Computer-controlled portable stimulator for paraplegic patients

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ABSTRACT

A six-channel lightweight, portable and computer-controlled stimulator for the functional activation of paraplegic patients is described. To enable programming of the various functions, the stimulator was designed to work in a remote-control mode hosted by an IBM PC or compatible computer, in addition to its normally used local mode. The stimulus parameters, including current intensity, stimulus frequency and pulse width, are individually adjustable and programmable for each channel. The power source is 12 V 500 mAh^{-1}, from 10 rechargeable nickel cadmium batteries, with a run time of 1.5 h for a load of 200 mA in four channels. Various training programmes for the activation of paraplegics in the sitting, standing and walking positions are described. The final design of the stimulator is based on experience gained from 25 patients, treated and evaluated during the course of development. Ongoing work including clinical, biomechanical and physiological studies is carried out to evaluate performance of the activated patients and to optimize stimulation.

Keywords: Functional electrical stimulation (FES), paralysed muscles, stimulator, transcutaneous stimulation

INTRODUCTION

The activation of the muscles of the legs of paraplegic patients by functional electrical stimulation (FES), to restrengthen their atrophied muscles and to regain the ability to stand and to walk, is a major achievement in the rehabilitation of paraplegics. Our group has worked on the development of sophisticated but simple-to-use stimulation apparatus, in parallel with the treatment of paraplegic patients, in a carefully planned training programme[1]. We use external stimulation, i.e. by means of surface electrodes. This requires relatively high stimulation intensities; however, despite this drawback, it has several merits, the major one being that it is non-invasive and harmless, allows easy attachment and removal of the electrodes and can be readily learnt by the patient. The stimulator developed is portable and microprocessor controlled.

The first reported portable external stimulator system was designed for the mobilization of hemiplegic patients in a laboratory environment by Kralj *et al.*[2]. From this stimulator, a four-channel apparatus was developed for usage for the mobilization of paraplegics[3–5]. Several external stimulators have since been reported, differing from each other in the number of output channels, stimulation characteristics and input–output options. Belikan *et al.*[6] reported on an eight-channel current output stimulator. The range of parameters was 100 mA for current, 10–500 μs for pulse width and 0.5–50 Hz for frequency. Jaeger *et al.*[7] reported on a two-channel voltage output stimulator with a range of up to 400 μs for pulse width and 2–30 Hz for frequency. Borges *et al.*[8] reported on a multi-channel current output stimulator. The ranges this group used were 1–255 μs for pulse width and 4–200 Hz for frequency. Bogataj *et al.*[9] developed a two-channel stimulator with 50 mA current limit and 50–500 μs pulse width range. The frequency range was 5–120 Hz. Guttenberg *et al.*[10] reported on a multi-channel current output stimulator with similar characteristics.

This paper describes a small and lightweight portable stimulator developed by our group for the functional activation of paralysed muscles. The stimulator was designed for both clinical and laboratory use.

BACKGROUND AND METHODS

The stimulator was designed to serve paraplegic patients as a primary tool for muscle restrengthening and for the generation of standing and reciprocate walking. Previous work has shown that at least four channels are required for reciprocate walking[4,11]. Two of these channels are for stimulating the quadriceps muscles, which are responsible for knee extension during the stance phase. The other two channels are for stimulating the peroneal nerve which evokes the withdrawal reflex in the swing phase of gait. In

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some patients, stimulation of the gluteus maximus muscles for hip extension may also be necessary, requiring two additional electrodes. A six-channel stimulator was thus designed in which the intensities, rates and sequences of the pulse trains generated could be varied. To enable programming of the various stimulator functions, the stimulator was designed to work also in a remote-control mode hosted by an IBM PC.

The final design of the personal stimulator described in this study was based on experience gained from 25 treated and evaluated paraplegic patients for the functional activation of their paralysed muscles. Activation was carried out using laboratory stimulators, based on earlier versions of the present device. To allow optimization of the stimulator design, evaluation methods were developed, as described below.

Clinical evaluation

A procedure for the careful selection of paraplegics suitable for activation by FES was used before the actual training. The training procedures included: (1) optimization of the location of the electrodes; (2) usage of the various activation modes of the apparatus, for muscle strengthening in the sitting position, followed by supported standing and walking[1] (a general protocol which we developed was adapted to each patient individually); and (3) biomechanical and physiological studies, aimed at the optimization of the stimulation parameters.

Biomechanical and physiological evaluation

The biomechanical parameters studied were weight-bearing during standing, and the kinematics of the stride in walking[11]. The physiological parameters included heart rate, pulmonary function, oxygen consumption, blood flow and lactic acid levels[12–14].

More recently, the phenomenon of fatigue of the activated muscle during FES was studied. It was suggested that the leg of a paraplegic patient presents a unique system where, under conditions of low spasticity, the only active muscles are those which are stimulated by FES. Thus, the legs of a paraplegic patient can be analysed as a determinate system, enabling the calculation of the force output within the stimulated muscle. Dynamometers were, therefore, designed and constructed for on-line monitoring of the decaying muscle force output under both isometric and isotonic conditions[15,16]. The myoelectric activity was measured by means of surface EMG of the fatiguing muscle[17]. The metabolic state of the activated muscle was obtained by using non-invasive P-31 magnetic resonance spectroscopy (MRS) of the stimulated muscle, on a Gyrex 2T MRI instrument[18,19]. Each of the myoelectric and metabolic measurements was coupled with the measurement of the muscle force output. In this way, correlations between force and EMG, as well as force and metabolic state were obtained. These relationships are used for the selection of the stimulus parameters, stimulation procedures and activation programmes which minimize muscle fatigue.

STIMULATOR DESCRIPTION

Working conception

Stimulation is provided by means of a train of monophasic rectangular pulses. Operation of the stimulator is either in a remote or a local mode. The remote mode allows readjustment of all the stimulus parameters, including current intensity, pulse width and pulse frequency and the saving of these values in the host computer. The local mode is basically a preprogrammed mode and the current intensity is the only parameter which can be altered, as required for continuous readjustment in the process of muscle fatigue[16]. This mode is used for the actual running of preprogrammed training exercises. Five basic exercises as listed below have so far been incorporated:

1. Serial activation of the two legs in the sitting position. Activation of each leg consists of stimulation of the quadriceps for knee extension, followed by stimulation of the flexion reflex.
2. Alternate activation of the two legs in the stting position, during which stimulation of the quadriceps of one leg is accompanied by the simultaneous activation of the flexion reflex of the opposite leg.

In the above two exercises, timing of the activation, including the time length of a complete cycle, as well as the partial time length of each phase within the cycle can be adjusted in the remote mode.

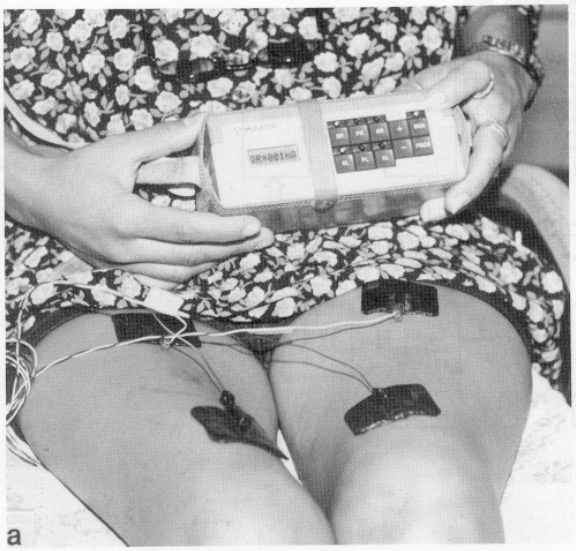
3. Synchronous activation of both legs: first the quadriceps, followed by the flexion reflex.
4. Supported standing.
5. Reciprocate supported walking.

In the last three exercises, activation and timing are manually controlled by the patient.

Running of the program starts with a muscle test procedure, to set the initial required current intensity. In this procedure, the operator (patient or therapist) increases the current until the requested muscle response is obtained. An upper limit of the current intensity is also set in accordance with safety requirements, the patient's condition and the exercise to be performed. To achieve a smooth transition from sitting to standing and vice versa, an ascending/descending current ramp is used. The command inputs are designed so that the patient is required to make as little conscious effort as possible and the switches are normally attached to the standing/walking support. Walking commands are made through two switches mounted on the walker, whilst both channel selector and current control are through two miniature joysticks, one on each side, also mounted on the walker.

Stimulator specifications

The stimulator is shown in *Figure 1*. It has six individually controllable current-source channels. The pulse trains in each channel consist of rectangular monophasic pulses. The stimulus current characteristics are: 0–400 mA for intensity, with a programmable upper limit, an adjustable frequency of 10–50 Hz and a range of 100–300 μs for pulse



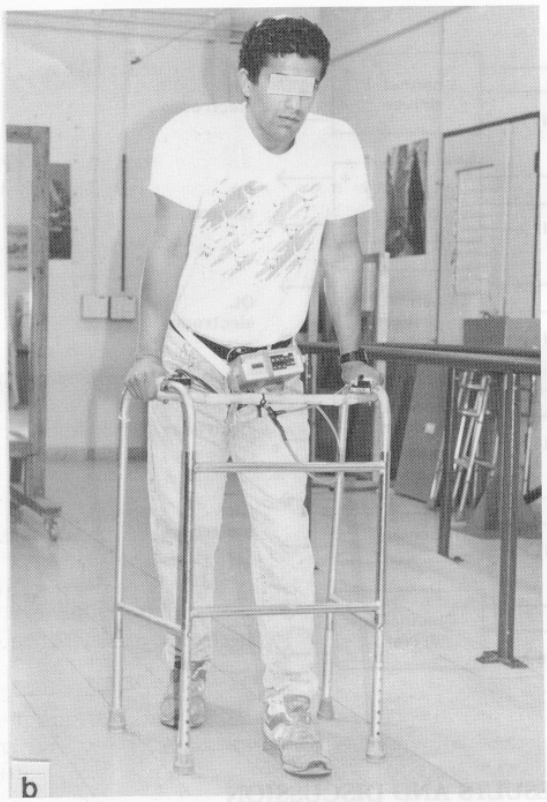


Figure 1 Six-channel portable stimulator: **a,** during exercise in the sitting position; **b,** worn by a patient while walking

width, individualy adjustable for each channel. The power source is 12 V 500 mAh^{-1}, from 10 rechargeable nickel cadmium batteries. The run time is 1.5 h, with a load of 200 mA in four channels. The stimulator's gross dimensions are $154 \times 85 \times 60$ mm, and the total weight, including the batteries, is 850 g.

Hardware description

The stimulator has two piggyback boards: the microboard and the power driver board.

1. *Microboard.* The CPU chosen for the portable stimulator is the Rockwell 65C02. The microboard has a non-volatile RAM for storing individual parameters. This memory can retain data almost indefinitely without external power, although the limiting factor is the shelf life of the lithium cell, which is typically 10 years. Communication between the stimulator and the host computer is through a serial port, isolated by opto-couplers within the stimulator, and a specially adapted RS232 card installed in the IBM PC or compatible. This interface is designed so that the stimulator continues to function even when the host computer is accidentally powered off. An 8-character alpha-numeric LCD display provides the user with data on the state of the stimulator. For safety reasons, the battery voltage is monitored when the stimulator is powered on and during exercise run time. A blinking character on the LCD display warns the patient when the battery has weakened and that the stimulator should be shut down within 5 min. The front panel and the function keys configuration of the present model have been designed to incorporate the modifications indicated by the experience gained on the previous models during five years of field testing. A block diagram of the stimulation microboard is shown in *Figure 2*.
2. *Power driver board.* The power driver consists of one pulse transformer, a transformer driver and six controlled current sources. The pulse transformer is able to deliver pulses of 300 μs with an amplitude of 300 V. Six LEDs on the keyboard indicate which channels are activated. For safety reasons, the connector accommodating the electrodes is also used for connecting the battery charger to the stimulator, making it impossible to wire up a subject to the stimulator when the batteries are being recharged. A block diagram of the power driver board is shown in *Figure 3*.

Software description

Stimulator system software. The stimulation program contained in the EPROM of the portable stimulator is written in Assembly language. The stimulation program is run in a two-level process:

1. interrupt level for the activation of the selected channels;
2. local or remote mode levels. The local mode is for reading the function keys, and updating the display and the parameter array. The remote mode polls the serial port, updates the communication buffer and the parameter array.

Laboratory system software. The stimulation program in the IBM PC is written in C language. This software controls all the stimulator functions in the remote mode. In this mode the stimulator keyboard is disabled. The communication protocol is bidirectional between the stimulator and the host computer and it operates as follows. The computer transmits a byte and waits for an acknowledgement message from the stimulator. Upon receiving a positive acknowledgement, the computer is able to transmit

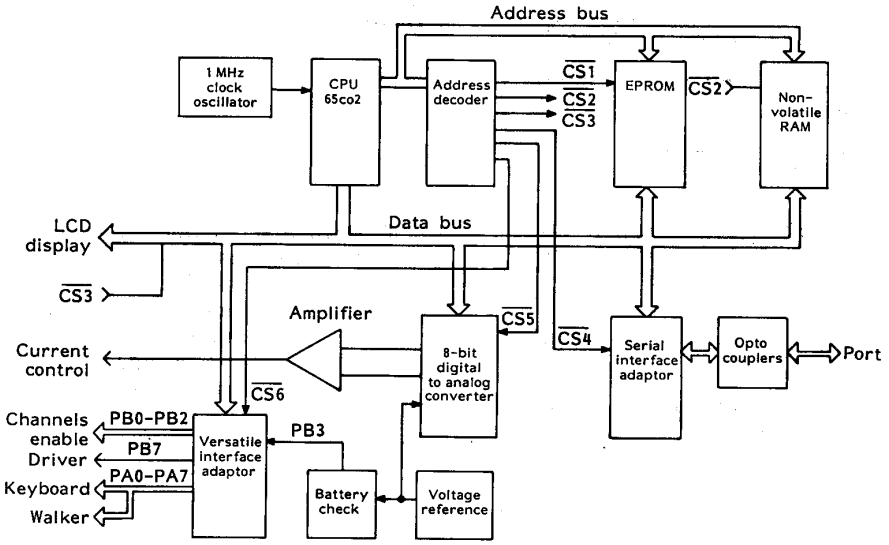


Figure 2 Block diagram of the stimulator microboard

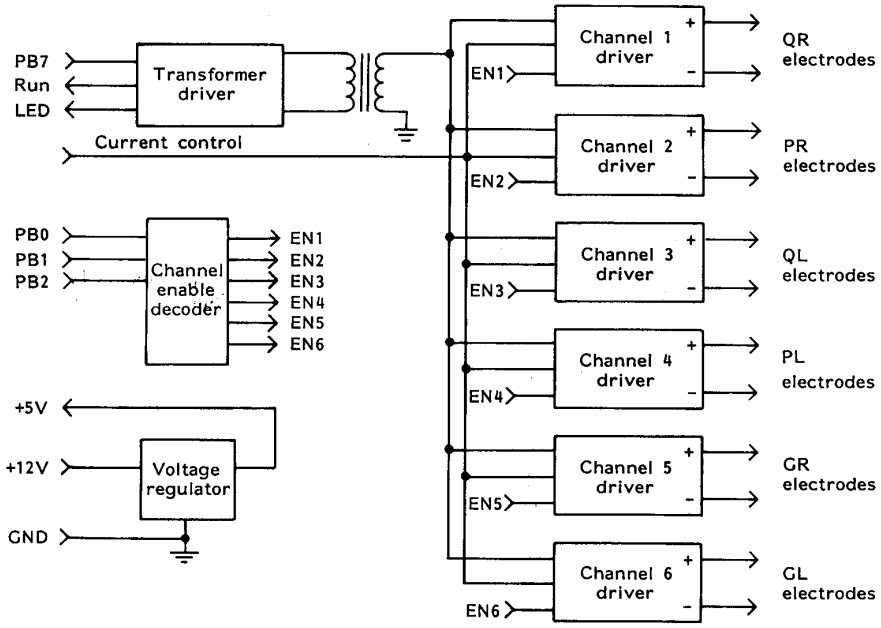


Figure 3 Block diagram of the stimulator driver board

the next byte. A negative acknowledgement message warns the operator (therapist, in this case) of the existence of a fault and the program is consequently aborted. The validity of the data is checked in the stimulatory for parity error or framing error. Depending on the data status, the stimulator responds with positive or negative acknowledgement messages. This communication protocol prevents the disruption of stimulator operation. Exercise selection is structured on a menu format. In all the exercises, the therapist is able to program the stimulator functions, such as stimulation frequency, channel pulse width and pattern timing. This feature allows the therapist to set and save the optimal parameters for each patient.

RESULTS AND DISCUSSION

Muscle performance

The following results demonstrate the torque and force obtained when the quadriceps muscles of paraplegics were isometrically stimulated. Recruitment of the muscle was shown to follow a sigmoidal curve. In well-trained muscles, the threshold current was found to be approximately 30 mA, after which the force developed within the muscle varied almost linearly with the stimulation current, until levelling-off of the recruitment curve occurred. At this stage the maximal force was achieved and the corresponding current intensity was 150 mA approximately. It

Table 1 Peak torques at the knee joint and maximal quadriceps tendon forces for trained muscles in isometric stimulation (SEM in parentheses)

	Knee angle 0°	30°	60°	90°
Peak torque (N – m)	22.5 (4.5)	40.5 (9.0)	72.0 (21)	60.4 (15.7)
Quadriceps tendon force (N)	560 (120)	820 (200)	1520 (410)	1420 (360)

should be noted that, in less trained muscles, the maximal achievable force was found to be reduced and in these cases generally more current was required to recruit the muscle. Typical peak torques at the knee joint and maximal quadriceps tendon forces for trained muscles are given in *Table 1*, for various knee flexion angles.

Our results for paraplegic patients activated by FES indicated a maximum torque at 60° knee flexion angle. This is slightly greater than for healthy subjects during maximum voluntary contractions, in whom the peak torques were reported at 50° of knee flexion[20]. In isokinetic measurements of quadriceps torque of electrically stimulated normal subjects, the knee angles of peak torques were reported to be in the same range as that obtained in this study: 55°[21]; 65°[22]; and 60°[23].

The quadriceps tendon forces obtained in our study were of the order of 1.5 kN. This is considerably lower than the forces reported for normal subjects (8 kN)[24].

When the quadriceps muscles were continuously stimulated at a constant intensity, a force decay was obtained exhibiting a double exponential curve. The early part was an acute decay and the latter part was an asymptotic curve reaching low and functionless values at the end of 3 min maximal stimulation, approximately 120 mA. For functional purposes, only the first section is the more significant. Comparative trials, conducted to identify the stimulation parameter values at which fatigue is minimized, revealed that frequency and pulse width should preferably be set at 20 Hz and 250 μs respectively.

Clinical outcome

The clinical outcome of 25 paraplegic patients who were activated with the stimulation described in this study is shown in *Figure 4*. After the muscle-strengthening phase of the training procedure (lasting three weeks on average), 17 patients were able to stand up and maintain the standing position. Of these patients, 12 reached the ability of reciprocate walking using one of the following supports: parallel bars (6 patients), a walker (5 patients), or forearm crutches (one patient). Typical results were 15 min for continuous standing time and over 60 metres for supported walking. Nine of these patients are already equipped with our stimulating apparatus for home use. In those patients, the apparatus is reset periodically in the laboratory, during the course of their training, and the parameter ranges are readjusted as required in accordance with their progress.

Although the developmental status of the apparatus is considered complete, the experience still being accumulated will serve for the future introduction of improvements and modifications.

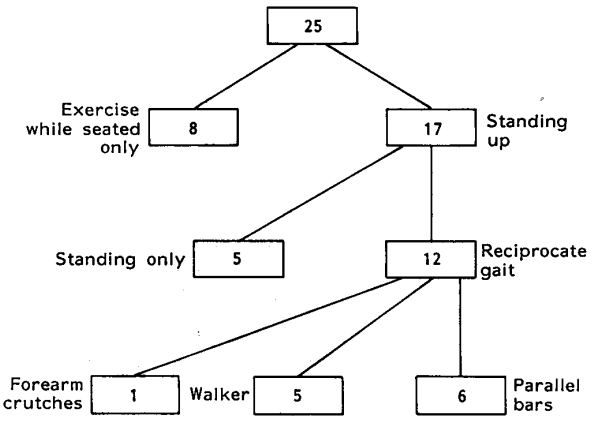


Figure 4 Clinical outcome of 25 paraplegic patients activated with FES

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REFERENCES

1. Braun Z, Mizrahi J, Najenson T, Graupe D. Activation of paraplegics by functional electrical stimulation: training and biomechanical evaluation. *Scand J Rehab Med* 1985; **Suppl. 12:** 93–101.
2. Kralj A, Trnkoczy A, Acimovic R. Hemiplegic gait improvement by means of a three-channel electrical stimulator. *Elektrotechnicni Vestnik* 1971; (4–5): A12–A15.
3. Bajd T, Kralj A, Sega J. Use of a two-channel functional stimulator to stand paraplegic patients. *Phys Ther* 1981; **61:** 526–7.
4. Bajd T, Kralj A, Turk R, Benko H, Sega J. The use of a four-channel electric stimulator as an ambulatory aid for paraplegic patients. *Phys Ther* 1983; **63:** 1116–20.
5. Strojnik P, Kralj A, Ursic I. Programmed six-channel electrical stimulator for complex stimulation of leg muscles during walking. *IEEE Trans Biomed Eng* 1979; **26:** 112–16.
6. Belikan T, Hollander HJ, Vossius G. Microprocessor controlled 8-channel stimulator with surface electrodes for FES of gait. *Proc 2nd Int Workshop on Functional Electrostimulation*, Vienna, Austria, September 1986; 71–73.
7. Jaeger RJ, Yarkony GM, Smith RM. Standing the spinal cord injured patient by electrical stimulation: refinement of a protocol for clinical use. *IEEE Trans* 1989: **BME-36:** 20–28.
8. Borges G, Ferguson K, Kobetic R. Development and operation of portable and laboratory electrical stimulation systems for walking in paraplegic subjects. *IEEE Trans* 1989; **BME-36:** 798–801.
9. Bogataj V, Kelih B, Malezic M, Filipic D, Kljajic M. Dual-channel electrical stimulator for correction of gait. In: B. Dejan Popovic, ed. *Advances in External Control of Human Extremities*. Belgrade: Nauka, 1990; 327–33.
10. Guttenberg V, Hollander HJ, Vossius G. 16-Channel stimulation systems for the use of FES and related

applications. In: B. Dejan, Popovic ed. *Advances in External Control of Human Extremities*. Belgrade: Nauka, 1990; 319–26.
11. Mizrahi J, Braun Z, Graupe D, Najenson T. Quantitative weight-bearing and gait evaluation of paraplegics using functional electrical stimulation. *Med Biol Eng Comput* 1985; **23:** 101–7.
12. Isakov E, Mizrahi J, Graupe D, Becker E, Najenson T. Energy cost and physiological reactions to effort during activation of paraplegics by functional electrical stimulation. *Scand J Rehab Med* 1985; **Suppl. 12:** 102–7.
13. Isakov E, Mizrahi J, Najenson T. Biomechanical and physiological evaluation of FES-activated paraplegic patients. *J Rehab Res Dev* 1986; **23** (3): 9–19.
14. Mizrahi J, Isakov E, Susak Z, Becker E. Mechanical and physiological gait factors of above-knee amputees and of paraplegics activated by functional electrical stimulation. In: Mital A, Karwowski W, eds. *Ergonomics in Rehabilitation*. London: Taylor and Francis 1988; 211–30.
15. Levy M, Mizrahi J, Susak Z, Solzi P. Fatigue of quadriceps muscles continuously activated by functional electrical stimulation. In: Wallinga W, Boom HBK,de Vries J, eds. *Electrophysiological Kinesiology*. Amsterdam: Elsevier, 1988; 65–8.
16. Levy M, Mizrahi J, Susak Z. Recruitment, force and fatigue characteristics of quadriceps muscles of paraplegics, isometrically activated by surface FES. *J Biomed Eng* 1990; **12:** 150–6.
17. Levy M, Mizrahi J, Steinvil Y, Susak Z, Solzi P. The time-dependent output of paraplegics' quadriceps muscles activated by FES. In: B. Dejan Popovic, ed. *Advances in External Control of Human Extremities*. Belgrade: Nauka, 1990; 555–70.
18. Levy M, Kushnir J, Shporer M, Mizrahi J, Itzchak Y. *In vivo* P-31 NMR studies of fatigue of paraplegic's muscle under functional electrical stimulation. 8th Annual Meeting of the Society of Magnetic Resonance in Medicine, Amsterdam, August 1989.
19. Levy M, Kushnir T, Mizrahi J, Itzchak Y. *In vivo* ^{31}P NMR studies of paraplegic's muscles activated by functional electrical stimulation. *Mag Reson Med* 1993; **29:** 53–8.
20. Moritz U, Svantesson G, Haffajee D. A biomechanical study of muscle torque as affected by motor unit activity, length-tension relationship and muscle force lever. In: Desmedt JE, ed. *New Developments in Electromyography and Clinical Neurophysiology*, Vol. 1. New York: Karger, 1973; 675–82.
21. Duvoisin MR, Doerr DF, Reed HE, Flores JF, Buchanan PA. A technique for quantification of muscle force during EMS. *Proc IEEE 8th Ann Conf Eng Med Biol* 1986; 588–91.
22. Fahey TD, Harvey M, Schroeder RV, Ferguson F. Influence of sex differences and knee joint position on electrical stimulation-modulated strength increases. *Med Sci Sports Exerc* 1984; **17:** 144–7.
23. Selkowitz DM. Improvement in isometric strength of the quadriceps femoris muscle after training with electrical stimulation. *Phys Ther* 1985; **65:** 186–96.
24. Van Eijden TMGJ, Weijs WA, Kouwenhoven E, Verburg J. Forces acting on the patella during maximal voluntary contraction of the quadriceps femoris muscle at different knee flexion/extension angles. *Acta Anat* 1987; **129:** 310–14.