Low-Intensity Blood Flow Restriction Training as a Preoperative Rehabilitative Modality to Improve Postoperative Outcomes for Anterior Cruciate Ligament Reconstruction

by

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ABSTRACT

One of the long-standing issues that has arisen in the sports medicine field is identifying the ideal methodology to optimize recovery following anterior cruciate ligament reconstruction (ACLR). The perioperative period for ACLR is notoriously heterogeneous in nature as it consists of many variables that can impact surgical outcomes. While there has been extensive literature published regarding the efficacy of various recovery and rehabilitation topics, it has been widely acknowledged that certain modalities within the field of ACLR rehabilitation need further high-quality evidence to support their use in clinical practice, such as blood flow restriction (BFR) training. BFR training involves the application of a tourniquet-like cuff to the proximal aspect of a limb prior to exercise; the cuff is inflated so that it occludes venous flow but allows arterial inflow. BFR is usually combined with low-intensity (LI) resistance training, with resistance as low as 20% of one-repetition maximum (1RM). LI-BFR has been used as an emerging clinical modality to combat postoperative atrophy of the quadriceps muscles for those who have undergone ACLR, as these individuals cannot safely tolerate high muscular tension exercise after surgery. Impairments of the quadriceps are the major cause of poor functional status of patients following an otherwise successful ACLR procedure; however, these impairments can be mitigated with preoperative rehabilitation done before surgery. It was hypothesized that the use of a preoperative LI-BFR training protocol could help improve postoperative outcomes following ACLR; primarily, strength and hypertrophy of the quadriceps. When compared with a SHAM control group, subjects who were randomized to a BFR intervention group made greater preoperative strength gains in the quadriceps and recovered quadriceps mass at an earlier timepoint than that of the SHAM group after

surgery; however, the gains made in strength were not able to be maintained in the 8-week postoperative period. While these results do not support the use of LI-BFR from the short-term perspective after ACLR, follow-up data will be used to investigate trends in re-injury and return to sport rates to evaluate the efficacy of the use of LI-BFR from a long-term perspective.

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CHAPTER 1

INTRODUCTION

MOTIVATION

Injuries to the anterior cruciate ligament (ACL) are an epidemic among adolescents, especially those who are active in sports that involve contact and frequent cutting motions. Over 200,000 ACL injuries occur annually in the United States, with 1 in every 60 adolescent athletes suffering an ACL injury at some point in their sports career.(Queen, 2017) Of those 200,000 ACL injuries, it is reported that approximately 94% will undergo surgical reconstruction, and that most of the population who undergoes ACL reconstruction (ACLR) are between the ages of 15 and 30.(Queen, 2017) As a result of this, ACLRs are among the most frequently performed orthopedic surgical procedures in the United States.(Buller et al., 2014)

Although it is not uncommon for orthopedic procedures to require significant rehabilitation, the recovery process for ACLR is uniquely heterogeneous and complex, and it is reported that only 24% of athletes are able to return to their pre-injury levels of activity after undergoing this procedure.(Ardern et al., 2011) The risk of experiencing a reconstructive surgery is high with approximately 29% suffering a secondary tear.(Queen, 2017) This risk is increased by movement and loading asymmetry between the surgical and nonsurgical limbs that occurs as a result of muscular atrophy and functional deficits after surgery.(Queen, 2017) Further, in addition to the extra financial burden placed on the healthcare system by the short- and long-term disability that results with each subsequent ACL tear, approximately 45% of those who undergo ACLR develop knee osteoarthritis within 10 years of reconstruction surgery.(Queen, 2017)

There are a number of variables that play a role in determining whether outcomes of ACLR and the subsequent rehabilitation period are successful; however, there is a lack of consensus regarding the ideal perioperative and rehabilitative approach. The operative timeline spans from the preoperative period until the patient returns to their activity or sport of choice, and even beyond that due to the increased risk of reinjury. Some aspects of this timeline are highly controversial; most notable is the controversy surrounding what is considered the "ideal" time for someone to return to sport following ACLR. For example, it is not uncommon for clinicians to utilize time-based criteria to determine when a patient is ready to return to sport; that is, the patient must simply wait a given amount of time after their surgery before returning to their sport without any restrictions. For clinicians who utilize time-based criteria, most typically require that their patients wait 9 months after surgery in order to reduce their risk of reinjury, based on results observed in literature.(Grindem et al., 2016) However, this criteria has recently been revisited as some literature suggests that athletes should wait 24 months after surgery to return to sport in order to mitigate the risk of reinjury based on biological and functional considerations.(Nagelli & Hewett, 2017) Other clinicians do not take this approach; instead, they utilize function-based criteria, which relies on functional and strength-based testing done in a clinical setting to measure any muscular deficits that may persist after ACLR. Most clinicians utilize both time- and function-based criteria and require their patients to reach postoperative time-based milestones while achieving specific functional and strength goals. This is just one example of the complex nature of clinical decision-making associated with ACLR recovery; there are many others that arise during the recovery and rehabilitative processes.

This issue is further complicated by the volume of literature existing on the topic as well as the ever-changing nature of clinical practice guidelines and whether those are implemented in clinical settings. Literature searches on the topic of ACLR recovery and rehabilitation often produce overwhelming amounts of evidence, and this evidence spans a range of quality from well-designed randomized control trials and meta-analyses to case studies that do not contribute novel information to the pool of literature. This emphasizes the need for high-quality research studies related to this topic, which can help to resolve some of the controversies surrounding ACLR recovery and rehabilitation.

SPECIFIC AIMS

The objective of this dissertation is to contribute a body of high-quality, level-I and -II evidence consisting of validated methodologies and clinically relevant outcomes to the existing pool of literature and evidence regarding ACLR recovery and rehabilitation. This will provide guidance for clinical decision making in order to optimize surgical outcomes of ACLR. We will compile a review of the most recent high-quality evidence to create a framework of the latest trends in ACLR recovery and rehabilitation. Then, we will compare these trends to those currently in clinical practice among orthopedic surgeons across the United States. Finally, we will assess the efficacy of a combination of the rehabilitative modalities presented in the systematic review to evaluate their impact on various surgical outcomes of ACLR.

Aim 1: *Compare current clinical trends in ACLR recovery and rehabilitation to the recommendations made in level-I and -II evidence published between 2012 and 2020.*

Hypothesis 1a: Clinical trends among orthopedic surgeons with regards to acute postoperative recovery and postoperative rehabilitation for ACLR will be consistent with the evidence published in literature.

Hypothesis 1b: The consensus among orthopedic surgeons regarding the use of technology to assist in determination of readiness to return to sport following ACLR is that while it can be highly beneficial, it is not commonly used in clinical practice due to low accessibility as a result of various barriers.

Aim 2: *Investigate the efficacy of low-intensity blood flow restriction training as a preoperative rehabilitative modality to improve surgical outcomes following ACLR.*

Hypothesis 2a: Postoperative muscular strength of the quadriceps femoris as measured with a handheld dynamometer and standardized leg press test and postoperative muscular hypertrophy of the quadriceps femoris as measured with musculoskeletal ultrasound will be greater in a group of subjects who have undergone a two-week course of preoperative low-intensity blood flow restriction training than that of a group of subjects who received a sham intervention while undergoing the same preoperative low-intensity training.

Hypothesis 2b: Postoperative gait speed and postural stability will be greater in a group of subjects who have undergone a two-week course of preoperative low-intensity blood flow restriction training than that of a group of subjects who received a sham intervention while undergoing the same preoperative low-intensity training.

ORGANIZATION

The chapters of this dissertation are organized in such a manner that the scope of each topic narrows as the dissertation progresses while also building off the previous

chapters. Chapter 2 provides an in-depth summary of background information related to ACL injuries. Chapter 3 is a systematic review of all level-I and II evidence published between 2012 and 2020 regarding recovery and rehabilitation modalities for ACLR. Chapter 4 reports on the results of a survey collected from orthopedic surgeons across the United States regarding their clinical practice patterns for ACLR recovery and reconstruction; these results are then compared with the findings presented in Chapter 3. Chapters 5 and 6 focus on a combination of two modalities that are presented in Chapter 3: supervised rehabilitation and blood flow restriction (BFR) training. These modalities were combined to develop a protocol for low-intensity BFR (LI-BFR) training that was employed during pre-operative rehabilitation before ACLR; this protocol was then implemented into a double-blinded, randomized, sham-controlled clinical trial. Chapters 5 reports on the results of this clinical trial as they pertain to the effects of the LI-BFR intervention on muscular strength and muscular hypertrophy as well as gait speed and postural stability of the quadriceps femoris.

CHAPTER 2

BACKGROUND

ANATOMY OF THE KNEE

The knee joint consists of two articulations: the patellofemoral articulation and the tibiofemoral articulation.(Flandry & Hommel, 2011) Within these articulations are bony, ligamentous, and soft tissue structures whose biomechanics govern the joint's stability. Because the primary focus of this dissertation is the anterior cruciate ligament (ACL), it is important to understand the arrangement as well as the primary function of the cruciate and collateral ligaments within the knee joint. Figure 2-1 shows the major soft tissue and bony structures that comprise the knee joint.

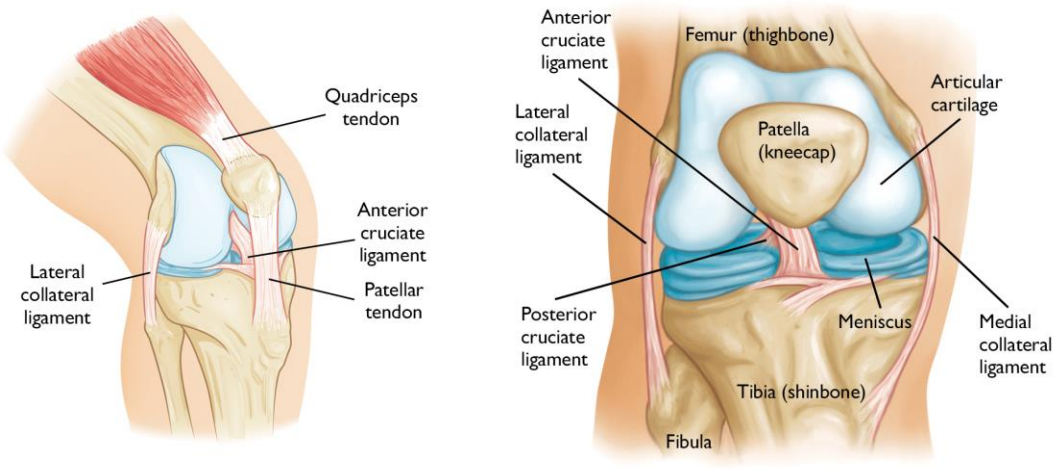

*Figure 2-1: Anatomy of the knee featuring the cruciate ligaments, collateral ligaments, and other bony and soft tissue structures(*Common Knee Injuries - OrthoInfo - AAOS, *n.d.).*

Cruciate Ligaments

The proximal attachment of the ACL is the posterolateral surface of the intercondylar notch of the femur and its distal attachment is the intercondylar eminence of the tibia.(Flandry & Hommel, 2011) It consists of two bundles of fibers: an anteromedial and a posterolateral bundle(Flandry & Hommel, 2011); the anteromedial bundle is taut in

flexion and the posterolateral bundle is taut in extension.(Hassebrock et al., 2020) Both bundles of the ACL can be seen in Figure 2-2. The ACL primarily prevents anterior translation of the tibia on the femur as well as helps preserve normal biomechanics of the knee to prevent meniscal damage.(Hassebrock et al., 2020) Substance tears of the ACL usually disrupt its blood supply permanently, which leads to poor healing potential and is a main reason why reconstruction is the preferred method of surgical intervention over repair.(Flandry & Hommel, 2011)

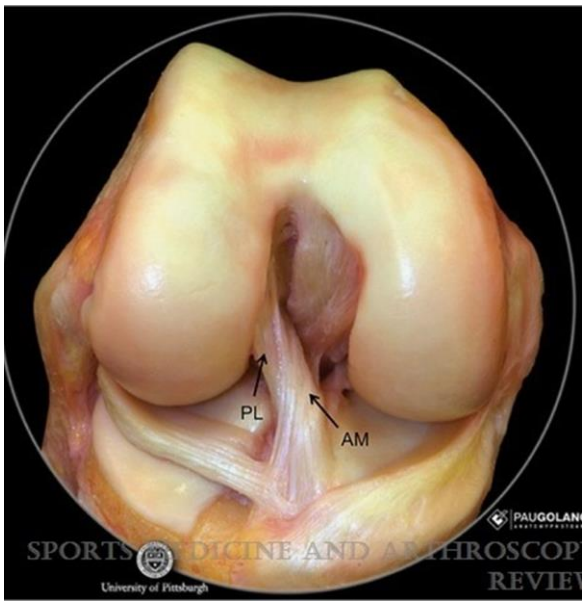

Figure 2-2: Image of knee joint in full flexion to show the anteromedial (AM) and posterolateral (PL) bundles of the ACL(Hassebrock et al., 2020).

The second cruciate ligament is the posterior cruciate ligament (PCL). Its origin is the medial surface of the intercondylar notch of the femur and its insertion is the fovea centralis of the proximal tibia.(Flandry & Hommel, 2011) Like the ACL, the PCL consists of two bundles: a posteromedial bundle and an anterolateral bundle(Flandry & Hommel, 2011); the anterolateral bundle is taut in flexion and the posteromedial bundle is taut in extension.(Hassebrock et al., 2020) The PCL prevents posterior translation of the tibia

relative to the femur(Hassebrock et al., 2020), and its blood supply is not typically lost permanently with injury.(Flandry & Hommel, 2011)

Collateral Ligaments

The medial collateral ligament (MCL) is contained within both the middle and deep layers of the medial compartment of the knee; the superficial MCL (sMCL) can be found in the middle layer and the deep MCL (dMCL) can be found in the deep layer.(Hassebrock et al., 2020) The MCL originates proximally from the posterior aspect of the medial femoral epicondyle and attaches distally along the proximal medial aspect of the tibia.(Andrews et al., 2017) The primary function of the sMCL is to serve as a static stabilizer to valgus stress on the knee and the dMCL restrains anterior translation of the tibia while also providing minor static stabilization to valgus stress on the knee.(Andrews et al., 2017)

The lateral collateral ligament (LCL) is contained within the deep layer of the lateral compartment of the knee.(Hassebrock et al., 2020) It originates proximal and posterior to the lateral epicondyle of the femur and attaches anterior to the lateral aspect of the fibular head.(Grawe et al., 2018) The primary function of the LCL is to resist varus forces and its secondary function is to resist tibial external rotation along with the popliteofibular ligament (PFL).(Grawe et al., 2018)

Menisci

Along with the aforementioned ligaments, the knee joint consists of two load-bearing cartilaginous structures known as the medial and lateral menisci. The menisci are located between the concave femoral condyles and the tibial plateau and enable articulation between these two surfaces.(Fox et al., 2015) The menisci are responsible for various biomechanical functions including but not limited to load transmission, shock absorption,

stability, nutrition, joint lubrication, and proprioception.(Fox et al., 2015) Meniscal injuries often accompany injuries to the ACL and are classified by the shape of the tear: vertical longitudinal, radial, horizontal, complex/degenerative, or bucket handle.(Fox et al., 2015)

Quadriceps Femoris

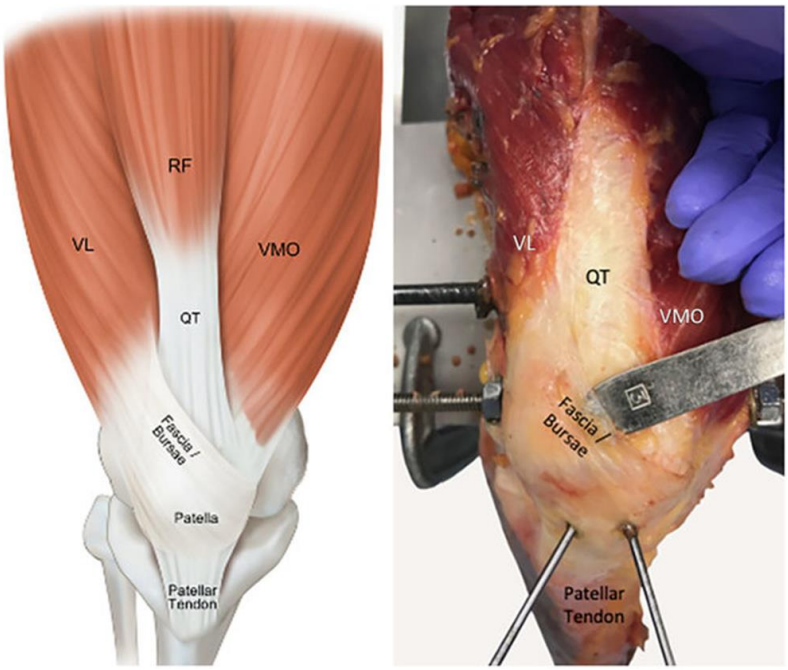

Figure 2-3: Anatomy of the quadriceps femoris and its components: vastus lateralis (VL), rectus femoris (RF), vastus medialis oblique (VMO), and the quadriceps tendon (QT)(Strauss et al., 2021).

The quadriceps femoris muscles comprise the anterior muscles of the thigh and consist of four muscle heads: the rectus femoris (RF), vastus lateralis (VL), vastus medialis (VM), and vastus intermedius (VI). These components can be seen in Figure 2-3. The rectus femoris is responsible for hip flexion with its attachment on the anterior inferior iliac spine while its synergistic action with the remaining three muscle heads are responsible for knee extension.(Bordoni & Varacallo, 2021) The quadriceps' proprioceptive afferent nerve fibers aid in the maintenance of appropriate posture and the muscle as a whole is responsible for actions such as gait, climbing stairs, and standing up from a seated position.(Bordoni & Varacallo, 2021)

Following ACLR, the quadriceps muscle atrophies quickly and loses its strength,(Ohta et al., 2003) and these impairments often persist for several months following surgery and can be the major cause of poor functional status following an otherwise successful ACLR procedure.(Žargi et al., 2018) Additionally, muscular strength and endurance deficits contribute to altered movement patterns of the injured limb and thus increase the risk of early onset knee osteoarthritis.(Žargi et al., 2018) Conversely, greater quadriceps strength has been linked to a lower risk of symptomatic knee osteoarthritis and reduced joint space narrowing as well as reduced pain and positive changes in physical function.(Hughes et al., 2017) Therefore, the primary goal of postoperative rehabilitation is to restore normal muscle activation and function as soon as possible.(Žargi et al., 2018)

MECHANISMS AND CLINICAL PRESENTATION OF ACL INJURY

Mechanism of Injury

The ACL is mechanically susceptible to injury when it is subject to excessive tensile force.(Yu & Garrett, 2007) These types of forces are either the result of contact with another person or can occur when a person themselves generates great forces or moments at the knee that load the ACL excessively.(Yu & Garrett, 2007) Direct contact injuries are the result of direct bodily contact by another individual to the involved extremity while indirect contact involves contact by another individual to any body part besides the involved extremity.(Montgomery et al., 2018) Contact injuries are prevalent in sports where bodily collisions are usually unavoidable such as American football, soccer, basketball, and rugby. Non-contact injuries are defined as injuries that occur without any bodily contact with another individual(Montgomery et al., 2018) and usually occur in sports that involve sudden deceleration, landing, pivoting, and lateral cutting.(Yu & Garrett, 2007)

Clinical Presentation

Accurate diagnosis of an ACL injury or rupture is typically dependent on a combination of evidence gathered through collection of patient history, clinical examination findings, and imaging.(Filbay & Grindem, 2019) The three key factors of patient history that should lead to a suspected ACL rupture are an injury mechanism that involves deceleration or acceleration combined with knee valgus load(Hewett et al., 2005), report of hearing or feeling a "pop" at the time of injury, or hemarthrosis (bleeding into the joint) within two hours of the injury.(Filbay & Grindem, 2019) Additionally, there are several clinical tests that can be performed to detect ACL injuries: the anterior drawer test, the Lachman test, and the pivot shift test.(Benjaminse et al., 2006) The anterior drawer test evaluates anterior translation of the tibia relative to the femur(Coffey & Bordoni, 2021) and has good sensitivity (92%) and specificity (91%) in chronic conditions, but not in acute conditions due to physiological changes within the knee joint such as reactive synovitis and muscular guarding.(Benjaminse et al., 2006) The Lachman test is a variation of the anterior drawer test with the knee flexed to 30 degrees instead of 90 degrees(Coffey & Bordoni, 2021) and is considered to be the most accurate clinical diagnostic test with a pooled reported sensitivity of 85% and specificity of 94%.(Benjaminse et al., 2006) While the anterior drawer and Lachman tests only evaluate anterior translation, the pivot shift test is able to assess the rotatory component of knee laxity.(Ayeni et al., 2012) The pivot shift test demonstrates excellent specificity at 98%; however, it has poor sensitivity at 32% and 40% in acute and chronic conditions, respectively.(Benjaminse et al., 2006)

In addition to these examination findings, magnetic resonance imaging (MRI) is a valuable imaging modality that can be used to confirm suspected ACL ruptures along with

any concomitant injuries that may be more difficult to diagnose clinically.(Filbay & Grindem, 2019) MRI's diagnostic accuracy is comparable with that of the Lachman test.(Van Dyck et al., 2013)

Objectives of Injury Management

The consequences of an ACL rupture are multifaceted and can be life-altering, particularly for individuals who lead active lifestyles. Knee pain, limitations on recreational activities, and impaired quality of life can persist for more than five years after sustaining an ACL injury.(Filbay et al., 2014, 2015) Additionally, high re-injury rates are associated with surgically reconstructed ACLs,(Webster & Feller, 2016) and a fear of re-injury could be a contributing factor in why many individuals do not return to their pre-injury levels of sport or activity.(Ardern et al., 2013) These factors all collectively have a detrimental impact on quality of life for those who sustain injuries to the ACL, and highlight the importance of identification of modifiable risk factors of poor outcomes so that personalized management strategies can be implemented to optimize long-term outcomes and quality of life.(Filbay & Grindem, 2019) Therefore, the primary objectives of injury management are restoration of knee function, addressing psychological barriers to participation in activities, prevention of further injury and osteoarthritis of the knee joint, and optimization of long-term quality of life.(Filbay & Grindem, 2019)

SURGICAL RECONSTRUCTION OF THE ACL

Graft Choices

The most widely utilized methods for surgical management of ACL injury is the anatomic single-bundle ACL reconstruction (ACLR) techniques.(Schreiber et al., 2010) As part of this technique, the ACL is reconstructed using a graft harvested from either the patient themselves (autograft) or from a cadaveric donor (allograft).(Lin et al., 2020)

Autografts are usually the preferred graft of choice from a biological healing perspective because they consist of viable autogenous tissue which maximizes the speed and likelihood of the graft's biological integration and avoids the risk of disease transmission.(Lin et al., 2020) The most commonly used autografts are bone-patellar tendon-bone (BTB) and hamstring tendon grafts, followed by quadriceps tendon grafts.(Mehran et al., 2015)

Bone-Patellar Tendon-Bone (BTB) Autograft

The harvest site of the BTB autograft is the central third of the patellar tendon and includes bone plugs on either end; one from the inferior aspect of the patella and the other from the tibial tubercle.(Mehran et al., 2015) The bone plugs are inserted into surgically created tunnels and are biologically integrated at these sites via creeping substitution.(Mehran et al., 2015; West & Harner, 2005) This bone-bone interface has been proven to be stronger and more reliable than healing at soft tissue-bone interfaces, with a quicker graft integration (eight weeks versus twelve weeks, respectively) as well.(Mehran et al., 2015; West & Harner, 2005) The biomechanical properties of a BTB autograft are also most similar to that of the native ACL; however, its cross-sectional area is smaller than that of the native ligament.(Mehran et al., 2015; West & Harner, 2005) While these functional and mechanical properties of a BTB autograft make it a preferential choice for use in ACLR, its primary disadvantages are increased incidences of anterior knee pain following surgery as well as an increased risk of patellar fracture or, rarely, rupture of the patella tendon at the harvest site.(Mehran et al., 2015)

Hamstring Tendon Autograft

Hamstring tendon autografts consist of the semitendinosus and gracilis tendons, and are harvested from the anteromedial side of the knee.(Mehran et al., 2015) Unlike BTB autografts, hamstring tendon autografts do not have bone plugs attached to their ends;

rather, the graft is prepared with sutures placed at both ends and the surgeon's choice of fixation hardware at both the femoral and tibial fixation sites. Types of fixation hardware include but are not limited to screws, posts, and titanium buttons. Instead of another titanium button, an interference screw is used to fixate the graft at the tibial site. Hamstring tendon autografts have exceptional biomechanical properties greater than that of both a BTB autograft and the native ACL; its ultimate tensile load, stiffness, and cross-sectional area are all greater than the latter options.(Mehran et al., 2015) Disadvantages of hamstring tendon autografts include but are not limited to hamstring weakness, potential tunnel widening at the femoral and tibial fixation sites, and increased knee laxity in patients who are considered ligamentously lax.(Mehran et al., 2015)

Quadriceps Tendon Autografts

The quadriceps tendon has recently emerged as an option for ACLR grafts. These grafts are harvested from the central third of the quadriceps tendon and the surgeon may choose to incorporate a bone plug from the superior aspect of the patella along with the tendon graft.(Mehran et al., 2015) Benefits of utilizing a quadriceps tendon graft include its greater cross-sectional area and the potential for reduced prevalence of knee pain and patellar fracture; however, due to the relatively new nature of this graft type, there is limited supporting evidence and a need for clinical studies focused on quadriceps tendons grafts in order to validate its advantages and disadvantages for use in ACLR.

Allografts

Allografts are harvested from the soft tissue of cadaveric donors and are typically taken from either the Achilles tendon, the tibialis posterior tendon, or the tibialis anterior tendon.(Mehran et al., 2015) They are typically reserved for use in patients who are older and less active as well as patients who have substantial tissue laxity or connective tissue

disorders.(Mehran et al., 2015) Benefits of using allografts include decreased postoperative pain and surgical time due to the absence of a need to harvest a graft from the patient's own soft tissue; however, disadvantages associated with allografts include but are not limited to delayed biological healing, greater financial cost, higher failure rates in younger populations, and the possible risk of disease transmission.(Mehran et al., 2015) Allografts are prepared and fixated using methods similar to that of hamstring tendon autografts.

Surgical Procedure

The surgical procedure for reconstructing a ruptured ACL is done via arthroscopy, a minimally invasive method that utilizes special equipment to visualize the knee joint space and repair structures. In arthroscopic procedures of the knee, small incisions called portals are made anteromedially and anterolaterally just above the joint line and above the meniscus.(Schreiber et al., 2010) A fiber-optic camera attached to the end of a scope is inserted into the anterolateral portal, and the anteromedial portal is used for working equipment that can grab, cut, or remove materials from within the joint space.

After adequate induction of anesthesia and before the procedure begins, the surgeon performs an exam under anesthesia which includes knee range of motion and effusion assessments as well as anterior drawer testing, Lachman testing, and pivot shift testing to assess laxity of the knee joint. Once the patient is prepped and draped and the surgical site and procedure have been confirmed by all involved parties, the surgeon begins the first portion of the ACLR. The arthroscopic portals are made, and equipment is inserted into the portals. The surgeon is then able to visualize the knee joint space and confirm the ACL injury as well as check for any concomitant injury to other structures.(Chhabra, n.d.-b) Once an intraoperative diagnosis of ACL rupture has been confirmed, the surgeon will

proceed with the graft harvest if the patient has elected to use an autograft.(Chhabra, n.d.-b) Otherwise, if the patient has elected to use an allograft, the graft harvest is not necessary and will not be performed. Once the graft has been obtained, it is prepared by the surgeon's assistant for use in the reconstruction. Excess muscle tissue is removed from the graft if present for hamstring grafts; bone plugs for BTB and quad tendon autografts are shaped and the ends are whip-stitched if no bone plugs are already attached.(Chhabra, n.d.-b) While the assistant prepares the graft, the surgeon proceeds with intra-articular preparation.

With the knee in full extension, the patellofemoral joint is visualized; this allows the surgeon to diagnose any incidences of patellofemoral tilt, subluxation, or chondral pathology.(Chhabra, n.d.-b) The scope is then advanced to the suprapatellar pouch as well as the medial and lateral gutters, where the surgeon checks for any synovitis or loose bodies.(Chhabra, n.d.-b) Next, the knee is placed in the figure-of-four position so that the lateral compartment can be visualized. In this position, the lateral meniscus and lateral chondral surfaces can be probed to diagnose any meniscal or chondral pathology.(Chhabra, n.d.-b) This presents an opportunity for the surgeon to perform a lateral meniscectomy or meniscus repair, if warranted. Otherwise, the knee is placed into slight flexion with valgus stress on the joint so that the aforementioned sequence can be repeated for the medial compartment.(Chhabra, n.d.-b) Once this is complete, attention is turned to the intercondylar notch.

An arthroscopic shaver is inserted into the intercondylar notch and the stump of the native ACL is removed.(Chhabra, n.d.-b) The surgeon uses either a medial portal technique or transtibial technique to drill the femoral tunnel and excess bone debris is removed; once the tunnel is cleared, a passing suture is pulled through.(Chhabra, n.d.-b) Next, the intra-

and extra-articular landmarks for the tibial tunnel are visualized. Intra-articular landmarks include the spines of the tibial stump of the native ACL, PCL, and the anterior lateral meniscus; extra-articular landmarks include the midportion between the tibial tubercle and the posteromedial border of the tibia.(Chhabra, n.d.-b) The tibial tunnel is drilled with respect to these landmarks and the graft is pulled through the tunnel. Once the graft is pulled through, axial tension is placed on the tibial side of the graft to confirm that there is adequate femoral fixation and C-arm fluoroscopy is used to confirm may be used to confirm button position on the femoral cortex.(Chhabra, n.d.-b) The knee is then cycled through full range of motion to confirm femoral fixation and graft tension, and the surgeon's choice of hardware is placed for tibial fixation with the leg in slight flexion and a posterior drawer placed on the knee.(Chhabra, n.d.-b) Once the graft is fixated on both ends, it is visualized with the arthroscopic camera and checked for placement, tension, range of motion, stability, and laxity.(Chhabra, n.d.-b) The knee is then flushed with irrigation, arthroscopic equipment is removed, and the incisions are closed with nylon sutures.

POSTOPERATIVE REHABILITATION

Postoperative rehabilitation protocols are typically phased; that is, patients must achieve certain time- and/or function-based criteria before they are permitted to advance to the next phase of their rehabilitation. These protocols can vary greatly between orthopedic practices; therefore, this section will be based on the Phased Rehabilitation Guidelines developed by Dr. Anikar Chhabra, MD, MS at the Mayo Clinic Sports Medicine Center in Tempe, AZ (Appendix A).(Chhabra, n.d.-a) These guidelines allow for a general progression back into activities of daily living with five distinct rehabilitative phases to be

completed under the supervision of a physical therapist and/or athletic trainer. Each phase consists of goals, bracing guidelines, and therapeutic exercise recommendations as well as criteria that must be achieved in order to advance to the next phase.

Phase I typically begins one week after ACLR and lasts until approximately six weeks after surgery.(Chhabra, n.d.-a) The goals of phase I are to protect graft fixation, achieve full knee range of motion, reduce pain and edema, normalize balance and proprioception, begin and enhance normalization of quadriceps recruitment, and educate the patient on rehabilitation progression.(Chhabra, n.d.-a) The patient's brace remains locked in extension for ambulation and sleeping for the first week after surgery, and then may be unlocked for all activity and removed for sleeping from post-op weeks 1 to 6.(Chhabra, n.d.-a) Therapeutic exercise recommendations for this phase include those that facilitate improvements in range of motion as well as recruitment of the quadriceps muscles such as passive extension, heel slides, straight leg raises, and quadriceps sets.(Chhabra, n.d.-a) In order to advance to Phase II, patients must exhibit a good quadriceps set, perform a straight leg raise without extension lag, achieve 90 degrees of flexion and full extension, and must be free from any signs of active inflammation.(Chhabra, n.d.-a)

Phase II begins approximately six weeks after surgery and typically lasts about four weeks.(Chhabra, n.d.-a) Goals of this phase include restoration of normal gait patterns, maintenance of full extension, progression of flexion, continued protection of graft fixation, and initiation of open kinetic chain hamstring exercises.(Chhabra, n.d.-a) Use of the brace and crutches are allowed to be discontinued once the patient exhibits full extension, straight leg raise without extension lag, and a non-antalgic gait pattern.(Chhabra, n.d.-a) Therapeutic exercise recommendations for this phase include stationary biking to

increase range of motion, wall slides to progress to mini-squats, and closed chain terminal knee extension with resistance bands.(Chhabra, n.d.-a)

Phase III begins approximately ten weeks after surgery and lasts until approximately five months post-op. Goals to be achieved in this phase include full range of motion, avoidance of overstressing the graft fixation, protection of the patellofemoral joint, and improved strength, endurance, and proprioception of the lower extremity to prepare for functional activities.(Chhabra, n.d.-a) Therapeutic exercise recommendations for phase III become more broad, as the patient should continue flexibility exercises as appropriate and advance their closed kinetic chain strengthening program as per the physical therapist's discretion.(Chhabra, n.d.-a) The patient may advance to phase IV once they have achieved full, pain-free range of motion with no evidence of patellofemoral joint irritation and strength and proprioception at approximately 70% of the uninvolved leg.(Chhabra, n.d.-a) Physician clearance is also needed to initiate advanced closed kinetic chain exercises and functional progression.(Chhabra, n.d.-a)

Phase IV begins approximately five months after surgery and its duration is typically four months.(Chhabra, n.d.-a) The goal of this phase is to progress strength, power, and proprioception to prepare for a return to unrestricted functional activities.(Chhabra, n.d.-a) The patient is allowed to continue and progress their flexibility and strengthening program, with the initiation of a plyometric program as appropriate to their functional goals.(Chhabra, n.d.-a) Sport-specific activities may also be initiated under the supervision of an athletic trainer or physical therapist at 6-7 months.(Chhabra, n.d.-a) The patient may be progressed to the final phase, phase V, when they are free from any patellofemoral or soft tissue complaints and have achieved the necessary joint range of

motion, strength, endurance, and proprioception as well as undergone education with regards to any possible limitations.(Chhabra, n.d.-a) It is within this phase that the patient may gradually return to their sports participation while continuing to maintain their exercise program for strength and endurance.(Chhabra, n.d.-a)

BLOOD FLOW RESTRICTION TRAINING

Blood flow restriction (BFR) training involves the application of a tourniquet-like cuff to the proximal aspect of a limb prior to exercise; the cuff is tightened or inflated so that it occludes venous flow but allows arterial inflow.(Vanwye et al., 2017) BFR is often combined with low-load (LL) or low intensity (LI) resistance training, with resistance as low as 20% of 1-RM (one rep maximum). BFR combined with LI resistance training can be seen as an emerging clinical modality for individuals who cannot safely tolerate high muscular tension exercise or those who cannot produce volitional muscle activity,(Vanwye et al., 2017) as well as a progressive clinical rehab tool in the process of return to high-load (HL) exercise.(Hughes et al., 2017) The American College of Sports Medicine (ACSM) recommends that resistance training be done at 70% of 1-RM in order to make improvements in muscular strength and hypertrophy; however, this is not always possible for certain populations including those who are recovering from injury, those who are in a postoperative state of recovery, and those with musculoskeletal disorders.(Loenneke et al., 2012)

In the case of patients who are postoperative, the primary goal of post-op rehabilitation is to restore normal muscle activation and function as soon as possible,(Žargi et al., 2018) which is especially critical for patients who have undergone ACLR. Atrophy of the muscles surrounding the knee, especially the knee extensor muscle, accompanied by

reduced muscular strength, is seen during the early post-op period of ACLR.(Ohta et al., 2003) Considerable impairments of the quadriceps often persist for several months following surgery, and are the major cause of poor functional status of patients following an otherwise successful ACLR procedure.(Žargi et al., 2018) Additionally, deficits in muscle strength and endurance contribute to altered movement patterns of the involved limb and thus increase the risk of early onset knee osteoarthritis.(Žargi et al., 2018) Conversely, greater quadriceps strength has been linked to a lower risk of symptomatic knee osteoarthritis and reduced joint space narrowing, as well as reduced pain and positive changes in physical function.(Hughes et al., 2017)

In order to pre-emptively address postoperative atrophy of the quadriceps, it is becoming increasingly common for surgeons to prescribe preoperative rehabilitation for patients undergoing ACLR ("prehab"). It has been demonstrated in literature that there is a positive correlation between preoperative quadriceps function and successful outcomes of ACLR.(Žargi et al., 2018) Prevention of atrophy and early recovery of muscular strength have also been reported to be associated with an early return to athletic activities.(Ohta et al., 2003) Therefore, preoperative LI-BFR training has the potential to be an excellent tool in improving postoperative outcomes by reducing postoperative atrophy and impairment of the quadriceps.

Safety of BFR Training

BFR training offers no greater risk than traditional exercise done without BFR.(Loenneke et al., 2012) The BFR approach has been applied to > 12,000 people in Japan with a number of pathologies including cerebrovascular, orthopedic, cardiac, respiratory, and neuromuscular diseases as well as obesity, diabetes, and hypertension, with

no significant side effects or rheological response reported.(Conceição & Ugrinowitsch, 2019) Another epidemiological study conducted in Japan reported low occurrence of any adverse side effects other than skin bruising.(Hughes et al., 2017) Further, the addition of BFR to low-intensity strength training does not appear to worsen condition or exercise-related pain(Hughes et al., 2017) or to induce additional inflammatory responses.(Cardoso et al., 2018) In fact, individuals may be able to tolerate perceptual changes during LI-BFR to a better extent due to lower joint forces and stress.(Hughes et al., 2017) However, it is important to consider that while the low mechanical forces used with BFR exercise may improve muscle strength, disproportionate adaptations within tendons could occur if progressions in exercise load are not implemented, increasing the risk for subsequent tendon injuries.(*Blood Flow Restricted Exercise for Athletes*, n.d.)

In order to determine the efficacy of safe implementation of BFR into clinical practice, one study reported on the incidence of various clinical conditions associated with restricted blood flow.(Vanwye et al., 2017) Investigation of LI-BFR in healthy individuals and older adults with heart disease found no change in blood markers for thrombin generation or vascular clot formation; the incidence of deep venous thrombosis (DVT) was < 0.06% and pulmonary embolism (PE) was < 0.01%.(Vanwye et al., 2017) The incidence of excessive muscle damage, or rhabdomyolysis, was < 0.01%.(Vanwye et al., 2017) Because LI-BFR training is not recommended to be done to the point of exhaustion, there is a minimal risk of excessive muscle damage.(Vanwye et al., 2017) The incidence of numbness due to interruptions in nerve conduction was < 2%; peripheral nerve irritation can be prevented through appropriate selection and application of the cuff.(Vanwye et al., 2017) Additionally, the risk of an adverse event due to intensified exercise pressure reflex

(EPR) can be mitigated by using relative cuff inflation pressures and by reducing the BFR pressure when possible.(Vanwye et al., 2017)

Certain precautions can be taken with the application of BFR to prevent adverse side effects or complications. For example, it is important that practitioners rule out potential causes of rhabdomyolysis such as infections and prolonged immobilization before implementing training.(Hughes et al., 2017) It is also considered the safest practice to utilize the lowest possible pressure to achieve a training response, which can reduce the discomfort and pain associated with BFR.(Vanwye et al., 2017)

Training Protocols

While the use of LI-BFR training is becoming more popular in clinical use, unfortunately, there is not yet an agreed upon standard protocol for its implementation. This includes variables such as how many training sessions to implement, how many weeks before and after surgery it should be done, the cuff pressure that should be used, the amount of resistance that should be used during exercise, which exercises should be done during training, the volume of repetitions that should be done, and more. Little work has been done to identify which of these variables are the most important to consider when designing an optimal LI-BFR training program;(Loenneke et al., 2012) however, there are published results that provide guidance regarding how to optimize some of these aspects as best as possible. Below are some of these recommendations as supported by literature.

With regards to exercise resistance intensity, LI-BFR training can be done at intensities as low as 20% of an individual's 1-RM strength and still make improvements in muscular strength and hypertrophy.(Vanwye et al., 2017) High volumes of repetitions for each exercise is ideal; specifically, 75 repetitions over four sets with 30-second rest periods

between each set.(Vanwye et al., 2017) The standard protocol is performing thirty repetitions in the first set followed by three sets of fifteen repetitions each; there should be a thirty to sixty-second rest interval between each set and the cuffs should be kept inflated throughout the training session.(Conceição & Ugrinowitsch, 2019) The largest effects have been observed with training 2-3 days per week; a frequency greater than this amount appears to be less effective.(Vanwye et al., 2017) Significant differences were found in strength and hypertrophy between training 2-3 days per week and 4-5 days per week, with greater gains found in the groups performing exercises 2-3 days per week.(Loenneke et al., 2012)

Another characteristic that has an impact on the efficacy of LI-BFR training is the cuff used to restrict blood flow. Wider cuff widths have a lower absolute arterial occlusion pressure than narrow cuffs.(Vanwye et al., 2017) The absolute cuff pressure needed for muscular adaptation is much less than commonly thought, especially when using a wider cuff to induce BFR.(Loenneke et al., 2012) Cuff pressures are typically prescribed at 40-90% of the individual's arterial occlusion pressure (AOP).(Vanwye et al., 2017) High occlusion pressure (80% AOP) produces greater muscular hypertrophy than moderate occlusion pressure (40% AOP) when exercising at low intensities (20% of 1-RM).(Conceição & Ugrinowitsch, 2019) It has been reported that the occlusive pressure used is one aspect that should be individualized in the pursuit of safe and effective application of BFR.(Hughes et al., 2017)

CHAPTER 3

ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION RECOVERY AND REHABILITATION: A SYSTEMATIC REVIEW

ABSTRACT

Background: The success of anterior cruciate ligament (ACL) reconstruction is influenced by effective rehabilitation. Previously published, comprehensive systematic reviews evaluating rehabilitation after ACL reconstruction have studied Level-I and II evidence published through 2012. Interval studies continue to evaluate the efficacy of various rehabilitative modalities.

Methods: A total of 824 articles from 2012 to 2020 were identified using multiple search engines. Fifty Level-I or II studies met inclusion criteria and were evaluated using the Consolidated Standards of Reporting Trials (CONSORT) criteria and National Institutes of Health (NIH) Study Quality Assessment Tools.

Results: Accelerated rehabilitation can be effective for patients with semitendinosus-gracilis grafts. Blood flow restriction (BFR) training with high-intensity exercise is not effective for ACL reconstruction recovery. Postoperative bracing does not offer any advantages or improve limb asymmetry. Cryotherapy is an effective analgesic when used perioperatively. The early introduction of open kinetic chain exercises may improve ACL reconstruction outcomes, and high-intensity plyometric exercise is not effective. Estimated pre-injury capacity (EPIC) levels may be more accurate than the Limb Symmetry Index (LSI) when using functional test results to predict reinjury rates, and hip external rotation strength may be the most accurate predictor of the hop test performance. Nerve blocks can provide postoperative analgesia with minimal complication risk. Neuromuscular electrical

stimulation is effective when used independently and in combination with rehabilitative exercises. Psychological readiness should be evaluated both objectively and subjectively before allowing patients to safely return to sport. Electromyography biofeedback may help to regain muscular function, and whole-body vibration therapy can improve postural control. Supervised rehabilitation is more effective than unsupervised rehabilitation.

Conclusions: Various rehabilitative modalities following ACL reconstruction are effective in improving surgical outcomes and return-to-sport rates. Further evidence and improved study design are needed to further validate modalities including accelerated rehabilitation, BFR training, functional testing, and return-to-sport criteria.

Level of evidence: Therapeutic Level II.

INTRODUCTION

Anterior cruciate ligament (ACL) reconstructions are among the most performed orthopaedic procedures in the United States, with an estimated 350,000 procedures performed annually.(Buller et al., 2014) Although many procedures involve considerable rehabilitation, ACL reconstruction recovery is uniquely heterogeneous, with return to pre-injury sport rates reported to be as low as 24%.(Ardern et al., 2011) Many factors have been hypothesized to play a role in successful rehabilitation; however, there has been no consensus with regard to the ideal rehabilitative approach. The most recent comprehensive systematic review with regard to ACL rehabilitation was performed by Kruse et al.(Kruse et al., 2012) and evaluated Level-I and II evidence from 2006 to 2010. Over the past decade, several studies have been published evaluating novel rehabilitative approaches. This systematic review offers an interval analysis and grades of recommendation of literature from 2012 to 2020.(Wright et al., 2005) The previous data discussed by Kruse et al. were

relevant; however, the goal of this current study was to offer a systematic review of the literature since the most recent comprehensive review. Although the previous data offered excellent support for some of the topics discussed here, this systematic review evaluated a larger number of topics.

MATERIALS & METHODS

PubMed, Embase, Scopus, Web of Science, and the Cochrane Database of Systematic Reviews (Cochrane DBSR) were searched using the terms as listed in Appendix B to identify studies published from January 2012 to September 2020. This study was registered with the International Prospective Register of Systematic Reviews (PROSPERO) under identification number CRD42021224071. The database search was performed by a librarian, and the results were reconciled among the 3 authors, resulting in the identification of 824 articles. The study Level of Evidence was determined on the basis of recommendations by the Oxford Centre for Evidence-Based Medicine(*OCEBM Levels of Evidence — Centre for Evidence-Based Medicine (CEBM), University of Oxford*, n.d.) and included high-quality randomized controlled trials (RCTs) categorized as Level-I evidence and lesser-quality RCTs and prospective cohort studies categorized as Level-II evidence. This systematic review excluded case-control studies, case studies, case series studies, systematic reviews, meta-analyses, and retrospective cohort studies. The 824 articles were reviewed individually by 2 primary authors, and 61 articles in total were identified as meeting inclusion criteria after the individual review. Five of those 61 articles were sent to a third author to review for conflict and were deemed to be excluded. Following conflict review and quality scoring, a total of 50 articles that met the inclusion criteria (peer-reviewed, English-language articles, describing Level-I and II studies

evaluating adolescents and adults who were ± 14 years of age) were included in this systematic review. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed (Fig. 3-1). Exclusion criteria included non-English language, non- Level-I or II studies, irrelevant subject matter, studies focused primarily on skeletally immature populations, studies performed on animals or cadaveric material, and conference and meeting abstracts and proceedings.

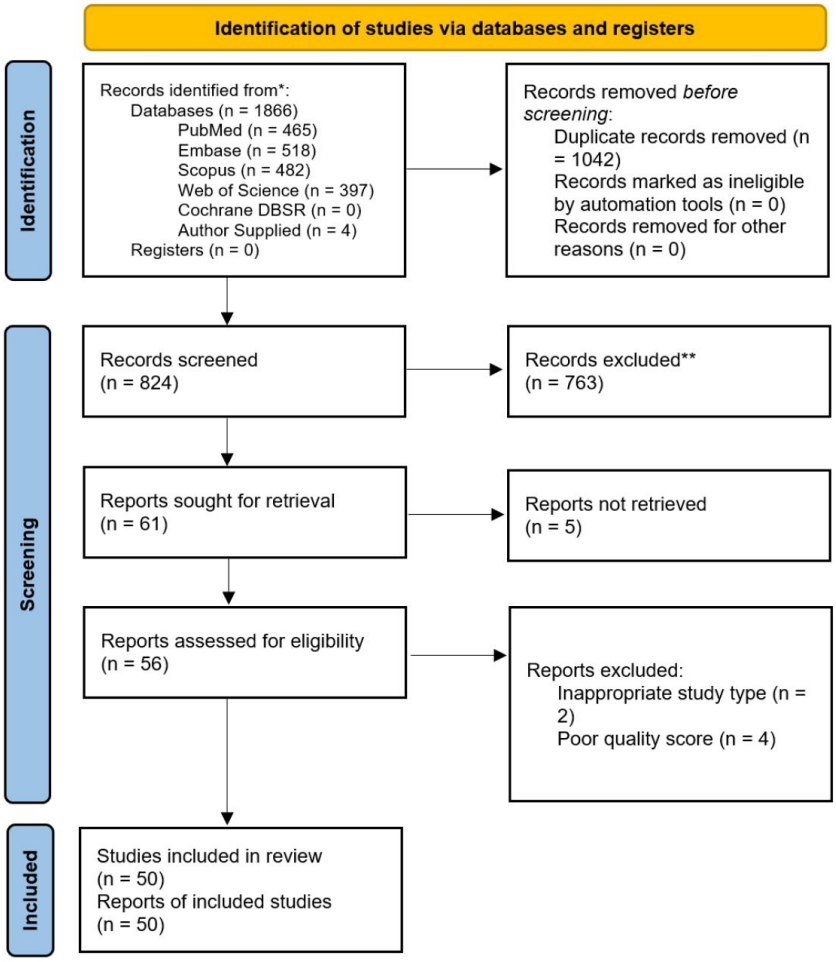

Figure 3-1: The PRISMA 2020 flow diagram for new systematic reviews that included the search of databases and registries for new studies that met the inclusion criteria. The asterisk indicates that results from multiple databases were specified and the double asterisk indicates that all excluded studies were excluded by a person and that no automation software was used.

Quality appraisal was performed using the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist when evaluating RCTs(Schulz et al., 2010) and the National Institutes of Health (NIH) Study Quality Assessment Tools(*Study Quality Assessment Tools | NHLBI, NIH,* n.d.) for prospective cohort studies, controlled intervention studies, and longitudinal (prepost, per the NIH [or before-and-after]) studies with no control group. The results and conclusions from these studies were summarized, and recommendations were made using The Journal of Bone & Joint Surgery (JBJS) grades of recommendation,(Wright et al., 2005) with grade-A recommendations indicating consistent Level-I evidence and grade-B recommendations indicating Level-II evidence. A comprehensive summary of all topics, results, and conclusions, as well as their grades of recommendation, can be found in Table 3-1. The senior author determined that 5 articles that had been considered to meet the inclusion criteria by only 1 of the 2 primary authors were to not be retrieved for inclusion in the systematic review. Following this conflict resolution, 2 studies were excluded for not meeting article study type criteria and 4 studies were excluded on the basis of a poor-quality score on the CONSORT or NIH evaluation (depending on the study type); the cutoff score for unacceptable studies was <40% on the applicable appraisal instrument.

TABLE 3-1: Summary of the Prior Investigations on Recovery and Rehabilitation Following ACL-R			
Modality Investigated	**No. of Studies**	**Results**	**Grade of Recommendation (JBJS)**
Accelerated Rehabilitation	3	Accelerated rehabilitation in patients after ACL-R utilizing an STG autograft with early, full ROM and weight-bearing in the immediate postoperative period(Christensen et al., 2013) along with a shortened timetable for exercise and functional activities(Gupta et al., 2017) may be equivalent to standard rehabilitation protocols in short-term outcomes and can be used for a general patient population(Feyzioglu et al., 2020)	B
Blood Flow Restriction Training	2	Results support argument against using BFR with high-intensity resistance exercise;(Curran et al., 2020) BFR done with low-intensity exercise leads to significantly lower knee joint pain.(Hughes et al., 2017)	B
Bracing	3	Postoperative knee bracing may not have any advantages or improve surgical outcomes such as limb asymmetry,(Dai et al., 2012) anteroposterior knee laxity,(Mayr et al., 2014) knee joint effusion,(Lindström et al., 2015) and various PROMs(Lindström et al., 2015)	B
Cryotherapy	2	Results provide evidence to support the use of cryotherapy both preoperatively(Koyonos et al., 2014) and postoperatively(Ruffilli et al., 2015) as an analgesic for patients undergoing ACL-R	B
Exercise Modalities	3	Early introduction of OKC exercise may improve ACL-R outcomes(Fukuda et al., 2013) and implementation of high-intensity plyometrics into rehabilitation protocols provides no significant benefits(Chmielewski et al., 2016)	B
Hop & Strength Testing	5	EPIC levels may be more accurate than LSI in using functional test results to predict reinjury rates(Harput et al., 2020) and hip external rotation strength may be the most accurate predictor of hop test performance.(Thomeé et al., 2012)	B

Nerve Blocks	3	Femoral nerve blocks and other types of local anesthesia provide primary pain relief following ACL-R with a relatively low risk of long-term deficits or complications(Kurosaka et al., 2018; Okoroha et al., 2018; Runner et al., 2018)	A
NMES*	3	Results provide micro-(Toth et al., 2020) and macro-level[35,36] evidence in support of NMES usage at varying time points before and after ACL-R; NMES may either be used on its own[34,36] or in addition to various exercises[35] with minimal risk	A
PROMs*	5	Athletic, motivated patients during rehabilitation are more likely to return to preinjury sport levels with increased knee satisfaction after surgery;[38] TSK-11) and ACL-RSI are valuable tools in evaluating appropriateness for RTS	B
Return to Sport/Reinjury Rates	7	Results support the importance of psychological readiness in RTS,[46] utilization of functional and objective testing results as return to sport criteria,[47–49] development of a secondary injury prevention program,[50] and the importance of having athletes refrain from participating in sports without limitations until at least nine months after ACL-R[43]	B
Sensorimotor Training	7	EMG biofeedback usage may improve muscular strength[53] while whole-body vibration therapy may improve postural control, muscular performance, and various functional testing outcomes.[54]	A
Supervised Rehabilitation	2	Supervised rehabilitation may be more effective than unsupervised exercise[59,60]	B

*NMES = neuromuscular electrical stimulation, PROMs = patient-reported outcome measures, STG = semitendinosus-gracilis graft, ROM = range of motion, BFR = blood flow restriction, EPIC = estimated preinjury capacity, LSI = limb symmetry index, RTS = return to sport, TSK-11 = Tampa Scale for Kinesiophobia, ACL-RSI = anterior cruciate ligament return to sport index, EMG = electromyography.

*According to Wright(Wright et al., 2005), grade A indicates good evidence (Level-I studies with consistent findings) for or against recommending intervention; grade B, fair evidence (Level-II or III studies with consistent findings) for or against recommending intervention; grade C, poor-quality evidence (Level-IV or V studies with consistent findings) for or against recommending intervention; and grade I, insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Table 3-1: Summary of the Prior Investigations on Recovery and Rehabilitation Following ACL-R

RESULTS

Accelerated Rehabilitation

Historically, rehabilitation after ACL reconstruction emphasized early immobilization and delayed weight-bearing to protect incorporating grafts, specifically semitendinosus-gracilis grafts. There has been interest in accelerated rehabilitation protocols with the goal of regaining early range of motion through the introduction of strengthening exercises. The definition of accelerated rehabilitation varies between studies; however, the underlying goal is an emphasis on the early unrestricted range of motion and weight-bearing exercises. Although there has been no standardization of accelerated rehabilitation, previous studies have suggested that it is likely unharmful, with minimal differences in clinical outcomes.(Janssen et al., 2018) Two RCTs and 1 prospective study have evaluated the effects of accelerated rehabilitation protocols, compared with the current standard of care, on recovery after ACL reconstruction with semitendinosus-gracilis graft since 2012(Christensen et al., 2013; Feyzioglu et al., 2020; Gupta et al., 2017) (Table 3-2); no studies were found with regard to accelerated rehabilitation performed in patients with other types of grafts. These studies suggested that accelerated rehabilitation after ACL reconstruction utilizing a semitendinosus-gracilis autograft, involving early, full range of motion and weight bearing in the immediate postoperative period(Christensen et al., 2013) along with a shortened timetable for exercise and functional activities(Gupta et

al., 2017), may be equivalent to standard rehabilitation protocols in terms of patient-reported outcome measures and can be used for a general patient population(Feyzioglu et al., 2020). However, the overall quality of evidence was varied, which limited the strength of the conclusions (Table 3-1). The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-2: Summary of Studies on Accelerated Rehabilitation

Study (Level of Evidence)	Study Design	Quality Score (Appraisal Criteria)	No. of Patients/Groups	Population Characteristics	Group Differences	Parameters Assessed	Significant Findings
Christensen et al. 2013(Christensen et al., 2013) (I)	RCT	26/37 (CONSORT)	36/2	Age 31.5 ± 10.6 years; Tegner score of at least 2	Aggressive vs. nonaggressive rehabilitation	A-P laxity, ROM, peak isometric force, IKDC	No significant differences between groups for any variables
Gupta et al. 2017(Gupta et al., 2017) (I)	RCT	16/37 (CONSORT)	40/2	Age range: 18-50 years	Accelerated 19-week rehab vs. standard 24-week rehab protocol	A-P laxity, KOOS, IKDC, single-leg hop test	Accelerated rehab group had better KOOS and IKDC after surgery; no other clinically significant differences
Feyzioglu et al. 2020(Feyzioglu et al., 2020) (II)	PPSNCG	9/12 (NIH PPSNCG)	30/2	Age range: 20-40 years; elite athletes and nonathletes	Elite athletes vs. nonathletes	Pain intensity, ROM, Lysholm, depression	Significant improvements in pain, knee flexion, Lysholm, and depression for both groups

*RCT = randomized controlled trial, PPSNCG = pre-post studies w/no control group, A-P = anteroposterior, ROM = range of motion, IKDC = International Knee Documentation Committee, KOOS = Knee Osteoarthritis Outcome Survey

Table 3-2: Summary of Studies on Accelerated Rehabilitation

Blood Flow Restriction (BFR) Training

BFR training has gained popularity for use in patients undergoing ACL reconstruction. It involves the use of tourniquet-like cuffs placed proximally on the lower extremity during exercise. Two studies were found that investigated the use of BFR(Curran

et al., 2020; Hughes et al., 2017) (Table 3-3); both studies employed twice-weekly BFR training programs for 8 weeks following the surgical procedure, with Hughes et al.(Hughes et al., 2017) beginning their program at postoperative time points based on the achievement of specific criteria and Curran et al.(Curran et al., 2020) beginning their program at 10 weeks after the surgical procedure. These studies recommended against using BFR in combination with high-intensity resistance exercise as it did not improve quadriceps strength, activation, or volume(Curran et al., 2020); however, BFR performed with low-intensity exercise was found to lead to significantly lower knee joint pain and greater muscular pain ratings without any significant difference in the rate of perceived exertion (RPE) when compared with high-intensity resistance training performed without BFR(Hughes et al., 2017) (Table 3-1). The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-3: Summary of Studies on Blood Flow Restriction Training

Study (Level of Evidence)	Study Design	Quality Score (Appraisal Criteria)	No. of Patients/Groups	Population Characteristics	Group Differences	Parameters Assessed	Significant Findings
Hughes et al. 2019(Hughes et al., 2017) (I)	RCT	27/37 (CONSORT)	28/2	Age 29 ± 7 years	High-intensity resistance training vs. low-intensity resistance training with BFR	RPE, muscle pain, knee joint pain	Knee joint pain was lower and muscle pain was higher in the BFR group
Curran et al. 2020(Curran et al., 2020) (II)	RCT	24/37 (CONSORT)	34/4	Age range: 14-30 years	Concentric exercise vs. eccentric exercise vs. concentric exercise with BFR vs. eccentric exercise with BFR	Isometric and isokinetic quadriceps peak torque, quadriceps muscle activation, rectus femoris muscle volume	No significant differences between groups for any variables

*RCT = randomized controlled trial, BFR = blood flow restriction, RPE = rate of perceived exertion.

Table 3-3: Summary of Studies on Blood Flow Restriction Training

Bracing

The use of knee braces as part of postoperative protocols has not been shown to provide substantial clinical benefit to patients beyond a psychological sense of security. In 3 articles, the authors further investigated their efficacy in postoperative recovery and the effect on other surgical and biomechanical outcomes.(Dai et al., 2012; Lindström et al., 2015; Mayr et al., 2014) The results suggested that postoperative knee bracing may not have any advantages, such as improving surgical outcomes including limb asymmetry(Dai et al., 2012), anteroposterior knee laxity(Mayr et al., 2014), knee joint effusion(Lindström et al., 2015), and various patient-reported outcome measures(Lindström et al., 2015) (Tables 3-1 and 3-4). Bracing after returning to sport was not evaluated by any of the included studies. The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-4: Summary of Studies on Bracing

Study (Level of Evidence)	Study Design	Quality Score (Appraisal Criteria)	No. of Patients/ Groups	Population Characteristics	Group Differences	Parameters Assessed	Significant Findings
Dai et al. 2012(Dai et al., 2012) (II)	PCS	10/14 (NIH PCS)	23/1	Age 16.5 ± 1.3 years	All participants tested while wearing a functional knee extension-resistant brace vs. no brace	3D kinematic and kinetic data while performing 35° side-cutting task	Significant kinematic and kinetic asymmetries between surgical and nonsurgical limbs, which persisted when the subjects wore a knee brace; bracing did not decrease asymmetry between surgical and nonsurgical limbs
Mayr et al. 2014(Mayr et al., 2014) (II)	PCS	12/14 (NIH PCS)	52/2	Age range: 21-65 years	Brace vs. no brace	IKDC, knee laxity, VAS	Significantly better VAS scores for braceless group under sports

							activity or heavy physical work; no significant differences in IKDC or laxity
Lindström et al. 2015(Lindström et al., 2015) (I)	RCT	30/37 (CONSORT)	60/2	Age 26 ± 8 years	Brace vs. no brace	Effusion, single-leg hop test, Lysholm, Tegner, KOOS, triple hop test, 6-m timed hop test, square hop test	Bracing had no effect on 3-month post-op presence of joint effusion; excessive effusion was found in 68% of subjects 3 months after surgery and was associated with prior meniscus injury and higher prior Tegner activity level

*PCS = prospective cohort study, RCT = randomized controlled trial, IKDC = International Knee Documentation Committee, VAS = visual analog scale for pain, KOOS = Knee Osteoarthritis Outcome Survey.

Table 3-4: Summary of Studies on Bracing

Cryotherapy

TABLE 3-5: Summary of Studies on Cryotherapy

Study (Level of Evidence)	Study Design	Quality Score (Appraisal Criteria)	No. of Patients/Groups	Population Characteristics	Group Differences	Parameters Assessed	Significant Findings
Koyonos et al. 2014(Koyonos et al., 2014) (I)	RCT	25/37 (CONSORT)	53/2	Age range: 14-55 years	30-90 minutes of immediate preoperative cryotherapy using a commercial non-compressive cryotherapy unit vs. no preoperative cryotherapy	VAS, pain medication usage	Less pain and narcotic use in the first 36 hours post-op for cryotherapy group; no other statistically significant differences
Ruffilli et al. 2015(Ruffilli et al., 2015) (II)	CIS	10/14 (NIH CIS)	47/2	Age 32.2 ± 6.7 years for intervention group & 31.4 ± 8.1 yrs for control group	Postoperative cryotherapy using temperature-controlled continuous cold flow device vs. standard ice bag	NRS, blood loss, knee volume, ROM, pain medication usage	Lower pain perception, blood loss, knee volume increase, and higher ROM for cryotherapy group; no difference in painkiller consumption

*RCT = randomized controlled trial, CIS = controlled intervention study, VAS = visual analog scale for pain, NRS = numeric rating scale for pain, ROM = range of motion.

Table 3-5: Summary of Studies on Cryotherapy

Cryotherapy includes the use of cold packs, ice massage, cold baths, vapocoolant sprays, and cold compression units and is an analgesic technique used to relieve muscular soreness following musculoskeletal injury.(Malanga et al., 2015) Two studies were included that investigated the use of cold therapy as an analgesic for populations undergoing ACL reconstruction(Koyonos et al., 2014; Ruffilli et al., 2015) (Table 3-5). The results provided further evidence to support the use of cryotherapy both preoperatively(Koyonos et al., 2014) and postoperatively(Ruffilli et al., 2015) as an analgesic for patients in ACL reconstruction (Table 3-1). The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

Exercise Modalities

Three of the included studies discussed the use of open kinetic chain (OKC) exercises compared with closed kinetic chain (CKC) exercises(Fukuda et al., 2013; Uçar et al., 2014) and plyometric exercise(Chmielewski et al., 2016) (Table 3-6). The results indicated conflicting outcomes for the use of OKC exercise postoperatively as Fukuda et al. found that early introduction of OKC exercise within the first 4 weeks after the surgical procedure may improve quadriceps strength without any significant difference in anterior laxity(Fukuda et al., 2013), and Uçar et al. found that CKC exercise had significantly greater improvements in thigh circumference and Lysholm scores(Uçar et al., 2014). Chmielewski et al. found that plyometric exercise intensity does not have an effect on knee function, knee impairments, or psychosocial status(Chmielewski et al., 2016) (Table 3-1). The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-6: Summary of Studies on Exercise Modalities

Study (Level of Evidence)	Study Design	Quality Score (Appraisal Criteria)	No. of Patients/ Groups	Population Characteristics	Group Differences	Parameters Assessed	Significant Findings
Fukuda et al. 2013(Fukuda et al., 2013) (I)	RCT	25/37 (CONSORT)	49/2	Age range: 16-50 years	4-week post-op (Early OKC) vs. 12-week post-op (Late OKC) introduction of OKC exercises to rehabilitation protocol	Quadriceps and hamstring strength, NPRS, Lysholm, single-legged hop test, crossover hop test, laxity	Improved quad strength at 19 weeks, 25 weeks, and 17 months post-op for EOKC compared to 12 weeks post-op; LOKC group only observed improvements at 17 months; no significant difference for pain and functional assessments
Uçar et al. 2014(Uçar et al., 2014) (II)	PPSNCG	9/12 (NIH PPSNCG)	58/2	Age range: 17-39 years	6 months of OKC vs. CKC exercise	VAS, ROM, thigh circumference, Lysholm	Improvements in VAS and knee flexion were significantly higher in the CKC group than the OKC group; greater improvement in Lysholm score observed at 6 months in the CKC group
Chmielewski et al. 2016(Chmielewski et al., 2016) (II)	RCT	28/37 (CONSORT)	24/2	Age range: 15-30 years; must participate in at least 50 hours per year in level I or II activities preinjury	8 weeks of postoperative low-intensity vs. high-intensity plyometric exercise introduced at a mean of 14.3 weeks (range: 12.1-17.7 weeks)	IKDC, biomarkers of articular cartilage degradation and articular cartilage metabolism, serum concentrations of the C-terminal propeptide of newly formed type II collagen and inflammation, maximal vertical jump, single-legged hop test, laxity, knee pain intensity, quadriceps strength, quadriceps symmetry index, kinesiophobia, knee activity self-efficacy, pain catastrophizing	No significant differences were found in either IKDC score or articular cartilage degradation between groups

*RCT = randomized controlled trial, PPSNCG = pre-post studies w/no control group, OKC = open kinetic chain, NPRS = numerical pain rating scale, CKC = closed kinetic chain, VAS = visual analog scale for pain, ROM = range of motion, IKDC = International Knee Documentation Committee.

Table 3-6: Summary of Studies on Exercise Modalities

Hop, Strength, and Isokinetic Testing

Hop, strength, and isokinetic testing have assisted in developing objective, quantitative criteria with regard to return to sport. Clinicians often use a combination of these tests after ACL reconstruction to assess patients at various stages of postoperative rehabilitation and traditionally consider a Limb Symmetry Index (LSI) of ± 90% as ready to return to sport.(Harput et al., 2020; Thomeé et al., 2012) The results of these tests assist in the identification of deficiencies in patients' muscular function or strength. Five studies discussed functional testing in ACL reconstruction recovery and rehabilitation(Harput et al., 2020; Ithurburn et al., 2019; Kline et al., 2018; Thomeé et al., 2012; Wellsandt et al., 2017) (Table 3-7). These studies compared the function and strength of injured and uninjured hip, quadriceps, and hamstring muscles(Ithurburn et al., 2019); evaluated the use of LSI(Harput et al., 2020) and its alternatives(Wellsandt et al., 2017); and cautioned against return-to-sport criteria based on the achievement of stringent LSI values alone(Thomeé et al., 2012). The authors of these studies suggested that there is benefit in integrating functional testing in return-to-sport criteria to assess the patient's return-to-sport potential and to predict a secondary injury and that hip external rotation is the only significant predictor of the hop test performance.(Kline et al., 2018) Estimated pre-injury capacity (EPIC) levels may be more accurate than LSI when using functional test results to predict reinjury rates(Wellsandt et al., 2017) (Table 3-1). The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-7: Summary of Studies on Hop, Strength, & Isokinetic Testing							
Study (Level of Evidence)	**Study Design**	**Quality Score (Appraisal Criteria)**	**No. of Patients/Groups**	**Population Characteristics**	**Group Differences**	**Parameters Assessed**	**Significant Findings**
Kline et al. 2018(Kline et al., 2018) (II)	CIS	8/14 (NIH CIS)	65/2	Age range: 18-45 years	Patients who underwent ACL-R vs. healthy control subjects	Peak isometric knee extension, hip abduction, hip extension, and hip external rotation strength; single leg hop tests, timed hop tests, triple hop tests, crossover hop tests	Knee extension and hip external rotation were significantly correlated to each hop test, with hip external rotation being the only significant predictor of hop test performance
Wellsandt et al. 2017(Wellsandt et al., 2017) (II)	PCS	11/14 (NIH PCS)	70/1	Age range: 14-55 years; athletes active in cutting and pivoting activities preinjury	N/A	LSI and EPIC for quadriceps strength tests and single-legged hop tests	EPIC levels were more sensitive to LSI in predicting second ACL injuries
Thomeé et al. 2012(Thomeé et al., 2012) (II)	PCS	11/14 (NIH PCS)	82/1	Age 28 ± 8.2 years	N/A	Knee extension power, knee flexion power, leg press test, countermovement jump test, hop for distance, and side hop test	Using more demanding criteria for a successful muscle function outcome, using batteries of tests, or increasing the acceptable LSI from 90% can lead to poor results when determining criteria for safe RTS
Ithurburn et al. 2019(Ithurburn et al., 2019) (II)	PCS	11/14 (NIH PCS)	124/1	Age 17.1 ± 2.4 years; planned to return to 50 or more hours of cutting or pivoting activities per yr after RTS	N/A	KOOS, single leg hop tests, isokinetic quadriceps and hamstring strength, LSI during hop and strength tests	Young athletes who returned to preinjury sport levels demonstrated greater absolute functional performance at RTS; limb symmetry

							measures did not differ
Harput et al. 2020(Harput et al., 2020) (II)	PCS	12/14 (NIH PCS)	38/1	Male athletes w/ preinjury Tegner score of 5 or greater; age range: 16-35 years	N/A	Quadriceps and hamstring isometric strength	Consistent increase in quad and hamstring strength of the involved limb with no notable change in uninvolved limb strength were observed; at 6 months post op
*PCS = prospective cohort study, CIS = controlled intervention study, RTS = return to sport, KOOS = Knee Osteoarthritis Outcome Score, LSI = limb symmetry index, EPIC = estimated preinjury capacity, RTS = return to sport.							

Table 3-7: Summary of Studies on Hop, Strength, & Isokinetic Testing

Nerve Blocks

TABLE 3-8: Summary of Studies on Nerve Blocks							
Study (Level of Evidence)	**Study Design**	**Quality Score (Appraisal Criteria)**	**No. of Patients/Groups**	**Population Characteristics**	**Group Differences**	**Parameters Assessed**	**Significant Findings**
Runner et al. 2018(Runner et al., 2018) (I)	RCT	31/37 (CONSORT)	102/2	Age 25.1 ± 1.8 years for ACB group & 24.2 ± 1.7 yrs for FNB group	Adductor canal block vs. femoral nerve block	Isokinetic quadriceps strength	No significant difference in quad strength at 3- and 6-months post op
Okoroha et al. 2018(Okoroha et al., 2018) (I)	RCT	29/37 (CONSORT)	43/2	Age > 16 years	Single shot FNB vs. local infiltration anesthesia	Isokinetic flexion and extension strength, single-leg hop test, 6-m single-leg hop test, single-leg triple crossover hop test	No significant difference found in strength at 10.6 months post-op; 13% motor/sensory complication rate for the femoral nerve block group that are not permanent
Kurosaka et al. 2018(Kurosaka et al., 2018) (I)	RCT	26/37 (CONSORT)	129/2	Age > 13 years	Periarticular injection vs. femoral nerve block	VAS, pain medication usage	PI group had significantly better pain scores and lower opioid consumption than the FNB group without increased complication rates
*RCT = randomized controlled trial, VAS = visual analog scale for pain, PI = periarticular injection, FNB = femoral nerve block, ACB = adductor canal block.							

Table 3-8: Summary of Studies on Nerve Blocks

Nerve blocks have been a popular analgesic option in ACL reconstruction; they function by inhibiting nerve impulse transmission at the nerve terminal, terminating the pain signal received by the cortex.(Wiederhold et al., 2021) The benefits of using peripheral nerve blocks include improvement in postoperative pain control, reduction in opioid usage, earlier participation in postoperative physical therapy, and improved patient satisfaction.(Joshi et al., 2016) Three studies investigated how the use of blocks affected surgical outcomes such as pain relief and muscular strength following ACL reconstruction

compared with other types of analgesics.(Kurosaka et al., 2018; Okoroha et al., 2018; Runner et al., 2018) The results provide evidence supporting the use of femoral nerve blocks as well as adductor canal blocks and periarticular injections to provide primary pain relief following ACL reconstruction with a relatively low risk of long-term deficits or complications (Tables 3-1 and 3-8). The grade of recommendation for this modality was A (good evidence for or against recommending intervention).

Neuromuscular Electrical Stimulation (NMES)

TABLE 3-9: Summary of Studies on Neuromuscular Electrical Stimulation

Study (Level of Evidence)	Study Design	Quality Score (Appraisal Criteria)	No. of Patients/Groups	Population Characteristics	Group Differences	Parameters Assessed	Significant Findings
Toth et al. 2020(Toth et al., 2020) (I)	RCT	25/37 (CONSORT)	21/2	Age range: 18-50 years	NMES vs. no NMES	Skeletal muscle fiber size and contractility, quadriceps muscle size and strength	Early NMES use reduced skeletal muscle fiber atrophy in MHC II fibers and preserved contractility in MHC I fibers
Labanca et al. 2018(Labanca et al., 2018) (I)	RCT	24/37 (CONSORT)	63/3	Male athletes w/Tegner score of 7-10; age range: 18-40 years	NMES + repeated STSTS vs. STSTS only vs. no additional treatment (NAT)	Isometric quadriceps and hamstring strength, sit to stand asymmetry, countermovement jump test	NMES + STSTS exercise resulted in higher strength of the knee extensors as well as lower perception of pain and higher symmetry in lower extremity loading than the NAT group

Taradaj et al. 2013(Taradaj et al., 2013) (I)	RCT	21/37 (CONSORT)	80/2	Male professional soccer players; age range: 17-29 years	1 month of rehabilitation subsidized with NMES vs. standard rehabilitation	Tensometry, muscle circumference, goniometry pendulum test for biomechanical changes in the knee joint	NMES resulted in an intensive increase in quadriceps power and mass after 1 month of rehab without significant disruption to the biomechanics of the knee
*RCT = randomized controlled trial, NMES = neuromuscular electrical stimulation, STSTS = sit to stand to sit exercise.							

Table 3-9: Summary of Studies on Neuromuscular Electrical Stimulation

NMES is used in rehabilitation after knee injuries to increase muscle fiber recruitment and activation of the quadriceps.(Hauger et al., 2018) Three studies investigated the use of NMES during rehabilitation for ACL reconstruction(Labanca et al., 2018; Taradaj et al., 2013; Toth et al., 2020) (Table 3-9). These studies provide micro-level(Toth et al., 2020) and macro-level(Labanca et al., 2018; Taradaj et al., 2013) evidence in support of NMES usage at various time points before and after ACL reconstruction. Additionally, NMES may either be used on its own(Taradaj et al., 2013; Toth et al., 2020) or to supplement various postoperative rehabilitation exercises(Labanca et al., 2018), with minimal risk (Table 3-1). The grade of recommendation for this modality was A (good evidence for or against recommending intervention).

Patient-Reported Outcome Measures

There are a number of studies that have evaluated patient-reported outcomes and psychological factors such as motivation and fear that influence successful outcomes. Current ACL reconstruction rehabilitation protocols emphasize functional testing, strength measurement, and quality of movement, but recent data have suggested that psychological

factors may also play a significant role.(Ardern et al., 2014) Five studies investigated these factors.(Paterno et al., 2018; Sadeqi et al., 2018; Saha, 2016; Sonesson et al., 2017; Zwolski et al., 2015) The results indicated that psychological readiness should be evaluated objectively and should be strongly considered before clearing an athlete for return to sport (Table 3-10). Athletic patients who are motivated during rehabilitation are more likely to return to pre-injury sport levels, with increased knee satisfaction, after the surgical procedure.(Sonesson et al., 2017) Notably, valuable tools in evaluating appropriateness for return to sport are the 11-item Tampa Scale for Kinesiophobia (TSK-11), particularly with scores of <15(Paterno et al., 2018; Saha, 2016), and the Anterior Cruciate Ligament-Return to Sport after Injury (ACL-RSI) scale, particularly with scores of >65(Sadeqi et al., 2018) (Table 3-1). Patient-reported outcome measures should be incorporated into return-to-sport criteria after ACL reconstruction. The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-10: Summary of Studies on Patient-Reported Outcome Measures							
Study (Level of Evidence)	**Study Design**	**Quality Score (Appraisal Criteria)**	**No. of Patients/Groups**	**Population Characteristics**	**Group Differences**	**Parameters Assessed**	**Significant Findings**
Sonesson et al. 2017(Sonesson et al., 2017) (II)	PCS	11/14 (NIH PCS)	65/1	Age range: 15-45 years	N/A	IKDC-SKF, expectations, motivation, satisfaction	Higher motivation during rehab was associated with returning to preinjury sport; those who returned to preinjury sport were more satisfied with their activity level and knee function 1-year post-op
Paterno et al. 2018(Paterno et al., 2018) (II)	PCS	10/14 (NIH PCS)	40/1	Age range: 10-25 years; intention to return to level I or II sports for at least 50 hours per year after rehabilitation	N/A	TSK-11, hop tests, quadriceps strength test	Patients with greater self-reported fear were less active, had lower single leg hop performance and isometric quad strength, and had an increased risk of secondary ACL injury in the 24 months after RTS
Sadeqi et al. 2018(Sadeqi et al., 2018) (II)	PCS	12/14 (NIH PCS)	681/1	Athletes age > 16 years	N/A	ACL-RSI	ACL-RSI scores improved progressively over time after ACLR and were strongly and significantly associated with RTS rates
Saha 2016(Saha, 2016) (II)	PCS	12/14 (NIH PCS)	100/2	Age range: 15-45 years; preinjury Tegner score of 5 or more	Those who RTS vs. those who do not RTS	IKDC, Tegner, Noyes, Lysholm, Marx, TSK,	Marx and TSK showed a significant difference between

						isokinetic quadriceps and hamstring strength, laxity	those who returned vs. did not return to their previous sports; fear of reinjury appears to be a major factor in RTS
Zwolski et al. 2015(Zwolski et al., 2015) (II)	PCS	11/14 (NIH PCS)	139/1	Young athletes; age range: 9-25 years	N/A	Isometric quadriceps strength, IKDC	Significant correlation between IKDC scores and peak isometric torque + quadriceps LSI was observed at time of RTS
*PCS = prospective cohort study, IKDC-SKF = International Knee Documentation Committee Subjective Knee Form, TSK-11 = Tampa Scale of Kinesiophobia, RTS = return to sport, ACL-RSI = Anterior Cruciate Ligament Return to Sport Index, LSI = limb symmetry index.							

Table 3-10: Summary of Studies on Patient-Reported Outcome Measures

Return-To-Sport and Reinjury Rates

There is no consensus on the criteria for determining readiness for return to sport with a minimal risk of reinjury. Some clinicians utilize time-based criteria in recommending return to sport, often allowing their patients to return to sport as soon as 9 months after the surgical procedure(A. D. Beischer et al., 2008), and others wait until 2 years for return without limitations(Nagelli & Hewett, 2017). There has been an increased utilization of objective milestones and benchmarks achieved through functional and isokinetic testing along with psychological readiness.(Nagelli & Hewett, 2017) Seven studies explored subjective and objective assessments and their relationship to return-to-sport and reinjury rates in the ACL-reconstructed knee(Angelozzi et al., 2012; Arundale et al., 2018a, 2019; A. D. Beischer et al., 2008; Grindem et al., 2016; Nawasreh et al., 2018; Webster et al., 2019) (Table 3-11). These studies provide evidence in support of aspects of

return to-sport decision-making including the importance of psychological readiness to return to sport(Webster et al., 2019), utilization of functional and objective testing results as return-to-sport criteria(Arundale et al., 2019; Grindem et al., 2016; Nawasreh et al., 2018), development of a secondary injury prevention program(Arundale et al., 2018a), and the importance of having refrained from participating in sports without limitations until at least 9 months after ACL reconstruction(S. Beischer et al., 2020) (Table 3-1). These modalities should be considered in clearing any athlete for return to sport. The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-11: Summary of Studies on Return to Sport/Reinjury Rates							
Study (Level of Evidence)	**Study Design**	**Quality Score (Appraisal Criteria)**	**No. of Patients/Groups**	**Population Characteristics**	**Group Differences**	**Parameters Assessed**	**Significant Findings**
Beischer et al. 2020(S. Beischer et al., 2020) (II)	PCS	11/14 (NIH PCS)	159/1	Age range: 15-30 years; preinjury Tegner score of 6 or greater	N/A	Isometric and isokinetic quadriceps and hamstring strength, single-leg hop tests	Achieving symmetrical muscle function or quad strength was not associated with secondary ACL injury in young athletes; returning to sport before 9 months post op was associated with an approximately 7-fold increased rate of secondary ACL injury
Webster et al. 2019(Webster et al., 2019) (II)	PCS	10/14 (NIH PCS)	222/1	All participated in sport at least 1 day per week; no age range reported	N/A	Marx, laxity, single and triple crossover hop tests, IKDC-SKF, ACL-RSI	Higher psychological readiness, greater LSI, higher subjective knee scores, and higher activity level were all associated with RTS
Nawasreh et al. 2018(Nawasreh et al., 2018) (II)	PCS	10/14 (NIH PCS)	107/1	Age range: 15-55 years; participation in level I or II sports involving jumping, cutting, pivoting, and lateral movements for at least 50 hrs per yr preinjury	N/A	Isometric quadriceps index, single-legged hop tests, KOS-ADLS, GRS	Return to participation at the same preinjury activity level at 12 and 24 months post op was higher in those who passed the 6 months RTS criteria; the hop tests were the most consistent predictors of this
Arundale et al. 2019(Arundale et al., 2019) (II)	PCS	11/14 (NIH PCS)	117/1	Female football players; age range: 16-25 years	N/A	Tuck jump test, drop vertical jump test	No difference in tuck jump score or peak knee

							abduction moment were observed based on rehab duration
Grindem et al. 2016(Grindem et al., 2016) (II)	PCS	11/14 (NIH PCS)	106/1	Age range: 13-60 years; preinjury participation in level I or II activities	N/A	KOS-ADLS, GRS, quadriceps strength, hop test symmetry	Subjects who returned to level I sports had 4.32 times higher reinjury rate than those who did not; the reinjury rate was significantly reduced by 51% for each month RTS was delayed until 9 months after surgery
Arundale et al. 2018[50] (I)	RCT	25/37 (CONSORT)	40/2	Male athletes; age range: 15-54 years; participation in level I or II sports for at least 50 hours per year preinjury	Strengthening, agility, and secondary prevention (SAP) vs. SAP with perturbation training (SAP+PERT)	Quadriceps LSI, single-legged hop tests, KOS-ADLS, GRS	One year after ACL-R, 95% of athletes had returned to sport with 78% at pre-injury levels; two years after ACL-R, 95% returned to sport at pre-injury levels with only one athlete experiencing a second ACL injury
Angelozzi et al. 2012[51] (II)	PCS	11/14 (NIH PCS)	45/1	Male professional soccer players; age 23.4 ± 4.7 years	N/A	IKDC; Tegner; laxity; MVIC; RFD at 30%, 50%, 90%	RFD deficits remained 6 months post-op despite full recovery of MVIC
*PCS = prospective cohort study, RCT = randomized controlled trial, IKDC-SKF = International Knee Documentation Committee Subjective Knee Form, ACL-RSI = Anterior Cruciate Ligament Return to Sport Index, LSI = limb symmetry index, RTS = return to sport, KOS-ADLS = Knee Outcome Survey-Activities of Daily Living Scale, GRS = global rating scale for function, MVIC = maximal voluntary isometric contraction, RFD = rate of force development.							

Table 3-11: Summary of Studies on Return to Sport/Reinjury Rates

Sensorimotor Training

Sensorimotor training places an emphasis on postural control while progressively challenging the neurologic system in patients with musculoskeletal pain, as a supplement to rehabilitation, by improving motor control.(Page, 2006) Six studies(Arundale et al.,

2017, 2018b; Capin et al., 2017; Christanell et al., 2012; Fu et al., 2013; Takahashi et al., 2012) addressed sensorimotor training in varying modalities; 1 study assessed electromyography (EMG) biofeedback therapy(Christanell et al., 2012), and 5 studies investigated the effects of perturbation training on ACL reconstruction recovery (Table 3-12)(Arundale et al., 2017, 2018b; Capin et al., 2017; Fu et al., 2013; Takahashi et al., 2012). The results indicated that EMG biofeedback usage may improve muscular strength(Christanell et al., 2012), and whole-body vibration therapy may improve postural control, muscular performance, and various functional testing outcomes(Fu et al., 2013) (Table 3-1). The grade of recommendation for this modality was A (good evidence for or against recommending intervention).

TABLE 3-12: Summary of Studies on Sensorimotor Training							
Study (Level of Evidence)	**Study Design**	**Quality Score (Appraisal Criteria)**	**No. of Patients/Groups**	**Population Characteristics**	**Group Differences**	**Parameters Assessed**	**Significant Findings**
Christanell et al. 2012(Christanell et al., 2012) (I)	RCT	20/37 (CONSORT)	16/2	Age range: 20-49 years	6 weeks of EMG biofeedback vs. 6 weeks of standard rehab without EMG biofeedback	HHD test; ROM; iEMG for vastus medialis; subjective knee function, swelling, and pain	Significantly better passive knee extension and HHD test scores in treatment group; no significant difference in knee function, swelling, or pain
Fu et al. 2013(Fu et al., 2013) (I)	RCT	29/37 (CONSORT)	48/2	Age range: 20.9-28.6 years	8 weeks of whole-body vibration therapy versus conventional rehabilitation	Joint position sense, postural control, knee isokinetic performance, ROM, stability, hop tests	Significantly better postural control, muscle performance, single-legged hop, and shuttle run was observed in the interventional group; no significant difference was observed in knee joint position sense, triple hop, carioca, ROM, or stability
Takahashi et al. 2012(Takahashi et al., 2012) (I)	RCT	17/37 (CONSORT)	20/2	Age range: 14-47 years	3 months of new CKC exercise with standing shaking board vs. 3 months of traditional rehabilitation	Muscular strength, cross-sectional area of flexor and extensor muscles	Greater increase in the cross-sectional area of the extensor muscles was observed at 3 months in the interventional group
Arundale et al. 2017(Arundale et al., 2017) (I)	RCT	25/37 (CONSORT)	40/2	Male athletes; age range: 15-54 years; participation in level I or II sports for at least 50 hours per year preinjury	Strengthening, agility, and secondary prevention (SAP) vs. SAP with perturbation training (SAP+PERT)	Quadriceps LSI, single-legged hop tests, KOS-ADLS, GRS	No significant differences were observed between groups for quadriceps symmetry, single-legged hop test limb symmetry, PROMs, knee

							function, or time to pass RTS criteria
Arundale et al. 2018(Arundale et al., 2018a) (I)	RCT	27/37 (CONSORT)	79/2	Age range: 13-54 years; participation in level I or II sports for at least 50 hours per year preinjury	Strengthening, agility, and secondary prevention (SAP) vs. SAP with perturbation training (SAP+PERT)	Quadriceps LSI, single-legged hop tests, KOS-ADLS, GRS	No differences were observed between groups for any measured variables; men made significant improvements in quadriceps LSI whereas women did not
Capin et al. 2017(Capin et al., 2017) (I)	RCT	23/37 (CONSORT)	40/2	Age range: 15-54 years; participation in level I or II sports for at least 50 hours per year preinjury	Strengthening, agility, and secondary prevention (SAP) vs. SAP with perturbation training (SAP+PERT)	3D motion analysis during overground walking	No significant differences were observed between groups for biomechanical gait variables
*PCS = prospective cohort study, RCT = randomized controlled trial, HHD = high-heel-distance, ROM = range of motion, iEMG = integrate electromyography, CKC = closed kinetic chain.							

Table 3-12: Summary of Studies on Sensorimotor Training

Supervised Rehabilitation

Rehabilitation after ACL reconstruction is typically done under the supervision of a licensed physical therapist. Two studies investigated whether formal supervision affected various outcomes following ACL reconstruction(Nyland et al., 2020; Przybylak et al., 2019) (Table 3-13). These studies suggested that rehabilitation supervised by a licensed therapist may be more effective than unsupervised exercise(Nyland et al., 2020; Przybylak et al., 2019) (Table 3-1). The grade of recommendation for this modality was B (fair evidence for or against recommending intervention).

TABLE 3-13: Summary of Studies on Supervised Rehabilitation							
Study (Level of Evidence)	**Study Design**	**Quality Score (Appraisal Criteria)**	**No. of Patients/ Groups**	**Population Characteristics**	**Group Differences**	**Parameters Assessed**	**Significant Findings**
Przybylak et al. 2019(Przybylak et al., 2019) (II)	CIS	7/14 (NIH CIS)	50/2	Mean age = 30.5 years	Supervised versus unsupervised physical therapy	Kujala, Tegner, KOOS, FMS, ROM	Higher activity levels and quality of life were observed in the supervised group
Nyland et al. 2020(Nyland et al., 2020) (II)	PCS	12/14 (NIH PCS)	150/1	Athletically active population who desired to return to sport; age 20.3 ± 7.2 years	N/A	KOS-SAS	Supplementation of standard rehab with the RTS bridge program resulted in improved patient outcomes and decreased ipsilateral knee reinjury and contralateral knee injury rates
*PCS = prospective cohort study, CIS = controlled intervention study, KOS-SAS = Knee Outcome Survey-Sports Activity Scale, KOOS = Knee Osteoarthritis Outcome Survey, FMS = functional movement screen, ROM = range of motion, RTS = return to sport.							

Table 3-13: Summary of Studies on Supervised Rehabilitation

DISCUSSION

Recovery protocols for ACL reconstruction remain heterogeneous in clinical practice secondary to a lack of consensus and in quality of evidence. This analysis offers a review of Level-I and II evidence from 2012 to 2020 to provide clinicians with a summary of results as they pertain to a variety of rehabilitative topics. Many reviewed studies had limitations in design, including but not limited to small sample sizes, lack of blinding, lack of long-term follow-up, or failure to randomize participants; however, the results presented provide valuable clinical evidence.

Accelerated rehabilitation has been investigated for ACL reconstruction utilizing hamstring autografts and may be equivalent to standard rehabilitation protocols in terms of short-term outcomes for general populations.(Feyzioglu et al., 2020) The early introduction of OKC exercise within 4 weeks after the surgical procedure may also aid improvements

in range of motion and muscular strength(Fukuda et al., 2013; Uçar et al., 2014), and the usage of NMES to supplement exercises can reduce atrophy of skeletal muscle fibers(Toth et al., 2020) and improve muscular strength(Labanca et al., 2018; Taradaj et al., 2013) and lower-extremity symmetry(Labanca et al., 2018).

Training with BFR has not been shown to cause substantial knee joint pain when used with low-intensity exercise; however, it is not recommended for use with high-intensity exercise, providing no additional benefit regarding quadriceps strength, activation, or volume.(Curran et al., 2020) Other studies have shown that BFR training is typically most effective when performed in combination with low-intensity exercise to increase muscular strength and hypertrophy in populations who cannot tolerate high-intensity exercise(Loenneke et al., 2012), although these findings were not supported by the studies that met the rigorous inclusion criteria of the current study. The incorporation of plyometrics into rehabilitation protocols has not been shown to provide any benefits after ACL reconstruction with respect to knee function or impairment.(Chmielewski et al., 2016) Postural control, muscular performance, and functional testing outcomes may improve through the use of whole-body vibration therapy.(Fu et al., 2013) Regardless of the modalities implemented, postoperative rehabilitation is most effective when completed under the supervision of a licensed professional.(Nyland et al., 2020; Przybylak et al., 2019) The small number of studies performed on supervised rehabilitation within the specified time period suggests a need for further evidence, as studies published before 2012 as reviewed by Kruse et al.(Kruse et al., 2012) provided conflicting evidence with regard to the efficacy of supervised rehabilitation compared with primarily home-based rehabilitation protocols.

The perioperative management techniques investigated include postoperative bracing, cryotherapy, and nerve blocks. Postoperative bracing was not found to improve surgical outcomes(Lindström et al., 2015; Mayr et al., 2014), nor did it reduce any asymmetries between the operatively treated extremities and the contralateral extremities(Mayr et al., 2014). This evidence is consistent with previous literature that has deemed bracing to have no beneficial effects.(Bordes et al., 2017) Both preoperative(Koyonos et al., 2014) and postoperative(Ruffilli et al., 2015) uses of cryotherapy were effective at reducing pain perception, and preoperative use also reduced painkiller consumption(Koyonos et al., 2014). Various types of intraoperative analgesia were investigated for their effects on postoperative pain scores and muscular function; periarticular injections were found to yield significantly better pain scores(Kurosaka et al., 2018), and both femoral nerve blocks and adductor canal blocks did not lead to any significant differences in long-term quadriceps muscular function(Okoroha et al., 2018; Runner et al., 2018).

The establishment of functional testing-based criteria for safe return to sport has eluded clinicians, with a lack of consensus on testing options and interpretation of the results of those tests. The included studies suggested that EPIC levels may be more accurate than LSI when using functional test results to predict reinjury rates(Wellsandt et al., 2017) and that hip external rotation strength may be the most accurate predictor of hop test performance(Kline et al., 2018). In addition to functional testing, psychological readiness is an important consideration in return-to-sport decision-making. The TSK-11(Paterno et al., 2018; Saha, 2016) and ACL-RSI(Sadeqi et al., 2018) are appropriate tools for determining psychological readiness. Higher psychological readiness, greater LSI, higher

subjective knee scores, and higher activity level have all been found to be associated with successful return to sport(Webster et al., 2019).

These results have been compared with results in previously published systematic reviews. The reviews published by Kruse et al.(Kruse et al., 2012) and vanMelick et al.(van Melick et al., 2016) provided a summary of results on the topics of postoperative bracing, supervised rehabilitation, OKC and CKC exercise, NMES, accelerated rehabilitation, cryotherapy, functional testing, and return to sport. Their results are consistent with those reported in this current systematic review, which provides further evidence with regard to ACL reconstruction recovery and rehabilitation.

CHAPTER 4

VARIATION AND CLINICAL TRENDS IN RECOVERY AND REHABILITATION PROTOCOLS FOLLOWING ACLR: A SURVEY OF ORTHOPEDIC SURGEONS

ABSTRACT

Purpose: To identify clinical practice patterns and trends among orthopedic surgeons as they pertain to postoperative recovery and activity progression following ACLR.

Methods: An online survey was distributed to members of the Arthroscopy Association of North America and the American Orthopaedic Society for Sports Medicine between November 2020 and September 2021. Participants reported on their clinical preferences for ACLR protocol development and patient selection, use of technology in ACLR recovery and rehabilitation, and preferences for advancing through multiple phases of the rehabilitative process.

Results: Responses from 46 orthopedic surgeons were analyzed. Patient-reported outcome measures were found to be underutilized at various phases of the perioperative period. Thirty-eight (82.6%) participants reported utilization of postoperative bracing. There was no consensus on when participants allow their patients to advance through rehabilitation, however, the majority report waiting 3-4 months for advancement to jogging/lateral movement, 6-8 months for return to noncontact sport, and 9 months of more for return to unrestricted sport. Many participants utilize functional and strength testing with associated limb symmetry indices to determine patient readiness to return to sport, with 18, 26, and 25 participants reporting use of functional testing and 28, 26, and 27 participants reporting use of strength testing at the return to jogging/lateral movements, non-contact return to sport, and unrestricted return to sport phases respectively.

Conclusion: There is substantial variation in rehabilitative patterns and preferences among surgeons after ACL reconstruction and a relative underutilization of patient-reported outcome measures. These findings highlight a lack of consensus and standardization of rehabilitative protocols.

Clinical Relevance: Postoperative rehabilitative protocols after ACL reconstruction vary by surgeon. Clarification regarding the rehabilitation practices of orthopedic surgeons in the United States dealing with adult patients is needed.

INTRODUCTION

Despite the nearly 300,000 anterior cruciate ligament reconstructions (ACLRs) performed in the United States each year(Steven B. Cohen & Jon K. Sekiya, n.d.) to treat anterior cruciate ligament (ACL) injuries, 37% of athletes undergoing this procedure do not return to their preinjury level of sports participation, and the majority (56%) do not return to competitive sport. Additionally, 18% of patients do not return to any form of sport after ACLR.(Ardern et al., 2011)

Postoperative rehabilitation plays a large role in achieving positive outcomes after ACLR; however, previous surveys have found that orthopedic surgeons and physical therapists differ substantially in practice regarding rehabilitation after ACLR, in particular when it comes to establishing criteria for return to sport milestones such as returning to jogging/lateral movement, returning to non-contact sport, and returning to unrestricted sport.(Ajuied et al., 2014; Greenberg et al., 2018, 2019; SIGASCOT Sports Committee et al., 2016) Clarification regarding the rehabilitation practices of orthopedic surgeons in the United States dealing with adult patients is needed.

While past surveys have focused on postoperative rehabilitation, there is evidence suggesting that preoperative rehabilitation may improve functional outcomes and return to sport rates after ACLR.(Carter et al., 2020; Failla et al., 2016) Further, the use of quantitative assessment technologies, such as motion capture systems and dynamometry have been shown to be beneficial adjuncts to ACLR.(Edwinia O'Malley et al., n.d.)

The purpose of this study is to identify the clinical practice patterns and preferences of orthopedic surgeons regarding ACLR rehabilitation through a survey of members of the Arthroscopy Association of North American (AANA) and the American Orthopaedic Society for Sports Medicine (AOSSM). Questions pertain to both preoperative and postoperative rehabilitation, including criteria for clearing patients to return to sport at various degrees and the use of quantitative assessment technologies in rehabilitation. We hypothesize that the results of this survey will illustrate a lack of consensus among practitioners with regards to the modalities utilized in recovery and rehabilitation for ACLR, with the most pertinent lack of consensus being seen in the criteria that practitioners use to determine patient readiness to return to sport.

METHODS

Survey Development

The primary authors (KG & ST) collaborated with the senior author (AC) to develop an electronic survey using REDCap electronic data capture tools, hosted at Mayo Clinic Arizona. The development phase consisted of identification of key transitional phased guidelines for rehabilitation as utilized in previously published reports and the clinical expertise of the senior author.

Survey participants were given a brief introduction to the survey's purpose and instructed to answer questions based on their current clinical practice of patients undergoing ACLR with no other ligamentous, cartilaginous, or bony injuries that would require any modifications to their postoperative recovery protocol. The electronic survey utilized branching logic in order to maximize efficiency by propagating follow-up questions only if specific responses were chosen in previous questions. Accordingly, the total number of questions answered by each participant varied. The survey consisted of 8 sections: (1) demographics and practice patterns, (2) ACLR protocol development and patient selection, (3) use of technology in ACLR recovery/rehabilitation, (4) preoperative phase, (5) postoperative rehabilitation phase, (6) return to jogging/lateral movement phase, (7) non-contact return to sport phase, and (8) contact/unrestricted return to sport criteria (Appendix C).

The authors reviewed and tested the survey for format, content inclusivity, clarity, and functionality. The survey was further pilot tested among a group of five physical therapists specializing in orthopedics and sports medicine and noted to take 5 to 10 minutes to complete.

Participants were recruited from the mailing lists of both AANA and AOSSM. An email containing an electronic link for survey access was sent to all orthopedic surgeons included on both mailing lists, and the electronic link was posted on both professional societies' respective websites for active research surveys. Surgeons interested in participating were able to follow the link, which directed them to an opening letter from the senior author (AC) explaining the study's purpose and eligibility criteria. Participants

were granted access to the survey after selecting "yes" to the question indicating their informed consent to participate. Participation was completely anonymous as no identifying information was collected. This study received approval from the Mayo Clinic institutional review board (IRB #20-008283, approval located in Appendix D) before any survey responses were collected. The Checklist for Reporting Results of Internet E-Surveys (CHERRIES) was used to ensure the quality of reporting the findings of this study.(Eysenbach, 2004)

Statistical Analysis

Data were analyzed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Descriptive statistics were utilized to summarize the distribution, frequency, and dispersion of participant responses.

RESULTS

Respondents' Profile

Of the 61 responses collected from surgeons performing at least 20 ACLR procedures per year, 46 completed at least 50% of the survey questions (75.4% completion rate). Demographic and professional characteristics of respondents are presented in Table 4-1. Fifteen states across various geographical regions were represented in the sample. Years in practice as an orthopedic surgeon was evenly distributed with 45.7% reporting less than 16 years of experience and 54.3% reporting greater than 16 years of experience in clinical practice. The majority of the sample were board certified in orthopedic surgery (93.5%), practiced in an academic or teaching hospital (58.7%), and treated adolescents aged 14-19 years (93.5%) and/or adults aged 19-65 years (97.8%) in their clinical practice.

TABLE 4-1: Demographics of Survey Respondents	
	N (%)
Years of experience as an orthopedic surgeon	
0-4	8 (17.4)
5-10	6 (13.0)
11-15	7 (15.2)
≥16	25 (54.3)
Primary practice setting	
Academic or teaching hospital	27 (58.7)
For-profit or not-for-profit hospital	4 (8.7)
Private practice	14 (30.4)
Military hospital	1 (2.2)
Region of practice	
South Atlantic (DE, FL, GA, MD, NC, SC, VA, WV)	7 (15.2)
Mid-Atlantic (NJ, NY, PA)	7 (15.2)
East North Central (IL, IN, MI, OH, WI)	4 (8.7)
West North Central (IA, KS, MN, MO, NE, ND, SD)	3 (6.5)
East South Central (AL, KY, MS, TN)	0 (0.0)
West South Central (AR, LA, OK, TX)	0 (0.0)
New England (CT, ME, MA, NH, RI, VT)	4 (8.7)
Pacific (AK, CA, HI, OR, WA)	6 (13.1)
Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	15 (32.6)
No. of ACLR procedures performed per year	
21-50	14 (30.4)
51-100	22 (47.8)
>100	19 (21.7)
Board certification in orthopedic surgery	
Yes	43 (93.5)
No	3 (6.5)
Patient populations treated in practice	
Children (<14 years)	29 (63.0)
Adolescents (14-19 years)	43 (93.5)
Adults (19-65 years)	45 (97.8)
Geriatrics (>65 years)	33 (71.7)

Table 4-1: Demographics of Survey Respondents

ACLR Protocol Development & Patient Selection

Respondents were asked to identify all the methods utilized to confirm whether a patient has an ACL injury. All respondents (n=46, 100%) reported that they use the Lachman test to assess ACL integrity. Forty-two (91.3%) reported using magnetic resonance imaging (MRI) and 38 (82.6%) reported using the pivot shift test to confirm ACL injury. Sixteen (34.8%) respondents indicated they utilize patient-reported outcome measures (PROMs); the PROMs reported by these sixteen respondents to assess injury status include the Lysholm Knee Scoring Scale (n=12, 75.0%) and Tegner Activity Scale (n=12, 75.0%), the International Knee Documentation Committee (IKDC) Score (n=3,

18.8%), the Pain Catastrophizing Scale (PCS) (n=2, 12.5%), and the Knee Self-Efficacy Score (K-SES), MARX Scale, and Patient-Reported Outcome Measure Information Systems (PROMIS) (n=1 for each, 6.3%).

Use of Technology in ACLR Recovery/Rehabilitation

Thirty-nine of the 46 (84.8%) surgeons reported that they believe quantitative assessment technology would help improve patient care and outcomes in ACLR recovery, while only 20 (43.5%) reported that they currently use this technology in their clinical practice. The twenty respondents who currently use this technology were asked to specify all the technologies they utilize. Responses included isokinetic dynamometry (n=10, 21.7%), video recording (n=9, 19.6%), handheld dynamometry (n=6, 13.0%), video and software packages (n=4, 8.7%), sensor-based systems (n=4, 8.7%), functional assessment screening (n=1, 2.2%), lab-based program (n=1, 2.2%), and force plates (n=1, 2.2%).

Respondents were also asked to specify all the factors that they believe limit the use of quantitative technology in their clinical practice, if any. Limiting factors that were specified included expense of technology (n=28, 60.9%), time needed to perform testing (n=25, 54.4%), lack of training of allied health staff (n=21, 45.7%), lack of defined protocols in literature (n=18, 39.1%), availability of allied health staff to perform assessments (n=18, 39.1%), lack of validation of technology (n=13, 28.3%), potential lack of availability of equipment at differing physical therapy clinics (n=1, 2.2%), and potential difficulty to recall patients for testing due to clinic location (n=1, 2.2%).

Preoperative Phase

Respondents were asked whether they provided patients with any preoperative education on the ACLR recovery process. Thirty-three out of 46 respondents (71.7%)

reported providing patients with written material, while nine (19.6%) provide a video, two (4.4%) engage in verbal discussion with patients, one (2.2%) provides online resources, and nine (19.6%) reported that they do not provide patients with any educational materials.

Postoperative Rehabilitation Phase

Next, participants were asked to provide information about the postoperative modalities that they prescribe or recommend to patients who have undergone ACLR with no other ligamentous, cartilaginous, or bony injuries that would require modification of the postoperative protocol. Participants were asked whether they allow for immediate mobilization of the knee after surgery as well as whether they utilize postoperative bracing, continuous passive motion (CPM) machines, cryotherapy, and home-based rehabilitation programs. These results can be found in Figure 4-1.

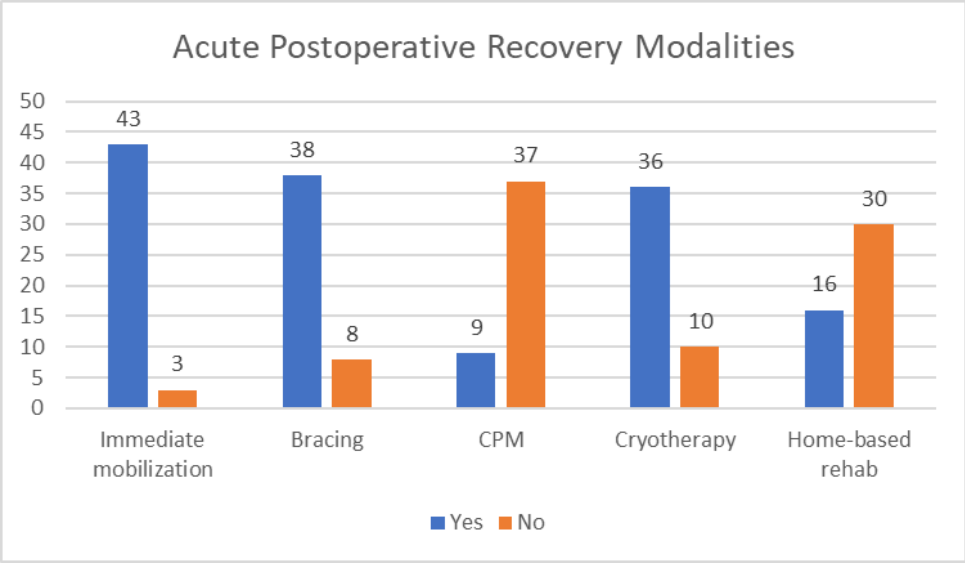

Figure 4-1: Acute Postoperative Recovery Modalities

Participants were asked to provide further details regarding the use of postoperative bracing, Of the 38 respondents who reported that they utilize postoperative bracing, 34 (89.5%) utilize a hinged knee brace while four (10.5%) use some other type of brace but did not specify the type. Four (10.5%) reported that their patients remain in a brace for less

than one week after surgery, seven (18.4%) require 1-2 weeks of bracing, three (7.9%) require 2-3 weeks, eight (21.0%) require 3-4 weeks, thirteen (34.2%) require 4-6 weeks, and three (7.9%) require their patients to remain in a brace for over six weeks following ACLR.

Return to Sport

The final three sections of the survey contained questions regarding three phases of returning to sport after ACLR: returning to jogging/lateral movement, returning to noncontact sport, and returning to contact/unrestricted sport. First, respondents reported the time frames at which they typically allow patients to advance to the next phase. These results can be found in Figure 4-2.

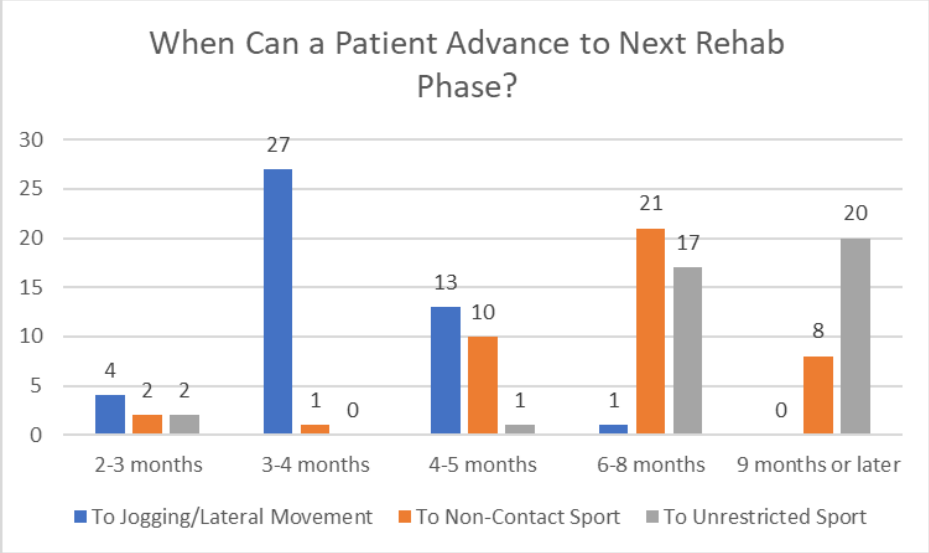

Figure 4-2: When Can a Patient Advance to Next Rehab Phase?

Forty-five participants provided a response regarding when they typically allow patients to return to jogging and lateral movement. Of these 45 responses, four (8.9%) reported that patients advanced to this phase 2-3 months post-op, 27 (60.0%) reported 3-4 months, 13 (28.9%) reported 4-5 months, and one (2.2%) reported 6-8 months.

Forty-two participants provided a response regarding when they typically allow patients to return to non-contact sport activities such as agility or sport-specific drills. Of these 42 responses, two (4.8%) reported that patients advance to this phase at 2-3 months post-op, one (2.4%) reported 3-4 months, ten (23.8%) reported 4-5 months, 21 (50.0%) reported 6-8 months, and eight (19.0%) reported waiting until 9 months or later.

Forty participants provided a response regarding when they typically allow patients to return to unrestricted sport activities. Of these 40 responses, two (5.0%) reported that patients advance to this phase 2-3 months post-op, one (2.5%) reported 4-5 months, 17 (42.5%) reported 6-8 months, and 20 (50.0%) reported waiting until 9 months or later.

Respondents were asked to specify any of the strength assessments they utilize to determine advancement readiness as well as the limb symmetry index (LSI) they require patients to demonstrate in their strength assessments before advancing to the next phase. These results can be found in Figures 4-3A and 4-3B, respectively.

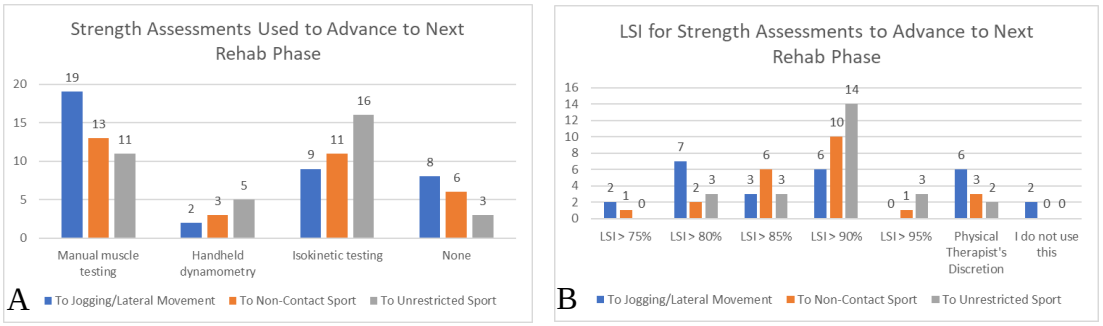

Figure 4-3: (A) Strength Assessments Used to Advance to Next Rehab Phase & (B) LSI for Strength Assessments

Thirty-six participants reported whether they utilize strength assessments in decision making for advancing patients to the jogging and lateral movement phase. Nineteen (52.8%) use manual muscle testing (MMT), two (5.6%) use handheld

dynamometry, nine (25.0%) use isokinetic testing, and eight (22.2%) do not utilize any strength assessments at this phase.

Twenty-six participants reported the LSI criteria they require patients to achieve in these strength assessments before advancing to jogging and lateral movement. Two (7.7%) reported LSI > 75%, seven (26.9%) reported LSI > 80%, three (11.5%) reported LSI > 85%, and six (23.1%) reported LSI > 90%. Six (23.1%) reported that this decision is made at the physical therapist's discretion, and two (7.7%) do not use LSI.

Thirty-two participants reported whether they utilize strength assessments in decision making for advancing patients to the non-contact return to sport phase. Thirteen (40.6%) use MMT, three (9.4%) use handheld dynamometry, 11 (34.4%) use isokinetic testing, and six (18.8%) do not utilize any strength assessments at this phase. Twenty-three participants reported the LSI criteria they require patients to achieve in these strength assessments before advancing to non-contact return to sport. One (4.3%) reported LSI > 75%, two (8.7%) reported LSI > 80%, six (26.1%) reported LSI > 85%, ten (43.5%) reported LSI > 90%, and one (4.3%) reported LSI > 95%. Three (13.0%) reported that this decision is made at the physical therapist's discretion.

Thirty participants reported whether they utilize strength assessments in decision making for advancing patients to the unrestricted return to sport phase. Eleven (36.7%) use MMT, five (16.7%) use handheld dynamometry, 16 (53.3%) use isokinetic testing, and three (10.0%) do not utilize any strength assessments at this phase. Twenty-five participants reported the LSI criteria they require patients to achieve in these strength assessments before advancing to unrestricted return to sport. Three (12.0%) each reported

LSI > 80% and 85%, 14 (56.0%) reported LSI > 90%, and three (12.0%) reported LSI > 95%. Two (8.0%) reported that this decision is made at the discretion of the physical therapist.

Respondents were also asked to specify any of the functional testing they utilize to determine advancement readiness as well as the limb symmetry index (LSI) they require patients to demonstrate in their functional assessments before advancing to the next phase. These results can be found in Figures 4-4A and 4-4B, respectively.

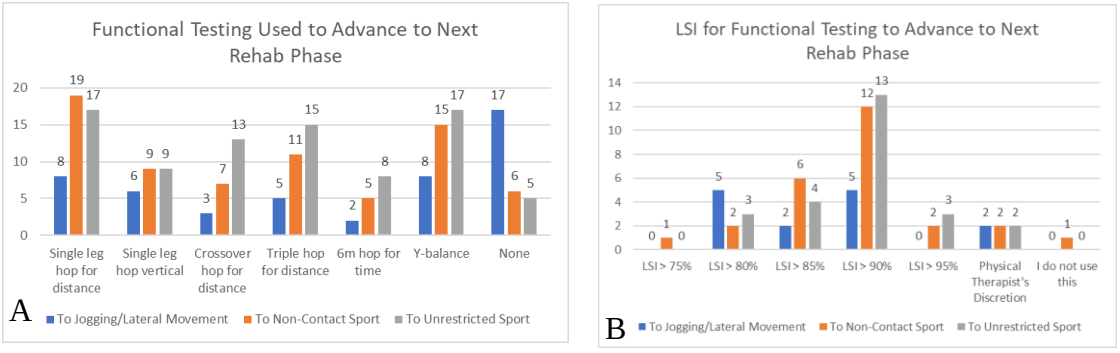

Figure 4-4: (A) Functional Testing Used to Advance to Next Rehab Phase & (B) LSI for Functional Testing

Thirty-five participants reported whether they utilize functional assessments in decision making for advancing patients to the jogging and lateral movement phase. Eight (22.2%) use the single-leg hop for distance, six (17.1%) use the single-leg hop vertical, three (8.6%) use the crossover hop for distance, five (14.3%) use the triple hop for distance, two (5.7%) use the 6-meter hop for time, eight (22.2%) use Y-balance testing, and 17 (48.6%) do not utilize any functional assessments at this phase. Fourteen participants reported the LSI criteria they require patients to achieve in these functional assessments before advancing to jogging and lateral movements. Five (35.7%) reported LSI > 80%, two (14.3%) reported LSI > 85%, and five (35.7%) reported LSI > 90%. Two (14.3%) reported that this decision is made at the physical therapist's discretion.

Thirty-two participants reported whether they utilize functional assessments in decision making for advancing patients to the non-contact return to sport phase. Nineteen (59.4%) use the single-leg hop for distance, nine (28.1%) use the single-leg hop vertical, seven (21.9%) use the crossover hop for distance, eleven (34.4%) use the triple hop for distance, five (15.6%) use the 6-meter hop for time, fifteen (46.9%) use Y-balance testing, and six (18.8%) do not utilize any functional assessments at this phase. Twenty-six participants reported the LSI criteria they require patients to achieve in these functional assessments before advancing to non-contact sport activities. One (3.8%) reported LSI > 75%, two (7.7%) reported LSI > 80%, six (23.1%) reported LSI > 85%, twelve (46.2%) reported LSI > 90%, and two (7.7%) reported LSI > 95%. Two (7.7%) reported that this decision is made at the physical therapist's discretion and one (3.8%) does not utilize LSI.

Thirty participants reported whether they utilize functional assessments in decision making for advancing patients to the unrestricted return to sport phase. Sixteen (53.3%) use the single-leg hop for distance, nine (30.0%) use the single-leg hop vertical, thirteen (43.3%) use the crossover hop for distance, fifteen (50.0%) use the triple hop for distance, eight (26.7%) use the 6-meter hop for time, seventeen (56.7%) use Y-balance testing, and five (16.7%) do not utilize any functional assessments at this phase. Twenty-five participants reported the LSI criteria they require patients to achieve in these functional assessments before advancing to unrestricted sport activities. Three (12.0%) reported LSI > 80%, four (16.0%) reported LSI > 85%, thirteen (52.0%) reported LSI > 90%, and three (12.0%) reported LSI > 95%. Two (8.0%) reported that this decision is made at the physical therapist's discretion.

Next, respondents were asked to identify all of the rehabilitative modalities they allow their patients to participate in for each phase of returning to sport. These results can be found in Figure 4-5.

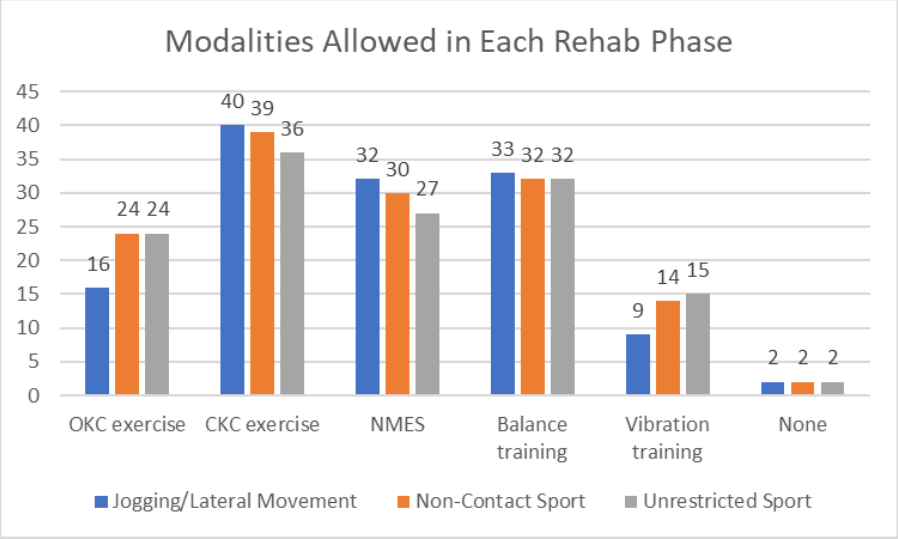

Figure 4-5: Modalities Allowed in Each Rehab Phase

Forty-three participants reported the modalities that they typically allow in the jogging and lateral movement phase. Sixteen (37.2%) use OKC exercise, 40 (93.0%) use CKC exercise, 32 (74.4%) use NMES, 33 (76.7%) use balance training, nine (20.9%) use vibration training, and two (4.7%) do not use any of these modalities.

Forty-two participants reported the modalities that they typically allow in the non-contact return to sport phase. Twenty-three (54.8%) use OKC exercise, 38 (90.5%) use CKC exercise, 29 (69.0%) use NMES, 31 (73.8%) use balance training, thirteen (31.0%) use vibration training, and two (4.8%) do not use any of these modalities.

Forty participants reported the modalities that they typically allow in the unrestricted return to sport phase. Twenty-four (60.0%) use OKC exercise, 36 (90.0%) use

CKC exercise, 27 (67.5%) use NMES, 32 (80.0%) use balance training, fifteen (37.5%) use vibration training, and two (5.0%) do not use any of these modalities.

Finally, respondents were asked to identify what they believe is the single most important factor in determining a patient's readiness to advance to returning to sport. Out of the 40 participants who responded to this question, 21 (52.5%) reported that functional testing scores are the single most important factor, 15 (37.5%) reported that time since surgery is the most important factor, two (5.0%) reported that muscle strength is the most important factor, and one respondent each (2.5%) reported that either knee symmetry or overall impression is the most important factor in advancing patients.

Appendix E contains supplementary results from additional survey questions.

DISCUSSION

The findings in this study offer a comprehensive evaluation of preferences and protocols in the perioperative and rehabilitative stages after ACLR in adolescents and adults. This analysis is particularly important given the current variability in clinical practice patterns and importance of appropriate rehabilitation to the success of ACLR.(Glattke et al., 2021)

With the current climate in healthcare transitioning to a larger emphasis on patient satisfaction scores as a marker for quality of care(van Eck et al., 2018) and recent literature suggesting their utility in identifying readiness to return to sport,(Paterno et al., 2018; Sadeqi et al., 2018) PROMs have continued to play a larger role in clinical practice. Despite this emphasis, of the orthopedic surgeons surveyed in this study, only 34% (n=16) utilized these tools in their practice and only 6.3% (n=1) incorporated the use of the NIH PROMIS

scale. Further, psychological factors have also emerged as an important component of effective return to sport,(Paterno et al., 2018; Saha, 2016) yet only 23.3% (n=7) of providers utilized any measure of psychological readiness. These results have been echoed in prior literature suggesting that less than 50% of practitioners regularly incorporate outcome measures in practice.(Greenberg et al., 2018, 2019)

Advances in technology to quantify stages in ACL rehabilitation assist in objectifying rehabilitative progress and have the potential to improve surgical outcomes. A large majority of surgeons in this study (84.8%, n=39) agree that this technology has the ability to improve patient care, but only 43.5% (n=20) incorporate it into clinical practice largely due to expense (60.9%, n=28) and time limitations (54.4%, n=25). These findings highlight the desire for technology that can help quantify effective rehabilitation as well as the fact that there are significant hurdles to overcome in implementation of said technology.

Preoperative optimization of the ACL patient is critical in setting the stage for a successful outcome. Prior literature has suggested that patients are often not informed appropriately on what to expect prior to surgery and the challenges in recovery which can result in decreased satisfaction and surgical outcomes.(Bouton et al., 2015; Cole et al., 2017; Renna et al., 2020) A study by Bouton et al. showed that at most, 29% of patients gained any knowledge from their physician and do not find leaflets or generic information helpful.(Bouton et al., 2015; Eggeling et al., 2018) Our survey showed that 19.6% (n=9) of providers did not provide any educational material to their patients and that among those who did, 71.7% (n=33) provided written materials. This contrast highlights the need to place a greater emphasis on patient education and development of supporting material.

In the immediate postoperative period, 82.6% (n=38) of surgeons reported utilizing bracing for their patients with a significant variability in the duration with the largest number recommending 3-4 weeks (32%, n=8), but with some providers requiring greater than six weeks (7.9%, n=3). Prior literature has suggested that there is no significant clinical benefit with the use of postoperative braces with regards to PROMs and joint effusion.(Lindström et al., 2015) Further, 84% (n=39) of providers recommended the use of NMES in this time period, which is consistent with prior literature suggesting its benefits in quadriceps strength(Taradaj et al., 2013) and reduced muscle fiber atrophy.(Toth et al., 2020) This was consistent throughout the rest of the study as well with 76.7% recommending its use in the joggling/lateral movement phase and 80% in the unrestricted return to sport phase.

Another rehabilitative modality, whole-body vibration therapy (WBVT) has been suggested to improve postural control, muscular performance and positively influence functional testing outcomes in prior literature.(Fu et al., 2013) The results of this survey show that at most, 37.5% (n=15) of providers utilize this modality in their rehabilitative protocols, which highlights WBVT as a likely underused modality.

There is currently no established consensus on the appropriate time to return to sport after ACLR, but prior literature has suggested that patients who delay full return to sport until 9 months after surgery have a significantly reduced risk of reinjury rate.(A. D. Beischer et al., 2008; Grindem et al., 2016) This may be due to a combination of biological factors along with physiologic recovery.(Wilk et al., 1994) In this study, the majority of respondents (50%, n=20) waited until at least 9 months before patients were allowed to

return to sport, but a large percentage (42.5%, n=17) allowed this within 6-8 months. This is consistent with prior literature with a study by Greenberg et al. showing 45.1% of providers allowed return to sport at >9 months and 38.1% between 6-8 months.(Greenberg et al., 2018) In a survey of Italian orthopedic surgeons, Grassi et al. found a larger percentage of surgeons (92%) allowed competitive return to play within 8 months and with 48% allowing a return within 6 months, suggesting a difference in opinion within the international community.(SIGASCOT Sports Committee et al., 2016) Despite the majority of providers delaying full return until 9 months, this lack of complete consensus is reflective of the variability of previously published research and the complexity of decision making for each athlete.(Greenberg et al., 2018)

Strength and functional testing have traditionally been a component in evaluating the recovery of muscular strength and function after ACLR. Results of these tests can help clinicians identify deficiencies and determine readiness to return to sport. In this study, 30 participants reported that they objectively evaluated muscular strength before final clearance to return to unrestricted sport with 56% requiring a LSI of greater than 90% to return to sport and 12% requiring a LSI of greater than 95%. Regarding functional testing, 52% of surgeons required an LSI >90% and 12% required an LSI >95%. Prior literature has supported the use of LSI in return to sport criteria but has heeded in using it as a sole measure.(Thomeé et al., 2012; Webster et al., 2019) Grassi et al. noted that muscle function testing was used by half of surveyed surgeons while functional testing was used by only a third in the same setting,(SIGASCOT Sports Committee et al., 2016) whereas Greenberg et al. noted that greater than 90% of physical therapists incorporated thigh muscular strength in their assessment.(Greenberg et al., 2018) When considering all factors in return

to sport, providers in this study indicated that functional testing was their single most important outcome (53.5%, n=21) with time since surgery being a close second (37.5%, n=15).

Overall, the results of this study continue to reflect lack of consensus and well-defined clinical evidence to support a standardized rehabilitative protocol and highlight the importance of continued research on this topic.(Ajuied et al., 2014; Greenberg et al., 2018, 2019; SIGASCOT Sports Committee et al., 2016) Some practices appear to be aligned with current literature (cryotherapy, NMES, time- and phase-based protocols) whereas others have yet to catch up to supporting evidence (PROMs). Prior literature has suggested there is a significant time lag before adoption into clinical practice.(Morris et al., 2011) Understanding the variation in clinical practice and limitations in adoption of gold standard guidelines continues to be an area of interest.

Limitations

There are some limitations within this study that need to be considered. Data was obtained using an Internet-based survey collection tool that incorporated anonymity; therefore, we do not know how many people were informed about the study and how many chose not to participate, which could constitute a selection bias. Further, our sample may not be representative of all orthopedic surgeons who perform ACLR, particularly with regards to geographic location. Finally, because of the survey's design that allowed participants to exit the survey program without responding to all questions, the completion rate was below 100% and some of the datasets analyzed were incomplete.

CONCLUSION

This study highlights the rehabilitative protocols and modalities utilized by practicing orthopedic surgeons in practice across the US. There is notably substantial variation in rehabilitative patterns and preferences with a relative underutilization in patient-reported outcome measures. As a whole, the findings in this study suggest a lack of consensus and standardization of rehabilitative protocol with a need for further research.

CHAPTER 5

LOW-INTENSITY BLOOD FLOW RESTRICTION TRAINING AS A PREOPERATIVE REHABILITATIVE MODALITY TO IMPROVE OUTCOMES FOR ACLR

INTRODUCTION

Injuries to the ACL are an epidemic among adolescents, especially those who are active in sports that include contact and frequent cutting motions. There are over 200,000 ACL injuries annually in the United States; with 1 in 60 adolescent athletes suffering an ACL injury at some point in their sports career.(Queen, 2017) After ACLR procedures, patients typically experience quadriceps atrophy and functional impairments; recovery of knee joint range of motion as well as quadriceps strength and hypertrophy are the primary goals of postoperative rehabilitation. In order to accelerate this recovery, blood flow restriction (BFR) training has recently gained traction for use in clinical and athletic settings. BFR training involves the application of a tourniquet-like cuff to the proximal aspect of a limb prior to exercise; the cuff is tightened or inflated so that it occludes venous flow but allows arterial inflow.(Vanwye et al., 2017) BFR is often combined with low intensity (LI) resistance training, with resistance as low as 20% of one-repetition maximum (1RM).(Vanwye et al., 2017) BFR combined with LI resistance training has been used as a clinical modality in improving strength and hypertrophy for individuals who cannot safely tolerate high muscular tension exercise or those who cannot produce volitional muscle activity(Vanwye et al., 2017), as well as a rehabilitative tool in the process of return to high-load (HL) exercise.(Hughes et al., 2017)

Quadriceps Strength & Hypertrophy

The American College of Sports Medicine (ACSM) recommends that resistance training be done at 70% of 1-RM in order to make improvements in muscular strength and hypertrophy; however, this is not always possible for those who are recovering from an injury or surgical procedure and those with musculoskeletal disorders.(Loenneke et al., 2012) For patients in the postoperative phase of surgery, the primary goal of rehabilitation is to expediently restore normal muscle activation and function.(Žargi et al., 2018) This is notably critical in patients who have undergone ACL-R, as atrophy and of the muscles surrounding the knee, especially the quadriceps femoris, is seen during the early post-op period of ACL-R.(Ohta et al., 2003) Considerable impairments of the quadriceps often persist for several months following surgery and may result in poor functional status of patients following an otherwise successful ACL-R procedure.(Žargi et al., 2018)

In order to address postoperative impairments of the quadriceps, surgeons will often prescribe preoperative rehabilitation, or prehab, for patients scheduled to undergo ACL-R. Literature has demonstrated a positive correlation between preoperative function of the quadriceps and successful long-term outcomes of ACLR.(Žargi et al., 2018) Prevention of atrophy and early recovery of muscular strength have also been reported to be associated with an early return to athletic activities after ACLR.(Ohta et al., 2003) Conversely, the consequences of progressive and injury-related loss of muscle strength may increase the risk of early onset osteoarthritis secondary to altered gait patterns and function.(Hughes et al., 2017) The **primary purpose** of this study is to evaluate if LI-BFR training utilized in a pre-rehabilitative setting for patients undergoing ACLR improves postoperative outcomes by minimizing postoperative atrophy and impairment of the quadriceps. *It is*

hypothesized that postoperative strength and hypertrophy of the quadriceps will be greater in a population that undergoes preoperative LI-BFR training than that of a population that undergoes LI-SHAM BFR training.

Postural Stability and Gait Speed

During the rehabilitation process following an ACLR procedure, functional tests are utilized to determine patient readiness to return to their preinjury levels of activity, including strength testing, jump and hop testing, and patient-reported outcome measures.(Webster et al., 2019) Together, these tests assess the success of a patient's postoperative rehabilitation and their readiness to return to their activity of choice. However, these testing protocols do not typically include postural stability and gait speed.

Postural stability is achieved through the aid of feedback mechanisms that generate appropriate actions to correct for naturally occurring body-sway movements that are detected by the body's proprioceptive systems.(Allum et al., 1998) The dominant sensory system that provides input to postural stability during unperturbed or "quiet" stance is the visual system.(Cooper et al., 2018) While balance is maintained with a lack of visual input, the magnitude of the body's sway will typically double in amplitude when visual deficits are present.(Dijkstra et al., 1994) Visual dependency and it's relation to postural stability can be quantified with the Romberg ratio(Kalron, 2017), which is calculated by dividing postural sway with the eyes closed by postural sway with the eyes open.(Furman, 1994)

Gait speed has been termed "the 6th vital sign" by clinicians due to its validity, reliability, and sensitivity in assessing functional status.(*Walking Speed: The Functional Vital Sign*, n.d.) Multiple bodily systems and functions come into play to result in gait speed, including but not limited to proactive and reactive postural stability, lower extremity

strength, proprioception, and vision.(*Walking Speed: The Functional Vital Sign*, n.d.) Because of this, gait speed can be considered a tool to guide clinical decision-making as a decreased speed can identify those at risk of adverse outcomes or in need of intervention.(*Walking Speed: The Functional Vital Sign*, n.d.)

While both of these variables have been studied extensively in populations who are considered to have an elevated fall risk(Allum et al., 1998; Dolatabadi et al., 2018; Jbabdi et al., 2008; Johansson et al., 2019; Mat et al., 2018; Puszczałowska-Lizis et al., 2016), they have not been thoroughly evaluated in younger populations.(Fu et al., 2013; Glattke et al., 2021) It has been shown that one of the effects of ACLR is decreased proprioception in the surgical limb(Lehmann et al., 2017; Relph et al., 2014), and that this loss of proprioceptive input from the lower limb can result in changes to balance corrections.(Allum et al., 1998) Therefore, the **secondary purpose** of this study is to investigate the effects of a preoperative rehabilitative modality on postural stability and gait speed in a population who have undergone ACLR. *It is hypothesized that a group who undergoes preoperative low-intensity blood flow restriction training will see reduced deficits in both postural stability and gait speed at 2 months after ACLR compared to a group who undergoes a SHAM BFR intervention before surgery.*

METHODS

Subjects

This study was a prospective, double-blinded, randomized, sham-controlled clinical trial, with all patients being recruited by a single board-certified orthopedic surgeon from Mayo Clinic Arizona in Tempe, AZ from December 2020 to November 2021 after a confirmed diagnosis of an isolated ACL rupture by clinical examination and magnetic resonance imaging. The treating orthopedic surgeon, the physical therapist involved in data

collection, and the subjects were all blinded to the intervention randomization. A separate physical therapist who was not involved in data collection activities was responsible for administering the randomized intervention to all subjects. The institutional review board of Mayo Clinic approved the study (IRB #19-008473, Appendix F).

Patients were asked to participate in this study after meeting the eligibility requirements. Inclusion criteria included patients between the ages of 13 and 50 years old who received a diagnosis of a primary ACL injury that required surgical intervention. Other inclusion criteria included having normal contralateral limb strength and an ability to comply with the two-week pre-operative rehabilitation schedule. Exclusion criteria included the following: any personal history of deep vein thrombosis (DVT) or any such history in their immediate family, any multi-ligamentous injuries to the knee that required modified postoperative weight-bearing restrictions, history of previous ACLR in either the affected or unaffected limb, and an inability or unwillingness of individual or legal guardian to give written informed consent. After subjects provided informed consent (Appendix G) for participation, the unblinded physical therapist randomized them into 1 of 2 treatment groups using the built-in randomization module within RedCap. Randomization was stratified for age and sex and the scheme was computer-generated before the study's initiation. Patients were randomized into either the LI-BFR group or the SHAM-BFR group and remained in their group for the duration of the study without any crossover.

Preoperative Rehabilitative Intervention

All subjects attended four pre-operative intervention visits with the unblinded treating physical therapist at a rate of two visits per week for two weeks. All subjects had a BFR cuff (Smart Tools, Strongsville, OH, USA) affixed to the proximal aspect of the femur of their affected limb, snugly under the gluteus maximus. A pressure gauge and handheld pump were attached to the cuff and a handheld doppler (Smart Tools, Strongsville, OH, USA) was used to locate the subject's dorsalis pedis pulse. Once the pulse was located, the physical therapist inflated the cuff until the dorsalis pedis pulse was fully occluded. For subjects in the LI-BFR group, the cuff's pressure was released until the pulse was 60% occluded (60% of total limb occlusion pressure), which has been demonstrated in literature to be a safe occlusion pressure for LI-BFR training.(Vanwye et al., 2017) For subjects in the SHAM-BFR group, the cuff's pressure was released until the pulse was 20% occluded, which constitutes a value that has been demonstrated in literature to maintain appropriate cuff placement without occluding blood flow.(Vanwye et al., 2017) After the respective intervention was adequately applied, subjects were instructed to complete the following exercises: one set of 30 repetitions followed by three sets of fifteen repetitions each of supine straight leg raises, seated long arc quads with weight as calculated by equation (1), body-weight squats, standing heel raises, and standing hamstring curls with weight as calculated by equation (1); these exercises were then followed by five repetitions of wall sits held for 30 seconds each. The cuff remained on the subject's leg throughout the duration of the exercises and subjects were asked to confirm whether they experienced any adverse effects such as pain, lightheadedness, dizziness, or nausea.

Weight for the above exercises was calculated based on the data collected from the handheld dynamometer (HHD). Tan et al. demonstrated a significant relationship between 1RM and HHD measures of strength as the value for 1RM of the quadriceps (1RMQuad) can be predicted using values of strength as measured by handheld dynamometry.(Tan et al., 2018) The average of the three attempts with the HHD for each subject was input into the following equation for prediction of 1RM:

(1) $$1RMQuad = 8.725 + (0.884*HHDQuad) - (8.472*gender)$$

In this equation, 1RMQuad and HHDQuad are both measured in kilograms. The value for gender is either 0 for males or 1 for females. The number calculated for 1RMQuad was then multiplied by .20 to determine 20% of 1RM(Vanwye et al., 2017), and converted from kilograms to pounds. This amount was rounded to the nearest pound for use during the above exercises.

Surgical Reconstruction & Postoperative Recovery/Rehabilitation

All subjects underwent a single-bundle ipsilateral reconstruction of the ACL with the graft type chosen by the consulting orthopedic surgeon: bone-patellar tendon-bone (BTB) autograft, semitendinosus-gracilis (STG) autograft, or allograft. Femoral nerve blocks were administered to all subjects before surgery for postoperative analgesia. After surgery, all subjects were placed in a postoperative brace (XACT ROM Lite, DJO, LLC, Lewisville, TX, USA) as well as a cryotherapy machine knee sleeve (DonJoy IceMan, DJO, LLC, Lewisville, TX, USA). The brace was locked in extension until subjects returned for their first postoperative follow-up appointment with the surgeon at 8-11 days after surgery, at which point the brace was unlocked for flexion. All subjects were

instructed to use bilateral axillary crutches for mobility and underwent preoperative gait training for education on weight-bearing as tolerated (WBAT) use of the crutches.

After the 8–11-day postoperative follow-up appointment, subjects were given clearance to begin their postoperative rehabilitation utilizing phased rehabilitative guidelines as provided by the consulting surgeon (Appendix A). Subjects were given the choice to pursue their postoperative rehabilitation either within the Mayo Clinic system or at a physical therapy clinic of their choosing. Subjects who did not choose to complete physical therapy at Mayo Clinic were given a written attestation to be signed by their physical therapist stating that they would not deviate from the surgeon's phased rehabilitative guidelines and that they would not administer BFR training while the subject was enrolled in the study. Subjects who underwent physical therapy at the Mayo Clinic Sports Medicine Center in Tempe, AZ were not treated by either physical therapist involved in the study and were also not permitted to deviate from the rehabilitative guidelines nor participate in postoperative BFR training for the duration of the study.

Outcome Measures

Subjects were followed throughout the duration of the 2-week preoperative period through the 24-week postoperative period. The primary outcomes were the difference in muscular strength and hypertrophy of the quadriceps femoris between intervention groups at 8 weeks postoperative. The secondary outcomes were the difference in static stability and gait speed between intervention groups at 8 weeks postoperative. Subjects were seen in the clinic for data collection visits at 2 weeks and 24-48 hours before surgery and 8-11 days, 4 weeks, 8 weeks, 14 weeks, and 24 weeks after surgery. The postoperative visit time

points were chosen to align with the surgeon's preferred postoperative follow-up visit schedule in order to reduce attrition.

Muscular strength of the quadriceps muscles was measured using two different methods: handheld dynamometry(Martins et al., 2017) and a leg press test(Drake et al., 2017). LSI was calculated as the ratio of strength of the involved limb divided by the strength of the uninvolved limb and multiplied by 100 for both strength tests.(Noyes et al., 1991) In order to preserve the integrity of the newly reconstructed ACLs after surgery, HHD testing was not performed until the 4 weeks postoperative visit and the leg press testing was not performed until the 8 weeks postoperative visit.

Handheld Dynamometer

For the HHD testing, subjects were seated on the edge of an exam table with their knees in 90° of flexion. Straps were used to prevent excess elevation of the hips and movement of the lower extremities as well as to stabilize the HHD (Lafayette Instrument Company, Lafayette, IN, USA). The HHD was held against the subject's shin and subjects were instructed to kick into the HHD until two beeps were emitted. This test was repeated three times for both limbs.(Martins et al., 2017)

Leg Press Test

The leg press test was performed on a standard leg press machine (Matrix Fitness; Cottage Grove, WI, USA). Subjects were asked to warm up with a double leg squat at body weight, followed by five repetitions at 60% Rate of Perceived Exertion (RPE) and five repetitions at 75% RPE. Subjects began with the uninvolved leg, followed by the involved leg, and performed 3-6 repetitions at a self-selected weight of their choosing. One-minute rest breaks were provided between sets until the subject reached a three-repetition maximum weight.(Drake et al., 2017)

Hypertrophy

Hypertrophy of the quadriceps was measured using musculoskeletal ultrasound imaging (Fujifilm Sonosite Inc., Bothell, WA, USA).(Friedman et al., 2001; Sahlani et al., 2016) Subjects were positioned in supine with the affected knee in full extension while the measuring physical therapist operated the transducer to obtain images of the subject's musculature according to the diagram in Appendix H. This was performed prior to both strength tests to ensure that muscle hypertrophy secondary to exercise did not happen. The physical therapist was trained in this technique by a board-certified radiologist who specializes in musculoskeletal imaging. Once images were obtained, they were de-identified and sent to a Physical Medicine and Rehabilitation physician who is board-certified in musculoskeletal ultrasound for interpretation and measurement reading. The physician utilized imageJ software(Schneider et al., 2012) to measure the cross-sectional areas of the rectus femoris, vastus lateralis, vastus medialis, vastus intermedius, and vastus medialis oblique.

Postural Stability & Gait Speed

Both postural stability and gait speed were measured using a smartphone application called the Lockhart Monitor.(Soangra & Lockhart, 2021) The application was downloaded to an iPhone 7 (Apple, Inc., Cupertino, CA) and the iPhone was clipped to an elastic belt worn around the subject's waist. This correlates with the location of the fifth lumbar vertebrae, or L5, which has been identified as the anatomical landmark that is closest to the body's center of mass.(Del Din et al., 2016)

For postural stability, subjects were instructed to stand still with both feet flat on the floor for 30 seconds with their eyes open. This was repeated one more time, and then subjects were instructed to repeat the test twice with their eyes closed. Subjects were

informed that the Lockhart Monitor application would emit audio cues to alert them of the test's beginning and end. Values for sway area and sway velocity were displayed on the phone's screen after each trial; these values were then recorded on each subject's data intake form and the values for each test condition were averaged. For gait speed, subjects performed two trials of the ten-meter walk test (10MWT).(Amatachaya et al., 2014) A distance of ten meters was marked on the floor with tape and subjects were instructed to walk the length of the ten meters when an audio cue was emitted by the Lockhart Monitor application, and stand still at the end of the marked distance until another audio cue was emitted to signal the end of the test. This test was repeated a second time and the values for gait speed as well as the two trials' average were recorded on the subjects' data forms. Subjects were permitted to use unilateral or bilateral axillary crutches during the walking test as needed.

Exploratory Outcomes

In addition to the measures taken for the primary and secondary aims, other exploratory outcomes were collected at each data measures visit as well. This includes range of motion of the knee joint (flexion and extension)(Hancock et al., 2018), effusion(Mathison & Teach, 2009), quadriceps lag(Stillman, 2004), static/postural stability(Paterno et al., 2010), gait speed(Slater et al., 2017), Lower Extremity Functional Scale (LEFS)(Alcock et al., 2012), visual analog scale (VAS) for pain(Hjermstad et al., 2011), Lysholm knee score(Briggs et al., 2009), and Anterior Cruciate Ligament Return to Sport Index (ACL-RSI)(Webster & Feller, 2018).

Statistical Analysis

Based on a two-sided, two sample Student's t-test test statistic, a Type I error rate of 5%, a Type II error rate of 10%, an assumed difference of 1.5 mm in muscle diameter

between the groups, an assumed standard deviation of 1.25 mm, and an attrition rate of 10%, we estimated that the primary endpoint would be sufficiently powered with a sample size of 28 subjects total. Analysis was conducted on all participants by the treatment group assigned at randomization, following an intent-to-treat approach.

Means and standard deviations of the demographic characteristics, days from injury to surgery, and surgery duration at baseline for each intervention group are reported in Table 5-1. Separate 2-way ANOVA tests were conducted with the factor of intervention group as well as time for each of the dependent variables: handheld dynamometer strength, leg press test strength, hypertrophy, gait speed, and postural stability. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A post-hoc Bonferroni multiple comparison test was performed with indicated $p \leq 0.05$ for all combinations of intervention group and time point for each dependent variable. IBM SPSS Statistics version 28 (IBM Corp, Armonk, NY) was used for all 2-way ANOVA tests and Excel (Microsoft Corporation, Redmond, WA) was used for all post-hoc Bonferroni multiple comparisons tests.

RESULTS

Thirty-four patients were screened for eligibility through an enrollment period from December 2020 to November 2021 (Figure 5-1). Thirty-three of these patients were assessed for inclusion or exclusion criteria and 29 patients were found to be eligible for enrollment. Fourteen males and 15 females underwent randomization and began the pre-operative rehabilitation protocol. Sixteen subjects were randomized to the SHAM-control group and 13 were assigned to the BFR intervention group. Baseline characteristics were

not different between groups with the exception of sex, with a greater percentage of females being assigned to the SHAM group (Table 5-1).

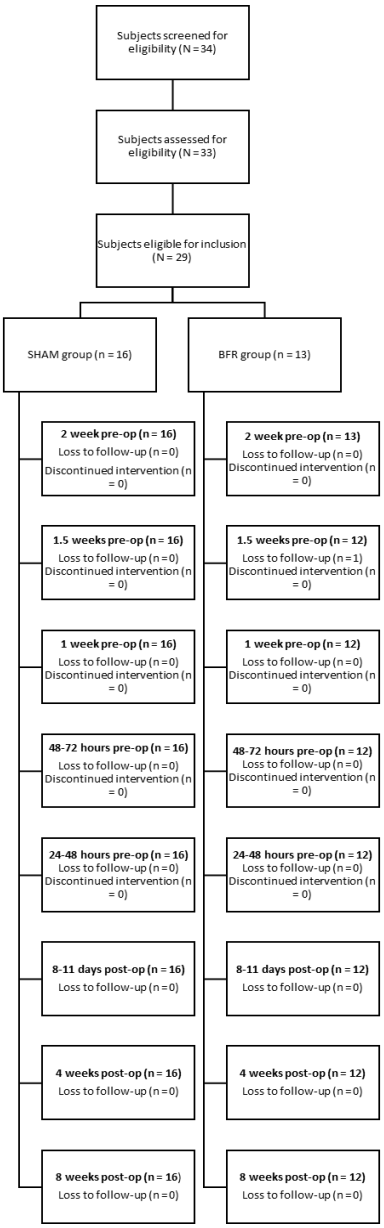

Figure 5-1: Enrollment and randomization of subjects

As randomization was stratified for sex and age, tests for association between these variables and intervention group were conducted. A chi-square test for association was conducted between sex and intervention group. All expected cell frequencies were greater

than five. There was not a statistically significant association between sex and intervention, $\chi 2(1) = 3.458$, $p = 0.063$. A Fisher's Exact test was conducted between age group (age ≤ 18 years and age 19 – 50 years) and intervention group. There was not a statistically significant association between age group and intervention group, $p = 0.705$. One subject in the BFR group was lost to follow-up at the second pre-operative intervention visit, leaving 28 subjects (16 in the SHAM group and 12 in the BFR group) with follow-up data for analysis.

Table 5-1: Baseline Characteristics of Study Participants

Characteristic	All subjects, N = 28	SHAM group, n = 16	BFR group, n = 12
Age, y, mean (SD)	23.9 (9.4)	25.69 (11.2)	21.5 (5.90)
Sex, male:female	13:15	5:11	8:4
Affected limb, right:left	16:12	9:7	7:5
Time from injury to surgery, d, mean (SD)	41.16 (17.86)	43.0 (17.48)	38.82 (18.90)
Activity level			
None, n (%)	2 (7.14%)	2 (12.5%)	0 (0.0%)
High school, n (%)	10 (35.71%)	6 (37.5%)	4 (33.33%)
Junior college, n (%)	5 (17.86%)	3 (18.75%)	2 (16.67%)
NCAA, n (%)	1 (3.57%)	0 (0.0%)	1 (8.33%)
Professional, n (%)	1 (3.57%)	0 (0.0%)	1 (8.33%)
Recreational, n (%)	9 (32.14%)	5 (31.25%)	4 (33.33%)
Activity type			
None, n (%)	2 (7.14%)	2 (12.5%)	0 (0.0%)
Contact, n (%)	17 (60.71%)	8 (50.0%)	9 (75.0%)
Noncontact, n (%)	9 (32.14%)	6 (37.5%)	3 (25.0%)
Graft type			
Hamstring, n (%)	10 (35.71%)	10 (62.5%)	7 (58.33%)
BTB, n (%)	17 (60.71%)	5 (31.25%)	5 (41.67%)
Allograft, n (%)	1 (3.57%)	1 (6.25%)	0 (0.0%)
Surgery duration, min, mean (SD)	90.7 (17.18)	85.31 (17.04)	97.92 (15.14)

Table 5-1: Baseline Characteristics of Study Participants

Exploratory Outcomes

Range of motion (flexion and extension), effusion, quad lag, and patient-reported outcome measures (LEFS, Lysholm Score, VAS for pain, and the ACL-RSI) were evaluated at baseline (2 weeks pre-op) and are reported in Table 5-2.

Table 5-2: Baseline Outcome Measures for Participants at 2 Weeks Pre-Op			
Outcome Measures, 2 weeks pre-op	**All subjects, N = 28**	**SHAM group, n = 16**	**BFR group, n = 12**
Handheld dynamometer strength, lbs, mean (SD)			
Affected Leg	78.76 (31.99)	70.36 (29.2)	89.96 (32.86)
Unaffected Leg	98.82 (33.46)	90.21 (30.5)	110.3 (35.04)
Leg press test strength, lbs, mean (SD)			
Affected Leg	107.32 (40.86)	96.88 (41.59)	121.25 (37.0)
Unaffected Leg	126.25 (36.78)	116.88 (37.37)	138.75 (33.45)
Hypertrophy, cm^2, mean (SD)	82.35 (13.09)	74.71 (9.55)	92.53 (9.92)
Postural stability-sway area, cm^2, mean (SD)			
Eyes Open	0.10 (0.08)	0.11 (0.09)	0.09 (0.06)
Eyes Closed	0.13 (0.18)	0.125 (0.19)	0.14 (0.16)
Postural stability-sway velocity, cm/s, mean (SD)			
Eyes Open	9.0 (4.69)	9.38 (5.71)	8.5 (3.0)
Eyes Closed	10.2 (6.09)	9.95 (6.38)	10.52 (5.94)
Gait speed, m/s, mean (SD)	0.44 (0.08)	0.44 (0.06)	0.44 (0.1)
Quad lag, deg, mean (SD)	8.61 (7.22)	8.56 (6.37)	8.67 (8.52)
Patient-reported outcome measures	46.07 (13.22)	47.31 (12.38)	44.42 (14.65)
LEFS, out of 80, mean (SD)	63.0 (18.69)	65.5 (18.17)	59.67 (19.64)
Lysholm Score, out of 100, mean (SD)	1.18 (1.85)	0.88 (1.78)	1.58 (1.93)
VAS for Pain, out of 10, mean (SD)	31.01 (24.43)	35.21 (25.21)	25.41 (23.2)
ACL-RSI, %, mean (SD)			

Table 5-2: Baseline Outcome Measures (mean and standard deviation) for Study Participants at 2 Weeks Pre-Op

Primary & Secondary Outcomes

Table 5-3: P-Values for 2-Way ANOVA for All Dependent Variables

	p-value		
Outcome Measure	**Time**	**Intervention**	**Time*Intervention**
Handheld dynamometer strength	2.04E-18	0.025	0.008
Leg press test strength	1.80E-9	0.543	0.751
Hypertrophy	1.13E-8	0.083	0.721
Gait speed	6.68E-16	0.508	0.410
Postural Stability			
Romberg Ratio (Sway Area)	0.200	0.872	0.883
Romberg Ratio (Sway Velocity)	0.509	0.438	0.823

Table 5-3: P-values for 2-way ANOVA conducted for each dependent variable between time point, intervention group, and interaction between time and intervention

Twenty-eight subjects were randomized into two intervention groups (SHAM and BFR) with no crossover between groups. Subjects underwent baseline testing at 2 weeks pre-operative and after the intervention was complete at 24-48 hours pre-operative. Subjects underwent follow-up testing at 8-11 days, 4 weeks, and 8 weeks postoperative. A 2-way ANOVA was conducted with the factor of intervention group as well as time and the dependent variable being each of the primary and secondary outcomes. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A summary of p-values for all 2-way ANOVA tests conducted can be found in Table 5-3. There was found to be a statistically significant difference for all dependent variables over time, $p < 0.001$, except for postural stability. Handheld dynamometer strength was found to have a statistically significant difference between intervention group, $p = 0.025$, as well as for an interaction between time and intervention, $p = 0.008$. Hypertrophy was found to be trending towards statistical significance for intervention group, $p = 0.083$.

Quadriceps Strength with Handheld Dynamometer

A 2-way ANOVA was conducted with the factor of group (SHAM versus BFR) as well as time normalized as the difference from the 24-48 hours pre-operative visit and the dependent variable being the strength of the quadriceps as measured by the handheld dynamometer. There was found to be a significant interaction within subjects between time and handheld dynamometer strength of the quadriceps at all of the time points, $p = 2.04E-18$. There was also a statistical significance between intervention group and handheld dynamometer strength, $p = 0.025$. Finally, there was a statistically significant interaction between time and intervention group on handheld dynamometer strength, $p = 0.008$. Mean handheld dynamometer strength between groups over time can be found in Figure 5-2A. A post-hoc Bonferroni multiple comparison test was performed with indicated $p \leq 0.05$. There was a statistically significant difference within the SHAM group between 2 weeks pre-op and 4 weeks post-op and between 2 weeks pre-op and 8 weeks post-op. There was a statistically significant difference within the BFR group between 2 weeks pre-op and 4 weeks post-op and between 2 weeks pre-op and 8 weeks post-op. Results of the Bonferroni multiple comparison test can be found in Figure 5-2B.

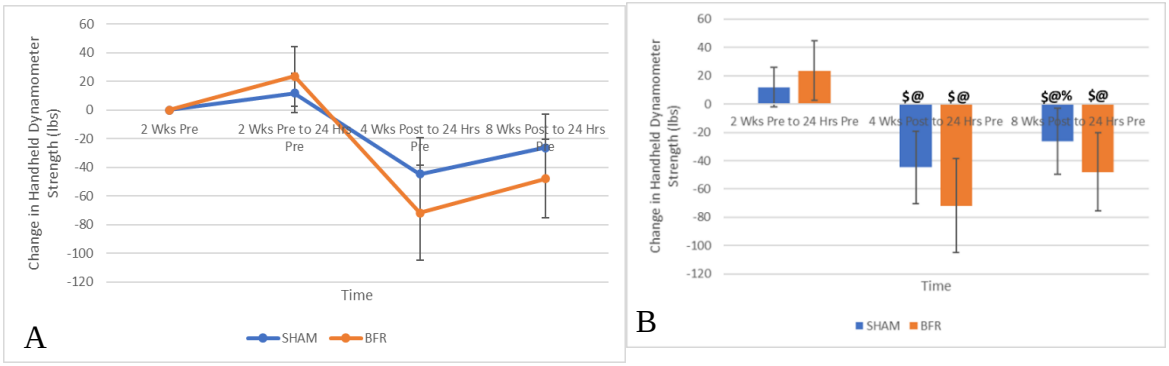

Figure 5-2: Handheld dynamometer strength with SHAM or BFR treatment. Twenty-eight subjects were randomized into two intervention groups (SHAM and BFR) with no crossover between groups. Subjects underwent baseline testing at 2 weeks pre-operative and after the intervention was complete at 24-48 hours pre-operative. Subjects underwent follow-up testing at 4 weeks and 8 weeks postoperative. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A 2-way ANOVA determined there was

a significant effect due to time (p=2.04E-18), intervention (p=.025), and the interaction between time & intervention (p=.008). Figure 5-2B displays results of a post-hoc Bonferroni multiple comparison tests with indicated p<0.05. Symbols representing comparisons are as follows: $ vs 2 wks pre SHAM, @ vs 2 wks pre BFR, ! vs 4 wks post SHAM, % vs 4 wks post BFR, # vs 8 wks post SHAM, and & vs 8 wks post BFR.

Quadriceps Strength with Leg Press Test

A two-way ANOVA was conducted with the factor of group (SHAM versus BFR) as well as time normalized as the difference from the 24-48 hours pre-operative visit and the dependent variable being the strength of the quadriceps as measured by the leg press test. There was found to be a significant interaction within subjects between time and leg press test strength of the quadriceps at all of the time points, p = 1.80E-9. There was not found to be statistical significance between the intervention groups and leg press test strength, p = 0.543. There was also no statistically significant interaction between time and intervention on leg press test strength, p = 0.751. Mean leg press test strength between groups over time can be found in Figure 5-3A. A post-hoc Bonferroni multiple comparison test was performed with indicated $p \leq 0.05$. There was a statistically significant difference within the SHAM group between 2 weeks pre-op and 8 weeks post-op and within the BFR group between 2 weeks pre-op and 8 weeks post-op. Results of the Bonferroni multiple comparison test can be found in Figure 5-3B.

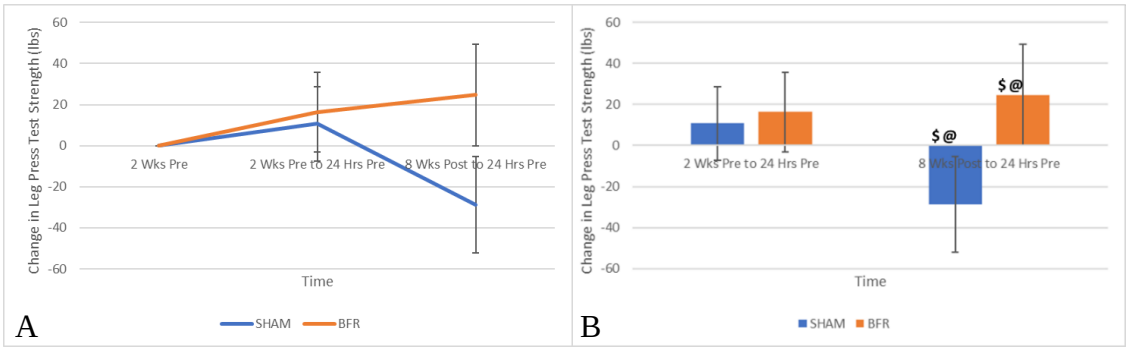

Figure 5-3: Leg press test strength with SHAM or BFR treatment. Twenty-eight subjects were randomized into two intervention groups (SHAM and BFR) with no crossover between groups. Subjects underwent baseline testing at 2 weeks pre-operative and after the intervention was complete at 24-48 hours pre-operative. Subjects underwent follow-up testing at 8 weeks postoperative. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A 2-way ANOVA determined there was a significant effect due to time (p=1.80E-9). Figure 5-3B displays results of a post-hoc Bonferroni multiple comparison tests with

indicated p<0.05. Symbols representing comparisons are as follows: $ vs 2 wks pre SHAM, @ vs 2 wks pre BFR, ! vs 8 wks post SHAM, and % vs 8 wks post BFR.

Quadriceps Hypertrophy

A two-way ANOVA was conducted with the factor of group (SHAM versus BFR) as well as time normalized as the difference from the 24-48 hours pre-operative visit and the dependent variable being hypertrophy of the quadriceps as measured by musculoskeletal ultrasound. There was found to be a significant interaction within subjects between time and hypertrophy of the quadriceps at all of the time points, $p = 1.13E-8$. There was not found to be statistical significance within subjects between the intervention group and hypertrophy, $p = 0.083$, although this value is trending towards significance. There was no statistically significant interaction between time and intervention on hypertrophy, $p = 0.721$. Mean hypertrophy as quantified by cross-sectional area of the quadriceps between groups over time can be found in Figure 5-4A. A post-hoc Bonferroni multiple comparison test was performed with indicated $p \leq 0.05$. There was a statistically significant difference within the SHAM group between 2 weeks pre-op and 4 weeks post-op and between 2 weeks pre-op and 8 weeks post-op. There was a statistically significant difference within the BFR group between 2 weeks pre-op and 8-11 days post-op, between 2 weeks pre-op and 4 weeks post-op, and between 2 weeks pre-op and 8 weeks post op. Results of the Bonferroni multiple comparisons test can be found in Figure 5-4B.

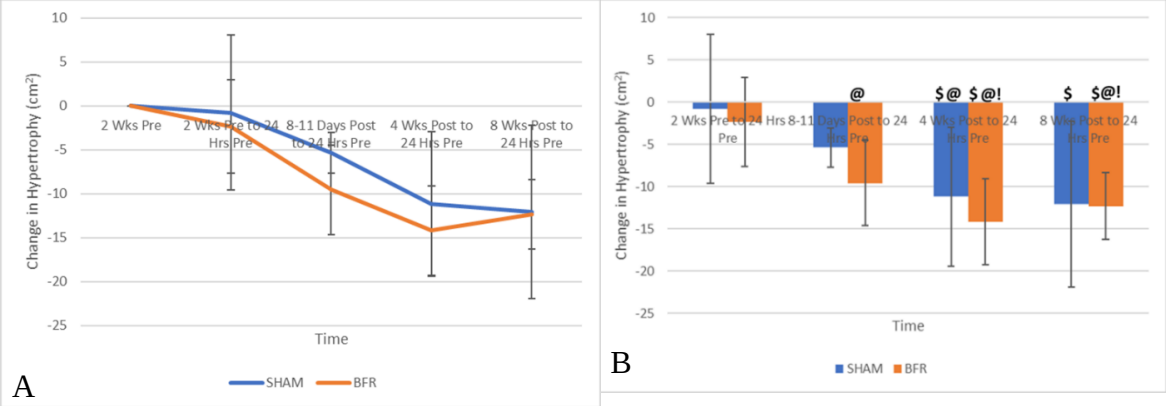

Figure 5-4: Quadriceps hypertrophy with SHAM or BFR treatment. Twenty-eight subjects were randomized into two intervention groups (SHAM and BFR) with no crossover between groups. Subjects underwent baseline testing at 2 weeks pre-operative and after the intervention was complete at 24-48 hours pre-operative. Subjects underwent follow-up testing at, 8-11 days, 4 weeks, and 8 weeks postoperative. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A 2-way ANOVA determined there was a significant effect due to time (p=1.13E-8). Figure 5-4B displays results of a post-hoc Bonferroni multiple comparison tests with indicated p<0.05. Symbols representing comparisons are as follows: $ vs 2 wks pre SHAM, @ vs 2 wks pre BFR, ! vs 8-11 days post SHAM, % vs 8-11 days post BFR, # vs 4 wks post SHAM, & vs 4 wks post BFR, ? vs 8 wks post SHAM, and ^ vs 8 wks post BFR.

Gait Speed

A two-way ANOVA was conducted with the factor of group (SHAM versus BFR) as well as time normalized as the difference from the 24-48 hours pre-operative visit and the dependent variable being gait speed as measured by the Lockhart Monitor application. There was a statistically significant difference between time and gait speed, $p = 6.68E\text{-}16$. There was not found to be a statistically significant difference between intervention group and gait speed $p = 0.508$. There was also no statistically significant interaction between time and intervention on gait speed, $p = 0.410$. Mean gait speed between groups over time can be found in Figure 5-5A. A post-hoc Bonferroni multiple comparison test was performed with indicated $p \leq 0.05$. There was a statistically significant difference within the SHAM group between 2 weeks pre-op and 8-11 days post-op, between 2 weeks pre-op and 4 weeks post-op, between 8-11 days post-op and 4 weeks post-op, and between 8-11 days post-op and 8 weeks post-op. There was a statistically significant difference within the BFR group between 2 weeks pre-op and 8-11 days post-op and between 8-11 days post-

op and 8 weeks post-op. Results of the Bonferroni multiple comparison test can be seen in Figure 5-5B.

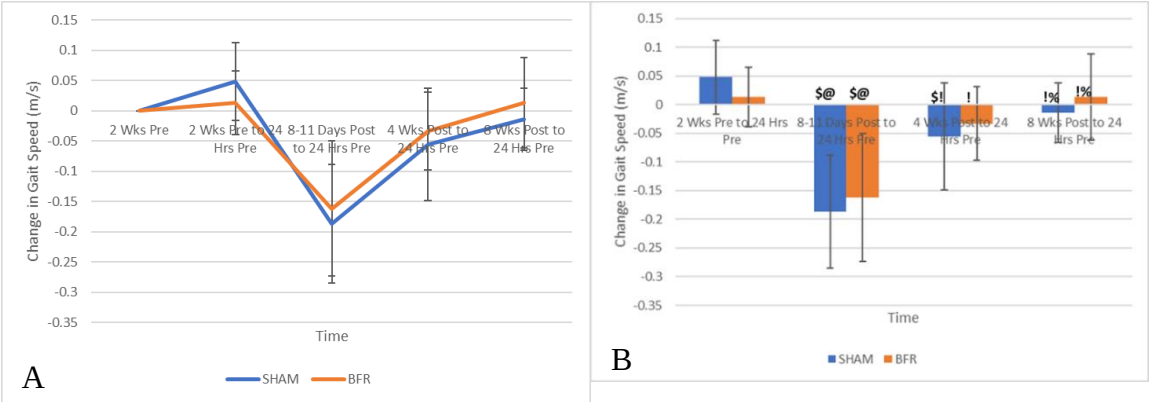

Figure 5-5: Gait speed with SHAM or BFR treatment. Twenty-eight subjects were randomized into two intervention groups (SHAM and BFR) with no crossover between groups. Subjects underwent baseline testing at 2 weeks pre-operative and after the intervention was complete at 24-48 hours pre-operative. Subjects underwent follow-up testing at, 8-11 days, 4 weeks, and 8 weeks postoperative. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A 2-way ANOVA determined there was a significant effect due to time (p=6.68E-16). Figure 5-5B displays results of a post-hoc Bonferroni multiple comparison tests with indicated p<0.05. Symbols representing comparisons are as follows: $ vs 2 wks pre SHAM, @ vs 2 wks pre BFR, ! vs 8-11 days post SHAM, % vs 8-11 days post BFR, # vs 4 wks post SHAM, & vs 4 wks post BFR, ? vs 8 wks post SHAM, and ^ vs 8 wks post BFR.

Postural Stability: Romberg Ratio with Sway Area

A two-way ANOVA was conducted with the factor of group (SHAM versus BFR) as well as time normalized as the difference from the 24-48 hours pre-operative visit and the dependent variable being Romberg Ratio as calculated with sway area measured by the Lockhart Monitor application. There was not found to be a statistically significant difference between time, intervention, or the interaction between time and intervention and Romberg Ratio, $p = 0.200$, $p = 0.872$, and $p = 0.883$, respectively. Mean Romberg Ratio between groups over time can be found in Figure 5-6A. A post-hoc Bonferroni multiple comparison test was performed with indicated $p \leq 0.05$. There was not found to be a statistically significant difference within any of the groups between time points or between any of the groups within time points. Results of the Bonferroni multiple comparison test can be found in Figure 5-6B.

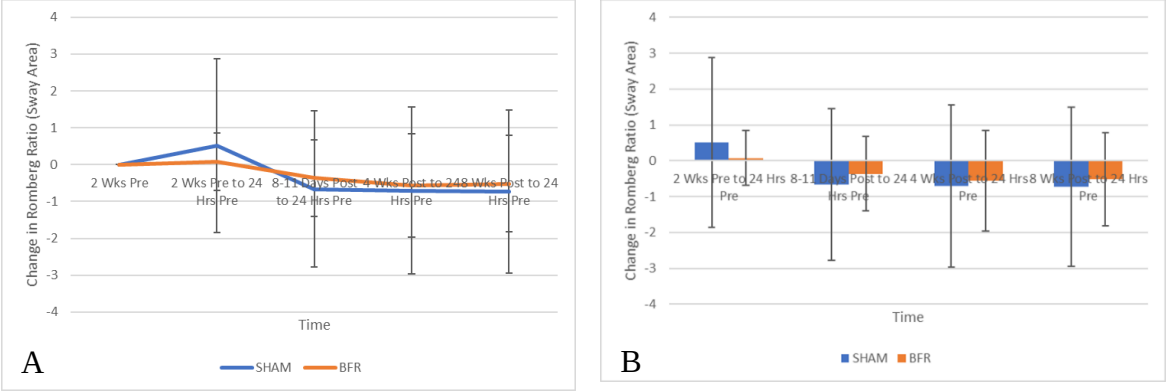

Figure 5-6: Sway area Romberg Ratio with either SHAM or BFR treatment. Twenty-eight subjects were randomized into two intervention groups (SHAM and BFR) with no crossover between groups. Subjects underwent baseline testing at 2 weeks pre-operative and after the intervention was complete at 24-48 hours pre-operative. Subjects underwent follow-up testing at, 8-11 days, 4 weeks, and 8 weeks postoperative. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A 2-way ANOVA determined there was no significant effect due to time, intervention, or the interaction between time and intervention. Figure 5-6B displays results of a post-hoc Bonferroni multiple comparison tests with indicated p<0.05. Symbols representing comparisons are as follows: $ vs 2 wks pre SHAM, @ vs 2 wks pre BFR, ! vs 8-11 days post SHAM, % vs 8-11 days post BFR, # vs 4 wks post SHAM, & vs 4 wks post BFR, ? vs 8 wks post SHAM, and ^ vs 8 wks post BFR.

Postural Stability: Romberg Ratio with Sway Velocity

A two-way ANOVA was conducted with the factor of group (SHAM versus BFR) as well as time normalized as the difference from the 24-48 hours pre-operative visit and the dependent variable being Romberg Ratio as calculated with sway velocity measured by the Lockhart Monitor application. There was not found to be a statistically significant difference between time, intervention, or the interaction between time and intervention and Romberg Ratio, $p = 0.509$, $p = 0.438$, and $p = 0.823$, respectively. Mean Romberg Ratio between groups over time can be found in Figure 5-7A. A post-hoc Bonferroni multiple comparison test was performed with indicated $p \leq 0.05$. There was not found to be a statistically significant difference within any of the groups between time points or between any of the groups within time points. Results of the Bonferroni multiple comparison test can be found in Figure 5-7B.

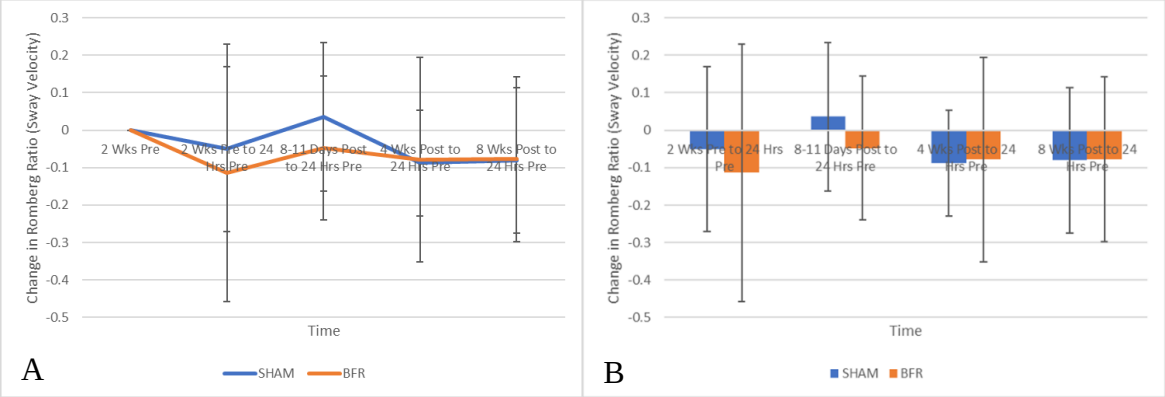

Figure 5-7: Sway velocity Romberg Ratio with either SHAM or BFR treatment. Twenty-eight subjects were randomized into two intervention groups (SHAM and BFR) with no crossover between groups. Subjects underwent baseline testing at 2 weeks pre-operative and after the intervention was complete at 24-48 hours pre-operative. Subjects underwent follow-up testing at, 8-11 days, 4 weeks, and 8 weeks postoperative. Data for all time points were normalized to that of the 24-48 hours pre-operative visit. A 2-way ANOVA determined there was no significant effect due to time, intervention, or the interaction between time and intervention. Figure 5-7B displays results of a post-hoc Bonferroni multiple comparison tests with indicated p<0.05. Symbols representing comparisons are as follows: $ vs 2 wks pre SHAM, @ vs 2 wks pre BFR, ! vs 8-11 days post SHAM, % vs 8-11 days post BFR, # vs 4 wks post SHAM, & vs 4 wks post BFR, ? vs 8 wks post SHAM, and ^ vs 8 wks post BFR.

Complications

One adverse event related to motion limitations was present in the SHAM control group. One patient underwent a manipulation under anesthesia without arthroscopy 24 hours after their 8-week postoperative follow-up visit as deemed necessary by the treating orthopedic surgeon.

DISCUSSION

The purpose of this study was to investigate the effects of pre-operative low-intensity blood flow restriction training on postoperative outcomes of ACLR: quadriceps strength, quadriceps hypertrophy, gait speed, and postural stability. Outcomes were assessed in a longitudinal manner following the continuum of care beginning at 2 weeks before surgery through 8 weeks after surgery. This study design allowed all outcomes to be assessed for statistical significance between all dependent variables and time, intervention, and the interaction of time and intervention. All data points were normalized to the 24-48 hours pre-op time point and calculated as the difference from that point.

Quadriceps strength as measured by both handheld dynamometry and leg press test as well as hypertrophy and gait speed were all found to be statistically significant between time points as a whole and between individual pairs of time points as shown in Figures 5-2B, 3B, 4B, and 5B. This is to be expected as surgical reconstruction of the ACL results in serious physiological changes in the lower limb, which has a profound impact on these respective variables.

Muscular strength of the knee extensor muscle, or the quadriceps, was measured using two different methods, handheld dynamometry and a leg press test, with each having its own distinct advantages and disadvantages. While the handheld dynamometer was able to more accurately isolate strength of the quadriceps, subjects had a tendency to report that they experienced anterior knee pain from the kicking motion performed as well as pain in the shin from the positioning of the dynamometer throughout testing. Conversely, while subjects were typically able to perform the leg press test without reporting anterior knee pain, the motion required to complete said test does not isolate the quadriceps and also utilizes the knee flexor muscles, or hamstrings, as well as the glutes. Additionally, the handheld dynamometer is able to detect smaller changes in strength as its measurement resolution is tenths of a pound while the leg press test weight is only able to be adjusted in increments of 5 pounds.

As seen in Table 5-2, the baseline measures before beginning the intervention for strength and hypertrophy of the BFR group was remarkably higher than that of the SHAM group. Handheld dynamometry and hypertrophy were the only dependent variables that were found to have a statistically significant difference as a whole between intervention groups. For handheld dynamometry, the BFR group experienced a greater decrease in

quadriceps strength from 1 day pre-op to both 4 weeks and 8 weeks post-op than the SHAM group. The BFR group also experienced a greater decrease in quadriceps hypertrophy from 1 day pre-op to 8-11 days and 4 weeks post-op; however, by 8 weeks post-op, both the BFR and SHAM groups had achieved almost similar differences in hypertrophy.

Despite the fact that randomization for intervention group placement was stratified for sex and age group, the ratio of males to females in each group (5:11 for SHAM and 8:4 for BFR, Table 5-1) was inversely proportional between groups. It has previously been shown in literature that there are differences in recovery patterns of quadriceps strength after ACLR in males and females(Goto et al., 2020), which could be an explanation for why the male-dominant BFR group experienced more atrophy in the quadriceps than the female-dominant SHAM group. Goto et al. found that only females made a significant improvement in quadriceps strength of the surgical limb from pre-op to time of returning to sport after surgery, while only males made a significant improvement in quadriceps strength of the non-surgical limb from pre-op to return to sport.(Goto et al., 2020) In this study, both SHAM and BFR groups experienced a similar pattern of quadriceps strength loss and subsequent recovery and illustrated in Figure 5-2A. Both groups experienced statistically significant losses in strength from pre-op to 4 weeks post-op; however, both groups also experienced significant recoveries of quadriceps strength from 4 weeks to 8 weeks post-op. Based on this trend, it would be expected that this recovery pattern would continue throughout the remaining duration of the postoperative rehabilitation period, with both intervention groups continuing to recover their quadriceps strength until reaching pre-operative levels.

Similar to quadriceps strength, quadriceps hypertrophy also exhibited a statistically significant difference over time between intervention groups as a whole. As shown in Figure 5-4A, both intervention groups experienced a similar trend of loss of quadriceps size from pre-op to 8-11 days and 4 weeks post-op; however, while the SHAM group continued to lose muscle mass from 4 weeks to 8 weeks post-op, the BFR group began to recover their muscle mass between these time points. This is notable because the typical trend as observed in literature shows that LI-BFR training leads to gains in hypertrophy before gains in strength, which is opposite that of traditional high-load resistance training.(Hughes et al., 2019) However, as the BFR intervention was not being utilized during the postoperative time period, it cannot be definitively concluded whether the training intervention was the sole reason this trend was observed.

Quadriceps strength as measured by the leg press test was found to only be statistically significant over time; this would be expected due to postoperative atrophy of the lower limb musculature. Gait speed was also found to only be statistically significant over time, which would be expected as acute postoperative gait speed as measured at 8-11 days postoperative would be the time point at which subjects would experience the largest impairments of gait due to physiological factors such as pain, swelling, and stiffness.

Finally, Romberg Ratio as calculated with both measures of postural stability, sway area and sway velocity, were not found to be statistically significant between any time points within either of the intervention groups. This shows that reliance on the visual system for maintenance of postural stability both before and after ACLR is not likely to be affected by either LI-BFR or SHAM-BFR training as pre-rehabilitation for ACLR.

Overall, these results show that utilization of LI-BFR training for a 2-week preoperative period before ACLR is not effective for the purpose of maintaining statistically significant amounts of quadriceps strength and hypertrophy for 8 weeks after ACLR. For this particular study, this could be due to the fact that the BFR group began the study protocol with higher strength and quadriceps cross-sectional area due to the male-dominant gender composition of that intervention group and therefore had more strength and mass to lose throughout the postoperative period. However, this commentary reports on an abbreviated data set and all subjects will be followed up with through 24 weeks after ACLR. This will provide an additional 16 weeks of time in which trends of quadriceps strength and mass recovery can be evaluated. Additionally, a long-term follow-up will be conducted with all subjects to evaluate rates of re-injury and return to sport at 1 year and 2 years after ACLR. This data will be remarkable as return to pre-op sport level and incidence of re-injury are often regarded as some of the most important indicators of successful ACLR surgery.

Limitations

Despite our best efforts to control for variability and quality where possible, there are still some limitations within the study's design that need to be addressed. First is regarding the equipment used to administer the BFR intervention as well as conduct the strength testing. The BFR training set that we utilized to administer the intervention was an older, first generation design that utilized a manual hand pump to inflate the cuffs and set a self-selected occlusion pressure. As a result of this, it is likely that there may have been small fluctuations in the inflation pressures throughout the exercise protocol due to unavoidable movement of the cuffs. Ideally, we would have liked to utilize a set of BFR

cuffs that operates with a dynamically updating pressure gauge; that is, cuffs that feature computerized sensors that are able to make small adjustments to the inflation pressure as necessary throughout exercise protocols. However, we did not have access to a set of cuffs with these features.

Despite the fact that belt-stabilized handheld dynamometry has been validated for use in strength testing(Martins et al., 2017), its set-up is cumbersome and relies heavily on the ability of the evaluating physical therapist to stabilize the handheld dynamometer throughout the test's duration. An alternative to this testing method would be the use of an isokinetic force frame, which provides a stable structure for subjects to kick into to evaluate strength of the knee extensor muscles. Unfortunately, this testing equipment was not available to our clinic at the time that this study was carried out.

Another limiting factor that could have impacted the results of this study was the length of time of the pre-operative intervention. Two weeks was chosen as the length of the intervention due to the fact that this is the amount of time that the consulting orthopedic surgeon typically recommends for patients to wait between their pre-operative check-up and scheduling surgery. Additionally, for athletes who experience an ACL injury, their primary goals are typically to return to sport as quickly as safely possible.(Webster & Feller, 2019) In order to help achieve this, time spent in the preoperative phase is often minimized as much as possible without compromising the conditions under which surgery will be performed. Therefore, it may be unappealing to some populations to undergo extended periods of preoperative rehabilitation at the risk of experiencing significant delays in return to their respective sports or activities. However, it would be beneficial for future

studies to be conducted to investigate whether the length of time utilized for the pre-operative intervention has a significant impact on postoperative outcomes.

Finally, another unanticipated limitation that was imposed on this study was the result of the COVID-19 pandemic. We experienced unavoidable delays in both scheduling of surgeries and clinic visits for data collections due to subjects' exposures to COVID and/or positive COVID test results. While these instances only occurred a handful of times, we did our best to mitigate these scheduling delays within the guidelines set forth by our institution.

CONCLUSION

The primary purpose of this study was to investigate whether LI-BFR training employed preoperatively has an effect on postoperative clinical outcomes within the first 8 weeks after ACLR. The results indicated that while there may be a statistically significant difference between time points within groups for handheld dynamometer quadriceps strength, leg press test strength, hypertrophy, and gait speed, only handheld dynamometer strength and hypertrophy exhibited statistically significant differences between intervention groups, as well. The BFR group was observed to experience greater losses in quadriceps strength as measured by the handheld dynamometer after surgery; however, this group also exhibited a faster recovery of quadriceps cross-sectional area beginning at 4 weeks post-op whereas the SHAM group continued to experience loss of quadriceps mass. Overall, further investigation would need to be conducted on an expanded dataset to investigate whether these trends continue to be observed from 8 weeks through 24 weeks postoperative.

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APPENDIX A

ACL PHASED REHABILITATION GUIDELINES

MAYO CLINIC

ACL Phased Rehabilitation Guidelines

Department of Sports Medicine - Arizona
Anikar Chhabra, M.D., M.S.

(Mayo Clinic/Medical Record Number and Name Above)

Patient Name	Date of Surgery

General Guidelines
- Allow 12 weeks for complete graft re-vascularization, longer with allografts
- CPM not commonly used
- Supervised physical therapy takes 3-9 months

General Progression of Activities of Daily Living
- Bathing/showering without brace after suture removal [keep wounds dry for 4-weeks]
- Sleep with brace locked in extension for 1 week
- Driving:
  - 1 week for automatic cars; left leg surgery
  - 3 weeks for standard cars; right leg surgery
- Brace locked in extension for 1 week for ambulation
- Use two crutches, brace for ambulation for 4-6 weeks
- Must be off crutches and pain pills before driving
- WBAT immediately post op without meniscal repairs or chondral surgery
- TTWB for 4-6 weeks with meniscal repairs or chondral surgery

Physical Therapy Attendance: no Formal PT

Rehabilitation Progression: the following is a general guideline for the progression of rehabilitation following ACL reconstruction. Progression through each phase should take into account patient status (e.g. healing, function) and physician advisement. Please consult the physician if there is any uncertainty concerning advancement of a patient to the next phase of rehabilitation.

PHASE I

Goals
- Protect graft fixation (assume 8 weeks fixation time)
- Full knee ROM
- Pain /edema reduction
- Normalize balance / proprioception abilities
- Begin and enhance normalization of quad recruitment
- Educate patient on rehabilitation progression

Brace
- 0-1 week: Locked in full extension for ambulation and sleeping
- 1-6 weeks: Unlocked for ambulation, remove for sleeping

Therapeutic Exercises
- Quad sets/hamstring co-contractions at multiple angles, 3x10 2-3x's daily
- Heel slides
- Begin patella mobilizations
- SLR, in all planes, with brace at 0° until quad control sufficient to prevent distal tibia from dropping 3x10 2-3x's daily
- Obtain full passive extension with bolster under heel or prone with leg off table
- Quad isometrics at 60° and 90°
- Modalities as needed
- Treadmill walking – forward and retro

MCS15246-35

PHASE II: Begins approximately 6 weeks post-op and extends to approximately 10 weeks

Criteria for advancement to Phase II
- Good quad set, SLR without extension lag
- Approximately 90° of flexion
- Full extension
- No signs of active inflammation

Goals
- Restore normal gait
- Maintain full extension (especially hip extension), progress flexion range-of-motion
- Protect graft fixation
- Initiate open kinetic chain hamstring exercises

Brace
- Discontinue use of brace and crutches as allowed by physician when the patient has full extension and can slr without extension lag
- Patient must exhibit non-antalgic gait pattern, consider using single crutch or cane until gait is normalized

Therapeutic Exercises
- Wall slides 0°-45°, progression to mini-squats
- 4-way hip
- Closed chain terminal extension with resistive tubing or weight machine
- Stationary bike to increase ROM, start with high seat and progress to normal seat height when able, resistance as tolerated
- Single leg stands for balance/proprioception on Airex pad or trampoline
- Hamstring curls
    - Aquatic therapy with emphasis on normalization of gait
    - Continue hamstring stretches, progress to weight bearing gastroc/soleus stretches
    - Monitor closely for patello-femoral signs and symptoms, manage them accordingly

PHASE III: Begins approximately 10 weeks post-op and extends to approximately 5-months

Goals
- Full range-of-motion
- Improved strength, endurance and proprioception of the lower extremity to prepare for functional activities
- Avoid overstressing the graft fixation
- Protect the patellofemoral joint

Therapeutic Exercises
- Continue flexibility exercises as appropriate for patient
- Stairmaster – start with shallow steps with feet flat on steps and weight on heels, progress depth as tolerated to normal step depth
- Versa Climber, Fitter, Nordic Track, and Elliptical Trainers etc.
- Advance closed kinetic chain strengthening (single leg squats, leg press 0°-45°, Unilateral step ups – start with 2" and progress to 8", emphasize control during the decent phase of step up)
- Progress aquatic program to include pool running, swimming (no breaststroke)

PHASE IV: Begins approximately 5 months and extends through approximately 9 months

Criteria for advancement to Phase IV
- Full, pain-free ROM
- No evidence of patellofemoral joint irritation
- Strength and proprioception approximately 70% of uninvolved leg
- Physician clearance to initiate advanced closed kinetic chain exercises and functional progression

Goals
- Progress strength, power, proprioception to prepare for return to functional activities

Therapeutic Exercises

- Continue and progress flexibility and strengthening program
- Initiate plyometric program as appropriate to patient's functional goals
- Functional progression including but not limited to:
  - Walk/jog progression
  - Forward, backward running ½, ¾, full speed
  - Lateral movements – stepping, shuffling, hopping, carioca
- Initiate sport specific activities under supervision of ATC or PT at 6-7 months

PHASE V: Begins approximately 7-8 months post-op

Criteria for advancement to Phase V

- No patellofemoral or soft tissue complaints
- Necessary joint ROM, strength, endurance, proprioception
- Patient education with regard to any possible limitations

Therapeutic Exercises

- Gradual return to sports participation
- Maintenance program for strength, endurance

By signing this referral, I certify that I have examined this patient and physical therapy is medically necessary.
This patient _____ would _____would not benefit from social services.

Physician Signature	Date
Printed Name	

APPENDIX B

SYSTEMATIC REVIEW SEARCH STRATEGY

PubMed Search Strategy: (((((("Anterior Cruciate Ligament Reconstruction"[Mesh]) OR ("acl reconstruct*")) OR (ACL-R)) OR ("anterior cruciate ligament reconstruct*")) AND (("proprioceptive training" OR "psychological scores" OR "open kinetic chain" OR "closed kinetic chain" OR "return to play" OR "return to sport*" OR "functional performance test*" OR "blood flow restriction training" OR "accelerated rehab*") OR ((postoperative) AND (bracing OR "CPM machine*" OR cryotherapy OR "neuromuscular electrical stimulation" OR "postoperative neuromuscular training" OR "home-based rehab*")))) AND (("Rehabilitation"[Mesh] OR "rehabilitation" [Subheading]) OR (rehabilitat* [tiab]) Filters English, from 2012 - 2020)

Embase <1974 to 2020 September 22> Search Strategy:

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1 exp anterior cruciate ligament reconstruction/ or acl reconstruct*.mp. (13523)
2 anterior cruciate ligament reconstruct*.mp. (13473)
3 1 or 2 (15171)
4 proprioceptive training.mp. (294)
5 psychological scores.mp. (264)
6 closed kinetic chain exercise/ or open kinetic chain.mp. or open kinetic chain exercise/ (311)
7 closed kinetic chain.mp. (444)
8 return to sport/ or return to play.mp. (5194)
9 functional performance test*.mp. (281)
10 blood flow restriction training.mp. (102)
11 accelerated rehab*.mp. (412)
12 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 (7007)
13 postoperative.mp. (1032400)
14 (bracing or "CPM machine" or cryotherapy or neuromuscular electrical stimulation or postoperative neuromuscular training or home-based rehab*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (28181)
15 13 and 14 (2716)
16 exp rehabilitation/ or rehabilitat*.mp. (611419)
17 12 or 15 (9678)
18 3 and 16 and 17 (716)
19 limit 18 to (english language and yr="2012 -Current") (518)

Scopus Search Strategy: (TITLE-ABS-KEY (acl-r OR "acl reconstruct*" OR "anterior cruciate ligament reconstruct*")) AND (TITLE-ABS-KEY (rehabilitat*)) AND (((TITLE-ABS-KEY ("proprioceptive training" OR "psychological scores" OR "open kinetic chain" OR "closed kinetic chain") OR TITLE-ABS-KEY ("return to play" OR "return to sport*" OR "functional performance test*" OR "blood flow restriction training" OR "accelerated rehab*"))) OR ((TITLE-ABS-KEY (postoperative) AND TITLE-ABS-KEY (bracing OR "CPM machine" OR cryotherapy OR "neuromuscular electrical stimulation" OR "postoperative neuromuscular training" OR "home-based rehab*"))))

AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014) OR LIMIT-TO (PUBYEAR , 2013) OR LIMIT-TO (PUBYEAR , 2012))

Web of Science Search Strategy: TOPIC: (acl-r OR "acl reconstruct*" OR "anterior cruciate ligament reconstruct*") AND (postoperative) AND TOPIC: (bracing OR "CPM machine" OR cryotherapy OR "neuromuscular electrical stimulation" OR "postoperative neuromuscular training" OR "home-based rehab*")OR TOPIC: (bracing OR "CPM machine" OR cryotherapy OR "neuromuscular electrical stimulation" OR "postoperative neuromuscular training" OR "home-based rehab*") AND TOPIC: (rehabilit*) Refined by: PUBLICATION YEARS: (2020 OR 2012 OR 2019 OR 2018 OR 2017 OR 2016 OR 2015 OR 2014 OR 2013) AND LANGUAGES: (ENGLISH) Indexes=SCI-EXPANDED, ESCI Timespan=All years

Cochrane Database of Systematic Reviews <2005 to September 17, 2020> Search Strategy:

1 ACL-R.mp. [mp=title, abstract, full text, keywords, caption text] (0)
2 acl reconstruct*.mp. [mp=title, abstract, full text, keywords, caption text] (12)
3 anterior cruciate ligament reconstruct*.mp. [mp=title, abstract, full text, keywords, caption text] (13)
4 1 or 2 or 3 (19)
5 rehab*.ti. or rehab*.ab. (260)
6 proprioceptive training.mp. (4)
7 psychological scores.mp. (3)
8 open kinetic chain.mp. (4)
9 closed kinetic chain.mp. (3)
10 return to play.mp. (0)
11 return to sport*.mp. (20)
12 functional performance test*.mp. [mp=title, abstract, full text, keywords, caption text] (4)
13 blood flow restriction training.mp. [mp=title, short title, abstract, full text, keywords, caption text] (0)
14 accelerated rehab*.mp. [mp=title, short title, abstract, full text, keywords, caption text] (1)
15 postoperative.mp. [mp=title, short title, abstract, full text, keywords, caption text] (1498)
16 bracing.mp. [mp=title, short title, abstract, full text, keywords, caption text] (55)
17 CPM machine.mp. [mp=title, short title, abstract, full text, keywords, caption text] (1)
18 cryotherapy.mp. [mp=title, short title, abstract, full text, keywords, caption text] (163)
19 neuromuscular electrical stimulation.mp. [mp=title, short title, abstract, full text, keywords, caption text] (28)
20 postoperative neuromuscular training.mp. [mp=title, short title, abstract, full text, keywords, caption text] (0)

21 home-based rehab*.mp. [mp=title, short title, abstract, full text, keywords, caption text] (16)
22 16 or 17 or 18 or 19 or 20 or 21 (257)
23 15 and 22 (67)
24 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 23 (97)
25 4 and 5 and 24 (0)

APPENDIX C

ACLR RECOVERY AND REHABILITATION SURVEY

Survey

Please complete the survey below.

Thank you!

Do you consent to participate in this survey?

- ◯ Yes
- ◯ No

Demographics & Practice Patterns

Are you an Orthopaedic Surgeon?

- ◯ Yes
- ◯ No

Are you board-certified in Orthopaedic Surgery?*

- ◯ Yes
- ◯ No

What country do you currently practice in?

- ◯ United States
- ◯ Akrotiri
- ◯ Albania
- ◯ Algeria
- ◯ American Samoa
- ◯ Andorra
- ◯ Angola
- ◯ Anguilla
- ◯ Antarctica
- ◯ Antigua and Barbuda
- ◯ Argentina
- ◯ Armenia
- ◯ Aruba
- ◯ Ashmore and Cartier Islands
- ◯ Australia
- ◯ Austria
- ◯ Azerbaijan
- ◯ The
- ◯ Bahrain
- ◯ Bangladesh
- ◯ Barbados
- ◯ Bassas da India
- ◯ Belarus
- ◯ Belgium
- ◯ Belize
- ◯ Benin
- ◯ Bermuda
- ◯ Bhutan
- ◯ Bolivia
- ◯ Bosnia and Herzegovina
- ◯ Botswana
- ◯ Bouvet Island
- ◯ Brazil

- ◯ British Indian Ocean Territory
- ◯ British Virgin Islands
- ◯ Brunei
- ◯ Bulgaria
- ◯ Burkina Faso
- ◯ Burma
- ◯ Burundi
- ◯ Cambodia
- ◯ Cameroon
- ◯ Canada
- ◯ Cape Verde
- ◯ Cayman Islands
- ◯ Central African Republic
- ◯ Chad
- ◯ Chile
- ◯ China
- ◯ Christmas Island
- ◯ Clipperton Island
- ◯ Cocos (Keeling) Islands
- ◯ Colombia
- ◯ Comoros
- ◯ Cook Islands
- ◯ Coral Sea Islands
- ◯ Costa Rica
- ◯ Cote d'Ivoire
- ◯ Croatia
- ◯ Cuba
- ◯ Cyprus
- ◯ Czech Republic
- ◯ Democratic Republic of the Congo
- ◯ Denmark
- ◯ Dhekelia
- ◯ Djibouti
- ◯ Dominica
- ◯ Dominican Republic
- ◯ Ecuador
- ◯ Egypt
- ◯ El Salvador
- ◯ Equatorial Guinea
- ◯ Eritrea
- ◯ Estonia
- ◯ Ethiopia
- ◯ Europa Island
- ◯ Falkland Islands (Islas Malvinas)
- ◯ Faroe Islands
- ◯ Fiji
- ◯ Finland
- ◯ France
- ◯ French Guiana
- ◯ French Polynesia
- ◯ French Southern and Antarctic Lands
- ◯ Gabon
- ◯ The
- ◯ Gaza Strip
- ◯ Georgia
- ◯ Germany
- ◯ Ghana
- ◯ Gibraltar
- ◯ Glorioso Islands
- ◯ Greece
- ◯ Greenland
- ◯ Grenada
- ◯ Guadeloupe
- ◯ Guam
- ◯ Guatemala
- ◯ Guernsey
- ◯ Guinea
- ◯ Guinea-Bissau
- ◯ Guyana
- ◯ Haiti
- ◯ Heard Island and McDonald Islands

- ◯ Holy See (Vatican City)
- ◯ Honduras
- ◯ Hong Kong
- ◯ Hungary
- ◯ Iceland
- ◯ India
- ◯ Indonesia
- ◯ Iran
- ◯ Iraq
- ◯ Ireland
- ◯ Isle of Man
- ◯ Israel
- ◯ Italy
- ◯ Jamaica
- ◯ Jan Mayen
- ◯ Japan
- ◯ Jersey
- ◯ Jordan
- ◯ Juan de Nova Island
- ◯ Kazakhstan
- ◯ Kenya
- ◯ Kiribati
- ◯ Kuwait
- ◯ Kyrgyzstan
- ◯ Laos
- ◯ Latvia
- ◯ Lebanon
- ◯ Lesotho
- ◯ Liberia
- ◯ Libya
- ◯ Liechtenstein
- ◯ Lithuania
- ◯ Luxembourg
- ◯ Macau
- ◯ Macedonia
- ◯ Malawi
- ◯ Malaysia
- ◯ Maldives
- ◯ Mali
- ◯ Malta
- ◯ Marshall Islands
- ◯ Martinique
- ◯ Mauritania
- ◯ Mauritius
- ◯ Mayotte
- ◯ Mexico
- ◯ Federated States of
- ◯ Moldova
- ◯ Monaco
- ◯ Mongolia
- ◯ Montenegro
- ◯ Montserrat
- ◯ Morocco
- ◯ Mozambique
- ◯ Namibia
- ◯ Nauru
- ◯ Navassa Island
- ◯ Nepal
- ◯ Netherlands
- ◯ Netherlands Antilles
- ◯ New Caledonia
- ◯ New Zealand
- ◯ Nicaragua
- ◯ Niger
- ◯ Nigeria
- ◯ Niue
- ◯ Norfolk Island
- ◯ Northern Mariana Islands
- ◯ North Korea
- ◯ Norway
- ◯ Oman
- ◯ Pakistan
- ◯ Palau

- ◯ Panama
- ◯ Papua New Guinea
- ◯ Paracel Islands
- ◯ Paraguay
- ◯ Peru
- ◯ Philippines
- ◯ Pitcairn Islands
- ◯ Poland
- ◯ Portugal
- ◯ Puerto Rico
- ◯ Qatar
- ◯ Republic of the Congo
- ◯ Reunion
- ◯ Romania
- ◯ Russia
- ◯ Rwanda
- ◯ Saint Helena
- ◯ Saint Kitts and Nevis
- ◯ Saint Lucia
- ◯ Saint Pierre and Miquelon
- ◯ Saint Vincent and the Grenadines
- ◯ Samoa
- ◯ San Marino
- ◯ Sao Tome and Principe
- ◯ Saudi Arabia
- ◯ Senegal
- ◯ Serbia
- ◯ Somalia
- ◯ South Africa
- ◯ South Georgia and the South Sandwich Islands
- ◯ South Korea
- ◯ Spain
- ◯ Spratly Islands
- ◯ Sri Lanka
- ◯ Sudan
- ◯ Suriname
- ◯ Svalbard
- ◯ Swaziland
- ◯ Sweden
- ◯ Switzerland
- ◯ Syria
- ◯ Taiwan
- ◯ Tajikistan
- ◯ Tanzania
- ◯ Thailand
- ◯ Timor-Leste
- ◯ Togo
- ◯ Tokelau
- ◯ Tonga
- ◯ Trinidad and Tobago
- ◯ Tromelin Island
- ◯ Tunisia
- ◯ Turkey
- ◯ Turkmenistan
- ◯ Turks and Caicos Islands
- ◯ Tuvalu
- ◯ Uganda
- ◯ Ukraine
- ◯ United Arab Emirates
- ◯ United Kingdom
- ◯ Afghanistan
- ◯ Uruguay
- ◯ Uzbekistan
- ◯ Vanuatu
- ◯ Venezuela
- ◯ Vietnam
- ◯ Virgin Islands
- ◯ Wake Island
- ◯ Wallis and Futuna
- ◯ West Bank
- ◯ Western Sahara
- ◯ Yemen
- ◯ Zambia
- ◯ Zimbabwe

Which state do you practice in?	◯ Alabama ◯ Alaska ◯ Arizona ◯ Arkansas ◯ California ◯ Colorado ◯ Connecticut ◯ District of Columbia ◯ Delaware ◯ Florida ◯ Georgia ◯ Hawaii ◯ Idaho ◯ Illinois ◯ Indiana ◯ Iowa ◯ Kansas ◯ Kentucky ◯ Louisiana ◯ Maine ◯ Maryland ◯ Massachusetts ◯ Michigan ◯ Minnesota ◯ Mississippi ◯ Missouri ◯ Montana ◯ Nebraska ◯ Nevada ◯ New Hampshire ◯ New Jersey ◯ New Mexico ◯ New York ◯ North Carolina ◯ North Dakota ◯ Ohio ◯ Oklahoma ◯ Oregon ◯ Pennsylvania ◯ Rhode Island ◯ South Carolina ◯ South Dakota ◯ Tennessee ◯ Texas ◯ Utah ◯ Vermont ◯ Virginia ◯ Washington ◯ West Virginia ◯ Wisconsin ◯ Wyoming
How many years have you been practicing as an orthopaedic surgeon?*	◯ 0-4 years ◯ 5-10 years ◯ 11-15 years ◯ 16+ years
What is your primary practice setting?*	◯ Academic/teaching hospital ◯ For-profit or nonprofit hospital ◯ Private practice ◯ Other

Please specify your primary practice setting:	_____
Which patient populations do you treat in your practice? Please select all that apply.	☐ Children (< 14 years old) ☐ Adolescents (14-18 years old) ☐ Adults (>19 years old) ☐ Geriatrics (>65 years old)
Approximately how many ACL Reconstructions do you perform in one year?	◯ 0 ◯ 1-20 ◯ 21-50 ◯ 51+

ACL-R Protocol Development & Patient Selection

If you have a written document outlining your preferred ACL-R recovery protocol, please upload it here.	
Which of the following factors influenced development of your ACL-R recovery protocol? Please select all that apply.	☐ Fellowship training/mentorship ☐ Physical Therapy guidance ☐ Institutional policy ☐ Other
Please specify any other factors that influenced development of your ACL-R recovery protocol:	_____
Do you utilize a separate protocol involving functional testing techniques for athletes to return to sport/play?	◯ Yes ◯ No
If you have a written document outlining your preferred return to sport/play protocol, please upload it here.	
Which tests do you utilize to confirm an ACL injury? Please select all that apply.	☐ Lachman ☐ Pivot shift ☐ MRI ☐ Anterior drawer ☐ KT1000/KT2000 for laxity ☐ Other

Please specify any other tests you may use to confirm an ACL injury:	_____
Do you utilize any Patient Reported Outcome Measures (PROMs) to identify potential surgical candidates?	◯ Yes ◯ No
Please select all Patient Reported Outcome Measures (PROMs) that apply.	☐ Knee Self-Efficacy Scale (K-SES) ☐ Modified Self-Efficacy for Rehabilitation Outcome Scale (SER) ☐ Pain Catastrophizing Scale (PCS) ☐ Self-Motivation Inventory (SMI) ☐ Lysholm Knee Score ☐ Tegner Activity Scale ☐ Lower Extremity Functional Scale (LEFS) ☐ Other
Please specify any other PROMs you may use to identify potential surgical candidates:	_____
How long do you typically wait to perform surgery following an ACL tear?	◯ < 1 week ◯ 1-2 weeks ◯ 3-4 weeks ◯ > 4 weeks
What factors determine how you advance a patient through your ACL-R recovery protocol?	◯ Time-based criteria (Patient cannot advance until a set time point) ◯ Phase-based criteria (Patient must meet certain criteria before advancing) ◯ Both
Who is responsible for determining an athlete's readiness to progress through the return to sport/play protocol?	◯ Orthopaedic surgeon ◯ Rehab specialist (PT, ATC, etc.) ◯ Both

Use of Technology in ACL-R Recovery/Rehabilitation	
Do you believe quantitative assessment technology (motion capture, dynamometry, isokinetic testing, wearable sensors, video recording, etc.) would help you improve patient care and outcomes in ACL-R recovery?	○ Yes ○ No
Do you currently use any quantitative assessment technology to help guide progression through your ACL-R recovery protocol?	○ Yes ○ No
What types of quantitative assessment technology do you currently use to help guide progression through your ACL-R recovery protocol? Please select all that apply.	☐ Video recording to assess movement quality (subjective knee angle, valgus, etc.) ☐ Video recording with prepackaged software (Kinect Camera, etc.) to assess movement quality ☐ Sensor-based systems (DorsaVi, etc.) ☐ Handheld dynamometer ☐ Isokinetic dynamometer ☐ Other
Please specify any other quantitative assessment technology you currently use to guide patients through your ACL-R recovery protocol:	_____
What factors, if any, limit your use of quantitative assessment technology in your practice? Please select all that apply.	☐ Expense of technology ☐ Time needed to perform testing ☐ Lack of validation ☐ Lack of defined protocols in literature ☐ Lack of training of allied health staff ☐ Availability of allied health staff ☐ Other ☐ None
Please specify any other factors that may limit your use of quantitative assessment technology in your practice:	_____

Pre-Operative Phase	
Do you typically prescribe any form of pre-rehabilitation (prehab) before ACL-R surgery?	○ Yes ○ No
Which aspects of a pre-rehabilitation program do you emphasize? Please select all that apply.	☐ Knee range of motion ☐ Quadriceps strength ☐ Hamstring strength ☐ Neuromuscular/proprioceptive training
Do you provide patients with any additional pre-operative education on the ACL-R recovery process? Please select all that apply.	☐ Video ☐ Written material ☐ Other ☐ None
Please specify any additional types of pre-operative education you may provide to patients before an ACL-R:	_____

Post-Operative Rehabilitation Phase

For the following portions of the survey, please answer the questions considering a patient who has no other ligamentous, cartilaginous (i.e meniscus tear) or bony injuries that would require any modifications to your post-operative recovery protocol.

Do you allow for immediate mobilization of the knee following surgery?	◯ Yes ◯ No
When do you typically allow your ACL-R patients to progress to full weight-bearing status following surgery?	◯ Immediately ◯ 1 week ◯ 2 weeks ◯ 3 weeks ◯ 4 weeks or later
Do you place your patients in a brace post-operatively?	◯ Yes ◯ No
What type of brace do you typically prescribe?	◯ Hinged knee brace ◯ Compressive sleeve ◯ Other
How long do you require patients to remain in a post-operative brace?	◯ Less than 1 week ◯ 1-2 weeks ◯ 2-3 weeks ◯ 3-4 weeks ◯ 4-6 weeks ◯ 6 weeks or longer
Do you typically prescribe CPM machines for post-operative use?	◯ Yes ◯ No
Do you typically prescribe cryotherapy machines for post-operative use?	◯ Yes ◯ No
Do you allow patients to utilize a home-based rehabilitation protocol (e.g., all exercises are completed at home and patient has 1 supervised PT visit per month to monitor progress, or something similar)?	◯ Yes ◯ No
How soon do you allow patients to begin strengthening and pushing for full range of motion after ACL-R surgery?	◯ Less than 1 week ◯ 1-2 weeks ◯ 2-3 weeks ◯ 3-4 weeks ◯ 4-6 weeks ◯ > 6 weeks
Which of the following modalities, if any, do you typically allow in the early post-op rehabilitative phase (0-4 weeks)? Please select all that apply.	☐ Open kinetic chain (OKC) exercises ☐ Closed kinetic chain (CKC) exercises ☐ Neuromuscular electrical stimulation ☐ Balance training (Ex. Single Leg Stands on Airex Pad/Trampoline) ☐ Vibration training (Ex. Power Plate, etc.) ☐ Other ☐ I do not use any of these

Return to Jogging/Lateral Movement Phase

Jogging movements include forwards and backwards movement at a jog-pace. Lateral movements include lateral stepping, shuffling, hopping and carioca. No explosive cutting.

When would you typically allow your patient to advance to jogging/lateral movement training?	○ 2-3 months ○ 3-4 months ○ 4-5 months ○ 6-8 months ○ 9 months or later
Are there any tests, exam findings, or criteria that you utilize to assist in your decision to advance a patient to the jogging/lateral movement phase?	○ Yes ○ No
Do you use any physical exam components to determine a patient's advancement to jogging/lateral movements? Please select all that apply.	☐ Range of motion ☐ Effusion ☐ Laxity exam ☐ Other ☐ I do not use this
Do you use any patient-reported outcome measures (PROMs) to determine a patient's advancement to jogging/lateral movements? Please select all that apply.	☐ International Knee Documentation Committee (IKDC) ☐ Knee Outcome Survey (KOS ☐ ACL Return to Sport after Injury Scale (ACL-RSI) ☐ Psychovitality Scale ☐ Lysholm Knee Score ☐ Tegner Activity Scale ☐ Lower Extremity Functional Scale (LEFS) ☐ Other ☐ I do not use this
Do you use any strength assessments to determine a patient's advancement to jogging/lateral movements? Please select all that apply.	☐ Manual muscle testing (MMT) ☐ Handheld dynamometry ☐ Isokinetic testing ☐ Other ☐ I do not use this
What Limb Symmetry Index (LSI) criteria (as quantified using a single leg press test, dynamometry, isokinetic testing, etc.) must a patient achieve for strength assessment to advance to jogging/lateral movement?	○ LSI (> 75%) ○ LSI (> 80%) ○ LSI (> 85%) ○ LSI (> 90%) ○ LSI (> 95%) ○ This is up to the discretion of the physical therapist ○ I do not use this
Do you use any functional testing to determine a patient's advancement to jogging/lateral movement? Please select all that apply.	☐ Single Leg Hop for Distance ☐ Single Leg Hop Vertical ☐ Single Leg Hop for Distance ☐ Crossover Hop for Distance ☐ Triple Hop for Distance ☐ 6 m Hop for Time ☐ Y-Balance ☐ Other ☐ I do not use this

What Limb Symmetry Index (LSI) criteria (as quantified using a single leg press test, dynamometry, isokinetic testing, etc.) must a patient achieve for functional testing to advance to jogging/lateral movement?	◯ LSI (> 75%) ◯ LSI (> 80%) ◯ LSI (> 85%) ◯ LSI (> 90%) ◯ LSI (> 95%) ◯ This is up to the discretion of the physical therapist ◯ I do not use this
Which of the following modalities, if any, do you typically allow in the jogging/lateral movement phase? Please select all that apply.	☐ Open kinetic chain (OKC) exercises ☐ Closed kinetic chain (CKC) exercises ☐ Neuromuscular electrical stimulation ☐ Balance training (Ex. Single Leg Stands on Airex Pad/Trampoline) ☐ Vibration training (Ex. Power Plate, etc.) ☐ Other ☐ I do not use any of these
Please specify any other types of modalities you may use during the jogging/lateral movements phase:	_____

Non-Contact Return to Sport Phase **Non-Contact RTP refers to non-contact cutting and sport-specific activities.**	
When would you typically allow your patient to advance to non-contact/limited return to sport activities (agility, sport-specific drills, etc.)?	◯ 2-3 months ◯ 3-4 months ◯ 4-5 months ◯ 6-8 months ◯ 9 months or later
Are there any tests, examination findings, or criteria that you utilize to assist in your decision to advance to non-contact RTP?	◯ Yes ◯ No
Do you use any physical exam components to determine a patient's advancement to non-contact RTP? Please select all that apply.	☐ Range of motion ☐ Effusion ☐ Laxity exam ☐ Other ☐ I do not use this
Do you use any patient reported outcome measures (PROMs) to determine a patient's advancement to non-contact RTP? Please select all that apply.	☐ International Knee Documentation Committee (IKDC) ☐ Knee Outcome Survey (KOS ☐ ACL Return to Sport after Injury Scale (ACL-RSI) ☐ Psychovitality Scale ☐ Lysholm Knee Score ☐ Tegner Activity Scale ☐ Lower Extremity Functional Scale (LEFS) ☐ Other ☐ I do not use this
Do you use any strength assessments to determine a patient's advancement to non-contact RTP? Please select all that apply.	☐ Manual muscle testing (MMT) ☐ Handheld dynamometry ☐ Isokinetic testing ☐ Other ☐ I do not use this
What Limb Symmetry Index (LSI) criteria (as quantified using a single leg press test, dynamometry, isokinetic testing, etc.) must a patient achieve for strength assessment to advance to non-contact RTP?	◯ LSI (> 75%) ◯ LSI (> 80%) ◯ LSI (> 85%) ◯ LSI (> 90%) ◯ LSI (> 95%) ◯ This is up to the discretion of the physical therapist ◯ I do not use this
Do you use any functional testing to determine a patient's advancement to non-contact RTP? Please select all that apply.	☐ Single Leg Hop for Distance ☐ Single Leg Hop Vertical ☐ Single Leg Hop for Distance ☐ Crossover Hop for Distance ☐ Triple Hop for Distance ☐ 6 m Hop for Time ☐ Y-Balance ☐ I do not use this

What Limb Symmetry Index (LSI) criteria (as quantified using a single leg press test, dynamometry, isokinetic testing, etc.) must a patient achieve for functional testing to advance to non-contact RTP?	◯ LSI (> 75%) ◯ LSI (> 80%) ◯ LSI (> 85%) ◯ LSI (> 90%) ◯ LSI (> 95%) ◯ This is up to the discretion of the physical therapist ◯ I do not use this
Which of the following modalities, if any, do you typically allow in the non-contact return to sport phase? Please select all that apply.	☐ Open kinetic chain (OKC) exercises ☐ Closed kinetic chain (CKC) exercises ☐ Neuromuscular electrical stimulation ☐ Balance training (Ex. Single Leg Stands on Airex Pad/Trampoline) ☐ Vibration training (Ex. Power Plate, etc.) ☐ Other ☐ I do not use any of these
Please specify any other types of modalities you may use during the non-contact RTP phase:	_____

Contact/Unrestricted Return to Sport Criteria	
What is the single most important factor you base your decision on for a patient's unrestricted return to sport?	◯ Functional testing scores ◯ Muscle strength ◯ Time since surgery ◯ Other
Please specify what your most important criteria is for determining when a patient can return to sport unrestricted:	_____
When would you typically allow your patient to advance to unrestricted return to sport activities?	◯ 2-3 months ◯ 3-4 months ◯ 4-5 months ◯ 6-8 months ◯ 9 months or later
Are there any tests, examination findings, or criteria that you utilize to assist in your decision to advance to unrestricted RTP?	◯ Yes ◯ No
Do you use any physical exam components to determine a patient's advancement to unrestricted RTP? Please select all that apply.	☐ Range of motion ☐ Effusion ☐ Laxity exam ☐ Other ☐ I do not use this
Do you use any patient reported outcome measures (PROMs) to determine a patient's advancement to unrestricted RTP? Please select all that apply.	☐ International Knee Documentation Committee (IKDC) ☐ Knee Outcome Survey (KOS ☐ ACL Return to Sport after Injury Scale (ACL-RSI) ☐ Psychovitality Scale ☐ Lysholm Knee Score ☐ Tegner Activity Scale ☐ Lower Extremity Functional Scale (LEFS) ☐ Other ☐ I do not use this

Do you use any strength assessments to determine a patient's advancement to unrestricted RTP? Please select all that apply.	☐ Manual muscle testing (MMT) ☐ Handheld dynamometry ☐ Isokinetic testing ☐ Other ☐ I do not use this
What Limb Symmetry Index (LSI) criteria (as quantified using a single leg press test, dynamometry, isokinetic testing, etc.) must a patient achieve for strength assessment to advance to unrestricted RTP?	○ LSI (> 75%) ○ LSI (> 80%) ○ LSI (> 85%) ○ LSI (> 90%) ○ LSI (> 95%) ○ This is up to the discretion of the physical therapist ○ I do not use this
Do you use any functional testing to determine a patient's advancement to unrestricted RTP? Please select all that apply.	☐ Single Leg Hop for Distance ☐ Single Leg Hop Vertical ☐ Single Leg Hop for Distance ☐ Crossover Hop for Distance ☐ Triple Hop for Distance ☐ 6 m Hop for Time ☐ Y-Balance ☐ I do not use this
What Limb Symmetry Index (LSI) criteria (as quantified using a single leg press test, dynamometry, isokinetic testing, etc.) must a patient achieve for functional testing to advance to unrestricted RTP?	○ LSI (> 75%) ○ LSI (> 80%) ○ LSI (> 85%) ○ LSI (> 90%) ○ LSI (> 95%) ○ This is up to the discretion of the physical therapist ○ I do not use this
Which of the following modalities, if any, do you typically allow in the unrestricted RTP phase? Please select all that apply.	☐ Open kinetic chain (OKC) exercises ☐ Closed kinetic chain (CKC) exercises ☐ Neuromuscular electrical stimulation ☐ Balance training (Ex. Single Leg Stands on Airex Pad/Trampoline) ☐ Vibration training (Ex. Power Plate, etc.) ☐ Other ☐ I do not use any of these
Please specify any other types of modalities you may use during the unrestricted RTP phase:	_____

APPENDIX D

MAYO CLINIC IRB #20-008283 APPROVAL

Principal Investigator Notification:

From: Mayo Clinic IRB

To: Anikar Chhabra

CC: Joseph Brinkman
Anikar Chhabra
Kaycee Glattke
Jeffrey Hassebrock
Sailesh Tummala

Re: IRB Application #: 20-008283
Title: Survey of Orthopedic Surgeons to Identify Trends in Anterior Cruciate Ligament Reconstruction Recovery Protocols
IRB Approval Date: 9/24/2020
IRB Expiration Date:

The above referenced application was reviewed by expedited review procedures and is determined to be exempt from the requirement for IRB approval (45 CFR 46.104d, Category 2). Continued IRB review of this study is not required as it is currently written. However, any modifications to the study design or procedures must be submitted to the IRB to determine whether the study continues to be exempt.
As protected health information is not being requested from subjects, HIPAA authorization is not required in accordance with 45 CFR 160.103.
AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and major protocol violations/deviations within 5 working days of becoming aware of the occurrence.
4) Compliance with applicable regulations for the protection of human subjects and with Mayo Clinic Institutional Policies.
Mayo Clinic Institutional Reviewer

APPENDIX E

SUPPLEMENTARY SURVEY RESULTS

ACLR Protocol Development & Patient Selection

Respondents were asked to identify all the factors that influenced the development of their postoperative protocols. Fellowship training/mentorship and guidance from physical therapy were chosen most frequently, with 39 (84.8%) and 33 (71.7%) surgeons choosing those options, respectively. Thirty-seven respondents (80.4%) reported that they utilize a separate protocol involving functional testing techniques to determine when athletes can return to sport.

The majority of respondents (n=26, 56.5%) indicated that they wait at least 3-4 weeks to perform ACLR surgery, while two (4.4%) wait less than one week, twelve (26.1%) wait 1-2 weeks, and six (13.0%) wait longer than four weeks to perform surgery.

The final two questions of this section asked respondents about how they advance patients through their rehabilitation protocols. Twenty-nine respondents (63.0%) reported that their protocols utilize both time- and phase-based guidelines to determine how patients advance, while fourteen (30.4%) utilize only phase-based guidelines and three (6.5%) only use time-based guidelines to advance their patients. The majority of respondents (n=42, 91.3%) reported that both the orthopedic surgeon and physical therapist are responsible for determining when patients may advance to the next stage of their protocol while only four (8.7%) reported that the orthopedic surgeon alone is responsible for the patient's advancement.

Preoperative Phase

Thirty-three (71.7%) respondents reported that they typically prescribe pre-operative rehabilitation, or "prehab" to their patients before undergoing ACLR. All 33 respondents who prescribe prehab reported that their prehab programs emphasize knee range of motion, while 22 (66.7%) reported emphasis on quadriceps strength, ten (30.3%) reported emphasis on neuromuscular and proprioceptive training, and eight (24.2%) reported emphasis on hamstring strength.

Postoperative Rehabilitation Phase

With regards to when participants allow their patients to progress to full weight-bearing status after surgery given no concomitant procedures were performed, 34 (73.9%) reported allowing patients to bear full weight on the operative extremity immediately after ACLR. Three (6.5%) allow full weight-bearing after one week, seven (15.2%) require patients to wait two weeks after surgery, while one participant (2.2%) each reported that patients must wait three weeks and four weeks to progress to full weight-bearing status.

Respondents reported the time period at which they allow patients to begin strengthening and pushing for full range of motion after ACLR. Nineteen (41.3%) reported allowing this less than one week after surgery, 17 (37.0%) wait 1-2 weeks, two (4.4%) wait 2-3 weeks, four (8.7%) wait 3-4 weeks, and two (4.4%) each wait 4-6 weeks and more than six weeks after surgery.

Return to Sport

Thirty-six out of 45 (80.0%) participants reported that they utilize tests, exam findings, or other objective criteria to determine when a patient is ready to return to jogging and lateral movements. Of these 36 responses, 34 (94.4%) utilize a range of motion exam, 32 (88.9%) utilize an effusion exam, and 24 (66.7%) utilize laxity exams. With respect to PROMs, six (16.7%) use the IKDC, one (2.8%) each uses the ACL Return to Sport Index (ACL-RSI) and the Psychovitality Scale, four (11.1%) each use the Lysholm Knee Score and Tegner Activity Scale, and two (5.6%) use the Lower Extremity Functional Scale (LEFS). Twenty-six of the 36 (72.2%) respondents reported that they do not utilize PROMs.

Thirty-two out of 42 (76.2%) participants reported that they utilize tests, exam findings, or other objective criteria to determine when a patient is ready to return to non-contact sport activities. Of these 32 responses, 30 (93.8%) utilize a range of motion exam, 27 (84.4%) utilize an effusion exam, and 26 (81.3%) utilize laxity exams. With respect to PROMs, ten (31.3%) use the IKDC, one (3.1%) uses the KOS, three (9.4%) use the ACL-RSI, one (3.1%) uses the Psychovitality Scale, 8 (25.0%) use the Lysholm Knee Score, seven (21.9%) use the Tegner Activity Scale, and one (3.1%) uses the LEFS. Eighteen of the 32 (56.3%) respondents reported that they do not utilize PROMs.

Thirty out of 40 (75.0%) participants reported that they utilize tests, exam findings, or other objective criteria to determine when a patient is ready to return to unrestricted sport activities. Of these 30 responses, 27 (90.0%) utilize a range of motion exam, 27 (90.0%) utilize an effusion exam, and 25 (83.3%) utilize laxity exams. Two of the 30 (6.7%) respondents reported that they do not utilize any physical exam components. With respect to PROMs, ten (33.3%) use the IKDC, two (6.7%) use the KOS, six (20.0%) use the ACL-RSI, one (3.3%) uses the Psychovitality Scale, eight (26.7%) use the Lysholm Knee Score, seven (23.3%) use the Tegner Activity Scale, and two (6.7%) use the LEFS. Thirteen of the 30 (43.3%) respondents reported that they do not utilize PROMs.

APPENDIX F

MAYO CLINIC IRB #19-008473 APPROVAL

From: IRBe
Sent: Tuesday, February 4, 2020 11:51 AM
To: Chhabra, Anikar, M.D.
Subject: 19-008473 - IRB Application has been Approved

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Anikar Chhabra
CC: Anikar Chhabra
Arthur De Luigi
Melissa Eden
Kaycee Glattke
Jedediah Lee
Daniel McGurren

Re: IRB Application # 19-008473

Application Title: Low-Intensity Blood Flow Restriction Training as a Pre-Operative Rehabilitative Modality to Improve Post-Operative Outcomes for ACL Reconstruction
Please note that all correspondence (modifications, continuing reviews, reportable events) related to this application must be submitted electronically in the IRBe system.

The following is an excerpt from the minutes of the Mayo Clinic Institutional Review Boards (IRB-C) meeting dated 1/31/2020:
DECISION: The Committee received the Deferral Response Form dated January 21, 2020, for the above referenced application. The investigator revised the application to include a request for a non-significant risk (NSR) determination for the device, Smart Cuffs Blood Flow Restriction Cuffs. The Committee determined that the concerns identified at the Committee meeting of January 10, 2020 were adequately addressed. The Committee reviewed and approved the above referenced application and noted that all requirements for approval of research (45CFR46.111 and 21CFR56.111) were met. This approval is valid for one year unless during that time the IRB determines that it is appropriate to halt or suspend the study earlier. IRB approval will expire on January 30, 2021. The Committee approved the accrual of 36 adult and pediatric subjects from a screening population of 100. The Committee approved the following site to conduct the study activities as specified in the application: Mayo Clinic in Arizona.

REVIEW: The Committee noted receipt of the protocol, version 1, dated October 15, 2019. The Committee agreed that the Investigator's Data Safety Monitoring Plan and the Data Safety Monitoring Board are appropriate for the study. Funding for the study is provided by Arizona State University Global Sport Institute. The Committee determined that the study device, Smart Cuffs Blood Flow Restriction Cuffs, was of non-significant risk (NSR) as proposed for use in this study as it does not meet the criteria for significant risk defined under 21CFR812.3(m). As such, the Investigator and sponsor are to comply with 21CFR 812.2(b), the abbreviated FDA requirements for Investigational Device Exemption (IDE). The investigator is referred to the Mayo Clinic Office of Research Regulatory Support Quick Reference Guide, "Responsibilities of the Sponsor and/or Investigator for Non-Significant Risk Device Studies" and the Mayo Clinic IRB Policy, "Use of an Investigational Device in Human Subjects Research" for additional information.
The Committee reviewed the manual, dated November 25, 2018, for the study drug Blood Flow Restriction Masterclass. The Committee noted receipt of Literature Review; Ultrasound Measurement Diagram; ACL Phased Rehabilitation Guidelines; PT Compliance Form (contract); SPAD email correspondence, dated December 3, 2019; Site Screening and Enrollment Log, Version 1.0, April 24, 2013; Pre-Operative Data Collection Sheet; Post-Operative Data Collection Sheet; and Study Device Information Sheet.
CONTACT MATERIALS: The Committee approved the questionnaires as submitted.
CONSENT: The Committee approved the consent form (00) as written. The final approved consent form will be provided under the Documents tab of the main study workspace in IRBe.
The Committee made the following determinations in regards to the Aim 3 portion of the study: 1) assent is required for subjects 13 to 17 years of age as they are capable of assenting; 2) assent of subjects 13 to 17 years of age should be documented on the consent form; 3) the permission of one parent is required; and 4) reconsent is required for all subjects who reach the age of majority.
REMINDER: The Committee:
Reminds the investigator to submit a continuing review report prior to the expiration date (reminder will be sent prior to expiration).

Attachments (if applicable):

name	version	dateCreated	dateModified
There are no items to display			

Clarke, Bart L. M.D., Chair
Gillian Currie , Correspondent
Mayo Clinic Institutional Review Boards
IRB-C

APPENDIX G

INFORMED CONSENT DOCUMENT FOR IRB #19-008473

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Low-Intensity Resistance Blood Flow Restriction Training as a Pre-Operative Rehabilitative Modality to Improve Post-Operative Outcomes for ACL Reconstruction

IRB#: 19-008473

Principal Investigator: Dr. Anikar Chhabra, M.D. and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to find out whether the use of low-intensity strength exercises during the 2 weeks before surgery, and while the blood flow to the leg is reduced, will improve the outcomes after surgery to repair an injured ligament of the knee.
What's Involved	The study will begin 2 weeks before your surgery and will end at approximately 6 months after your surgery. During the first 2 weeks of the study, before your surgery, you will have 5 physical therapy visits at which you will do a series of low-intensity strength exercises and while the blood flow to your leg is reduced. During this therapy, a cuff similar to a blood pressure cuff will be placed around the top of the thigh of your injured leg and inflated. You will be asked to perform a series of exercises. We will do tests to measure your range of motion, strength, stability, and the size of your quad muscle. You will

	also be asked to fill out some questionnaires about the pain and function in your injured knee. After your surgery, your physical therapy will follow the normal rehabilitation practice guidelines. However, we will repeat the same measures and questionnaires that we did in the beginning when you are 8-10 days, 4 weeks, 8 weeks, 14 weeks, and 24 weeks post-op. We will do these tests at the same time that you return for your post-op visits with Dr. Chhabra.
Key Information	You may feel some discomfort or slight bruising from the cuff while performing the exercises with the cuff applied to your leg. If you experience dizziness, light-headedness, or nausea during the training, we will remove the cuffs immediately and stop the training. If you are not able to perform any of the exercises without pain, we can remove them from your pre-op training protocol. Possible benefits from participating in this study include increased quad strength and size after your surgery. This can improve the stability of your knee after surgery and help you to return to your pre-op activity levels.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** Dr. Anikar Chhabra, M.D. Phone: 480-342-1629 **Study Team Contact:** Jedediah (Jed) Lee, PT, DPT, OCS, SCS Phone: 480-342-6807 **Institution Name and Address:** Mayo Clinic 5777 E. Mayo Blvd. Phoenix, AZ 85054

▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Why are you being asked to take part in this research study?

You have been asked to take part in this research because you have been diagnosed with an ACL injury that will require surgical reconstruction.

Why is this research study being done?

The purpose of this research is to find out whether the use of low-intensity strength exercises during the 2 weeks before surgery, and while the blood flow to the leg is reduced, will improve the outcomes after surgery to repair an injured ligament of the knee.

Information you should know

Who is Funding the Study?

This study is being partially funded by Arizona State University Global Sport Institute. All equipment involved in this study has been purchased by Mayo Clinic.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

The study will begin 2 weeks before your scheduled surgery and will end at approximately 6 months after your surgery.

You will complete 5 study visits before your surgery, and 5 study visits after your surgery.

What will happen to you while you are in this research study?

During this study, we will ask you to fill out questionnaires about the function in your injured leg and your ability and confidence in performing daily activities. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 15 minutes to complete.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the blood flow restriction (BFR) group or the SHAM-BFR group. You and the Principal Investigator can't choose your study group. You will have a 1 in 2 chance of being assigned to the BFR group. Neither you nor the Principal Investigator will know which group you have been assigned to.

BEFORE SURGERY:
During the first two weeks of the study, before your surgery, you will have 2 or 3 physical therapy visits per week (5 visits total) at which you will do a series of low-intensity strength exercises while the blood flow to your leg is reduced. During this training, a cuff similar to a blood pressure cuff will be placed around the top of the thigh of your injured leg and inflated. You will be asked to perform a series of exercises. These exercises include:

- **Body-weight squats:** 1 set of 30 reps, then 3 sets of 15 reps
- **Supine straight leg raises:** 1 set of 30 reps, then 3 sets of 15 reps or to fatigue
- **Standing heel raises:** 1 set of 30 reps, then 3 sets of 15 reps
- **Seated long/short arc quads:** 1 set of 30 reps, then 3 sets of 15 reps
- **Wall sits:** 5 x 30 seconds
- **Standing hamstring curls:** 1 set of 30 reps, then 3 sets of 15 reps

You will only be asked to perform the exercises that you can do without any pain in your knee. If you are unable to complete certain exercises, this will not exclude you from completing the study.

At your first pre-op physical therapy visit, we will do tests to measure your range of motion, strength, stability, and the size of your quad muscle. You will also be asked to fill out some questionnaires about the pain and function in your injured knee. The measurements and questionnaires are as follows:

- **Quad strength**: We will use a device called a dynamometer, which requires you to press your leg as hard as you can against a small handheld sensor. You will also be asked to perform a leg press test, which requires you to perform as many leg presses as possible with your injured leg and non-injured leg on a leg press machine at your 1-rep maximum until you are unable to continue.
- **Quad size:** We will use non-invasive ultrasound to measure the size of your quad and to determine if there is any swelling in your knee. A small amount of gel will be placed on your thigh and knee, and a handheld transducer will be moved along your leg so that we can take images of your muscles and soft tissue.
- **Effusion:** We will use a tape measure to measure the circumference of your leg to determine whether or not there is fluid present in your joint.
- **Static (balance in place) and gait (walking) speed:** We will use a smartphone application called the Lockhart Monitor to quantify your static stability while standing still and your gait speed while walking. We will clip a smartphone to your waistband and ask you to perform a series of activities including standing still on both legs and walking a short distance (10 meters). You will perform the balance tests two times each, twice with your eyes open and twice with your eyes closed.
- **Range of motion:** While you are lying on your back, the physical therapist will measure the range of motion in your knee by having you bend your knee and straighten your leg as much as you can without pain.
- **Lower Extremity Functional Scale (LEFS):** The LEFS is a questionnaire that consists of 20 questions about your ability to perform everyday tasks.
- **Lysholm Knee Scoring Scale:** The Lysholm Knee Scoring Scale is a questionnaire that consists of 8 questions about pain, instability, locking, swelling, limp, stair climbing, squatting, and need for support.
- **Anterior Cruciate Ligament Return to Sport Index (ACL-RSI):** The ACL-RSI is a questionnaire that consists of 12 measures that ask you to rate your confidence in returning to your preferred sport or activity of choice.

These measurements will be repeated at your final pre-op physical therapy visit, which will be 24-48 hours before your surgery.

AFTER SURGERY:

After your surgery, your physical therapy will follow the normal rehabilitation practice guidelines also known as standard of care. However, we will repeat the same measures and the questionnaires that we did in the beginning when you are 8-10 days, 4 weeks, 8 weeks, 14 weeks, and 24 weeks post-op. We will do these tests at the same time that you return for your post-op visits with Dr. Chhabra.

You may choose to do your post-op physical therapy at the Mayo Clinic Sports Medicine Center in Tempe, AZ; however, you may also complete your post-op physical therapy at a non-Mayo Clinic location. If you choose to do your physical therapy outside of Mayo Clinic, you will be provided a copy of Dr. Chhabra's ACL Phased Rehabilitation Guidelines that will outline the activities you may progress to in each phase after your surgery. You will also be provided with a contract that you and your physical therapist will need to sign stating that you will follow Dr. Chhabra's guidelines without deviating from them or making any amendments.

What are the possible risks or discomforts from being in this research study?

Exercise Risks:

You may feel some discomfort or slight bruising from the cuff while performing the exercises with the cuff applied to your leg. If you experience dizziness, light-headedness, or nausea during the training, we will remove the cuffs immediately and stop the training. If you are not able to perform any of the exercises without pain, we can remove them from your pre-op training protocol.

Confidentiality Risks:

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Standard of Care Risks:

Your doctor will discuss the risks of your surgery as this is a part of your standard clinical care.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. However, possible benefits from participating in this study include increased quad strength and size after your surgery, which can improve your post-op stability and help you return to your pre-op activity levels sooner.

What alternative do you have if you choose not to participate in this

research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Measuring quad strength and size with a handheld dynamometer and a leg press test
- Measuring quad size with noninvasive Ultrasound
- Measuring static stability and gait speed with a smartphone application
- Measuring effusion with a tape measure
- Measuring range of motion of the knee with manual flexion and extension tests
- Short questionnaires including LEFS, Lysholm Knee Scale, and ACL-RSI

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will not be paid for taking part in this study.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

You will not be identified by your name on any materials collected during the study, you will be assigned a subject number and that will be used to identify you throughout the study. All materials collected during the study with pen and paper will be locked in a cabinet located at the Mayo Clinic Sports Medicine Center. All digital data will be stored in a program located on password-protected computers.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study

information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?
Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Signature of Parent(s)/Guardian for Child:

I give permission for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Printed Name of Child

	/ /	: AM/PM
Printed Name of Parent or Guardian	Date	Time

Signature of Parent or Guardian

Person Obtaining Consent

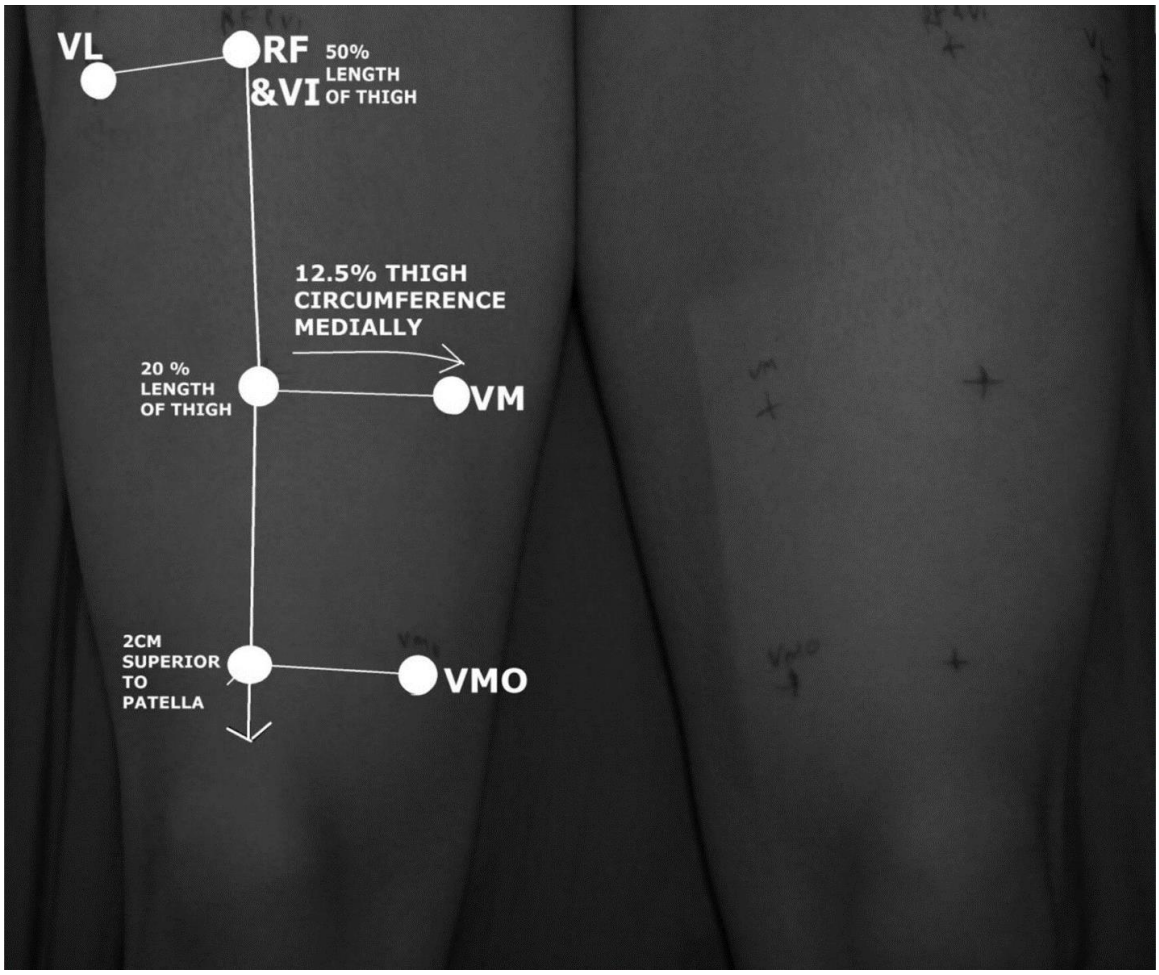
- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

APPENDIX H

MUSCULOSKELETAL ULTRASOUND DIAGRAM OF THE QUADRICEPS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APPENDIX I

PERMISSION FOR USE OF PUBLISHED MATERIAL

The doctoral candidate as named on the above dissertation has obtained permission from the co-authors of the published material of this work, Dr. Anikar Chhabra and Dr. Sailesh Tummala, for inclusion of said material in this dissertation.