

The Addition of the Protonics Brace System to a Rehabilitation Protocol to Address Patellofemoral Joint Syndrome

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Study Design: Randomized clinical trial.

Objectives: To investigate the clinical efficacy of the addition of the Protonics system to a standard exercise-based patellofemoral rehabilitation protocol.

Background: The Protonics system has been suggested as an intervention for patients with patellofemoral pain syndrome (PFPS). However, the effects of this system have not been compared to the effects associated with traditional exercise-based rehabilitation alone.

Methods and Measures: Seventeen of 34 females (mean age, 28 years; range, 13-55 years) diagnosed with PFPS were randomly assigned to wear the Protonics system while participating in a conventional exercise-based rehabilitation program. Functional and patient-reported outcome measures were evaluated, including Kujala score and the lateral step-up test. In addition, measurements of hip internal and external rotation, hip extension, and iliotibial band muscle length were compared between groups.

Results: Patients in both groups demonstrated improvement in Kujala score ($P < .001$), performance on the lateral step-up test ($P < .001$), and pain during the step-up test ($P < .001$) at the conclusion of the study. However, there was no difference between groups with respect to improvement in Kujala score ($P = .33$), step-up test performance ($P = .47$), or pain during the step-up test ($P = .24$). Patients using the Protonics system demonstrated greater gain in passive hip extension ($P = .023$) and increased hip external rotation motion ($P = .017$) at discharge versus patients treated with exercise alone. However, there was no difference in iliotibial band flexibility ($P = .80$) or hip internal rotation motion ($P = .09$) between groups. A greater proportion of patients in the Protonics group reported no pain with step-up testing at each 2-week interval. However, the 2.2 fewer visits required by patients in the Protonics group to meet discharge criteria did not achieve statistical significance ($P = .08$).

Conclusions: Patients using the Protonics system demonstrated a shift in available hip rotation and increased passive hip extension flexibility. However, these changes were not outside the bounds of potential measurement error and did not translate into significant functional differences from a similar group treated with exercise alone. The economic implications of an average 2.2-visit decrease in treatment sessions per patient using the Protonics system are uncertain. *J Orthop Sports Phys Ther* 2005;35:210-219.

Key Words: anterior knee pain, hip rotation, Kujala score, therapeutic exercise

Patellofemoral pain syndrome (PFPS) is considered to be the most common disorder involving the knee joint.^{4,10,29} Historically, patients with PFPS have been treated conservatively. Successful management of this condition has been reported using non-weight-bearing and weight-bearing exercises,^{4,17,28} patellar taping techniques,^{4,16} foot orthotics,⁷ and the use of biofeedback.⁴

The etiology of PFPS remains controversial. Many authors suggest that atrophy of the vastus medialis obliquus (VMO) results in lateral deviation of the patella, abnormal patellofemoral joint stress, and ultimately, PFPS.^{9,18} However, recent studies have refuted this concept.^{2,3,15,19,21,24} For example, Laprade et al¹⁵ identified no significant differences in muscle activity of the VMO and vastus lateralis (VL) for individuals with PFPS compared to healthy controls during isometric exercises. Similarly, Souza and Gross²⁴ and Cerny³ found no significant differences in VMO-VL

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electromyogram ratios between symptomatic subjects and those without complaints.

A large quadriceps angle (Q-angle) is another frequently suggested contributing factor to PFPS. The Q-angle is influenced by a number of factors including the anatomy of the quadriceps and trochlear groove, the mechanics of the foot, and the position of the tibial tubercle.¹¹ However, Hvid and Anderson¹³ suggest that this angle may be most strongly associated with excessive hip internal rotation, which displaces the trochlear groove medially, leading to lateral malalignment of the patella. Fulkerson⁹ further reports that repetitive high-frequency activities performed with a malaligned extensor mechanism may cause injury to structures including subchondral bone, lateral retinaculum, and peripatellar synovium.

The Protonics system (Inverse Technology Corporation, Lincoln, NE) 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.¹² Mechanically speaking, however, resistance to knee flexion increases hamstring activity only during non-weight-bearing activities. During weight bearing, resistance to knee flexion contributes a knee extension moment that may decrease patellofemoral joint contact force and subsequently, patellofemoral pain.

Unfortunately, at this time, the value of the addition of the Protonics system to a traditional patellofemoral exercise program remains unclear. Timm²⁷ reported a significant improvement in pain, function, and patellofemoral congruence angle for patients using the system 4 hours per day, compared to a control group that received no intervention. However, because the experimental group in Timm's²⁷ study was not compared to a group participating in a comparable exercise program, it is uncertain whether these improvements were due to the Protonics system alone or the exercises associated with use of the brace. Indeed, Timm²⁷ acknowledged that subjects in the control group might have been subject to a "Hawthorne-reverse placebo effect," in that they reported lower-than-actual scores because they did not receive any treatment for their pain.

To date, there exists no evidence to support the use of the Protonics system versus traditional rehabili-

tation techniques alone. Further, it remains unclear whether use of this system is associated with a reduction in the number of treatment sessions necessary for symptom resolution. Finally, there is no evidence that use of the system is associated with changes in such static structural measurements as hip flexibility or available passive range of motion (ROM), as advertised. Therefore, the purpose of this study was twofold. First, we intended to compare the impact of the addition of the Protonics system to a standard exercise-based patellofemoral rehabilitation protocol. As a secondary aim, we intended to examine the clinical variables suggested by the manufacturer to be affected by use of this system. Based on manufacturer expectations, we tested the hypothesis that the addition of the Protonics system to a conventional PFPS rehabilitation protocol would result in a greater decrease in pain, increase in Kujala score, and increase in performance on the lateral step-up test versus conventional PFPS rehabilitation alone. We also tested the hypothesis that, at discharge, those individuals selected to use the Protonics system would display increased hip external rotation, decreased hip internal rotation, increased iliotibial band (ITB) flexibility, and increased passive hip extension, as suggested by the manufacturer.

METHODS

Study Patients

The protocol for this study was approved by Essex Institutional Review Board, Inc. Thirty-four females exhibiting patellofemoral pain symptoms for more than 1 month (range, 1-36 months) participated in this investigation. Each patient was selected for inclusion in this study, based on an evaluation and diagnosis of PFPS by an orthopedic physician, and subsequently provided informed consent for participation in this study. All patients reported a pain level of at least 4 on a 0-to-10-point verbal pain scale (VPS) during at least 2 activities typically associated with patellofemoral pathology, such as squatting, prolonged sitting, ascending or descending stairs, walking, or running. While bilateral symptoms were not uncommon, all patients met the inclusion criteria for only 1 knee. Patients who recently experienced a traumatic injury to the knee joint or presented with signs or symptoms of a meniscus lesion or ligamentous-related pathology, as determined by the physician, were excluded from participation.

Examination

Functional Outcome Measures The functional level for each patient was evaluated using the lateral step-up

test²² at 2-week intervals and Kujala scale score¹⁴ at the beginning and conclusion of treatment. The lateral step-up test was chosen for 2 reasons. First, it is a quick and simple test that requires no special equipment and is, therefore, a practical clinical measure. Second, we felt that the weight-bearing nature of the this test makes it a reasonable choice to gauge the patient's tolerance for other weight-bearing activities traditionally affected by PFPS, such as ascending or descending stairs. Previous authors have established that the test-retest reliability of this test is high ($ICC_{2,1} = 0.90$).²² Based on the standard error of the measurement reported by Ross,²² a change of less than 2 step-ups is not considered to be a clinically meaningful change between trials. According to the procedures for this test,²² patients performed lateral step-ups as fast as possible on a 15-cm step for 15 seconds. The total number of step-ups completed during this time was recorded for analysis. Additionally, to evaluate symptoms during functional weight-bearing activities, patients were asked to report a VPS score during the step-up test at each test session. Patients in the Protonics group did not wear the brace during functional testing.

The Kujala score evaluates patellofemoral-related complaints on a 0-to-100-point scale based on pain associated with a variety of functional activities such as prolonged sitting, walking, running, and jumping. Scores closer to 100 indicate a higher overall level of function. The test-retest reliability of the Kujala scale score has also been determined to be acceptable (Spearman's $\rho = 0.86$).²⁰ Based on this reliability coefficient and the variability of this measure in a similar population,²⁰ we did not consider a change of 8 points or less to be clinically meaningful. All patients completed the Kujala scale at the beginning and conclusion of the study period for comparison.

Clinical Outcome Measures Clinical measurements were chosen based on impairments that the manufacturer believes would be improved through participation in this system.¹² All clinical measurements were performed by 1 of 2 trained physical therapists at different clinics at the initiation and conclusion of the patient's participation in the study. Clinical measurements included hip extension flexibility, ITB flexibility, and hip internal and external rotation passive ROM.

Hip extension and ITB flexibility were determined using the Thomas test, Ober's test, and a custom-made sliding caliper (T-bar). Intrarater reliability of these measurements was established prior to the study on a sample of 20 participants (10 males, 10 females). For reliability testing, each subject was measured twice by each rater and measured twice again by both raters 2 to 3 weeks after the original measurement. Patients wore their own loose-fitting

clothing for reliability testing and during data collection for the present study. The results of the reliability analysis established that the device was reasonably reliable for both the Thomas test ($ICC_{3,1} = 0.78$) and the Ober test ($ICC_{3,1} = 0.82$), using the procedures outlined below. Based on these reliability data, we estimated that the standard error of measurement for these tests was 2.3 and 2.2 cm, respectively.

For hip extension, the patient was positioned supine, with the thigh of each leg supported by the end of the examination table. The posterior aspect of the calf was separated from the edge of the examination table by 2.5 cm, with both knees flexed to 90° (Figure 1). The platform of the T-bar was positioned perpendicular to the patient and flush with the edge of the table. At this time, the examiner moved the contralateral hip of the patient to end-range hip flexion. Next, an assistant, blinded to group assignment, lowered the moveable arm of the T-bar until it touched the anterior thigh of the involved leg. The knee of the involved leg was maintained in 90° flexion throughout testing. The height of the moveable arm was recorded for analysis.



FIGURE 1. Measurement of passive hip extension flexibility using the custom-made sliding caliper.



FIGURE 2. Measurement of iliotibial band flexibility using the custom-made sliding caliper.

ITB length was determined using the Ober test (Figure 2). The patient was positioned in side lying with the medial malleolus of the involved (top) leg 2.5 cm distal to the end of the examination table. The knee of the involved leg was flexed to 90° before the hip was abducted as the examiner stabilized the iliac crest. The examiner released the distal portion of the involved leg, while the assistant, blinded to group assignment, lowered the moveable arm of the T-bar until it touched the lateral aspect of the knee. The examiner also attempted to maintain 0° of hip rotation during testing. The height of the moveable arm was recorded for analysis.

Hip internal and external rotation ROM were measured with the patient seated on the edge of the examination table. With the femur parallel to the floor, the examiner passively rotated the femur of the involved limb to end range internal rotation, while maintaining 90° of hip and knee flexion. The assistant positioned the stationary arm of the goniometer perpendicular to the floor and the moveable arm along the long axis of the tibia. The procedure was repeated for external rotation. Based on the reliability coefficient for hip rotation measured in sitting reported by Simoneau et al,²³ and the variability of this measure in a similar population,¹ a change of greater than 3.4° was considered to be a clinically meaningful difference.

Exercise Protocol

At the initiation of the study, each patient was randomly assigned to either the control group or Protonics group according to a coin flip. Patients in both groups performed the same exercise-based patellofemoral rehabilitation protocol with an emphasis on weight-bearing activities during all treatment sessions. Patients did not receive any modalities, taping, orthotics, or manual therapy that may have influenced their functional outcome or pain responses. However, every patient was prescribed a home exercise program to perform once daily, based on the frequency and intensity of the exercises the patient completed during their treatment sessions.

The rehabilitation protocol included 3 phases (Table 1). Exercises in each phase were prescribed to

foster quadriceps strengthening and generally involved movement within 0° to 50° knee flexion to minimize patellofemoral compressive forces.^{8,25} All exercises were initially prescribed as 1 set of 10 repetitions. Additional sets of 10 repetitions (up to 3 sets of 10 repetitions) were prescribed if their pain remained below 2 on the VPS for a particular exercise. Patients continued to exercise in each phase until they demonstrated the ability to complete 30 repetitions of each exercise in that phase with a pain rating of less than 2 on the VPS. At that time, patients progressed to the next phase of exercises, each initially prescribed as 1 set of 10 repetitions.

Patients in the Protonics group used the knee brace (Figure 3) during all home exercise sessions and outpatient treatment sessions. Additionally, these patients were asked to perform 10 repetitions of the 4 manufacturer-recommended warm-up exercises in the Protonics brace twice daily. These exercises included non-weight-bearing seated, supine, prone, and standing knee flexion against the resistance provided by the Protonics brace. One set of warm-up exercises was performed immediately prior to their clinical exercise routine and home exercise program. The other set of warm-up exercises was performed at the patient's convenience. The manufacturer recommends that patients perform these exercises regularly to facilitate neuromuscular reeducation of the hamstrings.

The resistance level for the Protonics brace was determined for each patient according to Protonics protocol guidelines. The goal of this protocol is to identify the lowest level of resistance required by the patient to exercise without pain. Patients performed 10 repetitions of each warm-up exercise prior to 5 lateral step-ups. If pain persisted, the protocol was repeated with a higher resistance setting until the patient reported no pain during the test movement.

Patients in this study attended outpatient physical therapy sessions 3 times per week for 6 weeks or until resolution of symptoms. All patients agreed not to miss more than 3 total appointments. Any patient who was unable to keep a scheduled appointment was rescheduled for the subsequent week. Patients who demonstrated the ability to perform 50 pain-free lateral step-ups on a 15-cm step (without the brace)

TABLE 1. Exercises prescribed per phase of rehabilitation.

Phase 1	Phase 2	Phase 3
<ul style="list-style-type: none"> • Quad sets* • Straight leg raises (SLRs)* • Standing hip flexion SLR with sport cord • Quadriceps, hamstring, iliotibial band, and hip flexor stretches 	<ul style="list-style-type: none"> • 45° squats • 45° thoracic wall slides • Resisted terminal knee extension in standing 	<ul style="list-style-type: none"> • Forward and lateral step-ups • Step-downs • Double-leg shuttle leg press • Single-leg shuttle leg press • Single-leg thoracic wall slides • Treadmill • Stairmaster

* Exercise performed with biofeedback over the vastus medialis muscle belly.



FIGURE 3. Protonics system knee brace. Photo courtesy of Inverse Technology Corporation.

and reported 0/10 pain on the VPS during all recreational activities were discharged from the study after all functional and clinical measures, as described above, were performed.

Data Analysis

Our aim for this study was to compare changes in pain, function, and clinical measures between patients who received exercise alone and patients who were prescribed the same exercises in addition to use of the Protonics system. Therefore, a 2-way repeated-measures analysis of variance procedure was conducted to test for group (exercise only and exercise plus Protonics), time (initial and discharge), and group-by-time interaction effects for each of the following outcome measures: Kujala scores, number of step-ups completed in 15 seconds, verbal pain scores associated with the lateral step-up test, passive hip internal and external rotation, hip extension flexibility, and ITB flexibility. Considering the research question above, we were particularly interested in the interaction term for each test, which indicates whether the pattern of change is different for each group from initial visit to discharge. Additionally, a

2-tailed independent *t* test was performed to check for differences in number of visits required for patients in each group from the initial appointment to discharge. The number of patients who reported zero pain with step-up testing at each of the biweekly assessments was analyzed using the Fisher exact test, with each patient's last observation carried forward following discharge from the study. The normality of the distribution and equality of the variance for each group were confirmed using the Kolmogorov-Smirnov test and Levene's test, respectively.²⁶

RESULTS

Study Patients

Patients in each group were not significantly different from each other with respect to age, Kujala score, or number of step-ups they could perform in 15 seconds at the initiation of the study (Table 2).

Number of Treatments

Patients in the Protonics group required an average of 2.2 fewer visits to meet the discharge criteria for this study ($P = .08$). Patients treated with exercise alone attended an average (\pm SD) of 15.5 (\pm 2.9) visits and patients treated with the same exercise program plus the Protonics device attended 13.3 (\pm 4.2) visits. Four patients in the Protonics group and none in the exercise-only group were discharged prior to the week-4 assessment. Over the next 2 weeks, 5 additional patients in the Protonics group and 5 patients in the exercise-only group met discharge criteria.

Functional Outcomes

The Kujala scale scores revealed that each treatment group improved substantially over the course of 6 weeks ($F = 157.9$; $df = 1,32$; $P < .001$). However, the

TABLE 2. Mean age, pain, and function scores for patients in each treatment group at the initiation of the study. Standard deviation in parentheses.

	Exercise Only	Exercise Plus Protonics	<i>P</i>
Age (y)	31.5 (9.8)	33.5 (8.8)	.56
Pain during activity (VPS)	4.8 (3.1)	4.6 (2.8)	.82
Kujala Score (points)	61.0 (15.5)	66.1 (12.6)	.30

Abbreviation: VPS, verbal pain scale.

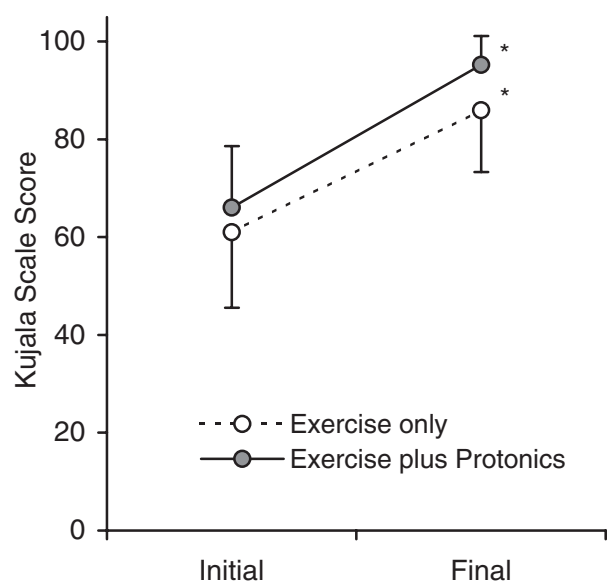


FIGURE 4. Mean Kujala scores at the initiation and conclusion of the study for patients using the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. Error bars represent the standard deviation of the mean for each group. *Significant main effect for time ($P < .001$).

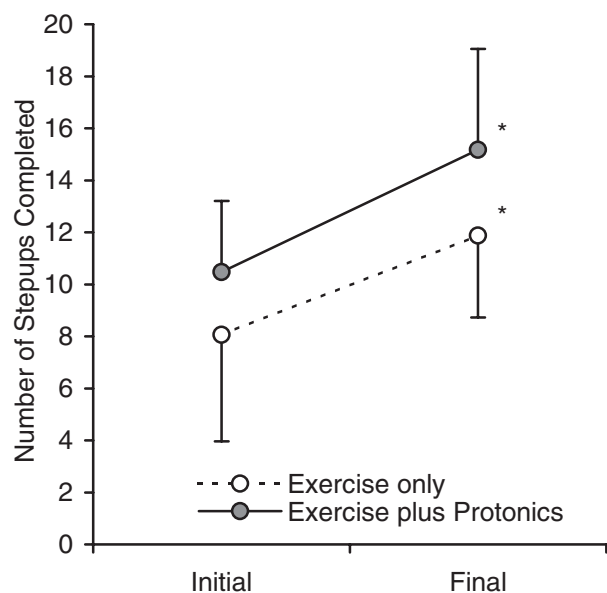


FIGURE 5. Mean number of step-ups completed in 15 seconds at the initiation and conclusion of the study for patients treated with the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. Error bars represent the standard deviation of the mean for each group. *Significant main effect for time ($P < .001$).

interaction between group assignment and time did not reveal greater improvement among patients using the Protonics system ($F = 0.97$; $df = 1,32$; $P = .33$) (Figure 4). Patients in both treatment groups performed a greater number of step-ups at discharge ($F = 49.7$; $df = 1,32$; $P < .001$) (Figure 5). The interaction between group assignment and time was not signifi-

cant ($F = 0.532$; $df = 1,32$; $P = .47$), indicating no difference in change between groups over the study interval. Similarly, patients in both groups reported less pain associated with the step-up test at discharge ($F = 59.1$; $df = 1,32$; $P < .001$) (Figure 6). However, the interaction between group and time was not significant ($F = 1.43$; $df = 1,32$; $P = .24$). Despite this fact, a greater proportion of patients in the Protonics group reported no pain with the step-up test at the week-2, -4, and -6 assessments (Figure 7). Specifically at the initial visit, no difference existed between groups in the proportion of patients who reported no pain after the step-up test ($P = 1.00$). By week 2, 59% of the patients treated with the Protonics device had no pain after this test, versus only 6% of patients in the control group ($P = .002$). By the fourth week, 82% of patients in the Protonics group versus 29% of patients in the control group were pain-free during the test ($P = .005$). Similarly, at the conclusion of the study 100% of patients in the Protonics group, versus 41% of patients in the control group, denied pain associated with this test ($P < .001$).

Clinical Tests

Patients in both treatment groups demonstrated increased ITB flexibility ($F = 15.7$; $df = 1,32$; $P < .001$) (Figure 8) and hip extension ($F = 8.94$; $df = 1,32$; $P = .005$) (Figure 9) at discharge. Patients in both treatment groups experienced similar improvement in ITB flexibility ($F = 0.062$; $df = 1,32$; $P = .80$). However, patients who were prescribed the Protonics system experienced a statistically greater increase in hip extension than patients prescribed exercise alone ($F = 5.70$; $df = 1,32$; $P = .023$). No consistent changes were noted in hip internal rotation ($F = 0.001$; $df = 1,32$; $P = .97$) (Figure 10) or external rotation ($F = 0.21$; $df = 1,32$; $P = .65$) (Figure 11) over the study interval when all subjects were considered together. However, analysis of the interaction effect revealed that patients who were prescribed the Protonics system in addition to exercise experienced a statistically significant increase in hip external rotation motion ($F = 6.39$; $df = 1,32$; $P = .017$) and a bias toward decreased hip internal rotation motion ($F = 3.00$; $df = 1,32$; $P = .093$), with respect to patients who were prescribed exercise only.

DISCUSSION

The purpose of this study was twofold. First, we compared the outcome of patients participating in conventional exercise-based rehabilitation for patellofemoral pain versus patients who received the same treatment with the addition of the Protonics system.

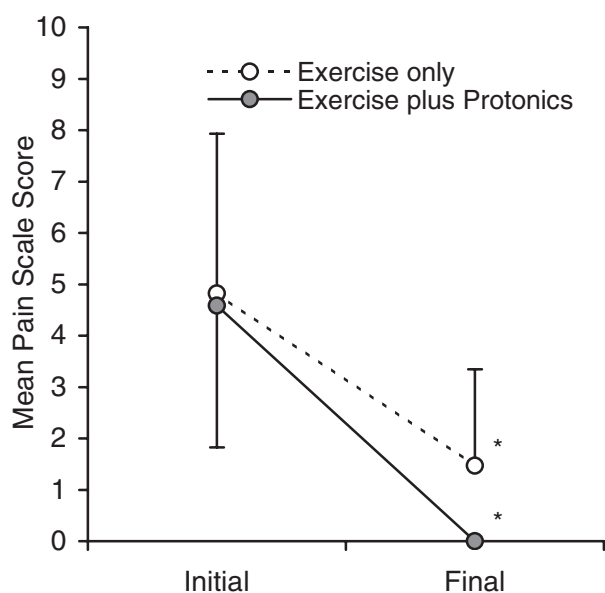


FIGURE 6. Mean verbal pain scale rating associated with the step-up test at the initiation and conclusion of the study for patients treated with the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. Error bars represent the standard deviation of the mean for each group. *Significant main effect for time ($P < .001$).

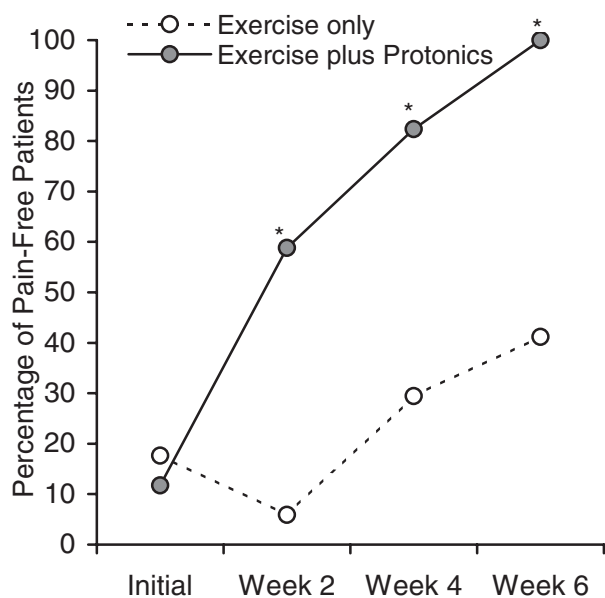


FIGURE 7. Proportion of patients who reported no pain associated with the lateral step-up test at each 2-week test session for patients treated with the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. * $P < .005$.

Second, we compared the clinical measures between groups that the manufacturer hypothesized would be affected by this system.

Patients in both groups demonstrated a significant reduction in pain and increase in Kujala score following a treatment program that included an exercise-based rehabilitation protocol. These results support the findings of previous authors who report successful management of PFPS using therapeutic

exercise. Doucette and Goble⁶ reported significant subjective and clinical improvement in patients with PFPS treated with VMO strengthening, ITB and lateral retinaculum stretching, and joint mobility exercises. These authors indicate that the mechanism for this improvement was a significant increase in ITB flexibility and associated reduction in patellofemoral congruence angle.⁶ Witvrouw et al²⁸ also reported significant improvement in VPS ratings and Kujala score following a 5-week exercise program consisting exclusively of either weight-bearing or non-weight-bearing exercises. These authors attributed these improvements to significant quadriceps and hamstring strength gains for both groups of patients at the conclusion of the study.²⁸

While both groups of patients demonstrated significant improvements over the course of the study, patients using the Protonics system required 2.2 fewer visits prior to discharge from treatment. Additionally, a greater proportion of pain-free patients were observed during step-up testing at each 2-week follow-up examination for patients in the Protonics group. Taken together, these results suggest that patients using the Protonics system in addition to the exercise program experienced functional improvements earlier than those patients prescribed only exercise. The economic implications of these results is uncertain. Third-party payers will likely consider the savings associated with a 2.2-visit-per-patient reduction in treatment sessions in light of the cost of purchase (\$995) or rental (approximately \$100 per month) of the system. Interestingly, as over half of the patients in the Protonics group were discharged before the

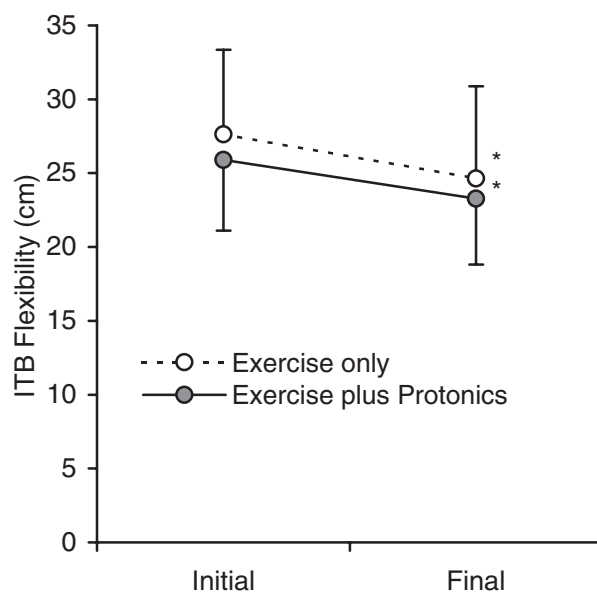


FIGURE 8. Mean iliotibial band flexibility at the initiation and conclusion of the study for patients treated with the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. Error bars represent the standard deviation of the mean for each group. *Significant main effect for time ($P < .001$).

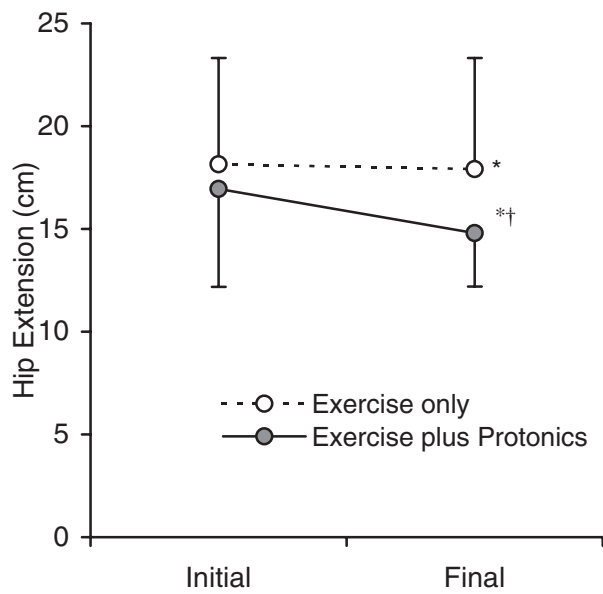


FIGURE 9. Mean hip extension flexibility at the initiation and conclusion of the study for patients treated with the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. Error bars represent the standard deviation of the mean for each group. *Significant main effect for time ($P < .001$). †Significant interaction effect ($P = .023$).

end of the first month of treatment, if therapists were to consider using Protonics in their rehabilitation programs, renting the device for 1 month may be more economically attractive than having patients purchase the device.

The mechanism behind the accelerated improvement identified among patients in the Protonics group is unclear. The manufacturer claims that resistance applied to the hamstrings by the Protonics system during non-weight-bearing knee motion increases hamstring activation and reduces tone in the psoas and tensor fascia latae (TFL) through reciprocal inhibition.¹² These changes are expected to promote an ipsilateral sagittal plane posterior pelvic rotation and permit a greater degree of hip external rotation. Indeed, patients in the Protonics group demonstrated a statistically greater change in passive hip extension flexibility and available hip external rotation. If this change in passive hip ROM shifts the rotation of the femur during dynamic activities, the trochlear groove could shift laterally beneath the patella, thereby decreasing lateral retropatellar contact pressure and pain. Such a consequence may explain the change in patellofemoral congruence angle identified by Timm²⁷ for patients prescribed the Protonics system to treat symptoms of patellofemoral pain. Unfortunately, although this mechanism is plausible, it remains unsubstantiated by the results of this study or previous work. In fact, increased hamstring activity has not been identified in healthy patients during walking with the Protonics brace set to resist knee flexion.⁵ Additionally, although the changes noted above were statistically

significant between groups, these differences were not outside the bounds of potential measurement error. Further studies using EMG and 3-dimensional motion analysis are required to determine the effect of the Protonics system on pelvic rotation and lower extremity alignment during functional activities.

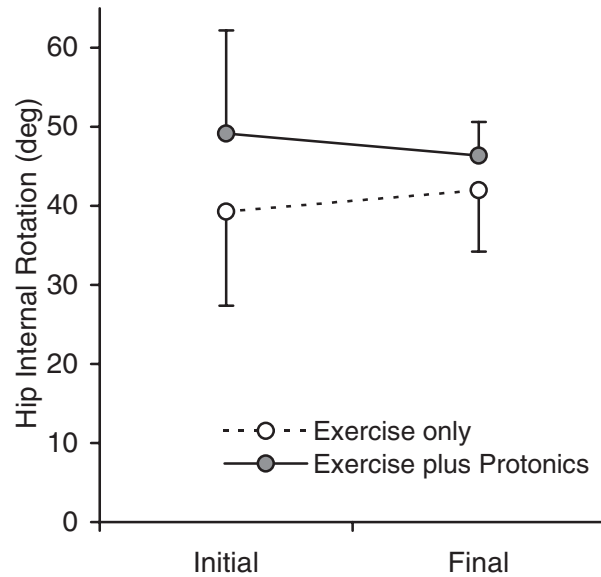


FIGURE 10. Mean hip internal rotation passive range of motion at the initiation and conclusion of the study for patients treated with the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. Error bars represent the standard deviation of the mean for each group. No statistically significant differences were found.

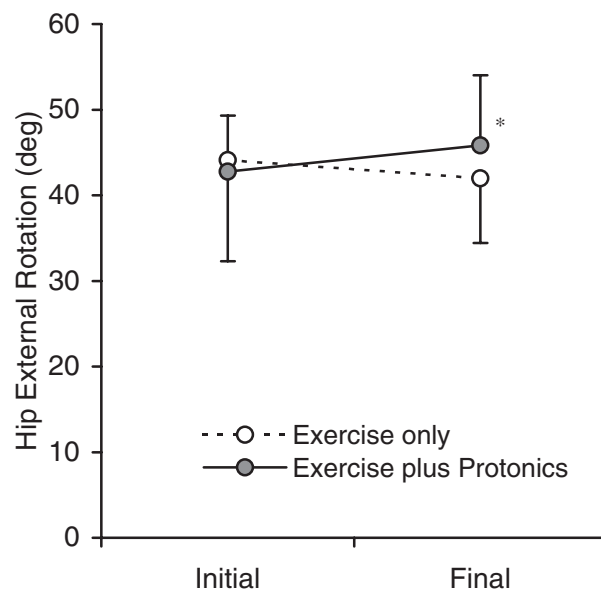


FIGURE 11. Mean hip external rotation passive range of motion at the initiation and conclusion of the study for patients treated with the Protonics system knee brace and therapeutic exercise versus patients treated with exercise alone. Error bars represent the standard deviation of the mean for each group. *Significant interaction effect ($P = .017$).

An alternative explanation for the improvement in pain reported by patients in the Protonics group is that the brace provided additional support to these patients during their weight-bearing exercises. To facilitate hamstring recruitment, the Protonics brace was set to resist knee flexion during non-weight bearing. However, during weight-bearing activities such as the step-up, the device provided an additional extension moment that reduced the demand on the knee extensors. Decreased quadriceps activity could have led to a reduction of patellofemoral contact pressure, which, over time, might have led to the earlier reduction in pain and faster progression through the exercise protocol.

Previous authors have also speculated on the mechanism associated with successful patient outcomes using the Protonics system. Timm²⁷ attributed improvement in pain and function to a 17.7° change in patellofemoral congruence angle in patients with PFPS using the Protonics system. However, Doucette and Goble⁶ previously reported that the patellar congruence angle could be significantly affected by exercise-based rehabilitation alone. Therefore, in the absence of adequate control, the results of Timm's²⁷ study may have been secondary to therapeutic exercise alone. Ours is the only study of Protonics, to date, that has incorporated a control group participating in a conventional exercise-based rehabilitation program. Further studies using stringent control for exercise prescription are necessary to validate these findings.

There are several limitations of this study. First, patients in the Protonics group may have been subject to a placebo effect. These patients may have reported lower VPS pain ratings due to the addition of a sophisticated accessory to their exercise program. These lower pain ratings would allow the clinician to advance the patient more rapidly through the exercise program, perhaps leading to an earlier discharge. Second, we were unable to verify the proportion of patients who experienced lasting relief in either treatment group. It is certainly possible that the Protonics brace is beneficial during the early phases of rehabilitation, but has limited value with respect to long-term results. Third, although we are not aware of any literature suggesting that gender affects the outcome of conservative treatment for PFPS, the patients in this study were all females and the results may not be generalizable to males. Fourth, although the assistant who positioned the T-bar and recorded all clinical measurements was blinded to group assignment, the clinician who positioned the patients for measurement and performed the lateral step-up test was not. Therefore, there was a potential for bias at each examination. Finally, the addition of the Protonics system to a traditional patellofemoral exercise program includes the addition of 4 sets of warm-up exercises to be performed twice daily by

patients in this group. While compliance with this recommendation was not monitored, patients in the exercise-only group were not prescribed an equivalent warm-up exercise routine. Therefore, it may be argued that these 4 non-weight-bearing knee flexion warm-up exercises partially account for the differences identified between groups. However, the goal of the system is to use the lowest resistance setting necessary to exercise without pain. Further, this resistance level tends to decrease over time. Taken together, we feel that it is unlikely the patients in this group experienced training effects from the warm-up exercises alone.

CONCLUSION

Patients in both treatment groups demonstrated relatively equal, but statistically significant, improvements in pain and function. However, patients utilizing the Protonics knee brace system demonstrated statistically significant increases in hip external rotation ROM and hip extension flexibility versus patients prescribed exercise alone. Additionally, patients in the Protonics group appeared to progress to advanced weight-bearing exercises with less pain and at a faster rate than patients utilizing exercise alone. As a result, patients using the Protonics system required 2.2 fewer outpatient appointments to meet their discharge criteria. Future studies of the Protonics system, including the analysis of gait mechanics, are needed to more fully determine the effect of the Protonics system.

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