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ORIGINAL ARTICLE

Effect of Low-Load Blood-Flow Restricted Training Versus Heavy Slow Resistance Training in Unilateral Patellar Tendinopathy: A Randomized Clinical Trial

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ABSTRACT

Patellar tendinopathy (PT) is a debilitating overuse injury, and one of the current recommended treatments is heavy slow resistance training (HSRT); Recently, low-load resistance training combined with blood flow restriction (LL-BFRT) has been advocated as a clinically relevant rehabilitation tool for PT since it does not involve large joint and tissue stresses and may accelerate recovery. This study aimed to investigate the effect of LL-BFRT compared with HSRT at 3, 6, 12 (primary endpoint), and 52 weeks. Participants with chronic unilateral PT were randomized to a 12-week rehabilitation program based on either LL-BFRT ($n = 16$) or HSRT ($n = 20$). The primary outcome was pain (numerical rating scale (NRS) 0–10) during a single-leg decline squat (SLDS). Secondary outcome variables included the Victorian Institute of Sports Assessment-Patella questionnaire (VISA-P), maximal isometric knee extensor strength, patellar tendon morphology assessed by ultrasonography (swelling, vascularization), and magnetic resonance imaging (MRI). Comparable clinically relevant improvements in pain (NRS during SLDS, least squares mean ± SEM) were observed in LL-BFRT (LL-BFRT: 0 weeks 3.9 ± 0.5, 12 weeks 2.2 ± 0.5, 52 weeks 1.8 ± 0.5) and HSRT (0 weeks 4.2 ± 0.4, 12 weeks 2.2 ± 0.4, 52 weeks 1.1 ± 0.5) ($p < 0.0001$). Likewise, clinically relevant improvements were reported on the VISA-P score. LL-BFRT and HSRT resulted in comparable short-term and long-term clinical improvements in males with chronic PT. These data advocate that LL-BFRT represents an effective rehabilitation tool in the treatment of chronic PT, while preventing high joint and tendon loads.

Trial Registration: Clinicaltrials.org (NCT04550013)

1 | Introduction

Patellar tendinopathy (PT) is a prevalent overuse injury affecting both non-athletes and athletes [1–3], especially in explosive sports such as basketball and volleyball [3]. PT is characterized by pain at the apex of the patella during physical activity and palpation together with increased tendon thickness and neovascularization visualized by ultrasonography (US) [4, 5]. Symptoms and reduced physical performance can be protracted; many athletes may not return to previous activity levels, with some even ending their sports career [6, 7].

Loading-based rehabilitation is the recommended first-line management [4, 8]. In this concept, heavy slow resistance training (HSRT) has emerged as an effective treatment approach for chronic tendinopathy when evaluated on clinical, structural, and biomechanical outcomes [9–12]. However, not all individuals can tolerate HSRT due to excessive pain when exposed to high (80% of 1 repetition maximum (RM)) exercise loads [4, 9, 11]. In contrast, resistance training using low-load muscle contractions (30% of 1-RM) performed under partial blood flow restriction training (LL-BFRT) does not involve the high joint and tissue stresses associated with HSRT [13], yet yields similar strength gains and similar muscle and tendon hypertrophy to that observed with HSRT [14, 15]. Consequently, LL-BFRT may represent a clinically relevant rehabilitation approach.

The possible mechanism(s) for LL-BFRT remain elusive, but it has been hypothesized that an ischemic and hypoxic milieu is generated, which induces high levels of metabolic stress [13, 16] that may increase circulating lactate levels [17, 18], hormone, immune, and oxidative stress responses [19] of a magnitude comparable to HSRT. Notably for connective tissue, increased lactate and growth hormone (GH) levels may lead to upregulated collagen synthesis [20]. Transient states of hypoxia have also been reported to increase collagen cross-linking and enhance the mechanical properties of collagen-rich tissues [21, 22].

A recent pilot study using LL-BFRT in patients with chronic unilateral PT indicated clinical improvements (50% reduced pain during decline single squat and > 30% reduced resting vascular perfusion) after 3 weeks of intervention [23], corresponding to the clinical response usually seen after 12 weeks of HSRT [9, 11, 12]. However, it remains unknown if these improvements with LL-BFRT in persons with tendinopathy are similar or even greater in magnitude compared to those achieved by HSRT. Therefore, the present study aimed to investigate the effects of LL-BFRT compared to HSRT in the short-term (3- and 6-week), mid-term (12-week; primary endpoint), and long-term (52-week) phases of recovery. Based on preliminary data indicating a substantial effect [23], it was hypothesized that LL-BFRT would lead to more favorable clinical (primary outcome; numerical rating scale (NRS) during a single-leg decline squat (SLDS) test) and structural outcomes than HSRT in the treatment of unilateral chronic PT.

2 | Methods

This study was designed as an assessor-blinded, prospective, randomized controlled clinical superiority trial with parallel groups. The study was conducted at Copenhagen University Hospital—Bispebjerg and Frederiksberg in Copenhagen, Denmark. Ethical approval was obtained from the Scientific Ethics Committees for the Capitol Region of Denmark (No. H-19039320) and the Danish Data Protection Agency (P-2019-551). Study data were collected and managed using REDCap electronic data capture tools [24]. All participants provided written informed consent prior to inclusion in the study. This study followed the Consolidated Standards of Reporting Trials (CONSORT) statement [25] and adhered to the WMA Declaration of Helsinki.

2.1 | Participants

For this study, the inclusion criteria were: Male participants between 18 and 70 years of age with chronic proximal unilateral PT (symptom duration > 3 months) and with patellar tendon pain of ≥ 4 on the NRS (0 being no pain and 10 being the worst imaginable pain) during preferred physical or sporting activity. Moreover, participants should also report tenderness to palpation corresponding to the painful area. Lastly, the clinical condition was confirmed by US with increased tendon thickness at the apex patella (> 1 mm compared to mid-tendon) and Power Doppler (PD) activity and/or visible hypoechoic areas. Exclusion criteria were: Female, bilateral chronic PT, smoking, any cardiovascular disease, diabetes, previous surgery or trauma to the knee joint with an effect on the presenting clinical condition, undergoing a resistance training-based rehabilitation program for the affected patellar tendon within the previous 3 months, and corticosteroid injections within the preceding year. Participants were recruited from the outpatient clinic of the Institute of Sports Medicine Copenhagen (ISMC) and via social media.

Sample size calculation was performed based on previous reports [9] using the NRS score during the SLDS test. A priori analysis revealed that each sub-group should contain 16 participants to detect a minimally clinically important difference (MCID) of more than 2 points [26] on the NRS during the SLDS test between the intervention groups at 12 weeks ($\alpha = 0.05$, $\beta = 0.2$, $\mu1 = 4.2$, $\mu2 = 2.2$, $\sigma = 2$). Consequently, 36 participants were included to account for an expected 10% dropout rate.

2.2 | Randomization

Participants underwent a telephone screening and, if deemed eligible, underwent a pre-examination performed by an experienced physician to verify inclusion criteria. Baseline testing was performed prior to randomization. A block-randomization sequence was computer-generated and implemented in REDCap using a 1:1 allocation ratio, with participants stratified according to symptom duration (< 12 months or ≥ 12 months) and age (< 35 years or ≥ 35 years).

2.3 | Blinding

The investigator performing all outcome assessments was blinded to treatment allocation. Data analysis was performed in accordance with the statistical analysis plan (SAP) which was published prior to analyzing and unblinding the data.

2.4 | Lower Limb Strength and Arterial Occlusion Pressure

Lower limb muscle strength was measured by 5-RM testing while individual arterial occlusion pressure (AOP) was assessed by experienced physical therapists. The 5-RM tests were performed at baseline and at the start of week 4, 7, and 10 to adjust training load and secure progression. The 5-RM tests began with the leg press exercise and were followed by the knee extension exercise. The tests were performed at a controlled tempo (1–2 s in the concentric and eccentric phases). During 5-RM testing, participants were allowed a maximum of four attempts with an inter-test rest period of 3 min in order to avoid exhaustion and accumulated muscle fatigue.

Individual AOP was obtained for all participants prior to the first training session. In brief, a pneumatic cuff was placed most proximally on the symptomatic limb, and AOP was determined using a portable Hitachi Aloka Noblus ultrasound machine (Hitachi Medical systems, Japan). Participants were seated with 90° flexion in their hips and knees. After a 10-min seated rest period, the popliteal artery was located in the popliteal fossa, and the pneumatic cuff was inflated to 120 mmHg. The pneumatic cuff was then incrementally inflated until the pulse from the popliteal artery was no longer visually present. The recorded pressure was used to calculate each participant's relative AOP. The target cuff pressure during exercise was set to 50% of relative AOP in week 1, 60% AOP in weeks 2–3, 70% AOP in weeks 4–8, and 80% AOP in weeks 9–12.

2.5 | Intervention Procedures

Prior to all training sessions, participants performed a 5-min warm-up on a stationary bike ergometer at a self-chosen light-to-moderate intensity. Both groups performed unilateral leg press and knee extension for only the symptomatic leg, and the total training volume was approximately similar for the two groups. The participants completed three weekly training sessions throughout the intervention period (total training weeks: 12), with at least 48 h of recovery between successive training sessions. A trained physiotherapist supervised one training session per week.

For the LL-BFRT group, a pneumatic cuff (Heine Gamma, G7, G5, GP, width 20 cm) inflated by hand and with no autoregulation was positioned most proximally at the symptomatic limb. For each exercise, participants completed an initial set consisting of 30 repetitions followed by 3 sets of 15 repetitions at an external training load of 30% 1-RM [27].

For the HSRT group, the treatment consisted of HSRT according to previously published protocols [9, 11]. The participants were instructed to perform each exercise in a slow, controlled manner with a 3-s eccentric phase and a 3-s concentric phase. Pauses between sets were 2 min with a 3-min rest period between exercises. A detailed overview of the training protocols is shown in Table 1 and in Appendix S1.

TABLE 1 | Training progression for HSRT group and LL-BFRT throughout the intervention period (Weeks 1–12).

Weeks	1	2	3	4	5	6–8	9–12
HSRT							
Number of sets	4	4	4	4	4	4	4
Total repetitions	60	48	48	40	40	32	24
% of 1-RM	55	65	65	70	70	75	80
LL-BFRT							
Number of sets	4	4	4	4	4	4	4
Total repetitions	75	75	75	75	75	75	75
% of 1-RM	30	30	30	30	30	30	30
% AOP	50	60	60	70	70	70	80

Note: Total repetitions include all repetitions performed across all sets. LL-BFRT performed 30, 15, 15, 15 repetitions across 4 sets. Repetitions for the HSRT group were evenly distributed across 4 sets.
Abbreviations: AOP, artery occlusion pressure; HSRT, heavy slow resistance training; LL-BFRT, low load blood flow restriction training; RM, repetition maximum.

2.6 | Load and Pain Management

Pain during exercises was accepted but should not exceed 5 points on the 0–10 NRS during training sessions or following the cessation of the exercise bouts; otherwise, training loads were reduced. Participants were allowed to perform sporting activities throughout the 12-week intervention period, while pain should not exceed 3 NRS points [11, 28].

2.7 | Training Registration

After each session, participants received an individual web link to access their electronic training diaries in REDCap, where they were instructed to register completed sets, repetitions, and loads for the two exercises.

2.8 | Primary Outcome

The primary outcome was NRS during the SLDS test, which is a recommended and reliable pain provocation test for patients with PT [29, 30]. The participants performed the SLDS test on a 25° decline board without any warm-up to avoid acute exercise-induced hypoalgesia. The participants first performed two trials on the asymptomatic limb, followed by two attempts on the symptomatic limb. The participants reported pain in the patellar tendon using the NRS (0 no pain, 10 worst imaginable pain/inability to perform the task).

2.9 | Clinical and Mechanical Outcomes

VISA-P was used as a patient-reported outcome measure questionnaire to report symptoms, function, and the ability to participate in sports [31]. The VISA-P score denotes 100 as having no pain or symptoms during function or physical activity. The VISA-P was administered with a brief explanation of the questionnaire but completed without assistance at all time points.

Maximal isometric knee extensor muscle strength (iMVC) was assessed in a custom-made setup recording force using a wireless transmitter (8-channel TeleMyo 2400TG2 Telemetry System), and MyoResearch XP Master Edition software Version 1.07 (Noraxon). The method has previously been described [11]. A total of four iMVCs, each of 5 s duration, were performed, interspaced by 2-min rest periods between trials. The length of the tibia was used to calculate the maximal knee extensor peak torque.

Physical activity was measured at baseline and at 12 and 52 weeks follow-up and included all weekly hours of self-reported physical activity. Maximal knee tendon pain during or following physical activity within the last 14 days was recorded using the visual analog scale (0 denoting no pain and 100 worst imaginable pain) at all timepoints. Participants evaluated their satisfaction with their symptoms using a 5-point global rating of change (GROC) scale (much worse—much improved) at 12 and 52 weeks follow-up. Adverse events were monitored at all timepoints.

2.10 | Ultrasonography

Baseline US data has previously been published [5]. US was used to assess tendon thickness, echogenicity, and PD activity. The US procedures and settings were identical to previous protocols [5, 11]. Participants were asked to avoid strenuous physical activity 24 h prior to scanning. US imaging was obtained using a HI VISION Ascendus ultrasound machine (Hitachi Medical Systems). The B-mode assessments of tendon thickness and hypoechoic were performed with the participants seated, hip and knee joints flexed at 90° and maintaining an upright posture. Recordings were obtained using an 8 cm long linear transducer (EUP-L53L, Hitachi Medical Systems). Two images were captured on both the symptomatic and asymptomatic tendon. The PD examination was performed using a 4 cm long linear transducer (EUP-L75, Hitachi Medical Systems). Participants were placed supine with relaxed and extended knee. At the location with the visually most PD, several 4-s Sine loops (raw AVI files containing 16 frames) were recorded.

All recorded sequences were exported to Fiji ImageJ (Version 1.53; National Institutes of Health), and the analysis was performed employing a custom-made macro to analyze tendon structure and PD activity. Only PD activity within the patellar tendon was included, and any visual noise was subjectively removed [5].

2.11 | Magnetic Resonance Imaging

Quadriceps muscle cross-sectional area (CSA), patellar tendon volume, and tendon fat fraction were assessed by magnetic resonance imaging (MRI) scanner (Phillips Ingenia Ambition 1.5 T scanner, software version 5.6.1.2, Eindhoven, The Netherlands) at baseline and 12 weeks. In brief, participants were placed in a supine position, with their legs strapped together at the feet, and their feet placed against a plastic footplate. A coronal isotropic 3D T1-weighted sequence was performed starting at the tibial tuberosity and extending as proximally as possible to capture the quadriceps muscle.

Horos v.3.3.6 open-source software was used to assess quadriceps muscle CSA, and ITK-SNAP (v4.0.1, Cognitica, Philadelphia, PA, USA) open-source software was used to assess patellar tendon volume. Quadriceps muscle CSA was measured 200 mm proximally to the tibial plateau and included all muscles in the extensor compartment. The images were measured in greyscale and to enhance the accuracy of the measurements, the NIH color scheme was used in combination. Patellar tendon volume was measured from the most proximal part of the free patellar tendon to the most distally free patellar tendon. To semi-automatically 3D segment the patellar tendon, the Region Competition Snake segmentation feature was used. Briefly, seed regions were placed within the patellar tendon and auto-filled by the software. Following the software-generated segmentation, any overflow was manually removed to ensure that only the free patellar tendon was included.

Lastly, fat fraction in the patellar tendon was assessed using an axial 6-point Dixon sequence. Fiji ImageJ (Version 1.53; National Institutes of Health) was used for fat-fraction analysis by combining the segmented volume in the 3D sequence with the Dixon sequence to extract the mean fat-fraction within the tendon volume [32].

Detailed descriptions for all outcome measures are provided in Appendix S2.

2.12 | Statistical Analysis

The SAP was registered at clinicaltrials.gov prior to any analysis and unblinding of data. Statistical analyses were performed in SAS (version 7.15, SAS Institute Inc., Cary, NC, USA), while graphs were made in GraphPad PRISM (version 9.5.1, GraphPad Software, San Diego, California, USA). Results are reported as least squares means and standard error of measurement (SEM) unless otherwise stated. Significance level was set to $\alpha = 0.05$. Quantile-quantile (Q-Q) plots were used to evaluate normal distribution of data. The principle of intention-to-treat was used for the main statistical analysis while a supplementary *per-protocol* analysis was performed on participants completing ≥ 75% of all training sessions. A linear mixed effects model was employed on all statistical analyses for between-group differences and change scores, with the random effects being participants and fixed effects being time and group allocation. Missing data was handled by the statistical model. Results were analyzed at baseline, 3, 6, 12, and 52 weeks. Mann–Whitney U test was used to analyze GROC scores for improvement between groups. Correlations between clinical changes (SLDS and VISA-P) and structural changes (patellar tendon volume, proximal tendon thickness, and PD activity) were performed using the Pearson correlation.

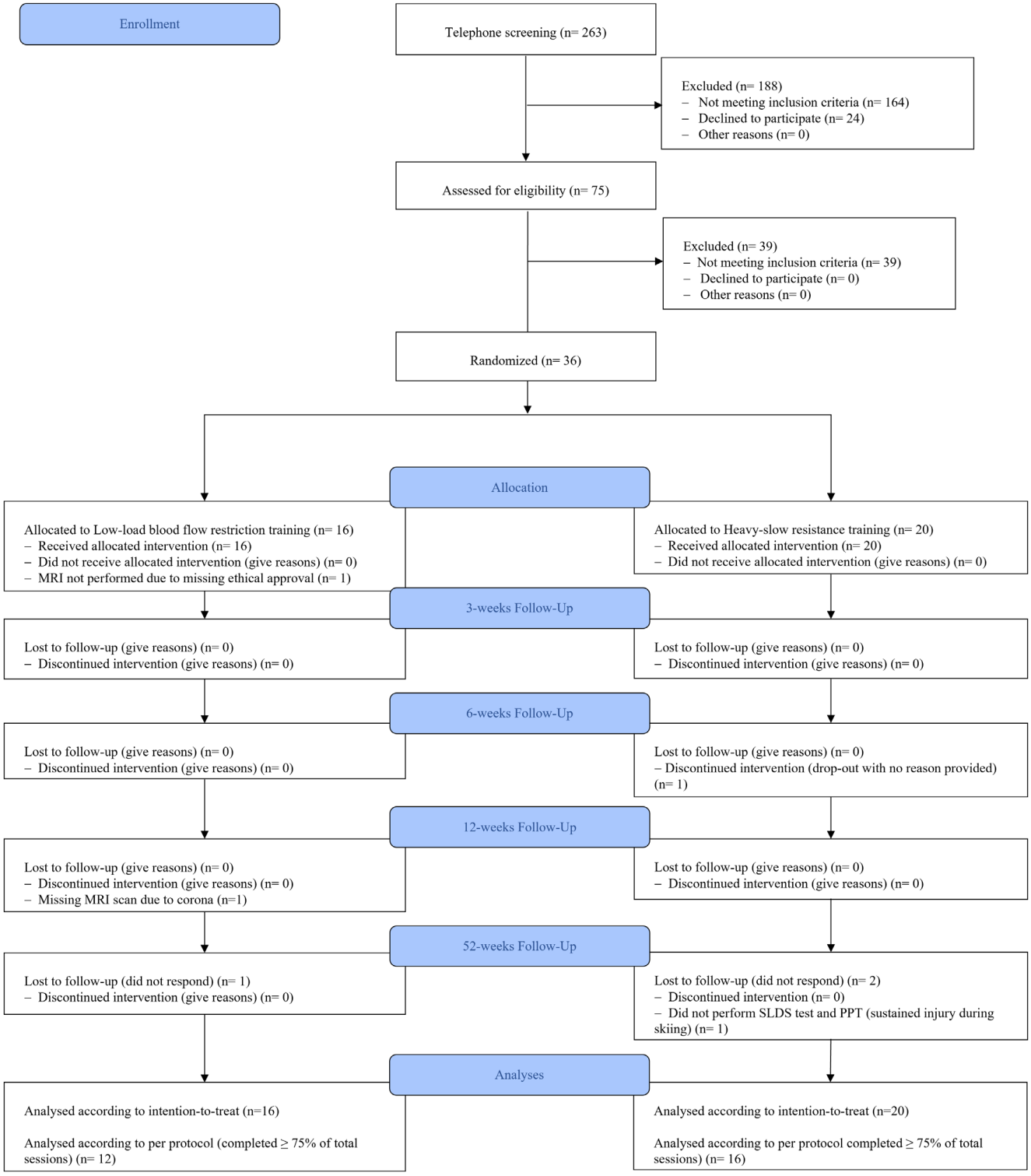

FIGURE 1 | Illustrating the flow of participants using the Consolidated Standards of Reporting Trials (CONSORT) flowchart.

3 | Results

3.1 | Participants

Thirty-six male participants were recruited between September 2020 and September 2022. The flow of participants is illustrated in Figure 1 and baseline demographic characteristics are presented in Table 2. The participants performed various types of sports/physical activity: football ($n = 9$), running ($n = 5$), volleyball/beach volley ($n = 4$), handball ($n = 3$), cross-fit and strength training ($n = 3$), padel ($n = 2$), tennis ($n = 1$), high jump ($n = 1$), dancing ($n = 1$), swimming [1], cross-country skiing ($n = 1$), badminton ($n = 1$), ice hockey ($n = 1$), gymnastics ($n = 1$), cycling ($n = 1$), and basketball ($n = 1$).

3.2 | Training Data and Physical Activity

Overall attendance rate was 77.3% ± 6.7% for the LL-BFRT group compared to 81.3% ± 6.0% for the HSRT. 5-RM lower limb strength (leg press, knee extension) increased significantly from baseline to 10 weeks with no between-group difference and AOP decreased significantly from baseline to 10 weeks (Table 3). One participant from the LL-BFRT group reported to be unsatisfied with the allocated intervention protocol whereas all other participants reported to be moderate-to-highly satisfied. For physical activity, there was no interaction ($p = 0.97$) or group effect ($p = 0.39$) although a significant time effect ($p = 0.004$) was observed. Specifically, there was a significant increase from baseline to 12 weeks ($p = 0.004$) but not from baseline to 52 weeks ($p = 0.07$) or from 12 to 52 weeks ($p = 0.12$).

TABLE 2 | Demographic characteristics.

	LL-BFRT ($n = 16$)	HSRT ($n = 20$)
Age (years)	30.0 ± 9.2	32.7 ± 10.8
Height (cm)	184.6 ± 6.1	186.7 ± 7.4
Weight (kg)	83.8 ± 9.2	85.5 ± 13.0
BMI	24.6 ± 2.4	24.5 ± 3.4
Symptom duration (months)[a]	10.0 (1st quartile 5.0; 3rd quartile 12.5)	9.5 (1st quartile 6.0; 3rd quartile 18.0)
Pain during physical activity (NRS)	5.9 ± 1.4	5.7 ± 1.6
Physical activity (h/wk)	4.8 ± 3.4	3.6 ± 3.5

Note: Data are presented in means ± SD unless stated otherwise.
Abbreviations: h/wk, hours per week; HSRT, heavy slow resistance training; LL-BFRT, low-load blood flow restriction training; NRS, numeric rating scale.
[a]Data are presented in median, 1st and 3rd quartile.

3.3 | Clinical Outcomes

3.3.1 | Primary Outcome

There was no significant interaction ($p = 0.70$) or group effect ($p = 0.84$) but a significant time effect ($p < 0.0001$) was observed with a decrease in NRS scores during the SLDS test. The *per-protocol* analysis demonstrated a similar effect.

3.3.2 | Secondary Outcomes

The VISA-P score did not demonstrate any significant interaction ($p = 0.36$) or group effect ($p = 0.94$); however, a significant effect of time ($p < 0.0001$) was observed. The *per-protocol* analysis demonstrated a similar effect. Results for the NRS during the SLDS test and VISA-P are presented in Figure 2. Maximal knee extensor strength (iMVC) demonstrated no interaction ($p = 0.50$) or group effect ($p = 0.97$), whereas a significant effect of time ($p = 0.002$) was observed for the symptomatic leg. iMVC increased from baseline to 12 weeks ($p = 0.02$) and 52 weeks ($p < 0.001$). For maximal tendon pain, no significant interaction ($p = 0.64$) or group effect ($p = 0.20$) was demonstrated; however, a significant effect of time ($p < 0.0001$) was observed with a decrease in pain intensity during or following physical activity. Maximal tendon pain decreased from baseline to 12 weeks ($p < 0.001$) and 52 weeks ($p < 0.001$). Patients' satisfaction with their symptom state at 12 weeks (13/16 [81%] LL-BFRT; 15/19 [79%] HSRT) demonstrated no significant between-group difference ($p = 0.54$). One participant in the HSRT group reported worsened symptoms at 12 weeks. Similarly, at 52 weeks (10/14 [71%] LL-BFRT; 16/17 [79%] HSRT), no significant between-group difference was observed ($p = 0.25$).

3.4 | US and MRI Outcome Variables

For PD activity, a significant interaction group × time ($p = 0.015$) was observed. Specifically, the interaction was observed at 3 weeks, where PD activity significantly decreased for HSRT ($p = 0.024$) with no change for LL-BFRT ($p = 0.32$).

TABLE 3 | Progression in 5-RM lower limb strength and arterial occlusion pressure.

	LL-BFRT				HSRT			
	Baseline	Week 4	Week 7	Week 10	Baseline	Week 4	Week 7	Week 10
5-RM								
Leg press %	NA	7.5 ± 4.0	13.7 ± 4.6	19.0 ± 5.2+	NA	4.4 ± 1.4	14.7 ± 2.5	23.4 ± 2.8
Knee extension %	NA	7.7 ± 2.8	15.8 ± 3.8	20.3 ± 3.8	NA	8.6 ± 3.6	18.7 ± 3.8	27.9 ± 5.7
Total AOP								
AOP mmHg	186.9 ± 2.8	186.9 ± 2.8	180.8 ± 2.9	180.3 ± 2.9				

Note: Data for 5-RM are presented in least squares mean SEM percent change from baseline. Data for total AOP is presented in absolute least squares mean ± SEM. Leg press: group × time ($p = 0.18$), group ($p = 0.87$), and time ($p < 0.0001$). Knee extension: group × time ($p = 0.35$), group ($p = 0.46$), and time ($p < 0.0001$). AOP: time ($p = 0.034$). Effect size (ES) for 5-RM leg press % between groups were: week 4 = 0.27, week 7 = 0.07, and week 10 = 0.26. ES for 5-RM knee extension % between groups were: week 4 = 0.06, week 7 = 0.18, and week 10 = 0.35.
Abbreviations: AOP, artery occlusion pressure; HSRT, heavy slow resistance training; LL-BFRT, low-load blood flow restriction training; RM, repetition maximum. mmHg, millimeter mercury.

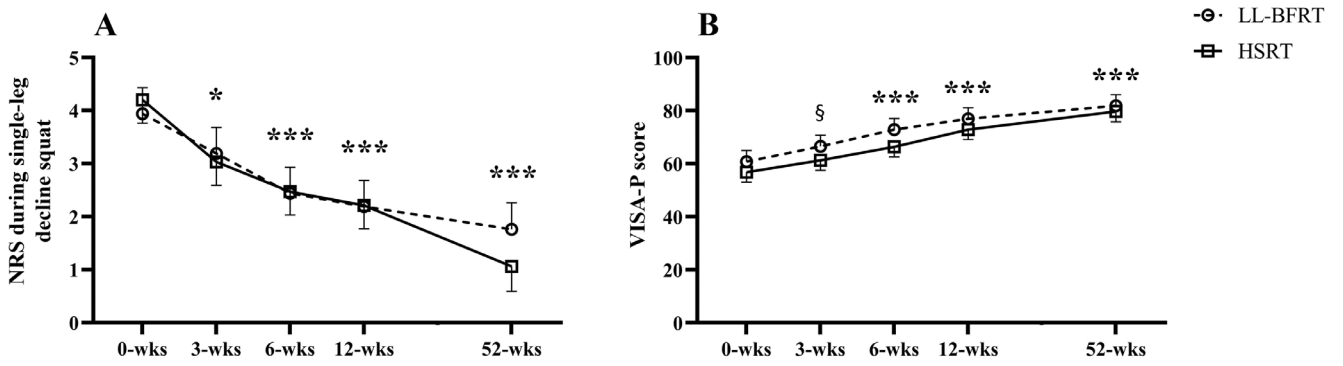

FIGURE 2 | The single-leg decline squat (SLDS) test (A) and the Victorian Institute of Sports Assessment—Patella (VISA-P) questionnaire (B) outcomes at 0-, 3-, 6-, 12-, and 52-week follow-up. Data are presented as least square means ± SEM. NRS, numerical rating scale. HSRT, heavy slow resistance training; LL-BFRT, low-load blood flow restriction training. $^{§}p < 0.05$, $^{*}p < 0.01$ from baseline. $^{***}p < 0.0001$ from baseline.

Further, there was a significant effect of time ($p < 0.001$) with a decrease in PD activity but no significant effect of group ($p = 0.38$). There was a significant decrease in PD activity from baseline to 52 weeks ($p < 0.001$).

For the symptomatic proximal tendon thickness, no significant interaction ($p = 0.16$) or group effect ($p = 0.28$) was observed. However, there was a significant effect of time ($p = 0.01$) where a significant decrease was observed from 6 to 52 weeks ($p = 0.004$) and 12 weeks to 52 weeks ($p = 0.002$). US data for the symptomatic patellar tendon are presented in Table 4.

There was no interaction ($p = 0.96$) or group effect ($p = 0.52$); however, a significant effect of time ($p = 0.002$) with an increase in quadriceps muscle CSA for the symptomatic limb was observed. For the asymptomatic limb, no interaction ($p = 0.24$) or group effect ($p = 0.15$) was observed, whereas a significant time effect ($p = 0.048$) was found, demonstrating a decrease in quadriceps muscle CSA. In addition, patellar tendon volume and fat-fraction did not show any significant interaction or effect of time and group.

3.5 | Correlations Between Clinical and Structural Outcome Variables

No significant correlations between any clinical and structural outcome variables were observed. For the SLDS and the structural outcomes, the correlation coefficients ranged from −0.23 to 0.17, and for the VISA-P, the correlation coefficient ranged from −0.14 to −0.03.

Detailed presentations of all results are available in Appendix S3.

3.6 | Adverse Events

During the intervention period, one participant in the LL-BFRT group reported a tingling sensation in the limb during training for the first 2 weeks; otherwise, no adverse events were reported as a result of the intervention protocols. Unrelated to the intervention, two participants sustained an acute knee injury during handball and football practice, three participants developed symptoms of PT on the asymptomatic leg (2 during the intervention period and 1 at 52-week follow-up), and one participant developed symptoms of biceps tendinopathy. One participant sustained a fractured lower leg and soleus tear at 52-week follow-up due to a skiing accident.

4 | Discussion

The present randomized clinical trial is the first to investigate the rehabilitative effect of LL-BFRT compared to HSRT in athletes with chronic PT. The main finding was that there were no between-group differences in the clinical and structural outcomes when comparing LL-BFRT to HSRT at 3, 6, 12 (primary endpoint) and 52 weeks. Both groups demonstrated statistically significant and comparable clinical improvements for the SLDS test and the VISA-P. Further, both groups demonstrated improvements in strength and PPT measured at the MPA and AP but did not demonstrate any significant differences in structural measurements of the patellar tendon. Collectively, the present results demonstrate that 12 weeks of LL-BFRT or HSRT lead to similar improvements in symptoms and function in male athletes with unilateral PT.

LL-BFRT and HSRT demonstrated clinically relevant improvements in pain and function as both groups demonstrated improvements close to or above MCID for both the SLDS test and VISA-P following 12 weeks training. Interestingly, significant improvement was also observed from 12 to 52 weeks for both groups, which corroborates prior data that also reported significant improvements at 52-week follow-up [11]. Notably, participants also demonstrated a similar level of symptom satisfaction. These observations, together with patient satisfaction and that LL-BFRT and HSRT have reported similar ratings of perceived exertion and discomfort [33], support the notion that patient preference should guide the choice of training regimen in the rehabilitation of chronic PT [11].

LL-BFRT has previously been investigated in various clinical populations, demonstrating significant clinical improvements [13, 34]. In terms of tendinopathy research, only case studies have been performed. One case series demonstrated a significant decrease in SLDS pain and PD activity following a 3-week intervention period [23]. A possible explanation for the similar

TABLE 4 | Structural properties of the symptomatic patellar tendon.

	LL-BFRT		HSRT		Mean difference (95% CI)
	Mean + SEM	95% CI, *p*	Mean + SEM	95% CI, *p*	
Power doppler area, mm^2					
0 wks	34.0 ± 6.5	21.2, 46.8	41.3 ± 5.8	29.8, 52.7	−7.3 ± 8.7; 95% CI: −24.4, 9.9; $p = 0.41$
3 wks	35.9 ± 6.5	23.1, 48.7	36.0 ± 5.8	24.6, 47.5	−0.2 ± 8.7; 95% CI: −17.4, 17.0; $p = 0.99$
6 wks	28.7 ± 6.5	15.9, 41.6	42.5 ± 5.8	31.1, 54.1	−13.8 ± 8.7; 95% CI: −31.1, 3.4; $p = 0.12$
12 wks	32.6 ± 6.5	19.8, 45.4	42.2 ± 5.8	30.7, 53.7	−9.6 ± 8.7; 95% CI: −26.8, 7.6; $p = 0.27$
52 wks	16.5 ± 6.5	3.6, 29.4	29.8 ± 5.9	18.2, 41.4	−13.3 ± 8.8; 95% CI: −30.6, 4.1; $p = 0.13$
Δ0 to 3 wks	1.9 ± 1.9	−1.9, 5.6; $p = 0.32$	−5.2 ± 2.3	−9.8, −0.7; $p = 0.02$	7.1 ± 3.0; 95% CI: 1.2, 12.9; $p = 0.02$
Δ0 to 6 wks	−5.3 ± 2.7	−10.7, 0.1; $p = 0.05$	1.2 ± 2.0	−2.8, 5.2; $p = 0.55$	−6.5 ± 3.4; 95% CI: −13.2, 0.2; $p = 0.06$
Δ0 to 12 wks	−1.4 ± 3.0	−7.4, 4.5; $p = 0.63$	0.8 ± 2.5	−4.2, 5.9; $p = 0.75$	−2.3 ± 3.9; 95% CI: −10.0, 5.5; $p = 0.57$
Δ0 to 52 wks	−17.5 ± 3.5	−24.4, −10.6; $p < 0.0001$	−11.5 ± 3.6	−18.7, −4.2; $p < 0.01$	−6.0 ± 5.1; 95% CI: −16.1, 4.0; $p = 0.24$
Proximal tendon thickness, mm					
0 wks	8.4 ± 0.4	7.6, 9.3	8.6 ± 0.4	7.8, 9.4	−0.2 ± 0.6; 95% CI: −1.3, 1.0; $p = 0.81$
3 wks	8.1 ± 0.4	7.2, 9.0	8.8 ± 0.4	8.0, 9.6	−0.7 ± 0.6; 95% CI: −1.9, 0.5; $p = 0.22$
6 wks	8.3 ± 0.4	7.4, 9.2	8.9 ± 0.4	8.2, 9.7	−0.6 ± 0.6; 95% CI: −1.8, 0.6; $p = 0.29$
12 wks	8.3 ± 0.4	7.5, 9.2	9.1 ± 0.4	8.3, 9.9	−0.8 ± 0.6; 95% CI: −2.0, 0.4; $p = 0.20$
52 wks	7.9 ± 0.5	6.9, 8.7	8.6 ± 0.4	7.8, 9.4	−0.8 ± 0.6; 95% CI: −2.0, 0.4; $p = 0.18$
Δ0 to 3 wks	−0.3 ± 0.2	−0.7, 0.01; $p = 0.06$	0.2 ± 0.2	−0.2, 0.7; $p = 0.24$	−0.6 ± 0.3; 95% CI: −1.1, −0.04; $p = 0.04$
Δ0 to 6 wks	−0.1 ± 0.2	−0.6, 0.3; $p = 0.60$	0.4 ± 0.2	−0.1, 0.8; $p = 0.11$	−0.5 ± 0.3; 95% CI: −1.1, 0.2; $p = 0.13$
Δ0 to 12 wks	−0.1 ± 0.2	−0.4, 0.2; $p = 0.52$	0.5 ± 0.2	0.2, 0.9; $p < 0.01$	−0.6 ± 0.2; 95% CI: −1.1, −0.2; $p < 0.01$
Δ0 to 52 wks	−0.7 ± 0.3	−1.2, −0.1; $p = 0.01$	−0.01 ± 0.3	−0.5, 0.5; $p = 0.97$	−0.7 ± 0.4; 95% CI: −1.4, −0.1; $p = 0.08$

Note: The above table demonstrates the structural outcomes for intratendinous power Doppler activity and proximal tendon thickness at baseline (0 weeks), 3, 6, 12, and 52 weeks. Data are presented in least squares means ± SEM. A mixed effect model was performed for all analyses with time and group as main factors.
Abbreviations: Δ, delta score; CI, confidence intervals; HSRT, heavy-slow resistance training; LL-BFRT, low-load blood flow restriction training; Wks, weeks.

clinical outcomes reported by Skovlund et al. [23] after 3 weeks (9 sessions of LL-BFRT) and those in the present study could be that the training volume was higher per session compared to those in the present study, and the participants were not allowed to perform sports/physical activity outside the study. Similarly, the decrease in PD activity could also be due to the restriction of physical activity outside the study [35]. Further, a case report showed a reduction in pain and improved tendon structure (thickness and echogenicity) along with increases in maximal knee extensor strength and VISA-P scores following an in-season 12-week

LL-BFRT rehabilitation program involving two elite decathletes [36]. This case report utilized a similar rehabilitation protocol as the current study, which likely explains the similar clinical improvements.

In the present study, HSRT participants demonstrated baseline scores and training-induced improvements that were comparable to previous studies [9, 11, 12]. A possible explanation for the similar clinical gains observed in the present intervention groups could be that LL-BFRT and HSRT may have induced a similar increase in hormone and immune responses, potentially involving increased secretion of GH and insulin-like growth factor (IGF-1) [19]. Both GH and IGF-1 may play an important role in the upregulation of collagen synthesis and the healing of connective tissue [37, 38]. Another explanation could be that volume and time under tension, rather than load per se, are of main importance in the rehabilitation of tendinopathic tendons, as both moderate- and HSRT have demonstrated similar clinical and structural outcomes in patients with PT [11].

Maximal tendon pain during or following physical activity decreased significantly from baseline to 12 and 52 weeks and from 12 to 52 weeks, indicating an increased tolerance load of the patellar tendon since physical activity level increased (12 weeks) or was similar (52 weeks) compared to baseline.

iMVC showed a significant increase of ~6% following the 12-week intervention period when groups were collapsed, which was maintained at 52-week follow-up. Previous studies with similar training protocols have demonstrated increases in strength measurements of a higher magnitude (10%–15%) [9, 11, 12]. However, increases in 5-RM lower limb muscle strength (+19.0%–27.9%) along with an increase in quadriceps muscle CSA (3%) indicate that the applied training protocols were sufficient to induce physiological adaptations.

The present data demonstrated an increase in the trained leg and a decrease in the untrained leg in quadriceps muscle CSA. This indicates that participants adhered to the training protocol, albeit the observed decrease could indicate that the contralateral leg was detrained; however, sports participation did not change significantly from baseline to 12 weeks follow-up (data presented in Appendix S3). Regarding patellar tendon volume, no difference was observed from baseline to 12 weeks in both groups. This complies to a previous report that also found no alteration in patellar tendon CSA after 12 weeks utilizing a HSRT rehabilitation protocol [11]. However, in contrast, another report demonstrated an increase in tendon CSA following a 12-week intervention period in tendinopathic patellar tendons [9]. The conflicting results could potentially be explained by different methodologies and/or disparate states of disease across studies. Additionally, no significant change in patellar tendon fat fraction from baseline to 12 weeks was observed for both the symptomatic and asymptomatic tendon. This indicates that fat infiltration may not be a feature of lower limb tendinopathy as a previous study also found no difference in Achilles tendinopathy and healthy tendons [39], however, the dearth in research of intratendinous fat infiltration in PT warrants further investigation.

No changes in US proximal patellar tendon thickness were observed at 12 weeks, in line with the present MRI data (patellar tendon volume) and supported by a previous study that also failed to demonstrate any changes in patella tendon morphology [11]. However, a significant decrease was observed from 12 to 52 weeks. A potential explanation could be that the rehabilitative effects initially target symptoms whereas structural changes may first emerge during the later stage of recovery. Lastly, no changes were observed for PD activity between baseline and 12 weeks; however, a significant decrease in PD activity was observed at 52 weeks relative to baseline and 12 weeks. In our study, the participants had more PD activity compared to other studies [11, 40]. The greater PD activity could be due to our inclusion criteria of ≥4 NRS pain during activity and no exclusion regarding symptom duration. Previous studies have also reported no changes in PD activity [11, 41], whereas others found a decrease in PD activity [9]. However, due to differences in methodology and US settings, it may be difficult to compare observations across studies.

No correlations were observed between clinical (SLDS and VISA-P) and structural outcomes (tendon thickness, patellar tendon volume, and Doppler) change scores. Associations between clinical and structural outcomes in tendinopathy are currently contradictory [9, 11, 42, 43]. A possible explanation could be the difference in the settings applied for US and MRI scanning [44], and differences in the methodology used to analyze the images. Lastly, due to inter-individual symptom manifestation variability, the non-significant and low correlations are not surprising.

5 | Limitations

This study has some limitations. Firstly, it included only participants with unilateral symptomatic PT; however, three participants developed symptoms in the contralateral, asymptomatic patellar tendon, suggesting the possible presence of undiagnosed/subclinical bilateral tendinopathy. Secondly, a "wait-and-see" group was not included; thus, we do not know to what extent the presented improvements emerged as a result of the participants' natural history; however, no significant improvements have been demonstrated in a "wait-and-see" control group [45]. Thirdly, only one weekly training session was supervised, which could have influenced adherence to the respective training protocols, albeit one weekly supervised training session is probably more comparable to clinical practice. Further, modest increases in quadriceps CSA and iMVC compared to previous reports [9, 11] could indicate lower adherence to the protocol; however, in contrast, significant improvement in clinical outcomes comparable to previously reported [9, 11] and significant increases in 5-RM tests suggests good adherence to the protocol. Lastly, the present study included male athletes only; thus, the results may not be readily transferable to female athletes.

6 | Conclusion

This study demonstrated no between-group difference in the short-, mid-, or long-term for any clinical and structural outcome variables when comparing LL-BFRT to HSRT in male athletes

with unilateral PT. Further, both groups demonstrated similar clinically relevant improvements on the SLDS test and VISA-P questionnaire from baseline to 12 and 52 weeks. However, no improvements in structural tendon parameters were observed at 12 weeks, whereas a significant decrease in Doppler activity was demonstrated at 52 weeks follow-up. Thus, LL-BFRT seems to be a viable and effective rehabilitation regimen in the treatment of chronic PT while preventing high joint and tendon loads during the phase of recovery.

7 | Perspectives

The present study did not demonstrate superior effects of LL-BFRT compared with HSRT in the rehabilitation of chronic PT. However, both LL-BFRT and HSRT yield comparable clinical improvements in pain and function, suggesting that clinicians may apply the rehabilitation regime best aligned with the patient's preference and tolerance to mechanical load.

Importantly, this study demonstrates that LL-BFRT may provide clinical value in the rehabilitation of chronic PT, particularly in situations where high mechanical loading is not feasible or contraindicated, such as in the early stages of rehabilitation, in athletes with concomitant joint pathology, or during in-season rehabilitation when minimizing tendon mechanical stress may be of importance for recovery. Ultimately, this study contributes to a more nuanced understanding of load management in tendinopathy and further supports individualized rehabilitation pathways in sports medicine.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Appendix S1:** sms70186-sup-0001-AppendixS1.docx. **Appendix S2:** sms70186-sup-0002-AppendixS2.docx. **Appendix S3:** sms70186-sup-0003-AppendixS3.docx.