

PERFORMANCE, PATIENT BENEFITS AND ACCEPTANCE OF A NEW GENERATION OF MICROPROCESSOR-CONTROLLED STANCE AND SWING CONTROL ORTHOSIS

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DOI: <https://doi.org/10.33137/cpoj.v1i2.32020>

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, a microprocessor controlled stance and swing orthosis (SSCO), 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 pilot study incorporating 3D gait analysis 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 and seven patients have been enrolled. Three patients have flaccid paralysis due to polio and four patients have traumatic lower limb paresis (one bilateral and two unilateral). Patients' mean age is 59.1 ± 10.6 years and the mean time since the diagnosis is 31.3 ± 22.5 years. Furthermore, mean height is 166.0 ± 10.1 cm and mean weight is 68.1 ± 13.8 kg. Preliminary data suggests very high user satisfaction with the new SSCO. Patients report of increased safety and reduction in difficulty of performing activities of daily living. In particular, the improvements could be observed in advanced activities of daily living such as walking in crowd, walking on uneven ground, stepping on small objects and stair descent. The study should be finalized and data collected by June 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.

SIGNIFICANCE

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.

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DISCLOSURE

Nadine Wismer and Christian Breuer are full time employees of the OttoBock Health Care Products GmbH.