NEW: Clinical Evidence for Microprocessor-Controlled Feet

Two larger real-world, cross-sectional studies on the use of the powered ankle-foot components Empower and BiOM by patients with unilateral transtibial amputations were published in 2022. Both studies found that powered feet have the potential to reduce knee pain in the sound and amputated limb, low-back pain, knee- and back-pain pain-related activity restrictions as well as to improve patient-reported mobility to clinically meaningful extents. The studies were approved by the Institutional Review Board (IRB) of the Baylor College of Medicine in Houston, TX. They invited 250 patients who had been fit with a BiOM or Empower foot in the past to answer an online survey. Patients were asked to answer some demographic and prosthetic questions and to rate their current foot and recall the ratings for their previously used prosthetic foot. Both studies inquired average sound knee pain, amputated side knee pain, and low-back pain using 0-10 numerical pain rating scales (NPRS). In addition, one study inquired the PROMIS Pain Interference Scale and the PLUS-M for patient-reported mobility (1). The other study surveyed the ADL domain of the Knee Injury and Osteoarthritis Outcomes Score (KOOS-ADL) for knee-pain-related activity restrictions and the Oswestry Disability Index (ODI) for back-pain-related activity restrictions (2). As patients tend to overrate past pain and function, recalled ratings were adjusted using recommendations in the scientific literature unless they would have favored the powered feet.

The first study enrolled 46 patients, of whom 31 patients had been fit a BiOM and 15 patients an Empower foot. At the time of the study, 18 patients were current powered foot users (8 BiOM, 10 Empower users), whereas 28 patients had reverted to passive feet. Current powered foot users reported significantly less sound knee pain than they recalled for the use of passive feet in the past. Results were even more impressive in current powered foot users who recalled moderate to severe pain (≥4/10 NPRS) when using passive feet. These patients reported significant and clinically meaningful reductions in sound and amputated side knee pain, and a clinically meaningful, though not statistically significant reduction in low-back pain. Current powered foot users also reported a significant and clinically meaningful improvement in mobility in the PLUS-M. This was almost three times as great as the minimal detectable change of the PLUS-M when patients had recalled moderate to severe pain with use of passive feet. However, patients who had reverted to passive feet did not recall any differences in musculoskeletal pain or mobility between the powered and passive feet (1).

The second study enrolled 57 patients who had all been fit an Empower foot. At the time of the study, 41 patients (72%) were current Empower users, whereas 16 patients had returned to passive prosthetic feet. Current Empower users reported significantly and clinically meaningfully less sound knee pain, amputated side knee pain, low-back pain as well as both less knee- and back-pain-related activity restrictions than they recalled for the use of passive feet. As in the first study, patients who had reverted to passive feet did not recall any differences in musculoskeletal pain or pain-related activity restrictions between the feet (2).

The reduction in sound and amputated side knee pain and low-back pain with use of a powered foot can be explained by well-published biomechanical mechanisms. Diminished push-off of the trailing limb results in increased collision work to be performed by the leading limb to accelerate the center of mass upward and forward. The consequence is higher forces acting on the knee of the leading limb. In patients with lower-limb amputation, restoration of push-off power of the prosthetic limb reduces the collision work to be performed by the leading sound limb. This, in turn, reduces the loading of the sound knee. In the amputated leg, knee unloading is achieved by the passive use of the range of motion of 22° for adaptation to non-level walking surfaces. As has been shown in studies with passive hydraulic and microprocessor feet, such adaptation to non-level surfaces results in the biomechanical unloading of the residual knee. Reduced push-off also causes an asymmetric activation of trunk and pelvic muscles which often results in low-back pain. Restoration of push-off with a powered foot may result in more symmetric muscle activation and, thus, less low-back pain.

The studies have also shown that acceptance rates and consistency of effects and benefits are much higher for the current Empower than the previous BiOM version of the powered foot. Nevertheless, selection of good patient candidates and support from Ottobock´s Professional Clinical Services (PCS) team remain crucial to drive high acceptance rates. By experience, patients with transtibial amputation and moderate to high K3 level, self-selected walking speed of 1.2 m/s or faster with their passive foot, daily ambulation of longer distances, and priority of function over weight and noise appear more likely to benefit and accept the Empower than others. As patients need to adapt their walking pattern to the external power delivered by the foot, patients with a talent for motor learning may have a better chance to effectively use a powered foot.

References

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