Research Report

The Rehabilitation of Gait in Patients With Hemiplegia: A Comparison Between Conventional Therapy and Multichannel Functional Electrical Stimulation Therapy

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Background and Purpose. *Gait rehabilitation in patients with severe hemiplegia requires substantial effort. Preliminary studies indicate potential beneficial effects of using multichannel functional electrical stimulation (MFES) for gait rehabilitation in these patients. In this study, a new method of gait rehabilitation for nonambulatory patients with hemiplegia by means of MFES added to conventional therapy was introduced. The results of the method's application were evaluated by comparing it with conventional therapeutic methods.* ***Subjects.*** *The proposed rehabilitation method was tested on a group of 20 patients with severe hemiplegia secondary to cerebrovascular accident. Subjects were randomly assigned to one of two groups. One group received 3 weeks of MFES followed by 3 weeks of conventional therapy. The other group received 3 weeks of conventional therapy followed by 3 weeks of MFES.* ***Methods.*** *The effects of each therapeutic method were evaluated by measurements of temporal-distance variables and ground reaction forces and by assessment of each subject's physical status according to the Fugl-Meyer evaluation scale.* ***Results.*** *There was improved performance of the subjects during MFES combined with conventional therapy as compared with conventional therapy alone.* ***Conclusion and Discussion.*** *The superiority of the MFES method as compared with conventional therapy was mainly attributed to the enhanced motor learning accomplished by application of MFES. These results, however, are preliminary, and further research is needed. [Bogataj U, Gros N, Kljajić M, et al. The rehabilitation of gait in patients with hemiplegia: a comparison between conventional therapy and multichannel functional electrical stimulation therapy. Phys Ther. 1995;75:490–502.]*

Key Words: *Electrotherapy, Functional electrical stimulation, Gait, Gait rehabilitation.*

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In patients with hemiplegia, the gait pattern is often destroyed. In mild cases, the damage is not extensive, which usually enables patients to start gait training immediately after stabilizing their medical condition. After finishing a rehabilitation program, some anomalies in gait remain in some patients, whereas in other patients there are no anomalies in gait. The situation is quite different in patients with severe involvement, which refers to the extent of impairment as a consequence of central nervous system lesion size. These patients are often bedridden for a prolonged period of

time. Muscle weakness due to inactivity and disturbed muscle control are usually accompanied by balance problems, disturbances in proprioception, contractures in joints, cognitive dysfunctions, aphasia, emotional lability, and so on.[1] In such patients, the relearning of gait is very difficult and long-lasting. The patient must learn to stand and perform independent straight standing, shifting weight from one leg to another and maintaining balance. We believe muscles must be strengthened by physical exercises or functional electrical stimulation. At the same time, the patient must regain confidence in the ability to use the affected side. In many cases, synergistic movement patterns develop (flexor or extensor), which additionally disturb coordinated movement.[2] The transition from standing to coordinated ambulation, therefore, represents quite an effort for the patient as well as for the therapist.

Soon after the introduction of single-channel functional electrical stimulators for drop-foot prevention,[3–5] researchers showed a tendency to selectively stimulate the muscles for dorsiflexion of the foot as well as the other main muscle groups in a paralyzed leg.[6–10] Vodovnik et al[6] suggested using a six-channel stimulator for the stimulation of six antagonistic muscles of the affected limb during gait. This started a period of development of different multichannel stimulators and study of control principles, stimulation sequences, correction of gait anomalies, and therapeutic effects of multichannel functional electrical stimulation (MFES).[7–13] Recent kinesiological studies and clinical assessments showed that surface MFES of the six main muscle groups of the affected limb can modify pathologic gait, accelerate rehabilitation, and enhance the endurance of the patient.[14–16] Despite the good results, surface MFES is not routinely used as an orthotic aid because numerous electrodes need to be positioned and patients find this difficult. Therapeutic use of MFES produced effects that were quite substantial during therapy and that tended to fade away 6 to 12 months after therapy.[14,15] The status of the patients, however, was not noticeably better than that of subjects in a nonstimulated control group.[14,15] These are probably the reasons why there are currently no reports on the routine use of MFES in rehabilitation of gait in patients with hemiplegia. Marsolais et al[17] reported the use of MFES for gait in patients with hemiplegia. These researchers, however, are working on the development and application of implantable systems designed not for therapy, but for orthotic use. The same group also reported beneficial results in a single-case follow-up of therapeutic application of MFES with intramuscular electrodes.[18]

Patients treated in previously reported studies were ambulatory patients, where the main reason for MFES application was to correct gait deviations.[12–15] The rapid and good correction of gait anomalies in those patients raised the question of whether MFES could be used to initiate the gait pattern in patients with severe hemiplegia. A pilot study was therefore carried out.[16] The pilot study showed that MFES can help to establish an initial gait pattern and improve weight bearing in nonambulatory patients. The pilot study, however, also showed there was no comparison with existing therapeutic programs.

The purpose of our study was to show the value of MFES added to conventional therapy in the rehabilitation of gait in patients with severe hemiplegia compared with the use of generally accepted methods and techniques of rehabilitation alone.

Method

Experimental Design

Each subject participated for half the time in the experimental procedure and for half the time in a control procedure. To avoid a problem of the bias produced by sequencing procedures, the patients who participated in the study were randomly assigned to two groups with reversed sequences of therapies. This design provides a method for controlling individual differences among subjects. A relatively more complex statistical analysis, however, is required to obtain valid results with such a design.[19] Each subject was monitored following the same methods through the period of 6 weeks, participating for 3 weeks in each therapeutic program.

Subjects

Twenty patients with severe hemiplegia due to cerebrovascular accident (CVA) participated in the study. They were randomly assigned to one of two groups, with 10 subjects in each group. One group started with conventional therapy and continued with MFES therapy, and the other group had the reversed sequence of therapies. To guarantee a random assignment of the subjects, the following method was used. The physician and therapist who were responsible for patient selection never knew into which group the next subject would be assigned. An engineer, however, who also participated in the program randomly assigned each subject to one of the groups before the patient selection and before he had any information about the possible candidates.

Candidates were selected on the basis of neurological, internist, physiatric, and psychological examinations. Subjects were included in our study on the basis of the following indications and contraindications:

1. The cardiovascular system of the patient had to be in such condition that exertion during therapy or measurement would not represent any hazard to the patient's health. Candidates with suspected or confirmed cardiovascular infarction or with a demand pacemaker were excluded.

2. The physical status and motor functions, especially of the lower extremities of the patient, had to be in such condition that the patient could stand independently or with the aid of a therapist. Only patients who required substantial weight-bearing support of one or two therapists (ie, the therapist actually

supported part of the patient's body weight) to ambulate were included.

3. The patient's perceptual and intellectual abilities had to be preserved.

4. Sufficient functional response (as determined by testing the patient's response to functional electrical stimulation in a seated or prone position of each designated muscle separately) or at least muscle contraction with indicated movement in the corresponding joint should be obtained by functional electrical stimulation.

5. Patients with extreme reflex activities (eg, massive reflex activities triggered by a very low stimulus, especially when triggered in the opposite direction to the desired direction), hypersensitivity, pains, lower motor neuron lesions, or changes to the skin in the area of stimulation and in bone-joint structures (eg, contractures, deformations) and patients who refused application of functional electrical stimulation were excluded.

6. Each patient who passed the described conditions was included in the study only on the basis of his or her informed consent to participate.

7. In the event a patient participated in the study and there arose a suspicion or possibility that continued therapy could endanger the patient's health, the program would be interrupted immediately and would be continued only after thorough examination of the patient and with the permission of the physician.

The subjects in group 1 (five male, five female) started with conventional therapy and continued with MFES. The two left-hemiplegic and eight right-hemiplegic subjects in this group ranged in age from 38 to 73 years ($\bar{X}$=53,4, SD=11.5) and in time between CVA and start of therapy from 53 to 273 days ($\bar{X}$=116, SD=66). The subjects in group 2 (six male, four female) started with MFES and continued with conventional therapy. The nine left-hemiplegic and one right-hemiplegic subjects in this group ranged in age from 43 to 75 years ($\bar{X}$=59.1, SD=9) and in time between CVA and start of therapy from 27 to 227 days ($\bar{X}$=104, SD=62). A *t* test showed no difference between the groups for the variables of age and time between CVA and start of therapy. Table 1 shows some basic data about the subjects. In all subjects, the pre-CVA side of dominance was the right side.

Table 1. *Basic Data About Subjects Participating in Study*[a]

Subject No.	Age (y)	Gender	Side of Paresis	T_d (d)	D_i (m)	D_f (m)
Group 1						
1	39	M	R	218	183	600 (7)
2	43	M	R	75	180	400
3	53	F	L	53	109	600 (4)
4	60	M	R	59	42	165
5	73	F	R	129	160	270
6	38	M	R	91	198	600 (13)
7	67	F	R	77	17	186
8	51	F	R	149	33	195
9	57	M	R	76	253	447
10	53	F	L	273	26	212
$\bar{X}$	53.4			116		
SD	11.5			66		
Group 2						
11	63	F	L	125	90	450
12	58	M	L	48	25	215
13	54	M	R	102	90	600 (15)
14	58	F	L	139	72	161
15	67	M	L	116	97	600 (7)
16	43	M	L	51	53	270
17	50	F	L	154	92	350
18	75	F	L	227	60	102
19	59	M	L	27	90	212
20	64	M	L	46	42	209
$\bar{X}$	59.1			104		
SD	9			62		

[a]Group 1 subjects started with conventional therapy and continued with multichannel functional electrical stimulation (MFES) therapy; group 2 subjects started with MFES therapy and continued with conventional therapy. T_d=time elapsed between cerebrovascular accident and start of our program. D_i=initial distance walked by subject on the first day of MFES therapy. D_f=final distance walked by subject on the last day of MFES therapy. If the subject reached the upper limit of 600 m, the number of therapy sessions, when accomplished for the first time, is included in parentheses. D_i and D_f data are not available for conventional therapy.

Conventional Therapy

Generally, the complete rehabilitation program for a person with hemiplegia in our facility lasts from 2 to 3 months, with the patient participating in the physical therapy program for 1 to 2 hours per day. In addition to physical therapy, patients also receive medical treatment, occupational therapy, speech therapy, sessions with a psychologist, sessions with a social worker, and a cultural program.

Before an adequate program of therapy could be prescribed, each subject's status was assessed and his or her past medical history, social history, and communication skills were evaluated. This assessment of the subject's status comprised information about the subject's functional level (reflex status, range of motion, coordination, sensation/perception, voluntary control, and activities in changing the positions [eg, standing up, sitting down, getting out of bed]), with special emphasis on gait evaluation.

The subject's functional abilities, or abilities to perform different movements or tasks (eg, pattern movements, selective movements, standing up, maintaining standing, walking) were the basis for treatment. There was no general pattern of therapy that would apply to all subjects. Each subject received the therapy adapted to his or her abilities, deficiencies, and needs. Three therapists were involved in the treatment. The same therapist worked with an individual subject throughout the program of conventional treatment. In general, the conventional treatment consisted of a passive and active approach.

With the passive approach, we wanted to reduce reflex activity, increase or preserve the range of motion in the joints, and enhance sensory input. To accomplish these goals, icing, heating, and brushing were applied, and the subject was placed in different positions (eg, sitting, "verticalization" on a tilt table [with the subject secured lying flat on the tilt table, the tilt table is slowly or gradually shifted into the vertical position]). Each of these modalities was usually applied separately. For some subjects, however, a combination of modalities was used (eg, application of heating for improved elbow mobility and application of icing to the biceps brachii and triceps brachii muscles for reduction of reflex activity).

The emphasis was on active methods with the purpose of normalizing posture and facilitating activities to achieve functional movement (Bobath technique,[20,21] proprioceptive neuromuscular facilitation,[2,20–22] biofeedback exercises[23]). The decision of which therapeutic approach or combination of approaches was to be used was made by each subject's therapist according to the therapist's professional training, personal preferences, and experience and status of the subject. For all subjects, different kinds of visual and audiovisual biofeedback devices (from mirrors to electromyographic biofeedback) were used. When the subject reached conditions for gait (ie, able to support most of his or her weight, maintain balance with some support, perform stepping, and so forth), he or she started gait training using a passive ankle-foot orthosis or knee-ankle-foot orthosis.

The therapy program was conducted at the Institute of the Republic of Slovenia for Rehabilitation in Ljubljana, Slovenia. All of the participating subjects were hospitalized in the center for at least the duration of our program (approximately 6 weeks).

Multichannel Functional Electrical Stimulation Therapy

Surface electrical stimulation was applied on the peroneal nerve for ankle dorsiflexion, the soleus muscle for ankle plantar flexion, the hamstring muscles (biceps femoris, semitendinosus, semimembranosus) for knee flexion, the quadriceps femoris musculature (rectus femoris, vastus medialis, vastus lateralis) for knee extension, the gluteus maximus muscle for hip extension and stabilization of the pelvis during stance, and optionally the triceps brachii muscle for reciprocal arm swing during the swing phase of gait for the ipsilateral leg. The stimulation sites were determined with cyclic stimulation before commencing the therapy. The same stimulator, of our own design, was used to determine the stimulation sites and to perform the MFES therapy. For gait, the stimulation sequences (described in the "Instrumentation" section) are triggered according to the signals from the footswitches. Optionally, the stimulation sequences can be triggered by an internal timer. The rate of the timer can be selected in a range of 1 to 5 seconds' duration for the stimulation sequence of the whole stride cycle. A repeated stimulation pattern of a 3-second stimulation train followed by a 1-second pause was usually used for stimulation site selection.

With the subject in a seated or prone position, one pair of electrodes (described in the "Instrumentation" section) were shifted along each muscle or muscle group selected for stimulation until an optimal response was obtained. When determined, the sites were marked on the skin with nonconductive, semipermanent ink. Amplitudes were raised until the functional response was satisfactory, or up to the level at which the subject still felt comfortable with the sensation if the functional response was unsatisfactory. A satisfactory functional response can be defined as actual movement in the joint performed by the stimulated muscle during functional electrical stimulation without any volitional movement performed by the patient (eg, functional electrical stimulation of the hamstring muscle should result in knee flexion in the range of 0°–70°). Stimulation was applied if increased muscle activity was assessed in the elbow flexors (eg, the subject relaxed the impaired arm and the arm remained in a position of 90° of elbow flexion, or the subject attempted passive extension of the arm and resistance could be felt). Stimulation was applied to the triceps brachii muscle during the swing phase of the ipsilateral leg to induce arm movement coordinated with gait (arm swing in the direction of elbow extension during the swing phase of the ipsilateral leg) to relieve the muscle activity, to prevent muscle subluxation,[24] and to break associated reactions.[2]

The following day, when commencing gait, the amplitudes of the stimulating pulses were set to about 80% of the previously determined value because muscle response on functional electrical stimulation in a standing position is different than in a seated or lying position. We believe excessive stimulation on all channels could disturb the patient instead of providing assis-

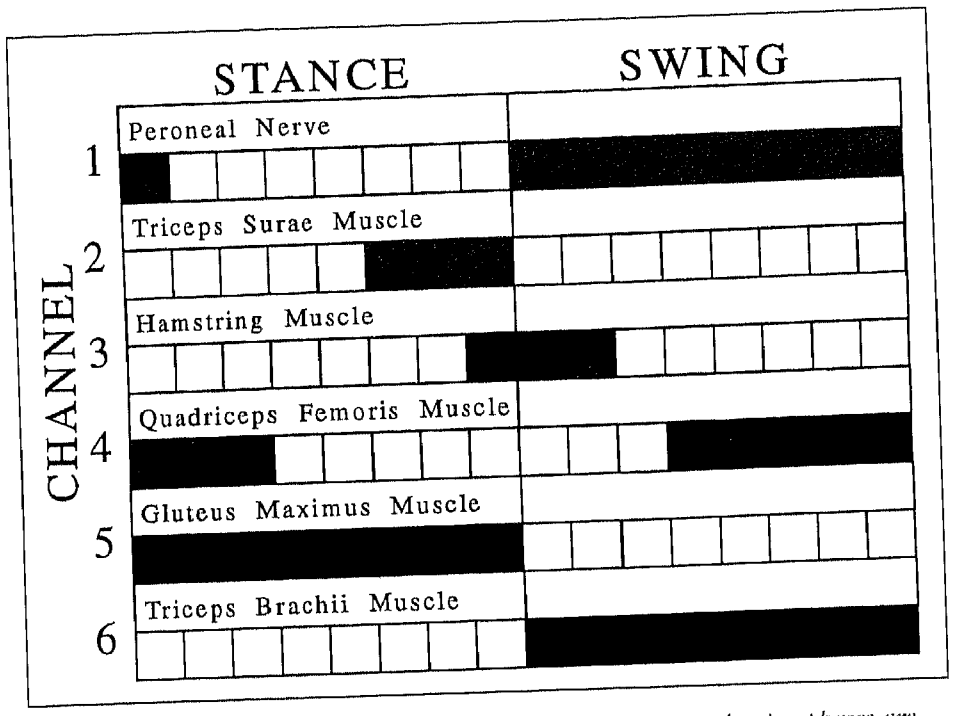

Figure 1. *Initial pattern of stimulation sequences. Stance and swing phases are each divided into eight equal time segments, which are represented by squares. Black squares represent stimulation on, and white squares represent stimulation off in the corresponding time segment of the stride phase (eg, in channel 3, stimulation of the hamstring muscle starts in the last one eighth of the stance phase and ends after two eighths of the swing phase).*

tance. All of the subjects started gait using a crutch on the nonaffected side. The order of switching channels on was different from subject to subject. The deficits in gait were the basis for the order. Each subject's first steps were begun with the stimulation of the peroneal nerve, and after several steps other channels were one after another gradually switched on. This was done for a period of approximately 10 steps. This procedure was performed only in the first two or three therapy sessions. Later, the subject started gait with all channels on immediately.

The therapist accompanying the subject, supporting him or her on the affected side, induced weight shifting from one leg to the other (by holding the subject's pelvis and shifting the pelvis laterally in the direction of the loaded leg), helped the subject perform a step by rotating the subject's pelvis, and provided some other essential instructions. In subjects with disturbances in coordination, another therapist assisted each subject in shifting and loading the crutch. Gradually, according to the progress of the particular subject, crutch assistance was reduced and gait support diminished. The MFES therapy session generally lasted from 30 minutes to 1 hour, including the application of electrodes.

In MFES therapy, the same therapist worked with all subjects. In all MFES sessions, an engineer was also present to operate the stimulator according to the instructions of the therapist, because the therapist was engaged in guiding and supporting the patient and could not handle the stimulator as well. The engineer adjusted the amplitudes and stimulating sequences, checked the correct operation of the stimulator, and was also needed in the event technical problems occurred.

An individualized stimulation sequence was determined for each subject, starting with a general initial pattern (Fig. 1) and modifying it during the first couple of stimulation sessions. Modification of a stimulation sequence consisted of prolonging, shortening, and shifting the stimulation cycle with regard to the foot-on and foot-off events of the gait cycle. A trial-and-error approach based on previous experience was used for the correction of stimulation sequences until an optimum correction of anomalies was achieved. This optimum correction was usually achieved during the first two or three sessions. The stimulation sequence was, in some cases, modified once more during the therapy if the subject developed some new gait anomaly (eg, knee hyperextension). In subjects with extensor synergy, more attention was paid to the stimulation of selected flexor muscles. Selected extensor muscles were stimulated with lower intensities so that reflex activities were not triggered. Similarly, we acted in the case of flexor synergy, where the extensors were stimulated to enable the subject's own extremities to bear the weight and make a step. The flexors were stimulated with a lower intensity. For hyperextension of the knee, knee flexors were stimulated during the second half of the stance phase and oral instruction was used to teach the subject to control his or her knee. For insufficient extension of the knee at the end of the swing phase, the quadriceps femoris muscle was stimulated.

During the MFES therapy period, the "conventional" gait therapy was replaced by MFES-assisted gait training. In our study, all subjects continued to attend their other prescribed programs. The MFES group, therefore, reflects the effects of MFES superimposed on a traditional method. Each subject participated in one therapy session per day (MFES or conventional therapy), five times a week. No therapy sessions were conducted on Saturdays and Sundays so that the subject could rest and go home for the weekend.

The subjects walked on a 100-m walkway. At the beginning of MFES therapy, the subjects walked a short distance, walking again after a rest period. The initial distance depended on the subject's ability to avoid over-

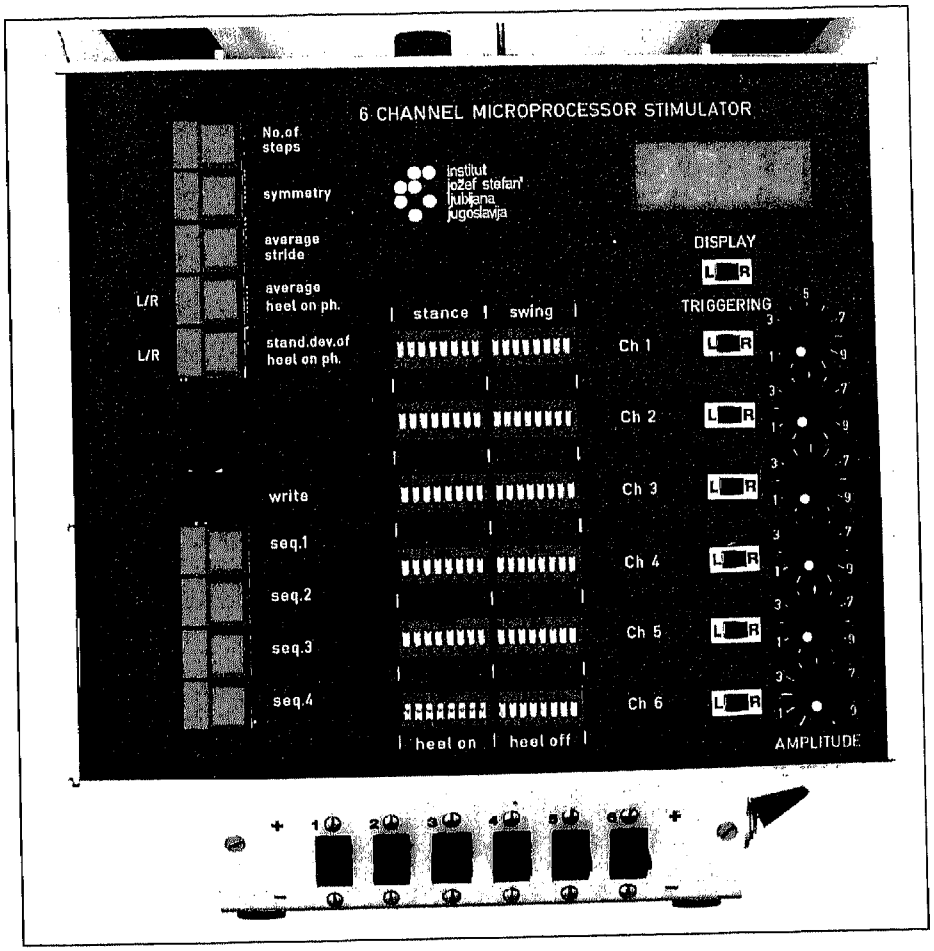

Figure 2. *Six-channel stimulator used in therapy.*

exertion, or it was determined by the subject's physician. During the course of treatment, the distance was gradually increased. The subjects, however, were instructed not to ambulate more than 600 m per session because they had to save some strength to participate in other rehabilitation programs. The distances that each subject walked on the first and on the last day of MFES treatment are shown in Table 1.

Instrumentation

The stimulator used in MFES therapy in this study contained six independent, galvanically separated channels (ie, no cross talk between channels) with intermittent rectangular monophasic stimulation pulses.[29] The selected stimulating sequence on each channel was triggered by a left or right footswitch of our own design. Each footswitch consisted of three switches connected in parallel, mounted into an insole, and positioned one under the heel, one under the head of the first metatarsal, and one under the head of the fifth metatarsal. The amplitude of stimulation pulses was set between 0 and 120 V in each channel separately. Frequency and pulse duration were preset to 30 Hz and 200 microseconds for all channels and were not varied. The maximum stimulating current was limited to 50 mA. No modulation of amplitude and pulse duration was used at the beginning and end of the stimulation sequence. Stimulation timing during one gait cycle (the stimulation sequence) was timed for each channel using 16 switches, 8 for the stance phase and 8 for the swing phase (Fig. 2). Each switch represented one eighth of the stance or swing phase. When the switch was on, stimulation occurred during the corresponding time interval of the stride phase. The durations of stimulation sequences were automatically adjusted to the walking rate of the subject by a microprocessor incorporated into the stimulator, permitting a stride time of up to 7 seconds. The durations of the stance and swing phases for both legs separately were extrapolated according to the durations of the last four phases, which were measured according to the signals from the footswitches.

We used 5×9-cm self-adhesive Pals Flex electrodes* or 5×8-cm felt pad electrodes of our own design for the stimulation of larger muscles (ie, quadriceps femoris, hamstring, gluteus maximus) and 5×5-cm electrodes for smaller muscles (ie, soleus, triceps brachii). We used 2.5-cm gauze button electrodes of our own design for peroneal nerve stimulation. The felt pad and button electrodes are soaked with tap water and fixed in position with elastic bandage. The felt pad electrodes, which were used in the first five subjects, were later replaced by self-adhesive electrodes, which enabled faster and simpler application. One pair of electrodes per channel were applied to the designated muscle or muscle group.

The stride analyzer, which is an integral part of the stimulator, enabled us to record the following gait measurements during stimulation without any additional equipment: number of strides, mean stride time, temporal symmetry, and mean stance times with their standard deviations for both legs. The temporal symmetry of gait was calculated as the ratio of the stance time of the left leg to the stance time of the right leg. All these gait measurements were derived and calculated from the signals from both footswitches. The data were displayed on the stimulator by pressing the corresponding push buttons after each session. The total walking distance was measured during each session,

*Axelgaard Manufacturing Co Ltd, 104 W Elder St, Fallbrook, CA 92028-2852.

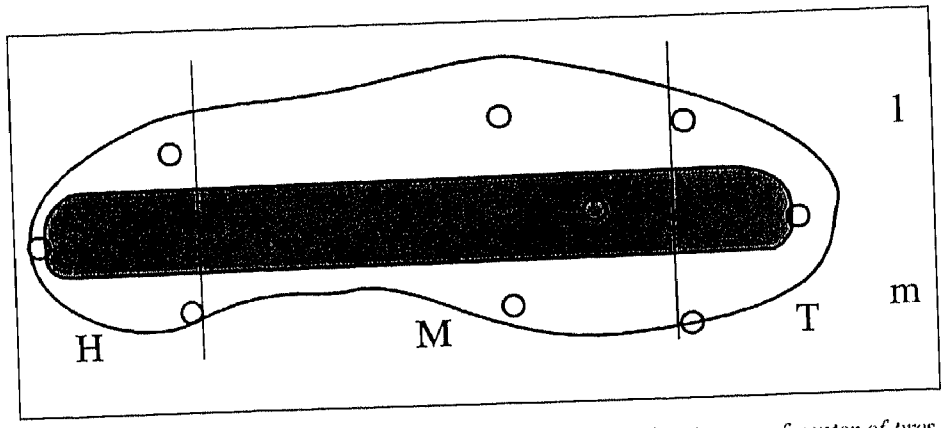

Figure 3. *Presentation of sole areas for classification of trajectory of center of pressure patterns. (H=heel region, M=middle region, T=toe region, l=lateral area, m=medial area.)*

which enabled us to calculate mean stride length (total distance by number of strides) and mean gait speed (mean stride length by mean stride time). These variables gave the therapist some information about performance that was used to optimize the stimulation sequences. These data were used for instant monitoring of the course of therapy and are not presented in this report.

At the beginning, middle, and end of the therapy period, the patient's gait was measured by a ground reaction measuring system. The general physical status of the patient was also evaluated according to the Fugl-Meyer evaluation. The ground reaction force measuring system enables us to measure the resultant vertical ground reaction force and the trajectory of center of pressure (TCP) under each foot through the stance phase.[26] The measuring system included five sizes of leather shoes with nine force transducers inlaid in each sole. The shoes were connected by cable through amplifiers to a PC-AT computer for data acquisition and off-line processing. One or two force-measuring crutches could optionally be connected to the same system. Stride length and speed were measured by a potentiometer with a wheel attachment and a fishing line attached to the subject.[27] The sampling frequency was 50 Hz. No filtering of raw data was performed. Measurements were taken with the subject walking on a 20-m walkway. Usually three runs were necessary to get a total of at least 30 regular strides. All of the measuring equipment has an accuracy of better than 5% (maximum error).

The measurements described are mostly aimed at measuring kinetic and kinematic variables during gait, but they tell little about the functional status of the patient. We therefore decided that an evaluation of each subject's physical performance should be made. We selected a Fugl-Meyer evaluation system[28] that is designed to evaluate motor function, balance, several sensation qualities, and joint function in patients with hemiplegia. The test was performed by all subjects and administered by the same therapist (NG). This test results in a cumulative numeric score (range=0–226 points), where a higher value represents better performance. The test evaluates the affected side and is divided into several parts: upper extremity, lower extremity, balance, sensation, and passive range of motion and pain. There are few different tests described in literature.[29–31] The Fugl-Meyer test was chosen because the test is designed for the evaluation of patients with hemiplegia and there are many reports on the use of this test.[32–34]

Statistical Procedures

The effects of the compared therapies were evaluated according to the following measured variables: mean gait speed, mean stride length, mean gait cadence, Fugl-Meyer test, and TCP. Each subject was measured at the beginning of therapy, at the middle of therapy when the treatment methods were alternated, and at the end of therapy. According to the selected experimental model, a multivariate analysis of variance (MANOVA) of results was performed on the first four variables.[35] Three factors were evaluated in the design: order of treatment (conventional/MFES, MFES/conventional), side of impairment (left, right), and performance of the subject (first, second, third). These factors led to a 2×2×3 MANOVA, with the first two factors being between-subjects factors and the last factor being a within-subjects (repeated-measures) factor. The performance of the subject was determined by a set of four measures: gait speed, stride length, gait cadence, and Fugl-Meyer score. The results of Wilk's multivariate tests of significance involving the performance within-subjects effect for the main effect of performance, for the order of treatment×performance interaction, and for the order of treatment×side of impairment×performance interaction are presented. The results of the test for side of impairment×performance interaction are not presented, because this interaction gives no meaningful information concerning the particular experiment.

Because the time-distance variables of gait are dependent on the height of the subject, all the data were normalized according to the leg length, which was defined as the distance from the greater trochanter to the floor while the subject was standing straight and barefoot. Use of normalized and raw data, however, showed no difference in the results. The results of the analyses of the nonnormalized data, therefore, will be presented.

The analysis of the TCP data was performed in such a way that TCPs were classified in different ranks according to the following criteria. An area on the sole (shaded) presented in Figure 3 was denoted as the area of normal patterns of TCP. This area was

determined by averaging TCPs of 20 asymptomatic subjects, also taking into account ±1 standard deviation. The area of the sole was divided longitudinally into three regions (heel [H], middle [M], and toes [T]) and transversally into a central area, a lateral area (l), and a medial area (m). For each subject, the pattern of TCP was described by a temporal sequence of the areas that were crossed by TCP from the beginning to the end of the stance phase for both feet. A target sequence would be HMT, which means that the subject makes foot contact with the heel, shifts his or her weight over the midsole, and performs push-off with the toes. If TCP falls into one of these regions out of the "normal" area, it is assigned index l or m. If TCP deviates to the border of the sole (b), index b is added to indexes l and m. The trajectory described by $M_{mb}T_l$, for example, means that foot contact was made by the medial border of the midsole and then the weight was shifted forward to push-off with the lateral part of the toes. The patterns in all subjects were classified according to this method in both feet for all three measurements. All of the existing patterns were classified in 18 different ranks according to their quality. The classification is presented in Table 2. The target pattern (HMT) was assigned rank 0, and the worst pattern (M_lM_l, in which TCP lasts during the whole stance phase in the lateral part of midsole) was assigned rank 17. Figure 4 shows an example of TCPs for one subject.

Each subject was assigned a rank that was the sum of ranks for the affected and nonaffected sides. It was necessary to include the nonimpaired side because the gait anomalies from the affected side are often reflected on both sides. Because the nonparametric statistical methods available in the literature do not support the experimental model with repeated measurements, the less sensitive Friedman's analysis of variance (ANOVA) by ranks was used for the comparison of the results.[40] Repeated measurements were evaluated as two independent measurements. Friedman's ANOVA was performed twice. In the first ANOVA, four different therapies were compared. The therapy applied first (in the first group) was considered different from the therapy applied second (in the second group), and vice versa. The difference in ranks between the beginning and end of a particular therapy was considered as its effect. In the second ANOVA, the effects of MFES and conventional therapy were compared, disregarding the period of application. The PC SPSS for Windows (Release 6.0) statistical program[†] was used for evaluating the results.

Table 2. *Assignment of Different Patterns of Trajectory of Center of Pressure to 18 Ranks*

Pattern[a]	Rank
HMT	0
$H_lMT=HM_lT$	1
$H_mMT=HMT_m$	2
$H_{lb}MT=H_{mb}MT$	3
$H_lM_lT=H_lMT_l=HM_lT_m=H_mMT_m=HM_mT_m$	4
$H_{lb}MT_m$	5
$H_{lb}MT_{mb}$	6
$H_{lb}M$	7
$H_{lb}M_l$	8
MT	9
$M_lT=MT_m$	10
$M_lT_m=MT_{mb}=M_{mb}T=M_{lb}T$	11
$M_{mb}T_m$	12
MM	13
$M_lM=M_{lb}MM_{lb}$	14
$M_lM_m=M_{mb}M=M_{lb}M$	15
$M_{lb}M_mM_l$	16
M_lM_l	17

[a]H=heel region, M=midsole region, T=toe region, l=lateral area, m=medial area, b=border of the sole.

Results

Table 3 shows mean measured variables for each subject before treatment and following each treatment. Table 4 shows the results of the MANOVA for four measures (gait speed, stride length, gait cadence, and Fugl-Meyer test score) represented as performance. There was a significant main effect for performance ($P=.013$). The MANOVA also revealed a significant interaction between order of treatment and performance ($P=.013$). Mean values of all individual measures that compose performance showed that during the therapy applied first, the mean improvement was greater compared with the improvement in the therapy applied second. The mean improvements during therapy with MFES added were greater compared with the mean improvements made during conventional therapy alone. These results show that MFES combined with traditional therapy is more successful than conventional therapy alone. In an experiment such as this, with a relatively small number of subjects, there is the possibility that a distribution of subjects may bias one of the tested methods. In the experiment described, that happened for the distribution of subjects according to their side of affection. This variable was not controlled by the protocol for assigning subjects to different groups. One group had nine subjects with left hemiplegia and one subject with right hemiplegia, and the other group had two subjects with left hemiplegia and eight subjects with right hemiplegia. To determine whether the affected side influenced the outcome of therapy, side of impairment was included as a factor in the MANOVA. No effect could be shown for the order of treatment×side of impairment×performance interaction ($P>.1$). The side affected did not appear to play a role in the outcome of the study.

Because the Fugl-Meyer test is designed to evaluate the physical status of the patient, we were also interested in determining whether this test could be replaced by the measurement of mean stride time, mean stride length, or mean gait speed. We therefore

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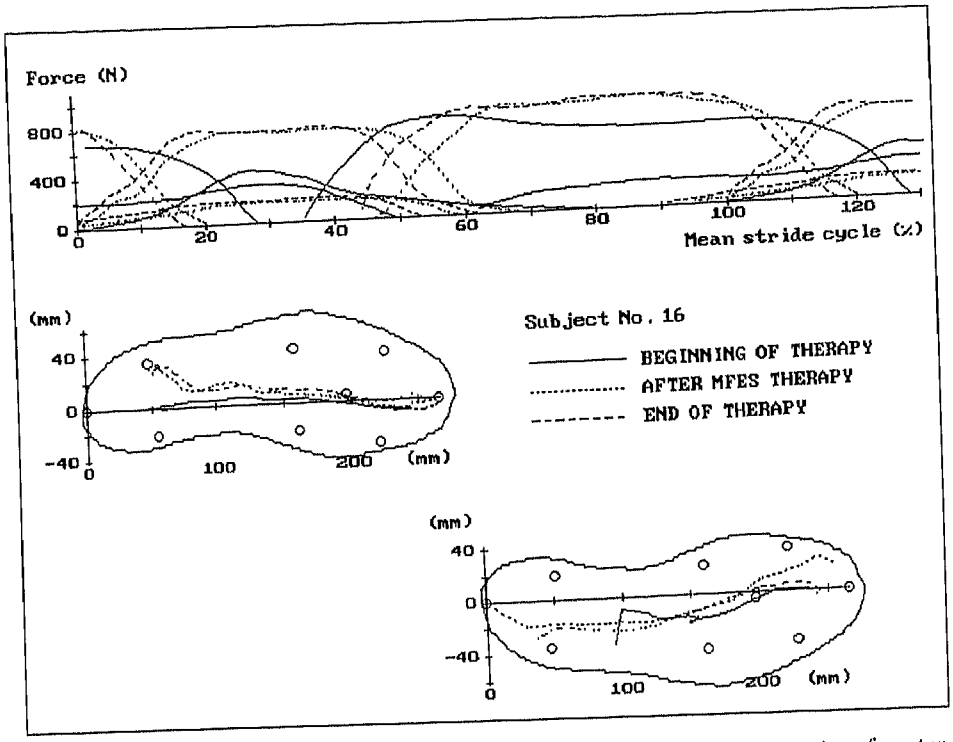

Figure 4. *Measurement results of ground reaction forces and trajectories of center of pressure for subject 16. Solid line= beginning of therapy, dotted line= after multichannel functional electrical stimulation (MFES) therapy, dashed line= end of therapy (after conventional therapy). High-amplitude curves in top diagram represent vertical component of ground reaction force for both feet, and low-amplitude curve represents vertical force on crutch.*

calculated the correlation coefficients (Pearson *r*) between the gait variables (mean stride time, mean stride length, mean gait speed) and the Fugl-Meyer test score (Tab. 5). A relatively poor correlation could be found between the Fugl-Meyer score and the gait variables. This finding means that although these measures all showed the same general result, a single gait variable (eg, gait speed) cannot be used for representation of a patient's general status. We were also interested in whether the measured variables were correlated with the age of the subjects and with the time elapsed between the onset of CVA and the beginning of our program (T_p). As shown in Table 6, there was almost no correlation between those variables. Most coefficients were negative, which means better improvement at lower ages and at lower T_p, but the correlations were very poor. Other authors[30,47,38] have found a high correlation of improvement during rehabilitation with age and T_p. Our results may differ from previous findings because our study group was relatively small and was not a representative sample of the whole population of persons with hemiplegia.

A correlation coefficient between the initial Fugl-Meyer score and improvement of the score during the whole 6 weeks of the program was calculated. This correlation coefficient (r=.29) shows that the two variables were not related very strongly.

Our subjects had severe hemiplegia; therefore, there was the possibility that certain factors influenced the results more than age or T_p. The question also arises of why the effect of therapy during the first period was greater than later on but the effectiveness of therapy was not correlated with T_p. From the time from onset of their CVAs to the beginning of therapy, the subjects did not receive any gait therapy, and this factor could influence the measured variables. We also contend that in our sample of subjects, the effects of "spontaneous rehabilitation of gait" were considerably lower than the effect of either therapeutic method. Further evidence of the balance of groups can be obtained by the use of a *t* test between the groups for the Fugl-Meyer score at the beginning of therapy. No difference could be found between these groups (P>.15). At the switch over of therapies, there was a difference between groups (P<.05). We believe this finding corroborates the MANOVA results. The result of the same test for the Fugl-Meyer score at the end of the second treatment period showed no difference between the groups. We interpreted this finding as evidence that the common result of both therapeutic methods was not different between the groups with respect to the different sequence of therapies.

Gait dynamics were estimated by measuring the vertical components of ground reaction force and the TCP under the soles of the measuring shoes. These variables reflect gait stability.[26] In Figure 4, an example of the average vertical ground reaction force for both feet and for the crutch (top diagram) and TCP for both feet (middle and bottom diagrams) is presented for subject 16 for all three measurements.

A Friedman's ANOVA for the TCPs yielded a chi-square value of 8.94, which means that the therapies resulted in differences of outcome at a confidence level of P=.03. The average ranks of therapies show that MFES combined with traditional therapy in the first period was more effective than either MFES combined with traditional therapy in the second period or conventional therapy alone during the first and second periods. In the second case, the effects of MFES and conventional therapy were compared disregarding the period of application. We obtained a chi-square value of 7.2, which means that the therapies are different at a confidence level of P= .007. These findings indicate that MFES and traditional therapy combined is more successful than conventional therapy alone.

Table 3. *Values of the Four Measured Variables for Each Subject and Their Group Means*[a]

Subject No.	Fugl-Meyer Score			Stride Length (m)			Gait Speed (m/s)			Gait Cadence (1/s)		
	1	2	3	1	2	3	1	2	3	1	2	3
Group 1												
1	112	120	128	0.89	0.74	0.98	0.48	0.42	0.57	0.54	0.56	0.58
2	117	121	137	0.85	0.76	0.85	0.37	0.33	0.30	0.43	0.44	0.35
3	153	163	195	0.61	0.67	0.81	0.20	0.28	0.41	0.33	0.41	0.50
4	124	126	137	0.55	0.72	0.81	0.22	0.29	0.33	0.40	0.40	0.39
5	94	112	124	0.41	0.49	0.53	0.09	0.11	0.16	0.22	0.22	0.30
6	104	119	122	0.57	0.78	0.93	0.20	0.34	0.44	0.34	0.42	0.47
7	113	116	119	0.68	0.66	0.56	0.27	0.21	0.21	0.38	0.36	0.38
8	75	77	89	0.20	0.25	0.41	0.04	0.05	0.13	0.21	0.19	0.31
9	97	103	111	0.65	0.72	0.85	0.30	0.32	0.46	0.45	0.44	0.53
10	79	80	101	0.56	0.59	0.80	0.14	0.20	0.33	0.24	0.33	0.40
$\bar{X}$	106.8	113.7	126.3	0.60	0.63	0.75	0.23	0.26	0.33	0.36	0.38	0.43
SD	22.7	24.3	28.5	0.20	0.16	0.19	0.13	0.11	0.14	0.11	0.11	0.09
Group 2												
11	102	112	116	0.37	0.48	0.50	0.15	0.25	0.25	0.38	. . .	0.49
12	176	203	209	0.32	0.99	0.96	0.17	0.69	0.65	0.51	0.69	0.67
13	108	139	141	0.82	1.31	1.12	0.33	0.80	0.58	0.40	0.61	0.51
14	104	112	118	. . .	0.79	0.53	. . .	. . .	0.17	0.24	0.36	0.32
15	78	87	87	. . .	1.01	0.90	. . .	0.27	0.23	0.27	0.26	0.25
16	141	177	177	0.44	1.01	0.94	0.11	0.55	0.50	0.24	0.54	0.53
17	96	109	113	0.44	0.60	0.68	0.11	0.23	0.22	0.23	0.38	0.31
18	185	197	197	0.65	0.74	0.83	0.25	0.31	0.41	0.38	0.41	0.49
19	130	148	147	0.54	0.65	0.68	0.19	0.25	0.28	0.35	0.38	0.41
20	140	147	146	0.70	0.79	0.73	0.23	0.37	0.36	0.32	0.45	0.45
$\bar{X}$	126.0	143.1	145.1	0.54	0.84	0.79	0.19	0.41	0.37	0.33	0.46	0.45
SD	35.0	39.4	39.2	0.17	0.24	0.20	0.08	0.21	0.17	0.09	0.14	0.12

[a]Group 1 subjects started with conventional therapy and continued with multichannel functional electrical stimulation (MFES) therapy; group 2 subjects started with MFES therapy and continued with conventional therapy. Each variable is represented by three measurements: (1) at the beginning of our program, (2) at switch over of treatments, and (3) at the end of the program. Ellipses represent missing values.

Discussion

Studies of MFES began before the 1970s,[6] and, if we do not take into account the development of different multichannel stimulators and studies of control principles, the first clinical results were published in the 1980s.[12,15,39] Although these studies showed a very good correction of gait anomalies, no long-term therapeutic effects were proven. The subjects in these studies were patients who were ambulatory. A good correction of gait was achieved, but after electrical stimulation was abandoned, the gait pattern deteriorated because the subjects developed or restored different pathological patterns (eg, knee hyperextension, circumduction in the hip). In our study, MFES was used for initiation of the gait pattern in patients with severe hemiplegia who were not ambulatory. Conventional physical therapy methods use different kinds of exercises to prepare the patient to bridge the gap between standing and gait. In our study, by using MFES combined with traditional therapy, we enabled the subjects to start gait training without any special pretraining right at the beginning of therapy. The results of such an approach or the long-term effects are easy to assess or measure. There are two variables that show the summation of effects of MFES therapy. One variable is independence in gait. If the patient accomplishes independence as he or she continues to perform gait, then the effect of the therapy is permanent. The second variable is the duration of therapy. It is impossible to claim for any patient who participated in the study that he or she would not have been able to manage gait without assistance if MFES were not applied. According to the course of therapy, however, we clearly see that the progress during MFES combined with traditional therapy was better than during conventional therapy alone. This progress means that patients need much less time in MFES combined with conventional therapy

Table 4. *Multivariate Analysis of Variance Results of Subjects' Performance Determined by Four Measured Variables (Gait Speed, Stride Length, Gait Cadence, Fugl-Meyer Score)*

Source	Value	Exact *F*	df_h	df_e	*P*
Performance	0.094	7.234	8.00	6.00	.013
Order × performance	0.094	7.244	8.00	6.00	.013
Order × side × performance	0.301	1.696	8.00	6.00	.268

[a] df_h=true or within-groups degrees of freedom; they are hypothetical due to repeated-measures design.

[b] df_e=error or within-groups degrees of freedom.

[c] *P*=probability established by Wilk's multivariate tests of significance.

to achieve the same state as they would with conventional therapy alone (ie, rehabilitation time is shorter and patients return to their normal environment sooner).

According to previous experience,[16,39] MFES therapy should last from 2 to 4 weeks, depending on the particular patient. Limited by the experimental model, the duration of therapy had to be fixed to 3 weeks. Due to its complexity in normal practice, we believe MFES therapy should be used only as long as the patient improves. In our opinion, when a patient starts to plateau, simpler methods and aids should be used instead.

We contend that MFES therapy should be regarded as an autonomous therapeutic method, and it should form only a part of a rehabilitation program. In our study, we felt that excluding patients from routine therapy because of MFES would be unacceptable from an ethical point of view. The subjects, therefore, continued to participate in all of their regular therapeutic programs. A reduction of the intensity of the subjects' participation in their other programs might have occurred in order not to overexert the subjects, but we did not monitor this.

The selection of measured variables was another dilemma. The measurements were divided into two levels: measurement of biomechanical variables of gait and assessment of the physical status of the subject according to the Fugl-Meyer scale. Measurement of biomechanical variables of gait comprised measurement of time-length variables of gait and ground reaction forces. Because we could not anticipate the results of the study, we measured as many variables as possible to describe the subjects' gait as well as possible. On the other hand, we dealt with severely involved patients who, especially at the beginning of therapy, were able to walk only short distances with the help of a therapist. We found reports that maximum walking speed is highly correlated with the stage of rehabilitation in patients with hemiplegia.[40–42] Despite these reports, we instructed our subjects to walk at their preferred speed. The main reason for this was that even gait at "normal" speed represents a maximum effort for individuals with severe hemiplegia. We felt that at higher speeds of gait, synergistic patterns would prevail, the subjects' tension would increase, and, in many cases, such gait would not be possible. The course of measurement was therefore adapted to each subject separately. The only restraint was that each subject had to make at least 30 regular strides in one measuring day in two or three runs with intermediate pauses. To prevent carryover effects, the measurements were performed in the morning before the subjects attended any kind of therapy.

Because all measured variables were related to gait or the lower extremities, the assessment of physical status of each subject according to the Fugl-Meyer scale was added. The poor correlation coefficients calculated between the changes in the Fugl-Meyer score and changes in stride time, stride length, and gait speed indicate that an improvement in gait speed does not necessarily mean an improvement in total physical performance. All these variables, however, showed a difference according to the therapy applied.

When we are looking for an explanation as to why MFES combined with tradiitional therapy is more successful than conventional therapy alone, we contend that MFES works on two levels: direct and indirect. The direct effects are functional movement as a result of muscle contraction induced by functional electrical stimulation, corrected synergistic movements, better coordination of the extremities, better security and self-confidence of the patient, and starting gait training immediately at the beginning of therapy. We contend that the indirect effects are improved and richer sen-

Table 5. *Correlation Coefficients (Pearson r) Between Fugl-Meyer Score (FM), Stride Time (T), Stride Length (L), and Gait Speed (V)*

	T	L	V
FM	.53	.57	.59

Table 6. *Correlation Coefficients (Pearson r) Between the Measured Variables (Fugl-Meyer Score [FM], Stride Time [T], Stride Length [L], Gait Speed [V]), and Age of Subjects and Time Between Onset of Cerebrovascular Accident and Beginning of Therapy (T_p)*

	Age	T_p
FM	−.29	−.19
T	−.17	.004
L	−.28	−.13
V	−.18	−.15

sory feedback information to the CNS, possible enhancement of CNS plasticity, better and faster motor learning, and high motivation to participate in the program. We, however, have no data to support this hypothesis.

There are some limitations with MFES therapy. The stimulator used in the study was heavy and relatively large (weight: 2.6 kg, dimensions: 210×210×90 mm) so that it sometimes additionally burdened the subject, who carried it on his or her back. In the most severe cases, another person had to carry the stimulator behind the subject. The daily application of electrodes is sometimes complicated and time consuming. The staff involved in the application of MFES need to be highly trained and experienced. These limitations are more or less related to technology and may be considerably reduced in the future by using high technology and a user-friendly stimulator design.

Conclusion

This study presented an aggressive approach to gait relearning in patients with severe hemiplegia by means of MFES combined with traditional therapy. Improved correction of gait anomalies and a shorter period in which to reach independence in gait were observed with MFES combined with conventional therapy. The MFES method is, however, in no case a comprehensive rehabilitation program; it serves only as a supplement to all therapeutic methods currently used in everyday practice. The target population comprised patients with severe hemiplegia who were unable to walk independently or with an attendant. The method described should help those patients to progress faster and easier through the period from getting out of bed to independence in gait or the point at which they can continue rehabilitation of gait using simpler functional electrical stimulation devices or various passive orthoses.

The experimental design, in which each subject served as his or her own control, turned out to be very effective. The number of subjects was reduced to 20, and despite the large heterogeneity of the hemiplegic population, highly significant statistical results were obtained.

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