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# Effects of Foot Orthoses on Quality of Life for Individuals With Patellofemoral Pain Syndrome

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**Study Design:** Repeated-measures analysis of intervention.
**Objectives:** To determine the effects of foot orthoses on quality of life for individuals with patellofemoral pain who demonstrate excessive foot pronation.
**Background:** Foot orthoses are a common intervention for patients with patellofemoral pain. Limited information is available, however, regarding the effects of foot orthoses on quality of life for these patients.
**Methods and Measures:** Sixteen subjects with patellofemoral pain who also exhibited signs of excessive foot pronation were studied. Subjects underwent a 2-week period of baseline study followed by custom foot orthotic intervention. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was administered to subjects at the time of screening, just prior to foot orthotic intervention, and at 2 weeks and 3 months following foot orthotic intervention.
**Results:** Wilcoxon matched-pairs signed-rank test results indicated statistically significant improvements in the pain and stiffness subscales 2 weeks following the start of foot orthotic intervention. All WOMAC subscale scores were significantly improved at 3 months compared with preintervention measurements.
**Conclusions:** Custom-fitted foot orthoses may improve patellofemoral pain symptoms for patients who demonstrate excessive foot pronation. *J Orthop Sports Phys Ther 2004;34:440-448.*

***Key Words:*** *biomechanics, knee pain, physical function, stiffness*

Patellofemoral pain affects as much as 25% of the general nonathletic population.[7] Although patellofemoral pain occurs in all age groups, it is more common among adolescents and young adults.[16] Symptoms include: persistent pain behind the patella[5,16]; pain aggravated by ascending and descending stairs, squatting, and prolonged sitting[5,7,16,19]; and crepitus, clicking, catching, and the sensation of ''giving way.''[19,20,28] According to Goodfellow,[16] joint effusion is rare, and range of motion (ROM) is not limited. Symptoms are typically bilateral and persistent, lasting over several years with little change.

Many theories have been suggested regarding the etiology of patellofemoral pain. These include: malalignment of the patella[8,16,19,29]; abnormal soft tissue forces[14,20,32,33]; increased Q angle[1,19,21]; tightness, pain, or neuromas in the retinacular structures[8,12,13,30]; and abnormal tibial and femoral rotation.[33,37] Patients with patella alta[20,34] and patellar subluxation[26] may also be prone to patellofemoral pain.

Tiberio[36] suggested that compensatory internal rotation of the femur may occur due to increased pronation at the subtalar joint. Compensatory internal rotation of the femur may cause increased compression between the lateral articular surface of the patella and the lateral femoral condyle. This change in patellar alignment may result in an increase in lateral tracking of the patella.[36] Buchbinder et al[6] suggested that the position of internal rotation of the lower limb might cause an abnormal quadriceps muscle force vector and patellar malalignment. These theories suggest that a reduction of foot pronation may influence patellofemoral tracking and patellofemoral pain by decreasing compensatory lower extremity internal rotation.

D'Amico and Rubin[9] have documented that foot orthoses significantly decreased Q angle for subjects who had been prescribed foot orthoses for a variety of reasons. Additionally, Nawoczenski et al[27] and McPoil and Cornwall[25]

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have reported that foot orthoses significantly decreased the magnitude of internal rotation of the leg when walking. Because excessive pronation can lead to excessive tibial and femoral internal rotation and lateral patellar displacement, some investigators have suggested the use of foot orthoses for treatment of patellofemoral pain.[10,11,23,27] The foot orthosis is designed to allow the foot to move through the normal range of pronation, yet limit excessive foot pronation, thereby reducing the excessive tibial and femoral internal rotation that may lead to abnormal patellofemoral tracking.

Klingman et al[23] examined the effects of a medial wedge on patellofemoral position with healthy subjects positioned in unilateral weight bearing without shoes. These investigators reported that foot orthoses caused a mean medial displacement of the patella equal to 1.08 mm (SD, 0.52), as compared to weight bearing without foot orthoses. Eng and Pierrynowski[11] examined the management of patellofemoral pain with orthoses by comparing an experimental group that received orthoses and exercise to a control group that received exercise alone. The effect of these interventions on knee pain was examined using a visual analog scale (VAS) for several functional activities. Foot orthoses combined with an exercise program reduced pain significantly more in female patients with patellofemoral pain than an exercise program alone.[11] Eng and Pierrynowski[11] only examined pain that was experienced with 6 functional activities. The difficulty or inability to perform various functional activities was not addressed.

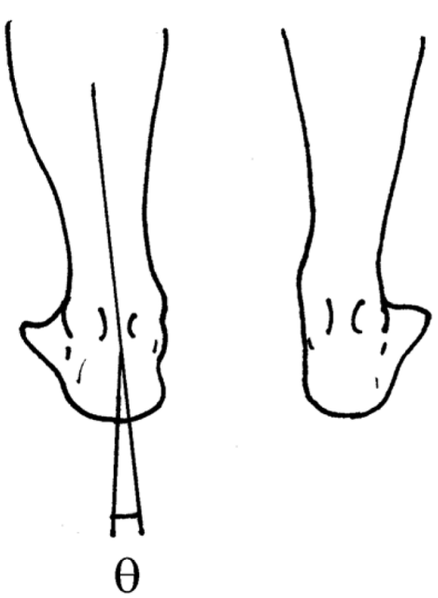


**FIGURE 1.** Rearfoot angle (θ) measured as the acute angle between the distal midline of the leg and the midline of the calcaneus.

In summary, patellofemoral pain is a common problem and many factors have been associated with its etiology, including tightness in soft tissue structures,[8,12] muscle imbalances,[26,32] abnormal structural alignment,[1,20,26,31,34] and abnormal patellar tracking.[19,29] Foot motion influences leg and thigh motion and vise versa.[33,37] VanKampen and Huiskes[37] have offered evidence that rotation at the tibia influences motion and tracking of the patellofemoral joint. Foot orthoses influence motion at the foot,[27] and some investigators have reported that foot motion has an effect on patellofemoral position.[23,27] The effects of orthoses and shoe wear on patellofemoral position and function for individuals with patellofemoral pain, however, have not been clearly identified. The purpose of this study was to determine the effects of foot orthoses on pain, stiffness, and physical function for subjects with patellofemoral pain syndrome.

## METHOD

### Subjects

Sixteen subjects with patellofemoral pain were recruited from the local community and physical therapy outpatient centers. Subjects were between 14 and 50 years of age. Additional inclusion criteria were: anterior knee pain of at least 2 months duration prior to enrollment, composite score of 200 or greater on the WOMAC Osteoarthritis Index out of a possible score of 2400; nontraumatic onset of anterior knee pain; tenderness with palpation on at least 1 patellar facet at the time of screening; ability to walk without an assistive device at least 10 m; ability to perform a unilateral unsupported squat to 45° of knee flexion; and active knee ROM from 0° of knee extension to 60° of knee flexion. The knee ROM requirements were based on additional testing that was completed as part of another study. Excessive foot pronation was also required for all subjects and was operationally defined as more than 9° of calcaneal valgus for rearfoot angle in bilateral weight bearing (Figure 1), and less than 141° longitudinal arch angle in bilateral weight bearing (Figure 2).[22] Sixteen additional individuals were screened for enrollment in the study but were excluded from participation in the study for various reasons, including WOMAC scores less than 200 (n = 11), inadequate foot pronation (n = 6), signs consistent with meniscal involvement (n = 2), signs consistent with patellar tendonitis (n = 1), and absence of tenderness at patellar facets (n = 1). Some of these individuals were excluded for more than 1 reason.

### Instrumentation

A standard analog floor scale was used to measure body mass. A standard goniometer with 1° demarca-

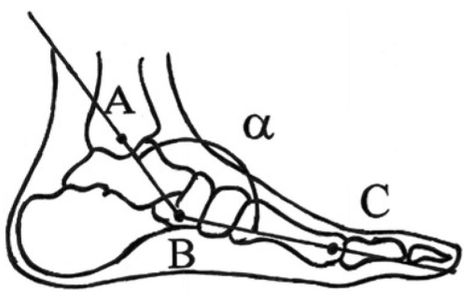


**FIGURE 2.** Longitudinal arch angle (α) measured as the obtuse angle formed by the line between the center of the medial malleolus (A) and the navicular tubercle (B), and a line between the center of the navicular tubercle and the first metatarsal head (C).

tions was used to measure rearfoot angle, longitudinal arch angle, and tibiofemoral joint ROM. A metric ruler with 1-mm demarcations was used to mark the bisection of the calcaneus and the leg for the measurement of the rearfoot angle. A small convection oven was used to heat the orthotic blanks prior to fabrication. An electric sander was used to grind the orthoses for proper fit and posting. The ruler with 1-mm demarcations was also used to measure the VAS recordings on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

The WOMAC is a health status measure developed for outcome measurement in osteoarthritis clinical trials of the hip and knee. The WOMAC is a self-administered disease-specific questionnaire that consists of 24 questions, each on a 100-mm VAS. The WOMAC assesses the dimensions of pain, stiffness, and physical function.[2] According to its creators, the WOMAC is valid, reliable, and sufficiently sensitive to detect clinically significant changes in health status following a variety of interventions including drug therapies and physical therapy.[2,4,35] The WOMAC has been documented as being more sensitive in detecting disease-specific changes associated with osteoarthritis than the SF-36 or the Health Utility Index, both of which are generic health status measures.[3] The WOMAC also is significantly related ($r$ = 0.72, $P<.001$) to a reliable self-administered pain severity scale that was developed and tested on 29 subjects with patellofemoral pain syndrome.[24]

## Testing Procedure Overview

Subjects were tested on 4 different occasions. The initial testing session consisted of performing the screening procedures, administering the WOMAC, and providing shoe wear recommendations. Subjects then underwent a 2-week period of baseline study with no intervention, followed by a second administration of the WOMAC and fitting with custom foot orthoses at the time of the second visit. Finally, WOMAC measures were acquired either in person or by mail 2 weeks and 3 months following the foot orthotic intervention. Each subject (and a parent or guardian when appropriate) signed a statement of informed consent and the rights of all subjects were protected throughout the duration of the study. The protocol for this study was approved by The Committee for the Protection of the Rights of Human Subjects at the University of North Carolina at Chapel Hill.

## Detailed Screening Procedure

The first (screening) visit was performed at a location of convenience for each subject. Demographic data were recorded. The ability to walk at least 10 m without an assistive device and perform a unilateral squat with at least 45° of tibiofemoral joint flexion was recorded. Palpation of the knee included palpation of the joint line, patellar tendon, quadriceps tendon, and patellar facets. The patellar facets were palpated by first displacing the patella medially to palpate the medial facet, and then displacing the patella laterally to palpate the lateral facet. Ligamentous stability tests and meniscal tests were performed if indicated, based on the patient's complaints, history, and response to palpation. The principal investigator measured each subject's longitudinal arch angle, rearfoot angle, tibiofemoral joint flexion ROM, and body mass.

The technique described by Jonson and Gross[22] and Hung and Gross[18] was used to measure the rearfoot angle and longitudinal arch angle. Both of these measures were assessed in standing to capture the functional characteristics of the foot weight-bearing postures. Separate lines representing the bisection of the calcaneus and the bisection of the distal third of the right lower leg were drawn with the subject positioned in prone. The subject was then positioned in bilateral standing with feet shoulder width apart and equal weight bearing. The right rearfoot angle (Θ) was measured as the acute angle formed by the leg bisection line and the calcaneus bisection line (Figure 1). The rearfoot angle for the left limb was measured in the same manner.

The subject stood for the measurement of the longitudinal arch angle. The centers of the medial malleolus, the navicular tuberosity, and the first metatarsal head were marked on the medial aspect of the foot. The longitudinal arch angle (Θ) was defined as the obtuse angle formed by the line between the medial malleolus and the navicular tuberosity and the line between the first metatarsal head and the navicular tuberosity (Figure 2). The longitudinal arch angle was recorded for each subject for both feet.

Pilot data were collected for our study to assess the interrater reliability for the measurement of the rearfoot and the longitudinal arch angles. The 2

investigators measured the rearfoot angle and the longitudinal arch angle for each of 12 subjects. The measurements occurred during the same day, but were performed in separate areas by the 2 examiners. All marks on the foot were made with a wax marker, and were removed from the foot and leg between measurements so that the second investigator would not be biased by previous markings. The mean absolute difference for paired rearfoot angle measurements was 1.8° (SD, 1.5°). Actual values for rearfoot angle ranged from 6° to 14° calcaneal valgus. The interrater intraclass correlation coefficient ($ICC_{3,1}$) value for the rearfoot angle measurements was 0.53. The mean absolute difference for paired longitudinal arch angle measurements was 3.2° (SD, 2.1°). The values for longitudinal arch angle ranged between 123° to 160°. The interrater $ICC_{3,1}$ value for longitudinal arch angle measurements was 0.91. The investigators believed that the restricted range of measurements for the rearfoot angle explained the ICC value for this variable, and that the mean absolute difference values for both measurements and the ICC value for the longitudinal arch angle justified using these data to describe the subject sample.

Individualized shoe recommendations were given to all subjects based on an assessment of each subject's shoes. Recommendations included a semicurved- or straight-shaped last, a combination or board last, firm midsole density, firm stiffness of the heel counter, no heel flare, and firm stiffness of the rearfoot portion of the shoe to bending and twisting.[15] The principal investigator assessed each subject's shoes with regard to these criteria and reviewed with the subject the degree to which the subject's shoes possessed each of the criteria. Subjects were asked to consider purchase of new shoes based on the recommendations provided. If the subject indicated that they intended to purchase new shoes, they were asked to do so before the fabrication of foot orthoses. The purchase of recommended shoe wear, however, was not required for participation in this study. Shoe wear selected by each subject for use in this study was recorded, including the type, age, condition, and key characteristics.

Each subject completed the WOMAC Osteoarthritis Index and an activity level questionnaire. Subjects were asked to complete the WOMAC based on their experience with the more painful knee, or either knee if they reported that their knees were equally painful. Subjects with a composite WOMAC score less than 200 were excluded from participation in the study. If the composite score on the WOMAC was 200 or greater, a clinic appointment for fabrication of foot orthoses was scheduled approximately 2 weeks following the initial screening procedure. The 2-week period was used to establish a baseline for symptoms on the WOMAC. Subjects completed the WOMAC and the activity level questionnaire for a second time during their clinic appointment, just prior to receiving their custom foot orthoses.

## Orthotic Fabrication

Orthoses were fabricated for the subjects by one of the investigators who has 23 years of experience as a physical therapist and 17 years of experience fabricating foot orthoses. Subjects sat on a stool with their foot resting on top of a molding cushion. The orthotic blanks (Fastech Labs, Troy, MI) were heated in a convection oven at 121°C for approximately 5 minutes. The heated orthotic blank was placed on the molding cushion and then the investigator placed the subject's foot on the orthotic blank. The subject's rearfoot was maintained in a relatively neutral position (ie, calcaneus midline qualitatively aligned with the midline of the distal leg). The investigator imposed an inferiorly directed force of approximately 223 N (50 lb) on the proximal dorsal surface of the foot. The investigator's other hand applied a superiorly directed force of approximately 22 N (5 lb) to the underside of the foam cushion to push the orthotic blank against the plantar surface of the foot. The foot was held in place for approximately 2 minutes and then the orthotic blank was prepared for the application of posting material.

Thermal cork was adhered to the inferior surface of the orthotic blank and was ground to accommodate the specific requirements of each subject. Cork material was used to fill the concavity underneath the medial longitudinal arch portion of the orthosis. A medial rearfoot post was provided for subjects who demonstrated foot pronation that was associated with varum of the distal leg. The need for medial forefoot posting was based on a qualitative assessment of the magnitude of forefoot varus present. All subjects were posted to try to maintain the rearfoot angle in a less everted position as they stood bilaterally with equal weight bearing and feet positioned shoulder width apart.

## Follow-up Procedures

Each subject completed the WOMAC Osteoarthritis Index twice following foot orthotic intervention at a location of convenience for the subject. The first follow-up WOMAC was administered 2 weeks after the subjects received their foot orthoses. The purpose of this time period was to provide subjects some experience with the use of the foot orthoses prior to their completion of the WOMAC. If a personal visit was not possible, the WOMAC was mailed to the subject. The subject was asked to complete the WOMAC within 48 hours of receipt and to return the WOMAC to the principal investigator in a self-addressed stamped envelope. An additional follow-up

WOMAC was completed by each subject 3 months following the foot orthotic intervention. At each follow-up session, all subjects also reported the number of hours per day and the number of days per week that they had worn the foot orthoses.

The principal investigator scored the WOMAC. Preintervention composite scores were tabulated, as well as scores for each of the 3 subsections (pain, stiffness, and physical function). Pain, stiffness, and physical function subsection scores were computed for all subjects for each additional administration of the WOMAC.

## Data Analysis

Descriptive statistics were generated for the demographic subject data, including height, age, mass, months since onset of symptoms, rearfoot angle, and longitudinal arch angle. WOMAC scores were assessed for normality for each WOMAC subscale and each time of administration. The Wilcoxon matched-pairs signed-ranks test ($\alpha$ = .05) was applied for paired comparisons because the data were not distributed normally. All WOMAC subscale scores were assessed using an intention-to-treat analysis approach.[17] For clinical intervention trials, this approach involves using the last observed data for any future data that are missing. This approach assumes, therefore, that the subject's status did not change from the last time that data were collected to the data collection time for which data are missing. WOMAC subscale scores were assessed for significant differences between: the 2 preintervention assessments; the second preintervention assessment and the 2-week postintervention assessment; the second preintervention assessment and the 3-month postintervention assessment; and the 2-week postintervention and the 3-month postintervention assessment.

## RESULTS

Descriptive data for the subjects appear in Table 1. The mean length of time since onset of the symptoms for subjects was 34.6 (SD, 33.6) months. Three of the 16 subjects purchased new shoes just prior to receiving foot orthotic intervention. Shoe wear recommendations included 6 criteria previously described in this report. Shoes used by the subjects had a mean of 3.6 (SD, 1.8) of the 6 motion control features that were identified for subjects. The mean age of the shoes used was 8.0 (SD, 10.0) months. The characteristics of the orthoses worn by the subjects are described in Table 2.

Subjects reported at the 2-week follow-up that they had worn their orthoses for a mean of 5.8 (SD, 1.2) days per week and 9.1 (SD, 2.1) hours per day. The investigators were only able to acquire WOMAC data for 15 of the 16 subjects at the 3-month follow-up test. The subject for whom data were not available had stopped wearing his foot orthoses 2 months following the foot orthotic intervention when he developed new unrelated complaints of pain. Using the intention-to-treat approach, this subject's WOMAC data at 2 weeks were carried forward and entered again for his 3-month WOMAC data.[17] Subjects reported at the 3-month follow-up that they had worn their orthoses for a mean of 5.5 (SD, 1.2) days per week and 8.7 (SD, 1.8) hours per day.

**TABLE 1.** Demographic data.

| Subject | Gender | Age (y) | Height (cm) | Mass (kg) | Rear Foot Angle (°) | Longitudinal Arch Angle (°) | Onset (mo) | WOMAC Composite Score |
|---|---|---|---|---|---|---|---|---|
| 1 | F | 23 | 168 | 54.5 | 10 | 139 | 84 | 322 |
| 2 | F | 27 | 168 | 70.5 | 9 | 128 | 36 | 382 |
| 3 | F | 14 | 165 | 64.5 | 9 | 130 | 4 | 878 |
| 4 | F | 31 | 163 | 76.4 | 10 | 129 | 4 | 389 |
| 5 | F | 24 | 178 | 63.6 | 9 | 120 | 24 | 267 |
| 6 | F | 24 | 168 | 55.5 | 18 | 132 | 14 | 342 |
| 7 | M | 32 | 191 | 93.2 | 11 | 136 | 3 | 287 |
| 8 | F | 45 | 165 | 52.7 | 10 | 135 | 18 | 1284 |
| 9 | F | 31 | 170 | 59.1 | 9 | 135 | 36 | 333 |
| 10 | F | 21 | 157 | 59.1 | 11 | 132 | 108 | 298 |
| 11 | F | 20 | 165 | 77.3 | 11 | 131 | 48 | 746 |
| 12 | M | 20 | 183 | 86.4 | 11 | 124 | 24 | 826 |
| 13 | F | 21 | 180 | 60.0 | 10 | 121 | 96 | 395 |
| 14 | F | 23 | 163 | 61.4 | 12 | 122 | 12 | 705 |
| 15 | M | 35 | 185 | 84.1 | 10 | 119 | 6 | 298 |
| 16 | F | 15 | 163 | 50.0 | 9 | 124 | 36 | 820 |
| Mean | | 25.4 | 170.8 | 66.8 | 10.6 | 128.6 | 34.6 | 535.8 |
| SD | | 7.9 | 9.6 | 13.1 | 2.2 | 6.3 | 33.6 | 300.2 |

**TABLE 2.** Foot and foot orthotic characteristics. All subjects received full-length orthoses.

| Subject | Presence of Forefoot Varus* | Medial Forefoot Post | Medial Rearfoot Post | Custom Arch Fill |
|---|---|---|---|---|
| 1 | Left foot only | Left foot only | Bilateral | Yes |
| 2 | Bilateral | Bilateral | Bilateral | Yes |
| 3 | Bilateral | Bilateral | Bilateral | Yes |
| 4 | Bilateral | Bilateral | Bilateral | Yes |
| 5 | Bilateral | Bilateral | Bilateral | Yes |
| 6 | Left foot only | Left foot only | Left foot only | Left foot only |
| 7 | Bilateral | Bilateral | Bilateral | Yes |
| 8 | Bilateral | No | Bilateral | Yes |
| 9 | No | No | Bilateral | Yes |
| 10 | No | No | Bilateral | Yes |
| 11 | Bilateral | Bilateral | Bilateral | Yes |
| 12 | Bilateral | Bilateral | Bilateral | Yes |
| 13 | Bilateral | Bilateral | Bilateral | Yes |
| 14 | Bilateral | Bilateral | Bilateral | Yes |
| 15 | Bilateral | Bilateral | Bilateral | Yes |
| 16 | Bilateral | Bilateral | Bilateral | Yes |

* Assessed qualitatively (see text).

The Wilcoxon matched-pairs signed-rank test indicated no significant differences between the 2 preintervention administrations of the WOMAC for the subscales of pain ($T$ = 43, n = 16, $P>.05$), stiffness ($T$ = 42, n = 16, $P>.05$), and physical function ($T$ = 65, n = 16, $P>.05$). Subjects demonstrated significant improvements in pain ($T$ = 21, n = 16, $P<.05$) and stiffness ($T$ = 19, n = 16, $P<.05$) scores at 2 weeks following intervention compared with the second set of preintervention WOMAC scores. WOMAC scores for physical function were not significantly different ($T$ = 31, n = 16, $P>.05$) at the 2-week follow-up compared with the second set of preintervention scores (Figure 3).

Data analyses indicated significant improvements in physical function ($T$ = 29, n = 16, $P<.05$) scores at 3 months, as compared to scores at 2 weeks. WOMAC subset scores for pain ($T$ = 44, n = 16, $P>.05$) and stiffness ($T$ = 46, n = 16, $P>.05$) were not significantly different at 3 months following intervention, as compared to the data 2 weeks following intervention (Figure 3). Wilcoxon analyses indicated significant improvements for all 3 WOMAC subscales of pain ($T$ = 9, n = 16, $P<.05$), stiffness ($T$ = 15, n = 16, $P<.05$), and physical function (T = 4, n = 16, $P<.05$) at 3 months compared with measures made just prior to foot orthotic intervention.

## DISCUSSION

Subjects experienced significant decreases in symptoms of pain and stiffness, and improvement in physical function following the foot orthotic intervention. Subjects experienced significant improvements in pain and stiffness within the first 2 weeks of the intervention, and significant improvement in physical function by the 3-month follow-up assessment. Although the mean WOMAC score for physical function had decreased at the 2-week follow-up, the change in this set of scores was not significant until the 3-month follow-up. The results, however, do indicate that subjects demonstrated significant improvements for all 3 WOMAC subset scores during the course of the study, and most of these changes occurred within the first 2 weeks of foot orthotic intervention. These improvements were also noted following a relatively lengthy time (±SD) over which subjects had experienced patellofemoral pain symptoms (34.6 ± 33.6 months). The design of this study included a baseline or nontreatment period rather than a control group. A randomized controlled trial studying the use of foot orthoses for treatment of patellofemoral pain would provide increased confidence in this intervention.

During pilot testing, we administered the WOMAC to 15 healthy subjects who had similar age and gender distribution to subjects in the current study. The mean composite WOMAC score for these pilot subjects was 28.6 (SD, 67.9). The mean (±SD) composite WOMAC scores for subjects in the current study (535.8 ± 300.2) suggest that these individuals had clinically significant symptoms at the time of their enrollment in the study. The mean length of time since onset of the symptoms also suggests that their patellofemoral pain was a chronic condition that was unlikely to improve spontaneously. Additionally, the data analyses indicated that WOMAC scores were stable over a 2-week period prior to intervention. Symptomatic changes postintervention, therefore, were more likely the result of the intervention than other factors.

All subjects who participated in this study would be classified as pronators based on the criteria provided by Jonson and Gross.[22] Subjects met the inclusion criteria for pronated feet based on rearfoot angle and

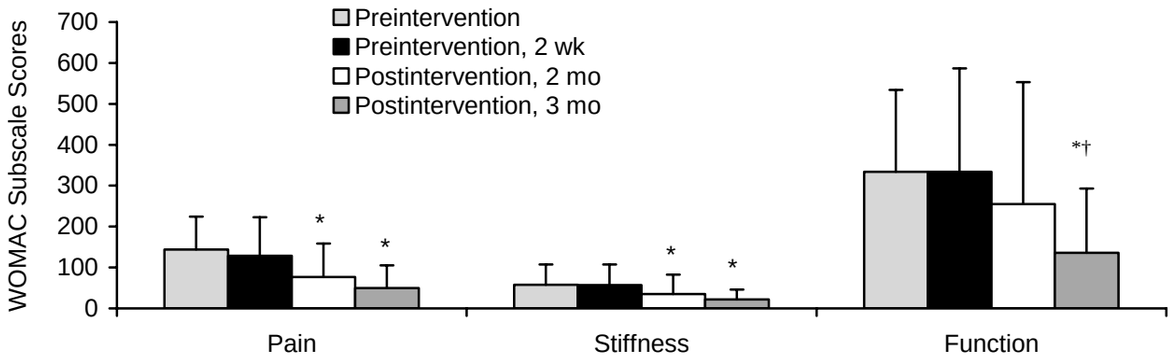


**FIGURE 3.** WOMAC Osteoarthritis Index mean scores for pain, stiffness, and physical function subscales. Scores are given for an initial preintervention assessment and a preintervention assessment 2 weeks following the first assessment. Scores also are represented for assessments 2 weeks and 3 months following foot orthotic intervention. Lower scores indicate an improvement in function. Error bars are 1 SD.

* Significantly lower as compared to the preintervention score ($P<.05$).

† Significantly lower as compared to the score 2 weeks postintervention ($P<.05$).

longitudinal arch angle measurements.[22] The inclusion/exclusion criteria resulted in 16 potential subjects with anterior knee pain being excluded from participation during the screening procedures. Fifty percent of these 16 potential subjects were excluded because they did not meet the criteria for excessive foot pronation. The clinical application of the results, therefore, may apply only to patients with patellofemoral pain who have a similar foot type and who are similar to our subjects with respect to the other inclusion/exclusion criteria. In addition to inadequate WOMAC scores and inadequate pronation measurements, subjects were also excluded due to absence of tenderness at the patellar facets, the presence of medial joint line pain or signs of meniscal derangement, and the presence of patellar tendon inflammation.

The WOMAC Osteoarthritis Index was used in this study to assess pain, stiffness, and physical function of the subjects prior to and following foot orthotic intervention. The WOMAC may not be sufficient in identifying pain patterns for all patients with patellofemoral pain. The WOMAC subscale of physical function includes activities that may be performed only intermittently, such as light domestic work, heavy domestic work, and shopping. The subjects, therefore, may not have had adequate opportunities to experience a change in symptoms with these items at the time of the 2-week follow-up assessment. Five of the 16 subjects who were excluded from this study were excluded solely due to an insufficient (<200/2400) score on the WOMAC. These subjects reported intermittent anterior knee pain particularly during or following participation in a recreational activity or sport. The WOMAC does not have items that relate to running or participating in a sport and as a result may not be sensitive enough to identify symptoms and changes in symptoms in more active patients with patellofemoral pain. Laprade et al[24] examined a Patellofemoral Pain Syndrome Severity Scale, which uses a VAS to rate pain experienced during various activities including jogging, running or sprinting, and participation in a sport. The Patellofemoral Pain Syndrome Severity Scale correlated well with the WOMAC ($r = 0.72$, $P<.001$) and may reflect the activities that relate to patellofemoral pain syndrome, particularly in a more active group.[24]

We noted throughout the study procedures whether subjects received physical therapy for their patellofemoral pain outside the study intervention. Only 1 subject had a course of physical therapy following the intervention, and completed treatments prior to the 3-month follow-up procedures. Removal of this subject's data did not change the results of any of the nonparametric analyses previously reported.

We did not constrain the shoes worn by subjects in our study. This procedure may simulate the reality of the clinical environment. Shoes selected by each subject were variable in terms of age, general condition, and the number of motion control features. Shoe wear, therefore, could have influenced study results. Although appropriate shoe wear recommendations were made to all subjects, only 3 subjects purchased new shoes prior to foot orthotic intervention. Because relatively few of the subjects purchased new shoes, the effects of the intervention on WOMAC subsection scores were more likely attributable to the foot orthotic intervention or the interaction between the effects of the foot orthoses and the subjects' shoes. The 3 subjects who purchased new shoes did follow recommendations of the investigators. These 3 subjects, therefore, not only had newer shoes, but also had shoes with more motion control features (mean number of motion control features, 6.0; SD, 0.0) than the remainder of the group (mean, 3.0; SD, 1.5). Exclusion of these 3 subjects from the data set, however, did not change the appearance of the data that are represented in Figure 3, and did not

result in consistent changes in the results of the nonparametric analyses. Further study is needed to determine the effectiveness that proper shoe wear may have on symptoms for people with patellofemoral pain who also pronate excessively.

Subjects were given an activity level questionnaire at each of the 4 assessment times. At the 3-month follow-up, 8 of the 16 subjects reported an increase in physical activity, 1 reported a decrease, and 7 reported no change in physical activity. These qualitative responses suggest that in addition to decreasing symptoms, some subjects may also have experienced increased tolerance for functional activities including recreational athletics.

## CONCLUSIONS

The results of this study suggest that custom-fitted foot orthoses may significantly improve pain, stiffness, and physical function for patients with patellofemoral pain who demonstrate excessive foot pronation. These results apply to patients who report a nontraumatic onset of symptoms. Additional study is warranted to replicate these findings and to assess if these positive results may extend beyond the 3-month follow-up period used in this study.

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## REFERENCES

1. Aglietti P, Insall JN, Cerulli G. Patellar pain and incongruence. I: Measurements of incongruence. *Clin Orthop.* 1983;217-224.
2. Bellamy N. *WOMAC Osteoarthritis Index: A User's Guide.* 2nd ed. London, Ontario, Canada: London Health Services Centre, McMaster University; 1996.
3. Bellamy N, Boers M, Felson D, et al. Health status instruments/utilities. *J Rheumatol.* 1995;22:1203-1207.
4. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol.* 1988;15:1833-1840.
5. Bentley G, Dowd G. Current concepts of etiology and treatment of chondromalacia patellae. *Clin Orthop.* 1984;189:209-228.
6. Buchbinder MR, Napora NJ, Biggs EW. The relationship of abnormal pronation to chondromalacia of the patella in distance runners. *J Am Podiatry Assoc.* 1979;69:159-162.
7. Callaghan MJ, Oldham JA. The role of quadriceps exercise in the treatment of patellofemoral pain syndrome. *Sports Med.* 1996;21:384-391.
8. Chrisman OD. The role of articular cartilage in patellofemoral pain. *Orthop Clin North Am.* 1986;17:231-234.
9. D'Amico JC, Rubin M. The influence of foot orthoses on the quadriceps angle. *J Am Podiatr Med Assoc.* 1986;76:337-340.
10. Eggold JF. Orthotics in the prevention of runners' overuse njuries. *Phys Sportsmed.* 1981;9:125-131.
11. Eng JJ, Pierrynowski MR. Evaluation of soft foot orthotics in the treatment of patellofemoral pain syndrome. *Phys Ther.* 1993;73:62-68; discussion 68-70.
12. Fulkerson JP. Awareness of the retinaculum in evaluating patellofemoral pain. *Am J Sports Med.* 1982;10:147-149.
13. Fulkerson JP. Diagnosis and treatment of patients with patellofemoral pain. *Am J Sports Med.* 2002;30:447-456.
14. Fulkerson JP, Shea KP. Disorders of patellofemoral alignment. *J Bone Joint Surg Am.* 1990;72:1424-1429.
15. Genova JM, Gross MT. Effect of foot orthotics on calcaneal eversion during standing and treadmill walking for subjects with abnormal pronation. *J Orthop Sports Phys Ther.* 2000;30:664-675.
16. Goodfellow J, Hungerford DS, Woods C. Patello-femoral joint mechanics and pathology. 2. Chondromalacia patellae. *J Bone Joint Surg Br.* 1976;58:291-299.
17. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ.* 1999;319:670-674.
18. Hung YJ, Gross MT. Effect of foot position on electromyographic activity of the vastus medialis oblique and vastus lateralis during lower-extremity weight-bearing activities. *J Orthop Sports Phys Ther.* 1999;29:93-102; discussion 103-105.
19. Insall J. "Chondromalacia patellae": patellar malalignment syndrome. *Orthop Clin North Am.* 1979;10:117-127.
20. Insall J. Current Concepts Review: patellar pain. *J Bone Joint Surg Am.* 1982;64:147-152.
21. Insall J, Falvo KA, Wise DW. Chondromalacia Patellae. A prospective study. *J Bone Joint Surg Am.* 1976;58:1-8.
22. Jonson SR, Gross MT. Intraexaminer reliability, interexaminer reliability, and mean values for nine lower extremity skeletal measures in healthy naval midshipmen. *J Orthop Sports Phys Ther.* 1997;25:253-263.
23. Klingman RE, Liaos SM, Hardin KM. The effect of subtalar joint posting on patellar glide position in subjects with excessive rearfoot pronation. *J Orthop Sports Phys Ther.* 1997;25:185-191.
24. Laprade JA, Culham EG. A self-administered pain severity scale for patellofemoral pain syndrome. *Clin Rehabil.* 2002;16:780-788.
25. McPoil TG, Cornwall MW. The effect of foot orthoses on transverse tibial rotation during walking. *J Am Podiatr Med Assoc.* 2000;90:2-11.
26. Merchant AC. Classification of patellofemoral disorders. *Arthroscopy.* 1988;4:235-240.
27. Nawoczenski DA, Cook TM, Saltzman CL. The effect of foot orthotics on three-dimensional kinematics of the leg and rearfoot during running. *J Orthop Sports Phys Ther.* 1995;21:317-327.
28. Nissen CW, Cullen MC, Hewett TE, Noyes FR. Physical and arthroscopic examination techniques of the patellofemoral joint. *J Orthop Sports Phys Ther.* 1998;28:277-285.

29. Papagelopoulos PJ, Sim FH. Patellofemoral pain syndrome: diagnosis and management. *Orthopedics.* 1997;20:148-157; quiz 158-149.
30. Post WR. Clinical evaluation of patients with patellofemoral disorders. *Arthroscopy.* 1999;15:841-851.
31. Radin EL. A rational approach to the treatment of patellofemoral pain. *Clin Orthop.* 1979;107-109.
32. Schutzer SF, Ramsby GR, Fulkerson JP. The evaluation of patellofemoral pain using computerized tomography. A preliminary study. *Clin Orthop.* 1986;286-293.
33. Sikorski JM, Peters J, Watt I. The importance of femoral rotation in chondromalacia patellae as shown by serial radiography. *J Bone Joint Surg Br.* 1979;61-B:435-442.
34. Singerman R, Davy DT, Goldberg VM. Effects of patella alta and patella infera on patellofemoral contact forces. *J Biomech.* 1994;27:1059-1065.
35. Sun Y, Sturmer T, Gunther KP, Brenner H. Reliability and validity of clinical outcome measurements of osteoarthritis of the hip and knee—a review of the literature. *Clin Rheumatol.* 1997;16:185-198.
36. Tiberio D. The effect of excessive subtalar joint pronation on patellofemoral mechanics: A theoretical model. *J Orthop Sports Phys Ther.* 1987;9:160-165.
37. van Kampen A, Huiskes R. The three-dimensional tracking pattern of the human patella. *J Orthop Res.* 1990;8:372-382.