Research Article

Exercise Intensity during Treadmill Walking with Gait-Patterned FES among Patients with Incomplete Spinal Cord Injury: Case Series

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Purpose. To determine the feasibility of increasing the cardiopulmonary exercise intensity during walking with gait-patterned functional electrical stimulation (GP-FES) among individuals with motor incomplete SCI. *Methods*. Two men with motor-incomplete SCI (Subjects A and B, age 45 and 50 years; Level of Injury: C4 and T10; AIS score: D and D, resp.) performed a three sequential four-minute continuous walking sessions [(1) regular gait (non-GP-FES-1); (2) gait with GP-FES (GP-FES); (3) regular gait (non-GP-FES-2)]. Oxygen consumption (V_{O_2}) was measured continuously during trials. *Results*. V_{O_2} was higher during GP-FES (Subjects A and B; 14.5 and 19.1 mL/kg/min, resp.) as compared to regular gait (Non-GP-FES-1: Subjects A and B; 13.4 and 17.0: mL/kg/min, resp.; non-GP-FES-2: Subjects A and B; 13.1 and 17.5: mL/kg/min, resp.). *Conclusion*. The exercise intensity of GP-FES walking was higher than that of regular walking among individuals with motor incomplete SCI. Further investigations are required to determine the clinical relevance of the exercise.

1. Introduction

Coronary artery disease (CAD) is the most significant complication and leading cause of mortality after spinal cord injury (SCI) [1–3]. It is most likely that the high CAD risk observed in people with SCI is related to their extreme physical inactivity [4]. Therefore, increasing physical activity may reduce CAD risk factors among people with SCI [5, 6]. Although, in order to maximize the physiological benefits of cardiopulmonary training, exercise at an appropriate intensity is essential [7–9], the motor and autonomic impairments related to SCI often limit exercise intensity.

Several exercise interventions using functional electrical stimulation (FES), such as FES arm or leg cycle ergometry training and FES walking, have been applied to enhance physical capacity and reduce CAD risk among persons with SCI [10–12]. FES is a technology that can restore useful movements by electrically stimulating and thereby artificially contracting paralyzed or paretic muscles [13]. Applications of FES can be divided into three classes: (1) neuroprostheses for use as a permanent assistive device; (2) facilitation of exercise; (3) short term as a therapeutic intervention to improve voluntary function [14, 15]. This latter application has been termed "FES therapy" (FET) [14].

Numerous reports over the past 30 years have asserted positive therapeutic effects of FES-assisted walking, including enhanced walking ability, among individuals with incomplete SCI [16–18]. However, there is growing evidence that regular use of FES by people with neurological impairments
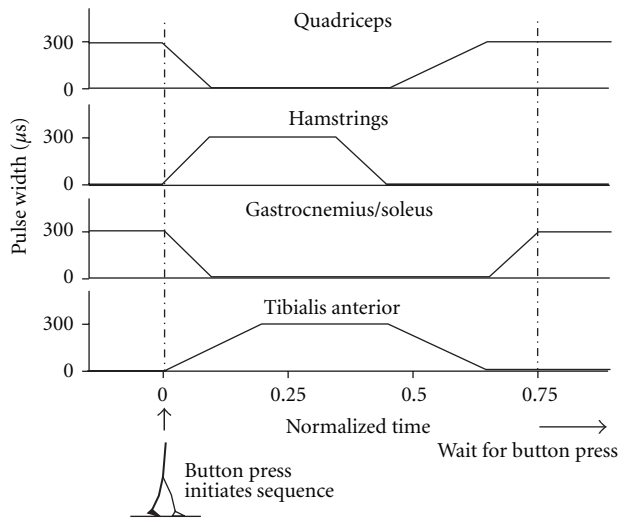
FIGURE 1: Stimulation program for a single leg. The stimulation begins from initial state representing late stance phase, and push-button triggers open-loop sequence beginning with swing phase.

can result in recovery of voluntary muscle control and improved functional abilities after cessation of FET [19, 20]. Many of the FES-assisted walking devices, especially those used for therapeutic interventions, induce the flexor withdrawal reflex to produce simultaneous hip flexion, knee flexion, and ankle dorsiflexion, to generate the swing phase of gait. This approach has been criticized because of the variability and rapid habituation of the flexor withdrawal reflex, and its propensity to produce nonphysiological gait patterns [18]. Thrasher et al. established a new FES system for walking termed "gait-patterned FES" (GP-FES) [18]. The stimulation patterns in GP-FES were determined based on the electromyography (EMG) recordings obtained during natural walking of able-bodied individuals (Figure 1), instead of the traditional method of inducing the flexor withdrawal reflex. They reported that following 12–16 weeks of 3 times a week GP-FES therapy, after the system is removed, the five chronic incomplete SCI individuals who took part in the study showed improved walking speeds with increases in both stride length and step frequency compared to baseline [18]. They concluded that GP-FES therapy has a potential to produce clinically relevant improvements in the gait of individuals with chronic incomplete SCI.

GP-FES stimulates both leg flexor and extensor muscles in a physiological pattern for a longer portion of the gait cycle. Therefore, it is likely that gait training with GP-FES is capable of assisting individuals with SCI to increase their oxygen consumption, by increasing their leg muscle activation, as shown in prior studies describing oxygen consumption during walking with FES (but not GP-FES) [21]. The purpose of this case series was to determine the feasibility of increasing the cardiopulmonary exercise intensity during walking with GP-FES among individuals with chronic incomplete SCI.

2. Methods

2.1. Subjects. Two adults with incomplete SCI were recruited by referral from clinical or support staff affiliated with Toronto Rehabilitation Institute, Toronto, Canada. We anticipated some acclimation effects of GP-FES on measured V_{O_2}, thus eligible subjects for this study were people who had completed four months of the GP-FES therapy using the protocol described by Thrasher et al. [18]. Both subjects were capable of walking independently with gait aids and without supervision at baseline. Subjects able to walk independently for 12 minutes without requiring a break or manual assistance on the treadmill were eligible. Note that we had only two subjects because these conditions were rarely sufficed. The Toronto Rehabilitation Institute Research Ethics Board approved the study protocol.

2.2. Experimental Protocol. Subjects participated in the experiment during two visits, with a one week gap between the visits. During the first visit, the subjects self-selected: (a) comfortable walking speed on the treadmill during GP-FES and (b) comfortable walking speed on the treadmill during regular gait (non-GP-FES). These velocities were measured and recorded for later use. Each subject wore a harness, without weight support, for safety purposes, and was permitted to hold the treadmill side rails during walking to maintain balance if needed. During the second visit, we measured oxygen consumption (V_{O_2}), while the subjects were walking with self-selected speeds measured during the first visit discussed above. During the data collection, subjects were asked to perform four tasks including: (a) 2 minutes of standing on the treadmill (REST); followed by (b) three consecutive 4 minute trials of (1) non-GP-FES-1; (2) GP-FES; (3) non-GP-FES-2 on the treadmill (Figure 2). The timeframe for data collection of 4 minutes was chosen based on the desire to limit the timeframe as much as feasible, to eliminate subject's fatigue as a confounder in the measurements and because the previously published data showed that V_{O_2} plateaus at about 2 min after the beginning of the exercise [22]. This testing protocol uses the ABA experimental design principles. The ABA experimental design is typically used to determine the effects of a treatment (in this particular case GP-FES) and the effect of removing treatment (in this particular case non-GP-FES) on the dependent variable (in this particular case of V_{O_2}). Thus, if there is an effect of treatment, and the effect disappears after removing the treatment, this implies an effect of treatment on the dependent variable. The other reason for implementing the ABA study design within a day was the anticipated day-to-day variations in patient performance with changes in temperature, spasticity, balance, and so forth. The ABA experimental design is generally powerful when day-to-day variability is large. A previous study demonstrated that there is larger day-to-day variability in the SCI subject's ability to ambulate, due to the effects of fatigue, balance, and spasticity on performance than same-day variability [23]. Therefore, the ABA design has been selected as the most appropriate under given circumstances.
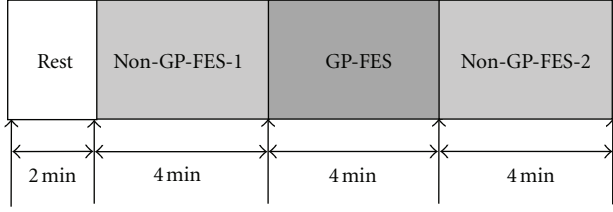
Figure 2: Experimental protocol. Rest: rest with standing position; non-GP-FES-1: first walking without GP-FES; GP-FES: walking with GP-FES; non-GP-FES-2: second walking without GP-FES.

Table 1: Demographic and impairment characteristics of subjects.

Subject	Subject A	Subject B
Age (years)	45	50
Sex	M	M
Height (cm)	175	170.2
Weight (kg)	77	83.1
Neurologic level	C4	T10
AIS	D	D
Year of postinjury	3	34

2.3. Gait-Patterned FES (GP-FES). GP-FES has been previously described in Thrasher et al. [18]. Two portable four-channel stimulators Compex Motion (Compex SA, Switzerland) were used to deliver the GP-FES bilaterally. Trigger buttons to initiate stimulation were connected to each stimulator. A separate set of stimulator and trigger buttons was used for each leg. Biphasic asymmetrical pulses (frequency 35 Hz and pulse duration 0–300 μs) were delivered to the lower extremity muscles using self-adhesive surface electrodes at four anatomic sites including the (1) quadriceps, (2) hamstrings, (3) gastrocnemius/soleus, and (4) tibialis anterior [16]. 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 perceived no further increase in muscle force or change in muscle contour with further changes in pulse amplitude. Since Thrasher et al. [18] previously reported that the optimal pulse amplitude to elicit enough leg joint movements and muscle contractions to generate walking was 75% of this afore-mentioned value, pulse amplitude was set at 75% of this afore-mentioned value for each muscle group. In the GP-FES protocol, trained research staff using the two push buttons manually triggered the feed-forward FES gait pattern. Stimulation was initiated in the late stance phase of gait to initiate swing followed by stance (Figure 1). This sequence was scaled with respect to time according to the average gait cycle duration recorded during the visit one, that is, treadmill walking test completed by each subject. 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 activation of the push button.

2.4. Cardiorespiratory Measurement. During all four conditions, (REST, non-GP-FES-1, GP-FES, and non-GP-FES-2) V_{O_2} (mL/kg/min) was recorded using a telemetric breath-by-breath respiration measurement system K4b2 (Cosmed Inc, Italy). Pulmonary ventilation (VE) and heart rate (HR) were also recorded. Data were continuously acquired and analyzed in real time. After the data collections, each cardiorespiratory parameter was averaged during the last 1 minute of resting stage (Subjects A and B; 12 and 21 data points, resp.) and during the last 2 minutes of each walking stage (Subjects A and B; 37–40 and 64–76 data points, resp.).

To determine the exercise intensity associated with each task, metabolic equivalents (METs) were calculated as an index of exercise intensity for all four conditions. METs values are the fraction of the V_{O_2} during motor tasks relative to the resting V_{O_2}:

$$\text{METs} = \frac{V_{O_2}\ \text{During gait (mL/kg/min)}}{\text{Resting}\ V_{O_2}\text{(mL/kg/min)}}, \quad (1)$$

where one MET is equivalent to the resting metabolic rate of 2.7 mml/kg/min [24].

3. Results

Table 1 summarizes the subjects' demographic and impairment characteristics. Both subjects were able to perform the four tasks without difficulty, exhaustion or stumbling. Table 2 shows the mean (SD) gait speed, V_{O_2}, VE, HR, and MET values for each subject during each phase of visit two. The comfortable walking speeds of subjects were the same during GP-FES and non-GP-FES. In both subjects, V_{O_2} increased during GP-FES compared to both non-GP-FES-1 and non-GP-FES-2. However, VE and HR tended to increase through non-GP-FES-1, GP-FES and non-GP-FES-2. METs values were 5.0 and 6.3 METs during non-GP-FES-1, 4.9 and 6.5 METS during non-GP-FES-2, and 5.4 and 7.1 METs during GP-FES in subject A and subject B, respectively.

4. Discussion

The study findings indicate that the exercise intensity during GP-FES tends to be larger than that of walking without GP-FES. The observed change during GP-FES in V_{O_2} is probably accounted for by the recruitment of additional muscle fibres through GP-FES, which the subjects cannot voluntarily activate themselves due to their spinal cord impairment.

The following is the likely explanation for the observed findings. We assume that the increment of V_{O_2} was mainly due to GP-FES because GP-FES facilitates additional leg muscle fibre recruitment above and beyond the muscle fibres activation that normally occurred during voluntarily executed locomotion. As a result, we were able to observe increase in oxygen utilization during GP-FES as compared to two non-GP-FES conditions. However, V_{O_2} is usually determined not only by examining the oxygen utilization in active muscles, but also by observing the VE [25]. In our experiments, the VE tended to increase throughout the sessions. Therefore, we were not able to assert that the increase in V_{O_2} during GP-FES could be solely attributed

TABLE 2: Walking speed, oxygen consumption (V_{O_2}), Pulmonary ventilation (VE), heart rate (HR), and METs values during non-GP-FES and GP-FES walking, where rest is rest with standing position; non-GP-FES-1 is first walking without GP-FES; GP-FES is walking with GP-FES; non-GP-FES-2 is second walking without GP-FES. Each cardiorespiratory parameter was averaged during the last 1 minute of resting stage and during the last 2 minutes of each walking stage.

Subject	Rest	Non-GP-FES-1	GP-FES	Non-Gp-FES-2
Walking speed (m/min)				
Subject A	—	35	35	35
Subject B	—	18.3	18.3	18.3
V_{O_2} (mL/min/kg)				
Subject A	3.6	13.4	14.5	13.1
Subject B	4.9	17.0	19.1	17.5
VE (mL/min/kg)				
Subject A	11.8	26.7	32.8	32.2
Subject B	11.9	31.2	37.0	38.1
HR (beat/min)				
Subject A	69.3	94.8	98.9	100.7
Subject B	82.0	113.7	128.0	141.0
METs				
Subject A	1.3	5.0	5.4	4.9
Subject B	1.8	6.3	7.1	6.5

to the changes due to the additional, FES-induced, muscle activation. However, if the increment of V_{O_2} was only due to increased VE, VE, and V_{O_2} should show similar trends. But in this study, VE kept increasing through all sessions, while V_{O_2} only increased during GP-FES, as compared to non-GP-FES-1 and non-GP-FES-2 conditions. This implies that the increase in V_{O_2} can be attributed not only to the VE, but also to the increased oxygen utilization in the exercising muscles. Another potential factor affecting V_{O_2} during GP-FES is arm usage as the patients kept their body balance using treadmill frames [26]. However, we believe that the increase in V_{O_2} during GP-FES was mainly due to the FES since the patients had relatively high functions and did not require much support from the treadmill frame. Further, in a previous study, it was shown that the application of FES to the lower limbs reduced the muscle activity in the upper arms instead of increasing them [27], which partially supports our assumption.

There are two previous studies, which determined oxygen consumption during walking with FES in people with incomplete SCI, while they did not use GP-FES. Stein et al. (1993) investigated energy consumption during walking with FES (1–4 channels with either surface, percutaneous or implanted electrodes) [28]. On average, the speed of locomotion was higher during walking with FES as compared to walking without FES, while the oxygen consumption was reduced somewhat. Sykes et al. investigated energy consumption and energy cost during walking, using the reciprocating gait orthosis (RGO) with FES (surface stimulation of quadriceps and hamstrings) [21]. In their study, walking speed and energy cost remained unchanged in one subject, whereas another subject increased his walking speed by 14.0%, increased his energy consumption by 8.4%, and his energy cost remained unchanged. Three subjects increased their walking speeds (by 12.4, 12.7, and 6.8%),

energy consumption (by 25.9, 20.4, and 18.4% resp.) and energy cost (by 11.6, 6.8, and 10.5%, resp.). On average, the energy consumption was increased by 15.3% during RGO walking with FES as compared to RGO walking without FES assistance. There results were contradictory in the sense that the additional FES increases the oxygen consumption or not, while the walking conditions, that is, with orthosis or not, and stimulated muscles were different. Our experiment was also in a different condition, that is, waling on a treadmill and with GP-FES. Therefore, we cannot compare our result and their results directly. However, we can conclude that the GP-FES walking has a potential to increase the oxygen consumption during walking and that this increase in oxygen consumption can be contributed to the increase in oxygen requirement of the stimulated muscles during FES-assisted walking.

Although the absolute increase in the exercise intensity from 1st non-GP-FES to GP-FES was small (0.4 and 0.8 METs), the relative increments were considerable (8.5, 12.7%, resp.). This suggests that the current result was not in the range of measurement error. The absolute METs values during GP-FES were 5.4 and 7.1 METs (Table 2). Based on most international physical activity guidelines for able-bodied people and currently published physical activity guideline for people with SCI, a moderate to vigorous intensity exercise, which is 3.0–6.0 METs, to maintain or improve health, including CAD risk are recommended [7–9]. In this sense, the obtained METs during GP-FES implied that the exercise intensity of GP-FES met the recommended exercise intensity. However, as the METs values without GP-FES were already within this recommended value range due to the patients' fitness levels, the clinical relevance of these increments to GP-FES remains unclear. Further investigation is needed to determine the clinical relevance of this increment to exercise intensity through intervention

studies using the GP-FES. Also more investigation is required for the change of HR, since HR kept increasing through all sessions, although we anticipated HR to show same characters as Vo_2.

In conclusion, we demonstrated the feasibility of increasing the exercise intensity during walking through use of GP-FES walking among individuals with chronic incomplete SCI. Further investigations are required to determine the clinical relevance of increases in Vo_2 through a GP-FES training intervention study aiming at preventing CAD or reducing CAD-related morbidity among individuals with SCI. With the current results, we propose future longitudinal studies with a larger sample of patients' with diverse walking ability.

Acknowledgments

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