

Myoelectrically driven functional electrical stimulation may increase motor recovery of upper limb in poststroke subjects: A randomized controlled pilot study

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Abstract—The objective of this randomized controlled pilot study was to assess the feasibility and effectiveness of myoelectrically controlled functional electrical stimulation (MeCFES) for rehabilitation of the upper limb in poststroke subjects. Eleven poststroke hemiparetic subjects with residual proximal control of the arm, but impaired volitional opening of the paretic hand, were enrolled and randomized into a treated and a control group. Subjects received 3 to 5 treatment sessions per week until totaling 25 sessions. In the experimental group, myoelectric activity from wrist and finger extensors was used to control stimulation of the same muscles. Patients treated with MeCFES ($n = 5$) had a significant ($p = 0.04$) and clinically important improvement in Action Research Arm Test score (median change 9 points), confirmed by an Individually Prioritized Problem Assessment self-evaluation score. This improvement was maintained at follow-up. The control group did not show a significant improvement ($p = 0.13$). The reduced sample size of participants, together with confounding factors such as spontaneous recovery, calls for larger studies to draw definite conclusions. However, the large and persistent treatment effect seen in our results indicate that MeCFES could play an important role as a clinical tool for stroke rehabilitation.

Key words: Action Research Arm Test, activities of daily living, electromyography, functional electrical stimulation, motor relearning, myoelectric control, rehabilitation, stroke, task-oriented therapy, upper limb.

INTRODUCTION

Most subjects experiencing a cerebrovascular accident (stroke) will have reduced upper-limb function [1–3]. Reduced upper-limb function influences activities of daily living (ADLs), limiting participation and thus adversely affecting the quality of life [4]. Recently, the behavioral, neuropsychological, and neurophysiological science of motor control has influenced the practice of rehabilitation [5–6]. Task-oriented therapy [7] involving ADLs has been found to promote motor relearning and improve hand function [8–9]. In fact, the movement is

Abbreviations: ADL = activity of daily living, ARAT = Action Research Arm Test, EMG = electromyography, FES = functional electrical stimulation, IPPA = Individually Prioritized Problem Assessment, IQR = interquartile range, MeCFES = myoelectrically controlled functional electrical stimulation, MWUt = Mann-Whitney U test, Post = end-of-treatment evaluation, Pre = baseline evaluation, TSS = time since stroke, WSRt = Wilcoxon Signed Rank test.

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represented in terms of specific action in the brain. The core of the motor system is not movement but action, defined by a goal and by expectancy. In the premotor area, different sets of neurons code the general goal of an action (i.e., grasping), the way in which a specific action must be executed (i.e., precision grip), and temporal segmentation of the action (i.e., a specific phase of the grip) [10]. Proper hand positioning requires synergistic activation of extensors and wrist flexors, while a typical clinical picture in patients with stroke includes overactivity of wrist and finger flexors [11] that, combined with weakness of the extensor muscles [12], causes a lack of active hand opening. Furthermore, inappropriate coactivation of the flexor and extensor muscles may prevent voluntary extension of the fingers and thus impede relaxation of the grip [13]. Functional electrical therapy, in which paretic muscle groups of the hand are stimulated in a synchronized sequence to assist the subject in performing functional movements, has been shown to be a valid method for increasing functional recovery of the hand [14–15], even in severe acute hemiplegic patients [16]. Though hand opening is limited or absent, the myoelectric signal from the wrist and finger extensors may be present and can be used for control of functional electrical stimulation (FES) in the same muscles [17]. Francisco et al. indicated that the myoelectric signal was feasible for triggering (as opposed to a mechanical trigger, for example) FES [18]. This method may have the additional effect of providing the user with feedback about the onset of muscular activity [19].

Cessation of muscle contraction may also be impaired after stroke. Therefore, a logical consequence seems to be to let the muscle be in direct control of the FES in order to follow onset and cessation, as well as intensity of volitional contraction [20]. Functional practice with a sensorimotor task-oriented approach during treatment can help patients better perceive movement of the arm and consequently improve somatotopic organization of the motor cortex and promote functional and structural changes at synapses in the circuits participating in a learning task. Performance and motor relearning have been found to improve when practice is distributed over time, and retention of the acquired skills appears increased when the practice is randomly ordered [21].

Another important factor in clinical trials is the dose effect. A rate of three or more sessions per week appears to correlate positively with the outcome [15,21–24], while additional daily training appears not to provide further

benefits [25]. Although early intervention after a cerebrovascular accident is one of the key factors for success of rehabilitation, there is growing evidence that further improvement is still possible more than 1 yr after stroke [26].

Shindo et al. recently published a study applying myoelectrically controlled stimulation to finger extensors on patients with subacute stroke for 8 h/d using a wrist splint and found a significantly greater gain in wrist/hand function than control patients who wore the wrist splint alone [20]. They set maximum stimulus intensity in order to achieve a 0° finger extension, i.e., a functional opening of the hand, during the voluntary finger extension attempt.

The purpose of the present work was to test the hypothesis that, in persons with reduced function of the arm after stroke, synergic movements induced by FES controlled by residual volitional activity of the prime mover during task-oriented functional movements would have a greater therapeutic effect than similar activities with placebo stimulation. Specifically, we aimed toward stimulation of the wrist and finger extensors, controlled by the same muscles, in order to increase hand opening during therapy applying the previously mentioned principles of task-oriented distributed practice.

METHODS

This is a subject-and-rater blinded randomized controlled pilot study. We assessed 31 patients with hemiparesis after stroke from a convenience sample for eligibility. Eleven patients met the inclusion/exclusion criteria and were enrolled (see flow diagram of the study, **Figure 1**).

Inclusion criteria were a first cerebrovascular accident more than 2 mo before the enrollment; age between 18 and 80 yr; paresis of the upper limb with compromised functionality but some residual proximal control; presence of electromyography (EMG) signal in forearm muscles; and ability to participate in the protocol, attending at least 3 treatment a week. Exclusion criteria were presence of implanted electronic devices, epilepsy, respiratory insufficiency, hepatic or renal insufficiency, pregnancy, peripheral neuropathies, cutaneous ulcers at the stimulation zone, other use of FES on the upper limb, presence of spasticity of wrist muscles (Ashworth scale more than 3), and serious cognitive or behavioral problems that could interfere with compliance to the protocol. Depending on the time since stroke (TSS), patients were

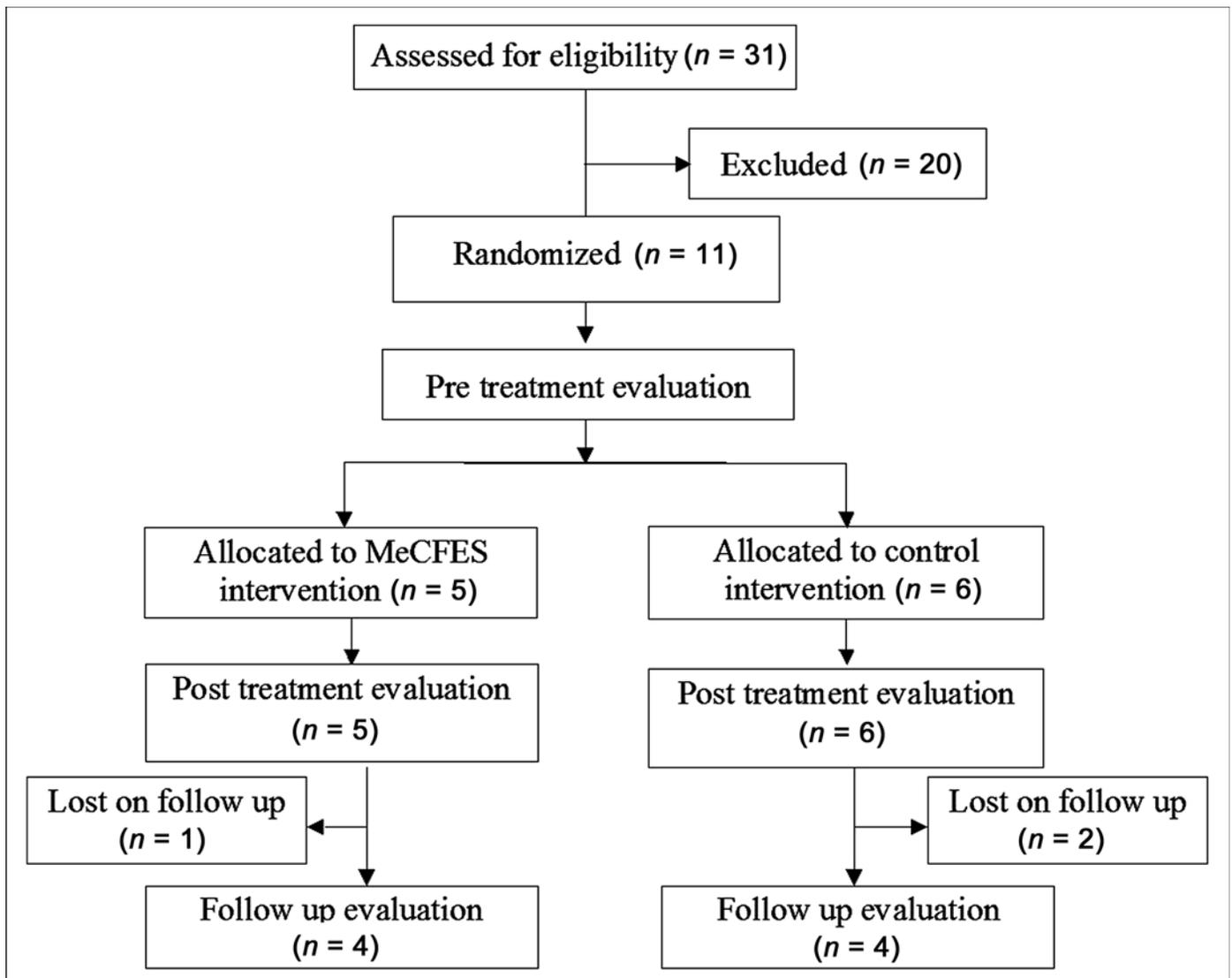


Figure 1. Flow diagram of study. MeCFES = myoelectrically controlled functional electrical stimulation.

classified as subacute (less than 6 mo) or chronic (more than 6 mo). Baseline evaluation (Pre), end-of-treatment evaluation (Post), and follow-up (3 mo posttreatment) evaluation were made to quantify the motor recovery.

Experimental treatment was performed with a myoelectrically controlled FES (MeCFES) device. After signing an informed consent form and following initial evaluation, patients were randomized to receive either MeCFES or sham subthreshold stimulation during the physiotherapy sessions. Patients were assigned to experimental treatment (group A) or control group (group B)

using allocation by minimization [27]. The TSS and initial Action Research Arm Test (ARAT) scores were used as minimization factor. Patients and raters were not aware of the treatment allocation. Both treatments were incorporated in the standard physiotherapy setting, with treatment duration of 45 min, for a total of 25 sessions, with 3 to 5 sessions per week. The first 5 min of each session were dedicated to mobilization of the arm and hand and mounting of the system, followed by 20 min of functional reaching and grasping tasks with MeCFES or sham stimulation. But, in the experimental group, we used more

time (at times the whole time slot) for MeCFES set-up in the first one or two sessions. Thereafter, MeCFES parameters and electrode placement would be replicated from session to session. However, the therapists were free to make adjustments during treatments. The control group sham stimulation was given by a 10 s periodic submotor threshold stimulation (1–5 mA), which just exceeded the sensory threshold. Participants were told that this would facilitate hand control. During treatments, patients were encouraged to perform exercises as close as possible to typical ADLs, to the extent allowed by the rehabilitation environment. Tasks included different actions with different goals, like reaching, grasping, pressing, turning, and manipulating several kinds of objects that required different grips, performed in the context of ADLs that were motivational and appropriate for the individual patient. In the last 20 min, the functional exercises were repeated without MeCFES/sham device to promote retention.

Apparatus

The MeCFES is a single-channel portable system comprising a special amplifier [28] for the myoelectric signal recording, a digital signal processor unit, and a charge-balanced stimulator [29]. The system was developed for homologous stimulation (stimulation of the same muscle from which the myoelectric signal is recorded), with specific attention on a hardware design optimized to reduce noise caused by the stimulation (stimulation artifacts). After sampling, the signal was processed digitally. The first 10 ms after each stimulation pulse of the recorded signal consisted mostly of the stimulation response and was eliminated. A first-order comb filter was used to suppress harmonics of stimulation responses. Then, the root-mean-square over the stimulation interval was calculated. To obtain a smooth estimate of the myoelectric level, a first-order infinite impulse response low-pass filter with a cut-off frequency of 1 Hz was applied. Stimulation amplitude was then computed as a piecewise linear function. The estimated myoelectric level was subtracted by an offset and multiplied by a gain. This was the level of stimulation current amplitude (I) that was limited between zero and a maximum level (I_{Max}).

$$(I = \min(\text{myoelectric level} - \text{offset}) \times \text{gain}, I_{Max}).$$

A consequence of this linear control was that the subject had direct control of the stimulation output level through

the volitional level of contraction. The stimulation consisted of biphasic 300 μ s rectangular impulses with a 300 μ s inter-phase interval and a 16.6 pulses per second fixed repetition rate. The dimension of the device was 11 \times 3 \times 6 cm with a weight of 200 g, and it was powered by two rechargeable 1.5 V AA type batteries.

A laptop computer was used to control the system parameters and provide feedback to patient and therapist of stimulation level. This feedback was given as a cursor indicating the position on the piecewise linear curve.

The MeCFES recorded the myoelectric activity from the 2/3 proximal part of the forearm at the level of innervation zones of extensor carpi radialis, extensor carpi ulnaris, and/or extensor digitorum communis as appropriate for the residual volitional activity of the patient. The recording electrodes were normal electrocardiography electrodes (Blue Sensor, MedicoTest A/S; Ølstykke, Denmark). Stimulation was applied using a different pair of electrodes for transcutaneous electrical nerve stimulation (PALS, Axelgaard; Fallbrook, California). Their position was found by trial during the first one or two sessions. Keeping stimulation and recording electrode pairs perpendicular to each other reduced stimulation artifacts, resulting in optimal control. Stimulation electrodes were placed along the extensors so the stimulation would induce wrist and/or finger extension, whichever was most appropriate to provide functional wrist extension and opening of the hand. A close spacing of stimulation electrodes could target one muscle, e.g., extensor carpi radialis, whereas a larger spacing were activating additional muscles, such as the extensor digitorum communis. The maximum level of stimulation (ranging from 10–20 mA) was individually set to avoid flexion reflex activation and/or inadvertent stimulation of flexor muscles because of spillover of current. Similarly, the offset was regulated to avoid that quiescent muscle activity and/or noise activated the stimulation prematurely. Finally, the gain was adjusted by trial and error as a compromise between being high enough to ensure that the patient could activate the full range of stimulation but also sufficiently low to avoid instability of the intrinsic feedback loop caused by stimulation responses and artifacts.

Assessments

The primary outcome of the study was the upper limb functionality as measured by the ARAT [30]. The ARAT assesses the ability to handle objects with qualitatively rated items and is a measure of arm- and hand-related

activity limitation. A change of 5.7 points is considered a clinically relevant change on the 0 to 57 points scale [30].

As a secondary outcome, the patient's perceived improvement was evaluated by the Individually Prioritized Problem Assessment (IPPA) [31]. This is a guided questionnaire on which the patient has to name up to seven problems caused by the impaired function and prioritize each on a Likert scale from 1 = no priority to 5 = high priority. The patient scores each problem with the perceived difficulty from 1 = no difficulty to 5 = impossible. The average of priority level times difficulty level yields the IPPA score from 1 to 25 [32]. In this study, we modified the IPPA by formulating questions that inquired as to which problems with arm/hand function the person expected to improve with the therapy. The same problems were re-evaluated for their respective difficulty after the treatment period. The postscore of IPPA was then again calculated as the average of priority (same as Pre) times the new level of difficulty.

Assessments were made before (Pre) and after (Post) the 25 therapy sessions. To observe whether the results were persisting in time, follow-up evaluation of ARAT was performed at 3 mo after the end of treatment.

Data Analysis

Because of nonnormal distribution of the variables, median/range values were used for descriptive statistics and nonparametric tests for statistical analysis. Differences between the experimental and control groups at Pre were tested with Mann-Whitney U test (MWUt).

Significance of within-group differences in ARAT scores between Pre and Post and between Post and follow-up evaluations was tested with the Wilcoxon Signed Rank test (WSRt). The WSRt was also used to test within-group differences between Pre and Post evaluations in IPPA scores.

Change scores were then calculated by subtracting Pre from Post scores of both ARAT and IPPA outcomes. Differences between the experimental and the control group were tested with the MWUt.

Since TSS might be a confounding factor because of the large spontaneous recovery early after stroke, we tested the association between ARAT change score and TSS.

All tests were performed in Statistica for Windows 6.0 (StatSoft, Inc; Tulsa, Oklahoma) with a significance level of $p = 0.05$.

RESULTS

The results of the patients are reported in the **Table**. There were four males and one female in the MeCFES group (A) and three males and three females in the control group (B), and patients were equally distributed with regard to side of lesion. There were no significant differences between allocated groups in TSS ($p = 0.75$) and ARAT score at baseline ($p = 0.06$). However, group A was younger (median 39 yr) than group B (median 57 yr, $p = 0.04$, MWUt).

In the control group (B), no statistically significant change was found from Pre to Post (median change 2 interquartile range [IQR] [0; 5], WSRt = 5, $p = 0.25$). Furthermore, there was no significant change from Post to follow-up (median change -2 IQR [-7.5; -1], WSRt = -5; $p = 0.13$). In the MeCFES group (A), there was a statistically significant increase (median change 9 IQR [7; 24], WSRt = 0, $p = 0.04$) in ARAT score between Pre and Post evaluation and all subjects had clinically relevant improvement (>5.7 points). With respect to the control group, this improvement was significant ($p = 0.03$, MWUt). There were no significant ($p = 0.99$, WSRt = 0) changes between Post and follow-up, thus indicating retention of improvements. **Figure 2** graphs the outcome of ARAT scores in the two groups.

The IPPA score (**Figure 3**) did not change significantly after treatment in any group ($p = 0.07$ group A, $p = 0.42$ group B, WSRt). However, the MeCFES group showed a median decrease of 3 points, meaning that the patients perceived less difficulty in performing their prioritized tasks after treatment. The median decrease from Pre to Post in IPPA score for the MeCFES group was significantly greater than that for the control group (-3.0 vs 0.3, $p = 0.03$, MWUt).

DISCUSSION

We hypothesized that MeCFES would produce greater improvement of arm function in patients after stroke than the same physiotherapy using sham stimulation. Using the MeCFES as a tool to initiate muscle activity in paretic muscles can be helpful for the physiotherapist in reactivating volitional movements, thus allowing the therapist to start earlier in the treatment to work with functional tasks. The findings of the present study indicate that MeCFES in conjunction with task-oriented

Table.

Main characteristics and outcomes of subjects enrolled in study. List was ordered by treatment allocation. A is myoelectrically controlled functional electrical stimulation (MeCFES) group and B is control group. Summary by group is given in bottom lines as number in each group, median with interquartile range. There are two subacute patients in each group (italicized).

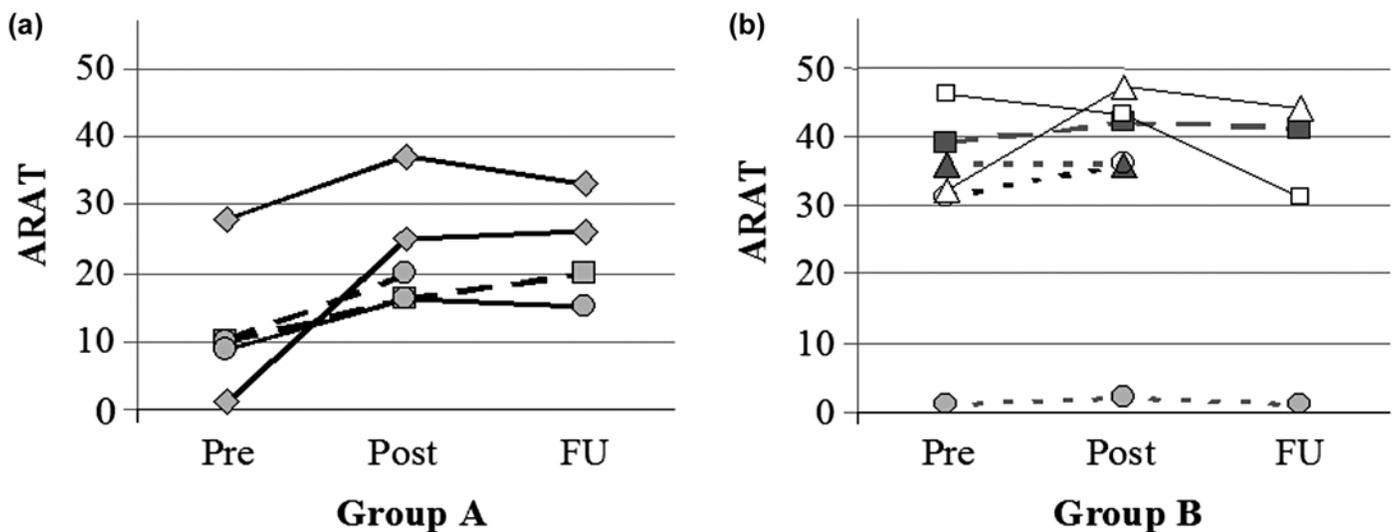
| Patient | Allocation | TSS (mo) | Age (yr) | Sessions/Wk | ARAT Pre | ARAT Post | ARAT Follow-Up | IPPA Pre | IPPA Post |
|----------|------------|------------|-----------|-------------|----------|-----------|----------------|-----------|-----------|
| <i>1</i> | A | <i>4.6</i> | <i>37</i> | <i>3.2</i> | <i>9</i> | <i>16</i> | <i>15*</i> | <i>20</i> | <i>17</i> |
| <i>2</i> | A | <i>3.1</i> | <i>50</i> | <i>4.4</i> | <i>1</i> | <i>25</i> | <i>26</i> | <i>25</i> | <i>23</i> |
| 3 | A | 77.2 | 39 | 3.1 | 28 | 37 | 33 | 19 | 16 |
| 4 | A | 8.6 | 54 | 4.2 | 10 | 16 | 20 | 18 | 18 |
| 5 | A | 8.3 | 33 | 3.7 | 10 | 20 | DO | 23 | 20 |
| 6 | B | 3.5 | 57 | 4.6 | 32 | 47 | 44 | 10 | 11 |
| 7 | B | 47.3 | 64 | 4.7 | 46 | 43 | 31 | NA | NA |
| 8 | B | 5.3 | 70 | 4.6 | 1 | 2 | 1 | 20 | 20 |
| 9 | B | 10.8 | 56 | 3.2 | 39 | 42 | 41 | 18 | 16 |
| 10 | B | 89.4 | 45 | 5.0 | 36 | 36 | NA | 16 | 15 |
| 11 | B | 7.0 | 47 | 4.0 | 31 | 36 | NA | 16 | NA |

Summary by Group

| | | | | | | | | |
|-------------------|----------|------------|---------|------------|------------|------------|------------|------------|
| A (<i>n</i> = 5) | 8 [5,9] | 39 [37,50] | 4 [3,4] | 9 [5,10] | 20 [16,25] | 23 [19,28] | 20 [19,23] | 18 [17,20] |
| B (<i>n</i> = 6) | 9 [6,38] | 57 [49,62] | 5 [4,5] | 34 [31,38] | 39 [36,43] | 36 [24,42] | 16 [16,18] | 15 [14,17] |

*Assessment delayed 3 mo.

ARAT = Action Research Arm Test, DO = drop-out patient, IPPA = Individually Prioritized Problem Assessment, NA = data not available because patient unable to attend evaluation, Post = end-of-treatment evaluation, Pre = baseline evaluation, TSS = time since stroke.

**Figure 2.**

Action Research Arm Test (ARAT) values for myoelectrically controlled functional electrical stimulation (MeCFES) for (a) intervention group A and for (b) control group B at Pre, Post, and Follow-up (FU) evaluation. The Pre-Post change was significant only for MeCFES group A ($p = 0.04$ Wilcoxon Signed Rank test).

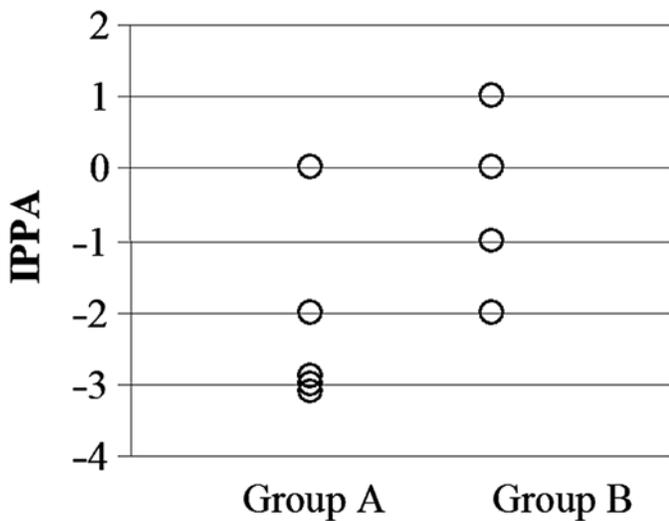


Figure 3. Baseline to end-of-treatment evaluation changes of Individually Prioritized Problem Assessment (IPPA) scores for myoelectrically controlled functional electrical stimulation for intervention group A and control group B. Negative value means that, after treatment, patient had less difficulty performing prioritized tasks.

therapy can provide a clinically relevant improvement of the upper limb in hemiplegic patients when used in the physiotherapy setting with at least three sessions per week. The presence of subacute patients (less than 6 mo since stroke) makes the “spontaneous recovery” a confounding factor. However, since they were evenly distributed in the two groups, treated and controls, this should not affect the results. Moreover, in a review on the effect of electrical stimulation in stroke rehabilitation, de Kroon et al. found that EMG-triggered stimulation was more likely to yield improvements in motor control regardless of subject characteristics, such as being in the subacute or chronic stage of stroke [33]. They emphasized the importance of the cognitive involvement of the patient in the stimulation. In accordance with our findings of effectiveness of EMG-controlled FES, Alon et al., in a treatment paradigm similar to that of the present study with acute and subacute stroke patients, found a larger improvement in hand function by EMG-triggered FES compared with a matching control group that did not receive FES [15]. A concurrent study on patients with less than 2 mo since onset conducted by Shindo et al. found bigger gains on hand function with the adjunct of an integrated volitional electrical stimulator to the use of a splint than with the use of the splint alone during ADLs [20]. The stimulator

device was used 8 h/d for 3 wk. Their experimental group gained 13 ARAT points, whereas their control group gained 8 ARAT points. The apparently lesser effect (9 ARAT points) of the current study may be attributed to less intensive treatment. Another technical difference between Shindo et al.’s approach and the present study is that in Shindo et al., EMG recording and current delivering was done through the same electrodes; therefore, positioning of stimulating electrodes was constrained and might not have been optimal to evoke the desired movement. Moreover, the device used in that study continuously delivers a submotor threshold stimulation intensity during no voluntary contraction [34].

It is noteworthy that the three chronic individuals treated with MeCFES gained clinically relevant improvements, whereas none of the chronic subjects in the control group gained improvement. This confirms the doubts expressed by several researchers about the validity of the “plateau” of recovery after which chronic patients apparently do not gain significant motor recovery [21–22,26,35–38]. It could be hypothesized that the treatment with MeCFES introduces a variation in the treatment, which causes a further increase of motor skill after the plateau is reached [21].

It should then be investigated whether MeCFES treatment again will have another plateau. The research question would then be different for subacute and chronic patients: Will the MeCFES accelerate motor relearning in subacute patients and will it provide further improvement for chronic patients? A much more difficult question is what effect such instrument-centered approach may have for the personal and social rehabilitation context [39]. Though follow-ups in the present study indicated retention of upper-limb improvement, the extent to which this improvement transfers to ADLs should be investigated further.

In its present embodiment, the MeCFES requires specific knowledge by the physiotherapist since an understanding of the inner workings of the device is required to successfully apply the device. During initial sessions of the present study, a technician was present to assist with system set-up for each patient. In some cases, it was difficult to find the optimal electrode configuration. Additional resource requirements for MeCFES-assisted treatment must be weighed against the potentially reduced cost of shorter rehabilitation and/or improved rehabilitation goals.

From a research standpoint, it is valuable to apply the technique to only one muscle group in order to limit the

number of variables and answer the fundamental question of feasibility. Therefore, only one stimulation channel was used in this study. However, from a clinical point of view, we observed that hand opening alone does not necessarily imply better upper-limb function. Without a good proximal function, this specific treatment protocol did not always result in better arm function as measured by ARAT because proximal control is important for performing some of the ARAT items. It is possible that clinical needs will be better met by patient-specific protocols addressing a variety of upper-limb (including more proximal) muscles and functions. Increasing the number of channels and investigating other sites of applications may address this issue and increase the number of patients who could benefit from the use of this technique.

CONCLUSIONS

We found that MeCFES can give a clinically relevant improvement of upper-limb function in patients with hemiparesis as measured with the ARAT. This improvement was supported by the patients' subjective judgments according to the IPPA questionnaire. The results indicate that the MeCFES could be a clinically important tool in functional training of the hemiparetic arm and hand. Since proximal function is crucial to the overall limb function, the application of this technique to multiple muscles of the upper limb must be investigated in future research.

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Participant Follow-Up: Out of respect for participant privacy, they will not be directly contacted. However, the results have been communicated at the end of the study and the publication will appear on the institutional Web site.

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