
Restoring Voluntary Grasping Function in Individuals with Incomplete Chronic Spinal Cord Injury: Pilot Study

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Background: Functional electrical stimulation (FES) therapy has been shown to be one of the most promising approaches for improving voluntary grasping function in individuals with subacute cervical spinal cord injury (SCI). **Objective:** To determine the effectiveness of FES therapy, as compared to conventional occupational therapy (COT), in improving voluntary hand function in individuals with chronic (≥ 24 months post injury), incomplete (American Spinal Injury Association Impairment Scale [AIS] B-D), C4 to C7 SCI. **Methods:** Eight participants were randomized to the intervention group (FES therapy; $n = 5$) or the control group (COT; $n = 3$). Both groups received 39 hours of therapy over 13 to 16 weeks. The primary outcome measure was the Toronto Rehabilitation Institute–Hand Function Test (TRI-HFT), and the secondary outcome measures were Graded Redefined Assessment of Strength Sensibility and Prehension (GRASSP), Functional Independence Measure (FIM) self-care subscore, and Spinal Cord Independence Measure (SCIM) self-care subscore. Outcome assessments were performed at baseline, after 39 sessions of therapy, and at 6 months following the baseline assessment. **Results:** After 39 sessions of therapy, the intervention group improved by 5.8 points on the TRI-HFT's Object Manipulation Task, whereas the control group changed by only 1.17 points. Similarly, after 39 sessions of therapy, the intervention group improved by 4.6 points on the FIM self-care subscore, whereas the control group did not change at all. **Conclusion:** The results of the pilot data justify a clinical trial to compare FES therapy and COT alone to improve voluntary hand function in individuals with chronic incomplete tetraplegia. **Key words:** chronic patients, functional electrical stimulation, grasping, therapy, upper limb

In the United States and Canada, there is a steady rate of incidence and an increasing rate of prevalence of individuals living with spinal cord injury (SCI). For individuals with tetraplegia, hand function is essential for achieving a high level of independence in activities of daily living.¹⁻⁵ For the majority of individuals with tetraplegia, the recovery of hand function has been rated as their highest priority.⁵

Traditionally, functional electrical stimulation (FES) has been used as a permanent neuroprosthesis to achieve this goal.⁶⁻¹⁴ More recently, researchers have worked toward development of surface FES technologies that are meant to be used as short-term therapies rather than permanent prosthesis. This therapy is frequently called FES therapy or FET. Most of the studies published to date, where FES therapy was used to help improve upper limb function, have been done in both the subacute and chronic stroke populations¹⁵⁻²³ and 2 have been done in the subacute SCI population.¹⁻³ With respect to the chronic SCI population, there are no studies to date that have looked at use of FES therapy for retraining upper limb function. In a review by Kloosterman et al,²⁴ the authors

have discussed studies that have used various combinations of therapies for improving upper extremity function in chronic SCI individuals; however, the authors found that the only study that showed significant improvements before and after was the study published by Needham-Shropshire et al.²⁵ This study examined the effectiveness of neuromuscular stimulation (NMS)–assisted arm ergometry for strengthening triceps brachii. In this study, electrical stimulation was used to facilitate arm ergometry, and it was not used in the context of retraining reaching, grasping, and/or object manipulation.

Since 2002, our team has been investigating whether FES therapy has the capacity to improve voluntary hand function in complete and incomplete subacute cervical SCI patients who are less than 180 days post injury at the time of recruitment in the study.¹⁻³ In randomized controlled trials (RCTs) conducted by our team, we

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found that FES therapy is able to restore voluntary reaching and grasping functions in individuals with subacute C4 to C7 incomplete SCI.¹⁻³ The changes observed were transformational; individuals who were unable to grasp at all were able to do so after only 40 one-hour sessions of the FES therapy, whereas the control group showed significantly less improvement. Inspired by these results, we decided to conduct a pilot RCT with chronic (≥ 24 months following injury) C4 to C7 SCI patients (American Spinal Injury Association Impairment Scale [AIS] B-D), which is presented in this article. The purpose of this pilot study was to determine whether the FES therapy is able to restore voluntary hand function in chronic tetraplegic individuals. Based on the results of our prior phase I¹ and phase II^{2,3} RCTs in the subacute SCI population, we hypothesized that individuals with chronic tetraplegia who underwent the FES therapy (intervention group) may have greater improvements in voluntary hand function, especially in their ability to grasp and manipulate objects, and perform activities of daily living when compared to individuals who receive similar volume and duration of conventional occupational therapy (COT: control group).

Methods

The study was designed to be a single center, open-label RCT. Participants recruited to the study had their injury at least 24 months prior to enrollment in the study (chronic SCI). However, upon completion of the study, we had 3 complete data sets for the control group and 5 complete data sets for the intervention group. Due to this small sample size, we present the results of the current study as a pilot clinical trial looking at benefits of FES versus COT. Toronto Rehabilitation Institute's Ethics Board approval was obtained for the study (TRI-REB-09-008). Participants were recruited through advertisements posted within Toronto Rehab Hospital–Lyndhurst Centre and through physician referrals. The study was also registered on www.clinicaltrials.gov (NCT01208688).

Individuals who consented to participate in the study were screened for eligibility, after which baseline assessments were conducted for eligible

individuals. Participants were then randomized to either the control or the intervention group. Participants randomized to the control group received 1 hour of COT and those randomized to the intervention group received 1 hour of FES therapy. All participants in both groups received therapy for both hands within the allocated 1 hour of therapy. Individuals in the control and intervention groups received 39 therapy sessions. The original plan was to deliver these 39 sessions as 3 sessions per week, each session lasting 1 hour over a 13-week time period. However, due to illness or other reasons not under the participants' control or our control, some participants required up to 16 weeks to complete all 39 sessions. Therefore, all participants received 39 sessions delivered during a 13- to 16-week time period.

Participants

Individuals were included who (a) had sustained a traumatic, motor or sensory incomplete SCI (AIS B-D) between C4 and C7, at least 24 months prior to enrollment in the study; (b) were 18 years old or older; and (c) were unable to grasp and manipulate various objects either unilaterally or bilaterally to allow independent performance of activities of daily living (ie, eating, dressing, grooming, etc).

Individuals were excluded who (a) had contraindications for FES, such as a cardiac pacemaker, skin lesions, or a rash at a potential electrode site; (b) had cardiovascular conditions such as uncontrolled hypertension or autonomic dysreflexia requiring medication; or (c) had denervated muscles (ie, individuals, who in addition to SCI, also sustained partial or complete damage of the peripheral nerves that were innervating muscles of interest).

Interventions

COT included (a) muscle facilitation exercises emphasizing the neuro-developmental treatment approach; (b) task-specific, repetitive functional training; (c) strengthening and motor control training using resistance to available arm motion to increase strength; (d) stretching exercises; (e) electrical stimulation applied primarily for

muscle strengthening (this was neither FES nor FES therapy, but electro-muscular stimulation); (f) practice of activities of daily living (ADLs), including self-care where the upper extremities were used as appropriate; and (g) caregiver training.

FES therapy used in this study was delivered with the Compex Motion stimulator.⁸ This stimulator uses surface self-adhesive stimulation electrodes. Prior to initiation of training, based on the individual participant's abilities and needs, FES stimulation protocols were designed for power grasp and precision grip. Muscles that were stimulated during therapy were *wrist flexors* – flexor carpi radialis and flexor carpi ulnaris; *wrist extensors* – extensor carpi radialis longus and brevis and extensor carpi ulnaris; *finger flexors* – flexor digitorum superficialis and flexor digitorum profundus; *finger extensors* – extensor digitorum; *thumb abductors* – median nerve or abductor pollicis brevis and abductor pollicis longus; *thumb flexors* – flexor pollicis brevis and flexor pollicis longus; and *thumb oppositors* – opponens pollicis. Each subject had customized stimulation protocols that were applied to these muscles on a per need basis. During therapy, the command for activating the stimulation sequence was issued with a push button by the treating therapist.

FES in this study was used solely for therapeutic purposes. The idea was to train individuals using FES over a period of 13 to 16 weeks; the expectation was that the participants would maintain the gains or improve further once the therapy was stopped. A detailed account of the methods used for FES application can be found in Popovic et al.² In this study, FES was used for re-training the neuromuscular system. The stimulation parameters used were balanced, biphasic, current-regulated electrical pulses; pulse amplitude from 8 to 50 mA (typical values 15–30 mA); pulse width of 250 μ s; and pulse frequency of 40 Hz. During intervention, the occupational therapist adjusted the placement of electrodes and guided the hand movements. The participants were encouraged to attempt the movement voluntarily through the time that they were being stimulated. The occupational therapist ensured that all movements were functional and

efficient and used normal movement patterns. An independent hand strengthening and stretching program was provided as needed to facilitate normal hand function.

Primary outcome measure

Toronto Rehabilitation Institute–Hand Function Test (TRI-HFT) is an evaluation tool used to assess improvement in hand function. The reliability and validity of the TRI-HFT has been established in the SCI population.²⁶ The objective of the test is to capture improvement in unilateral gross motor hand function. Hand functions tested are reach, grasp, and manipulation of various objects. There are 2 components of the test: evaluation of object manipulation for lateral or pulp pinch grasp and palmar grasp graded on a 0 to 7 scoring system,²⁶ and evaluation of strength of lateral or pulp pinch grasp and palmar grasp.

Secondary outcome measures

Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP) test combines the features of several other tests that have been used to assess hand and upper limb function in people with SCI.^{27,28} The various components of the GRASSP are strength testing, sensory testing, and qualitative and quantitative prehension testing.^{27,28}

In addition to the GRASSP, Functional Independence Measure (FIM)²⁹ and Spinal Cord Independence Measure (SCIM)³⁰ self-care subscores were used as secondary outcome measures.

Statistical analysis

The participants' impairment and demographic characteristics are shown in **Table 1**. Owing to the small sample size, especially of the control group, statistical analysis was not performed. We present raw data for each of the participants before therapy, after completion of 39 sessions of therapy, and at 6 months follow-up relative to baseline on the primary outcome measure and on all of the secondary outcome measures (**Tables 2–4**).

Table 1. Individual participant neurological data

Subject	Age, years	Cause of injury	Intervention start date years after SCI	AIS level
Control group: Received one dose of COT				
AAJU	61-90	MVA	6 ≤ start date < 8	B
AAKL	61-90	Sports	6 ≤ start date < 8	B
AAKC	15-30	Sports	2 ≤ start date < 4	B
Intervention group: Received one dose of FES				
AAKN	31-60	Fall	4 ≤ start date < 6	N/A
AAKR	31-60	MVA	8 ≤ start date	N/A
AALF	61-90	Gun shot	8 ≤ start date	N/A
AAMH	15-30	MVA	2 ≤ start date < 4	B
AAMI	15-30	Diving accident	2 ≤ start date < 4	B

Note: All participants in the study were male, and they had a neurological level at baseline in the range from C4 to C6. AIS = American Spinal Injury Association (ASIA) Impairment Scale; COT = conventional occupational therapy; FES = functional electrical stimulation; MVA = motor vehicle accident; N/A = not available.

Table 2. Summary of the mean test results for the control and intervention groups at baseline, after 39 sessions of therapy, and at the 6-month follow-up

Test	Control group (Mean scores)			Intervention group (Mean scores)		
	Before	After	6-month follow-up	Before	After	6-month follow-up
FIM self-care subscores	16.6	16.6	18	19	23.6	27.25
SCIM self-care subscore	5.6	6.3	6.3	7	9.2	10.5
TRI-HFT components						
Object Manipulation Test	31.99	33.16	32.33	40.2	46	47.25
Wooden Blocks Test	30	31.16	26	40.8	41.1	42.87
Instrumented Cylinder Test, <i>torque values (Nm)</i>	3.08	3.08	6.16	1.7	5.02	7.56
Credit Card Test, <i>force values (N)</i>	13.3	16.5	15	8.6	15.35	14.25
Eccentric Loading Test - thumb direction, <i>length values (cm)</i>	10	10	10	0.9	3.6	2.88
Eccentric Loading Test - little finger direction, <i>length values (cm)</i>	10	10	10	6	18	11.25
GRASSP components						
Strength	23.5	25	23.6	17.8	21.2	21.62
Sensibility	14.16	12.6	13	12.8	13.5	13.87
Qualitative grasp	2.83	4.66	3.33	3.2	4.3	4.12
Quantitative grasp	8	6.33	9.6	9.9	11.1	12.87

Note: FIM = Functional Independence Measure; GRASSP = Graded Redefined Assessment of Strength, Sensibility, and Prehension; SCIM = Spinal Cord Independence Measure; TRI-HFT = Toronto Rehabilitation Institute–Hand Function Test.

Table 3. Individual participant right and left hand scores pre and post therapy and at 6-month follow-up on some of the components of the Toronto Rehabilitation Institute–Hand Function Test

Subject	Object Manipulation test			Instrumented Cylinder test			Credit Card test		
	Pre	Post	6-month follow-up	Pre	Post	6 month follow-up	Pre	Post	6-month follow-up
Control group (right hand scores)									
AAJU	28	25	27	0	0	0	0	0	0
AAKL	60	60	60	3.5	3.5	20	40	45	42.5
AAKC	7	15	10	0	0	0	0	0	0
Intervention group (right hand scores)									
AAKN	22	40	31	0.3	7.5	5	7	28.5	7
AAKR	28	27	34	0	0	0	0	0	0
AALF	60	60	NA	5	5	NA	5	23	NA
AAMH	49	56	58	0	0.5	0	0	1.5	0.5
AAMI	38	60	46	2.5	8.5	17	16	31.5	25
Control group (left hand scores)									
AAJU	16	16	13	0	0	0	0	0	0
AAKL	60	60	60	15	15	17	40	50	42.5
AAKC	21	23	24	0	0	0	0	4	5
Intervention group (left hand scores)									
AAKN	30	50	45	0.7	0.7	0	20	27	39
AAKR	37	41	44	0	0	0	0	0	0
AALF	24	22	NA	0	0	NA	0	0	NA
AAMH	54	58	60	0	1	0	0.5	0	0
AAMI	60	46	60	8.5	27	38.5	37.5	42	42.5

Note: NA = not available.

Table 4. Individual participant scores pre and post therapy and at 6-month follow-up on the FIM and SCIM self-care subscores

Subject	FIM self-care subscore			SCIM self-care subscore		
	Pre	Post	6-month follow-up	Pre	Post	6-month follow-up
Control group: Received one dose of COT						
AAJU	20	19	22	6	8	8
AAKL	24	24	23	11	10	10
AAKC	6	7	9	0	1	1
Intervention group: Received one dose of FES						
AAKN	11	13	14	2	3	3
AAKR	16	15	16	4	4	4
AALF	11	15	NA	3	4	NA
AAMH	24	36	40	11	18	18
AAMI	33	39	39	15	17	17

Note: COT = conventional occupational therapy; FES = functional electrical stimulation; FIM = functional independence measure; NA = not available; SCIM = Spinal Cord Independence Measure.

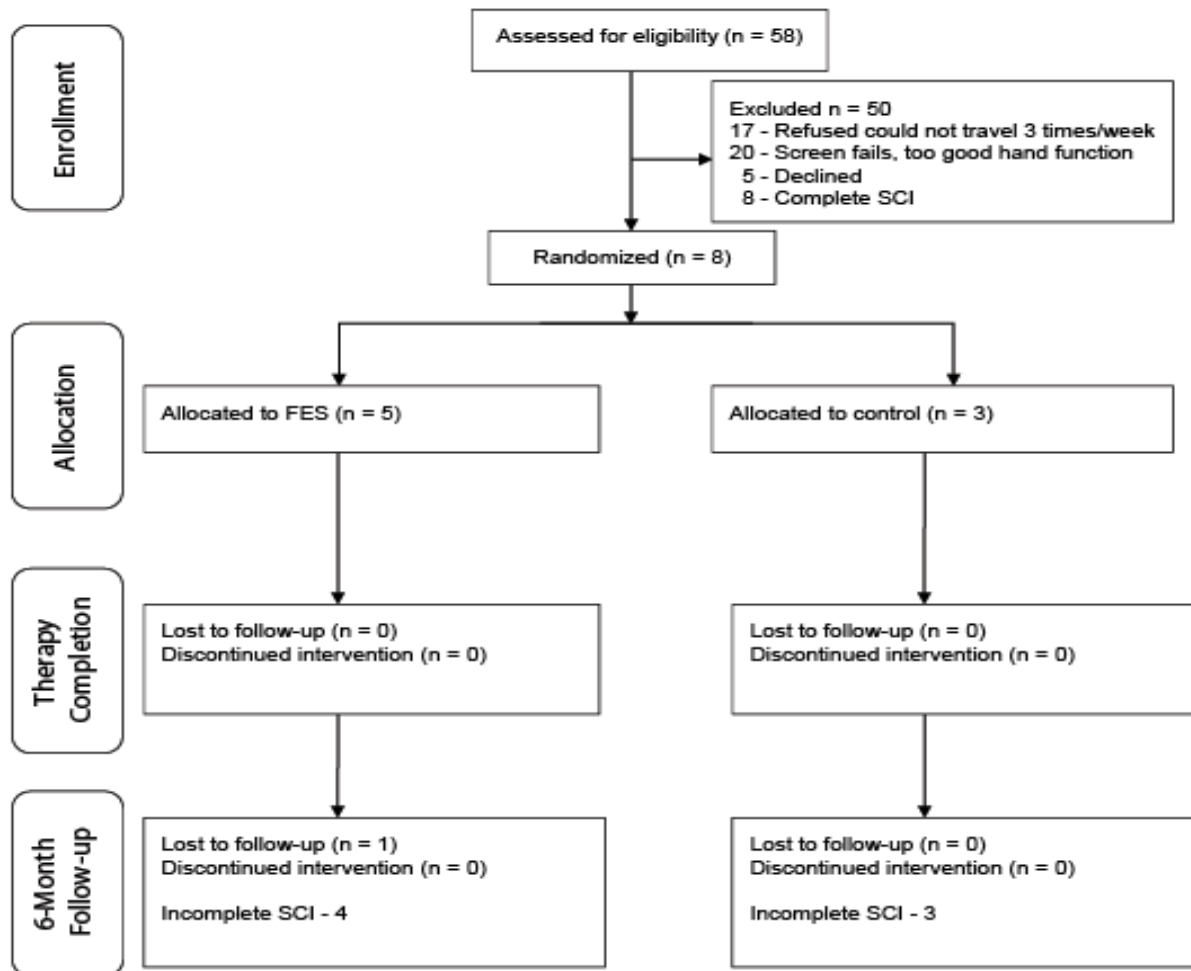


Figure 1. CONSORT diagram. FES = functional electrical stimulation.

Results

We were able to recruit 8 male, incomplete SCI individuals. All 8 individuals completed baseline and discharge assessments. However, only 7 individuals completed the 6-month follow-up assessment. Of the 8 individuals who completed the discharge assessment, 5 were allocated to the intervention group and 3 were allocated to the control group. One individual in the control group was 15 years old at the time of recruitment and was brought into the study at the investigator’s discretion. At 6-month follow-up, we lost 1 individual from the intervention group, which left 4 individuals in the intervention group and 3 in

the control group. Please refer to the CONSORT diagram for details (Figure 1).

Primary outcome measure results

TRI-HFT was the primary outcome measure. On the Object Manipulation Test, only 1 participant in the control group showed improvements in both the right and left hands, whereas 3 participants in the intervention group showed improvement in both the right and left hands. On the Wooden Blocks Test, 1 participant in each group showed improvement on both the right and left hands. On the Instrumented Cylinder Test, none of the

participants in the control group demonstrated any change, whereas 3 participants in the intervention group showed improvement in right hand scores and 2 showed improvement in left hand scores. On the Instrumented Credit Card Test for the right hand, 1 participant in the control group showed improvement whereas 4 participants in the intervention group showed improvement; for the left hand, 2 participants in both groups improved.

On the Instrumented Credit Card Test, in the control group 1 participant showed improvement in the right hand and 2 in the left hand, whereas in the intervention group 4 participants showed improvement in the right hand and 2 in the left hand. On the Eccentric Loading Test, no change was seen in the right and left hand scores for all 3 control group participants, whereas 2 of the 5 participants of the intervention group improved on the left side and 3 of the 5 improved on the right side. **Table 2** shows the mean scores of all participants on various components of the TRI-HFT test, and **Table 3** shows individual participant scores pre and post therapy and at 6-month follow-up.

Secondary outcome measures results

Similar results for the 2 groups were observed on the secondary outcome measures (ie, FIM self-care subscore, SCIM self-care subscore, and GRASSP). The control group showed no improvement on FIM self-care subscore and minimal and clinically irrelevant improvement on SCIM self-care subscore. With respect to the GRASSP test, the control group had minimal improvements on the strength and qualitative subcomponents of the test and a slight decrease on the sensibility subcomponent of the test. In case of the intervention group, we saw considerable improvements on both the FIM and SCIM self-care subscores (**Table 4**) as well as FIM and SCIM total scores pre and post therapy. Similarly, we saw improvements on all components of the GRASSP test, where most notable improvements have been recorded on the strength and quantitative subcomponents of the test. **Table 2** shows the mean scores pre therapy, post therapy, and at 6-month follow-up for the control and intervention groups.

Discussion

The results of the present pilot data collection suggest that a treatment consisting of repetitive FES therapy designed to improve hand function may promote recovery of voluntary grasping function in persons with chronic incomplete SCI. Moreover these pilot data suggest that these improvements may precipitate subsequent enhancement in the quality and complexity of tasks that individuals were able to execute with their hands. However, because of the limited number of participants, we are unable to test for statistical significance, and therefore these data may only serve to demonstrate the potential value of a clinical trial.

The mechanism of recovery in the individuals with incomplete chronic SCI is identical to the one observed in individuals with incomplete subacute SCI in our previous studies. It could be attributed to neurological recovery such as (a) an increase in muscle controllability, (b) better synchronization of different muscle groups, and (c) reactivation of previously inactive muscle groups. We have evidence from previous research that the repetitive application of FES therapy promotes neural plasticity in the spinal cord and allows neural signals from the periphery to bridge the site of injury and reach the cortex.³¹

The results of our research to date indicate that the following FES therapy practices are useful to maximize recovery: (a) applying individualized FES protocols that are monitored and adjusted by an occupational therapist on regular basis; (b) combining FES therapy with regular occupational therapy; and (c) incorporating FES therapy with functional tasks typically performed in activities of daily living. Our long-term follow-ups with chronic incomplete SCI individuals, presented in this article, and with subacute incomplete SCI individuals presented in our previous publication³ suggest that the results of the FES therapy are long lasting and persist undiminished for months following discharge.

Among SCI clinicians, it is commonly believed that motor improvement plateaus at 12 to 18 months after SCI³² and that one should not expect significant improvements thereafter. Our present pilot study begins to show some preliminary evidence against this belief, however it does not

have sufficient cases to demonstrate statistical significance and, therefore, scientific validity. This article begins to establish a foundation for future larger scale rehabilitation trials in the chronic SCI population. We believe that the presented pilot data warrant that further trials should be carried out with this patient population using our FES therapy and a larger pool of participants. The larger sample size will provide a scientifically valid test of the ability of the FES therapy to improve voluntary hand function in chronic incomplete SCI individuals.

The pilot data trends are consistent with our previous findings with subacute SCI individuals² and with the findings obtained in both subacute and chronic severe stroke individuals.^{15,16}

Limitations

At the start of the study, our hope was to recruit a sufficient number of participants so that the data could provide solid evidence regarding benefits of one type of therapy over the other. However, because of challenges with recruitment, the study ended as a pilot clinical trial with a small sample size prohibiting any statistical analysis. Therefore, the data represent only pilot data of insufficient quantity to test scientific hypotheses.

Conclusion

The pilot data presented represent a foundation for a clinical trial of repetitive FES therapy in combination with functional and task-specific training to determine whether it promotes recovery of voluntary grasping function in persons with chronic incomplete SCI and improves independence in performance of ADLs.

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