Research Report

Evaluation of Soft Foot Orthotics in the Treatment of Patellofemoral Pain Syndrome

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Background and Purpose. *The effectiveness of soft foot orthotics in the treatment of patients who have patellofemoral pain syndrome was investigated.* ***Subjects.*** *Subjects were 20 adolescent female patients, aged 13 to 17 years ($\bar{X}$=14.8, SD=1.2), who were diagnosed with patellofemoral pain syndrome and who exhibited excessive forefoot varus or calcaneal valgus.* ***Methods.*** *Subjects were randomly assigned to one of two groups: a control group (n=10), which took part in an exercise program, or a treatment group (n=10), which used soft foot orthotics in addition to participating in the exercise program. The exercise program consisted of quadriceps femoris and hamstring muscle strengthening and stretching exercises. A visual analogue scale was used to assess the level of pain of the subjects over an 8-week period.* ***Results.*** *Both the treatment and control groups demonstrated a significant decrease in the level of pain, but the improvement of the treatment group was significantly greater than that of the control group.* ***Conclusion and Discussion.*** *The results suggest that in addition to an exercise program, the use of soft foot orthotics is an effective means of treatment for the patient with patellofemoral pain syndrome. [Eng JJ, Pierrynowski MR. Evaluation of soft foot orthotics in the treatment of patellofemoral pain syndrome. Phys Ther. 1993;73:62–70.]*

Patellofemoral pain syndrome (PFPS) is the leading cause of chronic knee pain in adolescents.[1] The diagnosed incidence is on the rise, most likely as a result of greater emphasis on fitness in our society and an increased awareness of the condition by medical practitioners. Retropatellar pain experienced with PFPS can become a severe problem for adolescents, denying them full participation in sports and leisure activities. It is a significant psychological blow to those adolescents who are so restricted by their pain that they must abandon sports and related activities during their teen years. Much of the persistence of daily activity into adulthood depends on the perceptions of physical activity formed during childhood and adolescence.[2]

Although the exact etiology of PFPS is unknown, investigators[3–5] propose that abnormal patellofemoral mechanics are the primary cause of PFPS. A disturbance of the normal patellofemoral relationship results in an uneven distribution of shearing and compressive forces acting on the patellofemoral joint during normal activity.[6]

Malalignment of the patellofemoral mechanism is not only caused by local patellofemoral mechanics, but reflects anatomical variations throughout the entire lower extremities; indeed, PFPS is highly correlated with excessive pronation.[7–9] Excessive subtalar pronation during the stance phase can alter the normal rotation of the tibia in the frontal and transverse planes as a result of the anatomical congruency of the talus within the ankle mortise.[10] In turn, aberrant tibial rotation can disrupt the normal patellofemoral relationship.[7,11,12] To alter aspects of lower-extremity mechanics, one can use a foot orthotic, a device inserted between the foot and shoe, to modify foot positioning and

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Table 1. *Characteristics of Subjects (N=20)*

Variable	Control Group[a] (n=10)		Treatment Group[b] (n=10)	
	$\bar{X}$	SD	$\bar{X}$	SD
Age (y)	15.1	1.4	14.4	1.1
Height (cm)	160.5	9.6	159.4	4.0
Mass (kg)	53.2	10.0	50.2	8.0
Q-angle (°)	16.0	3.9	14.9	1.7
Forefoot varus (°)	12.6	2.8	12.4	3.7
Calcaneal valgus (°)	4.3	2.9	6.6	4.7
Knee pain (m)	9.7	9.9	10.0	9.8
Activity (h/wk)	7.4	5.2	7.2	5.6

[a]Control group=exercise only.

[b]Treatment group=exercise and orthotics.

lower-extremity function during the stance phase of the gait cycle.[3,13]

A complete analysis of the clinical effects of foot orthotics is necessary prior to their advocation and prescription. Although foot orthotics are frequently used in the clinical setting, there have been few investigations demonstrating their effectiveness. Some studies[3,7,13] have shown orthotics to be 70% to 80% effective in controlling the symptoms and recurrence of overuse injuries in runners. In a retrospective survey of 1,650 patients with injuries incurred from running, Clement et al[3] reported that most injured runners with varus foot deformities responded positively within 2 to 6 weeks when prescribed foot orthotics and were able to resume running and increase training volumes without recurrent injury.

Because matched controls were not used in any past investigations, cause-and-effect relationships between the use of foot orthotics and the symptoms of PFPS cannot be accurately determined. Although these reports contribute to our knowledge of orthotic effectiveness, they are flawed by selection bias, inconsistencies in the treatment duration, and the absence of control subjects. The results of these studies are also limited by widespread variation in subject age, diagnosis, and orthotic construction.

Reliable and valid measurements are required to provide quantitative measures of the clinical effectiveness of foot orthotics. Many contrasting views exist concerning the evaluation of the perception of the pain and the interpretation of the evaluation results. Previous researchers[3,7,13] used various methods that measured the percentage of subjects who achieved complete or partial pain relief with foot orthotics. We believe these methods tend to underestimate the value of the treatments, because they fail to detect treatments with slight, but worthwhile, analgesic properties. No indication of the rate of pain relief, variations in pain intensity, or possible increases in pain are given with these methods.

The use of a visual analogue scale (VAS) is considered to be one of the best methods for estimating the intensity of pain.[14,15] The VAS has been reported as a valid measure for the detection of clinical change in subjects with PFPS.[16] One drawback is the difficulty in establishing reliability in repeated measures of subjective states, because there is no reason to expect the pain to remain constant.[14] The effects of fluctuating pain levels can be minimized by requiring subjects to establish their maximum pain intensity over a specific time period (eg, 1 week) rather than their immediate pain at the time of the assessment. Hunter and colleagues[17] have shown that the memory for pain shows little decay after 5 days.

The purpose of our study was to evaluate the effectiveness of an 8-week program of foot orthotics combined with exercise in adolescent female patients with diagnosed bilateral PFPS. The following question was addressed in this study: Do patients receiving orthotic therapy in addition to participating in an exercise program show differences in the level of pain compared with patients participating in an exercise program only?

Method

Subjects

Twenty adolescent female patients, 13 to 17 years of age ($\bar{X}$=14.8, SD=1.2), diagnosed with bilateral PFPS were chosen to serve as subjects in this study because female adolescents have the highest incidence of PFPS.[1] Each subject provided informed consent. Subjects were randomly assigned to either a control group (n=10) or a treatment group (n=10). The control group subjects participated in an exercise program only. The treatment group subjects, in addition to participating in the exercise program, were fitted with foot orthotics bilaterally. Table 1 provides descriptive characteristics of the subjects.

The initial clinical diagnosis of PFPS was based on a dual examination by a physical therapist and a physician in which both examiners agreed on the diagnosis. The following criteria were used for inclusion in this study: duration of signs and symptoms greater than 6 weeks; history of bilateral retropatellar pain; insidious onset not related to trauma; and retropatellar tenderness on palpation, pain on patellar compression, or patellar crepitus.

Calcaneal valgus or forefoot varus greater than 6 degrees was also a requirement for inclusion in the

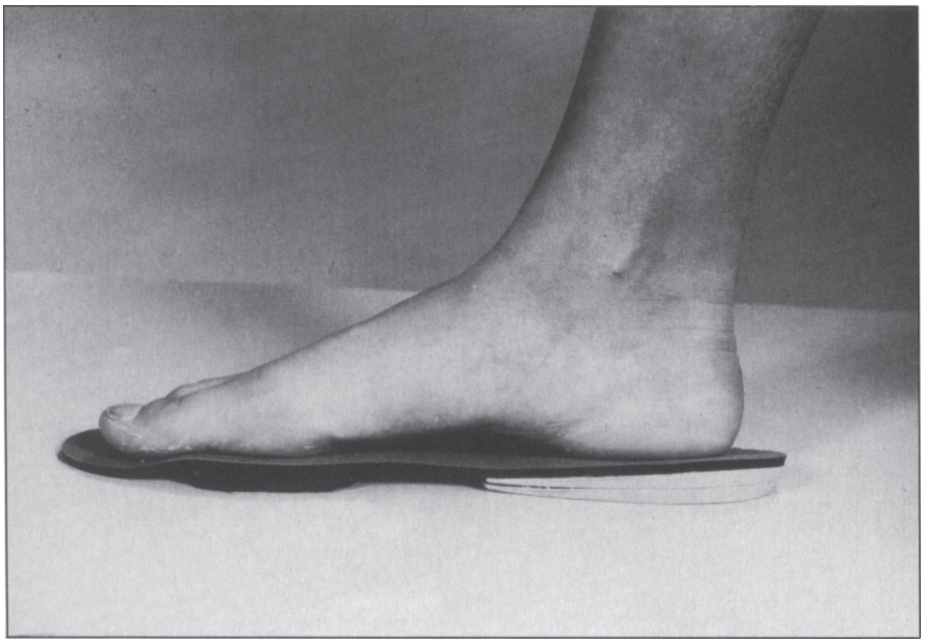

Figure 1. *Soft foot orthotic posted with medial wedges.*

study. Treatment is recommended for forefoot varus or calcaneal valgus greater than 5 degrees, as these amounts are likely to cause foot or lower-extremity symptoms.[18] This criterion ensured that all subjects displayed excessive pronation. To determine the subtalar neutral position, the subject was positioned prone with her feet over the end of a table. The degrees of inversion were measured as the angle between the bisection of the distal one third of the calf and the bisection of the posterior aspect of the calcaneus. The pivot of the goniometer was placed at the level of the subtalar joint. The same procedure was repeated to measure the degrees of calcaneal eversion, except the calcaneus was everted to the end of the range of motion (ROM). Subtalar neutral was computed by everting the calcaneus two thirds of the total ROM from its fully inverted position.[19,20] With the subtalar joint in the neutral position, forefoot varus was measured.[21] Calcaneal valgus was measured in a weight-bearing position as the angle between the Achilles tendon and the bisection of the posterior calcaneus. Forefoot varus and calcaneal valgus were measured according to procedures described by Donatelli.[22]

Excluded from this study were subjects who had had previous physical therapy or orthotic treatment, those with leg-length discrepancies greater than 1 cm, and those possessing any known pathological or neurological disorders that could affect their gait patterns. All subjects were without medication for these conditions.

Procedure

On the day of the examination, all subjects were asked to complete a VAS for each leg for each of the following activities: walking, running, sitting for 1 hour, ascending stairs, descending stairs, and squatting. The VAS consisted of a 10-cm straight line, the extremes of which were marked by perpendicular lines with the descriptors of "no pain" and "pain as bad as it could be." Subjects recorded the maximum pain they had experienced over the last week for each of the activities.

General activity (number of hours of activity per week) and the duration that the subject had experienced knee pain prior to commencing the study were recorded. Anthropometric measurements of height, mass, quadriceps femoris muscle angle, forefoot varus (non–weight-bearing), and calcaneal valgus (weight-bearing) were measured by the same tester (JJE). Test-retest trials produced intraclass correlation coefficients (ICC[1,1])[23] of .71, .97, and .94 for the measurements of forefoot varus, calcaneal valgus, and quadriceps femoris muscle angle, respectively. Reliability of the measurements of forefoot varus was not determined.

The treatment group was fitted with foot orthotics made by the same physical therapist. Orthotics can be categorized into rigid, semi-rigid, and soft or temporary devices. In this study, soft orthotics were chosen because they are inexpensive (less than $15 Canadian) and easily adjustable, which is important for an adolescent clientele. The foot orthotic was constructed from a flat Spenco insole* and posted medially with rubber wedges in the hindfoot and forefoot to position the subtalar joint toward a neutral position (Fig. 1). The forefoot posting ranged from 4 to 6 cm in length and extended proximally from the heads of the metatarsals. The hindfoot posting ranged from 6 to 8 cm in length and extended distally from the calcaneus. With calcaneal valgus between 4 and 6 degrees, a 2-degree hindfoot posting was used. With forefoot varus between 6 and 10 degrees, a 2-degree forefoot posting was used. If forefoot varus was greater than 10 degrees, 4- to 6-degree forefoot and 2- to 4-degree hindfoot postings were used.

The maximal posting was 6 degrees in the forefoot and 4 degrees in the hindfoot because larger postings were not comfortable for the subjects. Although the reliability of the forefoot varus measurement was not optimal (ICC=.71), we believe this did not likely have a major influence on the

*Spenco Sports Medicine Products, Toronto, Ontario, Canada M4W 3L9.

prescription of the postings, because the majority of subjects exhibited such large magnitudes of calcaneal valgus and forefoot varus (Tab. 1) that the maximal amount of posting was prescribed. The control group subjects were fitted with flat Spenco insoles, which were inserted into their shoes without any postings to decrease the bias between the two groups. The orthotic insole was worn whenever the subject was wearing shoes and could be transferred into different shoes (eg, running shoes, school shoes), depending on the subject's needs.

Subjects were monitored for 8 weeks. During this time, they visited the clinic twice each week. Every 2 weeks, the subjects completed six VASs to measure their pain response to the activities of walking, running, stairs ascent, stairs descent, sitting for 1 hour, and squatting. As all subjects were students, a regular 1-hour school period was the criterion that they used to estimate their pain for the activity of sitting for 1 hour. Subjects also recorded the number of hours they had participated in physical activities.

Exercise Program

On the first visit, all subjects were instructed in an exercise program of isometric quadriceps femoris muscle contractions and straight leg raising in a supine position. On the second visit, subjects were instructed in quadriceps femoris and hamstring muscle stretching exercises. To stretch the quadriceps femoris muscles, the subject stood on one leg and grasped the contralateral ankle. In the contralateral limb, the knee joint was flexed while the subject maintained a neutral or extended hip joint position. While one knee was flexed to 45 degrees in a long-sitting position, the subject stretched the hamstring muscle by lowering the chest toward the extended knee. Resisted straight leg raising and hamstring muscle strengthening were initiated on successive visits. Resistance was provided by small weights or by using an elastic material looped around the ankles. One set of 10 repetitions of all the exercises was to be performed twice a day at home. Three random phone calls were made to each subject to determine whether large discrepancies occurred between the control and treatment groups in their compliance with the exercise program. A positive response was given if the subject had performed the exercises the previous day. No significant difference was noted between the two groups regarding exercise compliance using a sign test ($P<.05$).

Data Analysis

Means and standard deviations were calculated for the descriptive characteristics. Independent *t* tests were used to compare these variables between the two groups. Significance was accepted at the .05 level.

As all subjects experienced bilateral knee pain, analysis was performed for the knee that was considered the most painful on the initial assessment. The VAS data were found to be normal in distribution using the Shapiro-Wilk W statistic of normality. In addition, the variance within the control and treatment groups was homogeneous. Parametric methods of analysis have been recommended for VAS data if the distribution of the variances is found to be homogeneous.[24,25] Independent *t* tests were performed to compare each activity of the VAS completed on the first visit to determine whether the control and treatment groups commenced the study from a similar baseline. The main statistical procedure was a three-factor (group versus activity versus week) analysis of variance (ANOVA) for repeated measures followed by a Newman-Keuls *post hoc* analysis when a significant F-ratio test result was observed.[26] The level of significance was accepted at .05.

Results

No significant differences were observed between the groups for the initial pain scales or for any of the descriptive variables (anthropometric measurements, duration of pain prior to the study, general activity during the study), suggesting that the groups were well matched.

Figure 2 demonstrates the differences between the control and treatment groups. The results of the repeated-measures ANOVA are presented in Table 2. Overall, subjects in both groups showed a significant reduction in the pain response. A significant difference of the pain response among the six activities was also observed.

Although both groups demonstrated a significant reduction in the reported pain, the treatment group demonstrated a significantly greater reduction than the control group. *Post hoc* analyses were performed to compare the treatment and control groups (1) for weeks 2, 4, 6, and 8 and (2) for the activities of walking, running, stairs ascent, stairs descent, sitting for 1 hour, and squatting. The *post hoc* analysis revealed significant differences between the treatment and control groups for weeks 4, 6, and 8, with the treatment group demonstrating a greater reduction of pain over the control group. The treatment and control groups demonstrated significant differences in the activities of running, ascent of stairs, descent of stairs, and squatting.

Discussion

It was expected that the activities would demonstrate significantly different pain responses, as the activities varied in the amount of stress placed on the patellofemoral joint. Both groups reported a significant reduction in the pain response. This improvement might be attributed to the exercise program, which was designed to encourage contraction of the vastus medialis oblique muscle for stabilization of the patella within the femoral groove and to stretch muscles that may contribute to increased patellar forces.

The treatment group reported a significant decrease in reported pain when compared with the control group at weeks 4, 6, and 8. It is diffi-

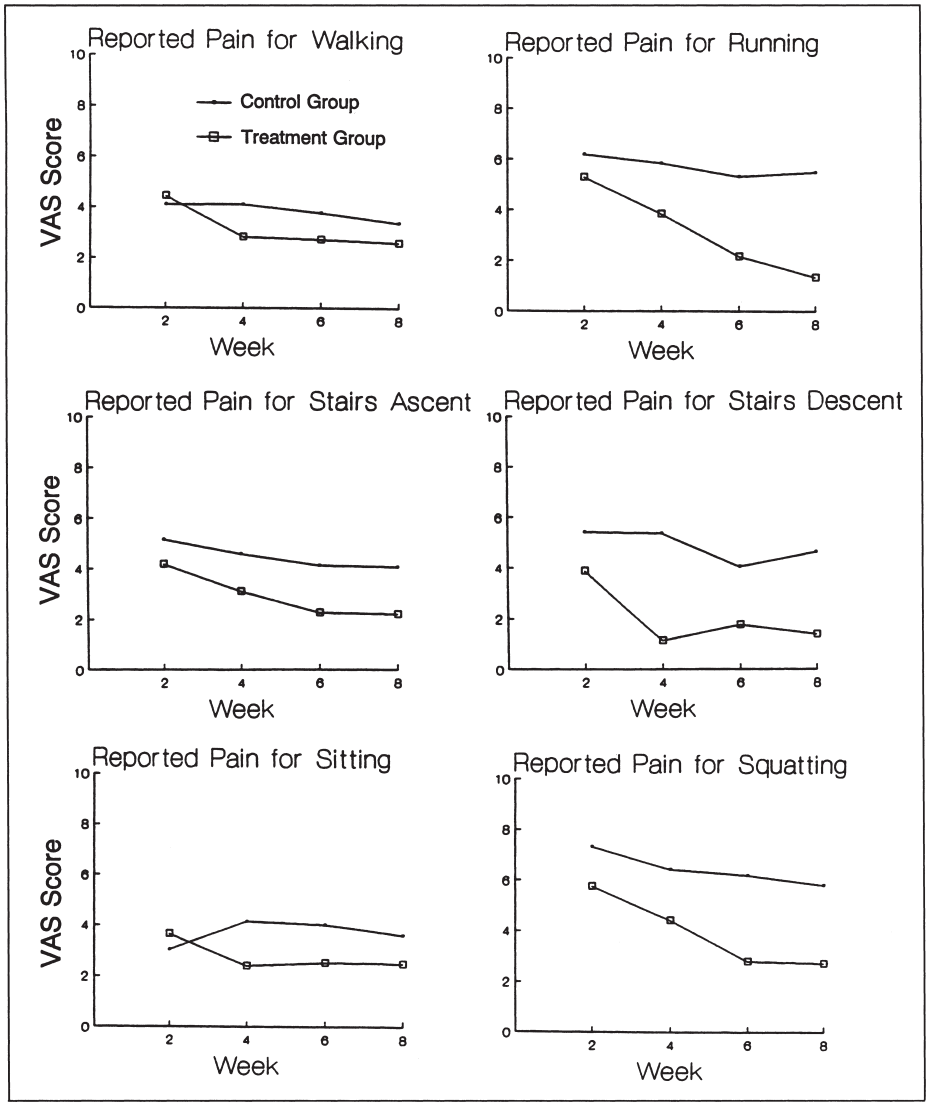

Figure 2. *Changes in reported pain on each test week of the treatment and control groups for the activities of walking, running, stairs ascent, stairs descent, sitting for 1 hour, and squatting. (VAS=visual analogue scale.)*

cult to compare the results of this study with those of most other studies because previous studies that examined the clinical effects of foot orthotics were anecdotal or a collection of cases without consideration of the population at risk. The results of this study are in agreement with the findings of Clement et al,[3] who also reported positive responses with foot orthotics within 2 to 6 weeks.

One would expect that a foot orthotic would be most effective during weight-bearing activities. The results reflect this to some extent, indicated by the fact that the results for running, stairs ascent, stairs descent, and squatting were significantly different between the control and treatment groups. In addition to reducing the discomfort experienced in specific activities, the foot orthotics likely had the effect of reducing overall irritation of the patellofemoral joint, which was reflected across all activities.

An examination of the effect of foot biomechanics on patellofemoral forces provides some insight as to why the treatment group improved more than the control group. Eng and Pierrynowski[10] reported that orthotics caused a reduction of eversion at the subtalar joint when walking and running, which subsequently affects the frontal and transverse motion of the tibia with respect to the femur. Smart and Robinson[27] reported a significant increase in valgus movement at the knee with foot orthotics in running and speculated that a reduction in the rotation in the frontal plane at the subtalar joint necessitated a transfer of motion proximally.

Extensive literature has been written about the abnormal biomechanics caused by excessive pronation, with the effects seen proximal to the ankle joint.[3,7,12] Several reasons may contribute to the reduction of pain with foot orthotics. First, as the foot is allowed to function more effectively with a foot orthotic, less effort is required for forward propulsion and better shock attenuation is attained. Second, the Q-angle, one of the measurements of lower-extremity alignment, is altered with foot orthotics.[28] Huberti and Hayes[29] determined contact areas and pressures of the patellofemoral joint and found that both increases and decreases in Q-angle resulted in higher peak contact pressures and in different pressure patterns. Increased peripheral loading of both the medial and lateral facets was observed or a transfer of the load completely to the lateral facet or medial facet took place in the absence of a normal Q-angle. Perhaps, by altering the Q-angle, an orthotic allows more normal patellofemoral contact pressure.

The effect of the foot orthotic may also be related to the patellofemoral joint reaction force (PFJRF). A two-dimensional model of the PFJRF assumes that the resultant force is directed posteriorly on the patella, is evenly distributed against both femoral condyles, and is influenced only by the flexion/extension motion of the knee. Although previous gait analyses[10,27] have shown that the sagittal motion of the knee does not change with foot orthotics, the direction of a three-dimensional resultant PFJRF vector is influenced by rotations in the frontal and transverse planes at the knee. A "malalignment" of the lower extremities would be associated

Table 2. *Analysis of Variance Summary for the Pain Response*

Source	df	SS	MS	F	P
Group	1	831.37	831.37	7.92	.012
Error	18	1889.40	104.97		
Week	3	263.97	87.99	25.72	.0001
Week×group	3	39.32	13.10	3.83	.015
Error	54	184.72	3.42		
Activity	5	277.29	55.46	4.82	.0006
Activity×group	5	83.70	16.40	1.45	.21
Error	90	1035.48	11.50		
Week×activity	15	17.34	1.16	1.13	.33
Week×group×activity	15	19.12	1.27	1.24	.24
Error	270	277.04	1.03		

with unequal transmission of the resultant PFJRF to the medial and lateral femoral condyles. If forces are applied to only one femoral condyle, one would expect a subsequent increase in load to the overlying patellar facets. It may be postulated that the foot orthotic has some influence on the location of the PFJRF. Perhaps one of the reasons for the effect of the orthotic is that by affecting the transverse and frontal rotations of the tibia on the femur, the location of the PFJRF is more evenly distributed between both condyles.

Clinical Implications

One might argue that a more appropriate study would compare the use of foot orthotics with a control without foot orthotics (no exercise program included). Although the merits of such a study are recognized, the realistic conservative management of PFPS is an eclectic one with the application of various treatment regimens. This study has examined only one of the possible treatments that may be beneficial to the patient with PFPS; in the actual clinical setting, several approaches are often applied at the same time, depending on the needs of the patient.

Soft foot orthotics is a very inexpensive and simple treatment for patients with PFPS who display excessive forefoot varus or calcaneal valgus. If clinicians select foot orthotics as a treatment for PFPS, we believe they should consider at least a 4-week trial period for their patients, as significant differences were not found at the 2-week period in this study. Patients who have success with orthotic treatment may then progress to a more permanent type of foot orthotic, because the soft orthotic will tend to break down with time and repeated usage.

Summary and Conclusions

In this clinical study, foot orthotics and an exercise program were found to reduce pain more significantly in female patients with PFPS than just an exercise program alone. Only a short-term follow-up was performed in this study, and recommendations beyond the 8-week period cannot be addressed. Hypotheses to explain the reduction of pain included a relationship between the motion of the tibiofemoral joint and (1) the distribution of forces between the medial and lateral femoral condyles and (2) the contact pressure and pattern between the patella and femoral condyles.

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Commentary

Patellofemoral pain syndrome (PFPS) is one of the most frequent musculoskeletal disorders affecting athletic youngsters[1] and may account for up to 10% of the cases seen in a sports injury clinic.[2] This disorder is often attributed to chondromalacia of the patella, even though several studies have now shown that chondromalacia patellae is present as an incidental finding.[3] Many patients with anterior knee pain also have normal patellar cartilage at arthroscopy.[4]

Retinacular pain associated with patellofemoral malalignment is the most frequent cause of anterior knee pain, and biopsies of the lateral retinaculum have shown that small nerves in this area can be injured as a result of chronic patellar imbalance.[5] Over time, patellofemoral imbalance can cause articular damage because of increased local stresses and decreased normal loading of the articular cartilage.[6]

Atrophy of the vastus medialis obliquus muscle is frequently associated with PFPS, possibly as a result of the interaction between mechanical and neuromuscular factors.[7] This atrophy is thought to result in extensor mechanism dysfunction, decreased muscle strength, and imbalance in control between the medial and lateral portions of the quadriceps femoris muscle.[8]

Physical therapy regimens have focused on vastus medialis obliquus muscle rehabilitation by terminal extension of the knee,[9] while restricting the activities that cause pain, possibly associated with patellar taping.[10]

To some extent, this study confirms what we already knew, namely, that any structured intervention in PFPS significantly improves its symptoms. This has been proven in uncontrolled studies,[11,12] and regimens incorporating the "closed-chain" concept have reported a 96% success rate.[10]

Oral nonsteroidal anti-inflammatory drugs are generally used in the early stages of treatment of PFPS,[13] but their effect is, at best, marginal. A more physiological approach to the pharmacological treatment of PFPS should be achieved, at least theoretically, by intra-articular injections of glycosaminoglycan polysulphate (GAGPS). Glycosaminoglycan polysulphate shows good affinity for the cartilage matrix, possibly protecting damaged cartilage by inhibiting catabolic enzymes and stimulating the metabolism of chondrocytes and synovial cells.[13] A recent trial compared the effect of intra-articular injections of GAGPS with conservative treatment and placebo injections administered in a randomized double-blind fashion in 53 patients with PFPS with an average duration of symptoms of 16 months. Results at 6 months proved that injection of GAGPS or saline did not provide significant improvements beyond the good results shown by the basic conservative treatment alone, with more than two thirds of the patients in each group achieving complete recovery.

Given this background, the results reported in the study by Eng and Pierrynowski should be viewed with caution. In practice, most patients, even those with a long history of PFPS, recover with conservative treatment alone. Foot pronation has been included as one of the factors determining mechanical imbalance at the patellofemoral joint, and orthoses correcting pronation should exert benefits on PFPS, as they should reequilibrate the mechanical stresses exerted on the whole leg. If this is true, however, then it is conceivable to ask, What happens when the patients discard the orthoses?

The study period was relatively short, hence no long-term directives can be given, and the study was carried out with a small number of subjects, thus making the results achieved difficult to generalize.

It is my firm belief that a composite treatment program should be implemented in these patients. Limitation of painful activities, quadriceps femoris muscle exercises, proprioceptive exercises, and orthotics all play a role in the conservative management of PFPS. It is difficult, however, to quan-