A preliminary clinical study using implantable microstimulators to facilitate recovery of upper limb function in hemiplegia

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Abstract

This paper presents an overview of the design of a preliminary clinical study to develop and test the feasibility of a triggered open-loop system using radio frequency controlled microstimulators. The study is in upper limb rehabilitation following stroke.

1. INTRODUCTION

Approximately 75% of middle cerebral artery infarcts result in a motor deficit, particularly of the upper limb (1) and 24% of patients have residual upper limb motor loss at three months post-stroke (2). Various longitudinal studies have investigated the long-term outcome following stroke: Kwakkel in his review quotes that for 30 to 60% of patients the paretic arm remains without function (3) and Wade that half of all acute stroke patients starting rehabilitation will have a marked impairment of function of one arm of whom only about 14% will regain useful upper limb function (4). Upper limb function is clearly a major problem and the objective of this project is to develop a system that allows voluntary activation and responsive control over stimulation during functional upper limb tasks and to test the feasibility of using radio frequency controlled microstimulators (RFM)s to improve motor re-learning and recovery of arm and hand function following stroke.

De Kroon's review (5) examined the relationship between stimulation parameters and methods of application, and improvement in upper limb function in post stroke hemiplegia. Her review found that the only factor that made a significant difference was voluntary activation of stimulation. The finding of this review supports motor learning theory which states that for motor learning to occur activities must be repetitive, goal orientated and at the limit of performance (6). It is also supported by recent translation of animal based findings showing that enriched environments may equate with augmented therapy and relate to cortical changes associated with improved motor function (7).

Studies using voluntary activated electrical stimulation have shown improved function (8-10) but surface stimulation has usability problems. Firstly the inconvenience and accurate placement of surface electrodes and secondly the inability to selectively activate wrist extensors and the muscles controlling finger and thumb extension and thumb abduction. Implanted neuroprosthetic systems such as the freehand have effectively achieved selective activation of different muscles and muscle groups, but such systems require invasive surgery and are not intended for relatively short term therapeutic use as part of a rehabilitation programme.

This paper describes the design of a study in which we have explored the feasibility of using implantable microstimulators for recovery of upper limb function following stroke. The safety of the system (Cosendai), surgical procedure (Davis) and preliminary results of changes in function and impairment over the first 12 weeks of the study (Turk) are presented elsewhere at the conference.

2. METHODS

1.1 Design

The study is in three phases: during the first phase we have implanted between six and seven devices in the arms of seven post-stroke hemiplegic participants to facilitate elbow, wrist, and finger and thumb extension and thumb abduction. We have designed open-loop function-based programmes that participants
were able to use at home for approximately two hours per day. During this phase we developed external sensors, interface, control system and programming software to provide a responsive triggered open loop system to enable participants to perform functional arm and hand movement. During phase 2 of the study we are designing participant specific programmes - each comprising a series of activity sequences that enable each participant to use the system to practice functional activities. During Phase 3 participants will use the system for 12 weeks at home without further input from the research team to test the reliability and usability of the system and therapeutic effect. Participants will then discontinue using the system for 12 weeks and be re-assessed to measure long-term carry-over effect.

1.2. The microstimulator
The RF microstimulators (RFMs), (Figure 1) used in the study have been developed by the Alfred Mann Foundation. They are injectable cylindrical microstimulators. RFMs are implanted through a small incision (5mm) under local anaesthesia using specially designed insertion tools. Devices are positioned either adjacent to a peripheral nerve or close to a motor point within a muscle. Risks associated with invasive surgical procedure and the presence of leads within the body is thus reduced. Each device is individually addressed, allowing control over timing, rise and fall times, amplitude and pulse width of stimulation. RFMs receive power supply and control signals from a control unit via an inductance coil. Stimulation parameters, set by a PC based fitting system respond to triggers issued by sensors.

Figure 1. The RFM

3. RESULTS
Two devices were implanted close to radial nerve branches to the medial and lateral heads of triceps (MHT and LHT) for elbow extension and either one or two devices close to the posterior interosseous nerve (PIN) to open the thumb and fingers. Wrist extension was activated by two devices close to the motor points of extensor carpi ulnaris and extensor carpi radialis (ECR and ECU).

Following implantation participants used the Phase 1 open loop system (Figure 2). Initially, individualised programmes were set up in the laboratory, using custom made software that was developed with input from the clinical team. Specific functional tasks were identified for each participant and the therapist determined which devices were activated, the required stimulation parameters and timing of each. A series of activity sequences were thus linked to form a functional programme. Once satisfactory programmes were established participants were able to take the system home and practice with it for about two hours per day. Phase 1 lasted for 12 weeks.

Figure 2. Phase 1 Open loop system

In Phase 2 external sensors were used to trigger the start of the programme and changes between activity sequences. We termed this ‘triggered open-loop control’ (Figure 3) and it has enabled the system, not only to be voluntary activated, but also responsive to the speed at which the patient performed the task.

Figure 3. Phase 2 Triggered open-loop control

Seven participants have completed Phase 1 of the study. Two participants are using the triggered open-loop system for reaching and grasping activities and the remaining five will enter Phase 2 over the next three months.
4. DISCUSSION AND CONCLUSIONS

The potential advantage of this system is that it not only allows voluntary activation of stimulation, so that it is activated on demand by the user, but also allows a greater functionality by responding without further intervention by the user to the speed of the activity.

Problems that will need to be addressed include designing a system which is quick and easy to programme so that it can be used in used by therapists in a clinical setting. If the system is shown to be feasible however it will provide exciting opportunities for employing other sensors such as EMG and for using implanted sensors that have the capability of communicating with the RFMs.

References


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