Restoration of ankle movements with the ActiGait implantable drop foot stimulator: a safe and reliable treatment option for permanent central leg palsy

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OBJECTIVE The ActiGait drop foot stimulator is a promising technique for restoration of lost ankle function by an implantable hybrid stimulation system. It allows ankle dorsiflexion by active peroneal nerve stimulation during the swing phase of gait. In this paper the authors report the outcome of the first prospective study on a large number of patients with stroke-related drop foot.

METHODS Twenty-seven patients who experienced a stroke and with persisting spastic leg paresis received an implantable ActiGait drop foot stimulator for restoration of ankle movement after successful surface test stimulation. After 3 to 5 weeks, the stimulator was activated, and gait speed, gait endurance, and activation time of the system were evaluated and compared with preoperative gait tests. In addition, patient satisfaction was assessed using a questionnaire.

RESULTS Postoperative gait speed significantly improved from 33.9 seconds per 20 meters to 17.9 seconds per 20 meters (p < 0.0001), gait endurance from 196 meters in 6 minutes to 401 meters in 6 minutes (p < 0.0001), and activation time from 20.5 seconds to 10.6 seconds on average (p < 0.0001). In 2 patients with nerve injury, surgical repositioning of the electrode cuff became necessary. One patient showed a delayed wound healing, and in another patient the system had to be removed because of a wound infection. Marked improvement in mobility, social participation, and quality of life was confirmed by 89% to 96% of patients.

CONCLUSIONS The ActiGait implantable drop foot stimulator improves gait speed, endurance, and quality of life in patients with stroke-related drop foot. Regarding gait speed, the ActiGait system appears to be advantageous compared with foot orthosis or surface stimulation devices. Randomized trials with more patients and longer observation periods are needed to prove the long-term benefit of this device.


KEY WORDS stroke; drop foot; ActiGait; implantable stimulator; functional neurosurgery
an improvement of walking speed and a restoration of the physiological ankle movement in patients with stroke-rele-
ated drop foot.\(^2,3,6\) The therapeutic effect was found to be
improved compared with surface stimulation, combined with an easier handling of the stimulation device.\(^3\) In this paper we present the first prospective clinical outcome study on a larger number of patients describing the benefit of the ActiGait implantable 4-channel drop foot stimulator for stroke-related drop foot.

**Methods**

**Patient Characteristics and Screening**

Twenty-seven patients (14 men, 13 women) with a stroke-related spastic hemiparesis, including a drop foot of at least 6-months duration, were treated with the implantable 4-channel drop foot stimulator, ActiGait (for patient characteristics see Table 1). The mean age of the patients was 51.0 years (range 24–66 years). The mean duration of stroke-related drop foot was 63.0 months (range 6–244 months). The drop foot was right-sided in 15 and left-sided in 12 patients. The cause of the central palsy was ischemic in 21 patients and hemorrhagic in 6 patients.

The drop foot was diagnosed according to the criteria of Perry et al. 1995,\(^14\) with a dragging foot during the swing phase. Prior to surgery, the possible benefit of the implantable ActiGait stimulator was tested by external functional surface stimulation of the peroneal nerve (CE-
FAR Step II, output 60 mA, frequency 20–100 Hz; Cefar-Compex Scandinavia AB). If a strong dorsiflexion of the ankle could be evoked, the patient was considered to be a candidate for stimulator implantation. In addition, MRI of the leg was performed prior to surgery to exclude any peripheral injury of the peroneal nerve and to determine the anatomical localization of the bifurcation of the sensible branch of the common peroneal nerve for a proper electrode positioning.

**Gait Tests and Quality of Life Survey**

To evaluate whether patients with an ActiGait stimula-
tor show changes in walking speed, they were asked to walk 20 meters, and the required time for this action was noted. This test was repeated 3 times without walking aids, with an ankle orthosis, with a surface stimulator preoperatively, and 6 weeks after implantation of the ActiGait system. In each case, the task was repeated with normal and maximal gait speed. Further, patients were asked to walk 6 minutes continuously pre- and postoperatively (walk endurance). The distance covered was measured in meters. Finally, the time needed to stand up from a chair, walk 3 meters, and return to sit down again was measured pre-
and postoperatively to determine the needed activation
time and to assess the risk of falls (timed up-and-go test).\(^15\) Furthermore, the patients were asked in a subjective quality of life survey about their satisfaction with the implanted device (Fig. 1). All tests were performed by a neurosurgeon (K.D.M.).

**ActiGait Drop Foot Stimulation System**

The ActiGait stimulation system consists of an implantable 4-channel nerve stimulator with a 12-contact
electrode cuff, an external control unit, and a heel switch (Fig. 2). The heel switch is worn in a sock and triggers the initiation and termination of each stimulation sequence by a radiofrequency wireless signal to the external control unit when the foot is lifted from the ground. The external control unit is fixed to a belt and can be linked to a personal computer by the physician to set up the individual stimulation parameters. The external control unit enables powering and controlling of the implanted nerve stimulator by an externally wired antenna positioned on the skin over the subcutaneously implanted nerve stimulator body. The nerve stimulator contains a receiver for power and control, and transmits the stimulation to the 12-electrode cuff through a subcutaneous wire.

**Surgical Procedure**

Surgery was performed under general anesthesia as previously described by Burridge et al.\(^2\) In brief, the com-
mon peroneal nerve was exposed above the knee for 4 cm using a longitudinal incision along the tendon of the biceps femoris muscle. For the implantation of the stimu-
lator body, another curved incision at the anterolateral aspect of the upper leg was performed. Ankle dorsiflexion was tested using a nerve stimulator (GN 015; maximum 6 V, 10 mA, 2.5 Hz; Aesculap). Afterward, the electrode cuff was closed around the nerve and the stimulator body was fixed to the lateral femoral fascia. Before the closure of the incisions, the correct position of the cuff and the stimulator was controlled visually in maximal flexion and extension of the knee, ensuring a free gliding of the cuff.

**Postoperative Care and Programming of the Stimulator**

During the first 3 to 5 weeks, the patients had to restrict the movement of his or her operated leg to a maximal knee flexion of 30°. During this period the Achilles tendon was passively stretched to avoid contractures. Afterward, the programming of the system was started. Programming parameters were frequency, stimulation intensity, ramp-
ing, and timing of the stimulation channels. Every channel was tested for the best dorsiflexion and the stimulator was activated with 1 mA, 20–30 Hz, and an optimal impulse duration of 70 μsec (Table 1). Patients were able to readjust the impulse intensity with a patient programmer. Finally, gait evaluation was performed after 4 weeks, measuring gait speed, walk endurance, and the timed up-and-go test. In addition, the subjective quality of life survey was administered.

**Statistical Analysis**

The values of the gait tests are expressed as means ± standard deviations. The significance level was calculated with a Wilcoxon rank-sum test using SPSS software (version 22, IBM). A p value < 0.05 was considered statistically significant.

**Results**

**Surgery and Postoperative Care**

The implantation of the ActiGait system in all patients was easy and without any technical complications. Post-
In all patients, the programming of the ActiGait stimulator was uncomplicated, as described above. Usually, channel 1 and/or 4 were activated to recruit the motor fibers located anteriorly in the nerve bundle. The handling of the ActiGait system was described by all patients as being uncomplicated and easy in daily living. There were no technical defects of the implanted components. However, in 80% of the patients, the external heel switch had to be replaced because of a defect. Depending on the activity level in their daily life, the patients had to charge the ActiGait stimulator every 3 to 7 days for approximately 1 hour.

### Walking Speed (20-m Gait Test)

The mean required time for 20 meters of walking with normal walking speed and without any walking aids was 33.9 ± 11.2 seconds. After implantation of the ActiGait

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**TABLE 1. Patient characteristics and individual stimulation parameters with the implantable ActiGait drop foot stimulator**

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age (yrs), Sex</th>
<th>Side w/ Drop Foot</th>
<th>Cause of Drop Foot</th>
<th>Duration of Drop Foot (mos)</th>
<th>Parameters of Stimulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>53, M</td>
<td>Lt</td>
<td>Ischemic</td>
<td>52</td>
<td>Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 330 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>2</td>
<td>62, M</td>
<td>Rt</td>
<td>Ischemic</td>
<td>221</td>
<td>Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 180 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>3</td>
<td>29, F</td>
<td>Lt</td>
<td>Ischemic</td>
<td>48</td>
<td>Channel 1+4 active; 1 mA; 35 Hz; optimal impulse duration 60/70 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>4</td>
<td>58, M</td>
<td>Lt</td>
<td>Ischemic</td>
<td>16</td>
<td>Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 90 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>5</td>
<td>25, M</td>
<td>Rt</td>
<td>Hemorrhagic</td>
<td>80</td>
<td>Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 80/50 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>6</td>
<td>59, M</td>
<td>Rt</td>
<td>Ischemic</td>
<td>23</td>
<td>Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 80 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>7</td>
<td>64, F</td>
<td>Rt</td>
<td>Ischemic</td>
<td>11</td>
<td>Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 100/75 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>8</td>
<td>36, F</td>
<td>Lt</td>
<td>Hemorrhagic</td>
<td>54</td>
<td>Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 80 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>9</td>
<td>57, F</td>
<td>Rt</td>
<td>Ischemic</td>
<td>27</td>
<td>Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 90 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>10</td>
<td>36, F</td>
<td>Lt</td>
<td>Ischemic</td>
<td>47</td>
<td>Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 330 µsec; heel switch (patient is only in the exercise-mode)</td>
</tr>
<tr>
<td>11</td>
<td>24, F</td>
<td>Rt</td>
<td>Ischemic</td>
<td>55</td>
<td>Channel 1+3+4 active; 1 mA; 30 Hz; optimal impulse duration 85/65 /45 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>12</td>
<td>52, F</td>
<td>Rt</td>
<td>Ischemic</td>
<td>71</td>
<td>Channel 1 active; 1 mA; 20 Hz; optimal impulse duration 150 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>13</td>
<td>58, M</td>
<td>Rt</td>
<td>Ischemic</td>
<td>19</td>
<td>Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 110/60 µsec; heel switch contralat</td>
</tr>
<tr>
<td>14</td>
<td>49, F</td>
<td>Lt</td>
<td>Ischemic</td>
<td>244</td>
<td>Channel 4 active; 1 mA; 35 Hz; optimal impulse duration 200 µsec; heel switch contralat</td>
</tr>
<tr>
<td>15</td>
<td>54, M</td>
<td>Lt</td>
<td>Hemorrhagic</td>
<td>6</td>
<td>Channel 4 active; 1 mA; 20 Hz; optimal impulse duration 150 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>16</td>
<td>66, F</td>
<td>Lt</td>
<td>Ischemic</td>
<td>90</td>
<td>Channel 1+4 active; 1 mA; 20 Hz; optimal impulse duration 110/90 µsec; heel switch ipsilat</td>
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<tr>
<td>17</td>
<td>54, F</td>
<td>Lt</td>
<td>Ischemic</td>
<td>138</td>
<td>Channel 4 active; 1 mA; 20 Hz; optimal impulse duration 120 µsec; heel switch contralat</td>
</tr>
<tr>
<td>18</td>
<td>64, F</td>
<td>Lt</td>
<td>Ischemic</td>
<td>17</td>
<td>Channel 1+4 active; 1 mA; 20 Hz; optimal impulse duration 105 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>19</td>
<td>43, F</td>
<td>Rt</td>
<td>Hemorrhagic</td>
<td>60</td>
<td>Channel 1+3+4 active; 1 mA; 20 Hz; optimal impulse duration 160/150 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>20</td>
<td>50, M</td>
<td>Rt</td>
<td>Hemorrhagic</td>
<td>55</td>
<td>Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 60 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>21</td>
<td>59, M</td>
<td>Rt</td>
<td>Ischemic</td>
<td>37</td>
<td>Channel 1+2+3 active; 1 mA; 20 Hz; optimal impulse duration 60/70/65 µsec; heel switch contralat</td>
</tr>
<tr>
<td>22</td>
<td>54, M</td>
<td>Lt</td>
<td>Ischemic</td>
<td>70</td>
<td>Channel 3 active; 1 mA; 25 Hz; optimal impulse duration 145 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>23</td>
<td>55, M</td>
<td>Lt</td>
<td>Ischemic</td>
<td>20</td>
<td>Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 110 µsec; heel switch contralat</td>
</tr>
<tr>
<td>24</td>
<td>54, F</td>
<td>Rt</td>
<td>Ischemic</td>
<td>97</td>
<td>Channel 3 active; 1 mA; 30 Hz; optimal impulse duration 100 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>25</td>
<td>48, M</td>
<td>Rt</td>
<td>Ischemic</td>
<td>25</td>
<td>Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 125/95 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>26</td>
<td>60, M</td>
<td>Rt</td>
<td>Hemorrhagic</td>
<td>54</td>
<td>Channel 1 active; 1 mA; 25 Hz; optimal impulse duration 150 µsec; heel switch ipsilat</td>
</tr>
<tr>
<td>27</td>
<td>55, M</td>
<td>Rt</td>
<td>Ischemic</td>
<td>63</td>
<td>Channel 1 active; 1 mA; 20 Hz; optimal impulse duration 130 µsec; heel switch ipsilat</td>
</tr>
</tbody>
</table>
The required time decreased significantly to 17.9 ± 5.1 seconds (p < 0.0001). The surface stimulation also revealed a highly significant (p = 0.0001) reduction of the mean required time to 26.3 ± 8.2 seconds, but this result still differed significantly from the results with ActiGait stimulation (p < 0.0001). The use of an ankle orthosis revealed no significant changes in walking speed compared with no walking aids. Similar results were observed under maximal gait speed conditions (for further details, see Fig. 3A and Video 1).

**Six-Minute Walking Test**

Gait endurance was registered by measuring the covered distance of patients once they had been walking for 6 minutes. Without any walking aids, patients covered on average 196 ± 40 meters in 6 minutes. With ActiGait stimulation, the mean distance increased significantly (p < 0.0001) up to 401 ± 32 meters (Fig. 3B).

**Timed Up-and-Go Test**

To compare the activation time and the risk of falls in patients without any walking aids and with the implanted ActiGait stimulator, the timed up-and-go test was performed. Without walking aids, the needed time was 20.5 ± 5.3 seconds, which means a functionally relevant mobility...
impairment (> 20 seconds needed). With ActiGait stimulation, the time was reduced significantly (p < 0.0001) to 10.6 ± 2.7 seconds, which can be described as mild mobility impairment (11–19 seconds needed; Fig. 3C).

Subjective Quality of Life and Patient Satisfaction Survey
For subjective changes in daily living after the implantation of the ActiGait stimulator, patients were asked to answer a short quality of life survey (Fig. 1). Twenty-one patients (78%) noticed a complete return to normal mobility and 5 patients (18%) stated a pronounced improvement of mobility. Only 1 patient (4%) observed no changes. Social participation improved for 2 patients (7%) marginally, 6 patients (22%) reported a marked improvement, and 18 patients (67%) noticed a complete return to normal. One patient (4%) reported no changes in social participation. The quality of life improved markedly for 6 patients (22%) and returned to completely normal for 20 patients (74%). One patient noticed no differences in quality of life. Twenty-three patients (85%) stated they would recommend the operation, while 3 patients (11%) were unsure and 1 patient (4%) would advise against implantation. This patient, who also reported no changes in quality of life, mobility, and social participation, suffered from the nerve injury mentioned above.

Discussion
For stroke-related drop foot, ankle foot orthosis and surface stimulator systems are common treatment options. However, ankle foot orthosis may promote development of contracture due to reduced ankle mobility and may appear uncomfortable. In contrast, chronic use of...
the surface stimulator appears to strengthen the activation of the motor cortex and their descending connections after long-term use, which may improve gait even when the stimulator is off. However, electrode positioning in hemiplegic patients is difficult and skin irritations may occur. Therefore, semi-implantable devices were considered. No therapeutic effect was found in a randomized controlled trial using a peroneal nerve stimulator with an external transmitter, a foot switch, and an implantable passive dual-channel stimulator.

In this study, we present the first prospective clinical outcome study on 27 patients with an implantable 4-channel drop foot stimulator (ActiGait) for stroke-related drop foot. Its efficacy and superiority compared with surface stimulation was already reported in another study, including a few patients who suffered a stroke. Previous to this study, complications have only rarely been reported, such as hematomas at the side of the cuff placement, postoperative lymphedema at the stimulator body (both occurred in 1 of 5 patients), wound healing deficit (1 of 15 patients), and infections (2 of 15 patients), but injury to the peroneal nerve may also occur. To avoid possible nerve injury, it is important to place the cuff without any nerve tension. The surgery and postoperative care were easy and uncomplicated. Patients had no problems using the ActiGait stimulator in daily living. Additionally, recent reports show that the implantable device was easier to use than the surface stimulator.

We showed in this study that walking speed could be increased significantly (47.2%) using the ActiGait system. This result is comparable with recent findings, in which ActiGait stimulation revealed an improvement of 19% and 25% in a 10-meter gait test. In our study, the implantable stimulation was significantly superior to an ankle foot orthosis and to surface stimulation. This may be explained by the fact that an implantable stimulator produces a considerable orthotic effect with more physiological kinematics in the lower limb. Furthermore, the electrodes of an implantable system directly surround the peroneal nerve and allow a more specific stimulation with finer adjustability of the stimulation parameters compared with surface stimulation. Patients’ gait endurance was also improved significantly by 51.2%. In the timed up-and-go test, which is a standard test to assess risk of falls, a highly significant improvement (48.2%) of the needed time was measured for ActiGait stimulation due to a safe gait. In this test, a normal gait without increased risk of falls is determined by a needed time of less than 10 seconds. With ActiGait stimulation, patients were able to pass the test in a median of 10.6 seconds, which means they had a mild mobility impairment (11–19 seconds needed). Finally, 96% of our patients noticed an improvement of mobility in daily living, in quality of life, and in social participation. Only 1 patient expressed regrets about the implantable stimulator. Although the presented results of our study are promising, they are limited by a lack of a randomized trial, by the few number of observed patients, and by short evaluation time of 6 weeks postoperatively. Further studies are needed to prove the long-term benefit of the patients regarding the daily usability, long-term satisfaction, quality of life, and functionality and durability of the device.

Conclusions

The ActiGait system is an advantageous treatment option for patients suffering from a drop foot caused by a permanent cerebral lesion, including insults or hemorrhages.

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References


Author Contributions

Supplemental Information
Videos

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