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Surplus value of implanted peroneal functional electrical stimulation over ankle-foot orthosis for gait adaptability in people with foot drop after stroke

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ABSTRACT

Background: Implanted peroneal functional electrical stimulation (FES) is an effective alternative treatment to ankle-foot orthosis (AFO) in people with drop foot after stroke. With FES no constraints on ankle mobility are imposed which might particularly be exploited in challenging walking environments that require adaptations of the gait pattern to environmental disturbances.
Research question: Is gait adaptability, by means of the capacity to avoid sudden obstacles while walking on a treadmill, superior with implanted FES compared to AFO in people with drop foot after stroke?
Methods: A 4-channel peroneal nerve stimulator (ActiGait®) was implanted in 22 persons with stroke (> 6 months) who regularly used an AFO. Gait adaptability was tested with an obstacle avoidance task on an instrumented treadmill up to 26 weeks (n = 10) or 52 weeks (n = 12) after FES-system activation. At assessments, 30 trials, in which obstacles were suddenly dropped onto the treadmill in front of the paretic leg, were recorded with each device (FES / AFO). Trials were grouped by available response times (ART) and success rates were calculated. The effect of device, ART and follow up time on success rates was tested using generalized estimated equations. Nonparametric correlations were calculated to associate changes in success rates with clinimetrics.
Results: Success rates of obstacle avoidance were higher when participants used their FES system compared to AFO (Δ4.7%, p = 0.03), which effect was largest for longest ARTs (Δ15%, p = 0.03). Participants with greater motor impairment of the paretic leg showed greater benefit from FES (r_s = -0.49, p = 0.04).
Significance: FES has been found equally effective as AFO in improving walking speed of people with drop foot after stroke. We now present superior walking performance in a complex walking environment for implanted peroneal FES compared to AFO. These findings underline the importance of using gait assessments that require interplay with the environment, besides assessment of stationary walking, in community ambulators.

1. Introduction

Hemiparetic drop foot is one of the most common gait impairments in people with stroke [1]. Ankle-foot orthosis (AFOs) are generally prescribed as a treatment for drop foot, keeping the ankle and foot in a neutral position during the swing phase and loading phase of gait [2]. Functional electrical stimulation of the peroneal nerve is an alternative for AFO as it can provide an active ankle dorsiflexion moment during swing and loading [3]. In contrast to AFO, no mechanical constraints are imposed by FES enabling normal ankle range of motion and allowing optimal use of residual plantarflexor activity. Indeed, we recently reported that late stance plantarflexion was enhanced with peroneal FES, resulting in increased peak plantarflexion power and gait propulsion [4,5].

In spite of this theoretical advantage of FES over AFO, scientific evidence for a surplus value of FES on functional outcome is limited. A meta-analysis showed that gait speed and functional capacity were not significantly different between AFO and FES [6]. Since most FES users included in this meta-analysis were community walkers (comfortable walking speed > 0.4 m/s), more complex gait skills than normal level walking are also relevant to this population. Indeed, walking in daily life demands continual adaptations to environmental challenges, such as inclination angles, uneven terrain or traffic. It may be that the advantages of unrestricted ankle motion and control with FES particularly

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surface in more complex walking environments where adaptation of gait is required. Perhaps these advantages may explain the fact that patient satisfaction has been shown to be consistently higher for FES compared to AFO [7].

Studies that compared FES with AFO in challenging conditions are yet scarce. Sheffler et al. did not find a significant difference between FES and AFO in the time it took to complete an obstacle course after only one day of FES use [8]. In contrast, in an RCT with a 12-month follow-up, others found that for the FES group the time to complete an obstacle course gradually decreased, whereas it did not for people using AFO [9]. In line with this finding, our previous work demonstrated that the capacity to avoid sudden obstacles on a treadmill was better with FES compared to AFO [10]. Interestingly, this superiority of FES over AFO seemed to be particularly present in patients with greater motor impairment (Motricity Index < 64%).

These previous studies on walking adaptability were all limited to surface-based peroneal FES systems, whereas (partially) implantable systems are now available that allow for direct electrical stimulation of the common peroneal nerve with potentially greater spatial and temporal precision [11,12]. Therefore, in this study we aimed to investigate the capacity of avoiding sudden obstacles while walking on a treadmill with an implanted FES system (Actigait®) compared to AFO in people in the chronic phase after stroke. We expected to observe higher avoidance success rates with implanted FES than with AFO, similar to our previous findings on the use of surface-based FES [10]. In addition, we aimed to study the benefit from implanted FES in relation to the available response time for obstacle avoidance.

2. Methods

2.1. Participants

Gait adaptability data were collected in two longitudinal observational cohorts. In the first cohort, 10 persons with stroke were included and followed-up for 26 weeks. In the second cohort, another 12 persons with stroke were included and followed-up for 52 weeks. Participants were recruited from the outpatient rehabilitation clinics of two University Medical Centers in the Netherlands. Eligible participants had sustained a clinically established supratentorial stroke (ischemic or hemorrhagic) at least 6 months prior to inclusion. They needed to have impaired paretic side ankle dorsiflexion (Medical Research Council scale ankle dorsiflexion force < 5) for which they used an AFO, a muscle tone of ankle plantar flexors Modified Ashworth Scale ≤ 3, and they needed to show a positive functional response to surface-based peroneal nerve stimulation (NESS L300, Bioness inc, Valencia, California). Furthermore, they had to have a functional walking capacity of at least 10 min without the use of walking aids. For additional inclusion and exclusion criteria, we refer to Schiemanck et al. [4]. At inclusion the treating physician obtained clinical scores as listed in Table 1. Both studies received approval from the local medical-ethical committee and all participants gave their written informed consent before participation.

2.2. Intervention

The ActiGait® system (Neurodan, Denmark, Otto Bock Group, 2006) is a 4-channel common peroneal nerve stimulator (Fig. 1). A neurosurgeon performed the implantation of the Actigait® system at each study site. Three weeks after surgery the system was activated and stimulation settings were determined. Use of the Actigait® system was then built up incrementally from 15 to 60 min per day in the first week up to minimally 6 h per day after three weeks. From three weeks on participants were free to use their FES system or AFO as they pleased. We refer to Schiemanck et al. for a more detailed description of the ActiGait system and the surgical procedure [4].

2.3. Study design

Both longitudinal studies used a within-subjects repeated measures design. The timeline of inclusion, system implantation, system activation, and gait adaptability assessments of both cohorts is presented in Fig. 2. Gait adaptability was tested at inclusion (T0) as well as 2 weeks (T1), 8 weeks (T2), 26 weeks (T3), and 52 weeks (T4; second study group only) after activation of the ActiGait® system. At T0, gait adaptability was assessed only with AFO. At follow up assessments, gait adaptability was tested both with AFO and with FES; the order was balanced across participants to neutralize possible time (e.g. fatigue) effects. Subjects used their own AFO and wore the same footwear during all measurements.

2.4. Gait adaptability measurement

Gait adaptability was tested with an obstacle avoidance task on an instrumented treadmill [10,13,14]. At baseline (T0), treadmill speed was set at either 2 or 3 km/h (depending on the participant's ability to walk safely on the treadmill) and kept constant across the entire follow-up period. Participants were requested to walk without the use of handrail support, but they were allowed to grab the handrail when needed in the case of fall risk. To protect participants against falling, they wore a safety harness that was attached to a rail fixated onto the ceiling. A wooden obstacle (length 40 cm, width 30 cm, and height 1.5 cm) with a magnet in its centre was held by an electromagnet just above the treadmill and was placed in front of the paretic leg. Participants were instructed to maintain a distance of about 10 cm from the

Table 1
Demographic and clinical characteristics of all participants (n = 22) and those used for analysis (n = 19).

	Group I (n = 10)	Group II (n = 12)	Used for analysis (n = 19)
Age (mean yrs ± SD)	47.4 ± 14.5	57.4 ± 9.6	54,4 ± 12,3
Body weight (mean kg ± SD)	80.5 ± 19.5	80.6 ± 12.2	83,3 ± 15,2
Body height (mean cm ± SD)	175.0 ± 7.6	177.3 ± 8.3	177,0 ± 7,2
Time since stroke (mean months ± SD)	67.7 ± 29.2	55.0 ± 49.8	59,9 ± 44,0
Sex (men/women)	5/5	8/4	14/5
Paretic side (left/right)	6/4	8/4	11/8
Type of stroke (ischemic, hemorrhagic)	8/2	9/3	14/5
Motricity index – paretic leg (median (range))	69 (28–99)	78.5 (42–91)	77 (28–99)
Fugl-Meyer Assessment – paretic leg (median % (range))	64 (25–88)	72.1 (53–88)	71 (25–88)
Berg Balance Scale (median (range))	52 (42–56)	54 (42–56)	53 (42–56)
Modified Ashworth Scale calf (median (range))	1 (0–3)	1 (0–2)	1 (0–2)
Vibration threshold paretic forefoot (median (range))	6 (0–8)	3.5 (0–8)	4 (0–8)
Vibration threshold paretic ankle (median (range))	5 (0–8)	3 (1–8)	4 (0–8)
Type of AFO used (fixed/hinged)	9/1	11/1	17/2
Baseline comfortable walking speed using AFO (mean m/s ± SD)	0.85 ± 0.2	1.00 ± 0.2	0.94 ± 0.2

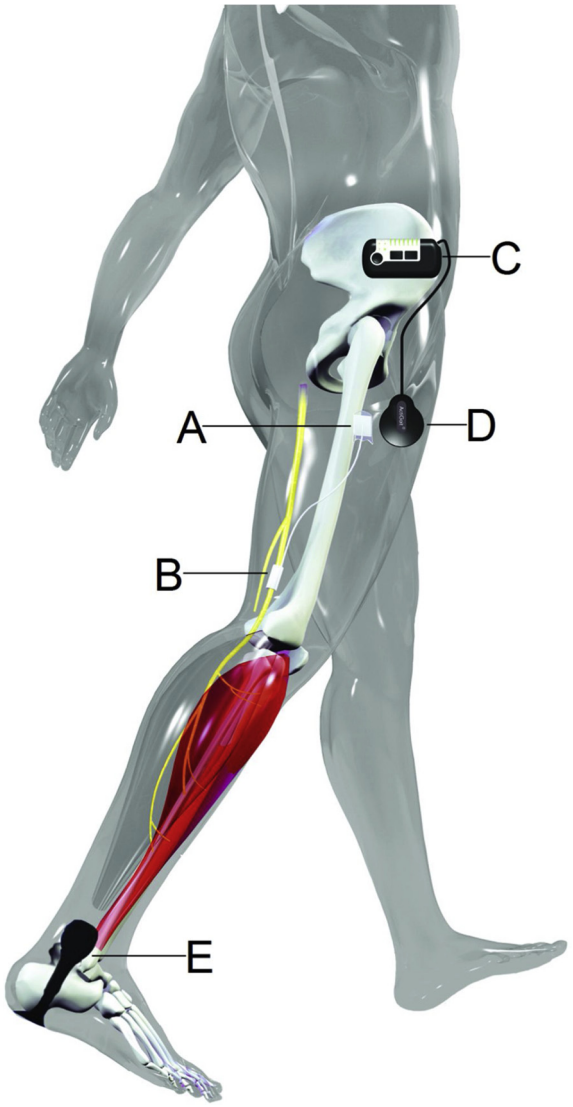

Fig. 1. The ActiGait® system. The implantable parts consist of a stimulator body (A) at the proximal end and a cuff electrode with four separate controllable electrodes at the distal end (B), connected by a lead wire. External parts (i.e. a control unit (C), antenna (D) and heel switch (E)) are used to activate and control the level of intensity of the stimulation. The ActiGait® system starts peroneal nerve stimulation shortly after the detection of heel rise in order to activate the foot dorsiflexors and evertors during the entire swing phase. After detection of heel strike, neurostimulation is continued during the subsequent loading response to regulate the first rocker. The system is inactive during midstance and push-off.

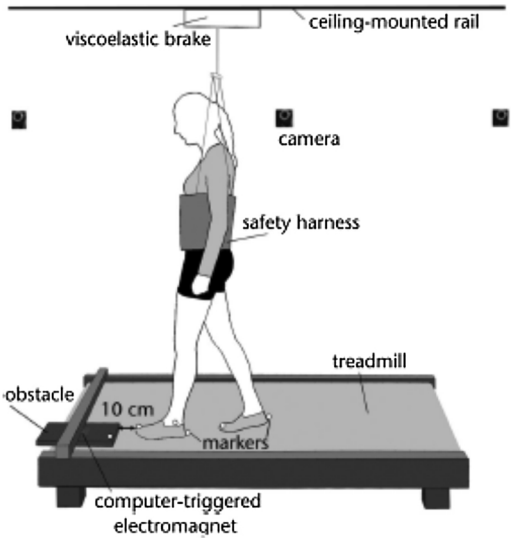

Fig. 3. Experimental setup.
Image adapted from van Swigchem et al. (2012).

toe of the affected foot to the hanging obstacle at the moment of foot strike (see Fig. 3).

Positions of both feet and the obstacle were collected with a 6-camera, 3D-movement analysis system (Vicon Motion Systems, Vicon-UK, Oxford, United Kingdom) at a sampling rate of 100 Hz. To this aim, a reflective marker was placed on the front edge of the obstacle and three markers were placed bilaterally at the lateral malleolus of the ankle, heel, and the dorsal head of the second metatarsal bone. Marker data of the paretic foot were processed online to determine the instant of foot strike and the step cycle duration. Based on this information, the obstacle was released in either the mid stance, late stance / early swing, or mid swing phase of gait in order to introduce distinct levels of difficulty. Obstacles dropped during mid swing were most difficult, because the available response time (ART) to adjust the ongoing step was very short. In contrast, ARTs were long for obstacles released during mid stance, which were relatively easy to avoid. In total, 30 trials were recorded with each device (FES / AFO). The instants of obstacle release were randomly distributed over the trials. Participants were instructed to avoid the obstacle once it was dropped onto the treadmill by either lengthening or shortening their paretic step. Contact of the foot with the obstacle and paretic steps parallel to the obstacle were classified as failures. Two assessors judged the success of the avoidance maneuver both online (during the assessment) and offline (based on video and marker recordings). At the beginning of each session, the participants performed five practice trials to familiarize themselves with the experimental setup.

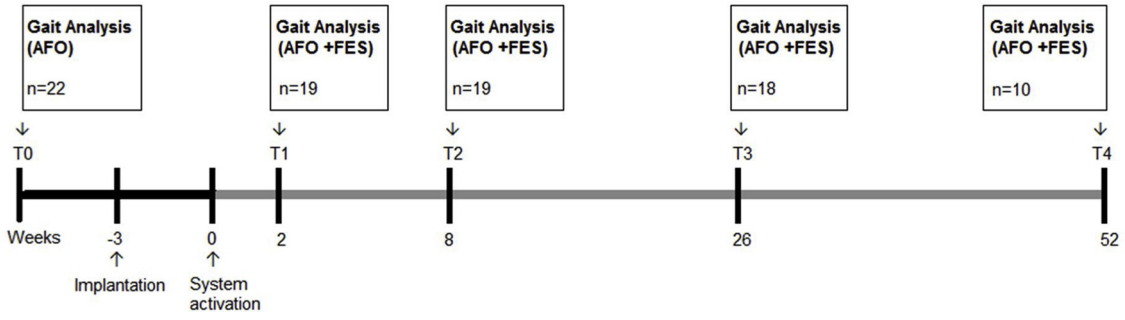

Fig. 2. Timeline of the two studies.

2.5. Data processing and statistical analysis

ART was quantified as the time between obstacle release and the moment that the toe of the paretic foot would have crossed the front edge of the obstacle in the case of an unaltered step [14]. The trials were then stratified into three ART categories corresponding to the phases of the gait cycle in which the obstacle was dropped: 450–600 ms (mid stance), 300–450 ms (late stance/early swing), and 150–300 ms (mid swing). For each participant and for both devices, success rates were calculated by dividing the number of successful trials by the total number of trials in each ART category.

Differences in success rates between FES and AFO were assessed using generalized estimated equation modeling (GEE with auto-correlated structure). *Time* (T1-T4), *device* (AFO, FES), and *ART* (450–600, 300–450, 150–300 ms) were used as within-subject factors. Similar to van Swigchem et al., the variance in the success rates was stabilized by subjecting the data to angular transformation before conducting the GEE [10]. To minimize the number of factors in the model, factors that were non-significant and showed no significant interaction effect with device were removed from the model.

To investigate whether the expected benefits of FES depended on clinical characteristics of the participants, bivariate nonparametric (Spearman) correlations were calculated between the change in success rates with FES (compared with AFO) at week 26 and each of the following clinical scores: Modified Ashworth Scale (for ankle plantarflexors), vibration threshold (from the lateral malleolus), lower-extremity Motricity Index, lower-extremity Fugl-Meyer Assessment, Berg Balance Scale, and comfortable walking speed with the AFO at baseline. We used SPSS version 15.0 (SPSS Inc, Chicago, Illinois) for all statistical analyses. The level of significance was set at $p < 05$.

3. Results

3.1. Participants

The characteristics of the participants included in both cohorts are presented in Table 1. Three participants were removed from the analysis. One participant (group I) dropped out of the study because of peroneal nerve damage after surgery, which had fully recovered after one-and-a-half year. One participant (group II) died prior to the first follow-up measurement, the cause of death being unrelated to the study. A third participant (group I) had severe calf muscle clonus in reaction to FES after the system activation. This clonus needed to be treated with botulinum toxin injections, which resulted in substantial protocol deviations with several missing follow-up measurements. In one participant (group II) the ActiGait implant failed after 26 weeks. Since sufficient follow-up data was obtained, this latter participant was included in the final analysis. Hence, a total of 19 participants from the two combined cohorts was analyzed.

3.2. Obstacle avoidance success rates

There was no significant change in success rates over time and no significant interaction between *time* and *device* (see supplementary table). Therefore, the factor *time* was removed from the model. Note that statistics were performed on angular transformed success rates, yet for clarity untransformed values are reported below and in the figures.

The GEE model revealed that success rates were on average 4.7% higher with FES than with AFO (55.4% vs. 50.7%, $p = 0.03$). However, this *device* effect was not uniform across the three ARTs, as indicated by a significant interaction between *device* and *ART* (see Fig. 4). Post-hoc analysis showed a significant difference of 15% in favor of FES for ART 450–600 ms ($p = 0.03$), a non-significant difference of 10% for ART 300–450 ms ($p = 0.059$), whereas no significant difference was observed for ART 150–300 ms ($p = 0.193$). Success rates differed significantly between ARTs ($p < 0.001$), indicating higher success rates for trials with longer ARTs (Fig. 4).

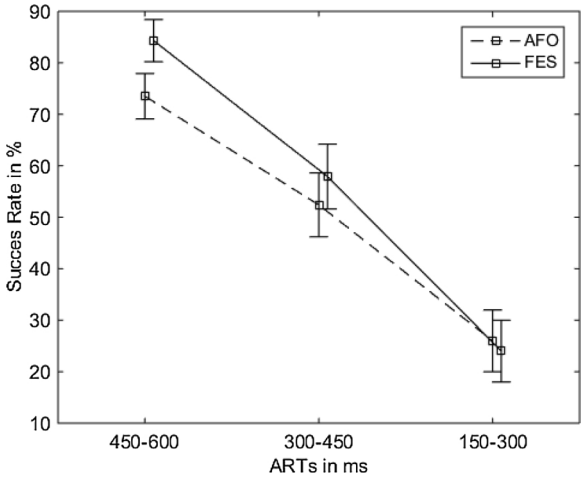

Fig. 4. Obstacle avoidance success rates (percentages) with FES and AFO for different available response times (ARTs).

The participants showed a wide range of individual differences in success rates between FES and AFO. At 26 weeks after system activation, differences between the devices ranged from -29% to 85%. Both Motricity Index ($r_s = -0.49$, $p = 0.04$) and Fugl-Meyer Assessment ($r_s = -0.47$, $p = 0.05$) scores of the paretic leg showed a moderately strong, negative correlation with the difference in success rate, indicating that participants with greater motor impairment had more benefits from FES (Fig. 5). Berg Balance Scale, Modified Ashworth Scale of plantar flexors, vibration threshold from the lateral malleolus, and comfortable walking speed did not significantly correlate with individual differences in success rates between FES and AFO (respectively $p = 0.26$, $p = 0.51$ and $p = 0.67$).

4. Discussion

The aim of this study was to investigate the surplus value of an implanted peroneal FES system (Actigait®) regarding the capacity to avoid sudden obstacles while walking on a treadmill in people in with drop foot after stroke. As hypothesized, success rates of obstacle avoidance were higher when participants used their FES system compared to AFO, which effect was larger with longer available response times. There was not a significant (interaction) effect for assessment time indicating that differences in success rates could not be attributed

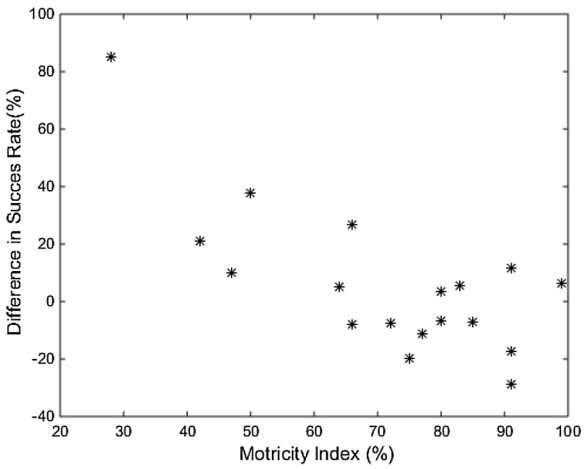

Fig. 5. Relationship between Motricity Index of the paretic leg (x-axis) and difference in obstacle avoidance success rate (percentages) at 26 weeks (FES-AFO; y-axis).

to task-specific learning effects. In addition, participants with greater motor impairment of the paretic leg showed the greatest benefit from FES.

Since implanted FES is applied directly onto the peroneal motor nerve we expected it to provide a more precise, and therefore functionally better, stimulation of the foot dorsiflexors compared to surface-based systems with adhesive electrodes. However, the mean difference in obstacle avoidance success rates between implanted FES and AFO reported in this study (4.7%) did not exceed the effect size obtained using a surface-based FES system in a previous study (7.9%, van Swigchem et al. [10]). Both reports revealed modest but significant device effects on success rates in favour of FES, albeit somewhat smaller in the current report. Hence, this indirect comparison of effect sizes provides no indication that implanted FES might be superior to surface-based FES systems with regard to obstacle avoidance.

In addition to the two studies mentioned above, demonstrating the surplus value of FES over AFO on gait adaptability under time pressure, other studies have compared the time to complete an overground obstacle course between peroneal FES and AFO. Our results are in line with those from a previous RCT that yielded faster obstacle course completion times with FES than AFO at long-term follow-up, indicating better functional capacity with FES [9]. In contrast, the lack of *immediate* surplus effects of FES on completion time as reported by Sheffler et al. [8] suggests that people with stroke need some time to adapt to walking with FES before they may experience its benefits on their gait adaptability. Taken together, there is growing evidence that people with stroke-related drop foot may particularly benefit from FES when performing challenging walking tasks that require adaptation of the gait pattern, whereas such benefits are less apparent during simple overground walking [15].

The better avoidance success rates with FES than AFO were most evident in trials with longer ARTs (450–600 ms). At short ARTs, people usually attempt to place the foot in front of the obstacle by quickly shortening their pre-crossing stride. This response greatly depends on the central nervous system's processing time for making the visuomotor transformation, and on the degree of recruitment of upper-leg muscles [16,17]. These processes are probably not impacted on by peroneal FES, which may explain the lack of differences between FES and AFO at ARTs of 150–300 ms. At longer ARTs, however, people commonly lengthen their crossing stride to land the foot behind the obstacle. Better success of enlarging the paretic crossing step with FES may indicate a more selective leg control during swing. However, in overground walking such benefits during swing phase have not been found for peroneal FES [5,18,19]. Alternatively, this movement of stride lengthening may have been facilitated by the increased ability for paretic ankle push-off, that we have previously reported with FES compared to AFO in the same group of participants [4,5], which also may explain the greater benefits of FES on avoidance success rates at longer ARTs. Yet, the exact mechanisms underlying the ART-dependent effects of FES need to be addressed in future research.

So far there is no consensus on which patients are most likely to benefit from peroneal FES [1]. In the present study, participants showed a wide range of differences in success rates between FES and AFO (i.e. −29% to 85%). Interestingly, and similar to our previous findings regarding surface-based FES [10], we found that people who had greater leg motor impairment (both reduced motor selectivity *and* muscle weakness) showed more benefit from implanted FES on their gait adaptability. Although the associations found in both studies were moderate, the consistency of these findings imparts confidence in their clinical significance.

Despite pooling of the two study cohorts, obvious limitations of the current report are the limited sample size and the lack of a control group. Conducting larger (multicenter) controlled studies in this area is (almost) unfeasible given the type of intervention, the complexity of the experimental setup and data analysis, and the considerable costs. Under the given circumstances, we believe that our within-subjects design using repeated obstacle-avoidance assessments was the most optimal strategy for investigating differences between peroneal FES and AFO. We designed the experimental task as to mimic adaptations to the environmental context during daily life walking, yet walking on a treadmill at a fixed speed does not allow natural adaptive behavior such as speeding up or slowing down. In future studies, gait adaptability under time pressure may be tested in a setup that resembles daily life more closely, which should also include dual tasking. Finally, it was not clinically verified whether the AFO worn throughout the study was optimal for each participant, but no participant expressed any AFO complaints.

In conclusion, this report supports the idea that walking performance in a more complex walking environment, demanding quick gait adaptations, shows superiority of implanted peroneal FES over AFO. These findings also underline the importance of using gait assessments that require interaction with the environment, besides assessment of stationary walking, in community ambulators.

Conflict of interest statement

None of the authors have potential conflicts of interest to be disclosed.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.gaitpost.2019.04.020.

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