Follow Up Visits:

Initiation of physical therapy should begin within the first week following your surgery.

Involvement in the study will begin at six weeks post –operation when the strengthening phase of your rehabilitation formally begins.

The duration of your involvement in this study is eight weeks. Whether you are involved in traditional physical therapy or physical therapy + BFR, you will have routine follow-up visits with your physician following your surgery.

At UOA we care about our patients and we want them to have a great patient experience. We are concerned about your safety and well- being.

As your physicians we would never recommend or suggest a treatment that had the potential for harm or contribute to a less than successful outcome.

Youtube Video Description:

For more information please visit:

https://www.uoanj.com/research-studies/

UOA
University Orthopaedic Associates

A Division of OrthoNJ

Study Sites:
University Orthopaedic Asscociates

- Avenel
- Morganville
- Somerset
- Wall

Primary Investigator: Charles J. Gatt, Jr., MD,
(732) 537-0909,
gattcj@rutgers.rwjms.edu

UOA
University Orthopaedic Associates

A Division of OrthoNJ

Blood Flow Resistance vs Traditional Physical Therapy for Rotator Cuff Repair

Rutgers IRB: PRO 2022000393

Why is this study being done?

Purpose:

The **purpose of the research** is to: see if blood flow restriction therapy (BFR) provides additional benefits when used with physical therapy for post-operative rehabilitation after rotator cuff repair surgery. You will be randomly assigned to one of two groups: one group will have BFR done with physical therapy and the other group will receive physical therapy only. If you are enrolled into the experimental arm, you will also under go BFR twice a week starting 6 weeks into rehabilitation therapy. This would be done along with your prescribed treatment by your physical therapist. You would also have your shoulder range of motion, flexion strength, and endurance measured. These measurements are taken at 6 weeks and 14 weeks after starting physical therapy. You will also fill out a pain scale and a survey called Quick Disability of Arms, Shoulder, and Hand (Quick DASH) which will take 5 to 10 minutes to complete. Your time in the study will take a total of 8 weeks.

***An alternative to taking part in the research study** is not to take part in it.

Who may take part in this study? And who may not?

Those who may be included in the study are adults age 18 years and older with a small to medium-sized rotator cuff tear that requires surgery. Those who are not included in the study are those with a prior history of shoulder surgery, history of complex regional pain syndrome after surgery, medical history of unstable hypertension, heart and lung disease, blood clots, and blood vessel disease. Those who do not speak English will be excluded as well.

What will I be asked to do if I take part in this study?

When enrolled in the study we will collect demographic information that includes your name, date of birth, race, gender, and email. This contact information is used in REDCap (a secure study registry) utilized to send you the Quick DASH survey via email or text. You will be renadomly assigned to one of two groups. One group will undergo physical therapy only, and the other group will undergo physical therapy + BFR. BFR will be utilize BFR 2x/week during your therapy session. It will be administered by your supervising physical therapist. Each group will complete strength and endurance measurements at 6 weeks post-operation and after completing physical therapy at 14 weeks. The total duration of the study involvement is 8 weeks.

.

UOA
University Orthopaedic Associates
A Division of OrthoNJ

Possible harms or burdens of taking part in this study:

If you are enrolled to the group undergoing BFR there may be some additional risks that may be experienced. They include delayed muscle weakness, bruising, numbness, dizziness, and muscle breakdown. Possible benefits of taking part may be recovering muscle function, strength, and endurance faster than traditional therapy without BFR.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Charles J. Gatt, Jr., MD at 2 Worlds Fair Drive, Somerset,NJ 08873. At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.