RAISING THE BAR:

OUTCOMES IN ATHLETES AFTER ACL INJURY AND RECONSTRUCTION

by

Mathew Failla

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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by

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ABSTRACT

Anterior cruciate ligament (ACL) injury is a transformative and demoralizing knee injury commonly affecting athletes who participate in activities where jumping, cutting, and pivoting maneuvers are frequently used. Emerging outcomes research suggests recovery after ACL injury is more vexed than previously thought. Many athletes continue to experience less than normal knee function despite modern advances in arthroscopic surgical technology, various graft options, and the development of rehabilitation standards. Merely reconstructing the ligamentous tear does not guarantee return to previous level of function, return to previous activity or activity level, and does not prevent post-traumatic osteoarthritis development.

While factors such as age, sex, body mass index (BMI), graft type, concomitant injury, and surgical variables are associated with altered outcomes; these factors are non-modifiable to rehabilitation professionals. Establishing modifiable factors associated with outcomes after ACL injury and ACLR can lead to the potential to impact standards of care and rehabilitation protocols to impede poor outcomes in the future. Pre-operative rehabilitation has been shown to lead to improved outcomes following ACLR. The addition of pre-operative milestones prior to undergoing ACLR have been used to reduce negative outcomes, such as arthrofibrosis and quadriceps strength weakness.

The purpose of this work is to examine the effects of pre-operative rehabilitation on improving outcomes 2 years after ACLR, examining pre- and early post-operative modifiable factors that are related to 2 year outcomes, and explore

second injury rates and predictors in a cohort that underwent extended pre-operative rehabilitation.

Athletes with ACL injury who underwent ACLR served as subjects for this work. Athletes completed demographic, clinical, functional, and patient-reported outcome measures before and after an extended program of pre-operative rehabilitation. Subjects returned at 6 months and 24 months after reconstruction for follow-up testing. Second injury rates and successful or unsuccessful outcomes assessment was completed at 2 year follow-up.

The addition of extended pre-operative training was associated with higher functional outcome scores at 2 years after reconstruction. Besides improving outcomes, waiting until completion of the extended pre-operative rehabilitation to perform a screening battery resulted in a more robust prediction of function 2 years after ACLR. Clinical and functional measures that are modifiable to rehabilitation specialists successfully predicted 2 year function as well as successful or unsuccessful outcome following ACLR. The benefits of additional rehabilitation and higher standards are evident throughout this work. Raising the bar of pre-operative strength, functional performance, and patient-reported outcome scores was associated with higher functional scores 2 years after ACLR. This highlights the importance of achieving higher clinical and functional standards before undergoing ACLR. In addition, the need to achieve higher standards of function early after ACLR features the importance of progressive post-operative protocols and utilizing objective

measures to identify those at increased risk of poorer outcomes or second ACL injury.

No matter the time-point, success was associated with higher clinical and functional outcomes further perpetuating the importance of rehabilitation in improving outcomes.

Chapter 1

THE STATE OF OUTCOMES AFTER ACL INJURY AND RECONSTRUCTION

1.1 The Need for Outcomes Research

Anterior cruciate ligament (ACL) injury is a transformative and demoralizing knee injury commonly affecting athletes who participate in activities where jumping, cutting, and pivoting maneuvers are frequently used.³⁵ The substantial growth of sports participation across all ages and genders of athletes has unfortunately been accompanied by an increase in the prevalence of ACL injury.⁵⁹ Patient perception and expectation of recovery after ACL injury and reconstruction (ACLR) is high, ²⁸ with a select few high profile professional athletes further perpetuating this misconception through almost miraculous accelerated recoveries. The truth, however, is these few athletes are the exception and not the rule. Emerging outcomes research suggests recovery after ACL injury is more vexed than previously thought. 27,32,36,69 Many athletes continue to experience less than normal knee function despite modern advances in arthroscopic surgical technology, various graft options, and the development of rehabilitation standards.^{8,37,69} Merely reconstructing the ligamentous tear does not guarantee return to previous level of function,³⁴ return to previous activity or activity level, 7,15,23,34,77,106 and does not prevent post-traumatic osteoarthritis development. 10,112,113

Outcomes research is important to better understand which treatments work best and for whom, and which outcomes are most important to patient satisfaction. Lynch and colleagues established consensus criteria to define successful outcomes after ACL injury and ACLR.⁷² Consensus was reached for no recurrent instability, no joint effusion, restoration of quadriceps strength symmetry, restoration of previous activity level and function, and returning to all pre-injury activity. With the establishment of these criteria, the next question can be asked: what factors are associated with these desired outcomes? While factors such as age,^{6,125} sex,¹²¹ body mass index (BMI),¹³ graft type,^{65,98} concomitant injury,^{11,13} and surgical variables¹³⁵ are associated with altered outcomes; these factors are non-modifiable to rehabilitation professionals. Establishing modifiable factors associated with outcomes after ACL injury and ACLR can lead to the potential to impact standards of care and rehabilitation protocols to impede poor outcomes in the future.

1.2 Differential Response to Injury

The variability in response to ACLR is troubling. Regardless of criterion-based rehabilitation protocols, athletes continue to experience quadriceps strength deficits, ^{89,90,100,122} lower scores on patient-reported outcomes, ^{65,68,69,88} limited activity participation, ^{3,23,117} and movement asymmetry ¹⁰⁰ at least two years after ACLR. Quadriceps strength deficits have been linked with poorer functional outcomes, ^{68,89,120} with 1/3rd of athletes having greater than 10% deficits at 2 years ⁹⁰ and reports of 6-9% deficits at 3 years. ⁸⁹ Patient-reported outcomes scores are lowest after surgery, and can continue to improve for up to 6 years. ^{50,58,79} International Knee Documentation Committee subjective knee form 2000 (IKDC) scores are 75-89 at 2 years after ACLR, ^{23,36} which vary more than reported normative data for young healthy individuals which ranges from 86-89. ⁶ In addition to improving function, the desire to return to high level activity, after ACL injury, is often used as an indication for

ACLR.⁵⁵ Unfortunately, many athletes do not achieve this goal,⁷ and activity limitation persists even after ACLR. 23,34 Almost half of athletes after ACLR are not able to return to their pre-injury level of competition, and nearly 1/3rd are unable to return to any level of their pre-injury sport. Trrespective of sport, more than half of individuals after ACLR do not achieve their pre-injury activity as measured by the Marx Activity Scale.²³ Fear of re-injury, and other psychological factors, which are potentially modifiable, also play a role in reduced activity participation and are associated with a lowered health-related quality of life. 8,61 Health-related quality of life continues to be lower than population normative values at least 5 years after ACLR.²⁹ Current post-operative rehabilitation protocols are based largely on tissue healing and mechanics, as well as expert opinion or consensus, with few using criterion based progression.² An evidence based understanding of what influences good or poor outcomes is needed to tailor these protocols to achieve the best outcomes possible. Outcomes of interest after ACLR include quadriceps strength, functional knee performance, patient-reported outcome measures, return to sport rates, and second injury rates. Prospective longitudinal data utilizing these outcomes is of utmost importance to rehabilitation professionals in order to optimize treatment protocols after ACLR.

The inconsistency in outcomes after ACL injury and ACLR begs the question, can we identify those that are likely to have a successful outcome or an unsuccessful outcome early after ACL injury and before surgery? Furthermore, can we identify clinical, functional and patient-reported predictors that can help with surgical decision making process? Fitzgerald and colleagues established screening criteria to classify differential response in athletes after ACL injury.³⁰ This differential response to injury

revolves around the ability to dynamically stabilize one's knee, despite the insult to a passive stabilizing ligament. While identification of stability status is prognostic in the short-term after injury, the longer-term prognostic accuracy of this classification system is in question.⁸⁰ This limited accuracy is largely due to the fluidity of classification at least 1 year after injury, meaning athletes are able to move between classification groups over time. While non-copers have previously been considered poor candidates for non-operative management, 30,31 non-copers can become potential copers following a program of neuromuscular training. 26,80 Few studies have examined the predictive ability of factors modifiable to rehabilitation professionals, for outcomes after ACLR. Pre-operative quadriceps strength is predictive of IKDC scores⁶⁸ and Cincinnati scores after ACLR,²⁴ and single legged hop tests 6 months after surgery are predictive of knee function determined by IKDC scores 1 year after surgery.⁶⁷ Reinke and colleagues found functional hop testing to be related to patient reported outcomes after ACLR. 99 Shelbourne et al found a decrease of 3 degrees of knee extension was associated with poor long-term joint health. 109 Hartigan et al found pre-operative age, quadriceps strength symmetry, and knee flexion moments to be predictive of the aptitude to pass or fail objective return to sport criteria 6 months after ACLR.⁴³ To our knowledge these are the only studies evaluating factors modifiable to rehabilitation professionals, and their influence on functional outcomes after ACLR. This highlights the paucity of clinical and functional data reported in outcomes research, despite its importance and potential for improving standards of care.

1.3 Second ACL Injury

Second injury, whether it is an insult to the ipsilateral graft or the contralateral ACL, is an outcome of growing importance with significant consequences. Besides missing more playing time, increasing healthcare costs, and greater psychological distress, patients with second injury and subsequent revision surgery have significantly worse outcomes and a greater risk for post-traumatic osteoarthritis progression compared to those with initial reconstruction. 11,133 Factoring in that the highest risk of second injury is in the young female athletic population, ¹²⁵ with rates approaching 30%, 94 the downstream healthcare costs will be a great burden on the healthcare system. This highlights the importance for preventing these second injuries, and the need for prospective longitudinally collected data to establish risk factors and predictors of second injury. Those at highest risk for second injury include young athletes¹²⁵ returning to high level sporting activity early, ³⁸ with men having a higher risk of ipsilateral graft injury, 12,108 and women having a higher risk of contralateral ACL injury. 93,94,132 Other risk factors include women in general, 44,47 family history of ACL injury, 12 and an increased body mass index. 13 The majority of modifiable factors associated with second injury are surgical in nature, with increased risk depending on graft type and size, intercondylar notch size, and tunnel placement. 12,65,98 Only Paterno et al have shown factors modifiable to rehabilitation professionals that are associated with second ACL injury.⁹⁷ They found abnormal frontal plane mechanics at initial contact during a jump landing task to be predictive of future second ACL injury. These abnormal movement patterns and flawed neuromuscular control are thought to both predispose the athlete to initial ACL injury, as well as contribute to second injury risk in both the ipsilateral and contralateral limbs. This work will

contribute to the understanding of early modifiable factor's influence on second injury risk.

1.4 Using Rehabilitation Strategies to Improve Outcomes

Neuromuscular training is one attempt to improve outcomes after ACL injury and reconstruction. A1,115 Specifically, perturbation training, has been studied in conjunction with a pre-operative rehabilitation program and is currently under investigation for its use after surgery. Perturbation training is effective at reducing inter-limb biomechanical asymmetries, and improving functional performance measures pre-operatively and in the short-term post-operatively. This training has allowed ACL deficient athletes to return to sport without the need for reconstruction, at least in the short-term. Six months after ACLR, however, these biomechanical changes are not maintained suggesting surgery may negatively affect movement patterns, which can persist for up to 2 years after reconstruction. The long-term effects of perturbation training on functional and patient reported outcomes after ACLR are unknown. Despite continued biomechanical asymmetry after ACLR, does this training improve neuromuscular control mechanisms and impairments associated with it that may decrease second injury risk and improve functional outcomes?

As the variability in outcomes after ACL injury and reconstruction become more apparent, the need for evidence based research to improve outcomes is more important than ever. Large community registers have emerged in the field of orthopedics in an attempt to better track outcomes after ACL injuries and surgery. These registers pool data from multiple collection centers to determine prognosis and predictors of outcomes on a large scale. The majority of the variables evaluated, however, are surgical or demographic in nature, and are non-modifiable to the

rehabilitation professional. The need for clinical and functional data easily collected and evaluated in a rehabilitation clinic is of utmost importance to rehabilitation professionals. Linking clinical and functional data to outcomes will not only help rehabilitation professionals fine tune rehabilitation protocols, but recognize the need for intervention earlier to prevent the poor outcome.

1.5 Innovation of this Work

Our cohort is uniquely positioned with prospective longitudinally collected clinical, functional, and biomechanical data after ACL injury and through their course of treatment 2 years after ACLR. Our cohort has been treated pre-operatively with perturbation training, allowing effectiveness comparisons to be made against what is considered usual care of those in the registry databases. This work has the potential to identify additional rehabilitation after ACL injury that may lead to improved outcomes. Through this work we will also be able to evaluate relationships between clinical and functional variables, and longer-term outcomes, which will significantly impact ACL injury and reconstruction rehabilitation protocols and prognosis. This work will fill a much needed void in ACL rehabilitation research, striving to turn expert consensus ACL rehabilitation protocols into evidence based rehabilitation protocols.

The impact of this research will also address the growing problem of second ACL injury. Rates reported as high as 30% in young active individuals, ⁹⁴ coupled with the growing knowledge and high prevalence of post-traumatic osteoarthritis after ACL injury, ¹⁰ regardless of surgical management, ³² make for epidemic proportions of young active individuals with poor knee health. The prospective and longitudinal design of our cohort allows us to evaluate factors after ACL injury, and early after

surgery, that are associated with second ACL injury. This work will help identify clinical and functional factors that place athletes at increased risk for second injury, allowing the rehabilitation professional to intervene and potentially prevent second injury.

1.6 Specific Aims

The overall goal of this work is to evaluate and improve outcomes after ACL injury and reconstruction through rehabilitation strategies including prehabilitation, identification of early factors modifiable to rehabilitation professionals that are associated with successful outcomes, and gaining a better understand of second ACL injury. We are proposing to accomplish these goals through the following specific aims:

AIM 1: To determine whether the combination of pre-operative neuromuscular training and post-operative rehabilitation leads to improved outcomes in athletes 2 years after ACLR.

<u>Hypothesis 1.1</u>: Athletes treated with pre-operative neuromuscular training and post-operative rehabilitation will have higher functional outcomes compared to standard care two years after ACLR.

<u>Hypothesis 1.2</u>: Athletes treated with pre-operative neuromuscular training and post-operative rehabilitation will have higher return to sport rates compared to standard care two years after ACLR.

AIM2: To determine early predictors of function 2 years after operative management following ACL injury.

<u>Hypothesis 2.1</u>: Early Clinical, functional, and patient-reported measures will predict IKDC scores 2 years after ACLR.

<u>Hypothesis 2.2</u>: Clinical, functional, and patient-reported measures will have greater predictive ability following extended pre-operative rehabilitation compared to early after injury in predicting IKDC scores 2 years after ACLR. <u>Hypothesis 2.3</u>: Early clinical, functional, and patient-reported measures will be predictive of successful outcomes 2 years after ACLR.

AIM3: To determine if clinical, functional, and patient-reported outcome measures after ACL injury and early after ACLR are associated with second ACL injury

<u>Hypothesis 3.1:</u> Explore demographics and characteristics of those who went on to second ACL injury.

<u>Hypothesis 3.2</u>: Baseline attributes, clinical, functional, and patient-reported outcome measures after ACL injury and early after ACLR will differ between those who went on to second injury and those who did not within 2 years after ACLR.

<u>Hypothesis 3.3</u>: Baseline attributes, clinical, functional, and patient-reported outcome measures after ACL injury and early after ACLR are predictive of second injury.

Chapter 2

CONTROVERSIES IN KNEE REHABILITATION: ANTERIOR CRUCIATE LIGAMENT INJURIES

2.1 Abstract

Controversy in management of athletes exists after anterior cruciate ligament injury and reconstruction. Consensus criteria for evaluating successful outcomes following ACL injury include no re-injury or recurrent giving way, no joint effusion, quadriceps strength symmetry, restored activity level and function, and returning to pre-injury sports. Using these criterions, we will review the success rates of current management strategies after ACL injury and provide recommendations for the counseling of athletes after ACL injury.

Keywords: Anterior Cruciate Ligament, Knee, ACLR, ACL, Physical Therapy, Athletes, Sports Physical Therapy

Key Points:

 Undergoing ACL reconstruction does not guarantee athletes will return to their pre-injury sport, and return to the pre-injury competitive level of sport is unlikely.

- The risk of a second ACL injury is high in young athletes returning to sport, especially in the near-term.
- The risk for developing osteoarthritis after ACL injury is high in the long-term regardless of surgical intervention, and even higher if a revision procedure is required.
- Despite common misconceptions, non-operatively managed athletes can return to sport without the need for reconstruction
- Without differences in outcomes between early reconstruction, delayed reconstruction, and nonoperative management, counseling should start by considering non-operative management.

2.2 Introduction

More than 250,000 anterior cruciate ligament (ACL) injuries occur yearly in the United States,³⁵ with 125,000-175,000 undergoing ACL reconstruction (ACLR).^{51,59} While standard of practice in the United States is early reconstruction for active individuals with the promise of returning to pre-activity injury levels,^{74,86} evidence suggests athletes are counseled that reconstruction is not required to return to high level activity³⁶ after a program of intensive neuromuscular training.¹¹⁵ Others advocate counseling for a delayed reconstruction approach,¹⁰⁷ however no differences in outcomes exist between delayed and early ACL reconstruction.¹¹² Furthermore, athletes in the United States are commonly counseled to undergo early ACLR with the

promise of restoring static joint stability,⁷⁴ minimizing further damage to the mensicii and articular cartilage,^{5,86} and preserving knee joint health,⁷⁴ however, not all athletes are able to return to sport or exhibit normal knee function following reconstruction.³⁴ Several factors, such as impaired functional performance, knee instability and pain, reduced range of motion, quadriceps strength deficits, neuromuscular dysfunction, and biomechanical maladaptations, may account for highly variable degree of success.

In order to identify the minimum set of outcomes that identify success after ACL injury or ACLR, Lynch et al⁷² established consensus criteria from 1779 sports medicine professionals concerning successful outcomes after ACL injury and reconstruction. The consensus of successful outcomes were identified as no re-injury or recurrent giving way, no joint effusion, quadriceps strength symmetry, restored activity level and function, and returning to pre-injury sports. Using these criterions we will review the success rates of current management after ACL injury and provide recommendations for the counseling of athletes after ACL injury.

2.3 Impairment Resolution

Following ACL injury or reconstruction, athletes undergo an extensive period of vigorous rehabilitation targeting functional impairments. These targeted rehabilitation protocols strive for full symmetrical range of motion, adequate quadriceps strength, walking and running without frank aberrant movement, and a quiet knee: little to no joint effusion or pain.² Despite targeted post-operative

rehabilitation, athletes commonly experience quadriceps strength deficits. 90,103,122 lower self-reported knee function, ⁶⁹ and movement asymmetry up to two years after reconstruction. 100 The importance of quadriceps strength as a dynamic knee stabilizer has been established, as deficits have been linked to lower functional outcomes. 24,68,103,114 In a systematic review of quadriceps strength after ACLR, quadriceps strength deficits can exceed 20% 6 months after reconstruction, 90 with deficits having the potential to persist for 2 years after reconstruction. Otzel et al reported a 6-9% quadriceps deficit 3 years after reconstruction, concluding that longterm deficits after surgery were the results of lower neural drive as quadriceps atrophy measured by thigh circumference was not significantly different between limbs.⁸⁹ Grindem et al reported at two-year follow up 23% of non-operatively managed athletes had greater than 10% strength deficits compared to 1/3 of athletes who underwent reconstruction.³⁶ Another study comparing operatively and nonoperatively managed patients 2-5 years after ACL injury found no differences in quadriceps strength between groups concluding reconstructive surgery is not a prerequisite for restoring muscle function.⁴ Regardless of operative or non-operative management, quadriceps strength deficits are ubiquitous after ACL injury, and can persist for the long term. The current evidence does not support ACLR as a means of improved quadriceps strength outcomes over non-operative management after ACL injury.

2.4 Outcomes

Individuals do not respond uniformly to an acute ACL injury and outcomes can vary. Most individuals decrease their activity level after ACL injury. 3,4,81,87,120,124 While a large majority of individuals rate their knee function below normal ranges after an ACL injury, which is a common finding early after an injury, some individuals exhibit higher perceived knee function than others early after ACL injury. This highlights the variability in outcomes seen after ACL injury. 25,30,31,79,80

Knee outcome scores are lowest early after surgery and improve up to 6 years post surgery. S0,58,79 Using the Cincinnati Knee Rating System, scores improved from 60.5/100 at 12 weeks post reconstruction to 85.9/100 at 1 year follow-up. By six months after surgery almost half of individuals score greater than 90% on the Knee Outcomes Survey- Activities of Daily Living Scale (KOS-ADLS) and Global Rating Scale of Perceived Function (GRS) and 78% have achieved these scores by 12 months. Using the GRS, scores improved from 63.1/100 taken at week 12 to 83.3/100 at week 52. Moksnes and Risberg reported similar post-surgical GRS results of 86.0/100 at 1 year follow-up. Poor self-report on outcome measures after ACLR are associated with chondral injury, previous surgery, return to sport, and poor radiological grade in ipsilateral medial compartment. ACLR revision and extension deficits at 3 months are also predictors of poor long term outcomes.

Patient reported outcomes from multiple large surgical registries are available concerning patients after ACLR. A study from the MOON consortium of 446 patients reported International Knee Documentation Committee Subjective Knee Form 2000 (IKDC) for patients 2 and 6 years after reconstruction. The median IKDC score was 45 at baseline, rose to 75 at 2 year follow up, and reached 77 at 6 years after

reconstruction. Grindem et al compared IKDC scores between athletes managed nonoperatively or with reconstruction at baseline and 2 years.³⁶ The non-operative group
improved from a score of 73 at baseline to 89 2 years after injury. The reconstructed
group improved from 69 at baseline to 89 2 years after surgery. There were no
significant differences between groups at baseline or at 2 year follow-up. Using the
Knee Injury and Osteoarthritis Outcome Score (KOOS), Frobell et al compared patient
reported outcomes at 5 years after ACL injury and found no significant differences in
change score from baseline to 5 years in those managed with early reconstruction
versus those managed non-operatively or with delayed reconstruction.³² Outcomes
after ACL injury, whether managed non-operatively or with ACLR, have similar
patient reported outcomes scores at up to 5 years after injury.

2.5 Long-term Joint Health

Preventing further intra-articular injury and preserving joint surfaces for long-term knee health is a purposed reason to surgically stabilize an unstable knee.⁷⁴

Patients who had increased knee laxity after an ACL injury are more likely to have late meniscal surgery⁷¹ and time from ACL injury is associated with the number of chondral injuries and severity of chondral lesions.¹⁰ Injury to menisci or articular cartilage places the knee at increased risk for the development of osteoarthritis.

Barenius et al found a 3 fold increase in knee osteoarthritis prevalence in surgically reconstructed knees 14 years after surgery.¹⁰ They concluded that while ACLR did not prevent secondary osteoarthritis, initial meniscal resection was a risk factor for osteoarthritis with no differences in osteoarthritis prevalence seen between graft types.

A recent systematic review compared operatively and non-operatively treated patients at a mean of 14 years after ACL injury and found no significant differences between groups in radiographic osteoarthritis. The operative group had less subsequent surgery and meniscal tears, as well as increased Tegner change scores however there were no differences in Lysholm or IKDC scores between groups. The current evidence does not support the use of ACLR to reduce secondary knee osteoarthritis after ACL injury.

2.6 Return to Pre-injury Sports

Returning to sports is often cited as the goals of athletes and health care professionals after ACL injury or ACLR. When asked, 90% of NFL head team physicians believed that 90-100% of NFL players returned to play after ACLR. ¹⁴ Shah et al found that regardless of position 63% of NFL athletes seen at their facility returned to play. ¹⁰⁶ A recent systematic review reported 81% of athletes return to any sports at all, but only 65% return to their pre-injury level and an even smaller percentage, 55%, return to competitive sports. ⁷ This review found that younger athletes, men, and elite athletes were more likely to return to sports. Similar reports within this range are common when examining amateur athletes by sport. McCullough et al. report that 63% of high school and 69% of college football players return to sport. ⁷⁷ Shelbourne found that 97% of high school basketball players return to play, 93% of high school women and 80% of high school male soccer players returned. ¹¹⁰

Brophy et al. found a slightly different trend in soccer players; 72% returned to play, where 61% returned to the same level of competition but when broken down by sex more men (75%) returned than women (67%).¹⁵ These studies highlight the fact that while there may be a link between sport and return to sport, due to a lack of high quality research, current literature was unable to come to any conclusion.

Reduced return to sport rates can be attributed to many factors, including age, sex, pre-injury activity level, fear and psychological readiness. Age and sex are two variables which have been identified in multiple studies, with men and younger athletes being more likely to return to sport. ^{7,15,125} Age, may be a proxy measure for changing priorities (i.e. family), commitments (i.e. employment), and/or opportunities to play at the same level (i.e. no longer have the competitive structure of high school, college, or club sports). Further, it has been hypothesized that "For those athletes whose life and social networks are inherently structure around participating in sport, a stronger sense of athletic identity may be a positive motivator for return to sport". While this hypothesis remains to be tested, this could explain the higher rates of return to sport in younger and elite/professional level athletes. Dunn et al found that higher level of activity at prior to injury and a lower BMI were predictive of higher activity levels at two years following ACLR.²³ Ardern et al found that elite athletes were more likely to return to sport that lower level athletes. Professional and elite level athletes may have access to more resources, particularly related to rehabilitation services, but motivation to return to that high level of play and athletic identity may also drive such return to sport. Interestingly, Shah et al. found that in NFL players return to play was

predicted by draft round.¹⁰⁶ Athletes drafted in the first four rounds of the NFL draft were 12.2 times more likely to return to sport than those athletes drafted later or as free agents. This could represent the perceived talent of the player as well as the investment of the organization in that player.

Despite common misconceptions, non-operatively managed athletes can return to sport without the need for reconstruction.³¹ Fitzgerald et al reported a decision making scheme for returning ACL deficient athletes to sport in the near-term, without furthering of meniscal or articular cartilage injury.³⁰ There is a paucity, however, of long-term evidence on non-operatively managed athletes returning to high level sports. Grindem et al compared return to sport in operatively and non-operatively managed athletes after ACL injury.³⁶ They found no significant differences between groups in level I sports participation, and higher level II sports participation in the non-operative group in the first year after injury. This is the only study to our knowledge comparing return to sport rates in the longer term. Further research is needed on long-term non-operatively managed athletes after ACL injury.

2.7 Second ACL Injury

Second injury, whether it is an insult to the ipsilateral graft or the contralateral ACL, is a growing problem after ACLR as rates appear to be higher than once thought. Risk factors for second injury include younger athletes¹²⁵ who return to high level sporting activities early,³⁸ with women having a higher risk of contralateral

injury, 93,94 and men having a higher risk of ipsilateral injury. 12,108 While second injury rates in the general population 5 years after reconstruction are reported to be 6%, 136 rates in young athletes are considerably higher. Paterno et al followed 78 athletes after ACLR and 47 controls over a 24 month period. 194 They found an overall second injury rate of 29.5% which was an incidence rate nearly 4 times that of the controls (8%). Over 50% of these injuries occurred within the first 72 athletic exposures, while in the control group only 25% were injured within the same time frame. The MOON cohort reported a 20% second injury rate in women and a 5.5% rate in men of 100 soccer players returning to sport after ACLR. 15 Shelbourne et al 165,108 and Leys et al both reported 17% second injury rates in younger athletes. Besides missing more athletic time, increasing healthcare costs, and increased psychological distress, re-injury and subsequent revision surgery has significantly worse outcomes compared to those after initial reconstruction. 133,135

2.8 Discussion

ACLR continues to be the gold standard treatment of ACL injuries in the young athletic population. A survey of American Academy of Orthopedic Surgeons reported 98% of surgeons would recommend surgery if a patient wishes to return to sport, with 79% believing ACL deficient patients are unable to return to all recreational sporting activities without reconstruction.⁷⁴ Revisiting the successful outcomes criterion after ACL injury, a successful outcome is considered no re-injury

or recurrent giving way, no joint effusion, quadriceps strength symmetry, restored activity level and function, and returning to pre-injury sports. 72 After reviewing the current literature looking at these criterions, counseling athletes to undergo early reconstruction after ACL injury may not be in the athlete's best interests. Undergoing reconstruction does not guarantee athletes return to their pre-injury sport, and return to the pre-injury competitive level of sport is unlikely. The risk of a second injury is high in young athletes returning to sport, especially in the near-term. Risk of secondary injury increases for the contralateral limb in females, or the ipsilateral limb in males. The risk for developing osteoarthritis is high in the long-term regardless of surgical intervention, and even higher if a revision procedure is required. A Cochrane Review found that there was insufficient evidence to recommend ACLR compared to nonoperative treatment, and recent randomized control trials have found no difference between those who had ACLR and those treated nonoperatively with regards to knee function, health status, and return to pre-injury activity level/sport after two and five years in young, active individuals. 32,36,113 With no differences in outcomes between early reconstruction, delayed reconstruction, and no surgery at all, counseling should start by considering non-operative management. Eitzen et al found a 5 week progressive exercise program after ACL injury led to significantly improved knee function before deciding to undergo reconstruction or remain non-operatively managed.²⁶ The authors reported good compliance with few adverse events during training. Non-operative management is a viable evidence based option after ACL injury, allowing some athletes to return to sport despite being ACL deficient, with

equivalent functional outcomes to those after ACLR. Given there is no evidence in outcomes to undergo early ACLR, non-operative management should be a first line of treatment choice in athletes after ACL injury.

Chapter 3

DOES EXTENDED PREOPERATIVE REHABILITATION IMPROVE OUTCOMES AFTER ACLR?

3.1 Abstract

Rehabilitation prior to anterior cruciate ligament (ACL) reconstruction (ACLR) is effective at improving post-surgical outcomes, at least in the short-term. Less is known about the effects of prehabilitation on functional outcomes and return to sport rates 2 years after reconstruction. The purpose of this study was to compare functional outcomes 2 years after ACLR in a cohort that underwent additional preoperative rehabilitation including progressive strengthening and neuromuscular training after impairments were resolved compared to a non-experimental cohort. We hypothesized that the cohort treated with extended pre-operative rehabilitation would have superior functional outcomes 2 years after ACLR.

This study compared outcomes after ACL rupture in an international cohort (Delaware-Oslo ACL Cohort, DOC) treated with extended pre-operative rehabilitation including neuromuscular training to data from the Multicenter Orthopedic Outcomes Network cohort (MOON). Inclusion and exclusion criteria from the DOC were applied to the MOON database to extract a homogeneous sample for comparison. Subjects achieved a quiet knee prior to ACLR and post-operative rehabilitation followed each cohort's respective criterion-based protocol. Subjects completed International Knee Documentation Committee Subjective Knee Form (IKDC) and

Knee Injury and Osteoarthritis Outcome Score (KOOS) at enrollment and again 2 years after ACLR. Return to sport rates were calculated for each cohort at 2 years.

After adjusting for baseline IKDC and KOOS scores, the DOC showed significant and clinically meaningful differences in IKDC and KOOS scores 2 years after ACLR. The DOC had a significantly higher (p<.001) percentage of patients returning to pre-injury sports (72%) compared to MOON (63%).

The cohort treated with additional pre-operative rehabilitation consisting of progressive strengthening and neuromuscular training followed by a criterion-based post-operative rehabilitation program had greater functional outcomes and return to sport rates 2 years after ACLR. Prehabilitation should be considered as an addition to the standard of care to maximize functional outcomes after ACLR.

3.2 Introduction

Early anterior cruciate ligament (ACL) reconstruction (ACLR) remains the gold standard of treatment for active individuals with ACL ruptures in the United States, ^{74,86} with up to 175,000 reconstructions being performed annually. ¹¹⁹ Goals for ACLR include restoring primary passive restraint, returning to pre-injury activity and previous level of function, and preserving long-term knee joint health. ^{74,86} Reconstruction, however, does not guarantee return to previous activity or functional levels, or prevention of post-traumatic knee osteoarthritis. ^{32,34,74}

Large multicenter orthopedic registries have been developed and implemented to track outcomes after ACLR in the United States and abroad. The Multicenter Orthopedic Outcomes Network (MOON) registry pools data together from 7 orthopedic centers across the United States.¹¹⁸ These centers are all highly active in

orthopedic and sports clinical treatment and research, with unified pre-operative milestones to undergo ACLR, and a single criterion-based post-operative protocol with objective return to sport criteria. The MOON cohort can serve as the benchmark or usual care for comparative effectiveness studies to compare ACLR outcomes. 118

Rehabilitation prior to surgery, termed prehabilitation, is the physical preparation for a period of immobility and reduced activity due to surgery. Few studies have explored the effects of prehabilitation on outcomes after ACLR. 40 Shaarani and colleagues completed a randomized controlled trial that found a 6 week prehabilitation program led to improved functional performance and self-reported function up to 12 weeks after reconstruction. 105 The addition of neuromuscular training to prehabilitation is another attempt to improve outcomes after ACL injury. Specifically, perturbation training, has been studied in conjunction with a preoperative rehabilitation program^{41,42,115} and is currently under investigation for its use after surgery. 129 Grindem and colleagues compared functional outcome measures 2 years after ACLR in the Norwegian half of our cohort to usual care as benchmarked by the Norwegian Knee Ligament Registry (NKLR).³⁷ There were statistically significant and clinically meaningfully better outcomes in the Delaware-Oslo ACL Cohort (DOC) as evidenced by higher Knee Injury and Osteoarthritis Outcome (KOOS) Scores. The limitation of this study, however, is the rehabilitation in the NKLR was not standardized. The question remains how the progressive preoperative rehabilitation that includes neuromuscular training affects outcomes after ACLR when both cohorts receive otherwise similar care.

The purpose of this study was to compare functional outcomes 2 years after ACLR in a cohort that underwent additional pre-operative rehabilitation including progressive strengthening and neuromuscular training after impairments were resolved compared to a non-experimental reference group (MOON ACL cohort). We hypothesized that the cohort treated with extended pre-operative rehabilitation would have superior functional outcomes 2 years after ACLR. The implications of this research could lead to changes in the standards of care prior to undergoing reconstruction after ACL injury.

3.3 Methods

This is a cohort study comparing outcomes in an international cohort (Delaware-Oslo ACL Cohort, DOC) treated with extended pre-operative rehabilitation including neuromuscular training with data from a non-experimental cohort (MOON ACL consortium). Outcomes of interest include pre- and post-operative International Knee Documentation Committee subjective knee form (IKDC) scores,⁶ as well as KOOS scores¹⁰² and return to pre-injury sports (RTS) rates. Eighty-four subjects from the Norwegian arm of the Delaware-Oslo ACL cohort were previously included in the comparison to the NKLR by Grindem and colleagues described above.³⁷

3.3.1 Subjects

The Delaware-Oslo ACL cohort is an ongoing international prospective collaboration evaluating the effects of neuromuscular training after ACL injury and reconstruction. This collaboration includes 150 subjects from the University of Delaware in the United States, and 150 subjects from the Norwegian Research Center for Active Rehabilitation, Norwegian School Sport Sciences in Oslo, Norway.

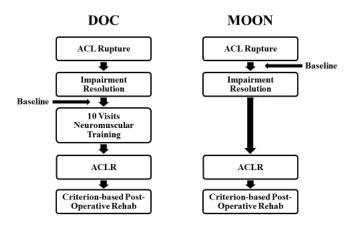
Subjects were enrolled at both centers between 2007 and 2012. Subjects were included if they had a unilateral primary ACL rupture within 7 months of enrollment, and participated in level I or II sports greater than 50 hours per year prior to injury.²⁰ Subjects were excluded if they had a concomitant grade III ligamentous injury, a full thickness articular cartilage lesion larger than 1 cm, a symptomatic meniscal tear, a potentially repairable meniscal tear, or a history of previous injury or surgery of the uninvolved knee. All subjects underwent initial impairment resolution (little to no swelling or pain, full range of motion, 70% quadriceps strength index) followed by progressive strengthening and neuromuscular training called perturbation training, as previously described by Eitzen.²⁶ Following completion of these additional training sessions, subjects selected to undergo ACLR or remain non-operatively managed. While all subjects were followed, only the subjects who underwent ACLR are included in this analysis. Those from the DOC who did not immediately undergo reconstruction following training continued on a home exercise program, if needed, for maintenance until reconstruction was performed. All subjects after ACLR underwent a criterion-based post-operative rehabilitation protocol with strict RTS criteria. 66 The University of Delaware Institutional Review Board and Region Ethics Committee for South East Norway approved all aspects of this study, and written informed consent was obtained for all subjects prior to enrollment.

The MOON cohort consists of subjects enrolled between 2002 and 2008 from 7 orthopedic/sports medicine centers around the United States. Subjects were included if they were scheduled to undergo a unilateral ACLR and were between the ages of 10 and 85 years. Subjects were enrolled at time of presentation to the orthopedic surgeon, and followed prospectively after surgery. This cohort is intended

to be community-based, with all ages, activity levels, injury history, and concomitant injury included. All subjects after ACLR underwent a criterion-based post-operative rehabilitation protocol with strict RTS criteria. Institutional Review Board approval was obtained from all participating centers and written informed consent was obtained for all subjects prior to enrollment.

For this study, inclusion and exclusion criteria from the DOC were applied to the MOON cohort and only those who met the criteria for DOC described above were included. MOON data were extracted based on these criteria and de-identified data were provided for analysis. Subjects whose imaging revealed a potentially repairable meniscal injury were excluded from enrollment in the DOC. During reconstruction, however, 11% of subjects from the DOC had concomitant meniscal repair despite initial presentation on imaging, and therefore, we included those with concomitant meniscal repair from the MOON dataset. Surgical variables recorded included graft type, concomitant meniscal procedures and articular cartilage pathology.

Figure 3.1 Differences in treatment course between cohorts



3.3.2 Criteria for Reconstruction

Both cohorts used guidelines to determine when athletes were ready to undergo ACLR. The recommendations for the DOC subjects to undergo ACLR were little to no knee joint effusion, symmetrical knee range of motion, no obvious gait impairments and a minimum of 70% quadriceps strength index (quiet knee). MOON preoperative guidelines included no obvious gait impairments, knee range of motion from 0-120, minimal knee joint effusion, and the ability to complete 20 straight leg raises without a lag.

3.3.3 Rehabilitation

Postoperative rehabilitation for the DOC subjects followed a rigorous criterion-based protocol. Objective clinical criteria, such as pain, range of motion, quadriceps strength and activation, and changes in knee joint effusion are used to monitor and determine progression through the different phases of postoperative rehabilitation. These criteria, in addition to functional performance testing and patient reported outcomes, are utilized in determining return to sport readiness for athletes. Subjects were followed for repeated testing at time-points of 6, 12, and 24 months following reconstruction. If subjects were not maintaining strength or functional levels required to return to sport, counseling was provided. The DOC post-operative protocol can be found in appendix D.

The MOON cohort subjects followed a unified postoperative protocol regardless of at which location their surgery or rehabilitation was performed. This protocol is criterion-based, utilizing measures of pain, range of motion, functional strength, and movement quality to progress patients through the phases of rehabilitation. Return to sport readiness was determined by a combination of objective

measures (functional performance testing, patient reported outcomes) and subjective measures (movement quality and confidence). Beyond those return to sport criteria, the MOON protocol also recommended isokinetic strength testing, vertical jump, and deceleration testing. The MOON post-operative protocol can be found in Appendix C.

3.3.4 Outcome Measures

Subjects completed the IKDC and KOOS pre-operatively and again 2 years after ACLR. The IKDC is a valid and reliable measure commonly used in the ACL population.^{6,104} The minimal clinically important difference (MCID) for the IKDC is 11.5.¹⁰⁴ The Knee Injury and Osteoarthritis Outcome Score (KOOS) is a valid and reliable outcome measure commonly used in the ACL injured population to assess outcomes in knee pain, knee symptoms, knee function in daily activity, knee function in sporting activity, and knee related quality of life.^{101,102} The proposed MCID for each subscale is 10 points.¹⁰¹

At enrollment, each subject was asked to report their primary sporting activity prior to injury. At 2 year follow-up, subjects were asked to name their primary sport currently (MOON) or if they had returned to their pre-injury sport (DOC). Subjects were considered to have returned to sport if they were participating in their pre-injury sport 2 years after ACLR.

3.3.5 Statistical Analysis

Group differences were analyzed using chi square for nominal variables and t tests for continuous variables. To account for differences in baseline IKDC, a one-way analysis of covariance was used to compare 2 year IKDC scores between groups with baseline IKDC scores as a covariate. To account for differences in baseline

KOOS, a one-way analysis of covariance was used to compare 2 year KOOS scores between groups with baseline KOOS scores as a covariate for each subscale. Because differences were found between groups in the proportion of concomitant meniscal surgery, analysis of variance was used to assess the interaction of group and meniscal surgery on 2 year IKDC scores. Because differences were found between groups in proportion of graft types used for ACLR, analysis of variance was used to assess the interaction of group and graft type on 2 year IKDC scores. All statistical analyses were performed using PASW version 23 (SPSS, Inc, IBM Company, Chicago, Illinois).

3.4 Results

Subjects who underwent ACLR from the DOC (n=192) and 1,995 subjects who met the DOC inclusion criteria were included from MOON. There were no differences between groups in age, sex, or body mass index. Baseline Marx scores were available in the MOON cohort (12.78 \pm 4) but not the DOC.

Table 3.1: Baseline differences between groups

	DOC (n=192)	MOON (n=1995)	p Value
Age	24.7 ± 9	24.3 ± 10	.593
Sex	55% men	54% men	.735
BMI	24.5 ± 4	25 ± 4	.098
Time from injury to enrollment	1.9 ± 1 months	< 6 months	

Surgical demographics revealed a higher proportion of patellar tendon autografts (p=.001) in the MOON cohort, and a higher proportion of hamstring autografts (p=.006) in the DOC cohort. There was also a significantly higher proportion of concomitant meniscal surgery performed (p=0.029) in the MOON cohort. There were no significant group by meniscal procedure (p=.345) or group by graft type (p=.073) interactions on 2 year IKDC scores.

Table 3.2: Surgical variables at time of ACLR

	DOC (n=192)	MOON (n=1995)	p-value
Patellar Tendon Autograft	21%	48%	.001
Hamstring Autograft	51%	36%	.006
Soft-tissue Allograft	28%	16%	.005
No Meniscal Procedure	60%	46%	.029
Meniscal Excision	18%	28%	.017
Meniscal Repair	11%	14%	.301
Meniscal Trephination	2%	2%	1.00
Combination of Meniscal Procedures	9%	11%	.433
Time from ACLR	2.1 ± .02 yrs	2.4 ± 0.4 yrs	.220

The DOC cohort had significantly higher baseline IKDC scores compared to the MOON cohort (70 ± 13 ; 50 ± 17 ; p<.001), which also exceeded the MCID (Figure 2). The DOC significantly improved from baseline to post-training (after prehab) in IKDC scores (70 \pm 13; 77 \pm 13; p<.001). Controlling for baseline IKDC scores, the DOC cohort continued to have significantly higher IKDC scores at 2 years after ACLR (84 \pm 25; 71 \pm 32; p<.001), again exceeding the MCID (Figure 3). Post-hoc power analysis revealed the ability to detect a difference of 2 points on the IKDC between groups. Baseline KOOS scores were available for 1991 subjects in the MOON cohort and 58 subjects in the DOC. The DOC had significantly higher baseline KOOS scores than the MOON cohort across all subscales: pain (84 \pm 11; 73 \pm 17; p<.001), symptom (75 \pm 14; 67 \pm 18; p<.001), ADLs (93 \pm 7; 82 \pm 17; p<.001), sports/recreation (66 \pm 19; 48 \pm 29; p<.001), and quality of life (51 \pm 19; 37 \pm 20; p<.001). The DOC cohort, after controlling for baseline KOOS scores, continued to have higher and clinically meaningful scores at 2 years on the pain (94 \pm 10; 78 \pm 33; p=.004), symptom (89 \pm 12; 72 \pm 32; p<.001), ADLs (98 \pm 5; 82 \pm 34; p=.006), sports/recreation (85 \pm 18; 70 \pm 33; p<.001), and quality of life (76 \pm 20; 64 \pm 32; p=.072) subscales of the KOOS (Figure 4). Return to sport rates were significantly higher in the DOC cohort (72%) compared to the MOON cohort (63%) (p<.001).

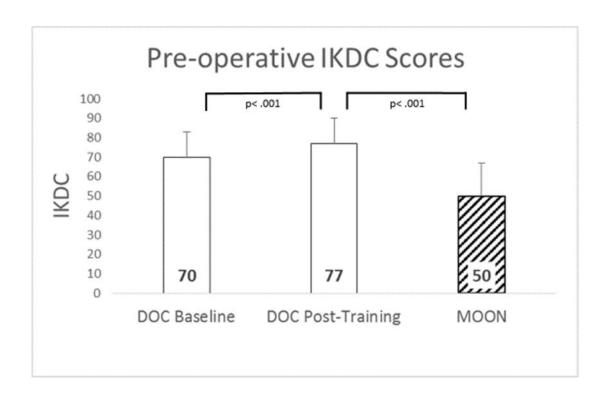
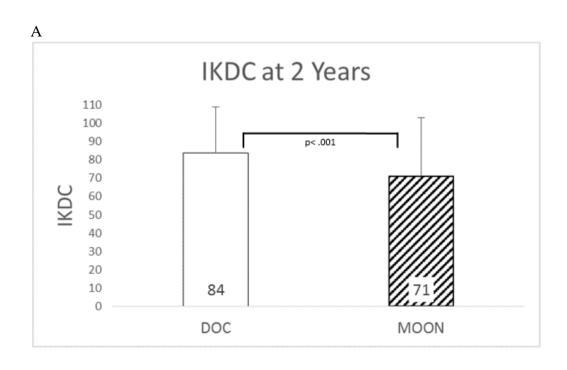


Figure 3.2: Baseline Pre-operative IKDC scores



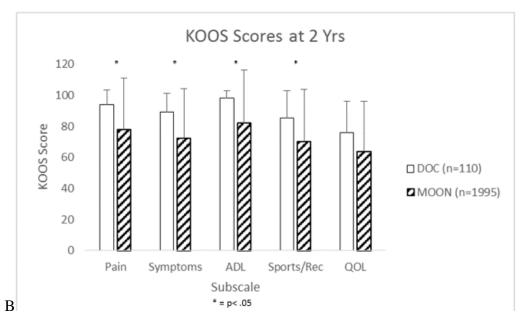


Figure 3.3: Post-operative IKDC scores (A) and KOOS scores (B) 2 years after ACLR between cohorts. Asterisk denotes p < .05

3.5 Discussion

The purpose of this study was to compare functional outcomes 2 years after ACLR in the DOC that underwent additional progressive pre-operative rehabilitation including neuromuscular training compared to the MOON ACL cohort. The primary findings of this study are the DOC had significantly higher and clinically meaningful patient-reported function, and higher RTS rates, 2 years after ACLR. Grindem³⁷ and colleagues found this pre-operative rehabilitation led to higher KOOS scores 2 years after reconstruction compared to the patients in the NKLR, however, the NKLR post operative rehabilitation was not standardized. Conversely, the subjects in the MOON cohort received specified post-operative care at facilities that were part of large orthopedic and sports medicine research centers, which allowed for a more homogeneous comparison between cohorts. This study did not determine what the optimal pre-operative rehabilitation program is, and did not differentiate which aspect of a program is most important (i.e. progressive strengthening, neuromuscular training), but does suggest giving patients additional rehabilitation beyond a quiet knee (full range of motion and quadriceps activation, little to no pain or joint effusion) before surgery may lead to meaningful improved outcomes 2 years after ACLR.

Pre-operative IKDC scores were higher in the DOC and may have been related to differences in the timing of baseline testing between cohorts. The baseline testing may have occurred prior to impairment resolution in the MOON cohort, however, the MOON protocol called for impairments to be resolved prior to undergoing reconstruction. Both cohorts had to achieve minimum criteria before surgery, ensuring that neither cohort had substantial impairments going into reconstruction. Several studies have shown pre-operative muscle performance maximization and ROM deficit minimization related to optimized post-operative outcomes. 24,56,68,82 This

is also consistent with previously published findings that pre-operative outcome scores significantly predict post-operative outcome scores. Eitzen and colleagues published findings from their randomized control trial that a 5 week pre-operative program can lead to improved functional outcomes after ACLR. Our overall findings are consistent with both Eitzen and Grindem in that progressive pre-operative rehabilitation is an important factor to maximize post-operative outcomes.

While each cohort used a different rehabilitation protocol for pre and postoperative rehabilitation, both protocols utilized a criterion-based approach. Criterionbased rehabilitation protocols utilizing tissue healing timeframes, factors associated with outcomes, and expert opinion are considered the most evidence-based protocols to our current knowledge. Both of the protocols used have been published and are considered standards of care after ACL injury.^{2,134} The primary difference between the post-operative protocols is the DOC protocol used primarily objective criteria and the MOON cohort used a mixture of objective and subjective criteria for program advancement. Patients in the DOC also underwent structured follow-up testing at 6 months and 1 year after ACLR, which may have benefited them in terms of progressing home exercise programs or providing counseling and/or consultation on current functional status. While differences between graft type and meniscal procedure proportions between cohorts also have the potential to influence outcome scores at 2 years, our analysis of graft type and meniscal procedure on IKDC scores suggest that differences in proportions of surgical variables between cohorts did not have an effect on the outcome scores.

The DOC had a significantly higher RTS rate 2 years after ACLR compared to the MOON cohort. The MOON cohort return to pre-injury sport rate of 63% is

consistent with the Ardern meta-analysis that reported 65% return to pre-injury sports.⁷ The DOC RTS percentage rate of 72% exceeded both MOON and that reported by Ardern. Objective return to sport criteria were used in both cohorts to determine individual readiness to return sport among patients. There is currently no consensus on specific RTS criteria, however, the use of clinical, functional performance, and patient-reported outcome measures have been suggested as the current standards after ACLR.⁶⁶ The DOC criteria used higher cutoff scores, which ensured higher symmetry between limbs prior to clearance for RTS. Functional performance symmetry restoration is needed to maximize patient-reported functional recovery,⁶⁹ and may also explain some of the variation in 2 year outcomes scores between cohorts.

Comparing two separate cohorts does not allow for a true cause and effect evaluation of extended pre-operative rehabilitation to post-operative outcomes. The strengths of this study are the large sizes of the cohorts, and the application of similar inclusion and exclusion criteria to both cohorts for a homogeneous comparison, and the use of criterion-based post-operative protocols. Future studies should use the randomized control trial study design to better assess the value of preoperative rehabilitation after ACL rupture.

3.6 Conclusion

The cohort treated with pre-operative rehabilitation consisting of progressive strengthening and neuromuscular training had higher functional outcomes and return to sport rates compared to the benchmark cohort that also used criterion-based post-operative rehabilitation program 2 years after ACLR. The standard of care in the United States is to achieve a quiet knee (little to no pain and effusion, full range of

motion and good quadriceps activation) prior to undergoing reconstruction. While achieving a quiet knee prior to surgery may thwart surgical complications such as arthrofibrosis, it may not be enough to maximize functional outcomes even with rigorous post-op rehabilitation. Progressive prehabilitation prior to ACLR should be considered as an addition to the standard of care to maximize functional outcomes after ACLR.

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Chapter 4

PREDICTORS OF OUTCOMES AFTER ACLR

4.1 Abstract

Clinical, functional, and biomechanical impairments are ubiquitous and persist after ACL injury and ACLR, and likely contribute to sub-optimal outcomes. In order to improve outcomes, a better understanding of how clinical and functional factors early after injury and reconstruction influence longer-term outcomes is needed. Age, sex, graft type, presence of bone bruise, meniscal pathology, concomitant injury, and other surgical variables have been studied for their effects on outcomes after ACLR. All of these variables, however, are not modifiable to rehabilitation professionals. Screening batteries utilizing clinical and functional measures have been used after ACL injury to differentiate between those with high knee function and those with low knee function. The longer-term utility of these screening batteries have not been evaluated to determine their relationship with function and outcomes after ACLR. The purpose of this study is twofold: 1) to determine if a pre-surgical screening battery of clinical and functional measures are predictive of 2 year function measured by the IKDC; and 2) to determine if pre-surgical or early post-surgical screening is predictive of successful outcomes 2 years after ACLR.

Following impairment resolution, subjects underwent baseline clinical and functional testing followed by 10 sessions of perturbation training combined with progressive quadriceps strengthening. Following the 10 sessions, subjects again underwent clinical and functional testing. Subjects returned for follow-up testing at 6

and 24 months after surgery. Subjects completed baseline demographic information including age, sex, BMI, weeks from injury to enrollment, and time from surgery to 2 year follow-up. At each time-point, subjects completed a screening exam consisting of quadriceps strength symmetry (QI), the 6 meter timed hop test (TimHp), the knee outcome survey activities of daily living scale (KOS) and the global rating scale (GLO). Success and failure 2 years after ACLR were operationally defined. Success was considered having normal knee function measured by the IKDC, returning to preinjury sports, and not sustaining a second ACL rupture at 2 years. Linear regression was utilized to predict 2 year IKDC scores utilizing screening data at baseline and post-training. Logistic regression was performed to predict 2 year success or failure.

66 subjects $(25 \pm 10 \text{ years}, 25 \pm 4 \text{ BMI}, 65\% \text{ men})$ had complete datasets for analysis. Subjects returned for testing at 2.1 ± 0.3 years after reconstruction and had a mean IKDC score of 93 ± 8 . The screening battery was predictive of 2 year IKDC scores at both baseline (p<.001) and post-training (p<.001) time-points. More variance in IKDC scores was explained at the post-training (r^2 =.364) time-point than the baseline (r^2 =.319) time-point. Age was the only individual significant predictor at both time-points. Of the 66 subjects, 40 (61%) were classified as successes and 26 (39%) were classified as failures. There were no differences between groups in age, sex, BMI, or graft type. The screen was not predictive of success at baseline (p=.227) or post-training (p=.133), but was predictive at 6 months (p=.005) after ACLR. The TimHP at 6 months after ACLR was the only significant individual predictor of success. ROC curve analysis of the TimHP at 6 months revealed an area under the curve of .686 which was statistically significant (p=.007). The cut off value for the TimHP was 96 with a positive likelihood ratio of 1.95.

The main finding of this study is a screening battery comprised of clinical and functional measures is predictive of both function and successful outcomes 2 years after ACLR. This study did not evaluate what the optimal predictors of 2 year function are or which rehabilitation strategies will have the greatest potential to improve outcomes, but it does suggest that improving scores on a screening battery of clinical and functional measures are related to function and successful outcomes 2 years after ACLR. Our findings suggest that subjects who achieve 96% symmetry on the 6 meter timed hop 6 months after reconstruction are nearly 2 times more likely to achieve a successful outcome at 2 years.

4.2 Introduction

Anterior cruciate ligament (ACL) surgical reconstruction (ACLR) remains the gold standard of care after ACL injury. However, reconstruction and subsequent rehabilitation do not guarantee normal knee function, return to pre-injury activity, or the prevention of post-traumatic osteoarthritis. Honoral, functional, and biomechanical impairments are ubiquitous and persist after ACL injury and ACLR, and likely contribute to these sub-optimal outcomes. Despite less than optimal outcomes, patient and caregiver expectations of ACLR are higher than ever. In order to improve outcomes following ACL injury and ACLR, a better understanding of how clinical and functional factors early after injury and reconstruction influence longer-term outcomes is needed.

Numerous studies have predicted outcomes after ACLR. ^{13,19,23,43,57,67,68,70,95–97,99,117,118} Age, ^{6,125} sex, ^{83,93,96,121} graft type, ^{12,58,64,65,126} presence of bone bruise, ^{91,116} meniscal pathology, ^{10,11,111,135} concomitant injury, ^{2,73,76} and other surgical

variables^{57,60,62,113} have been studied for their effects on outcomes after ACLR. All of these variables, however, are not modifiable to rehabilitation professionals. In order to improve outcomes through rehabilitation, longitudinal studies utilizing clinical and functional measures and their relationships to outcomes is of utmost importance.

Screening batteries utilizing clinical and functional measures have been used after ACL injury to differentiate between those with high knee function and those with low knee function. ^{30,52,52} While these screens are effective at differentiating knee function in the short term, the longer-term utility of these subgroups do not appear to be stable, as patients can transcend their initial classification over time. ⁸⁰ The longer-term utility of these screening batteries have not been evaluated to determine their relationship with function and outcomes after ACLR.

Pre-operative minimum standards have been studied, and led to a significant reduction in post-operative complications including arthrofibrosis. ^{76,107,109} Recent studies, however, utilizing an even more robust pre-operative rehabilitation program suggest even more potential to improve post-operative outcomes through rehabilitation. ^{37,105,123} Grindem ³⁷ and Failla ¹²³ showed superior outcome scores and return to sport rates 2 years after ACLR in cohorts that underwent additional pre-operative rehabilitation compared to cohorts that underwent standard care. Logerstedt ⁶⁸ and Eitzen ²⁴ both found pre-operative quadriceps strength predicted 6 month IKDC scores and 2 year Cincinnati knee scores respectively. Logerstedt also found hop test symmetry 6 months after ACLR predicted 1 year function. ⁶⁷ Little is known about how clinical and function measures, both pre-operatively and early post-operatively, are related to function and outcomes 2 years after ACLR.

What constitutes successful or unsuccessful outcomes after ACLR can vary widely between patients and caregivers. ^{28,72} The debate remains regarding whether patient-centered or medically centered outcomes are more important to the ultimate overall outcome. Lynch and colleagues polled sports medicine professionals around the world to establish consensus on what is considered a successful outcome. ⁷² Consensus was achieved on a mixture of both patient-centered and medically centered factors. The most important factors agreed upon by sports medicine professionals included clinical and functional symmetry measures, avoidance of repeat symptomatic laxity, returning to pre-injury activities, and measures of patient-reported function. While predictors of each of these outcomes have been studied individually, grouping these outcomes together into simple success or failure, has not been explored.

The purpose of this study is twofold: 1) to determine if a pre-surgical screening battery of clinical and functional measures are predictive of 2 year function measured by the IKDC; and 2) to determine if pre-surgical or early post-surgical screening is predictive of successful outcomes 2 years after ACLR. We hypothesize pre-surgical screening completed after pre-operative rehabilitation will explain more variance in IKDC scores than compared to screening completed at baseline. We also hypothesize the screening battery will be predictive of successful outcomes 2 years after ACLR.

4.3 Methods

4.3.1 Subjects

Subjects were included in this study if they had a unilateral isolated ACL rupture within 7 months of injury, and participated in level I or II sports greater than 50 hours per year. Subjects were excluded if they had a previous history of ACLR,

concomitant grade III ligamentous injury, concomitant articular cartilage surgery, or a potentially repairable meniscal tear. All subjects underwent initial impairment resolution and were enrolled when they achieved full symmetrical knee range of motion, a minimum of 70% isometric quadriceps strength symmetry, had little to no joint effusion or pain, no obvious gait impairments, and could hop in place without pain. Following impairment resolution, subjects underwent baseline clinical and functional testing followed by 10 sessions of perturbation training combined with progressive quadriceps strengthening. Following the 10 sessions, subjects again underwent clinical and functional testing. Subjects self-selected to undergo reconstruction or remain non-operatively managed, however, only those whom underwent reconstruction are included in this analysis. Subjects returned for follow-up testing at 6 and 24 months after surgery. All subjects after ACLR underwent a criterion-based post-operative rehabilitation protocol with strict RTS criteria. The University of Delaware Institutional Review Board approved all aspects of this study, and written informed consent was obtained for all subjects prior to enrollment.

4.3.2 Demographics

Subjects completed baseline demographic information including age, sex, BMI, weeks from injury to baseline, and time from surgery to 2 year follow-up. Subjects were asked at 2 years if they had sustained a second ACL rupture to either the ipsilateral graft or the contralateral ACL since reconstruction.

4.3.3 Screening Exam

At each time-point, subjects completed a test battery, as described by Fitzgerald and colleagues, ³⁰ which consisted of clinical, functional and patient-

reported measures. While the original screen included the number of episodes of knee instability, this was replaced in our screen with quadriceps strength testing, as quadriceps strength is a known predictor of function after ACLR. 24,68,90,114 The screen consisted of quadriceps strength symmetry (QI), the 6 meter timed hop test (TimHp), the Knee Outcome Survey Activities of Daily Living Scale (KOS) and the Global Rating Scale (GLO). QI was measured utilizing maximum voluntary isometric contraction (MVIC) on an electromechanical dynamometer (KinCom). The MVIC was recorded for each limb at 90 degrees of knee flexion. A symmetry index was created by dividing the involved limb score by the uninvolved limb score, and multiplying by 100. The TimHP measured how fast subjects could unilaterally hop down a 6 meter line. All subjects completed 2 practice trials per limb, followed by 2 recorded trials that were averaged for each limb. An index score was created by dividing the involved limb average time by the uninvolved limb average time and multiplying by 100. The KOS is a measure of knee symptoms and function that is valid and reliable for use in the ACL injured population.⁵³ The maximum raw score is 70, but is reported as a percentage score with 100% meaning no functional limitations or knee symptoms with activities of daily living. The GLO is a single question asking subjects to rate their knee function from 0 to 100 with 100 representing a full return to pre-injury knee function including sports participation.

4.3.4 Success and Failure

Success and failure 2 years after ACLR were operationally defined based on consensus criteria published by Lynch and colleagues defining successful outcomes after ACLR.⁷² Success was considered having normal knee function measured by the IKDC, returning to pre-injury sports, and not sustaining a second ACL rupture at 2

years. Normal knee function has been previously defined by Logerstedt and Grindem as meeting the 15th percentile or higher of age and sex matched normative values on the IKDC. ^{39,67,68} Returning to pre-injury sports was defined as returning to a level I or II sport 2 years after ACLR. Failure was considered not meeting the 15th percentile of age and sex matched normative IKDC values, not returning to a level I or II sport, or sustaining a second ACL injury at 2 years.

4.3.5 Statistical Analysis

Descriptive statistics and chi square and t-tests were used to report demographic information and characteristics of the groups. Linear regression was utilized to predict 2 year IKDC scores utilizing screening data at baseline and post-training. Logistic regression was performed to predict 2 year success or failure utilizing screening data from baseline, post-training, and 6 months after ACLR time-points. Receiver operator characteristic (ROC) curve, sensitivity, specificity, positive and negative likelihood ratios will be calculated for the strongest predictor of success. Significance was set at .05 a priori. All statistical analyses were performed using PASW version 23 (SPSS, Inc, IBM Company, Chicago, Illinois).

4.4 Results

Ninety-one subjects out of 150 subjects underwent ACLR. Sixty six subjects $(25 \pm 10 \text{ years}, 25 \pm 4 \text{ kg/m}^2, 65\% \text{ men})$ had complete datasets for analysis. Subjects returned for testing at 2.1 ± 0.3 years after reconstruction and had a mean IKDC score of 93 ± 8 . The screening battery was predictive of 2 year IKDC scores at both baseline (p< .001) and post-training (p<.001) time-points (table 4.1). Greater variance in IKDC scores was explained at the post-training (r^2 =.364) time-point than the

baseline (r^2 =.319) time-point. Age was the only individual significant predictor at both time-points (table 4.2).

Table 4.1: Predicting 2 year IKDC scores at Baseline and Post-training

Model	R ²	Adjusted R ²	P Value
Baseline	.319	.249	<.001
Post-training	.364	.287	<.001

Table 4.2: Model Predictors at Baseline and Post-training

В	t	95% CI	P Value
91.6	8.3	69.6 to 113.7	<.001
-0.3	-3.3	-0.5 to -0.1	.002
3.0	1.7	-0.5 to 6.6	.095
-0.1	-1.9	-0.3 to .01	.057
-0.04	-0.6	-0.2 to 0.1	.560
			.092
			.143
	91.6 - 0.3 3.0	91.6 8.3 -0.3 -3.3 3.0 1.7 -0.1 -1.9 -0.04 -0.6 0.2 1.7	91.6 8.3 69.6 to 113.7 -0.3 -3.3 -0.5 to -0.1 3.0 1.7 -0.5 to 6.6 -0.1 -1.9 -0.3 to .01 -0.04 -0.6 -0.2 to 0.1 0.2 1.703 to 0.4

(Continued) Table 4.2: Model Predictors at Baseline and Post-training

Post-training	В	t	95% CI	P Value
Constant	92	7.0	66 to 119	<.001
Age	-0.3	-3.3	-0.5 to -0.1	.002
Sex	3.5	1.9	-0.2 to 7.3	.065
QI	-0.1	-1.0	-0.3 to 0.1	.312
TimHP	-0.1	-0.7	-0.2 to 0.1	.465
KOS	0.2	1.3	-0.1 to 0.5	.205
	V.			
GLO	0.1	1.0	-0.1 to 0.2	.328

B= beta coefficient, t = t score, 95% CI = 95% confidence interval

Of the 66 subjects, 40 (61%) were classified as successes and 26 (39%) were classified as failures. There were no differences between groups in age, sex, BMI, or graft type (Table 4.3). Reasons for failing are shown in Figure 4.1. The screen was not predictive of success at baseline (p=.227) or post-training (p=.133), but was predictive at 6 months (p=.005) after ACLR (Table 4.4). The TimHP at 6 months after ACLR was the only significant individual predictor of success (Table 4.5).

Table 4.3: Group Differences in Characteristics

	Successful	Failure	P value	
Age	25 ± 10 yrs	26 ± 10 yrs	.617	
Sex	61% Men	69% Men	.419	
BMI	25 ± 4 kg/m ²	26 ± 5 kg/m ²	.302	
Graft Type	57% Allograft	54% Allograft	.927	

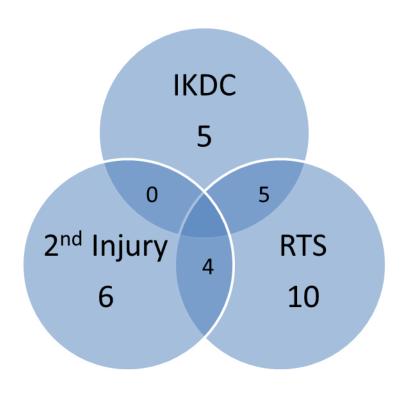


Figure 4.1: Reasons for Failure 2 Years after ACLR

Table 4.4: Screen Prediction of Success by Time-point

Time-point	Nagelkerke R ²	P Value
Baseline	.123	.277
Post-training	.189	.133
6 months post ACLR	.307	.005

Table 4.5: Individual Predictors of Success by Time-point

Baseline	В	P Value	Exp (B)
Constant	1.2	.704	3.2
Age	03	.151	.97
Sex	-0.3	.578	.75
QI	04	.100	.96
TimHP	.02	.250	1.02
KOS	.03	.371	1.03
GLO	01	.523	.99

Continued Table 4.5

Post-training	В	P Value	Exp (B)
Constant	4.9	.228	136.3
Age	03	.276	.97
Sex	.32	.578	1.37
QI	04	.111	.96
TimHP	01	.970	.99
KOS	04	.434	.97
GLO	.04	.055	1.04

6 Months	В	P Value	Exp (B)
Constant	-23.1	.014	.00
Age	03	.330	.97
Sex	85	.179	.43
QI	.02	.373	1.02
TimHP	.11	.018	1.11
KOS	.09	.311	1.10
GLO	.04	.302	1.04

ROC curve analysis of the TimHP at 6 months revealed an area under the curve of .686 which was statistically significant (p=.007) (Table 4.6). Discriminant Analysis is found in Table 4.7.

Table 4.6: ROC Analysis of the TimHP 6 Months after ACLR

	Optimum	Sensitivity	Specificity	Positive Likelihood	Negative Likelihood
	Cutoff			Ratio	Ratio
TimHP	96	.750	.615	1.95	0.40

Table 4.7: Discriminate Analysis of TimHP on Success

TimHP	Success	Failure	Total
Pass	30	10	40
Fail	10	16	26
Total	40	26	66

4.5 Discussion

The purpose of this study was to evaluate if a screening test battery is predictive of function 2 years after ACLR, and at what time-point the screening battery held the most predictive ability. The main finding of this study is a screening battery comprised of clinical and functional measures is predictive of both function and successful outcomes 2 years after ACLR. This is the first study, to our knowledge, that utilizes factors modifiable to rehabilitation professionals, to predict longer-term function and outcomes. Eitzen²⁴ and Logerstedt⁶⁸ found pre-operative predictors of function, however this was function early after ACLR and longer-term predictability remained unknown. Others have predicted function and outcomes at 2 years after ACLR, but these were primarily demographic and surgical variables which are not modifiable to rehabilitation professionals. This work not only predicts function and outcomes, but the time-points used for prediction are early in the rehabilitation process for the potential to intervene with rehabilitation strategies to potentially improve outcomes. This study did not evaluate what the optimal predictors of 2 year function are or which rehabilitation strategies will have the greatest potential to improve outcomes, but it does suggest that improving scores on a screening battery of clinical and functional measures are related to function and successful outcomes 2 years after ACLR.

IKDC scores 2 years after ACLR were successfully predicted from both baseline and post-training test batteries prior to reconstruction. The measures used from post-training, however, provided a more robust prediction than those from baseline. Undergoing early ACLR remains the gold standard in the United States,⁷⁴ and while delaying ACLR itself does not lead to improved outcomes,^{5,112} delaying to allow for a period of pre-operative rehabilitation does improve outcomes up to 2 years

after ACLR. 37,123 This study did not determine the value of pre-operative rehabilitation, but it does suggest that waiting until after a period of pre-operative rehabilitation is a more robust predictor of longer-term function. Having a more robust pre-operative model for predicting longer-term function after ACLR may help surgeons with the surgical decision-making process. This work strengthens the argument to avoid rushing to undergo reconstruction after ACL injuries. Quadriceps strength and the 6 meter timed hop did not achieve statistical significance as individual predictors within the model. Logerstedt⁶⁸ and Eitzen²⁴ both showed quadriceps strength as a significant predictor of post-operative function. Our lack of findings with quadriceps strength may be due to the subjects all needing to meet a minimum quadriceps strength index of 80% prior to surgery as well as the subjects needing to meet a minimum quadriceps strength symmetry of 90% to return to sport. Simply put, our pre-operative and return to sport requirements likely created a ceiling effect which influenced the predictive ability of quadriceps strength. Age was the only significant individual predictor of 2 year IKDC scores, with younger subjects having higher 2 year IKDC scores. This finding is consistent with healthy normative values of the IKDC, with younger people having higher IKDC scores.⁶

The screening battery was predictive of successful outcomes 2 years after ACLR when performed at 6 months after surgery, but not at either pre-operative time-point. Lynch⁷² and colleagues established consensus criteria of success after ACLR, and this is the first study to predict successful outcomes utilizing a combination of these criteria: patient-reported function, second ACL injury, and returning to pre-injury sports. These criteria are not only important to care providers, but also to the patients themselves.²⁸ Others have predicted return to sport,⁴³ second injury,^{92,97} and

IKDC scores individually;⁶⁸ but this is the first study to combine all of these outcomes into a successful or unsuccessful outcome 2 years after ACLR. The significance of this work is these predictors are modifiable to rehabilitation professionals and at 6 months after reconstruction there is still time to intervene in an attempt to improve the likelihood of a successful outcome.

The 6 meter timed hop was the only significant individual predictor of success. Logerstedt found the 6 meter timed hop was a predictor of 1 year function, which is consistent with our findings.⁶⁷ ROC analysis revealed a cutoff score of 96 on the timed hop symmetry index maximized sensitivity and specificity of successful outcomes. Return to sport criteria have traditionally suggested achieving between 80-90% for hop scores, ^{2,66} however recently it has been suggested to raise the criteria to 95%. Our findings suggest that subjects who achieve 96% symmetry on the 6 meter timed hop 6 months after reconstruction are nearly 2 times more likely to achieve a successful outcome at 2 years, while those who do not achieve 96% are 2.5 times more likely to fail at 2 years. While this study did not evaluate return to sport criteria, our evidence matches up closely with the proposed 95% cutoff to begin a return to sport progression. Neither of the pre-operative models were predictive of success at 2 years. Surgery is likely such an impactful event to the homeostasis of the knee, and this may explain why success was unable to be significantly predicted with pre-operative measures. In addition, there are also surgical and demographic variables, such as graft type, that were unaccounted for in the models but are known to influence return to sport and second ACL injury outcomes and may help explain the lack of predictability.

This study can only be applied to athletes with an isolated unilateral ACL injury. This study may not be generalizable to those with previous ACL injuries, concomitant ligamentous or articular cartilage injury, or non-athletes. All subjects received either a semitendinosis/gracilis autograft or a soft tissue allograft. Due to the sample size, only 6 predictors could be included in the model, and therefore, stronger models of prediction have the potential to exist.

4.6 Conclusion

A screening battery of clinical and functional measures was predictive of 2 year IKDC scores and 2 year successful outcomes after ACLR. Using clinical and functional measures as predictors allows rehabilitation professionals to intervene with rehabilitation strategies to potentially improve 2 year outcomes after ACLR. Waiting until after a period of pre-operative rehabilitation allowed for a more robust predictive model of 2 year IKDC scores. Achieving 96% symmetry on the 6 meter timed hop 6 months after reconstruction was nearly 2 times more likely to achieve a successful outcome, and not achieving that cutoff was associated with being 2.5 times more likely to fail 2 years after ACLR.

4.7 Acknowledgements

The authors would like to thank the University of Delaware Physical Therapy Clinic, the Delaware Rehabilitation Institute, and the research core for assistance with subject recruitment, scheduling, and assisting with treatment and data collection. We would like to specifically thank Martha Callahan, Angela Smith, Airelle Hunter-Giordano, Tara Manal, Andrew Lynch, Elizabeth Wellsandt, and Ryan Zarzycki for their assistance with subject treatment and recruitment.

Chapter 5

SECOND ACL INJURY

5.1 Abstract

While rates of second injury are relatively low in the general population, the rates in the young active sub-population are disturbingly high. Second injury rates reported in the athletic population range from 17%-35% depending on the specific patient population studied. Whether the risk is greater in the reconstructed limb or the contralateral limb remains controversial, but appears to be related to sex, with women having a higher risk of contralateral injury and men having a higher risk of graft rupture. Second ACL injury is commonly multifactorial in nature, with both intrinsic and extrinsic factors that may occur individually or in unison, and can be different in men and women. These factors can be grouped into modifiable and non-modifiable factors to the rehabilitation professional. While neuromuscular training programs have shown the ability to reduce index ACL injury prevalence, the effects of these programs in preventing second injury has not been studied. The purpose of this study is to 1.) examine the prevalence of second ACL injury in a prospective longitudinal cohort that underwent pre-operative perturbation training, 2.) compare early clinical, functional, and patient-reported measures between those who went on to second injury versus those who did not, and 3.) determine early predictors and/or risk factors related to second ACL injury.

While all subjects were followed, only the 91 subjects who underwent ACLR are included in this analysis. Second ACL injury was defined as rupture of the

ipsilateral ACL graft or the contralateral knee native ACL. All subjects were followed at a minimum of 2 years after ACLR. Demographic data recorded included the following baseline characteristics: age, sex, BMI, sport activity level according to the IKDC sporting classification, and time from ACL injury to baseline testing. Clinical measures include episodes of giving way, quadriceps strength, presence of quadriceps lag, joint effusion, ACL graft type, and presence of meniscal pathology at time of ACLR. Functional measures for this study included single-legged hop testing, Knee Outcome Survey Activities of Daily Living Scale (KOS), IKDC, Global Rating Score (GRS), Tampa Scale for Kinesiophobia 11 question form (TSK), and functional classification status. All subjects completed return to sport (RTS) testing prior to returning to their pre-injury sporting activities. The University of Delaware return to activity criteria requires a minimum of 90% scores on the following seven tests: quadriceps strength symmetry, 4 single-legged hop testing symmetry, the KOS, and the GRS. Analysis of variance (ANOVA) was used to longitudinally compare groups across the time points for each variable. Relative risk was calculated for graft type (allograft vs autograft), sex, screening classification (potential coper vs non-coper), age (25 and under), passing RTS criteria at 6 months, presence of pain at 6 months (no pain vs pain), and return to level I sports. Logistic regression was used to evaluate predictors of second injury. Predictors were chosen post-hoc based on group differences found.

Ten second ACL injuries were recorded out of 85 subjects that were available for follow-up, with 6 subjects being lost to follow-up. The ipsilateral second ACL injury percentage was 8% and the contralateral second injury percentage was 3.5% with a total second ACL injury percentage of 11.5%. Seven (70%) of the second ACL

injuries occurred within the first 15 months after ACLR. A significant group by time interaction was seen for the TSK (p=.033). There were no significant group by time interactions for QI (p=.483), TimHP (p=.221), KOS (p=.859), GRS (p=.852), or IKDC (p=.206). There were main effects of time seen for TimHP (p=.040), KOS (p<.001), GRS (p=.008), and IKDC (p<.001). Age, sex, days from injury to baseline, 6 month IKDC scores, 6 month TSK-11 scores, and 6 month GLO scores were entered into the model as predictors in the logistic regression. The model significantly predicted second ACL injury ($r^2 = .482$; p = .002). Days from injury to baseline was the only significant individual predictor in the model (p=.015).

The main findings from this study are younger athletes, returning to level I sports early after ACLR are at high risk for second ACL injury. An overall second injury rate of 11.5% was found in our cohort, which is lower than previously reported second injury rates in younger athletes. In addition, a combination of demographic and functional measures were predictive of second ACL injury. Our findings are consistent with published data, showing about a 3 fold increase in risk of second injury associated with being under age 25 and returning to a level 1 sport. Besides the TSK-11, the groups did not score differently over time in any of the other clinical or functional measures. This does show, however, that clinical and functional measures alone are not enough to mitigate risk of second ACL injury, and time from surgery and age of the athlete need to be taken into consideration.

5.2 Introduction

Second injury after ACLR, is a compromise of the ipsilateral graft or contralateral ACL, and is a hot topic in orthopedic literature currently. While rates of second injury are relatively low in the general population, 57,127 the rates in the young active sub-population are disturbingly high. 94,125 The negative sequelae associated with these injuries not only includes additional rehabilitation and/or surgical intervention, but psychological impact and an increased risk for poor long-term knee joint health. The majority of these injuries occur in the younger population, with many years left in the healthcare system. Unsurprisingly, the research interests within this area have exploded recently.

5.2.1 Prevalence of Second ACL Injury

While second injury was once thought to occur infrequently, emerging research suggests that this is not the case for all patient populations. Second injury in the general population is reported to be 6% up to five years after reconstruction. 12,132 Most of these individuals, however, are not active in cutting and pivoting sports, which may explain the relatively low second injury rates. The outlook for young active individuals is far more grim. Second injury rates reported in the athletic population range from 17%-35% depending on the specific patient population studied. 12,94,108 A large prospective study found young female athletes had a 29.5% second injury rate, with only an 8% ACL injury rate in the matched control group. 94 Other cohorts that have looked at the young active patient subset have found 17% second injury rates. A recent systematic review and meta-analysis found an overall second injury rate of 15% with 7% being graft rupture and 8% being contralateral ACL injury. When looking specifically at active participants under the age of 25,

the authors reported an overall second injury rate of 23%, with a 10% graft rupture rate and a 13% contralateral ACL injury rate.¹³⁰ Whether the risk is greater in the reconstructed limb or the contralateral limb remains controversial, but appears to be related to sex, with women having a higher risk of contralateral injury and men having a higher risk of graft rupture.^{93,130}

5.2.2 Risk Factors and Predictors of Second ACL Injury

The unexpected prevalence of second injury has led to a rush to determine risk factors and predictors related to these second ACL injuries. Second ACL injury is commonly multifactorial in nature, with both intrinsic and extrinsic factors that may occur individually or in unison, and can be different in men^{12,108} and women.^{93,94,132} These factors can be grouped into modifiable and non-modifiable factors to the rehabilitation professional. First and foremost, the single biggest risk factor and predictor of second ACL injury is a previous history of ACL injury. 12,125 Even after controlling for age, sex, and athletic exposures, those after ACLR have a nearly 6 fold higher risk of having a second ACL injury compared to healthy controls.⁹⁴ Nonmodifiable risk factors and predictors proposed include age, ^{38,125,130} sex, ^{93,121} family history, ^{12,125} joint architecture, ⁴⁵ hormonal changes ⁴⁹, and surgical variables. ¹³⁵ Beyond previous history of ACL injury, the strongest predictors of second injury appear to be age, with younger athletes at higher risk, and returning to high level cutting and pivoting sports. 38,125,130 While just returning to high level sport is a predictor of second injury, the timing of return after initial ACLR is also a factor. Grindem and colleagues found that delaying reutrn until at least 9 months after ACLR reduces the risk of second injury, especially when combined with quadriceps strength

symmetry.³⁸ For each month beyond 6 months, a delay in return to sport reduced second injuries by 51%.³⁸

5.2.3 Second ACL Injury Prevention

Second ACL injury is thought to be related, at least in part, to aberrant neuromuscular and biomechanical patterns commonly seen after ACLR. 48 Whether these deficits are a continuation of factors that led to the index injury, or are in response to surgical intervention remains unknown. Asymmetrical movement patterns can persist at least 2 years after ACLR, 18,33,100,128 and given the majority of second ACL injuries occur early in the return to sport process, ⁹⁴ these patterns are likely contributory. Second ACL injury prevention programs target these aberrant patterns as well as address modifiable risk factors for second injury. 46,85 These programs commonly target quantitative and qualitative impairments such as quadriceps strength symmetry, functional performance, and dynamic limb control through training of the neuromuscular system.^{21,78} Perturbation training is a form of neuromuscular training that targets selective muscle activation in response to an external perturbation. ^{17,115} Perturbation training improves gait asymmetries, improves functional performance, and allows for return to sport despite ligamentous instability. 22,41,115 While neuromuscular training programs have shown the ability to reduce index ACL injury prevalence, the effects of these programs in preventing second injury has not been studied.

The purpose of this study was to 1.) examine the prevalence of second ACL injury in a prospective longitudinal cohort that underwent pre-operative perturbation training, 2.) compare early clinical, functional, and patient-reported measures between those who went on to second injury versus those who did not, and 3.) determine early

predictors and/or risk factors related to second ACL injury. We hypothesize that second injury rates would be reduced in our cohort compared to published rates in similarly aged athlete cohorts. We also hypothesize early clinical, functional, and patient-reported factors would be related to second ACL injury. The implications of this research may add additional evidence for the use of neuromuscular training programs in reducing the incidence of second ACL injury.

5.3 Methods

This secondary analysis of prospectively collected data includes 150 subjects from the University of Delaware Physical Therapy Clinic with acute ACL rupture. Subjects underwent testing at the following time-points: baseline (impairment resolution), post-training (following extended pre-operative rehabilitation), 6 months after ACLR and 2 years after ACLR.

5.3.1 Subjects

Subjects were included if they had a unilateral primary ACL rupture within 7 months of enrollment, and participated in level I or II sports greater than 50 hours per year prior to injury. Subjects were excluded if they had a concomitant grade III ligamentous injury, a full thickness articular cartilage lesion larger than 1 cm, a symptomatic meniscal tear, a potentially repairable meniscal tear, or a history of previous injury or surgery of the uninvolved knee. All subjects underwent initial impairment resolution (little to no swelling or pain, full range of motion, 70% quadriceps strength index) followed by progressive strengthening and neuromuscular training called perturbation training, as previously described by Eitzen. Following completion of these training sessions, subjects selected to undergo ACLR or remain

non-operatively managed. While all subjects were followed, only the 106 subjects who underwent ACLR are included in this analysis. Those subjects whom did not immediately undergo reconstruction following training continued with a home exercise program, if needed, for maintenance until reconstruction was performed. All subjects after ACLR underwent a criterion-based post-operative rehabilitation protocol with strict RTS criteria. The University of Delaware Institutional Review Board approved all aspects of this study, and written informed consent was obtained for all subjects prior to enrollment.

5.3.2 Second ACL Injury

Second ACL injury was defined as rupture of the ipsilateral ACL graft or the contralateral knee native ACL. All subjects were followed at a minimum of 2 years after ACLR. Subjects were considered to have a second ACL injury if the injury occurred within 2 years after ACLR. All second injuries were confirmed by a physical therapist or orthopedic surgeon. In addition to second injury rate, time from ACLR to second injury, sport of second injury, and mechanism of second injury were recorded.

5.3.3 Demographics

Demographic data recorded included the following baseline characteristics: age, sex, BMI, sport activity level according to the IKDC sporting classification, and time from ACL injury to baseline testing. IKDC sporting classification groups sports based on the frequency of cutting, pivoting, and jumping required during sport. 6,54 Level I sports require frequent cutting, pivoting, and jumping such as soccer, American football, and basketball. Level II sports require less frequent cutting, pivoting, and jumping and include sports such as baseball, tennis, and martial arts.

5.3.4 Clinical Measures

Clinical measures included episodes of giving way, quadriceps strength, joint effusion, ACL graft type, and presence of meniscal pathology at time of ACLR. Episodes of knee giving way, or episodes of true knee instability, were recorded from initial injury to ACLR. These episodes were classified as instability if the patient described a shifting in their knee joints (similar to the instability felt during their initial injuries) that resulted in pain and/or increased joint effusion. Quadriceps strength was measured isometrically at 90 degrees of knee flexion on an electromechanical dynamometer (KinCom) utilizing the burst superimposition technique. Quadriceps strength maximum voluntary contraction is reported as a symmetry index where the involved limb score was divided by the uninvolved limb score and multiplied by 100. Graft type during ACLR was extracted from each subjects operative report and recorded as either autograft or allograft, and the specific tissue used was also recorded (i.e. hamstring, patellar tendon). Subjects were classified as either having meniscal involvement or not based on arthroscopic evaluation results recorded in the operative reports.

5.3.5 Functional Measures

Functional measures for this study included single-legged hop testing, Knee Outcome Survey Activities of Daily Living Scale (KOS), IKDC, Global Rating Score (GRS), Tampa Scale for Kinesiophobia 11 question form (TSK), and functional classification status. Single legged hop testing is a unilateral hopping test in which the functional performance of the involved and uninvolved limbs are compared and reported as a symmetry index.¹ This test involves 4 sub-parts: single hop (SHP), crossover hop (XHP), triple hop (THP), and the 6 meter timed hop (TmHP). Subjects

were allowed 2 practice hops followed by 2 recorded hops with the average of the 2 hops taken. All subjects wore a functional de-rotation brace during the hop tests. The KOS is a valid and reliable measure of patient-reported knee function in the ACL injured patient population.⁵³ The patient score is divided by the total score of 70 and then multiplied by 100. The IKDC is a reliable and valid score of patient-reported outcomes after knee surgeries and is commonly used in the ACL patient population. 6,54,104 A higher score indicates higher knee function and a lower score indicates more symptoms and less knee function. GRS is a single question asking to rate current knee function compared to pre-injury level of function, with 100% meaning back to all pre-injury function. TSK-11 is a reliable tool, modified to include only 11 questions, used to measure fear of pain and injury. 131 This tool was not developed for use in knee pathology, however, reports have shown increased scores in the ACLR population. Functional classification status was determined by classifying subjects pre-operatively as copers, potential copers, or non-copers. This screening exam for classification utilizes performance, patient reported, and giving way measures to classify subjects.

5.3.6 Return to Sport

All subjects completed return to sport (RTS) testing prior to returning to their pre-injury sporting activities. The University of Delaware return to sport testing requires a minimum of 90% scores on the following seven tests: quadriceps strength symmetry, 4 single-legged hop testing symmetry, the KOS, and the GRS. All subjects who passed this test were then cleared to enter the final phases of return to sport progression. Time from ACLR to passing the RTS criteria was recorded. Early RTS

completion was considered passing RTS criteria prior to 6 months, and late RTS completion was considered pass RTS criteria after 6 months after ACLR.

5.3.7 Statistical Analysis

Descriptive statistics included means and percentages of demographic variables. Group differences were compared with chi square and mann-whitney-u tests. Repeated measures Analysis of variance (ANOVA) was used to longitudinally compare groups across the time points for each variable. Relative risk was calculated for graft type (allograft vs autograft), sex, screening classification (potential coper vs non-coper), age (25 and under), passing RTS criteria at 6 months, presence of pain at 6 months (no pain vs pain),and return to level I sports. Logistic regression was used to evaluate predictors of second injury. Predictors were chosen post-hoc based on group differences found. Where significant predictors were found, receiver operating characteristic curves were utilized to determine cutoff points. All data was analyzed using PASSW 23.0 software (SPSS Inc. Chicago, IL). Significance was set at 0.05 a priori.

5.4 Results

Ten second ACL injuries were recorded out of 85 subjects that were available for follow-up, with 6 subjects being lost to follow-up (Figure 5.1). The ipsilateral second ACL injury percentage was 8% and the contra lateral second injury percentage was 3.5% with a total second ACL injury percentage of 11.5%. Demographics of those who had a second ACL injury and those who did not are reported in Table 5.1.

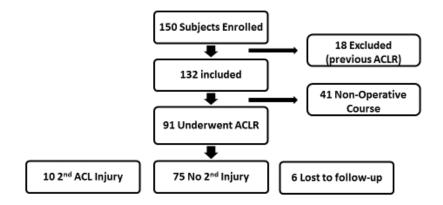


Figure 5.1: Second Injury Flowchart

Table 5.1: Second Injury Demographics

	2 nd Injury	No 2 nd Injury	P Value
Age	21 ± 6	26 ±11	.399
Sex	90% Men	62% Men	.076
BMI	24 ± 3	25 ± 5	.415
Classification	60% PC	58% PC	.854
Sport Level	90% Level I	76% Level I	.301
Graft Type	50% Allograft	37% Allograft	.595
Giving Way	.75 ± 1	.91 ± 2	.741
Mechanism of Injury	67% Non-Contact	67% Non Contact	1.000
Days from Injury to Baseline	87 ± 88	45 ± 41	.321
Weeks to 2 nd Injury	58 ± 24		

Body Mass Index (BMI), Potential Coper (PC)

Seven (70%) of the second ACL injuries occurred within the first 15 months after ACLR. A significant group by time interaction was seen for the TSK (p=.033).

There were no significant group by time interactions for QI (p=.483), TimHP (p=.221), KOS (p=.859), GRS (p=.852), or IKDC (p=.206) (Figure 5.2). There were main effects of time seen for TimHP (p=.040), KOS (p<.001), GRS (p=.008), and IKDC (p<.001).

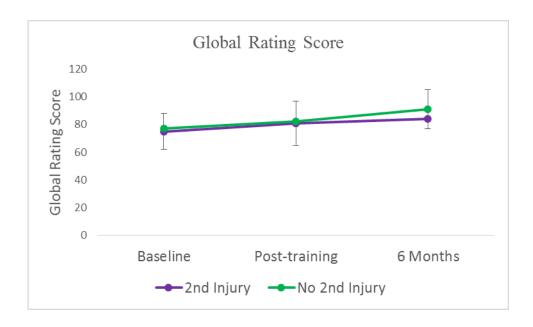


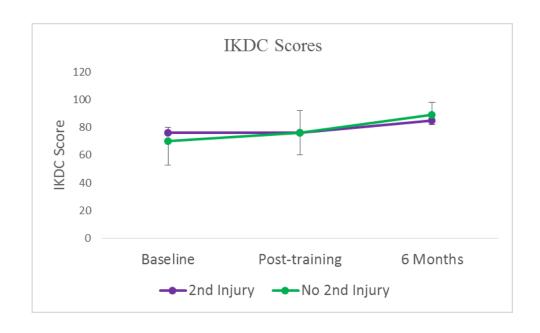
Figure 5.2: Group Differences Over Time





Figure 5.2 (continued)







Age, sex, days from injury to baseline, 6 month IKDC scores, 6 month TSK-11 scores, and 6 month GLO scores were entered into the model as predictors in the logistic regression. The model significantly predicted second ACL injury ($r^2 = .482$; p = .002). Days from injury to baseline was the only significant individual predictor in the model (p= .015) (table 5.2). ROC analysis was performed on days from injury to baseline showing an area under the curve of .625 which was not statistically significant (p= .159) (table 5.3). Relative risk calculations can be found in table 5.4.

Table 5.2: Predictors of second ACL injury

Predictor	В	P Value	Exp(B)	CI
Age	28	.098	.756	.543-1.053
Sex	-1.36	.423	.257	.009-7.152
Injury Days	.04	.011	1.04	1.01-1.073
GLO	02	.350	.978	.933-1.025
TSK-11	.21	.033	1.232	1.02-1.493
Constant	3.34	.627	28.16	

Table 5.3: ROC Analysis of Days from Injury to Baseline

	Optimum Cutoff	Sensitivity	Specificity	Positive Likelihood Ratio	Negative Likelihood Ratio
Days from					
Injury to	32	.667	.441	1.19	0.75
Baseline					

Table 5.4: Relative Risk of Second ACL Injury

Variable	Relative Risk	CI
Sex	.182	.024 - 1.352
Classification	1.000	.323 - 3.09
6 Month RTS Criteria	.838	.243 - 2.89
6 Month Pain	.804	.157 - 4.103
Return to Level I Sport	2.951	.402 - 21.64
Age (under 25)	3.10	.705 - 13.623

5.5 Discussion

The purpose of this study was to 1.) examine the prevalence of second ACL injury in a prospective longitudinal cohort that underwent pre-operative perturbation training, 2.) compare early clinical, functional, and patient-reported measures between those who went on to second injury versus those who did not, and 3.) determine early predictors and/or risk factors related to second ACL injury. The main findings from this study are younger athletes, returning to level I sports early after ACLR are at the highest risk for second ACL injury. An overall second injury rate of 11.5% was found in our cohort, which is lower than previously reported second injury rates in younger athletes. In addition, a combination of demographic and functional measures were predictive of second ACL injury.

Age, returning to level I sport, and time from surgery to return to sport have been previously reported as risk factors for second ACL injury. 38,125,130 Our findings are consistent with published data, showing about a 3 fold increase in risk of second injury associated with being under age 25 and returning to a level I sport. Grindem and colleagues found a 4 fold increase in risk with a return to level I sports, 38 and Webster found a 6 fold increase in risk with being under the age of 21.125 Age itself may not represent the increased risk, but other unknown factors that are associated with age may explain these findings. Younger individuals are more likely to return to high level sporting activities, and their neuromuscular impairments are predictive of second injury. 8,9,125 In addition, it has been postulated that younger athletes engage in more risky behavior than older athletes. Further research into the relationship of age and second injury risk is needed to determine if there is a biological component to second injury risk in young athletes, or if age is just a proxy for the extraneous factors previously discussed.

Seventy percent of the second ACL injuries occurred within the first 15 months after reconstruction. Returning to sport early after reconstruction is proposed as a risk factor for second injury. 38,63,94 Paterno and colleagues found the majority of the second injuries in their cohort occurred within the first 72 athletic exposures following return to sport.⁹⁴ Our results are consistent with these findings, the majority of these second injuries occur early after returning to sport. The high second ACL rates reported in the literature may in part be due to the lack of consensus on when return to sport is appropriate after ACLR, 66 and what criteria should be used for return to sport clearance. Using time alone as an indicator for readiness of return to sport is inadequate, 84 as many athletes can continue to have clinical and functional impairments well beyond one year after reconstruction. 18,33,69,92,128 Many practitioners have adopted 6 months after reconstruction as a time when return to sport is deemed safe. Grindem and colleagues reported returning to sport prior to 9 months after ACLR increased risk of second injury by 49% for each month prior to 9 months. 38 It remains unknown if this risk is associated with biological healing, insufficient rehabilitation, or a combination of both, but appears that returning to sport prior to 9 months is detrimental to longer-term success.

Seventy percent of the second ACL injuries occurred to the ipsilateral knee resulting in graft rupture. Ninety percent of the second injuries occurred in men. Men have been proposed to have higher risk of second injury in the ipsilateral knee, with women having a higher risk of contralateral ACL rupture. Given our subjects with second ACL injury were primarily men, the number of ipsilateral injuries are consistent with findings in the literature.

Our work, to our knowledge, is the only study to report clinical and functional longitudinal data prospectively collected prior to second injury. The only measure that had a significant time by group interaction was the TSK-11. Recent findings utilizing measures of fear and second injury have reported those with second ACL injury to have lower levels of fear and higher levels of confidence. We found the opposite in out cohort, with subjects that went on to second ACL injury having higher scores on the TSK-11 compared to those who did not. Given these two opposite findings, further research into psychological factors and second injury should continue. While too little fear may be representative of risk-taking behavior and therefore increase second injury risk, it is possible that too much fear may also be representative of increased second ACL injury risk. Besides the TSK-11, the groups did not score differently over time in any of the other clinical or functional measures. Our strict post-operative protocol and return to sport criteria likely did not allow for large enough differences between groups. This does show, however, that clinical and functional measures alone are not enough to mitigate risk of second ACL injury, and time from surgery and age of the athlete need to be taken into consideration.

5.6 Conclusion

Younger athletes returning to high level cutting and pivoting sports are at high risk for second ACL injury following ACLR. The majority of these second injuries occurred early after returning to sport. Using objective return to sport criteria is effective at reducing risk of second ACL injury, however, additional consideration of age, time from ACLR, and the type of sport being returned to may further mitigate second ACL injury risk in athletes.

5.7 Acknowledgements

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Chapter 6

IMPROVING OUTCOMES AFTER ACL INJURY THROUGH REHABILITATION TECHNIQUES

6.1 Purpose

The goals of this body of work were to 1) examine the effects of a preoperative rehabilitation program on outcomes after ACLR and 2) examine the
relationship between early modifiable factors and outcomes after ACLR. Through this
work we aimed to identify pre and post-operative factors that are related to improving
outcomes 2 years after reconstruction. We hypothesized that the addition of preoperative rehabilitation would improve outcomes 2 years after reconstruction, as well
as identify modifiable factors after injury and early after reconstruction that could be
addressed through rehabilitation techniques. We also hypothesized that clinical and
functional factors, which are modifiable to rehabilitation professionals, would be
associated with outcomes after ACLR.

6.2 Pre-operative Rehabilitation Improves Outcomes 2 Years after ACLR

AIM 1: To determine whether the combination of pre-operative neuromuscular training and post-operative rehabilitation leads to improved outcomes in athletes 2 years after ACLR.

<u>Hypothesis 1.1</u>: Athletes treated with pre-operative neuromuscular training and post-operative rehabilitation will have higher functional outcomes compared to standard care two years after ACLR.

<u>Hypothesis 1.2</u>: Athletes treated with pre-operative neuromuscular training and post-operative rehabilitation will have higher return to sport rates compared to standard care two years after ACLR.

Pre-operative rehabilitation is a topic of interest in orthopedic outcomes literature. The fiscal responsibility and visit limitations imparted upon the rehabilitation sector continues to grow, and with that comes the need for outcomes research answering how to improve outcomes and when to intervene to get the most bang for the buck. This work supported our hypotheses that those who underwent additional pre-operative rehabilitation had improved outcomes and return to sport rates compared to those who did not. This suggests there may be untapped potential to improve outcomes through higher pre-operative rehabilitation standards and milestones. Further research is needed to determine how much and what type of pre-operative rehabilitation is needed to improve outcomes. This work has the potential to impact standards of care after ACL injury, indicating that forgoing pre-operative rehabilitation to undergo early ACLR may not be in the athletes' best longer-term interests.

6.3 Clinical Factors are Associated with Functional Outcomes after ACLR

AIM2: To determine early predictors of function 2 years after operative management following ACL injury.

<u>Hypothesis 2.1</u>: Early Clinical, functional, and patient-reported measures will predict IKDC scores 2 years after ACLR.

<u>Hypothesis 2.2</u>: Clinical, functional, and patient-reported measures will have greater predictive ability following extended pre-operative rehabilitation compared to early after injury in predicting IKDC scores 2 years after ACLR. <u>Hypothesis 2.3</u>: Early clinical, functional, and patient-reported measures will be predictive of successful outcomes 2 years after ACLR.

The findings from aim 1 established the importance of pre-operative rehabilitation to improve outcomes after ACLR. Aim 2 added examining the associations of pre-operative clinical and functional measures with 2 year functional outcome measure scores. Predictors of function that currently exist largely utilize demographic measures or other measures that are not modifiable to rehabilitation professionals. 23,45,57,118,135 This work examined the ability of an established preoperative test battery to predict functional scores at 2 years, and whether this battery was a more robust predictor at baseline or following completion of pre-operative rehabilitation. Our hypotheses were supported based on the findings of this chapter showing a pre-operative test battery was predictive of 2 year function, and was more robust when implemented following a period of pre-operative rehabilitation. This is the first work to show a relationship between modifiable variables and functional outcomes measures 2 years after reconstruction. In addition, this further strengthens the argument of utilizing pre-operative rehabilitation two fold: 1) clinical and functional measures addressed through pre-operative rehabilitation were predictive of function and 2) waiting until after this period of pre-operative rehabilitation improved the prognostic ability to predict function at 2 years after ACLR. At 6 months postoperatively, clinical and functional measures were predictive of success or failure at 2 years. Higher scores pre-operatively and post-operatively on clinical and functional measures are associated with higher functional outcomes scores and success after ACLR. Further research is needed to determine what the best group of predictors for determining longer-term function are and identify those with the potential for poor outcomes early enough to intervene through rehabilitation to maximize outcomes.

6.4 The Relationship of Clinical and Functional Factors and Second ACL Injury

AIM3: To determine if clinical, functional, and patient-reported outcome measures after ACL injury and early after ACLR are associated with second ACL injury

<u>Hypothesis 3.1:</u> Explore demographics and characteristics of those who went on to second ACL injury.

<u>Hypothesis 3.2</u>: Baseline attributes, clinical, functional, and patient-reported outcome measures after ACL injury and early after ACLR will differ between those who went on to second injury and those who did not within 2 years after ACLR.

<u>Hypothesis 3.3</u>: Baseline attributes, clinical, functional, and patient-reported outcome measures after ACL injury and early after ACLR are predictive of second injury.

Second ACL injury is a negative outcome following ACLR that continues to strike fear in sports medicine professionals. Not only do these second ACL injuries have the potential to require additional surgery and rehabilitation, but the downstream effects of poor long-term knee joint health and the associated financial burden are alarming. It remains unknown why these second injuries are occurring at such a high rate in young individuals and how can these injuries be avoided. The first two aims of

this work addressed improving functional outcomes through rehabilitation. Aim 3 adds to this by exploring second injury rates and factors associated with second injury in a cohort that underwent pre-operative rehabilitation. The findings from this aim support age, and early return to high level sports as factors that increase risk of second injury. Second injury was predicted utilizing a mixture of demographics and outcome measures early after reconstruction. This is one of the first studies to establish a relationship between potentially modifiable factors and second ACL injury. Further research is needed to continue to establish risk factors and identify those who may be at increased risk for second injury and how to lower that risk through improved rehabilitation techniques.

6.5 Clinical Relevance

The theme of this work is improving outcomes after ACL injury and reconstruction through pre-operative and early post-operative rehabilitation techniques. The benefits of additional rehabilitation and higher standards are evident throughout this work. Raising the bar of pre-operative strength, functional performance, and patient-reported outcome scores was associated with higher functional scores 2 years after ACLR. This highlights the importance of achieving higher clinical and functional standards before undergoing ACLR. In addition, the need to achieve higher standards of function early after ACLR features the importance of progressive post-operative protocols and utilizing objective measures to identify those at increased risk of poorer outcomes or second ACL injury. No matter the time-point, success was associated with higher clinical and functional outcomes further perpetuating the importance of rehabilitation in improving outcomes. This work has

the potential to effect pre and post-operative rehabilitation guidelines, minimum standards of care, and may help aid in the surgical decision-making process.

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Appendix A

CONTROVERSIES IN KNEE REHABILITATION: ANTERIOR CRUCIATE LIGAMENT INJURY

Author's personal copy

Controversies in Knee Rehabilitation



Anterior Cruciate Ligament Injury

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KEYWORDS

- Anterior cruciate ligament Knee ACLR ACL Physical therapy Athletes
- · Sports physical therapy

KEY POINTS

- Undergoing anterior cruciate ligament (ACL) reconstruction does not guarantee athletes will return to their preinjury sport, and return to the preinjury competitive level of sport is unlikely.
- The risk of a second ACL injury is high in young athletes returning to sport, especially in the near term.
- The risk for developing osteoarthritis after ACL injury is high in the long term regardless of surgical intervention, and even higher if a revision procedure is required.
- Despite common misconceptions, nonoperatively managed athletes can return to sport without the need for reconstruction.
- Without differences in outcomes between early reconstruction, delayed reconstruction, and nonoperative management, counseling should start by considering nonoperative management.

INTRODUCTION

More than 250,000 anterior cruciate ligament (ACL) injuries occur yearly in the United States, ¹ with 125,000 to 175,000 undergoing ACL reconstruction (ACLR). ^{2,5} Although standard of practice in the United States is early reconstruction for active individuals with the promise of returning to preactivity injury levels, ^{4,5} evidence suggests athletes are counseled that reconstruction is not required to return to high-level activity after a program of intensive neuromuscular training. ⁵ Others advocate counseling for a

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delayed reconstruction approach⁷; however, no differences in outcomes exist between delayed and early ACLR.⁶ Furthermore, athletes in the United States are commonly counseled to undergo early ACLR⁵ with the promise of restoring static joint stability, minimizing further damage to the meniscii and articular cartilage, ^{4,8} and preserving knee joint health⁸; however, not all athletes are able to return to sport or exhibit normal knee function following reconstruction.⁹ Several factors, such as impaired functional performance, knee instability and pain, reduced range of motion, quadriceps strength deficits, neuromuscular dysfunction, and biomechanical maladaptations, may account for highly variable degrees of success.

To identify the minimum set of outcomes that identifies success after ACL injury or ACLR, Lynch and colleagues ¹⁰ established consensus criteria from 1779 sports medicine professionals concerning successful outcomes after ACL injury and reconstruction. The consensus of successful outcomes were identified as no reinjury or recurrent giving way, no joint effusion, quadriceps strength symmetry, restored activity level and function, and returning to preinjury sports (Table 1). ¹⁰ Using these criteria, the success rates of current management after ACL injury are reviewed and recommendations are provided for the counseling of athletes after ACL injury.

IMPAIRMENT RESOLUTION

Following ACL injury or reconstruction, athletes undergo an extensive period of vigorous rehabilitation targeting functional impairments. These targeted rehabilitation protocols strive for full symmetric range of motion, adequate quadriceps strength, walking and running without frank aberrant movement, and a quiet knee: little to no joint effusion or pain. ¹⁰ Despite targeted postoperative rehabilitation, athletes commonly experience quadriceps strength deficits, ^{11–13} lower self-reported knee function, ¹⁴ and movement asymmetry ^{15,16} up to 2 years after reconstruction. The importance of quadriceps strength as a dynamic knee stabilizer has been established, because deficits have been linked to lower functional outcomes. ^{12,17} In a systematic review of quadriceps strength after ACLR, quadriceps strength deficits can exceed 20% 6 months after reconstruction, with deficits having the potential to persist for 2 years after reconstruction. ¹³ Otzel and colleagues ¹⁸ reported a 6% to 9% quadriceps deficit 3 years after reconstruction, concluding that long-term deficits after surgery were the result of lower neural drive because quadriceps atrophy measured by thigh circumference was not significantly different between limbs. Grindem and colleagues ¹⁹ reported at 2-year follow-up that 23% of nonoperatively managed athletes

Table 1 Consensus criteria on successful outcomes after anterior cruciate ligament injury and reconstruction from 1779 sports medicine professionals					
Criterion	2 y After Operative Management (Consensus %)	2 y After Nonoperative Management (Consensus %)			
Absence of giving way	96.4	96.5			
Return to sports	92.4	92.7			
Quadriceps strength symmetry	90.3	90.7			
Absence of joint effusion	84.1	85.0			
Patient-reported outcomes	83.2	83.5			

Data from Lynch AD, Logerstedt DS, Grindem H, et al. Consensus criteria for defining "successful outcome" after ACL injury and reconstruction: a Delaware-Oslo ACL cohort investigation. Br J Sports Med 2013:1–9.

had greater than 10% strength deficits compared with one-third of athletes who underwent reconstruction. Another study comparing operatively and nonoperatively managed patients 2 to 5 years after ACL injury found no differences in quadriceps strength between groups, concluding that reconstructive surgery is not a prerequisite for restoring muscle function. ²⁰ Regardless of operative or nonoperative management, quadriceps strength deficits are ubiquitous after ACL injury and can persist for the long term. The current evidence does not support ACLR as a means of improved quadriceps strength outcomes over nonoperative management after ACL injury.

OUTCOMES

Individuals do not respond uniformly to an acute ACL injury, and outcomes can vary. Most individuals decrease their activity level after ACL injury. ²⁰⁻²⁵ Although a large majority of individuals rate their knee function below normal ranges after an ACL injury, which is a common finding early after an injury, ²⁰⁻³⁰ some individuals exhibit higher perceived knee function than others early after ACL injury, ²⁰⁻³⁰ highlighting the variability in outcomes seen after ACL injury.

Knee outcome scores are lowest early after surgery and improve up to 6 years after surgery. 29.31.32 Using the Cincinnati Knee Rating System, scores improved from 60.5/100 at 12 weeks after reconstruction to 85.9/100 at 1-year follow-up. 32 By 6 months after surgery, almost half of the individuals scored greater than 90% on the Knee Outcomes Survey–Activities of Daily Living Scale (KOS-ADLS) and Global Rating Scale of Perceived Function (GRS), and 78% achieved these scores by 12 months. 14 Using the GRS, scores improved from 63.1/100 taken at week 12 to 83.3/100 at week 52.32 Moksnes and Risberg²³ reported similar postsurgical GRS results of 86.0/100 at 1-year follow-up. Poor self-report on outcome measures after ACLR are associated with chondral injury, previous surgery, return to sport, and poor radiological grade in ipsilateral medial compartment. 33 ACLR revision and extension deficits at 3 months are also predictors of poor long-term outcomes. 34.35

Patient-reported outcomes from multiple large surgical registries are available concerning patients after ACLR. A study from the Multicenter Orthopaedic Outcomes Network (MOON) consortium of 446 patients reported International Knee Documentation Committee Subjective Knee Form 2000 (IKDC) for patients 2 and 6 years after reconstruction. The median IKDC score was 45 at baseline, increased to 75 at 2-year follow-up, and reached 77 at 6 years after reconstruction. Finder and colleagues compared IKDC scores between athletes managed nonoperatively or with reconstruction at baseline and at 2 years. The nonoperative group improved from a score of 73 at baseline to a score of 89 at 2 years after injury. The reconstructed group improved from 69 at baseline to 89 2 years after surgery. There were no significant differences between groups at baseline or at 2-year follow-up. Using the Knee Injury and Osteoarthritis Outcome Score, Frobell and colleagues compared patient-reported outcomes at 5 years after ACL injury and found no significant differences in change of score from baseline to 5 years in those managed with early reconstruction versus those managed nonoperatively or with ACLR, have similar patient-reported outcomes scores at up to 5 years after injury.

LONG-TERM JOINT HEALTH

Preventing further intra-articular injury and preserving joint surfaces for long-term knee health are purposed reasons to surgically stabilize an unstable knee.⁵ Patients who

had increased knee laxity after an ACL injury are more likely to have late meniscal surgery, ³³ and time from ACL injury is associated with the number of chondral injuries and severity of chondral lesions, ³⁶ Injury to menisci or articular cartilage places the knee at increased risk for the development of osteoarthritis. ³⁹ Barenius and colleagues ³⁹ found a 3-fold increase in knee osteoarthritis prevalence in surgically reconstructed knees 14 years after surgery. They concluded that although ACLR did not prevent secondary osteoarthritis, initial meniscal resection was a risk factor for osteoarthritis with no differences in osteoarthritis prevalence seen between graft types. ³⁹ A recent systematic review compared operatively and monoperatively treated patients at a mean of 14 years after ACL injury ⁴⁰ and found no significant differences between groups in radiographic osteoarthritis. ⁴⁰ The operative group had less subsequent surgery and meniscal tears as well as increased Tegner change scores; however, there were no differences in Lysholm or IKDC scores between groups. ⁴⁰ The current evidence does not support the use of ACLR to reduce secondary knee osteoarthritis after ACL injury.

RETURN TO PREINJURY SPORTS

Returning to sports is often cited as the goals of athletes and health care professionals after ACL injury or ACLR. When asked, 90% of National Football League (NFL) head team physicians thought that 90% to 100% of NFL players returned to play after ACLR.⁴¹ Shah and colleagues⁴² found that, regardless of position, 63% of NFL athletes seen at their facility returned to play. A recent systematic review reported 81% of athletes return to any sports at all, but only 65% returned to their preinjury level, and an even smaller percentage, 55%, return to competitive sports (Fig. 1).⁴³ This review found that younger athletes, men, and elite athletes were more likely to return to sports.⁴³ Similar reports within this range are common when examining amateur athletes by sport. McCullough and colleagues⁴⁴ report that 63% of high school and 69% of college football players return to sport. Shelbourne and colleagues⁴⁵ found that 97% of high school basketball players return to play, 93% of high school women soccer players, and 80% of high school male soccer players returned to play. Brophy and colleagues⁴⁶ found a slightly different trend in soccer players: 72% returned to play, whereas 61% returned to the same level of competition, but when broken down by

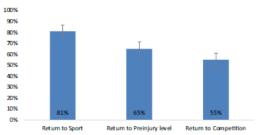


Fig. 1. Reported return-to-sport rates after ACLR from Arden and colleagues' 2014 systematic review and meta-analysis. (Data from Ardern CL, Taylor NF, Feller JA, et al. Fifty-five per cent return to competitive sport following anterior cruciate ligament reconstruction surgery: an updated systematic review and meta-analysis including aspects of physical functioning and contextual factors. Br J Sports Med 2014;48:1543–52.)

sex, more men (75%) returned than women (67%). These studies highlight that although there may be a link between sport and return to sport, due to a lack of high-quality research, current literature was unable to come to any conclusion.⁴⁷

Reduced return to sport rates can be attributed to many factors, including age, sex, preinjury activity level, fear, and psychological readiness. Age and sex are 2 variables that have been identified in multiple studies, 43,46 with men and younger athletes being more likely to return to sport. Age may be a proxy measure for changing priorities (ie, family), commitments (ie, employment), and/or opportunities to play at the same level (ie, no longer have the competitive structure of high school, college, or club sports). Furthermore, it has been hypothesized that "For those athletes whose life and social networks are inherently structure around participating in sport, a stronger sense of athletic identity may be a positive motivator for return to sport."43 Although this hypothesis remains to be tested, this could explain the higher rates of return to sport in younger and elite/professional level athletes. Dunn and Spindler⁴⁸ found that higher level of activity before injury and a lower body mass index were predictive of higher activity levels at 2 years following ACLR. Ardern and colleagues 43 found that elite athletes were more likely to return to sport than lower-level athletes. 43 Professional and elite-level athletes may have access to more resources, particularly related to rehabilitation services, but motivation to return to that high level of play and athletic identity may also drive such return to sport. Interestingly, Shah and colleagues⁴² found that in NFL players return to play was predicted by draft round. Athletes drafted in the first 4 rounds of the NFL draft were 12.2 times more likely to return to sport than those athletes drafted later or as free agents; this could represent the perceived talent of the player as well as the investment of the organization in that player.⁴²

Despite common misconceptions, nonoperatively managed athletes can return to sport without the need for reconstruction. Efitzgerald and colleagues ferported a decision-making scheme for returning ACL-deficient athletes to sport in the near term, without furthering of meniscal or articular cartilage injury. There is a paucity of long-term evidence, however, on nonoperatively managed athletes returning to high-level sports. Grindem and colleagues for compared return to sport in operatively and nonoperatively managed athletes after ACL injury. They found no significant differences between groups in level I sports participation, and higher level II sports participation in the nonoperative group in the first year after injury. Grindem's study is the only study to the authors' knowledge comparing return to sport rates in the longer term. Further research is needed on long-term nonoperatively managed athletes after ACL injury.

REINJURY

Second injury, whether it is an insult to the ipsilateral graft or the contralateral ACL, is a growing problem after ACLR because rates appear to be higher than once thought. Risk factors for second injury include younger athletes⁴⁹ who return to high-level sporting activities early, ^{50,51} with women having a higher risk of contralateral injury, ^{52,53} and men having a higher risk of ipsilateral injury. ^{54,55} Although second injury rates in the general population 5 years after reconstruction are reported to be 6%, ⁵⁶ rates in young athletes are considerably higher. ⁵¹ Paterno and colleagues ⁵¹ followed 78 athletes after ACLR and 47 controls over a 24-month period. They found an overall second injury rate of 29,5%, which was an incidence rate nearly 4 times that of the controls (8%). More than 50% of these injuries occurred within the first 72 athletic exposures, whereas in the control group, only 25% were injured within the same time frame. ⁵¹ The MOON cohort reported a 20% second injury rate in women and a 5.5% rate in men of 100

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soccer players returning to sport after ACLR. ⁴⁶ Shelbourne and colleagues⁵⁵ and Leys and colleagues⁵⁷ reported 17% second injury rates in younger athletes. Besides missing more athletic time, increasing health care costs, and increased psychological distress, reinjury and subsequent revision surgery have significantly worse outcomes compared with those after initial reconstruction (Fig. 2). ³⁴

DISCUSSION

ACLR continues to be the gold-standard treatment of ACL injuries in the young athletic population. A survey of American Academy of Orthopedic Surgeons reported 98% of surgeons would recommend surgery if a patient wishes to return to sport, with 79% thinking that ACL-deficient patients are unable to return to all recreational sporting activities without reconstruction. 5 Revisiting the successful outcomes criterion after ACL injury, a successful outcome is considered no reinjury or recurrent giving way, no joint effusion, quadriceps strength symmetry, restored activity level and function, and returning to preinjury sports. 10 After reviewing the current literature and looking at these criteria, counseling athletes to undergo early reconstruction after ACL injury may not be in the athlete's best interest. Undergoing reconstruction does not guarantee athletes return to their preinjury sport, and return to the preinjury competitive level of sport is unlikely. The risk of a second injury is high in young athletes returning to sport, especially in the near term. The risk of secondary injury increases for the contralateral limb in women or the ipsilateral limb in men. The risk for developing osteoarthritis is high in the long term regardless of surgical intervention, and even higher if a revision procedure is required. 56 A Cochrane Review found that there was insufficient evidence to recommend ACLR compared with nonoperative treatment, and recent randomized, controlled trials have found no difference between those who had ACLR and those treated nonoperatively with regard to knee function, health status, and return to preinjury activity level and sport after 2 and 5 years in young, active individuals. 19,37,59 With no differences in outcomes between early reconstruction, delayed reconstruction, and no surgery at all, counseling should start by considering nonoperative management. Eitzen and Moksnes⁶⁰ found a 5-week progressive exercise program after ACL injury led to significantly improved knee function before deciding to undergo reconstruction or remain nonoperatively managed (Fig. 3). The authors reported good compliance with few adverse events during training. Nonoperative management is a viable evidence-based option after ACL injury, allowing some

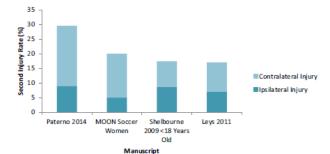


Fig. 2. Second ACL injury rates after ACLR.



Fig. 3. Unilateral rollerboard portion of perturbation training. The athlete attempts to maintain balance in slight knee flexion while the therapist performs manual perturbations. Progression includes adding sport-specific tasks while maintaining balance.

athletes to return to sport despite being ACL-deficient, with equivalent functional outcomes to those after ACLR. Given there is no evidence in outcomes to undergo early ACLR, nonoperative management should be a first line of treatment choice in athletes after ACL injury (Table 2).

Table 2 Decision-making scheme for ACL deficient athletes		
Test	Criteria	
Global rating of perceived knee function	≥60%	
KOS-ADLS	≥80%	
Episodes of giving way	≤1	
Timed hop limb symmetry index	≥80%	

Global rating of perceived knee function (GRS) is a scale from 0 to 100 asking the athlete to rate their current knee function, with 100 being back to all preinjury activity and function. KOS-ADLS is a patient-reported outcome measure evaluating knee function within daily activity. Episodes of giving way are true moments of instability in which a shifting occurs in the tibiofemoral joint, resulting in an increase in knee pain and joint effusion. The timed hop is one component of hop testing in which the athlete unilaterally hops down a 6-m line as fast as possible. Symmetry index is calculated by dividing the uninvolved limb time by the involved limb time and multiplying by 100.

by 100.

Data from Fitzgerald GK, Axe MJ, Snyder-Mackler L. A decision-making scheme for returning patients to high-level activity with nonoperative treatment after anterior cruciate ligament rupture.

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Appendix B

DOES EXTENDED PRE-OPERATIVE REHABILITATION

INFLUENCE OUTCOMES 2 YEARS AFTER ACLR?

Does Extended Preoperative Rehabilitation Influence Outcomes 2 Years After ACL Reconstruction?

A Comparative Effectiveness Study Between the MOON and Delaware-Oslo ACL Cohorts

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Background: Rehabilitation before anterior cruciate ligament (ACL) reconstruction (ACLR) is effective at improving postoperative outcomes at least in the short term. Less is known about the effects of preoperative rehabilitation on functional outcomes and return-to-sport (RTS) rates 2 years after reconstruction.

Purpose/Hypothesis: The purpose of this study was to compare functional outcomes 2 years after ACLR in a cohort that underwent additional preoperative rehabilitation, including progressive strengthening and neuronuscular training after impairments were resolved, compared with a nonexperimental cohort. We hypothesized that the cohort treated with extended preoperative rehabilitation would have superior functional outcomes 2 years after ACLR.

Study Design: Cohort study: Level of evidence, 3.

Methods: This study compared outcomes after an ACL rupture in an international cohort (Delaware-Oslo ACL Cohort [DOC]) treated with extended preoperative rehabilitation, including neuromuscular training, to data from the Multicenter Orthopaedic Outcomes Network (MOON) cohort, which did not undergo extended preoperative rehabilitation. Inclusion and exclusion criteria from the DOC were applied to the MOON database to extract a homogeneous sample for comparison. Patients achieved a quiet knee before ACLR, and postoperative rehabilitation followed each cohort's respective criterion-based protocol. Patients completed the International Knee Documentation Committee (IKDC) subjective knee form and Knee Injury and Osteoarthritis Outcome Score (KOOS) at enrollment and again 2 years after ACLR. RTS rates were calculated for each cohort at 2 years.

Results: After adjusting for baseline IKDC and KOOS scores, the DOC patients showed significant and clinically meaningful differences in IKDC and KOOS scores 2 years after ACLR. There was a significantly higher (P < .001) percentage of DOC patients returning to preinjury sports (72%) compared with those in the MOON cohort (63%).

Conclusion: The cohort treated with additional preoperative rehabilitation consisting of progressive strengthening and neuromus-cular training, followed by a criterion-based postoperative rehabilitation program, had greater functional outcomes and RTS rates 2 years after ACLR. Preoperative rehabilitation should be considered as an addition to the standard of care to maximize functional

Keywords: knee; return to sport; rehabilitation; prehabilitation; ACL reconstruction; outcomes

Early anterior cruciate ligament (ACL) reconstruction (ACLR) remains the gold standard of treatment for active patients with ACL ruptures in the United States, 20,22 with up to 175,000 reconstructions being performed annually.²⁸

The goals for ACLR include restoring primary passive restraint, returning to preinjury activities and previous levels of function, and preserving long-term knee joint health.^{20,22} Reconstruction, however, does not guarantee health. —— Reconstruction, however, does not guarantee a return to previous activities or functional levels or the pre-vention of posttraumatic knee osteoarthritis. 10,11,20 Large, multicenter orthopaedic registries have been developed and implemented to track outcomes after ACLR in the United States and abroad. The Multicenter

Orthopaedic Outcomes Network (MOON) registry pools data together from 7 orthopaedic centers across the United States. ²⁷ These centers are all highly active in orthopaedic and sports clinical treatment and research, with unified preparative milestones to undergo ACLR and a single criterion-based postoperative protocol with objective return-to-sport (RTS) criteria. ^{27,20} The MOON cohort can serve as the benchmark or usual care for comparative effectiveness studies to compare ACLR outcomes. 27

Rehabilitation before surgery, termed "preoperative rehabilitation" or "prehabilitation," is physical preparation for a period of immobility and reduced activity due to surfor a period of immobility and reduced activity due to sur-gery. Few studies have explored the effects of preoperative rehabilitation on outcomes after ACLR. ¹³ Shaarani and colleagues, ²⁵ in a randomized controlled trial, found that a 6-week preoperative rehabilitation program led to improved functional performance and self-reported func-tion up to 12 weeks after reconstruction. The addition of neuromuscular training to preoperative rehabilitation is another strengt to improve outcomes after an ACL. another attempt to improve outcomes after an ACL injury.^{6,7,14,15} Specifically, perturbation training has been studied in conjunction with a preoperative rehabilitation program⁹ and is currently under investigation for its use after surgery.²⁹ Grindem and colleagues¹² compared functional outcome measures 2 years after ACLR in the Norwegian half of our cohort to usual care as benchmarked by the Norwegian Knee Ligament Registry (NKLR). There were statistically significant and clinically meaningfully better outcomes in the Delaware-Oslo ACL Cohort (DOC) as evidenced by higher Knee injury and Osteoarthritis Outcome Score (KOOS) results. The limitation of this study, how-ever, is that rehabilitation in the NKLR was not standardized. The question remains how progressive preoperative rehabilitation that includes neuromuscular training affects outcomes after ACLR when both cohorts receive otherwise similar care.

The purpose of this study was to assess functional out-

comes 2 years after ACLR in a cohort that underwent additional preoperative rehabilitation, including progressive strengthening and neuromuscular training after impairments were resolved, compared with a nonexperimental ref-erence group (MOON cohort). We hypothesized that the cohort treated with extended preoperative rehabilitation

ould have superior functional outcomes 2 years after ACLR. The implications of this research could lead to changes in the standard of care before undergoing recon-struction after an ACL injury.

This was a cohort study comparing outcomes in an international cohort (DOC) treated with extended preoperative rehability bilitation, including neuromuscular training, with data from a nonexperimental cohort (MOON consortium). The out-comes of interest included preoperative and postoperative International Knee Documentation Committee (IKDC) sub-jective knee form² scores as well as KOOS²⁴ results and RTS rates. Eighty-four patients from the Norwegian arm of the DOC were previously included in the comparison to the NKLR by Grindem and colleagues¹² described above.

The DOC is an ongoing, international prospective collaboration evaluating the effects of neuromuscular training after an ACL injury and reconstruction. This collaboration includes 150 patients from the University of Delaware in the United States and 150 patients from the Norwegian Research Center for Active Rehabilitation, Norwegian School of Sport Sciences in Oslo, Norway. Patients were enrolled at both centers between 2007 and 2012. Patients were included if they had a unilateral primary ACL rup-ture within 7 months of enrollment and participated in level 1 or 2 sports (IKDC activity classification) for more than 50 hours per year before the injury.⁴ Patients were excluded if they had a concomitant grade 3 ligamentous injury, a full-thickness articular cartilage lesion larger than 1 cm², a symptomatic meniscal tear, a potentially repairable meniscal tear, or a previous injury or surgery of the uniquely large All patients wedevent initial impairs. were included if they had a unilateral primary ACL rupthe uninvolved knee. All patients underwent initial impairment resolution (little to no swelling or pain, full range of motion [ROM], 70% quadriceps strength index), followed by progressive strengthening and neuromuscular training called perturbation training, as previously described by Eitzen and Moksnes.⁹ After completion of these additional

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training sessions, patients selected to undergo ACLR or remain nonoperatively managed. While all patients were followed, only those who underwent ACLR were included in this analysis. Those from the DOC who did not immediately undergo reconstruction after training continued on a home exercise program, if needed, for maintenance until reconstruction was performed (see Appendix 1, available online at http://ajsmsagepub.com/supplemental). All patients after ACLR underwent a criterion-based postoperative rehabilitation protocol with strict RTS criteria. The University of Delaware Institutional Review Board and the Region Ethics Committee for South East Norway approved all aspects of this study, and written informed consent was obtained for all patients before enrollment.

The MOON cohort consists of patients enrolled between 2002 and 2008 from 7 orthopaedic/sports medicine centers around the United States. Patients were included if they were scheduled to undergo unilateral ACLR and were between the ages of 10 and 85 years. Patients were enrolled at the time of presentation to the orthopaedic surgeon and were observed prospectively after surgery. This cohort was intended to be community based, with all ages, activity levels, injury history, and concomitant injuries included. ²⁷ All patients after ACLR underwent a criterion-based postoperative rehabilitation protocol with strict RTS criteria (see Appendix 2, available online). ³⁰ Institutional review board approval was obtained from all participating centers, and written informed consent was obtained for all patients before enrollment.

For this study, inclusion and exclusion criteria from the DOC were applied to the MOON cohort, and only those who met the criteria for the DOC described above were included. MOON data were extracted based on these criteria, and deidentified data were provided for analysis. Patients whose imaging revealed a potentially repairable meniscal injury were excluded from enrollment in the DOC. During reconstruction, however, 11% of the DOC patients underwent concomitant meniscal repair, despite initial presentation on imaging, and we therefore included those who underwent concomitant meniscal repair from the MOON dataset. Surgical variables recorded included graft type, concomitant meniscal procedures, and articular cartilage condition (Figure 1).

Criteria for Reconstruction

Both cohorts used guidelines to determine when athletes were ready to undergo ACLR. The recommendations for the DOC patients to undergo ACLR were little to no knee joint effusion, symmetrical knee ROM, no obvious gait impairments, and a minimum of 70% quadriceps strength index (quiet knee). The MOON preoperative guidelines included no obvious gait impairments, knee ROM from 0° to 120° , minimal knee joint effusion, and the ability to complete 20 straight-leg raises without a lag.

Rehabilitation

Postoperative rehabilitation for the DOC patients followed a rigorous criterion-based protocol. Objective clinical criteria, such as pain, ROM, quadriceps strength and activation,

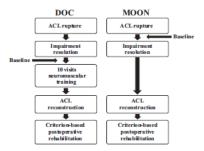


Figure 1. Testing timeline differences between cohorts. ACL, anterior cruciate ligament; DOC, Delaware-Oslo ACL Cohort; MOON, Multicenter Orthopaedic Outcomes Network.

and changes in knee joint effusion, were used to monitor and determine progression through the different phases of postoperative rehabilitation. These criteria, in addition to functional performance testing and patient-reported outcomes, were utilized to determine RTS readiness for athletes. Patients were observed for repeated testing at 6, 12, and 24 months after reconstruction. If patients were not maintaining strength or functional levels required to return to sport, counseling was provided. The respective rehabilitation rectored seen he found in Appendices 1 and 2

tion protocols can be found in Appendices 1 and 2. The MOON cohort patients followed a unified postoperative protocol regardless of the location at which their surgery or rehabilitation was performed. This protocol was criterion based, utilizing measures of pain, ROM, functional strength, and movement quality to progress patients through the phases of rehabilitation. RTS readiness was determined by a combination of objective measures (functional performance testing, patient-reported outcomes) and subjective measures (movement quality and confidence). Beyond those RTS criteria, the MOON protocol also recommended isokinetic strength testing, vertical jumps, and deceleration testing.

Outcome Measures

Patients completed the IKDC and KOOS preoperatively and again 2 years after ACLR. The IKDC is a valid and reliable measure commonly used in the ACL population. ^{2,16} The minimal clinically important difference (MCID) for the IKDC is 11.5 points. ¹⁶ The KOOS is a valid and reliable outcome measure commonly used in the ACL-injured population to assess outcomes in knee pain, knee symptoms, knee function in daily activity, knee function in sporting activity, and knee-related quality of life. ^{20,24} The proposed MCID for each subscale is 10 points. ²³
At enrollment, each patient was asked to report his or

At enrollment, each patient was asked to report his or her primary sporting activity before the injury. At 2-year follow-up, patients were asked to name their primary sport

TABLE 1 Comparison of Baseline Characteristics Between Cohorts a

	DOC (n = 192)	MOON (n = 1995)	P Value
Age, y	24.7 ± 9	24.3 ± 10	.612
Sex, % male	55	54	.144
Body mass index, kg/m ²	24.5 ± 4	25.0 ± 4	.231
Time from injury to enrollment, mo	1.9 ± 1	<6.0	

^aData are reported as mean ± SD unless otherwise indicated. DOC, Delaware-Oslo ACL Cohort; MOON, Multicenter Orthopaedic Outcomes Network.

	DOC (n = 192)	MOON (n = 1995)	P Value
Patellar tendon autograft	21	48	.001
Hamstring autograft	51	36	.006
Soft tissue allograft	28	16	.005
No meniscal procedure	60	46	.029
Meniscal excision	18	28	.017
Meniscal repair	11	14	.301
Meniscal trephination	2	2	>.999
Combination of meniscal procedures	9	11	.433
Time from ACLR to 2-y follow-up, y	2.1 ± 0.2	2.4 ± 0.4	.532

"Data are reported as % unless otherwise indicated. ACLR, anterior cruciate ligament reconstruction; DOC, Delaware-Oslo ACL Cohort; MOON, Multicenter Orthopaedic Outcomes Network. [AQ: 2]

currently (MOON) or if they had returned to their preinjury sport (DOC). Patients were considered to have returned to sport if they were participating in their preinjury sport 2 years after ACLR.

Statistical Analysis

Group differences were analyzed using chi-aquare tests for nominal variables and t tests for continuous variables. To account for differences in baseline IKDC scores, a 1-way analysis of covariance (ANCOVA) was used to compare 2-year IKDC scores between groups with baseline IKDC scores as a covariate. To account for differences in baseline KOOS values, a 1-way ANCOVA was used to compare 2-year KOOS values between groups with baseline KOOS values as a covariate for each subscale. Because differences were found between groups in the proportion of concomitant meniscal surgery, an analysis of variance (ANCVA) was used to assess the interaction of group and meniscal surgery on 2-year IKDC scores. Because differences were found between groups in the proportion of graft types used for ACLR, an ANOVA was used to assess the interaction of group and graft type on 2-year IKDC scores All statistical analyses were performed using PASW version 23 (SPSS Inc).

RESULTS

Patients who underwent ACLR from the DOC (n=192) as well as 1995 MOON patients who met the DOC inclusion criteria were included in this study. There were no

differences between groups in age, sex, or body mass index (Table 1). Baseline Marx scores were available in the MOON cohort (12.78 \pm 4) but not the DOC. Surgical demographics revealed a higher proportion of patellar tendon autografts (P=.001) in the MOON cohort patients and a higher proportion of hamstring autografts (P=.006) in the DOC patients. There was also a significantly higher proportion of concomitant meniscal surgery performed (P=.029 [AQ: 1] in the MOON cohort (Table 2). There were no significant group \times meniscal procedure (P=.345) or group \times graft type (P=.073) interactions on 2-year IKDC scores.

year IRDC scores. DOC patients had significantly higher baseline IKDC scores compared with the MOON cohort patients (70 \pm 13 vs 50 \pm 17, respectively; P<.001), which also exceeded the MCID (Figure 2). The IKDC score in DOC patients significantly improved from baseline to posttraining (after preoperative rehabilitation) (from 70 \pm 13 to 77 \pm 13; P<.001). Two years after reconstruction, 148 patients from the DOC and 1994 patients from the MOON cohort completed the IKDC. After controlling for baseline IKDC scores, DOC patients continued to have significantly higher IKDC scores than MOON cohort patients at 2 years after ACLR (84 \pm 25 vs 71 \pm 32, respectively; P<.001), again exceeding the MCID (Figure 3). Post hoc power analysis revealed the ability to detect a difference of 2 points on the IKDC between groups.

Baseline KOOS values were available for 1991 patients in the MOON ohort and 58 patients in the DOC. DOC patients had significantly higher baseline KOOS values than MOON cohort patients across all subscales: pain (84

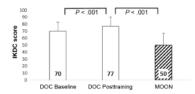


Figure 2. Baseline International Knee Documentation Committee (IKDC) scores between cohorts. DOC, Delaware-Oslo ACL Cohort; MOON, Multicenter Orthopaedic Outcomes Network.

 \pm 11 vs 73 \pm 17, respectively), symptoms (75 \pm 14 vs 67 \pm 18, respectively), activities of daily living (93 \pm 7 vs 82 \pm 17, respectively), sports/recreation (66 \pm 19 vs 48 \pm 29, respectively), and quality of life (51 \pm 19 vs 37 \pm 20, respectively) (all P < .001). After controlling for baseline KOOS values, DOC patients continued to have higher and clinically meaningful differences in KOOS subscale scores at 2 years compared with MOON cohort patients: pain (94 \pm 10 vs 78 \pm 33, respectively, P = .004, symptoms (89 \pm 12 vs 72 \pm 32, respectively, P < .001), activities of daily living (98 \pm 5 vs 82 \pm 34, respectively, P = .006), sports/recreation (85 \pm 18 vs 70 \pm 33, respectively, P < .001), and quality of life (76 \pm 20 vs 64 \pm 32, respectively, P = .072) (Figure 4). RTS rates were significantly higher in the DOC (72%) compared with the MOON cohort (63%) (P < .001).

DISCUSSION

The purpose of this study was to compare functional outcomes 2 years after ACLR in DOC patients who underwent additional progressive preoperative rehabilitation, including neuromuscular training, compared with the MOON chort. The primary findings of this study are that the DOC patients had significantly higher and clinically meaningful patient-reported function and higher RTS rates 2 years after ACLR. Grindem and colleagues from that preoperative rehabilitation led to higher KOOS values 2 years after reconstruction compared with the patients in the NKLR; however, the NKLRs postoperative rehabilitation was not standardized. Conversely, the patients in the MOON cohort received specified postoperative care at facilities that were part of large orthopaedic and sports medicine research centers, which allowed for a more homogeneous comparison between cohorts. This study did not determine what the optimal preoperative rehabilitation program is most important (ie, progressive strengthening, neuromuscular training), but it does suggest that giving patients additional rehabilitation beyond a quiet knee (full ROM and quadriceps activation, little to no pain, or joint effusion) before surgery may lead to meaningful improved outcomes 2 years after ACLR.

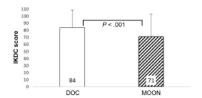


Figure 3. International Knee Documentation Committee (IKDC) scores 2 years after anterior cruciate ligament reconstruction. DOC, Delaware-Oslo ACL Cohort; MOON, Multicenter Orthopaedic Outcomes Network.

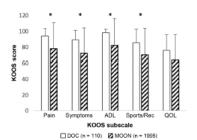


Figure 4. Knee injury and Osteoarthritis Outcome Score [KOOS] results by subscale at 2 years after anterior cruciate ligament reconstruction. "Statistically significant betweengroup difference (P < .05). ADL, activities of daily living; DOC, Delaware-Oslo ACL Cohort; MOON, Multicenter Orthopaedic Outcomes Network; QOL, quality of life; Sports/Rec, sports/recreation.

Preoperative IKDC scores were higher in the DOC and may have been related to differences in the timing of baseline testing between cohorts. Baseline testing may have occurred before impairment resolution in the MOON cohort; however, the MOON protocol called for impairments to be resolved before undergoing reconstruction. Both cohorts had to achieve minimum criteria before surgery, ensuring that neither cohort had substantial impairments going into reconstruction. Several studies have shown preoperative muscle performance maximization and ROM deficit minimization related to optimized postoperative outcomes. 55.18.21 This is also consistent with previously published findings that preoperative outcome scores significantly predict postoperative outcome scores. 26 Eitzen and Moksnes found that a 5-week preoperative program can lead to improved functional

outcomes after ACLR. Our overall findings are consistent with both Eitzen et al [AQ: 3] and Grindem et al 12 in that progressive preoperative rehabilitation is an important factor to maximize postoperative outcomes.

While each cohort used a different rehabilitation proto-

While each cohort used a different rehabilitation protool for preoperative and postoperative rehabilitation, both
protocols utilized a criterion-based approach. Criterionbased rehabilitation protocols utilizing tissue-healing
time frames, factors associated with outcomes, and expert
opinion are considered the most evidence-based protocols
to our current knowledge. Both of the protocols used
have been published and are considered standard of care
after an ACL injury. ^{1,30} The primary difference between
the postoperative protocols is that the DOC protocol used
primarily objective criteria and the MOON cohort used
a mixture of objective and subjective criteria for program
advancement. Patients in the DOC also underwent structured follow-up testing at 6 months and 1 year after
ACLR, which may have benefited them in terms of progressing home exercise programs or providing counseling
and/or consultation on current functional status. While differences between graft type and meniscal procedure proprotions between cohorts also have the potential to
influence outcome scores at 2 years, our analysis of graft
type and meniscal procedure on IKDC scores suggests
that differences in proportions of surgical variables
between cohorts did not have an effect on the outcome
scores.

The DOC patients had a significantly higher RTS rate 2 years after ACLR compared with the MOON cohort patients. The MOON cohort's RTS rate of 63% is consistent with the Ardem et al. meta-analysis that reported that 65% exceeded both that of the MOON cohort and that reported by Ardem et al. Dijective RTS criteria were used in both cohorts to determine individual readiness to return to sport among patients. There is currently no consensus on specific RTS criteria; however, the use of clinical, functional performance, and patient-reported outcome measures has been suggested as the current standards after ACLR. The DOC criteria used higher cutoff scores than the MOON criteria, which ensured higher symmetry between limbs before clearance for RTS. Functional performance symmetry restoration is needed to maximize patient-reported functional recovery. and may also explain some of the variation in 2-war outcome scores between chords.

2-year outcome scores between cohorts.

A limitation of our study is that comparing 2 separate cohorts does not allow for a true cause and effect evaluation of extended preoperative rehabilitation to postoperative outcomes. There were also some differences in the postoperative rehabilitation programs, graft types, and RTS criteria that may have affected the outcomes. The strengths of this study are the large sizes of the cohorts, the application of similar inclusion and exclusion criteria to both cohorts for a homogeneous comparison, and the use of criterion-based postoperative protocols. Future studies should use the randomized controlled trial study design to better assess the value of preoperative rehabilitation after an ACL rupture.

CONCLUSION

The cohort treated with preoperative rehabilitation consisting of progressive strengthening and neuromuscular training had higher functional outcomes and RTS rates compared with the benchmark cohort that also used a criterion-based postoperative rehabilitation program 2 years after ACIR. The standard of care in the United States is to achieve a quiet knee before undergoing reconstruction. While achieving a quiet knee before surgery may thwart surgical complications such as arthrofibrosis, it may not be enough to maximize functional outcomes even with rigorous postoperative rehabilitation. Progressive preoperative rehabilitation before ACIR should be considered as an addition to the standard of care to maximize functional outcomes after ACIR.

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Does Extended Preoperative Rehabilitation Influence

Outcomes 2 Years After ACL Reconstruction?: A Comparative Effectiveness Study Between

the MOON and Delaware-Oslo ACL Cohorts

Author: Mathew J. Failla, David S.

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Medicine

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Appendix C

MOON REHABILITATION PROTOCOL



MOON ACL Rehabilitation Guidelines

General Information: The following ACL rehabilitation guidelines are based on a review of the randomized controlled trials related to ACL rehabilitation. For many aspects of ACL rehabilitation there are either no studies that qualify as "best-evidence" or the number of studies is too few for conclusions to be drawn with confidence. In these circumstances, the recommendations are based upon the guidance of the MOON panel of content experts.

The guidelines have been developed to service the spectrum of ACL injured people (non-athlete & elite athlete). For this reason, example exercises are provided instead of a highly structured rehabilitation program. Attending rehabilitation specialists should tailor the program to each patient's specific needs.

The multi-center nature of the MOON group necessitates that the MOON ACL Rehabilitation Program only include treatment methods that can be employed at all sites without purchasing expensive equipment. Consequently, some treatment methods with supporting evidence (e.g., using a high-intensity electric stimulation training program for strength, aquatic therapy) are not included in the program because the expert panel believed that it is unreasonable to expect all sites to carry out such treatments.

Progression from one phase to the next is based on the patient demonstrating readiness by achieving functional criteria rather than the time elapsed since surgery. The timeframes identified in parentheses after each Phase are approximate times for the average patient, NOT guidelines for progression. Some patients will be ready to progress sooner than the timeframe identified, whereas others will take longer.

The recommended number of visits to the rehabilitation specialist (including visits merely for evaluation / exercise progression) is 16 to 24 visits with the majority of the visits occurring early (BIW x 6 weeks). However, it is recognized that some patient's health plans are severely restrictive. For this reason, the minimum number of post-ACL reconstruction visits to a rehabilitation specialist has been set at 6 visits for the MOON group patients.

If there are any questions regarding the MOON ACL Rehabilitation Guidelines, then please contact Dr. or the Sports Medicine Center's Rehabilitation Liaison:



Phase 0: Pre-operative Recommendations

- Normal gait
- AROM 0 to 120 degrees of flexion
- Strength: 20 SLR with no lag
- Minimal effusion
- · Patient education on post-operative exercises and need for
- · Educated in ambulation with crutches
- · Wound care instructions
- · Educated in MOON follow-up expectations

PHASE 1: Immediate Post-operative Phase (Approximate timeframe: Surgery to 2 weeks)

GOALS

M.O.O.N.

Orthopaedics Outcomes

Group Multicenter

Network

- Full knee extension ROM
- Good quadriceps control (≥ 20 no lag SLR)
- Minimize pain
 Minimize swelling
- · Normal gait pattern

Crutch Use: WBAT with crutches (beginning the day of surgery)

Crutch D/C Criteria: Normal gait pattern

Ability to safely ascend/descend stairs without noteworthy pain or

Instability (reciprocal stair climbing)

Knee Immobilizer: None (Exception: First 24 hours after a femoral

Cryotherapy: Cold with compression/elevation (e.g. Cryo-cuff, ice with compressive stocking)

- · First 24 hours or until acute inflammation is controlled: every hour for 15 minutes
- After acute inflammation is controlled: 3 times a day for 15 minutes
- Crushed ice in the clinic (post-acute stage until D/C)

EXERCISE SUGGESTIONS

• Extension: Low load, long duration (~5 minutes) stretching (e.g., heel prop, prone hang minimizing co-contraction and nocioceptor response)



- · Flexion: Wall slides, heel slides, seated assisted knee flexion, bike: rocking-for-range
- Patellar mobilization (medial/lateral mobilization initially followed by superior/inferior direction while monitoring reaction to effusion and ROM)

Muscle Activation/Strength

- Quadriceps sets emphasizing vastus lateralis and vastus medialis activation
- SLR emphasizing no lag
 Electric Stimulation: Optional if unable to perform no lag

Discontinue use when able to perform 20 no lag SLR

- Double-leg quarter squats
- Standing theraband resisted terminal knee extension (TKE)
 Hamstring sets

M.O.O.N.

Outcomes

Network

Group Multicenter Orthopaedics

- Hamstring curls
- Side-lying hip adduction/abduction (Avoid adduction moment in this phase with concomitant grade II III MCL injury)
- · Quad/ham co-contraction supine
- Prone Hip Extension
- Ankle pumps with theraband
- Heel raises (calf press)

Cardiopulmonary

UBE or similar exercise is recommended

Scar Massage (when incision is fully healed)

CRITERIA FOR PROGRESSION TO PHASE 2

- 20 no lag SLR
- Normal gait
- Crutch/Immobilizer D/C
- ROM: no greater than 5° active extension lag, 110° active

PHASE 2: Early Rehabilitation Phase (Approximate timeframe: weeks 2 to 6)

GOALS

- Full ROM
- Improve muscle strength
- · Progress neuromuscular retraining



EXERCISE SUGGESTIONS

ROM

- · Low load, long duration (assisted prn)
- Heel slides/wall slides
- · Heel prop/prone hang (minimize co-contraction / nociceptor
- Bike (rocking-for-range → riding with low seat height)
- · Flexibility stretching all major groups

Strengthening

M.O.O.N.

Multicenter

Outcomes

Network

Orthopaedics

Group

- Quadriceps:
 Quad sets
 - Mini-squats/wall-squats
 - Steps-ups
 - Knee extension from 90° to 40°
 - Leg press
 - Shuttle Press without jumping action

Hamstrings:

- Hamstring curls
- · Resistive SLR with sports cord

Other Musculature:

- Hip adduction/abduction: SLR or with equipment
 Standing heel raises: progress from double to single leg support
- Seated calf press against resistance
- · Multi-hip machine in all directions with proximal pad placement

Neuromuscular training

- · Wobble board
- Rocker board
 Single-leg stance with or without equipment (e.g. instrumented balance system)
- Slide board
- Fitter

Cardiopulmonary

- Bike
- Elliptical trainer
- Stairmaster



CRITERIA FOR PROGRESSION TO PHASE 3

- Full ROM
- Minimal effusion/pain
- Functional strength and control in daily activities
 IKDC Question # 10 (Global Rating of Function) score of ≥ 7 (See page 9)

PHASE 3: Strengthening & Control Phase (Approximate timeframe: weeks 7 through 12)

GOALS

- Maintain full ROM
- Running without pain or swelling
- Hopping without pain, swelling or giving-way

EXERCISE SUGGESTIONS

Strengthening

M.O.O.N. Group

Multicenter

Outcomes

Network

Orthopaedics

- Squats
- Leg press
- Hamstring curl
- Knee extension 90° to 0°
- Step-ups/down
- Lunges
- Shuttle
- Sports cordWall squats

Neuromuscular Training

- Wobble board / rocker board / roller board
- Perturbation training
- Instrumented testing systems
- Varied surfaces

Cardiopulmonary

- Straight line running on treadmill or in a protected environment (NO cutting or pivoting)
- · All other cardiopulmonary equipment



CRITERIA FOR PROGRESSION TO PHASE 4

- · Running without pain or swelling
- Hopping without pain or swelling (Bilateral and Unilateral)
 Neuromuscular and strength training exercises without difficulty

PHASE 4: Advanced Training Phase (Approximate timeframe: weeks 13 to 16)

GOALS

M.O.O.N.

Multicenter Orthopaedics

Outcomes Network

Group

- Running patterns (Figure-8, pivot drills, etc.) at 75% speed without difficulty
 Jumping without difficulty
 Hop tests at 75% contralateral values (Cincinnati hop tests: single-leg hop for distance, triple-hop for distance, crossover hop for distance, 6-meter timed hop)

EXERCISE SUGGESTIONS

Aggressive Strengthening

- SquatsLungesPlyometrics

Agility Drills

- Shuffling
- Hopping
- Carioca
- · Vertical jumps
- Running patterns at 50 to 75% speed (e.g. Figure-8)
- Initial sports specific drill patterns at 50 75% effort

Neuromuscular Training

- Wobble board / rocker board / roller board
- Perturbation training
- · Instrumented testing systems



· Varied surfaces

Cardiopulmonary

- Running
- Other cardiopulmonary exercises

CRITERIA FOR PROGRESSION TO PHASE 5

- Maximum vertical jump without pain or instability
 75% of contralateral on hop tests
 Figure-8 run at 75% speed without difficulty

- IKDC Question # 10 (Global Rating of Knee Function) score of
 8 (See page 9)

PHASE 5: Return-to-Sport Phase (Approximate timeframe: weeks 17 to 20)

GOALS

M.O.O.N. Group Multicenter

Orthopaedics Outcomes

Network

- 85% contralateral strength
 85% contralateral on hop tests
 Sport specific training without pain, swelling or difficulty

EXERCISE SUGGESTIONS

Aggressive Strengthening

- Squats
- LungesPlyometrics

Sport Specific Activities

- Interval training programs
- Running patterns in football
- Sprinting
- Change of direction
- · Pivot and drive in basketball
- Kicking in soccer
- Spiking in volleyball
- Skill / biomechanical analysis with coaches and sports medicine



RETURN-TO-SPORT EVALUATION RECOMMENDATIONS:

- Hop tests (single-leg hop, triple hop, cross-over hop, 6 meter timed-hop)
- Isokinetic strength test (60°/second)
- Vertical jump
 Deceleration shuttle test
- MOON outcomes measure packet (mandatory; should be completed post-testing)

RETURN-TO-SPORT CRITERIA:

- No functional complaints
- Confidence when running, cutting, jumping at full speed
 85% contralateral values on hop tests
- IKDC Question # 10 (Global Rating of Knee Function) of ≥ 9 (See page 9)

M.O.O.N. Group Multicenter Orthopaedics Outcomes Network

Appendix D

DELAWARE-OSLO ACL COHORT REHABILITATION PROTOCOL



Delaware Physical Therapy Clinic 540 S. College Ave Suite 160 Newark, DE 19713 302-831-8893

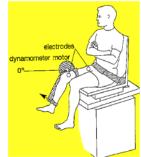
Rehab Practice Guidelines for: ACL Reconstruction

Assumptions: 1. Isolated ACL injury

2. Autograft (See specific graft types for precautions)

Primary surgery: ACL reconstruction
Secondary surgery (possible): See precautions section for modifications related to
Expected # of visits: 16-38
NMES Guideline:

- Electrodes placed over proximal lateral quadriceps and distal medial quadriceps. (Modify distal electrode placement by not covering superior medial (VMO) arthroscopy portal until stitches removed and skin is healed)
- Stimulation parameters: 2500Hz,
 To bursts, 2 sec. ramp, 12 sec. on,
 So sec. rest, intensity to max tolerable
 [at least 50% MVIC(see note at end)], 10
 contractions per session. 3 sessions per
 week until quadriceps strength MVIC is
 80% of uninvolved.
- Stimulation performed isometrically at 60° (dependent on graft site)



Pre-operative Goals: Full knee extension range of motion (ROM), absent or minimal effusion, and no knee extension lag with strainht lag raise /SLR\

extension lag with straight	i leg false (SEIV)	
Immediate Post-	Treatment	Milestones
operative		
(Week 1)	Wall slides, patellar mobilization, gait training ¹ , NMES ^{2,3} (see guidelines) Bike for ROM	AROM/PROM = 0-90° 4,5 Active quadriceps contraction with
TOTAL VISITS 1-3	Tx/HEP: supine wall slides, self patellar mobs 30-50X per day, QS, LAQ (90-45°), and SLR 3x10 (3X per day)	superior patellar glide
Early Post-operative		
(Week 2)	Step ups in pain free range	Flexion >110°
(Week 2)		
(Week 2)	Portal/incision mobilization as needed (if skin is	Walking without crutches
	Portal/incision mobilization as needed (if skin is healed)	Walking without crutches Use of cycle/stair climber without
(Week 2) TOTAL VISITS 4-6	Portal/incision mobilization as needed (if skin is healed) Stairmaster, Wall squats/sits ⁶	Walking without crutches Use of cycle/stair climber without difficulty
	Portal/incision mobilization as needed (if skin is healed) Stairmaster, Wall squats/sits ⁶ Progress to functional brace as swelling permits	Walking without crutches Use of cycle/stair climber without difficulty Walking with full extension
	Portal/incision mobilization as needed (if skin is healed) Stairmaster, Wall squats/sits ⁶ Progress to functional brace as swelling permits Prone hangs if lacking full extension ⁷	Walking without crutches Use of cycle/stair climber without difficulty Walking with full extension Reciprocal stair climbing
	Portal/incision mobilization as needed (if skin is healed) Stairmaster, Wall squats/sits ⁶ Progress to functional brace as swelling permits	Walking without crutches Use of cycle/stair climber without difficulty Walking with full extension

Intermediate Post- operative (Weeks 3-5) TOTAL VISITS 7-15	Tibiofemoral mobilization with rotation if limited Progress bike and Stair master duration (10 minute minimum) Begin Balance and proprioceptive activities	Flexion to within 10° of uninvolved side Quad strength > 60% uninvolved
Late Post-operative (Weeks 6-8) TOTAL VISITS 16-25	Progress exercises in intensity and duration Begin running progression**: on treadmill with functional brace (may vary with MD)* Transfer to fitness facility** * (If all milestones are met) **(see running progression below)	Quad strength >80% Normal gait pattern Full ROM (compared to uninvolved) Effusion < or = trace
Transitional (Weeks 9-12) TOTAL VISITS 25-38	Sports specific activities Agility exercises Functional testing (see description below) Follow up Functional Testing: 4 month, 5 month, 6 month, 1 year post-op, Recommending changes in rehab PRN.	Maintaining or gaining quadriceps strength (>80%) Hop tests >85% (see attached) KOS Sports questionnaire >70% Maintaining gains in strength (> or =
	Progression may include one-legged emphasis in gym, explosive types of activities (cutting, jumping, plyometrics)	Hop Test (> or = 90% to 100%) KOS Sports (> or = 80% to 100%)

MVIC: Maximum Volitional Isometric Contraction

Patient is asked to volitionally extend the involved leg as hard as possible while knee is maintained isometrically at 60° knee flexion. Side to side comparison: (involved/uninvolved X 100 = % MVC)

Precautions:

Precautions:

Patellar tendon graft technique

Be aware of patellofemoral forces and possible irritation during PRE¹s.

Treat patellofemoral pain if it arises with modalities, possible patellar taping.

Consider alteration of knee flexion angle to most comfortable between 45°-60° for MVIC and

NMES treatments.

Hamstring tendon graft technique

No resisted hamstring strengthening until week 12.

Partial meniscectomy
No modifications required; progress per patient tolerance and protocol.

No modifications required; progress per patient tolerance and protocol.

Meniscal repair

No weight-bearing flexion beyond 45° for 4 weeks.

Weight bearing in full extension OK.³

Seated Kinetron and multi angle quadriceps isometric can substitute for weight-bearing exercises.

Concomitant Abrasion Chondroplasty

WBAT with Axillary crutches 3-5 days

No modifications required, progress per patient tolerance and protocol

Concomitant Microfracture

NWB-ing 2-4 weeks with Axillary crutches

No weightbearing activities in treatment for 4 weeks

"Consider location and size of lesion for exercise specific alterations*

Chondral Repair (OATS, ACI, MACI)¹⁰

Follow procedure specific protocol if done concomitantly

Meniscal Transplantation

Follow procedure specific protocol if done concomitantly

MCL injury

Restrict motion to sagittal plane until week 4-6 to allow healing of MCL.

Perform PRE's with tibia in internal rotation during early post-op period to decrease MCL stress.

Consider brace for exercise and periods of activity if severe sprain and/or patient has pain. 11,12

Non Repaired ROM restrictions: Gr 1 no ROM restrictions; Gr 2 0-90° week 1, 0-110° week 2; Gr 3: 0-30° week 1, 0-90° week 2, 0-110° week 3

PCL injury 13

Follow PCL rehabilitation guidelines. (Not ACL protocol)

Posterolateral comer Repair 14

Minimize external rotation torques and varus stress 6-8 weeks

Avoid hover-extension

Avoid hyper-extension No resisted Knee flexion 12 weeks ACL Revision 15

Delay progression of running, hop testing, agility drills, and return to sport by 4 weeks. Crutches and immobilizer will be used 2 weeks following surgery. Otherwise follow same milestones

Running Progression: (requires: trace or less effusion, 80% or > strength, understand soreness rules)

	Running Pr	ogression
	Treadmill	Track
Level 1	0.1 mile walk/0.1 mile Jog repeat 10 times	Jog straights/Walk Curves (2 miles)
Level 2	Alternate 0.1 mile walk/0.2mile jog (2 miles)	Jog straights/Jog 1 curve every other lap (2 miles)
Level 3	Alternate 0.1 mile walk/0.3 mile jog (2 miles)	Jog straights/Jog 1 curve every lap (2 miles)
Level 4	Alternate 0.1 mile walk/0.4 mile jog (2 miles)	Jog 1¾ lap/Walk curve (2 miles)
Level 5	Jog full 2 miles	Jog all laps (2 miles)
Level 6	Increase workout to 2 ½ miles	Increase workout to 2½ miles
Level 7	Increase workout to 3 miles	Increase workout to 3 miles
Level 8	Alternate between running/jogging every 0.25 miles	Increase speed on straights/jog curves

Progress to next level when patient is able to perform activity for 2 miles without increased effusion or pain. Perform no more than 4 times in one week and no more frequently than every other day. Do not progress more than 2 levels in a 7 day period.

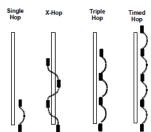
Functional Testing (Weekl2)

Testing: Patient performs one practice on each leg for each hop sequence. Patient performs 2 timed or measured trials on each leg for each hop sequence. Measured trials are averaged and compared involved to uninvolved for single, triple, crossover hop. Compare uninvolved to involved for timed hop.

Passing Criteria for Return to Sport: Greater than or equal to 90% on: quadriceps MVIC, hop testing, KOS-ADLS score,

and Global Rating of knee function score.

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This Clinical Guideline may need to be modified to meet the needs of a specific patient. The model should not replace clinical judgment.

Appendix E

EXTENDED PRE-OPERATIVE REHABILITATION PROTOCOL

UDPT Perturbation Training Program					
	Early (Estimated Treatment 1-3)	Middle (Estimated Treatment 4-7)	Late (Estimated Treatment 8-10)		
Date Completed					
Anterior/Poste rior and Medial/Lateral Roller Board	Position: Patient on board (bilateral 1st treatment, progress to unilateral) – Eyes straight ahead Application: Inform the patient of direction and timing of rollerboard movement – Slow application of force, Low magnitude, – Straight plane of movement (do all A/P reps before you begin M/L) Observe: Cue patient to avoid massive co-contraction at knee – Do not overstress beyond limit of stability (don't induce fall)	Position: Unilateral (avoid forefoot abduction/adduction) Application: Unexpected forces Rapid increasing magnitude force application Add rotation and diagonal motions Alternate plane of movement (start A/P, then M/L, progress to A/L/IR) Short delay between subsequent force applications Distraction: May begin to add distraction (ball toss, stick work) Observe: Observe difficulty with recovery but few to no falls	Position: Unilateral Application: Increased magnitude of force application - Random direction movements - Little to no delay between applications Distraction: Increase speed and magnitude of distraction - Consider sport specific positions Observe: Look for disassociation of hip, knee, and ankle		
Date Completed					
Anterior/Poste rior and Medial/Lateral Tilt Board	Position: Begin bilateral, progress to unilateral - Eyes straight ahead Application: Inform patient of direction and timing of tilting - Slow application of force, Low magnitude - Less force medial than lateral Observe: Cue patient to maintain equal weight bearing bilaterally - Cue patient to avoid massive co-contraction at the knee	Position: Unilateral (avoid forefoot abduction/adduction) Application: Unexpected forces - Rapid, increasing magnitude force application - Hold the board to the floor in one direction and unexpectedly release Distraction: May begin to add distraction (ball toss, stick work) Observe: Look for a rapid return to a stable base after perturbation - Look for dissociation of hip, knee and ankle	Position: Begin to place foot at a diagonal Application: Increased magnitude force application - Random direction movements - Little to no delay between applications Distraction: Increase speed and magnitude of distraction - Consider sport specific positions Observe: Look for minimal sway from stable stance at rest or following any perturbation		

Date Completed						1	
Rollerboard and Stationary Platform	Position: One foot on the rollerboard, one on the platform - Eyes straight ahead, equal weightbearing on both lower extremities Application: Inform patient of direction and timing of movement - Slow application of force, low magnitude - All directions A/P, M/L, IR/ER, diagonals Observe: Cue patient to maintain equal weightbearing bilaterally (watch for unweighting of the involved limb as level of difficulty increases) - Do not overpower the patient, board should not move > 1 or 2 inches - Match therapist's forces w/o excessive movement of roller board	Position: One foot one on the platforn - Eyes straight also weightbearing or extremities Application: Unex - Rapid, increasin, application - Begin combining movements (Ant Distraction: May I distraction (ball to Observe: Cue pation weightbearing bila unweighting of the difficulty level inc - Do not overpowe should not move - Cue patient to reforce (avoid rebomovement)	nead, equal n both lower spected forces g magnitude for g directional with IR) oegin to add ss, stick work; ent to maintain sterally (watch involved limit reases) er the patient, > 1 or 2 incheact as you ren	orce n equal for b as board	Position: One for one on the platformer on the platformer of the p	head, equal on both lower reased magnit ion movemen o delay betweens rease speed an reaction mal/sport speed split, backwitent to maint laterally (wat no involved lincreases) react as you not be the speed and the	rude tts ten d ciffic ard split) ain equal ch for nb as

Setup: The involved leg is placed on either the rollerboard or the stationary platform and after 3 sets of 1 minute, the legs are alternated and the treatment is repeated

Instructions: Meet my force, Don't beat my force.

"When I push the rollerboard, resist the exact movement in speed and magnitude. The board should remain in the same place. Do not overpower me and move the rollerboard away and do not let me overpower you."

COMMON THEMES IN PERTURBATION TRAINING

Time: 3 sets of 1 minute of

Tools: Roller Board, Tilt Board, Stationary Platform, Sport Specific Equipment

each, rest time for calf stretching as needed

Progressions: Vary by individual, estimates are noted above Phases: 10 treatments total

Application to Surface - As the therapist increases the stress to the patient in one area (i.e. change force application from expected to unexpected), the therapist may need to decrease the intensity of another application variable (i.e. magnitude of speed). Once the patient is successful, progress toward resumption of altered variable (magnitude or speed)

Distraction of Patient - When progressing a patient in difficulty level or progressing to the next phase of training, a therapist may need to decrease the distraction level for 1 or 2 treatments until the patient's skill level has improved. Once the patient is successful, progress toward resumption of the previous level of distraction and progress.

Observation of Patient- Each time a therapist adds stress to the training program (by application or distraction) you may see a decrease in

Early (Estimated Treatment 1-3) Middle (Estimated Treatment 4-7) Late (Estimated Treatment 8-10)	performance level. Th	his will require more cueing and feedback until the new skill is acquired and more				re stress can be ir	corporated.			
Resistive Quadriceps/Hamstr ings Training - Weights - Isokinetics Date Completed Agility Program (5 reps of each: begin 3-6 feet progressing to 10 feet) - Forward/backward running (plant on involved leg) - Side shuffle - Carioca/Braiding - Corner Turn/Pivot Turn/Pivot - Carioca/Braiding - Corner Turn/Pivot - Carioca/Braiding - Carioca/Braiding - Corner Turn/Pivot - Carioca/Braiding - Cor		Early (Estin	mated Treatm	ent 1-3)	Middle (Estir	nated Treatme	ent 4-7)	Late (Estima	ted Treatment	8-10)
Quadriceps/Hamstrings Training - Weights - Isokinetics Date Completed Agility Program (5 reps of each: begin 3-6 feet progressing to 10 feet) - Forward/backward running (plant on involved leg) - Side shuffle - Carioca/Braiding - Corner Turn/Pivot - Corner Turn/Pivot - Carioca/Braiding - Corner Turn/Pivot	Date Completed									
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Return to Sport Specific Activity	If return to sport before surgery: Start sport specific activities immediately If no return to sport before surgery: Sports specific activities not to be completed	Begin sports specific skills: - Dribble basketball, straight shots (no jumping) - Backboard tennis within arms' reach - Low level soccer ball handling - Stroking for skaters Progression: Patient specific based on performance in perturbation skills	Transition to Play: One on one basketball (time limit) Tennis with partner (easy on pivots) Begin soccer drills Begin skating spins and glides Progression: Patient specific based on middle phase progression and perturbation skills Goal to begin modified play by sessions 8-10
Goal: The goal of the	return to sports specific activity phase	is to return patients with acute ACL rupti	res to high level activities. This must

include progressive return to activities themselves. The time frame for return to sport specific activities is variable and patient dependent.

Appendix F

INSTITUTIONAL REVIEW BOARD DOCUMENTS



RESEARCH OFFICE

10 Hullihen Hall Jniversity of Delaware Newark, Delaware 19716-1551 %: 302/831-2136

DATE: April 21, 2016

TO: Lynn Snyder-Mackler, PT, ScD FROM: University of Delaware IRB

STUDY TITLE: [165436-12] Dynamic Stability of the ACL Injured Knee

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED
APPROVAL DATE: April 20, 2016
EXPIRATION DATE: May 20, 2017
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 insiblemefit 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 <u>informed consent</u> 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.

- 1 -

Generated on IRBNet

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

UNIVERSITY OF DELAWARE DEPARTMENT OF PHYSICAL THERAPY INFORMED CONSENT FORM

Study Title: Dynamic Stability in the ACL Injured Knee – Medium Term Follow-up Principal Investigator: Lynn Snyder-Mackler, PT, ScD

PURPOSE AND BACKGROUND

You are being asked to participate in a follow-up study that will investigate functional abilities and joint changes of individuals who have injured their ACLs. You have been referred to this study because you were a participant in the short term follow-up aspect of this study, evaluating the effects of perturbation training on people with ACL injuries.

Your participation is important in the aims of this study. We have data from your course of care after injury and at standard time points between injury and 2 years. With 3-7 year results, we can investigate relationships between your early injury performance and longer term outcomes. This will help us to better educate and treat athletes who tear their ACL in the future.

Participation in this research study is voluntary. This program will include testing protocols we currently use in our clinic to assess patients with ACL injury. Your surgeon and physical therapist have agreed that all of the testing procedures included in the study are acceptable.

The study includes clinical and radiographic assessment of your knee. There will be one (1) testing session 5 years after your ACL reconstruction or one to two (1-2) testing sessions 3-7 years after the completion of perturbation training if you have not had surgery. This research study will involve approximately one hundred fifty (150) subjects with ACL injury between the ages of 13-55 years at the time of injury. 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.

PROCEDURES

ACL Functional Test

Functional testing will take place in the Physical Therapy Clinic at the University of Delaware, 540 South College Avenue, Newark, DE 19713 and will last approximately 1 hour. Testing will be performed 3-7 years after surgery. This test is commonly performed at the University of Delaware Physical Therapy Clinic as part of our ACL rehabilitation protocol.

galof4	Subject's Initials

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 assuming there is minimal swelling in your knee and you demonstrate good thigh muscle strength. The tests are performed in the order seen in Diagram 1. You can wear your own knee brace or a standard off-the-shelf knee brace on your injured knee during this portion of the testing, if you desire.

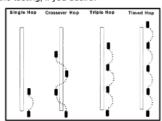


Diagram 1. Four (4) hop tests as part of the functional test protocol.

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 leas.

Questionnaires

You will be asked to complete a test packet which includes questions about your injury, past and current functional status, and perceived functional capabilities.

X-Rays

X-rays will take place at Abby Medical Center, One Centurian Drive, Newark, DE 19713, 3-7 years after your ACL injury or ACL surgery. You will have two types of x-rays taken while you are standing. These x-rays will allow us to look at the joint space in your injured knee, and will help a radiologist (a medical doctor specializing in medical imaging) determine the presence, severity, and location of any knee osteoarthritis you may have. These x-rays will be locked in a cabinet for research purposes only.

Subject's Initials____ Page 2 of 4

Risks/Discomfort

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. If you are injured during research procedures, you will be offered first aid at no cost. If you require additional medical treatment, you or your third-party payer (for example your health insurance) will be responsible for the cost. 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

The x-rays that will be taken are the same type that physicians use during regular clinical practice. This research study involves exposure to radiation from a standard radiograph. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive in this study is about 0.12 mSv or 12 mrem, and is approximately equivalent to a uniform whole body exposure of 15 days of exposure to natural background radiation. This use involves minimal risk per National Institutes of Health guidelines, and is necessary to obtain the research information desired. To reduce exposure all subjects will wear a lead apron to cover the rest of your body while the x-rays of your leg are captured.

Benefits

The benefits include comprehensive testing sessions that will document your progress following surgery. The results of this study may help us improve the way we treat patients with ACL injury.

Compensation

You will be paid an honorarium of \$100 for the functional testing and \$50 for the radiographs to compensate you for travel expenses and the time involved. If only the questionnaire packet is completed, you will be paid an honorarium of \$25.

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.

Page 3 of 4	Subject's Initials

Subject's Initials_____

Study Title: Dynamic Stability in the ACL Injured Knee Principal Investigator: Lynn Snyder-Mackler, PT, ScD

Subject's Statement:

Page 4 of 4

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.

risks and benefits, and I her procedures set forth above. If I am under 18 year	rmed of the above described pro reby consent/assent (for those un rs of age, I understand that paren dian has printed and signed his/h	der 18 years of age) to the tal or guardian consent is
Subject's Name	Subject's Signature	Date
Parent/Guardian's Name	Parent/Guardian's Signature	Date
Investigator		Date
Institutional Review Board is research conducted at the U Further quest	the Institutional Review Board (30 secated for the protection of hur Jniversity of Delaware. In Study may be Lynn Snyder-Mackler, ScD, PT al Therapy Department, (302) 83	man subjects involved in addressed to: