A preliminary clinical study using RF BION® microstimulators to facilitate upper limb function in hemiplegia

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Abstract

Surface electrical stimulation has been shown to improve upper limb function following stroke, particularly when stimulation is triggered by voluntary activity. Selectivity of muscles via surface stimulation limits the functionality of these systems. Unlike patients with spinal cord lesions, patients who have had a stroke often retain some voluntary control of elbow, thumb and finger flexion, and hand function is limited more by an inability to reach and open the hand for grasping. In this preliminary study we will support the extensor muscles of the arm and forearm, allowing the patient to use their own voluntary activity to grasp, hold and use everyday objects. RF BION microstimulators will be implanted into mm. triceps (medial and lateral heads), extensor carpi ulnaris and radialis, abductor pollicis and the extensors of the fingers and thumb. Using a variety of sensors (goniometers, force transducers and accelerometers) we are developing a responsive system to activate and control three phases of stimulation: elbow extension to reach (1) with wrist and finger extension and thumb extension and abduction to open the hand (2) and wrist extension without finger and thumb extension and abduction to allow voluntary activation of finger and thumb flexion and opposition to grasp (3).

1 Introduction

Unlike tetraplegic patients, whose motor impairment is specifically defined by the level and extent of the injury and whose main problem is grasping due to weak finger flexion, stroke patients, because of the nature of the lesion, have a more complex and varied pattern of motor impairment. Firstly, stroke patients are often unable to grip because of weak wrist extensors rather than an inability to activate finger flexors, and it is often spasticity of the flexor muscles that prevent opening of the hand, thus functionally impairing performance. To perform an effective power grip, or even to manipulate objects, requires the wrist to be held in a functional position of slight extension maintained by activity in the wrist extensors, mainly Extensor Carpi Radialis (ECR) and Extensor Carpi Ulnaris (ECU).

Functional Electrical Stimulation (FES) has been shown to have a therapeutic effect on hand and arm function (1) and when stimulation is associated with the person’s intention to move the effect is enhanced (2). Studies reported in the literature have used surface systems to activate muscle contraction, but such systems have the disadvantage of requiring donning and doffing and thus variable positioning of the electrodes on the skin, discomfort due to stimulation of sensory nerve endings in the skin and preferential activation of muscles close to the surface. In this study, implantable microstimulators will be used to try to overcome these problems. Using implanted devices we will activate individual muscles to provide finer control over hand movements, particularly maintaining wrist extension while releasing the finger extensors to allow voluntary grasping.

1.1 Radiofrequency (RF) BION Microstimulators

RF BION (RFB) microstimulators, shown in Figure 1, can be implanted in a minimally invasive procedure either adjacent to a peripheral nerve or close to a motor point within a muscle. Each device is individually addressed, allowing control over timing, rise and fall times, amplitude and pulse width of stimulation. In this study RFB microstimulators will be implanted into the extensor muscles of the wrist, fingers and elbow. RFB microstimulators receive power supply and control signals from a control unit via an
inductance coil. These, external components are illustrated in Figure 2.

![Image](image1.png)

**Figure 1: The RF Bion device**

![Image](image2.png)

**Figure 2: The external components of the RF Bion system**

1.2 Objectives

The objectives of the study are to develop the protocol for implantation in the arm and forearm, design and test control systems, and measure the effect of stimulation on a small group of subjects.

2 Methods

Between 6 and 15 post-stroke hemiplegic subjects with impaired arm and hand function will be recruited from Southampton University Hospital (SUHT) and Community Trusts and from the Stroke Rehabilitation Unit in Christchurch. Implantation will take place in the Neurosurgery Unit at SUHT and tests with subjects will be conducted at the University of Southampton Biomechanics Laboratory. Needle electromyography (EMG) will be used to identify injection sites prior to implant surgery, which will be done under local anaesthetic.

The study will be divided into three phases and during each phase subjects will initially use stimulation in the laboratory before a ‘take-home’ system is developed. During phase one, the forearm and if appropriate the upper arm muscles will be implanted and stimulation will be applied using a simple fixed time control system that allows up to three periods of stimulation: (1) The first to open the hand through stimulation of the wrist and finger extensors; (2) The second to allow voluntary grasping by switching off the finger extensors; and (3) If the upper arm muscles are implanted, the third to extend the elbow. During this phase, methods of identifying how stimulation periods can be controlled will be defined. In phase two, stimulation will be controlled by subject-operated triggers. During this phase an automatic, responsive control system will be developed. The system will incorporate body-worn sensors such as goniometers and accelerometers. Individual sensors will be evaluated on the bench and with a sample of normal volunteers to select devices, position and orientation on the body and method of signal processing to provide a useful control signal. In phase three, this control system will be incorporated and evaluated with the patients over a three-month period. Data will be recorded to measure the effect of using the system on function and used to inform the design of a clinical trial with a larger sample of subjects.

2.1 Outcome measures

The immediate and ‘carry-over’ effect of stimulation will be measured by the following outcome measures:

- Impairment: Motor control and muscle activation patterns and grip strength
- Function: Fugl-Meyer upper limb assessment and the Action Research Arm Test
- In addition the control system will be developed using data from a range of sensors possibly including accelerometers, goniometers and pressure sensors, each evaluated using a computerised motion analysis system.
2.2 Data collection and statistical analysis

Data will be recorded and analysed for each case to describe and summarize changes over time both with and without stimulation.

3 Results

The first patient will be implanted in fall 2004. Preliminary results from the testing of sensor system will be presented.

4 Discussion and Conclusions

This is the first clinical study in which RFB microstimulators will be used in an application requiring fine control over the timing and amplitude of stimulation from each device, both individually and in combination, to produce a responsive functional movement. The study will also provide an opportunity for the development of better sensors for the control systems that will have broad applications in FES.

References


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