

## Evidence Note

**Subject: Microprocessor-Controlled Knee-Ankle-Foot-Orthoses (MP-KAFO)**  
**Latest Review Date: 10/18/2023**

Microprocessor-controlled knee-ankle-foot-orthoses (MP-KAFO) provide the most current level of knee control for individuals with lower extremity weakness. The knee joint design and functionality was inspired by the control utilized in microprocessor knees (MPKs) for individuals with lower limb amputation requiring a prosthetic knee. Currently, the C-Brace® (Ottobock Healthcare Products GmbH, Vienna, Austria) represents the only knee joint that qualifies as a MP-KAFO as described in this document. It has similar stance and swing control function as the analogous prosthetic knee joint produced by the same manufacturer (C-Leg®, Ottobock Healthcare Products GmbH, Vienna, Austria).

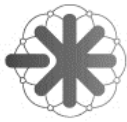
### **Clinical Benefits:**

In two separate randomized, clinical trials, the MP-KAFO has demonstrated clinical benefits over traditional knee control methods for knee-ankle-foot-orthoses (KAFOs).<sup>1,2</sup>

Rutz and colleagues evaluated the efficacy of the enhanced functionality of an MP-KAFO in reducing fall risk, improving gait, and enhancing patient quality of life as compared to a conventional KAFO over a 3-month use period.<sup>1</sup> The specific model of MP-KAFO used was used C-Brace®, similar results should be expected for MP-KAFOs with similar features. The study included 102 participants above 18 years of age who actively used a unilateral or bilateral LKAFO, posterior-offset (PO)-KAFO or stance-controlled orthosis (SCO) in the 3 months prior. The inclusion criteria consisted of a Berg Balance Scale (BBS) score below 45, commitment to use of the MP-KAFO at least 1-2 hours per day, 5 days per week; and the physical capability to be fit to the MP-KAFO. Each potential participant was screened and assessed for their ability to safely use the MP-KAFO trial tool prior to enrollment.

After three months of use, participants wearing the MP-KAFO demonstrated improved balance (i.e., higher BBS scores ( $p < 0.001$ )) than those wearing the conventional KAFO. Additionally, there was a significantly increased number of participants improved balance to no longer be classified as increased fall risk with MP-KAFO use than compared with KAFO use and at baseline (i.e., number of individuals with BBS scores below clinical threshold of 45,  $p < 0.05$ ). Furthermore, a significantly increased number of participants improved balance to extent of no longer being classified as “100% fall risk” with the MP-KAFO as compared with KAFO use and baseline (i.e., number of individuals with BBS scores below clinical threshold of 40,  $p < 0.05$ ).

After use of the MP-KAFO, the Dynamic Gait Index (DGI) was significantly improved compared to baseline and with conventional KAFO use. Similarly, the quality of stair ambulation evaluated with the Stair Assessment Index SAI showed a significant improvement in downstairs gait ( $p < 0.05$ ). The number of self-reported falls by participants was 80% lower with MP-KAFO use than with conventional KAFO use. In addition, the number of participants who fell multiple times during the three-month use period was significantly lower with the MP-KAFO than with KAFO use. Scores on the



Activity-specific Balance Confidence questionnaire (ABC) did not differ significantly at baseline -- however, ABC scores improved significantly with MP-KAFO use compared to baseline and the KAFO condition. Additionally, the number of participants with increased fall risk as indicated by ABC scores below 67 was significantly lower after MP-KAFO use than with KAFO use and at baseline. Similarly significant trends demonstrating benefits of MP-KAFO use over KAFO were observed with scores on the Orthotics & Prosthetics User survey – Lower Extremity Functional Status (OPUS-LEFS), the Reintegration into Normal Living Index (RNLI), portions of the Work Limitations Questionnaire (WLQ-25) and the EQ-5D-5L to assess health-related quality of life during the use of different orthoses. The study concluded that MP-KAFO use improves both performance-based and patient-reported mobility outcomes, as demonstrated by significant reduction in fall risk as well as improved functional abilities.

Deems-Dluhy et al.<sup>2</sup> conducted a randomized controlled trial to evaluate the potential of a MP-KAFO to improve balance, quality of life, and functional mobility in individuals with lower-extremity impairments as compared to a SCO and conventional KAFO over a use period of one month. The trial comprised 18 participants above 18 years of age who actively used a unilateral KAFO or SCO for impairments due to neurologic or neuromuscular disease, orthopedic disease, or trauma. Each potential participant was screened and assessed for their ability to safely use the MP-KAFO trial tool prior to enrollment.

After one month of use, significant improvements in performance-based measures were observed in participants using the MP-KAFO, but not the SCO. Significant improvement was found in participant's self-selected gait speed, measured by the 10-Minute Walk Test (10MWT) ( $p=0.023$ ), static balance measured by BBS ( $p=0.01$ ), dynamic balance measured by the FGA ( $p=0.002$ ) and stair descent measured by the SAI ( $p<0.001$ ). Similarly, significant differences were seen between the post-MP-KAFO versus post-SCO, with the MP-KAFO performing significantly better than the SCO for each of the above outcome measures at this timepoint. In addition, participants using the MP-KAFO walked significantly farther ( $p=0.013$ ) as measured by the 6-Minute Walk Test (6MWT) in comparison to the baseline group. Participants indicated significantly higher QOL scores on the OPUS-QOL after using the MP-KAFO compared to baseline ( $p=0.02$ ) and the post-SCO group ( $p=0.003$ ). Additionally, participants reported fewer falls when wearing the MP-KAFO versus an SCO or locked KAFO. The study concluded that MP-KAFO use led to improvements in both static and dynamic balance, gait speed, walking endurance, stair descent, and self-reported falls in contrast to SCO use. Through improvements in self-reported QOL, the sample also demonstrates how use of an orthotic device can aid the achievement of goals and increase participation in life activities.

The literature underscores the clinical advantage of MP-KAFO use for individuals with lower extremity weakness across functional markers of health, enabling affected patients to achieve a more optimal quality of life.



## Bibliography

1. Ruetz A, DiBello T, Toelle C, et al. A microprocessor stance and swing control orthosis improves balance, risk of falling, mobility, function, and quality of life of individuals dependent on a knee-ankle-foot orthosis for ambulation [published online ahead of print, 2023 Sep 26]. *Disabil Rehabil.* 2023;1-14. doi:10.1080/09638288.2023.2258342
2. Deems-Dluhy S, Hoppe-Ludwig S, Mummidisetty CK, Semik P, Heinemann AW, Jayaraman A. Microprocessor Controlled Knee Ankle Foot Orthosis (KAFO) vs Stance Control vs Locked KAFO: A Randomized Controlled Trial. *Arch Phys Med Rehabil.* 2021;102(2):233-244. doi:10.1016/j.apmr.2020.08.013