

Impairment-Based Rehabilitation With Patterned Electrical Neuromuscular Stimulation and Lower Extremity Function in Individuals With Patellofemoral Pain: A Preliminary Study

Neal R. Glaviano, PhD, ATC*; Ashley N. Marshall, PhD, ATC†; L. Colby Mangum, PhD, ATC‡; Joseph M. Hart, PhD, ATC, FNATA, FACSM§; Jay Hertel, PhD, ATC, FNATA§; Shawn Russell, PhD§; Susan A. Saliba, PhD, PT, ATC, FNATA¶

*College of Health and Human Services, School of Exercise and Rehabilitation Sciences, University of Toledo, OH; †Department of Interdisciplinary Health Sciences, A.T. Still University, Mesa, AZ; ‡College of Health Professions and Sciences, University of Central Florida, Orlando; §Department of Orthopedic Surgery and ¶Department of Kinesiology, University of Virginia, Charlottesville

Context: Patellofemoral pain (PFP) is a chronic condition that presents with lower extremity muscle weakness, decreased flexibility, subjective functional limitations, pain, and decreased physical activity. Patterned electrical neuromuscular stimulation (PENS) has been shown to affect muscle activation and pain after a single treatment, but its use has not been studied in a rehabilitation trial.

Objective: To determine the effects of a 4-week impairment-based rehabilitation program using PENS on subjective function, pain, strength, range of motion, and physical activity in individuals with PFP.

Design: Randomized controlled trial.

Setting: Laboratory.

Patients or Other Participants: A total of 21 patients with PFP (5 males, 16 females; age = 23.4 ± 7.6 years, height = 168.0 ± 7.5 cm, mass = 69.0 ± 19.5 kg).

Intervention(s): Participants completed a 4-week supervised rehabilitation program in conjunction with random assignment to receive PENS or sham treatments.

Main Outcome Measure(s): Subjective function, pain, strength, range of motion, and physical activity levels were assessed prerehabilitation and postrehabilitation. Subjective

function and pain were also assessed at 6 and 12 months postrehabilitation. Repeated-measures analyses of variance and Tukey post hoc testing were conducted with $\alpha \leq .05$. We calculated Cohen *d* effect sizes with 95% confidence intervals.

Results: Both groups had statistically and clinically meaningful differences in subjective function, pain, strength, range of motion, and activity level after 4 weeks of impairment-based rehabilitation. Improved subjective function was observed in both groups at 6 and 12 months after the interventions. The PENS group had improvements in current pain for all 3 postrehabilitation times compared with baseline measures.

Conclusions: An impairment-based intervention effectively improved subjective function, pain, strength, range of motion, and physical activity levels in individuals with PFP. Participants who received PENS in addition to the rehabilitation program had improved current pain at 6 and 12 months postrehabilitation compared with baseline scores.

Trial Registration: ClinicalTrials.gov identifier: NCT02441712

Key Words: knee, lower extremity, anterior knee pain

Key Points

- Patterned electrical neuromuscular stimulation used with a 4-week impairment-based rehabilitation program did not improve clinical measures more than a sham treatment.
- Current pain improved from prerehabilitation to postrehabilitation in patients receiving patterned electrical neuromuscular stimulation.
- An impairment-based rehabilitation program improved subjective and objective function in individuals with patellofemoral pain.
- Clinicians should focus on progressive rehabilitation targeting individual impairments to improve subjective and objective function in individuals with patellofemoral pain.

Patellofemoral pain (PFP) is one of the most commonly treated pathologic knee conditions seen in the general population,¹ active individuals,² and military personnel.³ It accounts for 7% of all diagnoses in patients seeking medical care and up to 25% of all treatment for knee-related injuries in sports medicine clinics.^{1,2} Whereas PFP is frequently seen in clinical practice, the cause of this chronic condition is unknown. Patients with PFP have retropatellar or peripatellar pain during common functional tasks, such as prolonged sitting, kneeling, jumping, and squatting. These tasks often produce pain due to increased stress placed on the patellofemoral joint.⁴

Individuals with a diagnosis of PFP often experience debilitating consequences that negatively affect their daily activities. Decreased physical activity due to pain is commonly seen in the short term after diagnosis.⁵ Muscle weakness and soft tissue restrictions have been noted in cohorts of individuals with PFP when compared with healthy counterparts.⁶⁻⁹ Weakness in the quadriceps and gluteus medius muscles have been documented during strength assessment and theorized to contribute to altered movement in a variety of functional tasks.^{6,10} These symptoms also negatively influence subjective function, as a linear relationship between decreased strength and increased pain for self-reported knee function has been found.¹¹

The long-term consequences of this pathologic condition are one of the challenges in treating PFP. Up to 90% of all individuals with PFP present with chronic subjective impairments and pain for up to 16 years after the initial diagnosis.^{12,13} The chronicity of this condition may be a predisposing factor for developing patellofemoral osteoarthritis.¹⁴ These alarming recurrence rates suggest that current treatment interventions might not be sufficient to improve long-term outcomes for PFP, possibly due to the heterogeneous presentation of PFP symptoms.

Interventions to address muscle weakness and soft tissue restriction are frequently used in clinical practice.¹⁵⁻²⁰ Strengthening exercises often focus on the quadriceps and gluteus medius muscles with a variety of knee-extension, hip-abduction, and hip-external-rotation tasks.¹⁸⁻²⁰ One concern when strengthening these muscles in patients with PFP is inhibition,²¹ which prevents patients from reaching their full capacity for muscular contraction. Neuromuscular electrical stimulation (NMES) is a treatment that clinicians use to overcome this muscular inhibition and promote neuromuscular reeducation of the atrophied or weakened muscles. Whereas NMES has been used with rehabilitation for individuals with PFP, this intervention typically targets only the quadriceps.^{22,23} In addition to this focus on a singular muscle, NMES has been associated with patient discomfort, muscle fatigue, and lack of functional applications.²⁴

To overcome these concerns, novel forms of electrical stimulation have been developed to improve clinical outcomes. Patterned electrical neuromuscular stimulation (PENS) is a treatment that delivers a rhythmic stimulus targeting the vastus medialis oblique and gluteus medius, key muscles in PFP rehabilitation programs.²⁵ The precise stimulus to these muscles has been theorized to replicate normal agonist-antagonist-agonist firing patterns based on healthy electromyographic activity.²⁵ After a single session

Table 1. Inclusion and Exclusion Criteria

Criteria
Inclusion
Nontraumatic peripatellar or retropatellar pain >3 mo
Worst pain over last week >3/10 assessed by visual analog scale
Pain with ≥ 2 of the following activities:
Stair ambulation
Running
Jumping
Prolonged sitting
Quadriceps contraction
Kneeling
Pressure over the patella
Exclusion
Previous knee surgery
Ligamentous instability defined by orthopaedic special tests (anterior and posterior drawer, valgus and varus stress test)
Additional source of anterior knee pain (eg, tendinitis, bursitis, patellar subluxation)
Lower extremity or back injury or concussion in the year before the study

of PENS intervention among individuals with PFP, researchers^{26,27} found improvements in lower extremity electromyographic activity, lower extremity kinematics, and pain. However, using PENS in combination with a rehabilitation program has not been evaluated among this population. Therefore, the purpose of our study was to evaluate changes in subjective assessments of function and pain, lower extremity strength, range of motion (ROM), and activity levels immediately after a 4-week impairment program, with or without PENS, among individuals with PFP. We also evaluated subjective function and pain at 6 and 12 months postintervention to assess long-term outcomes in these patients with PFP. We hypothesized that improvements in subjective and objective function after the impairment-based rehabilitation program would be present in both groups, with greater improvements in those who also received the PENS treatment.

METHODS

Participants

Volunteers were 21 patients with PFP (5 males, 16 females; age = 23.4 ± 7.6 years, height = 168.0 ± 7.5 cm, mass = 69.0 ± 19.5 kg) who were recruited from the local university, community, and orthopaedic clinics. The diagnosis of PFP was determined during the study screening via a score of less than 85% on the Anterior Knee Pain Scale and evaluation by a certified athletic trainer (AT) to assess whether volunteers met the inclusion or exclusion criteria²⁸ (Table 1). Volunteers were also screened for contraindications to electrical stimulation: biomedical device implants, history of neuropathy, hypersensitivity to electrical stimulation, lower extremity muscular abnormality, or active infection in the lower limb. If they presented with bilateral PFP, the limb they identified as having the more affected knee was selected for all testing, interventions, and analyses. Participants were randomized to a PENS ($n = 11$) or sham ($n = 10$) group. All participants provided written informed consent, and the

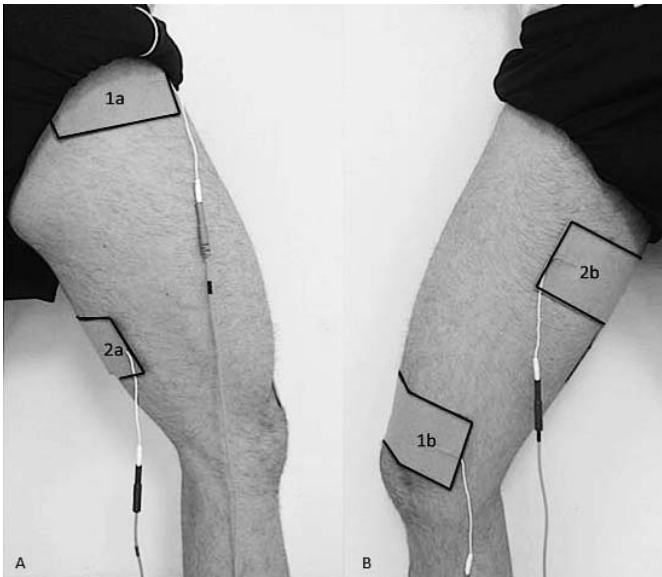


Figure 1. Patterned electrical neuromuscular stimulation electrode setup. Channel 1: 1a, gluteus medius; 1b, vastus medialis oblique. Channel 2: 2a, hamstrings muscle group; 2b, adductor muscle group. A, Posterolateral view. B, Anteromedial view. Reprinted with permission. Glaviano NR, Saliba SA. Immediate effect of patterned electrical neuromuscular stimulation on pain and muscle activation in individuals with patellofemoral pain. *J Athl Train.* 2016;51(2):118–128.

University of Virginia Institutional Review Board for Health Science Research approved the study.

Instruments

We administered PENS treatments using the Omnistim FX² (Accelerated Care Plus, Reno, NV). The device uses a 50-Hz pulse frequency, 70- μ s phase duration, and 200-millisecond stimulus train with an asymmetric biphasic square-waved stimulus. Alternating rhythmic contractions were generated using 2 stimulation patterns to target the agonist muscles (vastus medialis oblique and gluteus medius) and antagonist muscles (hamstrings and adductors; Figure 1). Four 3- \times 5-in (7.62- \times 12.70-cm) self-adherent electrodes were placed over these muscles, as suggested by the manufacturer, to deliver a 200-millisecond stimulus to the agonist muscles, a 200-millisecond stimulus to the antagonist muscles, and a 120-millisecond stimulus to the agonist muscles. Using concealed envelopes, we randomized participants into a true PENS group or a sham group. To achieve a strong motor response during the treatment, we increased the stimulus intensity for the PENS group. The sham-group participants received a minimal stimulation treatment (1 mA) during which all the machine's lights and timers were operating and visible to the participants, and they were informed that they would receive a subsensory stimulation treatment.^{26,27} Treatment setups for all participants were identical, and 15 minutes of the intervention were administered before therapeutic exercise during each rehabilitation session.

Procedures

Our participants were part of a larger double-blinded randomized controlled study on neuromuscular and gait

factors in patients with PFP. Participants eligible for study enrollment attended an initial laboratory assessment for prerehabilitation data collection. A single researcher (N.R.G.) conducted all prerehabilitation and postrehabilitation assessments of subjective function, strength, ROM, and activity level but was blinded to the allocation and treatment intervention.

Subjective Function. During the initial session, patient-reported outcome measures were collected before the objective measurements (Figure 2). The questionnaires (Anterior Knee Pain Scale [AKPS], Activities of Daily Living Scale [ADLS], Fear-Avoidance Beliefs Questionnaire-Knee [FABQ], Lower Extremity Functional Scale [LEFS], visual analog scale (VAS) for current [VAS-C] and worst [VAS-W] pain in the last week were collected to evaluate the function and impairments of the participants. These scales have been shown to be valid and reliable assessments among patients with PFP.^{29,30} The VAS-C and VAS-W in the last 24 hours were also collected on separate pieces of paper. *No pain* and *Worst pain imaginable* were at opposite ends of a 10-cm line, and participants were instructed to use a pen to make vertical marks for their pain levels.

Strength. Lower extremity strength of the hip and knee was assessed using a handheld dynamometer (Accelerated Care Plus). Force measurements were collected over three 5-second maximal voluntary isometric contractions for knee flexion, knee extension, hip abduction, hip internal and external rotation, hip extension with knee extension, and hip extension with knee flexion using standard methods.^{31,32} The “make” methods were used for all strength testing, with participants generating a maximal contraction over 2 seconds before the 5-second maximum hold for each muscle of interest. Participants were provided oral instructions and a practice trial. The average force in newtons of the 3 trials was averaged and normalized to the participant's body mass in kilograms. Excellent reliability (intraclass correlation coefficient [3,3] = 0.96–0.98) has been established for lower extremity strength testing.³³

Range of Motion. Range of motion of the hip, knee, and ankle was measured using both a 12-in (30.48-cm) International Standards of Measurement goniometer and a bubble inclinometer (Fabrications Enterprises Inc, White Plains, NY). Data from an average of 2 trials were collected for all assessments. Dorsiflexion was assessed via goniometer with the participant in a straight-knee, long-sitting position. Hamstrings flexibility was assessed during a supine straight-leg-raise test using the bubble inclinometer on the distal tibia.²⁹ With participants positioned prone, we evaluated quadriceps flexibility using a knee-flexion movement with the bubble inclinometer placed on the distal tibia. For the iliotibial (IT) band examination, participants were positioned side lying, and a bubble inclinometer was placed on the lateral knee joint.²⁹ Excellent reliability (intraclass correlation coefficient = 0.91–0.97) has been established for assessing ROM in individuals with PFP.³⁴

Activity Level. Participants were provided a FitBit Charge HR (FitBit Inc, San Francisco, CA) activity band at the end of the initial assessment. They were instructed to wear the band on their self-reported nondominant wrist at all times during the study, except while charging and showering, and to not alter their normal activity levels.³⁵ Each activity monitor was assigned an individual account

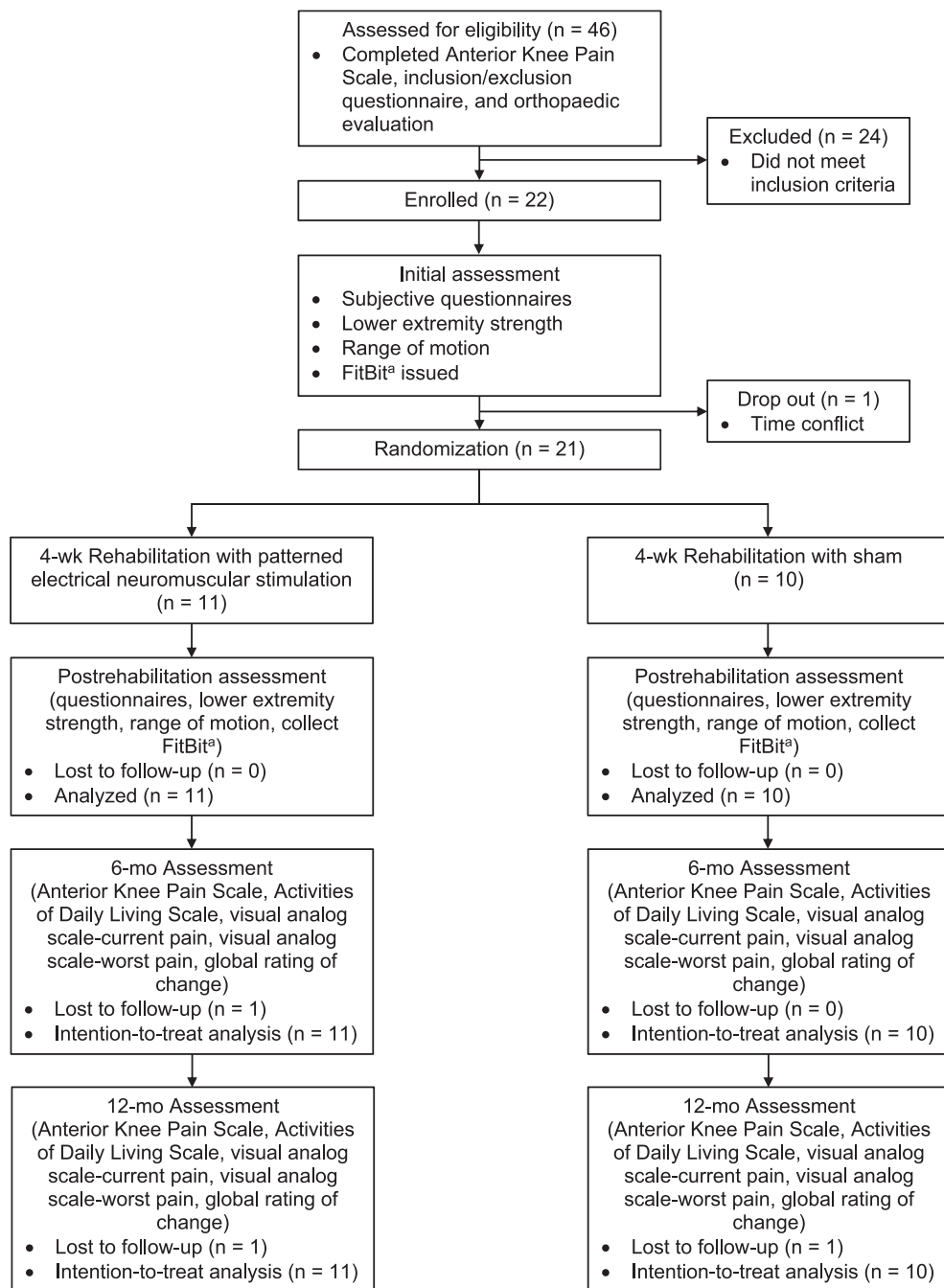


Figure 2. Study flow chart. ^a FitBit Charge HR (FitBit Inc, San Francisco, CA).

user name that was accessible only by the research team. The FitBit was synchronized each week via Bluetooth (Bluetooth SIG, Inc, Kirkland, WA) using the FitBit Connect application. Activity levels for each participant were exported from the FitBit Web site each week.

Rehabilitation Protocol

Rehabilitation was initiated within 96 hours after the initial assessment. Participants completed 12 rehabilitation sessions, which were administered as 3 sessions of supervised rehabilitation per week for 4 weeks. A single certified AT (A.N.M.) with more than 7 years of clinical experience supervised all rehabilitation sessions with the

PENS or sham PENS treatment for the duration of the study. Participants scheduled their rehabilitation sessions with this research team member for 3 sessions per week, with no more than 2 consecutive sessions. We instructed all participants to complete strengthening exercises of the knee, hip, and core and then assessed individual impairments for ROM, patellar mobility, and pronated foot.³⁶ Individual ROM, mobility, and foot-pronation impairments were defined by the objective thresholds reported by Selfe et al.³³ Patients with individual objective measurements that were less than the defined thresholds were included within the impairment-based programs. The duration of treatment was approximately 1 hour per rehabilitation session and consistent among treatment groups.

Table 2. Rehabilitation Program

Weeks	Exercise	Sets	No. of Repetitions or Time
1–2	4-way Straight-leg raise	2	10 repetitions
	Seated knee flexion and extension	2	10 repetitions
	Wall squats	2	10 repetitions
	Isometric hip abduction and external rotation	2	10 repetitions
	Clam shells	2	10 repetitions
	Pelvic tilt prone	2	20 s
	Pelvic tilt on Swiss ball	2	20 s
3–4	Single-legged balance (eyes open)	3	30 s
	Single-legged balance (eyes closed)	3	30 s
	4-way Straight-leg raise	3	10 repetitions
	Seated knee flexion and extension	3	10 repetitions
	Wall squats	3	10 repetitions
	Step-ups and step-downs	3	10 repetitions
	Lateral rotation in closed kinetic chain	3	10 repetitions
	Pelvic drops	3	10 repetitions
	Clam shells	3	10 repetitions
	Planks (anterior and lateral)	3	30 s
	Trunk extension on Swiss ball	3	10 repetitions
	Single-legged balance (eyes open)	3	30 s
	Single-legged balance (eyes closed)	3	30 s
	Single-legged squat with mirror training	3	10 repetitions
	Lunge with mirror training	3	10 repetitions
	Single-legged deadlift with mirror training	3	10 repetitions

The lone difference in the rehabilitation sessions was the administration of the PENS or sham treatment, which was conducted before each session's exercises. Before study enrollment, we used a random number generator (Excel; Microsoft Corp, Redmond, WA) to randomize the assignment of PENS or sham treatments for all participants. A 4-block randomization scheme was performed with group allocation concealed in envelopes.

The rehabilitation program was a modification of exercises previously described for individuals with PFP.¹⁸ Strengthening exercises and balance training were completed throughout the study, whereas functional retraining tasks were introduced on the seventh visit and performed for the remainder of the study (Table 2). Participants were instructed to perform strengthening exercises for a total of 4 seconds: 2 seconds each for the concentric and eccentric portions. They rested for 1 minute between sets and approximately 2 minutes between exercises. All strengthening exercises were individualized to a percentage of the maximal strength measure collected during the initial testing session (Appendix). This protocol was designed to challenge all participants from the start of the rehabilitation program depending on their lower extremity function. All exercises were progressed throughout the rehabilitation program based on the clinical judgment of the AT, with the goal of repetition to failure without increased pain. We assessed pain during each rehabilitation session to provide additional insight into daily modifications of the program to mimic clinical practice. Rehabilitation compliance and use of the activity band were also monitored 3 times per week during the sessions and recorded by the clinician.

Follow-Up Testing

Participants returned to the laboratory within 72 hours of the final rehabilitation session. They completed the same

subjective assessment consisting of the patient-reported outcome measures, lower extremity strength, and ROM. Activity levels during the 4-week rehabilitation period were collected from the FitBit. In addition, the global rating of change (GROC) questionnaire was administered to all patients to evaluate the change in their knee function since beginning the rehabilitation study. Printed handouts of the exercises performed during the intervention study were provided to all participants. Participants were contacted at 6 and 12 months after their last rehabilitation sessions to assess subjective function on the AKPS, ADLS, and VAS questionnaires and the GROC. They were also asked if they were still performing rehabilitation exercises and if so, the estimated frequency, and if they had received additional medical care for their PFP.

Statistical Analysis

Baseline anthropometric, subjective, and objective characteristics were compared between groups. Dependent variables were evaluated for normality with skewness, kurtosis, and the Levene test for normal variance. We conducted a mixed-model analysis of variance with repeated measures for self-reported function, pain, ROM, strength, and activity level. Tukey post hoc testing was performed to identify interactions between groups at the 2 time points. The within-subjects factor was time (prerhabilitation and postrehabilitation), and the between-subjects factor was group (PENS and sham). We calculated Cohen *d* effect sizes to examine the magnitude of change in dependent variables for the pooled postrehabilitation means of both groups compared with the pooled prerhabilitation means of both groups. Thresholds for effect sizes were set at *trivial* (<0.20), *small* (0.20–0.49), *moderate* (0.50–0.79), and *large* (≥ 0.80).³⁷ An intention-to-treat analysis was undertaken for the longitudinal data, using a last-value-carried-forward technique to account for missing data.³⁸ The α level was set a priori at $\leq .05$ for all statistical analyses. Data were analyzed using SPSS (version 20.0; IBM Corp, Armonk, NY).

RESULTS

The dependent variables, with the exception of hamstrings flexibility and duration of symptoms, were normally distributed based on skewness, kurtosis, and normal variance as assessed by the Levene test ($P > .05$). Between-groups comparisons of baseline anthropometric, subjective, and objective characteristics are presented in Table 3. All participants completed all 12 supervised rehabilitation sessions, as allocated with or without PENS, over a 4-week period (32.5 ± 2.4 days). Impairments assessed during the 4-week impairment-based program for all participants involved stretching (76%, $n = 16$), joint mobility (10%, $n = 2$), and a pronated foot (0%, $n = 0$). Individual muscles stretched included the quadriceps (63%, $n = 9$), hamstrings (75%, $n = 12$), IT band (50%, $n = 8$), and gastrocnemius (94%, $n = 15$).

Subjective Function

No group main effect or group-by-time interactions were identified on the AKPS, ADLS, FABQ, LEFS, or VAS-C (Table 4). We observed a main effect of time in the

Table 3. Baseline Anthropometric, Subjective, and Objective Characteristics

Characteristic	Group		P Value
	Patterned Electrical Neuromuscular Stimulation (n = 11)	Sham (n = 10)	
	Male/Female		
Sex, no.	3/8	2/8	Not applicable
	Mean ± SD		
Age, y	23.8 ± 5.6	23.0 ± 3.7	.70
Height, cm	169.1 ± 7.3	166.7 ± 7.8	.48
Mass, kg	68.2 ± 11.4	69.8 ± 19.0	.81
Duration, mo	26.3 ± 26.3	23.0 ± 27.8	.77
Activity level, average No. of steps per day	7963.7 ± 2949.0	8970.7 ± 1968.7	.37

combined groups' subjective function postrehabilitation: AKPS (prerehabilitation = 76.3 ± 7.5, postrehabilitation = 87.1 ± 7.7; $P < .001$), ADLS (prerehabilitation = 79.3 ± 10.0, postrehabilitation = 88.0 ± 5.5; $P = .001$), FABQ (prerehabilitation = 13.3 ± 4.4, postrehabilitation = 10.0 ± 4.7; $P = .004$), LEFS (prerehabilitation = 65.6 ± 8.5, postrehabilitation = 73.1 ± 4.6; $P < .001$), VAS-W (prerehabilitation = 4.9 ± 1.7, postrehabilitation = 2.1 ± 1.6; $P < .001$), and VAS-C (prerehabilitation = 1.3 ± 1.5, postrehabilitation = 0.6 ± 0.6; $P = .04$). We noted large

effect sizes on the AKPS, ADLS, LEFS, and VAS-W scores and moderate effect sizes on the FABQ and VAS-C scores (Table 4). The average GROC score immediately postrehabilitation for the combined groups was 4.4 ± 1.8, which equates to *moderately better*.

At the 6- and 12-month follow-ups, 95% and 90% of participants, respectively, responded. One participant in the PENS group did not respond at either follow-up time, and 1 participant from the sham group did not respond at the 12-month point. Both groups had improved in subjective

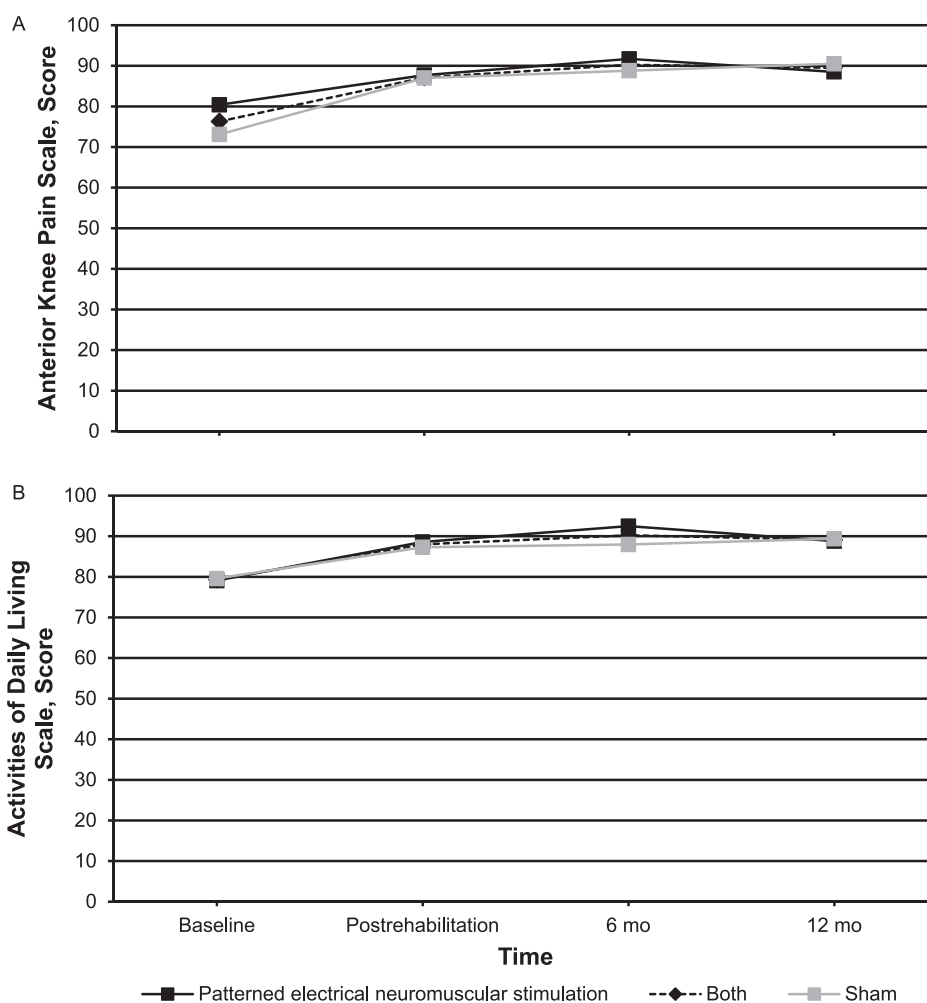


Figure 3. Long-term subjective function follow-up for the patterned electrical neuromuscular stimulation group, sham group, and both groups. A, Anterior Knee Pain Scale. B, Activities of Daily Living Scale. C, Visual analog scale-current pain. D, Visual analog scale-worst pain. Continued on next page.

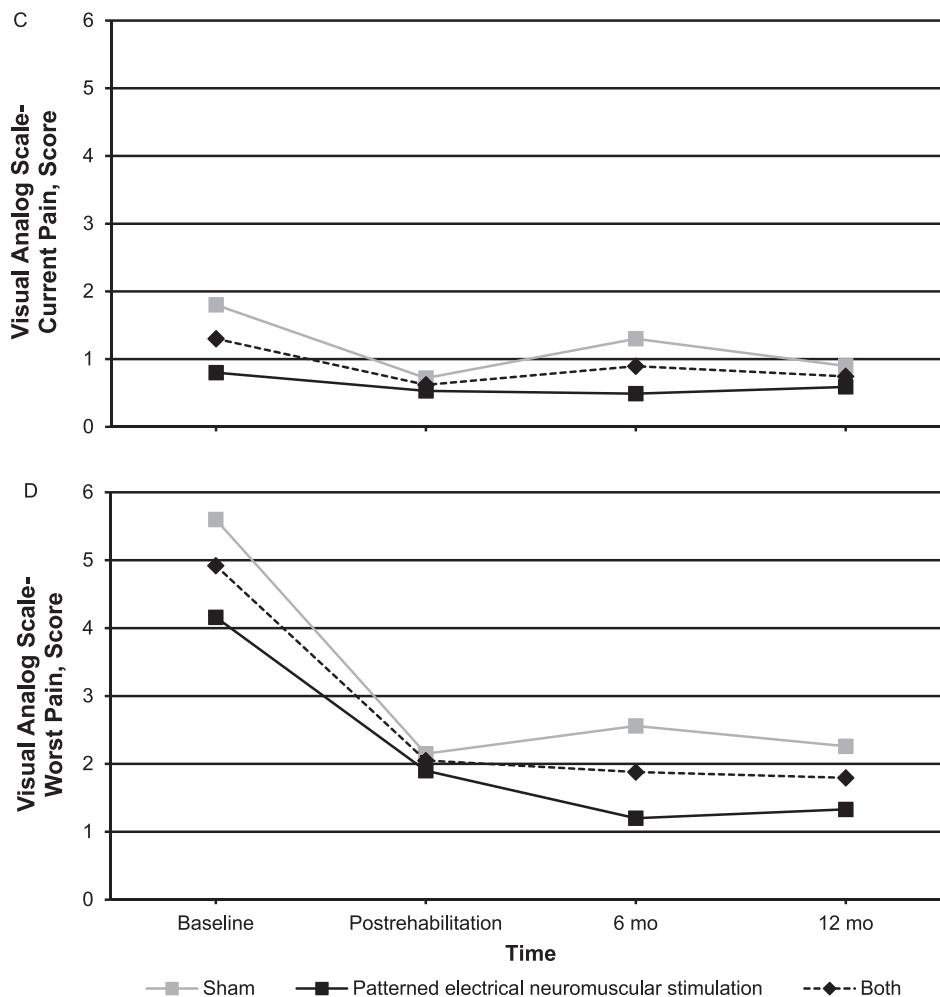


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function as assessed by the AKPS and ADLS at both 6 and 12 months compared with their baseline measurements (Figure 3). The PENS group had statistically different and clinically important improvements in their VAS-C from baseline (baseline = 1.4 ± 0.7) to postrehabilitation (0.5 ± 0.7 ; $P = .02$, Cohen d [95% confidence interval (CI)] = 1.21 [0.26, 2.17]), 6 months (0.5 ± 0.5 ; $P = .005$, Cohen d [95% CI] = 1.46 [0.47, 2.44]), and 12 months (0.6 ± 0.7 ; $P = .02$, Cohen d [95% CI] = 1.13 [0.18, 2.07]). Pain in the sham group improved immediately postrehabilitation but not at the 6- and 12-month follow-ups. At 6 months, only 4 individuals would have met the inclusion criteria based on their AKPS scores: 1 in the PENS group and 3 in the sham group. At 6 months, only 4 individuals reported occasionally performing some of the exercises conducted during the intervention: 1 in the PENS group and 3 in the sham group. Six individuals would have met the inclusion criteria at 12 months: 3 individuals in each group. At that time, only 1 participant in the sham group reported performing exercises and only when having knee pain.

Strength

Main effects of time demonstrated improvements in knee-flexion, hip-abduction, hip external-rotation, hip internal-rotation, and hip-extension strength (Table 5). No

main effects of group were found for any strength measures. We observed group-by-time interactions, with an increase in hip internal-rotation strength and a trend toward increased knee-flexion strength in the sham group. Combined strength differences between prerehabilitation and postrehabilitation were present in hip abduction (prerehabilitation = 2.9 ± 0.8 N/kg, postrehabilitation = 4.5 ± 2.5 N/kg; $P = .006$), hip internal rotation (prerehabilitation = 1.4 ± 0.5 N/kg, postrehabilitation = 1.7 ± 0.4 N/kg; $P = .007$), hip external rotation (prerehabilitation = 1.5 ± 0.4 N/kg, postrehabilitation = 3.2 ± 3.5 N/kg; $P = .03$), and hip extension (prerehabilitation = 3.5 ± 1.3 N/kg, postrehabilitation = 4.5 ± 1.3 N/kg; $P = .001$). We observed trends toward differences in both knee flexion (prerehabilitation = 2.2 ± 0.6 N/kg, postrehabilitation = 2.4 ± 0.7 N/kg; $P = .06$) and extension (prerehabilitation = 3.9 ± 1.5 N/kg, postrehabilitation = 4.9 ± 2.9 N/kg; $P = .06$).

Range of Motion

Range of motion of the quadriceps, hamstrings, IT band, and gastrocnemius showed main effects of time (Table 6). No main effects of group or group-by-time interactions were found in any ROM measures. We observed improvements in lower extremity ROM in the combined groups

Table 4. Prehabilitation and Postrehabilitation Self-Reported Subjective Function and Cohen d Effect Sizes With 95% CIs

Patient-Reported Outcome Measure	Group, Mean ± SD				P Value			Pooled Prehabilitation-Postrehabilitation Cohen d Effect Size (95% CI) ^a
	Patterned Electrical Neuromuscular Stimulation		Sham		Time Main Effect	Group Main Effect	Group × Time Interaction	
	Prehabilitation	Postrehabilitation	Prehabilitation	Postrehabilitation				
Visual analog scale-current pain in the last week score	0.8 ± 0.8	0.5 ± 0.6	1.8 ± 2.0	0.7 ± 0.6	.03 ^b	.16	.14	-0.58 (-1.21, 0.04)
Visual analog scale-worst pain in the last week score	4.2 ± 1.1	1.9 ± 2.0	5.6 ± 1.2	2.2 ± 1.2	<.001 ^b	.09	.39	1.92 (1.17, 2.67)
Anterior Knee Pain Scale score	80.4 ± 5.0	87.2 ± 9.7	73.1 ± 7.9	87.0 ± 5.6	<.001 ^b	.20	.05	1.40 (0.74, 2.11)
Activities of Daily Living Scale score	79.1 ± 8.5	88.6 ± 5.9	79.6 ± 12.0	87.3 ± 5.2	.002 ^b	.80	.81	1.07 (0.42, 1.73)
Fear-Avoidance Beliefs Questionnaire-Knee score	12.4 ± 5.3	8.6 ± 5.2	14.4 ± 3.6	11.4 ± 3.8	.005 ^b	.19	.71	-0.73 (-1.36, -0.09)
Lower Extremity Functional Scale score	67.0 ± 5.9	72.7 ± 4.9	64.2 ± 10.7	73.5 ± 4.6	<.001 ^b	.71	.28	1.09 (0.43, 1.75)
Global rating of change score		4.6 ± 1.8		4.2 ± 1.8		.63		

Abbreviation: CI, confidence interval.

^a Effect sizes were calculated to compare the pooled group's prehabilitation and postrehabilitation scores; a positive value denotes an increase in subjective function postrehabilitation.

^b Indicates difference ($P \leq .05$).

Table 5. Prehabilitation and Postrehabilitation Strength for the Patterned Electrical Neuromuscular Stimulation and Sham Groups and Cohen d Effect Sizes With 95% CIs

Strength Measure	Group, N/kg (Mean ± SD)				P Value			Pooled Prehabilitation-Postrehabilitation Cohen d Effect Size (95% CI) ^a
	Patterned Electrical Neuromuscular Stimulation		Sham		Time Main Effect	Group Main Effect	Group × Time Interaction	
	Prehabilitation	Postrehabilitation	Prehabilitation	Postrehabilitation				
Knee extension	4.3 ± 1.3	5.5 ± 3.6	3.7 ± 1.7	4.3 ± 1.9	.07	.36	.48	0.41 (-0.21, 1.03)
Knee flexion	2.5 ± 0.6	2.5 ± 0.7	1.7 ± 0.4	2.4 ± 0.6	.045 ^b	.26	.05	0.31 (-0.30, 0.93)
Hip abduction	3.0 ± 0.8	4.6 ± 2.9	2.9 ± 0.8	4.3 ± 2.3	.007 ^b	.74	.84	0.85 (0.21, 1.49)
Hip external rotation	1.7 ± 0.4	3.7 ± 4.4	1.4 ± 0.5	2.8 ± 2.5	.04 ^b	.50	.67	0.66 (0.03, 1.29)
Hip internal rotation	1.7 ± 0.5	1.7 ± 0.4	1.2 ± 0.4	1.7 ± 0.4	.002 ^b	.23	.006 ^b	0.67 (0.04, 1.30)
Hip extension	3.5 ± 1.1	4.2 ± 1.1	3.7 ± 1.5	4.8 ± 1.4	<.001 ^b	.45	.47	0.70 (0.08, 1.34)

Abbreviation: CI, confidence interval.

^a Effect sizes were calculated to compare the pooled group's prehabilitation and postrehabilitation scores; a positive value denotes an increase in strength postrehabilitation.

^b Indicates difference ($P \leq .05$).

Table 6. Prerehabilitation and Postrehabilitation Range-of-Motion Measurements and Cohen d Effect Sizes With 95% CIs

Muscle	Group, ° (Mean ± SD)						P Value	Group × Time Interaction	Pooled Prerehabilitation-Postrehabilitation Cohen d Effect Size (95% CI) ^a
	Patterned Electrical Neuromuscular Stimulation			Sham					
	Prerehabilitation	Postrehabilitation	P	Prerehabilitation	Postrehabilitation	P			
Quadriceps	134.9 ± 8.6	141.2 ± 3.6	135.0 ± 7.8	136.5 ± 8.9	.03 ^b	.45	.17	0.54 (-0.08, 1.16)	
Hamstrings	81.6 ± 29.7	97.7 ± 13.6	83.9 ± 14.8	91.8 ± 13.3	.01 ^b	.81	.34	0.71 (0.09, 1.35)	
Iliotibial band	31.4 ± 10.2	32.4 ± 9.6	23.0 ± 15.2	35.9 ± 4.4	.03 ^b	.51	.07	0.56 (-0.06, 1.19)	
Gastrocnemius	14.0 ± 5.8	15.4 ± 4.6	14.1 ± 7.9	20.0 ± 4.3	.03 ^b	.28	.18	0.55 (-0.07, 1.18)	

Abbreviation: CI, confidence interval.

^a Effect sizes were calculated to compare the pooled group's prerehabilitation and postrehabilitation scores; a positive value denotes an increase in range of motion after rehabilitation.

^b Indicates difference ($P \leq .05$).

from prerehabilitation to postrehabilitation: quadriceps (prerehabilitation = 134.8 ± 2.5 , postrehabilitation = 138.8 ± 2.1 ; $P = .03$), hamstrings (prerehabilitation = 81.8 ± 7.2 , postrehabilitation = 94.8 ± 4.2 ; $P = .01$), IT band (prerehabilitation = 28.0 ± 4.0 , postrehabilitation = 34.2 ± 3.4 ; $P = .044$), and gastrocnemius (prerehabilitation = 14.4 ± 2.2 , postrehabilitation = 17.7 ± 1.5 ; $P = .04$).

Activity Level

A main effect of time (both $P = .040$) was identified in steps per week for the PENS (prerehabilitation = 8660.2 ± 1932.4 , postrehabilitation = 9593.6 ± 2350.5) and sham (prerehabilitation = 8970.7 ± 1968.7 , postrehabilitation = 10128.6 ± 2987.7) groups. No main effects of group ($P = .69$) or group-by-time interactions ($P = .56$) were observed.

DISCUSSION

The purpose of our study was to evaluate the effects of a 4-week impairment-based rehabilitation program with or without PENS on subjective and objective measures in individuals with PFP. We did not observe differences in subjective function, strength, ROM, or activity levels between the PENS and sham groups. However, all individuals with PFP demonstrated improvements in subjective function, pain, knee and hip strength, lower extremity ROM, and activity level after the impairment-based rehabilitation. Individuals who received an impairment-based rehabilitation program with PENS had improved pain at 6 and 12 months postrehabilitation.

Subjective Function

At postrehabilitation, we found improvements in the AKPS,^{17,39} ADLS,⁴⁰ and LEFS^{39,41} scores similar to other rehabilitation programs for individuals with PFP. Subjective function was not different between groups over the 4-week rehabilitation program. However, combined subjective function improved on all 3 scales: AKPS (10.8 points), ADLS (8.7 points), and LEFS (7.5 points). These values improved and were greater than the minimal clinically important change threshold of the AKPS (8 points) and ADLS (7 points) but not the LEFS (9 points).^{30,39} The clinically meaningful improvements and large effect sizes that did not cross zero suggested that both interventions effectively improved subjective function in individuals with PFP. Whereas we expected PENS to improve the ability to gain strength and enhance self-reported function, perhaps the magnitude of change from the exercises made it difficult to detect the effect of any additional treatment.

Although the AKPS and LEFS are used more conventionally in the PFP literature, the ADLS produced some of the strongest psychometric properties both for evaluating the presence of PFP and assessing responsiveness to the interventions. Esculier et al⁴⁰ reported that runners with PFP who completed an 8-week rehabilitation program improved their ADLS scores by 17.8 points, compared with 8.7 points in our participants. Whereas a multimodal rehabilitation program was used in both studies to address the individual needs of patients, our rehabilitation program lasted only half as long as the rehabilitation program for runners. In addition to pursuing the longer rehabilitation program, the runners reported greater subjective impair-

ments (15 points less on the ADLS), which may have provided the potential for greater improvements during rehabilitation.

An impairment-based program with or without PENS also produced clinically important improvements in subjective function at 6 and 12 months. Changes in the AKPS and ADLS scores were greater than the minimal clinically important change threshold at 6 and 12 months. We observed improvements that were almost identical to those reported by Hamstra-Wright et al,⁴² who compared AKPS and VAS scores after knee-focused or hip-focused rehabilitation for patients with PFP immediately and at 6 months post-intervention. Fukada et al³⁸ found similar improvements at 6 and 12 months in subjective function and decreased pain in patients with PFP who completed a combined hip and knee intervention but not an isolated knee-strengthening program. Comparing our results with those of Fukada et al,³⁸ a more comprehensive rehabilitation program that targeted multiple muscles appeared to more effectively improve subjective function and pain 1 year postrehabilitation.

Using PENS with an impairment-based program effectively improved long-term pain levels in those with PFP. Whereas we evaluated only subjective function and pain at the 6- and 12-month time points, greater improvements in pain levels may allow these patients to be more physically active and improve their overall quality of life. Researchers^{26,27} demonstrated that using PENS in individuals with PFP resulted in immediate improvements in pain, gluteus medius muscle activity, and lower extremity kinematics. One potential hypothesis for long-term improvements in the PENS group may be the cumulative effect of PENS on lower extremity muscle activity over the 4-week intervention. Currently, PFP is attributed to increased stress on the joint, so improved gluteal muscle activity could result in improved frontal-plane motion and decreased joint stress. However, this is speculative, as we did not assess lower extremity biomechanics.

Strength

We observed baseline strength values similar to those reported by Ferber et al¹⁵; however, we saw greater improvements in postrehabilitation strength of the knee and hip muscles. A few reasons may exist for the difference between our findings and those of Ferber et al,¹⁵ whose patients completed 6-week knee- or hip-strengthening programs. Whereas our rehabilitation program was 2 weeks shorter, we administered more exercises during each rehabilitation session than Ferber et al,¹⁵ who administered as few as 3 exercises per session. Our study design was intended to improve the external validity by mimicking clinical practice. All of our participants completed lower extremity strength-training exercises for the duration of the protocol, as such training is considered the standard of care for patients with PFP. Our protocol was developed to individualize treatment, with a percentage of the participants' baseline strength-assessment values selected to challenge them from their initial visits.

Range of Motion

Improvements in ROM were observed for the quadriceps, hamstrings, IT band, and gastrocnemius independent of group intervention. Lower extremity ROM is commonly

prescribed in rehabilitation programs^{20,43,44} but is rarely evaluated as a dependent variable. We noted the largest soft tissue restriction in the hamstrings, as reflected by decreased hip-flexion ROM that improved by more than 10° postrehabilitation. The hamstrings play an important role in PFP: decreased flexibility has been theorized to increase quadriceps force production to complete functional tasks, which may increase stress on the patellofemoral joint.²⁹ Improvements in quadriceps, gastrocnemius, and IT band ROM were identified after this targeted intervention program. Improvements in these motions may also help decrease the stress placed on the patellofemoral joint, decreasing pain and improving subjective function.²⁹

Avraham et al⁴³ were among the few researchers to compare the effectiveness of various stretching and strengthening combinations for PFP treatment. They found that, whereas stretching improved both pain and function, greater improvement was seen in conjunction with strengthening programs. Combining multiple treatment options for the individual patient appears to improve impairments.

Activity Levels

Patients with PFP had decreased physical activity, which negatively relates to their subjective function.³⁵ We observed that 4 weeks of rehabilitation improved weekly physical activity in individuals with PFP by more than 1000 steps per day. Although this improvement appeared positive, a large discrepancy still existed between this postrehabilitation activity level and the activity levels in healthy individuals.³⁵ Physical activity has many health benefits, and investigators⁴⁵ have reported evidence of its ability to delay the development of osteoarthritis. Given that PFP may be a risk factor for patellofemoral osteoarthritis, interventions to improve activity levels in individuals with PFP should be evaluated to determine their effects on short- and long-term outcomes.

Limitations

Our study had limitations. First, we enrolled a relatively small number of participants, potentially decreasing the generalizability of the findings. Post hoc power was moderate; however, a study with a larger sample size should be conducted to further examine the effect of PENS on lower extremity clinical measures in a population with PFP. This would also allow for more advanced statistical analyses to determine which improvements may be more valuable measures for clinicians who commonly treat this condition. Second, we conducted only 4 weeks of rehabilitation, which would explain neuromuscular adaptations. Longer rehabilitation programs may be required to produce more hypertrophic gains. Third, whereas we had a true intervention group and a sham group, having a true blinded treatment for electrical stimulation is difficult in randomized trials. We could have studied a true control group, but due to the chronicity of PFP impairments, it is a safe assumption that clinical measures will not change in individuals who do not receive any treatment.

CONCLUSIONS

Using PENS in conjunction with a 4-week impairment-based rehabilitation program did not improve clinical

measures more than the sham treatment. However, clinical improvements in subjective and objective function were seen after the impairment-based rehabilitation program. Clinicians should focus on progressive rehabilitation that targets individual impairments to improve subjective and objective function in patients with PFP.

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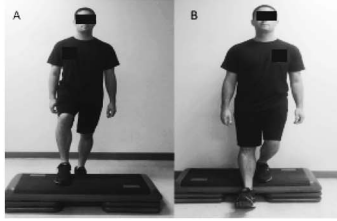


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Address correspondence to Neal R. Glaviano, PhD, ATC, College of Health and Human Services, School of Exercise and Rehabilitation Sciences, Mail Stop 119, University of Toledo, Toledo, OH 43606. Address e-mail to Neal.Glaviano@UToledo.edu.

Appendix. Rehabilitation exercises.

Exercise	Weeks	Progression Description	Illustration
4-Way straight-leg raise	1–2 3–4	2 Sets of 20 repetitions Resistance: ankle weights Initial load: 50% of 1 repetition maximum Exercise progression: increasing 0.5 kg 3 Sets of 12 repetitions Initial load: 75% of 1 repetition maximum Exercise progression: increasing 0.5 kg	
Seated knee extension and flexion (90°–45° of knee flexion)	1–2 3–4	2 Sets of 20 repetitions Resistance: weight-training device Initial load: 50% of 1 repetition maximum Exercise progression: increasing 2 to 5 kg 3 Sets of 12 repetitions Initial load: 75% of 1 repetition maximum Exercise progression: increasing 2 to 5 kg	
Wall squat (0°–60° of knee flexion)	1–2 3–4	2 Sets of 20 repetitions, with 5-s isometric contraction Progression: increasing 2-s hold 3 Sets of 12 repetitions, with 10-s isometric contraction Resistance: holding weights Initial load: 10% of body mass Progression: increasing 5% of body mass	
Step-ups (A) and –downs (B) from a 20-cm step	1–2 3–4	Not performed 3 Sets of 12 repetitions Resistance: holding weights Initial load: 10% of body mass Progression: increasing 5% of body mass	
Single-legged balance	1–4	3 Sets of 30 s Progressions: <ul style="list-style-type: none"> • Eyes opened to eyes closed • Solid surface to unstable surface • Perturbations to ball toss 	
Transversus abdominis and multifidus muscle training	1–2 3–4	Quadruped and supine (not shown) 2 Sets of 15 repetitions, with 10-s isometric contraction Sitting on the Swiss ball: 5 repetitions with 20-s isometric contraction Progression: increasing 5-s hold Not performed	

Exercise	Weeks	Progression Description	Illustration
Lateral bridge (A) and side bridge (B)	1–2	Not performed	
	3–4	5 Sets of 30 s Progression: increasing 5-s hold	
Trunk extension on a Swiss ball	1–2	Not performed	
	3–4	3 Sets of 12 repetitions Exercise progression: increasing 2 repetitions Performed with the arms crossing the thorax and progresses to hands behind the neck	
Hip abduction/lateral rotation in standing	1–2	Isometric (A) 2 Sets of 20 repetitions, with 5-s isometric contraction Exercise progression: increasing 2-s hold Hip flexion and forward trunk lean were emphasized	
	3–4	Hip lateral rotation in closed kinetic chain (B) 3 Sets of 12 repetitions Resistance: elastic band Initial load: 1 elastic resistance level lower than the 1 repetition maximum Exercise progression: increasing 1 elastic-resistance level	
Hip abduction/lateral rotation with slight knee and hip flexion in side-lying	1–2	2 sets of 20 Repetitions with 5-s isometric contraction Resistance: elastic band Initial load: 2 elastic-resistance levels lower than the 1 repetition maximum Exercise progression: increasing 1 elastic resistance level	
	3–4	3 Sets of 12 repetitions Initial load: 1 elastic-resistance level lower than the 1 repetition maximum Exercise progression: increasing 1 elastic-resistance level	

Exercise	Weeks	Progression Description	Illustration
Pelvic drop in standing	1–2 3–4	Not performed 3 Sets of 12 repetitions Resistance: ankle weight Initial load: 75% of 1 repetition maximum Exercise progression: increasing 1 to 2 kg	
Single-legged deadlift	1–2 3–4	Not performed 3 Sets of 12 repetitions Resistance: elastic band Initial load: 1 elastic-resistance level lower than the 1 repetition maximum Exercise progression: increasing 1 elastic-resistance level	
Single-legged squat	1–2 3–4	Not performed 3 Sets of 12 repetitions Resistance: elastic band Initial load: 1 elastic-resistance level lower than the 1 repetition maximum Exercise progression: increasing 1 elastic-resistance level	
Forward lunge	1–2 3–4	Not performed 3 Sets of 12 repetitions Resistance: elastic band Initial load: 1 elastic-resistance level lower than the 1 repetition maximum Exercise progression: increasing 1 elastic-resistance level	