Lateral wedge insoles worn for 12 months provided no symptomatic or structural benefit for people with medial knee osteoarthritis

Synopsis


**Question:** Do lateral wedge insoles or flat control insoles improve symptoms and slow structural disease progression in medial knee osteoarthritis? **Design:** A double blind randomised, controlled trial with stratification by disease severity (Kellgren and Lawrence Grades 2 and 3) and sex. Group allocation was carried out in permuted blocks of 6 to 12 using an independent researcher. **Setting:** Community setting in Melbourne, Australia. **Participants:** Men and women of 50 years or more with average knee pain on walking of more than 3 on an 11-point numerical rating scale (0 = no pain, 10 = worst pain possible) at telephone screening, pain located over the medial knee compartment, evidence of osteophytes in the medial compartment or medial joint space narrowing on an X-ray film, and radiological knee alignment of 185 deg or less indicating neutral to varus (bow leg) knee alignment. Key exclusion criteria included questionable or advanced radiographic knee osteoarthritis (Kellgren and Lawrence Grades 1 and 4), predominant patellofemoral joint symptoms on clinical examination, knee surgery or intra-articular corticosteroid injection within six months, and regular use of a gait aid. Randomisation of 200 participants allocated 103 to wear wedged insoles and 97 to wear flat control insoles. **Interventions:** Participants wore the insoles bilaterally in their own shoes every day. They were provided with two pairs of insoles, which were replaced every four months. The lateral wedge (5 degrees) insoles were made of high density ethyl vinyl acetate (similar to the midsole in a running shoe) and were wedged along the lateral border of the foot. The control insoles were made of easily compressible low density ethyl vinyl acetate but with no wedging. **Outcome measures:** Primary symptomatic outcome was change in overall average knee pain (past week). Primary structural outcome was change in volume of medial tibial cartilage from magnetic resonance imaging scans. Secondary symptomatic measures included changes of pain, function, stiffness, and health-related quality-of-life. Secondary structural outcome included progression of medial cartilage defects and bone marrow lesions. **Results:** 179 (89 lateral wedge insoles, 90 control insoles) out of 200 participants completed the trial. After 12 months between-group differences did not differ significantly for the primary outcomes of change in overall pain (−0.3 points, 95% CI −1.0 to 0.3) and change in medial tibial cartilage volume (−0.4 mm³, 95% CI −15.4 to 14.6), and confidence intervals did not include minimal clinically important differences. None of the changes in secondary outcomes showed differences between groups. **Conclusion:** Lateral wedge insoles worn for 12 months provided no symptomatic or structural benefits compared with flat control insoles.

Commentary

Weak recommendations based on low level evidence preceded the publication of a previous randomised controlled trial comparing the ideal condition of custom lateral wedged insoles to neutral insoles in the same walking shoes that found no difference at one year (Barrios et al 2009). The American Academy of Orthopaedic Surgeons Guideline on the Treatment of Knee Osteoarthritis guideline, published in 2009, consequently stated ‘We suggest lateral heel wedges not be prescribed for patients with symptomatic medial compartmental OA of the knee. Level of Evidence: II, Grade of Recommendation: B’ (Richmond et al 2010). This well-designed and executed study by Professor Bennell and colleagues demonstrates that in the most common prescription of these orthoses (off-the-shelf orthoses in the patient’s own shoes), there is no benefit in symptoms or progression of disease. ‘First, do no harm’ is the maxim from which the principal precepts of medical ethics, nonmaleficence, is derived. Nearly half of the participants complained that the lateral wedge insole caused discomfort; in 10% of these individuals the discomfort was severe. While 30% of participants in the neutral orthoses group had some discomfort, only 1% was rated as severe. While prescription of insoles is inexpensive and simple, it is now clear that lateral insoles provide no therapeutic or disease modifying benefit and cause discomfort in a large percentage of patients. This study should sound the death knell for the use of lateral wedged insoles for the treatment of medial compartment knee osteoarthritis.

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References