

A clinical prediction rule for identifying patients with patellofemoral pain who are likely to benefit from foot orthoses: a preliminary determination

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COMPETING INTERESTS

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ABSTRACT

Objective

To develop a clinical prediction rule to identify patients with patellofemoral pain (PFP) who are more likely to benefit from foot orthoses.

Design

Post-hoc analysis of one treatment arm of a randomised clinical trial.

Setting

Single centre trial in a community setting in Brisbane, Australia.

Participants

42 participants (mean age 27.9 years) with a clinical diagnosis of PFP (median duration 36 months).

Interventions

Foot orthoses fitted by a physiotherapist.

Main outcome measures

Five-point global improvement scale at 12-week follow-up, dichotomised with marked improvement equalling success.

Results

Potential predictor variables identified by univariate analyses were age, height, pain severity, Anterior Knee Pain Scale score, Functional Index Questionnaire score, foot morphometry (arch height ratio, mid foot width difference from non-weight bearing to weight bearing), and overall orthoses comfort. Parsimonious fitting of these variables to a model that explained success with orthoses identified the following: age (> 25 years), height (< 165 centimetres), worst pain visual analogue scale (< 53.25 millimetres) and a difference in mid-foot width from non-weight bearing to weight bearing (> 10.96 millimetres). The pre-test success rate of 40% increased to 86% if the patient exhibited three of these variables (positive likelihood ratio 8.8 (95% confidence interval 1.2 to 66.9)).

Conclusion

Post-hoc analysis identified age, height, pain severity and mid foot morphometry as possible predictors of successful treatment of PFP with foot orthoses, thereby providing practitioners with information for prescribing foot orthoses in PFP and stimulating further research.

Trial registration

Australian Clinical Trials Registry ACTRN012605000463673
ClinicalTrials.gov NCT00118521

INTRODUCTION

Foot orthoses are frequently used by practitioners in the management of patellofemoral pain (PFP) despite a dearth of research-based evidence for their clinical efficacy. Our recent randomised clinical trial (RCT) found that those who wore foot orthoses were 66% more likely to experience success than those who wore flat inserts at six weeks on a dichotomised measure of success.[1, 2] Although this effect was not evident at 12 and 52 weeks, the relatively wide confidence intervals (e.g. NNT 4 (99% CI 2 to 51)[1]) suggest a heterogeneous response to foot orthoses. This is consistent with evidence of non-systematic effects between individuals participating in laboratory-based research on the biomechanical effects of orthoses.[3-5] Unlike previous RCTs on foot orthoses for PFP, [6, 7], we did not use specific criteria, such as excessive pronation, as inclusion or stratification criteria. Thus, point estimates of effect from our RCT may well underestimate the effect for some patients, similar to previous reports for other body regions such as low back pain.[8-10]

Only one published study has investigated possible predictors of success with foot orthoses in the treatment of patients with PFP. Sutlive et al[11] collected an extensive range of lower limb measures of the thigh, knee and leg (e.g. Craig's test, Q angle, tibial varum/valgum) and the foot (e.g. great toe extension, forefoot and rearfoot posture, ankle dorsiflexion), as well as characteristics of the individual patient (e.g. age, sex) and PFP (e.g. pain severity, duration). They found that the best individual predictors of improvement with foot orthoses, indicated by a reduction in pain or disability greater than 50%, were forefoot valgus alignment of at least 2°, great toe extension less than or equal to 78° and navicular drop less than or equal to 3 millimetres. At best, these predictors increased the success rate from 60% to 86%. However, the reliability of these measures is questionable (ICC (SEM): forefoot alignment 0.25 (7.0°); great toe extension 0.55 (7.8°); navicular drop 0.51 (2.8 millimetres).[11] The authors also reported poor to moderate reliability for rearfoot measures, relaxed calcaneal stance, and tibial varum/valgum. These findings highlight the need for a more reliable approach to lower limb morphometry if such measures are to be considered as possible predictors of outcome. We employed a recently developed approach[12] that uses digital callipers to measure arch height and midfoot width in weight bearing (WB) and non-weight bearing (NWB). A pilot study demonstrated high intra-rater (ICC 0.97 to 0.99) and inter-rater (0.90 to 0.98) reliability associated with these measures[12].

In their review of foot orthosis research, Nigg et al[13] concluded that the traditional notion of skeletal re-alignment being the major function of foot orthoses was questionable, and highlighted the importance of comfort. They proposed that effective orthoses would be perceived as comfortable if they supported the skeleton's preferred path during a given movement task, possibly acting as a surrogate to optimal muscle activity and energy expenditure as well as minimising fatigue while improving function. On this basis, we posit that comfort may be a potential predictor of successful outcome with foot orthoses.

Practitioners and patients would benefit from the ability to a priori identify those with PFP who are likely to respond favourably to foot orthoses. Clinical prediction rules are tools used to improve decision making by identifying a parsimonious group of factors from the patient history and physical examination to maximise accuracy in predicting response to treatment.[14]

The aim of this post-hoc analysis was to identify possible predictors of successful treatment of PFP with foot orthoses; specifically, to determine if patient characteristics (e.g. age, height,

weight, gender, foot morphometry), perceived comfort of orthoses, or pain characteristics (pain severity and duration) measured at the outset could predict success at 12 weeks.

METHODS

We conducted a post-hoc analysis of data from a previously reported single-blind, single-centre randomised control trial of foot orthoses, flat inserts, physiotherapy, and foot orthoses plus physiotherapy in PFP.[1, 2] Only the group randomized to receive foot orthoses was used in this analysis. We limited analysis to 12 week data to minimise the number of comparisons and consequential risk of inflated type I error, and to curtail spurious associations through post-hoc data dredging.[15] We also considered 12 weeks a likely time point of interest to patients (i.e., several weeks after discharge). Ethical approval was conferred by The University of Queensland's Medical Research Ethics Committee.

Participants

Participants responded to calls for volunteers in the southeast corner of Queensland between May 2004 and May 2006. Inclusion criteria were: (1) age 18 to 40 years; (2) anterior or retro patellar knee pain of non-traumatic origin that was greater than six weeks duration and provoked by at least two predefined activities (prolonged sitting or kneeling, squatting, jogging or running, hopping, jumping, or stair walking); (3) pain on palpation of the patellar facets, or with step down from a 25cm step, or double leg squat; and (4) pain over the previous week of at least 30mm on a 100mm visual analogue scale. Exclusion criteria were concomitant injury or pathology of other knee structures; previous knee surgery; patellofemoral instability (history of subluxation or dislocation; positive apprehension test); knee joint effusion; Osgood-Schlatter's or Sinding-Larsen-Johanssen disease; any foot condition that precluded use of foot orthoses; hip or lumbar spine pain (local or referred); physiotherapy within previous year; prior foot orthoses treatment; or use of anti-inflammatory or corticosteroids.

Intervention

Participants attended six appointments (30 minutes) over a six-week period with one of 17 trained registered physiotherapists. These sessions were used to fit and modify the orthoses to optimise effectiveness, attempting to replicate clinical practice, and to encourage wearing of the orthoses for the duration of the study.

The foot orthoses and fitting protocol used have been described elsewhere.[2] In brief, participants were provided with four pairs (to fit a range of shoes) of prefabricated ethylene-vinyl acetate (EVA) foot orthoses (Vasyli International), which have a manufacturer specified 6° varus wedge and arch support inbuilt. Physiotherapists selected from a range of EVA densities (Shore A ratings of 75°, 60°, 52°) and modification techniques (heat moulding, wedge and heel raise additions) to suit the individual participant, and followed a standard protocol for orthosis fitting and modification that emphasised fitting firstly to optimise comfort and secondly to improve pain-free function.[2, 16]

Outcome measures

Participants rated their perceived effect of the orthoses on a five point Likert scale (marked improvement, moderate improvement, same, moderate worsening, marked worsening).

Patients were dichotomized as having experienced a successful outcome (those who scored “marked improvement”) or non-success (any other score on the scale).

Predictor variables (independent variables)

We collected data pertaining to participant characteristics, orthosis fit and the musculoskeletal condition (PFP) at baseline and the first intervention appointment. Participant characteristics covered usual demographic features of age, sex, height, weight and body mass index (BMI), as well as morphometric foot measures.[12] We took weight bearing (WB, equal weight on each foot) and non-weight bearing (NWB) measures of the mid foot (recorded at 50% of total foot length) using a digital calliper (Mitutoyo, Japan). WB arch height was also expressed as a proportion of the truncated foot length (posterior heel to first metatarsophalangeal joint line) and termed arch height ratio.[16-18] We also calculated the change in mid foot width from NWB to WB [12]. We conducted a pilot study on test retest reliability (n=10 participants, 3 raters) prior to the conduct of the RCT and found sound reliability (WB arch height ICC (SEM millimetres) 0.98 (0.4); WB midfoot width 0.92 (1.1)).

At the commencement of each physiotherapy appointment, participants rated the overall comfort of the foot orthoses on a visual analogue scale (0 mm = too uncomfortable to wear; 100 mm = no discomfort). They completed an identical scale following any modifications made to the orthoses during the appointment. Mundermann et al[19] found moderate reliability for a similar scale (ICC 0.799).

PFP was characterised by way of duration of knee pain, severity of worst and usual pain over the preceding week (visual analogue scale, 0 mm = no pain; 100 mm = worst pain imaginable)[20], the Anterior Knee Pain Scale[21], and the Functional Index Questionnaire[22]. The reliability of these measures in individuals with PFP has been established as fair to substantial[23] (worst pain ICC (SEM) 0.76 (0.6); usual pain 0.56 (0.6); Anterior Knee Pain Scale 0.81 (3.1); Functional Index Questionnaire 0.49 (1.2)).[20]

Statistical analysis

We used SPSS Version 15.0 statistical software package (SPSS Inc, Chicago, IL, USA) to determine whether any potential prognostic variables identified patients who benefited from orthoses. The reference criterion for success was a score of “marked improvement” on the global improvement scale at the 12-week follow-up. We tested individual variables from self-report measures, history, and foot morphometry for a univariate relationship with success by using independent samples t-tests for continuous variables and χ^2 tests for categorical variables. Those with a significance level of $p < 0.20$ were retained as potential prediction variables.[24] This liberal significance level was selected to increase the likelihood that no potential predictor variables would be overlooked.

For continuous variables with a significant univariate relationship, sensitivity and specificity values were calculated for all possible cut-off points, and plotted as a receiver operator characteristic (ROC) curves.[25] The point on the curve nearest the upper left-hand corner represented the value with the best diagnostic accuracy, and was selected as the cut-off defining a positive test.[25] Sensitivity, specificity, and positive likelihood ratios were calculated for each potential predictor variable. To determine the most accurate set of variables for prediction of treatment success, potential predictor variables were entered into a step-wise logistic regression model. A significance level greater than 0.10 was required for

removal from the equation to minimise the likelihood of excluding potentially useful variables.[24] Variables retained in the regression model were included in the clinical prediction rule as the most parsimonious subset of predictors for identifying success with foot orthoses.

RESULTS

At 12 weeks, data was available for 42 participants (Table 1). A successful outcome was recorded in 17 (40%) participants, with the remainder (25, 60%) rated as non-success. Analyses revealed 9 potential predictor variables (Table 2) that exhibited a significance level of less than 0.20; these were subsequently entered into the logistic regression. The cut-off values determined by the ROC curves and diagnostic accuracy statistics for all 9 variables are reported in Table 2. The positive likelihood ratios ranged from 1.5 to 4.4. Four variables were retained in the final regression model: age over 25, height less than 165 centimetres, worst pain less than 53.25 millimetres, midfoot width difference greater than 10.96 millimetres (Table 3). These four variables were used to form the most parsimonious combination of predictors for identifying patients with PFP likely to have dramatic improvement with orthoses. The pre-test probability for the likelihood of success with orthoses was 40%. If the patient exhibited 3 of the 4 variables the positive likelihood ratio was 8.8 (95% confidence interval 1.2 to 66.9) and the post-test probability of success increased to 86%. If the patient was positive on 2 of the 4 variables the positive likelihood ratio was 2.2 (1.1 to 4.2) with a 61% post-test probability of success. In real participant numbers, of the 33 who were positive on at least one variable, 17 experienced a successful outcome; of the 21 who were positive on at least 2 variable, 12 were in the success group and of the 7 who were positive on 3 variables, 6 were in the success group. There were no patients who satisfied all 4 criteria.

Table 1. Baseline participant characteristics for foot orthoses group (n=42). Values are mean (SD) unless otherwise stated.

Characteristics	Total group (n=42)	Success (n=17)	Non-success (n=25)
Age (years)	27.9 (5.5)	30.0 (5.1)	26.5 (5.5)
Number (%) of females	24 (57.1)	11 (64.7)	13 (52)
Height (cm)	172.3 (9.2)	169.8 (7.5)	174.1 (9.9)
Weight (kg)	77.2 (20.1)	73.8 (15.5)	79.5 (22.9)
Body Mass Index (kg/m ²)	25.8 (5.6)	25.5 (4.3)	26.0 (6.4)
Mid foot width (weight bearing) (mm)	84.8 (10)	85.3 (9.7)	84.5 (10.4)
Mid foot width (non-weight bearing) (mm)	75.2 (7.4)	74.1 (7.4)	75.7 (7.5)
Mid foot width difference* (mm)	9.6 (4.1)	11.1 (4.8)	8.8 (3.6)
Arch height	66.9 (7.4)	64.4 (8.3)	68.2 (6.7)
Arch height ratio	0.35 (0.032)	0.338 (0.029)	0.357 (0.032)
Bilateral knee pain: number (%)	25 (59.5)	10 (58.8)	15 (60)
Duration of knee pain (months): median (IQR)	36.0 (12.5 - 96.0)	24.0 (8.5 - 138)	42.0 (23.3 - 93.0)
Worst pain [^]	58.9 (15.8)	52.8 (11.4)	63.0 (17.2)
Usual pain [^]	38.5 (15.8)	34.0 (13.6)	41.6 (16.7)
AKP Scale [†]	71.2 (9.0)	73.9 (9.1)	69.3 (8.7)
FIQ [‡]	10.0 (1.9)	10.9 (1.2)	9.4 (2.1)

* Mid foot width difference = (mid foot width non-weight bearing) – (mid foot width weight bearing)

[^] Pain measured on a 100 mm visual analogue scale; 0 mm = no pain, 100 mm = worst pain imaginable

[†] Anterior Knee Pain Scale (0-100 points); 100 = no disability

[‡] Functional Index Questionnaire (0-16 points); 16 = no disability

Table 2. Potential predictors of success with foot orthoses at 12 weeks (pre-test success 40%). Values in parentheses represent 95% confidence intervals.

Variable	Sensitivity	Specificity	Positive likelihood ratio	Post-test
Age over 25 years	0.82 (0.56 to 0.95)	0.56 (0.35 to 0.75)	1.9 (1.1 to 3.1)	57%
Height less than 165 cm	0.41 (0.19 to 0.67)	0.92 (0.72 to 0.99)	4.9 (1.2 to 20.9)	77.3%
Midfoot width difference greater than 10.96 mm	0.56 (0.23 to 0.85)	0.81 (0.54 to 0.95)	3.0 (0.91 to 9.6)	67.6%
Arch height ratio less than 0.34	0.33 (0.09 to 0.69)	0.82 (0.56 to 0.95)	1.9 (0.47 to 7.5)	57%
Worst pain [^] less than 53.25 mm	0.53 (0.29 to 0.76)	0.64 (0.43 to 0.81)	1.5 (0.74 to 2.9)	51%
Usual pain [^] less than 24.75 mm	0.35 (0.15 to 0.61)	0.92 (0.72 to 0.99)	4.4 (1.0 to 19.3)	75.4%
AKP Scale [†] score greater than 66.5	0.82 (0.56 to 0.95)	0.48 (0.28 to 0.68)	1.5 (1.0 to 2.4)	51%
FIQ [‡] score greater than 9.5	0.76 (0.50 to 0.92)	0.56 (0.35 to 0.75)	1.7 (1.0 to 2.9)	54.2%
Overall comfort less than 77.5 mm	0.33 (0.13 to 0.61)	0.81 (0.57 to 0.94)	1.8 (0.56 to 5.44)	55.6%

[^] Pain measured on a 100 mm visual analogue scale; 0 mm = no pain, 100 mm = worst pain imaginable

[†] Anterior Knee Pain Scale (0-100 points); 100 = no disability

[‡] Functional Index Questionnaire (0-16 points); 16 = no disability

Table 3. Predictors of subgroup success from logistic regression (with 95% confidence intervals): age over 25, height less than 165 centimetres, worst pain less than 53.25 millimetres, midfoot width difference greater than 10.96 millimetres.

Variable	Sensitivity (95% CI)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Post-test	Number in Success Group	Number in Non-Success Group
1+	1 (0.77 to 1.0)	0.36 (0.19 to 0.57)	1.6 (1.2 to 2.1)	52.7%	17	16
2+	0.71 (0.44 to 0.89)	0.68 (0.46 to 0.84)	2.2 (1.1 to 4.2)	59.5%	12	8
3+	0.35 (0.15 to 0.61)	0.96 (0.78 to 0.99)	8.8 (1.2, 66.9)	85.4%	6	1
4	Unable to calculate as no patient satisfied all 4 criteria					

DISCUSSION

The probability of success when using foot orthoses indiscriminately (i.e., without any predetermined stratification on foot posture or any other patient characteristic) for the treatment of PFP was 40%. This can potentially be increased more than two-fold (i.e. to 86%) if the orthoses are supplied to patients who have three of the following features: worst pain severity greater than 53 millimetres, an increase in mid foot width of more than 11 millimetres when the foot is loaded, older than 25 years, or taller than 165 centimetres. Although these are preliminary findings from post-hoc analyses, it is readily apparent that careful selection or stratification of those receiving a specific intervention like foot orthoses is likely to substantially improve the probability of success.

There are three key differences between our findings and those of the only other published study on this topic.[11] First, a predictor set cluster emerged in our study (positive likelihood ratio 8.8; success rate improved from 40% to 86%) but not in that of Sutlive et al (best positive likelihood ratio 4; success rate improved from 60% to 86%). Second, our clinical prediction rule included pain severity along with patient characteristics (age, height and foot morphometry), whereas Sutlive et al found only foot measures of forefoot alignment, navicular drop, and great toe extension. Third, the foot measures used in our study exhibited high reliability, whereas those used by Sutlive et al may be sufficiently unreliable to compromise the validity of their testing. Notwithstanding these differences, there is a strong similarity in the nature of the foot measures identified in that they all represent surrogate clinical measures of foot mobility. In summary, future research of predictors of success would be best served by not only including reliable measures of foot morphometry, but also pain severity and patient characteristics (e.g. age and height).

In addition to the cluster of predictor variables, a number of variables had significant univariate relationships with successful orthoses outcome. These included measures of worse PFP (higher usual pain severity, and lower Functional Index Questionnaire and Anterior Knee Pain Scale scores), another foot posture measure (lower arch height ratio, indicating increased pronation), and an orthosis-related measure of comfort (lower overall comfort). The latter is a particularly interesting finding considering that we used comfort as the primary criterion for fitting the orthoses, and the work of Nigg et al[13]. Although this finding does contrast our hypothesis of success having an association with greater comfort, the small increase in probability of success should be kept in mind (40% to 55.6%). Nevertheless, this finding does highlight the need to further investigate the role of perceived comfort in clinical prediction rules for foot orthoses.

This post-hoc analysis was conducted as a preliminary investigation into a clinical prediction rule for success with foot orthoses. The nature of the data source is that the sample size was powered to detect between-group differences within a large RCT. As such, it is possible that the small sample size, as well as the inclusion of a number of variables in the logistic regression model, may have resulted in over-fitting of the model, which can lead to spurious findings. However, in the initial stages of identifying predictor variables it is important and necessary to include all potential predictors. Any variable that may have fallen out as a predictor also needs to be re-examined in future studies, especially given the likelihood of type II error in post-hoc analyses such as this. Nevertheless, this study provides preliminary findings that highlight the need for conduct of larger-scale investigations into clinical prediction rules for foot orthoses success in PFP.

CONCLUSION

This preliminary investigation of potential predictors of success with foot orthoses treatment in PFP has identified that a combination of three of the following (age, height, pain severity and foot width mobility) increases the probability of success from 40% to 86%. This post-hoc analysis serves as a basis for further studies and may be used by practitioners as a guide to assist clinical decisions in managing PFP with foot orthoses.

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