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FUNCTIONAL ELECTRICAL STIMULATION IN SPINAL CORD INJURY REHABILITATION

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INTRODUCTION

Spinal cord injury is defined as a "disconnection syndrome" that results in a loss of ability of the spinal cord to communicate ascending and/or descending impulses (Hamid and Hayak 2008). Due to its role as the primary conduit of motor and sensory impulses, spinal cord injury is widely regarded as one of the most catastrophic, survivable injuries a person can suffer. Depending on the severity and placement of the injury, the patient can experience a wide range of disability or death. A mild injury may result in the patient lacking strength in one limb, while a severe injury can place the patient on a ventilator for life (Field-Fote 2009).

Before World War II, treatment for a spinal cord injury was very limited and rehabilitation was almost non-existent. Life expectancy for a patient with a spinal cord injury (SCI) was very short. In most cases, secondary renal, cardiovascular, and pulmonary conditions took the life of the individual shortly following the injury. Advances in the past forty years have improved care to the extent that individuals living with a spinal cord injury can now expect to live nearly as long as able-bodied individuals (Hamid and Hayak 2008). The increased use of intermittent bladder catheterization dramatically cut down the chances of an individual developing renal complications, and advances in emergency medical care resulted in fewer incomplete spinal injuries turning into complete spinal cord injuries during stabilization and transport of the patient (Field-Fote 2009).

According to the Spinal Cord Injury Statistical Center, there are roughly 250,000 individuals living with spinal cord injury, with approximately 11,000 new injuries happening yearly. Between the 1970s and 2000, the average age of an individual with a spinal cord injury has risen from 28.7 years to 38 years. The rise in average age indicates that people are living longer with spinal cord injuries.

As people live longer with spinal cord injuries and the population of spinal cord disabled people increases, secondary conditions that SCI patients suffer become more apparent. The question of how the medical community can best service them becomes of more pressing importance. While the possibility of regaining the body's natural conduction system of sensory and motor impulses is far off in the future, there are numerous rehabilitative measures that can be employed to maximize the remaining healthy neural pathways and maintain optimal health.

While the central nervous system has suffered a cataclysmic injury from which it may never recover, the peripheral nervous system emerges mostly intact. This being the case, it is possible to generate muscle contractions in spinal cord patients using an external device to generate the impulse that would have otherwise descended from the brain via the spinal cord. Since as early as the eighteenth century, clinicians were using electrical impulses to generate muscle contractions (Hamid and Hayak 2008). In the 1960s, researchers began systematically applying electrical stimulation with the hope of helping patients recover. Muscle contractions were generated by stimulation that

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was delivered via electrodes placed proximal to the nerve that innervated the desired muscle.

As technology advanced, stimulation patterns became increasingly sophisticated and useful. Therapists and doctors began using this system, called Functional Electronic Stimulation (FES), to assist spinal cord patients with their rehabilitation and daily functioning needs (Prochazka 2009).

While the initial use of Functional Electronic Stimulation was simply to make the muscle contract and to apply the contraction to a functional motion, researchers began to notice that the technology may have other positive physiological effects on the users.

Aside from the obvious sensory and motor deficits that arise from a spinal cord injury, spinal cord injury patients typically suffer from a variety of secondary conditions caused by the injury itself and the sedentary lifestyle imposed on them by the injury. Muscular spasticity, muscular atrophy, cardiovascular and cardiopulmonary deficits are all common conditions amongst spinal cord injury patients (National Spinal Cord Injury Statistical Center 2009).

Researchers hypothesized that if they could utilize FES to keep spinal cord patients reasonably active, there is a good possibility that they can stop, slow, or even reverse the secondary conditions arising from the injury.

Care must be taken to distinguish between "neurotherapeutic" achievements and "neuroprosthetic" effects. The former refers to rehabilitative methods that result in a lasting therapeutic benefit that persists after the intervention is removed. The latter refers to the application of an external stimulus that allows for functional movement only as long as the external device is in use (Nogan-Bailey et al. 2010).

While many spinal cord patients regard walking again as the ultimate goal of rehabilitation, there are a number of issues that must be resolved before ambulation can be safely considered. This paper will follow the logical sequence of recovery that the patient and therapist must follow if he or she is to regain locomotion capacity. Spasticity management, atrophy reduction, and cardiovascular/cardiopulmonary fitness are all preconditions to successful, safe ambulation. For each of these, this paper discusses what it is, how it arises in spinal cord patients, how it affects spinal cord patients, and how FES may reduce its severity. Finally, an extensive look is taken at post-spinal cord injury locomotion.

To do this, published, peer-reviewed research on Functional Electronic Stimulation is reviewed and an attempt is made to state what, if any, are the therapeutic, rehabilitative, and functional improvements that patients experience when using Functional Electronic Stimulation as part of their rehabilitative regimen.

In preparing for this paper, twenty-five published peer-reviewed papers, eighteen of which are cited in the paper, were critically reviewed. A comprehensive textbook, *Spinal Cord Injury Rehabilitation*, written by Edelle C. Field-Fote, PT, PhD, a leading researcher in the field, provided much of the introductory material in each section of this paper. Data from the National Spinal Cord injury Statistical Center was also utilized.

SPASTICITY

While the descending excitatory impulses the spinal cord transmits may be the most noticeable, the inhibitory impulses are no less important. When these are disrupted by a spinal cord injury, the inhibitory functions of the spinal cord are affected. The lack of inhibition is most noticeable in the symptoms of spasticity. Spasticity is a hyper-reflexive response of a muscle to an outside stimulus (Field-Fote 2009). Spasticity is described as the fourth and final stage of spinal shock (Ditunno et al. 2004). Spinal shock is a condition immediately following a spinal cord injury that progresses from a period of absent reflexes, or hypo-reflexia, to the eventual emergence of hyper-reflexia. The reflexes emerge in a predictable pattern. The polysynaptic reflexes occur first, followed by the monosynaptic reflexes some weeks later. When the monosynaptic, deep-tendon reflex emerges, it is often highly sensitive to stimulation. The response is inappropriate in relation to the stimulus received and interferes with many activities the patient performs. Occasionally, the patient is able to anticipate the stimulus that causes the spasm and actually use the spasm for functional movement. More often, though, the spasm is an impediment. For example, some paraplegic patients are able to drive vehicles modified specially to accommodate their disability. For others, muscle spasms are triggered by passive stimulation as mild as the pressure the seat exerts on the driver when the driver executes a turn. The resulting spasm makes driving unsafe (Hamelburg 2009).

FES has been applied in an effort to reduce spasticity. Krause, et al. (2008) performed a crossover study of five patients with acute T3-T7 spinal cord injury. The patients performed both passive and FES activated leg-cycling movements on an ergometer. The FES activated muscles were the quadriceps, hamstrings, and gluteal groups. The results showed a consistent decrease in spastic muscle tone following the FES applied exercise, which was not always present following the passive muscle movements. Whatever reduction was experienced was gone by a week after the exercise. The reduction in spasticity can be explained by something as simple as muscle fatigue following the exercise, with the greater fatigue following active movement of the muscles involved. This study, however, is limited in a number of ways. The sample group was very small, and because the study was performed in an outpatient setting, the clinicians only personally tested the spasticity immediately before and after each session. All other data was subjectively reported by the participants themselves.

The Ashworth scale is a test often used to measure spasticity. Researchers question the validity of the test, because spasticity is an issue that can be more or less severe depending on the time of day, prior muscle activation, and patient fatigue. The test only scores spasticity at a single point in time. In this regard, subjective assessment by the patients themselves may actually be more useful than the Ashworth scale (Johnston et al. 2007).

Other studies have shown reductions in spastic muscle tone, but these, too, have been small studies. The physiological explanation of such reduction is also unclear. The use of FES in spastic muscle reduction thus seems limited (Thomas and Field-Fote 2009).

Atrophy

In the months following a spinal cord injury, the individual undergoes a dramatic amount of musculoskeletal atrophy. The atrophy carries with it a higher risk for secondary complications of SCI, such as pressure sores, deep vein thrombosis, and bone fractures (Baldi et al. 1998).

Muscles undergo two distinct types of atrophy following a spinal cord injury. The first is "disuse atrophy" and the second is "denervation atrophy." Disuse atrophy results from damage to the central spinal pathway. By interfering with the transmission of upper motor control, the injury prevents the patient from voluntarily initiating a contraction. The muscle remains physiologically capable of contracting, yet undergoes atrophy because the patient is unable to use it. Denervation atrophy results from damage to the lower motor neuron itself. The ability to conduct an impulse to the muscle is lost. Following this type of injury, an FES contraction is much harder to generate because the lower motor neuron is affected. The amount of muscles that undergo denervation atrophy is usually very small; the injury will only directly affect a small number of lower motor neurons. The majority of atrophy spinal cord injury patients experience is disuse atrophy (Gordon and Mao 1994). Even regarding denervation atrophy, the ability to contract the muscle is not lost completely. Because most muscles are innervated by more than one motor neuron, the intact remaining motor neurons can still generate a contraction. However, as the ratio of motor neurons to muscle decreases, the ability to grade contractions is compromised (Field-Fote 2009).

Reducing atrophy is crucial for the patient who wishes to walk again. If the muscle is unable to bear the weight of the patient, walking will remain impossible. It is, therefore, essential that the occurrence of atrophy be reduced as much as possible (Janssen and Pringle 2008).

Many studies have substantiated the claim that FES is useful in stopping atrophy. The increased muscle use of the activated muscles directly reduces the incidence of muscular atrophy (Nogan et al. 2007; Hamid and Hayak 2008; Johnston et al. 2007; Field-Fote et al. 2005). In fact, the use of resistance FES has been documented to prevent atrophy in weightless non-disabled individuals (i.e. astronauts), giving reason to believe that FES may also benefit neurologically deficient individuals (Baldi et al. 1998).

In using FES to reduce muscle atrophy, it is important to determine the best method of applying the stimulation to achieve the desired outcome (Gordon and Mao 1994). In this instance, the desired outcome is sufficient muscle strength and endurance to allow the patient to walk. The therapy is designed to enhance the muscle's ability to bear weight, as well as make the muscle less prone to fatigue. Generally speaking, exercises which are of a small load and long duration are best for increasing endurance, while exercises that place the maximum safe stress on the muscle, with fewer repetitions, will increase strength (Gordon and Mao 1994).

In targeting the muscles that need intervention most, studies have shown that weight-bearing muscles, such as the soleus (plantarflexion), undergo significant atrophy, while non weight-bearing muscles, such as the tibialis anterior (dorsiflexion), undergo little atrophy (Gordon and Mao 1994).

FES generated contractions do little to reduce existing atrophy in chronic spinal cord injury patients. Baldi et al. (1998) suggests that perhaps FES would be more successful in stopping or slowing atrophy than in reversing it. Until twenty years ago, there was no research that studied the effect of FES induced contractions on slowing the atrophic progress of spinal cord injury patients. Most of the research had been done on chronic SCI patients (>1 year post-injury), attempting to reverse existing atrophy. Baldi et al. cites animal studies that indicate that more muscle mass is lost during the first eleven months following injury than during the next eight years. While previous attempts at reversing atrophy in patients had been largely unsuccessful, researchers concluded that these disappointing results were because the muscle had reached a new "steady state" from which it was nearly impossible to be removed. By the time the patient received the FES, it was corrective, as opposed to prophylactic, in nature. Addressing this concern, Baldi et al. designed a study of six spinal cord injury patients in the acute stage of the injury to determine if preventive FES is more successful than the current model. He hypothesizes that if FES would be applied early enough, it would ward off the muscle atrophy, thereby reducing the degree of secondary complications the SCI patient suffers.

The study had two goals. One goal was to identify the amount of atrophy that occurs in the six months, starting not less than 4 weeks and not more than 15 weeks, after the injury. The second objective was to study the differences between cycle ergometer-load bearing (aka resistance training) and isometric FES.

Twenty-six subjects were randomly assigned to the FES-cycle ergometer load-bearing group, isometric FES group, or control group. All subjects were 4-15 weeks post a cervical or thoracic spinal cord injury. The FES-cycle ergometer group used the cycle ergometer three times a week for 30 minutes each session. Each participant wore a fitted garment over the surface electrodes to minimize slipping of the electrodes. The device stimulated the hip extensors, knee extensors, and knee flexors. The FES isometric contraction group received similar stimulation for one hour, five times weekly.

Six months following the start of the study, the participants were assessed to determine the lower-limb lean body mass (LL-LBM). The results were as follows: The control group lost 21.4% of LL-LBM. The cycle ergometer-load bearing group gained 9.3% LL-LBM. The isometric FES group lost muscle mass, but far less than the control group.

The finding that the isometric FES group experienced minimal amounts of atrophy is consistent with earlier findings that non-load bearing contractions are not capable of building muscle mass.

The results show that starting FES as soon as possible after the injury is beneficial in preventing or diminishing the degree of atrophy the individual will suffer. Safety of the patient must be taken into account, however. Following injury, most SCI patients experience "spinal shock" in which the muscles do not respond with a contraction to any stimulation at all. Patients also frequently experience hypotension, necessitating bed-rest. Therapists must also watch for dangerous conditions that are specific to spinal cord injury patients, such as autonomic dysreflexia, at all times.

CARDIOVASCULAR/CARDIOPULMONARY

The sedentary lifestyle that follows a spinal cord injury puts SCI individuals at a higher risk for conditions associated with lower fitness levels. Obesity, diabetes, and cardiovascular disease are all far more prevalent amongst spinal cord patients than the general population. While the normal resting heart rate for an able-bodied person is between 60-100 beats per minute, a spinal cord injury patient has a normal resting heart rate of only 50 beats per minute (Perret et al. 2010). According to the National Spinal Cord Injury Statistical Center, renal failure was the leading cause of death in spinal cord injury patients until the 1970s. With the increased use of intermittent catheterization, renal failure has ceded its top spot to cardiovascular problems.

Besides for the obvious difficulty in getting enough exercise if one is motor deficient, there are other cardiovascular problems that contribute to the overall reduction in cardiac health. If the injury is above T1, sympathetic activation of the heart is compromised and a low resting blood pressure is the result. Lower blood pressure causes atrophy of the left ventricle and further compromises the circulatory system. The lower blood pressure can increase the likelihood of heart disease or a deep vein thrombosis (Nash 2009). Decreased circulation coupled with muscle atrophy results in lower systemic O_2 consumption and, consequently, a lower CO_2 production (Janssen and Pringle 2008).

Typically, SCI individuals are limited to upper body exercises, neglecting the greater mass of the lower body. The need for safe methods for spinal cord patients to achieve their daily exercise needs is great (Field-Fote 2009).

Since the early 1980s, it has been well documented that FES is a relatively easy way for a spinal cord injury patient to maintain heart health (Janssen and Pringle 2008; Nash 2009). As the technology becomes increasingly convenient and affordable, FES is becoming a popular method of cardiovascular health maintenance for spinal cord compromised individuals. There is one device that has been the focus of a significant amount of research. The FES leg-cycle ergometer is a machine that activates the major muscle groups of the lower body and moves them around a stationary bicycle. The leg-cycle ergometer is a safe way for many spinal cord patients to maintain cardiovascular health.

The benefits of FES to a tetraplegic are obvious. Lacking motor capability in all limbs, the only means of cardiovascular benefits is an electronically stimulated contraction. Even for paraplegics, the FES leg-cycle ergometer is a useful way to reduce reliance on the possibly overburdened upper limbs (Perret et al. 2010).

Nogan et al. (2007) conducted an exhaustive case study of a participant with a C6-C7 injury. The participant received an implanted 8-channel system that allowed limited community ambulation once mastered. While the main focus of the study was the ambulation of the participant, the participant also underwent a thorough cardio evaluation pre and post FES training. Following the twelve weeks of training, the participant presented a reduced resting and working heart rate. The patient showed greater oxygen consumption, attributed to the increased walking speed achieved from the FES.

It was noted that after a period of several weeks of training, the patient reaches a plateau of cardiac activity that is hard to pass. This discourages the patient from maintaining the exercise schedule. Janssen and Pringle (2008) hypothesized that the plateau observed in patients using the leg-cycle ergometry training could be due to the design of the regimen of stimulation they use. Perhaps by modifying the stimulation pattern to generate greater overload of the muscles, better cardiac and muscular results would be observed. In effect, shorter, more intense sessions may prove better for those purposes. This would be accomplished by maximizing the current amplitude used to generate contractions and by modifying the duration of the sessions. To address this, they developed a modified method of applying the stimulation.

They tested the effects of the modified stimulation patterns on 12 patients, six tetraplegics and six paraplegics. The patients used the system 18 times over 6 weeks.

As stated earlier, the sessions were designed to apply shorter, more intense exercise periods on the participants. The results indicate that the maximum possible gain is observed after training on a system that is designed to produce more intense contractions for shorter duration. The significant findings are summarized in Table 1.

Table 1: Effects of Modified Leg-Cycle Ergometry.

	Standard	Modified	After Training
Peak O_2 Consumption (mL/min)	670 ± 208	818 ± 287	1065 ± 264
Peak CO_2 Production (mL/min)	765 ± 228	1154 ± 390	1405 ± 363
Peak Pulmonary Ventilation (L/min)	30.1 ± 9.0	41.3 ± 12.3	49.1 ± 9.1
Max Cardiac Output (L/min)	6.5 ± 1.4	8.6 ± 1.9	9.5 ± 2.3
Stroke Volume (mL)	82.6 ± 20.6	91.7 ± 23.5	91.2 ± 28.7
Max Heart Rate (bpm)	81.9 ± 17.3	97.4 ± 11.2	113.3 ± 23.0

Source: Janssen and Pringle 2008

There are findings in reviewing the data that highlight some interesting cardiac occurrences in the participants. While heart rate increased, cardiac output and stroke volume did not. This can be contributed to dilation of lower-limb blood vessels resulting in lower venous return, indicated by the lightheadedness reported by some of the participants following the treatments (Janssen and Pringle 2008).

Another interesting result was the increase in oxygen consumption that was not accompanied by any concurring increase of cardiac output. This could be explained by stating that there was improved blood distribution. The oxygen differential between the arteries and veins is, thus, improved while the cardiac output does not change. As noted earlier, better circulation through the body tissues reduces the atrophy that muscles undergo and the occurrence of pressure sores.

Generally, the recommendation for SCI patients is to use 1000-2200 kcal per week to maintain heart health. Perret et al. (2010) conducted a study to determine how much activity is needed to achieve this goal and whether or not this is practical for the general SCI community. The study looked at eight otherwise healthy individuals who had sustained a T3-T9 injury more than three years earlier. They conclude that 4-8 hours of intense FES cycling is enough to generate the 1000-2200 recommended kcal. Considering the normal variation of responses between different individuals, this is fairly consistent with the 30 minutes daily recommended by most therapists who work with FES.

While clearly beneficial, the system still has downsides. It is very time consuming to set up, and, often, the individual needs assistance in properly setting up the equipment. Given these facts, it may be better to use it fewer times a week for longer sessions (Perret et al. 2010). This conclusion does not accommodate the previous recommendation of shorter, more intense bursts of FES to maximize muscle overload and cardiopulmonary benefits. It disregards the benefit of the combination of short-intense and long-intense sessions which maximize strength as well as endurance and reduce occurrence of muscle atrophy. Reasonable disagreement in this regard is expected. One must keep in mind that the SCI patient has a disability that presents a logistical transportation obstacle that must be overcome each time he or she is to participate in therapy away from home. The benefits of frequent sessions are of little use if the patient cannot practically maintain the exercise schedule. The therapist must design an exercise schedule on a patient-by-patient basis, making sure to factor all considerations when recommending what the session duration and intensity should be.

Finally, Perret et al. (2010) suggest that the use of a rowing type machine for paraplegics, where the lower limbs are stimulated electronically and the upper-limb use is voluntary, could provide a good combination of upper and lower body exercise while maximizing cardiopulmonary advantages. This combination needs to be studied more before a recommendation can be made.

LOCOMOTION/AMBULATION

The use of FES to assist spinal cord injury patients in standing, sitting and walking started in the early 1980s. In 1982, a device was introduced by researchers at Wright State University in Ohio that could stimulate a spinal cord patient's muscles to allow for standing and level ground walking. The disadvantages of this early technology were obvious. The battery pack needed to operate this device weighed nearly eight pounds and was worn on the user's back. This was the lightweight option and was for walking only. A heavier battery was needed when the user wished to make use of the stand and sit feature. An updated device introduced in 1989 had its disadvantages too. Putting on and removing the system took around an hour. Phillips (1989) outlines in agonizing detail the procedure for generating the necessary pattern of stimulation and positioning of the patient to allow rudimentary locomotion. Clearly this was not a practical option for the average disabled individual.

In a case study, Nogan-Bailey et al. (2007) reports that some non-ambulatory individuals are able to combine their remaining volitional motor, sensory, and proprioceptive abilities with an FES device to allow limited ambulation.

For FES-assisted walking, the stimulation was formulated to accomplish three goals. The first goal was to "augment" existing volitional contraction. The second objective was to initiate contraction of paralyzed muscle. The third purpose was to reduce extensor tone for easier walking; for example, stimulation of hip flexors (iliopsoas) reduced tone in the hip extensor (biceps femoris) dramatically, making hip flexion easier for stepping. "Stimulation was the means to reducing extensor tone during standing to allow stepping."

The goal was to generate the strongest contraction that would not hurt the patient or overflow to a neighboring muscle group. Once this was accomplished, the maximum threshold has been reached.

The variable used as the baseline index for the study was voluntary walking following aggressive pre-study rehab using robotic-assisted body-weight-supported treadmill training. They hypothesized that "exercise and gait training with FES would improve voluntary motor control and baseline volitional walking ability. It would also increase the strength, endurance and repeatability of muscle contraction over maximal pre-implant levels."

This hypothesis was tested with pre and post implant assessments of gait function (speed, distance, symmetry, and physiological cost) and isokinetic muscle contractile properties (strength, endurance, and repeatability) of the knee extensors on a dynometer. The goal was to improve a nonambulatory patient's function to that of independent household ambulation or limited community ambulation. The patient selected for the study was unable to voluntarily initiate a single step with either leg. The patient was evaluated at the following points: after the pre-study therapy, after the implant, six weeks into FES training, and 12 weeks into FES training.

The participant used a hand trigger to manually initiate the impulse for each step. The patient needed to be trained in this device with a specific sequence of switches at different points in the gait.

While there were some small improvements attributable to the pre implant therapy, the patient remained functionally non-ambulatory prior to the implant (Nogan-Bailey et al. 2007).

At the 12-week assessment, the following results were obtained: Walking distance improved 20x (14m in 11 min to 309m in 30 min). Walking speed increased 10x (0.02m/s to 0.20m/s). The patient needed less standby assistance and a smaller walking aid than before.

The FES did not improve volitional ambulation or motor control at all. The results signified that the device is useful for household or limited community use.

While walking speed and cadence improved from pre to post implant, it peaked at 6 weeks and did not get any better at the 12-week checkup. The reason for this was a technical limitation of the system. Speed is largely a function of plantarflexor strength. The primary muscle of plantarflexion is the gastrocnemius. The gastrocnemius was not implanted due to a limited number of channels available on the system; priority was given to muscle groups needed for ambulation. The participant "thus relied on voluntary plantarflexion strength during walking … and this strength was lacking" (Nogan-Bailey et al. 2007).

In 2010, researchers published a single-subject study on the therapeutic effects of FES. The hypothesis was that it would seem reasonable to expect increases in volitional motor control following therapy which utilizes FES. "Neuroprosthetic interventions may have neurotherapeutic value" (Nogan-Bailey et al. 2010).

The subject was C6 incomplete. He was unable to stand without support and able to walk only limited distances (<30m) using both a wheeled walker and a left ankle-foot orthotic. The limiting factor in his ambulation was upper body exhaustion due to the use of his trunk and hip to elevate his weak left leg during the swing phase of gait. He presented with significant left side weakness as well as weakness in his trunk and upper limbs. Because the main deficit was on his left side, only the left leg was implanted. The muscles implanted were the iliopsoas (hip flexion), tensor fasciae latae (hip flexion and abduction), gluteus medius (hip abduction), posterior portion of adductor magnus (hip extension), gluteus maximus (hip extension), vastus lateralis (knee extension), tibialis anterior (ankle dorsiflexion), and peroneus longus (foot eversion). The patient followed a home exercise routine to build strength in the muscle groups that were stimulated. This included exercising the extensors as a group (standing), the flexors as a group (swing phase of gait), the ankle dorsiflexor, and the knee extensor. The patient self-reported participation in the home portion of the program.

At first, the therapist triggered the stimulation of the left leg as needed to initiate and continue the walking. As proficiency increased, the patient himself took over that function. Eventually, the patient was able to start a "continuous cycling stimulation" for locomotion (Nogan-Bailey et al. 2010).

Data was collected at the start of the program and after 36 sessions of FES training. The testing schedule was staggered to avoid any fatigue factors that could interfere with the results.

The data was statistically analyzed to determine the therapeutic effect of FES, how much the voluntary control of the muscles in question improved, and how useful the neuroprosthetic effect of FES was in restoring function

The patient experienced significant improvements in volitional walking ability. The max distance he could walk in six minutes increased to 80 meters from 28 meters, indicating a "strong neurotherapeutic effect." With the use of FES, his maximum walk distance in the six-minute test jumped to 248 meters, sufficient to allow limited community ambulation for the user. Similar results were obtained for the walking speed test. The baseline speed of 0.17 m/s increased to a volitional speed of 0.22 m/s, with a further increase to 0.27 m/s while employing the FES system. The neuroprosthetic effect here is an additional 20% walking speed. The gait analysis revealed a reduction of double support time, indicating a more dynamic gait.

The patient was unable to extend the knee voluntarily pre implantation. Post implantation, the patient was able to consciously generate 8.78±2.59 Nm of knee extension moment on the implanted side. When FES assisted, the patient was able to generate 30.22±1.07 Nm. The improvements in volitional abilities post training in walking speed, walking distance, and double support time demonstrate the neurotherapeutic effects of FES. These benefits can potentially increase the mobility of an individual to the level of limited community ambulation while using FES. Even without being attached to the FES system, the use of FES in rehabilitation seems to have led to significant improvements in walking speed, distance, and gait quality (Nogan-Bailey et al. 2010).

While there were therapeutic gains, it is difficult to determine which of these gains are results of FES and which would have happened with traditional gait training alone. Further studies are needed to determine the effect of FES that cannot be replicated by extensive traditional overground training and body-weight-supported treadmill training. In any case, this study demonstrated that FES is a viable therapeutic tool (Nogan-Bailey et al. 2010).

There are various methods available for locomotor training of SCI patients. A study was designed in 2005 to collect data on the various advantages and disadvantages each method has to offer (Field-Fote et al. 2005). The study looked at 27 patients with motor incomplete injuries at spinal level T10 or above, who were able to initiate a step with at least one leg. The methods tested were treadmill training with manual assistance, treadmill training with stimulation, over ground training with stimulation, and treadmill training with robotic assistance

While researchers agree that sensory input from locomotor training is an important aspect that contributes to the patient's improvements, there is disagreement as to the best way to provide that sensory input. Manual assistance has the advantage of the physical therapist being "hands on" and thereby able to provide very precise levels of assistance based on a moment-to-moment assessment of the patient's condition. The disadvantages of manual assistance are that the trainer cannot assist as consistently as an electronic stimulator and that therapist fatigue can also limit the duration of a session.

FES, likewise, has a number of advantages. The FES uses a spinal reflex that is thought to be important in healthy locomotion. "As such, repeated activation of this reflex may be associated with beneficial neural changes and may improve the synaptic efficiency of this circuit." The disadvantage of FES is that patients display a wide variety of therapeutic responses to the treatment. Thus, FES cannot be generalized as being advantageous and must instead be evaluated on a patient-to-patient basis (Field-Fote et al. 2005).

Overall, the various techniques resulted in a 37% increase in walking speed for a "long-bout" walking test (2 minutes) and a 55% increase in walking speed for a "short-bout" walking test (6 meters).

Detailed statistical analysis of the data shows a trend toward better walking improvements for the groups that had FES assisted locomotor training. While it is tempting to deduce from this result that FES training works best, the authors of the paper warn that as their research team works primarily with FES, it is possible that their practitioners are simply better acquainted with FES therapy and, therefore, obtain better results. Other rehab venues may get better results as well with their preferred method of gait training.

While all subjects in the study got better to some degree, none even came close to returning to community ambulation.

Volitional locomotion benefits for individuals with SCI were only observed in incomplete SCI patients. Patients with complete SCI may have been able to generate locomotion like movement on a treadmill but were not able to accomplish this over ground (Field-Fote et al. 2005).

THEORY OF GAIT TRAINING

Why does gait training in general and FES-assisted gait training in particular have a therapeutic effect following a spinal cord injury? The following theory has been proposed. After an injury to the spinal cord, the loss of descending neural control results in a massive and ongoing reorganization of the cerebral and spinal pathways. This evolution continues for years following the injury. The reorganization includes the formation of many new synapses and connections. The new synapses are largely abnormal and interfere with normal transmission of impulses. The result of these abnormal connections is uncoordinated movements and spasticity. Fine movements are impossible to generate. For example, attempting to flex the ankle often results in the entire leg flexing from the hip down (Fong et al. 2009).

The spinal cord can be retrained in the use of its walking patterns with locomotion training, with FES providing afferent input of the sensory patterns associated with walking. It has been theorized that when the descending motor impulse is generated at the same time that there are incoming sensory impulses that approximate normal ambulation impulses, this may retrain the spinal walking programs to allow for functionally useful synapses to form. Experiments on SCI cats demonstrate that the spinal cord has the ability to perform locomotion pattern behavior without upper nervous input. For many standard motor tasks, the spinal cord is, in large part, autonomous from the brain. The implications of these experiments in spinal cord rehab are enormous. If the spinal cord can generate walking patterns without being connected to the brain, there should be a way to rehabilitate SCI patients. This can help explain the therapeutic effects researchers have observed in patients who have used FES (Fong et al. 2009).

Researchers suggest that when intact lower spinal motor neurons lose the neurotransmitter input from upper motor neurons following a spinal cord injury, the now inactive synapse sprouts new "collateral" dendrites. The emergence of these new synapses can cause unwanted motor activity. If FES is applied to generate functional movements while the sprouting is in progress, this afferent input can direct the sprouting dendrites toward pathways that are functionally useful (Ditunno et al. 2004).

ELECTRODE TYPE AND SPILLOVER

There are two other general discussions related to FES induced walking. The first discussion is what type of electrode is used to generate the contraction, and the second is the concept of "spillover."

To generating contractions, the FES device can employ surface electrodes, percutaneous electrodes, or fully implanted electrodes. Surface electrodes have the advantage of no risk of infection and only a mild risk of skin irritation. The disadvantages of surface electrodes are threefold: first, they cannot be very precise; second, they cannot stimulate deep muscles; and third, when large muscles contract (i.e. the quadriceps) the trigger point can move two or more centimeters under the skin, thereby limiting the effectiveness of the impulse. Percutaneous electrodes have the advantage of precision but a very high risk of infection. Fully implantable electrodes are precise, long lasting, and only have a very small risk of infection. The disadvantages of fully implantable electrodes are that the procedure is invasive and that any repair to the equipment necessitates further surgery (Nogan-Bailey et al. 2007).

"Spillover" in FES refers to an unwanted contraction generated by the impulse. When the impulse reaches the minimum threshold of an unwanted muscle before the maximum useable contraction of the targeted muscle is reached, an unwanted contraction results. The rate of spillover was studied in 10 patients from 1988 to 1998 (Triolo et al. 2001). The total number of electrodes studied was just over 600. The purpose of the study was to map the most frequent sites of spillover in order to help surgeons place the electrodes better, as well as to help the therapist understand and anticipate movements a patient may make during therapy.

A common location of contraction spillover is where the desired contraction of the vasti muscles (vastus lateralis, medialis, and intermedius) to assist standing unintentionally generates contractions of the rector femoris and sartorius muscle, which leads to hip flexion that is counterproductive to standing. This happens because the electrode is placed proximal to the femoral nerve and can easily produce the undesired contraction. Where the desired effect of the vasti contraction is standing still, activation of the unintended muscles flex the hip or tilt the pelvis anteriority. The hip flexion can cause the patient to adopt a lordotic posture. Additionally, if the hip is flexed, the sartorius can rotate laterally and abduct the thigh. The disadvantages of walking in this manner become clear when considering the fact that all of these patients must walk with an assistive device.

LIMITATIONS

The applications of FES are numerous, but so are the limitations. First, and perhaps most serious, a study done by Bickel et al. (2004) indicates that there is a very real risk of muscle damage when load-bearing FES is applied to muscles that have been inactive for some amount of time. The muscles of SCI patients after an injury undergo structural changes in which the percentage of fast twitch fibers goes up as the percentage of slow twitch fibers goes down. The muscle fatigues quicker and is more susceptible to damage. This hypothesis was confirmed with MRI imaging of eight subjects who had suffered C5-T9 injuries years earlier. The risk of further injury can prevent patients from participating in the treatment. An actual injury can set the patient back months or years in treatment.

Getting up and walking around with a deficient spinal cord always carries greater risk than able-bodied walking. Muscle weakness and coordination difficulties make a fall more likely. Furthermore, bone density is typically compromised in SCI patients. This puts them at greater risk for fracture if they do fall.

Another limitation of FES-assisted walking is that the patients need significant upper-body strength to manage the system. Many patients exhibit varying degrees of weakness or a lack of coordination in their upper body following a spinal cord injury, preventing them from making use of FES for walking.

If sensation has been spared in the lower limbs, some patients will find the feeling of stimulation intolerable (Hamid and Hayek 2008). This presents another limitation to the use of FES.

There are also limitations in the design of the studies on FES. For the most part, studies of FES have been of small sample size and only included short follow up time (Hamid and Hayek 2008). Patients displayed a wide variety of therapeutic responses to the treatment. It is, therefore, difficult to predict what the benefit may be for a particular patient (Field-Fote et al. 2005).

One study suggested that the ability for the patient to self-administer the therapy at home is beneficial because it cuts out the need to arrange transportation to and from therapy (Johnston et al. 2007). A second study suggested that compliance to the therapy session suffers if patients are trusted to administer the therapy themselves. Therapy with FES, according to this study, is most beneficial if administered in a monitored setting (Field-Fote et al. 2005).

Finally, and perhaps most importantly, it is very difficult to generalize from any study of spinal cord rehabilitation for the rest of the "extremely heterogeneous" population of incomplete and complete spinal cord injuries. Because each patient has a unique degree of sensory and motor sensation loss, the effects of FES vary widely from patient to patient (Nogan-Bailey et al. 2010).

THE FUTURE OF FES

Technological advances in the past ten years have made FES more accessible, portable, cosmetically appealing, and more therapeutically helpful. As computers get more powerful, the microprocessors in portable FES systems are better able to process a host of factors that give greater control to the user. Computers can calculate, in real time, the variable muscle forces, fatigue, joint position, and other data available. It can then make instant dynamic adjustments to allow for smoother and safer ambulation (Hamid and Hayek 2008). For tetraplegic patients who lack upper-limb strength, walking may still be out of reach, but there are FES systems that can facilitate hand movements. Using vibrations generated by tooth clicks and detected by a Bluetooth like device worn behind the ear, patients are able to initiate FES impulses to grasp, squeeze, pinch, pull, twist, and execute other hand motions (Harvey et al. 2011).

In the future, FES systems may use more "natural" methods of activation. The descending motor commands would be intercepted, interpreted, and forwarded past the site of the injury to the limb. This would be particularly useful for tetraplegics who, due to their lack of upper-limb strength, are unable to utilize traditional FES to facilitate walking (Nogan-Bailey et al. 2010).

CONCLUSION

The uses of FES in spinal cord rehabilitation are numerous. Over the past thirty years, study after study has demonstrated the gains patients make in reduction of spastic muscle tone, attenuation of muscle atrophy, cardiovascular health, cardiopulmonary health, and volitional or FES-assisted walking.

Spastic muscle tone is reduced by FES. This reduction is only temporary, but, nevertheless, proves an important point about functional electrical stimulation. There are enough real, demonstrable, repeatable benefits of FES that the application of the therapy is recommended. The temporary reduction in spasticity can be considered a side perk of the primary reason for therapy.

Muscle atrophy is slowed by the application of FES. Research indicates that although the reversal of atrophy is not likely, nevertheless, FES slows the progress of atrophy. The earlier FES is applied, the better off the patient's muscles will be. Healthy muscle mass reduces pressure sores and is a precondition for safe standing, sitting, and walking. FES thus aids in retention of healthy muscle mass.

Spinal cord injury patients have a reduced resting and working heart rate. Vasodilation due to low smooth muscle tone causes low blood pressure that reduces venous return. Fewer skeletal muscle contractions means a further reduction in venous return. When applied as part of a structured routine that reaches the recommended level of weekly activity, FES serves the vital function of helping the patient maintain healthy cardiac performance.

The instantly recognizable disability of many spinal cord injury patients is the inability to walk. FES has been able to return a small number of patients to limited community ambulation. Can activation of spinal walking patterns using FES help the injured spinal cord redevelop its ability to generate useful reflexive or volitional contractions? That remains unclear. Some studies have shown improvement in volitional abilities in patients with less severe injuries, while others indicate that volitional abilities remain unchanged. These differing results indicate that the use of FES does not carry the same level of benefit for all patients. Existing research does not point to a conclusive recommendation regarding gait training using FES. Because the spinal cord population is "extremely heterogeneous," risk of further muscle damage or falls must be weighed against the potential gains made possible by the therapy. Aside from the functional and therapeutic applications of FES, there is an undoubted psychological benefit for patients to be able to "walk" again. Patients reported better self-esteem and lower incidence of depression (Hamid and Hayek 2008). Many subjects reported great improvements in their mental state. The ability to use bathrooms not compliant with ADA (Americans with Disabilities Act), the ability to move around the kitchen using the counters for support, and the ability to climb a flight of stairs all contributed to the patient's sense of purpose and functional well-being (Field-Fote et al. 2005). Regarding walking with FES, the decision whether or not to use FES must be made only after carefully considering all risks and benefits on a patient-by-patient basis.

FES definitely helps patients regain function. Exactly how FES achieves this and how to best use FES to achieve maximum function remains unclear. The studies cited in this paper and the majority of studies conducted overall are small and not well suited for generalization to the spinal cord injury population. There is a great need for large scale, long-term studies with control groups to further assess the role FES can play in spinal cord rehabilitation and to assess the methods of application that can elicit maximum recovery. Better understanding of the pathophysiology of the spinal cord disability can better guide research in the field. If the phenomenon of lower neurons stopping to communicate with each other following an injury is better understood, better treatments can be designed.

It may be some time, if ever, before the medical community is able to cure spinal cord injury paralysis. It was once thought that when FES became sophisticated enough, disabled individuals would be able to simply plug their damaged bodies into the system and walk again. This is not yet the case. Walking with FES is still too risky and inefficient to be the used on a large-scale basis. In the meantime, the goal of patients and therapists is to prevent spinal cord injury patients from developing conditions secondary to the spinal cord injury. While FES can only help a very limited number of patients walk, many patients can, and do, derive crucial health benefits with regard to atrophy reduction and cardiac health maintenance from a carefully structured use of the FES systems currently available.

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