Correlation Between Body Composition and Efficacy of Lateral Wedged Insoles for Medial Compartment Osteoarthritis of the Knee

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ABSTRACT. ***Objective.*** To investigate anthropometric measures that closely correlate with symptomatic relief of osteoarthritis (OA) of the knee in response to lateral wedged insole use.

Methods. Seventy-one patients with medial compartment knee OA were treated with insoles with subtalar strapping or insoles with talonavicular strapping. Randomization was performed according to birth date. The following variables were evaluated: age, disease duration, Kellgren-Lawrence radiographic stage, body mass index, percent body fat, waist to hip ratio, lower extremity lean body mass (L-LBM) per body weight, and radiographic femorotibial angle at baseline. The trial lasted 8 weeks. The correlation between each variable and the remission score (Δ score) using the Lequesne index of severity was analyzed.

Results. In the subtalar strapping group (n = 34), Δ score of knee OA was more strongly associated with age (p = 0.004, r = 0.48) than other variables. A significant correlation was also observed between L-LBM per body weight and Δ score (p = 0.041, r = –0.36) in the subtalar strapping group. No other variables significantly correlated with the Δ score in the subtalar strapping groups. No variable significantly correlated with the ? score in the talonavicular strapping group (n = 37).

Conclusion. We previously reported that use of insoles with subtalar strapping leads to valgus realignment of the femorotibial angle in patients with knee OA with varus deformity, and it may have a similar therapeutic effect to that of high tibial osteotomy. These data suggest that the insole with subtalar strapping is more efficacious for younger patients and those with a higher L-LBM per body weight, and less efficacious for older patients with sarcopenia. (J Rheumatol 2002;29:541–5)

Key Indexing Terms:
OSTEOARTHRITIS KNEE ORTHOTIC DEVICES CONSERVATIVE TREATMENT

Osteoarthritis (OA) of the knee is the most common joint disorder, accounting for a large proportion of disability in adults[1]. Remarkable progress has been made in surgical techniques such as high tibial osteotomy and total knee arthroplasty for treatment of knee OA. However, the majority of patients with knee OA are hesitant to undergo surgical treatment.

One of the first forms of conservative mechanical treatment for patients with medial compartment knee OA was a lateral wedged insole, popularized in Japan in the early 1980s[2,3]. However, the effect of traditional insoles on knee OA was limited by the lack of subtalar strapping. The femorotibial angle (FTA) was not significantly corrected by the inserted insoles due to loss of mechanical advantage at the subtalar joint. This resulted in an effect fundamentally different from surgical correction of the FTA with high tibial osteotomy[2].

In researching conservative alternatives to surgical correction of the FTA, this limitation of conventional insoles was addressed through the development of a novel lateral wedged insole with elastic strapping of the subtalar joint. Twenty-six participants with knee OA who had been treated with full length lateral wedged insoles attached at the talonavicular joint were then treated for 8 weeks with the insole with subtalar strapping[4]. The FTA and visual analog scale for pain were significantly reduced after wearing the insole with subtalar strapping, but not with use of the insole with talonavicular strapping[5]. This suggests that the insole with subtalar strapping is a more efficacious conservative therapy for correction of the FTA in patients with genu varum and medial compartment knee OA. However, this study provided very limited information concerning which patients might benefit most from use of insoles with subtalar strapping.

We investigated which variables correlate best with symptomatic relief of knee OA in response to the lateral wedged insoles with subtalar strapping. There are many demographic (e.g., age, sex), anthropometric (body mass index, lean body mass), and clinical (severity of deformity) features that could potentially correlate with therapeutic efficacy; we tested for a relationship between body composition and efficacy of lateral wedged insoles. Reports

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suggest that the mean body mass index (BMI) in patients with knee OA using traditional insoles who subsequently required arthroplasty (n = 17) was significantly higher than that of patients who did not require the operation (n = 112)[6]. Additionally, lean body mass and body fat distribution seem to be important in the pathogenesis and progression of knee OA[7,8]. Specifically, a decline in lower extremity lean body mass (L-LBM) per body weight, but not upper extremity or trunk lean body mass per body weight, may influence the pathogenesis of knee OA. Thus we investigated a correlation between segmental body composition and efficacy of lateral wedged insoles in patients with medial knee OA.

MATERIALS AND METHODS

New female outpatients in 2001 (≥ 45 years old, mean 65.2, SD 8.7) who complained of medial knee pain and who met American College of Rheumatology criteria for a diagnosis of knee OA were enrolled[9]. Patients with joint space narrowing, patellofemoral osteophytosis seen on lateral view, or lateral tibiofemoral compartment osteophytosis seen on anteroposterior (AP) view according to the *Radiographic Atlas of Knee Osteoarthritis* were excluded[10].

We recorded height, weight, percent body fat, waist to hip ratio (W/H), L-LBM, disease duration, index of severity for knee OA, FTA in the standing position, and the stage/degree of bone destruction. Height was measured to the nearest 1 cm using a stadiometer. Weight was measured to the nearest 0.1 kg in the standing position with subjects wearing underwear and robes without shoes. BMI was calculated as weight (kg)/height^2 (m).

Body composition measurements including percent body fat, W/H, and L-LBM were carried out by segmental bioelectrical impedance using 8 electrodes according to the manufacturer's instructions (In Body 2.0, Biospace, Seoul, Korea) as described[8]. The L-LBM was divided by body weight to estimate L-LBM per body weight (L-LBM/W).

Disease duration was measured by patient's recollection of the onset of knee pain. A research nurse blinded to the objectives of the study asked participants to assess their degree of pain using the Lequesne index of severity for knee OA[10]. Radiographs were evaluated for changes characteristic of OA in AP views using the Kellgren-Lawrence grade (K-L grade), as described in the *Atlas of Standard Radiographs*[11]. The FTA was measured radiographically as the angle formed by the axes of the distal one-third of the femur and the proximal one-third of the tibia with subjects standing on one leg with and without the insole. The following definitions were used following Lequesne, *et al*: participants with an index of severity ≤ 5 were classified as having mild knee OA[11]; K-L grade 2 or higher was considered definite knee OA[10].

In this study, 71 of 97 participants who had an index of severity ≥ 5 points and K-L grade ≥ 2 were treated with wedged insoles for 8 weeks. Two types of lateral wedged insoles were prepared: (1) urethane wedges made from household bath mat material with elevations of 6.35 mm fixed to an ankle sprain supporter (Sofra Wolfer®, Taketora Co. Ltd., Tokyo, Japan) designed to fit around the ankle and subtalar joints (insole with subtalar strapping, Figure 1A); and (2) sponge lateral heel wedges with an elevation of 6.35 mm (One Touch Arch Supporter®, Meidai Co. Ltd., Tokyo, Japan) (insole with talonavicular strapping, Figure 1B).

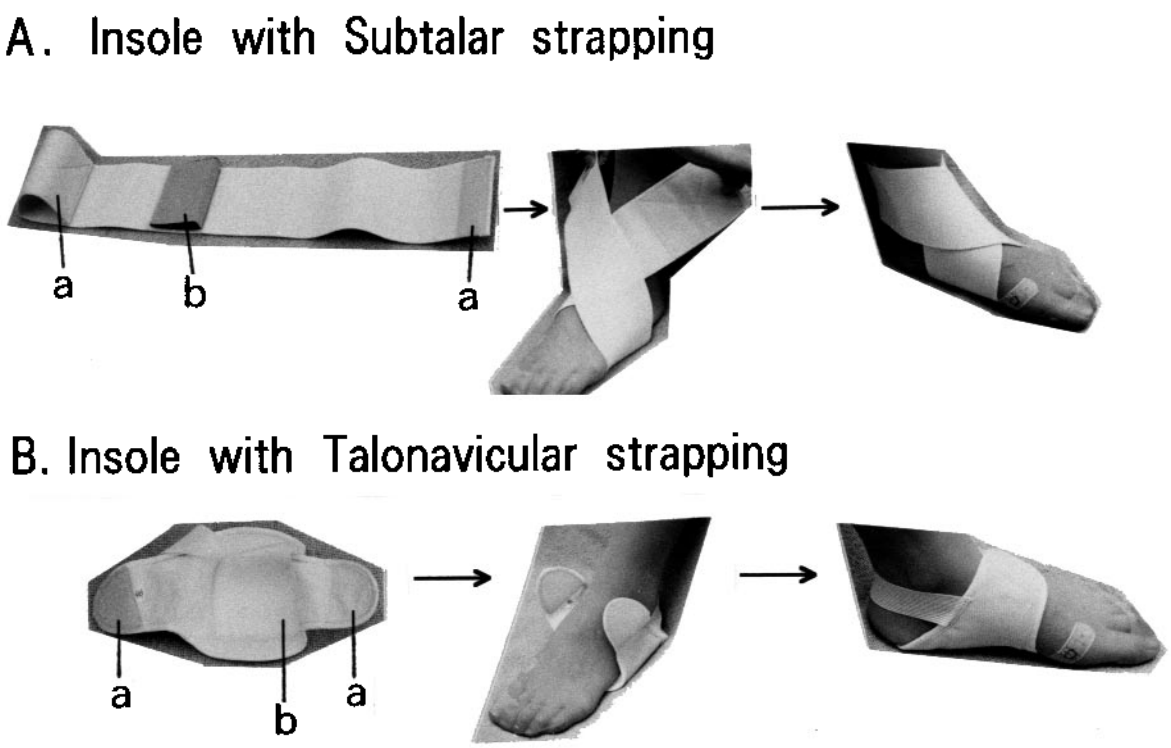

Figure 1. Construction of the 2 types of lateral wedged insoles. A. The ends of the insole with subtalar strapping were wrapped in a figure 8 around the ankle and subtalar joints. B. The insole with talonavicular strapping was attached to bind the foot with bandage. a: Velcro®, b: lateral wedge with an elevation of 6.35 mm.

Randomization was performed by date of birth. Participants with even numbered dates of birth were treated with the insole with talonavicular strapping and those having odd numbered dates of birth were treated with the insole with subtalar strapping. Each participant was instructed to use the insole without shoes in their home, for between 3 and 6 h each day. All participants were also treated with a nonsteroidal antiinflammatory drug (NSAID) (acemetacin, 30 mg) orally twice a day as adjunctive therapy.

The change in Lequesne index of severity (Δ score) was calculated by comparing the severity index at the initial and final assessments. Analysis for a correlation between the Δ score at 8 weeks and each variable at the initial assessment was performed.

Statistical analysis. Evaluation for significant differences in each group between the initial and final assessments was performed by one-way analysis of variance. The chi-square test was used to determine the statistical significance of differences in the distribution of K-L grade at the initial assessment. Significance of a correlation between the Δ score and other variables was assessed by Pearson's correlation coefficient. Statistical significance levels were considered $p < 0.05$.

RESULTS

All participants in both groups completed the 8 week study (i.e., returned for the final followup visit). There were 34 participants in the subtalar strapping group and 37 in the talonavicular strapping group. At the initial assessment, there were no significant differences between the groups for age ($p = 0.64$), disease duration ($p = 0.64$), index of disease severity ($p = 0.94$), BMI ($p = 0.64$), percent body fat ($p = 0.61$), waist to hip ratio ($p = 0.65$), L-LBM per body weight ($p = 0.61$), FTA ($p = 0.21$), or distribution of K-L grade ($p = 0.54$) (Table 1).

Femorotibial angle. In the subtalar strapping group, the FTA with insole use (179.0° ± 4.8°) was reduced an average of –3.2° ± 2.7° with respect to without-insole use. However, in the talonavicular strapping group, the FTA (180.2° ± 5.2°) differed by –0.4° ± 1.1° in comparison with the condition prior to insole use.

Correlation between variables and symptomatic relief with insole use. In the subtalar strapping group, symptomatic relief of knee OA (Δ score) was most strongly associated with age ($p = 0.004$, $r = 0.48$). A significant correlation was also observed between L-LBM per body weight and Δ score ($p = 0.041$, $r = –0.36$). There was no significant correlation between age and L-LBM per body weight in the subtalar strapping group ($p = 0.3$, $r = 0.13$). Disease duration ($p = 0.35$), BMI ($p = 0.37$), percent body fat ($p = 0.81$), waist to hip ratio ($p = 0.19$), FTA ($p = 0.63$), and K-L grade ($p = 0.25$) were not significantly correlated with the Δ score (Figure 2).

In the talonavicular strapping group, the statistical analysis revealed no significant correlation between the Δ score and any variable (Figure 3). Five of 8 patients (63%) with L-LBM/W < 18% in the subtalar strapping group reported worsening of symptoms at the final assessment compared with the initial assessment.

Relationship between Δ score and K-L grade. There were no significant differences in Δ score correlating to K-L grade in either test group (Figure 2). However, all patients in the talonavicular strapping group with K-L grade 4, the most severe OA (n = 3), reported no change in severity index (i.e., Δ score of 0). In contrast, 2 of 4 patients in the subtalar strapping group with K-L grade 4 (n = 4) had improvement in the Δ score (–8 and –2).

DISCUSSION

In this study, the insole with subtalar strapping resulted in a greater correction of the FTA than the insole with talonavicular strapping. Concurrently, symptomatic relief of knee OA correlated independently with age and lower extremity lean body mass per body weight in the subtalar strapping group. One possible explanation for the correlation with age may be related to the effect on muscle mass and joint protection. Hurley, *et al* assessed functional performance in young, middle aged, and elderly subjects[12]. With increasing age, there were decreases in quadriceps strength, joint position sense, and postural stability in positions that required greater reliance on muscle proprioceptors, suggesting an age related deterioration in sensorimotor function. Thus, the correlation between improvement in the subtalar strapping insole group and decreased age may be related to greater joint protection afforded by both the mechanical and neurosensory components of lower extremity lean body mass.

In the Japanese population, the confidence intervals for measurement of the FTA in standing radiographs ranged

Table 1. Characteristics of participants in the initial assessment.

	Age, yrs	Disease Duration, yrs	Lequesne Index, score	BMI kg/m^2	Body Fat, %	W/H, %	L-LBM/Weight, %	Femorotibial Angle, degrees	Radiographic Grade: No. of Cases
Subtalar strapping group									
Mean ± SD	64.4 ± 7.9	5.2 ± 5.9	10.4 ± 5.1	25.4 ± 3.4	33.0 ± 5.6	93.1 ± 4.0	18.8 ± 2.5	182.1 ± 5.1	Grade 2:28
Median	64	3	10	24.9	33.8	93.5	18	181	3:13
95% CI	61.7– 67.2	3.2–7.3	8.6–12.2	24.3–26.6	31.0–35.0	91.7–94.6	17.9–19.7	180.4–183.9	4:5
Talonavicular strapping group									
Mean ± SD	65.4 ± 8.4	4.6 ± 5.4	10.3 ± 4.8	25.1 ± 2.8	33.8 ± 6.4	93.5 ± 5.0	18.5 ± 2.3	180.6 ± 4.8	Grade 2:27
Median	67	2.5	9	24.3	34.3	93	18	180	3:14
95% CI	62.5–68.2	2.8–6.4	8.7–11.9	24.1–26.0	31.4–36.1	91.6–95.3	17.6–19.3	179.1–182.2	4:3

† Kellgren-Lawrence grade. W/H: waist to hip ratio; L-LBM: lower extremity lean body mass.

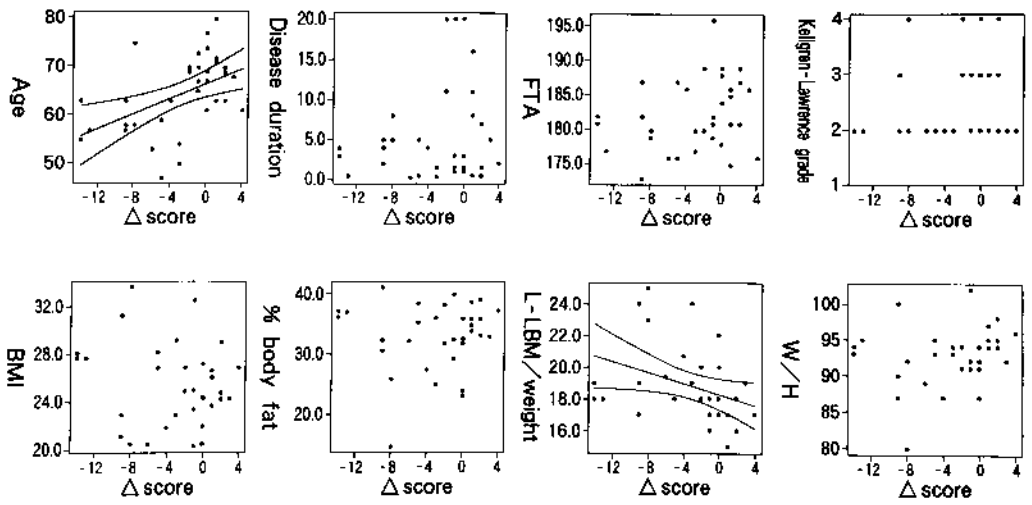

Figure 2. Scatter diagrams reveal the relationship between Δ score and each factor in the subtalar strapping group. Each point represents an individual. Where points overlap, only one is represented.

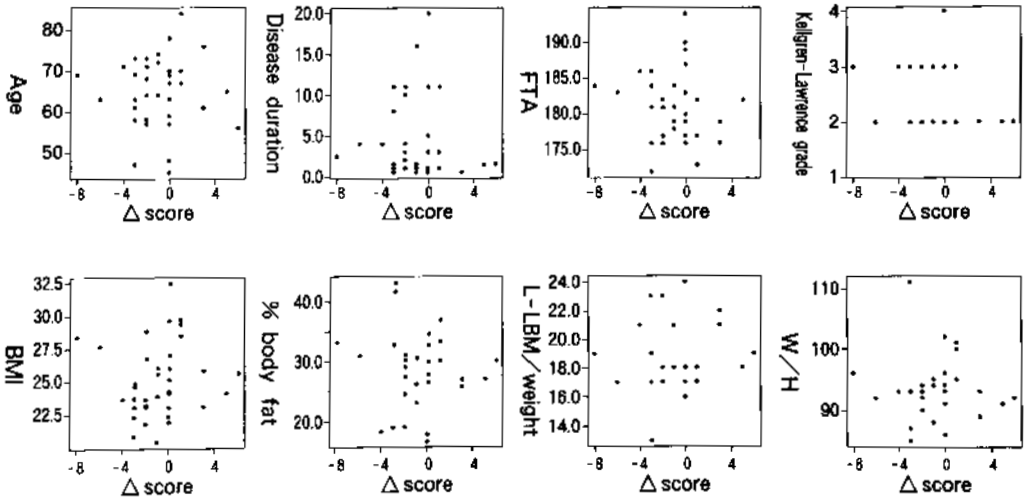

Figure 3. Scatter diagrams reveal the relationship between Δ score and each factor in the talonavicular strapping group.

from 175° to 180° in healthy subjects aged 25–35 and the standard value of the angle is considered to be 176° in healthy women[13].

The correlation with decreased L-LBM/W may be due to an insufficient muscle mass to preserve FTA realignment. If a varus deformity has been present chronically, deconditioning may result in an inability to support the knee even with lateral wedged insole FTA correction. Thus, without muscular support of the anatomic realignment, patients may retain their previous varus stance and gait, negating the effect of insole therapy. This suggests that lateral wedged insoles might be utilized best by patients with L-LBM per body weight > 18% (Figure 2). Studies have shown that non-weight-bearing lower extremity exercises and energy restriction diet therapy were efficacious for prevention of loss of L-LBM/W and symptomatic relief in women with knee OA[14,15]. Thus, patients with < 18% L-LBM/W may respond better to insoles with subtalar strapping if they are also provided adjuvant therapy for lower extremity muscle toning and dietary restriction.

We found there were relatively few patients with K-L grade 4 severity knee OA. The relationship between the effect of inserted wedged insoles without subtalar strapping and radiographic grade of knee OA was addressed by Keating, *et al*, who reported that participants with milder OA attained greater pain relief with use of the inserted

insole[16]. However, even participants with complete loss of the joint space and bony erosions showed some improvement. In this study, 2 out of 4 participants with K-L grade 4 in the subtalar strapping group attained symptomatic relief. However, this small number of cases with advanced knee OA was not sufficient for statistical analysis. This lack of power likely resulted from the selection of outpatients for this study — all patients could walk to our clinic and therefore were more likely to have milder knee OA. Future studies should include a larger number of patients with advanced knee OA to evaluate the effect of subtalar strapping on the FTA in those with more severe disease.

The majority of the Japanese population wears shoes outdoors but not inside their homes. Nearly all participants in this study were Japanese housewives who spend a considerable proportion of each day without footwear inside the home. Thus, in this study most patients used the insoles without footwear.

Previously, we reported a significant posterior shift of the point of impact during heel strike and a prolonged stance phase in patients with knee OA wearing the insole with subtalar strapping in comparison with footprint analysis without insole use (n = 24)[17]. This significant difference was not observed when patients wore the insole with talonavicular strapping. We inferred from these results that the correction of the FTA using the insole with subtalar strapping might be related to the posterior displacement of the heel strike. However, the current study was limited to radiographs taken in the stance phase. Future studies should assess for effect on the FTA when using the insole with subtalar strapping during the dynamic phase of gait.

Another possible limitation of this study was that there was no control group of patients who were treated only with the NSAID and neither insole. Such a group would enable a clearer evaluation of the effect of the NSAID. This limitation of the control group arose from experience in a pilot period in which patients who were assigned to treatment with only the NSAID noticed other patients receiving insoles and requested insoles. It is difficult to control for the effect of patients not being blinded to the types of treatments in the study design. The 2 devices compared here were formed into nearly identical shapes. The subtalar strap around the ankle and subtalar joints is an "extension" of the talonavicular strap used for the talonavicular joint. There were no patients who requested to change their assigned treatment group.

Appropriate selection of patients for conservative treatment of knee OA is of increasing importance with our aging population. This study was limited to assessment of the correlation of several anthropometric measures with symptomatic relief of knee OA in response to lateral wedged insoles with subtalar strapping. Future research directions also include assessment of other variables, which might help to better select patients who respond to conservative therapy. Through such studies, we hope to discover factors that will correlate with symptomatic relief in response to the insole even more closely than age and lower extremity lean body mass per body weight.

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