

Functional Electrical Stimulation Enhancement of Upper Extremity Functional Recovery During Stroke Rehabilitation: A Pilot Study

Gad Alon, PhD, PT, Alan F. Levitt, MD, and Patricia A. McCarthy, OTR

Objective. To test if functional electrical stimulation (FES) can enhance the recovery of upper extremity function during early stroke rehabilitation. **Methods.** Open-label block-randomized trial, begun during inpatient rehabilitation and continued at the patients' home. Patients were assigned to either FES combined with task-specific upper extremity rehabilitation ($n = 7$) or a control group that received task-specific therapy alone ($n = 8$) over 12 weeks. **Outcome measures.** Hand function (Box & Blocks, B&B; Jebsen-Taylor light object lift, J-T) and motor control (modified Fugl-Meyer, mF-M) were video-recorded for both upper extremities at baseline, 4, 8, and 12 weeks. **Results.** B&B mean score at 12 weeks favored ($P = .049$) the FES group (42.3 ± 16.6 blocks) over the control group (26.3 ± 11.0 blocks). The FES group J-T task was 6.7 ± 2.9 seconds and faster ($P = .049$) than the 11.8 ± 5.4 seconds of the control group. Mean mF-M score of the FES group at 12 weeks was 49.3 ± 5.1 points out of 54, compared to the control group that scored 40.6 ± 8.2 points ($P = .042$). All patients regained hand function. **Conclusion.** Upper extremity task-oriented training that begins soon after stroke that incorporates FES may improve upper extremity functional use in patients with mild/moderate paresis more than task-oriented training without FES.

Key Words: *Electrical stimulation—Stroke—Hand function—Task-specific training.*

Grasping, holding, and manipulating objects are daily functions that remain deficient in 55% to 75% of patients 3 to 6 months poststroke. Close to complete functional recovery has been documented in only 5% to 20% of stroke survivors.¹ Kwakkel et al² reported complete recovery of upper extremity function

From the University of Maryland, School of Medicine, Department of Physical Therapy and Rehabilitation Sciences (GA, PAM), and the University of Maryland, School of Medicine, Department of Medicine (AFL).

Address correspondence to Gad Alon, PhD, PT, University of Maryland, School of Medicine, Department of Physical Therapy & Rehabilitation Sciences, 100 Penn Street, Baltimore, MD 21201. E-mail: galon@som.umaryland.edu.

Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation enhancement of upper extremity functional recovery during stroke rehabilitation: a pilot study. *Neurorehabil Neural Repair* XXXX;X:xx-xx.

DOI: 10.1177/1545968306297871

6 months following an ischemic middle cerebral artery stroke in only 11.6% of patients with routine rehabilitation. There was no indication that the treatment phase in the study by Kwakkel et al included electrical stimulation.

Intervention studies to improve upper extremity recovery following stroke include increasing exercise duration and intensity,³⁻⁷ focusing on task-specific training,^{8,9} and enhancing training by surface neuromuscular electrical nerve stimulation.¹⁰⁻²² The clinical efficacy, as well as a number of inherent difficulties associated with the various therapeutic intervention options following stroke in general and upper extremity paralysis/paresis in particular, were recently reviewed.²³ Intense and task-oriented training was found to yield better upper extremity control, particularly in patients who demonstrated at least modest motor control prior to entering into a clinical trial. Indeed, several researchers reported that adding task-specific, repetitive training with or without constraining the nonparetic extremity had resulted in significantly faster performance of upper extremity function in both chronic and subacute stroke survivors.^{6-8,24} In contrast, increasing the intensity of exercise to 90-minute sessions and adding 36 sessions over 12 weeks of what the authors termed "physiologically-based" and therapist-supervised training yielded mostly insignificant changes in motor control and function of the upper extremity.^{4,5}

Surface neuromuscular electrical stimulation (NMES) applied to the muscles that move the wrist and fingers improved joint range of motion and volitional muscle contraction in patients with acute/subacute stroke.¹⁰⁻¹² NMES also promoted further recovery of motor control long after the spontaneous recovery period.^{13,16,17,19,20,25} More recent investigations have focused on regaining upper extremity function rather than simply minimizing impairments, in particular the recovery of the ability to grasp, hold, and release objects.^{13-15,19-21,25-27} A few of the cited studies were randomized controlled trials but were limited to a small sample size, usually <15 patients per group.^{11,17} One randomized controlled trial included 30 patients in each group¹² and one entered 77 chronic stroke survivors but had no control group.¹⁵

Two major shortcomings of most previously reported studies investigating NMES^{10-17,19,25,26} are late commencement and short duration of the treatment program. A third possible shortcoming is the research paradigm of using NMES without the addition of volitional, task-specific functional training.^{10-13,16,17,19,22,25} This separation has no apparent conceptual or evidence-based support. A few case-series^{14,15,27} and a randomized controlled clinical trial that included 22 patients²¹ combined the stimulation with both unimanual and bimanual task-oriented functional activities. The combination is most appropriately termed functional electrical stimulation (FES).

Using this concept of FES,²⁰ the patient is instructed to add volitional movements as much as feasible during the perception of stimulation on time. If the patient is unable to move volitionally, the movements are generated externally with the nonparetic extremity or by the therapist/caregiver while the patient is asked to imagine the movements. A typical example of task-specific movements that involve all joints of the upper extremity and may be combined with FES is the attempt to reach out, grasp an object, move it to a new location, and release. Initial results using FES indicated significantly better recovery of upper extremity function.^{18,21,27} However, these trials were terminated after an average of only 5 ± 1.7 weeks although improvement continued at the last testing session. Thus, the fullest amount of improvement in functional use of the hand that can be achieved when a study is beginning soon after stroke onset using a task-oriented FES paradigm of longer duration needs to be explored.

This study tested the hypothesis that FES with task-specific training can enhance the recovery of upper extremity function when begun shortly after the start of inpatient rehabilitation and continued for 12 weeks.

METHODS

Forty-one patients with first ischemic stroke were screened by two attending physicians as potential candidates using the medical criteria included in Table 1. A speech pathologist administered the Mini Mental State Examination to ensure the patient's ability to understand and follow the study instructions.²⁸ Twenty-six (63.4%) patients were excluded because of severe motor loss (modified Fugl-Meyer [mF-M] upper extremity score between 2 and 10) and much less likelihood of recovering hand function.² All patients began the standard rehabilitation with 3 hours of daily physical, occupational, and speech therapies within 1 to 2 days postadmission to the stroke unit at Kernan Hospital. Informed consent for the trial was obtained by 10.9 ± 5.4 days after admission, due to a variety of delays.

Fifteen patients who met all inclusion criteria (Table 1) were stratified into blocks of 10 points (11-20, 21-30,

Table 1. Inclusion/Exclusion Criteria

1. Single unilateral ischemic stroke that occurred no less than 2 weeks and no more than 4 weeks prior to study commencement (medically stable)
2. Paresis of the upper limb
3. Fugl-Meyer score between 11 and 40
4. No clinical evidence of limited passive joint range of motion
5. Age 20 to 90
6. Admitted to Kernan Hospital for at least 1 week and actively engaged in PT, OT, or both
7. Forearm and hand size compatible with the use of the H-200™ stimulation system
8. At least 60% of full finger flexion and extension response to stimulation (only FES group)
9. Able and willing to participate in a 12-week study
10. Adequate language function to respond to 2-step commands
11. Ability and willingness to sign the consent form

Exclusion Criteria:

1. Implanted electronic pacing or defibrillation device, unstable vital signs, or potentially fatal cardiac arrhythmia, because the safety of stimulation under these conditions is not known
2. Active reflex sympathetic dystrophy or existing residual weakness due to lower motor neuron lesions of either upper extremity
3. Inability to sit in a standard armless chair for 30 minutes
4. Any comorbid neurological disease
5. Clinical evidence of shoulder subluxation (one finger width or greater)
6. Caregiver unavailable to help with the training protocol
7. Refusal to be videotaped
8. Mini Mental Status Examination score 21 or lower

PT = physical therapy; OT = occupational therapy; FES = functional electrical stimulation.

31-40) on the modified Fugl-Meyer score (mF-M) for the upper extremity and block-randomized into a FES group ($n = 7$) and a control group ($n = 8$). They began study-related training 1 day after obtaining the baseline mF-M score and within 18.0 ± 8.7 (FES) and 15.6 ± 5.3 (control) days after stroke onset. Baseline upper extremity mF-M scores were 23.9 ± 7.4 and 21.9 ± 7.5 points for the FES and control, respectively. Patient characteristics are summarized in Table 2. Data extracted from the baseline mF-M revealed that all patients had scored 1 (partial volitional movement) for flexion of the fingers. Similarly, 6 of 7 FES and 7 of 8 control patients scored 1 on finger extension and wrist extension.

The control group followed a standardized, task-specific physical (PT) and occupational (OT) training program (see Appendix), and the FES group followed the same standardized, task-specific PT/OT that was synchronized with electrical stimulation and induced contraction

of the wrist/finger flexors and extensors to open and close the paretic hand. The FES group also applied the stimulation without specific exercises as described below.

The training protocol for both groups was composed of individually structured and guided physical and occupational therapy aimed at promoting motor retraining of the paralyzed muscles of the upper extremity. The PT/OT training was individually tailored to each patient and constructed through a selection of exercises from an "Exercise Bank" (Appendix). The number and complexity of the exercises were adjusted by the research therapist for each patient so that he or she was able to practice independently or with assistance from a family member after discharge from the inpatient rehabilitation hospital. The specific exercises were further modified by the research therapist as upper extremity performance continued to improve throughout the 12-week study period.

Patients practiced their individually tailored task-oriented program with the attending therapists (30-minute sessions, given twice daily) 5 days each week during hospitalization; after discharge they were instructed to practice 30 minutes twice a day without supervision. In addition, all patients continued to receive in-home OT/PT 1 to 2 times per week through their standard medical coverage. The researchers were not authorized to influence or monitor the standard therapy. The research therapist visited each patient once a week and modified the research-related exercise program based on patient progress. The actual amount of time that each patient exercised at home was not monitored, owing to budget constraints. Therefore, the degree of compliance was unknown. Patients reported that they were doing the exercises at home, but not always as instructed.

The FES group stimulation session was initially limited to 10 minutes repeated 4 times daily with 2 sessions as part of the 30-minute exercise session and the other 2 sessions without exercise. The duration of stimulation was increased by 5 minutes every day so that by day 11, the patient was instructed to stimulate for a total of 1 hour per session and repeat the 1-hour session 4 times each day. Thus, two 30-minute sessions per day were concurrently synchronized with task-specific exercise (FES) and the remaining 30 minutes of these 2 sessions, as well as the other 2 daily sessions of 1 hour each, were limited to stimulation of the wrist and finger extensors and flexors without specific exercises. The reason for limiting the exercise sessions of both groups to 30 minutes was based on prior clinical experience that most patients in the acute or subacute poststroke period are unable to exercise for a longer duration due to physical, emotional, and attention limitations. In contrast, stimulation without exercise has been tolerated for several hours without causing fatigue, muscle soreness, or other stimulation-dependent adverse responses.^{14,15,21}

Patients in the FES group received electrical stimulation by means of the H-200™ (Bioness, Inc, Santa Clarita, Calif), a microprocessor-based FES system. The system is composed of a forearm/hand molded-orthosis containing an array of 5 surface electrodes ranging in size from 2 × 2 cm to 6 × 4 cm. The electrodes were positioned over the extensor digitorum, extensor pollicis brevis, flexor digitorum superficialis, flexor pollicis longus, and thenar muscles. The position of the electrodes within the orthosis was custom-determined for each patient to ensure full flexion and extension of all 5 fingers. Once the desired positions were obtained, the 5 electrodes were secured within the orthosis. This individualized electrode positioning made it very easy for the patient to obtain a consistent level of contraction in each muscle group every day. The electrodes were connected to a stimulator/controller unit that delivered alternating current at a carrier frequency of 11 KHz, time-modulated to bursts at 36 Hz. The stimulator was set to deliver interrupted trains of pulses with the contraction and relaxation intervals both set at 7 seconds on and 7 seconds off. The microprocessor program delivered stimulation of reciprocal finger flexion and extension, as well as patterns of opening and closing that enabled the patient to grasp, move, and release objects with the paretic hand.

Outcome Measures

Due to low tolerance for lengthy testing and considerable paralysis of the upper extremity during inpatient rehabilitation, testing was restricted to 30-minute sessions. Functional assessments were limited to the Box & Block (B&B)²⁹ and the light object lift subset of the Jebsen-Taylor (J-T) test,^{29,30} two commonly reported yet not time- or burden-intensive functional tests. A video-based mF-M score for the upper extremity was used to measure motor control loss and recovery.²⁹ These outcome measures have shown test-retest and intertester reliability values of .8 or better. Data were obtained from both paretic and nonparetic upper extremities. The 3 outcome measures were recorded at baseline, and after 4, 8, and 12 weeks of training.

Modified Fugl-Meyer Test. The Fugl-Meyer test (F-M_{max} = 66 points) was modified so that only movements that can be seen clearly from a video-recording were scored (mF-M_{max} = 54 points). Therefore, the modified version did not include the original item A (reflex activity) and item D (coordination/speed). For the recordings, each patient sat on a standard armless chair (seat height 46 cm) facing the video camera (frontal or sagittal view) and was instructed to move the upper extremity in accordance with the F-M movement items. Twenty-seven movement items were scored as follows: no visible

Table 2. Entry Characteristics

Affected Upper Extremity	Gender	Stroke to Start of Study (days)	Initial Fugl-Meyer	Folstein Mini Mental	Infarct Location
Control					
R	M	13	12	30	Left pontine
L	F	17	22	22	Right internal capsule/basal ganglia
R	F	11	17	29	Left pontine/internal capsule
R	M	22	26	26	Left MCA
R	F	16	19	30	Left upper pontine
L	M	14	15	24	Right cerebellum
R	M	12	32	24	Left subcortical ICA
R	M	20	32	27	Left corona radiata/basal ganglia
FES					
L	F	29	17	30	Right pontine
R	M	16	33	25	Left subcortical
R	M	13	28	26	Left Brain Stem
R	F	12	20	30	Left Subcortical
R	F	19	32	27	Right MCA
L	M	14	23	27	Right pons
R	F	23	14	27	Left MCA

MCA = middle cerebral artery; ICA = internal carotid artery; FES = functional electrical stimulation.

Table 3. Study Outcome Measures (Median and 25th Percentile)

Test	FES Base	FES Week 12	Control Base	Control Week 12
mF-M	23 ± 17	51 ± 44	20.5 ± 15.5	39 ± 33.25
B&B	7 ± 0	48 ± 28	4 ± 0.5	25.5 ± 15
J-T	60 ± 18	5.7 ± 4.2	60 ± 39.75	10 ± 7.87

FES = functional electrical stimulation; mF-M = modified Fugl-Meyer; B&B = Box & Blocks; J-T = Jebsen-Taylor light object lift.

movement = 0, partial movement = 1, and full range movement = 2. The nonparetic extremity was not recorded, assuming that all patients could attain the maximum score.

Box & Blocks Test. The test included a commercially available box divided by a partition and containing 150 (2.54 × 2.54 cm) blocks located on one side. The box was placed on a desk in front of the patient (desk height of 76 cm) so that the box's partition bisected the midline of the patient's body. The box was placed 13 cm back from the desk's front edge. Patients were instructed to pick up one block at a time and to transfer it to the other side of the box as quickly as possible, and to repeat the activity for 60 seconds. The test was repeated 3 times with each hand, and the highest scores achieved (one paretic and one nonparetic) were the final outcome measure.

Jebsen-Taylor Light Object Lift Test. The Jebsen-Taylor test evaluates the ability to grasp, hold, move, and place large objects. Each participant sat facing 5 empty aluminum

cans (11 cm in height, 8 cm in diameter, and weighing 57 grams) placed in a row 5 cm apart in front of a board. The board was secured to the desk 13 cm from its front edge. Upon command to begin, the patient grasped a can, lifted it over a 5 cm vertical barrier, and placed it back on the board on the other side of the barrier. The time (in seconds) it took to move all 5 cans was measured using a stopwatch. Patients who were unable to perform the test or did not complete the test in 60 seconds received 60 seconds as their score. The test was repeated 3 times with each hand, and the fastest time recorded for each hand was the final outcome measure.

Statistical Analysis

Due to a small sample size, we used the Friedman nonparametric analysis of variance to compare the 2 groups at both baseline and the end of training. Significant chi-square values ($P = .05$) were further tested nonparametrically by the Mann-Whitney U test to determine significant differences between the groups' means

($P = .05$). The findings are reported in the text as means and standard deviations to make it easier to compare and contrast the study's outcomes with the majority of previously published data on upper extremity rehabilitation.^{10-13,15,16,18,19,21,25,27,30,31} The medians and 25th percentile data are summarized in Table 3.

To document relative residual deficit (Rd) in each outcome measure for the paretic upper extremity, we used the formula: $Rd = 100 - (\text{paretic}/\text{nonparetic} \times 100)$ to calculate individual patient percent deficit in each of the 3 outcome measures. The Mann-Whitney U test ($P = .05$) compared the groups' residual deficits at the end of training.

RESULTS

All 15 patients completed the 12 weeks of training and the 4 testing sessions. Patients in both FES and control groups tolerated the program well, and there were no reports of study-related adverse events such as recurrent stroke, TIA, cardiac symptoms, shoulder subluxation, reflex sympathetic dystrophy, or skin damage.

The B&B and J-T measures quantified the recovery of upper extremity function. Friedman's tests yielded overall significant differences in both measures (B&B, $P = .0015$; J-T, $P = .0010$). The number of blocks transferred in 60 seconds at baseline were similar for both groups (5.9 ± 6.0 blocks for the FES group and 5.3 ± 6.2 blocks for the control group). As seen in Figure 1, the mean number of blocks transferred increased more in the FES group; by the end of training, the mean B&B score was better in the FES group ($P = .049$) than in the control group (42.3 ± 16.6 blocks for the FES group vs 26.3 ± 11.0 blocks for the control group). The mean B&B scores for the nonparetic upper extremity at the last testing session were 58.7 ± 11.9 blocks for the FES group and 48.8 ± 9.2 blocks for the control group. The corresponding coefficients of variation were .20 and .19. Evidently, intersubject variability in performing the task with the nonparetic upper extremity was considerable. To account for this variability, residual functional deficits were determined by dividing each patient's paretic score by the nonparetic score followed by calculation of each group's mean and standard deviations. These normalized data approached significance ($P = .06$) and indicated less residual deficits in the FES group ($27\% \pm 17\%$) as compared to the residual deficits observed in the control group ($48\% \pm 18\%$). Furthermore, at baseline testing, 3 out of 7 FES patients and 2 out of 8 control patients were unable to transfer any block with the paretic extremity; during the final testing session, all patients in both groups were able to perform the B&B task with the paretic hand. Interestingly, 1 of 7

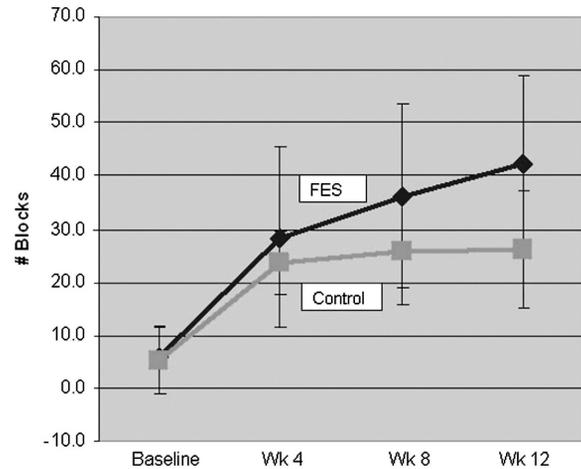


Figure 1. Improvement in performing the Box and Block test over the course of 12 weeks of training. The groups' scores were significantly different at the study's endpoint. FES = functional electrical stimulation.

FES patients and 4 of 8 control patients performed below 50% of their nonparetic B&B performance at the end of 12-week training.

The J-T light object lift test was the more difficult functional task to perform, as it required the ability to almost fully extend all 5 fingers in order to grasp and lift the test cans. At baseline testing, the paretic extremity J-T task time was 47.5 ± 21.3 seconds for FES and 50.9 ± 17.6 seconds for control. At the end of training, the J-T task times decreased to 6.7 ± 2.9 seconds (FES) and 11.8 ± 5.4 seconds (control) and favored ($P = .049$) the FES group. Figure 2 illustrates that the time to complete the J-T test declined more rapidly in the FES group. The J-T task times using the nonparetic upper extremity during the last testing session were similar for both groups (4.2 ± 0.7 seconds in the FES group and 4.9 ± 0.8 seconds in the control group). However, all patients moved the cans with the paretic hand considerably slower than with the nonparetic extremity. In the FES group, the paretic extremity data demonstrated a 1.6 ± 0.6 times slower performance; in the control group, the performance was 2.2 ± 0.9 times slower ($P = .037$). At baseline, only 2 participants in the FES group and 1 participant in the control group were able to perform the J-T test with the paretic extremity. At study endpoint, all 15 patients performed the J-T test successfully. However, most patients were considerably slower with the paretic hand and only 2 participants in the FES group and 1 control patient recovered the ability to transfer the cans within 12.2%, 20.6%, and 34.1% of the nonparetic hand task time, respectively.

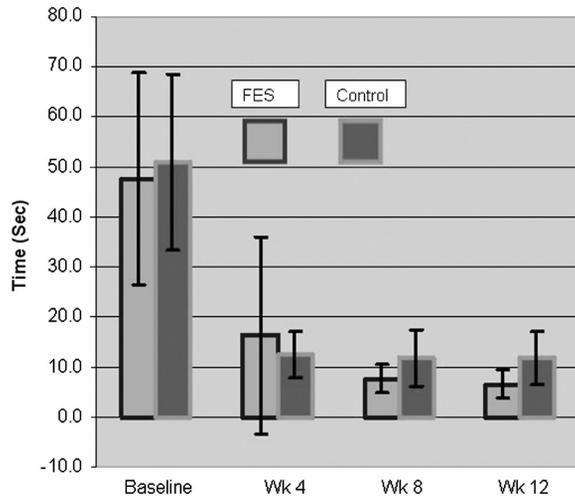


Figure 2. Improvement in performing the light object lift subtest of the Jepsen-Taylor test battery over time. The functional electrical stimulation (FES) group was significantly faster at the study's endpoint.

The nonparametric Friedman's test of the mF-M data also yielded overall significantly different groups' mean values ($P = .0003$). The difference between the baseline mean scores for the 2 groups were statistically nonsignificant (23.9 ± 7.4 FES vs 21.9 ± 7.5 control). After 12 weeks of training, the mF-M was better ($P = .042$) in the FES group (49.0 ± 5.1 points) than in the control group (40.6 ± 8.2 points). The improvement over time of both groups is illustrated in Figure 3. The residual motor control deficits of the paretic upper extremity when normalized to the maximal mF-M score of 54 points were $7.7\% \pm 9.4\%$ (FES) and $27.0\% \pm 15.2\%$ (control) at the end of 12 weeks training. These residual deficits were significantly lower in the FES group ($P = .042$).

Finally, we calculated the Cohen's effect size (d) using the formula: $d = M_1 - M_2 / s_{\text{pooled}}$ where $s_{\text{pooled}} = \sqrt{[(s_1^2 + s_2^2) / 2]}$. Within each group, changes over 12 weeks of training yielded a very large effect size ranging between 2.35 and 3.95, indicating a fast recovery of the study sample in the early poststroke phase. In comparing the FES group to the control group, the effect size of each of the 3 outcome measures at the last test session was also very large (mF-M $d = 1.23$; B&B $d = 1.18$; and J-T $d = 1.17$), reflecting close to 20% greater recovery of upper extremity function and motor control when training with FES versus task-specific training program without FES.

DISCUSSION

Pomeroy et al³² recently used the Cochrane paradigm of systematic review and meta-analysis to assess the

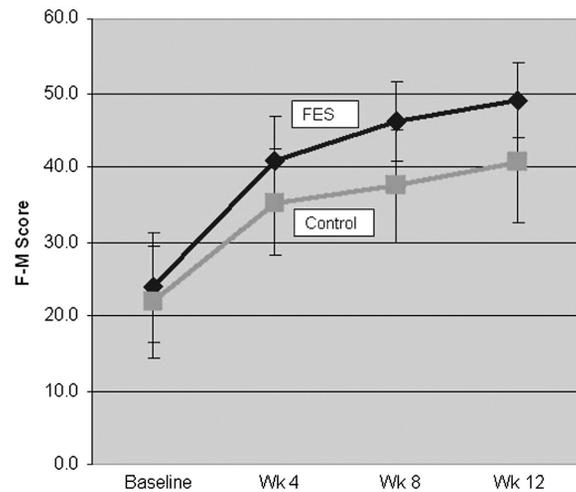


Figure 3. The nonlinear recovery profile of upper extremity motor control as measured by the modified Fugl-Meyer (F-M) upper extremity test. The 2 groups differed significantly at week 12. FES = functional electrical stimulation.

merit of controlled studies published by January 2004. The authors questioned the clinical value of comparing electrostimulation for neuromuscular retraining with no treatment. They went on to recommend that future clinical research should compare exercise versus electrostimulation, having a defined dose of stimulation, clearly described clinical characteristics of the study sample, and well-described training programs. Our study addressed some of their suggestions.

Kwakkel et al² identified moderate initial motor loss and rapid gain of motor control as 2 important markers for good prognosis in the recovery of upper extremity function shortly after suffering an ischemic stroke. Our sample of patients seems to demonstrate this fast recovery profile having a median gain of 28 points (FES group) and 18.5 points (control group) in the mF-M test in 12 weeks. Additionally, the recovery of upper extremity function in the control group as measured by the B&B and the light object lift subtest of the J-T test battery lends support to the previous observation that some patients with a first ischemic stroke in various subcortical loci can expect to recover upper extremity function when enrolled in an intensive task-specific exercise program.^{3,8,9,33,34} The main hypothesis that FES combined with task-specific exercises significantly enhances such recovery when compared to task-specific exercise alone was clearly demonstrated in this study.

Our interactive rather than isolated training paradigm represents a departure from several published training programs. The most notable difference was the combination of an early start of prolonged training that incorporated FES with an individually tailored, task-specific exercise program supplemented by nonexercise

neuromuscular stimulation. The task-specific program was modified in accordance with the individual patient's progress. Equally important, this program included unilateral as well as bilateral training (Appendix) that could be performed by the patient at home, and with help from a caregiver if necessary.^{15,20,21,26}

In this study, we also introduced an uncommon but potentially important approach to quantify the residual deficits (Rd) of the paretic upper extremity by normalizing the data of the paretic extremity to the performance of the nonparetic upper extremity. We proposed the approach for 2 main reasons. First, reporting both clinical and statistical improvement following exercises or electrical stimulation as done previously^{3-8,10-16,18-22,25-27,34-36} most likely leaves both patients and clinicians wondering how much further the patient can practically (not hypothetically) improve. Comparing the performance of patients to age-, gender-, and hand-dominance-matched healthy individuals is, arguably, of questionable value to both the patient and the clinician. Data are mounting that the nonparetic upper extremity's performance in poststroke patients is both slower and less consistent than that of healthy individuals.³⁷⁻⁴⁰ Similarly, hand dominance prior to stroke had no measurable influence on upper extremity recovery.⁴¹ Acknowledging the evidence that close to 90% of stroke survivors are not likely to completely recover hand function,² the nonparetic upper extremity assumes the role of the dominant hand.

Also, referencing the paretic to nonparetic functional ability should make it easier for clinicians and researchers to establish an individual patient's dimensionless, practical "gold standard" that in turn could facilitate comparison of the effectiveness and limits of various rehabilitation interventions regardless of the outcome measures. The finding reported herein of the high variability among patients' performance with the nonparetic upper extremity further supports the notion of documenting residual deficits based on the given individual patient's performance.

The task-specific FES protocol as described in this study contributed to improvement of hand function in all participating patients ranging from almost complete recovery to varying levels of partial recovery. Even patients who did not exhibit any functional ability at baseline were able to transfer blocks and to relocate empty food cans on a table by the completion of the 12-week training period. Compared to the nonparetic side, the residual deficits of the FES-trained patients ranged between approximately 8% and 28%; this seems considerably better than the 27% to 48% deficit in performance of the control group. These favorable results using a combined FES-exercise paradigm are likewise noteworthy when compared to the findings of previous clinical studies of poststroke hand function recovery. For example, Kwakkel et al² used the Action Research Arm

Test (ARAT) that contained 4 domains of grasp, grip, pinch, and gross movements; the authors identified patients as developing "some dexterity" of hand function if they scored more than 10 points on the ARAT scale, meaning that these patients were able to initiate grip or grasp. We propose that initiating grasp or grip may not represent meaningful upper extremity function, because to benefit functionally, patients should also be able to move and release objects, not just to grasp or grip.

Comparison with past clinical studies that used neuromuscular electrical stimulation (NMES) is indirect. Cauraugh and colleagues published several studies in which electromyographic-triggered NMES was used in combination with task-specific exercises to train chronic stroke survivors. The authors used the B&B as a main outcome measure.^{13,16,17,25} Taken together, these studies showed that 2 weeks of training resulted in an increase in the number of blocks transferred in 60 seconds, from as little as 1 block in one study to 8 blocks in another study. Similar results were documented by Kimberley et al who investigated home-based NMES training over a 3-week period.¹⁹ Whereas the increase in blocks transferred after training was statistically significant, transferring a few additional blocks may not represent clinically meaningful improvement in upper extremity function. In our study, the pre-post difference was 36 blocks (FES) and 21 blocks (control). Indeed, the timing of data collection in the acute/subacute versus chronic stage and the short training period of only 2 to 3 weeks in the other studies may preclude a fair comparison of the reported outcomes. Alternatively, the greater relative improvements reported in the current study may support the hypothesis that the effect of FES is magnified if it is commenced during early rehabilitation efforts following stroke, rather than at later time points, as has been the more traditional approach to FES¹⁵ or NMES training.^{13,16,17,19,25}

Two groups of investigators initiated NMES in the acute/subacute phase of rehabilitation to promote recovery of the paretic upper extremity following ischemic stroke. Chae et al¹¹ stimulated the wrist-finger extensors for only 3 weeks, whereas Powell and coauthors¹² stimulated the same muscle groups for 8 weeks in a randomized controlled trial. Chae and colleagues reported gains of 13.1 (NMES) versus 6.5 (control) points in upper extremity F-M score, reflecting significant recovery of motor control but not actual functional use of the upper extremity. Powell and coauthors showed significant effects of their NMES program on hand function (measured by ARAT); however, these benefits were no longer evident at the 24-week follow-up. The NMES was apparently not combined with task-specific training. Moreover, the very large effect size (ranging between 1.17 and 1.23) that our FES plus exercise produced, compared to outcomes of the exercise without FES, supports the hypothesis that task-specific, individually tailored, and continually modified FES

training as described in this study may help to maximize the recovery of upper extremity function of stroke survivors who have good prognostic indicators for hand function, based on initial pretreatment residual motor control.

At this time, it is not known how much functional recovery of the paretic extremity a stroke survivor requires before being able to reincorporate that upper extremity into bimanual and unimanual activities of daily living. If 50% recovery of the paretic extremity relative to the nonparetic extremity can be used to index functional recovery, then the findings of the current study demonstrate that the majority of acute/subacute stroke survivors who meet all entry criteria and are treated with a combination of FES and task-directed training are likely to regain sustainable functional use. Daily use of that hand is expected to further improve without specific training.⁸ The index offered in this discussion is based on the data presented in this study and excludes patients with initial motor loss of less than 11 points on the mF-M scale. Self-administered, mostly home-based FES training for no less than 12 weeks seems of equal importance to achieve successful outcome. Validation of this tentative hypothesis will require a larger, randomized controlled clinical trial.

One clear shortcoming of this study is the absence of a follow-up period to determine if the improvement in functional use of the paretic upper extremity is sustainable. Another shortcoming is associated with the inability to monitor patients' compliance with the exercise program because the research therapist could only visit the patients at their homes once a week due to limited funding. In addition, only a select group of patients was studied representing the minority of stroke survivors who have favorable prognostic indicators for the recovery of upper extremity function.^{2,39,40} The benefits from task-specific FES training to patients with more severe motor loss and a lower probability of recovering upper extremity function remain uncertain.

CONCLUSION

The interactive training program described in this study, which included FES that enable patients to reach, grasp, move, place, and release objects, resulted in better functional recovery of the upper extremity in ischemic stroke survivors than task-related exercise training alone.

ACKNOWLEDGMENT

This study was supported in part by a grant from Bioness, Inc Santa Clarita, CA. The authors have no commercial or other financial conflict of interest associated with the study.

APPENDIX Bank of Exercises

The list contains both simple and more complex tasks and upper extremity functional exercises.

1. Passive/Active ROM

- 1) Passive ROM: wrist/elbow/shoulder, self or by family member
- 2) Active/assistive ROM: wrist/elbow/shoulder bilateral with dowel, cane
- 3) Active ROM: wrist/elbow/shoulder in sitting and standing
- 4) Active ROM with resistance: wrist/elbow/shoulder in sitting and standing

2. Weight bearing and supportive reaction

- 1) Seated weight bearing (forearms on tabletop) with affected upper extremity
- 2) Extending arms, seated or standing with bilateral upper extremity weight bearing on table
- 3) Extended arms with transitional movements: side lying to sit, sit to stand, dips
- 4) Extended arms and wrist/hand on wall from anterior and lateral, progress to wall push up
- 5) Extended arms and wrist/hand on wall with change in base of support; example: weight shifting, single lower extremity support, lateral wall walking

3. Reaching activities

- 1) Forward supported reach bilaterally with cane on tabletop (elbow extension)
- 2) Forward supported reach with shoulder elevation, elbow/wrist extension
- 3) Reaching against gravity in frontal and sagittal planes
- 4) Reaching overhead with active wrist/hand movements
- 5) Dynamic reaching to a target; example: catch a ball

4. Grasping, holding and release

- 1) Maintaining digit extension with weight bearing
- 2) Grasp, hold and release containers with gravity minimized (on table)
- 3) Pick up and move/release small object on table
- 4) Pick up and move/release large objects without proximal support
- 5) Incorporate key and pinch grips in hold and release including stacking, lifting and overhead activity

5. Upper extremity ADL

- 1) Dressing, grooming
- 2) Carrying objects with bilateral upper extremities
- 3) Opening bottles, stabilizing with paretic extremity for reaching
- 4) Writing, drawing, manipulating small objects
- 5) Folding towels, vacuuming, sweeping, hanging towels, setting table
- 6) Self-feeding
- 7) Pre-work activities

ROM = range of motion; ADL = activity of daily living.

REFERENCES

1. Nakayama H, Jorgensen HS, Raaschou HO, Olsen TS. Compensation in recovery of upper extremity function after stroke: the Copenhagen Stroke Study. *Arch Phys Med Rehabil.* 1994;75(8):852-857.
2. Kwakkel G, Kollen BJ, van der Grond J, Prevo AJ. Probability of regaining dexterity in the flaccid upper limb: impact of severity of paresis and time since onset in acute stroke. *Stroke.* 2003; 34(9):2181-2186.
3. Kwakkel G, Wagenaar RC. Effect of duration of upper- and lower-extremity rehabilitation sessions and walking speed on recovery of interlimb coordination in hemiplegic gait. *Phys Ther.* 2002;82(5):432-448.
4. Duncan P, Studenski S, Richards L, et al. Randomized clinical trial of therapeutic exercise in subacute stroke. *Stroke.* 2003; 34(9):2173-2180.
5. Duncan P, Richards L, Wallace D, et al. A randomized, controlled pilot study of a home-based exercise program for individuals with mild and moderate stroke. *Stroke.* 1998;29(10):2055-2060.
6. Feys H, De Weerd W, Verbeke G, et al. Early and repetitive stimulation of the arm can substantially improve the long-term outcome after stroke: a 5-year follow-up study of a randomized trial. *Stroke.* 2004;35(4):924-929.
7. Page SJ, Sisto S, Levine P, McGrath RE. Efficacy of modified constraint-induced movement therapy in chronic stroke: a single-blinded randomized controlled trial. *Arch Phys Med Rehabil.* 2004;85(1):14-18.
8. Winstein CJ, Rose DK, Tan SM, Lewthwaite R, et al. A randomized controlled comparison of upper-extremity rehabilitation strategies in acute stroke: a pilot study of immediate and long-term outcomes. *Arch Phys Med Rehabil.* 2004;85(4):620-628.
9. Shepherd RB. Exercise and training to optimize functional motor performance in stroke: driving neural reorganization? *Neural Plast.* 2001;8(1-2):121-129.
10. Pandyan AD, Granat MH, Stott DJ. Effects of electrical stimulation on flexion contractures in the hemiplegic wrist. *Clin Rehabil.* 1997;11(2):123-130.
11. Chae J, Bethoux F, Bohine T, et al. Neuromuscular stimulation for upper extremity motor and functional recovery in acute hemiplegia. *Stroke.* 1998;29(5):975-979.
12. Powell J, Pandyan AD, Granat M, et al. Electrical stimulation of wrist extensors in poststroke hemiplegia. *Stroke.* 1999;30(7): 1384-1389.
13. Cauraugh J, Light K, Kim S, et al. Chronic motor dysfunction after stroke: recovering wrist and finger extension by electromyography-triggered neuromuscular stimulation. *Stroke.* 2000;31(6): 1360-1364.
14. Alon G, McBride S, Ring H. Improving selected hand functions using a noninvasive neuroprosthesis in persons with chronic stroke. *J Stroke Cerebrovasc Dis.* 2002;11:99-106.
15. Alon G, Stibrant-Sunnerhagen K, Geurts ACH, Ohry A. A home-based, self-administered stimulation program to improve selected hand functions of chronic stroke. *Neurorehabilitation.* 2003; 18:215-225.
16. Cauraugh JH, Kim SB. Chronic stroke motor recovery: duration of active neuromuscular stimulation. *J Neurol Sci.* 2003;215(1-2): 13-19.
17. Cauraugh JH, Kim SB. Stroke motor recovery: active neuromuscular stimulation and repetitive practice schedules. *J Neurol Neurosurg Psychiatry.* 2003;74(11):1562-1566.
18. Popovic MB, Popovic DB, Sinkjaer T, et al. Clinical evaluation of functional electrical therapy in acute hemiplegic subjects. *J Rehabil Res Dev.* 2003;40(5):443-453.
19. Kimberley TJ, Lewis SM, Auerbach EJ, et al. Electrical stimulation driving functional improvements and cortical changes in subjects with stroke. *Exp Brain Res.* 2004;154(4):450-460.
20. Sullivan JE, Hedman LD. A home program of sensory and neuromuscular electrical stimulation with upper-limb task practice in a patient 5 years after a stroke. *Phys Ther.* 2004;84(11):1045-1054.
21. Ring H, Rosenthal N. Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation. *J Rehabil Med.* 2005;37(1):32-36.
22. Yozbatiran N, Donmez B, Kayak N, Bozan O. Electrical stimulation of wrist and fingers for sensory and functional recovery in acute hemiplegia. *Clin Rehabil.* 2006;20(1):4-11.
23. Dobkin BH. Clinical practice. Rehabilitation after stroke. *N Engl J Med.* 2005;352(16):1677-1684.
24. Kwakkel G. Impact of intensity of practice after stroke: issues for consideration. *Disabil Rehabil.* 2006;28(13-14):823-830.
25. Cauraugh JH, Kim S. Two coupled motor recovery protocols are better than one: electromyogram-triggered neuromuscular stimulation and bilateral movements. *Stroke.* 2002;33(6):1589-1594.
26. Alon G, Ring H. Gait and hand function enhancement following training with a multi-segment hybrid-orthosis stimulation system in stroke patients. *J Stroke Cerebrovasc Dis.* 2003;12(5): 209-216.
27. Berner YN, Lif Kimchi O, Spokoiny V, Finkelov B. The effect of electric stimulation treatment on the functional rehabilitation of acute geriatric patients with stroke—a preliminary study. *Arch Gerontol Geriatr.* 2004;39(2):125-132.
28. Crum RM, Anthony JC, Bassett SS, Folstein MF. Population-based norms for the Mini-Mental State Examination by age and educational level. *JAMA.* 1993;269(18):2386-2391.
29. Platz T, Pinkowski C, van Wijck F, et al. Reliability and validity of arm function assessment with standardized guidelines for the Fugl-Meyer Test, Action Research Arm Test and Box and Block Test: a multicentre study. *Clin Rehabil.* 2005;19(4):404-411.
30. Bovend'Eerd TJ, Dawes H, Johansen-Berg H, Wade DT. Evaluation of the Modified Jebsen Test of Hand Function and the University of Maryland Arm Questionnaire for Stroke. *Clin Rehabil.* 2004;18(2):195-202.
31. Ferraro M, Demaio JH, Krol J, et al. Assessing the motor status score: a scale for the evaluation of upper limb motor outcomes in patients after stroke. *Neurorehabil Neural Repair.* 2002;16(3): 283-289.
32. Pomeroy VM, King LM, Pollock A, et al. Electrostimulation for promoting recovery of movement or functional ability after stroke. Systematic review and meta-analysis. *Stroke.* 2006.
33. Goodwin N, Sunderland A. Intensive, time-series measurement of upper limb recovery in the subacute phase following stroke. *Clin Rehabil.* 2003;17(1):69-82.
34. Pang MY, Harris JE, Eng JJ. A community-based upper-extremity group exercise program improves motor function and performance of functional activities in chronic stroke: a randomized controlled trial. *Arch Phys Med Rehabil.* 2006; 87(1):1-9.
35. Rodgers H, Mackintosh J, Price C, et al. Does an early increased-intensity interdisciplinary upper limb therapy programme following acute stroke improve outcome? *Clin Rehabil.* 2003;17(6): 579-589.
36. Gritsenko V, Prochazka A. A functional electric stimulation-assisted exercise therapy system for hemiplegic hand function. *Arch Phys Med Rehabil.* 2004;85(6):881-885.
37. Laufer Y, Gattenio L, Parnas E, et al. Time-related changes in motor performance of the upper extremity ipsilateral to the side of the lesion in stroke survivors. *Neurorehabil Neural Repair.* 2001;15(3):167-172.
38. Wolf SL, Catlin PA, Ellis M, et al. Assessing Wolf motor function test as outcome measure for research in patients after stroke. *Stroke.* 2001;32(7):1635-1639.
39. Kim SH, Pohl PS, Luchies CW, et al. Ipsilateral deficits of targeted movements after stroke. *Arch Phys Med Rehabil.* 2003;84(5): 719-724.
40. Pohl PS, McDowd JM, Filion D, et al. Implicit learning of a motor skill after mild and moderate stroke. *Clin Rehabil.* 2006; 20(3): 246-253.
41. Wolf SL, Thompson PA, Morris DM, et al. The EXCITE trial: attributes of the Wolf Motor Function Test in patients with sub-acute stroke. *Neurorehabil Neural Repair.* 2005;19(3):194-205.