Effect of a Novel Insole on the Subtalar Joint of Patients with Medial Compartment Osteoarthritis of the Knee

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ABSTRACT. ***Objective***. To assess the efficacy of a lateral wedge insole with elastic strapping of the subtalar joint for conservative treatment of osteoarthritis (OA) of the knee.

Methods. The efficacy of a novel insole with elastic subtalar strapping and a traditional shoe insert wedge insole was compared. Ninety female outpatients with OA of the knee were treated with wedge insoles for 8 weeks. Randomization was performed according to birth date. Standing radiographs with unilateral insole use were used to analyze the femorotibial and talar tilt angles for each patient with and without their respective insole. Visual analog scale (VAS) score for subjective knee pain at the final assessment was compared with that at baseline in both groups.

Results. Participants wearing the elastically strapped insole (n = 46) had significantly decreased femorotibial angle ($p < 0.0001$) and talar tilt angle ($p = 0.005$) and significantly improved VAS pain score ($p = 0.045$) in comparison with baseline assessments. These significant differences were not found in the group with the inserted insole (n = 44).

Conclusion. The novel strapped insole leads to valgus angulation of the talus, resulting in correction of the femorotibial angle in patients with knee OA with varus deformity, and may have a therapeutic effect similar to that of high tibial osteotomy. (J Rheumatol 2001;28:2705–10)

Key Indexing Terms:
KNEE   OSTEOARTHRITIS   SUBTALAR JOINT   ORTHOTIC DEVICES

Osteoarthritis (OA) of the knee is the most common joint disorder, accounting for a large proportion of disability in adults[1]. Knee OA is more common among women than men[2]. The prevalence of radiological knee OA was 12% and the prevalence of symptomatic knee OA was 6% in women aged 45–64 in the Chingford study[3]. Patients with knee OA usually present with major involvement in only one compartment, with the medial compartment involved nearly 10 times more often than the lateral compartment[4].

A mainstay of surgical therapy, high tibial osteotomy, is indicated for severe medial compartment knee OA. The operation induces valgus realignment of the femorotibial angle by wedged osteotomy at the tibia. Majima, *et al*[5] reported that the average knee function score (maximum amount of points = 100) improved significantly from 59.1 ± 5.5 (n = 44) prior to high tibial osteotomy to 85.1 ± 6.1 points at the one year followup. However, there are numerous severe complications associated with high tibial osteotomy. Intraoperative injury to the popliteal artery, tibial nerve, or peroneal nerve and its branches has been reported[6]. Magyar, *et al*[7] followed 308 patients after high tibial osteotomy and reported deep vein thrombosis in 4%, nonunion requiring further surgery in 2%, and pin-track infections in 51%.

One of the first forms of conservative treatment developed for patients with medial compartment knee OA was an inserted lateral wedge insole. This type of lateral wedge insole, made of sponge rubber material that is inserted into ordinary shoes (inserted insole), has become popular among patients with knee OA[8]. The purpose of the inserted insole is to alter the mechanical alignment of the lower leg by enhancing valgus correction of the calcaneus. Yasuda and Sasaki[9] characterized the mechanism of action of the inserted insole as reducing medial knee joint surface loading while concurrently reducing lateral tensile forces. However, they reported that the femorotibial angle in patients with varus deformity with medial compartment knee OA was not corrected by use of the inserted insole.

It is plausible that with the inserted insole movement of the talus may prevent calcaneal valgus correction, thereby preventing femorotibial valgus correction. Thus, the effect of the inserted insole is fundamentally different from surgical correction of the femorotibial angle (FTA) with high tibial osteotomy.

Using radiographic measurements with electrical stimulation of the peroneus longus, Vaes, *et al*[10] demonstrated that tape bandages significantly restrict talar tilt. With taping, the talar tilt was reduced from 13.3° to 4.9°, in their report. However, they did not address the clinical significance of

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Dr. Toda is currently applying for a patent for the novel insole used in this study.

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Submitted January 9, 2001; revision accepted July 24, 2001.

this finding. Considering that inserted insoles do not significantly rectify the FTA, it is reasonable to test whether subtalar strapping may augment the effect and thereby result in valgus correction. For this purpose, we assembled lateral wedge insoles with a belt supporter such as is used for limiting talar mobility after ankle sprains. If the lateral wedge insole with strapping of the subtalar joint using a belt support can lead to femorotibial valgus correction, the effect may provide a conservative alternative to high tibial osteotomy while preserving therapeutic advantage. To test this hypothesis, we compared visual analog scale (VAS) scores for knee pain and the radiographic effect on femorotibial alignment in patients treated with traditional inserted insoles with those treated with the novel insole, which provides subtalar strapping.

MATERIALS AND METHODS

This study was accomplished through prospective evaluation of patients with knee OA treated with the traditional insole, as well as those treated with the lateral wedge with subtalar strapping. The principal outcome measures were the Lequesne index of severity for knee OA, the VAS for knee pain, and the radiographic assessment of bony alignment. Additionally, side effects and complications of insole use were monitored.

After providing informed consent, 90 new female outpatients (≥ 45 yrs old, mean age 65.3 yrs, SD 8.6) seen in our Orthopedic Outcome Clinic in 2000, who met American College of Rheumatology criteria for a diagnosis of knee OA, were treated with wedge insoles for 8 weeks[11]. Patients were excluded for any history of congenital foot problems, fused joints, foot deformity, or limitation of range of motion of the subtalar joint. All participants were also treated with a nonsteroidal antiinflammatory drug (NSAID, indomethacin, 30 mg) orally twice a day as adjunctive therapy.

The age, disease duration, height, weight, index of severity for knee OA, VAS for pain, and the stage/degree of bone destruction were evaluated at baseline. Disease duration was based upon patients' recollection of the onset of knee pain. Height was measured to the nearest 1 cm using a stadiometer. Weight was measured to the nearest 0.1 kg with subjects standing erect, wearing underwear and robes without shoes. Body mass index (BMI) was calculated as weight/height^2.

A research nurse who was blinded to the objectives of the study asked participants to assess their level of pain using the Lequesne index of severity for knee OA and VAS[12]. Radiographs were evaluated for changes characteristic of OA in anteroposterior views using the Kellgren-Lawrence grade, as described in the *Atlas of Standard Radiographs*[13]. Two types of lateral wedge insoles were prepared: urethane wedges made from household bath mat material with elevations of 6.35 mm strapped to an ankle sprain supporter (Sofra Wolfer®, Taketora Co. Ltd., Japan) designed to fit around the ankle and subtalar joints (strapped insole, Figure 1A); and a traditional inserted insole (Wedge Heel Type®, Sanshinkousan Co. Ltd., Japan), a lateral rubber heel wedge with an elevation of 6.35 mm (inserted insole, Figure 1B).

Randomization was performed by date of birth. Participants with even numbered dates of birth were treated with the inserted insole and those having odd numbered dates of birth were treated with the novel insole with subtalar strapping. Each participant was instructed to use the insole whenever wearing shoes, for between 3 and 6 hours each day.

Before entering the 8 week study, standing radiographs of the knee and ankle joints in anteroposterior views were completed for baseline comparison. Participants stood on one leg (insole side) and radiographic analysis was performed for each subject with and without the respective insole. The following angles were radiographically compared with and without insole use:

1. The femorotibial angle, the angle formed by the axes of the femur and the tibia. A pair of parallel lines was drawn through the distal one-third of the femur and the proximal one-third of the tibia. The axes of the femur and tibia were considered to be the lines connecting the centers of parallel lines through the femur and tibia, respectively (Figure 2A).
2. The talocalcaneal angle, as described by Yang, *et al*[14]. Three points are defined: the center of a line connecting the medial and lateral convex ends of the trochanter talus (α in Figure 2B); the center of a line connecting the distal ends of the malleoli (ß in Figure 2B); and the center of the talus in a line parallel to floor through 2.5 cm distal to the lateral malleolus (γ in Figure 2B). The angle is formed by the line connecting α to ß and the line connecting ß to γ.
3. The tilt angle of talus is formed by a line parallel to floor and the tilt of trochanter talus (Figure 2C).

The radiographic assessment was determined by 3 orthopedic surgeons who were not informed of the category of the patients.

The trial lasted 8 weeks. The Lequesne index and VAS scores at the final assessment were compared with baseline in both groups. The urethane wedge or rubber heel wedge was replaced every 2 weeks and proper use of the insoles was confirmed by wear of the material. At the conclusion of the study period, participants were asked to report side effects and complications of use of the respective insoles, and the rate of adverse outcomes was compared between the 2 groups.

Statistical analysis. Baseline values for age, disease duration, height, weight, BMI, femorotibial angle, talocalcaneal angle, talar tilt angle, Lequesne index, and VAS scores were compared between the 2 groups using one-way analysis of variance. Radiographic grade was compared between the 2 groups using the chi-squared test. The paired t test was used for paired data to assess for statistically significant differences in Lequesne index, VAS score, femorotibial angle, talocalcaneal angle, and talar tilt angle between the baseline and final assessment in each group. Statistical significance levels were considered to be $p < 0.05$.

RESULTS

Characteristics of the participants. All participants in both groups completed the 8 week study (i.e., returned for the final followup visit). There were 46 participants in the strapped insole group and 44 in the inserted insole group. At the initial assessment, there were no significant differences between the groups for age ($p = 0.52$), disease duration ($p = 0.47$), height ($p = 0.30$), weight ($p = 0.96$), BMI ($p = 0.51$), and distribution of K-L grade ($p = 0.77$) (Table 1).

Radiographic assessment. Table 2 reveals the change in the femorotibial angle, talocalcaneal angle, and talar tilt angle before and after use of the wedged insoles.

There were no significant differences between groups at baseline for the talocalcaneal ($p = 0.15$), femorotibial ($p = 0.16$), or talar tilt ($p = 0.76$) angles. The strapped insole resulted in significant change in all angles, while the inserted insole produced a significant change only in the talocalcaneal angle (Table 2).

Clinical assessments. Comparison of the baseline with the final assessment in each group is shown in Table 3. Lequesne index ($p = 0.46$) and VAS scores ($p = 0.84$) in the initial assessment were not significantly different between the 2 groups. Lequesne index at the final assessment compared to the initial assessment was significantly improved in both groups. In the strapped insole group, VAS scores for pain were significantly decreased at the final assessment compared with the initial assessment, although

Table 1. Characteristics of the participants.

	Age, yrs	Disease Duration, yrs	Height, cm	Weight, kg	Body Mass Index, kg/m^2	Radiographic Grade*, no. of Cases
Strapped insole group, n = 46						
Mean ± SD	64.7 ± 8.8	5.1 ± 5.5	152.5 ± 7.3	59.5 ± 10.2	25.5 ± 3.4	Grade 2: 28
Median	64	3.5	151	59.6	24.9	3: 13
95% CI	62.1–67.3	3.5–6.8	150.4–154.7	56.5–62.5	24.5–26.5	4: 5
Inserted insole group, n = 44						
Mean ± SD	65.9 ± 8.4	4.3 ± 5.1	154.0 ± 6.1	59.5 ± 4.5	25.1 ± 2.6	Grade 2: 27
Median	67	2.8	153.5	59.6	24.5	3: 14
95% CI	63.3–68.5	2.8–5.8	152.2–155.9	57.2–61.8	24.3–25.9	4: 3

* Kellgren-Lawrence grade

Table 2. Comparison of radiographic angles with and without insoles at the initial assessment.

	Talocalcaneal Angle		Femorotibial Angle		Talar Tilt Angle	
	No insole,°	Insole, °	No insole, °	Insole, °	No insole, °	Insole, °
Strapped insole group, n = 46						
Mean ± SD	6.3 ± 8.3	10.3 ± 8.9*	182.3 ± 5.8	178.9 ± 5.4*	10.8 ± 5.6	9.9 ± 5.3†
Median	7.5	10.5	181	179.5	10	10
95% CI	3.8–8.8	7.7–13.0	180.6–184.0	177.3–181.7	9.0-12.5	8.2–11.5
Inserted insole group, n = 44						
Mean ± SD	3.7 ± 8.1	6.3 ± 7.7*	180.8 ± 4.6	180.2 ± 5.0	10.5 ± 3.9	10.8 ± 4.5
Median	4	7	180	179	10.5	10
95% CI	1.3–6.2	3.9–8.7	179.4–182.2	178.7–181.7	9.2–11.7	9.4–12.2

*Significant difference with respect to the angle without insole use; $p<0.0001$. †$p = 0.003$.

Table 3. Comparison of severity between initial and final assessment.

	Lequesne Index of Disease Severity		Pain VAS		Complication,
	Initiation	Final	Initiation, %	Final %	No. of Cases
Strapped insole group, n = 46					Popliteal pain: 3
Mean ± SD	11.1 ± 5.2	8.2 ± 5.4*	43.4 ± 20.6	34.6 ± 21.3‡	Low back pain: 2
Median	11	7	45	21.3	Foot sole pain: 1
95% CI	9.0–13.2	6.0–10.3	34.5–52.3	26.2–43.3	Total : 6 (13%)
Inserted insole group, n = 44					
Mean ± SD	10.1 ± 4.6	8.8 ± 5.3†	42.3 ± 19.4	43.8 ± 22.6	Foot sole pain: 1
Median	9	8.5	41	46.5	
95% CI	8.4 –11.9	6.8–10.8	35.1–49.5	35.3–52.2	Total: 1 (2%)

* Significantly different from the initial assessment; $p = 0.006$.
† $p = 0.009$, ‡ $p = 0.041$.

no significant difference in VAS score was detected between the initial and final assessments in the inserted insole group ($p = 0.58$).

Adverse effects were more common in the strapped group (13%) than in the inserted group (2%). In the strapped insole group, 3 participants complained of popliteal pain, 2 participants reported low back pain, and one participant had foot sole pain. Only one patient complained of foot sole pain in the inserted insole group. However, side effects were not severe enough to deter participants from continuing to wear the insole.

DISCUSSION

In this study, participants wearing the insole with subtalar strapping demonstrated significantly decreased femorotibial angle, talar tilt angle, and VAS ratings in comparison with values at baseline. These significant differences were not seen in the inserted insole group. This corroborates the find-

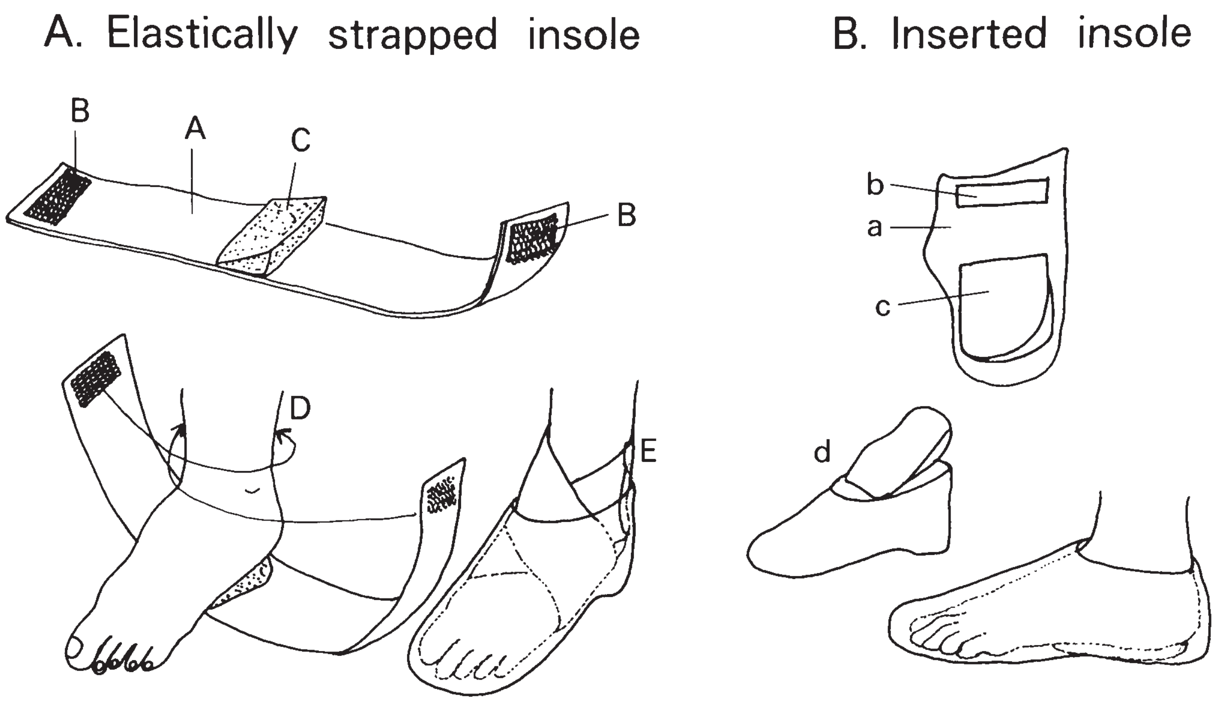

Figure 1. Construction of the 2 types of lateral wedge insoles. The strapped insoles consist of an ankle support band (A) with adhesive tape (B) and urethane lateral wedge with an elevation of 6.35 mm (C). The ends of the supporter were twisted in a figure 8 around the ankle and subtalar joints (D). The ends were affixed with adhesive tape at the posterior ankle and subtalar joints (E). The inserted insole consists of a nylon seat (a), adhesive tape (b), and lateral rubber wedge with an elevation of 6.35 mm (c). The insole was inserted into ordinary shoes (d).

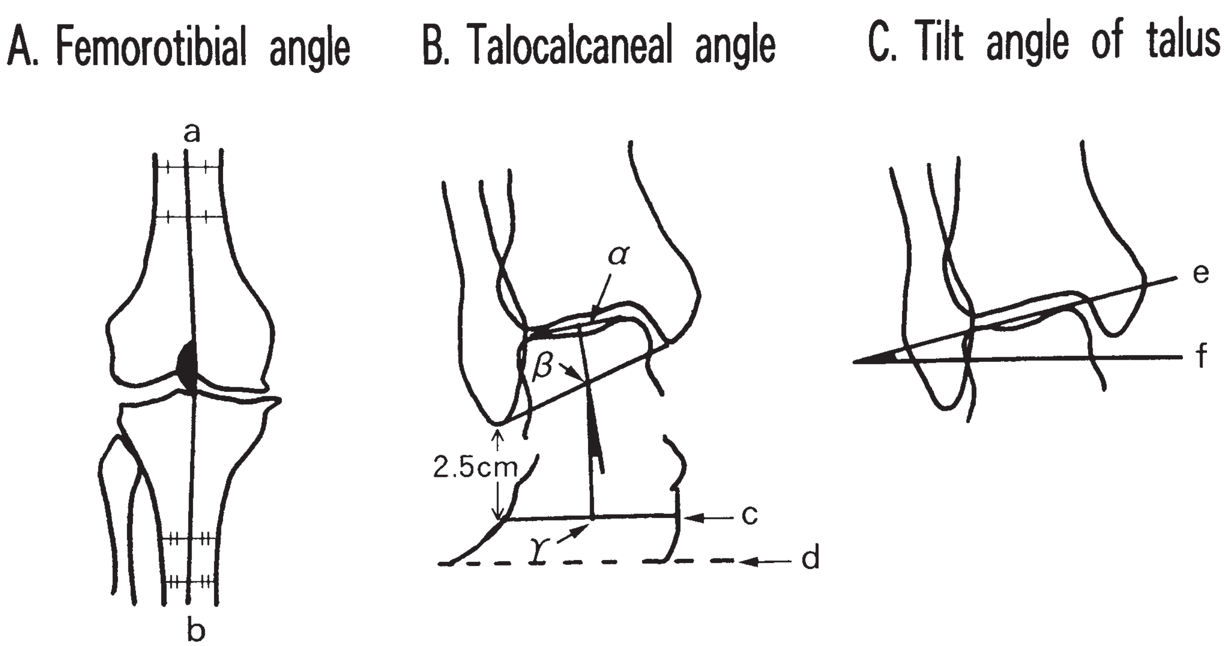

Figure 2. Radiographic analysis. Lines indicate the axes of the distal one-third of the femur (a) and the proximal one-third of the tibia (b), parallel line to floor through 2.5 cm distal to the inferior aspect of the lateral malleolus (c), floor line (d), tilt of trochanter talus (e), and line parallel to the floor (f). Also illustrated: the center of the trochanter talus (α), the center line through the distal end of the malleoli (ß), and the angle between the center of the talus and the line that is parallel to the floor through 2.5 cm distal to the lateral malleolus (γ).

C. Strapped full-length insole on talonavicular joint

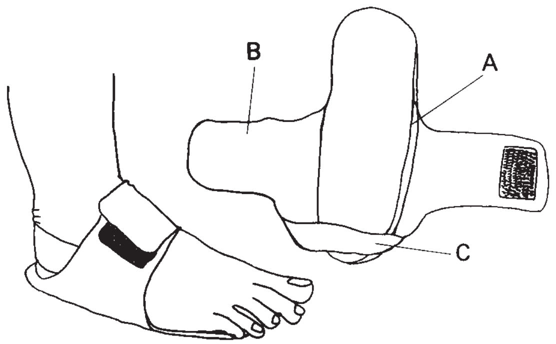

Figure 3. The insole assessed in the previous report[16]. The open-toe shoe type insole consisted of a full length lateral cork wedge with an elevation of 6.35 mm (A), an elastic band designed to fit around the talonavicular joint with adhesive tape (B), and an elastic band on the heel (C).

ings of Yasuda and Sasaki[9], who reported that the femorotibial angle is not significantly changed by use of a wedged sole board without subtalar strapping. Our findings suggest that the insole with subtalar strapping leads not only to calcaneal and talar valgus correction, but also to correction of the femorotibial angle in patients with genu varum and medial compartment knee OA. The concordance of the pain index and Lequesne index further suggests that there is a correlation between joint realignment and clinical improvement. Although these results demonstrate that the strapped insole was significantly more efficacious in correction of ankle and knee alignment and pain reduction, there is also evidence that the inserted insole can also be helpful for patients with medial OA of the knee. Specifically, the talocalcaneal angle with the inserted insole compared to that without an insole was significantly increased, and Lequesne index at the final assessment compared to baseline was also significantly improved.

In addition to lower extremity realignment, another advantage of the insole with subtalar strapping is its adaptability. The inserted insoles often slip in the shoes, requiring frequent repositioning, and are difficult to use when wearing open-toe shoes, boots, slippers, or high-heels. Further, most East Asian populations wear shoes outdoors but not inside the home, making the inserted insole of no use when patients are at home. In contrast, the insole with subtalar strapping does not slip or change position in shoes, and it is compatible with many types of footwear and can even be used barefoot.

The disadvantage associated with the strapped insole is a higher rate of complications reported by participants in this group, most commonly popliteal pain and low back pain. A possible etiology for this higher rate of complications is rapid reduction in femorotibial angle, resulting in an acute imbalance of surrounding muscles, which had been compensating for the joint deformity. This mechanism was described by Wolfe, *et al*[15], who observed that back pain could be a manifestation of intrinsic disease related to structural or functional abnormalities of the axial skeleton or its surrounding musculature in patients with knee OA. Through an analogous mechanism, enthesopathy of the biceps femoris may result in popliteal pain when there is an acute modification of the femorotibial angle.

In a pilot study, 26 participants with knee OA who had worn full length lateral wedge insoles (the open-toe shoe type insole, Figure 3) were then treated with the insole with subtalar strapping[16]. Participants were instructed to wear the insole with subtalar strapping without shoes on, in their home, for 4 hours each day. Comparing the results of that pilot study with the current study, foot pain with the novel insole is more common when used without shoes than when wearing shoes. The increased risk of foot pain when used without shoes may be multifactorial, due to the more form-fitting nature of the subtalar strapped insole and/or to differences in material.

Future areas for study include more detailed analysis of the most efficacious material, height of the lateral wedge, and the optimal duration of use of the insole with subtalar strapping. The observation period in this study was 8 weeks. Keating, *et al*[17] reported that participants who attained pain relief with use of the wedges generally noticed relief within the first 3 days to one week, and participants who received no relief in the first week generally received no relief with continued use. However, it will be necessary to continue the followup period to assess treatment efficacy over an extended observation period. Use of the insoles was limited to 3–6 hours in this study for the purpose of comparison with the inserted insoles, for the reason that nearly all participants were Japanese housewives who remove their shoes in their home and spend only several hours each day wearing shoes outside.

This study was limited to female subjects because males make up a minority of the knee OA population and because the duration of insole use would have been affected by their occupation[2]. A problem encountered in this study was the inability to assess the correlation between the efficacy of the insole with subtalar strapping and radiographic severity of knee OA. This was secondary to the relative paucity of participants with K-L grade IV (n = 5). In the study by Keating, *et al*[17], participants with milder OA attained greater pain relief with use of the wedge insole. However, even participants with complete loss of joint space and bony erosions showed some improvement[3]. It will be necessary to study this, including a larger number of participants with advanced knee OA.

Another possible limitation was that patients in this study were not blinded to the treatment. However, the 2 devices were formed in the same shape. Additionally, radiographs were taken in the static position in this study. The lateral wedge with subtalar strapping may act differently when subjects are walking or climbing stairs. The 3-dimensional gait analysis by Crenshaw, *et al*[18] was performed for each subject with and without a 5° lateral wedge inserted insole. In their study, there were no significant differences in temporal and spatial variables, joint angle at hip, knee and ankle, or kinetics at the hip and ankle between wearing and taking off the lateral wedge inserted insole. However, the external varus moment and estimated medial compartment load at the knee were significantly reduced with the addition of the lateral wedge inserted insole. When the insole with subtalar strapping is assessed by such gait analysis in future studies, joint angles at the knee and ankle may differ from the static results reported here.

The average femorotibial angle with use of the insole with subtalar strapping was 178.9° in this study. This angle is greater than that after high tibial osteotomy. Majima, *et al*[5] recommended that adequate correction after high tibial osteotomy should be between 164° and 168° on the standing radiograph. However, they cautioned that high tibial osteotomy may not protect against the progression of degenerative changes in the medial tibiofemoral joint. Billings, *et al*[19] reported that 21 of 64 patients available for longterm followup required a subsequent arthroplasty after high tibial osteotomy at an average of 65 months.

Considering the limitations and the complications of high tibial osteotomy, we believe conservative therapy, using the insole with subtalar strapping for initial treatment, will benefit patients with knee OA with genu varum and medial compartment knee OA. Recently, remarkable progress has been made in surgical techniques for treatment of knee OA. However, the vast majority of patients with knee OA are hesitant to undergo surgical treatment. Therefore, if conservative therapy such as use of an insole can provide a low cost, effective complement or alternative to surgical treatment, it will be very useful for patients and the health care economy.

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