

Randomized controlled trial of Protonics on patellar pain, position, and function

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ABSTRACT

TIMM, K. E. Randomized controlled trial of Protonics on patellar pain, position, and function. *Med. Sci. Sports Exerc.*, Vol. 30, No. 5, pp. 665-670, 1998. **Purpose:** Patellofemoral pain (PFP) and abnormal patellofemoral congruence (PFC) are common athletic problems whose treatment remains controversial. This study examined the effects of a high volume of submaximal knee muscle exercise on objective measures of PFP and PFC under a test-retest design. **Methods:** A sample of 100 subjects was randomly divided into two groups: control and treatment. All subjects of both groups were tested for PFC, using a Merchant x-ray view; function, via Kujala patellofemoral score (KPS), and pain, through a visual analog scale (VAS), initially and then 4 wk later. The treatment group exercised during activities of daily living (ADL) by wearing a Protonics device; the control group did not receive treatment. **Results:** One-way analysis of variance tests found no difference between pre- and posttest results for the control group but found significant changes in PFC, KPS, and VAS (all $P < 0.001$). PFC and joint function improved, and PFP decreased in all subjects of the treatment group. **Conclusions/Clinical Relevance:** It was concluded that the treatment reduced PFP and PFC as compared with the control. A high volume of submaximal knee exercise seems useful for clinical patients with PFP and abnormal PFC. **Key Words:** PATELLOFEMORAL CONGRUENCE ANGLE, PROGRESSIVE RESISTANCE EXERCISE, KNEE REHABILITATION, ANTERIOR KNEE PAIN, PATELLOFEMORAL PAIN, PATELLAR BIOMECHANICS, ACTIVITIES OF DAILY LIVING

Patellofemoral pain (PFP) is a common problem in athletes. PFP presents as the insidious onset of peri- or retropatellar pain that is aggravated by sports activity, by climbing or descending stairs, by squatting or kneeling, or through prolonged sitting with the knee flexed (the "movie sign") (2,11,15,19,21). The pain cannot be localized to a distinct anatomic structure (2,11). Other signs and symptoms include patellofemoral crepitation during knee movement, joint swelling, and an increased Q angle (9-11,15,19,21). The incidence of PFP ranges from 30 to 33% in sports medicine clinics (2,7,16).

Abnormal patellofemoral congruence (PFC) of the patella on the femoral groove has been suggested as a common cause of PFP (2,3,11,12,19). PFC may result from bony abnormalities of the patella or femur; tightness of the lateral retinacula, iliotibial band, hamstrings muscles, or gastrocnemius muscle; or lower extremity malalignment, such as genu valgum, genu recurvatum, femoral anteversion; external tibial torsion, or excessive subtalar pronation

(3,9-11,19). An imbalance of strength or neuromotor control between the vastus medialis obliquus (VMO) and vastus lateralis muscles, or premature fatigue of the VMO, has also been suggested as a cause of PFC (5,11,12,19,20,24,26,27).

The treatment of PFP from PFC remains controversial. Treatment methods have included biofeedback, bracing, closed kinetic chain exercise, electrical muscle stimulation, isometric exercise, open kinetic chain exercise, and patellar taping (2,4,5,9,10,15,17,19-21,24,26,27). The goal of these methods has been to functionally, through enhanced muscle activity, or mechanically, through an external support, position the patella medially to correct PFC (2,4,5,9,10,15,17,19-21,24,26,27). Twelve clinic sessions has been suggested as an effective duration (21).

Treatment results have been mixed. Exercise either increases or decreases PFC (2,9,10,14,19). Patellar taping either decreases both PFP and PFC or decreases PFP without an effect on PFC (2,4,17,19,20). A recent review stated that quadriceps muscle exercises were an effective treatment and that braces were not (2). Also, whereas short-term success is found in 75% of patients (6,12), there are reports that up to 70% of patients have a return of PFP within 12 months following treatment (8,12).

Another proposed method of PFP and PFC treatment is Protonics (Inverse Technology Corporation, Lincoln, NE).

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This method is based on a theory that a high volume of submaximal concentric contractions of the quadriceps and hamstrings muscle groups will facilitate an appropriate alignment of the patella in the femoral groove and reduce both PFC and PFP (14). However, this theory has not been tested on a clinical population or through a randomized controlled trial.

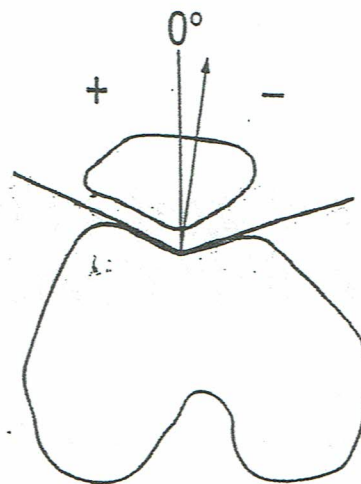
The purpose of this study was to determine the effects of Protonics on patella position and perceived pain in a clinical sample of patients with PFP through a randomized controlled trial. The null hypothesis under study was that Protonics would have no effect on patella position and perceived pain, as measured through clinical assessment procedures. The study employed a pretest-posttest experimental design.

METHODS

Subjects. One hundred ($N = 100$) clinical patients participated as subjects in the study. The subjects were referred into the study by seven different orthopedic surgeons; there was no treatment before referral. The subjects participated under the guidelines of informed consent (1). The study was approved by the Institutional Review Board for St. Luke's Hospital (Saginaw, MI).

All subjects had to meet four PFP criteria for inclusion in the study: pain during ascending/descending stairs, pain when rising from sitting, pain during squatting, and pain with prolonged sitting (the "movie sign"). Potential subjects were excluded from the study by one or more criteria: pain with palpation of the quadriceps tendon or patellar ligament, snapping sensation or palpable pain in the area of a medial synovial plica, pain during palpation of the knee joint line or during the McMurray test for meniscus injury, joint effusion where the midpatellar girth was 105% or more than the noninvolved knee, bilateral complaints of PFP, history of patellar dislocation or subluxation, history of knee surgery, and confirmed or possible pregnancy. The criteria for subject inclusion or exclusion were based upon previous studies (24,26).

The subjects were randomly divided into two groups. Group 1 was designated as control and group 2 was the treatment group. Randomization was achieved through odd-



Congruence angle

Figure 1—Patellofemoral congruence angle. The PFCA is the angle formed by the 0° reference line and the arrowed line (apex of the sulcus angle to the lowest articular point on the patella).

even assignment (23): the first subject was assigned to group 1, the second subject was assigned to group 2, the third subject was assigned to group 1, the fourth subject was assigned to group 2, and so forth through the 99th subject assigned to group 1 and the 100th subject assigned to group 2. The demographic information for both groups is shown in Table 1.

Measurements. The dependent variables were patellofemoral congruence angle (PFCA), Kujala patellofemoral score (KPS) (18), and visual analog scale (VAS) score. Pre- and posttest data were collected on all three variables for each subject. The PFCA was measured through Merchant (22) x-ray views of the patellofemoral joint. PFCA is obtained by bisecting the sulcus angle to establish a zero reference line. The sulcus angle is the angle from the highest point of the medial and lateral femoral condyles to the lowest point of the intracondylar sulcus. Another line is then drawn from the apex of the sulcus angle to the lowest articular point on the patella. The two lines create the PFCA (Fig. 1).

PFCA values medial to the zero reference line are designated as negative, and values lateral to the zero reference line are designated as positive (3,4,9,10,15,19,22). Merchant et al. (22) and Doucette and Goble (10) found that the mean PFCA in normal subjects was -6° ($SD = 11^\circ$), that a PFCA of $+16^\circ$ was abnormal at the 95th percentile, and that the mean PFCA with recurrent patellar dislocation was $+23^\circ$. Merchant et al. (22) and Doucette and Child (9) did not find significant differences when analyzing for gender, age, and side. The PFCA measurement procedures were based upon the methods of previous studies (3,4,9,10,15,19).

KPS was measured through the Kujala Score questionnaire (Table 2) (3,18). Each subject completed a pre- and posttest questionnaire to generate a KPS. The KPS has been found to be a reliable and valid measure of functional status in subjects with PFP (3,18).

TABLE 1. Subject demographics.

	Group 1: Control (N = 50)	Group 2: Treatment (N = 50)
Gender		
Men	29 (58%)	31 (62%)
Women	21 (42%)	19 (38%)
Knee		
Left	26 (52%)	30 (60%)
Right	24 (48%)	20 (40%)
Age (yr)		
Mean	29.1	32.4
SD	6.4	5.9
Range	24-44	25-47
PFP history (wk)		
Mean	12.6	12.4
SD	4.3	6.1
Range	7-18	5-19

TABLE 2. Kujala Score (18) Maximum 100 Points.

	Points
1. Limp	
a. None	5
b. Slight or periodic	3
c. Constant	0
2. Support	
a. Full support without pain	5
b. Painful	3
c. Weightbearing impossible	0
3. Walking	
a. Unlimited	5
b. More than 2 km	3
c. 1-2 km	2
d. Unable	0
4. Stairs	
a. No difficulty	10
b. Slight pain when descending	8
c. Pain both when descending/ascending	5
d. Unable	0
5. Squatting	
a. No difficulty	5
b. Repeated squatting painful	4
c. Painful each time	3
d. Possible with partial weightbearing	2
e. Unable	0
6. Running	
a. No difficulty	10
b. Pain after more than 2 km	8
c. Slight pain from start	6
d. Severe pain	3
e. Unable	0
7. Jumping	
a. No difficulty	10
b. Slight difficulty	7
c. Constant pain	2
d. Unable	0
8. Prolonged sitting with knees flexed	
a. No difficulty	10
b. Pain after exercise	8
c. Constant pain	6
d. Pain forces knee to extend	4
e. Unable	0
9. Pain	
a. None	10
b. Slight and occasional	8
c. Interferes with sleep	6
d. Occasionally severe	3
e. Constant and severe	0
10. Swelling	
a. None	10
b. After severe exertion	8
c. After daily activities	5
d. Every evening	4
e. Constant	0
11. Abnormal painful patellar movements	
a. None	10
b. Occasionally in sports activities	6
c. Occasionally in daily activities	4
d. At least one documented dislocation	2
e. More than two dislocations	0
12. Atrophy of thigh	
a. None	5
b. Slight	3
c. Severe	0
13. Flexion deficiency	
a. None	5
b. Slight	3
c. Severe	0

The VAS has been shown to be reliable and valid for the measurement of pain intensity (4,25). A 10-cm horizontal line marked "no sensation of soreness" on the left and "worst sensation of soreness imaginable" on the right was used for both pre- and posttests. Each subject made a mark on the VAS line, which corresponded to the perceived level

of pain. The distance from the left end of the VAS line to the subject's mark was measured (cm) and recorded as the VAS score. The subjects were instructed to rate their PFP during the four activities used as inclusion criteria for the study: ascending/descending stairs, rising from sitting, squatting, and prolonged sitting (the "movie sign") (24,26). This procedure was similar to the method used by Bockrath et al. (4).

Radiographic Procedures. Pretest and posttest Merchant x-ray views were taken of the knee with PFP on all subjects. A Picker Starlite G325S (Picker International, Inc., Cleveland, OH) x-ray machine was used to take all views. The knee was held at 45° flexion by an Axial Viewer (Orthopaedic Consultants, Mountain View, CA). Knee position was verified through goniometric measurement. The cathode ray tube was set 100.0 cm from the patella with a field size of 20.0 × 20.0 cm. The cross-hair illumination by the lamp was set on the most anterior aspect of the patella. The exposure variables were 100 mA, 0.05 s, and 70 kV. Both pre- and posttest views were taken with the quadriceps contracted. Each subject performed an isometric contraction against a 2.0-kg weight without letting their heel lose contact with the x-ray table during both views. All views were taken by a certified x-ray technician. These procedures followed the methods described in previous studies (4,15).

The PFCA for each x-ray was determined through digitization using a Numonics model electronic digitizer (Numonics Corporation, Lansdale, PA) interfaced to a personal computer (Gateway 2000, Sioux Falls, SD). All measurements were performed by a blinded examiner. Reliability was examined through the remeasurement of 20 PFCA's randomly selected from the data. A paired *t*-test analysis failed to reveal a statistically significant difference between measurement sets (mean difference = 0.3°). The PFC measurement procedure was deemed to be reliable. The procedures were based on the methods used in previous studies (4,9,15).

Treatment Procedures. Pre- and posttest data (PFCA, KPS, and VAS) were collected both before and after a 4-wk treatment period for each subject. The 4-wk period was based on the finding of McMullen et al. (21) that PFP can be resolved in about 12 clinic visits, three clinic sessions per week for 4 wk is a common treatment format. The format was also selected because it matched the guidelines for managed health care that were in place during the period of study. This should have enhanced the external validity of the results (23). Group 1 was the control and did not receive any treatment between pre- and posttest measurements.

Group 2, the treatment group, was limited to two clinical sessions. The clinical sessions were separate from the pre- and posttest measurement sessions. For the first clinical session, each subject of group 2 was fitted with a Protonics exercise device. The devices were similar to a hinged, long-leg knee brace (Fig. 2). However, the device was designed to provide progressive resistance exercise (PRE) stimuli to the knee flexor and extensor muscle groups and not to restrain motion or to protect the knee ligaments (14). The hinges of the device held a Protonics module, which provided a resistance against knee joint movement through

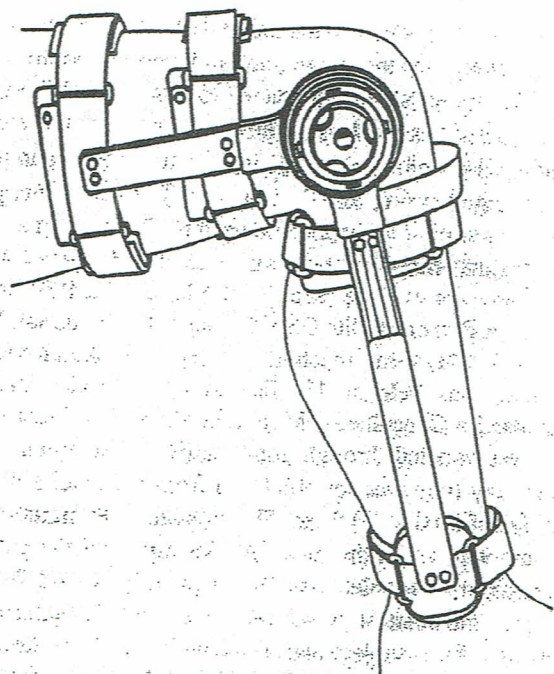


Figure 2—Protonics exercise device. The circular module on the hinge provides resistance during knee flexion and extension movements.

the sagittal plane. When in place, each subject received resistance against knee flexion and extension movements during walking. According to the manufacturer (14), resistance was selectable within a range of 2.7–34.4 N, was independent of joint velocity, but accommodated (became zero) when knee motion stopped.

Each device was configured to provide a “functional resistance setting” (FRS) (14) while worn by each subject. The FRS has been operationally defined as the lowest resistance setting that allows a subject to ascend and descend stairs with a normal gait but without PFP (14). The physiological mechanism responsible for this effect is not known. The FRS was determined through a series of trials in which each subject climbed and then descended two flights of stairs (16 steps) while wearing the exercise device. The resistance was adjusted after each trial of stairs (ascent and descent) until an FRS was found.

An FRS for knee movement without PFP while wearing the exercise device was found for each subject. All subjects were then instructed in the independent self-use of the exercise device. The subjects were asked to wear the device as much as possible during all routine activities of daily living (ADLs), especially those which involved walking, until the second clinical session.

The second clinical session occurred 2–3 d after the first clinical session. The second session was used to verify that the exercise device was fit correctly, working properly, and able to be used during ADLs for each subject. The FRS was examined to ensure that all subjects could walk without PFP while wearing the device. Each subject was then asked to continue wearing the exercise device as much as possible during their ADLs through the remainder of the 4-wk treatment period. All subjects signed a document in which they agreed to wear their exercise device for a period of at least

four consecutive hours per day, each day, for the remainder of the treatment period.

Data analysis. Paired *t*-tests were used to compare pretest measurements between groups on each dependent variable (PFCA, KPS, and VAS). This was done to examine group similarity before treatment (control versus exercise). The differences between pre- and posttest measurements were recorded as gain scores (posttest – pretest = gain score) (23) for each dependent variable. One-way analysis of variance (ANOVA) tests were then performed on the gain scores. This was similar to the procedures used by Doucette and Goble (10).

An alpha level of 5% ($P = 0.05$) was established before the start of data collection. However, the alpha level was adjusted to $P = 0.017$ ($0.05/3 = 0.017$), as per the suggestion of Greenfield et al. (13). The overall sample size ($N = 100$) provided the desired level of statistical power ($1 - \beta = 0.90$) with a medium effect size ($F = 0.25$) to minimize the chance of a type II error (23).

RESULTS

Pre- and posttest data for PFCA, KFS, and VAS scores appear in Table 3. Significant pretest differences did not exist between groups for any dependent variable. One-way ANOVA results appear in Table 4. Significant differences did not exist between pre- and posttest measurements for PFCA, KFS, and VAS in the control group.

However, there were significant gains in the treatment group. PFCA changed from lateral toward medial ($P < 0.001$), which indicated an improvement in PFC. Patellofemoral function (KPS) improved ($P < 0.001$). PFP, as measured by VAS, decreased ($P < 0.001$). Based on their self-reports, the treatment group subjects wore their exercise device an average of 6 h each day (mean = 6.1 h, SD = 1.8 h).

DISCUSSION

The results indicate that the Protonics exercise treatment had an important effect upon PFP as compared with the control. The subjects' pain decreased an average of 47% as measured by VAS (pretest = 6.50; posttest = 3.54; Table 3). Joint function, as measured by KPS, increased an average of 108% (pretest = 41.72; posttest = 86.76; Table 3). Finally, patellofemoral biomechanics, as measured by PFCA, improved by an average of 17.68° (pretest = 13.10°; posttest = -4.58°). The overall result was an improvement of PFP, which was not present in the subjects of the control group.

Previous studies have also found that PFP can be altered through clinical intervention. However, such findings have yielded inconsistent results. Bockrath et al. (4) reported a significant decrease in pain, as measured by VAS, from patellar taping. The speculated cause of pain decrease was neural inhibition via an increase in large nerve fiber input, which would override the transmission of pain signals to the brain (4). However, patellar taping did not affect PFC (4).

Larsen, et al. (19) found that patellar taping did not enhance PFCA after a PRE session. They theorized that PRE caused abnormal PFC secondary to fatigue of the VMO that could not be controlled through taping (19). In contrast, McConnell (20) reported that patellar taping improves the VMO:VL muscle performance ratio to decrease abnormal PFC during exercise. However, McConnell did not measure PFCA. Ingersoll and Knight (15) also found that PRE produced abnormal PFC in a group of asymptomatic subjects. They found that EMG biofeedback could reduce abnormal PFC and, therefore, improve PFCA (15).

Other sources report different results for the effect of PRE on PFC and PFP. Cerny (5) and Souza and Gross (26) found that PRE can improve PFP and joint function. The mechanism for improvement was an enhanced VMO:VL muscle performance ratio (5,26). However, they differed on the preferred method for PRE: isometric versus isotonic exercise, respectively (5,26). Doucette and Child (9) also found that PRE improves both PFP and PFC. Their results indicate that closed chain exercises are preferred during knee joint motion of 0–30° flexion and that open chain exercises are effective in arcs of motion beyond 30° knee flexion (9).

The current results agree with the previous findings that PRE improves PFC and PFP. However, this study differs in the application of PRE activities. Although previous methods have employed a near-maximal muscle training effect solely in the clinical setting, this study used a submaximal PRE effect in a home exercise program. This suggests that a high volume of submaximal PRE during a subject's ADL also may produce an outcome similar to those previously reported by Cerny (5), Doucette and Child (9), and Souza and Gross (26). However, further work is needed to verify this theory, especially as the physiological rationale for the observed treatment effects is not known and was not addressed by this study.

Clinically, the finding that a high volume of submaximal PRE during ADL corrected PFC and relieved PFP poses an interesting question: Could a home exercise program replace clinical methods for the effective treatment of PFC and PFP? The possibility that effective treatment for PFP could be trimmed back from a clinical treatment regimen to two clinical sessions and a program of self-management presents important functional and economic implications. However, further research is needed before such questions and implications can be answered and explored.

TABLE 3. Pretest and Posttest data.

	Pretest		P*	Posttest	
	Control	Treatment		Control	Treatment
PFCA					
Mean	12.44°	13.10°	0.31	12.58°	-4.58°
SD	5.10°	4.67°		6.84°	8.64°
KPS					
Mean	41.42	41.72	0.03	41.20	86.76
SD	3.87	4.21		3.95	6.65
VAS					
Mean	6.54	6.50	0.82	6.74	3.54
SD	0.97	1.07		1.05	0.97

* P, result of paired t-test (critical P = 0.017).

TABLE 4. One-way ANOVA results.

	SS	df	Source		
			MS	F	P
PFCA					
Group	6939.390	1	6939.390	1232.452	<0.001
Error	551.794	98	5.631		
KPS					
Group	50199.299	1	50199.299	466147.217	<0.001
Error	10.554	98	0.108		
VAS					
Group	190.385	1	190.385	34495.612	<0.001
Error	0.541	98	0.006		

Additional research is also needed to address the limitations of this study, as well as validate the results. Because the subjects were left "on their own" after the second clinic session, there was no direct or precise measurement of compliance for wearing the exercise device or for the PRE dosages. The accuracy of the subject self-reports for device usage on a daily basis (mean = 6.1 h, SD = 1.8 h) was not determined; the data could reflect the Hawthorne effect (23) of better-than-actual KPS and VAS scores. A placebo effect was also possible: the subjects may have improved simply because of the fact that they received a form of treatment. Finally, a combination Hawthorne-reverse placebo effect may have occurred; the treatment group reported better-than-actual KPS and VAS scores because they were receiving treatment while the control group reported worse-than-actual scores because they did not receive treatment.

In addition, there was no measurement of the specific PRE resistance used in the determination of the FRS for each subject. Also, the results are limited to static measures of PFCA at a specific joint angle, which may not translate to dynamic methods of measurement across other arcs of knee motion. Furthermore, this study did not examine other proposed causes of PFP, such as abnormal patellofemoral tracking. Finally, this study examined a short-term time frame of only 4 wk; no data exist for a long-term outcome. Follow-up data is needed to verify the long-term outcome, especially because a return of symptoms within 12 months has been found in 70% of patients (8,12).

CONCLUSION

Based upon the results, but within the stated limitations, it was concluded that the Protonics exercise program reduced PFP and improved PFC, as measured by PFCA, KPS, and VAS, when compared with the control group.

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This study received equipment support, in the form of a loan of Protonics exercise devices, from Inverse Technology Corporation, 1225 L Street, Lincoln, NE 68508. All devices were returned to the company following the completion of the study. The results of the present study do not constitute endorsement of the product by the author or The American College of Sports Medicine.

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