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Burridge, Jane H.; Haugland, Morten; Larsen, Birgit; Svaneborg, Niels; Iversen, Helle K.; Christensen, P. Brøgger; Pickering, Ruth M.; Sinkjær, Thomas

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SHORT COMMUNICATION

PATIENTS' PERCEPTIONS OF THE BENEFITS AND PROBLEMS OF USING THE ACTIGAID IMPLANTED DROP-FOOT STIMULATOR

Jane H. Burridge, PhD<sup>3</sup>, Morten Haugland, PhD<sup>1</sup>, Birgit Larsen, PhD<sup>1</sup>, Niels Svaneborg, MD<sup>4</sup>, Helle K. Iversen, MD<sup>5</sup>, P. Brøgger Christensen, MD<sup>6</sup>, Ruth M. Pickering, PhD<sup>3</sup> and Thomas Sinkjaer, MD<sup>2</sup>

From the <sup>1</sup>Neurodan A/S, <sup>2</sup>SMI, Faculty of Science, Technology and Health Science, University of Aalborg, Aalborg, Denmark, <sup>3</sup>University of Southampton, Highfield, Southampton, UK, <sup>4</sup>Brønderslev Neuro Rehabiliteringscenter, Sygehus Vendsyssel, Brønderslev, <sup>5</sup>Glostrup Hospital, University of Copenhagen, Glostrup and <sup>6</sup>Hammel Neuro Center, Hammel, Denmark

**Objective:** To evaluate patients' perceptions of the benefits and problems associated with using the ActiGait implanted drop-foot stimulator

**Method:** Thirteen participants who had suffered a stroke at least 6 months prior to recruitment, had a drop-foot that affected walking and had taken part in a trial in which an ActiGait drop-foot stimulator had been implanted, completed a postal questionnaire.

**Results:** Users agreed that the ActiGait had a positive effect on walking; they used it regularly and had little difficulty with putting it on and taking it off. Reliability was a greater problem at 90 days than at the final assessment. Ten of the 13 responders either agreed or strongly agreed with the statement that the ActiGait improved their quality of life at 90 days and 9 out of 12 at the final assessment: 11 of the 12 respondents would recommend the ActiGait to others.

**Discussion and conclusion:** From the users' perspective the ActiGait improved walking, it was reported to be used regularly and it appeared to be easier to use than a surface system. Users were equivocal about the reliability of the system at 90 days, but at the final assessment reliability had improved.

**Key words:** questionnaire, functional electrical stimulation, stroke and walking.

*Correspondence address:* Jane Burridge, SOHPRS, University of Southampton, Highfield, Southampton SO17 1BJ, UK. E-mail: [jhb1@soton.ac.uk](mailto:jhb1@soton.ac.uk)

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INTRODUCTION

Three studies have reported patients' perspectives of the value and problems associated with drop-foot stimulators (1–3). The most important was the study by Taylor et al. (2), which evaluated a surface drop-foot system (ODFS) (used by over 2000 patients, mainly in the UK). The primary reason for using the device was identified as reducing the effort of walking, and the main problems identified with the system were in putting it on and taking it off, particularly positioning electrodes, and irritation of the skin caused by the electrodes. Some patients also cited the reason for discontinuing using the system as the inconvenience of external components,

particularly the leads. The problems with surface stimulation can be overcome by an implanted system, of which the ActiGait stimulator is an example. In a recently published phase II trial of 15 patients with established hemiplegia due to stroke (4) the ActiGait system was found to be safe and effective in improving walking. In this paper we present the results of a questionnaire that examined the patients' perceptions of the benefits and problems of the system.

METHOD

The ActiGait is a 4-channel implantable drop-foot stimulator in which electrodes are embedded in a single cuff placed around the common peroneal nerve just above the knee. Independent adjustment of output from each channel enables fine control of the inversion and eversion components of dorsiflexion. Timing of stimulation is triggered by a wireless foot-switch and the user is able to switch the device on and off and adjust the level of stimulation via an external control unit. A fuller description of the system is given by Burridge et al. (4).

Ethical approval was granted for a trial (4) to evaluate the safety and efficacy of the ActiGait (VN 2002/56mch). All participants were referred by their rehabilitation consultant, gave written informed consent and understood that data recorded during the study would remain anonymous. Participants were over the age of 18 years: full eligibility criteria were reported previously (4). Participants were assessed at baseline, at a follow-up assessment 90 days post-implantation ( $n=13$ ), and at a final assessment (final) 15 months after the first participant was implanted ( $n=15$ ). Questionnaires were posted to participants immediately after each post-implantation assessment, and were completed with no input from either the researchers or the clinicians involved with the study.

The questionnaire was based on that used by Taylor et al. (2) in the evaluation of the ODFS, translated into Danish and adapted for use with an implanted system by removing questions about positioning electrodes and inconvenience of external wires. Although the questionnaire has not been formally validated it has been used in a number of studies (2, 3). The questionnaire comprises 9 items related to walking, 2 to the use of ActiGait, 2 to practical issues, 13 to the functionality of the ActiGait (including one open question), and 3 to general satisfaction. The phrasing of the questions is shown in Table I for use and practical issues, and in Table II for functionality. The effect on walking questions were phrased "When I use the ActiGait:... my walking is faster"; "...I can walk further"; "...walking is less effort"; "...I am less likely to trip and fall"; "...it is easier to walk on uneven ground"; "...I feel more confident walking"; "...I am more independent"; "...my walking is more like it was before I became ill"; and "...I am less likely to need a stick, other walking aid or help from another person". Respondents selected one of: "strongly agree", "agree", "disagree" and "strongly disagree" to each question, coded 4, 3, 2 and 1, with higher values indicating better assessment. Cronbach's alpha for the 9 questions calculated in Stata 9 was

Table I. Frequencies of responses concerning the use of the ActiGait and practical issues

Assessment		Normally				
		every day	3–6 d/w	1–2 d/w	<3 d/w	<1 d/w
On average how often do you use your ActiGait?	90 days (n=13)	12	1	0	0	0
	Final (n=12)	8	2	1	0	1
On the days that you use your ActiGait how long do you wear it?	90 days (n=13)	8	2	3	0	
	Final (n=11)	7	2	1	1	
How long in minutes does it take you or your carer to put on the ActiGait?	90 days (n=12)	8	3	0	1	
	Final (n=12)	10	0	2	0	
Do you need help to put the ActiGait on?	90 days (n=13)	Yes – 2/13 (15%)				
	Final (n=12)	Yes – 1/12 (8%)				

d: days; w: week.

0.951 at 90 days, and 0.741 at the final assessment, indicating excellent and reasonable internal consistency, respectively. An effect on walking score was constructed as the average of the 9 walking items.

Mean (standard deviation (SD)) and range (min–max) of responses on the effect on walking score are reported for the 90-day and final assessments, and a paired *t*-test was carried out to estimate the change over time amongst participants with available data at both time-points. The frequencies of responses are presented for the other questionnaire items. Responses from key questions are compared with the corresponding figures reported for the ODFS (2) in exact  $\chi^2$  tests carried out in StatXact 6.

### RESULTS

Fifteen participants underwent implantation surgery: demographic details of participants were published earlier (4). Thirteen completed questionnaires were received at 90 days and 12 at the final assessment. All questions were answered with the exception of 2 walking and 1 functionality question at the final assessment. The mean effect on walking scores were 2.9 (SD 0.8, range 1.3–4.0) at the 90 day and 3.0 (SD 0.5, range 2.0–3.8) at the final assessment. Amongst the 10 participants with available data, the mean effect on walking score was virtually the same at the 2 assessments (90 days to final assessment change 0.0; 95% confidence interval –0.4 to 0.4; *p* = 0.946). The device was worn regularly and the majority used it for most of the day at both the 90 days and the final assessment (Table I). Two people needed help putting it on at 90 days and one at the final assessment, and only 2 said it took longer than 6 min.

Functionality (Table II) was generally good, 12 participants responded that the implant gave no discomfort and one reported minimal discomfort at 90 days. Three respondents said they had some discomfort from the stimulation at 90 days, but at the final assessment none found the sensation of stimulation uncomfortable. Similarly, ability to adjust the controls improved. At 90 days, 5 respondents said they needed to make adjustments every 1 or 2

Table II. Frequencies of responses to questions concerning functionality

Assessment		Strongly agree	Dis-agree	Strongly disagree	
		Agree	agree	disagree	
I prefer to use the ActiGait rather than a splint	90 days (n=13)	8	4	1	0
	Final (n=12)	7	5	0	0
The ActiGait is easy to use	90 days (n=13)	5	6	2	0
	Final (n=12)	2	5	5	0
The ActiGait has been reliable	90 days (n=12)	4	4	2	2
	Final (n=12)	5	6	1	0
Any problems I have had have been addressed quickly and effectively	90 days (n=12)	6	5	1	0
	Final (n=12)	4	5	2	1
The training I was given was appropriate	90 days (n=13)	4	6	3	0
	Final (n=12)	3	8	1	0
The written instructions were clear and easy to understand	90 days (n=13)	4	9	0	0
	Final (n=12)	3	9	0	0
Do you have any discomfort from the implanted electrodes?	90 days (n=13)	Occ/None min Some Severe			
	Final (n=12)	12	1	0	0
Does the sensation from the stimulation cause discomfort?	90 days (n=13)	11	1	0	0
	Final (n=12)	6	4	3	0
Does the ActiGait work at the correct time when walking?	90 days (n=13)	4	8	0	0
	Final (n=12)	1	0	8	3
Does the ActiGait work at appropriate times, e.g. in sitting?	90 days (n=13)	7	2	3	1
	Final (n=12)	7	2	2	1
How often do the ActiGait settings require adjustment?	90 days (n=11)	When I put it on 2h Every >1/h Every 5 min			
	Final (n=10)	6	2	3	0
How easy is it for you to adjust the settings?	90 days (n=13)	10	0	0	0
	Final (n=12)	4	7	2	0
	90 days (n=13)	Very easy Fairly easy Difficult Very difficult			
	Final (n=12)	4	7	2	0
	90 days (n=13)	Very easy Fairly easy Difficult Very difficult			
	Final (n=12)	7	4	1	0

Occ: occasional; min: minimal.

hours, but at the final assessment all respondents (n=10) said they adjusted it only when they put the device on. Ability to adjust the controls did not seem to be a major problem and improved at the final assessment, but at 90 days 2 respondents reported difficulty in adjusting the controls: one because “I can only use one hand” and the other because “the switch turns on and off if my arm touches the control box accidentally, therefore it is difficult to say if it is adjusted correctly” (both textual responses translated from Danish). Timing of the stimulation was considered correct by most participants, with only one reporting that it rarely worked at the correct time.

Ten of the 13 responders to the general satisfaction questions at 90 days, and 9 of 12 at the final assessment, either agreed or

Table III. Comparison of usage and reliability between the Odstock Dropped Foot Stimulator (ODFS) and the ActiGait

	ODFS* (Ref 2)	ActiGait			
		90 days		Final	
		n (%)	p†	n (%)	p†
Used the device normally everyday	57/107 (53%)	12/13 (92%)	0.007	8/12 (66%)	0.543
Used the device all (ODFS) or most (ActiGait) of the day on the days that it was worn	41/107 (38%)	8/13 (62%)	0.038	7/12 (58%)	0.221
Needed help putting the device on	31/78 (40%) of those with stroke	2/13 (15%)	0.123	1/12 (8%)	0.050
The device was unreliable‡	43/107 (40%)	4/12 (33%)	0.762	1/12 (8%)	0.054

\*Users who were using the ODFS at the time of the questionnaire: 107 out of 160 (67%) of responders.

†Exact 2-sample  $\chi^2$  test against the proportion reported by Taylor et al. (2).

‡Disagreeing or strongly disagreeing with the statement that the ActiGait was reliable in the present study.

strongly agreed that the ActiGait improved their quality of life. Eleven of the 12 respondents would recommend the ActiGait to another person. At 90 days all responders either agreed or strongly agreed that the cosmetic appearance was good, but 3 disagreed at the final assessment.

## DISCUSSION

The mean effect on walking score of 2.9–3.0, corresponding to “I agree” with statements of benefit from the device, suggests that users thought the ActiGait improved their walking, and their opinion did not change with time from implantation. Devices are most commonly evaluated by objective measures of walking (4–7); however, these may not present a complete and accurate reflection of the benefit (or problems) of a system and subjective evaluation provides useful additional information about the effect on quality of life. Some problems with the timing of the stimulation occurred during the study and were resolved following modifications to the wireless connection between the foot-switch and the control unit. One user reported that this was still a problem at the final assessment.

The effect of the ActiGait on measured walking speed is similar to that reported with surface systems (5, 7). More regular and extended use may have resulted from the ease of putting on and taking off, convenience, reliability or the comfort of the system. The results of our study have enabled us to compare the patients' perspective of the ActiGait and the ODFS. Taylor et al. (2) reported results from a survey of current and past users of the ODFS who had been using the device for between 1 and 60 months. The comparison is summarized in Table III using only data from the continuing users of the ODFS (64% of responders). Ideally these results should be confirmed in a randomized trial.

Time taken to put the device on (whether help was given or not), was approximately 10 min for the ODFS. By comparison, 8 ActiGait users at 90 days and 10 at the final assessment said they were able to put the device on in less than 3 min and only one user said it took longer than 10 min (at 90 days). These differences may be due to not having to apply electrodes, particularly as positioning electrodes was cited by 43% of ODFS users as a problem. The initial cost of the ActiGait, including implantation is likely to be higher than a surface system, but running costs would be reduced. Future trials should include a cost-effectiveness component.

In conclusion, from the users' perspective the ActiGait improved walking, was used regularly and appeared to be easier to use than a surface system. Users were equivocal about the reliability of the system at 90 days, but at the final assessment reliability was reported to be good.

## Conflict of interest

At the time of the study Larsen and Haugland were both employees of Neurodan A/S, which has an interest in the commercialization of the ActiGait.

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