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Evaluation of control modalities and functional impact of a self-piloted grasp neuroprosthesis in stroke patients: preliminary results from a multi-crossover N-of-1 randomized controlled study

Ronan Le Guillou^{1,2,3}, Mathilde Couderc¹, Margot Morin¹, Camille Cormier^{3,1}, Christine Azevedo-Coste², David Gasq^{1,3}

¹Department of Physiology - Functional Explorations, University Hospital of Toulouse, Toulouse, France

²CAMIN INRIA, Montpellier, France

³ToNIC, Toulouse NeuroImaging Center, Université de Toulouse, Inserm, UPS, Toulouse, France

Introduction

Stroke is the leading cause of acquired motor deficiencies in adults. Improving prehension abilities is challenging for individuals who have not recovered active hand opening capacities post-stroke. Functional electrical stimulation (FES) applied to finger extensor muscles to restore grasping abilities in daily life, called grasp neuroprosthesis (GNP), remains confidential in post-stroke population. Thus, we developed a GNP and control modalities adapted to the characteristics of this population and assessed its impact on functional restoration of grasping abilities.

Methods

A GNP prototype was designed with specific control modalities (voice control, foot and head movements). A software allowing configuration and monitoring, interprets user commands through input signals from sensors (IMUs and microphone) and triggers a pre-programmed external electrical stimulator. Over 5 days, the users tested and selected a preferred control modality before training with the GNP to perform unimanual and bimanual tasks in a seating position. Its functional impact was assessed in a blinded evaluation multi-crossover N-of-1 randomized controlled trial (clinicaltrials.gov: NCT04804384), followed with a QUEST questionnaire.

Results

Preliminary results from eight subjects (1 to 17 years post-stroke; Fugl-Meyer motor upper-extremity score 21 to 48/66) showed a preference for non-paretic foot triggering (7/8). All subjects selected the key-pinch task as the primary outcome and the palmar grasp task as secondary outcome. All subjects successfully completed from 83% to 100% of the tasks using the GNP (100% for 5 subjects; χ^2 : $p < 0.001$), while none of them could complete the task without GNP activation. QUEST ranged from 29 to 35 (median of 33/40).

Conclusion

These preliminary results attest that the GNP prototype and its control modalities are well suited to the post-stroke subjects in terms of self-triggering, while allowing to restore grasping capabilities. A wearable version of this device is being developed to improve prehension at home in daily life.