Spinal Cord (2015) 53, 866–869

www.nature.com/sc

ORIGINAL ARTICLE

The effect of functional electrical stimulation cycling on late functional improvement in patients with chronic incomplete spinal cord injury

This article has been corrected since advance online publication and a corrigendum is also printed in this issue.

E Yaşar, B Yılmaz, S Göktepe and S Kesikburun

Study design: Prospective single-arm study.
Objectives: To investigate the effect of functional electrical stimulation (FES) cycling on late functional recovery, spasticity, gait parameters and oxygen consumption during walking in patients with chronic incomplete spinal cord injury (SCI).
Setting: Turkish Armed Forces Rehabilitation Center, Ankara, Turkey.
Methods: Ten patients with chronic (duration of more than 2 years) incomplete SCI who could ambulate at least 10 m independently or with the assistance of a cane or walker, but no hip-knee-ankle-foot orthosis. The subjects underwent 1-h FES cycling sessions three times a week for 16 weeks. Outcome measures including the total motor score, the Functional Independence Measure (FIM) score, the Modified Ashworth Scale for knee spasticity, temporal spatial gait parameters and oxygen consumption rate during walking were assessed at baseline, 3 and 6 months after the baseline.
Results: There were statistically significant improvements in total motor scores, the FIM scores and spasticity level at the 6-month follow-up ($P<0.01$). The changes in gait parameters reached no significant level ($P>0.05$). Oxygen consumption rate of the patients showed significant reduction at only 6 months compared with baseline ($P<0.01$).
Conclusion: The results suggest that FES cycling may provide some functional improvements in the late period of SCI.
Sponsorship: The study was supported by The Scientific and Technological Research Council of Turkey (TUBITAK).
Spinal Cord (2015) **53,** 866–869; doi:10.1038/sc.2015.19; published online 17 February 2015

INTRODUCTION

The possibility of functional recovery is not expected in the late period of spinal cord injury (SCI). Motor recovery occurs mostly within the first 6 months postinjury and continues during the second year at a slower pace and to a smaller degree. Conversion from neurologically complete to motor incomplete status has been reported at rates of only up to 2.1% between 1 and 5 years postinjury, whereas in the period from initial early examination to 1-year follow-up, the rate of this conversion has been reported as 8.8%.[1] However, the possibility of late recovery in SCI with 'activity-based therapies' has been mentioned.[2] In this context, functional electrical stimulation (FES) cycling has been suggested to promote recovery after incomplete SCI.[3,4] External electrical stimulation has been shown to affect neural plasticity.[5] It was hypothesized that stimulation of the motor axons restore the nerve conduction by modifying the synaptic organization in the central nervous system.[6] Reciprocal movements similar to walking such as cycling may also lead to central activation via lower extremity reciprocal sensory feedback.[3] Based on these principles, FES cycling may have a potential therapeutic effect for functional recovery.

Studies on FES cycling in SCI have focused on its preventive effect on long-term cardiopulmonary and metabolic dysfunctions.[7,8] As non-ambulatory subjects have been mostly recruited in those studies, the effect of FES cycling on functional recovery and ambulation has not been sufficiently studied in patients with chronic incomplete SCI. The objective of this study was to investigate the effect of FES cycle training on late functional improvement, muscle tone, gait parameters and energy consumption in patients with chronic incomplete SCI.

MATERIALS AND METHODS

Study design and participants

A prospective single-arm experimental design with a 6-month follow-up was undertaken to show the effects of FES cycling in chronic SCI. One hundred and forty-three patients with SCI who were admitted to our rehabilitation center were considered for inclusion against the following inclusion criteria: (1) age of 15 to 65 years (excluding pediatric and geriatric patients), (2) minimum duration of 2 years postinjury, (3) incomplete SCI of traumatic origin, (4) ability to walk independently or with a cane/walker (without a knee-ankle-foot orthosis) at least 10 m and (5) ASIA (American Spinal Injury Association) impairment scale of C or D. Patients were excluded if they had (1) cardiopulmonary instability, (2) severe spasticity or joint contracture in the lower extremities that interfered with cycling, (3) metallic implants in the lower extremities, (4) lower motor neuron injury (cauda equina and conus medullaris syndrome) and (5) any other neurological or muscular disorders. Patients who met these criteria were also tested with the electrical stimulation, and those not responsive to electrical stimulation or who could not tolerate the required stimulation level were also excluded.

Gülhane Military Medical Academy, Department of Physical Medicine and Rehabilitation, Turkish Armed Forces Rehabilitation Center, Ankara, Turkey
Correspondence: Dr E Yaşar, Gülhane Military Medical Academy, Department of Physical Medicine and Rehabilitation, Turkish Armed Forces Rehabilitation Center, Ankara 06530, Turkey.
E-mail: evrenyasar@yahoo.com
Received 21 August 2014; revised 9 January 2015; accepted 14 January 2015; published online 17 February 2015

Of the 20 patients who met the study criteria, 5 did not wish to participate in the study, and thus 15 patients underwent the electrical stimulation test. Following the test, 5 patients were excluded, leaving 10 patients for evaluation in the study. All participants provided written informed consent. The study protocol was approved by the Local Ethics Committee.

Intervention

The patients were placed in their own wheelchair in front of the FES cycling system (RT 300-SLSA; Restorative Therapies, Baltimore, MD, USA). The feet and legs of the patients were securely strapped to the pedals and calf rests of the cycling system. Quadriceps, hamstrings and gluteal muscles were stimulated bilaterally with six channels via $3\times4\,cm^2$ adhesive surface electrodes to provide muscle contraction for cycling without manual assistance. Active electrodes, placed on the quadriceps, were at the midpoint between the anterior superior iliac spine and the patella. Active electrodes, placed on the hamstrings, were at the midpoint between the iliac tuberosity and popliteal fossa. Active electrodes, placed on the gluteal muscles, were at the midpoint between the iliac crest and iliac tuberosity. Reference electrodes were placed 2 cm above the patella, 2 cm above the popliteal fossa and 2 cm above the iliac tuberosity on the quadriceps, hamstrings and gluteal muscles, respectively. Stimulation parameters were as follows: pulse width, 250 μs; pulse frequency, 20 Hz; and amplitude, between 10 and 140 mA. The stimulation intensity was adjusted according to a palpable muscle contraction and a sensory discomfort felt by the patients who had an incomplete SCI. The range of pedaling cadence was set to 40–50 rotations per minute. Electrical stimulation controlled by the system was applied in a proper pattern to the bilateral quadriceps, hamstrings and gluteal muscles to produce a smooth pedaling motion. The patients were warned not to make any voluntary muscle contraction during cycling and the legs were passively moved. One-hour cycling sessions were conducted three times a week for 16 weeks. After finishing the 16-week FES cycling program, the patients had no additional training program until check visit at 6 months. They were instructed to do only routine daily activities.

Outcome measures

Outcome measurements included the following: (1) total motor score obtained from the standardized AIS (American Spinal Injury Association Impairment Scale) clinical exam, (2) the Functional Independence Measure (FIM) score, (5) Modified Ashworth Scale (MAS) assessed on both knees (quadriceps and hamstring) for spasticity evaluation,[9] (4) three-dimensional gait analysis and (5) oxygen consumption during walking. Outcome measures were assessed at baseline, then at 3 and 6 months after the baseline measurement.

The FIM score is the sum of the ratings for each of 18 tasks including 13 motor items and 5 cognitive items.[10] Each task rating ranges from one (full assistance required) to seven (complete independence). Hence, the total FIM score ranges from 18 (least favorable) to 126 (most favorable). The assessment of the FIM score, motor score and MAS were conducted by the same investigator.

Table 1 Demographic and clinical characteristics of the patients

Patients	*Sex*	*Age (years)*	*Neurological lesion level*	*AIS*	*Time since SCI (months)*	*Etiology*
1	M	26	T5	C	31	Trauma
2	M	33	T12	D	28	Trauma
3	M	26	T9	D	24	Trauma
4	F	58	C4	D	24	Trauma
5	M	34	C5	D	32	Trauma
6	M	54	C4	D	24	Myelomalacia
7	F	25	T11	D	33	Trauma
8	F	24	T12	D	30	Trauma
9	M	54	C4	D	24	Trauma
10	F	41	C4	D	24	Trauma

Abbreviations: AIS, American Spinal Injury Association (ASIA) Impairment Scale; C, cervical; F, female; M, male; SCI, spinal cord injury; T, thoracic.

Gait analysis was performed using a three-dimensional, seven-camera, VICON 512 motion measurement system (Oxford Metrics Ltd, Oxford, UK). The VICON Clinical Manager software was used for calculating and plotting data. Fifteen reflective markers were placed on specific anatomic landmarks bilaterally of the subject's pelvis, thighs, shanks and feet. Anthropometric measures including height, weight, leg length and width of ankles and knees were taken for appropriate anthropometric scaling. After three or four practices in the laboratory, each subject was instructed to walk at a self-selected speed along a walkway with two force plates embedded in the floor. As many walks as necessary were carried out by each patient to achieve a clean trial on at least three occasions. Temporal spatial parameters including gait velocity ($m\,s^{-1}$), cadence (steps per min), step length (m) and stride length (m) were analyzed.

Oxygen consumption during walking was estimated with a collection of expired gases from the mouth. Oxygen consumed was calculated as the difference between the amount of oxygen that entered and the amount that left the respiratory chamber. Oxygen consumption was measured with the breath-by-breath method using an open-circuit indirect calorimeter (Vmax 29c; Sensormedics, Yorba Linda, CA, USA). After receiving an introduction, each patient practiced using the mask and treadmill beforehand. After an adequate rest period with the facemask, the test was performed for 5 min of treadmill walking at a speed of $0.5\,m\,s^{-1}$. Aerobic demand (VO_2) was determined from an expired air sample collected during the final 2 min of each 5-min walk. Gait analysis and oxygen consumption measurements were carried out on the same day with sufficient resting periods.

Statistical analysis

Data analysis was performed using SPSS for Windows, version 13.0 (SPSS Inc., Chicago, IL, USA). Data are presented as mean ± s.d., unless otherwise indicated. Repeated measurement comparisons within the groups were evaluated by the Friedman test. *Post hoc* analysis with Wilcoxon's signed-rank tests was conducted with a Bonferroni correction. A value of $P<0.05$ was considered statistically significant.

RESULTS

Six male (60%) and 4 female (40%) subjects with a mean age of 37.5 ± 13.3 years participated in the study. The mean time since injury was 27.4 ± 3.8 months. There were five patients with cervical injury (50%) and five patients with thoracic injury (50%). Detailed demographic and clinical characteristics of the patients are presented in Table 1.

There was a significant increase in the motor score and in the FIM score at 3 and 6 months in comparison with baseline ($P<0.01$, Wilcoxon's test). The spasticity level of both the rectus femoris and hamstring muscles showed a significant decrease at 3 and 6 months compared with baseline ($P<0.01$, Wilcoxon's test). In gait analysis, temporal spatial parameters including gait velocity, cadence, step length and stride length increased, but reached no significant level, neither at 3 nor at 6 months ($P>0.05$, Wilcoxon's test). Oxygen consumption rate of the patients showed a reduction, which indicated an improvement in the efficiency of treadmill walking, and reached a significant level only at 6 months compared with baseline ($P<0.01$, Wilcoxon's test). Study outcome data are presented in Table 2.

DISCUSSION

FES cycle training resulted in a significant improvement in the motor score and the FIM score of patients with chronic SCI at the 6-month follow-up. Reduced muscle tone with the intervention was demonstrated in the study. Gait analysis did not show any significant changes in the temporal spatial parameters. FES cycling decreased oxygen consumption during walking.

FES cycling reduces muscle atrophy by providing contraction of the paralyzed muscles and increases the limb muscle mass without changing adipose tissue in SCI.[11] FES exercise programs have been

Table 2 Study outcome data[a]

	Baseline	*3 Months*	*6 Months*
Motor score	78.0 (72.2–94.0) [79.9 ± 11.8]	80.5 (73.5–5.0) [81.6 ± 11.2][b]	81.0 (77.7–95.5) [84.6 ± 8.6][b]
FIM score	116.0 (108.5–119.5) [109.8 ± 19.9]	119.5 (113.2–123.5) [113.9 ± 17.9][b]	120.0 (115.2–123.7) [116.5 ± 13.3][b]
Spasticity (MAS)			
Rectus femoris	2.0 (2.0–2.0) [2.1 ± 0.3]	1.0 (0.0–1.0) [0.6 ± 0.5][b]	1.0 (0.0–1.0) [0.9 ± 0.7][b]
Hamstring	2.0 (1.0–2.0) [1.7 ± 0.4]	0.0 (0.0–1.0) [0.4 ± 0.5][b]	1.0 (0.0–1.0) [0.7 ± 0.4][b]
Temporal spatial parameters			
Gait velocity ($m s^{-1}$)	0.33 (0.13–0.62) [0.38 ± 0.24]	0.46 (0.18–0.70) [0.44 ± 0.25]	0.45 (0.16–0.69) [0.42 ± 0.24]
Cadance (steps per min)	56.5 (37.0–84.2) [58.7 ± 28.4]	65.1 (40.2-88.5) [63.9 ± 28.8]	59.7 (40.2-89.3) [62.2 ± 28.7]
Step length (m)	0.37 (0.30–0.45) [0.36 ± 0.12]	0.41 (0.34–0.51) [0.41 ± 0.13]	0.43 (0.30–0.46) [0.41 ± 0.13]
Stride length (m)	0.77 (0.52–0.95) [0.75 ± 0.23]	0.78 (0.63–0.95) [0.80 ± 0.26]	0.83 (0.71–0.93) [0.82 ± 0.25]
Oxygen consumption (VO_2) ($ml\,kg^{-1}$ per min)	7.90 (6.72–9.50) [8.03 ± 1.71]	5.95 (5.60–9.35) [7.23 ± 2.08]	5.70 (5.60–7.87) [6.53 ± 2.19][b]

Abbreviations: FIM, Functional Independence Measure; MAS, Modified Ashworth Scale.
[a]Median (interquatile range) [mean ± s.d.].
[b]Significant difference in comparison with baseline ($P<0.01$, Wilcoxon's test).

seen to provide larger muscle hypertrophy than regular exercise programs in human and animal models.[12] FES cycle training produces a gain in muscle strength and motor score as well as muscle hypertrophy in patients with SCI.[13,14] In a randomized controlled trial by Johnston *et al.*[15] of pediatric SCI cases, an increase was seen in quadriceps strength with 6 months of FES exercise in comparison with passive cycling and non-cycling electrical stimulation and an increase in quadriceps muscle volume was determined with both FES and non-cycling electrical stimulation. Duffel *et al.*[16] reported improvements in quadriceps torque and power output with a 1-year FES cycling exercise program in patients with SCI. In addition to studies assessing the effect of FES cycling on muscle in a laboratory setting, the clinical relevance of this gain in muscle strength and size by FES has also been evaluated by clinical outcomes reflecting functional improvement in SCI. Donaldson *et al.*[3] reported an improvement in the voluntary strength of the knee extensors and leg functions with FES cycling in patients with a 10-year history of incomplete SCI. In a retrospective cohort study by Sadowsky *et al.*,[4] significantly greater gains were determined in motor–sensory score, with a higher increase in quadriceps and hamstring muscle strength, higher quality of life and daily function measures in patients with chronic SCI who received FES cycling compared with those of control patients who received only exercise therapy. Kuhn *et al.*[17] showed that a 20-min FES cycling program 2 days per week for 4 weeks implemented in the acute care unit improved the size and strength of the lower extremity muscles and the walking ability measured with clinical testing in patients with complete and incomplete SCI, most of whom were in the early phase of injury. The present study revealed improvements with FES cycling in the motor score of patients with SCI of minimum 2-year duration. This functional recovery is likely based on mechanisms of plasticity and neural regeneration. FES cycling produces a sensory feedback and neural activity to spinal cord in a similar to normal pattern, which was not seen after SCI. This neural activity is suggested to elicit a molecular and cellular events required for regeneration.[4,18–20] This functional improvement might also have a positive effect on daily living activities. It is possible that the increase in FIM is related to the increase in the motor score at the 6-month follow-up. In the present study, FES cycling led to a decrease in spasticity, which was consistent with previous studies.[17,21,22] Increase in muscle strength may allow to counteract spasticity in a more effective manner. FES-induced neural activity may change the balance of excitation in favor of inhibition in spinal cord by inducing neuroanatomical plasticity.[4] The improvements in the motor score, FIM score and spasticity, while significant, is small and should be considered in the light of the fact that the study was neither controlled nor blinded. In addition, the motor score was determined by manual muscle testing, which was a subjective tool.

Temporal spatial parameters in gait analysis improved in accordance with the functional recovery, although they did not show significant changes. As spasticity has a role in the pattern of abnormality in gait after SCI,[23] a decrease in spasticity may have a positive effect on gait parameters in the study. However, this improvement did not evoke a significant change, probably because of the small number of subjects. Future studies of a larger population may reveal the possible positive effect of FES on gait parameters. Measuring the oxygen consumption provides comprehensive information on gait performance in patients with SCI.[24] The energy expenditure of walking after SCI was found to be high.[25] The results of the current study showed that FES cycling exercises decreased oxygen consumption during walking. It could be regarded as another parameter in favor of improvement in gait performance of the subjects. Increase in muscle strength and decrease in spasticity might allow a better posture and body movements during walking, which reduced deviations from normal gait pattern and led to need a less energy for the activity of walking.

The small patient group, the lack of a control group and blinding are the primary limitations of this study, as the measurements used required a level of subjective judgment. Even if the same person assessed the outcome measures, the day-to-day reliability of these assessments was not known in the study. Although this study demonstrated beneficial effects of FES cycling on functional recovery, future studies with randomized controlled design and a larger number of subjects are required to confirm the role of FES exercises in the management of chronic SCI. In terms of generalizability of the results, sample size could be increased in the future studies. One drawback of the study is that these patients had incomplete injuries and it is possible that their improvements could be due to voluntary efforts during the cycling rather than to the electrical stimulation itself. It is also impossible to determine whether the functional gains were due to neurological changes or to simply increasing muscle mass. If a measure of power output had been used, it might have shown how much work was being carried out via muscle contractions. Future studies with a control group that got cycling exercise without electrical stimulation would also account for this controversial point. Nonetheless, there was a significant improvement after FES exercises. A limitation with respect to methodology is that there was a period of about 2 months between the completion of training and the final follow-up measure at 6 months, which was not controlled except for requesting that participants only engage in routine activities. It should be noted that the results at 6 months might have been influenced by what was carried out in this 2-month period.

CONCLUSION

In conclusion, a 16-week FES cycling exercise program increased the muscle motor score and FIM score of patients with chronic incomplete SCI. Gait parameters did not show a significant improvement, whereas oxygen consumption during walking decreased with the intervention. These results suggest that FES cycling might be used to promote late functional improvement in chronic SCI.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

The study was supported by The Scientific and Technological Research Council of Turkey (TUBITAK-108S229).

1 Kirshblum S, Millis S, Mckinley W, Tulsky D. Late neurologic recovery after traumatic spinal cord injury. *Arch Phys Med Rehabil* 2004; **85**: 1811–1817.
2 Lorenz DJ, Datta S, Harkema SJ. Longitudinal patterns of functional recovery in patients with incomplete spinal cord injury receiving activity-based rehabilitation. *Arch Phys Med Rehabil* 2012; **93**: 1541–1552.
3 Donaldson N, Perkins TA, Fitzwater R, Wood DE, Middleton F. FES cycling may promote recovery of leg function after incomplete spinal cord injury. *Spinal Cord* 2000; **38**: 680–682.
4 Sadowsky CL, Hammond ER, Strohl AB, Commean PK, Eby SA, Damiano DL *et al.* Lower extremity functional electrical stimulation cycling promotes physical and functional recovery in chronic spinal cord injury. *J Spinal Cord Med* 2013; **36**: 623–631.
5 Daly JJ, Marsolais EB, Mendell LM, Rymer WZ, Stefanovska A, Wolpaw JR *et al.* Therapeutic neural effects of electrical stimulation. *IEEE Trans Rehab Eng* 1996; **4**: 218–230.
6 Rushton DN. Functional electrical stimulation and rehabilitation—an hypothesis. *Med Eng Phys* 2003; **25**: 75–78.
7 Davis GM, Hamzaid NA, Fornusek C. Cardiorespiratory, metabolic, and biomechanical responses during functional electrical stimulation leg exercise: health and fitness benefits. *Artif Organs* 2008; **32**: 625–629.
8 Fornusek C, Gwinn TH, Heard R. Cardiorespiratory responses during functional electrical stimulation cycling and electrical stimulation isometric exercise. *Spinal Cord* 2014; **52**: 635–639.
9 Craven BC, Morris AR. Modified Ashworth Scale reliability for measurement of lower extremity spasticity among patients with SCI. *Spinal Cord* 2010; **48**: 207–213.
10 Hall KM, Cohen ME, Wright J, Call M, Werner P. Characteristics of the Functional Independence Measure in traumatic spinal cord injury. *Arch Phys Med Rehabil* 1999; **80**: 1471–1476.
11 Scremin AM, Kurta L, Gentili A, Wiseman B, Perell K, Kunkel C *et al.* Increasing muscle mass in spinal cord injured persons with a functional electrical stimulation exercise program. *Arch Phys Med Rehabil* 1999; **80**: 1531–1536.
12 Wise AK, Morgan DL, Gregory JE, Proske U. Fatigue in mammalian skeletal muscle stimulated under computer control. *J Appl Physiol* 2001; **90**: 189–197.
13 Fornusek C, Davis GM, Russold MF. Pilot study of the effect of low-cadence functional electrical stimulation cycling after spinal cord injury on thigh girth and strength. *Arch Phys Med Rehabil* 2013; **94**: 990–993.
14 Griffin L, Decker MJ, Hwang JY, Wang B, Kitchen K, Ding Z *et al.* Functional electrical stimulation cycling improves body composition, metabolic and neural factors in persons with spinal cord injury. *J Electromyogr Kinesiol* 2009; **19**: 614–622.
15 Johnston TE, Modlesky CM, Betz RR, Lauer RT. Muscle changes following cycling and/or electrical stimulation in pediatric spinal cord injury. *Arch Phys Med Rehabil* 2011; **92**: 1937–1943.
16 Duffell LD, Donaldson Nde N, Perkins TA, Rushton DN, Hunt KJ, Kakebeeke TH *et al.* Long-term intensive electrically stimulated cycling by spinal cord-injured people: effect on muscle properties and their relation to power output. *Muscle Nerve* 2008; **38**: 1304–1311.
17 Kuhn D, Leichtfried V, Schobersberger W. Four weeks of functional electrical stimulated cycling after spinal cord injury: a clinical cohort study. *Int J Rehabil Res* 2014; **37**: 243–250.
18 McDonald JW. Repairing the damaged spinal cord: from stem cells to activity-based restoration therapies. *Clin Neurosurg* 2004; **51**: 207–227.
19 Becker D, Sadowsky CL, McDonald JW. Restoring function after spinal cord injury. *Neurologist* 2003; **9**: 1–15.
20 Gary DS, Malone M, Capestany P, Houdayer T, McDonald JW. Electrical stimulation promotes the survival of oligodendrocytes in mixed cortical cultures. *J Neurosci Res* 2012; **90**: 72–83.
21 Krause P, Szecsi J, Straube A. Changes in spastic muscle tone increase in patients with spinal cord injury using functional electrical stimulation and passive leg movements. *Clin Rehabil* 2008; **22**: 627–634.
22 Rayegani SM, Shojaee L, Soroush MR, Baghbani M, Amirani OB. The effect of electrical passive cycling on spasticity in war veterans with spinal cord injury. *Front Neurol* 2011; **2**: 39.
23 Krawetz P, Nance P. Gait analysis of spinal cord injured subjects: effects of injury level and spasticity. *Arch Phys Med Rehabil* 1996; **77**: 635–638.
24 Waters RL, Yakura SJ, Adkins RH. Gait performance after spinal cord injury. *Clin Orthop* 1993; **288**: 87–96.
25 Ulkar B, Yavuzer G, Guner R, Ergin S. Energy expenditure of the paraplegic gait: comparison between different walking aids and normal subjects. *Int J Rehabil Res* 2003; **26**: 213–217.