INITIAL CLINICAL EVALUATION OF THE MODULAR PROSTHETIC LIMB SYSTEM FOR UPPER EXTREMITY AMPUTEES

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BACKGROUND

This study evaluates the performance and usability of the Modular Prosthetic Limb (MPL) in the clinical setting to assess usability and optimize its control and features.

The MPL provides intuitive control schemes to command up to 17 independent joints using real-time embedded software to replicate the functionality of a normal arm and hand, achieved with an array of sEMG sites for intuitive movement via pattern recognition.

METHODS

This is a non-randomized clinical optimization study. Up to 24 upper extremity amputees will be enrolled, with the first 12 to achieve the minimal level of VIE-based pattern recognition control progressing to clinical use. Optimization is based on performance and usability in pattern recognition training and functional improvements with respect to the number of available, controllable degrees of freedom.

This study consists of a virtual training Phase 1 and integrated training-and-use Phase 2. During Phase 1, participants train in a miniature virtual integrated environment to learn pattern recognition.

During Phase 2, prosthetic sockets are integrated with sEMG electrodes to allow users to operate the MPL. Data is obtained during performance of activities of daily living and from standardized, validated self-report and functional assessments administered in clinical sessions.

RESULTS

Seven participants across multiple levels of upper extremity amputation have completed the protocol to date. Participants were able to control a greater number of individual joint and hand motions and increase proficiency with these motions over time. All participants, except one, improved in average motion completion percentages and path efficiencies—normalized by the total number of motions tested—on a Target Achievement Test over time, independent of level or cause of amputation. While speed to complete tasks with the MPL did not approach the speed with a conventional prosthesis, participants utilized a greater number of motions than with their conventional prosthesis and the fidelity of MPL control continued to improve.

CONCLUSION

Participants demonstrated the ability to control a greater number of motions, utilize multiple task-appropriate grasps, and describe a more intuitive control experience than currently available with conventional prostheses. While quantitative functional assessment scores were lower than conventional, MPL use and pattern recognition control improved over time with respect to the number and quality of motions controlled without plateau, indicating further potential function gains.