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Reduced knee adduction moments for management of knee osteoarthritis: A three month phase I/II randomized controlled trial

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ABSTRACT

Wedged insoles are believed to be of clinical benefit to individuals with knee osteoarthritis by reducing the knee adduction moment (KAM) during gait. However, previous clinical trials have not specifically controlled for KAM reduction at baseline, thus it is unknown if reduced KAMs actually confer a clinical benefit. Forty-eight participants with medial knee osteoarthritis were randomly assigned to either a control group where no footwear intervention was given, or a wedged insole group where KAM reduction was confirmed at baseline. KAMs, Knee Injury and Osteoarthritis Outcome Score (KOOS) and Physical Activity Scale for the Elderly (PASE) scores were measured at baseline. KOOS and PASE surveys were re-administered at three months follow-up. The wedged insole group did not experience a statistically significant or clinically meaningful change in KOOS pain over three months ($p = 0.173$). Furthermore, there was no association between change in KAM magnitude and change in KOOS pain over three months within the wedged insole group ($R^2 = 0.02$, $p = 0.595$). Improvement in KOOS pain for the wedged insole group was associated with worse baseline pain, and a change in PASE score over the three month study ($R^2 = 0.57$, $p = 0.007$). As an exploratory comparison, there was no significant difference in change in KOOS pain ($p = 0.49$) between the insole and control group over three months. These results suggest that reduced KAMs do not appear to provide any clinical benefit compared to no intervention over a follow-up period of three months. ClinicalTrials.gov ID Number: NCT02067208

1. Introduction

Osteoarthritis (OA) is a degenerative disease that commonly affects the medial tibiofemoral compartment of the knee [1]. As no cure exists for knee OA, and knee joint replacement is typically reserved for last line therapy, clinical management is often aimed at conservative non-surgical strategies [2,3]. Biomechanically, reduction of medial compartment load, often quantified as the knee adduction moment (KAM) [3,4], has been a goal of conservative management. This biomechanical strategy is supported based on evidence that increased KAMs have been related to OA severity [5], pain [6], and disease progression [7].

Laterally wedged footwear insoles/orthotics tend to reduce KAMs [8–11], and have therefore been the subject of much research for management of knee OA over the past 15 years. Traditionally, lateral wedges were applied to all study participants without measuring their effects on KAMs at baseline [12,13], and it would simply be assumed that KAMs were reduced for all participants. However, recent evidence has shown that up to 33% of individuals receiving a lateral wedge insole experience increased KAMs during walking [10], and it has been suggested that perhaps wedged insoles may be best suited to only biomechanical responders [11].

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This may partly explain why clinical pain responses to lateral wedges have been mixed across trials and highlights the notion that the influence of reduced KAMs on reduced pain is not known, because it has not been controlled for. One study failed to show an association between KAM reduction and immediate, same-day pain reduction [14]; however, it is not known if this finding also holds for longer follow-up durations.

Like lateral wedges, medial wedges affect KAMs during gait [15–17], and may increase or decrease KAMs depending on the individual. Consequently, medial wedges may also serve as an appropriate intervention for patients who experience KAM reductions with this wedge type.

Considering the lack of longitudinal evidence regarding the effects of reduced KAMs on pain for individuals with medial knee OA, a three-month randomized controlled trial was performed, comparing wedged insoles (KAM reduction) to usual footwear (no KAM change) to test the hypothesis that pain reduction over three months is associated with individuals experiencing reduced KAMs. Moreover, it was hypothesized that pain reduction would have a dose-response relationship to KAMs, where larger KAM reductions would be associated with larger reductions in pain. As these questions have not been studied previously, this study was intended as a phase I/II trial to assess the hypotheses related to reduced KAMs and the mechanism of pain reduction, and to provide general insight to possible clinical benefit.

2. Methods

2.1. Study design

The detailed protocol of this study has been described previously [18]. Any modifications to the previously described protocol have been outlined in this manuscript.

The study was a single-blind, parallel groups, randomized controlled trial conducted at the University of Calgary between January 2015 and October 2015. The study was approved by the Conjoint Health Research Ethics Board of the University of Calgary. Written informed consent was obtained from all participants prior to any data collection, testing, or evaluation of medical histories. The study was registered with ClinicalTrials.gov (ID# NCT02067208).

Study participants consisted of individuals from the greater Calgary, Alberta area. Inclusion criteria were age between 40 and 85 years, Knee Injury and Osteoarthritis Outcome Score (KOOS) of 75 or lower on the pain subscale on initial contact, confirmed diagnosis of unilateral or bilateral knee OA based on the American College of Rheumatology criteria [19], and confirmation that medial compartment disease was the primary location of symptoms based on clinical exam by a physician. Contrary to our original proposal [20], individuals of any Kellgren-Lawrence (KL) grade $\geq$1 were included in the study. The original criteria of KL grade 1–3 was modified since individuals with KL grades of 4 may still preferentially select conservative therapy over surgery. Full inclusion and exclusion criteria, as well as details regarding assigning Kellgren-Lawrence radiographic severity grades are provided in the Supplementary file.

2.2. Footwear

2.2.1. Usual footwear

Usual footwear was defined as the footwear that the participant had used most regularly over the past two months. Although use of an orthotic/insole was described as an exclusion criteria previously [18], this approach was modified to consider previous orthotic/insole use as acceptable under the assumption that if this is what the individual was used to wearing, a reduction in KAMs relative to this usual footwear should still be beneficial.

2.2.2. Wedged insoles

The wedged insoles evaluated were 6 mm laterally wedged insoles, and 6 mm medially wedged insoles. For both insole types, wedges ran the length of the foot [21], and were fabricated using a 3D printer (New Balance Athletic Shoe Inc., Boston, MA). The material used was stiff in compression, but flexible along the anterior-posterior and medial-lateral axes of the insole, similar to ethylene vinyl acetate (EVA), which has been used for insoles previously [17]. When evaluating insoles at baseline, and when utilizing insoles during the three month study period, insoles were applied bilaterally in the participant's usual footwear. If this footwear had a sock liner, insoles were placed beneath the sock liner. If no sock liner was present, the insole was placed within the shoe without any further sock liner added. If the usual footwear included an orthotic/insole that the individual was already using, this orthotic/insole was removed when the experimental insoles were applied.

2.3. Procedures & measurements

2.3.1. Baseline testing

All participants meeting clinical eligibility underwent baseline testing, which included completion of the KOOS full-version (relative to most symptomatic knee) [22], physical activity scale for the elderly (PASE) [23], and UCLA physical activity scale surveys [24]. Additionally, a report of co-intervention use over the past week was provided. History of surgery to the most symptomatic knee was also recorded. Finally, participant baseline characteristics such as sex, age, height and body mass were recorded, and dual x-ray absorptiometry (DXA) testing was performed to quantify total body fat percentage, and whole body bone density (Hologic QDR 4500, Hologic Inc., Bedford, MA).

Biomechanical gait analysis during walking was performed on all participants while wearing their usual footwear, usual footwear with the lateral wedge insole, and usual footwear with the medial wedge insole. For each participant and condition, the first peak knee adduction moment (KAM) was determined, and participants rated their perceived overall comfort using a 100 mm visual analogue scale. Participants who were found to experience KAM increases with both the lateral wedge and medial wedge were then eliminated from further study. Thus the study consisted of only biomechanical responders to wedged insoles. Since the minimum clinically relevant reduction in KAM is not known, this study considered any KAM reduction as a valid reduction. The first peak KAM was selected as the primary biomechanical variable of interest to maintain consistency with most other studies on knee OA [3,14,25,26], and since a number of other biomechanical variables were calculated to provide a better representation of total knee load. Specifically, the additional biomechanical variables calculated for each footwear condition included the knee adduction angular impulse (KAAI) during stance phase, the 3D resultant knee moment, the amount of varus thrust during stance phase, and the frontal-plane ankle joint angle, frontal-plane knee joint angle, and left to right frontal-plane knee joint spacing.

Detailed descriptions of the procedures used to collect and process all baseline survey and biomechanical data are available in the Supplementary file and elsewhere [18].

2.3.2. Randomization, blinding and allocation

Following baseline data collection, participants were randomized using block-randomization sequences in a 1:1 ratio that were generated using a computer program, and stratified based on sex, to either an insole (KAM reduction) group, or a waitlist control