CLINICAL EVALUATION OF THE LJUBLJANA FUNCTIONAL ELECTRICAL PERONEAL BRACE

NATIONAL ACADEMY OF SCIENCES

1973

CLINICAL EVALUATION
OF THE
LJUBLJANA FUNCTIONAL ELECTRICAL PERONEAL BRACE

Subcommittee on Evaluation

COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
DIVISION OF MEDICAL SCIENCES--NATIONAL RESEARCH COUNCIL

This study was supported by Contract SRS-72-7, Amendment #1, between the Social and Rehabilitation Service, HEW, and the National Academy of Sciences

NATIONAL ACADEMY OF SCIENCES
Washington, D.C.

1973

REPORT E-7

NOTICE

The project which is the subject of this report was approved by the Governing Board of the National Research Council, acting in behalf of the National Academy of Sciences. Such approval reflects the Board's judgment that the project is of national importance and appropriate with respect to both the purposes and resources of the National Research Council.

The members of the committee selected to undertake this project and prepare this report were chosen for recognized scholarly competence and with due consideration for the balance of disciplines appropriate to the project. Responsibility for the detailed aspects of this report rests with that committee.

Each report issuing from a study committee of the National Research Council is reviewed by an independent group of qualified individuals according to procedures established and monitored by the Report Review Committee of the National Academy of Sciences. Distribution of the report is approved, by the President of the Academy, upon satisfactory completion of the review process.

CONTENTS

PARTICIPATING CENTERS

UNITED STATES

Case Western Reserve University, Cleveland, Ohio

Moss Rehabilitation Hospital, Philadelphia, Pennsylvania

Northwestern University, Chicago, Illinois

Rancho Los Amigos Hospital, Downey, California

Wadsworth Veterans Administration Hospital, West Los Angeles, California

Sepulveda Veterans Administration Hospital, Los Angeles, California

OVERSEAS

Poland

- Konstancin Rehabilitation Institute, Konstancin
- GORNICZE Rehabilitation Center, Repty
- Institute for Orthopaedic Surgery and Rehabilitation, Academy of Medicine, Poznan

Yugoslavia

- Center for Prosthetics, Belgrade
- Ljubljana Rehabilitation Institute, Ljubljana

CLINICAL EVALUATION OF THE LJUBLJANA FUNCTIONAL ELECTRICAL PERONEAL BRACE

PART I. BACKGROUND INFORMATION

Kratzenstein (1745)[6] is said to have been the first to have used electrical stimulation to contract a muscle for treatment. Jallabert[5] also wrote in 1748 on the subject. It is Galvani[4] to whom is ascribed the beginning of experimental neurophysiology in 1792 when he published his clinical experiments on the sciatic nerves of frogs' legs.

Duchenne de Boulogne[3] in 1867 was using electrical stimulation therapeutically in the mid-nineteenth century but later it fell into disuse until World War I. From the turn of the century there had been many neurophysiologists who had studied the effects and nature of neuromuscular response to electrical stimulation. This resulted in the use from World War I until after World War II of two forms of electrical stimulation in neuromuscular rehabilitation. The first was the use of an interrupted direct or galvanic current to stimulate muscle fibres in lower motor neuron disease in the hope that this would lessen the degeneration pending recovery. The second was the use of a surged alternating or faradic current from an induction coil which was used to stimulate the intact or recovered lower motor neuron to produce muscular contraction in the treatment of paralysis. After World War II the rationale and efficacy of both treatments were questioned and their use was greatly curtailed. At that time neither was considered suitable for use in upper motor neuron disease because it was alleged that their use would increase the spasticity.

DEVELOPMENT OF FUNCTIONAL ELECTRICAL STIMULATION

Electrical stimulation is used and has been used for many years as a therapeutic measure to aid recovery in other diseases as well as neuromuscular disease. The therapeutic use implies that the stimulus is applied by a skilled operator in the expectation of promoting recovery and that eventually the treatment may be stopped.

Functional electrical stimulation is a concept which has developed since World War II. It is the long-term or permanent use of an

electrical stimulus to initiate and maintain a physiological response to supplement or replace an impaired or lost function. Although with the passage of time it may help in recovery, that is not its objective.

The heart pacemaker is probably the most highly developed, documented, and used example of functional electrical stimulation, but there are many other fields of medicine where its use is currently being explored.

Lee *et al.*[7] used continuous tetanizing currents in 1950 to relieve spasms. Weinstein *et al.*[13], 1951, used faradism in the treatment of hemiplegics and Levine and co-workers[8] in 1952 noted the relaxation of spasticity by the electrical stimulation of antagonist muscles.

In February 1961, Liberson and co-workers[9] published the first of a series of papers on the use of functional electrical stimulation of the peroneal nerve in stroke patients. Research into many aspects of electrical stimulation in the treatment of disease progressed in a number of centers in the U.S.A.

In 1964 a multidisciplinary program of research into the use of Functional Electrical Stimulation in the rehabilitation of the disabled was initiated in Yugoslavia by the Department of Clinical Neurophysiology, Laboratory for Medical Electronics and Biocybernetics, Surgical Clinic, and Institute for Rehabilitation of the Disabled at Ljubljana. This group published a progress report in 1967[10].

In 1969, the Committee on Prosthetics Research and Development organized an international meeting at Cacapon State Park, Berkeley Springs, West Virginia, to survey the practice and ongoing research in prosthetics and orthotics throughout the world. Electrical stimulation was one of the subjects under discussion and representatives from Ljubljana attended. The group in Ljubljana were even then in communication with various centers in the U.S.A., notably Case Western Reserve University and Baylor University. The Cacapon meeting enhanced interest in the subject. Following the meeting, the Social and Rehabilitation Service of the Department of Health, Education, and Welfare

decided to support the program in Ljubljana in close collaboration with Case Western Reserve University and Baylor University, to develop a system for practical use on the patient. The groups have pursued their fundamental research since but with a clinical use as the goal, using surface, transcutaneous and implanted electrodes at varied sites[11,12]. In 1971, the Ljubljana group considered that they had a device using surface electrodes to stimulate the common peroneal nerve which would give dorsiflexion and eversion in the swing phase of gait in stroke patients. Their estimate, following extensive clinical trials, was that it was effective in 30% of hemiplegic patients. The Social and Rehabilitation Service thereupon arranged to purchase 100 of these devices to submit them for clinical trial by CPRD.

At the same time a cooperative evaluation program to run concurrently was arranged by the Social and Rehabilitation Service at centers in Yugoslavia and Poland where they agreed to follow the same protocol.

The experiences and results of both the United States and European centers were reported at a meeting held at Portoroz, Yugoslavia, on November 8-10, 1972.

LITERATURE CITED

1. Committee on Prosthetics Research and Development, Research in limb prosthetics and orthotics--a report of an international conference, April 28-May 2, 1969. National Academy of Sciences, Washington, D. C., 1969.

2. Duchenne de Boulogne, G. B. A., Physiology of Motion (Physiologie des Mouvements demontree a l'aide de l'experimentation electrique et de l'observations clinique et applicable a l'etude des paralysies et des deformations. 1867). Translated by E. B. Kaplan, W. B. Saunders, 1959.

3. Duchenne de Boulogne, G. B. A., Selections from clinical works. Edited by G. V. Poore, London, 1883.

4. Galvani, L., Viribus Electricitates in Motu Musculari. Modena 1792, translated by R. Montraville Green (Commentary on the Effect of Electricity on Muscular Motion). E. Licht, Cambridge, 1953.

5. Jallabert, J. L., Experiences sur l'Electricite. Genova, 1748. Quoted from "Therapeutic Electricity and Ultraviolet Radiation." S. Licht, New Haven, 1959.

6. Kratzenstein, C. G., Schreiben von dem Nutzen der Electricitat in der Arzneiwisseschaft. Halle, 1745, 1746, 1772. Quoted from "Therapeutic Electricity and Ultraviolet Radiation." S. Licht, New Haven, 1959.

7. Lee, W. J., J. P. McGovern, and E. N. Duval, Continuous tetanizing currents for relief of spasm. Arch. Phys. Med., 31:766-770, 1950.

8. Levine, M. G., G. Knott, and H. Kabat, Relaxation of spasticity by electrical stimulation of antagonist muscles. Arch. Phys. Med., 33: 668-673, 1952.

9. Liberson, W. T., H. J. Holmquest, D. Scott, and M. Dow, Functional electrotherapy: Stimulation of the peroneal nerve synchronized with the swing phase of gait of hemiplegic patients. Arch. Phys. Med., 42, February 1961.

10. Ljubljana Rehabilitation Research Project. Division. Functional electrical stimulation. Ljubljana, 1967.

11. Ljubljana Rehabilitation Research Program, Development of orthotic systems using functional electrical stimulation and myoelectric control. Ljubljana, April 1970.

12. Ljubljana Rehabilitation Research Program, Use of functional stimulation in rehabilitation of hemiplegic patients. Ljubljana, June 1972.

13. Weinstein, M. V., and A. Gordon, The use of faradism in the rehabilitation of hemiplegics. Phys. Ther. Rev., 31:515-517, 1951.

PART II. THE LJUBLJANA FUNCTIONAL ELECTRICAL PERONEAL BRACE* AND THE RATIONALE OF ITS USE

THE DEVICE

The device (Fig. 1) consists of a shoe insole incorporating a heel tape switch that switches the device off when pressure is applied during the stance phase of gait, and on at heel rise during the swing phase. This is connected by hearing-aid cable through a three-point connector at leg level to the electrical stimulator. The connection at the stimulator is by a five-pin plug which also carries the leads to the electrodes.

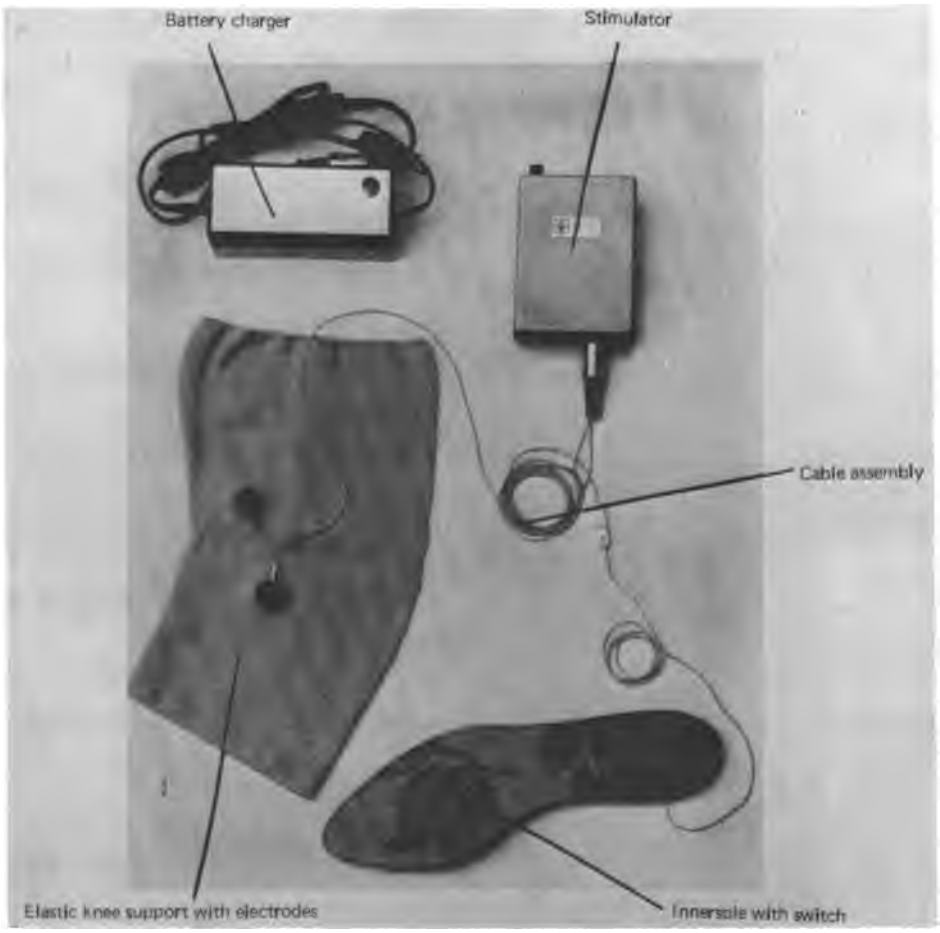


Fig. 1

*We are retaining the term "brace" in reference to the name of the unit as it was the designation given before the term "orthosis" was adopted officially.

The stimulator is powered by rechargeable nickel cadmium batteries and has the following parameters:

Output voltage	55V + 5V (Load 4.7 Kohms/.15uF)
Stimulation period	0.25 - 1.5 sec.
Frequency (PRR within train)	33 - 55 Hz
Pulse width	0.5 - 1.0 in sec.

The stimulator has two controls available to the patient, a push-button on/off switch and a wheel-voltage output control. There are also two potentiometers which can only be reached by opening the stimulator so that the therapist may vary the frequency and the stimulation period to match the patient's needs (Fig. 2). None of these controls has any form of calibration.

Fig. 2. Internal components and adjustment points of stimulator.

From the stimulator through the five-pin plug, a hearing-aid cable goes to two metal electrodes to which it is connected with snap fasteners. These electrodes were originally tin-plated steel discs which corroded. Subsequently aluminum discs were substituted. These discs were covered with gauze and encapsulated in waterproof polyethylene except for a circular area 2.5 cm in diameter for skin contact. They are wetted with tap water before application (Fig. 3).

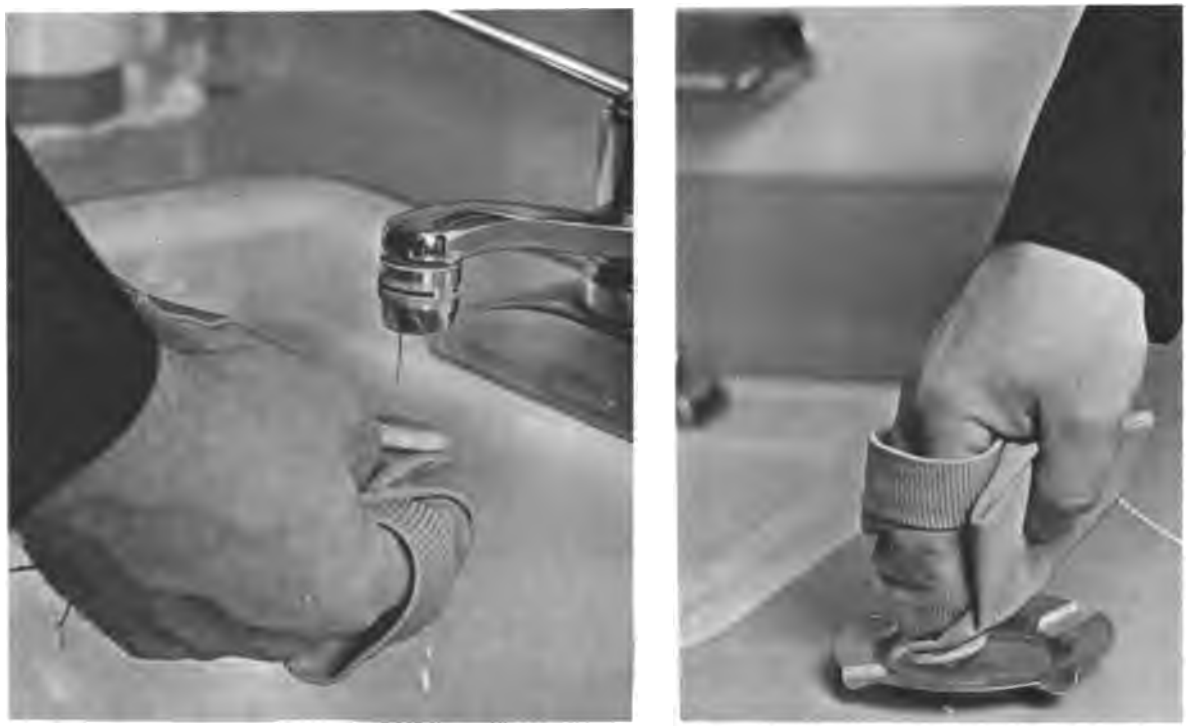


Fig. 3. Two possible ways to dampen the electrodes.

The electrodes are placed--one over the common peroneal nerve as it emerges from behind the lateral hamstring muscle, and the other over the nerve as it winds round the neck of the fibula. They are held in place by an elastic knee support (Fig. 4).

Fig. 4. Position of elastic knee support.

RATIONALE OF USE

Since the total effects of electrical stimulation of motor nerves are not fully understood and the explanations of much of what is known are often controversial, any short explanation of the rationale must be superficial and subject to dispute.

At heel rise the stimulator is activated. It provides a square wave pulse of short duration (0.5 - 1.0 m sec) repeated at 35-50 Hz for most of the duration of the swing phase, at a voltage adequate to stimulate the motor fibres of the common peroneal nerve.

This stimulation promotes contraction of the dorsiflexors and evertors of the foot which in turn stimulates the fusiform fibres and the Golgi system to inhibit the antagonists. The peroneal nerve is a mixed nerve and there is direct stimulation of the afferent neurons to reinforce this effect. There is also some response in other segments through the interuncial spread in the spinal cord. In surface electrode stimulation there may be some skin stimulation which is also known to inhibit spasticity. The summation of these effects is to produce dorsiflexion with some eversion in the swing phase (Fig. 5).

Fig. 5. *A*, Gait of patient without use of Ljubljana FEPB; *B*, Gait of the same patient with Ljubljana FEPB.

[Attention is drawn not only to correction of the drop foot, but also to the very important changes in posture.]

In the Ljubljana FEPB as supplied, the pulse train is predetermined to last for a limited period of time which is intended to be about 3/4 of the swing phase. In another version the stimulus is cadence-controlled being switched off at heel contact.

In order to prevent inordinately long or continuous stimulation, there is an automatic cutout after 2 secs.

PART III. ORGANIZATION OF THE CLINICAL EVALUATION

To arrange clinical evaluation of a device it is desirable to:

1. Establish that the device meets accepted standards of safety and is of a quality which will withstand the expected use.

2. Enlist participating teams in centers of merit with a suitable case load.

3. Inform and instruct these teams in the purpose of the assessment, patient selection, rationale of use, and application of the device.

4. Establish a protocol of patient selection and data collection within the capabilities of and common to all the participants.

5. Have a coordinating service to provide exchange of information and to help solve problems as they arise. This service should also collect and process the data.

6. Ensure that once the program is started there is no undue delay in supplies of devices or components.

7. Report the outcome of the evaluation.

CPRD does not claim that all these objectives have been fully achieved.

1. Dr. Franjo Gracanin, Director of the Institute of Rehabilitation Medicine, Ljubljana, and Mr. Joseph Canzoneri, M.S.E.E., Director of Biomedical Engineering of the Texas Institute for Rehabilitation and Research, conducted a full investigation into the possible electrical hazards in accordance with the standards described by the Association for the Advancement of Medical Instrumentation, and their report was satisfactory.

Initially the Veterans Administration Prosthetics Center, New York, agreed to test each device individually to insure that they were all serviceable. They had to relinquish this task, partly because

the technical staff involved had other work and partly because there was a high incidence of failure from various causes, and the VAPC did not consider they could provide the necessary immediate and back-up servicing required.

CPRD then arranged with Medtronic, Inc., a commercial firm in negotiation with the developers, to report on the device, and an abstract of their report is given in Appendix A. It is emphasized that there was little to criticize in the engineering design or overall quality of manufacture. The faults seemed to arise from an inadequate inspectorate. There are a number of defects in design which could not have been anticipated and could only have been demonstrated by the evaluation itself. Following this report Medtronic, Inc., undertook the preliminary inspection and servicing of the devices for the program without fee.

2. CPRD initially invited the following centers to participate in the program:

Moss Rehabilitation Institute
Rancho Los Amigos Hospital
Veterans Administration Hospital, Wadsworth
Northwestern University

The Veterans Administration Hospital, Wadsworth, had to withdraw from the program because of closure due to earthquake damage. The VA Hospital, Sepulveda, attempted to continue with the program but it proved impractical. Nevertheless these two hospitals provided seven documented case histories.

When the Veterans Administration Hospitals withdrew, Case Western Reserve University, where the device had already been used in physiological research, and the University of Miami were added to the participating teams.

The Texas Institute of Rehabilitation Research was not included in the evaluation program. They had used the Ljubljana stimu-

lator, had made their own assessment, and developed their own device which, although similar, had many modifications. It was therefore not considered appropriate that they should partake in the program. CPRD would like, however, to acknowledge the unstinting help and cooperation received from TIRR throughout the program. Their expertise was most valuable.

The teams in Poland and Yugoslavia selected for participation in the study were:

POLAND

Konstancin Rehabilitation Institute, Konstancin; GORNICZE Rehabilitation Center, Repty; Institute for Orthopaedic Surgery and Rehabilitation, Academy of Medicine, Poznan.

YUGOSLAVIA

Center for Prosthetics, Belgrade
Ljubljana Rehabilitation Institute, Ljubljana

The Ljubljana developing group reported that the stimulator was suitable for use as a brace in the activities of daily life in 30% of hemiplegics. The participating centers of merit all were considered to have an adequate case load to provide an evaluation within the projected period. In practice these centers were only able to find at most some 5% of suitable patients in their stroke services. The discrepancy between the two figures has not been explained. United States observers who have seen the Ljubljana service in action have no reason to suppose that their claims are exaggerated. The majority of hemiplegic patients in the United States and many European communities are due to atherosclerosis which shows its effects in later life and is considered to be due to an overindulgent diet. The population of Yugoslavia has suffered the rigors of enemy occupation in two World Wars and are mostly a hardy mountain race. The etiology and age incidence might therefore be considered factors. This view is not supported by the analysis of the age and etiology distribution reported in Part V.

The participants being centers of merit might have been thought to attract a high incidence of transfer from other hospitals of difficult, and therefore unsuitable, cases. This can only be partly true as some of the centers are county hospitals with a considerable intake of patients of all categories. The answer may be, in fact, in the age and etiology factor. Although in our program the decades between 50 and 70 with a high incidence of atherosclerosis were the most successful, this was after selection. No figures are available to us of the total etiological and age incidence in the 2,000,000 stroke patients in the U.S.A.

With hindsight it is therefore evident that the chosen centers had not a readily available pool of suitable patients for speedy evaluation.

Rancho Los Amigos Hospital had particular difficulty in that their stroke service carries a heavy load of referrals from other hospitals and that they were themselves engaged in a development program of an implanted device calling for patients with the same disability.

3. Information and instruction into the purpose, patient selection, rationale, and use of the device was given to the invited participants and others in an orientation session arranged for CPRD and hosted by TIRR at Houston, Texas, April 19-21, 1971. At this three-day meeting there was a full discussion by the developers from Ljubljana and those with experience at TIRR on the neurophysiology, engineering, patient selection, psychology, and theoretical application of the device. Relatively little time was given to actual instruction in its application, mostly to therapists, of whom two out of four left the program before the actual clinical trials started. Project leaders then lacked enough expertise to supervise and instruct new staff in the practical application. This made it necessary to arrange at a later date for a special instructional course at TIRR with Miss Miriam Partridge, R.P.T.

4. One half-day session was given at the orientation session in Houston to the development of an agreed protocol. This resulted in a lengthy, largely subjective, and unworkable protocol which later had to be withdrawn and for which the protocol in Part IV was substituted. A longer period to discuss it might have resulted in a shorter protocol. Since the techniques of data collection are being studied the program can also have been an evaluation of the protocol which is discussed in Part VII. Suffice it to say that it proved to be beyond the capabilities of some centers and strained the resources of others. An Instruction Manual giving full details was provided for all participants.

5. The staff surgeon paid three site visits to most centers and circulated information gained on these visits in letters to all participants. He also visited Ljubljana for four days in December 1971 to study their techniques and results. A meeting to study progress was held at Rancho Los Amigos Hospital on March 18, 1972, and the staff engineer visited centers with Dr. Gracanin in May 1972. The staff of CPRD were always available by letter or telephone to participants.

The staff of Medtronic, Inc., were also most helpful at all times in trying to alleviate the many frustrations which arose from equipment defects. They were always available to participants and CPRD for aid and advice in technical difficulties and gave service beyond their contractural obligations.

The collection of data was difficult, incomplete, and slow. The reasons for this are discussed in the assessment of the protocol.

6. There was considerable delay after the orientation session in March 1971 before any units were available, and there was further delay while they were being rectified, so that participants could not start the program until November 1971. Subsequently some urgently needed spares were delivered after the program had ceased. There was no undue delay in the United States and there was apparent cooperation by the developers. Such delays blunt the enthusiasm of participants. In international cooperative projects of this nature, proper channels

must be used if confusion is to be avoided but, in the interests of international accord between developers and evaluators, it would help if there were methods of speeding the flow through the channels or at least identifying the log jam.

7. The clinic teams from Poznan, Konstancin, Repty (Poland), Belgrade and Ljlubjana (Yugoslavia) met at Bled, Yugoslavia, June 13-19, 1971, to receive instruction in application and maintenance of the units and in use of the data-collection forms that had been developed by CPRD. Each team was provided with ten units.

The clinic teams met again November 8-10, this time in Portoroz, Yugoslavia, with representatives from CPRD and SRS and the developers. The findings were amazingly similar to those made by the U.S. clinical teams. The results of the individual teams are included here as Appendixes *B*, *C*, *D*, *E*, and *F*.

At the closing session of the meeting in Portoroz a new set of specifications for the FEPB were drawn up using a set drawn up originally by CPRD as a point of departure. The specifications agreed upon are included as Part VI of this report.

PART IV. PROTOCOL

INSTRUCTIONS TO CLINICS PARTICIPATING IN THE CPRD CLINICAL STUDY OF THE LJUBLJANA FUNCTIONAL ELECTRICAL PERONEAL BRACE

A. Each participating clinic will select patients from those with full hospital medical records who meet the following criteria:

1. An upper-motor neuron hemiparesis of not less than four weeks duration of any etiology (etiology to be recorded).

2. Male or female.

3. Age between 15-70 years.

4. In need of an orthosis but able to stand and walk with heel contact when wearing normal footwear.

5. Without shortening or severe fixed soft-tissue or bony deformities. Without genu recurvatum and with fair knee and hip stability.

6. Without undue sensory loss so that sensation is adequate for proprioception and to feel stimulation. They should not have loss of body image.

7. Patient should be cooperative and of reasonably good physical condition, emotionally stable and have a good attitude.

B. Patients selected for the study will sign a Patient's Consent Form (FEPB-1)

C. Each participating clinic will select at least 15 suitable patients, treating them with the Ljubljana FEPB.

D. Data Collection:

1. Relevant details will be transferred from the hospital's own medical records to the AAOS Technical Analysis Form with supplement by CPRD (FEPB-2)

2. Functional performance will be recorded on the Gait Performance Form FEPB-3.

3. The orthoses supplied, estimated usage, maintenance and change of orthoses will be recorded on the Orthosis Record Form (FEPB-4).

4. The Evaluation Questionnaire will be completed with the assistance of the clinic team at the end of the trial (FEPB-5).

5. The clinic team should complete a written assessment of the effectiveness of the orthoses and, where comparison is possible, the merits and demerits of each.

E. All patients must have relevant parts of forms FEPB-1, 2 and 3 completed before an orthosis under test is supplied.

All patients will have a 3-4 week training period and will be assessed at 1, 3, 6 and 12 months.

F. Unless determined otherwise at a later date, the data will be retained by the clinics until the completion of the study.

Members of the CPRD staff will visit the clinic teams from time to time to discuss any problems that may arise and to help correlate the study. The cooperation of the teams in undertaking this clinical study is greatly appreciated.

PATIENT'S CONSENT FORM

The _____

Study has been explained to me and I agree to participate as a test subject. All data and photographs taken may be used for future publication.

Date _____ Signature _____

DIAGNOSIS _____ NAME _____

_____ NO. _____ SEX _____

_____ AGE _____ HEIGHT _____ WEIGHT _____

DATE _____

MAJOR IMPAIRMENTS:

A. Musculoskeletal:

1. Bone & Joint: Normal ☐ Abnormal _____
2. Muscle: Normal ☐ Flaccid ☐ Spastic ☐
   Other _____
3. Ligament: Normal ☐ Abnormal ☐: Knee: AC ☐ PC ☐ MC ☐ LC ☐
   Ankle: MC ☐ LC ☐
   Other _____

B. Sensation: Normal ☐ Abnormal ☐

1. Anaesthesia ☐ Location _____
   Protective Sensation: Lost ☐ Retained ☐
2. Proprioceptive Loss ☐
   Location _____ Degree: Mild ☐ Moderate ☐ Severe ☐
3. Pain ☐ Location _____

C. Skin: Normal ☐ Abnormal _____

D. Vascular: Normal ☐ Abnormal ☐ RT ☐ LT ☐

1. Arterial ☐ 2. Venous ☐ 3. Coagulation Defect ☐

E. Balance: Normal ☐ Impaired: Mild ☐ Moderate ☐ Severe ☐

F. Extremity Shortening: None ☐ LT ☐ RT ☐
   Amount of Discrepancy:

I.T. – Heel _____

I.T. – M.T.P. _____

M.T.P. – Heel _____

X-ray _____

LEGEND

= Direction of Translatory Motion

= Abnormal Degree of Rotary Motion (60°)

= Fixed Position (30°, 1 CM.)

= Fracture

Volitional Force

G = Good
F = Fair
P = Poor
T = Trace
Z = Zero

Spastic Muscle (SP)

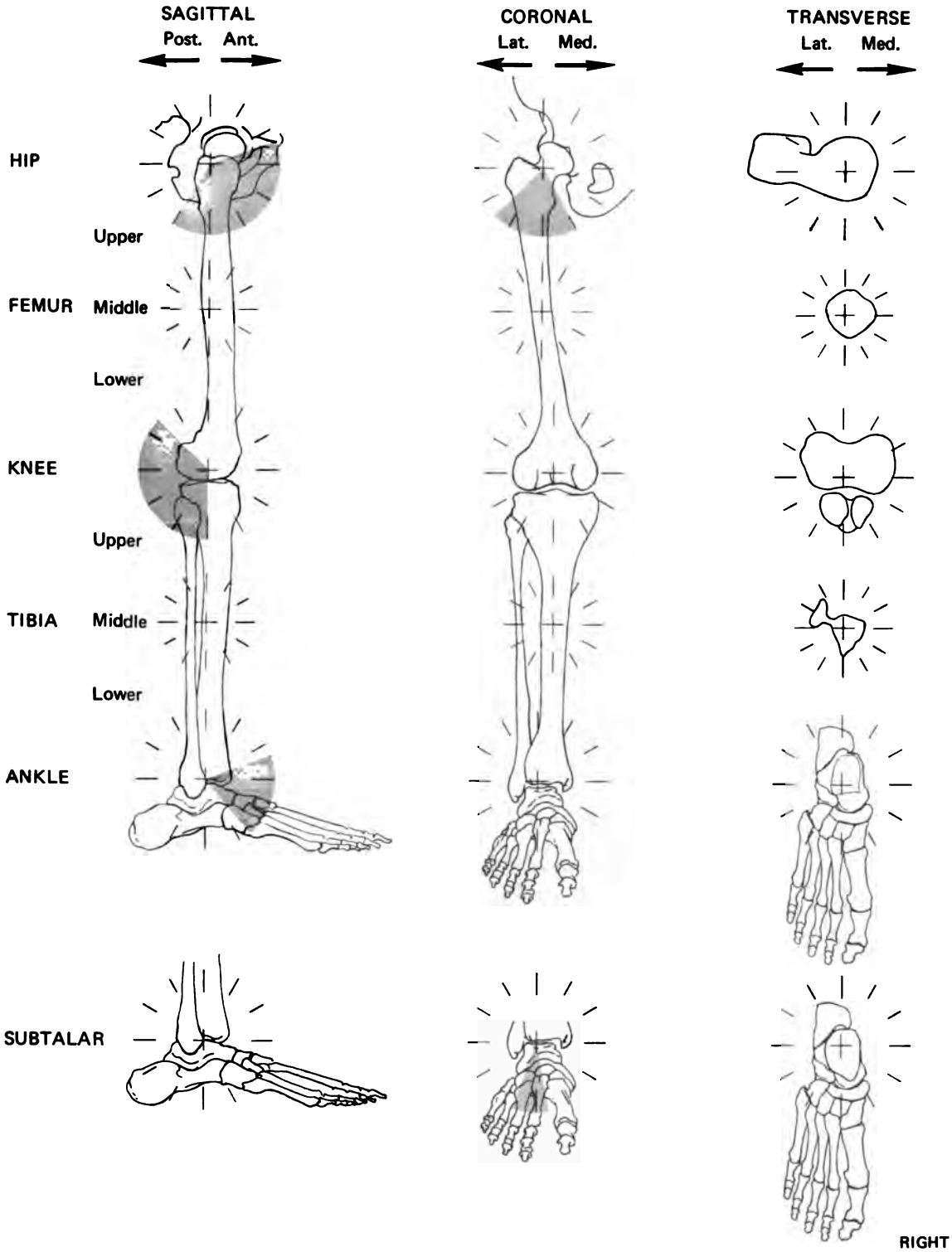
SP_M = Mild
SP_{MO} = Moderate
SP_S = Severe

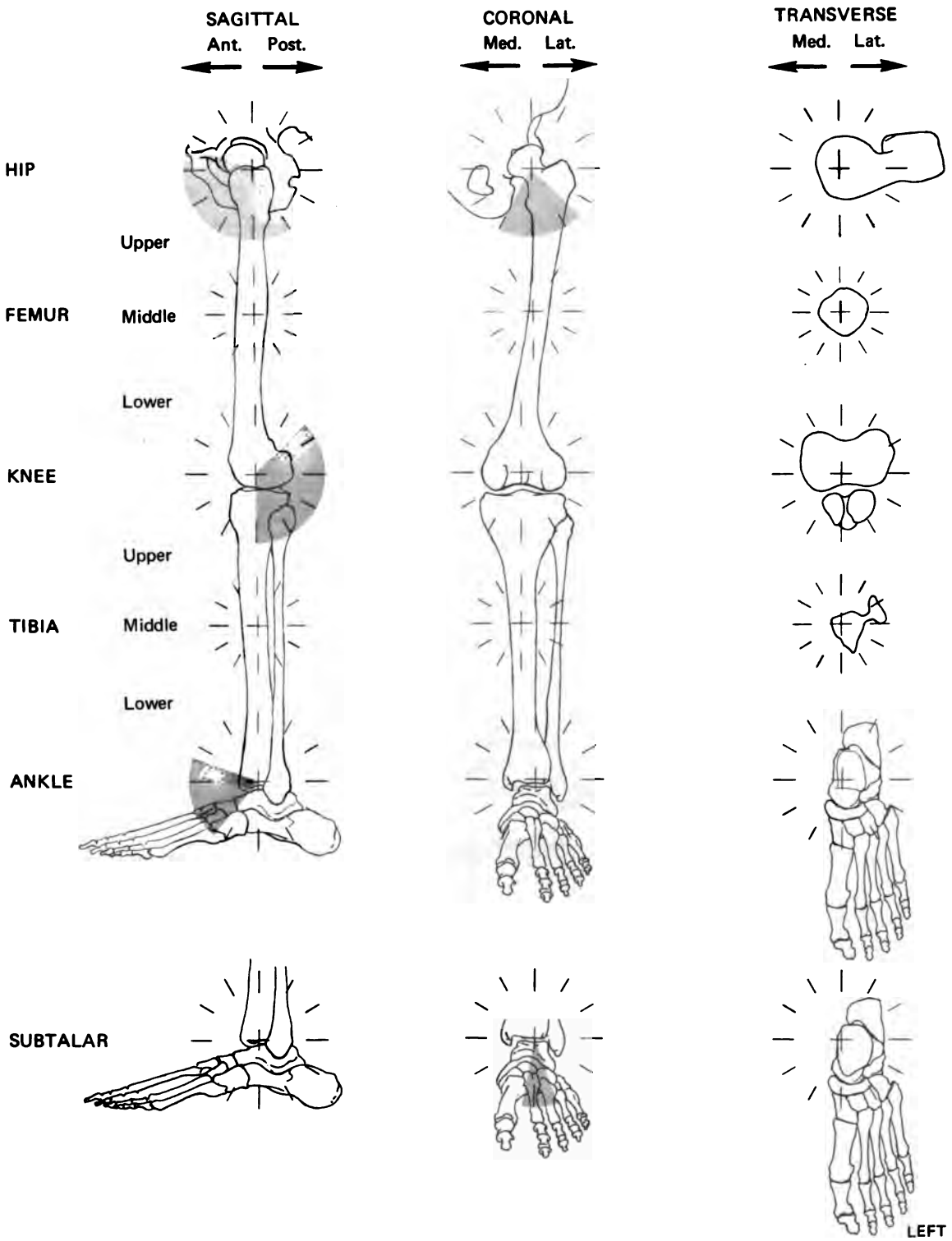
= Pseudarthrosis

= Absence of Segment

E = Edema

D = Local Distension or Enlargement





(OVER)

Summary of Functional Disability _____

_____

_____

_____

_____

_____

Orthotic Recommendation _____

_____

_____

TECHNICAL ANALYSIS FORM SUPPLEMENT

1. Hand Dominance prior to hemiplegia:

   Right _____ Left _____

2. Speech:

   Normal _____ Abnormal _____

3. Vision (with glasses if worn)

   Normal _____ Abnormal _____

4. Hearing:

   Normal _____ Abnormal _____

GAIT PERFORMANCE

Name _____ Hospital No. _____ FES No. _____

Hemiplegia Cause _____ Side _____ Dominant Hand _____

TIME TO WALK 50 FEET AT A COMFORTABLE RATE IN SECONDS

VISITS	DATE	WITHOUT ORTHOSIS	WITH ORTHOSIS	WITH F.E.S. BUT NOT STIMULATING	WITH F.E.S. STIMULATING	REMARKS	OBSERVER'S INITIALS
1st							
2nd							
3rd							
4th							
5th							

TIME TO WALK 50 FEET TURN 180° AND RETURN IN SECONDS

VISITS	DATE	WITHOUT ORTHOSIS	WITH ORTHOSIS	WITH F.E.S. BUT NOT STIMULATING	WITH F.E.S. STIMULATING	REMARKS	OBSERVER'S INITIALS
1st							
2nd							
3rd							
4th							
5th							

WALKING GAIT CYCLE IN INCHES

VISIT	DATE	LENGTH IN INCHES
1st		
2nd		
3rd		
4th		
5th		

TIME IN SECONDS OF STANCE AND SWING PHASE OF LOWER LIMBS AND RATIO

		RIGHT			LEFT		
VISIT	DATE	STANCE	SWING	RATIO	STANCE	SWING	RATIO
1st							
2nd							
3rd							
4th							
5th							

FEPB-4

NAME_____

PATIENT ORTHOSIS RECORD FORM

Date Fitted_____ Type of Orthosis_____ If FEPB Serial #_____

Date Seen	Reason for Visit or Nature of Problem	Disposition

FEPB-5

EVALUATION QUESTIONNAIRE

PART A: To be completed by the patient (with the assistance of the clinic team where necessary).

1. Was the User's Manual beneficial? Yes ___ No ___

   If "No," why?

2. Was the exact site for stimulating the nerve difficult to find? Yes ___ No ___

3. Was the exact site, once found, difficult to maintain? Yes ___ No ___

   If "Yes," why?

4. Did electrical stimulation volume change with wearing of the brace? Yes ___ No ___

   If "Yes," increased _____; decreased _____.

5. Did use of the brace at any time make walking difficult? Yes ___ No ___

   If "Yes," please explain.

6. Was the brace comfortable? Sometimes ____ Always ____ Never ____

7. What was the most common "every-day problem" with this brace? Explain.

8. Was walking ability improved by the brace? Yes ___ No ___

9. Were mechanical problems Frequent ____ Infrequent ____

   Explain

10. How much help did you need to put on the brace? Explain.

11. Have any physical problems arisen from the use of the brace? Yes ___ No ___

    If "Yes," explain.

12. Did you feel more comfortable wearing the brace socially? Yes ___ No ___

13. Did you normally wear your brace socially? Yes ___ No ___

14. Describe briefly, the main disadvantage of the brace.

15. Describe briefly, the main advantage of the brace.

16. How many hours per day was your orthosis worn? _____

PART B: To be completed by the clinic team.

1. Was the patient's gait improved without the orthosis? Yes ___ No ___

2. Was the patient's gait further improved with the previous orthosis (if any) if worn? Yes ___ No ___

3. Was the patient's gait still further improved by FEPB than with an orthosis? Yes ___ No ___

4. Was there any carry over?* Yes ___ No ___

5. In the team's opinion did patient in fact use FEPB? Sometimes ___ Yes ___ No ___

6. If patient abandoned FEPB was it due to:

   Unreliability _____

   Difficulty in placing electrodes _____

   Ineffectiveness _____

   Other _____

7. If patient uses FEPB is it in the clinic team's opinion better than a mechanical orthosis? Yes ___ No ___

8. Remarks:

* "Carry Over" - the continued effect for a significant time of F.E.S. after stimulator has stopped

PART V. DATA RELATED TO THE CLINICAL EVALUATION OF THE LJUBLJANA FUNCTIONAL ELECTRICAL PERONEAL BRACE

Eighty-nine patients were included in the American program. Of these, 10 patients were stated by the participating hospital not to meet the criteria of patient selection laid down in the protocol. All 10 patients failed.

Of the remaining 79 patients said to meet the criteria, one died leaving 78. It is probable that the standards of patient selection were somewhat laxly applied to some included in this number thereby adversely loading the outcome. Of these 78 patients 50 were unsuccessful and 20 were successful in the activities of daily life, a ratio of 1.8:1.

In this number of 78 patients were six under the age of 20, four of whom were successes. Data from two of the centers were incomplete but we received detailed records on a total of 46 patients which included the one death.

The following analysis is based on the records of these 45 patients: 26 were male and 19 female, giving a ratio of 1.37:1.

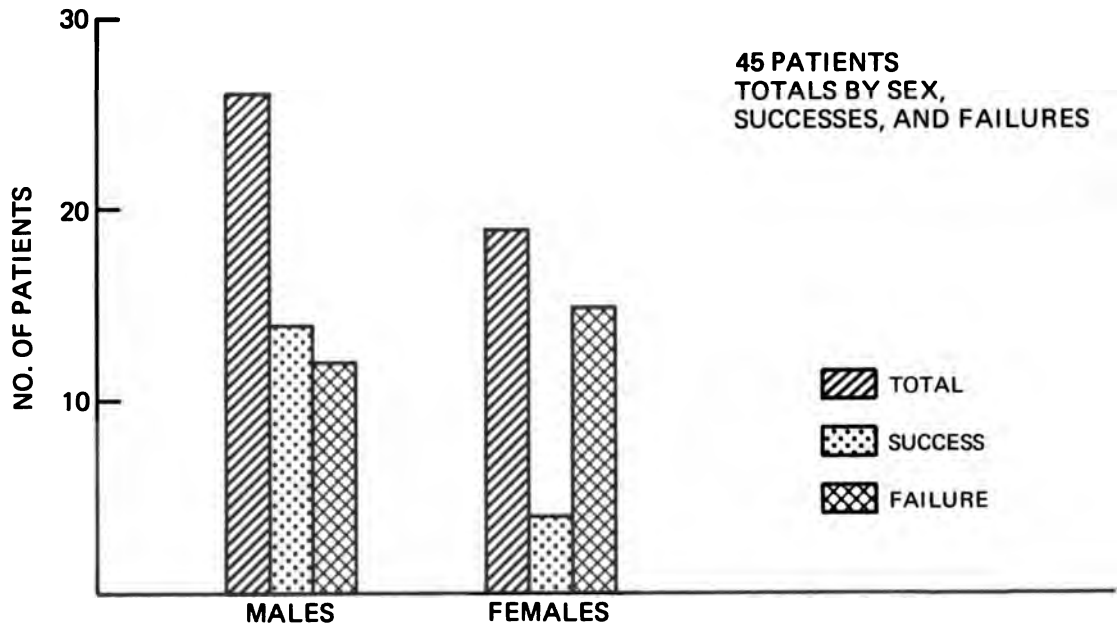


Fig. 1. This histogram shows that 14 males were successful to 12 that failed, a ratio of 1.16:1, whereas only 4 women were successful to 15 that failed, a ratio of 0.27:1. The ratio, therefore, of successful outcome between men and women with these criteria seems to be 2.5:1.

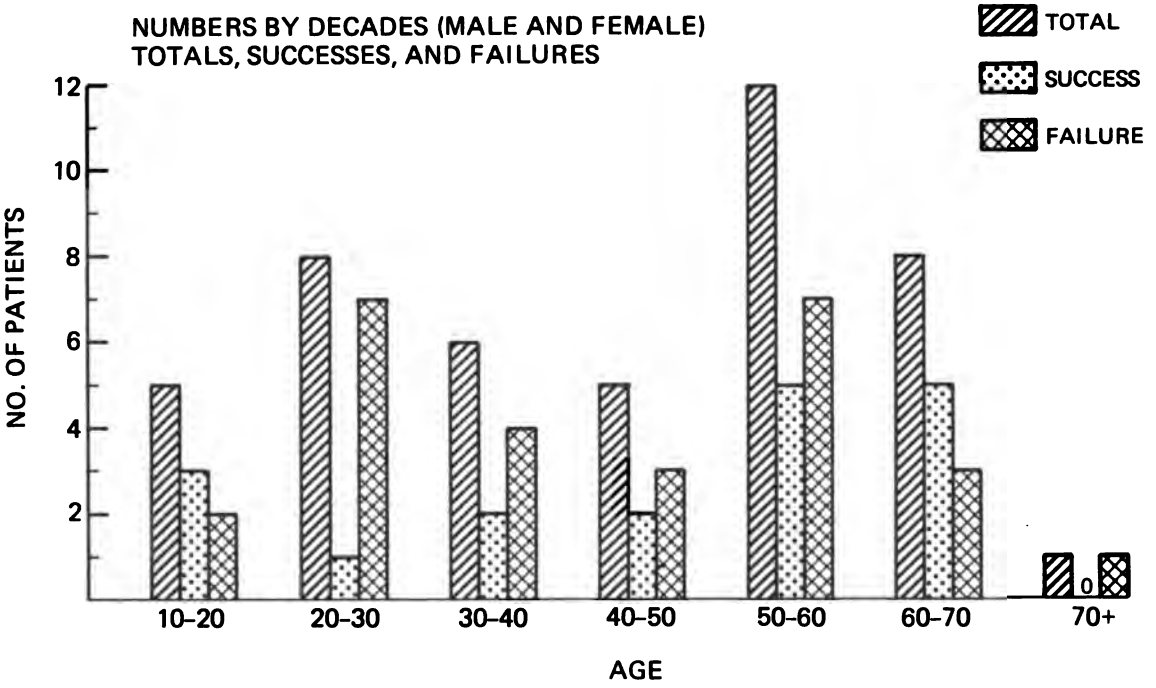


Fig. 2. This is a histogram which shows the total numbers, by decades, of successes and failures. The numbers are probably too few to draw any definite conclusions but the figures do indicate that the outcome is better in the older age groups.

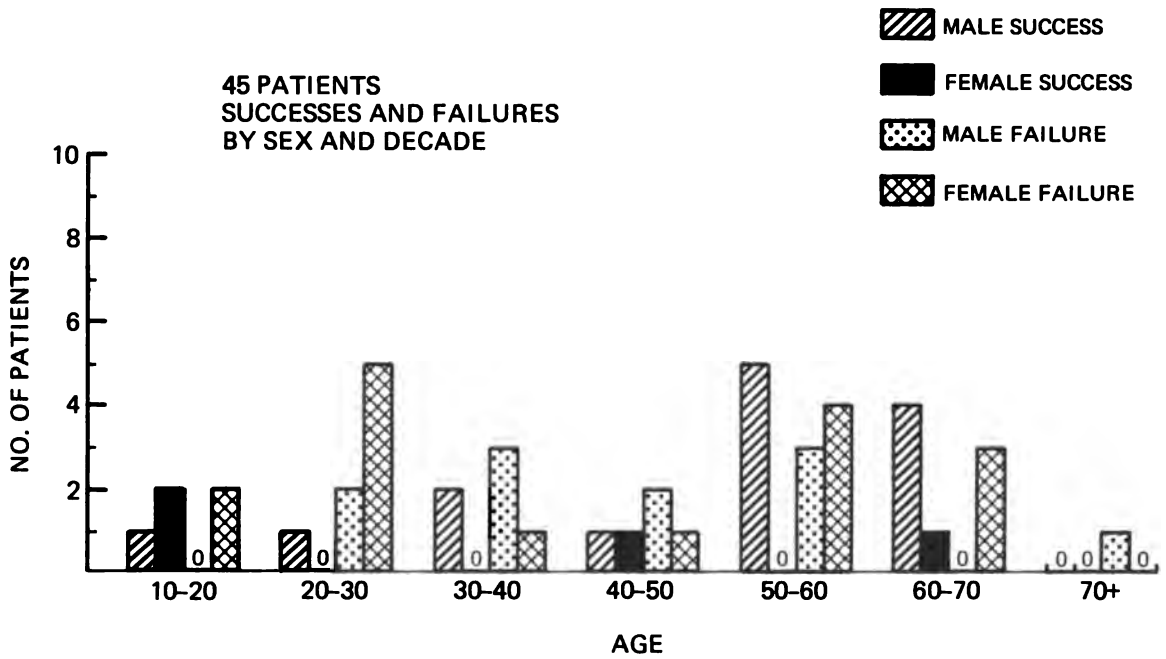


Fig. 3. This shows the success and failure by sex in each decade. It will be seen that in this small sample two out of four females were in the under-20 group.

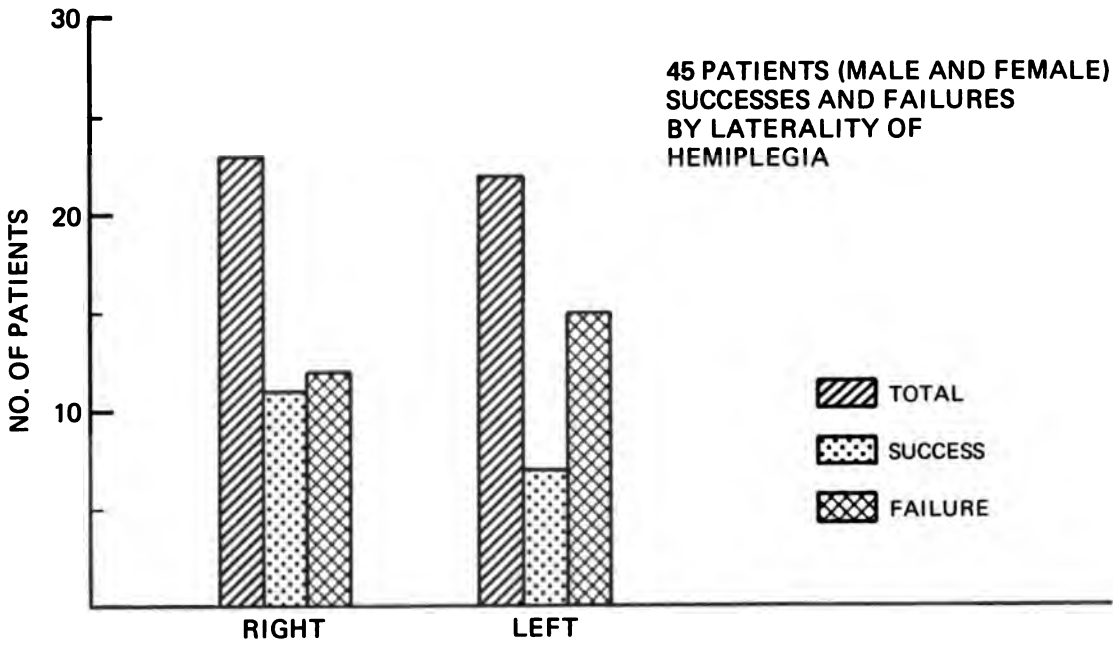


Fig. 4. This shows the success or failure in 45 patients according to the site affected. With right-sided hemiplegia the success-to-failure ratio is 0.92:1, whereas for the left hemiplegic it is only 0.32:1.*

*** Records were kept of success or failure related to hand dominance with precisely the same figures.**

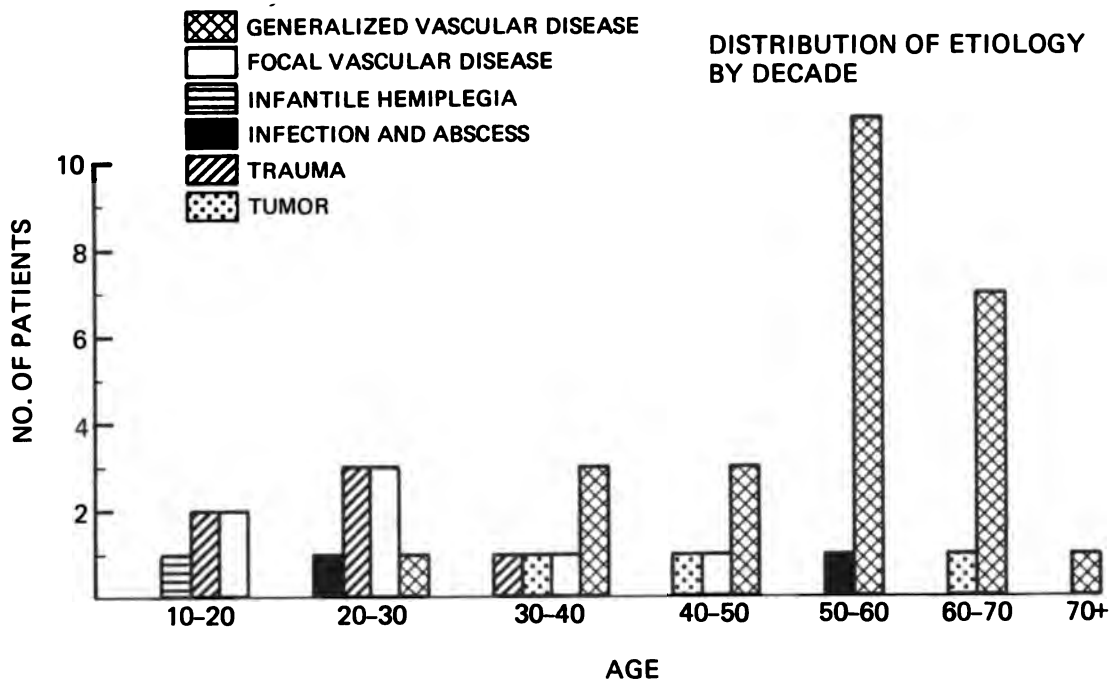


Fig. 5. This shows the etiological cause of hemiplegia in the 45 patients by decades. It shows that in the later years generalized vascular disease is the overwhelming cause. Five patients were under 20 in this group, of whom one was male and four female. The male and two females were successful. The two females were half the successful women.

Twenty-seven patients failed. Eleven had medical causes given as the prime cause of failure:

Four due to diabetes;

Four due to impedance of undetermined etiology;

Two due to cardiac failure;

One due to intercurrent surgery to the foot.

Sixteen had equipment given as the reason for failure. This was partly due to lack of motivation on the part of patients, particularly women, to overcome the difficulties in donning and wearing the

unit which might be overcome by redesign. It was also due to the frequent component failures which also were in part due to design rather than fabrication. If we ignore these patients, some of whom would have succeeded and some failed if there had been no equipment problems, there were 18 successes to 11 failures, a ratio of 1.63:1. A detailed report on causes of equipment failure found at servicing was supplied by Medtronic, Inc. Although only 16 failed because of equipment during the program, it is known that some have abandoned it since for this reason. Even successful patients and those who failed for medical reasons had much frustration from this.

Participants were specifically asked to look for the phenomenon of carryover. It was frequently seen as lasting for short periods but never significantly long enough for clinical use in this series.

The extremes of age ranged from 12 years to 71 years with an average age of 44.4 years. There was no significant difference in the average age from the various centers.

The number of patients fully documented is too small to reach valid conclusions on some aspects. Larger numbers might have shown less sex discrepancy, have pin-pointed etiological factors, or demonstrated clearly the role of hand dominance. It is considered that they were adequate to make valid the following conclusions:

1. That functional electrical stimulation using surface electrodes can be used as an orthotic device in the activities of daily life.

2. That for selected patients it may be better than available mechanical devices or other treatment.

3. That a figure of 30% use is excessive for the total hemiplegic population of the U.S.A., but might represent the percentage of those capable of wearing and needing an orthosis.

4. That the Ljubljana Functional Electrical Brace as presented for evaluation is not yet suitable for distribution for general use.

5. That nevertheless functional electrical stimulation of the peroneal nerve by surface electrodes promises to be an improved method for many patients.

The following recommendation is therefore made:

That there be further development of such devices to improve the design so that they may be acceptable to patients.

To serve as guidelines for such development, those engaged in this evaluation suggest the specifications on the following pages.

PART VI. SPECIFICATIONS OF MINIMUM REQUIREMENTS SURFACE ELECTRODE FUNCTIONAL ELECTRICAL ANKLE-FOOT ORTHOSIS

1.0 *Introduction*

As the prime users of the device will be hemiplegics, it must be designed for one-handed management in all phases of use, e.g., donning, operation, and maintenance.

2.0 *Component Specifications*

2.1 *Stimulator*

2.1.1 *Parameters*

2.1.1.1 The output voltage should be patient adjustable from 10 to 60 volts.

2.1.1.2 The pulse width should be fixed at 0.5 $\pm$ 0.2 milliseconds. Variable pulse width might be considered for a further development.

2.1.1.3 Frequency should be therapist adjustable from 20 to 50 Hz.

2.1.1.4 Stimulation time should be swing phase cadence controlled, with a maximum of 2.0 seconds with a heel switch override. If a therapist adjustable pulse train is retained it should be adjustable from 0.25 to 1.5 seconds with a heel switch override.

2.1.2 *Stimulator Design Criteria*

2.1.2.1 The dimensions shall be less than 13cm x 7cm x 4cm.

2.1.2.2 Weight shall be less than 200 grams.

2.1.2.3 The battery should be a conventional 9V transistor-radio battery with a minimum

life in normal use of two weeks. If rechargeable batteries are retained the charger circuit must be redesigned. Batteries must operate between 0° and 50°C and store between -20° and 60°C.

2.1.2.4 All variable controls should have markings to enable restoration of any given setting.

2.1.2.5 The patient-operated on/off switch and output controls should be designed as an integral unit so that inadvertent stimulation at maximum output is obviated. Slight tapping or brushing against the clothing must not change the amplitude setting.

2.2 *Heel Switch*

2.2.1 *Design*

2.2.1.1 The heel switch should be incorporated in an insole which can be used for either right or left foot and be trimmable to fit at least three sizes of shoe.

2.2.2 *Specifications*

2.2.2.1 Should have sealed tape switch with a surface diameter of at least 4cm.

2.2.3 *Heel Switch Cable*

Consideration must be given to the use of a radio link to replace this. If the cable is retained certain criteria are necessary.

2.2.3.1 The union of the cable to the heel switch at the insole needs improving.

2.2.3.2 The 3-prong connector in the cable should have positive locking.

2.2.3.3. A less flexible cable should be considered to overcome entanglement. Enclosure in a polyethylene tube has been tried.

2.3 *Electrode System*

2.3.1 *Design Criteria*

2.3.1.1 Electrodes should give at least three months' service.

2.3.1.2 Electrode dimensions should have a minimum effective surface area of eight square cm.

2.3.1.3 Electrodes must be flexible to conform to the body contours.

2.3.1.4 Additional contact materials. Conducting materials are currently available which can be used dry, wetted with tap water, or with gel. *The relative merits would need study.*

2.3.1.5 Improved methods of fixing the electrodes so that they do not shift in use are required.

2.3.1.6 The electrode cable requires modification as indicated for the heel switch.

PART VII. AN ASSESSMENT OF THE PROTOCOL

The Committee on Prosthetics Research and Development, from its inception, has been concerned with the conduct and evaluation of fundamental research, development, and clinical application programs. It has a Subcommittee on Evaluation which has over the years gained a body of experience. The Subcommittee on Fundamental Studies has set up a task force to examine the standardization of research data where possible so that comparative studies can be made. It has been in being 2½ years and has yet to report, which is in itself a measure of the difficulties of the task.

Each clinical evaluation program has hitherto been conducted *de novo* on an *ad hoc* basis. The relations between the conduct of one program and another has been based on the memory of past experience rather than planned. Consideration is now being given to the study of clinical evaluation techniques and the possibility of having some standardized data on motor function in both the upper and lower limb so that valid comparisons between varied studies can be made. With this in mind, a critical eye has been cast at the protocol used in this study.

In fundamental research or development studies, the volume of effort at any one time can be controlled. The hours involved and numbers and types of personnel are assessed, and any additional professional or secretarial help are estimated and paid.

Clinical evaluation is of two types, one retrospective, the other is a field trial to establish suitability for routine clinical use.

Retrospective clinical evaluations are largely reviews of past clinical material. Like fundamental research and development the volume can be estimated and the flow controlled. Although it may

be an assessment of clinical material, it often need not be conducted in a clinical situation. Time and personnel can be allotted on a regular basis.

Clinical evaluations of new treatments cannot be so arranged. They have to be made in a clinical atmosphere by the clinic team. Three or four suitable and willing candidates may present in one week and then no more for weeks. It is impractical to engage additional professional or secretarial aid. The burden of the additional work must fall on the shoulders of the clinic team. This would be of no consequence if it was only filling in idle hours, but those teams interested in helping in evaluation are necessarily centers of merit and consequently are usually heavily committed. It should, therefore, be the object in drawing up the procedures to keep the burden as light as possible, commensurate with obtaining the necessary evaluation. In general it can be said that because they are clinicians the physical work of applying the treatment and examining the patients is well tolerated. It is the added documentation which is often resented and poorly done. Much of the information has to be recorded in the hospitals' own records but because each hospital has its own method of record keeping, protocols need to have a form common to every center which will then differ in detail from the hospitals. Data should therefore preferably be recorded by machine. These records can then be analyzed by others at leisure. Such data-recording machines should be either standard hospital equipment, or low-cost equipment likely to be of continued daily clinical use.

Clinical evaluation can be done on a purely empirical treatment. The evaluation is not concerned with the mode of action or rationale which are part of fundamental and development studies. The opportunity of making such studies during a clinical evaluation is desirable and the clinic team should be encouraged to do so. They are not, however, part of the clinical evaluation and should not be

written into the protocol. Each team should be encouraged to pursue such added research in their own way. It may often be a suitable addition to a research project which is already funded.

Clinical evaluation of a new treatment is concerned with the following queries:

1. Does it work clinically?
2. Does it work better than other available treatments?
3. For what patients?
4. Does it have added effects which are beneficial?
5. Does it have added effects which are harmful?
6. Is it durable?
7. Will patients accept it?
8. Cost effectiveness?

It cannot be said that the protocol produced answers to all these questions but is examined here in detail to see where it succeeded and where it failed.

At the Orientation Session held at Texas Institute for Rehabilitation and Research, Houston, April 19-21, 1971, some time was given to developing a protocol which was the consensus of all the participants at the meeting. It resulted in a protocol which was quite unworkable. The documentation was too extensive for the clinic to record, too detailed if it had been recorded for analysis, much too subjective to be considered scientific, and much was concerned with research and development. The protocol reviewed here was developed in October 1971 somewhat hurriedly, because of the urgent need for a workable protocol. This experience--and other similar experiences--would indicate that evaluation needs some expertise. It is suggested that the Subcommittee on Evaluation or its delegates should develop protocols, after consultation with the developers, designed to establish the criteria listed above. They should then consult with the clinics they propose to invite to take part in the

program and make any adjustments to the protocol deemed desirable. The clinics should then be asked to furnish evidence of an adequate load of suitable patients and personnel. In this study all clinics had difficulty in finding enough patients. There are many suitable patients to be seen walking the streets of our big cities, but, perhaps because they are walking the street, they were not to be found in the clinics. It is understandable that the stroke patient services invited to partake thought they would have no difficulty in finding patients. In retrospect, it might have been better to have had a count of the numbers seen in the previous year. The relative paucity of suitable patients actually attending might then have been discovered and other clinics have been added to obtain the desired number of patients in the study. Such a census might also have alerted the clinics to the real state and have obviated some frustration.

Frustration was unfortunately a key word in this evaluation. The clinic team left the orientation session at Houston in April fired with enthusiasm. There was delay in getting the devices--and later in getting spare parts--and the devices after arrival in the United States needed considerable attention before they could be delivered. The first devices only became available in late October 1971, and some clinics received none until mid-November. Such delays, combined with the original unworkable protocol, can blunt enthusiasm and it is to the credit of the clinics that they maintained their morale.

It is suggested therefore that, although potential evaluators should be approached early in the project, a full Orientation Session should not be held until all the documentation and additional data-recording machines are available. Where the treatment needs special materials--whether devices or drugs--supplies should also be available for uninterrupted conduct of the assessment by the evaluating teams.

The criteria laid down in Part A of the protocol for patient selection proved remarkably good. All patients who had any major deviation, or more than one minor deviation from these criteria, failed. As suggested above a numerical assessment before beginning the program of patients meeting the criteria might have been useful.

Part B is a form which is necessary for the protection of the patient in that it acknowledges a basic human right to know that the treatment one is receiving is experimental and is given with consent, and for the protection of the clinic team in that the patient has approved. However, in the present state of litigation, it might be desirable to put in precise, albeit lay, terms the nature of the treatment, its rationale, and known potential difficulties as well as advantages so that the patient could not claim that it had not been fully explained.

Part C indicates the intended extent of the trial. In the first protocol it was intended that alternate patients only would have a trial so that there would be a control group. However, partly because there is considerable variation from one patient to another, but largely because it was evident that patients were not plentiful, it was decided to eliminate the control group--it being argued that the whole past experience formed a control.

Part D is concerned with data collection. The first form is the Technical Analysis Form developed for the American Academy of Orthopaedic Surgeons to which was added some supplementary data on hand dominance and gross analysis of certain sensory losses.

The Technical Analysis Form initially proved difficult. It is formidable in appearance and, in some aspects of fundamental neurological studies, is inadequate. It is, however, becoming more widely used in many studies and with familiarity becomes less formidable. It is nationwide and therefore should become familiar in all hospitals engaged in this type of investigation. The CPRD supplement proved

useful in that hand dominance does seem to have some relevance with which, as might be expected, goes aphasia. Sight and hearing did not appear to be significant.

The functional Gait Performance Form, D 2, was intended to give objective data which would establish whether the patient had improved or not. The first part of this form asks for a record of the time taken to walk 50 feet at a comfortable rate in seconds. Comfortable rate has been shown to be the least energy-consuming in a number of gait studies. Unfortunately, the energy expenditure curves have considerable areas on either side of the absolute minimum which allow variation of gait with little alteration of the energy expenditure. Patients who accept experimental treatment are hopeful of improvement and usually like to please the physician. They are therefore liable subconsciously to walk more slowly before treatment and faster after treatment, with little added energy expenditure. This test and others depending on velocity are liable to give results which are dependent on the wish fulfillment of the patient. Velocity, however estimated, is probably no valid estimate of improvement. Better would be an estimate of energy expenditure, or possibly some of the records on stress. Unfortunately, energy-expenditure methods known to the CPRD staff are cumbersome, and mostly with a high degree of experimental inaccuracy. They are not suitable for use in a clinical situation. If methods of such estimates are not in fact available it seems desirable for many reasons that methods of making such estimates reliably in a clinic should be developed.

The next part of this form requires an estimate of the time taken following a turn through 180 degrees. This test was intended to show whether lack of balance was any factor. In reality there are simpler methods of establishing a patient's sense of balance. No patient in whom balance was a serious problem should have been included in the program so this part of the gait analysis was redundant. Both the first and second part included information on the performance times without a standard orthosis, and with (if worn) the

Ljubljana device not stimulating and stimulating. Fortunately, this was an area in which the data, for the reasons given, would have been of little use, and if fully recorded would have been beyond the possibility of analysis. The stride length and stance and swing phase records were desirable but because the methods of recording them were very different the results were too variable to be valid. In a current program evaluating a similar implanted device, a system using electrical switches on the heel, first and fifth metatarsal heads and toes, developed by Dr. Jaquelin Perry in the kinesiology laboratory at Rancho, is being used to give uniform data of all these forces. It is probable that after experience the system may be altered but at present it gives a record which can be analyzed at leisure which gives velocity, stance and swing phase, stride length, and the pattern of foot placement. Such a system needs the least documentation by the clinic staff while not excluding them from seeing the results.

D 3 asks for a maintenance record of the device. Unfortunately, although asked not to do so, clinic teams, most of whom were technically capable of doing so, made some local repairs. All technical failures should be sent to and be examined by a central agency for examination, record, and repair. This implies that a servicing agency providing more service than should be necessary in normal service must be established if a true record of equipment failure is to be kept. The records kept in this evaluation are in fact favorable because of local repairs due to an inadequate spare-part backup system.

D4, the Evaluation Questionnaire, was perhaps the most useful document in the questionnaire. Although each questionnaire is itself largely subjective, in aggregate the answers become objective and many of the relevant answers used in the analysis were derived from this questionnaire. It was probably excessively long for the purpose in hand. However, it puts the onus of completion to a large extent onto the patient and family who, as they have only to complete it once, will usually comply. It provided the essential answers as to whether the patient will use it.

The protocol had, therefore, many defects. What did it achieve in relation to the objectives of clinical evaluation postulated above?

1. Does it work clinically?

The program established to the satisfaction of the assessors that Functional Electrical Stimulation in stroke patients to overcome some degrees of equinovarus deformity could be used in the activities of daily life.

2. Does it work better than other available treatments?

This protocol made no attempt to make this assessment. A record was kept of previous orthoses but no true record was kept, nor was it practical to do so, of alternative treatments.

The possible alternatives involve numerous surgical procedures, the use of drugs, phenol and alcohol injections, other improved mechanical orthoses, even acupuncture, all of which might need consideration. Comparison on this scale needs a very large number of patients, standardized data recording, and is probably better conducted as a retrospective survey after some period of clinical acceptance.

3. For what patients?

The criteria laid down in the protocol proved satisfactory, for the failure rate among those who did not meet the criteria showed that they were substantially correct. However, those suitable certainly are not as numerous in relation to the total stroke population as in Yugoslavia. This is almost certainly due to a different age and etiological factors. However, if the estimate of 2,000,000 stroke patients, given in the PHS Publication No. 1427 (revised 1971), is correct, 5% benefiting is still 100,000 patients.

4. Does it have added effects which are beneficial?

This study did not establish some of the beneficial effects others have claimed but the results confirmed rather than dis-

proved them. Many of the patients who had previously used a conventional mechanical orthosis preferred Functional Electrical Stimulation. Their preferences varied from better cosmesis, better function, to better proprioception. For statistical analysis a larger sample is desirable. Carry-over, the continuance of improvement after the cessation of stimulus, was established but not in this study of clinical significance.

5. Does it have added effects which are harmful?

The developers and evaluators were conscious of the possible adverse effects of the use of these devices. Before the program was started electrical safety was established. However, despite the experience elsewhere, it had been suggested that it might increase spasticity. This was not so. It was also anticipated that there might be skin problems arising. There were none significant. It had been thought that there might have been electrical burns, but there were only some cases of mild erythema.

6. Is it durable?

The report on the component failures shows that the device as submitted for trial was not sufficiently durable.

7. Will patients accept it?

Although the outcome of this evaluation was to recommend that the device as submitted was not suitable for general use and needs redesign, this assessment showed that some patients, despite its disadvantages, are willing to accept it.

8. Cost effectiveness.

This is an aspect of treatment which is always difficult or impossible to assess. The actual cost of treatment may be offset by less hospital time, earlier return to employment, or even to better employment, so that initial cost may be more than absorbed by the lower cost of care or even that the patient becomes a taxpayer. As the circuitry is little or no more difficult than that of commercial

transistor radios, it would seem that with a potential market of 100,000 and a yearly intake of 20,000 devices, they could be produced at a cost which would be comparable with currently available mechanical orthoses.

The protocol was unnecessarily complex. It demanded written records which could have been better obtained from machines. Nevertheless, it produced valid results.

MEDTRONIC, INC.
MINNEAPOLIS, MINNESOTA 55418

We have completed a visual inspection and electrical check on seven units and make the following recommendations:

Visual Inspection - The potential problems at this time seem to be divided into four areas:

1. Soldering of Components - The soldering workmanship in some cases is marginal. Also the lead wires have not been tinned causing strands to break.

2. Potential shorting problems - Transistors (TS-3 and TS-6) are too close to other components and the transformer leads should be insulated.

3. Component leads - All component leads are bent too close to the body resulting in added stress on the components.

4. Connectors - The white plastic three prong connectors attaching the electrode and heel switch to the stimulator connector are very easily pulled apart.

We will touch up the bad solder joints and insulate or move components that are in close proximity with each other. The bending of the component leads cannot be rectified at this time. Some attention might be directed towards a fastener on the plastic connector to eliminate inadvertent unplugging.

Electrical Checks - We have written a preliminary acceptance sheet for the stimulator and battery charger based on specifications listed in the Yugoslavian literature, V.A. proposed batch inspection procedure and our own knowledge of the stimulation levels required. As I pointed out to you, we are checking for output amplitude stimulation period and repetition rate potentiometer adjustment range in Section 4 of the procedure. We feel that the maximum amplitude

APPENDIX A-2

(50-60 V peak) minimum stimulation period (0.20 to 0.30 sec) and minimum repetition rate (27-33 hz) are probably the most important guidelines to check for at this time.

APPENDIX B

EXPERIMENT OF THE WARSAW SCHOOL OF MEDICINE REHABILITATION DEPARTMENT WITH APPLICATION OF THE LFEPB IN THE REHABILITATION OF HEMIPLEGIC PATIENTS

Stimulation by the method, and by means of the apparatus developed at the Zavod za Rehabilitacijo Invalidow, Ljubljana, was applied in 19 patients (Table 1).

Stimulated in all patients was the nervus peroneus and nervus radialis. The functional condition of the patients was controlled by the following methods:

1. clinically
2. psychologically
3. electromyographically
4. basographically
5. by means of photography.

The clinical examination consisted in measurement of the range of active and passive movements, measurement of superficial and deep sensation within the paralysed limb, and measurement of walking speed over 50 meters. Also estimated was the degree in which the patient was able to put the stimulation apparatus on and take it off without help.

The psychological examination involved, first of all, the acceptance of the LFEPB method, and the accuracy of the stimulation performed at home. Also registered was the opinion of patients on the improvement in the gait function, and function of the hand.

ELECTROMYOGRAPHIC EXAMINATION

The bioelectric activity of the tibialis anterior, triceps surae, and rectus femoris was registered by means of surface electrodes. It was recorded at active and passive movements of the foot, and during walking.

Registered in the upper limb was bioelectric activity of flexors and extensors of the hand and fingers, and of the biceps

brachii, namely, at active and passive flexion and extension of the hand and fingers, and at clenching of the fist.

Basographic measurements were performed at a station consisting of two metal plates, each 350 cm long and 20 cm wide, mounted on the laboratory floor, and resting on tensometers. Measured was the pressure of the feet on the floor, and this was registered by means of a polygraph in the form of curves. Calculated on their basis was the duration of the stance and swing phases of both limbs, the time of the double stance, and the degree of release of the limb at walking with a stick. Measurements were performed once a week during the patient's hospitalization, and later at every control examination.

Photographic documentation consisted of taking photographs during the patient's ambulation, at the swing phase of the paralysed limb, with stimulator on and off. Electromyographic examinations and the photographic documentation were made at the moment of admission of the patient for treatment, and then after 4 and 8 weeks, and after 3, 6 and 12 months.

RESULTS

As can be seen in Table 1, three patients died of cardiac infarcts; in three cases the application of LFEPB was discontinued: in two of them because of progressing hyperextension of the knee, and in the third, due to psychasthenia. In one case the observation time covered more than 12 months. The patient, B.J. (male), aged 42, twelve years earlier suffered cerebral shock, the second one occurred in 1971. Application of stimulation started 7 months after the second shock. The preliminary examination showed inefficient gait with a stick, foot drooping with tendency towards spastic positioning in equinovarus position; hand bent in the wrist, fingers bent, thumb within the fist. At the present moment the patient walks efficiently, rather fast, using a stick for longer distances. The proper positioning of the foot was obtained by means of a special boot with a single upright brace with a spring. He cannot walk in regular footwear due to spastic position of

the foot (equinovarus position). Spasticity with the previous brace is more pronounced now than early in the treatment period, whereas the gait with stimulator, even in a regular shoe, is more or less correct, with no equinovarus spastic position of the foot. There is a trace of active extension movement in the hand. The patient uses it as his auxiliary hand. No increase in spasticity was found. Considering the patient's acceptant attitude towards the applied treatment, stimulation has been extended for the next 6 months.

The electromyographic examination revealed stepped-up voluntary activity in the tibialis anterior. Passive movements produce a higher reaction to extension in the tibialis anterior and triceps surae than was the case before. During walking, both at the initial examination and at control examinations, phase activity of the tibialis anterior was observed. As per our assessment, this case does not provide any base for estimation of efficacy of treatment by the LFEPB method.

In the other patients, in whom the period of observation was from 1 month to 7 months, the following was observed:

1. Clinical condition: appearance of or improvement in the active dorsal foot flexion movement. The gait is more normal. No dragging of the paralysed limb to the healthy one is observed, but it swings forward which causes alternate gait.

As regards the hand, the return of active extension of wrist and fingers was not observed.

The gait of these patients improved, both in elegance and speed.

2. The psychological condition of the patients improved. This improvement is expressed by a greater engagement in the program of treatment by movement, and by a stepped-up overall activity. All patients don the electrodes themselves, with the knee support, and then connect the wires. They also remove the appliance without help.

3. In the electromyographic picture, as early as after 4 or 5 weeks of stimulation, higher bioelectric activity of the tibialis anterior is observed during active dorsal foot flexion. At walking, the tibialis anterior is active by phases, not continuously.

4. The basographic examination demonstrated extension of the shortened stance phase of the paralysed extremity.

At walking without stimulation, the spastic dropping of the foot continues. Some of the patients use an elastic band to prevent the foot from dropping.

The Konstancin Rehabilitation Institute considers the application of the LFEPB method advisable. The cases previously qualified for surgery (muscle transplantation and fixation of foot joints) are now usually qualified for treatment by functional electrostimulation.

As I, personally, approve the LFEPB method, inasmuch as it is physiological, I suggest that neurologists be acquainted with it. The dissemination of this method--which, in Poland, arouses increasing interest--makes it necessary to have a larger number of stimulators available.

At the Konstancin Institute of Rehabilitation the Ljubljana stimulators are also used in treatment of paraplegics at the acute stage. Patients with tetraplegia in condition of spinal-cord shock with areflexia receive sequential stimulation of the nervus femoralis and nervus tibialis of one limb, the other one being treated as the control limb. Theoretically, it seems possible to pave the way by this method to extension reflexes.

TECHNICAL REMARKS ON LFEPB

The stimulation apparatus is a unit easy to handle, and patients are willing to use it. The experiment conducted and the observations of our material of patients over more than 12 months confirmed the high reliability of both stimulator and feeding appliance. There has been some trouble only with the wiring connecting the heel contact

and the electrode with the stimulator, and the electrodes themselves. The most frequently occurring damage was disconnection of the wiring from the contacts in the boot insert. As regards electrodes, our objections are: 1) corrosion sets in, causing increase in their resistance. The result was that, in certain instances, the stimulator operated with the pulse value regulation knob set up at nearly maximum value. It happened sometimes that an adequate foot movement effect was impossible to obtain as the impulse amplitude was insufficient. In these instances we were forced to add saline to the electrodes which, in turn, stepped up the corrosion process. 2) The short life of the electrodes made it necessary to apply the spare ones and, at this moment, we need new electrodes for all the stimulators we have (eleven in all).

Another difficulty was the feed source, namely, the nickel-cadmium battery. After a few months its capacity seemed exhausted and, despite charging it for a dozen or so hours, the energy stored in it sufficed only for from a few to about a dozen minutes of normal operation of the apparatus. After that the amplitude of stimulation impulses decreased, and the apparatus had to be recharged again. The elimination of the deposit, and careful cleaning of every battery segment in the units in which this was feasible at all produced a good effect. We had to do it for the batteries available in Poland have different dimensions, and their use would necessitate certain structural changes within the stimulator system.

Table 1. Information Relating to Patients

a.	Total hemiplegic population	40
b.	Total suitable for FES	20
c.	Percent of b. to a.	50%
	Total number in program	19
	Total using A.D.L.	13
	In training	9
	Failures	3

APPENDIX B - 6

Table 2. Causes of Failure

PATIENT	Physical	2 (3 dead)
	Psychological	1
TEAM INEXPERTISE		-
DEVICE	Switch	-
	Cable assembly	-
	Electrode placing	-
	Electrode suspension	-
	Stimulus painful	-
	Stimulus none	-

Table 3. Information re Device

SWITCH	Operating	s
	Durability	ns
CABLE	Durability	ns
	Donning	s
	Maintaining Position	s
	Cosmesis	s
ELECTRODES	Durability	ns
	Donning	s
	Maintaining Position	s
STIMULATOR	Donning	s
	Operating	s
PARAMETER	Pulse width	s
	Duration	s
	Amplitude	s
	Frequency	s

This form will be completed at the meeting on an "all or nothing" basis.

Each will be either satisfactory (s) or not satisfactory (ns). It is assumed that many items adequate for use could be improved. They will be marked "s." The purpose is to identify items which are unsatisfactory and must be improved.

APPENDIX C

THE EVALUATION OF THE LJUBLJANA FUNCTIONAL ELECTRONIC PERONEAL BRACE

Gornicze Centrum Rehabilitags Seczniczej i Zawodowej
Repty seaskie Poland

In the rehabilitation center in Repty the LFEPB was applied in patients who met in full extent the criteria demanded in the instructions to clinics participating in the CPRD clinical study.

The patients had been examined also according to the instructions. The observations and the results we had obtained were recorded on Forms FEPB 1-7. Some data from those forms we had transferred to the attached Tables 4 through 7. All patients have been trained at least 4 weeks in the center. When they had overcome all problems in independent use of the brace, they were released from the center and were assessed at the demanded period of 3-6-12 months.

In Table 4 are collected the data about sex, age, diagnosis, time of fitting, duration of the lesion and subjective and objective improvement of the gait. Among the treated patients were 3 women and 7 men--the ages were between 30-58, the average 41.7. This was a selected group. We excluded older persons with advanced arteriosclerosis and cardiovascular complications, which make the larger part of the hemiplegic population. Details about major impairment and the education of the patients are given in Tables 5 and 6.

RESULTS

The results are given in Tables 4 and 7. Six patients use the brace for the activities of daily living. Two patients are in training (No. 3 and No. 9). Two patients had interrupted the training: Patient No. 5, a professor of medicine, because he was afraid that a longer stimulation might cause irreversible damage in the stimulated nerve. It was difficult to convince him that up to now experiences with functional electrical stimulation had shown that it did not damage the nerve. Patient No. 7 interrupted the use because he developed an infectious hepatitis. By the first assessment after 3 months we noted an improvement of the gait. The complications which occurred in 3 patients are shown in Table 7.

APPENDIX C - 2

Table 1. Information Relating to Patients

a.	Total hemiplegic population	150
b.	Total suitable for FES	15
c.	Percent of b. to a.	10%
	Total number in program	10
	Total using A.D.L.	6
	In training	2
	Failures	2

Table 2. Causes of Failure

PATIENT	Physical	1
	Psychological	1
TEAM INEXPERTISE		-
DEVICE	Switch	-
	Cable assembly	-
	Electrode placing	-
	Electrode suspension	-
	Stimulus painful	-
	Stimulus none	-

Table 3. Information re Device

SWITCH	Operating	s
	Durability	ns
CABLE	Durability	ns
	Donning	s
	Maintaining Position	ns
	Cosmesis	n
ELECTRODES	Durability	ns
	Donning	s
	Maintaining Position	ns
STIMULATOR	Donning	s
	Operating	s
PARAMETER	Pulse width	s
	Duration	s
	Amplitude	ns
	Frequency	s

This form will be completed at the meeting on an "all or nothing" basis.

Each will be either satisfactory (s) or not satisfactory (ns). It is assumed that many items adequate for use could be improved. They will be marked "s." The purpose is to identify items which are unsatisfactory and must be improved.

Table 4.

No.	I.L of Name	Sex	Age	Diagnosis	Months from Onset of Hemiplegia to applying of LFEPB	Duration of Observation (months)	Improvement of Gait	
							Patient	Observer
1	K.E.	F	38	Arterial hypertension Hemiplegia dex.	8	13	+++	++
2	K.J.	F	34	Arterial hypertension Hemiplegia sin.	24	16	+++	+++
3	H.A.	F	42	Mitral stenosis cerebral embolus Hemiplegia sin.	7	1	+	+
4	Z.E.	M	34	Cerebral tumor /astrocytoma/ Hemiplegia sin.	59	12	+++	++
5	R.W.	M	57	Mitral stenosis Cerebral embolus after cardioversion Hemiplegia dex.	44	11	++	+
6	N.J.	M	41	Arterial hypertension Hemiplegia dex.	35	7	+++	++
7	K.J.	M	58	Atherosclerosis Occlusive cerebral disease Hemiplegia sin.	5	7	++	
8	CH.L	M	46	Arterial Hypertension Hemiplegia dex.	41	8	+++	+
9	P.M.	M	37	Arterial Hypertension Hemiplegia	37	1	+++	++
10	Z.R.	M	30	Craniocerebral trauma Hemiplegia dex.	45	6	++	+++

Table 5. Major Impairment

No.	Bone Joint	Sensation	Skin	Vascular	Speech	Central Integration	Gait
1	normal	mild proprio-ceptive loss /ankle, toes/	normal	normal	Expressive aphasia	No impairment	lateral flexion hip: externally rotated knee: hyperextended ankle: in varus
2	normal	mild proprio-ceptive loss /ankle, toes/	normal	normal	normal	no impairment	mild lateral flexion ankle: in varus toes: flexed
3	normal	proprioceptive loss /ankle & toes/	normal	normal	normal	recent memory deficit	lateral flexion hip: externally rotated ankle: in varus
4	normal	mild proprio-ceptive loss /ankle, toes/	normal	normal	normal	no impairment	lateral flexion hip: externally rotated ankle: in varus
5	normal	normal	normal	normal	dysarthria	no impairment	forward at hip knee: hyperextended ankle: in varus toes: flexed
6	normal	mild proprio-ceptive loss /ankle, toes/	normal	normal	expressive aphasia	no impairment	lateral flexion ankle: in varus
7	normal	normal	normal	normal	normal	no impairment	lateral flexion hip: externally rotated knee: hyperextended ankle: in varus
8	normal	mild proprio-ceptive loss /ankle, toes/	normal	normal	expressive aphasia	no impairment	forward at hip hip: externally rotated knee: hyperextended ankle: in varus
9	normal	mild proprio-ceptive loss /ankle, toes/	normal	normal	normal	no impairment	lateral flexion hip: externally rotated ankle: in varus
10	contracture of Achilles tendon	mild proprio-ceptive loss /ankle, toes/	normal	normal	normal	recent memory deficit	lateral flexion hip: externally rotated ankle: in varus

Table 6.

No.	Educational Level	Living Condition		Occupation		
		City inhabitants	Country	Before Disability	Present Occupation	
1	High school	200,000		executive	runs the house	
2	High school	200,000		executive	runs the house	
3	7th grade	200,000		runs the house	under observation	
4	High school		1,000	turner	technician	drives a bicycle
5	University	140,000		professor of medicine	unemployed	
6	High school	60,000		engineer	engineer	
7	High school	50,000		engineer	engineer	
8	University	500,000		doctor of medicine	half-time employed	drives a car
9	High school	140,000		a director of a "house of culture" at a coal mine	librarian	
10	7th grade	150,000		skilled worker	unemployed	

APPENDIX C - 6

Table 7. Patient Information Questionnaire

No.	Understanding the purpose of the brace	To what extent is it possible to find the exact site for stimulation of the nerve	To what extent is the walking ability improved by the brace	Found the use safe or dangerous	The degree to which the wearing of the brace was felt comfortable on social occasions	Improvement	Complications
1	1	4	1	1	2	The muscles are stronger The knee better stabilised The gait more efficient The drop foot less marked also after cessation of stimulation	After 2-3 hours of using the brace feels pain in the shank which disappears within 20-30 minutes after cessation of stimulation
2	1	1	1	1	1	The gait was easier The drop foot less marked After cessation of stimulation some volitional movement appeared /dorsiflexion/	No complications
3	2	0	2	0	0	Immediate effects very good, a trace of volitional movement appeared /dorsiflexion/	
4	1	1	2	1	1	The gait was more efficient The drop foot less marked after the stimulation	After a longer use of the brace /2-3 hours every day/ has had an increased pinprick sensation
5	2	1	4	1	3	Better stabilisation of the knee The gait is easier No lasting effects	No complications
6	1	1	2	1	3	Diminishing of the hyperextension of the knee gait more efficient	No complications
7	1	0	2	1	0	Immediate effects very good After the stimulation a volitional movement appeared /dorsiflexion/	
8	1	4	0	2	1	The gait was easier but not more efficient The hyperextension of the knee joint less marked	After using the brace for longer than 2 hours, the leg got tired and the gait worse Next day it improved again
9	1	1	1	1	2	The immediate effects very good foot control of the dorsiflexion during walking	
10	1	1	2	1	2	The walk was easier	No complications

REPORT ON THE EVALUATION OF THE LJUBLJANA FEPB POZNAN, POLAND

Ten sets of the LFEPB were given for evaluation at the Institute for Orthopaedic Surgery and Rehabilitation, Academy of Medicine, Poznan, Poland.

Eight stimulators have been given to patients. Because one was given only four weeks ago and two patients did not come for final assessment, our experience will be reported on the basis of observations of five patients.

There were four patients with hemiplegia of different etiology (one embolus, two hypertension haemorrhage, one iatrogenic after arteriography) and one with a spastic hemiparesis as a result of C_5/C_6 fracture.

Their age ranged from 17 to 67 years; three patients are active professionally.

The LFEPB was supplied to the patients between 10 to 34 months after the onset of their injury, with the exception of the patient with the spinal-cord lesion who received the stimulator 12 years after the injury.

The observation time in the five patients was 11 to 14 months.

Potential subjects were screened in the outpatient department, and those who responded to the stimulation were admitted later to the hospital for two to four weeks of training. Follow-up examinations were done on an outpatient basis in three cases, while two patients were admitted for two to three days.

The team involved in the evaluation process consisted of two physical therapists, one electronics engineer, and one physician, all trained during the Seminar held in Bled in June 1971. We think that we obtained a sufficient amount of theoretical and practical training during that seminar to be able to carry out the evaluation program.

APPENDIX D-2

CLINICAL IMPRESSIONS

All of the five patients available for assessment are very much satisfied and they use their stimulators for five to eight hours each day. In one case we know that a patient refused to continue the stimulation, and he is one of the two who did not come for final evaluation.

As for the improvement of gait it was found that, after the stimulation was applied, our patients were able to cover the distance of 30 meters in 30% less time than without the unit. Those who walked with a stiff knee or on a bent knee improved to almost normal swing-through patterns. One patient told us that the stimulation provided him with a better posture while standing, because he was receiving a stimulus the moment he wanted to release his heel from the floor.

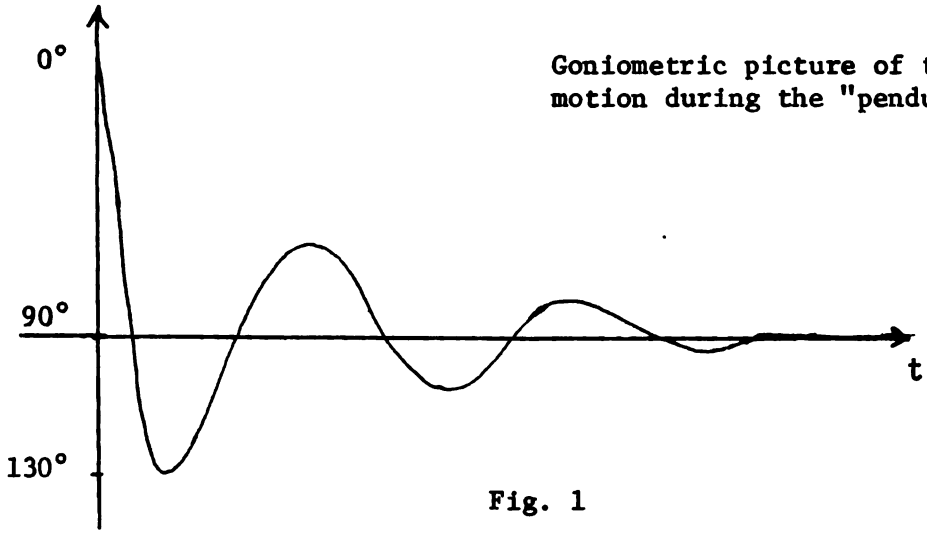
Because an independent program of evaluation of spastic patients was carried on at our Institute, we have used some of these techniques for comparative evaluation of our patients. These included a routine EMG study, a pendulum test, and a clonus test.

The pendulum test consisted of goniometric and electromyographic recording of the knee joint as it was allowed to bend freely from the 0° position. The damping effect of spastic quadriceps and hamstrings muscles was evaluated (Fig. 1).

Similarly the clonus test consisted of a mechanically induced clonus of the spastic foot and of observation of the forces involved in it by means of a strain gauge (Fig. 2).

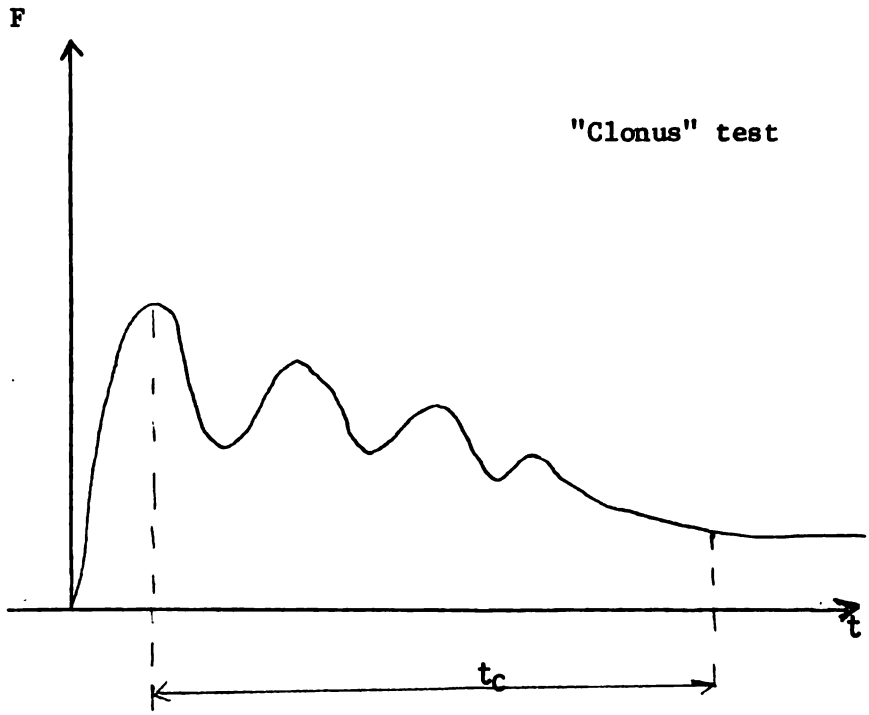
The above-mentioned tests showed in two of our patients a definite improvement. One patient showed mixed results (improvement only in the EMG pattern) and two patients showed no change.

In the spinal-cord-lesion patient we found some skin irritation in the area of the electrodes, but we never saw this among the patients with cerebral lesion.



Goniometric picture of the knee joint motion during the "pendulum test"

Fig. 1



"Clonus" test

Fig. 2

APPENDIX D-4

TECHNICAL PROBLEMS

The greatest problem we encountered was the breaking of the wires in different locations, but mostly at the entrance of the cable into the sole. Recently we have tried to improve this situation by putting a thin nylon string shorter than the wire itself between the sole and the three-pin connector and thus the breaking force is absorbed first by the nylon string.

Another problem was the corrosion of the electrodes which, combined with the relatively strong snap fastener, lead to mechanical damage of the electrodes. No studies were done as to the conducting properties of the corroded electrodes.

In three cases the heel contact broke and we think it was due to thinness of the inner sole used in worn shoes.

In general it is our belief that functional electrical stimulation is a physiological method with great future possibilities. The very system of the LFEPB we found to be already practical and acceptable by the majority of patients whom it is supposed to serve.

Table 1. Information Relating to Patients

a.	Total hemiplegic population	50/year	At the Institute for
b.	Total suitable for FES	12	Orthopaedic Surgery and
c.	Percent of b. to a.	18% - 20%	Rehabilitation, Poznan
	Total number in program	8	
	Total using A.D.L.	5	
	In training	1	
	Failures	2	

Table 2. Causes of Failure

PATIENT	Physical	-
	Psychological	2
TEAM INEXPERTISE		-
DEVICE	Switch	-
	Cable assembly	-
	Electrode placing	-
	Electrode suspension	-
	Stimulus painful	-
	Stimulus none	-

Table 3. Information re Device

SWITCH	Operating	s
	Durability	ns
CABLE	Durability	ns
	Donning	s
	Maintaining Position	s
	Cosmesis	s
ELECTRODES	Durability	ns
	Donning	s
	Maintaining Position	s
STIMULATOR	Donning	s
	Operating	s
PARAMETER	Pulse width	s
	Duration	s
	Amplitude	s
	Frequency	s

This form will be completed at the meeting on an "all or nothing" basis.

Each will be either satisfactory (s) or not satisfactory (ns). It is assumed that many items adequate for use could be improved. They will be marked "s." The purpose is to identify items which are unsatisfactory and must be improved.

APPENDIX E

REPORT ON THE EVALUATION OF THE LJUBLJANA PERONEAL ELECTRONIC BRACE CENTER FOR PROSTHETICS BELGRADE, YUGOSLAVIA

At the Seminar, which took place in Bled in June 1971, dedicated to the application of the Ljubljana Functional Peroneal Brace, the applicative and technical characteristics of this type of brace have been demonstrated in detail. At the same time, the need of establishing a certain number of study groups, provided with FEPB with the aim of participating in the evaluation procedure, has emerged.

One of such study groups has been established within the Center for Prosthetics in Belgrade.

At this Seminar, the Belgrade group was provided with ten FEPB in order to carry out the evaluation, according to criteria and scheme established on the part of the Social and Rehabilitation Service from Washington and the Ljubljana Study group.

For the reason of better continuation of the whole work, a team consisting of physicians, electroengineers and physiotherapists has been established, in order to carry out the selection of subjects convenient for the electrostimulation procedure as well as the whole clinician procedure, the training of patients in the use of brace, and to follow up in the anticipated term.

For that reason, besides already obtained questionnaires we have developed some additional forms for psychological and technical testing concerning not only the FEPB but the stimulators designed in our Laboratory in the course of the expired period.

Our work began in September 1971. From that time, until the end of October 1972, we examined 63 in and outpatients. Because the majority of the above-mentioned subjects have not met the requirements for participating in the Study group, we have selected only 15 patients corresponding more or less to the proposed conditions specified in the Forms (good physical condition with stabilized knee and hip joints with-

out prominent bone deformities, having the proper heel contact during the stance phase). Six of those patients have not agreed to participate in the evaluation procedure due to the insufficient motivation and adaptation to the present condition, as well as due to the transportation problem (far distance from the Center) during the training period. For all the above-mentioned reasons, we have been limited to carry out the evaluation procedure on the rest of the patients.

During the selection procedure, we have had a female patient with a foreign metal body in the shank and she could not participate in the study. As we all know, the presence of the foreign body would be one of the main contraindications in any electro procedure. To our opinion, this fact could be considered and included in the questionnaire as the additional criterion.

For the reason that we wanted to follow up the efficiency of various methods of treatment of the hemiplegics, we have tried to establish three basic groups. The first group was treated only with classic therapeutic exercises, the second with the combination of therapeutic exercises and the application of the stimulation, and the third group consisting of subjects with hemiparesis has been treated only with the peroneal brace. Having in mind that this report reflects only results of the evaluation of the Ljubljana FEPB, we are to present only the data about the third group, holding the right to reveal afterwards the parallel assessment and analysis of our work.

Out of ten obtained stimulators, one has undergone the destructive test procedures, while the remaining nine have been applied to the following cases:

Case No. 1 - K.H., 43 years old, administrative clerk, admitted to our Center with the following diagnosis: Left hemiparesis cerebrovascular accident. The onset occurred in July 1970. In the course of the rehabilitation procedure, the subject was trained to walk with the aid of a cane. When admitted, the external rotation of paretic extremity with circumduction while walking and pes equinovarus have

been noted. When standing, good heel contact with the floor was present. At the same time, there was a small mediolateral instability within the talocrural area. The function of upper limb has been diminished to a great extent. In spite of the emotional instability, the patient had a good motivation and has accepted the FEPB. During the checkout procedure, the main objection concerns the need for help while applying the brace, due to dysfunction of the upper limb and certain impatience of subject while carrying out the whole procedure himself.

Case No. 2 - P.V., 57-year-old economist, admitted to our Center as an outpatient, with the following diagnosis: right hemiparesis post croniatomy decompression for Tumor. In 1962, following the removal of the meningioma, the hemiparesis of the right side of the body occurred. During the rehabilitation procedure, which has been carried out several times, only the paresis of the left leg has persisted as the sequelae of the disease, while the function of the hand has been completely recovered. The subject has been admitted to our Center for the application of the FEPB. When admitted, besides the paresis of peroneal area and the varus position, there was not any other difficulty. The subject has accepted the FEPB. By the aid of stimulation, the satisfactory dorsiflexion and foot eversion, as well as the better stability while walking, have been achieved. By regular checkout, after one and six months and following one year, it has been noted that the patient has used the stimulator mainly at home and in the office (in the well-known environment), but not on social occasions (due to the difficulties in adjusting the electrodes when changing the body position, adjusting the intensity and the problem of location of the electronics into the pocket).

Case No. 3 - J.V., 59-year-old retired teacher, admitted to our Center with the diagnosis: left hemiparesis spastica cerebrovascular accident. The onset occurred at the end of 1966. Through the previous rehabilitation program she became capable of walking with a cane. When admitted, besides the mild muscle spasticity, minor circumduction

of paretic extremity and the varus position, there was not any other neurologic problem. When standing, there is good heel contact with the floor. The upper-limb function has been impaired to a great extent. The patient was fitted with the FEPB, and trained in its use. During the regular checkout following six months' use, the toe flexion has been noted in the course of stimulation and due to the use of the stimulator, and the special orthopedic shoes have been prescribed in order to enable her to apply the FEPB. At the last follow-up visit, it has been noted that the complete condition has been improved, although there was still the toe flexion, and within the interphalangeal joints, cellosity has been formed. When applying the stimulator, she does not need any help, even though it takes a lot of time and patience. She uses the stimulator mainly at home while working.

Case No. 4 - S.M., 20-year-old driver, admitted to our Center following a traffic accident in October 1971, with the following diagnosis: left hemiparesis. Immediately upon admission, due to the sequelae of the peroneal paralysis but without the contractures, bony deformities and the spasticity. The patient was involved in the Study group. He accepted the FEPB and was trained to walk without the cane.

He had not returned for the regular checkout, but had informed us that he was not using the brace any longer for the reason that he was able to walk without difficulties. He returned it by mail.

Case No. 5 - S.C., 53-year-old retired clerk, admitted to our Center as the outpatient with the following diagnosis: left hemiparesis after the CVA dated from 1960. Following a rehabilitation procedure in one institution, he was able to walk with the cane. The objective finding reveals the small external rotation of the paretic extremity with a mild muscle spasticity and a small degree of mediolateral instability of the ankle joint, as well as the varus position. The subject has accepted the stimulator. During the first checkout, the improvement of stability and coordination of the gait has been noted. Deviations have not been evident. Due to the aggravation of the cardio-

vascular state (myocardial infarction), he has not returned for the six-month checkout. He has come to the Center following his recovery and returned the brace. We have established that the over-all gait was more stable even without the brace and the cane, which he was using for psychological reasons only.

Case No. 6 - R.S., 63 years old, a retired cook, admitted to our Center as an outpatient with the following diagnosis: right hemiparesis due to thrombosis cerebral vessels, dated from March 1972. She had been previously treated in a rehabilitation institution, and was capable of walking with the cane. Referred to our Center for the application of the FEPB. The paretic leg, besides the small spasticity and the varus position, has not any other changes. When standing, there is a good heel contact with the floor. The right hand is paretic and functionally disordered. The subject has accepted FEPB in spite of the fact that she is psychologically unstable. At the first checkout, there was no change in the paretic extremity. She needs the time for selection of the proper site for the location of the electrodes, due to the paresis of the extremity. The main objection concerns the fact that when changing the position (standing up from the chair), she has to search again the proper site for the electrodes. Objectively, the gait is more stable.

Case No. 7 - M.K., 68 years old, retired person, admitted to our Center as an outpatient with the following diagnosis: right hemiparesis hypertension and diabetes mellitus. Apoplectic onset occurred in April 1972. She had been previously treated in a rehabilitation institute and is capable of walking with a cane. When walking, the only sequela is the paretic foot. The function of the hand has been improved. The subject has accepted the stimulator and she tolerates it very well. At the checkout, no changes of the paretic leg were evident.

Case No. 8 - L.B., 61-year-old housewife, admitted to our Center with the following diagnosis: right hemiparesis due to subarachnoids haemorrhage. The onset occurred in May 1972. She was treated in a rehabilitation institution and referred to our Center for the ap-

plication of the FEPB. At admission, the right leg was paretic in small external rotation and the varus position of the foot. When walking, there is the evident circumduction. The right hand is also paretic with damaged function. The subject has accepted the stimulator. The condition of the paretic extremity during the checkout has not changed. There is no objection concerning the brace. The application of the brace is somewhat difficult, due to the paretic hand.

Case No. 9 - T.S., 59 years old, retired clerk, admitted to our Center as an outpatient with the following diagnosis: right hemiparesis CVA occurred in July 1972. The patient was treated in a rehabilitation institution and referred to our Center for the application of the FEPB. When admitted, besides the right foot paresis no other changes were evident. The right hand was functional. The subject has accepted the brace. At the first checkout a small active motion of the paretic leg (dorsiflexion of foot) was noted. He was an active wearer of the brace. No objection to the FEPB.

DISCUSSION

Upon reviewing the patients with the applied peroneal brace, no differences could be noted regarding the sex but there were in respect to the age. The men belonged to the age group between 20 and 59, while females were between 59 and 68. In connection with the basic diagnosis, the greatest number of patients had the CVA (6), one case had subarachnoid hemorrhage, one with the head trauma, cerebral contusion, and one hemiparesis post-craniotomia decompressive due to Tumor. Concerning the duration of the disease and the beginning of the application of the stimulator, four subjects had had the lesion for more than one year duration (between one and nine years), and five other cases had the fresh lesion of about three to six months.

Due to the small number of the participants it is difficult to state anything about the different effects of the application of the brace in respect to sex, age and duration of disease, as well as about the basic etiological diagnosis. The better success had been noted

among the patients with the fresh lesions for the reason that there was not time for the development of the long term changes at the osteo-articular formation.

During the training period, nearly all the patients have stated that upon removing the brace they could walk much easier and felt paretic extremity as somewhat lighter. We have also noted that all the patients have been impressed by the first application of the brace for the reason that upon the effect of stimulation they are able to achieve the motion which they could not obtain voluntarily before.

In the course of the training period, two subjects (case 1 and 6), due to emotional instability and over-excitement, have lost patience and given up the application of the brace.

The training of the use of the FEPB was much easier with the in and outpatients mainly due to the transportation problem.

CONCLUSIONS

Based on 63 examined patients in the course of the evaluation procedure, the following could be concluded:

1. Following the precise criteria of the Form, only a very small number of patients have fulfilled completely all the requirements necessary for the application of the brace.

2. It is necessary to consider and eventually add certain criteria for the patients with foreign metal body in the extremity.

3. As treated patients there is a significant improvement as regards the gait stability, as well as the reduction of deviation when walking.

4. It has been also noted that the impaired upper-limb function has more frequently rejected the stimulator due to the difficulty when applying the stimulator with one hand. Those patients needed some help.

5. It is necessary to consider the possibility of locating the electronics in the pocket of the jacket or some other place on the side of the normal hand (the best solution is in the knee area or even at lower level) because the patients do not wish to use the brace on social occasions. They felt unpleasant when they had to turn on and off the "brace" located in the pocket of the trousers, for the reason that somebody could think they were behaving impolitely, i.e., they were scratching themselves.

6. The greatest problem of the whole system is that of electrodes, and it is even a greater problem than the stimulator itself.

The remarks of all patients concern the displacement of the electrodes when changing the body position (from sitting to standing).

7. The patients' remarks as regard the technical part have concerned the weakness in cable junction, very fast knee unit destruction, and the size of electronics location in the pocket of trousers.

8. It is necessary to carry out the complete technical evaluation of the FEPB, as we have already mentioned in the introduction of this report.

In view of the fact that a relatively small number of subjects have been involved in this evaluation, to our opinion, we have to direct our future work toward the investigation of differences in the effect of stimulation as regards the sex, age, basic diagnosis and duration of diseases, as well as to the comparative study in respect to already mentioned groups of patients.

APPENDIX F

REPORT ON THE EVALUATION OF THE LJUBLJANA FUNCTIONAL ELECTRONIC PERONEAL BRACE LJUBLJANA REHABILITATION INSTITUTE PORTOROZ, YUGOSLAVIA

The regular and complex treatment of hemiplegic patients in our Institute was initiated in 1967. The program of complex rehabilitation of these people was worked out. In the first year 52 subjects were admitted to the Rehabilitation Institute. On the basis of the experiences collected through the treatment of these first hemiplegic patients, we improved our therapy programs as well as our staff and other capacities. The number of patients admitted and treated at our Institute was increasing from year to year. In 1971 admitted were 201 hemiplegic subjects; 153 people were admitted for the first time.

Thirty-six hemiplegic people hospitalized at our Institute have been approximately constantly included into the program of complex rehabilitation. All the admitted patients are included into the program of training with FES as it has been utilized as the routine method together with other programs for the complex treatment of patients.

In the area of Ljubljana approximately 600 hemiplegic patients a year are registered, which represents about one-third of all hemiplegic persons in our Republic. Unfortunately we are not familiar with the exact situation in Slovenia as these people are registered in various health centers. If we presume these centers represent the remaining two-thirds we can come to the conclusion that the situation in our country does not strongly differ from that of the statistics in the world according to which there is one percent of subjects affiliated with hemiplegia.

Our Institute has been admitting people from the whole territory of Slovenia but persons from the region of Ljubljana prevail. Unfortunately we cannot admit all those who would like to be treated at our Institute. We are lacking corresponding staff and premises. Basic principles had to be determined according to which patients are selected and given priority over others.

APPENDIX F-2

Priority is generally given to younger people who are socially and professionally still active, if their prognosis is promising, if there is hope they can benefit from complex rehabilitation and be integrated into the normal environment again.

Then, admitted are also all those persons whose psychic and physical functions are preserved to such a degree that they are capable of collaborating in the program of complex rehabilitation.

On the basis of the above criteria about two-thirds of 1200 hemiplegic subjects are the candidates for successful rehabilitation. Owing to the above reasons about 13 percent are admitted to the Institute. Since 1969, when FES was included into our therapeutic programs, 412 hemiplegic persons have been treated of which 356 people have been fitted with the FEPB for either therapeutic reasons or for gait training. In 138 subjects the Ljubljana FEPB was applied as the orthotic device. They have been utilizing it at home now. One hundred forty-one subjects were given the conventional peroneal brace as the permanent aid.

On the basis of the systematic analysis of data collected through our work with these patients, our presumptions that approximately 30 percent of those having been admitted may utilize the Ljubljana FEPB have been confirmed.

According to the program of evaluation of the Ljubljana FEPB agreed upon during the Seminar in Bled 1971, systematical research was started in November 1971. We were utilizing the prescribed forms for the registration of our observations of hemiplegics included into the training.

The evaluation has been performed by Dr. Ruza Acimovic-Janezic as the researcher, and by two physical therapists. Thirty patients with the lapse of time from six weeks to eight years from onset of the disease were included into the evaluation training. Ten subjects were fitted with the Ljubljana FEPB as an orthotic device.

In the remaining 20 persons the FEPB could not or was not needed to be applied as the permanent device for the following reasons:

1. Eleven patients were not capable of using the device owing to severe forgetfulness, equilibrium disorders, sensory disorders, etc.

2. Three patients exhibited joint contractures despite the intensive physiotherapeutic programs.

3. Two subjects exhibited a strong psychic aversion toward the electrical current so that they were not in a position to make use of the device.

4. In four patients the first control showed the status improved to such a degree that the Ljubljana FEPB was not necessary any more as the permanent device but only during the gait training. Six months later the FEPB was not necessary either as the orthotic or therapeutic device.

The 11 patients under 1. were fitted with the conventional peroneal brace to make use of it permanently. In the group of 10 subjects utilizing the FEPB as the permanent device, three persons had utilized the conventional device. These three people cannot walk with the assistance of the conventional device any more since the Ljubljana FEPB has been completely incorporated into their present way of walking.

As mentioned before, we started with the evaluation in November 1971. In one person the FEPB could be applied after a couple of weeks, while in the last subject it could not be applied earlier than in February 1972 as it was first necessary to treat contractures of the joints.

Thus far two controls of the subjects fitted with the Ljubljana FEPB have been performed. The third one has just been carried on.

The first two controls show our indications and further procedures were justifiable since the persons are satisfied with the

application. The long-term utilization of the device usually requires adjustment of parameters, i.e.:

1. The increase of frequency of impulses in single stimuli
2. The decrease of voltage
3. The length of the stimulus does not change significantly even though it tends to change somewhat.

As for the very functioning of the device, no malfunctioning has been established. The only malfunction was a) the broken wire in the heel switch during the first control, and b) the broken wire in the knee contact at the second control.

The majority of persons complained about the plugs as they are extremely small and thus difficult to provide single contacts considering the patients' deficits in movements of the hand.

It would be of interest to note that in an early application of the FEPB, correction of the gait and posture in patients is achieved much earlier than in those with a long-lasting hemiplegia. In the former instance joint contractures are not yet developed, spasticity is not so strongly exhibited and the central scheme of the irregular posture and gait has not been fixed.

A much more detailed picture about the FEPB as an orthotic device will be obtained through a complex and detailed analysis of data from the prescribed forms, i.e., following the last control.

Finally, I should like to point out that we had some problems at the beginning of the evaluation as none of us charged with this duty attended the 1971 Seminar at Bled where methodology and instructions regarding the evaluation according to uniform criteria were explained. There were some difficulties while trying to clarify several items of the questionnaire. Despite the above obstacles we hope our work will be a success.