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MID AND LONG TERM VARIATIONS OF GROSS MUSCLE FORCE DUE TO FUNCTIONAL ELECTRICAL STIMULATION IN HEMIPARETIC PATIENTS.

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KEY WORDS

Biomedical engineering, rehabilitation, electrical stimulation, hemiplegia, physical therapy.

ABSTRACT

The effect of Functional Electrical Stimulation (FES) on the maximal voluntary contraction force of paretic muscles has been shown by many authors to be significant in hemiparetic patients. It was the purpose of this work to study the performance of a single group of 12 patients during a two month period. The patients received traditional physiotherapy treatment during both months and FES of the peroneal nerve during the second month only.

The maximal voluntary moment of ankle dorsal flexion was measured twice a week and the second month pattern was compared with the first month pattern for each patient.

In eight patients the second pattern was significantly better than the first ($p < 15\%$), in two there was no significant change and in the last two a stabilization pattern was observed. Altogether the average slope of the second month was higher than that of the first month at the 0,2% level of significance. An improvement of the non affected side was also observed in all subjects. The patients were dismissed and seven of them could be recalled two months later. An average drop of about 10% was observed in the maximal dorsal flexion moment of the paretic side while no significant change was observed on the healthy side.

INTRODUCTION

Functional electrical stimulation is a well known orthotic and therapeutic technique for the rehabilitation of hemiparetic patients. (4) Its therapeutic value has been investigated by means of clinical and quantitative evaluation (EMG, basographic and kinesiological analysis, force measurements, etc.) (1-5).

In particular, measurements of maximal voluntary dorsal flexion of the plegic foot have been reported by Vodovnik et al. (1973) and Stefancic et al. (1976), who studied the short and mid term effect of FES on such parameter and by Merletti et al. (1978) who carried on a control study. Despite the results of statistical analysis, the wide range of variability of hemiparetic patients may still justify some criticism of previous data.

In order to provide further evidence, an experimental plan was designed in which each patient would sequentially perform the role of control and of treated subject.

It was the purpose of this work to evaluate the recovery pattern of paretic muscle force of patients treated with regular physiotherapy only during a first period (one month) and with the addition of FES during a second period (the following month) and to compare the two patterns on a statistical basis.

MATERIALS AND METHODS

Twelve hemiparetic in - patients of the Medical Center of Montescano (9 males, 3 females, 8 right hemiparetics, 4 left hemiparetics) were randomly selected among those able to cooperate and to understand the experimental pattern. None had previously used FES and none had previous physiatric treatment. Age ranged from 38 to 80 years, time from lesion was between 1,5 and 6 months with one case of 10 months. All patients had some degree of hypertonus of the soleus and gastrocnemius muscles.
Maximal voluntary dorsal flexion of the ankle joint was measured by means of an isometric brace in which the leg and the foot were bound at a 90° angle (1, 2, 5).
A bridge of strain-gages produced a signal proportional to the moment (torque). After amplification the signal was recorded on a chart recorder and displayed by a meter. The patient was asked to produce the maximal deflexion of the meter.

The maximal voluntary torque was evaluated as the average value of 10 programmed contractions lasting 5 sec. each and with a 5 sec. spacing between each other. The patient was in a confortable sitting position. Such measurements were performed twice a week on the paretic side and about once a week on the healthy side for two months.

All patients had the traditional physiotherapeutic treatment during both months and all had FES treatment in the second month for an average of half hour daily with the exception of three patients who used the device as an orthosis for 20, 40 and 92 hours respectively during the second month.
No patient used myorelaxantdrugs during the two months.
Stimulation was given by applying cutaneous electrodes either on the fossa poplitea and on the head of the fibula or directly on the tibialis anterior muscle.
The movement produced was a dorsal flexion of the foot with slight eversion.
Stimulation parameters were: pulse duration 0,3 msec., pulse frequency 30 pulses/sec., pulse train duration 1 sec., pause between trains 3 sec.

The three patients who used the device as an orthosis employed the same frequency and pulse duration. Stimulation was synchronized with the swing phase of the gait by a switch placed in an insole. The pulse train duration was walking rate dependent and lasted about as long as the preceeding stance phase.

MID TERM EVALUATION

The experimental values obtained following the procedure described above appeared to be arranged according to the four patterns reported in Fig. 1.
It also appeared that the data of each period could be reasonably well interpolated by straight lines.

With the exception of case 8 who showed a step-like pattern, all patterns were described by the minimum square lines (m.s.l.) interpolating the data of the first and of the second month. The average values of the healthy side moment were also calculated for the first and second month for each subject.

The performance of each patient was described according to the model of Fig. 2.

Out of the 12 subjects considered, 7 showed the pattern a) of Fig. 1, one showed the pattern b), two the pattern c) and two the pattern d).
In order to give a quantitative description of such patterns, the slopes S_1 and S_2 of the two regression lines of each case were compared for statistical significance by means of the Fisher test. The average values of the healthy side H_1 , H_2 were also compared by means of the Student test.
Table 1 shows the results obtained.

A few observations are apparent from table 1:

a) five patients had a downward pattern in the first month while all patients had an up-ward pattern in the second month

b) in 10 cases out of 12 the second pattern was better than the first and in 8 cases the difference was statistically significant ($p < 0,15$)

c) two out of the three patients who used stimulation extensively had the most significant improvement

d) all patients showed an increase of healthy side moment. The average increase was 16% of H_1 ($p = 10\%$). Patients 1, 2 and 11, who used a peroneal brace as orthosis, showed an improvement of 18%, 24% and 41% respectively.

No clear correlation could be established between the change of slope ($S_2 - S_1$) and the extent of use of stimulation: the number of cases was too limited for this purpose and the treatment was too uniform. However, case 1 is particularly interesting in this regard since the brace was used 20 min/day for the first week and 4 hours/day for the following weeks. Fig. 3 shows the experimental results.
In all other cases stimulation was uniformly distributed in time.
A clinical observable decrease of spasticity of plantar flexors of the paretic foot was noted in the second month in cases 1, 3, 5, 6 and 10.

LONG TERM EVALUATION

All patients were dismissed at the end of the two months evaluation. Seven of them (No. 1, 2, 4, 6, 7, 8, 11) could be recalled about two months later. None of them had used FES any longer, two of them had regular physiotherapy at home (No. 2 and 6).
The maximal voluntary dorsal flexion moments of the healthy and of the paretic sides were measured twice in two different days according to the procedure described in Materials and Methods. The results were averaged and defined as H_3 and P_3 as shown in Fig. 2.
Fig. 3 and Fig. 4 show three such cases while table II shows the changes (in percent) of the healthy side (with respect to H_1) and of the paretic side (with respect to P_2).

As it can be seen, only one patient had a spontaneous increase of the paretic side moment.
The other six patients showed a decrease averaging13,8% (considering also case 1 the average loss was 9,2%).
The healthy side showed a slight and not significant decrease of about 2%.
The two patients who had home physiotherapy had respectively a drop of 14,9% and 5,2% of maximal moment of the paretic side.

CONCLUSIONS

Our results support the conclusions of Merletti et al. 1978 based on a control and a treated group of patients. The statistical analysis of our 12 cases and of the 50 cases previously studied show that hemiplegic patients with time from lesion in the range of one to six months, treated with FES and traditional physiotherapy recover about three times more muscle force than those treated with physiotherapy only (about half hour/day of FES and of physiotherapy).
These results are, to some degree, affected by the type and quality of physiotherapy. Battistini et al. (*) for example found smaller differences (personal communication).

It also appears that FES, used as an orthotic technique in daily life, leads to more significant recovery of force of both the paretic and healthy side. Finally, our data show that interruption of FES for two months led to a drop of paretic muscle force in six cases out of seven, including the two cases who continued physiotherapy at home.

We are of course fully aware that maximal voluntary force represents only a limited side of the hemiplegic picture. Coordination patterns and muscular tonus are at least as important, as well as patients' subjective feedback.
Muscle force improvement does not necessarily imply better walking patterns or patient's acceptance of the device. Despite these limitations,

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however, we feel that our work may bring a novel quantitative and statistically sound support to clinical observations.
This work is continuing with the evaluation of patients using FES devices at home and with the quantification of parameters other than force.

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TABLE I

Results of the "mid-term" evaluation

See Fig. 2 for explanation of symbols

N	Pt. Initials	Age (years)	time from lesion (months)	Sex	Side of lesion	S_1 Nm/m	S_2 Nm/m	+ p %	Hours of stimul. per month	H_1 Nm	H_2 Nm
1	C.	45	4	M	R	-0,30	4,11	$\angle$0,5	20	17,5	20,7
2	D.	38	4	M	R	1,74	11,7	$\angle$1	92	23,9	29,7
3	G.	73	2	M	R	-3,03	8,88	$\angle$2,5	6,6	15,6	17,5
4	S.	67	1,5	M	R	-6,94	5,4	$\angle$2,5	8,3	15,8	16,75
5	M.	68	1,5	M	R	-0,15	3,9	$\angle$2,5	7,3	12,1	13,9
6	M.	52	10	F	L	0,18	2,89	$\angle$10	6,3	10,4	12,4
7	D.	61	6	M	L	-0,075	3,66	$\angle$15	7,6	17,1	18,6
8	Q.	71	1,5	F	L	4,66*	8,45*	$\angle$0,02	7,3	/	/
9	P.	80	3	M	L	0,975	3,75	>15	7,6	11,5	12,2
10	F.	57	5	F	R	0,135	0,39	>15	7,3	9,4	9,6
11	D.B.	47	2,5	M	R	4,35	1,68	$\angle$10	40	12,6	17,8
12	V.	46	2	M	R	6,09	1,86	$\angle$10	8	15,7	19,1
Average		58,75	3,58			0,344	4,383			14,69	17,11
St.de-viation		12,65	2,38			3,02	3,13			3,92	5,15
						++ P=0,13%				++P = 10%	

M = male
F = female
R = right
L = left

* Average value of moment (not included in the calculations of average and standard deviation)

\+ Test of Fisher for two regression lines

++ Test of Student for difference of means

TABLE II

Results of the "long term" evaluation.

See Fig. 2 for symbol explanation

N	Initials	$\frac{H_2-H_1}{H_1}$ %	$\frac{H_3-H_1}{H_1}$ %	$\frac{P_3-P_2}{P_2}$ %	Pt. at home
1	C	18.1	5	18.2	
2	D.P	24,2	33,4	-14,9	*
4	S	6	-2,3	-12,9	
6	M	19,7	15,15	- 5,2	*
7	D.G.	9,3	1,6	- 8,6	
8	Q	/	/	-36,4	
11	D.B.	41,6	54,3	- 4,8	
Average		19,8	17,6	- 9,2	

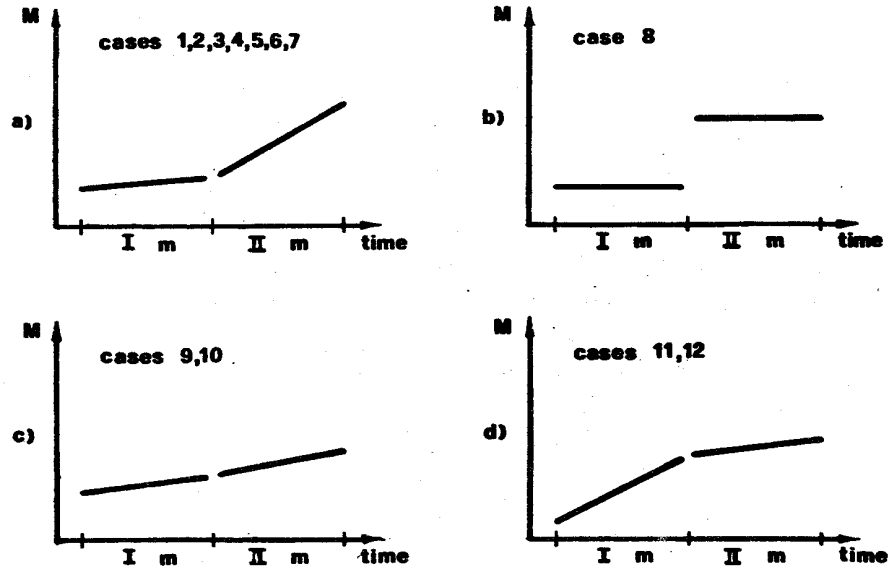

Fig. 1

Schematic diagram of the four types of pattern observed in the 12 subjects studied.

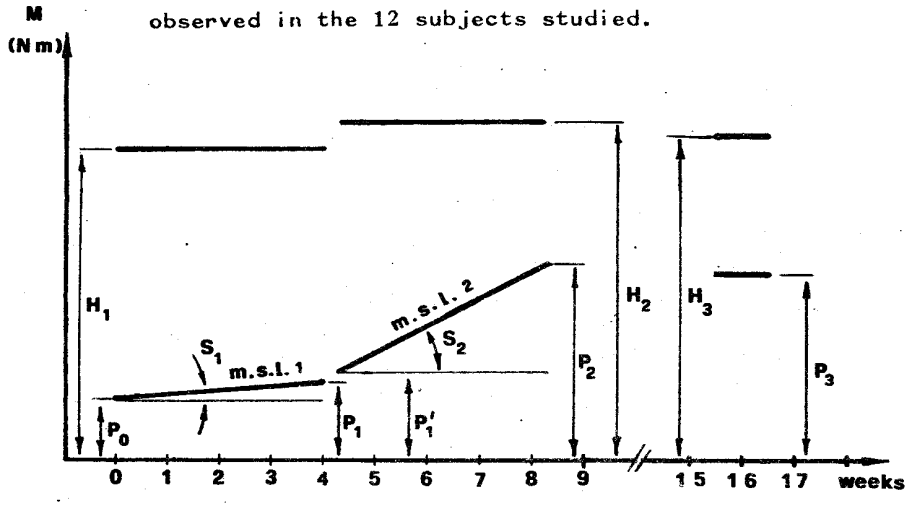

Fig. 2. General pattern diagram and definition of the parameters used for the quantitative evaluation of the results.

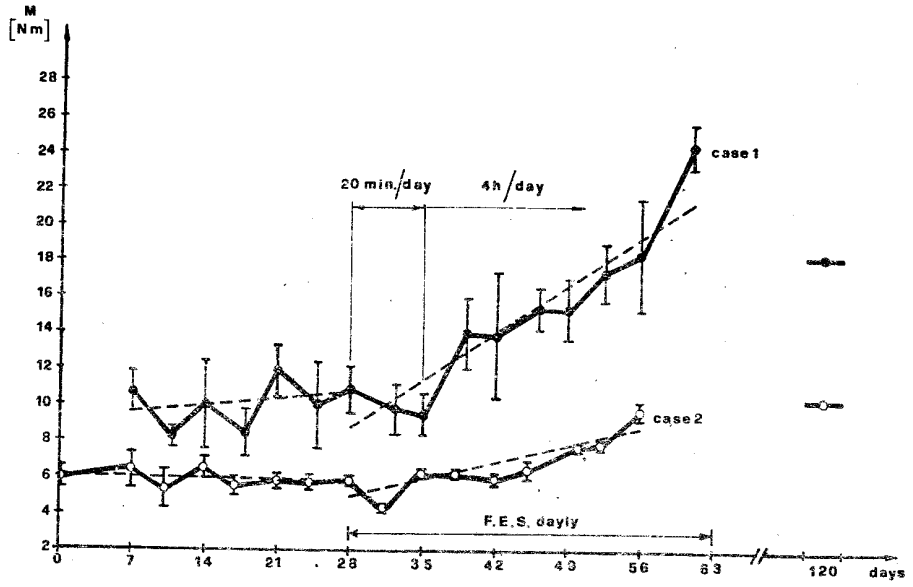

Fig. 3. Experimental results obtained from cases 1 and 2.

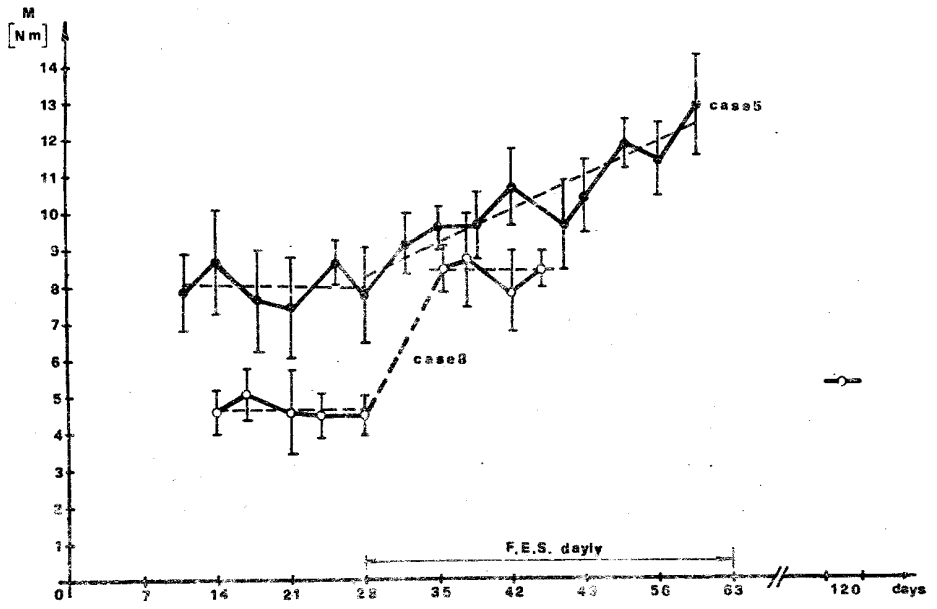

Fig. 4. Experimental results obtained from cases 5 and 8.