Post-stroke Upper Extremity Rehabilitation using 5-7 Implanted Microstimulators: Surgical Procedures.

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Abstract

Seven Participants with post-stroke upper extremity weakness and spasticity were chosen and agreed to have 5-7 RF Microstimulators (RFM) implanted on Radial Nerve branches and then to undergo 3x 1 hour sessions/day of programmed electrical stimulation to extend the elbow, wrist and fingers. Their stroke had occurred earlier at a mean of 3.9yrs (1.1 to 10.5yr.); there were 4 Male and 3 Females, mean age of 49yrs, with a range of 32-62yrs.

These 7 surgeries started in April 2005 and extended to March 2006. Pre-operatively, implantation sites were identified by needle EMG. Under local anaesthesia, using a 5mm incision, the targeted nerve/motor-points (N/MP) were identified using the inserted probe with stimulation, and then the RFM is inserted using the introducer and ejection tools. Each device receives power and activation commands via a 2 MHz RF inductive link from the external cuff coil connected to the Control Unit. RFMs can be retrieved during surgery and up to 8 days. Initially a total of 41 RFMs were implanted. In Pt #4, 2 more RFMs were inserted 6 months later in the triceps' N/MPs for improvement of elbow extension. Implantations took 4.9 hours (3.5 to 6 hrs). No RFMs have failed, no infections have occurred.

1. INTRODUCTION

In the USA, 1.69% or 4.6 million people have had strokes, with 1 occurring every minute. 85% of stroke survivors regain the ability to walk but over 80% of those who have upper limb problems **do not** regain useful function. Typically, there is difficulty reaching with an ineffective grip (**loss of extensor muscles**). This study of **7** post-stroke Participants is concerned with improving recovery of upper limb function by stimulating individual radial nerve branches using implanted radio-frequency microstimulators (RFM) [1].

2. METHODS

2.1. Subjects

Seven subjects have been included with a chronic stroke causing a hemiplegia, with an impaired arm/hand function due to poor control and weakness of wrist extension and elbow extension; and with some voluntary control of finger flexors and proximal arm and shoulder muscles. Their stroke had occurred at a mean of 3.9yrs (1.1 to 10.5yr.) earlier; there were 4 Male and 3 Females, mean age of 49yrs, with a range of 32-62yrs. Subjects have given written informed consent, and the protocol was approved by the Thames Valley multicentre research ethics committee, UK (#04/12/021), and by the Medicines and Healthcare products Regulatory Agency (CI/2004/0027). The study was conducted following guidelines of good clinical practices.

2.2. Microstimulator and Control System

The RF Microstimulator (RFM) is cylindrical (2.4 mm x 17 mm) with an eyelet attached at the anodal end, to which a dissolvable suture is tied allowing the RFM to be retrieved from the tissues during implantation and up to 8 days post-operatively. The RFM is a single-channel, implantable stimulator that produces capacitively-coupled, charge balanced, asymmetric, biphasic, and constant-current pulses. In each subject, 5 to 7 devices were implanted on nerves/motor-points (N/MP) of Radial Nerve branches to extend the elbow, wrist and fingers in each subject. For the 7 subjects, a total of 41 devices were inserted; however in Pt #4, 2 more RFMs were inserted 6 months later in the medial and lateral triceps' N/MPs to improve elbow extension.

Once implanted, the devices receive power and stimulation commands via a 2 MHz RF inductive link provided by 2 external cuff-coils, one for the forearm and the other for the upper arm; both are connected to a Control Unit. The stimulation parameters are set by a laptop based fitting system, and can be programmed to respond to triggers issued by sensors.

2.3. Surgical Implantation Procedure

2.3.1. Target Sites

Each RFM is inserted adjacent to target muscle motor-point/nerve (N/MP) using the surgical insertion tools and techniques developed by the Alfred Mann Foundation (Valencia, CA) [1,2]. The upper extremity implantation sites (Table 1) are the N/MPs of each of the medial and lateral triceps muscles (MHT/LHT) for elbow extension, N/MPs of the extensor carpi radialis (ECR) and ulnaris (ECU) for wrist extension, and 1-2 branches of the posterior interosseous nerve (PIN/ED) for finger and thumb extension.

Subject #	Upper arm	Forearm	RFMs	Retrieval
1	LHT, MHT,	ECU, ECR, PIN	5	0
2	LHT, MHT,	ECU, ECR, PIN, ED	6	2
3	LHT, MHT,	ECU, ECR, PIN, ED	6	0
4	LHT, MHT, / MHT, LHT (R)	ECU, ECRL+B, PIN, ED	7 (+2)	9
5	LHT, MHT,	ECU, ECR, PIN	5	10
6	LHT, MHT,	ECU, ECR, PIN, ED	6	4
7	LHT, MHT,	ECU, ECR, PIN, ED	6	4
			Total: 41(+2R)	29

Table 1

2.3.2. Pre-operative Functions

During the pre-operative week, an EMG study was performed (by CW) to identify and mark the N/MP of each of the target sites. At commencement of the procedure, an IV dose of Cefuroxime 1.5 gm was given and an additional dose of 0.75gm was given 6 hours later, before subjects were discharged home. The affected hand, forearm and mid to lower upper arm areas are thoroughly scrubbed with antiseptic solution for 5-7 minutes, then side towels are placed. A plastic drape impregnated with an iodinated antiseptic, is placed over the skin and peripheral sterile towels/drapes.

Prior to implantation, the RFMs are tested, a dissolvable suture is tied to an eyelet attached to the anode, and the devices are stored temporarily in sterile saline solution with antibiotic: colomycin 1,000,000 units in 500 ml.

2.3.3. Insertion Procedure

Local anaesthesia was used, 2 subjects required IV Benzodiazepine during the procedure because of discomfort. At 4-7 cm distal on the arm to the target skin marking, a 5mm skin incision was made allowing insertion of a rounded-tip probe (dia: 0.7 mm) which connects with an external pulse generator for stimulating. The target N/MP is identified by which muscle contracts. If correct, the #7Fr. Gauge introducer (outer sheath + dilator; Fig.1) is slide down the probe to be within 2-3 mm from the probe tip. Stimulation to the probe is repeated to make sure of that the relationship with the N/MP is unchanged. The probe and the dilator are withdrawn; the RFM's cathode is inserted into the sheath, then the ejection tool is inserted into the sheath to gently push the RFM down to where the tip of the cathode is protruding from the sheath. The stimulation RF coil is placed so as to activate & control the RFM to cause a stimulus to the N/MP which causes the target muscle to contract. The sheath has small holes in the distal 1/3 of the shaft, when saline/antibiotic solution is injected into the sheath from the ejector tool, the cathodal current from the RFM stimulus can return to its anode inside the sheath. Prior to ejecting the RFM into the tissues, more saline/antibiotic solution is instilled into the sheath and surrounding tissues. The sheath is withdrawn up the shaft of the ejector tool so uncovering the entire length of the RFM in the tissues. Care is taken not to pull on the attached sutures emerging from the skin opening. Further RF coil testing is done to ensure that the muscle response is capable of moving the distal joint significantly. If this is acceptable then the skin incision is pressed down and the sutures are cut-off at skin level, the skin pressure is released and the suture ends are now lying below the subcutaneous tissue, available to be withdrawn during the next 8 days before encapsulation occurs. If the muscle response is not adequate then the emerging sutures are gently pulled with the stimulation coil still placed close to the inserted RFM; this will give a chance that the muscle response could improve with this retrograde withdrawal. If this

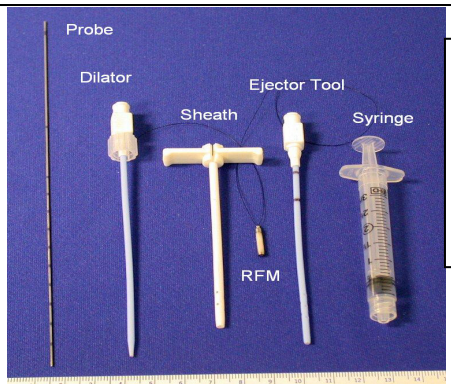


Fig.1 Surgical Instru-ments

manoeuvre is not successful then reinsert the probe and RFM again.

2.3.4. RFM Retrievals

Of the 41 RFMs inserted, 5 of the 7 subjects required 29 retrievals of the RFMs by suture withdrawals due to the insertions not producing an adequate target muscle response (Table 1). The most difficult N/MPs to target were for the Triceps muscles, especially the medial head which required 8 retrievals in 5 subjects.

Once the devices are inserted in the position that elicits acceptable motor response, motor thresholds are measured, the incision is irrigated with antibiotic saline, and the skin is closed usually with one 4‘0’ suture. Final verification of the device placement is done with the 2 RF cuff-coils positioned over the upper arm and forearm.

3. RESULTS

3.1.1. Implant Time

The completed implantations in the 7 subjects took an average of 4.9 hours (3.5 to 6 hrs). The forearm insertions with 3/4 devices/subject averaged 40.7 min/device, while in the upper arm (2 devices / subject) was 50.9 min/device. Subjects were given a prescription for a 10 day supply of Cefalexin 250mg 3/day. Radiological films were taken after each surgery.

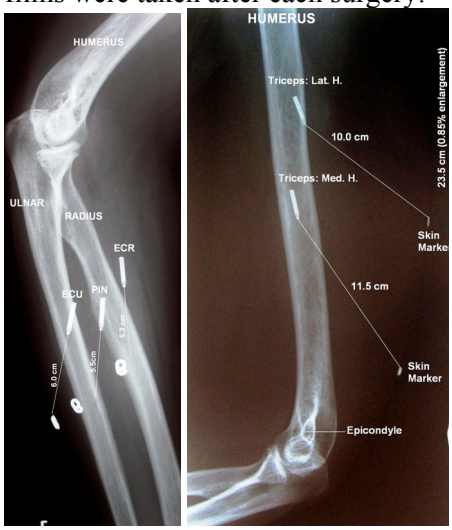
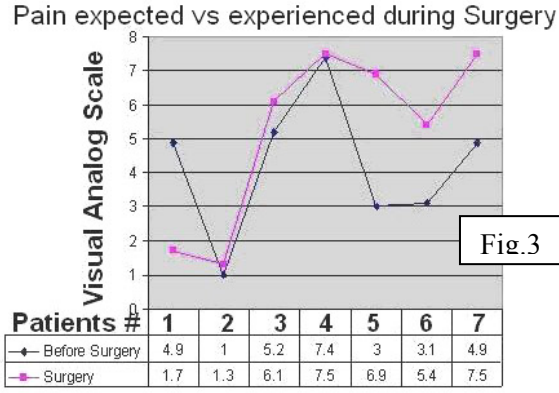


Figure 2 Forearm and upper arm.

After surgery, 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.

3.2.1 Adverse Events

With 43 devices implanted, there have been no serious adverse events. No sign of infection or allergic reaction have been observed. Those Subjects, who expected, did experience surgical pain on VAS (0-10) ranging from 1.3-7.5 (mean: 4.8 SD+/-2.7; Fig.3). Paracetamol was sufficient to resolve the pain. Minor post-operative adverse events included moderate post operative pain in 2 subjects for 1 week and in 1 subject for 4 weeks.



Patients #	1	2	3	4	5	6	7
Before Surgery	4.9	1	5.2	7.4	3	3.1	4.9
Surgery	1.7	1.3	6.1	7.5	6.9	5.4	7.5

Fig.3

Three subjects showed signs of swelling in the forearm for 2 weeks after surgery. 2 subjects showed mild tenderness on one of the implant sites. 1 subject showed moderate bruising. 1 subject had a small amount of bleeding at one implant site after 1 week, which required early dressing change. 1 subject reported digestive problems associated with antibiotics after 1 week. These events are within the normal scope of symptoms experienced subsequent to implant surgical incisions and implants.

4. CONCLUSION

From this pilot study of 7 post-stroke subjects, it has been possible with specially developed insertion tools and local anaesthesia, to safely and effectively implant 5-7 RFMs per subject onto targeted nerves or motor-points in the upper extremity with only minor side effects in order to start rehabilitation of their impaired neurological functions.

References

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[2] Davis R, Cosendai G, Ripley A, et al. Retrieval of Microstimulators at Human Implant Surgery and Post-Operatively. Proc. 9th Int. Funct. Electr. Stim. Soc. 6-9th September, 2004; Bournmouth, UK; pp 386-388.