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Biomechanical Footwear for Osteoarthritic Knee Pain

To the Editor Dr Reichenbach and colleagues[1] reported that among participants with knee pain from osteoarthritis, use of biomechanical footwear compared with control footwear resulted in an improvement in pain after 24 weeks of follow-up. There are several issues regarding the trial that are worth considering.

First, the positioning of the external pods on the biomechanical footwear was individually adjusted based on the clinical judgment of the therapists. Although the adjustment was made in accordance with gait patterns and reported pain intensity during walking, it is not known how these standards were applied; therefore, replication of the findings in the trial may be difficult.

Second, patients randomized to the biomechanical footwear group had more self-reported visits with a physiotherapist than patients in the control footwear group (22 vs 12, respectively), which resulted in more contact time. Although the difference was not statistically significant, this may have accentuated placebo effects and therapeutic alliance and may have contributed to an improvement in pain.

Third, more patients in the biomechanical footwear group (9 of 111) underwent or planned to undergo knee replacement surgery than in the control footwear group (5 of 109). Although the total number was small and the difference was not statistically significant, this finding warrants further investigation.

Fourth, the primary outcome was pain in the index knee assessed with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscore, which is a subjective measure. At the end of treatment (24-week follow-up), the WOMAC pain subscore in both groups was generally low and may not be sensitive enough to detect a potential reduction in pain.

Fifth, this study failed to explore changes in knee adduction moments. It has been demonstrated that the knee adduction moment reflects medial-to-lateral knee joint load distribution during gait, and has emerged as an important treatment target in osteoarthritis.[2] The absence of important objective data may weaken the value of the study.

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In Reply Dr Lei and colleagues correctly state that the positioning of the external pods of the biomechanical footwear in our trial[1] was individually adjusted. The treatment protocol for adjusting the pods was described in detail in Supplement 3 in the article. This is considerably more detail than most physical therapy or exercise intervention trials provide. Adjustments were done according to this protocol by experienced and trained technicians based on gait patterns and patient-reported symptoms. The attempt to shift the center of pressure in the shoe and foot laterally in patients with medial knee osteoarthritis has been a central principle of most shoe modifications and wedge insoles tested for medial knee osteoarthritis.[2,3] Independent groups aiming to replicate our findings should follow the treatment protocol but will additionally need to ensure appropriate training of therapists by the manufacturer of the footwear.

Lei and colleagues argue that a between-group difference in the self-reported number of visits to physiotherapists may have biased the results of our trial. These visits were unrelated to the trial and took place as part of routine care. The reasons for health care use were not collected; therefore, it remains unclear whether visits to physiotherapists were related to knee osteoarthritis or to other conditions. In addition, the number of trial-specific study visits and the contact time with technicians

and study nurses were identical between groups. To address this concern, we adjusted the analysis of the primary outcome, WOMAC pain subscores standardized to range from 0 to 10, for the self-reported number of visits to physiotherapists. The estimated mean difference after adjustment was −1.4 (95% CI, −1.8 to −0.9), and the overall conclusions remain unchanged.

Two knee replacement surgeries were performed in participants allocated to the control footwear group compared with none in participants allocated to the biomechanical footwear group. These participants reported WOMAC pain subscores of 4.4 and 4.3 at the clinical visit before surgery. At the end of the trial, an additional 12 participants reported planned knee replacement surgeries. Median WOMAC pain subscores at 24 weeks were 2.6 (interquartile range, 1.0-6.0) in those with planned knee replacement surgery vs 1.3 (interquartile range, 0.6 to 2.6) in those without planned knee replacement surgery. Trials with longer follow-up are required to assess the long-term efficacy and safety of the biomechanical footwear.

The WOMAC pain subscore is a widely used primary end point in knee osteoarthritis research. We included participants with mild to moderate knee pain and acknowledged that the results of our trial may not be generalizable to individuals with severe pain. However, the WOMAC pain subscore is sensitive to change, as shown by marked differences within groups between baseline and follow-up at 24 weeks and between groups at 24 weeks.

It was beyond the scope of our trial to assess changes in knee adduction moments using 3-dimensional gait analyses. However, motion analyses of this biomechanical footwear previously have been shown to reduce the adduction moment in people with medial osteoarthritis.[4,5]

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Delayed Antibiotic Prescriptions

To the Editor Drs Rowe and Linder[1] argued too strongly that when clinicians prescribe delayed antibiotics, they are abdicating their responsibility and doing harm, and they did not cite relevant evidence.

Nuanced interventions cause mixed messages if used carelessly. Nested qualitative work within trials of delayed prescription suggests that when used properly, delayed prescriptions are unlikely to give mixed messages about the need for antibiotics. The systematic review referenced in the Viewpoint suggests delayed prescriptions result in approximately 30% of patients taking an antibiotic, but a policy of initially not offering an antibiotic results in 15% of patients ultimately being prescribed antibiotics (ie, not that marked of a difference).

Adequately powered prognostic studies document that 15% to 20% of patients with initially uncomplicated illness consult with ongoing, worsening, new, or progressive symptoms, and some (0.5%-2%) require hospital treatment. Allowing for confounding by indication, delayed prescription has been associated with a significant reduction in reconsultations with prolonged or progressive symptoms in very large cohorts (n = 28 883 in 3C,[2] risk ratio [RR], 0.64; n = 12 829 in DESCARTE,[3] RR, 0.61; n = 8320 in TARGET,[4] RR, 0.55) compared with immediate or no antibiotics. Complications or hospital admissions were reduced by 20% in 3C and TARGET (albeit not significantly).[2,4] The largest trial of antibiotics for lower respiratory tract infections found that for bacterial and viral coinfection (10% of the sample), antibiotics reduced reconsultation with prolonged or progressive illness.[5] Plausibly when an initial viral infection is followed by an opportunistic bacterial infection, a delayed prescription effectively and promptly deals with any progression, hence reducing reconsultations with progressive illness.

Efficient use of scarce health care resources is important. Economic modeling by the National Institute for Health and Care Excellence suggested that delayed prescriptions are more efficient than no offer of antibiotics due to lower reconsultation and complications rates.[1]

Most patients do not need antibiotics, even for conditions advocated in current US guidelines (otitis, sinusitis), and it is not necessary to advocate the blanket use of delayed prescriptions. However, if clinicians are considering antibiotics, a delayed prescription may be preferable because it is associated with reduced reconsultations for worsening illness. Given some advantages of delayed prescriptions, a balanced approach for the future is perhaps the