Reviewer’s report

Title: Laterally wedged insoles in knee osteoarthritis: do biomechanical effects decline after one month of wear?

Version: 1 Date: 6 July 2009

Reviewer: Yoshitaka Toda

Reviewer’s report:

I have been very impressed by the excellent and active works of this group on laterally wedged insole for osteoarthritis of the knee. Furthermore, I noticed current study was the first to evaluate change in the biomechanical effects of laterally wedged insole over any time. This report is very interesting for me. However, I do need some reassurance on some aspects of the trial before feeling completely confident.

Major essential revision:

The authors already reported immediate effects of laterally wedged insoles on walking pain, knee adduction moment, and static alignment, and whether these immediate effects predicted clinical outcome after three months of wearing insoles in medial knee osteoarthritis. Forty patients with knee OA were tested in random order with and without a pair of 5 degrees full-length lateral wedges. Regression analyses demonstrated that magnitude of immediate change in walking pain and the first peak adduction moment with insoles were predictive of clinical outcome at 3 months (Arthritis Care & Research 2008 59: 408-15).

Is the current study supplementary report of study published in AC&R?

I think the originality is the most important factor for scientific reports, an author should not report many papers from same study design in different journals and series studies should summarize in one report for readers to understand easily. Please be clarified the importance of the result form this study comparing with previous study in the discussion section.

Minor essential revision:

1. The authors did not consider the effect of heel heights of participants own shoes from recent reports.

Kerrigan et al. showed that even women’s shoes with a 1.5 inch heel (moderate high-heeled shoes) significantly increased knee varus moment compared with walking barefoot (Kerrigan DC, Johansson JL, Bryant MG, Boxer JA, Della Croce U, Riley PO. Moderate-heeled shoes and knee joint torques relevant to the development and progression of knee osteoarthritis. Arch Phys Med Rehabil. 2005 86:871-5). On the other hand, Shakoor et al. reported that peak joint loads at the knees significantly decreased during barefoot walking, with an 11.9% reduction noted in the knee varus moment compared with when wearing
commercial walking shoes. It was of interest that they observed relative load reductions of nearly 12% at the knee merely by walking barefoot, which appears to be substantially greater than the experience with lateral wedge inserts by Kerrigan et al. (Shakoor N, Block JA. Walking barefoot decreases loading on the lower extremity joints in knee osteoarthritis. Arthritis Rheum 2006 54:2923-7). Shakoor et al. mentioned that most commercial walking shoes have a partial lift at the heel; thus, the complete lack of a "heel" during barefoot walking may be effective for reducing the peak torque at the knee.

In this study, inserted full-length insole reduced 5.1% and 4.2 % at the peak 1 knee adduction moment in baseline and one month assessments, respectively. Comparing to the result by Shakoor, is the full-length of insole more effective clinically than taking off shoes for patients with knee OA?

Concerning to the clinical study about shoes like barefoot condition, the shoes had scaphoid sole named “Massai Barefoot Technology shoes” could significantly reduce pain evaluated by WOMAC index in subjects with moderate knee OA as shown by Nigg et al (Nigg BM, Emery C, Hiemstra LA. Unstable shoe construction and reduction of pain in osteoarthritis. Med Sci Sports Exerc 2006 38:1701-8).

2. The usage of laterally wedged insole was not only placing within the shoes. Western life style is not unique whole over the world. The insole without shoes would be different results from this study.

Kuroyanagi et al. showed that the varus moment was reduced 13.1% due to wearing the lateral wedged insole with elastic strapping of the subtalar joint (the strapped insole), which was reported by Toda et al., added to a bare foot, compared with walking barefoot for 37 patients with knee OA (Kuroyanagi Y, Nagura T, Matsumoto H, Otani T, Suda Y, Matsuzaki K et al: Biomechanical effect of the lateral wedged insole with ankle strapping for the patients with medial knee osteoarthritis. Osteoarthritis Cartilage 2007 27: 932-6). Toda et al compared the improvement of Lequesne index in the 12 week study between a neutrally wedged insole inserted into shoes (n=45), a wedged insole inserted into shoes (n=45), a sock-type ankle supporter with a wedged insole when wearing socks or flat footwear (n=46), the subtalar strapped insole when wearing shoes (n=45) and the strapped insole with socks or flat footwear (n=46). The most improvement was found in the group wearing the strapped insole with socks or flat footwear (Toda Y, Tsukimura N. Influence of concomitant heeled footwear when wearing a lateral wedge insole for medial compartment osteoarthritis of the knee. Osteoarthritis Cartilage. 2008 16:244-253).

Please insert the possibility that other type of insole may develop different results from current results in the discussion section.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable
**Statistical review:** Yes, and I have assessed the statistics in my report.