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Functional Electrical Stimulation as a Treatment for Spinal Cord Injuries

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Functional Electrical Stimulation
as a Treatment for Spinal Cord Injuries

by

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Bachelor of Science in Physical Therapy
University of North Dakota, 1995

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

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This Independent Study, submitted by Gail Marie Garrett in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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Title                    Functional Electrical Stimulation as a treatment for Spinal Cord Injury

Department              Physical Therapy

Degree                  Masters of Physical Therapy

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ABSTRACT

Injury of the spinal cord resulting in quadriplegia or paraplegia is one of the most devastating conditions a person can experience. The majority of these individuals that suffer from a spinal cord injury are young males. The inability to ambulate is generally a major concern for these patients, but there are also degenerative and deconditioning effects of the spinal cord injury which may lead to devastating secondary complications that must be addressed.

Functional electrical stimulation (FES) has been the subject of much research concerning the rehabilitation for patients with spinal cord injury. Functional electrical stimulation is a way to activate motor neurons to elicit a muscular contraction in order to achieve a functional or therapeutic effect.

The purpose of this paper is to analyze and review the literature regarding current uses of functional electrical stimulation in the person with a spinal cord injury to restore functional movement in the lower extremities. This study will be focused on cardiovascular conditioning, muscle development, and applications of FES to assist standing and ambulating. The physiological benefits of
these activities will also be explored and the role functional electrical stimulation plays in preventing and correcting secondary complications will be discussed.

Information resulting from this study will serve as a reference to aid physical therapists in the clinical management and rehabilitation of patients with spinal cord injuries through the use of functional electrical stimulation.
CHAPTER 1

INTRODUCTION

It is estimated that 11,000 new cases of spinal cord injuries that result in some type of functional impairment occur in the United States each year.\textsuperscript{1,2} This implies that there are approximately 200,000 people living in the United States with spinal cord injuries.\textsuperscript{1} Of these injuries, 7000-8000 are due to trauma and the remaining are caused from disease and congenital anomalies.\textsuperscript{2}

Spinal cord injuries are most prevalent in young adults.\textsuperscript{3} Sixty percent of all spinal cord injuries occur between the ages of 16-30.\textsuperscript{3} Eighty-five percent of all injuries occur to people under the age of 40.\textsuperscript{1,3-4} The overall health care cost is estimated to be 30 to 40 billion dollars annually. Surprisingly, the majority of expenses are not due to the initial acute and rehabilitation care costs. Rather, the costs are largely due to subsequent hospitalization and secondary complications of the SCI.

History of Spinal Cord Injuries

References to spinal cord injury have been discovered in
records as far back as five thousand years ago. Egyptian physicians described symptoms of complete spinal cord lesions. These physicians diagnosed SCI as an "ailment not to be treated." Early pessimistic attitudes were exemplified throughout the thousands of years to follow. Before the 1940's, people with spinal cord injuries only lived for a brief period of time, thus, they were given very minimal medical attention. This was still evident during the second World War. The patients who sustained spinal cord injuries during the war had very short life expectancies, primarily due to sepsis from urinary tract infection and pressure sores. The medical complications were viewed as inevitable, therefore, little was done to try and rehabilitate the patients.

The rehabilitation for the patient with a spinal cord injury was at its infantile stages of development during World War II. Nevertheless, much to the surprise of medical personnel, small numbers of patients with low level spinal cord injuries were surviving. However, patients continued to be plagued with urinary tract infections and other complications due to the absence of antibiotic drugs, and most remained hospitalized. By the 1950's, antibiotics became available and many patients with SCI's were able to live and survive at home.
Advances in SCI rehabilitation were continually being applied throughout the 1960's and 1970's.\textsuperscript{4,5} During the 1970's, advances in emergent services and development of special care centers increased the survival rate of patients with SCI. However, the quality of life for the individuals with spinal cord injuries were becoming a concern.\textsuperscript{4}

Recently, research\textsuperscript{2} has focused on increasing the quality of life for patients with SCI. Treatments for patients with spinal cord injury are continuing to improve. Different organizations and programs such as vocational rehabilitation are giving patients more opportunities and chances to become productive members of society.\textsuperscript{8} For example, the International Medical Society of Paraplegia is an organization dedicated to improving spinal cord injury care and increasing quality of care.\textsuperscript{8}

Phases of Care

The treatment plan for the patient with a SCI is broken down into four phases: these are the emergent care phase, the acute care phase, the rehabilitation phase, and the community phase.\textsuperscript{3} Emergent care for the patient is very critical, and proper care starts for the patient at the time of injury. The patient must be handled
and immobilized properly and moved with extreme caution. Emergent care plays a crucial and direct role in patient outcome.

The acute care phase is also of extreme importance. This phase includes realignment and stabilization of the spine. A general assessment of the patient is performed at this time to determine the lesion level, to identify general functional abilities, and to help formulate the appropriate treatment plan. Areas included in the assessment are: respiratory function, muscle strength and tone, sensory function, and skin condition. The acute phase continues until the patient is able to begin the rehabilitation phase.

During the rehabilitation phase, the patient learns skills to increase independence. Specific long-term functional goals are established as an overall rehabilitation plan. The patient is more stable and more mobile during this phase, thereby allowing specific testing and assessment of the patient. This phase is usually very strenuous and exhausting for the patient.

The final phase is the community phase, which continues throughout the patients’ life. This phase involves different challenges such as employment, independent living, and social activities. Integrating the patient back into society is an important goal to most patients with SCI.
Roles of Physical Therapy

Grundy and associates,\textsuperscript{4} recommended that physical therapy for the patient with a spinal cord injury begin as soon as possible. It should be initialized in the acute setting, once the patient has been stabilized. The physical therapist's focus during this time is to maintain range of motion by preventing contractures through range of motion exercises, stretching exercises, and positioning.\textsuperscript{4} Therapists also work to maximize the available musculature and to get the patient into a sitting position as soon as possible. The patient should be able to tolerate a sitting position well before initiating the rehabilitation phase.\textsuperscript{1}

Obtaining a vertical position is achieved only through a slow progression.\textsuperscript{3} The vertical position causes cardiovascular insufficiencies that may result in hypotention, vertigo, diaphoresis and visual disturbances. Ace wrapping, compression pumps, and compression stockings are used on the lower extremities to combat the venous insufficiencies that are prominent in SCI.\textsuperscript{1,4}

The major goal for the rehabilitation phase is to maximize the level of independence for the patient.\textsuperscript{1,4,5,6} Grundy et al,\textsuperscript{4} recommended that realistic goals be set by the physical therapist and the patient with the SCI. Appropriate goals are based on the
patient’s parameters, his or her capabilities, and the support systems available including: family, friends, and funding sources.

Secondary Complications

Muscular atrophy, decreased circulation and decreased oxygen uptake in the paralyzed musculature, demineralization of bone, and decreased cardiovascular function are effects of SCI which result in an increased risk for secondary complications. These risks include: increased risk of decubiti, increased respiratory complications, increased thrombophlebitis, and increased urinary tract complications. Secondary complications of SCI also cause an increased risk of heart disease, which is the number one cause of death in the SCI population.

A number of factors are associated with cardiovascular conditions in SCI. When viewing the general population, Ragnarsson concluded that an inverse relationship exists between high-density lipoproteins (HDL) and coronary heart disease. It’s believed that regular aerobic exercise may raise the serum HDL level. Serum HDL levels are significantly lower in the SCI patients when compared to the nondisabled population.

It has been documented that cardiovascular fitness is reduced in SCI due to insufficient voluntary muscle mass available to
produce the necessary cardiovascular stress. Cardiovascular stress is vital for maintenance of an adequate cardiovascular fitness level. Complaints of fatigue and poor general endurance post SCI may be related to the lack of cardiovascular fitness.\textsuperscript{10}

The total muscle mass needed to perform voluntary exercise is limited to the upper extremities and trunk in patients with paraplegia.\textsuperscript{7,9,10} Patients with quadriplegia are limited to a small part of the shoulder and neck musculature. This muscle mass is not adequate to produce the cardiovascular stress necessary to improve or even maintain fitness. Also, it is believed that with upper extremity exercise alone, compensatory vasodilatation does not occur in paralyzed musculature, resulting in the following problems: poor distribution of blood to exercising musculature, lower blood pressure, and inadequate cardiac output. Upper extremity exercise has been shown to be less effective for cardiovascular fitness in the nondisabled population as well.\textsuperscript{7} The reduced cardiovascular exercise response (reduced maximal heart rate and cardiac output) may also be affected by the loss of supraspinal sympathetic control in complete cervical and high thoracic SCI.\textsuperscript{8,9}

The loss of voluntary muscle control causes a loss of venous circulation and an impaired fibronolytic activity.\textsuperscript{10} This is directly
related to the high incidence of deep venous thrombosis (DVT). Blood is normally "pumped" through the venous system by active contraction of the lower extremity musculature. With the absence of lower extremity muscular contraction, the flow of blood is slowed, allowing a higher concentration of procoagulants to develop in localized areas. This, in turn, results in a predisposition to thrombus formation. Absence of muscular activity also contributes to leg edema during the rehabilitative and community phases.9

In the SCI population, weight loss occurs initially.15,16 However, due to their subsequent sedentary lifestyle, weight gain and obesity may become a concern. Increased weight is not only a health risk, but may also interfere with activities of daily living (ADL's) and function. Even when weight gain is not apparent, studies of body composition have shown that the paralyzed limbs contain more body fat than muscle mass.7,10

Osteoporosis is a disease that often effects the SCI population.4,6,7,16 The bones in the paralyzed limbs do not receive mechanical stress due to the absence of muscle contractions. There is also decreased longitudinal loading as a result of decreased weight bearing. Without these necessary stresses, there is a lack of proper
bone remodeling resulting in faster reabsorption of bone than formation of bone.

Muscle atrophy is also apparent in SCI due to the disuse of the paralyzed muscles.\textsuperscript{7,11,12} Spastisity is often seen in the SCI population, but this does not deter muscle atrophy. The muscle wasting is associated with certain histochemical changes within the muscle.\textsuperscript{7,11} There are more type II muscle fibers (fast twitch, anaerobic) than there are type I (slow twitch, aerobic). There is also a reduction in mitochondria concentration, oxidative enzyme level, and number of capillaries, which provides evidence of muscle wasting. In addition, researchers,\textsuperscript{11} concluded that the atrophy of the gluteus musculature leads to the frequent development of ischial pressure sores.

Disuse of paralyzed musculature is also believed to influence somatic and autonomic spinal reflexes.\textsuperscript{7} Dysynergic neurogenic bladder, irregular evacuation of bowels, autonomic dysreflexia, circulation disturbances, and spasticity may be related to lack of muscular contraction. There is no conscious sensation from the paralyzed body parts; however, peripheral nerves are functioning. The afferent stimulation can not be transferred to the brain because of the lesion. When the sensory input is strong, for example, when
suffering from multiple ailments, signals are spread through the internuncial neurons at various levels and may produce strong motor responses.\textsuperscript{7,11} These motor responses may appear through increased spasticity of striated muscles, or hypertonicity of smooth muscles, which could adversely affect many organ systems. Ragnarsson,\textsuperscript{7} proposed that these symptoms could be reduced with elimination of noxious stimuli, such as those from pressure sores, stiff joints, and edema through physical exercise.

Secondary complications associated with SCI are related to and increased by the lack of physical exercise.\textsuperscript{7,10-14} It is believed that these secondary complications can be controlled through fitness training achieved by using functional electrical stimulation (FES) of the lower extremity for an exercise effect. Physiological benefits of FES induced exercise and ambulation with orthotics as an adjunct may help prevent osteoporosis, increase muscular strength, increase endurance, increase aerobic fitness, and increase cardiac output and improve physiological function. Of equal importance are the psychological benefits associated with exercise and the ability to stand independently.

The purpose of this paper is to analyze and review the literature regarding current uses of functional electrical stimulation
in the person with a spinal cord injury to restore functional movement in the lower extremities. Topics that will be discussed include: cardiovascular conditioning, muscle development, prevention of secondary complications, physiological benefits, and applications of FES to assist standing and walking.
CHAPTER II

ACTIVE PHYSICAL THERAPY

Active physical therapy (APT) has been defined as a system in which functional electrical stimulations are applied to paralyzed extremities.\textsuperscript{17,18} Closed-looped functional electrical stimulation is used to activate the paralyzed muscles so they are made to perform useful work.\textsuperscript{17,18} This enables previously deconditioned muscles to participate in the physical reconditioning. The paralyzed limbs are electrically stimulated to activate the muscles to perform specific motions at a certain load and rate. In APT, the muscles are contracting and acting upon their environment to produce the exercise effect. When contrasted to conventional physical therapy (no FES), it is the environment manipulating the passive muscles to get the exercise effect. Functional Electrical Stimulation (FES) or Functional Neuromuscular Stimulation (FNS) has been used to recondition muscular strength and endurance in SCI and also to elicit functional ambulation in conjunction with orthotics.

Petrofsky and Phillips,\textsuperscript{17,18} were the first to describe APT. The equipment utilized in APT includes an FES isokinetic leg trainer and
an FES exercise bicycle ergometer. With the development of a functional ambulation system, FES in conjunction with orthodics, much of the focus has been directed to patients with SCI and ambulation. However, prior to FES augmented ambulation, the patients with SCI are required to participate in strengthening and cardiovascular endurance training with the isokinetic leg trainer and bicycle ergometer.

The leg trainer system was developed to provide a form of isokinetic exercise for paralyzed muscles.\textsuperscript{16,17} In essence, the leg trainer system is a form of weight lifting. The quadriceps of one leg are stimulated and a certain amount of weight is connected to a weight pan. The patient performs 45 degrees of knee extension and flexion in repetitive cycles.\textsuperscript{18} The patient generally exercises each leg for fifteen minutes (total of thirty minutes). Fatigue is said to occur when the patient can no longer lift his or her leg through 30 degrees of motion.\textsuperscript{18,19,20} This is the typical protocol for the training program prior to bike ergometry. The isokinetic leg trainer consists of a closed loop computer directed stimulation unit. Close loop control is achieved through a sensor placed in series with a weight pan to provide input for the computer. This allows stimulated
muscle contractions to occur in a slow and smooth manner and also prevents hyperextension of the knee.

There has been a training effect documented with the previously described leg trainer.\textsuperscript{18,19,20} Subjects from a number of studies\textsuperscript{7,17-19} demonstrated increased strength and endurance during FES leg training. Petrofsky and Phillips\textsuperscript{17} reported an approximate doubling of quadriceps strength over a three week training period. A seven fold increase in quadriceps strength in a twelve week training period was reported by Collins et al.\textsuperscript{20-22} Both groups used a high intensity protocol to achieve the results.\textsuperscript{17,20} Other studies,\textsuperscript{7,17,18,19} have reported increased thigh girth measurements, quadriceps strength, and decreased spasticity with FES leg training.

The other component of the APT system, the bicycle ergometer, was developed to provide a type of aerobic exercise for paralyzed muscles.\textsuperscript{22,23} This is of particular interest since this more aerobic form of exercise has the potential to improve cardiovascular fitness.

The bicycle ergometer (known commercially as the ERGYS clinical rehabilitation system) offers a unique opportunity to improve the state of health and overall fitness level of patients with SCI.\textsuperscript{24} The bicycle ergometer uses advanced computer technology to
stimulate muscles at multiple sites in the lower extremity in an organized, cyclic pattern.24

Electrodes are applied to the skin directly over the individual muscles causing them to contract. The pattern in which the muscles contract is controlled by the computer built into ERGYS (bicycle ergometer). The electrical stimulation is supplied through the ERGYS.

The ERGYS uses a closed loop control system to deliver, monitor and regulate the stimulus.24 Through the use of feedback sensors, proper monitoring and control of muscle activation is accomplished for six separate channels of sequential stimulation. Stimulation is delivered to the quadriceps, hamstrings, and gluteal musculature. Position sensors coupled to the crank of the ergometer continuously monitor the position and velocity of the users leg. This enables the computer to apply stimulus to the muscles in the correct sequence, for the proper duration, and at the appropriate amplitude to achieve smooth, rhythmic pedaling motions on the ergometer.

The computer constantly adjusts the level of stimulus applied to muscles in an attempt to maintain a pedaling speed of 50 RPM's (revolutions per minute).24 If the speed rises above the preselected speed, the computer automatically reduces the stimulus so the velocity drops to the target rate. Conversely, if the speed should
drop below 50 RPM stimulus levels are increased. However, the stimulus rise is also controlled by a current output which is limited to approximately 130 mA.\textsuperscript{17,24}

If the amount of stimulation is not sufficient to maintain 50 RPM, the pedaling speed will drop to some lower level.\textsuperscript{24} The computer will allow this decrease in speed to occur until the user is unable to maintain at least 35 RPM, at which point the run is automatically interrupted. This is done for two reasons: first, the inability to maintain a higher pedaling rate at maximum stimulus levels is an indication of muscle fatigue; and second, at speeds below 35 RPM the user may no longer be gaining the full medical benefits of the therapy.\textsuperscript{24}

In addition to monitoring the speed and stimulus level, the computer continuously measures the resistance applied to the flywheel.\textsuperscript{24} Pedaling resistance is added automatically and gradually by the computer. If the computer senses the onset of fatigue, it decreases resistance in order to increase the probability of completing the session.

In bicycle ergometers designed for SCI usage, the chair is equipped with adjustable height and seat depth for production of
optimal firing angles. Shoulder and lap belts are utilized to maintain appropriate posture. Seats are made to rapidly recline to the horizontal position. Knee stabilizers and leg restraints allow for pedaling to take place in a planer motion and protective boots are worn to prevent skin abrasions while cycling.

As previously explained, the computer constantly monitors the performance of the user in order to control the proper application of stimulus. This monitoring allows the system to detect the onset of fatigue and to automatically terminate the run before the point of overexertion is reached. This same mechanism allows the computer to sense spasticity or other abnormal muscle responses and interrupts treatment. The bicycle ergometer is equipped with the capacity to measure the impedance of the electrode-gel-skin interface and continuously evaluate the integrity of that current path. It automatically will stop the application of stimulus if an increased impedance is detected. These protective options on the ERGYS ensure the safety of the patient.

With the use of FES bicycle ergometer, a wide range of benefits have been reported including: reduced muscle spasm frequency and a decrease of disuse atrophy. Several studies have shown that patients with SCI exhibit significantly higher
post training peak power output (PO), oxygen uptake (VO₂), pulmonary ventilation (VE), heart rate (HR), blood flow capacity (Qt), and a significantly lower total peripheral resistance (TPR).

Studies²⁷-³¹ have demonstrated an increased peak in VO₂ levels, which is used as a index for cardiovascular fitness. However, questions to which physiological system, peripheral or central, support the higher levels of metabolism post FES lower extremity bicycle ergometry exercise persist.³⁰-³³ FES peripherally induces muscle contractions, and SCI interrupts pathways for autonomic sympathetic control of these systems. Therefore, typical responses with voluntary lower extremity exercise in the nondisabled population may not occur to the same extent with FES lower extremity ergometry exercise by persons with SCI.

As previously mentioned, physiological adaptations to exercise may be categorized as peripheral or central adaptations.³⁰,³¹ Peripheral adaptations (within muscles) are related to histochemical changes such as hypertrophy of muscle fiber, greater capillary density, increased concentration of oxidative enzymes, increased concentrations of mitochondria, and increased storage of fuel substrates and high energy compounds.²⁵-²⁸ These types of changes result in enhanced muscular strength and endurance capacities.
Central adaptations result in improved function of the cardiorespiratory system. Central adaption changes result in enhanced capabilities of delivering blood, oxygen, and fuel to exercising muscles. Therefore, for the most desirable outcomes of aerobic training, both peripheral and central adaptions are required to enhance the ability to pickup, deliver and consume oxygen.

In the peripheral muscular system, it is believed that FES induced ergometry may cause histochemical changes in paralyzed muscles that are able to support greater levels of aerobic and anaerobic metabolism. Histochemical changes include increased concentrations of glycogen, mitochondria, oxidative and glycolytic enzymes combined with increased capillary density in musculature and therefore, greater blood perfusion. Increases in endurance are in part, attributed to hypertrophy of muscular fibers and changes in muscle characteristics from type II fibers (fast anaerobic) to type I fibers (slow aerobic).

Despite the disruption of autonomic sympathetic outflow, studies have reported that bicycle ergometry can elicit relatively high levels of metabolic and cardiopulmonary responses in SCI. In fact, following a period of training, the magnitude of these
responses may be similar to those of able-bodied individuals during walking or a slow jog.\textsuperscript{12}

For persons with paraplegia, there is a decrease in resting blood pressure and total peripheral resistance, and an increased stroke volume.\textsuperscript{33,34} This reveals that cardiorespiratory adaptations are similar to those seen in the able-bodied population (with the exception of a nonsignificant decrease in heart rate) who participate in a voluntary aerobic exercise program.\textsuperscript{12,30} Compared to patients with paraplegia, patients with quadriplegia have demonstrated lower resting blood pressure and heart rate pre and post training.\textsuperscript{12,35} This is thought to be due to the cervical transection which disrupts suprasegmental control over the sympathetic nervous system resulting in decreased resting plasma levels of epinephrine and norepinephrine.\textsuperscript{12,35} Also, because of a lack of sympathetic control to the heart, there is vagal dominance which results in a reduction in heart rate and an unstable blood pressure.\textsuperscript{24}

Although the precise control mechanisms for pulmonary and cardiovascular responses during FES lower extremity bicycle ergometry remain unknown; it appears that appropriate central circulatory adjustments to higher post training peak VO\textsubscript{2} are
present. However, the theories based upon increased central training effects have not been proven unequivocally. Therefore, controversy still exists over increases in peak aerobic metabolism and increases in power output being attributed to peripheral muscular training, central cardiac training, or both.

FES lower extremity ergometry has also been postulated to have positive effects on secondary complications related to SCI. A study of 51 SCI subjects who underwent FES lower extremity ergometry for one year were compared to 6000 SCI patients without FES lower extremity ergometry. The report revealed that lower incidence of pressure sores, fractures, kidney infections, bladder infections, and thrombophlebitis were found in the group undergoing FES ergometry. Health care costs were also found to be significantly reduced in this study, because not one of the patients in the exercising group required hospitalization during that year spent performing ergometry. This is compared to an estimated $12,000 per year spent on the control group. Petrofsky has estimated medical savings to be two million dollars per SCI patient over his or her lifetime.

The medical criteria for SCI patient participation in any type of FES training has been described by Phillips. The phrenic nerve
(nerve roots C3, C4, C5) innervates the diaphragm, which is necessary for breathing. The upper limit of SCI for participation is at C4-C5, to ensure sufficient diaphragmatic breathing. The upper limit for FES with conjunction with orthotics is set a little lower, at C6-C7. The lower level for APT participation is defined at T11-T12. At this level, the injury is still considered an upper motor injury. If the injury is at a lower level, it results in an equina type injury in which peripheral alpha motor nerves are injured. It has been well established that FES is not successful with lower motor neuron lesions.\(^\text{17}\)

Muscle spasms must be minimal or controlled by medication. It is potentially hazardous to stimulate movement in prescribed movement patterns during spastic muscle activity.\(^\text{17,37,39}\) As predescribed, the computer is programmed to shut down once a muscle spasm is detected.\(^\text{24}\)

A major precaution for APT is disuse osteoporosis. An osteoporosis scale has been defined at five levels: normal, mild, moderate, moderate-severe, or severe osteoporosis.\(^\text{17,39,40}\) In order to participate in APT the patient must be at a moderate level or better. The reason is that fractures are a primary risk in APT. The hip, knee, and ankle joints must be evaluated. If moderate to severe degenerative joint disease (DJD) is present, APT is contraindicated.
Patients presenting with angina, coronary artery disease, chronic obstructive pulmonary disease, and chronic skin disease should be closely monitored by respective specialists prior to and during any FES exercise program. Absolute contraindications for patient participation in APT program include patients with uncontrolled hypertension, respiratory infections, and chronic renal disease.
CHAPTER III

SCI AMBULATION

There have been numerous benefits reported regarding achievement of an upright position by persons with spinal cord injuries.\textsuperscript{37-39,41,42} The postulated benefits of standing include: prevention of contractures in lower limbs, diminished osteoporosis, stimulation of circulation, reduction of spastisity, improved positioning of internal organs, improved renal functions, and reduced chance of pressure sores.\textsuperscript{37,38,43-48} In addition, increased functional abilities while standing may enhance personal self-esteem.\textsuperscript{37} For these reasons, standing has been emphasized in many rehabilitation programs.\textsuperscript{37} One of the main goals of many patients with SCI is to stand and walk again.\textsuperscript{37,43}

Numerous methods for restoring standing and walking for the patient with SCI have been reported in the literature.\textsuperscript{37-40,48-50} Options for achieving standing and ambulation include: bracing, passive standing, and functional electrical stimulation. During the last two decades, investigators have been trying to improve standing
and ambulation techniques through rehabilitation engineering.\textsuperscript{38} Efforts have been invested in two different directions. First, improvement of conventional long leg bracing; and the second, through applications of electrical stimulation for functional activities of the lower limbs.

Traditionally, standing and ambulation for patients with SCI have been with a knee-ankle-foot orthosis (KAFO), or hip-knee-ankle-foot orthosis (HKAFO) and crutches or other types of walking aids.\textsuperscript{38-40} The literature indicates a high rejection rate for this technique. Heinemann et al,\textsuperscript{40} has shown that only 26\% of patients who were prescribed with KAFOs continued to use them for any purpose, with only 4\% using them as a sole means of mobility. Significant energy consumption, which has been shown to be 5 to 12 times that of normal gait, is a major reason for the high rejection rate of KAFOs.\textsuperscript{41,42} Other reasons include difficulty in donning and doffing the device, frequent pressure sores, heaviness, cosmesis, and need for individual fitting and fabrication.\textsuperscript{37-39} One advantage of bracing is that it provides stable mechanical support.\textsuperscript{38} A Craig-Scott orthosis, an updated version of the KAFO, was shown to have improved patient compliance rates although energy costs remained high; therefore, long term functional use remains limited.\textsuperscript{38}
Other orthosis, such as the ORLAU swivel walker,\textsuperscript{43} reciprocal gait orthosis (RGO),\textsuperscript{44,51,52} and hip guidance orthosis (HGO)\textsuperscript{45} have been developed primarily for gait facilitation. Ambulation has been achieved in a safe manner and improvements in energy expenditure are noted. However, the RGO, which is the most energy efficient of the above listed orthosis, still requires three times the energy consumption compared to normal gait.

The other field of interest lies in the use of functional electrical stimulation as a method of standing and ambulation for patients with SCI. In 1960, Kantrowitz,\textsuperscript{37} reported on the use of electrical stimulation to enable a paraplegic to stand. Since that time a number of researchers have obtained standing and ambulation with patients with SCI using a variety of FES approaches.\textsuperscript{37}

FES has been applied using three different types of stimulation methods: implanted electrodes on nerves that stimulate the extensor muscles,\textsuperscript{46} percutaneous intramuscular electrodes,\textsuperscript{47} or electrodes on the surface of the skin.\textsuperscript{48} Difficulties have been found with each of these stimulation methods. Implantable systems require an extensive surgical procedure, thus many patients opt not to undergo such an evasive procedure. The percutaneous electrode system involves direct electrode placement on motor points through a
needle-like sheath. This system allows a higher number of muscles to be stimulated, with minimal intensity due to lack of skin impedance, and allows selectivity for deep musculature. Disadvantages of this system include increased risk of infection, and a tendency for electrodes to migrate from their original site or to break. Percutaneous electrodes also fail at a rate of approximately 2% per month, thereby it is difficult to use them on a long term basis.\textsuperscript{37} Surface electrodes require daily placement and removal.

Yarkony\textsuperscript{37} and others\textsuperscript{38,49,51} have focused on surface electrode placement with an open-loop control system (without direct force and position feedback from muscles or limbs). Researchers\textsuperscript{37,38,49,51} have focused on using the patient's remaining capabilities. Patients with a SCI still have spinal cord reflexes, the applied systems take advantage of this fact. The swing phase of gait in this type of system is accomplished by peroneal nerve afferent stimulation which triggers a reflex synergistic flexion response, thereby reducing the number of muscles to be stimulated for flexion and leg advancement.\textsuperscript{51} The stance phase is achieved by locking the knee into extension through continuous stimulation of the quadriceps while the patient stands in a hyperlordotic posture, thus enabling hip stabilization through ligament tension.\textsuperscript{51}
A minimal of four channels are required for synthesis of a simple reciprocal gait pattern.\textsuperscript{37} The stimulation frequency can be varied between 5 to 500 Hz, and the duration of rectangular monophasic pulses between 0.05 to 3 msec.\textsuperscript{51} The amplitude of stimulation voltage can be adjusted from 0 to 150v.\textsuperscript{51} The electrical stimulation is controlled through three different phases of stimulation: double stance, left swing, and right swing. This is accomplished with the use of two hand switches mounted on the walking device. When neither of the switches are pressed, the quadriceps are stimulated. When the switch is pressed in the right hand, the right leg is stimulated to flex, and when the left switch is pressed the left leg is subsequently flexed. A special electronic circuit takes care of possible erroneous simultaneous pressing of both switches, where no stimulation change occurs.

Balance around the ankle is obtained by using the upper extremities and a balance aid such as a walker, parallel bars, or a standing frame. FES has not been successfully applied to stabilize ankle joints. The ankle joint is far away from its anatomical limits of extension and flexion and the muscle pair acting on the joint cannot provide stabilization.\textsuperscript{38}

Some researchers\textsuperscript{48} have implemented a six channel system
much like the above prescribed system. The two additional channels are used to stimulate the gluteus muscles. This results in hip extension, which helps move the flexed leg forward by preventing a forward tilt of the pelvis, and hip abduction which helps prevent the legs from crossing. The gluteus muscles are stimulated during both stance and swing phases.

FES or “electrical bracing” has been applied to patients with SCI for standing and ambulating in efforts to eliminate the need for orthotic devices which are generally custom made, expensive, and difficult to don and doff. FES may solve some of the problems with orthotics, and it has also been reported to give the added benefit of increased muscle bulk. However, the use of FES has been shown to be nonfunctional outside the laboratory primarily due to the very high energy consumption associated with its use. Researchers have found energy consumption with open loop control systems to be up to 20 times that of normal standing and walking. Fatigue of stimulated muscle contractions is also a limiting factor. Subjects with walkers were able to go 800 feet and patients with crutches were limited to 20 feet before total fatigue. Proposed solutions involving sequential activation of muscles to reduce stimulation frequency and postural switch depending on weight
bearing are under investigation. Another area of concern is the open loop system used with FES application to achieve ambulation. The open loop system may cause charcot joints and degenerative joint disease due to continuous hyperextension of the anesthetic joint.37,38

The most efficient and clinically feasible system appears to be a "hybrid" orthosis; a system that combines a reciprocating gait orthosis (RGO), with functional electrical stimulation. With a "hybrid" orthosis, the brace serves to support the patient's body weight, while the electrical stimulation is used to provide propulsion of the limbs, thereby, combining the benefits of each component. The main benefit the patient receives is a higher safety level.6

The lower extremity orthosis used most efficiently with FES, is the reciprocating gait orthosis. The RGO was developed by the Louisiana State University Medical Center and has been used with a wide spectrum of disabilities. The RGO is a bilateral HKAFO with a hip and knee joint, a pelvic support band, thoracic support straps, and a cable system. The cable system allows coupling of the left and right lower extremities in such a manner that hip extension in either leg tends to force the contralateral lower extremity into
flexion. This coupling provides coordinated motion between the lower extremity making a "reciprocal gait" possible. The ankle of the RGO consists of a solid ankle-foot orthosis, which is set in approximately seven degrees of plantar flexion to assist in raising the body's center of gravity during heel-off through toe-off phases of gait, thus decreasing the need for lateral shift, while still clearing the swing leg. The custom fit pelvic girdle acts as a lever to help facilitate hip extension. The prime mover of the RGO system is hip extension of the stance limb, which also results in flexion of the contralateral leg to allow swing phase.

Although the RGO enables patients with SCI functional improvements through ambulation, limitations are still very evident. RGOs require great upper body strength and truck control, thereby demanding high energy consumption. Isakov et al. showed that most subjects were unable to achieve standing without assistance due to the fact that the knees are locked into extension throughout the whole procedure. In order to combat these insufficiencies, Petrofski, incorporated FES in conjunction with a RGO orthosis.

A closed loop system, with sensors on the orthosis giving feedback to a computer which controls the modulated electrical
stimulation, was developed by Petrofski. To allow more function with ambulation, a portable computer small enough to fit on the wrist was developed from this model. Researchers have also developed stimulators especially for electrically stimulated gait, called electrical muscular stimulators (EMS). With this system four to six electrical muscular stimulators are worn on a belt. In a dual channel set up, fourteen to sixteen surface electrodes are applied to the quadriceps, gluteal musculature, and hamstrings. To decrease the time and complexity of applying these electrodes, a transcutaneous transducer garment (TTG) is used. A TTG is an electrode garment made of lycra and nylon with embedded electrodes. TTGs are connected to the stimulators through snap connectors and allow for rapid application, ease of use, and non-exposed wires.

The hybrid orthosis ambulation system interacts with the patient to allow a variety of tasks including standing up, ambulating, turning, and sitting down. In order for subjects to come to a standing position, the patient must first sit with their forelegs bent slightly beyond 90 degrees and lean forward at the hips. The quadriceps are then stimulated through an ascending ramp for a
smooth transmission. Once erect, the patient inclines backwards to lock his or her knees. Hamstrings and gluteus musculature are stimulated briefly in order for the patient to extend and lock his or her hip joints. At this point, the subject is ready to walk.

Ambulation is achieved by the following process. Weight is shifted to the stance leg so that all the weight is bore on that limb. Simultaneously, the hamstrings and gluteus musculature are stimulated to achieve extension. Through the cable system of the RGO and stimulation of the rectus femoris, the contralateral limb is flexed, achieving the swing phase of gait. Repeating this process will result in a reciprocating gait.

In order for the patient to achieve a sitting position, the patient stands four to six inches in front of the chair. The patient then manually unlocks the hip and knee joints while stimulating the quadriceps, hamstrings, and gluteus muscles. These muscles are subsequently allowed to ramp down when stimulation is deactivated and the subject is allowed to smoothly sit down.

Comparing the hybrid system (using FES in conjunction with a RGO) to other ambulation systems used by the SCI population, a substantial and consistent increase in efficiency and a reduction in energy consumption has been shown. Isakov et al,
reported the physiological cost index (PCI) to be 2.55 and 1.54 beats per minute for the RGO and the hybrid system respectively. The physiological cost index is a reliable tool used to evaluate walking performance which uses the walking heart rate minus the resting heart rate in bts/min divided by the walking speed in meters per minute. Isakov also reported increased cadence and walking velocities with the hybrid ambulation system. Petrofski and associates, showed that from a physiological standpoint the hybrid ambulation system requires a similar amount of energy used by voluntary walkers. The hybrid system has been shown to have almost a 15% reduction in energy cost compared to other walking systems. Hirokawa et al found the FES/RGO “hybrid” system required the least energy expenditure and energy cost when compared with ambulation systems of RGOs alone, FES alone, HGOs and long leg braces. Phillips and Hendershot concluded that the hybrid system had a better aerobic training effect compared to RGO alone. Their subjects demonstrated a reduced VO₂ with an increased task cost while using the hybrid system.

Stand-up and sit-down functions have been found to be much easier using the hybrid system. The results from a study by Isakov indicated that the hybrid system enabled a higher number
of repetitions in two minutes and a smaller demand in effort as shown by the smaller increase in heart rate. Subjective reports from this same study indicated that patients were able to control their steps better, felt more comfortable, and felt less tired.\textsuperscript{37}

The use of the reciprocating gait orthosis powered with brief electrical stimulation of the thigh muscles to initiate the gait cycle in patients with SCI results in substantial reduction of energy cost when compared to other options.\textsuperscript{54-56} The advantages of such a system can provide persons with SCI an attractive alternative to wheel chair transportation, with the added benefits of preventing osteoporosis and pressure sores, improving cardiovascular functions, and improving attitude and daily living functions.
CHAPTER IV

CONCLUSION

Functional electrical stimulation has been successfully used on patients with SCI to replace the lost central control of motor pathways.22,25,29-34 Thereby, enabling patients with SCI to accomplish functional lower extremity movement and to receive therapeutic effects.

FES augmented strength training has increased muscle strength and muscle girth, and has decreased spasticity in patients with SCI.30-33 Although not considered functional activities, these are important contributions to later ambulation and aerobic exercise.

FES lower extremity bicycle ergometry has shown to improve cardiovascular fitness by increasing aerobic metabolism and oxygen uptake.21,27,29-30 FES ergometry has also been shown to increase pulmonary ventilation, power output, and blood flow capacity. However, further investigations are necessary to demonstrate more clearly the central cardiovascular effect on FES induced exercise, especially in patients with higher level SCI. FES lower extremity ergometry is also a precursor for FES augmented ambulation.
Standing and ambulation have been achieved through bracing and functional electrical stimulation. Both methods have been found to be ineffective, mainly due to high energy consumption. However, a hybrid system consisting of FES in conjunction with an RGO has shown to produce safe, independent ambulation with reduced energy expenditure.

Functional electrical stimulation has shown several beneficial factors. It is evident, however, that work remains to be done to further improve functional electrical stimulation in areas of function (stair climbing for example), cosmetic factors, and further reduction in energy consumption. In conclusion, the results of this literature review showed that FES is an exceptionally efficient training method to increase the muscle strength and cardiovascular fitness in patients with spinal cord injuries. Physical Therapists should incorporate FES exercise into the treatment programs of SCI patients, more often than what is being done today, for this purpose. Further research is needed in the area of FES augmented ambulation, to develop new techniques to improve functional ambulation in the SCI population.
REFERENCES


