Clinical Experience of the STIMuSTEP Implanted Dropped Foot Stimulator

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Abstract

A mixed population of 46 people have received the STIMuSTEP implanted dropped foot stimulator. 42 use the device successfully while 2 are unable due to device failure and 2 have been explanted. The performance of the device was evaluated using 10m walking speed, physiological cost index, distance walked in 3 minutes, the psychosocial impact of assistive devices scale (PIADS) and the SF36 quality of life scale. Comparisons were made with the response to an external FES device used before implantation. An 18% increase in walking speed, a 9% reduction in PCI and a 23% increase in distance walked in 3 minutes was recorded when the device was used. There was also a positive impact on quality of life. There was no significant difference between the external FES device and the implant in any outcome measures. Initial versions of the implant were subject to cable fracture but this has been eliminated by design modifications. There is a risk of short term neuropraxia which resolves after a few weeks or months. The STIMuSTEP is a viable alternative to external FES for the correction of dropped foot where difficulties in placing electrodes, skin irritation or skin sensation prevent its successful use.

Introduction

Dropped foot due to an upper motor neurone lesion can be successfully corrected using external FES systems. These devices stimulate the common peroneal nerve as it passes distal to the head of the fibula bone, using skin mounted electrodes. Stimulation causes dorsiflexion and eversion and when timed to the gait cycle the device significantly aids the swing through phase of gait, reducing the effort of walking, reducing the incidence of falls and increasing walking speed1,2. Further, because a good position of the foot is achieved at initial contact, the ankle stability is significantly improved through stance. Despite a good orthotic response and high compliance with these devices, some difficulties can remain. To achieve optimal weight acceptance heel strike is required with dorsiflexion and a small degree of eversion and this requires careful positioning of the electrodes which can be a challenge to some FES users who have poor hand function or cognitive issues. The response to stimulation will also change as the condition of the electrodes deteriorates with use. Skin electrodes can also produce skin irritation after prolonged use, which, while it can be clinically managed in most cases, persistent irritations can prevent long term or regular use of FES. Finally, stimulation of the skin sensory receptors can be uncomfortable. These issues can be addressed using an implant device.

The University of Twente and Finetech Medical Ltd have developed an implantable device called the STIMuSTEP3,4,5. Two channels of stimulation are used to stimulate the 2 branches of the common peroneal nerve. The deep branch produces dorsiflexion and inversion while the superficial branch produces eversion and plantarflexion of the foot. By adjusting the relative proportions of stimulation to both nerves, the exact movement of the foot can be controlled. The device consists of a passive receiver that receives stimulation pulses from an external controller strapped to the leg over the receiver via close coupled radio telemetry. The device uses epineural electrodes (9x2.75x0.8mm assembly with 1mm dia. contacts separated by 5mm) inserted in to each nerve and held in place using tags 10mm from the electrode that are sutured to the outer surface of the epineurium. The device is controlled using a pressure sensitive footswitch place in the shoe. This paper reports our experience in providing the STIMuSTEP as part of a clinical FES service within the UK National Health Service begun in 2006.

Materials and Methods

Candidates for the STIMuSTEP were selected from existing users of the Odstock Dropped Foot Stimulator (ODFS). The same selection criteria was used for the implant and the ODFS; a dropped foot due to an upper motor neuron condition; able to walk at least 10 m unaided by FES; not pregnant; no cancerous tumours in the area of the electrodes and free of poorly controlled epilepsy2. In addition for the implant candidates had to be medical stable, not diabetic, able to tolerate a general anaesthetic and demonstrated a good response to use of the ODFS over at least 6 months. Candidates were put forward if they experienced difficulty with daily use of the ODFS due to persistent skin irritation or electrode placement or if long term use of FES was believed to justify the daily convenience of the implant.

The device was implanted in a 1 hour day case procedure under general anaesthetic. Three weeks were allowed for healing after which the external controller was set up. Follow up was provided at 5, 10, 20, 46 weeks post-surgery and then yearly for as long as the device was used.

Outcome measures: 10m walking speed, 3 minute walking distance, physiological cost index (PCI), short form 36 (SF36) quality of life questionnaire and the psychosocial impact of assisted devices scale (PIADS)6. Outcomes were recorded pre implantation with the ODFS and at 20 week follow up. Paired data was compared using the Student T test.

Results

46 people have received the STIMuSTEP between 2006 and 2011; 18 stroke, 17 multiple sclerosis (1 bilateral), 3 traumatic brain injury, 2 incomplete spinal cord injury, 1 brain tumour (removed), 1 Parkinson’s disease, 1 neurofibromatosis, 2 transverse myelitis and 1 cerebral palsy (bilateral). 42 are current users of the device. 2 have non-functioning implants while 2 have been explanted, 1 due to an infection and 1 due to unsuccessful revision surgery following a poor response associated with abnormal nerve anatomy. All 4 have returned to using the ODFS.

Table 1. Mean 10m walking speed and PCI
Tables 1 and 2 show the results for 10m walking speed, PCI and 3 minute walk. Both devices produced the same improvement in walking performance with no statistically significant difference found between any of the indices for STIMuSTEP and ODFS. Table 3 shows the results for PIADS. Both devices produced a significant positive impact on device related quality of life but again there was no difference between device although a strong trend was present in the self-esteem domain. There was no significant difference in SF36 scores between groups.

### Table 3. PIADS

<table>
<thead>
<tr>
<th></th>
<th>Competence</th>
<th>Adaptability</th>
<th>Self-esteem</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODFS</td>
<td>1.47 (0.62)</td>
<td>1.44 (0.85)</td>
<td>1.20 (0.63)</td>
</tr>
<tr>
<td>STIMuSTEP</td>
<td>1.52 (0.67)</td>
<td>1.39 (0.84)</td>
<td>1.51 (0.76)</td>
</tr>
<tr>
<td>P</td>
<td>0.759</td>
<td>0.784</td>
<td>0.068</td>
</tr>
</tbody>
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Scores between 0 to 3 indicates an improvement.

### Adverse events

The first 16 cases received the same implant design that was used in the original trial to obtain CE marking. Patient 11 experienced intermittent function form channel 2 of the device (superficial nerve) after 10 months of use. Revision surgery indicated that the electrode may have become loose and so was sutured more firmly in place. A good response was found in theatre and again at set up three weeks later. However, after 3 weeks the device was again intermittent and therefore second revision surgery performed at which the implant was replaced. By then the design of the implant had been modified, increasing the size of the suture tags from 2 x 12mm to 4 x 12mm, to enable a more secure fixing of the electrode. Unfortunately it was not possible to fully examine the explanted device due to damage sustained in explantation. At the first assessment after surgery it was noted that the stimulation threshold for channel 2 had risen but a good movement was achieved. Three weeks later the response from the channel 2 had significantly declined and it was not possible to produce adequate eversion even at maximum stimulation. Nerve damage was confirmed using nerve conduction studies. It was reasoned that nerve damage may have occurred due to external pressure from the controller and strap on the implant and nerve. For this reason a separate transmitter coil with a hollow centre was used to power the implant, avoiding direct pressure on the receiver and electrodes. Nerve recovery occurred over the next 6 months and the function of the device was restored.

A further 5 implant failures occurred in the first 16 users, one following a significant fall. On these occasions it was possible to determine that in each case the lead had failed within one of the electrodes. Bench testing confirmed that this was a weak point subject to stress fracture and so the electrode was reinforced to reduce flexing, increasing its overall dimensions to 9x3x1mm and strain relief added. The next 11 patients received this design. One further electrode failure was experienced after 22 months of use. Additionally 4 reports of nerve dysfunction were reported. In each case the dysfunction was evident at the first assessment after surgery after good response in surgery. After a full case series review it was reasoned that the nerve injury may be due to the increased rigidity of the electrode / nerve interface due to the larger suture tags and increase number of sutures used. The size of the tag was reduced to the original design and the number of sutures limited to 1 per each side of the tag. Since 2010 19 people have received the new design (2 bilaterally). No further implant failures have occurred. 5 cases of nerve dysfunction have occurred, which have all resolved after a few weeks (2) or months (3).

Five people have experienced sensitivity to the positioning of the control box relative to the implant. Small movements of the controller have caused significant changes to the response to stimulation. This has been successfully addressed by providing the separate transmitter coil mentioned above. The coil is 65mm in diameter, 25mm more than the controller’s integral coil. This ensures that the response remains constant for displacements of around 20mm in any direction.

### Discussions

Our experience indicates that the implanted STIMuSTEP device provides a similar performance in terms of dropped foot correction as the external ODFS. Users report that the device is quicker and easier to set up each day, produces less sensation when stimulating and does not cause skin irritation. Use of an implant caries increased risks over an external ODFS. Users report that the device is quicker and easier to use than an external device associated with the operative procedure, and the presence of a “foreign body” within the leg. There is a risk of nerve injury but so far this has been temporary and has not resulted in long-term non-use of the device. Initial problems with implant reliability have been overcome with no breakages occurring in the current design after approximately 385 man months of use. The response from its users has been very positive. One STIMuSTEP user described using the device as like “driving a Mercedes after driving a cheap car. Both get you from A to B but you don’t want to drive the cheap car again after the Mercedes.”

### Conclusions

The STIMuSTEP is a viable alternative to external FES for the
correction of dropped foot where difficulties in placing electrodes, skin irritation or skin sensation prevent its successful use.

References


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