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Published in:
British Journal of Sports Medicine

DOI (link to publication from Publisher):
10.1136/bjsports-2019-100935

Publication date:
2020

Document Version
Accepted author manuscript, peer reviewed version

Citation for published version (APA):
Matthews, M., Rathleff, M. S., Claus, A., McPoil, T., Nee, R., Crossley, K. M., Kasza, J., & Vicenzino, B. T. (2020). Does foot mobility affect the outcome in the management of patellofemoral pain with foot orthoses versus hip exercises? A randomised clinical trial. *British Journal of Sports Medicine*, *54*(23), 1416-1422. https://doi.org/10.1136/bjsports-2019-100935

Does foot mobility affect the outcome in the management of patellofemoral pain with foot orthoses versus hip exercises? A randomised clinical trial

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Summary

What are the new findings?

- Contrary to expectation, those with patellofemoral pain and greater foot pronation (measured as midfoot width mobility) did not have superior benefits using foot orthoses, compared to hip exercises.
- This randomised clinical trial provides evidence that foot orthoses and hip exercises offer similar global outcomes in the management of patellofemoral pain.

Impact on clinical practice

- These results suggest that clinicians and patients can consider either foot orthoses or hip exercises in managing patellofemoral pain.

ABSTRACT

Objectives

To test (i) if greater foot pronation (measured as midfoot width mobility) is associated with better outcomes with foot orthoses treatment, compared to hip exercises, and (ii) if hip exercises are superior to foot orthoses, irrespective of midfoot width mobility.

Methods

A two-arm parallel, randomised superiority clinical trial was conducted in Australia and Denmark. Participants (18-40years) were included who reported an insidious onset of knee pain (≥6 weeks duration); ≥3/10 numerical pain rating, that was aggravated by activities (e.g. stairs, squatting, running). Participants were stratified by midfoot width mobility (*high* ≥11mm change in midfoot width) and site, randomised to foot orthoses or hip exercises and blinded to objectives and stratification. Success was defined a-priori as *much better* or *better* on a patient-perceived 7-point scale at 12 weeks.

Results

Of 218 stratified and randomised participants, 192 completed 12week follow-up. This study found no difference in success rates between foot orthoses versus hip exercises in those with *high* (6/21 v 9/20; 29% v 45% respectively) or *low* (42/79 v 37/72; 53% v 51%) midfoot width mobility. There was no association between midfoot width mobility and treatment outcome (Interaction effect *P*=0.19). This study found no difference in success rate between foot orthoses versus hip exercises (48/100 v 46/92; 48% v 50%).

Conclusion

Midfoot width mobility should not be used to help clinicians decide which patient with patellofemoral pain might benefit most from foot orthoses. Clinicians and patients may consider either foot orthoses or hip exercises in managing patellofemoral pain.

Word count: 247

Trial Registration

Australian New Zealand Clinical Trials Registry. (ACTRN: 12614000260628).
https://www.anzctr.org.au/Trial/Registration/TrialReview/FOHX_trial

Funding

National Health and Medical Research Council (Ref: 631717) and Vionics International.

INTRODUCTION

Persistent pain affects approximately 126 million people in the United States, costs over $560 billion annually and severely affects the quality of life of the individual [1, 2]. One such recalcitrant pain condition is patellofemoral pain (PFP). The prevalence of PFP is between 23 and 29% in the general and adolescent populations [3]. It is associated with a high risk of long-term pain, as one in two will continue to suffer after 5-8 years [4]. Radiographic and magnetic resonance imaging evidence suggests PFP could be one of the earliest manifestations of patellofemoral joint osteoarthritis [5]. The aetiology of PFP remains unknown, but is considered multifactorial with a combination of underlying biomechanical, neuromuscular and/or psychological contributors [6-8]. Patellofemoral pain is a clinical diagnosis based on a typical presentation of pain around or behind the patella during daily activities such as negotiating stairs, squatting or sitting [9].

Systematic reviews [10, 11] and international consensus [12] recommend foot orthoses [13, 14] and especially a focus on hip exercises [15, 16] in the management of PFP. The quandary is how to best tailor the most efficacious treatment to the individual's presentation and characteristics to ensure optimal outcomes. [17] Evidence suggests that greater mobility of the midfoot (defined as a change of 11mm or more in midfoot width when moving from non-weight bearing to weight bearing [18]), is associated with better outcomes following foot orthoses [19, 20]. Crucially, methodological considerations in previous literature, such as lack of a comparator treatment and potential over-fitting of models for outcomes, may have created spurious findings, compromising their clinical applicability [10, 21]. Further investigation is needed to examine if a simple clinical measurement of the foot [18] can be used to determine which patient will benefit the most from which treatment (i.e. foot orthoses versus another comparable treatment for PFP; i.e., hip exercises).

The aims of this trial were to: (i) evaluate if greater midfoot width mobility is associated with a better outcome following treatment with foot orthoses when compared to hip exercises, and (ii) compare the treatment effectiveness of foot orthoses relative to hip exercises at 12 weeks, irrespective of midfoot mobility, in the management those with PFP. The hypotheses were that (i) those with greater midfoot width mobility will have greater benefit with foot orthoses, compared to hip exercises, and (ii) those that receive hip exercises will report greater overall benefits than those who receive foot orthoses.

METHODS

Study Design

A two-arm parallel, multi-centre randomised superiority clinical trial was conducted in a community setting in Brisbane, Australia, and hospital outpatient department in Aalborg, Denmark. The trial was prospectively registered (ACTRN12614000260628) and the protocol published elsewhere [22]. The trial adhered to the principles of the Declaration of Helsinki [23] with ethical approval granted by the University of Queensland Medical Research Ethics Committee (2013000981) and the ethics committee in the North Denmark Region (N-20140022). The trial was conducted in agreement with the registration and more specifically the published protocol [22], with the exception that the patient specific functional scale and international physical activity questionnaire were not analyzed due to reporting errors. The reporting of this clinical trial follows the CONSORT statement and TIDieR for describing interventions [24-26].

Participants

Volunteers from Brisbane, Australia and Aalborg, Denmark responded to advertisements or were referred by health care practitioners. Inclusion criteria were: age 18-40 years; insidious onset of anterior, retro or peri-patellar pain aggravated by at least two activities (e.g. stair ambulation, squatting, jogging/running); reported pain of at least 3 out of 10 on a numerical pain rating scale (10 representing worst pain imaginable) over the last 7 days; greater than six weeks' duration and tenderness on palpation of the patellar borders with reproduction of pain completing a step down or double leg squat. Participants were excluded if they reported traumatic onset of symptoms; concomitant injuries or pain from the hip, lumbar spine, or other knee structures that manifested with similar symptoms; patellar dislocation or instability; previous knee surgery; evidence of knee joint effusion; any foot condition that precluded use of foot orthoses; the use of anti-inflammatory drugs or corticosteroid medication; or previous treatment for PFP that included foot orthoses or hip exercises. Eligible participants were required to have comprehension of written and spoken English (Brisbane, Australia) or Danish (Aalborg, Denmark).

Stratification

Midfoot width mobility at baseline was defined as the difference between non-weight bearing and weight bearing measurements of the width of the participant's midfoot (defined as 50% of total foot length) [18]. This measurement is highly reliable (inter-rater $ICC_{(2,1)}$ >0.83, intra-rater $ICC_{(2,1)}$ >0.97), with standard error of the measure being less than 0.19mm [18]. Stratification occurred using a pre-determined cutoff for midfoot width mobility of 11mm [19, 20]; those who presented with equal to, or greater than 11mm midfoot width mobility were defined as *'high mobility'* and those with less than 11mm as *'low mobility'* [22].

Randomisation and blinding

An independent off-site body generated a randomisation schedule by computer for all participants at both the Australian and Danish sites before trial initiation. They were sent to the two study sites and kept in a locked cabinet. Allocation to each treatment via sealed and opaque envelopes was done in a 1:1 ratio using random permuted blocks of sizes 8 to 16; with stratification by midfoot width mobility and site (Brisbane or Aalborg). A researcher determined eligibility and collected all baseline measurements, except midfoot width mobility status. A separate researcher, blind to all baseline information, measured each participant's midfoot width prior to allocation to one of the treatments. Randomisation occurred once participants were stratified on midfoot width mobility. A separate researcher communicated with the randomisation centre, trial participants, and physiotherapists and sites. The outcome assessor was blind to treatment allocation and midfoot width mobility status. Physiotherapists were kept blind to the participant's stratification and study hypothesis. Participants were informed the study involved two evidence-based treatments (foot orthoses or hip exercises), but were kept blind to midfoot width mobility status and study hypothesis.

Interventions

Registered physiotherapists completed three pre-trial familiarisation sessions prior to applying both interventions [22]. The first session covered trial details and foot orthoses prescription, the second to practice the hip exercise program, and the third was for checking/revising content from the previous sessions. Prescription of foot orthoses followed the protocol utilised in a previous randomised clinical trial [13]. The hip exercises targeting posterior-lateral hip muscles are reproduced from a previous randomised clinical trial in those with PFP [15], with their efficacy supported in clinical trials [15, 16]. Fees and costs for the interventions, including materials, were covered by the project.

Foot orthoses

Physiotherapists fitted commercially available prefabricated foot orthoses (Vionics International, Australia) and a pair of orthosis-like contoured sandals [27]. Physiotherapists followed a standardised fitting process that prioritised comfort [28], with scope to review size, length and hardness [22]. Participants performed a home exercise program twice per day, consisting of calf stretches and anti-pronation foot exercises, aimed to improve foot awareness, with full details previously published [22]. Participants attended six sessions over six weeks to fit and revise orthoses and ensure home exercise fidelity. No instructions were given with regards to continuing or discontinuing foot orthoses after the six sessions.

Hip exercises

The hip exercise protocol followed recommended prescribing guidelines [29]. Full details of the exercise protocol are previously published [22]. Progressive, resisted hip exercises were performed bilaterally and focused on the hip abductor, external rotator, and hip extensor muscle groups in side lying, supine and standing. Participants attended a physiotherapist-supervised one-on-one exercise session, three times per week for four weeks (12 sessions total). Physiotherapists selected predetermined lengths and grade of elasticated band at each session, which provided sufficient resistance for participants to achieve a maximum of 10 repetitions and perceived exertion of 5 to 7/10 (*Hard* to *Very hard*) per exercise. No instructions were given with regards to continuing or discontinuing hip exercises after the 12 sessions.

Primary outcome

The primary outcome measure was a 7-point Likert global rating of change (GROC) scale with categories of *much better*, *better*, *a little better, no change, a little worse, worse* or *much worse*. This measure has been previously utilised in similar trials on PFP [13, 30]. A successful outcome was a-priori defined as being *much better* or *better* at the primary time point of interest at 12 weeks.

Secondary outcomes

Secondary participant rated outcomes included the single assessment numeric evaluation (SANE) to rate the normality of their knee and their recovery out of 100% (100% being defined as having no problems at all and fully recovered), patient acceptable symptom state (PASS) by answering if their current condition was satisfactory, taking into consideration their general functioning and current pain (yes/no), perception of success by answering if they agreed their treatment was successful (yes/no), Kujala anterior knee pain scale, knee injury and osteoarthritis outcome scale (KOOS), numerical rating of pain severity over the last seven days, hospital anxiety and depression scale, Euro-Qol™ (EQ-5D), kinesiophobia, and pain catastrophising [22]. Physical performance tests included hip strength measures and number of pain-free (i) step ups, (ii) step downs (25cm step), and (iii) squats to a metronome set to 96 beats per minute [22].

Statistical analysis

Sample size calculations were based on proportions of patients in each group rating themselves as “much better” or “better” on the GROC score. The primary aim was to detect an interaction effect of 50 percentage points between midfoot mobility stratum and treatment group. This would mean that a treatment effect favoring foot orthoses (the difference between the foot orthoses and hip exercise groups in the proportions of participants who had

successful outcomes at 12 weeks) was 50 percentage points higher in participants with *high mobility* than in those with *low mobility*. Assuming that: (i) in participants with *high mobility*, 80% would have successful outcomes with foot orthoses compared to 30% with hip exercises, (ii) 20% of participants would have *high mobility* (based on previous data [20]), and (iii) loss to follow-up would be up to 15%, 220 participants (110 per group) were required to have 80% power to detect the aforementioned interaction effect using a two-sided significance level of 0.05 [22, 31].

A statistical analysis plan was published prior to analysis and is available on request (https://espace.library.uq.edu.au/view/UQ:623536). A biostatistician blinded to group allocation conducted all analyses. All analysis of data was conducted on an intention-to-treat basis including all randomised participants. Characteristics of treatment groups were summarised as mean (standard deviation) for continuous variables and as count (percentage) for categorical variables. Data were analysed on an intention to treat basis using Stata v14.1 (StataCorp), including all randomised participants in their assigned group. Missing baseline variables were imputed using single mean imputation [32]. Estimates from 20 imputed datasets were combined using Rubin's rules [33]. Datasets were imputed using chained equations, with predictive mean matching from the three nearest neighbours for continuous outcomes and logistic regression for binary outcomes. Imputation was done separately for each treatment arm, including a range of variables in the imputation models. For dichotomous outcomes, binary regression models with a logarithmic link were fitted using generalised estimating equations with an exchangeable working correlation matrix to account for the two follow-up measurements per participant (at 6 and 12 weeks). That is, baseline measures were not included as outcomes in the models. Models included a three-way interaction between treatment group, midfoot mobility stratum, and follow-up visit number (1 or 2), all two-way interactions, main effects, and a term for country (Australia or Denmark). The relative risk (RR) comparing treatment groups in each midfoot mobility by time stratum was calculated with 95% confidence intervals. To compare outcomes between treatment groups, similar models including only a main effect for midfoot mobility were fitted. Similar models for continuous outcomes were fitted, again using generalised estimating equations, additionally including a term for the baseline level of the outcome.

Patient involvement

Patient representatives were engaged in the development stages of the study. Prior to providing consent, all participants were informed of the study requirements, asked if they were willing to undergo their allocated intervention, and informed they will be emailed the final results.

RESULTS

Participants

Between June 2014 to April 2017, 220 participants enrolled in the study. Two non-randomised cases were erroneously included and were removed when identified as such after close out, resulting in 218 participants (138 in Australia, 80 in Denmark). Forty-nine (22%) participants were classified as *high* mobility and 169 (78%) as *low* mobility (Figure 1). Treatment groups and treatment-by-mobility groups were well matched at baseline (Table 1). One participant in the *low* mobility foot orthoses group received hip exercises incorrectly. Participants who did not provide a GROC score were deemed to have been lost to follow-up. There were 197 (90%) participants followed up at 6 weeks and 192 (88%) at 12 weeks.

Figure 1: CONSORT Flow of participants through the study

Table 1: Baseline characteristics of participants for intervention and stratified groups.

	Foot Mobility Strata	Total	Hip Exercises	Foot Orthoses
Site				
Both (n (%))	High	49 (22.5)	25 (22.9)	24 (22.0)
	Low	169 (77.5)	84 (77.1)	85 (78.0)
	All	218	109	109
Australia (n (%))	High	28 (12.8)	14 (12.8)	14 (12.8)
	Low	110 (50.1)	55 (50.1)	55 (50.1)
	All	138 (63.3)	69 (63.3)	69 (63.3)
Denmark (n (%))	High	21 (9.6)	11 (10.1)	10 (9.2)
	Low	59 (27.1)	29 (26.6)	30 (27.5)
	All	80 (36.7)	40 (36.7)	40 (36.7)
Sex	High	32 (65.3)	16 (64.0)	16 (66.7)
Female (n (%))	Low	119 (70.4)	54 (64.3)	65 (76.5)
	All	151 (69.3)	70 (64.2)	81 (74.3)
Bilateral symptoms	High	37 (78.7)	17 (73.9)	20 (83.3)

Yes (n (%))	Low	109 (66.1)	52 (63.4)	57 (68.7)
	All	146 (68.9)	69 (65.7)	77 (72.0)
Study Knee (most problematic) Right (n (%))	High	30 (63.8)	16 (69.6)	14 (58.3)
	Low	81 (49.4)	43 (52.4)	38 (46.3)
	All	111 (52.6)	59 (56.2)	52 (49.1)
Age (years mean (SD))	High	27.8 (5.8)	29.2 (4.9)	26.4 (6.3)
	Low	28.2 (6.1)	28.0 (6.3)	28.3 (5.9)
	All	28.1 (6.0)	28.3 (6.0)	27.9 (6.0)
Height (cm mean (SD))	High	170.0 (10.5)	169.1 (10.1)	170.9 (11.1)
	Low	171.5 (9.3)	172.1 (9.7)	171.0 (8.9)
	All	171.2 (9.6)	171.4 (9.8)	171.0 (9.4)
Weight (kg mean (SD))	High	76.0 (14.9)	80.7 (15.5)	71.0 (12.7)
	Low	73.3 (17.0)	73.7 (17.0)	72.9 (17.1)
	All	73.9 (16.5)	75.3 (16.9)	72.5 (16.2)
BMI (kg/m^2 mean (SD))	High	26.3 (4.8)	28.3 (5.3)	24.3 (3.4)
	Low	24.8 (4.8)	24.7 (4.5)	24.9 (5.1)
	All	25.1 (4.8)	25.5 (4.9)	24.7 (4.8)
Duration of Symptoms (months mean (SD))	High	62.6 (69.0)	67.6 (67.0)	57.7 (72.1)
	Low	51.3 (58.8)	47.9 (60.1)	54.8 (57.7)
	All	53.8 (61.2)	52.3 (61.9)	55.4 (60.8)
Self-reported measures				
Worst Pain (NRS mean (SD))	High	6.4 (2.0)	6.4 (2.4)	6.2 (1.9)
	Low	6.25 (2.0)	6.2 (2.0)	6.1 (2.3)
	All	6.3 (2.0)	6.3 (2.0)	6.3 (2.0)
Tampa (mean (SD))	High	39.3 (6.7)	39.3 (6.5)	39.2 (7.0)
	Low	39.5 (5.5)	38.9 (5.4)	40.0 (5.5)

	All	39.4 (5.7)	39.0 (5.6)	39.9 (5.8)
HADS Anxiety	High	6.4 (3.1)	6.2 (3.1)	6.2 (3.4)
(mean (SD))	Low	5.8 (3.9)	5.6 (3.8)	6.0 (3.9)
	All	5.9 (3.7)	5.8 (3.6)	6.0 (3.8)
HADS Depression	High	2.9 (2.5)	3.0 (2.7)	2.8 (2.2)
(mean (SD))	Low	3.0 (2.6)	3.0 (2.7)	3.0 (2.6)
	All	3.0 (2.6)	3.0 (2.7)	3.0 (2.5)
Pain Catastrophising Scale	High	13.4 (8.3)	12.6 (7.5)	13.7 (9.5)
(mean (SD))	Low	12.5 (9.5)	11.9 (8.5)	13.0 (10.5)
	All	12.7 (9.3)	12.2 (8.2)	13.3 (10.2)
Percentage of normal	High	59.7 (19.1)	54.0 (25.5)	55.6 (24.2)
(0-100% mean (SD))	Low	59.6 (21.5)	55.8 (25.8)	52.1 (28.0)
	All	59.6 (20.9)	60.3 (20.3)	58.8 (21.6)
KOOS (mean (SD))	High	65.6 (16.0)	66.1 (15.8)	65.2 (16.4)
Symptoms	Low	68.1 (15.3)	69.3 (16.2)	66.9 (14.4)
	All	67.6 (15.4)	68.6 (16.1)	66.5 (14.8)
Pain	High	69.1 (12.1)	67.2 (12.4)	70.9 (11.7)
	Low	69.0 (12.9)	69.5 (13.0)	68.5 (12.9)
	All	69.0 (12.7)	69.0 (12.9)	69.0 (12.6)
Activities of daily living	High	78.9 (13.4)	79.4 (14.5)	78.4 (12.5)
	Low	79.3 (13.0)	79.7 (12.7)	78.9 (13.4)
	All	79.2 (13.1)	79.6 (13.1)	78.8 (13.1)
Sporting and recreation	High	52.5 (22.9)	49.2 (23.4)	55.8 (22.3)
	Low	52.4 (21.6)	55.5 (20.9)	49.2 (22.0)
	All	52.2 (21.6)	54.1 (21.5)	50.7 (22.1)
Quality of Life	High	48.4 (16.7)	48.4 (13.9)	48.4 (19.4)
	Low	44.9 (15.8)	45.9 (16.9)	43.9 (14.6)

	All	45.7 (16.0)	46.5 (16.3)	44.69 (15.8)
KOOS Patellofemoral	High	52.9 (19.1)	51.1 (19.0)	54.9 (19.5)
(mean (SD))	Low	52.3 (16.1)	52.5 (15.2)	50.0 (17.7)
	All	52.3 (16.1)	52.2 (16.1)	51.0 (18.1)
Physical measurements				
Functional tests study knee	High	13.5 (8.3)	13.6 (8.4)	13.5 (8.4)
Step-up (n mean (SD))	Low	13.1 (8.6)	13.1 (8.6)	13.2 (8.6)
	All	13.2 (8.5)	13.2 (8.5)	13.3 (8.6)
Step-down (n mean (SD))	High	8.7 (8.5)	8.4 (8.6)	9.0 (8.6)
	Low	7.7 (7.5)	7.5 (7.3)	8.0 (7.7)
	All	7.9 (7.7)	7.7 (7.6)	8.2 (7.9)
Squats (n mean (SD))	High	9.9 (7.3)	10.7 (7.5)	9.0 (7.1)
	Low	9.2 (7.7)	8.5 (7.5)	9.9 (7.9)
	All	9.4 (7.6)	9.0 (7.5)	9.7 (7.7)
Beighton Joint Mobility	High	2.3 (2.3)	1.9 (2.4)	2.6 (2.3)
(mean (SD))	Low	2.2 (2.3)	1.9 (2.3)	2.4 (2.2)
	All	2.2 (2.3)	1.9 (2.3)	2.5 (2.2)
Hip Strength study knee	High	1.39 (0.33)	1.35 (0.29)	1.44 (0.38)
Abduction	Low	1.43 (0.41)	1.47 (0.42)	1.39 (0.39)
($Nmkg^{-1}$ mean (SD))	All	1.42 (0.39)	1.44 (0.40)	1.40 (0.39)
Adduction	High	1.45 (0.40)	1.44 (0.43)	1.46 (0.37)
($Nmkg^{-1}$ mean (SD))	Low	1.43 (0.47)	1.49 (0.49)	1.38 (0.44)
	All	1.44 (0.45)	1.48 (0.48)	1.40 (0.43)
External rotation	High	0.48 (0.12)	0.49 (0.13)	0.47 (0.11)
($Nmkg^{-1}$ mean (SD))	Low	0.45 (0.12)	0.46 (0.12)	0.44 (0.13)
	All	0.46 (0.12)	0.46 (0.12)	0.45 (0.12)
Hip ROM study knee	High	25.3 (7.6)	23.4 (8.4)	26.2 (8.3)

Internal rotation	Low	26.9 (8.0)	26.5 (7.6)	27.3 (8.3)
(degrees mean (SD))	All	26.5 (7.9)	26.0 (7.5)	27.0 (8.3)
External rotation	High	32.8 (7.7)	32.0 (9.8)	32.2 (8.2)
(degrees mean (SD))	Low	32.8 (7.4)	33.1 (8.0)	32.5 (6.8)
	All	32.7 (7.4)	33.1 (7.8)	32.4 (7.1)
Midfoot width Mobility				
study side	High	12.6 (1.5)	12.7 (1.4)	12.5 (1.7)
(mean (SD))	Low	7.4 (2.3)	7.9 (2.0)	6.9 (2.6)
	All	8.5 (3.1)	9.0 (2.7)	8.1 (3.4)
Foot Posture Index study				
side	High	6.0 (4.0)	6.0 (4.6)	5.8 (3.5)
(mean (SD))	Low	3.3 (4.0)	3.6 (3.9)	2.9 (4.1)
	All	3.9 (4.2)	4.2 (4.2)	3.6 (4.2)
Navicular Drop study side	High	8.3 (4.3)	8.4 (4.9)	8.0 (3.8)
(mm mean (SD))	Low	5.5 (3.8)	5.6 (3.5)	5.3 (4.1)
	All	6.1 (4.1)	6.3 (4.0)	5.9 (4.1)
Ankle Dorsiflexion study				
side	High	126.0 (35.9)	116.2 (32.3)	135.8 (37.4)
Bent knee	Low	118.1 (33.4)	112.1	121.4 (31.0)
(mm mean (SD))	All	119.9 (34.1)	115.2 (34.7)	124.6 (32.9)
Straight knee	High	36.9 (5.4)	35.0 (5.1)	38.7 (5.2)
(degrees mean (SD))	Low	37.0 (5.5)	36.2 (5.8)	37.9 (5.1)
	All	37.0 (5.5)	35.9 (5.7)	38.1 (5.1)

BMI = body mass index; NRS = Numerical rating scale

Adherence:

Ten participants did not attend their allocated treatment (n=3 foot orthoses, n=7 hip exercises). Participants allocated to foot orthoses attended on average 5.5/6 (92%, (1-6)) of the sessions and reported to have worn their foot orthoses for 74% of waking hours. Participants allocated to hip exercises attended on average 10.1/12 (84%, (1-12)) of their sessions.

Effect of midfoot width on success rates

There was no difference in success rates following foot orthoses or hip exercises in either the *high* (29% v 45% respectively) or *low* midfoot mobility (53% v 51% respectively) strata at 12 weeks (interaction *P*=0.19) (Fig 2, Table 2). A secondary analysis including midfoot width mobility as a continuous interval measure showed similar results (P-value 0.66, Appendix *e*Table 1). There was no evidence of any significant interactions between treatments and midfoot mobility strata in any of the secondary outcome measures (Appendix *e*Table 2).

Figure 2: Percentage and number of participants rating perceived global change across categories from *much better* to *much worse*

Table 2: Treatment outcomes for foot orthoses versus hip exercises at 12 weeks, grouped according to midfoot width mobility stratification

Midfoot Width Mobility	Hip Exercises (successful[+]/total (%))*	Foot orthoses (successful[+]/total (%))*	Foot orthoses vs Hip exercises^	
			Relative Risk (95% CI)	*P*-value
High (≥11 mm)	9/20 (45.00)	6/21 (28.57)	0.58 (0.26, 1.32)	0.20
Low (<11 mm)	37/72 (51.39)	42/79 (53.16)	1.02 (0.76, 1.36)	0.91
All	46/92 (50.00)	48/100 (48.00)	0.94 (0.72, 1.24)	0.67

[+] successful defined as *much better* or *better* on GROC, * frequency counts are complete-cases, ^ point estimates (Relative Risk) are based on multiply imputed data

Foot orthoses versus hip exercises

There was no difference in success rates patients randomised to foot orthoses (48%) relative to hip exercises (50%) (RR 0.94, 95% CI (0.72 to 1.24) Table 2). Although there appeared to be small p-values favoring hip exercises versus foot orthoses at 12 weeks on three KOOS subscales (symptoms (75.8 vs. 71.7, coefficient -2.92 (-5.52 to -0.32), p=0.028), pain (80.7 vs. 76.4, coefficient -4.09 (-7.63 to -0.55), p=0.023) and daily living (88.6 vs. 84.9, coefficient -3.37 (-6.54 to -0.20), p=0.037)), the clinical significance of these findings are questionable. There was no evidence of any differences between groups with respect to the other 22 secondary outcome measures (Appendix *e*Table2)

Co-interventions

Two participants reported undertaking additional treatments. One participant from the low mobility-foot orthoses group commenced yoga between the 6 and 12-week follow-up sessions, and another used knee wraps while exercising with heavy weights.

Adverse events

Fourteen participants allocated to foot orthoses (14/109, 13%) reported temporary toe and/or foot discomfort (n=7) or rubbing/ blistering (n=7) of the skin. Five participants allocated to hip exercises (5/109, 5%) reported increased discomfort in the hip region after exercises. No adverse events prevented participants from continuing treatment.

DISCUSSION:

There was no moderating effect of foot mobility on treatment effects

The results do not support the hypothesis that greater midfoot width mobility, as a cut-off (≥11mm) or as a continuous measurement, as a treatment effect modifier for prescribing foot orthoses over hip exercises. This conclusion should be tempered by considering the wide confidence intervals of the interaction effect does not rule out the existence of a potentially important interaction. There was no evidence to indicate hip exercises or foot orthoses were more effective than the other in improving PFP outcomes.

Previous clinical trials have shown foot orthoses to be effective compared to a wait-and-see or flat inserts [13, 20]. Theoretical and preliminary evidence [6, 19, 20] suggested that individuals with greater foot pronation (measured as midfoot width mobility) would benefit most from foot orthoses intervention. Our study contradicts these preliminary findings and suggests midfoot mobility should not be the primary deciding factor in prescribing foot orthoses.

There was no difference between foot orthoses and hip exercise: is this because there was no change over time (baseline to 12 weeks) in both groups?

Our finding that there was no strong evidence of an interaction or treatment effects could stem from there being no change over time in both treatments. When we compare the change over time of foot orthoses using a similar outcome (i.e. global rating of change), the changes we observed were similar to others (48% vs 47% [20]). Likewise, when we use similar outcomes for exercise programs that included hip exercises (i.e. change in self-reported pain and/or anterior knee pain scales), we see similar changes (71% vs 80% [16]). Overall the changes over time in the foot orthoses or hip exercise groups is similar across a number of studies and various self-reported outcome measures, [16, 20, 30] which increases our confidence that our treatments were similar to other trials.

Is four weeks of exercise sufficient?

Whilst our study did not compare different durations of exercise interventions, the response to four weeks of exercise was sufficient to induced comparable strength changes and success rates to previous trials [16]. Exercise therapy is recommended for those with PFP [12] but exercise protocols vary between trials, [15, 16] and generally lack specific exercise descriptors [29].-A study with the highest success rates (80%) after six weeks of hip and core exercises [16], reported a notable increase in hip external rotator and abductor muscle strength (8% and 11% increases respectively). Their six-week exercise protocol consisted of a supervised and home-based program (6 days/week) that targeted hip abductor, extensor, internal and external rotator muscle groups (three-sets of 10 repetitions), and a balance air-pad exercise (three-sets of 30-60seconds). We observed a similar success rate (71%) and change in muscle strength of the same muscle groups, 11% and 6% respectively, with our four-week physiotherapist-supervised program (3 days/week). The exercises targeted the hip abductor, external rotator and extensor muscles, performed at a *hard* to *very hard* perceived level of exertion with each repetition having a five second time-under-tension cycle. Adherence was high (84%). We noted that hip strength improvements were maintained between week 6 and 12, despite the cessation of exercises after four weeks (appendices – eTables 2). Despite some differences in exercise parameters between studies, there were comparable success rates and increases in muscle strength suggesting improvements can be gained by doing simple exercises.

Limitations

Several limitations need to be considered when inferring from our results. First is the imbalance in the number of sessions between the hip exercise group (12) and the foot

orthoses groups (6). Whilst regular visits to the clinician would assure adherence and fidelity to the treatment, this would plausibly be more resource intensive. Resource requirements (e,g., costs, training) and possible implications due to the imbalance in treatment sessions between groups was not collected. Second, clinicians delivered both interventions and may have conveyed a preference of one over the other to a patient, thereby biasing outcomes. Third is the use of only one form of prefabricated foot orthoses, and while it was previously shown to be effective, this might well be a limitation. Other foot orthoses may be more or less effective and their outcome predictable from basic foot measures. Fourth, those allocated to foot orthoses were instructed to undertake foot exercises at home, and as such we are unable to determine if the foot exercises, orthoses, or both were the active components in the foot orthoses group. Fifth, the four week exercise duration might not be considered a sufficiently long enough period of exercise, this limitation seems somewhat mitigated because changes over the 12 weeks in the exercise group in our study was comparable to those in studies of longer duration exercise [16]. Sixth, based on previous evidence [34], it is possible there was a subgroup of those with PFP who did not have hip muscle weakness, or foot mobility issues, but were allocated to hip exercises or foot orthoses respectively. This would only be a valid concern if the notion that hip muscle weakness or mobility are treatment effect modifiers, the latter we showed not to be the case. Seventh, sample size calculations were based on one follow-up visit per participant, however, in our analyses we analysed both outcomes for each participant simultaneously using generalised estimating equations. Our sample size calculations thus did not account for multiple measurements per participant: doing so would have reduced the required number of participants. Eighth, due to the presence of nonadherence to assigned treatments, the estimated effects in this study must be interpreted as estimating the effect of assignment to either foot orthoses or hip exercises, rather than the effect of actually engaging with the assigned treatments [35, 36].

Clinical implications

In the management of individuals with PFP, we found that hip exercises or foot orthoses are equally effective treatments. We feel confident that either treatment is better than no treatment, because previous studies have shown foot orthoses or thigh exercise to be superior to wait and see or usual care [16, 20, 30]. In the absence of any differences between those with greater midfoot width mobility and between the treatments, other determinants ought to be considered in clinical decisions when managing PFP. For example, patient preference, resource requirements, and time required for each intervention should guide treatment selection.

CONCLUSION

Greater midfoot width mobility was not associated with greater patient-perceived improvement with foot orthoses versus hip exercises. Both hip exercises and foot orthoses offer similar outcomes in reducing pain and improving function.

CONTRIBUTORS

MM contributed to the study conception and design, recruitment of participants, management of study proceedings, data collection, and drafting and revision of the manuscript. AC, TM, RN, and KC contributed to the study conception and design, and drafting and revision of the manuscript. MR contributed to the study design, recruitment of participants, management of study proceedings, data collection, and reviewed the manuscript. JK contributed to the statistical analysis and reviewed the manuscript. BV contributed to the study conception and design, recruitment of participants, data management, and the drafting and revision of the manuscript. BV and MM act as guarantors to affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

DECLARATION OF INTEREST

BV reports grants from Commonwealth of Australia National Health and Medical Research Council (Ref: 631717) and from Vionics International for this research. MM is supported by an Australian Postgraduate Award. BV and TM are voluntary (non-compensated) members by invitation on the Vasyli Think Tank. The funders of the study had no role in design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review or approval of the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

ACKNOWLEDGEMENTS

We thank those who enabled the study to be conducted, the participants who volunteered into the study and the physiotherapists that carried out treatments.

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