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Long-term effects of lateral wedge orthotics on hip and ankle joint space widths

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ABSTRACT

Background: Lateral wedge insoles have been used for the treatment of medial knee osteoarthritis (OA) and have been shown to reduce loading of the medial compartment of the knee. However, as the entire lower extremity acts as a single kinetic chain, altering the biomechanics of the knee may also have significant effects at the ankles or hips. We aimed to evaluate the effects of lateral wedge orthotics on ankle and hip joints, compared to neutral orthotics, by assessing the changes in joint space width (JSW) during 36 months of continuous use.
Methods: We prospectively enrolled 109 subjects with symptomatic osteoarthritis of the medial knee according to the American College of Rheumatology criteria. The trial was double blind and patients were randomized to either wedged or neutral orthotic shoe inserts. Hip and ankle JSWs were quantified using plain radiographies at baseline and at 36-months follow-up.
Findings: 45 patients completed the 36 month study. 31 of those who completed the study were using the lateral wedge versus 14 were using neutral orthotics. 2 patients in the wedge group had missing radiographs and were not included in the JSW analyses. There were no significant differences between the wedge and the neutral orthotics groups in the magnitude of JSW change at either the hip or the ankles at 36 month.
Interpretation: We found no significant adverse effects of the lateral wedges on ankles or hips. (ClinicalTrials.gov NCT00076453).

1. Background

Osteoarthritis (OA) is a leading cause of knee pain, especially in older adults. The pathophysiology is complex and as of yet not entirely understood. However, clinical studies have suggested that mechanical factors play a significant role in the progression of knee OA. Coronal plane (Varus or valgus) alignment deformities are both associated with faster disease progression [1]. Lateral wedge insoles have been studied as one option to modify the mechanical environment of the medial knee. Insoles with subtalar strapping have been reported to be effective in reducing adduction moment, as well as pain [2–4] and have been included as a conditional recommendation in the American College of Rheumatology (ACR) 2012 recommendations for therapy of knee OA, if the patients have medial compartment OA [5]. Lateral wedge insoles might also protect the contralateral knee from progressive degeneration, in patients with unilateral medial osteoarthritis by reducing bilateral medial knee loading [6]. Furthermore, lateral wedge insoles consistently reduced the overall magnitude of medial compartment loading during stair ascent and descent [7]. Results of studies investigating the clinical efficacy of lateral wedge insoles without subtalar strapping for the palliation of symptomatic medial knee OA have been mixed [8,9].

Studies focusing on the biomechanics of lateral wedge insoles have demonstrated that they may have significant effects in reducing the dynamic loads across the medial knee [4,10,11] and that the insoles tend to be well tolerated despite some evidence of relatively minor adverse events such as discomfort [12]. Peak external knee adduction moment (EKAM), a validated and conventional surrogate measure for dynamic loading of the medial knee, has been demonstrated to be reduced in subjects with medial compartment knee OA using lateral wedge insoles [13,14]. As elevated dynamic loads have been associated with the progression of knee OA, long-term reductions of such loads may be physiologically important in any effort to delay OA progression. A recent meta-analysis of the available literature suggests that lateral wedge insoles lead to small but significant reductions in

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external knee adduction moments in medial knee OA, and that wedged insoles may be useful in certain biomechanical phenotypes [15].

The mechanical effects of lateral wedges may not be restricted to the knee. It has been shown that laterally wedged foot orthotics used for treating medial knee osteoarthritis may alter biomechanics of other lower extremity joints by promoting foot pronation and/or restricting foot supination during gait in subjects with or without pes planus or pes cavus [16,17]. These mechanical alterations may have structural consequences in the hips and ankles during long-term use. In this study, we evaluated the effects of long term use of lateral wedge orthotics on the ankles and hips by assessing radiographic joint space widths (JSW) quantitatively in subjects using lateral insoles vs. neutral orthotics during 36 months of follow-up. Quantitative assessments of the joint space widths (JSW) have been shown to be more sensitive to change compared to qualitative grading systems in the knees, and therefore we preferred this method to evaluate the ankles [18].

2. Materials and methods

We prospectively enrolled 109 subjects with symptomatic osteoarthritis of the medial knee (Fig. 1). Patients were subjects of a longitudinal randomized double-blind placebo controlled three-year trial evaluating the effects of lateral wedge orthotics in patients with medial knee OA. Subjects were recruited to the study both from the Rush University clinic system and through public service announcements in the local media. Each subject met the following criteria to be eligible: presence of symptomatic OA of the knee according to the ACR's Clinical Criteria for Classification and Reporting of OA of the knee [19] (if symptoms were bilateral then the side identified by the patient as the more symptomatic served as the index knee in this study); pain greater than 30 mm on a 100 mm visual analog scale in at least one knee while walking on a flat surface; radiographic OA of the knees, with the more symptomatic knee (index knee) having a radiographic severity of Grade 2 or 3 according to the modified criteria of Kellgren-Lawrence [20] and the contralateral knee having a Grade 1, 2 or 3; medial compartment OA defined as either qualitative medial joint space narrowing of $\geq$1 0–3 scale according to the atlas [21] or the presence of medial bone cyst, sclerosis, or osteophyte; predominant medial compartment OA, defined as narrowing of the medial joint space in excess of the narrowing of the lateral joint space by at least one grade on a 4-point scale [22]. Patients with clinically evident OA in the hips or ankles and clinically significant intrinsic foot disease upon podiatric examination, those with prior arthroplasty of any joints in either lower extremity, as well as substantially obese patients were excluded. The study was approved by the Institutional Review Board and written informed consent was obtained from each patient. Custom-made contoured foot orthosis were used. The topographical surface of the plantar foot was obtained using standard neutral suspension casting techniques performed by a single experience clinician (RL).The foot orthosis was made from 4 mm polypropylene $^{3}/_{4}$ length shells to met heads with 70 durometer (Shore A) extrinsic rearfoot and forefoot posts and shell length vinyl top covers. The finished foot orthosis either had a 7° valgus post (lateral wedge orthotic, active group) or 0° post (neutral orthotic, placebo) depending on randomization. Both extremities received either the active or placebo matching orthotics. The subjects wore their own shoes for the testing and duration of the study. However, it is understood that footwear can contribute to dynamic knee loading. Based on this understanding each subjects footwear was evaluated to ensure that they had neutral designed shoes that did not have a medial or lateral mechanical variation such as dual density midsoles, medial or lateral stability bars, external rigid shanks, excessive heel heights or other devices that may alter the mechanical effect of the foot orthosis. The subjects and clinical staff were blinded to the group assignments. Only the podiatrist fabricating and maintaining the orthotic was aware of the assignment.

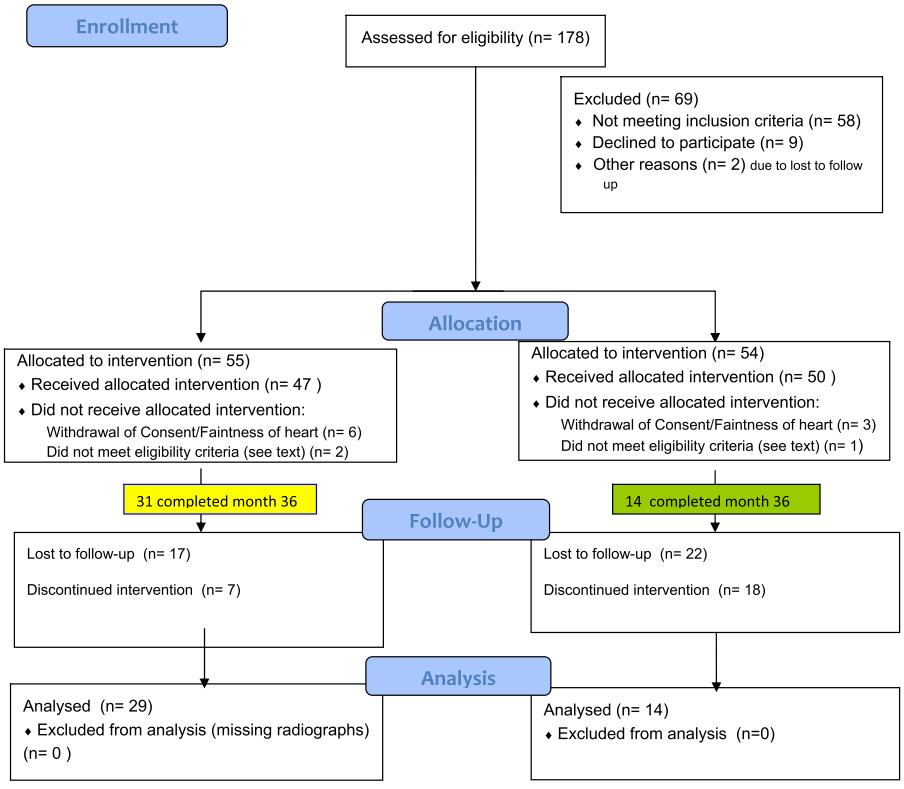

Fig. 1. CONSORT 2010 Flow diagram.