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FES-cycling training in Spinal Cord Injured patients

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Abstract— **Among the objectives of spinal cord injury (SCI) rehabilitation, (i) prevention of bony, muscular and joint trophism and (ii) limitation of spastic hypertone represent important goals to be achieved.**

The aim of this study is to use functional electrical stimulation (FES) to activate pedaling on cycle-ergometer and analyse effects of this technique for a rehabilitation training in SCI persons.

Five spinal cord injured subjects were recruited and underwent a two months FES-cycling training.

Our results show an increase of thigh muscular area and endurance after the FES-cycling training, without any increase of spasticity.

This approach, which is being validated on a larger pool of patients, represents a potential tool for improving the rehabilitation outcome of complete and incomplete SCI persons.

I. Introduction

Spinal Cord Injury (SCI) is damage to the spinal cord that results in loss of functions such as mobility. Moreover, strength deficits and progressive reduction of trophism at muscolar, joint, bone level due to total (complete lesion) or limited (incomplete lesion) loss of mobility.

In addition to loss of voluntary motility, a muscular spasticity pattern, characterized by an exaltation of reflex involuntary muscular contraction often hinders motor recovery.

Among the objectives of SCI rehabilitation, (i) prevention of bony, muscular and joint trophism and (ii) limitation of spastic hypertone represent important goals to be achieved. This strategy is important for incomplete SCI persons, where recovery of underlesional voluntary motility is pursued also for functional aims, such as gait but it is fundamental for complete SCI persons in order to facilitate standing posture which represents an important factor of gait.

These persons can achieve gait thank to potential use of innovative robotic orthosis for lower limbs, recently developed.

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Functional Electrical Stimulation (FES) [1] consists in delivering current on nerves and muscles for activating muscular contraction of plegic muscles, such as those underlesional of SCI, in a determined time corresponding to that necessary for physiologic activation of a function, such gait step, hip and knee flexion-extension during cycling [2]-[7].

Previous studies investigated the effects of FES cycling on muscle properties and spasticity [8]-[14]. The novelty of our study consists in the integration of clinical and instrumental evaluations of the effects of FES cycling in complete and incomplete SCI persons.

The aim of this study is to use FES to activate pedaling on cycle-ergometer and analyse the effects of this technique for a rehabilitation training in SCI persons.

II. Methods

The study was performed at the Spinal Cord Centre, University Hospital in Pisa, Italy, according to the principles outlined in the Declaration oh Helsinki. Each subject provided an informed consent.

A. Participants

Five subjects complete and incomplete spinal cord injured (SCI) subjects (mean age 43.0±11.8, four men and one woman) were recruited. The SCI patients were evaluated (Table I) using the ASIA scale [15], [16] and the SCIM (maximum value 100) [17]. Three have complete motor lesions (ASIA A and B) and two incomplete (ASIA C).

TABLE I. Characteristics of SCI Subjects

ID	*Gender*	*Age*	*ASIA*	*Lesion level*	*SCIM*
P1	M	50	C	C7	53
P2	F	42	B	T10	68
P3	M	44	A	T12	71
P4	M	24	B	C7	56
P5	M	55	C	T12	70

B. Training protocol

A motorized cycle-ergometer was used in conjunction with FES (Pegaso, BioTech Srl, Italy). Each subject, after providing informed consent, was asked to perform the exercises planned by the clinical protocol, composed by 20 sessions, three sessions per week for seven weeks, using the cycle-ergometer.

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For each subject, in addition to FES cycling, exercises to increase control movement of the head, arm and trunk were included in the rehabilitation programme. The first session was addressed to familiarization, the duration of the second session was 15 minutes, from the third to the twentieth session 5 minutes were incrementally added, till to 30 minutes.

Electrical stimulation was delivered through 6 independent channels each delivering up to 140 mA current (waveform: balanced biphasic pulse; timing: 50-500μs) on the following muscles (both on right and left leg): quadriceps, femoral biceps and gluteus. Each session was formed by the following four phases: 1) Warm-up (90 sec., maximum speed: 40 cycles/min); 2) Preparation (2 min., maximum stimulation: 30%; 3) Active phase (30 min, target speed: 30 cycles/min, resistance: 5 Nm); 4) Defatigue (20 sec., speed kept by motor: 20 cycles/min).

The motor plays a double role: i) assisting pedaling when muscles are not trained enough, ii) applying a controlled resistance when muscle are able to achieve a minimum power. During 3) electrical stimulation adjusts muscular contractions in order to provide a support to the subject to pedaling using his/her muscular strength. If muscles are not able or trained enough to reach the target speed, resistance is kept at 0 Nm and the motor assists pedaling below a predefined support speed.

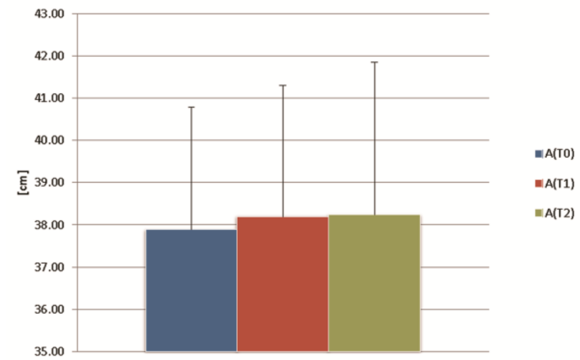
Clinical assessment was carried out before starting the treatment (T0), at mid-treatment (T1), that is after 10 sessions, and at the end of the treatment (T2), that is after 20 sessions. The following outcome measures were collected: (T0): ASIA, SCIM, Modified Ashworth Scale (MAS) [18], 4-point Spasms Scale [19], evaluation of muscle area through measurement of thigh circumference at 5 (A), 10 (B) and 15 (C) cm from the knee cap upper limit; (T1): MAS, Spasms Scale, evaluation of muscle area, cycle parameters; (T2): SCIM, MAS, Spasms Scale, evaluation of muscle area, cycle parameters. The recording of thigh circumference was carried out through a ruler by an experienced therapist.

The following variables were recorded during FES cycling on each session: mean speed, maximum speed, resistance, mean power, maximum power and distance.

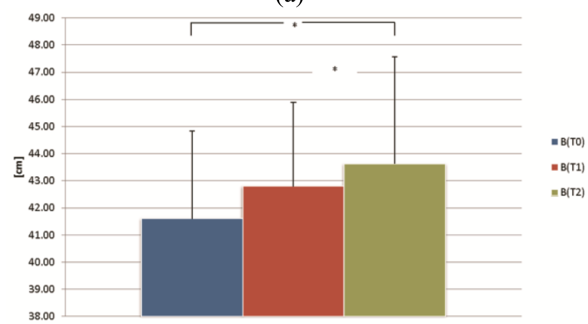
TABLE II. PARAMETERS RECORDED DURING FES CYCLING

	TO	T1	T2
Mean speed (r/min)	20.60±2.51	23.80±4.15	25.40±6.27
Max speed (r/min)	29.80±2.49	32.60±4.04	34.80±6.02
Resistance (Nm)	3.40±2.19	2.80±2.28	3.40±1.67
Mean power (W)	2.86±1.07	3.96±1.99	3.86±2.26
Max power (W)	7.22±5.03	8.28±3.19	7.78±4.11
Distance (m)	2103.80±565.84*	3638.40±997.37	4167.20±1679.71*

Values expressed as mean ± standard deviation. * indicates p<0.05



(a)



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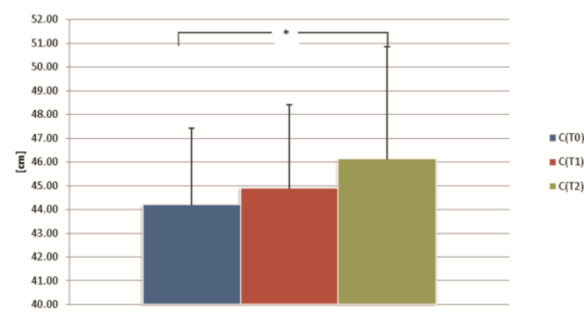

(c)

Figure 1. Thigh circumference values recorded at T0 (blue), T1(red) and T2 (green): measurement at (A) 5, (B) 10, (C) 15 cm from the knee cap upper limit. Bar values expressed as mean ± standard deviation (* indicates p<0.05).

C. *Statistical analysis*

Values of cycling parameters recorded at different times (T0, T1 and T2) were compared using one way analysis of variance (ANOVA) and Kruskal-Wallis One Way ANOVA on Ranks test in case of failure of normality test and/or equal variance test.

The post-hoc pairwise multiple comparison procedure was performed using Holm-Sidak method, and Tukey test in case of failure of normality test.

A paired t-test was used to compare values of thigh circumference between T0 and T1, T1 and T2, and T0 and T2. In case of failure of normality test a Wilcoxon Signed Rank test was used.

A Mann-Whitney Rank Sum test was used for comparing MAS and Spasms Scale values between T0 and T1, T1 and T2, and T0 and T2.

III. RESULTS

Figure 1a, Figure 1b and Figure 1c show values of thigh circumference A, B and C respectively, recorded at T0, T1 and T2. Significant changes were observed in values associated with thigh circumference at 10 cm (B) and 15 cm (C) from the knee cap upper limit at T0 and T2.

Parameters extracted from cycle-ergometer are presented in Table II: mean speed, maximum speed, resistance, mean power, maximum power and distance recorded at T0, T1 and T2.

No significant changes were observed on these parameters ($p>0.05$), except for distance ($p<0.05$) between T0 and T2.

No significant changes were observed on MAS (T0: 2.60±0.89; T1: 2.40±0.55; T2: 2.20±0.84) and Spasms Scale (T0: 1.40±0.89;T1: 1.40±0.89; T2: 1.40±0.89). Anyway, patients referred a sensation of decreased lower limbs rigidity, since the second training session.

IV. DISCUSSION AND CONCLUSION

Our results show an increase in thigh muscular area in complete and incomplete SCI persons after FES cycling. The increase of distance observed after 10 sessions highlights an increased muscular endurance due to FES-cycling.

The results from MAS and Spasms Scale demonstrate that spasticity did not increase during the training. Indeed, patients felt a decreased rigidity.

Based on these preliminary results and previous studies, FES cycling training can provide important advantages to SCI persons in terms of prevention of muscular atrophy.

Additional potential benefits are represented by reduction of spasticity, which is addressed by ongoing study, and increase of bony density.

These preliminary results have to be confirmed by studies on a larger pool of patients, currently in progress.

As future perspective, FES cycling can be used at the patient home as training for maintenance of trophism and can represent an effective tool to facilitate standing posture in complete SCI persons.

REFERENCES

[1] M. R. Popovic, A. Curt, T. Keller, and V. Dietz, "Functional electrical stimulation for grasping and walking: indications and limitations," *Spinal Cord*, vol. 39, pp. 403-412, 2001.

[2] R. K. Shields, S. Dudley-Javoroski, and L. A. Law, "Electrically induced muscle contractions influence bone density decline after spinal cord injury," *Spine*, vol. 31, pp. 548-553, March 2006.

[3] A. Frotzler, S. Coupaud, C. Perret, T. H. Kakebeeke, K. J. Hunt, and P. Eser, "Effect of detraining on bone and muscle tissue in subjects with chronic spinal cord injury after a period of electrically-stimulated cycling: a small cohort study," *J Rehabil Med*, vol. 41, pp. 282-285, Mar 2009.

[4] H. C. Lo, C. Y. Yeh, F. Su, and K. H. Tsai, "Comparison of energy costs leg-cycling with or without functional electrical stimulation and manual wheelchairs for patients after stroke," *J Rehabil Med*, vol. 42, pp. 645-649, Jul 2010.

[5] C. Perret, H. Berry, K. J. Hunt, N. Donaldson, and T. H. Kakebeeke, "Feasibility of functional electrical stimulated cycling in subjects with spinal cord injury: an energetic assessment," *J Rehabil Med*, vol. 42, pp. 873-875, Oct 2010.

[6] T. E. Johnston, B. T. Smith, O. Oladeji, R. R. Betz, and R. T. Lauer, "Outcomes of a home cycling program using functional electrical stimulation or passive motion for children with spinal cord injury: a case series," *J Spinal Cord Med*, vol. 31, pp. 215-221, 2008.

[7] J. S. Petrofsky, and R. Stacy, "The effect of training on endurance and the cardiovascular responses of individuals with paraplegia during dynamic exercise induced by functional electrical stimulation," *Eur J Appl Physiol*, vol. 64, pp. 487-492, 1992.

[8] K.J. Hunt, J. Fang, J. Saengsuwan, M. Grob, and M. Laubacher, "On the efficiency of FES cycling: A framework and systematic review," *Technology and Health Care*, vol. 20, pp. 395-422, 2012.

[9] C. Fornusek, G.M. Davis,. and I. Baek, "Stimulation of shank muscles during functional electrical stimulation cycling increases ankle excursion in individuals with spinal cord injury," *Archives of Physical Medicine and Rehabilitation*, vol. 93, pp. 1930-1936, November 2012.

[10] J. Szecsi, and M. Schiller, "FES-propelled cycling of SCI subjects with highly spastic leg musculature," *NeuroRehabilitation*, vol.24, pp. 243-253, 2009.

[11] P. Krause, J. Szecsi, and A. Straube, "Changes in spastic muscle tone increase in patients with spinal cord injury using functional electrical stimulation and passive leg movements," *Clinical Rehabilitation*, vol. 22, pp. 627-634, 2008.

[12] L. D. Duffell, N. D. N. Donaldson, T. A. Perkins, D. N. Rushton, K. J. Hunt, T. H. Kakebeeke, and D. J. Newham, "Long-term intensive electrically stimulated cycling by spinal cord-injured people: effect on muscle properties and their relation to power output," *Muscle and Nerve*, vol. 38, pp. 1304-1311, October 2008

[13] A. Frotzler, S. Coupaud, C. Perret, T. H. Kakebeeke, K. J. Hunt, N. D. N. Donaldson, and P. Eser, "High-volume FES-cycling partially reverses bone loss in people with chronic spinal cord injury," *Bone*, vol. 43, pp. 169-176, July 2008.

[14] A.M.E Scremin, L. Kurta, A Gentili, B. Wiseman, K. Perell, C. Kunkel, and O. U. Scremin, "Increasing muscle mass in spinal cord injured persons with a functional electrical stimulation exercise program," *Archives of Physical Medicine and Rehabilitation*, vol. 80, pp. 1531-1536, December 1999.

[15] P. Baranowski, "Application of the international standards for the neurological and functional classification of spinal cord injuries (the ASIA scale)," *Ortop. Traumatol. Rehabil*., vol. 2, pp. 31-34, 2000.

[16] M. Jonson, A. Tollbäck, H. Gonzales, and J. Borg, "Inter-rater reliability of the 1992 international standards for neurological and functional classification of incomplete spinal cord injury," *Spinal Cord*, vol. 38, pp. 675-679, 2000.

[17] A. Catz, M. Itzkovitch, F. Steinberg, O. Philo, H. Ring, J. Rosen, R. Spasser, R. Gepstein, and A. Tamir, "The Catz-Itzkovich SCIM: a revised version of the spinal cord independence measure," *Disability and Rehabilitation*, vol. 23, pp. 263-268, 2001.

[18] R. W. Bohannon, and M. D. Smith, "Interrater reliability of a modified Ashworth scale of muscle spasticity," *Phys Ther*, vol. 67, pp. 206–207, 1987.

[19] R. D. Penn, S. M. Savoy, D. Corcos, M. Latash, G. Gottlieb, B. Parke, and J. S. Kroin, "Intrathecal baclofen for severe spinal spasticity," *N Engl J Med*, vol. 320, pp. 1517-1521, 1989.