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The Use of Functional Electrical Stimulation (FES) to Produce Functional Movement in Individuals with Paraplegia

Melissa Jendro
University of North Dakota

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The Use of Functional Electrical Stimulation (FES) to Produce Functional Movement in Individuals With Paraplegia

by

Melissa Jendro
Bachelor of Science in Physical Therapy
University of North Dakota, 1996

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

Grand Forks, North Dakota
May 1997
This Independent Study, submitted by Melissa L. Jendro 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.

(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
PERMISSION

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ABSTRACT

Spinal cord injury (SCI) affects approximately 7600 to 11000 people per year, and alters every aspect of the individuals’ lives. SCI primarily affects young Caucasian adults. The majority are between 16 to 30 years old, with the average age being 19. Motor vehicle accidents account for 35% to 40% of SCI cases reported, with violence in close second at 25%. Currently, the highest neurological category is of complete paraplegia followed by incomplete quadriplegia. SCIs often cause many complications due to decreased physical activity and changes in bodily functions.

Among treatment options, functional electrical stimulation (FES) is used to restore a variety of physical and physiological functions. Some of the most promising and controversial research lies in the areas of bowel and bladder elimination, gait and exercise training, and also walking. It functions by stimulating the peripheral nerve, sending electrical impulses through electrodes placed on the skin in order to generate a muscular contraction. The goal of FES is to generate purposeful, goal-oriented movement, aimed at completing a task. Based on past research, FES has shown to benefit paralyzed individuals by reducing secondary complications, improving physiological responses, producing bone and muscle changes, and increasing cardiovascular fitness.
The purpose of this literature review is to determine whether or not FES produces beneficial functional movement in paraplegics. The procedure used to perform this study will be a literature review based on a collection of journal entries, articles, statistics, and experimentations of scientists, various health professionals, and other researchers.
CHAPTER I
INTRODUCTION

There are currently an estimated 500,000 Americans, including men, women and children who suffer from paralysis.¹ Approximately 203,000 to 250,000 of these individuals suffer from spinal cord injury (SCI), with an average annual incidence rate of 7,600 to 11,000 new cases reported each year.²,³ Many of these Americans are young adults, with 58% to 60% between the ages of 16 to 30; the most frequent age is 19. The majority of these victims are males (70% to 80%), with 56% being Caucasian, 28.3% African American, 12.7% Hispanic, and 0.4% American Indian.²,³,⁴,⁵

The causes of spinal cord dysfunction are variable. Every year, motor vehicle accidents account for 35% to 40% of SCIs.²,³ Violence (primarily gun shots) is the next highest contributor with 25%, which has steadily been increasing since 1973. Falls come in a close third accounting for 21% of injuries, and a small proportion are the result of work and sports related accidents.

SCI occurs as a result of trauma to the vertebral column, usually causing the spinal cord to become compressed. Damaged spinal cords can no longer transmit messages from the brain to the muscles or from parts of the body back to the brain.¹ Depending on the level and severity of the injury, sensation and movement below the
level of injury may be absent. As a result, nerve cell function is lost and axon degeneration occurs.

Due to advances in technology and medical care for persons with SCIs, “life after injury” looks brighter. Life expectancies will vary depending on the individual’s health, age at time of injury, and the level at which the lesion occurred. Generally, individuals who are younger and healthier at the time of injury, and who have a lower injury level, will have a longer life expectancy postinjury. See Table 2 for current life expectancies. Mortality rates are significantly higher the first year (approximately 3.75%), but tend to taper off in later years (1.61% the second postinjury year, and roughly 1.2% over the next 10 years). The leading cause of death for this population has shifted since 1973 from renal failure to pneumonia, pulmonary emboli, and septicemia in 1995.

In the past, many people with SCIs were forced to spend the remainder of their lives in nursing homes or institutional settings, due to the lack of modern technology and skilled care giving assistance outside medical establishments. From 1974 to 1993, initial hospital stays declined from 122 days to 69 days for individuals with paraplegia and from 150 days to 80 days for those with quadriplegia. Today, 89% of individuals with a SCI who are discharged from the hospital live in private, residential settings (such as their home) or group homes with skilled supportive staff. Individuals with quadriplegia and those with additional medical complications may require more medical attention than can be provided for in these settings.

Paralysis is only part of the problem, injury victims must overcome emotional, social, and physical barriers. Medical aftereffects can also be extensive, involving
Table 1. Current Life Expectancies, Following the First Year Post-injury.3

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<tr>
<th>Current age</th>
<th>Normal</th>
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<th>Quad(C5-C8)</th>
<th>Paraplegic</th>
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<td>20</td>
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<td>50</td>
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<td>20.5</td>
<td>11.0</td>
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respiratory, urinary, digestive, cardiovascular, and circulatory system problems, along with problems related to pressure sores, skin breakdown, joint problems, and muscular atrophy. The economic costs of hospitalization, rehabilitation, equipment, follow up home care, and the overall lifetime costs involved with patients with SCIs are quite high. Specific costs will be discussed further in chapter seven. Returning to regular living activities and work can be very challenging. These individuals, especially those with quadriplegia, may need assistance with daily living activities for an extended period of time or even indefinitely. According to a survey obtained from the American Paralysis Association (APA), more than half (61.4%) of the people with SCI attending a rehabilitation system said they had a job prior to their injury. Eight years after their injury, 38.7% of the people with paraplegia were employed, as were 25.8% of individuals with quadriplegia.

In order to achieve more normal functional mobility to carry out daily living activities and ambulate at home or in the community, it is essential for an individual with paraplegia to use adaptive devices (i.e. orthotics) and other balance aids such as walkers or crutches. Orthotic devices are currently made out of lighter, more durable, and more cost effective materials, making purchasing and frequent use more practical. These units are becoming increasingly more innovative, facilitating reciprocal movement of the paralyzed lower extremities with less trunk and upper extremity muscle energy expenditure. Although the use of orthotics allows for upright mobility, they also involve high energy consumption, difficulties donning and doffing, an uncoordinated gait pattern,
and cumbersome bracing.\textsuperscript{7,8,9,10} These problems have spurred researchers to develop better technology for application of such devices.

There are several organizations and foundations designed to provide effective treatment and care for most individuals with spinal cord dysfunction, in an attempt to make the transition back into the community as smooth as possible. Rehabilitation and functional electrical stimulation (FES) research facilities are dedicated to making new strides toward discovering a cure for SCIs, along with providing new innovative technology that will allow paralyzed individuals to function at their optimal potential in today’s society. A long term goal for FES researchers is to produce systems that will allow individuals with paralysis to travel rough terrains, such as stairs, and permit sports, work, and entertainment related activities to be performed as close to normal functioning as possible.\textsuperscript{11}

Functional electrical stimulation is controlled by a computer which stimulates the nerve to produce movement in paralyzed limbs.\textsuperscript{12} These systems try to replace tiny electrical currents, that are present naturally in the body, and are carried throughout the body by nerves and tissues that supply motor (muscle) and sensory functions.\textsuperscript{13} A stimulator is a device which produces electrical currents that travel to electrodes placed on the skin or in the body (under the skin, in muscle, or in nerve), which relay the impulses to the appropriate muscles. All electrical stimulation systems must use some device to regulate the current transmitted through the electrodes. Microprocessors, miniature computers, sensors, and radio frequency transmission are a few methods used
to control output from stimulators. Simply put, FES reproduces the connection between the brain and muscle via computer.

The first, and perhaps most practical idea involves the use of FES, along with the use of an orthosis to provide stability for the paralyzed musculoskeletal system, thereby creating a "hybrid" orthosis.\textsuperscript{7,8,10,14} Hybrid orthoses have therapeutic and functional applications. Therapeutic purposes range from tissue repair, iontophoresis, pain management, strengthening, decreasing circulatory problems and spasticity, prevention of skin breakdown, joint contractures, and muscle deterioration.\textsuperscript{15,16} Functional restoration involves improved cardiac and respiratory functioning, urinary control, sexual functions, exercise, and manipulation of paralyzed limbs for standing and walking.

This literature review will focus on what physiological changes occur to the spinal cord due to trauma applied to the cord, and how FES systems work to reestablish the connection between the central nervous system (CNS) and the musculoskeletal system, thereby restoring functional movement. Different types of orthotics and FES systems will be reviewed, along with advancements being made in medical technology to provide more complex units with less side effects (such as muscular fatigue, cross stimulation of different muscle planes, or cumbersome bracing). Finally, information regarding present FES research will be provided to give an overview of future prospects in regards to new technological advances, rehabilitation facilities where they are presently under functional testing, and the financial impact of SCIs.
CHAPTER II

THE SPINAL COLUMN

Anatomical Composition of the Spinal Cord

To understand what an SCI entails, it is important to understand the basic anatomical and physiological characteristics of the spinal cord and the important structures surrounding it. The spinal cord runs inside the vertebral foreman of the vertebral column, starting from the medulla oblongata, passing through the foramen magnum, and down to the first or second lumbar vertebrae (L1 or L2). The vertebral column is composed of 33 vertebrae; including 7 cervical, 12 thoracic, 5 lumbar, 5 sacral and 4 coccygeal. The intervertebral disc separates the cervical, thoracic, and lumbar vertebrae, providing shock absorption to the column during movement. Spinal column stability is provided by several ligaments including; the anterior and posterior longitudinal ligaments, the ligamenta flava, supraspinous and interspinous ligaments, and the articular capsule. The main functions of the vertebral column include: providing a supporting structure for the thorax, an attachment for muscles and ligaments, a sustaining rod allowing an upright, dynamic posture, and controlled trunk movement, and as a housing unit to protect the spinal cord.

The spinal cord consists of two parts: 1) The gray matter, an H-shaped area located at the center, composed of sensory cell bodies dorsally, lower motor neuron (LMN) cell bodies ventrally, and preganglionic and sympathetic fibers laterally (present
only in the thoracic and higher lumbar regions).\textsuperscript{5} 2) The white matter surrounds the gray matter, and contains the ascending and descending tracts carrying both sensory and motor fibers. Refer to Figure 1.

Each level of the spinal cord has a sensory and motor nerve root that exits the vertebral foramen above the corresponding vertebrae for spinal nerves C\textsubscript{1} through C\textsubscript{7}, and below the corresponding vertebrae for spinal nerves T\textsubscript{1} and below, except for C\textsubscript{8}, which exits below C\textsubscript{7}.\textsuperscript{5} It is important to remember that the spinal cord is shorter than the spine, so the nerve roots exiting the lower thoracic and lumbar vertebral segments must travel down a few segments before leaving the vertebral canal.\textsuperscript{5,17,18} Refer to Figure 2.

The necessary nutrients and blood supply to the spinal cord is supplied by the anterior and posterior spinal arteries, which are interconnected except in the region of the conus medullaris.\textsuperscript{5} The anterior spinal artery supplies the anterior and anterolateral parts of the white matter of the spinal cord, along with the gray matter. The posterolateral and posterior white matter receive their blood supply from the posterior spinal artery, which is joined by communicating vessels. Damage to the spinal cord will result in impairment of spinal circulation, leading to ischemia and swelling.

**Spinal Cord Trauma**

The majority of SCIs are due to trauma applied to the vertebral column, either by direct insult or more commonly by impingement by other structures.\textsuperscript{5,18,19,20} Initially following the injury, neurological damage ensues affecting the neuron cell bodies and gray matter of the spinal cord, but the edema and hemorrhaging may later spread outward to the white matter, causing further destruction. The area of greatest damage to the cord
Figure 1. Cross-section of the Spinal Cord, Showing the White and Gray Matter
Figure 2. Relationship of the Vertebrae, Spinal Cord, Nerve Roots, and Cauda Equina
usually spreads over one to three segments, decreasing in intensity above and below the lesion level. Spinal shock occurs, causing spinal reflexes, sensory and voluntary motor function, and autonomic control to cease below the lesion. The actual cause is unknown, but spinal shock usually begins to resolve in approximately 24 hours and is often alleviated within a few weeks.

The level of the spinal cord lesion correlates with the type of vertebral injury sustained. The three most common types of vertebral injuries involve the cervical, thoracic and lumbar areas of the spine. Most spinal cord injuries are caused by impingement of the cord by other bony or tissue structures, as a result of violent motions of the head and trunk, rather than by severance of the cord itself. Cervical injuries account for the highest incidence rate due to the weak mechanical stability of the cervical spine especially between C5 and C7, allowing it to be more vulnerable to trauma as compared to the other parts of the column. Flexion injuries are more prevalent and usually affect the spinal cord at lower cervical segments. Extreme trauma is needed to cause damage to the spine between T1 and T10, due to the greater stability of the spine in this area, provided by the rib cage. A common site of injury occurs at the T12 and L1 or L2 junction, where there is a transition to the more flexible lumbar spine. Most injuries to this area are wedge compression fractures due to forced forward flexion of the spine causing the anterior part of the vertebral bodies to compress against each other. Injuries to the lumbar region of the vertebral column are the second most frequent injury site, due to its intermediate stability, making it more flexible than the thoracic spine, but less than the cervical region.
The level of the spinal cord lesion will determine whether the individual has paraplegia (paralysis of the lower body and of both legs), which accounts for approximately 55% of the SCI population, with the majority being complete lesions. Forty-four percent of individuals with SCI suffer from quadriplegia (paralysis of all four extremities and trunk).\textsuperscript{1,3,21} The severity of the injury depends on the intensity and direction of the force applied to the vertebral column, along with the level and degree of cord compression or severance, which will determine whether the lesion is complete or incomplete. A complete lesion results in total and permanent loss of sensory and voluntary motor function in muscular areas innervated.\textsuperscript{5,18,19} An incomplete lesion occurs when there is some sensory or motor function existing approximately more than three segments below the lesion level.\textsuperscript{5} With an incomplete lesion, neurological deficits will vary depending on the area of the cord affected.\textsuperscript{5,18,19,22} The neurological lesion level is the lowest level of the spinal cord that has retained sensory and motor function.\textsuperscript{5} To be classified at a certain neurological level of injury, the muscle in which that cord segment represents must exhibit at least a fair grade (3 out of 5) strength, with the muscle innervated by the next highest nerve segment exhibiting a grade strength of 4 out of 5. Sensory levels are well defined on the body, and a spinal cord lesion will result in sensory loss or diminished sensation below the lesion level innervated by that neurological segment.

An injury below $L_1$ or $L_2$ often results in a LMN lesion, because the end of the spinal cord terminates here, and is followed by the cauda equina (collection of spinal nerve roots).\textsuperscript{5,17,18,19} A LMN lesion occurs when there is damage to the anterior horn cell
or peripheral nerve, causing flaccid paralysis of the muscle innervated by that segment.\textsuperscript{5,11,12,13,23} Damage to the descending tracts results in an upper motor neuron (UMN) lesion (involving the brain, brainstem, or spinal cord), causing spastic paralysis to the muscles innervated by the cord segments below the level of the lesion.

Depending on their severity and level, spinal cord lesions can cause spasticity, loss of sensory and respiratory function, decreased range of motion, increased risk of osteoporosis and deep vein thrombosis, gastrointestinal and urinary tract infections, autonomic dysreflexia for a lesion above T\textsubscript{6}, and possibly heterotropic ossifications appearing generally 1 to 4 months post injury.\textsuperscript{5,18,19,24,25} Pressure sores (decubiti), bowel functions, cardiovascular activities, sexual functioning, and the person’s ability to control their body’s thermoregulation can also be affected by a spinal cord injury.

SCI Regeneration

Early research began in the 1830’s with the discovery of Schwann cell by anatomist Theodore Schwann.\textsuperscript{2} When transplanted to the damaged spinal cord, these cells were thought to help repair nerves whose wrapping had been damaged due to the injury. Other important studies have also been made due to past research discoveries. In 1890, Santiago Ramon y Cajal, father of modern neuroscience, blamed the failure of mammalian nerves to regrow on the harsh environment of the CNS.

The beginning of the 20\textsuperscript{th} century brought new changes. Approximately at the time of WWII, bacteria-killing drugs and the development of neurosurgery allowed individuals to survive the initial stages of SCI, by preventing previously fatal lung, bladder and skin infections.\textsuperscript{2} In 1951, a nerve growth factor (NGF), necessary for
survival of nerve cells in the human brain following injury, allowed regeneration of nerves in lower animals. This discovery was made by Nobel Prize winners Rita Levi-Montalcini and Viktor Hamburger.

Raisman\(^2\) made an important contribution in 1969 with the discovery that new synapses (connections) form in the adult brain after injury. His work showed that the CNS could reorganize itself and make new connections. Research conducted by Albert Aguayo in 1981, proved that nerve axons could regrow in a rat’s CNS after a nerve graft, although the regenerating axons stopped almost immediately when placed on the other side of the graft.

Until 1988, it was thought that the spinal cord could not regenerate due to the absence of nerve growth factors, but Schwabb showed that there are two myelin associated proteins that prevent growth in damaged human cords.\(^2\) It was about this time that the first effective treatment for SCIs was discovered. Studies showed that large amounts of the steroid, methylprednisolone (MP) could improve neurologic recovery in human spinal cord injuries by 20% if administered within eight hours of injury. Advances continue with reports by Fred Gage in 1994 that skin cells, which secrete growth factors and neurotransmitters, cause large amounts of regeneration of sensory nerve cells in the spinal cord. Another important discovery made by Martin Schwabb showed that a combination of the antibody, IN-1, and growth-promoting factor NT-3, caused traumatic regrowth of partially severed rat spinal cords.

The American Paralysis Association (APA) was created in 1982, and is a national non-profit organization based in Springfield, New Jersey, which encourages and supports
research to find a cure for paralysis due to SCIs and other neurologic disorders. It has also funded researchers and invested more than $11 million toward research progress. The APA Consortium was organized in 1995, and currently focuses on understanding the molecular and cellular make up of the injured spinal cord, finding ways to restore recovery of nerve cell function and axon regrowth, and experimenting with theories to replace nerve cells destroyed by the injury. It currently pools the scientific expertise of eight world-class neuroscientists from all over the country in order to discover a cure for paralysis due to spinal cord dysfunction.

Research for new technological devices and advanced medical care is also funded by the Spinal Cord Research Foundation (formerly called the Paralyzed Veterans of America). The foundation has awarded approximately $8 million to scientists and researchers since 1975. Some of the world class research facilities it supports include: Fayola, Cornell, Harvard, Chicago, Boston, and Stanford University Medical Schools, Columbia Presbyterian Medical Center, Case Western Reserve University, University of Michigan Medical Center, Rehabilitation Institute of Chicago, Cleveland Veterans Administration Medical Center, and Palo Alto Veterans Administration Medical Center.

These facilities and many others are dedicated toward developing devices aimed to restore lost function due to SCIs. Technological advances have created FES systems that help alleviate secondary complications associated with SCI, and even enable some individuals to stand and walk. The physiological and functional applications of these systems and research pertaining to Fes will be discussed in the following chapters.
CHAPTER III

FUNCTIONAL ELECTRICAL STIMULATION

Background of FES

Following a SCI, neural transmissions between the brain and body are lost, but the distal part of the nerve usually retains some blood supply, and the myoneural junction (point where the nerve intersects the muscle) maintains its ability to respond to stimulation. FES, also known as functional neuromuscular stimulation (FNS), is used to generate purposeful, goal-oriented movement in order to accomplish a functional task such as walking or grasping an object. FES is only effective for an UMN lesion involving the brain, brainstem and spinal cord. When there is peripheral nervous system (involving the LMN) damage, the muscles usually supplied by those nerves have lost their innervation. Because the muscles are denervated, electrical simulation applied to the nerve cannot reach the muscle and a contraction is no longer possible.

The use of electrical stimulation for therapeutic purposes has been in existence for hundreds of years. Electrical stimulation was first used on human beings in the eighteenth century. In 1757, Benjamin Franklin began his own experiments with electricity and paralyzed limbs. After several days of using static electrical sparks on lame limbs, people reported prickling sensations and even return of voluntary movement. Then in 1791, Luigi Galvani, an Italian physician, discovered twitching of
nerves in frog's legs without having to contact metals in a circuit, and later researched electricity's role in the human body for functional movement. Duchen proved in 1855 that surface electrical stimulation could be used to help a person with paraplegia stand. In the 1920's, the "animal electricity theory" flourished as the fascination of electric current grew.

Since the late 1950's, advancements began with designing and testing electrical stimulation devices to help people with paralysis walk. Approximately 30 years ago, physicians demonstrated that electrical stimulation can help prevent footdrop in stroke victims. Lieberson and colleges, in 1961, developed a simple functional electrical stimulator system was known as the peroneal stimulator. It supplies a single channel of stimulation to the peroneal nerve to control foot clearance during the swing phase for individuals with footdrop. Stimulation is initiated with stepping, which activates a switch trigger placed on the heel.

Multichanneled FES systems came into use by selected patients in the 1970's. These systems were more advanced and allowed stimulation of many muscles to perform complex tasks. Around 1979, important advances were made with the use of electrical stimulation for functional activities such as standing and sitting, which showed that future bipedal gait restoration was a possibility. Enthusiasm intensified when Nan Davis, a paraplegic, walked with the use of FES on her legs to receive her diploma at Wright State University in 1983.

Electrical stimulation systems are designed to benefit most individuals with paralysis in some manner, but not all. According to research experts at Case Western
Reserve University in Cleveland, FES systems have the potential to restore standing and walking function in only 10% to 20% of individuals with SCIs.\textsuperscript{14,29} Potential FES users are examined by a physician, and chosen according to their general health condition, type of injury or disease, and what part of the nervous system is affected. Contraindications would most likely include the following; an unhealed fracture or a history of a fracture in the lower body, along with incomplete injuries due to possible sensory problems, pregnancy, severe osteoporosis or spasticity, and limited range of motion of the hip, knee, and ankle joints.\textsuperscript{23} Most studies are conducted on individuals who have had the SCI for at least 6 to 12 months to ensure that they are neurologically and psychologically stable.\textsuperscript{15}

In regards to functional applications, ambulation requires some trunk stability along with the ability to tolerate an upright posture, so lesions above T\textsubscript{3} and T\textsubscript{4} are usually not appropriate.\textsuperscript{4,7,28} LMN lesions usually result from injuries below T\textsubscript{12}, and would not be appropriate for FES stimulation, because the peripheral nerve is no longer in tact. Balance aids such as parallel bars, walkers, and crutches are essential, therefore bilateral intact upper extremity use is required, also.\textsuperscript{4,11,14,24,30}

Multichanneled FES systems are not as widely available as compared to other stimulation systems (i.e. TENS, galvanic high volt). These systems are generally more complicated than other systems, highly expensive, and designing them to be safe and effective takes time.\textsuperscript{13,14} There is also a shortage of clinicians with expertise to evaluate candidates and to apply the system. It was not until recently that the Parastep system of Sigmedics Inc., Illinois, U.S.A., was approved by the Food and Drug Administration (FDA), despite the fact that other models have been under study for several years.\textsuperscript{7,8}
Components of FES Systems

A general FES system is composed of basically three parts: the command source, which is activated by an external source, begins the stimulation process; the stimulator, a miniature computer unit, interprets the signals sent from the command source and is the decision maker regarding muscular stimulation; and the electrodes, which receive electrical messages from the stimulator device and transmit this electrical energy to the muscle tissue. Two channel stimulation systems are generally used for standing, and four to eight channel systems are being used for ambulation purposes in experimentation settings. Current systems use an open loop method of stimulation, but experiments are being conducted to develop closed loop units for functional applications.

Command Source

The stimulation process begins with the command source. Initial messages are sent from the command source to the stimulator, where they are interpreted, sent on to the electrodes, and finally arrive at the muscle. Command sources can vary based on the type of injury and personal preferences. For individuals with paraplegia, they are usually a button mounted on crutches, walkers, or other assistive aids, and activated by the patient to start the sequencing pattern for standing and walking, or trigger different sequences for stopping gait and sitting.

Stimulator

The stimulator device is known as the “brain” of FES systems, because it decides which muscles must be stimulated, and what stimulation intensity and sequence is
required. It is composed of a microprocessor unit and memory chips, which interpret the messages received from the command source and sends them on to the electrodes via cables (wires), or radiofrequency. Stimulators may be internal or external. Internal stimulators are used with totally implanted electrodes, whereas external stimulators are used with surface electrodes or percutaneous electrodes. They must be programmed initially by a computer with information regarding the patient's muscle activity patterns, voltage intensities, and the muscle force prior to system usage.

Electrodes

There are three types of electrodes: surface electrodes (placed on the skin), percutaneous (placed through the skin usually on the nerve near the motor point), implanted (in the muscle belly itself). Each of the different types of electrodes have their advantages and disadvantages with regards to muscular stimulation and patient preferences.

The most common type of electrodes used with ambulation and during exercise training, are those involving surface electrodes. Surface electrodes are often preferred over other types because of their easy application, ease in fitting, and cost-effectiveness. They are made up of a flexible material (i.e. rubber), and are attached on the outside surface of the skin (by a conductive gel like substance or by self adhesion) over the muscle’s motor point or along the nerves innervating the appropriate muscle. Stimulation is passed through skin receptors to the underlying muscle, thereby producing a muscular contraction.
Faults of this type of stimulation include: inadequate stimulation of deep muscles, increased chances of cross-stimulation, poor quality and velocity of gait obtained, lack of smooth muscle recruitment (stimulates groups of muscles), and high amounts of current needed to produce a functional gait pattern, which causes increased muscular fatigue and metabolic costs.\textsuperscript{8,14,15} Continuous donning and doffing of the electrodes may also cause the motor point location to be easily lost, making control of muscle forces difficult. To address these deficits, percutaneous and implantable systems are presently being tested.

Percutaneous electrodes are placed through the skin generally on the nerve or in the muscle, and stimulate motor points of the muscles, allowing muscle contractions to occur at lower voltages.\textsuperscript{8,15} They are inserted via a hypodermic needle and left near the motor points of the muscle. The electrodes are often made up of Teflon\textsuperscript{TM} insulated multifilament and form a helical coil structure, with the end bent to ensure proper anchorage. This type of electrode usage allows for better muscular selectivity as compared to surface electrodes.\textsuperscript{8,14,15} However they are prone to cause infection, so the site where the wire enters the skin must be properly cared for and inspected frequently. There is also an increased risk of the wires kinking during movement due to their crossing of many muscle planes, causing their average life span to be approximately one year. This form of stimulation is often considered cosmetically unacceptable because of the wires placed through the skin.

Implanted electrodes alleviate the problem of wire misplacement and crossing during movement. They are sutured directly over the motor points, a process which
involves a surgical procedure to find the exact location of the nerve entry into the muscle.\textsuperscript{15} With this type of electrode stimulation system, the electrodes and stimulator are both totally implanted.\textsuperscript{8,14,15} Advantages of this procedure involve high cosmetic acceptability and easier application of multichanneled systems. Although, cable failures may be a concern with implantable electrodes.

The capabilities of the FES system depend on how many channels and electrodes it uses, the sequence of stimulation, whether it uses feedback, and how complex the computer system is.\textsuperscript{14} The fewer electrodes and channels used, the simpler the FES system, and the more bracing required to maintain upright stability. Presently, most ambulation systems under experimentation are open loop systems.

Open Loop and Closed Loop Systems

Open loop systems involve no feedback mechanism to determine whether too little or too much information was sent to the muscles.\textsuperscript{15} With these systems, the patient has no skin, joint or muscle sensation to regulate activities so they must rely on their visual sensations to regulate movement.

Closed loop systems allow the patient to be aware of his limb location and position in space, and provide feedback electronically.\textsuperscript{14} In lower limbs, this type of system can prevent footdrop by stimulating electrodes placed over the peroneal nerve. For instance, every time the patient raises his heel, there is a heel switch that activates the stimulator, and the peroneal nerve is fired causing dorsiflexion and eversion of the foot during the swing phase of gait (facilitates foot clearance). They can also consist of electromyography (EMG) signals, which involve sensors that detect a movement about to
take place, send the message to the stimulator, which then activates the necessary muscles
to carry out the action. This type of command source is more natural in that it requires
less concentration by the patient, but the signals may also be easily misread. EMG
signals are still under experimentation, but future availability is hopeful. Closed loop
systems can also be used in the upper extremity. Sensors are placed on the fingertips
which monitor the amount of force necessary to hold or carry an object as delicate as an
egg without crushing it or to use something as heavy as a hammer with controlled
movement. Closed loop systems will provide regulated movement by stimulating the
muscles at various intervals when needed, instead of continuously as with open looped
systems, thereby decreasing muscular fatigue and contributing to more efficient
functional movement, such as standing and walking.

Prior to performing functional tasks, FES systems are being used in the
rehabilitation settings from exercise to improve cardiovascular fitness and respiratory
function, reduce post injury complications, and increase muscular strength and
endurance. FES exercise training is often a precursor to standing and ambulation, in
order to ensure that the subject is in good physical condition and motivated toward
rehabilitation.
CHAPTER IV
FES EXERCISE TRAINING

Inactivity due to a SCI can lead to degenerative conditions, secondary complications, and long term health problems. Past research suggests that FES exercise training may result in increased circulation, increased bone density (which may help to prevent fractures), prevent muscular atrophy (and aid in hypertrophy), decrease chances of skin breakdown, and improve cardiovascular fitness. Some of the most commonly used exercise techniques for individuals with paraplegia usually involve a combination of FES knee extension strength training, and leg cycle exercise training. Although some researchers believe that standing and walking without prior exercise training, provides enough conditioning and strengthening. There is speculation that increased load resistance during training may enhance peak load resistance and aerobic metabolism. These findings would indicate that FES training affects strength gains and endurance of paralyzed individuals, which may in turn delay the onset of fatigue during electrically induced standing and gait protocols. This chapter will break down FES exercise training into three phases, describing the various equipment used, and the physiological and musculoskeletal changes that occur.

Phases of Training

The first phase (Phase 1) of exercise training usually consists of FES stimulation of the quadriceps muscles, used to evoke increases in lower limb muscle strength,
endurance, and reconditioning of joint mobility prior to stimulated standing or gait.\textsuperscript{35} Surface electrodes are applied to the anterior region of the thigh around the suprapatellar region near the femoral nerve.\textsuperscript{28}

In past studies, strengthening following a SCI (usually at least 6 months or more) ranged from weeks to several months (average 1 to 3 months).\textsuperscript{24,35,36} The stimulation protocol according to studies conducted by Bremner and colleges\textsuperscript{24}, Malezic and Hesse\textsuperscript{35}, and Arnold et al\textsuperscript{36}, for complete and incomplete SCIs involved isotonic strengthening, and progressed to resisted isokinetic quadriceps conditioning. Each repetition ended when the patient's muscle torque increased by approximately 50% of its initial value.\textsuperscript{35} These exercises were continued for an average of 3 to 6 months.\textsuperscript{28,31,35} Stimulation would begin with sessions ranging from 5 to 8 seconds on and 5 to 10 seconds off for 20 to 30 minute periods two times per day.\textsuperscript{9,24,28} Training would often advance to two 60 to 90 minute sessions daily, alternating between the right and left leg.\textsuperscript{9} Increased resistance consisted of increasing the angular velocity (from 30°/sec to 90°/sec) or by adding weights (average of five pounds).\textsuperscript{31,36} For quadriceps strengthening, the patient was positioned either lying supine with the knees elevated or sitting.\textsuperscript{9,32} Stimulation parameters included pulses of 0 to 120 v, 1 to 120 mA, 20 to 35 Hz, and .375 to .400 msec pulse width. Measurements to determine stimulation induced quadriceps strength were recorded by a strain guage cantilever beam and/or a Cybex isokinetic dynamometer.\textsuperscript{24,31}

The second phase of exercise training is receiving increasing amounts of research in respects to SCI patients and cardiovascular fitness, and involves the use of a leg cycle
ergometer (LCE) in combination with FES. Research has shown that FES leg cycle ergometer exercises provided superior central hemodynamic results to that of arm cycle ergometry (ACE), and is currently the popular method of training.34

Computerized electrical stimulation bicycle ergometry was developed by Petrofsky and colleges in 1984.32,36 Bicycle ergometry gained approval from the FDA, and generally consists of the REGYS I and ERGYS I clinical rehabilitation systems. The REGYS I is mainly used in the clinical setting, and training with this includes ergometer exercises, along with lower extremity strengthening by doing leg lifts. The ERGYS I functions solely as an ergometer, and is used at home for experienced individuals.32 There are other styles of exercise cycles and equipment available in addition to those mentioned in this chapter.

The FES protocol for the second phase (Phase 2) of training consists of ergometry, and synchronous stimulation of the quadriceps, hamstrings, and gluteal muscles using the ERGYS I machine, which can also be used in the first phase for strengthening.24,32,34,36,37 The patients started by “bicycling” 1 to 2 min via electrical stimulation, with gradual increases in time to 20 to 30 min. Each training session included a warm-up period (approximately five min), followed by 25 min of cycling at 50 rpm.32,36,37 A monophasic waveform was applied with 0 to 130 mA current, 30 to 35 Hz frequency, and .375 to .400 msec duration. If the bicycling rate fell below 35 rpm, then the unit was shut off because the resistance was too much for the patient to overcome. For the majority of experiments, the power output ranged from 0 to 12.2 W for the quadriplegic subjects and 0 to 18.3 W
for the paraplegic individuals, allowing them to exercise for the entire period without becoming fatigued. 37

During the third phase (Phase 3), resistance is often applied using the ERGYS I system at home. Resistance was added from 0 to \( \frac{7}{8} \text{kp} \) depending on the patient (max levels recorded were at \( \frac{4}{8} \text{ to } \frac{5}{8} \text{kp} \)). This phase would continue as long as the patient maintained their exercise regime.

Physiological and Musculoskeletal Changes

A study conducted by Grant B433-R from the Rehabilitation Research and Development Service of the U.S. Department of Veterans Affairs in 1989 on 14 subjects (seven with quadriplegia, and seven with paraplegia), assessed their physiological responses to FES cycle ergometer exercise an ERGYS I leg-cycle following stimulation parameters outlined in phase two. 37 This exercise protocol resulted in nonsignificant increases in heart rate (HR), oxygen uptake (VO2), minute pulmonary ventilation (VE), from five minutes to the completion of the 30 program. 37 Significant increases in respiratory exchange ratio (RER) values were seen at the end of the exercise as compared to the resting period, which declined from 5 minutes to 30 minutes. The individuals’ pH level was significantly higher at the completion of the exercise than at 10 minutes within the program. Individuals with paraplegia tended to have greater reductions in plasma volume (PV) during cycling. The oxygen extraction from the vessels only slightly increased (about 4% for individuals with paraplegia), showing that oxygen was being delivered to the muscles via the blood flow, and not by voluntary contractile muscle. The authors feel that the increases in cardiac output (CO) and stroke volume (SV) enable
cardiovascular training in individuals with SCI, by creating a large enough cardiac-volume.

A similar study conducted by Hooker et al,34 looking at physiological changes related to leg-cycle exercise, concluded that there was a significant increase in power output (PO) following a 13.6 week training program (± .9 weeks) consisting of 36 sessions 30 minutes long, beginning with 0 W of resistance initially, increasing to 6.1 W after three sessions. This study also found there to be significant increases in VO2, VE, HR, and CO in posttraining verses pretraining measurements. Refer to Table 2. According to Hjeltnes, and Lannem,31 FES exercise training is considered to be an effective method for increasing strength and endurance in paralyzed muscles. Four subjects were looked at, who were given stimulation to the quadriceps bilaterally, with knee extension torque measured by the Cybex isokinetic dynamometer. Angular velocities began at 0 degrees/sec to 240 degrees/sec, and the thigh circumference was repeatedly measured monthly, 20 cm above the lateral femoral condyle. The patients underwent stimulation sessions two times daily for approximately 5 to 10 minutes following stimulation parameters similar to those mentioned in Phase 1 of exercise training, and increased to 4 or 5 sessions for about 30 minutes each. Overall, their study showed that FES is beneficial in increasing strength and endurance in paralyzed muscles. Muscle endurance increased five times the initial value within three weeks, and knee extension torque doubled within 10 weeks for two subjects. The first subject had an increase in thigh circumference from 41.5 to 45 cm within 10 weeks, along with a greater physical endurance capacity (from 28 ml/kg/min to 31 ml/kg/min) following the study.
Table 2. Physiological Responses for Pre- and Postexercise Training; means (p≤.05)³⁴

<table>
<thead>
<tr>
<th>Physiological Responses</th>
<th>Pretraining(mean)</th>
<th>Posttraining(mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen Uptake (VO₂)- l/min</td>
<td>0.78</td>
<td>0.95</td>
</tr>
<tr>
<td>Power Output (PO)- W</td>
<td>13.6</td>
<td>19.7</td>
</tr>
<tr>
<td>Pulmonary Ventilation (Ve)- l/min</td>
<td>28.1</td>
<td>35.7</td>
</tr>
<tr>
<td>Heart Rate (HR)- bpm</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td>Stroke Volume (SV)- ml/l</td>
<td>91</td>
<td>97</td>
</tr>
<tr>
<td>Cardiac Output (CO)- l/min</td>
<td>8.5</td>
<td>9.6</td>
</tr>
<tr>
<td>Mean Arterial Pressure (MAP)- mmHg</td>
<td>90</td>
<td>85</td>
</tr>
<tr>
<td>Total Peripheral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resistance (TPR)- mmHg/min</td>
<td>11.3</td>
<td>9.7</td>
</tr>
</tbody>
</table>
She was also able to walk for 30 min continuously in the parallel bars with FES assistance by three months and for a distance of more than 60 m using FES and a walking frame or crutches. The other three subjects showed increases in thigh circumference, strength, endurance, and were either able to walk in or outside the parallel bars at some point during the study. Another study by Arnold et al,\textsuperscript{36} also showed significant increases in quadriceps strength after 12 weeks of following Phase 1 exercise training, in addition to increases in thigh girth following the 4 to 6 month ergonometry phase (Phase 2).

Overall, researchers feel that FES exercise training has positive effects on the cardiovascular, respiratory, and musculoskeletal systems. Many authors agree that exercise training increases the body’s physical endurance and strengthens the muscles necessary for standing and walking. In addition to being physically fit, SCI individuals are often required to wear an orthotic device when using FES for functional purposes.
CHAPTER V
ORTHOTIC DEVICES AND HYBRID SYSTEMS

Orthotic Devices

Braces and orthotics are a necessity when ambulating for individuals with lower extremity paralysis, due to a SCI. Achieving dynamic and semi-dynamic balance is crucial, and individuals with SCIs are generally dependent on crutches, walkers or other assistive devices to maintain upright balance control and stability during those unstable phases of the gait pattern. The introduction of thermoplastics has made a significant impact on orthotics; resulting in orthoses that are usually lighter and cosmetically more acceptable than those used in the past. There are a variety of different types and styles of orthotics and braces under experimentation today. This chapter will describe some of the more acceptable models currently being used.

Today, there are at least three mechanical systems in widespread use for restoring upright mobility to the SCI population. First of all, there is the traditional long leg brace (LLB), otherwise referred to as the knee ankle foot orthosis (KAFO). This system functions by locking the leg joints with a metal or plastic frame; providing antigravity support to the knees and ankles. The individual is able to stand and take steps by either externally rotating the legs and alternately swinging each leg forward, or by using a swing through gait pattern, where the person swings both braced lower extremities forward.
simultaneously.\textsuperscript{15,16,38,39} Both methods require excessive force of the upper extremity and trunk muscles for upright support.\textsuperscript{7,38}

Secondly, there is the hip guidance orthosis (HGO), also known as the ORLA Parawalker, developed in Oswestry, England.\textsuperscript{7,14,15,38} This system involves a rigid hip knee ankle foot orthosis (HKAFO) with low friction hip joints. It allows motion at the hip joint to occur freely for a certain range of flexion and extension, but the patient must also use his arms to provide stability of the hip joint and trunk. It is thought to provide a more efficient gait pattern with less energy expenditure as compared to the LLB, due to the added hip support. Increased walking speeds are more beneficial in regards to muscle energy expenditure with this model, because as the walking speed increases, less time is spent in the double stance phase of the gait cycle. As a result, less energy is required of the upper body.

Thirdly, there is the reciprocating gait orthosis (RGO), developed at Louisiana State University. This orthotic device was developed to decrease the effort used by individuals with paraplegia when walking.\textsuperscript{7,10,38,39} It is a thoracic hip knee ankle foot orthosis (THKAFO) with an additional dual cable design, which preserves energy by permitting the right and left sides to work together. For instance, hip flexion of one leg is facilitated, while hip extension of the opposite leg is maintained. There are several RGO devices currently being researched, and the design of these orthoses is basically the same.\textsuperscript{26} The body is braced from the mid-trunk to the feet, providing energy-free antigravity support for the knees and ankles as well as the hip, creating more efficient ambulation as compared to other orthotic devices.\textsuperscript{38} The patient can assume a fully
balanced and stable upright posture with minimal use of his trunk musculature and none from his upper extremities. The hips are prevented from going into adduction, but provide flexion and extension. By facilitating flexion at the hip, these orthoses permit steps to be taken with less effort and energy expenditure. Tilting the pelvis allows the trailing leg to clear from the ground and move ahead, and the body is moved forward using crutches, walker, etc. for balance and upper extremity support.

Individuals with lower lumbar neurological lesion levels may be able to ambulate using an ankle foot orthosis (AFO) without FES. This brace extends from the foot to just below the knee, and consists of a flat, rigid sole and a plastic half-shell. They are lighter and easier to put on as compared to the long leg brace, and individuals are able to wear them under clothing.

Hybrid Systems

While the orthosis assists with the swinging motion of the body, FES provides improved control of the pelvis and trunk, limits the degrees of freedom in joint motion, compensates for insufficient muscle force due to weakness or reflex inhabituation, and functions as a back up support in case of collapse. Because of the energy inefficiency in using the orthoses alone, the walking distance is usually limited to approximately 20 meters. Hundreds of meters to several miles can be achieved using the hybrid systems. Despite the bulkiness and slowness of applying these FES and orthotic units, people are often pleased with the combination of stability and mobility that these systems allow.

A study conducted by Petrofsky and Smith, compared the use of an RGO alone and an RGO with electrical stimulation on the bilateral hamstring and gluteus maximus
muscles. The effect of FES on speed of gait and physiologic costs was measured. Four subjects were selected between the ages of 20 to 35 years, who had sustained their SCIs between the fourth and twelfth thoracic vertebrae. Electrical stimulation was applied for .75 sec at a frequency of 30 Hz, and a pulse width of 350 usec., which increased from 0 mA to 75 mA in amplitude. VO\textsubscript{2} and CO were measured using a metabolic chart, with scores taken before and after each trial. Their HR was also recorded by an electrocardiograph (ECG) machine, and blood pressure (BP) taken with a sphygmomanometer placed on the left arm.

The upper body muscles were tested to determine their electrical activity during three trials of three second maximum effort.\textsuperscript{29} These muscles consisted of the biceps, triceps, and pectoralis major muscles. Once the maximum strength of these muscles was discovered, separate contractions were exerted for 2 to 3 sec periods at 20%, 40%, 60%, and 80% of their maximum strength. Between each contraction the muscles were allowed to rest for three min. Lower extremity activation included an isometric force of the hamstrings and gluteus maximus muscles during steps with each leg.

Results of the experiment showed that the maximum aerobic capacity of the leg muscles was reached at 60% to 80% of their maximum strength.\textsuperscript{29} The activity of the arm muscles work about 70% of their maximum aerobic capacity when walking in braces without FES, but when walking in braces with FES, this drops to 32% for the arms and to 25% for the legs. When compared to ambulation with able bodied controls, the FES system shows slightly higher VO\textsubscript{2} and non significant stress on the cardiovascular system. In contrast, ambulation without the FES system was very inefficient and placed high
stress on the body. Unassisted FES ambulation for subjects with paraplegia was slower (approximately half of the maximum speed) and less efficient, causing a non-steady increase in BP and HR throughout the work duration, and became so inefficient that VO\textsubscript{2}, HR, and BP increases continued for one mile. The subjects assisted by FES were able to walk the distance (1 mile) easily.

The Marsolias FES system currently utilizes the most muscle energy and is less efficient than the other types of devices.\textsuperscript{38} The muscles stimulated cover at least two joints, therefore forces are applied to two joints at each contraction instead of just one (like with hybrid systems). For this reason, and the fact that no orthotic device is used, this particular system requires more energy expenditure. To maintain an upright posture, tension in several muscles is necessary to keep antigravity support. Increased speeds reduce the muscle energy expenditure, because the individual does not have to keep static stability.

The Petrofsky/Smith Energy Orthosis is one orthotic device currently under extensive research at the Petrofsky Center for Rehabilitation and Research Center in Ohio.\textsuperscript{30} Refer to Figure 3. Instead of restricting unwanted motion, this device actually assists with ambulation. This unit, like other orthoses, can be used alone or in conjunction with FES. It is designed to meet the special needs of the user, whether that involves use for special occasions or stability for daily FES exercise.

Future designed bracing is continually evolving, to include “...small, computer activated, electromechanical joint motion control mechanisms, such as electric motors, wrapped-spring clutches and magnetic particle brakes.”\textsuperscript{15(p52)} These systems will allow
Figure 3. Petrofsky/Smith Energy Orthosis
for more normal knee motion during the swing phase. Currently, they are limited, due to cost and individual access.

The University of Alberta in Edmonton, Canada is working on a device in which the bracing is divided into separate sections for the legs and trunk. There are feedback controls used by the leg sections to provide stimulation only when needed. This device further reduces energy burdens of the user, and plans to conduct trials at several centers is in progress. Specific hybrid systems used for standing and ambulation will be discussed further in chapter six.
Standing for individuals with spinal cord injuries promotes increased circulation and bladder function, weight bearing to decrease bone demineralization, decreased muscle atrophy, increased chest expansion to reduce respiratory complications, and a decrease occurrence rate of pressure sores.\textsuperscript{9,30} While these functions are important to the clinician, FES may be important to the SCI patient for other reasons. For instance, FES induced standing enables the paralyzed individual to perform functional tasks such as reaching items up in the cupboard, and standing over the sink to brush their teeth or to look in the mirror to comb their hair.\textsuperscript{16,30} According to a study conducted at Shriner’s hospital in Philadelphia on SCI individuals, “...primary reasons for wanting to use an FES standing system outside of the hospital would be to stand in front of a mirror, to stand for photographs, and to stand in order to speak at eye level with another individual.”\textsuperscript{16(p9)}

Standing methods using electrical stimulation will be described through the use of different studies conducted on subjects who have sustained SCIs between thoracic vertebral levels T\textsubscript{4} through T\textsubscript{12}. The majority of systems used are open loop systems, which involve continuous stimulation of the quadriceps muscles in order to stand and possibly the gluteus maximus, gluteus medius, hamstrings, adductor magnus, gastrocs,
and soleus depending on the technology of the system. These systems require continuous stimulation, because they do not receive feedback regarding the standing state, leaving them unable to adjust stimulation intensities based on the need for postural stability as compared to able bodied individuals. Due to constant stimulation, muscular fatigue often results, although frequencies between 18 to 25 Hz are generally used to reduce chances of fatigue.

A study conducted by Yarkony et al, in 1990 on 21 subjects with complete motor and either complete or incomplete sensory lesions, defined standing as, “...the ability of the subject to stand in the parallel bars, using bilateral simulation of the quadriceps, with more than 95% of the body weight supported by the legs for more than one minute.” Standing was begun after the patients had exercised their quadriceps using an exercise stimulation protocol similar to that described in chapter three. The subjects used KAFOs and assistive devices such as parallel bars or walkers during the standing process.

The standing protocol involved bilateral FES quadriceps stimulation using surface electrodes to stabilize the knees, with the patient assuming an upright posture. The hips were kept in a hyperextended posture to provide more stability in standing, eliminating knee support due to gravity. The patient’s ability to maintain an upright posture in standing using FES was assessed by having the patient release his hands for approximately two seconds from the stable support, frequently palpating the patella to make sure the quadriceps were contracting, and occasionally reducing the stimulation voltage, allowing the knees to buckle.
Proper weight bearing was tested by placing scales under both feet. The weight borne on each foot and the difference between both feet was recorded by using a dual scale platform. Ground reaction vectors (GRV) were recorded using a biomechanics force platform, which read the ground forces produced by the individuals, and how much body weight was actually supported by the legs.

The actual stimulator which enabled the subjects to stand, was regulated by an on/off switch located on the front panel. The "postural change" button, also located on the panel, was pressed to begin the standing process. A warning sound was emitted preceding a two second delay after depression of the button to allow the subject to position and prepare himself for standing. The stimulation intensity was gradually increased from 20 Hz initially to allow a smooth transition to the standing posture. When sitting was required, the subjects would press the postural change button again, another two second delay and warning noise was sounded, and the body was slowly lowered with a gradual decrease in stimulation intensity. Initial stimulation intensities were later changed to 13 Hz to decrease muscle fatigue. When standing was performed at home, a standing frame with a padded bar placed in front of the knees was used for additional support in case of knee collapse. Results of this study showed that 6 of the 21 patients were able to stand at home without physical therapy assistance, and 15 of the 21 subjects were able to stand in the clinic with supervision. This protocol was beneficial due to the fact that the equipment was lightweight and easy to use, and did not mandate a surgical procedure or custom made orthotics (such as KAFOs).
Another study by Malezic and Hesse\textsuperscript{35}, did not use lower extremity exercise prior to standing or walking. Electrical stimulation was supplied in the study by a four channel surface electrical stimulator, first to both quadricep muscles to provide standing, and then to the hamstrings, gluteal muscles, and peroneal nerve to initiate stepping. Four subjects aged 24 to 38 years were used in this study, with spinal cord lesions at T\textsubscript{3}, T\textsubscript{4}, T\textsubscript{6}, and T\textsubscript{11}. FES sessions were given one to two times per day for the first month, consisting of passive standing using a standing board (frame). Standing was achieved by stimulation of the quadricep muscles using bipolar eight cm by five cm felt pads supplying 150 mA biphasic constant current pulses at 20 Hz frequency and a .25 ms pulse duration\textsuperscript{30,35}

There were no cardiovascular or orthopedic problems during the study, and the subjects were able to stand in a standing frame from 1.5 to 10 min during the first session, and reached 25 to 40 min of standing in 10 to 17 days\textsuperscript{35}. After the seventeenth day, a walking program was initiated. Researchers felt that the standing process alone provided enough exercise and strengthening, as compared to an exercise program completed prior to standing, as seen in other studies. During this experiment, the subjects’ quadriceps were strengthened isometrically during standing and required active participation of the patients’ trunk, upper extremity muscles and postural equilibrium reactions.

In 1993, researchers at the Faculty of Electrical and Computer Engineering, University Rehabilitation Institute, and the University of Ljubljana in Ljubljana, Slovenia, claimed that only 10\% of SCI individuals are able to participate in FES rehabilitation, with only 50\% of these individuals using walkers and 10\% using crutches for balance\textsuperscript{11}. These researchers confirmed that FES static standing time is currently limited from
several minutes to one hour, but could be extended using intermittent electrical stimulation of different muscles, or by using hybrid orthoses.

When using hybrid orthoses, patients can remain in a standing position for almost unlimited times. These devices usually have a calf strap that acts as a load measuring transducer. Tension on the strap signifies that ankle dorsiflexion is likely, and increased stimulation is applied to the quadriceps, to maintain the knee extension posture.

Walking

Walking, for the SCI population with paraplegia has been made more efficient with the development of the hybrid orthosis, a combination of the conventional orthosis, such as the RGO and HGO, with FES. These hybrid orthoses provide stimulation to the necessary muscles through surface, percutaneous, or implantable electrodes.

The muscles required for a coordinated gait pattern are stimulated in two stages. First, the quadriceps are activated by FES to produce a standing posture, and once upright, sensors attached to the orthoses lock the knee joint to prevent buckling. After this is accomplished, walking is created by stimulation of the gluteus maximus and hamstring muscles, which help propel the opposite leg forward.

This form of ambulation using the hybrid orthoses has several advantages as compared to the mechanical orthoses without FES assistance. This method decreases muscle energy cost, increases movement velocity, and increases walking endurance. Ambulation is also safer, and excess or undesirable movements are eliminated. There are disadvantages for using this method of ambulation, including difficulty donning and doffing the braces, the system’s cosmetic appearance (they may
not be easily acceptable to the user), and the gait pattern produced does not equal that of a normal gait pattern in regards to muscle energy costs, speed, smoothness, and coordination.\textsuperscript{10,11,16,30}

Current hybrid systems are using FES to stimulate forward propulsion and not just stabilization and support. These systems use 4 to 8 channels and stimulate an average of 2 to 4 muscles per leg, by using surface electrodes.\textsuperscript{7,11,14,16,35} In addition to stimulation of the hip and knee extensor muscles (gluteals, quadriceps, and hamstrings), a flexion reflex is also activated to produce foot clearance by stimulating the peroneal nerve. This type of system allows the individual to adjust their gait pattern to the demands of the environment, and walking in the rehabilitation and community settings has been demonstrated.

Stimulation intensities often play an important role in the walking protocol. Studies show that frequency intensities of 16 Hz for the quadriceps and 60 Hz for the peroneal nerve are optimum stimulation intensities, in conjunction with approximately 150 mA at a .25 ms pulse duration.\textsuperscript{30,35} One study conducted at Louisiana State University Medical Center, New Orleans, LA., on six persons with paraplegia and lesions between T\textsubscript{1} to T\textsubscript{10}, showed that .208 m/sec is the most efficient velocity for walking using an RGO with FES assistance over the full range of walking speeds.\textsuperscript{40}

Walking speeds will vary from person to person and will depend on the type of orthotic device. A study using the RGO Parastep, selected average walking speeds between 4.6 m/min. to 24.3 m/min as minimum velocities for individuals with spinal cord injury.\textsuperscript{7} The University of Southwestern discovered that the physiological cost index
(PCI) ranged between 2.30 to 6.26 beats/min in five patients with lesions between T4 to T12. Isakov and coworkers\textsuperscript{7} reported that when the RGO was used in combination with FES the PCI dropped from 2.55 to 1.54 beats/min. HR was also shown to increase with RGO and FES assisted ambulation from 88 beats/min at pretrial to 119 beats/min after ambulation, an approximate 35.2% increase. These statistics were substantially lower as compared to the RGO alone (52.3% increase from 86 to 131 beats/min), along with the LLB and HGO, as shown by some studies done at Louisiana State University Medical Center.\textsuperscript{40}

Increasingly complex systems involving up to 48 channels are currently being developed and experimented with by individuals with SCIs. Most of these systems use intramuscular implantation of electrodes, which decreases the risk of cross over and kinking of the cables due to the many channels they have. Almost all the muscles involved with ambulation and some trunk muscles can be stimulated using this method. A modified version of the eight channel Marsolias FES System, was recently developed and should have been available for experimentation in 1995.\textsuperscript{15,29} This system is called the Marsolias Model and uses 32 channels of stimulation.\textsuperscript{29} With it, individuals have increased control over functions they wish to perform such as sitting, standing, walking or exercise by activating simple thumb switches on the walker or crutches that allow a variety of activity selections.\textsuperscript{29}

Advantages of this system include: increased fluidity and speed of movement, decreased bracing, more independent control of muscles, and better quality of ambulation.\textsuperscript{16} There is also less reliance on assistive devices and upper extremity
support, which results in less muscle energy costs. The maintenance and complexity of these systems is a major disadvantage, which is one reason they are still mainly used in the experimental setting.

The Parastep System is the only FES system that has received FDA approval, and is currently available for community usage. This system involves an RGO design with six channels of stimulation controlled by on/off switches located on the handles of a walker.\textsuperscript{7,14} The Parastep includes a microprocessor computer and surface electrodes placed over the hip and knee muscles bilaterally and over the deep peroneal muscles on both lower legs. To initiate the gait sequence, the patient presses a button, which stimulates a single step on the ipsilateral side and extends the limb on the opposite side. Another button is pressed to initiate the same sequence on the opposite side, facilitating reciprocal movement of the lower extremities.

Research is also being conducted at the Petrofsky Center for Rehabilitation and Research in Irvine, CA, by Dr. Jerrold Petrofsky, neurophysiologist and professor of biomedical engineering.\textsuperscript{25} The ERGY I and REGYS I leg cycle machines, and the Parawalker 9000 FES ambulation system are some of his present FES assistive devices for ambulation and exercise. The Parawalker 9000 is a hybrid RGO system, which involves a challenge 900 computer and the Petrofsky/Smith Energy Orthosis.\textsuperscript{25} Petrofsky has been modifying his walking system since 1982 when he displayed his first unit on the television show, 60 Minutes. The original system was cumbersome and involved the use of an overhead harness, parallel bar support, bulky orthosis, miles of wires, and a large computer. The girl using this system was Janni Smith, RN, and a T4 paraplegic, who
three years later was walking outdoors with a wheeled walker, followed by a seven mile marathon in Honolulu in 1992. She currently helps with research at the Petrofsky Center, and feels that the benefits of FES go beyond physical fitness, by enhancing the social and psychological aspects of health as well and states, “It is much more difficult to be excluded than it is to be paralyzed.”\textsuperscript{25(p4)}
There are currently no cures for spinal cord dysfunction. Due to developing research, the medical care and treatment of paralyzed individuals is constantly improving. Scientists are dedicated to finding a cure for spinal cord injury, but as of yet, the possibility of regenerating or repairing damaged spinal cords is nonexistent. This chapter will highlight important research discoveries made in the past and those occurring presently. It will also address the current progress and future aims of FES research facilities, which strive to fill the temporary loss of function and independence due to a SCI. The goal of these centers is to provide a current means by which individuals with paralysis can maintain their role in society, as optimally as possible, until an actual cure is available. Finally, this chapter will include information regarding the overall costs related to SCIs.

FES Research

There are several institutes dedicated to developing innovative technologies in regards to FES research, making strides towards more effective treatment of paralyzed individuals with SCI. The National Institute on Disability and Rehabilitation Research, U.S. Dept. of Education, presently sponsors 13 systems ranging from the east to the west coast. Case Western Reserve University (CWRU) of Cleveland, Ohio, is where a majority of research is conducted. CWRU is one of the most advanced centers in the
world in regards to FES. Marsolias, Keith, Freehafer, Crago, and Chizeck are a few of their leading researchers for designing an FES ambulation system, state-of-the-art FES adaptive controls, digital controls, and methods for tendon transfer. Louisiana State University, headed by Salomonow, is working on developing a RGO, which overcomes muscle fatigue problems encountered by the CWRU group when using the FES alone. A major program entitled the CALIES project (Computer Aided locomotion by Implanted Electrical Stimulation), involves several countries and "...aims to teach engineers and surgeons about the technological and surgical aspects of FES, and how to implant electrodes for FES in patients."\textsuperscript{15(p433)}

Whether or not FES systems are truly beneficial for individuals with SCIs is a controversial issue. Research institutes such as the Walker Institute, the Petrofsky Center for Rehabilitation and Research, the Peers Program, Walk Back, Help Them Walk Again, and the Universal Institute have their own opinion.\textsuperscript{39} "The braces eventually wind up in the closet, but for some people, it's important to try to make sure they haven't missed out on something. The question is whether or not it's worth it, and that's a question people have to answer for themselves," states Ragnarsson, Mount Sinai Medical Center.\textsuperscript{39(p152)} "We don't say ambulation is for everyone. We just want to give them the opportunity to do it. If it makes them feel better, why not?"\textsuperscript{39(p151)} adds Berns, M.D., Peer Program.

Today, hope has truly replaced a majority of skepticism. Martin Schwabb, Ph.D., neuroscientist at the University of Zurich, Switzerland and a member of the APA's Science Advisory Council sums it up well, "A treatment for spinal cord injury is on the horizon."\textsuperscript{2(p2)}
Costs

For the approximate 250,000 SCI individuals living in the United States, their injuries are not all they have to worry about. They are also burdened with the expensive medical costs and living expenses. Individuals are better off if they can live at home following their injury, but even then costs range from $140,000 and up.\(^2\) This amount covers their initial hospital stay (approximately 100 days), adaptive equipment, and home modifications. Lifetime costs for this population on average is $600,000, and can reach up to $1.3 million. Costs will vary depending on the age of the individual at the time of injury, the level, and the severity of injury.\(^1,3\) The lifetime care, medical and adaptive costs for individuals who must maintain institutionalized may average approximately $4 million.\(^2\)

The use of FES can reduce health care costs by an estimated 90% (for those individuals able to use FES systems), to less than $1,000 per year, by decreasing secondary complications, and allowing the disabled individual more independence in performing functional activities.\(^29\) For instance, the financial impact of a decubiti ulcer is outstanding, with hospitalization and treatment running as high as $100,000 per ulcer in 1992.\(^25\) The average cost for each ulcer is usually around $26,000, making them the most costly medical problem in the United States today. In addition, each year one of every ten people with SCIs sustain a fracture, which will more than likely not heal well. FES allows for increased function and upright mobility, which will reduce the risk of pressure sores, fractures, and other systemic and physical problems related to CNS dysfunction.
Although FES systems have been shown to be beneficial in many ways, some sources say that exercise provided by these systems is possibly one of the greatest.23 There was plenty of excitement when the ERGYS I home-bicycle was developed by Petrofsky and colleagues in 1984, and is widely accepted and offered by many rehabilitation centers today. In 1987, Therapeutic Technologies, Inc. (TTI) came out with their home-use bike. As was promised, the bike increased muscle bulk and strength, but costs range around $18000 for the bike, plus $550 for the electrode package and $365 for the stimwear (a three piece garment which hold the electrodes in place). The cost of this system makes it almost impossible to purchase for home use.32

Another cost individuals with SCIs must consider is that of assistive devices, such as braces and orthotics. Braces and orthotics are essential for ambulation, providing increased balance and trunk support. They may also provide lower extremity stability for extracurricular activities. Boot/braces cost approximately $4500, followed by LLB ranging from $2000 to $8000.36 The KAFO brace, designed by Thorkild Engen, averages around $1000, and the RGO unit designed by Douglas in 1967 costs about $10000. The cost of these units may vary as compared to the cost of other RGOs and HGOs made by different companies.

The Parastep FES ambulation system costs approximately $15000.14,29 The Parawalker System, designed in Ostewsky, England, is currently under study, and costs about $12000. Petrofsky’s Parawalker 9000 FES system averages around $40000. Neither of these systems are very accessible for home-use or for experimental purposes due to their high cost.
The current cost concern regarding SCI individuals is addressed in the July 12, 1996 issue of the PT Bulletin. The PVA association is worried that the present efforts to control health care costs will deprive individuals with SCIs the proper care and treatment needed. Specific interest is being placed on the current plan to begin in 1998, which will allocate the PVA aid based on the number of patients served. Mr. Mansfield, executive director of the PVA is not very supportive of this system. "Even the high-end capitation rate we are hearing proposed does not meet the costs per bed of many SCI centers."

The cost of FES systems is staggeringly high, making availability and experimental research difficult. As new innovative technology emerges, the use of electrical stimulation for functional purposes, such as walking, should become available within the next ten years. One reason for such high health care costs, is the fact that advances in technology and medical care have been made, which allow a person with an SCI to live a near normal life span. The United States currently spends $400 billion on direct health care costs and an additional indirect cost for people with neurological conditions. With the increasing amount of SCIs per year (7600 to 11000), and the decreasing mortality rate for victims with SCIs, costs will most likely continue to increase. In 1992 alone, there were 10000 new cases of SCIs reported nationwide, and projected costs for these injuries totaled $10 billion. According to the APA, if the United States would spend more effort developing therapies for these people with SCIs and concentrate on preventing the occurrence of more injuries, the "U.S. would save as much as $400 billion on future direct and indirect SCI lifetime costs."
CHAPTER VIII

CONCLUSION

Spinal cord injury affects hundreds of thousands of individuals a year, with the numbers gradually increasing. The majority of injuries are caused by trauma to the vertebral column, resulting in complete or incomplete spinal cord injuries. Due to advances in medical technology and health care, these people are living near normal life spans, and are enjoying hobbies or other interests they had prior to their injury.

The ability to perform these activities has been enhanced with the use of hybrid orthoses, which combine orthotic devices such as LLB, HGO, and RGO, and FES to produce movement patterns similar to those of able bodied individuals. By allowing upright mobility, these systems reduce secondary complications and increase the individual's overall health status. The financial impact of purchasing special equipment, obtaining appropriate medical care, and receiving necessary rehabilitation services is very expensive and plays an important role in determining future objectives for individuals with SCIs.

The use of electrical stimulation to restore functional movement in patients with paraplegia is becoming a reality due to today's technology. Research has lead to developments in more complex electrical stimulation systems, which enable standing and walking with less complications such as muscle fatigue due to continuous stimulation, difficulties donning and doffing the prosthesis, and high muscle energy costs of the trunk.
and upper extremity muscles. In addition, current developments in thermoplastics have resulted in orthotics that are more durable, lighter, and more efficient as compared to those used in the past. FES allows individuals with spinal cord injuries to live fuller and more productive lives, and accomplish tasks once thought to be impossible. “For years the reversal of paralysis was considered hopeless. Today, we see it happening everyday,” states Janni Smith, a T4 paraplegic. Ambulating for individuals with a spinal cord injury is one of the most gratifying aspects of an FES rehabilitation program. “Being able to look at someone eye to eye is psychologically very uplifting,” comments Franklin Alaya, a quadriplegic. “If someday they do come up with anything that will repair the spinal cord, I want to be in shape. I want my muscles to be ready,” adds Karen Fernbaugh, a T11 paraplegic.
REFERENCES


