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Do wedged insoles improve outcomes in patients with knee osteoarthritis?

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SUMMARY

Biomechanical factors have a critical role in the onset and progression of osteoarthritis (OA). A recent carefully designed, randomized, controlled trial by Rodrigues and colleagues examined the use of an 8 mm medial-wedge insole for the management of lateral compartment knee OA associated with a valgus deformity. In this study the use of a wedged insole, together with ankle straps to provide ankle stability, was associated with substantial improvements in pain and functional status compared with a control, neutral insole; however, the trial sample size was small. Previous studies on lateral-wedge insoles for medial compartment knee OA have had conflicting results. Until larger, more-definitive trials are conducted, it would be reasonable for clinicians to provisionally recommend medial-wedge insoles for patients with lateral knee OA and a valgus deformity.

Keywords

alignment; insole; knee; osteoarthritis; valgus deformity

COMMENTARY

Symptomatic osteoarthritis (OA) affects over 27 million people in the US.¹ The cost and burden of OA are likely to increase markedly in the next few decades as populations age and the global obesity epidemic deepens. Unfortunately, research on the biological mechanisms of OA has not translated into pharmacological therapies that arrest or reverse the structural consequences of the disease. In fact, it is not yet clear which tissues should be targeted by pharmacological interventions, as OA is characterized by pathological changes in, among others, cartilage, bone, meniscus and synovium.²

Whereas progress on the pharmacological front has been slow, there is growing recognition that biomechanical factors have a critical role in the onset and progression of OA. In

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COMPETING INTEREST

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particular, obesity and valgus and varus alignment deformities at the knee are associated with OA incidence and progression.³ These observations conform with the recognition that hip dysplasia and other congenital or acquired mechanical abnormalities can be associated with early OA, and that realignment procedures such as acetabular osteotomy can ameliorate symptoms in this setting.⁴

The importance of biomechanical factors in the pathogenesis of OA has stimulated interest in biomechanical approaches to treatment of knee OA, which include obesity management to reduce joint loading and a variety of realignment strategies. High tibial osteotomy has been successful in patients with predominantly medial compartment knee OA,⁴ providing proof of principle for the potential role of realignment in this setting. The procedure is invasive and expensive, however, and is associated with serious, albeit infrequent, complications. Thus, less invasive approaches to realignment are being sought.

Wedge insoles are an appealing realignment strategy for patients with predominantly unicompartment knee OA. To date, most research has focused on lateral-wedge insoles for medial knee OA. The lateral lift at the foot provided by such insoles shifts load from the medial to the lateral compartment of the knee. Whereas earlier studies of this approach demonstrated modest clinical benefits,⁵ a recent rigorous, randomized, controlled trial of a 5 ° lateral-wedge insole failed to demonstrate any improvement.⁶ Thus, the efficacy of lateral-wedge insoles for medial knee OA remains uncertain. Furthermore, little is known about the use of wedged insoles for lateral compartment knee OA, a less common condition than medial knee OA.

Rodrigues and colleagues compared a medial-wedge insole with a neutral insole among patients with lateral knee OA.⁷ The biomechanical goal of the intervention was to shift loading to the medial knee compartment. In addition, the investigators used an ankle strap to reduce compensatory subtalar motion, thereby optimizing the effect of the insole at the knee.

Despite the small sample size ($n = 30$) and short duration of the study (8 weeks), the results were striking. Patients randomly assigned to receive neutral insoles ($n = 14$) showed little improvement on the primary measures of knee pain and functional status. Those who wore medial-wedge insoles ($n = 16$), however, improved by more than 1 SD on measures of pain at rest and pain on movement, as well as on Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Lequesne functional status scores. Furthermore, the femorotibial tilt angle changed in the expected direction in the wedged insole group, confirming the biomechanical success of the intervention. Although the work by Rodrigues and colleagues is welcome at this time of therapeutic standstill in the pharmacologic management of OA, caution should be exercised when translating their findings to clinical care, for several reasons. Firstly, the study was limited by its small sample size. Secondly, patients randomly assigned to receive the wedged insole had higher pain and WOMAC scores at baseline than did those in the control group. Although these differences did not reach statistical significance, some of them (e.g. a difference of 9 points in WOMAC score) are clinically relevant and raise the question of whether the groups differed in important ways that could not be measured and adjusted for. Randomization, especially in the absence of stratification, is no guarantee of balance in studies with small sample sizes.

These caveats are particularly important in view of the negative results of a study by Baker and colleagues, in which a number of the methodological limitations of earlier, smaller studies of lateral-wedge insoles were overcome.⁶ Biomechanical factors could account for the differential effectiveness of wedged insoles in medial versus lateral knee OA. Furthermore, it is possible that the concomitant use of an ankle strap—employed by Rodrigues and colleagues but not by Baker *et al.*—is critical to the success of the insole intervention. The use of subtalar strapping or bracing in the context of wedged insole use should be examined in a trial setting.

On the basis of Rodrigues and co-workers' findings, it would seem reasonable to recommend medial-wedge insoles together with an ankle brace in patients with valgus deformity and lateral knee OA—there is little to lose. This recommendation should be provisional, however, as larger trials are needed to confirm the efficacy of medial-wedge insoles and adjunctive ankle support in this setting.

PRACTICE POINT

Although its efficacy remains to be definitively established, the use of a medial-wedge insole with an ankle strap can be provisionally recommended for patients with lateral compartment knee osteoarthritis and a valgus deformity.

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REFERENCES

1. Lawrence RC, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: part II. *Arthritis Rheum.* 2008; 58:26–35. [PubMed: 18163497]
2. Felson DT, et al. Osteoarthritis: new insights. Part 1: the disease and its risk factors. *Ann Intern Med.* 2000; 133:635–646. [PubMed: 11033593]
3. Sharma L, et al. The mechanism of the effect of obesity in knee osteoarthritis: the mediating role of malalignment. *Arthritis Rheum.* 2000; 43:568–575. [PubMed: 10728750]
4. Steppacher SD, et al. Mean 20-year followup of Bernese periacetabular osteotomy. *Clin Orthop Relat Res.* 2008; 466:1633–1644. [PubMed: 18449617]
5. Brouwer RW, et al. Braces and orthoses for treating osteoarthritis of the knee. *Cochrane Database of Systematic Reviews.* 2005; (Issue 3) Art No.: CD004020.
6. Baker K, et al. A randomized crossover trial of a wedged insole for treatment of knee osteoarthritis. *Arthritis Rheum.* 2007; 56:1198–1203. [PubMed: 17393448]
7. Rodrigues PT, et al. Effectiveness of medial wedge insole treatment for valgus knee osteoarthritis. *Arthritis Rheum.* 2008; 59:603–608. [PubMed: 18438931]