TESTING OF PERONEAL MUSCLE STIMULATORS IN SWEDEN

S Dillner, G Georgiev, A Karsznia
EFTO (Unit of Applied Orthotics), Dept. of Rehabilitation Medicine, Central Hospital, Jönköping, Sweden

SUMMARY

The testing of peroneal muscle stimulators sponsored by the Swedish Institute for the Handicapped at EFTO started in 1973 and is performed according to test instructions for technical tests and clinical function testing. The technical type test includes an examination and dimensional inspection, mechanical tests, climatic tests, and durability (extended life) tests. The clinical function testing follows a special routine where a medical record of the patient notes specific data regarding the peroneal muscle stimulator: diagnosis, loss of function, sensitivity, social and psychological factors, vocation, etc., various kinds of technical aids, application routine, training method, and improvement of function.

Four types of peroneal muscle stimulators have been tested: Philips from the Netherlands, Teufel FEPO 8 and FEPA 10 from Yugoslavia, and LIC from Sweden.

During the period 1973 to 1977, 65 patients have been fitted. This report concerns the testing of peroneal muscle stimulators on 43 patients. Some of them were supplied bilaterally. Most patients tried all available systems and together with the physiotherapist they decided which system to choose. Main diagnosis was multipel sclerosis and second was hemiplegia.

36 patients improved their function and are regular users of the stimulators.

There was no special remark in the technical type tests against any of the systems and the two commercially available systems FEPA 10 and LIC are recommended for prescription.

INTRODUCTION

The testing of peroneal muscle stimulators sponsored by the Swedish Institute for the Handicapped at EFTO started in 1973. It is performed according to test instructions for clinical function testing and technical type tests.

The clinical function testing follows a special routine where a medical record of the patient notes specific data regarding the peroneal muscle stimulator: diagnosis, loss of function, sensitivity, social and psychological factors, vocation, etc., various kinds of technical aids, application routine, training method, and improvement of function.

Four types of peroneal muscle stimulators have been tested [1,2,3,4]:

Philips from the Netherlands
Teufel FEPO 8 and FEPA 10 from Yugoslavia
LIC from Sweden

Many evaluations of peroneal muscle stimulators have been made since Liberson's report on functional electrotherapy [5]. It is common that the evaluation is performed by the people who developed the stimulators. If the testing is done without reported test instructions and requirement specifications, it is difficult for an outsider to make any use of the results. Still, there are many useful reports and the one from the National Academy of Sciences, 1973, has the best stated test instructions [6,7,8,9].

CLINICAL FUNCTION TESTING

During the period 1973 to 1977, 65 patients have been fitted. This report concerns the testing of peroneal muscle stimulators on the first 43 patients. Six of them were supplied bilaterally. Most patients tried all available systems and together with the physiotherapist decided which system to choose.

15	patients	chose	Philips
11	"	"	FEPO 8
7	"	"	FEPA 10
10	"	"	LIC

Main diagnosis was multiple sclerosis (26 patients) and second was hemiplegia (13 patients). The tests were performed according to our proposed test instructions for peroneal muscle stimulators from 1973 [10]. These instructions have been revised and translated to English and most of the stimulators have been tested according to the revised version, Proposed test instructions for peroneal muscle stimulators, [11]. 25 patients were women and 19 men. Their age varied between 28 and 75 years with a mean value of 52.9 years. Most of the patients had old gait disturbances. Unfortunately, we do not have the experience of hemiplegic patients immediately after acute stage. 19 patients were employed. The stimulators were tried mostly on patients with poor dorsiflexion and pronation in the wrist. In some very few patients the stimulator was tried when the patient had fairly good dorsiflexors but, due to spasticity, were very easily exhausted or had very little functional strength because of the spasticity. Their range of motion in the lower extremities was recorded as well as reflexes, balance, and sensitivity. Their spasticity was assessed.

The gait of the patients was assessed according to the test based on Signe Brunnström gait analysis form [12]. The tests were performed with gait on gravel, up and down stairs, up and down a slope, and walking over sticks at different heights. Time and height was measured, as well as the quality of the gait, with and without a stimulator and, in some cases, compared with an ordinary ankle-foot orthosis.

Results of the function testing	--	-	0	+	++
Increased walking speed	-25%	-6 - -25%	±5%	6-25%	25%
1. on plain floor			11	16	10
2. on gravel			5	14	9
3. on stairs	1	1	13	14	7
4. step height		2	12	5	10
5. using time relatively 14 hours percentage			7	12	24

6. Patient's assessment of energy consumption during walking:

no difference	2 patients
less	32 "
much less	9 "

7. The patient's assessment of gait improvement with the stimulator:

greatly improved	18 patients
improved	19 "
unchanged	4 "

8. The assessment of the clinical team:

38 had very good and good help of the stimulator
5 had undecided help of the stimulator

These clinical gait analyses may not be quite relevant for assessment of the value of the stimulator for the patient but still they do give a certain idea of the degree of improvement.

Stroboscopic photography registration of some of the patients (20), with and without the stimulator, showed, among other things, better dorsi-flexion of the foot, less vertical displacement of the body, and, in some cases, better flexion in the knee during the swing phase.

The temperature of the stimulated leg was recorded for 10 patients. The mean value of the temperature of the m. tibialis anterior was increased with 3.2°C after 15 minutes of stimulation.

7 patients felt less spasticity due to the stimulation.

4 patients with multiple sclerosis noted an increase of spasticity.

6 patients got some sort of a flexor reflex, which gave them not only a dorsi-flexion of the foot but also flexion in the knee and hip. This was only noted with patients with multiple sclerosis with pronounced spasticity.

3 patients could prevent hyperextension in the knee when using the stimulator.

8 patients got a better response after 2-3 months use of the stimulator and could decrease their stimulation amplitude.

Many patients said that they got an increase in self-confidence and increase of safety and balance while walking with the stimulator. The patients felt the functional electrical stimulation as a treatment.

14 of the patients had used ankle-foot orthoses earlier and all of them, except one, preferred using the stimulator instead of the ankle-foot orthosis. The patients felt that the greatest disadvantage with the stimulators was the low reliability of the cables and connectors.

Of the described 43 patients, 36 still use their stimulators regularly. 3 patients were not motivated enough to use their stimulators in spite of their functional benefit. We found no significant difference between the different stimulators from patient point of view. That is why we reported the clinical results without differentiation between the stimulators. 2 patients have gradually got worse and are now bound to wheel-chairs and 2 patients got so much better when using the stimulator for one year that they consider themselves now being able to walk well even without it.

One patient who could not use surface electrodes because of skin irritation and one with too deep peroneal nerve had the Ljubljana implant system Fepa 12. The implantations were successful but are not reported here.

TECHNICAL TESTING

In the technical testing, the peroneal muscle stimulators have been checked regarding the mechanical and electrical specifications. The maximum output current has been checked and compared with the maximum current allowed through a human body proposed by IEC SC 62 A, 10 mA R.M.S., also given in our proposed requirement specification for peroneal muscle stimulators [13,14].

All the stimulators have a voltage regulated output signal except the LIC stimulator which is current regulated. From a clinical point of view, we have found no difference between these two types of generators.

We have not had the possibility to make destruction tests and climatic testings.

We have made some tests on how many steps a stimulator can perform on one charge and on one primary battery.

The test is performed with an electronic cycling control unit which triggers the stimulator. It is set to give a stimulation of 0.6 seconds and pause 0.6 seconds. It runs continuously but with 3 minutes pause every 30 minutes.

The FEPA 10 system made about 200,000 steps with alcaline battery.

The FEPA 10 system made about 94,000 steps with standard primary battery.

The LIC stimulator made about 35,000 steps/charge.

The Philips system has not been checked.

The Philips system and Teufel's FEPO 8 are now out of production. There are still some stimulators available from Philips in Sweden. Philips has no further development project in this area.

The FEPO 8 system has been replaced by the FEPA 10 developed in Ljubljana.

SOME SUGGESTIONS ON APPLICATION OF PERONEAL MUSCLE STIMULATORS:

1. When supplying a patient with relatively complicated technical aids, it is absolutely necessary to give him an adequate training with the aid. Patients supplied with peroneal muscle stimulators must have 3-4 days of training before they can be discharged from the hospital. The training should be given directly after the application at the hospital. Policlinical training should be avoided.

2. A good clinical gait analysis of the patient must be made where the different complications of the gait should be expressed.

3. In the application, the stimulator must be adapted to the individual need of the patient. The parameters should be adjusted to the patient's individual gait and his speed, spasticity, and other things to be considered.

4. In the training, the patient must learn how to put on and take off the stimulator, how to use it in different situations, and how to use the trouble shooting table.

5. To simplify the daily application for the patient, he should be tattooed on the stimulation spot.

6. An application requires well coordinated and well performed team work.

7. Each application needs its own follow-up. The patient needs to be checked several times after discharge to be helped with his problems. If necessary, he should be taken in for further treatment.

8. It is our experience that patients with multiple sclerosis benefit more from functional electrical stimulation than hemiplegic patients.

CONCLUSION

Our experience of the testing of peroneal muscle stimulators is that they are not only a functional technical aid but also very useful for treatment of patients with central motor point lesion. All the tested peroneal muscle stimulators are recommended for prescription.

REFERENCES

1 Peroneus muscle stimulator; Philips product information, XM 1301, X-71.

2 Gračanin, F: Instruction Manual for usage of the Ljubljana Functional Electronic Peroneal Brace. Ljubljana: Institution of S.R.S. for Rehabilitation of Disabled, 1972.

3 Gračanin, F, Vrabič, M: Instruction Manual for usage of the Ljubljana Functional Electronic Peroneal Apparatus, FEPA-10. Ljubljana: Zavod SRS za rehabilitacijo invalidov, 1974.

4 LIC: Patienter med centrala pareser går bättre med Peroneusstimulator. LIC brochure 74:48, 1974.

5 Liberson, W T, Holmquest, H J, Scot, D, Dow, M: Functional electrotherapy: Stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients. Arch Phys Med Rehabil, 42: 101-105, 1961.

6 Milner, M, Rapley, L F, Wakefield, P E: Functional Electrostimulation: Some Clinical Uses of the Electronic Peroneal Brace. S.A. Medical Journal, Vol. 47, 2nd June 1973, pp. 921-924.

7 van Leeuwen, H J, Vredenbregt, J: A muscle stimulator for hemiplegic patients. Philips Technical Review, Vol. 30, No. 1, pp. 23-24, 1969.

8 Clinical Evaluation of the Ljubljana Functional Electrical Peroneal Brace: National Academy of Sciences, Report E-7, 1973.

9 Larsson, L-E (Ed.): Clinical tests with the LIC-stimulator for functional electrical stimulation in gait on patients with central paresis in the legs. Ril-KNF-0024, 1975. (Swedish). Report to the Swedish National Board of Health and Welfare, 1976.

10 Dillner, S, Georgiev, G, Karsznia, A: Förslag till provningsanvisningar för peroneusstimulatorer. (Swedish). Jönköping: EFTO-report No. 5/76, 1976.

11 Dillner, S, Georgiev, G, Karsznia, A: Proposed test instructions for peroneal muscle stimulators. Jönköping: EFTO-report No. 10/77, 1977.

12 Brunnström, S: Movement Therapy in Hemiplegia. Harper & Row, New York, 1970.

13 Continuous LEAKAGE and PATIENT AUXILIARY CURRENTS 3.7: International Electrotechnical Commission; Subcommittee 62 A (IEC SC 62 A), 1973.

14 Dillner, S, Georgiev, G, Karsznia, A: Proposed requirement specification for peroneal muscle stimulators. Jönköping: EFTO-report No. 9/77, 1977.

15 Dillner, S: Inventering av provningsföreskrifter och provningsrapporter för peroneusstimulatorer. (Swedish). Jönköping: EFTO-report No 9/74, 1974.

16 Dillner, S, Georgiev, G, Ottosson, L-G: Rapport över provning av Philips peroneal muscle stimulator. (Swedish). Jönköping: EFTO-report No 11/74, 1974.

17 Dillner, S, Georgiev, G, Karsznia, A: Teknisk och klinisk funktionell provning av peroneusstimulatorer från LIC och Teufel. (Swedish). Jönköping: EFTO-report No 3/77, 1977.