THE EFFECT OF A SHORT FUNCTIONAL ELECTRICAL STIMULATION TRAINING PROGRAMME ON GAIT PARAMETERS IN CHRONIC STROKE SURVIVORS

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ABSTRACT

Functional electrical stimulation (FES) is a procedure that is increasingly accepted as part in the rehabilitation programme of stroke survivors. The effectivness of FES upon gait parameters (speed, stride length, energetic consumption) is generraly proven (different studies showing improvement in some or in all parameters) for training programmes of 2 weeks to 2 months or more. We have investigated the effectiveness of a short programme (6 days) of peroneal nerve stimulation with an ODFS2 device. Stimulation was synchronised with the swing phase of gait. 15 chronic stroke survivors (average time from stroke 13 months, SD=8.21) have been training for 30-45 minutes each day, 6 days. Speed, stride length and physiological cost index have been measured over a 25 m straight course, with and without the use of FES. Increase in speed, stride length and a decrease of effort (physiological cost index, PCI) were recorded after 6 days, both for normal gait and for the FES enhanced gait, but statistical significance was not reached for normal gait PCI . There was a significant supplementary increase in speed for FES gait compared to normal gait. No changes were recorded in spasticity (Ashworth scale), voluntary movement (Brunnstromm scale), independence (Barthel index). We concluded that even short time use of FES training can be beneficial to stroke patients.

Key words: functional electrical stimulation, peroneal nerve stimmulation, stroke survivors, ODFS, speed

INTRODUCTION

Progress in supportive medicine has lead to a substantial increase in survival, making of stroke one of the principal causes of disability in adults. Although some spontaneous improvement occurs in most cases, the overall functional prognosis remains bleak for more than 60% of the survivors, who remain dependent and bring considerable costs to health services.

Neuroscience research has highlighted some of the processes involved in rehabilitation, and stressed the importance of repeated exercise in acquiring new motor skills. Rehabilitation techniques are widelly used. Although the exact effective techniques are not clearly individualised, an intensive training programme has been shown to be beneficial for the stroke patients.

Repeated attempts have been made over the years to substitute an electronic device to the missing parts of the nervous system. The aim was to bypass damaged centers and to allow control of remote parts of the body. Functional electrical stimulation (FES) is used in standing and gait from the 1960's (11), and since then different devices have been developped to enhance the voluntary control of the limbs. FES involves the use of a current generator wich delivers an electric impulse to the

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peripheral nervous structures, thus eliciting the physiologic response. The stimulus pattern and delivery are controlled by the patient (usually by a control pannel) and by physiological triggers (as is “take off” of the foot during gait) so that it integrates into an almost normal act (like gait).

During the years FES has been proven to improve gait in hemiplegic patients. Single or multichannel devices were used, with surface or implanted electrodes. In 1978, Stanic et al 16 found that multichannel FES, given 10 to 60 minutes, 3 times per week for 1 month, improved gait performance in hemiplegic subjects Improvement of dorsiflexion of the foot is the easiest and most frequently encountered procedure.

The treatment period in published papers ranges from 3 weeks to long term home use. Bogataj et al 1 compared 2 groups of stroke survivors receiving 3 weeks of FES, preceded or followed by 3 weeks of conventional therapy.

Treatment was given 5 days per week for 7 to 21 days. The results showed that more subjects were able to walk and lived independently after FES. These observations are supported by 2 meta-analyses by Glanz et al (6) and Chae and Yu, (4) who reviewed articles on randomized clinical trials that assessed the efficacy of neuromuscular electrical stimulation in hemiplegia between 1966 and 1999. They found only 8 single-blinded randomized clinical trials. The initial treatment time varied from 14 to 29.2 months after stroke. Only one study had a placebo group. Most authors have studied only the immediate effect

Due to the short stay of the patients in our clinic, a short rehabilitation programme (of maximum 10 days) is available. We have investigated the usefullness of a short (6 days) programme of FES training on chronic stroke patients.

MATERIALS AND METHODS

The study has been carried out on a number of 15 patients with ischaemic stroke that were admitted in our clinic between april and august 2009. Patients’ age ranged from 45 to 73 (on average 59.8 years, SD = 9.69). They were neurologically stable and without major cardiac problems. Participants were chronic stroke survivors, 2-24 months poststroke, on average 13 months, SD = 8.21) with unilateral hemiparesis who had sufficient endurance and motor ability to ambulate at least 25 meters continuously, independently or with minimal assistance. Footdrop resulted in gait instability or an inefficient gait pattern. Passive ankle range of motion was normal, intact skin and absence of edema of the affected leg were required.

The patients have received 30-45 minutes of FES training daily for 6 days. During these 6 days they also took part in the usual rehabilitation program in our clinic (physical therapy for 30 min - 2 hours daily). Accomodation with the device, identification of specific stimmulation parameters and training of the patient were performed during the first day, and then the same training conditions were applied during the next sessions.

We have used a single channel stimulator (ODFS I) that can deliver a 20-80 mA stimulus (for the symmetrical byphasic output) with 40 Hz. The stimmulator is lightweighted and can be attached to the belt of the patient. The patient has acces to a switch that modifies the intensity of the stimmuli. The autoadesive electrodes (Pals Platinum 5x5 cm, Nidd Valley Medical) are positioned on the skin. Precise positioning of the electrodes permits control over the quality of movement by balancing dorsiflexion with inversion and eversion. The active electrode is positioned over the common peroneal nerve, just below the head of the fibula, while the indifferent electrode is located distally and medially over the motor point of the tibialis anterior. The foot swich is placed under the heel of the patient (we have used the “heel rise” mode, with the swich on the affected side). The footswitch is a 3-mm-thick, insole pressure-sensing device that is worn in the shoe. Through the use of the footswitch as a command-controller, the stimulus is timed to coincide with the swing phase of the gait cycle.

For the analysis of the data we have used the statistical package in Microsoft Excel (averaging, standard deviation, trendline ecuation and r square calculation; T-test was used for significance).

OUTCOME MEASURES

Speed, length of step and physical effort were the primary outcome variables.

The physical effort was approximated by the phisyological cost index (PCI), that integrates heart rate and gait speed.

Other parameters that were studied were spasticity (measured on the Ashworth scale), voluntary movement (on the Brunnstromm scale) and global functional scores (modified Rankin scale and Barthel index).

Gait parameters (speed, stride length and heart rate) were measured on a 25 m course (without obstacles or turns). The patients were required to walk the whole distance without stop, maintaining an alert (but not uncomfortable) pace. Heart rate was measured before and after going the 25 m distance, and a difference was calculated. The patients respected a 10 minutes rest period before starting the test and measuring the “resting” heart rate. Stride length was calculated by counting the number of steps and then dividing the 25 m distance by that value. Speed was calculated by measuring with a stopwatch the time required to complete the distance. These parameters were measured on each day of the study, before and after FES training, with and without the use of FES.

Spasticity, voluntary control, and functional scores were evaluated before and after the 6 days training programme.

The physiological cost index (PCI) was calculated using the formula:

$$PCI\ (beats/m) = \frac{\Delta HR\ (beats/\min)}{Speed\ (m/\min)}$$

ΔHR = working heart rate (beats/min) – rest heart rate (beats/min).

RESULTS

The evolution of the walking speed during the 6 days training program is presented in Figure 1 and in Table 1. Overall average speed (measured for all patients during all days) was 0.54 m/s (SD = 0.223) for normal gait (without FES) and 0.57 m/s (SD = 0.25) for FES enhanced gait.

We have applied a linear regression model for the average daily speed (with and without FES). Speed had an ascending trend both for normal gait (slope of the trendline = 0.04, R2=0.987) and for FES stimulated gait (slope of the trendline = 0.049, R2=0.986). The increase was statistically significant when we compared the averaged values for the first 3 days with the averaged values for the last 3 days, p=0.00013 for independent gait and p=0.00001 for FES gait). Comparation between last and first days was significant for FES enhanced gait (p=0.0064) and for normal gait (p=0.014).

After 6 days of training the speed has increased with 58% (0.25 m/s) for FES enhanced gait and with 47% (0.21 m/s) for normal gait (difference between averaged speed on day 6 and on day 1). Speed increase for FES enhanced gait is more important than for normal gait (p=0.017).

The evolution of stride length during the study is presented in figure 2 and table 2. Average daily values for normal and for FES enhanced gait and trendlines associated them (and the corresponding equations) are presented in figure 2. In table 2 we present the values calculated for each patient in the first and last days and the individual average value.

Overall average stride length (measured for all patients during all days) was 0.87 m (SD = 0.07) for normal gait (without FES) and 0.89 m (SD = 0.09) for FES enhanced gait.

We have applied a linear regression model for the average daily stride lenth (with and without FES). Stride lenth had an ascending trend both for normal gait (slope of the trendline = 0.037, R2=0.978) and for FES stimulated gait (slope of the trendline = 0.038, R2=0.744).

Table 2. Stride lenght with and without use of FES (first and last days, average speed, SD)

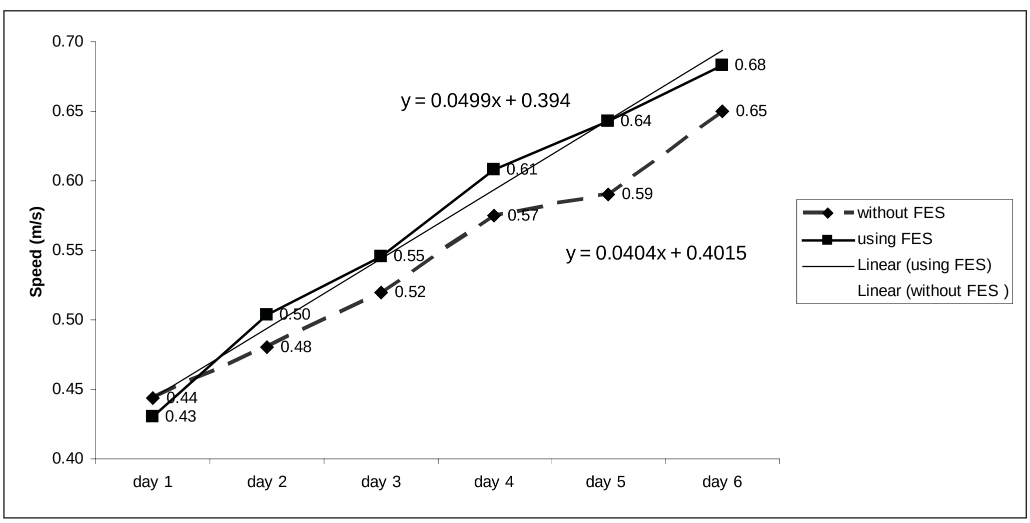

FIGURE 1. *The evolution of walking speed during the study (and trendlines).The averaged values for the 15 subjects measured without and with the use of FES.*

Speed (m/s)	Without FES				Using FES				Difference (FES-noFES)
	Day 1	Day 6	Average	SD	Day 1	Day 6	Average	SD	
Patient 1	0.39	0.74	0.524	0.127	0.53	0.76	0.609	0.096	0.085
Patient 2	0.4	0.79	0.626	0.156	0.48	0.79	0.748	0.217	0.122
Patient 3	0.83	1.11	0.978	0.141	0.83	1.14	1.024	0.156	0.046
Patient 4	0.66	0.68	0.642	0.029	0.61	0.83	0.667	0.109	0.025
Patient 5	0.28	0.71	0.489	0.179	0.26	0.75	0.527	0.191	0.038
Patient 6	0.48	0.96	0.677	0.165	0.52	0.89	0.67	0.126	-0.007
Patient 7	0.89	0.96	0.894	0.08	0.83	1.19	0.97	0.148	0.076
Patient 8	0.18	0.22	0.202	0.019	0.18	0.23	0.202	0.022	0
Patient 9	0.49	0.71	0.644	0.081	0.36	0.63	0.553	0.108	-0.091
Patient10	0.4	0.57	0.499	0.068	0.29	0.57	0.465	0.102	-0.034
Patient11	0.33	0.43	0.406	0.058	0.32	0.45	0.415	0.05	0.009
Patient12	0.34	0.26	0.258	0.045	0.19	0.24	0.225	0.024	-0.033
Patient13	0.19	0.45	0.353	0.106	0.21	0.52	0.393	0.118	0.04
Patient14	0.57	0.86	0.696	0.129	0.6	0.93	0.775	0.123	0.079
Patient15	0.23	0.3	0.262	0.024	0.24	0.33	0.285	0.034	0.023

TABLE 1. *Gait speed with and without use of FES (first and last days, average speed, SD)*

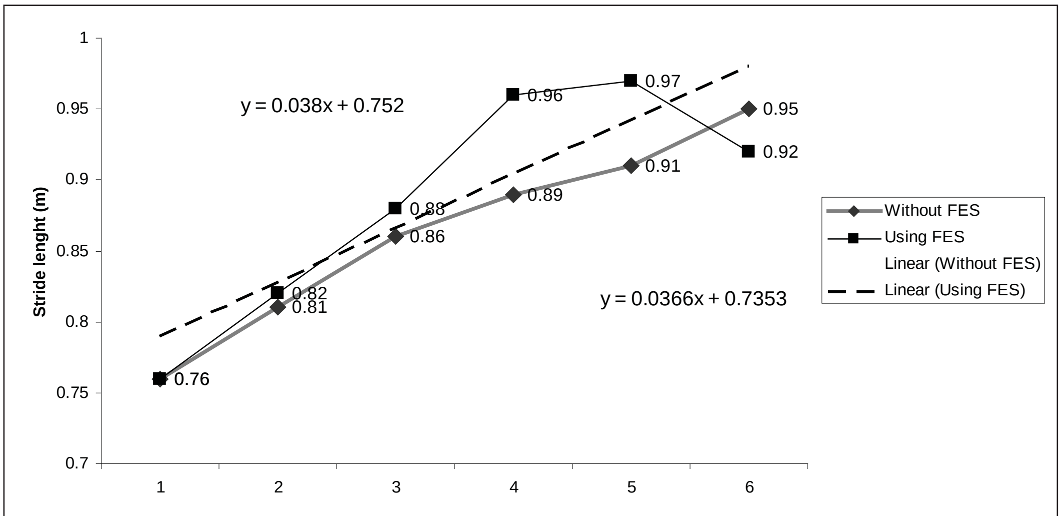

FIGURE 2. *The evolution of stride length during the study (and trendlines). The daily averaged values for the 15 subjects measured without and with the use of FES.*

Stride length (m)	Without FES				Using FES				Difference (FES-noFES)
	Day 1	Day 6	Average	SD	Day 1	Day 6	Average	SD	
Patient 1	0.7	1	0.806	0.114	0.82	1	0.873	0.093	0.067
Patient 2	0.94	0.94	1.06	0.099	0.98	1.19	1.196	0.193	0.136
Patient 3	0.96	1.16	1.082	0.091	1	1.19	1.107	0.075	0.025
Patient 4	1	1.02	1.001	0.026	0.93	1.09	1.017	0.162	0.016
Patient 5	0.61	0.94	0.784	0.147	0.54	1.04	0.827	0.191	0.043
Patient 6	0.79	1.16	0.948	0.126	0.85	1.19	1.089	0.367	0.141
Patient 7	1	1.14	1.076	0.077	0.96	1.19	1.121	0.115	0.045
Patient 8	0.54	0.65	0.611	0.048	0.56	0.66	0.621	0.054	0.01
Patient 9	0.82	1.04	0.971	0.085	0.7	0.98	0.88	0.11	-0.091
Patient10	0.69	0.82	0.78	0.05	0.61	0.82	0.725	0.079	-0.055
Patient11	0.69	0.81	0.774	0.049	0.66	0.83	0.762	0.064	-0.012
Patient12	0.36	0.42	0.381	0.034	0.3	0.38	0.369	0.038	-0.012
Patient13	0.57	0.91	0.787	0.134	0.65	1.02	0.846	0.155	0.059
Patient14	1.11	1.32	1.239	0.081	1.11	1.43	1.29	0.107	0.051
Patient15	0.66	0.72	0.681	0.027	0.69	0.77	0.718	0.045	0.037

TABLE 2. *Stride lenght with and without use of FES (first and last days, average speed, SD)*

After 6 days of training the stride length has increased with 21% (0.16 m) for FES enhanced gait and with 25% (0.19 m) for normal gait (difference between averaged lenth on day 6 and on day 1). Stride length has significantly increased during the study (when comparing average values for the first 3 days with the values for the last 3 days, p=0.00005 for independent gait and p=0.00125 for FES gait). Comparation between first and last days has shown a significant difference for normal gait (p=0.0001). For FES enhanced gait p=0.02.

In figure 3 and in table 3 are presented the values we have obtained for PCI.

The average PCI calculated for gait without FES (all patients, all days) is 0.261 betas/m (SD=0.267). PCI for FES enhanced gait was 0.128 beats/m (SD=0.201) (P=0.0001).

The PCI had a descending trend both for normal gait (slope of the trendline = -0.0257, R2=0.469) and for FES stimulated gait (slope of the trendline = -0.0248, R2=0.344).

After 6 days of training the PCI has decreased with 56% (0.091 beats/m) for FES enhanced gait and with 37% (0.098 beats/m) for normal gait (calculated as difference between averaged PCI on day 6 and on day 1). The effort (when comparing last to first days) has significantly diminished during the study for the FES group (p=0.0004) but the significance treshold was not reached for normal gait (p=0.06). Comparison between averaged values from the first 3 days versus the last 3 days did not reach significance (p=0.08 for normal gait and p=0.07 for FES gait).

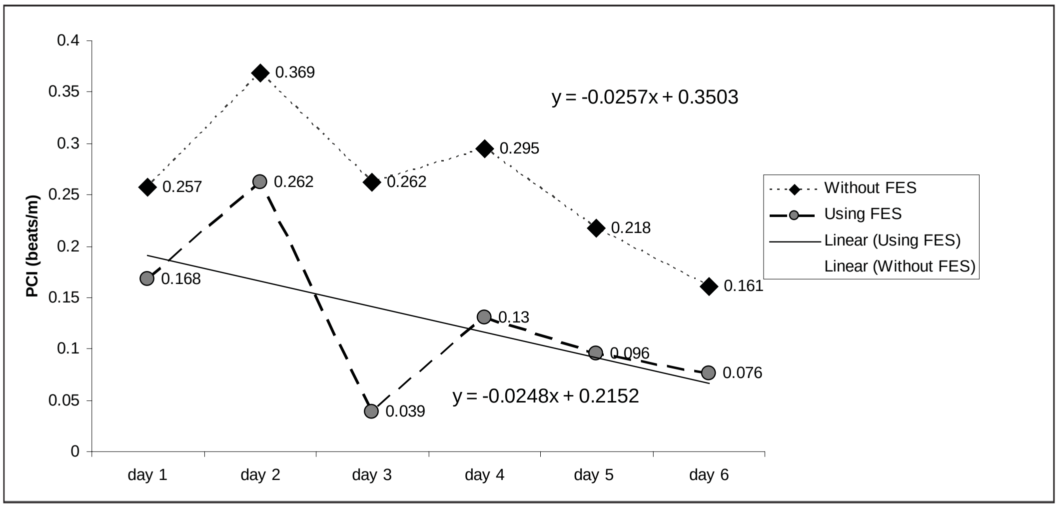

FIGURE 3. *The evolution of PCI during the study (and trendlines).The daily averaged values for the 15 subjects measured without and with the use of FES.*

PCI (beats/m)	Without FES				Using FES				Difference (FES-noFES)
	Day 1	Day 6	Average	SD	Day 1	Day 6	Average	SD	
Patient 1	0.085	0.091	0.094	0.066	0.125	0.085	0.098	0.05	0.004
Patient 2	0.083	0.042	0.104	0.093	0.139	0.040	0.091	0.05	-0.013
Patient 3	0.080	0.060	0.088	0.058	0.020	0.028	0.041	0.022	-0.047
Patient 4	0.051	0.049	0.087	0.112	0.027	0.019	0.065	0.099	-0.022
Patient 5	0.352	0.187	0.3	0.36	0.129	0.043	0.014	0.148	-0.286
Patient 6	0.347	0.381	0.233	0.194	0.160	0.036	0.165	0.118	-0.068
Patient 7	0.112	0.069	0.17	0.158	0.140	0.027	0.072	0.038	-0.098
Patient 8	0.184	0.299	0.316	0.151	0.185	0.141	0.058	0.226	-0.258
Patient 9	0.340	0.117	0.215	0.084	0.274	0.077	0.166	0.086	-0.049
Patient10	0.083	0.059	0.108	0.115	0.116	0.056	0.191	0.281	0.083
Patient11	0.912	0.116	0.398	0.375	0.362	0.036	0.163	0.117	-0.235
Patient12	0.444	0.384	0.836	0.373	0.349	0.204	0.399	0.548	-0.437
Patient13	0.176	0.187	0.343	0.261	0.160	0.123	0.148	0.172	-0.195
Patient14	0.464	0.155	0.303	0.117	0.196	0.087	0.105	0.079	-0.198
Patient15	0.144	0.224	0.317	0.174	0.137	0.097	0.15	0.199	-0.167

TABLE 3. *PCI value (with and without FES) (first and last days, average speed, SD)*

Effort of walking was significantly lower with FES (P<0.0001).

During the study the secondary parameters did not show any changes.

DISCUSSION

All the primary outcome parameters showed an improvement (although it did not reach the significance treshold in some situations), both for FES assisted gait and for independent gait. Due to the small sample and to the reduced duration, we have considered p<0.01 as the treshold for statistical significance in this study. If it was set at p<0.05 most improvements could have been considered significant.

Activity-dependent neuroplastic changes or motor relearning may be responsible for the functional ambulation improvements noted. Still, the short duration of the training programme raises the question whether such mechanisms had enough time to become manifest. Transcranial magnetic stimulation (TMS) studies have suggested that FES mediated repetitive movement training enhances motor cortex excitability and facilitates motor-evoked potentials of the tibialis anterior. (8,9) Similar results have been published for upper limb rehabilitation. Other possible causes of the improvements in functional parameters of ambulation include exercise-mediated muscle strengthening and conditioning, effect of FES on peripheral receptors, proprioceptive systems in the spine and mechanisms that are involved in spasticity, and overall cardiovascular conditioning.

Recent reviews have documented the neuroprosthetic effect of peroneal nerve stimulation (PNS) with positive impact on multiple specific gait parameters (12, 13) and speed of ambulation. (10) An evidence-based review of stroke rehabilitation has concluded that there was strong evidence that peroneal nerve stimulators improve hemiplegic gait parameters. (19)

Taylor et al (18) reported significant improvements in device-free walking speed in a retrospective review of 151 stroke survivors treated with the Odstock Dropped Foot Stimulator (ODFS) for an average of 4.5 months. Robbins and colleagues noted that the FES effect size was high in individuals at the subacute stage, though the treatment's impact on chronic-stage patients was low. (14) Kottink et al suggested that FES seemed to have a positive orthotic effect on walking speed (meta-analysis of 8 studies). (10)

Other studies have also found increases in gait speed after the use of FES, alone or in combination with other procedures. (2,3,5,7,15,17)

Our study has shown a statistically significant increase in speed compared to baseline for both independent and FES supported gait. The magnitude of the change is more important for FES supported gait (this difference being also statistically significant). The changes are comparable with most of those reported in positive studies.

Stride length had a clear ascending trend for the first 4 days, that continued only for independent gait. We have noticed a marked and unexpected decrease of stride length during the last day. It may be due to psichological factors (patient got used to the device and tried to increase speed by increasing the cadence). Because of that, the last-to first day comparation shows significant increase only for independent gait. If we compare the average values from the first 3 days with those from the last 3 days the increase is significant for both independent and FES assisted gait. Overall there was a tendency for better improvement with FES, although for some of the patients normal gait improved more than FES assisted gait (table 2). On the whole the difference was not significant (p=0.11).

PCI values fitted the least into a linear pattern. There was an initial increase of effort both for independent and for FES assisted gait during the second day, followed by a decrease during the 3rd day and again increase during the 4th day. It is possible that this is due to patient's ability to learn how to use the maximum of the ODFS device. Other authors have shown improvement in gait efficiency (7, 15). Our results are similar to those of Burridge (3) whith a significant improvement only during FES use. A tendency for better results was noted also for independent gait, but it did not reach statistical significance. The more complex pattern of distribution of averaged values of the PCI suggests the involvement of more environmental and personal factors. A short program of rehabilitation will probably not exert any influence upon the overall effort capacity, but continuation of exercises might result in a liniary pattern of distribution due to activation of other mechanisms.

The secondary parameters did not change during the study. It is possible that their sensitivity was not fitted for very discrete changes (Rankin scale, or Barthel index). Subjective changes in spasticity were reported by some of the patients, but there were no changes on the Ashworth scale. Also, we did not record any obvious improvement of voluntary dorsiflexion or of the voluntary movement of the lower limb (Brunnstromm scale). It is possible that a longer training period might induce changes to these paramaters too (as they are reported in literature).

Even though the duration of the study was shorter than that of most others, a similar improvement was attained. Normally we can expect improvement to continue due to mechanisms that start acting later (neuroplasticity, spinal chord mechanisms) and due to an increase of the global muscular and cardiovascular condition. Still, the same factors may constitute a limitation – cardiovascular condition might need more sustained exercise to improve. It is also possible that a plateau phase is reached, at least for this level of training intensity.

It is difficult to explain exactly which of the mechanisms involved in rehabilitation are responsible for the improvement, or whether the gain will be sustained or needs permanent reinforcement.

CONCLUSIONS

A significant improvement was noted at the end of the training period on all parameters (speed, stride length and PCI) for FES enhanced gait. Speed and stride length have also significantly improved in not assisted gait, a fact that cannot be explained singularilly by the ortothic effect of FES. All parameters have shown a tendency to improve more with the use of FES than without it. We can say that even a short training program is useful for stroke survivors. Overall, FES appears to be a safe and usefull method for rehabilitation of stroke patients.

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