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Immediate effects of foot orthoses on pain during functional tasks in people with patellofemoral osteoarthritis: A cross-over, proof-of-concept study

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ABSTRACT

Background: The purpose of the study was to determine whether prefabricated foot orthoses immediately reduce pain during functional tasks in people with patellofemoral osteoarthritis, compared to flat insoles and shoes alone.
Methods: Eighteen people with predominant lateral patellofemoral osteoarthritis (nine women; mean [SD] age 59 [10] years; body mass index 27.9 [3.2] kg/m^2) performed functional tasks wearing running sandals, and then wearing foot orthoses and flat insoles (random order). Participants rated knee pain during each task (11-point numerical rating scales), ease of performance and knee stability (five-point Likert scales), and comfort (100 mm visual analogue scales).
Results: Compared to shoes alone, foot orthoses ($p = 0.002$; median difference 1.5 [IQR 3]) and flat insoles ($p < 0.001$; 2 [3]) significantly reduced pain during step-downs; foot orthoses reduced pain during walking ($p = 0.008$; 1 [1.25]); and flat insoles reduced pain during stair ambulation ($p = 0.001$; 1 [1.75]). No significant differences between foot orthoses and flat insoles were observed for pain severity, ease of performance or knee stability. Foot orthoses were less comfortable than flat insoles and shoes alone ($p < 0.05$).
Conclusions: In people with patellofemoral osteoarthritis, immediate pain-relieving effects of prefabricated, contoured foot orthoses are equivalent to flat insoles. Further studies should investigate whether similar outcomes occur with longer-term wear or different orthosis designs.

1. Introduction

Patellofemoral osteoarthritis (PF OA) is associated with considerable pain and morbidity [1]. The patellofemoral joint is the first and most common knee joint compartment affected by OA [2,3], with isolated PF OA predicting future tibiofemoral OA development [3]. PF OA is also a potent source of knee pain and symptoms, more so than the tibiofemoral joint [1]. Mild radiographic features of OA in the PF joint are associated with greater pain and functional limitations than similar changes observed in the tibiofemoral joint [4]. Magnetic resonance imaging (MRI) studies have found that PF osteophytes and reduced patellar cartilage volume are associated with pain and functional limitations, but tibiofemoral osteophytes and cartilage volume are not [5,6]. People with PF OA experience anterior knee pain, particularly during tasks that load the patellofemoral joint such as

Abbreviations: ADL, activities of daily living; BMI, body mass index; EVA, ethylene-vinyl acetate; IQR, interquartile range; KOOS, Knee injury and Osteoarthritis Outcome Score; NRS, numerical rating scale; OA, osteoarthritis; PF, patellofemoral; QoL, quality of life; RCT, randomised clinical trial; VAS, visual analogue scale.

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squatting, stair ambulation and running, which can negatively affect daily, occupational and exercise-related activity. Despite the prevalence and impact of PF OA, and in direct contrast to tibiofemoral OA, there is a paucity of evidence for conservative and surgical management.

Similarities in symptoms, biomechanics and muscle impairments between PF OA and patellofemoral pain in younger adults [1] suggest that interventions with known efficacy for patellofemoral pain may also be effective for PF OA. Foot orthoses are inserts worn in everyday footwear that are contoured to match the shape of the foot. Worn bilaterally, they have the potential to exert pain-relieving effects on the lower limb, via kinematic, shock attenuation or neuromotor control mechanisms [7], every time the foot hits the ground. This is critical for PF OA, which is typically characterised by pain during weight-bearing activities. Multiple studies have demonstrated that prefabricated ('off-the-shelf') foot orthoses, that are generically shaped and can undergo small patient-specific modifications, can reduce patellofemoral pain in young adults [8–10]. Our previous randomised clinical trial (RCT) found that prefabricated foot orthoses prescribed based on comfort (rather than foot type) reduce patellofemoral pain in young adults (aged 18 to 40 years) over 12 months, and have superior effects to flat insoles over six weeks [8]. Thus, prefabricated foot orthoses may also be an effective intervention for older adults with PF OA. However, in contrast to the extensive body of literature that has evaluated shoe inserts in people with medial tibiofemoral OA [11–14], the use of foot orthoses for PF OA has not been investigated. An important consideration for foot orthosis prescription is perceived comfort, as this may impact on their therapeutic effects [15]. An investigation of the efficacy and comfort of this simple, non-invasive and low-cost intervention in people with PF OA is timely.

The primary aim of this proof-of-concept study was to determine the immediate effects of prefabricated foot orthoses on pain during functional tasks in people with PF OA. We hypothesised that foot orthoses would result in significantly less pain than flat insoles and no insoles (shoes alone). Secondary aims were to: (i) explore the immediate effects of foot orthoses on ease of performance and knee stability; and (ii) evaluate foot orthosis comfort.

2. Materials and methods

This study used a within-subject, repeated measures, crossover design. Ethical approval was obtained from The University of Melbourne's Behavioural and Social Sciences Human Ethics Sub-Committee (ID: 0721163).

2.1. Participants

People with predominant lateral PF OA were recruited from volunteers for an existing RCT [16]. Inclusion criteria were: (i) aged ≥40 years; (ii) anterior or retropatellar knee pain aggravated by at least two patellofemoral joint loading activities (e.g. stair ambulation, squatting, rising from sitting); (iii) pain during these activities on most days in the past month, of ≥30 mm on a 100 mm visual analogue scale (VAS); and (iv) osteophyte grade ≥1 in the lateral patellofemoral compartment (skyline X-ray). Volunteers were excluded if they had concomitant pain from other knee structures (including TFJ), hip, foot or lumbar spine; treatment for PF OA pain in the preceding six months; history of knee arthroplasty or osteotomy; moderate or severe concomitant tibiofemoral OA (Kellgren and Lawrence grade ≥3 on anteroposterior radiograph); any neurological or systemic arthritis conditions; or inability to understand written and spoken English. All participants provided written informed consent prior to participation.

Sample size calculations were performed using G*Power (version 3.1.7, Heinrich-Heine University, Dusseldorf, Germany). A sample size of 18 provided 95% power ($\alpha = 0.05$) to detect a minimum clinically important difference in pain VAS of 19.9 mm (standard deviation 21.5 mm) [17] between conditions.

2.2. Procedure and outcome measures

Participants underwent a single testing session in the Human Motion Laboratory, Department of Mechanical Engineering, University of Melbourne. To characterise the cohort, demographic data (age, sex, height, weight) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) were recorded at the start of the session, and body mass index (BMI) was calculated. The KOOS consists of five individual subscales pertaining to knee pain, symptoms, function in activities of daily living (ADL), sport and recreation function, and knee-related quality of life (QoL). Normalised scores from 0 (extreme knee problems) to 100 (no knee problems) were calculated for each subscale. The KOOS is reliable and valid in people with knee OA [18].

Participants performed four functional tests (proposed to be associated with progressively greater patellofemoral joint load) in a standardised order, wearing running sandals (Nike Strap Runner; Nike Inc., Beaverton, OR, USA; Figure 1A). This sandal was chosen because it allows secure fit of shoe inserts, while accommodating potential differences in foot size and shape within the study population. This is particularly important for an older cohort, due to age-related increases in foot length and width that accompany reductions in arch height [19]. Participants performed level walking at a self-selected speed for two laps around the research laboratory (each lap in opposing directions), equating to a total distance of approximately 40 m. The second task involved five continuous, double-leg squats. Squatting is a task that commonly reproduces pain in people with PF OA [1]. In contrast to full-range squat tests used in younger people with PF pain [20,21], we restricted the depth of squat to the point at which the participant could just see their toes over their knees. This was due to the older age of our cohort and potential lower functional ability, and to reduce the risk of aggravating their knee pain with repeated functional loading over the test session. For the stair ambulation test, participants walked at a self-selected speed up and down a set of four steps (step height

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