ORIGINAL ARTICLE

A Comparative Study on the Use of Lateral Heel Wedge and Lateral Wedge Insole in the Treatment of Medial Compartment Osteoarthritis of Knee with Varus Deformity

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Abstract

Background: Osteoarthritis (OA), a degenerative joint disease, has a strong predilection for weight-bearing joints, the most common being the knee. It commonly affects the elderly obese female population. In a world of modern medical marvels, the percentage of elderly population is increasing. The problem of OA especially involving knee joint has become rampant, leading to greater physical, financial, and emotional burden on the patient, family, and society at large. Hence, extensive research has gone into various facets in the treatment of OA, viz., nonpharmacological, pharmacological, and surgical methods, with varying results. This study was concerned with a particular aspect of nonpharmacological therapy, viz., the use of two lateral wedge orthotics, i.e., lateral heel wedge and lateral wedge insole in OA of medial compartment of knee joint with varus deformity. It has been proved through prior research that patients have benefited from each of the above type of lateral wedge orthotics, but there is a paucity of studies that compares them. This study is an attempt toward addressing this gap using various relevant outcome measures. Standard statistical tests were performed and conclusion drawn based on the research findings.

Materials and methods: This is a single-blind randomized parallel group trial conducted in the Department of Physical Medicine and Rehabilitation in Institute of Postgraduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital, Kolkata, for a period of 18 months, considering a minimum of 28 subjects in each group. Symptomatic patients having grade II or higher Kellgren–Lawrence radiological grading of tibiofemoral OA along with medial compartment narrowing and varus deformity in standing anteroposterior (AP) view were included. Patients excluded had history of knee trauma or surgery in the past 6 months. Parameters studied were Western Ontario and McMaster (WOMAC) scale, visual analog scale (VAS) score, and 50 ft walk time. Selected patients were divided into two groups randomly and written informed consent was taken from all. One group was given lateral heel wedge of 1/6th inch and the other group was given lateral wedge insole of the same dimension. Selected patients were examined at baseline using the parameters mentioned above and were further examined after intervals of 4 and 8 weeks. The results have been analyzed according to the standard statistical methods to fulfill the aim and objectives of the study.

Discussion: Majority of the patients were elderly, overweight females with grade III OA on the Kellgren–Lawrence scale. Outcome measures showed significant difference in both groups, with slightly greater significance in lateral wedge insole group but compliance was higher in lateral heel wedge because of greater comfort level.

Keywords: Comparative study, Lateral heel wedge, Lateral wedge insole, Medial compartment narrowing.

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Introduction

Osteoarthritis (OA), which is often erroneously called degenerative joint disease, represents failure of the diarthrodial (i.e., movable synovial) joint. Osteoarthritis, though primarily involves progressive loss of articular cartilage, involves all structures of the joint—subchondral bone, synovial fluid, and synovial membrane are major sites of change in the course of the disease process.[1]

Joint involvement is usually asymmetrical with a predilection for weight-bearing joints and of the various common sites, OA knee is the most common, which could be uni-, bi-, or tricompartmental; among which the most common is the medial compartmental OA changes.[2] Risk factors for OA include age (most important), obesity, bone density, genetics, and gender.[3]

Extensive research has gone into various facets in the treatment of OA, viz., nonpharmacological, pharmacological, and surgical methods with varying results.

This study was concerned with a particular aspect of nonpharmacological therapy, viz., the use of lateral wedge orthotics of two types in OA of medial compartment of knee with varus deformity. The two types of lateral wedge orthotics are lateral heel wedge and lateral wedge insole.

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It has been proved through prior research that patients have benefited from each of the above types of lateral wedge orthotics. This study was aimed to evaluate the effectiveness between them using measuring parameters such as VAS for pain, Western Ontario

and McMaster (WOMAC) University Index of OA scale, 50 ft walk time. Statistical tests were performed and conclusion reached based on the research findings.

Aims and Objectives

The aim of the study was to evaluate the effectiveness of shoe correction using lateral wedge orthotics by observing clinical and functional improvement in a comparative study between lateral heel wedge and lateral wedge insole in medial compartment OA of the knee with varus deformity.

Materials and Methods

After Institutional Ethics Committee clearance, the individual informed consent was taken from every patient who was included in the study. The study was conducted in the Department of Physical Medicine and Rehabilitation, Institute of Postgraduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital, Kolkata, and was carried out for 18 months from February 2011 to August 2012, and a minimum of 28 subjects was the requirement per group. For the purpose of sample size estimation, the pain component of WOMAC index was considered as the primary outcome measure. It was a single-blind randomized parallel group trial. All subjects having grade II or higher Kellgren–Lawrence radiographic severity of tibiofemoral OA along with medial compartment narrowing and varus deformity in standing AP view, pain in the knee for most days in the past month, and pain score of at least 3 on a 0–10 VAS score were included. Patients who were excluded had a history of knee trauma or surgery in the past 6 months, history of other types of arthritis, neurological disease, intra-articular steroid or hyaluronate injection over past 6 months, calcaneovalgus deformity, and everted foot. Parameters studied were WOMAC scale, VAS score, and 50 ft walk time.

Study Technique

In the study, patients suffering from medial compartment OA of knee with varus deformity were selected for intervention after obtaining informed consent (considering inclusion and exclusion criteria). The selected patients were examined at baseline (visit 1 or V1) using the parameters mentioned above. They were randomly put into two groups (1) group using lateral heel wedge of 1/6th inch (4.23 mm) and (2) group using lateral wedge insole of 1/6th inch (4.23 mm). The wedge insoles and heel wedges were constructed with plain rubber. The patients were examined using the above-mentioned parameters after intervals of 4 weeks (visit 2 or V2) and 8 weeks (visit 3 or V3). Parameters of functional improvement were noted. The results were analyzed according to the standard statistical methods to accomplish the aims and objectives of the study. In all cases, exercises were shown to the patients, which the patients were instructed to practice at home.

Results

Data was normally distributed and summarized using descriptive statistics and represented graphically. Change from baseline (V1) to study end (V3) assessed through repeated-measure analysis of variance (ANOVA) for normally distributed data, Fisher's *F* value, and R^2 value noted in each case to determine the level of significance and comparison. Numerical variables between groups were compared by Student's *t* test (Mann–Whitney) where applicable. Tukey's *post hoc* tests for ANOVA was conducted for each parameter to observe the fine-grained differences between visits (from V1 to V2, V1 to V3, and V2 to V3) where significance was noted in ANOVA test. All statistical analyses were two tailed and $p < 0.05$ considered statistically significant.

Demographics

Age

Figure 1 represents histogram showing the age profile of the two groups. The age distribution of the population sample resembles a bell-shaped curve, and the peak is seen in the age bracket 50–53 years. Both groups individually have a similar age profile.

Gender

Figure 2 represents histogram showing the gender frequency distribution in each of the groups. There is preponderance of females in both groups.

Body Mass Index

Figure 3 depicts histogram showing the body mass index (BMI) frequency distribution among the two groups under study. The frequency distribution roughly approximates a normal distribution curve, though leaning toward the overweight side of the bell curve. Peak is seen at 24–26 BMI group and the majority in our study population are overweight.

Radiological Grading

Figure 4 represents histogram showing the frequency distribution of the patients in both groups for the radiological grading. Kellgren–Lawrence grading system has been used. Majority in both experimental groups fall in grade III, followed by grade II and a few in grade IV. Grade I patients have not been included in the study.

Statistical Results for Outcome Measures

50 ft Walk Time

Table 1 shows greater significance for insole group, and Table 2 shows significant results for both groups for V1 to V2 and V1 to V3 but significance for only insole group for V2 to V3. Appreciable reduction in average 50 ft walk time (2.82 seconds) is observed for the group using lateral wedge insoles from V1 to V3.

VAS Pain Score

Table 3 shows stronger results for VAS pain reduction in the wedge insole group. Table 4 shows significant results for both

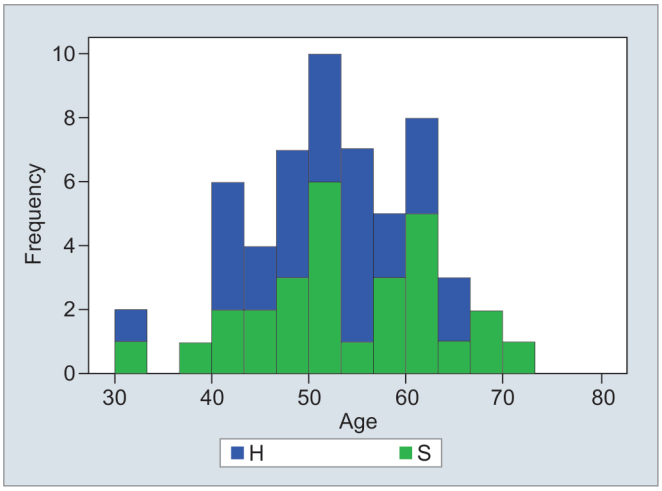

Fig. 1: Histogram showing the age profile of the two groups (H, heel wedge group and S, wedge insole group)

groups for V1 to V2 and V1 to V3 but significance for only the insole group for V2 to V3. Appreciable reduction in average VAS pain score (2.29) is observed for the group using lateral wedge insoles from V1 to V3.

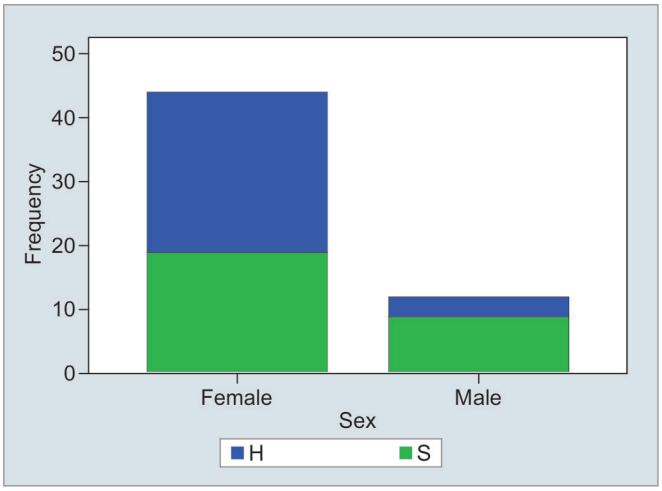

Fig. 2: Histogram showing the gender frequency distribution in each group (H, heel wedge group and S, wedge insole group)

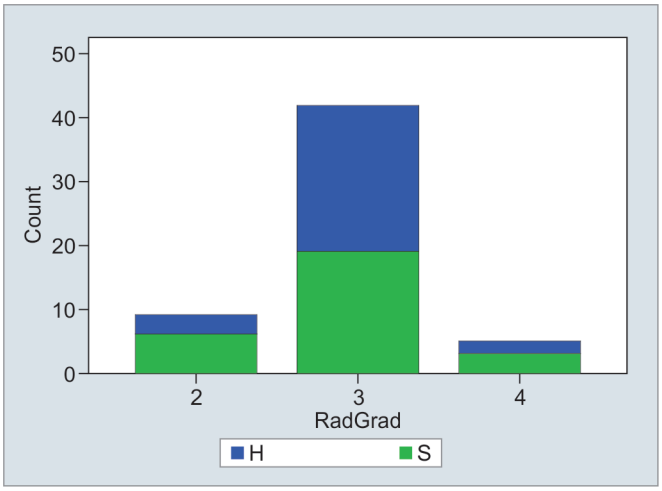

Fig. 4: Histogram showing the frequency distribution of the patients in both groups for the radiological grading (H, heel wedge group and S, wedge insole group)

WOMAC Pain

Table 5 shows stronger significance for the insole group. Table 6 shows significant results for both groups from V1 to V2 and V1 to V3 for both groups but no significance from V2 to V3 for both groups. Appreciable reduction in average WOMAC pain score (2.75) was observed for the group using lateral wedge insoles from V1 to V3.

WOMAC Stiffness

In Table 7, significance is observed from V1 to V2 and V1 to V3 for insole user group. Stiffness reduces for this group sharply from V1 to V2 followed by a slight increase in stiffness from V2 to V3.

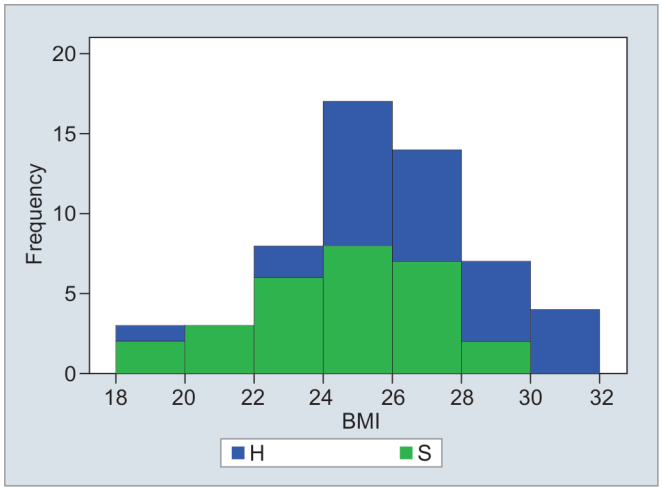

Fig. 3: Histogram showing the body mass index (BMI) frequency distribution among the two groups under study (H, heel wedge group and S, wedge insole group)

Table 1: Repeated-measures analysis of variance for 50 ft walk time for both lateral heel wedge and lateral wedge insole user groups

Repeated-measures ANOVA	*Heel*	*Insole*
p value	$p < 0.0001$	$p < 0.0001$
p value summary	***	***
Are means signif. different? ($p < 0.05$)	Yes	Yes
Number of visits	3	3
F	19.5	50.1
R^2	0.42	0.65

***$p \leq 0.001$

Table 2: Tukey's multiple comparison tests for 50 ft walk time for both lateral heel wedge and lateral wedge insole user groups

Tukey's multiple comparison test	*Mean difference (seconds)*	*q*	*p < 0.05?*	*Summary*	*95% CI of difference*
Heel—50 ft walk time					
V1 vs V2	1.75	7.96	Yes	***	1.00–2.50
V1 vs V3	1.61	7.31	Yes	***	0.857–2.36
V2 vs V3	−0.143	0.65	No	ns	−0.893–0.607
Insole—50 ft walk time					
V1 vs V2	2.07	10	Yes	***	1.37–2.78
V1 vs V3	2.82	13.7	Yes	***	2.12–3.53
V2 vs V3	0.75	3.63	Yes	*	0.0458–1.45

ns, $p > 0.05$; *$p \leq 0.05$; ***$p \leq 0.001$

WOMAC Functional Score

Tables 8 and 9 show significance from V1 to V2 and V1to V3 for both groups. V2–V3 shows insignificance in both cases. Appreciable increase in functionality for both groups (mean score reduced by 6 and 7 for heel and insole users, respectively) from V1 to V3.

Table 3: Repeated-measures analysis of variance for visual analog scale pain score for both lateral heel wedge and lateral wedge insole user groups

Repeated-measures ANOVA	*Heel*	*Insole*
p value	$p < 0.0001$	$p < 0.0001$
p value summary	***	***
Are means signif. different? ($p < 0.05$)	Yes	Yes
Number of visits	3	3
F	39.3	94.3
R^2	0.593	0.777

***$p \leq 0.001$

Statistical Result for Comfort Level

Table 10 shows significance between the two groups in the comfort level of using their shoes.

Dropout

Of the 30 and 33 cases for lateral heel wedge and lateral wedge insoles, respectively, included in the study, 2 and 5 cases did not report for follow-up and dropped out of the study. Thus, the final sample population was 28 per group. The dropout numbers in both groups suggest that compliance in insole users is less.

Discussion

The effectiveness of using lateral heel wedges[4] and lateral wedge insoles[5–7] in the treatment of medial compartment OA of knee with varus deformity has been studied for long. But there is lack of studies which compares the effectiveness between these orthotics. This study focused on OA knee prevalent in older population as shown in Figure 1, and majority of patients were female as depicted

Table 4: Tukey's multiple comparison tests for visual analog scale pain score for both lateral heel wedge and lateral wedge insole user groups

Tukey's multiple comparison test	*Mean difference*	*q*	*p < 0.05?*	*Summary*	*95% CI of difference*
Heel—VAS pain score					
V1 vs V2	1.54	10.7	Yes	***	1.05–2.02
V1 vs V3	1.57	11	Yes	***	1.08–2.06
V2 vs V3	0.0357	0.25	No	ns	−0.452–0.524
Insole—VAS pain score					
V1 vs V2	1.79	14.4	Yes	***	1.36–2.21
V1 vs V3	2.29	18.5	Yes	***	1.86–2.71
V2 vs V3	0.5	4.04	Yes	*	0.0779–0.922

ns, $p > 0.05$; *$p \leq 0.05$; ***$p \leq 0.001$

Table 5: Repeated-measures analysis of variance for Western Ontario and McMaster pain score for both lateral heel wedge and lateral wedge insole user groups

Repeated-measures ANOVA	*Heel*	*Insole*
p value	$p < 0.0001$	$p < 0.0001$
p value summary	***	***
Are means signif. different? ($p < 0.05$)	Yes	Yes
Number of visits	3	3
F	28.1	40.8
R^2	0.51	0.602

***$p \leq 0.001$

Table 7: Repeated-measures analysis of variance for Western Ontario and McMaster stiffness score for both lateral heel wedge and lateral wedge insole user groups

Repeated measures ANOVA	*Heel*	*Insole*
p value	0.2077	$p < 0.0001$
p value summary	ns	***
Are means signif. different? ($p < 0.05$)	No	Yes
Number of visits	3	3
F	1.62	12.8
R^2	0.0565	0.321

ns, $p > 0.05$; ***$p \leq 0.001$

Table 6: Tukey's multiple comparison tests for Western Ontario and McMaster pain score for both lateral heel wedge and lateral wedge insole user groups

Tukey's multiple comparison test	*Mean difference*	*q*	*p < 0.05?*	*Summary*	*95% CI of difference*
Heel—WOMAC pain score					
V1 vs V2	1.93	8.4	Yes	***	1.15–2.71
V1 vs V3	2.25	9.8	Yes	***	1.47–3.03
V2 vs V3	0.321	1.4	No	ns	−0.462–1.10
Insole—WOMAC pain score					
V1 vs V2	2	8.99	Yes	***	1.24–2.76
V1 vs V3	2.75	12.4	Yes	***	1.99–3.51
V2 vs V3	0.75	3.37	No	ns	−0.00905–1.51

ns, $p > 0.05$; ***$p \leq 0.001$

Table 8: Tukey's multiple comparison tests for Western Ontario and McMaster stiffness for lateral insole wedge user group. The heel wedge group exhibited insignificant change in Western Ontario and McMaster score for stiffness and due to the statistical insignificance, Tukey's test was not relevant

Tukey's multiple comparison test	*Mean difference*	*q*	*p < 0.05?*	*Summary*	*95% CI of difference*
Insole—WOMAC stiffness score					
V1 vs V2	0.536	6.76	Yes	***	0.265–0.806
V1 vs V3	0.429	5.41	Yes	**	0.158–0.699
V2 vs V3	−0.107	1.35	No	ns	−0.378–0.163

ns, $p > 0.05$; **$p \leq 0.01$; ***$p \leq 0.001$

Table 9: Repeated-measures analysis of variance for Western Ontario and McMaster functional score for lateral heel wedge and lateral wedge insole user groups

Repeated-measures ANOVA	*Heel*	*Insole*
p value	$p < 0.0001$	$p < 0.0001$
p value summary	***	***
Are means signif. different? ($p < 0.05$)	Yes	Yes
Number of visits	3	3
F	31.2	51.7
R^2	0.536	0.657

***$p \leq 0.001$

Table 11: Mann–Whitney test (*t* test) to determine the difference in comfort level between lateral heel wedge and lateral wedge insole groups

Test: Mann–Whitney	
p value	0.0052
Exact or approximate *p* value?	Gaussian approximation
p value summary	**
Are medians signif. different? ($p < 0.05$)	Yes
One- or two-tailed *p* value?	Two tailed

**$p \leq 0.01$

Table 10: Tukey's multiple comparison test for Western Ontario and McMaster functional score for both lateral heel wedge and lateral wedge insole user groups

Tukey's multiple comparison test	*Mean difference*	*q*	*p < 0.05?*	*Summary*	*95% CI of difference*
Heel—WOMAC functional score					
V1 vs V2	5.36	9.02	Yes	***	3.33–7.38
V1 vs V3	6.07	10.2	Yes	***	4.05–8.10
V2 vs V3	0.714	1.2	No	ns	−1.31–2.74
Insole—WOMAC functional score					
V1 vs V2	5.29	10.4	Yes	***	3.55–7.02
V1 vs V3	7	13.8	Yes	***	5.27–8.73
V2 vs V3	1.71	3.38	No	ns	−0.0166–3.45

ns, $p > 0.05$; ***$p \leq 0.001$

in Figure 2. Obesity is a contributing factor as shown in Figure 3, indicating leaning toward the overweight side of the bell curve. As shown in Figure 4, majority of the patients were in Kellgren–Lawrence grade III.

Statistical analysis of primary outcome measures shows significant results for 50 ft walk time for both heel and insole wedge user groups from baseline V1 to V2 and from V1 to V3, but significance was observed only for the insole group from V2 to V3. Appreciable reduction in average 50 ft walk time (2.82 seconds) was noticed for the group using lateral wedge insole from baseline to V3 as depicted in Tables 1 and 2. For VAS pain score, considerable reduction in pain was observed from V1 to V2 for both groups. Heel user group shows insignificance across V2 and V3, but in insole user group significance was also seen from V2 to V3 visit as depicted in Tables 3 and 4. In addition, Tables 5 and 6, which show WOMAC pain score, exhibit similar statistical significance in both groups, i.e., from mean baseline to V2 pain reduction is similar in both groups, but mean V2 to V3 pain reduction is appreciable for the insole user group, though not statistically significant. Statistical study of WOMAC stiffness score as shown in Tables 7 and 11 shows insignificant change in score for lateral heel wedge user group but significance is observed for V1 to V2 visit and V1 to V3 visit for insole user group and slight increase in stiffness from V2 to V3. Tables 8 and 9 which depicts statistical study of WOMAC functional score shows there is significant improvement from V1 to V2 and V1 to V3 visit for both groups, whereas the change from V2 to V3 in both cases was insignificant.

In statistical result for comfort level, as shown in Table 10 and Figure 5, it is clear that heel wedge users are more comfortable with their modified shoes compared to full-length lateral wedge insole users.

Thus, per the above findings, there is a trade-off between higher efficiency of biomechanical effects of full-length wedge insole with the greater comfort and comparatively slightly less efficiency of heel wedge orthotics.[8] The decision to use the type of shoe modification should therefore be customized per the patients' typical requirements and shoe usage pattern.

Limitations

The limitations of this study and further research interests are-

- Most of the patients being female, ideal shoe wearing time that is around 5–6 hours per day to bring appreciable change in

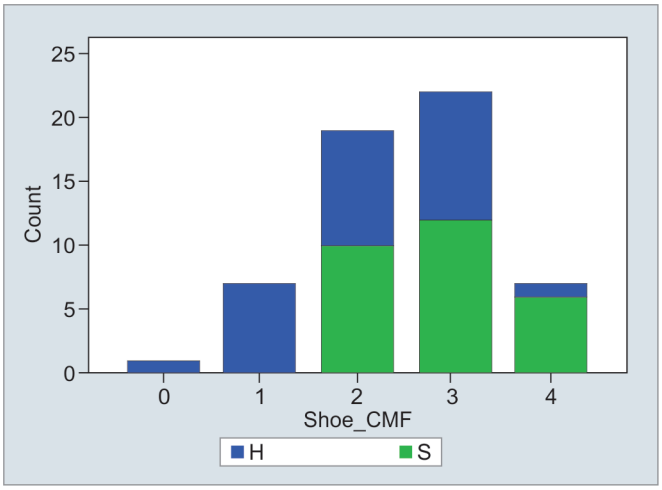

Fig. 5: Histogram of the comfort level (on a scale of 0–4, 0 being very comfortable and 4 being highly uncomfortable) of wearing the shoes with both types of wedges. It is clear that heel wedge users are more comfortable with their shoes, with no insole users in the 0 and 1 comfort category. There is preponderance of insole users in comfort category 4 (highly uncomfortable) (H, heel wedge group and S, wedge insole group)

outcome parameters was not adhered to due to the household chores required of them, where wearing shoes at home is generally not possible.

- Compliance of the patient was an area of concern for various causes like sociocultural issues and also for comfort factor where wearing lateral wedged insole was more inconvenient than wearing lateral heel wedges.
- A longer time period longitudinal study for determining the comparative efficacy of the two groups can be more beneficial than the present 8 weeks' study.
- Lateral wedge insoles reduce the external knee adduction moment (EKAM). However, in some cases an increase in EKAM is seen.[9] Understanding the role of ankle joint in every case will throw more light on this subject. This was not in the scope of this study and can be investigated later. Moreover, the relation between the decrease in medial knee loading and the subsequent reduction in pain is inconsistent and can be studied further.[10]
- The 1/6th inch wedge orthotics was chosen, as the wedge angle remains within 6° with the inserts and heel for various shoe sizes for the subjects.[11] This leads to greater compliance. However, steeper and milder angled wedge orthotics can be used and a comparative study can be carried out between them.

Conclusion

Comparing the outcome measures, it was seen that for both lateral wedge insole and lateral heel wedge users, a significant improvement was observed in most of the parameters, whereas slightly greater significance was seen in lateral wedge insole user group. But it was also observed that though sharper angled insoles provided greater efficacy, this was less comfortable, leading to less compliance. In conclusion, it can be affirmed that wedge insoles and heels offer great potential as simple, inexpensive treatment strategies for knee OA in the early stages. However, keeping in mind the various limitations of this approach, it can be deduced that further research is needed to determine the precise estimation of efficacy and the responsiveness of diverse patient groups to this mode of OA management.

Disclosure Statement

This study was not funded by any governmental or nongovernmental organization or any pharmaceutical company, and no financial or other benefit was related to this study, and there was no commitment or agreement or scope of benefit from any commercial entity.

References

1. Brandt KD. Harrison's Principles of Internal Medicine, 16th ed., ch. 312; 2005. pp. 2036–2045.
2. Wilkins AN, Philips EM. Essentials of physical medicine & rehabilitation Frontera WR, Silver JK, Rizzo TD 2nd ed., ch. 130; 2008. pp. 745–751.
3. Felson DT. Preventing knee and hip osteoarthritis. Bull Rheum Dis 1998;47(7):1–4.
4. Tohyama H, Yasuda K, Kaneda K. Treatment of osteoarthritis of the knee with heel wedges. Int Orthop 1991;15(1):31–33. DOI: 10.1007/BF00210530.
5. Kerrigan DC, Lelas JL, Goggins J, et al. Effectiveness of a lateral-wedge insole on knee varus torque in patients with knee osteoarthritis. Arch Phys Med Rehabil 2002;83(7):889–893. DOI: 10.1053/apmr.2002.33225.
6. Sasaki T, Yasuda K. Clinical evaluation of the treatment of osteoarthritic knees using a newly designed wedged insole. Clin Orthop Relat Res 1987(221):181–187. DOI: 10.1097/00003086-198708000-00021.
7. Yasuda K, Sasaki T. The mechanics of treatment of the osteoarthritic knee with a wedged insole. Clin Orthop Relat Res 1987(215):162–172. DOI: 10.1097/00003086-198702000-00024.
8. Rubin R, Menz HB. Use of laterally wedged custom foot orthoses to reduce pain associated with medial knee osteoarthritis. A preliminary investigation. J Am Podiatr Med Assoc 2005;95(4):347–352. DOI: 10.7547/0950347.
9. Chapman GJ, Parkes MJ, Forsythe L, et al. Ankle motion influences the external knee adduction moment and may predict who will respond to lateral wedge insoles? an ancillary analysis from the SILK trial. Osteoarthritis Cartilage 2015;23(8):1316–1322. DOI: 10.1016/j.joca.2015.02.164.
10. Felson DT, Parkes M, Carter S, et al. The efficacy of a lateral wedge insole for painful medial knee osteoarthritis after prescreening: a randomized clinical trial. Arthritis Rheumatol 2019;71(6):908–915. DOI: 10.1002/art.40808.
11. Bennell KL, Bowles KA, Payne C, et al. Lateral wedge insoles for medial knee osteoarthritis: 12 month randomised control trial. Br Med J 2011;342:d2912. DOI: 10.1136/bmj.d2912.