Pilot study to evaluate the safety and efficacy of an implanted dropped foot stimulator (IMPULSE)

Paul Taylor*, Geraldine Mann, Duncan Wood John Hobby
Dept. Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire SP2 8BJ, p.taylor@salisburyfes.com


Introduction
Dropped foot following stroke can be successfully alleviated using surface stimulation devices such as the Odstock Dropped Foot Stimulator (ODFS). These devices stimulate the common peroneal nerve as it passes over the head of the fibula bone, causing the foot to dorsiflex. When timed to the gait cycle using a pressure sensitive switch placed under the heel, the device significantly aids the swing through phase of gait, reducing the effort of walking and increasing walking speed. Despite a good orthotic response and high compliance with these devices, users report difficulty with using them, in particular, correctly replacing electrodes. This problem could be alleviated by the use of implanted electrodes, avoiding the day to day variation in the user placement of electrodes. Additionally the sensation from the stimulation would be reduced and the risk of skin allergy eliminated. The University of Twente, Finetech Medical Ltd and European Technology for Business (ETB) have developed an implantable device 1. 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. This paper reports the findings of a pilot study of the device.

Methods
The ODFS Questionnaire
A questionnaire was sent out to 140 experienced (1 year +) users of the ODFS. They were asked to identify what problems they had experienced and rate the seriousness of those problems on a visual analogue scale. They were also asked if they would consider an implanted device.

Clinical trial: Selection criteria
a) First stroke of at least 12 months duration with a stable neurology.
b) Dropped foot identified by an inability to achieve a normal heel strike during walking.
c) Able to walk at least 100m with aids.
d) Must be able to understand the use of the equipment and purpose of the trial.
e) Able to give informed consent
f) Aged between 18 and 65
Exclusion criteria
a) Evidence of inversion contractures;
b) Serious medical conditions
c) Regular surface peroneal stimulator users

Clinical trial: Procedure
Subjects were first assessed through a 1 month base line period to demonstrate stability. After receiving the implant, three weeks were allowed for healing of the operation site. 2 months were then allowed for training with the device and assessments were then repeated in the following three months, once a new gait pattern had become established.

Clinical trial: Assessments
Safety was assessed by nerve conduction studies. Spontaneous discharges at EMG needle insertion were also examined for evidence of denervation.

Walking speed and physiological cost index (PCI) was measured over 10m. PCI is equal to the difference between resting heart rate and the heart rate at the end of 10m divided by the walking speed in m/min. This gives an indication of the effort expended in walking. Three runs were recorded both with and without the stimulator and the order randomised to compensate for fatigue. Additionally the distance walked in 6 min was recorded by walking repeated lengths of a 13.5m corridor.

The implant's effect on kinematics parameters was recorded using a Biotech Datalink system. Penny and Giles goniometers were placed over the ankle, knee and hip joints to measure dorsiflexion, eversion, knee flexion and hip flexion / extension and adduction abduction.

User opinion of the device was collected using a purpose written questionnaire.

Results
ODFS user survey: 98 questionnaires were returned from 140 sent to current ODFS users. On average they had used the ODFS for 3 years (SD 2.1 years). While 52% were well satisfied or 41% moderately satisfied with the ODFS, problems were reported with skin reaction (28% - serious 6%), electrode placement (72% - serious 17%), donning and doffing (58% - serious 15%), coping with wires (58% - serious 19%) and sensation (36% - serious 3%). 67% would consider an implant.

Clinical Trial
Five people received the implant. 4 were right sided hemiplegics and 1 was left sided following stroke.

No change in nerve conduction velocity was reported following the implant procedure. Nor was there any evidence of denervation observed on EMG needle insertion.
Mean walking speed with the device was 24% faster with the implant compared to pre op without and 14% faster than without the device post op. No significant changes were seen in PCI. Mean distance walked in 6 minutes increased by 37% pre to post op. (table 1)

Dorsiflexion and Eversion were compared walking with and without the device at the point just before heel strike. This is before any loading response has occurred. Use of the implant resulted in a 15 and 9 degree increase in dorsiflexion and eversion. There was also a reduction in hip abduction of 2 degrees that may be due to reduced circumduction in the swing phase, which is a compensatory response to aid ground clearance. A trend to reduced knee flexion when the implant was used was also seen. This could also be less compensatory activity but may indicate knee flexion is reduced by stimulation (table 2).

Table 1. Walking speed, PCI and Endurance, pre op and post op both with and without the implant (n=5). The results here are the mean of 4 measurements made in the final 3 months period.

<table>
<thead>
<tr>
<th></th>
<th>Walking speed m/s No stim</th>
<th>PCI Bt/m No stim</th>
<th>Walking speed m/s With stim</th>
<th>PCI Bt/m With stim</th>
<th>Endurance Metres</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre op mean</td>
<td>0.59</td>
<td>0.87</td>
<td></td>
<td></td>
<td>188.92</td>
</tr>
<tr>
<td>Post op mean</td>
<td>0.65</td>
<td>0.75</td>
<td>0.74</td>
<td>0.71</td>
<td>264.81</td>
</tr>
<tr>
<td>Mean % change pre / post op</td>
<td>9.0%</td>
<td>6.3%</td>
<td>24.0%</td>
<td>-2.4%</td>
<td>37.5%</td>
</tr>
<tr>
<td>p=0.250</td>
<td>p=0.343</td>
<td></td>
<td>p=0.040</td>
<td>p=0.343</td>
<td></td>
</tr>
<tr>
<td>Mean % change stim / no stim</td>
<td>14.2%</td>
<td></td>
<td>-6.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p=0.022</td>
<td>p=0.112</td>
<td></td>
<td></td>
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</tbody>
</table>

Table 2. Hip, knee and ankle angle while walking with and without the implant (n=4), at end month 5.

<table>
<thead>
<tr>
<th></th>
<th>knee flexion (max swing)</th>
<th>Hip Flexion (max swing)</th>
<th>Hip abduction (max swing)</th>
<th>Dorsiflexion (pre loading response)</th>
<th>Eversion (pre loading response)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Degrees No stim</td>
<td>39</td>
<td>18</td>
<td>7</td>
<td>-9</td>
<td>-9</td>
</tr>
<tr>
<td>Mean Degrees With stim</td>
<td>32</td>
<td>19</td>
<td>5</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Difference Degrees</td>
<td>-7.0</td>
<td>-0.7</td>
<td>1.9</td>
<td>15.2</td>
<td>9.2</td>
</tr>
<tr>
<td>Wilcoxon p</td>
<td>0.07</td>
<td>0.36</td>
<td>0.03</td>
<td>0.03</td>
<td>0.03</td>
</tr>
</tbody>
</table>
User questionnaire

3 users used the device every day while one used it 4 to 6 days a week and one 2 to 3 days a week. On days that the device was used, one user used it all day, one 9 to 12 hours, two 6 to 9 hours and one less than 3 hours a day. The device was used for every type of activity by 3 users while one used it outdoors only and one for longer walks only. Two users regularly walked between 10 and 100 yards, one between 100 and 500 yards, one between 500 yards and 1 mile and one walks more than one mile.

From a list of 12 possible replies, the users were asked to select any reasons that were relevant to them and indicate the most important reason for using the device. All users said they were more independent when using the device and 4 said they were more confident and could walk on uneven ground. 3 users stated they could walk further, walk faster and walk with less effort when using the implant and 2 users used it because they could discard a splint or walking stick. 2 users felt using the device helped to keep them fit while only one user used it because it prevented them from tripping or falling. Each user chose a different main reason for using the device. The reasons were: I can walk faster, I can walk with less effort, I am less likely to trip or fall, I am more independent and The exercise keeps me fit.

Two users required help putting on the device while 3 were independent and the perceived average time to do this was 4.8 minutes (median 4 minutes). Three users believed their spasticity had reduced since using the device, one believed it was the same and one believed it had increased although in the last case this was at odds with the opinion of the physiotherapist. The device had an effect on the use of aids. Two people stopped using walking sticks while walking and one reduced their use of a walking stick. One user reduced their use of a wheelchair, one reduced their use of an AFO and one stopped using an AFO.

Three users stated that the device worked correctly all of the time while 2 stated it worked correctly most of the time while walking. While sitting, 4 users said the device never gave false outputs while 1 reported this happened rarely. 2 users stated they always adjusted the controls themselves while 2 always had an assistant do this for them. Three users stated that adjustments were only occasionally needed, one only when it was put on and one user never adjusted the device. Two felt these adjustments were very easy to make, 1 easy and 2 fairly easy. Three users stated they only adjusted the position of the box when it was put on while the other users adjusted it occasionally or every few hours.

The users were asked if they agreed with the following statements:

- I am glad that I have the IMPULSE - All 5 strongly agree
- I would recommend IMPULSE to another person - 4 strongly agree, 1 disagree
- IMPULSE allows me more independence - 3 strongly agree, 1 agrees
and 1 indifferent

- I feel more confident when I use IMPULSE - 3 strongly agree, 1 agree, 1 indifferent
- I am more independent since I received the implant - 2 strongly agree, 2 agree, 1 no response
- IMPULSE has improved my quality of life - 3 strongly agree, 1 agree, 1 strongly disagree
- IMPULSE has a good cosmetic appearance when worn - 2 agree, 2 indifferent, 1 strongly disagree
- The sensation from the electrodes is comfortable - 1 strongly agree, 4 agree

3 users stated that the box never got knocked in daily use while one said it occurred occasionally and one said it occurred frequently. The latter user said the control knobs on the box pressed into the thigh when the knee was at 90 degrees and also the box got knocked getting in and out of a car.

Users were asked to rate the sensation from using the device on a 1 to 10 analogue scale where 1 was no sensation, 5 was a mild, comfortable sensation and 10 was a severe sensation. Two rated the sensation as 1; two rated it as 5 and one as 6.

**Discussion and Conclusions**

The Finetech implanted dropped foot stimulator was found to perform in a similar manner to surface devices but with the most of the advantages predicted. However, users still experienced some problems with its use. The response from the device is sensitive to small changes in the position of the transmitter, requiring some care in its placement. Also, three of the users were aware of the sensation from the device although this may have been from the strong muscle action required to overcome calf tone. The trend to reduced knee flexion is a possible concern. However, recently, a new version of the device that allows the addition of a rising ramp to the output, has been tried with one subject who reported that knee flexion was made easier. This may be due to reduced spastic tone, which may, in the previous version, have been induced by the rapid movement causing stretch reflexes.

Overall the users were enthusiastic about the device. A larger trial is now required to fully demonstrate its efficacy.

**References**

Acknowledgements

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The device is available from Finetech Medical ++44 1707 330 942