

The Impact of 6-Degree Lateral Wedge Insoles on Pain, Functional Parameters, and adduction Moment in Patients with Knee Osteoarthritis: A Six-Week Randomized Controlled Trial

Ali Asghar Jamebozorgi ^a, Mehdi Rezaei ^{b*}

^a Department of Occupational Therapy, Faculty of Rehabilitation, Shahid Beheshti University of Medical Sciences, Tehran, Iran; ^b Department of Orthotics and Prosthetics, School of Rehabilitation, Shahid Beheshti University of Medical Sciences, Tehran, Iran

* **Corresponding author:** Mehdi Rezaei, Department of Orthotics and Prosthetics, School of Rehabilitation, Shahid Beheshti University of Medical Sciences, Tehran, Iran, **E-mail:** me.rezaei@sbmu.ac.ir

Submitted: 2023-01-11; **Accepted:** 2023-05-08; **Doi:** <https://doi.org/10.22037/jcpr.v8i3.47274>

Abstract

Knee osteoarthritis (OA) is a prevalent degenerative joint disease that significantly impacts physical function and quality of life. While traditional management strategies focus on pharmacological and surgical interventions, the role of footwear modifications, such as lateral wedge insoles, has gained attention. This study aimed to investigate the effects of 6-degree lateral wedge insoles on pain, functional outcomes, and biomechanical parameters, such as the adductor moment, in patients with knee OA over six weeks. This was a randomized clinical trial study that twenty-one participants aged 50–75 years with moderate to severe knee OA were randomized into an intervention group (n=11), which received 6-degree lateral wedge insoles, and a control group (n=10), which used flat insoles. Pain levels, functional performance, and adductor moment were assessed at baseline and after six weeks. Results showed significant improvements in pain (45% reduction, $P=0.003$) and joint stiffness (30% reduction, $P=0.001$) in the intervention group, along with a 13% reduction in the adductor moment ($P=0.021$). Immediate effects also demonstrated a 35% reduction in pain ($P=0.007$) and a 42% reduction in stiffness ($P=0.001$). These findings suggest that 6-degree lateral wedge insoles can provide both immediate and sustained benefits for knee OA patients, highlighting their potential as a non-invasive management strategy.

Keywords: Adduction Moment; Biomechanics; Functional; Knee Osteoarthritis; Lateral Wedge Insoles; Pain

Please cite this paper as: Asghar A, Rezaei M. The Impact of 6-Degree Lateral Wedge Insoles on Pain, Functional Parameters, and adduction Moment in Patients with Knee Osteoarthritis: A Six-Week Randomized Controlled Trial. J Clin Physio Res. 2023; 8(3): e92. Doi: <https://doi.org/10.22037/jcpr.v8i3.47274>

Introduction

Knee osteoarthritis (OA) is a degenerative joint disease characterized by the progressive breakdown of articular cartilage, leading to pain, stiffness, and functional movement limitations (1). It is one of the most common forms of arthritis, particularly affecting older adults, and poses a significant public health burden due to its impact on mobility and quality of life patients (2). The prevalence of knee OA is increasing globally, with estimates suggesting that over 250 million people are affected worldwide. This condition not only diminishes physical function but also contributes to psychological distress and reduced participation in daily life activities (3).

Conventional management strategies for knee OA including; pharmacological treatments, physical therapy, and surgical

interventions (4). However, these approaches often have limitations, such as side effects, high costs, and variable efficacy. As a result, there is growing interest in non-invasive interventions that can alleviate symptoms and improve functional outcomes. Among these treatments approach, footwear modifications, such as lateral wedge insoles have gained attention for their potential to reduce knee joint loading and improve biomechanical alignments of individuals with knee OA (5).

Lateral wedge insoles are designed to shift the load distribution away from the medial compartment of the knee, which is often the most affected area in knee OA (6). By shifting the foot into a slight valgus position, these insoles can reduce the Knee Adduction Moment (KAM), a key biomechanical parameter associated with knee OA (7). Previous studies have demonstrated that lateral wedge insoles can provide significant pain relief and improve functional

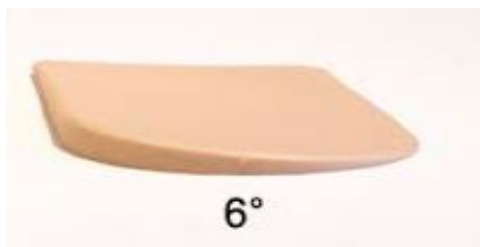


Figure 1. Polyurethane 6-degree lateral wedge insole

performance in Patients with knee OA (8). However, there is limited research on the specific effects of 6-degree lateral wedge insoles on pain, functional movement outcomes, and biomechanical parameters over both immediate and long-term use.

This study aimed to address this gap by investigating the impact of 6-degree lateral wedge insoles on pain, functional movement parameters, and the adductor moment in patients with knee OA over six weeks. By assessing both immediate and sustained effects of Lateral wedge insoles in patients with knee OA, this research provides valuable insights into the potential benefits of lateral wedge insoles for managing knee OA symptoms.

Methods

Participants

In this Randomized Clinical Trial (RCT) study, a total of 21 participants (10 males, 11 females) aged 50–75 years with a clinical diagnosis of knee OA classified as grade II and III according to the Kellegrane-Lawrance scale were recruited. Inclusion criteria included moderate to severe pain levels (≥ 4 on the Visual Analog Scale [VAS]) and no history of knee surgery or severe comorbid conditions (Altman *et al.*, 1986). Participants were put into an intervention ($n=11$) and a control groups ($n=10$) randomly.

Intervention

The intervention group received polyurethane 6-degree lateral wedge insoles, designed to reduce knee joint stress by shifting the load away from the medial compartment of the knee (Figure 1). The insoles were integrated into participants' usual footwear and featured additional cushioning and arch support. Participants were trained to wear the insoles for at least six hours a day over the six-week study period in a comfortable shoes.

The control group received flat insoles (0-degree incline) made from the same material as the lateral wedge insoles but without biomechanical modifications (9). This ensured that any observed effects in the intervention group could be attributed specifically to the lateral wedge design rather than usual insole use.

Outcome Measures

Pain Levels: Measured using the Visual Analog Scale (VAS) (10). The VAS is a subjective measure used to assess pain levels by themselves. Participants indicate their pain intensity on a 10 cm line, with one end representing "no pain" and the other "worst pain imaginable." Higher score reflects greater pain intensity, while lower score indicates improvement. This straightforward tool allows for quick assessments of pain, making it useful in clinical settings to monitor changes over time.

Functional Performance: Assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (11). The WOMAC is a comprehensive questionnaire designed to evaluate functional performance in individuals with knee OA. It consists of 24 items categorized into three sections: pain (5 items), stiffness (2 items), and physical functions (17 items). Higher scores on the WOMAC indicate worse symptoms and greater functional limitations, while lower scores suggest improved performance and reduced symptoms. This tool is essential for assessing the impact of interventions on patients' quality of life.

Biomechanical Parameters: The KAM was measured using a Vicon motion capture system during functional tasks to assess changes in joint force loading. Higher KAM values indicate increased medial knee loading, which is associated with a higher risk of OA progression. Conversely, lower KAM values suggest reduced joint loading, indicating potential improvement in knee function. Monitoring KAM is crucial for understanding the mechanical stresses on the knee and guiding rehabilitation strategies (7).

Assessments were conducted at baseline and after six weeks by blinded assessor.

Procedure

The study was conducted in collaboration with orthopedic specialists and physiotherapists. Participants were recruited from private clinics and rehabilitation centers in Tehran. After obtaining written informed consent, participants were randomly assigned to either the intervention or control group.

Marker placement was performed according to the Helen Hayes marker set protocol. Sixteen reflective markers (14 mm in diameter) were placed on specific anatomical landmarks, including: Anterior and posterior superior iliac spines (ASIS and PSIS) bilaterally, Greater trochanters bilaterally, Lateral femoral epicondyles bilaterally, Midpoints of the thighs bilaterally, Lateral malleoli bilaterally, Heels bilaterally, Second metatarsal heads bilaterally (7).

Participants were asked to walk a 13-meter walkway at their natural pace while data were collected using the Vicon motion capture system and Kistler force plates. The Vicon system consisted of six infrared cameras operating at 120 Hz,

synchronized with the force plates to capture kinetic data simultaneously. For extracting motion capture data and moments, advanced systems like the Vicon and Kistler force plates are utilized. In this process, reflective markers are placed on anatomical landmarks, and participants walk naturally on a walkway. The Vicon system consists of multiple infrared cameras that simultaneously collect kinematic and kinetic data alongside Kistler platforms that measure forces. This data includes information about body movements and the forces generated during walking, which can be used to analyze moments and motion parameters effectively(7).

Data Collection

Participants underwent baseline assessments, including pain (VAS), functional mobility (WOMAC), and biomechanical evaluation (KAM). After six weeks of using the prepared insoles, the same assessments were done by blind assessor.

Statistical Analysis

Data were analyzed using SPSS software (Version 25, IBM Corp., Armonk, NY, USA). Descriptive statistics, paired t-tests, and analysis of covariance (ANCOVA) were used to evaluate within-group and between-group differences. A p-value <0.05 was considered statistically significant.

Results

The study included 21 participants with an average age of 60.1 (± 3.24) years and a mean body mass index (BMI) of 28.4 (± 2.2). Baseline characteristics were similar between groups (Table 1).

Immediate Effects

The intervention group showed a significant reduction in pain ($P=0.007$) and a significant decrease in joint stiffness of approximately 42% ($P=0.001$) immediately after using the lateral wedge insoles. The KAM decreased by 30% ($P=0.054$), though this was not statistically significant (Table 2).

Effects of 6 weeks usage

After six weeks, the intervention group demonstrated a significant reduction in pain ($P=0.003$), a 30% reduction in joint stiffness ($P=0.001$), and a 13% reduction in the KAM ($P=0.021$) (Table 3).

Discussion

This study investigated the effects of 6-degree lateral wedge insoles on pain, functional mobility outcomes, and biomechanical parameters in patients with knee OA over a six-week period. The

results demonstrated significant improvements in pain reduction, joint stiffness, and the KAM in the intervention group compared to the control group. These findings were align with previous research highlighting the potential of biomechanical interventions, such as lateral wedge insoles, to alleviate symptoms and improve function in patients with knee OA (12, 13).

The immediate effects of the lateral wedge insoles were particularly noteworthy, with a 35% reduction in pain and a 42% reduction in joint stiffness observed after the first use. These findings suggested that lateral wedge insoles can provide rapid symptom relief, which is crucial for enhancing patient adherence and their quality of life. The reduction in the KAM, although not statistically significant in the short term, indicates a favorable biomechanical effect that may contribute to long-term joint preservation (14).

Over the six-week intervention period, the lateral wedge insoles continued to provide significant benefits, with a 45% reduction in pain and a 30% improvement in joint stiffness. However, the magnitude of these improvements diminished slightly compared to the immediate effects, suggesting that the initial benefits may plateau over time. This trend highlights the need for complementary interventions, such as physical therapy or exercise, to maintain and enhance the long-term benefits of lateral wedge insoles (15).

When compared to the control group using flat insoles, the intervention group showed significantly reduction in pain, stiffness, and improvement in biomechanical parameters. The control group's lack of significant improvement underscores the importance of biomechanical modifications in footwear design for managing knee OA (16). Flat insoles, while providing some cushioning and support, did not address the underlying biomechanical issues contributing to pain and joint degeneration (17).

This study has several limitations that should be acknowledged. First, the sample size was relatively small, which may limit the generalizability of the findings. Second, the study duration was limited to six weeks, which may not be sufficient to evaluate the long-term effects of lateral wedge insoles on knee OA progression. Third, the study did not account for potential confounding factors, such as variations in physical activity levels or adherence to the intervention. Finally, the use of a single type of lateral wedge insole (6-degree) may not capture the full range of biomechanical effects that could be achieved with different wedge angles or designs. And finally this study has not follow up too.

Recommendations

Future studies should address these limitations by including larger sample sizes, having follow-up stage, and more diverse patient populations. Additionally, research should explore the combined

Table 1. Demographic characteristics of patients ($P<0.05$)

Variables	intervention	Control group	Significance Level (P -value)
Patients (N)	11	10	-
Average Age (years)	59.3 (5.28)	61(1.2)	0.8
- Male	5	4	-
- Female	6	6	-
BMI (kg/m ²)	27.5 (3.2)	29.3(1.2)	0.09
Duration of Symptoms (years)	3.5 (1.2)	4 (1.2)	0.074

Table 2. Mean (SD) of immediate Effects of prepared insoles on Variables

Variables	Before Intervention	After Intervention	Percentage Change	Significance Level (P -value)
Knee adduction moment (N/M)	0.54 (0.15)	0.38 (0.19)	30%	0.054
Pain (Score)	7.28 (0.75)	4.71 (0.48)	35%	0.007
Function (Score)	58.28 (14.8)	33.71 (6.09)	42%	0.001

SD: standard deviation; Significant level<0.05

Table 3. Mean (SD) of six weeks usage effects of prepared insole on Key Variables

Variable	Control group	intervention group	Percentage Change	Significance Level (P -value)
Knee adduction Moment (N/M)	0.54 (0.15)	0.47(0.17)	13%	0.021
Pain (score)	7.28 (0.75)	4.00 (0.97)	45%	0.003
Function (score)	58.28 (14.8)	40.32 (5.97)	30%	0.001

SD: standard deviation; Significant level<0.05

effects of lateral wedge insoles with other therapeutic modalities, such as exercise, weight losing, surgery, and pharmacological treatments, to optimize outcomes for patients with knee OA. Further investigation into the biomechanical mechanisms underlying the effects of lateral wedge insoles, including the role of foot posture and gait mechanics, is also warranted. Finally, the development of personalized insole designs based on individual patient characteristics, such as knee alignment and severity of OA, could enhance the effectiveness of these interventions.

Conclusion

This study provides strong evidence supporting the use of 6-degree lateral wedge insoles as an effective non-invasive interventions for managing knee OA symptoms. The immediate and sustained improvements in pain, functional mobility, and joint mechanics highlight the potential of lateral wedge insoles to enhance patient performances. However, the diminishing effects over time suggest that lateral wedge insoles should be used as part of a comprehensive management plan that includes other therapeutic modalities, such as exercise and weight management. Future research should explore the long-term effects of lateral wedge insoles and their combination with other interventions to optimize outcomes for patients with knee OA.

Acknowledgment

None

Ethical consideration

IR.SBMU.RETECH.REC.1399.372

Funding support

None.

Conflict of interest

None.

Authors' contributions

MR: supervision, data curation, formal analysis, investigation, and methodology, writing, original draft. AJ: supervision, resources, and writing, original draft.

References

- Giorgino R, Albano D, Fusco S, Peretti GM, Mangiavini L, Messina C. Knee Osteoarthritis: Epidemiology, Pathogenesis, and Mesenchymal Stem Cells: What Else Is New? An Update. *International journal of molecular sciences*. 2023;24(7).
- Jang S, Lee K, Ju JH. Recent Updates of Diagnosis, Pathophysiology, and Treatment on Osteoarthritis of the Knee. *International journal of molecular sciences*. 2021;22(5).

3. Roos EM, Arden NK. Strategies for the prevention of knee osteoarthritis. *Nature reviews Rheumatology*. 2016;12(2):92-101.
4. Ferreira RM, Duarte JA, Gonçalves RS. Non-pharmacological and non-surgical interventions to manage patients with knee osteoarthritis: An umbrella review. *Acta reumatologica portuguesa*. 2018;43(3):182-200.
5. Baert IA, Nijs J, Meeus M, Lluch E, Struyf F. The effect of lateral wedge insoles in patients with medial compartment knee osteoarthritis: balancing biomechanics with pain neuroscience. *Clinical rheumatology*. 2014;33(11):1529-38.
6. Xing F, Lu B, Kuang MJ, Wang Y, Zhao YL, Zhao J, et al. A systematic review and meta-analysis into the effect of lateral wedge arch support insoles for reducing knee joint load in patients with medial knee osteoarthritis. *Medicine*. 2017;96(24):e7168.
7. Fischer AG, Ulrich B, Hoffmann L, Jolles BM, Favre J. Effect of lateral wedge length on ambulatory knee kinetics. *Gait & posture*. 2018;63:114-8.
8. Khosravi M, Arazpour M, Sharafat Vaziri A. An evaluation of the use of a lateral wedged insole and a valgus knee brace in combination in subjects with medial compartment knee osteoarthritis (OA). *Assistive technology : the official journal of RESNA*. 2021;33(2):87-94.
9. Lee S, Brown JR, Bartolomei C, Turnbull T, Miles JW, Dornan GJ, et al. Effects of Lateral Opening-Wedge Distal Femoral Osteotomy on Meniscal Allograft Transplantation: A Biomechanical Evaluation. *Orthopaedic journal of sports medicine*. 2023;11(6):23259671231156639.
10. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. *Pain*. 1983;17(1):45-56.
11. Bellamy N. WOMAC: a 20-year experiential review of a patient-centered self-reported health status questionnaire. *The Journal of rheumatology*. 2002;29(12):2473-6.
12. Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis and cartilage*. 2008;16(2):137-62.
13. Khosravi M, Babaee T, Daryabor A, Jalali M. Effect of knee braces and insoles on clinical outcomes of individuals with medial knee osteoarthritis: A systematic review and meta-analysis. *Assistive technology : the official journal of RESNA*. 2022;34(5):501-17.
14. Lewinson RT, Collins KH, Vallerand IA, Wiley JP, Woodhouse LJ, Reimer RA, et al. Reduced knee joint loading with lateral and medial wedge insoles for management of knee osteoarthritis: a protocol for a randomized controlled trial. *BMC musculoskeletal disorders*. 2014;15:405.
15. Ishii Y, Deie M, Fujita N, Kurumadani H, Ishikawa M, Nakamae A, et al. Effects of lateral wedge insole application on medial compartment knee osteoarthritis severity evaluated by ultrasound. *The Knee*. 2017;24(6):1408-13.
16. Hunt MA, Takacs J, Krowchuk NM, Hatfield GL, Hinman RS, Chang R. Lateral wedges with and without custom arch support for people with medial knee osteoarthritis and pronated feet: an exploratory randomized crossover study. *Journal of foot and ankle research*. 2017;10:20.
17. Fantini Pagani CH, Hinrichs M, Brüggemann GP. Kinetic and kinematic changes with the use of valgus knee brace and lateral wedge insoles in patients with medial knee osteoarthritis. *Journal of orthopaedic research : official publication of the Orthopaedic Research Society*. 2012;30(7):1125-32.