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ORIGINAL REPORT

IMPLANTED PERONEAL NERVE STIMULATOR TREATMENT FOR DROP FOOT CAUSED BY CENTRAL NERVOUS SYSTEM LESION: A TWELVE-MONTH FOLLOW-UP OF 21 PATIENTS

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Objective: **Drop foot is a common impairment following stroke or other causes of central pathology. We report data on patient self-perceived performance, satisfaction with performance, walking ability, and adverse effects after surgical implantation of the ActiGait® drop foot stimulator.**

Design: **Prospective case study with a 12-month follow-up.**

Subjects: **Twenty-one participants with drop foot caused by central nervous system lesion.**

Methods: **The patients' self-perceived performance and satisfaction with performance were evaluated using the Canadian Occupational Performance Measure (COPM). Walking ability was assessed using a 10-m walk test and a 6-min walk. Nerve conduction of the peroneal nerve was examined in 10 patients.**

Results: **At follow-up, COPM self-percieved performance from 3.2 to 6.7 points, the median increase being 2.8 (interquartile range (IQR) 2.2–5.0), $p < 0.001$. Likewise, the COPM satisfaction with performance increased from 2.6 to 6.9 points, the median increase being 4.2 (IQR 2.8–5.8), $p < 0.001$. Walking velocity increased 0.1 m/s from a baseline measurement of 0.73 m/s (95% confidence interval (95% CI) 0.03–0.2), $n = 21$, $p < 0.01$, and walking distance increased by 33 m, from a baseline measurement of 236 m (95% CI 15–51), $n = 21$, $p < 0.001$.**

Conclusion: **Stimulation of the peroneal nerve by an implantable stimulator increases self-perceived performance, satisfaction with performance, and ambulation in patients with long-lasting drop foot caused by a central nervous system lesion.**

Key words: drop foot gait; implantable neurostimulator; neurological rehabilitation; walking speed.

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LAY ABSTRACT

Drop foot is a common impairment following stroke or other causes of disease in the nervous system. This study of 21 patients with drop foot caused by various diseases in the central nervous system reports data on patient self-perceived performance, satisfaction with performance, walking ability, and adverse effects after surgical implantation of the ActiGait® peroneal nerve stimulator. The patients' self-perceived performance and satisfaction with performance were evaluated using the Canadian Occupational Performance Measure. Walking ability was assessed using a 10-m walk test and a 6-min walk test before implantation and at follow-up. At follow-up, patient self-perceived performance, satisfaction with performance, walking velocity, and walking distance increased. No changes in nerve function were demonstrated. In conclusion, implantable peroneal nerve stimulation increases self-perceived performance, satisfaction with performance, and ambulation in patients with long-lasting drop foot caused by central nervous system lesion.

Drop foot as a result of paresis of the ankle dorsiflexor muscles, calf spasticity or ankle stiffness is a common impairment following stroke (1) or other causes of central nervous system pathology, including spinal cord injury. Standard treatment is an ankle foot orthosis (AFO), which provides stable support of the ankle joint during the swing phase and initial contact during walking. The disadvantages of using an AFO is that it limits the normal range of ankle movement, resulting in increased ankle stiffness and reduced adjustment of the foot to the walking surface (2).

An alternative to AFO is functional electrical stimulation (FES) applied by surface electrodes above the common peroneal nerve. Peroneal nerve stimulation activates the muscles of the lower leg that dorsiflex and evert the foot, which, correctly timed, ensures foot clearance during swing and controlled heel strike during initial contact. FES has been shown to provide an effective alternative to AFO (3, 4). However, difficulties such

as positioning the electrodes and skin irritation caused by surface stimulation (5, 6) led to the development of partly implantable drop foot stimulator systems (7, 8). ActiGait®, CE-marked for the European market in 2006, has been shown to be safe and effective in patients after stroke (8), with high patient satisfaction (9) and with improvement in gait kinematics (10).

To observe the long-term effects of ActiGait® as a treatment for drop foot, a clinical case study was conducted, with follow-up evaluating patient self-perceived performance, satisfaction with performance, walking ability and safety concerns.

MATERIAL AND METHODS

Design

This prospective single case study with 6- to 12-months follow-up included all 21 Danish patients with ActiGait® implantation since completion of a previously published phase II safety study (8), henceforth called the Danish ActiGait® cohort.

The first 10 patients (ID 1–10) participated in a manufacturer-supported phase III feasibility and safety study, with preliminary data previously reported in a conference abstract (11). Patient self-perceived performance and satisfaction with performance were evaluated at baseline, at 3 months and at 6 months after activation of the ActiGait® device. Walking ability was assessed at baseline and at 3-, 6- and 12-month follow-ups.

The remaining 11 patients (ID 11–21, henceforth called the "clinical group") were implanted after completion of the above-mentioned phase III study and financed by the Danish healthcare system. Patient self-perceived performance and satisfaction with performance were evaluated at baseline and at follow-up 12 months after activation of the ActiGait® device. Walking ability was examined at baseline and at 3- and 12-month follow-up.

Manufacture of the commercially available ActiGait® device ceased in 2017.

Participants

Baseline demographic characteristics and performance data for the 21 participants with drop foot caused by ischaemic (12) or haemorrhagic stroke (6), cervical fracture (1), traumatic brain injury (1) and multiple sclerosis (1) are shown in Table I. Walking aids at inclusion included AFO, cane and walker, but not walking frames.

Inclusion criteria were:

- clinically verified and symptomatic drop foot related to central lesion minimum 6 months prior to implantation;
- walking distance without personal support of at least 100 m;
- both heels touching the ground when patient is standing with extended knees;
- range of movement of the affected ankle joint of at least 30°;
- medio-lateral stability of the ankle joint during loading phase;
- clinical improvement in walking symmetry, walking velocity and comfort during walking with application of an external drop foot stimulator prior to inclusion, but with unacceptable side-effects.

Table I. Demographic data of study participants (n = 21)

Characteristics	
Age (years)	55 (27; 79)
Sex (male/female)	8/13
Affected side (right/left)	13/8
Type of lesion (ischaemic/ICH/medullary/TBI/DS)	12/6/1/1/1
Time since onset (months)	73 (25; 216)
Walking speed (m/s)	0.73 (0.25; 1.23)
Walking distance, 6MWT (m)	236 (73; 450)

Data are reported as median (range).

ICH: intra-cerebral haemorrhage; TBI: traumatic brain injury; DS: disseminated sclerosis; 6MWT: 6-min walk test.

Device

ActiGait® comprises a surgically implanted peroneal nerve stimulator, an external heel switch, a control unit and a software package (Fig. 1). The implant consists of the stimulator body, a cable and a nerve cuff electrode positioned around the common peroneal nerve. The cuff electrode allows independent stimulation of different fascicles within the nerve by 4 sets of electrodes. The heel switch, which is positioned in the contralateral shoe, triggers the initiation and termination of stimulation sequences with respect to the stride phase by a radio-link to the external control unit, usually carried at the waist. An antenna hard-wired to the control unit is positioned on the skin above the stimulator body, by which power and settings are transferred to the implant. During use the control unit allows the patient to switch stimulation on and off and increase/decrease stimulation intensity within the clinical set range of intensities.

Surgical procedure

The ActiGait® implantation was carried out under general anaesthesia. After surgical exposure of the common peroneal nerve, the implant was positioned laterally on the thigh and the cuff electrode sutured around the peroneal nerve just above the knee, as described in detail elsewhere (8). After surgery, the knee joint was immobilized with tape in an extended position for 14 days. The implantations in the Danish ActiGait® cohort were carried out from 2009 to 2016.

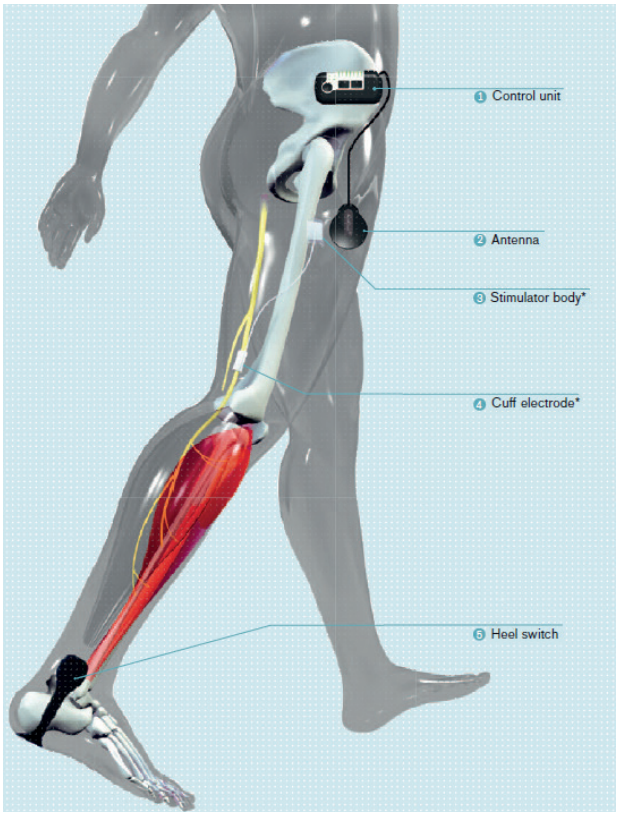

Fig. 1. The ActiGait® partly implantable drop foot stimulator system.

Activation of peroneal stimulation

Two weeks after implantation the device was activated and the patients were offered 5×1.5 h of individual training at Aalborg University Hospital, Denmark, administered during a period of 2 weeks by a certified physio-therapist skilled in ActiGait® training and instruction. These training sessions included initial adjustment, patient instruction and patient education in operating the device. Furthermore, the patient was taught how to handle and mount the ActiGait® hardware and learned to become familiar with the ActiGait user interface. The proper use of ActiGait® was trained in order to accept and take advantage of the stimulation during walking, standing up, sitting down, climbing stairs and handling clothing, as well as other relevant activities of daily living (ADL).

Protocol and outcome measures

The Canadian Occupational Performance Measurement (COPM) was applied in order to verify whether use of ActiGait® met patients' expectations of their own set up goals for the treatment. COPM is a commercially available (https://www.thecopm.ca) validated tool (12) that has been used previously to evaluate satisfaction with peroneal surface stimulation in patients with multiple sclerosis (MS) (13). COPM is usually applied to identify problems in connection with daily activities (ADL), plan exercise programmes with individualized training of ADL, show patient's prioritization of daily living problems, and assess patients' self-perceived performance and their satisfaction with their performance or training in relation to patient-prioritized problem areas (14). The patients identified the individual daily activities that they found difficult to perform within the categories: A, self-care; B, productivity; and C, leisure. Each patient individually identified and prioritized the 5 most important everyday issues restricting their participation in everyday living, and subsequently scored each issue for self-perceived performance and satisfaction with performance on a scale from 1 to 10, resulting in 2 sub-scores, the COPM self-perceived performance, and the COPM satisfaction with performance, respectively. A change in score of 2 or more is considered clinically relevant (13). Ninety-five percent of activities chosen by the participants were directly related to gait or walking. All procedures with regard to COPM were performed by an experienced neurological occupational therapist trained in the use of COPM.

Walking velocity and walking endurance were assessed by a trained PT, using the 10-m walk test (10mWT) at self-selected pace and with flying start, and a 6-min walk test (6MWT) at self-selected pace, as described elsewhere (15). At baseline, the 10mWT was repeated 3 times without interspersed rest periods, followed by a 6MWT. At all follow-up assessments, the 10mWT was repeated 3 times without stimulation, followed by 3 times with stimulation, and the mean was used for further calculations. Finally, the 6MWT was performed with stimulation.

Change in walking velocity and walking endurance were evaluated by comparing the baseline walking velocity or walking distance without stimulation with walking velocity or walking distance with stimulation at follow-up.

The patients were allowed to use their preferred walking aids during testing, if needed, including an AFO. In only a few cases did the need for walking aids change during study participation.

Imaging and nerve conduction

The first 10 participants (participants in the phase III study) underwent magnetic resonance imaging (MRI) of the knee for examination of subcutaneous tissue thickness prior to implantation and neurophysiological measurement of nerve conduction velocity and amplitudes, using surface electroneuronography (ENG) to ensure normal peroneal nerve conduction velocity and amplitude. ENG was repeated 12 weeks after implantation to rule out nerve damage. The

remaining 11 participants received neither MRI nor ENG, since it was not part of the evaluation after completion of the phase III trial, and since no change was observed (11).

Statistical analysis

The COPM self-perceived performance and COPM satisfaction with performance were analysed using Wilcoxon's test. The data from the COPM are on an ordinal scale, and the distribution is asymmetrical, and therefore non-parametric analysis was used. The change in walking velocity and walking distance were analysed using a paired *t*-test. Data from walking test are on an interval scale, and testing for normality by Shapiro-Wilk test in SPSS showed no significant difference from normal distribution. In both Wilcoxon's tests and the paired *t*-test a significance level of 0.05 was adopted.

Primary outcome measures are patient self-perceived performance and satisfaction with performance on the COPM.

Secondary outcome measures are walking velocity on a 10mWT and walking endurance, reported as walking distance at a 6MWT. Length of follow-up on COPM patient self-perceived performance and satisfaction with performance varies in the Danish ActiGait® cohort, being 6 months in the phase III trial and 12 months in the clinical group. Separate calculations were made, in each group (the Phase III trial participants and the Clinical group) and the effect size in each group is shown in Table II for clarity. The baseline, 6- and 12-month COPM follow-up data are subsequently pooled together; hence the data are analysed and reported as follow-up for the Danish ActiGait® cohort representing 6- to 12-month follow-up data. Data for each group at baseline and at 3-, 6- and 12-month follow-up are descriptively summarized.

Likewise, data on walking velocity and walking endurance are pooled together and analysed and reported at baseline and follow-up for the Danish ActiGait® cohort, whereas, data per group are only descriptively summarized.

Ethical considerations

The protocol of the phase III study was submitted to the local ethics committee, who found that the study was to be considered a quality follow-up study, and application and ethics approval were therefore not required. Patients gave their written informed consent to enter the study.

RESULTS

All 21 patients receiving an ActiGait® implant at Aalborg University Hospital completed the follow-up. One patient developed an infection after opening of the sutures above the knee, and was explanted 12 weeks after implantation. However, the patient remained motivated for implantation, and remained eligible, and was re-implanted 18 months later without further complications. Another patient stopped using the device altogether 2 months after implantation, due to disappointment of still having a hemiparetic

Table II. Canadian Occupational Performance Measure (COPM) values and change at baseline and follow-up

COPM	Baseline		3 months			6 months			12 months			6–12 months combined		
Self-perceived performance														
Phase III trial (*n* = 10)	4	(1.5)	5.5		(2.1)	6.3		(2.2)	n.p.					
Clinical group (*n* = 11)	3	(1.6)	n.p.			n.p.			6.9		(1.7)			
Danish ActiGait® cohort (*n* = 21)	3.2	(1.6)	n.p.			n.p.			n.p.			6.7		(1.9)
Satisfaction with performance														
Phase III trial (*n* = 10)	3	(1.6)	5.3		(2.3)	6.1		(1.8)	n.p.					
Clinical group (*n* = 11)	2.2	(1.3)	n.p.			n.p.			7.6		(1.9)			
Danish ActiGait Cohorte (*n* = 21)	2.6	(1.5)	n.p.			n.p.			n.p.			6.9		(2.0)
Change COPM (follow-up – baseline)			Diff		*p*-value	Diff		*p*-value	Diff		*p*-value	Diff		*p*-value
Self perceived performance														
Phase III trial (*n* = 10)			0.95	[0.5–2.1]	0.028	2.3	[1.1–2.8]	0.009	n.p.					
Clinical group (*n* = 11)			n.p.			n.p.			4.8	[2.8–5.4]	0.004			
Danish ActiGait® cohort (*n* = 21)			n.p.			n.p.			n.p.			2.8	[2.2–5.0]	< 0.001
Satisfaction with performance														
Phase III trial (*n* = 10)			1.7	[1.3–2.6]	0.005	3.0	[2.0–4.2]	0.007	n.p.					
Clinical group (*n* = 11)			n.p.			n.p.			5.0	[3.7–6.8]	0.003			
Danish ActiGait® cohort (*n* = 21)			n.p.			n.p.			n.p.			4.2	[2.8–5.8]	< 0.001

Data in the upper panel are reported as mean (standard deviation; SD).
Data in the lower panel (change at follow-up) are reported as median difference between the scores. [IQR]: interquartile range;
n.p.: not performed. Diff: Difference between follow-up and baseline
Phase III trial participants: 10 individuals participating in a previous published clinical trial (reference 11).
Clinical group: 11 individuals implanted with the ActiGait® device after completion of the phase III trial.
Danish ActiGait cohort (*n* = 21): all phase III trial participants (*n* = 10) and all individuals in the Clinical group (*n* = 11).

walking pattern, but completed the follow-up and was not excluded.

Absolute test values and changes are shown in Tables II and III.

Canadian Occupational Performance Measure

At follow-up, the self-perceived performance improved from 3.2 to 6.7 points in the Danish ActiGait® cohort, the median difference between the scores being 2.8 (interquartile range (IQR) 2.2–5.0). The improvement was statistically significant ($p<0.001$) and clinically relevant. Nineteen participants reported improvement, whereas 2 participants reported a minor decrease in self-perceived performance, of 0.5 and 0.6, respectively (Fig. 2).

Also, the participants' satisfaction with their performance improved from 2.6 to 6.9 points at follow-up, the median difference between the scores being 4.2 (IQR 2.8–5.8). Likewise, the improvement was statistically significant ($p<0.001$) and clinically relevant, and 20 participants reported improvement, with only 1 participant reporting a slight decrease of 0.3 points (Fig. 2).

10-m walk test

Analysis of the walking velocity on a 10mWT in the Danish ActiGait® cohort at follow-up revealed a statistically significant mean increase from 0.73 m/s to 0.83 m/s (95% CI 0.03–0.2), $p<0.01$ (Table III). Four participants had a decrease in walking velocity, ranging from 0.03 to 0.19 m/s, and, in a further 6 participants, an increase in walking velocity of <0.07 m/s.

Walking velocity increased 0.1 m/s from a baseline measurement of 0.73 m/s (95% CI 0.03–0.2), $n=21$, $p<0.01$.

Six-min walk test

All patients ($n=21$) walked continuously during the 6MWT before and after implantation. At follow-up there was a significant increase in walking distance of 33 m from 236 to 269 m (95% CI 15–51), $p<0.001$ (Table III). This increase amounts to approximately 14% increase in walking distance during the 6MWT, indicating a clinical meaningful change (15). One participant had a decrease in walking distance of 41 m.

Neurophysiological assessment

There were no changes in nerve conduction velocity or amplitude of the common peroneal nerve 3 months after ActiGait® implantation in the Phase III trial participants ($n=10$). The patient being explanted and subsequently re-implanted did not have any change in nerve conduction velocity at subsequent measurement of conduction velocity.

Adverse events

In 1 patient the implant had to be removed due to infection. The patient was treated with antibiotics and, subsequently re-implanted with no side-effects and no changes in nerve conduction velocity of the common peroneal nerve. One patient developed ankle joint instability without stimulation during the trial. No other adverse effects were reported.

Table III. Walk test and change at baseline and follow-up

Ambulation	Baseline		3 months			6 months			12 months		
10mWT gait velocity (m/s)											
Phase III trial (n = 10)	0.71	(0.23)	0.75	(0.24)		0.76	(0.28)		0.78	(0.32)	
Clinical group (n = 11)	0.74	(0.37)	0.83	(0.38)		n.p.			0.87	(0.41)	
Danish ActiGait® cohort (n = 21)	0.73	(0.30)	0.79	(0.32)		n.p.			0.83	(0.36)	
6 MWT distance (m)											
Phase III trial (n = 10)	232	(74)	242	(80)		244	(90)		256	(93)	
Clinical group (n = 11)	239	(120)	263	(127)		n.p.			281	(124	
Danish ActiGait® cohort (n = 21)	236	(98)	253	(105)		n.p.			269	(108)	
Change (follow-up – baseline)			Diff		p-value	Diff		p-value	Diff		p-value
10mWT gait velocity (m/s)											
Phase III trial (n = 10)			0.03	[−0.04–0.1]	0.34	0.05	[−0.05–0.2]	0.27	0.07	[−0.04–0.2]	0.19
Clinical group (n = 11)			0.09	[0.03–0.2]	0.006	n.p.	n.p.		0.13	[0.02–0.2]	0.03
Danish ActiGait® cohort (n = 21)			0.07	[0.02–0.1]	0.007	n.p.	n.p.		0.1	[0.03–0.2]	0.01
6 MWT distance (m)											
Phase III trial (n = 10)			9	[−13–32]	0.32	12	[−12–35]	0.29	24	[−6–53]	0.11
Clinical group (n = 11)			24	[5–44]	0.02	n.p.	n.p.		42	[18–67]	0.003
Danish ActiGait® cohort (n = 21)			17	[3–31]	0.017	n.p.	n.p.		33	[15–51]	< 0.001

Data in the upper panel are reported as means (SD).

Change at follow-up in the lower panel are reported as means [95% confidence interval; 95% CI].

10mWT: 10-m walk test; 6MWT:6-min walk test.

n.p.: not performed; Diff: Difference between follow-up and baseline

Phase III trial participants: 10 individuals participating in a previous published clinical trial (reference 11).

Clinical group: 11 individuals implanted with the ActiGait® device after completion of the phase III trial. Danish ActiGait® cohort constitutes all phase III trial participants (n = 10) and all individuals in the Clinical group (n = 11).

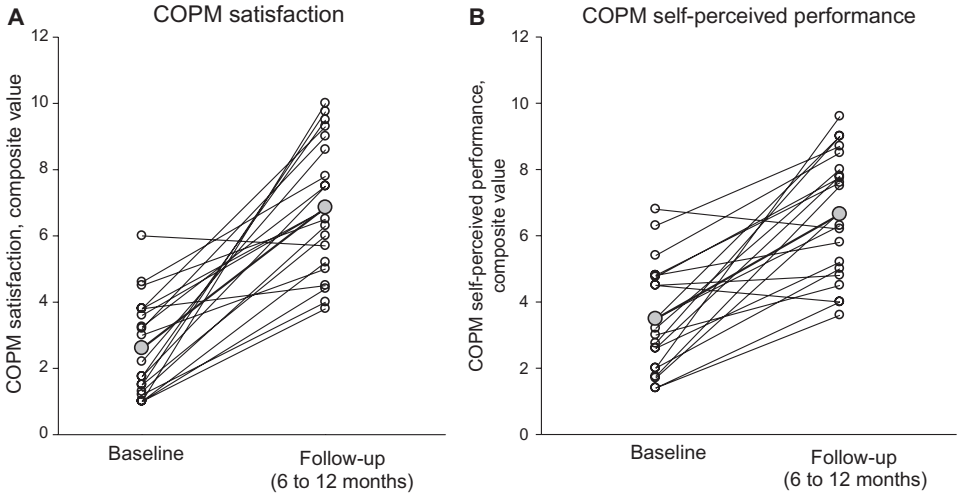

Fig. 2. Canadian Occupational Performance Measure (COPM) at baseline and follow-up. (A) COPM satisfaction with performance at baseline and at 6- to 12-month follow-up. (B) COPM self-perceived performance at baseline and at 6- to 12-month follow-up. *Bold line* and *grey dot* indicate median values.

DISCUSSION

The main results of this prospective single case study of 21 patients with drop foot caused by various damage to the central nervous system are: at follow-up there was a significant increase in patient self-perceived performance and satisfaction with performance, as assessed by the COPM; there were positive effects of ActiGait® stimulation on walking speed on the 10mWT and walking endurance on the 6MWT; and there were no negative effects of electrode implantation on the common peroneal nerve.

In general, the participants' COPM self-perceived performance and COPM satisfaction with performance increased during the intervention period with peroneal nerve stimulation. Nonetheless, the COPM self-perceived-performance score for 1 patient decreased slightly, despite an actual increase in both walking speed and COPM satisfaction with performance. The patient was not diagnosed with depression or other psychiatric conditions, but no other explanation for the patient's self-perceived loss of performance, despite an actual improvement in function, could be identified. It is worth noting, however, that the decrease in self-perceived performance in this patient was <2, this being the clinically important change, and that the change at 12 months compared with baseline was as low as 0.5. Another patient stopped using the device altogether 2 months after implantation, because he felt his gait still appeared hemiplegic, despite an increase in COPM self-perceived performance score. This indicates that expectations and acceptance of implanted devices can be difficult in some patients, despite thorough information, expectations alignment and shared decision-making before surgery. Furthermore, it emphasizes that a comprehensive selection procedure is necessary prior to implantation.

The actual effect on preferred walking speed on a 10mWT and walking endurance on a 6MWT with ActiGait® stimulation must be interpreted with care, due to the lack of a controlled design. However, data indicate an improvement within the limits of clinical meaningful change, as reported in the literature (15, 16).

The 10mWT is a short test, and may not account for, for example, improved ability to change direction, improved obstacle avoidance, or other indicators of improved confidence during ADL, as indicated by patients' own evaluation on the COPM.

Previously reported data on changes in walking velocity after ActiGait® implantation vary with regard to actual reported change from 0.03 to 0.22 m/s, but also with regard to methodology (8, 17–21), making comparison difficult. Furthermore, previous studies report primarily on walking-related outcome parameters, making interpretation of the actual impact on daily living difficult. In the study by Buentjen et al. small, but significant, changes are reported in comfortable walking speed; however, it is also speculated that even small changes in walking speed may be a surrogate marker for therapeutic effects (22).

The current study evaluated patients' self-perceived performance and self-reported satisfaction with performance, measures of participation, as well as change in walking velocity, thus setting the improvement in walking velocity in perspective with regard to the impact on the patients' daily life. The majority of participants reported a significant impact from the intervention.

Despite ActiGait® being commercially unavailable at present, the methodology with implanted nerve-cuff-electrode for peroneal nerve stimulation has been validated to be reliable and with long-term safety (8, 10). The method has, in the current study, shown the ability to improve patient satisfaction and

participation, as well as measurements of walking velocity. Improvement in gait kinematics has been reported previously (10). As technical solutions for brain machine interface (BMI) or brain computer interface (BCI) are expected to become reliable and commercially available in future, the authors hope that the ActiGait® system will become available again, perhaps in an upgraded version, without a heel-switch, ready for use with a BMI- or BCI-controlled user interface.

This study has a number of limitations. The design combined data from a phase III trial and subsequent patients operated in an identical clinical setting, resulting in COPM evaluations being performed at various time-points; however, this is illustrated clearly in Table II. With regard to all other aspects of the setup, there was no difference. An important limitation is the uncontrolled and unblinded design, with the risk of introducing a learning effect at follow-up. In reality, blinding was difficult, due to the fact that participants could feel when the stimulation was turned on. Also, there was no systematic data collection regarding the amount of home-based rehabilitation during the follow-up period, and there was no in-hospital training. The participants in the study are heterogeneous with regard to diagnosis; however, Buentjen et al. show consistent effects in patients with different causes of the central lesion (22).

CONCLUSION

Follow-up of 21 patients receiving a partly implantable peroneal nerve drop foot stimulator (ActiGait®) has shown long-term reliability, and that patients' satisfaction on the COPM is high on tests of self-perceived performance and satisfaction with performance. Furthermore, measurements of walking velocity indicate clinically relevant improvements. ActiGait® is currently commercially unavailable, but it is considered that the now-validated methodology is relevant and available for integration with future solutions, including BMI or BCI solutions.

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The authors have no conflicts of interest to declare.

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