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STABILITY Study: A multicentre RCT comparing ACL reconstruction with and without lateral extra-articular tenodesis for individuals at high risk of graft failure

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Kinesiology

STABILITY STUDY – A MULTICENTRE RCT COMPARING ACL RECONSTRUCTION WITH AND WITHOUT LATERAL EXTRA-ARTICULAR TENODESIS IN INDIVIDUALS AT HIGH RISK OF GRAFT FAILURE

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by

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Abstract

Seventy patients undergoing anterior cruciate ligament (ACL) reconstruction (ACLR) were randomly assigned to receive ACLR alone or ACLR plus a lateral extra-articular tenodesis (LET). Our primary outcome was Limb Symmetry Index (LSI) calculated using a series of four hop tests at six months postoperative. Secondary outcomes measures included pain, subjective function and isokinetic strength testing. We found no statistically significant difference between the two groups in LSI calculations. We found statistically significant differences favoring the ACLR alone group in quadriceps average power and peak torque symmetry measurements at six-months postoperative when we adjusted for baseline measurements. No other statistically significant differences were found. This thesis presents the six-month preliminary results of a larger continuing study and at this time no definitive conclusions can be made.

Keywords

Anterior cruciate ligament reconstruction, anterior cruciate ligament, ACL, lateral extra-articular tenodesis, Lemaire tenodesis, anterolateral ligament.

Co-Authorship Statement

This study was designed in collaboration with Dr. Alan Getgood and Dr. Dianne Bryant along with the rest of the STABILITY Study group (see next page). I was responsible for obtaining local ethics approval and registering the trial with the help of Dr. Bryant and Dr. Getgood. I worked with Dr. Bryant, Saoirse Ling and the rest of the staff at Empower Health Research Inc. to create the study database and to train the research staff at the other centers to use the database. Throughout the study I acted as a liaison for the centers to help them get up and running and to assist with any issues that came up. It was also my responsibility to schedule routine conference calls for the group. I also worked with the staff at EmPower Health Research Inc. and the other centers to ensure completeness of data collection across all sites.

I was responsible for screening incoming referrals at the Fowler Kennedy Sport Medicine Clinic, recruiting eligible patients and going through the informed consent process. I attended all operations to perform randomization and collect intra-operative data. Following surgery, I assisted with scheduling appointments and was responsible for data collection.

For this thesis, I performed the data analysis and wrote the original draft of the manuscript. Dr. Bryant and Dr. Getgood provided me with suggestions and comments regarding the final submission.

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Chapter 1

1 Introduction

Anterior cruciate ligament (ACL) injuries are one of the most common knee injuries to occur during sport[1] and ACL reconstruction (ACLR) is the sixth most common procedure performed in orthopaedics, with costs exceeding half a billion dollars annually[2]. The aim of ACLR is to regain functional stability of the knee, allowing patients to return to their pre-injury level of activity[3]. The reconstruction procedure itself has evolved significantly since the early 1900's, when the first ACLR was performed.[4] Although the techniques have changed, the goal of the surgery remains the same and a large volume of literature has been published examining the results of the different surgical techniques.

Conventional ACLR techniques perform well subjectively, however rotational control is often lacking. Numerous studies have found a residual positive pivot shift, a clinical test for rotational stability of the knee, in patients following ACLR[5-8]. Biomechanical assessments following ACLR have further demonstrated an inability to restore normal tibial rotation[9,10]. Furthermore, many studies have shown high graft failure rates in young individuals who return to pivoting contact sports following ACL reconstruction[7,11-14]. This is particularly prevalent in females[14]. The combination of patients exhibiting poor rotational stability and higher failure rates in young patients is suggestive that further investigational work is required to re-establish normal knee joint kinematics following ACLR.

Extra-articular reconstruction is not a new concept. Early approaches to ACL deficiency included a lateral extra-articular tenodesis (LET) procedure with multiple surgeons publishing their respective techniques[4,15-18]. Reports of poor results eventually resulted in this approach giving way to more advanced intra-articular reconstruction procedures[16,19,20]. However, a number of authors performed an extra-articular procedure along with intra-articular reconstruction, reporting excellent results in a number of studies[21-37]. More recently, extra-articular reconstructions have been employed in augmenting revision ACLRs with good results[4,16,17,38].

Numerous studies comparing patients who underwent ACLR plus an extra-articular procedure to patients who underwent ACLR alone have been published with mixed results[21,23,24,39-65]. However, most of these studies lack adequate power and serious flaws in methodology make it difficult to draw definitive conclusions[66]. Differences in populations, graft choices, surgical techniques and outcome measurements further add to the inability to draw definitive conclusions about the role of extra-articular augmentation of ACLRs. The purpose of this study is to conduct a pragmatic, methodologically rigorous study to definitively compare ACLR plus LET to ACLR alone. The goal of providing a rotationally stable knee following ACLR remains difficult to achieve therefore a surgical procedure addressing rotational stability is of utmost importance when treating the ACL deficient knee.

Chapter 2

2 Literature Review

2.1 Anatomy

2.1.1 The Knee Joint

The knee joint is composed of two tibiofemoral articulations between the lateral and medial condyles of the femur and the tibial condyles, and one patellofemoral articulation between the femur and the patella[67]. The knee is a hinge-type synovial joint primarily allowing flexion and extension. These hinge movements are combined with gliding, rolling and rotation about a vertical axis. Since there is incongruence between the tibia and femur, the articulation is relatively weak mechanically and requires support from other surrounding structures to increase the stability of the joint.

There are five extra-articular ligaments surrounding the joint: the patellar ligament, the medial collateral ligament (MCL), the lateral collateral ligament (LCL), the oblique popliteal ligament and the arcuate popliteal ligament[67]. Along with the surrounding musculature, these ligaments play a role in strengthening the joint capsule.

There are two fibrocartilaginous, crescent-shaped menisci located on the articular surface of the tibia to enhance joint congruence and they play a role in shock absorption[67]. At the center of the joint are two intra-articular ligaments called the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL)[67]. The cruciate ligaments crisscross each other obliquely like the letter X. These structures play a role in further supporting the joint.

2.1.2 The Anterior Cruciate Ligament (ACL)

2.1.2.1 Anatomy

The anterior cruciate ligament travels obliquely from the lateral and posterior aspect of the knee, originating on the medial aspect of the lateral femoral condyle, to the medial and anterior aspect of the knee, inserting on the anterior intercondylar area of the tibia, posterior to the attachment of the medial meniscus[67]. The ligament is approximately 31 to 38 mm in total length with a cross-sectional area of 44 mm^2, though these measurements vary throughout the range of motion of the knee[2].

It is composed of two separate bundles – the anteromedial (AM) bundle and a posterolateral (PL) bundle - named for their relative location of insertion on the tibia[2]. Histological studies have shown a septum of vascularized connective tissue separating the two bundles. When the knee is fully extended these two bundles lay parallel to each other however as the knee moves into a flexed position the two bundles cross over each other[2]. The PL bundle is tightest in extension whereas the AM bundle is reaches maximum tightness as the knee approaches 60 degrees of flexion.

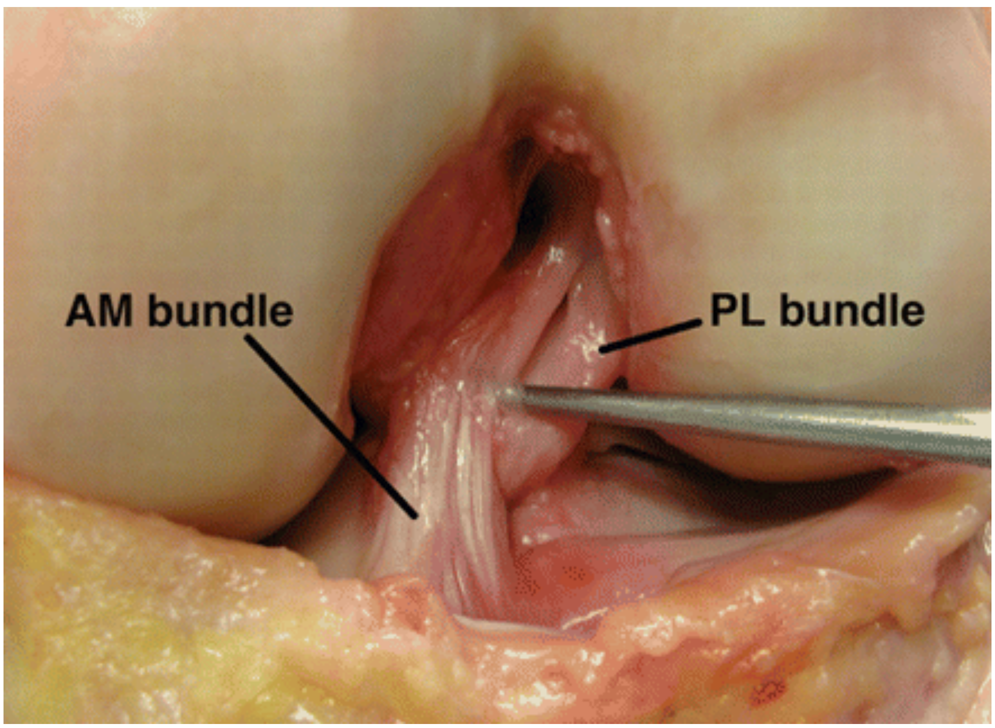

Figure 1: Anterior view of the ACL showing the distinct anteromedial (AM) and posterolateral (PL) bundles (left knee).

Reproduced with permission from: Ziegler et al., Arthroscopically Pertinent Landmarks for Tunnel Positioning in Single-Bundle and Double-Bundle Anterior Cruciate Ligament Reconstructions, American Journal of Sports Medicine, 2011, 39(4), 743-752[68].

2.1.2.2 Function

Because of the dynamic nature of the two bundles of the ACL, it plays a complex role in stabilization of the knee joint. The ACL is primarily responsible for resisting anterior tibial translation with respect to the femur[2]. It also plays an important role in rotational stability of the knee joint by acting as a secondary restraint to internal tibial rotation[69]. The role of the ACL as a secondary restraint to external rotation and varus-valgus angulation is generally accepted though it is less understood[70].

The ACL contains mechanoreceptors that play an important role in proprioception[69]. These mechanoreceptors provide the central nervous system with afferent information about joint position via the tibial nerve. Sensory information provided by the ACL may assist in the coordination of muscle activity and result in dynamic stability of the knee joint[71].

2.2 Mechanism of Injury

There are three major types of ACL injuries: direct contact (external force applied directly to the injured knee), indirect contact (external force applied to the athlete but not directly to the injured knee) and non-contact (force applied to the knee resulted from the athlete's own movement and did not involve contact with another athlete or object)[72]. The majority of injuries are non-contact, with the rate of non-contact injuries ranging from 70 to 84%[73,74]. These non-contact injuries occur when the athlete is landing from a jump, pivoting or suddenly decelerating to stop or change directions[1]. The most common mechanism is a result of a deceleration task combined with dynamic valgus rotation with the body weight shifted over the injured leg and the plantar surface of the foot fixed flat on the playing surface[73].

Most ACL injuries are the result of the complex interaction between multiple factors[75]. Both intrinsic and extrinsic factors may contribute to the injury. Extrinsic factors include competition, footwear, playing surface, weather and equipment[76]. Intrinsic factors include anatomical risk factors (body mass index, joint laxity, posture, lower extremity alignment, intercondylar notch size and tibial slope), hormonal risk factors (sex hormones), biomechanical risk factors, neuromuscular risk factors (muscular strength and recruitment, joint stiffness and stability and muscular fatigue), psychological factors and prevention strategies[73,75-77].

2.2.1 Associated Injuries

Though ACL tears can occur in isolation, it is more commonly associated with injury to other structures in and around the knee[1]. Meniscus tears occur during approximately 50% of ACL injuries, with tears of the lateral meniscus occurring more frequently in acute ACL injuries and medial meniscus tears occurring more frequently in patients with chronic ACL deficiency[76]. Injury to other ligaments may occur also, though this is more rare. The Norwegian National Knee Ligament Registry found ACL injury was associated with medial collateral ligament injury in five percent of cases and lateral collateral ligament injury in only one percent[78].

Bone marrow lesions, more commonly referred to as bone bruises, can be seen on magnetic resonance images of 80 to 100% of knees with acute ACL injuries and have been suggested to represent a footprint of the injury mechanism, showing where the femur and tibia came into contact[79,80]. Furthermore, ACL injuries may also be associated with articular cartilage lesions. The Norwegian National Knee Ligament Registry found lesions in 26% of patients, and 59% of those patients required surgical treatment[78].

2.3 Epidemiology

Approximately 250 000 ACL injuries occur in Canada and the United States each year with an annual incidence rate as high as one in 3 000 being reported for the United States[70,81]. Of these injuries, approximately 80 000 are complete ACL tears. In Europe, the overall annual incidence of ACL tears in the general population was reported as 81 per 100 000 inhabitants aged 10-64 years[1]. Each year, between 75 000 and 100 000 ACL reconstructions are performed in the United States costing over $2 billion[1,2].

There is a vast amount of literature exploring the incidence of ACL injuries in specific sports, level of competition, age groups and between genders[11,72,82-86]. However, few studies have been published reporting the incidence of ACL injuries in the general population. A 2008 study by Gianotti et al.[72] analyzed the numbers and types of ACL and other ligamentous knee injuries that occurred in New Zealand over a five-year period. During the time of the study, 238,488 knee injuries were claimed. Of these, 9197 required surgery, 7375 of which were ACLs (80%), for an incidence rate of 36.9 per 100 000 persons per year.

Granan et al.[78] published two-year results of the Norwegian National Knee Ligament Registry and found 2793 primary ACL reconstructions were performed at 57 hospitals, for an annual incidence rate of 34 per 100 000 citizens. The annual incidence of citizens between the ages of 16- and 39-years of age was 85 per 100 000 citizens. It is important to note that the registry only accounted for those ACL injuries receiving surgical treatment, thus not accounting for all ACL injuries.

2.3.1 Incidence in Specific Groups

Because of the multifactorial nature of ACL pathology, ACL injury rates are age, gender and sport specific. Most ACL injuries are sports related, and the highest incidence has been found in individuals aged 15- to 25 years old who participate in sports involving pivoting motions[74]. Furthermore, female athletes are at a two to nine times greater risk of sustaining an ACL tear than their male counterparts[1].

In the New Zealand population-based study, 65% of all ACL injuries occurred at a place of recreation or sport[72]. Twelve sports accounted for 89% of all ACL injuries, with rugby, netball and soccer accounting for 58% of them.

In 2007, Prodromos et al.[85] conducted a review of the peer-reviewed published data on the incidence of ACL tears. Thirty-three articles were included in their analysis. They found that basketball and soccer accounted for the highest number of ACL tears. Basketball was found to have an overall incidence rate of 0.17 per 1000 exposures while the incidence rate in soccer was 0.07 per 1000 exposures at the recreational level and 0.21 per 1000 exposures at the collegiate level. They concluded that females have a roughly 3.5 times greater risk of ACL tears than males in basketball and a 2.7 times greater risk in soccer. Female athletes who participate year round in soccer and basketball have an ACL tear rate of 5%.

They also found that in the studies reporting rates for soccer with an ACL injury-reduction training program cohort, trained athletes had a significantly lower ACL injury rate than untrained athletes (p=0.0001)[85]. One study showed a 24% reduction rate in tear incidence[87].

Alpine skiing was found to have an overall incidence of 0.49 per 1000 exposures in the general population. Recreational skiers had a 16-fold higher incidence than expert skiers. Volleyball was found to be a low-risk sport for ACL tears rather than high-risk as was previously thought. Alpine skiing and lacrosse were the only sports with no gender differences in incidence rates[85].

In 2006, Hootman et al.[88] analyzed a sample of 16 years of data from the National Collegiate Athletic Association's (NCAA) Injury Surveillance System (ISS) for 15 different sports. In their sample they found approximately 5000 ACL injuries over the study period, an average of 313 per year in their sample. This equates to an annual average of more than 2000 ACL injuries in these sports since they estimated their sample represented approximately 15% of the total population of the NCAA. Overall, the largest total number of ACL injuries occurred in football (2538/4800 ACL injuries). Gymnastics, however, had the highest rate of ACL injuries with a rate of 0.33 per 1000 athlete exposures. Football, women's gymnastics, women's basketball and women's soccer all had significantly higher injury rates than any other sport. Furthermore, the rate of ACL injuries increased significantly over the sample period.

Bradley et al.[83] further explored the epidemiology of ACL injuries in the National Football League. During the five year period analyzed, an average of 2 100 injuries were reported each year, 20% of which were knee injuries. A total of 209 ACL tears occurred, or 2% of all injuries. More recently, Dragoo et al. (2012)[86] reviewed the NCAA ISS football injury database to determine the incidence and epidemiology of ACL injuries in collegiate football players during a five-year period. A total of 318 ACL tears were reported for 2 222 155 athlete exposures for an overall incidence rate of 1.42 per 10 000 athlete exposures. They found that the injury rate during games was significantly greater than during practice, with players being 10.9 times more likely to sustain an ACL injury during a competition.

Similar results were found in a cohort study examining the epidemiology of ACL injuries in athletes at the United States Military Academy at West Point over a 10 year period[89]. A total of 353 ACL injuries were reported for an overall four-year incidence rate of 3.24 per 100 for men and 3.51 for women. For males, 34.8% of injuries were sustained in football, 15.2% in rugby and 8.3% in basketball. For females, 17.6% occurred in basketball, 13.7% in gymnastics and 9.8% occurred in soccer. When male-only sports were excluded, the overall ACL injury rate was significantly greater in females.

2.4 Treatment

2.4.1 Diagnosis

The diagnosis of an ACL tear is based on history and clinical examination. A 2015 study found orthopaedic surgeons were able to successfully recognize 94% of ACL tears based on history and physical examination alone[90]. In most cases imaging is not required, however, it can play an important role in ruling out other associated injuries[1].

A thorough history is crucial in the diagnosis of ACL injury. Most important is the mechanism of injury[3]. Anywhere from two-thirds to 80% of patients will state they heard a “crack” or a “pop” at the time of injury. Since the ACL is a capsular structure, injury to the ligament is often associated with hemarthrosis (swelling within the first 3-4 hours)[3]. Pain is often worse on the lateral side of the knee, and may be due to an associated lateral bone bruise. Patients will report that they were unable to continue activity at the time of injury[1]. Following an ACL tear, patients will experience episodes of instability or “giving way” of the knee.

There are three main diagnostic tests used in the diagnosis of ACL tears. These include the Lachman test, the anterior drawer test, and the pivot shift test.

The Lachman test is the most sensitive test used in the diagnosis of ACL injuries (sensitivity = 0.81; specificity = 0.81)[91]. With the patient lying supine, the examiner brings the knee into 20 to 30 degrees of flexion. The femur is stabilized with one hand and while the other hand is placed under the posterior aspect of the proximal tibia and applies an anterior translation force in the direction of the joint line[92]. A grading scale of 0-3 is used and the grade is always a comparison to the contralateral limb (Grade 0: -1 to 2 mm; Grade 1: 3 to 5 mm; Grade 2: 6 to 10 mm; Grade 3: >10 mm). A positive test is an increase in anterior translation compared to the contralateral limb with a soft end point. An end point is defined as the stopping sensation felt by the examiners as the ligament is stretched to its maximal length.

The anterior drawer test is similar to the Lachman test. It is performed by having the patient lie supine with the knee flexed to 90 degrees with his or her foot resting on the table[92]. The examiner stabilizes the foot and applies an anteriorly directed force to the tibia. An increased displacement of the tibia forward indicated a positive test. Tibial translation is compared to the contralateral limb and a grading scale of 1 to 3 is used (Grade 1: 5 mm; Grade 2: 5 to 10 mm; Grade 3: >10 mm). The anterior drawer test has been found to have a sensitivity of 0.38 and a specificity of 0.81[91].

The pivot shift test is the most specific test used in the diagnosis of an ACL tear with a sensitivity of 0.28 and a specificity of 0.81 (0.98 under anesthesia), however it is also the most technically difficult to perform. It is a test of anterolateral rotatory laxity[91,92]. The examiner internally rotates the tibia and brings the limb through full range of motion while applying a valgus stress on the lateral proximal tibia, replicating the “giving way” sensation patients may experience. One challenge of the test is getting the patient to relax fully and allow the examiner to move the limb freely. The pivot shift is compared to the contralateral limb and graded using a scale of 0-3 (Grade 0: Normal; Grade 1: Glide; Grade 2: Clunk; Grade 3: Gross). A systematic review by Ayeni et al. found that the pivot shift test correlated with clinical outcomes following ACL reconstruction[93]. The most common outcomes reported were the International Knee Documentation Committee (IKDC) scale, the Lysholm score and the Tegner activity level.

It is recommended that an X-ray of the knee be performed when an ACL tear is suspected. In most cases the radiographs will appear normal, however, may reveal a

Segond fracture, an anterolateral capsular avulsion at the lateral margin of the tibial plateau[1]. A Segond fracture is strongly associated with ACL injury (75-100%)[94,95]. Magnetic resonance imaging (MRI) has been shown to be a useful tool in the diagnosis of ACL injuries, with a sensitivity of 0.61 and a specificity of 0.82[96]. MRI is also useful to detect associated meniscal and cartilage pathologies when these injuries are suspected clinically[1]. Ideally all patients with an ACL injury would undergo an MRI, but because of the high cost, long wait times in Canada and because ACL injury can be reliably diagnoses through physical examination, MRI is considered unnecessary [2,97,98]. However, many patients still present to orthopaedic centers with MRI images.

2.4.2 Conservative Treatment versus Surgical Treatment

Following ACL rupture, the optimal treatment is unknown and the decision whether to pursue conservative treatment versus surgical treatment is difficult[1]. Treatment options include non-operative management, surgical reconstruction, bracing and rehabilitation programs.

In 2010, Frobell et al. performed a randomized controlled trial comparing structured rehabilitation plus early ACLR with a structured rehabilitation with the option of later ACLR if needed in a population of 121 young, active adults (18- to 35-years of age) with acute ACL tears[99]. Demographics were relatively similar between the two groups except the delayed reconstruction group had a higher percentage of females (34% vs. 19%). Furthermore, elite athletes and those who did not participate in sports were excluded from the study. Of the 59 patients allocated to the delayed reconstruction group, only 23 went on to receive an ACLR. At two-years postoperative, no differences were found between the two groups for any of the outcomes. The authors concluded that early ACL reconstruction had no benefits over a structured rehabilitation program with the option for ACLR later on, and the latter strategy reduced the frequency of reconstructions. However, the optional delayed reconstruction group suffered more adverse events with 19 patients suffering from subjective or clinical instability and 13 having meniscal signs or symptoms compared to two suffering from instability and one having meniscal symptoms in the early ACLR group.

In a critical review of the literature, Delinked and Ghafil[100] found that conservative treatment is a viable option and may provide satisfactory results. However, in many of the studies the patients who underwent non-operative management were required to modify their activity levels, in particular avoiding contact sports. Furthermore, those patients who underwent early ACLR had a lower incidence of further meniscal injury.

Brukner et al.[1] argue that the decision whether to reconstruct or not should be made in consensus between the physician and patient. Concomitant meniscal injuries, patient activity level and episodes of instability should all be taken into consideration.

2.4.3 Surgical Treatment Options

Anterior cruciate ligament reconstruction (ACLR) is the sixth most common orthopaedic procedure performed[2]. The goal of ACLR is to replace the torn ACL with a graft to reproduce the normal kinetic functions of the ligament and to restore stability to the knee[1]. Graft tissue can be broken down into three categories: a) allografts, cadaveric tissue coming from another human donor; b) autografts, tissue harvested from the individual; or c) synthetic grafts[70]. Autografts and allografts are most commonly used.

The use of an allograft is appealing as there is no donor site morbidity for the patient[2]. However, allografts are associated with a risk of disease transmission, require sterility considerations, present a variation in biological response of the patient, are costly and there is a limited availability of grafts[101]. In a meta-analysis of five studies, Cvetanovich et al.[102] found no differences in outcomes between patients undergoing ACLR with a soft-tissue allograft compared to those with a hamstring autograft. Higher failure rates were associated with allograft but the analysis lacked sufficient statistical power. They found that the quality of included studies was poor, and concluded that the results could not be extrapolated to younger populations.

These results were similar to those found in a previous systematic reviews by Foster et al.[103] and Carey et al.[104]. A meta-analysis of 20 studies by Prodromos et al.[105] reported a 5% failure rate in autograft reconstructions compared to a 14% failure rate in allograft reconstructions. Kaeding et al.[13] further supported these findings when presenting the results of the Multicenter Orthopaedic Outcomes Network (MOON) and found the odds of graft failure with an allograft reconstruction were four times higher than those of autograft reconstructions. In a 2015 update, Kaeding et al.[12] found the odds of graft failure to be 5.2 times higher in allograft reconstructions. Recent studies suggest the increased risk of failure in allograft reconstruction is a result of the sterilization techniques used, and when non-irradiated allografts were used they found no difference in outcomes when compared with autograft reconstructions.[106]

The most common autografts used are the hamstring (HT) graft consisting of the semitendinosus and gracilis harvested from the ipsilateral limb, or a bone-patellar-tendon-bone (BPTB) graft[1]. The quadriceps tendon and grafts harvested from the contralateral limb may also be used. There is a considerable amount of debate on graft choice, and multiple systematic reviews have been published comparing hamstring and BPTB grafts with varying results[107-113].

In 2011, Mohtadi et al.[8] performed a systemic review comparing patellar tendon autografts versus hamstring autografts for ACLR in adults. Nineteen trials were found, however, many were at high risk of bias. Meta-analysis showed no differences between the two graft choices for functional assessment (single leg hop test), return to activity, Tegner and Lysholm scales and subjective measurements of outcome. Furthermore, no differences were found regarding re-rupture rates with 15/575 re-ruptures in the patellar tendon group and 19/581 in the hamstring group. When testing for stability of the joint via instrumented laxity testing, Lachman or Pivot shift, patellar tendon grafts resulted in a more statically stable knee compared to hamstring grafts. Conversely, more patients experienced anterior knee pain in the patellar tendon group as well as a statistically significant loss of extension. Kaeding et al.[12] further supported these findings by reporting no difference in the odds of re-tear between patellar tendon grafts and hamstring grafts.

2.4.4 Results of Anterior Cruciate Ligament Reconstruction

Conventional ACLR techniques perform well subjectively; however, rotational control is often lacking. Yunes et al.[5] performed a systematic review of controlled trials comparing patella tendon and hamstring tendon grafts in ACLR. They found four studies that met their requirements and were included in the analysis. Meta-analysis showed that following ACLR, between 16% of patients receiving patellar tendon grafts and 25% of patients receiving hamstrings grafts had a residual positive pivot shift. Furthermore, 27% and 40% had greater than 3 mm side-to-side difference on maximum manual KT1000 testing, and only 64% of patients with hamstrings grafts and 75% of patients with patellar tendon grafts were able to return to their pre-injury level of sport. However, return to sport may not be a valid assessment of success given psychological and lifestyle factors may also play an important role[114].

In 2005, Prodromos et al.[6] performed a further meta-analysis comparing hamstrings and patellar tendon reconstructions. Again, suboptimal results were found with only 77% of the hamstring reconstructions and 66% of patellar tendon reconstructions achieving normal stability rates. In a similar study, the same group analyzed the difference in rates of stability between autograft and allograft[85]. Autograft stability was reported as normal in 72% of cases with only 59% of allograft cases being reported as normal.

Mohtadi et al.[7] recently presented the results of a level one randomized controlled trial comparing patellar tendon grafts to single bundle hamstrings and double bundle hamstrings grafts. Significant numbers of patients in all three groups had a postoperative pivot shift greater than or equal to two. The rate of traumatic failure in the single bundle hamstrings group was reported as 13% at two years, compared to 3% in the patellar tendon group and 12% in the double bundle hamstrings group. Atraumatic failures were also recorded as 19%, 18%, and 22% in the single bundle hamstrings group, patellar tendon group and double bundle hamstrings group respectively.

A number of studies examining the incidence of graft failure and need for subsequent revision surgeries have been published. Kaeding et al.[13] reported the results from the MOON cohort on the epidemiology of ACL failure and revision surgery. They found that younger age and the use of allograft were associated with higher failure rates. Lind et al.[11] published the results of the Danish ACL registry, which showed that patients under the age of 20 had an increased risk of need for ACL revision surgery (Adjusted Relative

Risk 2.58). Magnussen et al.[14] also reported that patients under the age of 20 years old and those who had a graft with a diameter less than 8 mm were at greater risk of ACL graft failure, in a cohort of hamstring autograft reconstructions.

Other studies have focused on the biomechanical assessment of patients who underwent ACL reconstructed and have demonstrated an inability to restore normal tibial rotation compared to the contralateral knee. Ristanis et al.[9] compared 20 patients who underwent ACLR with a patellar tendon graft to 15 matched controls. They found that abnormal tibial rotation occurred in the ACL reconstructed knee when compared to the contralateral limb when descending stairs and pivoting. The same group repeated the study on patients who underwent ACLR with a hamstrings graft and found similar results.[115] They concluded that although ACLR restored abnormal anterior-posterior tibial translation, current techniques were unable to restore tibial rotation to previous physiological levels. Tashman et al.[10] showed similar findings when investigating running in an ACL reconstructed knee.

To attempt to address these issues, recent modifications in surgical techniques have included adjustments to tunnel placement, new fixation techniques and double-bundle reconstructions [116].

2.4.5 Double-Bundle versus Single-Bundle ACLR

The lack of rotational control following ACLR led surgeons to reconsider the anatomy and biomechanics of the ACL, particularly the posterolateral (PL) bundle[18]. The majority of ACLR techniques essentially reconstruct the anteromedial (AM) bundle, resulting in anterior tibial translation not being controlled in extension[2]. Therefore, a number of authors have proposed reconstructing both the AM and PL bundles using a separate graft for each[2]. Numerous techniques using either one or two tunnels on both the tibia and femur, different graft sources and different graft tensioning methods have been described.

Multiple techniques for double-bundle ACLR were proposed in the 1970's, 1980's and 1990's, however these original techniques used only one tunnel in the tibia or femur[18]. In 1994, Radford et al.[117] performed an in-vivo analysis of both single- and double-bundle

ACLR in an ovine model. Like humans, the ACL in sheep has a distinct double-bundle structure. The authors compared three techniques: double-bundle ACLR (n=8), single-bundle ACLR using a tibial tunnel (n=8) and single–bundle ACLR through a femoral tunnel (n=8). The author found no differences in anterior or rotational laxity when comparing the three groups. Furthermore, the double-bundle reconstruction resulted in more joint surface degradation. They concluded that the clinical use of a double-bundle ACLR technique was not indicated.

However, in 2004, Yasuda et al.[118] revolutionized the idea of a double-bundle reconstruction when they performed an anatomic study on eight cadaveric knees. In five of the knees they examined the role of the individual fibers of the ACL throughout flexion and extension, and to determine the attachment of the individual bundles. In the three remaining knees anatomic reconstruction of the two bundles was performed and the movement was observed. They suggested using a separate graft for each bundle with unique femoral and tibial tunnels for each.

These results were translated to a clinical setting, and they performed double-bundle ACLR using this new technique on a consecutive series of 57 patients. At 24 months followup they found a positive Lachman's in four patients and a positive pivot shift in only one patient. No postoperative complications were found. Their results were promising, and they concluded that this double-bundle technique is able to restore rotational stability following ACLR and further clinical studies comparing it to the single-bundle technique should be performed.

Since then, numerous trials comparing single-bundle reconstructions to double-bundle reconstructions have been performed. Furthermore, multiple meta-analyses have been performed[119-123]. In the most recent meta-analysis by Xu et al.[121], 19 randomized trials comparing double-bundle and single-bundle ACLR techniques were found. There was a considerable amount of variability between the articles in regards to population, graft choices and fixation techniques. The authors found that patients in the double-bundle group were more likely to be graded as normal on the pivot shift (RR: 0.77, 95% CI: 0.67 to 0.89). However, heterogeneity was high (I^2= 83.8%). Lachman's, KT-1000 measurements and IDKC score were also found to be different, with all favoring the double-bundle group. No differences were found in subjective scores. However, the authors failed to report complications within the included studies.

Many complications and issues with double-bundle ACLR techniques have been reported. First and foremost, the technically demanding procedure has a long and difficult learning curve and requires a detailed knowledge of the ACL bundle anatomy and insertion sites[18,101]. The use of two separate tunnels doubles the possibility of committing an error in positioning. Furthermore, additional fixation is required making the surgery more costly[2]. Two tunnels also increases the difficulty in performing a revision ACLR in the event of a graft failure[4,101]. Some authors have also found strength deficits associated with the double bundle technique[2].

Although a number of biomechanical studies have shown improvements in rotational control with these techniques[124-129], no clinical study has shown superior patient reported outcomes over conventional single-bundle techniques[123,130]. Furthermore, double-bundle reconstructions are associated with increased technical difficulty, higher costs and complications associated with the use of two tunnels, particularly in the event of graft failure. Future studies with long-term followup and functional outcomes are still needed.

2.4.6 The Anterolateral Ligament (ALL)

More recently, a significant focus has been placed on the anterolateral ligament (ALL), a fibrous condensation of the anterolateral capsule[131]. Anatomical studies have shown this to be a distinct entity that exhibits ligamentous properties when histological analyses were performed.[132] Though the exact origin and insertion is debated, it is generally accepted that it originates from the lateral femoral condyle and travels anterodistally to its attachment on the tibia, lateral to Gerdy's tubercle[133,134]. Furthermore, some studies describe an attachment or branching attachments to the lateral meniscus while other studies suggest the fibers come close to the meniscus however no interaction exists.

Biomechanical analyses of the ALL have found that it aids in knee stability, particularly in the control of anterolateral rotation by limiting internal rotation[132]. Kennedy et al.[133]found that it is capable of withstanding significant forces of up to 175 N. ALL injury is thought to occur in association with ACL injuries, however the exact relationship is not fully understood. Increased anterior translation in flexion and extension, along with increased internal rotation at 90° has been shown in combined ACL and ALL injury[135]. Serial sectioning of the ACL followed by the ALL has shown an increase in anterior tibial translation and internal rotation as graded by the pivot shift[136]. Furthermore, the ALL has been hypothesized to be the cause of the Segond avulsion fracture of the anterolateral proximal tibia, which is pathognomonic of acute ACL injury[134]. Recognizing the importance of the anterolateral capsule in knee stability, a number of authors have proposed extra-articular procedures to address anterolateral instability following ACL injury[136].

2.4.7 Extra-Articular Reconstruction

Extra-articular reconstruction is not a new concept. Early approaches to ACL deficiency included a lateral extra-articular tenodesis (LET) on its own. The LET is analogous to the ALL in function, however the two differ anatomically. The proximal fibres of the ALL are integrated with the origin of the LCL, run superficial to the LCL and insert on the tibia between Gerdy's tubercle and the insertion point of the LCL[131]. Most LETs run from the femoral epicondyle and are fixed at Gerdy's tubercle, often running deep to the fibular collateral ligament (FCL)[15]. Strickler (1937), Macintosh (1972), Lemaire (1975) and numerous other surgeons all published their respective techniques[4,15-18].

Strickler routed a long strip of fascia through the joint and across the anterolateral capsule and was attached to itself at the entry point of the femur, thus forming a loop[15]. He hypothesized that this loop would address both ACL and PCL deficiencies. Lemaire employed a distally attached central strip of the iliotibial band (ITB) that was routed under the lateral collateral ligament (LCL) and into a bone tunnel slightly posterior to the lateral femoral condyle[15]. This was then folded back and sutured to its origin at Gerdy's tubercle. Macintosh's 'lateral substitution reconstruction' was a variation of the Lemaire technique[15]. To avoid the use of a bony tunnel he threaded the fascia through the lateral intermuscular septum. Various other techniques addressing anterolateral instability by methods of capsular tightening, various fascial and tendon slings and repositioning of ligament attachments became popular around the same time[15]. The most commonly used procedures are modifications of the MacIntosh, Losee, Hughston, Andrews and Ellison procedures[58].

Reports of poor results, such as those described by Neyret et al.[20] and Garcia et al.[19], eventually resulted in this approach giving way to more advanced intra-articular procedures[16,19,20]. However, a number of authors continued to perform an extra-articular procedure in combination with the more advanced intra-articular reconstructions to improve rotational stability, reporting excellent results in a number of studies[21-37]. Furthermore, Wilson et al.[137] and Bignozi et al.[138] argue that an extra-articular procedure helps to protect the intra-articular graft during the critical phase of remodeling and maturation by diminishing potentially damaging torsion forces. More recently, extra-articular reconstructions have been employed in augmenting revision ACLR's with excellent results[4,16,17,38,139].

2.4.7.1 Cadaver Studies

The effectiveness of extra-articular reconstructions has been evaluated in biomechanical studies on cadaveric knees. Engebresten et al.[140] examined the immediate postoperative mechanical state of knees using an experimental testing system. They measured forces on intact ACLs and on repaired grafts and repaired grafts augmented with a Kennedy Ligament Augmentation Device placed either anatomically or in an over-the-top position (lateral extra-articular reconstruction). When the graft repair was augmented with the extra-articular procedure, a 43% decrease of force on the repaired ACL graft was observed compared to the repaired graft alone. They concluded that an extra-articular procedure plays a supportive role for the repaired graft following intra-articular repair.

In 1990, Draganich et al.[141] evaluated the biomechanical effectiveness of intra-articular ACLR alone (patellar tendon), extra-articular ACLR alone (Müller iliotibial band tenodesis) and combined intra- and extra-articular ACLR in six fresh-frozen cadaver knees (mean age = 64.5 years). The stability of the cadaver knees in response to anterior drawer and internal rotatory torque was tested with liquid metal strain gages sutured to the centre of each graft. All knees underwent testing under five conditions: intact knee, transection of the ACL, extra-articular reconstruction, combined intra- and extra-articular reconstruction and intra-articular reconstruction alone (extra-articular reconstruction removed). They found that the extra-articular reconstruction alone did not return normal anterior stability to the ACL-deficient knee ($p<0.05$). Furthermore, the isolated extra-articular reconstruction was found to constrain internal rotation between 30 and 90 degrees when compared to both the intact condition and the ACL excised condition. However this was not the case in both the ACLR alone and the combined condition. There were no differences in any of the graft strain measurements. The authors concluded that ACLR alone was sufficient to restore anterior stability to the specimens without over-constraining internal rotation, however, augmentation with an extra-articular procedure may be advantageous in protecting the intra-articular reconstruction.

Most recently, Spencer et al.[136] investigated the effect of ALL transection on rotational knee kinematics in 12 cadaveric knee specimens. They reported that internal rotation as classified by the pivot shift test was significantly greater when the ACL and ALL were both transected compared to the condition with only the ACL transected ($p=0.02$). Furthermore, they found that following LET there was a significant decrease in anterior translation compared to the transected ACL and ALL condition ($p<0.01$). The authors suggested that an LET procedure might be highly advantageous in combination with ACLR by reducing the force across the graft.

Kittl et al.[142] examined length change patterns and isometry using eight cadaveric knees to determine the optimal femoral insertion and graft paths for lateral extra-articular reconstructions. Isometry can be defined as a constant distance between two moving points. Though exact isometric behavior does not exist for the ACL, it is accepted that a degree of isometry in ligament reconstructions reduces the risk of unwanted graft behavior. Using a kinematic rig, they found that the anterior fibre region of the iliotibial band displayed significantly different length change patterns compared to the posterior region ($p<0.01$). Therefore, the posterior fiber region should be used. Furthermore, they found that graft attachment proximal to the lateral epicondyle and deep to the lateral collateral ligament provides the most desirable graft behavior, without excessive tightening or slackening during range of motion. They concluded that a correctly positioned LET might provide benefit in ACLR; however, further studies examining the load on the grafts are needed.

2.4.7.2 ACLR alone versus ALCR plus LET

Numerous studies directly comparing ACLR with an extra-articular augmentation to ACLR alone have been published, however, the majority of these are non-randomized.

2.4.7.2.1 Non-randomized Studies

One of the first studies examining the effect of an extra-articular procedure was published in 1982 by Hefti et al.[53], when they compared four surgical techniques used in the replacement of the ACL. One group underwent a MacIntosh LET on its own (n=12) while 25 patients underwent ACLR with a patella tendon (PT) autograft. The remaining patients underwent ACLR combined with a MacIntosh over-the-top tenodesis performed using either a quadriceps and PT autograft (n=31) or carbon fibers (n=25). Outcome measures included clinical examination, range of motion and overall rating according to the Hospital for Special Surgery (HSS) evaluation system. The LET alone group scored the worst on all outcomes, except for range of motion, while the ACLR alone group scored the best. The combined procedure produced satisfactory results; however the results of the carbon fiber were worse than those of the autograft. The authors concluded that an intra-articular procedure is most important in ACLR, however further research into the addition of an LET was needed.

A couple of years later, in 1986, Paterson and Trickey[59] reviewed 40 cases following ACLR with a PT autograft, 17 of which were augmented with a MacIntosh LET. A greater proportion of patients in the combined group were rated as a good result (15/17) compared to the ACLR alone group (14/23). No other differences were found. The authors concluded that though most patients had good results, there were potential added benefits of an additional extra-articular procedure that needed to be further explored.

In 1987, Roth et al.[45] conducted a retrospective cohort study to determine whether an extra-articular procedure improved the efficacy of intra-articular ACLR. They compared the results in a group of 50 patients who underwent ACLR alone to 43 patients who underwent ACLR combined with a transfer of the superficial portion of the biceps femoris tendon, an extra-articular procedure advocated as a dynamic back up to intra-articular ACLR. The intra-articular reconstruction was performed using a combination of an autograft (quads tendon, prepatellar periosteum and PT) and a polypropylene braid. Patient evaluations consisted of a subjective questionnaire, physical examination (Lachman's, Pivot-Shift, Anterior Drawer), objective functional testing (KT-1000, isokinetic strength, one-legged hop for distance) and radiographs.

At a mean follow-up of 38 months for the control group and 44 months for the experimental group, only 24 patients receiving the biceps femoris tendon transfer were rated normal or mildly positive on the anterior drawer test, compared to 36 in the ACLR alone group. No other significant differences were found. The authors concluded that the extra-articular procedure compromised the stability of the knee post-operatively and thus did not recommend the use of the transfer of the biceps femoris tendon.

The next year, Ferkel et al.[51] published their results of 100 ACLR cases using a torn meniscus as a graft. In 29 of the cases the ACLR was augmented with either an Ellison or modified Ellison LET. No statistically significant differences in pivot shift were found when they performed a subgroup analysis to analyze the effect of the LET. They concluded that there was no benefit of an additional extra-articular procedure in ACLR.

Similarly, Strum et al.[44] (1989) conducted a retrospective study to determine whether or not the addition of an extra-articular procedure to intra-articular ACLR differed from ACLR alone. They reviewed the charts of 84 patients who had undergone ACLR alone (meniscus graft or PT graft) and 43 patients who had undergone ACLR combined with an extra-articular procedure (Ellison, Galaway, MacIntosh or Lemaire). Patient evaluation consisted of a subjective questionnaire, physical examination (Lachman's, Anterior Drawer, Pivot-Shift), instrumented knee ligament testing (KT-1000), thigh atrophy and muscle strength, range of motion and radiographs. An overall score using the James rating form[143] was given.

At an average follow-up of 45.8 months, they obtained good to excellent results in 67% of patients in the ACLR alone group and 70% of patients in the ACLR plus LET group.

The only statistically significant difference between the groups was in thigh atrophy with the combined group averaging 0.5-1.0 cm more atrophy than the ACLR alone group. The authors acknowledged a bias towards performing the combined procedure in patients with more severe grades of instability, and more patients in the combined group required more joint debridement at the time of surgery. Strum and his colleagues concluded that the combination of ACLR with an extra-articular procedure provides no benefit over ACLR alone therefore intra-articular ACLR alone is sufficient for addressing ACL deficiencies. However, these results should be taken with caution because of the use of the meniscus as a graft. The role of the meniscus in the development of osteoarthritis is now better understood and surgeons attempt to preserve as much of the meniscus as possible[144].

Sgaglione et al.[62] (1990) retrospectively reviewed 72 acute ACL injuries in athletes treated with a repair of the ligament, which was augmented by a Marshall over-the-top intra- and extra-articular procedure using a HT autograft in 51 cases. Evaluation included physical examination (Lachman's and pivot shift), KT-1000 measurements and the HSS ligament rating score. At an average followup of 38.5 months, no significant differences were found. However, problems directly related to the lateral sling were present in 15.7% of patients in the combined group. The authors concluded that the extra-articular supplementation does not increase stability and contributes to a poor outcome therefore it should not be used.

In 1991, Noyes et al.[21] conducted another cohort study to compare the results of an intra-articular ACLR combined with an extra-articular reconstruction to the results of ACLR alone in a population of patients with chronic ACL deficiencies. This time they used a Losee-type iliotibial band LET. Sixty-four patients underwent ACLR alone using a PT allograft and 40 patients underwent a combined ACLR plus LET. Five patients who underwent ACLR alone were excluded from the study because they had a rupture of the allograft before the two-year evaluation (n=3) or an increase in anterior-posterior displacement was found early in the postoperative period (n=2). The ACLR alone group was made up of 66% males while the combined group was composed of 90% males and patients in the combined group had a higher grade on the pivot test in relation to the contralateral limb when compared with the ACLR alone group. Patients underwent an objective evaluation (KT-1000 ligament testing and isokinetic strength testing), a comprehensive examination of the knee (Pivot shift test, general, tibiofemoral, patellofemoral and alignment-related factors), a subjective evaluation and an overall rating.

All included patients returned for a mean follow up of 34 months in the ACLR alone group and 36 months in the combined group. Post-operatively a significant difference was found in the amount of anterior-posterior displacement between the two groups ($p<0.01$) with 74% of patients in the combined group having a 2.5 millimeter or less difference between the two limbs compared to only 54% in the ACLR alone group. The rate of failure, defined as six millimeters or more of displacement or need for another operation, was higher in the ACLR alone group (16%) compared to the combined group (3%) ($p<0.05$). Patients in the combined group had a higher over-all knee rating when compared with the ACLR alone group ($p<0.01$). The authors concluded that ACLR combined with an extra-articular procedure is effective in providing support to the healing intra-articular allograft and is useful in young, active patients.

That same year, O'Brien et al.[58] published their results retrospectively examining the effect of an iliotibial band extra-articular augmentation on the long-term outcomes of ACLR using an autogenous BPTB graft. Eighty reconstructions were reviewed, 60% of which had the extra-articular augmentation. Patient evaluation included a physical examination, KT-1000 measurements and the HSS ligament rating scale. At a mean followup of four years, no differences were found between the two groups on physical examination of KT-1000 measurements. Furthermore, 40% of patients with the augmentation had chronic pain and/or swelling directly related to the lateral procedure. The authors therefore concluded that an extra-articular procedure should not be performed in addition to ACLR.

Similarly, Barber-Westin and Noyes[48] (1993) compared KT-1000 arthrometer measurements to examine the effect of an advanced rehabilitation program following ACLR. ACLR was performed using a BPTB allograft alone in 51 patients and BPTB allograft plus an iliotibial band tenodesis in 32 cases. At followup, 72% of patients in the combined group had a less than 3 mm side-to-side difference compared to only 46% in the ACLR alone group ($P<0.05$). The authors concluded that the addition of an LET provides increased stability following ACLR.

Barrett and Richardson[49] (1995) performed a retrospective study of 70 patients to determine the effect of an added extra-articular reconstruction to ACLR. ACLR was performed using a PT autograft and in 32 cases this was combined with an iliotibial band LET. Patient evaluation consisted of a subjective questionnaire, visual analog pain scale, Tegner scale, Lysholm scale, and objective evaluation consisting of thigh circumference, range of motion, instrumented knee ligament testing (KT-1000) and clinical examination (Lachman test and Pivot Shift test). At a mean follow-up of 2.9 years for the ACLR alone group and 2.8 years for the combined group, no statistically significant differences were found between the two groups in either subjective or objective measurements. The authors concluded that augmentation with an extra-articular procedure is not necessary in ACLR.

Laffargue et al.[56] (1997) evaluated the results of ACLR according to the IKDC and Arpège scoring systems to analyze the influence of an LET. Seventy-nine patients underwent ACLR for chronic instability with a BPTB autograft, which was augmented with a Lemaire LET in 43 cases. Evaluation also included the Lachman's test, pivot shift and both static and dynamic radiographs. At a mean followup of 2.5 years, no differences were observed with the addition of an LET. They concluded that an extra-articular procedure should not be performed to supplement ACLR.

In 1998, Lerat et al.[23] conducted a prospective cohort study to evaluate the role of an extra-articular procedure in ACLR by comparing the results of ACLR alone (n=50) and ACLR combined with a Marshall-MacIntosh LET using a quadriceps tendon autograft (n=60). The authors argued that using a quadriceps tendon autograft would avoid sacrificing knee stability by interrupting the iliotibial band. Evaluation included clinical examination (Lachman's and pivot shift), KT-1000 measurements, dynamic radiographs and a subjective functional evaluation.

The two groups differed demographically in time from initial injury to surgery, which was a mean of 27.6 ± 37 months for the combined group and a mean of 12.3 ± 14 months for the ACLR alone group, and pre-injury sport participation, with the ACLR alone group having 30 competitive athletes compared to only 20 in the combined group. The combined group had a mean follow-up of 44.1 ± 23 months and the ACLR alone group had a mean follow-up of 75.2 ± 30 months. The only difference between the two groups was in laxity of the lateral compartment as measured on dynamic radiographs ($p<0.002$ at 4 years). The authors therefore concluded that an added extra-articular procedure improved the results of ACLR in patients with chronic ACL deficiencies.

Kanisawa et al.[55] (2003) evaluated the weight-bearing knee kinematics in patients who underwent ACLR with a HT autograft (n=6) or ACLR with a HT autograft plus an iliotibial band LET using dynamic fluoroscopy. They selected patients with at least one year of followup and good or excellent results according to IDKC score. They found no statistically significant differences in knee kinematics between operated and normal knees and no differences were observed between the two surgical groups. The ACLR plus LET group exhibited a trend toward decreased anterior translation in the lateral compartment, however the small sample size did not allow for adequate power. Furthermore, their technique had a statistical threshold of 3 to 5 mm for translations and 5° of axial rotation.

A few years later, Monaco et al.[57] (2007) directly compared a cohort of patients who underwent single-bundle ACLR with an LET to those who underwent double-bundle ACLR to determine the effect of the LET on internal rotation of the tibia using an intraoperative computer navigation system. The single bundle reconstruction was performed with a HT autograft with a Coker-Arnold iliotibial band (ITB) tenodesis. In this procedure, a piece of the ITB is detached proximally, reflected and passed under the LCL and attached to Gerdy's tubercle while the tibia is in maximal external rotation. The double-bundle reconstruction was performed using a HT autograft. They selected 20 male patients with a body mass index <30, and alternately assigned them to one of the two groups. They found that prior to surgery the mean maximal manual internal rotation of the tibia was 21.1 ± 4.2° before reconstruction, 16.3 ± 5.4° after single-bundle ACLR and

10.9 ± 5.7° after the addition of the LET. The mean maximal manual internal rotation in the double-bundle group was 16.6 ± 4.0° following the reconstruction. This difference was statistically significant ($p<0.05$). No differences in anterior-posterior translation or external rotation of the tibia were observed. The authors concluded that both single-bundle and double-bundle ACLR are adequate in addressing ACL deficiency, however the addition of an LET is beneficial in reducing internal rotation of the tibia.

Savalli et al.[61] (2008) investigated the impact of an extra-articular reinforcement on resumption of sports following ACLR. Twelve months after hospitalization the IKDC subjective questionnaire was sent to 2248 athletes who had undergone ACLR. The response rate was 43%, and significantly more females responded ($p=0.01$). Among other techniques, 54% underwent ACLR with a HT graft, 16% of which were augmented with an LET, and 43% with a PT graft, 7% with an additional LET. They found that the presence of the LET was not significantly associated with resumption of sporting activity. Furthermore, a subgroup analysis of the patients who received a HT graft found no differences in resumption of sports activities or IKDC scores when comparing those with the HT graft alone to those with the additional LET.

In 2011, Sonnery-Cottett et al.[63] retrospectively reviewed a consecutive series of 1957 patients who underwent ACLR to report the prevalence of septic arthritis, 188 of which had a combined LET. They found that the addition of an LET was significantly associated with septic arthritis following ACLR (OR = 4.8, 95% CI: 1.04-18.04, $p=0.02$). However, they also found that professional athletes were at a higher risk of septic arthritis, and the LET was performed in 23% of the professional athletes and only 9% of the general population. Due to competing variables, these conclusions need to be taken with caution.

Most recently, Dejour et al.[50] (2013) compared three surgical procedures for ACLR: BPTB autograft (n=25), double-bundle HT autograft (n=25) and PT autograft plus a modified Lemaire LET (n=25). Outcome measures included subjective and objective IKDC scores, pivot shift, dynamic radiographs, ability to kneel and walk over a hard surface, return to sport and anterior knee pain. At a mean followup of two years, the

BPTB plus LET procedure allowed for a greater absolute correction of anterior tibial translation in the lateral compartment as calculated on dynamic radiographs. No other statistically significant differences were found. The authors concluded that the addition of an LET provides increased stability and can be used in the primary setting for athletes with ACL-deficiencies.

2.4.7.2.2 Randomized Studies

In 2001, Anderson et al.[40] conducted a prospective randomized study to determine differences in results between three methods of ACL reconstruction: BPTB autograft (n=35); HT autograft combined with a Losee iliotibial band LET (n=35); and HT autograft alone. From 1991 to 1993, 105 patients met the inclusion criteria and consented to the study. Randomization was performed using a computer-generated list of the three procedures. Patient demographics were balanced between the three groups. Outcome measures included physical examination, KT-1000 arthrometer ligament laxity testing, quadriceps and hamstrings muscle strength-testing, radiographs, the Hospital for Special Surgery knee score and the International Knee Documentation Committee (IKDC) Knee Evaluation Form. One hundred and two patients were available for a mean follow-up of 35.4 ± 11.6 months. No statistically significant differences were found between the three groups. Anderson et al. concluded that an extra-articular procedure did not improve the results of the ACL reconstruction therefore there is no benefit to the combined procedure.

Aït Si Selmi et al.[145] presented their findings of a prospective, randomized trial examining the influence of an extra-articular procedure associated with a BPTB graft in the treatment of chronic anterior laxity of the knee at the Lyon Knee Surgery Meeting in 2002. Patients were randomized to receive a BPTB autograft alone (n=60) or a BPTB autograft with a Lemaire LET using a semitendinosus autograft. Evaluation included the IKDC clinical and subjective scores, Lachman's, pivot shift and radiographs. Patient demographics were balanced between the two groups. Followup consisted of 51/60 patients in the BPTB alone group at a mean 16.5 ± 8 months and 56/60 patients in the BPTB plus LET group at a mean 18.5 ± 8 months. An equal pivot compared to the contralateral limb was found in 91.1% of the BPTB plus LET group compared to only 80.4% in the BPTB alone group. No other differences were found. The authors concluded that a BPTB graft alone does not treat all laxities of the knee, and the addition of an LET is beneficial.

Acquitter et al.[39] (2003) performed a prospective randomized study to analyze the impact of an LET in ACLR with a free-PT-bone autograft. One hundred patients were randomly allocated to ACLR with a Marshall-MacIntosh quadriceps tendon LET (n=50) or ACLR alone (n=50). Randomization was generated by a number table and placed in concealed envelopes. Patient demographics were balanced between the groups except for time from injury to surgery, which was shorter for the ACLR plus LET group (23 ± 29 months versus 35 ± 43 months). Outcome measures included KT-1000 laxity testing and functional outcome assessed using the IKDC criteria. No patients were lost to follow-up. At a mean of 58 months, no statistically significant differences were found. The authors concluded that the addition of an LET is unnecessary in the treatment of the ACL deficient knee.

Giraud et al.[41] (2006) compared two randomized series of ACLRs, one using a PT autograft (n=34) and the other using a PT autograft with a “Mac-InJones” quadriceps tendon lateral tenodesis (n=29), in patients with significant laxity (7 to 12 mm) in the medial compartment, measured on passive dynamic radiographs with the knee flexed at 20 degrees. The “Mac-InJones” procedure is performed using by passing the quadriceps tendon through the femoral tunnel of the ACL reconstruction, passing it under the LCL, then passing it through a tunnel drilled in Gerdy’s tubercle and suturing it back onto itself. Patient demographics were balanced between the two groups. Outcome measures included clinical assessment, IKDC subjective functional scores, KT-1000 measurements and dynamic radiographs. Only 76.5% of patients in the PT alone group and 68% in the PT plus Mac-InJones group returned for an average followup of 102 months and 93 months respectively. A positive pivot shift was found in 38.1% of patients in the PT alone group compared to only 21.1% of patients in the PT plus ‘Mac-InJones’ group. No other statistically significant differences were found. The authors concluded that though the pivot shift demonstrated better control with lateral augmentation, there is no advantage to adding an extra-articular procedure.

In 2006, Zaffagnini et al.[24] published their results of a randomized controlled trial comparing three techniques of ACLR in patients involved in cutting sports at the competitive or amateur level. The three techniques were: BPTP graft (n=25), HT graft (n=25) and HT graft plus a lateral extra-articular plasty via over-the-top fixation (n=25). Evaluation included IKDC scores, Tegner scores, thigh circumference, anterior knee pain, pivot shift, Lachman's, KT-2000 measurements, range of motion, time to return to activity and radiographic evaluations. Randomization was performed using alternate systematic sampling and patient demographics were balanced between the two groups.

All patients returned for evaluation at five years postoperative. There was a significantly higher incidence of a positive pivot shift in patients in the HT alone group, with 36% having a positive pivot compared to 12% in the BPTB group and 8% in the HT plus lateral plasty group. Furthermore, a positive Lachman's test was found in 22% of patients in the HT alone group compared to 12% in the BPTB group and only 8% in the HT plus lateral plasty group. Patients in the HT plus lateral plasty also had higher IKDC subjective scores compared to the other two groups (p=0.04). Patients in the lateral plasty group were able to return to sport in less time compared to the other two groups. The authors concluded that a lateral plasty should be used in combination with intra-articular reconstruction in the ACL-deficient athlete.

Zaffagnini et al.[47] (2008) conducted a randomized trial to compare the aforementioned extra-articular procedure[24] to a more anatomic double-bundle reconstruction. The double bundle reconstruction was performed using a HT autograft. Seventy-two patients were randomized to single bundle plus lateral plasty (n=35) or double-bundle reconstruction (n=37). This time randomization was performed using computer-generated randomization tables and demographics were balanced between the groups. They used the same method of evaluation as the previous study with the addition of the Marx Activity Rating Scale and a Psychovitality Questionnaire. All patients returned for a mean followup of 3.9 years. The double-bundle group reported a higher percentage of normal knees according to the IKDC score, with 86.5% classified as normal compared to 62.9% in the HT plus lateral plasty group (p=0.04). Furthermore, two patients in the HT plus lateral plasty group were found to have a positive pivot shift compared to zero in the double-bundle group. Subjectively, patients in the double-bundle group reported an average score of 88.4% compared to the HT plus lateral plasty group which reported an average score of 83.9%, though this difference was not statistically significant ($p=0.09$). Results for the Marx Activity Rating Scale were also higher in the double-bundle group (12.2 versus 9.6, $p<0.01$). All patients in the double-bundle group returned to their pre-injury level of activity whereas only 91% in the HT plus lateral plasty group returned. Patients in the double-bundle group were also able to return in a shorter period of time (3.8 versus 6.4 months, $p<0.01$). The authors concluded that anatomic double-bundle reconstruction of the ACL was superior to single bundle reconstruction with a lateral extra-articular plasty.

In response to the mixed results being published, some authors hypothesized that an extra-articular procedure may be warranted for specific patient populations only. In 2013, Vadala et al.[43] conducted a randomized controlled trial to evaluate the role of Cocker-Arnold's extra-articular procedure in reducing postoperative rotational knee laxity following ACLR in female athletes. Between 2005 and 2006, 60 patients were recruited and were designated via a draw to either ACLR with a HT autograft (32 patients) or HT autograft plus an extra-articular MacIntosh procedure modified by Cocker-Arnold. Patient demographics were balanced between the two groups. Outcome measures included a visual analog pain score, subjective rating of success by the patient, physical examination (consisting of the Lachman test, pivot-shift test and range of motion), the Tegner scale, the Lysholm, knee score, IKDC 2000 knee score and KT-1000 arthrometer laxity testing.

Fifty-five of the 60 patients were available for a mean follow-up of 44.6 months. Pivot-shift was found to be negative in 81.4% of patients in the combined group and 42.9% of patients in the ACL reconstruction alone group, which was found to be statistically significant ($p=0.003$). There were no statistically significant differences between the two groups for the other outcomes. Vadala et al. concluded that an extra-articular significantly reduces post-operative rotational instability of the knee in female patients.

Trichine et al.[42] (2014) performed a prospective randomized controlled trial to assess the influence of extra-articular augmentation in patients with advanced-stage chronic ACL-deficiencies. The authors did not provide a specific definition for 'chronic'. Patients were allocated to either BPTB autograft (n=60) or BPTB autograft combined with an iliotibial band LET as described by Kenneth Jones (n=60) using a computer generated randomized list of procedures. There was limited demographic information presented on the two groups, however the information that was presented was balanced. Interestingly, all patients were male. Patients in the BPTB alone group had a mean of 37.9 months for the time from injury to surgery compared to 35.5 months in the BPTB plus LET group. Patients were evaluated using the IKDC score, pivot shift, Lachman's and dynamic radiographs.

A total of 52 patients in the BPTB alone group and 55 patients in the BPTB plus LET group returned for an average followup of 24.5 months and 23.4 months respectively. No significant differences were found in functional scores, subjective scores or clinical stability. On dynamic radiographs, the LET provided a greater improvement in laxity in the lateral compartment compared to the BPTB alone reconstruction. The authors concluded that use of an extra-articular augmentation is beneficial radiographically, especially in patients with chronic deficiencies.

2.4.7.2.3 Systematic Review and Meta-Analysis

We performed a systematic review of the literature to determine whether the addition of an LET to ACLR provided increased rotational stability and improved clinical outcomes when compared to ACLR alone[66]. We included all studies examining primary ACLRs in adult, human populations with clinical and patient reported outcomes. Eight randomized trials and 21 non-randomized cohort studies met the eligibility criteria. However, for most studies we were either unable to determine the risk of bias because of poor reporting or the risk of bias was high according to the Cochrane Collaboration Tool for Assessing Risk of Bias[146] (Table 1 and Table 2).

Table 1: Cochrane Collaboration tool for assessing risk of bias ratings of randomized studies comparing ACLR alone to ACLR plus LET.

Authors	Random Sequence Generator	Allocation Concealment	Blinding of Participants and Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Reporting	Other Bias
Acquitter et al.[26]	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk	Low risk
Anderson et al.[27]	Low risk	Unclear	Unclear	Unclear	Low risk	Low risk	Low risk
Giraud et al.[28]	High risk	Low risk	Unclear	High risk	High risk	Low risk	Low risk
Kerschbaumer et al.[29]	Unclear	Unclear	Unclear	Unclear	Unclear	Low risk	Low risk
Trichine et al.[30]	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk	Low risk
Vadalà et al.[31]	High risk	Low risk	Unclear	Low risk	Low risk	Low risk	Low risk
Zaffagnini et al.[32] (2006)	High risk	High risk	Unclear	Unclear	Low risk	Low risk	Low risk
Zaffagnini et al.[33] (2008)	Low risk	Low risk	Unclear	Low risk	Low risk	Low risk	Low risk

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Table 2: Cochrane Collaboration tool for assessing risk of bias ratings of non-randomized studies comparing ACLR alone to ACLR plus LET.

Authors	Evidence of Selection Bias/Prognostic Imbalance	Blinding of Participants and Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Reporting
Barber-Westin and Noyes[34]	Unclear	Unclear	Unclear	Low risk	Low risk
Barrett and Richardson[35]	Low risk	Unclear	Unclear	Low risk	Low risk
Dejour et al.[36]	High risk	Unclear	Low risk	Low risk	Low risk
Ferkel et al.[37]	High risk	Unclear	Unclear	Low risk	Low risk
Goertzen and Schulitz[38]	High risk	Unclear	Unclear	Low risk	Low risk
Hefti et al.[39]	Unclear	Unclear	Unclear	Unclear	Low risk
Hernández-Hermoso et al.[40]	Low risk	Unclear	Unclear	Low risk	Low risk
Kanisawa et al.[41]	High risk	Unclear	Unclear	Low risk	Low risk
Laffargue et al.[42]	Low risk	Unclear	Unclear	Low risk	Low risk
Lerat et al.[43]	High risk	Unclear	High risk	High risk	Low risk
Monaco et al.[44]	High risk	Unclear	High risk	Low risk	Low risk
Noyes and Barber[45]	Low risk	Unclear	Unclear	High risk	Low risk
O'Brien et al.[46]	High risk	Unclear	Unclear	Low risk	Low risk
Paterson and Trickey[47]	High risk	Unclear	Unclear	Unclear	Low risk
Riel et al.[48]	Low risk	Unclear	Unclear	High risk	Low risk
Roth et al.[49]	High risk	Unclear	Unclear	Low risk	Low risk
Savalli et al.[50]	High risk	Unclear	Unclear	High risk	Low risk
Sgaglione et al.[51]	High risk	Unclear	Unclear	Low risk	Low risk
Sonnery-Cottet et al.[52]	High risk	Unclear	Unclear	Low risk	Low risk
Strum et al.[53]	Unclear	Low risk	Low risk	Low risk	Low risk
Verdano et al.[54]	Unclear	Unclear	Low risk	Unclear	Unclear

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Reconstruction: A Systematic Review of the Literature, Arthroscopy: The Journal of Arthroscopic & Related Surgery, 2015, Available online 24 June 2015[66].

Surgical technique, graft choice and outcome measures varied greatly between the studies, making it difficult to compare the groups. A meta-analysis of 14 studies found a statistically significant difference in the presence of a postoperative pivot shift, favoring the ACLR plus LET group (p<0.01) (Figure 2). No differences were found in KT-1000 arthrometer measurements or International Knee Documentation Committee (IKDC) Objective scores. These findings suggest a potential benefit of the addition of an LET to ACLR, however, future methodologically rigorous studies are needed.

	ACL plus LET		ACL alone		
Study	# of events	Sample size	# of events	Sample size	Odds Ratio (95% CI)
Anderson et al.[27]	11	34	22	68	1.00 (0.41 to 2.41)
Barrett and Richardson[35]	1	32	6	38	0.17 (0.02, 1.51)
Dejour et al.[36]	2	25	10	50	0.35 (0.07 to 1.73)
Goertzen and Schulitz[38]	0	32	3	24	0.09 (0.00 to 1.92)
Hefti et al.[39]	2	23	2	52	2.38 (0.31 to 18.04)
Kerschbaumer et al.[29]	2	37	5	13	0.09 (0.01 to 0.56)
Noyes and Barber[45]	10	40	26	64	0.49 (0.20 to 1.17)
O'Brien et al.[46]	7	48	6	32	0.74 (0.22 to 2.45)
Roth et al.[49]	21	43	27	50	0.81 (0.36 to 1.84)
Strum et al.[53]	6	43	13	84	0.89 (0.31 to 2.52)
Trichine et al.[30]	4	55	11	52	0.29 (0.09 to 0.99)
Vadala et al.[31]	5	27	16	28	0.17 (0.05 to 0.58)
Zaffagnini (2006) et al.[32]	2	25	12	50	0.28 (0.06 to 1.34)
Zaffagnini (2008) et al.[33]	2	35	0	37	5.60 (0.26 to 120.80)
Overall	75	499	159	642	0.50 (0.32 to 0.78)

Heterogeneity: Chi² = 19.75, df = 13 (P = 0.10); I² = 34%

Test for overall effect: Z = 3.06 (P = 0.002)

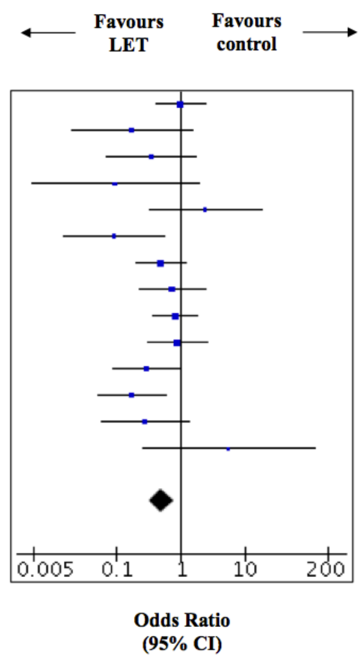

Figure 2: Meta-analysis comparing postoperative pivot shift in patients undergoing ACLR plus LET and patients undergoing ACLR alone.

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Around the same time, Rezende et al.[147] published their meta-analysis of randomized controlled trials comparing combined intra- and extra-articular ACLR with intra-articular ACLR alone. They found eight studies that met their eligibility criteria for a total population of 682 participants. They found the included studies to be of moderate quality. Meta-analysis found no difference between the two groups in IKDC evaluation, return-to-activity and Tegner Lysholm scores. Patients who underwent the combined procedure were more likely to have improved stability based on the pivot shift test (Risk Ratio (RR): 0.95, p=0.02) and the Lachman's test (RR: 0.93, p=0.01). Furthermore, no differences were found in general complications or failure rates with 8 graft failures in the combined group and 2 in the ACLR alone group based on 5 studies (9=0.13).

The authors performed a sub-group analysis to determine whether outcomes varied according to graft type. No differences were found between the groups for Lachman's or pivot shift results in the patients who received a BPTB graft. For the studies using a HT graft, the proportion of patients with a normal or nearly normal Lachman grade was higher in the combined group (RR: 0.87, p=0.03). The proportion of patients with a less than 3 mm side-to-side difference on KT-1000 arthometer measurements was also greater in the combined group (RR: 0.87, p=0.03). No differences were found in pivot shift results (p=0.21), however, according to the classification suggested by Higgins et al.,[148] the heterogeneity of the analysis was high (I^2=69%) and should therefore induce caution.

The authors concluded that the addition of an extra-articular procedure may provide an advantage regarding knee stability tests; however, it is unclear whether or not this is justified at the cost of the additional procedure. Furthermore, data regarding complications and adverse events is limited and not reported by most studies. The authors suggest that future studies focusing on outcomes detecting function and complications, such as graft failure and stiffness, are needed.

2.4.8 Summary

Injury to the ACL is a common and debilitating injury, particularly in young athletes. ACLR is often necessary to allow for return to pivoting sports and to protect the knee joint from further injury. Early approaches to ACL deficiency included an extra-articular reconstruction on the lateral side of the knee known as an LET. Poor results eventually resulted in this approach giving way to more advanced, intra-articular reconstruction techniques. Conventional techniques of ACLR perform well subjectively, however, research has shown that rotational control is often lacking. Furthermore, re-injury rates as high as 25% have been reported.

Some authors have continued to perform extra-articular reconstructions to augment intra-articular reconstructions, reporting excellent results. Other studies have suggested there is no benefit to the addition of an LET, and it may result in more complications and a worse outcome. However, a review of the literature has shown that the majority of studies examining the effect of an LET are at a high or unclear risk of bias, and lack adequate power to make definitive conclusions. Although this is not a new concept, an adequately powered, level one randomized clinical trial is needed to investigate the potential impact of an LET on intra-articular ACLR.

Chapter 3

3 Objectives

Our primary objective was to conduct a methodically rigorous study to compare outcomes between patients undergoing anterior cruciate ligament (ACL) reconstruction augmented with a lateral extra-articular tenodesis (LET) to those undergoing anterior cruciate ligament reconstruction alone. Our primary outcome was Limb Symmetry Index as calculated using the results of the hop test at six months postoperative. Secondary outcome measures were the 4-Item Pain Intensity Measure (P4), quadriceps and hamstrings strength and the Lower Extremity Functional Scale (LEFS).

We hypothesized that there would be no difference in Limb Symmetry Index between patients undergoing ACL reconstruction with an LET and those undergoing ACL reconstruction alone at six months postoperative. However, we hypothesized that patients in the ACL plus LET group would perform better on the hop test at later time points due to increased rotational control. We also hypothesized that immediately following surgery there would be a difference in pain but that by six months postoperative there would be no difference in pain between the two groups. We did not expect to see any differences in isokinetic strength or the Lower Extremity Functional Scale at six months postoperative.

Chapter 4

4 Methodology

This was a multicenter randomized clinical trial involving eight centers in Canada and two centers in Europe. Local patient recruitment began February 2014.

4.1 Institutional Approval

Local ethics approval was obtained from the Western University Health Sciences Research Ethics Board (HSREB) following full board review for the use of human participants (REB file number: 104524) (Appendix A). Approval was obtained from Lawson Health Research Institute's Clinical Research Impact Committee and Lawson Administration (Lawson Approval Number: R-14-059) (Appendix B). The trial was also registered on www.clinicaltrials.gov (NCT02018354).

4.2 Eligibility Requirements

Patients were eligible to participate in the study if they: (A) had an ACL deficient knee requiring surgical reconstruction; (B) were skeletally mature up to 25 years of age at the time of surgery; and (C) had two or more of the following: (1) participated in a competitive pivoting sport; (2) had a positive pivot shift of grade two or higher; or (3) had generalized ligamentous laxity (Beighton[149] score of four or greater) or had genu recurvatum greater than 10 degrees.

Patients were excluded if they: (1) had undergone previous ACL reconstruction on either knee; (2) required bilateral ACL reconstruction; (3) required surgical repair or reconstruction of the posterior cruciate ligament, medial collateral ligament, lateral collateral ligament, or posterolateral corner; (4) had a symptomatic articular cartilage defect requiring treatment other than debridement; (5) had greater than three degrees of asymmetric varus alignment; (6) did not speak, read, or understand English, French or Dutch; (7) had a cognitive impairment or psychiatric illness that precluded informed consent or rendered the patient unable to complete questionnaires; (8) had a medical illness where life expectancy was less than two years; (10) incompetency or unwillingness to provide informed consent; or (11) had no fixed address or no means of contact and were not available for the two year follow up period.

4.3 Subject Recruitment

Local patients were consecutively recruited from the practices of three orthopaedic surgeons at the Fowler Kennedy Sport Medicine Clinic in London, Ontario, Canada. Informed consent was obtained from all patients (Appendix C).

Other sites included: Banff Sport Medicine in Banff, Alberta, Canada; Fraser Health Authority in Vancouver, British Columbia, Canada; Pan Am Clinic in Winnipeg, Manitoba, Canada; Kingston General Hospital in Kingston, Ontario, Canada; McMaster University Children's Hospital, Ontario, Canada; Glen Sather Sports Medicine Clinic in Edmonton, Alberta, Canada; Foothills Medical Centre in Calgary, Alberta, Canada; University of Calgary Sport Medicine Centre, Calgary, Alberta, Canada; Antwerp Orthopaedic Centre in Antwerp, Belgium; and University Hospitals Coventry and Warwickshire NHS Trust in Coventry, United Kingdom.

4.4 Randomization

Randomization was performed by either the research staff or the nursing staff, and took place in the operating theatre following confirmation of eligibility by the surgeon through diagnostic arthroscopy of the knee joint. Patients were randomized in permuted block sizes of two and four on a one-to-one basis into one of two groups: (1) ACL reconstruction with lateral extra-articular tenodesis (experimental) or (2) ACL reconstruction alone (control). Randomization was stratified by surgeon, gender and whether or not a meniscal repair requiring a change in post-operative rehabilitation was performed.

4.5 Interventions

4.5.1 Anterior Cruciate Ligament Reconstruction

All patients received an anatomic ACL reconstruction that was performed using an autologous hamstring graft (semitendinosus and semimembranosus) in a standardized fashion across all sites. If the diameter of the graft was less than eight millimeters, semitendinosus was tripled or quadrupled to provide a greater graft diameter. Femoral tunnels were drilled using an anteromedial portal technique, with femoral fixation provided by an Endobutton or equivalent. Tibial fixation was provided by an interference screw.

4.5.2 Lateral Extra-Articular Tenodesis (Experimental)

The LET procedure used was a modification of the Lemaire technique[150] and the procedure was standardized across all centers. Surgeons made an oblique skin incision between the lateral epicondyle and Gerdy's tubercle measuring approximately five centimeters. A one-centimeter by eight-centimeter strip of the posterior iliotibial band was fashioned, preserving the Gerdy's tubercle attachment. A No. 1 vicryl whip suture was applied to the free end leaving the needle attached. The graft was then tunneled under the lateral collateral ligament (LCL) and attached to the femur with a small-long Richards Staple (Smith & Nephew™) distal to the intermuscular septum and proximal to the femoral insertion of the LCL. Fixation was performed with the knee between 60 and 70^0 flexion and neutral rotation. Minimal tension was applied to the graft. The free end of the graft was then looped back onto itself and sutured using the No. 1 vicryl suture.

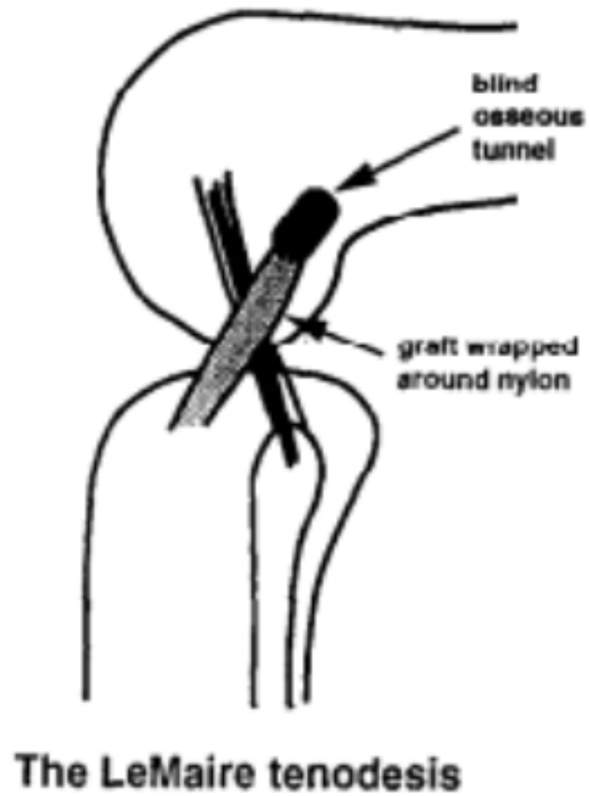

Figure 3: Diagrammatic representation of the Lemaire lateral extra-articular tenodesis (LET). In the modified Lemaire, the graft is passed under the lateral collateral ligament (LCL) and attached to the femur via staple fixation rather than an osseous tunnel. Nylon is not used in the modified technique.

Reproduced with permission from: Thomas et al., Clinical evaluation of the LeMaire anterior cruciate ligament lateral substitution procedure. A quality audit of the Leicester modification. Injury, 1998, 29 (6), 417-419[151].

All patients followed an identical postoperative rehabilitation protocol created by the Fowler Kennedy Sports Medicine Clinic Physical Therapy Department (Appendix D). Focus was placed on early range of motion and weight bearing as tolerated. This was standardized across all centers.

4.6 Outcome Measures

All patients were assessed preoperatively and at 3, 6, 12, and 24 months postoperatively. For the purposes of this thesis, we only analyzed data up to the six-month followup.

4.6.1 Primary Outcome Measure

4.6.1.1 Hop Test

The hop test, in general, is designed to evaluate neuromuscular control, strength, power and confidence in the limb. The combination of four different hop tests is particularly suitable for patients who are undergoing ACL reconstruction because it incorporates a variety of movement principles (i.e. direction change, speed, acceleration-deceleration, rebound) that mimic the demands of knee stability during sporting activities. The hop test was administered by a trained kinesiologist at each centre who was blinded to the operative procedure via a tubigrip on the operative limb.

Our primary outcome was Limb Symmetry Index (LSI) which was calculated using the combination of four hop tests as described by Noyes et al. (Figure 3)[152]. All hops were performed twice on the non-injured limb and twice on the post-operative limb and the average of the two trials was used in the analysis. The LSI expresses the test performance of the operative limb as a percentage of the non-operative limb. A higher LSI indicates a higher level of function for the operative limb. The hop test has demonstrated validity and excellent test-retest reliability[153].

For the single hop for distance, the patient stands on the limb to be tested, hops and lands on the same limb. The distance hopped is measured at the point of the great toe. In the timed 6-m hop test, the patient performs a series of one-legged hops on the same leg over the total distance. Time starts when the patient’s heel lifts from the starting position and is stopped when the foot passes the finish line.

In the triple hop for distance, the patient stands on one leg and performs three consecutive hops on the same leg, covering as much distance as possible. The total distance is measured. For the crossover hop for distance, the patient hops forward three times while alternately crossing over a 15-cm wide marking. The total distance hopped forward is measured. Patients are offered a rest period between each individual hop test trial (up to two minutes) if needed.

We chose the hop test because it was validated in previous research specifically looking at the effects of ACLR and is one of the most common functional outcomes used in ACL research[152-154]. The hop test gives a measure of overall lower limb function and when combined with other measures it can be useful to help determine when a patient is ready to return to activity. It is important to note that the test has not yet been shown to be predictive of injury.

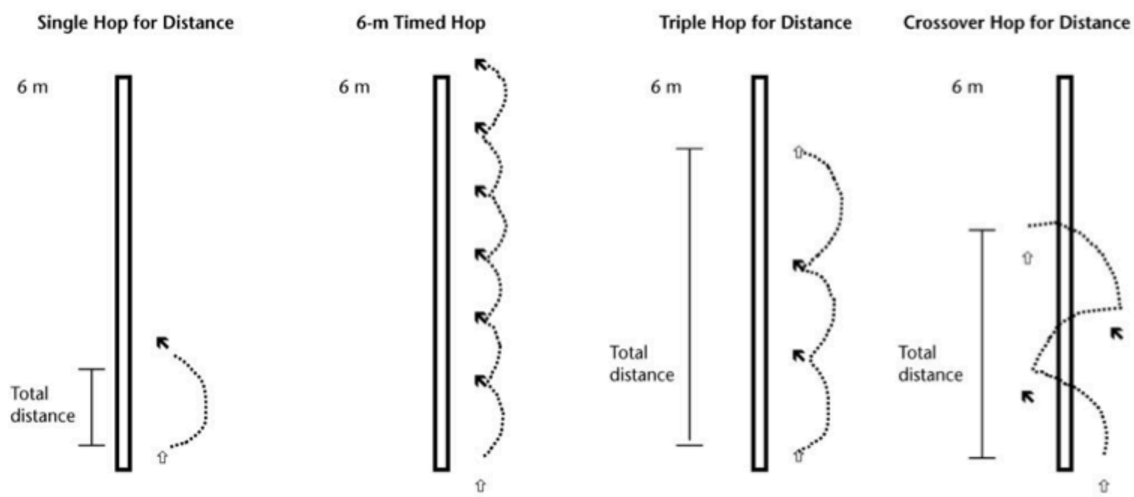

Figure 4: Diagrammatic representation of the series of four hop tests.

Reproduced with permission from: Noyes et al., Abnormal lower limb symmetry determined by function hop tests after anterior cruciate ligament rupture, American Journal of Sports Medicine, 1991, 19(5), 513-518[152].

4.6.2 Secondary Outcome Measures

4.6.2.1 Four-Item Pain Intensity Measure (P4)

The Four-Item Pain Intensity Measure (P4) is a patient-reported four-item questionnaire created by Spadoni et al.[155] that queries pain intensity in the morning, afternoon, evening, and with activity over the past two days (Appendix E). Each item is measured using an ordinal scale ranging from 0 (no pain) to 10 (pain as bad as it can be). Scores are calculated by adding the individual scores from each item, to give a maximum score of 40. The P4 has shown a test-retest reliability of 0.78 and a longitudinal validity of 0.63[156]. Patients completed the P4 questionnaire prior to surgery (baseline) and at 3 months, 6 months, 12 months and 24 months post-operatively.

Pain is a common complaint of patients with musculoskeletal injuries both pre-operatively and post-operatively[156]. The addition of the LET procedure increases the invasiveness of the surgery and therefore could potentially result in increased pain post-operatively. Visual analog scales (VAS) and numeric pain rating scales (NPRS) are most commonly used to measure pain however the ability of the measures to detect change is less than other self-reported functional status measure[156]. We chose the P4 scale because it is a more robust measure of pain and has been shown to be more adept at assessing change in pain intensity than the more commonly used VAS and single-item NPRS[156].

4.6.2.2 Lower Extremity Functional Scale (LEFS)

The Lower Extremity Functional Scale, developed by Binkley et al.[157], is a self-report functional measure for patients with lower extremity orthopedic conditions. This scale consists of 20 functional items with five response options each item (Appendix F). Response options range from 0 (extreme difficulty or unable to perform activity) to 4 (no difficulty). The patient's score is tallied, and the total possible score of 80 indicates a high level of function. The LEFS is a valid measure of function, is responsive to change, and is highly reliable[158]. Patients completed the LEFS prior to surgery (baseline) and at 3 months, 6 months, 12 months and 24 months post-operatively.

We chose the LEFS because it gives an overall measure of lower extremity function and is commonly used in research exploring ACLR[157]. Furthermore, it is often used in combination with the hop test and LEFS scores have been show to correlate with hop test measurements[153]. The LEFS has been show to have a superior capacity to detect change in lower extremity function when compared to the Short Form Health Survey (SF-36) function subscale[157].

4.6.2.3 Quadriceps and Hamstrings Strength

We measured strength prior to surgery (baseline) and at 6 months, 12 months and 24 months post-operatively using the Biodex System 3 PRO computerized isokinetic dynamometer (Biodex Medical Inc., Shirley, New York). Strength measurements were performed in a standardized fashion across all sites. The patient wore a tubigrip on the operative limb to conceal group allocation. The patient was seated with his/her back against a backrest oriented at 80° above the horizontal and his/her hips in approximately 80° of flexion. Two seatbelts securing the patient's pelvis were oriented diagonally from the dynamometer seat, across the anterior superior iliac spines and over the shoulders to the backrest. The axis of rotation of the dynamometer lever arm was positioned coaxial to the lateral femoral epicondyle.

Patients performed the test first with the non-injured limb then again with the injured limb. On each side they performed four practice contractions to familiarize themselves with the testing apparatus. Patients were given a 30-second rest period between the practice contractions and the actual test. Each test consisted of 6 consecutive alternating knee flexion (3 repetitions) and extension (3 repetitions) movements and was assessed using the maximal concentric muscle actions at an angular velocity of 90°/s. If the variance of the quadriceps or hamstrings contractions were greater than 10%, the test was repeated following a 60-second rest period.

Peak torque (Newton metres) and average power (Watts) measurements were recorded and strength scores were calculated by dividing the affected limb by the unaffected limb to get a percentage of function for both flexion and extension. Hamstrings to quadriceps ratios (percentage) were also presented for the affected limb. For all measurements a higher score indicates a higher level of function. The Biodex System 3 has been shown to perform with acceptable mechanical reliability and validity[159].

We chose to perform strength measurements because many studies have reported quadriceps and hamstrings deficits following ACLR[2,160,161]. Furthermore, greater limb asymmetry is related to poor self-reported function, functional performance and altered lower extremity mechanics during gait[161]. Quadriceps and hamstrings symmetry is a goal of post-operative rehabilitation following ACLR and when combined with other measures can be useful in determining when a patient is ready to return to activity.

Most studies using isokinetic strength measurements examine strength at multiple speeds, and increase the number of repetitions as speed increases. We chose to perform isokinetic measurements at 90 degrees/sec because we were interested in peak torque and power measurements rather than endurance and fatigability. Furthermore, 90 degrees/sec is conservative and allows for measuring peak torque without placing the ACL under too much stress. This protocol was more time efficient and allowed for standardization of strength testing across centers.

Figure 5: Biodex System 3 PRO Computerized Isokinetic Dynamometer.

4.7 Sample Size

The primary outcome of the full study was graft failure, defined by either a re-rupture requiring revision ACLR or an asymmetric positive pivot shift, which required a sample size of 600 patients (300 per group). Since our primary outcome was the limb symmetry index, we conducted a formal equality sample size calculation for this outcome using a two-sided alpha error rate of 0.05 with a statistical power of 80% to detect a moderate effect size of half of a standard deviation, which has been shown to represent a patient-important difference[162]. It was determined that 63 patients were required for each group. Based on previous studies conducted at the Fowler Kennedy Sport Medicine Clinic we expected a 15% loss to follow-up. Therefore, the sample size was increased to 73 patients per group, for a total of 146 patients.

4.8 Statistical Analysis

All data analyses were performed using IBM SPSS Statistics version 22 (IBM Corp., Armonk, NY)[163]. We used descriptive characteristics to present the demographic characteristics of the patients by group using means and standard deviations for continuous variables (age, height, weight, time from injury to surgery) and proportions for nominal variables (sex, operative limb, limb dominance, mechanism of injury, sport participation at the time of injury and associated injuries).

We presented all continuous data (Limb Symmetry Index from the hop test, P4, strength and LEFS) as a mean ± standard deviation. Since the hop test was only completed at six months postoperative, we used an independent groups t-test to evaluate whether the limb symmetry index between the two groups was statistically different. Since a large number of patients were unable to perform the hop test at six months postoperative, we also presented the proportion of patients in each group who could not complete the test and used a chi-square test to determine whether there was a statistically significant difference between the two groups.

For any outcome where we were able to collect a preoperative measure (P4, strength and LEFS), we conducted an analysis of covariance (ANCOVA) where the preoperative score served as the covariate, the postoperative score served as the dependent variable and the study group served as the independent variable. A $p<0.05$ was considered to be statistically significant. To compare the approaches over time we presented a plot of the mean scores with 95% confidence intervals for each outcome measure over time with each group as a separate line. For the P4 and LEFS, missing midpoint data was filled in using a growth curve imputation. We used last outcome carried forward to impute missing endpoint data.

Chapter 5

5 Results

5.1 Participant Flow

The flow of patients through each stage of the study is outlined in Figure 5. From February 2014 to May 2015, 533 patients were screened for eligibility. Of these, 251 did not meet the eligibility criteria and 20 declined to participate.

Two hundred and sixty-three eligible patients consented to participate in the study; thirteen were deemed ineligible at the time of surgery because they had a physical examination under anesthesia that suggested a low grade of rotational laxity (< grade 2 pivot shift; n= 4); diagnostic arthroscopy confirmed that they only had a partial ACL tear (n=5); they required reconstruction of an additional ligament (n=2); they had cartilage damage that required more than mechanical chondroplasty (n=1); or the ACL reconstruction was performed using a bone patellar tendon bone graft (n=1). One patient was withdrawn post-randomization because she had a physical examination findings positive for ACL tear on both sides. It was later confirmed that she did have bilateral ACL tears. One patient was missed by the research assistant.

At the time of this thesis, 232 patients were included in the study (115 ACL and 117 ACL plus LET). Only 70 patients were at least 6 months postoperative (36 ACL and 34 ACL plus LET) and, therefore, included in this analysis. Fewer patients completed hop testing because it was performed only at The Fowler Kennedy Sport Medicine Clinic and Banff Sport Medicine Clinic (n=62). Similarly, fewer patients completed isokinetic strength testing because it was performed only at the Fowler Kennedy Sport Medicine Clinic and Pan Am Sport Medicine Clinic (n=56).

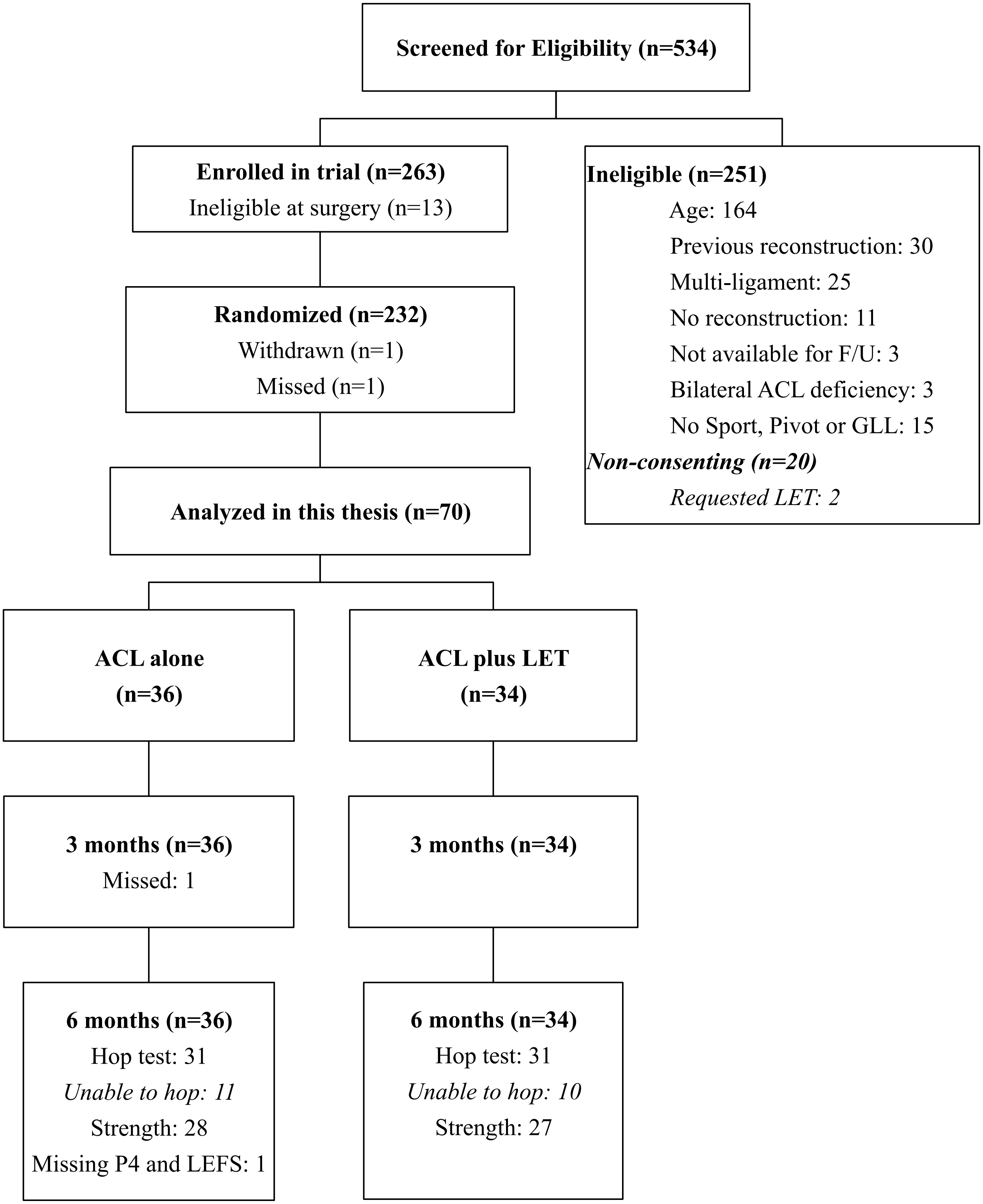

Figure 6: Participant Flow through the Trial.

5.2 Demographic Information

Patient demographics were similar between the two groups (Table 3).

Table 3: Baseline demographics for patients undergoing anterior cruciate ligament (ACL) reconstruction alone or with a lateral extra-articular tenodesis (LET).

Demographic Characteristic	Group 1: ACL alone (n=36)	Group 2: ACL plus LET (n=34)
Sex, n (%)		
Male	16 (44)	17 (50)
Mean Age ± SD (yrs)	19.3 ± 3.5	20.2 ± 3.2
Mean Height ± SD (cm)	172.9 ± 8.6	173.1 ± 9.0
Mean Weight ± SD (kg)	71.7 ± 14.0	74.3 ± 16.0
Mean time from injury to surgery ± SD (mos)	5.8 ± 8.4	6.8 ± 7.0
Operative Limb, n (%)		
Dominant	16 (44)	22 (65)
Mechanism of Injury, n (%)		
Contact	5 (14)	5 (15)
Non-contact	31 (86)	29 (85)
Sport participation at time of Injury, n (%)	35 (97)	32 (94)
Soccer	15 (42)	16 (47)
Basketball	8 (22)	4 (12)
Football	1 (3)	3 (9)
Other	11 (31)	9 (26)
Smoking Status, n (%)		
Currently Smoking	3 (8)	1 (3)
Quit	1 (3)	0 (0)
Never Smoked	32 (89)	33 (97)
Meniscal Pathology, n (%)		
Medial	9 (25)	9 (26)
Lateral	10 (28)	12 (35)
Both	6 (17)	7 (21)
Meniscus repair changing rehab, n (%)	5 (14)	4 (12)
Chondral Defect, n (%)	10 (28)	5 (15)

Abbreviations: SD = standard deviation, CI = confidence interval.

5.3 Primary Outcome Measure

5.3.1 Hop Test

At six months, 11 patients (5 male) in the ACL alone group (35%) and 10 patients (5 male) in the ACL plus LET group (32%) were unable to perform the hop test (p=0.79). One patient from the ACL plus LET group had an adverse event and required arthroscopic surgery at five-months postoperative and was therefore unable to complete the hop test at 6 months. Two patients from the ACL alone group were unable to complete the hop test because a registered kinesiologist was unavailable at the time of their appointment. Of the 62 patients who attempted the hop testing, the kinesiologist stopped the test because of pain or apprehension (n=7); stiffness (n=6); fatigue or loss of control (n=5); and valgus collapse (n=3).

Of the patients who were able to complete the test (n=41), the ACL alone group had a higher total Limb Symmetry Index (LSI) and a higher LSI on each individual component of the hop test, however, these differences were not statistically significant (Table 4).

Table 4: Six-month Limb Symmetry Index (LSI) scores from the series of four hop tests for patients undergoing ACL reconstruction with or without an LET.

Limb Symmetry Index	ACL alone *(n= 20)* (mean ± SE)	ACL plus LET *(n= 21)* (mean ± SE)	Mean Difference (95% CI)	p-Value
Single Leg Hop	94.1 ± 2.7	89.6 ± 2.4	4.6 (-2.7 to 11.8)	0.21
6-m Timed Hop	100.7 ± 6.4	92.6 ± 3.1	8.1 (-6.1 to 22.3)	0.25
Triple Hop	91.3 ± 1.8	88.7 ± 2.4	2.6 (-3.4 to 8.6)	0.38
Crossover Hop	96.2 ± 2.9	93.2 ± 2.2	3.0 (-4.3 to 10.3)	0.41
Total	95.6 ± 2.8	90.1 ± 2.0	4.6 (-2.3 to 11.5)	0.19

Abbreviations: SE = standard error, CI = confidence interval.

5.4 Secondary Outcome Measures

5.4.1 Four-Item Pain Intensity Measure (P4)

No statistically significant differences were found between the two groups using the Four-Item Pain Intensity Measure at any time point (Table 5). Figure 6 presents the unadjusted mean pain scores for both groups with 95% confidence intervals. Both groups reported improvements in pain scores at each time point postoperatively.

Table 5: Four-Item Pain Intensity Measure (P4) scores for patients undergoing ACL reconstruction with or without an LET (adjusted group means).

Time	ACL alone (mean ± SE)	ACL plus LET (mean ± SE)	Adjusted Mean Difference (95% CI)	p-Value
Preop	12.9 ± 1.3	9.3 ± 1.4		
3 mos	7.5 ± 0.9	6.9 ± 0.9	0.6 (-2.0 to 3.1)	0.66
6 mos	4.4 ± 0.7	3.6 ± 0.8	0.9 (-1.3 to 3.0)	0.41

Abbreviations: SE = standard error, CI = confidence interval, Preop = preoperative scores, 3 mos = 3 months, 6 mos = 6 months.

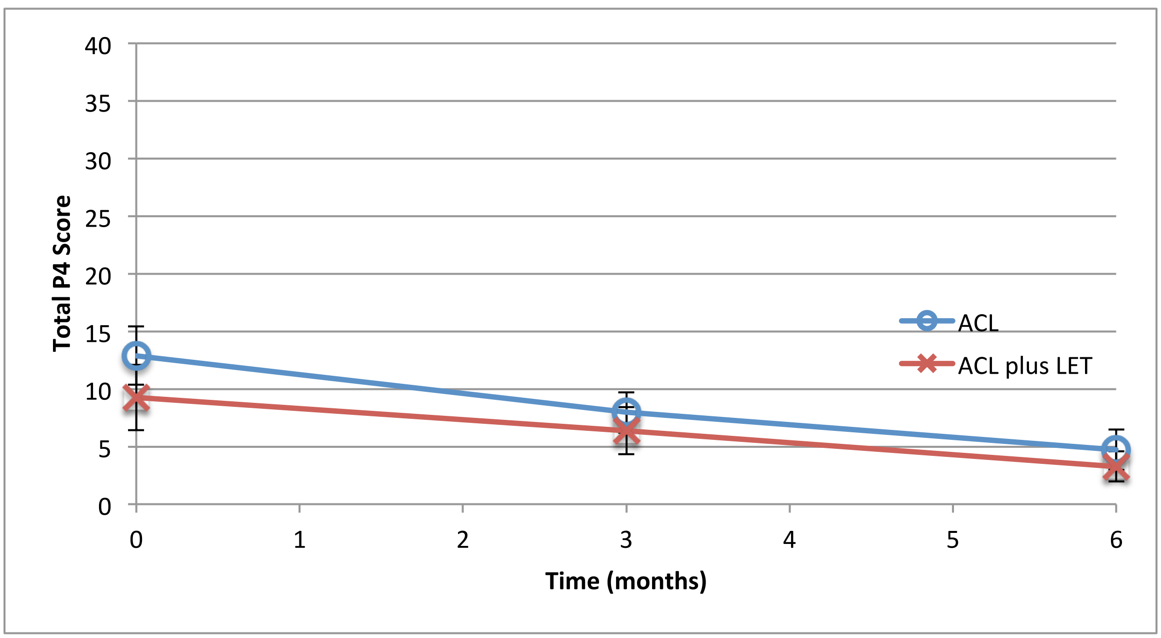

Figure 7: Four-Item Pain Intensity Measure (P4) scores for patients undergoing ACL reconstruction with or without an LET (unadjusted group means with 95% confidence intervals).

5.4.2 Lower Extremity Functional Scale (LEFS)

No significant differences were found between the two groups at any time point using the Lower Extremity Functional Scale (Table 6). Unadjusted mean scores with 95% confidence intervals are presented in Figure 7. LEFS scores of both groups improved at all time points.

Table 6: Lower Extremity Functional Scale (LEFS) scores for patients undergoing ACL reconstruction with and without an LET (adjusted group means).

Time	ACL alone (mean ± SE)	ACL plus LET (mean ± SE)	Adjusted Mean Difference (95% CI)	p-Value
Preop	50.1 ± 2.3	56.1 ± 2.4		
3 mos	58.5 ± 1.5	58.3 ± 1.5	0.1 (-4.2 to 4.5)	0.95
6 mos	69.6 ± 1.1	69.2 ± 1.1	0.4 (-2.7 to 3.6)	0.79

Abbreviations: SE = standard error, CI = confidence interval, Preop = preoperative scores, 3 mos = 3 months, 6 mos = 6 months.

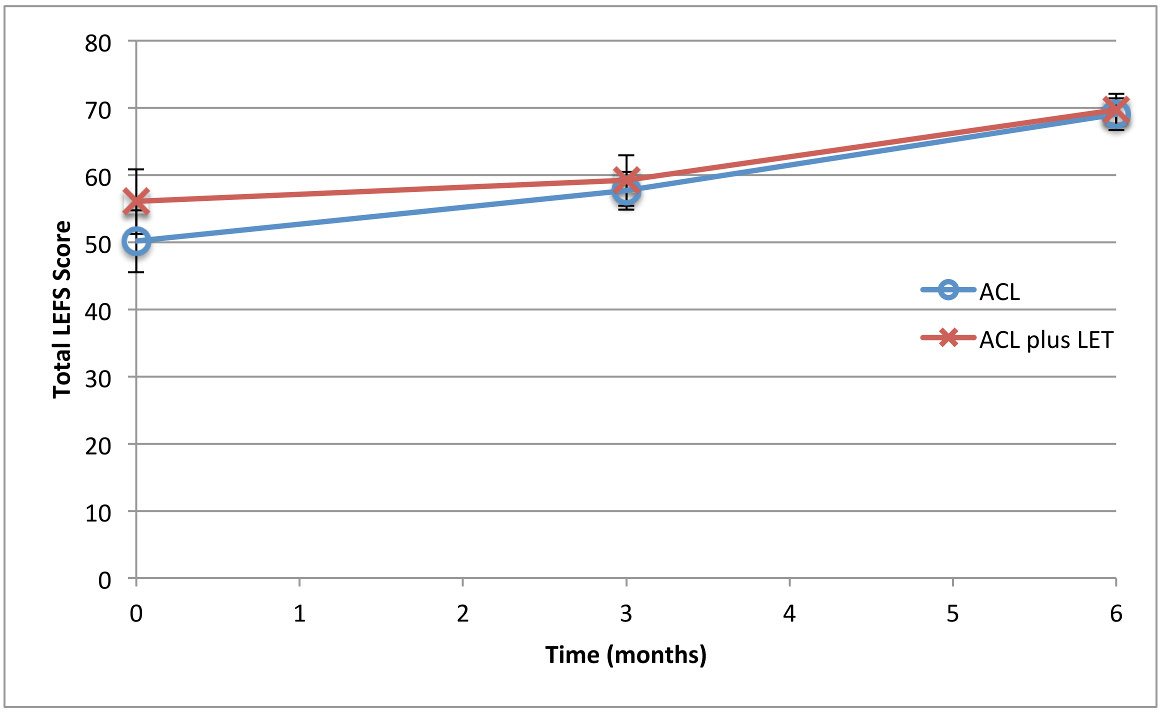

Figure 8: Lower Extremity Functional Scale (LEFS) scores for patients undergoing ACL reconstruction with or without an LET (unadjusted group means with 95% confidence intervals).

5.4.3 Quadriceps and Hamstrings Strength

Nine patients were unable to complete the strength test preoperatively because of a flexion contracture (inability to fully straighten the knee) as a result of a suspected meniscal pathology (n=6), pain during the practice test (n=1) or the inability to come to the clinic prior to surgery (n=2). Because we did not have preoperative strength measurements for these patients, they were not included in the adjusted analysis. Therefore, a total of 21 patients in the ACL alone group and 25 patients in the ACL plus LET group were included in the analysis (n=46).

The ACL alone group improved postoperatively on all variables except hamstrings to quadriceps ratio. The ACL plus LET group scored lower on all variables postoperatively compared to their baseline scores except for the hamstrings to quadriceps ratio, which saw a small improvement. The adjusted mean difference between the two groups for both peak torque and average power in the quadriceps muscles was statistically significant (Table 7).

Table 7: Quadriceps and hamstrings measurements for patients undergoing ACL reconstruction with and without an LET (adjusted group means).

Time	Measurement	ACL alone *(n=21)* (mean ± SE)	ACL plus LET *(n=25)* (mean ± SE)	Mean Difference (95% CI)	p-Value
Preop	Quads Peak Tq	73.1 ± 3.6	80.6 ± 3.0		
	Quads Avg Pwr	73.2 ± 3.7	82.9 ± 3.4		
	HT Peak Tq	79.4 ± 3.0	92.3 ± 2.7		
	HT Avg Pwr	75.1 ± 3.8	89.1 ± 3.4		
	HT/Quads Ratio (involved)	58.0 ± 2.1	56.6 ± 2.2		
6 mos	Quads Peak Tq	85.2 ± 3.1	74.8 ± 2.8	10.4 (1.9 to 18.9)	0.02*
	Quads Avg Pwr	84.7 ± 2.7	76.0 ± 2.5	8.7 (1.1 to 16.3)	0.03*
	HT Peak Tq	86.2 ± 3.2	86.4 ± 2.9	-0.2 (-9.4 to 8.9)	0.96
	HT Avg Pwr	78.8 ± 2.9	78.4 ± 2.7	0.4 (-7.8 to 8.7)	0.92
	HT/Quads Ratio (involved)	52.3 ± 2.5	57.9 ± 2.3	-5.6 (-12.6 to 1.3)	0.11

Abbreviations: SE = standard error, CI = confidence interval, Preop = preoperative scores, 6 mos = 6 months, Quads = Quadriceps, HT = Hamstrings, Tq = torque, Avg Pwr = average power.

5.5 Adverse Events

Two patients in the ACL alone group and seven patients in the ACL plus LET group experienced adverse events. One patient in the ACL group suffered from a staphylococcus epidermidis infection postoperatively and required aspiration followed by a surgical washout and antibiotics administered via a central line. The infection was resolved and the line was removed at three weeks postoperative. Another patient in the ACL alone group had a grade 3 effusion requiring aspiration at six weeks postoperative that resolved without any further intervention.

One patient in the ACL plus LET group suffered an injury to the femoral attachment of the lateral collateral ligament at the time of surgery. This was repaired at the time of surgery. One patient suffered from a superficial infection over the LET incision and required a course of antibiotics at two weeks postoperative. These events were directly associated with the LET procedure. One patient developed periostitis at one-week postoperative. Two patients had grade 3 effusions at two weeks postoperative; one required an aspiration. At three months, one patient suffered from suspected synovitis. This was resolved with a cortisone injection. At five months postoperative one patient suffered from severe stiffness and loss of motion and required an arthrolysis and manipulation under anesthetic.

Chapter 6

6 Discussion

The purpose of this preliminary six-month analysis was to compare outcomes for patients undergoing anterior cruciate ligament reconstruction (ACLR) randomized to receive ACLR alone (control group) or ACLR plus a lateral extra-articular tenodesis (LET) (experimental group). Patients were assessed for limb symmetry index (LSI) by means of four hop tests, pain, quadriceps and hamstrings isokinetic strength and subjective function. At this early analysis, the ACLR alone group had statistically significant higher quadriceps peak torque and power measurements. The ACL plus LET group had a statistically significant higher hamstrings to quadriceps ratio. No other statistically significant differences were found between the two groups for any of the other outcome measures.

At six-months postoperative we did not expect to find differences in limb symmetry indices between the two groups. In line with the hypothesis, we found that patients who underwent ACLR alone had a mean total LSI of 95.6%, which was slightly higher than the ACLR plus LET group that had a mean total LSI of 90.1%. This difference was not statistically significant (p=0.19). Previous published studies consider a LSI of 85% or higher to be normal following ACLR[164], though some authors advocate for a LSI greater than 90% for patients to successfully return to sport[154]. In our study, both the patients who received ACLR alone and ACLR plus LET met or surpassed these recommendations. However, patients only completed hop tests if both the surgeon and the kinesiologist felt the patient was fit to complete the test which may have biased the results. Since six months is still early in the ACL rehab process, one- and two-year results may be more informative.

Other studies have compared ACLR plus LET to ACLR alone, however, few studies have used functional outcome measurements. In 1987, Roth et al.[45] retrospectively compared a cohort of patients who underwent ACLR combined with a transfer of the superficial portion of the biceps femoris tendon (n=43), an extra-articular procedure advocated as a dynamic back up to ACLR, to a cohort of those who had undergone ACLR alone (n=50). Though the biceps tendon transfer differs greatly from the iliotibial band tenodesis used in this study, both are extra-articular procedures advocated to augment intra-articular reconstructions of the ACL to address rotational deficiency. In Roth's study the intra-articular reconstruction was performed using an autograft (quadriceps tendon or the patellar tendon and the prepatellar periosteum) reinforced with a polypropylene braid while all intra-articular reconstructions were performed using a hamstrings autograft in this study. At a minimum of two years postoperative, they reported no differences between the two groups in Limb Symmetry Index (LSI) for the single leg hop for distance. The ACLR plus biceps tendon advancement group had a mean index of 89.7% while the ACLR alone group had a mean index of 89.6%. These scores are similar to the indices we calculated for the single leg hop test at six- months postoperative. While patients in the experimental group had a mean LSI of 89.6%, patients in the control group had a mean LSI of 94.1%. The difference between the two groups was not statistically significant (p=0.21). Roth et al. only performed the single leg hop for distance so we were unable to compare total LSI scores.

Previous studies have found limb symmetry index to be directly correlated with quadriceps strength symmetry, with patients with lower quadriceps strength symmetries performing worse on functional tests such as the hop test[161,165]. However, in our study the ACLR alone group had significantly higher quadriceps peak torque and work symmetries when adjusted for baseline measurements.

There were no differences between the groups for pain at any time point as determined by the P4. Though no other studies used the P4 scale to measure pain, three other studies comparing ACLR plus LET to ACLR alone assessed pain and found similar results. Vadala et al.[43] found no differences between the groups using a visual analog scale (VAS). Noyes et al.[21] found no differences using a 10-point scale. Dejour et al.[50] also found no difference between the two groups in regards to anterior knee pain when classified as present or absent.

We found no difference between the groups for subjective function at any time point as determined by the LEFS. No other studies comparing ACLR plus LET to ACLR alone used the LEFS. Noyes et al.[21] used their own subjective assessment of function and found no differences between the two groups, which was similar to our findings.

We found a statistically significant difference in quadriceps peak torque and power symmetries between the two groups. The ACLR alone group had significantly higher quadriceps symmetries than the ACLR plus LET group when adjusted for baseline measurements. Given the small sample size, it is possible that these differences represent a sampling error. At this time, there is also a difference between the groups at baseline, again likely the result of a small sample size. In a post hoc analysis, we included those patients who only completed isokinetic testing at six-months and ran independent t-tests to compare the two groups. We found the differences between the groups was no longer significant, which speaks to the uncertainty within the data.

However, the decrease in quadriceps strength may also be a direct result of the LET procedure. In order to attach the LET to the femur the quadriceps the vastus lateralis muscle must be retracted, which may damage the muscle. Interestingly, Strum et al.[44] reported significantly greater thigh atrophy in the ACLR plus LET compared to ACLR alone. As the sample size increases and becomes more representative of the population and the randomization has had more time to balance prognostic factors like baseline strength, we will have greater certainty to make definitive conclusions. Furthermore, strength measurements at multiple speeds and increased reps would allow broader exploration of the effect of the LET on quadriceps and hamstrings endurance and fatigability.

A study by Anderson et al.[40] also found similar results when comparing patients who were randomized to one of three groups: ACLR with patellar tendon graft (n=35), ACLR with hamstring graft (n=33) and ACLR with hamstring graft plus a Losee LET. However, they used speeds of 60 and 180 deg/seconds and reported results at an average of 4.8 years postoperative. They found a similar trend with patients in the ACLR plus LET group having lower quadriceps symmetry than the other two groups, however these differences were not significant.

Roth et al.[45] reported isokinetic strength measurements at 180 degrees/second, however, they reported power and work measurements for the operative limb only. They found no statistically significant differences between the groups. In our study we chose to report the measurements of the operative limb as a percentage of the measurements of the non-operative limb rather than mean scores for the operative limb alone. Strength asymmetry following ACLR has been shown to correlate with poor subjective outcomes, poor functional performance and altered lower limb mechanics during gait[161], therefore, symmetry provides more information than group mean power and mean work measurements alone.

In 1991, Noyes and Barber[21] compared a cohort of patients undergoing ACLR with a patellar tendon allograft plus an iliotibial band LET (n=40) to a group of patients undergoing ACLR with a patellar tendon allograft alone (n=64). Isokinetic strength measurements at 450 degrees/second were performed on 30 patients from the ACLR plus LET group (75%) and 39 patients from the ACLR alone group (61%). They found that 83% of patients in the ACLR plus LET group and 79% of patients in the ACLR alone had mild to no deficits in both quadriceps and hamstrings measurements (defined as zero to 20% deficit). These differences were not statistically significant. These results differ from our results as the majority of patients in this study had greater than 20% deficits. This is likely because of the difference in the time points of the two analyses, which was an average of 35 months postoperative in the Noyes and Barber study compared to six months postoperative in this analysis.

This study is unique for its methodological rigor and focus on functional outcomes. Numerous studies have compared ACLR plus LET to ACLR alone, however, only three studies to date have included functional outcomes[21,45,65]. Functional measurements including limb symmetry index, muscle strength symmetry and hamstring to quadriceps ratio are useful tools that can be used to help determine when a patient is ready to return to sport[154,161,166,167]. Therefore, these measurements are useful when comparing different techniques of ACLR and can provide surgeons with the information needed to make an informed decision when treating the ACL deficient knee, particularly in young and athletic individuals intending to return to sport.

6.1 Limitations

Limitations of this analysis include small sample size and an inadequate followup period. The most prevalent limitation was the small sample size resulting in wide confidence intervals and decreased precision. However, this was a preliminary analysis and a larger sample size will provide greater certainty in the outcomes measured.

Another limitation of this analysis was the short followup period. At six-months following ACLR, most patients will still be working with a physiotherapist with the ultimate goal of returning to sports between nine months and one year postoperative. Measurements at one- and two-years postoperative when patients have returned to activity would be more informative and provide a more accurate representation of lower limb symmetry and function.

The use of the hop test as a primary outcome is another limitation to this study. Though the hop test is often used as a tool to determine when a patient is ready to return to activity, it is a surrogate measure and no study has evaluated the magnitude of the association between a patient's score on the hop test and subsequent adverse outcomes; likely because it is not feasible to do so (low event rate).

The strength testing protocol is another limitation to this study. Most studies examining isokinetic strength measurements following ACLR perform the test at multiple speeds and increasing repetitions. This would have allowed us to examine quadriceps and hamstrings endurance and fatigability rather than only peak torque production.

Finally, all centers included in the trial are specialized sport medicine clinics and all surgeons are well experienced in performing ACLRs. Therefore, the results of this study may not be directly translatable to smaller centers with less experienced surgeons. Another limitation is the post-operative rehabilitation. Though a standardized protocol was given to all patients, we did not monitor compliance with the protocol.

Chapter 7

7 Conclusions

We found no significant differences between patients who received an ACLR with or without LET for LSI, pain or subjective function. Patients who underwent ACLR alone had higher quadriceps peak torque and power indices than those who underwent ACLR plus LET, while those in the ACLR plus LET group had a higher hamstrings to quadriceps ratio. However, these preliminary results are underpowered and no definitive conclusions can be drawn at this time.

7.1 Future Directions

For the current study, we will complete the data collection to include the calculated sample size and a two-year followup period. This will strengthen our results and provide more certainty around our estimates of effect size. Furthermore, we will include additional outcomes to determine if the LET procedure is able to improve postoperative rotational stability and successfully reduce the incidence of graft failure. Other additional outcomes will include range of motion, quality of life, return to sport and a biomechanical analysis of jumping mechanics.

Future directions should include a formal economic analysis examining the costs of the additional procedure and other indirect costs. Furthermore, a longer followup period (>10 years) would be beneficial to assess for group differences in the development of osteoarthritis.

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Appendices

Appendix A: UWO REB Approval

Western Research

Research Ethics

Use of Human Participants - Initial Ethics Approval Notice

Principal Investigator: Dr. Alan Getgood
File Number: 104524
Review Level: Full Board
Protocol Title: Multicenter Randomized Clinical Trial comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-articular Tenodesis in Individuals Who Are At High Risk of Graft Failure.
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor:
Ethics Approval Date: February 07, 2014
Ethics Expiry Date: September 30, 2023

Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Other	12 Month Clinical Assessment (Received Oct.11/13)	
Other	24 Month Clinical Assessment (Received Oct.11/13)	
Other	3 Month Clinical Assessment (Received Oct.11/13)	
Other	6 Month Clinical Assessment (Received Oct.11/13)	
Other	Baseline Clinical Assessment (Received Oct.11/13)	
Instruments	International Knee Documentation Committee (IKDC) Subjective (Received Oct.11/13)	
Instruments	Lower Extremity Functional Scale (LEFS)(Received Oct.11/13)	
Instruments	4-Item Pain Intensity Measure (P4)(Received Oct.11/13)	
Instruments	Return to Sport (Received Oct.11/13)	
Instruments	EQ-5D VAS (Received Oct.11/13)	
Instruments	Hop Testing (Received Oct.11/13)	
Instruments	Range of Motion (Received Oct.11/13)	
Instruments	Strength (Received Oct.11/13)	
Instruments	SF-12 Health Survey (Received Oct.11/13)	
Instruments	Knee injury and Osteoarthritis Outcome Score (Received Oct.11/13)	
Instruments	MARX Activity Rating Scale (Received Oct.11/13)	
Instruments	Mohtadi Anterior Cruciate Ligament Quality of Life Questionnaire (Received Oct.11/13)	
Western University Protocol	Original (received Oct.11/13)	
Letter of Information & Consent	Clean updated LOI and Consent	2013/11/30
Recruitment Items	Poster	

This is to notify you that the University of Western Ontario Health Sciences Research Ethics Board (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this HSREB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request form.

Member of the HSREB that are named as investigators in research studies, or declare a conflict of interest, do not participate in discussions related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number [redacted]

Signature

Ethics Officer to Contact for Further Information

___ Erika Basile (ebasile@uwo.ca)	___ Grace Kelly (grace.kelly@uwo.ca)	___ Mina Mekhail (mmekhail@uwo.ca)	Vikki Tran (vikki.tran@uwo.ca)

This is an official document. Please retain the original in your files.

[redacted]

Appendix B: Lawson Health Research Institute Approval

LAWSON
HEALTH RESEARCH INSTITUTE

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-14-059

PROJECT TITLE: Multicenter Randomized Clinical Trial comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-articular Tenodesis in Individuals Who Are at High Risk of Graft Failure

PRINCIPAL INVESTIGATOR:	Dr. Alan Getgood
LAWSON APPROVAL DATE:	March 17, 2014
Health Sciences REB#:	104524

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and Lawson Administration and the project:

Was Approved

Please inform the appropriate nursing units, laboratories, etc. before starting this protocol. The Lawson Approval Number must be used when communicating with these areas.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

All future correspondence concerning this study should include the Lawson Approval Number

[redacted]

cc: Administration

Appendix C: Letter of Information and Consent

FOWLER KENNEDY
SPORT MEDICINE CLINIC

LETTER OF INFORMATION

Title of Research:
Multicenter Randomized Clinical Trial comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-articular Tenodesis in Individuals Who Are At High Risk of Graft Failure.

Lead Researchers:
Dr. Alan Getgood [redacted]
Fowler Kennedy Sport Medicine Clinic, Western University
London, Ontario, Phone: (519) 661- 4003

Dr. Dianne Brya[redacted]
Elborn College, Western University
London, Ontario, Phone: (519) 661-2111 ext 80946

Study Sponsors:
International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS)
Orthopaedic Research and Education Foundation (OREF)

Information:
You are being invited to participate in a research study because your surgeon has determined that you have a torn anterior cruciate ligament (ACL) and you have elected to undergo surgery to reconstruct this ligament. The purpose of this letter is to provide you with information required for you to make an informed decision regarding participation in this research.

The purpose of this study is to compare outcomes (function, strength, range of motion and quality of life) between patients who receive the usual anterior cruciate ligament (ACL) reconstructive surgery to patients who receive anterior cruciate ligament reconstructive surgery with a lateral extra-articular tenodesis. A lateral extra-articular tenodesis is the creation of a new ligament-like structure using a piece of the Iliotibial (IT) band on the outside of the knee. The usual standard of care for an ACL tear is ACL reconstruction without this lateral extra-articular tenodesis (new ligament-like structure). Some studies have shown high graft failure rates (ACL re-tear) in young individuals who return to pivoting contact sports following ACL reconstruction. This study is designed to look at whether or not adding this extra structure reduces the risk of graft failure in this population. To determine whether one procedure is better than the other, we must randomize (like flipping a coin) you into one of the surgery groups. Six hundred (600) patients will take part in this study at different centres around the world. This centre will recruit one hundred (200) patients; approximately 100 per group.

Eligibility:
To participate in this study you must be 25 years of age or younger. You cannot have had

previous ACL reconstruction on either knee. You cannot have a multi-ligament injury (two or more ligaments requiring surgery). If you are currently participating in another research study, you must inform your surgeon and the research assistant.

Explanation of the Study Procedures:

The goal of anterior cruciate ligament reconstruction surgery is to replace the torn ACL with a tissue graft to provide stability to the knee. This is done through a surgical procedure that is performed arthroscopically (with a camera). Either spinal or general anesthesia is used. Small screws are placed into the bone to hold the tissue graft in place.

If, during the surgery, your surgeon determines that your knee does not meet the requirements for the study i.e. other ligaments are found to be torn, or it cannot be treated using the surgical procedure defined in the study protocol, he/she will withdraw you from the study and you will be treated according to standard practice of your surgeon.

Description of the Study:

The total time commitment of the study is two years. Visits for this study will coincide with follow-up visits that you would already attend with your surgeon after your surgery. Each visit with the surgeon will take approximately 40 minutes of your time. Before your surgery, you will be asked to complete ten questionnaires along with a strength assessment, hop test and range of motion measurement. Following your surgery you will receive instructions to undergo standardized physical therapy. You will be given a Rehabilitation Guide to give to your physical therapist.

After surgery, you will come in for an appointment with your surgeon at 3 months, 6 months, 1 year and 2 years where you will be asked to complete the same nine questionnaires. At that time, we will also measure your range of motion. Completing these questionnaires will take approximately 15 - 20 minutes of your time and collection of range of motion measurements, strength and hop testing will take approximately 45 minutes.

At 6 months, 1 year and 2 years post - surgery, we will measure your strength and assess your ability to perform a series of simple jumping tasks. Strength tests will be performed by bending and extending your knee 3 times to measure your strength against resistance. This is done using a computerized machine called an isokinetic dynamometer. During each test session, you will be seated with your back against a backrest with a seat belt securing you into place.

The jumping tests are subdivided into functional tests and biomechanical assessment. The functional tests include a single hop for distance, a timed 6 metre hop test, a triple hop for distance and a crossover hop for distance. The biomechanical assessment will use motion analysis equipment to look at the mechanics of your knee as you perform a vertical jumping task.

The single hop for distance test is performed by having you stand on your leg to be tested, and hop forward on the same leg. The timed 6 metre hop test is performed by having you perform large one - legged hops in series over the 6 metres. The triple hops for distance test is performed by having you stand on one leg and perform three hops in a row on the same leg, landing as far away as possible. The crossover hop for distance is performed by having you hop forward three times while making a "Z' pattern.

The biomechanical assessment will take place in the Wolf Orthopaedic Biomechanics Laboratory (WOBL) at the Fowler Kennedy Sports Medicine Clinic. The task will require you to jump onto a force plate while sensors monitor your movements and muscle activity. These sensors will be placed on your skin over your feet, knees, hips, arms and shoulders using double-sided tape. You will be asked to wear shorts (or tights) and a T-shirt or tank top in order to assist with the placement of these sensors. Although they are easily removed, the tape may cause some pulling of hair therefore we may ask to shave some areas with a plastic disposable razor in order to limit discomfort.

After becoming familiarized with the instrumentation we will ask you to perform a double leg drop vertical jump. This task will require you to drop/hop off a box (at an elevated height of 31cm) and land with both legs on a force plate outlined on the ground, following which you will immediately jump vertically as high as you can, as if rebounding a basketball.

Alternatives to Participation:
If you do not choose to participate in this study, you will receive the usual ACL reconstructive surgery provided by your surgeon.

Risks:
You could fall, injure or re - injure yourself while performing tests, however, the risks are no greater than those encountered with typical postoperative rehab protocols. There are no other known health risks associated with this study.

Benefits:
There are no direct benefits to you for participating in this study; however your participation will help inform surgeons and physiotherapists as to which surgical procedure offers patients who undergo ACL reconstruction the best outcome.

Cost/Compensation:
You will not be compensated for your participation in this study, however, you will not be required to pay for parking while attending appointments at the clinic with your surgeon.

Voluntary Participation:
Your participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. Should you choose to withdraw from this study, we will keep all data obtained up to the point that you chose to withdraw.

Participation in this study does not prevent you from participating in any other research studies at the present time or future. If you are participating in another research study, we ask that you please inform of us of your participation. You do not waive any legal rights by signing the consent form.

Request for Study Results:
Should you decide to participate and want to receive a copy of the study results, please provide your contact information on a separate piece of paper. Once the study has been published, a copy will be mailed to you. Please note that the results of this study are not expected for at least 5 years. Should your mailing information change, please let us know.

Confidentiality:
All information will be kept confidential to the best of our ability. The company that takes care of the research database is EmPower Health Research. Your identifying information (name, mailing address, phone number, email address, date of birth) is being collected as part of your participation in this study. Your data is protected by a username and password. It travels in a scrambled format to a server (storage computer) that is located in Montreal, Quebec, Canada. The company that houses the server is a professional company (Netelligent) with extremely high standards of physical and virtual security. We want to let you know however, that even with this high level of security, there is always a remote chance that your information could be accessed or "hacked" by someone who is not supposed to have your information. The chance that this information will be accidentally released is small. In any publication, presentation or report, your name will not be used and any information that discloses your identity will not be released or published.

Study data will be kept for seven years. Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Questions:

If you have questions about the conduct of the study or your rights as a research participant, you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute (519) 667-6649.

If you have questions or concerns about your surgery or physiotherapy, please contact your orthopaedic surgeon or physiotherapist. If you have any questions about this research, please contact Christopher Hewison at [redacted] or your orthopaedic surgeon.

This letter is yours to keep.

Sincerely,

Dr. Alan Getgood, MD
Dr. Dianne Bryant, PhD
Christopher Hewison, MSc (can.)
Nicole Kaniki, PhD (can.)
Alliya Remtulla, PhD (can.)
Chantel Arce, MSc (can.)
Michal Daniluk, MSc (can.)

CONSENT FORM

Title of Research:
Multicenter Randomized Clinical Trial comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-articular Tenodesis in Individuals Who Are At High Risk of Graft Failure.

I have read the letter of information, have had the nature of the study explained to me, and I agree to participate in the study. All questions have been answered to my satisfaction. I will receive a copy of the Letter of Information and this signed consent form.

______________________	______________________	________________
Printed Name of the Participant	Signature of the Participant	Date
______________________	______________________	________________
Printed Name of the Parent or Legally Authorized Representative (if required)	Signature of the Parent or Legally Authorized Representative (if required)	Date
______________________	______________________	________________
Printed Name of the Person Responsible for Obtaining Informed Consent	Signature of the Person Person Responsible for Obtaining Informed Consent	Date

FOWLER KENNEDY
SPORT MEDICINE CLINIC

☐ I would like to receive a copy of the results of this study.
Please mail to:

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Appendix D: Fowler Kennedy ACL Physiotherapy Protocol

PHYSIOTHERAPY ACL PROTOCOL

Rehabilitation following Anterior Cruciate Ligament Reconstruction (ACLR) is an essential part of a full recovery. This protocol is intended to provide the user with instruction, direction, rehabilitative guidelines and functional goals. The physiotherapist must exercise their best professional judgment to determine how to integrate this protocol into an appropriate treatment plan. Some exercises may be adapted depending on the equipment availability at each facility. As an individual's progress is variable and each will possess various pre-operative deficiencies, this protocol must be individualized for optimal return to activity. There may be slight variations in this protocol if there are limitations imposed from additional associated injuries such as meniscal tears, articular cartilage trauma, bone bruising or other ligamentous injuries.

This rehabilitation protocol spans over a 6 month period and is divided into 7 timelines. Each timeline has goals and exercise suggestions for several domains: range of motion and flexibility, strength and endurance, proprioception, gait, and cardiovascular fitness. Criteria for progression within each timeline are based on the attainment of specific goals and on their Lower Extremity Functional Scale (LEFS) score. The focus in early rehabilitation is on regaining ROM, normalizing gait and activation of the quadriceps muscle. To ensure the best possible outcome for a safe return to the same level of activity prior to the injury, the client should be followed for the entire 6 months. The emphasis of rehabilitation should be focused at the 4-6 month mark. In these later stages, crucial skills such as plyometric training, agility drills, instructions on take-off and landing mechanics, patterning drills, and functional testing suggestions are given to determine the client's readiness for return to sport/activity.

KEY POINTS

Lower Extremity Functional Scale (LEFS)

The LEFS is a self report questionnaire used to evaluate the functional status of an individual with a lower extremity musculoskeletal dysfunction. It is easy to administer and easy to score in the clinical and research environment. The LEFS consists of 20 items, each scored on a 5-point scale (0 to 4). Item scores are summed and total LEFS scores vary from 0 to 80, with higher values representing better functional status. The LEFS is a reliable and valid tool for assessing change in functional status. True clinically important change has occurred if the score changes 9 or more scale points from a previous score[51]. In each corresponding timeline of the protocol the ranges of the LEFS scores are presented. These scores were derived from data on 55 ACLR patients between the ages of 18-65 years of age from our facility. The LEFS scores provided should not be used in isolation as they are intended to be an adjunct to the protocol, the functional testing guidelines and to sound clinical reasoning.

Pre-Operative Rehabilitation

Rehabilitation should commence prior to surgery. After an ACL injury, deficits occur in strength[(39)], proprioception[(40,56)], muscle timing[(55)] and gait patterns[(13)]. In fact, strength and proprioceptive alterations occur in both the injured and uninjured limb[(10,21,52,55)]. The primary impairment with an ACL deficient knee is instability. This is manifested by episodes of 'giving way', which can lead to further joint damage and ultimately, long term degenerative changes[(19)]. Research has demonstrated that physiotherapy provided pre-operatively is effective in increasing strength and balance which may limit the number the episodes of 'giving way' and decrease the incidence of re-injury in the ACL deficient knee[(18,26)]. The main goals of a 'pre-habilitative' program prior to surgery include: full range of motion equal to the opposite knee, minimal joint swelling, adequate strength and neuromuscular control, and a positive state of mind[(45)]. All of these factors facilitate optimal post-operative recovery. It is important to maintain the highest level of strength and function possible in the unaffected leg as it will be used for comparison to assess the progress of the reconstructed knee, in the later stages of rehabilitation[(22,23)].

Range Of Motion & Flexibility[(1,47,48)]

After ACLR it is important to restore and maintain full range of motion (ROM) in the knee. Quadriceps re-training has been found to improve ROM in the early stages[(44)]. Attaining *full knee extension* as early as possible is *not* deleterious to the graft or to joint stability[(43)] and may prevent patellofemoral pain and compensatory gait pathologies. A stretching program is incorporated to maintain lower extremity flexibility. Research recommends that a 30 second stretch is sufficient to increase ROM in most healthy people. It is likely that longer periods of time, or more repetitions, are required for those individuals with injuries or with larger muscles. Body mass has been shown to be positively correlated with muscle stiffness (i.e., the bigger the muscle, the more stiffness/tension there exists)[(34)]. Therefore, for larger muscle groups in the lower extremity, it is suggested to increase in the number of repetitions (ie. 3-5 times) for optimal flexibility.

Gait Retraining

Altered gait kinematics from quadriceps dysfunction is typical during the first stages post ACL reconstruction. Typical adaptations include reduced cadence, stride length, altered swing and stance phase knee ROM, and decreased knee extensor torque with hip and/or ankle extensor adaptations[(11,13,15,30)]. Early weight bearing is advocated post ACLR in an attempt to restore gait kinematics in a timely fashion, facilitate vastus medialis function and decrease the incidence of anterior knee pain[(53)].

Treadmill training in the middle stages of rehabilitation can further assist in normalizing lower extremity ROM across all joints, especially with incline or backwards walking. Backwards treadmill walking has been shown in the literature to increase ROM and increase functional quadriceps strength, while minimizing patellofemoral stress. It is also beneficial for specific return-to-sport preparation requiring a re-training of backwards locomotion[(49)].

MUSCULAR STRENGTH & ENDURANCE TRAINING

Muscle analyses of the quadriceps post ACL injury have shown: i) similar degrees of atrophy in both type I (oxidative/endurance) and II (glycolytic/fast-twitch) muscle fibres, and ii) physiological metabolic shifts in muscle fibres from gylcolytic into oxidative compositions [35,50]. This means that ACL rehabilitation must include variable training parameters, which range from an endurance program of low load/high repetitions to a strength oriented phase of high load/low repetitions to focus on these deficits.

Depending on the graft type used for ACLR (patellar tendon vs. semitendonosis/gracilis), specific strength deficits have been found. With the patellar tendon graft, there are low velocity concentric extensor deficits specific to 60-95°; with the hamstring graft, there are high velocity, eccentric flexor deficits specific to 60-95° [23]. Strengthening exercises need to be velocity, ROM and contraction specific to address these deficits.

- ***Open (OKC) and Closed (CKC) Kinetic Chain Exercises***
  OKC exercises have previously been contraindicated in ACLR patients for 6 months up to a year post-operatively, although the concern about the safety of OKC training in the early period after ACLR may not be well founded. It was originally thought that OKC exercises increased anterior tibial translation, with the possibility of increasing strain on the new graft. However, research has demonstrated that there are minimal strain differences between OKC leg extension and CKC activities such as squatting [4,5]. With the addition of OKC training, subjects have shown increased quadriceps torque increases without significant increases in laxity [25,37]. Researchers are now advocating the addition OKC exercises, ***at the appropriate time and within a restricted range,*** to complement the classic CKC rehabilitative program [25,37,38].

- ***Quality vs. Compensation***
  Physiotherapists often feel compelled to progress patients by giving them new exercises each time they are in for therapy. It cannot be stressed enough that it is ***not*** beneficial to give patients exercises they are not neuromuscularly ready for. It is very important to observe the *quality* of the exercises that are being performed, specifically with CKC exercises. Weaknesses in specific muscle groups lead to compensations, which produce faulty movement patterns. These faulty patterns are then integrated into unconscious motor programs, which perpetuate the original weakness. Specifically, the research has indicated that knee extensor moment deficits are compensated for by hip and/or ankle extensor moments [11,15]. If these are allowed to occur and are not corrected, any joint or structure along the kinetic chain may be exposed to injury.

  For example: A squat [16] or lunge must be performed with the trunk perpendicular to the ground (to avoid excessive hip flexion), the iliac crests must be level (to avoid Trendelenburg/hip hiking), and the knee must be over the foot with the tibia perpendicular to the floor (to avoid excessive dorsiflexion). It is better to decrease the range of movement (half squat vs. full squat) than to do the exercise at a level that is too difficult to perform correctly without compensation.

- ***Precautions with Hamstring Grafts***
  The typical donor graft for ACLR at this facility is the hamstring (semitendinosis / gracilis). *Careful measures must be taken to avoid overstressing the donor area while it heals*. Although, isolated hamstring strengthening is initiated around the six-week mark in this group, it is important for the therapist to be aware of the natural stages of healing. There may be too much stress too early if the patient reports pain at the donor site during or after specific exercises.

NEUROMUSCULAR & PROPRIOCEPTIVE RETRAINING

Ideally proprioception should be initiated immediately after injury (prior to surgery), as it is known that proprioceptive input and neuromuscular control are altered after ACL injury(10,55). By challenging the proprioceptive system though specific exercises, other knee joint mechanoreceptors are activated that produce compensatory muscle activation patterns in the neuromuscular system that may assist with joint stability(9).

Post-operatively, proprioceptive training should commence early in the rehabilitation process in order to begin neuromuscular integration and should continue as proprioceptive deficits have been found beyond 1 year post ACLR(11,15,21,32). Proprioceptive exercises have been shown to enhance strength gains in the quadriceps and hamstring muscles post ACLR(31,57). In the later stages of rehabilitation, anticipated and unanticipated perturbation training is effective in improving dynamic stability of the knee(8,18). A dynamically stable joint is the result of an optimally functioning proprioceptive and neuromuscular system and functional outcome has been proven to be highly correlated with balance in the reconstructed ACL(46).

RETURN TO SPORT

Gradual return to sport is initiated at the 6-9 month mark *only* if the individual's knee does *not* present with pain or effusion, during or after functional sport specific training drills. LEFS scores should be 76 points or greater at this point in rehabilitation. The individual must also be able to demonstrate the appropriate strength and endurance needed for their specific sport. This recommendation is based on the evidence that knee cartilage and subchondral bone are damaged during the initial ACL trauma and may need additional time to recover in order to minimize the predisposition for future joint arthrosis(17,54,58).

A further consideration when returning the patient to sport is that a cautionary approach should be taken with the use of the uninjured limb as a comparison for a rehabilitation endpoint. It has been demonstrated in the literature that a significant detraining effect occurs in the quadriceps and hamstring muscles in both injured and uninjured extremities(22).

BRACING

Bracing should be discussed with the physiotherapist and surgeon prior to return to sport or strenuous activities post ACLR. The decision will be dependent on a number of factors including: type of sport, position, activity level and complexity of the initial injury. Some surgeons may recommend a rigid, functional knee brace or a neoprene sleeve. Research has demonstrated that a rigid knee brace does not provide superior outcomes when compared with a neoprene sleeve after ACLR(6). Bracing has not been proven to prevent re-injury or improve clinical outcomes after ACLR(33). However, there is evidence that any type of knee bracing (rigid /soft) improves proprioception measures(7,27).

0-2 WEEKS
LEFS range: 14-24

- ***GOALS***
  - Patient education re: weight-bearing status; changes to rehab guidelines with any concurrent pathologies (i.e. PF pain, MCL injury, meniscal repair vs debridement, etc.)
  - Decrease pain and swelling
  - Increase range of motion & restore full extension*
  - Maintain flexibility of hamstrings, calves
  - Quadriceps activation[44]
  - Proprioceptive/balance re-education[46]
  - Maintain cardiovascular fitness

- ***EXERCISE SUGGESTIONS***

ROM & Flexibility

**Remember - It is important to restore and maintain range of motion early, especially full extension. This is not detrimental to the graft or its stability [43].*

- Heel slides (+/– slider board)
- Supine with legs up wall – heels slides with gravity assisted
- Bike pendulums: high seat ½ circles forward/backward → full circles – lower seat
- Sitting passive leg extension with roll under heel OR prone leg hangs off end of bed/plinth
- Seated calf stretch with towel - knee bent (soleus), knee straight (gastrocnemius)
- Seated hamstring stretch (back straight)

Muscle Strength & Endurance

Quadriceps/Hamstrings:
- Quadriceps and hamstring co-contraction[2,41]
- Quadriceps isometrics[44] in standing/sitting/lying +/– muscle stimulation or biofeedback
- Sit to stand – progress by gradually decreasing height of seat
- Static lunge forward/side
- Mini wall squat (30°)
- Shuttle™: (one bungee cord) – 2 leg squat (¼ - ½ range) and 2 leg calf raises

Hip/Gluteals:
- Side lying abduction/adduction
- Gluteal squeezes supine or standing
- Prone hip extension
- Standing hip flexion/extension, abduction/adduction

Calves:
- Ankle pumping +/– with leg elevation
- Standing calf raises with/without support

0-2 WEEKS continued

Proprioception

With balance drills on unstable surfaces, be aware of and correct poor balance responses such as hip hiking with INV/EVER and trunk extension with DF/PF.
GOAL: maintain stance on board regardless of ability to control board position[20]

- Single leg stance 30-60 seconds
- Wobble boards with support (table, bars, poles) through full ROM: side-to-side, forward/backward

Gait

If patient has an antalgic gait pattern with use of 1 crutch, keep patient on 2 crutches until they can exhibit normal gait with 1 crutch.

- Weight shifting: side-to-side and forward/backward[28]
- Progress from 2 crutches to 1, always maintaining normal walking pattern

Modalities
- Ice 15-25 minutes[24]
- Interferential current therapy (pain relief)
- Muscle Stimulation[49]

3-6 WEEKS

LEFS range: 32-50

➢ ***GOALS***

- Achieve near or full ROM in knee flexion and extension
- Continue flexibility exercises of other joints
- Continue strengthening exercises with control: hip, hamstrings, quadriceps, calves
- Strengthen non injured leg (documented strength losses in unaffected limb)[22]
- Progress proprioception
- Normal WB gait
- Maintain cardiovascular fitness

➢ ***EXERCISE SUGGESTIONS***

ROM & Flexibility

- Continue as needed with slider board
- Continue on the bike full with circles forward/backward - begin to lower seat
- Prone assisted knee flexion (belt, opposite leg)
- Progress to standing stretches for gastrocnemius (knee straight) and soleus (knee bent), ensure back foot is straight
- Progress to a standing hamstring stretch (keep back straight)
- Assisted quadriceps stretch in prone or in standing
- Patellar and/or tibial-femoral joint mobilizations if needed to achieve terminal ROM (no ACL strain with passive movement)[3]

Muscle Strength & Endurance

Quadriceps:

- Progress on Shuttle™ from 2-1 leg squats/calf raises, increase range of motion and resistance as tolerated
- Sit-to-stand with muscle stimulation[49]
- Leg press machine: low weight 2 legs (½ – ¾ range)
- Wall squats with feet 12" from wall (45°-60°)
- Forward and lateral step-ups 2-4" (push body weight up through weight bearing heel slow and with control, also watch for hip hiking or excessive ankle dorsiflexion)[4]

Hamstrings/Gluteals:

- Prone assisted hamstrings (with belt, opposite leg)
- Hip strengthening with pulleys or ankle weights - all directions (do not allow a lot of trunk swaying)
- Supine on floor legs on swiss ball: isometric hamstrings/gluteals - progress to bridging (if pain free at donor site)

Calves:

- Standing calf raises 2-1 foot

3-6 WEEKS continued

Proprioception

Progression of balance retraining should be from: *looking forward → looking away, eyes open → eyes closed, on a stable base → on an unstable base*

- Continue with full ROM on wobble boards with decreased support - progress to maintaining balance on board
- Standing 747 eyes open/closed – progress to mini trampoline
- Dynadisc™ or BOSU™ (round) 2 leg balance → weight shift forward/backward, side-to-side, eyes open/closed → progress to mini squats (0-30°)
- Standing on ½ foam roller: balance→ rocking forward/backward

Gait

**Full knee extension is needed for normal gait.*

- "Cup walking"[14]: forced exaggeration of knee and hip flexion during the swing phase of gait rather than a rigid knee with a compensatory hip hike (may use plastic cups/mini pylons/foam rollers to walk over to accentuate hip/knee flexion)
- Progress from a single crutch to full weight bearing. Ensure NO antalgic gait pattern

Cardiovascular Fitness

- Bike with increasing time parameters
- May start elliptical trainer and progress to Stairmaster™[36] if adequate strength has been achieved (must have no hip hiking when pressing down on step)

6-9 WEEKS

LEFS range: 45-59

➢ *GOALS*

- Full and pain free knee range of motion
- Functional quadriceps strength
- Initiate isokinetic quadriceps strengthening in a **specific & limited** range[37]
  ***only if*: ROM is full, no swelling, adequate muscle control, and no meniscal or patellofemoral pathology
- Address documented quadriceps strength deficits (high and low velocity, concentric and eccentric, 0-95°)[23]
- Continue strengthening lower extremity muscle groups, specifically through full range hamstrings/quadriceps (without pain at donor site)
- Advance proprioception exercises
- Increase cardiovascular fitness

➢ *EXERCISE SUGGESTIONS*

ROM & Flexibility

- Mobilizations if needed to achieve end ranges

Muscle Strength & Endurance

Quadriceps:

- Terminal extension with tubing – forward and backward facing
- Shuttle™: full and inner range squats, 2 → 1 leg, increasing resistance
- Walking in Bungee™ cord forward/backward/side step with slow control on return
- Lunging in Bungee™ – forward/backward/diagonal
- Step-ups 6-8"step forward/lateral (vertical trunk, watch for hip hiking or excessive ankle dorsiflexion)
- Eccentric lateral step down on 2 → 4 → 6" step with control (watch for hip hiking or excessive ankle dorsiflexion)[15]
- Static Lunge (¼ - ½ range) → progress to dynamic lunge step (¼ - ½ range) with proper trunk and leg alignment
- Full wall squats to 90°
- Initiate isokinetic program if patient is appropriate and equipment is available (see reference for timelines and ROM restrictions)[37]**

6-9 WEEKS continued

Hamstrings/Gluteals:
- Continue hip strengthening with increased weights/tubing resistance
- Supine on floor legs on swiss ball: bridging plus knee flexion (heels to buttocks)
- Prone active hamstring curls – progress with 1-2 lb weights
- Standing hamstrings curls – when able to attain 90° ROM against gravity add 1-2 lb weights
- Sitting hamstring curls with light tubing/pulley system for resistance
- Fitter™: hip abduction and extension (poles for support)
- Shuttle™ standing kick backs (hip/knee extension)
- Tubing kickback (mule kicks)

Calves:
- Shuttle™ heel drops 2 →1 leg
- Mini trampoline: weight shift heel drops/bouncing

Proprioception
- Continue on wobble boards and begin to add basic upper body skills (i.e. throwing)
- Mini trampoline: single leg stance, +/– Bodyblade™ above/below head
- BOSU™ marching: progress with high knees
- Progress Dynadisc™ or BOSU™ 1 leg balance with/without support
- Dynadisc™ or BOSU™ squats (60-90°)
- Dynadisc™ or BOSU™ stand on 2 legs, with throwing to Rebounder™

Hydrotherapy / Pool
- Knee ROM
- Walking forward/backward, static lunge, lunge walking, squats, side shuffles, step up/down, calf raises (2-1 foot)
- Hip extension/flexion, adduction/abduction
- Deep water: stride walking, cycling, flutter kick

Cardiovascular Fitness
- Bike, increasing time or resistance
- Stairmaster™: forward/backward – progress to no hand support
- Swim - Flutter kick only
- Pool jogging – deep water jogging
- Treadmill – walking, increase speed +/– visual (mirror) or auditory (metronome) feedback[12,20]

9-12 WEEKS

LEFS range: 55-66

➢ *GOALS*

- Continue flexibility exercises
- Quadriceps strength progression
- Address documented hamstring strength deficits (high speed, eccentric 95-60°)[23]
- Continue lower chain concentric/eccentric strengthening of quadriceps & hamstrings, both inner range (60–95°) & full range
- Proprioceptive progression
- Sport specific cardiovascular fitness

➢ *EXERCISE SUGGESTIONS*

Muscle Strength & Endurance

Quadriceps:

- Progress resistance of Shuttle™: full ROM and inner range (60-95°), working on strength & endurance, 2 → 1 leg
- Static Lunge (full range) → dynamic lunge → lunge walking all with proper trunk and leg alignment
- Backward step up 4-6-8"step
- Clock face lunges with Bungee™ using mini pylon markers
- Quick walk forward/backward with Bungee™
- Quick side stepping with Bungee™
- Quick lunge forward with control (upright trunk, no forward thrust, no hip hiking)
- Eccentric Bungee™
- Eccentric step down with control on 6 → 8" step
- Shuttle™ jumping (low resistance) 2 legs →alternate legs (jogging) →single leg
- Shuttle™ ski hops (side-to-side)
- Continue / progress isokinetic program if patient is appropriate and equipment is available (see reference for timelines and ROM restrictions)[37]**

Hamstrings/Gluteals:

- Prone/standing pulley knee flexion
- Chair walking
- Prone eccentric hamstrings with pulleys/tubing, alternating inner range and full range
- Hydrafitness™ (hamstrings & quadriceps): 90-30°, resistance 1-3
- Continue hip strengthening with increased weights/tubing resistance
- Sitting and standing hamstring curls – Bungee™/pulleys/ weights sitting and standing positions - address full range concentrically and inner range from 95-60° eccentrically and high velocity (if pain free & without difficulty)
- Supine eccentric hamstrings with knee in extension

Calves:

- Eccentric heel drops

9-12 WEEKS continued

Proprioception

- On boards/Dynadisc™/BOSU™/foam roller/mini trampoline: catch and throw (2 hands/1hand) at varying angles and directions with partner or using rebounder
- Dynadisc™ or BOSU™ throwing on rebounder feet side-to-side, forward/backward, 2-1 foot
- Perturbation drills[8,42] with tubing on boards/ Dynadisc™/BOSU™ /foam roller/mini trampoline
- Single leg stance on Dynadisc™ or BOSU™ with unaffected leg performing kicking drills +/– tubing/pulleys
- Single leg stance on Dynadisc™ or BOSU™ performing kicking drills +/– tubing/pulleys
- Single leg stance on Dynadisc™ or BOSU™ performing higher end upper body skills

Hydrotherapy / Pool

- Increase time, speed, repetitions of exercises
- Pool running

Cardiovascular Fitness

- Bike: increased resistance and time parameters
- Fitter™: slalom skiing without ski pole support
- Treadmill walk +/– incline[29] → quick walk

12-16 WEEKS

LEFS range: 55-66

➢ ***GOALS***

- Continue with flexibility exercises for the lower chain
- Continue strengthening of the lower chain
- Sport specific quadriceps & hamstrings strengthening
- Sport specific proprioception training
- Sport specific cardiovascular fitness

➢ ***EXERCISE SUGGESTIONS***

Muscle Strength & Endurance

- Continue with concentric and eccentric strengthening of hamstrings and quadriceps, working through full & inner range
- Backward lunge – progress to backward lunge walking (with proper trunk and leg alignment)
- Bungee™ jogging - progress to running
- Split squat jumps – progress to BOSU
- Single leg drop landing 2" step

Agility

Agility is the ability to move, and change direction and position of the body quickly and effectively with control.

- Ladder drills – forward/backward, side-to-side (focus on footwork/speed/timing)
- 2 legged lateral and forward jumping
- Side step-overs (hurdle) – progress to side hop-overs
- Carioca patterning
- Tuck jumps
- Skipping
- Initiate 2 legged hop tests (hop for distance, 6-m timed hop, triple hop, crossover hop) prior to single leg hop tests in next stage - ensure patterning and landing is proficient prior to 1 leg progression

Proprioception

- Mini trampoline: 2 feet jump & land →jogging →1 leg hopping (1L/1R, 2L/2R, 3L/3R…)
- Continue progressing skill difficulty
- Single leg stance – tap down clock drill with mini pylons
- Dynadisc™ or BOSU™: 1 leg balance with upper body or opposite leg skill i.e. throwing, phantom kicking with Bungee™ resistance, hockey shot….

12-16 WEEKS continued

Hydrotherapy / Pool

- Progress to plyometrics: 2 leg hopping, forward/backward/side-to-side
- Split squat jumping

Cardiovascular Fitness

- Bike – standing with interval training
- Sport specific cardiovascular training: aerobic vs. anaerobic training
- Jogging – straight on flat ground, no cuts/no downhill
- Treadmill – jog → interval running→ running

**Note: Progression to running may only occur once a symmetric and proficient pattern has been attained to prevent abnormal tissue/joint loading in the lower extremity. Running should NOT be initiated if swelling, loss of motion or patello-femoral pain is present.*

16-20 WEEKS

LEFS range: 61-76

➢ ***GOALS***

- Sport specific quadriceps, hamstrings and lower chain strengthening progressing to plyometrics
- Proprioception training
- Sport specific cardiovascular fitness

➢ ***EXERCISE SUGGESTIONS***

Muscle Strength & Endurance

- Continue with lower extremity strengthening with specific emphasis on client–specific deficits
- 2 → 1 leg progression for all exercises

Plyometrics and Agility

Plyometrics are exercises that enable a group of muscles to reach maximal strength in as short a time as possible. They help bridge the gap between speed and strength training. Adequate concentric & eccentric strength is essential before initiating plyometrics. If needed, start them in the pool in shallow water to decrease stress on the tibiofemoral and patellofemoral joints; otherwise initiate on land as tolerated.

Agility drills should commence by introducing proper footwork, timing and speed. Once the client is able to successfully and appropriately run in a straight line,without difficult, non-linear activities may be initiated, such as cutting and pivoting. These drills should commence by introducing large angles and low speeds (ie. large figure 8s) and progress to more advanced drills with sharper angles and increasing speeds[20]

- Ladder drills – incorporate lateral movements/diagonals, adding single leg and crossover patterns
- Running/lunging/vertical jump/ run-plant-sidestep with Bungee™ - may incorporate upper/lower body skill – kicking, jumping, catching, pass & shoot
- Shuttle™ hopping 2 – alt – 1 (high resistance, increased speed)
- Shuttle™ Ski hops (high resistance, increased speed)
- Carioca ¾ jog
- Mini trampoline: 2 leg jump off – 2 leg land with progression to one leg land on/off balance pad/BOSU (watch for proper landing mechanics)
- Single leg forward and lateral hopping
- Hop tests: single hop, 6-m timed hop, triple hop, crossover hop
- Vertical jumps – single leg
- Box hop up /down
- Box jump down with sprint forward
- Box drop jump 2 legs with proper form may progress to drop jump with vertical hop for maximum height
- Single leg drop landing 4-6-8-10" step

16-20 WEEKS continued

Proprioception

- Continue progressions e.g. mini trampoline with upper skills
- Forward hop and lateral hop – maintain balance for 5 sec on landing
- Cutting drills with quick stop and maintain balance
- Bungee™ run plant/push off L&R

Cardiovascular Fitness

- Increase distance, duration or intensity with bike, Stairmaster™, treadmill, outdoor running/cycling depending on the demands of the particular sport
- Treadmill: running → sprinting: assess sprinting form - should have normal pain-free rhythmic stride (audible monitoring of foot contact)[20]
- Jogging and running on an uneven surface
- Jogging with turns 90/180/360°
- Jogging and cutting with 45° change of direction
- Acceleration and deceleration running, add on tight turns and hills as tolerated
- Cycling outdoors
- Swimming - no whipkick

20-24 WEEKS

LEFS range: 61-76

- ***GOALS***
  - Adequate cardiovascular fitness, strength, power, agility neuromuscular control, symmetry and stability
  - Continue with upper body strengthening
  - Back to sport practice for upper skills (as able)
  - Return to sport skills on own at practice with minimal risk of re-injury

- ***EXERCISE SUGGESTIONS***

Plyometrics and Agility

- Single leg drop jump 6" step
- Large Figure 8's
- Carioca running full speed
- Last minute decision drills
- 2 and 1 foot hopping with control
- Forward and lateral hop with control and comparable distance L&R
- Triple jump and landing with control and comparable distances L&R
- Single limb hop for distance (within 15% of uninvolved side)
- Single-limb crossover triple hop for distance (within 15% of uninvolved side)
- Single-limb timed hop over 6 m (within 15% of uninvolved side)
- Single limb vertical power hop (within 15% of uninvolved side)
- Single limb drop landing (within 15% of uninvolved side)
- Single limb drop-jump
- 10 second single limb maximum vertical hop (both sides)

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Appendix E: Four-Item Pain Intensity Measure (P4)

STABILITY

4-Item Pain Intensity Measure

When answering these questions, think only of the pain you are experiencing in relation to the problem for which you are having treatment.

On average, how bad has your pain been:

In the morning over the past 2 days?

no pain	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10	pain as bad as it can be

In the afternoon over the past 2 days?

no pain	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10	pain as bad as it can be

In the evening over the past 2 days?

no pain	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10	pain as bad as it can be

With activity over the past 2 days?

no pain	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9	○ 10	pain as bad as it can be

Appendix F: Lower Extremity Functional Scale (LEFS)

STABILITY

Lower Extremity Functional Scale (LEFS)

We are interested in knowing whether you are having any difficulty at all with the activities listed below because of your lower limb problem for which you are currently seeking attention. Please provide an answer for each activity.

Today, do you or would you have any difficulty at all with:

	Extreme difficulty or unable to perform	Quite a bit of difficulty	Moderate difficulty	A little bit of difficulty	No difficulty
1. Any of your usual work, housework, or school activities	○	○	○	○	○
2. Your usual hobbies, recreational or sport activities	○	○	○	○	○
3. Getting into or out of the bath	○	○	○	○	○
4. Walking between rooms	○	○	○	○	○
5. Putting on your shoes or socks	○	○	○	○	○
6. Squatting	○	○	○	○	○
7. Lifting an object, like a bag of groceries from the floor	○	○	○	○	○
8. Performing light activities around your home	○	○	○	○	○
9. Performing heavy activities	○	○	○	○	○

around your home					
10. Getting into or out of a car	○	○	○	○	○
11. Walking 2 blocks	○	○	○	○	○
12. Walking a mile	○	○	○	○	○
13. Going up or down 10 stairs (about 1 flight of stairs)	○	○	○	○	○
14. Standing for 1 hour	○	○	○	○	○
15. Sitting for 1 hour	○	○	○	○	○
16. Running on even ground	○	○	○	○	○
17. Running on uneven ground	○	○	○	○	○
18. Making sharp turns while running fast	○	○	○	○	○
19. Hopping	○	○	○	○	○
20. Rolling over in bed	○	○	○	○	○

Appendix G: Image Permissions

Figure 1: Anterior view of the ACL showing the distinct anteromedial (AM) and posterolateral (PL) bundles (left knee).

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Table 1, Table 2 and Figure 2 from*: Hewison et al., Lateral Extra-Articular Tenodesis Reduces Rotational Laxity When Combined with Anterior Cruciate Ligament Reconstruction: A Systematic Review of the Literature, Arthroscopy: The Journal of Arthroscopic & Related Surgery, 2015, Available online 24 June 2015*[66].

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Author:	Christopher E. Hewison,Michael N. Tran,Nicole Kaniki,Alliya Remtulla,Dianne Bryant,Alan M. Getgood
Publication:	Arthroscopy: The Journal of Arthroscopic & Related Surgery
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Figure 3: Diagrammatic representation of the Lemaire lateral extra-articular tenodesis (LET).

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Title: Clinical evaluation of the LeMaire anterior concrete ligament lateral substitution procedure. A quality audit of the Leicester modification

Author: O.L. Thomas,O.O.A. Oni,L. Howard

Publication: Injury

Publisher: Elsevier

Date: July 1998

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Curriculum Vitae

Christopher Eric Hewison

EDUCATION:

Master of Science	Kinesiology, Sport Medicine *Collaborative Musculoskeletal Health Research* Western University, London, Ontario, Canada. September 2013 – August 2015
Bachelor of Science	Kinesiology McGill University, Montreal, Quebec, Canada. Class of 2013

RESEARCH EXPERIENCE:

Western University Graduate Student 2013-2015	STABILITY Study: A Multicentre Randomized Clinical Trial Comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-Articular Tenodesis in Individuals at High Risk of Graft Failure. *Supervisors: Dr. Dianne Bryant and Dr. Alan Getgood*
Western University Research Assistant 2013-2015	Fowler Kennedy Sport Medicine Clinic Knee Registry
Western University Graduate Student 2014-2015	Meniscus Allograft Extrusion Under Physiological Load - A Cadaveric Comparison of Two Surgical Techniques. *Supervisors: Dr. Alan Getgood and Dr. Karen Gordon*
Western University Graduate Student 2014-2015	Analysis of 3D Strain in Medial Meniscal Allograft Transplants Following Two Surgical Techniques. *Supervisors: Dr. Alan Getgood and Dr. Karen Gordon*
McGill University Undergraduate Student 2013-2015	McGill University Ice Hockey Research Group *Supervisor: Cameron Lawrie and Dr. David Pearsall*

PUBLICATIONS:

C. Hewison, M. Tran, N. Kaniki, A. Remtulla, D. Bryant, A. Getgood. Lateral Extra-Articular Tenodesis Reduces Rotational Laxity when Combined with Anterior Cruciate Ligament Reconstruction – A Systematic Review of the Literature. *Arthroscopy: The Journal of Arthroscopic and Related Surgery, Available online 24 June 2015 (In press).*

T. Lording, **C. Hewison**, P. Neyret, S. Lustig. Irradiated Versus Non-Irradiated Allografts for Anterior Cruciate Ligament Reconstruction – A Systematic Review. *International Orthopaedics.* (In press).

CONFERENCES:

Chicago, Illinois. May 2015	International Cartilage Repair Society World Congress 2015 *Poster presentation:* Meniscus Allograft Extrusion Under Physiological Load – A Cadaveric Comparison of Two Surgical Techniques. *Poster presentation:* Analysis of 3D Strain in Medial Meniscal Allograft Transplants Following Two Surgical Techniques.
London, Ontario. May 2015	Western University Bone and Joint Research Retreat *Session Chair:* New Directions in Research – Maintaining Mobility Throughout the Lifespan. *Poster Presentation:* STABILITY Study: A Multicentre Randomized Clinical Trial Comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-Articular Tenodesis in Individuals at High Risk of Graft Failure.
London, Ontario. April 2015	1st Annual KGSA Research Symposium *Poster Presentation:* STABILITY Study: A Multicentre Randomized Clinical Trial Comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-Articular Tenodesis in Individuals at High Risk of Graft Failure.
London, Ontario. March 2015	Faculty of Health Sciences Research Day *Poster Presentation:* STABILITY Study: A Multicentre Randomized Clinical Trial Comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-Articular Tenodesis in Individuals at High Risk of Graft Failure.
London, Ontario. September 2014	Fowler Kennedy Annual Homecoming Sports Medicine Symposium *Oral Presentation:* Research Update - STABILITY Study: A Multicentre Randomized Clinical Trial Comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-Articular Tenodesis in Individuals at High Risk of Graft Failure.

Toronto, Ontario. May 2014	Bodies of Knowledge Graduate Research Symposium *Oral Presentation:* STABILITY Study: A Multicentre Randomized Clinical Trial Comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-Articular Tenodesis in Individuals at High Risk of Graft Failure.
London, Ontario. May 2014	Western University Bone and Joint Research Retreat
London, Ontario. January 2014	Bone and Joint Injury and Repair Inaugural Conference *Poster Presentation:* STABILITY Study: A Multicentre Randomized Clinical Trial Comparing Anterior Cruciate Ligament Reconstruction With and Without Lateral Extra-Articular Tenodesis in Individuals at High Risk of Graft Failure.
London, Ontario. September 2013	Fowler Kennedy Annual Homecoming Sports Medicine Symposium

RELATED WORK EXPERIENCE:

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Western University 2013-2015	Western Graduate Research Scholarship