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Title

First results on safety, walking and satisfaction with an innovative microprocessor - Controlled 4 axes prosthetic foot component

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Summary

The first use of a new microprocessor controlled (MPC) prosthetic foot (Meridium) was analysed for 88 subjects. The device is favoured by subjects preferring more normal gait and have the need to safely and comfortably negotiate uneven terrain. The weight of the device remains a limitation.

Introduction

Bionic prosthetic foot components have been available in the market for some time 1,2. Such prosthetic feet comprise active elements to adapt characteristics such as dampening, foot position or energy storage and return. We report on the results of an innovative microprocessor controlled hydraulic component (Meridium, Ottobock)³. During walking, the foot is continuously being adjusted using signals from ankle moments and angular velocities as well as from an inertial motion unit informing about velocities, distances and spatial orientation. A 4 axis kinematic system design is supporting a more natural gait. A carbon heel spring and a carbon ankle spring supports energy return. Dampening and range of motion is continuously (real-time) adjusted and hence the system reacts immediately on new gait situations, changing of walking velocities and cadences.

Methods

Data taken on first trial fittings during November 2014 and April 2015 in selected environments were analysed. Routine fittings with certified and approved products were conducted in Europe, Australia and in North America. These fittings were followed for 100 days on average. Questionnaires were provided to support data collection and to retrieve feedback from CPOs

as well as the end users. Descriptive analysis was performed on a pseudonymized data set. Data retrieved referred to demography, the fitting process, safety, ADL and user satisfaction.

Results

Data on 88 users were analyzed. Users were mainly male (80%), mean age 46.7ys (SD13.5ys). Mean time since amputation was 13.9ys (SD13.2ys), amp. level was TT in 59% (TF/KD 41%) and mob. grade (MG) was MG3 in 61% and MG4 in 39%. Amp. etiology included trauma (69%), tumor (12%) and vascular disease (11%). Prosthetic knees were C-Leg (36%), Genium (61%). Previous feet included ESR (84%), hydraulic ESR (5%) and MPC feet (8%). Alignment was achieved in 46% during the 1st and in an additional 36% during a 2nd visit. For 16% a 3rd and in 2% a 4th visit were required. Static and dynamic alignment was rated favorably in 78% and 65%, respectively. In 4% it was rated unfavorable. Acclimation period was reported as 1d in 40%, 2ds in 15%, 3 to 7ds in 30% (> 8ds in 15%). Improvements in level ground walking were reported in 56%, on uneven ground in 84%. Safety while standing was favored by 55%. Disfavored ratings were 16%, 4% and 21% respectively. 37% of trial participants favored the new foot based on a more natural gait (54%), safer negotiation on ramps and uneven ground (54%), heel adjustment (23%) and relief mode (19%). Reasons for lesser interest were weight (60%) and dynamic response (38%). Amputation level, age and mobility grade did not influence preference. Positive response was sig. higher in the Genium group (62%) and here mobility grade had influence (83% for MG 3, 20% for MG 4). Shorter time postamputation was positively related to user satisfaction (64%: 1 to 4ys since amp.).

Conclusion

First fittings with Meridium showed the utilization of functional benefits in a distinct user population. Handling of the fitting by the prosthetist requires experience but has not been rated as being exceedingly challenging.

Responders seem to be more recent amputees with a preference for natural walking and the requirements to safely and comfortably negotiate uneven terrain and slopes. While amputation level, age and general mobility grade seems to be of lesser distinguishing power, in TF amputees the use of Genium seems to significantly increase the potential of utilizing the functional benefits offered by the new component. The component seems to be less

avored by users more sensitive to weight and those who prefer a high dynamic response of the component. Individual assessment and trial seems to be essential to identify the most appropriate component.

References

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