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Gait Restoration in Paraplegic Patients: A Feasibility Demonstration using Multichannel Surface Electrode FES [a]

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ABSTRACT

Recent advances in science have aided research toward the restoration of biped gait in paraplegic patients by means of functional electrical stimulation (FES). In this paper it is shown how FES-restrengthened muscles of paraplegic patients have been used for simple FES-assisted standing. Those experiments subsequently led to biped gait-initializing experiments and to simple forms of biped gait synthesis. The purpose of this paper is to show the feasibility of using FES for standing and for restoring biped gait in many paraplegic patients—to present the past achievements, focus on problems, and highlight directions for future research.

The results of gait obtained in three complete spinal cord injured patients (out of a series of 17) are shown, using four to six channels of FES. It is also shown how preserved reflex mechanisms of the transected spinal cord can be incorporated and employed for obtaining improved function while at the same time simpliflying the FES hardware. Of the three patients reported on in detail here, two patients have managed to walk in parallel bars while the third patient has mastered independent unassisted walking over shorter distances with the aid of a roller walker. The biomechanical and control problems of this last patient's gait are presented in detail.

INTRODUCTORY REVIEW

The advances in electronics during the last decade, particularly miniaturization, improved reliability, and lower prices, have facilitated the research and clinical application of advanced electronics in various fields, including Functional Electrical Stimulation (FES). The achievements in neurophysiology and extensive research in locomotion engineering have opened new approaches in rehabilitation. In spite of these helpful developments, the problem of locomotion in spinal cord injured (SCI) patients still requires better solutions. In past decades the main medical problems of these patients were considered first and locomotion in wheelchairs was generally accepted as the only realistic means of mobility. But it is obvious that environmental barrier problems could be more suitably reduced for SCI patients by restoring some degree of non-wheelchair locomotion. Doing this by FES might also be less expensive, more functional, and more attractive for the patient (and society) than the wheelchair. Therefore, since the year 1972 we have focused our research on feasibility studies of FES-assisted biped gait in SCI patients. Other researchers have followed the same rationale (1, 2, 3, 4). The early work by Kantrowitz (1), Willemon et al. (2), and Kralj et al. (3) provided evidence that FES-stimulated muscles in paraplegic patients could

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perform work when restrengthened by means of FES. More recently it has been shown that functions such as standing and even rising from a sitting position to standing can be accomplished in complete SCI patients.

Research was also conducted in exploring the changes in muscle properties and tissue because of prolonged periods of FES as used in restrengthening (5, 6, 7, 8, 9). Peckham et al. (5) and Mortimer et al. (6, 7) focused their work on such physiological changes as metabolism, contractile properties, muscle fiber changes, etc. It is important to note that their basic findings have confirmed the conclusions of earlier authors. Today it is common knowledge that partly disused, atrophied, and upper-motor-neuron-lesioned muscles can be restrengthened by means of FES. These muscles are later used for performing functional tasks requiring high muscle forces; for example, providing joint torques for standing-up (3) or knee locking in gait and in standing (2, 8). The first reported uses of implanted functional electric stimulators in SCI patients which provided knee locking via FES of M. Quadriceps muscles were in work performed in 1971, by Willemon et al (2) and in 1979 by Brindley et al (8). These authors made multichannel implants for enabling SCI patients to walk in a swing-to or swing-through mode gait assisted by FES (with FES knee locking substituting for long leg braces). All the previously described achievements have demonstrated that FES of paraplegic muscles is feasible. In Ljubljana, Yugoslavia, the researchers have used stimulation through surface electrodes to obtain prolonged standing of the patient (10, 11, 12). The work was based on their earlier experiences using multichannel FES in stroke patients (13, 14, 15). The research reviewed here has been focused on the problems of standing-up, maintaining erect position, and balance. Most recent emphasis has been given to the problems and requirements for weight shifting between supporting limbs assisted by FES, and the problems of single-limb and double-limb support as they take place during gait. All this has led to research on the possibilities of synthesizing functionally useful FES-assisted biped gait in paraplegic patients.

FES: a realistic and better solution in paraplegia?—The artificial synthesis of gait using FES has, at times, looked like a problem whose complexity grows very rapidly as research improves our awareness of the physiological, neurological, and bioengineering facts. No doubt this is typical of most sustained work in intrinsically complex areas of study: the investigators are sustained by confidence that their own work and that of others periodically leads to fresh insight and understanding—and ultimately to simplification. Along the way the investigators can hope for encouraging signs that practical clinical benefits (or even major gains in life-style) for the majority of paraplegic patients could emerge from the work in FES-enabled gait.

Signs that achieving useful gait via FES is a truly important goal may be seen in various bits of information. For example, biomechanical studies in the United States, comparing wheelchair propulsion with braced crutch-walking (in swing-to or -through modes of gait) gave evidence that "...patients with paraplegia who require two KAFO's...usually do not continue to walk at all" after learning to walk in a rehabilitation hospital (quote from page 1133, Physical Therapy, Vol. 60, No. 9 (Ref. 16)). The high energy demand of today's crutch walking is the reason. In contrast, biped gait via FES now seems unlikely to impose unacceptably (or even uncomfortably) high energy demands once a healthy patient has been trained in the use of restrengthened muscles for FES-enabled biped gait.[c]

The advantages of using the FES method for re-enabling gait in paraplegic patients are many. Natural bone support of body weight and existing joints, ligaments and muscle power are used. No external braces such as KAFOs, etc, or force transfers with levers, are needed for FES orthopedic devices. The muscle provides a self-regenerating energy supply, and electrical stimulation is used only for triggering, therefore FES orthotic devices will have low battery needs which suggests good autonomy.

Preserved Reflexes Employed—An additional very important advantage of FES is that it can take advantage of preserved spinal reflexes and neuromuscular mechanisms. When these mechanisms are employed, FES is applied as sensory stimulation to provide triggering and facilitation of preserved functions such as the flexion synergistic response, agonist or antagonist, and contralateral extensor/flexor inhibition or excitation. Because of the advantages discussed above, the FES method has a theoretical advantage over other methods (such as the powered "exoskeleton", etc.) which use external control for locomotion. Such an external device typically fails to become (or to be perceived as) an integral part of the patient, and even when the devices function well they are only rarely well-accepted by patients. In contrast, FES, when delivered by means of an implanted stimulator, becomes virtually an integral part of the patient and has therefore a good possibility of being well received by the patient. This reasoning, if confirmed, would clearly suggest that research toward totally body-implanted FES systems should be emphasized in the future.

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[c] The authors believe that, in the near future, FES-assisted paraplegic gait with crutches will be feasible.

Disadvantages of Using FES—There are also disadvantages to using FES. These include difficulties with electrode placement, inadequate selectivity, the need for costly technology, and insufficient present knowledge of neurology, neuroanatomy, FES, and related fields and of the information processing required for decision-making and control. It seems that most of these disadvantages could be minimized in the near future by further research.

Up to now, only fragments and notes regarding the work in Ljubljana, Yugoslavia, with FES-assisted gait in paraplegic patients have been published. This paper will explain in some detail the methodology used, and critically summarize the results obtained so far on 17 patients.

GENERAL METHODOLOGY

Patient Suitability

Because of the lack of previous experience, no patient-selection criteria were available initially (in 1972). Spinal-cord-injured patients with thoracic lesions between T5 and T12 were selected. They were at the end of their standard rehabilitation program, facing discharge[d].

In general, the subjects were middle-age and younger patients with good physical health, showing no heart, lung, or bladder problems. Major contraindications were contractures, osteoporosis, joint ossification, ulcers, or very severe spasticity.

The data obtained from three patients are described in detail in the "Clinical Observations" section. The patients are those who proved to perform the best in our series of 17 randomly selected patients. Some of the other patients did not complete the program because of various reasons (e.g., being discharged, marriage, going to school, etc.). Owing to this the patient population which could benefit in the future from this method cannot now be precisely specified, but considering only standing enabled by FES, practically all the patients who suit the criteria in Table 1 can be expected to be able to master the standing in a time of 2–3 months.

Testing Muscles for Suitability—Patients were fully informed of the research procedures when admitted to the program. Then, after being checked for the general requirements, the patients were tested for muscle response to FES. Only main hip, knee, and ankle-joint muscles were tested. Rectangular d.c. pulses of 0.3 ms with frequency of 20 Hz were used. The amplitude of stimulation was in the range of 40 V to 120 V. The stimulator used has been previously described (14). Standard water-soaked foam-rubber-covered sheet metal electrodes were used (17).

The FES testing was used to verify that the main muscles had not suffered lower-motor-neuron lesions (muscles which have suffered such lesions cannot be used for FES).

During these initial stimulation trials, recordings were made to display maximum force and the fatiguing rate of stimulated muscles. At the same time, the standard testing for reflexes was performed. Stretch reflexes and gross extension and flexion patterned reflex movements were initiated as a proof that the spinal-cord levels below the transection were still functional and had not been destroyed during the acute phase because of ischemia, edema, hematoma, surgery, physical handling, or other reasons. Typically, and in a majority of patients tested, the muscles innervated close to the level of injury are peripheral-denervated (do not respond to FES); the muscle tissue is missing because of atrophy and the muscles lost for FES treatment. This can also be determined by visual inspection, because the muscle tissue is lessened to the extent that bony prominences are clearly seen. Muscles such as M. Quadriceps may show disuse atrophy very rapidly—even in cases with intact periph-

TABLE 1.
Patient indications for FES

1. Lesion level T-4 through T-12
2. Upper motor neuron lesion
3. Positive results of FES restrengthening program
4. No joint contractures or other involvements (e.g., ossification, osteoporosis)
5. No major skin problems
6. Normal balance sensation
7. Good physical, mental, and emotional condition
8. Motivated and cooperative

TABLE 2.
Contraindications for FES

1. Osteoporosis
2. Ossification of Joints
3. Peripheral lesion of main leg muscles
4. Severe atrophy of muscles so that restrengthening is impossible
5. Pressure sores
6. Obesity
7. Very severe spasticity
8. Inadequate sitting balance

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[d] It must be noted that some patients many years postinjury can be admitted to the program with the same success. It is important that their status corresponds to the limitations outlined in the criteria for selection (Table 1 and Table 2). The derivation of these suggested criteria is described in the "Clinical Observations" portion of this paper.

FIGURE 1
Standing by means of FES and the wheelchair-attached supporting frame.

eral innervation. In the latter case, even when atrophy has begun the muscle force can frequently be restrengthened by means of FES, even to a fair functional level, if the initial force is at least on the order of 20 percent of normal functional strength. (So far, there are no methods developed enabling the prediction of the restrengthening results).

Because of various reasons, levels of injury at T12 and below frequently result in peripheral denervation of the muscles involved. Injuries at lumbar levels all result in peripheral nerve lesions because of damage to the cauda equina.

Muscle Restrengthening Program

After initial testing, the FES muscle restrengthening program was started. Isotonic exercising was performed using bilateral movements or reciprocal movements patterned similarly to gait. FES was initially administered for about 10−15 minutes twice daily. At this point, control was via switches operated by the physiotherapist or the FES was triggered by a cycler. The patient was then taught how to apply the stimulation, or relatives were taught to do it for him.

The FES of spastic muscles can increase, decrease, or have no effect on spasticity. If it does increase the spasticity, FES should be discontinued. Inhibition of spasticity by means of FES is not fully understood (18, 19, 20, 29). The FES sessions for muscle restrengthening were gradually increased to stimulation times of 150 minutes twice daily. The optimal timing and procedure for muscle restrengthening have not yet been established. The gain in muscle force was measured weekly or biweekly and recordings for fatigue monitoring were made. Records were also made of the patient's weight and length of body segments, for later mathematical modelling (12). When the joint torques produced by FES reached a functional level, standing-up and sitting down training was started, allowing the patient to assist himself freely with his arms. The erect standing time was gradually increased to the point when fatiguing of knee locking prevents further standing. During this phase of the program, M. quadriceps muscles were continuously stimulated bilaterally during standing. Occasionally, FES of hip extensors was added for insuring good posture with hyperextended hips. The patients were taught to keep their balance with the upper body and to use their arms only for larger body shifts and to prevent the development of unstable postural situations. The patients had to master hand-assisted weight shifting for right and left single stance. (In some patients, FES of hip abductors was added for weight shifting and prevention of overlapping of the feet.) For the patient's exercise and later possible use in gait, the M. soleus and M. gastrocnemius were cyclically stimulated, providing lifting on their toes.

Simple Gait Training Started

Once the patient felt safe and comfortable while standing, simple gait-pattern training could be started, beginning with walking in parallel bars. As an intermediate stage to allow walking over longer distances, a walker frame was used (9). Later, walking by means of a roller walker could even be performed. One patient was taught how to adjust the electrodes and the stimulator itself for independent roller-walking. Once he had mastered walking with FES biped gait, measurement assessments were made.

After the FES clinical program was terminated, six patients were supplied with their personal two-channel stimulators for home use. These units provided only standing and muscle exercising. So far, only one patient has been given a roller-walker with a 4-channel stimuator for home use, enabling him to walk at home. For patients who considered FES standing functional, a special wheelchair-attached collapsible supporting frame was developed, allowing them to use erect standing at any location indoors or outdoors (Fig. 1) (12, 21).

Patients using FES at home were visited frequently and closely monitored. Their most frequent complaints were about tedious electrode positioning and the required redressing; the latter was particularly unpleasant in winter. However, surface electrodes will continue to be used in the University Rehabilitation Institute to collect more knowledge, refine the methodology, and evaluate the entire procedure.

GAIT SYNTHESIS

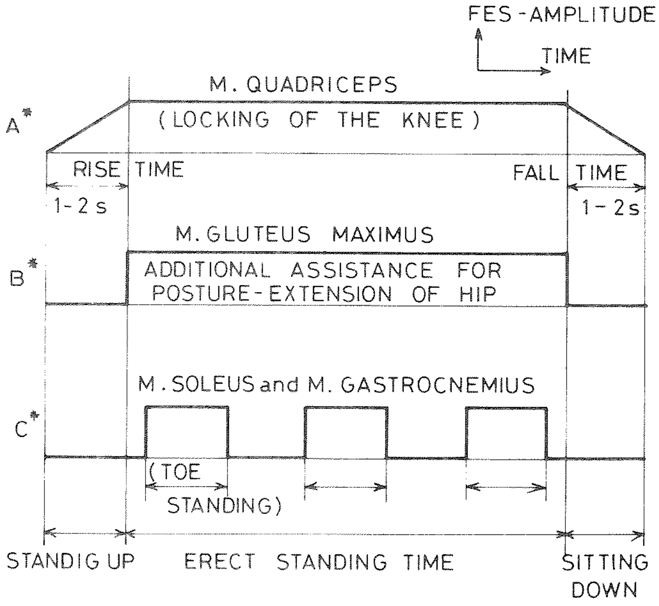
The proper timing of FES for each muscle, and the coordination of the patient's trunk maneuvers, are essential for achieving good walking. Therefore, it is important that the patient has control of major events. For a particular function we have to select an appropriate stimulation activity-program, subsequently referred to here as an FES sequence.

The act of gait synthesis is the development and establishment of the FES sequences which produce the necessary movements which will result in the execution of a particular function in time (e.g. standing-up, sitting-down, or biped walking). FES can be applied in two ways: as efferent-motoric stimulation resulting in a contraction of the selected muscle, or as afferent-sensory stimulation of nerve endings which provides triggering of reflex events (e.g., the flexion withdrawal movement which can be incorporated in gait) and hence the stimulation sequence is appropriately determined.

Improper FES sequences will provoke movements which deviate from the desired function and which could even create hazardous situations. Synthesizing the gait by means of FES consists of selecting and determining the order, duration, and synchronization of events which are necessary to obtain a simple gait pattern. During the development of the needed FES sequence we have to take into account the limitations as well as the arsenal of preserved movements which may be exerted voluntarily by the patient, and then we enable the remaining needed movements by FES. The patient assembles the events by his voluntary movements (which may in some cases themselves be used to trigger FES stimulation of the next movement) and employs commands under his direct control (as in the case of a switch which is patient operated) in such a manner as to result in the planned and wanted function. The synthesis of FES-assisted gait requires professional knowledge of biomechanics of gait, of functional electrical stimulation, neurophysiology, and musculoskeletal anatomy and physiology. This procedure of determining the FES sequences is a creative and demanding task.

Consider the stimulation sequence for standing. In Figure 2 the stimulation sequence is shown for M. quadriceps-assisted standing (A). The kneee joint is locked. (Standing, assisted also by hip extensors M. gluteus maximus and M. gluteus medius, is also shown (Fig. 2, B); this provides better hyperextension of the hip and hence better posture). FES for providing cyclical "toe standing" (body lifting) movements during erect standing requires the activation of M. soleus and M. gastrocnemius muscles bilaterally, as shown in Figure 2 (C).

The gradual increase and decrease of stimulation



* APPLIED BILATERALLY

FIGURE 2
The FES for standing-up and erect standing, with or without toe lifting and sitting-down.

during standing-up and sitting-down is important because this gives the patient time for executing the proper associated body movements. Without the rise and fall times (gradually increasing/decreasing stimulation) the patient may collapse when sitting-down at the precise moment when the M. quadriceps stimulation is automatically switched off. The patient must be taught to be aware of this and to remember that a given but limited time is available for normal performance of standing-up or sitting-down, in which his awareness, performance, and assistance play an important part.

Gait Pattern Possibilities

It is obvious that there are numerous possible gait patterns for a biped gait. The most simple and fundamental ones, displaying only the main events of a biped gait, are termed "simple" biped gait patterns. To generate a simple gait we need, first, a double-stance-phase period. This is the period of greatest stability. During this phase the weight transfer between legs will take place. The weight transfer can be provided by hand pushing movement or by stimulation of ankle plantarflexors. Next, a rather short single-stance phase on one side and swing phase to the opposite side is needed. This single-stance/swing-phase period is terminated when the swing-leg heel strikes the ground. The antigravity support and swing functions can be provided by FES, while the rest of the functions (body weight transfer, hip abduction during single stance, stability, etc.) can be provided either by appropriate correlated voluntary maneuvers of the upper body and arms by the patient himself or by selected FES of additional muscles. In the latter case, the FES sequence would become more complicated. Stimulus settings for each muscle include, in principle, time-delay for the onset referenced to an event or command, the FES duration and amplitude. At the present time it is simpler to leave the burden of correlation and proper timing of as many functions as possible to the patient; this simplifies the FES hardware. This philosophy gave rise to the basic gait mode described in this paper and the resulting stimulation sequences which are shown.

FES Sequences

Before describing the FES sequences in detail it must be explained that, at present, the whole antigravity support function is provided by motoric FES of muscles. In contrast, for providing the swing phase, the required flexion of joints can be obtained in two ways: (i) by motoric (efferent) stimulation of the main flexors, or (ii) by the sensory (afferent) stimulation to trigger the flexion withdrawal movement. The first given possibility for providing flexion of joints needed during the swing phase requires at least two pairs of electrodes for stimulation of ankle-joint dorsal flexor and knee-joint flexor (M. tibialis anterior and M. biceps femoris), and a forward-leaning posture. The setting of 6 FES parameters, three for each muscle, must be made. (A setting is composed of the stimulation amplitude, stimulation onset, and duration.) The requirements would be even more demanding incorporating hip flexors and using three pairs of electrodes. The proposed method is not feasible because the hip flexors cannot be adequately stimulated with surface electrodes. To compensate to a certain extent for the missing hip flexion, reinforced knee flexion may be introduced, but the latter can be obtained by an additional FES pair of electrodes for stimulation of additional knee-joint flexion muscle tissue. On the other hand, the setting of FES parameters for motoric-efferent stimulation is simple, because we can copy the muscles' activity in normal gait.

The second possibility for obtaining flexion of joints during swing uses only one pair of electrodes, but makes advantageous use of the preserved mechanisms of the transected spinal cord. Therefore the hardware requirement is reduced, but the adjustment of parameters influencing the movement is demanding. Electrophysiological knowledge of how the different stimulation parameters and electrode locations influence the resulting flexion reflex-withdrawal movement is essential. From the literature (22, 23, 24, 28) it is known that during a flexion reflex movement of the lower extremity, hip and knee flexion and ankle-joint dorsiflexion can be obtained. But published data describing how to control the degree of obtained flexion, and the timing using FES, are rare. It is obvious that the swing-phase control via flexion reflex response is less precise, and requires more sound judgement, but it requires less hardware. Since the primary function of the swing phase is bringing the leg forward, the exact swing trajectory is not strictly prescribed, but the proper timing of the toe-off and heel-strike are. In all of our simple gait patterns the forward propulsion is provided by the patient with his upper-body movements and with forces exerted through the hands. In addition, the equivalent of the required abduction forces for the hip are also controlled by the patient's hands and the side-leaning movements of his trunk. FES can efficiently provide the hip abduction forces if needed, as our trials showed. The activation of M. tensor fasciae latae with M. gluteus medius and minimus requires the setting of two additional pairs of electrodes and the adjustment of 6 new stimulation parameters.

The abduction and hip extension torques can also be obtained just by using the M. quadriceps channel; in that case the upper M. quadriceps electrode is moved and placed proximal to the crest of the pelvis and placed slightly lateral-dorsal. This placement can be used partly for co-contraction of M. gluteus medius with the tensor faciae latae.

Thus forward propulsion in the push-off phase of gait can be provided by FES of appropriate muscles, but again, additional hardware and settings are needed—it can be seen that additional functions require hardware and the need to set more parameters. The latter, in turn, present additional requirements for information processing and control.

The reasoning just described provides the background for understanding our selection of the initial experiments and the use of the simplest possible gait modes. This approach requires the least hardware and control processing. Following the experience gained in multichannel stimulation we actually incorporated the switch ON/OFF control, providing only timing for the starting and duration (termination) of swing and stance phase for each leg. In this case the burden for proper timing is taken by the PT and later the patient himself (once he controls the switches) and hence no external signal processing is required.

The FES sequence which, so far, has been found to be most practical and has been mostly used, is given in Figure 3. The figure shows traces 1−1′ for M. Quadriceps activation and traces 2−2′ for the flexion reflex activation (together, 4 channels). The required stimulation amplitudes are pre-set and maintained constant (readjustments are made only because of fatiguing) and set at an 80 percent level for maximum M. quadriceps stimulation and fairly above the threshold for just triggering the flexion reflex. Also in Figure 3, the proper timing for the hand switches is given, and the stimulation (traces 3−3′) for obtaining hip extension and abduction shown.

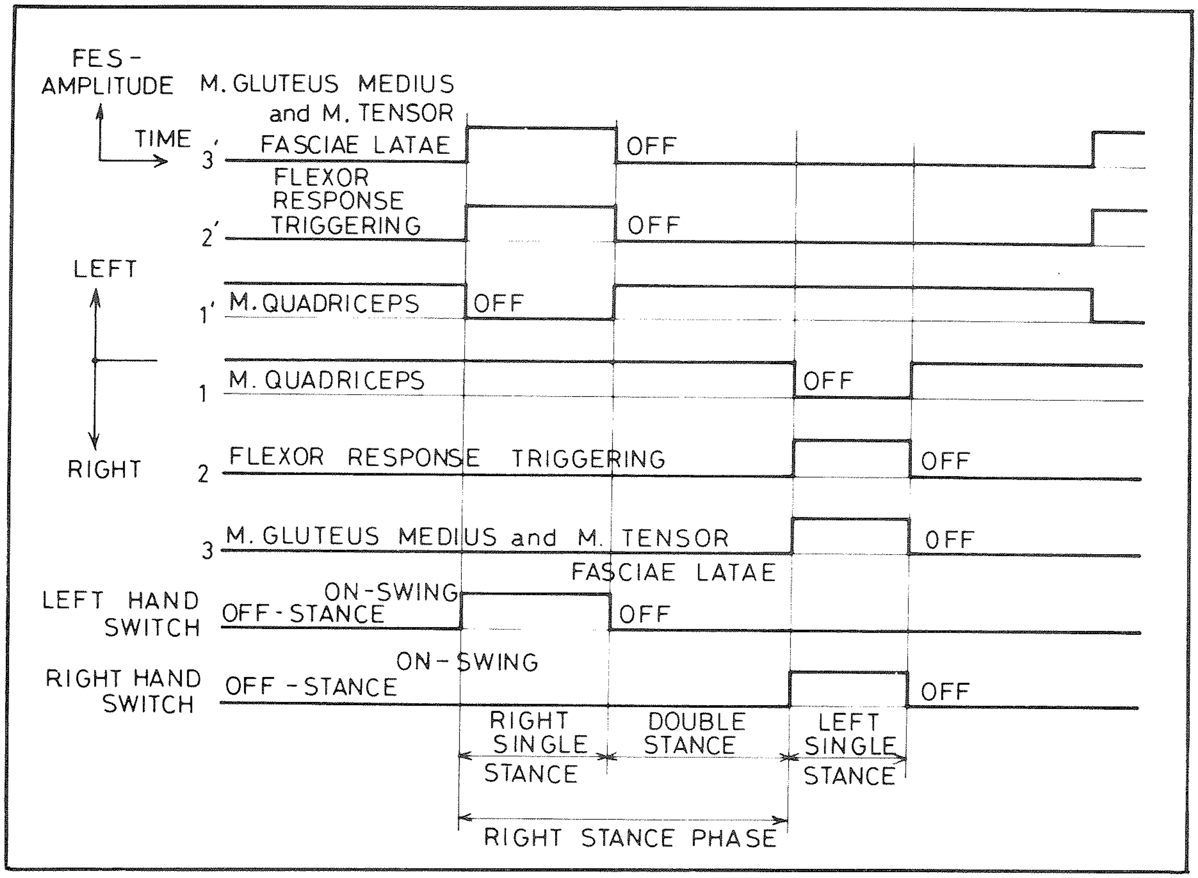


FIGURE 3
The six-channel stimulation sequence using left (LS) and right (RS) side hand switches controlled by the P.T.

Applications in Three Patients

One of the first stimulation sequences for simple gait used on patient No. 1[e] consisted predominantly of motoric stimulation. The gait cadence was determined by the physiotherapist walking behind the patient; the physiotherapist pressed the switches and gave voice signals to the patient for taking each step. The forward-leaning posture of the patient influenced the step length. The forward swing of the leg was assisted by gravity (Figure 4). Omitting channel 3−3′ in Figure 3 simplified the hardware; gait was still feasible but with more assistance from the patient. Later, flexion reflex triggering was improved by changing the electrode location, so that the gait improved because of longer step length and better swing phase—the requirement for forward-leaning posture was then eliminated.

The same FES sequence was used for the second patient (No.2) shown in Figure 5. The site for flexion reflex stimulation was selected distally one centimeter anterior from the caput fibulae at the site of N. peroneus. This location requires higher stimulation amplitudes. Later, the site of active electrode placement in the popliteal fossa over the peroneal nerve was used, providing larger flexion joint angles with lower stimulation amplitudes. The addition of stimulation channels 3−3′ (Fig.3) resulted in jerky movements of the trunk because of strong hip-extension torques; the patient was able to walk in a soldier-like erect position as shown in Figure 5.

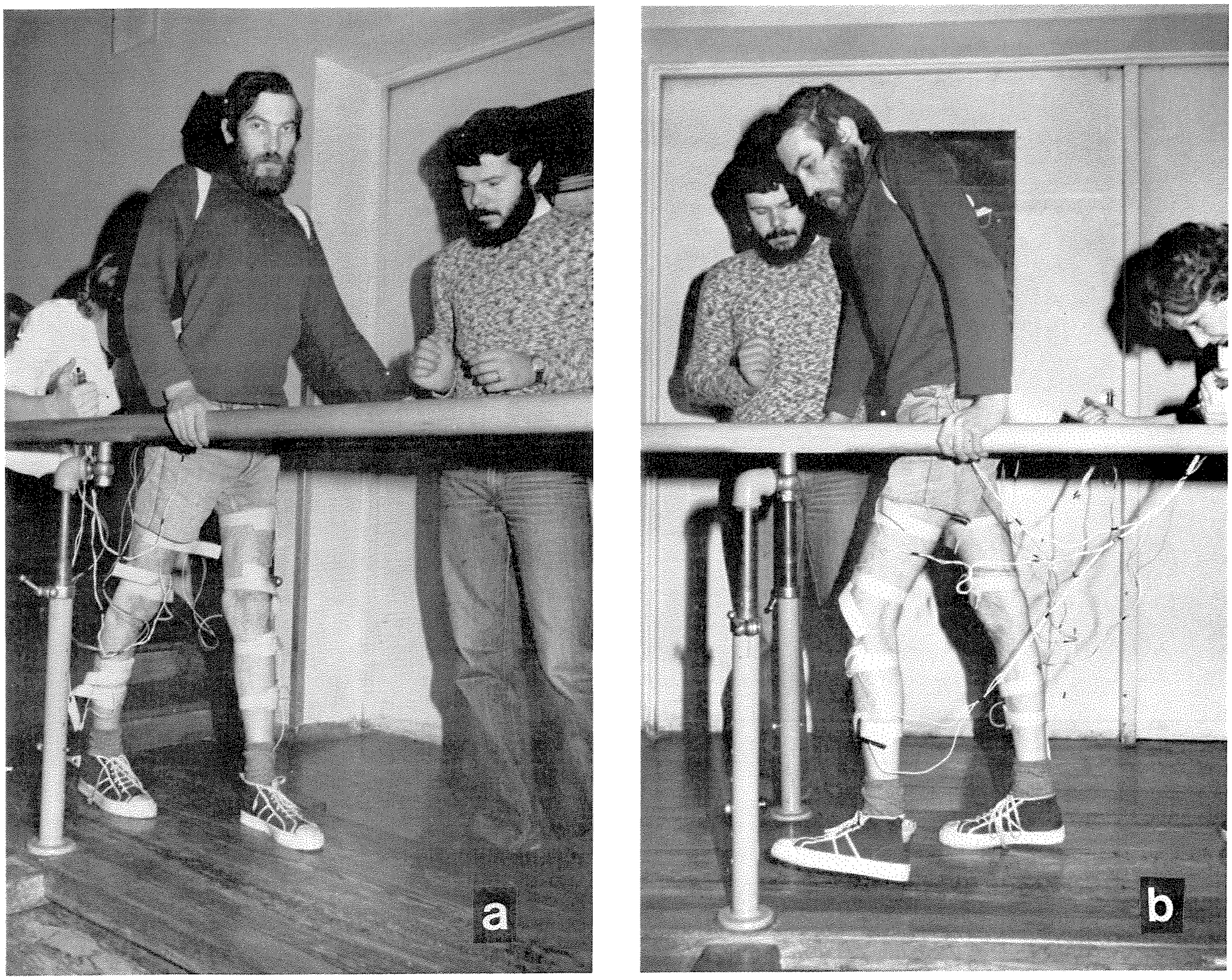


FIGURE 4
Patient No. 1 while walking (a) in double-stance phase and (b) in left swing phase. Excessive side lean can be seen.

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[e] The three patients (No.1, No.2, and No.3) described here are the "best-performing" subjects from the 17-patient clinical series of this research program, as noted earlier. They are also discussed under "General Methodology" and "Clinical Observations", elsewhere in this paper.

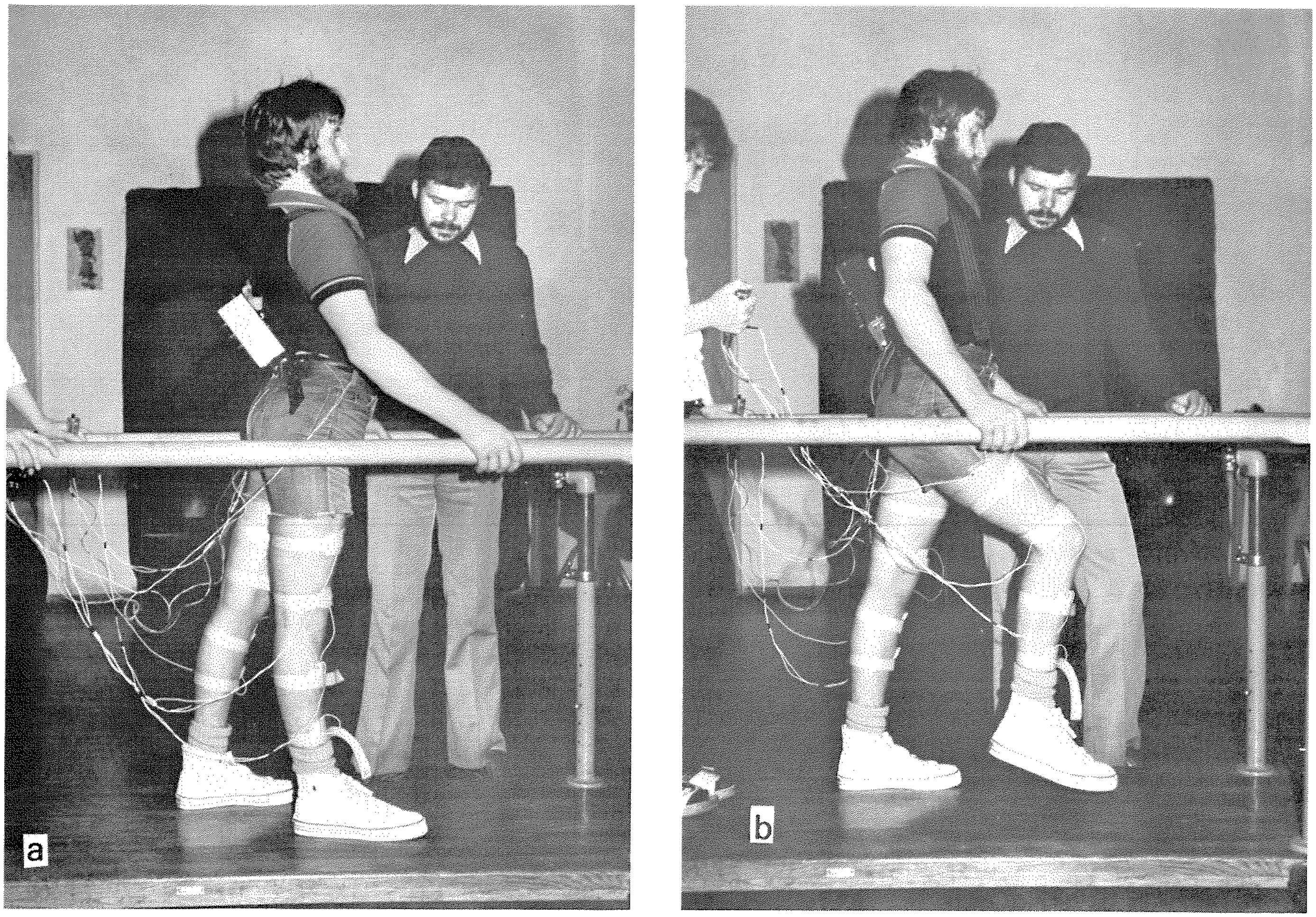

FIGURE 5
Patient No. 2 during double-stance (a) with applied electrodes for 4- channel and 6-channel stimulation, and (b) during swing phase.

In accordance with the findings for the third patient (No.3), a 4-channel FES sequence was adopted (M. quadriceps and flexion-reflex stimulation bilaterally). This patient also tried to control the stimulation events himself, using switches placed into the handles of a roller-walker. This arrangement enabled better coordination of preserved body movements with the movements produced by the stimulation. In such gait the roller-walker was used for providing balance and partial support. It also afforded better mobility and hence longer runs. This third patient is shown walking in Figure 6. (In Figure 6 the knee strap fastens two electrodes.)

One would expect that the extension-patterned spasms would have interfered with the stimulation for obtaining flexion, but this did not occur for us in our patients—the flexion-reflex stimulation overrides the extension pattern. All of these three patients reported that FES decreased their "spasticity".

Most of the other SCI patients in the FES program also reported decreased spasticity as a result of stimulation. In some patients, FES similar to that used for the muscle restrengthening is used prior to walking for about 30 minutes to reduce spasticity. In some patients, FES exercising of hip extensors and abductors was introduced for reducing adduction and/or hip-flexion spasms, particularly in patients with shortened hip flexors because of prolonged sitting. During the standing-up the hip flexors are stretched,which frequently triggers hip-flexion and abdominal spasms. With adequate hip-flexor stretching, this problem can be minimized and in a period of 2–4 weeks, overcome.

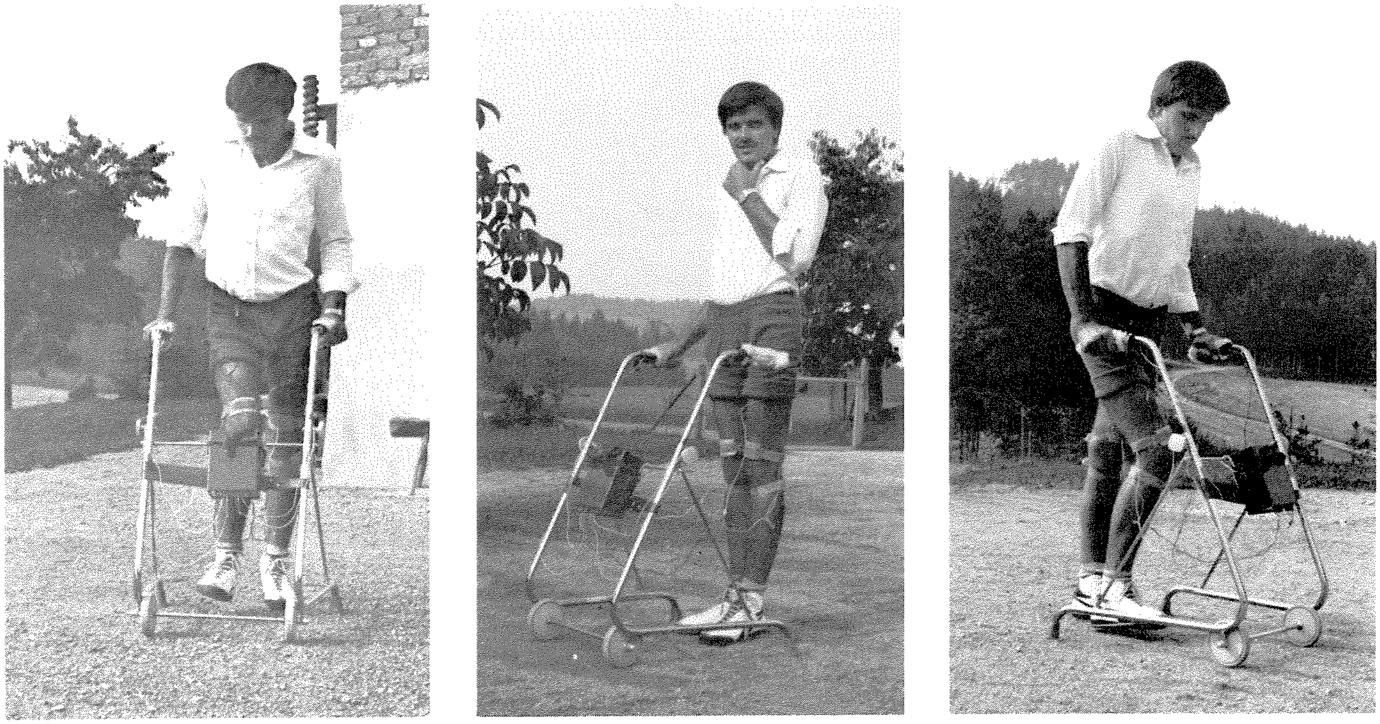

FIGURE 6
No. 3 patient walking outside. Good stability but excessive pelvis shifting can be seen (a, b, c).

CLINICAL OBSERVATIONS

Patient Selection: A Backward Look

As noted earlier, because of lack of previous experience no patient-selection criteria were available. Initially, traumatic lesion patients were selected, having no medical problems, and with a stable spine. They were all well along in their rehabilitation. Most of the selected patients were neurologically characterized as patients with complete lesions.

It has proved desirable to minimize the relatively long muscle restrengthening time. This time appears to be shortest in patients with slight spasticity and who start approximately 6–12 months after injury. These patients in most cases did not have substantial disuse atrophy and no contractures or other problems (e.g., no pressure sores, obesity, etc.).

In most cases patients having mild spasms turned out to be the best suited because of the well-preserved muscles. (Patients with severe spasticity also had well-preserved muscles, but in most cases they also had contraindications such as "tight" joints or even contractures.) Patients having pressure sores, or who are obese, or not cooperative, or who have contractures, etc., are least suitable.[f] In Table 1 the major indications for patient selection are given, and in Table 2 the major contraindications are listed: these lists reflect the data, experience, and opinions acquired and developed over the course of the work described here.

From a neurological point of view, the most suitable candidates are patients having some preserved innervation to the long upper-back muscles, with respiratory reserve and some trunk control. The data so far have indicated that patients with lesions between T5 and T12 are the most suitable candidates.

If during the initial evaluation of the patient the left-side and right-side muscle forces are found to be substantially different, those patients are not suitable for FES.

Frequently patients have joint stiffness with associated spastic muscles, such as hip-joint flexion contracture and plantarflexion contracture associated with spastic M. gastrocnemius and M. soleus. In most cases the spasticity can be reduced with FES exercising (18, 25). The stimulation of agonist muscles can inhibit spasticity by reciprocal inhibition of the antagonists, or the stimulation of spastic muscle can result in lowering of spasticity by several possible mechanisms discussed elsewhere (25).

The muscle-restrengthening FES procedure is combined with FES for inhibition of spasticity if necessary. Based on the severity and the synergy of spasticity, an appropriate FES pattern is selected. We frequently use the stimulation pattern of unilateral stimulation of M. quadriceps (if needed, other extensors are added), combined with opposite-side flexion-reflex withdraw-

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[f] Professor Kralj has pointed out that, while patients with pressure sores and other problems were not used in the research reported here, such individuals are not necessarily excluded from the use of FES once their problems are cured, if they then conform with the selection criteria as outlined in Tables 1 and 2—Editor.

al movement stimulation.

Restrengthening: Procedures, Effects

The duty cycle for a single-muscle restrengthening (e.g., M. quadriceps) is selected with a ratio such as 1:2 (2 seconds on and 4 seconds off), or perhaps 1:3. Shorter duty cycles (longer stimulation times) result in rapid neuromuscular function transmitter depletion, and cessation of movements. We believe the aim of muscle restrengthening is better served if the muscles have the opportunity to become fatigued because of work; that is why longer duty cycles (4 s on and 8–12 s off) seem to be more appropriate.

It should be stressed that at this time the optimal restrengthening procedure which would provide the best force increase and longest fatiguing time is not known. Nor do we know how to select the stimulation for best spasticity inhibition, or how in general to fit the FES program to the patient for optimal results. Obviously the initial joint angles, duration and timing of FES loading of muscles, etc., are important, but at present no scientifically proved criteria are available for their selection. However, in nearly 80 percent of the 17 treated patients of the present study, the muscle strength increased and fatiguing decreased. In addition, we observed improved skin condition which we attribute to improved blood supply. Similiar results have been noted and reported by other researchers (2, 3, 6, 8, 9). Additional research is needed to provide more knowledge and for establishing the methodology for prediction of results of the FES strengthening program.

The results for spasticity reduction associated with FES are very unpredictable. At this point, measurable improvements can be observed in only 50 percent to 60 percent of the patients.

Three Patients: A Record of Improvement

The data from the three patients mentioned earlier (from our series of 17) are described in detail here.

Patient No. 1, age 31, had a complete traumatic lesion at T5, caused by automobile accident. The patient was admitted to the program 12 months postinjury after the completion of standard rehabilitation.

Patient No. 2, age 25, with a traumatic complete lesion at T10, was admitted to the FES program after completion of rehabilitation, several months postinjury.

Patient No. 3, 23 years old, suffered a car accident resulting in complete lesion at T5 and was admitted to the FES program two years after the injury.

Up to now only these three patients have been closely examined with regard to the feasibility of gait restoration by means of FES. The results of this gait restoration are here described chronologically—with each patient we gained some knowledge and were able to improve the application method.

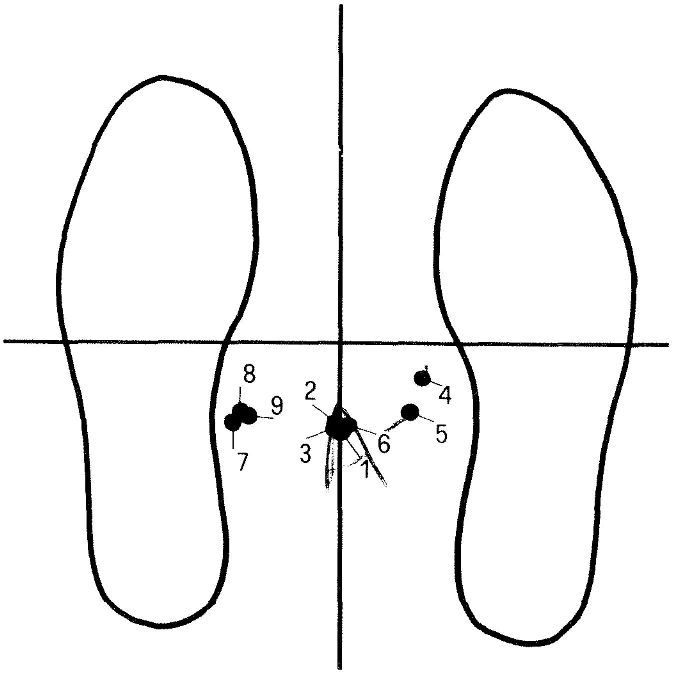


FIGURE 7
The vertical ground-reaction force vector location. Points 1, 2, 3 and 6 for quiet standing; the points 7, 8, 9 and 4, 5 have resulted because of weight-shifting caused by FES.

The first patient of these three underwent extensive testing and training, starting in August, 1978, before attempting the first step. Much effort was made in regard to safety and to ensure that no injury was likely; this was particularly important because of the possibility of collapsing, which could cause more injury. After prolonged standing (of at least 20–30 minutes) was mastered and the patient was familiar with the erect standing posture, teaching for single-limb stance began.

In Figure 7, the points 1, 2, 3, and 6 represent the positions of reaction for quiet standing. Points 7, 8, 9, and 4 and 5, represent the shifting of ground-reaction vector caused only by FES of hip abductors. Clearly, transfer of ground-reaction vector beneath a single leg is hard to produce by use of FES alone. Therefore, in most cases, the patient was taught to assist the body weight transfer to one limb by means of arm control. FES of hip abductors was in most cases then unnecessary.

At this stage the patient started to walk in parallel bars. Good physiotherapy assistance was secured. The physiotherapist, behind the patient, verbally instructed the patient to transfer the body weight with commands like "left" and "forward right", etc., at the same time pressing the switches for terminating the stance-phase stimulation in the leg which instantly received stimulation for the swing phase as described

FIGURE 11
The average ground-reaction forces record. It is seen that the supporting force is mainly located at the arch region of the foot, and the force supporting vector displacement is narrow and does not use, as in normal gait, the whole sole length.

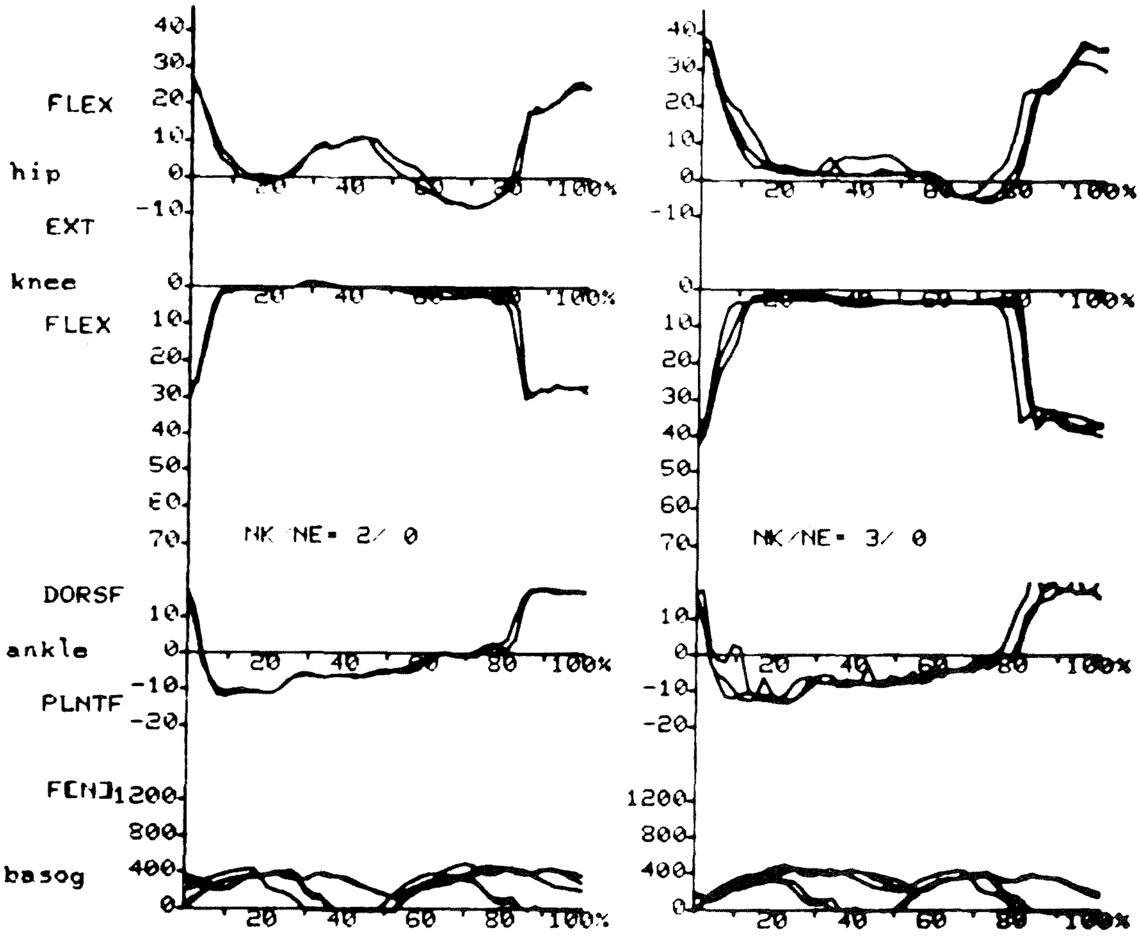


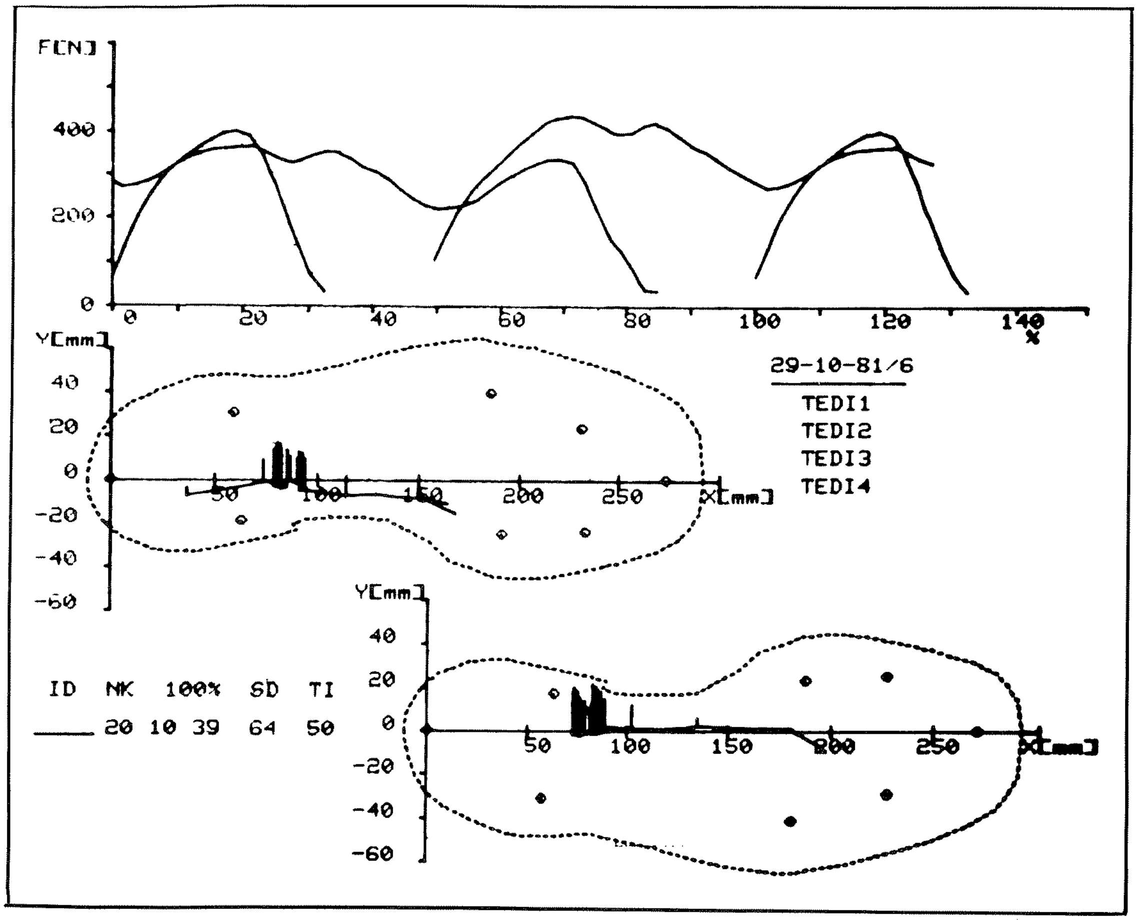
FIGURE 10
The consecutive records of goniograms for 2 left steps and 3 right steps of No. 3 patient.

with the knees extended and locked. The goniograms of this gait mode have no similarity with plots of normal gait; that fact is more easily recognized if we analyze the ground-reaction forces record shown in Figure 11. The average record is shown for the first run of (NK=20) 20 steps. The average stance time lasts 82 percent and the swing time is only 18 percent of the stride cycle, compared to normals where the corresponding numbers are 60 percent versus 40 percent. The double-stance time lasts 27%–32% of a stride. In Figure 11 we recognize that the horizontal axes time interval 0–27 corresponds to the double-stance time, the horizontal time interval 27–47 to the swing phase, and the duration 0–84 to one step vertical force record (starting by the lower part and ending by 84-lower trace). The time scale is given for the records in Figures 11, 12, and 13 in percentages of the stride time (which is 11.2 s).

Figure 9 shows a relatively narrow field of standard deviation and the same is true of the vertical force plot in the ground-reaction record given in Figure 12 for the second run. In Figure 12 the average ground-reaction vertical force is displayed (solid line) for 26 steps; the standard deviation range is displayed by the dotted line.

In Figures 11, 12, and 13 the locations of the force

FIGURE 12
The ground reaction forces displayed together with the standard deviation for 26 steps. Also the spatial distribution of the center of pressure is shown.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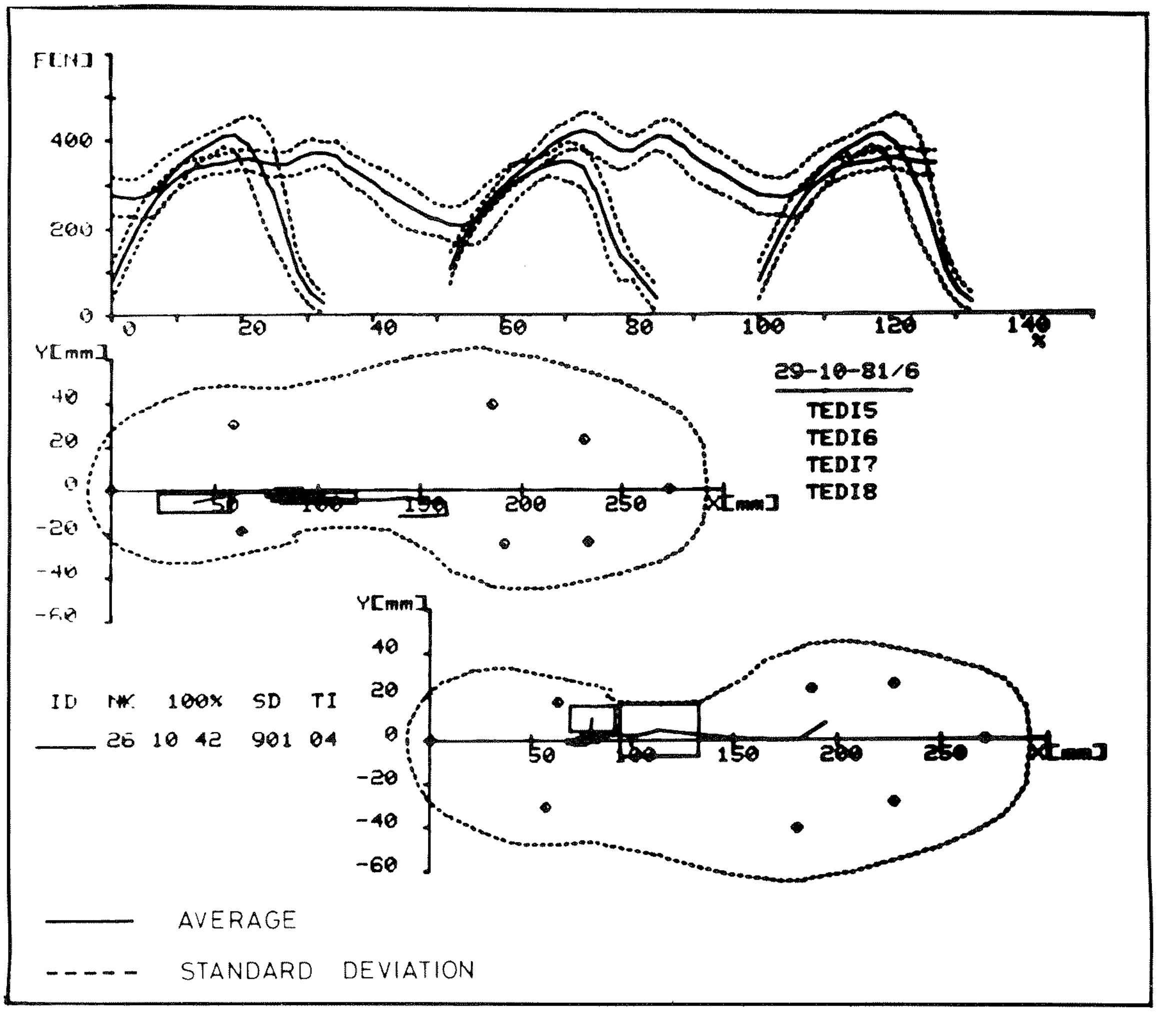
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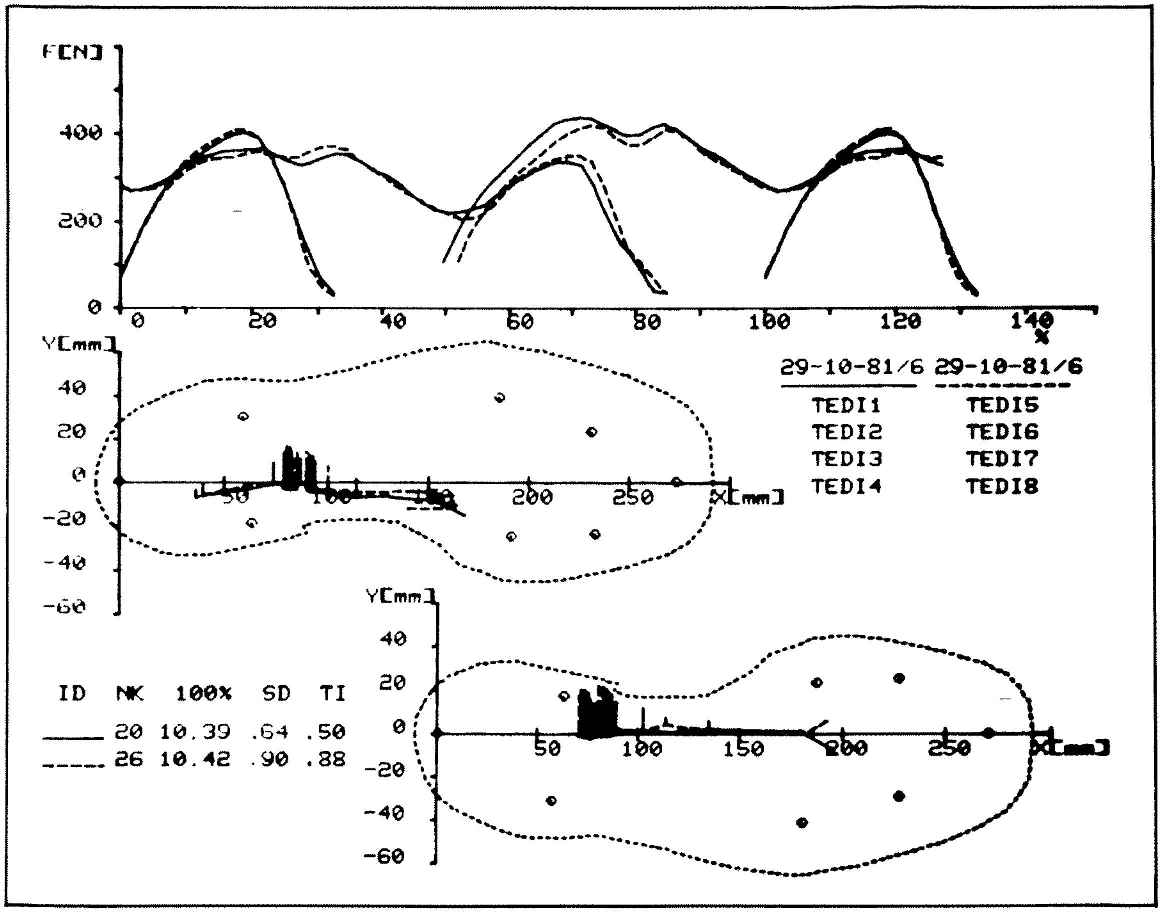

FIGURE 13
The comparison of ground-reaction forces plots for run 1 and run 2. Good repeatibility and symmetry can be seen (solid line = first run, dashed line = second run).

pick-up transducers (all together eight on each force-shoe) are shown together with the shoe contour. The force shoes are made by Kljajic, et al. (26, 27) at the Josef Stefan Institute in Ljubljana and have proved to be very convenient for statistical kinetic gait studies.

In Figure 12 also, the ground-reaction vertical force vector trajectory is plotted along the shoe sole. The height of the vertical lines (Figure 13) pictured on the force-vector trajectory plotted across the shoe sole represents the actual force amplitudes and their locations in time (intervals of TI=0.50 in Figure 13). In Figure 12, the rectangles plotted onto force displacement trajectory display the standard deviation range for both X and Y displacements.

The average records for vertical force and vertical force-vector displacements versus distance and time for both runs are plotted in Figure 13. Again it can be seen that the gait was symmetrical, and showed good repeatability. The ground-force supporting vector displacement is very narrow and relatively stationary. For nearly 90 percent of the stride time, the vector remained in the area of the foot arch.

Patient No. 3, even after walking for a relatively long time, (60 minutes or more), did not complain of being tired, but at this state of our work we have not yet tried to confirm the assumption that the FES-generated biped gait does have the important characteristic of low power consumption which is associated with the normal biped gait mode.

DISCUSSION

This preliminary research work should be understood as a feasibility demonstration. The work described has shown that perhaps as many as 80 percent of paraplegic patients who conform with the selection criteria (Table 1 and Table 2) are able to stand for prolonged periods by means of surface FES, and standing balance sufficient for performing single-limb support required during biped gait has been routinely achieved. The patients were able, in spite of their relatively high lesions (even at T5) to control the trunk alignment by means of trunk-leaning movements with the help of their remaining voluntarily controlled long body muscles (M. erectus spinae, M. rectus abdominis, M. latissimus dorsi, etc.) and the hands.

The multichannel surface FES described did enable paraplegic patients to exert simple biped gait patterns if they were assisted by parallel bars or a walker. It was demonstrated that the patients were able to walk for reasonably long periods and over moderate distances. One patient ambulated even if unattended.

Additional research is needed to refine and improve this method to make it functional and safe for daily use by paraplegic patients. If this work is pursued it seems that functional standing enabled by FES need not be very far from being implemented in daily life.

Implanted Electrodes: the Probable Method—The experience gained so far has shown that patients' acceptance will probably usually be better if FES is delivered by means of an implanted stimulator. And although as investigators we hope that much more knowledge regarding the restoration of paraplegic patients' gait enabled by FES can be obtained by using surface electrodes, we nevertheless believe the orthotic FES via implanted selfcontained units will prove to be the practical and suitable method for the daily use by patients.

Preserved Reflexes and Feedback

The paraplegic patient represents a unique and complicated system not yet fully understood. The results reviewed here have shown clearly that research is warranted toward better understanding and control of the biomechanical events associated with gait restoration by means of FES. Together with this, more information must be gained regarding the functional use of preserved reflex organization of the transected spinal cord. Research for implanted multichannel FES devices, and nerve electrodes, must be stressed.

In regard to biomechanical problems, we intend to conduct research in the biomechanics of standing-up, weight-shifting between supporting legs, and the muscle coordination associated with different events in gait. Research aimed toward the possibilities of increasing gait speed, biomechanical understanding, improved control, stability, and other events in a multichannel FES-assisted gait is needed. Further attention should be paid particularly to the biomechanical problems involved in controlling gait direction changes by FES.

All the described activities might be performed better and more simply if biofeedback could be added. And for all the mentioned topics, the control problems should be studied with the goal of developing patient-activated control. At the end of our discussion, without arguing, it can be imagined that FES-assisted paraplegic gait is a new alternative mode for locomotion in the rehabilitation of some of these patients, and a means of overcoming barriers posed to them ■

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