## Original Article

# Gait training regimen for incomplete spinal cord injury using functional electrical stimulation

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**Study design:**   Case series, and repeated assessments of the same individuals.
**Objective:**   To demonstrate the feasibility and efficacy of a multiweek intervention on walking function in people with chronic, incomplete spinal cord injuries.
**Setting:**   Rehabilitation hospital for spinal cord injury (SCI) in Toronto, Canada.
**Methods:**   A convenience sample of five subjects with chronic, incomplete SCI trained for 12–18 weeks using a new multichannel neuroprosthesis for walking. The following outcome measures were recorded throughout the training period: walking speed, step frequency and average stride length based on a 2-min walk test. Also identified were which walking aids and orthoses subjects preferred to use, and whether they employed a step-to or step-through gait strategy. Follow-up measurements of three subjects were made up to 10 weeks after treatment.
**Results:**   All subjects demonstrated significant improvements in walking function over the training period. Four of the subjects achieved significantly increased walking speeds, which were due to increases in both stride length and step frequency. The fifth subject experienced a significant reduction in preferred assistive devices. Follow-up measurements revealed that two subjects walked slightly slower several weeks after treatment, but they still walked significantly faster than at the start of treatment.
**Conclusion:**   The gait training regimen was effective for improving voluntary walking function in a population for whom significant functional changes are not expected. This application of functional electrical therapy is viable for rehabilitation of gait in incomplete SCI.
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## Introduction

Functional electrical stimulation (FES), is a technology that can restore useful movements by activating paralyzed or paretic muscles. FES devices have been put into use for many different applications over the last four and a half decades, including standing, walking and grasping.[1] Applications of FES can be divided into two classes: (1) neuroprostheses for use as permanent assistive devices, and (2) FES to facilitate exercise and be used in temporary therapeutic interventions to improve voluntary function. This latter class of applications has been termed functional electrical therapy (FET).[2] The past focus has been mainly on the development of permanent neuroprostheses; however, there is growing attention given to FET for restoring

voluntary function as well as treating secondary complications of SCI.[3]

Numerous reports over the past 25 years have asserted positive therapeutic effects of FES-assisted walking in incomplete spinal cord injury (SCI).[4,5] There is growing evidence that regular use of FES by people with neurological disabilities can result in recovery of voluntary muscle control and improved function after the stimulator is taken away.[6,7] A carryover effect in terms of overground walking speed has been demonstrated in a large population of incomplete SCI patients using a variety of neuroprostheses for walking.[8]

Most surface FES systems for walking stimulate the flexor withdrawal reflex to induce simultaneous hip flexion, knee flexion and dorsiflexion. A major disadvantage of this approach is that the flexor withdraw reflex is highly variable and subject to rapid habituation.

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There is growing evidence that under certain conditions the damaged central nervous system is able to adapt and form new neural pathways for voluntary function. In humans, there is evidence that the injured spinal cord continues to reveal a great deal of plasticity even several years after SCI.[9] External electrical stimulation has been shown to affect neural plasticity.[10] Furthermore, a hypothetical mechanism has been proposed in which motor neurons within the spinal cord can modify synaptic organization to restore conduction after an incomplete lesion.[11] When electrical stimulation of motor axons coincides with voluntary muscle effort, restorative modifications in the central nervous system may be induced. Therefore, we hypothesized that direct muscle stimulation would have greater rehabilitative potential than the stimulation of reflexes. It is vital, however, that the user coordinates voluntary effort with the electrical stimulus. In this study, we developed and implemented an FES-walking system that puts these ideas into practice.

## Methods

### Subjects

Five adults with incomplete SCI participated. Subjects were recruited by referral from clinical staff at our institution. Table 1 summarizes the personal data of each participant at the time when baseline measurements were recorded. All participants were capable of walking independently using walking aids and without supervision. Two of the subjects walked with a step-to gait pattern, which was defined as gait in which the point of heel-contact of one foot always occurs behind the toe of the other foot, while the point of heel-contact of the other foot always passes the foot in question. All other cases were defined as 'step-through'. None of the subjects had any previous experience using FES. During the study, one subject (Subject B) had been receiving regular physiotherapy before the treatment, and she continued receiving physiotherapy throughout our study.

### Neuroprosthesis

Stimulation was applied using Compex Motion stimulators (Compex SA, Switzerland).[12] Biphasic asymmetrical pulses were delivered to the body via eight self-adhesive gel electrodes to target the following four muscle groups bilaterally: quadriceps, hamstrings, gastrocnemius/soleus and tibialis anterior. A constant stimulation frequency of 35 Hz was used. Pulse width was modulated between 0 and 300 $\mu$s during the stimulation sequence. Pulse amplitudes varied between 18 and 110 mA depending on subject and muscle. For each muscle an investigator applied manual resistance to the appropriate joint and gradually increased the pulse amplitude until the subject expressed discomfort or the investigator could perceive no further increase in muscle force or muscle contour. The pulse amplitude was set at 75% of the value resulting from this test.

An FES program designed to stimulate the gait cycle through open-loop control was defined and scaled to each subject. The stimulation sequence was delivered as follows. During the mid stance and late stance phases, the quadriceps and gastrocnemius/soleus were stimulated continuously, while the hamstrings and tibialis anterior received no stimulus. When the subject was about to initiate swing phase (approximately 300 ms
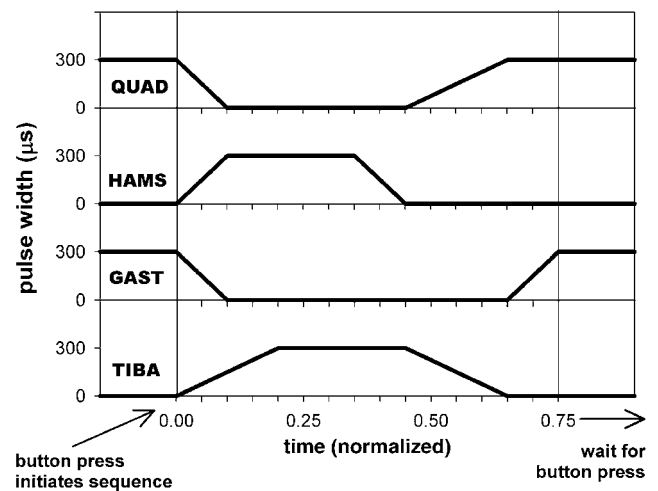


**Figure 1** Stimulation program for a single leg. The stimulation begins from initial state representing late stance phase, and pushbutton triggers open-loop sequence beginning with swing phase

**Table 1** Subject data at beginning of study

| Subject | Age | Sex | SCI level | ASIA score | Years postinjury | Cause of injury[a] | Assistive devices | Stepping pattern |
|---------|-----|-----|-----------|------------|------------------|-------------------|-------------------|------------------|
| A | 36 | M | T6 | n/a | 7 | VHLS | Two canes | Step-through |
| B | 24 | F | T12 | D | 5 | Fall | Two canes, one KAFO | Step-through |
| C | 46 | M | C5 | C | 7 | Fall | Two-wheel walker | Step-to |
| D | 72 | F | T4 | D | 2 | MVA | Four-wheel walker | Step-through |
| E | 67 | F | T6 | C | 24 | MVA | Two-wheel walker | Step-to |

[a]VHLS = Von-Hippel Lindau syndrome; MVA = motor vehicle accident
n/a = not applicable

before toe-off), he or she would press the button, which would trigger the preset sequence shown in Figure 1. This sequence was scaled with respect to time according to the average gait cycle duration recorded during a 2-min overground-walking test performed at the beginning of each session. At the end of the sequence (75% of the gait cycle), the stimulator would return to the initial state of extension and await the next button press. According to this scheme, toe-off was expected to occur around 0.2 (normalized time) after the button press, and heel contact was expected to occur around 0.5–0.6. Each user had to learn to press the button at an appropriate time for the stimulation to coincide with the motion of the legs.

This sequence was based loosely on muscle timing patterns recorded in electromyographic (EMG) studies of normal gait[13,14] and modified according to the recruitment behaviour of FES. A gradual ramp-up was used to prevent the stimulation of peroneal nerve afferents resulting in reflex spasms, and a gradual ramp-down was used to minimize foot-slap.

### Treatment program

Based on an initial gait evaluation, it was determined whether the subject had a dominant leg, which was defined as one of the following: (1) the leading leg in a step-to gait pattern, (2) the leg not using a brace if the other is, or (3) a leg that scores 4 or greater on knee flexion/extension, ankle dorsiflexion and plantar flexion in the Manual Muscle Test. If so, the neuroprosthesis was only applied to the weak leg. If both legs appeared similar in strength and function, the neuroprosthesis was used on both legs. Four subjects had a dominant leg, therefore only the nondominant leg was stimulated. Table 2 indicates which legs were stimulated, how frequently treatment sessions occurred and where walking was performed.

Each subject used the neuroprosthesis under laboratory supervision two to five times per week for a period of 12–18 weeks. During the first four to eight sessions, subjects underwent a muscle strengthening protocol consisting of stimulation applied to the extensors (quadriceps and gastrocnemius/soleus) and flexors (hamstrings and tibialis anterior) alternately in 20-s duty cycles (10 s extensors on and flexors off followed by 10 s extensors off and flexors on) while the subject was seated and manual resistance was applied to the joints.

**Table 2** Treatment regimens for individual subjects

| Subject | Leg stimulated | Sessions per week | Walking location | Duration of treatment (weeks) |
|---------|----------------|-------------------|------------------|-------------------------------|
| A | Right | 2 | Hallway | 16 |
| B | Left | 3 | Hallway | 12 |
| C | Left | 5 | Hallway | 16 |
| D | Both | 2 | Treadmill | 18 |
| E | Left | 2 | Treadmill | 18 |

These exercises were performed in four sets of 5 min with 5-min rests between. When all muscle contractions elicited by FES were capable of creating joint movement against gravity (ie strength of grade 3 or more), the muscle strengthening protocol was terminated and walking exercises began.

Walking exercises were performed either on a treadmill in the laboratory or overground in the hospital hallway. During treadmill walking, subjects held onto parallel bars. During overground walking, subjects used their preferred walking aids, such as canes or walker. Pushbuttons for the neuroprosthesis were mounted on each of the parallel bars or both handgrips of the walking aid. Each subject walked using the neuroprosthesis for a total of 15–30 min per session, taking seated breaks when desired. When the treadmill was used, the belt speed was set to 120% of the walking speed measured by the previous 2-min test. During overground walking exercises, subjects selected their own walking speed.

### Outcome measures and statistical analysis

At baseline and at the beginning of every session (before FES was applied), each subject was administered a 2-min walking test,[13] and the distance and number of steps were recorded. From this, self-selected overground walking speed, average stride length and average step frequency were calculated. It was also noted by a trained observer which gait pattern, walking aids and orthoses subjects used.

The walking speed, step frequency and stride length measurements from the first five sessions (including the baseline) were compared to the measurements from the last five treatment sessions using a Wilcoxon rank sum test with a significance level of $P < 0.05$. These tests were performed within subjects only. Three of the five subjects continued returning for follow-up testing up to 10 weeks after treatment was terminated. The last five follow-up measurements were tested for changes against
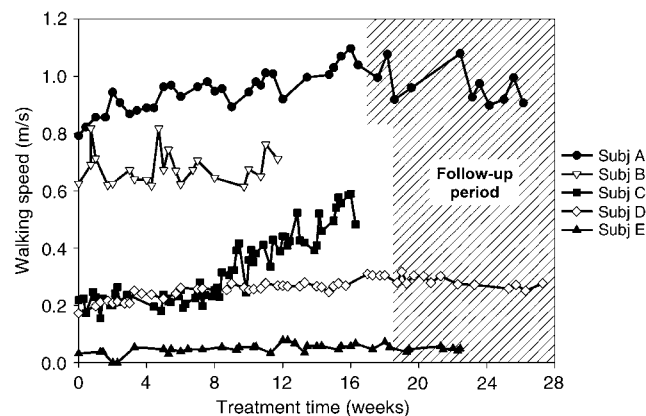
**Figure 2** Walking speed measurements for all subjects over the course of treatment. Shaded region indicates follow-up period after treatment had stopped

the end of treatment measurements using the same test as above.

## Results

Figure 2 shows the change in walking speed over the course of treatment and during follow-up for all subjects. All subjects except for Subject B demonstrated a steady increase in overground walking speed throughout the treatment period. Subject C's sudden increase at the ninth week was due to a sudden shift from a step-to to a step-through gait pattern. At the beginning of the study, Subject B walked with two canes and one knee-ankle-foot orthosis (KAFO) on her left leg with knee locked. During the seventh week of treatment, this subject changed her preference to walking without the brace.

All statistical comparisons are shown in Figure 3. Four of the five subjects demonstrated significant increases in walking speed over the course of treatment. Of the three subjects who participated in follow-up measurements, two had experienced a reduced walking speed that was still significantly higher than walking speed at the start of treatment. Significant increases also occurred in step frequency and stride length over the course of treatment for the four subjects whose walking speed increased. Subject A's step frequency returned to baseline in the follow-up measurements. Only one subject experienced a significant loss in stride length after treatment stopped; however, it was still greater than baseline.
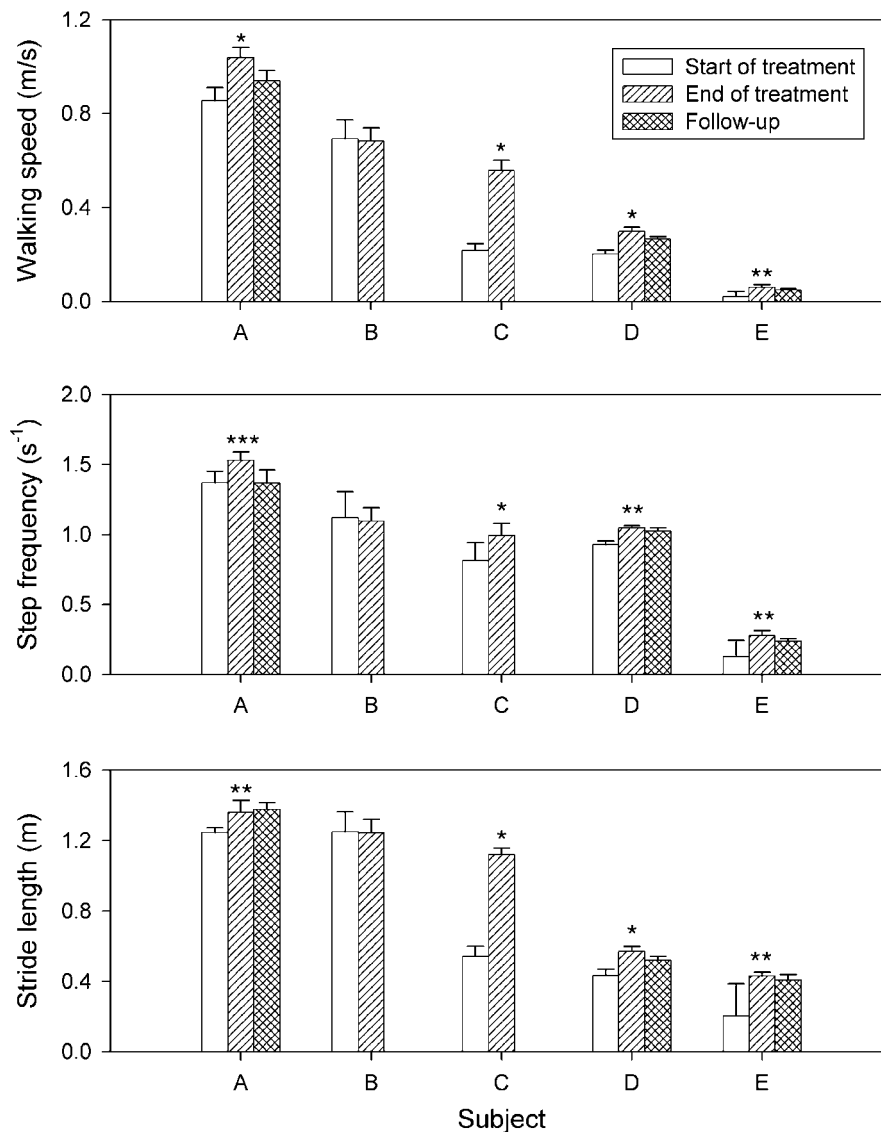


**Figure 3** Gait parameter measurements at start of treatment, end of treatment and follow-up for all subjects. A single asterisk '*' indicates that walking speed differed significantly between all measurement phases. A double asterisk '**' indicates that only the measurements at the start of treatment differed from the other two. A triple asterisk '***' indicates that only the measurements at the end of treatment differed from the other two

## Discussion

The purpose of this study was to implement a simple, practical neuroprosthesis that could be easily applied in a clinical setting. Our system was based upon the hypothesis that restoration of neural conduction can be provoked by combining direct FES with voluntary effort.[11] Our neuroprosthesis differed significantly from the conventional FES-assisted walking devices of the last 25 years, which rely on peroneal nerve stimulation to elicit flexor withdrawal reflex. This reflex is subject to rapid habituation, and the rehabilitative effect of repeatedly stimulating a reflex arc is unclear.

The results of this study reflect very positively on the application of FET-walking as an intervention for individuals with chronic incomplete SCI. All five subjects demonstrated significant improvements in walking function, most in terms of walking speed, and one in terms of preferred assistive devices. Considering that all subjects were at least 2 years postinjury, and therefore neurologically stable, significant improvements in walking function were not expected. It is likely that this technology could be equally, if not more beneficial, in the acute SCI population. The follow-up measurements indicated that for some subjects there is some partial attenuation of walking speed several weeks after treatment was terminated. It should be noted that four of the five participants had thoracic injuries, which is unusual since a majority of eligible subjects have cervical injuries. This may indicate a bias in our recruitment process, which was based on referrals by clinical staff members who were not instructed in the details of the study.

When using the neuroprosthesis, the relative timing of the button press, toe-off and heel-contact depended greatly on the subject's voluntary activity. The stimulation sequence was designed to increase muscle activity at the right time during the gait cycle and through repetitive exercise, promote better walking function. It also facilitated walking at a slightly faster speed than the subjects' self-selected walking speed. A previous study has shown that FES facilitates faster walking than walking with no FES.[15]

FES is scarcely a new technology. Neuroprostheses for gait have been used in rehabilitation for decades, and the benefits to SCI have been widely published. Nevertheless, the technology is largely absent from clinical practice. This is perhaps because clinicians may find existing systems clumsy, unnecessarily time-consuming, and/or practically unavailable. Considering the potential benefits of neuroprostheses in SCI rehabilitation, it is very important that accessible, effective systems be developed. Further study is warranted to compare the rehabilitative effects of FES to conventional physiotherapy.

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