A randomized clinical study to evaluate the employment of FES cycling in the rehabilitation of post-acute stroke patients: preliminary results.

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Abstract

Cycling induced by functional electrical stimulation (FES) is an interesting method in the rehabilitation of post-acute stroke patients. A randomized, single-blinded, clinical study is ongoing to evaluate the efficacy of this treatment. The patients are shared in 2 groups: the first performs daily 25 minutes of FES cycling, the second 25 minutes of FES cycling placebo. Quadriceps, hamstrings, tibialis anterior and gluteus of both the legs are stimulated. The trial is carried out on a motorized cycle-ergometer, at 20 rpm. The patients are evaluated before, after the treatment (20 days) and in a follow-up session, by the following tests: motricity index, trunk control test, upright motor control test, maximum voluntary contraction, voluntary pedaling. Up to now 23 patients have been included. The first FES cycling patient who concluded the treatment improved significantly the muscular strength and strongly reduced the pedaling unbalance after the treatment; the same results were maintained in the follow-up tests. On the contrary, the first placebo patient who finished the treatment did not show a significant motor functional improvement. A statistical analysis to compare the 2 groups will be performed at the end of the study.

1 Introduction

In industrialized countries, stroke represents the first cause of long term disability. Most of the recovery after stroke is achieved in the first 6 months following the event due to the plasticity of the central nervous system [1]. Clinical studies on neuroplasticity support the role of FES-induced goal-oriented, repetitive movements in the training of the paretic limb to enhance motor re-learning [2]. Indeed, FES offers the patients the proprioceptive afference of the task which could accelerate the process of functional recovery. Riding an ergometer is an often used training modality in the lower limbs rehabilitation of stroke patients even before gait training is possible. The application of FES synchronized to the cycling movement (FES cycling) may enhance the rehabilitation progress of these patients. Recently some clinical studies were carried out to assess the efficacy of FES cycling on stroke patients [3, 4, 5]. Ferrante at al. compared FES cycling and standard rehabilitation (SR) in a controlled randomized study including 20 sub-acute stroke patients [3]. Quadriceps, hamstrings, gluteus maximum and tibialis anterior of both the legs were stimulated while the patients did not contribute voluntarily to isokinetic cycling. Exercises, lasting 35 minutes, were performed daily for 4 weeks. The study showed that rehabilitation including FES cycling was more effective in promoting muscle strength and motor recovery of the legs than therapist-assisted SR alone. In another randomized clinical study performed on 12 chronic stroke patients, no differences were found between the effects of FES cycling with sensory stimulation and those of FES cycling with maximal tolerated stimulation intensity [4]. In this study the patients were trained twice a week for 6 weeks on an isotonic cycle-ergometer stimulating the quadriceps, hamstrings and gluteus maximum. Szecsi et al. analyzed the kinetic and kinematic effects of FES cycling in 39 patients with sub-acute stroke on a tricycle test bed with adjustable resistance [5]. Only the quadriceps and hamstrings of the affected leg were stimulated. During ergometric measurements, volitional pedaling was alternated by combined pedaling (volitional supported by stimulation). The data revealed significant correlations between the improvement of smoothness of the cycling movement and the electrically evocable isometric torque. The published studies reveal that there are no standard protocols for FES cycling at the moment, defining the best number of stimulation channels, the side of stimulation (one or two legs) and the training intensity. The studies are also difficult to compare because of different patient groups (sub-acute, chronic), ergometer settings (isokinetic, isotonic) and different involvement of the patient during the exercise (active, passive). Resistance levels are also not well reported. Therefore, the aim of the present study was to carry out a randomized, single-blinded, clinical study to evaluate the short and the long-term efficacy of the FES cycling treatment in the rehabilitation of post-acute stroke patients.

2 Methods
2.1 Subject and selection criteria

Thirty post-acute (less than 6 months after the event) stroke patients have been including in the study ongoing in the Rehabilitation Center of Villa Beretta. The protocol was approved by the Ethical Committee and all the included patients have to sign a written informed consent.
The selected patients are affected by an ischemic or hemorrhagic ictus; they are collaborative, able to understand simple instructions and to sit in a wheelchair for about 30 minutes. Furthermore, a low spasticity for all the muscles of the lower limbs (Ashworth < 2) and a good joint mobility (a knee extension up to 150° and a hip flexion up to 80°) are required. Patients with cardiac pacemaker or allergic to adhesives or electrodes are excluded.

Participants are randomly shared into 2 groups: a FES cycling group, performing daily FES cycling and a placebo group, performing daily FES cycling placebo. All the patients perform the treatment in addition to the standard rehabilitation (SR). The SR performed with therapists included stretching, muscular conditioning with active or passive motility, exercises to recover the trunk control, the standing position and walking training. Both the groups undergo about 3 hours a day of rehabilitation. The sequence and composition of SR exercises is customized on each patient.

### 2.2 Assessment tests

To evaluate the improvements produced by the treatment on each patient, some assessments tests are performed before, after the treatment (20 days) and in a follow up session (3-5 months after the end of the treatment). The selected tests could be divided in clinical tests (motricity index (MI); trunk control test (TCT) and upright motor control test (UMC) [4]) and in biomechanical tests, which are:

- **maximal voluntary contraction (MVC)** to measure the forces produced by the quadriceps, biceps femoris and tibialis anterior of both the legs during MVC. The forces are measured by a load cell (L 2350/200LBS, Tekkal, Italy). To perform MVC of the quadriceps and biceps femoris, the patient sits on a bench with the leg flexed and the knee angle fixed at 90°. The MVC of the tibialis anterior is recorded while the patient is flat on his back with the ankle angle fixed at 90°. For each muscle we computed the $F_n$, i.e., the ratio between the force produced by the muscle of the paretic side and the one produced by the same muscle of the healthy leg.

- **voluntary pedaling** to analyze the pedaling unbalance during 2 minutes of voluntary pedaling. During the test, the subject sits on a motorized cycle-ergometer equipped by resistance strain gauges mounted on the crank arms to provide the right and left torques produced during cycling [6]. The output measure for voluntary pedaling test was defined as the percentage ratio between the mean power output produced by the paretic leg and the healthy leg in each revolution ($PO_n$); values equal to 1 indicate a good pedaling balance; values lower than 1 indicate that the paretic leg is doing less work than the healthy one; finally, negative values mean that the paretic leg is hindering the exercise.

### 2.3 Treatment protocol

The treatment consists in a daily trial performed for 4 weeks. Each trial lasts 25 minutes:

- 5 minutes of passive cycling
- 15 minutes of FES cycling / FES cycling placebo
- 5 minutes of passive cycling

During all the sessions 4 muscular groups per each limb are stimulated: quadriceps, hamstrings, gluteus maximums and tibialis anterior. Each muscle is stimulated in a particular range of the crank angle, according to [4]. The MOTOmed viva2™ ergometer (Reck GmbH, Germany) has been chosen for the treatment. A current-controlled 8–channel stimulator, RehaStim Pro™ (Hasomed GmbH, Germany) is used. During the FES cycling treatment, the stimulation frequency is 20 Hz, the pulse width is fixed at 300 µs and the current amplitudes are set individually on each muscle at a value, tolerated by the patient, which produces a visible good muscular contraction. Also during the FES cycling placebo treatment the electrodes and stimulator are connected but all the currents delivered are equal to zero.

During the trial, the patients sits on a chair or a wheelchair in front of the ergometer and their legs are stabilized by two foot orthoses fixed at the pedals, so that the trial is safe and comfortable.

During the initial and final minutes of passive cycling, the patient is not stimulated at all and his legs are moved solely by a motor mounted inside the ergometer, which guarantees a constant speed of 20 rpm.

Patients are explicitly required to not participate voluntarily to the movement to assure a repeatable, symmetrical and smooth cycling.

### 3 Results

Up to now 23 patients have been already included in the study; 18 concluded the treatment and performed the post-treatment assessment tests; 4 carried out also the follow up evaluation. In the following, the results of 2 patients, who concluded the whole study, are shown.

Table I reports the clinical and demographic details of Patient A and Patient B, who belonged to the FES cycling and FES cycling placebo group, respectively. In the table, the results of the clinical tests in the 3 evaluations (pre, post-treatment and follow up tests) are also reported. These results show that Patient A, starting from a really impaired motor condition, recovered completely the mobility of the paretic leg (MI),
the trunk control (TCT) and balance (UMC) after the treatment and maintained the same outcome also in the follow up session. Patient B recovery was definitely less efficient, showing a slight improvement of MI and UMC, with respect to the starting condition; also in this case the follow up results are similar to those of the post-treatment tests.

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<th>MI 3</th>
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Table 1 Demographic and clinical details of Patient A and Patient B. Also the results of the clinical tests obtained before (1), after (2) the treatment and in the follow up session (3) are reported.

Figure 1 Each panel shows $F_{\text{norm}}$ produced by Patient A (panels (a-c)) and Patient B (panels (d-f)).

Figure 2 The two panels show $P_{\text{norm}}$ per revolution produced during voluntary pedaling. Panel (a) is referred to the Patient A; panel (b) to Patient B.

Figure 1 shows the results of the MVC trials: a definitely different trends could be observed comparing muscular strength recovery of the two patients. Patient A, starting from really low values of $F_{\text{norm}}$ (less than
20%), increased significantly the forces produced by all the investigated muscles of the paretic leg after the treatment and maintained or improved the achieved values in the follow up tests. On the contrary, Patient B shows only a partial recovery of the muscular strength: the values of $F_{\text{norm}}$ produced by the muscles of the impaired leg were less than 20% also in the follow up tests.

Figure 2 reports the data of the $PO_{\text{norm}}$ for the two patients performing voluntary pedaling. Both the patients in the first trial (blue data) showed a completely unbalanced pedaling, being the healthy leg compensating the paretic one. In particular, Patient B produced negative values of $PO_{\text{norm}}$ which means that the paretic leg was hindering the pedaling, maybe because of muscular stiffness. At the end of the rehabilitation (red data) the two patients performances were absolutely different: Patient B who performed FES placebo did not improve his initial unbalance, even if he was able to conclude the trial differently from his initial test; the same result was obtained also in the follow up session (green data). On the contrary, Patient A showed an encouraging balance in the voluntary pedaling test at the end of the treatment as well as in the follow up test.

4 Discussions

A detailed design of a randomized, single-blinded clinical study comparing post-acute stroke patients performing a treatment of FES cycling with patients undergoing FES placebo cycling, i.e. passive cycling, is currently ongoing at Villa Beretta. The aim of the study is to assess if exercises supported with stimulation of the two legs muscles in a coordinated manner could help in the recovery of autonomous coordination in complex tasks, more than passive execution of similar exercises. The evaluation of the patients is performed either at the end of the treatment, assessing short term benefits and after 3 to 5 months to verify whether such benefits are stable and efficient over long term. The study will include 30 patients; up to now 23 patients have been recruited.

The results of two initial patients (one, Patient A, belonging to FES group and one, Patient B, to placebo group) are compared to show how the assessment will be carried out. Patient A improved significantly both the muscular strength and the pedaling unbalance after 20 days of treatment. Interestingly, follow up tests confirmed that the motor functional improvement showed in the post test was stable and kept similar after few months. On the contrary, Patient B did not show a significant recovery of the motor function of the paretic leg. A slight improvement can be noticed comparing the post and follow up tests. This could mean that the patient needs a longer rehabilitation treatment.

The significance of the reported results is very reduced and only preliminary. A statistical analysis will be performed at the end of the study in order to compare the results of the two groups. Only if a significant difference between the improvements obtained after FES cycling treatment and the ones achieved by means of passive cycling is found, it will be possible to affirm the usefulness of FES cycling to improve and accelerate motor recovery in the lower limbs rehabilitation of post-acute stroke patients.

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6 References


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