Clinical effectiveness and participant perceptions of an implanted closed-loop neurostimulator-sensor system for arm rehabilitation post-stroke

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Abstract

Therapeutic functional electrical stimulation has been shown to be effective in improving upper limb function post-stroke and when stimulation is associated with a patient’s own voluntary activation the effect is enhanced. This paper presents results from the end phase of a feasibility study using implanted microstimulators with a closed-loop control system. The system used sensors (goniometer, touch mat and button switch) to allow voluntary activation and timing of stimulation to be responsive to participants’ speed of movement. Participants used the system in a daily home exercise programme for 12 weeks. Functional and impairment measures were taken before and after the treatment period and compared with participants’ perspectives assessed using a questionnaire. Clinical results showed this stimulation system effective to bring about a mean (SD) improvement of 5 (5.2) in the Action Research Arm Test and a statistically significant change in the Fugl Meyer test (5.3 (4.0), p=0.021). Participants also perceived the sensors to be effective but the goniometer and touch mat to be unreliable. Future systems with external control mechanisms need to be both effective and reliable.

1 Introduction

Half of all stroke patients receiving conventional rehabilitation fail to regain upper limb function1. A common functional problem of the upper limb following stroke is the inability to open the hand to grasp and release objects. Reaching away from the body to position the hand to manipulate objects can also be difficult. The aim of therapy is to promote functional recovery through the facilitation of motor control and skill acquisition using repetitive and goal directed movements. Therapeutic functional electrical stimulation is one way in which intensity of treatment can be increased without concomitant increase in therapy time and has been shown to be effective in improving upper limb function post-stroke especially when coupled with voluntary functional exercise2. Implanted systems remove some of the problems associated with surface stimulation, such as accurate placement of electrodes, and may provide finer control of muscle activation and thus more functional movement. Furthermore, a recent review concluded that when stimulation is associated with a patient’s own voluntary activation the therapeutic effect is enhanced3. Others have described the use of external devices such as electromyography (EMG) for voluntary activation of stimulation4 though these are triggers and do not provide closed-loop control.

This paper presents results from the end phase of a feasibility study using implanted radio-frequency controlled microstimulators (RFMs) with a closed-loop control system using sensors responsive to voluntary movement. Results of a questionnaire on the participants’ views of the system are also presented.

2 Methods

2.1 Study Design

The study was in three phases: during the first phase we implanted between five and seven devices in the arms of seven post-stroke hemiparetic participants to facilitate elbow, wrist, finger and thumb extension, and thumb abduction. Open-loop function-based programmes were used at home for 12 weeks5. In the second phase of the study a closed loop control (CLC) system was designed and bench tested using sensors to allow timing of stimulation to be responsive to the speed at which the participants performed the activities. In Phase 3 participants used the CLC system at home for one to two hours per day for 12 weeks.

2.2 The Microstimulator and implantation

The RFM, developed by the Alfred Mann Foundation (AMF), is a wireless cylindrical implantable neurostimulator. The surgical procedure undertaken under
local anaesthesia using specially designed insertion tools is minimally invasive (5mm incision). In this study one or two devices were implanted close to the posterior interosseous nerve (PIN) to open the thumb and fingers. Wrist extension was selectively activated by two devices close to the motor points of extensor carpi ulnaris and extensor carpi radialis longus (ECU and ECRL). Two devices were implanted close to radial nerve branches of the medial and lateral heads of triceps (MHT and LHT) for elbow extension.

Fig. 1 External components of the system: (A) Control Unit (CU), (B) arm coil, (C) CU to coil cable, (D) goniometer cable, (E) touch mat, (F) externally connected trigger, (G) externally connected stop button, (H) trigger interface box (TIB), (I) TIB to CU cable

2.3 External Devices and Communication Scheme

The external system is shown in figure 1. RFMs are individually addressed and receive power and control signals from a control unit (CU) via an inductance coil with one cuff worn on the upper arm and the other on the forearm. The CU has a sensor port to which four channels of sensors may be connected via a trigger interface box for signal processing. In this study, in order to facilitate stimulation of the participant’s muscles synchronized to the sequence of their volitional movements, three external sensors were incorporated. The sensors consisted of a commercially available goniometer (consisting of a light source and a light sensor, connected by a fiber optic cable) to detect the elbow joint angle, a touch mat (a hard plastic mat and load cell) to detect pressure of the hand or object and a start button switch. All equipment was bench tested for safety, functionality and reliability.

2.4 Stimulation Programme set-up

During post-implantation sessions stimulation parameters were set for the microstimulators using custom made software on a laptop. Specific functional tasks were identified for each participant and the therapist set up a series of stimulation sequences by determining which devices were activated, the required stimulation parameters and timing of each, to form a functional programme. Up to three stimulation programmes were downloaded to the CU. The participants used a standalone system (laptop not present) at home. In phase two and three the activity programmes were set up to include external sensors to activate stimulation sequences.

Fig. 2 Example of a phase 3 stimulation programme

In an example of a typical activity programme (figure 2) the button switch was pressed using the non-hemiplegic hand to start the sequence and facilitate reach, the goniometer then detected elbow extension movement and at a set angle triggered opening of the hand. The mat detected touch of the object stopping the stimulation to allow grasp of an object. The participant used the object and then when ready pressed the button switch to reach and place the object on the mat, this triggered opening of the hand to release the object and after a set delay the stimulation stops to allow the participant to rest. This completed one full cycle and the start button was pressed again to repeat.

2.5 Outcome Measures and Participant Questionnaire

Outcome measures were applied at the start and end of Phase 3. The main functional outcome measure was the Action Research Arm Test (ARAT). Impairment measures included the Fugl Meyer (upper limb motor section) (FM (motor)) and measures recorded in a validated instrumented wrist rig which included a test of wrist motor control (ability to track a target moving horizontally at 0.5Hz - Tracking Index (TI)).

A purpose-designed questionnaire was developed in order to assess participant perceptions of the effectiveness, convenience and reliability of the system, the difficulties in adhering to the prescribed exercise programme and their ideas on improvements for future systems. The questionnaire comprised statements and responses using a 5 point likert scale (strongly disagree to strongly agree), as well as open questions. The statements relating to the effectiveness and reliability of the phase 3 sensor system were:
The mat enables me to release objects when I want to.
The mat works all the time.
The goniometer makes the stimulation respond to the way I move.
The goniometer works all the time.
The button allows me to switch the stimulation on or off when I want.
The button works all the time.

We also asked participants to indicate which of the sensors they preferred.

### 3 Results

Six of the original seven participants progressed from phase 1 to phase 2 and 3. One drop out occurred due to health problems. Table 1 shows the Normal (SD) values and mean (SD) values for function (ARAT) and impairment (FM (motor), Motor control (TI)) measures pre-phase 3 and end of phase 3. Statistically significant improvement was found with the FM (motor) test (p<0.05).

<table>
<thead>
<tr>
<th>N=6</th>
<th>Normal (SD)</th>
<th>Pre-phase 3 (SD) Range</th>
<th>Phase 3 (SD) Range</th>
<th>Mean change P-value [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARAT</td>
<td>57 (0)</td>
<td>27.8 (11.9) 7 - 43</td>
<td>32.8 (14.2) 7 - 47</td>
<td>5.0 (5.2) P=0.064 [-10.43, 0.43]</td>
</tr>
<tr>
<td>FM</td>
<td>66 (0)</td>
<td>96.8 (8.9) 85 - 111</td>
<td>102.2 (9.2) 92 - 114</td>
<td>5.3 (4.0) P=0.021 [-6.22, -0.78]</td>
</tr>
<tr>
<td>TI</td>
<td>192.6 (10.9)</td>
<td>120.0 (48.1) 53.5-168.7</td>
<td>135.0 (41.0) 76.7-178.9</td>
<td>15.1 (27.9) P=0.244 [-44.37, 14.25]</td>
</tr>
</tbody>
</table>

The bench testing of the sensors found no safety issues. The touch mat was found to be very sensitive to a drop test and participants were verbally warned about this and caution labels were used. Despite this four touch mats had to be replaced during phase 3. The output of the touch mat’s load cell proportional to force, and the goniometer output voltage with angle, both displayed good linearity and this was validated clinically when using the system with participants. In terms of functionality, electrical noise from other system components occasionally caused false triggers with the touch mat. The trigger level was therefore set at a level which prevented false triggers but did require a modest pressure application which in practice was not always easy for less able participants. Two goniometers had to be replaced due to irreversible bending of the fibre optic cable causing a change in output voltage values.

The number of participants who in the questionnaire agreed or strongly agreed with each sensor being effective and reliable, and their preference for each sensor, are shown in Table 2.

### Table 2: Participant perceptions and preferences

<table>
<thead>
<tr>
<th>N=6</th>
<th>Touch Mat</th>
<th>Goniometer</th>
<th>Button switch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness</td>
<td>5</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Reliability</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Preference</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

### 5 Discussion and Conclusion

The Phase 3 CLC system generally functioned well. All the sensors were used throughout the exercise period and the majority of the participants perceived them to be effective. The clinical results also show the system to be effective to bring about a statistically significant improvement in impairment of the whole arm measured with the FM (motor), an improvement in arm function (ARAT) which did not quite reach statistical significance, possibly due to the small sample size, and a small improvement in motor control at the wrist.

Participants, however, found the reliability of the goniometer and touch mat to be a problem. They were both sensitive to general wear and tear and the effects of noise (mat only). They and the TIB were also bulky and inconvenient. At the end of the study the participants’ preference was to use a system with only the simple but reliable button switch despite it being a less natural movement to use their non-hemiplegic hand. Future systems with external control mechanisms need to be both effective and reliable, as well as compact. Ultimately an implantable device with its own sensors such as EMG, goniometry and accelerometers is a worthy research objective.

### 5 References