INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

STUDY INFORMATION

- **Title of Project:**

Blood Flow Restriction vs Traditional Physical Therapy in the Non-Operative Treatment of Femoroacetabular Impingement- A Randomized Prospective Study

- **Principal Investigator Name**

Charles J. Gatt, Jr., MD

- **Principal Investigator Div. & Dept.**
  Associate Professor, Chairman, Department Orthopaedic Surgery, Rutgers, RWJMS
- **Principal Investigator Contact Info:**
  [cjgatt@rutgers.edu
  [2 Worlds Fair Drive, Somerset, NJ 08873
  [732-537-0909

- **Protocol Version and Date:**
  CJGatt, - PRO2021002413 v3, 12.5.22

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1.0 Research Design

1.1 Purpose/Specific Aims

Femoroacetabular Impingement (FAI) is a common cause of hip and groin pain in both adolescents and adults. The first line treatment of FAI is most commonly non-surgical, with an emphasis on core, gluteal, and lower back strengthening[1]. When physical therapy and other non-operative modalities are not successful in relieving pain, hip arthroscopy is indicated, and has been shown to have a high rate of success in relieving groin pain and returning patients to their sport.

Blood flow restriction (BFR) is an adjunct to traditional physical therapy that continues to grow in popularity and evidence for its efficacy in the literature. BFR is increasingly being utilized to treat operative and non-operative conditions in physical therapy and athletic training settings. BFR involves adding a non-occlusive tourniquet to the arm or leg to partially occlude the arterial and fully occlude the venous flow during exercise. Compression of the vasculature results in muscle hypoxia, blood pooling, and increased intramuscular pressure below the cuff[2]. This results in increased muscle strength and hypertrophy, which has a benefit in the treatment of conditions with muscle weakness and asymmetry such as FAI.

Although traditionally used to enhance muscle hypertrophy distal to the site of occlusion, there has been literature to support a proximal benefit in the upper extremity[3]. We propose studying the results of BFR attached to the mid-thigh on the outcomes of FAI treatment.

A. Objectives

-Determine the effectiveness of BFR on traditional PT for non-operative management of FAI

B. Hypotheses / Research Question(s)

Blood flow restriction therapy, when added to traditional physical therapy, can improve isometric strength in the non-operative treatment of Femoroacetabular impingement

1) Does the addition of BFR to non-operative management of FAI improve hip strength and outcomes
2) Does the addition of BFR to the post-operative protocol for hip arthroscopy improve patient reported outcomes

1.2 Research Significance

Determining the impact of BFR for improving muscular strength of the hip could positively impact rehabilitation recommendations for conservative treatment of hip related problems, including FAI.

1.3 Research Design and Methods

Randomized control trial

A. Research Procedures

. The project will be a randomized control trial where all patients who present to our office with groin based hip pain, radiographic evidence of FAI, and a positive anterior impingement test would be recruited. Two groups will then be separated: one being the traditional physical therapy group, and the other with the addition of BFR to traditional PT.

Standard radiographs would be obtained and would include a standard AP pelvis, Dunn view, and false profile view.

Initial office visit would record the patient's degree of hip flexion, result with anterior impingement testing, alpha angle (on dunn view), lateral center edge angle (on AP pelvis) and anterior center edge angle (on false profile view). Additionally, we would evaluate for the presence of ischial spine sign, cross over sign, and if the proximal femoral physis was present on radiographs. MRI will not be routinely ordered on the initial visit, but if this has already been obtained, the presence of a labral tear based on the radiology report will be recorded.

Demographic data would be collected which would include age, sex, primary sport, duration of symptoms, and previous treatment.

Physical therapy protocol would include traditional PT focusing on core and gluteal strengthening. Additionally, avoidance of activities and exercises that result in pain or high hip flexion and internal rotation would be recommended. After 6 weeks, if the patient remained symptomatic, an ultrasound guided intra-articular hip injection would be offered to the patient. If the patient remained persistently symptomatic, then hip arthroscopy would be offered to the patient.

B. Data Points
- Objective strength measurements utilizing a hand held dynamometer
- Results of PROM.
- Demographic and surgical data

C. Study Duration
- 1 year – total study time,
- Individual commitment – 2 x wk, x 8 weeks involvement in physical therapy program.

D. Endpoints
- Patient ops out of study
- Re-injury/Alternate injury
- Completion of 8 week rehab program

1.4 Preliminary Data
- Pre-intervention PRO data
- Clinical Exam – determine baseline status

1.5 Sample Size Justification

Previous similar studies have recruited 35 to 60 subjects for similar studies looking at functional outcomes with BFR treatment.[4, 5] We are conducting an a priori power analysis with Rutgers RUBIES to determine the sample size required for 80% power with an alpha of 5%.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

1. . Physical Therapy Protocol
    a. Standard PT protocol focusing on core and glute strengthening would begin 2x/week for duration of 8 weeks.
2. BFR protocol

a. If patient randomized to BFR arm, begin with 50% limb occlusion pressure at proximal leg.
b. *Start with quadriceps contractions, step-ups, single and double squat, monster walk, then progress to wall squats, clam shell, leg press, glute bridges and stationary biking.*
c. *Four sets of each activity (30/15/15/fatigue). 30 second rest in between.*
- 2x/week for 8 weeks

B. Dependent Variables or Outcome Measures

a. Isometric strength- hip flexion,
b. Muscular endurance (repetitions to fatigue [RTF]; 20% maximum; with and without 50% occlusion) were measured before and after training.
c. ROM
d. VAS initial, week 2, 4, 8.
e. PROMIS-10, modified harris hip scope, IHOT-12

1.7 Drugs/Devices/Biologics

A. Schedule and Administration
NA

B. Drug/Device Accountability and Storage Methods
NA

1.8 Specimen Collection

NA

A. Primary Specimen Collection

- **Types of Specimens**:
- **Annotation**:
- **Transport**
- **Processing**:
- **Storage**:
- **Disposition**

B. Secondary Specimen Collection - NA

:

- **Types of Specimens**:
- **Annotation**:
- **Transport**:
- **Storage**
- **Disposition**:

1.9 Data Collection

A. Primary Data Collection

Data will be collected by Physical Therapists during their treatment visits at a UOA physical therapy clinic.

- **Location**: - UOA, Non-Rutgers approved facility, recorded via RedCap Survey Tool
- **Process of Data Collection**:Data will be collected by physical therapists providing standard patient care. .
- **Timing and Frequency**: Pre/Post intervention, PROMs – Pre, 2, 4, 8 weeks.
- **Procedures for Audio/Visual Recording**: **NA**
- **Study Instruments**:
  - **VAS** – Visual Analog Pain Scale – (0-10)
  - **PROMIS-10** – Pre/Post intervention
  - **Modified Harris Hip Score** – Pre/Post intervention

- **IHOT**-12 – Pre/Post Intervention
- **Ethnographic Studies, Interviews, Or Observation**:
- **Subject Identifiers** – Upon volunteering for the study, patients will be assigned a study number. All data collected will be associated with the no personal identifiers.

B. Secondary Data Collection NA

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

Data Abstraction Form(s):

1.10 Timetable/Schedule of Events

Subjects will be advised of the study by referring Physician. Potential participants will be referred to physical therapy and notified of study. After private review, and answering of all questions, the subjects will volunteer to participate, and sign consent form. Pre-Intervention PROMs will be completed prior to involvement in the study. Supervising physical therapists will collect Baseline pre-intervention assessment including measurement of ROM, strength and endurance as measured by Microfet handheld dynamometer @weej 2, 4, 8 week intervals.. VAS will be collected by PT @ week 2, 4, 8 week intervals. PROMs will be repeated at the completion of physical therapy program.

2.0 Project Management

Project management will be overseen by the supervisor of physical therapy, PI and study coordinator. Each will be involved in regular review of therapy, adherence to study guidelines and reporting of any adverse incidents.

2.1 Research Staff and Qualifications

Lead investigators are high experienced and qualified healthcare providers.
Physical Therapists are licensed by the NJ State Board of Physical Therapy and trained in the Use of BFR.

Charles Gatt, Jr.MD- Board-Certified orthopaedic Surgeon Associate Professor of Orthopaedic Surgery, Director of the Department of Orthopaedic Surgery, Rutgers, RWJMS.
Patrick S. Buckley, MD – Board certified orthopaedic Surgeon, Clinical Assistant Professor.
Kenneth G. Swan, MD – Boarrd Certified Orthopaedic Surgeon, Clinical Assistant Professor.
Eric Nussbaum, MEd, ATC – certified athletic trainer who will oversee study operations
Dean Pinciotti, PT – Licensed physical therapist, Director of physical therapy, UOA
Ryan Kay, PT, DPT – Licensed Physical Therapist,
Joseph Abadir – PT, DPT – Licensed Physical Therapist
Benjamin Glider, PT, DPT – Licensed Physical Therapist
Jessica DeFrancessco – PT, DPT- Licensed Physical Therapist

2.2 Research Staff Training

Each member of the study team will participate in a group educational session to ensure continuity of care and commitment to the study.

2.3 Other Resources

UOA offers ample room and equipment to conduct the processes of the study.

2.3 Research Sites

UOA – 2 Worlds Fair Drive, Somerset, NJ
UOA – 4810 Belmar Blvd, Wall Twp, NJ
UOA – 1050 Rt 1 North, Avenel, NJ
UOA – 280 Rt 9 North, Morganville, NJ

3.0 Multi-Center Research

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects
Patients with FAI, who meet defined study criteria, present for care with a UOA physician will be invited to participate in the study..

B. Recruitment Details
Physicians will identify potential subjects and share notification of study brochure. Patients will be referred to physical therapy. Physical therapists will review study details, share protocol, and answer questions that may be associated with the study. After all questions have been answered, subjects may volunteer to participate in the study by signing a consent to participate form with the supervising physical therapist.

C. Subject Screening
Patients will be screened for inclusion by participating surgeons.

- **Inclusion Criteria**
  - Age 18 yrs or older
  - FAI diagnosed in office
  - Groin pain and + anterior impingement testing
- **Exclusion Criteria**
  - History of DVT, VTE, or clotting disorder
  - History of CRPS or current radicular leg pain
  - Trochanteric bursitis as primary diagnosis
  - Pre-existing hip condition (SCFE, perthes, AVN)
  - Osteoarthritis (Tonnis >2) on xrays
  - Stress fracture

D. Privacy Protections
All patients are protected by HIPPA, FERPA and medical information is maintained in a secure EMR. d

4.2 Obtaining Identifiable Information About Non-Subjects NA

4.3 Number of Subjects

A. Total Number of Subjects
A review completed by RUBIs determined that 26 subjects is needed to make formal determination of validity.

B. Total Number of Subjects If Multicenter Study NA

C. Feasibility
Given there have been other studies published in the literature that also evaluated BFR with similar enrollement, this study is feasible to be carried out over one year. With several physicians managing patients with FAI, there is significant volume to draw the necessary patients.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  All potential participants will be appraised of the study by participating surgeon during the office visit to assess their reported hip pain. Subjects will sign a formal Consent to participate in the study in the physical therapy clinic where they will undergo their therapy. (Somerset, Wall, Morganville and Avenel)

  Ongoing Consent
  NA

- **Individual Roles for Researchers Involved in Consent**
  Individual surgeons will identify patients who may qualify for involvement in the study. Physical therapists will collect acknowledgement and consent to participate in the study..

- **Consent Discussion Duration**
  Patients will be provided the study description to review for 5 minutes. The physic therapist will answer any questions the patient may have about involvement in the study. The patient may drop out of the study at any time without reprisal.
- **Coercion or Undue Influence**
  Patients will be advised of the study, provided information about the study, and then the therapist will leave the room, allowing the patient to review in private. Patients are also given the opportunity to ask questions prior to making a decision about participation. .
- **Subject Understanding**
  Patients will be asked to explain their role in the study prior to the physical therapist, prior to signing of the acknowledgement.
- **Protecting Privacy**
  Patients will be provided a private room to review study description and materials.

B. Waiver or Alteration of Consent Process

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

C. Documentation of Consent

- **Documenting Consent**
  Participants will be asked to sign study consent prior to enrolling in the study. Participants can opt out of the study at any time without reprisal.
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature) NA**

4.5 Special Consent Populations
NA

A. Enrolling Minors-Subjects Who Are Not Yet Adults NA

- **Parental Permission**
- **Non-Parental Permission**
- **Assent Process**
- **Documentation of Assent**
- **Reaching Age of Majority During Study**

B. Enrolling Wards of the State
NA.

- **Research Outside of NJ Involving Minors**

C. Enrolling Non-English-Speaking Subjects
NA

- **Process for Non-English-Speaking Subjects**
- **Short Form Consent for Non-English Speakers**

D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)
NA

- **Assessing Adult Capacity to Consent**
- **Selecting a Surrogate & Consent Process**
- **Subject Assent**
- **Selecting a Witness to the Surrogate Consent Process NA**
- **Removing a Subject -**
  The subject will provide written intention of withdrawal to the PI. The PI will notify study coordinator and supervising therapist of subject withdrawal.

E. Special Consent Considerations
NA

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
There are no expenses related to this participating in the study that will be incurred by the study participant. .

B. Compensation/Incentives
Participation in the study is voluntary and study participants will not receive any compensation.

C Compensation Documentation NA

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  There is no more than minimal risk to participate in this study. Use of BFR may cause some leg soreness, bruising, short term numbness or tingling. The study also requires a time commitment to be able to participate in physical therapy twice a week.
- **Risk of Harm from an Intervention on a Subject with an Existing Condition NA**
- **Other Foreseeable Risks of Harm**
  Other foreseeable risks may include risks associated with a possible loss of confidentiality.

- **Observation and Sensitive Information**

B.
C. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
NA.
D. Risks of Harm to Non-Subjects
NA
E. Assessment of Social Behavior Considerations
NA
F. Minimizing Risks of Harm

All therapy-related activities will be performed by trained medical professionals with years of training. All collected data will be recorded directly to REDCap by study members at the time of the research visit. Access to REDCap will be password-protected and limited to only study team members, and data recording will be performed on password-protected computers at UOA sites. All supervising therapists have received formal training with the use of BFR and will utilize the pressure cuff appropriately. Subjects will be evaluated after each use and appropriate care provided if there are any associated injuries.

- **Certificate of Confidentiality NA**
  NA.
- **Provisions to Protect the Privacy Interests of Subjects**

G. 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 record name, date of birth, and sex. Authorization for PHI utilization is detailed in the written consent form.

5.2 Family Educational Rights and Privacy Act (FERPA)
NA.

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

NA

A. Special Populations

5.4 General Data Protection Regulation (GDPR) -
5.5 NJ Access to Medical Research Act (Surrogate Consent)
NA

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6.0 Data Management Plan

6.1 Data Analysis
Rutgers RUBIES will conduct a priori power analysis for determining the appropriate sample size. Functional outcome measures (ROM, strength, muscle endurance) will be analyzed via Student's t test. PROMs (IHOT, mHHS, VAS, PROMIS-10) will be analyzed via Wilcoxon unranked sum test.

6.2 Data Security
All collected data will be recorded directly to REDCap by study members at the time of the research visit. Access to REDCap will be password-protected and limited to only study team members, and data recording will be performed on password-protected computers at UOA sites. Paper copies of data will not be kept. Data will be kept on REDCap for 6 years after which it will be deleted.

6.3 Data and Safety Monitoring
NA

A. Data/Safety Monitoring Plan
Input of data will be periodically monitored by the study coordinator to ensure complete data collection within RedCap.

B. Data/Safety Monitoring Board Details
In the event of a significant issue, the PI, Study coordinator, and supervisor of Physical Therapy will discuss and appropriately resolve the issue. Any significant issues will be reported directly to the IRB.

6.4 Reporting Results

A. Individual Subjects' Results
Study results will not be shared with subjects anyone else.

B. Aggregate Results
Study results will be shared upon request of subjects at the completion of the study.

C. Professional Reporting
Once the data has been gathered, analyzed, and conclusions have been reached, we will aim to publish this data in a peer-reviewed journal. The journal will be identified at a future date.

D. Clinical Trials Registration, Results Reporting and Consent Posting
NA.

6.5 Secondary Use of the Data

7.0 Research Repositories – Specimens and/or Data

NA

8.0 Approvals/Authorizations

- Non- Rutgers Approved study site Approval
- IAA, 1811, 1812a, 830 forms have been uploaded

9.0 Bibliography

References:

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2. Lambert B, Hedt C, Daum J, Taft C, Chaliki K, Epner E, McCulloch P. Blood Flow Restriction Training for the Shoulder: A Case for Proximal Benefit. Am J Sports Med. 2021 Aug;49(10):2716-2728. doi: 10.1177/03635465211017524. Epub 2021 Jun 10. PMID: 34110960.
3. Patterson SD, Hughes L, Warmington S, Burr J, Scott BR, Owens J, Abe T, Nielsen JL, Libardi CA, Laurentino G, Neto GR, Brandner C, Martin-Hernandez J, Loenneke J. Blood Flow Restriction Exercise: Considerations of Methodology, Application, and

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