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Effects of Disease Severity on Response to Lateral Wedged Shoe Insole for Medial Compartment Knee Osteoarthritis

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ABSTRACT.

Objective: To determine the effects of lateral wedged insoles on knee kinetics and kinematics during walking, according to radiographic severity of medial compartment knee osteoarthritis (OA).

Design: A prospective case control study of patients with medial compartment OA of the knee.

Setting: Gait analysis laboratory in a university hospital.

Participants: Forty-six medial compartment knees with OA of 23 patients with bilateral disease and 38 knees of 19 age-matched healthy subjects as controls.

Interventions: Not applicable.

Main Outcome Measures: We measured the peak external adduction moment at the knee during the stance phase of gait and the first acceleration peak after heel strike at the lateral side of the femoral condyles. Kellgren and Lawrence grading system was used for radiographic assessment of OA severity.

Results: The mean value of peak external adduction moment of the knee was higher in OA knees than the control. Application of lateral wedged insoles significantly reduced the peak external adduction moment in Kellgren-Lawrence grades I and II knee OA patients. The first acceleration peak value after heel strike in these patients was relatively high compared with the control. Application of lateral wedged insoles significantly reduced the first acceleration peak in Kellgren-Lawrence grades I and II knee OA patients.

Conclusions: The kinetic and kinematic effects of wearing of lateral wedged insoles were significant in Kellgren-Lawrence grades I and II knee OA. The results support the recommendation of use of lateral wedged insoles for patients with early and mild knee OA.

Key Words: Gait; Osteoarthritis; Orthotic devices; Rehabilitation.

Application of lateral wedged shoe insole[1,2] is reported to be effective in patients with medial compartment knee osteoarthritis (OA).[3-8] The kinetic effects of lateral wedged insoles on changes in the spatial position of the lower limb and in the subtalar joint angle were examined previously by radiography in standing position, and the results indicated the effectiveness of this appliance in patients with medial compartment OA knee (eg, reduction of excessive load on the medial joint surface and excessive tensile force on the lateral side).[1] Recently, the effects of treatment were assessed by computerized joint moment analysis using 3-dimensional gait analysis.[9-12] Maly et al[13] reported that lateral wedged insole does not reduce the adduction moment on the affected knee, however, they did not analyze their findings in relation to the radiographic severity of OA. On the other hand, Ogata et al[14] reported the positive effect of lateral wedged insoles on the lateral thrust, as examined by accelerometry during walking. Thus, there is controversy in previously reported kinetic and kinematic studies regarding the effects of lateral wedged insoles in patients with medial compartment OA during walking.

In previous studies, the clinical effects of lateral wedged insoles were examined in patients with early medial compartment knee OA,[2] particularly those with associated pain,[14] and also in those with mild to moderate knee OA[8] in the medial side. Marks and Penton[15] indicated that wedged foot orthotics are effective in patients with mild medial compartment knee OA. However, to our knowledge, there is no report that examined the relationship between radiographic severity of knee OA and the effects of lateral wedged insoles on walking conditions, evaluated by kinetic and kinematic computerized gait analysis.

Clinically, the kinematic effects can be assessed visually[16] by determining the magnitude of the lateral thrust. When the kinematic and kinetic effects of application of lateral wedged insoles are similar, the kinematic effects could reflect the kinetic effects such as reduction of adduction moment. In other words, clinicians could infer the kinetic effects of the treatment from the kinematic effects assessed visually without instrumentation. We hypothesized that the kinematic effects of application of lateral wedged insoles are similar to the kinetic effects. The present study was thus designed to determine the effects of lateral wedged insoles on knee kinetics and kinematics during walking in patients with medial compartment knee OA. Another aim of the study was to determine the relationship between radiographic severity of knee OA and biomechanic effects of lateral wedged insoles, to test the hypothesis that biomechanic effects of lateral wedged insoles is more remarkable in early to moderate OA patients than those with severe OA.

Methods

Patients and Healthy Volunteers

The recruited subjects were 23 patients with bilateral medial compartment knee OA (ie, 46 knees), representing all consecutive patients examined at the Gait Analysis Laboratory, Division of Physical Therapy and Rehabilitation, Fukui University Hospital, between December1998 and February 1999, who fulfilled the following exclusion criteria. The exclusion criteria were knee pain due to pathologic conditions other than OA, such as rheumatoid arthritis and pseudogout, and knee with flexion contracture greater than 20°. In addition, patients with hip problems, symptomatic lumbar spine disease, spinal cord disease, or those showing ataxic gait related to neurologic disorders were excluded from the study. We also studied 19 age-matched, healthy volunteers (38 knees) as the control group. The demographic data of the patients and controls are shown in table 1.

The hip-knee-ankle angle was measured on a full-length anteroposterior radiograph taken for each OA patient in standing position. The angle represented the medial deviation angle from 180° at the intersection between the mechanical axes of the femur and tibia, and was a plus value for valgus alignment and minus value for varus alignment. The severity of OA was evaluated by radiography using the Kellgren and Lawrence grading system,[17] in which grade 0 is normal; grade I is possible osteophytic lipping; grade II is definite osteophytes and possible joint space narrowing; grade III is moderate and/or multiple osteophytes, definite joint space narrowing some sclerosis, and possible bony attrition; and grade IV is large osteophytes, marked joint space narrowing, severe sclerosis, and definite bony attrition. Using this system, 11 knees were classified as grade I, 11 as grade II, 13 as grade III, and 11 as grade IV.

The study protocol was approved by the ethics reviewing committee guidelines of our university, and a written informed consent was obtained from each subject.

Gait Analysis

The gait analysis system and its performance as well as data processing were described previously by our group (fig 1).[18,19] The computerized gait analysis system (model G1812A)[a] used in this study included 2 forceplates (each 250×40cm) and a light source spot measuring device (model G2250M).[a] The latter consisted of light-emitting diodes attached to the body and 4 opto-electronic cameras that capture the emitted light. The 2 forceplates are placed on the floor on either side of the centerline of the 8-m long walk way. Three-dimensional ground reaction forces obtained by the forceplates were synchronized with goniometric measurements using an analog-to-digital converter (model G1812CS)[a] and a microcomputer (model G3852CS).[a] The errors of the light source spot measuring device were less than 1% of the field of view, and errors of the forceplates were less than 2% of full scale deflection.

Markers for the light source spot measuring device were attached on the left and right anterior superior iliac spine of the ileum, iliac crest, greater trochanter, lateral side of the femoral condyles, lateral malleolus of the fibula, lateral side of the calcaneus, and the head of the fifth metatarsal bone. The markers of iliac crest and greater trochanter were 5cm apart and attached to the skin using jigs (fig 1). After 3 walking trials to get used to the lateral wedged insole, the subject was asked to ambulate on the forceplates 3 times without lateral wedged insoles at his/her natural speed with both arms folded in front of the chest so as not to interfere with the lights from the light source (baseline measurements). Then, wearing lateral silicon rubber-made wedged insoles with 10-mm lateral elevation extending from the posterior aspect of the heel to approximately 6cm distal to the center of the heel,[b] OA patients were asked to ambulate on the forceplates 3 times at a speed similar to that at baseline and gait was recorded and analyzed. The sampling frequency was set at 50Hz.

Data Analysis

The step length, stride width, and walking velocity were calculated through the floor-reaction forces and the data over 3 strides were averaged. Step length was calculated as the distance from the initial position when 1 foot landed on the forceplate to the initial position when the opposite foot landed on the other forceplate in the sagittal plane. In a similar way, stride width was calculated in the frontal plane. Walking velocity was calculated by multiplying stride length by stride time. Stride time represented the time between landing of one foot on the forceplate and the landing of the same foot on another forceplate. The positions of the centers of the hip, knee, and ankle joint were identified relative to the positions of the skin markers. The centers of the hip joint on the frontal plane were approximated at the mid-point of the line between the center of the pelvis and the greater trochanter. The distance was measured on the anteroposterior radiographs of each joint. The center of the knee on the frontal plane was located by identifying the mid-point of the line between the peripheral margins of the medial and lateral plateaus at the level of the joint line. The center of the ankle joint was estimated at the mid-point between lateral and medial malleoli.[20,21] Data of distances from skin marker to the center were entered into the computer. Moments of the knee joint in the frontal plane were computed by the use of the 3-dimensional rigid body link model of Bresler and Frankel,[22] incorporating data on the 3-dimensional location of each segment, the inertial properties of the limb segment and the data on the floor reaction forces. In this study, we collected data of knee joint moment in the frontal plane not in the transverse plane and, thus selected this simple model for analysis. After averaging the values of the 3 strides, the peak external adduction moment values were obtained.

Kinematic data of the knee were obtained from the motion of the marker on the lateral side of the femoral condyles during ambulation. Then the horizontal mediolateral component of acceleration of the motion of this marker was calculated. After averaging the data of three strides, the first acceleration peak values after heel strike (indicating thrust motion at the knee) were employed.[14] Data of peak adduction moment and first acceleration peak were estimated separately for each knee in each patient but not healthy subjects because the severity of knee OA differed occasionally in the same patient.

Statistical Analysis

A 5×2 analysis of variance for repeated measures was used for comparison of peak adduction moment and first acceleration peak values between OA patients and controls, and between before and after application of lateral wedged insoles in OA patients. The Scheffé post hoc test was used for comparison between OA patients and controls, and paired *t* test was used for comparison between before and after application of lateral wedged insoles in OA patients. Nonpaired and paired *t* tests were used for comparison of step length, stride width, and walking velocity between subjects. Correlations between the magnitude of peak adduction moment and first acceleration peak without lateral wedged insoles, and the magnitude of reduction of peak adduction moment and first acceleration peak during wearing lateral wedged insoles in OA patients were calculated using the Spearman's correlation coefficient. Nonpaired *t* test and chi-square test were used for comparison of characteristics between subjects. All data were analyzed with the SPSS[c] statistical software. A probability of 5% was considered statistically significant.

Results

Table 2 lists the values of step length, stride width, and walking velocity. These parameters were significantly lower in OA patients than the control. The use of lateral wedged insoles in OA patients did not change the step length and walking velocity, but significantly increased the stride width. Peak adduction moment during the stance phase of the gait cycle was significantly higher in knee OA patients than the control (table 3, fig 2). The use of lateral wedged insoles significantly decreased peak adduction moment values of OA patients with Kellgren-Lawrence grades I and II, whereas the reductions in these values were insignificant in Kellgren-Lawrence grades III and IV. The magnitude of reduction of peak adduction moment, when lateral wedged insoles were applied, was 5.1% (range, −3.7% to 14.3%) in Kellgren-Lawrence grade I, 6.6% (range, 0%–9.0%) in grade II, 3.3% (range, −4.7% to 7.1%) in grade III, and 5.0% (range, −3.1% to 11.1%) in grade IV. There was no gender effect in the observed changes in peak adduction moment values.

The mean value of first acceleration peak after heel strike was higher in patients with OA than the control (see table 3). Application of lateral wedged insoles resulted in significant reductions of first acceleration peak values in OA patients with Kellgren-Lawrence grades I and II, but the reductions were insignificant in Kellgren-Lawrence grades III and IV. The magnitude of first acceleration peak reduction in patients wearing lateral wedged insoles was 32.9% (range, −18.2% to 78.1%) in Kellgren-Lawrence grade I, 28.7% (range, −36.3% to 98.2%) in grade II, 9.0% (range, −64.3% to 50.3%) in grade III, and 5.1% (range, −96.0T to 64.8%) in grade IV. There was no sex effect in the observed changes in first acceleration peak values. The correlation between the peak adduction moment and first acceleration peak values under the condition of not wearing lateral wedged insoles (R^2=.006, P=.447), and the correlation between the magnitude of reduction of peak adduction moment and that of first acceleration peak during wearing the lateral wedged insoles (R^2=.046, P=.151), were not significant in OA patients.

Discussion

A positive correlation between the magnitude of the knee moment and walking velocity has been already reported.[23] Walking velocity may also influence the magnitude of first acceleration peak. However, in the present study, application of lateral wedged insoles did not result in significant changes in these parameters in knee OA patients. Our results of the intrinsic effect of the lateral wedged insoles in knee OA patients excluded the effect of walking velocity. On the other hand, increase of stride width may affect the magnitude of peak adduction moment or first acceleration peak, because a wide-based gait may lead to changes in the moments at the knee joint via the more laterally shifted location of the center of pressure. Increase of stride width might be part of the biomechanic effect of lateral wedged insoles.

The adduction moment of the knee is a major determinant of medial-to-lateral load distribution,[24] and is considered the most influential factor, producing medial joint force in joints with varus deformity.[25, 26] Therefore, it seems responsible for the biomechanical abnormality of the medial compartment OA of the knee.[27] Sharma et al[28] reported that the dynamic load during walking correlates with the severity of the disease in tibiofemoral knee OA. They suggested that the magnitude of knee adduction moment possibly influences the structural outcome in medial compartment knee OA. Moreover, Miyazaki et al[21] reported that the baseline adduction moment at the knee could predict radiographic progression of OA at the 6-year follow-up in medial compartment knee OA patients.

In our study, reduction of peak adduction moment (average, 4.4%) was seen in OA patients after the use of insoles and the effect was significant in patients with Kellgren-Lawrence grades I and II but not III and IV. Kerrigan et al[10] reported that the use of 5° lateral wedged insoles reduced the peak adduction moment value by about 6% and the 10-mm height lateral wedged insoles reduced the peak by about 8% in patients with Kellgren-

Lawrence grades III and IV, though they did not show data of static alignment. Kakihana et al[12] also described a 5.6% reduction of the knee joint varus moment during walking by the application of 6° lateral wedged insoles. They did not report the radiographic severity of OA or static alignment. Maly et al[13] showed no differences in peak adduction moment values when subjects wore their routine footwear and the valgus heel wedge. However, they also did not examine the correlation between peak adduction moment and radiographic severity of OA and did not show the data on static alignment. Our results of reduction in peak adduction moment value (average, 4.4%), on application of the lateral wedged insoles, were smaller than the data reported by Kerrigan[10] and Kakihana.[12] In addition, the effects of reduction of peak adduction moment were not significant in Kellgren-Lawrence grades III and IV knees in disagreement with the results of Kerrigan.[10]

The relationship between the adduction moment of the knee and static alignment has been reported by several studies.[28-31] Moreover, the adduction moment of the knee correlates with the severity of OA [28,31,32] and our results provide support to these studies. We suggest that the static alignment of OA patients differs between our patients and those of previous studies. We propose that the mechanism of reduction of adduction moment of the knee with the usage of insoles is a lateral shift in the center of pressure on the foot, thereby reducing the moment arm of the adduction moment, which was hypothesized by Maly.[13] Patients with Kellgren-Lawrence grades III and IV had severe varus deformity compared with those of Kellgren-Lawrence grades I and II. Changes in the center of pressure and changes in the moment arm induced by the insoles are probably trivial in patients with Kellgren-Lawrence grades III and IV.

Our results suggest obvious kinetic effect of lateral wedged insoles on peak adduction moment in mild OA patients, and these effects are relatively small in moderate to severe knee OA. Toda et al[6] developed a new type of lateral wedged insoles with strapping of the subtalar joint using a belt support that can correct femorotibial valgus. In another study,[7] they also reported that the use of subtalar-strapped insole did not only improve visual analog scale of pain and Lequense index scores consisting of pain and functional scores, but also significantly reduced the femorotibial angle in patients with Kellgren-Lawrence grades II, III, and IV at 6-month follow-up assessment. The use of lateral wedged insoles without subtalar strapping, which was used in the present study, might have certain limitations; for example, talus movement might prevent calcaneal valgus correction.[6] More effective insoles that can transmit the corrective force to the femorotibial joint via the calcaneus and talus are needed for patients with severe knee OA.

Lateral thrust is the visualized dynamic bowing out of the knee laterally, that is, the abrupt first appearance of varus (or the abrupt worsening of existing varus) while the limb is bearing weight during ambulation.[16] Chang et al[16] reported that lateral thrust increased the odds of progression among varus aligned knees when considered separately, suggesting that knees with thrust were a subset of varus-aligned knees at particularly high risk for progression of OA. In our study, 17.6 % reduction in first acceleration peak, which reflects the magnitude of lateral thrust motion, was noted after the use of insoles in OA patients and the change was significant in patients with Kellgren-Lawrence grades I and II but not III and IV. Ogata et al[14] reported that the amplitude of first acceleration peak decreased with the usage of valgus insoles in all 50 knees with medial OA, and the mean reduction in first acceleration peak amplitude with the usage of insoles was 23.7%, a value similar to that found in our study. They did not show the relationship between radiographic severity of OA and reduction of the amplitude of first acceleration peak, but showed the relationship between radiographic severity of OA and pain relief when shoe insoles were applied. Thus, they recommended the use of insoles for patients with painful early medial compartment OA. We do agree with their recommendation and our results demonstrated that the use of insoles reduce the magnitude of lateral thrust in patients with mild OA.

There was no relationship between the magnitude of reduction of peak adduction moment and that of first acceleration peak when wearing lateral wedged insoles in OA patients. In addition, the peak adduction moment values did not correlate with first acceleration peak before wearing lateral wedged insoles, suggesting different pathogenic processes. Based on our data, we recommend the use of insoles for mild to moderate OA patients, however, other biomechanic factors (muscular strength, joint laxity, proprioception) must be considered also as factors that could alter the effects of lateral wedged insoles.

Our work described the kinetic and kinematic effects of lateral wedged insoles during ambulation and the relationship between the radiographic severity of knee OA and biomechanical effects of lateral wedged insoles. In the present study, we did not attempt to examine the relationship between radiographic severity of knee OA and clinical results of wearing lateral wedged insoles, and thus further study may be required to assess such effects. However, our results support the proposal made by several groups; the use of lateral wedged insoles for mild knee OA, but not for severe OA, based on pain relief[2,8,14] and improvement of motional function.[2]

Study Limitations

Our study had several limitations that might reduce the generalization of our results. First, gait measurements were taken soon after the application of lateral wedged insoles. If gait measurements were taken several months after wearing of lateral wedged insoles, biomechanic effects of lateral wedged insoles might be different from our data and further study may be required. Second, the stature of the patients in the present study was small and the sample contained a relatively small number of male patients. Finally, statistical analysis of the magnitude of peak adduction moment and first acceleration peak in each grade was underpowered due to the small sample size.

Conclusions

We confirmed in the present study the kinetic and kinematic benefits of wearing lateral wedged insoles in grades I and II medial compartment knee OA patients. However, there was no correlation between kinetic and kinematic effects, suggesting different pathogenic mechanisms. However, we support the clinical recommendation of the use of lateral wedged insoles for patients only with early and mild knee OA.

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Suppliers

a. Anima Corp, 3-65-1 Shimoishihara, Chofu, Tokyo 182-0034, Japan.

b. Nakamura Brace Co Ltd, 132 Omori, Ohda, Shimane 694-0305, Japan.

c. Version 14.0J; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Figure Legends

Fig 1. Outline of the gait analysis system. Abbreviations: A, acceleration of the marker motion to the lateral side; M, external adduction moment at the center of the knee.

Fig 2. Joint moments of the knee in sagital plane. Each datum was averaged during an averaged gait cycle.

Table 1: Demographic Data of Patients and Controls

Characteristics	Knee OA	Controls	*P*
No. of subjects	23	19	
Age (y)	67.0±8.7	66.4±9.3	NS†
Sex (male/female)	6/17	5/14	NS‡
Height (cm)	150.2±7.2	148.3±9.0	NS†
Body weight (kg)	60.3±7.1	51.5±8.5	<.001†
Hip-knee-ankle angle (deg)*	–6.2±4.4	NA	

NOTE. Values are mean ± standard deviation (SD) or as otherwise indicated.

Abbreviation: NA, not applicable; NS, not significant.

*The medial deviation angle from 180° at the intersection between mechanical axes of the femur and tibia.

†Nonpaired *t* test.

‡Chi-square test.

Table 2: Parameters Used in Gait Analysis and Results

Parameters	Knee OA				Healthy Controls	*P*†	Cohen *d*
	No Insole	With Insole	*P**	Cohen *d*			
Step length (cm)	38.8±9.0	39.8±8.0	.266		48.0±5.1	<.001	1.26
Stride width (cm)	12.3±2.7	13.9±2.8	.001	0.58	14.6±2.6	<.001	0.87
Walking velocity (m/s)	36.7±9.0	37.0±8.3	.315		50.7±8.4	<.001	1.61

NOTE. Values are mean ± SD.

*Paired *t* test between knee OA patients with and without insoles.

†Nonpaired *t* test between knee OA patients without insoles and healthy controls.

Table 3: Peak Adduction Moment and the First Acceleration Peak

Parameters	Peak Adduction Moment (Nm/kg)				First Acceleration Peak (m/s^2)			
	No Insoles	With Insoles	*P**	Cohen *d*	No Insoles	With Insoles	*P**	Cohen *d*
Knee OA	0.90±0.20	0.86±0.19	<.001	.21	1.65±0.69	1.36±0.76	.018	.40
Kellgren-Lawrence grade I	0.79±0.21†	0.75±0.18	<.043	.21	1.52±0.52	1.02±0.51	.024	.97
II	0.91±0.11‡	0.85±0.12	<.001	.52	1.57±0.56	1.12±0.67	.043	.73
III	0.91±0.26‡	0.88±0.24	<.058		1.56±0.45	1.42±0.50	.400	
IV	1.01±0.19‡	0.96±0.17	<.086		1.95±1.10§	1.85±1.07	.800	
Healthy controls	0.59±0.12†‡	NA			1.19±0.56§	NA		

NOTE. Values are mean ± SD.

*Paired *t* test between knee OA patients with and without insoles.

†*P*=.047, *d*=1.17, between Kellgren-Lawrence grade I and healthy subjects (Scheffé post hoc test,).

‡*P*<.001, among Kellgren-Lawrence grades II (d=2.78), III (*d*=1.58), IV (*d*=2.64), and healthy subjects (Scheffé post hoc test).

§*P*=.020, *d*=.86, between Kellgren-Lawrence grade IV and healthy subjects (Scheffé post hoc test).

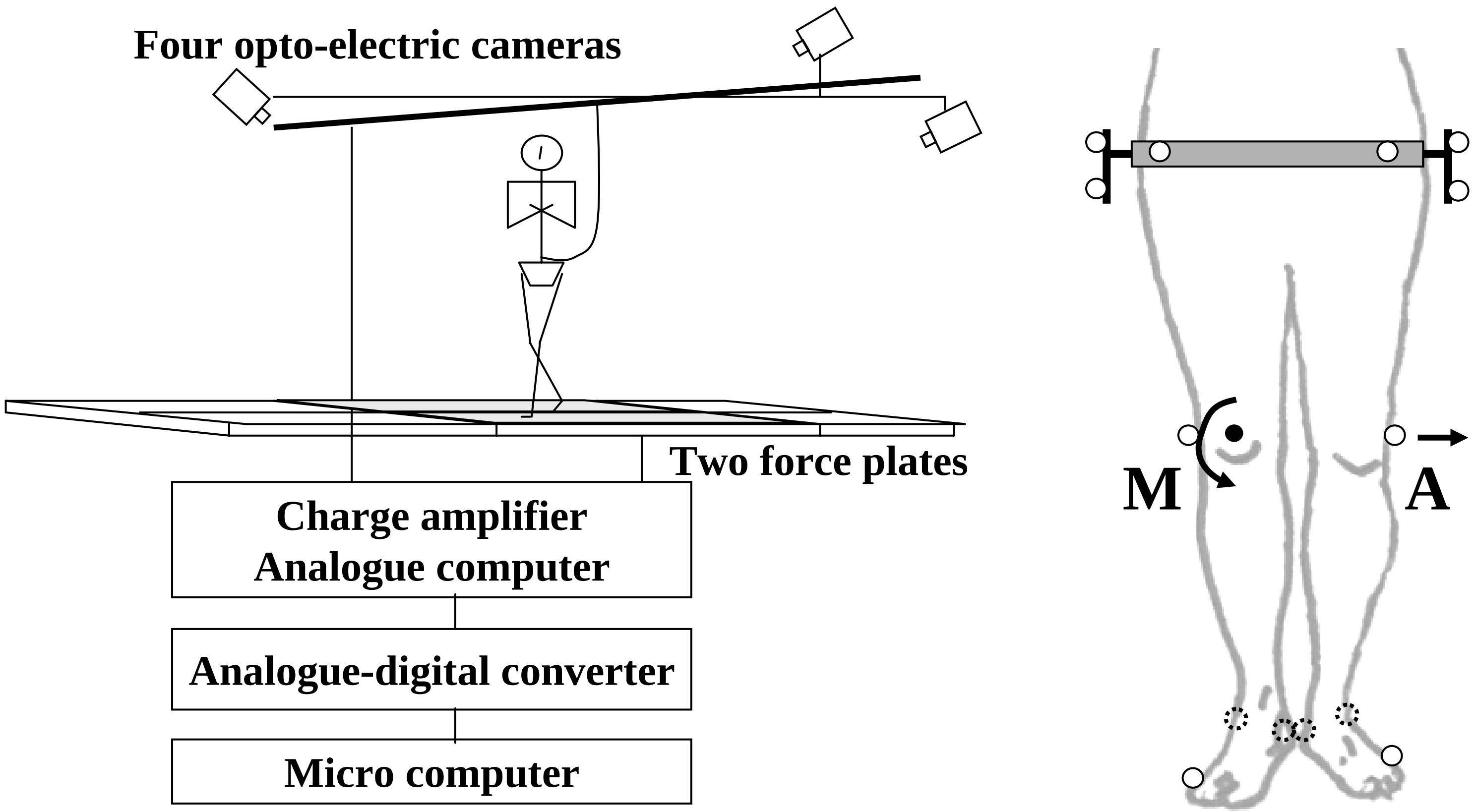
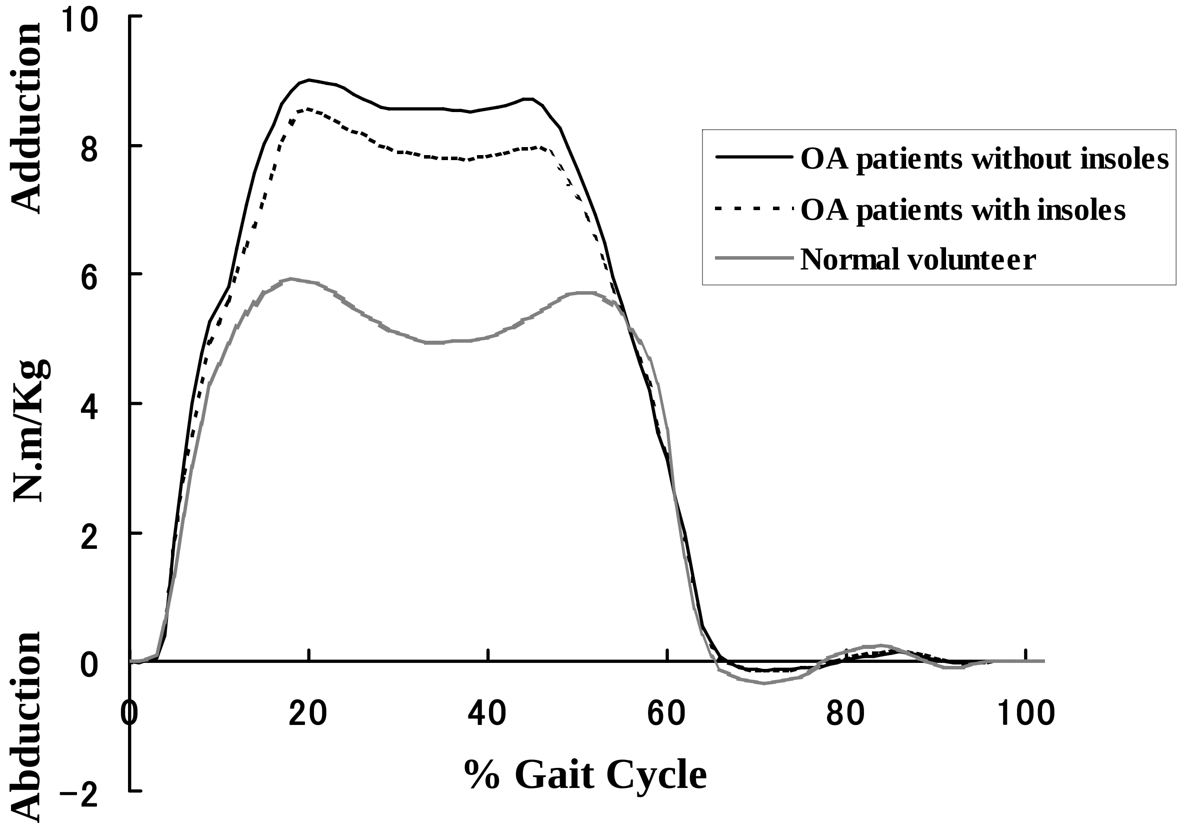

Four opto-electric cameras
Two force plates
Charge amplifier
Analogue computer
Analogue-digital converter
Micro computer
M
A

Figure 1.



Adduction
N.m/Kg
Abduction
10
8
6
4
2
0
−2
0
20
40
60
80
100
% Gait Cycle
OA patients without insoles
OA patients with insoles
Normal volunteer

Figure 2.