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# The Effects of Short-Term Wearing of Customized 3D Printed Single-Sided Lateral Wedge Insoles on Lower Limbs in Healthy Males: A Randomized Controlled Trial

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Statistical Analysis C  
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**Background:** Unbalanced standing and gait asymmetry are common in individuals with musculoskeletal disorders. Achieving symmetrical posture and gait is an important goal of rehabilitation. This study investigated the biomechanical differences in the lower extremities observed immediately after an insole was used and without the use of different one-sided insoles.





**Material/Methods:** Thirty young, healthy adult males received 3 different insole interventions: experimental group A had a customized 3-dimensional (3D)-printed single-sided lateral wedge insole (CLWI) inserted on the left side, and experimental group B had on the left side, a traditional single insert. The control had unilateral flat insoles; no insole inserted into the socks. Motion mechanics and gait parameters were collected at the 2-time points, after insertion of the insole and after 20 minutes of walking with the insole.

**Results:** Asymmetric posture and gait appeared immediately after using the 2 insoles (lower joint moment,  $P < 0.05$ ). Compared with the control group, the abnormal posture and gait of experimental group B after wearing the traditional insole for 20 minutes were not obvious ( $P > 0.05$ ). However, the asymmetrical posture and gait remained in experimental group A after wearing the CLWI for 20 minutes ( $P < 0.05$ ). The center of pressure (COP) trajectory of the left foot of experimental group A was significantly higher than that of experimental group B and the control group at the 2-time points ( $P < 0.05$ ).

**Conclusions:** The asymmetry of posture and gait can be observed in a short time using a customized 3D-printed single-sided lateral wedge insole. This experiment provides guidance for the application of customized 3D-printed single-sided lateral wedge insoles for gait rehabilitation.

**MeSH Keywords:** **Foot Orthoses • Gait • Pressure • Torque**

**Full-text PDF:** <https://www.medscimonit.com/abstract/index/idArt/919400>

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## Background

Gait asymmetry has long been known as an abnormal manifestation of individuals with neurological and musculoskeletal injuries [1] such as unilateral knee osteoarthritis (UKOA) [2]. Patients have shown a decrease in the length of the affected limb compared to that of the unaffected limb and have shown prolonged standing and single support time [3]. In addition, gait asymmetry is associated with balance disorders [4]. Asymmetrical gait has a long-term health impact because it limits daily activities [5]. Therefore, restoring gait symmetry is one of the important goals of rehabilitation [6].

Unilateral knee osteoarthritis is a common joint disease that can cause knee pain and asymmetry in the elderly [7]. In UKOA, the patient's medial tibiofemoral compartment defect is approximately 10 times greater than the lateral compartment defect. The pressure center (COP) of the patellofemoral joint is located on the inside of the knee joint, and the contact force of the medial tibiofemoral compartment is therefore much larger than that of the lateral compartment [8,9]. Many studies have evaluated the impact of medial tibiofemoral compartment on the internal knee load, which is related to the ratio of internal and external joint reaction forces [10,11]. The knee joint adduction torque is directly related to the pain and progression of knee osteoarthritis [12]. Therefore, reducing the knee joint adduction torque is the fundamental purpose of rehabilitation therapy for knee osteoarthritis patients.

Knee osteoarthritis patients adjust their gait by slowing down the gait, tilting the torso, and flipping the toes outward to reduce the knee joint adduction torque [13,14]. Wearing a lateral wedge insole (LWI) is often used as a conservative treatment. The LWI moves the plantar COP to the side of the foot, reducing the ground reaction force (GRF) to the moment of the knee joint [15,16]. Customized 3-dimensional (3D)-printed wedge insoles are more suitable for patients than traditional insoles are, that is, through computer-aided design, the arch can be improved, the forefoot and heel can be thickened, and rapid production can be achieved through computer-aided manufacturing. Consequently, pressure sharing can be achieved, mitigating damage and improving bilateral posture control [11].

Much literature has been published on the effects of orthopedic insoles in balance and gait, but the focus of previous research has been on both insoles. Using 3D-printed insole can help redistribute weight between lower limbs and reduce the risk of impaired movement [17]. Aruin et al. demonstrated that the discomfort caused by a single insole leads to asymmetry in static and dynamic balance control as well as asymmetry in healthy individuals' gait [18]. However, this previous study only evaluated the effects of non-individual insoles on posture and gait symmetry. The effects of posture symmetry of

patients and individual factors (customized insoles) on the gait were not investigated. Therefore, the hypothesis of this study was that, in the short term, over time, customized 3D-printed single-sided lateral wedge insole (CLWI) would play a better role in standing and gait asymmetry than traditional insoles.

## Material and Methods

### Study participants

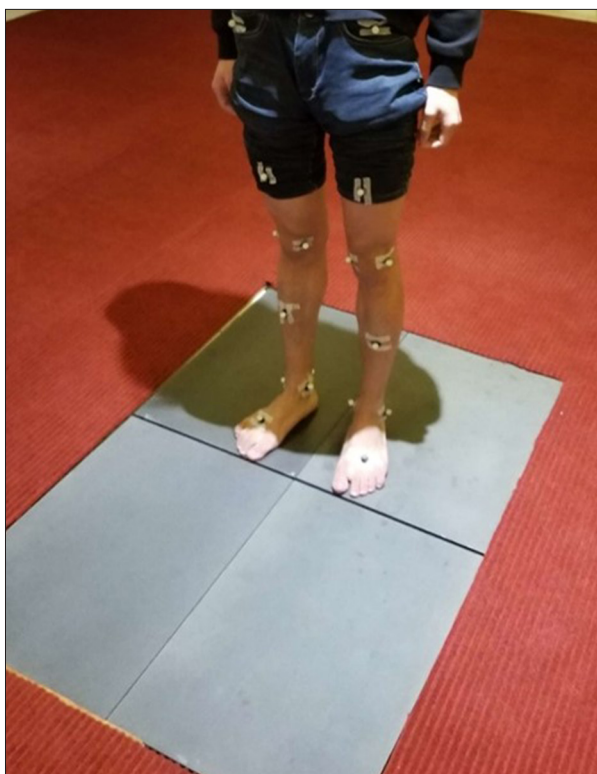
Thirty males (age:  $21\pm 1$  years; height:  $1.72\pm 0.15$  m; body weight:  $60.23\pm 13.72$  kg; mean $\pm$ standard deviation), with no history of musculoskeletal disease in the lower extremities within 1 year, participated in the study. Prior to the survey, all participants completed informed consent to participate in the experiment. The Ethics Committee of the Second Hospital of Jilin University approved the study. All experiments are carried out in strict accordance with the Helsinki Declaration.

### Insole design

Traditional flat insoles without inclination and CLWIs with a  $6^\circ$  inclination were made of polyvinyl acetate. The thickness of the flat insole was 4 mm, and the wedge insole was designed to have a thickness in accordance with individual foot pressure distribution characteristics. The CLWI was designed and manufactured using the Bodyarch<sup>®</sup> 3D-printing system. The study participants stood in the center of the scanning plate, and the contours of the foot were captured through the Bodyarch<sup>®</sup> foot scanning system. The insole model was created on the Bodyarch Designer<sup>®</sup> software and manufactured by the Bodyarch X1 printer<sup>®</sup>.

### Motion and mechanics analysis

The assessment of motion and dynamics was performed in a gait laboratory using a 3D gait analysis system (Motion Analysis<sup>®</sup>, including 6 camera motion analysis systems using mass motion analysis and force plates), which were measured blindly by the same assessor. We use the Helen Hayes model [19,20] for markers placement and model building. A 10 m long runway served as the walking route. The digital camera recorded the participants movements from the front side, the back side, the left side, and the right side. The camera was placed in a gait direction 2 m away from the participants, and the participants were asked to wear shorts and be barefoot for the joint activity to be observed. Stretchable Velcro was used to attach reflective markers to the participants, namely in the center of the participants' sacral spine, left and right sacral spine, anterior superior iliac spine, medial and lateral ankle joints, instep, and right side and inside



**Figure 1.** Stretchable Velcro was used to attach reflective markers to the following areas on the study participant's body: center of the sacral spine, left and right sacral spine, left and right anterior superior iliac spine, left and right medial and lateral ankle joints, instep, right side and inside and outside of the left side of the knee joint. There was a total of 15 marker points.

and outside of the left side of the knee joint. There was a total of 15 marker points (Figure 1).

All participants wore uniform socks that are suitable for themselves. Experimental group A's socks had CLWI inserts, experimental group B's socks had conventional one-sided flat insole inserts, and the control group's socks had no inserts.

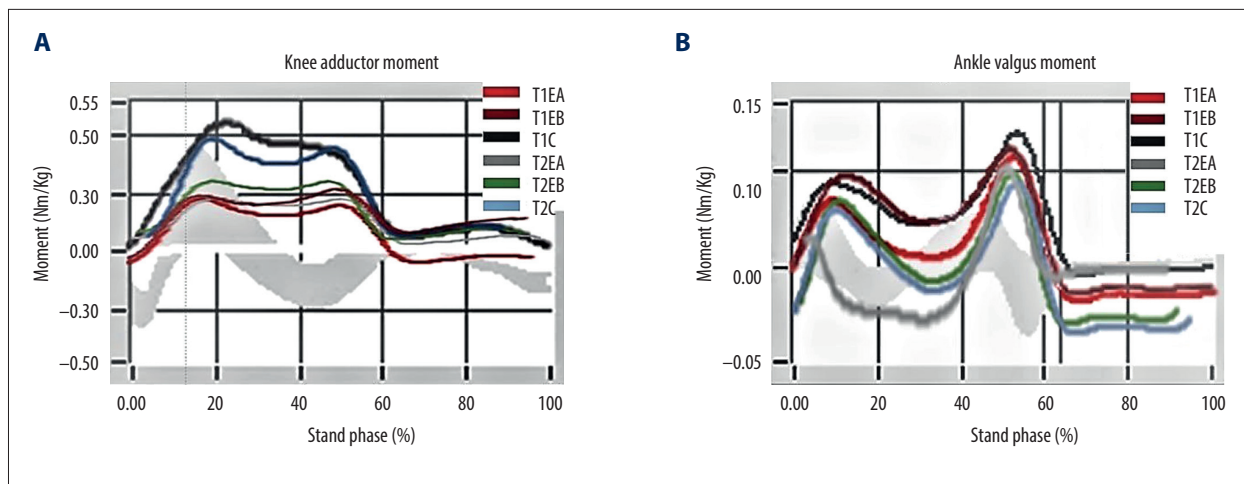
Bilateral standing and gait assessments were performed at 2-time points. Time point 1 was started immediately after the placement of to insert intervention and given a familiar time of 1 minute. Time point 2 was evaluated after 20 minutes of walking with the insole insert intervention. The test sequence was randomized, and all participants received 3 interventions. All participants were asked to walk back and forth 5 times under the 3 intervention conditions at their normal speeds.

The 3D motion capture device was used to capture the motion trajectory of the marker points, and the coordinates of the marker points were generated for later data processing.

The COP was measured using a pressure plate with a piezoelectric force sensor, on which the participant was required to stand. After 1 minute on the board, the participant was instructed to open their arms and stare at them. In order to eliminate the fatigue effects of standing and ending, the first and last 15 seconds of the data were deleted. The computer obtained the data captured by the system and performed biological model analysis. The related processing software was QT661S and Motion Analysis. The QT661S software system provided raw data on the participant's spatiotemporal parameters. The reflective markers which were attached to the body had a 12 mm diameter. When the participant walked on the mat, the foot's contact with the sensor was recorded in real time. Raw data were collected and saved by the same operator for all trials in all participants. According to the video recordings of the participants, the operator imported the QT661S collection action model data into the Motion Analysis software for data filtering and separated the gait cycle. The computer calculated the average value of each time and space gait, variance, and other values. The final result was the space-time parameter summary table or spatiotemporal parameter fluctuation curve in gait cycle

### Data analysis

Inverse dynamics were used to calculate knee extension and ankle valgus moment during standing. The movement at the ankle and knee was broken down into a coordinate system that was fixed to the distal segment reference system. The position of the COP was calculated as the distance from the longitudinal axis of the foot, and a positive value indicated a lateral shift. The moment arm of the GRF at the center of the knee joint was calculated as the vertical distance in a plane composed of the longitudinal axis and the intermediate axis in the coordinate system. After estimating the joint torque, the GRF and joint torque were normalized to the weight of each participant and the duration of the standing period. In each gait cycle, there were 2 peaks (P1 and P2) at the time of knee adduction. We analyzed P1 and P2 as the maximum knee adduction (Figure 2A). In addition, the valgus moment, the GRF, and the positional change of the COP at the time similar to the peak of the knee joint retraction force were calculated. The results are shown as the mean±standard deviation of 5 trips per walk. Using the statistical software SPSS 24.0, experimental group A, experimental group B, and the control group were tested for gait parameters, kinematic data, COP position, and moment arm differences by paired *t*-test to relate the lateral wedge-shaped insole to the lower limb biomechanics impact of the participant. For all analyses, the significance level was set to  $P < 0.05$ .



**Figure 2.** Joint moments of left knee adduction (A) and ankle valgus (B) during walking with a customized 3-dimensional (3D)-printed lateral wedge insole inserted into the left sock (experimental group A), a traditional flat insole inserted into the left sock (experimental group B), and no insole in the sock (control group). Mean curve for 3 interventions at 2 time points (T1 – just inserted into the insole; T2 – wearing the insole for 20 minutes); T1EA – time 1 experimental group A; T1EB – time 1, experimental group B; T1C – time 1, control group; T2EA – time 2, experimental group A; T2EB – time 2, experimental group B; T2C – time 2, control group; thick curve – average value provided by the software.

## Results

### Knee joint adduction moment

Two peaks were shown in the early (18.0–21.5%) and late (50.0–55.0%) gait cycles of the walking state (Figure 2A). In the experimental group, the adduction torque of the left knee joint was significantly lower than that in the left knee joint of the control group ( $P < 0.05$ ). Compared with experimental group B, the left knee joint adduction torque of experimental group A decreased significantly at both time points ( $P < 0.05$ ). At the 2-time points, no significant difference happened in the moment of the left knee joint between the 2 peaks of experimental group A ( $P > 0.05$ ).

### Ankle joint moment

The ankle joint moment on the positive plane showed the valgus moment (Figure 2B). At the second-time point, the lateral wedges reduced the valgus moment at the first peak ( $P < 0.05$ ). There was no significant difference between the 3 interventions at the 2-time points at the second peak ( $P > 0.05$ ).

### Bilateral standing

In the absence of an insole, the percentage of weight on the right side was 50.90% of the body weight (Figure 3A; the weights mentioned are averaged data for the 2-time points). When the participant used a traditional flat bottom in the shoes on the left side, the load on the right side increased to 55.44%. When the CLWI was provided, the load on the right

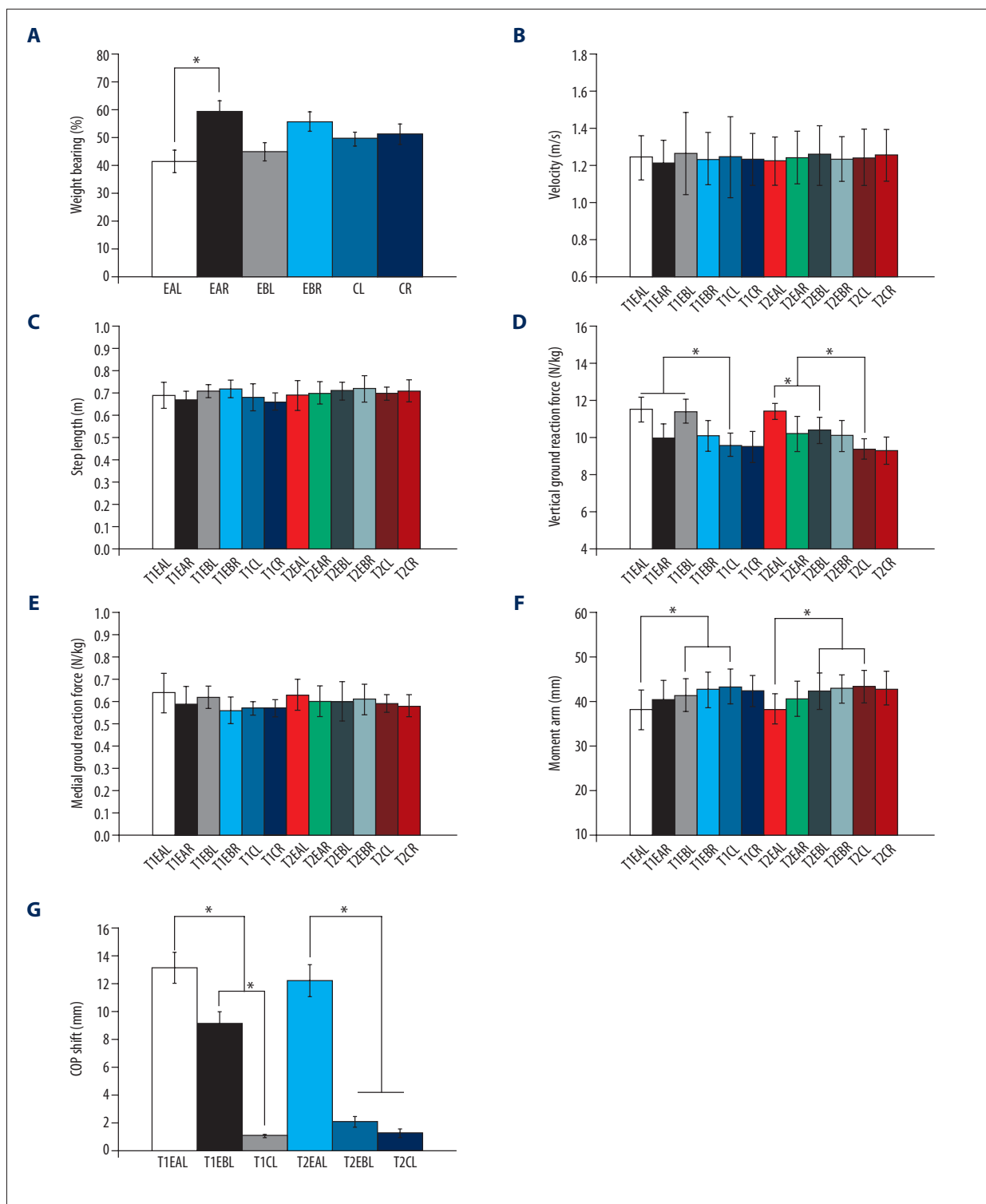
side increased, and the left and right sides was significantly different ( $P < 0.05$ ). On the contrary, there was no significant difference in the load between all groups ( $P > 0.05$ ).

### Gait parameters

Under the 3 intervention conditions, there were no significant differences in the steps of the left and right foot speeds (Figure 3B, 3C) ( $P > 0.05$ ). There was no significant difference in footstep speed between the 2-time points ( $P > 0.05$ ).

### Ground reaction force (GRF) and moment arm

At the 2 time points, the vertical GRF on the left side of the experimental group (Figure 3D) was significantly higher than that of the control group ( $P < 0.05$ ). In experimental group A, the vertical GRF on the left side at the second-time point was significantly higher than that in experimental group B ( $P < 0.05$ ). In contrast, at the 2-time points, the GRF (Figure 3E) increased in the experimental group, but there was no significant difference compared with the control group ( $P > 0.05$ ). The GRF of experimental group A was not significantly different at the 2-time points ( $P > 0.05$ ), and the GRF of the left side of experimental group B at the second-time point was significantly lower than that at the first time point ( $P < 0.05$ ). At the 2-time points, the GRF of experimental group A to the moment arm of the left knee joint center (Figure 3F) was significantly reduced ( $P < 0.05$ ) compared with that of experimental group B and the control group. On the right side, there were no significant differences between the 3 conditions at the 2-time points ( $P > 0.05$ ).



**Figure 3.** Means and standard deviations of gait variables during standing and walking (2 time points: immediately after wearing insole and after wearing insole for 20 minutes) with left side lateral wedge insole (experimental group A), left side traditional flat insole (experimental group B), and without insoles (control group). Significant difference ( $P < 0.05$ ) is shown with an asterisk. (A) EAL – experimental group A, left side; EAR – experimental group A, right side; EBL – experimental group B, left side; EBR – experimental group B, right side; CL – control group, left side; CR – control group, right side. (B–G) T1 – time 1; T2 – time 2; the meaning of EAR, EBR, CL, CR are the same as in (A).

## COP

When the participants wore the insole, the displacement of the left side COP (Figure 3G) to the right was considered to be an asymmetrical gait, the side wedge insole increased the lateral moment of the COP, and the participants' left COP shifted to the right, as shown in Figure 3G. At the first-time point, compared with the control group, the left foot COP immediately moved to the right, and the displacement range was significantly larger than that of the control group ( $P < 0.05$ ). The COP displacement range of experimental group A was significantly larger than that of experimental group B ( $P < 0.05$ ). Compared with the control group and experimental group B, the COP displacement of the left foot was significantly increased to the right side ( $P < 0.05$ ) at the second-time point, and there was no significant difference between experimental group B and the control group at the second-time point ( $P > 0.05$ ).

## Discussion

We examined the effects of CLWI on the biomechanics of lower limbs in healthy, young adult males while they were walking. The purpose of the study was to figure out the biomechanical differences in the lower extremities observed immediately after a short period of time, without the use of insoles and with the use of different unilateral insoles. The results show that after starting to use the insole, the differences in weight bearing and gait symmetry on both sides were immediately visible. After 20 minutes of walking, wearing a CLWI could still produce load-bearing differences and gait symmetry changes, which proved the hypothesis that, in the short term, over time, the CLWI was more effective in improving standing and gait asymmetry than traditional insoles were.

### Single insole affects static balance symmetry

Inserting the insole into the left shoe caused the weight to move to the right, and this transition occurred immediately after the insole was provided in accordance with the results of previous studies [21]. Although the insole was used to distribute a part of the weight on the unworn side to the wearing side, there was no significant difference compared with being barefoot, which was different from some existing one-sided insoles [18]. This could be caused by the method of insole design of this study which was mainly aimed to change the gait rather than to change the plantar load distribution.

### Single insole affects gait symmetry

The main direction of the latest studies focused on measuring COP and joint motion mechanics parameters to analyze the effect of a single insole on gait symmetry. The insole in the left

shoe caused the gait asymmetry to appear as a shift of the COP to the right. This asymmetry caused in healthy individuals helps to improve understanding of the gait and posture asymmetry in patients with unilateral knee arthritis [22]. Previous studies have clearly indicated that improving COP symmetry in patients with unilateral knee arthritis can improve their walking stability [23]. Experiments have shown that the focus of rehabilitation in patients with unilateral lower extremity is to improve the symmetry of COP displacement and enhance the gait and balance of patients [24].

In terms of COP, although the range of COP movement was significantly increased after wearing 2 insoles, only participants wearing a CLWI still had a large COP shift after 20 minutes, indicating that the design of the insole can maintain gait asymmetry in the short term to achieve improved torque and gait parameters.

In terms of knee adduction torque, our results show that the CLWI significantly reduced knee adduction torque during walking ( $P < 0.05$ ). At the same time, under all gait conditions, the knee joint adduction torque and the GRF moment arm reduction ratio was similar, and these reduction rates were similar to those observed in previous studies [25]. The aforementioned indicates that the insole can improve the stability of the affected side of a patient with asymmetric motion. Of course, since the participants were healthy individuals, there would be a large difference in body feeling and limb control from that of an actual patient, and that is a limitation of this study.

Although the increase in GRF was small in this study, the LWI reduced the moment arm in the early and late stages of horizontal walking, similar to the results of previous studies [26,27]. The reduction of ground reaction torque and knee adduction torque was similar under all walking conditions. Therefore, the main reason for the LWI reducing the knee joint adduction torque during ramp walking was to shorten the GRF moment arm. The GRF is close to the center of gravity during walking. Therefore, the lateral displacement of the COP can increase the medial GRF. However, the increase in medial force is much smaller than the vertical GRF and has little effect on the angle of the ground reaction vector. The lateral shift of COP in this study offset the effect of increased internal reaction on the moment arm.

In the experiment, the left side ankle valgus moment was reduced because of the side wedge insole, which was different from the results of previous studies [28]. The increase in the lateral movement of the COP shortened the axis of the GRF to the axis of the heel, resulting in a decrease in the valgus moment. Therefore, in contrast to the traditional insole, the CLWI had the effect of reducing ankle injury.

There was no significant difference in pace and step size measured with and without the insole. Therefore, the insole factor does not affect the mobility function. This important finding, together with the change in gait symmetry observed after the insole was used, shows that using a single-sided insole, especially a CLWI, might become a tool for improving the gait symmetry of affected individuals.

### Limitations

Our research had limitations. We only examined the effect of a single-sided wedge insole during walking of a healthy young males without examining the effect of patients wearing a one-sided wedge insole. Patients with knee joint disharmony and knee instability might have different responses to the incisor wedge insole [29]. Moreover, this study only estimated the knee joint load by studying the knee joint adduction torque. Therefore, it is necessary to further study the effects of joint mechanical parameters, such as joint internal reaction force, on unilateral knee arthritis patients to clarify the role of the side wedge insole during walking. At the same time, this study

only investigated the role of wearing a one-sided side wedge insole over the short term and did not conduct long-term follow-up investigations. Therefore, it is meaningful to further study the biomechanics effects of long-term wearing of the one-sided wedge insole on the lower limbs of participants.

### Conclusions

The single-sided lateral wedge insole reduced knee joint adduction torque during walking due to the alternating lateral displacement of the COP and the ground reaction force moment arm. The asymmetry of posture and gait could be seen after a short time using a customized 3D-printed single-sided lateral wedge insole. The results of this study provide a baseline for future studies using customized 3D-printed orthopedic insoles in gait rehabilitation.

### Conflicts of interest

None.

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