The effects of lateral wedge insoles on primary knee osteoarthritis patients
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Background
Osteoarthritis is the most common degenerative joint disease. Knee osteoarthritis (KOA) is the most common disability due to pain and dysfunction; it typically affects the medial tibiofemoral joint compartment.

Objectives
The use of orthosis as lateral wedge insoles (LWIs) helps in the reduction of symptoms and improvement of function and can reduce many of the biomechanical risk factors for disease development in osteoarthritis patients.

Aim
The study aimed to determine the possible mechanical and clinical effects of the different LWIs to assess their role in the management of the medial compartment KOA.

Method
The study included 48 knees divided into three groups, group A received only conventional physiotherapy, group B received LWI and group C received subtalar strapped (STS) LWI for 4 months.

Results
The Western Ontario and McMaster Universities osteoarthritis index score showed high significance, P value less than 0.001, for most subscales, femorotibial angle and plantar pressure peaks at the five metatarsal areas (M1, M2, M3, M4, M5), midfoot, medial heel and lateral heel areas, and center of pressure showed high significance, P value less than 0.001 for both insoles.

Conclusion
The positive outcomes suggested that LWI and STSLWI insert are viable alternatives in the conservative management of patients with medial KOA. The use of LWI and STSLWI helps to prevent the progression of medial KOA if used. In early grades of medial KOA as grades 2 and 3. The results not only suggested clinically symptomatic improvement with an inexpensive conservative therapy, but also a less complicated comfortable orthosis of alignment benefit to KOA.

Keywords:
femorotibial angle, lateral insole, osteoarthritis, plantar pressure, Western Ontario and McMaster Universities osteoarthritis index

Introduction
Knee osteoarthritis (KOA) affects the medial tibiofemoral joint compartment [1]. Gait analysis has served to quantify knee joint biomechanics [2] and muscle activation differences [3]. It explains altered muscle activation during gait in the medial compartment KOA compared with similar age asymptomatic individuals [4]. Shoes with a variable-stiffness sole reduced the peak knee adduction moment with KOA [5]. Reductions of 6.0 and 8.0% were found with 5° and 10° lateral wedge insoles (LWIs), respectively [6]. Foot pain and structure has been linked to KOA; thus, poor footwear choices may play a role [7]. Health professionals have a responsibility to consider footwear characteristics in their management plans [8]. Pressure assessment systems provide data that evaluate the treatment outcomes [9]. A large amount of research has focused on foot dynamics and pressure analysis in human gait [10]. Pressure measurement systems are used by clinicians to measure foot parameters [11].

This study aims to determine the possible mechanical and clinical effects of the different LWIs to assess its role in the management of the medial compartment KOA.
Patients and methods
The 48 knees were divided into three groups each of 16 knees.

Group A received conventional physiotherapy for KOA (ultrasound, transelectrical nerve stimulation, and exercises).

Group B received conventional physiotherapy for KOA and LWI (Fig. 1).

Group C received conventional physiotherapy for KOA and subtalar strapped (STS) LWI (Fig. 2). All the three groups received three sessions per week for 4 months and were assessed at the beginning and at the end of the study. Exclusion criteria: patients who use a gait aid, insoles, and foot orthotics were excluded. Patients with lateral tibiofemoral compartment joint space narrowing greater than medial and patients with foot or ankle problems and those with hip or knee joint replacement were also excluded. In addition, radiography findings grade 1 or severe radiographic disease grade 4 (Kellgren and Lawrence) and valgus knee alignment more than 185° on a standardized standing knee radiography were excluded. Any patient with MBI more than or equal to 36 kg/m² and balance impairment (cerebrovascular accident, multiple sclerosis, and Parkinson’s) or other causes of arthritis or musculoskeletal disorder of the lower limb (rheumatoid arthritis, gout, seronegative arthroplasty, diabetic, hemochromatosis, Wilson’s disease, hemophilia, neuropathies, and other causes of secondary OA), and those who had suffered mechanical knee trauma were all excluded from this study. The severity was assessed functionally by Western Ontario and McMaster Universities osteoarthritis index (WOMAC) score Likert scale questionnaire. The data were assessed using WOMAC. The pain score ranges from 0 to 20 to assess knee pain; the highest score indicates worst pain. The stiffness score ranges from 0 to 8; the higher the score the more the stiffness. The function score ranges from 0 to 68 to assess impairment in physical function; the higher the score the worst the function [12]. Plain radiograph of the knee joints was used to diagnose medial compartment OA. Severity was assessed by using the Kellgren and Lawrence grading system for OA severity [13]. Genu varum was assessed by measuring the femorotibial angle (FTA) in the anteroposterior view [14]. The primary medial compartment KOA patients were subjected to measurement of plantar pressure and force with and without the lateral wedge using the MatScan plate (Tekscan Inc., South Boston, Virginia, USA). Plantar pressure distribution in sites of foot at the five metatarsal areas (M1, M2, M3, M4, and M5), midfoot (MF), medial heel and lateral heel (MH, LH) areas and center of pressure were assessed (Fig. 3).

Results
There was no significant difference between groups for age, weight, height, and BMI, as P value more than
All groups of the study were matched with regard to age, weight, height, and BMI at the start of the study (Table 1).

The WOMAC score before and after the end of the study’s statistical analysis showed that there was a highly significant difference in pain, stiffness, and function for groups A, with \( t = 5.96, 6.43, \) and 11.63; \( P \) value less than 0.001, respectively, and no significant difference \( P \) value more than 0.05 for total WOMAC for groups A \( t = 1.31 \) (Table 2).

Although statistical analysis of all WOMAC subscales showed that there was high significance \( (P \leq 0.001) \) for group B \( (t = 9.70, 11.06, 5.28, \) and 9.91, respectively) (Table 3), group C showed high significance \( (P \leq 0.001) \) for pain, stiffness, and function \( (t = 8.88, 7.32, \) and 4.74, respectively); total statistical analysis showed significance \( (P \leq 0.05) \) for group C \( (t = 5.92) \) (Table 4).

The mean of FTA before and after the end of the study in groups A, B, and C showed highly significant difference \( (P \leq 0.001) \) for groups B and C, while group A statistical analysis showed no significant difference \( (P \geq 0.05) \). Figure 4 shows the difference comparing all groups before and after the study.

Plantar pressure peak in group A statistical analysis showed a significant difference \( (P \leq 0.05) \) for the MF area \( (t = 2.42) \), while other plantar pressure areas, as well as FTA, showed no significant difference \( (P \geq 0.05) \) (Table 2).

Plantar pressure peak statistical analysis showed no significant difference \( (P \geq 0.05) \) for all pressure areas in group A before and after the study, except for MF area, which showed a significant difference \( (P \leq 0.05, t = 2.42) \) (Table 2). Plantar peak pressure showed a statistically high significant difference \( (P \leq 0.001) \) for all pressure (M3,4,5, M1, M2, MF,

![MatScan barefoot peak pressure in stance.](image1)

![Femorotibial angle (FTA) before and after.](image2)

| Table 1 Descriptive data of demographic data in all study groups A, B and C |
|---------------------------------|-----------------|-----------------|-----------------|
| Demographic data                | Group A (mean±SD) | Group B (mean±SD) | Group C (mean±SD) |
| Age (years)                     | 57.25±7.3 (46–68) | 50.12±6.8 (36–60) | 54.75±8.06 (46–67) |
| Weight (kg)                     | 86.75±7.2 (75–97) | 90.25±4.8 (83–97) | 88.25±7.45 (76–99) |
| Height (cm)                     | 161.12±5.2 (155–169) | 163.75±5.2 (152–169) | 162.50±6.25 (156–173) |
| BMI (kg/m²)                     | 33.76±1.6 (31.5–36.8) | 33.66±1.8 (31.6–36.9) | 33.39±1.30 (31.2–35.8) |

![Mean values of FTA in groups A, B, and C before and after the end of the study. FTA, femorotibial angle.](image3)
MH, and LH) areas (t = 4.39, 19.00, 19.36, 19.32, 19.00, 19.36, and 14.34, respectively) in group B before and after the study (Table 3). Plantar peak pressure showed a statistically high significant difference (P < 0.001) for all pressure (M3,4,5, M1, M2, MF, MH, and LH) areas (t = 4.13, 23.89, 17.49, 22.33, 21.94, and 25.03, respectively) in group C before and after the study (Table 4).

Table 2 Group A comparison between before and after the study

|            | Before       | After        | Paired t | P value | Significance |
|------------|--------------|--------------|----------|---------|--------------|
| Pain       | 14.81±1.74   | 14.33±1.64   | 5.96     | <0.001  | HS           |
| Stiffness  | 5.90±0.35    | 5.46±0.49    | 6.43     | <0.001  | HS           |
| Function   | 50.05±4.35   | 49.53±4.35   | 11.63    | <0.001  | HS           |
| Total      | 70.88±4.67   | 70.00±3.63   | 1.31     | >0.05   | NS           |
| FTA        | 182.81±2.94  | 182.81±2.94  | 1.00     | >0.05   | NS           |
| M3,4,5     | 0.74±0.12    | 0.74±0.12    | 1.00     | >0.05   | NS           |
| M1         | 0.79±0.05    | 0.79±0.05    | 1.00     | >0.05   | NS           |
| M2         | 0.88±0.02    | 0.88±0.02    | 1.00     | >0.05   | NS           |
| MF         | 0.628±0.1    | 0.625±0.1    | 2.42     | <0.05   | S            |
| MH         | 0.85±0.22    | 0.85±0.22    | 1.46     | >0.05   | NS           |
| LH         | 0.87±0.27    | 0.87±0.27    | 1.00     | >0.05   | NS           |
| COP        | −5.17±1.24   | −5.12±1.27   | 1.52     | >0.05   | NS           |

Table 3 Group B comparison between before and after the study

|            | Before       | After        | Paired t | P value | Significance |
|------------|--------------|--------------|----------|---------|--------------|
| Pain       | 13.50±1.80   | 12.95±1.80   | 9.70     | <0.001  | HS           |
| Stiffness  | 6.20±0.48    | 5.71±0.53    | 11.06    | <0.001  | HS           |
| Function   | 46.36±2.89   | 45.70±2.69   | 5.28     | <0.001  | HS           |
| Total      | 66.08±5.02   | 64.36±4.86   | 9.91     | <0.001  | HS           |
| FTA        | 183.69±2.32  | 181.94±3.90  | 7.51     | <0.001  | HS           |
| M3,4,5     | 0.786±0.081  | 0.781±0.084  | 4.39     | <0.001  | HS           |
| M1         | 0.80±0.05    | 0.78±0.05    | 19.00    | <0.001  | HS           |
| M2         | 0.88±0.03    | 0.85±0.03    | 19.36    | <0.001  | HS           |
| MF         | 0.64±0.09    | 0.62±0.09    | 19.32    | <0.001  | HS           |
| MH         | 0.85±0.02    | 0.83±0.02    | 19.00    | <0.001  | HS           |
| LH         | 0.87±0.02    | 0.84±0.02    | 19.36    | <0.001  | HS           |
| COP        | −5.23±0.87   | −4.97±0.86   | 14.34    | <0.001  | HS           |

Table 4 Group C comparison between before and after the study

|            | Before       | After        | Paired t | P value | Significance |
|------------|--------------|--------------|----------|---------|--------------|
| Pain       | 14.47±2.17   | 13.66±2.07   | 8.88     | <0.001  | HS           |
| Stiffness  | 6.03±0.47    | 5.22±0.33    | 7.32     | <0.001  | HS           |
| Function   | 46.51±4.07   | 41.90±1.97   | 4.74     | <0.001  | HS           |
| Total      | 67.02±6.70   | 60.78±4.04   | 5.92     | <0.05   | S            |
| FTA        | 183.00±2.16  | 179.44±2.30  | 27.81    | <0.001  | HS           |
| M3,4,5     | 0.74±0.83    | 0.73±0.07    | 4.13     | <0.001  | HS           |
| M1         | 0.77±0.05    | 0.73±0.05    | 23.89    | <0.001  | HS           |
| M2         | 0.86±0.02    | 0.82±0.02    | 17.49    | <0.001  | HS           |
| MF         | 0.62±0.08    | 0.58±0.08    | 22.33    | <0.001  | HS           |
| MH         | 0.84±0.01    | 0.80±0.01    | 21.94    | <0.001  | HS           |
| LH         | 0.85±0.01    | 0.82±0.01    | 25.03    | <0.001  | HS           |
| COP        | −5.20±0.66   | −4.80±0.62   | 12.22    | <0.001  | HS           |

COP, center of pressure; FTA, femorotibial angle; HS, high significance; LH, lateral heel; M3,4,5, M1, M2, metatarsal areas; MF, midfoot; MH, medial heel; NS, no significance; S, significance.
Discussion
This study evaluated the effects of LWIs on medial KOA and compared them between two orthoses (LWI and STSLWI) (Figs 1 and 2); the study aimed to determine the possible mechanical and clinical effects of the different LWIs and their effect in management. Findings from the study confirmed the benefit of the use of LWI for medial compartment OA. The WOMAC score assessed for different symptoms, the measure of FTA for alignment and, lastly, the different plantar pressure areas for deformities. The WOMAC score used suggested that laterally elevated wedged insoles are more effective than neutrally wedged insoles, in pain relief of KOA [15]. The WOMAC score subscale of pain showed improvement for all three groups with a highly significant change, as well as stiffness and function, while the total WOMAC score showed no significant change for the patients receiving only physiotherapy (group A). These data suggested that pain, stiffness, function, and total WOMAC improved by using the wedge insole orthosis leading to symptom relief. It was reported that the LWI itself should change the mechanical axis, but it was not able to correct the lower limb alignment, while the strapping insole was able to correct FTA in patients with genu varum [16]. In this study, with regard to FTA, there was a highly significant change in both groups B and C. This suggested that both the lateral wedge insoles improved alignment of the lower limb. This difference in changing the limb alignment can be explained by the effect of STS. The varus deformity of the knee will not be changed by LWI because its effect is thought to be canceled in the subtalar joint. In contrast, the elastic strap would fix the subtalar and ankle joints and cause valgus angulation both in the talus and the tibia. The strapping of the joints would result in correction of varus alignment of the lower limb in patients with varus KOA. The LWI were effective for both grades 2 and 3 of OA, while the STSLWI had less effect in advanced knee grade [16]. Thus, for advanced KOA, LWI was the choice. However, STSLWI was the choice for the less advanced KOA, as it delays progression of the deformity. When standing, leg alignment was controlled by supinating or pronating the subtalar joint, corresponding to the valgus or varus deformity of the knee joint [17]. In contrast with this study, however, the alignment was improved in both groups with wedge insole; this may be due to limitations of the study; a larger sample size may show different results. The peak plantar pressure in this study also showed significant change between both groups with LWI, while the group with physiotherapy only showed minimal improvement. MF showed a significant change in group A. Joint deformity and foot posture may mediate the relationship between plantar loading and foot pain [18]. In KOA, percentage plantar weight (load) distribution pattern gets altered, resulting in pain and functional disability. The knowledge of this altered plantar weight distribution and its variation with change in functional position may serve as a therapeutic tool for formulating an effective context-specific intervention strategy for improving pain and functional status in patients with early KOA [19]. Increased plantar loading in patients with KOA may lead to foot pronation and gait changes during walking that appear on different plantar areas such as plantar peak pressure on MatScan (Fig. 3). Plantar loading may be offered to patients with KOA when considering footwear and foot orthoses. Foot mechanics during walking are interrelated to knee and hip joint kinematics because the entire lower extremities act as an integrated kinetic chain; a biomechanical abnormality in the joint can influence the loading at any other point in the lower extremities [20]. Increased rearfoot eversion, rearfoot internal rotation, and forefoot inversion are associated with reduced knee adduction moments during the stance phase of walking [21]. Patients with KOA experience greater plantar loading at MF, M1, and M2 loading in comparison with patients without KOA. Increased plantar loading may lead to foot pronation and gait changes during walking. Reducing plantar loading by using foot orthosis should be used [22]. Foot orthoses used in the study were both effective to improve clinical symptoms, alignment and positively influenced disease progression and deformity.

Limitations
This study assessed a relatively small sample over a short-term (4 months) follow-up. Additional analyses examining longer-term outcomes and follow up, as well as alternative mechanisms of pain relief, are indicated.

Conclusion
In conclusion, this study aimed to determine the possible mechanical and clinical effects of the different LWIs to assess their role in the management of the medial compartment KOA. Both of the insoles used LWI, and STSLWI suggested a clinical symptomatic improvement and both suggested alignment biomechanical improvement.
Furthermore, there was no provision for arch support in MF of inserted insoles; hence, it was possible that a flexible low arched foot would pronate as a result of the lateral wedge. Future research could evaluate the combination of the lateral wedge with arch support.

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Conflicts of interest
There are no conflicts of interest.