

## Safety and Efficacy of Functional Electrical Stimulation in subjects with Acute Spinal Cord Injury

H Rischbieth<sup>1</sup>, J Clark<sup>1</sup>, S Donohoe<sup>1</sup>, M Jelbart<sup>1</sup>, P Atherton<sup>1</sup>, J Strayer<sup>1,2</sup>, R Marshall<sup>1,2</sup>, FES Clinic<sup>1</sup>, and Spinal Injuries Unit<sup>2</sup>, Hampstead Rehabilitation Centre, South Australia.

### **ABSTRACT**

***Aim:** To assess the safety and efficacy of functional electrical stimulation (FES) applied to the lower limbs commencing within a month of sustaining a spinal cord injury (SCI).*

***Method:** Eighteen subjects aged between 18 and 70 years were recruited from prospective acute admissions to the Spinal Injuries Unit of the Royal Adelaide Hospital. Eligibility was determined by a doctor, a physiotherapist and a psychologist. Subjects with unstable medical condition, fractures or insufficient range of movement of lower limbs, or inability to give informed consent were excluded. Ethics approval was obtained from the Human Ethics Committee of the Royal Adelaide Hospital. Stimulation was progressed to 15 minutes to quadriceps femoris and tibialis anterior muscles of each limb twice daily.*

***Results:** Electrically stimulated contractions were attained in all subjects, even those in spinal shock. Subjects exhibited significant wasting of quadriceps muscles prior to entry, and muscle hypertrophy was soon evident. Electrically stimulated contractions rapidly regained endurance, and reached target level within 10 days.*

***Conclusion:** FES can be safely and effectively applied to patients with a spinal cord injury from as early as three weeks post injury. The endurance times achieved may make other electrically stimulated exercise programs feasible.*

Mystique and magical powers were attributed to functional electrical stimulation (FES) as a result of inappropriate applications during the 1800's, and it fell into disrepute. Since its return to regular use research has tended to err on the conservative, and be limited to subjects who are medically stable.

Extensive FES research after chronic SCI and other neurological diseases has identified numerous benefits, providing physical, functional and physiological effects. However prejudice continues to some extent, and research during the acute or active phase of these diseases is scant.

### **FES after Spinal Cord Injury**

Therapeutic FES is commonly used during rehabilitation to facilitate return of voluntary muscle function in patients with some spared neurological function. Treatment usually starts after the period of spinal shock, and is applied to muscles according to clinical indications. Clinical applications include facilitating return of hand function, strengthening shoulders, and improving gait.

Spinal shock persists for up to two months after a spinal cord injury. The safety and efficacy of FES during the early period were unclear. Would neuromuscular responses be elicited, and if so, what, if any adverse effects could that cause?

The FES Clinic, at Hampstead Rehabilitation Centre, in Adelaide, South Australia is undertaking a clinical trial of twice daily FES during acute SCI rehabilitation. The study was planned on the assumption that stimulated muscles would respond to FES during

spinal shock, despite absence of the H reflex.

As the subjects were in a hospital environment adverse reactions would be recognised and appropriately managed.

A preliminary study (reported IMSOP 1999) identified three weeks post injury as the optimal recruitment period. It was therefore necessary to approach subjects in the very early period post injury, when emotional state and ability to make decisions are recognised as a potential constraint to recruitment. A psychologist assessed subjects' ability to give informed consent prior to inclusion in the study.

This paper discusses the use of FES in early SCI as part of a larger study investigating changes in body composition following SCI.

**METHOD**

Eighteen subjects with mean age 29.1 ± 7.9 years were recruited from acute admissions to the Spinal Injuries Unit during the first two weeks post injury.

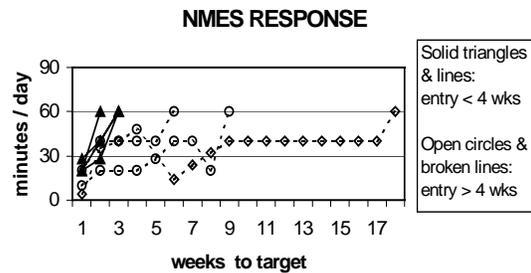
After gaining consent and screening, stimulation was applied alternately to quadriceps femoris (QF), and tibialis anterior (TA) muscles on each leg. Stimulation time was progressed from 5 to 15 minutes as endurance improved. A roll was placed under the knee to allowed isotonic QF contractions as strength increased. TA contractions were isotonic from the outset.

**RESULTS**

At study entry 95% of subjects had no spared muscle function (ASIA A & B), and 86% had no sensory function below their neurological level (ASIA A).

Despite spinal shock, effective QF responses were obtained in all subjects. Two subjects displayed poor responses at TA, suggesting neurapraxia, which improved in one subject.

Previously we showed muscle response is related to time since injury. Acute subjects beginning stimulation less than 3 weeks since injury achieve target stimulation time within two weeks. In contrast, subjects starting stimulation more than four weeks after injury take five to seventeen weeks to reach target stimulation time.



**Figure 1** – weeks to reach target stimulation time

Potential Subjects	Subjects Recruited	Mean Age	Abnormal response
	18	29	2

**Table 1** – Study demographics.

Five subjects were withdrawn from the study. The investigators withdrew a subject for non-compliance and another for medical reasons. Three requested withdrawal due to inability to commit to the stimulation schedule.

**OBSERVATIONS / FINDINGS**

Early use of FES is well tolerated by individuals with acute SCI. Typically, when applied during spinal shock responses will be similar to those seen in subjects recruited months to years after SCI.

Muscle catabolism/atrophy, a feature of early SCI, was evident in all subjects at two weeks.

Subjects, including those with spared sensation, reported relaxation during electrical stimulation. However spared sensation also limited tolerance and thus stimulation intensity.

We observed no adverse physiological reactions, such as triggering of autonomic dysreflexia, injury to muscle or skin, or respiratory challenge in medically stable subjects.

However adverse reactions may occur with concomitant medical complications such as infection (pneumonia, UTI, etc.). The usual medical precautions to aerobic exercise were observed throughout the study.

### DISCUSSION

Target stimulation time – The study aim was 30 minutes of stimulation applied twice daily. This was designed to integrate into the busy rehabilitation schedule.

Previous studies showed 30 minutes of lower limb FES applied twice daily maintained strength and endurance in persons with chronic SCI. Exercise physiology texts suggest 30 minutes is the ideal and safe low intensity training time, supporting choice of that time.

### Conclusion

FES can be safely applied from as early as two weeks after acute traumatic or medical spinal cord insult. Spinal shock does not prevent electrically stimulated muscle contractions. Thus stimulation responses will be the same as those seen months to years after SCI. Fatigue resistance is relatively retained during the first three to four weeks after injury, and lost more rapidly after that time.

Including two half-hour stimulation sessions into the busy rehabilitation schedule proved difficult at times, and tended to become more of a problem after discharge for those with paraplegia.

Use of technology in other populations identified better acceptance and longer-term use following earlier introduction. Our experience supports this, with 56% of subjects continuing to use stimulation after returning home.