BLOOD FLOW RESTRICTION TRAINING VERSES MULLIGAN TECHNIQUE IN TREATMENT OF LATERAL EPICONDYLITIS : RANDOMIZED CONTROLLED TRIAL

By

Majed Abdulrahman Alghamdi

B.sc of musculoskeletal physical therapy, Umm Al-Qura University (2012)
M.sc of musculoskeletal physical therapy, Umm Al-Qura University (2021)

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Faculty of Physical Therapy

Cairo University

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SUPERVISION

Prof / SALWA FADL ABD EL MAJEED

Professor of Physical Therapy for Musculoskeletal
Disorders and its Surgeries
Faculty of Physical Therapy
Cairo University

Prof / Nasr Awad Abd El Kader

Assistant Professor of Physical Therapy for Musculoskeletal
Disorders and its Surgeries
Faculty of Physical Therapy
Cairo University

Dr. / ABDELGALIL ALLAM ABDELGALIL

Lecturer of Physical Therapy for Musculoskeletal
Disorders and its Surgeries
Faculty of Physical Therapy
Cairo University

List of Abbreviations

Abbreviation	Full Form
LE	Lateral epicondylitis
BFR	Blood-flow restriction
BFRT	Blood-flow restriction training
1-RM	One repetition maximum
PrTEE	patient-rated tennis elbow evaluation
LL-BFR	Low-load BFR
LL-RT	Low-load resistance training
HL-RT	High-load resistance training
MWM	Mulligan Mobilization with movement

CHAPTER I

INTRODUCTION

Lateral epicondylitis (LE) is a work-related musculoskeletal disorder caused by the tendon's inflammation of either one or both of the extensor carpi radialis longus and extensor carpi radialis brevis. It is often referred to tennis elbow. It manifests as pain on the lateral side of the elbow and reduced range of motion, which results in weakening and impairment in the forearm muscles **(Ahmad et al., 2013)**.With no sex predisposition, LE is a widespread ailment that affects up to 3% of the population **(Vaquero-Picado et al., 2017)**. Etiological factors of LE include overuse, repetitive movements, physically forceful occupational activities, exercise errors, misalignments, flexibility problems, ageing, muscle imbalances and psychological (e.g. job strain) factors. The estimated incidence of LE ranges from 2.0–11.3 per 100 worker-years in specific activity sectors **(Herquelot et al., 2013; Bongers et al., 2002)**.

The prevalence of tendinopathy has risen significantly along with the popularity of sports. Treatments and nonoperative methods for various diseases are constantly being developed and improved. Up to 3% of adults between the ages of 40 and 55 suffer with LE, a prevalent and painful degenerative tendinopathy of the lateral elbow **(Shiri et al., 2006)**. With a constantly increasing number of players and courts throughout over 40 different countries, the sport is becoming more and more popular **(Demeco et al., 2022; Escudero-Tena et al., 2021)**. However, depending on the disease and sex, medial epicondylitis is commonly reported to affect the working population, with a frequency ranging from 0.3 to 4.0% **(Chiarotto et al., 2023)**.

LE is treated with a variety of techniques, such as electrophysical modalities (low-level laser therapy, low-frequency electrical stimulation, and extracorporeal shockwave therapy), exercise therapy (stretching and resistance exercises), and manual therapies (massage and joint mobilization), with the goals of reducing pain, preserving range of motion, and enhancing the strength and endurance of the afflicted muscles **(Coombes et al., 2015)**.

Blood-flow restriction training (BFRT), which may also be referred to as Kaatsu, occlusion or hypoxic training, has become an increasingly popular method of resistance training in recent years **(Rolnick et al., 2021)**. BFRT involves the application of straps or pneumatic cuffs around an upper or lower limb extremity, with cuff pressure aiming to partially restrict arterial blood flow, while also occluding venous outflow while the cuff pressure remains intact **(Patterson et al., 2019; Lorenz et al., 2021)**. BFRT has been shown to be an effective resistance training method for enhancing muscle strength and hypertrophy in healthy populations and in the rehabilitation of musculoskeletal pathologies and following orthopedic surgery **(Hughes et al., 2018; Barber-Westin & Noyes, 2019; Lowery et al., 2014; Nitzsche et al., 2021)**.

According to **Baker et al.(2013)** mobilization with movement is a modern technique developed by Mulligan to treat the symptoms of tennis elbow or LE. Mulligan mobilization with movement (MWM) is a form of manual therapy that includes sustained lateral glide movements to the elbow joint along with physiological movements **(Hing et al., 2015; Mani et al., 2017; Bessler & Beyerlein, 2019)**. MWM has been shown to reduce pain and increase functional activity **(Janikowska & Fidut, 2013; Ahuja, 2014)**.

Statement of the Problem

This study will try to answer to the following question:

What is the comparative effectiveness of BFRT versus Mulligan's technique in improving pain, grip strength, and functional outcomes in patients with LE ?

Gap of knowledge:

While BFRT has shown promise in improving muscle strength and reducing pain in patients with LE, there is no evidence on its effectiveness when compared to Mulligan's technique. Mulligan's technique has been used to address joint dysfunction and pain in various musculoskeletal conditions, but its role in LE management, particularly when compared to BFRT, remains unclear. Additionally, there is a lack of randomized controlled trials (RCTs) comparing the effectiveness of BFRT versus Mulligan's technique. This study seeks to fill this gap by providing evidence on the comparative effectiveness of these interventions, which could inform clinical decision-making and optimize rehabilitation protocols for LE.

Purpose of the Study

The purpose of this study is to evaluate the effectiveness of blood flow restriction training (BFRT) verses Mulligan's technique in improving pain, grip strength, and functional outcomes in patients with lateral epicondylitis (LE).

Significance of the Study

This study holds significant clinical and practical implications. While various treatment modalities, including physiotherapy, corticosteroid injections, and surgical interventions, have been explored, there remains a need for non-invasive, cost-effective, and evidence-based interventions that provide lasting relief **(Coombes et al., 2015)**. This study is significant as it investigates the comparative effects of Blood Flow Restriction Training (BFRT) and Mulligan's technique, two promising but underexplored approaches in the management of LE.

By evaluating the effectiveness of BFRT versus Mulligan's technique and their combined application, this study aims to provide clinicians with valuable insights into optimizing rehabilitation strategies for LE. Blood Flow Restriction Training has gained attention for its ability to enhance muscle strength and promote tissue healing with low-load resistance exercises, potentially reducing stress on the affected tendons **(Rolnick et al., 2021; Patterson et al., 2019; Lorenz et al., 2021)**. Meanwhile, Mulligan's technique is known to improve pain-free movement and joint function. Understanding whether these techniques are most effective individually or in combination could refine rehabilitation protocols and enhance patient outcomes **(Hing et al., 2015; Mani et al., 2017; Bessler & Beyerlein, 2019)**.

Hypotheses

It will be hypothesized that:

1. There will be no significant difference between BFRT or Mulligan's technique on pain in patients with lateral epicondylitis (LE).
2. There will be no significant difference between BFRT or Mulligan's technique on grip strength in patients with LE.
3. There will be no significant difference between BFRT or Mulligan's technique on functional outcomes (measured by PRTEE scores) in patients with LE.

Basic Assumptions

The study is based on the following assumptions:

1. Participants will adhere to the prescribed BFRT and Mulligan's mobilization protocols.
2. The outcome measures (e.g., pain intensity, grip strength, PRTEE scores) are valid and reliable indicators of functional improvement in patients with LE.

3. The BFRT or Mulligan's mobilization protocols will be applied consistently and safely across all participants.
4. The effects observed in the study population can be generalized to other individuals with LE.

Delimitations

The study is delimited by the following factors:

1. **Population**: The study will focus on 36 male and female adults aged between 18-50 diagnosed with LE, excluding individuals with other upper limb conditions or contraindications to BFRT or Mulligan's mobilization (e.g., vascular disorders, joint instability).
2. **Intervention**: The study will evaluate a specific BFRT protocol (e.g., 20–30% of 1RM, 50% limb occlusion pressure) and Mulligan's mobilization technique, with predefined parameters for frequency, duration, and intensity.
3. **Outcome Measures**: The primary outcomes will be pain intensity, grip strength, and functional ability (measured by PRTEE scores), with secondary outcomes including patient-reported global improvement and range of motion.
4. **Duration**: The intervention will be conducted over a 4-week period, with follow-up assessments at 4 weeks to evaluate long-term effects.

CHAPTER II
LITERATURE REVIEW

The literature review will be written under the following headings:

1. Lateral epicondylitis
2. BFRT Application Overview
3. Mechanisms of BFRT
4. Musculoskeletal Rehabilitation Outcomes of BFRT
5. BFRT in Tendinopathy Rehabilitation
6. Mulligan mobilization concept
7. Mulligan and LE

Lateral epicondylitis:

Lateral epicondylitis, a degenerative disorder that compromises the extensor tendons originating from the lateral epicondyle, extending infrequently to the joint. These are associated with repetitive tasks, forceful exertions, vibrations, mechanical compression, and sustained or awkward positions that can affect almost any movable part of the human body. Symptoms could restrict participation in physical activity, sports, and work, as well as recur and persist for years **(Ahmad et al., 2013)**. It is usually diagnosed through a combination of physical examination and, in some cases, imaging tests. A doctor will assess the symptoms, including pain and tenderness on the outer elbow, and may perform specific tests to reproduce the pain. Imaging, such as X-rays or MRI, may be used to rule out other conditions or evaluate the extent of tendon damage **(Coombes et al., 2015)**.

Hence, it is conferred that therapists implement a variety of treatment techniques to improve range of motion, dexterity, and hand use in daily activity, with manual techniques, scar management, and edema control cited among the most critical and frequently used interventions. In hand therapy, practitioners assess and implement tailored intervention programs to address a range of diagnoses with varying severity, complexity, and chronicity **(Sloane et al., 2020)**.

BFRT Application Overview:

The application of BFRT involves key considerations related to training parameters, cuff selection, and safety. Training loads typically range between 20–40% of one repetition maximum (1-RM) to enhance strength and hypertrophy. The most common protocol includes four sets of 75 repetitions (30, 15, 15, 15), performed to muscular failure or completion, with short inter-set rest periods of 30–60 seconds while maintaining cuff restriction . Training frequency is recommended at 2–4 times per week, similar to traditional resistance training, with interventions lasting at least three weeks for optimal adaptations **(Burton & McCormack, 2022)**.

A tourniquet or pressurized cuff is applied to the proximal region of the body part being trained during BFRT, a strengthening exercise. After that, the tourniquet's cuff is inflated to a predetermined pressure (usually 150 mmHg) to provide both partial and complete venous occlusion **(Scott et al., 2015)**. By utilizing pressure cuffs to simulate a hypoxic environment, BFRT attempts to replicate the effects of high-intensity exercise. It is thought that hypoxic conditions speed up the healing process required for injuries to muscles and tendons. In addition to being less tolerant of strengthening training regimens, those with LE exhibit a marked decline in handgrip function and muscle strength, which requires attention. Because low-intensity exercise is generally easier for people with pain or other inflammatory conditions, such as LE, to endure, BFRT can be helpful in situations where it can produce a hypoxic environment similar to high-intensity exercise **(Scott et al., 2015; Wilson et al., 2013)**.

The mechanisms of action of BFRT in muscular adaptation are not fully elucidated but are thought to be related to increased inflammation, mechanical tension and metabolic stress which augments plasma growth hormone and blood lactate levels **(Lixandrao et al., 2018; Teixeira et al., 2018)**. Due to a paucity of research, it is unclear what effects BFRT may have on tendons, but the induced muscular milieu in response to ischemia may facilitate adaptations in morphological and mechanical tendon properties through enhanced collagen metabolism and tendon remodeling **(Pearson & Hussain, 2015; Klein et al., 2001)**.

Cuff application is critical, with factors such as pressure, width, and material influencing outcomes. Arterial occlusion pressure varies by individual and is typically set at 40–80% of arterial occlusion pressure. Cuff widths range from 3–18 cm, with wider cuffs requiring lower pressures. Cuff materials (e.g., elastic, nylon) do not significantly impact outcomes if occlusion pressure is properly applied **(Ellefsen et al., 2015)**.

Safety is paramount, as BFRT induces systemic cardiovascular and vascular responses. While it has a comparable safety profile to traditional resistance training, clinicians must monitor for risks like deep vein thrombosis **(Minniti et al., 2020; Warmington et al., 2016)**. Tools like the Well’s criteria can help assess clotting risk. Despite its benefits, barriers to implementation include determining pressures, access to technology, and managing patient discomfort. Evidence-based strategies to address these barriers include using lower, individualized pressures, preferring narrow cuffs, employing intermittent BFRT, avoiding training to failure, incorporating familiarization periods, and emphasizing the importance of effort to patients.

Mechanisms of BFRT:

The exact mechanisms behind BFRT's effects remain unclear, but several theories suggest it enhances muscular strength and hypertrophy. The hypoxic microenvironment created by BFRT leads to metabolite accumulation, increased anabolic signaling, and hormonal responses due to greater muscular fatigue and activation. This metabolic stress raises plasma growth hormone and blood lactate levels, accelerating neuromuscular fatigue earlier than traditional resistance training. Research indicates that low-load BFRT significantly increases blood lactate levels, comparable to high-load resistance training. The accumulation of metabolites, along with increased inflammatory cytokines and myokines, promotes muscle satellite cell activation **(Rossi et al., 2018; Shimizu et al., 2016)**.

In response to reduced oxygen availability, reactive oxygen species such as nitric oxide and vascular endothelial growth factor increase, stimulating angiogenesis similar to traditional resistance training. Muscular fatigue also leads to greater motor unit recruitment. Endocrine responses linked to BFRT include elevated free testosterone, serum growth hormone, insulin-like growth factor-1, and changes in gene activity, such as decreased myostatin mRNA expression **(Cook et al., 2014; Drummond et al., 2008; Sieland et al., 2021)**. While traditional resistance training also induces metabolic stress and hormonal responses, the combination of mechanical tension and metabolic effects in BFRT may enhance muscular adaptations **(Teixeira et al., 2018)**.

Beyond muscle growth, BFRT positively affects multiple physiological systems, including cardiopulmonary function, vascular compliance, bone health, psychological well-being, musculoskeletal and neural function, and anaerobic and aerobic capacity, making it a valuable tool in rehabilitation **(Burton & McCormack, 2022)**.

Musculoskeletal Rehabilitation Outcomes of BFRT:

Recent research suggests that low-load BFR (LL-BFR) training may be highly effective in early musculoskeletal rehabilitation, promoting muscular hypertrophy and being only slightly less effective than high-load resistance training (HL-RT) for strength gains **(Couppe et al., 2015; Loenneke et al., 2012; Nielsen et al., 2017; Manini & Clark, 2009)**. Traditional resistance training typically requires loads of 70% or more of 1-RM, whereas BFRT uses lower loads (20–40% of 1-RM), making it more suitable for patients unable to tolerate high muscle-tendon loads while still preventing muscle atrophy. Additionally, BFRT has been shown to induce exercise-related hypoalgesia through endogenous opioid and endocannabinoid mechanisms, making it a potential tool for pain management in early rehabilitation **(Hill, 2020; Hughes et al., 2021; Hughes & Patterson, 2020; Hughes & Patterson, 2019)**.

Interventional studies have found superior or similar outcomes for pain improvement with low-load BFRT compared to conventional high-load resistance training for various other musculoskeletal disorders such as osteoarthritis **(Nitzsche et al., 2021)**. Recent evidence suggests that low-load BFRT may be a superior method for augmenting muscular adaptations in early musculoskeletal rehabilitation, which has been found to have comparable outcomes for inducing muscular hypertrophy and for increasing muscular strength compared to high-load resistance training **(Loenneke et al., 2012)**.

BFRT has gained increasing attention in clinical populations. A systematic review and meta-analysis of 20 studies found it moderately effective for strength gains, though slightly less so than HL-RT **(Nitzsche et al., 2021)**. However, BFRT was more effective and tolerable compared to low-load resistance training (LL-RT). Another review of 10 randomized controlled trials on lower limb musculoskeletal conditions reported that LL-BFR increases muscle strength and volume while reducing pain at levels comparable to both

LL-RT and HL-RT **(Lowery et al., 2014)**. A meta-analysis on knee osteoarthritis found little to no difference between LL-BFR and HL-RT in terms of pain relief, function, strength, and muscle size improvements **(Hayhurst et al., 2021)**. Similarly, reviews on osteoarthritis and rheumatoid arthritis showed LL-BFR to be as effective as moderate and HL-RT for strength, muscle mass, and functional outcomes while outperforming LL-RT **(Grantham et al., 2021)**.

Meta-analysis also support BFRT for rehabilitation following anterior cruciate ligament reconstruction, knee surgery, osteoarthritis, muscle atrophy, sarcopenia, and various knee conditions, including patellofemoral pain and post-arthroscopy recovery **(Dos Santos et al., 2021)**. Research confirms BFRT's safety in rehabilitation, with a systematic review of 19 studies showing no increased risk of adverse events compared to standard exercise therapy **(Hunt et al., 2012)**.

The growing body of research also indicates BFRT's efficacy for a range of musculoskeletal conditions, including polymyositis, dermatomyositis, rheumatoid arthritis, and muscle atrophy. Additionally, early evidence suggests it may benefit ankle sprains, fractures, shoulder injuries, reactive arthritis, thoracic outlet syndrome, and spinal cord injury. Beyond musculoskeletal rehabilitation, BFRT is being explored for chronic medical conditions such as type 2 diabetes, chronic kidney disease, hypertension, cardiovascular disease, cancer, and even coma patients **(Burton & McCormack, 2022)**.

BFRT in Tendinopathy Rehabilitation:

Three studies have explored LL-BFR for tendinopathy rehabilitation, all focusing on patellar tendinopathy. Two case reports and one case series have demonstrated positive outcomes. One case report examined two collegiate decathletes with patellar tendinopathy who performed LL-BFR using single-leg press and decline squat exercises twice per week for 12 weeks **(Yow et al.,**

2018). Both athletes showed improvements in pain, function, strength (leg press 1-RM), tendon thickness, and hypoechoic tendon regions on ultrasound. Another case report investigated LL-BFR in a basketball player, incorporating various exercises at 30% of 1-RM for 5–6 days per week. The patient improved clinically, returned to competitive basketball, and exhibited reduced tendon signal intensity on magnetic resonance imaging, indicating structural improvements **(Cuddeford & Brumitt, 2020)**.

A case series of seven patients with patellar tendinopathy tested a three-week LL-BFR protocol using single-leg press and knee extension exercises at 30% of 1-RM. Patients trained three times per week, progressing volume based on pain response. Despite the short duration, all participants experienced reduced pain, improved function, increased strength, and a 31% decrease in tendon vascularity, though tendon thickness remained unchanged. The study also reported a high adherence rate of 98%, suggesting LL-BFR is a feasible and effective rehabilitation method **(Sata, 2005)**.

Although no definitive clinical guidelines for BFRT in tendinopathy exist, protocols such as Skovlund et al. may serve as models for implementation. The commonly recommended BFRT protocol of four sets (30, 15, 15, 15 repetitions) has been studied in both tendon pathology cases and healthy tendons, making it a potential alternative for Achilles and patellar tendinopathy rehabilitation. Few studies showed the direct benefit of BFRT for LE; however, several studies show the effectiveness of BFRT in rehabilitation for tendinopathy problems. A previous case series **(Skovlund et al., 2020)**, on the effect of LL-BFR exercise on chronic patellar tendinopathy, showed similar results to this study where through 3 weeks of LL-BFRT, there was a 50% reduction in pain scores during single-leg decline squat functional activity.

Another study found that BFR could activate the mechanistic target of rapamycin signaling pathway as an essential cellular mechanism to enhance muscle-tendon protein synthesis during the tendon healing process **(Fujita et al., 2007)**. Thus, LL-BFRT intervention might have facilitated the repair of tendon structure in LE patients.

The main benefit of providing BFRT for the subject is that with a low load, it can achieve the same morphological and mechanical changes and adaptations as resistance exercise using a high load. Low loads tend to provoke little or no symptoms when compared to high loads, so BFRT is best used when the goal of treatment is to improve muscle strength, but resistance exercise (with high loads) tend to provoke the symptoms, which tends to make the subject feel uncomfortable, affects the subject's psychological condition that makes them refuse to do exercises, and can even increase the risk of tendon re-inflammation **(Kinandana et al., 2023)**.

The previous meta-analysis study **(Slysz et al., 2016)**, with a total of 400 participants from 19 different studies, supported this study regarding the effectiveness of BFR exercise in increasing muscle size and strength. The authors of this study explained that adding BFRT during exercise could consistently increase muscle size and strength, although the effect size varied among the loads (i.e., low-intensity or moderate-intensity) and types of exercise (i.e., aerobic or anaerobic). They suggested the arterial occlusion pressure was >150 mmHg and the load applied to BFRT >25% of 1 repetition maximum (1-RM) to produce muscle hypertrophy **(Slysz et al., 2016)**, which has verified that this study used a load range of 20 - 40% of 1-RM and has shown promising results compared to high-intensity RE.

Despite these potential beneficial physiological mechanisms of BFRT on tendon healing, BFRT has received a paucity of attention in tendon rehabilitation. Reported side-effects include perceptual type responses (ie, fainting, numbness, pain, and discomfort), delayed onset muscle soreness, and muscle damage. There may be heightened risk to the cardiovascular system, in particular increased blood pressure responses, thrombolytic events, and damage to the vasculature **(Brandner et al., 2018)**. However, while these may be of some concern there is no evidence to suggest that BFRT elevates the risk of complications any more than traditional exercise modes.

Several modifiable extrinsic factors for risk minimization include selecting the appropriate BFR pressure and cuff width, as well as completion of a pre-exercise safety standard questionnaire to determine any contraindications to BFR or indeed the prescribed exercise. On the basis of the available evidence, the side-effects of using BFR are minimal, and further minimized by the use of an appropriate method of application in the hands of a trained practitioner **(Brandner et al., 2018)**.

Mulligan mobilization concept:

The Mulligan concept of MWM is a manual therapy technique that has been designed to address positional faults for restoration of normal arthrokinematic and osteokinematic motion. Mulligan hypothesized that a positional fault has been identified and corrected when MWM abolishes pain, restores function, and provides a long-lasting therapeutic effect **(Baker et al., 2013)**. MWM may be appropriate for relief of pain, movement impairments, reduced muscle length, and positional faults. All precautions and contraindications associated with joint mobilization and manual therapy are applicable to MWM, which could have an adverse effect on an injured joint. MWM involves a sustained passive joint glide while the patient actively moves the joint (or motion segment) **(Hing et al., 2015)**. The accessory glide may or may not be applied by the clinician while the patient is performing active movements **(Lucado et al., 2019)**. Upon completion of the MWM technique, the clinician assesses the ability of the patient to perform the same movement without manual application of the accessory glide or the patient’s ability to perform a functional task (e.g., reaching for an object in a range of motion that was previously impaired) **(Baker et al.(2013)**.

Mulligan and LE:

MWM is more beneficial than comparison groups at improving pain on the visual analogue scale in the short term (<3 months) and intermediate term on patients with LE **(Lucado et al., 2019)**. Meta-analytic pooling found statistically significant models for MWM on the visual analogue scale, and the heterogeneity between the studies was low. In addition, MWM is more beneficial than control groups at improving grip strength in the short term on patients with LE. Meta-analytic pooling found a statistically significant model for MWM on grip strength with low heterogeneity. Based on the available body of evidence of this meta-analysis, the authors recommend the clinical use of MWM directed at the elbow for a moderate positive effect on self-reported pain and decreased pain-free grip strength in the short term **(Lucado et al., 2019)**.

The Mulligan technique, which can be summarized as a combination of active movement and mobilization of the joints in the correct position within the framework of biomechanical principles, aims at painless recovery. This technique includes natural apophyseal glides, sustained natural apophyseal glides, and MWM **(McDowell et al., 2014)**. **Anap et al.** proposed that Mulligan MWM technique restored normal tracking of the radius over the capitulum so that strengthening of the forearm muscles can be done without painful symptoms, which led to pain-free grip strength (**Anap et al., 2012)**. In 2003, Paungmali et al. showed that Mulligan MWM produces sensory input sufficient to recruit and activate descending pain inhibitory systems that result in most of the pain-relieving effects **(Paungmali et al., 2003)**.

CHAPTER III
PATIENTS, MATERIALS AND METHODS

Settings and design:

This study will be a randomized controlled trial. The study will use a pre-test and posttest control group design that aims to determine the effectiveness of BFRT verses MWM regarding grip strength, pain intensity and functional ability in an individual with LE. The study will be conducted in Cure private clinics in Egypt and an informed consent will be obtained from each patient **(Appendix 1)**.

Ethical Approval

The protocol of this study will be reviewed by the ethics committee of scientific research at the faculty of physical therapy, Cairo University.

Participants:

The inclusion criteria in this study will be:

1) 36 subjects of both gender aged between 18 and 50 years with a positive test of LE (Positive Cozen's, Maudsley's, and/or Mill's test), which has been determined based on physical therapy assessment procedures; 2) the presence of pain in the lateral epicondyle of the humeral bone; and 3) show decreased muscle strength and functional ability.

While the exclusion criteria of this study will be 1) refusal to be a sample in this study; 2) presences of bilateral symptoms; 3) presences of sensory and motor impairment of the upper extremities; 4) samples with systemic disease and metabolic disorders; 5) history of trauma and surgery on the elbow; 6) having a history of malignancy and peripheral vascular disorders.

Sample size calculations:

The sample size for this study was calculated using the G*power program 3.1.9 (G power program version 3.1, Heinrich-Heine-University, Düsseldorf, Germany). A priori: Compute required sample size based on F tests (MANOVA: repeated measures, between factors), Type I error (α) = 0.05, power (1-α error probability) = 0.80, Pillai V = 0.2350061, and effect size f2 (V) = 0.32 with 3 independent groups comparison for 3 major variable outcomes. The appropriate minimum sample size for this study was 30 patients (10 patients in each group as a minimum) and the total sample will be raised to account for the dropout, reaching 36, 12 per group (**Faul et al., 2009**).

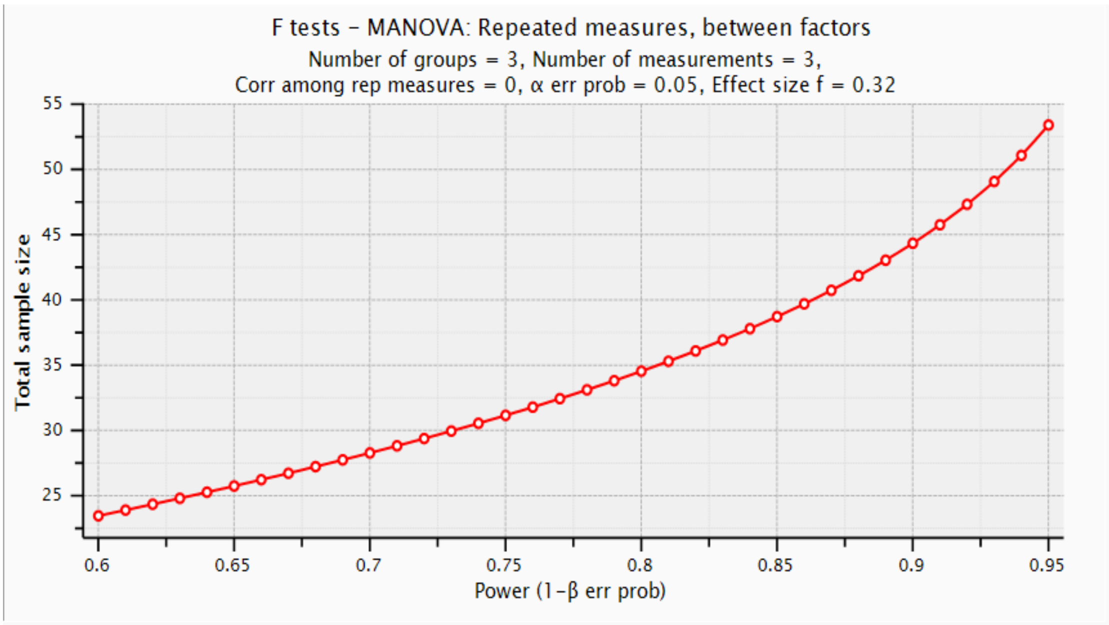

Figure 1. Sample size calculation

Procedures:

According to sample size calculations 36 samples will be included for randomization. These samples will be then randomly allocated into the intervention group that will receive exercises and BFRT (Group A), Group B (exercises+ MWM), and Group C (control group; home exercises) with 12 samples in each group. The home exercises of the participants will be followed up by calling them with mobile phones.

Intervention Groups

1. **BFRT Group (Group A)**:
    - Low-load resistance training with **blood flow restriction (BFR) (Appendix 2)**.
    - Occlusion pressure: 40%-50% of complete arterial occlusion **(Figure 2)**.

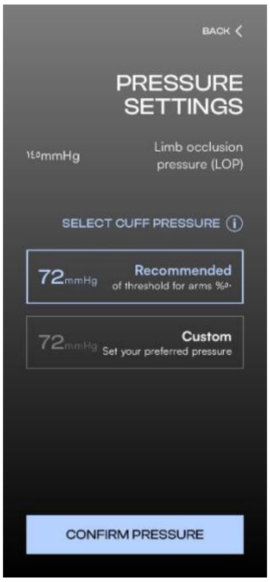

Figure 2. Pressure setting in SAGA application

The physical therapist will apply the occlusive cuff on the upper arm (brachium) with a pressure of 0.5 times of patient's systolic blood pressure. The physiotherapist will use the BFR cuffs from SAGA **(Figure 3)**. The BFR e-book for full description of the device can be found at: https://saga.fitness/pages/bfr-ebook.

Figure 3. BFR on the brachium.

The wearable BFRT device can be used as a valid and reliable tool to assess the AOP of the limbs in the supine position during BFRT **(Zhang et al., 2024)**. After the end of each session, SAGA application will send us a report for the session **(Figure 4)**.

Figure 4. Session report from the application.

2. **Group B:** In addition to home exercises, the MWM group performed MWM three times a week for a total of 12 times according to the principle of pain-free movement. The MWM technique will be applied by an experienced and certified physical therapist. First, the pain-free angle of application will be determined for each patient. The lateral condyle of the humerus will be fixed by the first bar space of the physiotherapist. A

belt is used by the therapist to apply a sustained lateral glide to the elbow joint (usually the radial head or proximal forearm), freeing the therapist's hands to assist or guide the patient's movement. **(Figure 5)**. The elbow joint will be glided until no pain will be felt in the elbow joint and the hand will be in the contracted position. Participants will be asked to repeat the movement of the elbow joint and pressing the ball 10 times without pain. The same procedure will be performed in three sets, with each set consisting of 10 repetitions of the exercise to control pain. The pauses between sets will be 15–20 s, and the interval between repetitions in each set will be 30 s.

Figure 5. MWM technique

3. **Group C:** Stretching and strengthening exercises for the forearm extensors will be performed daily by the control group for four weeks. Eccentric training for the extensor carpi radialis brevis muscle, the most affected wrist extensor tendon, and static stretching exercises for the extensor carpi radialis brevis muscle will be provided as a home exercise program. The weight that patients could lift at 10 maximal repetitions for eccentric training will be calculated, and they will be asked to work with this weight. The best stretching position for the extensor carpi radialis

brevis tendon will be achieved with extension of the elbow joint, pronation of the forearm, and flexion of the wrist with ulnar deviation. Each participant will be taught to perform each exercise with 10 repetitions and 10 s. Patients performed these exercises in a sitting position. In the control group, the daily exercises will be performed under the supervision of a physiotherapist.

Training Program

•Stage 1 (Initial Phase):

All exercises performed with BFR, MWM, and the combination group.

Exercise Protocol:

▪Elbow flexion/extension: 4 sets (30-15-15-15 reps) at 30% of 1RM

▪Wrist flexion/extension & supination-pronation: 3 sets of 10 reps with minimum weight (pain monitoring: <2/10)

▪Load progression: +0.5-1 kg weekly based on pain tolerance

▪Stretching: 3 reps × 30 sec (wrist extensors & flexors)

• Stage 2 (Progression Phase):

Initiated after at least 2 weeks if pain-free

Continuation of Stage 1 exercises

New exercises:

▪Wall push-ups

▪Wrist extension-flexion with rubber bar

▪Hand grip using a soft ball

▪Standing rowing exercises

•Additional Training Parameters:

Rest Periods:

- 30 sec between sets
- 1 min between exercises

Cuff deflation: Between different exercises, not between sets

•**Home Exercise & Monitoring**

- Home exercises performed every other day
- Supervised physiotherapy twice per week (30-45 min/session) for 4 weeks
- Weekly diary to track adherence and cointerventions

Outcome measures:

- **Assessment Timeline**: Baseline, immediate and 4-week follow-up.
- **Recorded by a Blinded Assessor**:
    - Demographic characteristics (age, duration of symptoms, body mass index, previous symptoms, dominant side, cause)
- **Primary Outcome Measures**:

1. **Evaluation of grip strength**

The patients' maximal grip strength will be measured with a hand dynamometer **(Figure 6)**. Measurements will be performed in two positions. In the sitting position, measurements will be performed in shoulder adduction, 90 flexion of the elbow, neutral position of the forearm, 0 –30 extension of the wrist, and 0 –15 ulnar deviation. While standing, shoulder abduction, elbow extension, and neutral position of the forearm will be measured. Patients will be asked to press the dynamometer for 3 s with their maximum force, and this value will be recorded as the maximum grip force. Measurements will be repeated three times at 30-second intervals on the affected limb, and the average of the measurements will be recorded. Values will be expressed in kilogram (kg) force.

Figure 6. Digital hand dynamometer

2. **Pain Intensity**

- Measured using an **11-point numeric pain-rating scale (Appendix 3)**.
- MCID: **2.1 points** (>30% reduction from baseline).
- The Arabic Numeric Pain Rating Scale will be used to assess pain intensity **(Alghadir et al., 2016)**. It is a reliable and valid instrument for measuring pain, with psychometric properties in agreement with other widely used scales.

3. **Patient-Rated Tennis Elbow Evaluation (PRTEE) Score**

- Arabic version of PRTEE questionnaire **(Appendix 4)**.
- Measures **pain and disability** (0-100 scale, with 100 = worst pain & disability).
- MCID: **11 points**
- The Arabic version of PRTEE **(Abdelmegeed et al., 2022)** will be used. It has 20 items; 5 items for pain and 15 for function divided into two subsections: specific and usual functional activities. The total score of the questionnaire is 200 and the higher the scores, the worse the outcome. The scores per item will be summed up and divided by 100 to get the total score in percentage (%). The PRTEE is a reliable and sensitive

instrument for LE with excellent internal reliability and consistency (0.94, 0.93, 0.85 for pain, specific activities, and general activities subscales, respectively).

Statistical analysis:

The mean and standard deviation of patients' characteristics will be calculated in both study groups. The Kolmogorov-Smirnov test will be used to examine the normal distribution of the variables. The ANOVA test will be conducted to examine the characteristics of the subjects, while the Chi-squared test will be utilized to compare the distributions of sex and affected side across the groups. Mixed ANOVA will be used to compare the effects of groups on Grip strength, Numeric Pain Rating Scale, Patient-Rated Tennis Elbow Evaluation (PRTEE) Score. For additional multiple comparisons, a post-hoc analysis will be conducted using the Bonferroni correction. A significance level of $p < 0.05$ was established. All statistical analyses will be performed using IBM SPSS, Chicago, IL, USA's version 27 of the statistical package for social studies (SPSS).

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Appendix 1:

Informed Consent Form

I am /....................freely and voluntarily consent to participate in a research study with title/ Effectiveness of blood flow restriction training verses mulligan technique in lateral epicondylitis. a randomized controlled trial. A thorough description of the procedure has been explained, and I understand that I may withdraw my consent and discontinue participation in this research at any time without prejudice to me.

Participant Name:

Date: