Four weeks of functional electrical stimulated cycling after spinal cord injury: a clinical cohort study

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The aim of this study was to determine the efficacy and the effects of functional electrical stimulated cycling (FES cycling) in patients with spinal cord injury during their rehabilitation in a special acute care unit. Thirty patients [10 with American Spinal Injury Association Impairment Scale (AIS) grade A, three with AIS grade B, 15 with AIS grade C, two with AIS grade D] aged 44±15.5 years and 2 (median) (interquartile range, 1.0–4.25) months after spinal cord injury were included in the study. The patients participated in a 20-min FES-cycling program 2 days per week for 4 weeks during their acute inpatient rehabilitation. The influence on muscle cross-section, muscle and leg circumference, spasticity, and the walking ability parameter (distance, time, aids) was measured. Muscle stimulation intensity and output parameters (pedalling time and distance) were also recorded. Spasticity decreased during hip abduction and adduction (70 and 98.1%, respectively). Spasticity during knee flexion and knee extension decreased by 66.8 and 76.6%, and a decrease was found during dorsal foot extension (67.8%; for all, $P<0.05$). Presession–postsession comparisons showed that after 4 weeks of FES cycling, an increase in the circumference of the cross-sectional area of 15.3% on the left and of 17% on the right m. rectus femoris could be observed in group AIS A+B. In the AIS C+D group, the circumference of the left m. rectus femoris increased by 25% and that of the right m. rectus femoris by 21% (for all, $P<0.05$). The results of the study show that FES cycling in combination with function-oriented physiotherapy and occupational therapy can have a positive influence on spasticity, walking ability, and muscular reactivation. It seems to support circulatory processes within the rehabilitation of paraplegics already after a 4-week intervention. ***International Journal of Rehabilitation Research*** **37:243–250 © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

Every year, approximately 19 individuals per one million inhabitants in Europe suffer from spinal cord injury (SCI) (Wyndaele and Wyndaele, 2006). In Germany, 24 special care centers with a total of 1139 beds exist (Giesecke and Röhl, 2010). A traumatic SCI caused by an accident mostly occurs in individuals aged between 16 and 30 years (Sadowsky *et al.*, 2002). In case of paralysis, all areas of life change markedly. Among others, the most relevant medical problems after a SCI are reduced sensory–motor capacities and disorders of cardiovascular functions [e.g. risk of a disturbed vasoregulation (Jacobs and Nash, 2004), and deep vein thrombosis (Myers *et al.*, 2007)] below the damaged area of the spinal cord. As a consequence, patients with SCI experience significant deterioration in almost all activities of daily life (e.g. standing and stepping) (Sadowsky *et al.*, 2002).

Functional electrical stimulation (FES) is considered to be an important training supplement for the prevention of secondary diseases in SCI such as deep vein thrombosis and vascular dysfunctions (Phillips *et al.*, 2011). This therapeutic intervention can lead to improved blood flow in the stimulated muscle and limb by stimulating peripheral nerves and inducing muscle contractions, which finally result in joint movement.

It has been proven that spasticity and frequency of spasms can be reduced by FES (Sadowsky *et al.*, 2002; Jacobs and Nash, 2004; Davis *et al.*, 2008). FES training can delay the reduction in muscle fiber size (Crameri *et al.*, 2000) and the change in myosin heavy-chain composition from type 2b to 2a (Mohr *et al.*, 1997). For FES cycling, surface electrodes are used for muscle stimulation combining single muscle contraction and cycling with a complete 360° cycle. Thus, functional movement of the affected limb can be achieved. The use of this specific therapeutic intervention method is recommended for both paraplegic and tetraplegic patients (Wilder *et al.*, 2002; Jacobs and Nash, 2004). In detail, the activation of muscle motor control, tissue perfusion, and spasticity reduction are aims that should be pursued for both groups to achieve the best possible treatment results.

The application of FES cycling requires the presence of a physiological range of motion in the lower extremities, a moderate level of spasticity and frequency of spasms,

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a stable skin condition, and no bone fractures or metal implants in the stimulation area. The stimulation of a muscle with impaired motor function requires an intact lower motor neuron.

In established therapeutic SCI treatments, aiming for functional improvements, it is very difficult to maintain sufficient blood circulation in the paralyzed lower extremities as well as muscles.

This study was designed to assess the possibility of determining measurable effects on lower extremity muscle and leg size, as well as changes in muscle tone and parameters of ambulation using low level FES-cycling parameters during the acute rehabilitation after SCI.

Materials and methods

Patients

This prospective clinical cohort study was carried out in the Spinal Cord Injury Center of the Berufsgenossenschaftliche Kliniken Bergmannstrost (Halle, Germany). All 30 patients were classified on the basis of the American Spinal Injury Association Impairment Scale (AIS) (Savic *et al.*, 2007). Thirteen motor complete and 17 motor incomplete male SCI patients (13 tetraplegics and 17 paraplegics) between 20 and 67 years of age voluntarily served as study participants. All 30 SCI patients included in the study were part of the acute-stationary rehabilitation process in the SCI unit. The mean age of the patients was 44±15.5 years. The time after SCI ranged between 0 (< 4 weeks) and 122 months [2.0 (interquartile range 1.0–4.25)]. The lesion of the spinal cord was located between the fourth cervical and the fifth lumbar segment. Thirteen patients (43.4%) had a cervical, 11 patients (36.7%) had a thoracic, and six patients (20%) had a lumbar spinal lesion. Thirteen patients (43.3%) had no motor function below the neurological level (10 AIS A; three AIS B) and 17 patients (56.7%) had function in the key muscles below the neurological level (15 AIS C; two AIS D; see Table 1). Patients 2, 8, and 26 were included in the study because they were immobilized over a long period because of severe paralysis-related complications and were integrated into the acute inpatient treatment during their healing process like the other patients.

Inclusion/exclusion criteria

All patients received a pretraining screening

Inclusion criteria were SCI below the forth cervical segment, truncated spinal shock, no severe joint contracture, mobilization in the wheelchair, and possible stimulation with determined stimulation parameters.

Exclusion criteria were previous or unconsolidated bone fractures in the trochanteric and in the pelvis area of both legs, metal implants in the area of stimulation, decubitus ulcer, cardiac pacemaker, acute heterotopic ossification, severely reduced flexibility of joints in the lower extremities, and severe leg spasticity [Modified Ashworth Scale (MAS) grade 4].

Table 1 Anthropometric and injury-related data of the patients

Patient number	Age	Lesion level	Level AIS	Months after injury
1	57	C5	D	6
2	57	Th12	A	13
3	22	Th12	C	1
4	46	Th7	A	1
5	45	L1	C	1
6	59	C6	B	3
7	20	Th5	A	2
8	31	Th12	C	54
9	34	Th8	A	2
10	58	Th5	C	2
11	28	Th12	D	7
12	67	C7	C	0
13	55	C4	C	0
14	26	C4	C	4
15	65	L5	C	2
16	63	C6	C	1
17	32	C6	A	1
18	47	L1	C	4
19	66	Th8	A	2
20	29	C6	A	7
21	67	Th4	C	1
22	26	C6	C	2
23	23	L1	C	5
24	53	C7	A	2
25	31	C6	A	2
26	37	C6	B	122
27	43	C4	B	2
28	34	L2	C	1
29	40	Th11	A	3
30	59	L1	C	0

AIS, American Spinal Injury Association Impairment Scale; C, cervical lesion of the spinal cord; L, lumbar lesion of the spinal cord; Th, thoracic lesion of the spinal cord (Savic *et al.*, 2007).

Study design

During the 4-week study period, measurements were made at the beginning and at the end of every week (T1–T8). In total, all patients received eight FES interventions. At every intervention, circumferential measurement and spasticity testing before and after FES cycling (pretest/post-test) were performed. Ultrasound, walking tests, and manual muscle test were only performed at the beginning of week 1 (T1) and at the end of week 4 (T8). All measurements were performed by the same examiner (D.K.).

On days without FES cycling, function-oriented physiotherapy and occupational therapy [Hauptverband der gewerblichen Berufsgenossenschaften (HVBG), 1995; Beckmann and Klein-Neuhold, 2005] to an extent of up to 45 min a day were performed on the basis of the intervention protocol. Considering the current functional status and the exercise capacity of the patients, neurophysiological therapies (proprioceptive neuromuscular facilitation) and passive/active assistive exercises as well as motor-functional single therapies (e.g. resource adaptations) were applied. All patients were informed about the study protocol and they provided written consent to participation in this study. After the audit (ID No. 34/09), the Medical Ethical Committee of the Medical Association Saxony-Anhalt gave its approval to the realization of this study.

Functional electrical stimulated-cycling training

FES cycling was part of the acute-stationary therapeutic treatment and followed the stimulation program 2–3 times a week over a period of 4 weeks. Every training session included 20 min of FES cycling. The physiotherapeutic intervention was primarily focused on proprioceptive neuromuscular facilitation techniques, whereas occupational interventions were focused on activities of daily life. The physiotherapeutic treatment was performed on days without FES cycling and had, just as occupational therapy, a fixed time of 40 min.

For FES training, a computer-controlled leg cycle was used. This technical device consists of the leg trainer MOTOmed Viva 2 (RECK-Medizintechnik GmbH & Co. KG, Betzenweiler, Germany) and the eight-channel stimulation device Rehastim II (Hasomed GmbH, Magdeburg, Germany). This equipment has two displays. The first display shows pedal cadence, symmetry, time, and resistance. The other display indicates stimulation time, stimulation frequency, pulse width, and the used current. Muscle contraction and relaxation are controlled by a stimulation computer (Berkelmans, 2008).

For stimulation, self-adhesive 5 cm × 9 cm latex-free surface electrodes were used. Muscles were stimulated with six channels and electrodes were positioned on the hamstring, quadriceps, and the gluteal muscles on both sides of the body. The feet and lower legs of the patients were fixed and the wheelchair was coupled in a rigid manner with the training device.

The stimulation parameter used with biphasic rectangular pulses had a frequency of 30 Hz and a pulse width of 250 μs. The stimulation amplitude was between 10 and 130 mA (for details, see Table 2).

To receive correct stimulation parameters, stimulation intensity was, respectively, chosen according to a palpable muscle contraction and a sensitive irritation for those patients who had an incomplete SCI with preserved sensation. The range of the pedalling cadence was set between 15 and 55 rotations per minute. When the minimum cadence could not be reached actively (supported by stimulation), the pedalling was performed passively by motor power. When 55 rotations per minute were exceeded, the resistance was adapted manually (~3 W). Active and passive distance values, active and passive time period, power output, and torque were recorded during each session.

Table 2 Stimulation parameters of the functional electrical stimulated cycling

Muscle	Range	Minimum	Maximum	Mean±SD
Left quadriceps	114	16	130	69.07±29.02
Right quadriceps	114	14	128	66.47±29.89
Left hamstring	74	16	90	51.07±19.47
Right hamstring	80	20	100	58.63±23.49
Left gluteus	92	12	104	59.40±24.73
Right gluteus	92	16	108	52.93±18.69

Stimulated muscle stimulation amplitude (mA) is given as range.

Circumferential measurement

To determine the extent of changes in the lower limb in SCI patients, a circumferential measurement can be performed at defined points on the thigh (Belanger *et al.*, 2000; Heesterbeek *et al.*, 2005). In this study, circumferential measurements were made on four different places on the leg to evaluate changes. To examine the circumferential measurement of the thigh, two marks on the skin were set at 10 and 20 cm above the medial knee joint cavity on both legs. These two markers were used to measure the change in circumference before and after FES cycling.

These circumferential measurements were complemented by the verification of calf and ankle diameter. For this examination, the patient was placed in a supine position, legs stretched, on a height-adjustable examination couch. Measurements were made using a tape measure.

Muscular ultrasound measurement

To measure muscle effects on FES, other studies used computer tomography, MRI (Mohr *et al.*, 1997; Scremin *et al.*, 1999), or muscle biopsies (Kern *et al.*, 2005). The diagnostic ultrasound applied was used as a valid noninvasive alternative to measure muscle size objectively (Pretorius and Keating, 2008; Dudley-Javoroski *et al.*, 2010).

A mark 15 cm above the medial knee joint cavity served as an orientation for the diagnostic ultrasound assisted examination of the m. rectus femoris at the beginning and at the end of the study. This examination was performed using a sonographic device (Toshiba Famio XG SSA-530A/E4 B/W; Toshiba Medical Systems, Otawara, Japan) with a linear ultrasonic transducer. The measurement was also performed in a supine position with stretched legs. The m. quadriceps femoris was examined during the first and the last session; three times before and after the performed FES cycling, to evaluate changes in the cross-sectional area and the extent of change of the m. rectus femoris in the defined area. Mean values were calculated from three measured results.

Manual muscle test

In addition, the measurement of muscular strength was performed in patients with muscular function (AIS C + D). The manual muscle test is a widely used instrument in clinical routine (Bajd *et al.*, 1999) and is additionally applied to the classification of SCI on the basis of the AIS. All stimulated muscles were assessed using the Janda test (Janda, 1983).

This scale includes six grades of muscle strength (0: no contraction of the muscle; 1: muscle contraction, but no movement; 2: full movement possible, but not against gravity; 3: movement possible against gravity, without resistance by the examiner; 4: movement possible against resistance by the examiner; 5: normal strength).

Patients were again placed in a supine position. To evaluate changes in muscle force, all stimulated muscles (m. quadriceps femoris, hamstrings, m. glutaeus maximus) were tested before FES cycling at the beginning (T1) and at the end (T8) of the study.

Spasticity

Spasticity was evaluated according to the MAS (Table 3, Ghotbi *et al.*, 2009) on the hip (abduction, adduction), the knee joint (extension, flexion), and the foot (dorsal extension or plantar flexion). These examinations were performed and recorded before and after each session (pre/post). Patients lay in a supine position and the investigator moved the leg passively to detect the spastic muscle tone. According to test specifications of the MAS, this examination was performed with only one repetition for each testing direction on both legs.

Walking ability

The ability to walk was assessed on the basis of the Walking Index for Spinal Cord Injury II (WISCI II). The WISCI classifies the ability to walk 10 m without aids, braces, or physical assistance. This walking scale includes 20 items to assess the walking ability of a patient with incomplete SCI. The reliability and validity of the first form of this test were confirmed by Ditunno *et al.* (2000). The WISCI scale does not really reflect all aspects concerning walking abilities in patients with SCI. Additional tests are necessary (Curt *et al.*, 2004). Therefore, the WISCI was complemented by the Timed Up & Go (TUG) Test and the 6-min walking distance (6MWD).

Table 3 **Changes in the leg circumference 20 cm above the medial knee joint cavity at study onset (T1) and after 4 weeks (T8)**

	Left leg (cm)			Right leg (cm)		
	Pre	Post	*P*	Pre	Post	*P*
AIS A+B (*n*=13)						
T1	42.8±4.8	43.3±4.8	0.06	42.4±5.3	42.6±5.3	0.068
T8	43.2±5.4	43.7±5.2*	0.016	42.7±5.1	43.2±4.9*	0.02
AIS C+D (*n*=17)						
T1	46.2±5.0	46.4±5.2	0.219	45.9±4.3	46.3±4.5*	0.003
T8	46.9±5.5	47.3±5.4*	0.034	46.5±4.5	47.0±4.7*	0.001

Data are given as mean±SD.

Pre, before functional electrical stimulated (FES) cycling; post, immediately after FES cycling.

*$P<0.05$ as compared with pre (*t*-test for matched pairs).

These tests allow assessment of the quantitative walking capacity. Furthermore, they provide additional information (e.g. increase in walking speed) on the capacity achieved between several levels of the WISCI (Curt *et al.*, 2004). Such supplemental tests are valid and reliable and therefore suitable for cross-section paralysis (Van Hedel *et al.*, 2005).

The TUG includes a 6 m walking distance, with change of direction after 3 m. The time needed for walking this distance is recorded, including the required time to stand up and sit down. In the second complementary test, the 6MWD, the walking distance in a time window of 6 min is measured. The walking tests were performed immediately before FES cycling at the beginning (T1) and the end (T8) of the study. The first walking test just before stimulation was the TUG, which was followed by the 10 m walk and the 6MWD.

Statistical analysis

For evaluation of statistical data, the Statistical Package for Social Sciences (SPSS 18.0; SPSS Inc., Chicago, Illinois, USA) was used. For determination of data skewness, the Shapiro–Wilk normality test was chosen. In case of a normal distribution, the *t*-test for dependent samples was applied. The Mann–Whitney–Wilcoxon test was used for variables that were not normally distributed and for ordinally scaled variables (e.g. MAS). All data are shown as mean values±SD or as median with interquartile ranges. The level of significance was determined at *P* value less than 0.05.

Results

All 30 patients completed the 4 weeks of training with eight sessions of 20 min stimulation.

Before inclusion, all patients participated in an excitability test of lower extremity muscles. Twenty-three percent (nine) of all tested patients had to be excluded because of nonexistent muscle excitability. Our sample group was heterogeneous in terms of the duration of injuries and AIS classification. No patient had previous experience with FES cycling. All patients were included in the statistical analyses.

Training

During all sessions, muscles were stimulated with six channels. The stimulation intensity used (frequency 30 Hz, pulse width 250 μs) on both legs was 67.8±29.2 mA for the m. quadriceps femoris, 54.8±21.7 mA for the hamstrings, and 56.2±22 mA for the m. glutaeus maximus.

The actively performed pedalling time (stimulation supported) increased by +47.6% from 12.2±7.7 min (T1) to 18.1±2.0 min (T8; $P=0.01$) in the AIS A+B group and by 6.7% from 18.3±4.5 min (T1) to 19.6±0.2 min (T8) in the AIS C+D group ($P=0.08$).

The recorded active pedalling distance (active cycling is defined as arbitrary or stimulation-assisted leg movement supported by muscle strength) in the AIS A + B group increased by 68.8% from 2.53 ± 2.0 km (T1) to 4.3 ± 1 km, (T8; $P = 0.002$). The associated passive pedalling distance (passive cycling is defined as motor-assisted cycling) in the AIS A + B group decreased by 72.7% from 1.1 ± 1.2 km (T1) to 0.3 ± 0.3 km (T8; $P = 0.028$).

In the AIS C + D group, the actively reached distance increased from 4.6 ± 1.5 km (T1) to 5.6 ± 0.7 km (T8) (+ 21.7%; $P = 0.009$) over the duration of the study. The passively cycled distance decreased by 66.7% from 0.3 ± 0.8 km (T1) to 0.1 ± 0.2 km (T8; $P = 0.071$).

Circumferential measurement (pre/post)

The ankle and calf circumference measured at T1 and T8 showed no changes in all AIS groups. In both AIS groups, the leg circumference only increased by 20 cm above the medial knee joint cavity. In the AIS A + B group, the circumference immediately after FES cycling changed only within the last session (T8). In the AIS C + D group, the circumference increased immediately after FES cycling only at the right leg from within T1 and on both legs within T8.

Muscular ultrasound measurement (pre/post)

An increase in the cross-sectional area of the m. rectus femoris in the AIS group A + B and in the AIS C + D group could be found immediately after FES cycling at T8 (Table 4).

Manual muscle test

All 17 patients with a voluntary muscle function in the lower extremity (AIS C + D group) were included in the manual muscle test. The manual muscle test showed an increase from 2.3 ± 1.5 to 3.3 ± 1.6 (+ 43.5%; $P < 0.001$) for the m. quadriceps femoris, from 2.4 ± 1.5 to 3 ± 1.6 (+ 25%; $P < 0.001$) for the m. glutaeus maximus, and from 2.3 ± 1.6 to 2.9 ± 1.5 (+ 26.1%; $P < 0.001$) for the mm. ischiocrurali from T1 to T8.

Table 4 **Changes in the cross-sectional area of the m. rectus femoris at the beginning of the study (T1) and after 4 weeks (T8)**

	Left leg (mm^2)			Right leg (mm^2)		
	Pre	Post	*P*	Pre	Post	*P*
AIS A+B (n=13)						
T1	88.8±49.7	97.1±34.0	0.196	79.2±46.9	102.4±46.1*	0.016
T8	87.4±34.3	100.8±37.5*	0.046	89.4±40.4	104.6±49.0*	0.019
AIS C+D (n=17)						
T1	103.1±58.9	115.1±65.7	0.406	109.7±55.3	117.7±69.7	0.115
T8	105.2±45.3	131.5±47.3*	0.001	134.5±77.4	162.8±96.4*	0.006

Data are given as mean±SD.

Pre, before functional electrical stimulated (FES) cycling; post, immediately after FES cycling.

*$P<0.05$ as compared with pre (t-test for matched pairs).

Spasticity (pre/post)

Directly following FES cycling, the pooled data analysis of all 30 enrolled patients indicated a spasticity reduction of 70% ($P = 0.002$) during hip abduction, 98.1% during hip adduction ($P = 0.016$), 66.8% during knee flexion ($P = 0.003$), and 76.6% during knee extension ($P < 0.001$). In the feet, spasticity was reduced by 67.8% ($P = 0.001$) during dorsal extension. During plantar flexion, no change in spasticity could be observed (Fig. 1).

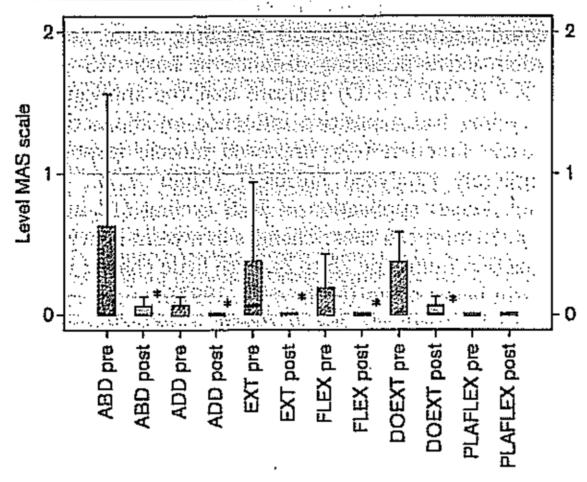
Walking ability

Of all patients included, seven showed walking ability at the end of the study. Two of these seven patients achieved sufficient walking ability (adequate for walking test) during the course of the study. The remaining five patients already showed partial walking ability at the beginning of the study. For this group, an increase of 46.5% from 4.3 ± 7.1 (T1) to 6.3 ± 8.8 (T8; $P = 0.04$) in the WISCI level could be found as a result of the intervention. The required time for the TUG was reduced from 11.7 ± 21.9 to 10.1 ± 18.1 s (13.68%; $P = 0.5$). The mean 6MWD walking distance increased from 62.3 ± 135.3 to 94.3 ± 167.1 m throughout the study (32.1 m or 51.36%; $P = 0.03$).

Discussion

All 30 patients could successfully handle the FES-cycling equipment and completed their participation in this study. The intensive pretraining screening and the short duration of the intervention in comparison with other

Fig. 1



Modified Ashworth Scale (MAS) of the legs before (pre) and immediately after (post) functional electrical stimulated cycling of American Spinal Injury Association Impairment Scale. Levels A–D: ABD, abduction of the hip; ADD, adduction of the hip; DOEXT, dorsal extension of the foot; EXT, extension of the knee; FLEX, flexion of the knee; PLAFLEX, plantar flexion of the foot. *$P<0.05$ as compared with pre (Wilcoxon for matched pairs).

studies (Mohr *et al.*, 1997; Demchak *et al.*, 2005) may be responsible for the high compliance. The easy handling of the equipment and the perception of immediate and positive effects of FES cycling (in particular spasticity) resulted in a high intrinsic motivation.

The rather small numbers of interventions – compared with other studies (Mohr *et al.*, 1997; Crameri *et al.*, 2000; Demchak *et al.*, 2005) – originate from the question of whether significant effects can be achieved already after a short application time. Positive results could facilitate the integration of FES cycling into the function-oriented clinical and therapeutic concept.

Compared with other studies, a high number of patients could be included (Chilibeck *et al.*, 1999; Crameri *et al.*, 2000; Krause *et al.*, 2008).

Conservative and nonpharmacologically supported spasticity reduction is an essential factor in the therapeutic routine. The reduction in the muscle tone in the lower extremities after FES cycling found in this study corresponds to the results of other authors (Krause *et al.*, 2008). The effect of spasticity reduction was also found in AIS A + B and AIS C + D patients. The beneficial effects of the dorsal extension on spasticity can be attributed to rhythmical passive leg movements, which supposedly are effective in reducing spasticity (Rösche *et al.*, 1997).

Because of the constant baclofen medication, the initial MAS level was low. However, the reduced muscle tone of hip and knee muscles can be considered a consequence of the application of FES cycling.

However, improvements in muscular endurance, the increased actively performed pedalling time, and the recorded active pedalling distance in both AIS groups (AIS A + B; AIS C + D) indicate that the application of FES cycling had a positive influence on the activation of muscle function (e.g. improved muscle response of incompletely paralyzed muscles) (Mohr *et al.*, 1997). A much longer application of FES cycling (12 months, 3/week, 30 min) can cause changes in myosin heavy-chain composition from type 2b to 2a, with little change in type 1 myosin heavy chain (Mohr *et al.*, 1997).

The significant reduction in the TUG associated with an increased walking distance of the 6MW emphasizes the value of the leg trainer. In addition, the average improvement of two points from level 4 to level 6 indicates an improved walking ability in terms of the WISCI scale from walking with an auxiliary individual (level 4) to a mobile walking ability with splints and an auxiliary individual in a walking rack (level 6) (Ditunno *et al.*, 2000). After a period of 8 weeks of FES cycle ergometer training (3/week, 30 min), Chilibeck *et al.* (1999) reported a proportional increase in muscle fiber area and capillary number. On this basis, the use of FES cycling is recommended for incompletely SCI patients to support the regeneration of type 1 muscle fibers (slow oxidative/slow twitch fibers) and improvement in functional parameters.

Another consequence of 4 weeks of FES cycling-supported therapy was an increased muscle function in the three muscle groups (quadriceps, hamstrings, and gluteus) in the AIS C + D group. Nevertheless, the measurement of the manual muscle test does not seem to be sensitive enough for the evaluation of muscle strength grade 4 and higher, being able to detect small or moderate increases of strength (Noreau and Vachon, 1998).

Furthermore, a general improvement in arterial blood flow to the lower limbs in patients with spinal cord lesions is expected by the application of FES cycling in a relatively short period of time (6 weeks) (Gerrits *et al.*, 2001). These results can be confirmed by the considerable increase in the muscle cross-section of the m. rectus femoris (AIS A + B; AIS C + D) within session T8 after an FES application of 4 weeks (ultrasound).

The nonsignificant results of the generally increased muscle mass of the m. rectus femoris after 4 weeks of training can possibly be substantiated by the short exercise period and low stimulation parameters compared with other studies (Chilibeck *et al.*, 1999; Belanger *et al.*, 2000). The integration of sensible complete SCI patients and patients with preserved sensations and the comparability of the results were the reasons for the use of this moderate level of stimulation parameters.

Nevertheless, the nonsignificant change in muscle cross-sectional areas in both AIS groups during the course of the study can possibly be explained by the fact that these values of motor complete SCI patients 6 weeks after trauma were up to 45% lower (Castro *et al.*, 1999) than the values of able-bodied control individuals in the same period of time. The reduction in muscle cross-sectional areas in patients with preserved motor function and sensations was 33% lower than that in inactive healthy control individuals during the same time (Gorgey and Dudley, 2007). For this reason, even a nonsignificant general increase in the size of the muscle cross-section in 4 weeks especially in completely paralyzed patients is a positive effect reducing the atrophy of stimulated muscles. It is also important to mention that FES cycling (3 days/week for 13 weeks) already used in the first weeks after traumatic SCI attenuates the loss of muscle mass (Demchak *et al.*, 2005).

Patients with SCI have a lower capillarization (Chilibeck *et al.*, 1999) and also a higher proportion of smaller and more type 2 muscle fibers (fast glycolytic/fast twitch fibers) (Gerrits *et al.*, 2000). A longer period of FES training without cycling (16 weeks, 5/week, 60 min) can slow down the reduction of fiber size or even reverse it (Crameri *et al.*, 2000).

The results of the study suggest that SCI patients can achieve reduction in spasticity, and improvement in their walking abilities and motor function with FES cycling during the rehabilitation process.

Limitations

The positive changes in muscle function should be verified in future studies using a larger sample size and by integrating a control group of SCI patients without FES cycling. The inclusion of a larger number of patients and future studies in other SCI centers would yield more meaningful data to optimize the impact of FES cycling in the rehabilitation of SCI patients. To integrate FES cycling into the clinical and therapeutic daily routine, a longer stimulation time should be applied. Higher stimulation parameters in sensible complete SCI patients would probably yield better results in terms of performed pedalling time and active pedalling distance and a greater change in the muscular structures of the m. rectus femoris (muscle cross-sectional area, circumference).

In all SCI patients, especially those with incomplete lesions, the regeneration process progresses up to 12 months after the injury. This may influence the study results. Another influential factor could be the fact that the patients also received other function-oriented therapies (physiotherapy, occupational therapy) in addition to FES cycling.

Conclusion

The results of the present study show that an early intervention with FES cycling in combination with function-oriented physiotherapy and occupational therapy after a SCI can lead to improved walking ability and reduced spasticity in the lower extremities. The positive muscular effects observed, such as the increase in muscle cross-section in the stimulated areas in patients with a complete and incomplete SCI, suggest that the comparatively short training phase can yield favorable results. FES cycling can positively influence therapeutic measures during the acute phase of rehabilitation. Further research with multicenter studies with a larger number of SCI patients is needed as well as a longer application period including applications at home to confirm the above-mentioned results.

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Conflicts of interest

There are no conflicts of interest.

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