

Functional Electrical Stimulation for Grasping and Walking: Indications and Limitations

**Milos R. Popovic PhD^{1,3}, Armin Curt MD², Thierry Keller^{1,2},
and Volker Dietz MD²**

¹ Automatic Control Laboratory, Swiss Federal Institute of Technology Zurich – ETH Zürich, Switzerland

² ParaCare - Institute for Rehabilitation and Research, University Hospital Balgrist Zürich, Switzerland

³ *currently with the* Institute of Biomaterials and Biomedical Engineering, University of Toronto, Canada

e-mail: fes@aut.ee.ethz.ch
<http://www.aut.ee.ethz.ch/~fes/>

Address for correspondence:

Prof. V. Dietz
ParaCare - Institute for Rehabilitation and Research
University Hospital Balgrist
Forchstrasse 340
Zürich, CH-8008
Switzerland
Tel: +41-1-386-3901
Fax: +41-1-386-3909
e-mail: dietz@balgrist.unizh.ch

Summary

This article describes the state of art in the field of Functional Electrical Stimulation (FES) and its impact on improving grasping and walking functions in acute and chronic Spinal Cord Injured (SCI) patients. It is argued that during the early rehabilitation period the FES systems with surface stimulation electrodes should be used to assist training of hand and leg movements in SCI patients. Our clinical trials have shown that a number of acute SCI patients with impaired walking and grasping functions could improve these functions due to training with adjustable FES system to the point that they finally did not need the FES system to carry out these tasks. Other acute SCI patients, who did not recover the desired function, were enabled to perform either walking or grasping with the FES assistance. We believe that the subjects who can perform grasping or walking with the help of FES, and use the neuroprosthesis still 6 months after being subjected to the FES training, should consider using the FES system as a prosthetic device in Activities of Daily Living (ADL).

Despite significant technical progress that was achieved in last 10 to 15 years in the FES field there is a general consensus that these systems are not sufficiently advanced and that they need further development. The limited acceptance of the FES technology can be in part explained by the fact that it is not completely mature and that the patients still require daily assistance to use the FES systems. Nevertheless the present FES treatments combined with conventional occupational and physical therapy still remain the most promising approach in rehabilitating SCI patients. In this article advantages and limitations of different FES systems that are used to restore grasping and walking functions are discussed.

Keywords: Functional Electrical Stimulation; Neuroprostheses; Grasping Function; Walking Function;

1. Introduction

One of the most promising approaches to improve motor function in complete and incomplete paraplegic and tetraplegic patients with permanent limb impairment is the Functional Electrical Stimulation (FES). Although, the first FES trials were described almost 40 years ago and considerable technical improvements were achieved since, so far the FES technology had very limited impact on rehabilitation of paraplegic and tetraplegic patients¹.

Today FES is routinely applied only for cardiac pacemakers, bladder voiding, and pain suppression. In recent years few neuroprostheses for grasping and walking were introduced but their impact on rehabilitation of Spinal Cord Injured (SCI) patients is still limited. For example, case reports indicate that complete paraplegic patients with the help of FES were able to walk distances up to 500 m. However this type of walking was frequently accompanied with significant energy expenditure and high heart rates. In addition, the patients who used these systems often ambulated much faster with a wheelchair compared to walking with the FES system. The limited application of FES in SCI patients rehabilitation could be also explained by the fact that both patients and their families often have too high expectations from this technology, and after initial enthusiasm soon become disappointed since results do not match the initial expectations.

Nevertheless, it is clear that FES is an important tool in the rehabilitation of SCI patients and that SCI patients can benefit from this technology by training both locomotion and hand functions. The aim of this article is to highlight the actual state of art in the field of FES and to suggest both the indications and the limitations of its applications in restoring grasping and walking functions.

2. Technical Background

FES is a methodology that uses bursts of short electrical pulses to generate muscle contraction^{2,3}. If these electrical pulses are applied to motor nerves they can elicit Action Potentials (AP) that propagate along the axons towards the target muscle. Once these AP reach the muscle they cause muscle contraction. To achieve a continuous muscle contraction (tetanization) the FES system has to induce at least 20 AP per second, otherwise the muscle would not generate a steady output force and would only twitch. Since generation of AP and their propagation occur in the axons, the motor nerves of the stimulated muscles have to be intact (muscle should not be “denervated”). In principle, the motor nerves can be stimulated using monophasic and biphasic current or voltage pulses². Since monophasic pulses can potentially cause skin burns and tissue damage due to the galvanic processes, the majority of FES systems implement biphasic current pulses.

The motor nerves can be stimulated using either surface (transcutaneous) or implanted (percutaneous) electrodes². The transcutaneous stimulation is performed with self adhesive or non-adhesive electrodes that are placed on the subject’s skin on top of the nerve bundles^{2,4}. The percutaneous stimulation uses implanted electrodes that are

attached to the nerves or to the muscles close to the nerves^{4,5,6,7,8}. With implanted stimulation electrodes a higher muscular selectivity can be achieved compared to the surface stimulation electrodes^{9,10}. In addition to the stimulation selectivity, it is of advantage that an implanted FES system once it is implanted requires less time to put it on and to take it off compared to a surface stimulation system. On the other hand, a surface FES system does not require surgical intervention. This feature allows one to easily remove the surface FES system if the patient is not content with its performance, what is not the case with the implanted systems. In addition, surface FES systems can be applied at a very early stage of the rehabilitation unlike the implanted FES system.

3. Clinical and Electrophysiological Prerequisites

3.1 Clinical Assessment

The clinical examination according to the ASIA protocol is the first step in defining the level of lesion, and the extent of motor and sensory impairment, i.e. the severity of neurological deficit¹¹. In addition, the changes of muscle tone (spasticity and flaccid muscle paresis), which affect the upper or lower limb function, have to be assessed. Especially, an increased muscle tone is often able to severely disturb preserved limb functions. Besides muscle tone, contractures of muscles and joints with consecutive restriction of the range of movement (active and passive; heterotopic ossification) have to be recognized. The pre-accident skills and general physical condition of the patient also have to be taken into consideration, as this often has strong influence on the capacity the patient has to implement new and unusual movements he/she needs to relearn to achieve a desired functions.

There are several clinical tests describing the extent and capacity of hand function in tetraplegic patients¹². Similarly, one can assess the walking capacity of a SCI patient using the WISCI test¹³. However, none of these tests has been proved to be helpful in predicting usefulness of FES treatment for improving either grasping or walking function, and the relevance of these test for FES treatment outcome prediction yet need to be evaluated.

There is no evidence that the age of a patient might be relevant in deciding whether FES should be applied or not. However, the influence of age could play a significant role in the case of FES of lower limbs, since such treatments require from the patients to have adequate function of the cardio-vascular system to support the treatment.

3.2 Electrophysiological Assessment

In spinal cord and conus/cauda injuries, damage of motoneurons (anterior horn cells) or radicular motor nerves occurs with different extent and severity. A spinal cord injury is always accompanied by a damage of parts of the peripheral motor system. The extent of these lesions influences the excitability and stimulation capacity of the motor nerves and the related muscles, which limits the application of FES.

The extent of peripheral nerve lesions can be estimated and predicted by the neurophysiological recordings¹⁴. Although the clinical examination can indicate typical signs of peripheral motor nerve lesion (loss of muscle-tendon reflexes, reduced muscle tone, and muscle atrophy) it cannot provide precise information about the severity and extent of the damage.

Neurophysiological examinations can give quantitative and reliable data about the impairment of the peripheral nervous system early after the SCI. Neurographic recordings of motor and sensory nerves can provide information about the extent of peripheral nerve damage within 10 days after trauma. In addition, lesions of the spinal cord can be differentiated from accompanying damage of peripheral nerves. In lesions of the spinal cord and cauda equina sensory nerve fibers reveal preserved peripheral responses in nerve conduction studies. This is due to the fact that the dorsal root ganglia subservient to the peripheral nerve fibers are located outside the spinal cord and are not involved in spinal cord or cauda equina lesions.

EMG examinations can also indicate a peripheral nerve lesion by showing signs of denervation, which appear only after a time interval of about 20 to 30 days after SCI. However, neurographic recordings can provide quantitative data about the applicability of FES earlier after trauma.

3.3 Schedule of FES Application

To ensure success FES application has to be coordinated with the rehabilitation program. The implanted FES systems have the disadvantage that they can only be applied after the expected neurological recovery is achieved and a further significant improvement of function is unlikely. This time period can last up to two years after trauma. From our experience an early application of FES treatment is preferred since patients can train with the FES system already during the early rehabilitation period. Therefore, the surface FES systems for training of grasping and walking functions can be administered during the early rehabilitation period, and this training often helps patients to learn skills

required to carry out these two functions. In the case the patient that is subjected to this training does not recover the function and is dependent on a neuroprosthesis to perform the function in ADL, the patient should consider using the FES system as a prosthetic device. In the case the patient decide to use the FES system as a prosthetic device he/she should be informed about the existing implanted and surface FES systems. Medical doctors, occupational therapist, family, and psychologist should assist the patient in deciding which of the existing systems is the most appropriate for him/her.

3.4 Application Procedure

Typically in our hospital several grasping and walking functions are clinically tested with the surface FES system in order to assess which one can be potentially improved or restored in a SCI patient. Once a decision is made which function should be assisted by FES the patient is subjected to a muscle strengthening training that last form 1 up to 5 weeks, depending on the muscle condition and muscle response to electrical stimulation. At the end of muscle strengthening program, the functional training is introduced and the achieved function is repeatedly evaluated. During both strength and functional training, which are administered daily, the stimulation intensity and the stimulation frequency are constantly adjusted. The objective of these adjustments is to achieve good function with the minimum stimulation intensity and minimum stimulation frequency, to avoid early muscle fatigue. The FES training is carried out in the hospital with the aim that the patient can use the function effectively in ADL. In our setting, this training phase is also used by our technical team to prepare the system for the patient to take it home. Afterwards, the patient is only trained how to apply the function in ADL and is encouraged to use the system during the whole day.

Several follow-up measurements can provide evidence if the FES application improves the desired function and to which extent. Relevant criteria in assessing FES assisted functions are that movements are less energy consuming, that they are performed faster, with higher repetition frequency, and easier compared to performing the same function without FES.

4. Functional Considerations

4.1 Improving Function by Training with Functional Electrical Stimulation

By applying FES to upper or lower limb muscles one can potentially improve or restore muscle functions that were lost due to SCI. This functional improvement depends on the following basic requirements:

1. The limb muscles that are intended for FES treatment have to be accessible for placement of the stimulation electrodes.
2. The central part of paresis of the stimulated muscles has to prevail. There should not be a major degree of motoneuron or nerve-root damage of the stimulated muscle. In a considerable number of patients with a SCI, the amount of the peripheral nerve damage (motoneurons and nerve-roots) restricts the application of FES^{15,16,17,18,19,20}. By means of neurographic recordings within the first two weeks after SCI, the extent of peripheral nerve damage, and consequently, the potential application of FES can be determined¹⁴.
3. The function of proximal upper/lower limb muscles should be preserved, i.e. the improvement of function should be restricted to distal limb muscles. For example, in the case of the upper limbs, muscles needed for the opening and closing of the hand can be stimulated by a FES system, while the muscles used for reaching and arm placement tasks have to be intact, and the subject should be able to voluntarily control them. Similarly, in lower limbs paretic distal muscles can be stimulated to compensate for the “drop foot” problem or to generate the gait sequence in both legs while the muscles that facilitate balancing and posture during walking have to be voluntarily controlled by the patient.

If the above requirements are fulfilled one can immediately apply surface FES within the daily rehabilitation program. The FES application has to be customized to the patient's needs and condition in order to optimize the outcome. The early application of FES and its introduction into the rehabilitation program seems to be important to train functional movements. We found that the patients benefit the most from the FES technology when it is applied to assist movements in a physiological way. There is increasing evidence that SCI patients often re-learn certain movements better if the spinal neuronal centers that are responsible for the control of these movements are provided with a physiological feedback²¹. Our studies have shown that in many patients that were trained to perform functions such as grasping and walking using FES eventually recover these functions to the point that they do not need FES any

longer to perform them^{22,23,24}. Despite these findings, sufficient body of evidence that can clearly demonstrate beneficial effects of FES training compared to spontaneous recovery of functions in SCI patients does not exist yet.

An important finding that came out of our clinical trials is that application of FES during the rehabilitation training requires continuous adjustments of the stimulation program and the placement of the stimulation electrodes. This finding further stresses the importance of the flexibility of FES systems that are applied during the early stage of recovery. The patients benefit the most from the physical and occupational therapy if these are supplemented with a FES treatment²². Thus early FES application has to be carried out with the surface FES technology that provides sufficient flexibility to change stimulation objectives (stimulation programs and positions of stimulation electrodes) during the rehabilitation program.

4.2 Implanted versus Surface FES Systems

The obvious advantage of the surface FES systems, is their flexibility to support various rehabilitation programs and treatments. This advantage is partially counterbalanced by the shortcoming that the surface FES systems are less convenient in the ADL. Almost all surface FES systems that were proposed to generate grasping or walking functions, such as Handmaster²⁵, Bionic Glove²⁶, Parastep^{27,28}, WalkAid²⁹, or Odstock 2³⁰, either require assistance to place the system on a patient or require frequent technical support. These two problems might have contributed to the fact that the majority of patients that used surface FES systems did not use them on long-term basis.

The alternative solution that compensates for these shortcomings are implanted FES systems that are now available for improving or restoring upper and lower limb functions in para- and tetraplegic patients^{6,7,9,31,32}. However, up to now the implanted FES systems did not achieve a break through mainly due to the fact that they can be implanted only 18-24 months after injury when the patients are in chronic state. However, after this time the rehabilitation and the training of ADL have been completed and the patient and his/her family are already accustomed to the actual impairment of the patient. Therefore, by implanting a system at such a late stage patients usually do not gain sufficient improvement of function, which would justify an extensive surgery. Nevertheless some patients can profit from such a system to improve the hand function, although they still require the same amount of assistance as before the system was implanted³³. Furthermore, the implanted systems have a shortcoming that even at a chronic state the behavior of stimulated muscles can change, with the consequence that an imbalance among muscles could occur that can lead to a

dysfunction of the intended movement. This problem combined with a potential failure of a component of the implanted system could require an additional surgery to rectify the problem.

As a consequence, in the future a combination of the two FES techniques might reduce or even avoid these shortcomings. The surface stimulation technique should be predominantly applied early after the SCI to rehabilitate and train a function. Once the rehabilitation period is over and if the patient still depends on the FES system to perform a functional movement then an implanted FES system should be considered.

4.3 Future Developments

The present FES systems are mainly pre-programmed systems designed to execute specific and fixed tasks. Hence, they almost exclusively apply the feed-forward control strategies (e.g. grasping of an object or lifting of the foot during locomotion). In the future, further improvement of function with the help of FES might be achieved if the movements are not induced by a fixed program but are continuously adapted to the actual needs of the patient. This could be achieved in the case of grasping function by adjusting the grasping style and the grasping strength according to the task that needs to be carried out. Some promising results in that direction were already published by Lickel and Sinkjaer^{34,35} who used the impulses from skin receptors of the index finger to control the slippage of the object during grasping. Similarly, an attempt was made to control the foot lifting by using activity of the afferent peroneal nerve fibers during locomotion (Sinkjaer, personal communication). The refinement of this technique, which only would be applicable in chronic patients, could potentially lead to a wider application of FES technology.

5. Neuroprostheses for Grasping

5.1. Clinical Indications

In tetraplegic patients the most important function to achieve a high level of independence in ADL is the hand function. The extent to which these patients can use their hands represents a measure of their independence, which is commonly assessed by scores in ADL, such as the Functional Independence Measurements (FIM) and Spinal Cord Independence

Measure (SCIM)³⁶. These measures are also used to determine the extent of support and assistance the patient would need during the day, and in how far the accommodation and employment environment have to be adapted to fit the patient's needs.

In principal, the grasping function can be differentiated into holding and manipulation tasks, which again can be differentiated in mono- or bi-manual handling tasks. Two main objectives in applying FES in tetraplegic patients to improve the hand function are either to create a reliable and long lasting power grasp or to generate a smooth pulp-pinch grasp that is used to manipulate small objects. Regardless of the grasping strategy it is essential that the grasp can be easily commanded by the patient, and that the strength of grasp can be adjusted by the patient. In supporting the hand function the FES system should not interfere with the patient's preserved upper limb function, such as wrist extension that generates the tenodesis grasp or the ability to position the arm/hand at the desired place. Furthermore, the hand and arm movements generated by the FES should be carried out in a physiological way. FES induced movements should not oppose natural joint movements, and they have to respect the anatomy of bone and soft tissue composition.

The indication of FES application for grasping has to be customized and cannot be simply predicted from the neurological level of lesion. The acceptance of the devices depends on specific needs of the patient. Therefore, various grasping strategies have to be evaluated to find the FES grasp that is functionally most useful for the patient.

5.2. Existing Neuroprostheses

Neuroprostheses for grasping are FES systems designed to restore or improve grasping function in tetraplegic subjects. The well-known grasping neuroprostheses are the Freehand system⁷, Handmaster²⁵, Bionic Glove²⁶, NEC-FES system⁶, and the systems developed by Vodovnik et. al.³⁷ and Popovic et. al.³⁸. Recently our team developed a neuroprosthesis for grasping, better known as the ETHZ-ParaCare neuroprosthesis²². Except for the Freehand and NEC-FES systems all other neuroprostheses for grasping are FES systems with surface stimulation electrodes.

The *Freehand system* has eight implanted epimysial stimulation electrodes and an implanted stimulator (see Figure 1). The stimulation electrodes are used to generate flexion and extension of the fingers and the thumb. The hand closure and the hand opening are commanded using a position sensor that is placed on the shoulder of the subject's opposite arm. The position sensor monitors two axes of shoulder motion protraction/retraction and elevation/depression. The control strategy can be varied to fit different shoulder motion capabilities of the subject. Typically, the protraction/retraction motion of the shoulder is used as a proportional signal for hand opening and

closing. The shoulder elevation/depression motion is used to generate logic commands that are used to establish a zero level for the protraction/retraction command and to “freeze” the stimulation levels (“locking”) until the next logic command is issued. An additional switch is also provided to allow a user to choose between palmar and lateral grasp strategies. The shoulder position sensor and the controller are not implanted. The Freehand system is the first neuroprosthesis for grasping approved by the USA Food and Drug Administration (FDA). Thus far the Freehand system was provided to more than 130 patients and is commercially available.

One of the main advantages of the Freehand system is that it is implanted and the time needed to put on (donning) and to take off (doffing) the system is significantly shorter compared to the surface stimulation FES systems. On the other hand, the Freehand system can be applied only 18-24 months after the injury. This in turn limits the potential benefits the FES training has when it is applied during early stage of rehabilitation. Furthermore the patients are often subject to an additional surgery that is required to replace failed hardware components or to correct the positions of the stimulation electrodes.

The *NEC-FES neuroprosthesis* was developed by Handa et al. in cooperation with NEC Inc.⁶. This system is used to restore both grasping and walking functions in disabled subjects. The NEC-FES neuroprosthesis is an implanted FES system with 16 stimulation channels. 200 systems were manufactured and are almost exclusively used for research purposes. This device applies trapezoidal stimulation patterns to various muscles and muscle groups, which are derived from EMG activity recorded from muscle groups used by able body subjects during grasping. The stimulation sequences of the NEC-FES system are triggered with a push button or a pneumatic pressure sensor. Unlike the Freehand system the NEC-FES neuroprosthesis is not available outside Japan.

*The neuroprosthesis developed by Vodovnik et. al.*³⁷ is one of the first FES systems for grasping. This system has three stimulation channels (two stimulation electrodes per channel), which are used to generate the grasping functions by stimulating the finger flexors and extensors, and the thumb flexors. Although this device was developed more than two decades ago it is one of the rare FES systems that allows the subject to control the stimulation train via different sensory interfaces such as EMG sensor, sliding resistor, and pressure sensor. As a result, the subject can choose the most appropriate man-machine interface to control the neuroprosthesis.

The group that developed the Freehand system³⁹ also tried to use different man-machine interfaces but these interfaces did not become a standard feature of their system. The option to choose the neuroprosthesis control interface is important since it allows one to tailor the neuroprosthesis to the subject. The main disadvantage of the neuroprosthesis developed by Vodovnik et. al. is that donning and doffing times are longer than in the case of the

Freehand system and only a person who had previous FES experience can properly place the electrodes. To the best of authors' knowledge the neuroprosthesis developed by Vodovnik et. al. is not commercially available.

The *Handmaster*²⁵ is a neuroprosthesis for grasping with three pairs of surface stimulation electrodes. The system can be used to generate grasping function in tetraplegic and stroke patients. Originally this system was envisioned as an exercise and rehabilitation tool but is also used as a permanent prosthetic system. The Handmaster is controlled with a push button that triggers hand opening and closing, and with the sliding resistor the patient can regulate the way in which the thumb flexes. This feature allows a patient to adjust the grasp to the size and the shape of the object he/she wants to grasp. In addition, the subject can increase or decrease the grasping force using two additional push buttons. One of the advantages of the Handmaster is that it is easy to put on and to take off. The Handmaster is predominately used as an exercise tool for stroke subjects and is commercially available in a limited number of countries. One of the disadvantages of the Handmaster is that it does not provide the user with sufficient freedom to place the stimulation electrodes. In addition, the Handmaster's orthosis is too short and does not allow stimulation of the finger flexors at a proximal position on the forearm that provides good finger flexion with negligible wrist flexion activity. Another limitation of this system is its stiff orthosis that restricts the range of the wrist motion. In particular, the subjects can not perform full supination.

The *Bionic Glove*²⁶ is a neuroprosthesis for grasping designed to enhance the tenodesis grasp in patients that have active control of the wrist flexion and extension (see Figure 2). The tenodesis grasp is a passive grasp obtained by extending the wrist. Due to limited length of finger flexors a voluntarily extension of the wrist leads to passive finger flexion (e.g. C6-C7 spinal cord injured patient). The Bionic Glove uses a position transducer attached to the wrist to detect wrist flexion and extension. When the patient voluntarily flexes the wrist, the finger extensors are stimulated generating hand opening. When the patient voluntarily extends the wrist the finger flexors are stimulated to obtain hand closure. The Bionic Glove has three self adhesive surface stimulation electrodes that are placed over the motor points of the target muscles, and one balancing (anodic) electrode that is placed proximal to the wrist crease. Each stimulation electrode has a metal stud on its back that is connected to one of four stainless steel meshes placed inside the neoprene glove above the expected electrode positions. Once the glove is placed on the subject's arm the stimulation electrodes automatically establish electrical contact with the steel meshes inside the glove. The stimulator used by the glove is located on the forearm part of the glove.

The six months multi-center trial (our center also participated in this study) showed improved ADL following training with the Bionic Glove²⁴. The power grasp and the handling of big objects were significantly improved. It was

also shown that the Bionic Glove has an important therapeutic effect during the ADL training. Once the training was completed the several patients did not need the system any longer to perform the ADL tasks.

Although the Bionic Glove has some exceptional technical solutions it suffers from a couple of shortcomings. The stimulator located on the forearm is exposed to frequent impacts against objects (our patients frequently use forearms to hit doors and drawers in order to close them). The position transducer mechanism is delicate and has to be replaced frequently. Also, the contacts between the electrodes and the steel meshes are often disrupted due to arm movements. To the best of authors' knowledge the Bionic Glove is not commercially available at the moment.

The *Belgrade Grasping System (BGS)* proposed by Popovic et. al.³⁸, represents a neuroprosthesis for grasping that in addition to the grasping function also provides a reaching function. The BGS has four stimulation channels three of which are used to generate the grasping function, and the fourth channel is used to stimulate the triceps brachii muscle to allow the subject to extend the elbow in order to reach objects he/she otherwise cannot reach. The grasping function is controlled via a push button that triggers the hand opening and closing. The reaching function is achieved by measuring the subject's shoulder velocity with a goniometer and by generating a synergistic elbow motion by stimulating the triceps brachii muscle. Similarly, the Cleveland group also combined the grasping and reaching functions using the Freehand system^{39,40}. However, their neuroprosthesis measures the position of the arm in space and for certain arm positions it automatically triggers stimulation of the triceps brachii muscle. In parallel with the triceps brachii muscle stimulation, the subject has to voluntarily contract the biceps muscle to control the position of the arm. The BGS system, similar to the system proposed by Vodovnik et. al.³⁷, requires more time to place the electrodes compared to the Handmaster system²⁵ and it is not yet commercially available.

The *ETHZ-ParaCare neuroprosthesis* was designed to improve grasping and walking functions in SCI and stroke patients²². This surface stimulation FES system is programmable, has four stimulation channels, and can be interfaced with any sensor or sensory system. The ETHZ-ParaCare neuroprosthesis is used to develop the custom made neuroprosthesis that can be used in ADL. The ETHZ-ParaCare neuroprosthesis for grasping can provide both palmar and lateral grasps. The system can be controlled using the following strategies: proportional EMG, discrete EMG, push button, and sliding resistor. Thus far more than 12 patients used the system. Four patients used the neuroprosthesis at home in daily living activities. One of the main disadvantages of this system is that it requires between 7 and 10 min to don and doff the system. The system is not yet commercially available. Our current efforts are aimed at designing a new generation of the ETHZ-ParaCare portable electrical stimulator with surface stimulation electrodes. This project is done in collaboration with Swiss company Compex SA from Ecublens. The new generation of the stimulator should become available at the end of 2001.

6 Neuroprostheses for Walking

6.1 Clinical Indications

The FES devices that were designed to support or enable locomotion in SCI patients require voluntary control of upper extremities to maintain stability and balance during walking. In the majority of cases the patients also have to support part of their body weight. Therefore, only paraplegic patients who have strong and functional upper extremities can benefit from the FES systems for locomotion. In patients with complete paraplegia the main aim of applying a FES system for locomotion is to enable the patient to stand and to gain a limited walking capacity. Commonly such FES system is used to enable the patient to walk for a limited time period in well known and controlled environment (patient is not expected to walk on uneven terrain, uphill, or downhill). The main disadvantage of these FES systems is that they require significant physical effort, which is reflected in a high heart rate during walking. Therefore, patients do not apply these devices in ADL but mainly use them as training devices to maintain the overall muscle and bone condition of lower and upper limbs, and to exercise the cardio-vascular system. This type of training was also found instrumental in preventing pressure sores. In the case the patient cannot control the trunk stability external support might be needed to provide lower back stability.

In patients with incomplete paraplegia we distinguish two impairments. In patient with spastic paraparesis the swinging phase is impaired with an inability to get the foot in front during walking, i.e. to make a forward step. When a “drop foot” syndrome predominates (difficulty to dorsiflex the foot of the impaired leg), the patient cannot generate sufficient clearance during walking, which can lead to stumbling and fall. In these patients the FES systems for locomotion are predominately used to assist standing and to support walking by stimulating the disabled leg while the healthy leg is used by the patient to support body weight and to pace the gait. These FES systems are used as prosthetic and therapeutic devices. It is well established that these systems can help patients to improve the walking style and speed, and to allow patients to walk longer distances.

6.2 Existing Neuroprostheses

The first walking neuroprosthesis was proposed in 1961 by Liberson and colleagues⁴¹. This system was developed to compensate for the “drop foot” problem in hemiplegic subjects. By stimulating the peroneal nerve the prosthesis elicits

a flexion reflex which generates simultaneous hip, knee, and ankle flexion allowing the subject to make a step with the disabled leg. Since 1961 a number of neuroprostheses for walking have been designed and tested with various patients. These devices can be divided into the systems that were designed to compensate for the “drop foot” problem such as Fepa⁴², MikroFES⁴³, WalkAid²⁹, and Odstock 2³⁰, and the systems that facilitate walking in subjects who have both legs paralyzed such as Parastep^{27,28}, RGO^{44,45}, HAS⁴⁶, Praxis24³¹, and the systems proposed by Kralj et. al.⁴⁷ and Kobetic et. al.^{9,32}.

The “drop foot” FES systems predominately apply the surface stimulation technology (one generation of the Fepa system had an implanted electrode but this idea was abandoned in favor of the surface stimulation⁴²) with one or at most two stimulation channels. The stimulation sequences are triggered with a push button, foot switch, or a pendulum resistor. These FES devices are most frequently used for short-term therapeutic application in the clinical environment, although some subjects use these systems as a permanent orthotic device⁴⁸. All mentioned systems are small, fairly reliable, and simple to use. Some of them, such as the Odstock 2 and the MikroFES systems were fitted to more than 500 subjects. Thus far only the WalkAid was FDA approved. The Fepa, MikroFES, and Odstock 2 systems are all commercially available.

The other FES systems for walking were designed for complete paraplegic patients. The Parastep and the system proposed by Kralj et. al. are FES systems for walking with six stimulation channels. Two stimulation channels are used to stimulate the peroneal nerves bilaterally, two channels to stimulate the quadriceps muscles bilaterally, and the paraspinals or the gluteus maximus/minimus muscles are stimulated with the remaining two channels²⁸. The last two channels are applied in subjects who cannot voluntarily extend the lower back. The quadriceps muscles are stimulated during standing up and during the stance. The peroneal nerve stimulation is used to evoke peroneal reflex, i.e. to generate simultaneous hip, knee, and ankle flexion, allowing the subject to make a step. The stimulation sequences are triggered with a push button that is attached to the walker or crutches. The Parastep system was successfully applied to more than 600 subjects (Daniel Graupe, personal communication) and was the first FES system that was FDA approved (see Figure 3). The Parastep is one of the few FES systems that are commercially available. The system proposed by Kralj et. al. was also successfully applied to more than 50 subjects, but this system is not commercially available.

The Praxis24 and the system proposed by Kobetic et. al. are implanted FES systems with 24 and 32 electrodes, respectively, and are used to restore walking in paraplegic subjects. The Praxis24 system also provides bladder voiding, which is not the topic of this review. Both these systems were designed to provide walking and standing functions similar to the previously mentioned surface stimulation systems^{9,32,47}. The difference is that these

two systems are implanted and therefore should provide better stimulation selectivity and more natural walking patterns. Both the Praxis24 and the system proposed by Kobetic et. al. are used for research purposes and are not commercially available.

The *HAS* and the *RGO* walking neuroprostheses are devices that in addition to the surface FES system also had active and passive braces, respectively. The braces are introduced to reduce the high metabolic rate observed in subjects with the FES systems for walking by providing additional stability and support during standing and walking^{28,49}. Thus far the RGO system has been successfully applied to more than 40 subjects. Both the HAS and RGO are mainly used for research purposes.

The *ETHZ-ParaCare neuroprosthesis for walking* was designed to improve walking in incomplete SCI subjects and stroke subjects²². The system was designed to improve walking by generating a step cycle in the impaired leg. In most cases, the stimulation of the peroneal nerve elicits a flexion reflex that evokes the swing phase. The flexion reflex induces a simultaneous contraction of the hip, knee, and ankle flexor muscles that lift the leg off the ground. Besides the peroneal nerve other muscle groups are stimulated to provide additional support or smoother movements during walking. In general the *ETHZ-ParaCare neuroprosthesis for walking* uses four pairs of surface stimulation electrodes and its stimulation sequences are triggered using a push button, a foot switch, or a gait phase detection sensor^{22,50}. The *ETHZ-ParaCare neuroprosthesis for walking* was successfully applied to more than 10 subjects. Although this system was designed to be used in daily living activities, most of the patients use it only during rehabilitation training. The *ETHZ-ParaCare neuroprosthesis for walking* is not yet commercially available.

Conclusions

The FES can be used to successfully rehabilitate patients with SCI if the following criteria are respected:

1. The patient was carefully selected according to clinical and electrophysiological examinations.
2. The patient is motivated and fully supported by his/her family to join the FES program.
3. The FES training is supported and combined with the conventional occupational and physical therapy.
4. The function that is trained with the neuroprosthesis is physiological and that it reproduces a natural limb function.
5. The training is initiated as early as possible after trauma, preferably during the early rehabilitation phase.

Under these conditions the FES treatment can give good results in retraining grasping and walking functions in SCI patients.

During the acute rehabilitation phase the neurological condition of the patient is unstable and neurological recovery may occur. In this early phase flexible FES system should be applied to assist certain limb functions. Such system has to allow for effortless: 1) changes of the treatment objectives; 2) adjustments of the stimulation sequences and stimulation parameters; 3) repositioning of the stimulation electrodes; and 4) implementation of different sensors for neuroprosthesis control. We firmly believe that the surface FES systems are the most appropriate to carry out functional training during early rehabilitation, due to their inherent flexibility. This flexibility also allows one to withdraw the FES treatment without any disadvantage to the patient. The functional training typically has three possible outcomes. One is that the system does not generate an adequate function or the patient is not motivated to use the system. The second outcome is that the patient recovers the function and does not need the FES system to perform the desired function. The third outcome is that the patient can generate the function only with the help of FES. In this case the patient should be encouraged to use the FES system as a prosthetic device. If the patient accepts the system and is using it daily the patient should be informed about the existing commercially available FES systems and should be encouraged to consider an implanted FES system if such a system can generate the function patient was trained to perform.

References

- 1 Kantrowitz A. Electronic Physiological Aids. *Report on the Maimonides Hospital Brooklyn*, 1960;4-5.
- 2 Baker L., McNeal D., Benton L., Bowman B., Waters R. *Neuromuscular Electrical Stimulation - A Practical Guide*. 3rd edn. Rehabilitation Engineering Program, Los Amigos Research and Education Institute, Rancho Los Amigos Medical Center, USA, 1993.
- 3 Guyton A., Hall J. *Textbook of Medical Physiology*. 9th edn. W.B. Saunders Company. 1996.
- 4 Quintern J. Application of functional electrical stimulation in paraplegic patients. *NeuroRehabilitation*, 1998;10:205-250.

- 5 Cameron T., Loeb G., Peck R., Schulman J., Strojnik P., Troyk P. Micromodular implants to provide electrical stimulation of paralyzed muscles and limbs. *IEEE Tr. Biomed. Eng.*, 1997;44:781-790.
- 6 Hoshimiya N., Handa Y. A master-slave type multichannel functional electrical stimulation (FES) system for the control of the paralyzed upper extremities. *Automedica*, 1989;11:209-220.
- 7 Smith B., Peckham P., Keith M., Roscoe D. An externally powered, multichannel, implantable stimulator for versatile control of paralyzed muscle. *IEEE Tr. on Biomech. Eng.*, 1987;34:499-508.
- 8 Tyler D., Durand D. A slowly penetrating interfascicular nerve electrodes for selective activation of peripheral nerves. *IEEE Tr. on Rehab. Eng.* 1997;5:51-61.
- 9 Kobetic R., Morsolais E. Synthesis of paraplegic gait with multichannel functional neuromuscular stimulation. *IEEE Tr. on Rehab. Eng.* 1994;2:66-78.
- 10 Mortimer J. Motor prostheses. *Handbook of Physiology - The Nervous System II*, American Physiological Society, 1981;155-187.
- 11 Ditunno J.F., Young W., Donovan W.H., Creasy G., The International Standards Booklet for Neurological and Functional Classification of Spinal Cord Injury. *Paraplegia*. 1994;32:70-80.
- 12 Sollerman C, Ejekkar A, Sollerman hand function test: A standardized method and its use in tetraplegic patients. *Scand J Plast Reconstr Surg Hand Surg*. 1995;29:167-76.
- 13 Ditunno J.F., Ditunno P.L., Graziani V., Scivoletto G., Bernardi M., Castellano V., Marchetti M., Barbeau H., Frankel H.L., D'Andrea Greve J.M., Ko H.-Y., Marshall R., Nance P. Walking Index for Spinal Cord Injury (WISCI): An International Multicenter Validity and Reliability Study. *Spinal Cord*. 2000;38:234-243.
- 14 Rutz S., Dietz V., Curt A. Diagnostic and Prognosis value of Compound Motor Action Potential of Lower Limbs in Acute Paraplegic Patients. *Spinal Cord*. 2000;38:203-210.
- 15 Curt A., Dietz V. Traumatic Cervical Spinal Cord Injury: Relation Between Somatosensory-Evoked Potentials, Neurological Deficits, and Hand Function. *Arch. Phys. Med. and Rehab.* 1996;77:48-53.
- 16 Curt A., Dietz V. Neurographic Assessment of Intramedullar Motoneurone Lesions in Cervical Spinal Cord Injury: Consequences for Hand Function. *Spinal Cord*. 1996;34:326-332.
- 17 Curt A., Dietz V. Nerve Conduction in Cervical Spinal Cord Injury: Significance for Hand Function. *NeuroRehabilitation*. 1996;7:165-173.
- 18 Curt A., Dietz V. Ambulatory Capacity in Spinal Cord Injury: Significance of Somatosensory Evoked Potentials and ASIA Protocols in Predicting Outcome. *Arch. Phys. Med. and Rehab.* 1997;78:39-43.

- 19 Curt A., Keck M., Dietz V. Clinical Value of F-wave Recordings in Traumatic Cervical Spinal Cord Injury. *Electroenceph. Clin. Neurophysiology*, 1997;105:189-193.
- 20 Curt A., Dietz V. Electrophysiological Recordings in Patients with Spinal Cord Injury: Significance for Predicting Outcome. *Spinal Cord*. 1999;37:157-165.
- 21 Dietz V, "Neurophysiology of Gait Disorders: Present and Future Applications," 1997;103:333-355.
- 22 Popovic M.R., Keller T., Pappas I.P.I., Dietz V., Morari M. Surface-Stimulation Technology for Grasping and Walking Neuroprostheses. *IEEE Eng. in Med. and Biol. Magazine*, 2001;20:82-93.
- 23 Bajd T., Kralj A., Turk R., Benko H., Sega J. Use of functional electrical stimulation in the rehabilitation of patients with incomplete spinal cord injuries. *J. of Biomed. Eng.* 1989;11:96-102.
- 24 Popovic D., Stojanovic A., Pjanovic A., Radosavljevic S., Popovic M., Jovic S., Vulovic D. Clinical evaluation of the Bionic Glove. *Arch. of Phys. Med. and Rehab.* 1999;80:299-304.
- 25 Ijzerman M., Stoffers T., In 't Groen F., Klatte M., Snoek G., Vorsteveld J., Nathan R., Hermens H. the NESS Handmaster orthosis: Restoration of hand function in C5 and stroke patients by means of electrical stimulation. *J. of Rehab. Scien.* 1996;9:86-89.
- 26 Prochazka A., Gauthier M., Wieler M., Kanwell Z. The Bionic Glove: An electrical stimulator garment that provides controlled grasp and hand opening in quadriplegia. *Arch. of Phys. Med. and Rehab.* 1997;78:1-7.
- 27 Graupe D., Davis R., Kordylewski H., Kohn K.H. Ambulation by traumatic T4-12 paraplegics using functional neuromuscular stimulation. *Critical Rev. Neurosurgery*. 1998;8:221-231.
- 28 Graupe D., Kohn K.H. Functional neuromuscular stimulator for short-distance ambulation by certain thoracic-level spinal-cord-injured paraplegics. *Surgical Neurology*. 1998;50:202-207.
- 29 Wieler M., Naaman S., Stein R.B. WalkAid: An improved functional electrical stimulator for correcting foot-drop. *Proc. of the 1st Annual Conf. on the Int. FES Society*. 1996;101-104.
- 30 Taylor P.N., Wright P.A., Burridge J.H., Mann G.E., Swain I.D. Correction of bilateral dropped foot using the Odstock 2 channel stimulator (O2CHS). *Proc. of the 4th Annual Conf. on the Int. FES Society*. 1999;257-260.
- 31 Davis R., Houdayer T., Andrews B., Barriskill A. Paraplegia: Implanted Praxis24 - FES system for multi-functional restoration. *Proc. of the 4th Annual Conf. on the Int. FES Society*, 1999;155-158.
- 32 Kobetic R., Triolo R., Morsolais E. Muscle selection and walking performance of multichannel FES systems for ambulation in paraplegia. *IEEE Tr. on Rehab. Eng.* 1997;5:23-28.
- 33 Taylor P., Esnouf J., Hobby J. Pattern of use and User Satisfaction of Neuro Control Freehand System. *Spinal Cord*. 2001;39:156-160.

- 34 Haugland M., Lickel A., Haase J., Sinkjaer T. Control of FES thumb force using slip information obtained from the cutaneous electroneurogram in quadriplegic man. *IEEE Tr. on Rehab. Eng.* 1999;7:215-27.
- 35 Lickel A. Restoration of lateral hand grasp in a tetraplegic patient applying natural sensory feedback. *Center for sensory-motor interaction SMI, Aalborg University, Denmark.* 1998.
- 36 Catz A., Itzkovich M., Agranov E., Ring H., Tamir A. SCIM – Spinal Cord Independence Measure: A New Disability Scale for Patients with Spinal Cord Leasions. *Spinal Cord.* 1997;35:850-856.
- 37 Rebersek S., Vidovnik L. Proportionally controlled functional electrical stimulation of hand. *Arch. of Phys. Med. and Rehab.* 1973;54:168-172.
- 38 Popovic D., Popovic M., Stojanovic A., Pjanovic A., Radosavljevic S., Vulovic D. Clinical evaluation of the Belgrade Grasping System. *Proc. of the 6th Vienna Int. Workshop on FES.* 1998:247-250.
- 39 Hart R.L., Kilgore K.L., Peckham P.H. A comparison between control methods for implanted FES hand-grasp systems. *IEEE Tr. on Rehab. Eng.* 1998;6:208-218.
- 40 Grill J.H., Peckham P.H. Functional neuromuscular stimulation for combined control of elbow extension and hand grasp in C5 and C6 quadriplegics. *IEEE Tr. on Rehab. Eng.* 1998;6:190-199.
- 41 Liberson W.T., Holmquest H.J., Scot D., Dow M. Functional electrotherapy: Stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients. *Arch. Phys. Med. Rehab.* 1961;42:101-105.
- 42 Vodovnik L., Kralj A., Stanic U., Acimovic R., Gros N. Recent applications of functional electrical stimulation to stroke patients in Ljubljana. *Clinical Orthopaedics and Related Research.* 1978;131:64-70.
- 43 MicroFES – Manual. *Institut "Jozef Stefan" Ljubljana, Slovenia,* 1991.
- 44 Solomonow M., Aguilar E., Reisin E., Baratta R., Best R., Coetzee T., D'Ambrosia R. Reciprocating gait orthosis powered with electrical muscle stimulation (RGO II) Part I: Performance evaluation of 70 paraplegic patients. *Orthopedics.* 1997;20:315-324.
- 45 Solomonow M., Reisin E., Aguilar E., Baratta R., Best R., D'Ambrosia R. Reciprocating gait orthosis powered with electrical muscle stimulation (RGO II) Part II: Medical evaluation of 70 paraplegic patients. *Orthopedics.* 1997;20:411-418.
- 46 Popovic D., Tomovic R., Schwirtlich L. Hybrid assistive system - the motor neuroprosthesis. *IEEE Tr. on Biomed. Eng.* 1989;36:729-737.
- 47 Kralj A., Bajd T., Turk R. Enhancement of gait restoration in spinal injured patients by functional electrical stimulation. *Clinical Othopaedics and Related Research.* 1988;223:34-43.

- 48 Bajd T., Kralj A., Stefancic M., Lavrac N. Use of functional electrical stimulation in the lower extremities of incomplete spinal cord injured patients. *Artificial Organs*. 1999;23:403-409.
- 49 Phillips C.A. An interactive system of electrical stimulators and gait orthosis for walking in the spinal cord injured. *Automedica*. 1989;11:247-261.
- 50 Pappas I.P.I., Popovic M.R., Keller T., Dietz V., Morari M. A Reliable Gait Phase Detection System. *To appear in the IEEE Tr. on Neural Sys. and Rehab. Eng.*, accepted in February 2001.

Acknowledgments: The project presented in this paper is supported by the Swiss National Science Foundation (project No. 5002-057811.1), the Committee for Technology and Innovation (project No. 4891.1) and company Compex SA, all located in Switzerland. Additional information regarding this and other projects of our group can be found at <http://www.aut.ee.ethz.ch/~fes/>.

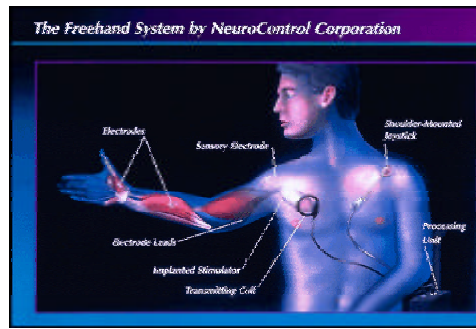


Figure 1: Freehand system by NeuroControl Corporation, USA



Figure 2: Bionic Glove developed by Arthur Prochazka from the University of Alberta, Canada



Figure 3: Parastep Electrical Stimulation System developed by Daniel Graupe from the University of Illinois, USA