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ORIGINAL REPORT

MONITORING OF SPASTICITY AND FUNCTIONAL ABILITY IN INDIVIDUALS WITH INCOMPLETE SPINAL CORD INJURY WITH A FUNCTIONAL ELECTRICAL STIMULATION CYCLING SYSTEM

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Background: **The aim of this study was to investigate the integration of motor function and spasticity assessment of individuals with spinal cord injury into cycling therapy.**

Methods: **Twenty-three participants with incomplete spinal cord injury performed 18 training sessions (standard deviation (SD) 14) on an instrumented tricycle combined with functional electrical stimulation. Each therapy session included a power output test to assess the participants' ability to pedal actively and a spasticity test routine that measures the legs' resistance to the pedalling motion. In addition, the required time for the therapy phases was monitored.**

Results: **The results of the power output test showed a monthly increase in power output of 4.4 W (SD 13.7) at 30 rpm and 18.2 W (SD 23.9) at 60 rpm. The results of the spasticity assessment indicate a 12.2 W (SD 9.7) reduction in resistance at 60 rpm after the functional electrical stimulation training for the subject group with spasticity.**

Conclusion: **In clinical use over a time-period of 2 years this combined form of therapy and motor function assessment was well accepted by participants. The active power output test and the spasticity test routine offered a proper tool to monitor participants' progress in functional rehabilitation and changes in spasticity.**

Key words: spasticity; SCI; paraplegia; tetraplegia; FES; cycling; 10MWT.

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INTRODUCTION

One of the major challenges in the rehabilitation of individuals with spinal cord injury (SCI) is to improve functional independence and prevent the deterioration of musculoskeletal and cardiovascular systems. Cardiovascular disease is an increasing cause of mortality in chronic SCI (1). O'Neill & Maguire (2) reported that the general benefit of sporting activity in clinical rehabilitation was recognized by 78.8% of participants and the rehabilitation benefit by 69.7%. Self-reported benefits were cited by 26 participants and included increase in fitness, quality of life, confidence and social contact (3).

Sport activities that are usually offered for clients in rehabilitation centres mainly address the upper extremities and consequently do not prevent atrophy and functional changes in leg muscles and decrease in bone density in the lower extremity. As the muscle mass of the lower body is more than 50% of the total muscle mass (4), it is important to include the lower limbs to achieve training effective heart rates. Specific training with functional electrical stimulation (FES) can cause significant improvements in the cardiovascular and pulmonary systems (5, 6), reduce atrophy of skeletal muscle (7, 8), increase bone density and lead to psychological benefits (9–13).

FES cycling is a suitable training method for the lower extremities of individuals with SCI, as, in contrast to walking, problems with balance can easily be avoided by appropriate seat design, and muscle force is converted into drive power with relatively high efficiency during pedalling. Mobile cycling by means of FES is attractive for individuals with SCI, as it allows them to move independently with power generated by their own leg muscles. FES cycling ergometers are commercially available; the first commercialized leg cycling exercising system was ERGYS (Therapeutic Alliances Inc.) in 1984. However, cycling training with FES is assumed to be time-consuming and complex and is only applied in clinical routine to a moderate extent.

The periodic assessment of the functional abilities of individuals with SCI is important in order to monitor rehabilitation progress and to evaluate existing and new therapy approaches. To assess, for example, walking ability, the 6-Minute Walk Test (6MWT) or the 10-Metre Walk Test (10MWT) are established (14). The Walking Index for Spinal Cord Injury (WISCI II) scores the amount of physical assistance, braces or devices required for walking over a distance of 10 m. It is an SCI-specific test and covers the entire range of walking ability (15) with levels 0 (client is unable to stand and/or participate in assisted walking) to 20 (ambulates with no devices, no braces and no physical assistance over a distance of 10 m). For the neurological and functional status, the American Spinal

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Injury Association Impairment Scale (AIS) is also used. This is a 5-point ordinal scale that classifies individuals from A (complete SCI) to E (normal sensory and motor function) (16). Nevertheless, van Hedel (17) points out that testing of functional outcome, as provided by these scores, can be improved by interval-scaled measurements.

In matters of clinical spasticity assessment the currently used scales, e.g. Penn Spasm Frequency Scale (PSFS) or Modified Ashworth Scale (MAS), correlate poorly with each other (18). Both intra- and inter-tester repeatability of the MAS are questionable (19, 20). Biering-Sorenson et al. (20) also point out the need of simple instruments, which provide a reliable quantitative measure with a low inter-rater variability. A reliable method for the quantification of spasticity could support the neurologist's decision on the type and dose of anti-spastic medication.

The aim of this study is to integrate reliable and easy assessment of both the participants' motor function, as an indicator for the progress of rehabilitation, and spasticity into FES cycling training. An instrumented FES cycling and measurement system was used that can be applied as both a stationary cycling ergometer and a mobile FES cycle, which gives the system high flexibility and allows the training to be adapted to the users' needs and preferences. Predefined test- and training routines are thought to combine the positive physiological effects of the cycling training with the assessment of clinically meaningful parameters within an acceptable expenditure on time and effort for both patient and therapist.

MATERIAL AND METHODS

Cycling and measurement system

For this study an instrumented FES-cycling system (21) was applied (Fig. 1). The system is based on a commercially available tricycle (AnthroTech Leichtfahrzeugtechnik GmbH, Eckental, Germany) that was adapted to meet the special requirements to enable measurements and to perform FES cycling training for persons with SCI.

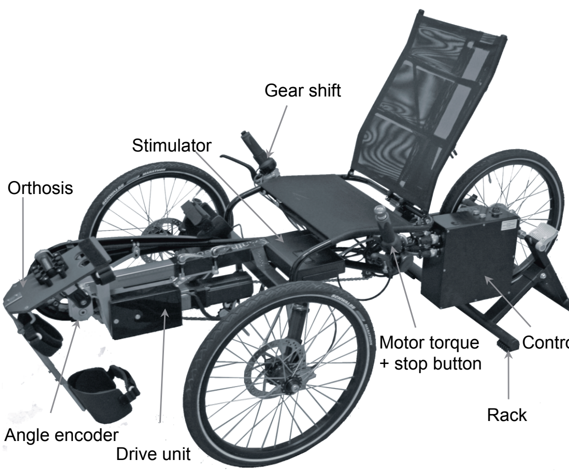

Fig. 1. Instrumented functional electrical stimulation-cycling system and its main components. The drive unit implements a brushless servo motor, a planetary gear set, an electromagnetic coupling, and a bevel gear. Via a chain and a sprocket on the bevel gear shaft the torque is transferred to the cranks. The control box contains the digital motor controller (Epos 70/10, Maxon Motor AG, Sachseln, Switzerland) and the accumulators.

The drive unit can brake or propel the crank with defined torque, keep it at constant angular velocity or hold the crank in a defined angular position for isometric measurements. For safety reasons the maximum torque is limited by the motor control. The therapist can operate different training modes and specified test routines via a laptop. For an easier transfer the correct steering rod can be swivelled down and a transfer board can be hugged onto the frame.

The power applied to the pedals is measured via the induced drive current. The angle encoder at the crank axis transmits the actual crank angle to the 10 channel stimulator, which stimulates the involved muscles in predefined crank angle ranges. The system can be used as a stationary cycle fixed on a rack or as a mobile FES cycle. The drivers' legs are stabilized on the pedals via orthoses.

Participants

The study was approved by the ethics review board of Lower Austria. Twenty-six persons with incomplete SCI gave written consent to participate in the study. Three participants could not continue after the first therapy session because of instability of the upper body and lack of time. Twenty-three participants (7 tetraplegic, 16 paraplegic, 3 females, 20 males, mean age 40 years (standard deviation (SD) 14), lesion height: L1 to C4, AIS Score: B–D, time since injury: 9 (SD 7) months) performed training sessions 3 times a week over an average time-period of 2 months. Table I lists the participants and gives information on gender, age and SCI status. For the spasticity assessment the MAS scale was chosen where the scorer passively moves the tested limb and rates the level of stiffness with 0 (no increase in muscle tone), 1, 1+, 2, 3 or 4 (affected part(s) rigid in flexion or extension) (22). For this study, the therapist manually moved the lower legs of the participant and quantified the passive resistance of the knee joints according to the MAS scale. The mean MAS stands for the MAS scores averaged over all performed therapy sessions (1.5 was set for the MAS score 1+ to allow a mathematical calculation of the mean value). The participants with a mean MAS < 1 form the non-spastic and those with a mean MAS ≥ 1 the spastic SCI group (Table I).

In addition, a control group of 13 able-bodied participants (4 females, 9 males, mean age 35 years (SD 9)) performed the training session twice. Their mean results from the spasticity test routine are compared with the spastic and the non-spastic SCI groups.

Training protocol of the therapy sessions

Each therapy session followed the training protocol illustrated in Fig. 2.

The pre-training phase starts with the spasticity assessment according to the MAS. After the transfer from wheelchair to the training system and the attachment and connection of the surface electrodes (Axelgaard CF5090, 2×9 cm, Fallbrook, California) the training phase is started with the spasticity test routine. This is a 3-min test where the legs of the participant are passively propelled at 6 isokinetic cadences. The system performs 8 crank turns at 10, 20, 30, 40, 50 and 60 revolutions per min (rpm) each and records the induced drive current. The peak value of the joint angular velocity at the knee joint is 30º/s at 10 rpm and 200º/s at 60 rpm at the hip joint 24º/s and 140º/s, respectively. A program written in LabView 7.0 (National Instruments, Austin, Texas, USA) processes the data and gives a mean resistance value for each crank angular velocity.

The active pedalling begins with 5 min of warm-up, where the cranks are moved at 30 rpm and low-density stimulation (amplitude 20 mA) is applied to *quadriceps femoris*, hamstrings and *gluteus maximus* of both legs. During the following 5 min of isokinetic training the participant is asked to pedal actively and a supporting stimulation is added. The angular ranges for the stimulation of the right leg are set to 330–100º (at crank angle 0º the right crank points up vertically) for the *m. quadriceps femoris*, 100–250º for the m. hamstrings and 0–180º for the *m. gluteus maximus* (23). For the left leg the stimulation pattern

Table I. *List of participants*

Age, years/ gender	Time since injury (months)	Motoric lesion height	American Spinal Injury Association Impairment Scale	Paraplegia/ tetraplegia	Traumatic/non-traumatic	Mean Modified Ashworth Scale
15/F	4	L2	D	Para	Traumatic	0.0
53/M	2	T9–11	D	Para	Traumatic	0.0
38/F	7	L1	C	Para	Traumatic	0.0
44/M	6	C3/C4	D	Tetra	Traumatic	0.0
47/M	14	T11	D	Para	Traumatic	0.0
53/M	4	T11	C	Para	Non-traumatic	0.0
26/M	29	C4/C5	D	Tetra	Traumatic	0.0
31/M	6	L1	D	Para	Traumatic	0.1
19/M	3	C5	B	Tetra	Traumatic	0.2
47/M	2	T4	D	Para	Traumatic	0.3
31/M	12	C7	C	Para	Traumatic	0.3
25/F	18	T10	D	Para	Non-traumatic	0.4
62/M	7	T4	C	Para	Non-traumatic	0.4
56/M	7	L2	C	Para	Traumatic	0.5
32/M	2	C4,5	C	Para	Traumatic	0.7
57/M	8	T6	B	Para	Traumatic	1.5
27/M	18	C6	B	Tetra	Traumatic	1.5
56/M	7	C6/C7	C	Tetra	Traumatic	1.9
45/M	10	C6/C7	D	Tetra	Traumatic	1.9
35/M	5	T6	C	Para	Traumatic	2.0
55/M	8	C6	C	Tetra	Traumatic	2.0
18/M	1	T5–10	C	Para	Traumatic	2.3
47/M	18	L1	B	Para	Non-traumatic	2.9

M: male; F: female.

is shifted 180º. Due to the activation dynamics (24) of the muscles the stimulator shifts the stimulation start and end points prior to the set values. This shift depends on the activation and deactivation time constants of the muscle and the actual cadence of the crank and satisfies the equation E2.1 [units in rectangular brackets]. For the applied stimulation the activation and deactivation time constants were set to 0.12 and 0.08 s, respectively (25).

E2.1: shift [º] = (de)activation time constant [s] × 60 × cadence [rpm]

The applied stimulation signal consists of rectangular biphasic pulses with a frequency of 50 Hz and pulse duration 600 µs. The amplitude is set to a level at which the stimulation is not uncomfortable for the participant, but a clearly visible contraction of the stimulated muscle group occurs. For the reported group the mean amplitude was 39 mA (SD 11).

Subsequently, the participant performs the active power output test, which is carried out without stimulation and runs at two isokinetic cadences. First, the participant is propelled passively for 10 revolutions at constant 30 rpm to assess the necessary drive torque for passive movement. An acoustic signal advises the participant to start active pedalling with maximal effort during 10 isokinetic crank revolutions. The mean power output generated by the active muscle forces is calculated by subtracting the passive from the active drive torques multiplied by the angular velocity. Next, the same test is performed at a cadence of 60 rpm. The results of active pedalling at the two cadences, 30 and 60 rpm, are used to examine both the development of muscular force and the participant's coordinative progress. The increase in active muscle force is mainly reflected by the power output test at 30 rpm. In addition, at 60 rpm the coordinative progress of the participant can be quantified. Due to muscle activation dynamics the optimal timing of muscle contraction is more difficult at higher velocities and, consequently, the better the participants' coordinative abilities the higher the power output at higher cadences. Healthy individuals without any motor disorders can generate higher active power during pedalling at 60 rpm than at 30 rpm (26). Periodical active power output tests over a longer time-period allow monitoring the motor rehabilitation progress of each individual participant.

Next a 5-minute training is performed with constant motor torque and FES (constant torque training), where the motor supports or brakes the system with constant torque depending on the physical abilities of the participant. The motor support or motor resistance is set by the therapist in a current range of ±1000 mA to enable the participant to perform a smooth pedalling motion. Before the concluding spasticity test, the isokinetic training is repeated for 5 min.

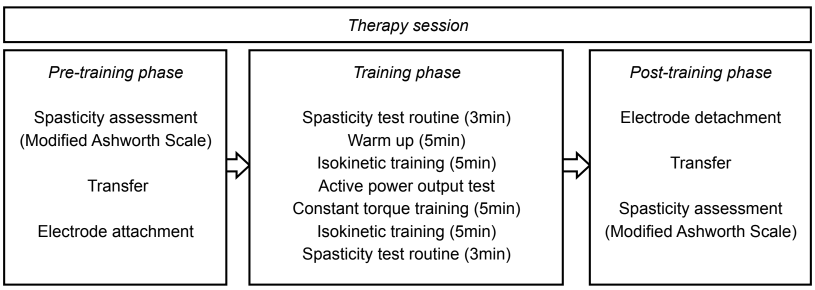

Fig. 2. The 3 phases of the therapy session.

In the post-training phase the therapist detaches the surface electrodes, supports transfer to the wheelchair, and again assesses the spasticity of the participant via MAS.

The total duration of the 3 phases of the therapy session is used as one of the evaluation parameters for clinical applicability of FES cycling therapy.

At the end of the study period the participants had the opportunity to perform FES-supported cycling in the gymnasium of the rehabilitation centre.

RESULTS

Time needed for therapy sessions

The mean time needed for one therapy session was calculated from 417 therapy sessions with 23 participants. Each participant attended a mean of 18 therapy sessions (SD 14). The pre-training phase took 10.7 min (SD 4.2) and the post-training phase 7.6 min (SD 3.3). The training phase required 33.6 min (SD 6.1).

Monitoring of the rehabilitation progress via the active power output test

As an example, Fig. 3 shows the results of the active power output test of a 53-year-old man with an incomplete spinal cord lesion at TH11. The ascending linear trend lines picture the continuous progress in power output over the therapy time-period of 5 months.

Fig. 4 shows the results of the active power output test for a participant with incomplete tetraplegia (male, 55 years, lesion height C6, AIS C) over a therapy time-period of 1.5 months with progressive linear trend lines.

Fig. 5 shows the results of a participant who had already started FES cycling therapy by 2 months after injury, with decreasing power output at 30 rpm.

The active power output results of the 20 further participants differ only by the dynamic of the progress and by their absolute values. The monthly increase in power output averaged over all participants was 4.4 [W] (SD 13.7) at 30 rpm and 18.2 [W] (SD 23.9) at 60 rpm. The enhanced power output also encouraged the participants' performance in mobile FES cycling at the end of the study period.

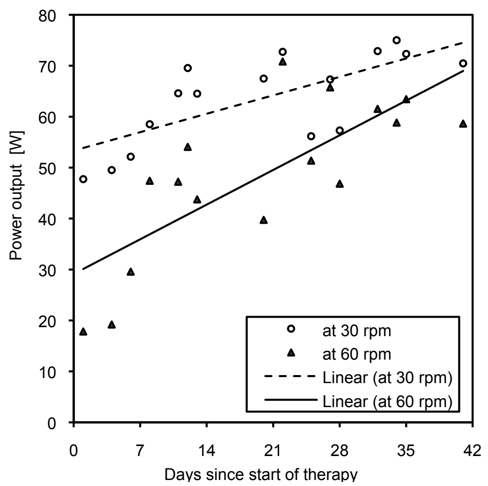

Fig. 4. Results of the active power output test at 30 and 60 rpm for a subject with incomplete tetraplegia (male, 55 years, lesion height C6, American Spinal Injury Association Impairment Scale: C) over a therapy time-period of 1.5 months. The related linear trend lines have been added.

Results of the spasticity assessment

The bar chart in Fig. 6 expresses the results of the spasticity test routine for the test participants divided into 3 groups. Group A includes 8 individuals with SCI and mean MAS > 1 (Table I, mean MAS 2.0 (SD 0.4)), group B 15 individuals with SCI and mean MAS < 1 (mean MAS 0.2 (SD 0.2)) and group C 13 able-bodied individuals. The decrease in resistance to the passive movement is calculated for each test subject at each of

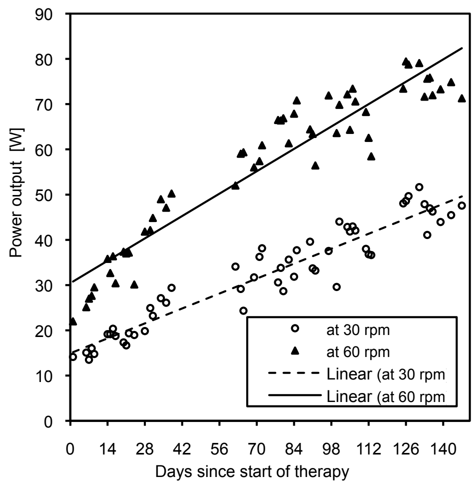

Fig. 3. Results of the active power output test at 30 and 60 rpm for a subject with incomplete paraplegia (male, age 53 years, lesion height T11, American Spinal Injury Association Impairment Scale: C) over a therapy time-period of 5 months. The related linear trend lines have been added.

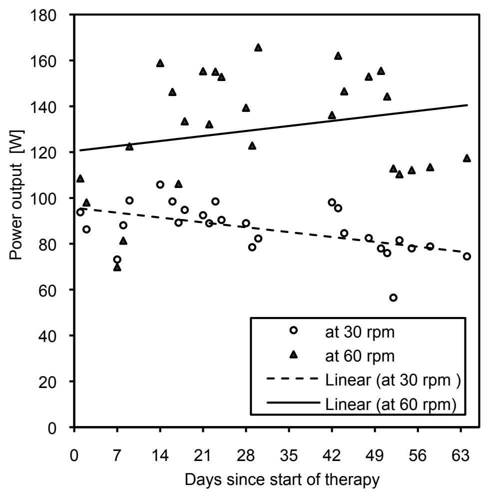

Fig. 5. Results of the active power output test at 30 and 60 rpm of a subject with incomplete paraplegia (male, 47 years, lesion height L1, American Spinal Injury Association Impairment Scale: D) over a therapy time-period of 2 months.

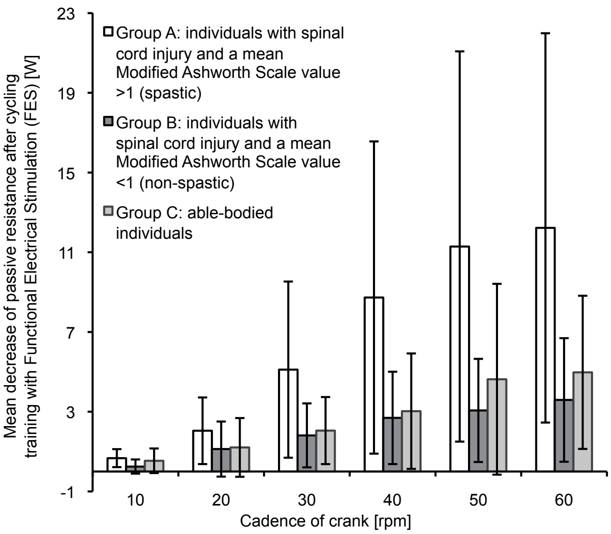

Fig. 6. The bar chart represents the instantaneous decrease in passive resistance [W] due to the functional electrical stimulation (FES) cycling training. For each training session the decrease in passive resistance was calculated by subtracting the resistance values measured with the spasticity test routine at the end of the training session from the respective values at the beginning of the training session. The bars depict the mean values with standard deviations (SD) of these results for the 3 groups of participants and for the 6 tested crank cadences. The spastic group A (8 individuals with spinal cord injury and a mean Modified Ashworth Scale (MAS) value >1, averaged mean MAS = 2.0, SD 0.4) shows the highest decrease in passive resistance after the FES cycling training. The difference from the non-spastic groups B (15 individuals with spinal cord injury and a mean MAS value < 1, averaged mean MAS = 0.2, SD 0.2) and C (13 able-bodied individuals) increases at higher cadences.

the selected cadences by subtracting the mean value from the spasticity test routine at the end of the training session from the respective value at the beginning of the training session. The resulting values represent the instantaneous decrease in passive resistance due to the FES cycling training. The spastic group A clearly shows the greatest reduction in resistance after the FES training and the difference from the other two groups increases at higher cadences. Groups B and C show very similar results. The legs' resistance to the passive pedalling motion is also decreased after the FES cycling training for the non-spastic groups B and C, but the values are much lower than for the spastic group A.

DISCUSSION

The aim of this study was to integrate reliable and easy assessment of both the participants' motor function as an indicator for the rehabilitation progress and spasticity into FES cycling training on an instrumented FES cycling and measurement system. Predefined test routines were designed to simplify handling and keep the time effort low for clinical applicability.

The results show that one therapy session with approximately 30 min of FES cycling training, which can be mobile or stationary depending on the available facilities and the users' preferences, can be handled by one therapist in approximately 50 min, which is an important indication for clinical applicability. When using the device as a mobile cycle in the gymnasium of the rehabilitation centre the stimulation amplitude and, consequently, the FES induced power output, was limited by the sensibility of the participants. Therefore the driving speed of the participants with AIS B was slow; for the participants with AIS C and D a higher speed could be reached due to the additional torque they could produce by active muscle force.

To quantify this contribution the active power output test proved to be an effective tool that can be also used to document the participants' progress in motor rehabilitation. Due to the measurements at two different crank velocities it is possible to analyse the development of the muscle forces as well as the coordinative status during rehabilitation. The results depicted in Fig. 3 show that the power output is higher at 60 rpm than at 30 rpm, indicating that the participant's coordinative abilities are good. In Fig. 4 a constant progress in force and coordination is pointed out, but the power output is lower at 60 rpm than at 30 rpm. This indicates that the participant has problems coordinating the leg muscles at higher cadences. The reason for this effect may be decreased trunk stability due to the lesion height C6. In Fig. 5 the decrease in power output at 30 rpm may be caused by the reduction in muscle mass in the first months after the injury. However, the increasing values at 60 rpm highlight progress in the participant's coordinative abilities. Further investigation could focus on the correlation between cycling and walking abilities, e.g. by comparing the described power output test with the 6MWT, the 10MWT or the WISCI II.

The results of the spasticity assessment show that the resistance of the legs to the passive pedalling movement is decreased in the spastic group after the FES cycling training. The relaxation increases with velocity, which indicates that spasticity, which is usually velocity-dependent, may be decreased. These results agree with the findings of Krause et al. (27). The decrease in resistance in the able-bodied group showed slightly higher values than in the non-spastic SCI group, which may be caused by difficulty in relaxing completely when being pedalled during the assessment. Further research is required in order to quantitatively assess spasticity with the described approach and to find related long-term effects of FES cycling on spasticity.

Limitations of this study

Due to the fact that spasticity is influenced by numerous factors and can change between therapy sessions, it was not easy to classify the participants into a spastic and a non-spastic group. We used a mean MAS value for this classification also a resulting decimal MAS value of, for example, 0.7 does not exist by definition. If this value was <1 the participant was classified as non-spastic else as spastic. In addition, it could be useful to use the Penn spasm frequency scale, which measures frequency and type of spasms (28). For spasticity assessment on the cycling system additional EMG measurements could provide further information on which muscles are spastic.

It should also be pointed out that the contribution of the FES cycling therapy to the monthly increase in power output cannot be quantified using this study design, because, on the one hand, the healing process of incomplete SCI is still in progress 9 months after injury and, on the other hand, the participants also attended numerous other therapies in parallel.

In conclusion, these results show that the introduced system might be a valuable tool in clinical rehabilitation, allowing the physiological benefits of FES cycling training to be combined with reliable assessment of clinically significant parameters, and acceptable expenditure of time and effort for both the client and the therapist.

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