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IMPLANTABLE PERONEAL UNDERKNEE STIMULATOR - EVALUATION

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Abstract. In 1981 an implantible peroneal system was technologicaly developed to such a stage as to permit clinical evaluation. In two years and a half 20 implants were applied in the case of hemiplegics after CVI (18) lesion, 1 implant after a high cervical lesion, and 1 in the case of a paraparetic after a high thoracic lesion. We studied the influence upon the correction of anomalies during gait at different stimulation parameters, eventual noxious influences upon n. peroneus (peripheral neuron), examined reliability of the system, and recorded, with respect to the patients' statements, occasional difficulties in positioning the aid. The results obtained were evaluated qualitatively - clinically - and quantitatively - biocybernetically - by comparing the state before the applicatin with that at controls after 8 to 12 months and after 2 years. The system is intended primarily to serve as an orthotic aid on the basis of an external movement control in patients with a proximal motoneuron lesion.

Introduction. Taking into account the results of the investigations on implantible systems with us (3) and abroad (5), as well as practical experiences on electrical aids, we started a new series of implantible systems (6) in order to provide patients with a functional, reliable and simply adjustable orthosis (Fig. 1). As in the rehabilitation of locomotor invalids suitable gait is of utmost importance in overcoming environmental barriers, we considered an implantible system a highly advantageous orthosis to be applied in the cases of diseases and impairments of the central nervous system. For that purpose it was necessary to determine the effects on the correction of pathologic synergy, submit evidence on the reliability of the system and simplicity of positioning, and also to ascertain eventual noxious effects. The results were expected to indicate the application of an industrially available orthosis.

Procedure and Results. Included in the first group were hemiplegics with a longer anamnesis with whom a permanent orthosis was indicated and who had been using an electrical stimulator with surface electrodes or a peroneal brace of another type for a longer period of time. All of the patients stated greater or lesser problems involved in positioning and moistening the electrodes, as well as frequent technical troubles and exhaustion of spare parts representing durable goods.

A methodology of evaluation was conceived, namely, a qualitative evaluation - clinically, e. g. motor functions, clinical kinesiological analysis of gait (1), study of functional response in the case of surface FES, and quantitatively, by measuring the forces of loading, symmetry of gait, heel-on, velocity of gait (2), movements in hips, knees and ankle joints in teh sagittal plane (4). Added thereto were electrophysiological measurements of EMG muscles in the innervation field of n. peronei, speed of conduction velocity of n. peroneus and

M-wave in order to determine eventual noxious effects exterted upon the peripheral neuron, since the implant is inserted along its length behind capitulum fibulae.

In all of the twenty implantations we proceeded - and will do so also in the future - in the same way, and attended to analyses and measurements before the application, after a few days of walking with the aid of electrical stimulation induced by the implant (electrophysiological measurements excepted), after 8 to 12 months, and after 2 years. The functioning of the device has been (and will be) subject to observation in order to determine eventual defects as well as to take note of the patient's remarks referring to the positioning and the duration of daily use.

The implantation is effected by means of a surgical intervention at local anaesthesia lasting 20 minutes at the most, the test of functional response in situ included.

Results.

- The effect upon the correction of pathologic synergy is revealed primarily as a correction of equinovarus during the swing phase (Table 1).
- No effects can be established with respect to the reorganization of motor functions, since all the time correction is possible exclusively by means of the aid, whereas an active control remains absent also after a period of some months.
- Measurements of reaction forces (Fig. 2) and goniograms (Fig. 3) reveal an essential difference between the gait without and by electrical stimulation, which is evident from a better heel-on, a better transfer of weight onto the affected side, a greater velocity, an improved symmetry, and better mobility. All of this makes part not only of the first measurements but also of all later control measurements.
- The walking distance gradually increased, with two patients to no less than 10 km on different surfaces, and that after an application of some months.
- Electrophysiological measurements confirm the absence of noxious effects upon the peripheral neuron both at the control after 8 to 12 months (11 patients) and the control after 2 years (4 patients).
- The functioning of stimulators is reliable and practicaly without break-downs. There was required merely the substitution of spare parts, e. g. elements with switches. The positioning of the device is simple and the patients' statements quite favourable.
- In one case the X-ray showed a shift of the implant after one year and five months of use. As all tests (electrophysiological, histological) revealed no pathological changes of the surrounding tissue, we decided upon a reimplantation.
- We studied also the correction of gait - above all foot movement - at changing parameters of stimulation and observed an important effect upon functional response. Most of all in the course of the first months pulse width revealing different individual values (from 10 microseconds to 180 microseconds) was adapted a number of times.

Discussion. The results obtained after the first series of applications are rather favourable and point to the advantages of the system as orthosis. The surgical intervention involved is simple, the post-operative course normal. The correction of gait is satisfactory, which contributes to a longer daily use, a longer walking distance, and velocity of gait. The absence of therapeutic effects could be explained by the fact that in this group of patients a longer period of time (several years in some cases) has elapsed since the beginning of the illness so that the state of restitution has become definite. The most favourable results are revealed in that there is no danger of peripheral neuron lesion, furtheron, in reliable functioning of the device, and finally in that patients have no problems as regards positioning and application. Somewhat different results might be expected of the application in an earlier phase following the insult when therapeutic effects might not be excluded. When selecting patients, care should be taken to select those capable of satisfactory cooperation and enjoying a suitable psychophysical condition.

Tab. 1: Correction of anomalies of the impaired gait pattern using implantible systems (kynesiological analysis of gait)

0 - no
1 - mild
2 - moderate
3 - severe

JOINT	Before stim.				With stim.				After using 8-12 month								No. patients
									without stim.				with. stim.				
	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	
HIP J.	-	6	6	4	-	11	5	-	-	6	8	2	1	10	5	-	16
KNEE J.	-	4	6	6	-	5	8	3	-	4	7	5	-	7	6	3	16
ANKLE J.	-	-	-	16	15	1	-	-	-	-	-	16	15	1	-	-	16

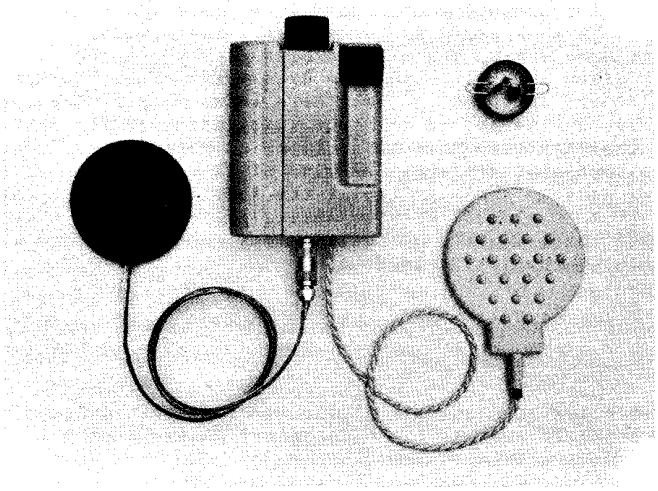

Fig. 1: The underknee implantible system (6)

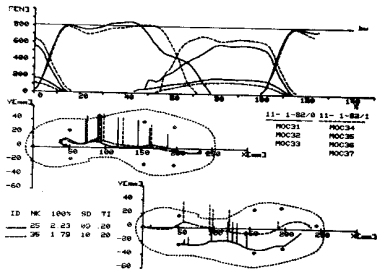

Fig. 2: Ground reaction forces measured by special measuring shoes (M.F., h.d.)

_____ without stimulation
_ _ _ _ _ with stimulation

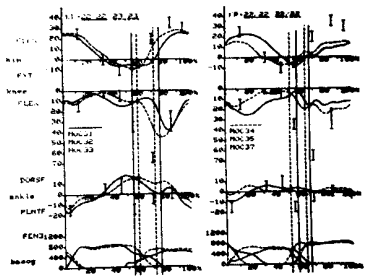

Fig. 3: Electrogoniograms (M.F.,h.d.)

——— with stimulation
----- without stimulation

REFERENCES:

1. Aćimović, R., U., Stanič, A., Trnkoczy, N., Gros, T., Bajd, V., Valenčič: Clinical evaluation of digital six-channel walking rate dependent stimulator in: Biomechanics VI B, Asmussen, K. Jörgensen, eds, Intern. Series on Biomechanics, University Park Press, Baltimore, 1979, vol. 2 B, pp 349-356

2. Aćimović, R., N., Gros, J., Krajnik, M., Maležič, M., Kljajič, M., Stopar, U., Stanič: Measurements of gait correction with hemiplegic patients by means of electrical stimulators, Zdrav. vestnik 51/1981, pp 194-197, 5th Congres ISEK, Ljubljana, 1982

3. Jeglič, A.: Two-channel implant Approach to an Orthotic Device, 4th Int. Symp. on External Control of Human Extremities, Dubrovnik, Yugosl. Commitee for Electronics and Automation, Belgrade, Yugosl., 1972

4. Krajnik, J., M., Kljajič, M., Maležič, U., Stanič, M., Stopar, R., Aćimović, N., Gros: Ground reaction measuring shoes as an aid in the clinical assessment of pathological gait. Proc. 17th Symposium on External Control of Human Extremities, Dubrovnik, 1981, pp 379-389

5. McNeal, D., W.K., Wilemon, V., Mooney, R., Bogga, T., Tamaki: The Effect of Peripheral Nerve Implanted Electrical Stimulation on Motor Control in Stroke Patients, World Congres of Nevrological Sciences, N. Y., Sept. 1969

6. Strojnik, P., E., Vavken, R., Aćimović, U., Stanič: A new Ljubljana implantible peroneal stimulator, Proc. of the World Congres on medical Physics and Biomedical Engineering, 1982, Hamburg, pp 12.08

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