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ORIGINAL ARTICLE

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A comparative study on the effect of the insole materials with subtalar strapping in patients with medial compartment osteoarthritis of the knee

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Abstract This study was conducted to assess the symptomatic effects of the insole with an elevation of 12 mm composed of urethane (urethane insole) or of sponge rubber (rubber insole) with subtalar strapping in patients with medial compartment osteoarthritis of the knee (knee OA). The setting was an outpatient clinic. Eighty-four patients with knee OA were prospectively randomized, and evaluated and treated with the urethane or rubber insole for 4 weeks. Randomization was performed according to birth date and each participant was categorized into the urethane group or the rubber group. The percentage of remission of Lequesne index of severity for knee OA was compared between urethane and rubber insole groups at the conclusion of the study. Participants were asked to report adverse effects of use of the respective insoles. The percentage of remission was significantly improved in the urethane insole group ($n = 42$) compared with the rubber insole group ($n = 42$) ($P = 0.001$). Adverse effects were more common in the rubber insole group (17 out of 42, 40.5%) than in the urethane insole group (8 out of 42, 19.0%), and this was statistically significant ($P = 0.028$). The inserted insole in combination with subtalar strapping had a more natural form-fit to the sole than the insole insert alone. In our study of the subtalar strapping insole, an insole composed of urethane, was more comfortable than that of rubber sponge.

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Potential conflict of interest: Dr. Toda owns a patent, U.S. Patent No. 6,585,674 B2, for the insole with subtalar strapping used in this study.

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Key words Insole · Knee · Material · Orthotic device · Osteoarthritis

Introduction

Osteoarthritis of the knee (knee OA), which occurs symptomatically in approximately 6% of adults 30 years of age and older and in 11% of adults 65 years of age and older, accounts for more mobility disability in the elderly than any other disease.[1] 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.[2]

While surgeons have made remarkable progress in techniques such as high tibial osteotomy and total knee arthroplasty for treatment of medial compartment knee OA, the vast majority of patients are hesitant to undergo surgical treatment. One of the first forms of conservative mechanical treatment for patients with medial compartment knee OA was the use of lateral wedged inserted insoles. Yasuda and Sasaki[3] reported, however, that the inserted insole failed to correct the femorotibial angle in patients with varus deformity and medial compartment knee OA. 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 with high tibial osteotomy.

In research conducted on conservative alternatives to surgical correction of the femorotibial angle, this limitation of the inserted insoles was addressed through the development of a novel lateral wedged insole with elastic strapping of the subtalar joint. The subtalar strapping insole resulted in a significant change in the talocalcaneal angle, the talar tilt angle, and the femorotibial angle, while the inserted insole alone produced a significant change only in the talocalcaneal angle on standing radiographs.[4] The insole with subtalar strapping produced the desired realignment. This

led to the conclusion that an insole with elastic fixation obtained with tension of a subtalar and ankle joint band leads to valgus angulation of the talus. This corrects the femorotibial angle in patients with varus deformity knee OA, and may have a therapeutic effect similar to that of high tibial osteotomy.

Further studies suggested that the subtalar strapping increased the effectiveness of the insole in treating the symptoms of OA of the knee measured as increased maximum distance of ambulation and for pain reduction while asleep, upon awakening, and upon standing up from a seated position.[5] A significant correlation was observed between lower extremity lean body mass per body weight and symptomatic relief of knee OA by treatment with the subtalar strapping insole.[6] Without muscular support of the anatomic realignment, patients may retain their previous varus stance and gait, negating the effect of insole therapy. In another study, we assessed the optimal tilt of the lateral wedged insole with subtalar strapping.[7] Patients with knee OA were treated with a lateral wedge with elevations of 8, 12, or 16 mm with subtalar strapping. We concluded from the results that the 12-mm wedge is best suited for routine and regular use.

Despite advances in our understanding of the lower extremity valgus realignment and symptomatic improvement induced by the insole with subtalar strapping, and its indication and optimal tilt, the optimal material of the lateral wedge has not yet been elucidated. Therefore, this study was designed to assess lower extremity valgus realignment, symptomatic relief, and adverse effects in patients treated with the insole composed of sponge rubber or urethane with subtalar strapping.

Materials and methods

This study was accomplished through prospective, randomized evaluation of patients with knee OA treated with the lateral wedged insole composed of sponge rubber with subtalar strapping, as well as those treated with the insole composed of urethane with subtalar strapping. The principal outcome measures considered were pain improvement using a clinical index and the radiographic bony alignment. Additionally, side effects and complications of the use of these insoles were measured. The procedures outlined in the Helsinki Declaration were followed.[8]

Subjects were defined as patients with medial compartment OA knee, according to the American College of Rheumatology criteria, and a standing femorotibial angle greater than 176° by X-ray (the standard value of femorotibial angle in standing radiographs is 176° in healthy Japanese adult females).[9,10]

Exclusion criteria following the report by Maillerfert et al.[11] were functional class of IV (Steinbrocker), radiographic grade of IV according to Kellgren and Lawrence,[12] greater or similar reduction in lateral than medial femorotibial joint space width (concomitance with lateral knee OA) on plain posteroanterior X-rays, bilateral knee OA, secondary knee OA, hip OA, ankle OA, hallux rigidus, valgus deformity of the midfoot, other symptomatic deformity of the foot, advanced arthroplasty of the hindfoot, any disease treated with insoles, previous ankle arthrodesis, tibial osteotomy, and intra-articular corticosteroid injection within 1 month.

After providing informed consent, 84 new female outpatients with knee OA (>45 years old, mean age 63.4, standard deviation 8.9) seen in our Orthopedic Outcome Clinic from May to July in 2003 and January in 2004 were treated with the insole with subtalar strapping for 4 weeks. All participants were also treated with a nonsteroidal anti-inflammatory drug (NSAID) (acemetacine, 30 mg) orally twice a day as adjunctive therapy. All other adjunctive therapies were discontinued, including intra-articular hyaluronan injections and physical therapy.

Each symptom relating to knee OA was evaluated according to the Lequesne index[13] for OA knee including: (1) pain during nocturnal bed rest with full extension of the knee, (2) duration of morning stiffness or pain after getting up, (3) increased pain with standing for 30 min, (4) pain on walking, (5) pain when getting up from sitting position without the help of arms, (6) maximum distance walked, (7) ability to climb stairs, (8) ability to descend stairs, (9) ability to squat, and (10) ability to walk on uneven ground. Items (1) and (2) concerning pain during nocturnal bed rest and pain after awakening were evaluated by patient self-report, as patients could not be observed at night or early in the morning. All other items were assessed under stable conditions by research nurses who were uninformed of the objective of the study at the commencement of treatment and then again at the fourth week thereafter.

Disease duration was based upon patients' recollection of the onset of their knee pain. Height was measured to the nearest 1 cm using a stadiometer and weight was measured to the nearest 0.1 kg with subjects standing erect, wearing underwear and robes without shoes. 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. Radiographs were evaluated for changes characteristic of OA in anteroposterior views using the Kellgren and Lawrence grade (K-L grade), as described in the Atlas of Standard Radiographs.[14] The age, disease duration, height, weight, index of severity for knee OA, and K-L grade were evaluated at baseline.

Two types of materials were prepared: urethane was made from PORON L-24 (Rogers Corp., Rogers, CT, USA), with a density of 240 kg/m^3, 0.54 MPa pull strength, 115% stretch rate, and 1.8 N/mm rip strength; and sponge rubber was made from PORON MO-48 (Rogers Corp.), with a density of 480 kg/m^3, 2.92 MPa pull strength, 153% stretch rate, and 8.1 N/mm rip strength. The urethane (PORON L-24) was suitable as a cushion material under the buttons of a cellular phone. The sponge rubber (PORON MO-48) was usually used as skid material inside shoes.

The urethane and sponge rubber were both manufactured into a lateral wedged insole with an elevation of 12 mm. The wedged insole was wrapped and fixed to the

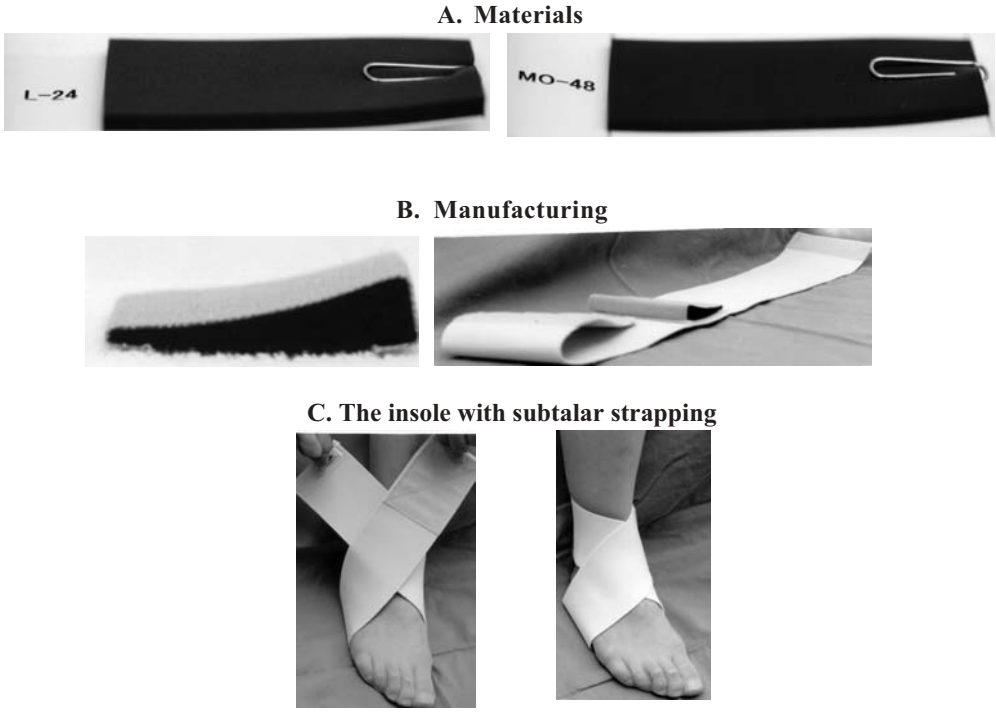

Fig. 1A–C. Construction of the two types of insole. **A** Concerning the hardness of materials, the urethane (*L-24*) was so soft that a paperclip cut into its flesh, although the clip did not cut into the sponge rubber (*MO-48*). **B** The urethane and sponge rubber were manufactured into lateral wedged insoles with elevations of 12 mm. The surface was wrapped and fixed to the skid by an adhesive elastic bandage. The strapped insoles consist of an ankle support band and the lateral wedge. **C** The ends of the support were twisted in a figure-of-eight around the ankle and subtalar joints. The ends were affixed with adhesive tape at the posterior ankle and subtalar joints

skid by an adhesive elastic bandage with a rough surface (Breabun, Taketora, Tokyo, Japan). The insoles were fixed to an ankle sprain support (Sofra Wolfer, Taketora), designed to fit around the ankle and subtalar joints. The two insoles were formed into the same shape and color (Fig. 1).

Randomization was performed by date of birth. Participants with even-numbered dates of birth were treated with the sponge rubber insole (the rubber insole group) and those having odd-numbered dates of birth were treated with the urethane insole (the urethane insole group). Participants were instructed to use the insole without shoes in their home, for a period of 3–6 h each day.

Before initiating the 4-week study, standing radiographs of the knee joints in posteroanterior views were completed for baseline comparison. The arms were positioned at 90° of shoulder flexion with the hands gripping an adjustable height stabilization bar. Participants stood on one leg (device side) in the position of full knee extension, standing 1 m from the X-ray source, with constant and reproducible foot position (foot map). The X-ray beam centered on the joint space and was oriented parallel to the tibial plateau. When the participant's posture was stabilized, the roentgenogram was taken. The radiographic analysis was performed for each subject with and without the respective device (Fig. 2A). Concerning the active range of motion of the knee, the average degree of flexion was 111.7 (SD 12.9, minimum 80, maximum 130) and that of extension was −3.4 (SD 3.0, minimum −10, maximum 0).

The femorotibial angle was measured as 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 (Fig. 2B). We did not use a long-leg film because this study was focused on the change of knee alignment caused by the insoles.

The radiographs were sent to another hospital via the Internet. The radiographic assessment of severity and femorotibial angle were determined by three orthopedic surgeons who were blinded as to the category of the patients. The three surgeons discussed each case and reported their findings.

The trial lasted 4 weeks. The Lequesne index at the final assessment was compared with the baseline in each group. The percentage of remission was calculated by dividing the difference between final and baseline scores by the baseline score and multiplying by 100%. The insole was checked every week and proper use of the insole was confirmed by the wear of the material. At the conclusion of the study period, participants were asked to report side effects and complications associated with the use of the respective insole, and the rate of adverse outcomes was compared between the two groups.

Statistical analysis

Characteristics at baseline (age, disease duration, height, weight, femorotibial angle, and Lequesne index), radiographical changes with and without the insole, and the percentage of remission of the Lequesne index at the conclusion were compared between the two groups using a one-way analysis of variance. Radiographic grade and the rate of adverse outcomes were compared using the chi-squared test. Statistical significance levels were set at $P < 0.05$.

Table 1. Characteristics of the participants

	Age (years)	Disease duration (years)	Height (cm)	Weight (kg)	Femorotibial angle at baseline	Index of disease severity[a] score	Radiographic grade[b] (no. of cases)
Rubber insole group (n = 42)							
Mean ± SD	64.2 ± 8.8	4.2 ± 5.0	154.7 ± 7.9	60.4 ± 8.7	181.3 ± 5.2	9.5 ± 5.1	
Median	65	2	153	60.3	181	5.1	Grade 2: 32
95% CI	61.5–67.0	2.6–5.8	152.2–157.2	57.7–63.2	179.7–183.0	7.9–11.1	Grade 3: 10
Urethane insole group (n = 42)							
Mean ± SD	62.8 ± 9.0	2.3 ± 4.5	155.5 ± 7.6	57.6 ± 8.2	180.1 ± 3.6	9.7 ± 5.2	
Median	62.5	0.6	156	57.7	180	10	Grade 2: 37
95% CI	59.9–65.6	0.9–3.7	153.1–157.9	55.0–60.1	179.0–181.2	8.1–11.4	Grade 3: 5

CI, confidence interval
[a] Lequesne index
[b] Kellgren–Lawrence grade

Fig. 2A,B. Method of measuring the femorotibial angle. The axis of the foot map was drawn perpendicular to the radiographic film. The femorotibial joint space was marked on adhesive tape and the X-ray beam centered on the joint space (**A**). The femorotibial angle was defined as the angle formed by the axes of the distal one-third of the femur and the proximal one-third of the tibia (**B**)

Results

Characteristics of the patients

All of the participants completed the 4-week study (i.e., returned for the final follow-up visit). There were 42 participants in the rubber insole group and 42 in the urethane insole group. At the initial assessment, there were no significant differences between the groups for age (P = 0.48), disease duration (P = 0.07), height (P = 0.73), weight (P = 0.13), femorotibial angle (P = 0.14), index of disease severity (P = 0.93), or distribution of K-L grade (P = 0.13) (Table 1). From observation of the wear of the material, we judged that each participant used the device as instructed.

Femorotibial angle

In the rubber insole group, the femorotibial angle with insole use (178.9° ± 4.8°) changed an average of −2.8° ± 2.4° as compared to that observed without insole use. In the urethane insole group, the femorotibial angle (177.8° ± 3.5°) changed by −2.3° ± 1.5°. There was no significant difference in the change between the rubber and urethane insole groups (P = 0.30) (Fig. 3).

Clinical assessments

Compared with the initial assessment, the percentage of remission on the Lequesne index showed greater improve-

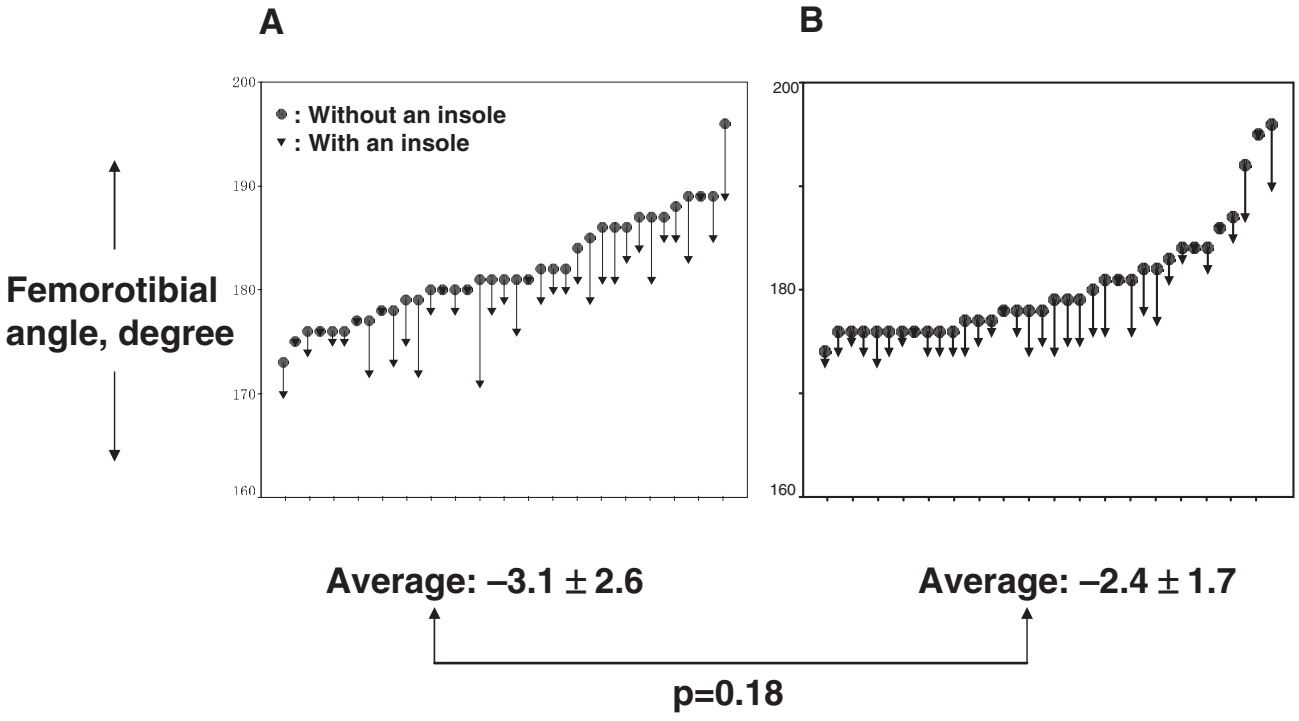

Fig. 3A,B. Comparison of femorotibial angles with and without an insole at the initial assessment. **A** The rubber insole group. **B** The urethane insole group

Table 2. Percentage of remission and complications at the final assessment

	Lequesne index of disease severity		Complications (no. of cases)
	Finality	Percentage of remission	
Rubber insole group (n = 42)			foot pain: 8
Mean±SD	6.6 ± 5.1	−24.0% ± 51.9%	Popliteal pain: 6
Median	6	−20.1%	Low back pain: 3
95% CI	4.9–8.2	−40.2% ± −7.8%	Total: 17 (40.5%)
Urethane insole group (n = 42)			Popliteal pain: 4
Mean±SD	4.4 ± 4.7	−58.4% ± 34.9%	Foot pain: 3
Median	2.5	−62.3%	Low back pain: 1
95% CI	3.0–5.9	−69.3% ± −47.5%	Total: 8 (19.0%)

Significant difference between the two groups; * P = 0.001, ** P = 0.028

ment at the final assessment in the urethane insole group than in the rubber insole group. There was a significant difference in the percentage of remission scores between the two groups (P = 0.001).

Although they were not severe enough to deter participants from continuing to wear the insole, adverse effects were more common in the rubber insole group (17 out of 42, 40.5%) than in the urethane insole group (8 out of 42, 19.0%). There were significant differences in the rates of adverse effects between the two groups (P = 0.028). The most common side effect in the rubber insole group was foot pain (8 out of 17, 47%), (Table 2).

Discussion

This is the first study of which we are aware that has examined the effect of the lateral wedged insoles composed of different materials in patients with knee OA. The results of this study demonstrate that there were effects from the cushioning nature of the insole material itself, which account for changes in pain symptoms of knee OA.

In this study, the percentage of remission score was significantly improved in the urethane insole group compared with that found in the rubber insole group. There was no significant difference in the change of femorotibial angle between the urethane and rubber insole groups. The rubber insole was associated with varying degrees of discomfort. A possible etiology for this higher rate of complications by the rubber insole is that the inserted insole in combination with subtalar strapping had a more natural form-fit to the sole than the inserted insole alone. Although ordinary inserted lateral wedged insoles for knee OA have been made of sponge rubber, we inferred from these results that the sponge rubber is too hard to use for the insole with subtalar strapping.

With regard to the comparison of complications caused

by urethane and rubber insoles, the same results found in this study might be obtained from a study using nonwedged insoles composed of urethane and rubber. However, even if urethane and rubber nonwedged insoles were studied, the clinical effect could not be compared due to the fact that nonwedged insoles would not affect the varus alignment. Kerrigan et al.[14] reported that a 5° lateral wedged insole was associated with an almost 6% overall reduction in knee varus torque compared with a nonwedged insole. They concluded that significant differences between the lateral wedged and nonwedged insole show that the effect of the wedge is the result of directly altering the knee joint biomechanics rather than being merely the result of insole cushioning.

The observation period in this study was 4 weeks. Keating et al.[15] reported that participants who attained pain relief with use of the wedges generally noticed relief within the first 3 days to 1 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 follow-up period in order to assess treatment efficacy over an extended observation period.

This study was limited to female subjects as males comprise a minority of the OA knee population in Japan, and the use of the insole might have been affected by occupation.[16] The Lequesne index was used for evaluation of the clinical improvements in this study. The rationale for using the Lequesne index was that its number of items was less than others, including the Western Ontario and McMaster University index (WOMAC), and the Lequesne index was relatively easy for the participants to demonstrate under objective observation when they presented to our clinic.

In this study, each participant was instructed to use the insole for a period of 3–6 h each day. This was done because the vast majority of the Japanese population wears shoes outdoors, but not inside their home. Nearly all of the participants in this study were Japanese housewives who spend a considerable proportion of each day without footwear inside their home. Most study patients used the device without footwear.

The standing full-length radiographs including hip and ankle joints might have been necessary for the measurement of the knee alignment in this study. However, Koshino mentioned that undergoing standing full-length radiographs required a precise instrument or a high quality of technique. When only the femorotibial angle was measured, the standing comparative short radiographs, including mid-thigh and mid-calf, would be conventional clinically.[9]

In our previous study, the mean value of inter/intraobserver error of femorotibial angle without insoles at baseline ($n = 61$) was 0.16° (95% confidence interval: −0.28–0.35; $P = 0.83$) using the paired t-test.[17] We believe our methodology has reliability for femorotibial angle measurement. Single-measurement radiographic analyses were employed in this study, because applying radiographic analyses several times will increase the radiation in the patients' bodies.

The disadvantages associated with the strapped insole were the decreased freedom of the subtalar joint and increased pain with ambulation on uneven ground.[5] The insole was predicted to be not suitable for the patients with concomitant ankle or subtalar disorders.

Urethane may be considered as the material worn out more easily, but remarkable progress in its chemical synthesis has been made recently. The urethane that we used in this study had the function of form memory. Future directions of study include finding the optimal material among new products for use in the insole with subtalar strapping.

The optimal material of the lateral wedged insole with subtalar strapping may be affected by patients' characteristics including aging or obesity. There were too few patients in the current study for a proper assessment to be made of the materials of the lateral wedge according to patients' characteristics, and it will be necessary to evaluate this correlation in a future study.

The prevalence of knee OA is increasing due to the escalating proportion of the elderly in our society. Therefore, conservative treatment of knee OA is of increasing importance. Through such studies, it will be possible to select the appropriate materials for the insole for knee OA according to patients' characteristics, thus improving their quality of life while simultaneously reducing costs and complications.

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