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Case Series

The Effects of Exercise with Blood Flow Restriction (BFR) in the Post Operative Rehabilitation of Anterior Cruciate Ligament (ACL) Reconstruction Patients: A Case Series

Christina Karampampa[1,2*], Efthymios Papasoulis[1], Dimitrios Hatzimanouil[2], Georgios Koutras[3], Trifon Totlis[1], Ioannis Terzidis[1,2]

[1]Thessaloniki Minimally Invasive Surgery (TheMIS), Orthopaedic Center, St. Luke's Hospital, Thessaloniki, Greece

[2]Aristotle University of Thessaloniki, Faculty of Physical Education and Sports Science, Laboratory of Biological Evaluation Human Performance, Thessaloniki, Greece

[3]Physical Therapy, Technological Education Institute of Thessaloniki, Greece

[*]**Corresponding Authors:** Christina Karampampa, Aristotle University of Thessaloniki, Faculty of Physical Education and Sports Science, Laboratory of Biological Evaluation Human Performance, Thessaloniki, Greece

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Abstract

The purpose of this study was to demonstrate whether addition of BFR interventions to a postoperative ACL rehabilitation program can reverse muscle atrophy, improve strength, and restore imbalance between the two limbs following ACL Reconstruction (ACLR). Sixteen patients aged 15 to 40 years, that had been treated with ACLR, were randomly divided into two exercise groups: the experimental group that performed a BFR protocol in addition to the standard physical therapy, and the control group that performed only standard physical therapy. Interventions were performed during weeks 12-18 postoperatively. Measurements at the beginning and after the completion of the intervention program included assessments of a) muscle morphology of the injured limb by measuring the perimeter of the quadriceps at 10cm and 20cm proximal to the superior patellar pole, b) muscle strength deficit at 60°/s as measured using the CYBEX isokinetic evaluation, c) clinical outcome using IKDC, KOOS & VAS Scores. There were statistically significant improvements in thigh circumference of the BFR group compared to the control group at 10cm (1.4 ± 0.9% vs 0.6 ± 0.9%) ($p<0.004$) and 20cm (2.25 ± 1.6% vs 1.1 ± 1.2%) ($p<0.001$). Significantly greater attenuation of knee flexors strength deficit at 60°/s was observed in the BFR group ($p<0.024$). No statistically significant differences were found neither in the strength deficit of the extensor muscles ($p>0.226$) nor in clinical scores between the two groups. This study suggests that BFR intervention during rehabilitation of patients following ACLR are beneficial in terms of muscle mass and strength.

Keywords: Anterior cruciate ligament; Blood flow restriction; Muscle atrophy; Rehabilitation; Resistance training

Introduction

Anterior Cruciate Ligament (ACL) injury is one of the most frequent musculoskeletal conditions worldwide. In the USA, more than 250,000 cases per year are reported [1]. Muscle weakness and atrophy of the quadriceps and hamstrings is a common feature in patients following operations such as ACL reconstruction [2]. The reduced weight bearing and unloading context of ACL rehabilitation during the early postoperative stages predispose to muscle atrophy [3]. In recent decades, postoperative rehabilitation methods have been significantly differentiated from an approach of minimal muscle activity and full immobilization [4-6] towards one of increased muscle activation and range of movement (ROM) in the early stages following surgery [4,5]. The American College of Sports Medicine recommends a minimum resistance training load of 60% to 70% of 1 repetition maximum (1 RM) in order to gain strength and 70% to 85% of 1 RM to achieve muscle hypertrophy. Nevertheless, training with these high loads may not be feasible or safe in painful early-operated knees [2].

Studies have shown that exercise with Blood Flow Restriction (BFR) is an efficient technique to attenuate muscle atrophy and ameliorate muscle strength and hypertrophy in patients following ACLR surgery [3,7-9]. BFR is an innovative training method that aims to partially restrict arterial inflow and fully restrict venous outflow by placing a pressurized cuff to the proximal thigh during exercise [1]. During low-resistance exercises, reduced oxygen is delivered to muscle cells. The induced anaerobic environment has been reported to promote muscle hypertrophy by initiating cell signaling and hormonal changes that trigger protein synthesis, proliferation of myogenic satellite cells, and preferential activation and mobilization of type II muscle fibers [10,11]. By using BFR as a rehabilitation tool after ACL reconstruction, it has been shown that exercises performed at lower loads (20%-50% of 1RM) can enhance muscle hypertrophy similar to traditional strengthening protocols without causing pain or straining the knee joint [3,10,12-14]. At the early post-operative stage of an ACLR surgery (0-2 weeks), the application of passive BFR can mitigate muscle atrophy [15]. Additionally, low intensity NMES (neuromuscular electrical stimulation) combined with BFR have interestingly increased thigh size and strength, without placing any strain on the graft or exacerbating any cartilage, meniscal and bruising injuries, in the acute phase of ACLR [15]. During the progressive limb loading phase of ACL rehabilitation, low-load BFR training could be integrated to accelerate muscle hypertrophy and improve strength [3]. Nevertheless, there are only few studies that have investigated BFR-RT in the post-operative ACL rehabilitation [7,9,16]. The main objective of this trial was to evaluate if the addition of BFR interventions to a postoperative ACL rehabilitation program (12^{th}-18^{th} week post ACLR) can reduce muscle atrophy, improve strength, and muscle hypertrophy, and restore imbalance between the two limbs compared to conventional physical therapy.

Materials and Methods

Study Design

This study was a parallel group, two-arm, between-groups, randomized clinical trial and conducted at the physiotherapy department of our Orthopaedic Center. Informed consent was sought and acquired. This trial has been designed in agreement with the CONSORT guidelines for reporting randomized controlled trials.

Participants

We enrolled 16 patients who had undergone an ACLR with a hamstring autograft prior to 12^{th} postoperatively week (Table 1). Inclusion and exclusion criteria are described in detail in Figure 1. Moreover, both groups were evaluated to find out that they met the criteria required to join the intervention program. The swelling in the operated limb, the range of motion of the knee (0-90o), as well as the ability to lift their body weight without the appearance of pain (sit to stand test) were examined. Once all these criteria were qualified, participants attended a familiarization session and underwent some measurements.

(Mean ± SD)	**Group A**	**Group** B	**p-value**
Sample Size (M/F)	8 (4/4)	8 (4/4)	N/A
Age (y)	21.3 ± 7.9	23 ± 6.0	0.314
Body mass (kg)	67.8 ± 11.5	71.0 ± 6.1	0.51
Height (cm)	1.72 ± 0.1	1.76 ± 0.1	0.344
Body Mass Index (BMI)	22.9 ± 3.5	22.9 ± 1.7	0.982
Pre-injury activity level (Tegner)	6.9 ± 1.4	7.2 ± 1.8	0.32
Time from ACLR surgery (days)	92 ± 2	94 ± 2	0.063

BFR-blood flow restriction, ACLR anterior cruciate ligament reconstruction

Table 1: Demographics.

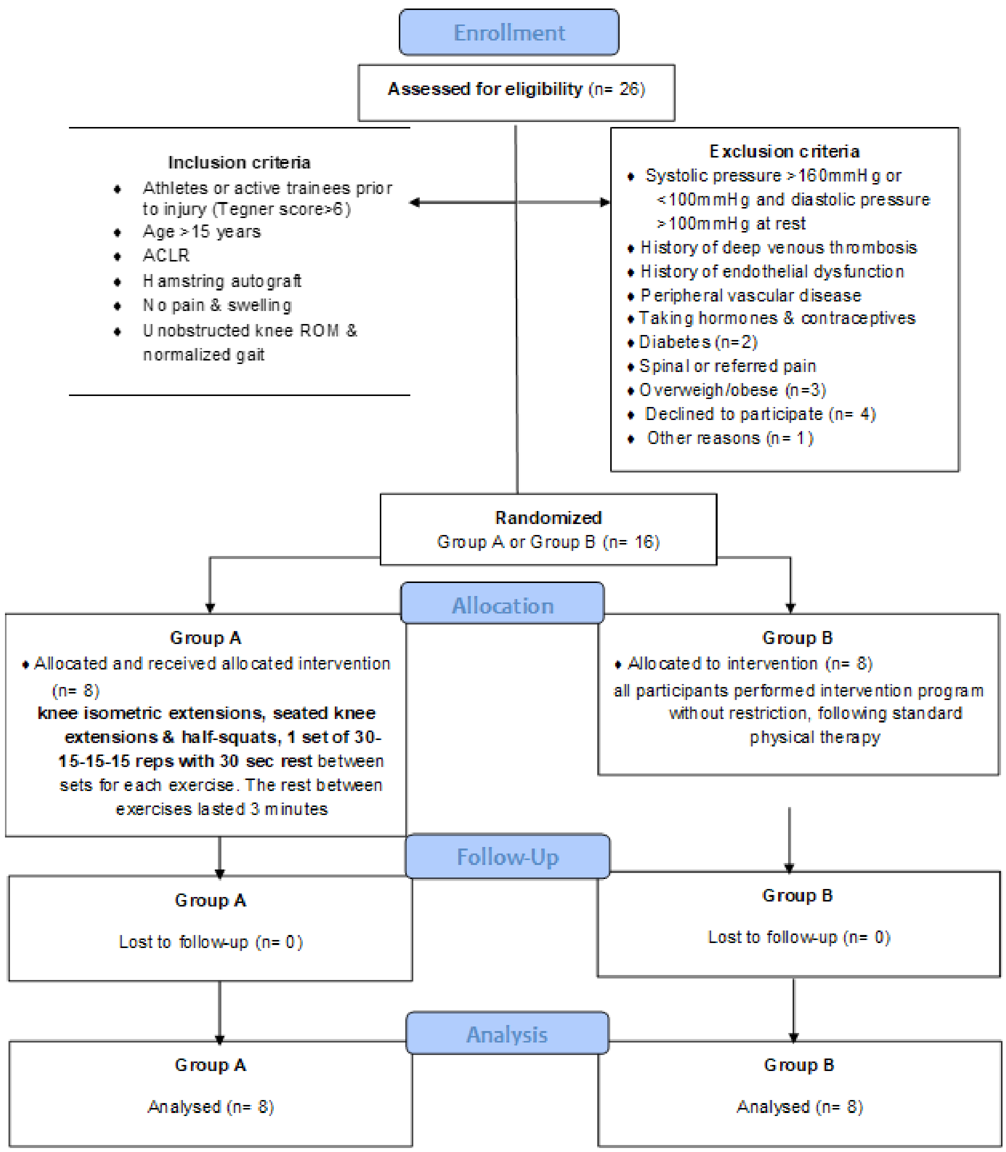

Figure 1: CONSORT statement flow diagram.

Randomization and Blinding

Patients who consent and met the eligibility criteria were randomly divided into two groups: Group A: the BFR group that performed Blood Flow Restriction (BFR) protocol in addition to the standard physical therapy and Group B: the control group that performed exercise protocol without restriction, following standard physical therapy (3 times per week, including passive and active ROM exercises, open/closed kinetic chain resistance exercises, balance & proprioceptive training) supervised by an appointed physiotherapist at the designated outpatient rehabilitation unit. Randomization was performed using a random number generator. An independent member of the research team then chose a random unmarked envelop in order to assign each number to one of the groups: blood flow restriction training or standard physical therapy.

Experimental Procedure

The only difference between the two groups was the application or not of BFR protocol. The study was performed during the 12th-18th week postoperatively. A 6-week intervention program (week 12th -18th) begun at 12 weeks following ACLR surgery and completed at 18 weeks for the Group A.

Blood Flow Restriction Pressure Calculation

In this study, an automatic personalized tourniquet system (MAD-UP system, Angers, France) was used only in the injured limb to achieve partial vascular occlusion of the lower limb (LOP), defined as the minimum pressured required for full arterial occlusion (AOP). MAD-UP patented technology allows you to adjust the pressure applied to the limb via the cuffs. During the session, pressure is regulated in real time and is synchronized with movement and muscular contraction. Additionally, the physiological evolution of the participant is continuously analyzed and taken into account so as to attain safety and comfort. Prior to intervention program the cuff was placed on the proximal thigh and LOP was calculated in the supine position. BFR pressure was set at 80% LOP to increase fast twitch fibre recruitment and induce hypertrophic adaptations.

Interventions

The Group A performed an intervention program twice a week, totaling 12 sessions each separated by a minimum of 48 h. All BFR interventions were conducted under the direct supervision of a trained member of the research team. Three strengthening exercises were selected: a) knee isometric extensions, b) seated knee extensions and c) half-seats performed slowly (2s concentric, 2s eccentric phase, paced by a metronome). One set of 30-15-15-15 repetitions with 30 seconds rest between each set for each exercise were performed and the rest between exercises lasted 3 minutes. The Group A performed each exercise with partial vascular occlusion (60-80%) of the LOP in addition to standard physical therapy. For the first two weeks occlusion was at 60% of the LOP. From the 3rd to the 6th week occlusion increased to 80% of LOP and a small load corresponding to 10-20% of 1RM was added (10-20% of 1RM was calculated approximately according to the feedback we received from the participants and was adapted to the dynamics of each one individually). The BFR-cuff remained inflated throughout the session. In case participants were incapable of completing the repetitions without pain or discomfort, the external load was reduced. Regarding the Group B, all participants completed the intervention program without the addition of BFR.

Outcome Measurements

Outcome evaluation included muscle bulk, muscle strength and symptoms evaluation as measured by patient-reported scores. Measurements were performed at the beginning and after the completion of the intervention program of both groups.

Muscle Morphology

Thigh girth measurements were taken at 10-cm and 20-cm measured proximal to the superior patellar pole using a standard tape measure in order to identify the muscle thickness of both limbs (operated & healthy). All measurements were taken with participants lying supine.

Muscle Strength

Muscle deficits of knee extensor and flexor muscles were measured with the isokinetic evaluation on a Cybex Isokinetic Dynamometer by an experienced physical therapist. Isokinetic strength testing was performed after a 5-minute bicycling warm-up. Each patient was positioned on the dynamometer as per manufacturer's instructions in an upright, seated position. Following five submaximal warm-up repetitions and 3 min of rest, participants performed five maximal effort repetitions of knee extension and flexion through full ROM at 60˚/s.

Patient-Reported Outcome Measures

Patient-Reported function was assessed using IKDC, KOOS and VAS score. The International Knee Documentation Committee (IKDC) Questionnaire is a knee-specific patient-reported outcome measure, which assesses symptoms, sports activity, and knee function in daily living. It is scored on a 0-100 scale with 100 representing higher knee function. The Knee Injury and Osteoarthritis Outcome Score (KOOS) is a questionnaire that assesses both the long-term and short-term consequences of knee injury and osteoarthritis. It consists of 5 domains: pain, symptoms, activities of daily living, quality of life, and sport functions. It is scored on a 0-100 scale with 0 representing extreme symptoms and 100 representing no symptoms. Pain was also measured using the visual analog scale (VAS). As 0 rates no pain and 100 rates extreme pain.

Statistical Analysis

For the statistical processing of the data collected from the above measurements, the statistical program SPSS 20.0 (Statistical Package for Social Sciences) software for Windows was used. Levels of importance of the statistically significant differences was set at $p < 0.5$. Normal distribution of data was assessed using the Shapiro-Wilk of Normality test ($p > 0.05$) and Independent t-test. For nonparametric data, Wilcoxon signed-rank test & Mann-Whitney U Test were used.

Results

Demographics

Twenty-six patients were enrolled, randomized and assessed for eligibility in order to complete the study protocol. Six participants were excluded from the study because they did not meet the participation criteria and prerequisites of the survey and four participants declined to participate. There were no significant differences between groups for any baseline anthropometric variable (Table 1). Both groups joined during the same postoperative stage (92 ± 2 days vs 94± 2 days) and completed the same measurements before the implementation of the BFR protocol (12th week postoperatively) and after the completion of 12 sessions (18th week postoperatively) in order to identify and evaluate differences between the two groups.

Muscle Morphology

Table 2 shows the results of thigh circumference at 10cm and 20cm for both groups. There was statistically significant improvement for group A at 10cm ($p < 0.004$) and 20cm ($p < 0.001$) (1.4 ± 0.9% and 2.25 ± 1.6%) compared to the Group B (0.6 ± 0.9% and 1.1 ± 1.2%).

	PRE BFR		POST BFR			
Mean (Std. deviation)	**Healthy Leg**	**Injured Leg**	**Healthy Leg**	**Injured Leg**	**Difference in injured leg**	**P-value**
Perimeter at 10cm proximal to patella						
Group A	43.7 (3.8)	40.9 (5.2)	43.3 (3.8)	42.4 (5.2)	1.4 (0.3)	**0.004**
Group B	43.6 (3.8)	41.6 (3.8)	43.3 (3.7)	42.3 (3.7)	0.6 (0.3)	0.559
Perimeter at 20cm proximal to patella						
Group A	50.6 (6.8)	47.1 (6.8)	50.0 (6.1)	49.4 (6.7)	2.2 (0.5)	**0.001**
Group B	50.1 (5.0)	47.1 (4.9)	49.8 (5.0)	48.3 (4.8)	1.1 (0.5)	0.25

Table 2: Thigh Girth (cm) Proximal to Superior Patellar Pole.

Scaled Isokinetic Strength

Table 3 shows the muscle strength deficits for the injured limb as measured with the use of the isokinetic evaluation at 60 N/s from pre-BFR protocol to post-BFR protocol. There was statistically significant improvement for the muscle deficit of flexor muscles between the two groups ($p < 0.024$), while no significant changes were observed in extensor muscles ($p > 0.226$).

Mean (Std. deviation)	**PRE intervention**	**POST intervention**	**Difference**	**Percentage of difference**	**P-value**
Strength deficits in flexors 60/s(Nm/kg)					
Group A	27.6 (4.3)	14.1 (5.0)	-13.4 (4.0)	-48.9% (15.6%)	**0.024**
Group B	24.8 (2.1)	15.2 (4.8)	-9.6 (4.0)	-39.4% (15.7%)	
Strength deficits in extensors 60/s(Nm/kg)					
Group A	35 (7.6)	23.6 (7.1)	-11.3 (4.2)	-33.5% (14.4%)	0.226
Group B	36.7 (6.9)	27.1 (8.4)	-9.5 (2.1)	-28.0% (13.0%)	

Table 3: Muscle strength deficit at 60/s (Nm/kg) through the isokinetic evaluation CYBEX.

Patient-Reported Outcome Measures

Patient-reported outcomes (KOOS, IKDC, VAS) improved statistically significant for the Group A before and after the BFR interventions (Table 4). For the Group B no such difference was observed (Table 5). In-between groups analysis however, showed no statistically significant differences, probably due to small sample size (Table 6). No patients BFR group reported any adverse effect during this trial.

Group A				
Measure	**Initial (Mean & Range)**	**Final (Mean & Range)**	**Improvement**	**P**
KOOS				
Symptoms and Stiffness	69.6 (35.7- 96.4)	84.3 (64.2- 96.4)	14.7	0.091
Pain	76.0 (57.3- 97.2)	87.1 (69.4- 97.2)	11.1	0.058
Function, daily living	82.9 (57.3- 95.5)	90.0 (67.6- 98.5)	7.1	0.207
Function, sports and recreational activities	28.1 (10.0- 45.0)	60.6 (15.0- 90.0)	32.5	**0.017**
Quality of Life	43.7 (12.5- 56.2)	56.2 (18.7- 87.5)	12.4	0.057
Total	68.9 (45.8-85.1)	82.0 (63.7-93.5)	13.0	**0.036**
IKDC	55.1 (37.9-73.6)	72.5 (52.9-90.8)	17.3	**0.012**
VAS	45.0 (30.0-90.0)	23.7 (10.0- 40.0)	-21.2	**0.034**

Table 4: Patient-Reported and Physical Outcome Measures.

Group B				
Measure	**Initial (Mean & Range)**	**Final (Mean & Range)**	**Improvement**	**Group Diferrences**
KOOS				
Symptoms and Stiffness	61.7 (35.7-85.7)	71.8 (60.1-83.0)	10.0	
Pain	65.9 (57.3-75.0)	73.7 (62.5-86.0)	7.8	
Function, daily living	68.9 (56.2-82.1)	77.6 (60.1-90.0)	8.6	
Function, sports and recreational activities	30.0 (15.0-40.0)	56.8 (40.0- 70.0)	26.8	
Quality of Life	40.3 (18.1-62.5)	55.5 (35.0-75.0)	15.2	
Total	52.9 (40.1-64.8)	65.1 (53.0-74.8)	12.2	**0.065**
IKDC	53.1 (37.9-73.6)	63.5 (48.5-88.5)	10.3	**0.872**
VAS	51.2 (30.0-80.0)	35.0 (20.0- 50.0)	-16.2	**0.585**
Independent Samples Test				

Table 5: Patient-Reported and Physical Outcome Measures.

	Group A (1) OR Group B (0)	N	Mean	Std. Deviation	p Independent t-test	p Mann-Whitney U test
IKDC diff BFR	0	8	10.3	4.5	0.065	0.052
(pre-post)	1	8	17.3	8.7		
VAS diff BFR	0	8	-16.2	7.4	0.585	0.664
(pre-post)	1	8	-21.2	24.1		
KOOS Total diff BFR	0	8	12.2	4.7	0.874	0.713
(pre-post)	1	8	13	13		

Table 6: Between groups statistics of Patient-Reported and Physical Outcome Measures.

Discussion

The main subject of this study was to examine if the addition of BFR interventions to a progressive limb loading phase of ACL rehabilitation program (12th-18th week) can reduce muscle atrophy, improve strength and hypertrophy, and ameliorate physical function. The main findings of this study were that: (1) Group A achieved greater improvements in quadriceps bulk and flexors strength compared to control group, (2) Group A increased physical function and reduced knee joint pain according to patient-reported outcomes, (3) no patients BFR group reported any adverse effect during this trial.

Muscle Morphology

According to the existing literature, muscle strength, activation and volume can be improved when BFR method is added to aerobic and resistance training in healthy populations [17]. Few studies, to our knowledge, has examined the effectiveness of BFR training following ACLR surgery and the findings of these studies were controversial. Iversen et al. reported that quads atrophy wasn't reduced by light load resistance training with BFR in the first 2 weeks after ACLR [7]. Likewise, Curran et al. found no difference in the change in the quadriceps cross-sectional area in patients undergoing ACLR that completed a high load resistance training (70% 1RM) with BFR (HLRT-BFR) compared to non-BFR group beginning at 10 weeks postoperatively [17]. It is possible that BFRT is not effective when delivered alongside high-intensity resistance exercise, as the mechanisms leading to adaptations in muscle hypertrophy with BFRT are not additive [17]. Contrary, Hughes et al. reported that BFR-RT can cause hypertrophic and strength adaptations similar to HL-RT during the early post-operative stage (2nd-8th week) [3]. In addition, muscle thickness improved by 5.8% for the BFR-RT and 6.8% for the HL-RT following 8 weeks of training after ACLR surgery [3]. Moreover, Ohta et al. found substantial increases in size and strength of extensor and flexor muscles compared to standard light load resistance training during the 2nd- 16th week interval postoperatively [9].

Similarly, in our study 6 weeks of BFR-RT caused considerable increases in thigh circumference of the injured limb at both 10cm and 20cm proximal to the patella compared to control group whilst utilizing a light external load. More specifically, the rate of change at 10cm and 20cm perimeter was 3.6% and 4.9% respectively. Given that, 5-12 weeks of resistance training is required in order to achieve improvements in thigh size approximately 6-8%, these findings prove that BFR method can be equally effective at increasing muscle mass compared to standard resistance training [3,18,12,19]. The exact mechanism for the early hypertrophic adaptations induced after BFR training remain unknow and further investigation is needed.

Muscle Strength

The existing literature examining the effects of BFR-RT on the recovery of muscle strength in patients undergoing ACLR is limited and presents mixed results. Ohta et al. showed significantly less postoperative strength deficits in isokinetic knee extension at 60°/s ($p<0.001$), isokinetic knee extension at 180°/s ($p=0.004$) and isometric contraction at 60° knee flexion ($p<0.001$) after LL-BFRT compared to non-BFR training [9]. Hughes et al. examined the effectiveness of BFR training compared to high load resistance training (HL-RT) in early-postoperative ACLR patients [3]. In this trial the HL-RT group observed greater decreases in extensors strength deficits (-13%) to BFR-RT (-8%), suggesting that high load resistance training (70% 1RM) might be more efficient in order to regain muscle peak torque [3]. In a study by Curran et al. patients undergoing ACLR performed high intensity exercise (single leg press at 70% 1RM) with or without BFR, beginning at 10 weeks postoperatively and no difference in knee extensors muscle strength or activation at 60°/s was found between groups [17]. The present study has shown that 6 weeks of BFR-RT resulted in substantial increases in muscle strength and minimized muscle deficits while utilizing light external load compared to standard physical therapy. Regarding this trial, both strength deficits of extensor and flexor muscles at 60°/s seemed to decrease in both groups. More specifically, decreases of -12% and -9% of knee extensors and -13% and -9% of knee flexors muscle deficits of the operated limb measured at 60°/s were observed following BFR-RT and conventional PT, respectively. However, we cannot ignore the fact that no statistically significant improvements were observed in knee extensors. In summary, BFR could be an alternative method that might induce additive hypertrophic and strength adaptations while minimizing mechanical stress to the knee joint, during ACL rehabilitation process, compared to standard physical therapy.

Patient-Reported Outcome Measures

In this study, Group A increased physical function and reduced knee joint pain according to patient-reported outcomes. These findings are in line with Hughes et al. in which the BFR-RT group observed significantly greater improvement in all measures of patient self-reported function (IKDC, LEFS, KOOS) compared to HL-RT after ACLR surgery [3]. The reduction in pain and effusion, the improvement in ROM and overall function may be attributed to the lighter load used (30% vs. 70% 1RM) compared to HL-RT [3]. Similar results were seen with another study, which obtained a significant difference in physical function of the BFR group compared to control group regarding the IKDC questionnaire. De Mello et al. showed that the intervention group, which performed BFRT with 30% 1RM during 4th to 12th week postoperatively had greater pain improvement compared to control group (HL-RT 70% 1RM) [20]. Contrary, Curran et al. noticed no significant differences in the change from preintervention to postintervention or change from preoperative to return to activity (RTA) for the IKDC Score between groups following ACLR surgery, while adding BFR to a HL-RT exercise (70% 1RM) [17].

Tennet et al. observed 1.5-2 times greater improvements in all subscales of KOOS score for the BFR group following ACLR surgery [21]. Similarly, Hughes et al. showed greater reductions in KOOS-pain (− 67% vs. − 39%) after LL-BFRT compared to non-BFR training [22]. In the present study, greater reduction in VAS-pain (-21% vs -16% respectively) were also noticed, which is in agreement with literature comparing two different training groups in ACLR patients. Korakakis et al. observed that the alleviation of knee joint pain seemed to be sustained 45 minutes after the BFR intervention compared to LLRT [23,24]. In addition, recent studies have shown that a hypoalgesia effect might be induced by BFR-RT, particularly in ACLR patients, where knee pain was found to be significantly reduced, immediately after and at 24 h following BFR-RT compared to HL-RT [16,23,24]. However, no study has previously examined the exact mechanism of BFR training inducing acute pain reduction. Recently, it has been suggested that the mechanisms may include: i) conditioned pain modulation through the diffuse noxious conditioning controls (DNIC)-like effect, ii) exercise related release of endogenous substances which inhibit nociceptive pathways, and iii) induced hypoxia following BFR training [23,24]. The current study reinforces the existing literature suggesting that the implementation of BFR method at ACLR patients can be a reliable tool of reducing pain rather than standard physical therapy or light load training [25-29].

Strength and Limitations

This clinical study examined and compared the effect of BFR-RT on muscle morphology, strength, function and pain during the progressive limb loading phase of ACL rehabilitation, using recommended protocols for the application of BFR. The present study enrolled patients, all of whom were active athletes and trainees, having similar demographics findings. However, this trial included an age-specific subgroup of ACLR patients, which limits transference of the findings to other ages (e.g., pediatric). Moreover, the current study focusses on a specific phase of ACLR rehabilitation only and the results may not generalize to the broader populations due to the small sample size. In addition, this study included mixed population (men & women), who suffered from different meniscal or cartilage injuries, suggesting that the patients may have been treated differently. Moreover, this study has not strictly controlled the exercise intensity, whilst the external load was calculated approximately according to the feedback we receive from the patients. Future research should consider total load as independent factor, which may influence greater hypertrophic adaptations. Another important area of future research is determining in which ACLR postoperative stage can the BFR training be more effective and investigating the optimal parameters of BFR intervention (pressure, time, load volume).

Conclusion

The results of this study indicate that LL-BFR training during a progressive limb loading phase of ACL rehabilitation program may be beneficial on quadriceps mass and flexors strength compared to non BFR- training with non-detrimental effects on ACL graft. However, more randomized controlled trials with standardized intervention protocols and outcome measurements are needed to provide evidence on the clinical value of LL-BFR training during ACL rehabilitation process.

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