ABSTRACT

Background: Foot orthotics are commonly utilized in the treatment of patellofemoral pain (PFP) and have shown clinical benefit; however, their mechanism of action remains unclear. Patellofemoral joint stress (PFJS) is thought to be one of the main etiological factors associated with PFP.

Hypothesis/Purpose: The primary purpose of this study was to investigate the effects of a prefabricated foot orthotic with 5° of medial rearfoot wedging on the magnitude and the timing of the peak PFJS in a group of healthy female recreational athletes. The hypothesis was that there would be significant reduction in the peak patellofemoral joint stress and a delay in the timing of this peak in the orthotic condition.

Study Design: Cross-sectional

Methods: Kinematic and kinetic data were collected during running trials in a group of healthy, female recreational athletes. The knee angle and moment data in the sagittal plane were incorporated into a previously developed model to estimate patellofemoral joint stress. The dependent variables of interest were the peak patellofemoral joint stress as well as the percentage of stance at which this peak occurred, as both the magnitude and the timing of the joint loading are thought to be important in overuse running injuries.

Results: The peak patellofemoral joint stress significantly increased in the orthotic condition by 5.8% (p = .02, ES = 0.24), which does not support the initial hypothesis. However, the orthotic did significantly delay the timing of the peak during the stance phase by 3.8% (p = .002, ES = 0.47).

Conclusions: The finding that the peak patellofemoral joint stress increased in the orthotic condition did not support the initial hypothesis. However, the finding that the timing of this peak was delayed to later in the stance phase in the orthotic condition did support the initial hypothesis and may be related to the clinical improvements previously reported in subjects with PFP.

Level of Evidence: Level 4

Keywords: Biomechanics, knee, patellofemoral pain
INTRODUCTION
Patellofemoral pain (PFP) is the most common running-related injury treated within a sports medicine setting. In fact, it is twice as common as the next most frequently reported condition (iliotibial band syndrome). Unfortunately, in many cases it can persist and limit sports participation and impair function years after the initial diagnosis. It has also been proposed to be a risk factor in the development of patellofemoral osteoarthritis. As a result, developing effective treatment options and optimizing current management approaches is of great interest to clinicians involved in the treatment of PFP. This topic has particular relevance to the female recreational athlete as the incidence of PFP has been reported to be two times higher in females in comparison to males of similar activity levels, although the exact reason for this discrepancy remains unclear.

PFP is a complex condition, with contributing factors proximal, local, and distal to the knee joint. Increased patellofemoral joint stress (PFJS) is one of the most commonly accepted etiological factors in the development of PFP. An increase in PFJS can occur due to an increase in the patellofemoral joint reaction force, a reduction in the contact area between the patella and the femur, or some combination of these two factors.

Alterations in the frontal and transverse plane kinematics of the hip and knee are thought to impact the mechanics of the patellofemoral joint. This may lead to a reduction in the patellofemoral contact area which may ultimately increase PFJS. Cadaver studies have confirmed the fact that manipulating the position of the tibia and the femur in the frontal and transverse planes can have a significant effect on the patellofemoral joint contact area. It has also been reported that females with PFP demonstrate increased hip adduction and internal rotation and increased knee external rotation during running, in comparison to healthy subjects.

The behavior of the foot has been theoretically linked to PFJS as excessive pronation is thought to alter the mechanics of the knee and hip in the frontal and transverse planes. As a result of the possible link between the mechanics of the foot and the etiology of PFP, foot orthotics designed to limit excessive pronation via relatively conservative degrees of medial rearfoot wedging (4-6°), are often used in the management of PFP. Clinically, these types of orthotics have been shown to have a positive effect in regards to pain and function and may have similar effects to a multimodal physical therapy intervention (i.e. joint mobilization, patellar taping, quadriceps strengthening, and patient education) in the early management of PFP.

While it appears that some patients with PFP may benefit from the use of a foot orthotic, there is less evidence to support the theoretical basis behind their proposed mechanism of action. Several researchers have investigated the effects of a foot orthotic on the kinematics of the knee and hip during running and have reported small and inconsistent effects in the frontal and transverse planes. It has also been consistently reported that a foot orthotic significantly increases the magnitude of the knee abduction moment. This does not support their use in the management of PFP as increased loading in the frontal plane has been found to increase the risk of developing PFP in both retrospective and prospective analyses. There appears to be little consensus regarding the mechanism of action behind the positive clinical effects of a foot orthotic in patients with PFP, which makes providing clear recommendations regarding orthotic design and prescription challenging. Until a clearer understanding of the mechanism of action of a foot orthotic is established, it is unlikely that this intervention will reach its peak efficacy.

While the biomechanical effects of a foot orthotic have been traditionally analyzed in the frontal and transverse planes, sagittal plane knee dynamics may also significantly influence PFJS. Brechter and Powers developed a sagittal plane model to estimate PFJS with inputs of the knee flexion angle and knee extension moment. Using this model, they found that subjects with PFP had significantly greater peak PFJS in comparison to a healthy control group during a fast walking condition. The same modeling approach has been used to estimate PFJS during running. Similar to the results from the walking analysis it has been reported that subjects with PFP demonstrate greater peak PFJS in comparison to healthy control subjects. It is possible that the clinical benefit of a foot orthotic in runners with PFP may be related to the orthotics’ effect on PFJS.
The primary purpose of this study was to investigate the effects of a prefabricated foot orthotic with 5° of medial rearfoot wedging on the magnitude and the timing of the peak PFJS in a group of healthy female recreational athletes. The peak PFJS was chosen because this has been shown to be greater in subjects with PFP during walking\textsuperscript{31} and running\textsuperscript{18} and is thought to be a primary contributor in the development of PFP. The effects of the orthotic on the timing of this peak was also analyzed as the importance of considering the temporal characteristics of joint loading has also been previously highlighted.\textsuperscript{23,35,36} It was hypothesized that the peak PFJS would be significantly less and would occur later in the stance phase with the application of the foot orthotic. These results may help to explain the mechanism of action of a foot orthotic in the management of PFP and may be of interest to those involved in orthotic prescription and design.

METHODS
This cross-sectional study included 18 female subjects between the ages of 18-45 years old, who ran with a rearfoot strike pattern, and were considered recreationally active based on the Tegner Activity Level scale score of greater than or equal to five out of ten.\textsuperscript{37} Exclusion criteria included: 1) any medical condition which would limit physical activity, 2) any previous history of lower extremity surgery, 3) any lower extremity injury in the previous six months which limited training, or 4) a history of orthotic use. The decision to include healthy runners is based on a previous study which reported that the effects of a medially-wedged foot orthotic on the mechanics of the knee are similar between subjects with and without PFP.\textsuperscript{22} Therefore, it seems that healthy subjects can serve as a model for the mechanical effects which can be expected in a group with PFP. Female subjects were included in this study because of the greater incidence of PFP in this group in comparison to males\textsuperscript{8} and the fact that previous studies which have used a similar modeling approach to estimate PFJS during running have also included females.\textsuperscript{18,32,34} This allowed for the comparison of the results of this analysis to studies which have included a similar subject group. The study received approval by the institutional review board at the University of Wisconsin – Milwaukee and all subjects provided informed consent to participate. All necessary measures were implemented in order to ensure that the rights of the subjects included within the study were protected.

During a single testing session, three-dimensional kinematic data were collected at 200 Hz with a ten-camera Eagle system (Motion Analysis, Inc., Santa Rosa, CA), and ground reaction forces (GRF) were synchronously recorded at 1000 Hz using an AMTI force plate (OR6-5; Advanced Mechanical Technology Inc., Watertown, MA). All trials were performed in standard laboratory footwear (NBA-801; New Balance, Brighton, MA) which had no heel counter in order to allow for direct observation of the rearfoot.\textsuperscript{23} The orthotic was prefabricated, three-quarter length, and had a 5° medial rearfoot wedge (L3060 Basic Foot Orthosis; Freedom Prosthetics and Orthotics, Houston, TX).

Retroreflective markers were placed on the left and right ASIS and PSIS in order to track the motion of the subject’s pelvis. Additional, four-marker clusters were placed on the right thigh, leg, and calcaneus in order to track the subject’s thigh, leg, and foot. A standing calibration was recorded with additional calibration markers placed on the most superior aspect of the left and right iliac crests, as well as on the greater trochanters, right lateral and medial femoral epicondyles, right lateral and medial malleoli, and the right first and fifth metatarsal heads. These markers were removed following a three-second static standing trial. The participants then performed running trials with (Orthotic) and without (Baseline) the orthotic, with the order of the conditions being randomized. Subjects were allowed practice trials in order to accommodate to the orthotic. They then completed 10 successful running trials down a 15-m runway at a speed of 4.0 m/s (± 5%) in each of the two conditions with their running speed monitored with two photoelectric timing gates positioned along the runway.

The raw three-dimensional coordinate and force data were filtered using a 4\textsuperscript{th}-order, zero lag, recursive Butterworth filter with a cutoff frequency of 12 Hz and 50 Hz, respectively.\textsuperscript{21} Right-handed Cartesian local coordinate systems for the pelvis, thigh, shank, and foot segments of the stance leg were defined to describe the position and orientation of each segment. Three-dimensional joint angles were calculated using a joint
The joint center of the knee was estimated by finding the midpoint between the medial and lateral femoral epicondyles while the ankle joint center was estimated by finding the midpoint between the medial and lateral malleoli. The hip joint centers were estimated to be located at 25% of the distance from each of the greater trochanter markers. Joint kinetics were calculated using a Newton-Euler approach with previously estimated body segment parameters. The calculation of the joint angles and moments during the stance phase was performed with Visual3D software (C-Motion, Inc., Rockville, MD) with initial contact and toe off determined when the vertical GRF exceeded and fell below 20 N, respectively. All data were time normalized to 101 data points to reflect the percentage of the stance phase.

Next, the patellofemoral joint stress (PFJS) was calculated using custom written Matlab code (MathWorks, Inc., Natick, MA). The model used to estimate the PFJS was initially developed by Brechter and Powers in order to compare PFJS between groups with PFP and a healthy control group during walking. However, it has also been used extensively to estimate PFJS during running. The inputs required to estimate PFJS are the internal net knee extension moment and the knee flexion angle. The first step is to calculate the effective moment-arm \( r \) of the quadriceps musculature using a non-linear equation (Equation 1) provided by Salem and Powers which was fit to the data from van Eijden et al.

\[
\begin{align*}
  r(m) &= 8.0e^{-5}x^3 - 0.013x^2 + 0.28x + 0.046 \\
  x &= \text{knee flexion angle}
\end{align*}
\]

Next, the estimated quadriceps force \( QF(N) \) was calculated by dividing the net knee extension moment \( M_{ext} \) by the effective moment arm \( r \) (Equation 2).

\[
QF(N) = \frac{M_{ext}(Nm)}{r(m)}
\]

A constant \( k \) described by Brechter and Powers (Equation 3) was used to calculate the patellofemoral joint reaction force \( PFJRF \) (Equation 4).

\[
k = \frac{4.62e^{-01} + 1.47e^{-03}x - 3.84e^{-05}x^2}{1 - 1.62e^{-02}x + 1.55e^{-04}x^2 - 6.98e^{-07}x^3}
\]

\[
x = \text{knee flexion angle}
\]

**Equation 3.**

\[
PFJRF(N) = k \times QF(N)
\]

The patellofemoral joint contact area (PFJCA) was calculated as a function of the knee flexion angle using data from Connolly et al and an equation (Equation 5) which has previously been used for running trials.

\[
PFJCA(mm^2) = 0.0781x^2 + 0.6763x + 151.75
\]

Patellofemoral joint stress (PFJS) was calculated by dividing the patellofemoral joint reaction force by the patellofemoral joint contact area (Equation 6) with the PFJS in units of millipascals (MPa).

\[
PFJS(MPa) = \frac{PFJRF(N)}{PFJCA(mm^2)}
\]

The primary dependent variables of interest were the ten-trial mean peak PFJS and the mean percentage of stance in which this peak occurred (time to peak). Secondary dependent variables were the peak knee flexion angle, peak knee extension moment, peak PFJRF, and the peak PFJCA. These secondary dependent variables were tested once it was determined that the orthotic had a statistically significant effect on the PFJS, allowing for the assessment of which factor(s) (PFJRF, PFJCA, or some combination of both) promoted the difference in PFJS. Paired t-tests were used to compare each of these variables between the Baseline and Orthotic trials. The alpha level for all tests was set at \( p < .05 \). Effect sizes were reported as Cohen’s d, which is the difference between the means of the conditions (Baseline, Orthotic) divided by the average of the standard deviations from both these conditions. All statistical tests were performed using SPSS (v22, SPSS, Inc.).
RESULTS

The subjects’ mean (SD) age, mass, and height were 23.7 (6.0) years, 61.65 (12.72) kg, and 1.65 (0.07) meters, respectively.

There was a significant increase in the peak PFJS and a significant delay in the timing of this peak (Figure 1 and Table 1). This peak increased by 5.8%, and the timing of this peak was delayed by 3.8% in the orthotic condition. The increase in stress was associated with an increase in the PFJRF, while the contact area was not different between conditions (Figure 2 and Table 1). The contact area was a function of the knee angle, which was not different between conditions, and the joint reaction force was a function of the increased knee extension moment (Figure 3 and Table 1).

DISCUSSION

The primary purpose of this study was to investigate the effects of a prefabricated foot orthotic on the magnitude and the timing of the peak PFJS in a group of healthy female recreational athletes. The hypothesis for this study was that the peak PFJS would be significantly reduced and would occur later in the stance phase with the application of the foot orthotic. The results did not support the hypothesis in regards to the magnitude of the PFJS as the subjects in this study demonstrated a statistically significant increase in the orthotic condition. However, the results did support the hypothesis that there would be a statistically significant shift in the timing of the peak PFJS to later in the stance phase in the orthotic condition. It is possible that the clinical benefit of a foot orthotic in patients with PFP is related to their effect on the timing of the PFJS.

The increase in the peak PFJS does not support the use of an orthotic in the treatment or prevention of PFP as subjects with PFP demonstrate greater peak PFJS in comparison to healthy control subjects during fast walking\textsuperscript{11} and running.\textsuperscript{18} Also, this elevated PFJS is thought to be a main etiological factor in the development of PFP and reducing this stress is often a primary objective of interventions designed to treat PFP.\textsuperscript{41} As a result, it does not appear that the beneficial effects of a foot orthotic are due to their influence on the peak PFJS. Other studies have incorporated a similar modeling approach with running in a sample of female recreational athletes and reported peak PFJS values which are very similar to the results reported in this study.\textsuperscript{18,33,34} For example,

**Table 1.** Dependent variable mean (SD) values and the results of the statistical analysis

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Orthotic</th>
<th>p</th>
<th>ES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak PFJS (MPa)</td>
<td>10.40(2.44)</td>
<td>11.00(2.64)</td>
<td>.024*</td>
<td>0.24</td>
</tr>
<tr>
<td>Time to peak PFJS (%)</td>
<td>37.89(2.91)</td>
<td>39.33(3.25)</td>
<td>.002*</td>
<td>0.47</td>
</tr>
<tr>
<td>Peak PFJCA (mm(^2))</td>
<td>346.75(36.35)</td>
<td>350.85(38.57)</td>
<td>.065</td>
<td>0.11</td>
</tr>
<tr>
<td>Peak PFJRF (N/kg)</td>
<td>58.30(12.20)</td>
<td>62.67(13.74)</td>
<td>.003*</td>
<td>0.34</td>
</tr>
<tr>
<td>Peak knee angle (°)</td>
<td>-45.59(4.53)</td>
<td>-46.14(4.72)</td>
<td>.055</td>
<td>0.12</td>
</tr>
<tr>
<td>Peak knee moment (Nm/kg)</td>
<td>2.66(0.37)</td>
<td>2.78(0.40)</td>
<td>.037*</td>
<td>0.31</td>
</tr>
</tbody>
</table>

ES= Effect size, PFJS= patellofemoral joint stress, PFJCA= patellofemoral joint contact area, PFJRF= patellofemoral joint reaction force
* Indicates statistically significant difference (p<.05)
Kernozek et al.\textsuperscript{34} recently reported a peak PFJS of 9.81 MPa in a group of healthy female recreational athletes running at a similar speed (3.52 – 3.89 m/s) to the subjects included in the current study when they implemented a similar PFJS modeling approach. The peak PFJS reported in this study is only slightly higher (within 6\%) than the peak PFJS reported by Kernozek et al.\textsuperscript{34} Although the model used in the current study cannot be validated, it has been used extensively in relation to running injuries and the results are comparable to previous reports.

The effects of the orthotic on the peak PFJRF and the PFJCA were analyzed in order to understand which variable had the greatest influence on the increase in PFJS. The orthotic did not significantly influence the PFJCA; in fact there was a trend towards increased contact area in the orthotic condition, which would effectively reduce the PFJS. However, it is important to note that this effect was not statistically significant. This was consistent with the finding that the orthotic had no effect on the peak knee flexion angle, as the PFJCA is a function of the knee flexion angle. Previous studies have also reported that a foot orthotic with a similar degree of wedging does not have a significant effect on the peak knee flexion angle.\textsuperscript{26,27} The subjects in this study did demonstrate a statistically significant increase in the PFJRF, which was consistent with the finding that the orthotic significantly increased the peak knee extension moment. Similar effects on the peak knee extension moment have also been previously reported with the application of an orthotic during running trials.\textsuperscript{26} Since the increase in the sagittal plane moment and PFJRF occurred without a significant effect on the knee flexion angle, it would seem the orthotic affected the orientation of the GRF. It is possible that the effect of the orthotic is less dependent on the 5\(^\circ\) of medial wedging and more dependent on the heel lift it provides (approximately 1 cm).
This small degree of elevation of the heel may result in the change in the orientation of the GRF which results in the increase in the knee extension moment. While this idea is novel, it needs further analysis.

The orthotic did influence the timing of the peak PFJS as this peak occurred later in the stance phase in the orthotic condition. While the magnitude of this effect was not overtly large (ES = 0.47), it was fairly consistent as 12 of the 18 subjects demonstrated a shift towards later in the stance phase, while only one subject demonstrated a shift towards earlier in stance with the application of the orthotic. To the authors’ knowledge, this is the only study which has reported the effect of a foot orthotic on the timing of the peak PFJS. While it cannot be determined whether or not this effect on the timing of the PFJS is the reason why patients with PFP benefit from a foot orthotic, it is possible as the rate of loading is thought to be an important variable to consider in regards to running-related injuries such as PFP.22,23,28 However, since the delay in the timing of the peak PFJS occurred in combination with an increase in the peak PFJS it would seem that the effect of these two factors would off-set each other in regards to the rate of loading to the tissue, making this an unlikely mechanism of action.

It is important to note that the results of this study do not imply that the mechanics of the hip and the knee in the frontal and transverse planes do not play a prominent role in the etiology of PFP. They simply highlight the fact that since it is unclear how the effects of a foot orthotic in the frontal and transverse planes relate to clinical improvements in subjects with PFP22,23,28 it is possible that there may be a sagittal plane component to an orthotics’ mechanism of action. Three-dimensional kinematic and kinetic data are typically not available within a physical therapy clinic due the cost, space requirements, and technical expertise required to operate the motion capture equipment. However, there are two-dimensional measures that have been developed for clinical use during dynamic activities which attempt to analyze a subject’s mechanics in frontal and transverse planes of motion. These measures may be used in clinical practice in order to make intervention choices. For example, Wouters et al45 used a two-dimensional measure related to the medial position of the knee (the frontal plane projection angle) to identify female subjects who may specifically benefit from a lower extremity neuromuscular training program. From a clinical perspective, the results of the current study suggest that even if mechanics in the frontal and transverse planes appear to be within normal limits when comparing between limbs or to some reference data, it does not mean that the patient would not benefit from an orthotic intervention, as their mechanism may be related to their effects in the sagittal plane. This is an important point to consider, as foot orthotics are often prescribed based on the theory that they correct some type of lower extremity biomechanical dysfunction, often in the frontal and transverse planes.12,13 In order to determine the mechanism which may promote clinical improvement in patients with PFP, future research may benefit from analyzing the effects of an orthotic in those who have had a positive response to an orthotic intervention. The results of the current study indicate that future studies of this nature should not focus exclusively on the frontal and transverse planes as an orthotic also has a significant effect on the magnitude and the timing of the joint loading in the sagittal plane of the knee.

Although the results of this study provide new insight into the mechanical effects of a foot orthotic, it is important to highlight some key limitations. One major limitation is the relatively simplistic modeling approach utilized. The main limitation of this model is that it only incorporates joint angles and moments from the sagittal plane. As previously mentioned, the mechanics in the frontal and transverse planes can also have a prominent effect on the contact area between the patella and the femur and subjects with PFP have been reported to demonstrate mechanics in both of these planes which differ from those without PFP.15,18 Another limitation associated with the modeling approach is the inverse dynamics based methodology used to estimate the quadriceps muscle forces. Kernozek et al14 recently reported that this approach may significantly underestimate the quadriceps muscle force estimates in comparison to more sophisticated modeling approaches which can account for co-contraction of the muscles which surround the knee joint. This is a valid point which means that the absolute values provided in this report may actually underestimate PFJS. However, since the same model has been employed previously and the model was consistent between the conditions, the patterns reflected in the
data should still be valid. Another limitation of this study is related to the subject group. Although healthy subjects served as a model, it cannot be determined whether or not similar effects would be observed in a group with PFP. This may be considered a preliminary analysis into another possible mechanism of action of an orthotic. It is also important to point out that the results of this study only reflect the immediate effects of the orthotic as all data were collected during a single session. There may be long-term adaptations that occur with the application of an orthotic. However, this has not been shown in a previous study which investigated a six-week orthotic intervention.27

CONCLUSION

In conclusion, a prefabricated foot orthotic had a significant effect on the magnitude and the timing of the PFJS in a group of female recreational athletes. While the orthotic resulted in an increase in the peak PFJS, which does not support their use in runners with PFP, it also shifted the timing of this peak to later in the stance phase. This delay in the timing of this peak may be associated with the beneficial effects previously reported with the application of a foot orthotic in a group with PFP, although this suggestion requires further analysis. Clinicians involved in the management of PFP should understand that an orthotics’ effects are not limited to the frontal and transverse planes and that the dynamics of the knee joint in the sagittal plane are also affected. As a result, patients may benefit from an orthotic intervention even if they do not demonstrate mechanics in the frontal and transverse planes which are thought to be associated with PFP.

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