A Functional Electric Stimulation—Assisted Exercise Therapy System for Hemiplegic Hand Function

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Objective: To test a functional electric stimulation (FES)—assisted exercise therapy system for improvement of motor function of the hemiplegic upper extremity.

Design: A before-after trial, with 2-month follow-up.

Setting: A university research laboratory.

Participants: A convenience sample of 6 subjects (3 men, 3 women). Main inclusion criteria were that stroke had occurred more than 1 year before the study (mean time poststroke, 5.6±4.4y) and had resulted in hemiplegia, and that FES produced adequate hand opening.

Intervention: A prototype workstation with instrumented objects was used by subjects to perform a set of tasks with their affected hand during 1-hour sessions for 12 consecutive workdays. A FES stimulator was used to assist hand opening.

Main Outcome Measures: Kinematic data, provided by the workstation sensors, and 3 clinical tests.

Results: Kinematic data indicated statistically significant improvement in subjects' performance (pre-/posttreatment effect size [pre/post ES] of the mean performance scores=5.46; mean pretreatment/follow-up ES [pre/FU ES]=3.44). Two of 3 clinical tests showed improvement in hand function (mean pre/post ES=.51; mean pre/FU ES=.61).

Conclusions: Improvement in hemiplegic hand function because of FES-assisted therapy was documented in a small group of people with hemiplegia whose motor impairment would exclude them from participation in constraint-induced movement therapy. However, the long-term clinical relevance of such improvement needs further study.

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

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A CCORDING TO STATISTICAL DATA from the Heart and Stroke Foundation of Canada,¹ about 40% of all the people who have had a stroke are forced to live with a moderate to severe impairment. The most widely used rehabilitative techniques aimed at restoration of motor control after stroke are neurodevelopmental treatment² (NDT) and proprioceptive neu-

romuscular facilitation³ (PNF). Although both techniques are forms of exercise therapy, they rely on different principles to facilitate recovery of movement. The main principles of NDT are to inhibit unwanted muscle patterns, such as flexion synergies, and to facilitate automatic reactions, such as protective extension. The main principle of PNF is to strengthen functional movement patterns with sensory stimuli—for example, by increasing resistance to movement or by using traction to stimulate proprioceptors. Both therapeutic techniques are equally effective in restoring movement after 6 weeks of treatment.⁴

Another technique constraint-induced movement therapy

Another technique, constraint-induced movement therapy (CIMT), was more recently developed specifically for rehabilitation of upper-extremity function.⁵ Reports have appeared of large gains in function of the hemiplegic extremity in activities of daily living⁵ (ADLs). However, only a small percentage of people with hemiplegia have enough voluntary hand opening to qualify for CIMT. Another approach is based on using functional electric stimulation (FES) of muscles to augment hand function.⁶ Although reports show improved hand function when FES has been used as an exercise program, the functional gains were modest and of limited duration.6 Combining the last 2 approaches into 1 FES-assisted exercise therapy may allow a larger group of stroke patients to benefit from both types of therapy. A recent study by Popovic et al⁷ tested this idea in a group of subacute stroke subjects. Popovic reported better performance of everyday tasks by subjects, who practiced tasks with FES assistance, as compared with control subjects, who exercised without FES.

The first goal of our study was to build and test an exercise workstation for implementation of FES-assisted exercise therapy, which would permit us objectively to assess improvement in upper-extremity function on an everyday basis. The second goal was to make an initial assessment of the effectiveness of the therapy in improving hemiplegic upper-extremity function in a group of people whose level of motor function would have ruled them out for CIMT. We hypothesized that FES-assisted exercise therapy would result in measurable improvements in upper-extremity function.

METHODS

System

The therapeutic system consisted of a workstation and an FES stimulator. The workstation included a desk with a number of instrumented objects (fig 1). The objects were chosen to represent household items, manipulation of which would require movements of the whole upper extremity in various configurations. A spring-loaded doorknob and a handle attached via a cord and pulley to an adjustable set of weights were instrumented with potentiometers, which allowed us to monitor their displacement and velocity. The other objects consisted of 3 rectangular blocks and a cylinder, which were transferred by the subjects between 2 docking bays. These were instrumented with internal infrared sensors, which generated an electric signal when an object entered the bay. This allowed us to time movements of the objects between the 2 bays. The

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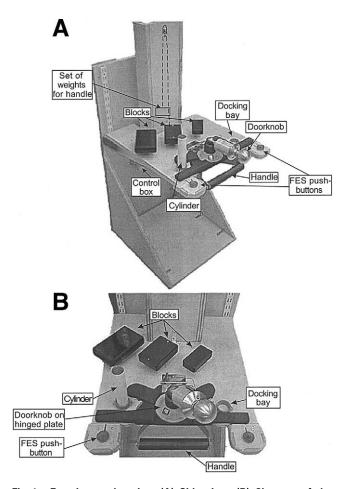


Fig 1. Exercise workstation. (A) Side view. (B) Close-up of the objects. The handle and the doorknob were instrumented with rotational potentiometers to measure displacement. Docking bays were instrumented with photoelectric sensors to detect time of insertion of the cylinder or 1 of the blocks.

sensor signals were processed with a custom-built control circuit and then digitized (200 samples/s) by a CED Power 1401 laboratory interface.^a The data were stored on a desktop computer and later analyzed by using Matlab, version 6.1,^b and SigmaStat, version 2.03,^c software.

To assist subjects with hand opening, we used a modified Impact Cuff⁸ stimulator^d with a pair of surface electrodes to stimulate wrist and finger extensor muscles. The subjects triggered the Impact Cuff by pushing one of the buttons on the workstation (fig 1) just before grasping an object and when they wanted to release it.

Participants

To test the system, we recruited a convenience sample of 6 subjects with hemiplegia, whose characteristics are summarized in table 1. All subjects were more than a year poststroke, by which time the recovery of upper-extremity function is thought to reach a plateau. The subjects served as their own controls. The following inclusion criteria were used during subject enrollment: stroke having occurred more than a year before the study and inability to voluntarily grasp and release any 3 objects on the workstation. The following exclusion criteria were also used: (1) inability of FES to open the impaired hand or intolerance of FES by the subject; (2) no

voluntary movements of the shoulder and elbow; (3) serious cognitive deficit (Mini-Mental State Examination¹⁰ score, <16), visual hemineglect¹¹ (letter cancellation test, >2 letter difference), or severe depression (Center for Epidemiological Studies Depression Scale¹² score, >16); (4) other serious medical conditions; or (5) injuries to arms or hands. The procedure was approved by the local hospital ethics committee, and all subjects signed a letter of informed consent after receiving a description of the project.

Intervention

Therapeutic intervention consisted of daily 1-hour sessions for 12 consecutive workdays, during which subjects performed 3 tasks for about 20 minutes each. The tasks consisted of reaching, grasping, moving (eg, pulling, rotating), and releasing an object on the workstation with the hemiplegic upper extremity. The objects were chosen on the basis of the subject's ability to grasp them with FES assistance at the beginning of the training period. If a subject was able to grasp more than 3 objects, the 3 most difficult tasks were chosen. If a subject was not able to grasp 3 objects because of inability of FES to adequately open the hand, this subject was excluded from the study. Once chosen, objects were not varied during the therapeutic intervention. During an exercise session, each task was repeated as often as possible for 20 minutes, which resulted in the number of repetitions being between 5 and 15 in 1 session. Only successful trials were saved for further analysis; hence, if an object was dropped or mishandled in any other way, the trial was disregarded.

Assessment and Statistical Analysis

Two types of outcome measure were used to assess functional improvement in upper-extremity function: kinematic measures and clinical tests. Kinematic measures were obtained from sensors fitted to the manipulated objects. These measures were the time taken to reach and grasp the object, mean velocity of the handle, and maximum amplitude of rotation of the doorknob. Rather than analyzing these values separately, we combined them in a performance score by using the following analysis. We normalized the kinematic measures and their standard deviation (SD) in relation to their maxima over all exercise sessions for each subject, which made them vary between 0 and 1. Then we calculated the mean score for each task by averaging normalized kinematic measures and normalized SD. Values of variables, such as the time to reach an object and the SD, decreased with improvement in performance, whereas the rest increased. Therefore, the normalized values of the time taken to reach and grasp an object and the SD were subtracted from 1, so that the maximum value of the cumulative score represented maximum improvement. For each subject, these task scores were then averaged into a final score that represented each subject's performance during each

Table 1: Subjects' Characteristics

No. of subjects	
Men	3
Women	3
Mean age (y)	53.5±14.8
Side of stroke	
Dominant hemisphere	4
Nondominant hemisphere	2
Mean no. of years poststroke	5.6±4.4
viean no. or years poststroke	5.0.

NOTE. Values are n or mean ± standard deviation (SD).

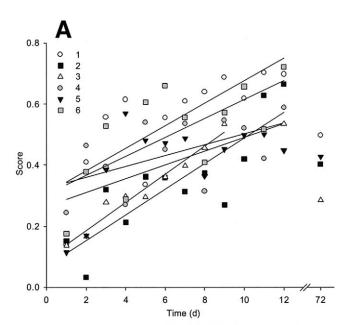
exercise session. The final performance (FP) scores for all subjects were pooled and analyzed with the 1-way repeated-measures analysis of variance (ANOVA), followed by Dunnett multiple comparisons, treating FP score values recorded on the first day of exercise as control measures.

Clinical measures included assessment of active range of motion by using the upper-extremity portion of the Fugl-Meyer Assessment¹³ (FMA) and of motor impairment with the Wolf Motor Function Test¹⁴ (WMFT). Subjects' performance during these 2 tests was videotaped by a researcher and later rated by a volunteer clinician, who was unaware of the time the assessment was made (pretreatment, posttreatment, follow-up). The Motor Activity Log¹⁵ (MAL) was used to estimate involvement of the hemiplegic extremity in subjects' daily lives. Statistical analysis of the clinical measures from 4 subjects was performed by using the 1-way repeated-measures ANOVA, followed by Dunnett multiple comparisons. Two subjects who declined to undergo the follow-up assessment were excluded from statistical analysis of clinical scores. The study was performed in 2001–2002.

RESULTS

Figure 2 shows the FP scores of 6 subjects using the workstation for 12 days and the FP scores of 4 subjects using the workstation on a follow-up session (day 72). Figure 2A shows individual FP scores, whereas figure 2B shows the FP scores averaged over all subjects. The data show gradual improvement in subjects' performance with continued use of the workstation. The maximum change in the mean FP scores between the first and the last day of exercises was 287% (pre-/posttreatment effect size [pre/post ES] of the mean FP scores=5.46). Statistical analysis of the FP scores showed that improvement of subjects' performance was statistically significant (F=8.210, P < .001). Dunnett multiple comparison (q) analysis showed that the FP scores starting from the third day of exercises differed significantly from the FP scores on the first day of exercises (q for columns 3-12=4.242, 3.651, 4.686, 5.371, 5.481, 4.508, 5.942, 5.841, 6.023, 7.136, respectively; *P*<.05 in all cases). At the 2-month follow-up (FU), the improvement in performance was still present, although somewhat reduced (pre/FU ES of the mean FP scores=3.44). Dunnett multiple comparison analysis showed that the follow-up FP scores differed significantly from the control scores (q=3.795, P<.05).

Figure 3 summarizes the clinical assessments of upperextremity function in the same subjects. At the end of treatment, functional ability scores of the WMFT increased on average to 111% of pretreatment values (fig 3A) (mean pre/ post ES=.57). At the 2-month follow-up, the WMFT scores further increased on average to 119% of corresponding pretreatment values (mean pre/FU ES=.54). ANOVA of the functional ability scores from 4 subjects showed that changes in the values were statistically significant (F=6.112, P=.036). Mean time to perform tasks in the WMFT decreased by the end of treatment on average to 90% of pretreatment values (mean pre/post ES=.28) (fig 3A) and at the follow-up to 74% of corresponding pretreatment values (mean pre/FU ES=1.02). ANOVA of the mean time values showed that the changes in the values were not statistically significant (F=1.805, P=.243) because of larger variability of data. The changes in the MAL scores were rather variable from subject to subject. The amount of use (AOU) scores increased posttreatment on average to 187% of pretreatment values (fig 3B) (mean pre/post ES=.61). At the follow-up, AOU scores had declined on average to 153% of corresponding pretreatment values (mean pre/FU ES=.64). The pattern for the quality of movement (QOM) scores of the MAL was very similar to the AOU scores (mean



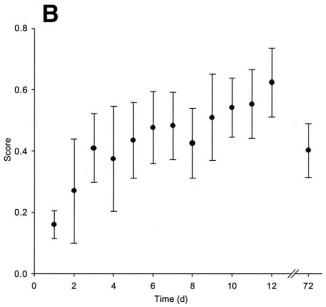


Fig 2. FP scores. (A) FP scores for each subject. Each bullet represents the FP score per day per subject. Regression lines were fitted to the data to indicate trends in subjects' performance during the exercise period. (B) Mean final performance scores. Values of the FP scores averaged over all subjects ± SD.

pre/post ES=.60; mean pre/FU ES=.24) (fig 3B). ANOVA of both QOM and AOU scores of the MAL did not show statistically significant effects of the treatment (QOM: F=1.121, P=.386; AOU: F=.831, P=.480). There were no significant changes in the FMA scores (mean pre/post ES=.13; mean pre/FU ES=-.17; F=3.273, P=.109).

DISCUSSION

This pilot study indicated that 12 hours of exercise on the workstation was associated with modest improvements in upper-extremity function in 6 subjects with chronic hemiplegia. Workstation sensors recorded statistically significant improve-

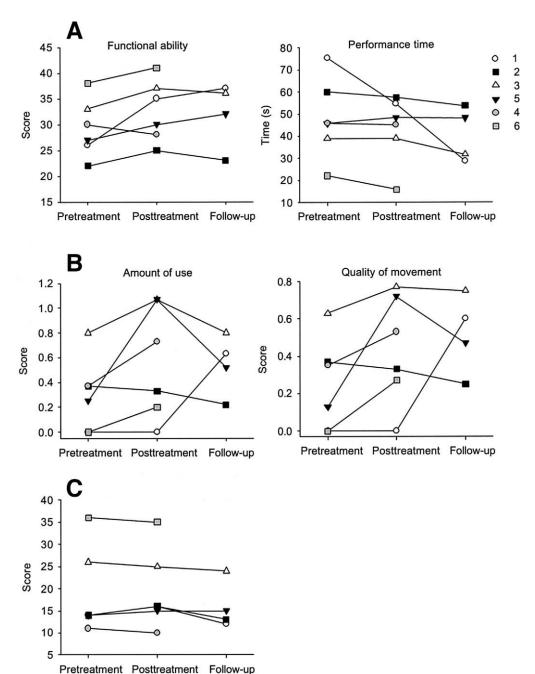


Fig 3. Clinical assessment data. (A) Results from the WMFT, (B) results from the MAL, and (C) results from the FMA for all subjects. Twomonth follow-up was done for 4 of 6 subjects.

ment in hand function in all 6 subjects. All subjects included in the study were more than a year poststroke, at which time no spontaneous recovery is expected. Therefore, we believe that the quantitative results represent genuine improvements in hemiplegic hand function resulting from the exercises using the workstation. Because changes in subjects' performance were also shown to be present with the WMFT, we believe that some improvement in hand function carried over to unpracticed tasks.

Two months after the intervention, hand function was still augmented in comparison with the first day of treatment, according to the workstation sensors and the WMFT. This shows the possible long-term benefit of exercise therapy using the workstation, in accordance with results reported in other exer-

cise therapy studies.¹⁵⁻¹⁷ However, because only 4 of 6 subjects were available for the follow-up, the long-term benefits of the therapy may be under- or overestimated and will need further study.

MAL scores failed to show a statistically significant carryover effect of the improvement in hand function into the patients' ADLs. This may be because the improvements in hand function, which occurred after using the workstation for 2 weeks, were not large enough to make a significant impact on the subjects' daily activities.

The FMA results support this conclusion. We believe that the FMA, being a measure of overall motor impairment, is relatively insensitive to modest changes in hand function.¹⁸ Failure of the MAL to measure statistically significant carry

over of functional improvements to the patients' ADLs may also be because of the limited selection of tasks in the log. Subjects included in our study had very limited hand function. It is possible that if more simple ADL tasks, which more likely would be attempted by severely affected subjects, were included in the MAL, the carry over of improvements would be more apparent. To summarize, because neither the MAL nor the FMA showed statistically significant changes in the scores, the clinical relevance of documented improvements in hand function have not been shown and merit further study.

The functional gains in hemiplegic hand function resulting from the use of the workstation were lower than gains reported for CIMT.5 Factors such as fewer hours of therapeutic intervention in our study⁵ and less intensive daily exercise protocol19 may account for this difference. Also, the subjects in our study were at a lower level of sensorimotor function than those in the CIMT studies. The inclusion criteria in those studies specified a minimum of 10° of extension at the metacarpophalangeal and interphalangeal joints and 20° of extension at the wrist.15 It has been reported that stroke survivors with lower sensorimotor function have a decreased potential for recovery than those who are less severely affected.²⁰ Because of the absence of a control group, we cannot completely rule out the possibility that other forms of exercise therapy of similar duration would be as effective as using the workstation. However, the goal of our study was to make an initial evaluation of the efficacy of a workstation in delivering goal-directed exercise therapy with quantified outcomes to a group of stroke patients who usually receive no therapy at all. In this regard, the workstation approach proved to be viable and useful not only in formalizing exercise sessions, but also in providing quantitative evaluation data. A controlled, blinded study, using an improved system and longer training period, is now under way.

CONCLUSIONS

Our study showed that the use of FES-assisted exercise therapy in conjunction with an instrumented workstation was associated with improvements in hand function in a group of hemiplegic people whose level of motor function would have excluded them from CIMT. The eventual goal of this research is to provide workstations for home use that will allow people with hemiplegia to engage in regular teletherapy sessions to improve upper-extremity function.

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