Application of a programmable dual-channel adaptive electrical stimulation system for the control and analysis of gait

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Abstract—A dual-channel electrical stimulation system with a stimulator and a programmer/stride analyzer was designed for clinical rehabilitation of gait and for subsequent daily use as an orthotic aid. The stimulator, with controls to adjust amplitude only (50 mA), adapts chosen stimulation sequences to the walking rate of a patient. Pulse duration (50–500 μ s), frequency (5–120 Hz), shape (symmetrical biphasic, monophasic), stimulation sequences (16 stride segments) and their cycle (2–12 sec), and right/left foot-switch choices are selected for each patient and programmed into a separate unit. The programming unit also statistically processes the foot-switch data collected by the stimulator. The device was evaluated with regard to the programmable parameters, effectiveness during gait, and feasibility in clinical use. It was applied to 11 stroke patients and 10 brain injury patients during gait, stimulating 22 combinations of peroneal nerve and hamstring, quadriceps, triceps brachii, and gluteus maximus muscles. Forces on both feet, equinovarus, knee extension and hyperextension, elbow flexion, and hip extension were corrected. Selection of the stimulation sequences, their adaptation, range of pulse duration, and valid statistics were verified. Improved forces and joint angles were recorded together with significant changes in the stride time, length, and velocity by the stimulation.

Key words: *electrical stimulation, evaluation, gait, gait analysis, multichannel stimulator, orthosis.*

INTRODUCTION

This paper represents an outcome of research by the Ljubljana Rehabilitation Engineering Center on multichannel electrical stimulation for the initiation of gait of severely disabled persons with upper motor-neuron lesion (1,2,3,4,5). Studies on therapeutic and orthotic dual-channel stimulation (6), together with substantial clinical practice, led to a prototype of a dual-channel device programmed by DIP switches, which was tested on 18 stroke and brain-injury patients (7). The prototype was followed by a new adaptive dual-channel electrical stimulation system with individually programmable stimulation parameters by a programming unit, suitable for therapy and control of paralyzed gait outside of the clinical environment (8,9). Five prototype units, including a stimulator and a programmer/stride analyzer, were constructed. Their evaluation within a rehabilitation institution resulted in a preliminary report (10).

In conceptualizing the stimulator, contradictory requirements were met: the stimulator was designed as an orthotic aid for the patient at home and as a therapeutic stimulator in rehabilitation centers. Therefore, it had to be as small as possible so that it would not disturb the patient, but it also had to accommodate a wide selection of pulse shapes, durations, frequencies, and stimulation sequences, continuously adapting to the gait cadence, in order to satisfy the individual requirements of various

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patients. In addition, it needed to record some basic gait parameters without additional kinesiological measurements. If the stimulator was to be used as an orthotic device at home, the stimulation parameters, except for the on/off and amplitude controls, could not be accessible to the patient. The stimulator was thus designed as two devices—the stimulation unit and the programmer/stride analyzer unit—allowing the therapist to preprogram all stimulation parameters, except the amplitudes, and to obtain statistical recording of basic time parameters of a patient's gait (**Figure 1**).

After completion of the stimulator, its evaluation was carried out in the clinical environment. The evaluation included a methodical review of the programmable parameters of stimulation such as pulse amplitudes, duration, frequencies, waveforms, and stimulation sequences, along with adaptability to changes in stride duration. Objectives of the study also incorporated effectiveness of the appliance to improve gait deficiencies in a wide population of motor-disabled patients and its feasibility in clinical use as a therapeutic and orthotic device with a possibility of stride analysis without additional kinesiological measurements.

METHODS

The new dual-channel stimulation system was designed (9) based on experiences with six-channel (1,2,3,4,5) and dual-channel electrical stimulation (6,7,8,11,12). Five prototypes were functionally tested. The evaluation consisted of:

1. selection of patients suitable for the dual-channel therapy and determination of stimulation sites;
2. application of the stimulation for 1 week with the stimulation parameters determined according to general kinesiological data (13,14,15) and individually adjusted during 1-hour daily sessions;
3. kinesiological measurements of joint angles by a 3-D TRIAX™ electrogoniometric system, ground reaction forces and time parameters by force shoes (16), and stride length and velocity by a potentiometer with a wheel and fishing line (17) during three trials without and three trials with the stimulation on a 10-meter walkway;

Figure 1.

Dual-channel adaptive electrical stimulation system with stimulation unit and programming/stride-analyzing unit.

4. estimation of the ability of the patients to apply the electrodes and control the stimulator by themselves.

Stimulator

The dual-channel stimulator, as shown in **Figure 1**, comprises two electrically separated channels with symmetrical biphasic or monophasic constant current pulses, the latter permitting adjustment of the peroneal nerve stimulation by the polarity. The device has independent settings of stimulation sequences for both channels during the stance and swing phases of gait. Duration of each stimulation sequence continuously adapts to the cadence of a patient's gait, adjusting every stride phase time to the previous ones. The adaptation algorithm applies a linear extrapolation of the previous four stride times when they are equal or decreasing, and an extrapolation weighted toward the more recent ones when the patient is slowing (7,8,9). The sequences of each channel can be triggered by either or both foot-switches. When three or four channels are required, two devices can be interconnected. Cyclic triggering of the stimulation sequences is also available for muscle training and selection of the stimulation sites.

With at least one foot-switch connected, the stimulator operates in a walking-rate-dependent

mode. When both switches are disconnected, it operates in a cyclic mode. The chosen stimulation sequences are then repeated in an interval from 2 to 12 seconds, selected in 0.5-second increments. In the walking-rate-dependent mode the stimulation sequence is executed according to the foot-switches. When the switch turns on (foot contact), the stimulation sequence for stance phase is started and when it turns off (lifting of foot), the sequence for swing phase is executed. Two or more stimulation units can be interconnected by paralleling the switches.

Amplitudes of the constant-current symmetrical biphasic or monophasic stimulation pulses are controlled by potentiometers with on/off switches in the range of 0–50 mA. The stimulator is turned on by raising the amplitude on either of the channels. Above each amplitude knob there is a LED indicator displaying the current through electrodes. A reset circuit starts the microprocessor after the power has been switched on, and a protection circuit prevents damage of the electronics in case of reversed battery polarity. Parameters of gait, such as number of strides in the stimulation session, right and left stride duration, and stance and swing durations, are gathered and partly processed by the stimulator. The programmer/stride analyzer unit can read, statistically process, and display average values with standard deviations and right/left stride symmetry for up to 65,536 strides or 77.67 hours of walking, when the stride duration exceeds 4.27 sec (19).

Subjects

Evaluation of the dual-channel stimulator was carried out on 11 patients after cerebrovascular accident (CVA) as shown in **Table 1** and on 10 patients after traumatic brain injuries (TBI) as shown in **Table 2**.

Among the CVA patients there were two women and nine men with a mean age of 59 and a standard deviation (SD) of 11 (**Table 1**). The group comprised four right-side hemiplegic and seven left-side hemiplegic patients with an average of 11 months after insult (onset range = 1.3–36 months). The subjects all walked with a forearm crutch, and four of them required the additional support of a therapist at the beginning of stimulation.

TBI patients (**Table 2**) included four women and six men with a mean age of 35 (SD = 11). The

Table 1.

Cerebrovascular accident (CVA) patient information.

Patient	Sex	Age	Onset	Diagnosis
1	male	76	11 months	CVA L hem
2	male	63	7 months	CVA R hem
3	male	67	7 months	CVA R hem
4	male	47	5 months	CVA L hem
5	male	43	5 months	CVA R hem
6	male	53	36 months	CVA L hem
7	female	62	5 months	CVA L hem
8	male	75	4 months	CVA L hem
9	male	60	6 months	CVA L hem
10	female	43	35 months	CVA R hem
11	male	58	1.3 months	CVA L hem

R/L hem: right-/left-side hemiplegic patient.

Table 2.

Traumatic brain injury (TBI) patient information.

Patient	Sex	Age	Onset	Diagnosis
12	male	32	24 months	TBI L hem
13	male	30	12 months	TBI R hem
14	male	53	25 years	TBI qpar
15	female	38	6 months	TBI R hem
16	male	25	24 months	TBI L hem
17	male	24	21 years	TBI R hem
18	female	38	18 months	TBI L hem
19	female	57	6 months	TBI qpar
20	female	21	2.5 months	TBI R hem
21	male	33	17 months	TBI ppar
22	male	33	17 months	TBI ppar

R/L hem: right-/left-side hemiplegic patient

qpar: quadriparetic patient

ppar: paraparetic patient

last male TBI patient was included in the evaluation program twice (Patient 21/22) in order to examine various combinations of stimulating channels. There were four right-side hemiplegic, three left-side hemiplegic and two quadriparetic patients, and one paraparetic patient at an average of 5 years after the

injury (onset range = 2.5 months to 25 years). Of the ten TBI patients, four walked independently without any support, one used a cane, and three a forearm crutch, while two required a crutch and the additional support of a therapist.

There was a large variation in walking ability in the study population (e.g., a 4.8–86.9 cm/sec range in gait velocity) as seen in **Table 5** and **Table 6**. A few very poor walkers were included in the study in order to thoroughly check the stimulator and its effects in demanding conditions. Due to large standard deviations of gait parameters, the paired *t*-test was applied in comparing the stride duration, length, and velocity with and without the stimulation.

Determination of stimulation sites

In the 1985–1986 grant period of the Ljubljana Rehabilitation Engineering Center, the gait deficiencies of 2,100 patients treated by functional electrical stimulation (FES) were classified with regard to single-, dual-, or six-channel stimulation (18). Viable combinations where the dual-channel stimulator can be applied, included:

- Stimulation of both peroneal nerves in bilaterally disabled patients for correction of equinovarus during the right and left swing phases;
- Stimulation of the soleus muscle in order to provide or correct the push-off in the terminal stance and preswing phases, together with stimulation of the peroneal nerve for correction of equinovarus during the swing phase later on;
- Stimulation of the peroneal nerve for correction of equinovarus during the swing phase with simultaneous stimulation of the triceps brachii muscle for the reciprocal arm swing during the swing phase of the ipsilateral lower limb in hemiplegic patients;
- Stimulation of the peroneal nerve for correction of equinovarus during the swing phase together with stimulation of the gluteus medius and minimus muscles in order to prevent hip adduction in the terminal swing phase and also, in some patients, contralateral pelvis drop in the stance phase;
- Bilateral stimulation of the gluteus medius and minimus muscles in order to prevent hip adductions in both terminal swing phases that results in crossing of the lower limbs during gait;
- Stimulation of the peroneal nerve for correction of equinovarus during the swing phase together with

stimulation of the quadriceps muscle for correction of knee extension in the terminal swing, initial, and midstance phases;

- Stimulation of the hamstring muscles in order to establish or correct knee flexion in the preswing and initial swing phases together with stimulation of the quadriceps muscle for the correction of knee extension in the terminal swing, initial, and midstance phases; and,
- Stimulation of the quadriceps muscle in the terminal swing phase and during the stance phase together with stimulation of the gluteus maximus muscle throughout the stance phase to enable weight shift to the affected lower limb in patients with prevailing flexor synergies and enable support in patients with weak knee and hip extensors and minor contractures in knee and hip joints.

After the first examination of selected patients in the current study, the stimulation sites were chosen according to the combinations noted above. Following observation of their gait deficiencies, the stimulation sequences were adjusted to meet the goal of improving the gait of an individual patient.

RESULTS AND DISCUSSION

Stimulation parameters

In 10 CVA patients, the peroneal nerve was stimulated for correction of equinovarus during the swing phase. Quadriceps stimulation for knee extension in the late swing phase and loading was added to the peroneal stimulation by the second channel in five patients. Stimulation of the triceps brachii for reduction of flexor spasm and reciprocal arm swing was applied together with the peroneal stimulation in three patients. The peroneal nerve and hamstring muscles were stimulated in two patients in order to provide knee flexion in the terminal stance and initial swing phases. Quadriceps and gluteus maximus muscles were stimulated in the remaining patient, where foot drop was corrected by a passive orthosis.

Combinations of the stimulation sites, stimulation sequences, sides of the triggering foot-switch, stimulation amplitudes, pulse shapes (biphasic, monophasic), frequencies, and pulse durations are summarized in **Table 3**. Stimulation of the peroneal nerve was delayed after lifting of the heel in two patients in order to allow a push-off, and was

Table 3.
Stimulation sites and parameters of CVA patients.

Patient	Stimul. Site	Sequence		Trigg.	Ampl. (mA)	Shape	Dur. (μ s)	Freq. (Hz)
		Heel-On	Heel-Off					
1	per hamst	*-----:*****		L	40	B	200	25
		-----*:**-----		L	50	B	400	
2	per quad	*-----:*****		R	20	B	250	35
		-----:-----		R	30	B	400	
3	per tribr	**-----:*****		R	20	B	150	25
		*****:-----		L	30	B	250	
4	per quad	**-----:-----*		L	25	B	150	25
		**-----:-----*		L	40	B	250	
5	per quad	-----:-----*		R	30	B	150	25
		*****:-----*		R	40	B	250	
6	per tribr	*-----:*****		L	20	M	250	30
		*****:-----**		R	30	B	250	
7	per quad	*-----:*****		L	25	M	250	30
		-----:-----*		L	30	B	350	
8	per hamst	*-----:*****		R	10	B	250	35
		-----*:***-----		R	40	B	400	
9	per tribr	*-----:*****		L	15	B	250	35
		-----*:*****		L	30	B	250	
10	quad glmax	*****:-----*		R	45	B	500	35
		*****:-----		R	45	B	500	
11	per quad	-----:*****		L	25	M	250	30
		*****:-----*		L	30	B	350	

per = common peroneal nerve; hamst = hamstring muscles; quad = quadriceps muscle; tribr = triceps brachii muscle; glmax = gluteus maximus muscle; -/* = stimulation off/on; trigg = side of triggering foot-switch; B/M = symmetrical biphasic/monophasic pulses.

prolonged into the initial stance phase in eight patients in order to prevent foot-slap. The stimulation of quadriceps increased knee extension in the terminal swing phase, facilitated weight transfer, and stabilized support when prolonged into the stance phase. The stimulation of quadriceps and gluteus maximus muscles provided more stable support to the affected limb, thus enabling Patient 10 to make a longer step.

Similar data are presented in **Table 4** for the TBI patients. There the peroneal nerve was stimulated in all 11 combinations, bilaterally on 3 patients. The second channel was applied to the hamstring muscles in six patients: in two against insufficient knee flexion in the initial swing phase,

and in four to prevent knee hyperextension in the stance phase. The quadriceps was chosen for the second channel in the terminal swing phase of one patient, and triceps brachii in the swing phase of another patient.

Clinical observations pointed out noteworthy corrections of equinovarus in both CVA and TBI patients. Stimulation of the knee flexors was mainly applied in order to prevent knee extension thrust during loading or hyperextension in the stance phase. It was less visible in the gait pattern itself than the stimulation of the quadriceps muscle. Stimulation of the triceps brachii muscle was included for the cosmetically and kinesiology important arm swing as an integral part of locomotion.

Table 4.
Stimulation sites and parameters of TBI patients.

Patient	Stimul. Site	Sequence		Trigg.	Ampl. (mA)	Shape	Dur. (μ s)	Freq. (Hz)
		Heel-On	Heel-Off					
12	per	-----:*****		L	15	M	150	25
	hamst	*****--:--**----		L	45	B	450	
13	per	*-----:*****		R	20	B	150	25
	hamst	*****--:-----		R	35	B	250	
14	R per	-----:*****		R	20	B	150	30
	L per	-----:*****		L	15	B	150	
15	tribr	*****:-----		L	35	B	150	35
	per	-----:*****		R	20	B	200	
16	per	-----:*****		L	30	B	200	35
	hamst	-----:***----		L	40	B	300	
17	per	**-----:*****		R	30	B	150	35
	hamst	*****--:-----		R	35	B	250	
18	per	-----:*****		L	30	B	150	30
	hamst	-----*:*****--		L	40	B	400	
19	L per	-----:*****		L	20	B	200	30
	R per	-----:*****		R	35	B	200	
20	per	-----:*****		R	30	B	150	30
	hamst	*****--:-----		R	50	B	200	
21	L per	-----:*****		L	20	M	300	35
	R per	-----:*****		R	10	M	300	
22	per	-----:*****		L	10	M	100	40
	quad	-----:--*****		L	25	B	400	

per = common peroneal nerve; hamst = hamstring muscles; quad = quadriceps muscle; tribr = triceps brachii muscle; glmax = gluteus maximus muscle; -/* = stimulation off/on; trigg = side of triggering foot-switch; B/M = symmetrical biphasic/monophasic pulses.

tion, influencing both the step length and push-off velocity (19). It successfully helped to reduce elbow flexion and initiated the reciprocal arm swing during the swing phase of the ipsilateral lower limb.

As shown in **Table 3** and **Table 4**, 22 combinations of the dual-channel stimulation were applied in the patients. The peroneal nerve was the most frequent stimulation site. It was stimulated 21 times, bilaterally in three of the patients. The second channel was applied to the hamstring muscles in eight patients, to quadriceps in six, and to triceps brachii in four patients. The quadriceps and gluteus maximus muscles were stimulated in one patient.

The possibility of programming the stimulation sequences of both channels in 16 stride-time increments was fully utilized: every available increment

was used at least once in the 22 chosen combinations of stimulation sites. A higher resolution than eight equal parts of the stance phase and eight of the swing phase did not seem to be required. The stimulation sequences adequately adapted to the changing walking rate of a patient. However, the adaptation algorithm, directly extrapolating the previous four strides during speeding up and weighting them for a faster change during slowing, was not examined in detail.

The control signals for triggering and adaptation of the stimulation sequences came from 1 foot-switch in 16 patients and from 2 foot-switches in 6 patients. However, bilateral switches were always applied in order to obtain data for the stride analyzer statistics. Shoe insoles with heel-, midfoot-,

and toe-switches, connected in parallel, were applied in three patients instead of the regular heel-switches in order to obtain real stance and swing phases instead of the heel-on and heel-off times. In the subject with left-side hemiplegic TBI (Patient 16), this was also required to obtain a reliable triggering of the stimulation. The statistical data (number of strides in the stimulation session, and their mean stride, swing, and stance times with SD and stride symmetry), obtained by the programmer/stride analyzer unit, complied with the values measured in the kinesiological laboratory.

A symmetrical biphasic pulse shape was used in 16 patients and a monophasic one in 6 patients on the first channel, while the biphasic pulses were applied 21 times and the monophasic 1 time on the second channel. Monophasic pulses were used for the peroneal stimulation, where different responses to the change of polarity helped to obtain more functional movements. With proper capacitively coupled, charge-balanced pulses, as tested by the early prototype (7), both more acceptable sensations and different responses with the polarity change would be achieved.

Average applied amplitudes were 25 mA (range = 10–45 mA) for the first channel and 34 mA (range = 10–50 mA) for the second channel. Patients 1 and 20 required the highest amplitude for stimulation of hamstring muscles by 10×5 cm electrodes. Pulse duration could remain at a comfortable 200 μ s in Patient 20 and had to be raised to 400 μ s in Patient 1, in order to obtain sufficient stimulation intensity. For the same reason, amplitudes of both channels had to be set almost to a maximum 45 mA, with the maximum biphasic pulse durations of 500 μ s and a slightly raised frequency of 35 Hz in Patient 10. For various populations of patients, maximum stimulation amplitude might even be doubled to 100 mA, especially for spinal cord injury patients. Programmable maximum amplitude might solve the problem of unpleasant sensations in patients with preserved sensitivity.

Average pulse durations were 200 μ s for the first channel, used for stimulation of the peroneal nerve in 20 cases, and 300 μ s for the second channel, to which larger electrodes were connected. However, pulse durations from 100 to 500 μ s were needed, depending on the stimulation sites and electrode sizes. The pulse duration range proved to be adequate. Frequencies from 25 to 40 Hz were used,

with a mean value of 30 Hz. Taking into account only the neuromuscular stimulation and the higher maximum amplitude, a frequency range of 10–40 Hz would be more than adequate.

Quantitative evaluation of gait

To verify clinical findings regarding effectiveness of the dual-channel stimulator, a quantitative evaluation of gait was accomplished in the stimulated patients. According to the methodology used and measured data, normal goniometric and force functions (13,16) and clinical findings were compared with the improvements of anomalies by the stimulation and explained in biomechanical terms. A good relationship was found among clinical gait analyses, stimulation parameters, and quantitative estimates.

Experimental findings with dual-channel stimulation and without it, characterized by the average stride time, stride length, and gait velocity, are shown in **Table 5** for the CVA patients and in **Table 6** for the TBI patients.

Table 5.
Improvements of gait in CVA patients.

Patient	Stride (s)		Length (cm)		Speed (cm/s)	
	Stim.	Without	Stim.	Without	Stim.	Without
1	2.09	2.22	58.7	59.2	28.2	26.9
2	2.01	2.12	81.4	77.4	40.6	36.6
3	1.51	1.43	57.2	46.0	38.0	32.2
4	2.61	2.91	73.0	71.0	28.2	24.5
5	2.69	2.61	82.1	76.2	30.9	29.8
6	2.59	3.07	78.4	75.6	30.4	24.8
7	2.03	2.38	59.3	53.4	29.4	22.6
8	2.10	2.51	91.8	82.0	43.9	33.0
9	1.73	2.02	85.2	74.5	49.4	37.3
10	3.66	4.11	26.1	19.4	7.5	4.8
11	1.43	1.48	102.1	96.1	71.6	65.2
Mean						
Diff.	0.219		5.86		5.49	
(SD)	(0.203)		(3.69)		(3.54)	
<i>t</i>	3.41		5.02		4.90	
<i>p</i> <	0.005		0.005		0.005	

From data in **Table 5**, a mean decrease in the stride time of 10 percent, an increase in the stride length of 9 percent, and an increase in the stride velocity of 18 percent was observed in the CVA patients during the stimulation. Comparably, the TBI patients (**Table 6**) displayed a decrease in the mean stride time of 5 percent, an increase in the mean stride length of 8 percent, and an increase in the mean stride velocity of 22 percent during the stimulation.

In spite of unexceptional advancement of the gait parameters by the stimulation and large standard deviations, trends of the recorded changes were notably uniform in the whole population of CVA and TBI patients. Therefore, the paired *t*-test showed highly significant improvements of the stride duration, length, and velocity resulting from the stimulation in the CVA patients ($p < 0.005$). In the TBI patients, the stimulation helped to significantly improve the stride duration ($p < 0.025$), while stride length and gait velocity were highly significantly better (confidence levels $p < 0.01$ and $p < 0.005$), as shown in **Table 5** and **Table 6**. To illustrate the methods of evaluation, analyses of one subject from the population of CVA patients and one subject from the population of TBI patients are presented below.

Patient 7. In the left-side hemiplegic female patient, aged 62, 5 months after stroke (**Table 1**), the left peroneal nerve was stimulated during the swing phase and loading, while the quadriceps muscle was stimulated in the terminal swing phase (**Table 3**). Without stimulation, there was a substantial lack of hip and knee flexion accompanied by the ankle plantar flexion in the swing phase. She walked with a forearm crutch on the right side. When walking without ankle foot orthosis, manual correction by the therapist was required to prevent spraining of the ankle after stepping on the lateral border of her foot due to strong ankle varus, and to enable weight transfer to the flat foot. Her knee was either partly flexed throughout the stance phase or ended in a strong extension thrust after loading. With an unequal step ratio, her unimpaired foot landed behind the impaired one. With the stimulation, the swing equinovarus was corrected, enabling heel contact and loading, and the knee extension thrust was less frequent after loading.

Results of the measurements are shown in **Figure 2**, where ground reaction forces to the feet

Table 6.

Improvements of gait in TBI patients.

Patient	Stride (s)		Length (cm)		Speed (cm/s)	
	Stim.	Without	Stim.	Without	Stim.	Without
12	1.72	1.72	70.9	76.7	41.2	44.7
13	1.65	1.77	99.5	91.6	60.9	51.9
14	1.52	1.42	65.3	61.1	43.1	43.1
15	2.33	2.54	79.6	75.8	34.3	30.0
16	2.27	2.21	60.6	59.8	26.8	27.2
17	1.27	1.36	130.9	118.1	102.9	86.9
18	1.53	1.75	82.6	62.1	54.2	36.0
19	1.52	1.55	102.2	98.9	67.2	63.8
20	1.37	1.57	113.3	108.8	82.5	69.7
21	1.64	1.70	89.8	77.4	54.9	45.5
22	1.54	1.70	83.8	77.4	54.4	45.5
Mean						
Diff.		0.085		6.44		7.10
(SD)		(0.110)		(6.95)		(6.98)
<i>t</i>		2.44		2.93		3.22
<i>p</i> <		0.025		0.01		0.005

and crutch and courses of their points of action (POA) under both feet are presented together with goniometric functions of the hips, knees, and ankles in the sagittal plane. Dual-channel stimulation is displayed by solid lines, while dotted lines are used for the gait without stimulation. The stimulation itself is presented by solid bars. The patient walked with a freely chosen speed. Stimulation of the quadriceps muscle did not change the hip and knee flexions. Without the stimulation, force POA started at the mid-lateral foot of the impaired leg and was shifted to the center of the foot during stimulation of the peroneal nerve, starting at the heel. Then the trajectories under both feet also became similar. As shown in **Table 5**, there was a 17 percent decrease in the stride time, an 11 percent increase in the stride length, and a 30 percent increase in the stride velocity during stimulation. Shape and amplitude of the forces did not change.

There were also relevant changes in the goniometric functions. Due to complex interpretation of the analyzed 18 goniogram functions in all three planes together with forces and their POA,

Figure 2. Force basograms and sagittal plane goniograms of Patient 7 with stimulation (solid) and without stimulation (dotted).

only left ankle angles, dominantly affected by the stimulation of the peroneal nerve, and force POA are given besides the sagittal goniograms. The ankle position at foot contact without stimulation was -5° plantar flexion, -2° adduction, and 4° internal rotation, which corresponded to the initial POA in **Figure 2** (dotted line). Stimulation of the peroneal nerve and quadriceps muscle was reflected in the ankle 8° dorsal flexion, 6° abduction, and 4° external rotation at foot contact, which was in agreement with the initial POA (solid line). The angles without and with stimulation were only slightly shifted in frontal and lateral axes during the interval of 10–60 percent of stride without stimulation, while in the swing phase significant changes could be seen in all three directions. In the stance phase there were shifts on the unimpaired side, but the shapes remained the same.

Patient 21/22. In the paraparetic male patient, aged 33, 17 months after traumatic brain injury (**Table 2**), two different muscle combinations were stimulated to demonstrate the effect of a different stimulation approach on the gait pattern. First, right and left peroneal nerves were stimulated throughout both swing phases, then the left peroneal nerve and quadriceps muscle were stimulated during the swing phase and late swing phase, respectively (**Table 4**). The patient walked with his feet placed wide apart. Lack of left hip flexion and left knee extension was observed in the terminal swing and initial stance phase, as well as lack of left hip extension and left knee flexion in the terminal stance phase. Equinovarus during the swing phase was also expressed more noticeably on the left side. Internal rotation of the whole left limb was manifested during the stance phase.

At the beginning of therapy, bilateral stimulation of the peroneal nerves was chosen. Gait without stimulation is presented in **Figure 3** by dotted lines, while results of the stimulation are shown by dash lines. The stimulation of both peroneal nerves, denoted in the figure by empty bars, partly corrected the ankle anomalies toward the loading on heels. With an improved left stance-to-swing ratio, there was a 4 percent decrease in the stride time, a 16 percent increase in the stride length, and a 21 percent increase in the stride velocity during the stimulation (**Table 6**). Improvements in the left hip extension in the terminal stance phase of 10° , in the right hip flexion in the terminal swing and initial

stance phases of 5° , of 15° higher left and 6° higher right knee flexion in the initial swing phases, and of 5° better left ankle dorsal flexion during the swing phase were recorded with the stimulation. Moderate lack of left knee extension in the initial and midswing phase resulted in instability during loading, reflected in left trajectory of the force POA.

Therefore, a new approach was chosen with stimulation of the left peroneal nerve and quadriceps muscle after 1 week. Effects of this stimulation, shown by solid bars in **Figure 3**, are displayed by solid lines, showing additionally improved loading on the left heel in left trajectory of the force POA. With a stance-to-swing ratio similar to the previous stimulation, a 6 percent higher decrease of the stride time and 8 percent lower increase of the stride length was recorded during this stimulation (**Table 6**). Additional improvements of left hip extension in the terminal stance phase of 10° and left knee flexion in the initial swing phase of 30° permitted a rather symmetrical gait pattern with the stimulation. With 8° left dorsal flexion, a moderate lack of the right one was present during the swing phases. Better right and left hip abductions during the stance phases with a larger right knee varus and internal rotation were also recorded with the stimulation.

Various degrees of corrections were obtained in other patients. In eight CVA patients, good corrections of observed anomalies were recorded, while in Patients 3, 4, and 6 only partial improvements were achieved. In nine TBI patients, there were good corrections of the main anomaly and only partial success in Patients 16 and 19.

Use of the stimulation by patients alone

The profile of the CVA and TBI population at the Ljubljana University Rehabilitation Institute mainly consists of patients with rather extensive motor disabilities who are still in the process of recovery. When considered favorable, they are issued single-channel stimulators for personal use after thorough training toward the end of their hospitalization. From the stimulated population, only Patient 18 from the TBI group was an outpatient.

One week of dual-channel stimulation, which was assigned to a patient together with the kinesiological measurements, allowed just an estimation of the ability of the patients to manage the

Figure 3.

Force basograms and sagittal plane goniograms of Patient 21/22 with bilateral peroneal stimulation (dash), left peroneal and quadriceps stimulation (solid) and without stimulation (dotted).

stimulation by themselves. After a detailed explanation, patients were asked to attach the electrodes to the involved nerves or muscles, connect them to the stimulator, adjust the stimulation intensities, and connect the foot-switch(es). The trial application was not timed, but limited to 10 minutes. Only commercially available bipolar electrodes were included in the evaluation. A longer stimulation period, higher number of clinically rehabilitated outpatients, and electrodes dedicated to particular stimulation sites would render a higher number of persons eligible for independent use of the dual-channel stimulation.

The patients from the CVA group (**Table 1** and **Table 3**), at least in small part, depended on the help of a therapist during positioning of the electrodes and connection of the stimulator after 1 week. Stimulation sites also played an important role: positioning the electrodes on the triceps brachii muscle was more difficult than on the quadriceps; hamstring muscles were even more difficult, while placement on the gluteus maximus was almost impossible without assistance. In addition, the degree of disability and stage of rehabilitation determined the amount of required help. Of the CVA group, Patients 7 and 10 depended entirely on the therapist.

All patients from the TBI group (**Table 2** and **Table 4**) except one were able to cope with the stimulation of the peroneal nerve without help from the therapist. Patient 16 was physically and mentally not able to manage the stimulation alone, although he was very eager to use it. In Patients 14, 17, 20, 21, and 22, independent use of the stimulator would not cause major difficulties. Regarding their mental and physical handicaps, Patients 13, 18, and 19 could cope with the dual-channel stimulation after a prolonged period, while in Patients 12, 15, and 16 it might not prove successful without the assistance of another person.

CONCLUSION

The purpose of the clinical evaluation of the stimulator was to determine its performance in therapeutic and orthotic use. Therefore, the main effort was directed to the evaluation of flexibility of the program in different stimulation approaches, its simplicity and reliability, as well as the ability of

patients to carry out the stimulation independently. The evaluation was thus directed to the correction of gait and not to an integral assessment of gait.

The stimulator has proved to be adequate for the restitution of gait in chosen CVA and TBI patients. Simple stimulator units, fitted individually to each patient by a separate programming unit providing a large variety of stimulation sequences and parameters, can aid a large population of patients. With the ability to adapt the stimulation sequences to stride times of over 10 seconds, the stimulator can be applied either during the first stimulation sessions in initiating gait or as an orthotic aid for everyday use.

The stride analyzer, included in the programming unit, provides relevant statistical data over a large number of strides in a common environment, and does not require additional measurements. The number of strides, average values and standard deviations of right and left stride, stance and swing durations, and right/left symmetry can be followed up during the treatment. With a maximum number of 65,536 strides or 78 hours of walking, the gait parameters can be recorded either after every stimulation session of several hundred strides or at the control examinations of outpatients using the stimulator as an orthotic aid. The therapist can control effects of the stimulation with this information and modify further treatment accordingly.

The stimulator is convenient for orthotic use, while its application also depends on the ability of patients to apply the stimulating electrodes. This ability is conditioned by the stimulation sites and especially by the degree of disability in the upper extremities. A design of the electrodes for particular stimulation sites and assistance of the patient's family may considerably increase the outcome of orthotic stimulation. Additional populations of spinal cord injury patients, children with cerebral palsy, patients with multiple sclerosis, and other patients with upper motor-neuron lesions could benefit from this system.

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REFERENCES

1. Bogataj U, Gros N, Maležič M, Kelih B, Kljajić M, Aćimović R. Restoration of gait during two to three weeks of therapy with multichannel electrical stimulation. *Phys Ther* 1989;69(5):319-27.
2. Kelih B, Maležič M, Gros N, Kljajić M, Bogataj U, Aćimović R. Evaluation of gait during therapy with six-channel electrical stimulation. *Med Biol Eng Comput* 1985;23 Suppl(Pt 1):424-25.
3. Maležič M, Stanić U, Kljajić M, Aćimović R, Gros N, Krajnik J, et al. Multichannel electrical stimulation of gait in motor disabled patients. *Orthopedics* 1984;7(7):1187-95.
4. Maležič M, Kljajić M, Aćimović-Janežič R, Gros N, Krajnik J, Stanić U. Therapeutic effects of multisite electric stimulation of gait in motor-disabled patients. *Arch Phys Med Rehabil* 1987 Sept;68:553-60.
5. Maležič M, Bogataj U, Gros N, Kelih B, Kljajić M, Aćimović-Janežič R. Evaluation of gait with multichannel electrical stimulation. *Orthopedics* 1987;10(5):769-72.
6. Maležič M, Krajnik J, Stanić U, Stopar M, Aćimović R, Gros N. Optimization of number of channels for electrical stimulation of pathological gait. *Proceedings of the World Congress on Medical Physics and Biomedical Engineering*; 1982. Hamburg: International Federation for Medical and Biological Engineering, International Organization for Medical Physics, 1982.
7. Bogataj U, Maležič M, Filipič D. Preliminary testing of a dual-channel electrical stimulator for correction of gait. *J Rehabil Res Dev* 1987;24(3):75-80.
8. Bogataj U, Kelih B, Maležič M, Filipič D, Kljajić M. Dual-channel electrical stimulator for correction of gait. In: Popović DB, editor. *Proceedings of the Conference on Advances in External Control of Human Extremities X*. Belgrade, Yugoslavia: Nauka, 1990: 327-33.
9. National Institute on Disability and Rehabilitation Research. Design of modular and adaptive multichannel electrical stimulation system with stride analyzer for therapy and control of gait. Innovation Grant Project H133C80205 (R 1989). Washington (DC): NIDRR, 1989.
10. Maležič M, Vrtačnik P, Gros N, Dečman I, Bogataj U, Kelih B, et al. Evaluation of adaptive dual channel electrical stimulator for gait. In: Popović DB, editor. *Proceedings of the Conference on Advances in External Control of Human Extremities X*. Belgrade, Yugoslavia: Nauka, 1990: 387-402.
11. Jeglič A. Two channel implant—approach to an orthotic device. *Proceedings of the Fourth International Symposium on External Control of Human Extremities*. Dubrovnik, Yugoslavia: Yugoslav Committee for Electronics and Automation, 1972: 647-56.
12. Naumann S, Mifsud M, Carins BJ, Milner M. Dual-channel electrical stimulators for use by children with plegic spastic cerebral palsy. *Med Biol Eng Comput* 1985;23(5):435-43.
13. Isacson J, Gransberg L, Knutsson E. Three-dimensional electrogoniometric gait recording. *J Biomech* 1986; 19(8):627-35.
14. Kljajić M, Bajd T, Stanić U. Quantitative gait evaluation of hemiplegic patients using electrical stimulation orthoses. *IEEE Trans Biomed Eng* 1975;22(5):438-41.
15. Kljajić M, Krajnik J, Stanić U. A quantitative method of evaluation of gait under the influence of electrical stimulation in hemiparetic patients. *Scand J Rehabil Med* 1988;17 Suppl:105-09.
16. Kljajić M, Krajnik J. The use of ground reaction measuring shoes in gait evaluation. *Clin Phys Physiol Meas* 1987;8:133-42.
17. Bajd T, Kralj A. Simple kinematic gait measurements. *J Biomed Eng* 1980 Apr;2:129-32.
18. National Institute for Handicapped Research. Criteria for selection of patients for FES treatment: single, dual and six channel stimulation. Ljubljana Rehabilitation Engineering Research Project, NIHR G008300323 (R 1985). Washington (DC): NIHR, 1985.
19. Reberšek S, Gros N, Valenčič V. Functional electrical stimulation of arm swing during walking of hemiparetic patients. *Proceedings of the World Congress on Medical Physics and Biomedical Engineering*, 1982. Hamburg: International Federation for Medical and Biological Engineering, International Organization for Medical Physics, 1982.