Microprocessor Knees for Bilateral Amputees

A. Morris, M. Mileusnic, A. Kannenberg, E. Gonzales-Trejo, R. Lundstrom

Zusammenfassung / Summary
The study was designed to test software and minor hardware improvements in the Genium and Genium X3. The updates showed improvements, but these improvements were not detected in the standardized tests. With the new Genium, both bilateral and unilateral amputees had the function necessary for everyday life. Even with microprocessor knees, there still exists a statistically significant objective performance gap between unilateral and bilateral amputees.

Einführung / Introduction
Bilateral transfemoral amputation is widely known as a significant barrier to a person’s ability to perform activities of daily living. In addition to the well-published challenges a unilateral transfemoral or knee disarticulation amputee must face, a bilateral amputee cannot rely on a sound limb to compensate for any shortcomings in the prosthetic device. In a cross sectional study conducted by the Turkish Armed Forces, bilateral amputees fitted with mechanical, hydraulic knee joints were compared to unilateral amputees fitted with the same technology. Unilateral amputees had statistically significant advantages in Physical function, Role limitations due to physical health, and Role limitations due to emotional problems compared to bilateral amputees. Physically, unilateral amputees walked 40% further in a six-minute walk test. Knowing this history, we investigated the current functional gaps between bilateral and unilateral transfemoral amputees.
Methodik / Methodology

The clinical trial was divided into two phases (Figure 1). Each subject received a Genium or Genium X3 with updates, depending on their current prosthesis. If the subject did not have a Genium or Genium X3, a device was assigned at random. In Phase 1 the assigned devices only featured updated software. In Phase 2, the assigned devices featured both updated software and updated hydraulics.

Subjects in Phase 1 and Phase 2 answered questions regarding usage, comfort, falls, and stability during a one-month phone call follow up. Two months after the Phase 1 or Phase 2 fitting, patients returned to the clinic and answered a more detailed set of questions regarding the new features, general usage, comfort, falls, and other issues of the updated prosthesis.

At the end of Phase 1, subjects were asked non-standard questions during a clinic visit. At the end of Phase 2, two months after the finalized update, patients repeated all standardized assessments from baseline and, additionally, completed the 45-item ADL Questionnaire.
Resultate / Results

Unilateral amputees had more favorable scores compared to bilateral amputees. In the PLUS-M, which gauges patient perception of functional mobility, both bilateral and unilateral amputees were above normative values represented by blue lines. The Activities-specific Balance Confidence scale (ABC) showed that both bilateral and unilateral amputees scored above the clinically established cutoff for risk of falling represented by the red line. These scores indicate that the updated Genium microprocessor controlled knee allowed greater functional mobility than average prosthetic components, and that patients did not feel particularly at risk of falling.

The L-Test cutoff for risk of falling is anything above the red line, since slower performance can indicate imbalance. Bilateral amputees were right at the cutoff, and unilateral amputees had a better time that was statistically significant.
In the ADL Questionnaire (Table 1), bilateral amputees reported an average 36% greater ease and 41% greater safety than unilateral amputees across all activities for the updated prosthesis. A clear difference was detected in all but one category after the updates.

**Schlussfolgerung / Conclusion**

The results of this study highlight the importance of component selection in bilateral transfemoral amputees. Even with state-of-the-art microprocessor controlled knees, bilateral transfemoral amputees continue to display a clinically meaningful gap in physical ability compared to unilateral amputees. However, with a carefully considered rehabilitation program, bilateral amputees can move independently and achieve similar perceived balance, function, and mobility.

Incremental gains from updating high-end componentry requires more comprehensive assessments to detect changes. With many manufacturers releasing updated versions of prosthetic components, it may be in the interest of the industry as a whole to validate a new instrument designed to capture these differences.

**Referenzen / References**