CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

For a 57-year-old man recovering from a L-sided CVA that occurred 2 weeks ago, is an FES bike more effective than conventional non-FES gait training at improving gait symmetry?

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CLINICAL SCENARIO

The patient is a 57-year-old African American male admitted to an inpatient rehabilitation facility 2 weeks following a L-sided CVA. He presents with mild cognitive deficit, dysarthria, and R-sided hemiplegia. His primary functional deficit is impaired gait as evidenced by decreased dorsiflexion, hip flexion, and knee flexion on the R side during the swing phase of the gait cycle.

Reduced dorsiflexion, hip flexion, and knee flexion are 3 common gait deviations found in individuals who have suffered a CVA[13] and, thus, represent, common gait deviations that are seen in the clinic. These deviations make the leg functionally longer during the swings phase of gait, which can result in other compensatory deviations[13] and may place the patient at an increased risk for falling.

Functional electrical stimulation has been used previously to address gait in individuals following stroke.[14] However, in the clinic, many therapists are unsure if the FES bike should be used for this purpose and whether or not it is worth the time that it takes to set up.

A better understanding of the of utility of the FES bike will provide therapists with the information they need to make important clinical decisions regarding gait training in their patients who have suffered a CVA.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- A search of four databases yielded ten relevant articles: 7 randomized controlled trials, 2 quasi-experimental studies, and 1 case series
- Various protocols have been utilized in the literature to determine the effects of FES cycling on various measures of walking ability in patients with subacute stroke.
- No studies have examined the effects of FES cycling on gait symmetry. Walking ability has primarily been measured in terms of gait speed. Results regarding gait speed have been inconsistent.
- Despite inconsistent findings regarding gait speed, evidence suggests that subjects treated with FES cycling demonstrate greater improvements in their ability to ambulate with decreased levels of physical assistance.
- Higher quality evidence with a large sample size is needed to adequately compare FES cycling to conventional non-FES gait training.

CLINICAL BOTTOM LINE

Although no evidence to date has addressed the effects of FES cycling on gait symmetry, current best evidence suggests that FES cycling is an effective supplement to standard rehabilitation. In patients with subacute stroke, FES cycling as a supplement to standard rehabilitation has resulted in improved motor power, single limb standing capabilities, trunk control, walking ability, balance, and strength. However, an optimum protocol has yet to be identified. Frequency of FES cycling has ranged from three to five times per week for 20 to 35 minutes per session. Additionally, studies have examined both FES-induced and FES-assisted cycling, but no studies have compared these two forms of FES cycling to determine which is optimal. Therefore, future research should focus on determining the optimum protocol for FES cycling and should also examine the effects of FES cycling on gait symmetry. Until then, clinicians should exercise sound clinical judgement and consider using FES cycling as a supplement to standard rehabilitation and non-FES gait training.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
stroke CVA cerebrovascular accident	functional electrical stimulation FES bike bicycle cycling	gait training rehabilitation exercise physical therapy physiotherapy	gait walk* ambulat* gait symmetry

Final search strategy:

1. stroke OR CVA OR cerebrovascular accident
2. stroke (MeSH Major Topic)
3. (functional electrical stimulation OR FES) AND (bike OR bicycle OR cycling)
4. gait training OR rehabilitation OR exercise OR physical therapy OR physiotherapy
5. gait OR walk* OR ambulat* OR gait symmetry
6. #1 AND #3 AND #4
7. #1 AND #3 AND #4 AND #5
8. #2 AND #3 AND #4
9. #2 AND #3 AND #4 AND #5

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
Pubmed:		
#3	256	N/A
#1 AND #3	26	N/A
CINAHL:		
#3	107	N/A
#1 AND #3	13	N/A
PsycINFO:		
#3	16	N/A
#1 AND #3	0	N/A
Cochrane Library:		
#3	85	N/A
#1 AND #3	33	N/A

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• RCTS, systematic reviews, and meta-analyses • Case series • Quasi-experimental studies • Published in English • Human studies • Studies that involve subjects or patients who have had a stroke • Intervention includes FES bike or cycling

Exclusion Criteria
• Animal studies • Narrative reviews • Abstracts

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Study quality score	Level of Evidence	Study design
Alon G, Conroy VM, Donner TW (2011)[1]	Downs & Black: 14/29	4	Case Series
Ambrosini E, Ferrante S, Pedrocchi A, Ferrigno G, Molteni F (2011)[2]	PEDro score: 10/11	1b	Randomized Control Trial
Ambrosini E, Ferrante S, Ferrigno G, Molteni F, Pedrocchi A (2012)[3]	PEDro score: 10/11	1b	Randomized Control Trial
Bauer P, Krewer C, Golaszewski S, Koenig E, Muller F (2015)[4]	PEDro score: 9/11	1b	Randomized Control Trial
Ferrante S, Pedrocchi A, Ferrigno G, Molteni F (2008)[5]	PEDro score: 7/11	1b	Randomized Control Trial
Janssen TW, Beltman JM, Elich P, et al (2008)[6]	PEDro score: 7/11	2b	Randomized Control Trial
Lee SY, Kang SY, Im SH, et al (2013)[7]	PEDro score: 7/11	1b	Randomized Control Trial
Lo H, Tsai K, Su F, Chang G, Yeh C (2009)[8]	Downs & Black: 11/29	4	Quasi-experimental study
Lo H, Hsu Y, Hsueh Y, Yeh C (2012)[9]	PEDro score: 6/11	1b	Randomized Control Trial
Yeh CY, Tsai KH, Su FC, Lo HC (2010)[10]	Downs & Black: 15/29	4	Quasi-experimental study

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- **Ambrosini E, Ferrante S, Pedrocchi A, Ferrigno G, Molteni F (2011)[2]** – This RCT demonstrates the highest methodological quality (PEDro score 10/11) of all of the studies meeting the inclusion and exclusion criteria for this critically appraised topic (CAT). It should be noted that one other study by the same authors[3] demonstrated equivalent methodoloigical quality, however, this study is an extension of the 2011 study and is based on the exact same experimental data. The 2011 study was deemed to be more relevant to addressing the current clinical question. An experimental group receiving FES cycling is compared to a placebo group receiving passive cycling. Although gait speed is the only direct measurement of gait included in this study, other outcome measures include measures of motor power, trunk control, and single limb stance capabilities, all of which may be important to the task of walking.
- **Bauer P, Krewer C, Golaszewski S, Koenig E, Muller F (2015)[4]** – This RCT demonstrates high methodological quality (PEDro score 9/11) and examines the effects of FES cycling

compared to active cycling without FES. The most relevant outcome measures include gait speed and walking ability. However, this study examines the influence of FES cycling on other factors that may have an influence on gait quality, such as balance and muscle tone. Subjects in this study are similar in age to the patient described in the clinical question. Furthermore, the study's inclusion criteria include subjects who have suffered a stroke as recently as 7 days prior to starting the study.

- **Ferrante S, Pedrocchi A, Ferrigno G, Molteni F (2008)[5]** – This RCT demonstrates good methodological quality (PEDro score 7/11) and includes patients with subacute stroke whose time since stroke is similar to that of the patient described in the present clinical scenario. Furthermore, this study represents the only study that compares standard rehabilitation alone to FES cycling plus standard rehabilitation. As a result, this study more directly examines the benefit of supplementing conventional non-FES gait training with FES cycling. Relevant outcome measures include gait speed and number of steps taken during a 50 meter walk test as well as measures of trunk control and functional muscle strength of the hemiparetic limb.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of *Cycling induced by electrical stimulation improves motor recovery in postacute hemiparetic patients: A randomized controlled trial* by Ambrosini E, Ferrante S, Pedrocchi A, Ferrigno G, Molteni F. (2011)

Aim/Objective of the Study/Systematic Review:

The objective of this study was to determine whether FES-induced cycling is superior to passive cycling with placebo stimulation at improving motor recovery and walking ability in patients with postacute hemiparesis.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

- Double-blind, randomized controlled trial
- Random allocation to one of two groups: (1) FES-induced cycling (FES group) or (2) passive cycling with placebo FES (placebo group)
- Concealed allocation via computer-generated randomization and automated assignment
- Outcomes were measured (1) prior to the intervention, (2) immediately after the intervention, and (3) 3 to 5 months after the intervention
- An a priori power analysis determined that a sample size of 30 would provide 80% power to detect a minimal clinically important difference in gait speed of 0.16 m/s (standard deviation=0.22 m/s).

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

All study participants were inpatients at a single rehabilitation center in Costa Masnaga, Lecco, Italy.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- Subjects were recruited between May 2008 and July 2009. Each subject received an information sheet. No further information is provided regarding the specific recruitment strategy.
- 35 subjects met inclusion criteria and received group assignment (FES group, n=17; placebo group, n=18)
- Inclusion criteria: first-time diagnosis of stroke (n=32) or TBI (n=3) with resulting hemiparesis, event occurred less than 6 months prior the start of the study, adequate cognition to engage in standard rehabilitation, capable of sitting for at least 30 minutes, ample joint range of motion to perform cycling, and modified Ashworth score less than 2 for lower limb musculature
- Exclusion criteria: pacemaker, allergic to FES electrodes, intolerant of electrical stimulation
- 2 subjects in the FES group dropped out during the training period for reasons unrelated to the

intervention (1 subject suffered a femur fracture, 1 subject was discharged)
- 3 subjects in the placebo group dropped out during the training period for reasons unrelated to the intervention (1 subject had a heart attack, 2 subjects were discharged)
- 30 subjects (FES group, n=15; placebo group, n=15) completed the 20 session intervention and were included in the data analysis
- 22 subjects (FES group, n=11; placebo group, n=11) were available at follow-up 3 to 5 months later. For the 8 subjects who were unavailable at follow-up, their post-intervention data was used in the follow-up data analysis.
- Age, mean (SD), years: FES group, 59(10); placebo group, 56(14)
- Time since brain injury event, mean (SD), days: FES group, 48(43); placebo group, 48(36)
- Gender: FES group, 7 males, 8 females; placebo group, 11 males, 4 females
- Etiology: FES group, 11 ischemic stroke, 3 hemorrhagic stroke, 1 TBI; placebo group, 8 ischemic stroke, 5 hemorrhagic stroke, 2 TBI
- Paretic side: FES group, 6 right, 9 left; placebo group, 7 right, 8 left
- There were no significant between group differences regarding key demographics at baseline
- Amount of elapsed time between the end of the intervention and follow-up evaluation, mean (SD), days: FES group, 112(25); placebo group, 105(25)

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Placebo Group

- Subjects sat in a chair with their feet placed on the pedals of a motorized cycle-ergometer
- A bipolar electrode configuration was applied bilaterally to the quadriceps, hamstrings, gluteus maximus, and tibialis anterior muscle groups
- Subjects were told that they may or may not feel the electrical stimulation
- Subjects were instructed to concentrate on the exercise but to not put forth any voluntary effort to pedal the cycle-ergometer
- FES protocol: none, no stimulation was delivered; subjects' legs were moved entirely by the motorized ergometer at a constant speed of 20 rpm
- Total of 20 training sessions over the course of 4 weeks
- Training sessions occurred 5 times per week with each training session lasting 25 minutes (5 minutes of passive cycling to warm up, 15 minutes of placebo cycling, and 5 minutes of passive cycling to cool down)
- The cycle-ergometer maintained a constant speed of 20 rpm during the passive warm up and cool down periods
- Subjects also participated in a standard physical therapy program for 3 hours every day, which consisted of stretching, muscular conditioning, trunk control exercises, and standing and walking training
- Did not explicitly state who provided placebo intervention

FES Group

- Subjects sat in a chair with their feet placed on the pedals of a motorized cycle-ergometer
- A bipolar electrode configuration was used to apply electrical stimulation bilaterally to the quadriceps, hamstrings, gluteus maximus, and tibialis anterior muscle groups
- Subjects were instructed to concentrate on the exercise but to not put forth any voluntary effort to pedal the cycle-ergometer
- FES protocol: rectangular biphasic waveform, pulse width=300 μs, stimulation frequency=20 Hz, increase intensity to such a level that it provokes a visible muscle contraction but is tolerated by the patient
- Total of 20 training sessions over the course of 4 weeks
- Training sessions occurred 5 times per week with each training session lasting 25 minutes (5 minutes of passive cycling to warm up, 15 minutes of FES cycling, and 5 minutes of passive cycling to cool down)
- The cycle-ergometer maintained a constant speed of 20 rpm during the passive warm up and cool down periods
- Subjects also participated in a standard physical therapy program for 3 hours every day, which consisted of stretching, muscular conditioning, trunk control exercises, and standing and walking training
- Did not explicitly say who provided FES cycling intervention

Outcome Measures (Primary and Secondary)

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

1. **Motricity Index (MI), leg subscale:** Primary outcome measure used to assess motor power in the involved lower extremity; scores range from 0 (worst) to 100 (best).

2. **Gait speed:** Primary outcome measure attained by having subjects perform a 50-meter walking test. Subjects were instructed to walk at a self-selected speed and were permitted to use assistive devices as needed. Subjects were given a score of 0 if they were unable to complete the test.
3. **Trunk Control Test (TCT):** Secondary outcome measure used to assess trunk control; scores range from 0 (worst) to 100 (best).
4. **Upright Motor Control Test (UMCT):** Secondary outcome measure used to assess the single-limb standing capabilities of the involved lower extremity; scores range from 0 (worst) to 6 (best).
5. **Mean work produced by the paretic leg (W_{PL}):** Secondary outcome measure that was attained by measuring the work produced by the involved lower extremity during a pedaling test in which subjects were instructed to voluntarily pedal while trying to achieve symmetry between both legs. Measured in newton meters (Nm).
6. **Pedaling unbalance (U):** Secondary outcome measure that was attained by measuring the mean work produced by each lower extremity during a pedaling test in which subjects were instructed to voluntarily pedal while trying to achieve symmetry between both legs. Scored as a percentage from 0% (both legs perform an equal amount of work) to 100% (W_{PL} is 0 or negative).

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable]

After training, the FES group showed significant improvements in both primary outcome measures and 3 secondary outcome measures. MI scores improved by 30 points in the FES group (P<0.001) compared to 10 points in the placebo group (P=0.230). At baseline, 20% of the FES group and 27% of the placebo group were able to complete the 50-meter walking test. After training, the completion rate improved to 87% and 80% in the FES group and placebo group, respectively. Gait speed improved by 0.28 m/s in the FES group (P=0.028) compared to 0.18 m/s in the placebo group (P=0.357). TCT scores improved by 22 points in the FES group (P<0.001) compared to 9 points in the placebo group (P=0.511). UMCT scores improved by 2.3 points in the FES group (P<0.001) compared to 0.6 points in the placebo group (0.691). W_{PL} improved by 6.82 Nm in the FES group (P=0.036) compared to 2.11 Nm in the placebo group (P=0.947). All of these improvements in the FES group were maintained at follow-up.

Standardizing effect size using Cohen's d revealed large treatment effects after training for the FES group compared to the placebo group (MI: FES=1.09 [P<0.001], placebo=0.32 [P=0.230]; gait speed: FES=1.01 [P=0.028], placebo=0.69 [P=0.357]; TCT: FES=1.44 [P<0.001], placebo=0.48 [P=0.511]; UMCT: FES=1.43 [P<0.001], placebo=0.32 [P=0.691]; W_{PL}: FES=0.63 [P=0.036], placebo=0.26 [P=0.947]).

Although the placebo group did not demonstrate any significant changes after training, it did demonstrate significant improvements in MI (absolute effect size=18 points, P=0.002) and gait speed (absolute effect size=0.37 m/s, P=0.001) from baseline to follow-up.

Neither group showed any significant changes during the period after training to follow-up.

Statistical analysis revealed a time-by-group interaction for MI, TCT, UMCT and U, with all between group differences being in favor of the FES group. The between group mean difference for MI was 19 points (95% CI=8-30; P=0.002) after training and 21 points (95% CI=10-31; P<0.001) at follow-up. The between group mean difference for TCT was 20 points (95% CI=8-33; P=0.003) after training and 22 points (95% CI=10-35; P=0.001) at follow-up. The between group mean difference for UMCT was 1.6 points (95% CI=0.7-2.5; P=0.001) after training and 1.4 points (95% CI=0.1-2.7; P=0.032) at follow-up. The between group mean difference for U was -16% (95% CI=-31 to -1; P=0.032) after training and -14% (95% CI=-30 to1; P=0.118) at follow-up. Therefore, for these four outcome measures, between group differences were statistically significant both after training and at follow-up except for U, in which case the groups only differed after training.

There was no statistically significant difference in gait speed between the FES and placebo groups (mean difference based on pooled scores after training and at follow-up [95% CI]: 0.19 m/s [-0.23 to 0.60]). However, a separate analysis including only subjects with ischemic stroke revealed that the FES group was significantly faster than the placebo group (mean difference based on pooled scores [95% CI]: 0.54 m/s [0.12-0.96]; P=0.014).

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

Twenty sessions of FES-induced cycling over a 4-week period improve motor recovery and walking ability in patients with postacute hemiparesis. Furthermore, these improvements are maintained beyond the end of treatment for at least 3 to 5 months.

Critical Appraisal

Validity

[Identify the strengths and limitations of the study, including potential sources of bias. Comment on the overall methodological quality (including the score) as you determined from your assessment of the article. Comment on anything you believe was missing in the paper.]

- With a PEDro score of 10 out of 11, the study demonstrates high methodological quality. One point was deducted because the authors did not state whether or not the person administering treatment was blinded. Despite this shortcoming and potential for bias, the FES group and placebo group received identical treatments save for the fact that the placebo group did not really receive electrical stimulation.
- An a priori power analysis determined that a sample size of 30 was large enough to achieve 80% power to detect a minimal clinically important difference in gait speed of 0.16 m/s (standard deviation=0.22 m/s). The authors achieved this sample size despite the 14% who dropped out of training.
- Sixty-three percent (22 out 35) of subjects were available at follow-up. To supplement this missing data, available data from after training was included in the follow-up data analysis. This may have inflated the reported treatment effects at follow-up.
- Gait speed as measured in this study is somewhat of a misnomer. Subjects were given a score of 0 if they were unable to complete the 50-meter walking test. Therefore, in light of the fact that only 23% (7 out of 30) of subjects were able to complete the 50-meter walking test at baseline compared to 83% (25 out of 30) after training, actual gait speed at baseline was likely underestimated (given the vast number of subjects who received a 0) and treatment effects were likely overestimated. It is difficult to know how much of the change in gait speed is attributed to an actual increase in walking velocity versus an increase in endurance.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

The results favor the use of FES-induced cycling in the postacute phase of rehabilitation for individuals recovering from stroke. Groups were similar at baseline and experienced similar dropout rates and losses to follow-up. Furthermore, the study design and high methodological quality minimized the risk of bias and confounding. After training, FES-induced cycling had the largest treatment effect on MI (Cohen's d=1.09), gait speed (Cohen's d=1.01), TCT (Cohen's d=1.44), and UMCT (Cohen's d=1.43). Although the MDC and MCID were not reported for these outcome measures, the large effect sizes are suggestive of meaningful change. However, given the method by which the authors measured gait speed, this treatment effect is likely an overestimation of the actual improvement in walking velocity. Rather than walking faster after treatment, subjects may just be walking farther. This should be taken into account when comparing these results to other studies that measure gait speed. Regarding U, the FES group demonstrated a statistically significant improvement compared to the placebo group after training; however, this improvement was not deemed a statistically significant deviation from baseline. Lastly, it is unclear if the passive nature of placebo cycling provided an adequate control intervention. In order to determine the true clinical benefits of FES-induced cycling, it needs to be compared to a control group receiving a more active intervention, such as 25 more minutes of standard physical therapy or non-FES gait training.

(2) Description and appraisal of *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* by Bauer P, Krewer C, Golaszewski S, Koenig E, Müller F. (2015)

Aim/Objective of the Study/Systematic Review:

The objective of this study was to determine whether active FES-assisted cycling is capable of improving walking ability and balance in patients who are 7 days to 6 months post stroke and whether this intervention is more effective than active cycling without FES.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

- Pilot study
- Single-blind, randomized controlled trial

- Random allocation to one of two groups: (1) FES-assisted cycling (FES group) or (2) active cycling without FES (control group)
- Concealed allocation via a computer-generated randomization sequence
- Outcomes were measured (1) prior to the intervention, (2) immediately after the intervention, and (3) 2 weeks after the intervention
- The assessor of outcome measures was blinded to patients' group assignments.
- Data were analyzed by intention to treat

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

All study participants were inpatients at a single neurologic rehabilitation hospital in Germany.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- Inpatients were monitored at a single neurologic rehabilitation hospital over a 2-year period and were enrolled in the study by a neurologist.
- 40 patients were enrolled and received group assignment (FES group, n=21; control group, n=19)
- Inclusion criteria: ≥18 years old, stroke occurred between 7 days and 6 months ago and resulted in severe hemiparesis (quadriceps strength <3 according to the Medical Research Council scale), walking ability ≤2 according to the functional ambulation category (i.e., requires manual assistance for ambulation), able to cycle for at least 20 minutes, verbal expression of understanding the informed consent form 24 hours after it was originally explained by the neurologist
- Exclusion criteria: pacemaker, metal implants near the area of stimulation, insufficient lower extremity joint range of motion or severe spasticity that precludes cycling, dementia, psychosis, unstable cardiorespiratory issues, osteoporosis
- All patients allocated to the FES group began the experimental intervention. One of the patients allocated to the control group did not begin the control intervention secondary to spontaneous remission of hemiparesis prior to the start of the intervention (i.e., quadriceps strength improved to a grade of 3 between randomization and baseline).
- Two patients in the FES group were lost during intervention (1 had a viral infection, 1 was a severe pusher). None of the patients in the control group were lost during intervention.
- Ten patients in the FES group were lost to follow-up (1 refused to participate, 3 were discharged, 3 were lost due to logistical reasons, 2 were lost secondary to medical complications, 1 was lost secondary to an anxiety attack). Six patients in the control group were lost to follow-up (1 was discharged, 1 was lost due to logistical reasons, 4 were lost secondary to medical complications).
- No measures were taken to replace missing data. Post-intervention analysis included data from 19 patients in the FES group and 18 patients in the control group. Follow-up analysis included data from 9 patients in the FES group and 12 patients in the control group.
- Age, mean (SD), years: FES group, 59(14); control group, 64(11)
- Time since stroke, mean (SD), days: FES group, 62(43); control group, 42(45)
- Sex: FES group, 12 males, 7 females; control group, 9 males, 9 females
- Type of stroke: FES group, 15 ischemic, 4 hemorrhagic; control group, 10 ischemic, 8 hemorrhagic
- Paretic side: FES group, 5 right, 14 left; control group, 7 right, 11 left
- There were no significant between group differences regarding key demographics at baseline

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control group

- Active leg cycling without FES
- Patients sat in a wheelchair secured by an antitipper device with their feet placed on the pedals of a motorized cycle-ergometer
- Patients were instructed to actively cycle
- FES protocol: none
- Total of 12 training sessions over the course of 4 weeks
- Training sessions occurred 3 times per week with each training session lasting 20 minutes
- Patients also participated in a rehabilitation program that was tailored to their individual needs, which included physical therapy, occupational therapy, neuropsychology, and logopedics. No information was provided regarding the frequency of these other interventions.
- Did not explicitly state who provided control intervention

FES group

- Active leg cycling with FES
- Patients sat in a wheelchair secured by an antitipper device with their feet placed on the pedals of a motorized cycle-ergometer
- Electrodes were placed on the rectus femoris, vastus medialis, semitendinosus, and biceps femoris of the paretic lower extremity. No specific information was provided regarding the specific electrode configuration.
- FES protocol: rectangular biphasic waveform, pulse width=250 μs (positive phase), stimulation frequency=25 Hz, increase intensity as high as tolerated with the goal of eliciting a tetanic contraction.
- Patients were instructed to actively cycle. Stimulation did not start until patients achieved at least 20 rpm.
- Total of 12 training sessions over the course of 4 weeks
- Training sessions occurred 3 times per week with each training session lasting 20 minutes (1 minute of active cycling to warm up, 19 minutes of FES cycling)
- Patients also participated in a rehabilitation program that was tailored to their individual needs, which included physical therapy, occupational therapy, neuropsychology, and logopedics. No information was provided regarding the frequency of these other interventions.
- Did not explicitly state who provided experimental intervention

Outcome Measures (Primary and Secondary)

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

1. **Functional Ambulation Classification (FAC)**: Primary outcome measure used to assess walking ability. Rated on an ordinal scale from 0 (non-ambulatory or requires physical assistance from at least two people) to 5 (independent ambulator on even and uneven surfaces).
2. **Performance-Oriented Mobility Assessment (POMA), balance section:** Primary outcome measure used to assess balance and postural control; scores range from 0 (worst) to 16 (best)
3. **Motricity Index (MI), leg subscale:** Secondary outcome measure used to assess maximal voluntary muscle contractions in the involved lower extremity; scores range from 0 (worst) to 100 (best). Specific muscle groups tested include the ankle dorsiflexors, knee extensors, and hip flexors.
4. **Modified Ashworth scale (MAS):** Secondary outcome measure to assess spasticity; scores range from 0 (no increased tone) to 4 (rigid in either flexion or extension). Only the stimulated muscle groups (paretic quadriceps and hamstrings) were assessed.
5. **10-Meter Walking Test (10MWT):** Secondary outcome measure to assess gait velocity. Patients were instructed to walk as fast as possible while maintaining a feeling of safety. Patients were allowed to use assistive devices as needed. Only patients with an FAC ≥3 performed the 10MWT. All patients had an FAC <3 at baseline.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable]

There were no adverse effects from the intervention.

Both groups demonstrated significant improvements from baseline to postintervention and from baseline to follow-up on the FAC, POMA, and MI. From baseline to postintervention, FAC scores improved by 2 points in the FES group (P=0.001) and 1 point in the control group (P=0.016); POMA scores improved by 4 points in the FES group (P<0.0004) and 2 points in the control group (P=0.003); and MI scores improved by 11 points in the FES group (P=0.005) and 12 points in the control group (P=0.004). From baseline to follow-up, FAC scores improved by 2 points in the FES group (P=0.014) and 1 point in the control group (P=0.026); POMA scores improved by 5 points in the FES group (P=0.008) and 3 points in the control group (0.011); and MI scores improved by 17 points in the FES group (P=0.018) and 15 points in the control group (P=0.005).

Between-group comparisons revealed between-group differences in favor of the FES group on the FAC and POMA. From baseline to postintervention, the between-group mean difference on the FAC was 1 point (P=0.013) and the between-group mean difference on the POMA was 2 points (P<0.0004). There were no statistically significant between-group differences from baseline to follow-up.

Change in gait velocity was not examined given that none of the patients were self-ambulatory at baseline. At baseline, 30 patients (FES group, n=15; control group, n=15) met criteria for FAC level 0, three patients (FES group, n=2; control group, n=1) met criteria for FAC level 1, and four patients (FES group, n=2; control group, n=2) met criteria for FAC level 2. At postintervention, 15 patients (FES group, n=4; control group, n=11) met criteria for FAC level 0, four patients (FES group, n=2; control group, n=2) met criteria for FAC level 1, six patients (FES group, n=5; control group, n=1) met criteria for FAC level 2, eight patients (FES group, n=6; control group, n=2) met criteria for FAC level 3, and four patients (FES group, n=2; control group, n=2) met criteria for FAC level 4. Therefore, 8 subjects in the FES group became self-ambulatory (FAC ≥3) by the end of

treatment compared to 4 subjects in the control group. Gait velocity was measured in those individuals at this time. At postintervention, the control group (mean±SD, 22.3±12s) performed the 10MWT significantly faster than the FES group (mean±SD, 55.4±27.8s).

There were no statistically significant changes in muscle tone for either muscle group (quadriceps, P=0.258; hamstrings, P=0.988) in either the FES or the control group.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

In patients with hemiparesis who were 6 months or less poststroke, 12 sessions of FES-assisted cycling over a 4-week period improved both walking ability and postural control to a greater extent than active cycling without FES.

Critical Appraisal

Validity

[Identify the strengths and limitations of the study, including potential sources of bias. Comment on the overall methodological quality (including the score) as you determined from your assessment of the article. Comment on anything you believe was missing in the paper.]

- With a PEDro score of 9 out of 11, the study demonstrates high methodological quality. One point was deducted because subjects were not blinded. Given the nature of the intervention, however, failure to blind the subjects is unlikely to have produced much bias, as both interventions required assistance from a therapist. One more point was deducted for failing to blind the therapists providing treatment. Bias may have been introduced if therapists provided different levels of motivation between groups.
- The authors reported that an a priori power analysis determined that a sample size of 36 patients (18 patients per group) would provide 80% power to detect clinically relevant effects for both the FAC and the POMA. However, it was unclear what effect sizes were used in this analysis.
- Although the target sample size was achieved and available for pre- to postintervention analysis, loss to follow-up was significant, which increased the likelihood of making a type II error and may explain the lack of significant findings at follow-up.
- The authors stated that a pedaling cadence of 20 rpm was required to start the electrical stimulation. However, it was unclear if patients in the control group were required to achieve this same cadence and/or maintain it throughout the active cycling session.
- The authors failed to adequately describe the rehabilitation program. No mention was made regarding the timing, frequency, or duration of these other interventions.
- A strength of this study is that the control group performed active cycling. Therefore, the only difference between the groups was the use of FES.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

The results favor the use of FES-assisted cycling in patients with hemiparesis who are 6 months or less poststroke. Standard rehabilitation with a component of cycling (either active cycling or FES-assisted cycling) produced significant improvements on measures of walking ability, balance and postural control, and lower extremity volitional muscle contractions. FES-assisted cycling demonstrated an advantage over active cycling on measures of walking ability and balance and postural control. It is unclear, however, if this advantage resulted from the use of FES or a difference in cycling intensity between groups. The authors failed to adequately report whether or not the active cycling group was expected to maintain a certain pedaling cadence or intensity. Although FES-assisted cycling and active cycling, though perhaps to a lesser degree, have shown to improve rehabilitation outcomes for individuals with subacute stroke, it is unknown if these improvements are superior to those made with standard physical therapy alone. To make this determination, a similar study including a third group that receives only standard physical therapy is needed.

(3) Description and appraisal of *Cycling induced by functional electrical stimulation improves the muscular strength and the motor control of individuals with post-acute stroke* by Ferrante S, Pedrocchi A, Ferrigno G, Molteni F. (2008)

Aim/Objective of the Study/Systematic Review:

The objective of this study was to determine the effectiveness of FES-induced cycling as a supplementary

component of standard rehabilitation in individuals with subacute stroke.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

- Randomized controlled trial
- Random allocation via a computerized procedure to one of two groups: (1) FES-induced cycling plus standard rehabilitation (FES group) or (2) standard rehabilitation only (control group)
- Insufficient detail to determine if allocation was concealed
- No mention of blinding
- Outcomes were measured (1) prior to the start of the intervention and (2) at the end of the 4-week intervention period

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

Insufficient detail was provided to determine the exact setting of the study. However, given the sub-acute nature of the patients' conditions, the frequency and intensity of the rehabilitation protocols, and the authors' affiliation with Villa Beretta Rehabilitation Centre, it is presumed that the study took place at an inpatient rehabilitation center in Italy.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- 20 subjects met inclusion criteria and received group assignment (FES group, n=10; control group, n=10)
- Inclusion criteria: postacute hemiplegia status post ischemic or hemorrhagic ictus, able to follow simple instructions, capable of sitting in a wheelchair for about 45 minutes, Ashworth score less than 2 for lower limb musculature, at least 80 degrees of hip flexion and 150 degrees of knee extension
- Exclusion criteria: pacemaker, allergic to FES electrodes or adhesives
- There were no dropouts over the course of the study
- Age, mean (SD), years: FES group, 51(12); control group, 56(9.2)
- Time since brain injury event, mean (SD), days: FES group, 56.1(22.8); control group, 50.8(24.5)
- Gender: FES group, 5 males, 5 females; control group, 5 males, 5 females
- Etiology: FES group, 7 ischemic, 3 hemorrhagic; control group, 8 ischemic stroke, 2 hemorrhagic
- Plegic side: FES group, 7 right, 3 left; control group, 4 right, 6 left
- No p-values were reported for demographic or clinical details

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

- Standard rehabilitation only
- Standard rehabilitation was performed for about 3 hours per day, presumably on 5 days per week; however, this was not explicitly stated.
- Standard rehabilitation was performed under the guidance of a physiotherapist and was individualized for each patient. Components of standard rehabilitation included stretching, active or passive mobility, trunk control exercises, and standing and walking training.

Experimental

- Standard rehabilitation plus FES-induced cycling
- FES cycling was performed everyday for 4 weeks for a total of 20 treatment sessions.
- Each session of FES lasted 35 minutes (5 minutes of passive, 10 minutes FES-induced cycling, 5 minutes of passive cycling, 10 minutes of FES-induced cycling, 5 minutes of passive cycling).
- Patients sat in a chair with their feet secured to the pedals of a motorized cycle-ergometer.
- Patients were instructed to not put forth any voluntary effort to pedal the cycle-ergometer

- The cycle-ergometer maintained a constant speed of 40 rpm during passive cycling. It appears that this same speed was also maintained during periods of FES-induced cycling.
- Electrical stimulation was applied bilaterally to the quadriceps, hamstrings, gluteus maximus, and tibialis anterior.
- No description was provided regarding the electrode configuration or the FES protocol that was utilized.
- The experimental group also received standard rehabilitation under the guidance of a physiotherapist that was individualized for each patient. Components of standard rehabilitation included stretching, active or passive mobility, trunk control exercises, and standing and walking training.
- It was reported that both groups received about 3 hours of rehabilitation per day. Although not explicitly stated, it is assumed that the FES cycling intervention was included within these 3 hours of rehabilitation rather than serving as an additional 35 minutes of treatment.

Outcome Measures (Primary and Secondary)

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

1. **Trunk Control Test (TCT):** outcome measure used to assess trunk movement and balance from a seated position; scores range from 0 (worst) to 100 (best).
2. **Motricity Index (MI), leg subscale:** outcome measure used to assess voluntary mobility at the ankle, knee, and hip joints against gravity and external resistance; scores range from 0 (worst) to 100 (best).
3. **Upright Motor Control Test (UMCT):** outcome measure used to assess the functional muscle strength of the involved lower extremity. Separate scores are reported for both flexion and extension. It is not altogether clear how the test was scored. The cited reference by Perry et al reports that the total UMCT score ranges from 0 (worst) to 18 (best) and represents the sum of the scores obtained by the flexors and extensors of the hip, knee, and ankle.[11] However, it was found that the UMCT scores for the knee alone were predictive of community versus household mobility.[11] Based on the scores reported in the present study, which only range from 0 to 3, it appears that the authors only reported the UMCT scores for the knee flexors and extensors. Therefore, 0 represents the minimum score (worst) and 3 represents the maximum score (best).
4. **50-meter walking test:** outcome measure used to assess indoor walking ability. Specifically, the authors analyzed walking speed and number of steps taken.
5. **Sit-to-stand:** outcome measure used to assess motor control and the ability to modulate the speed of task performance; patients performed the task at their self-selected speed and were then instructed to repeat the task at a faster speed and a slower speed. Of interest were the percentage ratios between the various conditions. Proper performance was achieved when the slow speed was less than 90% of the self-selected speed *and* the fast speed was greater than 110% of the self-selected speed.
6. **Maximal voluntary contraction (MVC):** maximum isometric force produced by the quadriceps with a knee angle of 90 degrees; measured in newtons (N).
7. **Power Output (PO):** used to determine the contribution of both the involved and the uninvolved lower extremities during cycling. As such, PO was only measured in the experimental group. Maximum PO and minimum PO were obtained; measured in watts (W).

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable]

There were no between group differences in TCT, MI, or UMCT at pre- or post-intervention; p-values were not reported. Scores were reported as medians. The median TCT scores for the FES group improved from 43.0 at pre-intervention to 67.5 at post-intervention while the control group improved from 49.0 to 74.0. Median MI scores for the FES group improved from 29.0 to 49.0 while the control group improved from 15.0 to 48.0. Median UMC flexion scores improved from 0.0 to 1.5 for the FES group and 0.0 to 1.0 for the control group. Median UMC extension scores improved from 0.0 to 1.0 in both the FES and the control group.

Prior to the intervention, 5 patients in the FES group and 8 patients in the control group were able to perform a sit-to-stand transfer. However, only 2 patients from each group were able to demonstrate proper performance (i.e., slow speed/self-selected speed<0.90 and fast speed/self-selected speed>1.10). After the intervention, all 10 of the patients in the FES group and 9 patients in the control group were able to perform the transfer, with 7 FES patients and 0 control patients demonstrating proper performance. There were no between group differences in rising speeds at pre-intervention ($p>0.05$). At post-intervention, there was a statistically significant between group difference for slow speed/self-selected speed (FES group, median=53.2; control group, median=119.7; $p=0.02$) that was in favor of the FES group.

The FES group demonstrated significantly greater improvements in MVC for both the healthy lower extremity ($p<0.05$) and the involved lower extremity ($p<0.05$) compared to the control group. Exact values were not provided. However, graphical representation illustrates an improved MVC (reported as the median) in the involved lower extremity of about 85 N in the FES group compared to about 10 N in the control group. In the healthy lower extremity, the median MVC improved by about 110 N in the FES group compared to 10 N in the control group.

Prior to the intervention, only 2 patients in each group were able to walk 50 meters. After the intervention, all 10 of the patients in the FES group and 8 patients in the control group were able to walk 50 meters. There were no significant between group differences in number of steps or walking speed at either pre- or postintervention. At pre-intervention, the median number of steps taken by each group was 56 and 84 in the FES group and control group, respectively ($p>0.05$). At that same time, the median walking speed was 0.295 m/s and 0.403 m/s in the FES group and control group, respectively ($p>0.05$). At post-intervention, the median number of steps taken by each group was 79 and 76 in the FES group and control group, respectively ($p>0.05$). At that same time, the median walking speed was 0.305 m/s and 0.357 m/s in the FES group and control group, respectively ($p>0.05$).

Exact values of PO were not reported; however, graphic representation demonstrates that both maximum active PO and minimum active PO increased significantly from the first day of intervention to the last day ($p<0.05$). Furthermore, the active PO produced by both the involved and uninvolved lower extremities was always greater than 0 by the final day of FES-induced cycling (no point measures or measures of variability were provided). Additionally, the active PO was similar between both lower extremities on the final day of FES-induced cycling (no point measures or measures of variability were provided).

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

FES-induced cycling as a supplementary component of standard rehabilitation was more effective than standard rehabilitation alone in improving lower extremity strength and motor recovery.

Critical Appraisal

Validity

[Identify the strengths and limitations of the study, including potential sources of bias. Comment on the overall methodological quality (including the score) as you determined from your assessment of the article. Comment on anything you believe was missing in the paper.]

- With a PEDro score of 7 out of 11, the study demonstrates good methodological quality. Points were deducted for the absence of concealed allocation and failing to blind subjects, therapists who administered interventions, and assessors of outcome measures.
- A statistical comparison of baseline data with the associated p-values is needed to determine whether there were truly any baseline differences between groups. Nevertheless, the reported means and standard deviations appear quite comparable, suggesting similarity between groups at baseline.
- Although the authors reported that both groups were similar at both pre- and postintervention with regards to the TCT, MI, and UMCT, they failed to report whether or not the within group improvements were significant.
- Detail was lacking regarding the scoring of the UMCT, leaving the reader to make some assumptions regarding the range of possible scores.
- Data regarding PO was inadequately presented. No point measures or measures of variability were provided.
- There lacked sufficient detail regarding the FES protocol. There was no mention of the electrode configuration or the electrical stimulation parameters.
- The study was also limited by a small sample size
- A strength of the study was its 0% dropout rate. This allowed for pre- and postintervention data to be collected for all patients.
- Another strength of the study was its design. Compared to other studies in which the control group includes some component of cycling,[2,4] the control group in this study consisted only of standard rehabilitation. This allows for a more direct comparison between FES-cycling versus standard rehabilitation.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

Compared to standard rehabilitation, FES-induced cycling promoted significant improvements in muscle strength as measured by the MVC of the quadriceps. Although no mention was made regarding the MCID of quadriceps strength, graphical representation demonstrates at least an eightfold increase in MVC of the paretic lower extremity in the FES group compared to the control group and a tenfold increase in MVC of the healthy lower extremity in the FES group compared to the control group. Nevertheless, this increase in strength did not translate to significant between group differences on measures of functional strength (i.e., UMCT) and voluntary mobility of the hip, knee, and ankle joints (i.e., MI). On an arguably more functional task (i.e, sit-to-stand), however, the FES group demonstrated greater improvements in motor control compared to the control group. Seventy percent of the patients in the FES group were able to adequately modify the speed at which they

performed the task compared to 0% in the control group. In terms of walking ability, there was no clear advantage for either intervention as both groups were comparable in terms of number of steps taken and walking speed at both pre- and postintervention. With that being said, a strict focus on gait speed and number of steps taken fails to acknowledge any effect of intervention on other gait parameters such as stance time and step length asymmetries. The authors suggest that the similarities in PO between the involved and uninvolved lower extremities by the end of the intervention period may demonstrate that patients are performing a more symmetrical task. Whether or not this translates to a more symmetrical gait pattern is unknown. Overall, this study suggests that FES-induced cycling is an effective supplement to standard rehabilitation for improving lower extremity muscle strength in patients with subacute stroke.

EVIDENCE SYNTHESIS AND IMPLICATIONS

There is a dearth of research examining the role of FES cycling in improving gait symmetry in patients post stroke. A search of four databases revealed that no studies have examined this relationship to date. Eight articles were found that specifically included an intervention of FES cycling using a leg cycle-ergometer,[1-7,9] and two articles used an FES-assisted leg-cycling wheelchair.[8,10] These studies were quite heterogeneous in terms of outcome measures and subjects' average time since stroke. Of these ten articles, seven[2-5,7,8,10] examined the effects of the intervention on a population of patients whose time since stroke was similar to that of the patient described in the present clinical scenario. Overall, the methodological quality of the available evidence is good, with seven randomized controlled trials[2-7,9] receiving scores ranging from 6 to 10 out of 11 on the PEDro scale.[12]

The three articles examined in this critically appraised topic were chosen based on level of evidence, methodological quality, and relevance. In short, the evidence supports the use of FES-cycling as a supplement to standard rehabilitation. However, the specific benefits offered by FES-cycling are not altogether clear. This is largely due to discrepancies in FES protocols between different studies. In the literature, studies have examined both FES-induced and FES-assisted cycling. FES-induced cycling resulted in significant improvements in 5 out of 6 outcome measures while placebo cycling resulted in no improvements.[2] However, this may not be entirely surprising given the passive nature of placebo cycling. Studies in which the control groups received more active interventions, such as active cycling[4] and standard rehabilitation,[5] resulted in less disparate results between experimental and control groups.

Compared to control interventions, FES-cycling has produced significant improvements in motor power, single limb standing capabilities, trunk control, walking ability, balance, and strength.[2,4,5] However, results have not been consistent across studies. It is worth noting, however, that following FES-cycling more subjects were able to complete the 10-meter walking test, 50-meter walking test, and sit-to-stand task compared to subjects in the control groups.[4,5]

Although no research to date has examined the effects of FES cycling on gait symmetry, evidence suggests that patients are able to perform the cycling task with improved symmetry.[2,5] Whether or not this pedaling symmetry translates to gait symmetry is a topic for future research.

At this time, FES cycling should be considered as a supplement to standard rehabilitation and non-FES gait training techniques. For patients receiving daily therapy in an inpatient setting, frequency of FES cycling has ranged from three to five times per week for 20 to 35 minutes per session.[2,4,5] At this time, however, an optimal protocol has not been identified. Therefore, the clinician should exercise sound clinical judgement and refrain from over-relying on FES cycling. In the clinical setting where time is limited, utilizing FES cycling means that some other therapeutic intervention will inevitably be excluded for the day. Therefore, it is important for the clinician to know the degree to which FES cycling can replace other therapeutic interventions (e.g., transfer training, gait training, etc.) and still achieve an optimal outcome.

Future research needs to include better descriptions of the standard rehabilitation regimens that are used as well as the approximate amount of time allocated to each therapy. A patient whose standard rehabilitation regimen includes a larger component of speech and/or occupational therapy may not achieve the same mobility outcomes as a patient whose standard rehabilitation regimen consists primarily of physical therapy. This information may help explain discrepancies in outcomes between different studies and may also elucidate cases in which FES cycling is most beneficial.

Future research should also compare FES-induced cycling to FES-assisted cycling. Both interventions have yielded positive results, but it is unknown which method of FES cycling is optimal.

In conclusion, the best available evidence indicates that FES cycling is a reasonable intervention to consider when working with the patient described in the present clinical scenario. However, many questions remain regarding the optimal protocol that should be followed.

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