# Use of blood flow restriction (BFR) therapy in peri-operative rehabilitation following Rotator Cuff Tear

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## STUDY TITLE: Use of blood flow restriction (BFR) therapy in peri-operative rehabilitation

**following Rotator cuff tear**

## 1. STUDY AIM, BACKGROUND, AND DESIGN ABSTRACT

The purpose of this study is to examine the effect of utilizing blood flow restriction (BFR) therapy in patients treated both non operatively and operatively for rotator cuff tears (RCT). BFR has been proposed to work by restricting arterial inflow leading to an oxygen depleted environment and the ability to induce muscle adaptation at lower maximum repetition via reactive hyperemia. Muscle atrophy occurs following rotator cuff tear. Thus, physical therapy is used to regain strength with the ultimate goal of returning to activity.

The goal of this investigation is to determine if using BFR during therapy for non-operatively managed and operatively managed rotator cuff tears would lead to increased and expedited strength gains. Additionally, the investigators would like to determine if BFR is beneficial in preventing muscle atrophy and fatty infiltration often seen in the setting of rotator cuff tear, as it is known that cuff tears can subject the muscles to degenerative changes and these patients are at risk for poorer clinical outcomes. The investigators will also look at patient reported outcomes metrics and pain scores to determine if BFR has a significant impact on the patient experience surrounding rotator cuff tear after both nonoperative treatment with therapy and operative treatment with surgical repair and peri-operative rehabilitation.

The investigators hypothesize that the BFR group will have significantly greater strength gains at all time points. Previous studies have shown that BFR has potential in increasing muscle torque generation and cross-sectional area in the first six months following anterior cruciate ligament (ACL) reconstruction. While there have not been as many studies investigating the use of BFR following upper extremity surgery, previous research has demonstrate that BFR can be useful both proximal and distal to the targeted muscle groups in the upper extremity. In addition to the paucity of research on post-operative BFR following rotator cuff repair (RCR), there is no evidence on pre-operative use as well. The investigators believe that the use of BFR in the perioperative period surrounding rotator cuff tear and repair has the potential to significantly decrease muscle atrophy and lead to faster, more substantial strength gains and less muscle atrophy and fatty infiltration.

## 2. SUBJECT POPULATION AND ELIGIBILITY

Subject Population

- Subjects will be recruited from our ambulatory sports medicine clinics. We will include patients aged 18-60 who suffered a rotator cuff tear and are undergoing Rotator Cuff reconstruction.
- Subjects will be excluded if they are undergoing revision RCR reconstruction, history of DVT, neurovascular injury, unable to tolerate BFR treatment, unable to complete physical therapy and peripheral vascular disease

Enrollment and/or Screening

- Subjects will be identified when they present to our ambulatory clinics with RCR tears. We will not access the medical record prior to presentation to our clinics. At the presentation we will discuss the project with potential subjects and if they express interest, we will then delve further into the chart to ensure they do not meet any exclusion criteria. Additionally, we will discuss exclusion criteria with the patient during a detailed history. We will develop a series of questions to screen for exclusion criteria, particularly relating to the history or family history of DVT.

## 3. STUDY PROCEDURES

- Patients who are seen in clinic for rotator cuff pathology will undergo treatment for their rotator cuff based

on a shared decision-making process with the orthopedic surgeon, irrespective of this study. Once a treatment plan is in place, the patient will be introduced to this study and presented with the opportunity to participate. If the patient agrees, a formal consent process will take place in clinic and the patient will undergo initial, baseline testing of strength, range of motion, pain scores, and patient reported outcome scores.

Therefore, patients will be either in the nonoperative arm or the operative arm of this study. Within each arm, patients will be randomized via computer to be placed in either the blood flow restriction (BFR) cohort or the traditional (non-BFR cohort). Patients will prospectively undergo rotator cuff rehabilitation using BFR or conventional therapy by physical therapists with extensive experience in rotator cuff rehabilitation who will undergo training on use of BFR.

The nonoperative group will be given identical rehabilitation protocols, with the only difference being the use of a BFR cuff during rehabilitation for the BFR cohort. Similarly, the operative group will be given identical rehabilitation protocols, with the only difference being the use of a BFR cuff during rehabilitation for the BFR cohort.

Patients undergoing operative rotator cuff repair (RCR) will undergo preoperative rehabilitation prior to surgery for two weeks. Due to limitations of health insurance coverage of physical therapy sessions, the two weeks of preoperative "prehab" will consist of a structured home exercise program that is taught to the patient by a physical therapist during one session and recorded on a physical therapy (PT) diary by the patient during the two weeks leading up to surgery. Patients will be provided with video instruction and training on how to conduct the exercises and this will also be done with and without the use of BFR depending on group allocation (via randomization). Additionally, warning signs for BFR cuff intolerance such as increased pain, swelling, numbness/tingling of the arm will be communicated to the patient. Following surgery patients will immediately be started in a formal physical therapy regimen as an outpatient. Therapy will consist of a structured program progressing from range of motion to strength training and then functional tests. Patients will remain in their allocated BFR or non-BFR group.

Protocol as follows, both groups will use the same protocol with the only difference being use of BFR:

For surgical patients:

- Preop: Patients will undergo a home program consisting of isometric exercises including shoulder extension, abduction, external rotation and internal rotation pushing against a wall.

For both surgical and non-surgical patients:

- Post-op weeks 0-8: Passive shoulder range of motion (ROM) only
- Sling immobilization with active elbow, wrist and hand ROM
- Passive ROM only of shoulder including pendulums, supine elevation in scapular plane, external rotation with arm at side.

8-12 weeks being more active range of motion

- Discontinue sling
- Being active exercises including prone row, standing internal/external rotation with bands, wall slides into shoulder flexion

Weeks 12-20: Strength and function of Side lying shoulder external rotation, increase resistance band exercises

Throughout this protocol patients will have a pre-operative visit, an early 2 week post operative visit to check range of motion and wound healing, a six week visit to monitor range of motion and potentially clear for active ROM and sling discontinuation, and a three month visit prior to clearance to being return to more aggressive activity. Strength and range of motion will be recorded at each of these visits in order to assess the primary endpoint.

Outcomes:

Primary Outcome:

- Strength to be measured via dynamometer at each clinic visit

Secondary Outcomes:

- Range of motion via goniometer
- Pain via visual analogue scale (VAS) pain scale at each visit
- Patient reported outcomes scores at each visit
- Fatty infiltration and muscle atrophy measured via ultrasound and compared to pre-operative imaging

Plan to recruit patients starting in June 2020. Will enroll patients and collect data from June-2020 to May 2021. Manuscript writing and submission to occur in June 2021.

Data analysis: The primary endpoint of this study was a maximum repetition total work deficit of 15% between the BFR and control group as measured by dynamometer. This was based on previous data showing that a strength deficit of 15% represents a clinically significant difference that is not likely attributable to limb dominance. Work deficit was calculated in each group by comparing the operative leg with the nonoperative leg to obtain a deficit percent. A power analysis was performed before the study to assess the number of patients needed to detect a 15% total work deficit between the BFR and control groups. With a power of 80% (beta level ¼ 0.80, alpha level ¼ 0.05), a sample size of 34 (17 patients per group) was obtained. Data will be provided to and analyzed by trained statisticians to determine differences in primary and secondary outcomes.

All continuous data will be analyzed using independent 2-group t tests and reported as means ± standard deviations. Categorical data will be compared between the 2 groups using chi-square tests and reported as counts and percentages. A preliminary test to confirm the quality of variances will be conducted prior to utilizing the t test to confirm the appropriate statistical analysis. Nonparametric equivalents Wilcoxon rank-sum and Fisher exact tests will be used as needed for nonnormal distributions and low variable numbers, respectively. A multivariable regression analysis was performed to assess potential confounding demographic variables.

## 4. ANTICIPATED RISKS

Patients may experience discomfort from the blood flow restriction (BFR) cuffs. Previous studies have shown that prolonged tourniquet use can lead to pain, nerve injury, and swelling. Recent advancements in tourniquets have resulted in complication rate of .04-.08% when used during orthopedic surgeries.[4] Recent studies specifically on use of tourniquets for BFR have found very low complication rate and we will be using the tourniquet for a very short duration of time. There is concern that BFR may increase the risk of DVT, however multiple studies have shown that BFR does not increase thrombin clot

generation in in-vivo models.[1, 3] Regardless, in order to minimize risk we will exclude patients with a history or family history of DVT. Additionally, patient information will be kept de-identified on a password protected henry ford computer for the duration of the project. There is a minimal risk of privacy breach as only individuals who would regularly be involved in the peri-operative care of an RC tear patient will be included in the study.

## 5. ANTICIPATED BENEFITS

- Potential benefits include faster return to play following RCR, less pain following surgery, better ROM and a better overall satisfaction and result following RC tear and reconstruction.

## 6. RENUMERATION/COMPENSATION

- No compensation offered

## 7. COSTS

- Additional costs will primarily be focused on obtaining the pressure cuffs. The payment for this will be provided by the investigators. Additionally, there will be some time cost to train the patient and physical therapists on use of the cuffs, however this will be minimal additional time and voluntary. There are no additional monetary costs.

## 8. ALTERNATIVES

Patients do not have to participate in this study and are able to undergo typical physical therapy as is the current standard.

## 9. CONSENT PROCESS AND DOCUMENTATION

Consent will be obtained from patients to participate in this investigation. We will obtain consent during a preoperative clinic visit. All research personnel listed in the IRB including the PI and associates will be responsible for informed consent. This will be done at the end of clinic visits to ensure there is ample time to answer questions. Additionally, contact information will be provided for questions throughout the entire process. Consent or lack thereof to participate will in no way affect the level of care provided for each patient. If at any point the patients no longer wish to participate, they will be placed back into the usual post-operative care pathway. Minors will be consented along with their parents and either patient or parent may elect to participate or withdraw from the study. Patients will all be English speaking and have capacity to self-consent. Documenting consent will be done during the clinic visit. Documentation will be stored in a locked room and kept in a folder with no visible identifying information.

Information will be kept in a locked area only accessible to study personnel. This will be kept in folders so there is no visible identifying information. The results of questionnaires and functional tests will be kept on a password protected HF computer and there will be no identifying information aside from MRN kept on these forms. All data will be destroyed following publication of this study or after six months of inactivity.

## 10. WITHDRAWAL OF SUBJECTS

- Subjects will be withdrawn from the study if they are unable to tolerate the BFR therapy. Additionally, if they suffer from any complications of the therapy they will be withdrawn immediately. This will be facilitated by describing the reasons for withdrawal to the patient prior to initiating the study and ask patients and other providers to inform the investigators if there are any issues or concerns.

- Data collection on patients who were withdrawn will be terminated and data destroyed.
- Patients may withdraw from the study at any time for any reason without affecting the quality of their care

## 11. PRIVACY AND CONFIDENTIALITY

Data will be stored on a password protected HFH computer. Patient data will either be located in the chart or kept in a locked spreadsheet that contains no patient identification aside from a unique patient ID associated with their MRN. This will only be accessible to the investigators. Data will be destroyed following publication or after six months of inactivity. We will also obtain HIPAA authorization in order to access the medical record.

## 12. DATA AND SAFETY MONITORING PLAN

We will be consistently checking in on patients' safety as they undergo the usual post-operative RCR protocol. This will involve clinic visits in which we monitor the PT progress as well as the patient's adherence to the protocol. We will also be in weekly communication with therapists regarding patient progress and ability to complete protocol.

Unanticipated Problems and Adverse Events

We will report any problems or adverse events to the IRB via email

## 13. QUALIFICATIONS OF THE INVESTIGATOR(S)

Vasilios Moutzorous , MD Medical Education: Loyola University Medical School, Chicago, IL, Residency: Tufts University, Boston, MA, Orthopedic Surgery, Fellowship: Cleveland Clinic, Cleveland, OH, Sports. Additionally he has conducted and published multiple clinical trials and has extensive experience in the academic arena. The co-investigators are all medical school graduates and current orthopedic residents at HFH. Each has experience with conducting medical research and has multiple recent publications in medical literature.

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