

## Effects of footwear on medial compartment knee osteoarthritis

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**Abstract**—This pilot study investigated whether lateral-wedge insoles inserted into shock-absorbing walking shoes altered joint pain, stiffness, and physical function in patients with symptomatic medial compartment knee osteoarthritis (OA). Twenty-eight subjects wore full-length lateral-wedge insoles with an incline of 4° in their walking shoes for 4 weeks. Pain, stiffness, and functional status were measured with the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index at baseline and 4 weeks postintervention. Significant improvements were observed in all three WOMAC subscales (pain, stiffness, and function). Pain scores were significantly reduced for the most challenging activity—stair climbing. Subjects wore insoles daily and tolerated them well. The results of this study indicated that lateral-wedge insoles inserted into shock-absorbing walking shoes are an effective treatment for medial compartment knee OA.

**Key words:** functional status, knee, lateral-wedge insoles, orthoses, osteoarthritis, pain, rehabilitation, shock-absorbing shoes, stair climbing, stiffness, varus.

### INTRODUCTION

Knee osteoarthritis (OA) is a disease common in older adults that can result in significant disability because of pain, stiffness, and loss of joint motion. Current treatment is aimed at minimizing pain, maintaining or improving joint mobility, and decreasing functional impairment. Although the pathogenesis of knee OA is not well understood, biomechanical stresses that affect the articular cartilage and subchondral bone have been impli-

cated as important inciting factors [1–3]. During the mid-stance phase of gait, about 60 to 80 percent of the load is distributed through the medial compartment of the normal knee [4], which is one of the reasons knee OA frequently involves the medial compartment. Varus angulation deformity may occur in medial compartment knee OA and contribute to the progression of OA by causing increased load to the medial knee compartment, with subsequent damage to the articular cartilage and subchondral bone in that area [5].

Clinicians have used surgical wedge osteotomy for many years to correct varus angulation by shifting weight away from the diseased knee compartment [6]. An alternative nonoperative approach has been to realign the weight-bearing load through footwear modification. Shoe modifications, such as lateral-wedge insoles or shock-absorbing shoes with insoles, have been recommended for conservative therapy of mild knee OA [7–8]. Little objective data exist, however, regarding the effects of lateral-wedge insoles on clinical parameters such as pain and

**Abbreviations:** NSAID = nonsteroidal anti-inflammatory drug, OA = osteoarthritis, SD = standard deviation, VA = Department of Veterans Affairs, VAS = visual analog scale, WOMAC = Western Ontario and McMaster Universities (Osteoarthritis Index).

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functional status in patients with symptomatic medial compartment knee OA [9–10]. One randomized controlled study showed that subjects with medial compartment knee OA decreased nonsteroidal anti-inflammatory drug (NSAID) intake when they wore bilateral lateral-wedge insoles but did not report any change in pain, stiffness, or function as measured by the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index [11]. Women with medial compartment knee OA who wore bilateral lateral-wedge insoles with elastic strapping of the subtalar joint had a significant decrease in femorotibial angle and visual analog scale (VAS) score for subjective knee pain and an improvement in Lequesne index scores (a measure of disease severity) [12]. These changes were not observed in women who wore traditional shoe-inserted lateral-wedge insoles. A lateral-wedge insole reduces peak knee varus torque, external varus moment, and lateral thrust in patients with knee OA, which may be some of the mechanisms by which this insert reduces pain in knee OA [13–15].

In this uncontrolled pilot study, we investigated the short-term effects of full-length lateral-wedge insoles combined with shock-absorbing shoes on pain and function in the treatment of symptomatic medial compartment knee OA.

## METHODS

### Subjects

Twenty-eight community-dwelling individuals (mean age  $\pm$  standard deviation [SD] =  $67 \pm 11$  yr) who fulfilled American College of Rheumatology criteria [16] for knee OA were recruited for this study through flyers distributed in outpatient clinics of the Department of Veterans Affairs (VA) Greater Los Angeles Healthcare System and community newspaper advertisements. All subjects had grade 2 or higher Kellgren-Lawrence radiographic severity of tibiofemoral OA in the standing anteroposterior view [17], pain of at least 30 on a 0 to 100 mm VAS, and pain in the medial compartment of the knee for most days in the past month. Exclusion criteria were history of knee trauma or surgery, including arthroscopic surgery in the past 6 months; neurological disease; injury to or amputation of the lower-limb joints; history of other types of arthritis; symptomatic spine, hip, ankle, or foot disease; intra-articular steroid injection in the past 3 months; or hyaluronic acid injection in the last 9 months. Subject characteristics are reported in **Table 1**.

The index knee was identified as the painful OA knee at baseline, although seven subjects had bilaterally painful knees. Subjects wore lateral-wedge insoles on the side with knee pain and neutral-wedge insoles on the side without knee pain; a standard configuration recommended by healthcare practitioners when prescribing lateral-wedge insoles for patients with symptomatic medial compartment knee OA. The subjects who reported bilateral knee pain wore lateral-wedge insoles bilaterally.

The study was approved by the VA Greater Los Angeles Healthcare System Institutional Review Board, and informed consent was obtained from all subjects before they were enrolled in the study. This clinical trial was registered in the National Library of Medicine's clinical trials registry (<http://www.clinicaltrials.gov>).

**Table 1.**  
Subject characteristics ( $N = 28$ ).

Characteristic	Mean $\pm$ SD	Frequency*	%*
Age (yr)	$67 \pm 11$	—	—
<b>Sex</b>			
Male	—	18	64
Female	—	10	36
<b>Race/Ethnicity</b>			
Caucasian	—	20	72
African American	—	4	14
Other (Hispanic, Asian)	—	4	14
<b>Body Mass Index</b> (kg/m <sup>2</sup> )	$27.6 \pm 5.2$	—	—
<b>Index Knee</b>			
Right	—	9	32
Left	—	12	43
Bilateral	—	7	25
<b>Kellgren-Lawrence Grade</b> <sup>†</sup>			
II	—	10	36
III	—	10	36
IV	—	8	28
<b>Concurrent Medications</b> <sup>‡</sup>			
Nonsteroidal anti-inflammatory drugs	—	13	46
Acetaminophen-opioid combination	—	3	11
Acetaminophen	—	5	18
Glucosamine/chondroitin	—	1	4
Opioids	—	1	4

\*Frequency was divided by total number of subjects ( $N = 28$ ) to calculate percent.

<sup>†</sup>Kellgren-Lawrence Grading System (Source: Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthritis. *Ann Rheum Dis.* 1957;16(6): 494–502. [PMID: 13498604](https://pubmed.ncbi.nlm.nih.gov/13498604/)).

<sup>‡</sup>Numbers do not add up to 100 because not all subjects took medications and some took multiple medications.

II = only marginal osteophytes apparent in radiographs, III = mild-to-moderate joint space narrowing apparent in radiographs, IV = complete loss of medial joint space in tibiofemoral compartment apparent in radiographs, SD = standard deviation.

### Description of Insole and Footwear

To control for the effects of footwear, we fitted subjects with comfortable, lightweight shock-absorbing shoes (New Balance 833, New Balance Athletic Shoe, Inc, Boston, Massachusetts) that would accommodate the insoles (RJ Industries, Chicago, Illinois). Both full-length lateral-wedge insoles and neutral-wedge insoles were constructed from a custom cork composite similar to Thermocork™ (Aetrex Worldwide, Inc, Teaneck, New Jersey) with a density of 60 durometers. The material was engineered to provide shock absorption and high resistance to compressive deformation. The insoles were manufactured with a mediolateral incline of 4° for the lateral-wedge insole and 0° for the neutral-wedge insole. Both the lateral- and neutral-wedge insoles were cut to fit the individual shoe, designed with peel-and-stick self-adhesive, and placed under the removable insert that came in the shoes.

### Procedures

The baseline assessment consisted of the WOMAC, a validated and disease-specific questionnaire that separately addresses severity of joint pain (5 questions), stiffness (2 questions), and physical function limitation (17 questions) experienced during the 24 hours before assessment [18–19]. The VAS version of the WOMAC was used. Assessments of joint pain and stiffness focused on the index knee, unless subject had bilateral pain in which case both knees were considered collectively. When reporting functional limitations, all subjects were asked to consider both knees collectively. Information about analgesic use during the 24 hours before the assessment was also collected (Table 1). Subjects were instructed to begin wearing the walking shoes with the full-length inserts for as many hours a day and as many days of the week as they could tolerate for 4 weeks and continue taking their usual OA pain medication(s) as needed. Assessments performed at the end of 4 weeks

included adverse events, analgesic use during the past 24 hours, use of the insert, and the WOMAC.

### Data Analysis

The difference (change) between 4 week postintervention and baseline WOMAC subscale and total scores was calculated. The percent change was calculated as the change divided by the baseline score multiplied by 100. Negative values represented lower WOMAC scores postintervention, which were considered an improvement. Positive values represented higher scores postintervention, which were considered a decrement. Change and percent change were calculated for each subject for each subscale. Mean and SD were calculated for each WOMAC subscale, change, and percent change at both baseline and 4 weeks postintervention. Baseline and 4 week postintervention WOMAC subscale scores were compared with paired *t*-tests. An  $\alpha$  level of 0.05 (two-tailed) was used. We analyzed frequency counts for improvement levels (20%, 50%, and 70%) [20] to determine response to intervention. Subjects were categorized within the three improvement level groups based on whether they had the minimum percent improvement for a group but not the next higher level of percent improvement (i.e., 20% group:  $\geq 20\%$  but  $< 50\%$ ; 50% group:  $\geq 50\%$  but  $< 70\%$ ; and 70% group:  $\geq 70\%$ ) for each subset.

## RESULTS

When comparing the change from baseline to 4 weeks postintervention, we found WOMAC subscale and total scores significantly improved ( $p < 0.05$ ) (Table 2). While the average percent change was highly variable, almost 50 percent (range = 47%–53%) of the individuals demonstrated at least a 20 percent improvement in the WOMAC subscales (Figure) and more than 10 percent

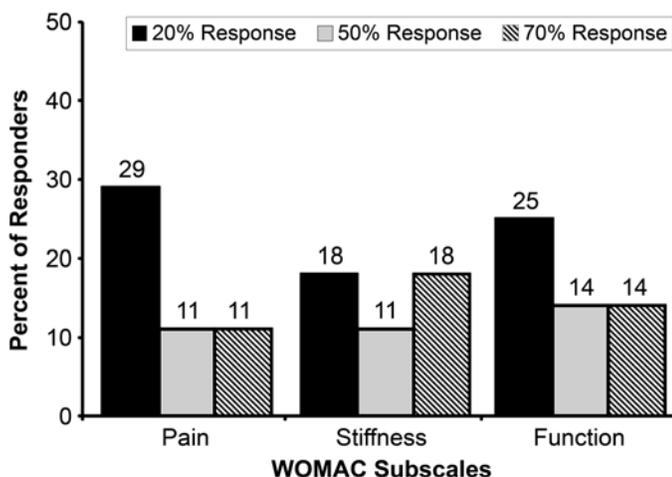
**Table 2.**

Mean  $\pm$  standard deviation Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index subscale scores at baseline and 4 weeks postintervention. Data presented as values for each time point, change between time points, and percent change between time points relative to baseline values.

WOMAC Subscale	Baseline	Postintervention	Change*	Percent Change†	<i>p</i> -Value
Pain	172.3 $\pm$ 95.0	137.0 $\pm$ 97.8	-35.3 $\pm$ 83.1	-17.0 $\pm$ 46.9	0.03
Stiffness	81.7 $\pm$ 56.2	65.5 $\pm$ 49.2	-16.3 $\pm$ 41.4	1.8 $\pm$ 91.8	0.05
Function	681.2 $\pm$ 329.2	569.4 $\pm$ 392.4	-121.8 $\pm$ 199.3	-18.0 $\pm$ 60.9	0.003

\*Change = postintervention – baseline; negative numbers represent improvement and positive numbers represent decrement.

†Percent change = [(postintervention – baseline)/baseline]  $\times$  100.



**Figure.**

Percent of subjects who demonstrated each level of improvement (20%, 50%, or 70%) within each Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index subscale following intervention.

(range = 11%–18%) of the individuals reported at least a 70 percent improvement in the WOMAC subscales (**Figure**).

When evaluating the specific components of the pain subscale, we found that the question about the most challenging activity (going up or down stairs) showed significant improvement (reduction in value postintervention) (**Table 3**). On this question, 64 percent of the individuals reported at least 20 percent improvement and 7 percent reported at least 70 percent improvement. However, subjects did not demonstrate significant change on any other question ( $p > 0.05$ ).

## DISCUSSION

Simple, inexpensive therapies for the treatment of pain from symptomatic medial compartment knee OA

include wearing shock-absorbing footwear, wedge heels, or insoles. The results of our short-term pilot study indicated that subjects experienced a significant decrease in pain, stiffness, and functional impairment when they wore a full-length lateral-wedge insole with an incline of 4° for the symptomatic limb and a full-length neutral-wedge insole for the asymptomatic limb in their shock-absorbing walking shoes. All subjects tolerated their orthoses well and wore the insoles daily. Subjects experienced decreased pain primarily during stair-climbing activities rather than while walking on a flat surface, standing, lying, or sitting. The combination of lateral-wedge insoles and shock-absorbing shoes appeared to be most efficacious for tasks that reflected greater knee compressive forces, such as stair-climbing activities [21].

Salsich et al. observed that individuals with patellofemoral pain had reduced peak knee extensor moments during stair-climbing activities. They suggested that quadriceps avoidance is used to reduce knee joint reaction forces, a compensatory strategy that is commonly observed in individuals with knee OA [22]. Fisher et al. reported that subjects with knee OA predominately lacked knee extensor moments due to weak quadriceps [23]. Quadriceps weakness has been well documented in subjects with OA [24]. Messier suggested that the quadriceps avoidance pattern was used by subjects with knee OA who had limited knee flexion so they could avoid any knee flexion that would require eccentric control via the quadriceps muscles [25]. Eccentric contraction of the quadriceps muscles requires more control and also tends to increase the compressive forces on the knee joint [26]. Stair climbing results in a significantly greater knee flexion angle, which in turn results in a greater knee extensor moment than level walking [27] and suggests why, during

**Table 3.**

Mean  $\pm$  standard deviation for individual questions on Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index pain subscale at baseline and 4 weeks postintervention. Data presented as values for each time point, change between time points, and percent change between time points relative to baseline values.

Pain Subscale Question	Baseline	Postintervention	Change*	Percent Change†	p-Value
Walking on Flat Surface	34.9 $\pm$ 27.8	26.9 $\pm$ 21.7	-8.0 $\pm$ 24.5	15.4 $\pm$ 136.9	0.096
Going up or Down Stairs	55.1 $\pm$ 24.8	41.4 $\pm$ 25.4	-13.6 $\pm$ 19.6	-23.2 $\pm$ 42.4	0.0001
At Night While in Bed	28.8 $\pm$ 26.6	21.3 $\pm$ 23.0	-7.5 $\pm$ 22.2	-5.3 $\pm$ 91.6	0.084
Sitting or Lying	26.3 $\pm$ 22.8	20.5 $\pm$ 21.6	-5.8 $\pm$ 23.2	15.8 $\pm$ 96.8	0.198
Standing Upright	27.4 $\pm$ 19.9	26.9 $\pm$ 22.1	-0.5 $\pm$ 16.0	27.9 $\pm$ 121.5	0.870

\*Change = postintervention - baseline; negative numbers represent improvement and positive numbers represent decrement.

†Percent change = ((postintervention - baseline)/baseline)  $\times$  100.

this short-term study, we found pain reduction in the activity that most challenged the knee musculature.

While we found short-term significant reductions in all three components of the WOMAC, Pham et al. found no changes in WOMAC pain, joint stiffness, and physical function subscales between those wearing full-length lateral-wedge insoles and those wearing neutral-wedge insoles in patients with medial femorotibial knee OA in a 2-year prospective randomized controlled study [11]. The group wearing the lateral-wedge insoles, however, did have a decrease in NSAID consumption and were more compliant in wearing insoles than the group wearing neutral-wedge insoles, prompting Pham et al. to suggest a beneficial effect from wearing lateral-wedge insoles in medial femorotibial OA [11]. This reduction in NSAID consumption may have biomechanical implications; Hurwitz et al. have demonstrated that subjects with knee OA pain relieved by analgesics continue to have abnormal loading of the knee joint with increases in peak external varus and extension moments [28].

Rubin and Menz studied the efficacy of incorporating a lateral-wedge insole into custom-molded foot orthoses in an uncontrolled pilot study and reported that all 30 patients had achieved some reduction in medial knee OA pain and that 28 patients tolerated their orthoses [29]. Toda and Tsukimura observed clinical and structural improvements at 6-month assessment in subjects who wore a subtalar-strapped lateral-wedge insole [12]. At the 6-month assessment, the subtalar-strapped lateral-wedge insole group demonstrated significantly decreased femorotibial angles, improved VAS scores, and improved Lequesne index scores compared with their baseline assessments, while those who wore the traditional shoe-insert wedge insole did not demonstrate changes [12]. At the 2-year assessment, the significantly decreased femorotibial angles and improved Lequesne index scores remained for those wearing the subtalar-strapped lateral-wedge insole [30]. Toda and Tsukimura suggested that the movement of the talus by the insole may interfere with calcaneal valgus correction and subsequently prevent femorotibial correction [12]. With the subtalar-strapped lateral-wedge insole, decreased femorotibial angles may restrict the progression of degenerative articular cartilage lesions of knee OA [30]. The decreased femorotibial angles may be related to correction of abnormal knee biomechanical loading. Mundermann et al. suggested that patients with more severe OA had greater varus alignment compared with patients with less severe knee OA, which resulted in greater knee adduction moments [30].

Overall, the lateral-wedge insoles appear to be well tolerated. Differences in outcome measure results, however, suggest a variety of factors may interact with use of the lateral-wedge insoles in this population. Our subjects wore lightweight, flexible, cushioned shoes designed for a neutral gait and sized to accommodate the insert. Some of the decrease in knee pain, stiffness, and functional impairment noted by our subjects may be the result of wearing shock-absorbing shoes sized to accommodate the insert. We, however, did not use static or dynamic alignment measures of the knee, ankle, and foot to determine the appropriate degree of incline for each subject. Kerrigan et al. demonstrated that both a 5° and a 10° lateral-wedge insole reduced knee external varus moment in patients with knee OA, suggesting that some individuals may benefit from greater degrees of wedge inclination [14].

While all of our subjects wore the insoles daily, Toda et al. suggested that the lateral-wedge insole with subtalar strapping needs to be worn between 5 and 10 hours a day for optimal valgus correction of the femorotibial angle and response to the Lequesne index [31]. Other factors that may contribute to the lack of response to lateral-wedge insoles include individual differences in lower-limb joint anatomy, quadriceps strength, knee proprioception, ligamentous laxity of the knee, and knee height.

## CONCLUSIONS

This pilot study demonstrated that short-term use of full-length lateral-wedge insoles inserted into shock-absorbing walking shoes will decrease pain, stiffness, and functional impairment in patients with symptomatic medial compartment knee OA of varying radiographic severity. Reduction in pain mainly occurred when subjects walked up and down stairs, which suggests biomechanical analyses are needed to determine thresholds of joint reaction forces and moments for restricting the progression of degenerative articular cartilage lesions of knee OA. Wedge insoles inserted into shock-absorbing walking shoes are an inexpensive, well-tolerated treatment for symptomatic medial compartment knee OA.

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