

Hatef MR, Mirfeizi Z, Sahebari M, et al. Superiority of laterally elevated wedged insoles to neutrally wedged insoles in medial knee osteoarthritis symptom relief. International Journal of Rheumatic Diseases 2014; 17:84–88.

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Design: Double-blind parallel treatment trial

Objective: To compare the effectiveness of laterally elevated and neutrally wedged insoles in patients with medial compartment knee osteoarthritis.

Population /sample size/setting:

- 150 patients with mild to moderate medial compartment knee osteoarthritis (OA) according to the Kellgren and Lawrence scale enrolled in this clinical trial; 118 completed the study in northeast Iran (Group A: 49 female and 8 male, mean age 48.2) and (Group B: 52 female and 9 male, mean age 48.6).
- Inclusion criteria included medial compartment knee OA according to the American College of Rheumatology (ACR) diagnosis criteria, symptomatic medial femoral-tibial OA, and pain on a daily basis for at least 1 month during the previous 3 months. Radiographic inclusion criterion was evidence for medial femoral-tibial OA on plain anteroposterior X-rays (Kellgren and Lawrence grade > 2).
- Exclusion criteria included secondary knee or hip OA, foot deformity, greater or similar reduction in lateral rather than medial femoral-tibial joint space width on plain anteroposterior X-rays, knee joint lavage within the previous 3 months, intra-articular corticosteroid injection within the previous month, tibial osteotomy within the previous 5 years and changes in drug treatment for OA within the previous week.

Interventions:

- Patients were randomly divided into two groups: group A (75 patients, 57 completed) received laterally elevated wedged insoles and group B (75 patients, 61 completed) received neutrally wedged insoles to wear for 2 months.
 - Group A wore bilaterally standardized laterally elevated wedged (5°) insoles made of ethyl vinyl acetate mounted on a leather strip, wedged along the entire lateral border of the foot. The thickness of these insoles was 10 mm on the lateral side and 4 mm on the medial side.
 - In group B, a neutrally wedged insole, made of the same material was used. The thickness in the neutrally wedged insoles was uniformly 4 mm.
- Outcome data was collected and measured before intervention (baseline) and after 2 months of wearing the insoles. Patients were asked about the severity of knee pain within the last 2 days, using the self-reported 100 mm visual analogues scale (VAS), the number of non-steroidal anti-inflammatory drugs (NSAIDs) taken during the last 2 weeks, and they were given the Edinburgh Knee Function Scale (EKFS) questionnaire to complete.
- At the end of each month, a rheumatologist, who was blinded to the patient's group designation, visited all patients. They were asked about the duration and method of wearing these insoles.

Main outcome measures:

- The primary outcome measures were the EKFS for function, the VAS for knee pain and the numbers of NSAIDs taken to relieve knee pain. Outcome measures were compared before and after intervention between the two groups.
- At baseline before intervention, there was no significant difference in mean age, severity of knee pain (VAS), EKFS and numbers of NSAIDs prescribed to the patients in the two groups.
- Two months after wearing the wedged insoles (laterally or neutrally wedged), a significant decrease in severity of knee pain (VAS) was shown in both groups. The mean difference from baseline to 2 months in group A was 29.3 (95% CI: 25.1-33.6, Wilcoxon rank test) and in group B was 6.25 (95% CI: 3.09-9.4, Wilcoxon rank test). However, according to gender, a significant decline in the severity of knee pain was revealed among women from group A which was not shown in group A men.
- Edinburgh Knee Function Scale was significantly improved in group A in comparison to baseline with a mean difference of 7.54 (95% CI: 6.3-8.8, Wilcoxon rank test). Group B did not show significant functional improvement. There was no significant difference observed in group B (0.54, 95% CI: -0.41-1.5). Although EKFS in group A was significantly improved in women, this was not evident in the men from this group.
- Numbers of NSAIDs used during the final two weeks of the study, significantly decreased compared with the baseline in group A (mean difference = 2.6, 95% CI: 1.3-3.9); while in group B, a reduction in NSAID use was not evident (mean difference = 0.05, 95% CI: -0.87-0.97).
- Patients' compliance, which was recorded according to duration of wearing the insoles, was significantly higher in the neutral wedged insoles' group ($P < 0.001$; Mann-Whitney test). 87% of patients in the neutral wedged insole group wore their insoles for 7 or 8 weeks, whereas only 49% of patients in the laterally elevated wedged insole group wore their insoles for 7 or 8 weeks.

Authors' conclusions:

- This study demonstrated that laterally elevated wedged insoles are significantly more effective than neutrally wedged insoles for pain reduction in medial knee OA, but both significantly reduced knee pain.
- Wearing laterally elevated wedged insoles not only improved the EKFS and VAS, but also significantly reduced the numbers of NSAIDs used to alleviate knee pain.
- This study found better compliance with neutrally wedged insoles in comparison to laterally wedged insoles which may be due to the fact that tightening of the shoes is greater with using the laterally elevated wedged insoles. The neutrally wedged insoles were simply more comfortable to wear than the thicker, laterally elevated wedged insoles.
- The results have shown that both interventions have a potential role in conservative pain management of osteoarthritis of the knee. The lateral elevated wedged insole proved better at reducing pain.

Comments:

- Laterally elevated wedged insoles have a small beneficial effect in knee OA and this conclusion is in agreement with the 2005 Cochrane on this topic (Brouwer). The significant clinical effects in pain reduction and improved function might be regarded as modest, but the accompanied biomechanical changes as shown by Jones (2013) could potentially aid in reducing disease progression.
- A true no intervention control group was not utilized in this study even though for this type of intervention it would be ethically appropriate.
- The authors did report the number of weeks insoles were worn by each group, but failed to report the daily usage results for the two interventions. As with any intervention requiring persistent use, accurate measurement of usage is required to both capture the true benefit and possible adverse effects. Perhaps the laterally elevated wedged insole group would have shown even greater improvement if the insoles had been worn for a greater number of weeks.
- Despite the fact that men in group A participating in this study failed to show any significant benefits in pain reduction, improvement in function, or reduction in the numbers of NSAIDs used for alleviating pain, these outcomes improved in the men from group A after intervention. The number of male participants was small in each group (only 8 in Group A and 9 in Group B) which most likely limited the power of this small subset analysis to show any significant differences.
- Analyses of between group differences for the main outcome measures was not reported by the authors. This information would have been useful to determine if there were any significant differences between the two treatments in any of the clinical outcomes.
- Sample size calculations were not reported and so it is unknown whether the study was adequately powered to find significant differences.
- One potential limitation of this study is that the effect of weight reduction on knee pain was not examined.
- This study did not go beyond a 2 month intervention period for all outcomes, and it is possible that there are benefits of intervention beyond 2 months that this study did not capture. Limiting the study protocol to a total of 2 months for each intervention may have impacted the ability of the study to achieve the maximal therapeutic benefit of orthoses for many participants and thereby reduced the ability of the study to show a greater effect for either intervention. This would underestimate the effect of the intervention.
- It was impossible to blind participants to the intervention they were receiving in this open label trial. Assessment of the outcome measures was therefore liable to ascertainment bias.
- Side effects of either of the interventions were not addressed by the authors.
- Future research should seek to identify the longevity of the biomechanical and clinical effects, focusing on whether the observed biomechanical changes could prevent disease progression.

Assessment:

This study is adequate for some evidence that laterally elevated wedged insoles are more effective in reducing pain, improving function, and reducing NSAID usage than neutrally wedged insoles in adults with medial compartment knee osteoarthritis. Participants wore

the neutral insoles more consistently than the elevated insoles, and this may reflect on their comfort and greater acceptance of use.

Reference:

Brouwer R, Van Raaij T, Jakma T, et al. Braces and orthoses for treating osteoarthritis of the knee. *Cochrane Database of Systemic Reviews* 2005; Jan 25(1).

Jones RK, Nester CJ, Richards JD, et al. A comparison of the biomechanical effects of valgus knee braces and lateral wedged insoles in patients with knee osteoarthritis. *Gait and Posture* 2013; 37:368-372.