South and West Regional Development and Evaluation Committee (DEC) Approval.

In December 1995 the results of the trial were presented to South and West Regional DEC. The report (which follows) also include data from other subjects using the ODFS who were not included in the trial bringing the total number of subjects to 178. The current and proposed services were outlined and a cost benefit study made in terms of QALYs (Quality Added Life Years).

After reviewing the evidence put forward, the DEC recommended the use of the ODFS for use within the NHS.

REPORT TO THE DEVELOPMENT EVALUATION COMMITTEE

COMMON PERONEAL STIMULATION FOR THE CORRECTION OF DROP-FOOT

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1996

SUMMARY

- This proposal is for Common Peroneal Stimulation to be offered as treatment of drop foot.
- Drop foot is a common problem for Stroke patients and other Upper Motor Neurone Lesions such as Incomplete Spinal Cord Injuries, Multiple Sclerosis and Head Injuries.
- A drop foot hinders walking, patients develop an abnormal, inefficient and unsafe gait.
- Correction by splinting is unsatisfactory and rejected by 20% of patients.
- With the Odstock Drop Foot Stimulator (ODFS) walking speed is increased by a mean of 14%. Effort, as measured by the Physiological Cost Index (PCI) is reduced by a mean of 39%.
- The results of a Randomised Controlled Trial (RCT) conducted in this department showed significant increase in walking speed and reduction in Physiological Cost

Index (PCI) in the stimulated (FES) group with no significant changes in the controls.

- A significant difference was seen between the FES and control group in PCI, Functional Mobility and HAD scores.
- A study conducted by Strathclyde University (1994) showed an overall improvement in medio-lateral foot stability using stimulation with 10 out of 17 subjects showing significant orthotic benefits. The Odstock Drop Foot stimulator allows for finer control of stimulation parameters than the stimulator used in the Strathclyde study. There are no other RCT on this form of treatment.
- Each patient using the ODFS is estimated to gain 0.065 QALYs whereas the controls, who received physiotherapy only, had an estimated QALY gain of 0.023.
- The cost per QALY if patients continue to use the stimulator for 5 years is £10,307, if the stimulator is used for one year this cost is increased to £19,821

1. Statement of the proposed service:

This paper considers the use of Common Peroneal Stimulation for the correction of drop foot.

2. Background

Drop foot is a common problem for patients with Upper Motor Neurone lesions. It is caused partly by poor active motor control of the anterior tibial muscles and partly by spasticity of the calf muscles. Drop foot prevents the patient from effectively swinging the leg when walking. This in consequence leads to an inefficient, unsafe gait characterised by hip hitching and circumduction and causing the patient to stumble. The increased effort involved not only means that walking is slow, tiring and unsafe but also leads to further increase in spasticity.

3. **Incidence, prevalence and projected trends**

90% of patients using the ODFS have suffered a stroke. There are 100,000 hospital admissions for stroke in Great Britain annually; 20% are fatal and 80% of survivors have a restricted lifestyle. (Stroke Towards better management RCP 1989) There are no statistics to show how many of these patients have a drop foot but 20% (Merletti et al 1979) would be a conservative estimate. 80% of patients referred for treatment are suitable; giving a potential of 12,800 patients per year. 178 patients have been treated in the last three years.

Despite an ageing population there has been a steady decline in the incidence of stroke of 1% per annum since 1970. This is partly accounted for by:

i) Effective treatment of hypertension

ii)Improved lifestyle

iii)Awareness of predisposing factors

The projected trend is for a continued decline of 30% over the next decade.

Incomplete Spinal Cord injuries and MS accounts for fewer than 10% of patients referred for treatment.

4. Outline of current service

Correction of drop foot is conventionally through splinting, either a plastic, semi-flexible ankle-foot orthosis or a caliper. 11% of patients referred for treatment were using a splint. A further 20% had used and rejected this method of correction. Many patients had been discouraged from using a splint because of the problems caused by them such as: increased calf spasticity, discomfort, restricted ankle movement leading to further gait abnormalities.

Few patients receive physiotherapy more than one year post stroke, studies have shown that there is little evidence of continued benefit. There is no evidence that physiotherapy alone can improve ankle dorsiflexion.

5. Outline of proposed service

This proposal is for the Odstock Drop Foot stimulator to be offered as a treatment for drop foot resulting from an Upper Motor Neurone lesion. The service will include supply and maintenance of equipment and consumables, setting up stimulation systems and monitoring of patients progress. Most of the clinical work will be done by a physiotherapist who will often spend some time on gait re-education or liaise with the patients own physiotherapist.

6. Justification for this service

Literature justifying the use of stimulation to correct drop foot rests mainly on case studies, uncontrolled trials and retrospective reviews. Much is anecdotal and outcome measures lack standardisation but oxygen consumption, walking speed and gait analysis predominate. No studies other than the RCT conducted in this department and the Strathclyde study have used patient-centred outcome measures.

A study of a sample of 50 patients using a drop foot stimulator similar to the ODFS, but with less ‘fine tuning,’ in Veruno, Italy 1979 (ref Scan J Rehab) showed improved gait and reduced oxygen consumption in 75% of patients.

Case studies of 3 hemiplegic subjects (Hesse et al) measured increases of 33% in gait speed, 5% in cadence, 26% stride length and 18% in stair climbing. These patients also increased their score on Rivermead Motor Assessment, 19.5%. Ashworth test showed 11% reduction in spasticity.

A study of 22 patients at the Rehabilitation Institute in Ljubljana, Slovenia, measured a mean increase in walking speed of 0.49 m/s, increased stride speed of 0.49s and increased stride length of 5.49 cms.

A study at Strathclyde University (Granat et al 1995) which used an A-B-A design demonstrated improved gait parameters in 14 out of 15 subjects while using a drop foot stimulator; with no change during the control period. Significant orthotic benefit was seen in 10 out of 17 subjects. The pattern of stimulation used in this study was effective in correcting ankle inversion, the gait analysis results reflect this by improved medio-lateral stability. Flexible electrode positioning and polarity reversal allow for finer control over the stimulated ankle movement with the ODFS than with the stimulator used in the Strathclyde Study.

7. Benefits

80% of patients referred for Functional Electrical Stimulation (FES) for the correction of drop foot have been suitable for treatment.

Drop foot systems have been set up for 178 patients.

25 patients have since discontinued using the drop foot stimulator. Reasons for discontinuing are:

7 - Improved ankle control - orthosis no longer needed

6 - Problems using the system skin irritation, increased spasticity, unable to set up stimulator

3 - Walking deteriorated

5 - Insufficient benefit

1 - Cosmetic

3 - Died

153 patients are continuing to use a drop foot stimulator. The only documented evidence of the effect of long term use of the stimulator is a report by Karsnia et al 1990 reviewing 99 patients who had used drop foot stimulation for 10 years. The first patients to use the ODFS were in 1988, those who are continuing have not demonstrated any problems other than those mentioned above which become apparent in the first few months of use.

The treatment of drop foot by Common peroneal stimulation is supported by the results of a RCT conducted by the Medical Physics and Biomedical Engineering Department Salisbury District Hospital and funded by the Medical Devices Agency at the Department of Health.

The structure and results of the trial are summarised:

The purpose of the trial

The trial assessed the efficacy of the Odstock Dropped Foot Stimulator (ODFS) as part of a physiotherapy programme for stroke patients. It enabled clinical protocols to be developed for its use with patients who are unable to achieve active, functional, ankle dorsiflexion when walking.

Design

Randomised Controlled Trial

Suitable subjects (n = 32, mean age 56.5 years, mean time from stroke 4 years 5 months) referred for treatment were identified following selection criteria (appendix). Subjects gave informed consent and were then allocated to either the treatment (FES) (n = 16) or control group (n = 16). Allocation was made at random following the first assessment. All subjects received the same amount of treatment time. The treatment group used the drop foot stimulator at home and as part of their physiotherapy sessions.

A battery of tests were performed prior to stimulation; after 1 month (during which time subjects received physiotherapy) and at 3 months.

Results

Walking Speed

FES group

At the end of the trial period 13 FES subjects walked faster, 2 no change and 1 walked more slowly. Mean increase in speed (all FES subjects) = 0.22 m/s SD 0.09 mean % increase =18.1%

Increase in speed was significant (paired T test) $p < 0.0002$

Control group

In the control group 6 subjects walked faster, 6 at the same speed and 3 more slowly. Mean increase in speed (all control subjects) = 0.03 m/s SD 0.09. mean % increase = 5.1%

Increase in speed was not significant (paired T test $p<0.604$)

There was no significant difference in the change in walking speed between the FES and control group (student T test) $p<0.0713$.

It is interesting to note that:

The mean walking speed of the control group increased from 0.48 m/s to 0.50m/s during the first month when subjects received physiotherapy but fell to 0.49 m/s at the 3 month assessment.

The mean walking speed of the FES group increased from 0.68m/s to 0.75m/s in the first month and this improvement was maintained without further physiotherapy.

There was no significant change in the walking speed of the FES subjects without stimulation.

Physiological Cost Index (PCI)

FES group

PCI is a measure of the effort of walking which relates increased heart rate to walking speed

At the end of the trial period 10 FES subjects had a lower PCI, 4 no change and in 2 subjects it was higher. Mean reduction in PCI (all FES subjects) = 0.21 SD 0.27 mean % reduction = 46.44%

Reduction in PCI was significant $p < 0.0067$ (paired T test)

Control group

In the control group 5 subjects had a lower PCI, 8 no change and in 3 subjects it was higher. There was a mean reduction (all control subjects) of 0.02 which was not significant $p<0.7101$ (paired T test).

There is a significant difference in change in PCI between the FES and control group $p<0.0466$ (student T test)

Although there was a slight improvement in PCI without stimulation in the FES group it was not significant.

Conclusions

- A significant reduction in PCI with stimulation.
- There was a trend toward increased walking speed in the FES group but this was not significant when compared with the Control group. A larger sample size may show significance.
- A small but not significant increase in walking speed with physiotherapy which was not maintained when physiotherapy was discontinued.
- There was no significant carry-over i.e. therapeutic benefit of stimulation.

Mobility Questionnaire

Maximum score = 16

Mean increase in score during the trial period:

FES group = 2.50

Control group = 0.85

There was a significant difference between the change in the FES group and the change in the control group $p < 0.0489$ (Fisher exact probability test). No significant difference was seen at the start of the trial.

Hospital Anxiety and Depression Scale (HAD)

Patients taking part in the trial were also asked to complete HAD questionnaires at each assessment. A significant reduction in both anxiety and depression in the FES group over the three month period $p<0.0028$ (anxiety scores) and $p<0.0047$ (depression scores) No significant improvement was seen in the control group. The difference between control and FES groups was not significant $p<0.0820$. It is interesting to note, however, that the improvement over the first month was almost the same in both FES and control groups while both groups received physiotherapy. Improvement continued in the FES group but not in the controls.

8. Disbenefits

12% of subjects showed no benefit, none were made worse.

Skin irritation has been a problem with 3% of subjects 1 is unable to continue using the stimulator. A possible cause of skin irritation is the formation of electro-chemical compounds when stimulation produces a charge imbalance. A recent modification of the stimulator which inverts the wave form on alternate pulses effectively avoids a charge imbalance. 5 patients are using these stimulators. 1 patient continues to have skin irritation.

The stimulation system involves wearing self adhesive electrodes on the leg, a switch in the heel of the shoe, and leads connecting these to the stimulator which is worn either in a pocket or on belt. This is an inconvenience and time is taken setting it up each day. Implanted systems have been used but these continue to have problems. 14 of the 16 subjects in the trial were able to set the stimulator up independently but 3 of these said they usually had help. 2 subjects were unable to set it up without help. 4 subjects said they often had difficulty finding the correct electrode positions and 4 said they found the system an encumbrance. The sensation of stimulation has been described as like a momentary nettle rash, 4 subjects said it was slightly uncomfortable, none found it too uncomfortable to use.

9. Costs

Treatment is charged at £166 per episode. This includes the cost of building and maintaining the stimulator and the supply of consumables.

Careful application, support and training of patients using these devices is important (Karsnia et al 1990). Two treatment episodes are therefore needed to set up the stimulator and to ensure that the patient and/or carer are able to use it effectively. Patients are followed-up at 6 weeks with 2 further appointments during the first year. In subsequent years patients are reviewed at 6 monthly intervals.

Therefore the cost in the first year is £830 and £332 in subsequent years.

If an estimate of a mean of 5 years use is taken the **cost per year is £431.60**

Assuming that stroke patients effectively using a drop foot stimulator will benefit for a mean of 5 years. (mean age of subjects 54 years). Then an estimated 0.042. QALYs may be gained by each patient and the cost / QALY would be **£10,307**.

If a patient only uses the stimulator for 1 year the cost would be **£830**

The cost per QALY would be **£19,821**

Some patients may benefit for as long as 10 years (Karsnia et al) the **cost per year would be £381.80**

and the cost per QALY **£9118**

Benefits to the patient are demonstrated by reduced physical disability through increased walking speed, decreased effort of walking and increased mobility. Improvement in these were measured by the randomised controlled trial.

Scoring for Speed, PCI, Mobility Questionnaire and HAD and correlation to points on the Rosser Matrix.

Walking speed, PCI and Mobility Questionnaire scores are considered to relate to disability. HAD scores are related to Distress. It was estimated that all patients were in the categories E1 to E4 and D2 to D6 at both the start and end of the trial. Any movement was considered to be within these categories. Walking speeds, PCI values, Mobility and HAD scores were ranked in the range 0-10. Speed and Mobility scores were ranked in the range 0-8. Scores for Speed PCI and Mobility were then summed to give a disability value.

Example: subject 8 who was at point D4 on the Rosser Matrix at the start of the trial. Walking speed was 0.37 m/s (40% of normal walking speed) (score 2). PCI 0.98 (3* normal)(score 3). Mobility Questionnaire score 12. (score 6) The total disability score of

11 is equal to the sum of these scores. Subject 8 could stand independently from a wheelchair and walk over 500m but always used a walking stick unless supported, only occasionally walked outside alone and not on uneven ground unless with help. At the end of the trial walking speed was 0.55 m/s (score 3) PCI was 0.33 (score 9). Mobility score was 15 (score 8). Giving a total Disability score of 15. She did not use a stick, walked outside regularly and was able to walk on uneven surfaces which enabled her to walk her dog in the New Forest. Point on the Rosser Matrix was therefore D3.

Walking Speed (m / s)										
<0.1	0.1-0.29	0.3-0.49	0.5-0.69	0.7-0.89	0.9-1.09	1.1-1.29	1.3-1.49	>1.5		
0	1	2	3	4	5	6	7	8		
PCI beats per (min / metres per min)										
>1.31	1.21-1.3	1.1-1.2	0.91-1.0	0.81-0.9	0.71-0.8	0.61-0.7	0.51-0.6	0.41-0.5	0.31-0.4	<0.3
0	1	2	3	4	5	6	7	8	9	10
Mobility Questionnaire										
<1	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16		
0	1	2	3	4	5	6	7	8		

HAD										
>18	18-17	16-15	14-13	12-11	10-9	8- 7	6- 5	4 3	2-1	<1
0	1	2	3	4	5	6	7	8	9	10
Total Distress (Emotional) score										
<2	3-5	6-8	>9							
E4	E3	E2	E1							
Total Disability score										
<6.9	7.0-10.9	11-14.9	15-18.9	>19						
D6	D5	D4	D3	D2						

Comment

- The weakness of this proposal lies in the lack of support from the literature. There are no RCTs and few well documented case studies. Until recently research into Functional Electrical Stimulation has been engineering based, departments such as Medical Physics and Biomedical Engineering Department in Salisbury, where there is a close liaison between clinicians and engineers, are rare and it is only with this multi disciplinary base that work such as this can develop.
- The results from this RCT were more promising than studies which used other, similar designs of drop foot stimulators. It is thought that the range of stimulation parameters such as ramp, timing, triggering and flexible electrode positioning,

together with careful application and follow up with physiotherapy have contributed to the benefits to the patients.

Although changes in QALY scores are not great these should be seen in context with alternative treatment available. Stroke is a very common and debilitating disease for which there is little effective medical treatment beyond the initial 3 - 9 month rehabilitation stage.
