

COMPARATIVE EFFECTS OF LATERAL HEEL WEDGES FABRICATED FROM POLYPROPYLENE AND ETHYLENE VINYL ACETATE ON PAIN, FUNCTIONAL DISABILITY AND QUALITY OF LIFE IN PATIENTS WITH KNEE OSTEOARTHRITIS

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Keywords

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Abstract

Background: Knee osteoarthritis (KOA) is a chronic musculoskeletal condition commonly associated with pain, stiffness, functional disability, and reduced quality of life. Lateral heel wedges are used as a conservative biomechanical intervention to redistribute loading away from the medial compartment of the knee. However, limited evidence is available regarding whether the material used to fabricate the wedge influences clinical outcomes.

Objective: To determine the comparative effectiveness of lateral heel wedges fabricated from polypropylene (PP) and ethylene vinyl acetate (EVA) on pain, functional disability, and quality of life in patients with knee osteoarthritis.

Methodology: A randomized controlled trial was conducted at Shifa International Hospital, Islamabad, over six months. Fifty patients with clinically diagnosed medial compartment knee osteoarthritis (Grade I–III), aged above 35 years, were randomly allocated into two equal groups. Group A received PP lateral heel wedges, while Group B received EVA lateral heel wedges. Outcomes were assessed using the WOMAC and SF-36. Data were analyzed using paired-sample and independent-sample t-tests, with statistical significance set at $p < 0.05$.

Results: The mean age of participants was 49.34 ± 6.44 years. Both groups showed significant improvements following intervention ($p < 0.05$). Between-group analysis demonstrated significantly greater improvement with EVA than PP in overall clinical outcomes, including pain, stiffness, functional status, and quality of life (all $p < 0.001$). For example, the overall WOMAC score showed a significant between-group difference ($p < 0.001$), while the overall SF-36 score also demonstrated a significant difference ($p < 0.001$).

Conclusion: Both PP and EVA lateral heel wedges were effective in improving clinical outcomes in patients with knee osteoarthritis; however,

EVA demonstrated significantly greater overall benefits than PP. EVA may therefore be a more effective material for lateral heel wedges in improving symptoms, function, and quality of life.

INTRODUCTION

Knee Osteoarthritis (KOA) is a chronic musculoskeletal condition common in all age groups, which is defined by the progressive change in the structure and function of the knee. It is a combination of failure of articular cartilage, subchondral bone remodeling, synovial inflammation, meniscal pathology and changes in the periarticular muscles and other joint tissues (1). Current evidence suggests that KOA is a whole-joint disorder, rather than a cartilage-specific disease, and is influenced by mechanical, metabolic, inflammatory, genetic, and age-related factors. The knee joint is involved in many cases of persistent pain and physical disability in middle-aged and older adults, and KOA is one of the most common examples of the condition (2).

The burden of osteoarthritis has risen significantly over the last few decades, mainly due to population ageing, high prevalence of obesity and population growth. The rising prevalence of KOA has significant implications for health care systems, given that, KOA is associated with long-term health care utilization, impacts on productivity, physical activity restrictions and dependence on the family and/or caregivers (3).

In the clinic, the common symptoms of KOA include a painful knee, stiffness, decreased range of motion, swelling, crepitus, muscle weakness, and difficulty getting on and off the floor or off a chair. It usually lasts for a few hours in the morning, but can also happen in the morning after a period of rest. As symptoms progress, it may become difficult to get the patient to perform activities of daily living, and the patient may have less participation in recreational, occupational, and social activities. Most important, the severity of radiographic joint changes does not always closely track the intensity of symptoms experienced by any single patient, so patient-reported pain and functional status must be assessed in addition to structural findings (4).

One of the key symptoms that leads people to seek treatment when they have KOA is pain. This cycle of pain limiting activity and activity loss causing physical capacity loss and physical function loss can occur and can be a major cause of persistent knee pain. Thus, KOA must be considered as not just a structural joint disorder but as a condition that may get progressively getting worse and impacting a person's physical independence and overall health (5).

Another significant impact of KOA is functional disability. Impaired physical function can also make activities such as walking, climbing stairs, getting from a seated position to standing and daily activities at home or work more difficult, and this can lead to weight gain, sedentary behaviour and other cardiometabolic issues. This combination of pain, decreased mobility and comorbidities can further exacerbate the disease burden (6).

In addition, KOA significantly influences on health-related quality of life (HRQoL). Contemporary KOA management focuses on outcomes not only related to the radiographic or structural aspect of KOA, but also on pain reduction, restoration of physical function, and improvement of quality of life, which may all be influenced by psychological factors such as anxiety and depressive symptoms that can coexist with chronic KOA (7).

Although conservative treatment can be effective for KOA, patients often continue to have symptoms, and this situation is becoming more common around the world, there is a need for readily available treatments that can decrease pain and increase functional capacity. Biomechanical interventions that influence knee loading, such as foot orthoses and lateral heel wedges, have been of great interest both clinically and to researchers in this context (8).

Mechanical loading over the tibiofemoral articulation has a strong effect on knee OA. The ground reaction force during walking is applied to

the lower limb and generates an external knee adduction moment (KAM) that is considered to be an indirect measure of loading in the medial compartment (9). Therefore, interventions that redistribute loads from the medial compartment have been explored as conservative treatment for symptomatic KOA, especially in those with predominantly medial compartment KOA, where the increased medial loading may play a role in the development of pain, functional limitation and progression of the disease (10).

Line of foot/ankle may affect the mechanical environment of the knee. Excessive pronation or alterations in foot mechanics can change the location of the ground reaction force in relation to the knee joint in people with medial compartment KOA. The influence of these changes on the distribution of forces between the medial and lateral compartments, as well as on frontal plane knee moments, are what make the design of foot orthoses and wedged insoles a bit tricky. These changes can affect how the foot interacts with the ground and change the alignment of the lower limbs and the loads on them while they are on the floor (11).

A lateral heel wedge is an orthotic intervention in which the lateral side of the heel is raised compared to the medial side of the heel. This causes a valgus effect at foot and lower leg during stance. The proposed biomechanical mechanism is that the wedge would alter the location of the ground reaction force relative to the knee joint centre, thereby decreasing the external knee adduction moment, and hence the load through the medial tibiofemoral compartment, which is important for patients with medial compartment KOA(12).

Response to a lateral wedge can vary between patients due to different values of wedge angle, thickness, location, foot posture, footwear type, gait pattern and individual lower-limb alignment, and in addition, KOA is a heterogenous condition with variations in structural damage, foot posture, muscle strength, walking pattern and pain sensitivity. Thus, the biomechanical change a single orthotic can achieve in one person can be

different in another person and result in different clinical changes (13).

While the biomechanical justification may be strong, the reduction in knee adduction moment is not necessarily directly related to clinically relevant pain or function changes. The clinical effectiveness of a lateral heel wedge should be assessed by patient-centred outcomes (pain, functional disability, quality of life) and not just on biomechanical variables, as pain in KOA is a multifactorial condition (14).

Another factor is what kind of material is used to make the wedge. These are significant characteristics, including stiffness, flexibility, cushioning, durability, weight and how mechanical forces are transferred through the foot, that are determined by the material. This may affect the biomechanics as well as the comfort of the patient when using it for extended periods. Therefore, though the principle of lateral wedging is the same, there may be some variation in the therapeutic effectiveness and acceptability of different materials produced for the wedge (15).

Lateral heel wedges have been studied as a conservative biomechanical intervention in patients with medial knee osteoarthritis (OA) as their predominant knee complaint. They suggest that their clinical benefit would be mainly due to weight-bearing redistribution of the knee joint load. Lateral wedges may produce a lateral shift of the ground reaction force, which could reduce the external knee adduction moment and perhaps the increased loading to the medial compartment of the knee as a result of internal knee adduction moment, providing a rationale for considering lateral wedges as an intervention that should be evaluated as a relatively simple and non-invasive strategy in the treatment of symptomatic KOA (16).

There have been mixed findings about the impact of lateral wedges on pain. Reduction in knee pain has been reported several times in studies and systematic reviews, but the magnitude of the benefit has differed significantly between studies, indicating that response to the use of lateral wedge insoles may be dependent on patient characteristics, type of wedge, duration of use,

degree of mechanical correction, and the severity of the underlying disease (17).

Another key functional outcome to consider in the clinical effectiveness of lateral wedges is functional disability. Reduction in pain may improve walking and all weight bearing activities, and better biomechanics of the lower limbs may improve functional performance. However, more recent studies that evaluated foot orthoses for the treatment of medial KOA have shown changes in gait biomechanics as well as clinical outcome but it is unclear whether the changes in the biomechanical parameters result in meaningful improvements in functional ability in everyday life. Thus, functional measures should be assessed directly and not necessarily depend on biomechanical correction for the improvement of function (18).

Another factor to consider is the quality of life, as KOA has a bigger impact than the physical structures of the knee. Thus, an intervention that results in a small biomechanical modification and an unchanged functional status and/or patient perception of wellness may be of limited clinical importance. Patient-reported outcomes like pain, disability, health-related quality of life, therefore, take a more comprehensive measure of treatment efficacy (19).

The clinical effectiveness of a lateral heel wedge could be influenced not only by the geometry and amount of the wedging but also on the material used for the manufacturing of the wedge. Material characteristics like stiffness, elasticity, cushioning, weight, durability and deformation after repeatedly loading can affect the transmission of forces from the foot to the ground, especially for later shoes with lateral heel wedges for frequent users with the diagnosis knee osteoarthritis (20).

Polypropylene (PP) is a thermoplastic polymer, which is used in the manufacture of orthoses as it is relatively stiff, strong, lightweight and can be thermoformed to custom shapes, which help the orthosis retain its structural integrity when repeatedly loaded. The relatively rigid nature of PP can potentially help maintain the desired wedging angle and offer a constant mechanical correction during stance and walking for a lateral heel wedge.

But there are also some drawbacks to increased rigidity, as it can also decrease cushioning and in some cases could lead to increased plantar pressure or discomfort when worn, especially for extended periods of time (21).

Ethylene vinyl acetate (EVA), on the other hand, is a lightweight, flexible and resilient polymer which is widely used in footwear and orthotic applications. The cellular structure also offers cushioning and shock absorbing properties, which can make it more comfortable than relatively hard materials; EVA can also be chosen based on mechanical and cushioning properties depending on its density and hardness. In recent studies, the use of EVA has been shown to be beneficial when pressure redistribution and cushioning are the major factors involved, while more rigid materials may be preferred for their more important structural support and mechanical control (22).

These differences could be clinically significant in KOA. The polypropylene wedge could offer a more consistent mechanical correction compared to the EVA wedge that could offer more cushioning and impact absorption. Therefore, different effects on pain and functional performance can be expected between the two materials even if their geometric characteristics of the lateral wedge are kept the same. Patient comfort and compliance are specifically relevant to considering orthotic interventions. An intervention that causes a biomechanical correction that is not comfortable will lead to less duration and/or frequency of use, decreasing the intervention's practical effectiveness. On the other hand, a softer material could be more comfortable and may deform more with repeated loading, thus changing the size of the desired mechanical correction over time(23).

Although PP and EVA are well-known materials for use in orthotics, there have been no direct clinical comparisons of these materials when specifically fabricated as lateral heel wedges for knee OA. In recent years there has been a greater focus on individually prescribed orthotic design and orthotic material selection, however research evidence showing the relationship between orthotic materials and pain, functional disability

and quality-of-life outcomes in KOA remains limited. Thus, comparing polypropylene with EVA lateral heel wedges could be useful to assess whether material properties affect clinical outcomes in patients with KOA. Such a comparison may be clinically helpful for physiotherapists and orthotists in choosing the right type of wedge material for the mechanical correction, cushioning, comfort and functionality of the product (24).

Lateral heel wedges are commonly used as a conservative biomechanical intervention for reducing medial knee loading in patients with knee osteoarthritis. However, their effectiveness may be influenced by the material used for fabrication. Polypropylene provides greater rigidity and structural stability, whereas ethylene vinyl acetate offers greater flexibility and cushioning. These differences may influence pain, functional disability, comfort, and quality of life. Despite their widespread use in orthotic fabrication, limited evidence directly compares these materials when used as lateral heel wedges in knee osteoarthritis. Therefore, this study aims to compare polypropylene and EVA lateral heel wedges to determine their effects on pain, functional disability, and quality of life.

LITERATURE REVIEW

Ferreira et al. (2022) studied if there were biomechanical differences in knee osteoarthritis patients when small differences in lateral wedge insoles angles were made. The purpose was to assess if the incremental differences in the wedge angle have an effect on the lower-limb biomechanics while walking. Participants were tested in various lateral wedge positions, and analysis of the changes in joint kinetics and kinematics was carried out. The results showed that the biomechanical parameters of the lower limb could change due to even relatively small changes in the wedge angle. This indicates that the lateral wedging response to mechanical deformation depends on the geometry of the orthosis, and that there could be variation in the response amongst individuals with the same standardized wedge angle. Care needs to be taken

when designing lateral wedge insoles and the authors concluded that wedge angle should be carefully considered when designing lateral wedge insoles. It also reinforces the general idea that foot orthotic prescription can enhance its ability to alter foot biomechanics, and suggest that other orthotic design variables, such as the orthotic material used for fabrication, should be explored (25).

A pilot feasibility randomized controlled trial was performed to assess the effectiveness of lateral wedge insoles with and without contoured arch support in patients with knee osteoarthritis and concurrent foot pain by Hunt et al. (2026). The goal was to evaluate the feasibility, acceptability, compliance and initial clinical and biomechanical responses to the two orthotic designs over a 12 week period. Thirty participants were allocated to the two intervention groups randomly. Results showed the intervention to be feasible as there were no major adverse events, relatively high comfort level, and high adherence. The insole was generally found to be "moderate to good" in terms of comfort when worn by the participants. There were similar trends for both groups of improvements in knee pain and physical function, and of decreases in knee adduction loading measures. The study was, however, primarily a feasibility study and was not powered to make definitive clinical statements between groups. The authors concluded that the lateral wedge insert seems to be feasible and safe, and that further changes in the design of the weds, such as contoured arch support, should be investigated in larger trials (26).

Xu et al. (2026) examined how a lateral wedge insole would affect cumulative knee loading and affect physical activity in individuals with knee osteoarthritis. The goal was to progress from the assessment of instantaneous biomechanical parameters and to investigate if the lateral wedging would be able to decrease cumulative medial knee loading during daily activities. Twenty-one participants were assessed with gait analysis and activity monitoring methods pre and post intervention. The study showed pain and cumulative knee adductor loading decreases after

use of the lateral wedge insoles. Knee adduction moment impulse was also decreased immediately after the intervention and after three months of use. However, there was no significant increase in steps per day. Physical activity parameters, such as standing/ walking time, even decreased after the intervention. The authors concluded that lateral wedge insoles would be able to decrease the cumulative mechanical loading and pain but that the biomechanical unloading would not necessarily be accompanied by greater physical activity (27).

The purpose of this systematic review and meta-analysis by Jiang et al. (2026) was to investigate the acute and mid- to long-term changes in gait biomechanics and clinical characteristics in individuals with medial knee OA after foot orthoses treatment. The aim was to integrate evidence on the ability of foot orthoses to change knee loading, gait characteristics, pain and function. The literature included in the review included studies examining various categories of foot orthoses, and orthotic interventions were shown to alter gait biomechanics parameters associated with medial knee loading parameters. Still, significant variation was found in the way orthotics were designed, in subjects' characteristics, intervention duration, and in the way outcomes were assessed. This variability renders it hard to come up with a single best fit for orthotics for everyone with medial KOA. The authors concluded that foot orthoses may be biomechanical interventions, but treatment effects will vary according to the individual and foot orthose. The results indicate further research is warranted to investigate the specific orthotic design(s) and materials to see which combinations offer the best clinical benefit (28).

Li et al. (2026) summarized the biomechanical changes and interventions on the medial knee OA. The aim was to review the current understanding of abnormal loads applied to the frontal plane and assess the efficacy of conservative treatments to minimise the excessive loading of the medial knee plane. Lateral wedge insoles and other biomechanical interventions which aim to shift load from the medial compartment were

reviewed. The authors emphasized the role of the knee adduction moment and other biomechanical factors in the understanding of medial compartment loading. They did note, however, that patients are highly variable in terms of alignment, foot posture, gait, muscle strength, and how patients will respond mechanically to interventions. Therefore, not all people will benefit from the same unloading strategy. The authors found that biomechanical interventions are still promising and should be tailored more and more to individual patient characteristics. The results support further exploration of the construction variables of orthotics such as wedge geometry, stiffness, and material, instead of assuming that all lateral wedges are mechanically comparable (29).

A systematic review of all intelligent orthotic technologies for the management of diabetic foot diseases and knee osteoarthritis was performed by Soubra et al. (2026). The goal was to review advancements in the design of the orthotic, pressure sensing, material properties, customization, and technology-based methods of orthotic care. The review emphasized the growing significance of individual orthotic design and advanced materials and fabrication techniques. It highlighted how the material properties can affect the distribution of lift, mechanical support, cushioning, durability and patient comfort. A review was not specifically written with the intent of comparing polypropylene lateral wedges with EVA lateral wedges, but the results of the review are most pertinent to the selection of orthotic materials. The authors concluded that future orthotic interventions should not only take into account the geometric design of an orthosis, but also the material and mechanical properties of the orthosis. This offers theoretical justification for directly comparing various materials for lateral heel wedges in knee osteoarthritis (30).

Du et al. (2024) conducted a study on the biomechanical responses of the lower-limb joints to lateral wedge insoles. The aim was to assess the influence of lateral wedging on the motion and forces of the lower limbs during walking. Sixteen healthy participants were evaluated under various

wedge conditions: 7 mm lateral wedge and 10 mm lateral wedge. The results showed alteration of some of the biomechanical parameters of the lower limb. Lateral wedge conditions caused knee flexion to increase, and ankle dorsiflexion to decrease. Changes were also noted in internal rotation, forefoot inversion/eversion and adduction. Also identified were changes in vertical ground reaction force. The results suggest that the lateral wedges are not only used at the knee, but on the whole lower limb kinetic chain. The authors found that while these changes were made to decrease medial loading on the knee, the authors suggest that the dimensions of the wedge should be carefully considered since they have a simultaneous effect on ankle and foot mechanics (31).

The study by Mahmoodi et al. (2024) aimed to assess the impact of various lower-limb orthoses on knee pain, functional status, quality of life, and knee joint alignment among people with medial knee osteoarthritis. The goal was to determine the differences between knee orthoses, ankle-foot orthoses and foot orthoses after six weeks of use. Thirty subjects were divided into 3 groups. The subjects were divided into three groups with 30 subjects in each group. The results showed that the participants wearing knee orthoses and ankle-foot orthoses had improvements in some KOOS domains, and those wearing foot orthoses had less prominent improvements. This study suggests that the clinical efficacy of various types of orthotics could vary based on their design. Importantly, pain, symptoms, activities of daily living, sport and recreation and quality of life outcomes have been assessed, not just biomechanical outcomes. The authors suggested that there were some foot orthoses that may offer beneficial clinical outcomes in medial KOA; however, the benefit of foot orthoses use may differ between individuals (32).

The authors of Qiu et al. (2025) have examined the current knowledge on OA as a multifactorial, whole-joint disease and the state of current management of this condition. This was to provide a summary of the molecular mechanisms, pathological changes, risk factors and conservative

and emerging treatments of OA. Mechanical loading was highlighted as playing an interaction role with inflammatory, metabolic, structural and neuromuscular factors in symptomology and disease development. Mechanical loading reduction (MLR) was found to be potentially beneficial for some patients through conservative management and can be achieved using orthoses or lateral wedge insoles. The authors noted, however, that management of KOA should be tailored to the patient due to the variation in disease phenotype and response to treatment. They agreed that none of the single interventions would be effective in all people and multimodal treatment is required. This study has facilitated the investigation of lateral wedges as an adjunctive intervention, and has highlighted the need to assess patient-centred outcomes including pain and function (33).

The effects of various insoles on the biomechanics of the entire lower limb in patients with medial knee osteoarthritis has been examined by Jaques et al. (2023). The goal was to see if the changes caused by the insoles were just in the knee or in the hip, knee, ankle, and foot. It was shown that various insoles were able to influence biomechanics at several joints when walking. These results suggest that altering the foot-ground interaction can affect the whole lower-limb kinetic chain. Although reducing medial knee loading may help, alterations at ankle and foot may potentially exert compensatory mechanical effects. The authors came to the conclusion that the biomechanical assessment of orthotic interventions should not be restricted to the knee adduction moment. Rather, the entire lower leg should be evaluated when determining the pros and cons of an orthosis. This study is significant for the current research because the change in wedge material could affect the transmission of forces through the lower limb as well (34).

Hunt et al. (2023) looked at clinical and laboratory-based factors for biomechanical responses to lateral wedge insoles, in both standalone and supported versions, in individuals with knee OA. The goal was to determine the characteristics of patients who might be likely to

benefit from lateral wedging. Results showed that there was significant inter-individual biomechanical response. Response to the intervention was correlated with clinical and biomechanical characteristics, suggesting a need to consider patient-specific factors when determining the effectiveness of lateral wedge interventions. The comparison of standalone and supported wedge configurations also showed that mechanical response can be affected by design of the orthotic. The authors concluded that patient selection and optimal orthotic prescription could be better improved by identifying predictors of response. They found that this does not hold true for all patients with medial KOA, as some patients' responses to a particular wedge were different from that of others (35).

In patients with medial knee OA, Schwarze et al (2021) studied the effects of insoles that were laterally wedged versus ankle-foot orthoses. The aim was to see if these two types of orthotics had varying clinical results. The researchers tested patients who were on both treatments in a randomized, cross-over design. The results indicated that both orthotic interventions had a significant impact on symptoms and function; however, there was not always a large difference between the interventions. The study demonstrated the challenges of correlating biomechanical correction with clinically relevant improvement. The magnitude of response may vary depending on patient-specific factors and mechanical properties of the orthosis. The authors found both the lateral wedge insole and ankle-foot orthoses to be conservative treatments for some patients with medial KOA (36).

There have been a few studies that have examined lateral heel wedges for knee OA, but most of the evidence has been directed at the angle of the wedge, the biomechanical effects, the author's choice of footwear and the overall effectiveness of the orthotic. Only a few studies have investigated the effect of the type of fabrication on clinical results. Particularly, there are few direct comparisons of polypropylene (PP) and ethylene vinyl acetate (EVA) lateral heel wedges. In addition, the focus of previous studies has been

more on knee adduction moment and gait biomechanics, and less studies have assessed pain, functional disability and quality of life simultaneously. Stiffness, flexibility, cushioning and durability of each material, PP vs EVA, can have a therapeutic effect and patient comfort effect. Hence, a comparison between PP and EVA lateral heel wedges should take place to overcome the evidence gap.

OBJECTIVE

To determine the effectiveness of lateral heel wedges fabricated from polypropylene and ethylene vinyl acetate on pain, functional disability and quality of life in patients with knee osteoarthritis

CHAPTER THREE RESEARCH METHODOLOGY

3.1 Study Design

The study was Randomized Control Trial.

3.2 Study Setting

The study was conducted at conducted at Shifa International Hospital Islamabad.

3.3 Study Duration

The study was conducted over a period of 6 months after the approval of synopsis.

3.4 Study Population

Patients with clinically diagnosed medial compartment knee osteoarthritis (Grade I-III), aged above 35 years.

3.5 Sample Size

Sample size is calculated using OpenEpi tool on the basis of mean and standard deviation values. Outcome variable "pain". The required sample after adding 10% attrition rate is 50 (37).

3.6 Sampling Technique

A non-probability convenience sampling technique was used.

3.7 Sample Selection Criteria

3.7.1 Inclusion Criteria

- Both male and female
- Age above 35 years.
- Clinically diagnosed medial compartment knee OA (grade I to III)

3.7.2 Exclusion Criteria

- Individuals diagnosed with diabetic neuropathy, as altered sensation and nerve dysfunction may influence plantar pressure distribution and pain perception.
- Patients with previous knee surgery.
- Patients with rheumatoid arthritis or other inflammatory joint diseases.
- Patients with severe knee osteoarthritis (Grade IV).
- Patients with significant foot deformities or other conditions affecting plantar pressure distribution.

3.8 Group Allocation

After baseline assessment, eligible participants were randomly assigned to one of two intervention groups using a computer-generated randomization sequence.

- Group A: Patients using Polypropylene (PP) Lateral heel wedge
- Group B: Patients using Ethylene Vinyl Acetate (EVA) lateral heel wedge.

3.9 Outcome Measurement tools

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC):

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a generic patient-reported outcome measure specifically for the evaluation of hip and knee OA. It has 24 items that are divided into 3 Domains: Pain (5 items), Stiffness (2 items) and Physical Function (17 items). There are also domain scores for the instrument, which can be reported individually to assess pain and functional limitations (range 0-48 per domain). WOMAC has proven to be a reliable and valid instrument for patients with knee OA and is useful in clinical research to measure changes in pain and functional disability after

lateral heel-wedge treatment; these psychometric properties make it an ideal tool for assessing change after lateral heel-wedge treatment in the knee OA population (38).

Quality of life SF-36:

The SF-36 is a generic, highly validated patient reported outcome measure for evaluation of health-related quality of life (HRQoL) that includes 36 items. It has 36 items across eight domains: bodily pain, general health, mental health, role limitations due to emotional problems, social functioning, vitality, role limitations due to physical health and physical functioning. The domains can be encapsulated into Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. The SF-36 has been found to be reliable, construct and responsive in musculoskeletal conditions such as Knee OA (KOA) patients, and is suitable to use in assessing the effect of polypropylene and EVA lateral heel wedges on a wider spectrum of health-related quality of life than pain and functional disability (39).

3.10 Data Collection Procedure

Recruitment:

Participants were recruited from the outpatient departments of physiotherapy and orthopaedic clinics based on the predefined inclusion and exclusion criteria. Eligible patients were informed about the purpose and procedures of the study. Participants who agreed to participate provided written informed consent before enrollment.

Enrollment:

Based on the pre-intervention assessment, participants were randomly assigned into the two groups.

Randomization:

The randomization process employed a computer-generated randomizer, and allocation concealment ensured through the sealed envelope method.

Blinding:

This study was a single blinded.

Treatment:

The participants in study were divided into two group.

Treatment Procedure

Group A Polypropylene (PP) Lateral Heel Wedge

Participants in Group A were provided with a lateral heel wedge fabricated from polypropylene (PP). The wedge was designed to elevate the lateral side of the heel compared with the medial side, producing a valgus effect and facilitating redistribution of load away from the medial compartment of the knee. Participants were instructed to use the PP lateral heel wedge during their routine daily activities.

Group B Ethylene Vinyl Acetate (EVA) Lateral Heel Wedge:

Participants in Group B were provided with a lateral heel wedge fabricated from ethylene vinyl acetate (EVA). The wedge was designed with the same lateral-wedging principle, while EVA provided greater flexibility and cushioning. Participants were instructed to use the EVA lateral heel wedge during their routine daily activities.

3.11 Ethical Consideration

Ethical approval for the study was obtained from the Research Review Board (RRB), Department of Physical Therapy and Rehabilitation Sciences, Faculty of Allied Health Sciences, The Superior University, Lahore, before the commencement of data collection. All research procedures were

conducted in accordance with the ethical principles outlined in the Declaration of Helsinki for research involving human participants.

Participants were informed about the purpose, objectives, study procedures, expected duration, potential benefits, and possible risks associated with the research before enrollment. Written informed consent was obtained from each participant prior to participation. Participants were informed that their participation was entirely voluntary and that they had the right to refuse participation or withdraw from the study at any stage without providing any reason and without any negative consequences.

The findings of the study were used solely for academic and scientific purposes and could be published in scientific journals or presented at conferences without revealing the identity of any participant.

3.12 Data Analysis Procedure

The collected data were entered into IBM SPSS Statistics Version 27.0 for analysis. The level of statistical significance was set at $p < 0.05$.

Descriptive statistics: Frequency tables, pie charts, and bar charts were used to present summaries of group measurements over time.

The distribution of continuous data was assessed using the Shapiro-Wilk test because of the relatively small sample size.

Parametric tests: Independent t-tests for between group analysis and paired sample t-tests for within group analysis were employed for comparing variables with non-significant normality test results.

CHAPTER FOUR

RESULTS

Table 4.1 Statistics of age

Statistics of age	
N	50
Mean	49.3400
Std. Deviation	6.4357
Minimum	35.00
maximum	60.00

Table 4.1 shows that the study included 50 participants, with a mean age of 49.34 ± 6.44 years. The participants' ages ranged from 35 to 60 years,

indicating that the study population consisted of adults within the specified age range.

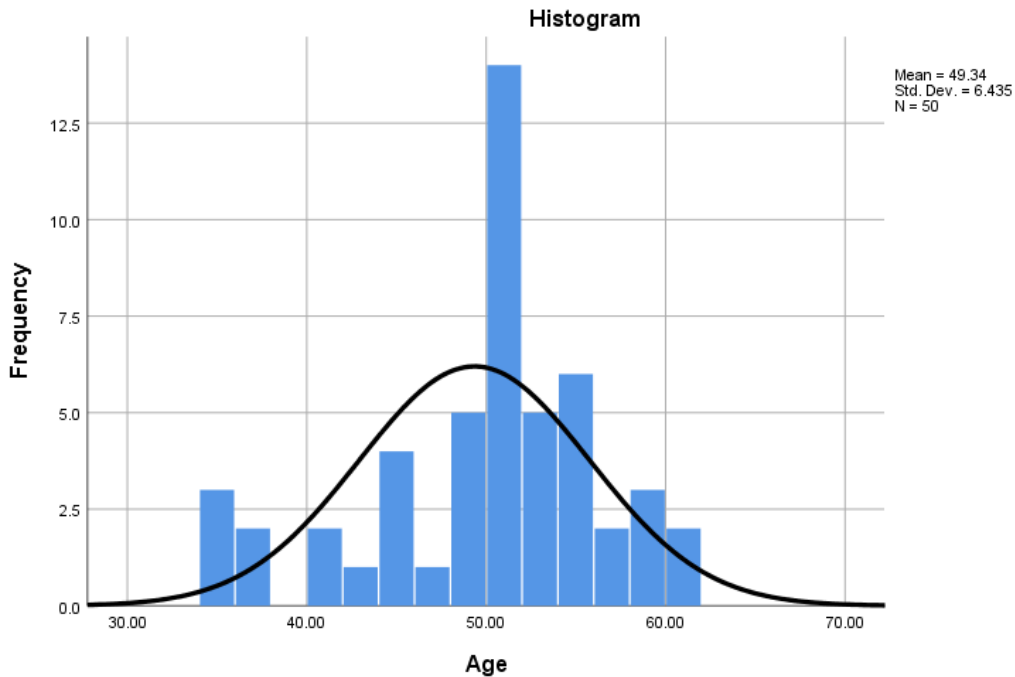


Figure 4. 1 Histogram of Age

Table 4.2 Gender

Gender		
	Frequency	Percent
Male	11	22.0
Female	39	78.00
Total	50	100.0

Table 4.2 shows that the majority of participants were female, with 39 participants (78%), while 11 participants (22%) were male. Overall, females

represented more than three-quarters of the study population, whereas males accounted for less than one-quarter of the participants.

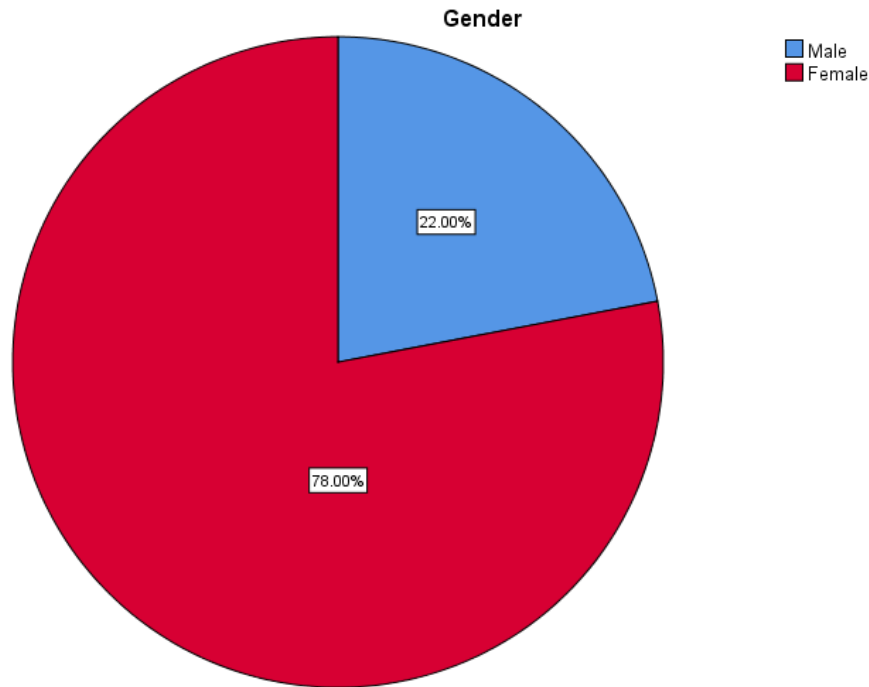


Figure 4. 2 Pie chart of Gender

Table 4.3 Study groups

Study groups	Frequency	Percent
Group A Polypropylene (PP) Lateral heel wedge	25	50.0
Group B Ethylene Vinyl Acetate (EVA) lateral heel wedge	25	50.0
Total	50	

Table 4.3 shows that the participants were equally distributed between the two study groups. Group A, which received the polypropylene (PP) lateral heel wedge, included 25 participants (50%), while

Group B, which received the ethylene vinyl acetate (EVA) lateral heel wedge, also included 25 participants (50%). Thus, both groups had an equal number of participants.

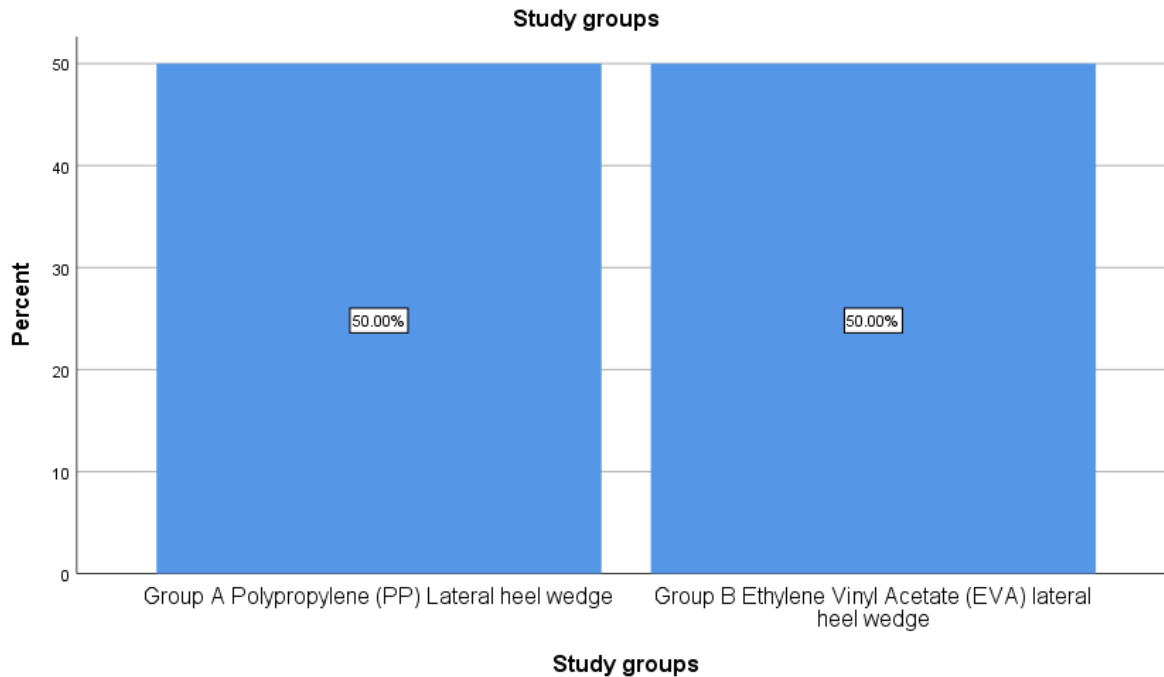


Figure 4. 3 Bar chart of Study groups

Table 4.4 Tests of Normality

Tests of Normality			
	Shapiro- Wilk		
	Statistic	df	Sig.
Pre: WOMAC (Pain)	.938	50	.571
Pre: WOMAC (Stiffness)	.864	50	.147
Pre: WOMAC (Physical function)	.982	50	.631
Pre: WOMAC cumulative score	.972	50	.267
Pre: SF-36 (Physical component)	.971	50	.247
Pre: SF-36 (Mental component)	.975	50	.374
Pre: SF-36 score	.979	50	.503

Table 4.4 presents the Shapiro-Wilk test results for the pre-intervention outcome measures. All variables demonstrated p-values greater than 0.05, including WOMAC pain ($p = 0.571$), stiffness ($p = 0.147$), physical function ($p = 0.631$), cumulative score ($p = 0.267$), SF-36 physical component ($p =$

0.247), mental component ($p = 0.374$), and overall SF-36 score ($p = 0.503$). Therefore, the data for all pre-intervention variables were normally distributed, supporting the use of parametric statistical tests for further analysis.

Table 4.5 Independent sample T test between groups analysis of WOMAC (pain)

	Group A	Group B	Mean difference	p-value
Pre WOMAC (pain)	12.40	12.64	-0.24	0.555

Post WOMAC (pain)	9.24	5.84	3.40	<0.05
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Table 4.5 presents the independent-samples t-test comparing Group A (PP) and Group B (EVA) for WOMAC pain. At baseline, the mean pain score was 12.40 in Group A and 12.64 in Group B, with a mean difference of -0.24 and no statistically significant difference ($p = 0.555$), indicating that both groups were comparable before the

intervention. After the intervention, the mean pain score decreased to 9.24 in Group A and 5.84 in Group B, with a mean difference of 3.40. The post-intervention difference between the groups was statistically significant ($p < 0.05$), indicating greater improvement in pain in the EVA group compared with the PP group.

Table 4.6 Independent sample T test between groups analysis of WOMAC (stiffness)

	Group A	Group B	Mean difference	p-value
Pre WOMAC (stiffness)	5.28	4.80	0.48	0.093
Post WOMAC (stiffness)	3.88	1.96	1.92	<0.05

Table 4.6 presents the independent-samples t-test comparing Group A (PP) and Group B (EVA) for WOMAC stiffness. At baseline, the mean stiffness score was 5.28 in Group A and 4.80 in Group B, with a mean difference of 0.48 and no statistically significant difference ($p = 0.093$), indicating that both groups were comparable before the

intervention. After the intervention, the mean stiffness score decreased to 3.88 in Group A and 1.96 in Group B, with a mean difference of 1.92. The post-intervention difference was statistically significant ($p < 0.05$), indicating greater improvement in stiffness in the EVA group compared with the PP group.

Table 4.7 Independent sample T test between groups analysis of WOMAC (physical function)

	Group A	Group B	Mean difference	p-value
Pre WOMAC (physical function)	42.32	42.68	-0.36	0.757
Post WOMAC (physical function)	34.48	25.52	8.96	<0.05

Table 4.7 presents the independent-samples t-test comparing Group A (PP) and Group B (EVA) for WOMAC physical function. At baseline, the mean physical function score was 42.32 in Group A and 42.68 in Group B, with a mean difference of -0.36 and no statistically significant difference ($p = 0.757$), indicating that both groups were comparable before the intervention. After the

intervention, the mean physical function score decreased to 34.48 in Group A and 25.52 in Group B, with a mean difference of 8.96. The post-intervention difference was statistically significant ($p < 0.05$), indicating greater improvement in physical function in the EVA group compared with the PP group.

Table 4.8 Independent sample T test between groups analysis of WOMAC (cumulative score)

	Group A	Group B	Mean difference	p-value
Pre WOMAC (cumulative score)	64.12	68.84	-4.72	>0.05
Post WOMAC (cumulative)	47.20	27.20	20.00	<0.05

Table 4.8 presents the independent-samples t-test comparing Group A (PP) and Group B (EVA) for the WOMAC cumulative score. At baseline, the mean cumulative score was 64.12 in Group A and 68.84 in Group B, with a mean difference of -4.72 and no statistically significant difference ($p > 0.05$), indicating that both groups were comparable before the intervention. After the

intervention, the mean cumulative score decreased to 47.20 in Group A and 27.20 in Group B, with a mean difference of 20.00. The post-intervention difference was statistically significant ($p < 0.05$), indicating greater overall improvement in WOMAC outcomes in the EVA group compared with the PP group.

Table 4.9 Independent sample T test between groups analysis of SF-36 (Physical component)

Time	Group A Mean	Group B Mean	Mean Difference	p-value
Pre SF-36 (Physical component)	38.04	38.48	-0.44	0.583
Post SF-36 (Physical component)	47.36	55.48	-8.12	<0.05

Table 4.9 presents the independent-samples t-test comparing Group A (PP) and Group B (EVA) for the SF-36 physical component. At baseline, the mean score was 38.04 in Group A and 38.48 in Group B, with a mean difference of -0.44 and no statistically significant difference ($p = 0.583$), indicating that both groups were comparable before the intervention. After the intervention,

the mean SF-36 physical component score increased to 47.36 in Group A and 55.48 in Group B, with a mean difference of -8.12. The post-intervention difference was statistically significant ($p < 0.05$), indicating greater improvement in physical health status in the EVA group compared with the PP group.

Table 4.10 Independent sample T test between groups analysis of SF-36 (Mental component)

Time	Group A Mean	Group B Mean	Mean Difference	p-value
Pre SF-36 (Mental component)	44.32	44.44	-0.12	0.841
Post SF-36 (Mental component)	50.44	57.64	-7.20	<0.05

Table 4.10 presents the independent-samples t-test comparing Group A (PP) and Group B (EVA) for the SF-36 mental component. At baseline, the mean score was 44.32 in Group A and 44.44 in Group B, with a mean difference of -0.12 and no statistically significant difference ($p = 0.841$), indicating that both groups were comparable before the intervention. After the intervention,

the mean SF-36 mental component score increased to 50.44 in Group A and 57.64 in Group B, with a mean difference of -7.20. The post-intervention difference was statistically significant ($p < 0.05$), indicating greater improvement in mental health status in the EVA group compared with the PP group.

Table 4. 11 Independent sample T test between groups analysis of SF-36 score

Time	Group A Mean	Group B Mean	Mean Difference	p-value
Pre SF-36 score	40.96	41.20	-0.24	0.737
Post SF-36 score	48.96	60.40	-11.44	<0.05

Table 4.11 presents the independent-samples t-test comparing Group A (PP) and Group B (EVA) for the overall SF-36 score. At baseline, the mean SF-

36 score was 40.96 in Group A and 41.20 in Group B, with a mean difference of -0.24 and no statistically significant difference ($p = 0.737$),

indicating that both groups were comparable before the intervention. After the intervention, the mean SF-36 score increased to 48.96 in Group A and 60.40 in Group B, with a mean difference

of -11.44. The post-intervention difference was statistically significant ($p < 0.05$), indicating greater improvement in overall quality of life in the EVA group compared with the PP group.

Table 4. 12 Paired sample T test within group A analysis of WOMAC (Pain)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group A	Pre: WOMAC (Pain)	12.40 ± 1.47	<0.05
	Post: WOMAC (Pain)	9.24 ± 1.27	

Table 4.12 presents the paired-samples t-test for WOMAC pain within Group A (PP). The mean WOMAC pain score decreased from 12.40 ± 1.47 before the intervention to 9.24 ± 1.27 after the

intervention. This reduction was statistically significant ($p < 0.05$), indicating that the polypropylene lateral heel wedge significantly improved pain among participants in Group A.

Table 4. 13 Paired sample T test within group A analysis of WOMAC (Stiffness)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group A	Pre WOMAC (Stiffness)	5.28 ± 1.14	<0.05
	Post WOMAC (Stiffness)	3.88 ± 0.67	

Table 4.13 presents the paired-samples t-test for WOMAC stiffness within Group A (PP). The mean stiffness score decreased from 5.28 ± 1.14 before the intervention to 3.88 ± 0.67 after the intervention. This reduction was statistically

significant ($p < 0.05$), indicating that the polypropylene lateral heel wedge significantly improved stiffness among participants in Group A.

Table 4. 14 Paired sample T test within group A analysis of WOMAC (Physical function)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group A	Pre WOMAC (Physical function)	42.32 ± 4.05	<0.05
	Post WOMAC (Physical function)	34.48 ± 3.64	

Table 4.14 presents the paired-samples t-test for WOMAC physical function within Group A (PP). The mean physical function score decreased from 42.32 ± 4.05 before the intervention to 34.48 ± 3.64 after the intervention. This reduction was

statistically significant ($p < 0.05$), indicating that the polypropylene lateral heel wedge significantly improved physical function among participants in Group A.

Table 4. 15 Paired sample T test within group A analysis of WOMAC cumulative score

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group A	Pre WOMAC cumulative score	64.12 ± 3.59	<0.05
	Post WOMAC cumulative score	47.20 ± 5.83	

Table 4.15 presents the paired-samples t-test for the WOMAC cumulative score within Group A (PP). The mean cumulative score decreased from 64.12 ± 3.59 before the intervention to 47.20 ± 5.83 after the intervention. This reduction was

statistically significant ($p < 0.05$), indicating that the polypropylene lateral heel wedge significantly improved the overall WOMAC score among participants in Group A.

Table 4. 16 Paired sample T test within group A analysis of SF-36 (Physical component)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group A	Pre SF-36 (Physical component)	38.04 ± 2.79	<0.05
	Post SF-36 (Physical component)	47.36 ± 2.53	

Table 4.16 presents the paired-samples t-test for the SF-36 physical component within Group A (PP). The mean SF-36 physical component score increased from 38.04 ± 2.79 before the intervention to 47.36 ± 2.53 after the

intervention. This improvement was statistically significant ($p < 0.05$), indicating that the polypropylene lateral heel wedge significantly improved the physical component of quality of life among participants in Group A.

Table 4. 17 Paired sample T test within group A analysis of SF-36 (Mental component)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group A	Pre SF-36 (Mental component)	44.32 ± 2.04	<0.05
	Post SF-36 (Mental component)	50.44 ± 2.12	

Table 4.17 presents the paired-samples t-test for the SF-36 mental component within Group A (PP). The mean SF-36 mental component score increased from 44.32 ± 2.04 before the intervention to 50.44 ± 2.12 after the

intervention. This improvement was statistically significant ($p < 0.05$), indicating that the polypropylene lateral heel wedge significantly improved the mental component of quality of life among participants in Group A.

Table 4.18 Paired sample T test within group A analysis of SF-36 score

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group A	Pre SF-36 score	40.96 ± 2.49	<0.05
	Post SF-36 score	48.96 ± 2.24	

Table 4.18 presents the paired-samples t-test for the overall SF-36 score within Group A (PP). The

mean SF-36 score increased from 40.96 ± 2.49 before the intervention to 48.96 ± 2.24 after the

intervention. This improvement was statistically significant ($p < 0.05$), indicating that the polypropylene lateral heel wedge significantly

improved the overall quality of life among participants in Group A.

Table 4. 19 Paired sample T test within group B analysis of WOMAC (Pain)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group B	Pre: WOMAC (Pain)	12.64 ± 1.38	<0.05
	Post: WOMAC (Pain)	5.84 ± 1.11	

Table 4.19 presents the paired-samples t-test for WOMAC pain within Group B (EVA). The mean WOMAC pain score decreased from 12.64 ± 1.38 before the intervention to 5.84 ± 1.11 after the

intervention. This reduction was statistically significant ($p < 0.05$), indicating that the ethylene vinyl acetate lateral heel wedge significantly improved pain among participants in Group B.

Table 4. 20 Paired sample T test within group B analysis of WOMAC (Stiffness)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group B	Pre WOMAC (Stiffness)	4.80 ± 0.82	<0.05
	Post WOMAC (Stiffness)	1.96 ± 0.68	

Table 4.20 presents the paired-samples t-test for WOMAC stiffness within Group B (EVA). The mean WOMAC stiffness score decreased from 4.80 ± 0.82 before the intervention to 1.96 ± 0.68 after the intervention. This reduction was

statistically significant ($p < 0.05$), indicating that the ethylene vinyl acetate lateral heel wedge significantly improved stiffness among participants in Group B.

Table 4. 21 Paired sample T test within group B analysis of WOMAC (Physical function)

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group B	Pre WOMAC (Physical function)	42.68 ± 4.12	<0.05
	Post WOMAC (Physical function)	25.52 ± 3.44	

Table 4.21 presents the paired-samples t-test for WOMAC physical function within Group B (EVA). The mean physical function score decreased from 42.68 ± 4.12 before the intervention to 25.52 ± 3.44 after the

intervention. This reduction was statistically significant ($p < 0.05$), indicating that the ethylene vinyl acetate lateral heel wedge significantly improved physical function among participants in Group B.

Table 4. 22 Paired sample T test within group B analysis of WOMAC cumulative score

Study group		Paired difference	
		Mean± Std. Deviation	P value
Group B	Pre WOMAC cumulative score	68.84 ± 3.36	<0.05
	Post WOMAC cumulative score	27.20 ± 3.43	

Table 4.22 presents the paired-samples t-test for the WOMAC cumulative score within Group B (EVA). The mean cumulative score decreased from 68.84 ± 3.36 before the intervention to 27.20 ± 3.43 after the intervention. This reduction was

statistically significant ($p < 0.05$), indicating that the ethylene vinyl acetate lateral heel wedge significantly improved the overall WOMAC score among participants in Group B.

Table 4. 23 Paired sample T test within group B analysis of SF-36 (Physical component)

Study group		Paired difference	
		Mean $\pm$ Std. Deviation	P value
Group B	Pre SF-36 (Physical component)	38.48 ± 2.84	<0.05
	Post SF-36 (Physical component)	55.48 ± 2.84	

Table 4.23 presents the paired-samples t-test for the SF-36 physical component within Group B (EVA). The mean SF-36 physical component score increased from 38.48 ± 2.84 before the intervention to 55.48 ± 2.84 after the

intervention. This improvement was statistically significant ($p < 0.05$), indicating that the ethylene vinyl acetate lateral heel wedge significantly improved the physical component of quality of life among participants in Group B.

Table 4.24 Paired sample T test within group B analysis of SF-36 (Mental component)

Study group		Paired difference	
		Mean $\pm$ Std. Deviation	P value
Group B	Pre SF-36 (Mental component)	44.44 ± 2.16	<0.05
	Post SF-36 (Mental component)	57.64 ± 2.51	

Table 4.24 presents the paired-samples t-test for the SF-36 mental component within Group B (EVA). The mean SF-36 mental component score increased from 44.44 ± 2.16 before the intervention to 57.64 ± 2.51 after the

intervention. This improvement was statistically significant ($p < 0.05$), indicating that the ethylene vinyl acetate lateral heel wedge significantly improved the mental component of quality of life among participants in Group B.

Table 4. 25 Paired sample T test within group B analysis of SF-36 score

Study group		Paired difference	
		Mean $\pm$ Std. Deviation	P value
Group B	Pre SF-36 score	41.20 ± 2.54	<0.05
	Post SF-36 score	60.40 ± 4.48	

Table 4.25 presents the paired-samples t-test for the overall SF-36 score within Group B (EVA). The mean SF-36 score increased from 41.20 ± 2.54 before the intervention to 60.40 ± 4.48 after the intervention. This improvement was statistically significant ($p < 0.05$), indicating that the ethylene vinyl acetate lateral heel wedge significantly

improved the overall quality of life among participants in Group B.

CHAPTER FIVE

DISCUSSION AND CONCLUSION

To assess the impact of lateral heel wedges made of polypropylene (PP) and ethylene vinyl acetate (EVA) on pain, functional disability and quality of

life in patients with knee osteoarthritis. There were statistically significant improvements in WOMAC pain, stiffness, physical function and WOMAC cumulative score, SF-36 physical component score, mental component score and overall score (all $p < 0.05$) for both PP and EVA lateral heel wedges. There were statistically significant differences in favor of EVA in all four of the primary indexes (WOMAC pain $p < 0.001$, stiffness $p < 0.001$, physical function $p < 0.001$, cumulative score $p < 0.001$) between the groups. Likewise, substantial between-group differences were seen for SF-36 physical component ($p < 0.001$), mental component ($p < 0.001$) and overall SF-36 score ($p < 0.001$). Therefore, both materials were effective, but EVA demonstrated much greater improvement than PP in the measured pain, functional disability and quality of life outcome measures. The results of this study suggest that there is a greater clinical benefit of EVA than PP in the present group of patients suffering from medial compartment knee OA.

Schwarze et al. (2021) found improvements in symptoms and functional status for the patients with medial knee osteoarthritis when wearing either laterally wedged insoles or ankle-foot orthoses. The authors did note, however, that the differences between the two orthotic interventions were not consistently statistically significant which means the clinical response may be dependent on orthotic characteristics and individual patient factors. The findings of the current study are also consistent with the general findings of other studies as both PP and EVA lateral heel wedges resulted in significant improvement in overall clinical condition of patients ($p < 0.05$). The present study, however, differs from Schwarze et al. because there was a significant difference between the two different materials ($p < 0.001$) with EVA showing greater overall improvement than PP. This may be attributed to the rigidity of PP as well as the flexibility and cushioning ability of EVA material. Based on the current findings, Schwarze et al. also argue that material choice might affect the size of the clinical benefit of lateral wedging as a conservative treatment, but further study on this is necessary (36).

Ferreira et al. (2022) studied the effects of different lateral wedge angles on lower-limb biomechanics among individuals with knee OA. The study revealed that even relatively small wedging angles could lead to changes in the lower-limb biomechanic parameters, suggesting that the mechanical effect of lateral wedging is dependent on the orthotic design. The changes in the biomechanics were statistically significant ($p < 0.05$). The results of this study agree with the current study since the lateral heel wedges, both PP and EVA, resulted in significant improvements after use ($p < 0.05$). Ferreira et al., however, studied the wedge geometry, while this study examined the fabrication of the wedge, while keeping the lateral-wedge principle intact. The present study also revealed that there was a significant difference between PP and EVA, in favor of EVA, where there was a greater overall clinical improvement ($p < 0.001$). Therefore, both studies have shown that there is the potential for characteristics of the orthosis to affect treatment response. Finally, Ferreira et al. highlighted the significance of wedge angle, and the results of the present study indicate that the materials used also could be a factor in the clinical effectiveness differences (25).

Hunt et al. (2023) conducted a study on factors that predict biomechanical effects of lateral wedge insoles (with and without support) in individuals with knee OA. There was significant inter-personal variation in response, and the authors reported patient characteristics and orthotic configuration were related to biomechanical response. The results of their research then indicated that the same lateral wedge might not have the same effect on all patients. All results were significant at $p < 0.05$. The results obtained are similar to the present study, as both PP and EVA were found to be statistically significant in patients with knee OA ($p < 0.05$). The present study, however, shows that the type of wedge material used can also affect response to treatment. The overall improvement rate of EVA was significantly higher than PP ($p < 0.001$). Hence, the emphasis of Hunt et al. was on patient-related variability, while the emphasis of this study

is on the material-related variability. These results taken together indicate that orthotic management to be successful might require consideration of both patient-specific parameters and suitable orthotic construction and material (35).

In 2024, Du et al. examined the biomechanical response of the lower-limb joints to lateral wedge insoles, revealing that lateral wedging resulted in changes not just at the knee but also at the ankle and foot. Their findings suggested that lateral wedges have a widespread effect on the whole lower limb kinetic chain, thus emphasizing the broader biomechanical chain reaction effects of orthotic intervention. Biomechanical changes that were statistically significant were reported ($p < 0.05$). A similar result as in the current study was found, as both lateral heel wedge (made from PP and EVA) produced significant clinical improvement ($p < 0.05$). In contrast, Du et al. studied biomechanical responses and the present study focused on clinically oriented outcomes for patients. It was importantly demonstrated in the current study that EVA was significantly more effective than PP in producing overall improvement ($p < 0.001$). The difference could be linked to EVA's flexibility and cushioning, potentially influencing how forces are transmitted and comfort is felt when bearing weight. However, Du et al. offer biomechanical support for lateral wedging, and the present study supplies evidence that material choice could impact clinical benefit (31).

Mahmoodi et al. (2024) compared different lower-limb orthoses in patients with medial knee osteoarthritis and found that the clinical response differed according to the type of orthosis used. Improvements were observed in several clinical outcomes among participants using knee and ankle-foot orthoses, whereas improvements associated with foot orthoses were less pronounced. The study therefore demonstrated that different orthotic designs may provide different levels of clinical benefit ($p < 0.05$). These findings are consistent with the current study because both PP and EVA lateral heel wedges significantly improved the overall clinical condition of participants ($p < 0.05$). However, the

present study demonstrated a clearer difference between two materials, with EVA producing significantly greater improvement than PP ($p < 0.001$). The contrast may be explained by differences in orthotic design and material properties. EVA provides greater cushioning and flexibility, whereas PP provides greater rigidity and structural stability. Thus, Mahmoodi et al. support the principle that orthotic design influences clinical outcomes, while the current study extends this concept by demonstrating that fabrication material may also be an important determinant of treatment effectiveness (32).

Jiang et al. (2026) conducted a systematic review and meta-analysis examining the effects of foot orthoses on biomechanical and clinical outcomes in medial knee osteoarthritis. The authors concluded that foot orthoses can modify gait biomechanics and may improve clinical outcomes, but substantial variation existed between studies because of differences in orthotic design, patient characteristics, intervention duration, and outcome assessment. Consequently, the authors emphasized that there is unlikely to be one optimal orthotic configuration for every patient. The review supports significant beneficial effects of foot orthoses ($p < 0.05$). This finding agrees with the current study, in which both PP and EVA lateral heel wedges produced significant overall improvements ($p < 0.05$). However, the current study provides additional evidence by directly comparing two fabrication materials and demonstrating significantly greater improvement with EVA than PP ($p < 0.001$). Therefore, Jiang et al. support individualized orthotic prescription based on patient and orthotic characteristics, while the present findings further suggest that material selection should be considered as part of individualized orthotic prescription for patients with medial knee osteoarthritis (14).

CONCLUSION

This study concluded that lateral heel wedges fabricated from both polypropylene (PP) and ethylene vinyl acetate (EVA) were effective in improving pain, stiffness, functional disability, and quality of life in patients with knee

osteoarthritis. However, EVA lateral heel wedges demonstrated significantly greater overall clinical improvement compared with PP wedges. The findings suggest that, in addition to the biomechanical effect of lateral wedging, fabrication material may influence treatment effectiveness. EVA, because of its flexibility and cushioning properties, may provide greater clinical benefit than the relatively rigid PP material. Therefore, EVA lateral heel wedges may be considered a more effective conservative orthotic option for improving clinical outcomes in patients with medial compartment knee osteoarthritis.

LIMITATIONS

1. Lack of long-term follow-up: The study did not assess whether the improvements achieved with PP and EVA lateral heel wedges were maintained over a longer period.
2. Limited assessment of patient adherence: The study did not provide detailed objective monitoring of how consistently participants used the prescribed wedges during their daily activities, which may influence treatment outcomes.
3. Limited range of outcome measures: The study primarily assessed pain, stiffness, physical function, and quality of life; other potentially relevant factors such as patient comfort, satisfaction, and gait-related changes were not comprehensively evaluated.

RECOMMENDATIONS

1. Long-term follow-up studies should be conducted to determine whether the benefits of PP and EVA lateral heel wedges are maintained over extended periods.
2. Patient comfort and satisfaction should be assessed in future studies to determine whether the cushioning and flexibility of EVA improve acceptance and compliance compared with PP.
3. Biomechanical assessment using gait analysis and plantar-pressure measurement should be included in future research to better understand how PP and EVA influence knee loading and pressure distribution.
4. Future studies should investigate different wedge angles and material densities to identify the

most effective combination for patients with knee osteoarthritis.

5. Clinicians should consider EVA lateral heel wedges as a potential orthotic option when the primary goals are reducing symptoms and improving functional ability and quality of life.

REFERENCES

1. Sharma L. Osteoarthritis of the knee. *New England Journal of Medicine*. 2021;384(1):51-9.
2. Katz JN, Arant KR, Loeser RF. Diagnosis and treatment of hip and knee osteoarthritis: a review. *Jama*. 2021;325(6):568-79.
3. Lv Y, Sui L, Lv H, Zheng J, Feng H, Jing F. Burden of knee osteoarthritis in China and globally from 1992 to 2021, and projections to 2030: a systematic analysis from the global burden of disease study 2021. *Frontiers in public health*. 2025;13:1543180.
4. Wang C, Du W, Li Z, Chen W. Effects of custom-made insole on the mechanical response characteristics of the foot during static standing and walking. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*. 2025;239(4):360-9.
5. Petersen KK-S, Ciampi de Andrade D, Pickering G, Giordano R, Hertel E, Edwards RR, et al. The complexity of pain in osteoarthritis. *Nature Reviews Rheumatology*. 2026:1-12.
6. Bliddal H, Bays H, Czernichow S, Uddén Hemmingsson J, Hjelmæsæth J, Hoffmann Morville T, et al. Once-weekly semaglutide in persons with obesity and knee osteoarthritis. *New England Journal of Medicine*. 2024;391(17):1573-83.
7. Feng Q, Weng M, Yang X, Zhang M. Anxiety and depression prevalence and associated factors in patients with knee osteoarthritis. *Frontiers in psychiatry*. 2025;15:1483570.

8. Gelber AC. Knee osteoarthritis. *Annals of internal medicine*. 2024;177(9):ITC129-ITC44.
9. Johnson A, Gao RZ, Marriott K, Dickerson CR, Maly MR, Ren CL. Electronics-free soft robotic knee brace for dynamic unloading during gait for knee osteoarthritis: a proof-of-concept study. *Journal of Medical Devices*. 2023;17(4):041004.
10. Langworthy M, Dasa V, Spitzer AI. Knee osteoarthritis: disease burden, available treatments, and emerging options. *Therapeutic Advances in Musculoskeletal Disease*. 2024;16:1759720X241273009.
11. Guan S, Mei Y. Biomechanics and obesity in osteoarthritis: from mechanism to precision medicine. *International Journal of Rheumatic Diseases*. 2026;29(1):e70539.
12. Wang H, Cui L. Evolving Strategies for Knee Osteoarthritis: A Narrative Review of Integrated Rehabilitation, Pharmacologic, and Joint-Preserving Interventions. *Medical Science Monitor: International Medical Journal of Experimental and Clinical Research*. 2026;32:e952864.
13. Dwarakanathan R, Mohanty RK, Sahoo S, Prasad S. Efficacy of unloader knee orthosis and lateral wedge insole on static balance in medial knee osteoarthritis. *Journal of Orthopaedics, Trauma and Rehabilitation*. 2022;29(1):22104917221095256.
14. Jiang Z, Studer PB, Zäh M, Kryenbühl C, Wang T, Taylor WR, et al. 3D-printed shoe soles with structural properties towards reducing knee adduction moments during walking. *Frontiers in Bioengineering and Biotechnology*. 2026;14:1734486.
15. Geng R, Li J, Yu C, Zhang C, Chen F, Chen J, et al. Knee osteoarthritis: Current status and research progress in treatment. *Experimental and therapeutic medicine*. 2023;26(4):481.
16. Piri M, Malmir K, Otadi K, Shadmehr A. Medial heel wedge in balance training improves stability and function in chronic ankle instability. *Scientific Reports*. 2025;16(1):2536.
17. Ueda T, Chikamoto T, Asaeda M, Araki T, Ueda K, Ushio K, et al. Kinematic effects of lateral wedged insoles in patients with medial knee osteoarthritis. *Journal of Physical Therapy Science*. 2023;35(9):667-72.
18. Shtroblia V, Petakh P, Kamyshna I, Halabitska I, Kamyshnyi O. Recent advances in the management of knee osteoarthritis: a narrative review. *Frontiers in Medicine*. 2025;12:1523027.
19. Saxena S, Singh U, Wadhwa S, Yadav S, Handa G, Gamnagatti S, et al. Lateral Wedge Orthotic Footwear in Managing Knee Osteoarthritis: A Quantitative Analysis. *Indian Journal of Physical Medicine & Rehabilitation*. 2025;35(3):181-5.
20. Khaliliyan H, Ansari M, Bahramizadeh M, Ghaffari F, Sharafatvaziri A, Jouibari MF, et al. The role of orthotic devices in managing hallux rigidus: A systematic review and meta-analysis of clinical and biomechanical outcomes. *The Foot*. 2026;68:102264.
21. Bădiță-Voicu L-L, Nechita R-M, Voicu A-C, Anton M-I, Deselnicu D-C, Dumitrescu C-I, et al. Hybrid Decision-Making Management for Material Selection in the Design of Wearable Pressure-Sensing Orthoses in Neurorehabilitation. *Biomimetics*. 2026;11(6):395.
22. Aydin L, Karatoprak AP. Hybrid fabrication and biomechanical validation of a patient-specific therapeutic footwear with a replaceable insole for Charcot deformity. *Rapid Prototyping Journal*. 2026;32(1):71-82.
23. Li J, Jung I, Lang C, Lee S. Effects of gyroid lattice relative density on wear and mechanical performance of 3D printed TPU and flexible nylon for footwear. *Iscience*. 2026;29(6).
24. Sarwar MA, Stampone N, Usman M, editors. From static to adaptive: a systematic review of smart materials and 3D/4D printing in the evolution of assistive devices. *Actuators*; 2025: MDPI.

-
25. Ferreira V, Machado L, Vilaça A, Xará-Leite F, Roriz P. Can slight variations to lateral wedge insoles induce significant biomechanical changes in patients with knee osteoarthritis? *Biomechanics*. 2022;2(3):342-51.
26. Hunt MA, Krowchuk NM, Zhang H, Ryan MB, Birmingham TB, Charlton JM. Lateral Wedge Insoles With and Without Contoured Arch Support for People With Knee Osteoarthritis and Foot Pain: A Pilot, Feasibility Randomized Controlled Trial. *Journal of Foot and Ankle Research*. 2026;19(3):e70171.
27. Xu H, Xiao W, Ding C, Zou J, Zhou D, Wang J, et al. Global burden of osteoarthritis among postmenopausal women in 204 countries and territories: a systematic analysis for the Global Burden of Disease Study 2021. *BMJ Global Health*. 2025;10(3):e017198.
28. Jiang Z, Gröbli M, Nasab SHH, Taylor WR, Zhang Q. Immediate and Mid-Long-Term Effects of Foot Orthoses on Gait Biomechanics and Clinical Characteristics in Medial Knee Osteoarthritis: A Systematic Review and Meta-analysis: Ziang Jiang et al. *Annals of Biomedical Engineering*. 2026:1-16.
29. Li Z, Baghi R, Zhang L-Q. Off-axis biomechanical alterations and related interventions in medial knee osteoarthritis: a mini review. *Frontiers in Rehabilitation Sciences*. 2026;7:1759442.
30. Soubra WO, Cordato DJ, Fatima Shad K, Lal S. Intelligent Orthotics Technology in the Management of Diabetic Foot Ulcers and Knee Osteoarthritis: A Comprehensive Systematic Review. *Applied Sciences*. 2026;16(13):6301.
31. Du W, Guo Y, Wang C, Cui W, Chen W, Li X. Biomechanical response of lower limb joints to lateral wedge insoles. *Scientific Reports*. 2024;14(1):107.
32. Mahmoodi M, Arazpour M, Mousavi ME. Comparing the effects of lower limb orthoses on knee pain, function, quality of life, and knee joint alignment in people with medial knee osteoarthritis. *Journal of Rehabilitation and Assistive Technologies Engineering*. 2024;11:20556683241277179.
33. Qiu L, Alhaskawi A, Moqbel SAA. Osteoarthritis: multitissue pathology, molecular mechanisms, clinical management, and emerging precision and regenerative therapies. *Frontiers in Pharmacology*. 2025;16:1697192.
34. Jaques G, Ulrich B, Hoffmann L, Jolles BM, Favre J. Walking with different insoles changes lower-limb biomechanics globally in patients with medial knee osteoarthritis. *Journal of clinical medicine*. 2023;12(5):2016.
35. Hunt MA, Tse CT, Ryan MB, Scott A, Sayre EC. Clinically-accessible and laboratory-derived predictors of biomechanical response to standalone and supported lateral wedge insoles in people with knee osteoarthritis. *Journal of foot and ankle research*. 2023;16(1):74.
36. Schwarze M, Bartsch LP, Block J, Alimusaj M, Jaber A, Schiltewolf M, et al. A comparison between laterally wedged insoles and ankle-foot orthoses for the treatment of medial osteoarthritis of the knee: A randomized cross-over trial. *Clinical Rehabilitation*. 2021;35(7):1032-43.
37. Im Yi T, Lee EC, Son NH, Sohn MK. Comparison of the forefoot pressure-relieving effects of foot orthoses. *Yonsei Medical Journal*. 2022;63(9):864.
38. da Silva Júnior JEF, Dibai-Filho AV, Santos IS, Protázio JB, Júnior JDA, de Oliveira DD, et al. Measurement properties of the short version of the Western Ontario and McMaster Universities Arthritis Index (WOMAC) for individuals with knee osteoarthritis. *BMC Musculoskeletal Disorders*. 2023;24(1):574.
-

39. Barnett A. SF-36 health survey.
Encyclopedia of quality of life and well-being research: Springer; 2024. p. 6421-2.

