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REVIEW ARTICLE

LATERAL WEDGE INSOLES IN KNEE OSTEOARTHRITIS: A POST-EULAR 2023 REVIEW OF BIOMECHANICAL AND CLINICAL OUTCOMES

WKŁADKI Z LATERALNYM KLINEM W CHOROBIE ZWYRODNIENIOWEJ STAWU KOLANOWEGO – PRZEGLĄD WYNIKÓW BIOMECHANICZNYCH I KLINICZNYCH PO AKTUALIZACJI ZALECEŃ EULAR Z 2023 ROKU

Julia Anna Świerczek[1,A,B,D], Weronika Targosz[1,A,B,D], Wiktor Jabłoński[2,B–D], Adam Perek[2,B–D], Klaudia Kapelka[3,B–D], Julia Raszewska[2,B,E], Gabriel Mandera[2,B,E], Dawid Sobański[4,E], Karolina Pyrtek[5,E], Aleksandra Wesołowska[6,F]
[1]Data Analysis, KKS Statistics, Ruda Śląska, Poland
[2]Medical Internship, St. Barbara Regional Specialist Hospital in Sosnowiec, Poland
[3]Medical Internship, Regional Specialist Hospital of the Blessed Virgin Mary in Częstochowa, Poland
[4]Medical Internship, Regional Hospital in Poznań – Greater Poland Specialist Centre, Poland
[5]Medical Internship, District Hospital in Zawiercie, Poland
[6]Medical Internship, Pope John Paul II Regional Hospital in Zamość, Poland

ABSTRACT

Introduction

Knee osteoarthritis is a chronic condition leading to pain, functional limitations, and structural joint changes. Non-surgical management includes patient education, exercise therapy, and weight reduction. The use of lateral wedge insoles (LWIs) remains controversial, and current evidence regarding their effectiveness is inconclusive.

Aim

This review aimed to examine recent studies published after the 2023 European Alliance of Associations for Rheumatology (EULAR) guidelines on the use of LWIs in the management of knee osteoarthritis (KOA), with particular emphasis on their effects on joint biomechanics and clinical outcomes.

Materials and methods

A targeted search was conducted in PubMed for publications from May 2022 to 2025 related to KOA and LWIs. Nine studies were included in the analysis: five randomized controlled trials, one network meta-analysis, two experimental studies, and one non-randomized clinical-control study. Biomechanical outcomes (knee adduction moment, tibial rotation, center of pressure displacement) and clinical outcomes (pain and joint function) were evaluated.

Author responsible for correspondence:
Julia Anna Świerczek, Data Analysis, KKS Statistics, 75 Podgórska St., 41-706 Ruda Śląska, Poland
swierczekjuliaanna@gmail.com
https://orcid.org/0009-0007-0350-5978

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Results
Some studies reported beneficial effects of LWIs on biomechanical parameters and subjective pain perception, including improved gait comfort, reduced lateral knee displacement, and decreased pain. Other studies found no significant clinical effects, and observed biomechanical changes did not consistently translate into functional improvements. Variability in outcomes may reflect differences in individual biomechanics, severity of joint degeneration, duration of insole use, and the design of the intervention.

Conclusions
LWIs may improve selected biomechanical parameters of the knee joint, but their clinical efficacy remains uncertain. They should not be used as a standalone treatment. Further research is needed to identify predictors of therapeutic response.

Keywords: biomechanics, knee osteoarthritis, clinical outcomes, lateral wedge insoles

Introduction

Knee joints are the largest joints in the human body, and the tibiofemoral and patellofemoral joints make the knee a complex synovial joint [1,2]. They are structures subjected to high mechanical loads during daily activities [3,4]. Consequently, prolonged overloading, as well as aging, may lead to the development of degenerative changes, most commonly affecting the knee joint [5,6].

From a biomechanical perspective, parameters describing joint loading during gait play an important role in the pathogenesis and progression of knee osteoarthritis (KOA). The most frequently analyzed parameters include the knee adduction moment (KAM) and the knee flexion moment. It has been shown that the magnitude and rate of increase of KAM constitute some of the most sensitive biomechanical indicators associated with the presence and severity of degenerative changes, particularly in the medial compartment of the knee [7–9]. Moreover, increased ground reaction forces (GRFs), center of pressure (COP), and propulsive forces also appear to be associated with higher loading of joint structures [10–12].

KOA is a chronic and progressive disease, characterized by structural changes within the joint, leading to restricted mobility and the occurrence of pain [13–16]. In over 90% of cases, degenerative changes are located in the medial tibiofemoral compartment [17]. KOA occurs more frequently in women [18].

Age-standardized incidence of KOA in Central Europe, including Poland, in 2021 was 2.74–2.91%, whereas prevalence was 3.21–3.32%. In Poland, incidence of KOA between 1990 and 2021 increased by 8.03%, and the number of prevalent cases of KOA increased by 8.72% compared to 1990. In 2021, the global prevalence of KOA and the prevalence per 100,000 individuals were highest in the 55–59-year-old group [19]. The observed increase in incidence in recent years, both in Poland and the European Union, is related to the aging of the population [13,20].

One of the methods for treating advanced KOA is surgical intervention in the form of total knee arthroplasty. The mean age of patients undergoing this procedure in Poland is 68 years [21]. In this age group, comorbid chronic diseases often coexist, increasing perioperative risk, which highlights the importance of effective non-surgical treatment methods in KOA [22].

Guidelines for the management of KOA, developed by European Alliance of Associations for Rheumatology (EULAR), European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis, Osteoarthritis Research Society International, American

College of Rheumatology, and World Health Organization, clearly emphasize the importance of patient education, appropriately tailored exercise therapy, and weight reduction. In particular, the latest 2023 EULAR recommendations emphasize a highly individualized approach to the patient, positioning non-pharmacological strategies – such as regular aerobic and resistance exercise, alongside psychological support – as the absolute foundation of first-line therapy prior to the initiation of pharmacotherapy [6,23–26]. It has been shown that even a 5% reduction in body weight provides significant clinical benefits. The aim of these interventions is to reduce symptom severity and improve joint function [27].

Although the 2023 EULAR recommendations point to a single randomized controlled trial (RCT) showing a significant reduction in knee pain in individuals using biomechanically modified footwear compared to the control group, they also indicate that most evidence does not support the routine use of lateral wedge insoles (LWIs) for pain reduction in patients with KOA. Clinically, it is also recommended to wear comfortable, stable shoes that provide adequate support and sufficient toe space during weight-bearing as part of comprehensive management of KOA patients [23,28].

Despite numerous guidelines, recommendations regarding LWIs remain, at best, conditional. Until the publication of these guidelines, there was a lack of clear evidence confirming the impact of this type of non-pharmacological intervention on pain reduction, functional improvement, or slowing disease progression. However, since 2023, several interesting studies on this topic have been published, which will be presented in this review.

Aim

The aim of this study was to review scientific articles published after the release of the 2023 EULAR guidelines for the management of KOA, which could provide new insights into the use of LWIs as a non-pharmacological adjunctive therapy for this condition. Focusing the analysis on literature published post-2023 is intentional, as this year marked the release of the latest recommendations by EULAR, which currently serve as the most up-to-date and pivotal reference point for clinical practice in Europe. Consequently, an additional objective of this review was to identify and present recent publications addressing this topic, as well as to indicate potential factors that may explain discrepancies observed in previous studies assessing the effects of LWIs on patients' clinical status and knee joint biomechanics.

Materials and methods

A targeted literature search was conducted in the PubMed database. The search strategy included both controlled Medical Subject Headings (MeSH) terms and keywords appearing in the title and abstract of articles: ("Osteoarthritis"[MeSH] OR osteoarthritis[tiab]) AND (insole*[tiab] OR "lateral wedge"[tiab] OR "lateral wedge insole"[tiab] OR "wedged insole"[tiab]).

The retrieved results were sorted by publication date. Studies published from May 27, 2022 (i.e., after the completion of literature collection for the 2023 EULAR guidelines) to the end of 2025 were included. This approach allowed for the identification of the most recent reports regarding biomechanical parameters relevant to the course of KOA, such as KAM, tibiofemoral rotation abnormalities, and other indicators potentially affecting knee joint stability, as well as patients' clinical status assessed using numeric rating scale, visual analog scale, and Knee injury and Osteoarthritis Outcome Score (KOOS) scales.

The review included articles available in English. In one of the initial stages of the selection process, the titles and abstracts of the identified papers were screened, while in a subsequent stage, the full-text articles were evaluated. Both of these steps were performed independently by two investigators, and any discrepancies regarding study eligibility were resolved by a third author. From each study, relevant information was extracted, including the year of publication, country, study type, study design, participant characteristics, characteristics of the insoles and other experimental conditions, functional tasks, data collection methods and outcomes, reported results, and a summary of findings. These data were synthesized and presented in a tabular format to enable a clear and structured comparison of the included studies.

The PubMed publication date filter (2022–2025) initially identified 79 records. The study selection process is presented in Figure 1. For the final analysis, 9 articles were selected, including 5 RCTs (4 crossover trials and 1 parallel-group trial), 1 network meta-analysis, 2 experimental studies with repeated laboratory measurements, and 1 non-randomized clinical case-control study.

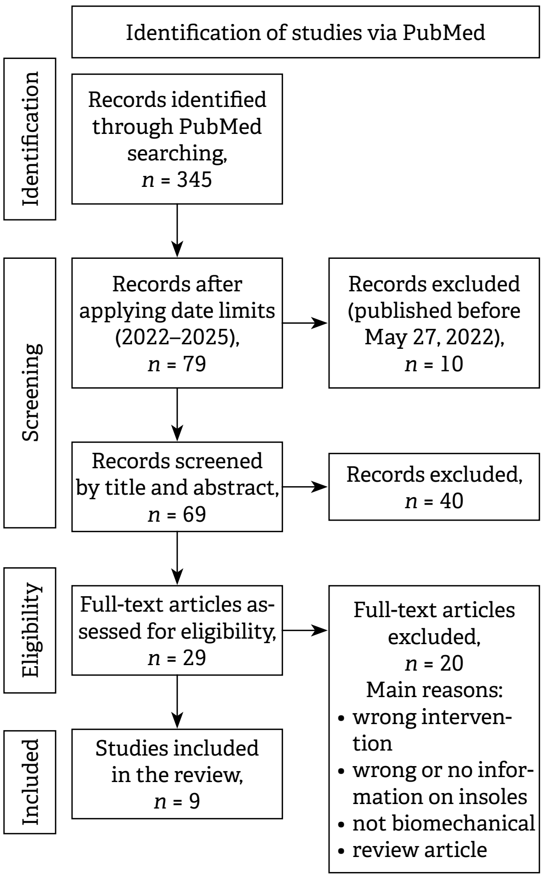

Figure 1. Selection diagram

Results

In several studies, the reported outcomes and conclusions suggest a beneficial effect of LWIs on clinical symptoms or knee joint biomechanics, supporting their potential use as an adjunct intervention for the management of KOA. For example, Sabet *et al.* [29] demonstrated that lateral wedges integrated into specially designed slipper-sock footwear significantly improved walking comfort and reduced perceived pain compared to barefoot walking. The study also reported favorable kinematic modifications, suggesting that these insoles may indirectly reduce medial compartment loading of the knee joint (Table 1 and 2).

Du *et al.* [30] reported that the use of LWIs increased hip and knee flexion, ankle internal rotation, and lateral displacement of the COP. The insoles also influenced GRFs. These changes may shorten the lever arm of the KAM, thereby reducing medial compartment loading. Ishii *et al.* [31] found that long-term use of lateral wedges reduced lateral knee thrust and gait variability. Simultaneously, they observed significant reductions in pain and improvements in KOOS scores. Improvements in pain and functional outcomes were not observed in the study by Hsu *et al.* [32]; however, stability was improved, providing a protective effect against adverse foot-to-forefoot displacement. Differences in pain and functional outcomes across these studies may be related to differences in the intensity of insole use. In Ishii *et al.* [31], use was higher, but the study was non-randomized, which may have influenced the results (Table 1 and 2).

In predictive studies, Hunt *et al.* [33] identified clinical factors that may indicate greater efficacy of LWIs. Higher walking speed, lower foot pain, and lower degrees of osteoarthritic changes according to the Kellgren-Lawrence classification were associated with a stronger biomechanical response to insoles,

Table 1. Characteristics of included studies

Authors	Year	Country	Study	Study design	Participants	Insoles and other conditions characteristics	Functional tasks	Data collection and outcomes
Sinclair, and Zhang [34]	2025	UK	Toe-in and toe-out walking patterns and LWIs: a musculoskeletal simulation and probabilistic modelling assessment of medial tibiofemoral cartilage mechanics	Experimental study with repeated measures conducted under laboratory conditions	*N* = 15; men; age 31.7 ± 5.0 years; height 172 ± 6 cm; weight 69.3 ± 9.9 kg; BMI 23.5 ± 2.8 kg/m^2; 18-45 years, healthy, no OA or other musculoskeletal pathologies, no knee pain	Conditions: neutral gait, toe-in, toe-out; LWIs: 5°; heel 11 mm; continuous lateral wedge; material: EVA (Shore A 65)	Walking; 22 m walkway; self-selected speed; 4 conditions; 5 valid trials/condition, 1 gait cycle/trial	Gait biomechanics analysis; motion capture (8 cameras, 250 Hz), piezoelectric force plate (1000 Hz, 20 N threshold), anatomical markers and segment clusters; walking speed, step length, COP (ML), medial tibiofemoral contact forces, peak forces, cartilage stresses and strains; computational knee model
Sabet *et al.* [29]	2025	Austria	Acute effects of LWIs on lower limb joint kinematics and symptoms in women with medial compartment KOA during walking	Crossover RCT	*N* = 23; women; age 55.2 ± 4.5 years; height 1.60 ± 0.08 m; weight 67.6 ± 5.9 kg; BMI 26.7 ± 2.4 kg/m^2; bilateral medial KOA (KL II-III), citizens of Iran	Conditions: barefoot, SAN: sandals with integrated LWIs 6°, SOC: slipper-sock with integrated LWIs 6°; LWIs design: variable stiffness (laterally plastazote, medially EVA), longitudinal and transverse arch support, metatarsal pad; SOC: neoprene, rubber stabilizing strap	Static standing + walking; 10 m walkway; self-selected speed; 3 conditions (random order); ≥ 3 familiarization trials/condition; 2 min seated rest between trials	Clinical scales + gait biomechanics analysis; WOMAC, VAS, Likert scale + optoelectronic system (8 IR cameras, 120 Hz), 30 anatomical markers, clusters on the thigh and shank; hip FE angle, hip AA angle, hip IER rotation angle, knee FE angle, ankle DF/PF angle, subtalar joint IV/EV angle, waveform shapes

Table 1. Cont.

Authors	Year	Country	Study	Study design	Participants	Insoles and other conditions characteristics	Functional tasks	Data collection and outcomes
Chen *et al.* [35]	2025	Multiple (meta-analysis)	Clinical efficacy of different therapeutic options for KOA: a network meta-analysis based on randomized clinical trials	Network meta-analysis	*N* = 9644; age ≥ 18 years; KOA (KL II–III), presence of knee pain	Therapeutic interventions: LLLT, HILT, TENS, IFC, shortwave diathermy, ultrasound, LWIs, knee brace, exercise therapy, hydrotherapy, kinesiotaping, ESWT	Various functional tasks; walking, daily activities, physical therapy modalities (depending on the RCT)	Systematic review of RCTs in multiple databases (PubMed, Embase, Cochrane, etc. – until December 2023); eligibility based on KOA diagnosis, intervention type, and outcome reporting (WOMAC, VAS); data extracted using a standardized form; quality assessed with the Cochrane Risk of Bias tool; analyzed via network meta-analysis with SUCRA ranking and inconsistency checks
Du *et al.* [30]	2024	China	Biomechanical response of lower limb joints to LWIs	Crossover RCT	*N* = 16; 10 F; age 26 ± 2 years; height 1.67 ± 0.08 m; weight 58.6 ± 12.0 kg; BMI 20.9 ± 2.9 kg/m^2; healthy, no musculoskeletal disorders	Conditions: barefoot walking, flat insole (FI, 0 mm), LWIs 7 mm (~5° valgus), LWIs 10 mm (~7° valgus); material: EVA; lateral height increase	Walking; ~10 m walkway; self-selected speed; 4 conditions: barefoot (always first) and with three types of insoles (random order); 5 valid right-foot contacts with the force plates	Gait biomechanics analysis; motion capture (100 Hz), force plates (1000 Hz) and 29 markers; GRFs, gait cycle event identification, COP

Table 1. Cont.

Authors	Year	Country	Study	Study design	Participants	Insoles and other conditions characteristics	Functional tasks	Data collection and outcomes
Hunt *et al.* [33]	2023	Canada	Clinically accessible and laboratory-derived predictors of biomechanical response to standalone and supported LWIs in people with KOA	Crossover RCT	*N* = 53; 39 F; age 64.4 ± 6.9 years; BMI 26.6 ± 3.9 kg/m²; medial KOA (KL 2–4), knee pain > 6 months, mean pain ≥ 3/10	Custom insoles: flat control (3 mm EVA), standalone LWIs 5° (EVA), LWIs 5° with individualized variable-stiffness arch support (EVA + plastazote)	Level walking; 10 m walkway; self-selected speed; FLAT (always first), WEDG, WEDG + V-ARCH (random order); mean of 5 successful trials/condition	Clinical data + gait biomechanics analysis; FFI, knee pain (NRS), FPI, subtalar ROM, tibial alignment + motion capture (14 cameras, 100 Hz) and force plates (2000 Hz): gait speed, foot progression angle, clinical tests
Ueda *et al.* [36]	2023	Japan	Kinematic effects of LWIs in patients with medial KOA	Experimental study with repeated measures and a healthy control group conducted under laboratory conditions	*N* = 15; KOA group: *n* = 11; women; age 71.8 ± 3.0 years; height 148.9 ± 4.0 cm; weight 60.5 kg; BMI 27.2 ± 4.4 kg/m²; FTA > 170°; medial KOA | healthy control: *n* = 4; women, age 22 years	Conditions: barefoot, LWIs 7 mm, LWIs 10 mm, LWIs 13 mm	Sit-to-stand; chair height 40 cm; self-selected speed; 4 conditions	Knee joint rotation; magnetic 3D system (POLHEMUS); 60 Hz; tibial rotation relative to the femur (IER) during sit-to-stand
Jaques *et al.* [37]	2023	Switzerland	Walking with different insoles changes lower-limb biomechanics globally in patients with medial KOA	Crossover RCT	*N* = 10; 1 F; age 57.2 ± 8.3 years; height 1.73 ± 0.94 m; weight 88.9 ± 12.6 kg; medial KOA (KL I–III)	Conditions: own footwear (sneakers), insole with full-length arch support, arch support + full-length LWIs 5°, custom insole for medial KOA	Walking; self-selected, slower and faster speeds; 4 conditions (randomized); 3 successful trials/speed; total 36 trials/patient	Gait biomechanics analysis; motion capture (14 cameras, 120 Hz) and 2 force plates (1200 Hz); gait variables: pKAM, iKAM, pKFM, pKEA, pAEM, pHAM

Table 1. Cont.

Authors	Year	Country	Study	Study design	Participants	Insoles and other conditions characteristics	Functional tasks	Data collection and outcomes
Ishii *et al.* [31]	2023	Japan	The effect of LWI on gait variability assessed using wearable sensors in patients with medial compartment KOA	Non-randomized case-control study	*N* = 28; KOA group: *n* = 15; 6 F; age 64.9 ± 9.6 years; BMI 25.0 ± 2.8 kg/m²; KL > 1, FTA > 174°, insoles worn 8.1 ± 3.0 h/day | healthy control: *n* = 13; 7 F; age 65.0 ± 4.4 years; BMI 22.5 ± 1.4 kg/m²	Custom LWIs: 7 mm (~7°); material: silicone	Walking; 2 × 10 m walkway; self-selected speed; without LWIs (baseline), with LWIs immediately (T0) and after 1 month (T1); analysis of acceleration during the middle 4 steps	Clinical scales and gait biomechanical analysis using inertial sensors; VAS, KOOS + IMU (accelerometers, gyroscopes; 100 Hz), lateral thrust, gait variability, spatiotemporal parameters (Gait speed, Stride length, Stride duration, Stance duration, Swing duration)
Hsu *et al.* [32]	2022	Taiwan	A study on the effects of LWI on plantar-pressure pattern for medial KOA using the wearable sensing insole	Parallel RCT	*N* = 23; LWIs group: *n* = 13, 8 F, age 70.0 ± 4.5 years, BMI 24.3 ± 2.2 kg/m² | control: *n* = 10, 9 F, age 67.9 ± 8.8 years, BMI 24.4 ± 3.1 kg/m²; KOA (KL II-IV)	Insoles: LWIs + arch support (6°), standard insole with arch support; material: TPU and polyurethane	Standing + walking; standing 30 s, walking 20 m; T0 (before insoles) and T1 (after 20 weeks, using insoles ≥ 4 h/day)	Clinical scales + gait biomechanics analysis; VAS, WOMAC + measurement insole (89 sensors, bluetooth, 30 Hz), plantar pressure distribution (%PFP), COP displacement, COP path parameters (%Long, %Trans)

AA – adduction/abduction, BMI – body mass index, cMTF-CL – cumulative MTF compressive load, COM – center of mass, COP – center of pressure, DF/PF – dorsiflexion/plantarflexion, ESWT – extracorporeal shock wave therapy, EVA – ethylene vinyl acetate, F – female, FE – flexion/extension, FFI – Foot Function Index, FPI – Foot Posture Index, FTA – femorotibial angle, GRFs – ground reaction forces, HILT – high-intensity laser therapy, IER – internal/external rotation, IFC – interferential current, iKAM – impulse of KAM, IMU – inertial measurement unit, IV/EV – inversion/eversion, KAM – knee adduction moment, KL – Kellgren and Lawrence scale, KOA – knee osteoarthritis, KOOS – Knee Injury and Osteoarthritis Outcome Score, LLLT – low-level laser therapy, LWIs – lateral wedge insoles, MF – muscle force, ML – mediolateral, MTF – medial tibiofemoral, NRS – numeric rating scale, OA – osteoarthritis, pAEM – peak ankle eversion moment, pHAM – peak hip adduction moment, pKEA – peak knee extension angle, pKAM – peak KAM, pKFM – peak knee flexion moment, pMTF – peak medial tibiofemoral, pMTF-CF – peak MTF compressive force, %Long – percentage of the anteroposterior length of the COP path to the foot length, %PFP – partial foot pressure as the percentage of body weight, %Trans – percentage of the transverse width of the COP path to the maximum foot width, RCT – randomized controlled trial, RF – rectus femoris, TENS – transcutaneous electrical nerve stimulation, TPU – thermoplastic polyurethane, VAS – visual analogue scale, WOMAC – Western Ontario and McMaster Universities Osteoarthritis Index

Table 2. Effects of lateral wedge insoles (LWIs) on clinical and biomechanical outcomes

Authors	Study	Outcomes reported	Summary of findings
Sinclair and Zhang [34]	Toe-in and toe-out walking patterns and LWIs: a musculoskeletal simulation and probabilistic modelling assessment of medial tibiofemoral cartilage mechanics	Gait speed, COP position relative to foot COM, pMTF-CF, cMTF-CL, vasti MF, RF force, whole-body metabolic power, pMTF stress, pMTF strain, MTF cartilage failure probability	Peak medial tibiofemoral compressive force, stresses and strains were greater during neutral and LWI conditions than during toe-in and toe-out gait. Cumulative medial tibiofemoral compressive loads were greater during neutral conditions than during toe-in and toe-out gait, lateral insoles exceeded toe-out. Toe-out walking produced the highest rectus femoris force, whole-body metabolic power and reduced walking velocity. LWIs did not significantly reduce medial tibiofemoral loads, stresses, strains, or cartilage failure probability compared with neutral gait. Probability of medial tibiofemoral cartilage failure was higher in neutral gait compared with toe-in and toe-out. Gait modifications (toe-in and toe-out) may reduce biomechanical risk factors for medial tibiofemoral osteoarthritis, although toe-out gait was associated with increased metabolic cost. Toe-in resulted in a more lateral COP compared with all other conditions; neutral was more lateral than toe-out and lateral insoles. Vastus intermedius, lateralis and medialis forces were greater in neutral and lateral insoles than in toe-out; toe-in showed intermediate values.
Sabet *et al.* [29]	Acute effects of LWIs on lower limb joint kinematics and symptoms in women with medial compartment KOA during walking	WOMAC, Likert scale, VAS, hip FE angle, hip AA angle, hip IER angle, knee FE angle, ankle DF/PF angle, subtalar IV/EV angle, waveform shapes	The slipper-sock condition with integrated LWI (SOC) resulted in the highest perceived comfort and the lowest pain intensity, followed by sandals with LWIs (SAN), while barefoot walking showed the lowest comfort and highest pain levels. Lateral wedge insoles reduced hip external rotation angles (SAN and SOC), increased hip flexion angles (SOC), reduced hip abduction angles (SOC) and reduced knee flexion angles (SOC) compared with barefoot walking. LWIs reduced ankle plantarflexion (SAN) and subtalar eversion (SOC) compared with barefoot walking. Overall, LWIs – particularly in the SOC configuration – improved subjective symptoms and induced favorable alterations in lower-limb kinematics, suggesting a beneficial biomechanical effect.
Chen *et al.* [35]	Clinical efficacy of different therapeutic options for KOA: a network meta-analysis based on randomized clinical trials	WOMAC, VAS (rest, activity)	Network meta-analysis showed that knee bracing was the most effective intervention for pain reduction, functional improvement, and stiffness reduction in KOA. Hydrotherapy, exercise therapy, and high-intensity laser therapy ranked next depending on outcome. LWIs demonstrated relatively low clinical effectiveness across most outcomes. Physical modalities such as laser therapy, transcutaneous electrical nerve stimulation, and extracorporeal shockwave therapy showed moderate effects but were generally less effective than bracing, hydrotherapy, and exercise. Overall, LWIs do not appear to be a first-line treatment for KOA

Table 2. Cont.

Authors	Study	Outcomes reported	Summary of findings
Du *et al.* [30]	Biomechanical response of lower limb joints to LWIs	Spatiotemporal gait parameters (gait speed, step/stride length, cadence), hip FE angle, hip AA angle, hip IER angle, knee FE angle, ankle DF/PF angle, ankle IV/EV angle, ankle IER angle, forefoot-hindfoot DF/PF angle, forefoot-hindfoot IV/EV angle, forefoot-hindfoot AA angle, hindfoot-tibia DF/PF angle, hindfoot-tibia IV/EV angle, hindfoot-tibia IER angle, hallux-forefoot DF/PF angle, lateral COP shift, GRF changes, correlations between kinematic changes and wedge height.	LWIs increased hip (flat insoles), knee flexion angles (all insoles) and ankle internal rotation (all insoles) and reduced ankle dorsiflexion (all insoles) compared with barefoot walking. Forefoot-hindfoot inversion/eversion and adduction angles decreased for all insoles, and hindfoot-tibia internal rotation decreased, particularly with higher wedge angles. GRFs showed condition-specific changes, including increased posterior force and mediolateral peaks. The COP shifted laterally with LWIs. Correlation analyses indicated wedge-height-dependent kinematic adaptations. These biomechanical changes may indirectly reduce medial knee loading by shortening the KAM lever arm, highlighting the need for individualized insole design.
Hunt *et al.* [33]	Clinically accessible and laboratory-derived predictors of biomechanical response to standalone and supported LWIs in people with KOA	FPI, NRS, FFI (pain), gait speed, ankle/subtalar EV motion, foot progression angle, frontal plane tibial/knee angle, predictive variables for response to WEDG and WEDG + V-ARCH.	Higher gait speed predicted a biomechanical response to LWIs with or without arch support across multiple response thresholds. Other predictors associated with an increased likelihood of response included lower foot pain and a lower Kellgren-Lawrence grade for LWI alone. For LWIs combined with arch support, additional predictors of response were lower foot pain, a lower Kellgren-Lawrence grade, female sex, less varus knee alignment, and older age.
Ueda *et al.* [36]	Kinematic effects of lateral wedged insoles in patients with medial KOA	Tibiofemoral rotation angle during sit-to-stand	Patients with medial KOA showed reduced and abnormal tibial rotation compared to healthy controls. Lateral wedged insoles further decreased tibial internal rotation by increasing tibial external rotation and did not restore normal knee rotational mechanics. Increasing wedge height did not improve rotational motion, suggesting LWIs do not correct abnormal knee rotation during weight-bearing functional tasks.
Jaques *et al.* [37]	Walking with different insoles changes lower-limb biomechanics globally in patients with medial KOA	Changes in: pKAM, iKAM, pKFM, pHAM, pAEM, pKEA; intra-patient correlations between pKAM and other gait variables; effect of adding lateral wedge	Substantial inter-individual variability was observed, with at least moderate-to-large effect sizes in ≥ 36.7% of trials across all gait variables. pKAM decreased significantly, while iKAM was positively correlated with pKAM in all patients. Changes in pHAM and pAEM were also correlated with pKAM for all and most of the patients. Adding a lateral wedge to an arch-supported insole reduced pKAM, iKAM, and pAEM. These findings highlight that relying solely on pKAM may overlook relevant biomechanical adaptations and support personalized, multi-variable biomechanical assessments.

Table 2. Cont.

Authors	Study	Outcomes reported	Summary of findings
Ishii *et al.* [31]	The effect of LWI on gait variability assessed using wearable sensors in patients with medial compartment KOA	VAS, KOOS, lateral thrust, gait variability, spatiotemporal gait parameters (gait speed, stride length, stride duration, stance duration, swing duration)	Baseline lateral thrust was higher than in post-intervention and control conditions. Gait variability decreased following long-term use of LWIs. Clinical outcomes improved, with reduced pain (VAS) and improved KOOS subscale scores both shortly after insole usage and after 1 month. These results suggest that prolonged use of LWIs improves gait stability by reducing dynamic knee instability.
Hsu *et al.* [32]	A study on the effects of lateral-wedge insoles on plantar-pressure pattern for medial KOA using the wearable sensing insole	VAS, WOMAC, COP displacement, %Long, %Trans, %PFP	LWIs with arch support did not significantly improve pain or knee function compared with standard insoles. However, they prevented deterioration of plantar pressure patterns observed in the control group. Forefoot plantar pressure increased and heel pressure decreased over time in the standard insole group, whereas LWIs stabilized plantar load distribution. These findings suggest a protective biomechanical effect on plantar pressure distribution despite limited symptomatic improvement.

AA – adduction/abduction, BMI – body mass index, cMTF-CL – cumulative MTF compressive load, COM – center of mass, COP – center of pressure, DF/PF – dorsiflexion/plantarflexion, ESWT – extracorporeal shock wave therapy, EVA – ethylene vinyl acetate, F – female, FE – flexion/extension, FFI – Foot Function Index, FPI – Foot Posture Index, FTA – femorotibial angle, GRFs – ground reaction forces, HILT – high-intensity laser therapy, IER – internal/external rotation, IFC – interferential current, iKAM – impulse of KAM, IV/EV – inversion/eversion, KAM – knee adduction moment, KL – Kellgren and Lawrence scale, KOA – knee osteoarthritis, KOOS – Knee Injury and Osteoarthritis Outcome Score, LLLT – low-level laser therapy, MF – muscle force, MTF – medial tibiofemoral, NRS – numeric rating scale, OA – osteoarthritis, pAEM – peak ankle eversion moment, pHAM – peak hip adduction moment, pKEA – peak knee extension angle, pKAM – peak KAM, pKFM – peak knee flexion moment, pMTF – peak MTF, pMTF-CF – peak MTF compressive force, %Long – percentage of the anteroposterior length of the COP path to the foot length, %PFP – partial foot pressure as the percentage of body weight, %Trans – percentage of the transverse width of the COP path to the maximum foot width, RCT – randomized controlled trial, RF – rectus femoris, TENS – transcutaneous electrical nerve stimulation, TPU – thermoplastic polyurethane, VAS – visual analogue scale, WEDG – 5° lateral wedge insole, WOMAC – Western Ontario and McMaster Universities Osteoarthritis Index, V-ARCH – lateral wedge with variable stiffness contoured arch support

particularly when combined with additional arch support. These findings highlight that appropriate patient selection for LWIs as an adjunct to KOA therapy may increase the benefits of the intervention and may also explain variability in responses observed in other studies (Table 1 and 2).

In other studies, reported outcomes and conclusions suggest a negative effect or no effect of LWIs on clinical symptoms or knee joint biomechanics, indicating limited justification for their use as a standalone intervention. Sinclair and Zhang [34] showed that lateral wedges did not reduce peak forces and stresses in the medial compartment of the knee compared to neutral walking, and gait modification would be a more favorable intervention in the context of KOA. A network meta-analysis conducted by Chen *et al.* [35] demonstrated that LWIs have relatively low clinical efficacy in reducing pain, improving function, and decreasing stiffness in KOA compared to other interventions such as physiotherapy, hydrotherapy, or knee braces (Table 1 and 2).

Regarding biomechanics, Ueda *et al.* [36] found that LWIs did not restore normal tibial rotation in patients with KOA – in fact, they increased external tibial rotation and did not normalize knee mechanics during weight-bearing activities of daily living, such as rising from a chair. Similarly, Jaques *et al.* [37] reported substantial individual variability in biomechanical responses to LWIs. Some patients showed a reduction in KAM and changes in muscle activity, while others did not. This indicates that despite the potentially beneficial effects of lateral wedges on selected knee biomechanical parameters, their effects are not uniform across all patients, and the evaluation of LWIs effects on knee joint biomechanics should consider more parameters than just peak KAM (pKAM) (Table 1 and 2).

Discussion

The lack of conclusive evidence that LWIs positively affect knee joint biomechanics or the clinical presentation of patients with KOA explains why these insoles are not recommended in the aforementioned guidelines. Although other reports indicate potential benefits (e.g., reduction of KAM, improved comfort, and decreased pain) [28,38,39], their efficacy in treating KOA remains inconclusive. It is possible that factors such as individual gait biomechanics, foot morphology, the degree of osteoarthritic changes, and insole characteristics may modify their effects, opening new avenues for further research.

In another study, Yosuke Ishii [38] aimed to evaluate how the degree of medial meniscal extrusion (MME) and cumulative mechanical loading of the knee might influence the effectiveness of LWIs in KOA patients. This analysis indicated that individual differences in joint biomechanics and meniscal anatomy may determine which patients respond favorably to insoles and which show limited therapeutic benefit. The results suggest that considering these factors in therapy planning may improve intervention tailoring and increase the likelihood of pain reduction and improved knee function.

In a subsequent study, Ishii *et al.* [39] examined how the duration of LWIs use affects the mid-term response in MME and whether it is associated with KOA progression. The authors demonstrated that longer daily use of LWIs (over 5 hours per day) maintained MME reduction after one year and was associated with slower osteoarthritic progression and more stable limb alignment. These findings suggest that the lack of conclusive evidence on the effectiveness of LWIs may partly result from insufficient observation periods or inadequate intervention duration needed to reveal their potential therapeutic effect.

Additionally, in an earlier study (Ishii et al. [40]), dynamic ultrasound assessment of MME during walking was used to directly examine the short-term effect of LWIs on knee mechanics and immediate pain perception. The results showed that both MME and knee pain during walking were significantly lower with LWIs compared to the no-insole condition, and patients showing greater MME reduction also experienced greater immediate pain relief ($p < 0.01$). These data suggest that the mechanism of LWIs may depend on their ability to limit dynamic MME, further highlighting the importance of individual joint biomechanics and meniscal structure in determining therapeutic response.

Okamoto *et al.* [41] analyzed the impact of gait modification on MME in KOA patients. Results showed that adopting a "toe-out" gait significantly reduced the increase in meniscal extrusion under load and the second peak of KAM compared to normal gait. Interestingly, combining this gait modification with LWIs did not demonstrate an additional synergistic effect. These findings suggest that individual gait pattern modification may be crucial for controlling biomechanical knee loading, and the therapeutic effect of lateral wedges may depend on the patient's walking style. Factors such as gait biomechanics and specific knee joint characteristics may determine which individuals achieve real benefits in reducing meniscal extrusion and medial compartment loading, highlighting the need for personalized therapy.

Furthermore, the results of Magalhães *et al.* [42] confirm that the response to foot orthotic interventions – regardless of wedge direction – is strongly conditioned by individual biomechanical characteristics. The authors showed that individuals with a specific foot and lower limb alignment profile were less likely to respond to wedging, failing to achieve the expected modification in KAM. Although this study examined medial wedges, its conclusions are generalizable and emphasize that the effectiveness of insoles – including lateral wedges – may depend on a complex set of biomechanical parameters. This underscores the need for individualized insole selection and caution when formulating clinical recommendations.

In another study, Bartsch *et al.* [43] demonstrated that abnormal varus knee alignment may limit the efficacy of LWIs and ankle orthoses in patients with medial KOA. The analysis included 28 participants who wore a 5-mm lateral wedge and an ankle brace for 6 weeks in random order. Although both interventions reduced pain compared to baseline, a significant correlation was observed between greater mechanical axis deviation (larger varus) and smaller pain reduction. The authors indicated a mechanical threshold of approximately 3° varus, above which the intervention's effectiveness is limited. These results suggest that individual limb alignment may determine patient response to insoles and braces, highlighting the importance of considering joint biomechanics in therapy planning and partially explaining the inconsistent effects observed in previous studies.

The study by Tse *et al*. [44] provides further evidence that the biomechanical response to LWIs may be more complex than previously assumed. The authors demonstrated that both the lateral wedge alone and the wedge combined with arch support increased joint contact area in the medial compartment under load. At the same time, different types of insoles led to distinct changes in contact location, indicating that insole configuration significantly influences its effect. These findings support the concept that LWIs efficacy may depend on individual biomechanical characteristics and insole design specifics, partially explaining discrepancies in prior study results.

Iwamoto *et al*. [45] examined the effect of lateral wedge length on KAM reduction, which may also explain the inconsistent outcomes regarding LWIs in KOA patients. The results showed that different wedge lengths could lead to varying joint loading and, consequently, differences in efficacy in reducing KAM. This suggests that optimizing insole geometry according to individual anatomy and biomechanics may be critical. Considering such factors in insole design and selection could improve clinical efficacy, enhancing both comfort and knee function in KOA patients.

Overall, the summary of studies included in this review further highlights that discrepancies in evaluating the effectiveness of LWIs may result not only from differences in study populations but also from varying experimental conditions and selected endpoints. Moreover, differences in insole design (e.g., wedge angle, presence of arch support, material), duration of use, and type of functional tasks performed (walking, rising, standing) may significantly influence outcomes. Importantly, some alternative interventions, such as gait pattern modification, may exhibit greater biomechanical efficacy than insoles alone under certain conditions. These findings indicate that LWIs effects should be considered in a broader therapeutic context rather than as an isolated treatment. Collectively, these data suggest that inconsistencies in study results may not stem from insole inefficacy per se, but rather from their complex, multifactorial mechanism of action and insufficient tailoring of the intervention to individual patient characteristics.

The primary limitations of the included studies predominantly relate to small sample sizes and the short duration of the tested interventions. Furthermore, a significant methodological challenge stems from the fact that the evaluated studies focus on a wide variety of distinct outcomes. In order to gather a representative number of publications and compile a comprehensive review on this topic, it was necessary to broaden the eligibility criteria to encompass additional endpoints. However, this high heterogeneity among measured parameters acts as a confounding factor, hindering a definitive and straightforward analysis of the true impact of LWIs in the management of KOA.

A limitation of this review is that only one database (PubMed) was searched, which may have led to the omission of additional relevant studies indexed elsewhere.

Conclusions

Available evidence suggests that LWIs may exert beneficial effects on selected biomechanical parameters of the knee joint; however, their clinical effectiveness in terms of pain reduction and functional improvement remains inconclusive. The effects of therapy appear to be strongly dependent on individual patient characteristics as well as intervention-related factors. Despite numerous reports indicating potential benefits, study findings remain inconsistent, and some studies have not demonstrated significant clinical or biomechanical effects. Moreover, observed biomechanical changes do not always translate into clinically meaningful improvements in pain perception or joint function. Therefore, LWIs should not be used as a standalone treatment but rather may be considered as part of a combined therapeutic approach, particularly in appropriately selected patients. Further research in this area is warranted.

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