Clinical Predictors of Foot Orthoses Efficacy in Individuals with Patellofemoral Pain

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ABSTRACT

BARTON, C. J., H. B. MENZ, and K. M. CROSSLEY. Clinical Predictors of Foot Orthoses Efficacy in Individuals with Patellofemoral Pain. Med. Sci. Sports Exerc., Vol. 43, No. 9, pp. 1603–1610, 2011. Purpose: There is emerging evidence that foot orthoses are effective in the management of patellofemoral pain syndrome (PFPS). However, the identification of those most likely to benefit from foot orthoses has not been adequately explored. The aim of this study was to develop a preliminary clinical prediction rule to help identify individuals with PFPS who are most likely to benefit from foot orthoses. Methods: A total of 60 individuals with PFPS were issued with noncustomized prefabricated foot orthoses containing built-in arch supports and 4° rear foot varus wedging. Patient-reported level of improvement was documented at 12 wk. Potential baseline predictor variables of interest included patient demographics, pain characteristics, footwear motion control properties, foot and ankle characteristics, and functional performance measures. Results: Fourteen (25%) participants reported marked improvement at 12 wk. The number of participants with marked improvement increased to 78% if three of the following four criteria were met: footwear motion control properties score of G 5.0 (indicative of less supportive footwear), usual pain G 22.0 mm, ankle dorsiflexion range of motion (knee flexed) G 41°, and reduced single-leg squat pain when wearing the orthoses. Conclusions: Individuals with PFPS who wear less supportive footwear, report lower levels of pain, exhibit less ankle dorsiflexion range of motion, and report an immediate reduction in pain with foot orthoses when performing a single-leg squat are more likely to benefit from foot orthoses. Key Words: PATELLOFEMORAL PAIN SYNDROME, ANTERIOR KNEE PAIN, INSOLES, CLINICAL PREDICTION RULE, FOOTWEAR, FUNCTIONAL PERFORMANCE

Patellofemoral pain syndrome (PFPS) is one of the most frequent presentations to sports medicine clinicians (32). Symptoms resulting from PFPS often diminish functional performance (4,16,28), and chronic knee pain may be linked to osteoarthritis development later in life (33,34). Owing to the multifactorial nature of PFPS, a variety of conservative treatment options with variable levels of efficacy have been proposed (7). One commonly advocated intervention for PFPS with emerging evidence is the prescription of foot orthoses (1,10,17,18,21,25,31). However, because all individuals are unlikely to have positive results from a single intervention, it is important to identify PFPS individuals most likely to benefit from foot orthoses prescription.

The majority of previous studies evaluating foot orthoses in individuals with PFPS have used observations of excessive foot pronation as part of their inclusion criteria (1,17,18,21,25). However, evidence linking excessive foot pronation to clinical success in PFPS populations is limited. In a recent randomized clinical trial (RCT) evaluating foot orthoses efficacy for individuals with PFPS (10), participants were recruited regardless of foot type. This study revealed that a significantly greater number of participants receiving foot orthoses reported positive clinical outcomes compared with those receiving flat inserts (10). Despite this, not all individuals receiving foot orthoses reported improvements. Considering this, Vicenzino et al. (36) developed a post hoc clinical prediction rule in the same cohort to identify those most likely to report marked improvement.
Four predictive variables were identified, namely, older individuals, shorter individuals, individuals with lower baseline pain, and individuals with greater foot mobility. Although this is a good preliminary clinical prediction rule, it was not developed from a purposely designed study. As a result, the analysis was inadequately powered for the number of variables entered into the regression equation (12), and evaluation was limited to patient demographics and foot morphometry.

Sutlive et al. (31) also attempted to identify predictors of PFPS individuals most likely to improve after prefabricated foot orthoses prescription, using a military cohort. The study identified three predictors of >50% pain reduction after 3 wk (positive likelihood ratio > 2.0), including greater forefoot valgum, reduced first metatarsophalangeal joint (MTPJ) dorsiflexion, and reduced navicular drop (less pronated foot type) (31). However, because of the poor interrater reliability reported for prediction variables (ICC = 0.25–0.55) and poor sensitivity values (0.13) of the non–weight-bearing forefoot and first MTPJ measurements, the findings have limited utility. Further research using reliable weight bearing methods for these foot characteristics is required to establish their validity as predictors of foot orthoses outcomes in individuals with PFPS.

In addition to foot characteristics, sagittal-plane motion at the ankle requires consideration. Restricted ankle dorsiflexion range has been reported to delay the time to reinversion of the rear foot during walking (13). This relationship may be particularly important considering the traditional theoretical rationale for foot orthoses prescription when treating individuals with PFPS. Although this theory lacks scientific validation, Tiberio (35) proposed that foot orthoses should be prescribed to PFPS individuals with delayed reinversion of the rear foot in an attempt to reduce any associated excessive tibial and femoral internal rotation.

Several factors unrelated to foot and ankle characteristics have also been proposed to be associated with foot orthoses efficacy in individuals with PFPS. These include comfort (10,24), immediate improvements in functional performance (4), and footwear characteristics (4,22). Although the recent PFPS clinical prediction rule study by Vicenzino et al. (36) indicated that the level of foot orthoses comfort was not associated with clinical outcomes (36), enhancing comfort was the primary aim of the foot orthoses customization protocol used in this study (36). Therefore, additional research evaluating the association of comfort with clinical outcomes is needed. The ability of functional performance measures and footwear characteristics to predict foot orthoses outcomes in PFPS is also yet to be evaluated (6).

Considering the variable response to foot orthoses intervention of individuals with PFPS, the aim of this study was to identify predictors of foot orthoses efficacy in individuals with PFPS. Specifically, the ability of clinically applicable measurements including patient demographics, pain characteristics, footwear characteristics, foot and ankle characteristics, and immediate changes to functional performance and footwear comfort with foot orthoses to predict patient-perceived marked improvement at 12 wk was evaluated.

METHODS

Participants

Sixty individuals with PFPS (16 men and 44 women) were recruited via advertisements placed at universities, hospitals, and community notice boards in the greater Melbourne area. Mean ± SD age, height, and weight of participants were 26 ± 5 yr, 1.70 ± 0.08 m, and 68 ± 12 kg, respectively. The study was approved by La Trobe University’s Faculty of Health Sciences’ human ethics committee, and each participant gave written informed consent before participation. Diagnosis of PFPS was based on definitions used in previous high-quality RCTs (10,15). Inclusion criteria were as follows: aged 18–35 yr; insidious onset of peripatellar or retropatellar knee pain of at least 6 wk in duration; worst pain in the previous week of at least 30 mm on a 100-mm visual analog scale (VAS); pain provoked by at least two activities from running, walking, hopping, squatting, stair negotiation, kneeling, or prolonged sitting; and pain elicited by patellar palpation, patellofemoral joint (PFJ) compression, or resisted isometric quadriceps contraction. Exclusion criteria were as follows: use of foot orthoses in the previous 5 yr; physiotherapy treatment in the previous 6 months; current use of anti-inflammatory medications; or concomitant injury or pain arising from the lumbar spine or hip, knee internal derangement, knee ligament insufficiency, previous knee surgery, PFJ instability, or patellar tendinopathy.

Intervention

Participants attended a single-treatment (15 min) and data collection (60 min) session. During this session, all baseline data were collected before issuing each participant with a pair of prefabricated foot orthoses. The orthoses were commercially available three-quarter-length devices with lateral cutouts (Vasyli Pro; Vasyli International, Labrador, Queensland, Australia), made of ethylene-vinyl acetate of medium density (Shore A 55), containing built-in arch supports and 4° varus rear foot wedging (Fig. 1). No customization of the orthoses was performed. However, size was individualized, ensuring that the first MTPJ was just distal to end of the orthoses. These orthoses were chosen because during pilot testing they were able to fit into most footwear and were generally perceived as comfortable while still providing improved support to the foot.

Participants were asked to wear footwear that was able to accommodate the orthoses whenever possible. To assist with compliance, each participant was provided with a diary, which each participant was required to enter daily the physical activity completed, what footwear each wore, and how often each used the foot orthoses. In addition, participants were instructed to refrain from using any additional treatment for their knee pain (e.g., physiotherapy or a new form of
limitations due to pain, two functional tasks previously a 100-mm VAS (10,15). To objectively measure functional worst pain severity during the previous week measured on been reported to be a valid and reliable measurement tool in International Physical Activity Questionnaire, which has assured using the long version of the 7-d self-administered

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produced by the foot orthoses. Any additional treatment was to be documented in the diary.

Primary Outcome Measure

At 12 wk after foot orthoses prescription, each participant rated the perceived improvement in symptoms using a five-point Likert scale, consistent with previous PFPS RCTs (10,15). The five responses included markedly better, somewhat better, same, somewhat worse, and markedly worse. For the purpose of developing a clinical prediction rule, those reporting marked improvement were considered to have obtained a successful outcome. Those who reported to be moderately better, the same, moderately worse, or markedly worse were considered unsuccessful.

Baseline (Predictor) Variables

Before issuing participants with foot orthoses, we collected a range of baseline data including patient demographics, pain characteristics, footwear characteristics, and foot and ankle characteristics. We also evaluated the immediate changes to functional performance and footwear comfort produced by the foot orthoses.

Patient demographics. Patient demographics of interest included sex, age, height, body mass, and weekly physical activity levels. Physical activity levels were measured using the long version of the 7-d self-administered International Physical Activity Questionnaire, which has been reported to be a valid and reliable measurement tool in similarly aged populations (14).

Pain characteristics. Subjective pain characteristics reported included duration of symptoms and usual and worst pain severity during the previous week measured on a 100-mm VAS (10,15). To objectively measure functional limitations due to pain, two functional tasks previously reported to be impaired in individuals with PFPS were recorded (4). These included the number of pain-free step downs from a 20-cm-high step (to a maximum of 25 repetitions) and single-leg rises from sitting (to a maximum of 20 repetitions) (4). Step downs involved tapping the floor with contralateral limb and then returning to bipedal stance while maintaining the tested limb in a fixed weight bearing position (4). Single-leg rises from sitting involved repeatedly standing from sitting and then returning to sitting with arms crossed with the tested in a comfortable position anterior to the chair and contralateral limb out in front of the body (4).

Footwear motion control characteristics. Footwear assessment was completed using the motion control properties scale from the Footwear Assessment Tool (3). Items within the scale include evaluation of fixation method (laces, other, or none), presence or absence of dual density soles, heel counter stiffness (rigid, moderate, minimal, or absent), and midfoot sagittal and torsional stiffness (rigid, moderate, or minimal) (3). Scoring for the scale is out of 11, with 11 indicating the greatest possible motion control properties and 0 indicating the poorest possible motion control properties. Assessment was completed by a single rater with previously established intrarater (ICC = 0.93) and interrater (ICC = 0.93) reliability (3). The motion control properties scale was completed on all footwear used throughout the study by participants and converted to single scores for each participant by calculating a weighted average (i.e., taking into account the percentage of time each footwear pair was worn throughout the study period as indicated by participants’ diaries).

Foot and ankle characteristics. Foot posture measurements included the Foot Posture Index (FPI) and normalized navicular drop (NND) measured in bilateral weight bearing. These clinical measures were chosen because they are easy to implement and have been shown to be reliable and associated with PFPS (2). In addition, the range of first MTPJ dorsiflexion and ankle dorsiflexion (with the knee flexed) was also measured in weight bearing (2). All measurements were taken by a single rater with previously established ICC values for intrarater (FPI = 0.97, NND = 0.88; first MTPJ dorsiflexion = 0.93, ankle dorsiflexion = 0.75) and interrater reliability (FPI = 0.92, NND = 0.78, first MTPJ dorsiflexion = 0.85, ankle dorsiflexion = 0.54–0.63) (2).

Change in functional performance. The immediate change in pain during a single-leg squat with foot orthoses was measured on a five-point Likert scale (markedly more painful, somewhat more painful, same, somewhat less painful, and markedly less painful) (4). The between-days reliability of this functional performance measure has been established in a previous study (κ = 0.79) (4).

Change in footwear comfort. Participants were asked to rate the immediate change in footwear comfort with the addition of the foot orthoses during a 20-m walk using a five-point Likert scale (markedly better, somewhat better, same, somewhat worse, markedly worse). Between-days reliability was established for change in comfort in a pilot study evaluating 20 individuals with PFPS (κ = 0.75).
TABLE 1. Univariate comparisons of dichotomous variables, defining efficacy as marked improvement (\(n = 57\) unless otherwise specified).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Markedly Better ((n = 14))</th>
<th>Moderately Better, Same, Moderately Worse, or Markedly Worse ((n = 43))</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>11</td>
<td>31</td>
<td>0.898</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Comfort</td>
<td>+ve</td>
<td>5</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>−ve</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>SLSq pain ((n = 50))*</td>
<td>+ve</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>−ve</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

\(^*\) \(P < 0.20\).
+ve, reduction in pain/improved comfort; −ve, no change, or more pain/less comfort; SLSq = single-leg squat.

Statistical Analysis

Statistical analysis was performed using SPSS Version 17.0 (SPSS, Inc., Chicago, IL). A clinical prediction rule was developed for those reporting marked improvement at 12 wk. First, each variable was tested for its univariate relationship with marked improvement. Differences between efficacy categories for continuous variables were tested using independent samples \(t\)-tests. Clinical tests using Likert scales were converted to dichotomous data with any positive response (better/less pain) considered to indicate an improvement and any “same” or negative response (worse/more pain) considered to indicate an absence of improvement. Dichotomous variables were tested for univariate relationship with marked improvement using \(\chi^2\) statistics. All variables with a significance level of \(P < 0.20\) were retained for multivariate prediction analysis to minimize the risk of excluding potentially valuable predictors from further analysis (20).

Continuous variables with univariate relationships with foot orthoses efficacy \((P < 0.20)\) were plotted as receiver operator characteristic (ROC) curves to determine values with the best predictive accuracies (i.e., the point nearest the upper left hand corner) (27). The sensitivity, specificity, and positive likelihood ratios for each variable were calculated from these cutoff values. Cutoff values were then used to dichotomize data for each retained variable. All dichotomous variables were then entered simultaneously into a direct logistic regression model to determine the most accurate set of predictor variables. A significance level of \(P > 0.10\) was required for removal from the model to minimize the likelihood of excluding potentially useful variables (20).

RESULTS

Fifty-seven (95%) of the 60 participants enrolled completed the study at 12 wk. Of those who completed the study, four failed to return or complete accurate diaries containing footwear and compliance data. In addition, seven participants did not experience pain during the single-leg squat. None of the participant diaries indicated the commencement of any new form of treatment.

A total of 14 (25%) participants reported that they were markedly better with the foot orthoses. Univariate analysis of dichotomous variables can be found in Table 1. Univariate analysis of continuous variables can be found in Table 2. Reduced pain during a single-leg squat with the foot orthoses \((P = 0.001)\) and limited ankle dorsiflexion range \((P = 0.049)\) were found to be associated with marked improvement in the univariate analyses.

TABLE 2. Univariate comparisons of continuous variables, defining efficacy as marked improvement (\(n = 57\) unless otherwise specified).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Markedly Better, Mean ± SD, (n = 14)</th>
<th>Moderately Better, Same, Moderately Worse, or Markedly Worse, Mean ± SD, (n = 43)</th>
<th>Mean Difference (95% CI)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient demographics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yr)</td>
<td>26 ± 5</td>
<td>26 ± 5</td>
<td>0 (−4 to 3)</td>
<td>0.987</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.70 ± 0.1</td>
<td>1.69 ± 0.08</td>
<td>0.01 (−0.05 to 0.06)</td>
<td>0.829</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>68 ± 8</td>
<td>67 ± 13</td>
<td>1 (−7 to 8)</td>
<td>0.829</td>
</tr>
<tr>
<td>Baseline physical activity—IPAQ (METs·wk(^{-1}))</td>
<td>4450 ± 4119</td>
<td>3498 ± 3886</td>
<td>952 (−1478 to 3383)</td>
<td>0.436</td>
</tr>
<tr>
<td>Pain characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration (months)</td>
<td>64 ± 51</td>
<td>70 ± 61</td>
<td>−6 (−44 to 32)</td>
<td>0.756</td>
</tr>
<tr>
<td>Usual pain (mm)*</td>
<td>26.9 ± 25.3</td>
<td>36.1 ± 19.0</td>
<td>−9.2 (−21.9 to 3.6)</td>
<td>0.156</td>
</tr>
<tr>
<td>Worst pain (mm)*</td>
<td>52.4 ± 19.2</td>
<td>55.6 ± 18.6</td>
<td>−3.2 (−14.7 to 8.4)</td>
<td>0.587</td>
</tr>
<tr>
<td>Step-downs at baseline</td>
<td>13.5 ± 8.5</td>
<td>12.2 ± 9.3</td>
<td>1.3 (−4.3 to 6.9)</td>
<td>0.647</td>
</tr>
<tr>
<td>Single-leg rise from sitting at baseline</td>
<td>7.3 ± 7.1</td>
<td>7.4 ± 7.1</td>
<td>−0.1 (−4.5 to 4.2)</td>
<td>0.943</td>
</tr>
<tr>
<td>Foot and ankle characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FPI</td>
<td>2.9 ± 3.0</td>
<td>3.5 ± 3.2</td>
<td>−0.7 (−2.6 to 1.3)</td>
<td>0.493</td>
</tr>
<tr>
<td>NND (% foot length)*</td>
<td>1.72 ± 1.70</td>
<td>2.33 ± 1.95</td>
<td>−0.61 (−1.78 to 0.56)</td>
<td>0.303</td>
</tr>
<tr>
<td>First MTPJ DF (°)</td>
<td>55.1 ± 9.4</td>
<td>53.5 ± 12.4</td>
<td>1.5 (−5.7 to 8.8)</td>
<td>0.678</td>
</tr>
<tr>
<td>Ankle dorsiflexion (knee flexed) (°)*</td>
<td>40.1 ± 13.2</td>
<td>45.2 ± 6.0</td>
<td>−5.1 (−10.3 to 0.0)</td>
<td>0.049</td>
</tr>
<tr>
<td>Footwear/diary data ((n = 53))</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Footwear motion control score (weighted mean)*</td>
<td>4.87 ± 1.19</td>
<td>5.71 ± 1.74</td>
<td>−0.85 (−1.70 to 0.01)</td>
<td>0.053</td>
</tr>
<tr>
<td>Compliance (% time orthoses worn)</td>
<td>79.9 ± 16.3</td>
<td>81.6 ± 15.1</td>
<td>−1.7 (−11.4 to 8.0)</td>
<td>0.735</td>
</tr>
</tbody>
</table>

\(^*\) \(P < 0.20\).
\(^{a}\) Pain measured on a 100-mm VAS: 0 mm = no pain, 100 mm = worst pain imaginable.
\(^{b}\) Measured using the motion control properties scale from the footwear assessment form (4): 0 = poorest support possible, 11 = greatest support possible.
\(^{c}\) Higher values indicate more pronated foot type; lower values indicate more supinated foot type.
IPAQ, International Physical Activity Questionnaire.
DISCUSSION

There is emerging evidence that foot orthoses are an effective intervention for PFPS (1,10,17,18,21,25,31). However, not all PFPS individuals respond in a similar manner to foot orthoses prescription. Predictor variables identified in this study add to the limited body of knowledge regarding the contribution of individual features to predicting the efficacy of foot orthoses in individuals with PFPS (31,36). This is also the first clinical prediction rule study to evaluate the association of footwear properties, functional performance measures, and compliance with orthoses use.

In this study, 25% of participants reported marked improvement after 12 wk of wearing noncustomized prefabricated foot orthoses. In addition, identification of a clinical prediction rule using easy-to-implement clinical measurements substantially increased the prediction outcomes. Specifically, the likelihood of marked improvement increased from 25% to 78% if three of the following four clinical criteria were met: footwear motion control properties score (weighted mean) <5.0, usual pain <22.0 mm, ankle dorsiflexion range of motion (knee flexed) <41.3°, and reduction in pain with the foot orthoses during completion of a single-leg squat were associated with marked improvement (P < 0.10). The greatest accuracy in predicting marked improvement was produced by positive findings on three of four of these variables (posttest success = 78%; Table 4).

Direct regression analysis. Four variables were retained as potential predictors (P < 0.20) of marked improvement (Table 3). Direct regression analysis indicated that a footwear motion control properties score of <5.0 (indicative of less supportive footwear), usual pain <22.0 mm, ankle dorsiflexion range of motion (knee flexed) <41.3°, and reduction in pain with the foot orthoses during completion of a single-leg squat were associated with marked improvement (P < 0.10). This would indicate that customizing foot orthoses to enhance functional performance may optimize outcomes in the current study.

The observation of excessive foot pronation has traditionally formed the basis of foot orthoses prescription in individuals with PFPS (9,19,23). In response to this theoretical rationale, most previous clinical trials evaluating foot orthoses in individuals with PFPS have used indicators of excessive pronation as part of their inclusion criteria (1,17,18,21,25). Interestingly, foot posture and foot mobility (as measured by the FPI and NND, respectively) were not found to be associated with foot orthoses efficacy in the current study. This compounds the inconsistent findings related to the predictive ability of foot posture and foot mobility in previous studies (31,36). As a result, the ability to identify individuals who are likely to respond favorably to foot orthoses prescription using clinical measures of foot morphometry must be questioned.

There are several possible explanations for the lack of association between foot morphometry and foot orthoses outcomes in this study. The most likely is that static clinical measurements used in the current study may not accurately represent dynamic foot function. Using a subpopulation of 26 participants from this study, our group recently found that greater peak rear foot eversion during walking was predictive of marked improvement (5). This would indicate that dynamic evaluation of foot function may be more appropriate than currently available clinical measures of foot morphometry. However, development of clinically appropriate measures of dynamic foot function is needed.

A second possible explanation for foot morphometry findings in this study is that participants were excluded if they had worn foot orthoses in the previous 5 yr. This lead to only 8% (5/60) of participants possessing highly pronated foot postures (FPI score ≥ 9). Interestingly, each of these participants reported moderate improvement at 12 wk. Finally, this study did not seek to customize foot orthoses, a procedure that may benefit those with more pronated

### TABLE 3. Potential predictors of marked improvement at 12 wk (pretest = 25%).

<table>
<thead>
<tr>
<th>Variable (Number With Improvement/Number Positive on Predictor)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Likelihood Ratio (95% CI)</th>
<th>Regression P</th>
<th>Posttest Prediction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Footwear motion control properties (weighted mean) &lt;5.0 (10/25)</td>
<td>0.71 (0.45–0.88)</td>
<td>0.62 (0.46–0.75)</td>
<td>1.9 (1.1–3.1)</td>
<td>0.054</td>
<td>40</td>
</tr>
<tr>
<td>Usual pain &lt;22.0 mm (9/20)</td>
<td>0.64 (0.39–0.84)</td>
<td>0.74 (0.60–0.85)</td>
<td>2.5 (1.3–4.8)</td>
<td>0.030</td>
<td>45</td>
</tr>
<tr>
<td>Ankle dorsiflexion (knee flexed) &lt;41.3° (6/18)</td>
<td>0.43 (0.21–0.67)</td>
<td>0.72 (0.57–0.83)</td>
<td>1.5 (0.71–3.3)</td>
<td>0.054</td>
<td>33</td>
</tr>
<tr>
<td>Reduced pain during SLSq (10/22)</td>
<td>0.91 (0.62–0.98)</td>
<td>0.69 (0.54–0.81)</td>
<td>3.0 (1.8–4.9)</td>
<td>0.011</td>
<td>45</td>
</tr>
</tbody>
</table>

* Retained after regression analysis (P < 0.10).

SLSq, single-leg squat.

Cox PH analysis. Cox regression analysis identified that a footwear motion control properties score of <5.0 (indicative of less supportive footwear), ankle dorsiflexion range of motion (knee flexed) <41.3°, and reduction in pain with the foot orthoses during completion of a single-leg squat were associated with marked improvement (P < 0.10). The greatest accuracy in predicting marked improvement was produced by positive findings on three of four of these variables (posttest success = 78%; Table 4).
feet. The influence of highly pronated foot postures on foot orthoses efficacy and the need for customization require further evaluation.

On the basis of the theoretical paradigm proposed by Nigg et al. (24), Collins et al. (10) customized prefabricated foot orthoses in their RCT using enhanced comfort as the primary aim. However, reduced foot orthoses comfort was found to be associated with successful prescription in the Collins et al. (10) cohort in univariate analyses (36). The current study found no association between change in footwear comfort after foot orthoses prescription and 12-week outcomes. Therefore, using comfort enhancement as a primary aim when customizing prefabricated foot orthoses may not be the most appropriate approach.

Despite the intimate relationship between foot orthoses and footwear, previous research evaluating foot orthoses in individuals with PFPS has not evaluated footwear characteristics (1,10,17,18,21,25,31). Consistent with our recent finding of immediate improvements in functional performance with foot orthoses (4), we found that less supportive footwear (i.e., lower motion control properties scale scores) was associated with greater improvement at 12 wk. Specifically, pretest probability for marked improvement increased from 25% to 40% when participants wore footwear with a motion control properties score (weighted mean) of <5.0. Given this observation, the influence of altering footwear on clinical outcomes requires further evaluation.

A recent prognostic study reported that greater baseline pain levels were associated with poorer prognosis in individuals with PFPS (11). Consistent with this and other clinical prediction rule findings (36), lower baseline pain (usual pain) was associated with greater improvements. Therefore, baseline pain levels should be carefully considered and discussed with the patient in relation to the likelihood of improvement when prescribing foot orthoses in a clinical setting. Specifically, the likelihood of marked improvement in this study was 14% (5/37) if usual pain levels were 22.0 mm or greater. If it was <22.0 mm, the likelihood of marked improvement increased to 45%. These results indicate that foot orthoses without customization as a stand-alone treatment may only be appropriate for individuals with mild pain. In those with more severe pain, additional foot orthoses customization or combining with other therapies such as exercise and PFJ taping may be needed to optimize outcomes.

Reduced ankle dorsiflexion (knee flexed) was included as part of the clinical prediction rule in this study. Owing to the absence of concurrent kinematic evaluation with and without foot orthoses in this study, there is no clear explanation for this finding. One possible hypothesis is that the foot orthoses provided compensation for reduced sagittal plane motion at the ankle because of their three-quarter-length design. Reported links between restricted ankle dorsiflexion range and delayed reversion of the rear foot during walking may explain the need for this compensation. The traditional theoretical rationale for foot orthoses prescription in individuals with PFPS is based on the belief that delayed reversion requires correction to prevent associated increases to tibial and femoral internal rotation (35). Further research evaluating the influence of limited ankle dorsiflexion and foot orthoses on lower limb kinematics in individuals with PFPS is needed.

Patient demographics (i.e., sex, age, height, weight, or baseline physical activity levels) were not retained in the clinical prediction rule developed in this study. This finding is in contrast to findings reported by Vicenzino et al. (36), where height (<165 cm) and age (>25 yr) were associated with marked improvement. However, these variables were among nine evaluated in a cohort of just 42 participants in the Vicenzino et al. (36) study, which is less than the recommended 10-participants-per-predictor variable to be entered into a regression equation (30). Therefore, height and age may have been retained because of regression overfitting (30).

This was the first study to evaluate the influence of compliance with wearing foot orthoses on clinical outcomes in PFPS. Intuitively, it would be expected that greater compliance would improve the likelihood of improvement. Interestingly, no association between success and compliance was found in this study. However, it must be considered that compliance from all participants in this study was generally high, with 94% (50/53) of participants wearing their orthoses 60% or more of the time. This high rate of compliance may be due to the accommodative design of orthoses used and/or the influence of being enrolled in a research study. Further research is required to determine whether there is a dose response to wearing foot orthoses, and if there is an optimal wearing time to facilitate the therapeutic benefits of foot orthoses in individuals with PFPS.

Greater chronicity (i.e., longer duration of symptoms) was recently reported to be associated with poorer prognosis in individuals with PFPS (11). However, consistent with previous clinical prediction rule findings (36), the duration of symptoms was not associated with clinical outcomes in this study. This discrepancy may be explained by methodological differences between the studies. In the current and previous clinical prediction rule study (36), patient-perceived clinical improvement was the primary outcome measure. However, subjective measures of pain and function were used as outcome measures to evaluate prognosis (11). It is possible for individuals with greater chronicity to perceive improvements in their condition (i.e., primary outcome measure in this study) after intervention. However, they may score poorly on prognostic measures including subjective pain and function outcome measures if baseline levels of the same prognostic variables are poor to begin with. Baseline functional performance levels (number of pain free step downs and single leg rises from sitting) may have been unable to predict foot orthoses outcomes for the same reason.

Limitations. The findings of this study need to be considered in the context of several limitations. First, the presence of pain during a single-leg squat is required to assess the ability of foot orthoses to reduce it. However, pain was not present during a single-leg squat in 12% (n = 7) of individuals who completed this study. A solution to this in
a clinical setting and future clinical trials may be to evaluate changes in other functional performance measures in those without single-leg squat pain. This study did not contain a control group, and therefore, the clinical prediction rules identified are preliminary. Validation of these prediction rules is now required in a larger randomized controlled trial before their use can be strongly encouraged in the clinical setting. It is possible that some individuals improved during the 12-wk period because of natural progression, which may have affected the results. Therefore, marked improvement was chosen as the marker for success, because it was considered unlikely that natural progression would result in this level of improvement, particularly in such a cohort with long-term symptoms (i.e., mean duration of symptoms > 5 yr). Finally, although this study evaluated a broader array of possible predictors compared with previous clinical prediction rule studies (31,36), the list was not exhaustive of all possible predictors. Future clinical prediction rule studies may benefit from the addition of dynamic foot function, alignment and function at the hip and knee, cold sensitivity (29), fear avoidance beliefs (26), and psychosocial factors (8). Although gender was not identified as a predictor of outcomes, it may still be a factor that influences other potential clinical predictors of foot orthoses efficacy in individuals with PFPS. Evaluation of this in future studies will require greater participant numbers from both genders to allow adequate statistical power.

CONCLUSIONS

This study identified that the combination of three of four predictors (poor footwear motion control properties, less usual pain, reduced pain during a single-leg squat, and reduced ankle dorsiflexion range of motion) increased the probability of marked improvement with foot orthoses from 25% to 78%. The preliminary clinical prediction rule identified in this study may assist clinical reasoning when considering foot orthoses prescription in individuals with PFPS.

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Findings from this study do not constitute endorsement by the American College of Sports Medicine.

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