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Influence of Blood Flow Restriction in the Early Phase After Anterior Cruciate Ligament Reconstruction with Hamstring Graft: Proposal for a Randomized Multicentric Experimental Protocol

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ABSTRACT

Background: The rupture of the anterior cruciate ligament is a recurrent injury, especially in athletes (70%), and surgery is often preferred. However, a consequent post-surgical quadricipital atrophy is commonly noticed. Here, we present a research project proposing early quadricipital muscle strengthening under Blood Flow Restriction (BFR) in post-surgery patients. The objectives are to assess the impact of early post-surgical muscle strengthening under BFR on quadricipital strength and spatio-temporal parameters during gait analysis.

Methods: A prospective, interventional, experimental, and multi-center study is proposed comparing a control group benefiting from muscle strengthening alone to an experimental group benefiting from muscle strengthening under BFR. The protocol was carried out between D3 and D31 post-surgery on a sports population.

Results: We expect this study to provide an additional therapeutic option in the anterior cruciate ligament's immediate and early post-operative protocols in athletes.

Conclusion: This study project aims to offer innovative and efficient rehabilitation that answers the athlete's needs and aligns with an evidence-based practice approach.

Keywords: blood flow restriction, early rehabilitation, anterior cruciate ligament, strengthening.

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INTRODUCTION

The anterior cruciate ligament (ACL) injury is a recurrent injury, especially in athletes (70%) [1], any pivotal sport is a risk [2, 3], and reconstruction surgery is often preferred. Currently, 40,000 ACL reconstruction operations take place per year in France.

Many musculoskeletal consequences but not only present themselves to the patient during the postoperative period: in particular, it is common to notice consequent quadricipital atrophy, which subsequently marks a functional deficit in activities of daily living.

Therefore, optimizing this rehabilitation from the immediate postoperative period is essential to limit complications as much as possible and thus achieve efficient treatment. Therefore, on the one hand, to minimize these short-term deficits and on the other hand to influence the long-term results to be in line with the patient's goals.

To do this, we looked at an innovative technology in therapy, allowing early muscle strengthening, submaximal, and favoring metabolic stress to mechanical stress, made impossible by the therapeutic window. This technology, which is blood flow restriction (BFR), allows in particular gains in strength and trophicity comparable to muscle strengthening at high load while being only 20-30% of the muscle patient's maximum resistance (MR) [4,5].

According to several studies, training with BFR is potentially beneficial for people recovering from orthopedic or other problems requiring rehabilitation care, but training with higher loads is contraindicated [6,7].

From this information, we developed the following problem: in athletes who have benefited from ACL reconstruction, does early muscle strengthening under BFR provide musculo-functional advantages compared to muscle strengthening alone?

This study aims to assess the impact of early post-surgical muscle strengthening under BFR on quadriceps strength on the one hand and assess spatio-temporal parameters during gait analysis.

MATERIALS AND METHOD

The study is carried out prospectively, experimentally, and interventionally in a multi-center context.

The main objective of this study is to assess the strength of the quadriceps in patients undergoing knee surgery as part of ACL reconstruction, who underwent strengthening under BFR compared to subjects undergoing muscle strengthening alone.

The secondary objective of this study is to assess the effects on the Spatio-temporal parameters of the sports subject who received rehabilitation under BFR compared to subjects under muscle strengthening alone.

The study's primary endpoint is based on measuring the quadriceps strength of the operated limb of each athlete (In kilograms).

For this, we will use the "Leg press test" [8] to estimate the RM using the Brzycki formula [9-11].

The secondary endpoint relates to the Spatio-temporal walking parameters of sports subjects.

For this, we use G-walk technology [12] through a 10-meter (m) walk test, allowing G-walk ® technology to collect the data necessary for the walk analysis. (7m)

The hypotheses of this experimental research are an increase in superior quadriceps strength in subjects subjected to reinforcement under BFR compared to reinforcement alone. As well as a notable improvement in walking quality in the group subject to BFR compared to the control group.

The criteria for including patients in the study are:

According to the World Health Organisation, Athletic patient achieves a minimum of 150 minutes of moderate-intensity endurance activity or at least 75 minutes of sustained-intensity endurance activity per week.

- Age from 18 to 35 inclusive.
- Have undergone a Hamstring graft.
- Be able on Day (D) 3: to have an active "full" extension of the knee. (5 ° of flessum tolerated)
- Have 80 ° of active knee flexion range.

The criteria for not including subjects in the study are:

- Heart, lung, metabolic or hematological disease [13].
- Pregnancy. (Woman with a confirmed pregnancy, i.e., three months) [14].
- Any history of damage to the ipsilateral and/or contralateral ACL.
- Associated ligament and / or meniscal lesions.
- Other musculoskeletal affections of the lower limb.
- Neuropathy or vascular pathology of the lower limb.
- Known central or peripheral neurological impairment.
- As well as the contraindications relating to BFR.[14]

The exclusion criteria for study subjects are:

- Recurrent ACL rupture (partial or complete) during the study.
- Failure to adhere to the planned protocol within four weeks.
- Persistent pain after exercise or inability to perform the protocol.
- Bleeding was seen at the level of the dressing.
- Sign of phlebitis, complex regional pain syndrome, fever or sign of infection, deterioration of the general condition, neurogenic pain, obstructive arterial disease of the lower limbs

This study will be carried out with n patients.

Suppose we estimate the target population at 41,000 people. In that case, that is to say, the number of patients operated on for an anterior cruciate ligament over a year, tolerating a margin of error of 5% and admitting a level of 95% confidence. Thus, the sample size required to obtain potentially meaningful results is 381 participants.

We use the following equipment for this study: a "leg extension" type weight machine and a "leg press" type machine. In addition, we use MAD-UP ® technology for working capital. As well as G-walk ® technology for walk analysis.

During this therapeutic management, the patient receives

the protocol according to the group in which it has been allocated. Thus, this muscle strengthening program is part of comprehensive and specific management of ACL rehabilitation concerning rehabilitation objectives.

Each physiotherapist carries out the diagnostic assessment during the first session with the patient. Then, a randomized allocation stratified by the study center follows to minimize selection bias and confusion in the study and balance the numbers of each group concerning the characteristics specific to each patient and consequently to favor the comparability of the groups about these characteristics. Therefore, it is impossible to envisage any single or double-blind approach here.

We perform an initial post-operative D3 assessment which consists of measuring the concentric force of the quadriceps to assess our primary endpoint. Then, we continue with a review of the spatio-temporal parameters of walking to objectify our second judgment criterion.

When the patient is included on postoperative D3, an anonymous patient file is created once the free and informed consent of the patient has been obtained.

First, to have objective data, an analysis of the spatio-temporal parameters of the patient's walking without technical assistance (TA) is carried out by the physiotherapist using the G-walk ® device, through a 10-meter (m) walk test.

We collect the different spatio-temporal parameters: speed, cadence, stride length, duration of posture, duration of the oscillating phase, double support, and single support [12].

Then, in a second step, the physiotherapist measures the concentric force of the quadriceps. For this, we use the "Leg press test" [8] to estimate the RM in concentric quadriceps using the Brzycki formula to avoid excessive knee loading.

After that, the patient is randomly allocated to the control group or the experimental group.

After following a 4-week strengthening program using the methods proposed in each group, the same battery of tests is carried out for the final assessment on D31 postoperative.

The experimental protocol

Test group - Muscle strengthening + BFR:

From D3 to D14

- Warm-up: 15 repetitions of 0.5 kilograms (Kg) on unilateral "leg extension" [8].
- Dynamic work of the quadriceps in extension (80 ° to 0 °) under BFR on unilateral "leg extension" at 30% of the estimated MR [6], 4 series: one series of 10, one series of 8, one series of 6 then one of 4 repetitions, 3 times per week, at 80% Limb occlusion pressure (LOP) (to be gradually increased with the workload) [13]. With 30 sec of rest between each exercise, continuous pressurization, and a speed of execution of 4 sec [14].

From D14 to D31

- Warm-up: 15 repetitions × 2 kg [8].
- Resistance work on "leg press" under BFR, by series of 30-15-15-15 repetitions, at 30% of the MR [6], at 80% of LOP, twice a week [15], at 48 hours minimum interval [13], with 30 sec of rest between each exercise, continuous pressurization, and speed of execution of 4 sec [15].
- Walking work: 3 times a week for 20 minutes (min), at 80% LOP, at 4km / h. [16], without technical help.

NB:

- RM is re-evaluated between the 2 phases of the protocol. (leg press test)
- The quadricipital effort is always carried out only in concentric mode.

Control group - Muscle strengthening without BFR:

From D3 to D14

- Warm-up: 15 repetitions × 0.5 kg on one-sided "leg extension".
- Dynamic work of the quadriceps in extension (80 ° to 0 °) on unilateral "leg extension" at 30% of the MR (reassessed between the 2 phases of the protocol), 3 times a week, 4 series: one series of 10, a series of 8, a series of 6 then one of 4 repetitions, with 30 sec of rest between each exercise, speed of execution of 4 sec.

From D14 to D31

- Warm-up: 15 repetitions × 2 kg
- Resistance work: sets of 30-15-15-15 at 30% of the MR, 2 times a week, separated by 48 hours minimum, on a press, with 30 sec of rest between each exercise, speed of execution of 4 sec.
- Walking work: 3 times a week, 20 min, at a speed of 4 km / h.

DISCUSSION

We expect results from this protocol to show the effectiveness of reinforcement under BFR on strength gain and the functional parameters of walking studied here.

Better spatio-temporal parameters and a more substantial increase in force in the group that has performed the protocol under BFR are expected.

In this post-surgical context, it isn't easy to achieve optimal weight-bearing. But it is essential that in the early periods after surgery, the rehabilitation program incorporates load to prevent muscle atrophy and loss of strength, which will facilitate recovery from functional activities, such as walking [17].

Open kinetic chain (OKC) exercises can be helpful when it comes to isolating a muscle and limiting the involvement of other muscle groups, thereby ensuring better muscle activation and fatigue of the target muscle. Some studies have shown that open kinetic chain exercises combined with closed kinetic chain exercises (CKC) are more effective than CKC exercises alone in improving quadriceps strength after ACL reconstruction [17].

Within these rehabilitation objectives, the OKC is used more and more. However, it is criticized, through the "leg extension" in particular, it should be known that it is viable despite the beliefs on this mode of exercise. This is because safe and even essential for the patient after an ACL reconstruction. Indeed, according to a recently published article, the OKC and the CKC are necessary to restore a

quadriceps with good functions and ensure an excellent return to the sport. The immediate post-operative exercises in OKC are safe. You should know that the stresses on the ACL are 2 to 3 times greater when walking than when exercising in OKC. The sole use of the CKC exercise mode would even be harmful, leading to compensations without sufficiently strengthening the quadriceps [18].

In addition, in the patient with compromised weight-bearing (soon after surgery), inhibition of the quadriceps is substantial and, as such, cannot achieve the required load for activation and necessary stimulus allowing in fine to provide a favorable adaptation to the reduction of this atrophy and this inhibition. BFR may be a viable therapeutic alternative here. Thanks to the low-intensity resistance training possible with BFR, it is possible to train to achieve greater strength and muscle hypertrophy than resistance training with the same intensity in normal flow, BFR-free, and it is comparable to gains from moderate to high intensity [17].

As such, low load BFR therapy may be a valuable tool for building muscle strength in patients who cannot perform high resistance exercises or patients who have persistent weakness in the extremities despite traditional treatment. In addition, it can be used as part of a postoperative strength training program [17].

Metabolic stress and mechanical strain have been described as "primary hypertrophy factors" and raised to activate other mechanisms for inducing muscle growth. These proposed mechanisms include production of hormones, swelling of cells, production of reactive oxygen species, intramuscular anabolics, signaling and increased recruitment of fast fibers (type II muscle fibers), and a decrease in myostatin expression, thus promoting the increase in muscle mass [19, 20].

BFR treatment is indicated after knee surgery in patients with a state of lift or muscle inhibition or those with significant postoperative pain to counter muscle atrophy. Additionally, it is helpful for patients trying to re-establish their pre-injury muscle strength levels [21].

According to this recent from Hughes et al. of 2019, ACL reconstruction patients experienced less knee joint pain. In addition, they reported similar results on perceived effort during and after strengthening exercise on BFR compared to strengthening alone. The BFR could, therefore, according to them, be more advantageous during the first phases of postoperative rehabilitation [22, 23].

Finally, according to an English study with similar objectives, strengthening with BFR may improve hypertrophy and skeletal muscle strength to a similar extent to traditional strengthening. The addition of BFR to a reinforcement would even have a protective effect at the bone level. In addition, however, BFR is associated with a more significant reduction in knee joint pain and effusion, leading to an overall improvement in physical function. Consequently, reinforcement under BFR may be more appropriate for early after ACL surgery rehabilitation in patients identified within the National Health Service [4, 22, 23].

We expect this study to provide a therapeutic option in athletes' immediate and early ACL reconstruction protocols. The main objective is for this protocol to become commonplace and a real therapeutic option to overcome the multiple objectives of the athlete.

To ultimately achieve optimal recovery needs from an injury that remains high impact. (Psychological, psychosocial, economic,…).

Whether this is in the perspective of post-surgical rehabilitation of an ACL or, thanks to future studies, that this tool integrates the therapeutic arsenal of the physiotherapist in his daily life.

The objective of this research thesis and study project is to offer both innovative and efficient rehabilitation that meets the needs of the athlete and is part of an Evidence-Based Practice approach.

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