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

*Klaus Daniel Martin, MD,¹ Witold Henryk Polanski, MD,¹ Anne-Kathrin Schulz,¹ Michael Jöbges, MD,³ Hansjoerg Hoff, MD,² Gabriele Schackert, PhD,¹ Thomas Pinzer, MD,¹ and Stephan B. Sobottka, MD¹

¹Department of Neurological Surgery, Carl-Gustav-Carus University Hospital of the Technical University of Dresden; and

²Radiologische Praxis Dresden, and ³Neurologic Rehabilitation Centre, Brandenburg Klinik, Bernau-Waldsiedlung, Germany

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.

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KEY WORDS stroke; drop foot; ActiGait; implantable stimulator; functional neurosurgery

CONTRALATERAL hemiplegia is one of the most frequent causes of disability in stroke patients.^{11,14} In up to 20% of stroke patients, a persisting weakness of the contralateral foot is a major cause of gait impairment, usually described as “drop foot.”¹⁵ The patients are not able to actively dorsiflex the foot during the swing phase of gait, which results in undesirable compensatory movement patterns, decreased gait velocity, restricted functional mobility, and increased risk of falls.^{4,8,9}

Surface stimulation of the peroneal nerve and an an-

kle foot orthosis have been shown to improve the gait of these patients, as well as social participation and quality of life.^{1,12,17,18} Comparing ankle foot orthosis and drop foot surface stimulation, no significant difference in gait speed was found in a randomized single-blind trial. However, user satisfaction was significantly higher in the drop foot stimulation group.¹²

Recently, an implantable 4-channel drop foot stimulator (ActiGait; Neurodan A/S), with independent electrode adjustment resulting in a more specific stimulation, showed

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* Drs. Martin and Polanski contributed equally to this work.

an improvement of walking speed and a restoration of the physiological ankle movement in patients with stroke-related 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 stimulator 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 Burrige et al.² In brief, the common 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 stimulator 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, ramping, 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 μ sec (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 $\pm$ 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-

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

Case No.	Age (yrs), Sex	Side w/ Drop Foot	Cause of Drop Foot	Duration of Drop Foot (mos)	Parameters of Stimulation
1	53, M	Lt	Ischemic	52	Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 330 μ sec; heel switch ipsilat
2	62, M	Rt	Ischemic	221	Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 180 μ sec; heel switch ipsilat
3	29, F	Lt	Ischemic	48	Channel 1+4 active; 1 mA; 35 Hz; optimal impulse duration 60/70 μ sec; heel switch ipsilat
4	58, M	Lt	Ischemic	16	Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 90 μ sec; heel switch ipsilat
5	25, M	Rt	Hemorrhagic	80	Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 80/50 μ sec; heel switch ipsilat
6	59, M	Rt	Ischemic	23	Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 80 μ sec; heel switch ipsilat
7	64, F	Rt	Ischemic	11	Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 100/75 μ sec; heel switch ipsilat
8	36, F	Lt	Hemorrhagic	54	Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 80 μ sec; heel switch ipsilat
9	57, F	Rt	Ischemic	27	Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 90 μ sec; heel switch ipsilat
10	36, F	Lt	Ischemic	47	Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 330 μ sec; heel switch (patient is only in the exercise-mode)
11	24, F	Rt	Ischemic	55	Channel 1+3+4 active; 1 mA; 30 Hz; optimal impulse duration 85/65 /45 μ sec; heel switch ipsilat
12	52, F	Rt	Ischemic	71	Channel 1 active; 1 mA; 20 Hz; optimal impulse duration 150 μ sec; heel switch ipsilat
13	58, M	Rt	Ischemic	19	Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 110/60 μ sec; heel switch contralat
14	49, F	Lt	Ischemic	244	Channel 4 active; 1 mA; 35 Hz; optimal impulse duration 200 μ sec; heel switch contralat
15	54, M	Lt	Hemorrhagic	6	Channel 4 active; 1 mA; 20 Hz; optimal impulse duration 150 μ sec; heel switch ipsilat
16	66, F	Lt	Ischemic	90	Channel 1+4 active; 1 mA; 20 Hz; optimal impulse duration 110/90 μ sec; heel switch ipsilat
17	54, F	Lt	Ischemic	138	Channel 4 active; 1 mA; 20 Hz; optimal impulse duration 120 μ sec; heel switch contralat
18	64, F	Lt	Ischemic	17	Channel 1+4 active; 1 mA; 20 Hz; optimal impulse duration 105 μ sec; heel switch ipsilat
19	43, F	Rt	Hemorrhagic	60	Channel 1+3+4 active; 1 mA; 20 Hz; optimal impulse duration 160/150 μ sec; heel switch ipsilat
20	50, M	Rt	Hemorrhagic	55	Channel 1 active; 1 mA; 30 Hz; optimal impulse duration 60 μ sec; heel switch ipsilat
21	59, M	Rt	Ischemic	37	Channel 1+2+3 active; 1 mA; 20 Hz; optimal impulse duration 60/70/65 μ sec; heel switch contralat
22	54, M	Lt	Ischemic	70	Channel 3 active; 1 mA; 25 Hz; optimal impulse duration 145 μ sec; heel switch ipsilat
23	55, M	Lt	Ischemic	20	Channel 4 active; 1 mA; 30 Hz; optimal impulse duration 110 μ sec; heel switch contralat
24	54, F	Rt	Ischemic	97	Channel 3 active; 1 mA; 30 Hz; optimal impulse duration 100 μ sec; heel switch ipsilat
25	48, M	Rt	Ischemic	25	Channel 1+4 active; 1 mA; 30 Hz; optimal impulse duration 125/95 μ sec; heel switch ipsilat
26	60, M	Rt	Hemorrhagic	54	Channel 1 active; 1 mA; 25 Hz; optimal impulse duration 150 μ sec; heel switch ipsilat
27	55, M	Rt	Ischemic	63	Channel 1 active; 1 mA; 20 Hz; optimal impulse duration 130 μ sec; heel switch ipsilat

operatively, the implantable device did not appear bulky, but was palpable in all patients. Patients 1 and 10 suffered from a nerve injury but recovered completely after 18 months. In both patients, a reoperation was completed. In patient 1, no organic correlation was found, whereas in patient 10 the nerve injury appeared to be due to a nerve pull by the cuff electrode, which was corrected intraoperatively. In patient 8, a wound healing disorder was found that was then treated locally with a wound examination; no further complications were found. Patient 27 suffered from neurodermatitis and developed an infection of the implant, which ultimately had to be removed. Bleeding was not observed, although 21 patients with an ischemic stroke were treated with acetylsalicylic acid 100 mg per day continuously.

In all patients, the programming of the ActiGait stimu-

lator 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

FIG. 1. Quality of life and patient satisfaction survey of the patients who received the ActiGait drop foot stimulator.

stimulator, 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).

VIDEO 1. Clip showing the pleasant walking speed test in a patient without walking aids (left) and after implantation of the ActiGait nerve stimulator (right). Copyright Klaus Daniel Martin. Published with permission. Click here to view with Media Player. Click here to view with Quicktime.

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

FIG. 2. Illustration of the ActiGait drop foot stimulation system. The hybrid system consists of an implanted nerve stimulator connected to the 12-electrode cuff around the peroneal nerve and an external control unit that contains the power supply, which is triggered by the external heel switch. Copyright Klaus Daniel Martin. Published with permission. Figure is available in color online only.

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.^{5,10,13} In contrast, chronic use of

FIG. 3. Results from the pre- and postoperative gait tests of the patients who received the ActiGait drop foot stimulator. **A:** Maximal and pleasant walking speed without walking aids, with ankle foot orthosis, and with a surface stimulator (all preoperatively) compared with postoperative walking speed with the ActiGait system. **B:** Pre- and postoperative walking endurance measured by the distance that was covered within 6 minutes. **C:** Pre- and postoperative timed up-and-go test.

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.⁷ 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.¹³

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.¹⁸ 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),¹⁸ wound healing deficit (1 of 15 patients), and infections (2 of 15 patients),² 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.³

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%² and 25%¹⁸ 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.¹⁸ 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.¹⁶ 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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Author Contributions

Conception and design: Martin. Acquisition of data: Martin, Polanski, Schulz, Hoff. Analysis and interpretation of data: Polanski, Schulz, Jöbges, Hoff, Sobottka. Drafting the article:

Polanski, Sobottka. Critically revising the article: Polanski, Jöbges, Schackert, Pinzer, Sobottka. Reviewed submitted version of manuscript: Polanski. Statistical analysis: Polanski, Pinzer. Administrative/technical/material support: Polanski, Schackert. Study supervision: Sobottka.

Supplemental Information

Videos

Video 1, Media Player. http://mfile.akamai.com/21490/wmv/digitalwbc.download.akamai.com/21492/wm.digitalsource-na-regional/jns14-2110_video_1.asx.

Correspondence

Klaus Daniel Martin, Department of Neurological Surgery, Carl-Gustav-Carus University Hospital of the Technical University of Dresden, Fetscherstr. 74, 01307 Dresden, Germany. email: daniel.martin@uniklinikum-dresden.de.