Functional Electrical Therapy of Walking: Pilot Study

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Abstract

The Functional Electrical Therapy (FET) in this study was a 4-week, 30 minutes daily walking exercise assisted with multi-channel electrical stimulation in acute post-stroke hemiplegic subjects. The FET used three channels of muscle stimulation to enhance the stance phase, push-off, and swing of the paretic leg. The timing of the stimulation was programmed to match the volitional, life-like sequences of muscle activities. We analyzed the speed and symmetry between the paretic and nonparetic legs in the FET group (5 subjects) and Control group (5 subjects), who received sham stimulation during the walking sessions. The maximum walking speed increased from 0.2 to 0.8 m/s in the FET group, and 0.25 to 0.68 m/s in the Control group, and the symmetry index decreased for about 10 % in the FET group and 6 % in the Control group. These results call for large randomized clinical trial.

1 Introduction

Cardio-vascular accidents (CVA) often cause a life-long sensory-motor disability that has a tremendous impact on the quality of life. The disability commonly causes "a cycle of deconditioning" in which the physical functioning deteriorates, leading to further reduction in physical activity levels. Therefore, it is important to develop rehabilitation programs that are sufficiently practical, accessible, and compatible with the individual's life-style, that will prevent deconditioning.

Recent clinical studies in acute post-CVA hemiplegics suggested that intensive task-related treatment augmented with electrical stimulation lead to better functional gains compared with conventional rehabilitation [1]. This treatment was termed Functional Electrical Therapy (FET). The conclusions from our study contradicts most of the clinical trials in which electrical stimulation was applied in post-CVA hemiplegics with minimal carry over effects Recently several studies have indicated that appropriate treatment leads to better walking in post-stroke hemiplegic subjects [2-3]. In our clinical studies in upper extremities we showed that the FET works better if applied in the acute phase of hemiplegia compared with the chronic phase [1]. Thereby, we designed a functional electrical stimulation treatment for restoring walking that is suitable for acute post-stroke hemiplegic subjects capable of standing with hand support. The principal innovation of this study is the implementation of a new multi-channel stimulation paradigm that augments both the stance and swing phases of the gait cycle. The stimulation pattern was designed to mimic natural able-bodied movement. The need to make the treatment applicable in clinical environment, and even more important to convince referring physicians to consider it for regular use, posed two strong constraints: the system must operate with the simplest possible hardware, and the user interface must be very simple.

2 Methods

Subjects. 10 post-CVA hemiplegic patients were included in this pilot study. They met the following criteria: 1) first ever stroke evidenced by imaging, 2) no additional neurological and/or orthopedic deficiencies impairing ambulation, 3) no cardiac, respiratory or medical condition that could interfere with the therapeutic protocols, 4) no severe cognitive or communication impairment that could hamper the understanding of simple instructions, 5) onset of stroke not more than 8 weeks after stroke, and 6) ability to ambulate with a single cane. These patients were randomly selected to receive the FET (FET group), or to receive sham stimulation (Control group) in addition to the customary treatment provided by the rehabilitation center. All subjects signed the informed consent approved by the local ethics committee. The study was conducted in accordance with the Declaration of Helsinki.

Procedure. Three channels of electrical stimulation were applied in both groups. We selected the following muscle groups as the targets: *Quadriceps m.*, *Gastrocnemius m.*, and *Tibialis Anterior m.* These 3 muscle groups were selected since they provide: 1) support during the stance, 2) push-off at the end of the stance and better stability at the foot contact, and 3) foot clearance during the swing phase. The time sequence for the stimulation was developed by using the simulation of walking in the sagittal plane. The simulation paradigm is described elsewhere [4]. Fig. 1 shows a characteristic stimulation sequence.

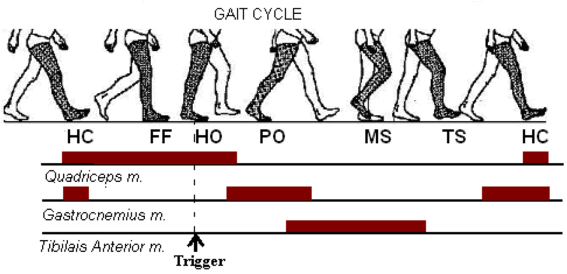

Fig. 1: The timing of stimulation for the FET of walking. HC - Heel Contact, FF - Foot Flat, HO – Heel Off, PO – Push Off, MS – Middle Swing, TS – Terminal Swing.

The difference between the stimulation in the FET and the Control group was the intensity of stimulation: 1) FET group used stimulation that produced functional movement (I = 20–50 mA), 2) Control group was stimulated (sham) at a level that produced cutaneous sensation but no motor response (I=2 mA). In both cases the frequency was 50 pulses per second, and the pulse duration was 300 μs.

The stimulation sequence was triggered by a trained physical therapist. The stimulation was triggered once per step at the instant when the paretic leg was at the end of foot-flat phase (heel off). Since the timing of the required stimulation varied with the speed of walking different timing protocols of stimulation (duration and delays at different channels) were stored in the micro-computer controlled portable multi-channel stimulator [5], and selected appropriately to match the performance of the individual subject. This allowed simple change of the stimulation pattern during the walking session. The training sessions in both groups lasted for 30 minutes. The task was to walk for at least 15 minutes at each session. Subjects were required to participate in minimum of 15 walking sessions during the 4 weeks long study.

Assessment. All assessments were done without stimulation. The measures of performance were: 1) maximum walking speed and 2) symmetry between paretic and nonparetic legs. The time was measured by using switches mounted in the insoles of the heel and toe regions of the left and right shoes. We calculated the walking speed by determining the time to cover 10 meters in the center of a 15 meters long walking at maximum speed. The stance and swing phases durations were measured as the time intervals: heel-contact to toe-off, and toe-off to heel-contact. The assessments were done at the beginning (week 0), after 2 weeks, and after 4 weeks (end of treatment). Patients walked with a single cane in all assessment sessions. Therapist did not provide any assistance to subjects during the assessment sessions. The results are the average from the 3 consecutive days recordings.

The symmetry index (SI) was calculated for the stance and the swing phases by using the formula proposed by Robinson et al. [6]:

$$SI[\%] = 2\frac{T_{nonparetic} - T_{paretic}}{T_{paretic} + T_{nonparetic}} x\,100$$

The times $T_{paretic}$ and $T_{nonparetic}$ are the durations of the stance or swing phases for the paretic and nonparetic leg. SI can be positive or negative, and the ideal symmetry index is SI = 0.

3 Results

Fig. 2 shows averaged maximum velocities for the FET and Control groups. There are no

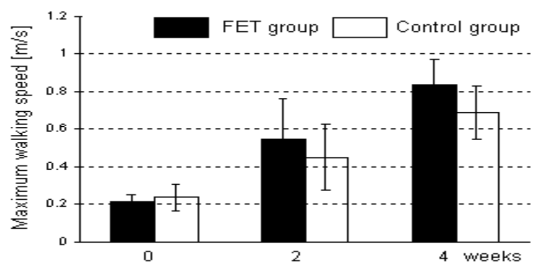

Fig. 2: The average maximum walking speed ± S.D. for the FET and Control Groups assessed at 0, 2, and 4 weeks.

significant differences between the groups. The differences in the means are about 15% in favor of the FET treated group at two and four weeks.

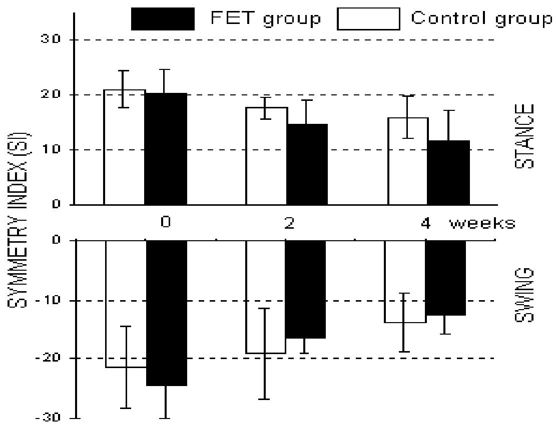

Fig. 3: The SI ± S.D. for the stance and swing phases of the gait estimated at 0, 2, and 4 weeks for the FET and Control groups.

Fig. 3 shows the SI for both groups. The SI for the stance phase is positive because the stance on the nonparetic leg is longer compared with the stance on the paretic leg, and *vice versa,* the SI is negative for the swing phase. There is no statistical difference between the groups; however, there is an obvious trend in favor of FET treated group. The stance phase SI decreased for about 4% (2 weeks), and 9% (4 weeks) in the FET group. The swing phase SI also decreased for 7% (2 weeks), and 12% (4 weeks) in the FET group.

4 Discussion and Conclusions

The maximum walking speed achieved by the subjects after the 4 weeks of therapy was about 0.85 m/s, which is close to the average walking velocity of able-body people (approximately 1.4 m/s). This speed achieved in the FET group is close to the value that is typically considered practical for daily life (1 m/s). The SI in humans with no known disabilities is bellow 6% [7]. The SI for the FET group decreased from 23% to about 10%, while the SI for the Control group decreased from 22% to about 15%.

While the results reported show a tendency suggesting an improvement in the walking speed and symmetry for the subjects in the FET group, they call for a larger randomized clinical study that will provide better evidence of benefits of the FET for the rehabilitation.

This study also showed that the programmable stimulator used was suitable to mimic functional gait.

During the study therapists indicated that the stimulation sequences were not always synchronized with the voluntary movements; hence, stimulation somewhat interfered with the walking. Therapists had to fine tune the timing (not practical for daily clinical use) in order to compensate for this. Therefore, we are developing a sensory driven control for the stimulator that will secure that the timing of stimulation matches volitional movements. The results of the pilot study with only 10 subjects are not conclusive.

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