Biomechanical effects of lateral and medial wedge insoles on unilateral weight bearing

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Abstract. [Purpose] Lateral wedge insoles reduce the peak external knee adduction moment and are advocated for patients with knee osteoarthritis. However, some patients demonstrate adverse biomechanical effects with treatment. In this study, we examined the immediate effects of lateral and medial wedge insoles under unilateral weight bearing. [Subjects and Methods] Thirty healthy young adults participated in this study. The subjects were assessed by using the foot posture index, and were divided into three groups: normal foot, pronated foot, and supinated foot groups. The knee adduction moment and knee-ground reaction force lever arm under the studied conditions were measured by using a three-dimensional motion capture system and force plates. [Results] In the normal and pronated groups, the change in knee adduction moment significantly decreased under the lateral wedge insole condition compared with the medial wedge insole condition. In the normal group, the change in the knee-ground reaction force lever arm also significantly decreased under the lateral wedge insole condition than under the medial wedge insole condition. [Conclusion] Lateral wedge insoles significantly reduced the knee adduction moment and knee-ground reaction force lever arm during unilateral weight bearing in subjects with normal feet, and the biomechanical effects varied according to individual foot alignment.

Key words: Wedge insoles, Knee adduction moment, Foot posture index

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INTRODUCTION

Knee osteoarthritis (OA) is one of the most common musculoskeletal disorders worldwide, and a leading cause of knee pain and disability in the elderly. The number of patients (aged ≥40 years) in Japan with knee OA diagnosed from radiological findings is estimated to be approximately 25.3 million, and approximately 8 million patients are estimated to exhibit OA symptoms but do not have a definitive diagnosis1). Therefore, there is an urgent need to reduce the progression and incidence of knee OA in Japan.

The medial tibiofemoral compartment of the knee is the part most commonly affected by OA2). The peak force is higher in the medial compartment of the knee than in the lateral compartment during walking and other weight-bearing activities3, 4). Excessive knee load is a significant risk factor for an increased risk of structural progression4, 5). A high knee adduction moment (KAM) reflects increased compressive forces acting on the medial aspect of the knee6) and is widely considered a surrogate measure of medial knee compression7).
Lateral wedge insoles (LWIs) are one of the treatment options frequently recommended in clinical guidelines for the management of medial knee OA. LWIs have been shown to reduce KAM and pain, and to prevent or delay the progression of medial knee OA. On the other hand, medial wedge insoles (MWIs) tend to increase KAM. The efficacy of LWIs may be limited because they fail to reduce KAM or increase KAM in certain persons. Therefore, MWIs may be better indicated for reducing KAM. However, no study has evaluated the effects of LWIs and MWIs, or has identified nonresponders to those types of therapy.

The possible explanations for nonresponders are variations in the foot alignments and gait patterns. It is recommended that the assessment of patients with knee OA should include foot evaluations because these patients have been shown to exhibit a more pronated foot type compared with controls. In addition, previous studies have reported that patients with knee OA demonstrate changes in gait patterns, such as increased toeing out, reduction in gait speed, and leaning of the trunk in the direction of the stance leg, to reduce KAM during gait. Therefore, to more accurately investigate the effects of a wedged-insole intervention, unilateral weight bearing was analyzed as a movement task that assumed the mid-stance during gait according to a previous study.

Thus, the primary purpose of this study was to evaluate the immediate effects of LWIs and MWIs under unilateral weight-bearing conditions in healthy young adults. The secondary purpose was to examine whether variations in foot alignment influence the changes in KAM. It was hypothesized that KAM in subjects who have normal foot alignment would significantly decrease under the LWI condition than under the barefoot (BF) and MWI conditions.

**SUBJECTS AND METHODS**

The subjects were 30 healthy young adults without disease and/or present illnesses that would affect unilateral standing (mean age, 21.2 ± 1.9 years; mean height, 1.62 ± 0.08 m; mean weight, 55.6 ± 9.5 kg; and mean body mass index [BMI], 21.1 ± 2.2 kg/m²). Before the experiments, the purpose of this study was explained to the participants and informed consent was obtained from them. This study was approved by the Ethics Committee of Human Research, Hiroshima International University (no. 13-4).

Before motion analysis, foot alignment measurements were performed for all subjects by using the foot posture index (FPI). The FPI is a six-item foot posture assessment performed with the subject standing and relaxed in the bipedal position. The six items of FPI include talar head palpation, curves above and below the lateral malleoli, calcaneal angle, talonavicular bulge, medial longitudinal arch, and forefoot to rearfoot alignment. Each item was scored on a five-point scale between −2 and +2, which provided a total sum of all items between −12 (highly supinated) and +12 (highly pronated). All subjects were assessed by using FPI as follows: normal foot (total score between 0 and +5), pronated foot (total score between +6 and +12), and supinated foot (total score between −12 and −1).

A three-dimensional motion analysis system that included eight infrared cameras (VICON MX; Vicon Motion Systems, Oxford, UK) and two force plates (AMTI, Watertown, MA, USA) were used to record the kinematics and kinetic data at the sample frequency of 100 Hz. Kinematic and kinetic data were low-pass filtered with a fourth-order Butterworth filter with cutoff frequency at 6 and 15 Hz, respectively. A total of 40 reflective markers were placed at the following landmarks on both sides of the subjects: the acromion process, olecranon, radial styloid process, anterior superior iliac spine, posterior superior iliac spine, superior aspect of the greater trochanter, medial and lateral femoral condyles, midpoint between the greater trochanter and the lateral femoral condyles, medial and lateral malleoli, midpoint between the lateral knee joint line and the lateral malleolus, posterior distal aspect of the calcaneus, posterior proximal aspect of the calcaneus, lateral calcaneus, sustentaculum tali, and head of the first and fifth metatarsals. These anatomical markers were used to construct anatomical segmental models for the trunk, pelvis, thigh, shank, and foot segments. In addition, a marker was attached to the right scapula to distinguish the right and left sides.

This study involved a within-subject design where every subject was tested under three conditions. All subjects were instructed to stand on their left leg under three different conditions. The three conditions were BF, with LWIs, and with MWIs. The LWIs had a base height equal to that of the fifth metatarsal and were medially inclined, and the outside was 7 mm thicker than the inside. The MWIs had a base size equal to that of the fifth metatarsal and were medially inclined, and the inside was 7 mm thicker than the outside. The insoles were made of high-intensity silicon rubber (Nakamura Brace, Ohda, Japan), with a hardness of durometer type A (Shore A) 40. Following a previous study, the subjects were asked to stand on one leg with a toe-out angle of 0° and to flex the contralateral hip to 30° while maintaining the contralateral hip at neutral abduction/adduction and rotation, with their hands on their abdomen. Before collecting experimental data, the subjects practiced standing on one leg under each condition several times, to become familiar with the task. They were then instructed to stand on one leg while looking straight ahead for 10 s. The three conditions were applied in a random order, and measurements were repeated three times for each condition.

Data analyses were done by using the BodyBuilder software (Vicon Motion Systems, Oxford, UK). The coordinates of each joint center were calculated according to methods described in previous studies. An eight-link segmental model was developed to calculate the hip, knee, and ankle kinematic and kinetic data by using inverse dynamics according to the techniques described by Vaughan et al. Anthropometric parameters for mass, center of mass, and moment of inertia for each segment were obtained from the report by Okada et al. A knee joint moment was calculated by using the tibial coor-
dinate system with the origin in the knee joint center. In this study, KAM was defined as the external knee adduction moment after normalization to the subject’s body mass (Nm/kg). Furthermore, a knee-ground reaction force lever arm (KLA) was calculated, defined as the perpendicular distance between the ground reaction force and the knee joint center in a laboratory frontal plane, based on the report by Hinman et al.\(^27\). In this study, changes in KAM and KLA between the LWI and MWI conditions were independently examined. The change as the difference was calculated between each subject’s KAM and KLA when using LWIs or MWIs, and their KAM and KLA in the BF condition. The percentage change was calculated as follows:

\[
\text{Percentage change} = \left( \frac{\text{KAM or KLA under the LWI or MWI condition}}{\text{KAM or KLA under the BF condition}} \right) \times 100.
\]

The above equation expresses the change in KAM or KLA as a percentage of the value under the BF condition. Although data during a 10-s duration was recorded for each condition, the time between 5 and 6 s was used for the analysis to eliminate the initial unstable phase associated with the transition from the initial stance to standing on one leg\(^22\). The mean value during this 1-s duration was calculated for all variables, and the mean value of three trials was determined for each subject.

All statistical analyses were performed with EZR on R commander v1.10 (Easy R, Saitama, Japan). The normality of data distribution was assessed by using the Shapiro-Wilk test. To compare the three conditions, repeated-measures one-way analysis of variance with a post hoc Tukey’s test was used to evaluate the differences that were normally distributed, or the Kruskal-Wallis test with a post hoc Steel-Dwass test for those that were not. Similarly, to compare the changes in KAM and KLA between the LWI and MWI conditions, the paired t-test or Wilcoxon signed-rank test was used to evaluate the differences. Pearson’s correlation or Spearman’s rank correlation was also used to examine the associations between the changes in KAM and KLA. Statistical significance was set at \(p < 0.05\).

**RESULTS**

Concerning the reliability of the FPI, the results showed an intraclass correlation (ICC\(_{1,1}\)) of 0.87. Therefore, the intraclass reliability of these measurements was found to be good. All subjects (\(N = 30\)) were classified into three subgroups according to the left foot alignment results of the FPI. The characteristics of the three groups are summarized in Table 1. The subjects’ age, height, body weight, and BMI were similar between the subgroups.

Table 2 shows the value and standard deviation of KAM and KLA under the BF, LWI, and MWI conditions. Neither KAM nor KLA was significantly different between the conditions. On the other hand, concerning the changes in KAM and KLA

<table>
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<tr>
<th>Table 1. The characteristics of the three groups based on FPI</th>
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<td>Normal group ((N = 18))</td>
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</tr>
<tr>
<td>Age (years)</td>
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<tr>
<td>Height (m)</td>
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<tr>
<td>Body weight (kg)</td>
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<td>BMI (kg/m(^2))</td>
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Values are expressed as mean ± SD

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<th>Table 2. KAM and KLA for three conditions ((N = 30))</th>
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<tr>
<td>BF</td>
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<td>---------------------------</td>
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<tr>
<td>KAM (Nm/kg)</td>
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<td>KLA (mm)</td>
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BF: bare foot, LWI: lateral wedge insole, MWI: medial wedge insole, KAM: knee adduction moment, KLA: knee-ground reaction force lever arm. Values are expressed as mean ± SD

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<th>Table 3. The change in KAM and KLA under the LWI and MWI conditions ((N = 30))</th>
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<td>LWI</td>
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<tr>
<td>KAM (%)</td>
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<td>KLA (%)</td>
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Values are expressed as median (IQR) *\(p < 0.05\)
as a percentage of the value under the BF condition, both of these variables significantly decreased under the LWI condition compared with the MWI condition (Table 3).

Under the LWI condition, the change in KAM positively significantly correlated with the change in KLA ($r = 0.356$, $p < 0.05$). However, under the MWI condition, there was no significant association between the change in KAM and KLA ($r = 0.307$, $p = 0.11$).

The changes in KAM and KLA under the LWI and MWI conditions between the subgroups are presented in Table 4. In the normal and pronated groups, the change in KAM significantly decreased under the LWI condition compared with the MWI condition ($p < 0.05$). However, it was not significantly different between conditions within the supinated group. In the normal group, the change in KLA also significantly decreased under the LWI condition compared with the MWI condition ($p < 0.05$). In contrast, it was not different between conditions within the pronated and supinated groups.

### DISCUSSION

In this study, we evaluated the immediate effects of LWIs and MWIs under unilateral weight bearing conditions in healthy young adults. The findings from our study revealed that both the KAM and KLA were not significantly different between the three conditions. However, the change in KAM and KLA significantly decreased in the LWI condition compared with the MWI condition. These variables were normalized to the value in the BW condition, which suggests that the LWI may have effects of decreasing the KAM and KLA, whereas the MWI may have effects of increasing those variables. Additionally, in the LWI condition, the change in KAM was positively correlated with the change in KLA. Therefore, this study has demonstrated that the primary mechanism of the biomechanical effects of lateral wedges is related to a reduced KLA.

Our results showed that KAM and KLA were not significantly different between the three conditions. These results did not agree with those of previous kinematic studies that demonstrated that LWIs significantly reduced KAM in patients with knee OA. The difference in findings can be assumed to be due to a difference in the measurement tasks. Most of the previous studies analyzed KAM during gait, particularly a value of peak during the stance phase. On the other hand, Takacs and Hunt reported that KAM increased significantly with a contralateral pelvic drop during unilateral weight bearing. To eliminate the influence of gait speed and patterns that affect KAM in the present study, we also selected unilateral weight bearing for the measurement tasks. Therefore, the lack of a difference between the three conditions may have been caused by variations in individual motor control. We therefore conclude that the common LWI and MWI conditions could not affect KAM and KLA during unilateral weight bearing when compared with the BF condition.

Under the LWI condition, the change in KAM positively correlated with the change in KLA. A previous study reported that LWIs of approximately 5° reduced the peak KAM and knee adduction angular impulse. Furthermore, a stepwise regression analysis demonstrated that the reduction in the peak KAM may have been the result of a decreasing KLA. Similar to their findings, our results demonstrated that the change in KAM mildly correlated with the change in KLA under the LWI condition. In brief, the reduction in KLA with LWIs may be the central mechanism explaining the load-reducing effect, which also led to the reduction in KAM with LWIs. However, there was no association between the change in KAM and that in KLA under the MWI condition. A previous study demonstrated that there were no significant changes in either the first or second peak KAM during the gait stance phase with the addition of medial arch supports in patients with knee OA. Moreover, the researchers observed considerable individual variations in response to the arch support across participants. On the other hand, in the present study, we observed that the changes in both KAM and KLA significantly increased under the MWI condition compared with the LWI condition. These results suggest that although MWIs may cause an increase in KAM and KLA, the increase in KAM does not necessarily correlate directly with the increase in KLA.

As a result of the FPI classification, the changes in KAM and KLA significantly decreased under the LWI condition than under the MWI condition in the normal group. In contrast, the change in KAM significantly decreased under the LWI

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<th>Table 4. The change in KAM and KLA under the LWI and MWI conditions between the subgroups</th>
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<tr>
<td><strong>KAM (%)</strong></td>
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<td>Normal (N=18)</td>
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<td>Pronated (N=6)</td>
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<td>Supinated (N=6)</td>
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Values are expressed as mean ± SD or median (IQR) *p < 0.05
condition than under the MWI condition in the pronated group; however, the change in KLA was not significantly different under the two conditions. These results suggest that persons with a pronated or flat foot receive a beneficial effect with a reduction in KAM; however, this could not be closely correlated to the reduction in KLA. A previous study reported that the reduction in the peak KAM correlated with a reduction in peak hip adduction during the stance phase27). Another previous study revealed that healthy subjects could decrease the first peak of KAM by 65% compared with a normal gait by walking while leaning their trunks toward the stance limb31). Therefore, the present study suggests that the mechanism of reducing KAM can be potentially explained by not only the decrease in KLA but also another kinematic or kinetic change such as a response of the hip, pelvis, or upper trunk.

Neither the change in KAM nor that in KLA was significantly different between the LWI and MWI conditions in the supinated group, indicating that LWIs or MWIs could not change these values in persons with a supinated or hollow foot. Furthermore, this suggests that such persons do not experience positive effects on KAM, which is considered a surrogate measure of medial knee compression. Therefore, the present results provide important insights that could help clinicians decide whether LWIs will be efficacious for patients with medial knee OA by using a simple clinical examination.

The present study has some limitations. First, because our study did not clarify the influence on gait, the findings need to be interpreted with caution. Second, as our study involved healthy participants, we can only draw conclusions about the effects of LWIs without the limitations of diseases. The purpose of the present study was to evaluate the inherent effect of LWIs and MWIs on KAM without possible confounding parameters such as the severity of knee OA and gait speed. Third, our decision to categorize participants by using the FPI resulted in a decrease in the sample size per group. The findings from our study suggest that not only changes in KLA but also those of another factor may have an influence on the change in KAM in some persons with a particularly pronated or flat foot. Therefore, in addition to the assessment of the foot alignment by using the FPI, future research should be performed with a larger number of subjects, and should aim to examine additional kinematic and kinetic factors that indicate decreased KAM. Furthermore, longitudinal studies are needed to examine both the immediate and long-term effects of LWIs for knee OA patients. Despite these limitations, our findings suggest that the assessment of foot alignment would assist in the identification of persons who may respond positively to LWI treatments.

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