FES Rehabilitative Systems for Re-Education of Walking in Incomplete Spinal Cord Injured Persons

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■ **ABSTRACT**

Objective. The aim of the paper is to present various relatively simple functional electrical stimulation (FES) systems that affect neural circuits and reflex behavior by providing necessary peripheral input to the lower extremities of incomplete spinal cord injured (SCI) persons.

Methods. The proposed FES re-education walking systems make use of feedback information that is transmitted from the paralyzed limb to the nonparalyzed part of the patient's body. A single gait variable can be analogously transmitted to the walking subject in a form of sensory stimulation. The information about several gait variables can be first integrated and afterwards delivered to the walking subject as a single command.

Conclusions. Significant improvements in the duration of the double support phase, metabolic energy expenditure, and physiologic cost index were observed when using FES-assisted training of walking in incomplete SCI persons. ■

KEY WORDS: functional electrical stimulation, gait, incomplete spinal cord injury.

INTRODUCTION

It is a general observation that each year more incomplete spinal cord injured (SCI) patients are arriving in spinal units. Among them there are more incomplete tetraplegic than paraplegic cases. About one half of the incomplete SCI patients recover and need no orthotic aid after leaving the rehabilitation center. Functional electrical stimulation (FES) can be used as a therapeutic treatment in the early post-trauma phase within a great majority of the incomplete SCI cases(1,2).

FES represents one of the rare rehabilitative approaches restoring walking patterns in stroke(3) and incompletely paralyzed SCI subjects soon after the accident(4). The aim of an FES rehabilitative system for re-education of walking, which we are proposing in this paper, is not only to deliver electrical stimulation to the paralyzed muscles, but also to assess the sensory information from the paralyzed limb. In order to foster the re-education process, the electrical stimulation should be voluntarily controlled by the patient where the sensory information is fed back to the patient and not to the stimulator control unit. These systems are intended to be used in incomplete SCI persons soon after the accident or onset of disease. The re-education FES systems are to be used within the rehabilitation centers and applied by therapists. Surface electrical stimulation is therefore appropriate. The sensory information

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can be assessed by the use of artificial sensors attached to the paralyzed limbs, e.g., goniometers, accelerometers, foot-switches, pressure insoles. This information can be delivered to the walking subject through electrical stimulation, tactile stimulation, audio signal, or haptic interface. In this paper we propose two of such FES re-education systems. In the first case the information about the joint angle is analogous to the force delivered to the patient through a haptic interface. In the second case the information from several artificial sensors is first integrated and afterwards delivered to the patient through sensory electrical stimulation.

ANALOG SENSORY FEEDBACK SYSTEM

In FES-assisted walking of SCI patients, vision represents the only useful feedback. However, vision should be primarily used for observing the surroundings and not to control the movement of the lower extremities. To overcome this disadvantage an analog sensory feedback system was developed. This system provides information to the user in the form analogous to the measured gait variable. This gait variable is usually assessed by the use of various sensors, mounted on the segments of the lower extremities in order to replace the natural sensory feedback. The problem arises how to present the feedback information to the walking SCI subject. One of the possible solutions is to use the haptic interface, providing a force feedback to the user. A haptic interface is known as a force-to-force feedback from the area of robotics where the end-effector force is transmitted to the steering handle(5). In general the force feedback can be analogous to any other kind of sensory information.

The FES re-educational systems for walking of incomplete SCI subjects with the assistance of crutches can make use of various sensors in order to determine position of the lower extremities, velocity, acceleration, or ground reaction forces. The proposed analog FES system uses a single goniometer to provide the information on ankle joint angle. The original FES orthotic aid(2) comprised only a pushbutton to trigger voluntarily the stimulation of the peroneal nerve. Mounting a goniometer to the subject's ankle joint causes a demand for a special steering lever that can provide a force feedback. The proposed FES re-educational system helps SCI subjects to "feel" the ankle joint angle in a form of a counteracting torque acting on the control lever(6) during each walking cycle.

A haptic interface for the FES orthosis (Fig. 1) consists of the following parts: control unit including the peroneal stimulator, stimulation electrodes, control lever with electrical motor, and goniometer. The user defines the intensity of electrical stimuli by changing the angular position of the control lever built in the handle of the crutch. The control unit computes the corresponding FES amplitude and stimulates the ankle dorsiflexors using the surface stimulation electrodes. The resulting ankle dorsiflexion is measured by the goniometer attached to the ankle joint. The measured angle is reflected as a counteracting torque in the hand control lever. The torque is produced by the electrical motor actuating the axis of the control handle.

The viability of the proposed analog sensory feedback system was evaluated by using computer modeling. In the preliminary investigation some of the miniature hardware parts were replaced by larger units. A large electrical motor with a control lever was built to serve as a haptic interface and to replace the miniature control lever, which was to be built together with the motor into the crutch handle. The biomechanical model of the human ankle replaced the human lower extremity and was software-generated. Its output was the ankle joint angle. Fatiguing of the electrically stimulated muscle was included

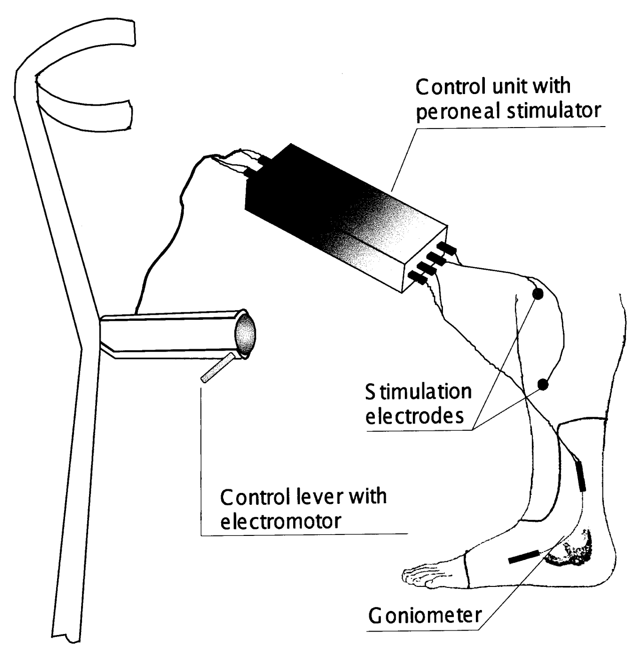
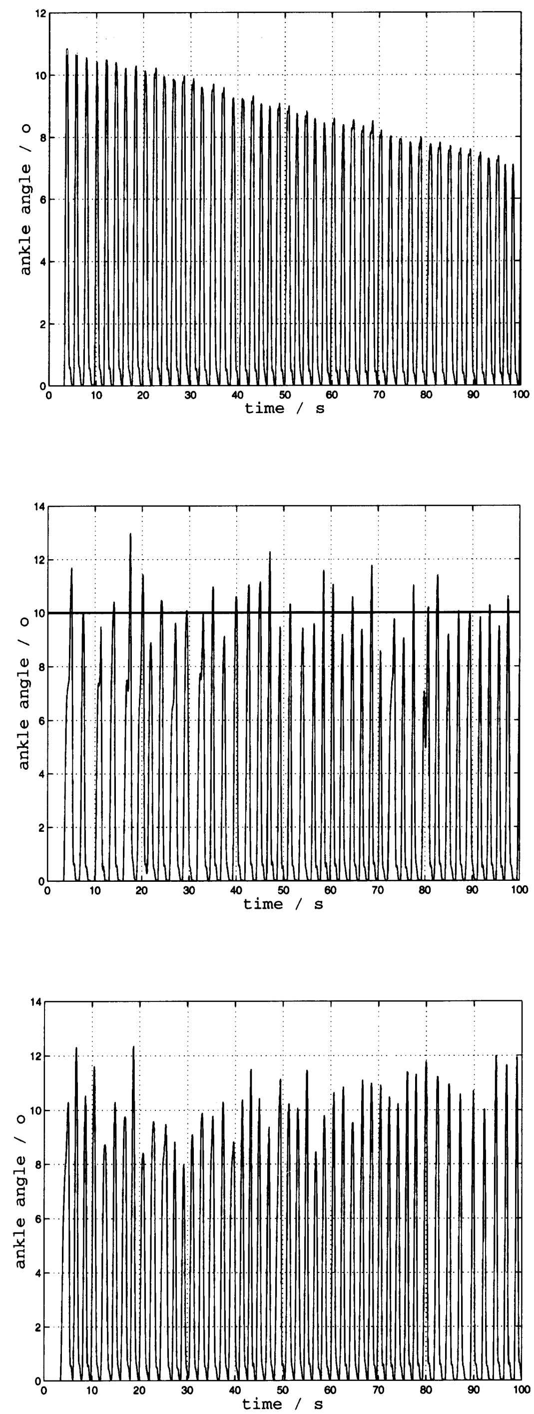


Figure 1. FES peroneal orthosis based on haptic interface.

into the muscle model. The electrical stimulator and the control unit were both simulated as software models. The first one was represented by a software pulse generator and was input to the biomechanical model(6) of the ankle joint, the second one was a controller calculating the control voltage proportional to the ankle angle. A voltage-controlled electrical motor provided the counteracting torque to the lever and consequently to the user.

Testing of the haptic interface experimental setup was carried out in six unskilled users. Their task was to actuate repeatedly the control lever in a similar way as during walking. The simulated gait was divided into two phases. During the swing phase the dorsiflexors were electrically stimulated for the duration of approximately one second, while during the stance phase of about the same duration the muscle relaxation occurred. The events of virtual walking were assessed by the computer and displayed on the screen. The duration of each test was five minutes.

In the first test (Fig. 2a) a train of electrical stimuli with constant amplitude was applied to the simulated ankle dorsiflexors. At this point it was our aim to demonstrate the problem of muscle fatigue occurring with the presently used stimulation systems. The second test included visual feedback in the form of the time course of the simulated ankle angle displayed on the computer screen, while the haptic interface was simultaneously providing the counteracting torque. The displayed diagram comprised also the desired peak value of the ankle joint angle (the line in Fig. 2b). The subject's goal was to maintain the maximal value of the ankle angle as constant as possible at the angle of 10° of ankle dorsiflexion. The inherent muscular fatigue was the obstructive factor, decreasing the ankle angle. This test was considered as training for the use of the haptic interface without visual feedback. The third test was a real evaluation of the haptic interface. The subjects were asked to control the ankle joint dorsiflexion by the use of the haptic interface information without any other feedback. A two-hour training made possible to control the ankle angle within a range of ± 2° (Fig. 2c).



A

B

C

Figure 2. The ankle goniogram during simulated FES assisted walking without sensory information (a), with the use of visual and haptic feedback (b), and while using the haptic interface alone (c).

SENSORY INTEGRATED FEEDBACK SYSTEM

An incomplete SCI person's walking relies primarily upon the visual information about the position of the paralyzed extremity. Frequent inappropriate looking down to the legs is therefore necessary, resulting in rather slow walking. This is specially noticeable during the foot contact phase when the patient is checking whether the leg which comes into the contact with the ground will provide reliable support to the body. The aim of the developed FES re-education system is to provide to the patient simple and efficient information based on sensory integration(7). Information, provided in the form of sensory stimulation, is delivered to the patient's nonparalyzed upper arm in order to reward the patient for successful progression from the swing phase into the double support phase.

The laboratory version of the FES re-education system runs on a personal computer (Fig. 3). The following transducers are connected to the data acquisition module: crutch pushbuttons, knee goniometers, and foot-switches. Hand pushbuttons are built into the handles of the crutches and are used for voluntary control of a two-channel stimulator. The signals from the pushbutton are also used for recognition of the current phase of walking. When the pushbutton is pressed, the stimulation is delivered to the ipsilateral peroneal nerve resulting in flexion response, i.e., simultaneous hip and knee flexion and ankle dorsiflexion. The stimulated leg is in the swing phase of walking. The subject remains in the swing phase of walking as long as he is pressing the pushbutton. When the walking subject releases the hand pushbutton, the peroneal stimulation is discontinued and the stimulation of the knee extensors is started making the contact of the stimulated leg with the ground. The stimulation frequency was 20Hz, the pulse duration 0.3 ms, and the amplitude of stimuli up to 150 V. The knee angle was measured by the use of flexible goniometer (Biometrics Ltd, Gwent, UK). This goniometer can be easily attached to the knee joint and causes only small errors due to the skin movement. The foot-switches were attached under the heel. In most severely paralyzed incomplete SCI patients the described stimulation channels and transducers were applied bilaterally while frequently unilateral application of the FES gait re-education system was sufficient. The computer controls also an additional stimulation channel providing sensory stimulation feedback. The sensory stimulation was delivered to the patient through a pair of electrodes placed over the skin of the ipsilateral upper arm. The stimulation frequency was 50 Hz, pulse duration 0.3 ms, and the amplitude between 30 and 40 V. This reward sensory signal lasted for a predetermined time interval of 0.2 s and was generated in the beginning of the double support phase when the stimulated leg made the contact with the ground. From the control algorithm point of view, the double support phase started after the patient voluntarily released the crutch pushbutton. During this phase the patient must make a

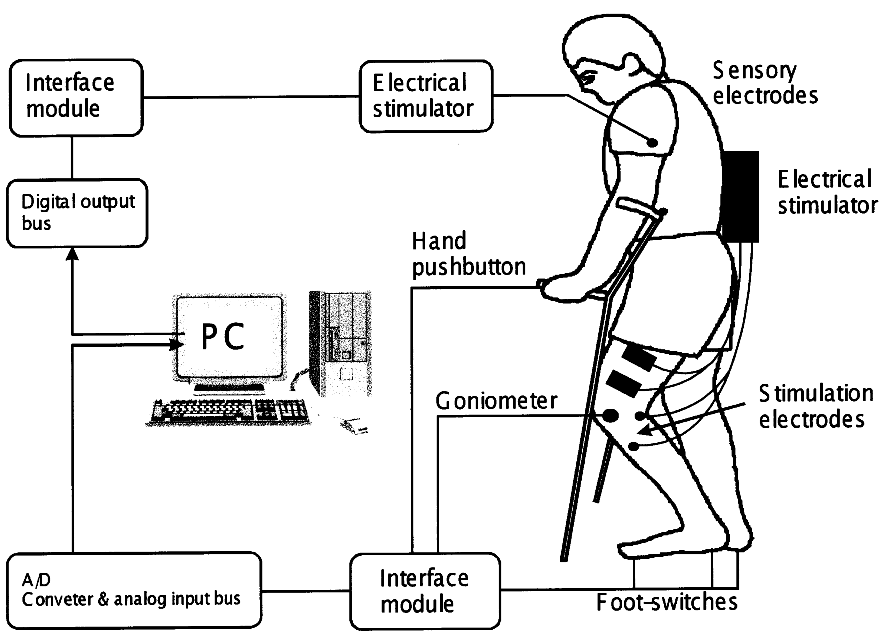


Figure 3. Sensory integrated feedback system.

contact with the ground having the leg extended. The successful foot contact was recognized when the knee angle was lesser than the maximal allowed knee flexion and the heel switch was in the ON state. In this situation the reward sensory signal was generated.

Testing of the proposed FES gait re-education system was performed in three rather severely handicapped SCI patients(7) having thoracic spinal cord lesion. Bilateral stimulation of knee extensors and peroneal nerve was needed in all three subjects. The purpose of this preliminary testing was to demonstrate that the improvements in walking occur as a consequence of applying the sensory feedback system. The gait measurements lasted for a month. During the first week the average values and variability of basic gait parameters were assessed when walking with FES but without sensory feedback. In the next three weeks the basograms were measured while training the patient to walk by the help of the described sensory feedback. The aim of the FES re-education system was to shorten the double support phase and thus increase the speed of walking. It is of utmost importance to make the double stance phase as short as possible because of fatiguing of the stimulated knee extensors. The average values and standard deviations of the double support time appertaining to the right and left leg are shown in Fig. 4. Comparing the gait data at the beginning and at the end of the investigation it can be concluded that the patient with T-12 spinal cord lesion(14 months after the accident) adopted a new and considerably faster technique for double stance phase performance.

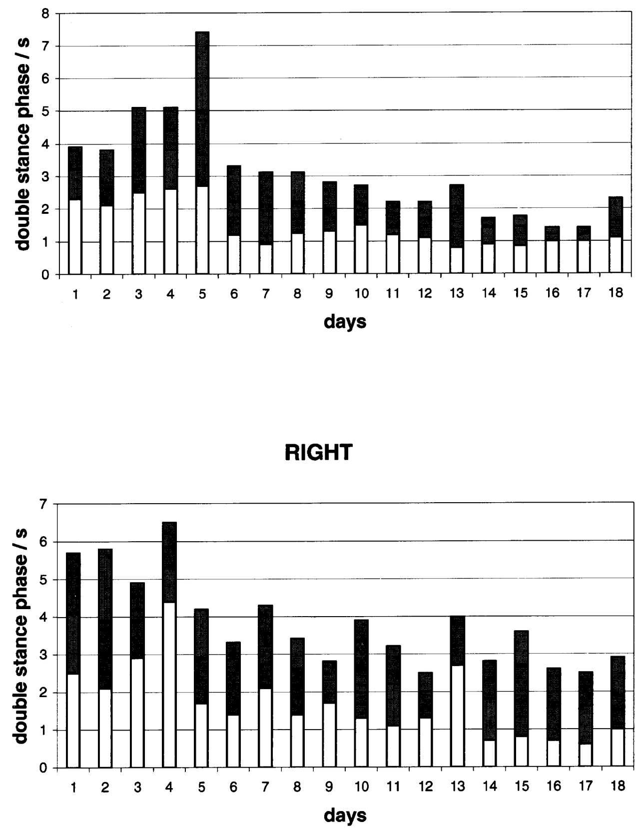


Figure 4. Influence of gait re-education on the duration of the double stance phase.

FES SYSTEM FOR PERMANENT USE

When more effects of the exercise and intensive task-dependent training are expected, the incomplete SCI patient may be a candidate for permanent application of an FES orthotic system. Simple peroneal stimulators can turn several of them into community walkers, effectively using the stimulator throuhout the day. It was our observation that the peroneal nerve stimulation was found useful in at least 10 percent of incomplete SCI patients to augment ankle dorsiflexion and knee and hip flexion in a lower limb reflex pattern.

Simple manual tests of voluntary muscle strength were performed in 31 incomplete SCI patients. The tests were carried out immediately after their arrival to the rehabilitation unit. Only the patients who were unable to walk on the day of examination were considered. The muscle groups governing the hip, knee, and ankle joint movement were evaluated. In the manual muscle tests voluntary muscle responses were estimated by six grades (0–5). The results of the muscle strength testing performed in 31 incomplete SCI patients with a central type (thoracic or cervical) of spinal cord lesion are presented in Fig. 5. It can be observed that hip and ankle antagonists were rather severely affected in most of the subjects. The strongest muscle group was knee extensors. Only rare incomplete SCI patients are candidates for application of permanent FES to their quadriceps muscles. Patients with very weak knee extensors are bound to the wheelchair. Patients with sufficently strong knee extensors are candidates for FES-assisted walking. Only one-channel electrical stimulators were given to these patients after release from the

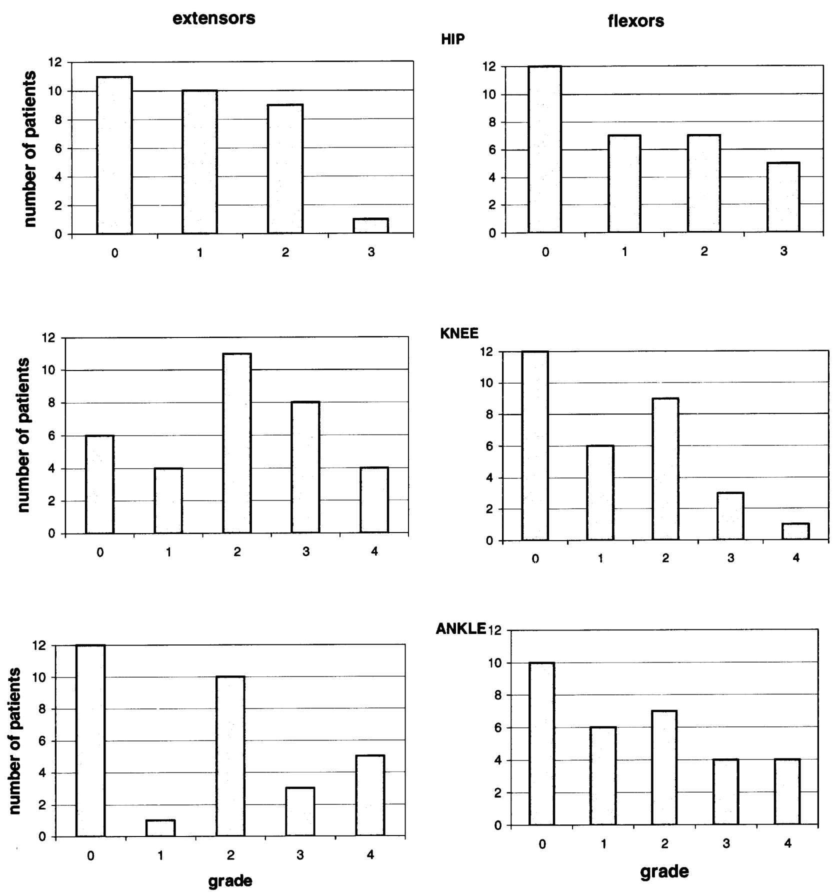


Figure 5. Distribution of the muscle strength in agonist and antagonist muscles of hip, knee, and ankle as assessed in a group of incomplete SCI persons.

rehabilitation center. One-channel FES was delivered to the peroneal nerve, resulting in a flexion response of the lower extremity. Here it also must be noted that significant nonsymmetry of the neuromuscular properties of the right and left paralyzed legs was often observed in incomplete SCI patients. In this way the peroneal stimulation was most often applied unilaterally.

It was our further observation that the incomplete SCI patients who are candidates for permanent use of the peroneal stimulator are all crutch users(2). In this respect we found it more appropriate to use the hand pushbutton built into the handles of the crutches to trigger the electrical stimulation than the more often used heel-switch. In addition, a moderate to high degree of extensor spasticity was usually observed in the lower extremities of the incomplete SCI persons. This extensor responses increased when loading the leg during standing posture or during the stance phase of walking. The extensor response is useful from the point of view of supporting the body, but is quite cumbersome during the transition from the stance into the swing phase. The patients have difficulties breaking the spontaneous extensor activity in order to be able to lift the heel and thus start the peroneal stimulation.

Interconnecting wires between the crutches and the stimulator are inconvenient in daily activities and are a frequent source of malfunctions. They hinder a patient when standing up or sitting down. The wire connection was found particularly inappropriate in situations when patients, while sitting, wish to discard the crutches. To overcome these problems, a telemetry system was developed providing reliable and interference resistant wireless control of FES-assisted walking(8). The crutch pushbutton signals are coded and transferred from the transmitter placed in the crutch to the receiver which is part of the stimulator and is firmly attached to the patient's lower leg. Another important achievement of the telemetric system is the improved appearance, since the stimulator can be hidden under the clothing of the patient.

The influence of the peroneal stimulation on gait efficiency and energy consumption was investigated. Gait performance on an incomplete SCI subject was compared to a healthy person's walking. The patient was a 48-year-old male. The level of injury, which took place four years ago, was C3-C4. The patient was using the peroneal stimulator in everyday life. Two already established gait evaluation methods were used: measurement of oxygen consumption and heart rate analysis.

The metabolic energy expenditure was calculated from the difference between oxygen consumption during walking and rest (9). The net energy physiologic cost index (EPCI) was calculated:

$$EPCI = (E_w - E_r)/v,$$

Where E_w is energy expenditure during walking, E_r is energy expenditure during rest, and v is walking speed. The heart rate was recorded by a system for physiologic measurements. Average heart rate and physiologic cost index (PCI) were calculated(10):

$$PCI = (HR_w - HR_r)/v,$$

where HR_w and HR_r denote average heart rate during walking and rest, respectively. The expired air collection and heart rate monitoring took place during the last two minutes of resting and walking. The patient walked first without any orthotic aid and afterwards by using the peroneal stimulator.

Both assessment approaches showed major differences between the gait of the normal subject and the patient. The results illustrate that the patient's gait is less energy efficient than the gait of the normal subject (Fig. 6). Performance of the patient's gait with the use of FES is much improved as compared to the gait without FES. It is evident that peroneal stimulation can significantly reduce energy consumption and improves incomplete SCI patient's gait efficiency.

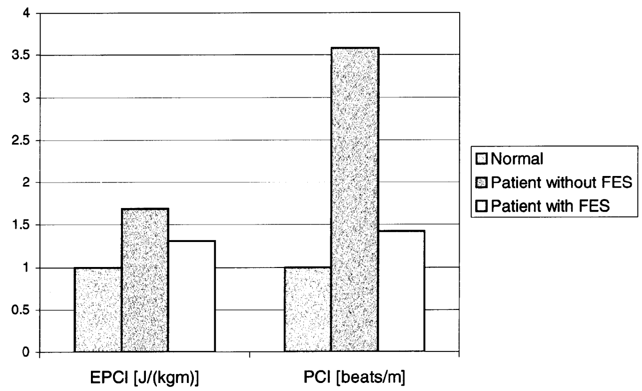


Figure 6. Energy efficiency of walking with and without FES represented by two gait assessment methods (the values are normalized to the results in healthy subject).

DISCUSSION

The use of FES for lower extremities in incomplete SCI persons can be split into two phases. First is the post-trauma phase when the stimulation is delivered to the paralyzed persons soon after the accident in the rehabilitation center. The second phase starts after the patients are released from the rehabilitation unit and when they use the electrical stimulator as community walkers during their daily activities.

The candidates for therapeutic post-trauma stimulation are all incomplete SCI patients with central lesion to the spinal cord. These are the patients with thoracic and cervical levels of SCI. The simplest application of FES is cyclical electrical stimulation delivered to a selected muscle group. It was our observation that voluntary response increased after a program of cyclical electrical stimulation in a vast majority of the incomplete SCI persons. A study should be made with a control group to distinguish the spontaneous improvements from the benefits of the FES therapeutic program. Such an investigation has not yet been performed. The reason is mainly because it is difficult to explain to the patient why he will not be included into the FES training program. Also, the cyclical electrical stimulation is a simple therapeutic program from the point of view of application of the surface electrodes and adjustment of the stimulation parameters and is quite often used by the therapists.

Electrical stimulation cannot only produce repetitive isolated movements in the paralyzed extremities. FES can provide support to the body while standing or walking and can also produce the swing phase of the extremity. The main goal of this paper was to introduce the FES-assisted gait re-education systems. The idea of these rehabilitative systems is the maximal commitment of the patient during the FES gait training. The patient has to control voluntarily the onset and intensity of the FES. At the same time the information from the paralyzed extremities is fed back to the patient. Two different groups of the FES-assisted gait re-education systems were proposed in this paper. In the first case a single gait variable was selected. Its value was analogously transmitted to the walking subject in a form of sensory feedback information. In the second case the information about several gait variables was first integrated and than delivered to the walking subject as a single command. The clinical value of both systems proposed must be further evaluated in future studies.

Many of the incomplete SCI patients recover to such an extent that they need no rehabilitative aid when released from the rehabilitation center. Nevertheless, it was our observation that at least 10 percent of the population are candidates for chronic application of an electrical stimulator. In most of incomplete SCI patients the knee extensors are strong enough to provide the necessary support during the stance phase. For chronic use these patients predominantly need only single-channel FES of the peroneal nerve resulting in the flexion response, producing the swing phase of walking. It was also observed that the candidates for permanent use of an FES walking aid are crutch users. In this way the control of FES by crutch pushbutton can overcome many problems of the heel switch triggering of the peroneal stimulator. The most important observation in this group of patients is the significant improvement in energy efficiency of walking assisted by FES orthotic device. These patients are also excellent candidates for implanted FES systems.

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