

Post-stroke Upper Extremity Rehabilitation using 5-7 Implanted Microstimulators: Thresholds and Orthotic Effects

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Abstract

43 microstimulators were implanted in a feasibility study of rehabilitation of arm function in subjects with stroke. The motor thresholds were low and stable. The original goal of the study was to demonstrate that subjects can achieve therapeutic improvements with the stimulation. In addition we wanted to demonstrate direct orthotic effect of the stimulation. Results of motor thresholds, and orthotic effect measurements with the system are presented. These results suggest that the orthotic effect is reliable.

1 Introduction

85% of stroke survivors regain the ability to walk but less than 14% of those who have upper limb problems regain useful function¹. Many subjects have difficulty in reaching and have ineffective grip. Electrical stimulation therapy was shown to improve function² especially when voluntarily activated. Previous work³ demonstrated the safety, and this paper shows orthotic effectiveness of a feasibility study designed to improve recovery of upper limb function following stroke, using implantable microstimulators⁴.

2 Methods

2.1. Subjects

Seven subjects have been included with a chronic stroke causing a hemiparesis, at least 3 months post stroke. These subjects had impaired hand function due to poor control and weakness of wrist and finger extension, and of elbow extension. They had some voluntary control of finger flexors and proximal arm and shoulder muscles. Subjects gave written

informed consent, and the protocol was approved by the Thames Valley Multicenter Research Ethics Committee (#04/12/021), and by the Medicines and Healthcare Products Regulatory Agency (CI/2004/0027). This study was conducted following guidelines of good clinical practice.

2.2. Microstimulator system

The microstimulator is a miniature (cylinder 2.4 mm x 17 mm), single-channel, implantable stimulator that produces capacitively-coupled, charge balanced, asymmetric, biphasic, constant-current pulses. In this study 5 to 7 devices have been implanted in each subject, for a total of 43 devices.

The implant surgery involved a micro stimulator inserted onto the nerve/motor-point (N/MP) of each of the medial and lateral triceps muscles for elbow extension. For wrist extension, a microstimulator was positioned on each N/MP of the extensor carpi radialis longus and ulnaris. For finger and thumb extension, 1-2 microstimulators were inserted onto the posterior interosseous nerve.

Once implanted, the devices receive power and stimulation commands via a 2 MHz RF inductive link provided by an external coil, connected to a Control Unit (See Figure 1). The stimulation parameters are set by a laptop-based fitting system, and can be programmed to respond to triggers issued by sensors.

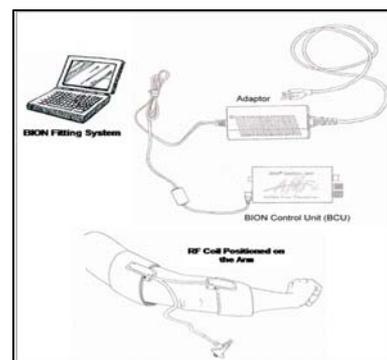


Figure 1 External System

2.3. Thresholds

The subjects were followed up at 7 days, 15 days, 30 days and 90 days post surgery. Stitches were removed after 15 days. During each follow up session, implant sites were examined, operation of the devices was verified, and motor thresholds were measured.

Motor thresholds were measured at 30 Hz repetition rate. The pulse width was fixed at 200 μ s and pulse current was increased to get a coarse value of threshold. Then pulse amplitude was set at a specific value (generally 1.62 mA) and pulse width was varied to get the exact value of motor threshold.

Subjects were also tested to evaluate the therapeutic outcome of the procedure (Ref. See Mrs Turk's communication).

2.3. Orthotic Effect Measurements

The orthotic effect of stimulation, force and range of movement at the wrist joint with stimulation was assessed using standardised commercial neuromuscular testing equipment (System 2, Biodex, New York USA).

The stimulation level was set for all subjects at 0 and then at 20 exponential steps ranging from 32nC to 1400nC (22% steps). The stimulation level was increased until the stimulation reached a plateau, or until overflow to other muscles occurred. Previous upper limits had been set to prevent stimulation reaching a level that caused discomfort and these were not exceeded. For each level, the force and the movement achieved by the stimulation were recorded.

3 Results

MOTOR THRESHOLDS

Longitudinal motor thresholds are displayed in Fig. 2 on the day of the surgery and up to 3 months after surgery. Left ordinate scale shows the charge per phase of the stimulation pulses.

All but one threshold (97%) remained stable over time, allowing for test – retest repeatability. The motor threshold of the device targeted at the medial head of the triceps of subject #4 changed significantly immediately after the surgery. This threshold is highlighted as the black dashed line.

At 3 months after implantation 90% of thresholds had a value below 0.22 micro Coulombs (8.4 μ C/cm²) which is 1.1% of the maximum output of the micro stimulator.

The right ordinate scale shows the computed equivalent current of 0.2 ms pulses. Dotted gray lines show individual thresholds for all devices. The bold black line shows the value of the median, and the error bars display the 10th and the 90th percentile of thresholds.

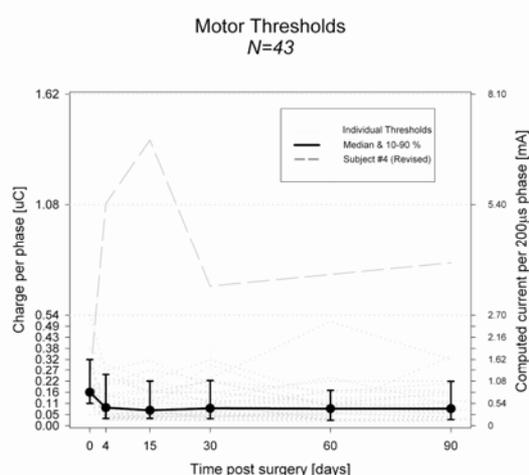


Figure 2 Longitudinal Motor Thresholds

FORCE MEASUREMENTS

Elbow Force in Function Of Charge Delivered Normalized to Threshold

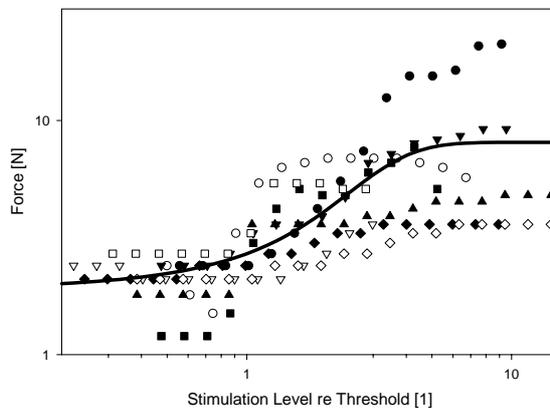


Figure 3 Force Measurement

Force recorded at the wrist of 4 subjects when stimulation was delivered to the lateral head of the triceps and to the medial head of triceps is displayed in Fig. 3.

Bottom abscissa has been normalized to the motor threshold of each muscle. Left ordinate shows the force recorded at the wrist in Newtons. The maximal force recorded ranged from 3.6N to 21N.

RANGE OF MOVEMENT

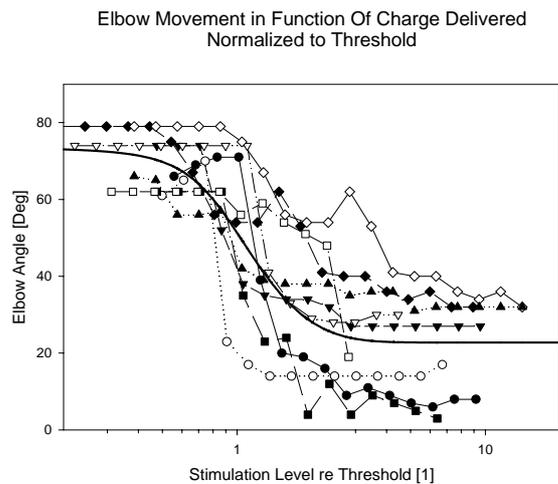


Figure 4 Elbow Angle

The Elbow Angle of 4 subjects when stimulation was delivered to the lateral head of the triceps and to the medial head of triceps is displayed in Fig. 4.

Bottom abscissa has been normalized to the motor threshold of each muscle. Left ordinate shows the angle of the extension movement recorded at the wrist in Degrees relative to right angle.

The maximal movement recorded ranged from 58Deg to 87Deg.

4 Discussion and Conclusions

The follow up of the motor thresholds showed that they were stable and that they had a level very low (1.1%) compared with the available range of stimulation of the device. Ninety percent of the thresholds were below 0.22 micro Coulombs ($8.4 \mu\text{C}/\text{cm}^2$).

The Force and range of movement data shows that the stimulation delivered by the RFM could effectively achieve partial to complete extension of the forearm in all subjects measured.

These data suggest that in addition to the therapeutic benefit provided by the RFM system, (also reported at this conference by Dr Burridge), the orthotic effect of the system has also been demonstrated. The system has the potential to be used as a functional neuroprosthesis.

In conclusion, as we have confirmed previous findings⁴ that micro stimulators could be implanted safely with only minor side effects.

In addition we showed that the system proved reliable. The low level and the stability of the thresholds indicate that the electrical stimulation delivered by micro stimulators were effective and stable in 97% of cases.

The use of the system for stroke subjects may provide both an orthotic and therapeutic effect.

References

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