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## Acute effects of the Protonics system on patellofemoral alignment: an MRI study

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**Abstract** This study used magnetic resonance imaging (MRI) to determine whether changes in patellofemoral alignment occur after initial treatment with the Protonics exercise device. The first scan was obtained before the device was used. After performing a set of exercises with no resistance on the device the device was removed, and a second scan was obtained. The same set of exercises was again performed with resistance on the device set at the appropriate level, and a final scan was obtained with the device removed. An isometric leg press was maintained as each image was obtained to simulate more closely a functional weight-bearing activity. Subjects were 26 women with complaints of patellofemoral pain. The main outcome measures were: patellar tilt angle, bisect offset, and lateral facet angle. Nonparametric repeated measures analysis of

variance tests showed no differences between test conditions for any of the three measures of patellofemoral alignment. We conclude that after an initial treatment session using the Protonics system there is no change in patellofemoral alignment as determined by MRI.

**Keywords** Patellofemoral pains · Anterior knee pain · Magnetic resonance imaging · Patellar alignment

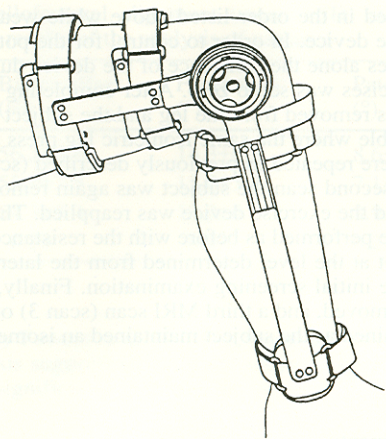
### Introduction

Patellofemoral pain syndrome (PFPS) may account for nearly one-third of all complaints of knee pain in active female athletes [1]. However, the definitive cause and treatment of PFPS remains elusive. Factors thought to contribute to the development of PFPS include malalignment, muscular imbalance, and overuse [15]. Alignment issues may refer to entire lower extremity malalignment or specifically to the patellofemoral articulation. Muscular imbalance issues have focused mainly on the relationships among activation patterns within the quadriceps, more

specifically between the vastus lateralis and vastus medialis. Frequently the onset of symptoms is associated with an increase or change in activity level. A few recent prospective studies have helped to provide insight into the significance of these various factors in the development of PFPS, but our present knowledge remains incomplete [8, 17].

Treatment options for PFPS are as varied as the proposed mechanisms and are no more conclusive [1]. Traditional rehabilitation protocols focus on strengthening the quadriceps through the use of either open or closed kinetic chain exercises or both. Other popular options include biofeedback, bracing, and taping.





**Fig. 1** The Protonics exercise device

More recently a theory has been proposed that the underlying mechanism of PFPS may be related to muscle imbalances within the lumbopelvic region [5, 6]. The theory suggests that weakened and lengthened abdominal, hip extensor, and hamstring muscles along with tight and overused hip flexor, abductor, back extensor, and quadriceps muscles produces predictable patterns of lower extremity malalignment that may predispose an individual to develop symptoms. More specifically, these muscle imbalances are thought to lead to an increase in anterior tilt of the pelvis leading to excessive medial femoral rotation. Medial femoral rotation, in turn, increases compression of the lateral patellar facet thereby producing pain.

This idea led to the development of the Protonics system, which includes a hinged device that provides adjustable resistance against knee flexion movements during exercise and functional activities (Fig. 1). The application of high volumes of resistance exercises to the hamstrings is believed to restrain anterior pelvic tilt and to correct the associated muscle imbalances and medial femoral rotation, thereby improving patellofemoral alignment and relieving lateral compression and pain. After 4 weeks of treatment with the device Timm [16] showed improvement in pain, function, and patella position as determined from radiographs.

Patients who use the device frequently report a temporary decrease in pain symptoms within the first treatment session even after the exercise device is removed. The device is thought to induce neuromuscular changes that result in immediate, although transient, pain reduction. Chronic use of the device may facilitate persistence of these changes and ultimately effect the changes in musculoskeletal alignment observed by Timm [16]. Whether pain reduction after initial application of the device is due at least in part to similar changes in patellofemoral alignment has not been studied. Therefore the purpose of this study was to use magnetic resonance imaging (MRI) to determine whether changes in patellofemoral alignment

occur after a single treatment session with the Protonics system.

## Materials and methods

### Subjects

Subjects for this study were 26 female volunteers between 18 and 30 years of age (mean  $21.1 \pm 3.3$ ) with complaints of intermittent retropatellar pain of at least 3 months' duration. A history and physical examination was carried out initially to exclude subjects with a history of knee surgery and pathology including meniscal tears, ligament injuries, Osgood-Schlatter disease, patellar dislocation, and acute traumatic patellofemoral joint pain attributable to a specific event. Subjects who currently used orthotics or had a history of more than three ankle sprains on the painful side were also excluded from the study. All subjects were required to read and sign an informed consent approved by the institutional review committee of the University of Kentucky prior to their participation in the study. Subjects were recruited from the local community and area sports medicine clinics.

Patients completed a visual analog pain scale (0–100) that described the average pain level experienced during daily activities including sitting, stair climbing, and recreational activities. All participants considered themselves active recreational athletes and reported symptoms of anterior knee pain during physical activities such as running, jumping, stair climbing, and squatting. In addition to retropatellar pain, positive results for the Ober and Thomas tests on the painful side were required for inclusion in the study. These tests were part of the inclusion criteria because the application guidelines for the device state specifically that patients who display these signs are the most appropriate candidates to benefit from this treatment approach [6]. In theory, the device, in combination with the prescribed exercises, works by reducing the tonic activation of the hip abductors and flexors that are thought to contribute to the malalignment problem by maintaining the pelvis in an anteriorly tilted position.

At the end of the examination, subjects were fitted with the Protonics exercise device and the resistance of the device was set at a level that eliminated pain during a lateral step-down test from a 15.25 cm (6 in.) step. This setting was recorded for each subject and used in subsequent testing during the MRI. The device was then removed and an additional step-down test was performed to verify that symptoms remained improved immediately after the initial application.

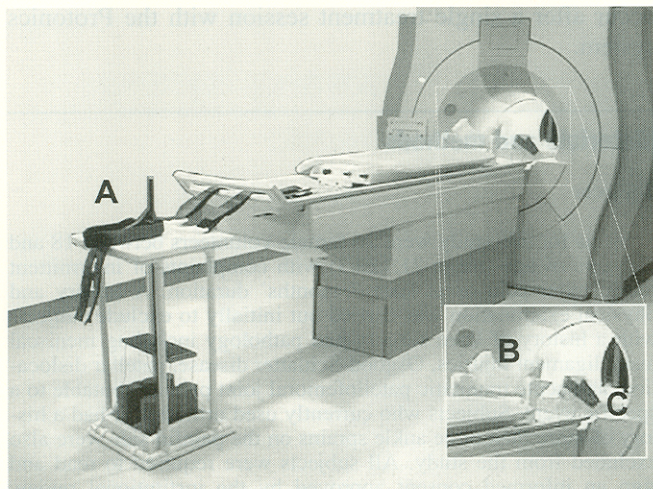
### Procedures

A series of MRI scans were performed to assess changes in patellofemoral alignment before and after a single treatment session using the Protonics system. All images were obtained with a 1.0-T MRI unit (Gyrosan S15; Philips Medical Systems, Best, The Netherlands).

Each subject was first positioned supine on the scanning table in a comfortable resting position with the knees fully extended. T1-weighted sagittal and axial images were obtained of the painful knee with sections aligned parallel to the long axis of the patella and parallel to the joint line, respectively. Slice thickness was 4 mm in blocks of 20 slices (time to repeat 692 ms, time to echo 20 ms, flip angle  $100^\circ$ ). These images were used to confirm the absence of meniscal, ligamentous, and chondral pathology.

The subject was then removed from the scanning table, and a custom positioning device (Chamco, Cocoa, Fla., USA) was attached to the machine. The positioning device was made entirely of nonferromagnetic materials and included a pulley system and foot plate that allowed subjects to maintain an isometric leg press





**Fig. 2A-C** Positioning device and pulley system used to perform leg press activity during MRI scanning. **A** Weight pan. **B** Thigh support for maintaining desired knee angle. **C** Foot plate with strap to secure the foot during isometric leg press

as each subsequent image was obtained. An adjustable support for the thigh was provided to maintain the knee at 20° flexion during imaging. An illustration of the setup for the leg press activity is shown in Fig. 2.

With the positioning device in place, the patient was returned to the scanning table to obtain axial images of the knee from which baseline measurements could be made for each of the dependent variables (Time to repeat=205 ms, time to echo=4.4 ms, flip angle=60°). The dependent variables of interest were patellar tilt angle, bisect offset, and lateral facet angle. For these scans, the subjects' foot was strapped to the foot plate and the weight pan attached to the pulley system was loaded with a weight approximately equal to 25% of the subjects' body weight. The subject was then asked to press downward on the foot plate lifting the weight pan until the posterior surface of the thigh contacted the support on the positioning device. A goniometer was used to confirm that the knee would be supported at the desired 20° flexion angle during imaging. An isometric leg press was maintained for approximately 4 min during each scanning procedure.

After the baseline scan (scan 1) was completed, the subject was removed from the table and the Protonics exercise device was applied to the subject's affected leg. The subject was then asked to perform a series of exercises that are part of the protocol for use of the device in the clinic. These exercises include standing hamstring curls, supine hamstring curls, prone hamstring curls, and seated hamstring curls. Ten repetitions of each of the exercises

were performed in the order listed above while wearing the Protonics exercise device. In order to control for the potential effects of the exercises alone the resistance of the device during this first series of exercises was set to zero. After completing the exercises the device was removed from the leg and the subject was returned to the MRI table where the same isometric leg press and scanning procedures were repeated as previously described (scan 2).

After the second scan the subject was again removed from the MRI table, and the exercise device was reapplied. The same set of exercises were performed as before with the resistance of the exercise device set at the level determined from the lateral step-down test during the initial screening examination. Finally, the exercise device was removed, and a third MRI scan (scan 3) of the affected knee was obtained as the subject maintained an isometric leg press as before.

#### MRI measurements

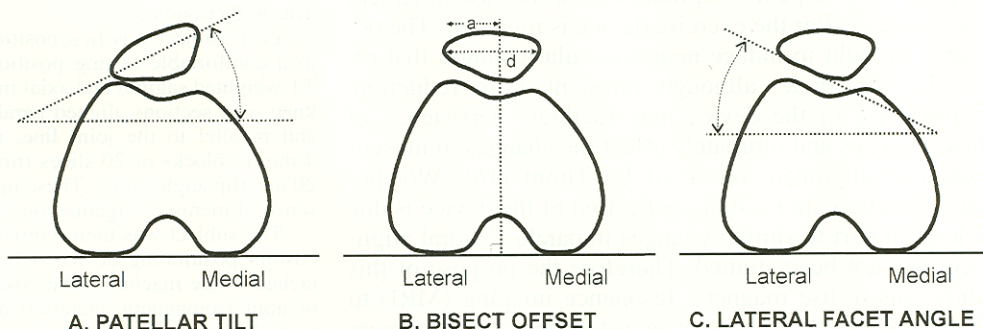
All measurements were taken directly from enlarged images on MRI films by a single investigator (V.M.S.). Measurements of each subject's patellofemoral alignment from scans 1–3 included patellar tilt angle, bisect offset, and lateral facet angle. Each of these measurements was made from the axial slice through the femoral condyles that showed the greatest patellar width. Patellar tilt angle and bisect offset measurements were performed according to the method described by Powers et al. [11]. Patellar tilt angle was the angle formed by a line joining the maximum width of the patella and a line tangent to the posterior femoral condyles (Fig. 3A). Bisect offset was measured by drawing a perpendicular line projecting anteriorly through the deepest point of the trochlear groove from the line connecting the posterior femoral condyles (Fig. 3B). This line intersects the line that connects the widest points of the patella. Bisect offset represents the mediolateral position of the patella and is expressed as a percentage of the total patellar width. Lateral facet angle was determined by the angle between a line drawn parallel with the lateral patellar facet and the line connecting the posterior femoral condyles (Fig. 3C).

Reliability of each of the measurements used in this study was tested by having the same person repeat each of the measurements on ten randomly selected scans. Reliability estimates (ICC 2,1) were 0.85, 0.88, and 0.95 for patellar tilt angle, bisect offset, and lateral facet angle, respectively.

#### Data analysis

Because the data were not normally distributed, Friedman's test for repeated measures analysis of variance on ranks was used to assess differences in patellofemoral alignment among the three scans (SYSTAT 7.0, SPSS, Chicago, Ill., USA). A separate analysis was conducted for each of the three dependent measures (bisect offset, facet angle, and patellar tilt angle). Based on the measurement er-

**Fig. 3A-C** Methods used to measure patellar tilt, bisect offset, and lateral facet angle from axial MRI scans. **A** Patellar tilt angle formed by a line through the maximum width of the patella and a line parallel to the posterior femoral condyles. **B** Bisect offset representing the mediolateral position of the patella expressed as a ratio of  $a:d$ . **C** Lateral facet angle formed by lines drawn parallel to the lateral patellar facet and posterior femoral condyles





**Table 1** Patellofemoral alignment (mean  $\pm$ SD) after each test condition and results of the analysis of variance

	Bisect offset (%)	Facet angle (°)	Patella tilt angle (°)
Baseline	56.2 $\pm$ 6.8	14.3 $\pm$ 6.3	8.6 $\pm$ 4.8
Scan 2	55.9 $\pm$ 7.5	15.0 $\pm$ 5.2	7.1 $\pm$ 5.0
Scan 3	54.3 $\pm$ 8.4	13.9 $\pm$ 6.9	8.9 $\pm$ 6.0
<i>P</i>	0.54	0.99	0.23

ror reported by Powers et al. [11] and a standard deviation of  $\pm 7^\circ$ , a priori analysis suggested that 25–30 subjects would be adequate to determine significance with 80% power.

## Results

The median visual analog pain scale rating for daily activities in our sample was 38 out of 100 (range 21–76). The pain scale rating during the lateral step-down test was decreased to 0 out of 100 while wearing the Protonics exercise device adjusted to the appropriate level of resistance. No differences were found among the three test conditions for any of the variables used to represent patellofemoral alignment. Means, standard deviations, and corresponding *P* values for each of the dependent measures are summarized in Table 1.

## Discussion

In practice, patients commonly report a temporary reduction or elimination of patellofemoral pain symptoms after an initial treatment session using the Protonics system. Indeed, such an effect was reported by each of the subjects participating in the present study during a lateral step down test even after the exercise device was removed. Therefore this study was undertaken to investigate whether these acute effects could be attributed to changes in patellofemoral alignment. Using MRI, our results showed no differences between test conditions for any of the three measures of patellofemoral alignment used in this study.

Treatment using the Protonics system has been shown to affect patellar position when used for longer periods of time. Using radiographs with the knee in full extension, Timm [16] reported that patellofemoral congruence angle improved by an average of  $17.7^\circ$  after a 4-week treatment period. Perceived pain decreased an average of 47%. Together with our study, these findings suggest that the mechanisms of pain relief after initial exposure to this treatment approach may be different from longer term effects.

Recent research suggests that certain neural factors may need to be considered as potential mechanisms to affect patellofemoral pain. A study by Sanchis-Alfonso et al. [12] showed diffuse damage to nerve tissues in the lateral retinaculum in a group of patients with symptomatic patellofemoral malalignment. The authors believe that re-

ceptors within the retinaculum play an important role in transmitting specific somatosensory afferent signals to the central nervous system, especially for proprioception. Damage to these receptors may result in alteration of joint afferent information and subsequent inability to control the position and stability of the patellofemoral articulation. Jerosch and Prymka [7], who recently reported a significant reduction in knee proprioception following patella dislocation, provide further evidence that neural factors may be involved. These findings suggest that one explanation for the acute effects of treatment with the Protonics device could be alteration of large fiber sensory input that inhibits pain rather than immediate changes in patellofemoral alignment. More sophisticated research methods would be necessary to address this hypothesis.

Other authors have also argued that increased proprioception could explain treatment effects in patients with patellofemoral pain. Bockrath et al. [2] reported a 54% reduction in perceived pain in 12 patients with PFPS after a single treatment with patellar taping, another popular form of treatment purported to affect patellofemoral alignment. Similar to our findings, the authors showed that the reduction in pain was not associated with a change in patella position since no difference was found in radiographic measurements of patellofemoral congruence angle or patella rotation angle.

The Protonics device is designed to provide resistance to knee flexion during exercise and functional activities. Therefore during weight bearing activities the device provides a support moment to the knee, thereby reducing the demand for muscle activity from the quadriceps. The decrease in quadriceps activity may in turn lead to a reduction in patellofemoral compression force. Such a mechanism could explain the decrease in pain reported by patients as they perform activities such as the lateral step-down test. How such a mechanism could affect symptoms once the device is removed, however, is more difficult to conceive. Perhaps as a result of increased resistance to the hamstrings, a carry-over effect is produced by enhancement of reciprocal inhibitory signals to the quadriceps that lasts for a short time after the device is removed. Studies utilizing electromyography may help to substantiate these potential alternatives.

Another possibility that must be considered is a placebo effect. Decreased pain may simply be the result of the application of a sophisticated piece of equipment and the personal interaction between the patient and therapist. In practice, however, patients report a reduction in symptoms only after resistance on the device is set to an appropriate level. Further testing with adequate controls is needed to fully understand these effects.

Several limitations need to be considered in the interpretation of our results. Although all of the participants in this study had complaints of PFPS of more than 3 months duration, none of them showed any gross abnormality in patellofemoral alignment in baseline scans. Therefore changes in alignment after treatment may have been difficult to detect. Repeating the study with a sample of pa-



tients who display significant malalignment would be helpful in confirming or refuting these results. In addition, the design of the study required that subjects be accurately repositioned in the MRI after each application of the exercise device. Subject repositioning might have affected the reliability of the measurements obtained. However, using the same method of measurement, Powers et al. [11] reported moderate to high reliability for patellar tilt and bisect offset from images obtained more than 2 weeks apart.

Knee angles from full extension to 30° flexion are believed to be the most useful in detecting patellofemoral malalignment because the patella is not yet seated in the trochlear groove. Therefore we chose to measure patellofemoral alignment statically at 20° knee flexion. While dynamic visualization of patellar motion using kinematic MRI has been shown to be superior to static measurements in evaluating patients with PFPS [3, 9, 10, 13], the hardware necessary to conduct these types of studies is not yet widely available. Studies using active movement during image acquisition are needed to determine whether changes in patellofemoral motion occur after treatment that cannot be detected using static measurements.

Recent research has suggested that measurements of patellofemoral alignment differ between loaded and unloaded conditions and that loading may improve the ability to identify abnormalities [4, 14]. In the present study a leg press exercise was used to provide a load that would activate the quadriceps and simulate a situation that was

more functionally relevant. Based on pilot work, a load equal to 25% body weight was chosen to avoid fatigue during the 4 min that was required to obtain each MRI scan. Muscle fatigue would have made it more difficult to maintain a static position of the knee and would have distorted the image. However, this level of resistance may not have been enough to reproduce the forces leading to abnormal patellofemoral alignment. Loads during activities that commonly provoke symptoms in patients with PFPS, such as stair climbing, are considerably greater than 25% body weight. Ultimately advances in technology are expected to allow quantitative analysis of patellofemoral motion with the patient in weight bearing positions. Future studies using these methods are needed to more fully understand the effects of various treatments.

## Conclusions

In a group of patients with PFPS no changes in patellofemoral alignment were measured with MRI following a single treatment session using the Protonics system. More research is needed to identify the underlying mechanism of reduced pain using this treatment method.

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