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GAIT EVALUATION IN HEMIPARETIC PATIENTS USING SUBCUTANEOUS PERONEAL ELECTRICAL STIMULATION

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ABSTRACT. In hemiparetic patients with an implantable peroneal stimulator for correction of drop foot the gait pattern was studied over several years. The gait parameters and M-waves of subcutaneously stimulated muscles were compared with the results obtained before implantation and their variation was observed over time. Of a group of 35 patients with previously implanted electrodes 19 were evaluated. Significant improvements of gait were found although in some cases an excessive eversion of the foot was observed. Nine of these patients had reimplantation because of displacement of the stimulation electrodes after an average time of 3.5 years of proper functioning of the implant. After the reimplantations, similar gait patterns and muscular responses to stimulation were observed as after the initial implantation.

Key words: functional electrical stimulation, peroneal nerve implants, gait, evaluation.

Electrical stimulation of the peroneal nerve has been widely accepted as a therapeutic and functional method for correction of drop foot in patients with upper motor neuron lesion (4). Stimulation is applied to the nerve of the affected lower limb and prevents equinovarus positioning of the foot in the swing phase. An implanted system, permanently attached next to the peroneal nerve at the lateral head of the fibula, was used to avoid problems with daily positioning of the surface electrodes, unwanted reactions of the skin (1, 9, 11) and possible unpleasant sensations.

In Ljubljana, 35 hemiparetic patients had peroneal stimulators implanted during the period 1981 to 1991. The system, which consisted of a disc-shaped implant and platinum electrodes implanted close to the peroneal nerve, was radio frequency powered by an external unit with a transmitting antenna (8). The stimulation was applied during the swing phase of gait and was controlled by a foot switch which triggered the train of stimulation pulses when the heel was lifted. The electrode position was selected during a minor surgical procedure by moving the implant along the exposed common peroneal nerve until functional ankle movement was obtained. Clinical evaluation of implanted patients has shown that the quality of gait correction was not always satisfactory. With a still relatively functional correction, an excessive eversion could be observed in several cases. Displacement of the stimulation electrodes from their initial position at the nerve was supposed to be the cause of such results.

To test reliability of the electrode position and quality of the stimulated gait a quantitative evaluation method was investigated. It comprised a determination of the gait dynamics with and without stimulation before and after implantation together with recording of the EMG responses (M-waves) of the tibialis anterior, peroneus longus and soleus muscles to peroneal nerve stimulation. The gait pattern was assessed each year following surgery in an attempt to analyze the effectiveness of the implantable stimulator over a longer period.

The relationship between the isotonic ankle responses of the stimulated muscles and quality of the gait control as a function of the electrode position was also studied.

METHODS

Correction of drop foot was evaluated by a description of ankle movement and recording of EMG responses to subcutaneous stimulation of the peroneal nerve together with an estimation of gait dynamics with and without stimulation.

The common peroneal nerve was stimulated at the head of the fibula by bipolar subcutaneous platinum electrodes. The pulse duration of 20 Hz pulse train with amplitudes from 1–5 V or 10 mA (depending on the type of implant) was adjusted from 0.1–0.5 ms to obtain optimal response. Stimulated ankle movement was described as rotation in the sagittal plane (dorsal flexion, plantar flexion) and in the lateral plane (eversion, inversion). The patient was standing with his weight shifted to the healthy lower limb during the experiment, thus simulating conditions during the swing phase of gait. Strong

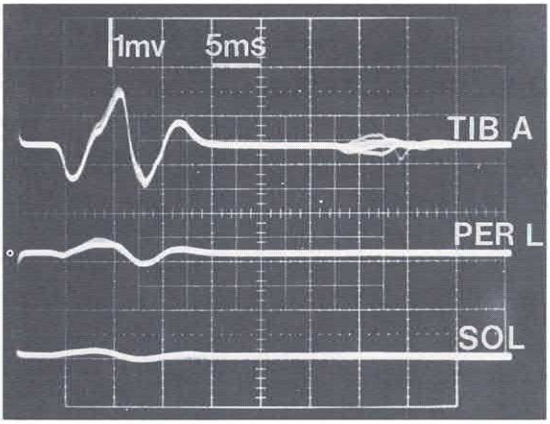

Fig. 1. EMG responses of tibialis anterior, peroneus longus and soleus muscles to subcutaneous stimulation of peroneal nerve in patient 11, with right-sided hemiplegia.

dorsal flexion with moderate eversion was qualified as functional ankle movement.

EMG responses of the tibialis anterior, peroneus longus and soleus muscles to the stimulation of the peroneal nerve were recorded at the same time (5). Different combinations of M-waves in the observed muscles correlated fairly well with the direction of isotonic ankle movement. Again, strong activation of the tibialis anterior, a moderate one of the peroneus longus and only a minor M-wave in the triceps surae indicated a good electrode position. As an example, M-waves in the tibialis anterior, peroneus longus and soleus muscles of case 11 with strong dorsal flexion (DF) and moderate eversion (mEV) are shown in Fig. 1. Average values of 32 responses to the 20 Hz, 0.3 ms subcutaneous stimulation are presented with the patient with hemiplegia of the right side in a standing position.

Gait dynamics was determined by measuring vertical components of the ground reaction force and its point of action (POA) under the soles of measuring shoes (2). At the same time 3 dimension goniograms of the hip, knee and ankle joints were measured together with average stride length and velocity. In this study, special attention was paid to POA, which was revealed to be rather sensitive and relevant for the clinical assessment of gait (3).

Stimulation was applied by the implanted electrodes during the swing phase of gait in order to correct drop foot. The 30 Hz train of pulses with amplitudes from 1–5 V or 10 mA and adjustable duration from 0.1–0.5 ms was used. Gait dynamics was compared with and without stimulation at freely chosen gait speed.

In Fig. 2 the average vertical ground reaction force and its POA during gait with and without stimulation are shown for the same patient. Different areas of POA were denoted with: H for the heel, M for mid-foot and T for the toe area in further analysis. They were given for loading, midstance and push off phases, e.g. H, M, T meant that the POA ran from the heel ground contact through the mid-foot to toe-off phase. When the POA ran laterally or medially outside the marked area, indices l or m were added to standard notation. A different combination of gait events as defined in Fig. 2 can occur on an affected and unaffected lower limb during gait. However, initial combination, transient condition and steady state are of primary interest.

Alterations of gait variables with respect to normal gait pattern and symmetry between the right and left side variables were chosen as a measure of gait quality. Alteration of M-waves, regarding the initial ones, could indicate changes in the electrode position, electrical characteristics of the implant or electrophysiological characteristics of the stimulated nerve, which could be tested separately. Comparison between the description of the stimulated ankle movement and gait dynamics could provide information about the electrode nerve interface and functionality of gait control, e.g. ankle response described as dorsal flexion and moderate eversion (DF, mEV) with strong activation of the tibialis anterior and a moderate one of the peroneus longus muscles by stimulation in Fig. 1 and the desired heel, mid-foot, toe POA (H, M, T) in Fig. 2 could be interpreted as a high correlation between gait dynamics and stimulation. However, ankle eversion (EV), activation of only the peroneus longus and heel, mid-foot, toe POA (H, M, T) in case 16 from Table I correlated poorly in spite of functionally stimulated gait.

RESULTS AND DISCUSSION

Clinical results

From the population of 35 patients three died within three years after implantation, 1 had his leg amputated for reasons unrelated to the implant, 4 implants were removed because of unpleasant sensations, 3 patients gave up stimulation owing to poor correction and 1 recovered his volitional control. The average lifetime of the remaining implants was 4.9 years (range 0.5–10 years). Out of 22 patients, 19 who had been using the stimulation daily were analysed. Patients 2, 4, 6, 13, 16 and 20 were implanted twice,

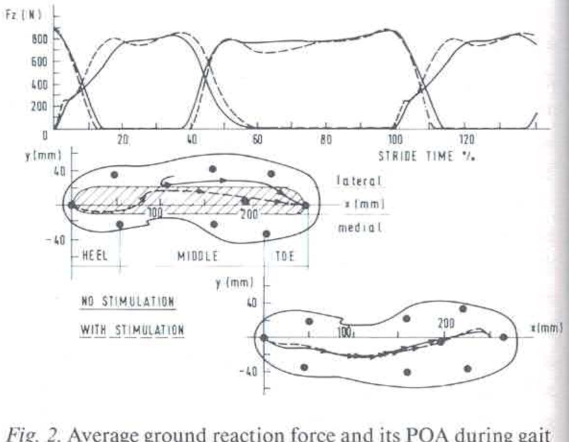

Fig. 2. Average ground reaction force and its POA during gait in patient 11 without (full line) and with stimulation (dash line). Marked area represents region of normal POA.

Table I. *Stimulated ankle movement and force point of action (POA) during stimulated gait*

R right, L left, HEM hemiplegic, PP paraplegic, TP tetraplegic, DF dorsal flexion, EV eversion, PF plantar flexion, eEV excessive eversion, mEV moderate eversion, H heel contact, M mid-foot, T toe-off, l lateral, m medial, b border, * third implantation, – cannot walk without stimulation

Pat.	Diag.	Ankle movement stim.	POA Stim.	POA No stim.
1	R HEM	DF, mEV	H, M, T	H, M, T
2	R HEM	DF, mEV	H, M, T	Mm, Tm
3	L HEM	eEV, mDF	H, Ml, T	H, Mm, T
4	L HEM	DF, mEV	H, M, T	H, Mm, T
5	L HEM	eEV	H, Ml, T	H, M, Tl
6	R HEM	DF, mEV	H, M, Tl	Mm, T
7	R HEM	DF, mEV	H, M, T	Mm, T
7*	R HEM	DF, mEV	H, M, T	Hl, M, T
8	T7 PP	eEV, mPF	H, M, Tl	Mm, T
9	L HEM	DF, eEV	H, Ml, T	Mm, T
10	C7 TP	EV/DF, mEV	H, M, T	M, T
11	L HEM	DF, mEV	H, M, T	Ml, T
12	L HEM	eEV	Hl, M, T	Hl, M, T
13	R HEM	eEV	H, M, T	Hl, M, T
14	R HEM	EV	H, M, T	Hl, M, T
15	L HEM	eEV, PF	Hl, M, T	Hl, M, T
16	L HEM	EV	H, M, T	Ml, T
17	R HEM	DF, mEV	H, M	–
17*	R HEM	DF, mEV	Hl, M, T	Mlb, Mlb
18	R HEM	EV	M, M	Ml, Mm
19	R HEM	DF, mEV	H, M, T	H, M, T

position 7 and 17 three times. The results of recent implantations are presented in Table I. The average lifetime of the second implants was 3.5 years (range 1.2–5.2 years), while the third implants lasted 5.3 and 4.1 years. The prime reason for the reimplantations was an inadequate response after a displacement of the electrodes due to fibrous capsule formation or muscle dynamics. Electrophysiological and histological tests showed no pathological changes in the stimulated nerve and surrounding tissue. With the exception of one broken electrode, the removed implants were electrically intact (6).

Gait analysis

The results of current assessments of ankle movement and gait measurements are shown in Table I. Descriptions of stimulated isotonic ankle movement and POA during gait with and without stimulation are also given. Patients 7 and 17 are presented for both reimplantations. Attributes in the decriptions follow a consecutive order of events. Correlation of the descriptions of stimulated movement while standing and POA during gait in the third and fourth column is a measure of the relationship between the stimulation itself and gait as a dynamic process.

Various combinations of stimulated ankle movement and correction of gait was found (Table I). Eight of the 19 patients displayed the desired ankle response: DF, mEV, and 11 patients the desired POA: H, M, T. No difference was found between POA with and without stimulation in patients 1 and 19 in a recent examination. In patient 17 adequate ankle movements could be stimulated by the first and second implant while standing. POA during gait with stimulation was inadequate but improved by the second implant. However, relative correction of gait by stimulation was outstanding, enabling the patient to walk without a brace. After the second implantation, the patient was even able to walk a limited distance without stimulation, stepping on the lateral border of the mid-foot.

Eleven of 19 patients exhibited an excessive eversion of the ankle, with even a moderate plantar flexion in patient 15. Various degrees of gait correction were reflected in POA with stimulation during the swing phase of gait. Thus in patient 16, with insufficient ankle response while standing, an adequate POA and functional gait were achieved by stimulation.

The variability of POA as a function of stimulation is shown in Table II where patients 1 and 4 are presented. There was practically no change of POA in patient 1 by surface stimulation before implantation. The principal changes appeared on the affected and unaffected side 14.5 months after implantation. Gait patterns of both sides were symmetrically exchanged with respect to surface stimulation. Twenty-eight months after implantation POA matched the normal gait pattern and difference between gait with and without stimulation disappeared. However, the patient continued to use stimulation.

In patient 4 one year after stroke, POA of the affected lower limb was well corrected by surface stimulation but there was a flat foot loading of the unaffected lower limb, which could be ascribed to compensation for stability. Similar POA of the affected lower limb to those with surface stimulation were recorded after the first and second implantations during the next four years. The POA of both sides was symmetrical and approached the normal gait pattern.

For numerical analysis, columns 3, 4 and 5 from

Table II. *Time behavior of force point of action (POA) during gait with and without stimulation*
S surface stimulation, I implantation, R reimplantation

		POA unaffected side		POA affected side	
Pat.	Test	Stim.	No stim.	Stim.	No stim.
1	03-03-83 S	H, M, T	Hl, M, T	Ml, T	Ml, T
	03-08-83 I				
	05-23-84	Ml, T	Ml, T	H, M, Tm	H, M, Tl
	07-18-85	H, M, T	Hl, M, T	H, M, T	H, M, T
4	03-07-83 S	M, T	M, T	H, M, T	Ml, Tl
	03-08-83 I				
	05-25-84	H, M, T	H, M, T	H, M, T	Hl, M, Tl
	03-07-85	H, M, T	H, M, T	H, Mm, T	H, Ml, T
	03-12-85 R				
	03-28-85	H, M, T	H, M, T	H, M, Tm	Hl, M, Tl
	04-23-87	H, M, T	H, M, T	H, M, T	Hl, M, T

Table I have been transformed according to the expression:

$$\mathrm{di} = \mathrm{abs}\,(\mathrm{Xd} - \mathrm{Xi})$$

where Xd represents sets of the desired events (target), Xi measured values and di distance between them. The set of events DF, mEV represents the target stimulated ankle movement and set H, M, T, the target POA. Sets of possible events were linearly ordered as

$$\mathrm{DF, mEV} < \mathrm{DF, eEV} = \mathrm{eEV, mDF} < \mathrm{EV} < \\ < \mathrm{eEV} < \mathrm{eEV, mPF} < \mathrm{eEV, PF}$$

with ascending values from 0 to 5 for the stimulated foot movement and

$$\mathrm{H, M, T} < \mathrm{H, M, Tl} = \mathrm{H, M, Tm} < \mathrm{Hl, M, T} = \\ \mathrm{Hm, M, T} < \mathrm{H, Ml, T} = \mathrm{H, Mm, T} < \mathrm{H, M} < \mathrm{M, T} < \\ \mathrm{Mm, T} = \mathrm{Ml, T} < \mathrm{M, M} < \mathrm{Mm, M, L} = \mathrm{Ml, Mm} < \\ \mathrm{Ml, Tl} = \mathrm{Mm, Tm} < \mathrm{Ml, Ml} = \mathrm{Mm, Mm} < \mathrm{Mlb, Mlb}$$

with ascending values from 0 to 11 for POA. Relations "<" or "=" between the two events denoted that the first one was closer or equally distant to the target.

POA events with a lateral or medial index were supposed to be equally worse than those running through the central foot area. However, the relation H, M, Tm < Hm, M, T depended on the assumption that heel contact was more important than toe clearance. To test possible impacts of such assumption on the results, both alternatives were examined in the valorization of uncertain gait events. Only minute differences were found in such cases, proving a proper selection of the criterion, e.g. relation Hm, M, T < H,

Table III. *Stimulated ankle movement, force point of action (POA) and stride time with and without stimulation*

Pat.	Distance stim. ankle movement	Distance POA		Stride time	
		Stim.	No stim.	Stim.	No stim.
1	0	0	0	1.78	1.84
2	0	0	8	1.75	2.50
3	1	3	3	1.70	1.86
4	0	0	3	1.78	1.74
5	3	3	1	1.30	1.28
6	0	1	8	1.37	1.36
7	0	0	6	1.65	1.99
7*	0	0	2	2.05	2.27
8	4	1	6	2.40	2.52
9	1	3	6	1.43	1.43
10	1	0	5	1.63	1.56
11	0	0	6	1.32	1.60
12	3	2	2	1.60	1.64
13	3	0	2	1.73	1.84
14	2	0	2	1.67	2.08
15	5	2	2	1.52	1.70
16	2	0	6	1.44	1.42
17	0	4	–	1.50	–
17*	0	2	11	1.58	1.82
18	2	7	9	1.70	1.52
19	0	0	0	2.11	2.12

M, Tm in Table III was changed to Hm, M, T ≡ H, M, Tm with no difference either for the correlation coefficient or the results of the t test. The results are listed in Table III, where stride time in seconds was added.

The gait parameters of these patients were corrected by stimulation. The paired t test showed significant improvements of POA by 72% ($p<0.005$), gait velocity increased by 20% ($p<0.005$), stride length by 14% ($p<0.005$) and stride time decreased by 7% ($p<0.01$). Measurements were performed at free gait cadence. The results were comparable with previous reports (8, 9). Spearman's rank correlation index 0.42 was found between stimulated ankle movement and POA during stimulated gait. A relatively small correlation index demonstrated that control of drop foot during gait is more complicated than stimulated ankle movement.

When splitting Table III into patients whose stimulated ankle movement achieved the target trajectory DF, mEV, and other patients, interesting results were obtained. In the first group rank correlation 0.67 was found between the stimulated movement and POA during stimulated gait with highly significant improvements of POA ($p<0.005$), gait velocity ($p<0.025$), stride length ($p<0.01$) and stride time ($p<0.05$). In spite of the homogeneous group with respect to the stimulated ankle movement and correlation, the relatively high 33% variation cannot be explained by a simple relation between the stimulation and gait parameters. In the second group there was no correlation between the stimulated ankle movement and POA with stimulation. Although gait parameters were not as good as in the first group, they were still significantly improved by stimulation: POA ($p<0.05$), gait velocity ($p<0.025$), stride length ($p<0.01$) and stride time ($p<0.1$). The results suggest afferent effects of stimulation besides direct ones.

The results in patients 1 and 19 can be explained by a long-term use of subcutaneous stimulation over several years, when they eventually achieved good functional gait even without stimulation. Similar effects have been reported by others (9, 10). In addition, chronic electrical stimulation reduced spasticity in the triceps surae, decreasing its tonic component (7). Stimulated ankle movement and gait measurements provided practical information on the quality of gait control by subcutaneous stimulation for each patient individually. The data were tested twice: with the t paired test and the Wilcoxon two-sample test in order to minimize errors of data estimation. Both tests gave similar results.

CONCLUSION

Follow-up of the M-waves, stimulated ankle movement and ground reaction force pattern over several years showed two characteristic groups: 10 patients who approached normal patterns and 9 patients who after a period of stability, exhibited a migration of the patterns to new, undesirable ones, mostly owing to excessive eversion. In these patients, reimplantation was required after an average of 3.5 years of appropriate functioning. After reimplantation, similar ankle responses and ground reaction force patterns were observed to those after the initial implantation. Although 57% of the analyzed patients displayed an excessive eversion, gait parameters were significantly improved by stimulation in general.

With careful positioning of the stimulating electrodes (5), subcutaneous stimulation may correct impaired gait to a similar extent to surface stimulation. Stability of the response depends on the electrode-nerve interface, which requires additional modification of the implant, shape and fixation of the electrodes. Effectiveness of the subcutaneous stimulation may also be improved by a dual-channel implantable system (10).

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