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Exciting innovations for the spinally injured

Spinal injury can be devastating, resulting, as it often does, in some paralysis and loss of sensation. Engineering plays an important role in spinal cord injury rehabilitation. Here, the authors survey current research into the uses of functional electrical stimulation to improve the quality of life of spinally injured people. Touching on the area of spinal cord repair and nerve regeneration, they also consider the question of whether technology can help paraplegics to take steps again.

Introduction

Every year in the United Kingdom around 1000 people sustain a spinal cord injury. The classical patient profile is a young person injured in a road traffic accident or fall, but causes and age range of spinal injury do vary widely. The effects can be devastating. Traumatic spinal cord injury frequently results in paralysis and loss of sensation below the level of the injury. As well as providing communication between the limbs and the brain, the spinal cord also transmits signals for the body's autonomic nervous system. This system of nerves works at an unconscious level to regulate many functions including heart rate, bladder and bowel control, breathing and sexual response. So in the first few days and weeks of spinal cord injury the patient is not only paralysed, but their body's basic self-regulation may be grossly deranged. Blood pressure and pulse are abnormally low, breathing may be very difficult and the bowel may temporarily stop working. This combination of paralysis and autonomic upset is potentially very dangerous but doctors and nurses can stabilise the newly injured patient with appropriate drugs and other treatment.

Following the initial period of acute medical care, the short-term aim of the subsequent hospital rehabilitation is to maximise the patient's ability to look after their body, bladder and bowels, and to learn how to dress and wash and how to use a wheelchair. They may need new or adapted housing. This will take six to nine months of intensive work from a team including doctors, nurses, physiotherapists, occupational therapists and social workers.

Patients whose injury is below the neck will have normal arm function but no leg strength and partial or good trunk control depending on the level of injury. These people are paraplegic and most will become fully independent. Patients with neck injuries and any degree of arm weakness are tetraplegic ('quadriplegic'). Some may have minimal hand weakness and can be independent. Higher neck injuries will result in complete hand or arm paralysis, and possibly in breathing difficulty. Some tasks such as dressing, washing and writing may be possible with hand splints but most of these people need several hours of care daily to ensure a high quality of life.

In the longer term, spinal injured people in work tend to have higher incomes, higher self-esteem and better quality of life than those on state benefits, so the aim is, if at all possible, for the person to return to work. Even patients with very high level paralysis, requiring mechanical ventilation, can return to work provided that they have appropriate desk-based skills. For older and unskilled people work may not be a realistic goal.

Engineering plays an important role in spinal cord injury rehabilitation, and for some patients in the maintenance of vital function (e.g. the requirement for mechanical ventilation of patients with a very high neck injury). A range of exercise and therapeutic devices has been developed to allow patients to maintain the condition of muscles unaffected by the injury and to retain voluntary control. Other devices are routinely used to move cyclically the joints in the paralysed limbs, in order to maintain the range of motion in joints. Passive standing frames are used to allow patients to stand, with appropriate bracing, in order to load the long leg bones in an attempt to address the problem of bone demineralisation.

This article focuses on an emerging technology, known as functional electrical stimulation (FES), in which low levels of pulsed electrical current are applied to the peripheral motor nerves in order to cause muscle contraction. In general, motor nerves below the level of the lesion, which are undamaged by the injury, maintain conductivity and the associated muscles retain the ability to contract. The engineering challenge in FES is to develop stimulation control methods and appropriate artificial sensors, so that FES-induced muscle contraction can be harnessed for useful function. This in turn can lead to an increase in muscle mass, better cardiovascular fitness, and improvements to general health.

Basic neurophysiology and control of the human musculo-skeletal system

The spinal nerves contain a mixture of both motor and sensory fibres, and the degree of dysfunction will depend on the level and completeness of the spinal cord injury. A complete cord lesion results in total loss of motor control and absence of sensation. An incomplete lesion, on the other hand, can result in quite complex and unique patterns of residual function and partial sensation. The diagram in Figure 1 shows the nervous system and the innervation of the upper and lower limbs.

As an example, consider a complete spinal cord lesion affecting nerve pathways below the spinal nerve emerging at the tenth thoracic vertebra, which is roughly in the middle of the trunk. This is called a 'T10' injury and will, among other consequences, result in complete paralysis of the legs and a total loss of sensation – the patient will be paraplegic. The consequences of a neck injury are more severe. For example, a complete lesion affecting nerves emerging below the fourth cervical vertebra ('C4') will, in addition to affecting the legs, result in total paralysis of the hands and the upper and lower arms – this is tetraplegia. A C4 patient

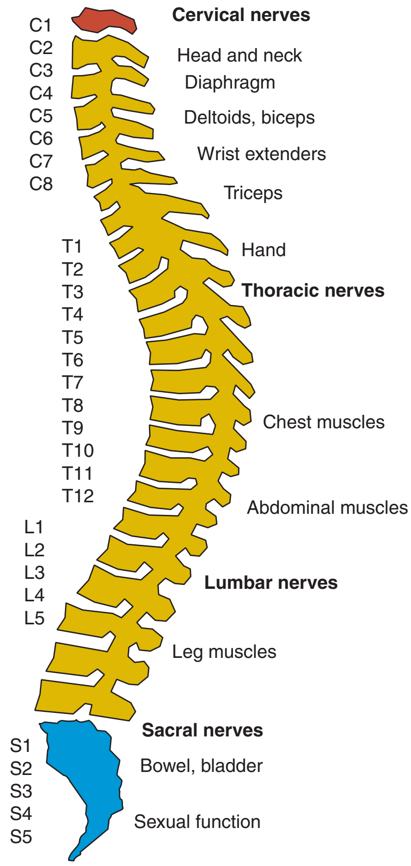

Figure 1: The spine, and emergence of spinal nerves

will, however, retain the ability to breathe, since the diaphragm is innervated primarily by the C3 and C4 spinal nerves.

The human central nervous system (CNS: the spinal cord and brain) receives a wide range of sensory information which is used to carry out accurate and coordinated movement. As a simple illustration, consider the task of knee-joint angle control, as shown in Figure 2. The left side of the illustration shows the natural sensing and control activity of a neurologically intact person. Sensory information on muscle force and joint position is relayed to the CNS via the afferent (sensory) nerves. This information is processed by the brain, and motor commands are sent down to the muscles controlling the knee joint via the efferent (motor) nerves, in order to achieve a desired knee-joint position.

Consider now an individual with a complete mid-thoracic spinal cord

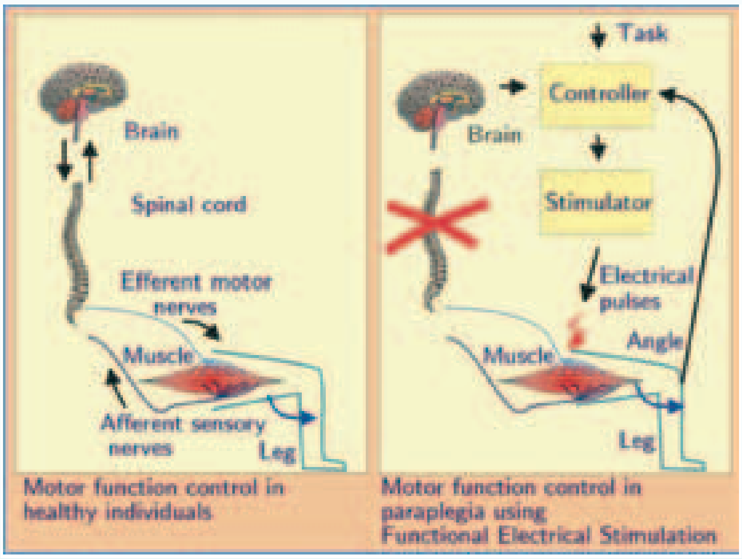

Figure 2: Sensory processing and motor commands for control of knee joint position

lesion, as illustrated in the right side of Figure 2. In this case the CNS does not receive any sensory information about the knee angle, and is completely unable to control the knee-joint-actuating muscles. However, an artificial feedback control system, utilising functional electrical stimulation, can be employed to restore knee joint function. Artificial sensors (e.g. goniometers attached across the joint) provide angle information. This information is processed by a control algorithm which then sends commands to an electronic stimulator unit. The stimulator activates the motor nerves of the muscles acting across the knee joint, thus causing joint motion. This closed-loop feedback system allows quite accurate knee angle control to be achieved.

An experimental illustration of FES control of knee-joint angle can be seen in Figure 3. The photograph on the right shows the experimental setup. The subject is a 57-year-old paraplegic male, with a complete spinal cord lesion at level T10. He has a pair of adhesive stimulation electrodes attached over the quadriceps muscle group of his right leg (the quadriceps are the main knee extensor muscles). Sensory information on knee-joint angle is provided by an ultrasonic measurement system. This comprises three sensors (small microphones) which can be seen attached to the upper thigh, close to the knee joint, and at the ankle of the right leg. The ultrasonic transmitter unit is positioned approximately 1 m to the right of the subject (seen in the bottom left of the photo).

The graphs on the left side of Figure 3 show the results of a closed-loop angle tracking experiment. The red line in the upper part of the plot is the reference angle for the controller, i.e. the angle profile which we would like the knee joint to follow (note that 180° corresponds to full extension, while 90° is measured when the shank is vertical). The black line in the upper plot shows the actual angle measured during the experiment – the reference angle is followed closely, with only a small phase lag. This knee-joint motion is achieved by stimulating the quadriceps with pulses whose pulsewidth is modulated according to the blue line in the lower part of the plot. We see that the pulsewidth is automatically varied by the feedback controller in a range up to 450 µs.

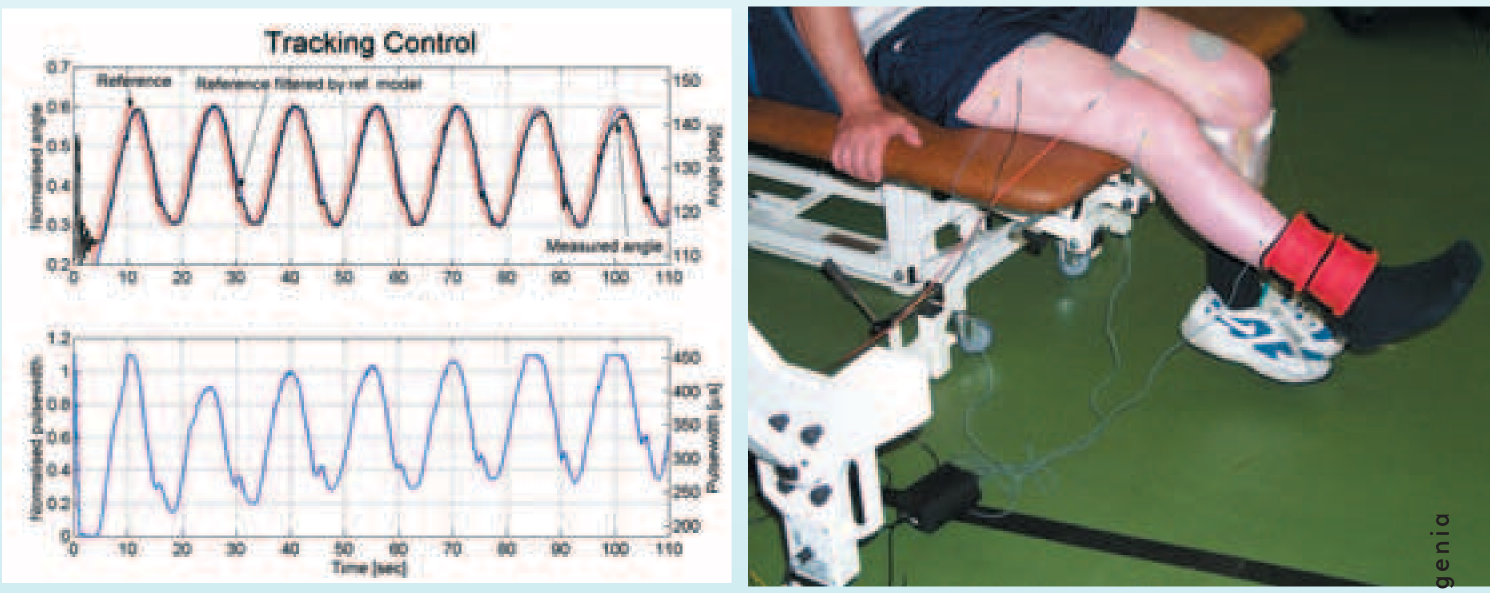

Figure 3: Experiment illustrating closed-loop control of knee-joint angle via FES

The key point of this illustrative example is that, with a spinal cord injury, the natural control provided normally by the central nervous system has to be replaced by an artificial system consisting of two components: sensors and actuators. At the present stage of technological development, actuation by means of FES is quite well established. However, the development of practical sensors, which are convenient for attachment to the human body, remains a major challenge. In the sequel we briefly review some very promising current research work which aims to record and transmit natural sensory information, which is available peripherally from the nerve afferents.

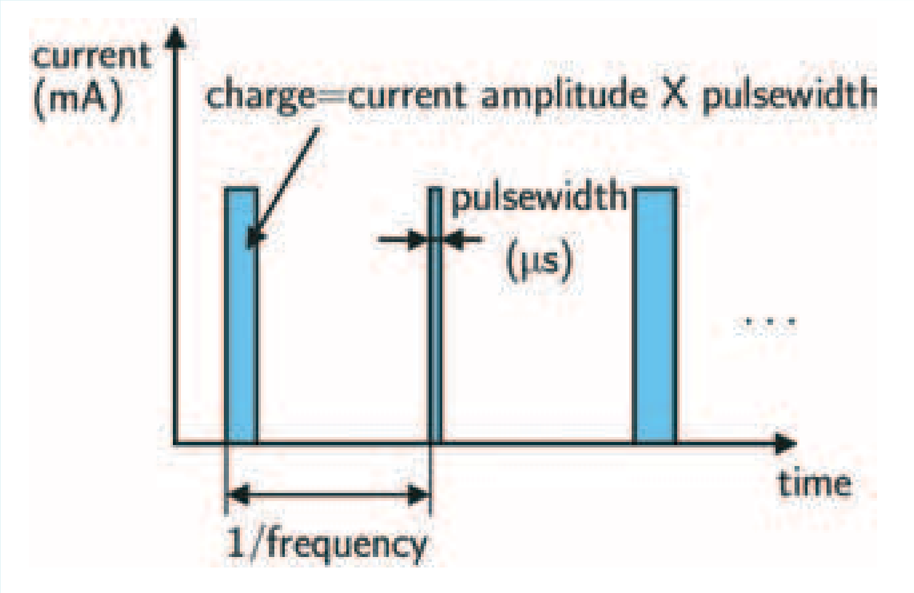

Figure 4: Stimulation waveform

Overview of FES: how does it work?

With functional electrical stimulation, controlled electrical impulses are applied to motor nerves by an electronic stimulator. The stimulation can be applied in one of a number of ways:

- transcutaneously, typically via self-adhesive pairs of electrodes placed on the skin surface
- or percutaneously, using needle electrodes which penetrate the skin and are positioned close to the nerve
- or by an implanted system, in which small cuff electrodes are surgically attached around the motor nerve – the electrodes are then attached by wires to an implanted stimulator.

In all cases the principle of FES is the same: when the motor nerve's conduction threshold is exceeded, action potentials are transmitted down the nerve, leading to muscle contraction in the normal way. Figure 4 illustrates a typical stimulation waveform.

Often, stimulation pulses are regularly spaced in time (frequencies of between 20 Hz and 50 Hz are typical), and they have an adjustable pulsewidth (for some applications a pulsewidth of up to 500 µs is common). The pulse amplitude is then fixed by controlling either the electrode voltage or current. For current-controlled surface stimulators a current of up to 140 mA might be used (for normal electrode impedances this would then result in a voltage of up to about 150 V).

There is a trade-off in the choice of surface or implanted stimulation systems. With surface stimulation, the electrodes can be easily applied and removed, but since the charge has to penetrate through the skin and subcutaneous tissue, relatively high levels of charge must be applied. The charge distribution is diffuse, which makes it difficult to target specific nerves and muscles, and it is possible that the wrong (antagonistic) muscles might be activated. In contrast, implanted stimulation electrodes are directly attached to the required motor nerves and much lower charge levels are needed. However, the use of implanted stimulation devices normally requires a major surgical procedure.

Current applications of FES

Functional electrical stimulation has been used to provide therapy and partial restoration of function in spinal cord injury, and in a range of other patient populations. It has been very effective in correction of 'drop foot' in hemiplegic stroke patients, and there are promising new research results in correction of gait in children with cerebral palsy.

Several FES devices have reached commercial maturity, and can be offered to patients as part of their clinical care:

- An implanted stimulation system for bladder control has been available for many years. The implanted device receives commands by radio link through the skin from an external control unit, thus offering the patient controlled voiding.
- Two companies offer implanted systems for phrenic nerve pacing. The phrenic nerve innervates the diaphragm, which is the main muscle used during inspiration. This type of system is appropriate for some patients for whom breathing has been compromised by a very high cervical cord injury.
- A relatively new implanted device has been made available for restoration of hand grasp for some patients with a C5–C6 injury. Again, the implanted stimulator receives commands by telemetry from an external control unit. The patient can control grasp and release by means of a joystick-like device attached to

the shoulder contralateral to the grasping hand.

- Finally, an FES system based on surface stimulation technology became available during the 1990s which provided the ability to stand and to take steps.

Current research in the field of FES is vibrant and a very wide range of systems is under active development. Research ranges from new implanted devices for nerve stimulation and sensory signal recording, design of implanted electrodes, biocompatible materials for implanted devices, through to the 'functional' end of the spectrum, where the focus is on practical systems for important functions such as standing, stepping and cycling.

As an example of a research area with considerable potential for clinical application we describe our work on the development of FES systems for paraplegic cycling. The system is based upon a commercially available recumbent tricycle, to which we add instrumentation for stimulation control and adapt for paraplegic users. The system is illustrated in the opening photograph, which shows a 57-year-old male subject, with a complete spinal cord injury at level T10.

Cycling motion is achieved by controlled sequential stimulation of three muscle groups on each side of the body:

- the quadriceps for the knee-extension phase
- the hamstrings for knee flexion
- the gluteal muscles for hip extension.

A pair of adhesive surface electrodes is attached to the skin over each of these muscles. Clearly, for effective cycling, these muscle groups must be switched on and off at the appropriate part of the 360° crank cycle. For this purpose we fit the trike with a sensor which measures crank position, and is interfaced to the electronic stimulator. Control software then switches each muscle group on and off according to the pattern illustrated in Figure 5. The

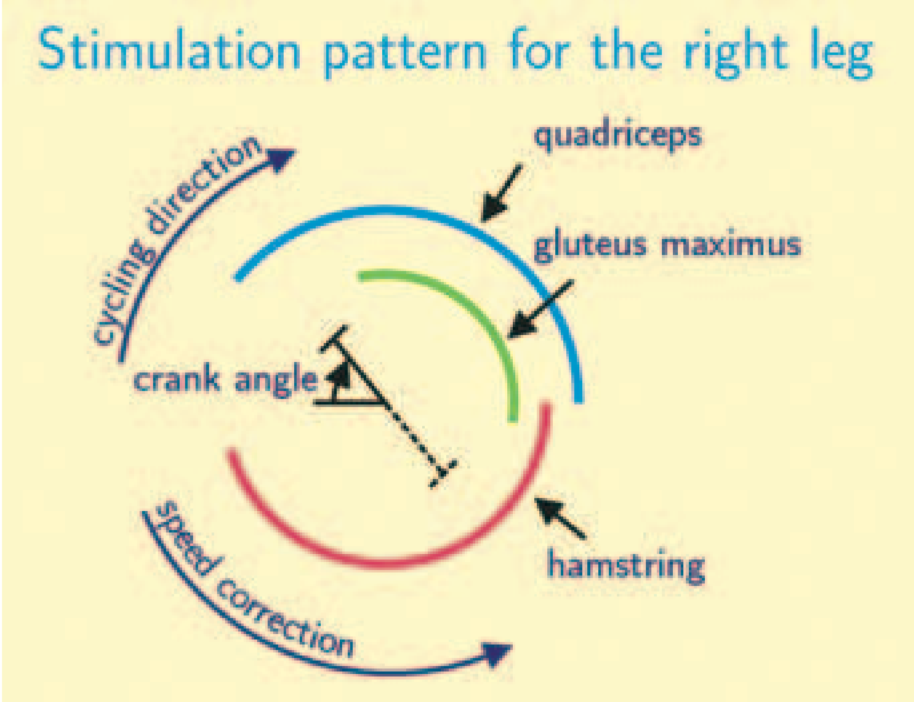

Figure 5: FES cycling

stimulator operates at a constant frequency of 20 Hz, and, before cycling begins, a fixed current up to 120 mA is determined for each muscle group. During cycling, the subject controls a throttle attached to one of the trike's handgrips. This gives direct control of the stimulation pulsewidth, thus allowing the cyclist to speed up or to slow down. We have found that even with a low-intensity training regime (one day per week) our subjects are able to cycle continuously for one hour with a workrate of around 20 W. This may seem low, but it is sufficient to propel the trike at low speeds for distances of over 3 km.

Perhaps the most significant feature of this development is the observation that lower-limb cycling induces very significant cardio-respiratory responses, thus giving a training effect and leading to improving fitness. This results from the fact that, for cycling, the large muscles of the lower limbs are recruited to do significant work. In contrast, it is difficult to induce equivalent exercise responses using only the much smaller arm muscles (which in turn are prone to over-use injury). Thus, FES cycling exercise offers paraplegic persons a new and effective exercise modality, with benefits for general fitness and health.

Future developments

The example described above where FES-induced limb motion is associated with large cardio-respiratory responses shows the potential of FES to be used as a means of exercise for improved fitness. We anticipate that in the near future traditional equipment used in spinal injury rehabilitation will be extended with FES options, thus allowing the paralysed limbs to contribute actively to the exercise. This is relevant for both paraplegic persons, where the lower limbs are stimulated, and also for tetraplegic patients, where the arm muscles (biceps and triceps) can be stimulated to provide arm-cranking motion; in addition the leg muscles might also be involved.

There is a great deal of activity worldwide in the development of multi-function implanted stimulation systems, and some commercial organisations are moving towards full-scale clinical trials. These devices offer great promise for functional stimulation of the upper and lower limbs, combined with additional key functions, such as bladder and bowel management.

Rapid progress is being made in research on implanted telemetry devices for recording sensory nerve traffic. Such devices can potentially provide information on joint positions and forces acting on the hands, feet and limbs. Accurate and reliable natural sensory information could then be used for stimulator control, and may remove the need for externally-worn sensors.

For the future we therefore anticipate fully implantable stimulation and sensing devices for FES applications, with a telemetry link to external systems for commands and programming, and for power requirements. Although such implanted systems will require a commitment to major surgery for those patients who choose them, the potential benefits in terms of accuracy and efficiency of stimulation control are large.

We believe that an increasing emphasis will be attached to the exercise, fitness and general health aspects of FES systems, and to more precise control of key bodily functions, such as bladder and bowel management.

Speculation often appears in the media on the question of whether technology will ever help paraplegics to walk again. Certainly, the development of systems for standing and stepping is a very active research area. However, current systems are able to provide stepping over quite short distances and at an abnormally high metabolic cost. Moreover, no system is yet able to produce a gait pattern which looks anything like 'normal' (hence we prefer the term 'stepping', rather than 'walking'). We note that the walking task involves a complex interaction of a large number of muscles and sensory inputs. Crucially, feedback control of balance is also required, since the standing and walking human represents an intrinsically unstable system. Thus we believe that the development of practical and effective FES systems for walking will remain a large challenge for some considerable time.

The search for a walking system also has a very real political agenda. Many people with spinal cord injury do not see regaining walking as the most vital thing in their lives. They have families, jobs, sports and interests outside hospitals and laboratories. Of course they would like to walk but because walking is such a distant hope some groups feel it is more important to improve the current social infrastructure for wheelchair users. Many of our cities are designed for able-bodied adult car users. The old, young, poor and disabled are disadvantaged and excluded. If the social environment were more friendly to paralysed people then walking might not be such an issue.

No review of spinal cord injury rehabilitation would be complete without mention of the recent advances in research on spinal cord repair and nerve regeneration. We can now offer complex and elegant engineering solutions to provide paralysed people with useful function. But our systems remain crude when judged against the complexity of the intact human nervous system. The best feedback and control system would be the body's own repaired nerves and this remains the focus of worldwide research.

The damaged human spinal cord is particularly resistant to healing. The cord nerve cells do not repair easily and the scar tissue also prevents cells regenerating. Researchers have therefore looked outside the cord for other nerve cells which could replace the central nervous system cells. Researchers have been looking at the use of olfactory cells from the nose, and stem cells, to provide regenerating nerve cells. It has been shown that nerve growth is achieved in the damaged cord in a rat model of spinal injury.

Nerve regeneration is however only one part of the problem. The cord is a loom with hundreds of thousands of wires and we do not know whether stem cells would automatically 'rewire' the loom to make the right connections. In addition, we would need new surgical techniques, bringing the associated risk of complex spinal surgery.

Despite these hurdles, we have no doubt that stem cell and other nerve cell implants will be increasingly common in human experimental studies over the next few years, even if it will be some considerable time before these techniques make a significant impact on the worldwide spinal injured population.

We suggest that the next few generations of spinal injured patients will continue to benefit from close collaboration between engineers and clinicians in the design and application of increasingly sophisticated FES devices. These systems ultimately exploit the body's own energy systems and, with improvements in sensory input, processing, activation and machine–muscle interface, they will offer real help to spinal cord injured people. ■

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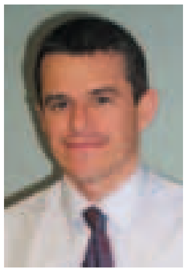

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