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Functional Electrical Stimulation Improves Motor Recovery of the Lower Extremity and Walking Ability of Subjects With First Acute Stroke

A Randomized Placebo-Controlled Trial

Tiebin Yan, MD, PhD; Christina W. Y. Hui-Chan, PhD; Leonard S. W. Li, MD

Background and Purpose—The effectiveness of functional electrical stimulation (FES) has been investigated in chronic hemiplegia. The present study examines whether FES, given during acute stroke, was more effective in promoting motor recovery of the lower extremity and walking ability than standard rehabilitation alone.

Methods—Forty-six subjects, 70.9 ± 8.0 years old and 9.2 ± 4.1 days after stroke, were assigned randomly to 1 of 3 groups receiving standard rehabilitation with FES or placebo stimulation or alone (control). FES was applied 30 minutes and placebo stimulation 60 minutes, 5 days per week for 3 weeks. Outcome measurements included composite spasticity score, maximum isometric voluntary contraction of ankle dorsi-flexors and planter-flexors, and walking ability. They were recorded before treatment, weekly during the 3-week treatment, and at week 8 after stroke.

Results—No significant differences were found in the baseline measurements. After 3 weeks of treatment, there was a significant reduction in the percentage of composite spasticity score, and a significant improvement in the ankle dorsiflexion torque, accompanied by an increase in agonist electromyogram and a reduction in electromyogram cocontraction ratio in the FES group, when compared with the other 2 groups ($P < 0.05$). All subjects in the FES group were able to walk after treatment, and 84.6% of them returned home, in comparison with the placebo (53.3%) and control (46.2%, $P < 0.05$) groups.

Conclusions—Fifteen sessions of FES, applied to subjects with acute stroke plus standard rehabilitation, improved their motor and walking ability to the degree that more subjects were able to return to home. (*Stroke*. 2005;36:80-85.)

Key Words: motor activity ■ stroke

Functional electrical stimulation (FES) has been used to treat chronic hemiplegia since the 1960s.¹ In 1978, Stanic et al² found that multichannel FES, given 10 to 60 minutes, 3 times per week for 1 month, improved gait performance in hemiplegic subjects. In 1989, Bogataj et al³ applied multichannel FES to activate lower limb muscles of 20 chronic hemiplegic subjects. After daily treatment 5 days per week for 1 to 3 weeks, subjects who previously were unable to walk, walked again.

In the 1990s, FES has been increasingly used to treat the lower extremity of stroke subjects. Bogataj et al⁴ compared 2 groups of stroke survivors receiving 3 weeks of FES, preceded or followed by 3 weeks of conventional therapy. Treatment was given 5 days per week for 7 to 21 days. The results showed that more subjects were able to walk and lived independently after FES.

However, most previous studies had not adopted a randomized control design.^{2,3} Treatment period within a study was often not standardized.^{3,4} Many studies failed to calculate the

sample size.²⁻⁴ Subjects were mostly examined during the chronic stage.²⁻⁴ The interval to therapeutic intervention after stroke varied within each study.^{2,4} These observations are supported by 2 meta-analyses by Glanz et al⁵ and Chae and Yu,⁶ who reviewed articles on randomized clinical trials that assessed the efficacy of neuromuscular electrical stimulation in hemiplegia between 1966 and 1999. They found only 8 single-blinded randomized clinical trials. The initial treatment time varied from 14 to 29.2 months after stroke. Only one study had a placebo group.

Methodological issues aside, numerous studies have revealed that motor experience after brain injuries plays a major role in the subsequent physiological reorganization that occurs in the adjacent intact tissues.^{7,8} Repetitive execution of identical or similar movements of the limbs have been identified as crucial for motor learning and recovery in stroke subjects.⁹ Using positron emission tomography, Nelles et al⁷ and Weiller et al¹⁰ observed similar brain activation patterns in stroke subjects during either active or passive movements.

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Their results highlighted the contribution of afferent synaptic activity to central motor control and indicated that reorganization of the sensory and motor systems occurred early after stroke.

Because FES produces functional movement, we hypothesize that the FES-induced afferent–efferent stimulation that results in limb movements plus cutaneous and proprioceptive inputs during the acute stage could be important in “reminding” subjects how to perform the movement properly. Therefore, we investigated whether FES combined with a standard rehabilitation (SR) program was more effective than SR given with placebo stimulation or alone in promoting the recovery of motor function and functional mobility during acute stroke.

Materials and Methods

Study Design

This study adopted a single-blind, stratified, randomized control design. The number of subjects was calculated a priori. According to a meta-analysis,⁶ the minimal effect size for FES in motor recovery of stroke subjects was 0.54. Thus, a sample of 33 subjects was necessary to achieve 80% chance ($\beta=0.20$) of detecting 20% difference ($\alpha=0.05$) in improvement among 3 treatment groups. In anticipation of possible dropout, this number was increased to 45.

After giving informed consent, subjects were allocated, in an unbiased manner by a random number produced by Jensen's¹¹ computerized method of minimization, to 1 of 3 groups receiving FES and SR, placebo stimulation and SR, or SR only (control). To minimize uneven distribution of known variables, the stratifications taken included age (45 to 59, 60 to 75, and 76 to 85), gender, type of stroke (cerebral ischemia and hemorrhage), side of hemiplegia, and muscle strength of affected hip flexors (grade of ≤ 2 to 3 according to manual muscle test).¹² This study was approved by local ethics committees.

Subjects

Forty-six subjects with first acute stroke were recruited. Subjects were included if they had a unilateral stroke within the carotid artery system according to computerized tomography, aged 45 to 85 years old, and were independent in daily activities before stroke (Figure 1). Exclusion criteria were brain stem or cerebella lesions, medical comorbidity, receptive dysphasia, or cognitive impairment denoted by scoring < 7 of 10 on the Abbreviated Mental Test.¹³

Five subjects (11%) did not complete the study. One FES subject had gastric bleeding; another one could not undergo assessment. One placebo subject had another stroke; another was discharged early. One control subject spoke a different Chinese dialect, which made assessment difficult.

Intervention

All subjects received the same SR including 60 minutes each of physiotherapy based on the neurodevelopmental facilitation approach and of occupational therapy focused on activities of daily living, given once per day, 5 days per week for 3 weeks.

Two dual-channel stimulators (Respond Select; Empi Inc) were connected with a program timer to form one stimulating unit for FES. Surface electrodes were applied on quadriceps, hamstring, tibialis anterior (TA), and medial gastrocnemius (MG) with subject side-lying and the affected lower extremity supported by sling. FES was delivered with 0.3-ms pulses at 30 Hz, maximum tolerance intensity (20 to 30 mA),^{3,4} using an activation sequence that mimicked normal gait (Figure 2).¹⁴ Subjects were treated within 3 days after being transferred from the acute hospital, 30 minutes per day, 5 days per week for 3 weeks. The placebo group received stimulation from an electrical stimulation device with disconnected circuit. Treatment frequency and period were identical to those of the FES group, except for the longer duration (60 minutes) thought to

optimize placebo effects.^{15,16} To promote similar mental set, subjects were told before treatment that they might or might not feel the stimulation. Control group received only SR.

Outcome Measurements

The following measurements were recorded before treatment, weekly during the 3-week treatment in hospital, and follow-up at week 8 after stroke. To eliminate possible bias during measurements, the assessor was blinded to the nature of intervention.

Composite spasticity scale (CSS) was developed by our group to more faithfully reflect the status of ankle plantar-flexor tone.^{15–17} It was adopted because the Ashworth scale has lower reliability¹⁸ and does not measure the relatively flaccid muscle tone prevalent during acute stroke. In contrast, the validity and reliability of CSS in evaluating spasticity had been demonstrated in stroke studies.^{15–17,19}

Maximum isometric voluntary contraction (MIVC) of ankle dorsiflexors and plantar-flexors was measured by joint torque and surface EMG. The knee joint was fixed at $\approx 50^\circ$ of flexion and the ankle in a neutral position. Two bar-shaped surface electrodes (B & L Engineering) were placed over TA and MG muscles. The electrodes were low-noise, with a pre-amplifier and a gain of 388. The input impedance was > 100 megohms, the common mode rejection ratio was 95 decibels (db), and the bandwidth was 12 Hz to 3.4 KHz. During data collection, subjects were asked to contract the ankle dorsiflexors or plantar-flexors maximally for ≈ 3 seconds. A total of 10 seconds was recorded, and 2 to 3 seconds before and 3 to 4 seconds after the contraction were taken as the baseline. Six trials were recorded under verbal encouragement, with 3 each for dorsiflexion and plantar-flexion after 2 to 3 minutes of practice. The EMG signals were sampled at 1000 Hz per channel, full-wave-rectified, and then (Butterworth) low-pass-filtered at 2.7 Hz for TA and 2 Hz for MG. The MIVC value over a 1-second window beginning from 0.5 ms before peak torque was used for normalization. The corresponding integrated EMG (IEMG) signals ($mV \cdot s$) of TA and MG muscles were computed. The cocontraction ratio was calculated as the IEMG area of the antagonist over that of the agonist plus antagonist.^{15,3} Walking ability was assessed with the timed “Up & Go” (TUG) test when the subject could walk 7 to 8 meters without personal assistance.²⁰ This test was originally designed for the elderly, but its validity and reliability had been demonstrated in Western²¹ and Chinese stroke subjects.²² Subjects were required to rise from a chair, walk forward 3 meters, turn, walk back, and sit down on the chair. After 1 to 2 practice runs, 3 trials were recorded.

All measurement protocols had been tested for their reproducibility in our pilot study, with intraclass correlation coefficients of 0.89 to 0.98 for CSS (26 subjects), 0.73 to 0.99 for ankle dorsiflexion torque and surface EMG (19 subjects), and 0.95 to 0.99 for TUG score (37 subjects),²² respectively.

Statistics

Descriptive statistics were used for subjects' relevant characteristics. Outcome measurements were analyzed with repeated measure analysis of variance using SPSS (version 10.0) to compare the main effects before, during, and after treatment, followed by post-hoc tests with Bonferroni correction to compare treatment effects among the 3 groups. For categorical variables, a χ^2 test was used. The significance level was set at 5% (2-tailed).

Results

No significant differences were found in the baseline values among subject groups (Tables 1 and 2), indicating that they were homogenous in these measurements before treatment.

CSS

Raw CSS scores of the affected plantar-flexors in the 3 groups were similar at the different assessment intervals (Table 2a). However, the percentage increases of CSS scores in the placebo ($50.0 \pm SD 88.4\%$) and control groups

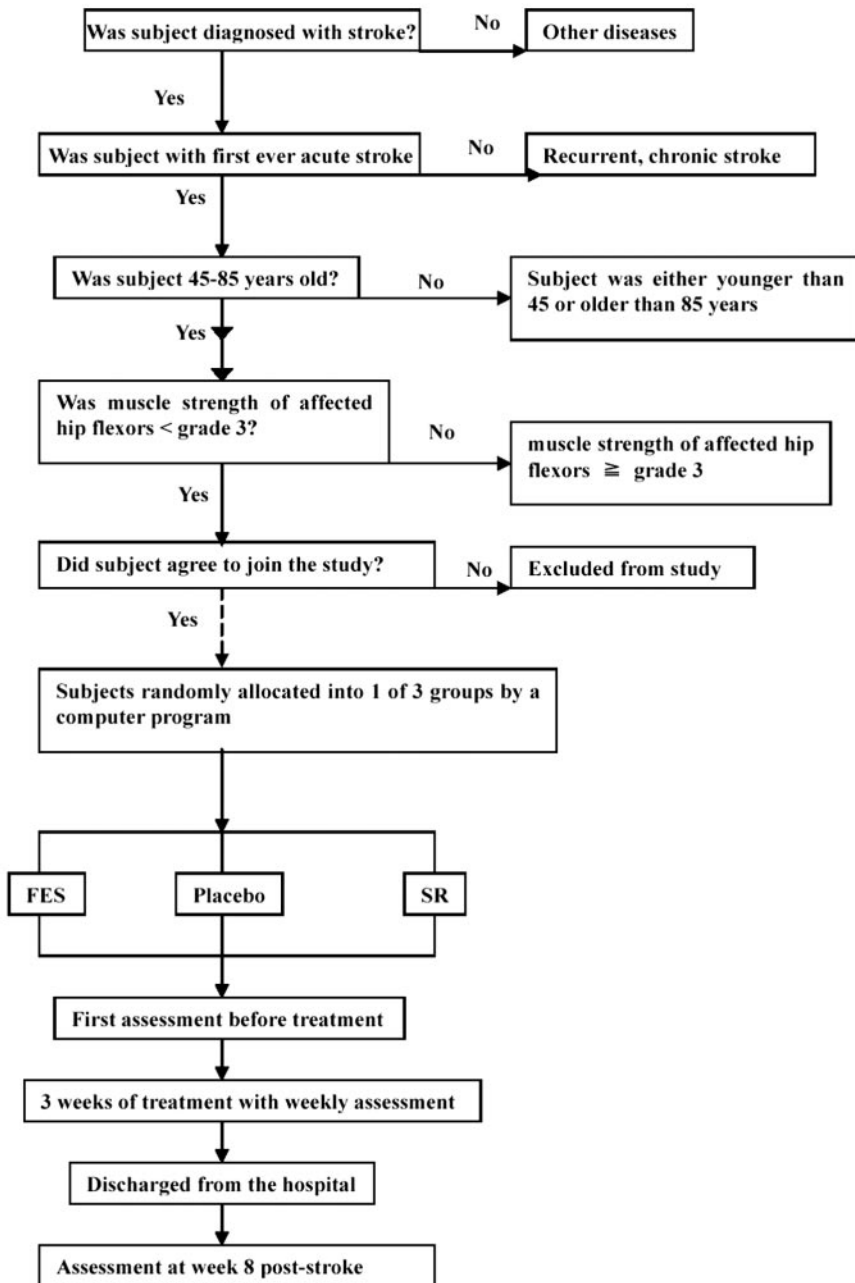


Figure 1. Flow diagram of subjects being recruited into this study.

($64.6 \pm 64.8\%$) at week 3 were significantly greater than that in the FES group ($30.5 \pm 35.3\%$) ($P < 0.05$). In contrast, no difference was found between placebo and control groups at all times.

MIVC

Table 2b and 2c summarize the raw data for MIVC torque and EMG cocontraction ratio during ankle dorsiflexion in the 3 groups. When comparing the results among groups, percentage increases in MIVC torques and IEMG of the FES group were significantly larger than those of the control group from week 1 onward ($P < 0.01$ to 0.05), and larger than the placebo group at week 3 ($P = 0.032$) (Figure 3a and 3b). In ankle plantar-flexion, a significant effect was found only at week 3 between the FES and the other 2 groups ($P < 0.01$, not

shown). Furthermore, the EMG cocontraction ratio during dorsiflexion of the affected ankle was significantly more reduced in the FES than the other 2 groups from week 1 or 2 onward ($P = 0.001$ to 0.042 ; Figure 2c).

Walking Ability

No differences were found in the TUG score among groups at any time (Table 2d). Before treatment, 12.2% (5/41) subjects were able to walk with a quadruped, 2 (15.4%) each in the FES and control groups and 1 (6.7%) in the placebo group. After treatment, this percentage increased markedly by week 8 in the FES group (84.6%) when compared with the placebo (60.0%) and control groups (46.2%). The χ^2 analysis confirmed the significant differences between the FES and the other 2 groups at week 2 or 3 and 8 ($P < 0.05$).

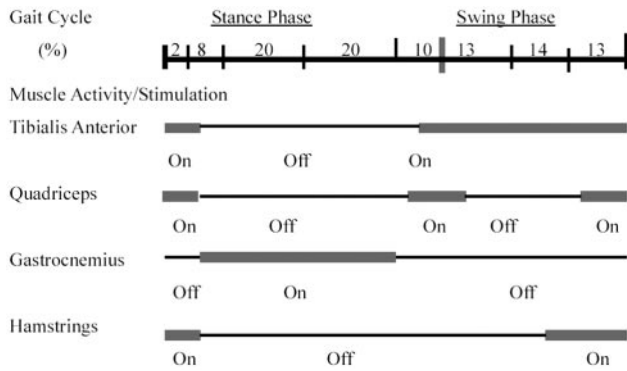


Figure 2. Timing of the stimulation sequence to simulate a gait cycle lasting 5 seconds.

In addition, the mean number of days until subjects were able to start walking in the hospital was 18.1 ± 8.4 , 20.2 ± 6.8 , and 21.2 ± 8.0 , respectively, for the FES, placebo, and control groups. Although there was no significant difference among groups at the $\alpha=0.017$ level, the FES group tended to walk 2 to 3 days earlier than the other 2 groups. An important finding was that more subjects receiving FES (84.6%) returned to their own home when compared with those receiving placebo stimulation (53.3%) and SR (46.2%, $P<0.05$; Table 1).

Discussion

Early and Intensive Intervention for Stroke Rehabilitation

Nearly all studies on the recovery of motor function in stroke survivors have found that the most rapid recovery occurs

TABLE 1. Subject Characteristics for Each Treatment Group

	FES (n=13)	Placebo (n=15)	SR (n=13)
Age, y	68.2±7.7	73.3±8.1	70.4±7.6
M (%)	7 (53.8)	7 (46.7)	6 (46.2)
F (%)	6 (46.2)	8 (53.3)	7 (53.8)
Type of stroke: Ischemia	11	13	11
Type of stroke: Hemorrhage	2	2	2
Paretic side: L (%)	6 (46.2)	9 (60)	8 (61.5)
Paretic side: R (%)	7 (53.8)	6 (30)	5 (38.5)
Weight, kg	57.9±8.7	54.5±6.9	55.0±9.0
Height, m	1.57±0.1	1.52±0.1	1.55±0.1
BMI, kg/m ²	23.4±2.3	23.3±3.3	22.8±3.2
AMT, score	8.4±1.7	8.2±1.7	8.4±1.3
CSS, score	7.3±3.1	5.9±2.7	6.1±2.9
LOS at acute hospital, d	5.7±5.0	7.2±3.4	7.2±3.5
Initial intervention from onset, d	8.7±5.8	10.1±2.8	9.1±3.5
LOS at sub-acute hospital, d	33.5±14.0	34.7±10.0	32.7±7.9
N of subjects returning home (%)	11 (84.6)	8 (53.3)	6 (46.2)*

Values are mean±SD.

FES, placebo, and SR denote groups receiving functional electrical stimulation+SR, placebo stimulation+SR, and standard rehabilitation (control), respectively.

BMI indicates body mass index; AMT, abbreviated mental test; CSS, Composite Spasticity Scale; LOS, length of stay; M, male; F, female; L, left; R, right.

* $P=0.03$ when compared with FES group.

TABLE 2. Comparison of Outcome Measurements Among the 3 Groups

	FES	Placebo	SR
(a) CSS Score			
Week 0 (mean±SD)	7.3±3.1	5.9±2.7	6.1±2.6
Week 1, % increase	13.9±86.8	30.8±38.4	26.6±60.2
Week 2, % increase	20.2±92.2	44.3±67.1	51.9±60.5
Week 3, % increase	30.5±35.3	50.0±88.4*	64.6±64.8*
Week 8, % increase	41.8±93.5	56.0±91.2	78.6±64.7
(b) MIVC Torque (Nm) During Dorsiflexion			
Week 0	2.0±2.2	2.2±2.2	2.3±2.0
Week 1	4.4±3.0	3.6±3.3	3.2±3.8
Week 2	7.5±4.9†	4.9±3.0	3.2±4.1
Week 3	9.0±4.6†	4.6±3.0	4.4±5.2
Week 8	9.9±5.2†	6.8±3.8†	6.2±6.8‡
(c) EMG Cocontraction Ratio (%)			
Week 0	34.9±17.5	35.0±21.6	37.8±15.3
Week 1	20.6±18.7†	23.6±17.4†	39.9±19.4
Week 2	12.3±8.8†	25.2±22.3†	28.6±19.2†
Week 3	7.8±5.3†	26.5±26.2†	27.5±19.4†
Week 8	12.9±11.7†	24.3±19.7†	25.6±16.9†
(d) TUG Scores (sec) and Percentage of Patients Able to Walk			
Week 1	66.0±29.5	49.7±22.9	56.6±33.7
	15.4	6.7	15.4
Week 2	46.8±27.2	28.7±14.2	39.5±36.8
	53.6	13.3*	23.1
Week 3	39.2±30.4	16.6±5.7	32.0±19.7
	76.9	50.0*	38.5*
Week 8	28.4±21.0	31.7±27.9	39.7±30.1
	84.6	60.0*	46.2*

* $P<0.05$ when compared with FES group.

† $P<0.01$

‡ $P<0.05$ when comparing percentage changes (not shown) for weeks 1 to 8 with week 0 within-group.

during the first few weeks after stroke.²⁴ In a meta-analysis of 36 clinical trials in stroke rehabilitation, Ottenbacher and Jannell²³ noted that early initiation of rehabilitation for stroke patients was related to improved motor and functional outcomes. Kwakkel et al²⁴ critically reviewed 9 controlled studies involving 1051 stroke survivors who received rehabilitation programs of different intensities. They found a small but statistically significant intensity–effect relationship. These results suggested that early and intensive intervention could significantly improve motor recovery and functional outcome in stroke survivors.

In the present study, FES was applied at 8.7 ± 5.8 days after stroke (Table 1). This was much earlier and the treatment was more intensive when compared with other studies. There was no significant difference in subjects’ characteristics before treatment (Table 1). Thus, any differences among the 3 groups could be largely attributed to the effects of intervention.

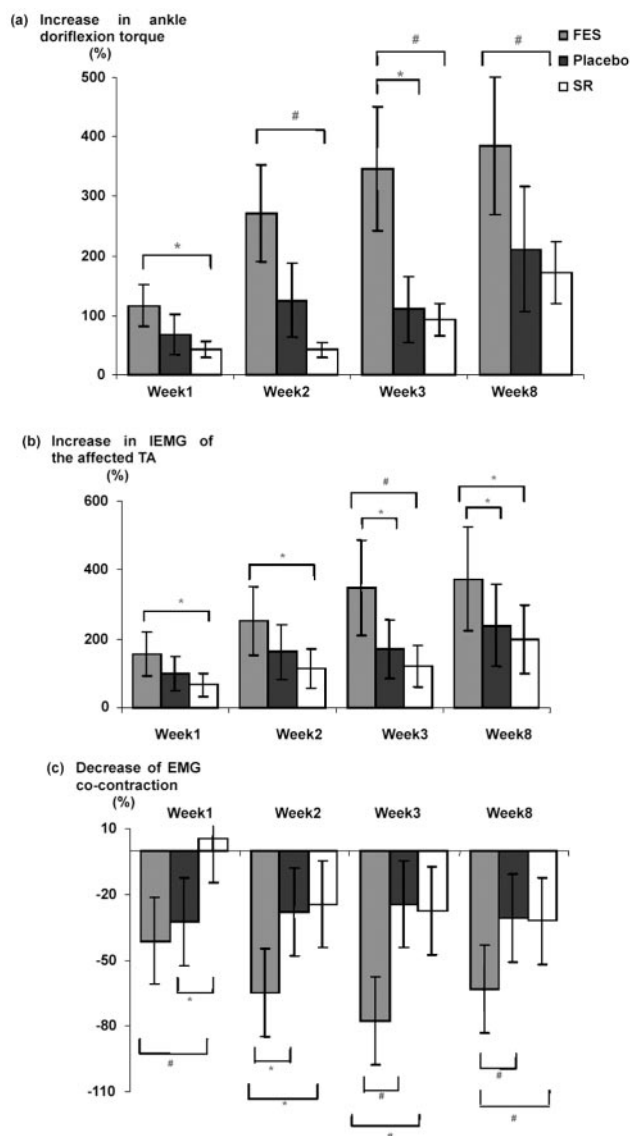


Figure 3. Comparison among the 3 groups: percentage increases in (a) ankle dorsiflexion torque and (b) integrated EMG of the affected tibialis anterior, and (c) percentage decrease of EMG cocontraction ratio during dorsiflexion of the affected ankle. * $P < 0.05$ and # $P < 0.01$

Effects of FES on Spasticity and Motor Recovery

In this study, all 3 groups had moderate spasticity as assessed by the CSS, but the increase in the score ratio was significantly less in the FES group at week 3 (Table 2a), indicating that FES might be able to normalize muscle tone in the affected ankle plantar-flexors.

In our study, FES was delivered reciprocally to the lower limb muscles to mimic normal gait. During the phase that mimics toe-off, FES could have activated the TA motoneuronal pool antidromically in addition to directly activating the TA muscle, leading to increased contraction of the paretic TA muscle, with negligible cocontraction of the antagonist spastic plantar-flexors that tended to occur in stroke subjects. Over time, this could have led to significant improvements in the FES group, as denoted by the percentage increases in MIVC torque and IEMG of the affected TA muscle, and the

percentage decrease of EMG cocontraction ratio during ankle dorsiflexion, when compared with the control group from week 1 onward, and with the placebo group from week 2 or 3 onward (Figure 3). Note that the plantar-flexion torque was also improved significantly by week 3. No significant difference was found between the placebo and control groups at any assessment interval except for the percentage decrease of EMG cocontraction ratio during week 1, thus demonstrating the general absence of any placebo effects.

Effects of FES on Early Mobility

Theoretically, there could be differences in TUG scores among the groups. However, at each assessment session, there were always new subjects who were able to walk added to each group. Hence, the scores could not be compared either within or among the groups.

Before treatment, only 12.2% (5/41) of subjects were able to walk. However, this percentage was significantly increased in the FES group, when compared with placebo and control groups, respectively, from weeks 2 and 3 onward ($P < 0.05$; Table 2d). In addition, the average first walking day in hospital was 18.1 ± 8.4 days after stroke for the FES group, as compared with 20.2 ± 6.8 and 21.2 ± 8.0 days, respectively, for placebo and control groups. This means that subjects receiving FES treatment tended to walk 2 to 3 days earlier than those receiving either placebo stimulation or SR alone. Note that the length of hospital stay would not have demonstrated significant difference among groups, because subjects had to stay at the hospital until they completed the 3-week treatment even if they had reached discharge criteria. Nevertheless, their placement at discharge should have reflected treatment effects to some extent (Table 1), because the criteria for a stroke survivor to return home in Hong Kong are that the patient should be able to perform self-care and live safely at home.

Possible Mechanisms for the Effects of FES in Subjects With Stroke

Asanuma and Pavlides²⁵ suggested that increase of synaptic efficacy in existing neural circuits, or formation of new synapses, may be involved in the earlier stages of motor learning. In addition, frequently repeated movements of the affected lower extremity of stroke subjects, induced by FES in this study, might reinforce network connection patterns. As Classen et al²⁶ noted, the phenomenon of motor cortical rearrangements could be the first step in skill acquisition. Such brain plasticity could underline improvements seen in the FES group.

Generalization of the results from this study should be performed with caution because of subject selection criteria, which did not cover all stroke categories or subjects aged younger than 45 or older than 85 years. Furthermore, more significant differences might have been detected earlier if the sample size were larger.

To conclude, 15 sessions of FES, given 30 minutes per session plus SR, 5 days per week, improved motor recovery and functional mobility in acute stroke subjects, more than placebo stimulation and SR, or SR only. In fact, 84.6% of subjects who received FES and SR returned home, versus

53.3% and 46.2%, respectively, of those receiving placebo stimulation and SR, or SR alone.

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