A new approach to orthotic treatment of knee osteoarthritis using an ankle-foot orthosis
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INTRODUCTION
Conservative treatment options of knee osteoarthritis (OA) include knee unloader braces that, according to a recent systematic review of clinical trials, result in moderate improvements in pain and function [1]. However, it also found that knee brace use is often discontinued due to constraining or poor fit, slipping, and skin irritations [1]. Therefore, an ankle-foot orthosis (AFO, Agilium Freestep) was developed to use the ground reaction force (GRF) in the frontal plane to unload the medial or lateral compartment of the knee without the adverse effects of a knee brace. The present study investigated the biomechanical effects of Agilium Freestep in the gait lab and the clinical effectiveness over 12 months.

METHOD
For the biomechanical study, 12 patients with medial knee OA (mean age 64.3±11.8 y) were subjected to instrumented gait analysis while walking with and without the Agilium Freestep AFO. For the clinical part of the study, 25 patients with symptomatic knee OA (mean age 60.5±11.7 y, 33% grade 1, 55% grade 2, 12% grade 3 after Kellgren & Lawrence, 78% had prior treatment with a knee sleeve or knee brace) were enrolled. After a baseline assessment of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and a visual analog scale (VAS) rating of knee pain, patients were fitted with Agilium Freestep and underwent follow-up assessments after 3, 6, 9, and 12 months. Statistical analyses were conducted using the Student’s t-test with a power of 80%.

RESULTS
In the biomechanical study, Agilium Freestep was found to shift the center of pressure (CoP) under the foot 7-10 mm lateral. In addition, it locks the subtalar joint and employs a calf upright to ensure proper force transmission to the knee joint. As a result, the lever arm of the GRF and thus the external knee adduction moment acting on the medial compartment of the knee was significantly reduced by 14% (p≤.01). In the clinical study, the WOMAC composite score improved significantly from 40.9±13.4 (baseline) to 25.1±22.3 (3-m FU; p=.03), 20.8±17.3 (6-m FU; p<.0001), 20.2±20.1 (9-m FU; p<.0001) and 16.6±23.3 (12-m FU; p<.0001). The three WOMAC subscores for pain, stiffness, and physical function also improved significantly at all follow-ups compared to baseline. The VAS knee pain rating showed improvements at all follow-ups, but attained statistical significance only after 6 and 12 months. Compliance was very high with only 2 patients discontinuing use for reasons unrelated to the orthosis.

DISCUSSION
This study suggests that the biomechanical effects and clinical effectiveness of the Agilium Freestep AFO in mild to moderate knee OA have the same magnitude as those known from biomechanical and clinical trials with knee unloaders [1, 2]. However, long-term patient acceptance of orthosis use might be improved by the AFO.

CONCLUSION
The Agilium Freestep AFO appears to be a promising orthotic treatment of knee OA with similar biomechanical and clinical effects as knee unloaders but improved long-term patient compliance.

REFERENCES

DISCLOSURE
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