THE EFFECTS OF NEUROMUSCULAR TRAINING ON THE ABILITY TO RETURN-TO-ACTIVITY FOR THE ACL RECONSTRUCTED ATHLETE

by

Kathleen White

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

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ABSTRACT

Each year 175,000 anterior cruciate ligament reconstructions (ACLR) are completed in the United States. Outcomes are poorer than previously reported with high rates of second knee injury and low rates of return to pre-injury activities. Abnormal movement patterns, low self-reported knee function and poor functional performance are suspected reasons for poor outcomes after surgery. Intervening after surgery, and before athletes return to activities, may benefit patients in the short-term. The ACL- Specialized Post-Operative Return to Sports (ACL-SPORTS) Training program was developed from current ACL injury prevention techniques and evidence-based rehabilitation to improve outcomes after surgery.

The goal of this work was to better prepare patients to return to activities after surgery. Gait biomechanics were used to evaluate movement patterns before and after completing ACL-SPORTS Training. Self-reported knee function measures were analyzed after training and one year after surgery to determine normal knee function. Readiness to return to activities was determined using return-to-activity criteria after training and one year after surgery.

These results suggest that symmetrical movement patterns may be more related to functional performance rather than specific treatment intervention. Knee function measures were not different between the treatment groups however, all subjects in the

current study demonstrated higher scores than those reported by large ACL ligament registries. Subjects who failed strict return-to-activity criteria after training had larger quadriceps femoris muscle strength deficits, however these individuals had a larger decrease in fear of movement/re-injury one year after surgery. These findings suggest the addition of a measure of fear of movement/re-injury after surgery to the return-to-activity criteria may identify subjects who are safe to return to activities.

Overall benefits of this work has allowed us to characterize athletes after surgery by comparing biomechanical, functional and clinical measures of two different return-to-activity training protocols to establish best-practice guidelines for this high-risk population. Characterizing patients with established outcome measures of perceived knee function, based on their readiness to return-to-activities, will allow clinicians to target areas of weakness for those who do not meet strict return-to-activity criteria. Evaluating common variables of interest utilized by researchers will allow for an easy comparison to other research groups.

Chapter 1

THE NEED FOR NEUROMUSCULAR TRAINING AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

1.1 Poor Outcomes after Anterior Cruciate Ligament Reconstruction

Anterior cruciate ligament reconstruction (ACLR) is standard care for active individuals who desire to return to high-level activities after ACL rupture;[9,48,56] however outcomes after surgery are variable. Success after ACLR is often defined by return to pre-injury activities and self-reported normal knee function.[6,44,48] Return to pre-injury activities, at the same level, has been reported to range from 33-84% after surgery, suggesting variable success.[6,7,11,12,48,57,78] One in four athletes experiences a second knee injury within the first year of returning to sports, as risk for re-injury is increased after primary ACLR.[49,63–65] Muscle weakness, abnormal movement patterns and low patient self-report of function persists up to two years after surgery despite evidence-based post-operative rehabilitation,[1,59] suggesting these guidelines may be inadequate for preparing athletes for the demands of high-level activities.[8,51,53,60,65,69,77] Clearance for athletes to return to activities often occurs six months after surgery and is largely time-based.[8] Athletes who demonstrate muscle weakness, abnormal movement patterns and low patient self-report when they are cleared to return to activities may be putting their knee at increased risk for re-injury, poor athletic performance and long-term degeneration.

1.2 Abnormal Movement Patterns

A knee stiffening strategy has been identified in subjects after ACL injury as a mechanism to increase knee stability during both walking and jogging.[73] Subjects exhibit truncated knee flexion and joint excursions as well as increased muscle co-contraction.[13,21,39,72,74] Neuromuscular training, before surgery, improves movement patterns in non-copers,[13,21] however one and two years after surgery, subjects continue to demonstrate limb-to-limb asymmetries regardless of pre-operative treatment.[69] Six months after surgery, subjects who demonstrate good knee function with return-to-activity criteria demonstrate adequate limb symmetry; however those with poor knee function demonstrate aberrant movement patterns.[20] Subjects that demonstrate limb asymmetries at the time of clearance to return to activities are more likely to experience a second knee injury.[65] While the exact mechanism to the development of knee osteoarthritis after ACLR is not understood, it is suspected that these abnormal movement patterns are contributors to the development of knee osteoarthritis.[84,87,88] Improving movement patterns after surgery may not only improves athletic performance, but may decrease the risk for re-injury and slow the progression of knee joint degeneration.

1.3 Poor Knee Function

Self-reported knee function has been measured with The International Knee Documentation Committee (IKDC 2000) subjective knee form for a variety of knee injuries, however it has been used extensively in the ACL-reconstructed population,[42] including operative and non-operative management,[31] return to pre-injury activities and those who have not return to activities[51] and those with low quadriceps femoris muscle strength and those with adequate strength.[77] Age- and sex-matched normative values have been established to allow clinicians to determine if a subject has achieved normal knee function after surgery.[3] Studies have identified demographic characteristics (BMI, smoking)[45] and functional measures (single-legged hop tests) that are predictive of achieving or failing to achieve normal knee function after surgery.[53,66] Most importantly, improvements in IKDC 2000 scores after ACLR have been reported to continue to occur up to one year after surgery, suggesting that normal knee function had not been achieved at a time when patients are often given clearance to return to activities.[53,54] The Knee injury and Osteoarthritis Outcome Score (KOOS), is another measure of knee function that has been used to evaluate differences between males and females after ACLR,[2,46] and differences between subjects who underwent early operative management, delayed operative management and non-operative management of their ACL injury.[25,26] Similar to IKDC 2000 scores, KOOS scores continue to improve up to one year after surgery suggesting that optimal knee function had not been achieved before athletes returned to activities.[70,71,76] The most sensitive and responsive subscales of the KOOS in the ACL population include the quality of life (QOL) subscale and function, sports and recreational activities (Sports/rec) subscale, which will be emphasized in this dissertation.[2,71,76] The KOOS has also been used in large national and international ACL registries (Multicenter Orthopaedic

Outcomes Network (MOON) Cohort and the Scandinavian ACL Registry)[81] and results of this study will be easily compared to large scale findings.

1.4 Fear of Re-injury

Fear of re-injury after ACLR is also a limiting factor for athletes to return to pre-injury activities.[14,15,51,86] The Tampa Scale of Kinesiophobia (TSK-11) has been used with patients after ACLR to evaluate fear of movement/re-injury in the first year after surgery,[14] and between subjects who have returned to activities and those who have not returned.[51] These scores have been found to improve over time, suggesting a decrease in fear of re-injury. However, subjects that have not returned to activities at one year after surgery report higher rates of fear of movement/re-injury compared to those who have returned to activities. This questionnaire has been modified from use with patients with low back pain and more than half of the questions are specific to pain. Pain is uncharacteristic of these ACL-reconstructed patients, other than the acute phase after surgery, resulting in a floor effect of this outcome measure at return to activity time points. A recent fear-related questionnaire was developed to evaluate psychometric responses related to athletes emotions, confidence in performance and risk appraisal after ACL injury or reconstruction; the ACL-Return to Sport after Injury (ACL-RSI) scale.[86] Few published studies have evaluated this new measure, but thus far it has been shown to be valid, reliable and easily translated.[10,47] ACL-RSI scores are reported to improve over time after ACLR, with significantly higher scores reported by subjects that have returned to pre-injury activities at one year after surgery.[5,50] Although these outcome measures include different questions and components of fear of re-injury and pain, both the TSK-11 and ACL-RSI improve similarly in ACL-reconstructed patients and are related to activity level at one year after surgery. Understanding the relationship between TSK-11 scores and ACL-RSI scores will allow researchers to objectively measure fear of re-injury and movement after ACLR and optimize post-operative interventions to improve knee function at a critical phase of rehabilitation.

1.5 Clearance to Return to Activities after Reconstruction

Determining clearance to return to activities after ACLR is commonly time-based.[8] While contemporary consensus is that objective criteria, rather than time from surgery, should be used to determine a patient's readiness to return to activities after ACLR,[8,37] there is not consensus on which measures to use. At the University of Delaware Physical Therapy Clinic, a battery of clinical, functional and patient self-report measures are used to determine readiness to return to activities. Quadriceps femoris muscle strength symmetry, single-legged hop limb symmetry and patient reported measures require ≥ 90% on all measures to pass these criteria. These criteria do not include measures of fear of movement/re-injury or knee function. This dissertation will evaluate measures of fear of movement/re-injury and knee function between subjects who pass our return-to-activity criteria and those who fail, to provide further insight into how these measures relate to functional performance. The addition of a fear- related and knee function score to these return-to-activity criteria may be needed to identify subjects that are adequately prepared to return to activities.

1.6 Neuromuscular Training in ACL Rehabilitation

Poor outcomes after ACLR support the need for additional physical therapy interventions. A pre-operative neuromuscular training program, perturbation training, has been used by our research team to improve patient status prior to surgery and permit potential copers to return to activities for short periods of time.[24,32] We have successfully seen a reduction in limb-to-limb asymmetries with biomechanical and functional measures initially after pre-operative perturbation training and initially after surgery.[21,32,33,54] Limb symmetry was seen for knee joint excursion measures six months after surgery for subjects who received pre-operative perturbation training compared to subjects who received pre-operative strength training.[32] Unfortunately, limb-to-limb asymmetries persisted in all subjects up to two years after surgery regardless of pre-operative treatment, suggesting surgery is a significant game-changing event.[69] Clinically, subjects who receive pre-operative perturbation training were no more likely to pass strict return-to-activity criteria compared to subjects who received pre-operative strength training.[33] Six months after surgery less than half of subjects were able to meet these return-to-activity criteria. One year after surgery over 75% of patients were able to meet these return-to-activity criteria suggesting large changes in patient performance continue to occur between six and 12 months after surgery.[33] These variable post-operative outcomes support the need to better characterize individuals after surgery to aid in the development of interventions to positively impact limitations that contribute to re-injury risk and incidence, and poor knee function long-term.

Only three post-operative neuromuscular treatment interventions have been published with ACL-reconstructed patients. Liu-Ambrose and colleagues[52] compared neuromuscular training to strength training a minimum of six months after surgery. Ten subjects were randomized to either a neuromuscular training group or a strength training group and completed training sessions three times a week for 12 weeks. All subjects made improvements in hop test scores and Lysholm scores after training, with no group differences. Involved limb quadriceps femoris muscle strength improved more in the neuromuscular training group; however the authors suggest this may be due to differences at baseline. The study was likely under powered and conclusions about the benefits or pitfalls of neuromuscular training cannot be made. Cooper and colleagues[16] compared a neuromuscular training group to a traditional strength training group acutely after surgery, for 6 weeks of training. Subjects were approximately 7 weeks after surgery and had minimal impairments (full knee range of motion, no quadriceps femoris lag, and minimal knee joint effusion). They reported that the strength training group made larger improvements in swelling, walking and squatting/kneeling compared to the neuromuscular training group, but no differences were seen in hop test scores between the groups. The authors concluded that there was no added benefit to neuromuscular training in the early phases of rehabilitation. Based on these studies, Risberg and colleagues[67] compared neuromuscular training to a standard strength training program in Norway that began immediately after surgery and concluded six months after surgery. At six months after surgery subjects reported higher Cincinnati Knee Scores and visual analog scores (VAS) for knee function in the neuromuscular training group compared to the strength training group. No clinical or functional measures (quadriceps femoris muscle strength, balance, proprioception, and single-legged hop tests) were different between the groups. The authors concluded that neuromuscular training improved knee function; however functional performance measures were not superior for subjects in the neuromuscular training group. These authors followed subjects one and two years after surgery and evaluated patient-reported measures, strength and function between the treatment groups.[68] One year after surgery, subjects in the neuromuscular training group had significantly higher VAS scores for knee function and lower VAS scores for pain compared to the strength training group. At one and two years, subjects in the strength training group had significantly greater hamstring strength measures. The authors concluded that the addition of neuromuscular training only partly improved long-term knee function compared to strength training; however they reported a lower compliance rate in the neuromuscular training group. Functional measures were used to evaluate patients in these three post-operative neuromuscular studies and no study evaluated the effects of neuromuscular training on biomechanical variables.

Success of our pre-operative perturbation training has encouraged our research group to initiate a novel post-operative training protocol incorporating perturbation training (ACL-Specialized Post-Operative Return To Sports (ACL-SPORTS)

Training)[24,89] that addresses these modifiable limb-to-limb asymmetries at a critical time when athletes are often given clearance to return to activities. This unique study protocol (Appendix D), derived from previous published research studies and prevention techniques, includes ACL injury prevention exercises,[34–36,38] agility drills and quadriceps femoris muscle strengthening exercises.[33] Patients are randomized to two treatment groups. Individuals in the standard care (STND) group receive all exercises listed, while the perturbation training (PERT) group receive standard care exercises augmented with perturbation training.[24] Pilot data from our lab has shown that post-operative perturbation training resulted in improved movement patterns, improved functional outcomes and improved patient self-report six months after surgery.[19,90] ACL-SPORTS Training is conducted at the University of Delaware Physical Therapy Clinic by experienced clinicians who have practice implementing research protocols, ensuring that the protocol is successfully executed. To guarantee unbiased reporting of results, an investigator blinded to group assignment collected all biomechanical, functional and clinical data.

Incorporating neuromuscular training in a formulated protocol will allow us to standardize rehabilitation guidelines after surgery, and prior to athletes returning to activities. This protocol is based on clinical milestones rather than time-based criteria after surgery and is conscientious of patient response to treatment ensuring patient safety and success. Because this study is currently being used in a clinical setting, the treatment protocol is easily translated to outside rehabilitation specialists. Initiation of this protocol requires all subjects to meet baseline criteria which also allows for practical use in a clinical setting. This protocol is generalizable to outpatient clinical settings and the directed progression makes it efficiently executable by the rehabilitation specialist.

Implementing a specialized training protocol for ACL-reconstructed patients at this time point is highly desirable. Patients are often discharged from traditional physical therapy treatment, given clearance to return-to-activities once impairments have been resolved and is commonly time-based.[8] Unfortunately, less than half of patients meet strict, objective return-to-activity criteria[33] and those that do not meet these criteria demonstrate meaningful limb-to-limb asymmetries.[20] Additional treatment at this time point is needed to improve movement patterns that will prepare athletes to return to activities and improve functional outcomes; however this is not standard practice. By implementing our novel protocol at this critical time point when many are given clearance to return to activities is a unique approach that may result in improved functional outcomes after surgery.

1.7 Aims and Hypothesis

The purpose of this study was to evaluate the effects of a specialized post-operative return-to-sports training program (ACL-SPORTS Training) (Appendix D) on gait biomechanics, knee function and readiness to return to activities. By comparing subjects who receive standard post-operative treatment augmented with perturbation training (PERT) to those who receive standard treatment (STND) we can further characterize subjects with successful outcomes after ACLR.

Aim 1. To evaluate gait biomechanics between limbs of subjects before and after 10-training sessions for subjects who receive PERT treatment and subjects who receive STND treatment.

- Hypothesis 1.1 After 10-training sessions, subjects who receive PERT treatment will have smaller hip and knee flexion angle limb-to-limb asymmetries during gait compared to subjects who receive STND treatment.
- Hypothesis 1.2 After 10-training sessions, subjects who receive PERT treatment will have smaller hip and knee moment limb-to-limb asymmetries during gait compared to subjects who receive STND treatment.
- Hypothesis 1.3 After 10-training sessions, subjects who receive PERT treatment will have smaller hip and knee joint excursion limb-to-limb asymmetries compared to subjects who receive STND treatment.

Aim 2. To determine normal knee function after 10-training sessions and one year after surgery in subjects who receive PERT treatment and subjects who receive STND treatment.

- Hypothesis 2.1 Subjects who receive PERT treatment will be more likely to return to their previous level of activity one year after surgery compared to those who receive STND treatment.

- Hypothesis 2.2 Subjects who receive PERT treatment will have higher IKDC 2000 scores after 10-training sessions and one year after surgery compared to those who receive STND treatment.
- Hypothesis 2.3 Subjects who receive PERT treatment will have higher KOOS-QOL and KOOS-Sport sub-scores scores after 10-training sessions and one year after surgery compared to subjects who receive STND treatment.

Aim 3. To characterize subjects' readiness to return to activities (RTA) after 10-training sessions and one year after surgery.

- Hypothesis 3.1 Subjects who receive PERT treatment will be more likely to pass RTA criteria after 10-training sessions and one year after surgery compared to subjects who receive STND treatment.
- Hypothesis 3.2 Subjects that do not pass RTA criteria after 10-training sessions and one year after surgery will demonstrate decreased QI (<90%) compared to those that pass.
- Hypothesis 3.3 Subjects that do not pass RTA criteria after 10-training sessions and one year after surgery will demonstrate knee function below normal ranges with IKDC 2000 scores compared to those that pass.

- Hypothesis 3.4 Subjects that do not pass RTA criteria after 10-training sessions and one year after surgery will report lower ACL-RSI scores and higher TSK-11 scores compared to those that pass.

1.8 Summary

Despite extensive rehabilitation after ACLR, the need for additional post-operative interventions to improve outcomes after surgery is paramount. The results of this study will allow us to characterize these individuals after surgery by comparing biomechanical, functional and clinical measures of two different, unique return to activity training protocols to establish best-practice guidelines for this high-risk population. Characterizing patients with established outcome measures of perceived function, based on their readiness to return to activities, will also allow clinicians to better target areas of need for those that do not meet strict return-to-activity criteria.

Chapter 2

MOVEMENT PATTERNS AFTER ACL-SPORTS TRAINING

2.1 Abstract

Background: Altered movement patterns persist after anterior cruciate ligament reconstruction (ACLR) despite resolving clinical and functional impairments. Neuromuscular training has been shown to improve limb symmetry before surgery. Implementing a neuromuscular training program after surgery may improve outcomes in the short- and long-term. The University of Delaware has developed a specialized post-operative return-to-sports (ACL-SPORTS) training program including ACL injury prevention exercises, agility drills, quadriceps femoris muscle strengthening exercises and neuromuscular training to improve outcomes after surgery. The purpose of this study was to evaluate gait biomechanics between limbs of subject before and after ACL-SPORTS Training.

Methods: Movement patterns were evaluated during gait, using standard motion capture techniques, for subjects before and after ACL-SPORTS Training. Subjects were randomized to one of two treatment groups: standard treatment group or perturbation group. Analysis of variance was used to evaluate the difference between limbs, between the two treatment groups, over time.

Results: Subjects in the perturbation group had large hip extensor moment asymmetries at initial contact and knee flexion angle asymmetries at peak knee extension prior to training. After training, limb symmetry was achieved for these subjects. Subjects in the perturbation group developed knee flexion angle asymmetries

at peak knee flexion after training. Subjects in the standard treatment group did not demonstrate changes after training.

Discussion: Small changes in movement patterns were seen in the perturbation group after ACL-SPORTS Training, however further examination identified subgroups of subjects who responded to the treatment intervention. Additional subjects are needed to further identify individuals who respond to the training program and those who do not.

2.2 Introduction

After initial anterior cruciate ligament (ACL) injury, patients commonly demonstrate abnormal movement patterns in an attempt to protect the injured knee.[40,72,73] These ACL-deficient individuals use a knee stiffening strategy resulting in decreased knee flexion angles and moments of the involved limb, and decreased knee contribution to the total support moment.[40,72,73] Despite restoring the knee joint anatomy with surgical reconstruction, abnormal movement patterns persist up to two years after ACL reconstruction (ACLR),[32,69] specifically, hip and knee limb-to-limb asymmetries.[69]

Despite these abnormal movement patterns, two years after surgery quadriceps femoris muscle strength measures were no different between limbs suggesting clinical measures alone are not predictive of movement asymmetries.[69] When comparing clinical and functional measures with gait biomechanics six months after surgery, symmetrical movement patterns were seen in subjects with higher functional outcomes compared to subjects with poor functional outcomes.[20] These data suggest that superior functional achievement with clinical and functional testing, after ACLR, may be needed to normalize movement patterns.

Before surgery, perturbation training[24] (Figure 2.1, Appendix B) was used as a neuromuscular training tool to normalize movement patterns, which effectively resulted in symmetrical knee joint kinematics, kinetics and excursions,[13,21,32] and eliminated co-contraction strategies.[39] With vast gait asymmetries persisting after surgery, implementation of perturbation training after surgery may be beneficial for these subjects. Pilot work within our research group, utilizing perturbation training after surgery[19] resulted in symmetrical movement patterns. Six months after surgery, when compared to subjects who received pre-operative perturbation training, subjects who received post-operative perturbation training demonstrated improved hip and knee limb symmetry.[19,90] These positive findings of improved limb symmetry with post-operative perturbation training has impelled our research group to develop a comprehensive post-operative (ACL-SPORTS) Training program utilizing perturbation training.[89]

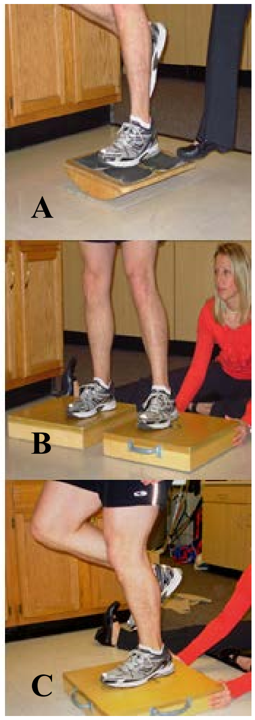

Figure 2.1 Perturbation training on three different board configurations. (A) rockerboard, (B) rollerboard and stationary platform, (C) rollerboard

The ACL-SPORTS Training protocol[89] was developed from current evidence-based ACL injury prevention and post-operative rehabilitation guidelines.[1,34–38] This protocol includes quadriceps femoris muscle strengthening exercises, agility drills and a series of ACL injury prevention exercises (Appendix D). Subjects in the standard treatment group (STND) received all exercises listed, while subjects in the perturbation group (PERT) received all exercises listed, augmented with perturbation training. Evaluating movement patterns after the completion of this training protocol will allow us to better characterize the use of perturbation training after surgery in the resolution of aberrant movement patterns.

The purpose of this study was to determine the biomechanical changes after ACL-SPORTS Training between subjects who received PERT training and subjects in the STND group. We hypothesized that subjects in the PERT group would demonstrate improved limb symmetry of hip and knee kinematics, kinetics and excursions after completing the training protocol compared to subjects in the STND group.

2.3 Methods

Forty-five subjects (33 males, 12 females, mean age 23.09 ± 7.79 yrs) (Figure 2.2) were included in this study, that had undergone a unilateral ACLR within the last 10 months. Eligible subjects between the ages of 13 and 55 were required to be regular participants (≥50 hrs/yr) in jumping, cutting and pivoting activities (Level 1 or 2) prior to their injury.[17] All subjects desired to return to their pre-injury activity level, demonstrated ≥ 80% quadriceps femoris muscle strength symmetry, minimal knee joint effusion,[83] and were at least 12 weeks after surgery[89] prior to enrollment. Subjects were excluded if they were not regular participants in level 1 or 2 activities, were > 10 months after surgery, had a history of previous ACLR, history of a serious ipsilateral or contralateral limb injury (i.e. Tibial fx) or large osteochondral defect > 1 cm^2. All eligible participants received clearance from their surgeon for study participation and subjects signed written informed consent for all research testing procedures (Appendix A, C). The Institutional Review Board approved all testing procedures.

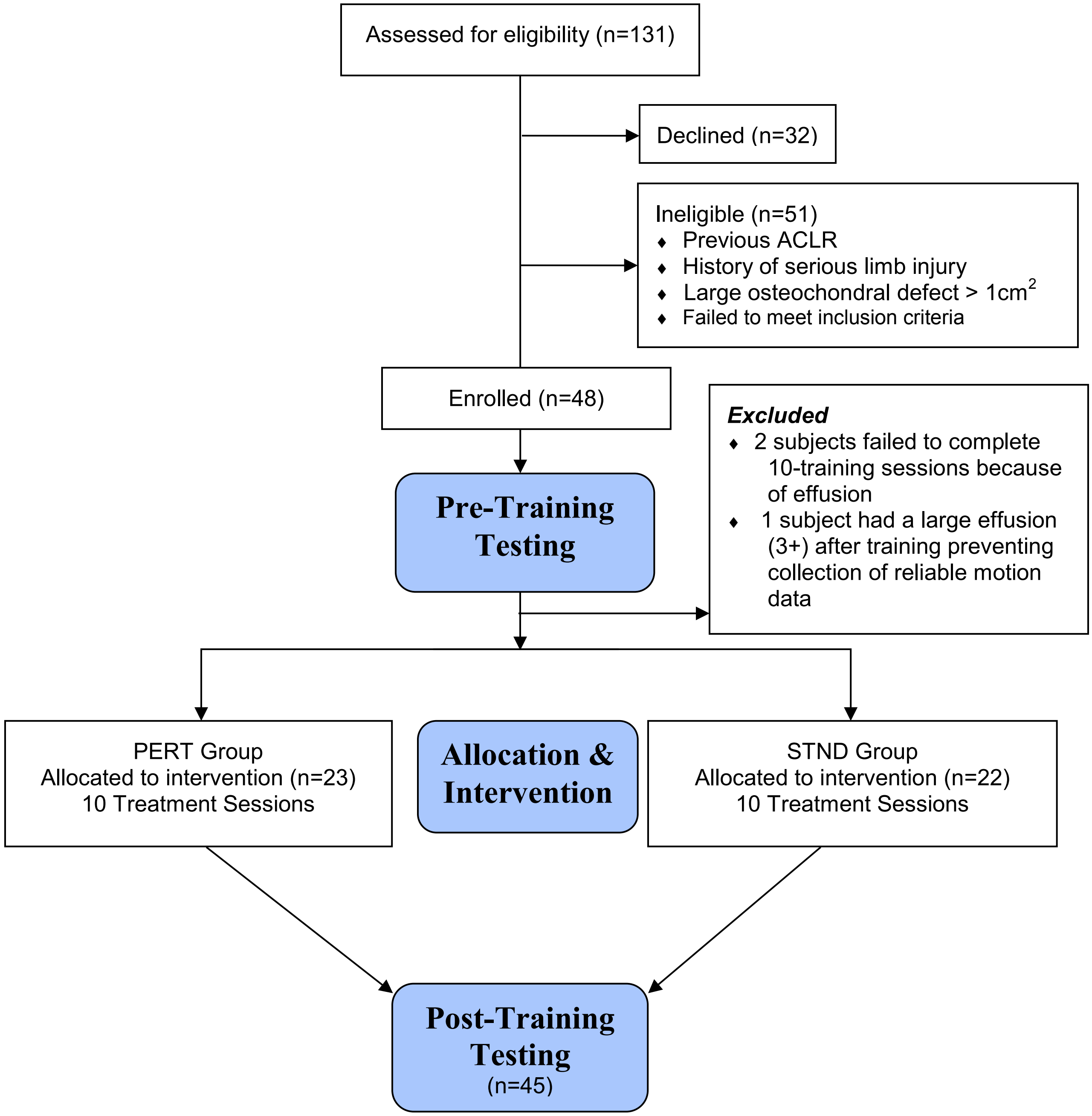

Figure 2.2 Consort diagram of subjects included in Chapter 2

Subjects were block randomized by sex to two treatment groups, PERT group or STND group (PERT, n=23, STND, n=22). The treatment consisted of 10-training sessions, over an average of 6.43 ±1.40 weeks, in which all subjects completed agility drills, ACL injury prevention exercises and quadriceps femoris muscle strengthening.[89] Subjects in the PERT group received additional neuromuscular training, perturbation training. Perturbation training is a neuromuscular training that progressively destabilizes patients in bilateral and unilateral stance on unstable surfaces[24] (Figure 2.1). Training is progressively increased in both speed and magnitude as per patient tolerance (Appendix B). Patients are cued to avoid muscle co-contraction strategies and to maintain upright posture during the task. Subjects in the STND group completed a unilateral balance control exercise. This exercise was not progressed to unstable surfaces to minimize neuromuscular adaptations in the STND group.

Gait biomechanics were collected at both pre-training and post-training testing (Figure 2.3). Three-dimensional motion capture systems were used to collect gait data (VICON, Oxford Metrics Ltd., London, England) sampled at 120 Hz. Twenty static retro-reflective markers were placed on the pelvis and lower extremities, and rigid shells were used to track limb segments. An embedded force plate (Bertec, Worthington, OH) simultaneously collected kinetic data at 1080 Hz, which was used to determine timing variables during the gait cycle. Five walking trials were collected for each limb while the subjects maintained a self-selected walking speed with ± 5% variability. These data were post-processed using rigid body analysis and inverse dynamics with custom software programming (Visual3D, C-Motion, Inc., Germantown, MD, USA; LabVIEW 8.2, National Instruments Corp., Austin, TX, USA). Kinematic and kinetic variables were lowpass filtered at 6 Hz and 40 Hz respectively. Initial contact and toe off were determined using a 50 Newton force plate threshold and all walking trials were normalized to 100% of stance before being averaged for statistical analysis. Hip and knee joint angles, internal joint moments and joint excursions were evaluated for both limbs in the sagittal plane at initial contact, peak knee flexion and peak knee extension during gait.

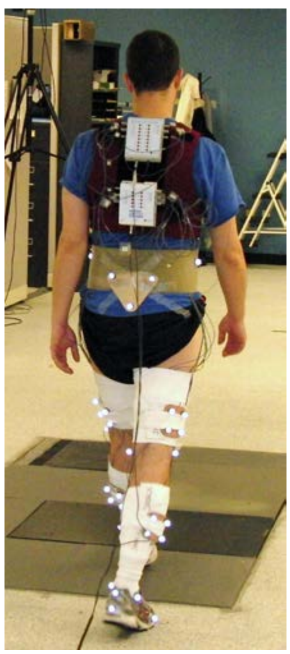

Figure 2.3 Set-up for 3-dimension motion capture gait analysis.

Knee joint excursions have been found to improve initially after pre-operative perturbation training and after surgery. Sample size for this aim was determined using knee joint excursion during weight acceptance as the primary variable of interest for this study. A power analysis with β=0.20, α=0.05, and a large effect size (0.83) based on preliminary data, indicated that 19 subjects were needed in each group (38 total) to identify differences between the groups after 10-training sessions.

2.4 Statistics

Independent t-tests were used to determine demographic differences between treatment groups. A 2x2x2 analysis of variance was used to evaluate differences between limbs, between treatment groups, over time. When statistical significance was found, paired and independent t-tests were used to determine where difference existed. Minimal clinically important difference (MCID) values have been established with 14 healthy individuals for sagittal plane hip and knee joint kinematics and kinetics and used to identify meaningful differences between limbs[20,21] (Hip and knee angles: $\geq 3°$, Hip moments:≥ 0.06 Nm/kg*m, Knee moments: ≥ 0.04 Nm/kg*m). MCID values were used to identify if statistically significant differences between limbs were clinically meaningful, as well as the change in the difference between limbs over time. If differences between limbs did not exceed MCID values then post-hoc t-tests were not computed. Significance level of $p \leq 0.05$ was set a priori.

2.5 Results

There were no differences between subjects in the STND group and subjects in the PERT group for age at surgery, body mass index (BMI) at enrollment, weeks of training, sex and graft type (Table 2.1).

Table 2.1 Subject demographics by treatment group. Values are means (standard deviations).

	STND Group (n=22)	PERT Group (n=23)	P-value
Age at surgery (yrs)	23.91 (7.26)	22.30 (8.35)	0.40
BMI at enrollment	26.05 (2.71)	26.94 (2.56)	0.44
Weeks of Training	6.62 (1.30)	6.24 (1.49)	0.22
Sex*	Males 16, Females 6	Males 17, Females 6	0.93
Graft Type*	Auto=14 , Allo=8	Auto=16 , Allo=7	0.67

STND= standard treatment group, PERT= perturbation group, yrs= years, BMI= Body Mass Index, *= number of subjects, Auto= autograft, Allo= allograft.

At initial contact (Table 2.2A,B), there was a limb x time x group interaction (p=0.005). Subjects in the PERT group had larger differences between limbs compared to subjects in the STND group before training. Both groups demonstrated small limb differences after training; however differences between limbs at both time points did not exceed the MCID values in either treatment group. There was a main effect of limb for the knee flexion moment (p=0.02), though differences between limbs were small and little to no change occurred over time. No statistically significant differences were seen for hip angles or moments (Table 2.2A,B), although subjects in the PERT group demonstrated differences between limbs for hip moments before training that exceed MCID values. Post-hoc t-tests demonstrated no significant difference between limbs (p=0.06). After training, PERT subject demonstrated symmetrical hip moments and the change in hip moments from before training to after training exceeded the MCID (Table 2.2A).

Table 2.2A Hip and knee angles (degrees) and moments (Nm/kg*m) between limbs of both treatment groups at initial contact during gait. Values are means (standard deviations).

IC	Group	PRE		Diff		POST		Diff		Diff Change
		Involved	Uninvolved		Sig.	Involved	Uninvolved		Sig.	
KFA	SNTD	6.28 (3.65)	6.94 (3.67)	0.66°	--	6.02 (3.09)	5.39 (4.19)	-0.63°	--	1.29°
	PERT	7.46 (3.74)	5.19 (2.98)	-2.27°	--	5.09 (3.69)	5.35 (4.17)	0.26°	--	2.53°
HFA	SNTD	28.64 (6.24)	28.32 (6.20)	-0.32°	--	27.89 (6.94)	27.36 (6.84)	-0.53°	--	-0.21°
	PERT	28.13 (6.24)	27.83 (5.54)	-0.30°	--	27.45 (7.44)	27.89 (5.59)	0.44°	--	0.74°
KFM	STND	0.18 (0.06)	0.19 (0.05)	0.01	--	0.17 (0.06)	0.18 (0.06)	0.01	--	0.0
	PERT	0.17 (0.07)	0.20 (0.08)	0.03	--	0.18 (0.06)	0.19 (0.06)	0.01	--	0.02
HEM	STND	0.32 (0.12)	0.33 (0.10)	0.01	--	0.31 (0.12)	0.28 (0.20)	-0.03	--	0.04
	PERT	0.29 (0.13)	0.35 (0.15)	***0.06***	0.06	0.32 (0.12)	0.30 (0.19)	-0.02	--	***0.08***

IC= initial contact, PRE= pre-training, Diff= differences between limbs, POST= post-training, Sig= significance, KFA= knee flexion angle, STND= standard treatment group, PERT= perturbation group, HFA= hip flexion angle, KFM= knee flexion moment, HEM= hip extension moment.

Table 2.2B Gait variables at initial contact. A check mark is used to denote differences between limbs that exceeded clinically meaningful differences.

IC	PRE		POST	
	SNTD	PERT	STND	PERT
KFA	--	--	--	--
HFA	--	--	--	--
KFM	--	--	--	--
HEM	✓	--	--	--

IC= initial contact, PRE=pre-training, POST= post-training, STND= standard treatment group, PERT= perturbation group, KFA= knee flexion angle, HFA= hip flexion angle, KFM= knee flexion moment, HEM= hip extension moment.

At peak knee flexion (Table 2.3A,B,C, Figures 2.4 and Figure 2.5), there was a significant limb x time x group interaction ($p=0.002$) for the knee flexion angle. Prior to training, subjects in the STND group demonstrated limb differences greater than 3° that were statistically significant ($p<0.001$), while subjects in the PERT group had small limb differences (less than 3°). After training, subjects in both groups demonstrated limb differences greater than 3° that were statistically significant (STND $p=0.001$, PERT $p<0.001$) with the involved limb demonstrating less knee flexion in both groups, at both time points. There was a main effect of limb for the hip flexion angle ($p=0.003$), however differences between limbs in both groups did not exceed MCID values at either time point. There was a significant main effect of limb for knee extension moments ($p<0.001$) with both groups exceeding MCID values before and after training, with little to no change over time. Post-hoc t-tests demonstrated a significant difference between limbs for both groups at both time points (Table 2.3A). There was no significant difference for hip extension moments and no measures exceeded MCID values (Table 2.3A,B).

Forty-seven percent (21 of 45) of subjects demonstrated knee flexion angle limb differences at peak knee flexion greater than 3° both before and after training (Table 2.3C) with a larger number of those subjects in the STND group. Twenty-two percent (10 of 45) of subjects made improvement in limb symmetry with ACL-SPORTS Training, seen with asymmetry prior to training and symmetry after training, determined based on MCID values. Six of those subjects were in the STND treatment group and four in the PERT group.

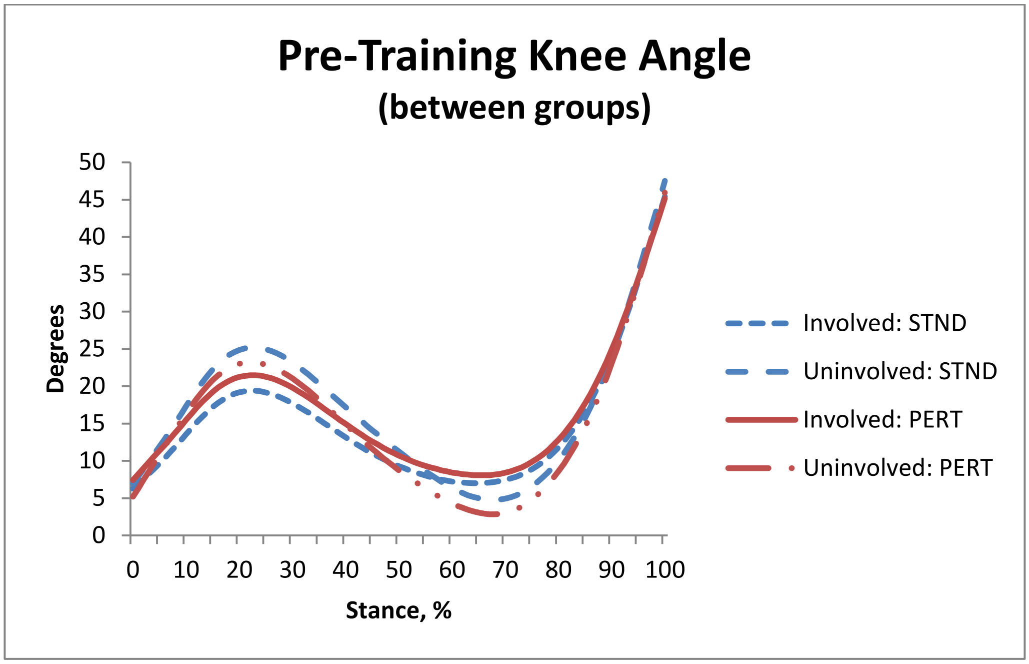

Figure 2.4 Knee angle during stance phase of gait before training between the standard and perturbation treatment groups. STND= standard treatment group, PERT= perturbation group

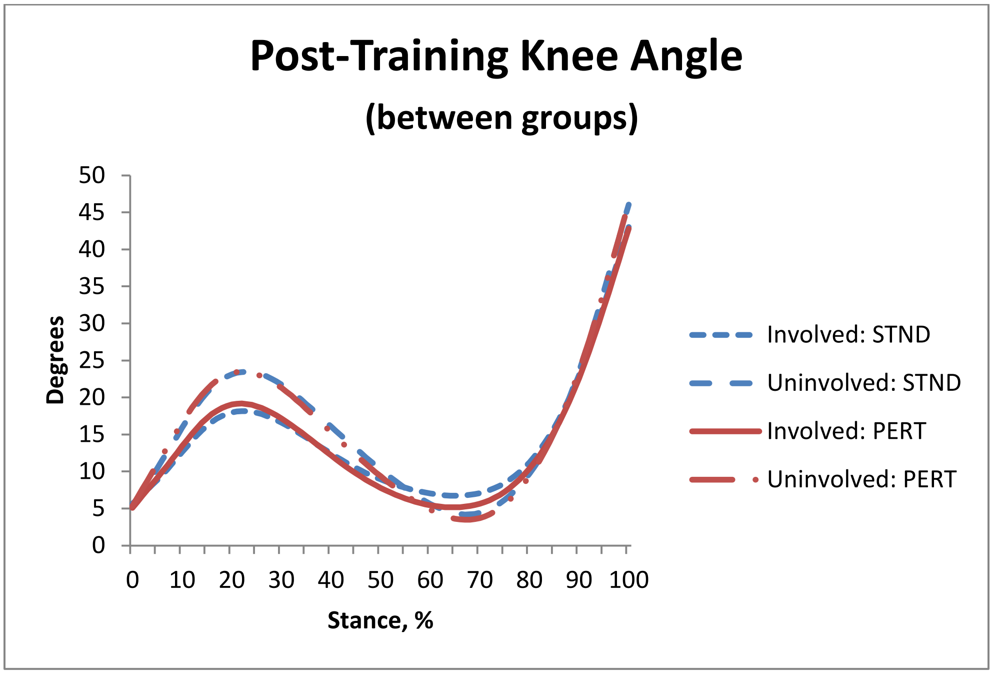

Figure 2.5 Knee angle during stance phase of gait after training between the standard and perturbation treatment groups. STND= standard treatment group, PERT= perturbation group

Table 2.3A Hip and knee angles (degrees) and moments (Nm/kg*m) between limbs of both treatment groups at peak knee flexion during gait. Values are means (standard deviations).

PKF	Group	PRE		Diff		POST		Diff		Diff Change
		Involved	Uninvolved		Sig.	Involved	Uninvolved		Sig.	
KFA	STND	19.66 (6.14)	25.29 (4.36)	***5.63°***	***<0.001***	19.33 (5.74)	23.57 (4.74)	***4.24°***	***0.001***	1.39°
	PERT	21.75 (6.31)	23.37 (3.90)	1.62°	--	19.33 (6.31)	23.60 (6.11)	***4.27°***	***<0.001***	-2.65°
HFA	STND	20.44 (10.23)	22.79 (7.39)	2.35°	--	20.57 (8.00)	21.57 (7.00)	1.0°	--	1.35°
	PERT	20.01 (6.11)	21.49 (6.17)	1.48°	--	19.91 (6.42)	21.65 (5.82)	1.74°	--	-0.26°
KEM	STND	0.38 (0.17)	0.50 (0.12)	***0.12***	***0.005***	0.40 (0.16)	0.49 (0.13)	***0.09***	***0.02***	0.03
	PERT	0.44 (0.15)	0.54 (0.12)	***0.10***	***0.002***	0.43 (0.15)	0.53 (0.16)	***0.11***	***0.001***	-0.01
HEM	STND	0.32 (0.14)	0.32 (0.14)	0.0	--	0.31 (0.13)	0.30 (0.16)	-0.01	--	-0.01
	PERT	0.33 (0.21)	0.30 (0.20)	-0.03	--	0.33 (0.11)	0.30 (0.14)	-0.03	--	0.0

PKF= peak knee flexion, PRE= pre-training, Diff= difference between limbs, POST= post-training, Sig= significance, KFA= knee flexion angle, STND= standard treatment group, PERT= perturbation group, HFA= hip flexion angle, KEM= knee extension moment, HEM= hip extension moment.

Table 2.3B Gait variables at peak knee flexion. A check mark is used to denote differences between limbs that exceeded clinically meaningful differences.

PKF	PRE		POST	
	STND	PERT	STND	PERT
KFA	✓	--	✓	✓
HFA	--	--	--	--
KEM	✓	✓	✓	✓
HEM	--	--	--	--

PKF= peak knee flexion, PRE= pre-training, POST=post-training, STND= standard treatment group, PERT= perturbation group, KFA= knee flexion angle, HFA= hip flexion angle, KEM= knee extension moment, HEM= hip extension moment.

Table 2.3C Limb symmetry of knee flexion angles at peak knee flexion before and after training. Number of subjects who demonstrated limb symmetry (less than 3° difference between limbs) and subjects who demonstrated limb asymmetry (greater than 3° difference between limbs) before and after training. Values are number of subjects (percent).

Knee Flexion Angle at Peak Knee Flexion		All Subjects	STND	PERT
Pre-Training	*Post-Training*	*N=45*	*N=22*	*N=23*
Asymmetry	Asymmetry	21 (47)	12 (54.5)	9 (39.1)
Asymmetry	Symmetry	10 (22)	6 (27)	4 (17.4)
Symmetry	Asymmetry	5 (11)	1 (4.5)	4 (17.4)
Symmetry	Symmetry	9 (20)	3 (14)	6 (26.1)

STND= standard treatment group, PERT=perturbation group

At peak knee extension (Table 2.4A,B, Figures 2.4 and Figure 2.5), there was a significant limb x time x group interaction (p=0.001) for the knee flexion angle. Subjects in the PERT group demonstrated clinically meaningful asymmetries (greater than 3°) for knee flexion angles prior to training, while subjects in the STND group had small differences between limbs (less than 3°). Both groups demonstrated symmetrical knee flexion measures (less than 3°) after training that were less than MCID values. Subjects in the PERT group had a large change in limb symmetry from pre-training to post-training that was greater than MCID values (3.49°). Post-hoc t-tests demonstrated a significant difference between limbs for PERT subjects before training (p<0.001). There was a significant limb x time x group interaction (p=0.04) for the knee flexion moment. Post-hoc paired t-tests demonstrated that both groups have significant differences between limbs both before and after training that exceed MCID values, with little to no change. There was a main effect of limb for hip flexion angles and moments (p<0.001). Hip flexion angles in both groups exceeded MCID values both before and after training (Table 2.4A,B), with little to no change over time. Post-hoc t-tests demonstrate a significant difference between limbs for both groups at both time points. Hip flexion moments before training exceeded MCID values in both groups (PERT p=0.004, STND p<0.001), however after training differences were less than 3° in both groups.

Nearly two-thirds of subjects (28 of 45) demonstrated knee flexion angle limb differences at peak knee extension prior to training, however more than half (15 of 28) demonstrated limb symmetry after training (Table 2.4C). Of these subjects with limb symmetry after training, nine subjects were in the PERT group and six subjects were in the STND group, suggesting minimal difference between the groups.

Table 2.4A Hip and knee angles (degrees) and moments (Nm/kg*m) between limbs of both treatment groups at peak knee extension during gait. Values are means (standard deviations).

PKE	Group	PRE		Diff		POST		Diff		Diff Change
		Involved	Uninvolved		Sig.	Involved	Uninvolved		Sig.	
KFA	STND	6.42 (3.53)	4.56 (3.98)	-1.86°	--	6.59 (2.65)	3.98 (4.53)	-2.61°	--	-0.75°
	PERT	7.64 (4.55)	2.60 (4.07)	***-5.04°***	***<0.001***	4.77 (4.55)	3.22 (4.46)	-1.55°	--	***3.49°***
HFA	STND	10.58 (6.79)	14.58 (5.73)	***4.0°***	***0.001***	9.95 (8.09)	14.40 (6.34)	***4.45°***	***<0.001***	-0.45°
	PERT	10.50 (6.07)	14.72 (4.95)	***4.22°***	***<0.001***	10.98 (7.17)	14.22 (6.79)	***3.24°***	***0.001***	0.98°
KFM	STND	0.06 (0.07)	0.11 (0.07)	***0.05***	***0.003***	0.05 (0.06)	0.12 (0.07)	***0.08***	***<0.001***	-0.03
	PERT	0.05 (0.08)	0.12 (0.08)	***0.07***	***<0.001***	0.07 (0.08)	0.13 (0.08)	***0.06***	***0.017***	0.01
HFM	STND	0.23 (0.10)	0.32 (0.09)	***0.09***	***<0.001***	0.24 (0.12)	0.29 (0.13)	0.05	--	0.04
	PERT	0.25 (0.16)	0.33 (0.14)	***0.08***	***0.004***	0.25 (0.12)	0.29 (0.17)	0.04	--	0.04

PKE= peak knee extension, PRE= pre-training, Diff= difference between limbs, POST=post-training, Sig= significance, KFA= knee flexion angle, STND= standard treatment group, PERT= perturbation group, HFA=hip flexion angle, KFM= knee flexion moment, HFM= hip flexion moment.

Table 2.4B Gait variables at peak knee extension. A check mark is used to denote differences between limbs that exceeded clinically meaningful differences.

PKE	PRE		POST	
	STND	PERT	STND	PERT
KFA	--	✓	--	--
HFA	✓	✓	✓	✓
KFM	✓	✓	✓	✓
HFM	✓	✓	--	--

PKE= peak knee extension, PRE= pre-training, POST=post-training, STND= standard treatment group, PERT= perturbation group, KFA= knee flexion angle, HFA= hip flexion angle, KFM= knee flexion moment, HFM= hip flexion moment.

Table 2.4C Limb symmetry of knee flexion angles at peak knee extension before and after training. Number of subjects who demonstrated limb symmetry (less than 3° difference between limbs) and subjects who demonstrated limb asymmetry (greater than 3° difference between limbs) before and after training. Values are number of subjects (percent).

Knee Flexion Angle at Peak Knee Extension		All Subjects	STND	PERT
Pre-Training	*Post-Training*	*N=45*	*N=22*	*N=23*
Asymmetry	Asymmetry	13 (29)	7 (32)	6 (26)
Asymmetry	Symmetry	15 (33)	6 (27)	9 (39)
Symmetry	Asymmetry	5 (11)	2 (9)	3 (13)
Symmetry	Symmetry	12 (27)	7 (32)	5 (22)

STND= standard treatment group, PERT=perturbation group

There was a main effect of limb ($p<0.001$) for knee excursion during weight acceptance and mid-stance (Table 2.5A,B,C, Figures 2.4 and 2.5). Prior to and after training, all subjects demonstrated knee excursion differences between limbs that exceed the MCID values. Post-hoc t-tests demonstrated that significant differences between limbs existed at both time points in both groups for knee excursions during both weight acceptance and mid-stance. There was a significant limb x time interaction ($p=0.004$) for hip excursions during weight acceptance, however differences between limbs did not exceed MCID values. During weight acceptance, hip excursions were larger on the involved limb in both treatment groups. There was a main effect of limb for hip excursion during mid-stance ($p<0.001$) where differences between limbs exceeded MCID values and excursions were larger on the uninvolved limb (Table 2.5A,B). Post-hoc t-tests demonstrated that significant differences between limbs existed at both time points in both groups for hip excursion during mid-stance.

Table 2.5A Hip and knee excursions (degrees) and moments (Nm/kg*m) between limbs of both treatment groups during gait. Values are means (standard deviations).

EXC	Group	PRE		Diff		POST		Diff		Diff Change
		Involved	Uninvolved		Sig.	Involved	Uninvolved		Sig.	
Knee WA	STND	13.38 (4.53)	18.34 (2.79)	***4.96°***	***<0.001***	12.75 (5.76)	18.18 (3.05)	***5.43°***	***<0.001***	-0.47°
	PERT	14.30 (3.86)	18.18 (3.32)	***3.88°***	***<0.001***	14.55 (5.94)	18.26 (3.75)	***3.71°***	***<0.001***	0.17°
Knee MS	STND	13.24 (6.43)	20.73 (5.49)	***7.49°***	***<0.001***	12.75 (5.76)	19.59 (4.62)	***6.66°***	***<0.001***	0.83°
	PERT	14.11 (4.65)	20.77 (3.42)	***6.84°***	***<0.001***	14.55 (5.94)	20.38 (4.72)	***5.83°***	***<0.001***	1.01°
Hip WA	STND	8.20 (5.36)	5.62 (2.19)	-2.58°	--	7.32 (3.54)	5.79 (2.49)	-1.53°	--	1.05°
	PERT	8.12 (3.72)	6.34 (3.39)	-1.78°	--	7.54 (3.80)	6.32 (3.78)	-1.22°	--	0.56°
Hip MS	STND	31.20 (9.31)	37.37 (5.51)	***6.17°***	***0.013***	30.52 (7.39)	35.96 (4.38)	***5.44°***	***<0.001***	0.73°
	PERT	30.34 (4.79)	36.21 (3.97)	***5.87°***	***<0.001***	30.89 (5.52)	35.87 (4.42)	***4.98°***	***<0.001***	0.89°

EXC= excursion, PRE= pre-training, Diff= difference between limbs, POST=post-training, Sig= significance, WA= weight acceptance, STND= standard treatment group, PERT= perturbation group, MS= mid-stance.

Table 2.5B Gait excursion variables during weight acceptance and mid-stance. A check mark is used to denote differences between limbs that exceeded clinically meaningful differences.

EXC	PRE		POST	
	STND	PERT	STND	PERT
Knee WA	✓	✓	✓	✓
Knee MS	✓	✓	✓	✓
Hip WA	--	--	--	--
Hip MS	✓	✓	✓	✓

EXC= excursion, PRE= pre-training, POST=post-training, STND= standard treatment group, PERT= perturbation group, WA= weight acceptance, MS= mid-stance

Changes in the difference between limbs, for each group, are reported in the last column of each table (Tables 2.2A-2.5A). Two measures had large changes that exceeded MCID values: the hip extensor moment (0.08 Nm/Kg*m) at initial contact and the knee flexion angle at peak knee extension (3.49°) for subjects in the PERT group (Tables 2.2A, 2.4A). Asymmetries were seen in PERT subjects prior to training and both hip extensor moments at initial contact and knee flexion angles at peak knee extension measures improved from pre-training to post-training with differences between limbs not exceeding MCID values after training. No subjects in the STND group had changes that exceeded MCID values.

2.6 Discussion

After ACL-SPORTS Training, there was no difference between the PERT and STND groups for knee and hip kinematics and kinetics during gait. The only difference between groups was seen prior to training. A change in the difference between limbs that exceeded MCID values was seen in the PERT group for hip extension moments at initial contact and knee flexion angle at peak knee extension. No change, that exceeded MCID values, was seen in the STND treatment group.

Subjects in the PERT group demonstrated limb symmetry for knee flexion angles at peak knee flexion prior to training. After training, PERT subjects demonstrated limb asymmetries that exceeded MCID values; however the change in limb difference was 2.65°. This change in the difference between limbs is small and most likely not clinically meaningful. Knee flexion angles at peak knee extension, prior to training for subjects in the PERT group exceeded MCID values, yet differences after training were less than 3°, suggesting an improvement in limb symmetry. This change in the difference between limbs was 3.49° and thought to be clinically meaningful.

A knee stiffening strategy in non-copers after ACL injury has been described as reduced knee flexion angles, reduced knee moments and co-contraction of knee musculature.[13] This pattern was seen for the knee flexion angle at peak knee flexion at pre-training for subjects in the STND treatment group, but not the PERT group. After training, mean measures for both groups demonstrated this stiffening strategy suggesting that a stiffening strategy persists after surgery. At peak knee extension, knee flexion angles for subjects in the PERT group were consistent with this knee stiffening strategy, with increased knee flexion on the involved limb. After training, subjects in the PERT group demonstrated increased knee extension on the involved limb, resulting in minimal limb differences. Knee joint excursion, during weight acceptance and mid-stance, was truncated on the involved limb for all subjects before training and after training. Again, these movement patterns are consistent with the knee stiffening strategy reported in non-copers after ACL injury, suggesting it persists after surgery.

With further evaluation of knee flexion angles at peak knee flexion, we were able to identify 12 subjects (27%) before training, who demonstrated greater knee flexion angles on the involved limb, compared to the uninvolved limb; the opposite of the stiffening strategy. Nine of these 12 subjects were randomized to the PERT group, which explains the small difference between limbs (less than 3°) for mean measures in the PERT group prior to training. These 12 subjects were enrolled in the study five weeks earlier after surgery than the rest of the subjects (18.18 weeks, vs 23.45 wks from surgery to enrollment) ($p=0.03$). Evaluating this factor further, weeks from surgery significantly explained 13% of the variance of the difference between limbs before training ($p=0.02$) in a linear regression model (Figure 2.4), however it did not explain the difference between limbs after training ($p=0.19$). This suggests that subjects who met enrollment criteria earlier after surgery may have symmetrical movement patterns compared to those subjects who take longer to resolve impairments. Of these 12 subjects, only four demonstrated limb differences greater than 3° after training suggesting that these subjects demonstrated adequate limb symmetry before and after training, and may be a subgroup of patients that is more likely to have successful outcomes after surgery. Regardless of treatment group, 31 subjects (69%) were identified as having limb asymmetries for knee flexion angles at peak knee flexion that exceeded MCID values prior to training. Of these 31 subjects, 10 (22%) demonstrated limb symmetry after training. These may be individuals that respond positively to the treatment intervention. Further evaluating how subjects respond to the treatment may provide better insight into which patients may respond (responders) or not respond (non-responders) to the treatment intervention.

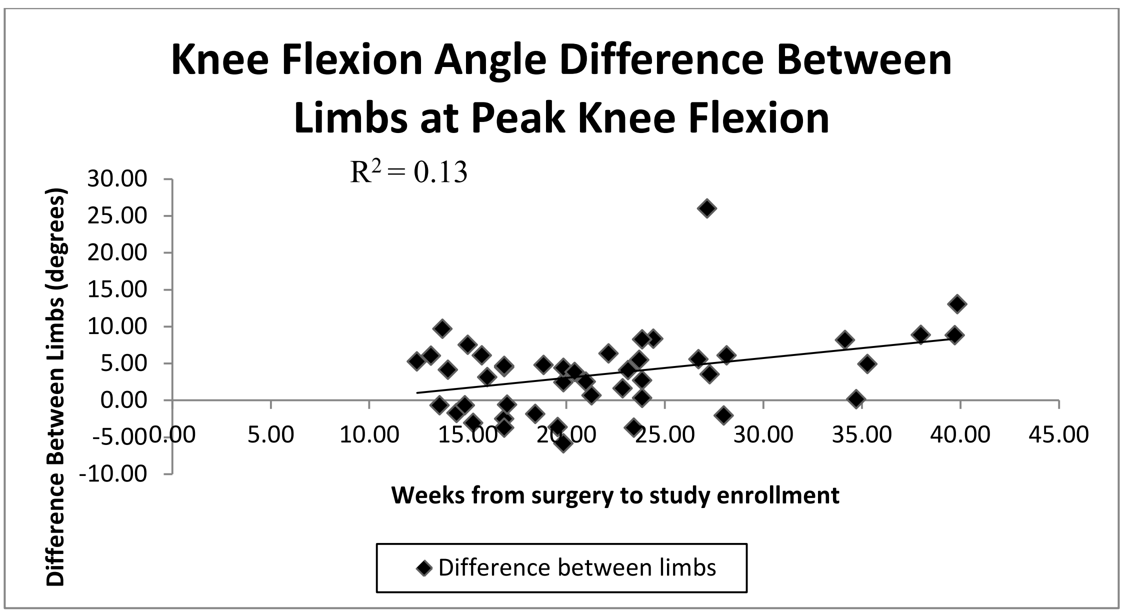

Figure 2.6 Linear regression line using weeks from surgery to enrollment to predict the difference between limbs of knee flexion angles at peak knee flexion before training.

Upon further investigation of knee flexion angles at peak knee extension, 12 subjects (27%) demonstrated greater knee extension on the involved limb compared to the uninvolved limb before training. This movement pattern is not consistent with the knee stiffening strategy. Seven of 12 subjects had limb differences less than 3°. Eight of 12 subjects were also randomized to the STND treatment group, which was seen by mean limb differences less than 3° before training. Seven of 12 subjects maintained this movement pattern after training, and five of these subjects demonstrated limb differences less than 3°. These individuals, who demonstrate greater knee extension on the involved limb at peak knee extension, may be more likely to have successful outcomes after surgery compared to subjects who demonstrate truncated knee extension and may not require additional neuromuscular training after surgery. Evaluating all subjects included in this study, 28 subjects (62%) demonstrated differences between limbs that exceeded MCID values before training. After training, only 18 subjects (40%) demonstrated asymmetries that exceeded MCID values. This suggests that there may be a subgroup of patients that benefit from this treatment intervention.

Functional performance has been found to be related to symmetrical movement patterns. Di Stasi and colleagues[20] identified subjects with good functional performance on a battery of return-to-activity criteria six months after surgery. Subjects who demonstrated ≥ 90% quadriceps femoris muscle strength symmetry, ≥90% limb symmetry on four single-legged hop tests and ≥ 90% on patient-reported outcome measures demonstrated adequate limb symmetry during gait compared to subjects who did not meet these criteria six months after surgery. This suggests achieving superior functional performance with these criteria may be more predictive of normal movement patterns after surgery than a specific treatment intervention.

Pre-operative perturbation training has demonstrated improvements in movement patterns, however two years after surgery, pre-operative intervention did not identify subjects with normal movement patterns.[69] This suggests that surgery may be a game-changing event. With small changes seen in subjects in this study, a more rigorous neuromuscular training program after surgery may be needed to elicit change in movement patterns.

There are several possible reasons for the lack of improvement in movement patterns after ACL-SPORTS Training. First, it is possible that a more rigorous neuromuscular training program is needed to alter movement patterns after surgery. Neuromuscular adaptations that have been identified acutely after ACL injury may be more easily altered early after injury. A combination of pre-operative and post-operative perturbation training may be needed to improve movement patterns prior to athletes returning to activities. Conversely, it is possible that this ACL-SPORTS Training program increases limb asymmetries because of the high-demand of these dynamic activities in the training program. These subjects are completing plyometric exercises for the first time after surgery and more sessions may be needed for these subjects to adequately improve movement patterns. Secondly, there may be a subgroup of subjects who respond positively to this treatment program that may be identified. Female subjects have been identified before surgery to demonstrate improvements in movement patterns after perturbation training.[21] A small number of female subjects in this sample may be limiting the ability to capture gender differences. This should be evaluated further with more female subjects. As mentioned previously, subjects who demonstrate good functional performance on return-to-activity criteria after surgery demonstrated adequate limb symmetry. Further examination of subjects after ACL-SPORTS Training who pass these criteria may determine that good functional performance of these measures is more important to limb symmetry than what treatment was used to reach that goal.

2.7 Conclusion

After ACL-SPORTS Training, there are small improvements in limb symmetry for subjects in the PERT group with hip extension moments at initial contact and knee flexion angles at peak knee flexion. Asymmetries persist in all subjects after training at peak knee flexion and with joint excursions. Evaluating subjects after training, based on good functional performance on return-to-activity criteria and evaluating sex differences may allow us to identify a subgroup of individuals who respond to ACL-SPORTS Training.

Chapter 3

IMPROVED KNEE FUNCTION AFTER ACL-SPORTS TRAINING

3.1 Abstract

Background: While athletes are often cleared to return to activities six months after anterior cruciate ligament reconstruction (ACLR), knee function measures continue to improve up to one year after surgery. Additional treatment at this time point, to improve knee function, may be needed to ensure successful return to activities. Our research team has developed a specialized post-operative return-to-sports (ACL-SPORTS) training program to improve outcomes after surgery. The purpose of this study was to evaluate knee function after ACL-SPORTS Training after training and one year after surgery.

Methods: Subjects were randomized to a standard treatment group or a perturbation group at the time of enrollment. Knee function measures were collected with the International Knee Documentation Committee (IKDC) 2000 subjects knee form, Knee Injury and Osteoarthritis Outcome Score (KOOS) sports and recreation and quality of life subscales after training and one year after surgery. T-tests and analysis of variance were used to identify differences between the treatment groups, over time.

Results: Eighty-five percent of subjects returned to their pre-injury activity level at one year. There were no significant differences between the groups for knee function measures after training, one year after surgery and with change scores. All

subjects in this cohort reported significantly higher knee function scores compared to national and international ACL ligament registries.

Discussion: Although there was no significant difference in knee function measures between the two treatment groups in this study, greater scores were reported compared to currently published studies. This suggests that regardless of treatment group, the ACL-SPORTS Training protocol may be beneficial at improving knee function after ACLR.

3.2 Introduction

Nearly 175,000 anterior cruciate ligament reconstructions (ACLR) are performed each year in the US[82] with the goal of restoring the knee joint anatomy and allowing individuals to resume athletic activities.[28,57] One year after surgery, only 66% of athletes participated in modified or full competition, and three years after surgery, only 45% had returned to pre-injury activities.[6] Although there are many reasons that athletes do not return to pre-injury activities after surgery, below normal knee function[53,54] is one of the many poor outcomes reported after ACLR.

Implementing a post-operative training protocol, prior to patients returning to pre-injury activities, that focuses on improving limb symmetry using neuromuscular training may improve short-term outcomes after surgery. The Anterior Cruciate Ligament-Specialized Post-Operative Return-to-Sports (ACL-SPORTS) Training protocol[89] was developed as a means to prepare patients, after impairments have been resolved, to successfully return to pre-injury activities. This protocol was developed to address post-operative neuromuscular impairments and predictors of second-injury.

The training program was derived and optimized from published research studies and ACL injury prevention techniques. Subjects are randomized to two treatment groups: standard care (STND) group or perturbation (PERT) group. It consists of a series of ACL injury prevention exercises, quadriceps femoris muscle strengthening exercises, agility drills and either perturbation training[24] (Figure 2.1, Appendix B) for individuals in the PERT group, or a control exercise for individuals in the STND care group. Evaluating knee function, between the treatment groups, after completion of this ACL-SPORTS Training protocol and one year after surgery will allow us to identify improvements in knee function at a critical time when athletes are participating in higher level activities.

The international medical community agrees that patient-reported outcome measures are a component of success after ACLR;[55] however, consensus on specific measures has not been reached. To assess knee function, the author's recommend utilizing the International Knee Documentation Committee (IKDC) 2000 subjective knee form to measure function after ACLR as well as the Knee Injury and Osteoarthritis Outcome Score (KOOS) to address knee pain, symptoms, function in daily living, function in sports and recreation (Sport/rec), and knee quality of life (QOL).

The IKDC 2000 is a valid and reliable measure of knee symptoms, knee function and sports activity in patients with a variety of knee conditions.[41] Six months after surgery, poor knee function has been reported in 25% of subjects,[54] which is a common time for athletes to be cleared to return to activities.[8] Normal knee function was established using the top 15th percentile of healthy age- and sex-matched individuals.[3] One year after surgery only 13% of subjects reported below normal knee function, suggesting that subjects continue to make improvements in knee function up to one year after surgery that is identified with the IKDC 2000. Utilizing this measure with subjects after our ACL-SPORTS Training protocol will allow us to evaluate improvements in knee function over time.

The KOOS has been used with individuals after ACLR to measure long-term outcomes (two to seven years),[57,66,75,85] however it has recently been used prior to and after ACLR as a measure of knee function.[77,80] The KOOS-Sport/rec and KOOS-QOL subscales specifically, have been reported to change the most after ACLR and assess knee dysfunction in higher level individuals,[71] suggesting these subscales may also be an effective measurement tool to evaluate improvements in knee function in the short-term after ACLR.

The purpose of this study was to evaluate knee function measures between subjects who received STND treatment and subjects who received PERT treatment after completion of this ACL-SPORTS Training protocol and one year after surgery utilizing the IKDC 2000, KOOS-Sport/rec and KOOS-QOL scales. The focus of this study is two-fold: (1) to determine the activity level one year after surgery between the treatment groups to identify who has returned to their pre-injury activity level, (2) to determine knee function using the IKDC 2000, KOOS-Sports/rec and KOOS-QOL after completion of the ACL-SPORTS Training protocol and one year after surgery.

3.3 Methods

Forty-five subjects (mean age at surgery 23.29 ±7.79yrs; Males=33, Females=12) included in this study underwent an isolated, unilateral ACLR (autograft=30, allograft=15) within the last 10 months and participated in our ACL-SPORTS Training protocol.[89] Subjects between the ages of 13 and 55 were included in this study if they were regular participants (≥50 hrs/yr) in level 1 or 2 activities prior to their injury[17] and desired to return to their pre-injury activity level. All subjects met the following criteria for enrollment: ≥ 12 weeks after surgery, demonstrated ≥80% quadriceps femoris muscle strength symmetry and maintained minimal knee joint effusion measured with the modified stroke test.[83] All subjects provided written informed consent at the time of study enrollment and the Institutional Review Board approved all research testing procedures for this study (Appendix A, C).

Subjects were randomized to two treatment groups: STND group (n=22) and PERT group (n=23) (Figure 3.1), which consisted of 10 treatment sessions for all subjects. The STND group received ACL injury prevention exercises, quadriceps femoris muscle strengthening exercises and agility drills[89] to target impairments in balance, dynamic tasks and muscle strength; all risk factors for initial ACL injury[58,59] and subsequent re-injury.[18] Subjects in the PERT group received all exercises listed, augmented with perturbation training.[24] The addition of perturbation training is targeted at addressing neuromuscular impairments including muscle co-contraction and abnormal knee kinematics and kinetics.[13,21,32,39]

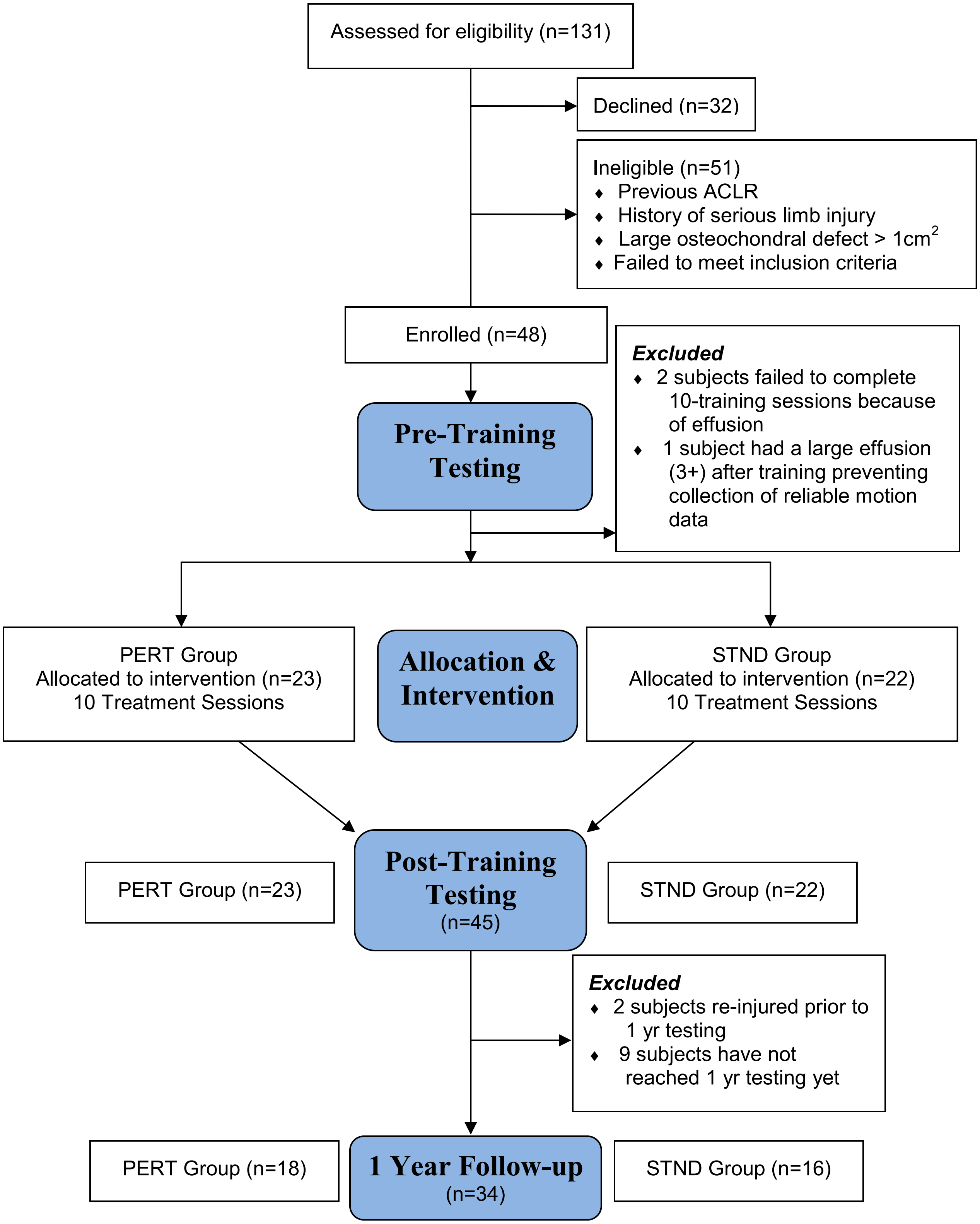

Figure 3.1 Consort diagram for subjects included in Chapter 3.

At the completion of 10-training sessions (n=45) and one year after surgery (n=34), subjects completed patient-reported outcome measures that included the IKDC 2000 subjective knee form, the KOOS-Sport/rec and KOOS-QOL subscales. The IKDC 2000 is used to quantify knee symptoms, knee function and sports activity on a scale from 0-100%. Normal knee function was determined using the top 15th percentile of age- and sex-matched healthy individuals.[3] The KOOS-Sport/rec subscale includes questions regarding the degree of difficulty individuals are having with tasks such as squatting, running, jumping and kneeling. The KOOS-QOL subscale includes questions about awareness of knee problems, any modifications subjects may have made to their lifestyle because of their knee and how much difficulty they are having with their knee. Both subscales are calculated as a percentage on a scale from 0-100%. To determine current activity level, subjects were asked to report their activity level prior to their injury using IKDC level 1-4 classification[17] as well as their current activity level at the time of testing. Individuals were only considered to have returned to their pre-injury activity level if they reported their current activity level was the same as their pre-injury activity level. For example, if a subject reported their pre-injury activity level as Level 1 and they reported their one-year activity level as Level 2, they were identified as having not returned to their pre-injury activity level.

3.4 Statistics

T-tests and chi-square tests were used to determine differences in patient demographics between subjects in the STND group and subjects in the PERT group. Chi-square tests were used to determine differences between subjects who had returned to their pre-injury activity level at one year between treatment groups as well as those who achieved normal knee function between treatment groups.

Independent t-tests were used to determine differences between IKDC 2000, KOOS-Sport/rec and KOOS-QOL scores after training and one year after surgery between treatment groups. A 2 x 2 analysis of variance was used to determine changes in scores between treatment groups, over time for subjects with complete data. Minimal detectable change (MDC) scores have been reported as 11.5 percent for the IKDC 2000[41] and 8 percent for all KOOS subscales,[70] and will be used to identify a true change in the measure that was not the result of measurement error. A significance level of $p \leq 0.05$ was set a priori.

IKDC 2000, KOOS-Sport/rec and KOOS-QOL scores were compared to the Multicenter Orthopaedic Outcome Network (MOON) cohort[80] and the Scandinavian ACL Registry[29,30] to compare mean scores from this ACL-SPORTS Training cohort to currently reported patient-reported outcomes. Available scores from the MOON cohort were reported as median values at two years after surgery and mean values for KOOS scores from the Scandinavian ACL registry were reported at one year.

Sample size was determined using power analysis (G*Power Version 3.1.0),[22] with α=0.05 and 1-β=0.80. Effect size was calculated using the sample mean and standard deviation of IKDC 2000 scores of preliminary data from this study. The addition of 11.5 percent as the MDC[42] was added to determine how many subjects were needed to identify a meaningful change on the IKDC 2000. A minimum of 12 subjects in each group (total of 24 subjects) is needed to identify a meaningful change in IKDC 2000 scores from after training to one year after surgery.

3.5 Results

There was no significant difference between subjects in the STND group and subjects in the PERT group for age at the time of surgery, body mass index (BMI) at post-training testing, sex and graft type (Table 3.1). Subjects were an average of 28.47 ±7.65 weeks after surgery at the time of post-training testing and 53.88 ± 3.67 weeks at one year testing.

Table 3.1 Demographics for subjects in the STND and PERT groups. Values are means (standard deviations).

	STND (n=22)	PERT (n=23)	P-Value
Age at surgery (yrs)	23.91 (7.26)	22.30 (8.34)	0.49
BMI at post-training	26.05 (2.71)	26.94 (2.56)	0.26
Sex*	M 16, F 6	M 17, F 6	0.93
Graft Type*	Allo 9, Auto 13	Allo 6, Auto 17	0.29
Surgery to post-training testing (wks)	29.01 (8.07)	27.96 (7.37)	0.65
Surgery to 1 year testing (wks) ‡	54.18 (2.79)	53.62 (4.38)	0.66

STND= standard treatment group, PERT= perturbation group, yrs= years, BMI= body mass index, M= male, F= female, Allo= allograft, Auto= autograft, *= values are number of subjects (n), wks= weeks, ‡ subjects at one year testing STND n=16, PERT n=18

Eighty-five percent (29 of 34) of subjects returned to their pre-injury activity level one year after surgery (Table 3.2). There was no effect of treatment group on returning to pre-injury activities (p=0.73). Three subjects the PERT group and two subjects in the STND group did not return to pre-injury activities. The reasons for not returning to activities are listed in Table 3.3. Of these five subjects, one subject never passed return-to-activity criteria,[1] which is required prior to receiving clearance to return to activities. Two subjects passed at post-training but reported that they had too little time to return to activities at one year testing. One subject did not have time to return to activities because of ROTC time commitments; however this subject only passed return to activity criteria five weeks prior to one year testing, leaving little time to reintegrate into pre-injury activities. One subject passed at one year follow-up testing and would not be expected to have returned to activities.

Table 3.2 The number of subjects who have returned and not returned to pre-injury activities one year after surgery. Values are number of subjects.

	STND	PERT	Total
Returned to Activities	14	15	29
Not Returned to Activities	2	3	5
	16	18	34

STND= standard treatment group, PERT= perturbation group

Table 3.3 Individual subjects and reasons for not returning to pre-injury activities one year after surgery.

	Reason reported	Passed RTAC (wks after sx)
Subject 1	Too little time to participate or had a change in lifestyle	25.57
Subject 2	Too little time to participate or had a change in lifestyle	19.43
Subject 3	Other: ROTC	46.86
Subject 4	Fear of re-injury or lack of confidence	Never passed
Subject 5	Not yet cleared from doctor to return to sports	51.29

RTAC= return to activity criteria, wks= weeks, sx=surgery, ROTC= reserve officer training corps

There was no difference between the groups for subjects who achieved normal knee function on IKDC 2000 measures after training (p=0.64) and one year after surgery (p=0.90) (Tables 3.4 and 3.5). Twenty subjects (44%) did not achieve normal knee function after training and four subjects at one year after surgery (14.7%).

There was no significant difference between the groups for IKDC 2000, KOOS-Sport/rec and KOOS-QOL scores after training and one year after surgery (Tables 3.4 and 3.5). The PERT group had larger standard deviations with all knee function measures after training compared to the STND group however at one year subjects in the STND group had larger standard deviations with all measures compared to the PERT group.

Table 3.4 Patient-reported outcome measures after training between treatment groups. Values are means (standard deviations).

Post-Training	STND (n=22)	PERT (n=23)	P-Value
IKDC 2000	85.86 (8.20)	86.78(10.91)	0.99
Knee Function*	Normal=13, Below=9	Normal=12, Below=11	0.64
KOOS-Sport/Rec	88.18 (11.19)	87.83 (14.68)	0.93
KOOS-QOL	68.47 (14.37)	72.55 (20.19)	0.44

STND= standard treatment group, PERT= perturbation group, IKDC 2000= International Documentation Committee 2000 subjective knee form, *=values are number of subjects (n), KOOS- Sport/Rec= Knee Injury and Osteoarthritis Outcome Score- Function, Sports and Recreational Activities, KOOS-QOL= Knee Injury and Osteoarthritis Outcome Score- Quality of Life

Table 3.5 Patient-reported outcome measures one year after surgery, between treatment groups. Values are means (standard deviations).

One Year	STND (n=16)	PERT (n=18)	P-Value
IKDC 2000	93.39 (9.14)	95.21 (8.18)	0.54
Knee Function*	Normal=14, Below=2	Normal=16, Below=2	0.90
KOOS-Sport/Rec	92.19 (11.10)	96.67 (4.85)	0.15
KOOS-QOL	86.72 (14.05)	84.72 (13.60)	0.67

STND= standard treatment group, PERT= perturbation group, IKDC 2000= International Documentation Committee 2000 subjective knee form, *= values are number of subjects (n), KOOS- Sport/Rec= Knee Injury and Osteoarthritis Outcome Score- Function, Sports and Recreational Activities, KOOS-QOL= Knee Injury and Osteoarthritis Outcome Score- Quality of Life

Evaluating change over time, there was no significant time x group interaction for all measures (IKDC p=0.96, KOOS-Sport/rec p=0.55, KOOS-QOL p=0.08), however there was a main effect of time for all measures (IKDC p<0.001, KOOS-Sport/rec p=0.004, KOOS-QOL p<0.001). Subjects in the STND group had a larger change in scores from after training to one year after surgery for IKDC 2000 scores and KOOS-QOL, though not significantly different from subjects in the STND group (Table 3.6). Subjects in the PERT group had larger changes on the KOOS-Sports/rec. The MDC was not exceeded by either group for IKDC 2000 scores. Mean scores for the KOOS-Sport/rec scores for subjects in the PERT group and KOOS-QOL scores for all subjects exceeded the MDC (Table 3.6).

Table 3.6 Patient-reported outcome change scores from post-training to one year follow-up testing. Values are means (standard deviations).

	STND (n=16)	PERT (n=18)	P-Value	MDC
IKDC 2000	8.55(7.93)	8.37 (11.49)	0.96	11.5
KOOS-Sport/rec	5.63 (10.78)	8.33(15.05)	0.56	8
KOOS-QOL	19.92 (13.54)	11.11(14.63)	0.08	8

STND= standard treatment group, PERT= perturbation group, MDC= minimal detectable change, IKDC 2000= International Documentation Committee 2000 subjective knee form, KOOS- Sport/Rec= Knee Injury and Osteoarthritis Outcome Score- Function, Sports and Recreational Activities, KOOS-QOL= Knee Injury and Osteoarthritis Outcome Score- Quality of Life

Mean scores for all subjects in this study at one year after surgery, regardless of treatment group, were significantly higher than currently published reports of IKDC 2000, KOOS-Sports/rec and KOOS-QOL scores by the MOON cohort and the Scandinavian ACL ligament registry (Table 3.7).

Table 3.7 ACL-SPORTS scores (all subjects) compared to current literature.

	ACL-SPORTS Subjects (Mean, 1 year)	MOON[1] (Median, 2 yrs)	Scandinavian ACL Registry[2] (Denmark, Sweden) (mean, 1 year)	P-Value
IKDC 2000	94.35	75	--	<0.001
KOOS-Sport/rec	94.56	85	-- 63, 64	<0.001 <0.001
KOOS-QOL	85.66	75	-- 60,60	<0.001 <0.001

1-Spindler et al. The prognosis and predictors of sports function and activity at minimum 6 years after anterior cruciate ligament reconstruction; a population cohort study. Am J Sports Med. 39(2), 348-59, 2011.
2-Granan et al. The Scandinavian ACL Registries 2004-2007: baseline epidemiology. Acta Orthopa 80(5): 563-7, 2009.
IKDC 2000= International Documentation Committee 2000 subjective knee form, KOOS- Sport/Rec= Knee Injury and Osteoarthritis Outcome Score- Function, Sports and Recreational Activities, KOOS-QOL= Knee Injury and Osteoarthritis Outcome Score- Quality of Life

3.6 Discussion

Knee function scores after completing the ACL-SPORTS Training protocol and one year after surgery were not significantly different between the two treatment groups. One-year measures within this cohort were significantly higher compared to national and international scores.[30,80] Consistent with the literature,[54] mean scores of all subjects in the current study improved over time, suggesting that improvements in knee function continue to occur up to one year after surgery. Increased variability within these data, seen with large standard deviations, may suggest that additional factors (age, sex and graft type), besides treatment group, may be influencing knee function scores.

Eighty-five percent of subjects returned to their pre-injury activity level one year after surgery. Only five subjects within this cohort did not return to their pre-injury activity level one year after surgery and this was not significantly different between the two treatment groups. Within our research group at the University of Delaware, subjects are not cleared to return to activities until they have passed our return-to-activity criteria, which evaluates clinical and functional measures.[1,33] These criteria require ≤ 10% deficit in quadriceps femoris muscle strength compared to the uninjured limb,[79] ≤ 10% deficit in dynamic limb symmetry measured by four single-legged hop tests[62] and ≥90% on patient-reported outcome measures (Knee Outcome Survey-Activity of Daily Living Scale and the Global Rating Score of perceived knee function). Once subjects meet these criteria they are cleared to begin slow reintegration into their pre-injury activities and given guidelines on how to monitor and manage effusion and soreness during this process. Of the five subjects who did not return to their pre-injury activity level at one year, subjects 1 and 2 (Table 3.3) passed at post-training testing, however they reported "too little time to participate or had a change in lifestyle" as the primary reason for not returning to activities at one year, rather than fear of re-injury or limitations with their knees. Subject 3 passed return-to-activity criteria five weeks prior to one year testing, suggesting that this limited time frame did not allow this individual to fully reintegrate to pre-injury activities. Subject 4 did not meet these return-to-activity criteria after training or at one year testing and would not be expected to report that they were participating at their pre-injury activity level at one year testing. Finally, subject 5 passed return-to-activity criteria at one year testing and was not cleared to return to activities prior to this follow-up. With only 14.7% of subjects in this cohort not returning to pre-injury activities at one year after surgery, this training protocol may be beneficial at improving knee function after ACLR. There may be additional factors, within these five subjects, that may be contributing to their inability to return to their pre-injury activity level, however further evaluation is needed.

IKDC 2000 scores were not significantly different between the treatment groups after training and one year after surgery, however both groups demonstrated a significant improvement over time. This improvement in scores is consistent with published findings.[54] Mean change scores however, did not exceed the MDC of 11.5 percent[41] suggesting that a meaningful change did not occur in this cohort from post-training to one year after surgery. Fourteen individual subjects (41%, STND=8, PERT=6) within this study had an improvements in scores that exceeded the MDC, while no subject had a decrease in scores that exceeded the MDC, supporting the benefit of this training protocol. These findings suggest that 1 in 3 subjects continues to make improvements up to one year after surgery and may not be adequately prepared to return to activities prior to one year.

KOOS-Sports/rec and KOOS-QOL scores were not significantly different between treatment groups after training and one year after surgery. Both groups improved from after training to one year testing; however there was no difference between the groups. KOOS-Sport/rec and KOOS-QOL mean change scores for the PERT group and KOOS-QOL mean change scores for the STND group exceeded the MDC of 8 percent[70] suggesting that meaningful change does occur up to one year after surgery. Eleven individual subjects (32%, STND=6, PERT=5) and 21 individual subjects (62%, STND= 13, PERT=8) had meaningful improvements in their KOOS-Sport/rec and KOOS-QOL scores respectively, from after training to one year testing. One subject in the STND group had a decrease in KOOS-Sport/rec score that exceeded the MDC, while two subjects (STND=1, PERT=1) had a decrease in KOOS-QOL scores that exceeded the MDC. Variability within these measures, seen with large standard deviations in both treatment groups, over time, may account for the absence of statistically significant differences between the treatment groups in this cohort.

Compared to the current literature, ACL-SPORTS subjects in this study reported almost 20% higher IKDC 2000 scores at one year after surgery, compared to subjects in the MOON cohort at two years after surgery. This suggests that this ACL-SPORTS Training intervention, regardless of treatment group, may be beneficial at improving knee function compared to traditional physical therapy treatment. The MOON cohort does not collect measures at one year after surgery; therefore comparison to two year data was most appropriate. Additional investigation of changes from one year to two years after surgery within this cohort may provide additional insight into possible differences between ACL-SPORTS scores and MOON scores. IKDC 2000 scores of the MOON cohort were reported as median values, and were the only available data to compare to the mean values of our data set. Additionally, the level of activity of subjects in the MOON cohort was not specified. Subjects in this current study were classified as level 1 or 2 athletes prior to their injury and desired to return to their pre-injury activities after surgery. If subjects participating in lower activity levels were included in the MOON cohort this may account for the lower IKDC 2000 scores at two years after surgery compared to the current study.

KOOS-Sports/rec and KOOS-QOL scores after ACL-SPORTS Training at one year were compared to both the MOON cohort at two years after surgery and the Scandinavian ACL registry at one year after surgery. KOOS-Sport/rec scores in the ACL-SPORTS subjects were almost 10% higher compared to the MOON cohort and 30% higher compared to the Scandinavian ACL registry scores. KOOS-QOL scores in ACL-SPORTS subjects were 10% higher compared to the MOON cohort and 25% higher compared to the Scandinavian ACL registry. Regardless of treatment group, ACL-SPORTS subjects reported significantly higher scores compared to both the MOON cohort and Scandinavian ACL registry. Similar to IKDC 2000 scores, the MOON cohort reported their data as median scores at two years after surgery and was the only available data to compare to our current findings. The Scandinavian ACL registry reported data at one year after surgery and reported mean values, allowing a direct comparison to the current study. The Scandinavian ACL registry did not report standard deviations within their data set, therefore variability of this data could not be assessed. The activity level of patients included in the Scandinavian ACL Registry was also not reported and all individuals who undergo ACL reconstruction and/or posterior cruciate ligament reconstruction at a Scandinavian (Denmark, Norway, Sweden) hospital are included in the Scandinavian ACL registry.[29] Although activity level was not reported, surgical reconstruction is typically only performed in high-level individuals (level 1 or 2), suggesting that subjects within the Scandinavian registry are likely to be high-level individuals. The patient-reported measures from this current study, regardless of treatment group, are significantly higher compared to current published research. This suggests that while there may be no difference between the treatment groups, the addition of this post-operative intervention to prepare patients to return to pre-injury activities may be beneficial.

Several limitations of the current study should be mentioned. Small sample size may account for the large standard deviations within the dataset as well as the non-significant findings between treatment groups. Although a power analysis was completed to determine the number of subjects needed to identify meaningful change with IKDC 2000 scores, this was not measured for each of the KOOS subscales. Additional subjects may be needed to identify differences between groups for KOOS measures. A sampling bias towards male subjects was present in this study (33 males, 12 females). Females are at higher risk for initial ACL injury and further re-injury;[63] therefore, differences in sexes may play an important role in describing knee function after surgery. Further examination of these measures between sexes is needed.

3.7 Conclusion

Patient-reported outcome measures used after training and one year after surgery to identify knee function were not significantly different between the two treatment groups of this ACL-SPORTS Training study. The unique finding of this study was that all subjects reported higher knee function scores at one year after surgery compared to national and international registries, which may suggest an overall benefit of this treatment protocol. Eighty-five percent of subjects returned to pre-injury activities at one year, suggesting that additional training after surgery to improve abnormal movement patterns may better prepare patients to restore knee function and allow successful return to their pre-injury level of activity. Continued analysis of these subjects is needed to determine if differences exist between sexes and if individuals are able to maintain normal knee function long-term.

Chapter 4

ACL-SPORTS TRAINING IMPROVES PATIENT-REPORTED OUTCOMES

4.1 Abstract

Background: Return to pre-injury activity rates after anterior cruciate ligament reconstruction (ACLR) are lower than previously reported. Using strict return-to-activity criteria to determine readiness to return to activities after surgery may better predict successful outcomes. Achieving ≥ 90% on quadriceps femoris muscle strength symmetry, four single-legged hop tests limb symmetry index, the Knee Outcome Survey-Activities of Daily Living Scale and the Global Rating Score of perceived knee function are recommended to determine readiness to return to activities. The purpose of this study was to determine differences in patient-reported outcomes after our specialized post-operative return-to-sports (ACL-SPORTS) training program and one year after surgery between subjects who pass return-to-activity criteria and those who fail.

Methods: After completing ACL-SPORTS Training, subjects complete return-to-activity criteria as well as self-reported measures of knee function and fear of movement/re-injury. T-tests were used to determine differences in scores between subjects who passed and subjects who failed after training and one year after surgery. Significant differences were used in logistic regression models to determine the ability to predict passing or failing these criteria.

Results: Quadriceps femoris muscle strength measures were significantly different after training between subjects who passed and those who failed. No

differences were seen one year after surgery. Subjects who failed after training had the largest change in scores and the TSK-11 was significantly different between those who passed and those who failed.

Discussion: Individuals who fail return-to-activity criteria after ACL-SPORTS Training demonstrate decreased quadriceps femoris muscle strength compared to those who pass, however no differences were seen at one year after surgery. Subjects who failed after surgery had the largest decrease in fear of movement/re-injury suggesting fear may be an important component of function after ACLR.

4.2 Introduction

Limited objective criteria are used to determine athlete clearance to return to activities after anterior cruciate ligament reconstruction (ACLR).[8] In a systematic review, only 13% of clinicians used objective clinical criteria to approve an athlete's participation in activities after surgery, while most clinicians use time-based criteria.[8] Despite clearing individuals to return to activities, these athletes continue to demonstrate decreased quadriceps femoris muscle strength of the involved limb compared to the uninvolved limb, decreased functional performance and report low knee function.[33,53,77] It is suspected that these deficits are contributing factors to the high rates of re-injury and low rates of return to pre-injury activities.[6,37]

To determine readiness to return to activities after ACLR, the University of Delaware has established a battery of objective tests to clear athletes to begin slow reintegration into athletic activities.[1,33] These tests require a score of greater than or equal to 90% on measures of quadriceps femoris muscle strength symmetry, four single-legged hop tests, the Knee Outcome Survey- Activities of Daily Living Scale and the Global Rating Score of perceived knee function.[24,62,79] Using these objective measures to determine readiness to return to activity by passing or failing these return-to-activity criteria may better predict successful outcomes after surgery.

Hartigan and colleagues,[33] in a randomized control trial, implemented a pre-operative neuromuscular training protocol, compared to a strengthening protocol. Using these return-to-activity criteria, neither treatment group was more likely to pass these criteria at six months and one year after surgery, suggesting that neither pre-operative treatment was superior to the other; although this may have been impacted by the trauma of surgical reconstruction. The number of subjects who passed these criteria at one year increased compared to the number of subjects who passed at six months, suggesting improvements continue to occur up to one year after surgery. Using these same return-to-activity criteria, subjects who passed these criteria six months after surgery demonstrated improved limb symmetry during gait compared to their counterparts who failed these criteria,[20] suggesting the ability to identify aberrant movement patterns with functional measures.

Schmitt and colleagues evaluated functional measures and patient report at the time of clearance to return to activities; however they did not utilize a battery of tests to determine clearance.[77] Despite receiving clearance to return to activities by their health care provider, subjects demonstrated quadriceps femoris muscle strength deficits of the involved limb, poor functional performance on single-legged hop tests and low knee function scores were reported. Subjects in both of these research studies received post-operative rehabilitation, yet impairments remained months after surgery suggesting traditional rehabilitation strategies may not be adequate for high-level athletes.

Successful knee function after ACLR has been defined by self-reported measures of normal knee function[44] using the International Knee Documentation Committee (IKDC) 2000 subjective knee form.[42] In the ACL-reconstructed population, IKDC 2000 scores have been reported to continue to improve up to one year after surgery, suggesting that normal knee function has not been achieved when patients are often given clearance to return to activities.[53,54] Improving knee function measures sooner after surgery may improve return to pre-injury activity rates and performance.

Fear of re-injury after ACLR is a large contributing factor to an athlete's decision to return to activities or not.[4,6,51] ACL-Return to Sport after Injury (ACL-RSI) scores, measuring fear of re-injury after ACLR,[86] have been reported to be significantly greater in individuals that have returned to activities compared to those that have not returned.[50] Similarly, lower Tampa Scale of Kinesiophobia (TSK-11) scores, indicating less fear of movement/re-injury, have been reported in individuals that have returned to activities.[51] These measures both evaluate fear; however the relationship between these two measures has not been evaluated.

Our research group has developed a post-operative neuromuscular training protocol, ACL-Specialized Post-Operative Return-to-Sports (ACL-SPORTS) Training,[89] with the goal of improving joint loading, gait biomechanics, and clinical and functional measures after ACLR. Subjects in this study are randomized to either a standard treatment group (STND) or a perturbation group (PERT), which includes an additional neuromuscular training component (Figure 2.1, Appendix B). After completion of this training protocol, subjects will be evaluated on their readiness to return to activities based on these established return-to-activity criteria.

The purpose of this study was to characterize patients' readiness to return to activities based on passing or failing strict return-to-activity criteria after ACL-SPORTS Training and one year after surgery. We hypothesized that (1) subjects in the neuromuscular training group (perturbation group) would be more likely to pass strict return-to-activity criteria, and (2) subjects that passed strict return-to-activity criteria would have greater quadriceps femoris muscle strength symmetry, report normal knee function and have less fear of re-injury and fear of movement/re-injury compared to subjects who failed these criteria.

4.3 Methods

Forty-five subjects (mean age at surgery 23.29 ±7.79yrs; 33 males, 12 females) were included in this study that underwent an isolated, unilateral ACLR within the last 10 months. All subjects were part of a larger randomized clinical trial.[89] Subjects were eligible for this study if they were regular participants (≥ 50 hrs/yr) in level 1 or 2 activities[17] prior to their injury, between the ages of 13 and 55 and desired to return to their pre-injury activity level. Subjects were excluded if they had a previous ACLR, history of serious lower extremity injury in either leg, large osteochondral defect

(>1cm^2), were >10 months after surgery and were not regular participants in level 1 or 2 activities prior to their injury. If subjects met these eligibility criteria, they were required to be at least 12 weeks after surgery, demonstrate ≥ 80% quadriceps femoris muscle strength symmetry and have minimal knee joint effusion prior to enrollment[83] (Figure 4.1). All subjects provided written informed consent prior to enrollment and the Institutional Review Board approved all research testing procedures (Appendix A, C).

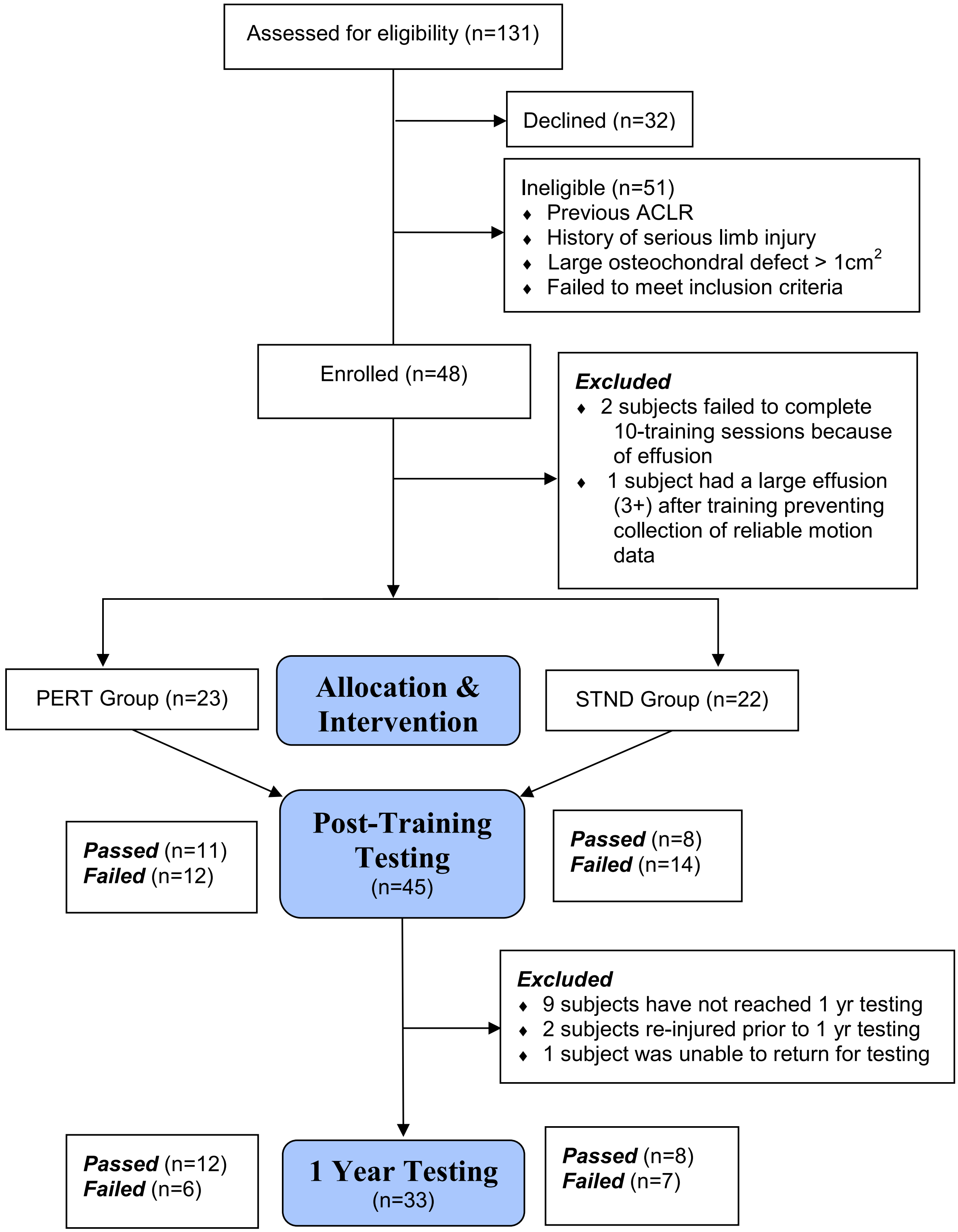

Figure 4.1 Consort diagram for subjects included in Chapter 4.

ACL-SPORTS Training consisted of quadriceps femoris muscle strengthening exercises, agility drills and ACL injury prevention exercises[89] for subjects in the STND group. Subjects in the PERT group completed all exercises listed, augmented with perturbation training as previously reported by Fitzgerald and colleagues[24] (Figure 2.1, Appendix B). Perturbation training is a neuromuscular training that provides progressive destabilization of patients while in unilateral and bilateral stance. This training has been shown to improve limb symmetry and decrease muscle co-contraction when implemented prior to surgery.[13,21,32,39] All subjects completed 10-training sessions by a licensed physical therapist.

Once the training sessions were completed, data were collected after training and one year after surgery. Measures included return-to-activity criteria: quadriceps femoris muscle strength, four single-legged hop tests and patient reported outcome measures of knee function (KOS-ADLs, GRS).[1,33,54,62,79] All clinical and functional testing was completed prior to patient-reported outcome measures. This battery of tests was used to determine readiness to return to activity after ACLR in which patients were classified as having passed or failed these return-to-activity criteria.

Quadriceps femoris muscle strength measures were obtained during a maximal voluntary isometric contraction (MVIC)[79] using an electromechanical dynamometer (KIN-COM; Chattanooga Corp, Chattanooga, Tennessee, USA) (Figure 4.2). Subjects were seated in an upright position with their hip and knee at 90 degrees of flexion. The uninvolved limb was tested first, followed by the involved limb. A quadriceps index

(QI) was calculated as a percentage of the involved limb divided by the uninvolved limb, multiplied by 100.

Figure 4.2 Set-up for bust superimposition testing[79].

Four single-legged hop tests, as previously described,[62] were completed on the uninvolved limb followed by the involved limb (Figure 4.3). Two practice hops were initially completed followed by two recorded values for the single hop for distance, cross-over hop for distance, triple hop for distance and 6-meter timed hop. A mean hop score was calculated for each leg and then a limb symmetry index (LSI) was calculated for distance hops as the involved limb divided by the uninvolved limb, multiplied by 100. The timed hop LSI was calculated as the uninvolved limb divided by the involved limb, multiplied by 100.[33]

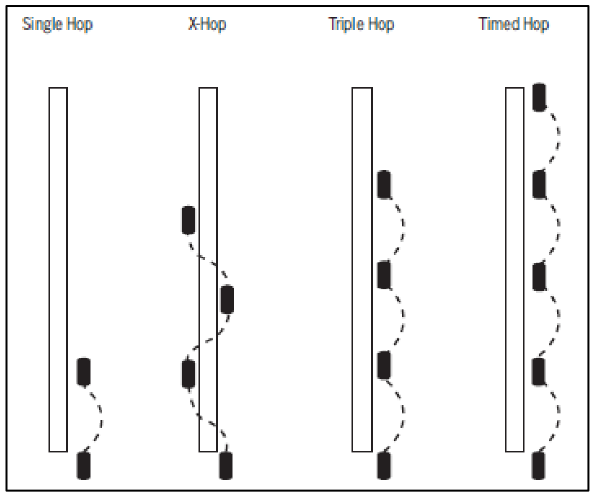

Figure 4.3 Four single-legged hop tests[62] Image. Adams D, Logerstedt D, Hunter-Giordano A, et al. Current concepts for anterior cruciate ligament reconstruction: a criterion-based rehabilitation progression. J Orthop Sports Phys Ther. 2012;42(7)601-14.

After all clinical and functional testing was completed, patients completed outcome measures including the KOS-ADLs, the GRS, the IKDC 2000, the ACL-RSI and the TSK-11. The KOS-ADLs is a 14-item questionnaire that asks patients about current knee symptoms and how those symptoms affect their knee function.[43] The GRS is one question that asks patients to rate their current knee function on a scale from 0 to 100%, where 0 represents the inability to perform any activity and 100 is their level of knee function prior to their injury, including sports.[23]

The IKDC 2000, ACL-RSI and TSK-11 are not included in the return-to-activity criteria; however they were used to evaluate knee function, fear of re-injury and fear of movement/re-injury. The IKDC 2000 is a measure of knee function used for a variety of knee injuries.[41] Normative IKDC 2000 scores have been used to better evaluate knee function by comparing subjects after ACLR to healthy individuals.[53] The top 15th percentile of subject-specific age- and sex-matched uninjured individuals was used to compare to ACL-reconstructed patients.[3] A minimal detectable change (MDC) score of 11.5 percent has been reported for this measure.[42] The ACL-RSI measures three psychometric responses related to returning to sports after ACLR: emotions, confidence in performance and risk appraisal.[86] Higher scores represent less fear of re-injury after ACLR.[50] Kvist and colleagues[47] recommended a change score of 0.3 points on the 10-point scale when comparing two treatment groups, as this exceeds the measurement error. The TSK-11 measures fear of movement/re-injury with lower scores indicating less fear of movement/re-injury.[14] A MDC of 4.8 points has been reported[27] (Table 4.1).

Passing return-to-activity criteria occurs when a subject achieves ≥ 90% on all seven return-to-activity criteria (QI, four single-legged hop tests, KOS-ADLs and GRS). When these criteria are met, subjects are cleared to return to activities and instructed in slow, progressive return to their specific sport. The inability to achieve 90% or higher on all measures resulted in failure of these return-to-activity criteria. Subjects were then re-tested every 2-4 weeks, depending on impairments, until they passed these criteria.

4.4 Statistics

Independent t-tests and chi-square tests were used to determine demographic differences between subjects in the STND treatment group and subjects in the PERT group as well as between subjects who passed and subjects who failed after training and one year after surgery.

T-tests were also used to determine differences in measures of QI, IKDC 2000, ACL-RSI and TSK-11 between those who passed and those who failed at both time points. Change scores were calculated for subjects who had complete data at both time points to identify a true change in the measure that was not the result of measurement error. Change scores were evaluated based on post-training pass or fail status and were compared to establish MDC scores (Table 4.1). Measures that were significantly different at each time point were included as independent variables in a logistic regression model to determine the ability to predict passing or failing at that time point. Significance level of $p \leq 0.05$ was determined a priori.

4.5 Results

Forty-five subjects completed the training as well as post-training testing. Thirty-three subjects returned for follow-up testing at one year and had complete post-training and one year data (Figure 4.2). There were no demographic differences between treatment groups at baseline (Table 4.2), between subjects who passed and subjects who failed at post-training testing (Table 4.3) and subjects who passed and subjects who failed at one year after surgery (Table 4.4). Treatment group did not significantly affect the ability to pass these criteria after training (p=0.44) or one year after surgery (p=0.44). Time from surgery to passing these criteria at one year was not different between the treatment groups (p=0.71), and failing after training was not indicative of failing at one year (p=0.73, Positive likelihood ratio: 0.87, sensitivity: 0.4, specificity: 0.54) (Tables 4.2 and 4.5). Three subjects in the STND treatment group have completed training and post-training testing, but have not passed return-to-activity criteria, therefore weeks after surgery to pass return-to-activity criteria in Tables 4.2, 4.3 and 4.4 are median values (post-training: STND n=19, PERT n=23, 1 year: STND n=13, PERT n=18).

Table 4.1 Minimal detectable change scores reported in the literature.

	MDC	Scale	Highest/Best score
IKDC 2000[42]	11.5%	0-100%	100%
ACL-RSI[47]	0.3 points	0-10 points	10 points
TSK-11[27]	4.8 points	11-44 points	11 points

MDC= minimal detectable change, IKDC 2000= international knee documentation committee 2000 subjective knee form, ACL-RSI= anterior cruciate ligament-return to sport after injury scale, TSK-11= tampa scale of kinesiophobia

Table 4.2 Demographic differences at baseline between treatment groups. Values are means (standard deviations).

	STND (n=22)	PERT (n=23)	P-value
Age at surgery (yrs)	23.91 (7.26)	22.30 (8.35)	0.49
BMI at enrollment	26.18 (3.35)	27.04 (2.69)	0.35
Weeks from surgery to enrollment	22.39 (8.06)	21.71 (6.77)	0.76
Post-training weeks from surgery	28.97 (8.17)	28.07 (7.41)	0.70
Weeks from surgery to pass RTAC‡	28.43 (7.55)	29.43 (8.64)	0.30
Pass or Fail Post-training*	Pass 8, Fail 14	Pass 11, Fail 12	0.44
Pass or Fail 1 year*†	Pass 8, Fail 7	Pass 12, Fail 6	0.44
Sex*	M 16, F 6	M 17 , F 6	0.93

STND= standard treatment group, PERT= perturbation group, yrs= years, BMI= body mass index, RTAC= return-to-activity criteria, ‡= three subjects have not passed RTAC therefore values are median (standard deviation) STND n=19, PERT n=23, *= values are number of subjects (n), † subjects at one year are STND n=15, PERT n=18

Table 4.3 Demographic differences between subjects who passed and subjects who failed after training. Values are means (standard deviations).

	PASS (n=19)	FAIL (n=26)	P-value
Age at surgery (yrs)	23.87 (7.52)	22.51 (8.08)	0.57
BMI at enrollment	25.93(2.41)	27.13 (3.36)	0.19
Weeks from surgery to enrollment	22.20 (6.85)	21.93 (7.82)	0.90
Post-training weeks from surgery	28.87 (7.29)	28.25 (8.14)	0.80
Weeks from surgery to pass RTAC‡	29.00 (7.08)	29.00 (9.06)	0.71
Sex*	M 15, F 4	M 18, F 8	0.47

PASS= passing return-to-activity criteria, FAIL= failing return-to-activity criteria, yrs= years, BMI= body mass index, RTAC= return-to-activity criteria, ‡= three subjects have not passed RTAC so values are median (standard deviation) STND n=19, PERT n=23,*= values are number of subjects (n)

Table 4.4 Demographic differences between subjects who passed and subjects who failed at one year after surgery. Values are means (standard deviations).

	PASS (n=20)	FAIL (n=13)	P-value
Age at surgery (yrs)	21.98 (5.51)	26.57 (11.57)	0.20
BMI at enrollment	26.36 (3.23)	27.54 (2.87)	0.30
Weeks from surgery to enrollment	22.31 (8.00)	21.41 (8.24)	0.76
Weeks from surgery to one year testing	52.94 (2.47)	54.63 (4.35)	0.17
Weeks from surgery to pass RTAC‡	21.94 (9.78)	28.18 (6.18)	0.32
Sex*	M 14, F 6	M 11, F 2	0.34

PASS= passing return-to-activity criteria, FAIL= failing return-to-activity criteria, yrs= years, BMI= body mass index, RTAC= return-to-activity criteria, ‡= two subjects have not passed RTAC so values are median STND n=13, PERT n=18,*= values are number of subjects (n)

Table 4.5 Frequency count of those who passed and failed return-to-activity criteria post-training and one year after surgery. Values are number of subjects.

Return-to-Activity Criteria	One Year		
Post-Training	PASS	FAIL	Total
PASS	8	6	14
FAIL	12	7	19
Total	20	13	33

PASS= passing return-to-activity criteria, FAIL= failing return-to-activity criteria

After training, 58% (26 of 45) of subjects failed return-to-activity criteria. The most frequently failed measure was the GRS (65%). Twenty-three percent (6 of 26 subjects; 2 Males, 4 Females) of those who failed return-to-activity criteria after training failed because of GRS scores alone. Since these subjects demonstrate adequate limb symmetry with clinical and function measures, these subjects are instructed to begin slow, progressive return to activity despite failing to achieve ≥ 90% on the GRS. Hop tests were the second most frequently failed test (62.5%), but there was no difference between the treatment groups (Table 4.6). The most frequently failed hop test was the single hop, followed by the crossover and triple hop.

Table 4.6 Frequency count of reasons for failing post-training between the treatment groups. Values are number of subjects.

Post-Training	All (n=45)	STND(n=22)	PERT (n=23)	P-value
Total Failed criteria	26	14	12	0.44
Total Failed criteria excluding GRS	21	3	2	0.66
Quadriceps Strength	11	7	4	0.26
All Hops	15	7	8	0.83
Single	8	4	4	0.95
Crossover	7	4	3	0.63
Triple	5	3	2	0.60
Timed	2	1	1	0.97
KOS-ADLS	3	3	0	0.07
GRS	17	10	7	0.30

All= all subjects, STND= standard treatment group, PERT= perturbation group, GRS= global rating score of perceived knee function, KOS-ADLS= knee outcome survey-activities of daily living scale

One year after surgery, 39% (13 of 33) of subjects failed return-to-activity criteria. Hop tests were the most frequently failed measure, followed by quadriceps femoris muscle strength, with no difference between treatment groups (Table 4.7). A small number of subjects failed each hop test, therefore statistics were not computed. Subjects in the STND group were the only subjects to fail the KOS-ADLS and GRS at one year, though only a small number of subjects failed these measures. One year after surgery, there were no patients that failed because of GRS scores alone.

Table 4.7 Frequency count of reasons for failing one year after surgery between the treatment groups. Values are number of subjects.

1 Year	All (n=33)	STND (n=15)	PERT (n=18)	P-value
Total Failed criteria	13	7	6	0.44
Quadriceps Strength	6	3	3	0.81
All Hops	8	4	4	0.77
Single	3	1	2	
Crossover	3	0	3	
Triple	2	1	1	
Timed	1	1	0	
KOS-ADLS	3	3	0	
GRS	2	2	0	

All= all subjects, STND= standard treatment group, PERT= perturbation group, KOS-ADLS= knee outcome survey-activities of daily living scale, GRS= global rating score of perceived knee function

Quadriceps femoris muscle strength was significantly different between subjects who passed and those who failed after training (p=0.005), although mean measures were greater than 90% for both groups. There was no difference between the groups one year after surgery (p=0.19) (Tables 4.8 and 4.9).

Table 4.8 Post-Training measures between subjects who passed and subjects who failed. Values are means (standard deviations).

Post-Training	PASS (n=19)	FAIL (n=26)	P-value
Quadriceps Strength	99.06 (5.51)	92.17 (9.82)	***0.005***
IKDC 2000	88.81 (8.25)	84.70 (9.48)	0.14
Knee function*	Normal=12, Below=7	Normal= 13, Below=13	0.28
ACL-RSI	7.71 (2.06)	6.87 (2.31)	0.22
TSK-11	16.21 (5.06)	18.23 (3.95)	0.14

PASS= passing return-to-activity criteria, FAIL= failing return-to-activity criteria, IKDC 2000= international knee documentation committee 2000 subjective knee form, *= values are number of subjects (n), ACL-RSI= anterior cruciate ligament-return to sport after injury scale, TSK-11= tampa scale of kinesiophobia

Table 4.9 Measures at one year between subjects who passed and subjects who failed. Values are means (standard deviations).

1 year	PASS (n=20)	FAIL (n=13)	P-value
Quadriceps Strength	102.60 (10.04)	96.19 (17.59)	0.19
IKDC 2000	96.49 (6.01)	90.72 (10.99)	0.10
Knee function*	Normal=18, Below=2	Normal=11 , Below=2	0.64
ACL-RSI	9.27 (0.90)	8.61 (1.85)	0.25
TSK-11	15.15 (4.02)	14.92 (3.62)	0.87

PASS= passing return-to-activity criteria, FAIL= failing return-to-activity criteria, IKDC 2000= international knee documentation committee 2000 subjective knee form, *= values are number of subjects (n), ACL-RSI= anterior cruciate ligament-return to sport after injury scale, TSK-11= tampa scale of kinesiophobia

IKDC 2000 scores were not significantly different between subjects who passed and those who failed after training (p=0.14) and one year after surgery (p=0.10) (Tables 4.8 and 4.9). Using the top 15^{th} percentile of healthy age- and sex-matched IKDC 2000 scores, there was no difference post-training (p=0.28) and one year after surgery (p=0.64) between subjects who passed and subjects who failed for achieving normal knee function. ACL-RSI scores were not significantly different between subjects who passed and subjects who failed post-training (p=0.22) and one year after surgery (p=0.25) (Tables 4.8 and 4.9). TSK-11 measures were not significantly different between subjects who passed and those who failed after training (p=0.14) and one year after surgery (p=0.87) (Tables 4.8 and 4.9). A logistic regression model demonstrated that quadriceps strength measures explained 20.8% of the variance of passing return-to-activity criteria after training (Nagelkerke R Squared 0.208, p=0.019). Regression analysis was not completed for one year measures since no significant differences existed between subjects who passed and subjects who failed.

Scores at one year were further examined based on post-training pass or fail status to determine how subjects performed over time. Subjects who failed after training had higher quadriceps femoris muscle strength, higher ACL-RSI scores and lower TSK-11 scores at one year after surgery; however, differences were not statistically significant (Table 4.10).

Table 4.10 Measures at one year, based on passing or failing after training. Values are means (standard deviations).

1 year measures (based on POST pass/fail)	PASS (n=14)	FAIL (n=19)	P-value
Quadriceps Strength	97.56 (12.59)	101.93 (14.41)	0.37
IKDC 2000	94.25 (8.80)	94.19 (8.79)	0.99
ACL-RSI	8.93 (1.02)	9.06 (1.60)	0.80
TSK-11	15.57 (4.43)	14.68 (3.35)	0.52

POST= post-training, PASS= passing return-to-activity criteria, FAIL= failing return-to-activity criteria, IKDC 2000= international knee documentation committee 2000 subjective knee form, ACL-RSI= anterior cruciate ligament-return to sport after injury scale, TSK-11= tampa scale of kinesiophobia

Change scores of 33 subjects with complete data were calculated based on post-training pass or fail status (Table 4.11). TSK-11 change scores were significantly greater for subjects who failed after training (p=0.001), although the MDC was not exceeded. There were no significant differences in change scores between those who passed and those who failed after training for quadriceps femoris muscle strength, IKDC 2000 scores and ACL-RSI scores. Subjects who failed after training had larger changes on all measures compared to subjects who passed after training, though differences were not statistically significant. ACL-RSI scores in both groups exceeded the MDC. There were no other change scores that exceeded the MDC.

Table 4.11 Change scores, based on post-training pass or fail status. Values are means (standard deviation).

Change scores	PASS (n=14)	FAIL (n=19)	P-value
Quadriceps Strength	-0.68 (11.88)	9.35 (17.93)	0.08
IKDC 2000	5.34 (7.15)	10.53 (11.34)	0.14
ACL-RSI	1.33 (2.22)	2.08 (1.88)	0.30
TSK-11	-0.5 (3.06)	-4.1 (3.77)	***0.001***

PASS= passing return-to-activity criteria, FAIL= failing return-to-activity criteria, IKDC 2000= international knee documentation committee subjective knee form, ACL-RSI= anterior cruciate ligament-return to sport after injury scale, TSK-11= tampa scale of kinesiophobia

4.6 Discussion

After ACL-SPORTS Training and one year after surgery, treatment group did not identify subjects who passed or failed return-to-activity criteria. After training, quadriceps femoris muscle strength was significantly greater in subjects who passed return-to-activity criteria compared to those who failed, however mean measures were greater than 90% in both groups. No differences were seen for knee function scores and measures of fear of movement/re-injury between subjects who passed and subjects who failed after training and one year after surgery. However, change scores of TSK-11 measures were significantly greater for subjects who failed after training and ACL-RSI measures exceeded MDC scores in both groups.

After training, no treatment group was more likely to pass return-to-activity criteria. In particular, six subjects after training passed clinical and functional measures but failed because of self-report measures on the GRS only. Four of the subjects were females (2 STND, 2 PERT) and two were males (2 STND), with four subjects randomized to the STND treatment group. Three of these six subjects passed return-to-activity criteria at one year, including the GRS. One subject failed at one year because of hop tests and one subject re-injured just prior to one year testing and was excluded from this analysis. One subject was unable to return to functional testing at one year because of geographic location. One year after surgery, only subjects in the STND treatment group failed the KOS-ADLs and the GRS, and three subjects have not passed return-to-activity criteria (3Males, 3 STND). It may be likely that females randomized to the STND treatment group are more likely to report lower scores of perceived knee function and males in the STND group are more likely to fail return-to-activity criteria; however, additional subjects are needed to determine this.

Mean measures of quadriceps femoris muscle strength were significantly different between those who passed and those who failed after training. Mean scores in the group that failed after training exceeded 90%, which is required to pass return-to-activity criteria, however 9 of 45 subjects (20%) after training failed to achieve ≥ 90% quadriceps femoris muscle strength. No difference in quadriceps femoris muscle strength was seen one year after surgery, and six of 33 subjects (18%) failed to achieve ≥ 90% strength measures. Despite mean scores exceeding the 90% threshold in both groups, nearly one in five subjects demonstrated decreased quadriceps femoris muscle strength at either time point. Quadriceps femoris muscle strength deficits after surgery have been reported with poor functional performance and low self-reported knee function.[77] Subjects in the current study with quadriceps femoris muscle strength < 90% may be more likely to experience poorer outcomes after surgery.

IKDC 2000 scores were not different between subjects who passed or failed after training and one year after surgery, and differences in mean scores between the groups were small. Compared to two year IKDC 2000 scores reported by the Multicenter Orthopaedic Outcomes Network (MOON) cohort,[80] all subjects in the current study at both post-training and one year after surgery, scored significantly higher ($p<0.001$) than subjects in the MOON cohort. This suggests that the ACL-SPORTS Training protocol, in general, may be beneficial to improve outcomes compared to standard rehabilitation.

ACL-RSI scores were not different between those who passed and those who failed after training and one year after surgery. Comparisons of scores were made with the original authors of the measurement tool.[50,86] Langford and colleagues measured ACL-RSI scores between subjects who returned to competition and those who had not at three, six and 12 months after surgery. Post-training measures of the current study were compared to six month measures from Langford and colleagues since the mean time from surgery to post-training testing for subjects in the current study was seven months. All subjects in the current study scored significantly higher than all subjects at six months after surgery ($p<0.001$) and at one year after surgery ($p<0.001$), suggesting that ACL-SPORTS Training may improve outcome measures at this time point. There may be an additional benefit of this ACL-SPORTS Training protocol to decrease self-reported fear of re-injury after ACLR.

TSK-11 scores were not different between subjects who passed and subjects who failed after training and one year after surgery. Lentz and colleagues[51] evaluated TSK-11 scores one year after surgery between subjects who returned to activities and those who did not. Comparing the TSK-11 scores of the current study to those reported by Lentz and colleagues, subjects who passed after training and one year after surgery reported similar scores to one year measures of subjects who returned to activities. After training, subjects who failed reported similar scores to subjects at one year who did not return to activities. However, subjects who failed at one year reported higher scores compared to subjects who did not return to activities. These findings suggest that after ACL-SPORTS Training, subjects who pass return-to-activity criteria post-training report similar scores to those who received standard rehabilitation and return to activities one year after surgery. This also suggests that subjects who fail these return-to-activity criteria after training may be similar to subjects who do not return to activities; however they continue to make improvements up to one year after surgery. These return-to-activity criteria may be predictive of future activity levels in the medium to long-term after ACLR, though longer follow-up is needed.

Subjects who failed return-to-activity criteria after ACL-SPORTS Training were no less likely to go on to pass these criteria at one year after surgery compared to subjects who passed after training. Once patients pass return-to-activity criteria, they are cleared to return to activities even if they fail future follow-up testing, unless the clinician believes it is unsafe for participation. This may include large deficits in quadriceps femoris muscle strength (80% or less), large knee joint effusion (1+ or greater) and limitations in range of motion. Within our research group (Dynamic Stability), subjects who received pre-operative perturbation training were tested six, 12 and 24 months after surgery using these return-to-activity criteria. Subjects who failed these criteria six months after surgery were twice as likely (Positive likelihood ratio: 2.0, sensitivity: 0.68, specificity: 0.67) to fail at one year and 1.72 times more likely (Positive likelihood ratio: 1.72, sensitivity: 0.62, specificity: 0.64) to fail at two years.[61] These data suggest that subjects who complete the ACL-SPORTS Training protocol and fail return-to-activity criteria after training are able to continue to make improvements over time, while subjects of Nawasreh and colleagues (unpublished) did not make improvements.

TSK-11 scores were the only change score that was significantly different between subjects who passed and those who failed after training. Subjects who failed after training had larger improvements in TSK-11 scores suggesting a decrease in fear of movement/re-injury at one year follow-up. Change scores exceeded the MDC for ACL-RSI scores only; however this was in both treatment groups. Subjects who failed after training demonstrated the largest improvement in scores over time, though not statistically significant. This suggests that these individuals who fail after training continue to make improvements up to one year after surgery.

There are several limitations to this study that should be addressed. There is a gender bias towards male subjects in this study (Males 33, Females 12). Females have been reported to have a higher risk of re-injury compared to their male counterparts within the first years after surgery.[63] Additional female subjects may allow us to identify where deficits in performance or self-report may exist. A smaller sample size of subjects at one year follow-up testing may have contributed to change scores not exceeding the MDC threshold. Additionally, subjects were not evaluated at one year based on activity level. ACL-RSI and TSK-11 scores at one year reported by Lentz and colleagues[51] and Langford and colleagues[50] were evaluated based on activity level. Further evaluating these subjects based on having returned to pre-injury activities or not may provide additional insight in the use of these measures of fear of re-injury and fear of movement/re-injury.

4.7 Conclusion

At this time, there is no significant difference between subjects in the STND group and subjects in the PERT group for the ability to pass return-to-activity criteria after training and one year after surgery. Quadriceps femoris muscle strength was significantly greater in subjects who passed after training compared to those who failed. Subjects who failed after training had a significantly greater decrease in fear of movement/re-injury compared to subjects who passed at one year. This suggests that subjects who fail after training are able to continue to make improvements up to one year after surgery. The addition of a fear of movement/re-injury outcome measure to the return-to-activity criteria may be needed to identify subjects who may not be prepared to return to activities. No differences between those who passed and those who failed were seen for other clinical measures and patient-reported measures after training and one year after surgery. Despite no differences between subjects in this study, outcome measures were significantly higher compared to measures reported in the literature and benefits of this ACL-SPORTS Training program may not be group dependent. Further evaluation should be completed with the addition of female subjects, additional subjects at one year follow-up testing and evaluation of scores based on activity level. This may provide additional information regarding the benefits of this treatment protocol.

Chapter 5

THE BENEFITS OF POST-OPERATIVE NEUROMUSCULAR TRAINING

5.1 Summary

The goal of this work was to evaluate the preliminary effects of a neuromuscular training protocol for patients after anterior cruciate ligament reconstruction (ACLR) based on movement patterns, knee function and readiness to return to activities. This novel ACL-Specialized Post-Operative Return-to-Sports (ACL-SPORTS) Training program is the first study to evaluate the effects of neuromuscular training with biomechanical variables after surgery.

5.2 Aim 1 Findings

Aim 1 of this dissertation was to evaluate gait biomechanics between limbs of subjects before and after 10-training sessions for subjects who receive perturbation (PERT) treatment and subjects who receive standard (STND) treatment.

Hypothesis 1.1 After 10-training sessions, subjects who receive PERT treatment will have smaller hip and knee flexion angle limb-to-limb asymmetries during gait compared to subjects who receive STND treatment.

Hypothesis 1.2 After 10-training sessions, subjects who receive PERT treatment will have smaller hip and knee moment limb-to-limb asymmetries during gait compared to subjects who receive STND treatment.

Hypothesis 1.3 After 10-training sessions, subjects who receive PERT treatment will have smaller hip and knee joint excursion limb-to-limb asymmetries compared to subjects who receive STND treatment.

The results of this first aim partially supported these hypothesizes. Subjects in the PERT group had improvements in hip flexion moments at initial contact and knee flexion angles at peak knee extension that exceeded the minimal clinically important differences (MCID). PERT subjects also had a worsening of limb symmetry for knee flexion angles at peak knee flexion; however the change was less than 3° and not thought to be clinically meaningful. Differences between the treatment groups were not seen after training for any biomechanical measure (knee and hip angles and moments at initial contact, peak knee flexion, peak knee extension and joint excursions). The only differences between treatment groups were seen at baseline.

Perturbation training after surgery has never been done before in a large randomized control trial, therefore findings of this work must be compared to pre-operative perturbation training. Females who received perturbation training before surgery demonstrated improvements in limb symmetry and muscle co-contraction strategies compared to their male counter parts,[21,39] suggesting that females may respond to this neuromuscular training. Due to the small number of female subjects in this sample, analysis between the sexes could not be completed, though is profoundly recommended with the addition of female subjects.

Pre-operative perturbation training has also been shown to decrease muscle co-contraction strategies.[13] A potential limitation of this analysis was that electromyography data were not evaluated. This may provide further insight into muscle strategies or patterns used before and after training. Pilot testing within our research group supports the use of post-operative perturbation training because of the improvement of limb symmetry after training.[19] One possible discrepancy between the current work and the pilot data is that the pilot work evaluated pre-operative biomechanics and post-training biomechanics, with no pre-training biomechanics collected. Also, differences in specific treatment interventions between pilot work and the current study may also explain the discrepancies. The pilot study intervention only included perturbation training and a home exercise program of agility drills. The current ACL-SPORTS Training protocol includes high-demand ACL injury prevention exercises, agility drills and quadriceps femoris muscle strengthening for all subjects and was augmented with perturbation training for half of the subjects. The STND treatment group received exercises beyond the scope of standard care and may be limiting group differences.

Limb symmetry six months after surgery has also been identified in subjects who passed strict return-to-activity criteria.[20] This suggests that improved performance on clinical and functional measures may be indicative of limb symmetry during gait. Preliminary analysis of gait biomechanics of patients in this study between subjects who passed return-to-activity criteria and those who failed, suggests that subjects who fail after training have greater asymmetries compared to those who pass. This suggests that meeting these criteria after surgery, regardless of treatment intervention, may be more important to normalize movement patterns, however further examination of these data is needed.

5.3 Aim 2 Findings

Knee function and return to pre-injury activities after ACLR has been evaluated with different self-reported measures and used to quantify success. Aim 2 of this dissertation was to determine normal knee function after 10-training sessions and one year after surgery in subjects who receive PERT treatment and subjects who receive STND treatment.

Hypothesis 2.1 Subjects who receive PERT treatment will be more likely to return to their previous level of activity one year after surgery compared to those who receive STND treatment.

This hypothesis was not supported with these findings. Eighty-five percent of subjects in this study returned to their pre-injury activity level one year after surgery, with no significant difference between treatment groups. There were several subjects that had not yet passed return-to-activity criteria, passed at one year testing or shortly before one year testing, which would affect their ability to return to pre-injury activities. A similar number of subjects in each group had not return to pre-injury activities suggesting that one group is not inferior to another at achieving return to activity status.

Hypothesis 2.2 Subjects who receive PERT treatment will have higher IKDC 2000 scores after 10-training sessions and one year after surgery compared to those who receive STND treatment.

Hypothesis 2.3 Subjects who receive PERT treatment will have higher KOOS-QOL and KOOS-Sport sub-scores scores after 10-training sessions and one year after surgery compared to subjects who receive STND treatment.

There was no significant difference between treatment groups for all knee function scores after training and one year after surgery. Scores one year after surgery for all subjects in the current study, were significantly higher than scores reported in the literature by large national and international ligament registries.[30,80] This suggests that ACL-SPORTS Training has a significant effect on knee function after surgery compared to standard rehabilitation guidelines. Two year follow-up data of ACL-SPORTS Training subjects will allow us to evaluate if improved knee function is maintained two years after surgery and continues to be superior to scores reported by the Multicenter Orthopaedic Outcomes Network (MOON) cohort and the Scandinavian ACL registry.[30,80]

5.4 Aim 3 Findings

Determining when a patient is ready to return to activities after ACLR has been reported many different ways, with time-based criteria as the most commonly used. Time-based criteria do not take into account quadriceps femoris muscle strength, dynamic functional performance and patient self-report. High rates of second knee injury and low rates of returning to pre-injury activities may be explained by the global use of time-based criteria. The purpose to this final aim was to characterize subjects' readiness to return to activities (RTA) after 10-training sessions and one year after surgery with the use of return-to-activity criteria.

Hypothesis 3.1 Subjects who receive PERT treatment will be more likely to pass RTA criteria after 10-training sessions and one year after surgery compared to subjects who receive STND treatment.

Subjects in the PERT group were no more likely to pass return-to-activity criteria after training and one year after surgery compared to subjects in the STND treatment group. The most frequently failed measure after training was the global rating score (GRS), followed by hop tests and quadriceps femoris muscle strength. A larger number of subjects failed the GRS in the STND treatment group compared to the PERT group, though differences were not statistically significant. One year after surgery, hop tests were the most frequently failed measure followed by quadriceps femoris muscle strength. KOS-ADLs scores after training and KOS-ADLs and GRS scores at one year were only failed by subjects in the STND group. Despite small sample size and limited statistical significance, this may foreshadow a difference between the treatment groups in patient's perception of knee function with self-reported measures. Additional subjects are needed to further evaluate these findings.

There was a subgroup of patients, after training, who passed all return-to-activity criteria, except the GRS. These six subjects demonstrated adequate quadriceps femoris muscle strength, good functional limb symmetry with single-legged hop tests and good self-reported knee function with activities of daily living, however they rated their knee as less than 90% compared to before their injury. These individuals should be further examined to determine if their risk for re-injury is increased, and if they reported increased fear of re-injury compared to those who passed all criteria, those who failed criteria, and how these individuals change over time.

Hypothesis 3.2 Subjects that do not pass RTA criteria after 10-training sessions and one year after surgery will demonstrate decreased QI (<90%) compared to those that pass.

Subjects who failed return-to-activity criteria after training had significantly lower quadriceps femoris muscle strength compared to subjects who passed, however mean values were greater than 90%. Quadriceps femoris muscle strength at one year after surgery in subjects who failed was greater than those who passed, but was not statistically significant. Hartigan et al[33] reported that insufficient quadriceps femoris muscle strength was the most frequent reason for non-copers failing return-to-activity criteria six months and one year after surgery. The results of the current study suggest that more subjects failed the GRS and hop tests, rather than quadriceps femoris muscle strength after the ACL-SPORTS Training protocol. It is possible that strength requirements and minimal knee joint effusion prior to enrolling in this study has controlled for quadriceps femoris muscle strength deficits. Subjects that are unable to achieve 80% or higher quadriceps femoris muscle strength symmetry are ineligible for the current study and therefore we may be unintentionally eliminating poorer functioning subjects from this treatment intervention. Adequate strength, however, is needed to perform this dynamic, high-level training program.

Hypothesis 3.3 Subjects that do not pass RTA criteria after 10-training sessions and one year after surgery will demonstrate knee function below normal ranges with IKDC 2000 scores compared to those that pass.

IKDC 2000 scores were not significantly different between those who passed and those who failed after training and one year after surgery. Normal knee function scores, determined by the top 15th percentile of age- and sex-matched healthy subjects were achieved by more than 56% of subjects in both groups after training and more than 88% of subjects at one year. Subjects who failed after training, had a larger improvement in IKDC 2000 scores one year after surgery, however it did not exceed the MDC score.

Hypothesis 3.4 Subjects that do not pass RTA criteria after 10-training sessions and one year after surgery will report lower ACL-RSI scores and higher TSK-11 scores compared to those that pass.

No significant differences were seen in TSK-11 or ACL-RSI scores between subjects who passed and those who failed after training and one year after surgery. Subjects who failed return-to-activity criteria after training had a significant change in TSK-11 scores at one year follow-up testing compared to those who passed. This suggests that despite failing return-to-activity criteria after training, subjects continued to make improvements in fear of movement/re-injury one year after surgery. Subjects who failed these criteria may need an additional intervention to decrease fear in preparation to return to pre-injury activities.

Subjects who failed after training, had a larger improvement in ACL-RSI and TSK-11 scores at one year compared to subjects who failed. ACL-RSI MDC scores were exceeded by both groups, however neither group exceeded these change scores for TSK-11 measures despite significant differences in TSK-11 scores.

ACL-RSI scores and TSK-11 scores in the literature have been evaluated between subjects who returned to pre-injury activities and those who have not with significant differences between the groups.[5,50] Further evaluation of these data based on return to activity level may provide further insight into fear of re-injury and fear of movement/re-injury.

5.5 Future Work

Further work is needed within this cohort to analyze movement patterns after neuromuscular training. Gender analysis has demonstrated that females respond differently to pre-operative perturbation training compared to their male counterparts.[21] At this time, treatment group does not identify subjects with normal movement patterns; however treatment group may be important between the genders. Superior functional performance with return-to-activity criteria has discriminated those with adequate limb symmetry during gait.[20] Further analyzing these data based on passing or failing these return-to-activity criteria may support these previous findings with pre-operative perturbation training.

Knee function scores after training and one year after surgery were not different between the treatment groups, however scores were superior to measures reported by large national and international ligament registries.[30,80] These registries do not report all measures at one year after surgery, limiting direct comparisons. Further evaluation of subjects from this study at two years after surgery will allow direct comparisons to national registries. This will help determine if this ACL-SPORTS Training program results in superior outcomes long-term and would benefit subjects who desire to return to high-level activities.

Finally, preliminary analysis of knee function and fear of re-injury based on passing or failing return-to-activity criteria identified decreased quadriceps femoris muscle strength after training in those who failed, however mean scores were greater than 90%. Fear of movement/re-injury, however changed significantly over time for subjects who failed return-to-activity criteria after training, suggesting that fear may still be a limiting factor for some individuals. Fear of re-injury has been reported to be higher in subjects who do not return to pre-injury activities after surgery.[5,50] Evaluating fear of re-injury after training and its relationship to returning to pre-injury activities at one year is needed. This may further suggest that a self-reported measure of fear of movement/re-injury may need to be included in the current return-to-activity criteria to determine readiness to return to activities.

The current results of this study have identified an improvement in knee function after ACL-SPORTS Training. These results also suggest that there may be a subgroup of patients, either females or those with poor functional performance, who would benefit largely from this training program. Additional subjects and long-term follow-up are needed to solidify these recommendations.

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Appendix A

PHYSICAL THERAPY CLINIC

053 McKinly Lab
University of Delaware
Newark, Delaware 19716
Ph: (302) 831-8893
Fax: (302) 831-4468

ACL-SPORTS Eligibility Form

As of today I, ____________________________, have been declared eligible for the ACL-SPORTS Training Project. I understand that if I choose to be a participant in this project I will receive therapy at no cost to me, however my insurance company will be billed for the treatment I receive.

_____________________________________ ____________________

Patient Signature Date

_____________________________________ _____________________

Treating Therapist Signature Date

Returned to Gina _________________/ ______________

Gina initials Date

Appendix B

UDPT Perturbation Training Program

	Early (Estimated Treatment 1-3)	Middle (Estimated Treatment 4-7)	Late (Estimated Treatment 8-10)
Date Completed			
Anterior/Posterior and Medial/Lateral Roller Board	**Position:** Patient on board (bilateral 1st treatment, progress to unilateral) – Eyes straight ahead **Application:** Inform the patient of direction and timing of rollerboard movement – Slow application of force, Low magnitude, – Straight plane of movement (do all A/P reps before you begin M/L) **Observe:** Cue patient to avoid massive co-contraction at knee – Do not overstress beyond limit of stability (don't induce fall)	**Position:** Unilateral (avoid forefoot abduction/adduction) **Application:** Unexpected forces – Rapid increasing magnitude force application – Add rotation and diagonal motions – Alternate plane of movement (start A/P, then M/L, progress to A/L/IR) – Short delay between subsequent force applications **Distraction:** May begin to add distraction (ball toss, stick work) **Observe:** Observe difficulty with recovery but few to no falls	**Position:** Unilateral **Application:** Increased magnitude of force application – Random direction movements – Little to no delay between applications **Distraction:** Increase speed and magnitude of distraction – Consider sport specific positions **Observe:** Look for disassociation of hip, knee, and ankle
Date Completed			
Anterior/Posterior and Medial/Lateral Tilt Board	**Position:** Begin bilateral, progress to unilateral – Eyes straight ahead **Application:** Inform patient of direction and timing of tilting – Slow application of force, Low magnitude – Less force medial than lateral **Observe:** Cue patient to maintain equal weight bearing bilaterally – Cue patient to avoid massive co-contraction at the knee	**Position:** Unilateral (avoid forefoot abduction/adduction) **Application:** Unexpected forces – Rapid, increasing magnitude force application – Hold the board to the floor in one direction and unexpectedly release **Distraction:** May begin to add distraction (ball toss, stick work) **Observe:** Look for a rapid return to a stable base after perturbation – Look for dissociation of hip, knee and ankle	**Position:** Begin to place foot at a diagonal **Application:** Increased magnitude force application – Random direction movements – Little to no delay between applications **Distraction:** Increase speed and magnitude of distraction – Consider sport specific positions **Observe:** Look for minimal sway from stable stance at rest or following any perturbation
Date Completed			
Rollerboard and Stationary Platform	**Position:** One foot on the rollerboard, one on the platform – Eyes straight ahead, equal weightbearing on both lower extremities **Application:** Inform patient of direction and timing of movement – Slow application of force, low magnitude – All directions A/P, M/L, IR/ER, diagonals **Observe:** Cue patient to maintain equal weightbearing bilaterally (watch for unweighting of the involved limb as level of difficulty increases) – Do not overpower the patient, board should not move > 1 or 2 inches – Match therapist's forces w/o excessive movement of roller board	**Position:** One foot on the rollerboard, one on the platform – Eyes straight ahead, equal weightbearing on both lower extremities **Application:** Unexpected forces – Rapid, increasing magnitude force application – Begin combining directional movements (Ant with IR) **Distraction:** May begin to add distraction (ball toss, stick work) **Observe:** Cue patient to maintain equal weightbearing bilaterally (watch for unweighting of the involved limb as difficulty level increases) – Do not overpower the patient, board should not move > 1 or 2 inches – Cue patient to react as you remove force (avoid rebound board movement)	**Position:** One foot on the rollerboard, one on the platform – Eyes straight ahead, equal weightbearing on both lower extremities **Application:** Increased magnitude force application – Random direction movements – Little to no delay between applications **Distraction:** Increase speed and magnitude of distraction – Consider diagonal/sport specific stance (forward split, backward split) **Observe:** Cue patient to maintain equal weight bearing bilaterally (watch for unweighting of the involved limb as difficulty level increases) – Cue patient to react as you remove force (avoid rebound board movement)

Rollerboard and Stationary Platform instructions:
Setup: The involved leg is placed on either the rollerboard or the stationary platform and after 3 sets of 1 minute, the legs are alternated and the treatment is repeated
Instructions: *Meet my force, Don't beat my force.*
"When I push the rollerboard, resist the exact movement in speed and magnitude. The board should remain in the same place. Do not overpower me and move the rollerboard away and do not let me overpower you."

COMMON THEMES IN PERTURBATION TRAINING

Tools: Roller Board, Tilt Board, Stationary Platform, Sport Specific Equipment
Time: 3 sets of 1 minute of each, rest time for calf stretching as needed
Phases: 10 treatments total
Progressions: Vary by individual, estimates are noted above

Application to Surface - As the therapist increases the stress to the patient in one area (i.e. change force application from expected to unexpected), the therapist may need to decrease the intensity of another application variable (i.e. magnitude of speed). Once the patient is successful, progress toward resumption of altered variable (magnitude or speed)
Distraction of Patient - When progressing a patient in difficulty level or progressing to the next phase of training, a therapist may need to decrease the distraction level for 1 or 2 treatments until the patient's skill level has improved. Once the patient is successful, progress toward resumption of the previous level of distraction and progress.
Observation of Patient- Each time a therapist adds stress to the training program (by application or distraction) you may see a decrease in performance level. This will require more cueing and feedback until the new skill is acquired and more stress can be incorporated.

	Early (Estimated Treatment 1-3)	Middle (Estimated Treatment 4-7)	Late (Estimated Treatment 8-10)
Date Completed			
Resistive Quadriceps/Hamstrings Training – Weights – Isokinetics			
Date Completed			
Agility Program (5 reps of each: begin 3-6 feet progressing to 10 feet) – Forward/backward running (plant on involved leg) – Side shuffle – Carioca/Braiding – Corner Turn/Pivot – On Command Drill	**Progression:** Increase speed/distance/unexpected direction change **Observe:** Willingness to rely on involved lower limb **Sport Specific:** Addition of equipment (i.e. dribble basketball while performing agility) **Modify Drills:** i.e. Run ahead and take pass to extreme right or left	**Progression:** Increase speed/distance/unexpected direction change **Observe:** Willingness to rely on involved lower limb **Sport Specific:** Addition of equipment (i.e. dribble basketball while performing agility) **Modify Drills:** i.e. Run ahead and take pass to extreme right or left	**Progression:** Increase speed/distance/unexpected direction change **Observe:** Willingness to rely on involved lower limb **Sport Specific:** Addition of equipment (i.e. dribble basketball while performing agility) **Modify Drills:** i.e. Run ahead and take pass to extreme right or left
Date Completed			
Return to Sport Specific Activity	**If return to sport before surgery :** Start sport specific activities immediately **If no return to sport before surgery :** Sports specific activities not to be completed	**Begin sports specific skills:** – Dribble basketball, straight shots (no jumping) – Backboard tennis within arms' reach – Low level soccer ball handling – Stroking for skaters **Progression:** Patient specific based on performance in perturbation skills	**Transition to Play:** – One on one basketball (time limit) – Tennis with partner (easy on pivots) – Begin soccer drills – Begin skating spins and glides **Progression:** Patient specific based on middle phase progression and perturbation skills – Goal to begin modified play by sessions 8-10

Goal: The goal of the return to sports specific activity phase is to return patients with acute ACL ruptures to high level activities. This must include progressive return to activities themselves. The time frame for return to sport specific activities is variable and patient dependent.

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

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University of Delaware
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Fax: 302/831-2828

DATE:	March 7, 2014
TO:	Lynn Snyder-Mackler, PT, ScD, FAPTA
FROM:	University of Delaware IRB
STUDY TITLE:	[225014-11] Can Neuromuscular Training Alter Movement Patterns(Renewal Period)
SUBMISSION TYPE:	Continuing Review
ACTION:	APPROVED
APPROVAL DATE:	March 7, 2014
EXPIRATION DATE:	March 14, 2015
REVIEW TYPE:	Full Committee Review

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

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

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

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

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

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

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

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

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

UD IRB Approval from 03/07/2014 to 03/14/2015

UNIVERSITY OF DELAWARE
DEPARTMENT OF PHYSICAL THERAPY
INFORMED CONSENT FORM

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

Principal Investigators: Lynn Snyder-Mackler, ScD, PT

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

PURPOSE AND BACKGROUND

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

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

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

Subject's Initials_______

PROCEDURES

ACL Functional Test

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

Strength Testing

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

Hop Testing

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

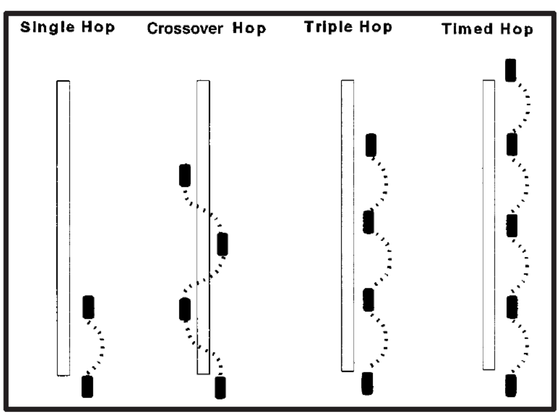

Diagram 1. Four (4) hop tests as part of the functional test protocol.

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

Subject’s Initials_______

Questionnaires

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

Motion Analysis Testing

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

Motion Analysis

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

Muscle Activity

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

Walking Trials

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

Subject’s Initials_______

Physical Therapy

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

Risks/Discomfort

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

Benefits

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

Compensation

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

Confidentiality and records

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

Subject's Initials_______

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

Principal Investigators: Lynn Snyder-Mackler, ScD, PT

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Subject's Statement:

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

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

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

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

____________________ ____________________ __________
Subject's Name | Subject's Signature | Date

____________________ ____________________ __________
Parent/Guardian's Name | Parent/Guardian's Signature | Date

________________________________ __________
Lynn Snyder-Mackler, Principal Investigator | Date

If you have any questions concerning the rights of individuals who agree to participate in research, you may contact the Institutional Review Board (302-831-2137). The Institutional Review Board is created for the protection of human subjects involved in research conducted at the University of Delaware.

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

White *et al. BMC Musculoskeletal Disorders* 2013, **14**:108
http://www.biomedcentral.com/1471-2474/14/108

BMC Musculoskeletal Disorders

STUDY PROTOCOL | Open Access

Anterior cruciate ligament- specialized post-operative return-to-sports (ACL-SPORTS) training: a randomized control trial

Kathleen White[1*], Stephanie L Di Stasi[2], Angela H Smith[3] and Lynn Snyder-Mackler[1,3]

Abstract

Background: Anterior cruciate ligament reconstruction (ACLR) is standard practice for athletes that wish to return to high-level activities; however functional outcomes after ACLR are poor. Quadriceps strength weakness, abnormal movement patterns and below normal knee function is reported in the months and years after ACLR. Second ACL injuries are common with even worse outcomes than primary ACLR. Modifiable limb-to-limb asymmetries have been identified in individuals who re-injure after primary ACLR, suggesting a neuromuscular training program is needed to improve post-operative outcomes. Pre-operative perturbation training, a neuromuscular training program, has been successful at improving limb symmetry prior to surgery, though benefits are not lasting after surgery. Implementing perturbation training after surgery may be successful in addressing post-operative deficits that contribute to poor functional outcomes and second ACL injury risk.

Methods/Design: 80 athletes that have undergone a unilateral ACLR and wish to return to level 1 or 2 activities will be recruited for this study and randomized to one of two treatment groups. A standard care group will receive prevention exercises, quadriceps strengthening and agility exercises, while the perturbation group will receive the same exercise program with the addition of perturbation training. The primary outcomes measures will include gait biomechanics, clinical and functional measures, and knee joint loading. Return to sport rates, return to pre-injury level of activity rates, and second injury rates will be secondary measures.

Discussion: The results of this ACL-Specialized Post-Operative Return To Sports (ACL-SPORTS) Training program will help clinicians to better determine an effective post-operative treatment program that will improve modifiable impairments that influence outcomes after ACLR.

Trial registration: Randomized Control Trial NIH 5R01AR048212-07. ClinicalTrials.gov: NCT01773317

Keywords: Anterior cruciate ligament reconstruction, Neuromuscular training, Return to Sport

Background

Anterior cruciate ligament reconstruction (ACLR) is standard practice for individuals that desire to return to high-level activities, but excellent outcomes are not as commonplace as previously reported [1-5]. Currently, success after ACLR is measured using return-to-sport rates, but second ACL injuries are not only common, but devastating, and have worse outcomes than primary ACLR [6-8]. Quadriceps weakness [9-11], abnormal movement patterns [4,12-16] and below normal knee function [17] are characteristic of athletes in the months following ACLR and often persist up to two years in spite of extensive rehabilitation. Neuromuscular training focusing on restoring limb symmetry and improving knee function using sports-related movements may reduce aberrant movement patterns which are predictive of second injury risk [4,12,18,19].

Risk of a second ACL injury is highest during the first year that athletes return to sports after primary ACL reconstruction [4,13,20-22]. Young females are 16 times more likely to sustain a second ACL injury after primary ACLR and the amount of participation time in high-level

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activities further increases this risk [23]. Risk to the contralateral limb is higher (5-24%) than the operated limb (4-15%) [4,23-28], suggesting deficits of the involved limb are not exclusively related to re-injury. Altered neuromuscular and biomechanical movement patterns are present bilaterally in response to injury and reconstruction which fails to resolve with post-operative rehabilitation. A neuromuscular training program focused on maximizing performance after ACLR may reduce the risk of a second ACL injury.

Despite current evidence-based post-operative guidelines [29-32], quadriceps strength deficits [9-11], altered biomechanics [4,13-16,33] and poor knee function [17] are reported six months and one year after surgery. International Knee Documentation Committee 2000 subjective knee form (IKDC 2000) scores continue to improve up to one year after surgery suggesting optimal knee function has not been met [17]. Despite clearance for return to sport activities by surgeons and rehabilitation specialists, quadriceps strength deficits of the involved limb compared to the uninvolved limb still exist, and movement asymmetries continue to persist [10,11,14,16].

One year after surgery only 67% of patients have attempted some sort of training or sport activity; males are more likely than females to attempt full return to sport [34]. Individuals often do not return to their pre-injury activity level for a variety of reasons; fear of re-injury being a large contributing factor [35-37]. Patients in the medium to long term after surgery (two to seven years) that have returned to their pre-injury activity level were less likely to be fearful of re-injury during athletic participation than those that had not returned to their pre-injury level [37]. Females were more fearful with poor environmental conditions during athletic participation than their male counterparts [37].

Neuromuscular training, consisting of destabilizing perturbations to both the involved and uninvolved lower extremities, has been an effective means of enhancing functional outcomes after ACL injury compared to strength training [12,38]. Neuromuscular training programs such as perturbation training (PERT) [39] before surgery reduce gait asymmetries in female non-copers [18]. After surgery, non-copers who received pre-operative PERT demonstrated improved knee excursion symmetry during gait compared to patients who received strength training [12]. However, regardless of pre-operative intervention, aberrant movement patterns persisted up to two years after surgery [14]. Pilot data from our lab strongly suggests that utilizing this neuromuscular training program after surgery will be an effective means of improving both short term outcomes (6 months), when clearance to return to sport often occurs, and medium term outcomes (1-2 years) after surgery. Successful primary ACL prevention programs utilize a combination of balance, plyometric and strengthening exercises to decrease ACL injury risk. Similarly, our ACL-Specialized Post-Operative Return To Sports (ACL-SPORTS) Training will incorporate dynamic prevention exercises and quadriceps strengthening exercises that promote symmetrical joint loading and abate abnormal movement patterns. A post-operative intervention incorporating these elements with the addition of PERT may be effective in resolving residual impairments after surgery.

The purpose of this study is to determine the effects of this ACL-SPORTS Training program on joint loading, biomechanics, and clinical and functional measures of level 1 and 2 athletes after ACLR. This body of work will further explain in detail each component of the training program as well as the methodology of this single blinded randomized control trial.

Hypotheses

Subjects who receive standard care plus PERT after surgery will demonstrate: 1) symmetrical knee joint loading, 2) symmetrical movement patterns, 3) improved clinical and functional outcomes and 4) improved knee function compared to subjects who receive standard care. Additionally, subjects who receive standard care plus PERT will have a higher return to pre-injury level rates in the short to medium term (6 months -2 years) compared to subjects who receive standard care.

Methods/Design

This study is a single-assessor blinded, parallel design randomized control trial that follows the CONSORT guidelines for non-pharmacological treatment studies [40]. Additional information about this study can be found at: Clinicaltrials.gov (Identifier: NCT 01773317).

Participants

Eighty level 1 and 2 athletes (40 men, 40 women) between the ages of 13 and 55 that have undergone an isolated, unilateral ACL reconstruction will be recruited for this study. Recruiting will be done primarily through the University of Delaware Physical Therapy Clinic. Additional recruitment will consist of newspaper advertisements as well as speaking with local surgeons and rehabilitations specialists. Athletes will be eligible for study enrollment if they were participants in level 1 or 2 activities [1] ≥ 50 hrs/year at the time of their injury, plan to return to their pre-injury level of activity, are ≥ 12 weeks after surgery, demonstrate ≥ 80% quadriceps strength index and minimal knee joint effusion [41].

Exclusion criteria

Subjects will be excluded if: (i) not regular participants in level 1 or 2 activities (< 50 hrs/yr), (ii) > 10 months after ACLR, (iii) history of previous ACLR, (iv) history of serious ipsilateral or contralateral limb injury (i.e. Tibial fx), or (v) large osteochondral defect > 1 cm^2 (Figure 1. CONSORT Flow Diagram of Study Protocol).

Procedure

Once a patient has consented to be contacted by research staff, eligibility will be determined from patient chart review and patient dialogue. All testing measures will be performed at the University of Delaware Physical Therapy Clinic by the same assessor, blinded to group assignment. Enrolled study participants will complete initial baseline testing and 10 treatment sessions followed by post-training, 1 year and 2 year follow-up testing sessions. Testing will be completed no more than two weeks prior to initiation and two weeks after the completion of the 10 training sessions. Ethical approval has been obtained from the University of Delaware Human Subjects Review board. All participants will provide written informed consent to all research testing procedures.

Randomization and allocation concealment

Enrolled subjects will be randomized to a perturbation treatment group (PERT) or a standard treatment group (STND). A statistical random number generator will be used to generate a randomization list, stratified by gender in which an equal number of female and male subjects will be assigned to each treatment group. The research coordinator will generically label the treatment assignments to group A and B to ensure blinding is maintained. This is a single-blinded study in that individuals collecting, recording and analyzing these data will be blinded to group assignment along with the primary investigator and biostatistician. Both the treating

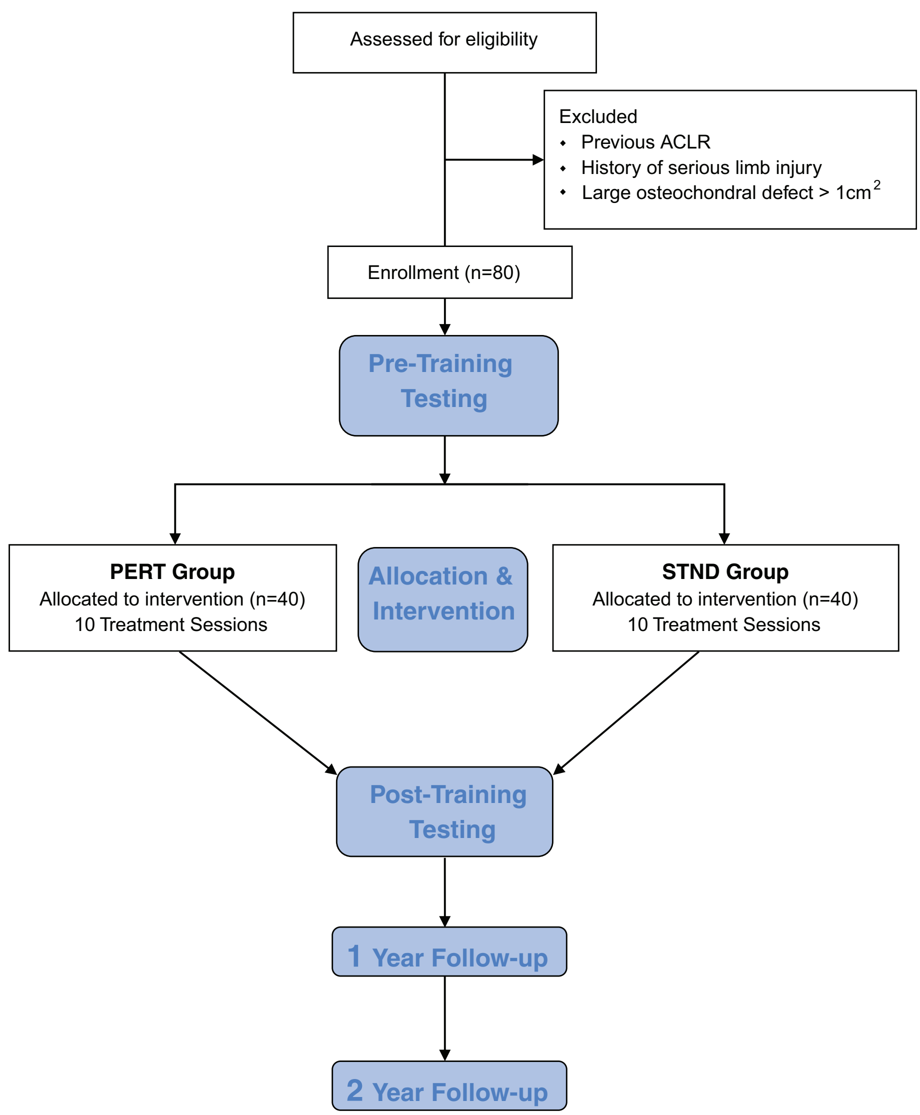

Figure 1 CONSORT flow diagram of study proctol.

physical therapist and the patient will not be blinded to group assignment.

Interventions

Treatment will be completed at the University of Delaware Physical Therapy clinic by the licensed staff therapists. The therapists have an average of 6.5 yrs experience (range 1 – 20 yrs). All therapists will participate in a training session involving discussion of the treatment program and how to manage changes in effusion, complaints of muscle soreness and still effectively complete the training program. A detailed protocol with visual aids and descriptions will be provided. Once training has been initiated procedural reliability will be completed by an unblinded investigator to ensure that the intervention is properly executed. An unmasked physical therapy clinic liaison will utilize a procedural reliability check list to review three treatment sessions for the first five subjects in each arm of the study. After that each subject's chart will be reviewed once (Additional file 1). Procedural reliability less than 85% will result in contacting the treating therapist to remedy the situation. Any additional questions regarding the training program will be intercepted by the clinic liaison to ensure blinding of those responsible for data collection is maintained.

The training protocol consists of 10 training sessions with treatment delivered by a licensed physical therapist, regardless of group allocation. Biomechanical and functional data will be collected prior to initiation of the 10 training sessions, after completion of the sessions, and 1 and 2 years after surgery. The training program consists of a series of "prevention exercises", quadriceps strengthening exercises, agility drills and either PERT training for individuals in the perturbation group or a control exercise for individuals in the STND care group. Details of these exercises are explained in further detail below.

Prevention exercises: A combination of balance, plyometric and strengthening exercises are effective in preventing initial ACL injury [30,42]. Plyometric training improves landing biomechanics in females [43] and decreases ACL injury rates [44]. Balance training not only improves lower extremity strength, but eliminates limb asymmetries [45], which are potential risk factors for ACL injury [4,46]. Strengthening programs alone do not reduce the number of ACL injuries [47], however when combined with plyometric training there is a significant reduction in ACL injuries, specifically female athletes [44]. Established injury prevention protocols were modified to develop the "prevention exercises" for this study (Table 1). Plyometric and balance exercises include triple single-legged hops, tuck jumps and box drops; strengthening exercises include nordic hamstring curls and squats with hip abduction resistance. Triple single-legged hops are done consecutively, forward and backwards as well as laterally. The initial drill will be completed by hopping over a line on the floor and progressed to hopping over 2 inch cups and ultimately 6 inch hurdles. Progression and cueing will be given by the treating therapist as per the patient's ability level with a training protocol as a guide (Table 1). Tuck jumps will not be completed until treatment sessions 7-10 to ensure that patients are able to tolerate jump landings safely and successfully. Box drops begin bilaterally and progress to unilateral jumps (involved limb to involved limb). Focus on mechanics during double limb tasks initially allows for an effective progression to single limb tasks [48]. The box height will be progressively increased by the treating therapist as per the patient's ability level using the training protocol as a guide (Table 1). This task will be completed in front of a mirror for visual feedback while the therapist provides verbal cues. Proper mechanics will be required including symmetrical limb takeoff and landing for bilateral tasks, good trunk control and neutral frontal plane knee alignment during takeoff and landing for bilateral and unilateral tasks. Nordic hamstring exercises will be completed on a low mat table with the therapist stabilizing the patient's ankles. Initially this eccentric hamstring activity will be done to about 30-45 degrees of knee flexion and repetitions as well as knee flexion angle will be progressed over the 10 training sessions. Resisted squat exercise will be done with a thera-band around the patient's knees to facilitate hip abduction. The resistance of the thera-band will increase as tolerated by the patient and additional upper extremity tasks such as a ball toss will be added to increase the difficulty of the task and challenge the patient. These exercises will be executed with the patient wearing a rigid functional knee brace if one has been prescribed by the surgeon. If a patient will be returning to sport without a knee brace then all testing and training sessions will be done without a brace.

Quadriceps strengthening: The results of baseline testing measures will be used to determine the patient's need for quadriceps strengthening during the 10 training sessions. A patient that demonstrates > 90% quadriceps strength index (involved limb strength/uninvolved limb strength × 100) will not be required to complete quadriceps strengthening exercises during training, but they may continue their prior gym program. All other patients with 80-90% quadriceps strength index will complete three quadriceps strengthening exercises during three of the first six training sessions including but not limited to, lateral step downs, leg press, LAQ and isokinetic strengthening. After the 6^{th} training session the patient will be given a home strengthening program because of the progressive nature of the program and the advanced level of tasks during the last 4 sessions.

Agilities: Agility drills will be completed as per the University of Delaware guidelines. Drills will be initiated

Table 1 ACL-SPORTS training protocol (2 times/wk)

	Session 1-3		Session 4-6	Session 7-10
Nordic Hamstrings	Partial 2 x 5		Partial 3 x 5	Partial 3 x 5
Kneeling on mat table, therapist stabilizing feet	(~30-45°)		(~30-45°)	(>60°)
Standing Squat	Session 1: 3x10 with focus on proper technique	3 x 10	3 x 10	
Must squat to knees at 90 degrees, tapping chair/table/box with gluts		Add t-band around knees	progress t-bands to black	X
Drop jumps**	3 x 10 BLE's to BLE's		3 x 10 BLE's to involved limb	3 x 10 Involved limb to involved limb off box
In front of mirror, monitor proper form with landing	Jump off appropriate height (4-6-8 inch)		Jump off appropriate height (4-6-8 inch)	Jump off appropriate height (4-6-8 inch)
Triple single leg hopping**	Forward/backward x10*		Forward/backward x15*	Forward/backward x15*
	Side to side x10*		Side to side x15*	Side to side x15*
	No object		Add low object to jump over (2 inch cups)	Increase height of object, appropriate for the pt. (4 inch cups or 6 inch hurdles)
This is for proper landing, NOT distance				
Tuck jumps**				2 sets, 10-20 sec
Proper form knees to 90°	X		X	Progress to 3 sets, 20-30 seconds each

**Brace worn if surgeon requires post-op functional brace for RTS activities. *1 rep= 3 consecutive hops forward, 3 hops backward or 3 consecutive hops laterally.

at 50% maximum effort and progressed to 100% effort and maximum speed over the 10 training sessions. Three to four agilities drills will be completed at each training session including forward/backward running, side shuffles, cariocas, figure eight's, circles and 90 degree turns. The treating therapist will determine which agility drills to use based on the patients sports participation and ability level. Progression of these drills will include eliminating linear drills, adding more advanced multidirectional drills and utilizing a ball consistent with the patient's sport of participation.

Perturbation training group: Patients randomized to the PERT group will complete additional PERT training as per Fitzgerald et al. [38]. PERT training is a neuromuscular training program that includes a series of progressive perturbations on unstable surfaces in both bilateral and unilateral stance. These are progressed as per patient tolerance in both magnitude and speed. Verbal distraction as well as the addition of simultaneous upper extremity or lower extremity tasks with perturbations will be used to target the individuals sport and challenge the athlete.

Standard treatment group: Patients in the STND group will complete an additional single leg balance task with added hip flexor resistance (Figure 2). This exercise will not be progressed to unstable surfaces to ensure that similar neuromuscular effects are not seen in this group. This exercise will only increase in duration and thera-band resistance (Table 2). All treatment sessions, regardless of group, will take about 1.5-2 hours to complete.

The expertise of the treating therapists will determine if any task is unsafe for the patient and should be held from the protocol at any point. If a patient develops increased knee joint effusion [41] or additional complaints of pain, a clinical decision making protocol has been established as a guide for the therapists to determine how to modify the training program (Figure 3). If a patient present with a 2+ effusion at any point during the training program the training protocol will be held and the patient will be treated with effusion management including retrograde massage, ice and elevation. The

Figure 2 STND Treatment Group Additional Exercise.

Table 2 STND treatment group additional exercise

Control subjects	Session 1-3	Session 4-6	Session 7-10
Single Leg Balance	3 x 30 sec	3 x 45 sec	3 x 1 minute
(**Do Not** "progress" with unstable surfaces or ball toss or perturbation)	(Level Ground)	Add sham progression: (stabilize t-band with standing leg, complete hip flexion with tband around ankle)	same

patient will be educated on proper effusion management techniques such as keeping the knee wrapped with a donut and compression wrap (Figure 4), as well as icing several times a day with the leg elevated. At the following session if the effusion has decreased to a 1+ the training will resume at the same level of difficulty, if the patient has trace or no effusion then the training program will be progressed accordingly. Conversely, if the patient continues to demonstrate a 2+ effusion the training will be held, the patient will be treated accordingly for effusion and the research team will be notified. Additional complications that occur throughout training will be treated as needed by the treating therapist. If additional symptoms or impairments are limiting completion of the training program the principle investigator will be notified. If the patient cannot resume the training program for any reason the training will be terminated and post-training data will be collected. The patient will continue to be treated accordingly for their impairments.

Outcomes measures

The primary outcome variables of interest for this study will include gait biomechanics, clinical outcome measures and knee joint loading.

Gait biomechanics will be assessed using a 3D motion capture system (VICON, Oxford Metrics Ltd., London, England) sampled at 120 Hz. Twenty static retro-reflective markers will be placed on the pelvis and lower extremities to identify limb segments. An embedded force plate (Bertec, Worthington, OH) will simultaneously collect kinetic data and used to determine timing variables during the gait cycle. Five walking trials will be collected for each limb while patients maintain a self-selected walking speed with ± 5% variability. These data will be post-processed using rigid body analysis and inverse dynamics with custom software programming (Visual3D, C-Motion, Inc., Germantown, MD, USA; LabVIEW 8.2, National Instruments Corp., Austin, TX, USA). Variables will be lowpass filtered at 6 Hz and 40 Hz. Initial contact and toe off will be determined using a 50 N force plate threshold. All walking trials will be normalized to 100% of stance before being averaged for statistical analysis. Hip and knee joint angles, moments and excursions will be evaluated between limbs in both the sagittal and frontal plane.

Clinical outcome measures will include quadriceps strength index, single-legged hop test measures and patient reported outcome measure. Quadriceps strength will be measured using a maximal voluntary isometric contraction (MVIC) with a burst superimposition technique [49]. Activation deficits and isometric quadriceps strength will be measured using an electromechanical dynamometer (KIN-COM, Chattanooga Corp., Chattanooga, TN). Patients will be seated in an upright position with the hip and knee flexed to 90 degrees. Testing will be completed on the uninvolved limb followed by the involved limb. A quadriceps index (QI) will be calculated as the quotient of the involved quadriceps MVIC to the uninvolved quadriceps MVIC multiplied by 100. The single-legged hop test measures [50] will consist of four hop tests in which each test will be administered as the uninvolved limb followed by the involved limb for the single hop for distance, crossover hop for distance, the triple hop for distance and 6-meter timed hop tests. A limb symmetry index (LSI) will be calculated from the average of two trials as the involved limb hop distance divided by the uninvolved limb hop distance multiplied by 100. The 6-meter timed hop will be calculated as the uninvolved limb hop time divided by the involved limb hop time multiplied by 100. Patient reported outcome measures will be completed after all objective clinical measures have been collected. The Knee Outcome Survey-Activities of Daily Living Score (KOS-ADLS) and the Global Rating Scale of Perceived Knee Function (GRS) will be used to determine the patients perceived knee function. A strict return to sport criteria, established by Fitzgerald et al. [38], requires the patient to achieve ≥ 90% on the following measures: QI, all 4 single-legged hop tests, KOS-ADL's and GRS. Patients will be required to meet these criteria after training to allow for progressive return to sport activities. If patients do not meet these criteria after training they will be repeatedly tested every 2-4 weeks until all measures are met prior to returning to sport activity. The ACL-Return to Sport after Injury (ACL-RSI) has been validated to measure fear in patients after ACLR. This patient reported outcome measure will be used to objectively measure patient fear in the short to medium term (6 months -2 years).

Joint loading

Electromyography (EMG)-driven musculoskeletal modeling will be used to estimate muscle forces from EMG muscle data during walking trials [51]. Anatomical modeling of the pelvis and lower limbs will be scaled initially for each subject. The model will then be calibrated based on muscle parameters used to determine the EMG-to-force relationship. Through iterative adjustments, the muscle

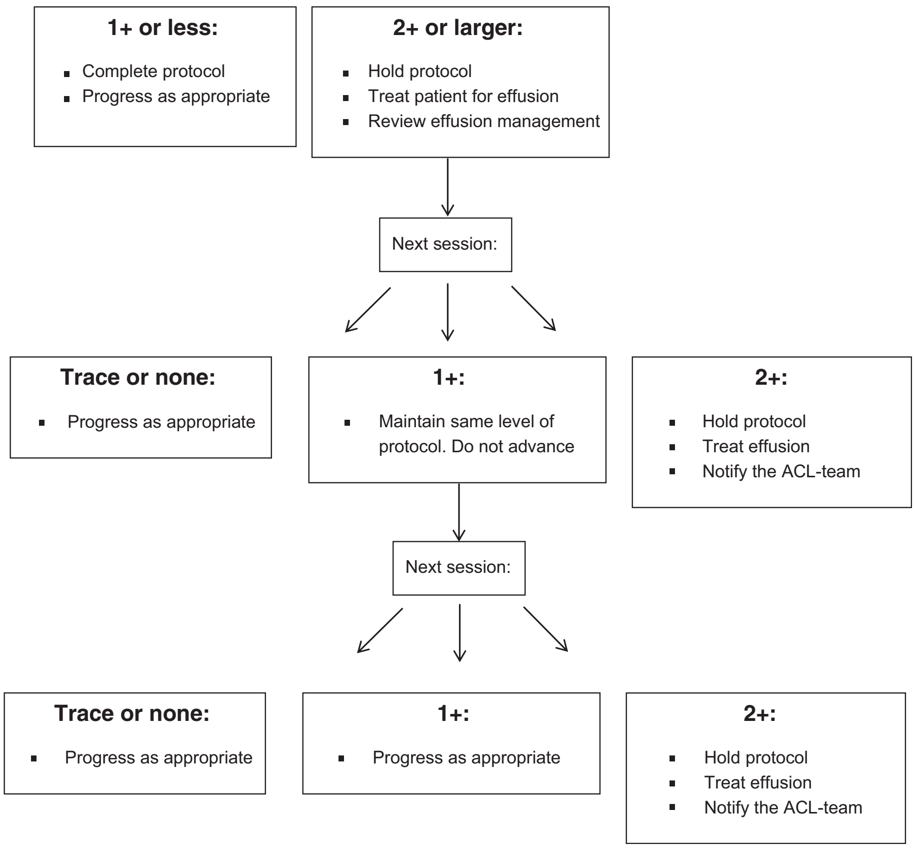

Figure 3 ACL-SPORTS training effusion protocol.

parameters will result in strong agreement with the sagittal plane net moments calculated from forward and inverse dynamics. Once the ideal model is determined, the muscle forces will be predicted from mathematical calculations from recorded EMG for three walking trials and converted to muscle force. A frontal plane moment balancing algorithm [52] will be used to calculate medial and lateral compartment contact forces. The knee adduction moment will be calculated using inverse dynamics and will be expressed about each contact point in the medial and lateral compartments. A balance of contact forces and muscle forces at each contact point will be summated to express the contact forces in the each compartment as well as the total joint forces.

Figure 4 Donut with compression wrap for effusion management.

Secondary outcome measures

Return to sport rates, re-injury rates and return to pre-injury level of activity rates will be evaluated 1 and 2 -years after surgery. Electromyography measures will be collected simultaneously with gait variables and will be used to further analyze muscle timing, co-contraction and activation patterns before and after the intervention as well as 1 and 2 years after surgery. IKDC 2000, Tampa Scale of Kinesiophobia (TSK-11), Knee Injury and Osteoarthritis Outcome Score (KOOS) including all 5 subsets and the Marx Activity Rating Scale (MARS) are additional patient reported outcome measures that will be collected at all-time points.

Sample size

Minimal clinically importance differences (MCID) for sagittal plane gait variables have previously been established [18]. A power analysis with $\beta = 0.20$, $\alpha = 0.05$ and a medium effect size (0.3) determined that 72 subjects would be needed to detect differences between groups based on MCID's. To account for a 10% patient drop out a total of 80 subjects will be enrolled in this study. Forty patients will be in each group dichotomized by gender.

Data and statistical analysis

Differences between groups will be analyzed using an analysis of covariance (ANCOVA) for biomechanical gait measures and an analysis of variance (ANOVA) will be used for clinical variables. Group assignment will be blinded to the researcher using A and B variables. Assumptions of ANOVA testing will be confirmed prior to statistical analysis. Training group randomization will be used as the between-subjects factor with a within-subjects factor of time. A significance level of $p < 0.05$ will be set a priori.

Timeline

Human subjects review board approval was obtained in July 2011 from the University of Delaware Institutional Review Board and recruitment and training was initiated in November 2011. A projected 25 patients will be enrolled in the study within the first year followed by 30 and 25 patients respectively in the subsequent years. Final enrollment is planned to be completed by November 2014 and final data collection and analysis is planned to be completed by November 2016.

Discussion

Both short and long term outcomes after ACLR are poorer than previously reported in high-level athletes [1-5]. The explanation of these low return to sports rates appears to be multi-factorial, but may be heavily influenced by lower perceived level of knee function and fear of re-injury [37,53,54]. The relationship of physical performance measures to these subjective evaluations and perceptions of ability are unknown. The aim of this project is to compare the outcomes of two different return to sport training programs in order to establish best-practice guidelines for this high-risk population.

Initial ACL injury rates continue to be elevated and subsequent re-injury rates are even higher despite the positive evolution of post-operative rehabilitation protocols [4,23-28]. Quadriceps weakness, abnormal movement patterns and decreased knee function persist after athletes have returned to sports, supporting the need for a bilateral, neuromuscular training program to promote improved outcomes after ACLR [4,9-17]. Our program was compiled from the latest evidence emphasizing prevention exercises, quadriceps strengthening and perturbation training as a plausible mechanism by which clinicians can maximize post-operative function and reduce second ACL injury risk.

Our study is the first randomized control trial to evaluate the effects of a post-operative intervention program on joint loading, gait biomechanics and clinical outcome measures. Implementing this program in our physical therapy clinic with therapists who have years of expertise executing research protocols allows us to make this post-operative training program generalizable to clinical practice while maintaining the rigor of scientific research. Our subjects will represent several different orthopedic surgeons with a variety of graft types which will allow us to evaluate additional factors outside of our rehabilitation protocol. Our criterion to implement training is based on an array of evidence based clinical measures rather than time based measures (i.e. 6 months) or surgical findings (i.e. bone bruise, meniscus repair) [29,30,38,55]. Group randomization by gender will ensure that effects of treatment are adequately captured. Blinding of researchers collecting these data allows for unbiased reporting of results.

Through this ACL-SPORTS Training program we will be able to better evaluate the effects of neuromuscular training after surgery on knee joint loading, gait biomechanics and clinical outcome measures for these athletes. These variables are modifiable factors reported in the literature and most commonly utilized in clinical practice. Results of this study will allow us to develop future treatment plans to maximize functional outcomes in the short and long term after ACLR.

Additional file

Additional file 1: ACL-SPORTS Training. Treatment Procedural Checklist.

Abbreviations

ACL: Anterior cruciate ligament; ACLR: Anterior cruciate ligament reconstruction; IKDC 2000: International knee documentation committee 2000; PERT: Perturbation; ACL-SPORTS: Anterior cruciate ligament- specialized post-operative return-to-sports; STND: Standard; MVIC: Maximal voluntary isometric contraction; QI: Quadriceps index; LSI: Limb symmetry index; KOS-ADLS: Knee outcome survey-activities of daily living score; GRS: Global rating scale; ACL-RSI: Anterior cruciate ligament- return to sports after injury; EMG: Electromyography; TSK-11: Tampa scale of Kinesiophobia; KOOS: Knee injury and Osteoarthritis outcome score; MARS: Marx activity rating scale; MCID: Minimal clinically important differences; ANCOVA: Analysis of covariance; ANOVA: Analysis of variance.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KW participated in developing the protocol, instructing the physical therapy staff on the treatment protocol, patient recruitment, research testing, contributed to trial registration on ClinicalTrials.gov, and drafted and critically revised this manuscript for important intellectual content. SLD contributed to the original idea of the study, developed a manual of operating procedures and critically revised this manuscript for important intellectual content. AHS participated in patient recruitment, procedural reliability, edited the treatment protocol, edited the procedural reliability forms and critically revised this manuscript for important intellectual content. LSM is the primary investigator of the randomized control trial and is responsible for the original idea of the study, registering the study on ClinicalTrials.gov, and critically revised this manuscript for important intellectual content. All authors read and approved the final manuscript.

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Gait Asymmetries Persist 1 Year After Anterior Cruciate Ligament Reconstruction

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Background: After anterior cruciate ligament reconstruction (ACLR), motivation to return to previous levels of activity is high. Very few studies have used return-to-activity criteria to determine when to permit athletic play. Return-to-activity measures objectively evaluate functional limb symmetry; however, previous biomechanical studies have found gait deviations in these individuals that persist up to 2 years after surgery.

Purpose: To evaluate gait biomechanics in a specific cohort of ACL patients 1 year after surgery and retrospectively compare individuals who pass return-to-activity criteria 6 months after surgery with those who fail.

Study Design: Prospective analysis.

Methods: A total of 40 athletes who participated regularly (>50 h/y) in cutting, jumping, and pivoting activities and who sustained an isolated, unilateral ACL rupture were included in this study. All participants underwent reconstruction by the same surgeon and received individualized postoperative rehabilitation. Performance-based and self-report data were measured 6 months after surgery to assess readiness to return to activity (90% outcome required to pass); 20 subjects passed return-to-activity criteria and 20 subjects did not. Motion analysis was performed 1 year after surgery, and knee flexion angles, moments, and excursions were measured during gait and evaluated for all subjects.

Results: There was no limb $\times$ group interaction or effect of group for all measures. Decreased knee measures were seen on the involved limb compared with the uninvolved limb for all subjects, and failed subjects demonstrated larger differences between limbs.

Conclusion: Patients continued to demonstrate biomechanical limb asymmetries 1 year after ACLR, regardless of performance-based measures at 6 months. Early return to activity did not ensure limb symmetry at 1 year.

Clinical Relevance: Gait asymmetries were seen in all subjects 1 year after surgery regardless of status at 6 months. Potentially prolonging athlete's timelines for returning to activity may prove beneficial for a successful return to activity as well as for long-term knee function.

Keywords: return to activity; anterior cruciate ligament; knee flexion angle; gait biomechanics

After anterior cruciate ligament reconstruction (ACLR), there is a strong desire for the athlete to return to high-level activities as quickly as possible. One of the challenges of postoperative management has been to determine a patient's readiness to safely and successfully return to activity, as multiple factors can influence return after ACLR.[24] The research on readiness for return to activity after ACLR shows that 60% of research reports use time from surgery to determine clearance, with 6 months as a common time point.[3] From a clinical perspective, time from reconstruction does not take patient performance into account, which can vary greatly after ACLR.[5] Only 15% of studies report using 1 or 2 objective criteria to determine clearance to return to activity.[3] This lack of clear objective criteria may place the ACL-reconstructed athlete at increased risk for reinjury or suboptimal performance. A battery of tests incorporating performance-based and patient-reported outcomes may be useful in accurately characterizing a patient's readiness to return to activity after ACLR. Hartigan et al[10] found that half of athletes were able to pass these return-to-activity criteria at or before 6 months after ACLR, regardless of preoperative physical therapy intervention. Passing rates improved 1 year after surgery, with more than 75% of athletes passing these return-to-activity criteria, suggesting that large improvements in functional performance occur from 6 months to 1 year after surgery. Objective, measurable criteria are critical to ensure that athletes are fully rehabilitated and their knees are ready to meet the demands of their sport.[3,10]

Movement asymmetries are pervasive following ACL injury and reconstruction, and have been reported to exist up to 2 years after surgery.[19,20] Altered movement patterns have been suggested to be an instigating factor in the initiation and development of osteoarthritis in the ACL-injured knee as well as a risk factor for future reinjury.[4,19,25] The first year after ACLR is a vulnerable time for athletes attempting to return to activity,[14] and the rate for a second knee injury is as high as 49%.[3] Athletes with multiplane biomechanical asymmetries at the hip and knee at the time of return to sport were at least

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3 times more likely to incur a second ACL injury within the next year than those without these asymmetries.[19] Using specific return-to-activity criteria 6 months after ACLR, subjects that passed these criteria demonstrate smaller limb-to-limb differences during gait compared with those who failed, supporting a relationship between clinical and functional measures and biomechanical findings.[6] Large improvements in functional measures from 6 months to 1 year have been reported; however, biomechanical asymmetries have been reported to persist up to 2 years after ACLR. Further classifying ACL-reconstructed patients as passing or failing these return-to-activity criteria will allow us to determine if limb symmetry is maintained from 6 months to 1 year or if differences between limbs deteriorate over time. The purpose of this study was to determine if patients who are ready to return to activity at 6 months based on clinical and functional measures demonstrate symmetrical movement patterns 1 year after ACLR. It is hypothesized that subjects who pass strict return-to-activity criteria at 6 months will continue to demonstrate small limb-to-limb differences during gait at 1 year, while those who fail will continue to demonstrate significant limb-to-limb differences at 1 year.

MATERIALS AND METHODS

A total of 40 athletes who suffered an isolated, unilateral ACL rupture (30 males, 10 females; mean age, 30.3 ± 10 years; range, 20.6-43.9 years) were included in this study. All subjects were regular participants (≥50 h/y) in jumping, cutting, and pivoting activities prior to their injury.[11] All subjects were classified as having poor dynamic knee stability according to a preoperative screening examination.[8] These subjects were part of a larger randomized control trial that evaluated preoperative physical therapy interventions up to 2 years after ACLR. All testing sessions were completed by a licensed physical therapist. This study was approved by the Human Subjects Review Board, and patients provided informed consent.

All subjects underwent hamstring autograft (n = 13; mean age, 27 ± 5.7 years) or soft tissue allograft (n = 27; mean age, 29.7 ± 4.3 years) ACLR by the same orthopaedic surgeon. After reconstruction, all subjects received the same criterion-based postoperative rehabilitation program.[1,17] Clinical and functional data including quadriceps strength and single-legged hop measures, and patient-reported outcomes were collected 6 months and 1 year after surgery.

Quadriceps strength measures were obtained during a maximal voluntary isometric contraction (MVIC)[22] using an electromechancial dynamometer (KIN-COM; Chattanooga Corp, Chattanooga, Tennessee, USA). Subjects were seated in an upright position with their hip and knee at 90° of flexion.[15] Testing was completed initially on the uninvolved limb followed by the involved limb. A ratio of quadriceps index (QI) was calculated as the quotient of the involved quadriceps MVIC to the uninvolved quadriceps MVIC multiplied by 100.

Four single-legged hop measures were completed as previously described[18] with the patient wearing a functional knee brace. Testing was completed on the uninvolved limb followed by the involved limb and consisted of the single hop for distance, crossover hop for distance, triple hop for distance, and 6-minute timed hop tests.[15,18] A limb symmetry index (LSI) was calculated for the distance hops from the mean of 2 measures, as the quotient of involved limb hop distance to the uninvolved limb hop distance multiplied by 100. The 6-minute timed hop was calculated as the quotient of uninvolved limb hop time to the involved limb hop time multiplied by 100. Subjects who did not achieve ≥80% QI or who demonstrated increased knee joint effusion did not complete single-legged hop tests, as this was determined to be unsafe.

Patient-reported outcomes were completed after functional measures. The Knee Outcome Survey–Activities of Daily Living Scale (KOS-ADLS)[13] and the Global Rating Score of Perceived Knee Function (GRS) were used to determine patients' perceptions of their knee function. The KOS-ADLS is a patient-reported measure of current symptoms and how these symptoms affect the knee during activities of daily living. Total scores are expressed as a percentage from 0% to 100%, with higher scores representing better knee function and fewer symptoms.[13] The GRS is a single question that asks patients to rate their current knee function, including sports activities, on a scale from 0 to 100, with 0 being the inability to perform any activity and 100 being the level of knee function prior to injury.[8,13]

A score of ≥90% was required on all test measures (QI, 4 single-legged hop tests plus LSI, KOS-ADLS, GRS) to meet our return-to-activity criteria. Subjects who met these criteria 6 months after ACLR were classified as passing subjects, while those who did not meet these criteria were classified as failing subjects.

Biomechanical variables were collected 1 year after ACLR. Kinematic data were collected with an 8-camera 3-dimensional motion capture system (VICON; Oxford Metrics Ltd, London, England) sampled at 120 Hz. Twenty static retroreflective markers were placed on the pelvis and lower extremities to identify joint centers and segment positions. Kinetic data were collected simultaneously with an embedded force plate (Bertec, Worthington, Ohio, USA) and were also used to determine timing variables during gait. Five walking trials were collected on each limb while the subjects maintained a self-selected walking speed with ±5% variability. Postprocessing of these data was completed using rigid-body analysis and inverse dynamics with custom software programming (Visual3D; C-Motion Inc, Germantown, Maryland, USA; LabVIEW 8.2; National Instruments Corp, Austin, Texas, USA). Kinematic and kinetic variables were low-pass filtered at 6 Hz and 40 Hz, respectively. Initial contact and toe off were determined using

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a 50-N force-plate threshold. All walking trials were normalized to 100% of stance before being averaged for statistical analysis.

All data were analyzed using SPSS version 19.0 (IBM, Armonk, New York, USA). Paired *t* tests were used to determine subject demographics and differences between groups. Knee kinematics and kinetics were evaluated for all subjects 1 year after surgery using a repeated-measures analysis of variance (ANOVA) with a between-subjects factor of return-to-activity status (*pass* or *fail*). Post hoc tests were used to determine where differences between limbs existed. Variables analyzed included knee angles and moments at initial contact, peak knee flexion (PKF), and peak knee extension (PKE). Knee excursions were also measured during weight acceptance (WA; from initial contact to PKF) and during midstance (MS; PKF to PKE). The a priori significance level was set at $P = .05$. Clinically meaningful asymmetries were determined to be present if values met or exceeded minimal clinically important differences (MCIDs). Motion capture data were collected from 10 healthy athletes and used to determine MCIDs between limbs (knee angles $\geq 3°$, knee moments ≥ 0.04 N·m/kg·m) irrespective of statistical significance.[6,7]

RESULTS

Six months after surgery, 20 subjects were classified as passing (10 autograft, 10 allograft) and 20 subjects were classified as failing (3 autograft, 17 allograft). Passing subjects were more than 3 times more likely to have had an autograft (positive likelihood ratio = 3.33) than were failing subjects. Passing subjects demonstrated significantly higher QI, single hop, crossover hop, timed hop, and GRS scores compared with failing subjects at 6 months (Table 1). One year after surgery, 29 subjects were classified as passing (12 improved from 6 months, 17 maintained status) and 11 were classified as failing (3 declined from 6 months, 8 maintained status). Based on classification at 6 months, 1-year functional testing showed significantly increased QI and GRS scores in passing subjects compared with failing subjects (Table 2). No other clinical or functional measures were different between the groups at 1 year. One year after surgery, there was no difference between groups regarding age at the time of surgery ($P = .14$), body mass index (BMI) ($P = .62$), or time from surgery to 1-year testing ($P = .96$) (Table 3). Though not statistically significantly, passing subjects were younger than failing subjects.

There was no significant limb × group interaction ($P > .13$) and no effect of group ($P > .054$) for all kinematic and kinetic measures. There was a main effect of limb for knee flexion angles at PKF ($P = .02$) and PKE ($P = .01$) (Table 4). Knee flexion angles at PKF were smaller on the involved limb compared with the uninvolved limb in both groups (pass, $P = .16$; fail, $P = .07$). The involved limb of all subjects was more flexed at PKE compared with the uninvolved limb (pass, $P = .10$; fail, $P = .051$); however, differences between limbs did not exceed MCID at both PKF and PKE (Table 4, Figure 1).

There was a main effect of limb for knee moments at initial contact ($P = .004$), PKF ($P < .001$), and PKE ($P = .002$) (Table 5). Measures at PKF and PKE exceeded MCID for all subjects. Limb differences were greater in failing subjects at PKF (pass, $P = .002$; fail, $P = .030$) and in passing subjects at PKE (pass, $P = .010$). Differences between limbs at PKE for failing subjects, while exceeding MCID, were not statistically significant (fail, $P = .052$) (Table 5).

There was a main effect of limb for knee excursion measures during WA and MS ($P < .001$) (Table 6). In both groups, knee angles were decreased on the involved limb compared with the uninvolved limb. Differences between limbs during

TABLE 1
Six-Month Functional Measures[a]

	Pass (n = 20)		Fail (n = 20)		
	Mean (SD), %	n	Mean, (SD), %	n	*P* Value
QI	100.34 (7.02)	20	91.32 (15.21)	20	**.02**
Single hop	96.94 (4.70)	20	87.39 (7.97)	19	**<.001**
Crossover hop	97.21 (6.60)	20	91.26 (8.18)	18	**.02**
Triple hop	95.16 (3.84)	20	92.73 (6.75)	18	.17
6-minute timed hop	99.57 (4.86)	20	95.28 (7.21)	18	**.04**
KOS-ADLS	97.51 (1.84)	20	95.64 (3.97)	19	.06
GRS	95.20 (3.64)	20	89.79 (6.21)	19	**.002**

[a]Significant differences appear in boldface. GRS, Global Rating Score; KOS-ADLS, Knee Outcome Survey–Activities of Daily Living Scale; QI, quadriceps index; SD, standard deviation.

TABLE 2
One-Year Functional Measures
Based on 6-Month Classification[a]

	Pass (n = 20)		Fail (n = 20)		
	Mean (SD), %	n	Mean (SD), %	n	*P* Value
QI	103.96 (12.92)	20	92.69 (7.84)	20	**.002**
Single	103.72 (6.69)	19	98.74 (11.73)	19	.145
Cross	103.35 (8.81)	19	97.07 (11.35)	19	.061
Triple	98.59 (4.57)	19	95.49 (7.72)	19	.153
Timed	99.93 (7.20)	19	97.59 (6.82)	19	.356
KOS-ADLS	97.16 (4.12)	20	96.65 (4.39)	20	.707
GRS	97.50 (2.72)	20	93.20 (5.97)	20	**.007**

[a]Significant differences appear in boldface. GRS, Global Rating Score; KOS-ADLS, Knee Outcome Survey–Activities of Daily Living Scale; QI, quadriceps index; SD, standard deviation.

TABLE 3
Subject Demographics[a]

	Pass	Fail	*P* Value
Age, y	27.83 (10.45)	32.74 (10.03)	.14
BMI, kg/m^2	28.45 (4.93)	29.24 (4.91)	.62
Testing, wk	54.20 (3.91)	54.25 (2.81)	.96

[a]Values are expressed as mean (standard deviation). BMI, body mass index.

TABLE 4
Knee Flexion Angles (in Degrees) During Gait[a]

Subjects	PKF, Mean (SD) Involved	PKF, Mean (SD) Uninvolved	Difference	*P* Value	PKE, Mean (SD) Involved	PKE, Mean (SD) Uninvolved	Difference	*P* Value
All	22.66 (8.82)	25.04 (6.52)	2.4	**.02**	4.50 (4.53)	2.58 (4.43)	1.9	**.01**
Pass	21.27 (8.82)	23.36 (6.52)	2.1	.16	4.54 (4.51)	2.82 (5.4)	1.7	.10
Fail	24.05 (10.28)	26.72 (6.36)	2.6	.07	4.47 (4.67)	2.35 (3.31)	2.1	.051

[a]Significant differences appear in boldface. PKE, peak knee extension; PKF, peak knee flexion; SD, standard deviation.

TABLE 5
Knee Moments (in N·m/kg·m) During Gait[a]

Subjects	PKF, Mean (SD) Involved	PKF, Mean (SD) Uninvolved	Difference	*P* Value	PKE, Mean (SD) Involved	PKE, Mean (SD) Uninvolved	Difference	*P* Value
All	0.42 (0.16)	0.50 (0.14)	0.08	**<.001**	0.09 (0.07)	0.14 (0.10)	0.05	**.002**
Pass	0.42 (0.14)	0.49 (0.13)	0.07	**.002**	0.08 (0.07)	0.13 (0.09)	0.05	**.010**
Fail	0.42 (0.18)	0.51 (0.14)	0.09	**.030**	0.10 (0.08)	0.14 (0.11)	0.04	.052

[a]Significant differences appear in boldface. PKE, peak knee extension; PKF, peak knee flexion; SD, standard deviation.

TABLE 6
Knee Excursion Measures[a]

Subjects	Knee Exc WA, Mean (SD) Involved	Knee Exc WA, Mean (SD) Uninvolved	Difference	*P* Value	Knee Exc MS, Mean (SD) Involved	Knee Exc MS, Mean (SD) Uninvolved	Difference	*P* Value
All	14.57 (5.67)	17.16 (4.56)	2.6	**<.001**	18.16 (7.14)	22.46 (5.43)	4.3	**<.001**
Pass	14.41 (5.12)	16.39 (4.08)	2.0	.053	16.74 (5.39)	20.54 (4.07)	3.8	**.002**
Fail	14.73 (6.29)	17.92 (4.98)	3.2	**.001**	19.58 (8.44)	24.37 (6.02)	4.8	**.001**

[a]Significant differences appear in boldface. Exc, excursion; MS, midstance; SD, standard deviation; WA, weight acceptance.

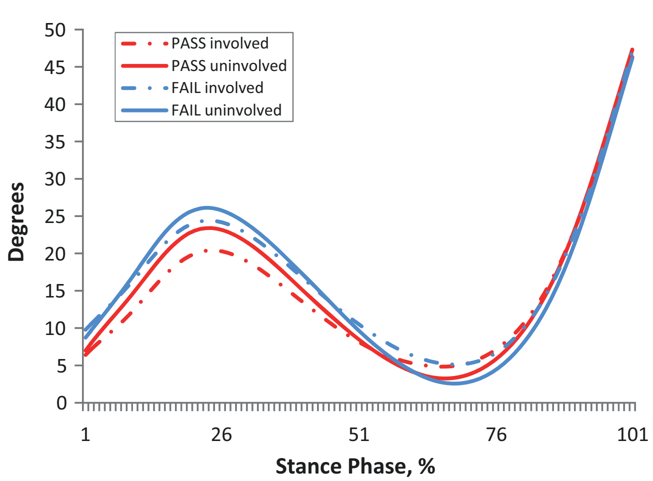

Figure 1. Knee flexion angle during stance.

WA exceeded MCID for failing subjects (pass, $P = .053$; fail, $P = .001$), and all subjects demonstrated MCID during MS, with failing subjects having larger differences between limbs (pass, $P = .002$; fail, $P = .001$) (Table 6, Figure 1).

Mean interlimb differences for knee flexion angles at PKF and PKE did not exceed MCID; however, more than one-half of subjects in both groups demonstrated clinically meaningful asymmetries at PKF (Table 7). Individuals with clinically meaningful asymmetries were further found to demonstrate significantly decreased knee flexion angles of the involved limb compared with the uninvolved limb at PKF ($P = .03$) and PKE ($P = .01$). There was no limb × group interaction (PKF, $P = .74$; PKE, $P = .84$), and no effect of group (PKF, $P = .9$; PKE, $P = .91$) for these knee flexion measures.

DISCUSSION

Gait asymmetries were seen in all subjects 1 year after ACLR, regardless of their return-to-activity status at 6 months. Smaller knee angles, moments, and excursions were seen on the involved limb compared with the uninvolved limb in all subjects at 1 year. Knee angles did not exceed MCIDs for all subjects. Meaningful differences between limbs were seen in all subjects for knee moments at PKF and in passing subjects at PKE. Mean knee excursion measures during WA for failing subjects and MS for all subjects were clinically meaningful based on an interlimb difference of ≥3°. Based on

TABLE 7
Subjects With Differences ≥3 Degrees[a]

Subjects	IC	PKF	PKE
Pass (n = 20)	7 (35)	11 (55)	6 (30)
Fail (n = 20)	6 (32)	11 (55)	10 (50)

[a]Values are expressed as n (%). IC, initial contact; PKE, peak knee extension; PKF, peak knee flexion.

these data, failing subjects continue to demonstrate greater limb-to-limb asymmetries 1 year after surgery; however, passing subjects demonstrated meaningful kinetic limb asymmetries and knee joint excursions during MS.

All subjects demonstrated statistically significant asymmetries for knee flexion angles and moments during gait at 1 year after ACLR. Continued limb asymmetry after ACLR may put these individuals at risk for reinjury in the future, as biomechanical asymmetries have been found to predict reinjury. Paterno et al[19] evaluated biomechanical variables of dynamic landing tasks and postural stability balance measures of individuals at the time that they returned to sport activities. Within the first year of play, 13 of 56 subjects (23%) suffered a second ACL injury, and those who were reinjured demonstrated altered movement patterns at the time of return to sport. Even though our study did not evaluate the same biomechanical tasks, both studies found sagittal plane asymmetries. Biomechanical asymmetries seen in activities of daily living, such as gait, may be magnified during dynamic tasks such as a drop landing.[12] Asymmetries 1 year after surgery may potentially increase the risk for a second ACL injury. Continued tracking of these subjects for reinjury will allow us to further quantify this risk.

Individuals who passed return-to-activity criteria 6 months after surgery demonstrated a less than 10% deficit in quadriceps strength, hop performance measures, and self-reported knee function—all commonly used clinical and functional measures.[10] Six months after surgery, half of subjects met these criteria. To date, these criteria are the most stringent published guidelines to determine return-to-activity readiness.[3] From this study, it was noted that individuals who failed these criteria 6 months after surgery demonstrated meaningful limb-to-limb asymmetries 1 year after surgery. These subjects may benefit from a targeted neuromuscular rehabilitation program that addresses these movement asymmetries and better prepares individuals for a safe and successful return to activity.[26]

Di Stasi et al[6] evaluated return-to-activity status and gait biomechanics 6 months after surgery. A relationship was seen between poor clinical and functional measures and greater limb-to-limb asymmetries. Failing subjects demonstrated greater kinematic and kinetic limb differences at the hip and knee compared to passing subjects, with clinically meaningful differences and moderate to large effect sizes in failing subjects, suggesting that these criteria are useful in discriminating the presence of meaningful gait asymmetries at the same time point. Similar to their findings, based on 6-month functional performance, greater limb differences at 1 year were seen in failing subjects compared with those who passed. The difference between their results and the present study is the lack of discrimination of 6-month clinical and functional measures to identify clinically meaningful limb-to-limb asymmetries at 1 year. Though differences existed in the present study for knee angles, they were not clinically meaningful, and kinetic differences were present for both groups. Overall, the findings of this study support the results of Di Stasi et al,[6] with greater asymmetries in failing subjects 1 year after surgery.

With further evaluation of the raw knee flexion values, the involved limb of passing subjects demonstrated smaller knee flexion angles, moments, and excursions compared with the uninvolved limbs of passing subjects and with both limbs of failing subjects. This pattern is typically seen in ACL-deficient individuals acutely after injury.[21] Rudolph et al[21] found that there was a difference between limbs of ACL-deficient patients with poor dynamic knee stability compared with ACL-deficient patients with good dynamic knee stability and control subjects. The involved limb of ACL-deficient patients with poor dynamic knee stability demonstrated significantly less knee flexion during gait compared with their uninjured limb and with both limbs of ACL-deficit patients with good dynamic knee stability as well as controls, a finding that they described as a stiffening strategy. They also found asymmetrical kinetic measures between limbs of ACL-deficient patients, with smaller moments on the involved limb. It has been suggested that truncated movement patterns result in altered loading patterns during gait. Failure to resolve this altered loading and stiffening strategy after surgery may be a potential mechanism for the progression of knee joint degeneration and poor long-term knee function.[9]

Despite mean knee flexion angles at PKF failing to exceed MCID, more than half of subjects demonstrated clinically meaningful asymmetries. Return-to-activity status was not able to discriminate individuals with knee angle differences ≥3° between limbs. Limb asymmetries during gait may become more pronounced during participation in athletic activities and may potentially predispose an athlete to a greater risk for reinjury.[12,19] Persistent movement asymmetries in both the frontal and sagittal planes during walking, running, and jumping activities have been suggested as a risk factor for long-term detrimental effects on the knee joint and have the potential to contribute to joint degeneration.[2,4,23,25] This subgroup of patients who fail return-to-activity criteria may require a prolonged period of rehabilitation prior to returning to activity to normalize movement patterns to ensure successful return to activity and long-term knee joint function and health.[12]

Several limitations need to be addressed in this study. A sampling bias toward male subjects was present in this study resulting in unequal groups (30 men, 10 women). While females are more likely to tear their ACL, a greater number of males participate in more high-risk activities.[16] Potential differences between sexes may not have been accounted for with this unequal distribution. Despite statistical significance, the mean knee flexion values were not clinically meaningful; however, more than half of subjects had ≥3° differences between limbs at PKF. Clinical and functional data regarding athletic participation for these subjects were not thoroughly evaluated 1 year after surgery. It is possible that not all subjects were participating in athletic activities at the time of 1-year follow-up testing.

CONCLUSION

Altered movement patterns were present in this cohort 1 year after ACLR in subjects who both passed and failed return-to-activity criteria, with greater differences between limbs in failing subjects. Failure to resolve these altered movement patterns may predispose a higher risk for reinjury as well as impact long-term knee joint health.[12,19,25] Determining safe return-to-activity criteria is currently not standardized among clinicians[3]; however, it is evident from this work that time-based criteria may not be appropriate since many patients continue to demonstrate functional deficits at 6 months and biomechanical asymmetries at 1 year. Early clearance to return to activities may be related to poor outcomes after surgery. Further work is needed to establish clinical and functional measures along with biomechanical criteria as a means to determine readiness to return to activities in an effort to allow a more safe and successful return.

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