FES cycling treatment on hemiplegic patients: preliminary results

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Abstract
This study reports the results obtained by the first stroke patients included in the experimental pilot study started in the Rehabilitation Centre of Villa Beretta. The main objective is to have a clinical evaluation of the FES cycling as a rehabilitation treatment for hemiplegics. A specific protocol was defined in collaboration with the clinical partners and the patients were assigned randomly to a control and a FES cycling group. The improvements of the two groups were compared analysing clinical parameters before and after the rehabilitative treatment. The performance obtained in each day of FES cycling was also analysed in terms of the torque produced at the crank stimulating 8 muscle groups. The preliminary results seem to be encouraging towards the possible integration of FES cycling in the clinical rehabilitation program. General strong conclusions will be possible only at the end of the whole experimental campaign.

1. INTRODUCTION
The study of a complete and rehabilitative method such as FES cycling, is extremely interesting for clinics. This exercise is already used on spinal cord injured (SCI) patients both in laboratory and in clinical environments [1, 2] because it can lead to improved cardiopulmonary fitness, with a corresponding reduction in the likelihood of cardiovascular disease and with an improvement in general health. Although the application of FES on upper extremities is well established in the rehabilitation of hemiplegic patients, there are not studies on the use of FES cycling as a rehabilitation tool. Yan et al. [3] used FES to stimulate 4 muscles (quadriceps, hamstring, tibialis anterior and medial gastrocnemius) of the affected lower limb in order to recreate the walking sequence with the patient side-lying on the bed. This movement is very important but it is not produced bilaterally in the real walking environment. The FES cycling could be more rehabilitative because the patient can learn the sequence of activation of the muscles involved, as in [4], but he can also see the symmetry of the movement and the bilateral use of the legs. FES cycling is assumed to be better than passive cycling because it gives to the patients the complete afference of the task.

In the rehabilitation centre of Villa Beretta, an experimental campaign has started and offers the possibility of having a clinical evaluation of the efficiency of FES cycling on stroke patients. In this paper the results obtained in the first patients are reported.

2. METHODS

2.1 Experimental setup
The THERA-live™ ergometer (Medica Medizintechnik GmbH, Germany) combined with the current-controlled 8 channel stimulator, RehaStim Pro™ (Hasomed GmbH, Germany) were chosen for the experiments. During training, the patient sat on a chair in front of the ergometer. The legs were stabilized by 2 ankle foot orthoses fixed to the pedals. It was possible to control the ergometer through a serial link, by changing the resistance and the speed or by directly setting the motor voltage with Pulsewidth Modulation.

2.2. Selection Criteria
The clinical study is aimed at analysing 30 hemiplegic patients. Patients were randomly shared in a control group, performing the standard rehabilitative program (SRP) and a FES cycling group, performing FES cycling in addition to the SRP. All the patients were post acute hemiplegics able to understand simple instructions, collaborative, without any joint rigidity and with an Ashworth<2 in all the lower limb muscles.

Up to now 3 FES cycling and 3 control patients have already finished the program.

2.3. Pre and post treatment tests
Patients carried out the following preliminary tests: the trunk control test (TCT), the motricity
index (MI), the upright motor control test (UMT), a walking test for 50 meters and a maximal voluntary contraction (MVC) trial to detect the maximum voluntary force developed by the quadriceps in isometric conditions. In addition, sit to stand trials were performed to measure the knee and hip speed and to evaluate the smoothness of the movement. Three different velocities (slow, normal and fast) were required to test the ability to modulate sit to stand execution on task request. FES trials were conducted to detect the force vs. stimulation frequency relationship. The fatigue performance was estimated in terms of force produced during a trial of 3 minutes of quadriceps stimulation. Once these tests had been conducted, the FES cycling rehabilitation started for the group of FES cycling while control group started SRP. The same tests were repeated at the end of the treatment.

2.4. FES cycling treatment

The FES cycling treatment consisted in a daily session of 35 minutes: 5 minutes of passive cycling, 10 minutes of FES, 5 minutes passive, 10 minutes FES and 5 passive. During all the sessions 8 muscle groups (Gluteus maximus, Hamstrings, Rectus Femoris and Tibialis Anterior for each leg) were stimulated and the motor maintained a constant speed of 40rpm.

3. RESULTS

The results obtained in the pre and post treatment tests are reported in table 1.

<table>
<thead>
<tr>
<th>Test</th>
<th>C1</th>
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Table 1: Results of the pre (grey) and post (white) treatment tests on control (C1, C2, C3) and FES (F1, F2, F3) patients. For each patient is reported the kind of stroke (E=morragic, I=ischemic) and the affected side (L=left, R=right). The mean values among C and F patients are also reported.

The FES cycling patients produced a greater improvement in all the tested parameters with respect to the patients of the control group, even though the initial values were similar or better for the control patients. In fact also when the final mean value of the FES patients seemed to be lower than the control one (final MI), the difference between the pre and post test was greater, so that the improvement was clear. In figure 1 the results of the sit to stand trials are shown in the upper panels for one control patient (C2 in table 1) and in the lower panels for one FES cycling patient (F3 in table 1). C2 was able to perform the task since the pre-tests but not modulating it correctly depending on the requested velocity. On the contrary, in the post-test he was better choosing the required speed of execution, even if very small differences were present between natural and fast execution. F3 instead was not able to understand/execute the request in the pre-test. In the post-test instead he was able to execute the task with the proper speed and with a greater range of motion than C2.

To evaluate quantitatively the performance of the FES cycling treatment, the active torque, i.e. the difference between the torque produced in the FES active phases and the passive torque (torque during passive cycling), was computed. Starting from this signal the active torque time integral (TTI) was calculated to evaluate the energetic effort involved in the exercise. The greater is the TTI, the greater is the active energy produced by the patient during the movement. An example of the improvement between the first and last day of treatment is shown in figure 2.
The improvement seems to increase with the going on of the days of treatment.

Anyway a first complete learning of avoiding any negative TTI was assessed by the end of the first week.

4. DISCUSSION AND CONCLUSIONS

The possibility of using a rhythmic, cyclic and bilateral movement such as cycling induced by a symmetrical stimulation pattern delivered to both the legs, seems to be an optimal rehabilitative method for post acute stroke patients. In fact in these patients, who had a monolateral motor impairment, would be very useful to relearn the correct use of both the lower limbs together to recover the motor control symmetry in more complex and demanding tasks, such as walking.

The results obtained in the first 3 patients during the treatment were very good and repeatable and FES cycling seemed to increase the strength, the functionality and the symmetry of the involved muscles in both the legs. Naturally the number of patients is yet too small to assert general conclusions. It would be also important to repeat the clinical tests 3 months after the end of the treatment to evaluate the long term effects.

An analysis of the reorganization of the cerebral cortex considering both the medium and long term effects will be very useful to analyse the real benefits of the treatment.

References


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