Significant Impact of Implantable Functional Electrical Stimulation on Gait Parameters: A Kinetic Analysis in Foot Drop Patients

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■ OBJECTIVE: **Neurogenic drop foot is a common result of acquired damage of the central nervous system and can cause severe restriction of mobility. ActiGait, an implantable functional electrical stimulation device, restores ankle dorsiflexion by active peroneal nerve stimulation. The aim of our study was to evaluate its effect on foot contact pattern during normal walk.**

■ METHODS: **Eight patients with drop foot who used ActiGait in everyday life performed a 20-meter comfortable walk test. Gait parameters were evaluated with an insole system (Medilogic). Percentage of biped stance in a double-step, effective foot length, width of gait, and overall plantar load were measured in comparison with and without activated drop foot stimulation.**

■ RESULTS: **Effective foot length increased in all patients on average from 46.0% to 60.2% ($P = 0.038$). However, percentage of biped stance in a double-step showed no significant difference (31.2% vs. 27.8% on average, $P = 0.063$), nor did width of gait (2.6% vs. 2.4% on average, $P = 0.73$) and overall plantar load (3.51 N/cm^2 vs. 3.39 N/cm^2, $P = 0.25$).**

■ CONCLUSION: **The ActiGait implantable drop foot stimulator significantly improves effective foot length during normal walk of patients with neurogenic drop foot. Further investigation is needed to confirm whether ActiGait has no effect on the other parameters or whether it facilitates permanent gait adaptations that persist without the activated device.**

INTRODUCTION

Neurogenic drop foot is a frequent disability in stroke patients. It is described as a motor deficiency caused by a total or partial central paralysis of the muscles innervated by the common peroneal nerve. It results in a lack of ankle dorsiflexion and subtalar eversion,[1] which compromises gait. Patients slap the affected foot onto the ground instead of stepping. This increases the risk of falling[2] and leads to compensatory movements such as hip circumduction and hip hiking.[3,4]

Drop foot results in lower gait speed, shorter stride length, and extended dual-limb stance phase[1] and in an increased risk of falling, increased effort of walking, and, in consequence, reduced mobility and independence.[2]

A basic treatment is an ankle foot orthosis (AFO), which fixes the ankle joint in a neutral position. Disadvantages are lack of comfort, activities of daily living (ADL) complications, and contractures.[3,5]

Functional electrostimulation (FES) of the peroneal nerve is an alternative treatment to restore gait in drop foot patients. This can be achieved through surface stimulation with electrodes placed on the skin above the peroneal nerve. A switch under the affected or contralateral heel triggers the stimulation. Several studies have

Key words
- ActiGait
- Foot drop
- Functional electrical stimulation
- Gait
- Neurologic drop foot
- Stroke

Abbreviations and Acronyms
ADL: Activities of daily living
AFO: Ankle foot orthosis
BS: Percentage of biped stance in a double-step
EFL: Effective foot length
FES: Functional electrical stimulation
PP: Overall plantar pressure
SD: Standard deviation
WG: Width of gaitline

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Table 1. Survey of Patients (N = 8)

Patient	Sex	Side with Drop Foot	Age at Stroke (years, months)	Age at Study (years, months)	Duration of Treatment (months)
1	M	L	58, 11	70, 7	42
2	F	L	23, 11	59, 8	16
3	F	L	47, 6	55, 4	6
4	F	R	41, 6	61, 4	14
5	F	R	51, 1	53, 11	9
6	M	L	54, 3	61, 2	68
7	F	L	28, 10	49, 10	14
8	F	L	41, 10	57, 10	37

shown that FES increases walking speed,[4,6,7] compared with AFO, and user satisfaction also tends to be better.[5] However, skin irritation and changes in skin resistance throughout the day are reported problems,[3,5] as is the inconvenience of using the external components, especially in donning and doffing the self-adhesive electrodes.[2]

An implantable 4-channel drop foot stimulator (ActiGait) might be superior to surface stimulation because of independent electrode adjustment.[8] It is able to increase walking speed[2] and stride length[3] and seems to be a feasible way of correcting drop foot in stroke patients.[9]

Foot contact analysis in stroke patients shows pathologic patterns, which relate to their neurologic status.[10] However, this has not been examined for an implantable FES system. Our question is whether using ActiGait results in improved foot contact patterns. Therefore, the purpose of this study was to describe the effects of the ActiGait system on spatial and spatiotemporal gait parameters.

MATERIAL AND METHODS

The ethics committee of the medical faculty of the University of Frankfurt/Main approved this study. Informed consent was obtained from all patients prior to testing.

Patient Characteristics

Eight participants were recruited from patients who had previously undergone implantation surgery of the ActiGait device at the University Medical Center Frankfurt/Main, Department of Neurosurgery, based on inclusion criteria and willingness to participate. Inclusion criteria were the ability to walk 200 meters within 5 minutes with or without gait aids, and at least 6 months use of the ActiGait device. All patients were investigated during their annual control examination after surgery. Table 1 gives a survey of the patients. To exclude external factors, the ActiGait treatment was compared against the untreated drop foot in the same patient. This was achieved by switching off the device by the patients themselves. Patients could choose their preferred shoes to walk in, and all participants chose flat footwear.

Patient 1 experienced an ischemic stroke at the age of 58 years. He had tried external stimulation before but reported dysesthesia. He had also tried a splint for the ankle and peroneal nerve but had found it very uncomfortable for longer walks.

Patient 2 experienced a cardioembolic stroke. She underwent external stimulation but reported difficulties in correct positioning of the stimulator. She therefore often used higher current doses to receive optimal stimulation. With use of the higher current, dysesthesia was often a discomforting problem for her.

Patient 3 had a drop foot because of multiple sclerosis. She underwent external stimulation and showed good results concerning the gait. For optical reasons, external stimulation was never a satisfying option for her.

Patient 4 experienced a stroke in the middle cerebral artery territory as a complication in the postoperative course (2 days after surgery) of an abdominal operation. She underwent external stimulation and splint for her drop foot but was not satisfied. She also reported dysesthesia while using external stimulation and discomfort with the splint.

Patient 5 also reported a stroke of the middle cerebral artery territory due to a spontaneous dissection of the internal cerebral artery. She underwent external stimulation, and her gait was more stable with the stimulation; therefore, she wished for the implant.

Patient 6 experienced hypertensive hemorrhage of the basal ganglia. External stimulation showed a better gait pattern, and the patient reported he was less likely to fall while using stimulation.

Patient 7 experienced a stroke due to antiphospholipid syndrome. She also experienced a better gait pattern while using external stimulation but found it discomforting because of skin reactions and dysesthesia.

Patient 8 experienced a thalamic stroke. He reported massive discomfort using the treatment with a splint. After successful external stimulation, he also wished for the implantation (Table 1).

ActiGait

The ActiGait system is a partly implantable nerve stimulator. It consists of a 4-channel implant, stimulating the peroneal nerve, steered through an external antenna by the external control unit, and a heel switch to trigger and interrupt the stimulation sequence.[2] The stimulator cuff electrode is implanted proximally to the bifurcation of the common peroneal nerve before it divides into the deep and superficial branches. There, the nerve is already spatially organized into fascicles that travel to different motor points or muscles. Thus, each pair of channel electrodes is adjacent to discrete fascicles, allowing it to stimulate different movements. The cuff electrode is connected to the receiver part of the implant placed at the thigh with a subcutaneous cable. The external control unit sends data to the receiver through an external antenna placed on the skin. Users can regulate stimulation intensity with the control unit, and stimulation also can be switched off completely. The setup of stimulation parameters (intensity, frequency, ramping, and channel timing) is done with a standard computer and a graphical software interface, which is connected to the external control unit by a wireless connection.

Surgical Procedure

Before surgery, patients received an electrophysiologic examination and knee magnetic resonance imaging of the affected side for anatomic guidance of the peroneal nerve. All surgical procedures were performed with the patients under general anaesthesia after

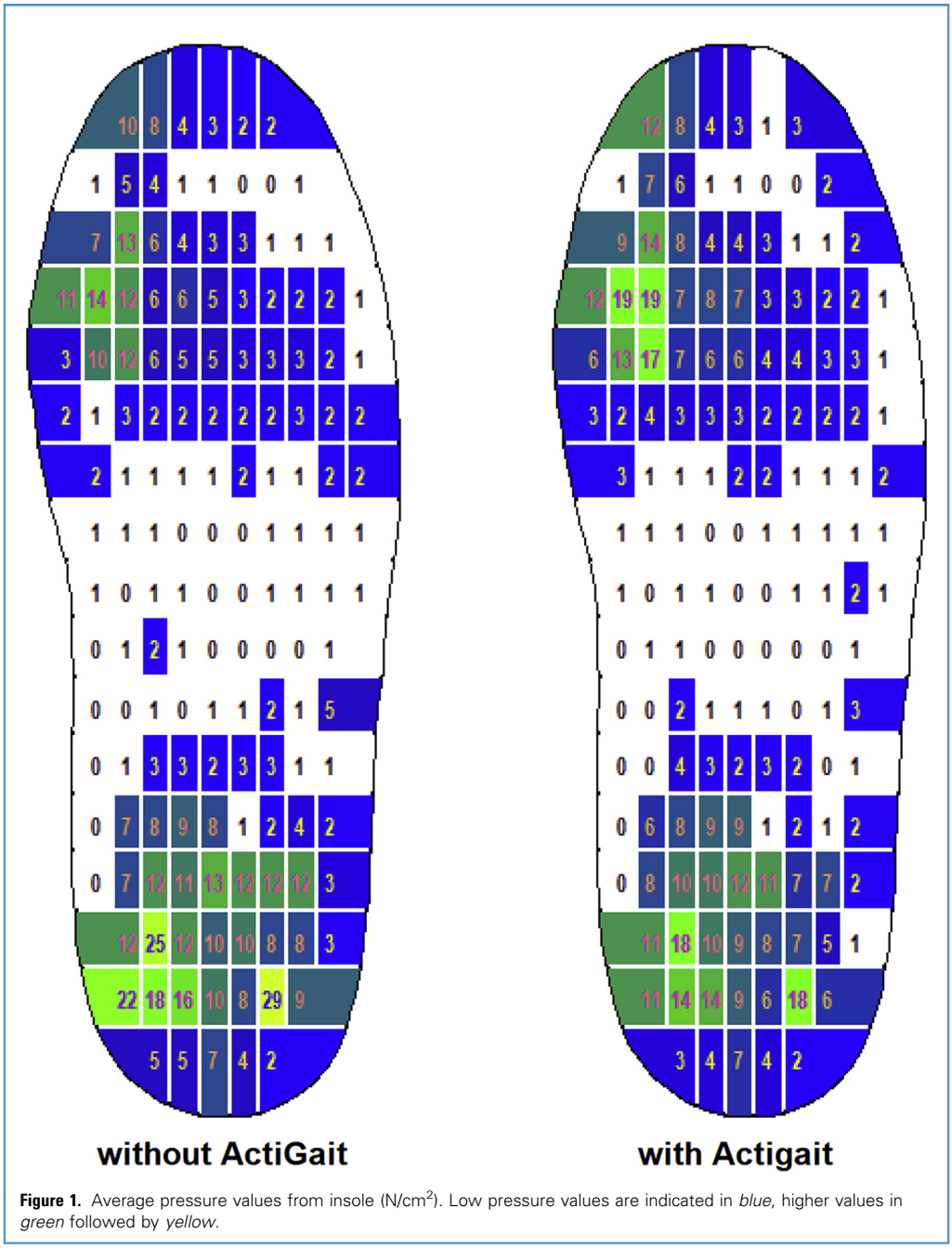

Figure 1. Average pressure values from insole (N/cm^2). Low pressure values are indicated in *blue,* higher values in *green* followed by *yellow.*

they had given written consent. First, a 4- to 5-cm incision was performed above the patient's knee fold to expose the peroneal nerve. The nerve was cleared from any remaining tissue. Dorsiflexion was tested by a nerve stimulator. Then, a curved incision at the patient's upper leg was performed for implantation of the stimulator. By use of a tunnelling tool, both incisions were connected, and the cable was pulled through. This cable has the electrode cuff on 1 end and the nerve stimulator on the other end. The electrode cuff was put around the nerve, and the stimulator was fixed to the lateral femoral fascia. Before wound closing, maximal flexion and extension was performed to verify correct position of the implant.

Measurements

For recording the gait data, Medilogic WLAN insoles (T&T Medilogic Medizintechnik GmbH, Schönefeld, Germany) were used. Matching foot-sized soles were placed into the patients' shoes to gather pressure load distribution from both feet (Figure 1). They were also equipped with a belt containing the WLAN transmission module. The patients were asked to perform a 20-meter walk test indoors on flat ground. No instructions regarding speed and gait were given, apart from not to walk faster than feeling secure. The track included a 180° turn. The first measurement was performed with activated ActiGait

Table 2. Gait Parameters without and with ActiGait Stimulation

Parameter	Without Stimulation	With Stimulation	*P* Value
EFL (%)	46.0 ± 12.4 (22.9–64.3)	60.2 ± 10.8 (37.4–72.7)	0.038
BS (%)	31.3 (27.0–46.0)	27.8 (27.0–37.0)	0.063
WG (%)	2.6 ± 1.2 (1.0–5.2)	2.4 ± 0.7 (1.6–3.9)	0.729
PP (N/cm^2)	3.5 ± 0.9 (2.7–5.2)	3.4 ± 0.9 (2.5–4.8)	0.248

EFL, width of gaitline; BS, percentage of biped stance in a double-step; WG, width of gaitline; PP, overall plantar pressure.

stimulation. Then the patients were asked to switch the device off to perform the second measurement. Raw data from the insoles were processed by the Medilogic software to calculate the metrics. Overall plantar pressure (PP) (N/cm^2) was analyzed to assess whether patients were able to transfer more load to the paretic limb. Furthermore, the effective foot length (EFL) (%) as the percentage of the foot that is effectively used during a walking step,[11] the width of gaitline (WG) (%) as the standard deviation (SD) of the x-coordinate of the gaitline,[11] and percentage of biped stance in a double-step (BS) (%) as the ratio of a double-step while both feet were in contact with the ground[11] were assessed.

Statistical Analysis

Percentage of biped stance in a double-step was tested with the Wilcoxon matched pairs test. Effective foot lengths were tested by a 1-sample *t* test. To compare the intervention within the patient, EFL with activated ActiGait was compared against EFL with deactivated device. Widths of gaitline were tested by a 1-sample *t* test. To compare the intervention within the patient, WG with activated ActiGait was compared against WG with deactivated device. Overall plantar pressure was tested by a 1-sample *t* test. To compare the intervention within the patient, PP with activated ActiGait was compared against PP with deactivated device.

All statistical analyses were performed in BiAS for Windows (Version 11.09), using $P < 0.05$ as a cutoff for statistical significance and a 95% confidence interval.

RESULTS

Eight patients with neurogenic drop foot who received an ActiGait implantable drop foot stimulator were included. Their mean age was 58.7 (SD, 6.1) years, 2 patients were men and 6 were women, and the mean time of treatment with the implant was 25.8 (SD, 21.4) months. Each patient performed 2 20 m walk-tests on flat ground to measure gait parameters with and without activated stimulation. Table 2 gives a survey of our results.

Mean effective foot length without stimulation was 46.0% ± 12.4%. Under active ActiGait stimulation, EFL increased significantly to 60.2% ± 10.8% ($P = 0.038$) (Figure 2).

Percentage of biped stance in a double-step revealed no significant change comparing no treatment against ActiGait (27.8% vs. 31.3%, $P = 0.063$).

Mean width of gaitline without stimulation was 2.6% ± 1.2%. Under active ActiGait stimulation, mean WG decreased to 2.4% ± 0.7%, but the change was not significant ($P = 0.729$).

Mean overall plantar pressure without stimulation was 3.5 N/cm^2 ± 0.9 N/cm^2. Under active ActiGait stimulation, mean PP was 3.4 N/cm^2 ± 0.9 N/cm^2, but the change was not significant ($P = 0.248$).

DISCUSSION

The FES can be a viable alternative to ankle foot orthosis in drop foot treatment.[4,6,7] Conventional surface stimulation can lead to

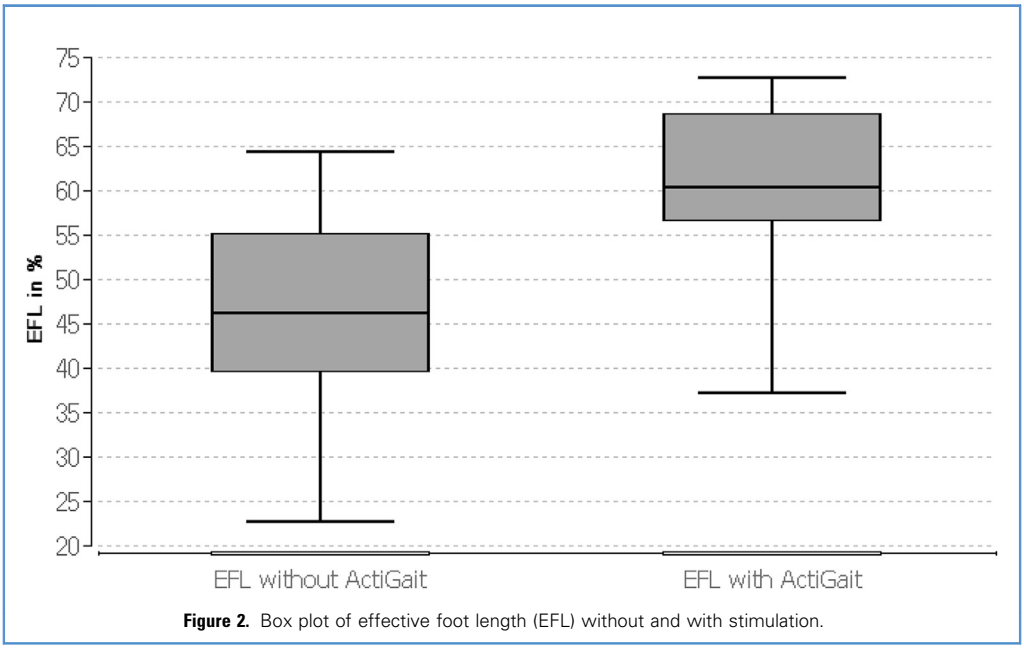

Figure 2. Box plot of effective foot length (EFL) without and with stimulation.

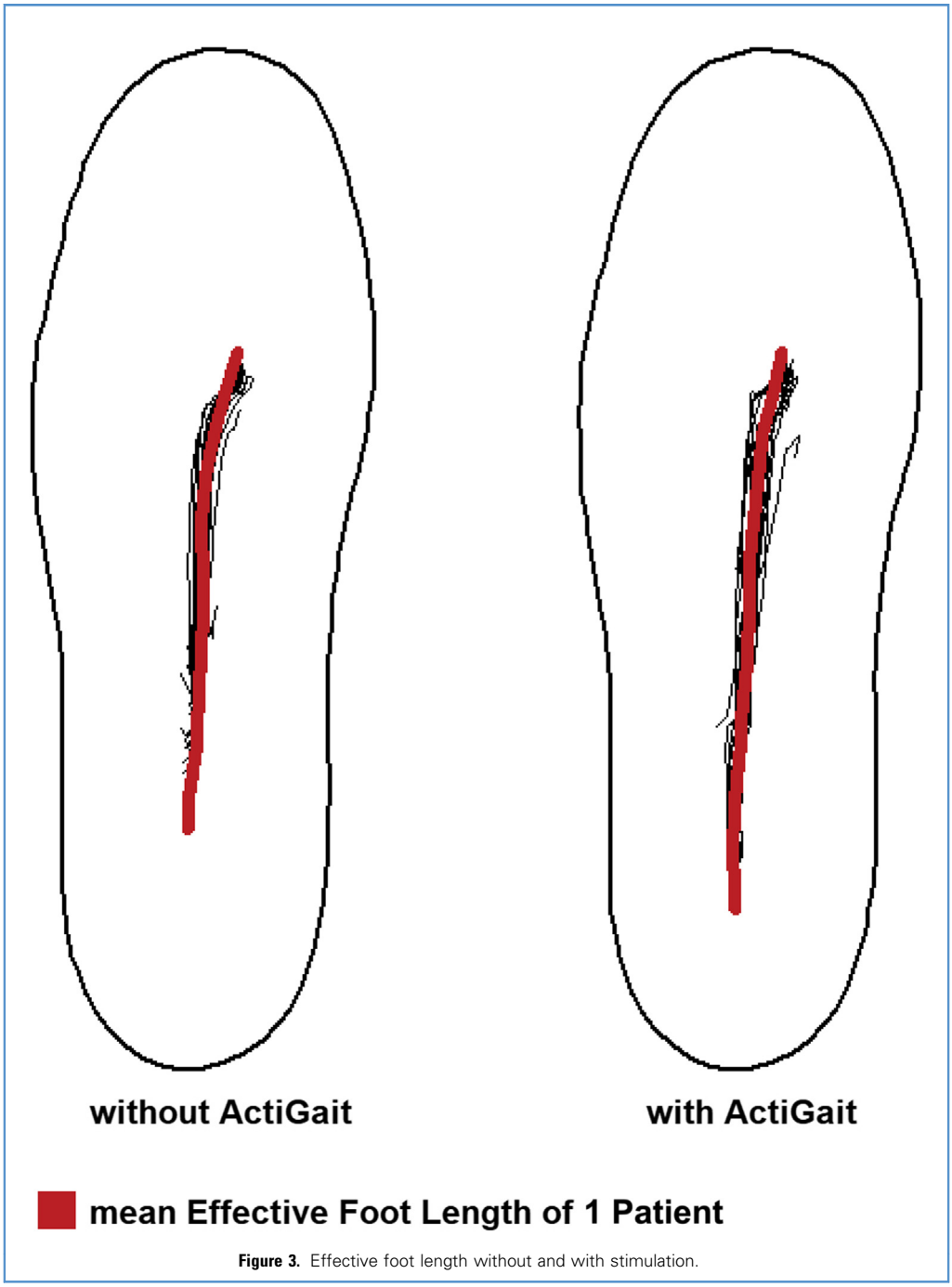

Figure 3. Effective foot length without and with stimulation.

skin irritation, and changes in skin resistance throughout the day may affect its potency.[3,5] Several authors have shown the advantages of an implantable 4-channel drop foot stimulator (ActiGait) over surface stimulation.[2,9] Martin et al.[8] showed an increase in patients' walking speed by 47.2% using the ActiGait system, and gait endurance was also improved by 51.2%. Yao et al.[3] found an increase in walking speed by 45% (vs. 41% with external FES) and in stride length by 22% (vs. 6% with external FES). Both discuss the direct stimulation of the peroneal nerve with independent electrodes and finer adjustability of stimulation parameters as a reason for its superior effect on gait recovery.[12]

Considering gait mechanics, Ernst et al.[9] found that FES restores physiologic ankle movements; during the initial ground contact of the heel, ActiGait restored the joint angle toward the physiologic range: 113° after 12 weeks (vs. 122°). This corresponds to an improved dorsiflexion during the swing

phase. Yao et al.[3] showed similar results; under ActiGait treatment, ankle dorsiflexion was increased at initial ground contact (11.6° vs. 1.3°) and also during midswing (17.0° vs. 11.3°).

Wong et al.[10] analyzed foot contact patterns in hemiplegic stroke patients. They described a close relation between patients' neurologic status and their gaitline patterns: patients with higher Brunnstrom stages and walking speed, step length, and cadence showed lower cyglogram, ground reaction force, and gaitline patterns. However, the effects of FES on foot contact patterns have not yet been fully evaluated.

The aim of this study was to investigate the effects of implantable FES on spatiotemporal gait parameters in patients with drop foot. We showed that effective foot length was improved significantly by 14.2% under ActiGait stimulation (60.2% vs. 46.0%) (**Figure 3**). However, percentage of biped stance in a double-step, and width of gaitline and overall plantar pressure, showed no significant change between application of FES and no treatment.

The increase in EFL is compatible with the previously described increased ankle dorsiflexion, inasmuch as it would be driven by the increased ankle angle at initial ground contact.[1] This is a function of the stimulation of the peroneal muscles during the swing phase and is an important safety aspect because it prevents stumbling.[3]

Our other findings do not stand in contrast to that, but they suggest that improvements in gait quality do not necessarily correlate with changes in all spatiotemporal gait patterns. Evareart et al.[13] also suggest that regular use of a foot drop stimulator strengthens activation of motor cortical areas and their residual descending connections, which may result in a therapeutic effect even when stimulation is switched off.

Concerning the indication for surgery, we are of the opinion that contracture is surely not a good indication for surgery. As mentioned, all patients underwent testing with the external stimulator. Only if the testing was successful, as observed by a neurosurgeon and by the patient's report of sensing an enhancement of gait, was the implantation planned and carried out. All patients had rest function of raising the foot, although in all cases raising was limited. Intraoperatively, all patients underwent testing again to ensure that elevation of the foot would work under stimulation. If contracture had been present, there would be no elevation of the foot under electrical stimulation.

The limitations of this study are the small sample size and the lack of a parallel group design. Even though only 1 of the evaluated gait pattern parameters showed significant improvement, we suggest that implantable FES can be a feasible therapeutic option because of its efficacy for treatment of neurogenic drop foot.

CONCLUSION

This study shows that the ActiGait implantable drop foot stimulator has a significant effect on foot contact patterns. by improving effective foot length during normal walk of patients with neurogenic drop foot. Further investigation is needed to differentiate whether ActiGait has no effect on the other parameters or whether it can lead to permanent gait adaptations as a result of a therapeutic effect that persists without the activated device.

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