Chapter 5

Functional Electrical Stimulation in Paraplegia

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Additional information is available at the end of the chapter

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1. Introduction

Functional Electrical Stimulation (FES) is a technique of eliciting controlled neural activation through the application of low levels of electrical current. FES was initially referred to as Functional Electrotherapy by Liberson [1] and it was not until 1967 that the term Functional Electrical Stimulation was established by Moe and Post [2]. In 1965 Offner patented a system used to treat foot drop with the title "Electrical stimulation of muscle deprived of nervous control with a view of providing muscular contraction and producing a functionally useful moment" [3]. Another term often used equally to FES is Functional Neuromusclular Stimulation (FNS or FNMS).

The first commercially available FES devices treated foot drop in hemiplegic patients by stimulating the peroneal nerve during gait. In this case, a switch, located in the heel end of a user's shoe, would activate a stimulator worn by the user.

Structural discontinuity in the spinal cord after injury results in a disruption in the impulse conduction resulting in loss of various bodily functions depending upon the level of injury. The initial goal of FES technology was to provide greater mobility to the patients after SCI. However, with the advances in biomedical engineering within the last 2 decades, FES is no more limited to locomotion alone. Therefore, the definition of FES has changed considerably and is now considered to be the technique of applying safe levels of electric current to stimulate various organs of the body rendered disabled due to SCI. Electrical stimulation in the form of functional electrical stimulation (FES) can help facilitate and improve limb mobility along with other body functions lost due to injury e.g. sexual, bladder or bowel functions.

2. Mechanism of FES operation

Both nerves and muscle fibres respond to electric current. However, for practical purposes FES is mostly used to directly stimulate nerve fibres, as a much lower amount of current is required to generate an action potential in a nerve than the one required for muscular depolarisation.

The main component of a FES system is the microprocessor-based electronic stimulator which determines when and how the stimulation is provided, with channels for delivery of individual pulses through a set of electrodes connected to the neuromuscular system. The microprocessor contains programs for sitting, standing, walking etc. It serves to generate a train of impulses that grossly imitate the neural triggers that would have normally passed through the spinal cord to the appropriate peripheral nerves below spinal cord lesion for these different programs. These stimuli thus trigger action potentials in the peripheral nerves which in turn activate muscle contractions in the associated muscles fibers [11]. When properly applied, the energy transfer is both safe and efficient. Low levels of current can be safely injected to neural tissue with a minimal but biologically acceptable response. Furthermore, the energy amplification is substantial, since a small stimulus can generate a considerable action. For example, an electrical stimulus of a few milliwatts generates as much as a hundred newton-meters of torque in the lower limb.

It is proven nowadays that FES exersice is improving cardiovascular fitness, and decreasing the risk of diabetes, as well as reducing osteoporosis [12, 54-59]. FES exercise and weight bearing also reduce the risk of pressure sores by improving tissue oxygen levels, increasing muscle bulk, and altering seated pressure distribution [12]

Another use of electrical signals is to use afferent signals from intact structures whose communication links with other body systems have been destroyed or diminished by an injury or disease to provide feedback to guide motor activity.

It is conceptually possible, therefore, to obtain "artificial" control with electrical stimulation over virtually all structures which rely upon neural communication for their activation. This encompasses virtually all of the critical motor and sensory pathways involved in paralysis of the central nervous system.

The frequency, pulse width/duration, duty cycle, intensity/amplitude, ramp time, pulse pattern, program duration, program frequency, and muscle groups activated are parameters taken into account. Frequency refers to the pulses produced per second during stimulation and is stated in units of Hertz (Hz, e.g., 40 Hz=40 pulses per second). The frequencies of electrical stimulation used can vary widely depending on the goals of the task or intervention, but most clinical regimens use 20-50Hz patterns for optimal results [20]. In order to avoid fatigue or discomfort, constant low frequency stimulation is typically used, which produces a smooth contraction at low force levels. In a study comparing several different frequencies and stimulation patterns, frequencies under 16Hz were not sufficient to elicit a strong enough contraction to allow the quadriceps to extend to a target of 40º. Commercial stimulators provide many different waveforms and pulse settings capable of producing contractions at therapeutic

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levels. The source should be flexible to generate complex electrical waveforms, such as triangular or quasitrapezoidal waveforms [60].

The numbers of channels, which can range from one to several, govern the sophistication required for complex outputs like FES assisted standing. The programmable microprocessor activates the various channels sequentially or in unison to synchronize the complex output of the stimulator. Electrodes provide the interface between the electrical stimulator and the nervous system. Various types of electrodes have been developed and are available ranging from non-invasive surface electrodes to invasive implantable ones. Implantable electrodes provide more specific and selective stimulation to the desired muscle group than the surface electrodes. The feedback control of the FES system can be either open-looped or closed-looped. Open-looped control is used for simple tasks such as for muscle strengthening alone, and requires a constant electrical output from the stimulator. In a closed-looped system, the parameters for electrical stimulation are constantly modified by a computer via feedback information on muscle force and joint position thus stimulating various muscle groups simultaneously leading to a combination of muscular contraction needed for a complex sophisticated functional activity such as walking.

3. Standing and walking

The efforts to develop a suitable human functional stimulator which can achieve synergistic activity of various muscles accelerated in the late 1980s and early 1990s. In 1987, Davis proposed the development of a FES system based on multi-cochlear implant technology to restore function in paraplegic patients [9]. Kralj proposed the use of FES for restoring standing and walking in spinal cord injured (SCI) patients [4]. Other parallel studies at that time also concluded that FES assisted walking is feasible in patients with incomplete SCI even with severe motor loss [7, 10]. In all lower limb applications the general method for restoration of standing is the application of electrical stimulation to the quadriceps. The restoration and/or improvement of gait has typically involved the stimulation of two sites. These have been the quadriceps, during the stance phase of gait and the peroneal nerve, producing a patterned flexion response during the swing phase of the ipsilateral limb [6]. FES has greater potential for functional use in incomplete spinal cord injury (ISCI) patients due to the preservation of some motor and sensory function [7,8]. Paraplegic patients using FES for ambulation still require the use of walker or other orthotic devices for stabilising the ankle, knees and hips. Several gait programs for the ISCI subjects have been established. Applications of FES can be divided into two classes: (A) neuroprostheses for use as permanent assistive devices, and (B) FES to facilitate exercise and be used in temporary therapeutic interventions to improve voluntary function. This latter class of applications has been termed functional electrical therapy (FET). Therapeutic applications include cardiovascular conditioning and the prevention of muscular atrophy through exercise. Functional applications assist with vital body functions lost due to SCI. The FES devices were initially designed in an attempt to provide assistance with standing or walking, provided the paraplegic patient had adequate upper body motor control and strength [13,32].

The use of these FES devices designed to permit or improve ambulation is not simple or without risks. Paraplegic patients require extensive training to build muscle strength in the upper body in order to achieve FES assisted ambulation. The amount of energy spent with FES walking is almost twice than that for normal walking, although the achievable speed is slower than that of normal walking [18,19]. The risk of injury with FES assisted ambulation is more likely to be higher due to fatigue of the stimulated muscle causing an increase incidence of fall and fractures. These factors limit the true functional utilisation of these systems. Another major practical problem associated with the current FES locomotive models is mainly related to feedback control. In spite of these associated limitations for everyday mobility in daily life, there are potential functional, medical and psychological benefits of FES assisted standing and walking. These devices can help increase their level of independence by providing some assistance with standing while transferring from the wheelchair to a car, climbing a few steps or reaching for a higher object.

3.1. Non-invasive FES systems

Parastep I is a FDA approved FES system for short distance ambulation that uses a walker support for balance [14,15]. The Parastep is a non-invasive system and consists of the following components:

- a microcomputer controlled neuromuscular stimulation unit
- a battery
- a unit for pre-testing main system operation and electrode cables
- surface applied skin electrodes
- power and electrode cables
- a control and stability walker with finger activated control switches.

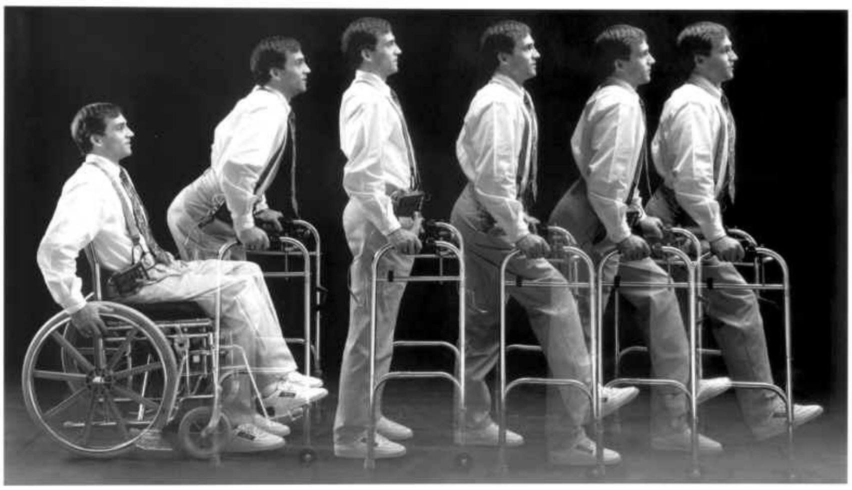

Figure 1. Advertisement of the Parastep System

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The system provides stimulation output to 12 surface electrodes that are attached to the skin at appropriate placements. These stimulation pulses trigger action potentials in the intact peripheral nerves to generate muscle contraction. Another noninvasive, transcutaneous FES system is the six-channel stimulator from the Ljubljana University but it was not commercialized and not FDA approved. In opposite the Parastep system received FDA approval in 1994 is nowadays widely available. It has been evaluated for its ambulation performance and medical/psychological effects.[14,16,17]. Factors considered to be a candidate for ambulation with the Parastep system include the presence of neurologically stable and complete SCI, level of injury (preferably between T4 and T12), patient motivation, degree of spasticity, muscle contractile response to electrical stimulation, cardio-respiratory capacity, and musculoskeletal integrity.

3.2. Implanted FES systems

Current technology using surface and percutaneous electrodes has distinct disadvantages. Systems using percutaneous electrodes are prone to infection if poorly maintained, and systems using surface electrodes make donning and doffing difficult. Moreover, as the number of channels increases, surface electrodes become impractical and inconvenient, making them generally best suited for short-term therapeutic applications. In addition, selectively activating individual muscles deep to the skin (such as the hip flexors) with surface stimulation or obtaining repeatable stimulated responses from day to day is difficult or impossible. Neural prostheses or Neuroprosthetics are implantable devices which use electrical current that can substitute a motor, sensory or cognitive modality that might have been damaged as a result of an injury or a disease. Familiar examples include cochlear implants and cardiac pacemakers. The Freehand system was the first motor-system neuroprosthesis to receive marketing approval. These devices have been safely and effectively installed worldwide in the upper limbs in patients with cervical SCI to provide active handgrasp after paralysis without major complications. External system components included a custom rechargeable wearable external control unit, command hand switch, transmitting coil, charger, and clinical programming station.

Fully implanted pacemaker-like systems offer numerous advantages over surface and percutaneous stimulation for long-term clinical use, including improved convenience, cosmesis, reliability, and repeatability. In these systems, muscle or nerve-based electrodes are installed surgically and connected to an implanted stimulation device, so no material crosses the skin.

FES systems using implanted intramuscular electrodes with percutaneous leads have provided up to 48 channels of stimulation for improved stability and forward progression and finer control of movement during walking. Multichannel implanted FES systems for walking after motor complete paraplegia have provided a swing-through and reciprocal gait [29,30]. They reduced donning time and improved day-to-day repeatability compared with surface FES systems and eliminated site care of percutaneous systems.

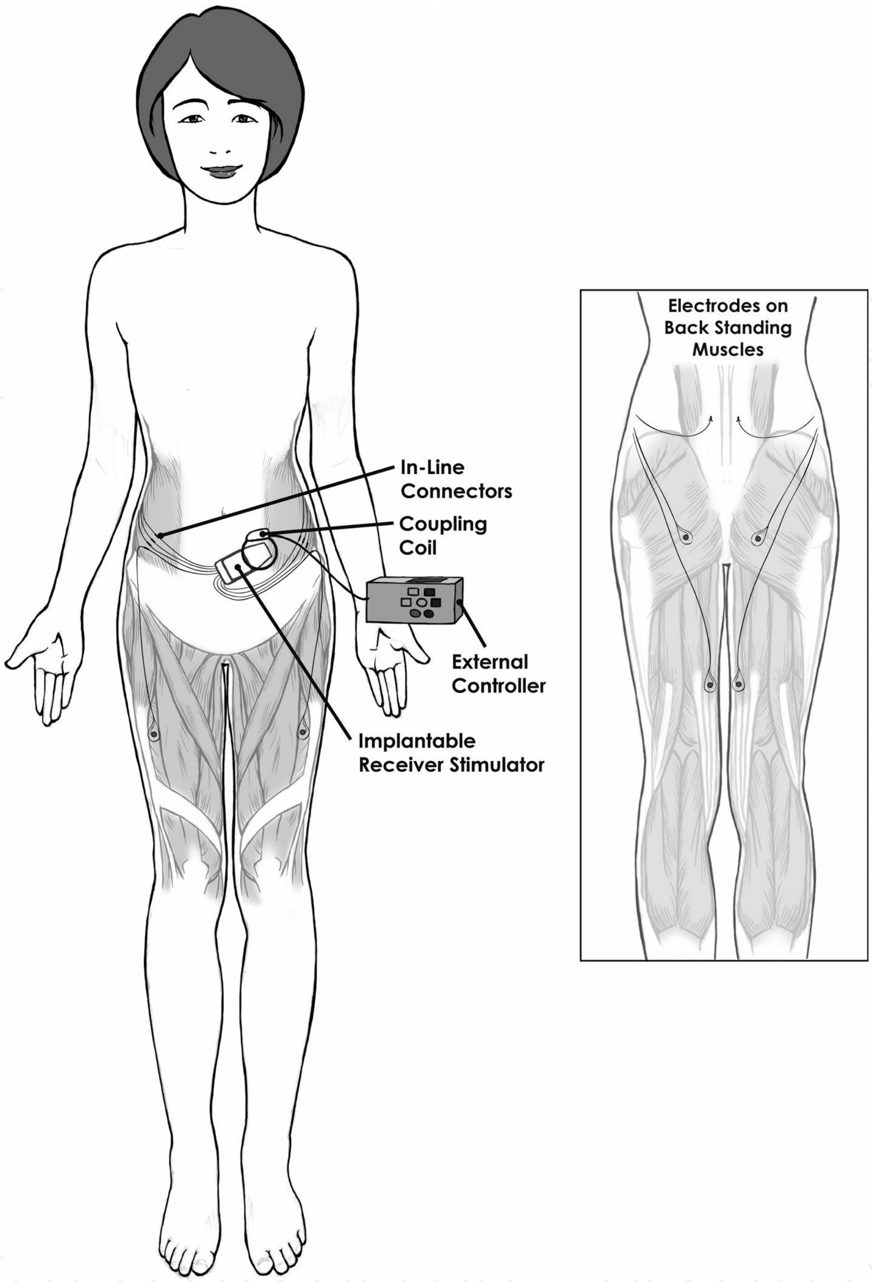

Figure 2. Cleveland FES Standing/Transfer System.

3.3. Hybrid FES-Orthosis ambulation systems

A variety of mechanical orthoses have been designed and tested for lower-limb function after SCI. The reciprocal gait orthosis (RGOs) stabilize ankles, knees, hips, and trunk to provide upright posture and couple hip flexion with contralateral hip extension to facilitate walking. The long leg braces only fix the ankle and knee joints to provide stability and prevent collapse. In some configurations, the addition of a pelvic band provides extra stability. Most orthoses provide good postural stability, especially when the hip joints are reciprocally coupled to prevent bilateral hip flexion. With all mechanical braces, upper-body strength is required for standing up and for forward progression during walking. Clinical reviews also indicate that brace users are consistently unable to achieve significant functional ambulation without some sort of pelvic control and that adequate hip flexion is an essential component of walking with braces. In conclusion only few individuals with paraplegia choose to use their orthosis for activities other than therapeutic exercise [34].

First in 1973, a hybrid actuator was described for orthotic systems in which the anatomical joint could be controlled internally by means of FES or externally by means of a hypothetical three-state joint actuator incorporated onto an exoskeletal brace [33]. This work initiated the field of hybrid orthotics and, specifically, defined the concept of a hybrid neuroprosthesis (HNP), in which FES is combined with external mechanical components.

Hybrid neuroprosthesis (HNP) potentially can combine the best features of mechanical bracing and FES into new systems for walking after SCI that offer more advantages than the individual components acting alone. The exoskeletal mechanical components of hybrid systems have been generally passive devices to minimize size, weight, and energy consumption, while the FES component serves as an active mechanism for limb propulsion.

Surface and intramuscular FES systems have been combined with a conventional trunk-hip-knee-ankle-foot orthosis (THKAFO) for reciprocal gait in individuals with complete thoracic level SCI. The addition of FES to the glutei for example during stance when individuals used lower-limb bracing reduced crutch forces [51,52] and provided forward propulsion by driving the stance leg into extension. Users with paraplegia (complete T4-T12 SCI) required 70 percent of their maximum upper-limb aerobic capacity when walking with an RGO alone, while walking with an RGO combined with FES required 32 percent of the upper-limb and 25 percent of the lower-limb aerobic capacity, effectively shifting the metabolic burden from the muscles of the arms, shoulders and trunk to the large, otherwise paralyzed, muscles of the legs [53].

The RGO Generation II is a reciprocating gait orthosis combined with FES which was developed by Louisiana State University Medical Center and Durr-Fillauer Medical, Inc. It employs concurrent electrostimulation of the rectus femoris and hamstrings to assist in rising and balancing and a ratchet-type latching device to improve safety and stability in standing. Alternating stimulation of the rectus femoris and contralateral hamstrings are used for locomotion [42].

In summary, an HNP combining bracing and FES has been shown to significantly improve walking distance and reduce energy consumption. A reciprocal coupling of the hips provides good trunk stability, and flexion-to-extension coupling ratios favoring flexion improve step length and energy cost. Unlocking the orthotic knee joints during the swing phase of gait improves foot-to-floor clearance and reduces energy cost, while locking them during stance postpones muscle fatigue from stimulation.

3.4. Hybrid FES – External Powered Orthosis Ambulation systems

To date only a few ambulatory external powered exoskeletons have been built. An ambulatory system named HAL that combines a powered exoskeleton with a customized walker was designed at the Sogang University [43-45]. A walker ensures complete balance and reduces the weight of the device by housing the battery, DC motors, and control unit, with cables transmitting power to the joints.

ReWalk developed by Argo Medical Technologies Ltd. enables paraplegics, with the aid of crutches for balance, to stand up, sit

down, walk about including slopes, and even climb stairs.[46]. ReWalk features servomotors located at the hip and knee joints, rechargeable batteries, and a wrist remote control that commands the type of desired motion. Since ambulatory exoskeletons are meant to be used by paraplegics and people with severely impaired locomotion capabilities, two crucial problems must be considered – ensuring full balance and determining the intention of the motion of the user. To overcome these problems, external balancing aids have been considered – crutches, canes, or walkers are used to ensured balance, whereas joysticks or keypads are used to command the desired motion.

In 2010 Berkeley Bionics unveiled eLEGS, which stands for "Exoskeleton Lower Extremity Gait System". eLEGS is another hydraulically powered exoskeleton system, and allows paraplegics to stand and walk with crutches or a walker. In 2011 eLEGS was renamed Ekso. Ekso weighs 20 kg, it has a maximum speed of 3.2 km/h and a battery life of 6 hour [47].

Figure 3. "eLegs" exoskeleton by Berkeley Bionics

A new promising exoskeleton named Indego is seeking for FDA approval in 2015 developed in Vanderbilt University [49,50].

All of these devices can be coupled with FES. Compared to using FES alone, the powered exoskeleton provides joint motions that are otherwise difficult to achieve consistently (e.g. hip flexion). Even for motions that can be achieved using FES, the exoskeleton ensures that the joint trajectories stay consistent in the presence of time-varying muscle behavior, providing consistent and repeatable gait. Compared to using a powered exoskeleton alone, the addition of FES reduces electrical power consumption while providing additional joint torques. Certain therapeutic effects of the use of FES have been studied. The medical advantages of short distance ambulation include increased blood flow to lower limbs, increase in lower limb muscle mass, reduced spasticity, lower heart rate at sub peak work intensities and beneficial effects on digestion, bowel and bladder. Psychological benefits achieved through FES assisted walking such as the associated increase in self esteem and reduction in depression are all well documented. Most of the studies conducted which have evaluated the role of FES assisted walking have a very small sample size and a short follow up time [48,51].

4. Bladder, bowel and sexual function

Other functional applications of FES which help to restore useful functions and thus improve the quality of life include bladder and bowel voiding and electro-ejaculation. Voluntary control of bowel and bladder function is either lost or considerably impaired depending upon the level and severity of SCI and can lead to multiple complications. The Vocare bladder system (Finetech-Brindley bladder system) is a surgically implantable sacral anterior root stimulator that allows individuals with complete spinal cord injury to urinate on demand [60].

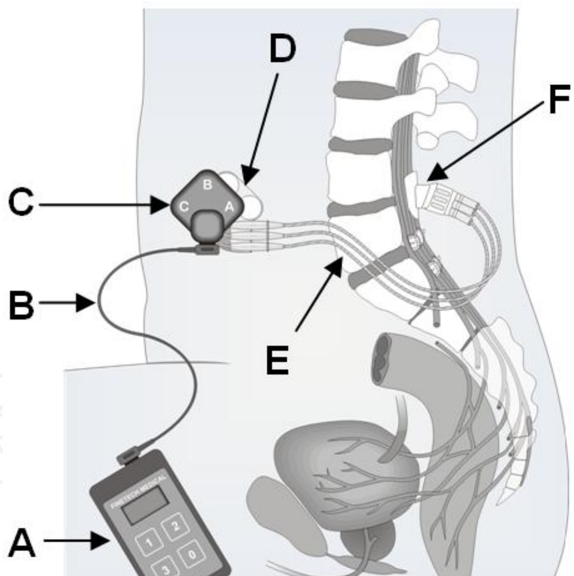

Figure 4. The Finetech-Brindley Bladder Control System

Secondary use of the device is to aid in bowel evacuation. It was approved by FDA in 1998. It consists of an external controller and transmitter and an implantable receiver-stimulator and electrodes. This system is operated by radio frequency signals transmitted to electrodes placed on the sacral spinal nerves (S2-S4) and leads to bladder/large bowel and urethral/ anal sphincter contraction. At the time of implantation, a posterior rhizotomy through laminectomy at sacral level is performed to abolish the uninhibited reflex bladder contractions. This eliminates the reflex incontinence caused by the activation of the sensory reflex pathway. However it also causes a loss of perineal sensations and reflex erection and ejaculation if present. Patient selection criteria for Vocare implantation include neurologically stable and clinically complete supra-sacral SCI and intact parasympathetic innervation to detrusor musculature. The major disadvantage of this system is the need for major surgery for implantation and posterior rhizotomy. However, this device offers an improved quality of life, social ease, as well as a reduction and prevention of urinary tract infections and their associated complication (61,62,65li) Another added benefit of this system is enhanced bowel evacuation with most patients reporting a reduction in the time required for bowel evacuation along with a reduction in constipation and faecal impaction. A slower stimulation time sequence is required for defeacation than for micturation. Approximately 60% of men can also produce penile erection using this device. Electroejaculation is one of the several techniques now available to harvest viable sperm for the purposes of artificial insemination or in vitro fertilization. An electric probe is inserted into the rectum near the prostate to stimulate the nerves and contract the pelvis muscles, causing ejaculation [63,64]. The ejaculate is collected from the urethra and prepared for use in artificial insemination. Caution need to be taken in men with SCI who have a history of autonomic dysreflexia as electroejaculation can cause a significant increase in blood pressure and heart rate.

4.1. FES cycling and rowing

A safe and economic alternative to FES-induced gait training is the employment of FES synchronized to the cycling movement, which entails a coordinated activation of the lower limb muscles, approximating the cyclic movements of locomotion. In contrast to FES standing and walking systems, an FES-cycling system uses stimulator cycling software to control sequential stimulation of the large leg-actuating muscles of paralyzed leg muscles to produce cyclical leg motion. Currently, FES cycling exercise (FESCE) is often used in rehabilitation therapy. There are a number of subsequent investigations reporting physiological adaptations after regular cycling exercise training, which demonstrated that cycling exercise increases muscle strength and endurance and bone density [66-71] suppresses spasticity [72,73], improves cardiopulmonary function, and provides many other physiological and psychological benefits for subjects with an SCI [74-78]. Typically, the quadriceps,hamstrings, and gluteus groups are activated in an appropriate sequence which is out of phase bilaterally to maintain a forward driving torque. The level of stimulation applied to the muscles (which, in turn, determines the amount of torque and cadence produced at the pedals) is controlled by the stimulation software. The advantage of FES-cycling over FES-walking and standing exercise is that individuals with paralysis can perform the exercise, and it can also enhance an individual's suitability for FES standing and walking. Presently, there are many commercial FES cycling ergometers available, such as the BerkelBike (BerkelBike BV, AV's-Hertogenbosch, the Netherlands), Ergys and Regys (Therapeutic Alliances, Fairborn, Ohio, USA), and Motomed (Reck, Betzenweiler, Germany).

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In general, FES cycling ergometers can be divided into two major types, mobile and stationary types. The mobile type, a locomotion device, focuses on muscle training as well as giving some mobility to subjects whose muscles can still be excited. Several research groups have developed a mobile cycling system using standard or recumbent tricycles for SCI subjects. Usually, the mobile type of cycling ergometer is an open-loop system, which is not only a rehabilitation modality but also a recreational activity.

Figure 5. The"RehaBike"by Hasomed (outdoor bike)

The stationary type of cycling ergometer is usually used for aerobic exercise training in subjects with an SCI to condition their muscle strength and enhance cardiopulmonary function.

Figure 6. "RehaMove" FES System coupled with Motomed stationary bike

The time course and training frequency are major factors that determine the therapeutic effects of cycling exercise. It is commonly recommended that subjects with an SCI receive at least 2-3 times per week and 30 min per time in a cycling rehabilitation program. In addition, it was reported that detraining from cycling exercise can soon induce a quick reversal of physical fitness within 1 week. The selection of electrical stimulation parameters is also an important issue considered in FESCE studies. Commonly, the FES cycling stimulation current is delivered to the large paralyzed leg muscles via surface electrodes. The stimulation output can either be regulated current or regulated voltage, which depends on the control design of the FES cycling stimulator. Commonly, the stimulation frequency is selected in the range of 10~50 Hz. However, a relatively higher stimulation frequency (> 50 Hz) can produce higher forces and therefore higher power for pedaling the ergometer compared to lower stimulation frequencies (10~50 Hz). But higher stimulation frequencies may rapidly result in ATP depletion at neuromuscular junctions and cause muscle fatigue.

In conclusion FES cycling plays an important role for each individual. It enables – in addition to the described beneficial physiological effects – the implementation of a physical activity and thereby, in terms of an improved participation, leads to a better quality of live.

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