INTRODUCTION

Mobility and safety while walking are major concerns for trans-femoral amputees. Many activities have been done to improve amputees mobility and comfort/safety in order to improve their quality of life. Microprocessor ankles and knees have been developed to help amputees achieve a more physiological gait and improve quality of life. This study investigates mobility and safety of trans-femoral amputees while using the first commercially available integrated knee-ankle microprocessor prosthesis, the SYMBIONIC LEG.

METHODS

In this multi-center trial we evaluated short term functional improvement, safety while walking and user assessments of the SYMBIONIC LEG in trans-femoral amputees at five study sites. Data collected included Timed-Up-and-Go Test (TUG), 6 minute walking test (6-MWT) and 26 parameters to evaluate patient’s safety and satisfaction. Data was collected before fitting and 3 hours after initial fitting with SYMBIONIC LEG.

RESULTS

Ten Amputees have been enrolled at five study sites. Patient characteristics: 9 trans-femoral + 1 knee exarticulation; 1 women, 9 men; mean age 44,0+/−10,1 years; time since amputation: 17,6 ± 11,1; Mobility score 3,2 ± 0,34. With SYMBIONIC LEG walking distance of the 6-MWT improved significantly from 348,9 ± 61,2 m (old prosthesis) to 365,9 ± 63,6 m with the SYMBIONIC LEG (p=0,01). Mean time needed for the TUG improved significantly from 9,6 ± 1,3 sec to 8,8 ± 1,4 sec with the SYMBIONIC LEG (p=0,02).

Safety while walking and amputees global assessment regarding the prosthesis improved by 11,3% and 9,2% respectively. Leg length inequality could be addressed in 8 of the 10 patients by 0,5 up to 2,5 cm.

DISCUSSION

The TuG is a validated test of fall risk; in a non-amputee population measures greater than 10sec indicates an elevated risk of falling Transtibial amputees are generally at higher risk of falling as their TuG tests range around 19secs. Baseline data indicates test users already showed high functional levels with TuG results below 10sec. Even with a short adaptation time of 2 hours, SYMBIONIC LEG TuG results were even better indicating SYMBIONIC LEG reduces risk of falling on the test population. It is possible that with a longer adaptation time TuG results could improve even more. The TuG test and the 6MWT are validated functional tests used in clinical situations.

CONCLUSION

Use of the SYMBIONIC LEG led to significant improvement of mobility, satisfaction and safety while walking in the observed amputees with an active life-style already in the short term follow up. The results suggest that even amputees with high mobility scores benefit from microprocessor controlled leg prosthetic systems that include a microprocessor controlled knee and ankle- such as the SYMBIONIC LEG.

REFERENCES


Table 1: TuG comparing Baseline versus Symbionic Leg