TECHNOLOGY TRANSFER AND DEVELOPMENT FOR WALKING USING FUNCTIONAL ELECTRICAL STIMULATION

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ABSTRACT

A new program of functional electrical stimulation (FES) for spinal cord injury has been developed at the University of Alberta. This paper describes early results using a variety of electrode types (surface, percutaneous, fully implanted), stimulators (1-6 channels), levels (C6 to T10) and type (complete, incomplete) of injury. All patients were more than a year post-injury so that the effects of stimulation could be evaluated against a stable baseline. The aim was to determine which approaches and types of patients would be most amenable to treatment with FES using commercially available devices as far as possible. The improvement with different numbers of channels of stimulation was determined by gait analysis. At present, the greatest success has been for patients having incomplete spinal cord injuries who require relatively few channels of stimulation to become functional walkers.

KEY WORDS: Spinal cord, functional electrical stimulation, technology transfer, locomotion

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INTRODUCTION

It is now nearly thirty years since Lieberson et al. (1961) first proposed the use of transient electrical stimulation to assist the gait of stroke patients. The use of functional electrical stimulation (FES) has expanded substantially over this period. Electrical pacing of the heart remains the most widely used form of functional electrical stimulation and the technology for heart pacemakers now represents a multi-billion dollar a year industry. The use of electrical stimulation to replace auditory function (cochlear prostheses) has also "taken off" and is now being applied to large numbers of patients worldwide. In contrast, progress in FES for restoration of gait has been much slower. Some prototype devices implanted over 20 years ago for preventing foot drop by stimulation of the peroneal nerve are still being used (Waters et al., 1975), but commercial production of such implantable, single-channel devices has only recently begun (see Table 1). Following the demonstration that gait could be restored for limited distances by multichannel surface stimulation of spinal cord injured subjects (reviewed by Kralj and Bajd, 1989), developments have been pursued in a number of countries with both surface stimulation (e.g., Petrofsky and Philips, 1983; Andrews and Baxendale, 1986; Braun et al., 1985) and implanted wires (Marsolais and Kobetic, 1983; Brindley et al., 1978; Stoehr et al., 1987). The most concentrated effort has however remained in Yugoslavia (Kralj et al., 1980, 1981; Bajd et al., 1982; Popović, 1986). Limited numbers of two and four channel devices for use with surface stimulation have been produced (Institut Jozef Stefan, Ljubljana; DES, Novi Sad, Yugoslavia), but have not been widely distributed. This paper describes our experience in initiating the first large trial of FES in Canada and our experience in transferring and developing technology for this purpose.

SINGLE-CHANNEL SYSTEMS

One channel of stimulation is only suitable for stroke patients or patients with incomplete spinal cord injuries. These patients may lack the ability to activate a single muscle group such as the ankle dorsiflexors with the result that the foot drops during swing and this "foot drop" can slow or prevent gait. Foot drop is commonly treated with an ankle-foot orthosis (AFO). This passive device can be made out of lightweight material, so that the foot is not loaded appreciably, but it still limits the amount of foot clearance by maintaining the ankle at approximately 90^{o} and restricts the push-off phase by making ankle plantarflexion virtually impossible. Alternatively, muscles innervated by the common peroneal nerve can be stimulated to produce ankle dorsiflexion when a footswitch indicates that the heel has come off the ground. The stimulating electrode is generally placed so that many sensory fibres from the common peroneal nerve are also stimulated. Sensory stimulation can lead to a flexor reflex and generate flexion at the knee and hip, as well as the ankle. In many stroke patients sensation is normal so that surface stimulation at a level that elicits a reflex may be painful, which was the original reason for using a fully implanted system (McNeal, 1973). However, in spinal cord patients sensation is often absent or reduced and flexor reflexes can be elicited without causing pain or skin problems. Fig. 1 shows the results of gait analysis from one patient who walked using arm braces with and without a one-channel peroneal stimulator (Microfes; Ljubljana, Yugoslavia). Joint angles were measured with a simple goniometer (Llewellyn, 1989) and the patient was videotaped while walking overground a standard distance of 5 m in each direction. The major effect of the

stimulation is to prevent the large plantar flexion (increased angle) of the ankle associated with foot drop. Stimulation also elicited a flexor reflex, as is evident from the increased hip flexion. Overall, the swing phase was markedly shortened from 0.84 s to 0.54 s on average, while the stride length was increased at the same time from 0.88 m to 0.95 m. As might be expected, the stance phase was not affected and was quite long (1.5 s) because of the patient's spasticity. The overall speed was increased from 0.41 m/s to 0.46 m/s on average.

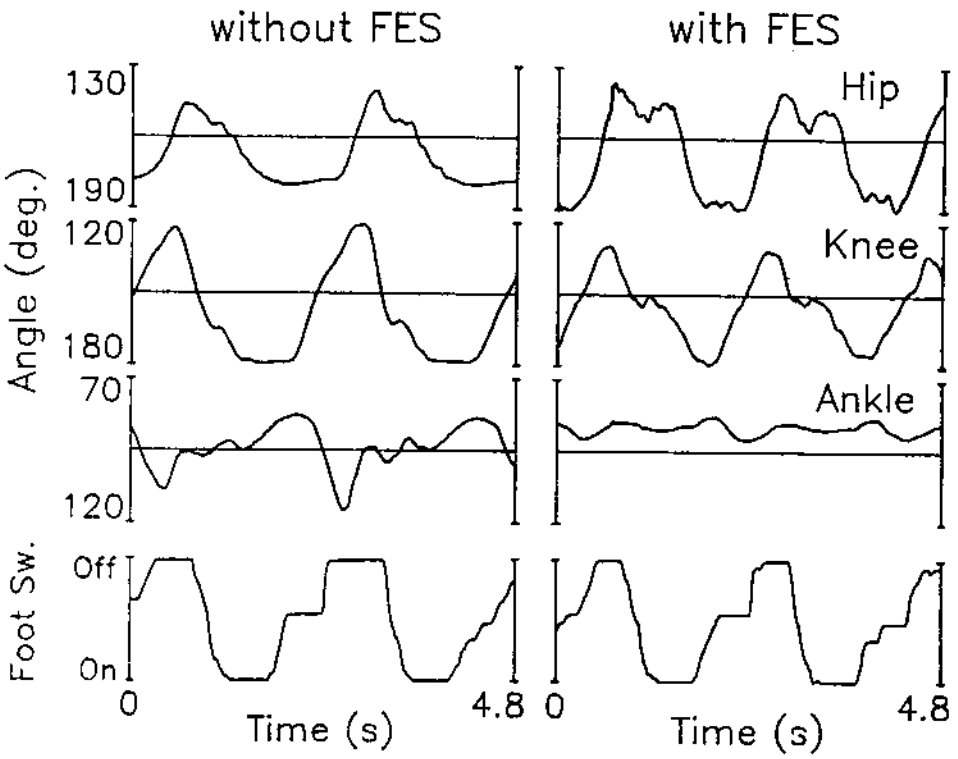

Fig. 1. Gait analysis of a patient (C.H.) with (right) and without (left) a one channel peroneal stimulator. The foot switch records are maximum when both heel and toe are off the ground (swing) and minimum when both are on the ground. An intermediate level is seen late in stance phase when the heel is off the ground, but the toe remains on the ground. The gradual change from one level to the next shows the variability from step to step. Records are averages of 9 steps aligned in the centre when the toe comes off the ground (beginning of swing phase). Note that without FES the ankle becomes strongly plantar flexed (nearly 120 degrees) after toe off, and this "foot drop" is prevented by FES. The swing phase is considerably shortened, as is the period when the knee and hip are fully extended.

The foot drop alone could be prevented by an AFO, but this patient found an AFO cumbersome and therefore did not use one on a regular basis. He immediately liked the effect of the Microfes stimulator and, after one day of testing it under a variety of conditions, took it to his home which is in a village about 1000 km from our centre. He has used it on a daily basis for three months with only two follow-up visits to Edmonton. His only complaint is that the heel switch requires a relatively large force for activation and the threshold can not be altered. Thus, the stimulator occasionally does not switch on when he walks over uneven ground. For patients such as this one, a single channel of stimulation can be an efficient cost-effective modality of treatment.

One adaptation that we have made to the Yugoslav protocol is the use of conductive, self-adhesive surface electrodes (Chattanooga Corp., Chattanooga TN) that are cut in size to a circle of diameter 2 cm for placement over the common peroneal nerve. The electrodes can be covered over with TransTac (Staodynamics, Longmont CO), a transparent, impermeable material that permits the patient to bathe or swim without the electrodes coming off or losing their adhesiveness. This covering is changed every 7-10 days and the electrodes can be used continuously for several weeks without skin problems. This avoids the need for determining the optimal stimulating point each day. The patient merely plugs into the electrode and turns the stimulator on when getting dressed in the morning. Nonetheless, there are advantages in reproducibility, ease of operation and reduced sensation if the system can be implanted. We have currently received ethical approval to install surgically a fully implantable, single-channel stimulator with a telemetry link that is also produced in the Institut Jozef Stefan, Ljubljana. This device will be tried in patients who have used the surface stimulator satisfactorily for a period of time (several months) and wish to try the fully implantable system.

TWO-CHANNEL SYSTEMS

Two channel systems can be required for a variety of patients. For example, if foot drop occurs in both legs, the two channels may consist of two one-channel stimulators. Alternatively, one leg may be more affected than the other and as a result, both knee extensors and ankle dorsiflexors may have to be stimulated alternately to provide stability during stance as well as flexion during swing. We will only discuss one, fairly unusual example here of a lady who suffered a burst aneurism at the C1 level. Subsequently, a syrinx developed that spread along much of the cervical cord, although to a lesser extent on the left side than the right, as shown in the MRI scans of Fig. 2. As a result she had considerable loss of hand function on the right side and bilateral, but asymmetric effects on her legs.

Without stimulation she could not walk because she could not lift her right leg off the ground. With a single channel peroneal stimulator (Microfes, Ljubljana) she could walk slowly with a walker (Fig. 3), but still had problems straightening and maintaining her contralateral knee in an extended position. As a result the clearance for her left leg to swing through was limited. A second channel of stimulation was added to her right quadriceps muscles and a simple delay circuit was used, so that the right quadriceps was extended about 200 ms after her peroneal nerve was stimulated to provide clearance and remained on for 600 ms after the end of peroneal stimulation to maintain stability until her leg returned to the ground. Because of the need for timing delays, one

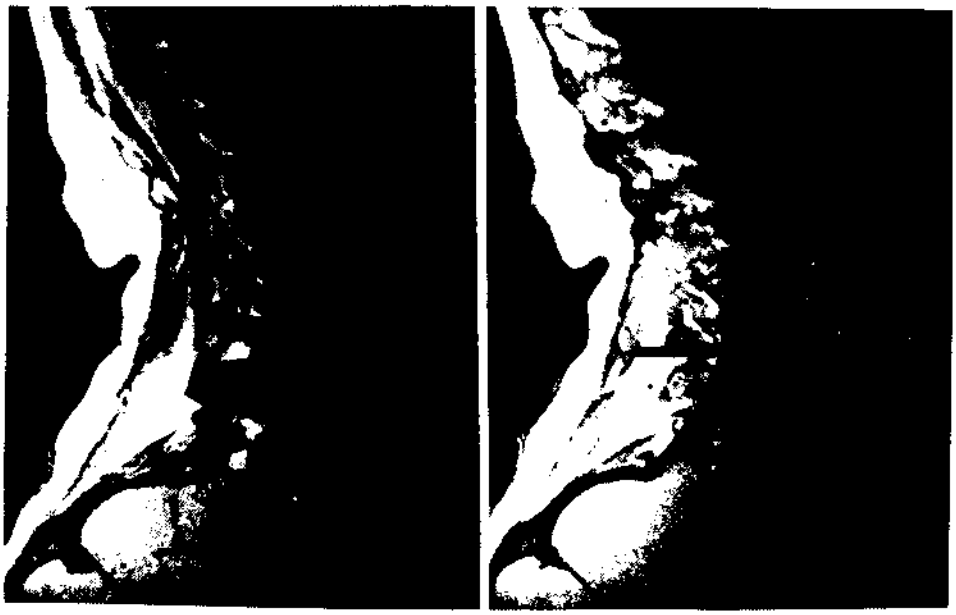

Fig. 2. Sagittal views of Magnetic Resonance Images (MRI) from a subject who suffered vascular injury. The hematoma (opaque area indicated by arrows in the left image) is located near C1 with a syrinx (darkened area in the spinal cord located more laterally in the spinal cord, indicated by an arrow in the right image) extending down to C5. The dimensions of the spinal cord appear normal below this level.

commercially available stimulator could not be used for both channels. However, the delay circuit could be used to activate an EMS/plus unit (Staodynamics, Longmont CO) that she had previously purchased which then stimulated her right leg. This patient preferred to use a hand switch, rather than a foot switch, so that she knew exactly when the activation of her muscles would occur and was not surprised by inadvertent triggering of the stimulators. The second channel increased the speed of walking from 0.057 to 0.072 m/s without changing the stride length. The extra speed was produced by shortening the very long stance phase from 6 to 4.8 s and the swing phase from 2.0 to 1.4 s (Fig. 3). The patient felt that the extra channel of stimulation substantially decreased the voluntary effort required to rotate her body weight to provide clearance. Although still very slow, she uses this system several hours daily for getting around her home.

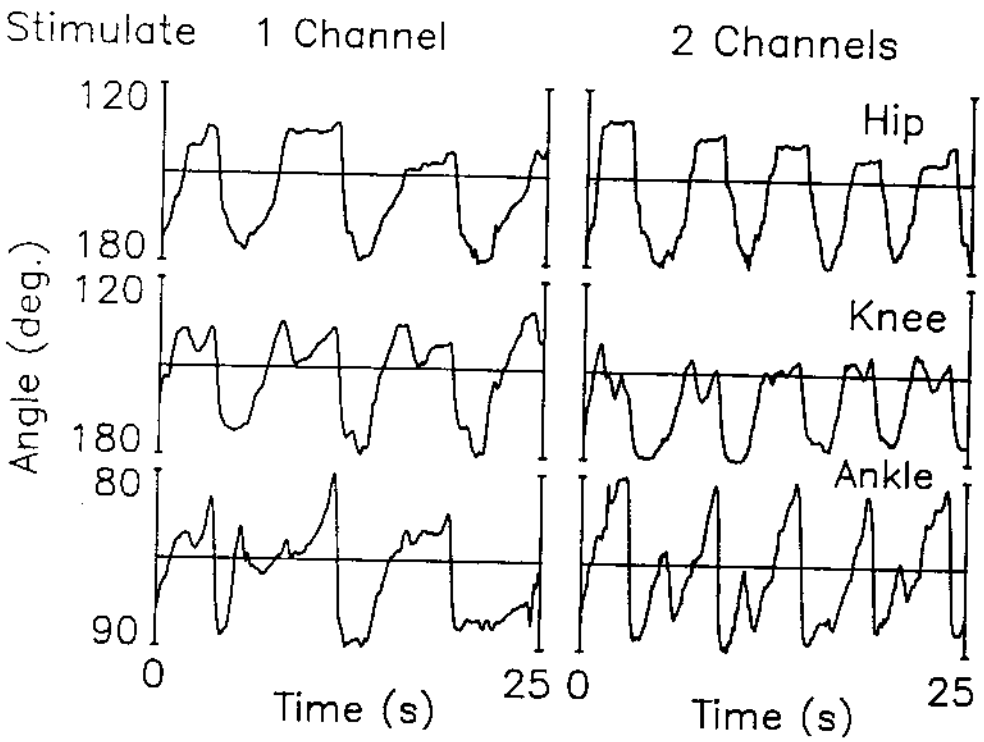

Fig. 3. Gait analysis of a patient (L.W.) who was able to walk with a single channel peroneal stimulator (left) controlled by a hand switch, but the gait was very slow and irregular because of problems in extending the contralateral leg (not shown). When stimulation was added to the contralateral quadriceps muscles with a delay circuit triggered from the same hand switch, the gait became faster and more regular. No averaging was done because of the irregular gait.

ADDITION OF PERCUTANEOUS ELECTRODES

We have also used percutaneous electrodes, both for FES in the upper extremity of quadriplegics (Peckham et al., 1980) and for the lower extremity (Llewellyn et al., 1988). Fig. 4 shows results of gait analysis from a patient who used two channels of surface stimulation on one side (quadriceps muscles for stance and common peroneal nerve stimulation for swing). Although his other side was also affected, he could move this limb under voluntary control without stimulation. The gait was very slow (0.057 m/s), the stride length was short (0.37 m) and the hip was only weakly and slowly flexed. We therefore implanted wires in a hip flexor (psoas muscle) for swing and a hip abductor to stabilize stance. Implantation of wires in psoas muscle has now been performed in three patients (2 spinal cord injuries and one stroke) and will be described below. Analogous procedures were used for the abductors.

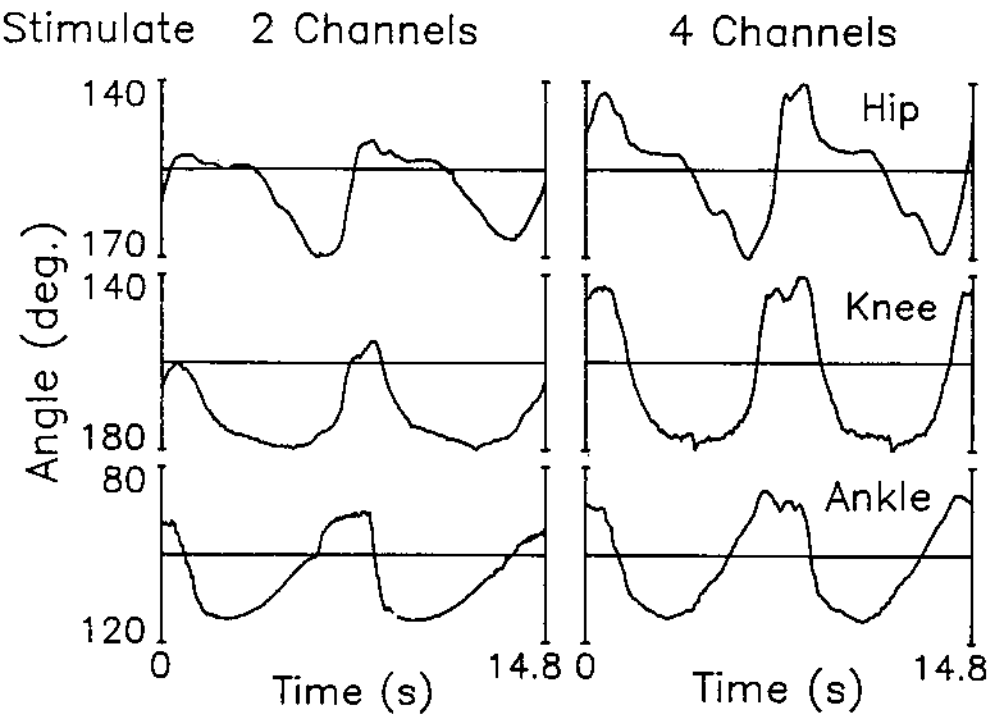

Fig. 4. Gait analysis of a patient (B.P.) with peroneal nerve and quadriceps muscle stimulation (left) and with added channels from percutaneous wires in the hip flexors and abductors (right). Note the increased hip flexion (and knee flexion, presumably from gravity as the hip flexed during swing). This increased flexion increased the stride length by 27% (not shown). Average of 3 steps aligned in the centre on the rapid phase of hip flexion.

The implant procedure was performed in a hospital operating room with anaesthesiologist and theatre nurses in attendance. Preoperative sedation and local anaesthesia minimized discomfort. The patient lay on his side with his affected leg supported by two slings, allowing the hip and knee to move freely. After preliminary marking of the skin and swabbing with antiseptic, a 25 cm long, 18G trans-lumbar aortogram needle, complete with an outer teflon sheath and inner stylus, was inserted into the lower back. The insertion, as monitored by fluoroscopy, was approximately 60 mm lateral to the L2 spinous process and the final position of the tip was about 10 mm lateral to the body of the L3 vertebra. Electrical stimulation was now applied through the 1 mm exposed tip to evoke hip flexion. If unwanted knee extension also occurred, the needle position was slightly adjusted until pure hip flexion was obtained. The needle and the stylus were briefly withdrawn, leaving the teflon sheath in place. The stylus was removed and a Cooner 632 stainless steel insulated wire electrode was threaded into the lumen of the needle at the tip end, until only a small part of its terminating anchor (20 mm of prolene surgical monofilament tied to the end to form a toggle) emerged. The loaded needle was now reinserted into the teflon sheath, and then withdrawn again. The terminating anchor was thereby pushed into, and became ensnared within the

muscle. Then, upon withdrawal of the needle and sheath, the wire remained in place, with its 1 cm de-insulated end segment in the psoas muscle. The part of the wire emerging from the skin was now routed subcutaneously to a surface connector patch located on the skin at the groin. As long as the skin is cleaned with alcohol every few days and kept covered in between, infection at the skin interface has not been a problem. Fig. 5 shows the wire which has been spiralled to increase flexibility and to provide slack to reduce the chances of lead breakage. Breakage of percutaneous leads appears to be a greater problem in the lower extremity than in the upper extremity (Peckham, personal communication), presumably because of the greater levels of stress produced in the leg during weight-bearing and gait.

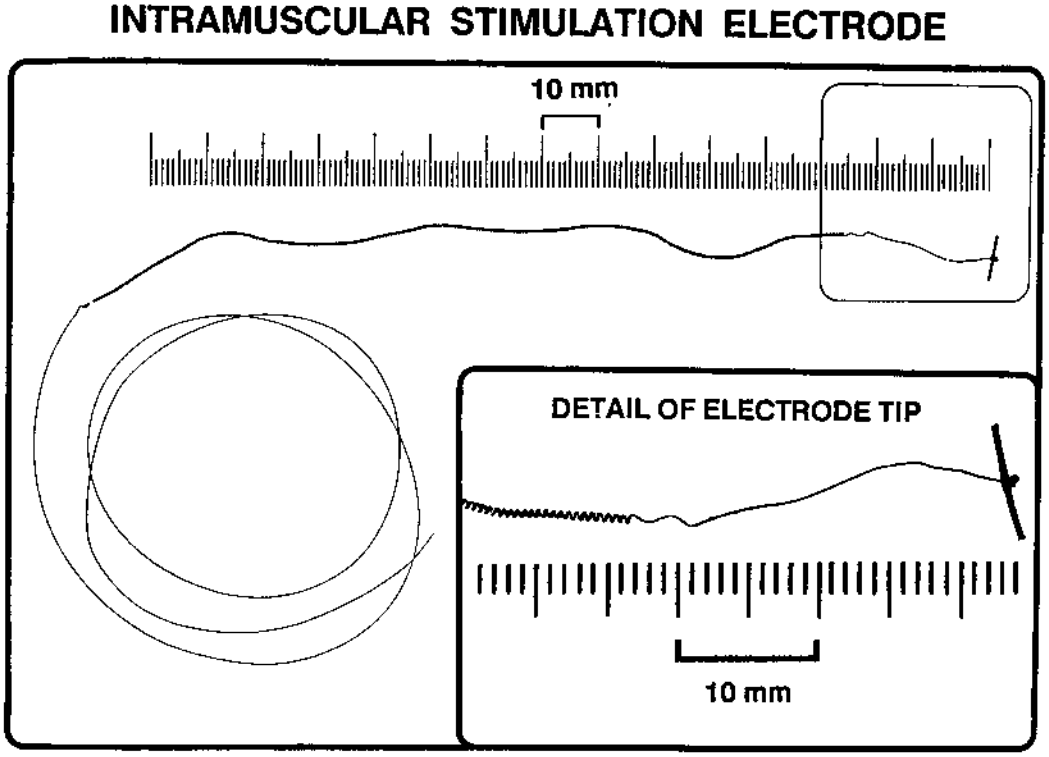

Fig. 5. Stimulating electrode developed for implantation in psoas muscle. Each electrode (total length = 75 - 80 cm) was constructed from multi-strand stainless steel wire insulated with a teflon sleeve. 15 cm of wire, starting 4 cm from the tip (detail, bottom right) was tightly coiled. An anchor was constructed from a 10 mm length of polypropylene and attached to the wire with two small knots. Teflon insulation was stripped from a 10 - 15 mm length of wire just behind the anchor. Electrodes were individually packaged and sterilized.

With the extra channels of stimulation, the hip flexion was faster and more forceful (Fig. 4). The knee also flexed considerably more, presumably passively as the hip flexion increased. The stride length was now 0.47 m and the velocity 0.069 m/s, increases of 27% and 17% respectively. The speed was still slow and limited by the

patient's spasticity and clonus, despite taking medication (Baclofen, 75 mg/day). Because of his clonus, a simple footswitch was not adequate. After heel contact, the clonus could cause the toe to lift and lower back onto the ground several times before stance was established. An array of force sensors was constructed on a mylar backing to determine which parts of the foot remained on the ground during bouts of clonus. By adjusting the threshold of the sensors appropriately, false triggering could be minimized by requiring that 1) both heel and toe be in contact with the ground, 2) the heel then come off to initiate flexor stimulation and 3) the toe also come off to reset the logic for the next cycle. The state diagram for the logic circuit is summarized in Fig. 6. The patient has used the system for several months on a daily basis, but mainly for exercise, rather than functional tasks.

MULTICHANNEL SYSTEMS

The patients described above all had incomplete spinal cord injuries and retained some capacity to voluntarily activate some leg muscles. For a patient with a complete motor lesion a minimum of four channels of FES is required (Kralj and Bajd, 1989). Stimulation of the quadriceps muscles bilaterally locks the knees during standing. Switching on stimulation of the common peroneal nerve on one side, while switching off the quadriceps stimulation on that side, produces the swing phase. Hand or foot switches can be used to provide the alternation needed for a slow forward or backward progression. Sufficient arm strength must be available to provide balance between parallel bars in a clinical setting or with a rolling walker in the home environment. We initially used a four-channel stimulator produced in Yugoslavia (DES, Novi Sad), but had repeated technical problems, mainly due to lack of sufficiently rugged construction to withstand dropping on the floor and breakage of knobs, leads and connectors. As a result a more rugged, isolated stimulator was developed and is now in limited production in Edmonton (Quadstim, Biomech Designs Ltd.). Again, we will only discuss a single patient here. He is, in fact, the most severely handicapped individual we have attempted to get standing and walking. This patient is a C6 quadriplegic who did not have a functional grasp, although his thumb would be brought in passively against the other fingers when he voluntarily extended his wrist (tenodesis). He did have sufficient strength is his elbow extensors (triceps brachii) to bring himself to the vertical position with the help of quadriceps stimulation. Because of the high level of his injury he could not bring his hips forward. He therefore had to bear too much of his substantial body weight (90 kg) with his hands and he fatigued readily. However, he is a resourceful person and tried different placements of the surface electrodes at home. Eventually, he found a more satisfactory position in which one electrode was placed distally on the quadriceps and the other more proximally on the hamstring muscles. This provided sufficient stimulation of the vastus medialis and lateralis muscles, that extend the knees without flexing the hips, to maintain his knee joint in an extended position. Stimulation of the hamstring muscles could not overcome the active knee extension, but did produce enough hip extensor torque to stabilize the patient. With this placement of electrodes, he is able to stand for 20 minutes or more at one time with only two channels of stimulation. Adding two more channels of stimulation (to the common peroneal nerves on each side) permitted him to walk a few steps at a time, but his hips became progressively more flexed. Essentially, the hamstring stimulation was able to maintain the hips in an extended position statically for long periods during stance, but was not able to extend the hips rapidly or strongly enough during gait. We

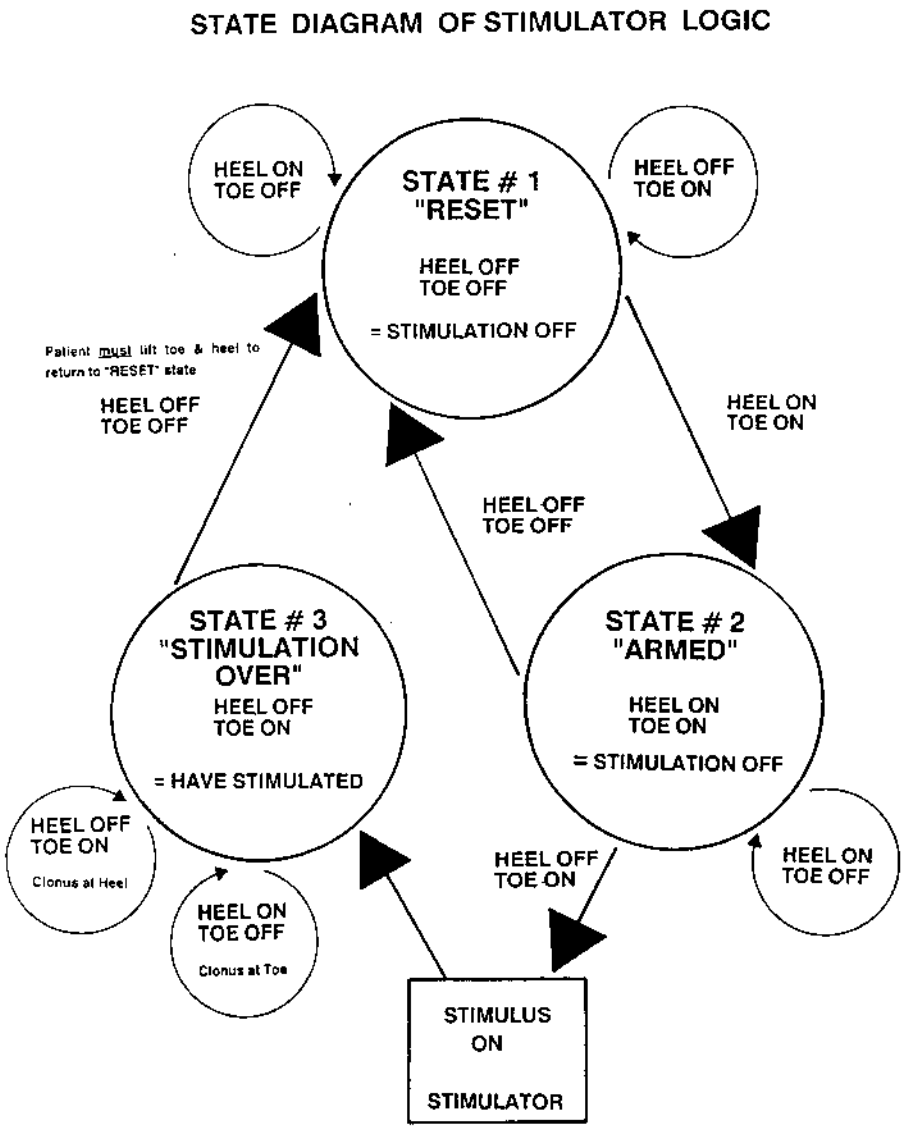

Fig. 6. State diagram of stimulator control logic. The diagram read clockwise from the top (state #1) and follows the sequence of heel and toe contact during the step cycle (thick arrows). Only three states can exist: 1) reset, 2) armed and 3) stimulation over. The stimulator (box at bottom) is triggered when the ipsilateral heel is raised with the toes on the ground at the start of the swing phase, provided the stimulator logic is in state #2 (armed). Between each stimulus the logic must fully cycle between all three logic state, so clonus (indicated by small circles is unable to continually retrigger the stimulator.

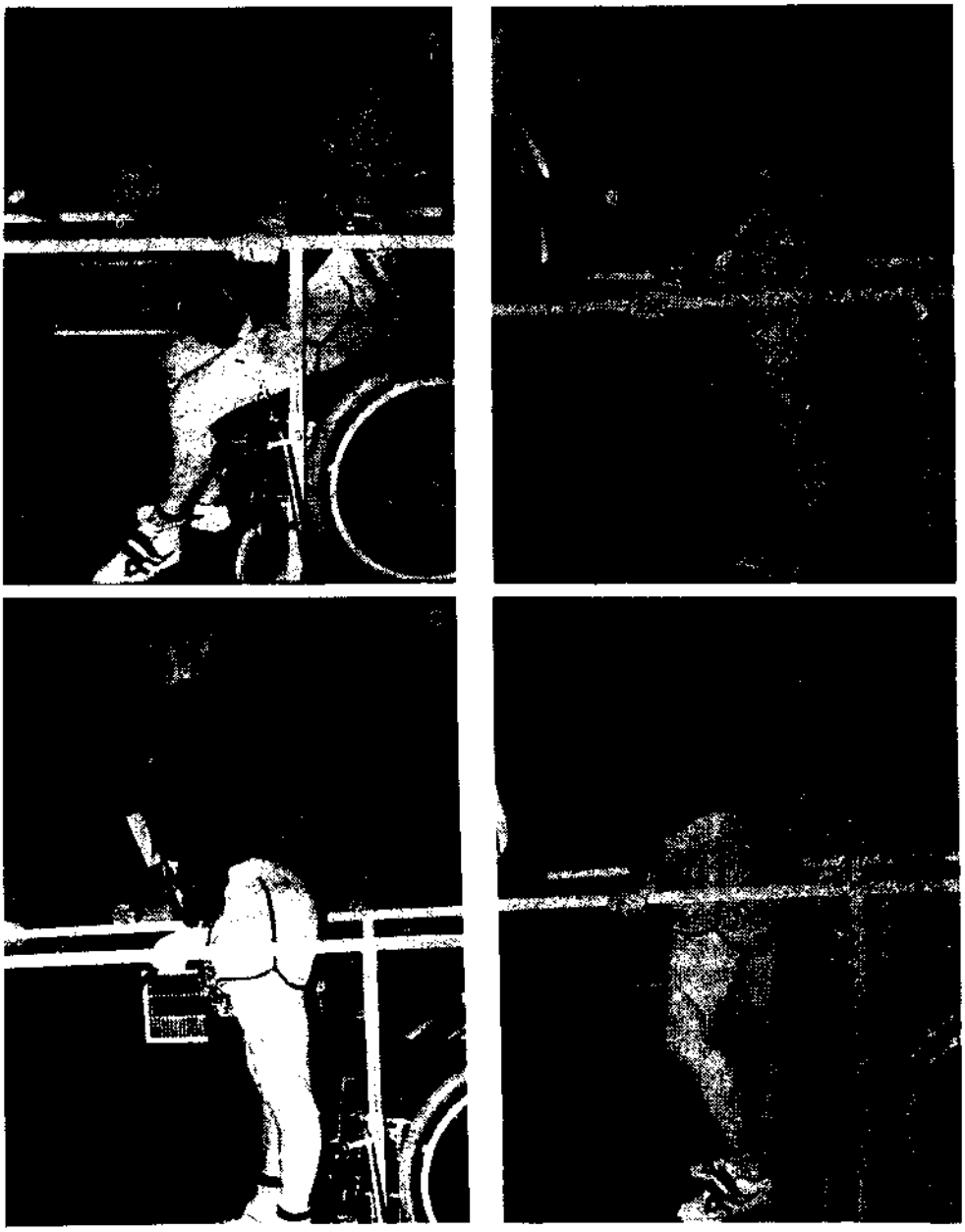

Fig. 7. With quadriceps stimulation on both sides a quadriplegic patient with a complete spinal cord injury (B.R.) could raise himself from a sitting (A) to a standing (B) position, by activating a chin switch, but he could not straighten his hips. Adding a second channel of stimulation on each side to activate gluteal and paraspinal muscles brings him to a more upright position (C). He could then begin to walk a limited distance by stimulating the left (D) and right common peroneal nerves alternately using other chin switches.

therefore added another channel of stimulation on each side with the electrodes placed over the gluteal muscles and the paraspinal muscles. This placement stabilized the hip and lower spine during stance. Stimulation was switched off on one side, together with the quadriceps stimulation, when the common peroneal was activated to produce the swing phase on that side. Since he did not have enough function to operate hand controls, we used an array of three chin switches. The central one turned on the 6-channel stimulator (which was a modified version of the Yugoslav 4-channel stimulator), while the left and right switches activated flexion of the left and right legs respectively. A picture of the patient using the system is shown in Fig. 7.

As the number of channels increases, so too does the time required to place the electrodes, connect the leads, adjust stimulation levels, etc. Therefore, we do not feel that a system of this complexity using surface electrodes is likely to be a practical long-term solution. Rather we view it as a short-term trial, both to test the efficacy for a given patient and to give him a realistic idea of what FES might be able to do in his daily life. If the patient and the research group are both satisfied of the system's utility, then wires can be implanted percutaneously. At the moment no six-channel, charge-balanced stimulator is available commercially for percutaneous stimulation, but Paul Meadows (Rancho Rehabilitation Center, Downey CA) is beginning production of an 8-channel device in limited numbers (Meadows et al., 1987). We have not yet had a chance to test this device with patients.

DISCUSSION

Currently, in our centre we are working with about a dozen spinal cord injured patients who require from 1-6 channels of stimulation for walking with FES. All are more than one year post-injury, so they provide a stable baseline from which the effects of stimulation can be judged. Several examples have been presented, using a variety of devices, most of which are commercially available. Table 1 compares the properties of the available ones we have tested extensively in a way that may be useful to other centres embarking on an FES program.

There is clearly a need for a multichannel device that is charge-balanced to minimize corrosion of implanted, percutaneous electrodes. Prototypes of several such devices have been reported (Meadows et al., 1987; Makikawa et al., 1987; Stoehr et al., 1987) but we have not been able to test them as to suitability and reliability. If the separate channels are not isolated from one another (e.g., they share a common anode), then it is important that the pulses be interleaved so that a) the current from several channels can not add and produce unwanted stimulation near the anode and b) electric field gradients remain independent for each channel. We have occasionally had unwanted stimulation from summation of stimuli at the anode with the Cleveland 8-channel device (Thrope et al., 1985) for use with percutaneous electrodes in control of the hand. We have omitted all details of the training, as these are well covered in the monograph by Kralj and Bajd (1989).

Device Manufacturer Adress	No. of Chann.	Max. Curr. mA	Curr. Cont.	Pulse Width μs	Stim. Rate Hz	Wave form	Comm. Distr.
1) **Microfes (surface)** Jozef Stefan Institute, Ljubljana, YU	1	100	no	150	25	Mono.	Ltd.
2) **Microfes (Implantable)** Jozef Stefan Institute, Ljubljana YU	1	30	yes	100-400	33	Biph.	Ltd.
3) **Respond II,** Medtronic Minneapolis MN, USA	2	100	yes	300	3-50	Biph.	Wide
4) **EMS/plus** Staodynamics Biph. Longmont CO, USA	2	100	yes	50-250	4-80	Mono. Biph.	Wide
5) **DES** Novi Sad, YU	4	140	yes	50-600	10-100	Mono.	Ltd.
6) **Quadstim** Biomech Designs Edmonton, Canada	4	140	yes	50-800	10-100	Mono.	Ltd.

Table 1. Properties of the stimulators used in this study. Abbreviations are as follows: Number of Channels, Maximum Current, Current Control, Stimulus Rate, Commercial Distribution, Limited, Monophasic, Biphasic

However, one point of interest is that, after the initial instruction at the University, the patients were given devices to take home where they do most of their training. This means that they need to see a therapist at most once a week, which reduces the cost of the program. We have not dealt at all here with hybrid systems that combine light-weight, mechanical braces with FES (Schwirtlich and Popović, 1984; Popović et al., 1989; Andrews et al., 1988; Solomonow et al., 1989). Although FES alone may be sufficient to bring patients with incomplete spinal cord injury over the threshold to becoming functional walkers in their home or in the community, hybrid systems will probably be required for most patients with complete spinal cord injuries to minimize the energy cost and increase the range and speed of locomotion. This topic may be discussed elsewhere in the conference. Finally, fully functional systems should incorporate various types of sensory feedback to adapt the locomotion to different environmental conditions. This again is a topic which will probably be discussed in other sessions. Microprocessor-based systems to use these signals in real-time control of FES should be available in the next few years. However, the present study shows that with available techniques and technology, substantial numbers of patients, particularly those with incomplete spinal cord injuries, can be helped to greater mobility with the use of functional electrical stimulation.

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