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Comparability of off the shelf foot orthoses in the redistribution of forces in midfoot osteoarthritis patients

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ABSTRACT

Background: Midfoot osteoarthritis (OA) is more prevalent and strongly associated with pain than previously thought. Excessive mechanical loading of the midfoot structures may contribute to midfoot OA and studies suggest that functional foot orthoses (FFO) may relieve pain through improving function. This exploratory study aimed to evaluate the mechanical effect of two off-the-shelf FFOs, compared to a sham orthosis in people with midfoot OA.

Methods: Thirty-three participants with radiographically confirmed symptomatic midfoot OA were randomly assigned to wear either a commercially available FFO or a sham orthosis. After wearing their assigned orthoses for 12 weeks, plantar pressure measurements were obtained under shoe-only and assigned orthoses conditions. Participants assigned to the sham, were additionally tested wearing a second type of FFO at the end of trial. Descriptive mean change (±95% confidence intervals) in plantar pressure for each orthoses condition, versus a shoe only baseline condition are presented.

Findings: Compared to the shoe only conditions, both FFOs decreased hindfoot and forefoot maximum force and peak pressure, whilst increasing maximum force and contact area under the midfoot. The sham orthosis yielded plantar pressures similar to the shoe-only condition.

Interpretation: Findings suggest that both types of off-the-shelf FFO may provide mechanical benefit, whilst the sham orthoses produced similar findings to the shoe only condition, indicating appropriate sham properties. This paper provides insight into the mechanisms of action underpinning the use of FFOs and sham orthoses, which can inform future definitive RCTs examining the effect of orthoses on midfoot OA.

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1. Introduction

Foot pain is a common problem, affecting between 20%–42% of adults aged 45 years and older [1–3], and limits activities of daily living [1,2,4–8]. Recent studies using a radiographic foot atlas [9], demonstrated midfoot OA is more prevalent and more strongly associated with pain than thought previously [10–13]. In the UK, 16% of people over 50 years old suffer from painful radiographic foot OA, which commonly affects midfoot joints [14]. Midfoot OA has been shown to alter foot posture causing significantly higher forces and plantar pressures acting on the midfoot than people without midfoot OA [15,16]. These plantar pressure differences also correlate moderately with pain [16], suggesting anatomical and/or biomechanical factors may contribute to the development of midfoot OA.

Foot orthoses are a common conservative treatment for many musculoskeletal problems [17–19], intended to alleviate pain and improve function. In people with midfoot OA, short-term non-randomised studies demonstrated functional foot orthoses (FFO) improve pain and function [20,21]. Similarly, a recent feasibility study demonstrated that midfoot OA participants randomly assigned to the FFO group reported significantly greater improvements in clinical and functional outcomes compared to a sham intervention group [22]. Taken together, these findings suggest increased forces and/or pressures acting on the midfoot may contribute to increased mechanical loading on joints, and FFOs

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may support these structures thereby reducing pain and improving function. In accordance with recently published recommendations on conducting trials examining treatment devices for OA [23], the aim of this exploratory study was to investigate the mechanism of action of two different off-the-shelf FFOs with differing properties; a firmer (shore 50) more controlling device (FFO A) and a softer (shore 35) more cushioning device (FFO B) compared to a sham device. Evaluating differences in plantar pressures when wearing either FFO or sham orthoses, in people with radiographically confirmed midfoot OA will provide objective information for designing/choosing an appropriate orthosis/sham for future RCTs.

2. Methods

Participants with foot pain were recruited from community musculoskeletal and podiatry services to participate in a feasibility trial testing foot orthoses as a treatment for midfoot OA. Participants were included if they were aged 18 years and older; reported localised midfoot pain for over three months using a standardised foot pain map [4]; reported midfoot pain when weight-bearing; and had evidence of radiographic OA in at least one of the following: talo-navicular joint, naviculo-medial cuneiform joint, cuneiform-first metatarsal joint, cuneiform-second metatarsal joint. A musculoskeletal radiologist verified all radiographs, defining the presence of OA in the relevant joints by a score of two or higher for either osteophytes or joint space narrowing, from either the dorso-plantar or lateral views according to a previously developed foot atlas [9]. Exclusion criteria included any lower limb orthopaedic surgery within the past 12 months, inflammatory joint disease, sensory neuropathy of the feet (insensate to 10 g monofilament at any of the 10 sites on the foot), radiographically evident stress fractures or a history of any clinically significant disease or major disorder that would not be conducive to study participation. Other exclusion criteria were the inability to undergo x-ray examination for medical reasons, inability to complete the gait analysis or current wearing of prescribed or off-the-shelf contoured or cast orthoses. Only the symptomatic foot was tested in this study. For bilateral OA participants, the more painful foot was defined as the study foot. If foot pain was equal in both feet, the study foot was defined by the participant's dominant foot as determined by the first step technique. Research Ethics approval was obtained for the study and all participants provided written informed consent prior to commencing the study.

2.1. Interventions

The present mechanism of action sub-study was nested within a 12 week, double-blind, two-arm parallel group randomised controlled feasibility study reported elsewhere [22], examining the effects of FFOs on symptomatic midfoot OA. Participants were randomly assigned to either an active functional foot orthosis (FFO A) group or a sham orthosis group. On completion of the feasibility trial, to explore further the mechanism of action, participants in the sham group were given the option to try an alternative off-the-shelf FFO (FFO B) (see Supplementary Fig. S1 in the online version at DOI: 10.1016/j.gaitpost.2016.07.012).

FFO A is a modifiable off-the-shelf orthotic device (VectOrthotic®, Healthy Step [Sensograph] Ltd UK, see Fig. 1a) consisting of a composite polypropylene plastic shell with a contoured arch and heel cup. The shell was modified, where clinically indicated (using hindfoot wedging) to optimise the potential functional effect of the device on the medial midfoot region (for more details on orthoses modification see [22]). FFO A was finished by adding a 4 mm compressed closed cell polyethylene foam cover with a brushed nylon top. The sham orthosis comprised only the top cover of the FFO A, thus similar in appearance to FFO A as possible (see Fig. 1b).

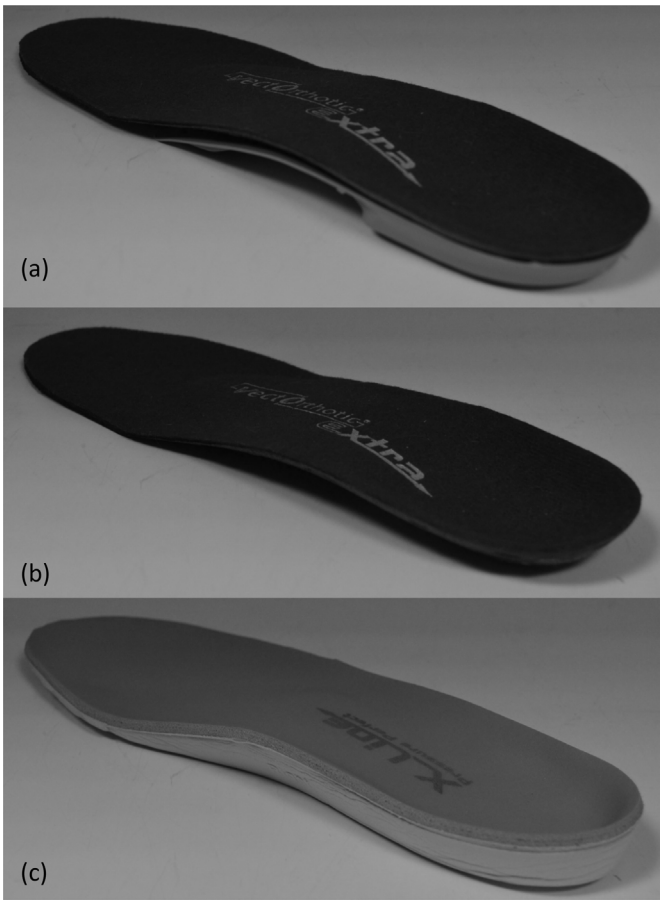

Fig. 1. Diagram illustrating the posterior-medial view of the (a) FFO A, (b) Sham orthoses and (c) FFO B.

FFO B (Pressure Perfect® Healthy Step [Sensograph] Ltd UK]) consisted of a contoured full length orthosis comprising of a 6 mm closed cell EVA foam base (see Fig. 1c) with a heel cup, an arch support and a metatarsal dome contoured into the base structure with a 3.2 mm polyurethane top cover. To minimise the confounding effect of different shoe types, a standardised shoe was worn by each participant during the data acquisition as described previously [22].

2.2. Procedures

At the 12 week follow-up appointment, plantar pressure measurements were captured using the Pedar® in-shoe measurement system acquiring at 50 Hz (Pedar, Novel Gmbh, Munich, Germany). Participants walked under two experimental conditions; 1) shoe only and 2) shoe plus their assigned orthoses, in a randomised order and participants were blind to their allocated intervention. Sham group participants who opted to try FFO B completed a third experimental walk (shoe plus FFO B) at the end of the testing session. For each experimental condition, the Pedar® insole was placed on top of the assigned orthoses and the combination inserted into the shoe. Each participant completed three laps of a 10 m walkway at a self-selected speed for each experimental condition. For analysis purposes, between 12 and 16 mid-lap steps were obtained per participant per experimental condition and averages were calculated.

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