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## Introduction

In North America, Spinal Cord Injury (SCI) survivors total 345,000, with 16,500 new cases added every year

Roughly 45% of SCI survivors are tetraplegic, often unable to use their arms and hands following the injury and consider regaining/improving arm and hand function their #1 priority. Despite intensive rehabilitation following SCI, functional recovery seldom occurs in these patients.

Most rehabilitation practitioners embrace activity based neuro-rehabilitation to improve upper limb function following SCI. They also embrace a concept that the neuro-rehabilitation therapy modality is not as critical as the duration and intensity of therapy.

# **Objectives**

To test whether therapy intensity is more relevant than the actual therapy modality in improving voluntary hand function in incomplete, sub-acute C3-C7 SCI individuals.

We elected to compare:

- LOW intensity Conventional Occupational Therapy (COT) for 45 min per day (COT1)
- HIGH intensity COT of 2 hrs per day (COT2)
- LOW intensity Functional Electrical Stimulation (FES) therapy for 45 min
- HIGH intensity FES therapy for 1 hr plus COT for 1 hr per day (FES+COT)

## Methods

Retrospective analysis of data pooled from Phase I (1) and Phase II (Clinical Trials.gov ID NCT00221117 - (2)) randomized control trials. conducted between 2003 and 2011.

#### Interventions

COT routinely used strengthening and stretching exercises and practice of Activities of Daily Living (ADLs) (1,2). Registered occupational therapists designed the rehabilitation program for individual participants based on individual needs.

FES performed ADLs while being assisted with electrical stimulation (see (1,2) for details). The FES therapy protocols generated power (circular grip and lateral pinch) and precision (opposition with 2 and 3 fingers) grasps on demand and delivered while performing functional tasks.

Figure 1. Examples of ADLs performed during FES therapy. All tasks presented in the figure have been carried out with the help of FES.







Table 1: Summary of Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria		
Sustained a traumatic incomplete SCI between C3 and C7, AIS B, C, or D, <6 months prior to baseline assessment;	Had contraindications for FES, such as a cardiac pacemaker, skin lesions, or a rash at a potential electrode site;		
18 years of age or older	Suffered from cardiovascular conditions		
Unable to grasp & manipulate objects, either unilaterally or bilaterally, to allow independent activities of normal living (i.e. eating, dressing)	Also sustained partial or complete damage of the peripheral nerves innervating muscles of interest		

# Results

Table 2: Summary of Baseline Patient Characteristics

Patient Characteristics	COT1 (n= 6)	COT2 (n=12)	FES +COT (n=10)	FES (n=7)
Age (years) mean (±SD) range	53.2 (± 10.8) (34 – 63)	44.8 (± 16.3) (20 – 65)	43.7 (± 17.7) (18 – 66)	37.7 (± 19.0) (19 – 64)
Sex (number (%))				
male	6 (100%)	9 (75%)	8 (80%)	7 (100%)
female	0 (0%)	3 (25%)	2 (20%)	0 (0%)
Level of SCI (n)				
C3	3	0	1	0
C4	2	7	3	1
C5	1	4	1	2
C6	0	1	5	3
C7	0	0	0	1
Time since SCI (days)				
mean ( ± SD)	39.2 (± 23.1)	58.3 (± 22.7)	69.9 (± 38.1)	62.3 (± 43.0)
range	(15 – 76)	(22 – 102)	(33 – 134)	(15 –142)
14.190	(.5 10)	(22 102)	(55 104)	(.5 -142)

Figure 2: SCIM Self-Care Subscore comparison of Intensity and Modality for individual patients before treatment and gain realized after treatment. (Maximum SCIM Self-Care Subscore. = 20 points)

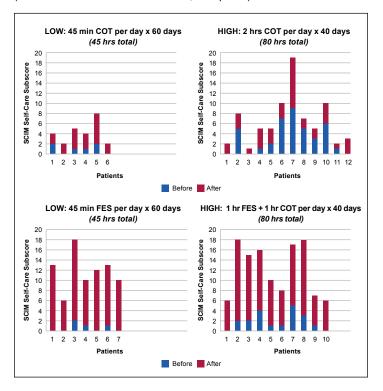


Table 3: Functional Outcome Measures

Low Intensity	Before	After	Gain	High Intensity	Before	After	Gain		
Average SCIM Self-Care Subscore									
45min COT (n=6)	1.0 (±0.9)	4.2 (±2.2)	3.2 (±1.6)	2hrs COT (n=12)	3.3 (±3.1)	6.4 (±5.0)	3.2 (±2.4)		
45min FES (n=7)	0.6 (±0.8)	11.7 (±3.7)	11.1 (±3.2)	1hr FES + 1hr COT (n=10)	1.9 (±1.7)	12.1 (±5.2)	10.2 (±3.9)		
Average FIM Self-Care Subscore									
45min COT (n=6)	7.3 (±2.1)	21.7 (±9.5)	14.3 (±7.8)	2hrs COT (n=12)	7.8 (±3.2)	17.8 (±10.8)	10.0 (±9.1)		
45min FES (n=7)	6.1 (±0.4)	30.0 (±8.4)	23.9 (±8.5)	1hr FES + 1hr COT (n=10)	8.1 (±2.4)	28.2 (±11.3)	20.1 (±10.1)		

Observations when comparing SCIM and FIM Self-Care Subscores (Figure 2 and Table 3):

- High intensity (80 hrs) COT (COT2) did not produce more favorable outcomes when compared to Low intensity (45 hrs) COT (COT1). This finding suggests that by simply increasing COT one does not necessarily generate better outcomes.
- 45 hrs of FES therapy and 40 hrs of FES + 40 hrs of COT therapy produced better outcomes than both Low intensity COT and High intensity COT. This suggests treatment modality selection is very important, and that the FES treatment modality, with or without COT. produces better outcomes than COT alone.
- 45 hrs of FES therapy compared to 40 hrs of COT + 40 hrs of FES therapy had essentially similar outcomes. This finding suggests that including or excluding pure COT, one does not affect the overall outcome of the FES therapy.
- · All patients in the FES therapy program improved their individual SCIM self-care subscores by at least 6 points. This is of great relevance to this patient population, considering the minimal clinically important gain one can demonstrate on the entire SCIM is 4 points (this includes self-care subscores).

### Conclusions

- · Increased rehabilitation intensity alone may not always be beneficial.
- · Intervention type plays a significant role in determining functional
- Regardless of intensity doses. COT alone resulted in similar outcomes. as did FES therapy with or without COT.
- Both High and Low Intensity FES groups yielded much better outcomes compared to High and Low Intensity COT interventions alone.
- · Observations warrant further larger studies to examine the impact of FES therapy in improving voluntary hand function in this SCI patient population.

## References

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- [ 3 ] Popovic et al. Spinal Cord. 2006;44(3):143-151
- [4] Data on File.

\*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