

Effects of Lateral Wedge Insole on Static and Dynamic Balance in Patients with Moderate Medial Knee Osteoarthritis

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ABSTRACT

BACKGROUND AND OBJECTIVE: Knee osteoarthritis (OA) is associated with diminished joint proprioception, balance deficits and increased risk of falls. Patients with medial knee osteoarthritis are at higher risk of balance deficits and falling due to the development of secondary varus deformity. Therefore, it is of great clinical importance to identify the treatment methods that could improve balance in knee OA. The purpose of this study was to evaluate the effects of Lateral Wedge Insole (LWI) on static and dynamic balance in patients with moderate medial knee osteoarthritis.

METHODS: Thirty patients with moderate medial knee OA participated in this semi-experimental interventional study. Patients were recruited from orthopedic and rheumatology clinics of the university. For each patient, the static and dynamic balance were assessed in two conditions including wearing shoes with flat insole and wearing shoes with lateral wedge insole, using a Prokin stabilometer. The balance variables were the anteroposterior and mediolateral velocity and standard deviation of the center of pressure (COP) displacement, and total stability indices. Patients performed two familiarization trials, then, three actual trials with at least 30 s interval for each test.

FINDINGS: Wearing LWIs resulted in significant decreases in the anteroposterior (static:1.78mm/s, dynamic:6.63mm/s) and mediolateral velocity of COP (static:1.53mm/s, dynamic:5.58mm/s) in comparison to wearing shoes with flat insole ($p<0.001$). The anteroposterior (static:1.04 mm, dynamic:1.57mm) and mediolateral SD of the COP (static:1.58mm, dynamic:2.02mm) were also decreased after using LWIs ($p<0.007$). Except for the anteroposterior stability index, other balance indices were also significantly improved ($p<0.05$).

CONCLUSION: Our findings suggest that using a LWI improve static and dynamic balance in patients with moderate medial knee OA.

KEY WORDS: *Foot Orthoses, Osteoarthritis, Knee, Postural Balance, Genu Varum.*

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Introduction

Osteoarthritis is a chronic destructive joint disorder, with a prevalence of 30-40% in the population over 65 years (1,2). Knee osteoarthritis is the most common type of osteoarthritis and one of the most important causes of chronic pain and disability in the world (3). Patients with knee osteoarthritis generally suffer from progressive pain and dysfunction in functional activities and balance disorders that pose a serious threat to the independence and quality of life of the individual in advanced stages of the disease (4). Knee osteoarthritis has no definitive cure and the aim of conservative treatment in these patients is to reduce the symptoms and control the progression of the disease by relying on a combination of pharmacological and non-pharmacological therapies (5,6).

Non-pharmacological treatments for this disease include physiotherapy, patient education, weight loss, and mechanical interventions such as the use of orthoses (7). Osteoarthritis can affect the internal, external, or patellofemoral joints to varying degrees. In the internal knee osteoarthritis, more degenerative changes are observed in the internal articular cartilage and the internal articular stenosis is more pronounced. Under normal conditions, the body's gravity travels through the inner compartment of the knee, thus, during walking, the cross-section of the internal compartment is about 2.5 times greater than the external compartment of the knee (8). In patients with internal knee osteoarthritis, this causes more and more rapid destruction of the articular cartilage, further reduction of the articular space of the medial compartment, and the gradual formation of secondary varus deformities (9,10). In internal knee osteoarthritis, abnormal distribution of articular forces and joint alignment changes affect sensory afferent nerves and consequently motor responses, causing postural balance disruption and increased risk of falls (11-15, 4).

Therefore, a part of the physiotherapy program focuses on improving balance through neuromuscular training and biomechanical interventions. One of the most common biomechanical interventions is the use of external wedge insole, which is used to correct the distribution of forces in the lower extremity chain and to improve the Joint proprioception (16,17). Until now, some studies have reported the positive effects of the use of external wedge insole on reducing varus torque and reducing the load on the internal knee joint (19). But the knowledge about the impact of this type of insoles on the balance of patients is still very limited. So far, several studies have investigated the effect of external

wedge insole, mainly on static balance, in patients with osteoarthritis, whose results have been inconsistent. In the studies of Ahmadi et al., and Zangi et al., the influence of insoles only on static balance (not dynamic equilibrium) and in groups consisting of individuals with varying degrees of osteoarthritis has been studied (20, 21), whereas balance disorder and falls generally occur during dynamic activities. Therefore, evaluating the effectiveness of therapies on dynamic balance has more clinical importance. In addition, the severity of osteoarthritis is a factor that can influence patients' response to using insoles (18), thus, the inclusion of patients with different severity of osteoarthritis in a treatment group may conceal the desirable effects of insoles on certain patient subgroups and lead to the wrong clinical conclusion.

In another related study, Hsieh et al. investigated the effect of insoles only on overall stability indices (22), while methodological studies show that equilibrium indices of standard deviation and center of displacement velocity are more sensitive to group differentiation. They have both healthy and ill patients and evaluate the effectiveness of treatments (23). Given the prevalence of balance disorders and the risk of falls in patients with internal knee osteoarthritis, understanding the therapies associated with improved balance in these patients has clinical importance.

This issue is particularly importance in patients with osteoarthritis of the internal compartment of the knee who are at greater risk of falling secondary due to the formation of secondary varus deformity. Therefore, the present study was conducted to investigate the effect of external wedge insole on the static and dynamic balance of patients with knee osteoarthritis. In order to identify more accurately the effects of external wedge insole and to prevent the interventional effect of intensity of radiographic changes on patients' response to treatment, this study was performed on patients with moderate radiographic intensity.

Methods

This Interventional quasi-experimental study was carried out on thirty patients with moderate-intensity knee osteoarthritis (grade 3 according to the Kellgren-Lawrence criterion) after approval in the Ethics Committee of Ahvaz University of Medical Sciences with registration code: IR.AJUMS.REC 559-1394 (9). Participants were referred to the orthopedic and rheumatology clinics of Jundishapur University of Ahvaz who were invited by telephone to participate in

the study. By telephone call, general conditions such as age, and history of specific illnesses were assessed based on patient report. Patients were then referred to the Radiology Center for knee radiography and evaluation of radiologic criteria. Eligible individuals were entered into the study after written consent. The study power based on the results of the pressure center displacement velocity in the anterior-posterior and internal-external directions with a sample size of 30 was 0.97 and 0.92, respectively. All participants had bilateral knee osteoarthritis with secondary varus deformity. Inclusion criteria were over 50 years old, internal orthopedic or rheumatologist diagnosed with internal osteoarthritis, knee pain more than 30 out of 100 based on visual acuity scale, grade 3 osteoarthritis according to KL criteria, and knee varus verification (9). In the KL system, grade 3 osteoarthritis involves multiple osteophytes, joint stenosis, sclerosis, and possible bone deformity (24). Exclusion criteria included predominance of symptoms of patellofemoral joint involvement and external compartment of the knee (greater reduction of articular space in external compartment than internal) (25), history of knee surgery and systemic arthritis, neurological disease associated with movement and balance disorders, and foot and ankle joint pathologies were contraindicated using insole (25). Level of performance was assessed by the Persian version of the WOMAC questionnaire, whose validity and reliability were reported to be 0.91 in patients with knee osteoarthritis (26).

The questionnaire contains three subscales for assessing pain, stiffness, and physical function. Each question is scored from zero (no problems) to four (severe problems) and then the raw score of each part is reported as a percentage. The severity of pain was assessed by Visual Analogue Scale (VAS). Participants were asked to indicate their average pain intensity over the past month on a 100 mm line with the left end indicating no pain (score zero) and the right end indicating unimagined pain (score 100).

To determine the angle of varus, a AP radiograph was performed during weight bearing with a flat knee, and to rule out patellofemoral joint involvement, a lateral radiograph was taken at approximately 30 ° flexion angle from the knee that was most commonly reported. To confirm knee varus, the angle between the tibia and femoral axis must be less than 180 degrees (9). To measure varus angle, first the anatomical direction of the knee was determined by Moreland method (27), and then the mechanical direction of the knee was

determined using Hinman equation (28) (Fig 1). In the Moreland method, the anatomical direction is determined by measuring the angle between the anatomical axis of the tibia and the femur. To draw the anatomical axis of the femur, a line was drawn from the center of the tibia spine to a point 10 cm proximal to the medial inner-outer width of the spine, and to determine the tibia axis, a line from the tibia axis to 10 cm. The distal mm was drawn in the middle of the inner-outer width of the tibia (Fig 1).



Figure 1. Anatomical alignment of the knee was determined based on the angle between the anatomical axis of the femur (AB line) and the tibia (AC line). The femoral axis was a line connecting the tibia to the midpoint of the transverse line of the trunk about 10 cm proximal. The tibia axis was a line connecting the tibia spine to the midpoint of the tibia shaft transverse line at a distance of 10 cm. Finally, the mechanical axis of the knee was calculated based on Hinman's equation (mechanical direction=13.895+(0.915 * anatomical angle) (28).

The mechanical direction was calculated by the following formula in which the angle less than 180 degrees indicates the direction of the varus (Equation 1). Repeatability within the measurement tester in the pilot study was 0.93. All radiographic evaluations were performed by an experienced radiologist.

$$\text{Mechanical Direction of the Knee} = 13.895 + (\text{Anatomical alignment} * 0.915)$$

For equilibrium evaluation, the Prokin device with 20 Hz sampling frequency was used (TecnoBody Prokin 252, Bergamo, Italy). The Prokin device contains a static and dynamic equilibrium balance plate that measures the balance based on the amount and velocity of the center of pressure in two internal-

external, anterior-posterior, and overall directions. For static equilibrium evaluation, the equilibrium plane is in a constant state, and for dynamic equilibrium estimation, the equilibrium plane is moving in all directions (360° space). The degree of difficulty in maintaining dynamic equilibrium is determined by the degree of deviation from the horizontal plane based on the angle. In this study, the difficulty level of the equilibrium test was adjusted to the dynamic level of 10, where the plate curvature relative to the horizon is 15 degrees and the lowest degree of stiffness. In this study, a full-length external wedge insole with 5-degree curvature angle and a simple insole were made for each patient from hard foam. Previous studies have shown that the tolerance of wedge insole with 5-degree curvature is easier for patients than those with higher curvature angles (18, 28). Before performing the tests, patients walked with wedge insoles for 5 minutes to ensure comfort for the patient.

Then, the static and dynamic equilibrium of patients in standing position with two feet with open eyes in two modes of wearing shoes with simple insole and wearing shoes with external wedge insole were evaluated in random order. Patients performed two experimental trials for familiarization, then three main trials, each with a duration of at least 15 s, with a rest of at least 15 s. During the tests, a re-test was repeated if the patient had to take the device's batches to maintain balance. Patients' pain was also monitored during the tests and excluded if the pain was exacerbated or feared. The research team provided patients with different sizes of shoes with the same design and manufacturer to eliminate the effect of the difference between the design and the material of the shoe. The equilibrium indices evaluated in this study were velocity and standard deviation of pressure center displacement in two directions: anterior-posterior and internal-external, oval area inscribed on oscillation center of pressure center and general stability indices in two simple insole modes. External wedge insoles were measured and compared. The Smirnov-Kolmogorov test was used to determine the normal distribution of the data and the paired t-test

was used to assess the effect of external wedge insole and $p < 0.05$ was considered significant.

Results

The Kolmogorov-Smirnov test results indicated that the distribution of participants' characteristics and participants' equilibrium indices were normal (Table 1). Paired t-test results compared to static equilibrium indices showed significant decrease in anterior-posterior velocity ($p = 0.001$, mean = 1.78 mm/s mean difference (MD) and internal-external ($p = 0.005$, mm/s 53/1MD) after using an external wedge insole compared to before (Table 2).

Table 1. Characteristics of participants

Variable	Mean±SD
Age (year)	61.7±6.9
Body mass index $\frac{\text{kg}}{\text{M}^2}$	27.7±4.3
Visual analog scale (0-100)	77.1±14.7
Varus malalignment (°)	175.5±2.7
WOMAC pain	38.1±18.2
WOMAC stiffness	56.3±14.8
Physical performance	49.9±16.3

Abbreviations: WOMAC: The Western Ontario and McMaster Universities Osteoarthritis Index

Anterior-posterior standard deviation ($p < 0.001$, MD: 1.04 mm), internal-external ($p < 0.001$, MD: 1.05 mm) and oval area ($p < 0.001$, MD: 150/58 mm²) were also reduced after using external wedge insoles (Table 2). The analysis of dynamic equilibrium data also showed a significant decrease in anterior-posterior velocity ($p < 0.001$, MD: 6.63 mm/s) and internal-external ($p < 0.001$, MD: 5.58 mm/s) after using external wedge insoles. The anterior-posterior standard deviation ($p = 0.007$, MD: 1.57 mm) and internal-external ($p < 0.001$, MD: 0.22 mm) dynamics were also significantly reduced (Table 3). Except for anterior-posterior stability index, other dynamic equilibrium variables also showed a significant decrease ($p < 0.05$) (Table 3).

Table 2. Influence of external wedge insole on static balance in patients with internal knee osteoarthritis

Variable	Without external Mean±SD	With external Mean±SD	Difference in means (CI-95%)	P-value
Anterior-posterior standard deviation) mm(	5.30±1.69	4.25±1.64	1.05(0.44-1.65)	0.001
External-internal standard deviation) mm(	6.71±1.49	5.13±1.56	1.58(0.46-1.38)	<0.001
Anterior-posterior velocity)mm/sec(	9.56±3.07	7.85±2.92	1.78(0.77-1.83)	<0.001
External-internal velocity) mm/sec(	9.4±3.09	7.87±3.46	1.53(0.51-2.56)	0.005
Oval area) mm ² (	423.54±174.49	272.79±135.17	150.78(96.28-205.20)	<0.001

Significance level was set at $p < 0.05$

Table 3. Effect of external wedge insole on dynamic balance in patients with medial knee osteoarthritis

Variable	Without external Mean±SD	With external Mean±SD	Difference in means (CI-95%)	P-value
Anterior-posterior standard deviation _(mm)	7.97±2.15	6.4±1.95	1.57(1.19-1.97)	0.007
External-internal standard deviation _(mm)	8.73±3.09	6.71±2.98	2.02(1.33-1.91)	<0.001
Anterior-posterior velocity _(mm/sec)	23.15±5.39	16.52±3.95	6.63(4.93-8.32)	<0.001
External-internal velocity _(mm/sec)	23.37±7.47	17.79±4.87	5.58(4.03-7.13)	<0.001
Oval area _(mm²)	937.68±363.14	607.61±161.4	230.06(217.71-442.42)	<0.001
Overall stability index	9.71±2.19	8.78±1.67	0.92(0.7-1.76)	0.01
The overall index of anterior-posterior stability	6.48±1.89	6.12±1.48	0.35(-0.27-0.98)	0.18
The overall index of internal-external stability	7.07±1.79	6.12±1.53	0.94(0.22-1.66)	0.007

Significance level was set at $p < 0.05$

Discussion

The results of this study showed that the use of external wedge insole significantly improved the static and dynamic balance of patients with moderate severity osteoarthritis. Insole use was associated with an improvement of approximately 20 to 30% in speed and standard deviation of pressure center displacement in both anterior-posterior and internal-external directions. This study is the first study to investigate the effect of external wedge insole on static and dynamic balance in a specific subgroup of patients with moderate to severe osteoarthritis. Previous studies have neglected the confounding effect of osteoarthritis severity on the effects of insoles (29) and examined the insect effect in groups containing patients with varying degrees of osteoarthritis (20,21). There is no similar study that can directly compare the results of the study. But overall, the results of previous studies on the effects of external wedge insole on patients with knee osteoarthritis are inconsistent (20,22).

In a study by Ahmadi et al., the researchers did not find a positive effect of the use of external wedge insole on the balance of patients with knee osteoarthritis (20). In the study of Ahmadi et al., the curvature angle of the external wedge was 8.5 °, which is not convenient for patients to use. In this regard, some researchers have previously reported the negative therapeutic effects of using high curvature insole (18,28). In contrast, in the study of Zangi et al. despite not seeing the immediate effect of external wedge insoles on patient balance, it improved after one month of using lateral balance insoles (21).

Contrary to the results of Zangi et al., Hsieh et al. did not observe a significant change in the balance of patients with knee osteoarthritis at one, three, and six months after using the external wedge insole compared to before use (22). Perhaps the reason for the inconsistency in the results of these studies is to ignore

the confounding effect of osteoarthritis severity on the outcome of therapeutic interventions. Loss of muscular strength and deep joint sensation are the most important causes of balance disorder and falls in patients with knee osteoarthritis (30,31). Knee disruption in patients with secondary deformity varus also has an adverse effect on knee deep sense (32), which is likely due to changes in the distribution of forces in the joint. The immediate impact of improving the balance of patients in our study is probably due to the improvement of deep sense and neuromuscular control mechanisms. The desirable effects of an external wedge insole to improve balance can partly be related to the possible change in ankle angle caused by the use of the insole (33). However, judgments about the mechanisms of the effectiveness of external wedge insole on balance improvement require comprehensive studies in which, in addition to balance indices, joint position sense and ankle joint angle with heel are examined. One of the limitations of this study was the small number of male participants. In fact, most referral patients were women with osteoarthritis, which could be related to specific social conditions, multi-occupation of men, and psychosocial issues. It is likely that easier adjustment and acceptance of pain for men and occupation have led to a decrease in men seeking treatment than women. Our results show that the use of external wedge insoles improves static and dynamic balance in both lateral and anterior-posterior plane of motion in patients with moderate-intensity knee osteoarthritis.

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