RUTGERS
Robert Wood Johnson
Medical School
DEPARTMENT OF ORTHOPAEDIC SURGERY

INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE

(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  Effects of Blood Flow Restriction training on rotator cuff and proximal shoulder musculature in post-operative repairs and shoulder arthroplasty

- **Principal Investigator Name**
  Charles J. Gatt, Jr., MD

- **Principal Investigator Div. & Dept.**
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- **Principal Investigator Contact Info:**
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- **Protocol Version and Date:**
  V3 5.8.2023

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1.0 Research Design

1.1 Purpose/Specific Aims

To investigate the utility of using blood flow restriction (BFR) therapy in improving rotator cuff and proximal shoulder strength after surgical rotator cuff repair.

A. Objectives

This study aims to compare the improvements in range in motion and muscle strength between traditional therapy alone and BFR-augmented therapy during phase two of rehabilitation.

B. Hypotheses / Research Question(s)

Blood flow restriction in addition to outpatient physical therapy post-operative therapeutic exercise protocol will help to enhance muscle strength and endurance compared to post-operative therapeutic exercises alone.

1.2 Research Significance

Following surgical repair for rotator cuff tears physical therapy is necessary to decrease pain, improve range of motion (ROM), joint mobility, myofascial restrictions, and to regain functional strength in the respective extremity. As patient's progress from phase I into phase II or phase III, strengthening of the RTC and parascapular muscles to sustain ROM and regain function of the extremity.

Blood Flow Restriction (BFR) training has gained popularity in outpatient orthopedic physical therapy for a variety of musculoskeletal conditions[1]. Pilot studies by Takarada et al. demonstrated that 50% limb occlusion with a tourniquet can induce muscle growth and increase limb strength.[2] Due to the use of light weight, high repetition training with partial occlusion of arterial inflow and venous return, patients have seen significant improvement in muscle hypertrophy and endurance. Many studies have looked at both proximal and distal improvements in hypertrophy, strength, and endurance with BFR on various musculoskeletal conditions. It has been previously demonstrated by Lambert et al. showed that BFR-augmented low intensity exercise increases lean shoulder and arm muscle mass, rotator cuff strength, and improved muscle endurance.[3] However, the utility of BFR in the post-operative setting has not been well described for the upper extremity.

1.3 Research Design and Methods

A. Research Procedures

Potential subjects will be screened for possible inclusion in the study at the time of their evaluation by the surgeon during their clinic visit. Once they are seen for physical therapy, the physical therapist will review the study with the subject, answer any questions and consent patients who volunteer to participate in the study. Participants will be randomized to one of two groups. The control group receives standard post-operative physical therapy for rotator cuff repair and the experimental group receives the same standard therapy along with BFR therapy. BFR therapy entails the use of a tourniquet (blood pressure) cuff inflated to 50% of blood pressure occlusion, on the affected arm just distal to the affected shoulder, and then completing 4 sets of exercise with 30 seconds of rest in between. Use of BFR will occur along with physical therapy twice/week. Demographic data will be collected pre-operatively. Functional outcomes and PROMs will be collected 6 weeks into physical therapy, and repeated at 14 weeks into physical therapy.

B. Data Points

Range of motion, muscle strength, and muscle endurance is to be measured by approved physical therapists.

C. Study Duration

The study is expected to collect and analyze data for 2 years.

D. Endpoints

- Primary endpoints:
  - Isometric muscle strength
  - Muscle endurance
  - Shoulder Range of Motion
- Secondary endpoints:
  - Quick Disability of the Arms, Shoulder, and Hand (qDASH) score

1.4 Preliminary Data

We have not conducted a pilot study and there are no preliminary observational studies looking at this patient population.

1.5 Sample Size Justification

Sample size estimation via a priori conducted by Rutgers RUBIS determined that at least 26 patients should be enrolled in this study..

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The independent variables of this study are the use of traditional physical therapy and the use of traditional therapy with BFR therapy.

B. Dependent Variables or Outcome Measures

Outcome measures recorded for this study include: muscle strength, muscle endurance, shoulder range of motion, and qDASH score.

1.7 Drugs/Devices/Biologics

A. Schedule and Administration

N/A

B. Drug/Device Accountability and Storage Methods

N/A

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1.8 Specimen Collection

A. Primary Specimen Collection

Types of Specimens: N/A

- **Annotation**: N/A
- **Transport**: N/A
- **Processing**: N/A
- **Storage**: N/A
- **Disposition**: N/A

B. Secondary Specimen Collection

N/A
Types of Specimens: N/A
Annotation: N/A
Transport: N/A
Storage: N/A
Disposition: N/A

1.9 Data Collection

A. Primary Data Collection

- **Location**: Data will be collected during physical therapy visits at the UOA research sites.(Somerset, Wall, Morganville and Avenel). The data entry form that is completed after enrollment will be done in the clinic where the subject was consented. Data collection forms on REDCap will be completed during the physical therapy sessions by study members.

- **Process of Data Collection**:
  Data will be collected by the specified team members. After enrollment to the study, the consenting team member will complete a data entry form that will record identifiers (name, email, phone number, race, gender and date of birth), gender, and date of surgery per the primary surgeon. After completing the specified physical therapy protocol per the study arm that the subject is assigned to, they will have range of motion (ROM) measured by a goniometer, muscle strength measured by a microFET 2 dynamometer, and muscle endurance measured by time to fatigue during exercise. qDASH questionnaires will be sent out to the subject and recorded to REDCap. All data collection will be done directly on REDCap.

- **Timing and Frequency**: Total duration of participation in this study will take 14 weeks. At the time of enrollment, demographic data will be collected. 6 weeks into post-operative physical therapy, functional outcomes (ROM, muscle strength, muscle endurance) and qDASH will be measured. At 14 weeks these same measures are repeated.
- **Procedures for Audio/Visual Recording**: N/A
- **Study Instruments**:
  - microFET 2 dynamometer
    - FDA Class II device
    - A handheld device that is used to measure muscle strength
    - The flat sensor is place of the muscle group to be tested, and then the subject flexes against the resistance of the device held against their limb
    - Device will record force in kilograms or pounds
  - Goniometer
    - FDA class I
    - A protractor designed to take measure joint angles
  - qDASH questionnaire
    - a validated questionnaire designed to assess how disability to the upper extremity affects quality of life.[4]
  - Intake Form
    - Form to be completed after enrollment to study
    - Will record subject identifiers (listed below), date of surgery, and gender
- **Ethnographic Studies, Interviews, Or Observation**: N/A
- **Subject Identifiers**:
  - name
  - Email
  - Phone number
  - Date of birth
  - Race
  - Gender

B. Secondary Data Collection

- **Type of Records**: N/A
- **Location**: N/A
- **Inclusion/Exclusion**: N/A

- **Data Abstraction Form(s):** N/A

1.10 Timetable/Schedule of Events

	Before Surgery	Surgery	Week 6 of PT	Week 14 of PT
Demographics	x	[redacted]		
Range of Motion (degrees)			x	x
Muscle Strength (kg)			x	x
Muscle Endurance			x	x
qDASH score			x	x

2.0 Project Management

2.1 Research Staff and Qualifications

Charles Gatt, MD
Faculty and Department Chair at the Department of Orthopaedic Surgery at Robert Wood Johnson Medical School, practicing sports surgeon at
University Orthopaedic Associates (UOA) in Somerset, and PI who will lead the study and provide study procedures, clinical care, and clinical follow up.

Eric Nussbaum, MEd, ATC, LAT
Athletic trainer at University Orthopaedic Associates study coordinator, will be overseeing data collection and reviewing patient complaints.

Patrick Buckley, MD
Volunteer faculty and Department Chair at the Department of Orthopaedic Surgery at Robert Wood Johnson Medical School, practicing sports surgeon at Univeristy Orthopaedic Associates in Wall, and site investigator who will oversee patient screening and manage study procedures at the Wall location.

James T. Monica, MD - Volunteer faculty and Department Chair at the Department of Orthopaedic Surgery at Robert Wood Johnson Medical School, practicing sports surgeon at Univeristy Orthopaedic Associates. Dr. Monica will assist in patient screening.

Kenneth G. Swan, MD
Volunteer faculty and Department Chair at the Department of Orthopaedic Surgery at Robert Wood Johnson Medical School, practicing sports surgeon at Univeristy Orthopaedic Associates in Woodbridge, and site investigator who will over see patient screening and manage study procedures at the Woodbridge location.

Dean Pinciotti, PT – Director of physical therapy and for UOA. He will be one of the physical therapists at the Somerset location who will consent subjects and record study data on study subjects.

Ryan Kay PT, DPT – Physical therapist for UOA. He will be one of the physical therapists at the Somerset location who will consent subjects and record study data on study subjects.

Joseph Abadir, DPT - Physical therapist for UOA. He will be the physical therapist at the Morganville location who will consent subjects and record study data on study subjects.

Benjamin Glider, DPT - Physical therapist for UOA. He will be the physical therapist at the Woodbridge location who will consent subjects and record study data on study subjects.

Jessica DeFrancesco PT, DPT - Physical therapist for UOA. She will be the physical therapist at the Wall location who will consent subjects and record study data on study subjects.

2.2 Research Staff Training

All study team members have been CITI certified and physical therapists have completed formal training on blood flow restriction.

2.3 Other Resources

All therapy equipment and space will be provided by UOA. Computers for data recording will be provided by UOA.

2.4 Research Sites **Add all sites to eIRB application 5.1**

UOA Somerset
2 Worlds Fair Drive
Sommerset, NJ 08873

UOA Wall
4810 Belmar Blvd
Wall Township, NJ 07753

UOA Woodbridge
1050 Rt. 1 North
Avenel, NJ 07001

UOA Morganville
280 Route 9 North
Morganville, NJ 07751

3.0 Multi-Center Research

IAA and form 811, 830, and 1812a to be uploaded for research sites.

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Potential subjects will be identified by their attending surgeon.

B. Recruitment Details

One of the physical therapists will meet with them after being notified by the surgeon of a potential subject. They will explain the purpose of the study, what the study procedures entail, what the benefits and risks of the study, the implication of choosing or denying enrollment to the study, and what costs may be incurred if any by the subject. They will be given alternatives to not enrolling the study. The written consent form will be explained to them. They will have up to one day to consider enrolling into the study.

C. Subject Screening

Team members who are consenting the subject will assess their eligibility for enrollment to the study. This will be done through talking to the subject and asking them in person about the inclusion and exclusion criteria.

- **Inclusion Criteria**
  - 18 years of age or older
  - Has a small to medium sized rotator cuff tear requiring surgery
- **Exclusion Criteria**
  - Non-English speaker
  - History of prior shoulder surgery
  - History of complex regional pain syndrome after surgery
  - History of unstable hypertension, cardiopulmonary disease, vascular disease, deep vein thrombosis

D. Privacy Protections

All data entry and collection forms will be destroyed by way of shredding once the study personnel transcribe the data onto Rutgers REDCap. Access to the REDCap is password-protected and limited to study members only. Subjects will be assigned a numerical code assigned to them by REDCap. The data entry form will have identifiers such as name, email and phone number which are needed for REDCap to send out qDASH surveys and record responses. These identifiers are never linked to the name of the subject. Signed consent forms will be kept in a locked cabinet at each study site.

4.2 Obtaining Identifiable Information About Non-Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

We plan to enroll 26 subjects based on previous studies that also evaluated BFR. A priori power analysis with RUBIES will be conducted for a more concise target recruitment number.

B. Total Number of Subjects If Multicenter Study

26 subjects across all study sites.

C. Feasibility

This study protocol is feasible to execute given the prevalence of rotator cuff repairs that are surgically treated and the ease to which the data points can be collected.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**

  Consent will be obtained at the follow sites:
  - UOA Somerset
  - Morganville
  - UOA Wall
  - UOA Avenel

  The consent process will be done privately in-person with the subject in patient rooms at each study site.

- **Ongoing Consent**

  While obtaining consent, patients will be reminded that they may contact any of the investigators with questions or concerns

- **Individual Roles for Researchers Involved in Consent**

The physical therapists will be responsible for obtaining consent for potential subjects. They will be notified by the attending surgeons who will screen patients regarding potential subjects for the study. At this time eligibility will be determined per the inclusion and exclusion criteria. Study team members will explain the purpose of the study, why the potential subject is being chosen for screening, what kind of time commitment and study activities the subject would be asked to participate in, potential risks and benefits associated with participating in the study, and what their alternative options are to joining the study.

- **Consent Discussion Duration**
  15 minutes

- **Coercion or Undue Influence**
  The primary surgeon caring the subject will not be a part of the consenting process to avoid undue pressure to join the study. Physical therapists will discuss the study with potential subjects and inform themt that their alternative to joining the study is to decline participation which not affect their care.

- **Subject Understanding**
  To ensure adequate understanding of the study, patients will be encouraged to ask questions about aspects they do not understand and the person obtaining consent will employ teach back methods to ensure patient understanding. They will have up to one day to decide whether they wish to join the study.

- **Protecting Privacy**
  The consent discussion will occur in a private room with only the patient and the consenting individual present.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details:** N/A
- **Destruction of Identifiers:** N/A
- **Use of Deception/Concealment:** N/A
  a. **Minimal Risk Justification:** N/A
  b. **Alternatives:** N/A
  c. **Subject Debriefing:** N/A

C. Documentation of Consent

- **Documenting Consent**
  The consenting person will document consent in ordinance with the IRB requirements as stated in the Toolkit form. The patient will sign the consent form which will then be included in the visit note for the patient. A copy of the signed consent form will be provided to the patient, and it will be scanned into their medical record.

- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
  N/A

4.5 Special Consent Populations

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- Parental Permission: N/A
- Non-Parental Permission: N/A
- Assent Process: N/A
- Documentation of Assent: N/A
- Reaching Age of Majority During Study: N/A

B. Enrolling Wards of the State
- Research Outside of NJ Involving Minor: N/A

C. Enrolling Non-English-Speaking Subjects
- Process for Non-English-Speaking Subjects: N/A
- Short Form Consent for Non-English Speakers: N/A

D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)
- Assessing Adult Capacity to Consent: N/A
- Selecting a Surrogate & Consent Process: N/A
- Subject Assent: N/A
- Selecting a Witness to the Surrogate Consent Process: N/A
- Removing a Subject: N/A

E. Special Consent Consideration: N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
The subjects will not incur any expenses specific to the research as the procedures are all part of standard medical care.

B. Compensation/Incentives
There will be no compensation or incentives for the subjects to participate in the study.

C Compensation Documentation
N/A

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects
- **Reasonably Foreseeable Risks of Harm**
  The use of blood flow restriction therapy carries a risk of developing late-onset muscle soreness, numbness, dizziness, and developing bruises under where the cuff for the tourniquet is placed. Muscle breakdown has also been reported in 0.008% of cases. (1)

- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  N/A

- **Other Foreseeable Risks of Harm**
  Data collected will be stored on REDCap. If these sources were to breached, there is a risk of losing confidentiality for the subject.

- **Observation and Sensitive Information**
  N/A

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks of Harm to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
N/A

E. Minimizing Risks of Harm
All paper documents containing data will be shredded by team members after recording the data points to REDCap. Access to REDCap will be limited to study member only and will be password protected. When it comes time for data analysis, the dataset will be exported from REDCap with the option to exclude any identifying material.

- **Certificate of Confidentiality**
  N/A

- **Provisions to Protect the Privacy Interests of Subjects**
  The subjects will only provide information to providers that they would by default provide information to at this institution, such as physicians and medical students regardless of whether they are participating in this study or not.

F. Potential Direct Benefits to Subjects
There are no direct benefits to subjects from their participation in this research.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
This study will utilize collect the identifying information previously listed. Authorization for PHI utilization is detailed in the written consent form.

5.2 Family Educational Rights and Privacy Act (FERPA): N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations) : N/A

A. Special Populations
- Pregnant Persons or Fetuses**:** N/A
- Prisoners**:** N/A
- Neonates**:** N/A
- Neonates of Uncertain Viability**:** N/A
- Children**:** N/A
- Students/Employees**:** N/A
- Adults Lacking Decisional Capacity**:** N/A

5.4 General Data Protection Regulation (GDPR): N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent): N/A

6.0 Data Management Plan

6.1 Data Analysis
RUBIES will conduct an a priori power analysis. The collected data will be analyzed with paired t-testing and Wilcoxon Ranked Sum Test to evaluate for significance.

6.2 Data Security
The REDCap server is password-protected, stored under the Robert Wood Johnson Medical School domain, with access limited to only study members. Data will be kept on REDCap for 6 years after which it will be deleted from REDCap. Subject data will be assigned a unique numerical code by REDCap. The study team will be trained no these practices and will be overseen by the PI, Dr. Charles Gatt.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan
Data will be periodically monitored by the study coordinator to ensure proper data collection and patient safety. Any complaints/concerns will be reported to the study coordinator and immediately addressed. Reports of significant issues will be reported to the IRB by the study coordinator/PI.

B. Data/Safety Monitoring Board Details
N/A

6.4 Reporting Results

A. Individual Subjects' Results
N/A

B. Aggregate Results
Aggregate research will not be shared with subjects.

C. Professional Reporting
Once recruitment has ended and data analysis is done, findings are expected be organized to abstracts and manuscripts for presentation and publication to medical journals and medical societies.

D. Clinical Trials Registration, Results Reporting and Consent Posting
Clinical trial registry in process.

6.5 Secondary Use of the Data
N/A

7.0 Research Repositories – Specimens and/or Data

N/A

8.0 Approvals/Authorizations

N/A

9.0 Bibliography

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