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EFFECT OF LATERAL WEDGED INSOLES WITH SUBTALAR STRAPPING ON GENU VARUM WITH MEDIAL COMPARTMENT KNEE PAIN

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ABSTRACT

Genu varum is known as one of the most common lower limb abnormalities, Lateral wedge insoles (LWIs) with subtalar strapping can shift the correction forces which are lost at the subtalar joint into the knee and may decrease the pain intensity in people with genu varum and medial compartment knee pain**. Objective:** The aim of this study was to investigate the effect of LWIs with subtalar strapping on genu varum with medial compartment knee pain. **Patients and Methods:** The study was conducted at the department of orthopedic and trauma surgeries, Assiut University Hospitals, and included 60 patients (aged 20 to 60 years) diagnosed with genu varum and medial knee pain. Participants were randomly assigned into two groups. **Group I:** Received corrective exercises which included (strengthening exercises for their hip extensors, knee extensors, hip abductors and hip external rotators) in addition to LWIs with subtalar strapping. **Group II:** Received the corrective exercise protocol only for 12 weeks. Pain measured by visual analogue scale and space between knees measured by vernier calipers were assessed before and after treatment. The data collected was analyzed and compared at the base line and the end of intervention. **Results:** There was no statistically significant difference between both groups post study in the mean values of pain and space between knees (P = 0.175 and 0.786) respectively.

Conclusion: There was no effect from adding lateral wedged insoles with subtalar strapping to corrective exercises on pain level and space between knees in genu varum with medial compartment knee pain.

Keywords: Knee pain, Wedged Insoles, Genu Varum.

INTRODUCTION

Genu varum is a malformation of the knee joint where the centers of the knees are moved outside of the mechanical axis of the limbs, causing a change in the normal alignment of the limbs. This malformation makes the patient's legs seem like they're in a parenthetical position while they stand [1].

Ambulatory activities generate asymmetric loading patterns within the knee joint, whereby the medial compartment bears about 2.5-fold more load than the lateral compartment. Such loading asymmetry could explain the higher frequency of medial compartment involvement seen in cases of tibiofemoral osteoarthritis (OA) [2].

Multiple therapeutic approaches focus on achieving lateral load redistribution across the tibiofemoral joint among medial knee OA patients. Among these, osteotomies represent the most invasive option. Conversely, conservative approaches, such as knee bracing for varus gonarthrosis, are more commonly recommended; however, long-term patient compliance remains a limitation. Alternatively, laterally wedged foot orthotic devices have been utilized to influence frontal plane knee loading by modifying the biomechanics of the foot, ankle, and tibia [3].

Insoles offer a highly targeted approach to modifying foot mechanics, which may directly affect the alignment and loading of the lower limb. These alterations can potentially initiate a sequence of adaptations or degenerative processes throughout the lower extremity joints and spinal structures. Recently, orthopedic insole systems have been implemented as minimally invasive, economically viable supplementary treatment approaches for patients with knee OA, foot disorders, and flatfoot deformities. In particular, lateral wedge insoles (LWIs) have become a focal point of research for their potential efficacy during the early and intermediate phases of medial knee OA [4].

The LWIs, inserted into footwear, offer a cost-effective and non-invasive strategy to reduce loading on the medial tibial plateau. This is achieved by modifying the external knee adduction moment (KAM) during gait. KAM emerges from the combined influence of ground reaction forces (GRF) and the perpendicular distance separating the GRF from the knee joint axis. The LWI promoted calcaneal valgus positioning relative to tibial orientation, lateral displacement of the foot’s center of pressure, and a more vertical GRF. This biomechanical modification increases femoral verticality and adduction movement, consequently shortening the GRF-to-knee center lever arm and reducing knee valgus angulation, thereby achieving KAM reduction [4].

Corrective exercise targeting genu varum may induce beneficial alterations in lower limb alignment, including modifications in Q angle, hip joint positioning, and knee spacing. When lower limb deformity arises from muscular imbalance rather than structural factors, regular exercise programs may effectively correct the malalignment [5].

The objective of this research was to analyze the effect of adding lateral wedged insoles with subtalar strapping to corrective exercises on pain level and space between knees in patients with genu varum and medial compartment knee pain.

Materials and Methods

Study design and randomization:

Parallel group randomized control trial (RCT) design. Patients were randomly distributed into two groups (computerized random table). The study was ethically approved by the Institutional Review Board of the Faculty of Physical Therapy, Cairo University **(P.T.REC/012/005074)** and registered as a clinical trial **(NCT06632639).**

Participants:

A total number of sixty subjects presenting with medial compartment knee pain associated with genu varum deformity. Data collection and intervention were performed at the department of orthopedic and trauma surgeries, Assiut University hospitals. They were assigned into two equal groups; They met the following predefined selection criteria: **Inclusion criteria:** Patients of both genders aged 20-60. patients with medial compartment pain. pain level of 3 or more on VAS. patients with varus deformity are defined as those whose femorotibial angle measures 0-10 degrees of genu varum on long film weight bearing x-ray **[6]**, patients with grade one O.A. on Kellgren-Lawrence classification system or without O.A, BMI less than 35**. Exclusion criteria:** Patients already wearing custom wedged insoles, patients with other inflammatory conditions like rheumatoid or systemic inflammatory arthritis, patients with central or peripheral nervous system disease, any previous surgical procedure to the knee joint, patients who are unable to walk without assistance (cane or a walker), Pregnancy, uncooperative patient types due to mental disorders or others., advanced O.A. (kellgren lawrence > 3), excessive hind foot valgus (>10) [**4**].

Interventions

The subjects were divided randomly into two groups equal in number, (group I) and (group II):

Group I: Performed corrective exercises which included (strengthening exercises for their hip extensors, knee extensors, hip abductors and hip external rotators) in addition to LWIs with subtalar strapping.

Group II: Received the corrective exercise protocol only.

For treatment:

- Patients followed the treatment protocol for insole wear and corrective exercise for 12 weeks.
- Description of the insoles **Fig (1)**:
- The material of the insole is Ethylene-vinyl acetate, a copolymer of ethylene and vinyl acetate. The vinyl acetate component generally constitutes 10–40% by weight. Increased VA proportion enhances the rubber-like characteristics of EVA resin materials.
- The insole featured a lateral elevation of 1 cm and a width of 7.5 cm, corresponding to an approximate inclination of 7.6°. The scaphoid-shaped insoles were adaptable for

use on the bare feet of all participants. The selection of this particular inclination angle was justified by 7.6° representing the median between 5° and 10°, according to findings from Kerrigan et al. indicating that both 5° and 10° LWIs produced significant reductions in knee varus moments.

- Wedge use commenced with one hour per day during the first week in appropriate footwear (excluding high-heeled or tight-fitting shoes). Thereafter, participants were instructed to gradually increase usage to at least 8 hours daily **(7)**.

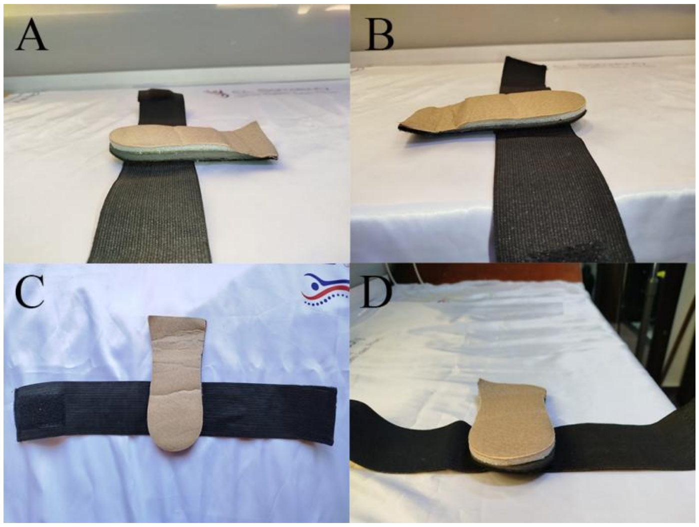

Fig. (1) lateral wedged insole with subtalar strapping

Corrective exercise protocol:

- The exercise program lasted for 60 minutes and included a ten-minute warm-up phase, a forty-minute Thera-band exercise, and a ten-minute cool-down phase. Thera-band exercises were specifically designed to target and strengthen the external rotator muscles, extensor muscle groups, quadriceps, and gluteal musculature **Fig. (2)**.
- Participants executed three sets of 15 repetitions for each prescribed exercise.

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Fig (2): The corrective exercises

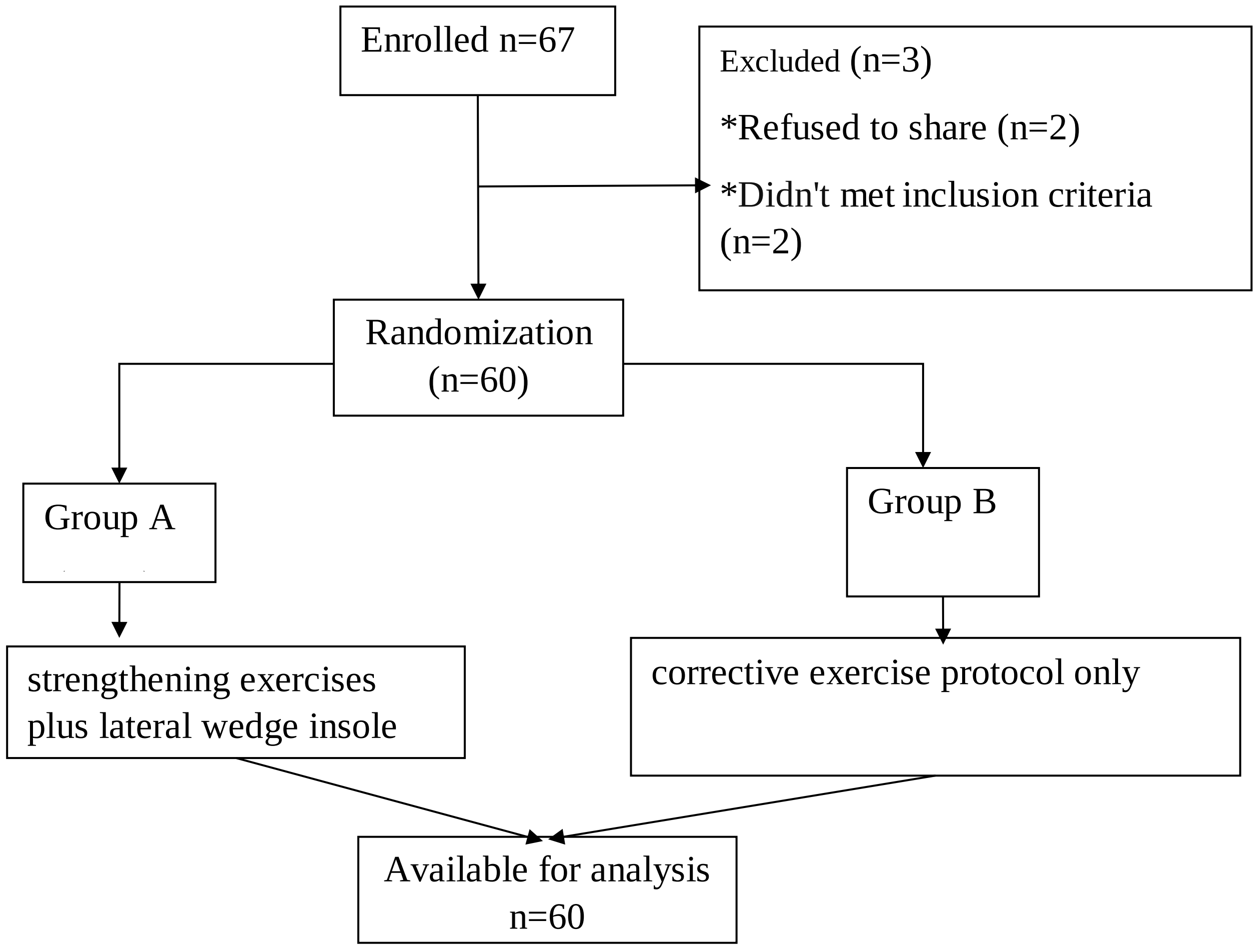

Fig (3): Flow chart of study participants

Outcome measures:

1.Visual analogue scale (VAS):

- Pain intensity was evaluated utilizing the Arabic-validated version of the visual analogue scale (VAS-AR). The VAS represents a uni-dimensional pain intensity measure consisting of a continuous 10-cm horizontal linear scale.
- Scale anchors include "pain-free" (0 rating) and "most severe pain imaginable" (10 rating).
- Increased scores reflect heightened pain intensity experiences.

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2.Measurement of space between knees using vernier calipers:

- Patients were instructed to put both feet together, so that both malleoli were together, and the space between both condyles was measured using vernier calipers**.**

Data analysis and statistical design:

Results are reported as mean ± SD. Group differences in demographic and baseline variables were evaluated using the unpaired t-test for continuous data and the chi-square test for categorical variables such as sex distribution. Shapiro-Wilk test was used for testing data normality. MANOVA was used to analyze the impact of intervention across groups and over time for pain and space between knees. Data analysis was conducted using the Statistical Package for the Social Sciences software (SPSS version 20.0 for Windows; SPSS Inc., Chicago, IL, USA). Statistical significance was established at P ≤ 0.05.

RESULTS

BMI and gender distribution (P > 0.05) **Table (1)**.

Table (1): General characteristics of subjects of both groups

Characteristics	group I (n=30)	group II (n=30)	t-value	p-value
Age (years)	34.43±11.13	38.63±8.74	-1.62	0.109
Weight (kg)	77.1±13.9	78.33±12.19	-0.37	0.716
Height (cm)	170.2±6.78	166.57±7.85	1.92	0.060
BMI (kg/m^2)	26.54±3.8	28.15±3.17	-1.78	0.080
Sex Males Females	 18 (60%) 12 (40%)	 20 (66.7%) 10 (33.3%)	Chi square 0.287	0.592

Data was expressed as mean ± standard deviation, p- value: significance

Regarding within group comparison, there was statistically significant decrease in mean value of pain in group I and II by 40% and 41.5% respectively (P = 0.001). regarding between groups comparison, there was no statistically significant difference between both groups pre and post study (P = 0.070 and 0.175) respectively **table (2), Fig. (4)**.

Regarding within group comparison, there was statistically significant decrease in mean value of space between knees in group 1 and II by 22% and 24% respectively (P = 0.001). regarding between groups comparison, there was no statistically significant difference between both groups pre and post study (P = 0.578 and 0.786) respectively **table (2), Fig. (5)**.

Table (2): Mean ±SD of measured variables pre and post study of both groups.

Measured variables	Group I Mean ±SD	Group II Mean ±SD	Mean difference (95% CI)	P-value[1]	η^2
Pain (cm)					
Pre study	4.3 ± 1.9	5.32 ± 2.35	-1.02 (-2.13, 0.09)	0.070	0.055
Post study	2.58 ± 1.21	3.1 ± 1.7	-0.52 (-1.29, 0.24)	0.175	0.031
MD (95% CI)	1.72 (1.05, 2.39)	2.21 (1.54, 2.9)			
% of change	40%	41.5%			
P-value	0.001*	0.001*			
Space between knees (mm)					
Pre study	38.17 ± 16.7	40.57 ± 16.55	-2.4 (-10.99, 6.19)	0.578	0.005
Post study	29.77 ± 15.12	30.8 ± 14.19	-1.03 (-8.61, 6.55)	0.786	0.001
MD (95% CI)	8.4 (4.76, 12.04)	9.77 (6.13, 13.4)			
% of change	22%	24%			
P-value	0.001*	0.001*			

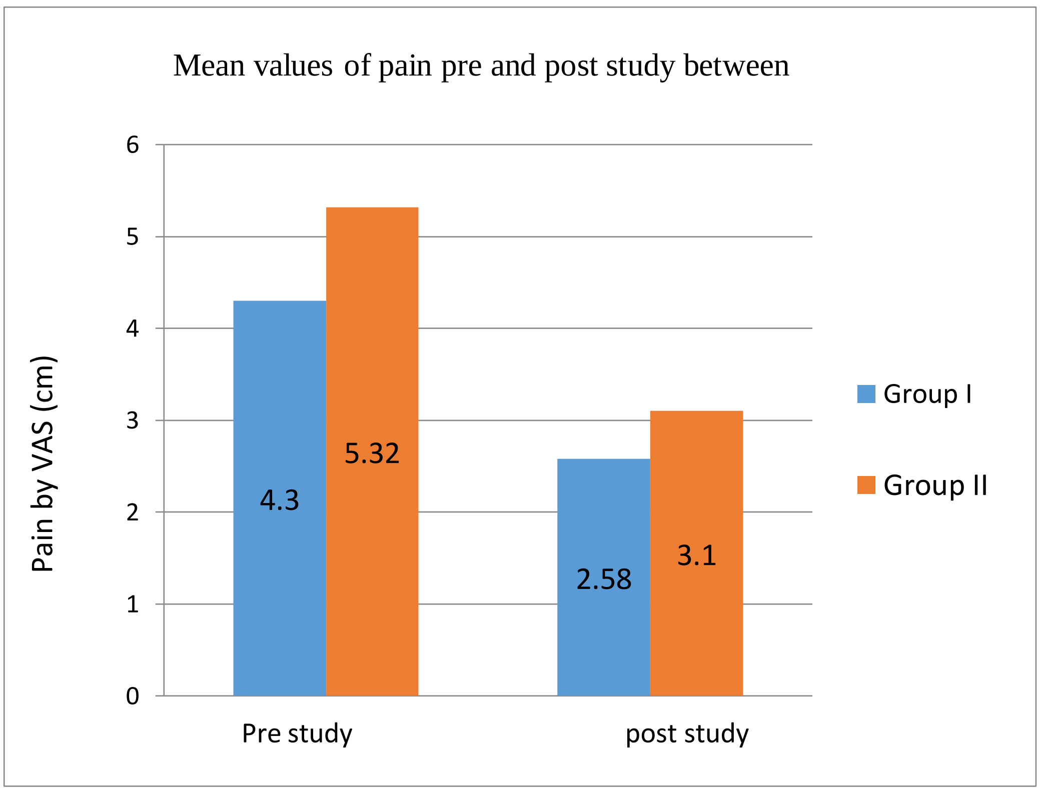

Figure (4): Mean values of pain pre and post study between groups

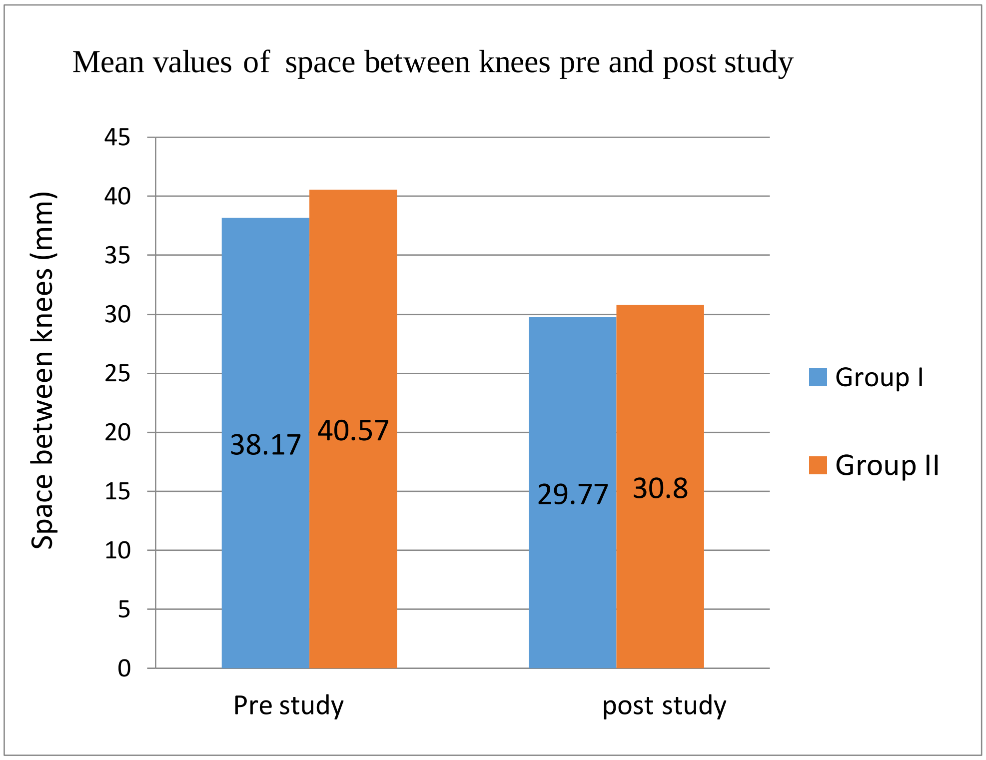

Figure (5): Mean values of space between knees pre and post study between groups

DISCUSSION

This study was conducted to evaluate how LWIs with subtalar strapping influence genu varum in patients experiencing medial compartmental knee symptoms. Sixty patients of both genders were enrolled in the trial; the subjects were allocated at random into two groups; intervention group (I) who were treated by LWIs with subtalar strapping in addition to corrective exercise protocol and control group (II) who were treated by the corrective exercise protocol only.

Two methods of assessment were used pre and post treatment to determine the level of improvement (pain level measured by VAS and space between knees measured by vernier calipers). The participants' age in the present study ranged from 20 to 60 with medial comp O.A. of no more than grade 1 to prevent the impact of medial compartment degeneration in advanced O.A. on genuvarum angle. The present study excluded patients who are already wearing custom wedged insoles, patients with other inflammatory conditions like rheumatoid or systemic inflammatory arthritis, patients with central or peripheral nervous system disease, any previous surgical procedure to the knee joint, patients who are unable to walk without assistance (cane or a walker), pregnant women, uncooperative patient types due to mental disorders or others, advanced OA (kellgren lawrence > 3), excessive hind foot valgus (>10) [4].

The period at which the intervention was introduced in this study was 12 weeks, which was longer than some of the previous studies which lasted 6 weeks. This study's findings indicated that, within groups; there was a significant reduction in pain and space between knees measured at post-treatment when compared with its corresponding value measured at pre-treatment in both groups I&II.

Between groups, there was no insignificant difference between both groups I&II in pain level and space between knees.

The current study's results corroborate those of [8], who compared the efficacy of two orthotic options, a lateral wedge with a subtalar strap worn barefoot and a LWI embedded in a sandal, for treating medial knee OA.

This quasi-experimental pre-post intervention study enrolled 29 medial knee OA patients, randomly allocated into two groups: Group (1) combined insole system (n=15) and Group (2) sandal-based system (n=14). Motion analysis systems evaluated their walking patterns both with and without orthotic interventions. Pain intensity and functional performance were measured utilizing the VAS, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the 30-second chair stand test, and the Timed Up and Go (TUG) test. Outcome measures were re-evaluated after 30 days.

Both orthotic interventions demonstrated a significant lowering in pain immediately following walking ($p<0.001$). Additionally, continued use of the orthoses over one month led to marked improvements in both pain and performance across both groups ($p<0.01$).

Similar conclusions were reached in the work of David et al. [9], examining the effectiveness of a LWI in patients suffering from painful medial knee OA, while excluding subjects with concurrent patellofemoral OA and those with pain scores under 4 on the 10-point rating system. Biomechanical screening eliminated participants whose gait analysis revealed insufficient KAM reduction (less than 2%) when comparing LWI to neutral insole conditions. The investigation employed a randomized design, with participants allocated to either lateral wedge or neutral insole interventions across 8 weeks, with an intervening 8-week washout phase. Primary outcome assessment involved participant-reported knee pain over the preceding week (0-10 scale), with additional evaluation including activity-associated pain and comprehensive assessment via the Knee Injury and Osteoarthritis Outcome Score questionnaire.

After excluding 25.3% of participants (21/83) for insufficient KAM reduction, analysis of the remaining 62 patients (mean age 64.2 ± 9.1; 37.1% female) revealed that lateral wedge insoles outperformed neutral insoles in pain reduction (mean difference 0.7, 95% CI 0.1–1.2; P = 0.02). However, the findings for secondary outcomes were inconsistent. Although the study demonstrated pain reduction among biomechanical responders without patellofemoral OA, the overall treatment effect was modest and likely to be clinically meaningful only in a subset of patients.

The results also agreed with the study of Bingbing et al.[10] who examined the impact of the Wedged Insole Compared with a Flat (Placebo) Insole. The researchers conducted a comprehensive systematic review, examining both published and unpublished literature across multiple databases (MEDLINE, EMBASE, CNKI, Cochrane Library, and Web of Science) from database inception through April 2018. Inclusion criteria were limited to RCTs investigating the comparative effectiveness of wedge insoles versus flat insole controls. Methodological quality evaluation and clinical relevance assessment were conducted, with subsequent outcome synthesis through meta-analytical techniques. The analysis included 413 records, from which eight studies met the predetermined inclusion criteria. WOMAC pain assessment showed statistically insignificant changes following wedge insole intervention (SMD=0.07), with low between-study heterogeneity (I^2 =22%) and a 95% confidence interval crossing the null value (95% CI: −0.09 to 0.24). Five distinct trials showed no meaningful pain score improvement (SMD = −0.02, 95% CI: −0.19 to 0.16). Analysis further revealed no statistically significant enhancement of Lequesne index outcomes (SMD = −0.27, 95% CI: −0.72 to 0.19). Meta-analytical synthesis of 2 distinct studies indicated significant femorotibial angle improvement (SMD = −0.41, 95% CI: −0.73 to -0.09). While lateral wedge insoles show potential for modifying joint alignment, their therapeutic impact on pain and function appears limited in knee OA populations.

The current study's findings disagreed with Bing bing et al. [10] who examined the effect of the Wedged Insole Compared with a Flat (Placebo) Insole. A thorough systematic review methodology was implemented, including published and unpublished sources from multiple electronic databases (MEDLINE, EMBASE, CNKI, Cochrane Library, and Web of Science) spanning from inception to April 2018. Only RCTs examining wedge insole effectiveness against flat insole controls were included. Bias risk evaluation and clinical relevance assessment were conducted, followed by quantitative synthesis via meta-analysis. Among 413 initially identified citations, 8 investigations satisfied the predetermined eligibility requirements. Their analysis showed no statistically significant difference in WOMAC pain outcomes (SMD = 0.07; 95% CI: −0.09 to 0.24; I^2 = 22%), with five trials showing no relevant pain reduction (SMD = −0.02; 95% CI: −0.19 to 0.16).

Results of this study were also not supported by [11] who did not find any significance difference in pain or function in RCTs assessing orthopedic insole interventions for knee OA. The analysis encompassed 15 studies from 13 RCTs, with 1,086 total participants. The included studies were characterized by moderate risk of bias, though their overall quality was considered acceptable.

Pooled analysis of pain outcomes measured by the WOMAC Index yielded a mean difference of –1.21 ($p<0.001$, 95% CI –2.61–0.18), with considerable between-study heterogeneity ($I^2=75\%$). Comparison between Asian and Caucasian cohorts yielded no significant differences ($p=0.28$). The analysis revealed no meaningful differences in pain scores or functional enhancement.

CONCLUSION

This study's results point out that there is no benefit to adding lateral wedged insoles with subtalar strapping to corrective exercises on pain level and space between knees in cases of genuvarum with medial compartment knee pain.

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