Functional Electrical Stimulation for Severe Upper Extremity Hemiparesis: A Randomized Controlled Study

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Introduction

50,000 Canadians and 795,000 Americans will experience a new or recurrent stroke each year.

Stroke remains the leading cause of long-term disability in North America and long-term disability is often associated with the persistent impairment of the upper extremity.

Despite receiving weeks of rehabilitative therapy, the majority of stroke survivors are unable to incorporate the affected upper extremity into daily activities at 6 months post-stroke.

Effective new treatment options are required to enhance a patient's independence and quality of life and to relieve the financial pressures incurred by the individual, their family, and the healthcare system.

Objective

To investigate whether treatment with a novel, non-invasive, functional electrical stimulation (FES) therapy improves recovery of voluntary arm function in severely disabled subacute stroke patients.

Methods

Design: Randomized controlled, two-arm, parallel group, single blind (assessor), single centre study

Participants: Twenty-one (21) stroke patients with severe upper extremity paralysis, i.e., individuals with Chedoke McMaster Stages of Motor Recovery scores of 1 or 2, who were at least two weeks (less than 6 months) after onset of stroke, took part in the study.

Interventions: The patients were randomized to receive either 1 hr/day of FES Therapy (Treatment group) or an equivalent dose (length and intensity) of conventional upper extremity therapy (Control group).

Assessments: Upper Extremity Fugl-Meyer (UE-FMA), Chedoke McMaster Stages of Motor Recovery (CMSMR), Barthel Index (BI), Functional Independence Measure (FIM™), and Self-Care FIM™ subscore (SC-FIM™).

FES Therapy Program

FES Therapy provides pre-programmed, coordinated muscle stimulation that coincides with the phase and type of arm motion a patient is striving to achieve.

Figure 1. The FES system offers a full range of reaching and grasping movements to facilitate shoulder, elbow, wrist and hand function.

As the patient recovers voluntary function, neuroprosthesis assistance is reduced and eventually removed.

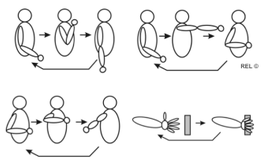
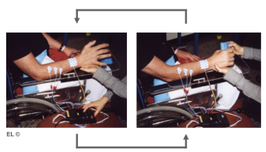


Figure 2. Shows a therapy session in which finger extension was preformed with neuroprosthetic assistance, and finger flexion was performed voluntarily. Hand function therapy sessions occur in the latter stages of the treatment program.



Results

Table 1: Summary of Baseline Patient Characteristics

Patient Characteristics	CONTROL (n= 11)	FES Therapy (n=10)
Age (years)		
mean (± SD)	64.8 (± 20.3)	51.0 (± 14.7)
range	(29 – 82)	(32 – 74)
Sex (number (%))		
male	6 (55%)	7 (70%)
female	5 (45%)	3 (30%)
Index Stroke Type (number (%))		
hemorrhagic	4 (36%)	3 (30%)
ischemic	7 (74%)	7 (70%)
Days from stroke to 1st treatment		
mean (± SD)	31.5 (± 11.6)	27.5 (± 12.0)
range	(19 – 47)	(16 - 57)

FES Therapy treatment group received an average of 40.4 (± 6.3) FES sessions. Control group received an average of 42.9 (± 8.4) sessions of conventional therapy. (1 session = 1 hour/day)

Functional Outcomes

The FES Therapy group realized statistically significant improvements in UE-FMA, CMSMR (arm & hand), BI, and self-care FIM™ over the Control group (Table 2). The FES group reported overall higher FIM™ compared to the Control group, but did not reach statistical significance.

Table 2: Functional Outcome Measures

Assessment	Control (n=11)		FES Therapy (n=10)		p-value
	Before	After	Before	After	
CMSMR (arm & hand)	3.5 (± 0.8)	4.3 (± 0.8)	3.1 (± 0.9)	5.4 (± 1.6)	< 0.02
UE-FMA	4.4 (± 4.6)	9.6 (± 13.7)	3.4 (± 4.8)	30.6 (± 15.5)	< 0.001
Barthel Index	42.7 (± 9.3)	74.5 (± 17.5)	42.5 (± 7.5)	89.5 (± 9.8)	< 0.05
FIM™	60.2 (± 11.6)	94.3 (± 19.2)	62.7 (± 9.1)	106.4 (± 6.6)	0.139
Self-Care FIM™	8.9 (± 3.5)	17.9 (± 8.8)	8.1 (± 3.3)	30.9 (± 6.6)	0.005

Five (5) of 10 patients in the FES Therapy group reported SC-FIM™ scores of 36 and 38, representing 86% and 90% of maximum SC-FIM™ = 42 (complete independence). No patient in the control group exceeded 30 points. The majority of the Control group remained ≤20 points, with 3 individuals in the Control group remaining highly dependent (≤10). (Table 3)

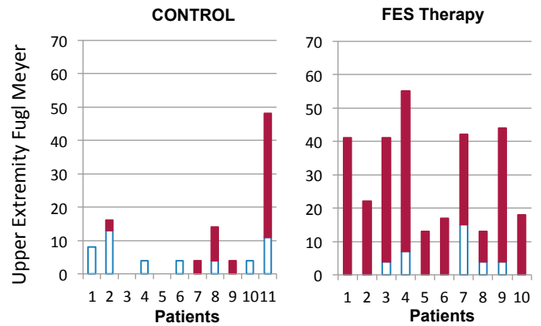
Table 3: Individuals in different SC-FIM™ ranges (min=6 indicates complete dependence; max=42 independence) before and after treatment.

Self Care-FIM™ Range	CONTROL (n=11)		FES Therapy (n=10)	
	Before	After	Before	After
≥31				5
21 - 30		4		5
11 - 20	4	4	1	
6 - 10	6	3	7	

Upper Extremity Fugl-Meyer (UE-FMA)

Every patient in the FES Therapy group realized a clinically significant gain in UE-FMA (median gain 24.5 points, range 9 – 48 points) while only 2 of 11 patients (18%) in the Control group realized gains of greater than 6 points. The median gain for the Control group was zero (0) (Figure 3).

Figure 3: Upper Extremity FMA for individual patients before (□) treatment and Gain(■) realized after treatment (Maximum UE-FMA = 66 points)



Conclusion

As compared to an equivalent dose of conventional rehabilitation therapy programs, functional electrical stimulation (FES) therapy significantly improved voluntary motor function and self-care functional independence in stroke survivors with severe upper extremity impairment.

References

[1] Thrasher et al. Neurorehabilitation and Neural Repair. 2008. 22(6): 706-714.
[2] Popovic et al. Neuromodulation. 2005. 8(1): 60-74.

*Declaration of Interest - Dr. Popovic is a founder, a shareholder and the Chief Technology Officer of MyndTec Inc, a healthcare company created to commercialize technologies described in this presentation

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