EVALUATION OF ADAPTIVE DUAL CHANNEL ELECTRICAL STIMULATOR FOR GAIT

Malezič M., Vrtačnik P., Gros N.*, Dečman I.*, Bogataj U., Kelih B., Kljajić M.

Jožef Stefan Institute and
*University Rehabilitation Institute
Ljubljana, YUGOSLAVIA

ABSTRACT

Adaptive dual channel stimulator/stride analyzer with programmable stimulation for the control of gait outside clinical environment, was designed and tested on 10 CVI and 10 TBI patients, stimulating 21 combinations of peroneus, hamstring, quadriceps, triceps brachii and gluteus maximus stimulation sites. Corrections of equinovarus, knee extension and hyperextension, elbow flexion and hip extension were recorded during gait. Five prototypes have shown adequate choice of individually programmable sequences in 16 stride increments, adaptation algorithm and ranges of other stimulation parameters. Two ranges of amplitudes were indicated for patients with various pathologies.

KEY WORDS: multichannel stimulation, gait, orthoses, evaluation

INTRODUCTION

The paper represents an outcome of research by the Ljubljana Rehabilitation Engineering Center from 1983 to 1988 on the multichannel electrical stimulation for the initiation of gait of severely disabled persons with upper motor neuron lesion. A new adaptive dual channel electrical stimulation system with individually programmable stimulation sequences, suitable for the therapy and control of paralyzed gait outside the clinical environment, was developed for this population of patients. Five prototype units, including a stimulator and a programmer/stride analyzer, were produced, tested and evaluated in the clinical environment.

Experiences with multichannel electrical stimulation (1, 2, 3, 4, 5, 6) have lead to two electrically isolated channels with 0 - 50mA optionally monophasic or biphasic constant current stimulation pulses for the dual-channel orthotic stimulator. The small device have independent settings of stimulation sequences for both channels during both stance and swing phases. The duration of each stimulation sequence continuously adapts to the cadence of a patient's gait. The sequences of each channel are optionally triggered by the left or right heel-switch. When three or four channels are required, two devices can be interconnected. Cyclic triggering of the stimulation sequences is also available for the muscle training and selection of the stimulation sites. The stimulator was designed as an orthotic aid for the patient at home or as a therapeutic stimulator in rehabilitation centers. It provides statistical recording of basic time parameters of a patient's gait.

In conceptualizing of the stimulator, contradictory requirements were met: the stimulator should be as small as possible so that it should not disturb the patient, the stimulation sequences should continuously adapt to the patient gait cadence, and the stimulator should be suitable for orthotic use by the patient at home. If the stimulator had been used as an orthotic device, the stimulation parameters, except for the on-off switch and amplitude knobs, should not have been accessible to the patient. Therefore the stimulator was designed as two devices: the stimulation unit and the programming unit, allowing the therapist to preprogram all stimulation parameters, except the amplitudes. Statistically processed time parameters of gait can also be read from the stimulator and displayed by the programming unit.

One or two heel-switches can be used for the triggering of stimulation during gait. When at least one switch is connected, the stimulator operates in a walking rate dependent mode. When both switches are disconnected, it operates in a cyclic mode. Then the chosen stimulation sequence is repeated in an interval from 2 to 12 seconds in preset 0.5 second increments. In the walking rate dependent mode the stimulation sequence is executed according to the heel-switches. When the switch turns on (heel contact), the stimulation sequence for stance phase is started and when it turns off (lifting of heel), the swing phase is executed. Two or more stimulation units can be interconnected by paralleling the switches.

Amplitude of the constant current monophasic or biphasic stimulation pulses is controlled by potentiometers with switches in the range of 0-50mA. 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 the electrodes. A power-on 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.

METHODOLOGY

The method of functional evaluation of the new stimulation system consisted of: (a) selection of patients suitable for dual- channel therapy; (b) application of the stimulation with qualitatively estimated parameters for one week (7, 8, 9); (c) kinesiological measurements of joint angles by a 3D electrogoniometric system (TRIAX™, Chattecx Corp.), ground reaction forces and time parameters by force shoes (10), and stride length and velocity by potentiometer with a wheel and fishing line (11) during three trials without and with the stimulation on a 10 meter walkway; (d) estimation of patients' ability to apply electrodes and control the stimulator by themselves.

SELECTION OF PATIENTS FOR DUAL CHANNEL STIMULATOR

In the Ljubljana REC 1985-1986 grant period, classification of 2100 patients treated by FES collated gait deficiencies with regard to single, dual or six channel stimulation (12). Viable combinations, where the dual channel stimulator can be applied, included:

Stimulation of **both peroneal nerves** was applied in bilaterally disabled patients for correction of the equinovarus during the right and left swing phases respectively.

Stimulation of the **triceps surae (soleus) muscle** was applied in order to provide or correct the push-off in the terminal stance phase and pre-swing phase together with stimulation of the **peroneal nerve** for correction of the equinovarus during the swing phase later on.

Stimulation of the **peroneal nerve** was applied for correction of the equinovarus during the swing phase together with simultaneous stimulation of the **triceps brachii muscle** for the reciprocal arm swing in hemiplegic patients.

Stimulation of the **peroneal nerve** was applied for correction of the 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, in some cases, also contralateral pelvis drop in the stance phase.

Bilateral stimulation of the **gluteus medius and minimus muscles** was applied in order to prevent bilateral hip adduction in both terminal swing phases respectively which resulted in crossing of the lower limbs during gait.

Stimulation of the **peroneal nerve** was applied for correction of the equinovarus during the swing phase together with stimulation of the **quadriceps muscle** for correction of knee extension in the terminal swing phase and stance phase of the gait.

Stimulation of the **hamstring muscles** was applied in order to establish or correct knee flexion in the pre- and initial swing phases together with stimulation of the **quadriceps muscle** for the correction of knee extension in the terminal swing, initial and mid-stance phases.

Stimulation of the **quadriceps muscle** was applied in the terminal swing phase and during the stance phase together with stimulation of the **gluteus maximus** muscle throughout the stance phase in order to enable weight shift to the affected lower limb in patients with prevailing flexor synergies and support in patients with weak knee and hip extensors and minor contractures in knee and hip joints.

CHARACTERISTICS OF PATIENTS AND STIMULATION

Evaluation of the dual channel stimulator was carried out on 10 patients after cerebrovascular insults (CVI), as shown in Table 1, and on 10 patients after traumatic brain injuries (TBI), presented in Table 2.

There were 2 females and 8 males with a mean age of 59 (standard deviation 12) in the CVI patients. They comprised 4 right hemiplegics and 6 left hemiplegics with an average 1 year after insult (onset range: 4 to 36 months). They all walked with a crutch and 3 of them required the additional support of a therapist.

Patient	**Sex**	**Age**	**Onset**	**Diagnosis**
1	male	76	11 months	CVI L hem
2	male	63	7 months	CVI R hem
3	male	67	7 months	CVI R hem
4	male	47	5 months	CVI L hem
5	male	43	5 months	CVI R hem
6	male	53	3 years	CVI L hem
7	female	62	5 months	CVI L hem
8	male	75	4 months	CVI L hem
9	male	60	6 months	CVI L hem
10	female	43	35 months	CVI R hem
	2f/8m	**59(12)**	**1y(4m-3y)**	**4Rhem/6Lhem**

Table 1: CVI patients

TBI patients included 4 females and 6 males with a mean age of 35 (standard deviation 11). The last male TBI patient was included in the evaluation program twice. There were 4 right side hemiplegics, 3 left side hemiplegics, 2 quadriparetics and 1 paraparetic with an average 5 year after injury (onset range: 2.5 months to 25 years). Out of the ten TBI patients, 4 walked independently without any support, 1 used a cane, 3 a crutch, while two with a crutch required the additional support of a therapist.

Patient	**Sex**	**Age**	**Onset**	**Diagnosis**
11	male	32	2 years	TBI L hem
12	male	30	1 year	TBI R hem
13	male	53	25 years	TBI qpar
14	female	38	6 months	TBI R hem
15	male	25	2 years	TBI L hem
16	male	24	21 years	TBI R hem
17	female	38	1.5 years	TBI L hem
18	female	57	6 months	TBI qpar
19	female	21	2.5 months	TBI R hem
20	male	33	1.4 years	TBI ppar
21	male	33	1.4 years	TBI ppar
	4f/7m	**35(11)**	**5y(2.5m-25y)**	**4R,3Lh/2qp/2pp**

Table 2: TBI patients

In 9 CVI patients, the peroneal nerve was stimulated for the correction of equinovarus during the swing phase. Quadriceps stimulation for knee extension in the late swing phase and loading was added by the second channel in 4 cases. Triceps brachii for reduction of flexor spasm and reciprocal arm swing was applied in 3 cases.

Hamstring muscles were stimulated in 2 cases, in order to provide knee flexion in terminal stance and initial swing phase. Quadriceps and gluteus maximus muscles were stimulated in one patient, where foot drop was corrected by a passive orthosis.

Stimulation of the peroneal nerve was delayed after lifting of the heel in 2 patients, in order to allow a push-off, and was prolonged into the initial stance phase in 8 patients, in order to prevent foot-slap. The stimulation of quadriceps increased the lack of 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 by the affected limb, thus enabling patient 10 to make a longer step.

Stimulation combinations, sequences, side of triggering, amplitude, pulse shape, frequency and pulse width are collated in Table 3:

Pat.	Muscle	Sequence Heel-On Heel-Off	Trigg.	Ampl.	Shape	Width	Freq.
1	per	*------- : ********	L	40	B	200	25
	hamstr	------** : **------	L	50	B	400	
2	per	*------- : ********	R	20	B	250	35
	quad	*------- : --******	R	30	B	400	
3	per	**------ : ********	R	20	B	150	25
	tricbr	******** : --------	L	30	B	250	
4	per	**------ : -*******	L	25	B	150	25
	quad	**------ : ---*****	L	40	B	250	
5	per	-------- : -*******	R	30	B	150	25
	quad	*****--- : ----****	R	40	B	250	
6	per	*------- : ********	L	20	M	250	30
	tricbr	******** : ------**	R	30	B	250	
7	per	*------- : ********	L	25	M	250	30
	quad	-------- : ---*****	L	30	B	350	
8	per	*------- : ********	R	10	B	250	35
	hamstr	-----*** : ****----	R	40	B	400	
9	per	*------- : ********	L	15	B	250	35
	tricbr	-------* : ********	L	30	B	250	
10	quad	*******- : -----***	R	45	B	500	35
	glutmx	*******- : --------	R	45	B	500	
4per/qdr		maximum :	8unl	8B/2M			30
3per/trb		*******- : ********	2bil	10B			25-35
2per/hst		******** : ********	25/10-45			250/150-500	
1qdr/gmx			37/30-50			350/250-500	

Table 3: CVI patients

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 6 patients, in 2 against insufficient knee flexion in the initial swing phase, and in 4 to prevent knee hyperextension in the stance phase. 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.

Pat.	Muscle	Sequence Heel-On : Heel-Off	Trigg.	Ampl.	Shape	Width	Freq.
11	per	-------- : ********	L	15	M	150	25
	hamstr	*****--- : --**----	L	45	B	450	
12	per	*------- : ********	R	20	B	150	25
	hamstr	******-- : --------	R	35	B	250	
13	R per	-------- : ********	R	20	B	150	30
	L per	-------- : ********	L	15	B	150	
14	tricbr	******** : --------	L	35	B	150	35
	per	-------- : ********	R	20	B	200	
15	per	-------- : ********	L	30	B	200	35
	hamstr	-------- : ****----	L	40	B	300	
16	per	**------ : ********	R	30	B	150	35
	hamstr	******-- : --------	R	35	B	250	
17	per	-------- : ********	L	30	B	150	30
	hamstr	-------* : *****---	L	40	B	400	
18	L per	-------- : ********	L	20	B	200	30
	R per	-------- : ********	R	35	B	200	
19	per	-------- : ********	R	30	B	150	30
	hamstr	******-- : --------	R	50	B	200	
20	L per	-------- : ********	L	20	M	300	35
	R per	-------- : ********	R	10	M	300	
21	per	-------- : ********	L	10	M	100	40
	quad	-------- : --******	L	25	B	400	
6per/hst		maximum :	7unl	8B/3M			30
3per/per		******** : ********	4bil	10B/1M			25-40
1per/qdr		******-- : ********	24/15-35			150/100-300	
1per/trb			32/10-50			300/150-450	

Table 4: TBI patients*

Clinical observations pointed out remarkable corrections of the equinovarus in all patients. Stimulation of the knee flexors was mainly applied in order to prevent knee hyperextension in the stance phase, and was less expressed in the gait pattern than that of the quadriceps. Stimulation of the triceps brachii successfully helped to reduce elbow flexion and initiated reciprocal arm swing.

Altogether 21 combinations of dual channel stimulation were applied in all the patients. The peroneal nerve was the most frequent stimulation site. It was stimulated in 20 cases, bilaterally in 3 patients. The second channel was applied to the hamstring muscles in 8 patients, to quadriceps in 5 and to triceps brachii in 4 patients. Quadriceps and gluteus maximus muscles were stimulated in one patient.

The possibility of programming stimulation sequences of both channels in 16 stride time increments was fully used: every available increment was used at least once in the 21 stimulation cases. A higher resolution than 8 equal parts of the stance phase and 8 of the swing phase did not seem to be required.

The control signals for triggering and adaptation of the stimulation sequences came from one heel switch in 15 cases and from two switches in 6 cases. 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 3 cases in order to obtain real stances and swings instead of the heel-on and heel-off times. In TBI patient 15 this was also required to obtain a reliable triggering of the stimulation.

A symmetrical biphasic pulse shape was used in 16 cases and monophasic in 5 cases on the first channel, while 20 cases of the biphasic and 1 case of the monophasic pulses were applied on the second channel. Monophasic pulses were used for peroneal stimulation, where different responses to the change of polarity helped to obtain more functional movements. With asymmetrical biphasic, i.e. charge balanced pulses, both more acceptable sensations and different responses with the polarity change would be achieved.

Average applied amplitudes were 25mA (range 10-45mA) for the first channel and 34mA (range 10-50mA) for the second channel. Patients 1 and 19 required the highest amplitude for the stimulation of hamstring muscles by 10x5cm electrodes. Pulse width could remain at a comfortable 200μs in patient 19 and had to be raised to 400μs in patient 1, in order to obtain sufficient stimulation intensity. For the same reason, amplitudes of both channels had to be set to almost a maximum 45mA with the maximum biphasic pulse widths of 500us and a slightly raised frequency of 35Hz in patient 10. For various populations of patients, maximum stimulation amplitude might even be doubled to 100mA, especially for spinal cord injury patients. Programmable maximum amplitude might solve the problem of unpleasant sensations in patients with preserved sensitivity.

Average pulse widths were 200us for the first and 300μs for the second channel. However, pulse widths from 100 to 500μs were used, depending on the stimulation sites and electrode sizes. The pulse width range proved to be adequate. Frequencies from 25 to 40Hz were used, the mean value being 30Hz. Taking into account the neuromuscular stimulation only and the higher maximum amplitude, a frequency range of 10 to 40Hz would be more than adequate.

QUANTITATIVE EVALUATION OF GAIT

To verify clinical findings regarding effectiveness of the dual channel stimulator, a quantitative evaluation of restoration of gait was accomplished. According to the methodology used (9) and measured data, normal goniometric functions (10) and clinical findings were compared with the improvements of anomalies by FES and explained in biomechanical terms. A good relationship among clinical gait analyses, stimulation parameters and quantitative estimates was found.

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 CVI and in Table 6 for the TBI patients.

Patient	Stride [s]		Length [cm]		Velocity[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
Mean	2.30	2.54	69.3	63.5	32.7	27.3
(SD)	(0.58)	(0.69)	(18.4)	(18.4)	(10.9)	(8.9)

Table 5: CVI patients

A mean decrease of the stride time by 9.5%, increase of stride length by 9% and stride velocity by 20% were observed during stimulation in the 10 CVI patients in Table 5.

In the 11 TBI patients in Table 6 there was a decrease of the mean stride time by 4%, increase of mean stride length by 8% and mean stride velocity by 20% during the stimulation.

However, standard deviations were rather large in the whole population of CVI and TBI patients. Therefore, there were no statistically significant changes in gait parameters caused by the stimulation. Considering the pathology, stimulation strategy and correction of initial gait anomalies, only individual differences were observed.

To illustrate the methods of evaluation, analyses of one subject from the population of CVI patients and two subjects from the population of TBI patients are presented:

Patient	**Stride [s]**		**Length [cm]**		**Velocity[cm/s]**	
	Stim.	**Without**	**Stim.**	**Without**	**Stim.**	**Without**
11	1.72	1.72	70.9	76.7	41.2	44.7
12	1.65	1.77	99.5	91.6	60.9	51.9
13	1.52	1.42	65.3	61.1	43.1	43.1
14	2.33	2.54	79.6	75.8	34.3	30.0
15	2.27	2.21	60.6	59.8	26.8	27.2
16	1.27	1.36	130.9	118.1	102.9	86.9
17	1.53	1.75	82.6	62.1	54.2	36.0
18	1.52	1.55	102.2	98.9	67.2	63.8
19	1.37	1.57	113.3	108.8	82.5	69.7
20	1.64	1.70	89.8	77.4	54.9	45.5
21	1.54	1.52	83.8	79.5	54.4	52.4
Mean	1.67	1.74	89.0	82.7	60.3	50.1
(SD)	(0.32)	(20.2)	(13.2)	(0.33)	(18.6)	(17.0)

Table 6: TBI Patients

Patient 7:

In the left side hemiplegic female patient aged 62, 5 months after stroke (see 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 (see Table 3). Without stimulation there was a lack of knee flexion accompanied by the ankle plantar flexion in the swing phase. Due to strong ankle varus, manual correction by the therapist was required to prevent spraining of the ankle after stepping on the lateral border of her foot and to enable weight transfer to the flat foot. The 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. The stimulation corrected the swing equinovarus, enabling heel contact and loading, and the knee extension in terminal swing phase, providing a longer step.

Results of the measurements are shown in Figs. 1 - 2, where the vertical ground reaction force and its points of action (POA) and 3D goniometric functions of hip, knee and ankle are presented. Dual channel stimulation is shown by solid lines while dashed lines are used for the gait without stimulation. The patient walked with a freely chosen speed. Without stimulation, force POA started at the mid-lateral foot of the impaired leg and was shifted to the center of the foot during stimulation, starting at the heel (Fig. 1). Trajectories under both feet were also similar then. Shape and amplitude of the forces did not change due to unchanged gait velocity.

There were also significant changes in goniometric functions. It is difficult to give a complex interpretation of 18 goniometric functions together with POA. Therefore left ankle angles (Fig. 2), dominantly affected by the stimulation of the peroneal nerve, and POA are analyzed. The initial ankle position without stimulation was -5^0 plantar flexion, -2^0 adduction and 4^0 internal rotation, which corresponded to the initial POA in Fig. 1. Stimulation of the peroneal nerve and quadriceps muscle was reflected in the initial position 8^0 dorsal flexion, 6^0 abduction and 4^0 external rotation, which was in agreement with the initial POA. The angles without and with stimulation were only slightly shifted in frontal and lateral axes during the interval of 10-60% of stride without stimulation, while in the swing phase significant changes in all three directions could be seen. In the stance phase there were shifts on the unimpaired side, but the shapes remained the same.

Patient 13:

In the quadriparetic male patient, aged 53, 25 years after traumatic brain injury (see Table 2), right and left peroneal nerves were stimulated throughout both swing phases respectively (see Table 4). The patient walked independently with rather strong trunk lateral leans accompanying weight transfers, as well as with moderate hip adductions and lack of hip and knee flexions during both swing phases. Both feet were in the equinovarus position with drags of the toe bases most of the time. In the stance phase, the right knee was moderately hyperextended with the ankle in plantar flexion. The stimulation corrected both feet and partly also increased the hip and knee flexions during swing phases.

Results of the measurements are shown in Fig. 3 - 4. The solid line represents the gait with stimulation and the dashed line the gait without it. In Fig. 3 the vertical component of the ground reaction forces and their POA are shown. During stimulation, corrections of POA at the heel strikes are evident on both sides. In Fig. 3 to 4, corrections of the joint angles during stimulation can be observed. Shifts into the ankle dorsal flexion and eversion, which were expressed in the three lower left diagrams of Fig. 4, were a direct consequence of stimulation. Increase of the right hip and knee flexions, right knee varus and external rotation, as well as left hip abduction and external rotation were also recorded during stimulation (Fig. 3 and 4). Synchronizing the angles with the POA trajectories, a high correlation of the results with and without stimulation was found.

Various degrees of corrections were obtained in other patients. In 7 CVI patients, good corrections of observed anomalies were recorded, while in patients 3, 4 and 6 only partial improvements were achieved. In 9 TBI cases, there were good corrections of the main anomaly and only partial success in patients 15 and 18.

USE OF THE STIMULATION BY PATIENTS ALONE

The profile of the CVI and TBI population at the University Rehabilitation Institute mainly consists of patients with rather more severe motor disabilities who are still in the process of recovery. When considered favorable, they are issued with single channel stimulators for personal use without surveillance by the therapist after thorough training towards the end of their hospitalization. From the stimulated population, only patient 17 from the TBI group was an outpatient.

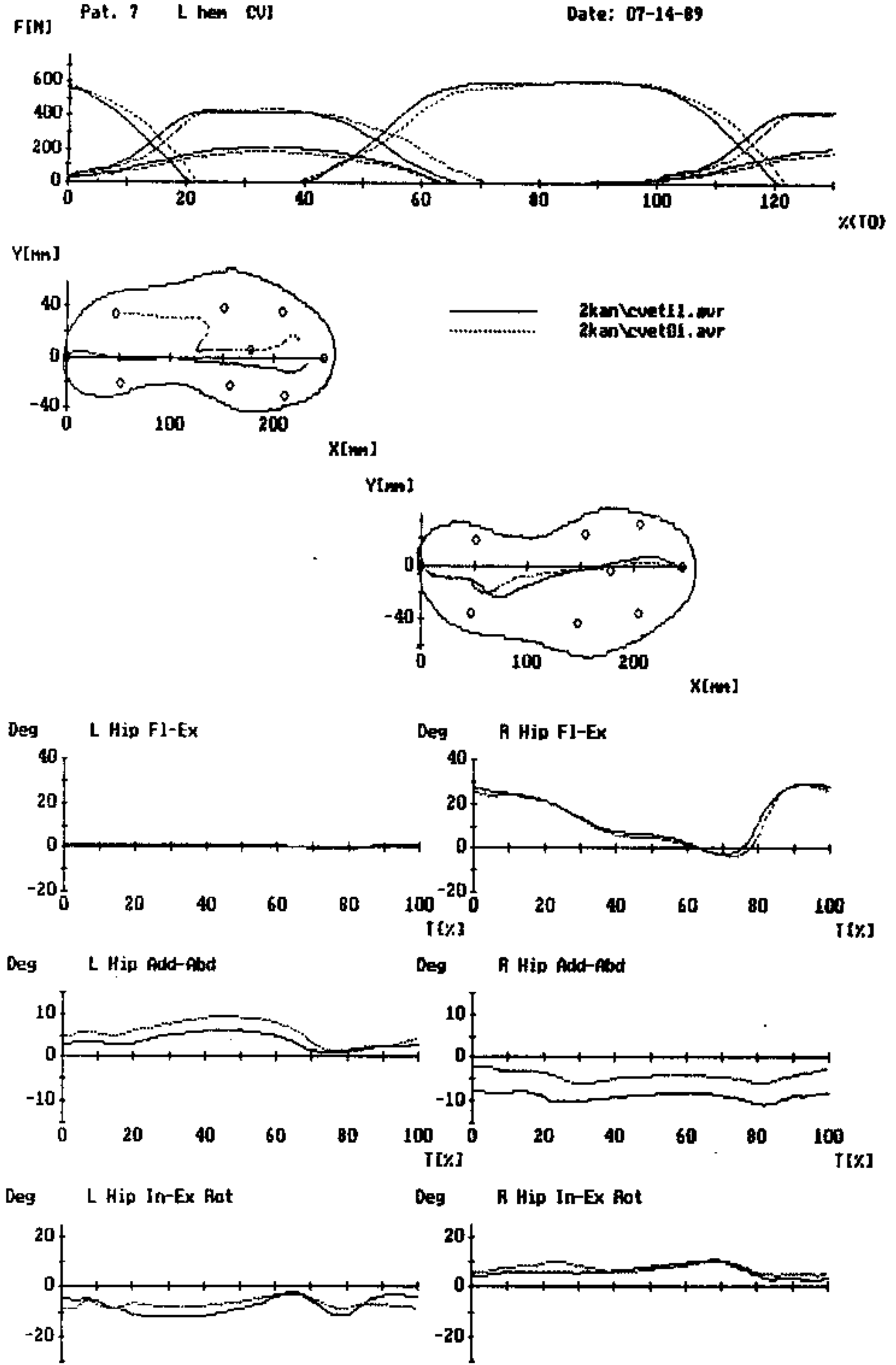

Figure 1: Force basograms and 3-D hip goniograms of patient 7 with (full) and without stimulation (dotted).

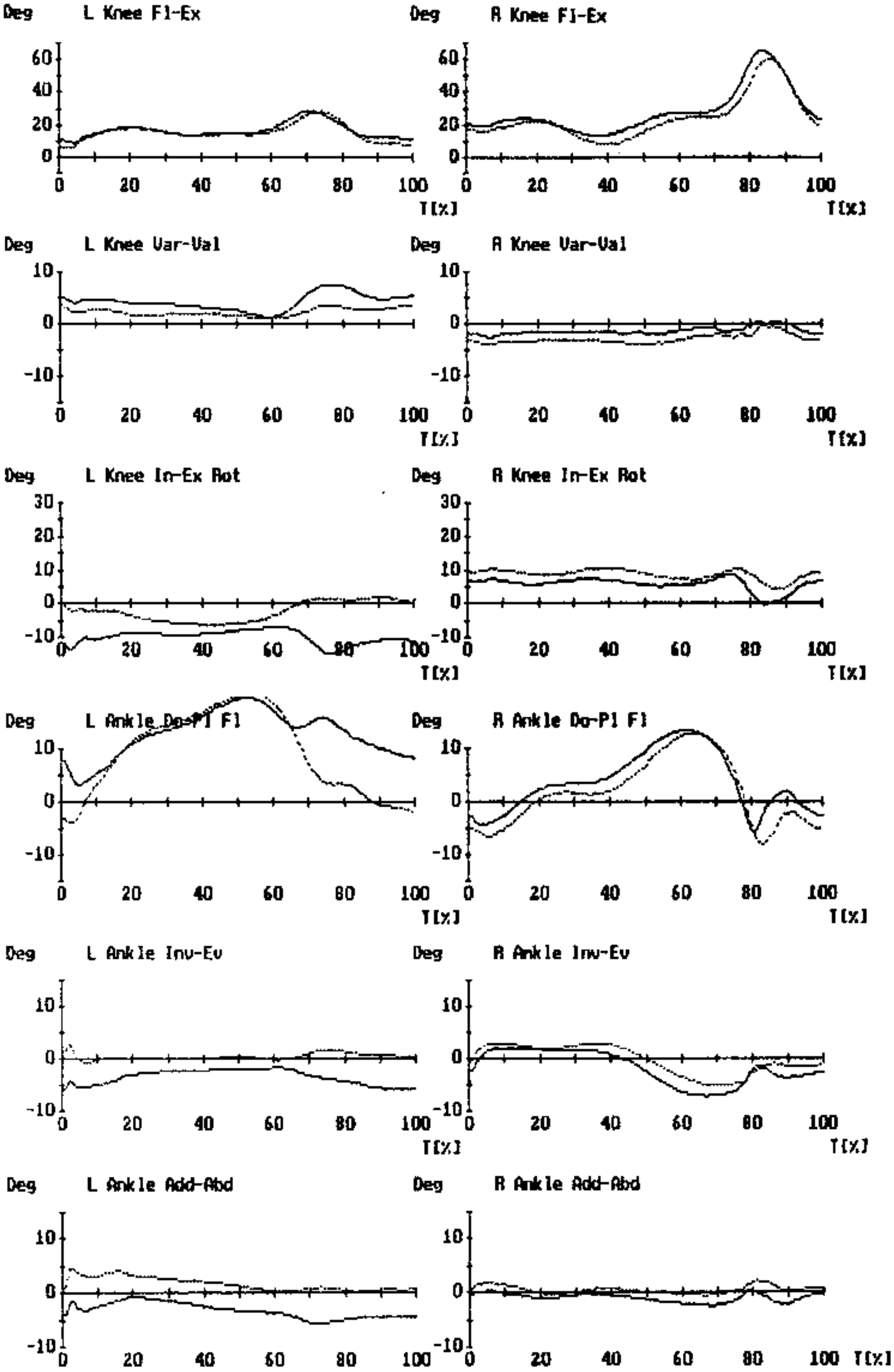

Figure 2: 3-D knee and ankle goniograms of patient 7 with (full) and without stimulation (dotted).

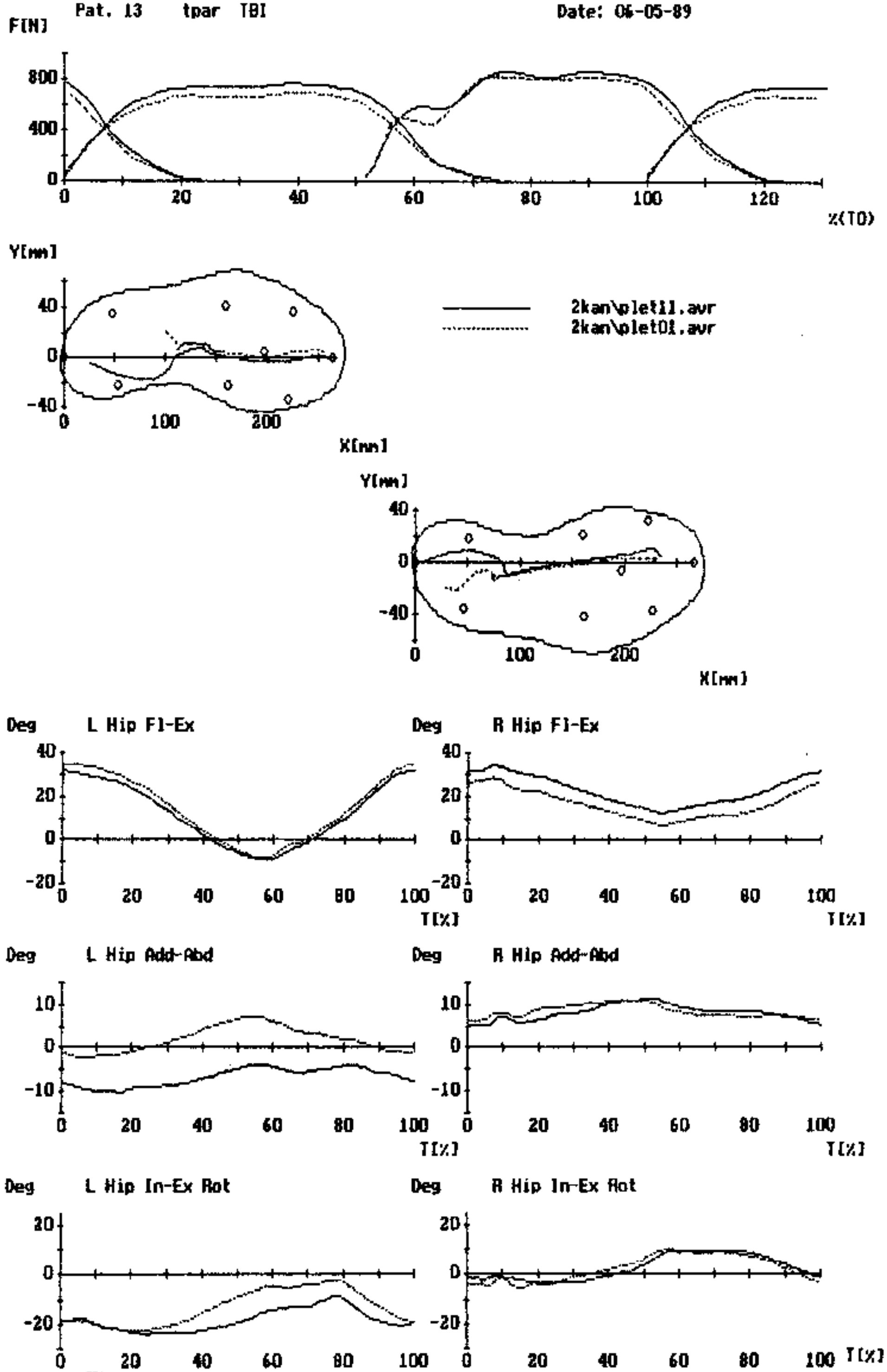

Figure 3: Force basograms and 3-D hip goniograms of patient 13 with (full) and without stimulation (dotted)

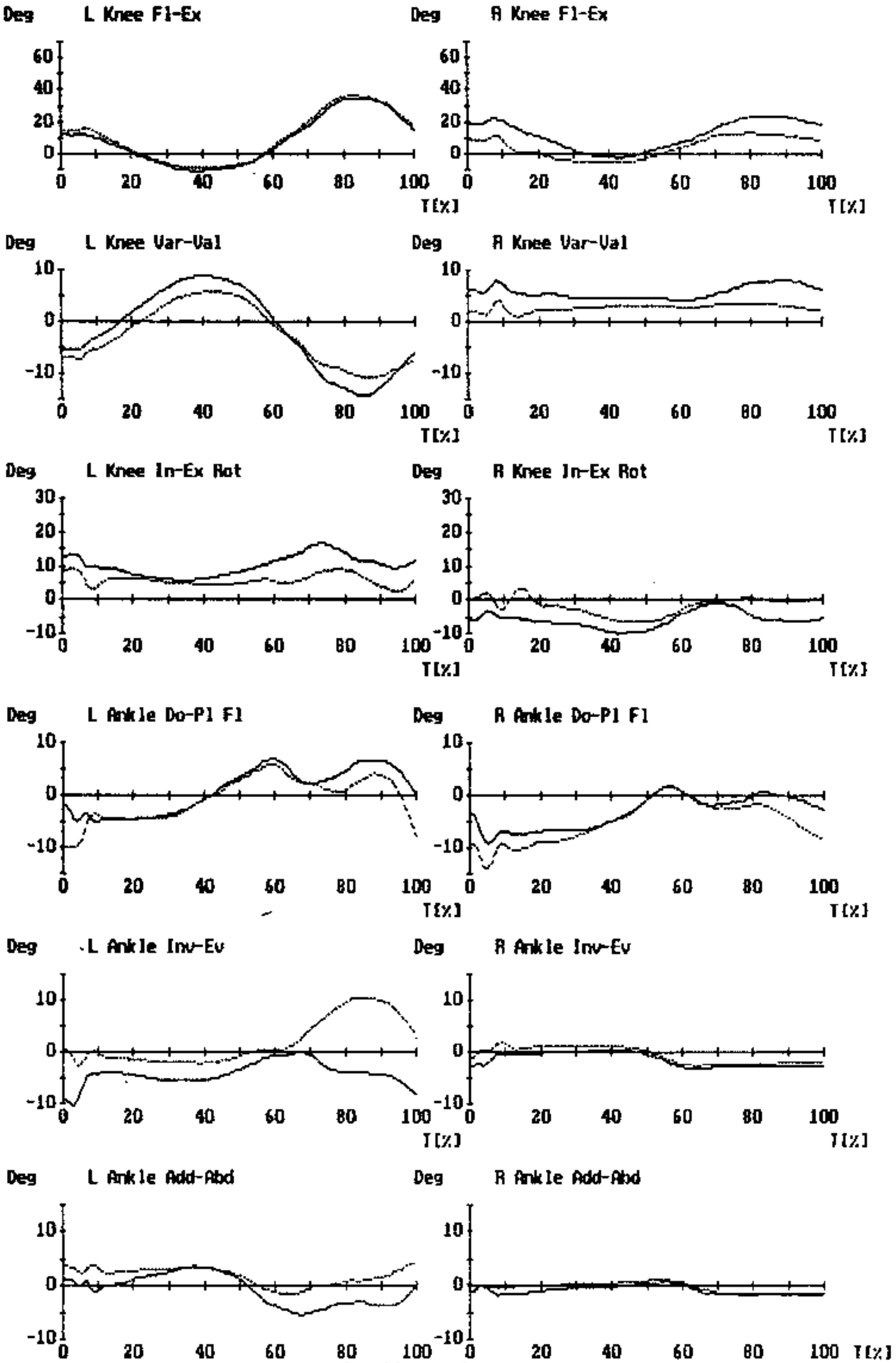

Figure 4: 3-D knee and ankle goniograms of patient 13 with (full) and without stimulation (dotted).

One week of dual channel stimulation, which was assigned to a patient together with the kinesiological measurements, allowed just an estimation of the patients ability to manage the stimulation by themselves. Besides, only commercially available bipolar electrodes were included in the evaluation. A longer stimulation period, higher number of clinically rehabilitated outpatients and more suitable electrodes fitted to particular stimulation sites would render a higher number of persons suitable for independent use of dual channel stimulation.

The patients from the CVI group (Tables 1 and 3), at least in small part, depended on the help of a therapist during positioning of the electrodes and connecting of the stimulator after one week. Stimulation sites also played an important role: positioning the electrodes to the triceps brachii muscle was more difficult than to the quadriceps; hamstring muscles were even more difficult, while gluteus maximus was almost impossible without assistance. Besides, the degree of disability and stage of entire rehabilitation determined the amount of required help. From the whole CVI group, patients 7 and 10 depended entirely on the therapist.

All patients except one from the TBI group (Tables 2 and 4) were able to cope with the stimulation of the peroneal nerve alone. Patient 15 was physically and mentally not able to manage the stimulation alone, although he was very eager to use it. In cases 13, 16, 19, 20 and 21 independent use of the stimulator would not cause major difficulties. Regarding their mental and physical handicaps, patients 12, 17 and 18 could cope with dual channel stimulation after a longer period, while in patients 11, 14 and 15 it might not prove successful without 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 strategies, its simplicity and reliability, as well as the ability of patients to manage 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 restoration of gait in chosen CVI and TBI patients. Simple stimulator units, fitted individually to every patient by an external programming unit, providing large varieties of stimulation sequences and parameters, cover a wide population of patients. The gait analyzer, included in the programming unit, provides relevant statistical data during gait with stimulation in a common environment, and does not require additional measurements. The therapist can control effects of stimulation with this information.

The stimulators are convenient for orthotic use, while their 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, cerebral palsy children, multiple sclerosis and other patients with upper motor neuron lesion could benefit from this system.

Acknowledgment: This work was supported by the National Institute on Disability and Rehabilitation Research Grant H133C80205, Washington D.C., U.S.A., and by Research Grant 032670 from Research Council of Slovenia, Ljubljana, Yugoslavia.

REFERENCES

1. Maležič, M., Stanič, U., Kljajić, M., Aćimović, R., Gros, N., Krajnik, J., Stopar, M.: Multichannel electrical stimulation of gait in motor disabled patients. Orthopedics 7: 1187-1195, 1984.

2. Kelih, B., Maležič, M., Gros, N., Kljajić, M., Bogataj, U., Aćimović, R.: Evaluation of gait during therapy with six- channel electrical stimulation. In Proc of XIV ICMBE and VII ICMP, Espoo, Finland, 9.23: 424-425, 1985.

3. Maležič, M., Krajnik, J., Stanič, U., Stopar, M., Aćimović, R., Gros, N.: Optimization of number of channels for electrical stimulation of pathological gait. In Proc. World Congr. on Physics and Biomed. Engng., Hamburg: 12.32, 1982.

4. 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. Physical therapy 69, 5: 319-327, 1989.

5. Jeglič A.: Two channel implant - approach to an orthotic device. In Proc. 4th Int. Symp. on External Control of Human Extremities, Dubrovnik, Yugoslavia: 647-656, 1972.

6. Naumann, S., Mifsud, M., Carins, B. J., Milner, M.: Dual-channel electrical stimulators for use by children with plegic spastic cerebral palsy. Med & Biol Engng & Comput 23: 435-443, 1985.

7. Kljajić, M., Bajd, T., Stanič, U.: Quantitative gait evaluation of hemiplegic patients using electrical stimulation orthoses. IEEE Trans Biomed Engng 22, 5: 438-441, 1975.

8. Kljajić, M., Krajnik, J., Stanič, U.: A quantitative method of evaluation of gait under the influence of electrical stimulation in hemiparetic patients. Scand J Rehab Med Suppl 17: 105-109, 1988.

9. Isacson,J., Gransberg,L., Knutsson, E.: Three-dimensional electrogoniometric gait recording. J Biomechanics 19, 8: 627- 635, 1986.

10. Kljajić, M., Krajnik, J.: The use of ground reaction measuring shoes in gait evaluation. Clin Phys Physiol Meas 8: 133-142, 1987.

11. Bajd, T., Kralj, A.: Simple kinematic gait measurements. J Biomed Engng 2: 129-132, 1980.

12. Criteria for selection of patients for FES treatment: single, dual and six channel stimulation. Ljubljana Rehabilitation Engineering Research Project, Grant No. G008300323, Progress Report: 23-26, National Institute for Handicapped Research, Department of Education, Washington, D.C., 1985.

Acknowledgment: This work was supported by the National Institute on Disability and Rehabilitation Research Grant H133C80205, Washington D.C., U.S.A., and by Research Grant 032670 from Research Council of Slovenia, Ljubljana, Yugoslavia.

REFERENCES

1. Maležič, M., Stanič, U., Kljajić, M., Aćimović, R., Gros, N., Krajnik, J., Stopar, M.: Multichannel electrical stimulation of gait in motor disabled patients. Orthopedics 7: 1187-1195, 1984.

2. Kelih, B., Maležič, M., Gros, N., Kljajić, M., Bogataj, U., Aćimović, R.: Evaluation of gait during therapy with six- channel electrical stimulation. In Proc of XIV ICMBE and VII ICMP, Espoo, Finland, 9.23: 424-425, 1985.

3. Maležič, M., Krajnik, J., Stanič, U., Stopar, M., Aćimović, R., Gros, N.: Optimization of number of channels for electrical stimulation of pathological gait. In Proc. World Congr. on Physics and Biomed. Engng., Hamburg: 12.32, 1982.

4. 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. Physical therapy 69, 5: 319-327, 1989.

5. Jeglič A.: Two channel implant - approach to an orthotic device. In Proc. 4th Int. Symp. on External Control of Human Extremities, Dubrovnik, Yugoslavia: 647-656, 1972.

6. Naumann, S., Mifsud, M., Carins, B. J., Milner, M.: Dual-channel electrical stimulators for use by children with plegic spastic cerebral palsy. Med & Biol Engng & Comput 23: 435-443, 1985.

7. Kljajić, M., Bajd, T., Stanič, U.: Quantitative gait evaluation of hemiplegic patients using electrical stimulation orthoses. IEEE Trans Biomed Engng 22, 5: 438-441, 1975.

8. Kljajić, M., Krajnik, J., Stanič, U.: A quantitative method of evaluation of gait under the influence of electrical stimulation in hemiparetic patients. Scand J Rehab Med Suppl 17: 105-109, 1988.

9. Isacson,J., Gransberg,L., Knutsson, E.: Three-dimensional electrogoniometric gait recording. J Biomechanics 19, 8: 627- 635, 1986.

10. Kljajić, M., Krajnik, J.: The use of ground reaction measuring shoes in gait evaluation. Clin Phys Physiol Meas 8: 133-142, 1987.

11. Bajd, T., Kralj, A.: Simple kinematic gait measurements. J Biomed Engng 2: 129-132, 1980.

12. Criteria for selection of patients for FES treatment: single, dual and six channel stimulation. Ljubljana Rehabilitation Engineering Research Project, Grant No. G008300323, Progress Report: 23-26, National Institute for Handicapped Research, Department of Education, Washington, D.C., 1985.