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Brief report

Don't bury Functional Electrical Stimulation too fast! An introspection based on gait improvement after an ecological 6-month training program at home for a stroke survivor

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Abstract: Foot drop is a common disability in post-stroke patients and represents a challenge for the clinician. To date, Ankle Foot Orthosis (AFO) combined with conventional rehabilitation is the gold standard of rehabilitation management. AFO has a palliative mechanical action without actively restoring the associated neural function. Functional Electrical Stimulation (FES), consisting in stimulation of the peroneal nerve pathway, represents an alternative approach. By providing a FES device (Bioness L-300, BIONESS, USA) for 6 months to a post-stroke 22-year-old woman with a foot drop, our goal was to quantify its potential benefit on walking capacity. Gait parameters and the temporal evolution of the speed were collected with a specific connected sole device (Feet Me®) during the 10-meter walking, the Time Up and Go, and the 6-minute walking tests with AFO, FES

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or without any device (NO). As a result, the walking speed changes on 10-meters were clinically significant with an increase from baseline to 6 months in AFO and FES conditions (+0.14m-1 and +0.36m-1), without any changes in NO condition. In addition, speed decreased at about 4-minutes of the 6-minute walking test in NO and AFO conditions, while speed increased in FES conditions at baseline and after 1, 3 and 6 months. Monitoring gait speed in an endurance test after an ecological rehabilitation training program helps to examine walking performance in post-stroke patients and to propose a specific rehabilitation program depending on a fatigue threshold.

Keywords: foot drop, walking, rehabilitation, ankle-foot orthosis, mobility, Functional Electrical Stimulation.

1. Introduction

Gait impairments observed in 20-30% of stroke survivors, typically characterized by foot drop caused by a deficit of central common drive of dorsi-flexor muscles, represent a major challenge for rehabilitation [1,2]. The gold-standard care combines physical rehabilitation with a passive Ankle Foot Orthosis (AFO), a device with substantial restriction of ankle movements which causes joint stiffness and possible sensory feedback loss without restoring any neural function [3]. While the AFO device allows limited ankle movement, Functional Electrical Stimulation (FES), introduced 60 years ago [4], represents a worthwhile alternative likely to prevent these issues. FES consists in stimulation of the peroneal nerve pathway combined with (or without) voluntary contraction during the swing phase of walking [5]. A recent meta-analysis, including 6 randomized controlled studies, nonetheless failed to provide evidence of FES superiority in comparison with AFO on walking performance [6]. Given this context, FES device is underused in functional rehabilitation program to treat the deficit of dorsi-flexor muscles' common drive and raised several concerns considering personalized approach and clinical evaluation. Is the ultimate clinical goal to improve walking performance in post-stroke rehabilitation? Is the FES being optimally delivered (frequency, intensity and duration) in functional rehabilitation program? Should we propose the use of FES for every patient presenting with a deficit of common drive of the dorsi-flexors?

1.1. Is the ultimate clinical goal to improve walking performance in post-stroke rehabilitation?

To date, functional rehabilitation programs have focused on walking performance, by assessing walking capacity with short-distance test (10 meters) and/or endurance with long distance/time tests (400 meters, 4-6 min walking test) [7,8]. Although walking speed is a crucial indicator to characterize functional mobility [9,10] and social participation [11,12], it is also limited by a restrictive view of functional capacity of an individual. For instance, in clinical practice we have all encountered patients for whom walking speed did not meet the minimal clinically important difference after a functional rehabilitation program, while walking time was improved, delaying the fatigue effect (walking capacity) for a day and dramatically enhancing the person's quality of life. For the sake of the patient, it would seem advisable to replace walking performance by a general health status evaluation including nature and localization of stroke, walking capacity related to the goal of the patient, quality of life, social factors, psychological distress, pain and functional capacity drawn from the recent multidimensional and composite outcomes proposed to characterize general health status in chronic pain patients [13–16]. This approach could highlight the potential benefit achieved with the FES device masked behind the walking performance achieved after a rehabilitation program.

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1.2. Is the FES being optimally delivered (frequency, intensity and duration) in functional rehabilitation program?

The limited FES prescription in functional rehabilitation program is currently based on the available randomized controlled trial synthetized in a recent meta-analysis [6], showing that FES was inconsistently delivered in inpatient for a duration of 3 to 12 weeks with sessions lasting between 15 and 40 minutes [3,17–19] or used in daily life at home for 8 to 26 weeks [20,21]. While FES in a hospital rehabilitation program limits the subject's exposure to the therapy, its use at home might represent a better way to potentiate its effects. In a multicenter randomized controlled trial, Everaert et al. [20] reported significant improvement of walking performance (4 min and 10 meter tests) after 6 weeks of daily use of the FES device in 69 chronic phase post-stroke patients, without any difference between FES and AFO devices. With the implantable peroneal nerve stimulator device in 29 chronic phase post-stroke patients, Kottink et al. [21] did not observe any significant improvement of walking speed (10 meter test) after 4, 8, 12, and 26 weeks of follow-up. Even though the literature has failed so far to show the added value of FES at home compared to a short inpatient rehabilitation program, home care should be further explored to potentiate benefits of FES on walking performance and global health status, taking into account the patients' characteristics [22].

1.3. Should we target the use of FES for every patient presenting with a deficit of common drive of the dorsi-flexors?

International stroke rehabilitation guidelines have established that early initiation of the rehabilitation program beyond the first week with the highest possible level of intensity provides variably greater recovery, depending on the nature and localization of stroke [1], with greater cerebral plasticity observed in acute than in chronic stroke patients [23,24]. In a randomized controlled trial, Morone et al. [17] showed greater improvement of walking speed (10 meters) following a 5-week rehabilitation program with FES (20 sessions of 40 minutes) than AFO in 20 subacute post-stroke patients. Although the results were clearly in favor of FES compared to AFO, the authors suggested potential bias induced by the age of the patients. There is currently no consensus in the literature regarding the influence of age on gait recovery, while some studies have reported better recovery in younger patients [25–27], others show contrasting results [27,28]. In addition, age could largely influence initial disability after stroke [25,27,29]. To date, the influence of age on walking recovery after a rehabilitation program with FES has yet to be examined, and could be a positive predictive factor for successful outcomes. In another study, based on a selection of spatiotemporal and kinematic parameters, Chantraine et al. [22] proposed a classification of stroke patients indicating that FES should be targeted to patients with limited ankle dorsiflexion during the stance phase of walking.

By aiming to determine the potential benefit effect of FES at home over a 6-month period, we delivered a FES device to a 22-year-old woman who suffered from a deficit of dorsi-flexor muscles following a stroke that had occurred 5 years earlier. Considering the different previously mentioned elements, i.e., long home care period, young age, limited dorsiflexion, we expected an improvement of the gait parameters assessed with connected sole before and after periods of 1, 3, and 6 months.

2. Materials and Methods

2.1. Patient

On May 2015, an 18-year-old woman, high school student and former basketball player, was admitted to Poitiers University Hospital and treated for a hemorrhagic stroke due to a left frontotemporal arteriovenous malformation. Severe left spastic hemiparesis

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and aphasia were found on examination as sequels. Modified Ashworth Scale (MAS) revealed scores of 2 for the quadriceps, 1+ for the triceps surae muscle, and 2 for the tibialis anterior inducing varus foot. The patient reported no ankle pathology prior to her stroke. She was initially referred to a French rehabilitation center from January 3rd to the March 15th, 2016, which led to limited walking recovery requiring use of an assistive cane and inducing fatigue after few meters. While patient denied any AFO due to discomfort, she used an elastic lifter. She had a 450m walking perimeter, was able to climb up and down stairs, but was not able to run. Thereafter, uncomfortable spasticity persisted and had to be treated with botulinum toxin injections. The last dose was injected in February 2018, and she underwent physical therapy twice a week. On April 8, 2019 (22-year-old), we offered her the opportunity to test functional electric stimulation using an electronic orthosis (Bioness L-300, BIONESS, USA). After making the adjustments and teaching the patient how to use the device, she was able to wear it daily. The objective was to set up functional rehabilitation with the FES at home, in an ecological situation during 6-month period.

2.2. Walking Assessment

Gait parameters were collected with a specific connected sole device Feet Me® (FeetMe®, France) placed inside the patient's shoes allowing continuous analysis of the parameters of the walk. Speed was collected to characterize gait in three functional walking tests: the 10-meter walking test (10-MWT), the Time Up and Go (TUG) test, and the 6-minute walking test (6-MWT). In addition, the speed changes occurring during the 6-MWT were recorded. All of the tests were performed in three conditions: without any orthosis (NO), with AFO, and with FES. All the measurements were assessed before (M0) and after 1 (M1), 3 (M3), and 6 (M6) months.

2.3. Data analysis

Wearing time of the FES device was reported on daily diary. Gait parameters data were collected and stored within the insoles with acquisition frequency of 140 Hz over the total duration of the tests (e.i., 10-MWT, TUG, 6-MWT). All data were transferred to a secured webplatform (FeetMe® Mobility Dashboard, via FeetMe®) and then computed offline [30]. The calculation of the derivative and the sum of sensor signals were filtered by the Savitzky–Golay filter [please see 31 for details]. Speed changes overtime occurring during the 6-MWT were analyzed using locally estimated scatterplot smoothing (LOESS) with local polynomial regression.

3. Results

Wearing time of the FES device per day increased from 15 to 60 minutes during the first week, 1 to 4 hours during the second week, and 4 to 10 hours during the third week in accordance with the protocol for use of the device. Over the following weeks, the patient wore the device all day long. The patient reported an increment of walking perimeter with a reduction of fatigue, and clinical assessment showed a decrease of varus foot without any adverse event such as burning, pain, or other uncomfortable sensations. Furthermore, she was able to run under supervision at M1 and without supervision from M3.

The 10-MWT walking speed changes were clinically significant (>0.14m.s^{-1}) [32] with a decrease from M0 to M3 in AFO and FES conditions (-0.32m.s^{-1} and -0.29m.s^{-1}, respectively), and an increase from M0 to M6 in AFO and FES conditions (+0.14m^{-1} and +0.36m^{-1}), without any clinically significant results in NO condition (Table 1).

Improvement of TUG test was clinically significant (>28%) [33] at M6 compared to M0 in AFO conditions (+35%), while the increases in other conditions were not clinically significant.

Table 1. Gait parameters for the 10-meter walking test (10-MWT), the 6-minute walking test (6-MWT), and the Time Up and Go (TUG) test in NO (without any device), AFO (ankle-foot orthesis)

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and FES (functional electric stimulation) conditions before (M0) and after 1 (M1), 3 (M3), and 6 (M6) months.

	M0	M1	M3	M6
10-MWT (speed in $m.s^{-1}$)				
NO	1.28	1.31	1.29	1.60
AFO	1.44	1.34	1.12	1.58
FES	1.37	1.29	1.08	1.73
TUG (duration in seconds)				
NO	6.0	7.2	5.0	4.9
AFO	7.8	6.0	7.0	5.0
FES	6.0	6.0	5.0	4.6
6-MWT (distance in meters)				
NO	427.3	446.5	449.7	451.0
AFO	429.5	439.5	445.1	449.8
FES	459.0	472.3	454.5	462.8

The 6-MWT distance increased from M0 to M1, M3, and M6 in NO, AFO and FES conditions (Table 1), but the difference was not clinically significant (<28 meters) [34,35]. On the other hand, the trajectories of the gait speed during the 6-MWT clearly showed that speed decreased throughout the test in NO and AFO conditions, while speed increased in FES conditions at M0, M1, M3, and M6 (Figure 1).

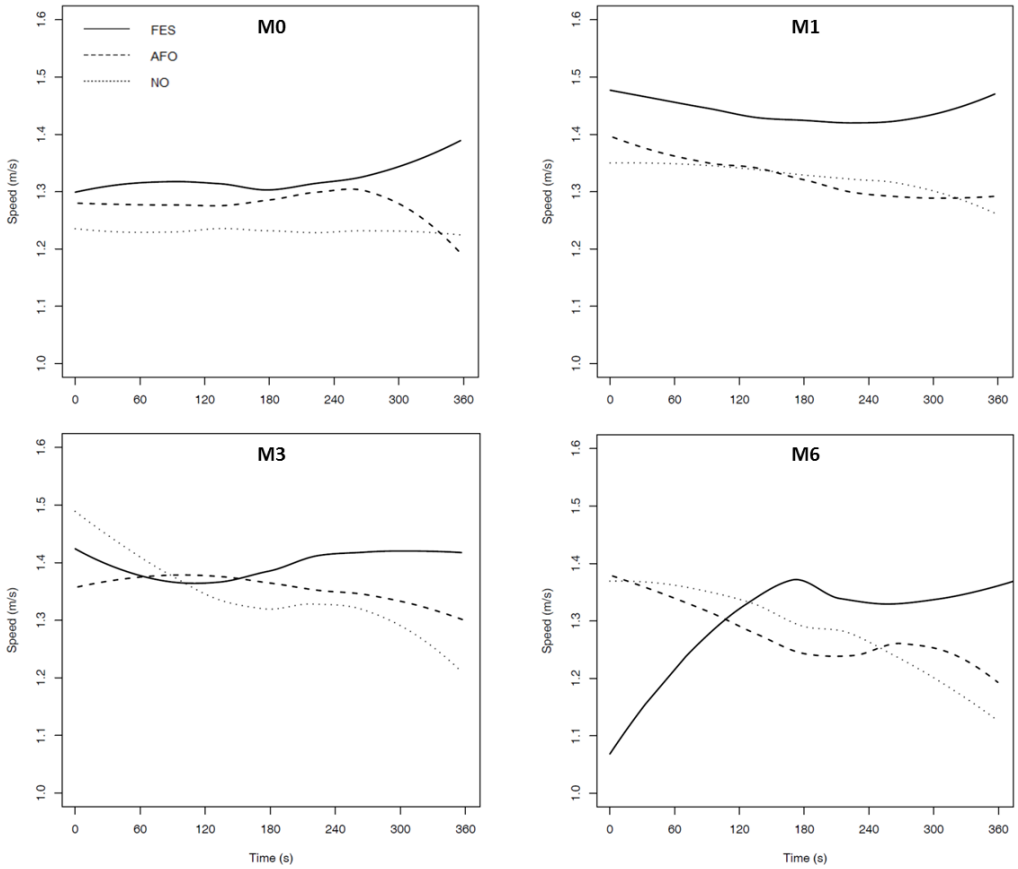

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Figure 1. Gait speed evolution during the 6-MWT with NO (without any device), AFO (ankle-foot orthesis) and FES (functional electric stimulation) conditions at baseline (M0) and after 1 (M1), 3 (M3), and 6 (M6) months.

4. Discussion

This case provided evidence that daily wearing of the FES device over a 6-month period can benefit post-stroke functional walking capacity. Three main results should be discussed.

First, walking speed decreased after 3 months and increased after 6 months. We can suggest that long-term daily wearing of the FES device is needed to obtain observable clinical benefit. Second, the walking speed improvement in FES and AFO condition seems not to be transferable to walking without any device. Although the patient was young, FES wearing occurred 5 years after the stroke episode. The chronic phase that characterized our case should be considered as an obstacle to FES benefit, notably as regards ability to effectively walk without any device and in more ecological situations. Third, the monitoring of gait speed during the 6-MWT enabled us to observe that the speed evolution profile is different with FES compared to NO and AFO conditions [36]. Our results clearly showed speed decrease with AFO or without any device at approximately 4 minutes, while speed tends to increase in FES conditions. We prudently suggest that in our case FES delayed the onset of fatigue and compensated for the fatigue shown to have occurred in the other conditions. This finding could help to delineate a personalized approach by developing specific programs related to the fatigue threshold observed in ecological situations, the objective being to delay this threshold. Accordingly, FES should be considered in young acute/subacute/chronic stroke population as a means of improving walking parameters in endurance effort, and which could help to achieve recommended physical activity [37,38], and substantially improve quality of life and social participation [11,12]. This approach could also be reinforced by individualized coaching at home [39].

Even though positive effects were reported after a long-term use FES in daily living, some concerns have to be considered. First, depending on the device, the stimulation settings require more or less intervention from an expert so as to deliver adequate stimulation during the swing phase of walking. In addition, depending on the country, the device and related consumables (electrodes) may not be covered by the health insurance system, causing a significant extra cost for the patient in comparison with AFO and consequently limiting access to and diffusion of the therapy. Additional data are needed (i) to determine the effectiveness of FES on the patient's general health assessed with a composite multidimensional index developed with the machine learning approach, (ii) to determine potential supra-spinal, spinal or muscular plasticity in an ecological long-term training program, and to delineate the cost-utility of the FES rehabilitation program compared to AFO via a medico-economic study.

5. Conclusions

Our study showed walking performance benefit with FES worn daily over a long-term period of 6 months in a young adult presenting with a chronic post-stroke. Moreover, monitoring the gait speed in an endurance test should help to examine walking performance rehabilitation in post-stroke patients and to delineate specific tailored rehabilitation programs. This approach needs to be investigated in randomized controlled trials to examine the cost-utility of the FES device in acute and subacute stroke patients.

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