

Clinical Study

Walking Training with Foot Drop Stimulator Controlled by a Tilt Sensor to Improve Walking Outcomes: A Randomized Controlled Pilot Study in Patients with Stroke in Subacute Phase

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Foot drop is a quite common problem in nervous system disorders. Neuromuscular electrical stimulation (NMES) has showed to be an alternative approach to correct foot drop improving walking ability in patients with stroke. In this study, twenty patients with stroke in subacute phase were enrolled and randomly divided in two groups: one group performing the NMES (i.e. Walkaide Group, WG) and the Control Group (CG) performing conventional neuromotor rehabilitation. Both groups underwent the same amount of treatment time. Significant improvements of walking speed were recorded for WG ($168 \pm 39\%$) than for CG ($129 \pm 29\%$, $P = 0.032$) as well as in terms of locomotion (Functional Ambulation Classification score: $P = 0.023$). In terms of mobility and force, ameliorations were recorded, even if not significant (Rivermead Mobility Index: $P = 0.057$; Manual Muscle Test: $P = 0.059$). Similar changes between groups were observed for independence in activities of daily living, neurological assessments, and spasticity reduction. These results highlight the potential efficacy for patients affected by a droop foot of a walking training performed with a neurostimulator in subacute phase.

1. Introduction

Foot drop is a common sign of many nervous system diseases, characterized by a patient's inability to dorsiflex the ankle, raising the foot. Conventionally, physicians use Ankle-Foot Orthosis (AFO) to correct foot drop during walking. An AFO is typically a polyethylene brace, supporting the ankle in a fixed position in order to help foot in swing phase avoiding forefoot contact with the floor.

Neuromuscular functional electrical stimulation (NMES) may be an alternative approach. It refers to stimulation of lower motor neurons to assist the muscle contraction, and to favour functional tasks as standing, ambulation, or activities of daily living (ADL) [1]. Functional electrical stimulation devices are also referred to as neuroprostheses.

Clinical applications of NMES may take place in stroke rehabilitation, providing both therapeutic and functional

benefits. In particular, treatments with NMES enhance function but do not directly provide function. The NMES can be timed with the swing phase of the gait cycle to stimulate the ankle dorsiflexor muscles. Only foot drop resulting from central nervous system diseases can be treated, because it needs nerve integrity [2]. Stimulating the Common Peroneal Nerve (CPN), NMES operates actively in the ankle dorsiflexion, strengthening the muscle and correcting foot drop. Everaet and colleagues showed that the use of neuromuscular stimulations lasting 3 months increased the maximum voluntary contraction and motor evoked potentials [3]. NMES-mediated repetitive movement therapy may also facilitate motor relearning [4], that is defined as the capacity of recovery of previously learned motor skills that have been lost following localized damage to the central nervous system [5]. Moreover, NMESs have been shown to provide physiologic changes in the brain

including activation of sensory and motor areas, reducing the intracortical inhibition, and increasing amplitude of motor-evoked potentials [6, 7].

In patients with hemiparesis due to stroke, NMES can be used for those that have not sufficient residual movement to perform active repetitive movement treatments. Necessary prerequisites for NMES-mediated motor relearning include high repetition, novelty of activity, capacity to effort, and high functional content [8].

A recent meta-analysis concluded that the use of functional electric stimulation is effective in improving gait speed in patients with stroke, suggesting a positive orthotic effect [9, 10].

However, it is still unclear whether NMES improves overall mobility function [4]. Furthermore, it has been also demonstrated as hemiplegic patients treated with AFO may obtain comparable results to that of those treated with peroneal nerve stimulator in terms of gait improvement [3, 11]. In fact, a multicenter trial demonstrated that both efficacy and acceptance of the stimulator were good in a population of subjects with chronic foot drop improving gait velocity and number of steps taken per day [3]. Finally, no studies have been conducted to compare different approaches of NMES (cyclic NMES, EMG-mediated NMES, and neuroprostheses).

In our study we investigated the use of a commercial stimulator using a tilt sensor (WalkAide, Innovative Neurotronics, Austin, TX, USA), which measures the orientation of the shank, controlling when turning the stimulator on and off.

The principal aim of the study was to evaluate the efficacy of the device in terms of walking speed in patients with stroke in a subacute phase. The secondary aim was to verify the effects on walking capacity, mobility and spasticity.

2. Material and Methods

2.1. Participants. Patients included in the study were affected by first stroke in subacute phase, aged between 18 and 80 years, with an inadequate ankle dorsiflexion during the swing phase of gait, resulting in inadequate limb clearance. Participants needed an adequate cognitive and communication function to give informed consent and understand the training instructions (MMSE > 24). The involved patients were able to ambulate with or without aid of one person with assistive device if needed (FAC 2, 3, or 4), at least 10 meters.

Patients were excluded with severe cardiac disease such as myocardial infarction, congestive heart failure, or a demand pacemaker; Patients were excluded if they had a severe cardiac disease such as myocardial infarction, congestive heart failure, or a pacemaker; if it was present a ankle contractures of at least 5 degrees of plantar flexion when knee is extended; if they had orthopaedics or other neurological conditions different from stroke affecting ambulation (e.g. parkinsonism, previous limb fracture, etc.). Twenty patients were enrolled (mean age: 57 ± 16 years) and randomized in two groups: one group performing therapy with WalkAide (WG) and a control group (CG) performing conventional neuromotor rehabilitation as reported in the following section.

Local ethical committee approved the study and all patients signed informed consent before starting the protocol.

2.2. Therapy. Study was designed as a randomized controlled with two groups of patients. After the enrolment, patients were evaluated by a blind physician and randomly assigned to treatment or control group. Raters were unaware to the group allocation. The intervention group performed 20 session, 40 minute, 5/time per week of walking training with Walkaide, whereas control group performed the same amount of walking training with an AFO.

For WG, a set-up phase was necessary in which a manual controller and a heel sensor pressure data were collected and connected to the other electronic components both by a telemetry link. Analyzing data obtained in the set-up phase and matching them with the rehabilitative purpose, it was necessary as preliminary phase to choose useful tilt parameters to correct foot drop.

Both groups undertook 40 minutes with a physiotherapy dedicated to improve activity of daily living and/or exercise for hand recovery. When needed, patients underwent also speech therapy or therapy for dysphagia.

2.3. Outcome Measures. All the outcome measures have been assessed before the beginning of walking training (T0) and at the end of this training (T1), about 1 month later.

The primary outcome measure was the time spent to walk for 10 m, that is, the time spent to complete the 10 m walking test (10 mWT). The walking speed (WS) during this test has been computed as the ratio between distance (10 m) and the time spent to cover it. Percentage increment of WS has been computed as the difference between WSs at T1 and T0 divided by that at T0 and multiplied for 100.

The secondary outcome measures were the scores obtained by the following clinical scales: Functional Ambulation Classification (FAC) [12] to assess the walking ability, Barthel Index (BI) [13] to assess the independency in activities of daily living, Rivermead Mobility Index (RMI) [14] to assess the mobility, Medical Research Council (MRC) [15] scale manually assessing the muscle strength, Canadian Neurological Scale (CNS) [16] to assess the neurological status of patients, and ashworth scale (AS) [17] to assess the spasticity of the lower limb.

The effectiveness of treatment in terms of scale scores was computed as the proportion of potential improvement that was achieved during treatment, calculated as $[(\text{final score} - \text{initial score}) / (\text{maximum score} - \text{initial score})] \times 100$. The advantages of using effectiveness was that if a patient achieved the highest possible score after rehabilitation, the effectiveness was 100%, and this measure is continued [18].

2.4. Statistical Analysis. Data are reported in terms of mean \pm standard deviation for continuous measurements and median (interquartile range) for scale scores. An analysis of variance was performed on the primary outcome measure using as main factor the group (WG versus CG, between subjects factor) and treatment (T0 versus T1, within subjects

factor), including in the general linear model also the interaction between these two factors. The percentage increments of WS have been compared between the two groups using unpaired t -test and mean difference, 95% confidence interval (CI_{95%}), and power analysis (with alpha error level set at 5%) were also computed and reported.

Nonparametric statistics was performed on ordinal measures such as clinical scale scores: FAC-score, BI-score, RMI-score, MRC-score, CNS-score, and AS-score, all assessed by means of Wilcoxon Signed Rank Test to assess the significance of changes in each group.

3. Results

The two groups resulted matched for age ($P = 0.267$) and for time from stroke ($P = 0.226$), although the WG was quite older (53.3 ± 14.6 versus 61.2 ± 16.2), but at admission their time from stroke event was quite longer than control group (27 ± 27 versus 13 ± 7 days). The duration of specific treatment for walking was not statistically different between the two groups (WG: 34.6 ± 11.2 days versus CG: 34.7 ± 7.6 , $P = 0.980$).

The primary outcome measure, that is, the time spent to walk for 10 meters, resulted is significantly affected by the interaction between group and treatment ($F_{df=1,18} = 5.419$; $P = 0.032$). As shown in Table 1, this revealed a higher improvement in terms of walking speed in WG ($168 \pm 39\%$) in respect of that of CG ($129 \pm 29\%$, $P = 0.021$, t -test). This mean difference (39%, CI_{95%} = 6; 72%) had a statistical power of 81.4%. The factor group did not mainly affected the time to complete the 10mWT ($F_{df=1,18} = 0.205$; $P = 0.656$), whereas the treatment did it ($F_{df=1,18} = 23.375$; $P < 0.001$). However, as shown in Figure 1, these results were mainly due to an initial difference of the performance of the two groups, more than to a difference after treatment. In fact, the subjects of WG before the treatment with Walkaide walked slower than CG, whereas they walked quite faster of CG at the end of treatment.

All these measures, but Ashworth-score, were significantly improved after treatment in both the groups, as detailed in Table 1. Between-group analysis showed that the effectiveness resulted higher in WG than in CG for all the five secondary outcome measures (Figure 2). These differences were statistically significant for FAC-score, and close to the significant threshold for RMI- and MRC-scores.

4. Discussion

Our results showed a significant improvement in both groups of subjects, with a higher proportion for WG than for CG, especially for the parameters related to walking. However, it should be noted that the initial values of the two groups, for their reduced sample size and for the effects of the randomization, were slightly different, although these differences were not statistically significant. WG was in fact younger and more affected, two factors that could be compensated each other, but also potentially inflating the improvements.

TABLE 1: Primary outcome measure walking speed (WS): mean (standard deviation) and P values of paired post hoc tests. Secondary outcome measures: median (interquartile range) of the scores, and P values of Wilcoxon signed rank test.

Outcome measures		WG	CG
Walking speed (m/s)	T0	0.31 (0.15)	0.38 (0.20)
	T1	0.50 (0.20)	0.49 (0.24)
	P	0.001	0.013
FAC-score	T0	2 (0)	2 (2)
	T1	4 (1)	3 (1)
	P	0.004	0.008
BI-score	T0	70 (16)	67 (16)
	T1	88 (7)	85 (9)
	P	0.005	0.012
RMI-score	T0	6 (4)	7 (4)
	T1	10 (2)	10 (2)
	P	0.005	0.007
MRC-score	T0	19 (9)	21 (11)
	T1	25 (11)	23 (12)
	P	0.005	0.010
CNS-score	T0	6 (3)	8 (3)
	T1	8 (3)	9 (4)
	P	0.011	0.015
AS-score	T0	2 (5)	2 (4)
	T1	3 (5)	3 (5)
	P	0.564	0.480

Nevertheless, the increase in walking speed was clearly higher in WG, and also the use of external aids for walking (assessed by FAC-score) was more limited at T1 in WG than in CG, suggesting a potential benefit by the use of NMES.

This is the first randomized controlled trial demonstrating the efficacy in patients affected by a droop foot of a walking training performed with a neurostimulator in subacute stroke phase.

In fact, a previous study had showed efficacy and good acceptance, but in a chronic population [3]. Similar effects were found when chronic stroke patients were stimulated during walking in the community [19].

In a subacute phase of stroke, Yan and colleagues have reported that the use of cyclic NMES reduces spasticity, strengthens ankle dorsiflexors, improves mobility, and increases home discharge rate inpatient stroke rehabilitation [20]. On the contrary, our results did not find significant changes in terms of Ashworth Score. Also Bogataj and colleagues have highlighted that the improvement in gait performance was maintained during time in respect to those treated with conventional therapy [21]. Different from cyclic NMES, NMES performed during walking on floor may give more benefits to improve walking because its practice is close to real condition and is more focused on improving an ability (walking) more than a function (dorsiflexion). Functional electrical stimulation has been proved to be efficacy in

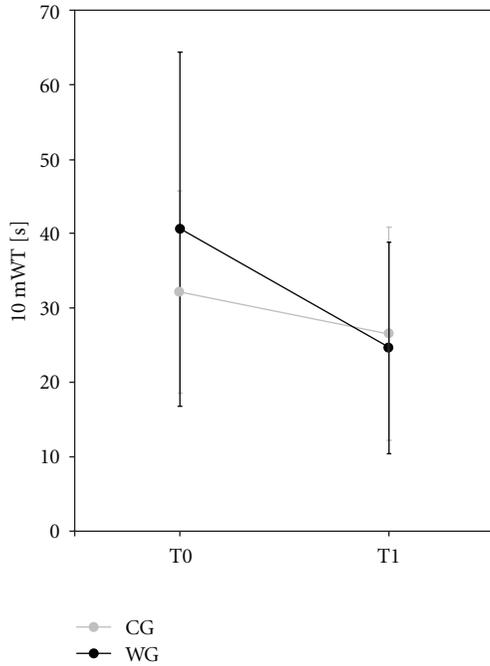


FIGURE 1: Mean and standard deviation of the time spent to walk for 10 m by Walkaide group (WG, black) and control group (CG, grey).

increasing walking speed in chronic stroke even if performed by implantable 2-channel peroneal nerve stimulator for correction of their drop foot [22].

As recently demonstrated, foot drop stimulator increases in the maximum voluntary contraction and motor-evoked potentials suggesting an activation of motor cortical areas and their residual descending connections, which may explain the therapeutic effect on walking speed [3].

A possible explanation of the positive effect on walking recovery in patients affected by a foot drop is that stimulating the peroneal nerve actively dorsiflexes the ankle and strengthens the muscles. At high levels, common peroneal nerve stimulation can produce hip and knee flexion and it has also been claimed to reduce or counteract spasticity [23–25]. This may lead to a global improving of walking function and, maybe, a lower cost in terms of oxygen consumption. Thus, patients during therapy may walk more and better, performing a more amount of steps with less overexertion. This hypothesis might be confirmed by further studies.

Despite these preliminary results of effectiveness, surface peroneal nerve stimulation is not common in the rehabilitative use. This is possibly due to difficulty with electrode placement, discomfort and inconsistent reliability of surface stimulation, insufficient medial-lateral control during stance phase, and lack of technical support. Moreover, NMES induces neuromuscular fatigue but the modification of the electrical stimulation parameters (i.e., frequency, pulse width, modulation of pulses, amplitude, electrode placement, and the use of variable frequency) can reduce fatigue [26, 27].

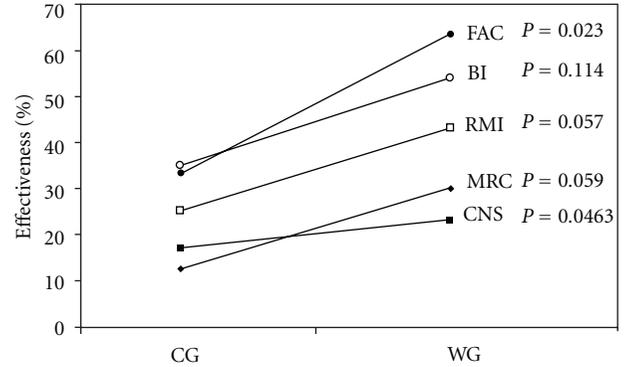


FIGURE 2: Effectiveness for control group (CG) and Walkaide group (WG) in terms of FAC (filled circles), BI (empty circles), RMI (empty squares), MRC (filled rhombus), and CNS (filled squares) scores with the relevant P values of comparison between groups.

The strength AFO is that it is easy to dress and the users can have it custom-molded; the limit of AFO is that it corrects foot-drop through a passive mechanism not involving neuromuscular, spinal, and brain circuits.

Further research on NMES should highlight top-down approach during subacute rehabilitation program transforming the actual human machine interaction [28] in online brain/human machine interaction by mean EEG signals [29].

Some limitations of this study deserve mentioning. Future investigations should be addressed on clinical outcomes at the level of activity limitation and quality of life. Moreover, a peculiar attention should be paid to the long-term outcomes to define the rehabilitative impact of the NMES use. Future studies should also determine the optimal dose and prescriptive parameters, tracking a line for a common use of clinicians and therapists.

In order to better define the role of motor relearning, systems should be addressed towards a neurocognitive use, combining also principle of basic science [30]. Moreover, neuroprostheses should be developed to provide goal-oriented, repetitive movement therapy in the context of functional and meaningful tasks, providing a clear functional, cost-effective benefit in patients with stroke [31].

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