

# A Preliminary Clinical Study using RF BION<sup>®1</sup> Microstimulators to Facilitate Upper Limb Function in Hemiplegia

## A brief background to Functional Electrical Stimulation

Functional Electrical Stimulation (FES) has been used to facilitate movement in people who have suffered an upper motor neuron lesion since Liberson designed the first drop-foot stimulator in 1960<sup>1</sup>. Since then the technique has been accepted by only a small number of clinicians and therapists. There are various reasons for this: firstly insufficient research and clinical evidence for its effectiveness - although there have been many papers published on the use of FES they have tended to be with small numbers of subjects and often employing weak methodology. Recently more convincing evidence from larger research studies has been published<sup>2,3,4</sup>, a systematic review<sup>5</sup> found evidence for improved upper limb motor control with surface FES systems, and systems that allow voluntary control over the activation of stimulation, such as through the same muscle EMG signal, have been shown to result in improved motor learning<sup>6</sup>. The Odstock drop-foot stimulator has probably gained more clinical acceptance than any other FES device with now over 2000 patients using it in the UK. Acceptance in this case has been due not only to research evidence<sup>7</sup> but also to strong clinical support and education of therapists in selection of suitable patients and application of devices. Even when the stimulator is set-up effectively however, wearing an external device that requires careful donning and doffing does not appeal to all patients, regardless of whether it is functionally effective. As rehabilitationists, we are more interested in interventions that can facilitate recovery to restore rather than replace lost movement.

This project aims to address the last two issues by using an implantable microstimulator that can remain implanted even if no longer needed and developing a system to facilitate recovery by supporting voluntary movement rather than replacing it.

## The BION microstimulator

The radio frequency (RF) BION (RFB) device has been developed by the Alfred Mann Foundation in the US. It is an injectable cylindrical microstimulator with a cathode electrode at one end and an anode at the other. It can be implanted through a small incision (5mm) using a cannula, thus reducing the expense and risks associated with other implantable devices due to the surgical procedure and the presence of leads within the body. Once implanted, the RFB receives power and stimulation commands (data) via a 2MHz RF inductive link from an external RF coil, which is connected to the BION Control Unit. A single RF Coil and BION Control Unit can simultaneously control several individually addressed RFBs implanted near each other. Figure 1 shows the RFB and the instruments used for implantation.

## Previous clinical experience

Similar devices have been used in the US in the treatment of subluxed shoulder and RFBs are currently being tested in the US in the treatment of obstructive sleep apnoea. These applications require minimal control of stimulation; in the arm rehabilitation project, developing the control system to activate the individual devices appropriately to facilitate a normal, functional movement is the major challenge.

## The objectives of this project

Approximately 75% of middle cerebral artery infarcts result in a motor deficit, particularly of the upper limb<sup>7</sup> and 24% of patients have residual upper limb motor loss at three months post-stroke<sup>8</sup>. 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<sup>10</sup>, and Wade reported 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<sup>11</sup>. Upper limb function is clearly a major problem, and because individuals are unable to perform functional repetitive movements with their hemiplegic arm, potential motor recovery is not realised. The objective of this project is to test the feasibility of using the RFB to improve motor re-learning and recovery of arm and hand function following stroke by facilitating functional arm movements. Movement will be elicited by electrical stimulation of the weak muscle groups in such a way that the phases of movement are responsive to the task.

## Project plan

A minimum of six and a maximum of fifteen subjects will be enrolled in the study. They will have had a stroke at least three months prior to recruitment and have impaired arm and hand control, but retain some functional grip and have sufficient elbow flexion to bring their hand to their mouth. RFBs will be implanted into the forearm to activate extensor carpi ulnaris and radialis, extensor digitorum superficialis, extensor pollicis longus and abductor pollicis. By positioning devices either adjacent to the nerve or within the muscle itself, close to the motor point, we expect to be able to activate these muscles using four devices. In the upper arm we will use two more devices implanted into the medial and lateral heads of triceps. With this combination of implants we aim to support elbow extension, wrist extension and opening of the hand. By 'switching off' the finger and thumb devices subjects will be able to use their own remaining control of finger and thumb flexion to grasp an object; while continued stimulation to the wrist extensors will maintain a functional hand position for grasping.



Jane Burrige is a senior research fellow in neurorehabilitation at the University of Southampton. Her main area of research is into functional electrical stimulation, the effect of this on motor learning and muscle activation patterns, and working with signal processing engineers, the development of control systems for voluntary activation of stimulation. Jane is also currently leading a European clinical trial to evaluate the effect on walking of an implanted drop-foot stimulator with stroke patients and is a member of a European consortium on measurement of spasticity.



Ruth Etherington is a Research Fellow working on the BION Project at the University of Southampton. She has worked as a Senior Physiotherapist in Neurorehabilitation, specialising in stroke rehabilitation. Her research interests are in upper limb therapy in patients with stroke, especially functional electrical stimulation and its effect on neglect and motor relearning.

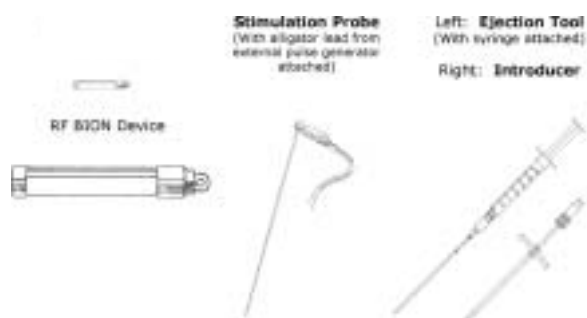


Figure 1 shows the RF Bion microstimulator and the insertion tools. A suture is attached to the eye in the end of device that enables it be withdrawn if necessary for up to two weeks following insertion.

<sup>1</sup>BION is a registered trademark of Advanced Bionics Corporation

The project falls into three phases. During the first and second we will be developing a control system that, in the third, will be tested using conventional outcome measures – the Action Research Arm Test and the Fugl-Meyer (upper limb section). Throughout the study the effect of stimulation on muscle force, motor control, antagonist co-activation during active flexion and extension and response to passive stretching will be assessed in a specially designed rig. Figure 2 shows the output from the tracking test in which the subject attempts to follow a tracking target, moving sinusoidally across a screen, by flexing and extending their wrist. EMG signals from the wrist flexors and extensors in this example show normal reciprocal inhibition, subjects who have poor control of movement and spasticity demonstrate less accurate tracking and more co-activation between the two muscle groups. Indices have been derived to quantify co-activation and we will be interested to see whether there is improvement after the RFBs have been used for functional exercise over a period of about six weeks.

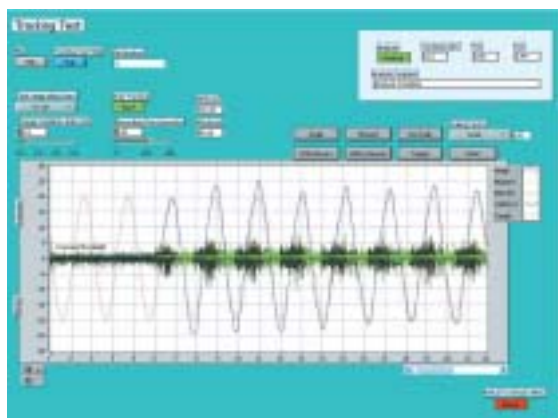


Figure 2 An example of the output from the wrist rig showing the tracking signal, the subject's attempt to follow it and the EMG signals from the wrist flexors and extensors. In this example of a normal unimpaired subject there is reciprocal inhibition between the two muscle groups and accurate tracking.

Initially, stimulation will be pre-programmed so that each RFB is active for a fixed period with a predetermined profile (amplitude, rise and fall time etc.). During the second phase we will use triggers operated either by the therapist or the patient so that stimulation periods can be varied according to the task being performed. Subjects will be able to use this system at home, while in the laboratory we will design and test ways of using signals from sensors such as accelerometers and goniometers to control the output from each device. This will enable stimulation to be controlled by the user's movement rather than by a conscious unrelated action. Figure 3 illustrates an example of how sensors may be used to trigger changes in stimulation.

The rationale that underpins this approach is that if the stimulation is responsive to the user's needs, enabling them to successfully achieve a variety of simple tasks, then motor-learning will be enhanced. A novel idea for controlling stimulation that we will test is a force sensitive mat; the user reaches to grasp an object resting on the mat, when the object is touched the small movement is recognised by the sensors embedded in the mat and the resulting signal is used to switch off finger and thumb extensor/abductor RFBs to allow the object to be grasped. When the object is replaced on the mat the signal becomes a command to switch on the finger and thumb

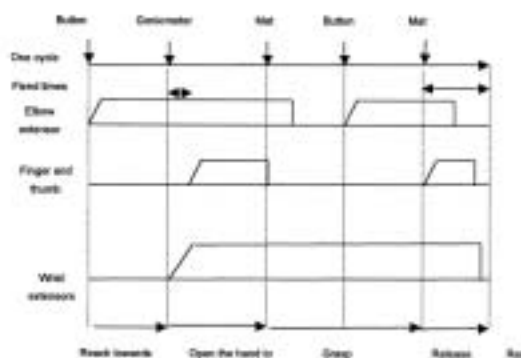


Figure 3. Shows a possible set-up for phase 3 of the project in which stimulation is controlled by body-worn sensors and a force sensitive mat. The sequence illustrates activation of triceps to reach for and replace the target object. Activation of wrist and finger extensors opens the hand and, when the object is touched a signal from the pressure sensitive mat triggers stimulation to the finger extensors to be switched while stimulation to the wrist extensors is maintained, allowing the object to be grasped. After the object has been 'used', a signal from the pressure sensitive mat detects when the object is replaced on the mat triggering the fingers to be re-activated to release the object.

RFBs allowing the object to be released. Other ideas are an accelerometer worn as a ring on the finger that detects movement of the hand and a goniometer worn across the elbow to control the triceps RFBs.

Future work

This is an ambitious project that we expect to take about 30 months. At the end, if we have a system that works and sufficient evidence for its effectiveness in improving arm and hand function, then we shall design and perform a clinical trial. The research is funded by the Alfred Mann Foundation (Valencia, CA, USA), who have been designing and testing a series of BION devices. Future generations of devices are currently being developed and these include battery-powered devices that will require a body worn coil and sensing devices that will be able to 'talk' to stimulating devices, thus removing the need for external sensors. The possibilities are very exciting and this project marks an important milestone in the evolution of FES.

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