

Effectiveness of Single Functional Electrical Stimulation in Neurological Patients with Ankle-Foot Orthoses

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Abstract

Background: Drop foot is a distal deficiency common in patients with central nervous system diseases that makes clearance difficult during swing phase, contributes to inefficient gait compensations, contributes to increase incidence of falls and energy expenditure. Aim of this study is to evaluate the effectiveness of a single application of functional electrical stimulation compared with ankle-foot orthoses in patients with drop foot.

Methods: Patients enrolled were unable to walk and to perform test without ankle-foot orthoses. They were evaluated by 10-meters walk test, obstacles test, up-and-down stair test, six-minute walk test and gait analysis with inertial sensors. All tests were performed with ankle-foot orthoses and with no ankle-foot orthoses and application of single functional electrical stimulation.

Results: Thirteen patients (8 males and 5 females) were recruited for this study out of 41 potential subjects. Data collected were processed by Student's t test and by Wilcoxon test for paired observations and by Student's t test and Mann-Whitney test for independent samples. $P \leq 0.05$ were considered significant. For each test suitable effect sizes (Cohen's d, and Pearson's r) were calculated. Analysis of results with ankle-foot orthoses and with no ankle-foot orthoses and application of single functional electrical stimulation showed no statistically significant difference in all test.

Conclusions: The use of single functional electrical stimulation showed same effects of ankle-foot orthoses on walking capacity and motor performance in chronic neurological diseases. More studies would be required to assess the long term effectiveness of functional electrical stimulation and to evaluate if its application in acute-phase may be used in association with traditional treatment.

Keywords: Drop foot; Functional electrical stimulation; Ankle-foot orthoses; Inertial sensor; Motor performance

Introduction

Drop foot is a distal deficiency common in patients with central nervous system diseases that makes clearance difficult during swing phase, contributes to inefficient gait compensations, contributes to increase incidence of falls and energy expenditure [1-4]. This leads to the typical "steppage gait" determined by the need to lift and flex the knee more than normal with an excessive external rotation and flexure of the hip. In this way the leg is lifted on and the stand begins before on the tip and then on the heel. To facilitate the gait is necessary to use an ankle-foot orthoses (AFO) that gives medium-lateral stabilization of ankle in static phase and improves the swing phase, facilitating the lifting of the path and a simultaneous lowering of the heel [5]. The AFO is inexpensive and of simple usage; it gives a stable support helping the patient on walking, managing fatigue and improving quality and symmetry of gait [6-8]. However it is often considered ineffective and does not enjoy good compliance by the patient. An alternative approach to the management of drop foot is the functional electrical stimulation (FES), which is based on the delivered electrical

stimulation of the common peroneal nerve during the swing phase of gait [9-11]. The FES promotes active muscle contraction, can help improve muscle strength [12], prevents disuse atrophy [13], reduces spasms [14], produces a more energetic efficient use of proximal limb muscles [15] and aids in motor relearning [16,17]. Evidences show that many applications of FES are equivalent to AFO, improving significantly the 10 meters-walk test (10 mWT) and the six minute-walk test (6MWT) [10, 18]. However, the authors were not able to find studies that demonstrate the efficacy of a single application of FES compared to a daily use of AFO. As known the effect of FES is obtained by modulating the frequency of stimulation (number of pulses/second) and intensity (amplitude or duration of individual pulses), however, is often associated with an imprecise control of strength and to a rapid muscular fatigue [19-23]. Aim of this study is to evaluate the effectiveness of a single application of functional electrical stimulation compared with chronic use of ankle-foot orthoses in patients with drop foot.

Methods

Patients

Patients with a chronic neurological diseases and drop foot were enrolled from Parma University Hospital in the Physical Medicine and Rehabilitation Department. The study was approved by the local ethics committee.

Sex	Age (years)	Side	Disease	Time since Disease (months)	Time with AFO (months)
F	63	Left	Stroke	108	34
F	75	Right	Stroke	48	47
M	64	Right	Stroke	72	46
M	39	Left	Stroke	132	108
M	74	Right	Stroke	120	96
M	74	Left	Stroke	84	72
M	76	Left	Stroke	96	89
M	45	Right	Stroke	144	120
F	49	Right	Multiple Sclerosis	120	108
F	41	Left	Multiple Sclerosis	204	101
M	73	Left	Multiple Sclerosis	180	144
M	64	Right	Multiple Sclerosis	264	69
F	41	Right	Multiple Sclerosis	180	144

Table 1: Description and characteristics of the studied population, AFO: Ankle-Foot Orthoses.

Inclusion criteria were: presence of chronic neurological diseases (over 4 years), drop foot that makes gait impossible with no AFO, regularly use of an AFO with which they did not experience any problems, independent walking ability with any walking aid and no pharmacological therapy or comorbidity that could compromise walk. Each patient was evaluated with AFO, with no AFO and after a single application of FES. Patients were assessed with 10 mWT to evaluate gait velocity, 6 MWT to assess endurance, up and down stairs in 30 seconds to evaluate step frequency, obstacles test on a proprioceptive carpet to assess orientation, and gait analysis with inertial sensors to evaluate stride length and swing speed [24,25]. The 10 mWT was performed asking the patients to make a 10 meters straight line for 2 consecutive times measured with a digital stopwatch. Gait endurance was assessed by 6 MWT, measuring the distance covered during 6 minutes timed with a stopwatch. The 6 MWT is easy to administer, better tolerated, and more accurately reflects activities of daily living than other functional gait assessments [26]. The step frequency was measured by inviting the patient to go up and down from a stair height 15 cm for a period of 30 seconds. In the end the patient was requested to walk on a proprioceptive carpet with some obstacles to overstep. Gait symmetry and regularity was assessed by means of an inertial

sensing unit. It is a triaxial sensor, consisting of a small case of 78x48x20 mm weighting 48 g only, easy to use. It required no specialized equipment; it did not interfere with regular walking, and could be used to analyze walking in clinical practice. The accelerometer, placed on a semi-elastic belt covering the L4-L5 intervertebral space, transmitted the data to a PC via Bluetooth. The sensitive axes of the sensing unit were automatically aligned along the anatomical vertical, medium-lateral, and anterior-posterior axis. The patient walked at normal speed for 10 meters for two times.

Statistical analysis

Data collected during the experiment were processed by Student's t test and by Wilcoxon test for paired observations and by Student's t test and Mann-Whitney test for independent samples. $P \leq 0.05$ were considered significant. For each comparison suitable effect sizes (Cohen's d, and Pearson's r) were calculated. The analyses were performed using the statistical package IBM-SPSS version 20 and the open source statistical system R v. 3.1.1 [R Core Team (2014). R: A language and environment for statistical computing, R Foundation for Statistical Computing, Vienna, Austria URL <http://www.R-project.org/>].

Treatment

All patients were treated with a single application of functional electrical stimulation, by a FES-device. The FES-device is a transcutaneous, 2-channel system; to elicit dorsiflexion with eversion, one electrode was located over the common peroneal nerve, posterior and distal to the fibular head, and a second electrode was located over the tibialis anterior muscle. A gait sensor that includes a pressure sensor worn underneath the shoe insole at the heel and a small transmitter attached to the shoe rim. The gait sensor used dynamic gait recognition algorithms to detect and analyze events during walking (heel strike and toe off). This information was transmitted, by wireless radiofrequency, to the system to control the timing of the stimulation [27]. The effectiveness which was produced by the strength of muscle contraction depended from different parameters: pulse amplitude (0-80 mA), width, modulated between 100 and 300 sec during the stimulation frequency, pulse rate (20-45 Hz) and the form of wave (symmetric, asymmetric, symmetric optimized for high impedance) of the electrical stimulation signal. Because of no one of the patients was able to walk and to perform any test with no AFO, the electrical stimulation signal have to be adjusted for everyone to guarantee an adequate foot balance during walking.

Results

Thirteen patients (8 males and 5 females) age average 59.8 and standard deviation 14.7 (range 39-76 years) were recruited for this study out of 41 potential subjects (18 males and 23 females). All of them used daily AFO to walk (Table 1). Twenty-five patients were excluded from the trial because they used walking aids or because they were unwilling to perform tests with no FES. All patients were able to perform test with ankle-foot orthoses and with FES stimulation. No one was able to perform test with no AFO. Because of no one of the patients was able to walk and to perform any test with no AFO, the electrical stimulation signal have to be adjusted for pulse amplitude, modulation amplitude and pulse rate to guarantee an adequate foot balance during test. All comparisons (10 mWT, 6 MWT, proprioceptive carpet and step) between the two treatments are reported in Table 2 as well as Cohen's d and Pearson's r effect size

coefficients; no statistically significant differences were observed. Calculated *d* and *r* suggest a small to moderate effect size. Power analysis shows that the effective power of our test is rather low and the required sample size to evidence a difference of this magnitude would range from a minimum of 60 to 300 patients.

Variables (N=13)	AFO	FES	p-value	Effect size
	mean (SEM)	mean (SEM)		(d; r)
6 MWT (m)	189.2 (23.7)	193.8 (23.6)	0.63	0.36; 0.18
10 mWT (sec)	18.5 (3.0)	17.9 (2.7)	0.32	0.60; 0.29
proprioceptive carpet (sec)	18.3 (2.9)	20.9 (4.6)	0.23	0.72; 0.34
step (n)	5.2 (0.5)	5.3 (0.5)	0.74	0.20; 0.10

d: Cohen's *d* effect size; r: Pearson's correlation coefficient used as effect size, AFO: Ankle-Foot Orthoses; FES: Functional Electrical Stimulation; 6 MWT: six minute-walk test; 10 mWT: 10 meters-walk test. SEM: Standard Error of the Mean.

Table 2: Results of test and differences between two treatments.

Discussion

Evidences shows that many applications of FES are equivalent to daily use of AFO [10,18]. However, this study is original because tested neurological patients who were not able to walk with no AFO and even because use only a single application of FES. In our knowledge the literature does not provided studies that demonstrate the efficacy of a single application of FES compared to a daily use of AFO. The statistical analysis is characterized by the limited sample size; therefore the power of the test is often insufficient to highlight real differences even when these are present. In order to compare the two treatments, regardless of statistical significance, we tried to establish a threshold of functional equivalence. We agreed that a difference in performance by 10% may be considered perfectly equivalent from the clinical point of view. For example, considering the 10mWT, a time of 20 seconds would be comparable to a time of 18 seconds. Similar considerations might be extended to all tests. The data obtained for all test (Table 2) show that the average values of the two treatments within a range less than 10% of variation. This analysis further supports that the two treatments, if not equivalent, however, are not too dissimilar. This study suggests that a single application of functional electrical stimulation has nearly the same effect that a prolonged use of an ankle-foot orthoses on walking capacity and motor performance in neurological patients. These data seems to confirm the efficacy and importance of including prolonged and repeated electrical stimulation in the rehabilitation program of neurological patients with drop foot, even in the acute-phase. The major limitations of the present study are the absence of follow-up and the small number of patients enrolled, which we intend to expand in the future to evaluate long-term rehabilitative effects of conventional physiotherapy with association of functional electrical stimulation. Further studies would be required to assess the effectiveness of functional electrical stimulation, related to pulse amplitude, modulation amplitude and pulse rate.

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