Author
Krebs, Alexander (None AT) | OA Dr., MSc
Orthopädisches Spital Wien Speising - Departement for Children and Foot Orthopaedics

Title
Performance, patient benefits and acceptance of a new generation of microprocessor-controlled stance and swing control orthosis

Coauthors
Braatz F, Schmalz T, Kranzl A, Breuer C, Wismer N

Summary
We show that patients suffering from lower limb paresis benefit from C-Brace, a stance and swing control orthosis (SSCO), compared to conventional KAFOs. Specifically performance and patient benefits from next generation of C-Brace will be assessed with gait analysis and questionnaires.

Introduction
By enabling users to flex the orthotic leg during swing phase and safely lock it during stance phase, stance control orthosis(SCO) offers clear benefits compared to locked knee-ankle-foot-orthosis (KAFO)1. Since such orthoses do not offer dampened knee flexion in the weight-bearing condition, this represents a limitation in everyday activities such as ramp and stair descent.

C-Brace overcomes many of those problems. Maximum knee flexion angle in stance and swing phase during level walking are closer to physiological values with C-Brace compared to conventional KAFOs2. The patients are with C-Brace able to descend stairs and ramps reciprocally2. Furthermore, patients report of safer and easier ability to perform activities of daily living3. The main aim of next generation C-Brace is a reduction in size and an increase of adaptability to the patient’s anatomic structure. Due to technological changes, improvements especially for difficult ADLs (e.g. walking on uneven ground) are expected.

Methods
In this prospective, multicenter 3D gait analysis pilot study patients suffering from either lower limb paresis or flaccid paralysis (unilateral or bilateral) will be enrolled. Patients’ previous orthosis, if available, will not be a criterion for inclusion / exclusion. After baseline measurement

with previous orthosis or no orthosis, patients proceed to phase I – the system set up. In the phase I the orthotic shells will be designed and fitted to the patients and they will be introduced to the use of the new SSCO. In the phase II the new SSCO will be used during daily life for 6 months. During that time measurements will be conducted every two month. Collected data include the following: (1) biomechanical 3D gait analysis to assess performance during walking and stair descent, (2) performance based measures assessing safety and walking performance, (3) self-reported outcome measures to assess activities of daily living, pain and quality of life.

Results

The study is currently running. Currently five patients have been enrolled. Two patients have flaccid paralysis due to polio and three patients have traumatic lower limb paresis (one bilateral and two unilateral). Patients mean age is 59.0 ± 13.0 years and the mean time since the diagnosis is 29.6 ± 21.6 years. Furthermore, mean height is 167.6 ± 13.0 cm and mean weight is 63.6 ± 15.1 kg. First experiences from phase I are very promising. Results from the first patient completing the study are expected by the beginning of 2018. The study should be finalized and data collected by April 2018.

Conclusion

In this study, extensive feedback from new SSCO users will be gathered after six months of home use. Due to the technological changes regarding the sensor system, it is essential to analyse and evaluate its impact on patient’s gait pattern and activities of daily living to be able to optimize and refine the control method. Testing the new SSCO under everyday life conditions is of special interest based on the fact that the potential user population shows large variation regarding activity level and residual motor function and therefore demand for stability / support and the behaviour during performance varies too.

Clinical outcome measures will provide quantitative data. Additionally, feedback from clinicians, orthopaedic technicians and physiotherapists will help to direct product development in a customer oriented fashion.

References

1. Zacharias B & Kannenberg A. Clinical benefits of Stance Control Orthosis Systems: An Analysis of the Scientific Literature. Journal of Prosthetics & Orthotics, 24(1), 2-7, 2012.

2. Schmalz T et al. A functional comparison of conventional knee-ankle-foot orthoses and a microprocessor-controlled leg orthosis system based on biomechanical parameters. Prosthetics and Orthotics International, 40(2), 277-286, 2016.
3. Pröbsting E et al. Safety and walking ability of KAFO users with the C-Brace Orthotronic Mobility System, a new microprocessor stance and swing control orthosis. Prosthetics and Orthotics International, 41(1), 65-77, 2017.