EVALUATION OF THE LJUBLJANA FUNCTIONAL ELECTRONIC PERONEAL BRACE

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The evaluation program was undertaken on behalf of and financed by the Scottish Home and Health Department. The project was conducted at the Dundee Limb Fitting Centre for a period of three years.
The team involved in the study, consisted of an orthopaedic surgeon, bioengineer and a physiotherapist with close cooperation of an independent neurologist.
Initially it was planned to evaluate two models of the brace namely the FEPA 8 and the FEPA 10, however, the FEPA 8 was discarded early in the project, because of technical unreliability and patient's discomfort.

In the absence of any formally documented stroke service the records of patients who had been treated for stroke in the main admitting hospital were examined by the project-physiotherapist. Selection was confined to those stroke patients who had responded to conventional treatment but still had a residual locomotor disability.
A letter was sent to all patients selected, requesting their participation.
Participating patients were subjected to a comprehensive assessment by the physiotherapist. A specially prepared document was used and information recorded under the following headings:

a. Full case history

Of particular importance is the interval between the onset and FES assessment, and details of the form of therapy already provided.

b. Definitive examination
Including sensation, proprioception, body-image, balance skin condition, etc.

c. Joint function
Including joint range of movement, muscle power (scoring 0-5, according to Daniels et al, 1956), spasm and clonus for both upper and lower limbs

d. Gait assessment
Indentified gait deviations exhibited by the patient were graded as either slight, moderate or extreme.

e. Motor function and co-ordination
Tests based on a series of simple tasks. The performance was graded from 0-5.

f. Stimulation
Stimulation parameters, electrode points and description of the foot movement were recorded.

g. Walking rate
For this test the patient was asked to walk 20 meters at a confortable speed.

On the basis of this examination a decision was made whether the patient would be accepted for the project.
The following factors would positively exclude the patient from participation:

a. Extreme sensory loss
b. Failure to establish communication with the patient
c. Negative stimulation test
d. Excessive musculo-skeletal changes
e. Patient non-ambulant.

All other patients were included for initial treatment.

After initial assessment the patient was referred to an independant neurologist for examination.

This test employed standard subjective neurological examination methods including reflexes, power, spasticity, arm and leg function and other body function i.e. hearing, vision and speech. The status of the patient was expressed as a score where the increased magnitude represented increased dysfunction.

When the patient commenced treatment with FES a video-tape recording was made of the patient's gait both with and without the use of the stimulator.
The gait pattern was analysed for deviations using the same subjective method employed at the initial assessment.

Training.
Patients were initially admitted to the project for a one week period of basic training, during which the patient was taught to apply and use the brace independently.
After this initial training a decision was made whether or not to continue treatment.
The criteria which were considered to disqualify the patient from further treatment were, lack of motivation and adverse response to stimulation.
Those patients who were selected for further training fell into two categories:

a. Those patients who were able to use the brace independently but who were unable to apply the brace, received daily out-patient treatment.
b. Those patients who could both apply and use the brace independently continued treatment at home while attending as an out-patient at weekly intervals.

Both categories of patients were recorded on video-tape for gait assessment at four weekly intervals.
Every patient received treatment for a minimum period of eight weeks after basic training. The decision to continue treatment thereafter was taken at four weekly assessments.

The decision to discontinue treatment was based principally on a judgement whether the response of the patient to the stimulation was clearly established.
When the patient had completed training the following aspects were re-assessed by the team:

a. Joint function
b. gait
c. motor function and co-ordination

A final video-tape recording was made of the patient's gait both with and without FES
The patient was referred again to the neurologist for final assessment using the same scoring system.

Results.

In the record search over a period of two years 988 stroke patients were discovered.

401 had died
474 were rejected for a number of reasons, that is domicile (too far out of the Dundee area), age, complete recovery and some because of physical and mental contra-indications, leaving
113 who were assessed.

Of the 113 assessed 63 patients were rejected for a variety of reasons for example:

Negative stimulation test
Extreme sensory loss
No dropfoot or walking problem, or
No dropfoot but a walking problem situated round hip and knee etc.

Leaving 50 patients deemed capable of completing trial. Of these 7 patients failed to complete the trial.

The time interval between the stroke and first assessment

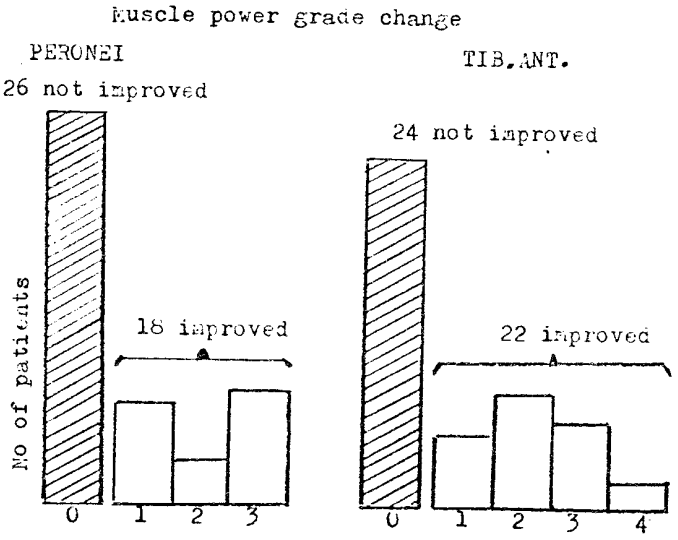
was as follows:

2 months in 3 cases,
3 months for 1 case,
up to 6 months in 8 cases,
6 months to 1 year for 8 cases,
1 year up to 2 years in 12 cases,
over 2 years up to 30 years for 16 cases.

16 patients had no time interval between physiotherapy and FES treatment, but 17 had an interval of more than 1 year.

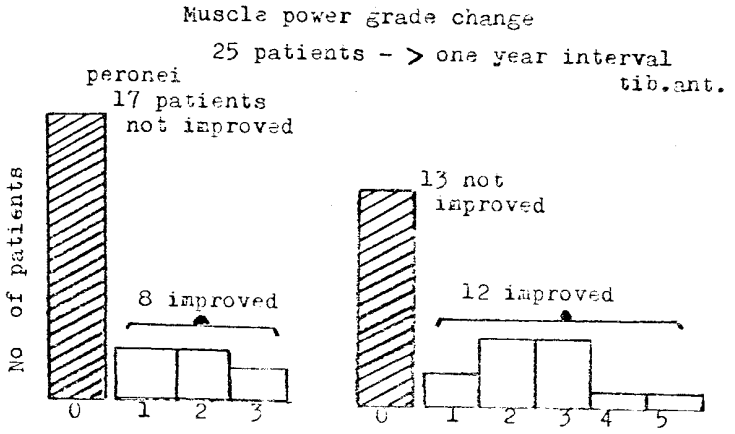
Muscle Power.

After FES treatment-assessment it was demonstrated that in terms of muscle power 26 patients improved in respect of either tibialis anterior or the peronei or both as illustrated in the following histograms:



Histograms showing status of peronei and tibialis anterior muscles after treatment. Position in columns determined by improvement on 0-5 scale. Thus in column 3 the patients had improved by 3 grades.

A common indicator for cessation of physiotherapy in the treatment of the hemiplegic is when there has been no demonstrable improvement in the general status of the patient over a period. We considered it useful to look at the change in muscle power, if any, in those patients who started FES treatment at least one year after onset. 25 patients fell into this catogory. In presenting any improvement the same convention was used.
Of the 25 patients 15 showed some improvement in respect of either tibialis anterior or the peronei or both.



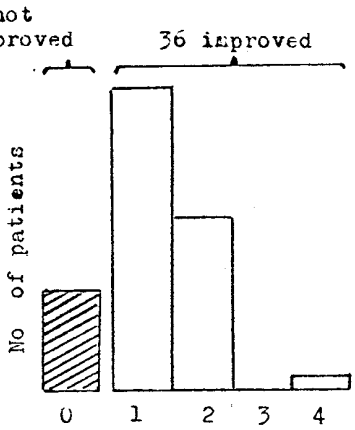
Status of peronei and tibialis anterior muscles after treatment. Position in columns determined by improvement on 0-5 scale. Thus in column 4 the patient had improved by 4 grades

Gait Analysis.

In gait assessment, deviations were categorised as either primary or secondary.
Primary deviations were those resulting directly from neuro-muscular dysfunction and secondary deviations in turn those consequent upon one or more primary deviations, by example circumduction of the leg as a consequence of dropfoot and diminished knee action.
The primary gait deviations were scored from 0 to 5, with

0 being normal and 3 extreme. This scoring was totalled up and gave the following result:

TOTAL GAIT DEVIATION

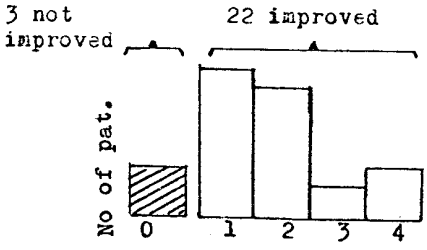


Shows number of patients whose gait improved. Scoring to include all primary gait deviations ranged from 0 (normal) to 33 (extremely bad gait). Thus patients in column 1 improved by 4 points, column 2 by 8 points, and column 4 by 16 points

Comparison of the gait before and after treatment without the brace show that 36 did improve

The following histogram shows the result of the 25 patients who had an interval of more than one year between their onset and FES treatment

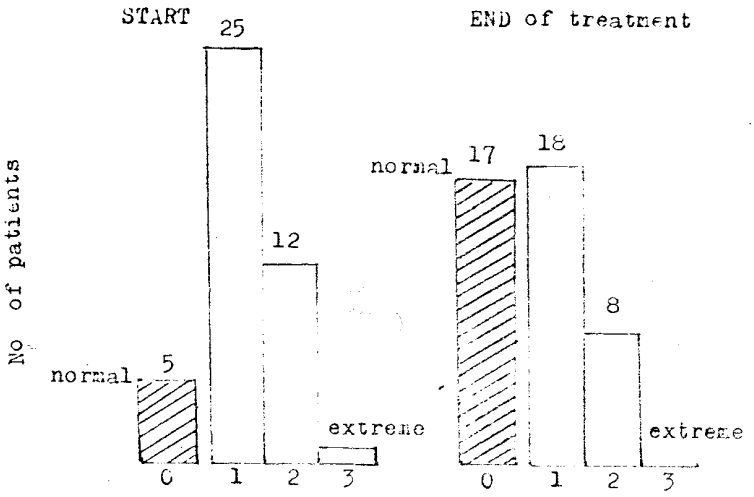
TOTAL GAIT DEVIATION - 25 PATIENTS



Column 1 by 2 points improvement, column 2 by 4 points, column 3 by 6 points and column 4 by 8 points

If attention is focussed solely on certain primary deviations, then we can see that in the case of foot drop there is a clear shift towards the normal as shown in the following histogram.

FOOT DROP IN SWING



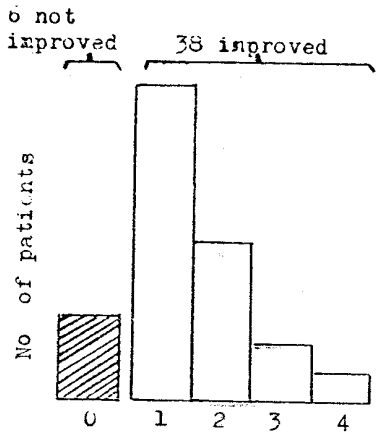
The histogram on the left shows that 5 patients had no drop foot at the start of their FES treatment and 1 patient had extreme foot drop. The histogram on the right shows that 17 patients had no foot drop at the end of FES treatment.

The result obtained for varus (sustained inversion) of the foot at initial foot contact showed a similar improvement. 2 patients had no inversion at the start of their FES treatment, while at the end of FES treatment 14 patients showed no inversion at initial foot contact.

Motor Function/Coordination

Tests of coordination and balance of the lower limb based on task performance while standing without any support showed at the end of the trial that 38 patients improved, as shown in the following histogram.

TOTAL IMPROVEMENT OF CO-ORDINATION-LOWER LIMB

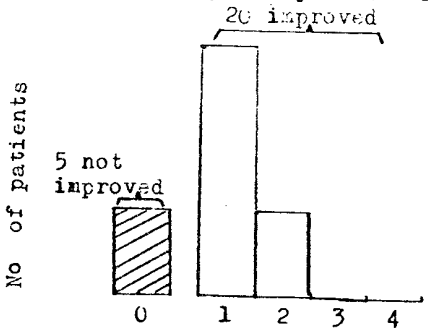


Histogram shows any improvement recorded in motor function in respect of balance. Scoring ranged from normal (25 points) to totally incapable of maintaining balance (0 points). In column 1, patients demonstrated 4 points improvement; in column 2, 8 points; in column 3, 12 points; and in column 4, 16 points.

Once again it is considered relevant to present the degree of improvement of motor function/ co-ordination of the 25 patients who had an interval of at least one year between onset and FES treatment.

Motor function of lower limb

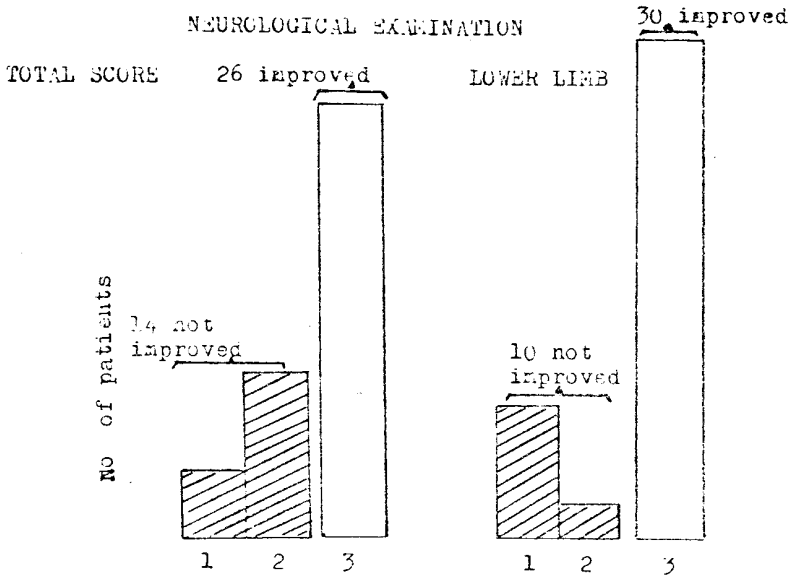
25 patients - > one year interval



The same key as above, in column 1, 4 points improvement, in column 2, 8 points

Neurological examination.

In the histogram we see on the left the total score and see that 26 patients showed improvement; on the right is the score of the lower limb only and then we see that 30 patients improved.



Indicates whether the patients neurological assessment score showed deterioration (column 1), status quo (column 2) or an improvement (column 3).

Discussion

No organised stroke service operates in Dundee District. The period of initial hospitalisation and the duration of in-patient and out-patient physiotherapy is somewhat haphazard and is largely dictated by the limitations on resources.

Initial patient indentification was achieved simply by reference to the recorded hospital admissions. Individual patient contact was achieved by written contact with the patient or general practioner. The limited number of patients who were admitted to the trial was governed therefore, by

the willingness on the part of the patient and the ability of the patient or G.P. to recognise the residual disability and the possibility of further improvement. It is considered as a consequence that the resulting test population represents a rather high proportion of those patients with a rather severe residual functional disability.

The feasibility of employing "control" techniques on the conduct of the trial was closely examined and rejected. The factors governing this decision being the relatively small numbers of patients available, the highly variable nature of the presenting disability and the variations in the methods of treatment.

Methods of assessment

The four principal methods used to assess changes in the patient status were

1. Voluntary muscle power
2. Motor function / co-ordination
3. Gait analysis
4. Neurological examination

In all cases the results of the tests were assessed subjectively.

The technique of gait analysis employed was developed by the evaluation team and is regarded as being somewhat more exhaustive and detailed than the customarly employed practises.

The effect of FES on patient status

Results have been presented both for the 25 patients who had an interlude of at least one year between the onset and FES treatment and for the total test population.

These results may be summarised as follows:

Numbers of patients exhibiting improvements in the test procedures.

TEST	MORE THAN 1 YEAR SINCE ONSET (25)	LESS THAN 1 YEAR SINCE ONSET (18)	TOTAL (43)
Muscle Power	15	11	26
Motor Function/co-ordination	16	17	33
Neurological Examination	17	13	30
Gait Analysis	22	13	35

Analysis of the frequency with which improvement were recorded in more than one test procedure

DURATION SINCE ONSET	No. of categories of improvement				
	0	1	2	3	4
More than 1 year	1	3	5	7	9
Less than 1 year	1	1	3	5	8
Total	2	4	8	12	17

Of the forty-three patients who completed the trial 41 exhibited an improvement in some respect. 17 patients exhibited improvement in all four aspects tested.
In spite of the subjective nature of the assessment techniques it is submitted that the correlation between the results recorded for the four test parameters may be regarded as proof of the generally beneficial effect of FES treatment on patient status.

The results presented for the 25 patients is further offered as evidence that the improvement in status is specifically as a result of the FES treatment and not the result of natural recovery or as a consequence of the physiotherapy.

In purely practical grounds attention is drawn to the 35 patients who demonstrated an improved gait pattern surely the most important factor, even although in ten of these cases no improvement in neurological status was noted.

Looking at the device from a technical point of view, there were no real problems, the main fault being breakage of leads.

FES as an orthosis.

The gait pattern of 48 patients shows an improvement when stimulated, the ankle becoming stable but remaining mobile even for the patients who have a serious disability.
There were 10 patients (including the 7 who failed to finish the trial) who did not like the stimulation and preferred an ankle/foot orthosis (normally made from polypropylene).
All other patients preferred the FES device because the ankle remaining mobile, walking up and down hill and going up and down stairs was easier while most ankle/foot orthoses normally blocked the ankle to a greater or lesser extent.

Conclusions.

Given due regard to prescription criteria and a proper training protocol we belief the Ljubljana Functional Electronic Peroneal Brace is a useful device for a number of hemiplegic patients as an orthosis, as a training and treatment device and as a necessary assessment tool for those patients considered to be candidates for an implanted device.
We further consider that if the device is to be prescribed it should only be prescribed by a team trained and experienced in its use. Ideally the physiotherapist and the prescribing doctor should be trained on a formal course of instruction

and in our judgement such a course must include careful step by step instruction, several clinical experiences and formal gait assessment elements. In all probability a period of 4 to 5 days is necessary to ensure proper training.

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