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The Use of Lower Extremity Functional Electrical Stimulation in Spinal Cord Injured Patients

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THE USE OF LOWER EXTREMITY FUNCTIONAL ELECTRICAL STIMULATION IN SPINAL CORD INJURED PATIENTS

by

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This Independent Study, submitted by Michelle A. McCrory 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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PERMISSION

Title	The Use of Lower Extremity Functional Electrical Stimulation in Spinal Cord Injured Patients
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ABSTRACT

Spinal cord injury (SCI) is a devastating, life-altering injury that presents a variety of rehabilitative and long-term medical management challenges. Not only must the inability to ambulate, which is generally of primary concern to the patient, be addressed, but also the inherent degenerative and deconditioning effects of SCI which may ultimately lead to various secondary complications.

Recently, functional electrical stimulation (FES) has been the subject of a variety of research concerning the rehabilitation of individuals with SCI. FES is a means of activating alpha motor neurons to stimulate muscular contraction and elicit a therapeutic or functional effect.

The purpose of this paper is to examine and review current uses of FES in the spinal cord injured individual to restore functional movement of the lower extremities. Specifically, it will focus on muscle conditioning, cardiovascular conditioning, and control of standing and ambulation with an explanation of the physiologic effect of each of these activities. The role of FES in combating and preventing secondary complications of SCI will also be reviewed.

This paper will involve an extensive literature review of the topics. The results of this paper will aid physical therapists in the clinical management of SCI through the use of FES.

CHAPTER I

INTRODUCTION

Spinal cord injury (SCI) is a devastating, life-altering injury that is of major public health importance. While the number of individuals with spinal cord injury is relatively small with an incidence of 2.5 cases per 100,000,[1] the overall health care expense is estimated to be 30 to 40 billion dollars annually.[2] Enormous medical management costs are largely due to subsequent hospitalizations and complications secondary to SCI rather than the initial expense of acute and rehabilitation management.

Traditionally, long-term medical management was not well developed due to the high incidence of death stemming from acute complications soon after the initial trauma. Medical care advances, such as improved transportation techniques, efficient critical care, advances in technology, and improved urinary and respiration management, have greatly improved survival and life expectancy rates.[3] With increased life expectancy, the deconditioning and degenerative effects, which ultimately predispose SCI individuals to a variety of secondary complications, require significant consideration.

Muscular atrophy, demineralization of bone, decreased circulation and oxygen uptake in paralyzed musculature, and decreased stress on the cardiovascular system increase risk for development of pressure sores, fractures, thrombophlebitis, respiratory disease, and, the number one cause of death in SCI population, cardiovascular disease.

Cardiovascular conditions in SCI are caused by a number of cumulative factors. It is well known that in the general population, an inverse relationship exists between high density lipoproteins (HDL) and coronary artery disease. Serum HDL is speculated to be increased with regular aerobic activity. SCI individuals have been shown to demonstrate decreased levels of HDL as compared to nondisabled population[4] which is speculated to stem from decreased aerobic physical activity. In addition to decreased levels of HDL, documentation has evidenced that cardiopulmonary fitness is reduced by SCI[5,6,7,8] due to insufficient voluntary muscle mass available to produce the necessary cardiovascular stress for maintenance of an adequate fitness level. Although regular upper extremity ergometry does produce increased strength and endurance of upper extremity musculature, it is generally not sufficient to increase central cardiovascular fitness.[8] It is thought that with upper extremity exercise alone, compensatory vasodilatation does not occur in paralyzed musculature; therefore, distribution of blood to exercising musculature is poor, blood pressure is lowered, and cardiac output is inadequate. Also, complete cervical and high thoracic lesions result in reduced cardiovascular exercise response (maximum heart rate and cardiac output) due to loss of supraspinal sympathetic control.

Deep venous thrombosis (DVT) formation is a life-threatening complication of SCI. It is postulated that increased incidence in this population is due to loss of the pumping effect generated from muscle contractions in nonparalyzed musculature. Decreased circulation and venous stasis causes increased concentration of coagulants in a localized area and impaired fibrinolytic activity resulting in formation of DVTs.[9] Absence of muscle contractions and the pumping effect, in conjunction with chronic dependent position of lower extremities, leads to chronic foot and leg edema.

Long-term weight gain after initial weight loss is very common in SCI population due to sedentary lifestyle. This is not only of medical concern but also of functional concern as increased weight may interfere with mobility and performance of activities of daily living. Body composition studies have shown even in absence of obesity a disproportionately higher amount of body fat to muscle mass exists in paralyzed musculature. Weight gain and composition changes are at least in part due to lack of physical exercise.

Osteoporosis is typically found to some degree in SCI individuals. A lack of mechanical stress due to absence of muscle contraction and significant decreased weight-bearing fails to facilitate proper bone remodeling as bone reabsorption exceeds bone formation and results in osteoporosis.

Disuse atrophy is also very pronounced with spinal cord injured population. In paralyzed musculature, histochemical changes take place along with changes in muscle fiber type.[10] A predominance of Type II muscle fibers which are fast twitch anaerobic over Type I slow twitch fibers exists. Also, a reduction in mitochondria concentration, oxidative enzyme level, and number of capillaries takes place in atrophied muscle.[4] Gluteal atrophy is of particular importance as it predisposes SCI individuals to ischial pressure sores. In addition, disuse of musculature is hypothesized to influence somatic and automatic spinal reflexes contributing to dyssynergic neurogenic bladder, irregular evacuation of bowels, autonomic dysreflexia, circulation disturbances, and spasticity.[4]

For the most part, rehabilitation of SCI currently focuses on strengthening of volitionally intact musculature and training for optimal self-sufficiency in daily life. Generally, passive range of motion is carried out for paralyzed limbs and fitness training is not a focus. Following initial rehabilitation, the vast majority of SCI individuals become sedentary and rarely partake in any form of regular fitness training.[11] Typical SCI individuals are, therefore, left with insufficient means to maintain an adequate fitness level.[8,12,13]

Secondary complications commonly associated with SCI have been shown to be related to or aggravated by the lack of physical exercise.[14] It is also speculated that secondary complications can be avoided or reduced through fitness training achieved utilizing functional electrical stimulation (FES) of the lower extremities for a therapeutic or functional effect. Physiological benefits of FES induced exercise and ambulation in conjunction with orthotics may include prevention of osteoporosis, increased strength of muscles receiving stimulation, increased endurance, increased aerobic metabolism, increased cardiac output, and improved physiological function.[15] Of equal importance are the psychological benefits associated with exercise and the ability to stand independently.

CHAPTER II

Functional electrical stimulation, also known as neuromuscular electrical stimulation, has served the purpose of restoring purposeful movements in paralyzed musculature (UMNL in nature) for the last quarter of a century.[16] Through technological advances, FES has been utilized to produce complex motor activities for the purpose of performing FES induced exercise and functional ambulation (with orthosis) in the spinal cord injured population.

The term Active Physical Therapy (APT) was coined by Petrofsky and Phillips[17] to describe activities in which FES is utilized to superimpose movement of paralyzed extremities in SCI individuals. In active physical therapy, muscle contractions are elicited which act upon their environment to produce an exercise effect with useful external work, as compared to conventional physical therapy (no FES) in which the environment acts upon paralyzed musculature to produce its effects.[18]

Two components, the isokinetic leg trainer and FES bicycle ergometer, were initially described by Petrofsky and Phillips for the purpose of performing APT.[17] After the development of a functional ambulation system, FES in conjunction with orthosis, walking systems became the focus of attention by many researchers. Candidates for FES augmented ambulation, however, are required to also participate in strength and endurance training with the isokinetic leg trainer and bicycle ergometer prior to ambulation.

The simplest form of APT, weight lifting, is provided by the isokinetic leg trainer which was developed to provide a means of isokinetic exercise for paralyzed musculature.[18] A relatively simple system of quadriceps muscular stimulation was developed to achieve this goal. The SCI patient simply sits in a chair much like those found in conventional isokinetic machines while stimulation to the quadriceps is achieved by electrodes placed over respective quadricep motor points. This allows for alternative stimulation to different musculature heads, thereby decreasing musculature fatigue and providing smooth contractions of the muscle.[2] A stirrup connected to a series of pulleys and affixed to a weight pan is placed around the ankle. When the quadriceps are stimulated and an adequate muscle contraction is achieved, work is produced as the lower leg movement elevates the weight pan. Closed loop control is achieved with a sensor placed in series with the weight pan to provide input for the computer which, in turn, stimulates muscular contractions in a slow and smooth manner to prevent hyperextension of the knee. Repetitions of equal velocity contractions through the above described mechanisms are produced at the knee resulting in repetitive cycles of knee flexion and extension. Recently, adaptive control (as opposed to closed loop control) has been successfully implemented in laboratory research with use in leg trainers;[19] however, this has not been widely applied. Clinically feasible systems have also been similarly reproduced through portable neuromuscular stimulators with ramped current output and ankle weights.[20]

While differing protocols and training programs have been described as a precursor to lower extremity bicycle ergometry and ambulation, some of the more common ones advocate stimulation parameters and adjustments of weight to achieve fatigue of muscles within a given time frame of repetitive flexion and extension cycles on each leg.[18,19,20] Fatigue has been defined as the point at which maximum stimulation levels are unable to produce a preset number of degrees (usually 30° to 40°) of knee extension.

A training effect has been documented with regular use of the previously described leg trainer. A doubling of quadriceps strength was reported by Petrofsky and Phillips[17] over a three-week period and Collins et al[18] found a sevenfold increase in quadriceps strength in a 12-week time frame with use of high intensity protocols. Similar studies[19,20] have demonstrated increases in thigh girth and quadriceps strength through FES augmented leg training. Faghri et al[20] also found FES knee extension training to provide a reduction in spasticity, although the exact mechanism is not currently fully understood. A reduction of spasticity is reported to occur with repetitive and prolonged stretching of paralyzed musculature through autogenic inhibition of tendon stretch reflexes and activation of muscle spindle afferents to inhibit motor neurons.[20] Whether the same process takes place with exercise elicited by FES is yet to be proven.

Generally, FES knee extension training is carried out prior to bicycle ergometry training to build muscular strength which may be significantly decreased depending on length of injury. While use of the isokinetic leg trainer has proven to be a highly effective means of gaining strength in UMNL paralyzed musculature, a need for endurance and cardiovascular training was provided by the development of computerized electrical stimulation bicycle ergometer.[22] Originally, Petrofsky and colleagues[23] designed a system allowing SCI individuals to pedal on an ergometer through computer controlled, sequential impulses delivered to paralyzed lower extremity musculature with closed loop control. This system was approved by the Federal Drug Administration (FDA) in 1984 and is currently available for clinical and home use as the Regys and Ergys clinical rehabilitation system. Regys is used in the clinical setting for bicycle ergometry, but also has the added feature of a chair that rotates which allows for the performance of leg lifts. The Ergys is designed for home use by experienced cyclers. Both ergometers consist of the following three main components: lower extremity ergometers, stimulus control unit, and patient's chair.[16]

The ergometer is like that of a standard ergometer with modifications to achieve reduction in resistance levels and safety through position sensors. The stimulus control unit is a computer which integrates information from sensors and controls and monitors output of electrical stimulation according to parameters entered through a remote control keyboard. Six channels, generally delivering stimulation to the quadriceps, hamstrings, and gluteal musculature, are available in this computer controlled, closed loop system. The frequency and pulse duration are entered into the computer, while the amplitude ranging from 0-132 milliamps is chosen by the stimulus control unit according to input from various sensors. Sensors relaying pedal position continuously monitor instantaneous position and average velocity. This information is used by the stimulator to determine precise stimulus amplitude required for each of the six muscle groups at any point in time to maintain a constant predetermined speed of fifty revolutions per minute (rpm).[4,16] Continuous closed-loop feedback, such as that provided by the pedal position sensor, allows for control of rate of pedaling and stimulation sequence ensuring a smooth and rhythmic pedaling movement.[4] The amplitude is maintained through constant current output unless pedaling speed drops below 35 rpm at which time the muscle will be considered to be fatigued, or a voltage of 220 volts or an impedance of 166 ohms[16] is attained at which time the computer will assume an electrode or wire is loose. In both cases, discontinuation of stimulation will ensue. In addition to pedal sensors, resistance sensors input information into the computer to guarantee that prescribed resistance is being carried out.

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

Protocols and stimulation parameters have varied in the research setting with uses of different ergometry systems. The use of lower extremity FES stimulation with the clinically available Ergys system has been safely accomplished with the following parameters.[20,24,25] Stimulation voltage output may range from 0 to 130 mA with a maximum of 130 mA, while pulse frequency has shown to be effective and safe at 30 Hz in conjunction with monophasic rectangular waveforms at .375 msec pulse duration.

Resistance in bicycle ergometry is set according to individual muscular strength and capabilities with increasing loads determined by preset criteria; i.e., successful completion of fifteen minutes of uninterrupted cycling at a given resistance prior to increase in load by small predetermined increments at the next training session. A maximum of a 7 kg load is recommended for safety by Faghri et al.[20] He[20] has set the following parameters for termination of FES induced bicycle ergometry as safety precautions: 1) fatigue of muscle determined by inability to maintain a pedaling speed greater than 35 rpms with maximum stimulation of 130 mA, 2) spasticity interfering with the ability to perform smooth muscular contractions, 3) heart rate that surpasses 85% of the predicted maximum value or arterial blood pressure exceeds 200/120 mmHg, and 4) arterial blood pressure that falls below 70/40 mmHg or any symptoms of hypotension.

With the knowledge that SCI interrupts autonomic sympathetic outflow, it was postulated that cardiorespiratory responses would be difficult to achieve with FES induced exercise. This has proven to be untrue despite autonomic sympathetic disturbances. Lower extremity bicycle ergometry has been shown to elicit relatively high levels of metabolic and cardiopulmonary responses.[16,23,25,26,27]

In the paraplegic population, the post-training effects of FES ergometry are similar to adaptations experienced by the general population for aerobic exercise. Decreases in resting blood pressure and heart rate along with increases in stroke volume and cardiac output during submaximal exercise are produced in both groups. On the contrary, FES ergometry has been shown to produce an opposite effect in quadriplegics producing increases in resting blood pressure and heart rate with short-term training protocols.[25,28,29] Quadriplegics typically, even at rest, exhibit low cardiac output, hypotension, and bradycardia due to loss of suprasegmental control over the sympathetic nervous system. The exact mechanism for the increases in heart rate and blood pressure are not currently known, although it is postulated that long-term FES bicycle ergometry can stabilize resting blood pressure and alleviate orthostatic hypotension by alterations of blood pressure and heart rate.

Short-term FES induced lower extremity cycling has been shown to increase peak aerobic metabolism and oxygen uptake which is used as an index for cardiovascular fitness. Significant post-training increases in peak pulmonary ventilation, stroke volume, and cardiac output have been produced[4,9,19,24,25] indicating greater cardiorespiratory capacity and, therefore, more appropriate cardiorespiratory responses at rest and during exercise. SCI individuals who demonstrate greater cardiorespiratory capacity may experience less stress during activities of daily living and become more functional due to requiring a lower percentage of cardiorespiratory capability when performing activities.[25,30] In addition, reduction of secondary cardiovascular disabilities may be achieved.

However, the above noted theories as to increased central (cardiac) training effects have not been unequivocally proven and some controversy exists as to whether proven increases in peak aerobic metabolism and power output when exercising are to be attributed to central cardiac training effects, peripheral muscle training effects, or a combination of both.[24,25] Significant increases in power output indicating increases in strength and endurance were found after completion of FES ergometry training and hypothesized to be in part due to local histochemical changes within the active muscle. Increases in power output may also be due to enhanced oxygen and energy substrate delivery to the trained muscles along with facilitation of metabolic end product removal.

Hypothesis for improvement include both central and peripheral metabolic and circulatory adaptations.[20] In the peripheral muscular system, it is believed that FES induced ergometry may cause histochemical changes in the paralyzed musculature that are able to support greater levels of aerobic and anaerobic metabolism.[16,20] Histochemical changes may include increased concentrations of glycogen, mitochondria, oxidative and glycolytic enzymes combined with increased capillary density in musculature and, therefore, greater blood perfusion.[16,20,25,31] Increases in endurance are in part attributed to hypertrophy of muscular fibers and changes in muscle fiber characteristics from fast anaerobic, Type II fibers to slow, aerobic Type I fibers.[4,16]

Centrally, FES may increase end diastolic volume and, therefore, increase the volume load of the heart by facilitating venous return of blood.[20] This results in increased stroke volume and cardiac output. Ultimately the above noted improved capacity supports higher levels of muscle performance by improving delivery of blood, oxygen, and fuel to exercising muscles and remove metabolic end products. Further research is required to determine which effects are due to peripheral training effects and which are due to central training effects.

Aside from physiological responses, FES has also been postulated to have positive effects on secondary complications related to SCI. A study was performed comparing data on secondary medical complications of a group of 51 SCI subjects who underwent FES lower extremity ergometry for one year to data on a group of 6,000 SCI injured patients from 17 national spinal cord centers.[32] A lower incidence of pressure sores, fractures, kidney and bladder infections, and thrombophlebitis was found in the group undergoing lower extremity FES ergometry. Health care costs were also found to be significantly reduced in this study as none of the patients in the exercising group required re-hospitalization during the one year spent performing FES ergometry. An estimated $12,000 (in 1985 dollars) per year was spent on the comparison group with approximately $7,000 associated with re-hospitalization costs. Petrofsky[2] has estimated medical savings over a patient's lifetime to be two million dollars per SCI patient.

SCI individuals must meet specific medical criteria and be carefully screened before being allowed to participate in any type of FES training. Phillips[18] has extensively outlined medical criteria for patient participation in electrical stimulation programs. It is generally agreed upon that the upper level of neurological injury for FES induced exercise is C_4/C_5 as phrenic nerve (C_3-C_4-C_5) stimulation is required to allow sufficient diaphragm function and adequate ventilation to sustain exercise. The upper limit for participation in FES in conjunction with orthosis ambulation appears to be slightly lower at C_6/C_7.[20] The lower level of neurological injury for both FES exercise and ambulation with an orthosis is T_{11}/T_{12}. Injuries lower than T_{12} result primarily in lower motor neuron lesions which cannot be successfully stimulated with functional electrical stimulation.

Spasticity must be minimal or under sufficient control by medication before SCI patients are allowed to participate in FES induced exercise. Special adaptations are made with the previously described ergometry system that allow for detection of muscular spasms and subsequent computer discontinuation of stimulation for patient's safety. Frequent episodes of computer shutdown, however, essentially make a program of regular exercise impossible to maintain and, therefore, are not allowed.

As spontaneous fractures are often experienced in SCI population and are primarily due to disuse osteoporosis, it is recommended that all possible candidates for FES exercise undergo conventional radiographs to determine the thickness of lower extremity cortical bone. It has been advised that only patients with moderate osteoporosis or better (on a five level scale of normal, mild, moderate, moderate-severe, or severe) be allowed to participate in FES induced exercise.[2] Patients exhibiting moderate to severe degenerative joint disease should not be candidates for FES exercise.

Patients presenting with angina, coronary artery disease, chronic obstructive pulmonary disease, chronic renal disease, and chronic skin diseases must be closely monitored by respective specialists prior to and during any type of FES exercise program. Absolute contraindications to participation in an FES exercise program include patients with uncontrolled hypertension, respiratory infections, and chronic renal disease.

CHAPTER III

Numerous benefits have been discussed with respect to attaining an upright posture through utilization of standing devices in the spinal cord injured population.[28,33,34] Alleviation of the chronic sitting posture through standing produces such benefits as prevention of contracture formation, reduction of pressure sore incidence, minimization of osteoporosis, stimulation of circulation, and reduction of spasticity. Standing has also been credited with the improvement of internal organ position and bowel and bladder function. For these reasons, standing has been stressed in many SCI rehabilitation programs.

Traditionally, standing was accomplished through the use of standing frames, orthotics, such as long leg braces or specialized wheelchair attachments, while ambulation was achieved through the use of calipers and crutches.[35] Recently, rehabilitation engineering research has focused on two approaches for improved ease of standing and ambulation in SCI patients. The improvement of orthotics has been explored by some while the application of electrical stimulation for functional activation of the lower extremities has been focused on by others.

Rose[36] has identified fundamental requirements for ambulation that must be met regardless of the system chosen. They include stabilization of the multi-segmental structure of the body to prevent collapsing or toppling, superimposition of propulsive forces and the control of both stability and propulsive forces. These conditions are required for any form of ambulation. In addition, to produce reciprocal ambulation, a mechanism allowing for the transmission of weight-bearing to the stance leg and for clearing of the contralateral swing is required in conjunction with the ability to perform forward swing and forward progression of the trunk over the stance leg.

A variety of systems have been developed in an attempt to satisfy the above objectives with varying degrees of success. The most widely prescribed system for standing, knee-ankle-foot orthotics (KAFO) or hip-knee-ankle-foot orthotics (HKAFO) provide a safe and stable form of mechanical support against gravity. A major drawback is the inherently high energy costs which have been shown to be five to twelve times that of normal gait.[33,37] Long term use of such braces is particularly low for this reason. One recent study[38] states that only 26% of patients who had received braces during their rehabilitation continued to use them for any purpose and only 4% use them as a sole means of mobility. Craig-Scott orthosis, an updated version of the KAFO, exhibit improved patient compliance rates although energy cost remains high for ambulation and therefore long-term functional use is very limited. Other orthoses, such as the ORLAU swivel walker,[39] hip guidance orthosis (HGO),[40] and reciprocal gait orthosis (RGO)[41] have been developed for gait facilitation. While ambulation has been achieved in a safe manner and improvements in energy expenditure are noted, the most energy efficient system of these, RGOs, still require three times the energy consumption of normal gait.[42]

A second area of walking systems research in rehabilitation engineering, functional electrical stimulation, was sparked by the work of Kantronite[43] and Lieberson[44] in the early 1960s as they reported standing through FES in paralyzed subjects in two separate studies. Since those reports, approximately 30 years ago, several research studies have been dedicated to the application of a neural prosthesis for standing and ambulation in the spinal cord injured individual through a variety of approaches.

Kralj[33,45] and others[31,46,47,48] have focused on surface electrode placement with open-loop control. Kralj[33,45] focused on utilization of a patient's remaining capabilities, namely preserved spinal cord reflexes, to reduce the need and complexity of external hardware used in other research. For example, the swing phase of gait in this approach is accomplished by peroneal nerve stimulation which triggers a reflex synergistic flexion response thereby reducing the numbers required to be stimulated for flexion and advancement of the lower extremity. The stance phase is achieved by locking the knee into extension through continual stimulation of the quadriceps while the patient stands in a hyperlordotic posture which enables hip stabilization through natural ligamentous tension. Difficulty stabilizing the ankle in stance has been encountered in all research projects solely using FES because the joint is far away from its anatomical limits of extension and flexion and it inherently has a high degree of freedom; therefore, bracing is generally utilized. With this approach, the author has been able to facilitate gait solely using a four-channel stimulator.

Percutaneous electrode systems which involve direct electrode placement on motor points through a needle-like sheath have also produced laboratory ambulation with open loop control.[49,50] This system allows a higher number of muscles to be stimulated without time consuming procedures related to repeated surface electrode placement. Also less intensity of stimulation is required due to lack of skin impedance with greater selectivity for deep musculature. Disadvantages specific to this system include increased risk of infection and a tendency for electrodes to move away from their original site or break. Results have shown electrode failure to be as high as 60% within six months of placement.[3] Implant systems have also been described in which extensive surgery procedures are required for implementation of as many as 100 electrodes.[51] Implantable pacemaker underdevelopment, lead wire breakage, and electrode breakage have all limited the usefulness of this system.[2] Research has also been difficult with this procedure due to the lack of subjects willing to undergo such evasive procedures.

The above described systems all have produced ambulation with assistive devices through different methods. An unfortunate commonality is that they are nonfunctional outside of laboratory use primarily due to the very high energy consumption associated with their use. Marsolasis[2] found energy consumption with open loop control systems to be up to 20 times that of normal standing and walking. The best subjects are limited to ambulating up to 20 feet with crutches or 700 to 800 feet with a walker prior to total fatigue. Also of concern in open loop systems is the possibility of producing Charcots joints and degenerative joint disease due to continued forced hypoextension on an anesthetic joint during stance phase.

To provide for a feedback system of joint position and allow for a more energy efficient system, closed-loop feedback has been investigated. Close-loop control also known as computer controlled walking uses the input from sensors to modify electrical stimulation output of the stimulator.[37] Sensors are generally placed on hips, knees, and/or ankles to provide joint position information. These systems process information from the sensors and produce just enough stimulation to obtain coordinated movement necessary for standing and walking and, therefore, are more energy efficient. With the increased capabilities of closed loop control also comes increased complexity of the system, which makes it less reliable. To attain acceptable posture with this system, large numbers of electrodes and sensors are required contributing to the high probability of malfunction. Postural stability and prevention from falling are not guaranteed with such a closed loop system. Due to the complexity, lack of safety features, and commercially unavailability of FES closed-loop control systems, they are unable to be used outside the controlled laboratory environment, although they are quite promising for the future.[37]

The most clinically feasible system appears to be a "hybrid" orthosis; one that combines a reciprocating gait orthosis (RGO) with functional electrical stimulation. This system was first described by Petrofsky et al in 1985.[37] He postulated that electrical stimulation of the lower extremities would reduce the long lever arm associated with inducing movement of the lower extremities through upper body movement in conventional bracing systems and, therefore, make ambulation more efficient. Also, the implementation of RGOs into a FES system allows for a significant decrease in the number of muscles required to produce ambulation as the knees and hips are restricted to two-dimensional movement by the orthosis.

Essentially, the RGO is a bilateral HKAFO with hip and knee joints, a pelvic band, a cable system, and thoracic support straps which offer stability for high level paraplegics or tetraplegics. This particular orthosis has distinctive biomechanical features which allow for transference of mechanical energy through a cabling system.[53]

Two cables are attached to the anterior and posterior aspect of each hip joint which creates a push pull mechanism allowing for a reciprocating action to take place at the hips. Upon extension of the stance leg in a closed kinetic chain, the cable is biomechanically put into a state of tension. As a result, mechanical energy is transferred to the opposite hip joint and the contralateral limb is flexed to accomplish swing through.

Another important engineering feature of the RGO is setting of the ankle-foot orthosis (AFO) in seven degrees of plantar flexion to assist in raising the body's center of gravity during heel-off through toe-off phases of gait.[53]

Prior to the coupling of this orthosis with FES, ambulation was achieved by lateral flexion of the upper trunk and excessive lumbar lordosis exerting a force on the posterior strap and hip extension to activate the cable system. Although this allowed for independent ambulation, it required great upper body strength and trunk control with its largest limitation being the high costs in energy for ambulation. The RGO system was also impractical for sit to stand transfers as the knee was required to be locked in extension throughout the procedure. The above disadvantages and lack of functional usefulness prompted Petrofsky to superimpose electrical stimulation on the previously described RGO system.[37] He did so using a laboratory based computer which modulated electrical stimulation to the lower extremities through a closed loop system with sensors on the orthosis generating feedback. From this model, a portable computer has been developed which is small enough to be worn on the wrist.[37] Stimulators that were specially designed for electrical stimulated gait in the laboratory have also been reported.[53] They generally have separate programs for exercising, standing, and walking. Most recently, studies have focused on transformation of research protocols into clinical models that contain physician prescribable, commercially available components.[15,54-56] By using commercially available electrical muscle stimulations (EMS), researchers were able to achieve a reduction in size and weight of the power source. Previously, power packs weighing up to eight pounds were carried on the user's back.[55,56] The power pack in the new system (EMS utilization) consists of a single nine volt alkaline battery housed in the EMS weighing a total of six ounces. The need for specially designed switches for system control has been replaced as the new system is able to utilize remote switches which are available as accessories to the EMS units. EMS provides complete stand-up and sit-down capabilities as well as walking; whereas, the previous systems required an additional unit to achieve sit-down, stand-up functions. In addition, the EMS system is much less costly.

In clinical use, four to six portable electrical muscle stimulators are worn on a belt. With dual channel utilization, 14 to 16 surface electrodes are applied to the quadriceps, gluteal musculature, and hamstrings through the use of transcutaneous transducer garments (TTGs).[2] TTGs are basically tight fitting shorts made of electrically conductive material with embedded electrodes which have significantly decreased the complexity of individual electrode placement. TTGs interface with the stimulator through snap connectors and offer the advantages of non-exposed wires, ease of use, and rapid application of electrodes.

Remote on/off switches available with the EMS units are incorporated into the system to allow for patient control. The switches are attached to the patient's walker, allowing for thumb or forefinger control, and connected through a cable to the manual override jack on the side of their respective muscle stimulators. When the switch is moved to the on position, the EMS unit is activated and stimulation current is allowed to flow through both channels of the unit to the electrodes of respective muscle groups. Systems have been described where two to four EMS units control quadriceps function and two units control gluteal and hamstring stimulation. Through the use of four to six units, complete stand up, walking, turning, and sit down functions are available.[54-56]

The procedure to allow for standing from a sitting position requires the patient to sit with his/her lower legs bent at an angle slightly greater than 90° and to lean forward with the hips also flexed less than 90°.[54] Standing is achieved through constant activation of the quadriceps musculature. Once in an upright position, the patient inclines backwards on their heels to lock the RGOs into extension. The two hamstring and gluteal units are then activated just long enough to provide hip extension and obtain a locked position of the hips. At this time, the patient is stable in standing and the quadriceps are deactivated as they are allowed to ramp down. Walking can be achieved through the transfer of weight to the intended stance leg and activation of that leg's hip extensors. By utilizing hip extension in a closed chain and the reciprocal action of the posterior cables, contralateral hip flexion is achieved. The process of reciprocal ambulation is accomplished by repeating the above procedure. Backward walking is also described using this system as open kinetic hip extension is activated with weight shift to the contralateral limb.[55] The sitting procedure requires the patient to stand four to six inches from the desired seat.[56] Unlocking of the hip joint is performed manually with the patient's hands and stimulation is applied to the hip extensors to maintain standing position. Activation of the quadriceps in the continuous mode is required with allowance of time to ramp up to maintain standing while knee locks are released. EMS quadriceps units are then deactivated and the sitting position is attained as the unit ramps down.

Utilization of the hybrid system has consistently produced a substantial reduction in energy expenditure when compared to other forms of ambulation in the SCI injured population.[15,53-59] Hirokawa et al[57] found a hybrid system of RGOs and FES similar to that outlined above to require the least energy expenditure (Kcal/kg-m) and energy cost (Kcal/kg-min) when compared with ambulation systems of RGOs alone, FES alone, and HGO and long leg braces. Similarly, Isakov et al[53] found hybrid systems to produce more efficient ambulation than RGOs alone or FES alone, with increased cadence and greater velocities of gait attainable. The physiological cost index measured in beats per minute (bts/min) was significantly decreased from 2.55 (bts/min) with RGOs alone to 1.54 bts/min with hybrid system. FES in conjunction with RGO ambulation has been shown to produce a chronic training effect. Petrofsky et al[60] have observed an average of 18% decrease in energy requirements from pre- to post-training measure with ambulation one hour, five times a week for a period of three months. They have also noted hybrid ambulation to require an oxygen consumption of only one and a half times that of normal ambulation.

Hybrid ambulation provides a plausible alternative to continuous wheelchair transportation for individuals meeting the criteria for usage.[19,42,56,57,59] Ambulation with combined RGOs/FES may include the added benefits of prevention of osteoporosis and pressure sores; improving cardiovascular, kidney, bladder, and circulatory function;[61] and improving ability to perform activities of daily living.[57] Psychological benefits, such as improved sense of well being, enhanced self image, and a feeling of independence, have also been associated with standing.

CONCLUSION

Functional electrical stimulation has been successfully applied in SCI patients to serve as a crude replacement for central control of alpha motor neurons. In doing so, functional lower extremity movement has been accomplished for the performance of a variety of activities to elicit a functional or therapeutic effect.

Through FES augmented strength training, SCI individuals are able to build strength and muscle girth of paralyzed musculature. This in and of itself does not produce a functional activity; however, it is required as a precursor to ambulation with a FES system.

FES induced lower extremity ergometry has been shown to increase pulmonary ventilation, stroke volume, and cardiac output. It has also been proven to increase peak aerobic metabolism and oxygen uptake indicating improved cardiovascular fitness. However, question still exists as to whether improvement in the above noted are due to central or peripheral circulatory adaptations. FES lower extremity ergometry has also been used with FES ambulation protocols prior to actual FES ambulation.

Investigations of superimposing electrical stimulation to produce lower extremity movement for the purpose of ambulation have utilized a number of approaches with varying degrees of success. Many approaches, such as those incorporating closed loop control, are still in the laboratory stage of development. Others, such as open loop purely FES ambulation systems and "hybrid" systems, have been used clinically. Open loop FES systems, while successful at producing ambulation, have been found to be inefficient in terms of energy expenditure. This problem has been addressed with the use of "hybrid" systems, particularly reciprocal gait orthosis combined with FES which has produced safe, independent ambulation with reduced energy expenditure. This system has been described as a physician prescribable, commercially available system which is safe for clinical use.

A number of physiological and psychological benefits have been proposed with the use of FES for exercise and/or ambulation; however, uncertainty exists as to practicality of widespread, generalized usage as utilization has thus far been limited to selective, small subject population.

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