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Influence of concomitant heeled footwear when wearing a lateral wedged insole for medial compartment osteoarthritis of the knee

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Summary

Objective: To compare the influence of concomitant heeled footwear when wearing a lateral wedged insole for medial compartment of osteoarthritis (OA) of the knee, between everyday walking shoes for outdoor use and socks or flat footwear without a heel for indoor use.

Design: A total of 227 outpatients were prospectively randomized and treated with a neutral wedged insole inserted into shoes (placebo with shoes; $n = 45$), a wedged insole inserted into shoes (inserted insole with shoes; $n = 45$), a sock-type ankle supporter with a wedged insole when wearing socks or flat footwear (inserted insole without shoes; $n = 46$), a subtalar strapped insole when wearing shoes (strapped insole with shoes; $n = 45$), and the strapped insole with socks or flat footwear (strapped insole without shoes; $n = 46$). The Lequesne index of knee OA at week 12 was compared with the baseline in each treatment group.

Results: Twenty patients withdrew from the study, and the 207 patients who completed the 12-week study were evaluated. At the final assessment, participants wearing the inserted insole without shoes ($P = 0.003$), the strapped insole with shoes ($P < 0.0001$), and the strapped insole without shoes ($P < 0.0001$) demonstrated significantly improved Lequesne index scores in comparison with their baseline assessments. No significant differences were found in the placebo ($P = 0.16$) or the inserted insole with shoes ($P = 0.2$) groups.

Conclusion: Concomitant heeled footwear may decrease the efficacy of an inserted lateral wedged insole. The optimal usage of a lateral wedged insole for knee OA would be the combination with socks or flat footwear without heels.

Key words: Osteoarthritis, Knee, Orthotic devices, Barefoot, Insole, Clinical study.

Introduction

One of the first conservative mechanical treatments for patients with medial compartment osteoarthritis (OA) of the knee was the use of a lateral wedged insole. However, there were discrepancies in the clinical effects reported for the use of the lateral wedged insoles between Japan and Western countries.

In Japan, Sasaki *et al.*[1] reported that during their 2.5-year (mean) retrospective study, participants treated by a combination of lateral wedged insoles, mainly used without shoes indoors, and taking indomethacine (600 mg/day) showed a significantly greater improvement in the Knee Rating Scale (KRS) score measured from questions about pain and walking ability, compared with participants treated with indomethacine alone. Tohyama *et al.*[2] also reported that during their 9-year (mean) retrospective study, knee OA patients treated with shoe-type heel wedges, used without shoes indoors and taking analgesics, showed a significantly greater improvement in the KRS score, compared with patients treated with analgesics alone.

Two prospective randomized and controlled follow-up studies conducted in France, a 6-month and a 2-year study, showed that subjects with knee OA had a decreased non-steroidal anti-inflammatory drug (NSAID) intake when they wore bilateral lateral wedged insoles inserted into their ordinary shoes, but they did not report any changes in pain, stiffness, or function as measured by the Western Ontario and McMaster Universities' (WOMAC) OA index[3–5]. From the results of a double-blind, randomized crossover trial in 90 patients with knee OA in the US, Baker *et al.*[6] concluded that the effect of treatment with an inserted lateral wedged insole for knee OA was neither statistically significant nor clinically important. In the UK, Reilly *et al.*[7] questioned the applicability of the lateral wedged orthotic devices for knee OA reported in Japanese studies to a more general population.

There are differences in both the life styles and the footwears worn in Japan and Western countries. Most Japanese wear footwear outdoors, but not inside their homes, and the patients with knee OA use lateral wedged insoles without shoes indoors. We hypothesized that a clue to the solution of the discrepancies in the results from clinical studies of lateral wedged insoles conducted in Japan and Western countries was the use of concomitant footwear when using the insoles.

Therefore, this study was designed to compare the pain improvement for 12 weeks using a clinical index in patients treated with a neutrally wedged insoles used as a placebo inserted in the regular shoes the patients used everyday as walking shoes, a lateral wedged insole inserted in regular shoes, a sock-type ankle supporter with a lateral wedged insole when wearing socks or flat footwear without a heel, a strapped insole when wearing regular shoes and the strapped insole with socks or flat footwear.

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Methods

STUDY DESIGN

This study was accomplished through a prospective evaluation of patients with medial compartment knee OA, treated with either a neutrally wedged insole (used as a placebo) with shoes, a lateral wedged insole inserted in shoes, a lateral wedged insole without shoes, a strapped lateral wedged insole with shoes, and a strapped lateral wedged insole without shoes. The setting for the study was an Orthopedic Outpatient Clinic. The principal outcome results considered were as follows:

- Algo-functional disability improvement using the Lequesne index[8,9].
- Pain improvement using the Visual Analogue Scale (VAS) for subjective knee pain.
- The number of days that participants needed the NSAID.

The procedures employed were conducted in accordance with the Declaration of Helsinki[10].

INCLUSION/EXCLUSION CRITERIA

Two hundred and sixty-one new outpatients seen in our Orthopedic Outpatients Clinic from July to December in 2006 were defined as patients with medial compartment OA knee, according to the American College of Rheumatology criteria and a criterion stipulating a standing femorotibial angle greater than 176° shown by X-ray (the mean and standard deviation of the femorotibial angle in standing radiographs in healthy Japanese adults is $174.6 \pm 1.7°$ and a value exceeding 176° is considered to show varus deformity)[11,12].

Exclusion criteria following the report by Maillerfert *et al.*[3] were employed; 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, or any other symptomatic deformity of the foot, advanced arthroplasty of the hindfoot, any disease treated with insoles, previous ankle arthrodesis, tibial osteotomy, and any intra-articular corticosteroid or hyaluronan (HA) injection within 1 month. Additional exclusion criteria included patients using custom or functional shoes for knee OA as their everyday walking shoes.

There were 11 patients who were not eligible, judged by the exclusion criteria given above, and 13 patients refused to participate in the study.

In the initial visit, the patients were asked about their drug use history, i.e., use of an analgesic, NSAID and alternative medication including glucosamine use within the previous week. There were 171 patients who had a positive drug history of the 237 participants who were eligible for inclusion (72.2%) in the study. It was required that these 171 patients should discontinue the use of previous medications during a 1-week washout period between the initial visit and the baseline assessment. During the washout period, 10 of these 171 patients (5.8%) could not quit their previous medications.

After providing informed consent, 227 outpatients including 27 males and 200 females with knee OA (mean age: 64.3, standard deviation: 9.0) were treated with an orthotic device or the placebo for 12 weeks (Fig. 1).

PROCEDURES

All participants were given a uniform NSAID (lornoxicam 4 mg twice daily) as an adjunctive therapy. In the course of

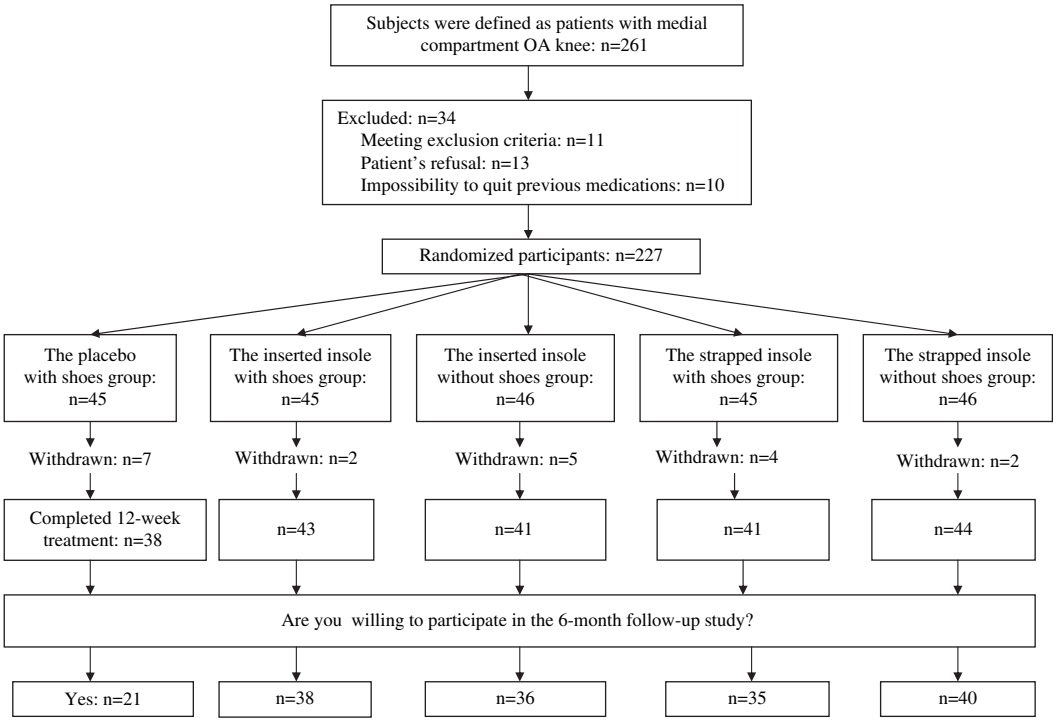

Fig. 1. Flowchart showing the patients who were lost to follow-up during the trial.

the study, each participant could intake the NSAID due to any painful conditions related to his/her knee OA, but the participants were instructed to record how many days they needed the NSAID in their diary.

TREATMENT GROUPS

Five types of orthotic devices were prepared:

1. A neutrally wedged insole for reducing foot odor used as a placebo inserted in regular shoes (Odor Eater®, Kobayashi Pharmaceuticals, Osaka, Japan) . The placebo insole [Fig. 2(A)] was inserted in the regular shoes the patients in this group wore as everyday walking shoes for outdoor use (the placebo with shoes).
2. A traditional shoe inserted insole (Wedge Heel Type®, Sanshinkousan Co. Ltd., Osaka, Japan) which had a lateral sponge rubber heel wedge with an elevation of 6.35 mm (tilt angle = 5°). The inserted insole [Fig. 2(B)] was inserted in shoes worn for outdoor use (the inserted insole with shoes).
3. A sock-type ankle supporter with the lateral rubber heel wedge insert sewn in. This insert was made of the same material and had the same tilt angle as the insert used for the above inserted insole, and it was inserted into the heel (Wedge heel supporter®, Sanshinkosan Co. Ltd., Japan). This sock-type ankle support [Fig. 2(C)] was employed for footwear for indoor use when wearing socks or flat footwear without any heel height (the inserted insole without shoes).
4. A urethane wedge with an elevation of 12 mm (tilt angle = 11.2°) which was fixed to an ankle sprain support, designed to fit around the ankle and subtalar joints (Sofra Wolfer OA^{R}, Taketoraa Co. Ltd., Tokyo, Japan). The ankle sprain support was made of 50% polyester, 30% nylon, and 20% polyurethane, with a 230% stretch rate. The strapped insole [Fig. 2(D)] was used either in combination with socks or flat footwear indoors (the strapped insole without shoes) or the patients' everyday walking shoes for outdoor use (the strapped insole with shoes).
5. Flat footwear [Fig. 2(E)] without any heel height (Tento-Yobo Shoes®, Taketora Co. Ltd., Tokyo, Japan) was used when a participant had a life style of wearing footwear indoors and was treated with the inserted insole without shoes or the strapped insole without shoes.

The 227 participants were randomly allocated into one of following groups using the intervention noted: the placebo with shoes group, the inserted insole with shoes group, the inserted insole without shoes group, the strapped insole with shoes group, or the strapped insole without shoes group (Fig. 1). The randomization procedure for the allocation was a computer-generated block method using sealed

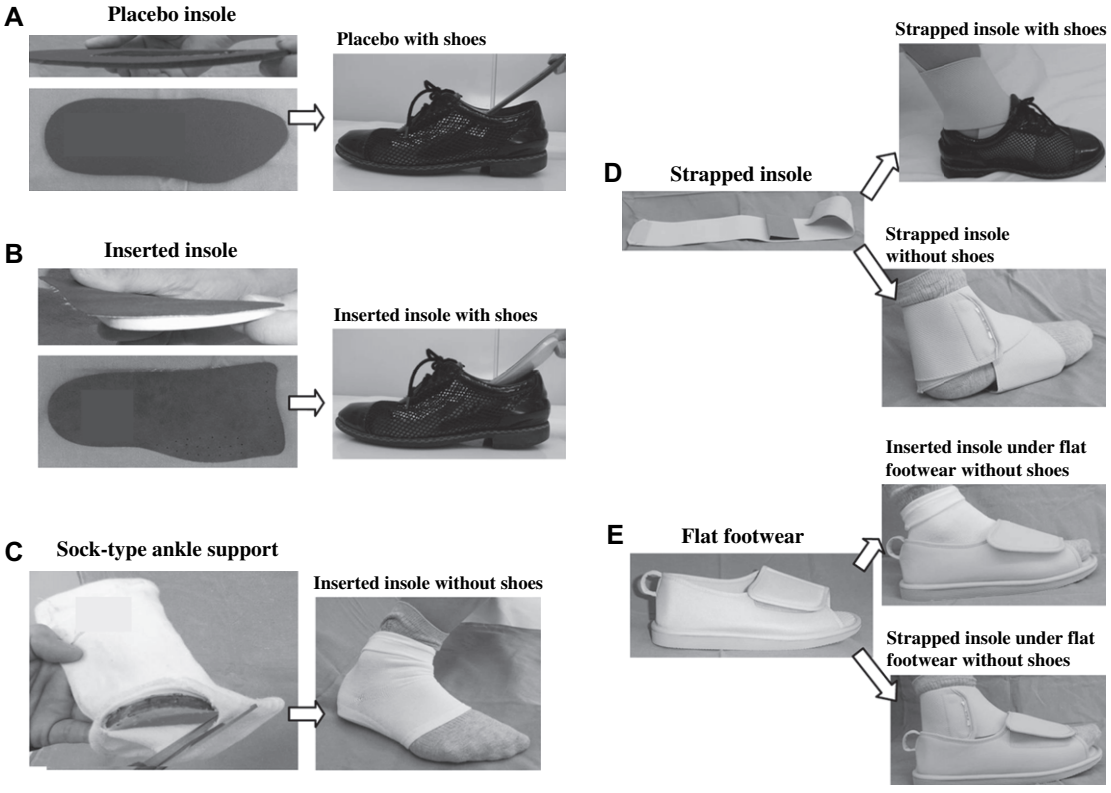

Fig. 2. The construction of the five types of orthotic devices. The placebo insole (A) was made by cutting a flat urethane sheet to match each patient's footprint. These flat urethane sheets contain an active carbon to reduce foot odor. The inserted insole (B) consisted of a nylon seat, adhesive tape, and a lateral rubber wedge with an elevation of 6.35 mm. The sock-type ankle supporter (C) extended from the to the metatarsals and a lateral wedged insole with an elevation of 6.35 mm was sewn into the heel. The strapped insoles (D) 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 flat footwear (E) has flat urethane soles with no heel.

envelopes. In the initial visit, clinicians were given randomly generated treatment allocations within sealed opaque envelopes in a series of blocks of 10. Once a patient had entered the trial in the baseline assessment, an envelope was opened and the patient was then offered the allocated intervention regimen.

Based on the results of our previous study, in which we investigated the optimal duration of daily wear for a strapped insole, participants in the inserted and strapped insole without shoes groups were instructed to use the insole in their homes between 5 and 10 h each day[13]. The participants in the placebo, inserted and strapped insole with shoes groups were advised to use the allocated insole whenever wearing shoes, between 5 and 10 h each day.

The device was checked every 2 weeks and proper use of the insole was confirmed by the wear of the material during that inspection.

CHARACTERISTICS OF THE PARTICIPANTS

The age, disease duration, gender, height, weight, Kellgren and Lawrence grade (K–L grade) for radiographic severity[14] and femorotibial angle assessed in standing radiographs were evaluated at the baseline. Disease duration was based upon the 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 from weight and height as weight (kg)/height^2 (m).

OUTCOME MEASURES

This study was accomplished through an intention to treat analysis. In the course of the 12-week study, every participant could propose quitting the allocated orthotic device for any discomfort that they did not feel before the use of the device. The reasons given for discontinuing the use of the allocated device were recorded for each group and the Lequesne index and the VAS at the last observation of material wear were carried forward.

A research nurse who was blind to the objectives of the study asked the participants to assess the Lequesne index and VAS for subjective knee pain at the baseline and 12-week assessments. The Lequesne index and VAS at the 12-week assessment were compared with the baseline recordings for each group. The analyses were repeated for the subset of women only, as knee OA biomechanics and footwear may differ between the sexes.

At the final assessment, the participants were asked how many days they needed the NSAID because of a painful condition related to his/her knee OA, based on their diary during the 12-week study. The number of days they needed the NSAID was compared between the five groups.

After receiving treatment for 12 weeks, all of the patients were asked whether they would be willing to participate in the 6-month follow-up study to evaluate the tolerability of the allocated orthotic device.

STATISTICAL ANALYSES

The characteristics of the participants (age, disease duration, BMI, and femorotibial angle), VAS and Lequesne index at the baseline assessment, and the number of days the participants needed the NSAID between the groups were compared using one-way analysis of variance (ANOVA). The radiographic grade, sex and the number of subjects willing to participate in the 6-month follow-up study were compared between the groups using the chi-squared test. Applying a Bonferroni adjustment for the use of the multiple ANOVA and the chi-squared test, 10 comparisons were conducted for the five groups, and we defined statistical significance at P less than 0.005 (0.05/10).

The paired t test was used to assess the statistically significant differences in the Lequesne index and the VAS between the baseline and the 12-week assessments in each group. Statistical significance levels for the paired t test were considered to be $P < 0.05$.

Results

CHARACTERISTICS OF THE PARTICIPANTS

Twenty of the 227 subjects (8.8%) did not complete the 12-week study, including seven in the placebo with shoes group, two in the inserted insole with shoes group, five in the inserted insole without shoes group, four in the strapped insole with shoes group, and two in the strapped insole without shoes group.

Of the 207 who completed the study, there were 38 participants in the placebo with shoes group, 43 in the inserted insole with shoes group, 41 in the inserted insole without shoes group, 41 in the strapped insole with shoes group, and 44 in the strapped insole without shoes group (Fig. 1). At the baseline assessment, there were no significant differences between any two of the five groups in age, disease duration, BMI, femorotibial angle, Lequesne index, VAS or distributions of gender, and K–L grade ($P > 0.005$) (Table I). Four of the 41 subjects (9.8%) in the inserted insole without shoes group and five of the 44 (11.4%) subjects in the strapped insole without shoes groups had a life style that included wearing footwear indoors. These nine subjects were instructed to use the allocated insole with the flat footwear indoors.

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

LEQUESNE INDEX

The mean values and standard deviations for changes in the Lequesne index at the final assessment, compared with the baseline assessment were, -0.66 ± 4.4 in the placebo with shoes group, -0.44 ± 3.7 in the inserted insole with shoes group, -1.7 ± 4.2 in the inserted insole without shoes group, -3.0 ± 4.8 in the strapped insole with shoes group, and -3.9 ± 5.0 in the strapped insole without shoes group. Participants wearing the inserted insole without shoes ($P = 0.003$), the strapped insole with shoes ($P < 0.0001$) and the strapped insole without shoes ($P < 0.0001$) demonstrated significantly improved Lequesne index values in comparison with their baseline assessments. These significant differences were not found in the groups with the placebo with shoes ($P = 0.16$) or the inserted insole with shoes ($P = 0.2$) (Table II).

VAS FOR SUBJECTIVE KNEE PAIN

Compared with the baseline assessments, the VAS for subjective knee pain in the strapped insole with shoes ($-6.3 \pm 21.1\%$) and the strapped insole without shoes groups at week 12 ($-8.7 \pm 21.7\%$) was significantly improved ($P = 0.009$ and $P = 0.002$, respectively). There

Table I
Characteristics of the participants who completed the 12-week study (n = *207*)

		Age (years)	Disease duration (years)	Body mass index (kg/m^2)	Femorotibial angle (degree)	Lequesne index (score)	VAS (%)	Sex (no. of cases)	Radiographic grade (no. of cases)
I. Placebo with shoes ($n = 38$)									
Mean (SD)		64.6 (9.8)	3.4 (4.8)	24.6 (3.1)	180.3 (5.3)	9.0 (4.8)	44.3 (19.0)	Men (6)	II (23)
Median		66	1.0	24.3	179.5	9.0	50.0	Women (32)	III (9)
95% CI		61.2–68.1	1.8–5.1	23.5–25.7	178.5–182.1	7.3–10.7	38.4–50.3		IV (6)
II. Inserted insole with shoes ($n = 43$)									
Mean (SD)		66.1 (8.6)	4.3 (5.2)	24.7 (2.9)	180.4 (4.5)	9.9 (4.8)	39.2 (19.9)	Men (5)	II (27)
Median		67	2.3	24.2	180.0	9.0	39.5	Women (38)	III (13)
95% CI		63.5–68.8	2.7–5.9	23.8–25.6	179.0–181.8	8.4–11.3	33.0–45.4		IV (3)
III. Inserted insole without shoes ($n = 41$)									
Mean (SD)		65.2 (8.6)	4.2 (5.3)	24.8 (2.9)	180.5 (4.2)	10.4 (5.0)	45.5 (21.2)	Men (5)	II (25)
Median		67	1.5	24.2	179.0	9.0	47.0	Women (36)	III (13)
95% CI		62.5–67.9	2.5–5.9	23.8–25.7	179.1–181.9	8.8–12.0	38.8–52.2		IV (3)
IV. Strapped insole with shoes ($n = 41$)									
Mean (SD)		62.9 (7.5)	4.7 (5.2)	25.7 (3.5)	181.7 (4.9)	9.8 (5.4)	38.5 (20.5)	Men (3)	II (28)
Median		63	3.0	26.1	181.0	10	40	Women (38)	I (8)
95% CI		60.4–65.4	2.9–6.4	24.5–26.8	180.1–183.3	8.0–11.6	31.7–45.4		IV (5)
V. Strapped insole without shoes ($n = 44$)									
Mean (SD)		64.0 (9.6)	4.6 (6.0)	25.2 (3.6)	181.6 (5.1)	9.9 (5.4)	38.1 (19.2)	Men (5)	II (30)
Median		65.5	1.8	25.1	180.5	10	39.5	Women (39)	I (9)
95% CI		60.9–67.0	2.7–6.5	24.1–26.4	179.9–183.2	8.2–11.6	31.9–44.2		IV (5)
P values between thegrades	I and II	0.49	0.42	0.84	0.92	0.49	0.33	0.59	0.42
	I and III	0.72	0.44	0.85	0.86	0.25	0.71	0.65	0.43
	I and IV	0.65	0.15	0.34	0.18	0.42	0.24	0.24	0.77
	I and V	0.99	0.16	0.66	0.21	0.39	0.19	0.56	0.75
	II and III	0.73	0.98	0.99	0.94	0.63	0.17	0.94	0.99
	II and IV	0.24	0.50	0.23	0.19	0.90	0.81	0.50	0.44
	II and V	0.46	0.54	0.50	0.22	0.86	0.72	1.0	0.40
	III and IV	0.41	0.49	0.24	0.22	0.72	0.12	0.48	0.42
	III and V	0.70	0.52	0.52	0.26	0.75	0.089	0.91	0.42
	IV and V	0.65	0.95	0.58	0.91	0.97	0.92	0.52	0.99

were no statistically significant differences between the VAS at the 12-week and baseline assessments in the groups with the placebo with shoes, the inserted insole with shoes and the inserted insole without shoes ($P = 0.13$, $P = 0.41$ and $P = 0.31$, respectively) (Table II).

WOMEN SUBSET ANALYSIS

In the subset of 183 women who completed the 12-week study, participants wearing the strapped insole with shoes ($n = 38$) and the strapped insole without shoes ($n = 39$) demonstrated both Lequesne index scores and VAS that were significantly improved, compared with their baseline assessments. These significant differences were not found in the placebo ($n = 32$) or the inserted insole with shoes group ($n = 38$). In the inserted insole without shoes group ($n = 36$), there was a significant difference in the Lequesne index score, but not in the VAS (Table III). The distribution of the statistical significances was the same as it was in the assessments for both male and female subjects.

NUMBER OF DAYS SUBJECTS NEEDED THE NSAID

Concerning the number of days the participants needed the NSAID during the 12-week study period, there were significant differences demonstrated between the groups with placebo with shoes (17.4 ± 10.9 days) and the inserted insole with shoes (12.5 ± 6.9 days) ($P = 0.004$), between the groups with the placebo with shoes and the inserted insole without shoes (11.8 ± 7.1 days) ($P = 0.001$), between the groups with the placebo with shoes and the strapped insole with shoes (10.7 ± 6.3 days) ($P < 0.0001$), and between the groups with the placebo with shoes and the strapped insole without shoes (11.2 ± 6.5 days) ($P < 0.0001$) (Fig. 3).

There were no significant differences between any other two groups in the number of days the participants needed the NSAID ($P > 0.005$).

OBSERVATIONS OF DROP-OUTS

Concerning the reasons for withdrawal, 13 of the 20 participants (65%) proposed quitting the allocated orthotic device, four withdrew due to family commitments, two moved, and one received total knee arthroplasty. The reason given for proposing to quit the placebo with shoes was its ineffectiveness ($n = 4$). One subject cited foot sole pain as the reason for discontinuing the use of the inserted insole with shoes. The reasons for discontinuing the use of the inserted insole without shoes were sweating of the foot ($n = 2$) and foot sole pain ($n = 1$). The reasons for discontinuing the use of the strapped insole with shoes was foot pain due to the foot being cramped inside their shoes ($n = 2$) and popliteal pain ($n = 1$). One subject cited popliteal pain as the reason for discontinuing the use of the strapped insole without shoes (Table IV).

Treatments for the 13 participants who indicated that they wanted to quit the allocated orthotic device were changed

Table II
*Comparison of the Lequesne index and VAS between baseline and 12 weeks (*n = *207)*

	Lequesne index			VAS (%)		
	12 weeks	Comparison with the baseline	*P* values between the baseline and 12 weeks	12 weeks	Comparison with the baseline	*P* values between the baseline and 12 weeks
Placebo with shoes ($n = 38$)						
Mean (SD)	8.1 (5.0)	−0.66 (4.4)		46.5 (15.3)	2.6 (10.0)	
Median	8.0	−0.5	0.16	50.0	0	0.13
95% CI	6.4–9.7	−2.1–0.78		41.4–51.5	−0.75–5.9	
Inserted insole with shoes ($n = 43$)						
Mean (SD)	9.1 (5.3)	−0.44 (3.7)		41.9 (23.1)	2.3 (18.5)	
Median	8.0	−1.0	0.20	46.0	0	0.41
95% CI	7.5–10.7	−1.6–0.7		34.8–49.0	−3.4–8.0	
Inserted insole without shoes ($n = 41$)						
Mean (SD)	8.4 (5.8)	−1.7 (4.2)		42.0 (25.4)	−3.5 (21.7)	
Median	7.0	−1.0	0.003*	44.0	−1.0	0.31
95% CI	6.6–10.2	−3–0.36		34.0–50.1	−10.3–3.4	
Strapped insole with shoes ($n = 41$)						
Mean (SD)	6.8 (5.1)	−3.0 (4.8)		29.4 (19.4)	−6.3 (21.1)	
Median	6.0	−2.0	$P < 0.0001$*	24.0	−4.0	0.004*
95% CI	5.1–8.5	−4.6–1.4		23.0–35.9	−13.3–0.78	
Strapped insole without shoes ($n = 44$)						
Mean (SD)	6.2 (5.3)	−3.9 (5.0)		27.4 (20.0)	−8.7 (21.7)	
Median	5.0	−3.0	$P < 0.0001$*	22.0	−8.0	0.002*
95% CI	4.5–7.9	−5.5–2.3		20.9–33.8	−15.7–−1.7	

*$P < 0.05$.

from the orthotic device to standard conservative treatments, including an intra-articular injection with HA. The four subjects who withdrew due to family commitments were lost for the follow-up study. We provided a letter of introduction to two subjects who moved and one who received total knee arthroplasty, so they could change hospitals.

The analyses were repeated, adding the 20 drop-out cases to the 207 who completed the study using the Last Observation Carried Forward method in order to handle the missing data ($n = 227$). Compared with the baseline assessments, the Lequesne index was significantly improved in the inserted insole without shoes group ($P = 0.006$), the strapped insole with shoes group ($P < 0.0001$), and the strapped

Table III
*Comparison of the outcomes for women subset between baseline and 12 weeks (*n = *183)*

	Lequesne index			VAS (%)		
	12 weeks	Comparison with the baseline	*P* value between the baseline and 12 weeks	12 weeks	Comparison with the baseline	*P* value between the baseline and 12 weeks
Placebo with shoes ($n = 32$)						
Mean (SD)	8.8 (5.1)	−0.62 (4.7)		47.8 (16.2)	2.9 (9.6)	
Median	8.0	0	0.22	50.0	0	0.11
95% CI	6.9–10.8	−2.4–1.2		41.7–53.9	−0.71–6.6	
Inserted insole with shoes ($n = 38$)						
Mean (SD)	9.4 (5.4)	−0.29 (3.9)		42.1 (23.4)	3.7 (18.6)	
Median	8.5	−0.5	0.34	45.5	2	0.23
95% CI	7.6–11.1	−1.6–1.0		34.4–49.8	−2.4–9.9	
Inserted insole without shoes ($n = 36$)						
Mean (SD)	8.7 (5.8)	−1.8 (4.4)		42.1 (26.2)	−3.7 (22.9)	
Median	7.0	−1.0	0.06	42.5	−0.5	0.34
95% CI	6.7–10.7	−3.3–0.25		33.2–50.9	−11.5–4.1	
Strapped insole with shoes ($n = 38$)						
Mean (SD)	6.9 (5.3)	−3.2 (4.9)		29.5 (19.0)	−7.4 (21.4)	
Median	5.5	−2.5	$P < 0.0001$*	24.5	−5.5	0.004*
95% CI	5.1–8.8	−4.9–1.5		22.9–36.1	−14.8–0.70	
Strapped insole without shoes ($n = 39$)						
Mean (SD)	6.1 (5.4)	−4.0 (5.2)		27.2 (19.2)	−9.4 (21.9)	
Median	5.0	−3.5	$P < 0.0001$*	22.0	−7.5	0.002*
95% CI	4.2–7.9	−5.8–−2.2		20.6–33.8	−17.1–1.8	

*$P < 0.05$.

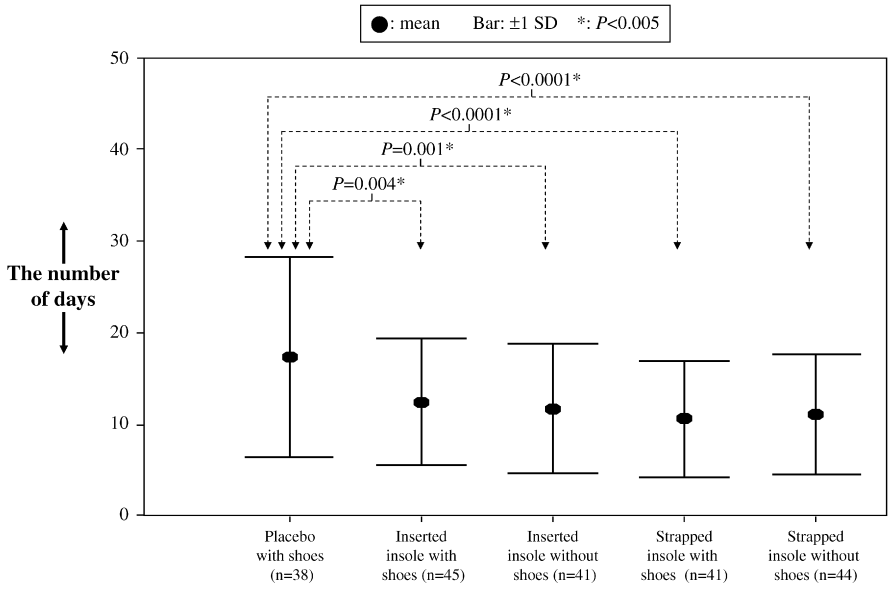

Fig. 3. Comparison of the number of days the subjects needed the NSAID between the five groups.

insole without shoes group ($P < 0.0001$), but not in the placebo with shoes group ($P = 0.51$) or the inserted insole with shoes group ($P = 0.33$). The VAS was significantly improved in the strapped insole with shoes group ($P = 0.006$) and the strapped insole without shoes group ($P < 0.0001$), but not in the placebo with shoes group ($P = 0.067$), the inserted insole with shoes group ($P = 0.37$) or the inserted insole without shoes group ($P = 0.64$). The distribution of the statistical significances was the same as it was in the assessments that only included subjects who completed the study.

WILLING TO PARTICIPATE IN THE 6-MONTH STUDY

Thirty-seven of the 207 subjects (17.9%) who completed the 12-week study, including 17 in the placebo with shoes group, five in the inserted insole with shoes group, five in the inserted insole without shoes group, six in the strapped

Table IV
The outcomes at the baseline and last assessments for drop-out cases (n = 20)

	The reason for withdrawal	The last assessment (weeks)	Lequesne index (points)			VAS (%)		
			Baseline	Last	Change	Baseline	Last	Change
Placebo with shoes								
Case 1	Inefficacy	2	6 points	9	3	40%	52	12
2	Inefficacy	2	7	9	2	45	63	18
3	Inefficacy	2	9	11	2	50	55	5
4	Inefficacy	2	10	20	10	49	61	12
5	Arthroplasty	10	13	16	3	40	46	6
6	Having moved	8	17	17	0	50	32	−18
7	Household commitments	6	18	17	−1	48	45	−3
Inserted insole with shoes								
Case 1	Foot sole pain	2	2 points	9	7	28%	57	29
2	Household commitments	6	14	13	−1	65	49	−16
Inserted insole with shoes								
Case 1	Foot sole pain	2	5 points	9	4	20%	63	43
2	Foot sole pain	2	5	8	3	50	63	13
3	Sweating in the feet	2	6	6	0	44	48	4
4	Sweating in the feet	4	11	9	−2	24	33	9
5	Having moved	6	16	14	2	31	35	4
Strapped insole with shoes								
Case 1	Feeling cramped inside shoes	2	2 points	4	2	50%	59	9
2	Feeling cramped inside shoes	2	6	5	−1	50	45	−5
3	Popliteal pain	4	8	9	1	75	67	−8
4	Household commitments	6	15	9	−6	78	61	−17
Strapped insole without shoes								
Case 1	Popliteal pain	2	4 points	7	3	27%	50	23
2	Household commitments	8	16	10	−6	50	24	−26

insole with shoes group, and four in the strapped insole without shoes group, did not want to wear their respective insoles continuously (Fig. 1).

The frequency of participants who did not want to wear their respective insoles continuously was significantly higher in the placebo with shoes group, compared with the other groups ($P < 0.0001$).

Discussion

In this study, participants wearing the inserted insole without shoes demonstrated significantly improved Lequesne index scores in comparison with their baseline assessments. These significant differences were not found in the placebo with shoes group. These results concur with the reports by Sasaki and Tohyama *et al.*[1,2], in which patients treated with inserted insoles mainly used without shoes indoors and an analgesia showed a significantly greater improvement than participants treated with an analgesia alone.

Although neither the VAS nor Lequesne index was significantly reduced at the 12-week assessment compared with the baseline assessment in the inserted insole with shoes group, there was a significant difference in the number of days the subjects needed the NSAID demonstrated between the placebo with shoes and inserted insole with shoes groups in the current study. These results corresponded to the results shown by Maillerfert and Pham *et al.*[3,4], which showed that subjects with knee OA demonstrated a decreased NSAID intake when they wore bilateral lateral wedged insoles inserted into their ordinary shoes, but no change in the WOMAC OA index.

One standard parameter assessed as a marker of knee loading is the external knee adduction moment, a varus moment on the knee that reflects the magnitude of medial compartment joint loading[15]. Kerrigan *et al.*[15] reported that the insertion of lateral wedged insoles into regular shoes can induce significant decrease in knee varus moment (by up to 5–7%) in subjects with medial compartment knee OA. They also showed that even women's shoes with a 1.5 inch heel (moderate high-heeled shoes) significantly increased knee varus moment compared with walking barefoot[16].

Shakoor *et al.*[17] reported that peak joint loads at the knees significantly decreased during barefoot walking, with an 11.9% reduction noted in the knee varus moment compared with when wearing commercial walking shoes. It was of interest that they observed relative load reductions of nearly 12% at the knee merely by walking barefoot, which appears to be substantially greater than the experience with lateral wedged inserts by Kerrigan *et al.*[15]. Shakoor *et al.*[17] mentioned that most commercial walking shoes have a partial lift at the heel, and thus, the complete lack of a "heel" during barefoot walking may be effective for reducing the peak torque at the knee. Kuroyanagi *et al.*[18] showed that the varus moment was reduced 13.1% due to wearing the lateral wedged insole with elastic strapping of the subtalar joint (the strapped insole) added to a bare foot, compared with walking barefoot for 37 patients with knee OA. Clinical results from a study on the use of strapped insole were also reported by Toda *et al.*[19]

According to the results from these reports[15–18], we considered that the differences in the varus moments between wearing the strapping insole added to a bare foot and wearing moderate high-heeled shoes alone might be greater than the differences shown between wearing moderate high-heeled shoes alone and when inserting wedges into the shoes. These biomechanical effects on the varus moment may reflect the clinical efficacy of treatments for knee OA using lateral wedged insoles. From these results, we concluded that the discrepancies in the reported clinical effects of inserted insoles between Japan and Western countries will depend on the differences of concomitant heeled footwear when using inserted insoles.

Yasuda and Sasaki[20] speculated that the beneficial effect of the inserted insole was due to the reduction in the medial knee joint surface loading with a concurrent reduction in lateral tensile forces, even though the device failed to correct the femorotibial angle in patients with varus deformity with medial compartment OA knee. In research conducted on alternatives to correct the femorotibial angle by a lateral wedged insole, this limitation of the inserted insoles was addressed through the development of a novel lateral wedged insole with elastic fixation of the subtalar joint (the strapped insole)[19]. The realignment produced by the strapped insole led to the conclusion that an insole with elastic fixation obtained with tension by a subtalar and ankle joint band leads to valgus angulation of the talus, resulting in correction of the femorotibial angle in patients with varus deformity knee OA[19].

In our prospective randomized controlled studies, a 6-month study and a 2-year follow-up study, participants wearing the subtalar strapped insole demonstrated significantly decreased femorotibial angles, and significantly improved Lequesne index values in comparison with their baseline assessments[21,22]. These significant differences were not found in the groups with the inserted insoles.

In the current study, even when worn with shoes, the strapped insole significantly improved both the VAS and Lequesne index values obtained at the 12-week assessment, compared with the baseline assessment. However, the disadvantage associated with the strapped insole concomitant with everyday walking shoes was that some patients felt foot pain due to feeling cramped inside their shoes in order to accommodate the thickness of the supporter and urethane insole. This disadvantage was demonstrated in the current study and also in previous studies[21,22].

In the current study, significantly improved VAS and Lequesne index values were demonstrated for the strapped insole without shoes group at week 12, in comparison with the baseline assessment. The number of days the subjects needed the NSAID was significantly less in the strapped insole without shoes group than that in the placebo with shoes group.

Considering these results, we concluded that when wearing socks or flat footwear without heels, the strapped insole would be more effective than an inserted insole with shoes for patients with knee OA. Although the change in life style will be difficult we would like to recommend taking off shoes with heels and walking, while wearing socks or flat footwear without heels with a strapped insole at home for Western people with knee OA.

The current study was limited in that the methodology employed for the confirmation of material wear was incomplete. We detected patients who did not use the insoles from the observations during the inspections of the material wear. When the participants in the strapped insole with shoes group used the insoles inside without shoes at home, 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 other reliability measures, including material testing, in a future study.

Future studies should assess the footwear heel height, which may be exaggerated, and therefore minimize the

effect of the lateral wedge. Kerigan *et al.*[23] showed that men's sneakers and dress shoes with an average 0.5 inch heel height did not exaggerate knee joints' torque, in men, compared with walking bare foot, although they also showed that women's shoes with a 1.5 inch heel height significantly increased the torque[16]. Thus, the actual lower limit for exaggerated footwear heel height may be between 0.5 and 1.5 inch.

The observation period in this study was only 12 weeks. One of the reasons we employed this length for the observation period was that the compliance of patients in the placebo group was considered to decrease in a long-term study, as the frequency of participants who were not willing to participate in the 6-month study was significantly higher in the placebo with shoes group than in the other groups. However, it will be necessary to continue the follow-up period in order to assess treatment efficacy over an observation period longer than the 12-week period, and we consider that it will be necessary to employ a control group different from the placebo group used in this study.

Concerning the different material employed for the inserted and strapped insoles, we assessed the lower extremity valgus realignment, symptomatic relief and adverse effects in patients treated with the insoles composed of sponge rubber or urethane with subtalar strapping in a previous study[24]. The lateral wedge in combination with subtalar strapping had a more natural form-fit to the sole than the insole insert alone. Although an ordinary inserted lateral wedged insole had been made of sponge rubber, we concluded that the sponge rubber is too hard to use for the insole with subtalar strapping.

In the current study, a ready-made, low cost and readily available insole was used as the placebo insole. The material employed for the neutral wedged insole used as the placebo was therefore not the same material employed for the inserted lateral wedge with shoes, although the two devices were formed into a nearly identical shape. In order to function as a true control, the neutral wedged insole should have been comprised of the same material as the lateral wedge, and this issue will be addressed in a future study.

Furthermore, there was no provision for arch support in the midfoot of the inserted lateral wedge with shoes, and therefore it was possible that a flexible low arched foot type would pronate in the midfoot as a result of the lateral wedging as opposed to translating the effect of the wedge to the knee. A future study should be conducted to evaluate the use of the inserted lateral wedge combined with arch support.

The prevalence of OA knee in our society is increasing due to the escalating proportion of elderly citizens. 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.

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