COMIRB Protocol

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Protocol #: 22-1052

Project Title: Comparison of methods in post operative knee arthroscopy rehabilitation

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## 1. Hypotheses and Specific Aims:

The aim of this study is to investigate the efficacy of blood flow restriction (BFR) therapy in post operative rehabilitation following knee arthroscopy. The current standard of care and post-operative pain levels can limit patients from applying load necessary to increase muscle size and strength development due to partial weight baring after surgery. We hypothesize that immediate and consistent use of BFR augmenting our current standard post operative knee arthroscopy rehabilitation protocol will result in greater improvement in strength and quicker achievement of phase-based rehabilitation goals. We hypothesize that these objective improvements in strength will correlate with clinically meaningful improvement in Tegner activity scale, International Knee Documentation Committee (IKDC), return to sport, Lower Extremity Functional Scale (LEFS), pain and resiliency (patient reported outcome, PRO) scores indicative of greater functional recovery compared to our standard rehabilitation protocol alone.

## 2. Background and Significance:

Blood Flow Restriction (BFR) training has become a consistent treatment option following surgical and non-operative treatment of orthopedic conditions as it is a highly effective, low intensity strength training program that offers soft tissue and joint protection, which is advantageous for those recovering from injury or surgery in which tissue healing time remains a consideration. Numerous studies have shown the efficacy of this training in increasing muscle strength, limb size, cross sectional area of muscle in lower extremities. This type of training has been more popular due to ability to limit weight bearing and load through joints, while still appropriately grading exercise for muscle hypertrophy and strength development. (Slyz et al 2016).

Increasing attention has been placed on the potential benefit of BFR use post surgically in common lower extremity surgeries due to these perceived benefits. Most commonly with Anterior Cruciate Ligament Reconstruction (ACLR) surgery, BFR use has shown improved post-operative function, muscle strength, and increased cross sectional area of muscle in quadriceps compared to standard of care control groups (Charles et al 2020). Due to weight bearing restrictions following surgeries, significant post operative weakness, and prevalence of capsulitis in this population following surgery, BFR use would be ideal in promoting recovery. Questions have been raised regarding efficacy of BFR training on muscles proximal to occlusion site. In a systematic review by Lu and authors, four studies showed significant muscle hypertrophy in quadriceps muscles (Lu et. al, 2020). Bowman 2019 also demonstrated similar effects in proximal muscle groups. The proposed study would contribute more robust evidence to the body of research regarding the effects of BFR training in the lower extremity, specifically with regard to proximal muscle training.

BFR has been shown to be both a safe and extremely effective intervention for older age groups, most likely due to decreased tolerance to joint loading. As such, BFR offers a more effective way to strengthen lower extremity muscles without increasing joint reaction forces (Yasuda et al 2014). Specifically, they found an increase in cross sectional area of 8% for quadriceps, 6.5% for adductor group and 4.4% for gluteus maximus following a BFR protocol of 20% 1 repetition max knee extension and leg press 2 times a week for 8 weeks. BFR for young active adults has also been shown to improve lean muscle mass post operatively in those using BFR compared to those who did not. Lambert and authors suggest this may be producing a protection of bone during physical therapy activities (Lambert, 2019).

In a meta-analysis from Hughes et al, eight studies using low load BFR training were analyzed. This review from 2017 included studies where BFR was used with non-operative patients in a clinical setting. Intensity was set at 10-30% of 1 rep max (RM) resistance exercises and 45% heart rate reserve (HRR) for aerobic and walking exercise. Length of treatment ranged from 2-16 weeks and 2-6 sessions per week. This review also reported the importance of re-evaluation of 1RM for continued adaptations to occur. The analysis showed low load BFR had a moderate effect on increasing muscle strength in individuals with weakness. In patients who cannot tolerate heavy resisted exercise, low load resistance training with BFR can be a good alternative at increasing strength.

Slysz et al (2016) further reviewed effects of BFR training. Of note, 30% 1RM intensity of use showed significantly greater gains in strength compared to 20% 1RM. Greater than eight weeks of training is needed to produce hypertrophic effects, with most studies citing 10 weeks or more for optimal training effect. Finally, they concluded at least 150mmHg is necessary for hypertrophy.

A review from 2012, by Abe et al, further showed need for intensity to be within 20-30% 1RM resistance training to produce hypertrophy. Interestingly, they also showed this intensity to produced hypertrophy in BFR and non-BFR muscles.

It is well established in the literature that high school athletes have knee injuries more frequently than other joint related injuries (Ingram, 2008). Knee injuries are estimated to be 60% of high school sport related injuries, and of those, 50% are ACL injuries (Joseph 2013). Thus, we intend to include 16 year olds and older for enrollment. In a recent study, adolescents added BFR to their post-op ACL rehabilitation and experienced minimal to no adverse events or side effects (Prue 2022).

BFR has been shown to be an effective training method with load and intensity are limited. In a surgical population that does have limited weight bearing and loading initially, low load BFR training can be a useful tool to progress rehabilitation.

- 3. Preliminary Studies: Currently, the 'sister' protocol to this study (#21-4753) has begun to enroll subjects post hip surgery. Enrollment is steady and there have been no protocol deviations, nor adverse events. We have less providers performing hip surgeries than we do for knee surgeries. We anticipate after approval of this protocol, that enrollment will be just as steady if not greater than 21-4753. Typically we may see anywhere from 3-6 ACL reconstructions per week within the UCHealth Steadman Hawkins Clinic Denver surgical center.
- 4. Research Methods
  - a. Outcome Measure(s):
    - i. Primary measure: Knee extensor strength

- Strength of knee extensors via handheld dynamometry (HHD) and reported as a measure of limb symmetry index (LSI) comparing operative limb to non-operative limb. By 3 months post operatively, patients should be greater than 75% LSI in order to safely initiate impact activities such as jogging. Prior to discharge from therapy, patients should achieve at least 90% LSI per standard protocol.
- ii. Secondary measures: additional hamstrings musculature strength, single leg squat test, Tegner Activity Scale, LEFS, PROMIS pain and physical function, Brief Resiliency Score, range of motion (ROM), PROMIS Pain, PROMIS physical function, pain VAS, ACL-RSI (return to sport after injury), and International Knee Documentation Committee (IKDC).
  - 1. Strength of knee flexors via handheld dynamometry (HHD) and reported as a measure of limb symmetry index (LSI) comparing operative limb to non-operative limb. By 3 months post operatively, patients should be greater than 75% LSI in order to safely initiate impact activities such as jogging. Prior to discharge from therapy, patients should achieve at least 90% LSI per standard protocol.
  - Performance on a Repeated Single Leg Squat test to 45 deg knee flexion over the course of 90 seconds reported as a measure of LSI. Prior to initiation of impact activities such as jogging (usually around 3 months), patient should be greater than 75% LSI per standard protocol and 90% by time of discharge.
  - 3. Tegner Activity Scale: Range 0 (disability because of knee problems) 10 (national or international level soccer)
  - 4. LEFS: Range 0 (extreme difficulty) 100 (no difficulty); MDIC =  $\Delta$  123
  - 5. Pain NPRS: Range 1 (low pain) 10 (high pain); MDC =  $\Delta$  34
  - 6. PROMIS Pain: Range 0 (low pain) 100 (high pain); MDC =  $\Delta$  85
  - 7. PROMIS Physical Function: Range 0 (low function) 100 (high function); MDC =  $\Delta$  85
  - 8. Brief Resiliency Score (BRS): Range 1 (low resilience) 5 (high resilience); MDC =  $\Delta$  low (1-2.99) to normal (3-4.3) to high (4.31-5)
  - 9. ACL-RSI: Range 1 (low function) 100 (high function); MDC =  $\Delta$ 15.1 for short form version
  - 10. IKDC : Range 1 (low function) 100 (high function); MDC =  $\Delta 8.8$  low to  $\Delta 15.6$  high
  - 11. All PROs are nationally validated measures.
- b. Description of Population to be Studied:
  - General: patients aged 16-60 years old with knee joint pain to be treated operatively with knee arthroscopy. Based off the power analysis for both knee extensor strength and Tegner, we will recruit at least 78 participants (39 per group).
  - ii. Timeframe: BFR protocol administered 0-12 weeks post operatively, but data will be collected up until 2 years post operatively. Patients may be consented at preop or will be consented in person before or during their first post-operative physical therapy appointment. After being consented, subjects will be contacted via email and/or text message to prompt survey completion.
    - 1. PRO's will be collected at:
      - a. Initial evaluation

- i. Form is sent 7 days before surgery with an 8-day window for completion
- b. 3 weeks
  - Form is sent 3 weeks after surgery with a 7-day window for completion
- c. 6 weeks
  - Form is sent 6 weeks after surgery with a 7-day window for completion
- d. 12 weeks
  - i. Form is sent 10 weeks after surgery with a 30-day window for completion
- e. 6 months
  - i. Form is sent 24 weeks after surgery with a 30-day window for completion
- f. 9 months
  - i. Form is sent 36 weeks after surgery with a 30-day window for completion
- g. 1 year
  - Form sent 365 days after surgery with a 30-day window for completion
- h. 2 years
  - Form sent 730 days after surgery with a 30-day window for completion
- 2. Strength, ROM and functional performance measurements will be collected at 6 weeks, 12 weeks, 6 months and at discharge.
- iii. Inclusion criteria: Patients with ACL reconstruction with quadriceps, hamstring, bone-patellar-bone or allograft graft, with/without meniscectomies. Patients must also have access to a smartphone device in order to utilize the SAGA BFR application for use. The application is free to use.
- iv. Exclusion criteria: Bilateral knee surgeries to be performed within 12 weeks of each other, meniscus repairs, chondral lesion repair/transplants, ACL revisions that utilize contralateral autografts, MCL repairs, and the following BFR contraindications: deep vein thrombosis (DVT), pulmonary embolism, hemorrhagic/thrombolytic stroke, clotting disorders, hemophilia or taking blood thinners, pregnant or up to 6 months postpartum, untreated hypertension, untreated hypotension, rhabdomyolysis or recent traumatic injury, does not understand English, and the following BFR contraindications:
  - 1. Contraindications for BFR
    - Deep Vein Thrombosis (DVT)
    - Pulmonary Embolism
    - Hemorrhagic/Thrombolytic Stroke
    - Clotting Disorders
    - Hemophilia or taking blood thinners
    - Pregnant or up to 6 months post-partum
    - Untreated Hypertension
    - Untreated Hypotension
    - Rhabdomyolysis or recent traumatic injury

- 2. Exclusion criteria will be evaluated via the medical record as well as by the expert opinion of the physician.
- 3. If at any point in the study a subject develops one of the above contraindications, they will be removed from the study.
- 4. If a subject becomes pregnant while participating in the intervention portion of the study, they will be removed.
- c. Study Design and Research Methods
  - i. Timeline: Treatment Protocol duration 12 weeks per participant beginning at first post operative physical therapy appointment in week 1 following knee arthroscopy. PRO's will be collected out to 2 years post-surgery and standard rehabilitation will follow the 12-week intervention period for both the control and experimental group. Study will be a 2-year timeline in total.
  - ii. Procedures: Patients will be randomized to control group, who will undergo Steadman Hawkins Clinic Denver's standard knee arthroscopy rehab protocol (see appendix) or to the intervention group, who will undergo standard rehab protocol with addition of BFR. Subjects will be randomized 1:1 for intervention vs. control and controlled for sex assigned at birth. SOC for surgeons will be standardized to prevent the need for randomization.
  - iii. Materials: Saga Fitness BFR cuffs will be utilized for this study. These are products that are designed for at home use and are directly available to the consumer. They are wireless, automated training cuffs that connect to the Saga Fitness app via Bluetooth where they are then controlled.
  - iv. Frequency of BFR Training: 6 days per week phase 1, 3 days per week phases 2 and 3
  - v. Frequency of clinic visits PT: 1 day per week for 12 weeks and then as needed
  - vi. Intervention Group: The following exercises outlined are the specific exercises that will be performed in addition to SOC. These exercises will be completed at home without professional supervision. The fitness app by SAGA is able to guide the user, and occlusion pressure is set manually by the PT at their first PT visit. Only these exercises will involve the use of the BFR cuff. Appropriate training on how to use the device will occur at the time of consent (approximately 20 minutes) and as requested by subject. The BFR cuff will be applied to the proximal thigh of the surgical leg beginning these specific exercises. 80% occlusion pressure will be determined by PT's in clinic through the use of a Delphi unit. Subjects will then be able to use the Saga Fitness app to adjust this pressure if it differs from the automatic calibrated pressure.
    - 1. Phase 1 (post operative weeks 0-2)
      - No BFR to be performed, subjects will follow standard protocol
    - 2. Phase 2 (weeks 3-6)
      - Dosage: 80% LOP. 30x15x15x15 repetitions with 30 sec rests between sets. At least 1 min rest between exercises with occlusion OFF
      - b. Frequency: All 3 resistive exercises performed at least 6 days per week. The first of these sessions will be performed in clinic supervised by PT to assess LOP and form prior to performance at home
      - c. Exercises:
        - i. Week 3: quadriceps set, gluteal set, hamstring set

- ii. Week 4: short arc quad, bridge, standing hamstring curl
- iii. Week 5: straight leg raise, side-lying abduction, bridge on ball or chair
- iv. Week 6: double leg squat, long arc quad, double leg RDL
- 3. Phase 3 (weeks 7-12)
  - Dosage: 80% LOP . 30x15x15x15 repetitions with 30 sec rests between sets. At least 1 min rest between exercises with occlusion OFF
  - b. Frequency: All 3 resistive exercises performed at least 3 days per week. The first of these sessions will be performed in clinic supervised by PT to assess LOP and form prior to performance at home
  - c. Exercises:
    - Weeks 7-12: Single leg step up/squat progression (weigh progression as tolerated), single leg RDL (weight progression as tolerated), long arc quad (band progression as tolerated)
- 4. Phase 4 (12+ weeks)
  - a. Prescribed BFR intervention will be discontinued at 12 weeks and participants will progress per standard protocol for the remainder of their rehabilitation course. The subject will have the option to purchase a personally BFR cuff after the conclusion of the 12-week intervention. Usage post intervention time will be tracked and recorded via a PatientIQ survey at all follow-up time points.
- vii. Control Group
  - 1. Control group will follow the standard of care outlined in Appendix A for both in clinic and at home exercises.
- viii. Criteria for progression within the BFR specific exercise protocol
  - Regardless of functional performance, patients will not be allowed to progress ahead of the time-based exercise prescription in the BFR protocol. However, if the treating therapist determines that the current week's exercise prescription is too difficult for the patient, they may return to the prior week's exercise set until able to advance.

Phase	Timepoint	Exercises	Measurements	PROs
0	Pre-op/	None	None	*Consent
	Surgery Day 0			All PROs
I	Week 1   Day	None	Knee Extension º; Knee	
	1-7		Flexion º; Swelling; Gait;	
			ROM Knee; Flexibility;	
			Functional Testing	
	Week 2   Day	None	Knee Extension º; Knee	
	8-14		Flexion º; Swelling; Gait;	
			ROM Knee; Flexibility;	
			Functional Testing	
II	Week 3   Day	[80% LOP] quadriceps set, gluteal set,	Knee Extension º; Knee	All PROs
	15-21	hamstring set {30x15x15x15x15}	Flexion º; Swelling; Gait;	
			ROM Knee; Flexibility;	
			Functional Testing	

	Week 4   Day 22-28	[80% LOP] short arc quad, bridge, standing hamstring curl {30x15x15x15x15}	Knee Extension º; Knee Flexion º; Swelling; Gait; ROM Knee; Flexibility; Functional Testing	
	Week 5   Day 29-35	[80% LOP] straight leg raise, side-lying abduction, bridge on ball or chair {30x15x15x15x15}	Knee Extension <sup>o</sup> ; Knee Flexion <sup>o</sup> ; Swelling; Gait; ROM Knee; Flexibility; Functional Testing	
	Week 6   Day 36-42	[80% LOP] double leg squat, long arc quad, double leg RDL {30x15x15x15x15}	Knee Extension º; Knee Flexion º; Swelling; Gait; ROM Knee; Flexibility; Functional Testing	All PROs
	Week 7   Day 43-49 Week 8   Day	[80% LOP] (holding weight/or band as tolerated) single leg step up/squat progression, single leg RDL, long arc quad	Knee Extension º; Knee Flexion º; Swelling; Gait; ROM Knee; Flexibility;	
	50-56 Week 9   Day 57-63	{30x15x15x15x15}	Functional Testing (@ 12 weeks will include strength)	
III	Week 10   Day 64-70			
	Week 11   Day 71-77 Week 12   Day 78-84			All PROs E-Stim
IVa	3-6 Months * advancement depends on progress *	[optional BFR] Progressive increase in load, high intensity with low load	(if seen) Knee Extension <sup>o</sup> ; Knee Flexion <sup>o</sup> ; Swelling; Gait; ROM Knee; Flexibility; Functional Testing	Use (6M) All PROs (6M) Cont. BFR Use
IVb	5-9 Months * advancement depends on progress *	[optional BFR] Strength and weight training; gradual return to sport	(if seen) Knee Extension <sup>o</sup> ; Knee Flexion <sup>o</sup> ; Swelling; Gait; ROM Knee; Flexibility; Functional Testing	(9m) All PROs
V	1 Year	[optional BFR] As needed/normal activity	N/A	All PROs
VI	2 Years	[optional BFR] As needed/normal activity	N/A	All PROs

Legend: PRO = Patient reported outcomes; RM = 1 rep maximum; LOP = limb occlusion pressure; E-stim = electrical musculature stimulation; {...} = set repetitions

## 5. Description, Risks and Justification of Procedures and Data Collection Tools

#### a. Risks

i. Although exceedingly rare at 0.008% incidence (9), rhabdomyolysis has been documented in a few isolated case reports in which BFR was used in conjunction with high intensity exercise. (Tabata et al 2016). Our study will be dosing exercise at low intensity (20-30% 1 repetition max). Venous thrombosis (0.055%)

and pulmonary embolism (0.007%) were also found in extremely rare cases. (9). There is also the potential for loss of confidentiality of the data collected in this study.

- ii. There is a possibility that pain at the occlusion site may occur.
- iii. The data and safety monitoring plan will consist of an annual review of the study's safety and efficacy done by the PI, study team members (e.g., PTs), and a professional that is not associated with the study.

#### b. Benefits

i. Given previous studies done with BFR in post operative patients, the intervention stands to accelerate post operative recovery, decrease pain and enhance functional status following surgery.

#### c. Data collection

- i. Primary strength and functional performance measures will be collected by a blinded athletic trainer and entered into the medical record for storage (Epic), which is also a HIPAA compliant, password protected platform:
  - 1. Handheld dynamometry strength assessment for surgical and non-surgical limb knee extensors and flexors to assess limb symmetry index
  - 2. Performance measure of repeated single leg squat to 30-45 degrees for 90 seconds to assess limb symmetry index
  - 3. PTs will also ask subjects about their usage of BFR throughout the week at each weekly visit in the first 12 weeks.
- ii. Secondary measures will be collected through PatientIQ platform for patient reported outcome measures including: Tegner, LEFS, pain and resiliency scores. Data will be collected via Patient IQ and electronically stored within the platform. Platform is HIPAA compliant, and password protected. PatientIQ is routinely used by Orthopedics clinically and for research, and is approved by CU Medicine and UCHealth.

#### d. Potential Scientific Problems

 Lack of compliance with BFR protocol, lack of compliance with general postoperative standards/restrictions, subjects lost to follow up, poor exercise technique/performance, difficulty with application and/or device malfunction, pain while using device

## e. Data Analysis Plan:

#### General Statistical Considerations:

All analyses will assume a two-sided test of hypothesis, alpha=0.05, and be run in SAS v9.4 (Cary, NC) or higher or R v4.1.1 or higher. Randomization will be checked by comparing baseline demographic and clinical characteristics between groups using t-tests, chi-square tests, Wilcoxon rank-sum or Fisher's exact tests, as applicable. Preliminary descriptive and graphical analyses (e.g., boxplots, scatterplots, and profile plots over time) will be used to check and visualize data. Transformations for outcome measures will be considered as necessary

- i. The primary analysis:
  - 1. Analysis will be an intent-to-treat (ITT) comparison of the differences between treatment groups in strength at the primary endpoint of 3 months. No interim analyses are planned. Statistical inference regarding the difference between treatment groups will be based on a restricted maximum likelihood linear mixed model including all time points with strength at 3 months as the response variable and group assignment as

the primary independent variable. Covariates will include sex (stratification variable) and additional covariates will be considered if group differences at baseline are identified for any demographic or clinical characteristic that is a plausible confounder. The conclusion about differences between treatment groups will be determined by this single statistical test to protect against an elevated risk of false positive conclusions. Measures at other time points (3 weeks, 6 weeks, 12 weeks, 6 months, 12 months & 24 months) will be evaluated using a restricted maximum likelihood, repeated-measures linear mixed-model including all time points, with linear contrasts to estimate within and between group differences over time. We anticipate that secondary timepoints will be correlated with the primary timepoint, so that similar effects on secondary time points will reinforce significant differences in the primary outcome/time point.

## ii. Secondary Analyses:

1. Secondary outcomes at primary endpoint of 3 months will be analyzed as described above. Secondary outcomes will be evaluated for their consistency with the primary outcome. We anticipate that secondary outcomes will be correlated with the primary, so that similar effects on secondary outcomes will reinforce significant differences in the primary outcome. Failure to observe consistency between primary and secondary outcomes will be taken as evidence that the effects of blood flow restriction training are not clear, and that further study is necessary to resolve inconsistencies. This approach reduces the risk of false-positive conclusions resulting from multiple statistical tests. Measures at other time points will be evaluated using a restricted maximum likelihood, repeatedmeasures linear-mixed model with linear contrasts to estimate within and between group differences in change over time. Sensitivity to noncompliance with BFR (<80% of prescribed sessions) and attendance at PT sessions (<80% attendance) will also be evaluated in secondary analyses; that is, a per-protocol analysis will be compared to the ITT results.

#### iii. Power

1. Reported mean ± SD in Bowman et al for differences in knee extension strength (Nm) were 11 ± 13 in limbs trained with BFR vs 3 ± 9 without BFR. This equates to a moderate effect size (Cohen's d) of 0.72. Using a two-tailed t-test, alpha-level of 0.05, and 80% power, a total sample size of 64 (32 per group) would be required to detect this difference between groups. We would need to recruit 78 participants (39 per group) to allow for up to 20% attrition.

## 6. Summarize Knowledge to be Gained:

a. In summary, this study will identify the clinical utility of BFR use in post knee arthroscopy rehabilitation with regard to improvement in strength, functional mobility, pain and resiliency. In doing so, this knowledge may help to accelerate functional recovery following knee arthroscopy.

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# Appendix I: Standard Protocol for Knee Arthroscopy, ACL Reconstruction

	Approxi- mate Time Frame (Weeks)	Activity	Goals
PHASE I	0-2	WB Status: PWB 50%* Brace: 0-90 x 6 weeks ROM: 0-120+* Manual: patella mobilization, gentle STM to reduce edema, soreness, stiffness above/below knee PRN Exercise:  Quad sets (w/NMES PRN)  P/AA range of motion exercises  Multiplane SLR/OKC hip w/knee straight  Calf raises/ankle strengthening Cardiovascular: Begin stationary bike when ROM allows	<ul> <li>♦ Extension to 0</li> <li>♦ SLR no lag</li> <li>♦ Control inflammation</li> <li>♦ Minimize DVT risk</li> <li>♦ 100-120+ flexion</li> <li>♦ Normalize PF mobility</li> <li>♦ Normalize gait with crutches</li> </ul>
PHASE II	2-6	WB: FWBAT no limp Brace: continue 0-90 until week 6 ROM: full Manual: STM/MFR PRN, scar mobilization once healed. Patella mobs 0/30. Aggressive patella/anterior interval mobilization on BTB grafts Exercise progression:  CKC double leg -> single leg progression  Concentric and eccentric considerations  Hip/core/calf strengthening  Proprioception  Hamstring strength-no ham curl w/external load for hamstring autograft  LE stretching w/consideration for harvest site Cardiovascular: Stationary bike w/resistance Short walks, Alter-G Deep pool running at week 4 and incisions fully healed	<ul> <li>◇ normalize gait</li> <li>◇ Minimize swelling, PF pain</li> <li>◇ Full ROM; extension equal to opposite side</li> <li>◇ Muscular endurance progressing into strength</li> <li>◇ Proper squat pattern; perform on two legs with good control, equal WB before progressing to single leg</li> </ul>

	Approxi- mate Time Frame (Weeks)	Activity	Goals
PHASE III	6-12	Manual: PRN to address ROM deficits/PF pain. Mobilize scars (BTB graft)  Exercise progression:  Independent myofascial management (FR, massage stick, ball)  Controlled movement series  CKC PRE's bilateral & unilateral, emphasizing single leg strength  Advance core program/accessory hip muscles  Hamstring grafts: gradually add resistance to knee flexion 8-10 wks  Cardiovascular:  Swimming, shallow pool running, elliptical 6 weeks  Outdoor biking 8-10 weeks  Interval CV work, Alter-G running 10-12 weeks  Running/Agility: Basic linear ladder drills week 10	<ul> <li>♦ Minimal to no PF pain as strength training advances</li> <li>♦ Full terminal motion</li> <li>♦ No effusion</li> <li>♦ 75% LSI of quads, hams</li> <li>♦ Single leg squat x 90 to at least 30 degrees</li> <li>With 75% LSI</li> </ul> Must meet goals in order to begin running
PHASE IVa	3-6 mos	Strengthening:  Advance PRE's of hip, knee, ankle  Incorporate power into training, considering individual need  Cardiovascular: High intensity low impact cardio to build fitness, lower intensity cardio for recovery and Alter-G for progressive loading.  Impact starting 2-3 days/week  Running Progression:  Basic ladder/linear drills with gradual advancement of difficulty  Walk/jog interval -3 months  Linear acceleration/deceleration-4months  Sprinting, cutting, lateral agility-5 months (gradually increase intensity)  Jumping: single response progressing to multiple response jumps  Double leg, low amplitude jumps starting 3-4 months  Progressing to single leg hop 4-5 months	<ul> <li>♦ Manual therapy only PRN to address terminal motion deficit and/or pain</li> <li>♦ Control inflammation with increasing loads/impact</li> <li>♦ Limb symmetry with all strength exercises</li> <li>♦ Normalize running gait</li> <li>♦ Y test &lt;4cm difference</li> <li>♦ Lateral dip x 1 minute with 90% LSI</li> <li>♦ IKDC &gt; 7/10</li> </ul>
PHASE IVb	5-9 mos	<ul> <li>Focus shifted to impact and sports specific activities</li> <li>Strength:         <ul> <li>Weight training volume is maintaining or decreasing, continue to increase resistance as tolerated 2-3x/week</li> <li>Perform strength training after running/agility OR on opposite days Plyometrics</li> <li>Progress based on sport demands, individual ability</li> <li>RTS progression: (see specific sport protocol for details)</li> <li>Unidirectional agility drills, progressing to multidirectional</li> <li>Begin position and sport specific skills-drills</li> <li>Non-reactive progressing to reactive drills-coach or PT directed Practice/game progression, after passing sports test:</li> <li>⇒ Participation in all practice drills</li> <li>⇒ Scrimmage participation with no contact</li> <li>⇒ Scrimmage or game situation with contact, limited playing time</li> <li>⇒ Return to sport with increasing game minutes</li> </ul> </li> </ul>	<ul> <li>◇ Reconditioning for sport demands</li> <li>◇ Correct faulty movement with high level tasks</li> <li>◇ Emphasize both limbs for injury prevention</li> <li>◇ RTS test @ 6+ months</li> <li>◇ IKDC &gt; 9/10</li> <li>◇ Return to practice with gradual progression to game play</li> <li>RTS test may be modified per therapist's discretion based on patient demographics and goals</li> </ul>