Long-term follow-up of patients using the ActiGait implanted drop-foot stimulator

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Abstract

The ActiGait® drop foot stimulator has been shown to be an effective and safe device for the treatment of drop foot following stroke, showing comparable results with surface drop foot systems [1,2]. The device comprises an implant, a control unit and a wireless heel switch that triggers stimulation. Stimulation of the common Peroneal (CP) nerve is through a nerve cuff placed around the CP nerve just above the knee. The cuff has four tri-polar electrodes, orientated to activate different nerve fibres within the CP nerve. Each channel is programmed independently via a PC. Fifteen patients who had suffered a stroke at least six months prior to recruitment were implanted with the ActiGait® drop-foot stimulator. Two subjects deviated from the study protocol and, at the 90 day assessment three subjects had technical problems. Fifteen months after the start of the study 13 subjects using the device have undergone a further assessment in which we repeated the walking tests with and without the stimulator. Results showed a statistically significant improvement in walking parameters when stimulation was applied. Mean increase in distance walked = 11.5m p=0.05 and increase in maximum walking speed 0.07 m/s p=0.01. Statistically significant improvements were also detected when walking parameters were compared with those at Baseline. In conclusion: when initial technical problems with the ActiGait implanted drop-foot stimulator were overcome the system was shown to be effective in improving walking and well accepted by users.

1. INTRODUCTION

The ActiGait drop foot stimulator comprises an implant, a control unit and a wireless heel switch that triggers stimulation. A nerve cuff with four tri-polar electrodes, orientated to activate different nerve fibres within the CP nerve, is placed around the common peroneal (CP) nerve just above the knee. A cable from the nerve cuff leads subcutaneously to the receiver positioned laterally on the upper thigh. A transmitter coil placed over the receiver is hardwired to the control unit worn on the belt. Each channel is programmed independently via a PC.

1.1. Previous work

In a preliminary study, the ActiGait® drop foot stimulator was shown to be a safe and effective way to improve walking in drop-foot associated with hemiplegia following stroke. Improvements in walking were measured, response to a subjective questionnaire was positive [3] and no device related changes in nerve conduction velocity were detected. During the study some technical problems were encountered that affected subjects' performance, these were: radio frequency communication between the foot-switch and the control unit and selection of appropriate size nerve cuff. Three subjects who had experienced problems due to nerve cuff size have undergone re-implantation. Following changes to the position of the antenna and receiver within the control box (to overcome the RF communication problem), all subjects have been fitted with a new control unit. Currently 13 of the original 15 subjects who took part in

the study have been followed-up (approximately 15 months after the start of the study). In this paper we report and compare the results at baseline with the 90 day and 15 month assessments.

2. METHODS

Fifteen patients who had suffered a stroke at least six months prior to recruitment were implanted with the ActiGait drop-foot stimulator. Two subjects deviated from the study protocol and, at the 90 day assessment three subjects had technical problems as described above.

Fifteen months after the start of the study 13 subjects underwent a further assessment in which we repeated the walking tests using the same protocol as in the original study. Walking was assessed by: (1) distance walked in four minutes over a 20m 'figure of eight' walk-way and [3,4], (2) maximum walking speed, measured as the fastest circuit during the four-minute walk test [5,6]. Patients will also complete a self-assessment questionnaire on the problems and advantages of the ActiGait drop foot. Data from this has not yet been analysed. Walking tests were performed with and without the stimulator in random order.

2.1. Statistical analysis

Descriptive statistics were used to present demographic characteristics of the sample, and mean (SD) and 95% Confidence Intervals for each variable. Paired sample t-tests have been used to detect significant ($p<0.05$) changes over time and differences with and without stimulation. Because of the experimental nature of this study per protocol analysis was used as opposed to intention to treat analysis and Bonferoni corrections were not made.

3. RESULTS

Thirteen of the 15 subjects who are using the device have been assessed at 15 months since the start of the study. Data is presented for these 13 subjects and for the 13 subjects who complied with the study protocol and were assessed at 90 days following implantation. Demographic data for the subjects is shown in Table 1. Subjects 14 and 15 deviated from the protocol (required re-implantation with a smaller cuff) and did not complete the 90 day assessment, but have been included in the 15 month assessment. Subject 1 was also re-implanted, but after the 90 day assessment and subject 3 has yet to complete the 15 month assessment.

Statistically significant improvement in walking parameters was measured when stimulation was applied at both the 90 day and 15 month assessments, but mean improvement was greater at the 15 month assessment. Statistically significant improvements were also detected in both distance walked in 4 minutes and maximum walking speed at the 15 month assessment compared with baseline, but only in maximum speed at 90 days. Details of the results of the walking tests are shown in Tables 2-4.

Table 1 shows the demographic data for the 15 subjects included in the study.

Gender	4 Female 11 male
Number of strokes	9 first strokes 3 second strokes 2 multiple strokes 1 unknown
Side of hemiplegia	7 Right 8 Left
Type of CVA	5 Haemorrhagic 9 Infarction 1 other
Mean (SD)Age Min-Max	56 yrs 10m (7yrs.7m) 46 - 68

Table 2 shows the mean (SD) distance walked in four minutes and maximum walking speed over one complete circuit (20m) at baseline, at the 90 day and 15 month long-term follow-up. Values with and without stimulation are shown for the 90 day and 15 month assessments.

	Baseline (n=15)	90 days (n=13)		15 months (n=13)	
	NS	NS	S	NS	S
Mean (SD) distance walked (m)	117.33 (46.7)	115.4 (49.3)	124.9 (47.0)	131.4 (51.5)	142.6 (49.3)
Min - Max (m)	34-184	40-189	54-194	43-203	59-199
Mean (SD) max speed (m/s)	0.50 (0.20)	0.52 (0.22)	0.55 (0.20)	0.58 (0.23)	0.65 (0.22)
Min - Max (m/s)	0.15-0.80	0.19-0.83	0.25-0.83	0.18-0.87	0.25-0.87

Table 3 Shows changes over time in distance walked in four minutes and maximum walking speed over one complete circuit (20m), Comparisons are shown between the baseline measures and measurements made with stimulation at the 90 day and 15 month follow-up assessments. Mean and 95% Confidence

Interval and the result of the Paired samples t-tests are shown.

	Baseline vs. 90 days (n=13)		Baseline vs. 15 months (n=13)	
	Mean (SD) difference (95% CI)	P Value	Mean (SD) difference (95% CI)	P Value
Distance walked in 4 min (m)	9.23 (-19.127, 0.665)	0.065	16.23 (-30.429,-2.033)	**0.028**
Max speed (m/s)	0.05 (-0.098, -0.002)	0.041	0.10 (-0.174, 0.032)	**0.008**

Table 4 shows the orthotic effect, calculated as change when stimulation was applied, on distance walked in four minutes and maximum walking speed over one complete circuit (20m). Measurements made with and without stimulation are compared at the 90 day and 15 month assessments. Mean and 95% Confidence Interval and the result of the Paired samples t-tests are shown.

	90 days S-NS (n=13)		15 month S-NS (n=13)	
	Mean (SD) (95% CI)	P Value	Mean (SD) (95% CI)	P Value
Distance walked in 4 mins (m)	9.5 (-16.549, -2.528)	**0.012**	11.5 (-23.042,-0.119)	**0.052**
Max speed (m/s)	0.03 (-0.705, -0.006)	**0.023**	0.07 (-0.113,-0.019)	**0.011**

4. DISCUSSION AND CONCLUSIONS

The ActiGait drop foot stimulator has been shown to be a safe and effective way of improving walking in people who have a drop foot as a result of a stroke. At the 90 day assessment problems with RF communication between the footswitch and control unit meant that stimulation was unreliable in some subjects and probably accounts for smaller improvement in walking parameters measured at that time. Interestingly however walking parameters measured without stimulation (NS) (Table 3) showed a small decrease in distance walked compared with baseline (-1.9m) and only a small improvement in maximum walking speed (0.02m/s) at 90 days. At 15 months there was an increase of 42.1m in distance walked and an increase of 0.04 m/s in maximum walking speed without stimulation compared with 90 days. This suggests a therapeutic affect that was not apparent until after 90 days.

Protocol for determining cuff size at the start of the study was in three cases, found to result in selecting a cuff that that was too large. Although initially this did not affect functioning of the system, after about eight weeks these subjects found a decreasing response to stimulation, which was found to be due to fluid collecting between the cuff and the nerve. The three subjects who have been re-implanted are now all using the system. Data collected at the 15 month assessment suggests that once these problems had been overcome the ActiGait implanted drop-foot stimulator was effective and well accepted by users. Although this study has been with patients who have had a stroke, the system may also be effective in other upper motor neuron lesions such as multiple sclerosis and incomplete spinal cord injury. It would arguably be the treatment of choice in cases where recovery of voluntary control was unlikely.

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