

A Determination of Efficacy and Therapeutic Benefits of Blood Floor Restriction Training in an Adolescent Population

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IS THIS A STUDENT OR TRAINEE PROJECT?    ☒ NO    ☐ YES

IF YES, INDICATE LEVEL:

☐ Medical/Dental Student

☐ Resident

☐ Fellow

☐ Undergraduate

☐ Other (specify \_\_\_\_\_)

IF YES, HAS FACULTY ADVISOR REVIEWED THE PROTOCOL?    ☐ NO    ☐ YES

*Note: Student researchers are required to attend the Scientific Review Committee meeting when their protocol is discussed.*

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## **Introduction**

Anterior cruciate ligament (ACL) injury is a very common injury for adolescents and young adults with over 200,000 ACL injuries reported in the United States each year [1]. The standard treatment for this injury includes ACL reconstruction surgery and physical therapy. Rehabilitation of this surgery requires that adequate quadriceps rehabilitation is important for full return function and activity. The role of quadriceps strength recovery after ACL reconstruction has been well studied and is associated with return to play times, knee kinematics and patient reported outcomes [2]. Paterno et al. reported that patients with greater fear on Tampa Scale of Kinesiophobia (TSK-11) were six times more likely to have a quadriceps LSI of less than 90% supporting the role of adequate quadriceps strength in reduction of risk of sustaining a contralateral ACL injury or re-injury [3]. Ithurburn additionally reported that athletes who demonstrated quadriceps strength asymmetry at time of return to sport (RTS) were likely to demonstrate lower knee related function [4].

## **Background**

Exercise training with blood flow restriction (BFR) is a technique increasingly used in physical therapy and rehabilitation settings as an alternative to heavy load resistance exercise, and has increased in popularity in clinical and healthy populations over the last two decades. Exercise is completed in conjunction with a surgical grade pneumatic cuff or tourniquet. Evidence has suggested that BFR assists with muscle hypertrophy, as well lower extremity and upper extremity strength in several populations including athletes, post-operation rehabilitation [5], and the elderly [6]. The clinical value of this technique has been posed to allow increased muscle adaptation and hypertrophy under low loads and intensity that could heretofore only be accomplished with impact activities and more intense training protocols. This is very attractive in a population of early post-operative patients who are not able to engage in this level of activity.

Following ACL reconstruction patients have demonstrated persistent quadriceps strength deficits during and after rehabilitation. Despite there being special attention paid to restoring quadriceps and hamstring strength to pre-operative levels, there is a need for additional intervention. The utilization of BFR in conjunction with current rehabilitation standards of care has shown potential [7]. A meta-analysis completed in 2017 comparing BFR training on musculoskeletal rehabilitation versus traditional low load training, and reported that low load BFR training to be more effective in helping patients regain strength than traditional low load strength training [7]. In a 2018 review of BFR during ACL rehabilitation the authors state the use of BFR as a safe alternative to heavy loads reducing the risk of damage to the graft, cartilage, and meniscus [8]. Current ACSM guidelines for resistance training recommend 70% of a single maximum repetition (RM) to elicit strength and hypertrophy adaptations [9]. BFR provides an alternative to heavy load resistance training due to the light loads prescribed to help reduce mechanical stress on the post-operative knee.

Connecticut Children's Sports Physical Therapy and Elite Sports Medicine have a long relationship of working collectively with the management of patients with ACL tears both surgically and with rehabilitation post-surgically. The current standard of care for the rehabilitation of ACL injuries includes several interventions and the process can last up to 12 months. The early phases of rehabilitation include the use of therapeutic exercise, manual therapy and modalities to help reduce pain, normalize range of motion and gait. In the later phases, a progressive lower extremity strengthening program is completed, in addition to plyometric and jump training. Finally, Standardized strength assessments at 3 months' post-operative, and return to sport test between 6 and 9 months are used to help physical therapists and surgeons in clinical decision making for progression with functional and recreational activities. Since early 2019, BFR training has been implemented consistently for post-operative patients at Connecticut Children's Sports Physical Therapy that have undergone ACL reconstruction, as well as patellar and shoulder stabilization procedures.

While there are a number studies that have reported on the use of BFR in the adult population [14], there is limited information about the use of BFR in the adolescent population. This study aims to

evaluate the use of BFR training in conjunction with traditional ACL reconstruction rehabilitation in adolescents.

### **Previous Work**

Until recently, previous studies have examined the use of BFR with respect to muscular strength, endurance and hypertrophy. With the rise in popularity of BFR, there has been increased attention to overall safety issues of training with BFR. The potential risks to the cardiovascular system that have been considered are increased blood pressure responses, thrombotic events and damage to the vascular system [10]. Despite these concerns, there have been several extensive reviews published demonstrating that the side effects are minimal [10, 11, 12], and that training with BFR and when compared with traditional methods shows no greater risk [13]. Additionally, a closer look at the literature has demonstrated that the use of BFR has shown significant strength adaptations in multiple patient populations:

- A 2017 study showed a 2-fold improvement in extension and flexion strength with the use of BFR in patients after knee arthroscopy [15].
- Patients with patellofemoral pain had greater improvements in knee extension strength following the use of BFR training [14].
- A 2003 study demonstrated improved quadriceps strength with BFR training in patients after ACL reconstruction [16].
- Greater improvements in thigh circumference as opposed to a standard group [17].

### **Research Question:**

The purpose of this study is to evaluate the addition of BFR-based exercise to traditional methods of physical therapy. Does the use of BFR-based exercise improve strength, hypertrophy, functional and patient reported outcomes after ACL Reconstruction in the adolescent population?

### **Purpose of the Research, Specific Aims and Hypotheses**

The purpose of this study is to determine the safety and efficacy regarding the addition of BFR-based exercise to traditional methods of physical therapy in the adolescent, post-surgical population.

Primary aims:

1. To determine the relationship between adjunct BFR training during post-surgical rehabilitation and isometric and isokinetic lower extremity strength measures (HUMAC isokinetic dynamometer).
  - a. We hypothesize that there will be a positive association between BFR training and isometric and isokinetic lower extremity strength
2. To determine the impact of adding BFR training during post-surgical rehabilitation on functional outcomes.
  - a. We hypothesize that BFR training will improve scores on lower extremity functional tests when compared to a control group.

## Secondary aim:

1. To determine the impact of adding BFR training during post-surgical rehabilitation on patient reported outcomes.
  - a. We hypothesize that BFR training will show greater patient reported outcome scores on the post-op when compared to a control group.
2. To determine the impact of adding BFR training during post-surgical rehabilitation on hypertrophy and mid-thigh circumference.
  - a. We hypothesize that BFR training will demonstrate significant increased mid-thigh circumference over measured time points.
3. To determine and record patient tolerance and reported side effects and to BFR training during post-surgical rehabilitation.
  - a. We hypothesize that patient tolerance to BFR will be consistent with previously published literature.

## **Study Design**

The planned pilot study is a prospective study to compare the use of exercises augmented with BFR with quantitative measurements of strength and patient reported outcomes. A total of 33 youth and adolescent patients undergoing a surgical procedure for ACL reconstruction at Connecticut Children's Elite Sports Medicine and completing physical therapy at Connecticut Children's Sports Physical Therapy will be recruited for this study. Additionally, 14 patients will be recruited that do not participate at Connecticut Children's Sports Physical Therapy and do not receive BFR training as prospective controls. Should we be unable to obtain 20 prospective controls, a review of data from 20 previous patients, matched for age, sex, BMI and surgical procedure that completed physical therapy at Connecticut Children's Sports Physical Therapy will be used as a comparison.

## **Target Population**

The target population for this study consists of patients post ACL Reconstruction whom have been treated and followed by Elite Sports Medicine at Connecticut Children's and completed physical therapy at Connecticut Children's Sports Physical Therapy. The inclusion and exclusion criteria will be the same for both the study and control groups.

## **Study Group Inclusion criteria:**

- Patients between the age of 12 and 18 years at the time of surgery.
- Post-primary ACL reconstruction
- Orthopaedic surgical intervention (including all additional procedures at the knee) completed by one of the Elite Sports Medicine physicians.
- Patient completed postoperative rehabilitation following standard protocols
- No contraindications to performing BFR, as outlined in the Owens Recovery [18] Science 2018 Personal Blood Flow Restriction manual.

## **Prospective Control Inclusion Criteria:**

- Patients between the age of 12 and 18 years at the time of surgery.
- Post–primary ACL reconstruction
- Orthopaedic surgical intervention (including all additional procedures at the knee) completed by one of the Elite Sports Medicine physicians.
- Patient completed postoperative rehabilitation following standard protocols
- Patient did NOT use BFR training during their rehabilitation
- Patient did NOT complete physical therapy at Connecticut Children’s Sports Physical Therapy.

## **Exclusion criteria for study group and prospective controls:**

### **a. Specific exclusions**

- Patients older than 18 and younger than 12 at the time of surgery
- Any additional diagnoses or deformity not related to knee injury that could affect knee strength
- Additional lower extremity injury at time of knee injury (e.g., ankle injury) requiring treatment

Previous surgical intervention on the knee (ipsilateral and contralateral)

Patients with weight bearing restrictions for greater than two weeks after surgery due to concomitant pathology such as meniscal root/radial repair, chondral pathology, or multi-ligament pathology. Generic exclusion: “Subjects not meeting all inclusion criteria.”

The exclusion of age is to ensure that the study population is old enough to complete testing on the HUMAC isokinetic dynamometer and young enough to be treated by one of our Elite Sports Medicine physicians.

The secondary diagnosis and previous knee injury exclusions are to limit the influence of other diagnoses or injuries on measured knee strength, as well as provide a more homogeneous group for comparison to past data.

## **Identification, recruitment, consent and retention of subjects**

### **Patient Screening and Determination of Eligibility**

#### **Pre-Screening**

All potential patients undergoing ACL reconstruction at Elite Sports Medicine will be approached for participation for this study. Patients scheduled to undergo ACL reconstruction will be screened by the individuals listed on this protocol using our pre-screening documentation form. All patients undergoing ACL reconstruction undergo a pre-operative appointment.

#### **Identification and Recruitment:**

Once identified as a potential candidate, the study purpose and protocol will be explained and a brief summary of the study will be provided at the conclusion of the pre-operative appointment. Patients must meet all the requirements of inclusion and exclusion criteria to be eligible for consent.

**Consent:** Consent will take place at the pre-operative visit. The patient/parent will be given a detailed description of the purpose and methodology for this study. They will have the opportunity to read the consent forms and ask any questions they may have about the research. If they agree to participate, they will be asked to sign the consent form and a copy will be provided.

If patients agree to enroll, all demographics and information listed in the protocol will be stored in a data collection sheet that is listed in the attachments. This sheet will be used to record all pertinent information for all active participants on the study and stored in a secure folder on the G drive.

**Retention:** Eligible patients will be required to be seen for a minimum of 90% of patient visits to be included in this study.

**Retrospective control:** Patients that will be used as part of the retrospective control will be collected using a billing run with CPT codes related to ACL reconstruction from January 2017- January 2019.

**Patient Reported Outcomes:**

- 1) 4 Patient reported outcome measures will be collected at 5 time points listed below:
  - a) Pre-operative visit
  - b) 3 months post-operative
  - c) Return to sport testing
  - d) 12 month follow up
  - e) 2 year follow-up over phone or email
- 2) Outcome measures completed:
  - a) International Knee Documentation Committee (IKDC)
  - b) Anterior Cruciate Return to Sport after Injury (ACL-RSI)
  - c) Knee Injury and Osteoarthritis Outcome Score (KOOS)
  - d) Marx Activity Rating Scale (MARX)

**Functional Outcome Definitions/Data Points Collected**

1. Demographic information will be collected and outcome measures will include the following:
  - a. Age
  - b. Medical record number
  - c. Date of ACL surgery and related surgeries
  - d. Sex
  - e. Graft Type
  - f. Surgeon
  - g. Sport
  - h. Level of competition in sport
  - i. Weight and Height
  - j. BMI
  - k. Weight bearing precautions (weeks)
  - l. Limb length (cm): ASIS to superior medial malleolus
  - m. Tegner Scale
2. Opened or closed Physis (or skeletal maturity)



3. Data will be collected at five different time points during the rehabilitation process. The current standard of care includes a pre-operative visit, a 3-month assessment visit, and a return to sport visit between 6-9 months post-operative, and a 1 year follow up. Additionally, we will collect data a 2 year phone/email follow up to record patient outcomes. These assessments are completed in conjunction with the surgeon's follow up visit. The physical therapist completing the assessment will record the outcomes in a secure Excel data collection form.(or Access data base)

4.

#### **A) Pre-operative visit**

- a. Isometric knee extension at 60 degrees on involved and involved side.
  - i. Quadriceps deficit=  $100 - (\text{Knee extension peak torque involved} / \text{knee extension peak torque uninjured})$
- b. Isometric knee flexion at 60 degrees on involved and uninjured side
  - i. Hamstring Deficit=  $100 - (\text{Knee flexion peak torque involved} / \text{knee flexion peak torque uninjured})$
- c. Isometric hip extension at 60 degrees on involved and uninjured side
  - i. Hip extension deficit=  $100 - (\text{Hip extension peak torque involved} / \text{hip extension peak torque uninjured})$
- d. Quad hypertrophy will be measured by thigh circumference measurement.
  - i. Measured at 10cm above the superior pole of the patella bilaterally

#### **B) 3 month evaluation:**

- e. Isometric knee extension at 60 degrees on involved and involved side.
  - i. Quadriceps deficit=  $100 - (\text{Knee extension peak torque involved} / \text{knee extension peak torque uninjured})$
- f. Isometric knee flexion at 60 degrees on involved and uninjured side
  - i. Hamstring Deficit=  $100 - (\text{Knee flexion peak torque involved} / \text{knee flexion peak torque uninjured})$
- g. Isometric hip extension at 60 degrees on involved and uninjured side
  - i. Hip extension deficit=  $100 - (\text{Hip extension peak torque involved} / \text{hip extension peak torque uninjured})$
- h. Quad hypertrophy will be measured by thigh circumference measurement.
  - i. Measured at 10cm above the superior pole of the patella bilaterally.

- i. Y Balance Test (all measures taken bilaterally)
  - i. 3 trials anterior reach involved and unininvolved (cm)
  - ii. 3 trials posteromedial reach involved and unininvolved (cm)
  - iii. 3 trials posterolateral reach involved and unininvolved (cm)
  - iv. Anterior reach difference= Max anterior reach involved – Max anterior reach unininvolved
  - v. Posteromedial reach difference= Max posteromedial reach involved- Max posterior reach unininvolved
  - vi. Posterolateral reach difference= Max posterolateral reach involved-Max posterolateral reach unininvolved.
  - vii. Involved and Unininvolved Composite score= (Max anterior reach+ Max posteromedial reach + max posterolateral reach)/(3\*Limb Length) \*100.
- j. 8” Anterior Stepdown Test (measures taken bilaterally)
  - i. Involved repetitions= Max repetitions in 1 minute.
  - ii. Unininvolved repetitions= Max repetitions in 1 minute.
- k. Elevated single leg bridge test completed with a 12” box (all measures taken bilaterally)
  - i. Involved repetitions= Max repetitions in 1 minute.
  - ii. Unininvolved repetitions= Max repetitions in 1 minute.
- l. Half kneeling dorsiflexion distance (all measures taken bilaterally)
  - i. Half kneeling difference = half kneeling involved- half kneeling non involved

## 5. Return to sport testing:

- a. Isometric knee extension at 60 degrees on involved and involved side.
  - i. Quadriceps deficit= 100- (Knee extension peak torque involved/knee extension peak torque unininvolved)
- b. Isometric knee flexion at 60 degrees on involved and unininvolved side
  - i. Hamstring Deficit= 100- (Knee flexion peak torque involved/knee flexion peak torque unininvolved)
- c. Isokinetic knee extension at 300 deg/ sec, 180 deg/sec, and 60 deg/ sec
  - i. Quadriceps deficit= 100- (Knee extension peak torque involved/knee extension peak torque unininvolved)

- d. Isokinetic knee flexion 300 deg/ sec, 180 deg/sec, and 60 deg/ sec
  - i. Hamstring Deficit=  $100 - (\text{Knee flexion peak torque involved} / \text{knee flexion peak torque uninvolved})$
- e. Isometric hip extension at 60 degrees on involved and uninvolved side
  - i. Hip extension deficit =  $100 - (\text{hip extension peak torque involved} / \text{hip extension peak torque uninvolved})$
- f. Quad hypertrophy will be measured by thigh circumference measurement.
  - i. Measured at 10cm above the superior pole of the patella bilaterally
- g. Anterior reach test (all measures taken bilaterally)
  - i. 3 trials anterior reach involved and uninvolved (cm)
  - ii. Anterior reach difference= Max anterior reach involved – Max anterior reach uninvolved
- h. Single leg heel raise testing (all measures taken bilaterally)
  - i. Maximum number of repetitions completed to maximum height at pace of 60 beats per second
  - ii. Heel raise difference = heel raise involved – heel raise non involved
- i. 8” Anterior Stepdown Test (measures taken bilaterally)
  - i. Involved repetitions= Max repetitions in 1 minute.
  - ii. Uninvolved repetitions= Max repetitions in 1 minute.
- j. Half kneeling dorsiflexion (all measures taken bilaterally)
  - i. Half kneeling difference = half kneeling involved- half kneeling non involved
- k. Single leg hop for difference (all measures taken bilaterally)
  - i. Single leg hop difference = maximum involved distance – maximum non- involved distance
- l. Timed hop for distance (all measures taken bilaterally)
  - i. Timed hop difference = time involved – time non involved
- m. Single leg triple hop for distance (all measures taken bilaterally)
  - i. Single leg triple hop difference = maximum involved distance – maximum non-involved distance
- n. Cross over hop for distance (all measures taken bilaterally)

- o. Cross over hop difference = maximum involved distance – maximum non-involved distance

6. 12-month testing

Tegner Activity Scale

- 7. Prospective control: All prospective controls will follow the ACL reconstruction protocol at an outside facility. These patients will complete outcome measures, and standardized strength assessments consistent with the standard current standard of care listed above. The same data points will be collected.
- 8. Retrospective controls: Outcome measures (RSI, IKDC) and the results of standardized 3 and 6mo + assessment results will be collected.
- 9. All data points listed above for all three groups will be stored in a Microsoft Excel spreadsheet on the G drive.

**Study Design/Procedures:**

The current standard of care for patients undergoing ACL reconstruction at Connecticut Children's and Elite Sports Medicine involves initiation of physical therapy approximately 2-5 days after surgery. All patients undergoing ACL reconstruction follow the surgeon's ACL rehabilitation protocol. Each participant will be evaluated by one of the sport physical therapists during their initial evaluation as part of the current standard of care for all new patients. Patient reported outcomes and strength measurements will be conducted according to the surgeon's protocol for ACL reconstruction patients. The current rehabilitation protocol includes a standardized assessment at 3 months post-operative and 6-9 months post-operative. These assessments help determine progression to the next phase of rehabilitation.

In addition to the standard ACL protocol, patients in this study will utilize the Owen Recovery Science exercise protocol for BFR [18]. The following guidelines will be followed concerning exercise progression, occlusion pressure and difficulties with volume achievement. To determine the appropriate resistance for each exercise, the patient's 1 repetition maximum (1RM) will be attained using a repetition test [19]. This test will use a previously validated algorithm to determine the 1RM based on the weight used to perform a 7-10 repetition test [20]. Patient will perform the exercise with a weight they can comfortably lift for several repetitions. Based on the weight or resistance used, and the patient's perceived exertion a 1RM will be estimated using the modified OMNI-RES scale. The starting load for each exercise will be 20-30% of their 1RM, or bodyweight resistance will be used when loading is not feasible.

Load progression of exercises will be based on the patient's ability to complete the prescribed number of repetitions. If the patient successfully completes all 75 repetitions, they will have their 1 RM reassessed in 1-3 session to increase the load.

If the patient completes between 60-74 repetitions, they will continue with the prescribed training and increase the rest periods between sets 3 and 4, to 45 seconds. They then will continue with the prescribed weight until the patient can complete 75 repetitions for 1 to 3 sessions.

If the patient completes between 45- 59 repetitions, they will continue with the prescribed weight, but will extend the rest period between all sets to 45 seconds. This exercise prescription will be followed until the patient can complete all 75 repetitions. After which the rest periods will be reduced to 30 seconds. Once the

patient can complete all 75 repetitions with 30 second break between sets for 1-3 session, they then would have their 1RM reassessed.

If the patient completes less than 44 repetitions, the load will be reduced by approximately 10% until the patient can complete 75 repetitions in the prescribed manor. After the patient has successfully complete 1-3 sessions, they will have their 1RM reassessed using the previously described repetition test.

## **Proposed Protocol**

### **Phase 1- Weeks 1 to 2**

- Quad Set: 10 second on, 10 second rest at 100% occlusion x10'
  - progress to isometrics at the edge of the table 60 degrees as clinically appropriate
- Side Lying Hip Abduction, 30/15/15/15, at 80% occlusion
- Hip Extension from prone 30/15/15/15, at 80% occlusion
- Re-check load at the start of each Phase, to determine 1 RM (7-10RM test on leg press)
- Total BFR time approximately 24 minutes per session, with 2 sessions per week

### **Phase 2- Weeks 3 to 4**

- Replace Quad Set with Long Arc Quad (90-30deg), 30/15/15/15 at 80% occlusion
- Replace Hip Extension with Leg Press (shuttle), 30/15/15/15 at 80% occlusion
- Hip Abduction, 30/15/15/15 at 80% occlusion
- Total BFR time approximately 24 minutes per session with 2 sessions per week

### **Phase 3- Weeks 5 to 6**

- Long Arc Quad (90-30deg), 30/15/15/15 at 80% occlusion
- Leg Press (shuttle), 30/15/15/15 at 80% occlusion
- Replace Hip Abduction with Bilateral Hip Bridge, 30/15/15/15 at 80% occlusion
- Total BFR time approximately 24 minutes per session, with 2 sessions per week

### **Phase 4- Weeks 7 to 8**

- Leg Press (shuttle), 30/15/15/15 at 80% occlusion
- Replace Long Arc Quad with Step Up 30/15/15/15 at 80% occlusion
- Bilateral Hip Bridge, 30/15/15/15 at 80% occlusion
- Total BFR time approximately 24 minutes per session, with 2 sessions per week

### **Phase 5- Weeks 9 to 12**

- Replace Bilateral Hip Bridge with Medial Step Down, 30/15/15/15 at 80% occlusion
- Replace Step up with Split Squat, 30/15/15/15 at 80% occlusion
- Leg Press (shuttle), 30/15/15/15 at 80% occlusion
- Total BFR time approximately 24 minutes per session, with 2 sessions per week

### **Phase 6- Weeks 11 to 12**

- Progressively load exercises from phase 5

Total BFR time approximately 24 minutes per session, with 2 sessions per week

a. At the conclusion of each exercise completed listed in the proposed protocol above, the following will be recorded:

- i) patient rating of perceived exertion (RPE) will be recorded in the exercise flow sheet.
  - ii) Ability or inability to complete the exercise session
- b. At the conclusion of each treatment session any side effect, as previously described by Brandner et al, 2018, will be recorded in the patient chart.

### **Sample Size Justification**

It is our intention to use all possible patients meeting the inclusion criteria in this study. According to the most recent clinical data available, approximately 100 patients per year receive care for ACL knee injury and 25 to 50 patients per year receive physical therapy at Elite Sports Medicine following ACL reconstruction.

### **Accrual and Expected Duration of Accrual**

Once approved, we expect that this study can be accomplished within two to three years. The open period for this study will be between January 1, 2020 and December 1, 2023.

### **Data Analysis:**

The endpoint of this study is when data is collected and analyzed from 20 patients who have completed a one year follow up from date of surgery.

Data will be collected on all patients who meet the inclusion criteria for this study and have agreed to participate through the consenting process. Descriptive statistics will be completed to help gain an overall understanding of the data for the effect of BFR training on lower extremity strength, mid-thigh circumference and outcome measures. T-tests between strength and outcome variables for the BFR and non-BFR group to test if there are differences between the two groups. Correlation tests will be used to determine association between lower extremity strength and BFR training. Corrections will be made for multiple comparisons.

We will be entering into a Data Use Agreement with University of Connecticut (UCONN) for assistance with data analysis and interpretation as well as statistical analysis. All data sharing procedures will be in accordance with Connecticut Children's policy. All data will be de-identified prior to sharing to assure patient's confidentiality. The UCONN collaborator is not engaged in human subject research (no access to identifiers) and will obtain an independent determination from the UCONN IRB.

### **Study Limitations:**

There are several limitations anticipated with this study that will impact its power and external validity. These limitations include an inherent sampling bias with our recruitment strategy, lack of patient or participant blinding, and small sample size.

Attempts will be made to reduce any potential bias by having standardized educational scripts regarding BFR training that each treating therapist will read to subjects prior to their first BFR session.

Subjects in our study will likely come from the same surgeon and the same type of ACL graft (QT). This could be a potential limitation in the generalizability of our results to other surgeons and graft types.

## **Administrative Organization**

### **Roles and responsibilities:**

Adam Weaver, PT, DPT: Will serve as the study's co-primary investigator and study coordinator. Adam will provide primary support for the SRC and IRB study protocol development and submission. He will review the required databases and pull the relevant data required to complete this study. He will also aid in data interpretation and manuscript preparation.

Allison Crepeau, MD: Will serve as the study's co-investigator. She will help with data interpretation and manuscript preparation.

Arthur Fredericks, MS, PT: Will serve as the study's co-investigator. He will provide support in development of SRC and IRB documents (review of literature). He will help with data collection. He will provide an orthopaedic perspective to data interpretation and ultimately utilization of the results in the clinical setting.

Nicholas Giampetruzzi, MS, PT: Will serve as the study's co-investigator. He will be essential for data interpretation and utilization of results.

Dylan Roman, PT, DPT: Will serve as the study's co-investigator. He will provide an orthopaedic perspective to data interpretation and ultimately utilization of the results in the clinical setting. He will provide support in development of SRC and IRB documents (review of literature).

Adel Lolic, MS, EP-C: Will serve as the study's co-investigator. Adel will help the physical therapists with data collection as needed during subject tests as well as organizing tabulated results. Adel is an exercise technologist at Connecticut Children's Sports Physical Therapy. He will provide support in development of SRC and IRB documents, and assist with patient recruitment.

Jennifer Prue, ATC, LAT, MEd: Will serve as the study's co-investigator. She will help the physical therapists with data collection as needed during subject tests as well as organizing tabulated results. She will provide support in development of SRC and IRB documents, assist with patient recruitment and consenting.

Mike Rieger, BS, CSCS: Will serve as the study's co-investigator. He will help the physical therapists with data collection as needed during subject tests as well as organizing tabulated results. He assist with patient recruitment and consenting.

### **Data Collection and Management**

a. Data collection forms: All data will be entered into a Microsoft Excel database to facilitate data analysis.

b. Data collection software: Data collection software will include Microsoft Excel to organize data. Statistics will be run using Microsoft Excel.

c. All outcome measures will be completed and stored in a secure online database: Microsoft Excel spreadsheet on G drive.

d. Adam Weaver will oversee data management. The data will be collected by investigators, and it will be stored in a secured folder on the G drive. The spreadsheet will only be accessible to those individuals included in this study.

e. Information will be reviewed prior to de-identification to insure there are no errors with transcription.

f. Data quality assurance: Data that is collected will be manually verified to ensure that no information has been entered into Excel incorrectly. Additionally, we will randomly check 10% of data in the Excel data base for accuracy after initial entry to insure accuracy.

CCMC Department of Research

g. Record retention and confidentiality will be dictated by the current procedures in place here at Connecticut Children's. All information will be stored in a private office and on a single password protected computer. No access to information is possible from an outside source.

## **Human Subjects Protections and Ethical Conduct of the Study**

### **Patient confidentiality statement**

Strict measures will be required for respecting and maintaining patient confidentiality. Application for IRB approval is currently being created for submission, and once IRB evaluation has occurred we will make any changes required to ensure HIPPA compliance. Collection of a patient identifier including medical record numbers and the patients name is necessary to ensure comprehensive inclusion of eligible subjects and accurate linking of data from different data sets. The database used for the study will be password protected and stored in a secure folder on the G drive. Once we have collected all the data, the data set will be frozen for analysis. At this time, we will completely de-identify all subjects. Medical record numbers as well as the patient's names will be removed and patients will be referred to by study number only. De-identification will take place once we have collected all data. In the event that further time is needed prior to de-identification of the data set, we will request a continuation through the IRB at the time of annual review of the protocol. We expect that these measures will minimize any risk to confidentiality very effectively, and that any unavoidable residual risk will be balanced generously by the potential benefit to society of the knowledge that will be obtained through this research.

**Financial:** There are no financial burdens for the subjects. There are no extra costs due to travel to extra appointments or therapy sessions as the subjects will follow standard of care protocols for timing and quantity of physical therapy and follow-up appointments with their surgeon. Again, the nature of this study will produce no cost to Elite Sports Medicine and Connecticut Children's Sports Physical Therapy, and we have specific time set aside to accomplish our research objectives.

**Benefits:** The results of this study would benefit surgeons, rehabilitation specialists, and of course future patients and their families by possibly providing a method of determining the patient's progress at an earlier stage and allow for early interventions to improve the patient's outcome.

### **Use of results of study**

The results of this study would provide the Elite Sports Medicine surgeons here at Connecticut Children's information to determine the effectiveness and application of the use of BFR in conjunction with exercise. The results of this research would also provide a basis for a future study to determine how the application of BFR with exercise following surgery can improve patient outcomes.

### **Study budget**

There is no budget for this study. All study personnel will be taking salary in kind for this project.

### **Budget Justification**

N/A



## **Appendices (as needed)**

Please see attached excel file.

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