

Therapeutic significance of insoles in patients with knee osteoarthritis

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Abstract. – OBJECTIVE: The effects of insoles on managing knee osteoarthritis (KOA) symptoms remain controversial. This systematic review provides insights into the therapeutic effects and outcomes of insole use in older adults with KOA.

MATERIALS AND METHODS: The PubMed database was reviewed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA). The articles' titles, abstracts, and eligibility per the inclusion criteria were screened for relevance. Duplicated articles were removed, and full-text articles were retrieved for further assessment, in accordance with the eligibility criteria. The included articles have been analyzed for general information, participants, and relevant findings, such as painful symptoms, loading rate, and external knee adduction moment (EKAM).

RESULTS: The initial search identified 335 articles. Nine studies, including seven randomized controlled trials, one cross-sectional study, and one cohort study, were included for review per the eligibility criteria. There were 639 KOA patients, of which the majority were female, diagnosed with Kellgren-Lawrence grades 2-3, with a mean age of 54.5 years. The lateral wedge insole helped reducing EKAM and loading rates in patients with KOA. We detected no significant reduction in pain following the use of lateral wedge insoles. However, lateral wedge insoles combined with customized arch support showed significant improvements in pain and physical function in KOA patients.

CONCLUSIONS: Lateral wedge insoles with arch support significantly improved pain and physical function in patients with KOA. Other insoles did not provide significant positive outcomes regarding pain reduction or joint deterioration in KOA patients.

Key Words:

Knee osteoarthritis, Insole, Lateral wedge insole, Foot, Biomechanics.

Introduction

Knee osteoarthritis (KOA) is one of the most common types of arthritis in older adults, and its prevalence has continued to rise, especially in Asia. The estimated global and regional prevalence of KOA from 2000 to 2020 was higher among Asian populations than European and American populations¹. It involves complex interactions between the knees' mechanical, structural, and biological systems and other gait-related parts such as the feet.

Even though KOA affects an increasing number of patients, a permanent cure has not been identified yet. Clinical treatment of KOA is solely based on medication, rehabilitation, and arthroplasty.

Insoles are a type of therapeutic management with long use in patients with KOA and take several forms: lateral, neutral, and those inclined at different degrees, with or without arch support. However, there is still controversy regarding how insoles of specific types can improve the symptoms of KOA^{2,3}. Therefore, the results of this review will offer insights into the therapeutic impact of insoles on painful conditions of KOA.

Materials and Methods

This systematic review was performed as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). To identify the therapeutic impact of insoles in patients diagnosed with different grades of KOA, PubMed was searched using the terms "Insole AND Knee Osteoarthritis," "Foot Insole AND Knee Osteoarthritis," and "Shoes Insole AND Knee Osteoarthritis".

Inclusion and Exclusion Criteria

Articles were screened according to the following inclusion criteria: 1) cohort retrospective or

prospective randomized controlled trials; 2) studies conducted between 2011 and 2021; 3) papers published in English; 4) studies with ≥ 20 participants; 5) Studies identifying the severity of KOA, type of classification, e.g., Kellgren-Lawrence (KL) grade, Knee Injury and Osteoarthritis Outcome Score (KOOS) or International Knee Documentation Committee (IKDC); and 6) studies identifying the source and type of insoles used. The exclusion criteria for this study were: 1) Other types of publication; 2) articles whose full texts were not available; and 3) cadaveric or animal studies.

Duplicate studies were manually removed, and full-text articles were retrieved for further assessment. Two reviewers (PJ and PP) independently reviewed the eligible studies. Different findings were discussed and concluded as a consensus by both reviewers. If a consensus could not be reached, the finding was confirmed by the senior author (CA).

The collected results were analyzed regarding the year of publication, country of origin, number of participants, grading of KOA and knee- or foot-related conditions, baseline data of the participants or patients, type of insoles, follow-up assessment, primary outcome, and relevant findings.

Results

From the initial search, 335 articles were found, and their titles were screened for relevance. Duplicate articles were removed, and full-text articles were retrieved for further assessment. Sixty-two articles were further screened for eligibility according to the inclusion criteria mentioned above. Thus, nine articles were included in the systematic review. A PRISMA flow diagram is presented in Figure 1, and a summary of these articles is presented in Tables I and II. The quality of the included articles was rated using Newcastle Ottawa Quality Assessment Scale, with a mean score of 5.8 points^{4,5}.

The nine articles, which included seven randomized control trials, a cross-sectional study, and a cohort study, were published in different countries from 2011 to 2021 (Egypt, Brazil, the United States of America [USA], the United Kingdom [UK], Australia, and Germany). There were 639 KOA patients, the majority of whom were female, diagnosed with an average KL grade of 2-3 and a mean age of 54.5 years. Although a similar KOA grading system was used, the KL classification, the conditions of KOA patients included in the studies were slightly different and

included medial KOA, varus alignment, pain, and other symptoms.

Regarding interventions, the type of insoles used to analyze the primary outcomes of each study were mostly lateral wedge types, with and without arch support. However, neutral wedge supports have also been used in some studies. The primary outcomes varied among studies in which there were clinical outcomes, such as Visual Analogue Scale (VAS), Western Ontario and McMaster Universities Arthritis Index (WOMAC), physical activities, and biomechanical outcomes, which included loading measures and knee adduction moment (KAM) changes. The number of included articles, separated by their outcomes, is shown in Figure 1.

Participants with KOA experienced knee pain due to pathological, mechanical, and even structural issues. Five articles reported a reduction in knee pain as measured by the WOMAC, KOOS, and physical activities. Hsieh and Lee⁶ found that the KOOS significantly score improved with soft lateral wedge insoles only for 3 months. Hsieh and Lee⁷ also observed a reduction in pain with physical functioning improvement, in which the participants' chair rising time during a 6-month follow-up period significantly decreased when wearing custom lateral wedge insoles with arch support. Even though wearing a lateral wedge with custom arch support for 2 and 4 months significantly improves WOMAC scores, physical functions, and foot function test results, there was no significant difference between wearing a lateral wedge alone in patients with medial tibio-femoral symptomatic KOA⁸.

Campos et al⁹ and Bennell et al² do not suggest in their studies significant differences between neutral and lateral wedge insoles, respectively, regarding clinical improvement at 2, 6, and 12 months. While a small reduction in overall knee pain was recorded in painful medial KOA wearing lateral insoles for 4 hours per day for 8 weeks in Felson et al¹⁰, there was no clinical improvement, specifically VAS, as reported by Jones et al¹¹.

Other outcomes were evaluated. Abdallah¹² emphasized their findings regarding the loading rate analyzed in medial KOA patients with varus alignment wearing 0, 6, and 11° lateral insoles with arch support. The results suggest that 11° insoles significantly decreased the loading rate. Several studies¹¹⁻¹⁴ investigated the relationship between KAM and KOA; KAM varies in different phases of the gait cycle and presents distinctively in patients with different conditions. Jones

Insoles in knee osteoarthritis

Table I. Summary information of studies regarding insoles for KOA part I.

Author	Country	Number of participants	KOA grading and conditions	Baseline	Type of insole	Follow-up assessments	Primary outcome	Findings
Abd El Megeid Abdallah ¹²	Egypt	33	KL grades 2 or 3 Medial type and varus alignment KOA Uni- and bilateral KOA	Females	0, 6, and 11° lateral insoles with arch support		Impact loading measures, loading rate	Unilateral 11° insoles significantly decrease the loading rate
Campos et al ⁹	Brazil	58	KL grades 1-4	Sex Race Mean age 64.3 years Mean weight 80.2 kg Mean height 1.6 m Body mass index (BMI) 30.6 kg/m ²	Lateral wedge and neutral insoles	At weeks 2, 8, and 24	WOMAC, VAS pain score, Lequesne questionnaire	Lower results for WOMAC at weeks 8 and 24 There was no significant difference between lateral wedge and neutral insoles
Felson et al ¹⁰	England	83	KL grades 2-4 Painful medial KOA	Mean ages 64.18 and 65.86 years old Mean BMI 28.21 and 28.56 Mean Hospital Anxiety and Depression Scale (HADS) depression scores 9.10 and 8.33 Mean HADS anxiety scores 12.17 and 12.48 for biomechanical responders and nonresponders	5° lateral wedge and neutral insoles, and own shoes	4 hours per day for 8 weeks.	Overall knee pain	A small reduction in overall knee pain Lateral wedge insoles do not provide pain improvement in most participants
Hsieh et al ⁶	Taiwan	90	KL grades 2-4	Age range from 40-85 years BMI 25+/-2.3 kg/m ² Education Comorbidity	Rigid 5° high-density ethyl vinyl acetate lateral wedge arch support insole and soft 5° polyurethane lateral wedge arch support insole	Before and after intervention for 1, 2 and 3 months	KOOS pain score.	Patients with KOA who used soft lateral wedge arch support insoles for a short term showed more significant improvement than those who used rigid insoles regarding pain, physical activity, daily living function, sports and recreation function, and quality of life

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Table II. Summary information of studies regarding insoles for KOA.

Author	Country	Number of participants	KOA grading and conditions	Baseline	Type of insole	Follow-up assessments	Primary outcome	Findings
Hunt et al ⁸	USA	26	KL Medial tibiofemoral symptomatic KOA (knee pain history for >6 months)	Age 64.0 Sex Mean BMI 27.2	5° lateral wedge foot insoles with and without custom foot arch support	2 and 4 months of wearing insoles	WOMAC, physical function test, and the foot function index	Wearing a lateral wedge with custom arch support improves these outcomes but is not significantly better than a lateral wedge alone
Bennell et al ¹⁴	Australia	200	KL grades 2 and 3	Age ≥50 years	5° lateral wedged insoles and flat insoles	12 months	Overall knee pain; WOMAC Change in volume of medial tibial cartilage	No significant difference in overall pain and medial tibial cartilage volume
Jones et al ¹¹	UK	70	KL grades 2 and 3 Painful KOA	Mean age 60.3 years Mean height 1.69 m Mean mass 87.3 kg	5° lateral wedge insole with supported medial wedges and typical wedges	-	VAS	Lateral wedge insoles with no medial support do not lessen knee pain
Hsieh et al ⁷	Taiwan	40	KL grade 2-4 Isolated medial compartment	Mean age 61 years Mean BMI 25 And other demographics	Custom molded 5° rigid lateral wedge insoles with arch support	1, 3, and 6 months	Physical activities	Reduced pain, improved physical functioning, and decreased chair rising time for 6months followup However, no effect on balance control
Schwarze et al ¹³	Germany	39	KL grades 1-3 Symptomatic medial KOA	Mean age 58 years Mean BMI 30	Lateral wedge insoles and ankle-foot orthosis (AFO)	6 and 12 weeks	Change in EKAM, other kinetic and kinematic changes, and patient-reported outcomes EQ-5D-5L, Oxford Knee Score, American Society Clinical Rating System, and the Hannover Functional Ability Questionnaire	AFO reduced medial knee load more than lateral wedge insoles. Nevertheless, no clinical Knee superiority could be shown

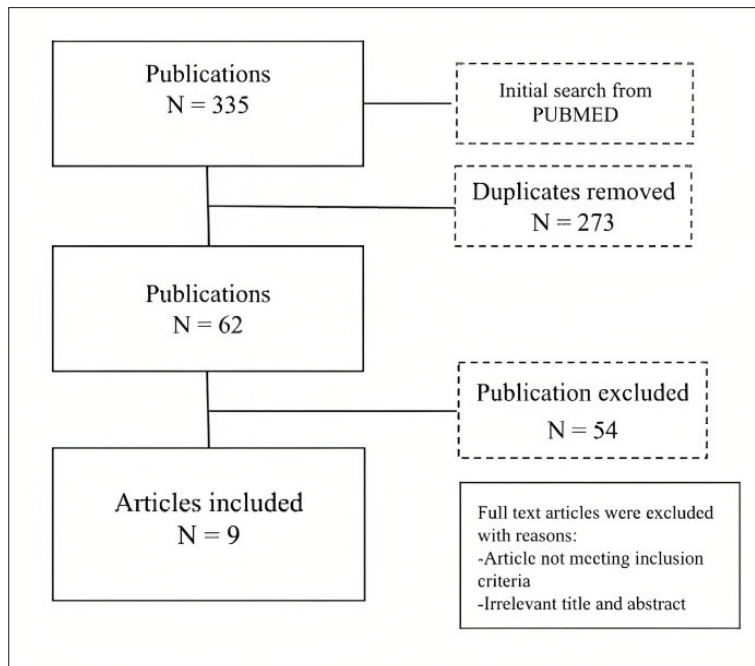


Figure 1. PRISMA flowchart.

et al¹¹ and Schwarze et al¹³ reported that lateral wedge insoles reduced the average external KAM (EKAM) in medial KOA patients. However, it fails to immediately reduce knee pain¹¹. These data suggest that failure of lateral wedge insoles to lessen immediate pain is less likely due to the consistent reduction in EKAM¹¹. Other structural changes involving medial tibial cartilage volume showed no significant between-group differences in the 5° lateral wedge and flat insoles over 12 months¹⁴.

Discussion

This systematic review highlighted the effects of insoles on aspects of KOA, especially painful symptoms, clinical outcomes, and biomechanical changes. Pain is indicative of KOA, in addition to crepitus, restricted movement, and bony protrusion¹⁵. Studying insoles provides insight into the future direction of KOA therapy, particularly regarding pain management. From this review, it can be said that most of the previous studies have suggested that lateral wedge-type insoles are not significantly different from neutral wedge or flat insoles in terms of pain measurement^{9,8,14}. Some scholars¹⁰ suggest small or even no pain reduction in participants wearing lateral wedge insoles. However, one of the included studies⁶ suggests a significant short-term, 3-month reduction in KOOS and WOMAC scores and enhancement of

daily function and quality of life resulting from the use of soft lateral wedge arch support insoles. In addition, custom-molded 5° rigid lateral wedge insoles with arch support helped in reducing pain, improved physical functioning, and decreased chair rising time during a 6-month follow-up period but did not affect balance control⁷.

Regarding the relationship between the biomechanical change following insole use and clinical outcomes, due to the alignment change of KOA patients' knees, their bodyweight distribution was shifted toward the medial knee joint during the mid-stance gait phase resulting in increased EKAM compared to KOA-free controls¹⁶. Thus, lateral wedge insoles have been widely studied as they may reduce EKAM. However, the reduction in EKAM does not show a relationship with reduced knee pain, as reported by Jones et al¹³. In addition, lateral wedge insoles may delay foot supination and aggravate pronation, which already exists in most KOA patients, by increasing ankle inversion¹⁷. Therefore, the mechanism of lateral wedge insoles may exacerbate pain in KOA¹⁸. As stated in a few studies in this systematic review, it is suggested that even though wearing a lateral wedge alone and neutral wedge insoles do improve knee pain, they do not have significant differences. Moreover, the effect of pain alleviation is small and unlikely to be clinically significant¹⁹.

For the positive clinical outcome following insole use, a study in this review suggests a significant

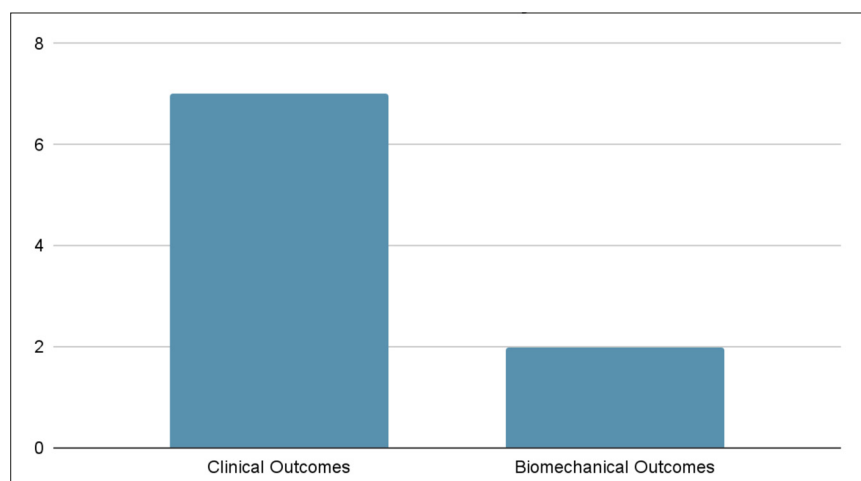


Figure 2. The number of included articles based on their primary outcomes.

short-term, 3-month reduction in KOOS and WOMAC scores and the enhancement of daily function and quality of life resulting from the use of soft lateral wedge arch support insoles⁶. Soft insoles, similar to lightweight and soft shoes, encourage activities and functions without heaviness in lifting the heel or stiffness²⁰. Hence, it is reasonable that a soft, customized lateral wedge with arch support might be the most suitable remedy for KOA because the types of patients belonging to that wedge vary (Figure 2). Moreover, custom-molded 5° rigid lateral wedge insoles with arch support helped reducing pain, improved physical functioning, and decreased chair rising time during a 6-month follow-up period but had no effect on balance control¹⁷. Therefore, the combination of a customized lateral wedge with arch support should be the insole of choice for treating patients with KOA (Figure 3), based on the evidence presented in this systematic review. This insole was made from Ethylene-Vinyl Acetate (EVA) foam based on the foot casting of a patient as the customized version.

Based on the etiology of KOA and its biomechanical changes following insole use, there are two types of KOA in general: primary osteoarthritis due to articular degeneration and secondary osteoarthritis due to consequences of unbalanced force across the joint¹⁵. This indicates that custom arch supports can provide personalized designs appropriate for patients' varying conditions. Furthermore, insoles, specifically those with an angle of 11°, also reduce the loading rate¹¹, which is strongly associated with joint degeneration²¹. Therefore, insoles could slow the progression of KOA. However, a high angle, such

as 11°, in lateral wedge insoles would increase the force at the knee joint and discomfort at the ankle and foot²⁰. These included articles, regardless of the primary outcomes, reported the crucial factors that may affect adherence to the treatment, such as foot and ankle discomfort. Pain may be a consequence of inappropriate footwear or an unfamiliar adjustment of foot and ankle alignment. A previous study²² proposed that the abnormalities in plantar pressure have been substantially shown in older adults with KOA. The mentioned information should be a basis for designing orthoses for the lower extremities that could relieve symptoms at the knee or foot or reduce KOA progression.

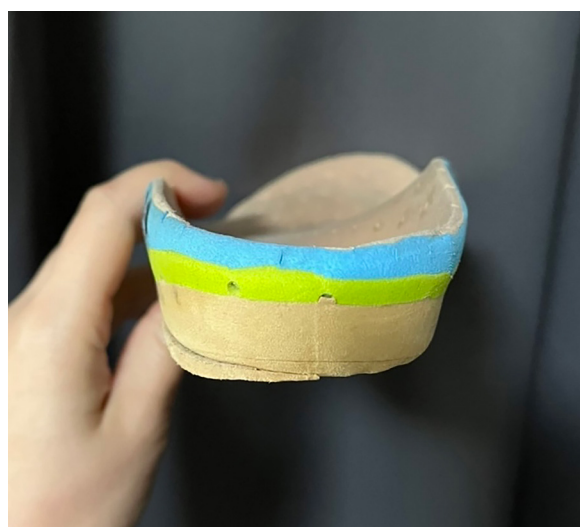


Figure 3. The sample of soft and customized lateral wedge with arch support on rear view.

Limitations

The main limitation of this review is that the measurement methods used to assess pain responses varied across different studies, and WOMAC, KOOS, and VAS scores were used. This may have affected the interpretation of the overall results. In addition, the average quality of the collected papers using the Newcastle Ottawa Quality Assessment Scale^{4,5} was not high; therefore, the conclusion of review data may need to be completed in the future with higher quality research.

Conclusions

This systematic review highlights the possible benefits of insoles in managing the symptoms of patients with KOA. Its impact on painful symptoms, loading rate, and EKAM was established. Even though there are some limitations regarding these studies, it was possible to conclude that insoles with certain designs or degrees of inclination, such as lateral wedge compared to neutral wedge insoles, do not show significant differences in supporting pain-reducing therapy in KOA. However, lateral wedge insoles combined with arch support showed significant improvement in pain and physical function in patients with KOA. Regarding biomechanical aspects, lateral wedge insoles helped reduce EKAM and the loading rate in patients with KOA

Informed Consent

Not applicable.

Ethics Approval

This paper did not involve the direct study of human subjects due to its design as a systematic review at the step of literature review; however, the overall project was approved by the authors' institutional ethical committees (The Research Ethics Committee of King Mongkut's Institute of Technology Ladkrabang, study code: EC-KMITL_65_052).

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Availability of Data and Materials

These parts of the current study are available from the corresponding author on reasonable request.

Authors' Contributions

PJ collected the data and drafted a manuscript; CA, created the research project, collected the data, drafted and edited a manuscript; PP, collected the data; PR, drafted a manuscript; NR, reviewed and edited a manuscript.

Conflict of Interests

No conflict of interest was declared in this study.

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