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SHORT COMMUNICATION

PATIENTS’ PERCEPTIONS OF THE BENEFITS AND PROBLEMS OF USING THE ACTIGAIT IMPLANTED DROP-FOOT STIMULATOR

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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 responders either agreed or strongly agreed with the statement that 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.

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

<table>
<thead>
<tr>
<th>Assessment</th>
<th>NORMALLY EVERYDAY</th>
<th>3–6 TIMES A WEEK</th>
<th>1–2 TIMES A WEEK</th>
<th>&lt;3 TIMES A WEEK</th>
<th>&lt;1 TIMES A WEEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>On average how often do you use your ActiGait?</td>
<td>90 days (n=13)</td>
<td>12</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Final (n=12)</td>
<td>8</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Most of the day</td>
<td>6–9 hours</td>
<td>2–5 hours</td>
<td>&lt;2 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On the days that you use your ActiGait</td>
<td>90 days (n=13)</td>
<td>8</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Final (n=11)</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>How long in minutes does it take you or your carer to put on the ActiGait?</td>
<td>90 days (n=12)</td>
<td>8</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Final (n=12)</td>
<td>10</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Do you need help to put the ActiGait on?</td>
<td>90 days (n=13)</td>
<td>Yes – 2/13 (15%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final (n=12)</td>
<td>Yes – 1/12 (8%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 were 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 χ² 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 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
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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