

Upper-Extremity Functional Electric Stimulation–Assisted Exercises on a Workstation in the Subacute Phase of Stroke Recovery

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ABSTRACT. Kowalczewski J, Gritsenko V, Ashworth N, Ellaway P, Prochazka A. Upper-extremity functional electric stimulation–assisted exercises on a workstation in the subacute phase of stroke recovery. *Arch Phys Med Rehabil* 2007; 88:833-9.

Objective: To test the efficacy of functional electric stimulation (FES)–assisted exercise therapy (FES-ET) on a workstation in the subacute phase of recovery from a stroke.

Design: Single-blind, randomly controlled comparison of high- and low-intensity treatment.

Setting: Laboratory in a rehabilitation hospital.

Participants: Nineteen stroke survivors (10 men, 9 women; mean age \pm standard deviation, 60.6 ± 5.8 y), with upper-extremity hemiplegia (mean poststroke time, 48 ± 17 d). The main inclusion criteria were: stroke occurred within 3 months of onset of trial and resulted in severe upper-limb dysfunction, and FES produced adequate hand opening.

Intervention: An FES stimulator and an exercise workstation with instrumented objects were used by 2 groups to perform specific motor tasks with their affected upper extremity. Ten subjects in the high-intensity FES-ET group received FES-ET for 1 hour a day on 15 to 20 consecutive workdays. Nine subjects in the low-intensity FES-ET group received 15 minutes of sensory electric stimulation 4 days a week and on the fifth day they received 1 hour of FES-ET.

Main Outcome Measures: Primary outcome measure included the Wolf Motor Function Test (WMFT). Secondary outcome measures included the Motor Activity Log (MAL), the upper-extremity portion of the Fugl-Meyer Assessment (FMA), and the combined kinematic score (CKS) derived from workstation measurements. The WMFT, MAL, and FMA were used to assess function in the absence of FES whereas CKS was used to evaluate function assisted by FES.

Results: Improvements in the WMFT and CKS were significantly greater in the high-intensity group (post-treatment effect size, .95) than the low-intensity group (post-treatment effect size, 1.3). The differences in MAL and FMA were not statistically significant.

Conclusions: Subjects performing high-intensity FES-ET showed significantly greater improvements on the WMFT than

those performing low-intensity FES-ET. However, this was not reflected in subjects' self-assessments (MAL) or in their FMA scores, so the clinical significance of the result is open to debate. The CKS data suggest that high-intensity FES-ET may be advantageous in neuroprosthetic applications.

Key Words: Electric stimulation therapy; Hemiplegia; Rehabilitation; Stroke.

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IN DEVELOPED COUNTRIES, about 1.5% of the population live with the after-effects of stroke (≈ 5.5 million in North America).¹ Functional recovery of the upper extremity on average is quite poor, with 55% to 75% of patients having significant permanent deficits in performing activities of daily living (ADLs).^{2,3} In many hemiparetic subjects, functional electric stimulation (FES) of the hand muscles can increase arm function by generating hand opening and a functional grasp.^{4,5} Voluntarily triggered FES has been the focus of recent studies of recovery in the upper extremity after a stroke.⁶⁻¹² A recent review concluded that "positive results were more common when electrical stimulation was triggered by voluntary movement rather than when non-triggered electrical stimulation was used."^{12(p65)}

FES-assisted exercise therapy (FES-ET) has been found to improve hand function during both the subacute stage of recovery from a stroke¹³⁻¹⁶ and the chronic stages.¹⁷⁻¹⁹ Despite numerous studies, the relative efficacy of different durations and intensities of exercise remains unclear. Furthermore, the exercises performed in most studies to date have been poorly defined and rarely quantified. Accordingly, our study had 2 main aims: (1) to compare functional outcomes in subjects randomly assigned to higher and lower intensity FES-ET groups and (2) to quantify these outcomes with an exercise workstation incorporating instrumented manipulanda representing ADLs. Our hypothesis was that the higher-intensity FES-ET group would develop better upper-extremity function whether they were tested with or without FES. Preliminary reports have been published.^{20,21}

METHODS

System

The therapeutic system consisted of a second-generation workstation that evolved from a previous design¹⁸ and a custom 2-channel FES stimulator. The workstation comprised a circular desk with a Lazy-Susan rotatable upper surface that supported a number of exercise objects (fig 1). These objects and the exercises associated with them represented items commonly manipulated in ADL. Each task required subjects to reach with their affected hand forward from an armrest, open their hand, grasp the object, manipulate it, release it, and bring their hand back to the armrest. Electronic sensors monitored

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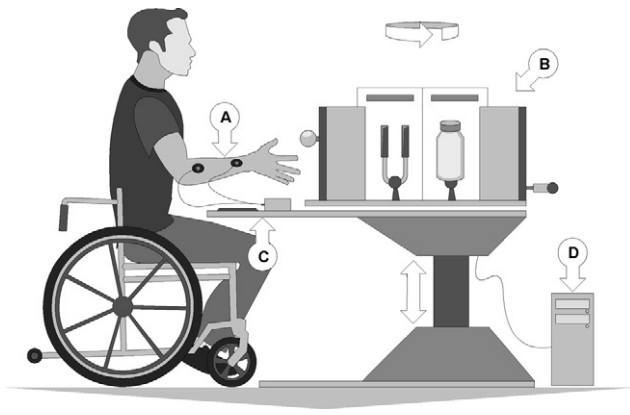


Fig 1. The FES exercise therapy workstation. (A) FES electrodes attached to hemiparetic arm. (B) Custom-built workstation with instrumented objects representing tasks of daily life. Objects included a jar with a screw-top lid, a handle attached via a cord and pulley to an adjustable set of weights, a spring-loaded caliper, a spring-loaded doorknob, and a box and a jar on position-sensing pads at different heights and locations. (C) Rest-position sensing pad and trigger button (on nonparetic side) to control FES. (D) Laboratory interface and computer to collect sensor data. The workstation layout was kept constant throughout the trial, and subjects were positioned in front of it in a standard way.

displacement or transit time of each object. Appendix 1 details the objects, sensors, and exercises. The purpose of instrumenting the workstation was to provide the experimenters with quantitative data.

The sensor signals were digitized at 20 samples per second with a custom-built control circuit incorporating a microcontroller^a and were stored on a desktop computer.

We used a custom FES stimulator in this study.¹⁸ It provided trains of stimuli (50 per second; 200 μ s biphasic, current-controlled pulses). A pair of electrodes, comprising 5cm diameter wetted cloth pads backed with stainless steel mesh and plastic covers, were fixed to the subject's forearm with elastic straps. The cathodic electrode (negative-going voltage in the first phase of each biphasic pulse) was positioned approximately over the extensor digitorum communis muscle. The reference electrode was fixed to the dorsal surface just proximal to the wrist joint. Optimal placement and stimulation strength for maximal hand opening aperture were determined by trial and error.

Participants

Nineteen volunteers from Edmonton's Glenrose Rehabilitation Hospital with stroke-induced hemiparesis participated in this study. The diagnosis of stroke was confirmed in the acute care facility on the basis of clinical evaluation and computed tomography scans. In all cases, subjects had only suffered 1 stroke.

We randomized the subjects into low-intensity (9 subjects) and high-intensity (10 subjects) treatment groups. Inclusion criteria were: (1) stroke less than 3 months prior to the onset of participation; (2) inability to voluntarily grasp and release any 3 objects on the workstation; (3) Brunnstrom stage for the arm and hand less than 4²²; (4) Mini-Mental State Examination score of greater than 16²³; and (5) tolerance of the level of FES needed for hand opening. Exclusion criteria were: (1) inability of FES to open the impaired hand sufficiently; (2) no voluntary movements of the shoulder and elbow; (3) visual hemineglect (on the letter cancellation test,

more than 2-letter difference)²⁴; (4) severe depression (Center for Epidemiologic Studies–Depression Scale score >16)²⁵; (5) other serious medical conditions; and (6) injuries to arms or hands. The procedure was approved by the University of Alberta Health Research Ethics Board and all subjects signed a letter of informed consent after receiving an information document describing the project.

Intervention

Subjects took part in the trial every workday for 3 to 4 weeks, in addition to their regular physiotherapy (described below). The high-intensity FES-ET group practiced 1 hour of FES-assisted exercise on the workstation every workday for 3 to 4 weeks (15–20 sessions). Each session consisted of the subject manipulating 3 objects on the workstation using his/her affected hand for about 20 minutes per object. The task was repeated as often as possible in the 20-minute span allocated. The 3 most challenging tasks the subject was able to manipulate were chosen on the first day of therapy and were maintained throughout the treatment period for that subject. If an object was mishandled or the task not performed properly, the trial was disregarded and the data were not saved.

The exercises focused on reaching, grasping, manipulating (pulling, rotating, etc), and releasing objects. If the subject was unable to reach for the tasks a conventional partial weight-support sling and frame was used to assist in the movements. FES-mediated hand opening was controlled by the subject with a pushbutton on a side arm of the workstation. If the subject had trouble coordinating button pushing with performance of the task, the therapist pressed the button instead. At the end of the treatment period, subjects were returned to their normal physiotherapy (PT) regime. No special instructions were given to them about exercise or rehabilitation after their release from hospital, and between the 2 follow-up evaluations at 3 and 6 months post-treatment.

We had originally intended to have a control group that did not receive any treatment beyond standard PT. However, this experimental design is open to the criticism that beneficial effects of the treatment could be partly due to a placebo effect of participation in a trial featuring a nonstandard component, namely, electric stimulation. To eliminate this effect, 4 days a week we provided the control group with 15 minutes of sensory electric stimulation of the dorsal surface of forearm causing sensation but no motor activation. On the fifth day each week, this group performed 1 hour of FES-ET on the workstation to allow comparisons of kinematic scores obtained from the workstation sensors with those of the treatment group. Rather than continuing to call this a control group, we have called it the low-intensity FES-ET group. Subjects were informed at the outset that they would be assigned to 1 of 2 treatment protocols, but that there was no way of knowing ahead of time whether 1 protocol would produce a better outcome than the other. The 2 therapists who assisted subjects were instructed not to divulge any aspects of the alternative treatment. The third therapist who performed the assessments (see below) did not know to which group subjects belonged, nor did she take part in any of the treatment sessions. We therefore believe that the conditions required of a single-blind study comparing 2 levels of treatment were successfully achieved.

In addition to the above exercise treatments, subjects received regular hand function therapy in 1-hour sessions, 3 to 4 times a week. This was customized both in time and type of exercise for each patient by the staff of the rehabilitation hospital and occurred independently of our study. Treatment focused primarily on learning compensatory strategies to cope with disability and increase independence. It included stretch-

ing, range of motion (ROM) exercises, guiding objects on a shaped track, whole arm resistance exercises with Thera-Band,^b placement tasks, use of a hand cycle, and, in the few subjects who had sufficient upper-limb function, shaping Thera-Putty.^b

Assessment

We used 2 types of outcome measure, clinical and quantitative, to gauge improvement in upper-extremity function.

First, clinical tests were performed and scored by a second therapist blinded to a given subject's treatment. The Wolf Motor Function Test (WMFT)²⁶ was chosen as the primary outcome measure, because it focuses on motor impairments assessed during tasks representative of ADLs. This test has been independently validated²⁷ and was performed the same number of times on subjects in the high- and low-intensity FES-ET groups in our study. For comparison, we also included the upper-extremity portion of the Fugl-Meyer Assessment (FMA),²⁸ which assesses elements of motor behavior including movement about single joints, synergies, ROM, and grasp. The FMA does not specifically evaluate ADLs. The Motor Activity Log (MAL)²⁹ provided self-reporting of the involvement of the affected extremity in ADLs. The WMFT, FMA, and MAL were performed and analyzed pretreatment, post-treatment, and at 3- and 6-month follow-ups.

Second, we derived kinematic scores from sensor readings on the workstation acquired every fifth day during the treatment session. Except for the shelf placement task, kinematic scores were obtained for each of the 3 tasks allocated to a given subject by dividing the maximal displacement by the time taken. For each task, this score was normalized to that of a group of 4 healthy subjects. The mean of the 3 normalized task scores was calculated. We call this the combined kinematic score (CKS). The CKS provided quantitative information on improvement in motor performance of the specific tasks on the workstation. Because workstation tasks were performed many more times by the high-intensity group, the CKS presumably reflected specific task learning as well as general motor improvement.

Statistical Methods

We implemented the Shapiro-Wilks W test for normally distributed data³⁰ for each set of scores in Excel 2003.^c To test the null hypothesis that the scores obtained by the high- and low-intensity treatment groups were from the same population, we performed F tests equivalent to an analysis of covariance with the regression package in SigmaPlot.^d For each outcome measure, linear regressions were performed on the data obtained from the high- and low-intensity groups and then on the combined data.³¹ Sums of squared differences (SSD) between the 3 regression lines and the 3 sets of data (2 separate, 1 combined) were computed. If the separate sets of data were significantly different, $SSD_{combined}$ was larger than the sum of the separate SSDs. F values were computed from the SSDs and corresponding degrees of freedom (*df*) according to the equation below, and the null hypothesis was tested ($P < .05$).

$$F = [(SSD_{combined} - SSD_{separate}) / SSD_{separate}] / [(df_{combined} - df_{separate}) / df_{separate}]$$

The Tukey honestly significant difference (HSD) was used post hoc to test for the significance ($P < .05$) of differences between the mean scores obtained by the high- and low-intensity treatment groups at given time points (eg, 3-mo, 6-mo follow-ups).³² All data sets (WMFT, MAL, FMA, CKS) were normally distributed according to the Shapiro-Wilks W test.

RESULTS

Table 1 shows the characteristics of subjects randomized into the high- and low-intensity treatment groups. Age, functional level, time poststroke, and treatment duration were well matched.

Figure 2 provides the CONSORT chart showing details of subject participation.

Clinical Scores

Table 2 shows group mean WMFT scores of motor impairment and median time taken to perform tasks during and

Table 1: Details of Subjects Participating in the Study

Variables	High-Intensity Treatment Group	Low-Intensity Treatment Group
Patient demographic		
Age (y)	59.4±19.7	61.7±11.0
Total no. of subjects	10	9
Male subjects, % (n)	40 (4)	67 (6)
Mean Brunnstrom stage: hand	1.8±0.4	1.9±0.6
Mean Brunnstrom stage: arm	2.1±0.3	2.2±0.6
Mean treatment duration (wk)	3.8±0.4	3.7±0.5
Months poststroke at onset	1.6±0.5	1.6±0.7
Percentage of right hemisphere strokes, % (n)	60 (6)	78 (7)
Percentage dominant hemisphere strokes, % (n)	50 (5)	33 (3)
Percentage of ischemic infarcts, % (n)	80 (8)	67 (6)
Percentage of hemorrhagic infarcts, % (n)	20 (2)	33 (3)
Patient workstation performance		
Hours exercising on the workstation	19.0±2.1	4.8±0.4
Percentage of subjects using the placement task, % (n)	100 (10)	100 (9)
Percentage of subjects using the doorknob task, % (n)	70 (7)	78 (7)
Percentage of subjects using the jar opening task, % (n)	20 (2)	22 (2)
Percentage of subjects using the handle pulley task, % (n)	50 (5)	67 (6)
Percentage of subjects using the spring-loaded caliper task, % (n)	40 (4)	22 (2)

NOTE. Values are mean ± standard deviation or as indicated.

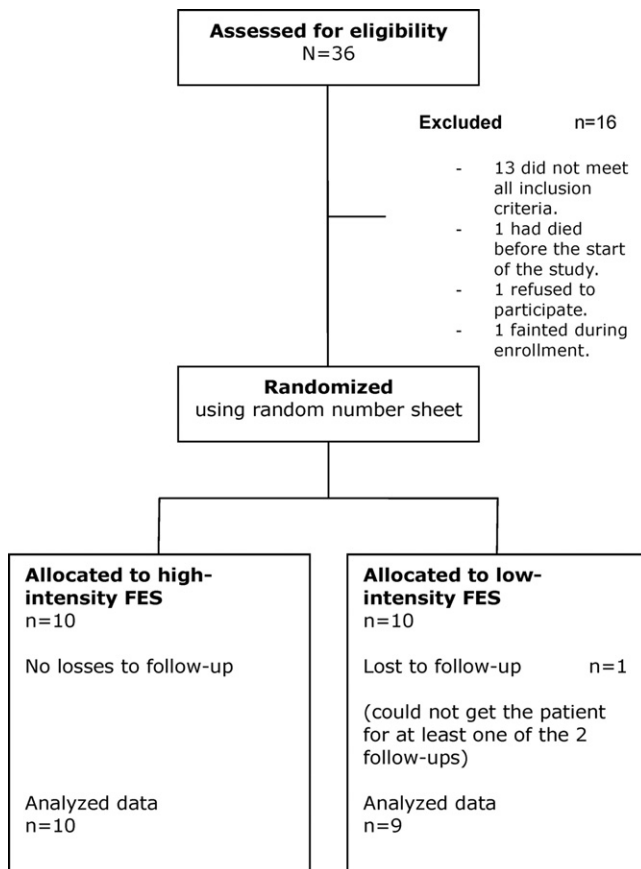


Fig 2. CONSORT flowchart showing details of subject participation.

after the treatment period. Each subject performed 15 tasks, each of which was timed and scored on the range 0 to 5 for function. The means of these 15 scores were calculated, and these were used to calculate the group means and standard deviations (SDs) of the means (standard errors) shown in table 2. An F test showed a significant difference between the high- and low-intensity groups in both parts (ability and median time) of the WMFT (F test, $P < .05$). Post hoc paired comparisons of the mean WMFT ability scores showed no significant difference between the groups at the onset of treatment. The difference immediately after treatment just failed to reach significance ($P = .054$) after correction for repeated measures (Tukey HSD). A significant difference had developed by the 3-month follow-up but significance was lost at 6 months.

Though individual paired post hoc comparisons of the mean MAL scores in table 2 did not reach significance, apart from 1 case (MAL quality of movement [QOM] at 3 months), F values of 3.32 (MAL amount of use) and 3.36 (MAL QOM) were significant.

FMA scores did not differ significantly between the high- and low-intensity FES-ET groups.

Combined Kinematic Scores

Figure 3 shows mean CKS values pretreatment and then at weekly intervals during the 4-week treatment. In all cases, these values were obtained during a single workstation session. In the treatment period, this session occurred at the

end of each week. Unfortunately, no kinematic data could be collected at the 3- and 6-month follow-ups due to the logistical difficulties of bringing subjects back to the hospital-based workstation from their home environments.

The mean CKS in the high-intensity group began to diverge significantly from that of the low-intensity group after 3 weeks of therapy (F test with post hoc Tukey HSD, $P < .05$; effect size, .80). By the fourth week, the CKS in the high-intensity group had more than tripled whereas in the low-intensity group, it had only increased by about 20%. The difference was significant (F test with post hoc Tukey HSD).

DISCUSSION

In this study, we compared the rehabilitative effect in subacute hemiplegic subjects of 2 levels of FES-ET performed on an instrumented workstation. Both groups showed improvements in the primary outcome measure, as might be expected from previous studies.^{12,33} The high-intensity group had significantly better WMFT scores overall than the low-intensity group.

Regarding the clinical importance of the differences between the high- and low-intensity groups, one measure in the literature is the Cohen d for effect size (difference between mean scores divided by the pooled SD³⁴). For the WFMT functional ability scores, the Cohen d value was .95 immediately post-treatment, 1.4 at 3 months, and 0.48 at 6 months. Cohen defined an effect size of 0.2 as small, 0.5 as medium, and 0.8 as large. Thus, the WFMT's ability score showed a large effect size post-treatment and at 3 months, and a medium effect size at 6 months. Unfortunately, there are no data in the literature on the minimal clinically important difference (MCID) for the WFMT.

The F test indicated that the mean MAL scores were significantly larger in the high-intensity FES-ET group than the low-intensity FES-ET group, though post hoc analysis of specific time points with the Tukey correction for multiple comparisons indicated that the difference only reached statistical significance in 1 case (MAL QOM at 3mo). The effect sizes were medium to large, but this may have been because the absolute MAL scores in both groups were very low. Regarding clinical significance, the MCID for MAL scores has been quoted as 0.5.³⁵ The largest increase in MAL score in our study was only .16, indicating that the gains in upper-extremity function in the absence of FES were not clinically significant. It is important to note that, in the absence of FES, the majority of patients in both groups still could not voluntarily open their more affected hand at the end of treatment.

The mean FMA evaluates whole-arm ROM. The upper-extremity exercises in our study may have been too specific to produce large enough improvements in this outcome measure to reach significance in our sample.

On the other hand, by the end of the 4-week treatment period, the high-intensity FES-ET group had more than tripled their CKS, whereas the low-intensity FES-ET group had not shown a significant change. The effect size of the difference between the high- and low-intensity groups at 4 weeks was 1.3 (large). It is worth stressing that, in both groups, the CKS data refer to workstation sessions in which FES was used, and furthermore, that the final CKS attained by the high-intensity group was still less than 20% of that of able-bodied subjects. The CKS data therefore show that FES-assisted motor function improves by a significant amount with higher-intensity FES-ET. This has not been shown

Table 2: Mean Clinical Test Scores

Test	Pre	Post	3 Months	6 Months
WMFT ability score				
High-intensity group	1.31±0.10	1.87±0.14	1.96±0.17*	2.36±0.33
Low-intensity group	1.24±0.15	1.39±0.18	1.35±0.17	1.96±0.32
Effect size (Cohen <i>d</i>)	NA	0.95	1.40	0.48
WMFT median time taken				
High-intensity group	115.5±4.5	45.5±16.4*	36.5±15.2*	23.7±13.5
Low-intensity group	99.3±13.8	90.7±13.5	91.0±14.7	69.7±17.4
Effect size (Cohen <i>d</i>)	NA	0.95	1.15	0.93
MAL AOU				
High-intensity group	.006±.004	.040±.017	.073±.027	.152±.044
Low-intensity group	.020±.011	.035±.012	.006±.004	.086±.036
Effect size (Cohen <i>d</i>)	NA	0.09	1.09	0.56
MAL QOM				
Low-intensity group	.017±.010	.032±.013	.008±.004	.089±.039
Effect size (Cohen <i>d</i>)	NA	0.29	1.2	0.56
FMA				
High-intensity group	7.8±1.5	14.2±2.6	17.0±3.8	23.1±4.7
Low-intensity group	6.0±2.0	9.6±2.8	12.3±3.5	19.0±5.4
Effect size (Cohen <i>d</i>)	NA	0.53	0.47	0.30

NOTE. Values are mean ± standard error.

Abbreviations: AOU, amount of use scale; NA, not applicable; QOM, quality of movement.

*Statistically significant differences between high- and low-intensity groups (post hoc Tukey HSD).

before and is of importance in relation to the long-term neuro-prosthetic use of FES in daily life.

A recent study¹⁵ showed that 0.5 hours a day of FES-assisted therapy continues to improve motor function for up to 12 weeks. This is also supported by previous studies with more intense and prolonged therapy sessions.^{19,36,37} Our study of subjects in the subacute stage of stroke recovery adds further support to the general conclusion that FES-assisted exercise therapy introduced in the early stages of

rehabilitation leads to clinically important improvements in upper-extremity function.

We cannot exclude the possibility of a learning effect in the CKS data, because the high-intensity FES-ET group performed the workstation tasks for 5 hours a week compared with 1 hour a week in the low-intensity FES-ET group. However, the high-intensity group also had significantly larger improvements in the WMFT, which tests performance in a different and more widely ranging set of motor tasks than those on the workstation. The learning of the specific tasks on the workstation thus apparently generalized to a broader range of motor activities.

Regarding the design of our trial, previous studies of FES-ET have either used patients as their own controls in a repeated-measures design,^{18,19} or they have compared treatment groups with control groups either receiving no treatment other than conventional PT, or some additional amount of conventional PT not involving electric stimulation.^{13,14,38} At face value, these designs provide a cleaner dichotomy between treatment and control groups. However, in our opinion, they do not take into account the motivational aspect of taking part in a clinical trial of a new form of treatment. The sensory electric stimulation and the 1-hour-a-week workstation sessions in our trial provided a plausible alternative treatment that we believe matched the motivational effect in the 2 groups.

Quantitative evaluation of motor improvement will, in our opinion, become increasingly important in the future, not only for evaluating and comparing treatments, but also for providing those participating in exercise treatments with unbiased feedback and incentive. This was our rationale for introducing the workstation concept³⁹ and developing it further in this study. Regarding the design of the workstation used, some features were more successful than others. Overall, the device was judged to be too bulky, especially if it is to be deployed in subjects' homes, as would be crucial if FES-ET is to be extended after release from the rehabilitation hospital. The rotating support surface, although good

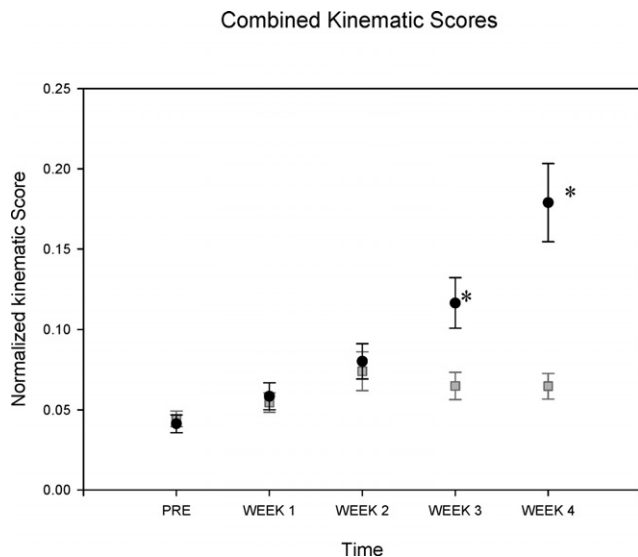


Fig 3. Mean CKS ± standard error computed from the workstation data over the 4-week duration of treatment. The pretreatment values are those obtained during a single workstation session during the assessment stage. Each group was tested at the end of each week. Legend: black symbols, high-intensity FES-ET group; gray symbols, low-intensity FES-ET group. *Significant difference with post hoc Tukey HSD ($P < .05$).

in principle because it allowed task modules to be positioned in front of subjects, turned out to be too heavy for subjects to rotate without assistance. Sometimes, nonattached objects on the workstation fell or moved out of reach, requiring the assistance of the supervising therapist. Accordingly, we have developed a new workstation in the form of a spring-loaded arm with attached manipulanda for future work.⁴⁰

CONCLUSIONS

The results of this study suggest that conventional therapy supplemented with FES-ET at a workstation for 1 hour a day

over 4 weeks can provide improvements in upper-limb motor impairment in the subacute phase of stroke recovery, although further work needs to be done to qualify clinically significant improvements in this group of patients. The study therefore offers further evidence in support of FES-assisted rehabilitation as a complement to traditional rehabilitation.

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APPENDIX 1: DETAILS OF OBJECTS ON WORKSTATION, SENSORS ATTACHED TO THEM, AND THE ASSOCIATED EXERCISES

Object	Sensor	Task
A spring-loaded doorknob	Potentiometer signaling rotational displacement	Rotation of the doorknob
A handle attached via a cord and pulley to an adjustable set of weights	Potentiometer signaling displacement	Pulling the handle toward the body
Rectangular blocks and cylinders of different sizes; shelves at 2 heights above surface	Photoelectric sensors signaling presence of object on pads or in docking bays	Transferring a block or cylinder from 1 location to another
A jar with a screw-top lid	Photoelectric sensor signaling 1 complete turn	Unscrewing the lid
A spring-loaded caliper	Potentiometer signaling displacement, from which force was derived	Squeezing the 2 arms of the caliper together between thumb and fingers

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Suppliers

- a. Model MC68HC811; Motorola, 1303 E Algonquin Rd, Schaumburg, IL 60196.
- b. The Hygenic Corp, 1245 Home Ave, Akron, OH 44310.
- c. Microsoft Corp, One Microsoft Wy, Redmond, WA 98052.
- d. Version 9.0; Systat Software Inc, 1735 Technology Dr, Ste 430, San Jose, CA 95110.