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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).

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Ethical Board Review Statement:

The study was approved by the Institutional Review Board of Rush Medical College

Conflict of interest

One of the authors (BG) has received travel funding from the Turkish Society for Education and Research in Rheumatology (Romatoloji Arastirma ve Egitim Dernegi).

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Keywords

osteoarthritis; orthotics; joint space widths

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 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].

Materials and Methods

We prospectively enrolled 109 subjects with symptomatic osteoarthritis of the medial knee (Figure 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 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 4mm polypropylene ¾ 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.

Conventional radiography and JSW measurements

Standard digital supine anteroposterior pelvis and weight bearing anteroposterior ankle radiographies were performed at baseline and at 36 months. JSWs were quantified using image J software (US , NIH, Bethesda, MD, <http://rsbweb.nih.gov/ij/>). JSWs of the hips

were measured at the narrowest interbone distance between the cortical surface of the acetabulum and the bone contour of the femoral head using our standard methodology [23] (Figure 2a). 15 hips JSWs were measured twice one week apart and CV was calculated as 4.8%. All the measurements were performed by a single reader (BG). The reader was blinded to the group assignments of the patients. Similarly, a validated method was employed to quantify the JSW of the ankles, measuring the narrowest distance between the superior edge of the talus and the distal tibia both medially and laterally, as we previously reported (Figure 2b)[24].

Statistics

Paired t-test was used to compare JSW at baseline and month 36 and t-test was used to compare change in JSW between groups. Statistical analyses were performed using SPSS 11.0 software (SPSS Inc, Chicago, IL). Post-hoc power analysis demonstrated that if SD is 0,6mm, 44 patients were needed to have 80% power to detect a difference of 0,36 mm with 95% confidence (with a two-tailed α of 0,05). A p value <0,05 was considered significant.

Results

Baseline characteristics of the study patients are given in Table 1. There was no statistically significant difference between the two groups at baseline with respect to age, gender, BMI, years since diagnosis of OA or index side.

The magnitude of JSW changes between baseline and month 36 revealed no significant differences between the wedge and the neutral orthotics groups, at either the hip or the ankles (Table 2).

Forty five patients completed the 36-month study. Although the number of drop outs was high, it is interesting to note that the majority of those who completed the 36 months study were in the lateral wedge group.(31 patients lateral versus 14 neutral). 2 patients in the wedge group had missing radiographs and were not included in the JSW analyses. By 36 months, there was statistically significant joint space narrowing at the hip joints in both the lateral wedge and the neutral orthotics groups. This narrowing occurred both at the index and the contralateral side and was symmetric in both study groups (Table 3). In contrast, there were no significant changes in the joint space widths of the ankles in either group.

There were no increased rates of reports of pain, injury or dysfunction of lower extremity joints or of the spine.

Discussion

We previously presented the beneficial mechanical effects of lateral wedged insoles at the knees and demonstrated that they provide sustained mechanical unloading and may delay the progression of joint space narrowing in medial knee OA[25, 26]. In this study, we tested the hypothesis that lateral wedge orthotics used for medial knee OA might affect the integrity of the other large joints of the lower extremities, using radiographic joint space narrowing as a widely accepted surrogate for progressive joint disease. To our knowledge, this has not

previously been systematically evaluated. In the ankles, there was no discernible change in radiographic JSW in either the wedge or the neutral orthotic group over 3 years, suggesting that altered loading of the medial knees does not produce significant response in the ankles. The hips did reveal progressive narrowing of radiographic JSW over 3 years, but there were no differences between the mechanically active wedge group and the placebo neutral group; moreover, the rate of narrowing was similar to previously reported joint space narrowing in hip OA, both from our own studies [23] and from others[27]. These results suggest that the use of the mechanically active orthotics for knee OA did not have substantial adverse structural effects on the ankles or hips during three years of use, while delaying the progression of joint space narrowing in medial knee OA.

The dropout rate was higher than expected. There are several potential reasons for this. The three-year duration of the study is an exceptionally long period to maintain strict follow-up. In addition, we hypothesize that those who benefitted remained in the study whereas those who did not dropped out; evidence for this is that the dropout rate was significantly higher among those randomised to wear the neutral insole compared to the lateral wedge, suggesting indirectly that the wedge may have been beneficial.

OA has historically been considered a degenerative process of articular cartilage [28], though it is now widely recognized to be a disease that affects all structures of the joint. Devices that alter load transmission and alter the biomechanics of the knees in an effort to reduce OA progression also affect loading of each of the other large lower extremity joints. As these external bracing and supportive devices are intended to be therapeutic, it is critically important to demonstrate that any alterations in lower extremity loads by such devices do not result in adverse effects on the hip and ankle joints. It has previously been reported that laterally wedged foot orthotic devices used to treat knee OA increased the rearfoot eversion and inversion moments but did not appear to influence hip mechanics[16]. In addition, it has been reported that short term use (6 weeks) of lateral wedge insoles is benign regarding adverse symptoms in the foot or elsewhere in the lower extremity[17]. Nonetheless, chronic loading over a several year period may have significant consequences because of prolonged “load history” that may be undetectable using gait kinematics. In contrast to gait testing, assessment of joint space narrowing provides a direct measure of structural consequences of mechanically active interventions.

Knee OA has been shown to be related with increased peak EKAM [29]. The effect of lateral wedge insoles on ankle biomechanics may also have impact on the insoles expected therapeutical role in reducing EKAM in medial knee osteoarthritis. Herein, especially peak eversion ankle angle and ankle angle at peak external knee adduction moment may be the key biomechanical parameters that indicate therapeutic response [30]. Although we have not evaluated the nature of biomechanical changes in ankle joints while using lateral wedge insoles, alterations in ankle biomechanics are shown not to have impact on ankle JSW.

There are limitations to our study. First, the drop out rate was higher than expected. Second, the study size was small raising the possibility of failure to detect a real yet subtle effect. However, the long follow-up period of 3 years suggests that any if a significant effect was truly missed, it must be fairly small. However, adverse events were collected systematically

and reported regularly to the data safety and monitoring board (DSMB) and there were no increased rate of reports of pain, injury or dysfunction of lower extremity joints that might suggest a rationale to this finding.

Conclusion

Conventional lateral wedge insoles, being used for the treatment of medial knee osteoarthritis are not likely to adversely affect the joint space widths of hip and ankle joints over 36 months. Our results suggest that even with prolonged use for knee OA over three years, wedged inserts do not appear to promote adverse consequences in the other joints of the lower extremity. These findings should be reassuring for those interested in using lateral wedged insoles to provide mechanical unloading in certain patients with medial knee OA.

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Highlights

- Lateral wedges do not lead to adverse effects on the joint space widths of ankles.
- Lateral wedges do not lead to adverse effects on the joint space widths of hips.
- Results suggest that lateral wedge insoles are safe for ankles and hips.

Figure 1. CONSORT 2010 Flow diagram

Figure 2.

- (a) The arrow shows narrowest interbone distance between the cortical surface of the acetabulum and the bone contour of the femoral head
- (b) The arrows show the narrowest distance between the superior edge of the talar dome and the distal tibia, medially and laterally

Table 1

Baseline characteristics of the patients completing the study.

	Lateral Wedge Orthotic	Neutral Orthotic	<i>P</i> value
Gender (Female/Male)	9/20	2/12	0.29
Age, years, mean (SD)	57.41 (8.03)	55.84 (10.5)	0.59
BMI, mean (SD)	28.55 (4.33)	28.78 (4.54)	0.87
Years since diagnosis of OA, mean (SD)	6.1(7.1)	3.7 (3.4)	0.56
Index Knee (Right/Left)	12/17	8/6	0.33

Table 2

The magnitude of changes in mean (SD) JSWs between baseline and 36 month in both groups.

	JSW [*] ,mm		
	Lateral Wedge	Neutral	<i>P</i> value
Index hip, mean (SD)	-0.38 (0.59)	-0.31 (0.28)	0.71
Contralateral hip, mean (SD)	-0.33 (0.47)	-0.42 (0.48)	0.59
Index ankle medial, mean (SD)	-0.08 (0.33)	-0.04 (0.28)	0.72
Index ankle lateral, mean (SD)	-0.04 (0.25)	-0.11 (0.26)	0.39
Contralateral ankle medial, mean (SD)	-0.01 (0.23)	0.04 (0.13)	0.44
Contralateral ankle lateral, mean (SD)	-0.07 (0.27)	0.03 (0.20)	0.23

* JSW at 36 month minus at baseline, in milimeters

Table 3

Index and contralateral sides hip and ankle mean (SD) JSWs at baseline and 36 month in lateral wedge and neutral orthotic groups.

	Baseline	Month 36	P value
Lateral Wedge			
Index hip, mean (SD)	3.69 (0.59)	3.29 (0.59)	0.002
Contralateral hip, mean (SD)	3.77 (0.69)	3.43 (0.60)	0.001
Index ankle medial, mean (SD)	2.63 (0.54)	2.56 (0.55)	0.29
Contralateral ankle medial, mean (SD)	2.63 (0.63)	2.63 (0.55)	0.99
Index ankle lateral, mean (SD)	2.49 (0.58)	2.45 (0.55)	0.53
Contralateral ankle lateral, mean (SD)	2.54 (0.66)	2.49 (0.56)	0.29
Neutral Orthotic			
Index hip, mean (SD)	3.77 (1.04)	3.45 (0.98)	0.002
Contralateral hip, mean (SD)	3.75 (0.90)	3.33 (0.83)	0.009
Index ankle medial, mean (SD)	2.47 (0.57)	2.43 (0.45)	0.56
Contralateral ankle medial, mean (SD)	2.43 (0.46)	2.48 (0.48)	0.23
Index ankle lateral, mean (SD)	2.47 (0.54)	2.36 (0.42)	0.14
Contralateral ankle lateral, mean (SD)	2.45 (0.51)	2.49 (0.53)	0.53