# A clinical controlled trial of the Odstock Dropped Foot Stimulator (ODFS) for correction of dropped foot in chronic stroke.

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## Introduction

There are 100,000 hospital admissions for stroke in the U.K. annually; 20% are fatal and 80% of survivors, despite making some recovery, lead a restricted life-style. (Stroke Towards better management R.C.P. 1989). There are no up-to-date statistics on how many of these patients have a drop-foot but 20% (Merletti et al 1989) would be a conservative estimate. 80% of patients referred for treatment are found to be suitable; giving a potential of 9600 patients per year.

Drop-foot following stroke is therefore a common problem. It is thought to be caused partly by poor active control of the anterior tibialis muscles and partly by increased and inappropriate tone in the extensor muscles of the leg; particularly the calf. Drop-foot prevents the patient from effectively swinging the leg when walking causing an abnormal gait characterised by hip hitching and circumlocution and toe catch . The increased effort required not only means that walking is slow, tiring and sometimes unsafe but may lead to further increase in spasticity.

Drop foot is conventionally corrected by splinting usually a plastic ankle foot orthosis and occasionally a more substantial splint attached to the shoe. Of the 32 subjects who took part in this study 8 were using a splint and 13 had rejected this method of correction and 11 had either been advised not to use it or had not been offered it. All subjects who used electrical stimulation to correct the drop-foot continued with this method in preference to conventional splinting. The disadvantages of splinting are as follows: The splint prevents passive dorsiflexion thus making bringing the centre of gravity forward over the base of support when standing from a chair more difficult. It also prevents active dorsiflexion so that the user cannot 'push-off ' at the end of stance phase. Splinting can lead to further loss of muscle control and reduces the proprioceptive input from the ankle joint resulting in further ankle instability, Many patients find the splint uncomfortable

sometimes exacerbating ankle oedema. In some cases patients do not find splinting an effective way of overcoming a drop-foot, it may, in fact lead to further increase in calf tone.

The Odstock Dropped Foot Stimulator produces dorsiflexion by electrically stimulating the common peroneal nerve, timed to the gait cycle by a pressure sensitive switch placed in the shoe. The stimulation elitists the withdrawal reflex which consists of dorsiflexion, knee and hip flexion. The relative amounts joint movement can be adjusted by controlling the stimulation output and by electrode placement. Timing can be controlled by either heel rise, where the foot switch is placed under heel of the effected leg or by heel strike, where the foot switch is placed under the heel of the ipsillateral side. The device, after a few days of practice, can be used all day as an orthotic aid or as a training aid in gait re-education.

**Hypotheses**

1. The correction of dropped foot will lead to a more normal gait pattern, improving the symmetry of temporal and spatial gait parameters.

2. The correction of dropped foot will give a more efficient gait causing a reduction in physiological cost index (PCI).

3. The correction of dropped foot will enable faster gait.

**Selection criteria.**

1. Chronic Hemiplegia of greater than 6 months.

2. A single dropped foot.

3. Sufficient ankle passive range of movement to allow dorsiflexion.

4. Subjects were not significantly mentally impaired and understood the use of the device.

5. A degree of expressive dysphasia was not a contraindication.

6. Significant medical complications was a contraindication.

7. Subjects could stand unsupported and walk at least 10m with an appropriate walking aid.

8. Subjects were able to stand from sitting independently and walk at least 50 m independently prier to stroke.

9. Subjects were not hypersensitive to the sensation of electrical stimulation.

10. Subjects gave written, informed consent.

11. Dorsiflexion could be produced by electrical stimulation of the common peroneal nerve and/or the antieria tibialis.

12. Subjects were able to attend regularly for assessments and treatment.

All subjects were referred by a GP or Consultant. Some subjects were initially self referred following publicity in a national newspaper and some subjects were initially referred by physiotherapists.

32 subjects were selected and randomly allocated to two groups of 16. The treatment group used the device and received 10 sessions of physiotherapy gait re-education. The control group received the same number of gait re-education sessions but without the stimulator. Thus both groups received equal contact time. The physiotherapy was given by a Bobath trained physiotherapist. While more than one physiotherapist took part, each subject was only treated by one therapist. Most of the gait re-education sessions took place in the fist month of the trial.

**Assessments**

All subjects were assessed before the onset of treatment, at one month and at three months. The assessments made considered in this paper are as follows:

1. Walking speed and PCI (Physiological Cost Index) measured over 10 m. A 10 m course was marked out in a corridor. 2m at either end of the course was allowed for acceleration and deceleration. The subject was asked to walk briskly. The time to walk the 10 m was recorded and the final heart rate at the end of the walking. The heart rate was recorded using a Polar Heart Rate Monitor. This device consists of a chest strap containing an ECG detector and radio transmitter. The signal is received by a wrist warn device which displays the mean heart rate over the previous 4 heart beats.

$$\text{PCI (bt/m)} = \frac{\text{Walking HR - Resting HR (Bt / min)}}{\text{Walking speed (m / min)}}$$

Three measurements were taken, and the average walking speed and PCI recorded. The resting heart rate was recorded prier to the measurement, after the subject had sat quietly for 3 minutes.

2. Gait parameters measured using a Mainstream Locomotion 2D manual video digitisation system. Reflective markers were placed on the toe, heel, ankle, knee, hip, shoulder, elbow and wrist on each side. Additionally the ears was used as a marker. The subject was videod as they walked over a 6m course. The video was then manually

digitised using a Acorn A5000 computer using a frame grabber and "clicking" on each point using a mouse. Each marker is then recorded as a two dimensional co-ordinate. The horizontal co-ordinates of the heel and toe of each foot were then plotted against time, producing a "Helix" diagram (see figures 1,2) By measuring along the X axis, temporal measurements can be made allowing swing time, stance time and double stance time (effected leg leading and non-effected leg leading) to be calculated. Measuring along the Y axis gives spatial measurements allowing step length and the distance one foot is placed in front of the other (both effected non-effected side) to be recorded. Each parameter was recorded twice and the mean value recorded. By comparing effected and non effected sides, a measurement of asymmetry of gait can be obtained.

**Results**

The results are shown here in tabular form. Only results that were statistically significant are given except where they are used to compare with other data.

Speed (10m walk)

| | 1st | 3rd | % change between groups | T test |
|---|---|---|---|---|
| Treatment group no FES | 0.64 m/s | 0.63 m/s | 1.5% decrease | $p>.05$ |
| Treatment group FES | 0.68 m/s | 0.75 m/s | 16% increase | $p<0.01$ |

There was a significant increase in walking speed in the treatment group with FES in comparison with the treatment group.

PCI(10m walk)

| | 1st | 3rd | % change between groups | T test |
|---|---|---|---|---|
| Treatment group no FES | 0.80 Bt.m | 0.76 Bt.m | 5% | $p>.05$ |
| Treatment group FES | 0.59 Bt.m | 0.54 Bt.m | 29% decrease | $p< 0.01$ |

There was a significant decrease in PCI in the treatment group when the stimulator was used.

Speed (gait analysis)

| | 1st . | 3rd | % change | T test |
|---|---|---|---|---|
| Treatment group no FES | 0.44 m/s | 0.56 m/s | 21.5% increase | p=0.01 |
| treatment group FES | 0.46 m/s | 0.60 m/s | 25% increase | p<0.01 |
| Control group | 0.40 m/s | 0.46 m/s | 13% increase | p=0.012 |

All groups showed an increase in speed at the 3rd assessment.

Cadence

| | 1st | 3rd | % change | T test |
|---|---|---|---|---|
| Treatment group no FES | 34.0 steps/s | 37.4 steps/s | 9% increase | p=0.014 |
| Treatment group FES | 34.1 steps/s | 38.2 steps/s | 10.8% increase | p= 0.02 |

The treatment group showed an increase in cadence at the 3rd assessment both with and without the stimulator.

Swing time asymmetry

| | 1st | 2nd | 3rd | % change 1st - 2nd | T test 1st - 2nd |
|---|---|---|---|---|---|
| Treatment group FES | 1.2 s | 0.935 s | 1.4 s | 22% | p = 0.049 |

There was a reduction in asymmetry at 2nd assessment in the treatment group with FES which was lost at the 3rd assessment.

Stance time

| | 1st | 3rd | % change | T Test |
|---|---|---|---|---|
| treatment group FES | 1.47 s | 1.17 s | 20.5% reduction | p =0.043 |

There was a reduction in the time that the hemi leg is on the ground when using FES at the 3rd assessment compared the first.

Double stance time (effected leg leading)

| | 1st | 3rd | % change | T - test |
|---|---|---|---|---|
| Treatment group no FES | 0.58 s | 0.41 s | 29.3% reduction | p =0.04 |
| Treatment group FES | 0.50 s | 0.37 s | 26% reduction | p = 0.02 |

There was a reduction in double stance time when the hemi leg is leading at 3rd assessment compared with the first when using FES. This is also seen in the treatment group without FES. This is not reflected in measurements of asymmetry.

Step length

| | 1st | 3rd | | |
|---|---|---|---|---|
| Treatment group no FES | 0.69 m | 0.80 m | 16% increase | p= 0.04 |
| Treatment group FES | 0.82 m | 0.95 m | 16% increase | p = 0.04 |

There was an increase in step length at 3rd assessment compared with first assessment both with and without FES for the treatment group.

One foot in front of the other distance

| | 1st | 3rd | % change | T -test |
|---|---|---|---|---|
| treatment FES | 0.36 m | 0.42 m | 14.3% increase | p<.01 |

| | | | | |
|---|---|---|---|---|
| hemi | | | | |
| treatment group norm | 0.37 m | 0.42 m | 12 % increase | p=0.02 |
| treatment no FES hemi | 0.35 m | 0.42 m | 16.7 % increase | p<.01 |
| treatment no FES norm | 0.35 m | 0.40 m | 12.5% increase | p<.01 |

Increase in both hemi leading and normal leading distance in both treatment group with and with out FES.

**Conclusions**

10 m Walk

1. There was a significant increase in walking speed when the stimulator was used.

2. There was a significant decrease in PCI when the stimulator was used.

3. There were no significant effects on speed or PCI on either control or treatment group without stimulator.

**Gait analysis**

1. There was an increase in walking speed in all groups. This was greatest when the stimulator was used but was maintained when walking unaided.

2. Cadence was increased in the treatment group, both with and without the stimulator.

3. Step length and the distance that one foot either foot is placed in front of the other both increased in the treatment group, both with and without the stimulator.

4. There is a reduction in the double stance time when the effected leg is leading both with and without the stimulator in the treatment group and a reduction in stance time while using FES in the treatment group.

5. There was no significant effect on the symmetry of either temporal or Spatial parameters except for a temporary change in the swing time at the second assessment.

**Discussion**

The discrepancy in results between measurements in walking speed over 10 m and measurement by gait analysis must be due to the way the measurements were made. Firstly the gait analysis was performed over 6 m this gave a shorter distance for acceleration and deceleration which would restrict the subjects movement. Secondly the subjects may have felt under more pressure to walk in a manor approved by the physiotherapist when under the scrutiny of the gait analysis video cameras while concentrated more on the simpler task of walking down the corridor on the 10 m walk. Finally the calculation of speed in the gait analysis is derived from the step length divided by the summation of the temporal parameters. This may lead to a greater error in the measurement. This discrepancy also casts doubt on the general significance of the rest of the data from the gait analysis which can only be considered valid in the particular circumstances of this measurement.

The lack of improvement in PCI and speed without the stimulator while walking over 10m may in comparison to the improvements recorded in speed by the gait analysis suggest that while there is some carry-over effect when the subject is walking carefully, this is not having a significant effect on every day life which is probably more accurately represented by the 10 m walk.

No significant effect was found on gait asymmetry. This suggests that while mobility may be improved by correction of the dropped foot, it is only one small component of gait leaving significant other problems. Some of these may be addressed by stimulating additional muscle groups. Increases in step length and reduction in stance and double stance time are consistent with increased walking speed and cadence.

Perhaps the most clinically significant result is the reduction in PCI. This means that using the stimulator saves the user effort while walking. This is a very direct return, enabling the user walk further and longer.

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