The Effect of Functional Electrically Stimulated Ambulation Training on Locomotor Function and Quality of Life in Individuals with Incomplete Spinal Cord Injury

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Abstract:

The purpose of this study was to investigate the effects of a 12-week FES-ambulation program on locomotor function and quality of life after incomplete spinal cord injury. Six individuals with incomplete SCI participated in the study. Over-ground walking endurance (6MWT), speed (10MWT), independence (WISCI II) and body-weight support were assessed. Quality of life was assessed via the SF-36, WHOQOL-BREF, Perceived Stress Scale, Center of Epidemiological Studies for Depression scale, and task self-efficacy. Participants experienced significant improvements in walking endurance (223.6±141.5m to 297.3±164.5m; p=0.03), body-weight support (55.3±12.6% to 14.7±23.2%; p= 0.005) and four of the six participants showed improvements on the WISCI II scale (1-4 points). In addition, there was a significant reduction in reported bodily pain (6.5±1.2 to 5.0±1.7; p=0.04). Therefore, FES-ambulation is an effective means for enhancing over-ground locomotor function in individuals with incomplete SCI. It may also be an effective method for reducing pain in individuals with SCI.

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List of Abbreviations:

AD – Autonomic dysreflexia

ADL – Activities of daily living

AIS – ASIA impairment score

ASIA – American spinal injury association

BP – Blood pressure

BWSTT – Body-weight supported treadmill training

CES-D – Center for Epidemiological Studies-Depression

CSA – Cross Sectional Area

FES – Functional electrical stimulation

HR – Heart rate

OH – Orthostatic hypotension

PSS – Perceived Stress Scale

QOL – Quality of life

SCI – Spinal cord injury

SWB – Subjective well being

WISCI II – Walking index for spinal cord injury II

ASIA SCALE:

ASIA A – Complete injury

ASIA B – Incomplete injury with sensory but no motor function below level of injury, including at the S4-S5 dermatome/myotome.

ASIA C – Incomplete injury with spared sensory and motor function below level of injury, including at the S4-S5 dermatome/myotome, but half of the key muscles below the lesion cannot be voluntarily moved against resistance of gravity.

ASIA D – Incomplete injury with spared motor and sensory function below the level of injury, including at the S4-S5 dermatomes/myotomes, and more than half of the key muscles can be voluntarily moved against resistance greater than that of gravity.

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Chapter 1 – Review of Literature

1.0 Introduction:

SPINAL CORD INJURY (SCI) is a neuromuscular condition that leads to many adverse physiological and psychological effects. To most, SCI is characterized by the lack of walking ability, however, it affects almost every physiological system in the body. The cardiovascular and musculoskeletal systems for example, are two systems in the body that are significantly affected by a SCI. Dysfunctions within these systems give rise to further secondary complications, such as metabolic diseases, which illustrates the wide range of health complications that accompany SCI. The negative effects of SCI are not only limited to physiological aspects, but psychological well-being as well, such as stress, depression and anxiety. Thus, SCI often results in a wide range of deficits that may have a negative impact on an individual's physical function and psychological well-being.

Fortunately, research has shown that certain forms of exercise rehabilitation may partially reverse some of the physiological and psychological consequences of SCI. Briefly, body-weight supported treadmill training (BWSTT) has been shown to improve walking ability, increase muscle mass and improve perceived quality of life (QOL) in individuals with SCI (Adams et al., 2006; Dobkin et al., 2007; Hicks et al., 2005). However, since this form of therapy is somewhat passive (i.e., therapists are required to move the participants' legs) and the muscles are not maximally engaged, it may not be an ideal means to promote activity-dependent improvements with regards to locomotor function (Huang and Ferris, 2004). Likewise, functional electrically stimulated (FES) cycling has been shown to increase muscle mass, improve cardiovascular function and improve muscle endurance in individuals with SCI (Gregory and Dudley, 2007; Faghri et al., 1992; Mohr et al, 1997). However, FES cycling is not a gait specific motion, and therefore, might not be an ideal means to enhance ambulation either. Recently, FES-ambulation exercise has been developed, as it may combine the benefits of BWSTT and FES exercise. This form of exercise is in its infancy and the potential benefits it may confer are yet to be determined.

This literature review will discuss the secondary health complications associated with SCI, especially the ones that pertain to ambulation, psychological well-being, cardiovascular fitness, and muscle morphology. It will then discuss the benefits and shortcomings of BWSTT and FES cycling as a means to reverse these complications. Finally, it will introduce FES-ambulation exercise and describe the potential benefits of this recently developed form of rehabilitation.

1.1 Classifications of SCI:

Understanding classifications of SCI is important, especially in a clinical setting, in order to determine an individual's expected function and the potential improvements he or she may gain from any given form of therapy. There are three general ways of classifying SCI: the level of injury, the severity of injury and whether the injury inflicted damage to upper or lower motor neurons. With respect to level of injury, an injury that inflicts damage to the cervical spine results in tetraplegia, which is associated with impairment or loss of motor/sensory function to the upper limbs, trunk and pelvic organs. In contrast, an injury that inflicts damage to the thoracic, lumbar or sacral spine results in paraplegia. In these cases, arm function is spared, but depending on the level of injury, the trunk, legs and pelvic organs may all be involved.

The severity of an injury refers to its completeness (Manyard et al., 1997). A SCI can be identified as complete or incomplete. In a complete injury, there is no sensory/motor function at some level below the neurological level of injury, including the S4-S5 dermatome/myotome, which corresponds to the anus. In an incomplete injury, there is spared motor and/or sensory function below the neurological level of injury, including at the S4-S5 dermatome/myotome. Damage to the upper motor neuron refers to damage to the spinal cord itself, and damage to the lower motor neurons is damage to the peripheral nerves, or the anterior horn, which is the location of the spinal cord where peripheral nerves exit from (Maynard et al., 1997)

Regarding the severity of injury, it is also important to determine the individual's ASIA impairment score [(AIS); where ASIA stands for American Spinal Injury Association]. An AIS A denotes a complete injury (i.e. no sensory or motor function below the neurological level of injury, including the S4-S5 dermatome/myotome). ASIA impairment score B indicates sensory but no motor function below the neurological level if injury, including the S4-S5 dermatome/myotome. Thus, AIS A and AIS B are considered motor-complete injuries. AIS C indicates spared motor and sensory function below the level of injury, including at the S4-S5 dermatome/myotome but half of the key muscles below the lesion cannot be voluntarily moved against resistance of gravity. AIS D indicates spared motor and sensory function below the level of injury, including at the S4-S5 dermatomes/myotomes, and more than half of the key muscles can be voluntarily moved against resistance greater than that of gravity (Maynard et al., 1997).

1.2 Epidemiology of SCI:

The incidence rate of SCI in Canada is estimated to be 4259 new cases per year. Of this, an estimated 42% (1785 cases) are the result of a traumatic SCI and 58% are from non-traumatic causes. The prevalence rate is estimated to be 85,556 persons living with a SCI in Canada. Of this total, 51% (43,974 cases) are the result of traumatic causes and 49% are from non-traumatic causes (Cassidy et al., 2010). Most injuries are acquired during young adulthood, between ages of 18 and 20, while the risk of acquiring an injury declines as age increases (Pirouzmand, 2010). Most injuries occur as a result of a motor vehicle accident, which account for approximately 66% of all injuries, followed by falls and industrial accidents. In Canada, the incidence of levels of injury is as follows: cervical 29%, thoracic 21% and lumbosacral 50% (Pirouzmand, 2010).

1.3 Ambulation after SCI:

The inability to walk or perform a proper gait pattern is the most visible characteristic of SCI. The loss of motor function and strength in the lower extremities contribute to functional limitations within one's personal and community life. It has been reported that gait speed of individuals with incomplete SCI is significantly lower than 1.2m/s, which is the required speed to cross a street within the time allowed by a traffic signal (Kim et al., 2004). In addition, reductions in walking speed and endurance may prevent an individual from effectively performing activities of daily living (ADL), manage in crowded areas and have independence at home (Kim et al., 2004). It has been reported that individuals with SCI consider regaining the ability to walk to be one of the top 7 priorities for improving QOL (Anderson, 2004). This highlights the importance of regaining walking ability, to allow an individual to integrate back into his or her community, to obtain a sense of independence, and to improve QOL and the psychological well-being.

1.3.1 Spontaneous Recovery:

There is a high possibility for individuals to regain some walking ability within the first two months of a traumatic SCI (Dobkin et al., 2007). This likelihood depends on the degree of spontaneous recovery that takes place shortly after an injury. After a SCI, spontaneous recovery occurs within the first couple of months, where an individual's AIS can increase by one or two grades. Previous studies have shown that approximately 25% of individuals who are graded AIS A at the onset of injury improved to AIS B. Only 20% of individuals with AIS

B do not improve, and 80% advance to either AIS C or AIS D (Gerrits et al., 2001). The greatest amount of improvement happens in individuals with AIS C at the onset of injury, where 75% will improve to AIS D within the first couple of weeks of their injury (Gerrits et al., 2001).

1.3.2 Walking Ability:

The degree of motor function an individual has before starting ambulation therapy is a good predictor of the amount of walking gains an individual might experience. Studies have shown that individuals with good lower extremity control and strength prior to walking therapy are more likely to recover the ability to walk than those with less lower extremity strength and control (Cohen et al., 1983). Therefore, individuals with AIS D injuries, who have the most amount of spared motor function, are expected to show the greatest amount of walking improvements. This is followed by individuals with AIS C grade injuries, who can also regain some walking ability due to their somewhat preserved motor function. Individuals with AIS A or B injuries at 8 weeks post-injury, however, are not likely to regain walking ability (Dobkin et al., 2007). Therefore, therapeutic walking interventions may be more beneficial to help regain walking ability for individuals with an AIS D injury compared to those with more severe injuries.

1.3.3 How is ambulation measured?

Locomotor measurements are usually divided into two categories: performance based measures and functionally based measures. Performance based measures usually consist of time to fatigue, distance to fatigue and walking speed on an assisted walking apparatus, such as the BWST (Hicks et al., 2005; Field-Fote, 2001; Dobkin et al., 2007). Typically, baseline values for locomotor performance are quite low for individuals with SCI, however, significant improvements have been shown to take place, even in individuals with an AIS B injury who cannot perform over ground walking, following ambulation therapy (Hicks et al., 2005; Field-

Fote, 2001). In addition, increases in walking speed and walking distance are highly correlated with one another (r=.98) and are indicators of increased muscle strength and endurance (Eng et al., 2002).

For individuals who are able to ambulate over ground, functionally based measures are used, in addition to the previously mentioned performance measures. Functionally based measures are usually captured with over ground walking tests that attempt to evaluate changes in an ambulatory capacity. For example, the Walking Index for Spinal Cord Injury 2 (WISCI II) (Ditunno & Dittuno, 2001), the 10 meter walking test (10MWT) and the 6 minute walking test (6MWT) are over ground walking tests that measure walking independence, gait speed and gait endurance, respectively.

1.4 Psychological-well being after SCI:

Quality of life is defined as the subjective and objective evaluations of the "goodness" of one's life overall as well as all the various domains that make up one's life (Lox et al., 2003). Six particularly important dimensions of QOL include: psychological health, physical health, level of independence, social relationships and the environment in which one lives (Lox et al., 2003). Spinal cord injury can certainly impact any one, or all, of these dimensions, especially physical and psychological health. Furthermore, it is of great importance to have a good understanding of the effects SCI has on QOL today, since individuals with SCI are living longer than ever before due to the improved medical care (Dijkers, 1997). A meta-analysis of 22 studies with an average size of 102 participants has shown that on average, individuals with SCI tend to report lower subjective well-being (SWB) and QOL than able-bodied individuals (Dijkers, 1997). This is mainly due to loss of independence, diminished physical function, and reduced physical activity, which makes activities of daily living much more difficult to perform (Hicks & Martin Ginis, 2008).

1.4.1 Pain & stress:

Chronic pain has been reported to affect approximately 94% of individuals with SCI, where 30-40% report severe, disabling pain (Rintala et al, 1998). To illustrate the impact pain has on individuals with SCI, in a survey of 200 individuals with SCI, 44% of the respondents indicated that pain interfered with daily activities, and 37% of individuals with higher level injuries and 23% with lower level injuries reported that they would trade pain relief for loss of bladder, bowel or sexual function (Nepomuceno et al., 1979). Unlike walking, where there is a possibility for spontaneous recovery, pain often gets worse with time post-injury. Pain is highly associated with anger, anxiety and depression, and further, it is associated with interferences in daily activities and lowers QOL (Rintala et al., 1998). Loubser and Donovan (1996) stated that chronic pain imposes an additional handicap for a given degree of disability, which therefore, augments the negative impact the disability already has on QOL. Furthermore, pain may prevent an individual from participating in a regular exercise program, which has been shown to improve perceived QOL (Ditor et al., 2003; Martin Ginis & Latimer, 2007). Ditor and colleagues (2003) reported a significant negative correlation between pain at the conclusion of an exercise program and adherence levels at a 3-month follow up period (r = -.91). Therefore, pain may have a negative impact on QOL, but it may also prevent an individual from participating in activities that can improve it.

The existence of pain has been found to increase the already heightened stress levels in individuals with SCI (Rintala et al., 1998). This increase in stress levels, in addition to the lack of independence and poor physical function, further reduces QOL. Ditor and colleagues (2003) found that 9-months of regular exercise, at a frequency of two times per week, significantly reduced the amount of perceived pain and stress, which occurred in connection with improvement in overall QOL ($P < .05$). Reduction in exercise adherence after the 9-month program was paralleled with an increase in reported stress levels and perceived pain and a reduction in perceived QOL (Ditor et al., 2003). Thus, stress levels are heightened after SCI, and can further decrease the already lowered QOL; however, adhering to a regular exercise program may improve QOL by reducing pain and stress levels.

1.4.2 Measuring Quality of Life:

It is important to measure QOL, especially health related QOL, in order understand the impact a chronic disease or disability has on an individual. Clinicians are usually interested in the physiological responses of a patient, however, objective measures of function do not always reflect the perceived health related QOL of the patient. For example, two individuals may have the same amount of function, and even similar ratings of objective observed health, but they may report different evaluations of happiness, or SWB (Guyatt et al, 1993). Thus, it is important to obtain subjective measures of QOL, which are usually done through questionnaires and allow the individual to rate his or her personal satisfaction over a wide range of physical and psychological factors that can impact QOL. For example, stress, pain and health related quality of life can be measured by the Perceived Stress Scale (PSS), the Short Form 36-Item Health Survey (SF-36), and the Perceived Quality of Life Scale (PQOL), respectively (Cohen et al., 1983; Ware et al., 1992; Martin Ginis., 2003).

1.5 SCI and the cardiovascular system:

Spinal cord injury may also cause significant alterations to the cardiovascular system. Historically, respiratory complications after SCI were the leading cause of mortality in this special population. Recently, reports have suggested that cardiovascular disease in individuals with chronic SCI has risen to be the leading cause of mortality (Garshick et al., 2005). In addition to the increased risk of cardiovascular disease after a SCI, cervical or high thoracic injuries also disrupt the autonomic control of cardiovascular function, especially sympathetic regulation (Teasell et al., 2000). This disruption can not only limit exercise performance, but it is also associated with potentially dangerous episodic variations in blood pressure (BP).

1.5.1 Autonomic control of cardiovascular function:

The cardiovascular system is highly regulated by the autonomic nervous system through a constant balance of sympathetic and parasympathetic activity (Brubaker et al., 2002). Parasympathetic activity is responsible for putting the body into a resting state, and therefore, is responsible for decreasing heart rate (HR). Parasympathetic activity is regulated through the vagus nerve, which originates from the brainstem. To decrease HR, the vagus nerve releases acetylcholine which binds to receptors on the SA node of the heart, causing a reduction in action potential firing rate (Brubaker et al., 2002). In contrast, sympathetic activity has an opposing role to parasympathetic activity, due to its association with the "fight or flight" response. The sympathetic nerves that regulate cardiovascular function stem from the T1-T12 segments of the spinal cord. When required to increase HR and BP, the brain sends excitatory efferent signals to the sympathetic nerves causing them to release norepinephrine. Norepinephrine binds to the SA node causing an increased firing rate, but also binds to the adrenoceptors on blood vessels to induce a vasoconstrictive effect, thus raising BP (Claydon et al., 2006).

1.5.2 Blood pressure after SCI:

Blood pressure complications are usually experienced after cervical and high thoracic SCI, with most of these individuals exhibiting chronic hypotension. The mechanism most probably responsible for the wide range of BP complications after SCI is the loss of supraspinal control over sympathetically regulated cardiovascular activity (Teasell et al., 2000). After a SCI, there is disruption to the descending pathways that carry sympathetic information from the brain to the autonomic nerves. Due to this disruption, or loss of supraspinal control, several BP complications manifest, such as chronic hypotension, orthostatic hypotension (OH), and autonomic dysreflexia (AD).

1.5.3 Hypotension after SCI:

Individuals with cervical or high thoracic SCI usually suffer from chronic hypotension. As mentioned, the release of norepinephrine from the sympathetic nerves between T1-T12 causes an increase in BP due to its vasoconstrictive effect (Claydon et al., 2006). Mathias and colleagues (1975) have shown that individuals with tetraplegia exhibit significantly less plasma norepinephrine levels compared to able-bodied individuals. The lower than normal norepinephrine levels were found in all SCI participants who suffered from chronic hypotension, with an average BP of 107/59 (Mathias et al., 1975). Specifically, it is the loss of sympathetic control over the splanchnic region that is the major contributing factor for the experienced hypotension (Bravo et al., 2004). The splanchnic vascular bed is found within the thoracic/abdominal region and contains a vast number of large blood vessels that contribute to whole body BP regulation. Thus, the reduced sympathetic tone after SCI prevents these vessels from vasoconstricting, resulting in a constant low BP (Bravo et al., 2004).

1.5.4 Orthostatic Hypotension:

Orthostatic hypotension is defined as a decrease in systolic BP of 20mmHg or more, and in diastolic BP of 10mmHg or more, upon the assumption of an upright posture from a supine position (Claydon et al., 2006). Symptoms of OH are light-headedness, dizziness, nausea, blurred vision and possibly syncope upon the assumption of an upright position (Claydon et al., 2006). Like most cardiovascular dysfunctions associated with SCI, the loss of supraspinal control over sympathetic activity is most likely the major contributing factor of OH (Teasell et al., 2000). Normally, when an individual assumes an upright position, there is an initial drop in BP due to the natural gravitational pull. To counter this drop in pressure, the sympathetic nerves release norepinephrine which causes the blood vessels to vasoconstrict in order to bring BP back to normal. Individuals with SCI, however, fail to release norepinephrine as a response to an orthostatic manoeuvre, due to the inability of regulating sympathetic activity as a result of the interrupted descending sympathetic pathways (Claydon et al., 2006). Thus, the absence of sympathetic activity and its vasoconstrictive effect result in an unopposed reduction in BP after assuming an upright position.

1.5.5 Autonomic Dysreflexia:

Autonomic dysreflexia is a condition characterised by an uncontrolled sympathetic outflow response to a noxious stimulus below the level of injury. The sympathetic reaction to the stimulus results in a moderate to severe increase in BP due to vasoconstriction below the injury level. Symptoms of AD are pounding headaches, profuse sweating and flushed skin above the level of injury, as well as pale skin below the level of injury, goose bumps and sometimes bradycardia (Shergill et al., 2003). Autonomic dysreflexia is mostly seen in those with lesion levels above T6. Due to the loss of supraspinal control over cardiovascular sympathetic regulation, the spinal circuits below the level of injury operate independently. Thus, a noxious stimulus below the level of injury may provoke a sympathetic reflexive reaction causing an unopposed, uncontrolled increase in sympathetic tone, resulting in a potentially dangerous increase in BP (Bycroft et al., 2005). Autonomic dysreflexia does not typically change with exercise, but it should be considered as a potential risk during exercise in the SCI population.

1.5.6 Heart rate after SCI:

A normal resting HR is usually between 70-100 beats per minute (bpm; Brubaker et al., 2002). However after a cervical or high thoracic SCI, bradycardia, or a resting HR of less than 60 bpm, is commonly experienced (Brubaker et al., 2002; Eriksson et al., 1988). This suggests that a vagal hyperactivity or vagal dominance takes place after a SCI. After a high level injury, sympathetically regulated activity is disrupted, but efferent cardiac parasympathetic pathways remain intact. Since sympathetic activity is low and parasympathetic nerves are still intact after an injury, individuals with tetraplegia are predisposed to unopposed vagal over activity which results in bradycardia (Eriksson et al., 1988). To illustrate, Eriksson, Lofstrom and Eklom (1988) reported a maximal average HR of a low 119 bpm in trained and untrained individuals with tetraplegia who performed maximal wheelchair ergometry.

1.6 Spinal cord injury and muscle morphology:

After SCI, several alterations to the musculoskeletal system take place which can cause functional disabilities and health complications. Some of these alterations are muscle atrophy, increased muscle fatigability, and muscle spasticity. These changes may lead to reduced strength, decreased fatigue resistance, decreased insulin resistance and increased risk for pressure ulcers, which can all contribute decreases in QOL.

1.6.1 Muscle atrophy:

Spinal cord injury is highly associated with muscle atrophy. Castro and colleagues (1999) reported that at 6 weeks post-injury, average muscle cross sectional area (CSA) was 45% smaller in those with SCI compared to able-bodied controls, suggesting a rapid atrophic process immediately after SCI. In addition, when examining CSA 24 weeks post-injury, the soleus and gastrocnemius muscles were 54% and 68% of the able-bodied controls, respectively (Castro et al., 1999). It is important to note that the degree of atrophy experienced in the first 6 weeks after SCI was significantly greater than that of bed ridden and lower limb suspended able-bodied individuals for the same duration. Thus, it is suggested that the marked atrophy experienced after SCI is due to extreme unloading but also central inactivation (Castro et al., 1999). In addition, Baldi and colleagues (1988) found that after 6 months of SCI, individuals showed a decrease in total lean mass, lower limb mass and gluteal lean mass by 9.5%, 21.4% and 26.8%, respectively.

Furthermore, it is believed that rapid muscle atrophy occurs in the few weeks post injury, but then gradually slows down. Gregory and Dudley (2007) found that individuals with incomplete SCI experienced a 33% reduction in skeletal CSA 6 weeks post-injury. The reduction in CSA did not change significantly during the following 3 months, indicating that the most amount of atrophy occurs only during the first couple of months after an injury (Gregory and Dudley, 2007). This suggests that any kind of treatment aimed at maintaining muscle mass should be implemented as soon as the individual is stabilized after an injury.

1.6.2 Muscle fatigability:

Individuals with SCI tend to experience muscle fatigue at a much quicker rate than able-bodied individuals. The reduced fatigue resistance can be attributed to a muscle fibre type shift towards the fast fatigable Type IIx fibers, a decrease in the fatigue resistant Type IIa muscle fibers, and possibly, a decrease in Type I muscle fibres as well (Burnham et al., 1997; Castro et al., 1999). The muscle fibre shift causes a reduction in fatigue resistance, which in turn, presents functional limitations to the individual (Burnham et al., 1997). Castro and colleagues (1999) showed that at 24 weeks post-injury, Type IIa muscle fibres decreased by 14% and Type IIx increased by 12% in individuals with SCI. In addition, these individuals experienced greater relative fatigue compared to able-bodied controls, as shown by a greater loss of isometric force generating capacity during electrical stimulation of the left quadriceps (Castro et al., 1999).

Another proposed mechanism for the reduced fatigue resistance in individuals with SCI is a reduction in the N^+K^+- adenosine triphosphatase (ATPase) enzyme (Ditor et al., 2004). Membrane-bound Na^+K^+-ATPase plays a major role in the prevention of fatigue in skeletal muscle by actively transporting Na^+ and K^+ ions across the sarcolemma such that membrane excitability is maintained during muscle contractions (Fowles et al., 2002). Ditor and colleagues (2004) compared the concentration of Na^+K^+-ATPase in the affected vastus lateralus and the unaffected anterior deltoid in individuals with complete paraplegia. Results showed that the Na^+K^+-ATPase concentration of the vastus lateralis was significantly less than that of the subjects' own deltoid muscle (141.6 + 50.0 vs. 213.4 + 23.9 pmol/g wet wt., respectively; $P < 0.05$). This reduction in $Na^{+}K^{+}$-ATPase concentration in individuals with SCI may contribute to the decreased fatigue resistance during electrical stimulation (Castro et al., 1999).

1.7 Body-weight supported treadmill training and functional electrical stimulation:

Body-weight supported treadmill training and FES-cycling are methods of exercise rehabilitation that have shown promise as a means of therapy for individuals with SCI (Baldi et al., 1998; Ditor et al., 2005; Effing et al., 2006; Fagri et el., 1992; Gerrits et al., 2000; Hicks et al., 2005). In BWSTT, participants are suspended over a treadmill, via a harness, and a certain percentage of their body weight is supported. Therapists move the lower limbs through the gait cycle, allowing the paralyzed or semi-paralyzed legs to experience an upright walking motion. Functional electrically stimulated cycling is another therapeutic intervention used by individuals with neuromuscular disorders. In FES cycling, surface electrodes are placed over the lower limbs and an electric current is passed to the peripheral nerves in a specific sequence causing muscle contractions, which in turn generate a cycling motion. The purpose of FES is to activate muscles that normally would not be voluntarily activated due to paralysis. Both BWSTT and FES have shown benefits and limitations as methods of therapy, and each will be discussed.

1.7.1 Ambulation:

Previous studies have shown that BWSTT can improve walking ability in individuals with incomplete SCI. Hicks and colleagues (2005) investigated the effects of a 12-month, thrice-weekly exercise program using BWSTT on locomotor function in 14 individuals with chronic incomplete SCI. Following training, all participants improved their treadmill walking ability as evidenced by a 180% increase in treadmill walking speed, 335% increase in treadmill walking distance and a 54% reduction in the amount of body weight support required to stand on the treadmill. In addition, 6 participants improved their over ground walking by the end of the 12-month training program, as indicated by higher scores on the Modified Wering scale (Hicks et al., 2005). Similarly, Wirz and colleagues (2005) showed that BWSTT lead to improvements in over ground walking, as indicated by improved performance on the WISCI II, the 10MWT and the 6MWT. Twenty individuals with chronic incomplete SCI, classified AIS C and D, participated in an 8 week study, using the BWSTT at a frequency of 3 to 5 times a week. Results showed that only 2 participants improved over ground walking ability, as determined by the WISCI II. One participant's WISCI II score increased from 12 to 15, and another participant's score increased from 19 to 20 (Wirz et al., 2005). Regarding the Timed Get Up and Go test, all but 2 of the ambulatory participants improved their time by an average of 25 seconds following the 8 week BWSTT program (Wirz et al., 2005). In a recent study, Field-Fote and Roach (2011) presented a randomized controlled trial that compared the effects of treadmill-based training with manual assisstance, treadmill-based training with stimulation, overground training with stimulation and treadmill-based training with robotic assistance on over-ground walking speed and distance in individuals with incomplete SCI. Significant improvements in walking speed were detected after over-ground training with stimulation (0.19-0.28m/sec), treadmill-based training with stimulaiton (0.18-0.234m/sec) and treadmill-based training with manual assisstance (0.17-0.22m/sec). Walking distance significantly improved only after overground training with stimulation (24-38.3m) and treadmill-based training with stimulation (20.6-24.4m) (Field-Fote and Roach., 2011).

The literature on the effects of FES cycling on walking is very scarce. However, some studies investigated the effect of combining FES with assisted walking. Field-Fote (2001) conducted a study in which FES was combined with BWSTT, in order to investigate this intervention's effect on over ground walking. Nineteen participants with an incomplete AIS C SCI were required to complete a 12-week, thrice-weekly exercise program of BWSTT while using FES to stimulate the peroneal nerve. The results of this intervention were promising, as all participants improved their over ground walking speed by an average of 77% (Field-Fote, 2001). In a similar study, Thrasher and colleagues (2006) showed that 12 to 18 weeks of FES-ambulation resulted in significant increases in walking speed, which was mediated by an increase in stride length and step frequency. These studies suggest that combining FES with over ground walking is a beneficial method of therapy for improving locomotor function in individuals with incomplete SCI.

In terms of walking improvements, Dobkin and colleagues (2007) suggested that individuals with more function, such as AIS D SCI, are most likely to obtain the greatest improvements from walking therapy. This may be due to a higher preservation of neural tissue which undergoes alterations that improve function after task training (Yang et al., 2006). For improvements in walking function to occur, partial preservation of the corticospinal tract is required, in addition to changes in cortical activation patterns (Yang et al., 2006). To illustrate, Winchester and colleagues (2005) demonstrated greater activation in sensorimotor cortical regions (S1, S2) and cerebellar regions following automated BWSTT. In addition, improvements in over-ground locomotion were only noted in those with the greatest activation of the cerebellum (Winchester et al., 2005). Furthermore, improvements in walking function, as shown by increased walking independence and walking endurance, have shown to be concomitant to increases in corticospinal tract function following BWSTT (Thomas and Gorassini, 2005).

One issue with using the AIS as a means of recruitment, however, is that one AIS level can consist of a wide range of functional capabilities. For example, two individuals can be classified as AIS D SCI, however, one may ambulate without any assistive devices while the other requires a walker. Lower extremity muscle scores (LEMS) obtained from the manual muscle test have been shown to be a critical predictor of locomotor improvements after BWSTT (Yang et al., 2011). In addition, it has been previously shown that those with higher LEMS (equal to or greater than 40), at the end of a 12-week BWSTT program were able to walk faster than those with lower LEMS (less than 40) at the end of the training program (Dobkin et al., 2007). This suggests that the higher the LEMS, the more likely an individual is to recover the ability to walk without physical assisstance (Dobkin et al., 2007). Thus, individuals with more preserved lower limb muscle strength are most likely to gain the greatest improvements in walking independence and walking speed following ambulation training.

1.7.2 Quality of life:

Quality of life has been reported on several occasions to be lower in individuals with SCI compared to able-bodied individuals (Anderson., 2005; Dijkers., 1997; Lin et al., 1997). In a survey questionnaire collected from 681 individuals with SCI, 95% indicated exercise to be an important aspect of functional recovery (Anderson, 2005). Thus, different methods of exercise should be prescribed to spinal cord injured individuals to improve functional recovery, which may enhance QOL and life satisfaction.

Hicks and colleagues (2005) investigated the effects of BWSTT on SWB in individuals with SCI. The study showed significant improvements in life satisfaction and satisfaction with physical function following the training program. Even participants who did not regain the ability to walk over ground reported increases in QOL (Hicks et al., 2005). It has also been reported that BWSTT may improve an individual's ability to stand or transfer into a car, thereby providing a sense of independence which can positively influence QOL (Semerjian et al., 2005). In addition, Martin Ginis and Latimer (2007) reported that a single bout of BWSTT may reduce the amount of experienced pain, which consequently, improves feeling states in individuals with incomplete SCI. This was shown as 14 participants with incomplete SCI reported reduced amounts of perceived pain parallel to higher scores in the Profile of Mood Scale and Feeling Scale following one bout of BWSTT exercise (Martin Ginis & Latimer, 2007). Taken together, these reports suggest that even if BWSTT does not help an individual to regain walking ability, BWSTT may still serve as a potentially powerful stimulus for enhancing SWB and QOL (Hicks & Martin Ginis, 2008)

The effect of FES-cycling exercise on QOL in individuals with SCI has not been investigated to date. However, anecdotally, participants in our lab who perform FES cycling have reported that seeing their leg muscles contract again while generating a movement gives them a sense of satisfaction. Therefore, further investigation regarding the effects of FES exercise on perceived QOL after SCI is warranted.

1.7.3 Cardiovascular fitness:

Studies investigating the effects of BWSTT on cardiovascular fitness are very limited. It has been suggested that due to the upright standing position during BWSTT, and the utilization of large leg muscles, this form of therapy may provide a greater cardiovascular challenge than more traditional forms of aerobic training for individuals with SCI, such as arm ergometry (Ditor et al., 2005). In addition, the partial supporting of one's body weight allows a prolongation of exercise duration, which may be required to realize maximal cardiovascular benefits (Ditor et al., 2005). Ditor and colleagues (2005) investigated the effects of 6 months of BWSTT on cardiovascular autonomic regulation in 8 individuals with incomplete tetraplegia. Following the exercise program, participants experienced a significant reduction in resting HR, and a shift towards vagal predominance over HR regulation (as measured by power spectral analysis of heart rate variability). Further, although there was no significant change in resting BP, there was a significant change in BP variability in a direction consistent with a reduction in cardiovascular risk (Ditor et al., 2005). In addition, for individuals with complete SCI, BWSTT has been shown to enhance femoral artery compliance, which may help to prevent vascular damage and therefore, reduce cardiovascular risk (Ditor et al., 2005).

Functional electrically stimulated (FES) cycling has also shown promise as a means to improve cardiovascular health and function. Faghri and colleagues (1992) demonstrated that 12 weeks of FES cycling can significantly increase power output, indicating an increase in strength and endurance of the paralyzed muscles. Also, FES cycling significantly increased resting HR and BP in individuals with tetraplegia and lowered BP and mean arterial pressure in individuals with paraplegia. Both groups experienced significant decreases in HR and BP during submaximal exercise, while significantly increasing stroke volume and cardiac output (Faghri et al., 1992). These results suggest that FES cycling may provide central and peripheral cardiovascular benefits to individuals with SCI.

1.7.4 Muscle morphology:

Body-weight supported treadmill training has been shown to be an effective method for partially reversing some of the muscular changes that take place after SCI. Stewart and colleagues (2004) have shown that 6 months of BWSTT, at a frequency of 3 times per week, improved muscle cross sectional area (CSA) and fiber type distribution in 9 individuals with AIS C SCI. Following 6 months of BWSTT, fiber type I and IIa CSA significantly increased from a range of 2283-4638μm^2 to 3668-6480 μm^2 and 2819-6438 μm^2, respectively, while type IIax/IIx CSA did not change significantly (Range 2507-6244 μm^2 to 2813-6393) (Stewart et al., 2004). In addition to an increase in CSA, fiber type redistribution was also shown to occur following 6 months of BWSTT. Type IIa distribution significantly increased from 27.4 $\pm$ 5.0% to 42.0 $\pm$ 7.0% of all fibers while type IIax/IIx distribution significantly decreased from 49.7 $\pm$ 6.0% to 36 $\pm$ 4.0% of all fibers (Stewart et al., 2004). Similarly, in a case series, Giangrigori and colleagues demonstrated an increase in lower limb CSA by a range of 3.8 to 56.9% in 5 participants with incomplete SCI, following approximately 6 months of BWSTT.

Therefore, these studies demonstrate BWSTT's abilitiy in partially reversing some of the muscle alterations that occur in individuals with motor complete and incomplete SCI.

Functional electrically stimulated cycling has been shown to provide similar muscular benefits to BWSTT. Mohr and colleagues (1997) demonstrated that FES-cycling may reverse some of the morphological changes that take place after SCI. This was shown as 10 individuals with chronic SCI (AIS B), who engaged in FES-cycling three times a week for a year, experienced a 12% increase in thigh muscle mass. Moreover, a shift towards more fatigue resistant contractile proteins was found. The percent of myosin heavy chain isoform IIa increased from 33% to 61% with a corresponding decrease in myosin heavy chain isoform IIb from 63% to 32% of all contractile proteins, respectively. In addition, these changes were accompanied by increases in fatigue resistance, as all participants were able to cycle for 30 minutes continuously by the end of the training program (Mohr et al., 1997). These results suggest that FES-cycling may reverse the muscle atrophy and fibre type redistribution seen after SCI. Reversing these adverse muscular consequences are beneficial to one's health, however, prevention may serve as a better alternate. Baldi and colleagues (1998) reported that implementation of FES-cycling within 3 months of an injury may prevent muscle atrophy. Compared to controls who lost an average of 9.5%, 21.4% and 26.8% after 6 months of SCI in total body lean mass, lower limbs lean mass and gluteal lean mass, respectively, individuals who engaged in FES-cycling at the same time after their injury maintained their muscle mass (Baldi et al., 1998)

1.8 Limitations of body-weight supported treadmill training and functional electrically stimulated cycling:

Even though BWSTT has been shown to improve walking ability in individuals with incomplete SCI (Hicks et al., 2005), it may still not be conducive to attaining maximal ambulatory gains due to its passive nature (Huang and Ferris, 2004). For motor learning to occur, an individual must provide sufficient effort to promote activity-dependent plasticity. Since BWSTT relies on a therapist to move the participants' legs through the gait cycle, the legs are not maximally engaged. This could minimize the amount of functional ambulatory gains an individual can obtain (Huang and Ferris, 2004). Thus, individuals with SCI may benefit more in terms of ambulation if the lower limbs are more actively engaged. Likewise, FES-cycling does activate the lower limb muscles, but the movement is not gait specific, and therefore, may not be an optimal means for enhancing ambulation. Thus, an intervention that combines FES with gait specific pattern may have optimum benefits for enhancing walking after SCI.

Chapter 2: The effects of Functional electrically stimulated ambulation on locomotor function and quality of life in individuals with incomplete spinal cord injury.

2.0 Introduction:

It is well known that SCI presents a number of detrimental physical and psychological effects on an individual. Walking is one of the functions that is almost always affected after a SCI, due to its regulation by relatively low segments of the spinal cord. The compromise in ambulatory function is usually accompanied by a reduction in independence, which is noted by one's inability to perform ADL and manage in crowded areas and at home alone (Kim et al., 2004). The limited independence, partly due to diminished physical function, has a negative impact on quality of life and subjective well-being, and is further exacerbated by the physical inactivity characteristic of SCI (Hicks & Martin Ginis, 2008). Accordingly, physical activity is a critical aspect of functional recovery (Anderson, 2005), and therefore should be implemented regularly in order to improve life satisfaction and subjective well-being. In addition, since the majority of individuals with incomplete SCI identify walking as one of their primary goals, one would assume that any improvements in functional ambulation could have a substantial impact on quality of life, subjective well-being and perceptions of handicap (Hicks et al., 2005).

There is a growing body of evidence indicating that BWSTT can improve locomotor function after an incomplete SCI (Dobkin et al., 2007; Field-Fote, 2001; Hicks et al., 2005; Wirz et al., 2008). In addition, the use of BWSTT has also shown to improve subjective well-being; which is partly mediated by improvements in physical function (Hicks et al., 2005; Hicks & Martin Ginis, 2008; Martin Ginis & Latimer, 2007; Semerjian et al., 2005). Despite the benefits associated with BWSTT, one limitation to this form of therapy is that it is somewhat passive, as the leg muscles are not completely engaged. In addition, physical therapy methods that rely on external assistance, such as the Lokomat, may cause patients to fight the assistance or become less active (Huang & Ferris, 2004). In contrast, FES-cycling may fully activate the muscles, but lacks the specificity for ambulation. Accordingly, the RT600 (Restorative Therapies; Baltimore, MD) has recently emerged, which is the first machine to combine FES and gait specific therapy. Although its benefits are still unknown, it may be an optimal means for improving locomotor function in individuals with incomplete SCI.

2.1 Purpose and Hypothesis:

2.1.1 Statement of Purpose:

The aim of this study was to investigate the effects of 12 weeks of FES-ambulation, at a frequency of 3 times per week, on 1) locomotor function, 2) subjective well-being, 3) lower limb muscle bulk, and 4) cardiovascular fitness in individuals with incomplete AIS D SCI.

2.1.2 Hypotheses:

It was hypothesized that 12 weeks of FES-ambulation would result in improved locomotor function, subjective well-being and cardiovascular fitness, as well as increased lower limb muscle bulk. In terms of locomotor function, we expect our participants to improve in walking endurance and gait velocity by at least 53% and 56%, respectively, which was shown to occur after only 8 weeks of using the Lokomat (Wirz et al., 2005).

In terms of QOL, it was hypothesized that 12 weeks of FES-ambulation would improve health related quality of life, specifically physical function, which has been shown to improve after BWSTT (Hicks et al., 2005; Ginis & Latimer., 2007). Therefore, if FES-ambulation has similar benefits to BWSTT, we expect improvements to take place in the physical function scores of the SF-36 and the WHOQOL-BREF. We also hypothesized that following 12 weeks of FES-ambulation, participants would report reduced stress, as indicated by the PSS. We also hypothesized that participants will report higher self-efficacies for walking longer distances, walking up and down a flight of stairs, and walking up and down a 30 meter slope. Finally, we hypothesized that depression would improve following 12 weeks of FES-ambulation, as indicated by the CES-D.

In terms of lower limb muscle bulk, we expected an increase in mid-thigh circumference following the 12-week FES-ambulation exercise program. This hypothesis is based on previous evidence which has shown vastus lateralis mean fiber area to increase by 27.1% following 4 months of BWSTT (Adams et al., 2006). For the cardiovascular measures, it was previously mentioned that the upright position assumed on the body weight supported treadmill may provide a great cardiovascular challenge (Ditor et al., 2005). By taking this into account, we can hypothesize that FES-ambulation will provide a greater cardiovascular challenge than BWSTT due to its upright position and electrically induced muscle contractions, which would result in a greater venous return than that experienced from passive treadmill training. Therefore, FES-ambulation is expected to provide more of a cardiovascular stimulus than BWSTT or FES-cycling alone.

2.2 Methodology:

2.2.1 Participants:

Six participants (age 60.5 ± 13.2 years) with incomplete AIS D SCI (AIS D; C4-L3; 9.3 ± 12.0 years post-injury) were recruited from Brock University's Neuromuscular Rehabilitation Lab by means of recruitment posters and word of mouth. The participant pool for the current study was exclusive to individuals with AIS D SCI, because these individuals are likely to experience the greatest amount of ambulatory gains following ambulation therapy (Dobkin et al., 2007). Participants had to be at least one year post injury to prevent any spontaneous recovery from occurring during the exercise program (Dobkin et al., 2007). Before participating in the exercise study, an exercise stress test was conducted as a means to determine readiness for exercise. Ethics clearance was granted by Brock University Research Ethics Board and all participants gave their informed consent when recruited. Table 1 provides participant characteristics.

Table 1: Participant Characteristics

Participant	Gender	Age	Years since Injury	AIS	Neurological Level	Traumatic vs. Non-Traumatic	Method of Transportation
1	Male	74	2	D	L4	Traumatic	Ambulation
2	Female	72	2	D	T6	Traumatic	Wheelchair
3	Female	59	1	D	L3	Traumatic	Ambulation
4	Male	65	2	D	C5	Traumatic	Wheelchair
5	Female	55	30	D	C5	Traumatic	Wheelchair
6	Male	38	18	D	C5	Traumatic	Ambulation

Exclusion criteria for the study included, i) participation in any FES-exercise of the lower limbs in the previous 3 months, ii) a history of heart disease or abnormal heart or lung sounds, iii) current pressure ulcers on the buttocks or the trunk, iv) a history of unpredictable and severe autonomic dysreflexia or orthostatic hypotension, v) a history of fragility fractures,

vi) a history of drug or alcohol abuse, or vii) any musculoskeletal condition that would preclude exercise.

2.2.2 Exercise Intervention:

Participants engaged in 12 weeks of FES-ambulation, at a frequency of 3 times per week on a Monday, Wednesday, Friday or a Tuesday, Thursday, Saturday schedule. Functional electrically stimulated ambulation was performed with the use of the RT600 (Restorative Therapies; Baltimore, MD). Before the start of each session, the participants changed into shorts to expose the legs for electrode placement. While the participants were seated on their chair, or a plinth, two 3" X 4" gel electrodes were placed over the quadriceps and hamstrings, two 2" X 3" gel electrodes were placed over the gluteus maximus, with one placed over the proximal portion and the other over the distal portion of the gluteus maximus. Two 2" X 3" wireless electrodes, called RT50's, were then placed over the tibialis anterior and gastrocnemius muscles. Participants then stood up with the support of a walker and the electrodes on the gluteus maximus were connected to a 6 channel stimulation cable.

A harness was then strapped around the waist with the use of two strap buckles. To ensure that the harness was placed correctly, the upper strap buckle was placed over the anterior superior iliac spine. Foam pads were placed over the anterior superior iliac spine to prevent direct contact with the buckles, which has been reported to be uncomfortable. After the harness was placed tightly around the waist, 2 groin straps with sheep fur were strapped over the groin area. For most participants, the sheep fur was not enough padding, and therefore, extra foam pads were placed between the participants' legs, over the groin area, to provide more padding for the groin straps. When the harness was fully fitted, the remaining electrodes on the quadriceps and hamstrings were connected to the remaining channels of the stimulation cable. During this process, the participants were allowed to sit down, as standing for long periods can be fatiguing.

Two front straps and back straps from the harness were then pulled over the participants' shoulders and clipped into the hoist of the RT600 by hook clips. The participants were then lifted off the ground by the motorized hoist and then wheeled towards the RT600. One steered the participants towards the RT600 while two therapists held each of the participants' legs to place them in the foot plates of the RT600. When the feet were placed in the footplates, they were secured with a single Velcro strap and then straps from the hoist were tightly buckled into the harness to prevent excessive hip sway. Before stepping started, the stride length of the RT600 step ergometer was adjusted to accommodate for different heights.

The exercise began with a 2-minute warm-up, which consisted of passively moving the legs through the gait cycle with the use of the RT600 motor. The warm-up was followed by the initiation of FES-ambulation therapy, where electrical stimulation to the lower limbs gradually increased until the maximum tolerable level without discomfort or pain. The amount of body weight the participants were bearing was measured by a feature in the hoist, and was displayed on the screen of the RT600. The higher the stimulation intensity, or the harder the participants pushed down on the footplates, the less body weight support was required. Throughout each exercise session, participants were continuously encouraged to increase their weight bearing, which was done by lowering the participants onto the RT600 ergometer in order to provide less external body weight support. The degrees of dorsiflexion and plantar flexion of the footplates were individually adjusted for each participant to provide comfort and optimal ankle movement throughout the exercise.

The duration ambulated, speed of ambulation and external body weight support were gradually progressed as individually tolerated over the 12 weeks. For duration, the goal was to complete 15 minutes of active exercise in the first session and participants were encouraged to increase the duration by 3 minutes for each of the following sessions, until an hour of continuous exercise was performed. For speed, most of the participants started ambulating at the maximum speed of the RT600 ergometer, which was 40RPM. Those who started at a lower speed were encouraged to increase their speed by 2 to 3RPM per session, until 40RPM was reached. External body weight support was progressively reduced based on individual strength. If participants were able to maintain a certain weight bearing percent for 5 minutes without fatiguing, body weight support was reduced until the participant could not fully extend his or her knee during the stance phase. The parameters of FES were set at a frequency of 50Hz, pulse width of 350µs, and a current level set individually for each muscle group (quadriceps, hamstrings, gluteus maximus, tibialis anterior, gastronemius) to achieve sufficient functional contractions without pain or discomfort. Stimulation intensity was initially set at a maximal tolerable level and was progressed based on participants' indication of tolerating higher simulation levels.

At the end of each session, the electrodes were disconnected from the stimulation cables, the hip straps were unbuckled, the participants' feet were taken off the footplates, the participants were steered away from the RT600 and lowered on either their chair or the plinth. Finally, when the participants were seated, the harness was unstrapped and the electrodes were taken off and placed in individualized bags. The parameters for each session (intensity, speed, body weight support, stride length) were recorded and saved in each participant's profile, so for the following session, each participant would begin exercising at the same parameters he or she left off with. Participants were required to maintain an adherence level of at least 75% over the 12-week program. This corresponds to 27 completed sessions out of the total possible 36. If a participant failed to adhere at this rate, his or her data was not included in the analysis. Participants were strongly encouraged to complete at least 14 sessions in the first 6 weeks.

2.2.3 Statistical Analysis

A student's dependent t-test using Microsoft Excel 2010 was used to analyze pre-testing and post-testing data. Pearson's r correlations were also performed using SPSS.

2.3 Outcome Measures:

Baseline testing for all outcome measures took place 24-48 hours prior to the first exercise session and final testing took place 48-72 hours after the last exercise session to ensure that any observed changes were due to chronic effects of the exercise, and not the acute effects of the last exercise session.

2.3.1 Locomotor Measures

The second version of the Walking Index for Spinal Cord Injury (WISCI II) was used to assess changes in walking independence (Ditunno and Dittuno, 2001) (See Appendix L). The WISCI II required the participants to walk on a straight, non-slippery 10 meter surface, at their own pace with their choice of assistive devices. A score of 0 indicates that a person cannot stand or walk on his or her own, and a score of 20 indicates that a person is able to walk 10 meters without any assistive devices or physical assistance. The WISCI II has shown to be a reliable measure of walking function with inter- and intrarater reliabilities of 1.00 (Marino et al., 2010).

The 10 meter walking test (10MWT) was used to assess changes in over ground walking speed (m/sec). The same assistive devices used during baseline testing were used during final testing. For the 10MWT, participants were instructed to accelerate for the first 2 meters, and then walk as fast as they can while maintaining balance for the next 6 meters, and then decelerate in the last 2 meters, before coming to a complete stop. Markings labeled Start, Go, Slow Down and Stop were placed on the floor to indicate the phase of the test. A therapist walked in front of the participants to ensure their safety and to provide verbal encouragement. The 10MWT is a very reliable measure of speed with inter- and intrarater reliabilities of r= .974 and r=.983, respectively (Van Hedel et al., 2005).

The 6 minute walking test (6MWT) was used to assess changes in walking endurance. Similar to the 10MWT, the assistive devices used during baseline testing were used during final testing. The test required participants to walk for 6 minutes with the distance covered being recorded (meters). Participants were allowed to take breaks by either standing in place or sitting on a chair that was carried behind them by a therapist at all times, however, timing continued during any breaks that were taken. Another therapist walked in front of the participants to ensure safety and to provide verbal encouragement. The 6MWT is a very reliable measure of endurance, with inter- and intrarater reliabilities of r= .970 and r= .981, respectively.

2.3.2 Quality of Life:

The short form 36 questionnaire (SF-36) was used to assess changes in health related quality of life (Ware & Sherbourne, 1992), as it is the most widely used and studied tool for assessment of health related QOL (Tate et al., 2002) (See Appendix M). The SF-36 is a generic, self-administered questionnaire, with 36 items to assess different domains of perceived health related QOL in the past 4 weeks. Although it is the most widely used tool for assessing health related QOL, the literature does not provide its reliability or validity for the SCI population. The SF-36 is divided into 8 different domains: physical function, general health perception, pain, vitality, role limitations due to physical problems, social functioning, mental health and role limitations due to emotional problems. The domains of the SF-36 can also be divided into two groups: physical component measures and mental component measures. The physical component measures consist of physical function, role limitations due to physical problems, pain and general health and the mental component measures consist of mental health, social function, vitality and role limitations due to mental problems (Ware and Gandek, 1998). The rating scale for the SF-36 employs higher scores for higher or better SWB. Measurement consisted of adding the scores of each domain individually and by combining the scores of the physical domains together and mental domains together to obtain group physical and mental component scores, respectively. For negative items, the scoring was reversed in order to maintain the consistency of higher scores denoting higher SWB.

The perceived stress scale (PSS) was used to measure changes in stress (Cohen et al., 1983) (See Appendix N). The PSS is a 10-item self-administered questionnaire which assesses the number of stressful situations experienced in the last month. The PSS employs a 4-point scale with lower scores pertaining to less frequent stress and higher scores pertaining to more frequent stress. Measuring the scores consisted of adding all the points together to come up with a final score, and a higher overall number denotes higher stress levels. For positive items, such as 4, 5, 7 and 8, the scoring was reversed in order to maintain the consistency of higher scores pertaining to higher stress levels. The PSS has shown to have a high internal consistency with an alpha coefficient of .85 (Cohen et al., 1983).

The World Health Organization Quality of Life Brief questionnaire (WHOQOL-BREF) was used to assess changes in physical and psychological health (The WHOQOL Group, 1998) (See Appendix O). The WHOQOL-BREF is a short form of the WHOQL-100. It is a self-administered 26 item questionnaire assessing 4 domains of quality of life: physical health, psychological health, social relationships and environment. For the purpose of the current study however, only physical and psychological health were assessed. The domains of physical and psychological health have demonstrated internal consistencies of 0.81 and 0.80, respectively (Skevington et al., 2004).

Depression was measured with the use of the Center for Epidemiologic Studies Depression Scale (CES-D) (Radolf, 1977) (See Appendix P). Participants were asked to state how often in the past week they experienced each of the 20 depressive symptoms explained in the questionnaire. Responses ranged from 0 (rarely or none of the time) to 3 (most or all of the time). Measuring the scores consisted of adding all the points to obtain an overall score. An overall score of less than 15 indicates no experienced high levels of depressive symptoms, a score of 15-21 indicates mild to moderate symptoms of depression and a score greater that 21 indicates the possibility of major depression (Radolph, 1977). For positive items such as 4, 8, 12 and 16 the scoring was reversed in order to main the consistency of higher scores pertaining to more depressive symptoms. The CES-D demonstrated high degrees of reliability with an internal consistency of .85 and .90 for the general population and the patient population, respectively (Radolph, 1977).

Finally, a self-developed task self-efficacy scale was used to measure participants' confidence in walking long flat distances, walking up and down a flight of stairs consisting of 5 steps and walking up and down a 30 meter ramp with a slope 4.8 degree slope (ratio 1:12) (See Appendix Q). A rating scale of 100 points was used for the assessment of confidence, with a score of 0 denoting no confidence in performing the task and a score of 100 denoting complete confidence. Measurement consisted of adding the scores of the flat distances walk, the ramp walk and the steps individually, with higher scores indicating more confidence in performing the required task. The reason confidence was measured in performing tasks other that walking flat distances, was to determine if the potentially obtained ambulation skills from the training program are transferable and generalizable to other skills such as walking up and down a ramp and up and down steps.

2.3.3 Cardiovascular fitness measures:

Cardiovascular measures included resting HR, resting BP, mean arterial pressure and pulse pressure. Resting HR was measured with a pulse oximeter placed on the earlobe, and resting BP was measured by auscultation over the left upper arm using an automated cuff. Both measures were taken after 10 minutes of supine rest. Mean arterial pressure was calculated using the formula [(2 X Diastolic) + Systolic] / 3 and pulse pressure was measured by subtracting the average diastolic BP from the average systolic BP.

2.3.4 Lower Limb Muscle Bulk:

Thigh circumference of the dominant leg was taken with a measuring tape 15cm above the proximal patellar margin. If participants were not sure which leg was dominant, the leg without any orthotics or the leg used to initiate walking was used.

2.4 Results:

2.4.1 Exercise Adherence:

Eight participants started the exercise program, however, two dropped out near the 6-week mark due to physical complications. The first participant dropped out due to excessive tone which prevented him from getting to the lab and the second participant dropped out due to pain from arthiritic hips. Six participants successfully completed 12-weeks of FES-ambulation with a compliance rate of 84.7±0.83%. Participants completed a range of 29 to 31 sessions out of the total possible 36 sessions.

2.4.2 Measures of Locomotor Function:

A student's dependent t-test from an excel program was used to determine if there were any significant changes in locomotor function at baseline and after 12 weeks of FES-training.

2.4.2.1 Six Minute Walk Test:

Twelve weeks of FES-ambulation resulted in a significant 33.0% increase in the distance ambulated in the 6MWT (223.6±141.5m to 297.3±164.5m; p=0.009, Figure 1). It is interesting to note that all participants experienced an increase in walking distance (Range 8.2-133.6m). It is difficult to generalize this finding to all AIS D spinal cord injured individuals, especially due to the small sample size, but this finding suggests that FES-ambulation with the RT600 may be very beneficial in improving walking endurance.

2.4.2.2 Ten Meter Walk Test:

Twelve weeks of FES-ambulation resulted in a trend toward an increase in walking speed during the 10MWT (0.69±0.36m/sec to 0.86±0.51m/sec; p=0.06, Figure 2).

2.4.2.3 WISCI II:

Twelve weeks of FES-ambulation resulted in a trend toward an increase in WISCI II scores (16±4.3 to 17.7±2.7; p=0.08). Participant 1 improved her score from 9 to 13, meaning she progressed from using a walker and an ankle brace to walking with a walker only. Participant number 3 improved her score from 18 to 19, meaning she progressed from walking with an ankle brace to walking with one cane/crutch only. Participant 4 improved his score from 13 to 17, meaning he progressed from using a walker to being able to walk with the assistance of one person only. Participant 5 improved her score from 16 to 17, meaning she progressed from walking with 2 crutches to walking with the assistance of one person.

2.4.2.4 Body Weight Support:

After 12 weeks of FES-ambulation, participants experienced a significant 73.4% decrease in the required body weight support (55.3±12.6% to 14.7±23.2%; p=0.0004, Figure 3).

2.4.3 Measures of Subjective Well-being:

A student's t-test from an excel program was used to determine if there were any significant changes subjective well-being at baseline and after 12 weeks of FES-training.

2.4.3.1 Short Form-36 - Physical Measures:

Twelve weeks of FES-ambulation resulted in a significant decrease in bodily pain (6.5±1.2 to 5.0±1.7; p=0.04). However, there were no significant changes in perceived physical function (17.5±6.9 to 16.5±4.8; p=0.76), perceived role limitations due to physical problems (6.0±1.9 to 5.5±1.4; p=0.49), perceived general health (18.5±3.3 to 20.2±3.6; p=0.58) (Table 2), or overall physical function (49.5±9.4 to 50.2±6.5; p=0.86, Figure 4).

2.4.3.2 Psychosocial Measures:

Following 12 weeks of FES-ambulation, there were no significant changes in vitality (13.7±4.3 to 15.5±2.9; p=0.16), social function (6.0±2.0 to 7.2±1.7; p=0.18), role limitations due to emotional problems (5.0±1.3 to 5.2±1.2; p=0.80), mental health (23.2±5.6 to 24.7±2.7; p=0.38) (Table 2), or overall mental function (47.8±12.6 to 54.2±6.7; p=0.10, Figure 4).

Table 2: Short Form-36

	Pre-Exercise	Post-Exercise	P-Value
Physical Function	17.5 ± 6.9	16.5 ± 4.8	0.76
Role-Physical	6.0 ± 1.9	5.5 ± 1.4	0.49
Body Pain	6.5 ± 1.2	5.0 ± 1.7	0.04*
General Health	18.5 ± 3.3	20.2 ± 3.6	0.57
Vitality	13.7 ± 4.3	15.5 ± 2.8	0.16
Social Function	6.0 ± 2.0	7.2 ± 1.7	0.18
Role-Emotional	5.0 ± 1.3	5.2 ± 1.2	0.79
Mental Health	23.2 ± 5.8	24.7 ± 2.7	0.37

2.4.3.3 WHOQOL-BREf - Physical Health:

Following 12 weeks of FES-ambulation, there was no significant change in physical health (52.3±11.0 to 55.3±10.0; p=0.30, Figure 5).

2.4.3.4 WHOQOL-BREf - Psychological Health:

Following twelve weeks of FES-ambulation, there was no significant change in psychological health (58.5±15.0 to 55.5±10.9; p=0.20, Figure 5).

2.4.3.5 Task Self-Efficacy - Walking Flat Distances:

Following twelve weeks of FES-ambulation, there was no significant change in the confidence to walk long flat distances (206.7±131.7 to 227.5±139.0; p=0.19) (Table 3).

2.4.3.6 Task Self-Efficacy - Walking Up and Down a Slope:

Following twleve weeks of FES-ambulation, there was no significant change in the confidence to walk up or down a 12.5 degree, 30 meter slope ramp (96.7±86.2 to 81.7±96; p=0.51, Table 3).

2.4.3.7 Task Self-Efficacy - Walking Up and Down Stairs:

Following 12 weeks of FES-ambulation, there was no significant change in the confidence to walk up or down a stair case of 5 steps (110.0±69.9 to 70.0±77.7; p=0.30, Table 3).

Table 3: Task Self-Efficacy

	Pre-Exercise	**Post-Exercise**	**P-Value**
Walking Flat Distance	206.7 ± 131.7	227.5 ± 129.0	0.19
Walking up/Down Slope	96.7 ± 86.2	81.7 ± 96.0	0.51
Walking up/Down Stairs	110.0 ± 70.0	70.0 ± 77.7	0.29

2.4.3.8 Perceived Stress Scale:

Following 12 weeks of FES-ambulation, there was no significant change in the PSS (15.5±8.5 to 13.5±5.1; p=0.34, Figure 6)

2.4.3.9 Center for Epidemiological Studies – Depression:

Following 12 weeks of FES-ambulation, there was no significant change in perceived depression, as indicated by the CES-D score (13.5±12.8 to 11.2±5.8; p=0.53, Figure 6).

2.4.4 Measure of Thigh Circumference

Twelve weeks of FES-ambulation resulted in no significant change in mid-thigh circumference (47.2±3.5cm to 48.3±4.8cm; p=0.24, Figure 7).

2.4.5 Measures of Cardiovascular Fitness:

2.4.5.1 Resting Heart Rate:

Following 12 weeks of FES-ambulation, there was no significant change in resting heart rate (70.67±7.4bpm to 70.8±8.3bmp; p=0.93, Figure 8).

2.4.5.2 Mean Arterial Pressure:

Following 12 weeks of FES-ambulation, there was no significant change in mean arterial pressure (97.0±6.8mmHg to 88.9±8.2mmHg; p=0.12, Figure 8).

2.4.5.3 Systolic Blood Pressure:

Following 12 weeks of FES-ambulation, there was no significant change in systolic blood pressure (132.0±14.0mmHg to 120.5±17.0mmHg; p=0.17).

2.4.5.4 Diastolic Blood Pressure:

Following 12 weeks of FES-ambulation, there was a trend toward a decrease in diastolic blood pressure (79.5±6.1mmHg to 73.2±5.3mmHg; p=0.10).

2.4.5.5 Pulse Pressure:

Following 12 weeks of FES-ambulation, there was no significant change in pulse pressure (52.5±14.1mmHg to 47.3±14.7mmHg; p=0.3).

2.4.6 Correlations:

Correlations between all measures of locomotor function were performed using SPSS, however, only the significant relationships are mentioned.

2.4.6.1 Locomotor Function:

A significant negative correlation was found between baseline WISCI II scores and the change in WISCI II scores following 12 weeks of FES-ambulation. (r=-.97, p=0.001, Figure

9). This indicates that individuals who began the program with a lower WISCI II score experienced the most amount of improvement in walking independence. A significant negative correlation was found between baseline 6MWT scores and the change in WISCI II scores (r=-.85, p=.03, Figure 10), suggesting that individuals who began the exercise program with less walking endurance experienced the most amount of improvement in walking independence. Finally, a significant negative correlation was found between baseline speed during the 10MWT and the change in WISCI II scores (r=-.84, p=..037, Figure 11), suggesting that slower ambulators at baseline experienced the most amount of improvements in walking independence.

2.5 Discussion:

The main findings of this study were that 12 weeks of FES-ambulation resulted in improved locomotor function in individuals with AIS D SCI. This was evidenced by a significant increase in the distance walked during the 6MWT (223.6±141.5m to 297.3±164.5m; p=0.03) and a significant reduction in required external body weight support (55.3±12.6% to 14.7±23.4%). The improvements in walking were also supported by a trend toward an increase in walking speed during the 10MWT (0.69±0.36m/sec to 0.86±0.51m/sec; p=0.06) and independence during the WISCI II test (16±4.3 to 17.7±2.7; p=0.08). In addition to the exercise-induced improvements in locomotor function, the 12-week FES-ambulation program also resulted in reduced percieved bodily pain (6.5±1.2 to 5.0±1.7; p=0.04)

2.5.1 Relevance to the Literature:

2.5.1.1 Locomotor Function:

Since this was the first study to examine the effects of the RT600 on locomotor function, it is important to compare the current values to those of other studies that have used different methods of ambulation training. Different methods of ambulation training that have been used in the past are traditional BWSTT, automated BWSTT with the Lokomat and combining BWSTT with FES. Both traditional BWSTT and the Lokomat have been shown to improve walking speed and endurance in individuals with AIS C and AIS D SCI. Field-Fote and Roach reported walking speed to improve to a greater degree after overground ambulation training with electrical stimulation and treadmill-based training, however, walking distance improved to a greater extent with overground ambulation training with electrical stimulation (Field-Fote and Roach., 2011). Moreover, Protas and colleagues (2001) reported improvement in walking speed (.118m/s to .318m/s) and endurance (20.3m/5min to 63.5m/5min) after 12 weeks of BWSTT. Similarly, Wirz and colleagues (2005) reported an increase in walking speed and endurance by 56% and 53%, respectively, following 8 weeks of ambulation training with the Lokomat.

Although rare, but more relevant to our intervention, BWSTT has been combined with FES, either to the common peroneal nerve only (Field-Fote, 2001), or to the muscles of the lower limbs (Thrasher et al., 2006). Both forms of FES-ambulation have shown to improve walking speed in individuals with incomplete SCI (Field-Fote, 2001; Thrasher et al., 2006). Based on the current study, FES-ambulation using the RT600 may not be as effective as FES combined with BWSTT for improving walking speed. For example, Field-Fote (2001) showed significant improvememnts in walking speed in individuals with AIS C SCI, following 12 weeks of BWSTT combined with FES to the common peroneal nerve (.12±0.8m/s to .21±.15m/s). Likewise, Thrasher and colleagues (2006) reported improved walking speed following 12-18 weeks of treadmill training combined with FES to the lower limbs. It is important to note that TR600's relative lack of effectiveness in improving walking speed may be due to technical and methodological issues that will be discused in the next section..

Although no significant changes in WISCI II scores were detected, 4 out of the 6 participants required lower assistive devices by the end of the exercise program. A potential reason for the lack of significant changes in the WISCI II scores is an obvious ceiling effect. For example, Participants 2 and 6 began the exercise program with a perfect baseline score of 20, thus no further improvement could have been achieved. Wirz and colleagues (2005) have shown that only 2 out of their 20 participants improved in WISCI II scores (Range 1-3) following 8 weeks of ambulation training with the Lokomat. This limited improvement in walking independence is also seen in results from Thrasher and colleagues (2006) who only had one participant improve in walking independence (12 to 16 on the WISCI II scale) following 12 weeks of BWSTT combined with FES. These data suggest that FES-ambulation, with the use of the RT600, may be at least comparable, and possibily superior, for improving walking independence after SCI. However, conclusive statements are difficult to make since all of the participants in the current study were classified as AIS D, while the other studies included individuals with AIS C and D injuries.

2.5.1.2 Quality of Life:

To date, the effects of ambulation training on QOL after SCI have not been extensively examined. The current study showed that the only aspect of health related quality of life to improve after FES-ambulation was perceived bodily pain. Reported body pain was expected to improve as Martin Ginis and Latimer (2007) previously reported that a single bout of BWSTT may reduce the amount of pain experienced, which consequently improves feeling states in individuals with incomplete SCI. Hicks and colleagues (2005) have shown that life satisfaction and satisfaction with physical function significantly improve after 12 months of BWSTT. In contrast, a case series of 3 individuals has shown that 12 weeks of BWSTT resulted in small and diverse changes to QOL (Effing et al., 2006). For example, the first participant judged his QOL as improved during the 12 weeks of BWSTT. Perceived quality of life, however, did not significantly change between the baseline and the 6-week washout phase, or after 6 months of follow-up. The second participant judged his QOL as unchanged during the intervention phase, and diminished during the wash-out phase. At the end of the follow-up phase, however, the participant’s perception of his quality of life had improved, reaching baseline levels. The final participant evaluated his QOL as unchanged during the intervention phase and washout phase, but as improved after the 6-month follow-up phase (Effing et al., 2006).

The current study showed no significant changes in perceived stress and depression after 12 weeks of FES-ambulation. Although exercise has been shown to improve SWB, perceived stress and depression after SCI (Ditor et al., 2003; Hicks et al., 2003, Hicks et al., 2005), participants from the current study did not exhibit such improvements. A potential reason no significant changes were detected in both measures may be due to the small number of participants. Another potential reason may be due to the lack of significant changes in perceived physical function, as shown by the SF-36 and the WHOQOL-BREF. Diminished physical function after SCI usually leads to an inability to perform ADL, and this inability to perform ADL becomes a continuous source of stress. The constant stress may eventually produce additional distress and emotional changes, such as depressive symptoms (Latimer et al., 2004). Hicks and colleagues (2003) showed that individuals who participated in a 9-month exercise program exhibited a significant 19-34% and 81% increase in upper body muscle strength and endurance, respectively. The participants also reported less pain and stress, fewer depressive symptoms and greater satisfaction with their physical function. The authors reported that these improvements in physical function may have caused an increase in the participants' perceptions of their ability to manage ADLs, and therefore, reducing stress and depressive symptoms (Hicks et al., 2003). This suggests that improvements in perceived physical function, along-side with reduction in pain, may serve as mediators for reduced stress and depressive symptoms (Hicks et al., 2003; Latimer et al., 2004). Accordingly, the participants in the current study did not report any improvements perceived physical function, suggesting that their perceived ability to manage ADL has not changed; which may very well be a potential reason to why no improvements in stress and depression were detected.

Task self-efficacy for walking flat distances, up and down a ramp and stairs also did not change after 12 weeks of FES-ambulation. Similarly to perceived stress and depression, a potential reason to why no changes were detected was due to the small number of participants in the study. Another potential reason may be that improved performance on the RT600, as shown by improved body weight bearing and exercise walking distance, may not be generalizable to other over-ground tasks. Another potential reason why confidence did not improve may have been because of the lack of improvement in perceived physical function.

Since improved performance is a mediator of confidence, task self-efficacy did not increase potentially due to the absence of improvement in perceived physical function. Since participants did not perceive themselves as stronger or physically more capable than before, as shown by the SF-36 and WHOQOL-BREF, it is no surprise that confidence in performing physically demanding tasks did not change.

2.5.2 Applicability of the RT600:

In addition to examining locomotor function and subjective well-being, a secondary component of this study was to determine the applicability, reliability and effectiveness of the RT600. With that being said, it is important to compare its applicability with regards to labour intensiveness and dependability to BWSTT, as it is the most studied ambulation therapy apparatus for the neurologically impaired population. The set-up time of the RT600 is longer than that of the BWSTT simply because of the required electrode placement. Not only does the electrode placement have to be considered, but placing the harness to prevent it from ripping the electrodes off also makes the process longer. Thus, set-up time is longer than that typical for BWSTT, but it can be reduced with well trained therapists to approximately 13 minutes. The required supervision for the RT600 is similar to that of BWSTT, where 2 to 3 therapists are required for each session.

Compared to BWSTT however, the RT600 has a number of set backs and complications that make its feasability questionable, if not addressed. First, during the exercise program, almost every session consisted of several interruptions due to electrode displacement. One of the safety features in the RT600 is that it comes to a complete stop whenever an electrode comes off the individuals' lower limbs. Due to the harness' placement directly over the gluteal electrodes and the electrodes being connected to a stimulation cable that gets tugged throughout the exercise, the electrodes are prone to coming off. This results in several stops throughout each session, which anecdotally have been reported to be frustrating to the participants, as it causes delays and because it requires a lot of energy to start ambulating again after the interruption. This may potentially impair performance on the RT600, as the expectation of a sudden stop could demotivate the participants from exerting maximal effort during the exercise session.

A second drawback to the RT600 was that the footplates often did not mimic the appropriate ankle kinematics throughout the gait cycle. Often times the foot plates would go into plantar flexion during the heel strike phase and dorsi flexion during the toe off phase. This may present a rehabilitative setback due to improper gait kinematics, which may prevent a participant from practicing the appropriate gait cycle in order to maximize his or her functional gains. Another problem with the footplates was that they were always slightly plantar flexed. The slight plantar flexion seemed to increase throughout each session, which prevented the participants from maximally weight bearing and it was often reported as painful. These issues are not present in BWSTT because of the flat surface used for ambulation, and therefore, perfect walking kinematics can be executed during training. The absence of hand rails on the sides of the RT600 was also a constant source of complaint by the participants. All of the participants indicated that they would have had a more intense exercise if hand rails were available, as in BWSTT, as they would be able to balance better and extend their trunk more. Another limitation to the RT600 was the limited maximal speed that the RT600 ergometer could reach, which was 40RPM. Four out of the 6 participants started the exercise program at this maximal speed, and therefore, could not make any progress during training, which may have contributed to the absence of significant changes in speed. Furthermore, unlike BWSTT, where therapists can provide less assisstance to the legs to allow the participants to do more work, the RT600 is constantly driving the participants' legs through the gait cycle, preventing them from practicing their stepping independently. A final factor to be considered is the reliability of the RT600. In addition to those issues that were just presented, the machine broke down several times due to various reasons. The hoist that is used to lift participants up and down broke down once, leaving a participant suspended in the air. The belts inside the footplates broke several times and were required to be changed approximately every 7 weeks. Finally, the motor inside the footplates burned out after only 6 weeks of using the RT600 and required replacement. By taking these points into consideration, it seems that the RT600 may not be as reliable as the BWSTT. However, this form of therapy is still in its infancy and many changes and improvements are expected to take place. Therefore, if the RT600 can be updated and improved by addressing those issues just mentioned, then it may have great potential as a means of locomotor therapy after SCI. However, with its current issues surrounding reliability and ease of use, other forms of ambulation therapy, like BWSTT, may be preferred.

2.5.3 Mechanisms Behind Findings:

2.5.3.1 Endurance:

Since the physiological changes that take place after FES-ambulation have not been examined, one might speculate thay they are similar to those experienced after BWSTT and FES-cycling. One of the possible mechanisms behind improved endurance after FES-ambulation is an increase in fatigue resistant type I muscle fibers. As mentioned, SCI is usually accompanied by a shift towards fast fatigabile type IIX muscle fibers, which is partly responsible for the reduction in fatigue resistance (Burnham et al., 1997; Castro et al., 1999). Both BWSTT and FES-cycling have been shown to reverse this fiber type shift and promote an increase in the fatigue resistant muscle fibers (Type I and Type IIa), with a concomitant increase in endurance (Adams et al., 2006; Crameri et al., 2002; Mohr et al., 1997; Stewart et al., 2004). In addition, an improvement in muscle oxidative capacity, specifically the activity of citrate synthase and 3-hydroxy-acyl-CoA dehydrogenase enzymes, have been credited for the improvememnt in endurance after BWSTT and FES-cycling (Mohr et al., 1997; Stewart et al., 2004). Therefore, based on these studies, we can speculate that endurance after FES-ambulation improved due to a muscle fiber type shift towards fatigue resistant muscle fibers, an improvement in muscle oxidative capacity, or a combination of both. Further research on the mechanisms behind the improvement in endurance after FES-ambulation is warranted.

2.5.3.2 Speed:

Since gait speed has been suggested to be the criterion standard of walking ability in neurologically compromised individuals (Field-Fote, 2001), it is critical to discuss why this outcome measure did not improve in the current study. The first potential reason is the high variability in baseline walking speed between the participants, and in fact, significant improvements in walking speed were detected after controlling for the baseline variations (100.0±0% to 84.6±14.5%; p=0.04). The high variability in walking ability between the participants suggests that the AIS alone may not be the best method for recruitment. This is because individuals with the same AIS can have a wide range of functional capabilities, as seen in the participants of the current study. For example, despite all participants having an AIS D classification, Participant 1 finished the 10MWT in 85 seconds, whereas Participant 2 finished in 11.1 seconds. One consideration that could have been made to reduce the amount of variability between the participants was to recruit individuals with an AIS D SCI who have similar lower extremity muscle scores (LEMS). This is because the severity of the motor impairment in the legs is best reflected by the total score from the initial manual muscle test (Yang et al., 2011). By recruiting participants with similar LEMS, we may have reduced the amount of variability within our participants. However, due to the small number of potential participants, an exclusion critera of that kind would have been prohibitive.

Another potential reason accounting for the lack of significant improvements in walking speed was the way the 10MWT was conducted. In previous studies that showed improvements in speed after ambulation training, speed was measured by timing participants as they walked a given distance as fast as they could (Field-Fote, 2001; Protas et al., 2001; Wirz et al., 2005). The way we conducted the 10MWT is acceptable, and has been used previously (Yang et al., 2011) due to the belief that incorporating transition time from a stationary stance to a walking stance better characterized a person's functional walking ability. However, it seems that any changes in maximal walking speed that may have occurred could have been masked by the acceleration and deceleration in the first and last 2 meters. A way to avoid this in future studies is to measure changes in individuals' maximal walking speed only, rather than incorporating the potentially confounding acceleration and deceleration phases.

Another potential reason for the lack of significant improvements in walking speed is the low number of successful FES-ambulation sessions. Protas and colleagues (2001), who demonstrated significant changes in walking speed, trained their participants via BWSTT for 12 weeks, at a frequency of 5 days per week. Wirz and colleagues (2005), who also demonstrated improvements in walking speed following training on the Lokomat, trained their participants for 8 weeks with a range of 24-37 sessions. Field-Fote (2001), who also showed significant changes in speed, trained participants for 12 weeks at a frequency of 3 times per week, with 1.5h hours per session. The current study required the completion of 36 sessions in 12 weeks, however, we had an average compliance rate of 84.7%, and 12.2% of those sessions were performed on the RT300 (Restorative Therapies, Baltimore, MD), an FES-cycle ergometer. The reason FES-cycling was used for 12.2% of the attended sessions, was because the RT600 often broke down due to technical or mechanical complications. The RT300 was therefore used when the RT600 was idle to prevent the participants from dropping out. This may very well have compromised the effectiveness of the exercise program, as 12.2% of the exercise was not gait specific, and therefore, significant improvements in speed were not attained.

Thus, the overall time the participants engaged in successful FES-ambulation throughout the 12 weeks was less than the overall exercise time in any of the mentioned studies (Field-Fote, 2001; Protas et al., 2001; Wirz et al., 2005). Accordingly, the amount of exercise the participants engaged in over the 12-week period may simply have not been enough to elicit significant changes in walking speed

2.5.3.3 Quality of Life:

The only significant change in health related quality of life that took place was a reduction in bodily pain. A potential mechanism for the reduction in pain is an exercise induced increase in Beta-endorphin. Beta-endorphin is a 31-amino-acid peptide, primarily synthesized in the anterior pituitary gland, and is expressed during exercise (Goldfarb and Jamutas, 1997). Treadmill training in able-bodied individuals has shown to act as a stimulus to greater Beta-endorphin secretion, reduction in its degeneration, or a combination. This is evidenced by a 2 to 5 fold increase in Beta-endorphin/Beta-lipotropin immunoreactivity (10pg/ml to 58.3pg/ml) following sub-maximal treadmill training (Farrell et al., 1982). In addition, Jarmulki and colleagues (1999) demonstrated the ability of Beta-endorphin to alter pain thresholds, as evidenced by an increase in pain tolerance to a radiant heat source (72 sec to 123 sec). These studies demonstrate the response of beta-endorphin to exercise and its analgetic effects, which could potentially be a contributing factor to the reduced pain following FES-ambulation exercise.

Another potential mechanism behind the reduction in pain is through distraction-induced analgesia. Distraction from the source of pain has been shown to be an effective and non-invasive technique to alleviate pain. For example, when placed in a virtual reality environment, participants experiencing repetitive heat stimuli reported reduced pain and exhibited reduced pain related activity in the brain, as shown by functional magnetic resonance imaging (Hoffman et al., 2007). Furthermore, Fowler-Kerry and Lander (1987) have shown that children who listened to music during immunization injections reported less pain scores compared to non-distracted controls (1.78 vs 1.34). These studies suggest that focusing on a task or a stimulus may induce analgesia, possibly through distraction from the source of pain.

Furthermore, as mentioned before, a potential reason why the participants did not report any other improvements was due to the smal sample size which resulted in the lack of statistical power. In addition, 12 weeks of ambulation training may not be long enough to induce beneficial changes in subjective well-being. As mentioned before, a previous 12 week ambulation training study also showed only modest changes in QOL (Effing et al., 2006). In contrast, Hicks and colleagues (2005) showed significant changes in life satisfaction (19.7±8.2 to 23.6±7.3) and satisfaction with physical function (7.1 ±7.0 to 11.4±4.9) after 12 months of BWSTT. This suggests that unlike physical, or more objective measures of function, SWB may require a longer period of time to show improvements.

2.5.3.4 Cardiovascular Fitness:

None of the cardiovascular measures were significantly altered as a result of the training program. A potential reason for the lack of cardiovascular improvements may be because the training method was just not intense enough to induce a cardiovascular stimulus. The partial body weight support allowes ambulation to be performed with more ease compared to full weight bearing, and therefore, puts less of a cardiovascular demand on the individual, thus reducing the exercises' intensity. In addition to partial weight support, because the legs are constantly guided through the gait cycle of the ergometer, voluntary effort to ambulate can be reduced. This reduction in voluntary effort can also decrease the exercise intensity and by that, prevent it from inducing a cardiovascular stimulus.

2.6 Limitations:

The main limitation to the current study was the small number of participants. Since the participant pool needed to be very specific, only individuals with AIS D classification, it was difficult to recruit a larger number of participants. Thus, the lack of statistical power, due to the small number of participants, makes it difficult to detect significant changes (Martin Ginis and Hicks, 2005).

Another limitation was the absence of a control group. Likewise, this too was mainly due to the small number of participants and the high potential for dropouts. It is important to note, however, that non-exercising control groups have been viewed as unethical in SCI research, since exercise is so critical in this population and depressive syndromes may develop if exercise is withheld (Martin Ginis and Hicks, 2005). Another alternative to employing a control group could have been to use the intervention group as their own controls. To do that, the outcome measures would have been tested throughout 12 weeks of no exercise prior to the exercise program, and the data from that time period is used as control values. Another alternative, which is more ethical than having a non-exercise control group, is to have a non-exercise information session control group. In this control group, participants would not exercise, but would attend information sessions twice or 3 times per week on SCI and living with such a disability. However, such control groups tend to have high dropout rates as participants are already informed and knowledgeable about the information given in such sessions (Martin Ginis and Hicks, 2005).

The high variability in the electric current provided to the participants, due to different pain thresholds, may also be a limitation. This resulted in varying amounts of muscular contractions, and therefore, not all participants may have benefited to the same degree. In addition, Participants 1 and 5 experienced asymmetrical hypersensitivity in their lower limbs. Due to this hypersensitivity, relatively low currents were used to prevent the participants from experiencing pain. Accordingly, with such low currents very small functional contractions were generated by the muscles which likely reduced the effectiveness of the intervention. Finally, the technical issues previously mentioned were also a major limitation to the study, and potentially the effectiveness of the exercise program.

2.7 Future Directions:

Since this novel study was the first to investigate the effects of the RT600 on locomotor function, future studies with more participants and varying degrees of injuries are warranted. In addition to more participants, employing a longer term study on the effects of FES-ambulation is required, especially since long term studies seem to be associated with significant changes in SWB. Future studies should also employ a washout and a follow-up period following training, in order to examine the maintenance of ambulatory gains. Lastly, and most importantly, studies that directly compare the RT600 to more traditional forms of ambulation therapy, such as the BWSTT and the Lokomat, are warranted.

2.8 Summary:

The current study was the first to examine the effects of FES-ambulation exercise, with the RT600, on locomotor function and SWB in individuals with incomplete SCI. The results suggest that FES-ambulation may be a beneficial form of ambulation therapy, as evidenced by an increase in walking endurance and a reduction in external body weight support. It may also be effective at reducing bodily pain after incomplete SCI. The lack of changes in walking speed and other measures of health related quality of life may be due to the small number of participants and the relatively short duration of the study. Thus, further long term studies with larger number of participants are warranted in order to obtain a better understanding of the potential rehabilitative benefits the RT600 may provide.

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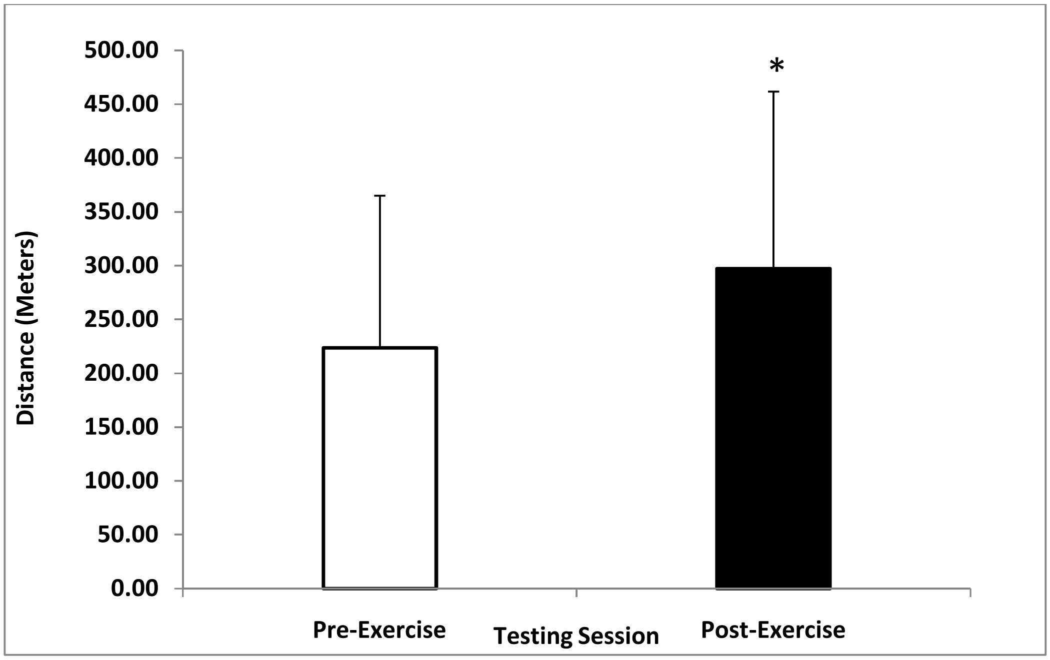
Figure 1: Distance ambulated during 6MWT at baseline and following 12 weeks of FES-ambulation.



* denotes a significant increase compared to baseline values (p=0.03)

Figure 2: Speed of ambulation during the 10MWT at baseline and following 12 weeks of FES-ambulation.

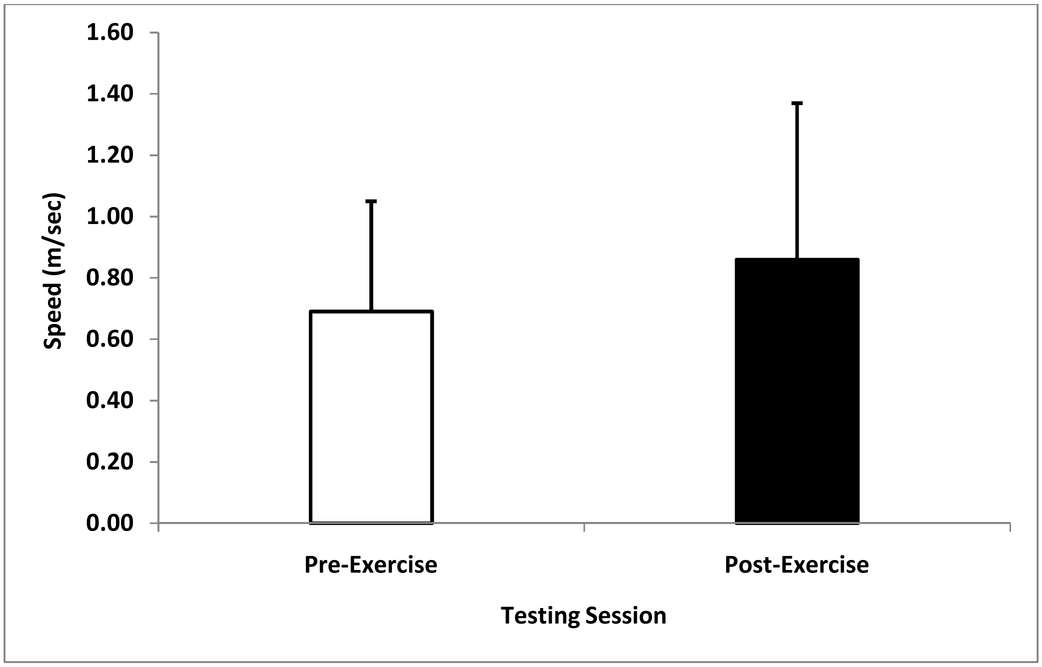
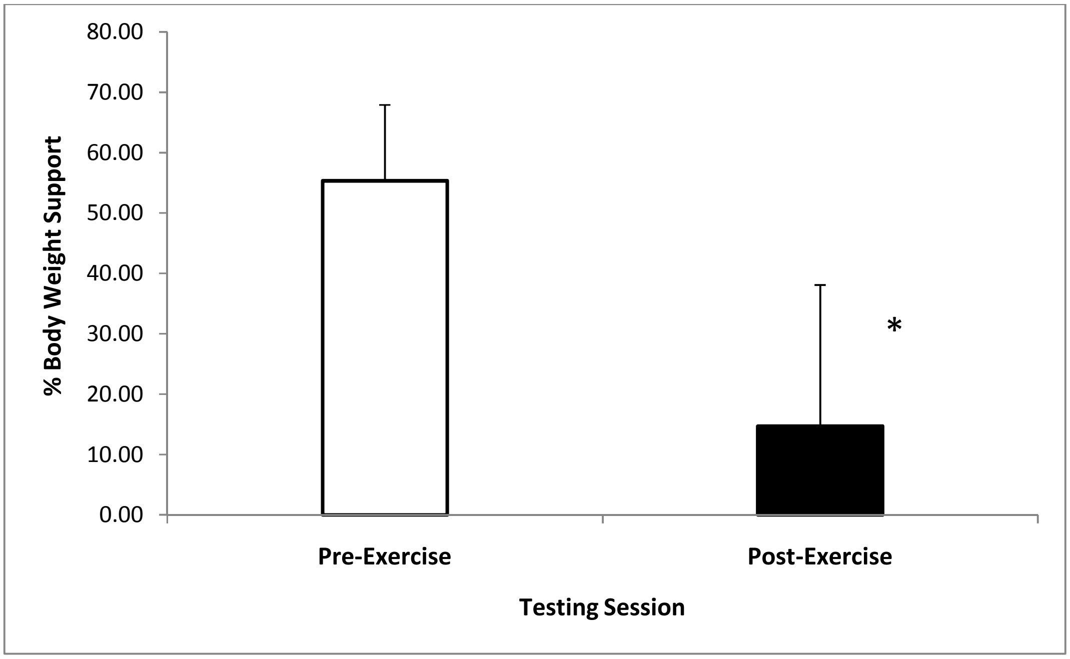


Figure 3: Required external body weight support at baseline and following 12 weeks of FES-ambulation.



* denotes a significant decrease compared to baseline values (p=0.005)

Figure 4: Physical component measures and mental component measures of the short form 36 at baseline and following 12 weeks of FES-ambulation.

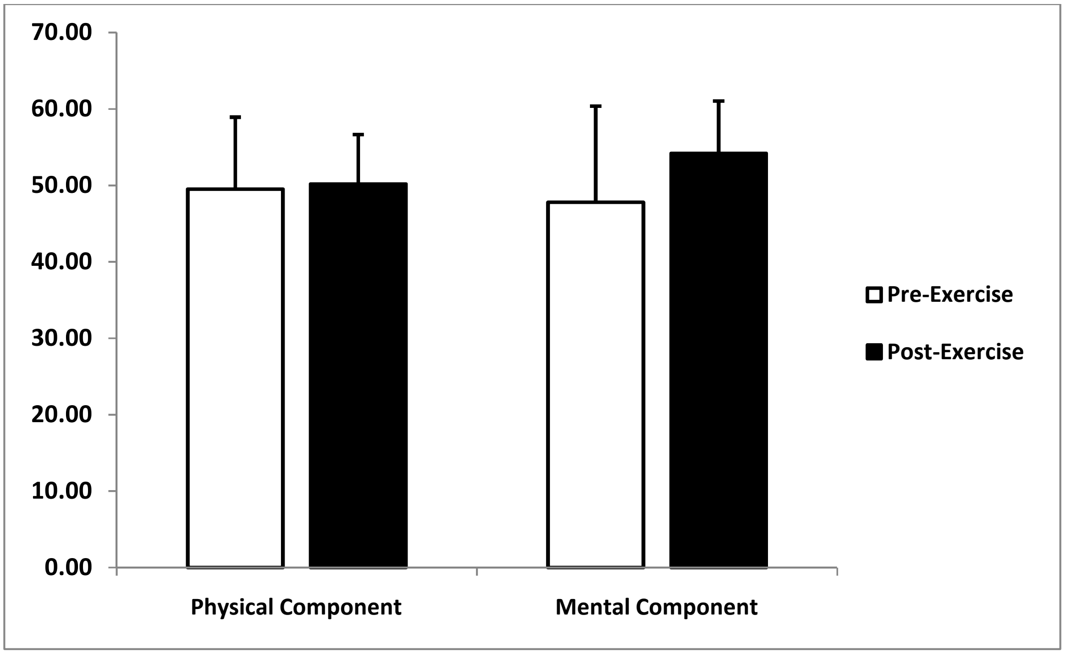


Figure 5: Physical health and psychological health of the WHOQOL-BREF at baseline and following 12 weeks of FES-ambulation.

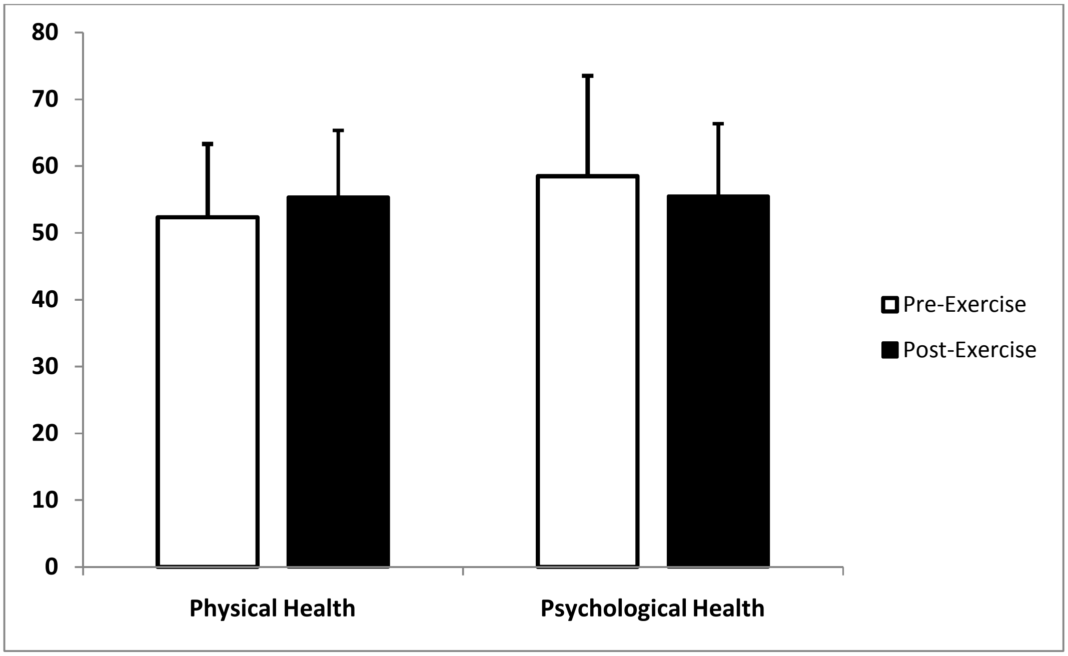


Figure 6: Perceived stress scale and center of epidemiological studies-depression scores at baseline and following 12 weeks of FES-ambulation.

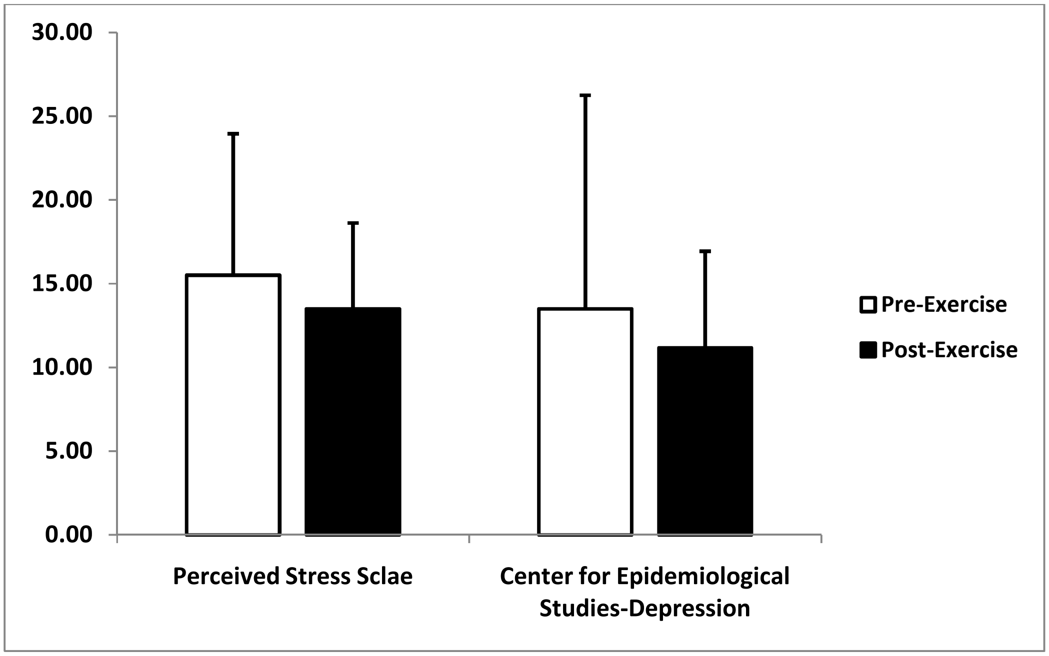


Figure 7: Mid thigh circumference at baseline and following 12 weeks of FES-ambulation.

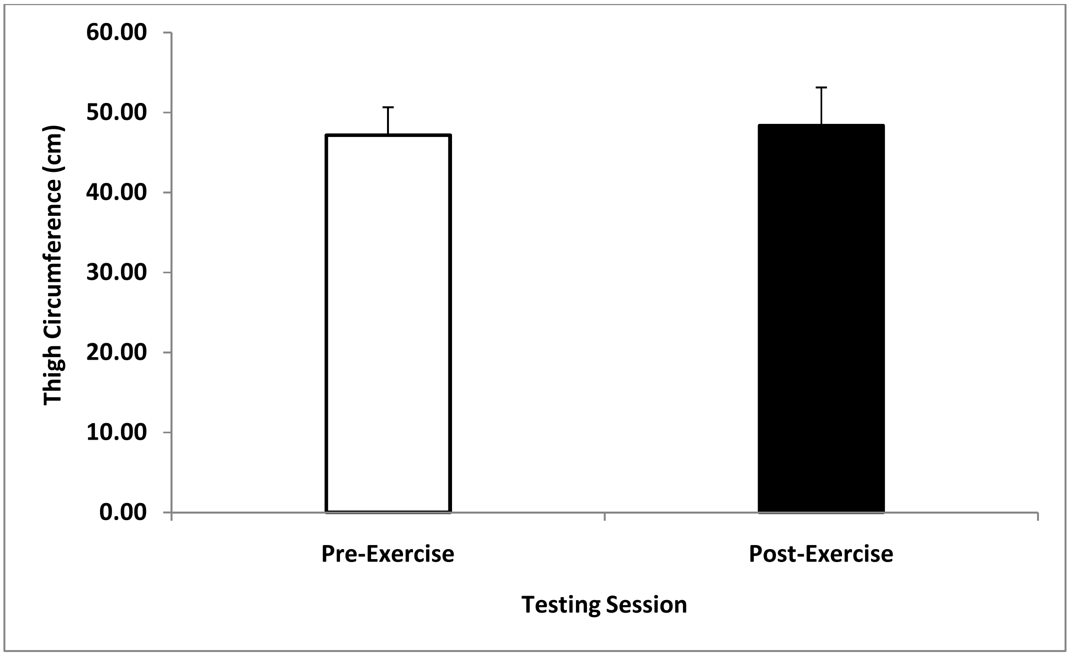


Figure 8: Resting heart rate and mean arterial pressure at baseline and following 12 weeks of FES-ambulation.

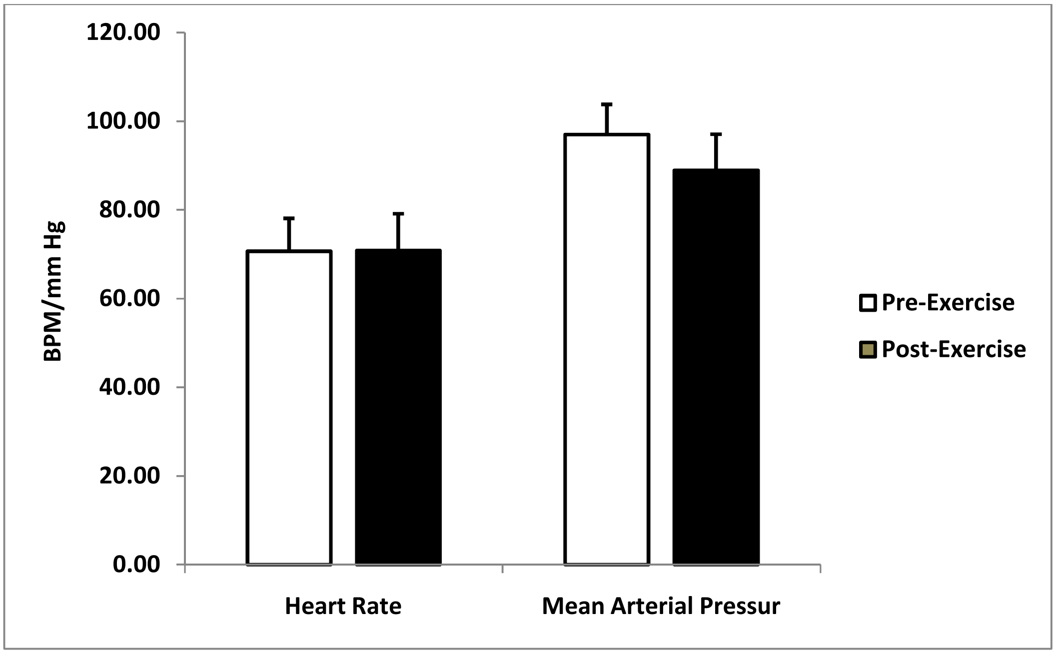


Figure 9: Correlation between baseline WISCI II score and changes in WISCI II score

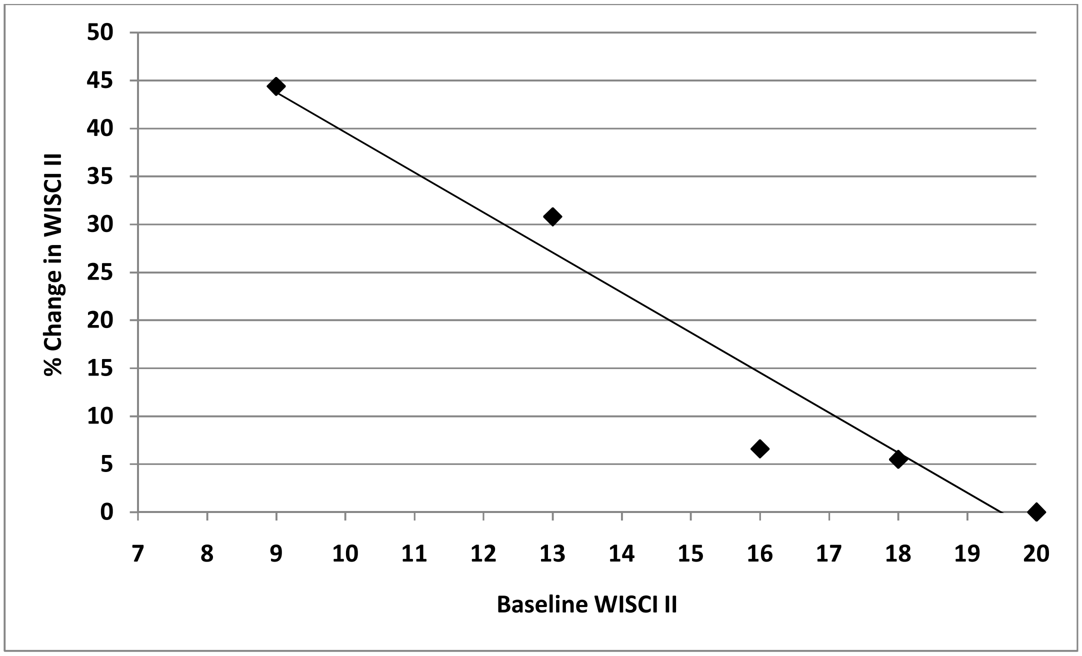


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Figure 10: Correlation between baseline endurance (6MWT) and changes in WISCI II score.

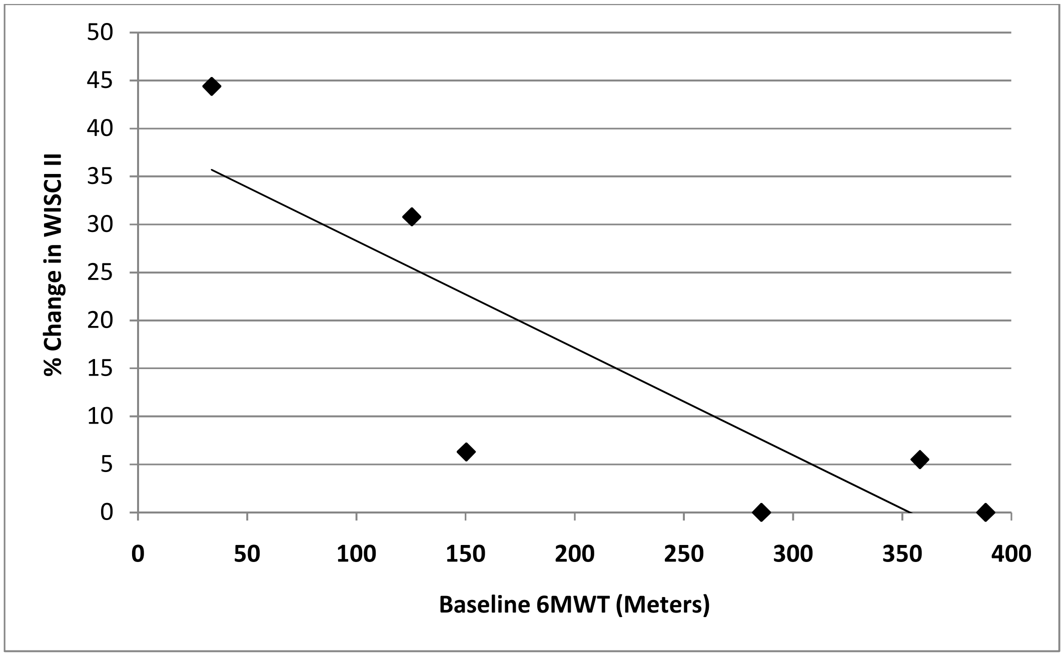
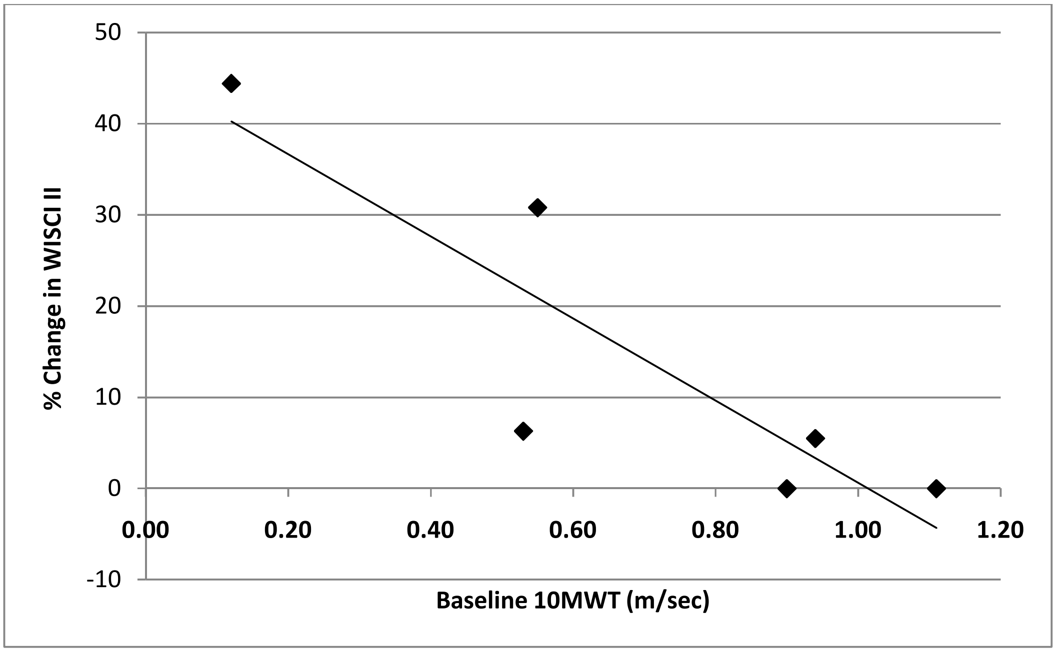


Figure 11: Correlation between baseline speed (10MWT) and changes in WISCI II score.



Appendices

Appendix A: RT600

Appendix B – Locomotor Data

Table 1: WISCI II scores at baseline and 12 weeks post FES-ambulation.

Participant	Pre-Exercise	Post-Exercise
1	9	13
2	20	20
3	18	19
4	13	17
5	16	17
6	20	20
AVG	16	17.7
S.D	4.3	2.7

Table 2: Distance (meters) walked during the 6 minute walk test at baseline and 12 weeks post FES-ambulation.

Participant	Pre-Exercise	Post-Exercise
1	33.8	42
2	388.3	478.2
3	358.1	461.9
4	125.4	259
5	150.4	210
6	285.6	332.5
AVG	223.6	297.3
S.D	141.5	164.5

Table 3: Speed (m/sec) ambulated during the 10MWT at baseline and 12 weeks post FES-ambulation

Participant	Pre-Exercise	Post-Exercise
1	0.12	0.1
2	0.90	1.3
3	0.94	1.3
4	0.55	0.5
5	0.53	0.7
6	1.11	1.3
AVG	0.69	0.89
S.D	0.36	0.5

Table 4: Required external body weight support (percent) at baseline and 12 weeks post FES-ambulation

Participant	Pre-Exercise	Post-Exercise
1	64.8	60
2	63	1
3	45	0
4	56	17
5	67.6	10
6	35.6	0
AVG	55.3	14.7
S.D	12.6	23.2

Appendix C: Short Form-36 Data

Table 1: Physical function:

Participant	Pre-Exercise	Post-Exercise
1	28	12
2	19	23
3	15	17
4	10	15
5	11	11
6	22	21
AVG	17.5	16.5
S.D	6.9	4.8

Table 2: Role limitation due to physical problems:

Participant	Pre-Exercise	Post-Exercise
1	5	4
2	7	7
3	4	4
4	4	6
5	8	5
6	8	7
AVG	6.0	5.5
S.D	1.9	1.4

Table 3: Body pain:

Participant	Pre-Exercise	Post-Exercise
1	7	5
2	7	3
3	7	7
4	7	6
5	7	6
6	4	3
AVG	6.5	5
S.D	1.2	1.7

Table 4: General health:

Participant	Pre-Exercise	Post-Exercise
1	24	24
2	22	21
3	17	22
4	21	22
5	16	18
6	17	14
AVG	19.5	20.2
S.D	3.3	3.6

Table 5: Physical measures:

Participant	Pre-Exercise	Post-Exercise
1	63	48
2	54	61
3	42	49
4	41	50
5	41	41
6	56	52
AVG	49.5	50.2
S.D	9.4	6.5

Table 6: Vitality:

Participant	Pre-Exercise	Post-Exercise
1	15	14
2	15	19
3	15	15
4	16	18
5	5	11
6	16	16
AVG	13.7	15.5
S.D	4.3	2.9

Table 7: Social function:

Participant	Pre-Exercise	Post-Exercise
1	7	5
2	8	8
3	5	7
4	5	7
5	3	6
6	8	10
AVG	6.0	7.2
S.D	2.0	1.7

Table 8: Role limitations due to emotional problems:

Participant	Pre-Exercise	Post-Exercise
1	5	5
2	6	5
3	4	3
4	6	6
5	3	6
6	6	6
AVG	5.0	5.2
S.D	1.3	1.2

Table 9: Mental health:

Participant	Pre-Exercise	Post-Exercise
1	21	25
2	28	28
3	22	22
4	28	27
5	13	21
6	27	25
AVG	23.2	24.7
S.D	5.9	2.7

Table 10: Mental measures:

Participant	Pre-Exercise	Post-Exercise
1	48	59
2	57	60
3	46	47
4	55	58
5	24	44
6	57	57
AVG	47.8	54.2
S.D	12.6	6.9

Appendix D – WHOQOL-BREF Data

Table 1: Physical health:

Participant	Pre-Exercise	Post-Exercise
1	44	44
2	63	69
3	69	63
4	44	56
5	44	44
6	50	56
AVG	52.3	55.3
S.D	11.0	10

Table 2: Psychological health:

Participant	Pre-Exercise	Post-Exercise
1	56	50
2	75	69
3	44	44
4	69	63
5	38	44
6	69	63
AVG	58.5	55.5
S.D	15.0	10.9

Appendix E – Perceived Stress Scale Data

Table 1: Perceived Stress Scale scores:

Participant	Pre-Exercise	Post-Exercise
1	21	20
2	8	10
3	17	16
4	14	12
5	28	17
6	5	6
AVG	15.50	13.5
S.D	8.46	5.1

Appendix F – Center for Epidemiological Studies-Depression Data

Table 1: CES-D Scores:

Participant	Pre-Exercise	Post-Exercise
1	13	8
2	5	11
3	14	16
4	8	7
5	38	20
6	3	5
AVG	13.5	11.2
S.D	12.8	5.8

Appendix G – Task Self-Efficacy Data

Table 1: Confidence in walking flat distances:

Participant	Pre-Exercise	Post-Exercise
1	60	70
2	300	340
3	250	260
4	130	115
5	100	180
6	400	400
AVG	206.7	227.5
S.D	131.7	129

Table 3: Confidence in walking up and down a slope:

Participant	Pre-Exercise	Post-Exercise
1	0	0
2	180	200
3	80	100
4	120	0
5	0	0
6	200	190
AVG	96.67	81.67
S.D	86.18	96.00

Table 5: Confidence in walking up and down a flight of stairs:

Participant	Pre-Exercise	Post-Exercise
1	0	0
2	140	160
3	200	120
4	100	0
5	150	0
6	70	140
AVG	110	70
S.D	69.86	77.7

Appendix H – Mid Thigh Circumference Data

Table 1: Thigh circumference at baseline and 12 weeks post FES-ambulation.

Participant	Pre-Exercise	Post-Exercise
1	46.5	50.5
2	43	44
3	53.5	57
4	48	47.5
5	45.5	46
6	46.5	45
AVG	47.2	48.3
S.D	3.5	4.8

Appendix I – Cardiovascular Measures Data

Table 1: Resting heart rate at baseline and 12 weeks post FES-ambulation.

Participant	Pre-Exercise	Post-Exercise
1	70	78
2	82	83
3	61	62
4	69	68
5	76	71
6	66	63
AVG	70.7	70.8
S.D	7.42	8.3

Table 2: Mean arterial pressure at baseline and 12 weeks post FES-ambulation.

Participant	Pre-Exercise	Post-Exercise
1	105	92.3
2	98.3	98.3
3	91.7	97
4	92	86
5	105	80
6	90	80
AVG	97	88.9
S.D	6.81	8.15

***Table** 3:* Systolic blood pressure at baseline and following 12 weeks of FES-ambulation

Participant	Pre-Exercise	Post-Exercise
1	155	137
2	135	135
3	115	131
4	132	120
5	135	100
6	120	100
AVG	132	120.5
S.D	14	16.93

***Table 4**:* Diastolic blood pressure at baseline and following 12 weeks of FES-ambulation

Participant	Pre-Exercise	Post-Exercise
1	80	70
2	80	80
3	80	80
4	72	69
5	90	70
6	75	70
AVG	79.5	73.2
S.D	6.1	5.3

Table 5: Pulse pressure at baseline and following 12 weeks of FES-ambulation

Participant	Pre-Exercise	Post-Exercise
1	75	67
2	55	55
3	35	51
4	60	51
5	45	30
6	45	30
AVG	52.5	47.3
S.D	14.1	14.7

Appendix J – WISCI II Guide

Walking Index for Spinal Cord Injury (WISCI II) Descriptors

Physical Limitation for walking secondary to impairment is defined at the person level and indicates the ability of a person to walk after spinal cord injury. The development of this assessment index required a rank ordering along a dimension of impairment, from the level of most severe impairment (0) to least severe impairment (20) based on the use of devices, braces and physical assistance of one or more persons. The order of the levels suggests each successive level is a less impaired level than the former. The ranking of severity is based on the severity or the impairment and not on functional independence in the environment. The following definitions standardize the terms used in each item:

Physical assistance: 'Physical assistance of two persons' is moderate to maximum assistance. 'Physical assistance of one person' is minimal to moderate assistance.

Braces: 'Braces' means one or two braces, either short or long leg. (Splinting of lower extremities for standing is considered long leg bracing). 'No braces' means no braces on either leg.

Walker: 'Walker' is a conventional rigid walker without wheels.

Crutches: 'Crutches' can be Lofstrand (Canadian) or axillary.

Cane: 'Cane' is a conventional straight cane.

Level Description

0 Client is unable to stand and/or participate in assisted walking.

1 Ambulates in parallel bars, with braces and physical assistance of two persons, less than 10 meters

2 Ambulates in parallel bars, with braces and physical assistance of two persons, 10 meters.

3 Ambulates in parallel bars, with braces and physical assistance of one person, 10 meters.

4 Ambulates in parallel bars, no braces and physical assistance of one person, 10 meters

5 Ambulates in parallel bars, with no braces and no physical assistance, 10 meters.

6 Ambulates with walker, with braces and physical assistance of one person, 10 meters.

7 Ambulates with two crutches, with braces and physical assistance of one person, 10 meters.

8 Ambulates with walker, no braces and physical assistance of one person, 10 meters.

9 Ambulates with walker, with braces and no physical assistance, 10 meters.

10 Ambulates with one cane/crutch, with braces and physical assistance of one person, 10 meters.

11 Ambulates with two crutches, no braces and physical assistance of one person, 10 meters.

12 Ambulates with two crutches, with braces and no physical assistance, 10 meters.

13 Ambulates with walker, no braces and no physical assistance, 10 meters.

14 Ambulates with one cane/crutch, no braces and physical assistance of one person, 10 meters.

15 Ambulates with one cane/crutch, with braces and no physical assistance, 10 meters.

16 Ambulates with two crutches, no braces and no physical assistance, 10 meters.

17 Ambulates with on devices, no braces and physical assistance of one person, 10 meters.

18 Ambulates with on devices, with braces and no physical assistance, 10 meters.

19 Ambulates with one cane/crutch, no braces and no physical assistance, 10 meters.

20 Ambulates with no devices, no braces and no physical assistance, 10 meters.

Appendix K – Short Form-36

1. In general, would you say your health is:
   - Excellent
   - Very Good
   - Good
   - Fair
   - Poor
2. Compared to one year ago, how would you rate your health in general now?
   - Much better than one year ago
   - Somewhat better than one year ago
   - About the same as one year ago
   - Somewhat worse now than one year ago
   - Much worse now than one year ago

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? **(Please circle one number on each line.)**

   (Yes, Limited A Lot – 1) (Yes, Limited A Little - 2) (Not Limited At All – 3)

   3(a) **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports.
   3(b) **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
   3(c) Lifting or carrying groceries
   3(d) Climbing **several** flights of stairs
   3(e) Climbing **one** flight of stairs
   3(f) Bending, kneeling, or stooping
   3(g) Walking **more than a mile**
   3(h) Walking **several blocks**
   3(i) Walking **one block**
   3(j) Bathing or dressing yourself

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? **(Please circle one number on each line.)**

   (Yes – 1) (N0 – 2)

   4a) Cut down on the **amount of time** you spent on work or other activities
   4b) Accomplished less than you would like
   4c) Were **limited** in the **kind** of work or other activities
   4d) Had **difficulty** performing the work or other activities (for example, it took extra effort)

5. During the past 4 weeks, have you had any of the following problems with your work or other daily activities as a result of any emotional problems (eg. Feeling depressed or anxious)? **(Please circle one number on each line.)**

   (Yes – 1) (N0 – 2)

5(a) Cut down on the **amount of time** you spent on work or other activities
5(b) Accomplished less than you would like
5(c) Didn't do work or other activities as **carefully** as usual

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?
   - Not at all
   - Slightly
   - Moderately
   - Quite a bit
   - Extremely

7. How much physical pain have you had during the past 4 weeks?
   - None
   - Very mild
   - Mild
   - Moderate
   - Severe
   - Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
   - Not at all
   - Slightly
   - Moderately
   - Quite a bit
   - Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that is closest to the way you have been feeling for each item. (**Please circle one number on each line.)**

   (All of the Time – 1) (Most of the Time – 2) (A Good Bit of the Time – 3)
   (Some of the Time – 4) (A Little of the Time – 5) (None of the Time – 6)

   9(a) Did you feel full of life?
   9(b) Have you been a very nervous person?
   9(c) Have you felt so down in the dumps that nothing could cheer you up?
   9(d) Have you felt calm and peaceful?
   9(e) Did you have a lot of energy?
   9(f) Have you felt downhearted and blue?
   9(g) Did you feel worn out?
   9(h) Have you been a happy person?
   9(i) Did you feel tired?

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfere with your social activities (like visiting with friends, relatives etc.)
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time

- None of the time

11. How TRUE or FALSE is each of the following statements to you? **(Please circle one number on each line.)**

    (Definitely True – 1) (Mostly True – 2) (Don't Know – 3) (Mostly False – 4) (Definitely False – 5)

    11(a) I seem to get sick a little easier than other people
    11(b) I am as healthy as anybody I know
    11(c) I expect my health to get worse
    11(d) My health is excellent

Appendix L – Perceived Stress Scale

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate with a check how often you felt or thought a certain way.

1. In the last month, how often have you been upset because of something that happened unexpectedly? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

2. In the last month, how often have you felt that you were unable to control the important things in your life? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

3. In the last month, how often have you felt nervous and "stressed"? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

4. In the last month, how often have you felt confident about your ability to handle your personal problems? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

5. In the last month, how often have you felt that things were going your way? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

6. In the last month, how often have you found that you could not cope with all the things that you had to do? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

7. In the last month, how often have you been able to control irritations in your life? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

8. In the last month, how often have you felt that you were on top of things? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

9. In the last month, how often have you been angered because of things that were outside of your control? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? ___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

Appendix M – WHOQOL-BREF

WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5

23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Appendix N – CES-D

During The Past Week

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	☐	☐	☐	☐
2. I did not feel like eating; my appetite was poor.	☐	☐	☐	☐
3. I felt that I could not shake off the blues, even with help from my family or friends.	☐	☐	☐	☐
4. I felt I was just as good as other people.	☐	☐	☐	☐
5. I had trouble keeping my mind on what I was doing.	☐	☐	☐	☐
6. I felt depressed.	☐	☐	☐	☐
7. I felt that everything I did was an effort.	☐	☐	☐	☐
8. I felt hopeful about the future.	☐	☐	☐	☐
9. I thought my life had been a failure.	☐	☐	☐	☐
10. I felt fearful.	☐	☐	☐	☐
11. My sleep was restless.	☐	☐	☐	☐
12. I was happy.	☐	☐	☐	☐
13. I talked less than usual.	☐	☐	☐	☐
14. I felt lonely.	☐	☐	☐	☐
15. People were unfriendly.	☐	☐	☐	☐
16. I enjoyed life.	☐	☐	☐	☐
17. I had crying spells.	☐	☐	☐	☐
18. I felt sad.	☐	☐	☐	☐
19. I felt that people disliked me.	☐	☐	☐	☐
20. I could not get "going".	☐	☐	☐	☐

Appendix O – Task Self-Efficacy

Task Self-Efficacy

Please state your <u>CONFIDENCE</u> in *your abilities* to <u>PERFORM</u> the following behaviours.

Use the scale below to answer.

WRITE the confidence value for each behaviour in the space provided.

0	10	20	30	40	50	60	70	80	90	100

How confident are you that you can:

1. Walk a distance of 100m continuously? ______
2. Walk a distance of 200m continuously? ______
3. Walk a distance of 300m continuously? ______
4. Walk a distance of 400m continuously? ______
5. Walk up a 30m, 1:12 slope ramp unassisted? ______
6. Walk down a 30m, 1:12 ramp unassisted? ______
7. Walk up a staircase consisting of 5 steps unassisted? ______
8. Walk down a staircase consisting of 5 steps unassisted? ______

Appendix P – Ethics Clearance

Bioscience Research Ethics Board

DATE: 6/14/2012

PRINCIPAL

INVESTIGATOR: DITOR, David - Physical Education and Kinesiology

RE: Final Report

FILE: 10-275 - DITOR

Original clearance date: 6/22/2011

TYPE:	Master's Thesis/Project	STUDENT:	Hisham Sharif
		SUPERVISOR:	David Ditor

Thank you for completing a ***Final Report*** for your project:

The effects of FES-ambulation exercise on walking ability, cardiovascular fitness and psychological well-being in individuals with incomplete spinal cord injury

The Social Sciences Research Ethics Board understands that research participants are no longer being studied or followed for the above research and therefore your file has now been closed.

*** Final Report Accepted.**

Brian Roy

Bioscience Research Ethics Board

BR/em