Title: A Novel Combo Slipper Sock with Lateral Wedge Insole for Pain Reduction and Enhanced Plantar Pressure Distribution in Knee Osteoarthritis: A Technical Note

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Abstract

Purpose: This study aimed to design and evaluate a novel combination of a slipper sock and lateral wedge insole (LWIs) specifically tailored for patients with knee osteoarthritis (KOA). The primary objectives were to assess its effectiveness in reducing pain and improving plantar pressure distribution during walking.

Methods: A total of 34 participants diagnosed with bilateral KOA were recruited based on predefined inclusion criteria. Pain levels were evaluated using the Visual Analog Scale (VAS) under two conditions: barefoot walking and walking with the researcher-designed slipper sock. Plantar pressure distribution was measured using a pressure plate system. The slipper sock featured a custom LWIs which supports both medial and lateral arch, and a metatarsal pad, and a subtalar strap to optimize foot alignment and load distribution. The insole was designed using Rhinoceros 3D software and manufactured from Plastazote and Ethylene-Vinyl Acetate foams, while the slipper sock was made of neoprene and featured with a subtalar strap, ensuring a secure fit and accommodating the insole. A paired samples t-test was performed to analyze differences in plantar pressure distribution and pain outcomes between the two conditions, with statistical significance set at $p \leq 0.05$.

Results: Wearing the slipper sock and orthotic combination significantly reduced pain levels ($p \leq 0.01$) and improved plantar pressure distribution ($p \leq 0.05$) compared to walking barefoot. VAS scores reflected decreased pain intensity with the slipper sock, while pressure plate data indicated favorable changes in plantar loading patterns.

Conclusions: The custom-designed slipper sock with an integrated LWIs demonstrates potential as a supportive intervention for individuals with KOA, offering significant pain relief and improved plantar pressure distribution during walking. These findings suggest that such a device could serve as an accessible and cost-effective alternative to conventional orthotic solutions. Further longitudinal studies and clinical trials are recommended to evaluate its long-term efficacy in pain management, functional mobility, and overall quality of life for individuals with KOA.

Keywords: Knee Osteoarthritis, Lateral Wedge Insole, Pain, Plantar Pressure Distribution, VAS

Highlights

- The combo slipper sock with a lateral wedge insole significantly reduced pain levels compared to barefoot walking, demonstrating its potential as an effective intervention for knee osteoarthritis.
- This study introduces a practical and cost-effective slipper sock designed to incorporate custom-made LWIs, providing a unique solution for managing KOA symptoms.
- Participants wearing the slipper sock exhibited improved plantar pressure distribution, with significant reductions in pressure on high-risk regions such as the hallux and medial heel.

Plain Language Summary

Knee osteoarthritis (KOA) is a prevalent degenerative joint condition that affects approximately 19.4% of the Iranian population, leading to pain, stiffness, and impaired mobility. The altered gait patterns associated with KOA often exacerbate joint discomfort and negatively impact overall functional ability. This study investigates the effectiveness of a novel slipper sock integrated with a lateral wedge insole (LWIs) in alleviating pain and enhancing plantar pressure distribution among individuals with KOA.

A total of 30 participants diagnosed with bilateral KOA, and an age matched control group including 10 healthy men and women were recruited to assess the impact of the slipper sock intervention. Pain intensity was measured using the Visual Analog Scale (VAS), a validated tool for subjective pain assessment, while plantar pressure distribution was analyzed using a foot scan pressure plate system. Participants were evaluated under two conditions: barefoot walking and walking while wearing the slipper sock.

The slipper sock was specifically designed to provide targeted biomechanical support through a LWIs having medial and lateral arch support, a metatarsal pad, and a subtalar strap. These features aimed to redistribute load away from the medial knee compartment, thereby reducing stress on affected areas. The results indicated a statistically significant reduction in pain levels among participants using the slipper sock compared to barefoot walking. Additionally, the intervention led to notable improvements in plantar pressure distribution, including decreased peak pressure on high-risk regions such as the hallux and heel, and enhanced stability during gait, as evidenced by prolonged initial contact and forefoot contact phases.

These findings suggest that the custom-designed slipper sock with a LWIs is a promising, cost-effective intervention for pain relief and improved weight-bearing patterns in individuals with KOA. By optimizing foot alignment and redistributing plantar pressure. Further longitudinal studies are recommended to evaluate the long-term benefits and clinical applicability of this intervention.

1. Introduction

Knee osteoarthritis (KOA) is a prevalent degenerative joint disorder characterized by progressive cartilage deterioration, resulting in pain, stiffness, and restricted mobility [1]. This condition affects approximately 19.4% of the Iranian population and is often associated with genu varum, a lower limb malalignment commonly observed among Iranian, Chinese, Korean, and Pakistani populations. This misalignment increases stress on the medial compartment of the knee joint, accelerating cartilage degradation and exacerbating KOA symptoms [1, 2].

Patients with KOA often exhibit altered gait mechanics and distinctive plantar pressure distribution patterns compared to healthy individuals [3]. Research indicates that individuals with KOA experience reduced weight distribution on the hallux and heel, with increased pressure localized in the central foot regions [4, 5]. These deviations in plantar pressure contribute to a forward shift in the center of pressure (CoP) at the start of walking and a backward shift at the end, alongside reductions in anteroposterior CoP path length (%Long) and transverse CoP path width (%Trans)[6]. Understanding these biomechanical alterations is essential for developing effective interventions to improve gait and reduce symptom severity.

Plantar pressure analysis is a widely utilized tool for assessing lower limb pathologies and gait mechanics, employing either pressure plate systems or in-shoe sensor technology. Lidtke et al. used pressure plate analysis to compare plantar pressure distribution in KOA patients and healthy individuals, revealing a medial shift in CoP trajectory in the KOA group, which suggests altered weight-bearing patterns [7]. The F-Scan sensor system, introduced in 1998, is another commonly used tool for in-shoe pressure measurement and gait analysis [8]. Zhang et al. further examined plantar pressure data among women with KOA and found increased midfoot and metatarsophalangeal joint loading, which may contribute to foot pronation and gait alterations [9]. Despite these advancements, gait laboratory evaluations remain costly and inaccessible for many patients, necessitating alternative methods for biomechanical assessment [10, 11].

Lateral wedge insoles (LWIs) have been widely recommended as a non-surgical intervention for medial KOA, aiming to redistribute load away from the medial tibiofemoral compartment to alleviate pain and enhance joint function [12]. Initially developed by Sasaki and Yasuda in 1987, these insoles were designed to mitigate the knee adduction moment and reduce excessive medial joint loading [13]. While numerous studies have demonstrated their effectiveness in biomechanical terms, their impact on pain relief and functional improvement remains inconclusive, with mixed findings across clinical trials [14-18]. The efficacy of LWIs largely depends on critical design factors, including wedge angle, material properties, and support features, which must be carefully tailored to the needs of KOA patients [19, 20].

Selection of appropriate insoles is often guided by individual comfort preferences, yet research suggests that a full-length lateral wedge with a 6° incline may provide optimal pain relief [21]. The material composition of the insole is also a determining factor; a firmer lateral foam minimizes compression under weight-bearing conditions, while softer medial elements enhance comfort and promote a more even plantar pressure distribution [22]. Furthermore, arch-supporting insoles that stabilize both longitudinal and transverse arches have been shown to optimize weight redistribution [23]. Additional design modifications, such as the incorporation of a subtalar strap, may improve joint stability and potentially slow KOA progression more effectively than LWIs alone [24]. However, such modifications may necessitate purchasing larger footwear, adding financial burden for patients.

Previous research has explored sock-integrated insole designs for convenient use in home environments, yet few products successfully combine all essential features necessary for KOA management [25]. An ideal sock-based intervention should include a secure fit, a detachable LWI, a stabilizing subtalar strap, and durable materials for sustained use.

Footwear selection plays a crucial role in the effectiveness of LWIs for KOA patients. Although closed-toe shoes or sandals are commonly recommended, the angled design of LWIs often requires wearing larger footwear, which imposes financial and practical limitations. Sandals, while potentially more compatible with LWIs in home environments, may not be suitable for populations with soft flooring or sedentary lifestyles, such as elderly individuals in Iranian households. Additionally, sandals generally offer inadequate ankle support and may compromise stability, particularly on uneven surfaces. These factors highlight the need for a more practical and cost-effective alternative to conventional footwear.

To address these limitations, we developed an innovative footwear solution resembling socks with an integrated LWIs and a supportive subtalar strap. This design provides a lightweight, comfortable, and stable alternative to conventional footwear, accommodating both sedentary and active individuals across diverse household environments while mitigating financial constraints.

The purpose of this technical note is to introduce a novel slipper sock incorporating a custom-made LWI designed specifically for individuals with KOA. This study aims to evaluate the effectiveness of this innovative intervention in reducing pain and redistributing plantar pressure. We hypothesize that the novel slipper sock with an integrated lateral wedge insole will significantly reduce pain and improve plantar pressure distribution in patients with KOA.

1. Materials and Methods

Participants, Inclusion, and exclusion criteria

This study recruited 34 female participants diagnosed with bilateral KOA from the medical and rehabilitation centers in Hamedan. The sample was selected from a larger pool of 133 surveyed individuals with KOA, with sample size determination guided by statistical methodologies relevant to biomechanical interventions in KOA populations. Each participant provided informed consent before enrollment. The sample size for this study was calculated using G*Power software for a paired t-test. An effect size of 0.446, with an alpha level of 0.05 and a desired power of 0.80.

Inclusion and Exclusion Criteria

Participants eligible for this study were those aged 45 years or older who had clinically diagnosed KOA. The diagnosis was established according to the clinical criteria set forth by the American College of Rheumatology, with severity determined using the Kellgren-Lawrence (K/L) grading scale; specifically, a K/L grade greater than 1 was required to confirm the presence of KOA. Only participants with K/L grades of 2 or 3 were included, as assessed through clinical examination and knee radiography conducted by a qualified physician [26].

Eligible individuals were required to have no history of cerebrovascular accidents (stroke), uncontrolled hypertension, neuromuscular disorders (such as multiple sclerosis or Parkinson's disease), or other neurological conditions (including cerebral palsy, dementia, or vertigo). Participants with a body mass index (BMI) greater than 40 kg/m², those with lower extremity fractures, concurrent hip osteoarthritis, or individuals who were pending knee arthroplasty were excluded from the study. Additionally, candidates must not require assistance in standing or walking, nor should they have received any form of treatment—such as medications, injections, or surgical procedures—within six months prior to the commencement of the study [12, 27, 28].

Pain assessment scale (Visual Analogue Scale)

Pain intensity was measured using the Visual Analog Scale (VAS), ranging from 0 (“no pain”) to 10 (“unbearable pain”). This scale, with an internal correlation reliability of ICC = 0.91, is well-established for its validity and reliability in chronic pain assessment. Participants completed two VAS assessments under different conditions: walking barefoot and walking with the combo slipper sock. For each condition, pain was measured three times, with the average taken as the final score for that condition. Measurements were taken in a standardized left-to-right order, and participants were blinded to their previous scores to avoid bias [29].

Plantar pressure distribution

A foot scan pressure plate device (RSscan International, Belgium) with a 40 x 100 cm surface, 8192 sensors, and a 253 Hz sampling rate was used to assess plantar pressure. The accompanying Footscan software (Gait 2nd Generation) divided the foot into 10 anatomical zones (medial heel, lateral heel, midfoot, metatarsals M1–M5, hallux, and lesser toes) and measured peak plantar pressure for each. The software further divided the stance phase into four subphases (initial contact, forefoot contact, foot flat, and forefoot push-off) based on distinct stance points (e.g., first foot contact, heel-off) (Figure 1)[27].

Participants walked naturally along a 12-meter walkway, with the device positioned mid-path. Each participant performed three trials for each condition (barefoot and slipper sock), with a three-minute seated rest between trials to prevent fatigue. Data were collected without participants viewing the recording screen to prevent alterations in gait. Before data collection, a familiarization session was conducted. Data collection order was randomized using Random.org, with a 48-hour gap between sessions to avoid fatigue effects [27].

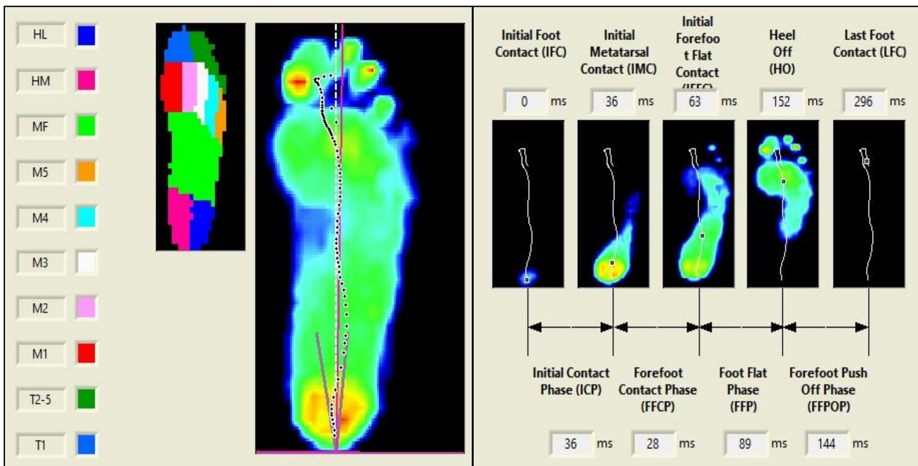

Figure 1. Plantar pressure parameters in ten-foot areas (left image) and five distinct instants of foot-over and its four subphases (right image) during walking gait

Design and Fabrication of the Lateral Wedge Insole (LWI)

The insole was designed in Rhinoceros 3D® software, incorporating medial and lateral arch support, a metatarsal pad, and a 6° medial heel and sole wedge. Separate G-codes were calculated for each side of the insole. To construct the foam block, two layers of Plastazote foam (Shore A 70) and ethyl vinyl acetate (Shore A 20) were cut, sanded, and adhered to form a 3 cm thickness. The block was then milled with a CNC machine based on the G-code, and the insole's upper surface was covered in artificial leather (Figure 2).

Figure 2. The designed lateral wedge insole

Combo Slipper Sock Prototype

Prototype and Finalization of the Combo Slipper Sock

A neoprene slipper sock was designed to fit the insole, following a template created by placing the insole on a standard shoe mold. The sock's upper was ventilated with three incisions to improve air circulation and reduce sweating. A 4 cm rubber subtalar strap was added, with a Velcro-secured attachment and metal ring for lateral stability. The design was finalized in CorelDraw software to standardize sizes across different foot dimensions (Figures 3 and 4).

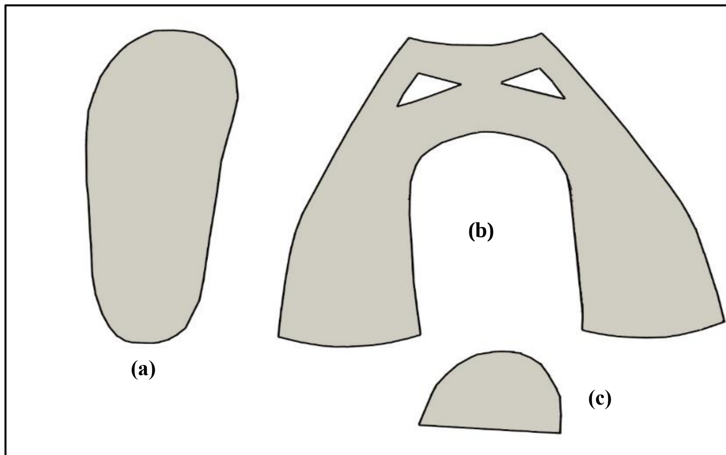

Figure 3. The first template of the combo slipper neoprene sock; a) the bottom part, b) the upper part, and c) the forefoot section

Figure 4. The combo sipper sock (the anterior part to prevent the anterior sliding of the insole, the top and lateral view with the subtalar strap of the final product)

Statistical Analysis

The data were first assessed for normality using the Shapiro-Wilk test. For plantar pressure distribution and related gait parameters, comparisons between the barefoot and combo slipper sock conditions were conducted using a paired samples t-test, as all data met normality assumptions. SPSS version 24 was employed for all statistical analyses, with significance set at $p < 0.05$.

2. Results

Table 1 displays the means (M) and standard deviations (SD) of participants' anthropometric and demographic characteristics.

Table 1. Anthropometric variables and subject characteristics (M ± SD)

Variable	M ± SD (n = 34)
Age (yr)	58.87 ± 5.12
Height (m)	1.57 ± 0.12
Mass (kg)	67.57 ± 15.07
BMI (kg/m^2)	27.46 ± 5.37

The results of the paired sample t-test, comparing the maximum plantar pressure and relative time for roll-over phases of the quadruple stance subphases between the two conditions of walking (barefoot and wearing combo slippers sock), indicated significant differences. Notably, the two conditions showed significant differences in both plantar pressure variables ($p = 0.03$) and the relative time for roll-over phases ($p = 0.04$). Additionally, the results regarding the VAS demonstrated that participants reported experiencing less pain when walking with combo slipper socks compared to walking barefoot ($t = 3.04$, $p = 0.01$). But no significant difference was observed in this index at rest.

Table two compares maximum plantar pressure parameters in ten-foot areas during walking gait, relative time for roll-over phases, and VAS between walking barefoot and walking with a combo slipper sock. The results show that participants had lower maximum plantar pressure in T1 ($t = 2.18$, $p = 0.04$), HL ($t = 2.15$, $p = 0.04$), and HM ($t = 2.15$, $p = 0.03$) areas when wearing the combo slipper sock. In contrast, participants experienced higher maximum plantar pressure in the M4 area (t = 2.22, p = 0.03) when walking barefoot. There were no significant differences in other values related to plantar pressure distribution across ten zones.

Regarding the relative time for roll-over phases, walking with the combo slipper sock resulted in more time spent in the ICP, FFCP, and FFPOP. Only the FFCP values (t = 2.32, p = 0.02) showed a significant difference. On the other hand, walking barefoot resulted in spending more significant time in the FFP (t = 2.21p = 0.03) compared to walking with the combo slipper sock.

Table 2. Results of Paired Sample t-Test Comparing Maximum Plantar Pressure Parameters, Relative Time for Roll-Over Phases, and VAS Scores Between Barefoot and Combo Slipper Sock Conditions During Walking

Variable	Barefoot		Combo slipper sock		Δ	p-value
	M ± SD	(95% CIs)	M ± SD	(95% CIs)		
Maximum						
plantar pressure						
(N/cm^2)	12.77 ± 4.09	(10.02, 15.52)	14.02 ± 3.11	(11.91, 16.13)	1.25	0.04*
T1	4.99 ± 1.35	(3.86, 5.52)	5.10 ± 2.71	(3.40, 6.80)	0.11	0.61
T2-5	13.33 ± 4.16	(10.78, 16.48)	12.37 ± 4.55	(9.82, 14.92)	-0.96	0.75
M1	26.53 ± 7.32	(22.96, 30.10)	25.78 ± 6.27	(20.15, 31.41)	-0.55	0.87
M2	31.67 ± 9.00	(27.23, 36.11)	31.22 ± 8.08	(26.14, 36.30)	-0.45	0.92
M3	30.75 ± 8.39	(26.67, 34.83)	26.71 ± 6.44	(23.51, 29.91)	-4.04	0.03*
M4	12.44 ± 3.80	(9.71, 15.17)	13.04 ± 4.19	(10.85, 15.23)	0.60	0.68
M5	7.43 ± 1.17	(6.33, 8.53)	6.09 ± 1.83	(4.26, 7.92)	-1.34	0.59
MF	20.41 ± 5.06	(17.28, 23.54)	23.35 ± 4.94	(20.81, 26.69)	3.04	0.03*
HM	17.80 ± 4.13	(15.08, 20.52)	19.71 ± 5.08	(17.23, 21.39)	1.81	0.04*
HL						
Relative time for						
roll-over phases	10.05 ± 2.12	(7.95, 11.35)	11.43 ± 3.55	(9.70, 13.16)	1.38	0.59
(% stance time)	15.46 ± 3.71	(12.12, 17.74)	18.43 ± 5.20	(13.24, 23.62)	2.97	0.02*
ICP	38.70 ± 6.16	(33.23, 45.93)	32.72 ± 6.33	(26.53, 38.91)	-5.98	0.03*
FFCP	35.67 ± 5.50	(29.73, 39.93)	37.35 ± 4.48	(32.87, 40.83)	1.68	0.73
FFP						
FFPOP	4.63 ± 1.07	(3.85, 5.34)	4.42 ± 1.24	(3.37, 5.67)	-0.21	0.51
VAS	6.81 ± 2.11	(4.90, 7.27)	4.94 ± 1.60	(3.20, 6.08)	-1.87	0.01*
Rest						
Walking						

Note: M, mean score; SD, standard deviation; CIs, confidence intervals; Δ, (combo slipper sock – barefoot); T, toe; M, metatarsal; MF, midfoot; HM, medial heel; HL, lateral hell; ICP, stands initial contact phase; FFCP, stands forefoot contact phase; FFP, stands foot flat phase; FFPOP, stands forefoot push-off phase; VAS, visual analogue scale; *, $p < 0.05$ was considered statistically significant.

3. Discussion

This study aimed to design and evaluate a novel combination of a slipper sock and a custom lateral wedge insole tailored for individuals with knee osteoarthritis (KOA). The primary objective was to assess its effectiveness in alleviating pain and optimizing plantar pressure distribution. The integration of a detachable insole, developed using computer-aided design and manufacturing (CAD/CAM), allows for versatile use both within footwear and independently at home. The slipper sock, constructed from neoprene, ensures comfort, washability, and affordability, offering a cost-effective and accessible solution for KOA patients.

The innovation behind this design lies in its simplicity and adaptability, distinguishing it from previous orthotic interventions. Earlier approaches, such as the dual-sole sock with an insole pocket designed by Egozi, primarily targeted in-shoe applications and utilized memory foam insoles [30]. Similarly, Saeedi et al. introduced a laminated sock-insole system for flat feet, but its rigid design lacked adaptability [25]. Johnson's method incorporated a customized wedge slab but failed to address wearability within different footwear settings [31]. Our study represents the first attempt to develop a hybrid slipper sock with integrated orthotic support explicitly designed for KOA patients, bridging the gap between in-shoe and at-home orthotic solutions.

Our findings revealed significant reductions in pain among individuals with medial KOA while walking with the combo slipper sock and LWIs. These improvements are likely attributed to biomechanical modifications, particularly the lateral shift in the center of pressure (COP), which effectively reduces the knee adduction moment arm and, consequently, the external knee adduction moment—a key contributor to pain and joint stress [11, 32].

These results align with previous studies that have demonstrated the efficacy of lateral wedge insoles in reducing pain and influencing COP trajectory and plantar pressure distribution in KOA patients [6, 16, 33-38]. By shifting the COP laterally, LWIs can reduce the knee adduction moment (KAM), which is a primary contributor to medial compartment loading in KOA. This reduction in KAM helps redistribute plantar loads, mitigating excessive stress on the knee's medial compartment, potentially decelerating KOA progression and enhancing functional mobility [6, 11].

Beyond pain reduction, our study highlights distinct alterations in plantar pressure distribution and functional mobility between KOA patients and healthy individuals. KOA patients exhibited lower maximum plantar pressure in the medial and lateral heel regions, with compensatory increases in midfoot and fourth metatarsal pressures. These shifts may reflect biomechanical adaptations aimed at minimizing medial knee joint loading, a characteristic feature of KOA progression [39].

Moreover, the observed shortening of initial contact and forefoot push-off phases suggests that KOA patients adopt gait modifications to reduce weight-bearing duration on the affected knee, likely as a pain-avoidance strategy [27]. This aligns with previous studies reporting reduced stance phase duration and altered CoP trajectories in KOA patients due to joint instability and discomfort [9]. LWIs may counteract these effects by promoting a more stable stance phase through improved foot pronation control, which can enhance weight distribution and reduce excessive medial knee loading [40]. Additionally, LWIs facilitate a smoother COP transition from heel-strike to toe-off, which may improve propulsion mechanics and reduce compensatory forefoot loading [41]. In contrast, the prolonged forefoot plantarflexion phase observed in KOA patients may represent an adaptive response to enhance balance and stability during weight transfer [27]. By encouraging a more natural gait pattern and redistributing plantar pressures, LWIs may help mitigate these compensatory gait alterations and enhance overall functional mobility [42].

Functional mobility assessments further reinforce these biomechanical alterations. The Timed Up and Go (TUG) test results demonstrated significantly prolonged completion times in KOA patients compared to healthy counterparts, indicative of reduced lower limb strength, balance, and coordination. These impairments heighten fall risk and hinder independence in daily activities. Prior research supports the reliability of the TUG test as a performance-based measure for individuals with KOA, linking prolonged test times to knee pain and quadriceps muscle weakness [26, 27].

The outcomes of this study underscore the potential of the combo slipper sock with a LWIs as a practical and conservative intervention for KOA management. Healthcare practitioners should consider LWIs as a non-invasive treatment option, particularly for patients with medial compartment KOA. However, their use should be individualized, as not all patients may respond favorably. Clinical guidance is crucial in ensuring appropriate patient selection and optimizing the therapeutic benefits of lateral wedge orthotics.

The versatility of this design allows patients to seamlessly integrate the insole into their daily routines. Those with unilateral KOA may wear the insole only on the affected side, opting for a non-wedged version on the opposite foot, ensuring greater adaptability. This individualized approach enhances patient compliance and treatment effectiveness.

4. Conclusion

This study provides compelling evidence supporting the efficacy of a novel combo slipper sock with a LWIs in reducing pain and modifying plantar pressure distribution in KOA patients. The findings contribute to a deeper understanding of the compensatory gait strategies adopted by individuals with KOA and their implications for functional mobility. By identifying specific regions of increased plantar pressure, clinicians can better tailor interventions to address both biomechanical and functional deficits.

Early intervention strategies aimed at redistributing plantar loads, enhancing knee joint stability, and improving overall functional mobility may help slow KOA progression and improve patients' quality of life. Future research should explore the long-term effects of such interventions and further investigate the interplay between foot alignment, gait biomechanics, and functional mobility in KOA management.

The combo slipper sock and custom-made lateral wedge insole presented in this study provide a practical, user-friendly solution, allowing patients to easily integrate the insole into their daily routines, whether at home or in a shoe. In cases of unilateral medial compartment KOA, patients can opt to wear the insole on the affected side only, choosing a non-wedged version on the opposite side, enhancing adaptability based on individual needs.

Ethical Considerations

Compliance with ethical guidelines

The design and fabrication of this new combo slipper sock with custom-made LWIs worn together specialized for KOA received approval from the ethics committee of Hamadan University of Medical Sciences, Hamadan, Iran (Reference No: IR.UMSHA.REC.1401.926).

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Authors' contributions

All authors of this technical note have made substantial contributions to the conception, design, and execution of the research, as well as the writing and revision of the manuscript.

Conflict of interests

The authors declare no conflict of interest.

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