Multi-contact epineural electrical stimulation to restore upper-limb functions

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Abstract: *We investigated the feasibility of a novel approach aiming at restoring functional movements in completely paralyzed upper limbs using neural stimulation. Two multi-contact cuff electrodes were wrapped around radial and median nerves, unilaterally, in 2 individuals with complete high tetraplegia. Electrodes were maintained for 28 days. Advanced stimulation configurations were implemented to achieve selective activation of fascicles and elicit different graspings. A control interface was developed to allow users to pilot movements of their hand by triggering stimulation. Both participants were able to execute palmar and key pinch grasping during functional tasks.*

Keywords: *tetraplegia, FES, cuff neural electrodes, selectivity.*

Introduction

Functional electrical stimulation (FES) makes possible the restoration of upper limb function in individuals with complete tetraplegia when functional tendon surgery or nerve transfers are not possible [1]. The majority of approaches that investigated implanted electrical stimulation used intramuscular or epimysial electrodes [2,3]. This implies implanting as many electrodes and wires as the number of muscles to be stimulated. Instead, we investigated the possibility of stimulating nerves proximally to reduce the number of implanted electrodes. In a previous study, we tested multi-source epineural stimulation of the median and the radial nerves intra-operatively in 8 patients with complete tetraplegia [4]. For all subjects, under general anaesthesia, it was possible to selectively stimulate muscle groups to generate various movements depending on the current path over the multi-contact electrodes. Based on this, we aimed to study the feasibility of the approach during a 28-days period with awake users [7]. The objectives were to study safety of procedures and feasibility of producing functional movements autonomously controlled by the users by means of an interface taking advantage of the remaining voluntary activities of contralateral upper limb. Some information is provided in the following and will be developed during presentation at the conference.

Methods

2 subjects with high tetraplegia C4, AIS A, group 0 of the International Classification for Surgery of the Hand in Tetraplegia were included. They signed informed consent. The study was approved by the National Ethics Committee (ClinicalTrials.gov identification number NCT04306328). The electrodes were placed during a first surgical procedure at day 0 and the explantation was performed 28 days later during a second surgical procedure. The full device was composed of 2 multi-contact cuff electrodes (CorTec GmbH Freiburg Germany, 8 central contacts for the median, 6 central contacts for the radial) with their individual percutaneous cable and extracorporeal connector, 2 extracorporeal cables, 1 external multi-source stimulator (STIMEP, INRIA, Montpellier) [8] connected to a computer (figure 1). Wireless sensors (Delsys, Natick, MA) were placed on the skin to measure voluntary muscle signals (electromyography (EMG)) and voluntary movements (inertial measurement units (IMU)). These signals were processed to detect the user piloting orders.

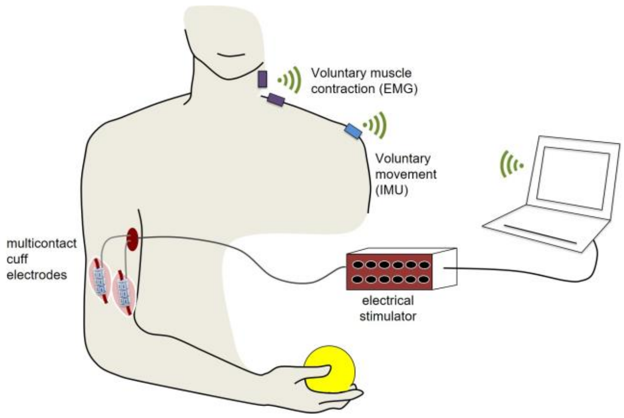

Figure 1: Principle of the solution proposed to restore hand function in individuals with complete tetraplegia. 2 multi-contact epineural electrodes are wrapped around median and radial nerves just above elbow.

4 to 8 EMG sensors (Delsys, Natick, MA) were also placed on the skin to wirelessly collect: 1) evoked electromyography (eEMG) data from muscle contractions

induced by FES, 2) forces applied on instrumented objects (force resistive sensors (FSR)). The eEMGs were post-processed to extract recruitment curves [9] and FSR data used to assess the pinch or grasping forces. 2 control modalities were explored [6] for the user to trigger the stimulation autonomously using the contralateral limb: 1) supralesional voluntary contractions captured by EMG and detected by a threshold detection algorithm, 2) voluntary stereotyped shoulder movements captured by IMU and processed by a classifier algorithm to detect predefined shoulder movements. A finite state machine (FSM) was defined to associate user commands (EMG threshold detection or recognition of a predefined movement (IMU)) with actions depending on the current FSM state. Participants performed 3 sessions a week over the 28 days when the parameters were tuned and optimised and induced movements were assessed.

Results

Tests confirmed the ability to produce multiple movements including functional and reproducible key-grip and digito-palmar grasping. In participant 1, voluntary muscle contraction detection and voluntary movement detection control interface modalities were successful. For participant 2, only the voluntary movement detection modality was possible due to an important fatigability of the shoulder muscles. The success rate in task execution was estimated using Motor Capacity Scale C score at 54% for patient 1 and 51% for patient 2. The results will be detailed during the presentation at the conference.

Figure 2: Example of 3 tasks achieved by participant 1. Top: key grip pinch. Middle and Bottom: palmar grasp.

Discussion

Our study suggests that multi-contact cuff neural combined with multi source electrical stimulation offers the possibility to selectively activate nerve fascicles in a reproducible manner. Multipolar neural electrical stimulation of the median nerve and radial nerve allowed for useful grasps and release in both participants. Future studies will consolidate this proof of concept by extending the number of participants.

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