Soft Knee Brace versus Lateral Wedge Foot Insole on Pain and Proprioception in Knee Osteoarthritis Patients

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ABSTRACT

Background: Knee osteoarthritis (OA) is a common degenerative joint disorder that leads to pain, reduced proprioception, impaired range of motion (ROM), and functional limitations. Non-invasive interventions different physical therapy modalities such as therapeutic exercises, proprioceptive training, electrotherapy, balance training, home education and orthoses. Soft knee braces and lateral wedge foot insoles are often used to alleviate symptoms and improve function. However, comparative evidence regarding their effectiveness remains limited **Objective:** This study aimed to compare the effectiveness of soft knee braces and lateral wedge foot insoles, in conjunction with traditional physiotherapy, on pain intensity, knee proprioception, ROM, and functional activity in patients with knee OA.

Methods: A single-blind randomized controlled trial was conducted on 60 patients aged 40–60 years diagnosed with knee OA. Participants were randomly allocated into three groups: Group (1) wore a soft brace group plus traditional physiotherapy, group (2) wore a lateral wedge insole group plus traditional physiotherapy and group (3) (Control group) received traditional physiotherapy only. The intervention lasted for 8 weeks, three sessions per week. Pain was evaluated by the visual analogue scale (VAS), proprioception and ROM were assessed by digital inclinometer, and function was assessed using the Arabic version of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Results: All groups demonstrated significant reduction in pain. The soft brace group indicated the highest improvement in pain (Mean reduction = 3.25). All groups demonstrated significant reduction (improvement) in proprioception the lateral wedge indicated the highest (Mean reduction = 3.18). All groups demonstrated significant improvement in knee flexion range of motion the highest was in the lateral wedge group (Mean reduction = -12.5), All groups demonstrated significant improvement in knee extension range of motion the highest was in the lateral wedge group (Mean reduction = 3.75). All groups demonstrated significant improvement in function, the highest was soft knee brace (Mean reduction =15.8). Between group comparisons, there were statistically significant differences between control and soft knee brace groups and between control and lateral wedge foot insole. While, there was no statistically significant difference between soft knee brace and lateral wedge foot insole groups. Conclusion: Both soft knee braces and lateral wedge insoles combined with traditional physiotherapy, were effective than physiotherapy only in alleviating pain increase proprioception, range of motion and enhancing function in knee OA patients.

Keywords: Knee osteoarthritis, Soft knee brace, Lateral wedge insole, Proprioception, Pain, Range of motion, WOMAC, Physiotherapy.

INTRODUCTION

Knee osteoarthritis (KOA) is a chronic, multietiological, and incapacitating disease, which impacts the entire knee joint. Depending on its etiology, KOA is categorized as primary or secondary. A multitude of variables, including as mechanical stress, inflammation, metabolism, immunology, and genetics, contribute to the intricate pathophysiology of primary KOA. Risk variables including age, genetics, body mass, gender, and ethnicity. Secondary KOA is mostly induced by iatrogenic injury, congenital joint abnormality, or trauma. KOA is defined by dynamic changes resulting from an imbalance between joint tissue injury and healing, rather than inert degeneration or wear-and-tear lesions. Lesions in the synovium, ligaments, articular or subchondral bones, joint capsule, and periarticular muscle tissues typically coexist with them. Pain and limited mobility are the primary clinical manifestations that diminish patients' quality of life (1). Physiotherapy remains a cornerstone in the conservative management

of knee OA. It incorporates both active exercise therapy and passive electrotherapy modalities. Exercise interventions commonly include stretching of tight musculature such as the hamstrings and gastrocnemiussoleus complex, as well as strengthening exercises targeting the quadriceps, particularly the vastus medialis obliquus, through drills like straight leg raises and resisted movements in various planes. Adjunctive modalities such as ultrasound (US), low-level laser therapy (LLLT), shortwave diathermy (SWD), transcutaneous electrical nerve stimulation (TENS), and interferential therapy (IFT) aim to relieve pain, reduce inflammation, and boost tissue healing through thermal and non-thermal mechanisms. These modalities complement physical exercises by modulating pain perception and enhancing patient compliance with rehabilitation programs (2).

Orthotic devices are frequently set for lower limb OA to provide mechanical support, correct alignment, and reduce joint loading. These orthoses are

Received: 14/01/2025 Accepted: 06/03/2025 categorized into rest orthoses, knee sleeves, and unloading braces. Clinical guidelines, such as those from the European Alliance of Associations for Rheumatology (EULAR), recommend their use as part of the non-pharmacological management strategy for knee OA. These external supports aim to alleviate symptoms by redistributing load across the joint compartments and stabilizing the joint during weight-bearing activities ⁽³⁾.

Both soft knee braces and lateral wedge insoles have been indicated to provide symptomatic relief and functional improvement in people with knee OA. Their individual or combined use may benefit different subsets of patients based on biomechanical alignment, compartmental involvement, and activity levels. Comparative research is necessary to provide individualized treatment choices and maximize results (4)

Soft knee braces, often made from elastic and breathable materials, are designed to provide comfort while enhancing proprioceptive feedback. Their non-rigid structure makes them suitable for daily use and particularly attractive for patients seeking non-invasive treatment options. These devices have gained traction in the conservative management of knee OA due to their simplicity and low risk profile ⁽⁵⁾.

The medial compartment, which normally carries more than 60% of the load during ambulation, is relieved by lateral wedge insoles, which may alleviate varus malalignment by moving the ground reaction force laterally. Although their effect size in pain reduction may be modest, they offer a non-invasive, inexpensive intervention with potential for large-scale application, especially in early disease stages or as an adjunct to other treatments ⁽⁶⁾.

Further insight is provided by earlier research in the field. Sasaki and Yasuda were among the first to propose the use of laterally wedged insoles to improve knee alignment and reduce medial compartment stress, **Rafiaee** *et al.* ⁽⁷⁾ found that 61% of participants reported improvement. Additionally, insoles with 5° and 10° angulation were found to significantly decrease varus torque during the stance phase of walking, supporting their efficacy in redistributing joint loading.

Considering the above, the current study may provide physiotherapists with comparative clinical data on the efficacy of soft knee braces versus lateral wedge foot insoles. These modalities combined with traditional physical therapy as a modality in intervention rehabilitation of knee osteoarthritis.

MATERIALS AND METHODS

Design and setting: A randomized control study was conducted at the Outpatient Clinic of Faculty of Physical Therapy, MUST University. This study was conducted to explore the efficacy of soft knee brace and lateral wedge insole in decreasing pain, enhancing

proprioception, increasing ROM and improving function in patients with KOA. The study ran from October 2024 to February 2025.

Sample size calculation: The sample size calculation utilized knee pain data, as referenced in Jones *et al.* ⁽⁸⁾, with 80% power at an α level of 0.05, including 2 assessments across 3 groups, and an effect size of 0.44, employing the F-test MANOVA for repeated measures within and between interactions. The necessary minimum sample size is 53 individuals, with an additional 7 subjects (13%) accounted for as potential dropouts, resulting in a total sample size of 60 people, distributed as 20 subjects per group. The sample size was determined utilizing G*Power software (version 3.0.10).

Participants: Sixty patients from both genders were recruited from Misr University for Science and Technology, Faculty of Physical Therapy Outpatient Clinic.

Inclusion criteria: Their ages range from 40-60 years old. The patients included according to American College of Rheumatology (ACR) criteria, namely, knee pain, morning stiffness longer than 30 minutes and/or joint crepitus. The patients' Kellgren Lawrence scores grade II–IV. All the patients had a minimum score of 25 on the WOMAC total scores. Unilateral symptomatic knee.

Exclusion criteria: High tibial osteotomy other realignment surgery. Knee replacement. Knee arthroscopy within the last 6 months. An intraarticular injection within the past 3 months. Rheumatoid arthritis or patellofemoral syndrome. Diabetic neuropathic pain or fibromyalgia. Foot or ankle ailments that made it inappropriate to apply load-modifying footwear interventions. Body mass index $(BMI) \ge 35 \text{ kg/m}^2$.

Following participants' collection, they were allocated through computer-generated random number table that was used to produce a block randomization schedule that assigned participants to one of the three treatment groups:

- Group I (experimental): Received traditional treatment + wearing soft knee brace.
- Group II (experimental): Received traditional treatment + wearing lateral wedgefoot insole.
- Group III (control): Received traditional treatment. Instruments: Instrument for measurement include visual analogue scale (VAS), digital inclinometer (DI), Western Ontario and McMaster Universities (WOMAC) Osteoarthritis (OA) Index (Arabic version):
- 1. The VAS is a line that is typically 10 cm long and ranges from zero, which represents no pain or discomfort, to ten, which represents the worst pain that a person could experience (Figure 1) ⁽⁹⁾.



Figure (1): visual analog scale (VAS).

2. When measuring active knee JPS in OA patients at a goal angle of 30° of knee flexion, a digital inclinometer is a reliable. At the target angle of 30° of knee flexion, however, there was low inter-class dependability and excellent intra-class reliability. Additionally, the investigation demonstrated the validity and reliability of another kind of digital inclinometer (SPI Tronic, Penn Tool Co., Maplewood, NJ) ⁽¹⁰⁾. An engineering tool used to detect surface inclination (in degrees) after it has been measured by gravity-sensitive sensors is the digital inclinometer (Figure 2) ⁽¹¹⁾.



Figure (2): Digital Inclinometer (SPI Tronic, Penn tool co, Maplewood, NJ, Made in USA).

3. The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis(OA) Index (Arabic version): The validity and reliability of the WOMAC Osteoarthritis Index (English version) have been evaluated, and the results indicate that it is both. More than fifty languages, including German (7), French (8), Spanish (9), Italian (10), Turkish (11), Moroccan (12), and traditional Arabic (13), have been translated and verified from the original English version of the WOMAC osteoarthritis Index. To correspond with the language used by the majority of Arabs, the first Arabic version of the WOMAC (ArWOMAC) was written in literal Arabic (12).

Procedures:

A Assessment methods

1. VAS: A popular outcome measure for such studies is the visual analogue scale (VAS). A point between "nopain at all" and "worst pain imaginable" is typically used to depict the patient's level of pain on a 100 mm horizontal line (13).

2. Digital inclinometer to assess knee proprioception:

All participants' affected extremities were assessed after the JPS test was administered, while they were sitting with their feet off the floor, in a quiet environment, and with their eyes closed. A band was used to brace the patient's thigh as they sat upright in a chair at an 80° angle. Additionally, a ring that was 3 cm above the lateral malleolus supported the tibia. The test began with the subject in a 90° flexion position. The evaluation

angle for proprioception was set at 30°. After five seconds, participants were instructed to return to their starting position after extending their tested knee to the desired angle of 30° from the starting position (90° knee flexion). In accordance with the test protocol, a familiarization trial was conducted before each measurement (10).

3. Digital inclinometer to measure knee range of motion:

• Knee flexion ROM measurement: The participant was positioned with their hips 90 degrees flexed and in dorsal decubitus. A thigh device that helped maintain the predetermined position was used to ensure hip alignment. The digital inclinometer was positioned proximally and anteriorly on the tibial crest.

• Knee extension ROM measurement

The person stretched legs and was in dorsal decubitus. The heel was used to elevate the assessed limb, and the stretcher made contact with the knee stability. Similar to the measurements taken for knee flexion, the instruments were positioned in relation to the area being measured (11).

4. The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis (OA) Index (Arabic version) to assess function ability: The ArWOMAC Index is a disease-specific, self-report instrument composed of 24 items split across three subscales: Pain, joint stiffness, and physical function. The pain subscale contains five items that assess pain during various daily activities. The stiffness subscale comprises two questions evaluating joint stiffness after rest or activity. The physical function subscale is the most extensive, consisting of 17 questions related to the difficulty experienced during routine activities of daily living (12).

Treatment:

A. Traditional physiotherapy: Participants underwent an **8-week physiotherapy intervention**, administered **three times per week**, with a focus on home education, muscle strengthening, flexibility, pain management through TENS proprioceptive training and functional exercise. The components of the program were standardized across all sessions to ensure consistency.

• Strengthening Exercises

The strengthening program aimed to improve joint stability and functional performance through targeted muscle activation. Each exercise was performed for 3 sets of 10 repetitions.

Quadriceps Strengthening, and Hip Strengthening Flexibility exercises:

To preserve joint mobility and decrease muscle tightness that could exacerbate symptoms, the following stretches were included in each session: Hamstring Stretch, Quadriceps Stretch and Calf Stretch.

Pain management using TENS

To assist in pain reduction, Transcutaneous Electrical Nerve Stimulation (TENS) was applied using the Gymna Duo 200 touchscreen unit. A conventional TENS protocol (High frequency & low intensity) was used, delivering electrical impulses for 30 minutes per session, three times per week, over the 8-week intervention period (14).

B. Soft knee brace intervention

Participants in the soft brace group received a commercially available soft knee brace (Orthomedics & serial number 86) in addition to traditional physiotherapy. The intervention lasted for 8 weeks, during which participants were advised to wear the brace during weight bearing. Participants continued their traditional physical therapy sessions.

C. Lateral wedge foot insole intervention

Participants in the insole group were instructed to wear standardized non-customized lateral wedge foot insoles with approximately 5 mm lateral elevation for a duration of 8 weeks, during weight bearing in conjunction with traditional physical therapy. Participants were advised to insert the insoles into their own everyday footwear and to wear them during all waking hours, This protocol was intended to optimize the biomechanical effects of the wedges during functional and ambulatory activities ⁽¹⁵⁾.

Ethical approval: The study was authorized by The Faculty of Physical Therapy's Institutional Review Board (IRB) at Cairo University with approval number: P.T.REC/012/005582 and on clinical trial approval number ClinicalTrials.gov ID: NCT06836934. The study was conducted in accordance with the World Medical Association's

(Declaration of Helsinki) code of ethics for research involving human beings.

Statistical analysis

The measured variables were statistically evaluated and compared using SPSS for Windows version 23 (SPSS, Inc., Chicago, IL), with an alpha level established at 0.05. The data were evaluated for normality, homogeneity of variance, and the existence of outliers. The Shapiro-Wilk test for normality indicated that the measured variables followed a normal distribution (p < 0.5). Data were presented as mean and standard deviation for all outcomes.

The Chi-square test was employed to compare gender between groups. A two-way mixed design MANOVA was employed to compare the groups on the collective impact of all outcomes. Upon obtaining statistically significant results from MANOVA, further univariate ANOVAs with Bonferroni correction were conducted for each outcome measure to mitigate type I error.

RESULTS

Demographic Characteristics: Table (1) presented the characteristics of patients across three groups. No statistically significant differences were seen in the patients' general characteristics across the three groups (p-value > 0.05). A mixed design multivariate analysis was performed to examine the impact of therapy on the assessed variables. A statistically significant difference existed across groups, with Wilk's Lambda = 0.55, F (5, 53) = 3.76, P < 0.001, and Partial Eta Squared (η^2) = 0.26. There was a statistically significant impact on time (pre-& post-treatment) with Wilk's λ = 0.02, F (5, 53) = 495.04, p < 0.001, η^2 = 0.98, and for the interaction between groups and time with Wilk's λ = 0.13, F (10, 106) = 18.56, p < 0.001, η^2 = 0.64.

Table (1). Baseline demographic characteristics of participants (N=60)*

Characteristics	Group A (control)	Group B (soft knee brace)	Group (C) (lateral wedge foot insole)	F-value	P Value
Age(years)	54.25±3.85	55±3.43	55.05±3.91	0.29	0.75
Weight(kg)	88.9±6.52	89.9±7.96	94.45±6.55	1.24	0.3
Height(cm)	170 ±11.45	172.4 ±9.4	172.85±8.6	0.46	0.63
BMI (kg/m ²)	30.75±3.77	30.2±2.85	31.67±3.09	1.04	0.36
Gender, n (%)					
Male	11 (55%)	13 (65%)	10 (50%)	0.95	0.62
Female	9(45%)	7 (35%)	10 (50%)	0.93	0.02

Between-groups comparison: Baseline and after eight weeks of intervention: At baseline, no statistically significant differences were observed among the three groups in all assessed variables (P-value > 0.05), as seen in table (2) & (3). Following eight weeks of intervention, statistically significant differences were seen between groups A and B, as well as between A and C, whereas no statistically significant difference was found between groups B and C, as illustrated in table (3).

Table (2): Clinical characteristics of participants at baseline and after 8 weeks intervention (N=60)*

Outcomes	time	Group A Group B (soft C		Group (C) (wedge	F-	P-
		(control)	knee brace)	foot insole)	value	Value
VAS (cm)	Baseline	7.15±1.27	7.1±1.16	7.35±1.14	0.25	0.78
	After 8 weeks	5.6±1.09	3.85±0.99	4.4±0.78	13.8	0.001
Knee	Baseline	3.5±0.65	3.47±0.95	3.43±0.95	0.02	0.98
proprioception	After 8 weeks	1.57±0.39	0.5±0.11	0.25±0.1	14.63	0.001
Knee flexion	Baseline	110.7±9.63	111.55±7.54	109.5±9.63	0.22	0.81
(degree)	After 8 weeks	116.65±8.7	123.7±7.71	126.85±5.37	7.39	0.001
Knee extension	Baseline	4.6±0.69	4.4±0.78	4.5±1	0.13	0.88
(degree)	After 8 weeks	2.95±0.78	0.85 ± 0.21	0.75±0.29	52.91	0.001
WOMAC	Baseline	59.75±7.57	60.3±9.52	60.7±7.87	0.07	0.96
(score)	After 8 weeks	54.05±7.66	44.5±5.69	47.8±3.69	6.94	0.001

Table (3): Between Groups Effects after 8 weeks of intervention

• /	Group A vs Group B		Group A vs Group C		Group B vs Group C	
Outcome	MD (95% CI)	P-Value	MD (95% CI)	P-Value	MD (95% CI)	P-Value
VAS (cm)	1.75 (0.91, 2.59)	0.001	1.2 (0.36, 2.04)	0.003	-0.55 (-1.39, 0.29)	0.34
Knee proprioception	1.07 (0.43, 1.7)	0.001	1.32 (0.68, 1.95)	0.001	0.25(-3.88,0.89)	0.99
Knee flexion (degree)	-7.05 (-13.75, -0.35)	0.04	-10.2 (-16.9,-3.5)	0.001	-3.15 (-9.85,3.55)	0.75
Knee extension (degree)	2.1(1.5, 2.7)	0.001	2.2(1.6, 2.8)	0.001	0.1 (-0.5, -0.7)	0.99
WOMAC (score)	9.55 (3.12, 15.98)	0.002	6.25 (5.69, 12.68)	0.04	-3.3 (-9.73, 3.13)	0.63

Within-groups comparison: There were statistically significant differences in all outcome measures when comparing the pre- and post-intervention results (p-value < 0.05) in groups A, B and C with more favor to groups B and C with no superiority for B or C as shown in table (4) as p-value ≥ 0.05 .

Table (4): Within group changes after 8 weeks of intervention

Outcomo	Group A (n=20)		Group B (n=20)		Group C (n=20)	
Outcome	MD (95% CI)	P-Value	MD (95% CI)	P-Value	MD (95% CI)	P-Value
VAS (cm)	1.55 (1.1, 2)	0.001	3.25 (2.8, 3.7)	0.001	2.95 (2.5, 3.4)	0.001
Knee proprioception	1.93 (1.36, 2.51)	0.001	2.97 (2.39, 3.54)	0.001	3.18 (2.61, 3.76)	0.001
Knee flexion (degree)	-5.95 (-8.74, -3.16)	0.001	-12.15 (-14.94, -9.36)	0.001	-17.35 (-20.14, -14.56)	0.001
Knee extension (degree)	1.65 (1.14, 2.16)	0.01	3.55 (3.04, 4.06)	0.001	3.75 (3.24, 4.26)	0.001
WOMAC (score)	5.7 (4.37, 7.03)	0.001	15.8 (14.47, 17.13)	0.0001	12.9 (11.57, 14.23)	0.001

MD, Mean Difference; CI, confidence interval; P-Value < 0.05 indicates statistical significance; cm: centimeter; WOMAC: western Ontario and McMaster Universities Arthritis index questionnaire, VAS: visual analogue scale.

DISCUSSION

The purpose of study was to investigate the difference between soft in knee brace and lateral wedge foot insole on pain, knee proprioception, range of motion and function in knee osteoarthritis patients, There were statistically significant differences in all outcome measures when comparing the pre- and post-intervention results in three groups with more favor to soft knee brace group and lateral wedge foot insole group with no superiority for both.

The results of this study is in accordance with Cudejko et al. (16) who found that soft knee braces reduce joint pain by providing external support and proprioceptive input. enhancing The compression and mechanical stability afforded by these elastic orthoses may activate cutaneous mechanoreceptors, which in turn modulate nociceptive transmission via spinal inhibitory pathways—a mechanism consistent with the gate control theory of pain.

In parallel, the observed pain improvement in the lateral wedge insole group can be explained by biomechanical unloading of the medial compartment, a common site of degeneration in knee OA. According to **Hinman** *et al.* (15), lateral wedges realign the lower limb by shifting the center of pressure laterally during gait, so decreasing the peak knee adduction moment—a surrogate marker for medial joint load. Though, the relatively modest pain relief achieved with insoles in this study may reflect the variability in patient response noted in broader literature. For instance, Felson et al. (6) emphasized that while lateral wedges offer some benefit, the magnitude of clinical improvement may be insufficient for a substantial subset of patients, possibly due to differences in foot biomechanics, OA severity, or adherence to the insole protocol. Collectively, these findings underscore the additive value of orthotic interventions in a multimodal rehabilitation approach for knee OA, particularly when tailored to individual patient characteristics and symptom profiles.

The substantial functional gains observed with the soft knee brace corroborate findings from **Paolucci** *et al.* ⁽¹⁷⁾, who emphasized that elastic knee braces can yield mild-to-moderate enhancements in performance-based function. This effect is believed to result from the braces' ability to reduce dynamic knee instability and support joint alignment during weight-bearing tasks such as walking, stair descent, or squatting. The proprioceptive stimulation provided by the soft brace material may also enhance neuromuscular control and facilitate smoother joint mechanics during movement.

With respect to lateral wedge insoles, the functional improvement observed in our study supports the notion that biomechanical interventions can indirectly affect mobility by alleviating medial compartment load. While, **Parkes** *et al.* (18) highlighted

mixed results regarding functional outcomes with wedged insoles, they acknowledged that individualized responses to orthotic configuration—particularly wedge angle, material, and footwear compatibility—play a critical role in their effectiveness. Our findings align with this perspective, illustrating that lateral wedge, when properly implemented alongside exercise therapy, may serve as a useful adjunct for improving patient-perceived physical function. These outcomes reinforce the importance of a patient-centered, multimodal rehabilitation approach in managing knee osteoarthritis, where orthotic supports are selected based on individual needs, comfort, and biomechanical profile.

In agreement with Cudejko et al. (19), who reported that the effect of soft knee braces on proprioception was highly variable and often dependent on individual responsiveness to sensory input? Factors such as brace fit, tightness, and user compliance may influence the degree of cutaneous stimulation and, by extension, proprioceptive feedback. Some individuals may not exhibit sufficient mechanoreceptor sensitivity to benefit from this modality. In agreement with Elkady et al. (20) who reported that the knee joint's stability is thought to be impacted by the soft brace's stimulation of the skin's mechanical sensors, which enhance the precision of the deep joint sense. This method of increasing knee joint stability may lessen activity limitations. Self-reported physical function improves somewhat too moderately and pain is moderately reduced when using a soft brace for KOA. In disagreement with Deyle et al. (21) who reported that physical therapy interventions—including strengthening, stretching, and manual techniques produced greater benefits in pain relief and functional performance than in restoring joint mobility. These findings highlight a key clinical reality, while exercise and orthotic supports can optimize neuromuscular control and reduce symptom burden, they may not substantially alter joint kinematics in the presence of chronic degenerative changes.

Baker et al. (22) reported that despite promising biomechanical evidence, clinical outcomes have been inconsistent. Several randomized controlled trials have failed to demonstrate significant improvements in pain or functional capacity with wedge insole use when compared to control interventions.

CONCLUSION

The current findings prove that the addition of either a soft knee brace or a lateral wedge foot insole to a traditional physiotherapy program may provide clinically valuable improvements in pain, proprioception, range of motion and function in patients with knee OA. This illustrates the importance of multimodal, long-term management strategies in addressing the complex and degenerative nature of knee osteoarthritis.

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