Optimising two channel stimulation to improve walking following stroke

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ABSTRACT:
The aims of the study were:

- *To identify patients most likely to benefit from two channel lower limb stimulation with the microcontroller based Compustim 10B stimulator.*
- *To investigate whether optimum muscle groups and control algorithms can be selected by simple clinical assessment or whether specialist gait analysis is required.*
- *To investigate the orthotic and re-education effects of using a second channel of stimulation.*
- *To develop a library of control algorithms for walking*

14 subjects (mean age 63.2, sd 6.7 years, 9 male 5 female) who had been treated with the single channel Odstock Dropped Foot Stimulator (ODFS) for a minimum of 6 months were recruited. All subjects followed a ***Control – Treatment – Control*** *(ABA) study design where* ***Treatment*** *was two channel stimulation with the Compustim 10B and* ***Control*** *was single channel common peroneal stimulation with the Compustim 10B. Walking speed and Physiological Cost Index were measured at approximately four – weekly intervals throughout the study. Gait analysis was performed at weeks 0, 12, 24 and 36.*

Results indicate a significant therapeutic and orthotic effect on walking speed from using a second channel of stimulation. There was poor correlation between clinical observation of gait and specialist gait analysis for both predicted algorithms and evaluation of correction of identified gait problems. Both clinical observation of gait and specialist gait analysis have their limitations. It may be more relevant to use a scoring system to analyse gait with a simple tool to collect ankle and knee angle data, rather than expensive specialist equipment. Video analysis to aid clinical observation would also improve accuracy.

Keywords: *FES, Stroke, Gait, Two Channel*

INTRODUCTION

Dropped foot following stroke can be corrected by electrical stimulation of the common peroneal nerve during swing phase of walking of the affected leg. Significant improvements have been demonstrated in walking speed and effort of walking in a randomised controlled trial of single channel common peroneal stimulation (1,2). However most patients experience weakness or poor control of additional muscle groups in the leg, which reduce the efficiency of their gait. Preliminary work indicated that stimulation of the hamstring or calf muscles in addition to common peroneal nerve stimulation gained the most effective response in improving walking. Stimulation of a second muscle group achieved improvement in gait parameters while the stimulator was used, which was maintained when patients stopped using the stimulator. It was felt that before a randomised controlled trial was considered, methods of selecting appropriate patients and muscle groups/ algorithms should be investigated. The Compustim 10B is a two – channel microcontroller based, neuromuscular stimulator with stimulation triggered by footswitches.

METHOD

The study design was ABA with each phase lasting twelve weeks and patients acting as their own controls. Each patient, still using the ODFS, was assessed at four weeks prior to the study (week –4), to establish whether the ODFS was further improving their gait. In the ‘A’ phase (weeks 0-12 and 24-36), the patient used the Compustim 10B in single channel mode, stimulating the common peroneal nerve of the affected leg during swing phase of gait. In the 'B' phase (weeks 12-24), the patient used the Compustim 10B in dual channel mode, stimulating a second muscle group in addition to the common peroneal nerve. Selection of the second muscle group and optimisation of the appropriate algorithm

Table 1 – Identified clinical problems (Y=yes) & selected algorithm (Hams1, Hams2, Calf) for 2nd.channel

Patient	Poor push-off	Poor knee control at initial stance	Poor knee control at terminal stance	Inadequate swing through	Algorithm selected for second channel
1	Y	Y	-	Y	Hams2, heel and toe switch
2	Y	-	-	Y	Hams2, heel switch
3	Y	-	Y	-	Calf, heel switch
4	Y	-	-	-	Calf, heel and toe switch
5	Y	-	-	-	Calf, heel switch
6	Y	-	-	-	Calf, heel switch on unimpaired side
7	Y	-	Y	Y	Hams2, heel and toe switch
8	Y	Y	-	Y	Hams2, heel and toe switch
9	Y	-	-	-	Calf, heel switch
10	-	Y	-	Y	Hams2, heel and toe switch
11	Y	-	-	-	Calf, heel switch
12	Y	Y	-	Y	Hams1, heel switch

was based on clinical observation alone, during weeks 8 to 12, whilst the patient was using the Compustim 10B in single channel mode at home. Progress was reviewed by clinical assessment every four weeks – measuring walking speed, effort of walking, as indicated by the Physiological Cost Index (PCI) and the Hauser Ambulation Index. Kinematic, kinetic and EMG data was collected using the CODA based Gait Analysis Laboratory at Southampton General Hospital, at weeks 0, 12, 24 and 36. Questionnaires were completed at weeks –4 and 36, inquiring about the use of each stimulator – (ODFS at week –4 , Compustim 10B at week 36) and any problems experienced.

RESULTS

14 subjects (mean age 63.2, SD 6.7 years, 9 male 5 female, mean time since stroke 43 months, 10 right and 4 left sided hemiplegics) who had been using a single channel ODFS for at least six months, were recruited. During the trial two patients withdrew before using the second channel. Of the remaining twelve one died and one did not perform the week 36 tests because of problems with the stimulator, their data, though incomplete, has been included in the results.

Selection of second muscle group and algorithm

From clinical observation

Patients presented with a dropped foot, which was corrected using the ODFS, and either or both, poor active push off or poor knee control.

The following algorithms were used:

- Hams.1 – hamstrings stimulated from initial stance through to mid-swing – to prevent knee hyperextension due to quadriceps spasticity and to improve swing through.
- Hams. 2 – hamstrings stimulated from mid-stance to mid-swing – to improve swing through.
- Calf – calf muscle stimulated from mid-stance through to toe-off – to assist in active push-off.

In three patients the identified clinical problems suggested using the Hams.1 algorithm, but in each case the greatest problem was inadequate swing through. This was best addressed by using the Hams.2 algorithm, initiating stimulation later in stance phase. It was felt that two patients would have benefited equally from calf or hamstring stimulation. The final choice was offered to the patients. Ideally two footswitches, under the heel and first metatarsal head of the affected side, should be used to achieve optimum timing of the second stimulation channel. One footswitch can be used effectively if appropriate delays and extension times are used. This is sometimes necessary when toe strike is unreliable. Unreliable heel strike necessitates placing the footswitch under the heel of the unaffected side.

Predicted algorithm from specialist gait analysis

Predictions of appropriate patient algorithms from CODA gait analysis were based on data from week 0 with no stimulation (0-NS) and week 12 with no stimulation and with single channel stimulation (12-NS and 12S1) (table 3). A scoring system of 1-3 (1= mild, 2= moderate, 3= severe) was developed to indicate the severity of each of the gait problems under investigation for treatment with a second channel of stimulation. Basically, categories with high scores influenced the predicted algorithm, noting that

Table 2 - Prediction of second muscle group and algorithm from CODA gait analysis

Patient	**Second channel**	**Push-off**			**Poor knee control at initial contact**			**Poor knee control at terminal stance**			**CODA prediction**
		0_ NS	12_ NS	12_ S1	0_ NS	12_ NS	12_ S1	0_ NS	12_ NS	12_ S1	
1	Hams2	1	1	1	3	3	3	2	1	2	Hams1
2	Hams2	1	3	1	2	2	1	3	2	3	Hams2
3	Calf	3	2	2	2	2	2	1	1	1	Calf
4	Calf	1	1	1	2	1	2	2	1	1	Hams1
5	Calf	3	3	3	3	3	3	1	1	1	Hams1 or Calf
6	Calf	3	3	1	2	2	2	2	2	3	Hams 1 or 2
7	Hams2	2	2	2	3	3	3	3	1	2	Hams1
8	Hams2	3	3	3	1	1	1	1	2	2	Calf
9	Calf	2	2	1	1	1	1	2	1	2	Hams2
10	Hams2	3	3	3	3	3	3	1	2	2	Hams1 or Calf
11	Calf	1	1	1	2	2	1	2	2	2	Hams2
12	Hams1	2	2	2	3	3	3	3	3	3	Hams 1 or 2

some scores were already improved using the stimulator in single channel mode. Table 2 summarises the results.

In four cases (patients 2,3,5,12) there was agreement between clinical observation and specialist gait analysis and in two (1,7) the same muscle group to be treated was selected although the other algorithm was used. In both these cases inability to swing the affected leg through adequately was observed to be a greater problem for the patient, resulting in the clinical decision to use the most appropriate algorithm to correct this. In one patient (8) the patient's poor push off was noted clinically but it was decided to stimulate the hamstrings to increase momentum to roll forward over the foot. Calf stimulation may well be tried at a later stage. In three patients calf stimulation was used but gait analysis indicated either that active push off was good (4,11) or that the problem had been corrected by single channel stimulation (6). All were predicted hamstrings stimulation from the CODA scoring. In patient 10 there was no agreement between clinical observation and gait analysis.

Effects of using second channel - Walking speed and PCI

Walking speed and PCI was measured over three consecutive 10 metre walks to investigate;

- Whether walking speed or PCI changed before using the Compustim10B (week0 to week-4, no stimulation)
- Any differences in walking speed or PCI between the ODFS and the Compustim10B (week0 to week-4, with single channel stimulation)
- Therapeutic effect of the second channel (week 12 to week 24, with no stimulation)
- Orthotic effect of using the second channel (two channel to single channel stimulation, at both weeks 12 and 24)

- Total orthotic and therapeutic effect of using the Compustim10B (two channel stimulation at week 24 to no stimulation at both weeks 0 and 12)

There was no significant difference in walking speed or PCI prior to using the Compustim10B and no difference in these measures when walking with the ODFS and the Compustim10B in single channel mode.

There was a significant therapeutic and orthotic effect on walking speed when stimulating a second muscle group with the Compustim 10B therapeutic (+11.2%, p= 0.003), orthotic (=6.0%, p=0.003), combined therapeutic and orthotic (+22.3%,p=0.003). There were no significant changes in PCI for either therapeutic or orthotic effects, from stimulating the second muscle.

Gait Analysis and Clinical Observation

Clinical observation deemed all patients to have had some improvement in their gait, although one patient using calf stimulation, after initial improvement, developed increased calf spasticity at week 24. CODA gait analysis demonstrated that of the six patients using hamstring stimulation only one showed a substantial improvement in the gait problem treated, 2 showing no change but three of these achieved a general improvement in knee flexion response. Patients who used calf stimulation one showed improvement in active push off and four were considered to have normal push off as a result of common peroneal stimulation alone. One patient showed no change. Calf stimulation was shown to affect knee angle response in five patients, three improving and two degrading. Gait analysis using the scoring system developed during the study did not support the clinical findings. The identified gait problem was only corrected in two patients.

Table 3 - Outcome in CODA characteristics from using second channel

Patient	Second channel	Push-off			Poor knee control at initial contact			Poor knee control at terminal stance		
		12_S1	12_S2	24_S2	12_S1	12_S2	24_S2	12_S1	12_S2	24_S2
1	Hams2	1	1	1	3	3	3	2	2	1
2	Hams2	1	1	1	1	1	2	3	3	3
3	Calf	2	2	2	2	3	2	1	2	1
4	Calf	1	1	1	2	1	1	1	1	1
5	Calf	3	3	1	3	2	2	1	1	1
6	Calf	1	2	1	2	3	3	3	3	3
7	Hams2	2	2	2	3	3	1	2	2	2
8	Hams2	3	3	3	1	1	3	2	2	2
9	Calf	1	1	1	1	3	3	2	1	1
10	Hams2	3	3	3	3	3	3	2	1	1
11	Calf	1	1	2	1	1	1	2	1	1
12	Hams1	2	2	2	3	3	3	3	2	2

DISCUSSION

The results from this study indicate a significant therapeutic and orthotic effect on walking speed from using a second channel of stimulation, greater than that achieved with single channel stimulation alone. Analysis of the gait data in this study was conducted using the scoring system described. Although not validated, it provided a good understanding of the characteristics of each patient's gait. It was disappointing to find poor correlation between predicted algorithms from clinical observation and those of gait analysis. However, both methods have their limitations. Clinical observation is subjective and open to error. Gait needs to be observed repeatedly and over a longer distance than is often possible for stroke patients, who fatigue easily. It is therefore difficult to make a totally comprehensive assessment of gait pattern. The use of video would have been helpful in improving accuracy, allowing gait to be analysed more thoroughly.

The patient fatigue factor applies equally to use of specialist gait analysis, where the need to strike the force plate in a particular way may necessitate a large number of attempts, causing not only fatigue but inevitably use of an unnatural gait pattern. There is inherent error in the application of the data collection equipment, which is often very time consuming. The unfamiliar environment and equipment may also cause patients' gait to be unrepresentative of their usual pattern. All these factors raise questions as to the level of confidence in analysing the results. Information provided by specialist gait analysis systems is not clinically useful unless it is used to answer specific questions, which may aid treatment and addresses the effects of compensations on the whole body. This study has highlighted the need for a simple, low cost gait analysis system that can be used in the clinical setting to identify gait problems, possibly including a simple method of collecting ankle and knee angle data. The use of video evidence would have assisted as a feedback tool and in providing a record, that may also have aided clinical predictions.

CONCLUSIONS

The therapeutic and orthotic effects on walking speed are encouraging evidence of the benefits of using a second channel of stimulation. Specialist gait analysis has limitations in collecting and processing data, which may affect confidence in the results. A simple method of collecting ankle and knee angle data may be more useful for assessment and outcome measurement, as would the use of video analysis to aid clinical observation. The scoring system, if validated, could provide a simple tool for gait analysis in the clinical setting.

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