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A 2-year follow-up of a study to compare the efficacy of lateral wedged insoles with subtalar strapping and in-shoe lateral wedged insoles in patients with varus deformity osteoarthritis of the knee

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Summary

Objective: This study was conducted in order to assess the effect of wearing a lateral wedged insole with a subtalar strap for 2 years in patients with osteoarthritis varus deformity of the knee (knee OA).

Design: The setting was an outpatient clinic. The efficacies of the strapped insole and a traditional shoe insert wedged insole (the inserted insole), as a positive control, were compared at the baseline and after 2 years of treatment. Randomization was performed according to birth date. The 61 female outpatients with knee OA who completed a prior 6-month study were asked to wear their respective insoles continuously as treatment during the course of the 2-year study. The femorotibial angle (FTA) was assessed by standing radiographs obtained while the subjects were barefoot and the Lequesne index of the knee OA at 2 years was compared with those at baseline in each insole group.

Results: There were 61 patients in the original study, but 13 patients (21.3%) did not want to wear the insole continuously and five (8.2%) withdrew for other reasons. The 42 patients who completed the 2-year study were evaluated. At the 2-year assessment, participants wearing the subtalar strapped insole ($n = 21$) demonstrated significantly decreased FTA ($P = 0.015$), and significantly improved Lequesne index ($P = 0.031$) in comparison with their baseline assessments. These significant differences were not found in the group with the traditional shoe inserted wedged insole ($n = 21$).

Conclusion: Only those participants using the subtalar strapped insole demonstrated significant change in the FTA in comparison with the baseline assessments. If the insole with a subtalar strap maintains FTA for more than 2 years, it may restrict the progression of degenerative articular cartilage lesions of knee OA.

Key words: Orthotic device, Knee, Osteoarthritis, Insole, Radiography.

Osteoarthritis (OA) of the knee is a leading cause of decreasing physical function among older adults, and it may limit a person's independence as well as affect the health-related quality of life[1]. Few of the factors contributing to the progression or advancement of OA disease of the knee have been identified, but it is thought that knee alignment plays an important role. Varus and valgus malalignments have been shown to increase the risk of subsequent medial and lateral OA knee progression[2]. Patients with knee OA usually show major involvement in only one compartment and the medial compartment is involved nearly 10 times more frequently than the lateral compartment[3].

The recognition of the importance of knee alignment has led to the development of various treatment methods, such as lateral wedged inserted insoles, to normalize the malaligned knee, attempting to reduce pain and OA progression. Keating *et al.*[4] reported that 61% of patients with medial OA knee had reported an improved pain score after using a wedged insole. Yasuda and Sasaki[5] speculated that the mechanism of the action of the inserted insole was a reduction of the medial knee joint surface loading with a concurrent reduction in lateral tensile forces. However, Yasuda and Sasaki[5] also reported that the inserted insole failed to correct the femorotibial angle (FTA) in patients with varus deformity with medial compartment knee OA.

We considered that, with the inserted insole, movement of the talus may prevent calcaneal valgus correction, thereby preventing femorotibial valgus correction[6]. Through radiographic measurements with electrical stimulation of the peroneus longus, Vaes *et al.*[7] demonstrated that tape bandages significantly restricted talar tilt. Through taping, the talar tilt was reduced from 13.3° to 4.9° in their report. In research conducted on conservative correction of the FTA, this limitation of the inserted insoles was addressed through the development of a novel lateral wedged insole with elastic fixation of the subtalar joint.

Standing full-length radiographs with unilateral insole use were used to analyze the talocalcaneal, talar tilt and FTAs for each subject with and without an inserted or a subtalar strapping insole. The subtalar strapping insole resulted in a significant change in the talocalcaneal angle, the talar tilt angle and the FTA, while the inserted insole alone produced a significant change only in the talocalcaneal angle on standing full-length radiographs[6]. The realignment produced by the insole with subtalar strapping led to the conclusion that an insole with elastic fixation obtained with

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tension by a subtalar and ankle joint band leads to valgus angulation of the talus. This talar position change corrects the FTA in patients with varus deformity knee OA.

Further studies suggested that pain during bed rest, pain after getting up, pain after standing up from a seated position and walking distance without pain was significantly improved in a subtalar strapped insole group compared with the baseline, but no improvement was found in the traditional insole group[8]. The insole with subtalar strapping was more efficacious for younger patients and those with a higher proportion of lean body mass per body weight in the lower extremities, and less efficacious for older patients with sarcopenia[9].

In a 6-month follow-up study, an insole with a subtalar strap maintained the valgus correction of the FTA in patients with varus knee OA for 6 months, indicating a longer-term clinical improvement[10].

However, the 6-month observation period was too short to evaluate the effect of the strapped insole on the progression of varus deformity of knee OA. It remained uncertain if the beneficial effect from using the insole with a subtalar strap would continue after 6 months of use. The results reported in this paper were obtained in assessments made after the use of a valgus heel wedge and strap for 2 years.

Patients and methods

PATIENTS

In the original study, 75 females were defined as patients with medial compartment OA knee, according to the American College of Rheumatology criteria and a standing FTA greater than 176°, determined by X-ray (the mean and standard deviation of FTA in standing radiographs in healthy Japanese adult females is $174.6 \pm 1.7°$ and an angle exceeding 176° is considered as varus deformity) (Fig. 1)[11,12].

The study was limited to female subjects because males comprise a minority of the OA knee population[13]. Exclusion criteria, according to a report by Maillerfert *et al.*[14], were a functional class of IV (Steinbrocker), a greater or similar reduction in the lateral than the medial femorotibial joint space width (concomitance with lateral knee OA) shown on plain postero-anterior X-rays, bilateral knee OA, secondary knee OA, hip OA, ankle OA, hallux rigidus, valgus deformity of the midfoot, other symptomatic deformities of the foot, advanced arthroplasty of the hindfoot, any disease treated with insoles, previous ankle arthrodesis, tibial osteotomy, or an intraarticular corticosteroid injection within 1 month.

There were seven patients who were not eligible, judging by the exclusion criteria given above, and two patients refused to participate in the study. Then, the remaining 66 participants were enrolled in the 6-month study (Fig. 1).

Two types of insoles were prepared: urethane wedges with elevations of 12 mm (tilt angle = 11.2°) which were fixed to an ankle sprain support, designed to fit around the ankle and subtalar joints (Wedge strapped insole for knee OA®, Taketora USA Inc., Torrance, CA, USA) [the strapped insole, Fig. 2(A)] and a traditional shoe inserted insole (Wedge Heel Type®, Sanshinkousan Co. Ltd., Osaka, Japan) which was a lateral sponge rubber heel wedge with an elevation of 6.35 mm (tilt angle = 5°) [the inserted insole, Fig. 2(B)].

The reason urethane was used for the strapped insole wedge was that the heel wedge in combination with a subtalar strap had a more natural form-fit to the sole than the insert. In our previous study of the subtalar strapping insole, an insole composed of urethane was more comfortable than that of rubber sponge[15]. The urethane used for the strapped insole was made of PORON L-24® (Rogers Co. Ltd., Chandler, AZ, USA), had a density of 240 kg/m^3, 0.54 MPa pull strength, 115% stretch rate, and 1.8 N/mm rip strength. The rationale for the discrepancy in the elevation of the

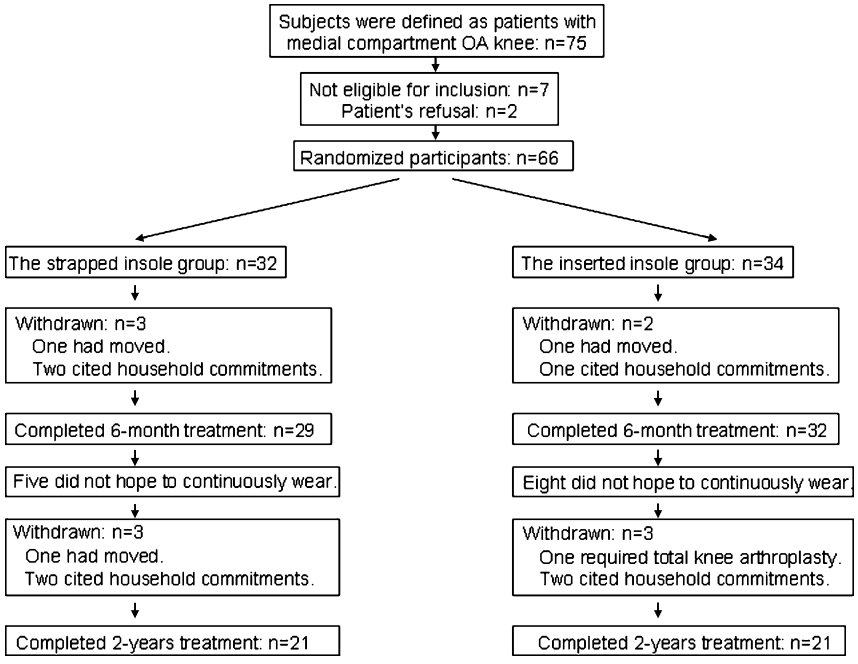

Fig. 1. Course of the 2-year randomized trial.

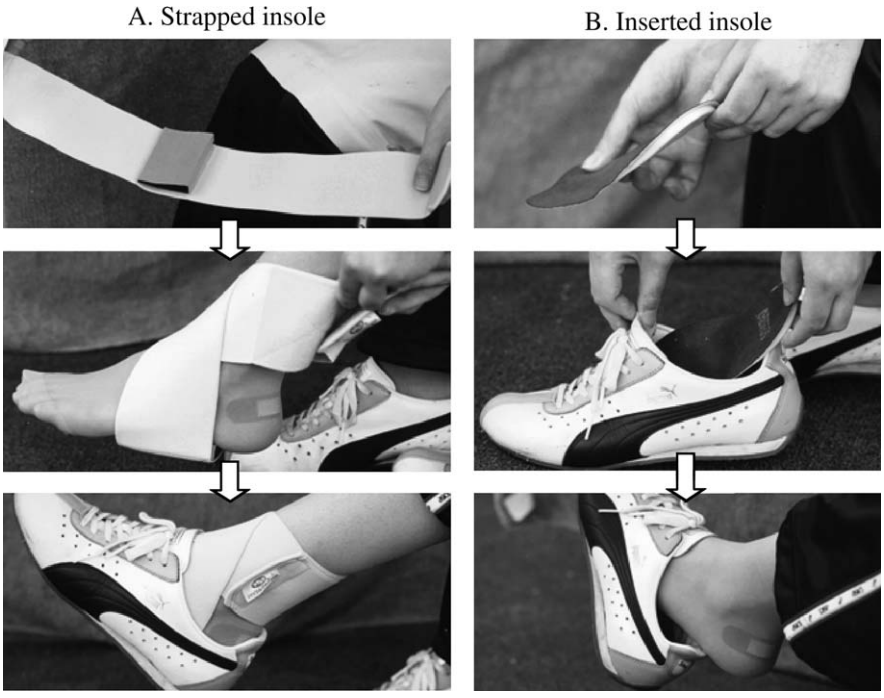

Fig. 2. Construction of the two types of lateral wedged insoles. The strapped insoles consisted of an ankle support band with adhesive tape and a urethane lateral wedge with an elevation of 12 mm. The ends of the supporter were twisted in a figure 8 around the ankle and subtalar joints. The ends were affixed with adhesive tape at the posterior ankle and subtalar joints. The inserted insole consisted of a nylon seat, adhesive tape, and a lateral rubber wedge with an elevation of 6.35 mm. The insole was inserted into ordinary shoes.

lateral wedge between the two types of insoles was the optimal tilt of each insole. Kerrigan *et al.*[16] reported that all subjects were comfortable wearing 5° wedged inserted insoles; nearly every subject reported varying degrees of mild discomfort wearing a 10° wedge, stating that their feet felt somewhat cramped inside their shoes. For constant routine use, the 12 mm elevation wedged insoles with a subtalar strap may be more comfortable than those used in our previous study[17].

Subjects were randomized by date of birth into two groups. Participants with even numbered dates of birth were treated with the traditional shoe inserted insole and those having odd numbered dates of birth were treated with the strapped insole.

Five of the 66 subjects (7.6%) in the original study including three in the strapped insole group and two in the inserted insole group did not complete the study. When the authors interviewed the dropouts by telephone, three cited household commitments, and two had moved (Fig. 1).

After receiving treatment for 6 months, all the patients were asked whether they would be willing to participate in the 2-year follow-up study. Thirteen of the 61 subjects (21.3%) who completed the 6-month study; including five in the strapped insole group and eight in the inserted insole group, did not want to wear their respective insoles continuously. The reasons given for discontinuing the use of the strapped insole was the necessity of shoes larger than ordinary ($n = 3$, 10.3%) and its ineffectiveness ($n = 2$, 6.9%). The reasons for discontinuing the use of the inserted insole were its ineffectiveness ($n = 4$, 12.5%), slipping or instability of shoes ($n = 2$, 6.3%), and the difficulty encountered in the use of many types of footwear, including open-toe shoes ($n = 2$, 6.3%).

The remaining 48 patients were enrolled in this 2-year follow-up study (Fig. 1).

STUDY DESIGN

This study was accomplished through the prospective evaluation of patients with OA of the knee, treated with the traditional inserted wedged insole, as well as those treated with the lateral wedge with a subtalar strap. The principal outcome factors considered were pain improvement using the Lequesne index for knee OA[18], radiographic bone alignment using the FTA and the grade of radiographic progression of knee OA according to Kellgren and Lawrence[19].

After providing informed consent, 48 female outpatients with knee OA (>45 years old; mean age, 65.8; standard deviation, 8.3) were treated with wedged insoles for 2 years.

INTERVENTION

We found that the optimal duration of insole with subtalar strapping wear for patients with knee OA would be between 5 and 10 h each day after starting the 6-month study, and that result was previously reported in this journal[20]. Although we have not seen any reports that investigated the optimal daily wear for an inserted insole, all the participants in the current study were instructed to use their respective insole whenever wearing shoes, for a period of 5−10 h each day according to our recent findings.

All participants were given a uniform nonsteroidal anti-inflammatory drug (NSAID) (lornoxicam 4 mg twice daily) as an adjunctive therapy. While we had prescribed acemetacine, which is one of the indoleacetic acids in the 6-month study, the half time of acemetacine (8 h) was shorter than that of lornoxicam (12.5 h), one of the oxicams. In the extension study, we considered that a long active NSAID would be beneficial for chronic pain due to knee OA and changed the NSAID from acemetacine to lornoxicam.

In the course of the study, each participant could intake the NSAID for any painful condition related to her knee OA, but she was instructed to record how many days she needed the NSAID in her calendar. The number of days she needed the NSAID was used for individual assessments.

EVALUATION

At the baseline, 6-month and 2-year assessments, participants stood barefoot on one leg, the affected side, and standing radiographs were obtained of the knee joint. The arms were positioned at 90° of the shoulder flexion with the hands gripping an adjustable height stabilization bar. Participants stood on one leg, with full knee extension, standing 1 m from the X-ray source, with a constant and reproducible foot position (foot map). The X-ray beam was centered on the joint space and oriented parallel to the tibial plateau. The roentgenogram was taken when the participant's posture was stabilized[7].

The FTA was measured as the angle formed by the axes of the femur and the tibia, according to Yasuda and Sasaki[5]. 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 the parallel lines through the femur and tibia, respectively.

The Kellgren and Lawrence grades (K–L grade) were evaluated for radiographic progression of knee OA as described in the Atlas of Standard Radiographs[19].

The radiographs were scanned and sent to another hospital via the Internet. Radiographic assessments of the K–L grade and the FTA were conducted by two orthopedic surgeons blind to the category of the subjects. Whenever the observers differed with regard to their evaluation of an FTA, they reviewed it again together, without knowing their previous scores for that radiograph.

In the original study, the investigators in our Clinic (interobservers) evaluated the FTA independently from the two orthopedic surgeons in another hospital (intraobservers) using the same method. The mean value of the inter/intraobserver error of the FTA without insoles at baseline ($n = 61$) was 0.16° (95% CI: −0.28 to 0.35, $P = 0.83$) using the paired t-test (data not shown). Thus, we believe the methodology employed showed reliability for FTA measurement, although we could not provide a reference for this method of assessing the reliability of measurement.

A research nurse who was blind to the objectives of the study asked participants to assess their level of pain using Lequesne index of severity for knee OA. The Lequesne index at the second year was compared with the baseline recordings in each group.

STATISTICAL ANALYSIS

Characteristics at the baseline (age, disease duration, height, weight, FTA, and Lequesne index) and the number of days participants needed the NSAID between the two groups were compared using a one-way analysis of variance. The degree of the FTA and the Lequesne index between the baseline and 2-year assessments were also compared using a one-way analysis of variance. The distribution of the K–L grades in the baseline assessment, the number of withdrawn cases, the rate of NSAID use prior to screening and the number of progressed cases in the K–L grade were compared between the two groups using the Chi-square test. Statistical significance levels were considered to be $P < 0.05$.

Results

Six subjects including three in the strapped insole group and three in the inserted insole group did not return for the 2-year follow-up visit. As a result, compared with the baseline assessment, 24 of the 66 participants (36.4%) were lost to the follow-up for the full 2 years.

There was no significant difference in the number of dropouts between the two groups ($P = 1$). When the authors interviewed the dropouts by telephone, five cited household commitments, one required total knee arthroplasty and two had moved. Except for the case requiring total knee arthroplasty five dropouts reported an improvement in comparison with the baseline, but of course the changes in the FTA were unknown (Fig. 1).

PARTICIPANT CHARACTERISTICS

Of the 42 who completed the study, there were 21 participants in the strapped insole group and 21 in the inserted insole group. At initial assessment, there were no significant differences between the groups for age ($P = 0.1$), disease duration ($P = 0.9$), height ($P = 0.54$), weight ($P = 0.97$), FTA ($P = 0.85$), Lequesne index ($P = 0.89$), or distribution of K–L grade ($P = 0.32$) (Table I).

From the observations of material wear, we judged that each participant used the insole as instructed.

Table I
Characteristics of the participants at the baseline assessment ($n = 61$)

	Age (years)	Disease duration (years)	Height (cm)	Weight (kg)	Radiographic grade*, no. of cases	Femorotibial angle at baseline (degrees)	Lequesne index at baseline (score)
Strapped insole group, $n = 29$							
Mean (SD)	63.1 (7.9)	5.7 (7.3)	154.4 (6.1)	58.6 (8.3)	Grade 2, 19	183.4 (6)	9.7 (5)
Median	64	2.3	154.5	57.9	Grade 3, 4	184	10
95% CI	60–66.1	2.9–8.6	152–156.7	55.4–61.8	Grade 4, 6	181.1–185.8	7.7–11.6
Inserted insole group, $n = 32$							
Mean (SD)	66.4 (7.4)	5.5 (6.5)	153.6 (6)	59 (8.1)	Grade 2, 21	184.1 (5.1)	9.9 (5)
Median	68	2.8	154.5	59.8	Grade 3, 8	184	9
95% CI	63.6–69.1	3.1–8.9	151.3–155.8	55.9–62	Grade 4, 3	182.2–186.1	7.9–11.8
P values between the groups	0.21	0.9	0.54	0.97	0.32	0.66	0.89

*Kellgren–Lawrence grade.

ADJUNCTIVE THERAPY WITH NSAID

Before enrolling in this study, 18 of the 21 participants (85.7%) in the strapped insole group and 17 of the 21 participants (81.0%) in the inserted insole group took NSAIDs during the previous week. There was no significant difference shown in the rate of NSAID use prior to screening between the two groups ($P = 0.5$). At the 2-year assessment, there was a statistically significant difference between the two groups ($P = 0.025$) in the number of days with NSAIDs intake. One participant in the strapped insole group and two participants in the inserted insole group complained of stomach pain, which was considered as being due to the deleterious effects of NSAIDs. However, the stomach pain was not severe enough to deter the participants from continuing to wear the insole, and an H2 blocker was administrated (femotidine 40 mg twice daily) (Table II).

Table II
*NSAID use at baseline and during 2-year study**

	Strapped insole group ($n = 21$)	Inserted insole group ($n = 21$)
Took NSAIDs during the week before enrollment	18 (85.7%)	17 (81.0%)
Number of days with NSAIDs intake during the 2-year study	50.8 ± 36.1	79.0 ± 42.2
Discontinued NSAIDs due to adverse effects†	1 (4.8%)	2 (9.5%)

*Values are the number (%). NSAID = nonsteroidal anti-inflammatory drug.
†Stomachache.

CLINICAL ASSESSMENTS

At the 2-year assessment, the FTAs in the strapped insole group (179.7 + 3.2°) were significantly lower than that at baseline ($P = 0.015$), but a significant difference was not detected in the inserted insole group (182.4 + 4.7°) ($P = 0.27$) (Table III).

In the inserted insole group, there was one case that progressed from the K–L grade 2 to 3 and one case that progressed from the K–L grade 3 to 4 over the 2 years. There were no cases showing progression in the K–L grade in the strapped insole group. However, there was no significant difference shown in the progression between the two groups by the Chi-square test ($P = 0.49$) (Fig. 3).

Compared with baseline assessment, the Lequesne index in the strapped insole group at 2 years (7.3 + 5.6) was significantly improved ($P = 0.031$). In the inserted insole group, there was no statistically significant difference between the index at 2 years (9.6 + 4.8) and the baseline assessment ($P = 0.79$) (Table III).

Discussion

In this study, only those participants using the subtalar strapped insole demonstrated significant change in the FTA, as well as an improved Lequesne index in comparison with baseline assessments. Furthermore, the number of days with NSAIDs intake in the group wearing the subtler strapping insole was significantly lower than that for the group using the inserted insole. Although there was no significant difference shown in the radiographic progression of knee OA, according to Kellgren and Lawrence, over the 2 years between the two groups, by Chi-square test, there were two cases that showed progression in the inserted insole group. No cases showing progression were found in the strapped insole group. The reason for this was that the 2-year observation period would be too short to evaluate the radiographic grade progression in patients with knee OA.

If the use of the insole with a subtalar strap can maintain the FTA for more than 2 years, it may restrict the progression of degenerative articular cartilage lesions of knee OA. We plan to continue monitoring our subjects for an additional 5–10 years in order to determine the long-term effect of the strapped insole.

The disadvantage associated with the strapped insole is the necessity of shoes greater than one size larger than those normally used, in order to accommodate the thickness of the supporter. In this study, three of the 29 subjects (10.3%) who completed the 6-month study did not want to wear their respective insoles continuously, and the reason they gave for discontinuing the use of the strapped insole was the necessity of shoes larger than those normally used.

However, Marks and Penton[21] have stated that surgery for knee OA is not without complications and bracing, a less intrusive means of alignment correction, may not be ideally suited for the morbidly obese or for those who have peripheral vascular disease, skin disease or an inability to apply a brace due to other physical limitations. Considering the disadvantages of the other therapies available for knee OA, we believe that conservative therapy using the insole with subtalar strapping for initial treatment will benefit patients with genu varum and medial compartment knee OA.

Although the inserted insole did not demonstrate a significant effect on the FTA or Lequesne index in this study, Pham *et al.*[22] reported that the number of days with NSAID intake was lower in the group with inserted laterally wedged insoles than in the neutrally wedged group in their 2-year prospective study.

In this study, there was no control group of patients who were treated with the neutrally wedged as a placebo insole. Including such a group would have enabled a clearer evaluation of the effect of the inserted insole.

A possible limitation of this study was that the number of participants was actually too small to be divided into two groups. The reason for this was that only those patients who hoped to continue use of the respective insole after 6 months were included in this trial. Thus, the study group was not representative of the population with knee OA. The rationale for using this study design was that the patient's impression and compliance in the use of an insole would be important to decide whether the patients should continue to wear or discontinue use of an insole. In the treatment for a chronic disease like knee OA, participants who were reluctant to continue use of the respective insole would not be able to follow our instructions, including the duration of insole use each day.

However, there were only 42 patients left after 2 years in this study. It will be necessary to study this subject further, including a large number of participants in the initial assessment to increase statistical reliability.

Standing, full-length radiographs, including the hip and ankle joints, might have been necessary for the measurement of the knee alignment in this study. However, Kraus *et al.*[23] reported that knee alignment assessed clinically by goniometer or measured on a knee radiograph is correlated with the angle measured on the more cumbersome and costly full-limb radiograph. From these results, they suggested that these alternative measurements have the potential to provide useful information regarding the risk of

Table III
The comparison of FTA and Lequesne index between baseline and final assessments

	Lequesne index of disease severity			Femorotibial angle		
	Baseline	6 months	2 years	Baseline	6 months	2 years
Strapped insole group						
Mean ± SD	9.7 ± 5	7.5 ± 5.8	7.3 ± 5.6	183.4 ± 6	180.7 ± 5.7	179.7 ± 3.2
Median	10	8	8	184	180	179
95% CI	7.7–11.6	5.3–9.6	4.8–9.9	181.1–185.8	178.5–182.9	178.2–181.1
		P=0.031			P=0.015	
Inserted insole group						
Mean ± SD	9.9 ± 5	9 ± 5	9.6 ± 4.8	184.1 ± 5.1	184.1 ± 5.1	182.4 ± 4.7
Median	9	10	10	184	183	183
95% CI	7.9–11.8	7.9–11.6	7.4–11.8	182.2–186.1	181.7–185.7	180.3–184.5
		P=0.79			P=0.27	

progression of knee OA when a full-limb radiograph is not available.

While results of Kraus *et al.*[22] were obtained from measurements in 114 knees, our results were obtained from 42 knees. The measurement of only FTA using knee radiographs might be insufficient for the assessment of alignment in such a small number of patients, as in this study. A future study should evaluate multiple angles using full-length radiographs to increase the reliability.

The radiographs were taken in the static position and the effect on the FTA when using the insole with subtalar strapping during the dynamic phase of gait was not assessed in this study. Andriacchi[24] stated that knee OA patients with varus deformity have a high adduction moment at the knee and increase in the adduction moment during walking has been directly related to an increase in medial compartment loading at the knee joint. Kuroyanagi *et al.*[25] reported that the adduction moment in patients with varus deformity knee OA while barefoot was significantly reduced after wearing the insole with subtalar strapping (−14.8%), compared with the use of the inserted insole (−9.4%), during the dynamic phase of gait ($P < 0.01$). Their results suggested that the insole with subtalar strapping may have a therapeutic effect by decreasing the medial compartment loading at the knee joint not only during the static, but also during the dynamic phase.

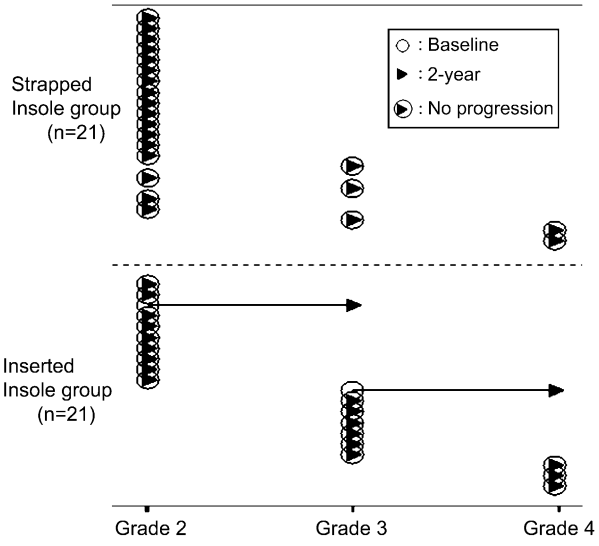

Fig. 3. The result of change of Kellgren–Lawrence grade.

The current study was limited in that it did not clarify the duration of insole use each day. We instructed the participants to record the number of days they needed the NSAID, but not the number of hours each day they wore the respective insole. However, we could detect patients who did not use the insole from the observation of the material wear. When the participants used the strapped insole inside the house without shoes, we could recognize this, as the parts of the support that touched the floor were more soiled than those only used with shoes. However, it will be necessary to consider reliability measures in a future study.

We changed the instruction for the duration of insole use each day and the type of NSAID used as an adjunctive therapy between the original and the extension studies. These different interventions would influence the results between 6-month and 2-year studies. Therefore, we did not compare the improvements shown between the 6-month and 2-year studies in this report.

For thirteen of the 24 participants (54.2%) who were lost to the follow-up for the full 2 years, the 6-month assessment was the last observation. These thirteen participants did not want to wear their respective insoles continuously. If we had a real intention to treat analysis using the method of Last Observation Carried Forward in order to handle the missing data, the changes in the instructions for the duration of insole use each day and the type of NSAID used as an adjunctive therapy after the 6-month assessment might introduce a bias at the clinical assessment. Thus, this study was completer analysis.

In this study, a completely randomized controlled trial was difficult. The randomizing using the date of birth was simple, but the investigators were aware of the group to which each patient had been assigned in this study. Moreover, the outcome assessors knew the results of the former published study[10]. A future study should be conducted and evaluated using a completely randomized and controlled trial method.

Concerning the study design, the intention to treat analysis was provided for the adjunctive therapy with NSAID. Any of the participants could quit the adjunctive therapy due to either knee pain relief or adverse effects, including stomachaches. However, there was no intention to treat analysis in the insole treatments and all participants were instructed to use their respective insole for the full 2 years. We are planning a new study in which any participant can quit the

use of the NSAID while using the insoles, according to their own decision to do so.

The prevalence of OA knee in our society is increasing due to the escalating proportion of elderly people. A conservative therapy such as use of an insole that provides a low cost, effective compliment or alternative to surgical treatment would be a very useful adjunct to the care of these patients and of benefit to the health care economy.

Acknowledgment

Dr Toda owns a patent, U.S. patent No. 6,585,674 B2, for the insole with subtalar strapping used in this study. This insole was granted FDA approval, and the establishment registration No. 3,004,473,061.

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