical Therapy Clinic at the University of Delaware, 540 S. College Ave, Newark, DE, 19713 and will last approximately 1 hour. Testing will be performed pre-intervention, immediately after intervention and 12 and 24 months after surgery. This is commonly done at the University of Delaware Physical Therapy Clinic as part of the post-operative ACL rehabilitation protocol.

Strength Testing

The test will measure the strength of the quadriceps muscle on the front of your thigh. You will be seated in a dynamometer, a device that resists your kicking motion, and measures how much force your muscle can exert. Self adhesive electrodes will be attached to the front of your thigh, and you will be asked to kick as hard as you can against the arm of the dynamometer. An electrical stimulus will be activated while you are kicking, to fully contract your muscle. During the electrical stimulus you may feel a cramp in your muscles, like a "Charlie Horse", lasting less than a second. Each test will require a series of practice and recorded contractions. Trials will be repeated (up to a maximum of 4 trials) until a maximum contraction is achieved for both legs.

Hop Testing

A series of four (4) single leg hop tests (Diagram 1) will be performed once the swelling in your knee has resolved and you demonstrate good thigh muscle strength. The tests are performed in the order seen in Diagram 1. You are required to wear a standard off-the-shelf knee brace on your injured knee during this portion of the testing.

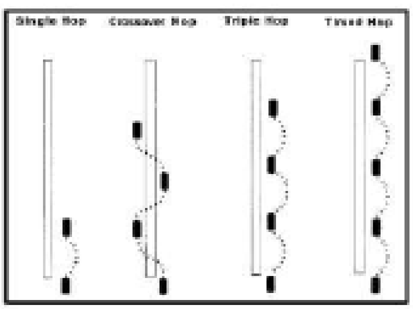

Diagram 1. Four (4) hop tests as part of the functional test protocol.

Two practice trials will precede each of the hop tests before the recorded testing begins. You can put your other leg down at any time to prevent yourself from losing your balance. However, only the two trials in which you are able to 'stick the landing' on one foot will be counted towards your scores. This series of hop tests will be performed on both legs.

Subject's Initials_______

Questionnaires

Following strength and hop testing, you will be asked to complete a test packet which includes questions about your injury, past and current functional status, and perceived functional capabilities. If you are unable to complete the strength and hop testing for any reason, you will still be asked to complete the test packet so that we may get as much information about the current status of your knee as possible.

Motion Analysis Testing

All subjects will be asked to perform motion analysis testing, which will take place in the Motion Analysis Laboratory at the University of Delaware, Department of Physical Therapy, 540 S. College Ave, Newark, DE, 19713. Motion analysis testing will take place pre-intervention, immediately after intervention, 12 and 24 months after your ACL surgery.

Motion Analysis

Markers will be affixed to your skin and sneakers on both legs using adhesive skin tape. Shells with markers on them will be placed on your pelvis, thighs and calves and will be held in place with elastic wraps. These markers will allow the cameras to track your leg positions.

Muscle Activity

Electrodes, taped to your skin, will be used to record the electrical activity of your muscles. After all electrodes have been placed, you will perform a maximum contraction of each muscle, with straps applied to your ankles to provide resistance. Nine electrodes will be secured to each leg and then plugged into a small (6" x 4" x 3") transmitter box that will be attached to the back of a vest with Velcro. The transmitter sends the signal to the computer so we can determine when the muscles are contracting during the activities. These measurements will also be taken during the walking trials of the motion analysis testing. The electrodes will be removed at the conclusion of the testing session.

Walking Trials

Immediately following the initial muscle activity testing, you will be asked to perform several walking trials in our laboratory. Walking trials will give us information about the way your hips, knees, and ankles move while you walk. You will be asked to perform 7 trials of walking at a comfortable, self-selected speed, although additional trials may be required to obtain enough data. While you are walking, a computer records the 3 dimensional motions of your hips, knees, and ankles. The entire motion analysis session will last approximately two (2) hours.

Subject's Initials_______

Physical Therapy

Twelve weeks after surgery, and when you have sufficient thigh muscle strength, you will be randomized into one of two different treatment groups, both of which incorporate higher level, progressive activities, including running and agility training. Ten sessions will be scheduled two to five times weekly, depending on your time constraints and your ability to progress with therapy.

Risks/Discomfort

You may experience discomfort from the removal of tape holding markers and EMG electrodes in place. Subjects with ACL injury could experience a loss of balance during testing, however your other leg is free to touch down to provide support and prevent loss of balance. The strength testing can be associated with local muscle soreness and fatigue. Following the testing, your muscles may feel as if you have exercised vigorously.

Benefits

The benefits include comprehensive testing sessions and post-operative physical therapy. All physical therapy sessions will be administered by a licensed physical therapist. The results of this study may help us improve the way we treat patients with ACL injury. Out-of-pocket expenses related to postoperative physical therapy treatment sessions, specifically your co-pay, will be covered by this grant. Medications, medical devices (e.g. braces) and other nonphysical therapy expenses are not covered.

Compensation

You will be paid an honorarium of $100 for the motion analysis testing and functional testing to compensate you for travel expenses and the time involved.

Confidentiality and records

Only the investigators, you and your physician will have access to the data. All of your data will be de-identified for the purposes of data management and processing. Neither your name nor any identifying information will be used in publication or presentation resulting from this study. A statistical report, which may include slides or photographs which will not identify you, may be disclosed in a scientific paper. Data will be archived indefinitely and may be used for secondary analysis of scientific and clinical questions that arise from this research.

Subject's Initials_______

Study Title: Can Neuromuscular Training Alter Movement Patterns? (Renewal Period), Experiment 2 (Aim 3), new randomized controlled trial.

Principal Investigators: Lynn Snyder-Mackler, ScD, PT

Co-investigators: Thomas Buchanan, PhD, Kurt Manal, PhD, Gregory Hicks, PT, PhD, Paul Kolm, PhD, Stephanie Di Stasi, PT, MSPT, PhD, David Logerstedt, PT, MPT, PhD, Andrew Lynch, PT,DPT, Michael J. Axe, M.D., Emily Gardinier, MS, Kathleen White, PT, DPT, Amelia Arundale, PT, DPT, Ryan Zarzycki, PT, DPT

Subject's Statement:

I have read this consent/assent form and have discussed the procedure described above with a principal investigator. I have been given the opportunity to ask questions regarding this study, and they have been answered to my satisfaction.

If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

I have been fully informed of the above described procedures, with its possible risks and benefits, and I hereby consent/assent (for those under 18 years of age) to the procedures set forth above.

If I am under 18 years of age, I understand that parental or guardian consent is required. My parent or guardian has printed and signed his/her name below.

____________________	________________________	__________
Subject's Name	Subject's Signature	Date
____________________	________________________	__________
Parent/Guardian's Name	Parent/Guardian's Signature	Date

__________________________________ __________

Lynn Snyder-Mackler, Principal Investigator Date

If you have any questions concerning the rights of individuals who agree to participate in research, you may contact the Institutional Review Board (302-8312137). The Institutional Review Board is created for the protection of human subjects involved in research conducted at the University of Delaware.

Further questions regarding this study may be addressed to:
Lynn Snyder-Mackler, ScD, PT
Physical Therapy Department, (302) 831-3613

 Subject's Initials______