Cover Page

The effect of blood flow restriction training on rotator cuff strength in the healthy, untrained shoulder

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1) Protocol Title

The effect of blood flow restriction training on rotator cuff strength in the healthy, untrained shoulder

2) Investigator

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3) Objectives

The aim of this study will be to determine the effect of upper extremity (UE) blood flow restriction (BFR) training for muscular strength improvement in individuals with no history of previous shoulder injury. The authors hypothesize that, participants who partake in BFR training will experience greater strength gains compared to a control group performing the same exercises.

4) Background

BFR training has been gaining popularity as a novel technique to develop greater strength and muscle mass in the rehabilitation setting. Many high-quality studies have examined the effects of muscle growth following controlled programs targeting strengthening at lower loads than typically used for hypertrophy. In rehabilitation, this provides the patient a significant advantage when muscular weakness and poor neuromuscular control predominate following an injury or surgery. If an individual is able to attain measurable improvements in muscle function utilizing low loads, then rehabilitation can be safer and more productive.

Recent publications have described the effects of BFR with exercise, including increases in muscle fiber hypertrophy at the cellular level[12,17,19,20], muscle size and strength improvements with various methods of exercise[2,6,10,26], and decreased muscle atrophy following injury or surgery.[14,21] In resistance training, muscle hypertrophy is carried out by mechanical tension and metabolic stress. It's hypothesized that metabolic stress factors play the dominant role in BFR training.[1] In horses, somatotropin, a hormone that induces the release of growth hormone, is significantly increased after a BFR walk for 5 minutes as compared with a control.[14] The somatotropin remained elevated at the 15 minute and 60 minute intervals. In humans, multiple studies have shown a significant increase in growth hormone following BFR with low resistance exercise as compared with high resistance exercise.[20,23] In addition to increased growth hormone expression, myogenic and proteolytic mRNA expression has been studied in human subjects undergoing low resistance BFR exercise. Interestingly, myogenic mRNA expression is unchanged. However, proteolytic gene (FOXO3A, Atrogin-1, and MuRF-1) expression is downregulated as compared to patients without BFR.[12,17] Gene expression of myostatin, a protein that inhibits myogenesis, was shown to be downregulated in a patient with inclusion body myositis after undergoing BFR low resistance exercises.[17]

Interestingly, one may speculate that muscles proximal to the occlusion cuff may not experience similar strength gains as found in those distal to the cuff. However, a systematic review by Dankel et al. (2016) found several instances of proximal gains in muscle size and strength.[8] Suggested mechanisms for this phenomenon include the typical high repetition characteristic of BFR exercises (upwards of 75 total repetitions per exercise)[8], purported synergistic effects of proximal musculature as the distal muscles fatigue[3] and higher recruitment of type II muscle

activation[25], and muscle cell swelling occurring during BFR.[11] This is important for future research of the utilization of BFR with proximal musculature.

What is currently unknown are the potential for improvements in strength of musculature proximal to the occluding cuff during BFR training. The rotator cuff serves as an excellent example due to its proximal location to typical UE placement as well as documented EMG specificity with certain exercises.[4,5,15,16] Any strength gains, if elucidated with given program, should be easily detectable. Data from this study may possibly provide foundational information for future studies utilizing similar methods with different populations

The most frequently encountered side effects of BFR training is bruising and muscle soreness at the tourniquet site.[12,25] BFR exercise does not show increase in markers for muscle damage such as myoglobin or creatine kinase.[3] Deep vein thrombosis is infrequently seen at a rate of less than .1%.[12,24]

5) Setting of the Human Research
The research will be conducted in an outpatient physical therapy clinic under close supervision of a trained and licensed physical therapist. Additional locations may include: Rice University Campus 6100 Main St. Houston, TX 77005.

6) Resources available to conduct the Human Research
Equipment required for study will include: Delfi PTS Blood Flow Restriction Tourniquet System, MicroFET 2 hand-held dynamometer, cable column machine, free weights, VICON motion capture system.

7) Study Design
Study participants will be randomly allocated in to 3 groups: control group (no exercise), exercise group, and BFR + exercise. Power analysis indicates the need for approximately 20 individuals in each group. Each exercise group will perform the same set of exercises 2 days/week for 8 weeks on their non-dominant upper extremity. Each group will also undergo strength testing at the same time throughout the protocol. Whereas the control group will only undergo testing in the same time periods. Muscle strength testing will be performed before the initiation of the program, at 4 weeks, and upon conclusion of the program. Testers will be blinded to group allocation. Muscle testing will be performed using manual hand-held dynamometry consistent with literature describing appropriate methods.[9,18] Each manual muscle test will be performed as maximal exertion one repetition maximum test (1RM) three times to ensure most accurate dynamometry reading. For any baseball pitcher participants, motion capture measures will be taken before week 1 and after week 8. This will include sensors that measure range of motion and arm biomechanics for a maximum of 25 pitches in each session. To ensure test-retest reliability, each participant will undergo testing by the same individual. A familiarization protocol will be enforced to ensure all participants are familiar with testing measures and to decrease the amount of variability in intratester performance.

Exercises are as follows:
1. Cable column external rotation (at 90 degrees of abduction)
2. Cable column internal rotation (at 90 degrees of abduction)

3. Sidelying external rotation with weight (0 degrees)
4. Standing scaption with weight
    - These exercises have been found to incorporate the greatest electromyographic muscle activity of the rotator cuff in the literature.[4,5,15,16]
    - The order of exercises will remain same for each participant in each group

BFR tourniquet placement will occur at the most proximal portion of the upper extremity. Tourniquet pressure will be applied at 50% of maximal limb occlusion pressure, to be re-measured each week. This is consistent with current literature recommendations for upper extremity BFR training.[6,8,13]

Resistances for each exercise will be determined by using 10-30% of 1RM (found during testing). This is consistent with current literature recommendations for upper extremity BFR training.[6,8,13] Resistance may be increased as the subject tolerates so long as they stay within the 10-30% 1RM range. Following strength testing at 4 weeks, resistances may be adjusted due to strength gains.

a) Recruitment Methods
Potential study participants will be recruited from the local area who will be able to access clinic and equipment. Participants will be surveyed to ensure all inclusion and exclusion criteria are met.

b) Inclusion and Exclusion Criteria
Inclusion: participants must be healthy, untrained, volunteers who accept all provisions of the study and agree to complete the program in its entirety. Ages accepted will be 18-65.
Exclusion: potential participants will be excluded if:
1. Previous history of shoulder injury occurring in the laterality of choice
2. Current painful dysfunction resulting in exercise limitation
3. Any health-related exercise limitation as ordered by physician
4. Vascular compromise or previous vascular surgery
5. Ages outside of 18-65
6. Inability to access clinic and equipment
7. Currently involved in structured strength training regimen of the upper extremity

c) Study Endpoints
Exercise programs for each individual will terminate upon the completion of 16 sessions over 8 weeks. If any subject reports adverse effects (pain, injury, decreased range of motion), their program will be terminated and referral given for treatment by physician. Subject recruitment will occur over the course of 6-12 months or until reasonable power is achieved.

d) Procedures involved in the Human Research
Eligibility will be explained during the consent process with each participant. Minimal risk will be explained to the patient regarding exercise and blood-flow restriction training.

e) Data management
The PI will be responsible for all data collected, its confidential storage, and deletion after the study is completed.

f) Withdrawal of subjects
Subjects may withdraw at any time for any reason. Their data will be included if the individual has performed at least 4 weeks of the program. If the individual withdraws prior to 4 weeks, any pre-program testing will be deleted.

8) Risks to subjects
Minimal risks are present but may include arm pain due to tourniquet pressure or possible deep vein thrombosis.

9) Potential benefits to subjects
Subjects in either group may experience strength gains consistent with a strength-training program.

10) Provisions to protect the privacy interests of subjects
PHI information will not be used or published in the study as all information will be used to form aggregate data. The data will be kept on a secure password protected, hospital server and will be deleted after the study is complete. Subject data will be coded according to initial randomized group allocation.

11) Provisions to maintain the confidentiality of data
See #10

12) Cost to subjects
No costs will be incurred to the subjects.

13) Consent process
Participants will be educated on the data accrual process when they obtain the inclusion survey. Participation is completely voluntary and submission of declaration of inclusion is mandatory to be allocated to grouping and undergo testing/exercise program.

14) Process to document consent in writing
The standard consent form for this project will be explained and if the subject wishes to participate the consent will be signed prior to the start of the questionnaire.

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