FUNCTIONAL ELECTRICAL STIMULATION OF PARAPLEGIC PATIENTS - FEASIBILITY STUDY

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Summary

This paper describes the basic characteristics of electrically stimulated paraplegic muscles. Attention has been focused on systematic examination of numerous paraplegic patients. It is particularly concerned with the responses of various paraplegic muscle groups to electrical stimulation. The problem of fatigue in stimulated muscles is illustrated. Results of an attempt to regenerate muscle force by means of stimulation program are described. A study of conditions which electrically stimulated muscles should fulfill to enable functional electrical stimulation of paraplegic patients is discussed. In conclusion preliminary experiments in these patients are reported, such as standing-up from a sitting position by means of electrical stimulation of the main muscle groups of the legs.

Introduction

Of the various possibilities for the external control in paraplegic patients electrical power seems to be the best solution in the form of FES. The greatest and the main problem is power consumption. Only FES seems ta have possibility to overcome this problem owing to the power generation in the electrically stimulated muscle. Figure 1 illustrates the electrical energy triggering only the stored energy in the muscle. Power amplification may be observed between the electrical stimulus power and the power exerted on the load. The power gain factor may be 2000 for surface stimulation, and up to 200,000 for implanted nerve stimulation. From the engineering point of view this is a very important advantage of FES. FES ortheses do not need force transfer attachment, levers, and fixation of hardware to the body because FES uses the natural exoskeletal system. This is also an important advantage. Such outstanding advantages of FES combined with the conventional bracing technique promises for a better motor development of paraplegic patients.

Before broader and more detailed investigations are initiated in this field it is economically justifiable tc perform feasibility studies first. From our standpoint the main questions that will have to be answered are those regarding the behaviour of the "muscle motor" which is obtained with FES of paraplegic muscle.

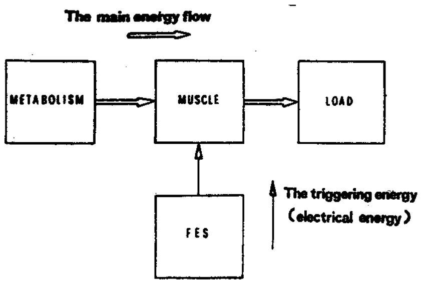

Fig. 1.

As a matter of fact, a knowledge of power triggering is the main thing we need if we want to understand and use it. Once this is done we can compare a stimulated muscle "force generator" with the other known possibilities. As there have been several other facts, such as deficient knowledge and the absence of technology for afferent and spinal cord stimulation we have had to limit our work to efferent electrical stimulation only.

Another question has been that regarding the number of patients that can benefit from FES according to age, localization of lesion and lapse of time following damage.

The third wish would be to know how paraplegic muscles respond to FES, to be familiar with the mechanical and dynamic properties of stimulated muscles, fatigue, the methods for muscle strengthening, etc. Once we get familiar with all the above problems the feasibility study can be started to provide detailed information on what paraplegic patients may still expect. A brief check and comparison between forces and moments needed for a patient to lift up the properites which could be obtained through FES of paraplegic muscles could be made.

Methodology

During our experiments rectangular stimulation pulses were used with a pulse width between 0.3 and 0.7 ms and repetition frequency of 50 Hz. It should be stressed that this is not the optimal stimulation. All the moments illustrated should not be considered as the absolute maximal values unless stated otherwise.

Only surface stimulation was utilized. The tin electrodes used are coated with gauze. For stimulation of the peroneal nerve the electrodes sizes were 3 x 3 cm, for M.gastrocnemius 4 x 5 cm and for large muscles e.g. M.biceps femoris, M.quadriceps sizes were 6 x 7 cm. An eight-channel mainsline powered stimulator with a built-in programer and two torque measuring braces used throughout the experiments. One is used for the ankle joint and the other for the knee joint. In the experiments the isometric moment was measured as the response to FES of various paraplegic muscles.

For muscle force testing, the well accepted R. W. Lovett method was used. Of course, the method is mainly performed for the testing of voluntary controlled forces, but there are no limitations for use of this method in testing forces produced by FES.

Selection of Patients

We first tried to find out the percentage of paraplegic patients in whom muscles are still capable of producing movements through FES in regard to their age, localization, and duration of lesion and other possible conditions. The related testing should be the best answer to the question whether FES may be useful in rehabilitation of this group of the disabled.

Of the total number of one hundred paraplegic patients selected, there were 55 who have been included in further investigations. Omitted were patients exhibiting skin damage, strong spasticity, hypersensitivity to electrical currents, partial lesions and other complications (mental deficiency, advanced age, concomitant diseases, etc.). In each patient stimulated were the following muscle groups on both sides: N.fibularis and M.tibialis anterior, M.gastrocnemius, M.biceps femoris, M.quadriceps and M.gluteus maximus. Our investigations have been engaged in leg muscles only. The results are summarized in Table 1.

From Table 1 could be shown that out of 55 selected patients at random, about 50 percent answered to FES with the contraction of nearly all the lower-extremity muscles. Those can be considered as the potential candidates for the FES.

During our experiments in some patients spasticity was observed. As there does not exist any exact method of measurement of it and the phenomenon in itself is still not clearly understood, spasticity is not mentioned in Table 1.

It is obvious that there does not exist any visible correlation between the localization of lesion, the property of muscles to be stimulated, and muscle force produced by FES. There is even no strong dependence of the muscle force generated by FES on the lapse of time

Table 1.

No.	Sex	Age	Lesion: Site	Lesion: Duration	Fibularis & tibial.ant. L	Fibularis & tibial.ant. R	Gastro-cnemius L	Gastro-cnemius R	Biceps fem. L	Biceps fem. R	Quadriceps fem. L	Quadriceps fem. R	Gluteus max L	Gluteus max R	Spa-sticity
1	2	3	4		5		6		7		8		9		10
1.	f.	26 y.	D 5-7	7 y.	-4	-4	-1	-2	-4	-4	-3	-3	3	2	
2.	f.	34 y.	L 1	4 y.	0	0	-2	-2	0	0	0	0	0	0	
3.	m.	33 y.	L 1	5 y.	0	0	-2	1	0	0	1	1	0	1	
4.	m.	36 y.	D 10	2 y.	0	0	0	0	0	1	0	0	1	1	
5.	m.	42 y.	D 9, L 3	31 y.	0	0	0	1	1	0	0	0	1	1	
6.	m.	29 y.	D 9	6 y.	3	5	1	1	3	3	-4	-4	-2	2	
7.	m.	21 y.	D 7,8	6 y.	3	4	-4	-3	-3	2	-4	-4	-2	-2	
8.	m.	25 y.	D 5	4 y.	0	0	0	0	1	1	1	0	1	1	
9.	m.	39 y.	D 12	4 y.	-4	2	0	0	-3	-3	1	1	2	1	
10.	m.	41 y.	D 12	11 y.	0	0	0	0	0	0	0	0	0	0	
11.	m.	25 y.	L 1	4 m.	3	3	0	0	1	1	0	1	1	1	
12.	m.	22 y.	D 3-7	2 y.	-4	3	-2	-2	2	2	5	4	-2	2	
13.	f.	24 y.	D 11	9 y.	-2	-2	1	0	-4	-4	-3	2	1	-2	
14.	m.	40 y.	D 7-8	13 y.	-3	3	2	-3	1	1	2	-2	1	1	
15.	m.	30 y.	D 3	7 y.	-4	3	-2	-2	3	3	2	-4	-3	3	
16.	m.	23 y.	D 12	1 y.	0	0	0	0	0	0	0	0	0	0	
17.	m.	21 y.	D 3-4	1 y.	0	0	-2	-2	-4	-4	-3	-3	2	2	
18.	m.	57 y.	D 4	14 y.	-4	-3	1	1	-3	3	-3	1	-2	-2	
19.	m.	25 y.	C 7	1 y.	0	0					-3	1	Hypersens.		
20.	m.	43 y.	D 12	3 y.	3	-3	1	1	1	-2	-3	-2	1	1	
21.	m.	32 y.	D 9	5 y.	0	0	0	0	0	0	0	0	1	1	
22.	f.	31 y.	D 9-10	7 y.	-2	1	0	0	-2	2	1	1			
23.	m.	36 y.	D 10-11	9 y.	0	0	0	0	0	0	0	0	0	0	
24.	m.	53 y.	D 7-8	15 y.	-3	2	-2	-2	-2	-2	-4	-4	-2	1	
25.	m.	31 y.	D 12	10 y.	-4	-4	0	0	-3	3	3	-4	-2	-2	
26.	m.	33 y.	D 12	4 y.	1	1	1	-2	2	-3	1	1	1	1	
27.	f.	27 y.	L 2	8 y.	0	0	0	0	0	0	4	4	0	0	
28.	f.	42 y.	L 1	1 y.	-2	0						Hypersens.			
29.	f.	26 y.	C 6-7	10 y.	0	-3	-3	-2	-3	-3	3	3	1	1	
30.	f.	44 y.	D 11-12	12 y.		3		0				-4			
31.	m.	26 y.	C 5	2 y.	1	0	-2	-2	0	0	1	1	1	1	
32.	m.	37 y.	C 6	4 y.	4	1	4	-4	-3	3	-3	-3	2	-2	
33.	f.	21 y.	C 3-5	5 y.	0	3	1	0	-3	-3	1	1	1	1	
34.	f.	30 y.	C 6-7	2 y.	3	-4	1	1	-3	-3	1	1	1	1	
35.	m.	21 y.	C 6-7	3 y.	0	0	0	0	1	0	1	2	-2	-2	
36.	m.	17 y.	C 6	1 y.	0	0	-2	1	2	3	3	-4	-2	-2	
37.	m.	29 y.	C 5	12 y.	4	3	1	1	-3	-2	5	5	-3	2	
38.	m.	26 y.	C 5	2 y.	0	0	0	0	0	0	1	0	1	0	
39.	m.	34 y.	C 6-7	11 y.	0	0	1	1	3	3	2	-2	-2	-2	
40.	m.	38 y.	D 5	1 y.	0	0	0	0	1	1	-4	4	1	-2	
41.	m.	28 y.	D 4-7	3 y.	-3	4	0	0	3	3	-4	-3	-2	-2	
42.	m.	49 y.	L 3	2 y.	4	-4	1	1	-3	-3	4	2	-2	-2	
43.	m.	24 y.	D 12	3 y.	-3	1	1	-2	-3	-3	-2	2	1	-2	
44.	m.	55 y.	D 11	3 y.	-2	2	0	2	1	1	1	1	1	1	
45.	m.	31 y.	L 1	5 y.	0	0	0	0	0	0	0	0	0	0	
46.	m.	35 y.	D 12	1 y.	2	-4	1	1	-3	-3	0	0	0	1	
47.	m.	34 y.	D 12	5 y.	0	0	1	0	0	0	0	-3	0	0	
48.	f.	32 y.	L 1	1 m.	0	0	1	0	0	1	0	0	0	2	
49.	m.	49 y.	D 3	2 m.	0	0	0	0	0	0	0	0	0	0	
50.	m.	39 y.	D 12 + L 1	1 m.	0	0	0	0	0	0	0	0	0	0	
51.	f.	67 y.	D 6	2 m.	-2	1	0	0	-2	-2	1	1			
52.	m.	25 y.	D 3	1 y.	0	-4	-4	-2	4	3	4	3	-2	-2	
53.	m.	34 y.	C 3-4	1 y.	1	1	0	1	-2	-2	1	1			
54.	m.	59 y.	C 7 - D 1	6 m.	3	2	0	0	-2	-2	1	1	-2	-2	
55.	m.	64 y.	C 6	2 m.		1	1	1	-2	-3	2	1	2	2	

after damage. This statement is clearly visible if we compare some patients mentioned in Table 1, as for instance the patients under No. 1, 12, 14, 25, 41, 52 and those under No. 8, 23, and 49. In the first group of the patients the answer to FES is good in comparison with the second group where such an answer of the muscles was not obtained.

During the muscle testing experiments it could be clearly observed that the muscle force soon decreased with time. Our attention was therefore directed toward the measuring of muscle fatigue period caused by permanent steady state stimulation.

In the next phase we made some detailed analyses on two selected paraplegic patients. Patient I is the Th 8-9 paraplegic patient 24 years of age with slight spasms 4 years following damage. Patient II is the 18 yearold with Th 10 lesion and with very slight spasticity, 2 years after lesion. The permanent electrical stimulation and various stimulation experiments caused no change in the status of spasticity. During the test-period the patients were carefully examined to determine bladder functioning. No influence of FES on the bladder mechanism could be observed.

Some Properties of the Electrically Stimulted Paraplegic Muscles

The first characteristic of electrically stimulated paraplegic muscle we investigated was fatigue. The knee joint of a patient was fixed into a torque measuring brace. The isometric moment of the electrically stimulated quadriceps was recorded as a function of time. Owing to the brace construction we did not try to measure the absolute maximum moment which may be iniciated with FES. The measured moments for the knee joint were in the range between 20 and 50 Nm, and those for ankle joint from 5 - 20 Nm. A typical isometrical moment plot versus time ($M_{iso}(t)$) is given in Figure 2 for M.gastrocnemius and Figure 3 for M.quadriceps.

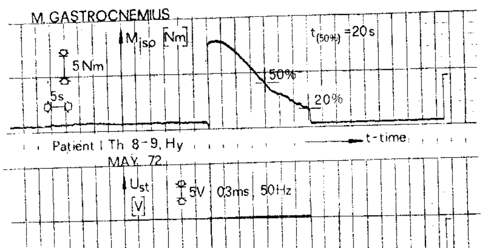

Fig. 2.

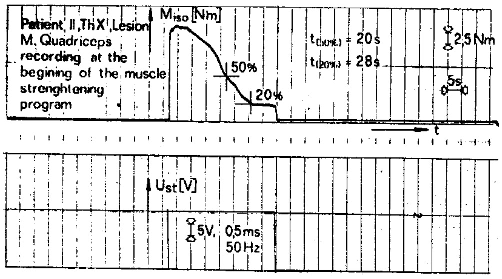

Fig. 3.

The moment decreases with time and the time for a 50% drop $t_{(50\%)}$ in most patients is in the range of 15 - 40 s. The fatiguing and hence the $t_{(50\%)}$ and $t_{(20\%)}$ time is the function of the initial moment. For a high initial moment the fatigue rate is higher, and slower when small initial moments are concerned. The initial force varies and can be 50 Nm for about 45 V stimulation or only 5 Nm for 30 V stimulation. The patients with spasms have good initial forces and the $t_{(50\%)}$ is often higher in the order of 40 - 50 s.

The cyclical stimulation e.g. 5 s stimulation and 5 s rest peroid (without stimulation) increases the $t_{(50\%)}$ time. After a continuous stimulation trial a rest period of 5 minutes is enough for the initial to be recovered and we obtain almost the same moment-versus-time plot. At the end of an experiment after the $t_{(20\%)}$ the change of stimulation frequency from 50 to 40, 60, and 70 Hz has no effect. Only the increased stimulation pulses width result in an increased moment (change from 0.5 to 1 ms).

The dynamic properties of electrically stimulated muscle play an important role once we decide that we would use such a "motor" for performing functional tasks. The dynamic properties of the moment increase and decrease as an answer to a unity jump in electrical stimulation versus time are illustrated in Figure 4. This is a typical curve. It might be of interest to mention that in the same patient essential changes in the delay time t_{01}, rise time t_{11}, fall time t_{44} among muscles were not established. M.quadriceps is recorded in Figure 5. The t_{01} time is in the range of 40 - 80 ms, the t_{11} time between 120 - 360 ms, the t_{04} time is is typical 90 ms ± 30% and the fall time between 50 - 180 ms. The quadriceps response for two unit

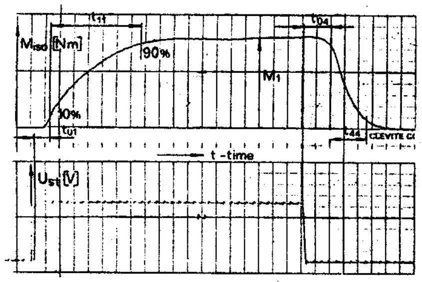

Fig. 4.

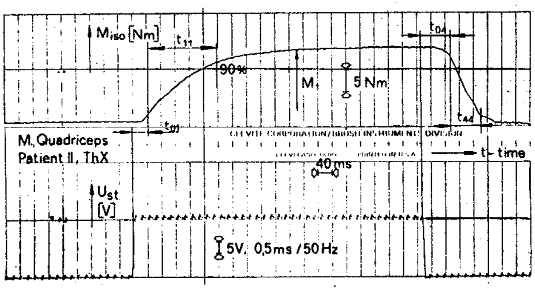

Fig. 5.

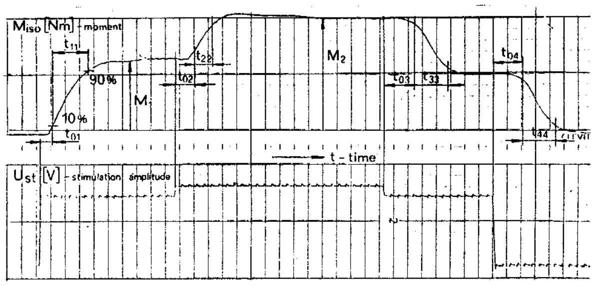

Fig. 6.

jumps one after another is shown in Figure 6. The t_{02} time is in the range of 70 ms, t_{22} varies between 100 - 360 ms, t_{03} between 100 - 200 ms and t_{33} between 60 - 90 ms. Figures 5 and 6 show that the t_{11} time is normally 2 - 3 times larger as compared to the t_{01}. t_{04} is to 1.5 larger than t_{01}. The same can be said of the fall time. A preliminary statement would therefore be that an electrically stimulated paraplegic muscle from a dynamic point of view does not differ much from the normal one. The only noticable difference appeared in the delay time t_{01} In most cases the delay time in normally inervated muscles is in the range of 20 - 30 ms, as compared to paraplegic muscles value 40 to 80 ms. For the rise time (t_{11}) and fall time great differences between the normal and paraplegic muscles cannot be established.

Paraplegic Muscle Strengthening Program

The initial forces with FES of paraplegic muscles diminish with time as the fatigue occurs. The question is raised whether it is possible to find a program both for increase of the initial force and for slowing down the fatiguing process. Willemon at al. /1/ described a paraplegic muscle strengthening program based on cyclical FES. They reported a stimulation program with cycles consisting of 10 s stimulation and 20 s rest periods, the whole process lasting 12 hours daily. After a two-month stimulation the fatigue time increased from 15 s to "two hours of sustained unremitting contraction". This muscle strength increase is very high and allows static muscle stimulation, e.g., for performing at least standing up and/or maintaining the extended legs during the standing position of the patient. Since 1968 we have been investigating the possibilities of developing an orthosis based on FES for paraplegic patients. The basic idea of such an orthosis is shown in Figure 7 /2/.

Encouraged by the published results, we have started with a slightly changed muscle strengthening program. The instrumentation set up in the stimulation program is given in Figure 8. At the beginning of the program each patient was stimulated 3 times, 10 min. daily. The stimulation time was increased daily and after two months we stopped at 3 times, 30 min. daily. The torque in the knee exerted from M.quadriceps was measured regularly and the muscle bulk 15 cm above the patella. The muscle recovery plot versus time is given in Figure 9. We see the initial muscle force and the joint torque increased almost 5 times, and the muscle bulk for nearly 3 cm. The fa-

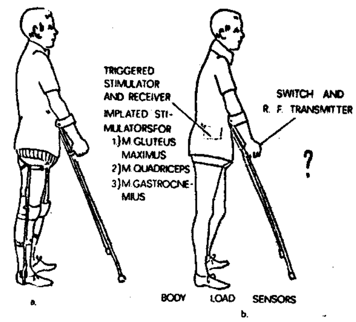

Fig. 7. (a) The patient stands by help of long leg braces and keeps the balance with crutches.
(b) The legs are extended because of electrical stimulated muscles the balance is achieved with help of crutches.

tiguing of M.quadriceps for continuous stimulation recorded after a 6 month muscle strengthening is given in Figure 9. It can be seen that the $t_{(50\%)}$ time is 121 s. If we compare this with Figure 3 we get a fatiguing time which is 6 times larger.

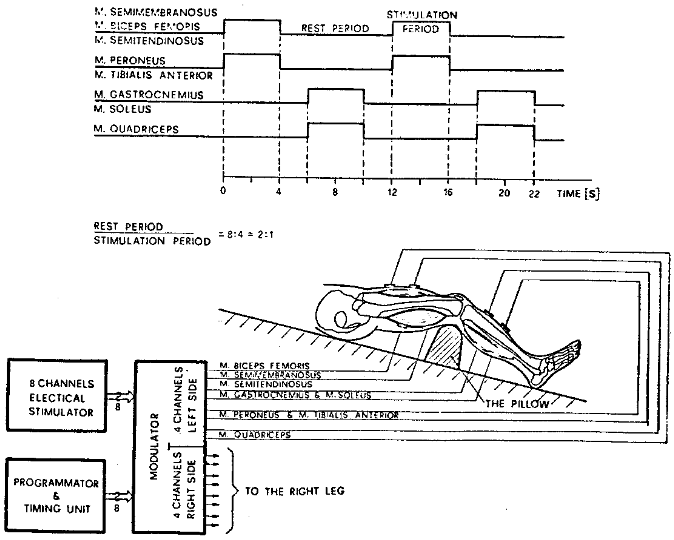

Fig. 8.

Isometric knee moment plot after FES of a normally inervated M.quadriceps versus time is illustrated in Figure 10. While comparing

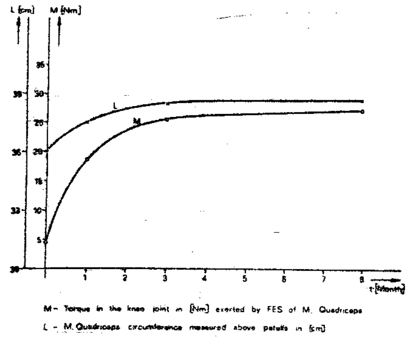

Fig. 9.

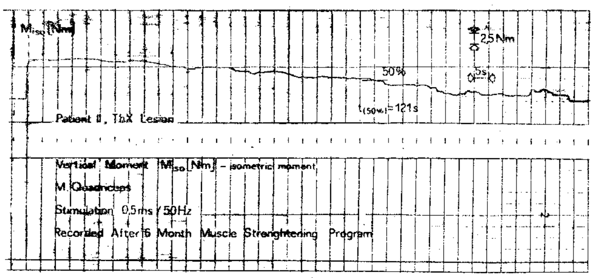

Fig. 10.

Figure 10 and Figure 11 we see that a strengthened paraplegic muscle does not differ much from a normal muscle as far as fatiguing is concerned.

These results show that after a three-month period of muscle strengthening by means of FES strength increase is small. The question is what the optimal muscle stimulation strengthening procedure should be. Especially, the daily stimulation time should be determined exactly as well as the stimulation and rest periods of one stimulation cycle. Furthermore the muscle loading during the program and the amount of load increments should be determined since this

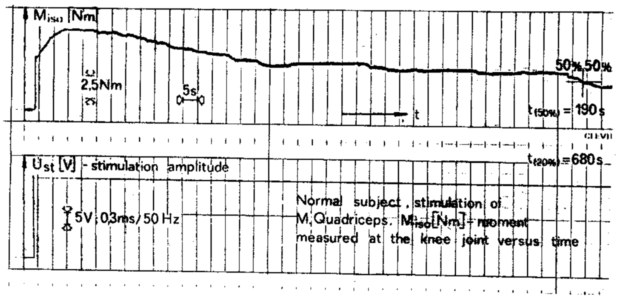

Fig. 11.

plays an important role, as shown by Rolls et al. /3/. Various muscles have various optimal loads /4, 5/. In regard to the above, this report can be considered only as an experiment showing that the paraplegic muscles could be strengthened with electrical stimulation. It would be interesting to mention that after a 7-month rest period without any stimulation the fatiguing curve recorded shows the typical shape of the curve obtained before strengthening program with the typical quick fatiguing a decreased initial force. The muscle bulk decreases too. This shows that muscles that are not used are quickly subject to atrophy.

Standing up - Preliminary Experiments

A simple calculation can determine the required muscle forces or moments in corresponding joints needed for standing up from a sitting position /6/. Only two leg muscles, the M.gastrocnemius and M.quadriceps have been stimulated thus far. The foot is placed flat on the ground with ties. A special support does not permit the patient to exert vertical movements of his body by the help of his hands. The M.quadriceps muscle is stimulated in a pattern related to the activity in the normal standing up pattern. The M.gastrocnemius muscle is correlated to this. In case the rise of the center of gravity of the segments about the knee joint does not pass too far from the knee joint rotation axis, the needed force of M.quadriceps produced by electrical stimulation will enable the patient to stand up. The M.gastrocnemius helps the knee joint rotation axis to stabilize and rise from the ground. In case the center of gravity line through the proper program selection and electrical stimulation of both muscles is kept within the given limits in regard to the distances between the center of gravity line and joint rotation axis, the needed forces of both muscles may be relatively small.

The basis for our stimulation program selection are the EMG records obtained during the standing up function of a normal subject under conditions similar to that in our paraplegic patient standing up, experiments. The whole experimental set-up could be understood from Figure 12. Till now we have made three standing-up experiments with FES. In these experiments our patients' hand support was not good enough and the setting of the program was to clumsy. In spite of this we were able to lift the patient with FES. The physical therapist added very slight lateral, ventral and dorsal corrections of the body position. In case these relations are not good enough the forces produced in muscles are not sufficient for lifting up the patient. We believe that with some hardware and the stimulation program patient could be lifted only by FES and without any external support using only self-balance regulation.

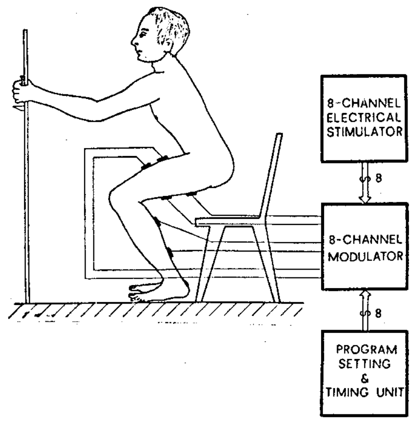

Fig. 12. FES of paraplegic patients standing up demonstration.

The described experiments have shown that the forces obtained by FES of paraplegic muscles may lift the patient's body up. The feasibility and basis is provided for electrical stimulation of the paraplegic patient.

Of course, there remains a very wide range of problems such as the coordination of muscles during standing up, the stimulation technology, control problems, etc.

Conclusion

The experiments confirm that by electrical stimulation of selected lower-extremity muscles or muscle groups in paraplegic patients we can obtain forces which are strong enough to enable the lifting of the patient's body from the sitting position. In this way the feasibility is proven for the use of FES in paraplegic patients as a therapeutic and rehabilitation method aiming at their active mobilization. At the same time, the experiments should be the basic step for the introduction of FES devices as a better and more functional substitution of the presentday crude and clumsy orthopaedic appliances.

Though our experiments we have found that permenent electrical stimulation does not have any influence on the patient's bladder automatism, and there was no special influence on the patient's spasticity. The clinical properties of the stimulated paraplegic muscle, even if not strengthened, do not differ much from those of the normally innervated muscle.

Acknowledgements

The authors wish to express their gratitude to Ing. S. Reberšek for the instrumentation assistance throughout the experiments and to M. Kovač, P. T. for her valuable work during the muscle strengthening program.

This work has been implemented under the grants of The Boris Kidrič Foundation Ljubljana, and HEW - SRS No 19-P-58415-P-01, and HEWD - SRS - Yugo No. 19-P-58388-F-01.

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