ORIGINAL ARTICLE

Functional Electrical Stimulation—Assisted Active Cycling—Therapeutic Effects in Patients With Hemiparesis From 7 Days to 6 Months After Stroke: A Randomized Controlled Pilot Study

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Abstract

Objective: To determine whether functional electrical stimulation (FES)-assisted active cycling is more effective than active cycling without FES concerning walking and balance. Specifically, walking ability was classified as to the amount of personal assistance needed to be able to walk and balance was evaluated for static and dynamic balance tasks.

Design: Monocentric, randomized, single-blinded, controlled trial.

Setting: Neurologic rehabilitation hospital.

Participants: Patients with severe hemiparesis due to stroke (N=40).

Interventions: Twenty minutes of active leg cycling with or without FES applied to the paretic vastus medialis and rectus femoris of quadriceps and to the biceps femoris and semitendinosus muscles, 3 times/wk for 4 weeks.

Main Outcome Measures: Functional ambulation classification (FAC) and performance-oriented mobility assessment (POMA) were the primary outcome measures. The leg subscale of the motricity index (MI) and the modified Ashworth scale were the secondary outcome measures. Evaluation was done before and after the intervention period and after an additional 2 weeks.

Results: After the intervention, the FAC, POMA, and the MI ($P<.016$) for both intervention groups improved significantly. The FAC of the control group increased by a median of 1 category and that of the FES group by 2 categories. The median change in POMA was 2 and 4 points for the control group and the FES group, respectively. The Mann-Whitney U test between-group comparisons revealed that these gains were significantly better in the FES group for both the FAC ($U=90$; $z=-2.58$; $P=.013$; $r=-.42$) and the POMA ($U=60$; $z=-3.43$; $P<.0004$; $r=-.56$). Because of missing data and slightly decreased effect sizes during the follow-up phase (FAC, $r=-.33$; POMA, $r=-.41$), differences did not reach statistically significant P values. The MI leg subscale showed significant improvements in both groups. However, there were no significant differences between the groups at any time. No changes were observed on the modified Ashworth scale.

Conclusions: FES-assisted active cycling seems to be a promising intervention during rehabilitation in patients with stroke.

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A stroke has several consequences, including loss of walking ability, postural control, and muscle strength, all of which lead to disability and additional secondary health impairments.[1] The main goal of rehabilitation for most patients is to improve their gait.[2] Task-oriented training, which includes a wide range of repetitive interventions for reacquiring skills, such as treadmill training,[3] rhythmic auditory stimulation,[4] or sit-to-stand training,[5] has been shown to improve the walking speed, distance, and function of patients with stroke.[6-9] For this reason, patients increasingly receive electromechanical-assisted training.[10,11] Walking function can be influenced by an alternative therapeutic option, ergometric

cycling.[12] Sibley et al[13] showed that cycling has positive effects on gait speed and cadence, especially when patients cycle with a lower preferred pedaling cadence. The sitting position provides a safe environment for these severely affected patients to actively use their lower extremities and to relearn reciprocal movements. The kinematic pattern of cycling exercise seems to be similar to that of walking.[14] For example, cycling generates reciprocal rhythmic movement patterns, which require an exactly timed intra- and intermuscular coordinated activation of leg muscles similar to that during walking, for example, changes between antagonistic and agonist muscles, between flexors and extensors of the hip and the knee, and movement patterns between the legs. Raasch and Zajac[14] identified 3 muscle pairs that are basic for cycling: uniarticular hip and knee extensors alternating with their anatomic antagonists, and ankle plantar flexors alternating with dorsiflexors and biarticular thigh muscles. They are suggested to be elements of the general strategy for controlling pedaling and may be generally applicable to other human locomotor tasks.[14]

In a systematic review,[12] some limited support for the efficacy of pedaling exercises was reported in early phase studies; in particular, muscle activity, muscle strength, balance, and functional independence after stroke were found to improve when the patient was treated with a single session of pedaling, as well as when the patient was stimulated with functional electrical stimulation (FES) over a period of up to 12 weeks. In recent years, cycling exercise has been combined with FES, which is a technique used to elicit a voluntary muscle contraction during a functional task. Low-level electrical current is applied either to the nerves that control muscles or directly over the motor end-plate of the muscle system.[15] This facilitates the reorganization of neuromuscular activity[16] and augments the neuronal excitability of the sensorimotor cortex.[17,18] The method has been reported to be safe and feasible.[19]

The additional benefits of FES cycling for patients with stroke over those of regular cycling are reported to be manifold. FES cycling increases muscle strength[20] and activates paretic muscles,[21] reduces hypertonia,[22] increases aerobic capacity,[23] improves cardiopulmonary function, minimizes complications due to immobilization, and improves symmetry and smoothness of the cycling movement.[24]

Most importantly, several studies have reported that FES cycling supports the rehabilitation of postural control[20,25,26] and walking function.[23,25] However, these studies had certain limitations. For example, one investigated only a single session of FES-assisted cycling,[27] another included patients with chronic stroke and good walking function,[23] and finally 2 studies[20,25] used passive cycling (no voluntary muscle contraction and device-induced cycling) in both the FES and control intervention groups.

The objective of the present study was to determine whether 4 weeks of active cycling training in severely affected non−self-ambulatory patients 7 days to 6 months after stroke can improve the performance of walking and postural control and whether FES-assisted cycling is more effective than cycling without FES

List of abbreviations:

FAC	functional ambulation classification
FES	functional electrical stimulation
MAS	modified Ashworth scale
MI	motricity index
POMA	performance-oriented mobility assessment
10MWT	10-Meter Walking Test

support. In addition, muscle power, muscle spasticity, and gait velocity were investigated.

Methods

A single-blinded, randomized, controlled, clinical pilot study with 2 parallel groups was conducted.

Participants

Patients fulfilled the following inclusion criteria: 18 years or older and diagnosis of a first stroke (7d to 6mo) resulting in severe hemiparesis with a grade less than 3 for the musculus quadriceps on the Medical Research Council[28] scale. The level of walking ability had to be 2 or lower according to the functional ambulation category (FAC, 0−5); that is, each patient required manual assistance to walk. Patients had to understand the informed consent form, which means that patients had to roughly repeat verbally the study procedures 24 hours after the neurologist had first explained it. Then, the informed consent form was signed. Patients had to be able to cycle for 20 minutes. Those who had not had cycle exercises before the study began were scheduled for 1 testing session. Testing was done once before study onset but not retested in the course of the study. Exclusion criteria were cardiac pacemakers, dementia, psychosis, unstable cardiorespiratory problems or osteoporosis, metal implants beneath the area of stimulation, limited range of motion, and severe spasticity in the lower extremities, thus making cycling impossible. Electrical stimulation had to induce a visible or palpable contraction of the musculus quadriceps femoris below the pain threshold. Inpatients at a neurological rehabilitation hospital were monitored during 2 periods, each lasting approximately 1 year. A neurologist (F.M.) enrolled all the patients who provided their written informed consent. The local ethics committee of the Ludwigs-Maximilians-Universität in Munich, Germany, gave approval. The study was registered in the German Clinical Trials Register (No. DRKS00004330).

Intervention

After study inclusion, one group of patients performed active leg cycling with FES (FES group, n=20); the other group (control group, n=20) performed active leg cycling without FES.

Both groups cycled for 20 minutes, 3 times/wk for 4 weeks, for a total of 12 sessions. Most earlier studies were performed over a period of 4[20,21] to 6 weeks,[23] with 2 sessions[23] to 5[20,21] sessions per week. Clinical feasibility and therapy management of the study's participating hospital were the reason for the decision to stimulate 3 times/wk. Therapy took place in a group room in which patients were seated in a wheelchair in front of a motorized cycle ergometer (MOTOmed viva 2[a]) that was synchronized with a current-controlled stimulator (RehaStim 2[b]) to activate the vastus medialis and rectus femoris of the quadriceps and semitendinosus and biceps femoris of the hamstring muscles. These muscles are important for knee and hip control, especially in patients severely affected by stroke. A minimum pedaling cadence of 20rpm was necessary to start the stimulation; patients then cycled at a self-selected speed. The paretic leg was secured to the pedal when necessary. Patients in both groups were instructed to cycle actively, which means that they had to cycle without the support of the drives of the cycle ergometer, if possible. Patients' wheelchairs were secured by an antitipper device (fig 1).

Fig 1 FES cycling.

In addition to the assigned group treatment, subjects were enrolled in a rehabilitation program consisting of physical and occupational therapy, neuropsychology, and logopedics, as needed according to their individual deficits.

FES protocol

The FES group was stimulated unilaterally on the paretic lower limb. Self-adhesive surface electrodes (9×5cm) were fixed ventrally on the musculus vastus medialis and rectus of the quadriceps femoris and dorsally on the semitendinosus and biceps femoris. Therapists applied the self-adhesive electrodes in the therapy room. Information on stimulation parameters in the literature is limited. Stimulation frequencies with FES cycling range from 20[25,27] to 60Hz[23] and pulse duration from 300[25,27] to 450μs.[23] To avoid fatigue and discomfort and to elicit a tetanic contraction, a low frequency of 25Hz and rectangular biphasic pulses with a pulse duration of 250μs (positive phase) were used.[29] Consequently, the interpulse interval was 39,750μs. Intensity was set as high as tolerated. The stimulation was synchronized with cycling movements. Each training session started with 1-minute warm-up of active cycling followed by 19 minutes of cycling with FES.

Outcome measures

Outcome measures were assessed by an independent, experienced rater who was unaware of the allocated intervention. Subjects were tested before and after the intervention; follow-up evaluations were made 2 weeks after the end of interventions. The functional performance was evaluated by 2 primary measures: the functional ambulation classification (FAC) and the performance-oriented mobility assessment (POMA).

Walking ability was measured by the FAC and divided into 6 categories, ranging from 0 (patient cannot ambulate or requires supervision or physical assistance from more than 1 person) to 5 (patient can ambulate independently on nonlevel and level surfaces).[30] According to the test manual, assistive devices such as rollators or ankle-foot orthoses are permitted, if necessary. A good predictive validity, responsiveness, and reliability were indicated for the FAC.[31,32]

POMA is a widely used instrument for evaluating balance and gait.[33] The balance section of POMA was used to measure the patient's sitting and standing balance ability over a range extending from inability to sit without assistance of therapists to ability to stand without assistance and with a narrow-based stance and closed eyes. POMA (gross and subsections) was reported to have moderate validity and good reliability in persons soon after stroke.[34]

Secondary outcome measures were the leg subscale of the motricity index (MI), the modified Ashworth scale (MAS), and a 10-Meter Walking Test (10MWT). The MI is an assessment for evaluating the patient's ability to generate volitional muscle contraction in the paretic lower limb.[35] Muscle strength of the ankle dorsiflexors, knee extensors, and hip flexors was tested against manual resistance while subjects were sitting on a chair, with hips and knees positioned in 90° flexion. Assessors rated patients' maximal voluntary contractions using a modification of the Medical Research Council scale system. The sum score ranges from 0 to 100. Psychometric properties have been shown to be good to excellent: criterion validity ($r = .78-.91$),[36] reliability (Spearman $\rho = .87$), and validity ($\rho = .75$).[37]

A common complication after stroke is spasticity.[38] FES-induced training has been shown to effectively reduce spasticity.[27] To evaluate this point as a secondary outcome, muscle tone was measured with the MAS.[39] Spasticity was graded from 0 (no increases in tone) to 4 (affected part[s] rigid in flexion or extension). Inter- and intrarater reliability of the MAS is good.[40]

The 10MWT was administered to measure gait velocity. Patients had to walk 10m as fast as possible but still feel safe while walking. Assistive devices, for example, a cane or an orthosis, were allowed. The test was reported to have good reliability.[41]

A sample size estimation for the FAC and POMA was made using G*power 3.[42] For statistical analysis of both outcome parameters, intraindividual differences were calculated between pre- and postintervention measurements. In an earlier study by Husemann et al[43] that included similar patients, a mean change of 1 ± 1.2 points was found in the FAC. A change by an additional 1 point in the experimental group seems to be a clinically relevant effect. In a review on the POMA, Faber et al[44] reported a minimal intervention effect of 3.5 points and a clinically relevant difference of 3 points between patients who used wheelchairs and those who used walkers whereas the SD was 3.

On the basis of an analysis with the Mann-Whitney U test (with an α error probability of .05 and a power of .80), intra-individual differences of the FAC and POMA were analyzed and the total sample size was estimated at 18 patients per intervention group. To account for a dropout rate of 10%, 40 patients had to be included in the study to reach a sufficient sample size. Block randomization with varying block sizes was used. The stratification criterion was the degree of paresis in the quadriceps muscle based on the presence or absence of a palpable contraction (MI: 0, <0). The computer-generated random allocation sequence and the assignment of participants to the interventions were done by a person not involved in patient recruitment (F.M.).

Statistical analysis

The chi-square test for comparisons of proportions and the Student t test for continuous variables (if the assumptions were not violated) were used to compare demographic and clinical characteristics of patients between both groups. Data of primary and secondary outcome parameters were analyzed using the Mann-Whitney U test for between-group comparisons before the intervention (FES vs control) and the paired sample Wilcoxon signed-rank test for within-group comparisons for each treatment group separately.
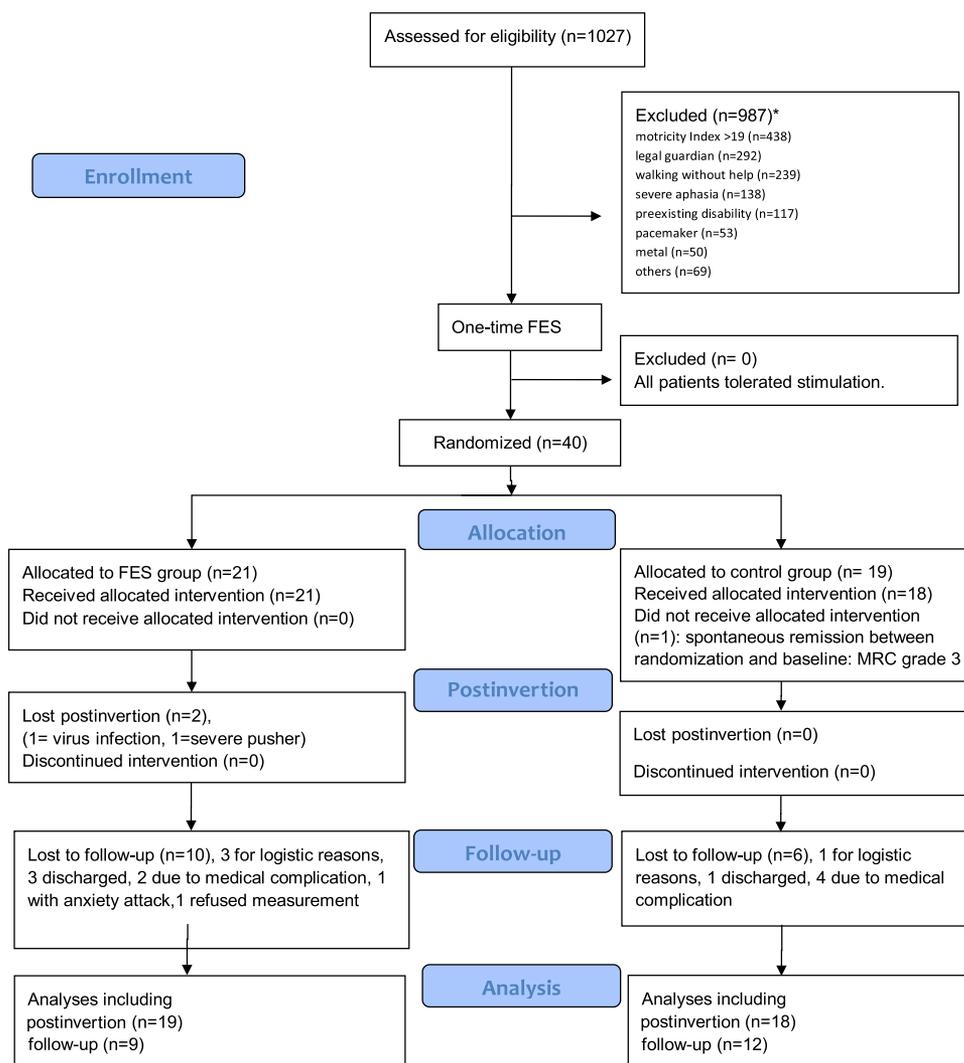
Assessed for eligibility (n=1027)

Enrollment

Excluded (n=987)*
motricity Index >19 (n=438)
legal guardian (n=292)
walking without help (n=239)
severe aphasia (n=138)
preexisting disability (n=117)
pacemaker (n=53)
metal (n=50)
others (n=69)

One-time FES

Excluded (n= 0)
All patients tolerated stimulation.

Randomized (n=40)

Allocation

Allocated to FES group (n=21)
Received allocated intervention (n=21)
Did not receive allocated intervention (n=0)

Allocated to control group (n= 19)
Received allocated intervention (n=18)
Did not receive allocated intervention (n=1): spontaneous remission between randomization and baseline: MRC grade 3

Postinvertion

Lost postinvertion (n=2),
(1= virus infection, 1=severe pusher)
Discontinued intervention (n=0)

Lost postinvertion (n=0)
Discontinued intervention (n=0)

Follow-up

Lost to follow-up (n=10), 3 for logistic reasons, 3 discharged, 2 due to medical complication, 1 with anxiety attack,1 refused measurement

Lost to follow-up (n=6), 1 for logistic reasons, 1 discharged, 4 due to medical complication

Analysis

Analyses including postinvertion (n=19)
follow-up (n=9)

Analyses including postinvertion (n=18)
follow-up (n=12)

Fig 2   Consolidated Standards of Reporting Trials flow diagram. Abbreviation: MRC, Medical Research Council. *Multiple answers possible.

For analyses of intervention effects, intraindividual differences were calculated using the following formula: "Value after intervention minus value before intervention" for changes during the intervention phase. Accordingly, "value at follow-up minus value before intervention" was calculated for changes during the whole study period. Intraindividual differences between both intervention groups were compared and analyzed using the Mann-Whitney U test.

Primary and secondary outcome data were analyzed as intention to treat. Missing data were not refilled with any imputation method. Consequently, calculations of intraindividual differences or the paired Wilcoxon signed-rank test were performed only when values were available before and after intervention or before intervention and follow-up, respectively. The 10MWT was analyzed with the Student t test.

All statistical analyses were performed using SPSS Statistics for Windows (version 17.0).[c] In general, an alpha level of .05 was chosen for the analyses. To test the study hypothesis (a significantly better improvement in walking [FAC] and postural control [POMA] due to the 4-week FES therapy compared with the

control intervention), 2 statistical tests were conducted. Consequently, the alpha level for those tests was set to .0125.

Results

Of 1027 screened patients with stroke, 40 were enrolled in the study. The flow of patients through the study and the description of missing data are shown in figure 2. Group and statistical values of patients' demographic and clinical characteristics (age, sex, type of stroke, time since stroke onset, side of paresis, and the stratification criterion: number of patients with an MI of 0 or above) can be found in table 1. There were no significant differences between the 2 groups for any of these parameters. The parameters "age" and "time since stroke onset" were analyzed with the Student t test. Age ($D(37)=.495$; $P=.967$) did not deviate significantly from normal, and the variances were equal for the FES group and the control group ($F_{1,35}=.844$; $P=.365$). Time since stroke onset ($D(37)=1.222$; $P=.101$) also did not deviate significantly from normal, and the variances were equal for the FES group and the control group ($F_{1,35}=.043$; $P=.836$).

Table 1 Baseline characteristics

Characteristic	Control Group	FES Group	Between-Group Comparisons
Age (y)	64±11	59±14	$t_{35}=1.162$, $P=.253$*
Sex: male/female	9/9	12/7	$\chi^2(1)=0.652$, $P=.515$†
Type of stroke: ischemic/hemorrhagic	10/8	15/4	$\chi^2(1)=2.308$, $P=.170$†
Time since stroke onset (d)	42±45	62±43	$t_{35}=-1.337$, $P=.190$*
Side of paresis: right/left	10/8	5/14	$\chi^2(1)=3.278$, $P=.099$†
MI: 0/>0	7/11	5/14	$\chi^2(1)=0.667$, $P=.495$†

NOTE. Values are mean ± SD unless indicated otherwise.
* The t test for independent samples.
† The chi-square test.

The assessment of the patients involved 18 patients postintervention and 12 at follow-up in the control group and 19 patients postintervention and 9 at follow-up in the FES group. Tolerance of FES was good, with none of the patients perceiving the stimulation as uncomfortable. Adverse effects were not observed. Patients of the FES group practiced with a mean of 36mA (range, 24−60mA) on the quadriceps and 35mA (range, 18−60mA) on the hamstrings. The planned 12 therapy sessions were not completed by all patients: 2 patients in the FES group and 4 patients in the control group received 11 units. Because of medical complications (virus infection and epileptic attacks), 2 patients of the control group received only 8 therapy sessions. For both groups, assistive devices for the ambulatory patients after intervention were canes (n=3), canes in combination with ankle foot orthoses (n=2), and rollators (n=3). Four patients had no assistive devices.

Group and statistical values of primary and secondary parameters are given in table 2. All parameters (FAC, POMA, and MI) did not significantly differ between the groups at baseline (before intervention). During the study period, both groups improved significantly over time. For both groups, Wilcoxon signed-rank tests revealed significant improvements between the pre- and postintervention values (FES group: FAC, $z=-3.464$, $P=.001$, $r=-.79$; POMA, $z=-3.837$, $P<.0004$, $r=-.88$; MI, $z=-2.796$, $P=.005$, $r=-.64$. Control group: FAC, $z=-2.41$, $P=.016$, $r=-.57$; POMA, $z=-2.96$, $P=.003$, $r=-.69$; MI, $z=-2.92$, $P=.004$, $r=-.69$), as well as between the preintervention and follow-up values (FES group: FAC, $z=-2.456$, $P=.014$, $r=-.82$; POMA, $z=-2.67$, $P=.008$, $r=-.89$; MI, $z=-2.371$, $P=.018$, $r=.79$. Control group: FAC, $z=-2.232$, $P=.026$, $r=-.64$; POMA, $z=-2.552$, $P=.011$, $r=-.74$; MI, $z=-2.807$, $P=.005$, $r=-.81$).

Comparisons of intraindividual differences revealed statistically significant better gains for the FES group during the intervention phase for POMA and the FAC with moderate to high effect sizes. Group and statistical values for intraindividual differences are presented in table 2. In the follow-up period, there were no statistically significant differences between the 2 intervention groups, neither for POMA nor for the FAC, which is a consequence of the missing data and slightly reduced effect sizes.

Table 2 Primary and secondary outcome measures

Measures	Time Point of Measure	FES Group	Control Group	Between-Group Comparison
FAC	Preintervention	0±0, 0 (0−0)	0±0, 0 (0−0)	$U=165$, $z=-.289$, $P=.845$, $r=-.04$
	Postintervention	2±0, 2 (1−3)	1±0, 0 (0−2)	$U=105$, $z=-2.11$, $P=.042$, $r=-.35$
	Follow-up	2±0, 3 (2−3)	1±0, 0 (0−2)	$U=31$, $z=-1.69$, $P=.111$, $r=-.37$
	Diff			
	Pre- to postintervention	2±0, 2 (1−3)	1±0, 0 (0−1)	$U=90$, $z=-2.58$, $P=.013$, $r=-.42$
	Preintervention to follow-up	2±0, 2 (2−2)	1±0, 0 (0−2)	$U=34$, $z=-1.52$, $P=.148$, $r=-.33$
POMA	Preintervention	2±1, 1 (1−4)	3±1, 2 (1−5)	$U=148$, $z=-.718$, $P=.499$, $r=-.11$
	Postintervention	6±1, 7 (3−9)	4±1, 5 (1−6)	$U=115$, $z=-1.73$, $P=.086$, $r=-.28$
	Follow-up	7±1, 9 (6−10)	6±1, 6 (2−8)	$U=39$, $z=-1.11$, $P=.277$, $r=-.24$
	Diff			
	Pre- to postintervention	4±1, 4 (2−5)	2±0, 1 (0−2)	$U=60$, $z=-3.43$, $P<.0004$, $r=-.56$
	Preintervention to follow-up	5±1, 5 (3−7)	3±1, 3 (0−5)	$U=28$, $z=-1.86$, $P=.069$, $r=-.41$
MI	Preintervention	25±4, 29 (10−38)	22±4, 17 (10−38)	$U=150$, $z=-.65$, $P=.538$, $r=-.11$
	Postintervention	36±5, 38 (24−48)	34±5, 38 (19−43)	$U=159$, $z=-.37$, $P=.730$, $r=-.06$
	Follow-up	45±6, 51 (40−54)	39±6, 42 (22−54)	$U=44$, $z=-.75$, $P=.464$, $r=-.16$
	Diff			
	Pre- to postintervention	11±3, 10 (0−20)	12±3, 10 (9−21)	$U=156$, $z=-.46$, $P=.651$, $r=-.08$
	Preintervention to follow-up	17±4, 22 (7−25)	15±3, 15 (8−21)	$U=48$, $z=-.46$, $P=.663$, $r=-.10$

NOTE. Values are mean ± SE, and median with 25% to 75% percentile in parentheses. Between-group comparisons were calculated using the Mann-Whitney U test.
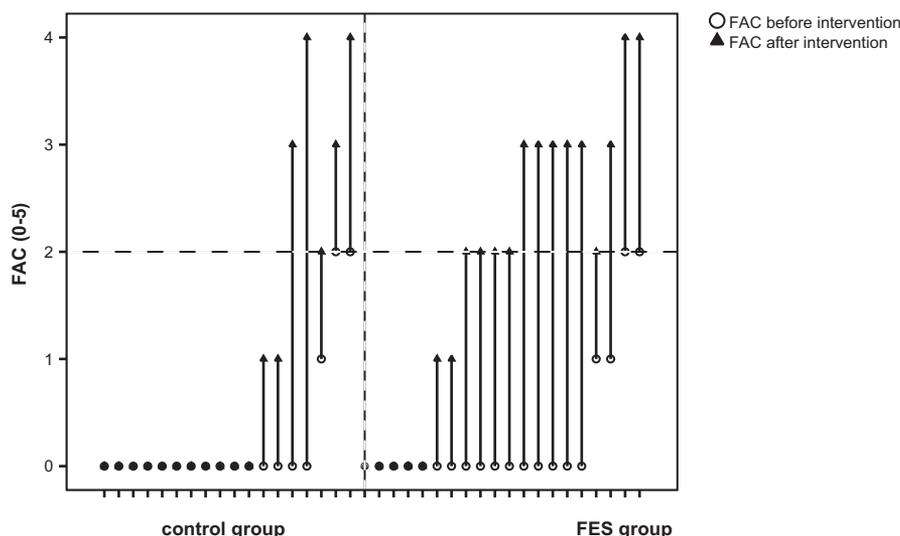Abbreviation: Diff, intraindividual differences.

Fig 3 FAC baseline and responder.

During the intervention phase, twice as many patients in the FES group (n=8) became self-ambulatory (FAC≥3, which means that patients require only verbal supervision or stand with help from 1 person without physical contact) than in the control group (n=4). Changes in the FAC of 37 individuals in both groups are shown in figure 3. For patients with an FAC of at least 3, the 10MWT was performed. At baseline, all patients had an FAC below 3. Consequently, no statistical analysis was performed. Postintervention, the statistical analysis revealed a significant difference between both intervention groups. The control group (mean ± SD, 22.3±12s; n=4) walked significantly faster than the FES group (mean ± SD, 55.4±27.8s; n=8) ($t_{10}=-2.236$; $P=.049$). The 10MWT did not deviate significantly from normal ($D(12)=.737$; $P=.649$), and variances were equal for the FES group and the control group ($F_{1,10}=1.899$; $P=.198$).

For the MI, no significant differences were found between the intervention groups at any time.

The effects of the intervention on the muscle tone of stimulated muscles (paretic vastus medialis and rectus femoris of quadriceps and biceps femoris and semitendinosus muscles) were evaluated. The results showed no statistically significant differences in score change, neither for knee flexors ($U=171$; $z=-.016$; $P=.988$; $r=-.003$) nor for knee extensors ($U=134$; $z=-1.246$; $P=.258$; $r=-.205$). Details are given in table 3. At baseline, there were no

statistically significant differences between both intervention groups neither for knee flexors ($U=161$; $z=-.346$; $P=.775$; $r=-.05$) nor for knee extensors ($U=151.5$; $z=-.924$; $P=.558$; $r=-.15$).

Discussion

This assessor-blinded, randomized, controlled pilot study investigated effects of *active* cyclic ergometer training with and without FES for lower extremities in severely affected patients with hemiparesis 6 months or less poststroke. In addition, to our knowledge, this is the largest randomized controlled trial to examine the effect of FES-assisted cycling in patients with stroke. It was shown that 4 weeks of therapy (including 12 sessions of cycling) improved walking ability and postural control. Moreover, because of the addition of FES to cycling, this group improved significantly more in these 2 parameters. Secondary outcomes such as muscle tone and force did not differ between the 2 intervention groups.

The possibility of using a rhythmic, bilateral cycling movement, with assistance of electrical stimulation for the paretic lower limbs, seems a promising therapeutic approach to improve the walking ability of subacute patients with severe hemiparesis. Twice as many patients in the FES group became self-ambulatory

Table 3 Changes in muscle tone due to the intervention

	MAS Score>0 Before Intervention			MAS Score=0 Before Intervention	
Group	Reduced Tone	No Change in Tone	Increased Tone	No Change in Tone	Increased Tone
Control group					
Quadriceps	−1/−1.5 (4)	(0)	(0)	(10)	1.3/1.5 (4)
Hamstrings	−1.0/−1.0 (3)	(2)	0.5/0.5 (3)	(6)	1.0/2.0 (4)
FES group					
Quadriceps	−0.8/−1.0 (2)	(0)	(0)	(10)	1.0/2.0 (7)
Hamstrings	−1.0/−1.0 (3)	(3)	0.5 (1)	(7)	1.5/1.5 (5)

NOTE. Values are median/maximum (n)

than in the control group. An improvement in ambulatory function of the FES group was also shown by Ambrosini[25] and Janssen,[23] and colleagues although neither study showed significant differences between the intervention groups. However, both studies included patients who had better ambulatory function. Compared with our study in which initial FAC scores were 0 to 2 with a median score of 0 in both groups, respectively, patients in the study of Janssen[23] had a mean baseline FAC score of 4.5 and 4.7 for the FES group and the control group, respectively. Ambrosini[25] examined 30 patients, of whom 7 could ambulate 50m at baseline. Like the FES group, the control group in our study also improved significantly during the intervention period, whereas the control group in the study by Ambrosini[25] did not. An important factor for motor learning seems to be the level of voluntary activity, that is, whether it is active cycling training as in our study or passive cycling as in the study of Ambrosini.[25] This has been shown in functional magnetic resonance imaging studies by Lotze et al[45] and Francis et al,[18] who demonstrated that a short period of active motor training (for the wrist[45] or the ankle[18]) is more effective than passive motor training in eliciting performance improvements and cortical reorganization. The positive effect of voluntary activation was also shown by Francis,[18] who detected enhanced activation of cortical and subcortical areas in FES-induced ankle dorsiflexion.

Active cycling also seems to influence muscle strength. Although Ambrosini[25] found a significant improvement in the FES group that was significantly superior to the control intervention (passive cycling), both of our intervention groups cycled actively and significantly improved their muscle strength in the muscles measured by the MI test. The difference between the 2 intervention groups, however, was not significant, a finding that agrees with Janssen.[23] Possibly, the patient characteristics, that is, chronic patients with good initial walking ability, explain this. Janssen[23] reported that the lack of improvement in muscle strength could also be explained by the nature of the exercise, which did not include a specific resistance-type exercise in their study. Future studies should consider adding increasing resistance to pedaling or increasing the speed of pedaling or both. The MI values of our FES group might have been improved if FES had been applied with higher electrical intensities.

One further aspect of FES cycling is the improvement in cardiovascular fitness. A relatively light workout (twice a week, each session lasting 25−30min, for 6wk) showed an enhanced aerobic capacity.[23] Modern rehabilitation after stroke should integrate exercise programs to enhance the cardiovascular fitness.[46] FES cycling could be a good therapy for patients who are non-ambulatory, because it is safe and provides the opportunity to activate the paretic muscles.

Our findings of a significantly better gain in walking function in the FES group in combination with a nonsignificant difference in muscle strength between both groups suggest that the gain in walking function is caused by an increase in coordination pattern rather than by an increase in muscle strength. This might also explain our findings on postural control. Both groups significantly improved their balance according to POMA. The comparison of group gains revealed that the FES group had significantly higher values. Similar findings have been reported by Ambrosini[25] and Janssen.[23] In contrast, Lo et al[26] did not show a difference in postural control for the FES group and the control group. However, they stimulated patients with stroke only once. An important finding in their study was the influence of therapy on patients with higher muscle tone. FES was more effective in patients with an MAS score of 3 or 4 than in a control intervention. We detected only slightly increased muscle tone in patients according to the MAS, both before and after the interventions. No differences in the effect of interventions were observed; that is, therapy with FES had no negative effect on muscle tone and did not cause spasticity.

Study limitations

The present study has certain limitations. For example, the relatively small number of follow-up evaluations has to be considered a study shortcoming. Patients of the present study were severely affected and consequently suffered several medical complications (see Consolidated Standards of Reporting Trials flow diagram in fig 2). Because of missing data in follow-up measurements, P values of statistical analyses did not reach a significance level. Therefore, results were presented as calculated effect sizes to handle the aspect of missing data.

A second limitation is the relatively small number of subjects. This small sample was, nevertheless, sufficient to allow us to find a statistically significant difference between the 2 intervention groups with regard to the FAC and POMA.

The small number of patients included compared with the large number of patients screened (see fig 2) could be considered another limitation because this suggests a low external validity or reduced generalizability. Crucial exclusion criteria for FES therapy are cardiac pacemakers, metal implants beneath the stimulation site, and pregnancy. All other criteria were set to keep the study population homogeneous. Consequently, we can assume that significantly more patients can be treated with this kind of FES therapy in daily clinical practice.

A fourth limitation is that we did not adjust the training according to sport-physiological standards, for example, with the use of higher resistance. We also did not increase the current intensity of the FES (whether due to mA, pulse duration, or frequency) according to the pain threshold in the study protocol. The MI values of our FES group might have improved even more if FES had been applied with increasing intensities or cycling had been driven with higher cycling frequencies or resistance. Sibley[13] showed that individuals with lower preferred cycling cadence had the greatest increase in preferred speed, cadence, and paretic leg step length ($P<.01$). These aspects have to be investigated in further studies.

Conclusions

The study demonstrated that 12 sessions of active leg cycling training with or without electrical stimulation on the paretic limb significantly improve walking ability, postural control, and muscle strength in subacute patients with severe hemiparesis. All parameters in both groups significantly improved over time; the walking ability of the FES group, however, improved significantly more. Active leg cycling is an essential intervention in patients with severe hemiparesis who are being rehabilitated for postural control and gait. When gait rehabilitation is combined with FES, gait will be enhanced.

Suppliers

a. RECK-Technik GmbH & Co. KG.
b. Hasomed GmbH.
c. SPSS, Inc.

Keywords

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