Protonics Knee Brace versus Hamstring Resisted Exercise (HRE) on Individuals With Patellofemoral Pain Syndrome

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Methodology

Design

This study is a randomized controlled trial with two treatment groups – the Protonics^{TM} knee brace group and the sport cord group. Subjects with PFPS were asked to complete a series of open-chain hamstring resistance exercises with either apparatus, for which the procedures are described below, for four weeks. After the intervention, knee joint function and clinical symptoms of PFPS were assessed and compared between groups.

Participants

Subjects were recruited based on the following inclusion criteria: male or female18-45 years of age; has exhibited patellofemoral pain symptoms for more than 1 month and have a pain level ≥ 3 on the NPRS; has experienced pain during at least 2 functional activities, such as squatting, ascending/descending stairs, and/or running. Individuals who had experienced traumatic injuries to the knee joint or lower extremity, displayed signs or symptoms of a meniscus lesion or ligamentous-related pathology, had been diagnosed with a neurological disorder, diabetes, osteoarthritis, osteoporosis, or rheumatoid arthritis, or reported taking any over-the-counter pain medications during the study period were excluded from the study. Screening of subjects was done by a licensed physical therapist under the supervision of an Orthopedic Clinical Specialist (OCS) with over 29 years of experience.

Flyers, emails, phone calls, and referrals were used to gather a convenience sample of subjects. Subjects were randomly assigned to either the Protonics^{TM} knee brace group or the sport cord group using simple randomization (Figure 1). All participants were required to sign an informed consent form. This study was approved by the Loma Linda University Institutional Review Board and was registered at http://clinicaltrials.gov (registration number NCT03042559).

Procedures

Subjects assigned to the Protonics™ knee brace group were asked to perform warm up exercises, followed by specific therapeutic exercises that are part of the Protonic Therapy Program (PTP)[18]. The Protonics system has been introduced to physical therapists as a potential treatment for PFPS. The system includes a brace set to resist knee flexion and a set of specific exercises to perform daily. Through resistance to knee flexion, the system is advertised to decrease retropatellar contact pressure due to changes in pelvis inclination and available hip rotation. Specifically, resistance to knee flexion is purported to increase hamstring activity and inhibit the activity of the tensor fasciae latae and psoas muscles. The manufacturer asserts that prolonged use of the system results in greater hamstring activation, which leads to permanent structural changes through reciprocal inhibition at the hip and pelvis[18]. The phases of the intervention are summarized in Table 1. The warm-up consisted of the subject wearing the Protonics™ knee brace set at a moderate resistance level and flexing the knees while sitting, standing, and reclining in the supine and prone positions. The exercises, were done in sets of 10-15 repetitions, 3 sets per day, 3 times per week, for 4 weeks. Each set took about 5 minutes for subjects to complete, or 15 minutes per day.

The PTP has three phases. At the start of each phase, subjects were given detailed instructions on how to perform the warm up and therapeutic exercises and instructed to perform them at home 3 times per week. During Phase I or day 1, subjects were asked to walk for 5 minutes or as tolerated at varying speeds while wearing the brace. Subjects also performed the Protonics™ gait and Protonics™ neuromuscular repositioning techniques. During Phase II or weeks 1 and 2, subjects performed the same Protonics™ techniques, and were asked to walk for 8 minutes or as tolerated at varying speeds and inclines. Subjects were also instructed to perform 10-15 repetitions of the hamstring curl in the prone, supine, and seated positions at home. The seated hamstring curl

is displayed in Figure 2. During Phase III or weeks 3 and 4, subjects were once again asked to perform the aforementioned Protonics™ techniques, but this time they were also asked to walk forwards and backwards at varying speeds and inclines for 10 minutes or as tolerated. They were also instructed to do 10-15 repetitions of the standing hamstring curl.

Subjects assigned to the sport cord group were asked to do the same warm-ups and exercises using the sport cord in the supine, standing, sitting, and prone positions. The prone hamstring curl can be seen in Figure 3. The only difference is that subjects were asked to only walk backwards instead of forwards in order to avoid activation of the hip flexor muscle. The appropriate level of resistance for each subject was calculated by multiplying their weight in pounds by 0.3. Subjects were then given either light, medium, or heavy resistance cords according to the following classification scheme: light (pink color) with resistance 3 (R3), 0-30 lbs.; medium (orange color) with resistance 5 (R5) 0-50 lbs.; heavy (yellow color) with resistance 7 (R7) 0-70 lbs. All subjects completed three study visits, and a total of four measurements were taken at baseline, immediately following the first session, at two weeks, and at 4 weeks.

Compliance

Several methods were employed to maximize subjects' compliance: During the initial visit, subjects were provided a thorough educational session on the appropriate use of the sport cord and knee brace and were given the opportunity to ask questions at any point of the study. The educational session included oral instructions as well as brochures which subjects could refer to for complete written instructions and visual depictions of the prescribed exercises. As the study was divided into three phases, subjects were asked to visit the lab at least three times and to return for additional visits if they wished. Additionally, a log sheet was filled out by each subject to track

completion of his/her exercises at home. Finally, text message reminders were sent to each subject throughout the study.

Outcome Measures

The primary outcome measures of the study can be divided into two categories: clinical outcomes and functional outcomes.

Clinical Outcome Measures:

APT was assessed using a palpation meter (PALM) inclinometer with the subject in the standing position; one arm of the caliper was placed on the anterior superior iliac spine (ASIS) while the other was positioned on the posterior superior iliac spine (PSIS). This technique was shown to be a reliable way of assessing sagittal pelvic position [19]. As described by Herrington, subjects were required to stand on a 30 centimeter high platform, look forward at a fixed point, and keep their arms crossed over their chest during palpation [20].

Hip internal/external rotation active range of motion (ROM) was measured from sitting position as follows: the measured hip was placed at 90 degrees flexion, in neutral position between adduction and abduction, and knee joint at 90 degrees flexion, as described by Han and colleagues [21]. While the contralateral hip placed on 30 degrees abduction. Using a fluid-filled inclinometer placed parallel to the shaft of distal tibia and proximal to medial malleolus. The tibia was vertically aligned at starting position and then the inclinometer was calibrated to zero [22].

Iliotibial band flexibility was measured using a modified version of the Ober's test in which an inclinometer was placed at the distal lateral thigh. In which, zero degree was recorded when thigh was horizontal, positive value was recorded if the thigh was abducted, and a negative value was recorded if the thigh was adducted past horizontal [23,24].

Functional Outcome Measures

Patient satisfaction was measured using the GROC scales, which is a commonly used method for quantifying subjects' self-perceived progress or decline over time. The GROC is scored on 15-point numerical scale from -7 to +7 where -7 represents "a very great deal worse," 0 represents "about the same" and +7 represents "a very great deal better" [25]. An a priori score of ≥5 was identified as the cut-off of a successful outcome [25]. The validity and reliability of the GROC scales has been demonstrated in multiple studies [26,27].

The Kujala score is a 13-item self-reported questionnaire, which quantifies subjects' reported pain levels during a wide variety of activities. The scale highest scores are 100 points, which indicate lower disability. It has been shown to be a reliable and valid method for assessing functional outcomes in subjects with knee pain [28,29].

The NPRS is a self-reported questionnaire with adequate reliability and validity [28]. Subjects were asked to rate their level of pain at baseline from three different reference points: the greatest amount of knee pain they had experienced, the least amount of knee pain they had experienced, and the level of knee pain that they were currently experiencing. These three values were then averaged to create a baseline measure of pain for each subject. All subsequent questionnaires corresponded only to subjects' present level of knee pain.

Finally, the lateral step down test (LSDT) is a measure of functionality that has been demonstrated to be both reliable and valid [30]. Subjects were instructed to stand with the test leg on a 15-cm step. They were then instructed to lower their body enough to cause the heel of the opposite leg to make contact with the floor directly in front of the step, and subsequently return the knee to the fully extended position. This represented a single repetition. Subjects completed as many repetitions as they could within 15 seconds, and the number of successfully completed

repetitions was recorded. This method has been widely used to ascertain functional performance in subjects with knee pain [30,31].

Statistical Analyses

A sample size of 50 subjects was estimated using a medium effect size of 0.25, a power of 0.80 and level of significance set at 0.05. However, we have complete data for 41 participants who were randomly assigned to either Protonics^{TM} knee brace or sport cord group.

Data analysis was performed using SPSS Statistics Software version 24.0 (IBM Corp, Armonk, NY). Mean $\pm$ SD was computed for quantitative variables and frequencies (%) for categorical variables. Normality of quantitative variables was assessed using Shapiro-Wilk test and boxplots. We compared mean age (years), Body Mass Index (kg/m^2) (BMI), pain duration, and the outcome measures at baseline in both groups at baseline using independent t-test when the distribution of the variable was approximately normal and Mann-Whitney test when the distribution was not normal. The distribution of qualitative variables (gender, affected leg) by group type was examined using Chi Square test. To examine the effect of the type of intervention on outcome measures over time (baseline versus immediate versus two weeks versus four weeks), a 2x4 mixed factorial ANOVA was conducted while controlling for age at baseline since the mean age was significantly different between the two groups. The level of significance was set at $p \leq$ 0.05.

Results

Subjects' Demographics

A total of 43 subjects with mean age of 28.8±5.0 years and body mass index of 25.6±4.7 kg/m^2 participated in the study. One subject was excluded as they had a meniscus lesion that prohibited them from participating in the study, and another subject voluntarily left the study due

to personal time constraints, therefore only data from the 41 remaining subjects who completed the prescribed intervention was analyzed. Fifty-one percent of the subjects were males (n = 21) and the majority had their right knee affected (56.1%, n=23. Twenty-one subjects (51.2%) were in the Protonics^{TM} brace group and 20 (48.8%) in the sport cord group. There was no significant difference between the two groups in mean baseline characteristics and outcome measures at baseline except for age (30.8±5.6 vs. 26.7±3.0, p=0.01) and LSDT score (7.0±2.8 vs. 9.1±2.7, p=0.02, Table 2).

Clinical Outcomes

Clinical improvement of subjects' patellofemoral movement impairments were assessed using four indicators: APT, hip internal/external rotation, and iliotibial band flexibility. Based on the results from all four indicators, a significant improvement was seen in all cases for both study groups for four weeks ($p<0.001$, Tables 3&4). APT, hip internal rotation, hip external rotation, and iliotibial band flexibility were measured at baseline, immediately following the first session, at two weeks, and at four weeks. The degree of APT decreased significantly in brace and sport cord groups (59.8% vs. 38.9%, $p<0.001$; respectively), however those in the brace group had sharper and quicker decrease in APT (Table 4). Hip internal rotation also increased significantly in both groups over the course of the study ($p<0.001$, Table 4). Similarly, hip external rotation significantly increased for both groups ($p<0.001$, Table 4). Lastly, iliotibial band flexibility increased significantly ($p<0.001$) for both the brace group and sport cord groups by 87.4% and 62.5%, respectively, with those in the brace group achieving a lower but non-significant mean score (Table 4).

Functional Outcomes

Function of the knee joint was assessed with the Kujala Score and the lateral step-down test. Satisfaction was evaluated with the GROC, and pain was assessed according to the NPRS score. The level of satisfaction observed in the brace group was significantly higher than that of the sport cord group at the end of the four-week intervention ($p<0.01$, Table 3). There were no significant differences between the two groups with respect to the other three outcomes. The results of the Kujala score indicated that there was a significant improvement in knee function for both groups (13.7% vs. 10.3%, $p<0.001$, Table 3). The mean score for the brace group improved by 74.6%, while those in the sport cord group had 47.4% improvement. All subjects were able to perform significantly better on the lateral step test post-intervention (($p<0.001$, Table 4). The brace group exhibited a 133.3% improvement in their performance, while those in the sport cord group demonstrated only an 85.3% improvement. NPRS score decreased significantly for both groups after four weeks (($p<0.001$, Table 3).

Tables

Table 1. Phases of Exercise Intervention

Phase	Week	Frequency	Activities
Phase I	1st Day of Week 1	1 Session	Education Warm-up Walking
Phase II	Weeks 1-2	3 Sessions per Week	Walking Hamstring curl in supine, prone, and sitting positions
Phase III	Weeks 3-4	3 Sessions per Week	Walking Hamstring curl in standing position

Table 2. Mean ± SD of baseline characteristics and outcome measures by study group (N=41)

Variables	Brace (n_1=21)	Sport Cord (n_2=20)	p-value
Female, n (%)	12 (57.1)	8 (40)	0.27
Right Leg,, n (%)	10 (47.6)	13 (65)	0.26
Age (year)	30.8±5.6	26.7±3.0	0.01
Height (cm)	167.9±10.9	166.9±9.2	0.75
Weight (kg)	69.3±16.4	75.1±16.4	0.26
BMI (kg/m^2)	24.4 ±4.2	26.8±4.8	0.09
Pain Duration*(days)	730 (30,4705)	530 (37,3650)	0.16
PNRS	4.5±1.5	3.8±0.7	0.07
Kujala score	74.8±15.0	79.3±8.11	0.24
Pelvic Tilt (º)	5.0±3.0	3.2±2.6	0.05
Lateral Step-Down Test	7.0±2.8	9.1±2.7	0.02
Hip Internal Rotation	25.9±6.3	28.8±7.6	0.19
Hip External Rotation	31.5±5.0	31.3±4.8	0.91
Iliotibial Band	3.5±3.0	3.2±2.4	0.74

Abbreviation: SD, Standard Deviation; BMI, Body mass index

*: median (minimum, maximum)

Table 3. Mean ± SD of pain, global rating of change scale, and Kujala score by study group over time (N=41)

Variable		Protonic Brace (n_1=21)			Sport Cord (n_2=20)					
Time	**Baseline**	**Immediate**	**Two Weeks**	**Four Weeks**	**Baseline**	**Immediate**	**Two Weeks**	**Four Weeks**	**p-value over time (η^2)**	**p-value between groups (η^{2*})**
NPRS	4.5± 1.2	3.0±1.9	1.9±1.7	1.1±1.7	3.8±1.2	3.2±1.9	2.5±1.7	2.0±1.7	<0.001 (0.50)	0.9 (0.01)
GROC	-	1.0±2.1	3.0±2.2	4.6±2.3	-	0.0±2.1	1.3±2.2	3.0±2.3	<0.001 (0.42)	<0.01 (0.20)
Kujala Score	74.8±12.1	-	84.4±12.8	87.5±15.1	79.3±12.1	-	84.4±12.8	87.5±15.1	<0.001 (0.38)	0.39 (0.02)

Abbreviations: PNRS, Numeric Pain Rating Scale; GROC, Global Rating of Change Scale; SD, Standard Deviation

$^{*}\eta^2$ = effect size

Table 4. Comparison of mean ± SD of HIR, HER, ITB flexibility, pelvic tilt (°), and LSDT by study group over time (N=41)

Variable			Protonic Brace (n_1=21)		Sport Cord (n_2=20)					
Time	Baseline	Immediate	Two Weeks	Four Weeks	Baseline	Immediate	Two Weeks	Four Weeks	p-value over time (η^2)	p-value between groups (η^2)
Pelvic Tilt	5.0±2.8	4.4±2.4	3.1±2.0	2.0±1.6	3.2±2.8	2.5±2.4	2.5±2.0	1.9±1.6	<0.001 (0.32)	0.08 (0.1)
LSDT	7.0±2.7	9.6±3.3	13.3±3.2	16.3±3.3	9.1±2.7	11.8±3.3	14.7±3.2	16.8±3.3	<0.001 (0.53)	0.35 (0.02)
HIR	25.9±7.0	25.5±5.5	29.2±5.0	29.4±5.8	28.8±7.0	29.3±5.5	31.6±5.0	32.6±5.8	<0.001 (0.24)	0.06 (0.1)
HER	31.3±4.9	32.2±5.0	32.3±5.2	33.9±5.7	31.3±4.9	32.2±5.0	32.3±5.2	33.9±5.7	<0.001 (0.15)	0.33 (0.03)
ITB	3.5±2.7	2.1±2.3	2.8±1.9	0.4±2.2	3.2±2.7	2.5±2.3	1.8±1.9	1.2±2.2	<0.001 (0.23)	0.96 (0.0)

Abbreviations: HIR, Hip Internal Rotation; HER, Hip External Rotation; ITB, Iliotibial Band; LSDT, Lateral Step-Down Test

Figures

Figure 1. Consort Flow Diagram.

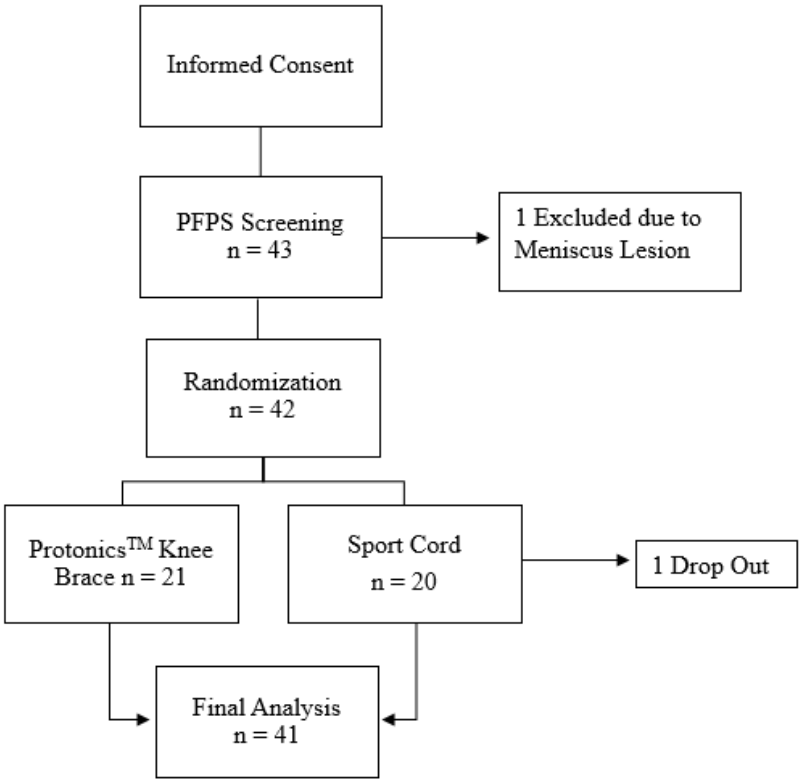

Figure 2. Demonstration of seated hamstring curl with Protonics™ knee brace.

Figure 3. Demonstration of prone hamstring curl with sport cord.

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