Jones RK, Nester CJ, Richards JD, and 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.

Critique author: Linda Metzger 12-05-14

Design: Randomized Cross-Over Study

Objective: To compare the biomechanical and clinical effects of valgus knee braces and lateral wedged insoles in patients with knee osteoarthritis.

Population /sample size/setting:

- 28 volunteers (16 males, 12 females, mean age 66.3 years) with unilateral medial tibiofemoral osteoarthritis were recruited in the United Kingdom.
- Inclusion criteria included Grade II or Grade III Kellgren Lawrence Scores and confirmation of medial joint space narrowing by a consultant orthopaedic surgeon.
- Exclusion criteria included lateral compartment or patellofemoral OA, rheumatoid arthritis, surgery within the past 6 months, previous stroke, hip or ankle symptoms, or a body mass index above 35.

Interventions:

- One intervention was wearing a pair of lateral wedged insoles manufactured and fitted by a podiatrist. The second intervention was wearing an off-the-shelf valgus knee brace (Donjoy OAdjuster, DJO, Vista, USA) fitted by the same trained individual according to the manufacturer's specification.
- Patients were instructed to wear the intervention every day during daily activities.
- Each intervention was worn by all patients for a separate two week period.
- Biomechanical and clinical data were collected before and after use of each intervention, with a two week wash out period when no intervention was used between the two interventions (weeks 2–4). Patient data was collected and measured within one day of the 2, 4, and 6 week due dates from their initial visit.
- Baseline data was walking with no intervention in a standardized shoe.
- The order of intervention use by each participant was randomized using block allocation.
- Biomechanical kinematic data (100 Hz) were collected using eight cameras (Qualisys Proreflex, Gothenburg, Sweden). Biomechanical kinetic data (200 Hz) were collected using two Kistler 9281C (Alton, UK) forces plates. Each patient completed a minimum of 5 walking trials at a self-selected pace. Patients wore standard footwear, which was a flat, thin soled, leather shoe.

Main outcome measures:

- The primary biomechanical outcome measured was external knee adduction moment (EKAM).
- The primary clinical outcomes measured were self-reported Western and McMaster Universities Osteoarthritis Index (WOMAC) pain score, WOMAC function score, and Visual Analog Scale (VAS) for pain. Daily pain scores were collected on diary cards for

14 days using the 100 mm Visual Analog Scale (VAS) while the participant wore the insole and the brace. An average intervention usage (compliance), and pain score for each intervention was determined by summing and averaging the scores while the interventions were worn over the 14 days. A reduction in all of the scores denoted improved pain, and function.

- All participants completed questionnaires and WOMAC and biomechanical assessments before interventions (baseline) and at each data collection time point (2, 4, and 6 weeks after baseline). Input and interpretation of WOMAC and other questionnaire data collected was completed by each assessor and participant without knowledge of the outcomes of the biomechanical data.
- Sample size: To achieve 80% power at a 2-sided 5% significance level, 28 patients were needed in order to find a significant difference at the 95% level between the valgus knee brace and the lateral wedged insole, with a predicted effect size of 0.78.
- Usage results were significantly different between the two interventions. Participants wore the lateral wedge insole significantly longer with 71% of the users wearing it longer than 4 hours each day. Only 29% of the users wore the knee brace for more than 4 hours per day. Participants rated the lateral wedge significantly more comfortable to wear than the knee brace.
- There was no significant differences in the external knee adduction moment (EKAM) or knee kinematics data between baseline 1 (week 0) and baseline 2 (week 4), thus indicating that there was no carry over effect between the use of the first and second intervention. In addition, there were no significant differences between any of the WOMAC sub-scores or VAS scores at baseline 1 and 2.
- Both the valgus knee brace and lateral wedged insole significantly reduced the EKAM compared to baseline data (0.555 N m/kg). There was a statistically significant greater reduction in EKAM in the lateral wedged insole (0.48 N m/kg or 12%) compared to the valgus knee brace (0.51 N m/kg or 7%).
- The WOMAC pain and function scores significantly decreased for both the knee brace (49.3 to 38.6 pain, 54 to 47.2 function) and the lateral insole (49.3 to 36.8 pain, 54 to 46.7 function) compared to baseline, along with a statistically significant reduction in pain (VAS) for both the knee brace (6.7 to 5.3) and the lateral insole (6.6 to 5.5) in comparison to the no intervention period. There were no significant differences between the two interventions for any of the pain or function measures.

Authors' conclusions:

- Both the valgus knee brace and the lateral wedged insole reduced the EKAM during walking. Greatest reductions were achieved by the lateral wedged insole (12% reduction compared to 7% for the valgus knee brace). These reductions might be regarded as modest but these biomechanical changes were accompanied by significant clinical responses in pain reduction and improved function in both cases.
- Improvements in pain and function scores were comparable for both the valgus knee brace and lateral wedged insole. There were no significant differences between the two treatments in any of the clinical outcomes.
- This study demonstrates that given the potential role of knee loading in osteoarthritis progression, both treatments reduce this, but lateral wedge insoles appear to have a greater effect.

- Subjective outcome measures, such as self-reported pain and physical function, as used in this study, are particularly subject to placebo responses. It is possible that a placebo effect or enhanced proprioception is responsible for the improved self-reported pain and function scores, although we would not expect either to alter knee alignment as seen in the brace, or change the EKAM produced by both devices.
- The results have shown that both interventions have a potential role in conservative management of medial tibiofemoral osteoarthritis of the knee. The lateral wedged insole proved better at reducing the EKAM. Clinical outcomes were the same, since comparable changes in pain and function were reported for both orthoses.
- 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.

Comments:

- In this randomized cross-over study participants acted as their own control and therefore a control group was not needed.
- The use of a cross-over design can be controversial, but is a major strength of this study. The advantage of this type of design is economy of sample size, particularly in a heterogeneous group. However, this design works well for osteoarthritis which is a fairly stable, chronic condition vs a progressive condition over the course of a short 6 week study and minimizes any period effects.
- The use of the cross-over design works well for the interventions selected as well. Since the validity of the comparison is based on a lack of carry-over between interventions, and this study showed no carry-over effect from either orthosis in biomechanical or clinical measures, the validity of the study is intact.
- Because the cross-over design is a “within subject” study design, it removes natural variation between subjects and provides a more precise comparison of interventions. Since the characteristics of the participants were equivalent at baseline for each of the intervention periods, confounding was minimized in the comparison of interventions.
- Since no carry-over effect was observed, this indicates that the orthoses did not have any sustained effect once they were no longer worn. This suggests achieving longer term benefits requires long term use. As with any intervention requiring persistent use, a longer term evaluation is required to both capture the true benefit and possible adverse effects.
- This study did not go beyond a 2 week intervention period for all outcomes, and it is possible that there are benefits of intervention beyond 2 weeks that this study did not capture. Limiting the study protocol to a total of 2 weeks 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.
- Reducing medial joint loading or the EKAM early is an optimal conservative treatment for knee osteoarthritis in an attempt to reduce pain, maintain function but also to potentially arrest disease progression.
- The lateral wedged insoles demonstrated greater levels of acceptance and compliance by patients. After the completion of the study, each participant was allowed to choose one of the two interventions. All participants chose the insole, with two combining it with the

valgus knee brace. Van Raaij (2010) also found greater compliance among insole users compared to brace users.

- 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.
- The authors diligently reported the daily compliance and usage of both interventions over the course of 2 weeks. Usage was much greater for the insole intervention than the brace with 71% of the insole users wearing it more than 4 hours per day compared to only 29% of the brace users. Perhaps the brace intervention would have shown greater improvement if its daily usage time was also greater.
- Side effects of either of the interventions were not addressed by the authors.

Assessment*:*

- This study provides some evidence that conservative management using either the valgus knee brace or the lateral wedged insole reduces pain and improves function in adults with medial tibiofemoral osteoarthritis of the knee. There were no significant differences between the two orthoses in any of the clinical outcomes. Participants wore the insoles more consistently than the braces, and this may reflect convenience and greater acceptance of use.

Reference*:*

Van Raaij TM, Reijman M, Brouwer RW, et al. Medial Knee Osteoarthritis Treated by Insoles or Braces A Randomized Trial. Clin Orthop Relat Res 2010; 468:1926–1932.