

FUNCTIONAL STIMULATION

AN OUTLINE OF PRINCIPLES AND METHODS UTILIZED IN EVALUATING IMPLANTED SYSTEMS FOR FUNCTIONAL ELECTRICAL STIMULATION

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Introduction

Functional electrical stimulation (FES) /1/ with skin electrodes is utilized as functional electro therapy /2/ or as an orthotic device /3, 4, 5/ in the control of drop-foot during walking of hemiplegic patients. All the systems developed, i.e. laboratory systems, prototype and commercially available ones such as the Ljubljana functional electronic peroneal brace, and similar systems developed in other centres thus far have proven to be more sensitive and to require more collaboration of the patient than was the case with conventional mechanical peroneal braces. Since the system for FES has many functional and conceptual advantages over the conventional ones, we have tried to develop such a system which would require minimum collaboration of the patient, and which would not be exposed to mechanical or other injuries or be otherwise delicate. In our efforts to obtain the above conditions we have had to avoid the most delicate points of the system such as wire connections, the electrodes for stimulation, every-day manipulation with connectors, placement of the electrodes, etc. A most satisfactory solution seems to be the development of the implanted system consisting of the receiver and stimulating electrodes, and radiofrequency control of triggering the stimulator /6/. Many years of experiments on dogs /7/ have shown no reaction of the tissue as well as constant responses to stimulation which enabled implantation on the volunteers, the researchers themselves /6/. One implant system that has been in place for eighteen months has not caused any reactions of the tissue. All the time the system has operated with reliability /8/. As the system is reliable and harmless we have begun to implant it in hemiplegic patients. Taking into account advantages and deficiencies of the system with skin electrodes /9/ and the implanted system, indications for the application of the system with the implant has to be determined prior to implantation.

Indications and Methods of Evaluation

The choice of patients for implantation was carried out by two teams. The clinical rehabilitation team for hemiplegia and the team for implantation. The first one had to evaluate medical, psycho-social, and other factors that could be significant for the satisfactory outcome of implantation and evaluation. On the basis of measurements that will be discussed later, final decisions are made in the second, sixth, and twelfth month following implantation.

Apart from the above mentioned previous utilization of functional electrical stimulation for at least 6 months without an essential improvement of impaired motor functions, was prerequisite to implantation. However, the patient with surface stimulation had had to manifest satisfactory correction of dorsal flexion and eversion of the foot during walking. On the basis of these statements implantation was performed in 10 patients.

Table 1 shows their age, the affected side, etiology as well as time of functional electrical stimulation with the implanted system, the period of time of independent use of functional electrical stimulation in months.

Table 1

No.	Name	Age at time of impl.	Sex	Affected side/L.R.	Etiol.	Time follow. impl./in months	Use of FES /in months
1.	V.L.	38	F.	L.	CVI	26	68
2.	T.V.	56.5	M.	L.	CVI	26	47
3.	K.A.	39.5	F.	L.	CVI	18	49
4.	Š.J.	45	M.	L.	CVI	17	28
5.	R.J.	59	M.	L.	CVI	12	36
6.	Š.F.	44	M.	R.	CVI	11	41
7.	R.I.	47	M.	L.	CVI	11	18
8.	K.A.	41	M.	L.	CVI	7	64
9.	S.I.	79	M.	R.	CVI	7	44
10.	K.J.	38	M.	L.	T	5	29

CVI - cerebrovascular insult

T - trauma

O - others

L. - left

R. - right

Performed were:

- CLINICAL OBSERVATION of the patients including his neurological, psychiatric, and psychological status with the
- TEST OF MOTOR FUNCTIONS and
- MANUAL MUSCLE TEST
- ELECTROPHYSIOLOGICAL ANALYSES of
 - electrical excitability
 - motor conduction velocity of the peroneal nerve, and the
 - analyses of the behaviour of the double reflex response
 - pattern to the conditioning stimulus (10).
- KINESIOLOGICAL ANALYSES OF GAIT (polyelectromyographic recording of the activity of single muscles during walking as well as the extent and speed of movements in the hip, knee and ankle joints) with and without functional electrical stimulation were performed
- STEREOTAXIC DETERMINATION of the most suitable position of the implanted system, and the answer the implanted system can elicit
- DYNAMICS OF MOTOR RESPONSE ANALYSES
- THE COURSE OF MUSCLE FATIGUE ANALYSES

Implantation can begin as soon as the above measurements are carried out provided the measurements give positive results /8/. The measurements are repeated two, six, and twelve months following implantation. Immediately upon implantation and a year later an X-ray of the implant is taken to state its position.

Discussion

Aside from the basic goal, i.e. to provide a more practical and less delicate system so that the use at home may be easier, deficiencies of the system in every-day use should also be found out before it is given to a larger number of hemiplegic patients. The measurements are intended for the establishment of the effects of functional electrical stimulation with the implanted system, and should be compared with the effects obtained with skin electrodes. We should be aware that with surface stimulation, conditions of stimulation can be easily changed every day and whenever necessary, which depends on the improvement of impaired motor functions, since the improvement of single impaired stimulated muscles is not achieved simultaneously. On the other hand,

the implanted system succeeds in avoiding additional afferent inflow coming from the skin receptor during surface stimulation.

From the medical and bioengineering standpoint, results of the measurements described will be of utmost importance to further work in the control of complex movements of the paretic extremities or the extremities exhibiting motor disturbances due to damage of the CNS structures.

Further studies which will include another 12 patients with hemiplegia will provide a definitive assessment regarding evaluation and use of the implanted system for FES of the peroneal nerve and correction of drop-foot during walking. Data which are of essential significance to the external control of muscle contraction with equal or similar characteristics as those of the peroneal muscles, will enable the introduction of implants in the control of complex movements of the extremities, control of dynamics and maintenance of equilibrium of the locomotor system.

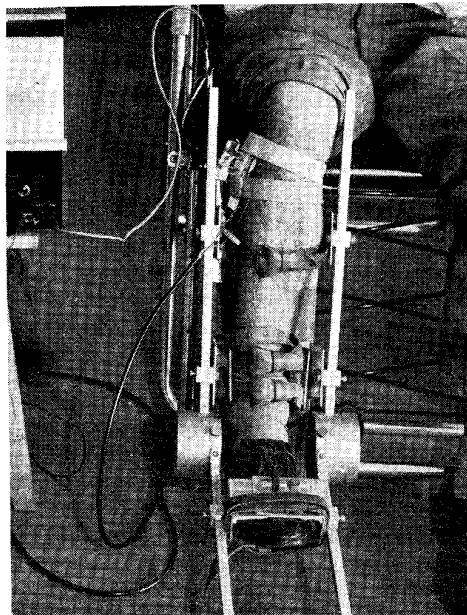


Fig. 1. The techniques of measuring of the motor response dynamics.

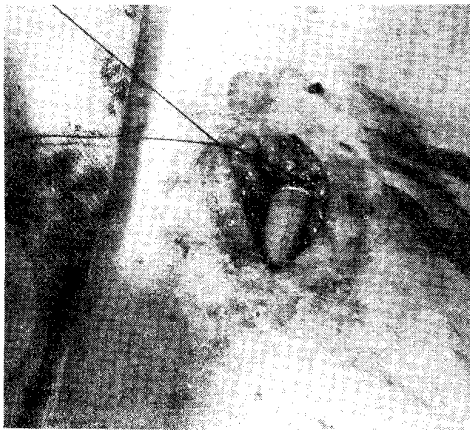


Fig. 2. The implant in situ.



Fig. 3. The patient walking with the implant.

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