

Functional electrical stimulation therapy for severe hemiplegia: Randomized control trial revisited

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La simulation électrique fonctionnelle pour le traitement d'une hémiplégié sévère : un essai clinique aléatoire revisité

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Key words: Activities of daily living; Rehabilitation; Recovery of function; Stroke; Upper limb.

Mots clés : Accident vasculaire cérébral; Activités de la vie quotidienne; Membre supérieur; Réadaptation; Rétablissement des capacités fonctionnelles.

Abstract

Background. Stroke is the leading cause of long-term disability. Stroke survivors seldom improve their upper-limb function when their deficit is severe, despite recently developed therapies. **Purpose.** This study aims to assess the efficacy of functional electrical stimulation therapy in improving voluntary reaching and grasping after severe hemiplegia. **Method.** A post hoc analysis of a previously completed randomized control trial (clinicaltrials.gov, No. NCT00221078) was carried out involving 21 participants with severe upper-limb hemiplegia (i.e., Fugl-Meyer Assessment–Upper Extremity [FMA-UE] ≤ 15) resulting from stroke. **Findings.** Functional Independence Measure Self-Care subscores increased 22.8 (± 6.7) points in the intervention group and 9 (± 6.5) in the control group, following 40 hr of equal-intensity therapy. FMA-UE score changes were 27.2 (± 13.5) and 5.3 (± 11.0) for the intervention and control groups, respectively. **Implications.** The results may represent the largest upper-limb function improvements in any stroke population to date, especially in those with severe upper-limb deficit.

Abrégé

Description. Les accidents vasculaires cérébraux (AVC) sont la principale cause d'invalidité à long terme. Les survivants d'AVC améliorent rarement la fonction de leur membre supérieur lorsque leur déficit est sévère, malgré les thérapies mises au point récemment. **But.** Cette étude a pour but d'évaluer l'efficacité de la simulation électrique fonctionnelle pour améliorer les mouvements visant à atteindre et saisir volontairement des objets chez des personnes ayant une hémiplégié sévère. **Méthodologie.** Une analyse post-hoc d'un essai clinique aléatoire effectué antérieurement (clinicaltrials.gov, # NCT00221078) a été réalisée; cet essai avait été effectué auprès de 21 participants ayant une hémiplégié sévère au membre supérieur (c'est-à-dire, l'échelle de Fugl-Meyer-Membre supérieur [FME-UE] ≤ 15) à la suite d'un AVC. **Résultats.** Les scores secondaires de la Mesure d'indépendance fonctionnelle ont augmenté de 22,8 points ($\pm 6,7$) dans le groupe ayant reçu l'intervention et de 9 points ($\pm 6,5$) dans le groupe témoin, après 40 heures de thérapie d'intensité égale. Les changements de scores du FME-UE étaient de 27,2 ($\pm 13,5$) pour le groupe ayant reçu l'intervention et de 5,3 ($\pm 11,0$) pour le groupe témoin. **Conséquences.** Ces résultats pourraient représenter les plus grandes améliorations de la fonction du membre supérieur obtenues jusqu'à présent pour toute population ayant subi un AVC, en particulier, pour des personnes ayant un déficit sévère au membre supérieur.

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In 2008, our research team published an article describing the use of advanced functional electrical stimulation (FES) therapy for improving voluntary reaching and grasping functions in individuals with severe upper-limb deficit following stroke (see Thrasher, Zivanovic, McIlroy, & Popovic, 2008), presenting data from a Phase 2 randomised control trial (clinicaltrials.gov, NCT00221078). The study was data rich, and at the time of publication, not all results were presented. The purpose of this article is to share previously unpublished clinically relevant findings from that work. We consider these results to be valuable to the community as some of the outcomes are among the highest achieved during the past 20 years. We feel strongly that clinicians need to be aware of these findings, which may be very useful in informing their future practice. We provide here another perspective on the data published in 2008 in addition to sharing previously unpublished findings from that work.

Background

Stroke, one of the leading causes of disability in the world (Cheeran et al., 2009), can result from rupture of blood vessels supplying the brain (haemorrhaging stroke) or from infarction (ischemic stroke) of one of these vessels. The interruption of the blood supply, following these events, damages neighbouring tissue and can produce necrosis. Stroke often results in hemiplegia—paralysis of one side of the body—as it often affects only one cerebral hemisphere. In turn, this paralysis reduces the independence, quality of life, and occupational performance of patients who have had a stroke. The functional impact of stroke is determined by the size and location of the lesion and ranges from very subtle (mild hemiplegia), in which patients retain the ability to move voluntarily, to high (severe hemiplegia), in which the ability to move is extremely limited or absent.

Rehabilitation after stroke focuses on restoring and/or maximizing the functional efficacy of any remaining ability to move. Unfortunately, existing therapies for recovering arm and hand function after stroke have limited success and often work only for patients who retain some ability to move. Patients with severe upper-limb hemiplegia rarely benefit from existing therapeutic modalities (Dobkin, 2004).

Individuals with severe upper-limb hemiplegia could potentially benefit the most from recovery of function, and thus emerging therapies should concentrate on this patient population. Recent therapeutic developments are highly motivated by neuroplasticity, the capability of the central nervous system to relearn how to perform different tasks—such as reaching, grasping, walking, talking, and swallowing—that might have been severely impaired or impossible following the stroke (Dobkin, 2004). Examples of these modern therapies for improving upper-limb function are constraint-induced therapy (CIT; Cirstea, Ptito, & Levin, 2006; Wolf et al., 2006), robotic-assisted rehabilitation (Kwakkel, Kollen, & Krebs, 2008), and FES therapy (Glanz, Klawansky, Stason, Berkey, & Chalmers,

1996; M. R. Popovic, Thrasher, Zivanovic, Takaki, & Hajek, 2005; Rushton, 2003).

Robotic-assisted therapy promises to make the therapeutic intervention available at home, where access to specialized personnel may be difficult. Automatic monitoring of the individuals's progress using the robot's dedicated sensors can lead to necessary adjustments that optimize the intervention. However, similar to CIT, the use of robotic therapies is restricted to individuals with residual movement. Specifically, CIT restricts the use of the less affected arm, forcing patients to use their affected limb while performing task-oriented activities.

To date, FES therapy is one of the most effective therapy modalities for improving voluntary movement in individuals with severe upper-limb impairments after stroke. The Evidence-Based Review of Stroke Rehabilitation (Teasell, Richardson, Allen, & Hussein, 2015), a Canadian initiative that includes reviews of over 1,400 randomized control trials, identifies FES therapy as a treatment with the strongest level of evidence (Level 1a) for improving upper-limb function in acute stroke (Foley, Mehta, Jutai, Staines, & Teasell, 2013). In the FES therapy that we present here, patients are first asked to attempt individual movements from a battery of functional reaching and/or grasping tasks. If the patient cannot perform part or the entire targeted task after a few attempts, the intended movement is produced using a train of electrical pulses delivered in a tightly controlled synergy (M. B. Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2002). It is believed that the active attempt to move combined with the actual movement of the arm produced by the electrical stimulation and the sensory feedback produced by the movement engages portions of the nervous system relevant to the specific task, promoting neural changes that in turn result in recovering voluntary movement (Daly & Wolpaw, 2008; Ramos Murguialday et al., 2013; Rushton, 2003).

We have created a series of FES technologies and therapies over the past two decades. The results of one of our studies exploring the efficacy of FES therapy to restore voluntary reaching and grasping function during subacute and chronic phases of rehabilitation after stroke were published in 2008 (see Thrasher et al., 2008). The change in voluntary movement was measured after participants received 1-hr therapeutic sessions daily for up to 5 days per week consecutively for 8 weeks (total of 40 hr). Twenty-one participants were randomized into two groups. The control group received best-practice occupational and physical therapy (conventional therapy), while the intervention group received FES therapy in addition to conventional therapy. The results suggested that FES therapy produces greater improvement in subacute patients; all observed changes were statistically significant and clinically meaningful. That study was unique due to its positive findings and in that all participants had severe hemiplegia (i.e., Fugl-Meyer Assessment–Upper Extremity [FMA-UE] ≤ 15). We performed a secondary, complementary analysis on the same study population used in Thrasher et al. (2008) to better understand the nature of the therapeutic effects of FES therapy for the rehabilitation of severe upper-limb hemiplegia after stroke.

Outcome measures in stroke rehabilitation can be categorized as those that are functional-based measures of upper-limb activity (e.g., the Wolf Function Motor Test), impairment-based measures (e.g., the Fugl-Meyer Assessment), and measures of functional independence (e.g., the Functional Independence Measure [FIM]). Improvements in one type of outcome (e.g., measures of impairment) may not be reflected in other outcomes (e.g., functional activities of daily life). Of particular importance to the provision of rehabilitation is improving a person's functional independence, as it will impact directly aspects such as discharge planning and economic forecasting. Since the original publication of the randomized control trial, the data collected during this study have come under scrutiny on multiple occasions by granting agencies requiring additional analysis. In particular, the FIM Self-Care and FMA-UE subscores have been repeatedly requested, as it was uncommon to provide these figures when the original report was produced. All the agencies and reviewers (often thought leaders influencing both academic and clinical occupational therapy) have considered the overwhelmingly positive results to be very helpful to the community and have suggested that we publish them. We present FIM Self-Care subscores (Dodds, Martin, Stolov, & Deyo, 1993) and FMA-UE subscores (Fugl-Meyer, Jääskö, Leyman, Olson, & Setglind, 1975), showing changes in functional independence and motor functioning, respectively. These measures are widely reported in the recent upper-extremity rehabilitation literature and have in themselves become an active field of research (see Page, Fulk, & Boyne, 2012; Woodbury et al., 2007, 2008). The Fugl-Meyer Assessment is a valid (Gladstone, Danells, & Black, 2002; Platz et al., 2005; Woodbury et al., 2008) and highly reliable (Duncan, Propst, & Nelson, 1983; Gladstone et al., 2002; Gowlan et al., 1993; Platz et al., 2005; Prabhakaran et al., 2007) measure of upper-limb impairment. We conducted assessments both at baseline and at the end of the intervention and analyzed their differences before and after the intervention (delta) between the intervention and control groups.

Method

Study Design

The study presented in this manuscript describes a randomized control trial comparing FES therapy and conventional therapy (described below) on a sample of individuals with subacute hemiplegia. The main characteristics of the study were (a) the study received approval from the local research ethics board; (b) patients were invited to participate in the study, and they gave consent before the inclusion/exclusion criteria were applied; and (c) after the patients were admitted to the program, they were randomly assigned to control or intervention group.

Participants

Participants were recruited from the Toronto Rehabilitation Institute–University Health Network. We obtained informed

consent from the participants to take part in the study approved by the Toronto Rehabilitation Institute–University Health Network Research Ethics Board. All participants had experienced a stroke 15 to 57 days prior to the beginning of the study and had severe upper-limb hemiplegia with scores of 1 or 2 in (a) a 7-point scale for arm function and (b) a 7-point scale for hand function on the Chedoke-McMaster Stages of Motor Recovery (CMSMR) assessment as well as FMA-UE score ≤ 15 . All participants had either spastic or flaccid paralysis of the arm and little or no voluntary movement of the hand.

Inclusion criteria to participate in this study were (a) eligibility to provide informed consent as determined by a social worker, (b) hemiplegia and the level of hemiplegia confirmed by an attending physiatrist, and (c) stroke confirmed with a computer tomography or magnetic resonance imaging scan in an acute care facility.

Patients were excluded from this study according to the following criteria: (a) global aphasia of significant language barrier as determined by an attending speech language pathologist; (b) skin rash, allergy, or wounds at the locations where stimulation electrodes were expected to be placed; (c) seizure episodes; (d) edema in the paralyzed arm or shoulder hand syndrome; (e) loss of proprioception, assessed by thumb localization test; (f) early signs of spontaneous recovery of the hemiplegic arm and hand function (within the first 3 weeks after the onset of stroke) and a score of motor recovery greater than 2 according to the CMSMR.

We used sealed envelopes, “shuffled” using a computerized random-number generator, to assign participants to the intervention or control group, receiving FES therapy and conventional therapy or conventional therapy alone, respectively. The following precautions were taken to ensure blinding: (a) Participants were told not to discuss their treatment with the evaluator, (b) the evaluator was part of the research team and did not have contact with the therapist who provided therapy to the participants, and (c) the statistician who processed the data was not a member of the core research team.

Despite our efforts to blind the evaluator from knowledge of which of the two groups individual patients were assigned, the evaluator was able to identify which subjects received the neuroprosthesis therapy. The reason for this was the substantial difference in final outcomes between the participants in the intervention and control groups.

Conventional Therapy

The conventional therapy consisted of muscle facilitation exercises, task-specific repetitive functional training (strengthening and motor control using resistance), stretching exercises, electrical stimulation for muscle strengthening (not functional training or FES therapy), activities of daily living including self-care involving the upper limb, and caregiver training.

FES Therapy

An upper-limb neuroprosthesis was created to facilitate reaching and grasping, which was donned by the participants

receiving FES therapy. We used a programmable stimulator COMPEX Motion (COMPEX SA, Switzerland; M. R. Popovic & Keller, 2005), which delivered stimulation trains of 10 to 50 mA at 40 Hz. Modulation of the stimulation sequences was achieved through control of its pulse width (0–300 microseconds). A therapist triggered the stimulation using a switch.

The FES therapy first focused on training the participants to reach with the affected arm forward, to reach laterally, and to reach different landmarks on the body, such as the mouth, opposite knee, and opposite shoulder. After the participants recovered the ability to reach different targets in their workspace, they were trained to perform grasping (lateral pinch grasp, pinch grasp, and palmar grasp) and hand-opening tasks. Electrical stimulation was applied to various muscles to produce these motions. Patients were asked to retrieve the arm back to its initial position after completing the task or to release a prehended object. In both cases, the patients were required to attempt to carry out the task on their own, and only the parts of the movement that they were unable to perform were facilitated using FES. Muscles targeted by the FES therapy were (a) anterior, median, and posterior deltoid, triceps brachii, and biceps brachii (various reaching and retrieving movements); (b) flexor carpi radialis and flexor carpi ulnaris (wrist flexion); (c) extensor carpi radialis longus and brevis, and extensor carpi ulnaris (wrist extension); (d) flexor digitorum superficialis and flexor digitorum profundus (finger flexion); (e) thenar (thumb flexion); and (f) extensor digitorum and lumbricals I to IV (finger extension and flexion).

Therapy Dose

All participants received a best-practice physical and occupational therapy training regime focused on function of the shoulder, elbow, wrist, and hand function. The control group received physical and occupational therapy daily for 45 min, for up to 5 days a week, for 12 to 16 weeks. The intervention group had the same training routine except the physiotherapy and occupational therapy were augmented with the FES therapy (i.e., the FES therapy dominated the sessions).

Three licensed occupational therapists, each with over 4 years of experience in stroke rehabilitation, provided the therapy. They received extensive training in the operation of the functional electrical stimulator used for this study. The training involved (a) an introduction to the principles of FES, (b) the use of the FES system, (c) treatment on course participant, and (d) training on patients and case studies to ensure that trainees understood how to use FES device. Each therapist provided treatment to both the intervention and control groups.

The participants in the intervention group on average received 40.4 treatment sessions, equivalent to 30.3 hr of therapy (range from 21 hr to 36.75 hr), and the participants in the control group on average received 42.9 treatment sessions, totaling 32.1 hr of therapy (range from 24.7 hours to 44.25 hr).

Outcomes

FIM Self-Care subscore. The FIM is an ordinal scale and has a maximum value of 126. The FIM Self-Care subscore has maximal and minimum values of 42 and 6, respectively, and involves eating, grooming, bathing, dressing upper body, dressing lower body, and toileting. A 7-point scale is used to measure graduations in independent and dependent behaviours. The scale is divided into a no-helper category (scores 6 and 7), where no other person is required to help with the activity, and a helper category (scores 1 through 5), where the patient needs total to minimal assistance, respectively, from another person to complete a task. Scaling is ordinal and consists of the following: 1 = *total assistance*, 2 = *maximal assistance*, 3 = *moderate assistance*, 4 = *minimal assistance*, 5 = *supervision*, 6 = *modified independence*, and 7 = *complete independence* (Oczkowski & Barreca, 1993).

A researcher blinded to the group allocation measured the FIM scores immediately before starting and after completion of the therapy program. The change in score (delta) was calculated by subtracting the end-of-treatment and baseline FIM Self-Care subscores.

FMA-UE subscores. As with the FIM results, we looked at the difference between the pre- and posttreatment FMA-UE subscores. The FMA-UE consists of 33 items for the upper extremity. Each item is scored on a 3-point ordinal scale (0, 1, and 2) with 0 generally corresponding to *no function*, 1 to *partial function*, and 2 to *perfect function*. The items are summed to the final maximal score of 66 (no impairment; See et al., 2013). The minimum score is 0, and the clinically important difference is 9 to 10 points.

Data Analysis

Statistical analyses were performed using R Version 3.0.2. *P* values less than or equal to .05 were considered significant and showing evidence of difference. Mean, standard deviation, and range of all continuous variables and frequency of all categorical variables were calculated. There were no missing values. Bivariate analysis was carried out to compare overall difference between the randomized groups. Differences between the intervention (FES therapy) and control groups in terms of FIM Self-Care subscore and FMA-UE subscores were tested using the nonparametric Wilcoxon rank sum test. This test was selected because the data were ordinal and not normally distributed. Notched box plots were used to compare the two treatment groups at baseline and after the therapy program and their difference in score. The plot consisted of a box showing the interquartile range, the whiskers that should include 99.3% of the data, the line showing the median, and the notch displaying the confidence interval around the median. The association between age and change in FIM Self-Care subscore and FMA-UE subscores was tested using a multivariate generalized linear mixed model.

Table 1
Study Participants Demographics: Categorical Descriptors

Category	Group			p value
	Total n (%) (n = 21)	Intervention (FES) n (%) (n = 10)	Control n (%) (n = 11)	
Sex				
Male	13 (62)	7 (70)	6 (55)	
Female	8 (38)	3 (30)	5 (45)	.7
Affected arm				
Left	11 (52)	6 (60)	5 (45)	
Right	10 (48)	4 (40)	6 (55)	.7
Hemispheric involvement				
Right	10 (48)	6 (60)	4 (36)	
Left	11 (52)	4 (40)	7 (64)	.4
Previous history of stroke				
No	19 (90)	9 (90)	10 (91)	
Yes	2 (10)	1 (10)	1 (9)	

Note. FES = functional electrical stimulation.

Findings

Participant Characteristics

Twenty-three participants were recruited, and two of them did not complete the study. One individual from the control group had to interrupt his participation due to medical problems unrelated to the intervention. The second one, assigned to the treatment group, received Botox therapy (not part of this study) and lost all function regained during therapy. Of the remaining 21 individuals, 10 participants were randomly assigned to the intervention group (FES therapy) and 11 to the control group. Sixty-two percent ($n = 13$) of the participants were male and 38% ($n = 8$) female; 52% had their left arm affected while 48% had their right arm affected. Ninety percent of subjects had no previous history of stroke, and none had other neurological disorders. Ninety-five percent ($n = 20$) of subjects had experienced other comorbidities, 76% were hypertense, and 48% had hyperlipidemia and hypercholesterolemia. The mean age of stroke was 58 years, and the range was between 29 and 82 years. Participants' characteristics are listed in Tables 1 and 2. Seventy percent of participants in the intervention group (FES therapy) were male, compared to 55% in the control group. Mean age of stroke in the intervention group was 51 ($SD = 14.7$) years, compared to 65 ($SD = 20.3$) years in the control group. No significant differences were observed between the two randomization groups in terms of their clinical and demographic characteristics. The participants in the intervention group on average received 40.4 treatment sessions (range from 28 to 49), and the participants in the control group on average received 42.9 treatment sessions (range from 33 to 59).

Table 2
Functional Independence Measure Self-Care Subscores and Fugl-Meyer Assessment—Upper Extremity Subscores at the Beginning and End of the Intervention

Variable	Group			p value
	Total M ± SD (range) (n = 21)	Intervention (FES) M ± SD (range) (n = 10)	Control M ± SD (range) (n = 11)	
Age at stroke	58 ± 18.8 (29–82)	51 ± 14.7 (32–74)	65 ± 20.3 (29–82)	.097
Treatment start date	29 ± 10.2 (17–57)	29 ± 11.8 (19–57)	29 ± 9.0 (17–44)	.859
Days between first and last assessment	53 ± 18.4 (33–96)	55 ± 16.2 (35–91)	52 ± 20.8 (33–96)	.307

Note. FES = functional electrical stimulation.

FIM Self-Care Subscores

The average overall FIM Self-Care subscore at baseline was 8.5 ($SD = 3.4$, range = 6–16). The intervention group had a mean score of 8.1 ($SD = 3.3$, range = 6–16), and the control group had a mean score of 8.9 ($SD = 3.5$, range = 6–16). There were no significant differences in FIM Self-Care subscore between the two groups at baseline ($p = .580$). Table 2 provides a summary of all results.

After the treatment program, the overall mean FIM Self-Care subscore increased to 24.1 ($SD = 10.1$, range = 16–38), and the difference between the groups in FIM Self-Care subscore was significant ($p = .005$). After the intervention, the mean score was 30.9 ($SD = 6.6$, range = 22–38) in the intervention group and 17.9 ($SD = 8.8$, range = 6–30) in the control group.

The difference in FIM self-care subscores had an overall mean of 15.6 ($SD = 9.5$, range = 0–32); this difference had a mean of 22.8 ($SD = 6.7$, range = 13–32) in the intervention group and 9 ($SD = 6.5$, range = 0–18) in the control group. This measure was significantly different between the two groups ($p = .001$). The notched plot of the FIM Self-Care subscore is shown in Figure 1. Figure 2 displays the individual change in FIM Self-Care subscore of each subject from baseline (before treatment). The changes in FIM Self-Care subscore were not significantly related to stroke age in each group (control group, $p = .094$; intervention group, $p = .755$). The purpose of the analysis was to provide evidence that the effects of FES therapy are independent of age. This decision was motivated by suggestions that age has an impact on the recovery of patients. A plot of FIM Self-Care subscore versus stroke age is shown in Figure 3.

FMA-UE Subscores

The average overall FMA-UE subscore at baseline was 3.9 ($SD = 4.6$, range = 0–15). The intervention (FES therapy) group had a mean score of 3.4 ($SD = 4.8$, range = 0–15), and

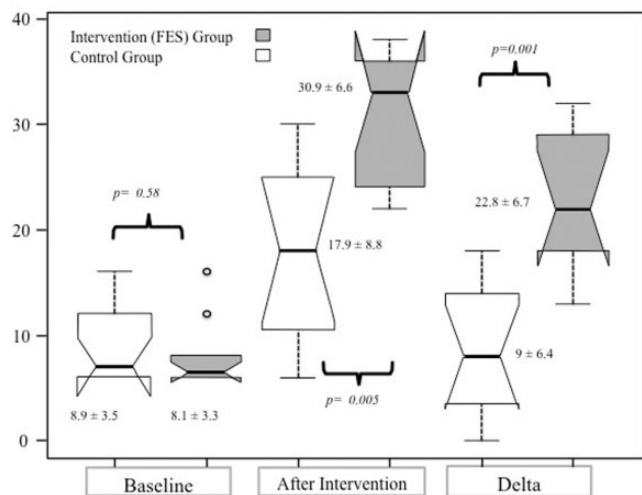


Figure 1. Functional Independence Measure Self-Care subscore. The notch plots show the median and the confidence interval around the median for each group distribution at baseline, after treatment, and for the change measured from baseline ($M \pm SD$); p values show the significant difference between the two groups at each time point. Note. FES = functional electrical stimulation.

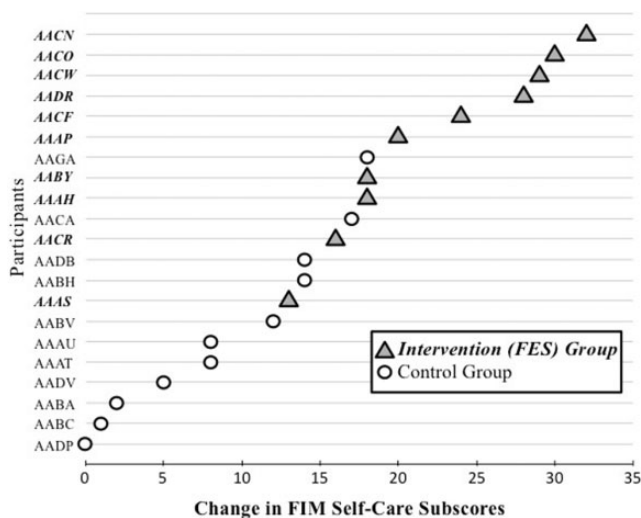


Figure 2. Individual differences between the baseline and end-of-treatment Functional Independence Measure (FIM) Self-Care subscores. Note. FES = functional electrical stimulation.

the control group had a mean score of 4.4 ($SD = 4.6$, range = 0–13). There were no significant differences in FMA-UE subscores between the two groups at baseline ($p = .574$).

After the treatment program, the overall mean FMA-UE subscore increased to 19.6 ($SD = 17.8$, range = 0–55), and the difference between the groups in FMA-UE subscores was significant ($p = .003$). After the treatment program, the mean score was 30.6 ($SD = 15.5$, range = 13–55) in the intervention group and 9.6 ($SD = 13.7$, range = 0–48) in the control group.

Difference in FMA-UE subscores calculated had an overall mean of 15.7 ($SD = 16.4$, range = 0–48); this difference had a mean of 27.2 ($SD = 13.5$, range = 9–48) in the intervention

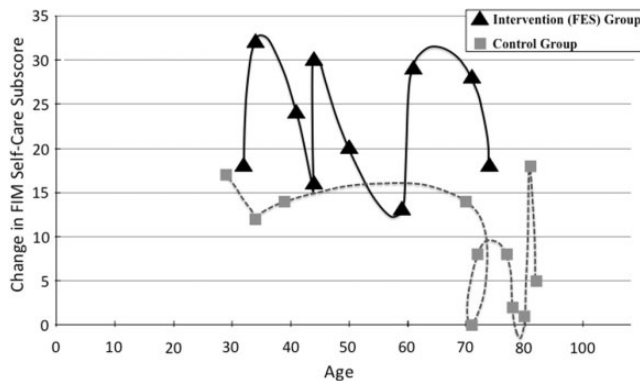


Figure 3. Changes in Functional Independence Measure (FIM) Self-Care subscores versus stroke age.

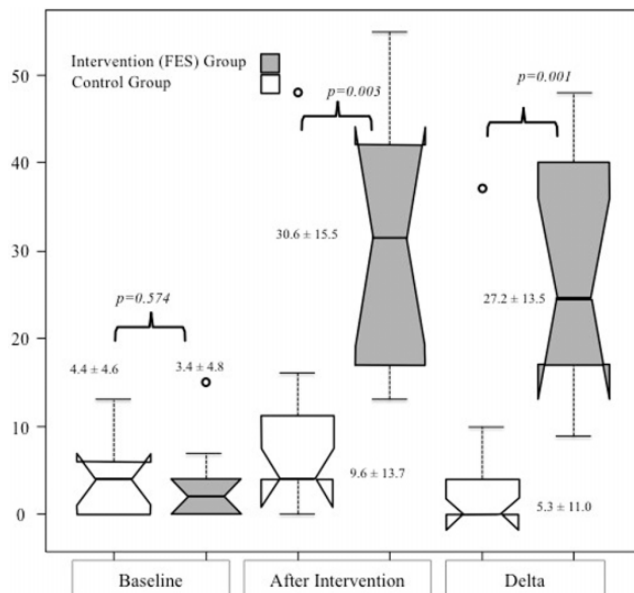


Figure 4. Fugl-Meyer Assessment–Upper Extremity subscore. The notch plots show the median and the confidence interval around the median for each group distribution at baseline, after treatment, and for the change measured from baseline ($M \pm SD$); p values show the significant difference between the two groups at each time point. Note. FES = functional electrical stimulation.

group and 5.3 ($SD = 11.0$, range = 0–37) in the control group. This measure was significantly different between the two groups ($p = .001$). The violin plot of the FMA-UE subscores is shown in Figure 4. Figure 5 displays the individual change in FMA-UE subscores of each subject from baseline (before intervention). Figure 6 shows that no significant association was detected between the change in FMA-EU subscore and stroke age in each group (control, $p = .305$; FES, $p = .324$).

Discussion

Following stroke, upper-extremity hemiparesis is one of the most commonly presented impairments and may also be the

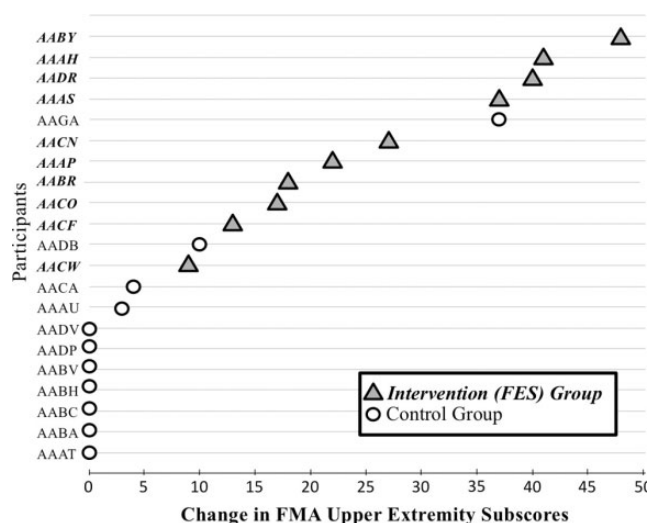


Figure 5. Individual differences between the baseline and end-of-treatment Fugl-Meyer Assessment (FMA)-Upper Extremity subscores. Note. FES = functional electrical stimulation.

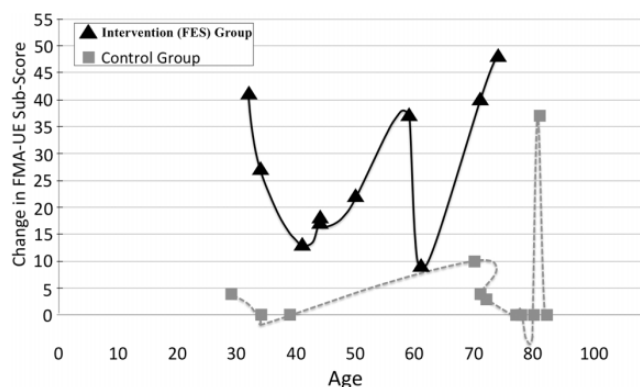


Figure 6. Changes in Fugl-Meyer Assessment-Upper Extremity (FMA-UE) subscores versus stroke age at the time of having a stroke. Note. FES = functional electrical stimulation.

most disabling, due to its impact on performance of activities of daily living. The results strongly support the FES therapy for upper limb as an effective treatment for stroke rehabilitation. Currently available upper-limb therapeutic interventions for stroke patients target individuals who have FMA-UE subscores ≥ 30 , and some newly proposed therapies target individuals with FMA-UE subscores ≥ 20 . In this study, we offered FES therapy to patients who had an FMA-UE subscores ≤ 15 and, although these patients are not typically offered upper-limb therapy due to their very low FMA-UE subscores (Dobkin, 2004), they experienced significant and clinically meaningful functional improvements.

The results of this study also suggest that participants who received our FES therapy for upper limb combined with conventional therapy improved their FMA-UE subscores substantially more than individuals who received conventional therapy only. Specifically, participants who received FES therapy experienced average improvements on FMA-UE of 27.2 points (range = 9–

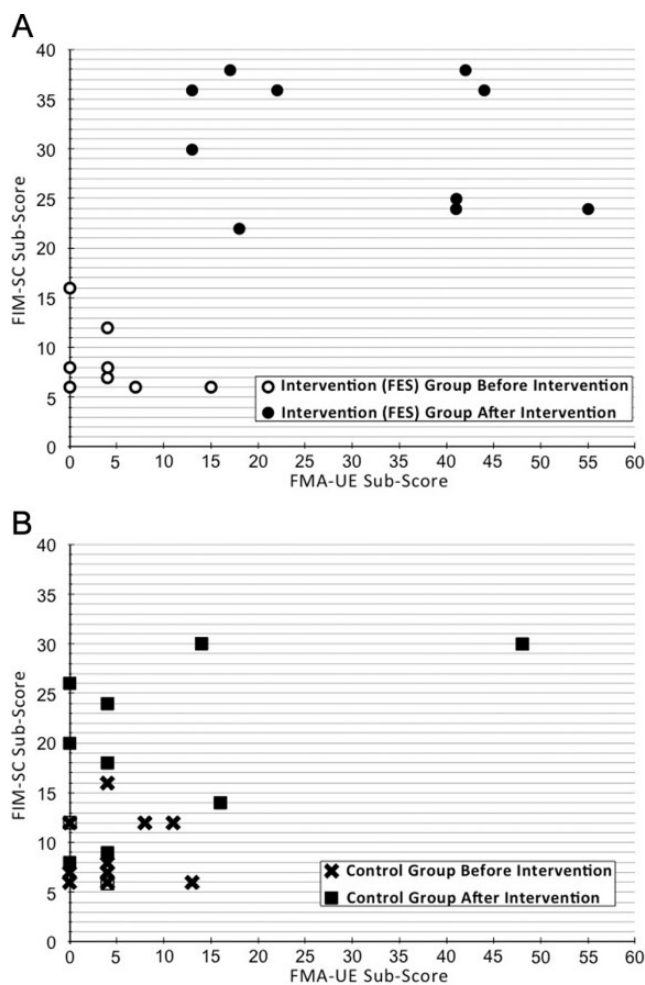


Figure 7. Fugl-Meyer Assessment-Upper Extremity (FMA-UE) subscores versus Functional Independence Measure Self-Care (FIM-SC) subscores before and after the intervention for (A) intervention (FES therapy) group and (B) control group. Note. FES = functional electrical stimulation.

48) compared to participants who received conventional therapy alone and achieved average improvements on FMA-UE of 5.3 (range = 0–37). These improvements are compelling. Furthermore, according to Arya, Verma, and Garg (2011), a minimal clinically important difference (MCID) for FMA-UE is 9 to 10 points. Knowing that MCID for FMA-UE is 10 and that competing rehabilitation interventions at best achieve FMA-UE subscores below 8 points in individuals who have FMA-UE subscores ≥ 30 , it is safe to say that our FES therapy for upper limb is probably the best available rehabilitation intervention for this patient population. Also, it is the only intervention applicable to individuals with initial FMA-UE subscores ≤ 15 .

Figure 7 shows FMA-UE subscore plotted against FIM Self-Care subscore. The images reveal that, compared to the intervention (FES therapy) group (for which significant improvements were found in both outcome measures), the control group underwent small improvements in FIM Self-Care subscores while the FMA-UE subscore remained virtually unchanged. These findings suggest that while the level of

independence increased in the control group, there was no increase in upper-limb function of the more affected arm. This, in turn, suggests that the improvement in the control group on the FIM Self-Care subscores can be attributed to the participants developing compensatory skills rather than actually improving their upper-limb function of the more affected arm.

Similarly, our results suggest that participants who received FES therapy combined with conventional therapy improved their FIM Self-Care subscores substantially compared to individuals who received conventional therapy alone. Specifically, participants who received FES therapy experienced average improvements on FIM Self-Care subscore of 22.8 points (range = 13–32) compared to participants who received conventional therapy alone and achieved average improvements on FIM Self-Care subscore of 9 (range = 0–18). These improvements are also compelling. Furthermore, according to the Rehabilitation Measures Database (Center for Rehabilitation Outcomes Research, 2010), the MCID for FIM Motor subscale (FIM Self-Care subscore is a component of this subscale) is 17 points. Lang, Edwards, Birkenmeier, and Dromerick (2008) reported that the MCID for FIM Self-Care subscore in this population ranges from 16% to 30% (i.e., 5.7 to 10.8 points). Knowing that the MCID for FIM Self-Care subscore is in the range of 5.7 to 10.8 points, the 22.8-point improvement on FIM Self-Care subscores achieved by FES therapy clearly suggests that FES therapy for upper limb needs to be considered seriously as a future best practice in upper-limb rehabilitation following stroke.

Figure 8 depicts total FIM scores, FIM Self-Care subscores, and total FIM scores after removing Self-Care subscores before and after the intervention. In addition to improvements in FIM Self-Care subscores for the intervention (FES therapy) group, the images reveal a difference in total FIM score as well. Of particular interest is that the FIM scores show no difference between the intervention (FES therapy) group and the control group after removing the Self-Care subscores, suggesting that improvement in FIM total score is attributable to changes in FIM Self-Care subscores alone, stressing the efficacy of FES therapy.

Study Implications

According to the Heart and Stroke Foundation of Canada, more than 13,000 Canadians lost their lives as a result of a stroke in 2012. Throughout the developed world, stroke is one of the main causes of death and disability (Johansen, Wielgosz, Nguyen, & Fry, 2006). In Canada, between 40,000 and 50,000 people have a stroke every year, and more than 400,000 Canadians live with stroke-related impairments. The yearly cost of heart disease and stroke to the Canadian economy is estimated to be more than \$20.9 billion in physician services, hospital costs, lost wages, and decreased productivity. In the United States, approximately 700,000 strokes occur each year, leaving 500,000 stroke survivors with a disability, and economic loss resulting from stroke approaches an estimated \$51.2 billion annually (Kwon, Hartzema, Duncan, & Min-Lai,

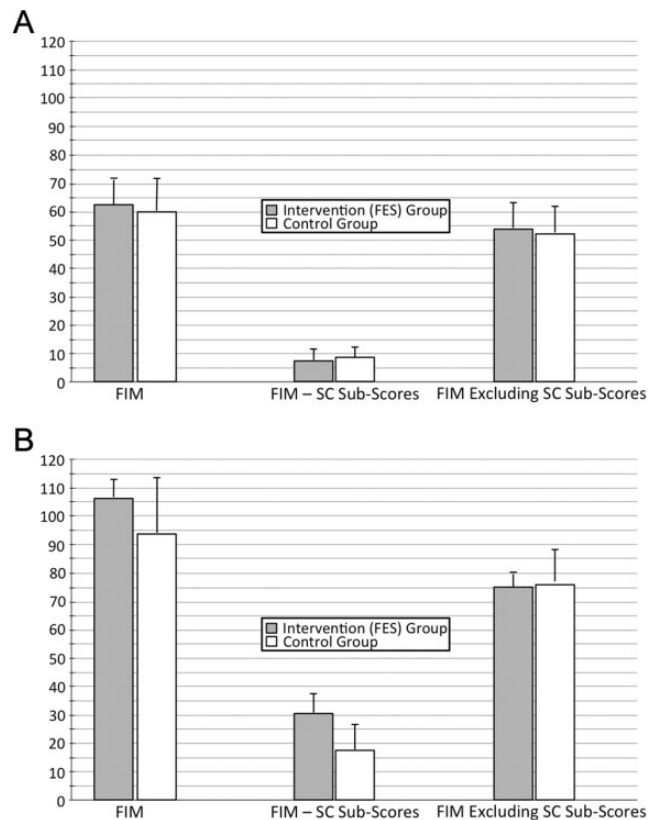


Figure 8. Functional Independence Measure (FIM) scores (A) before and (B) after the study. SC = Self-Care; FES = functional electrical stimulation.

2004). The ratio of indirect to direct costs is approximately 1.3, which indicates that indirect costs in stroke are higher than direct medical cost. Indirect costs result mostly from compromised physical functioning and caregiver involvement. The higher indirect cost of stroke makes the reduction of disability in poststroke patients a major interest of health care providers, researchers, and policy makers. Improving the independence and occupational performance of stroke survivors is the primary objective of poststroke treatment. Findings of a number of longitudinal studies indicate that 55% of stroke survivors with hemiplegia remain without arm function when measured 6 months after stroke. Literature reports only less than 10% of patients presenting with severe hemiplegia (CMSMR = 1 or 2) improve in their upper-extremity control (Page et al., 2012).

Our findings suggest that FES therapy, when added to standard physical and occupational therapy, results in a significantly greater recovery after stroke producing severe upper-limb hemiplegia. FES therapy is noninvasive, has no side effects, and can be delivered by trained occupational therapists at home or in a clinical setting, making this therapy particularly attractive for therapists and their clients. FES therapy offers the potential to shift patients from a state of dependence where they must rely on others for performing activities of daily living, such as eating, grooming, bathing, and dressing, to an increased level of independence in occupational performance. This shift in level of performance would result in cost savings associated

with reductions in long-term care, rehabilitation needs, hospital visits, and medication and assistive equipment requirements. Improved arm and hand function can translate into increased independence, a greater sense of self-worth, and greater engagement in community and professional life.

Occupational therapists have played a critical role in developing FES therapy for upper-limb function. They continue to make significant contributions to the field. For example, Soderback specifically requested that FES therapy be included in both editions of the *International Handbook of Occupational Therapy Interventions* (see Soderback, 2015, for the most recent edition) as an innovative therapeutic approach relevant to occupational therapy practice (see Craven, Hadi, & Popovic, 2015).

We hope that this article will help support occupational therapists who are already using FES therapy in their treatment of people with upper-limb impairment. The scores presented reflecting the participants' improvements are at least four times higher than the best results ever achieved with any other methodology, treatment, or device in the field. We find it essential that occupational therapists know of the intervention that their colleagues have designed, that outperforms any other existing intervention, and that helps their clients restore their upper-limb function, in particular for individuals with hemiplegia with severe upper-limb deficit. This level of improvement was unimaginable before this work was conducted.

Study Limitations and Future Research

Our study provides evidence for the efficacy of FES therapy. A multicenter randomized control trial with a larger sample size and more diverse patient population would be a great next step to determine whether our strategy and results during subacute rehabilitation are reproducible in other settings. The proposed investigational study will build on a successful Phase 2 stroke study and aims to confirm the effectiveness of FES therapy in improving voluntary arm and hand function in stroke survivors in a larger clinical trial across multiple clinical settings. The study will inform clinical best practices and guide future research efforts. If a restorative effect is confirmed, FES therapy could facilitate rehabilitation for thousands of stroke survivors and greatly reduce the burden of care for stroke survivors and their community.

Conclusion

We report on a post hoc analysis of data collected during a study to determine the efficacy of FES therapy to promote motor recovery of upper-limb function in stroke patients with severe upper-limb hemiplegia (i.e., with FMA-UE subscores ≤ 15). Our findings show that FES therapy results in a significantly greater recovery when added to standard physical and occupational therapy. Increases in FIM Self-Care subscores were 22.8 (± 6.7) points in the FES group compared to 9 (± 6.4) in the control group. Changes in FMA-UE subscores were 27.2 (± 13.5) and 5.3 (± 11.0) for the FES and control groups, respectively. These

results strongly suggest that FES therapy is an effective intervention for the restoration of reaching and grasping in patients with severe upper-limb hemiplegia.

Key Messages

- We observed an improvement of upper-extremity impairment outcomes (i.e., Fugl-Meyer Assessment–Upper Extremity score) after forty 1-hr sessions of functional electrical stimulation therapy.
- More importantly, the improvements in level of impairment were related to significant functional improvements.

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Book Review

Corcoran, Mary A. (Ed.). (2014). *Neurocognitive disorder (NCD): Interventions to support occupational performance*. Neurorehabilitation in Occupational Therapy Series, Vol. 1. Bethesda, MD: AOTA Press. 312 pp. US\$323.10. ISBN: 978-1-56900-358-9

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This text addresses occupational performance issues of individuals with mild to major neurocognitive disorders (NCDs), more commonly known as mild cognitive impairment and dementia. In keeping with the occupational therapy models of practice, the environmental and psychosocial components are included as well, with a description of several coping models and caregiver issues that should not be neglected.

The first two chapters set the foundations of neuroanatomy, etiology, symptoms, and progression of various types of NCDs. The next chapter tackles cognitive rehabilitation, including lifestyle and behavioural factors as well as theories of neuroprotection and various intervention models applied to the different populations. A brief description of cognitive versus performance-based testing is provided. Two separate chapters address the effect on occupation and occupational therapy evaluation and intervention of early to midstage as well as advanced NCDs. The role of the occupational therapist in community-based care is addressed in another chapter, and the last chapter introduces an evidence-based clinical service serving individuals with NCD and their care providers. The Skills₂Care program, which involves modifying the environment, simplifying the task, and training the caregiver to

develop skills and confidence, is used as an example of translating research to practice.

All chapters contain learning objectives, an introduction, and a conclusion as well as a detailed list of references. A glossary of medical terminology used throughout the book can be found at the end. The case example of Mrs. T, a fictitious client, is loosely weaved into the textbook and illustrates the clinical progression of mild to major NCD as well as occupational therapy evaluation and intervention approaches.

Perhaps because this edited text is the result of multiple contributors, most of whom are occupational therapists, I found this book somewhat repetitive. The notion of the rising prevalence of NCDs is repeated throughout many chapters, and the definition and neuropathological overviews of the various forms of NCDs are reiterated as well. Given that research findings are at times conflicting, I was left longing for the practical “how-to” implementation recommendations for clinical practice application.

As a whole, I feel the book could have been better presented for a more seamless flow to the reading process. That being said, this is an excellent text as a teaching tool and reference, and it should be highly relevant for occupational therapists working with this population. Personally, I will continue to refer back to this book and use the index to find the information required to assist in my professional practice. In addition, occupational therapists might be interested to know that this text is part of the Self-Paced Clinical Course from the American Occupational Therapy Association and allows for earning continuing education credits.

Louise Arpin