FUNCTIONAL ELECTRICAL STIMULATION : PRACTICAL EXPERIENCE IN THE CLINICAL SETTING

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Abstract

A clinical trial was conducted to provide and evaluate the use of Functional Electrical Stimulation (hereinafter FES), as a practical and reliable method of standing for paraplegic patients. A sample group of nineteen subjects were selected from forty eight paraplegic patients, all of whom had sustained a spinal cord injury between the levels of T1 and T12, resulting in an upper motor neurone paralysis.

Forming only part of a large composite study, in which many parameters were examined, this paper offers a detailed explanation of the practical application of a twelve week programme of FES, to strengthen the paralysed quadriceps and gluteal muscles, and discusses the implications thereof. It also shows that, on completion of the programme, a wide varience in results was seen, and that FES provided a means for standing in only five of the nineteen subjects.

The author concludes that FES is not suitable as a method of standing for all spinal cord injured patients, and that stringent selection procedures are of the utmost importance, in order for successful results to be attained.

Introduction

Functional Electrical Stimulation has been used in the treatment of spinal cord injury patients for over twenty years. (1). The paralysed muscles may be artificially activated by electrical stimulation of the motor nerve supplying that muscle, provided that the lower motor neurone axon from the spinal cord remains intact.

The use of FES to produce standing (2) and bipedal (3) gait in paraplegic patients, has been demonstrated by Kralj et al, using surface stimulation, and via an implanted system by Peckham (4).

In 1984, at the Royal National Orthopaedic Hospital, STanmore, a pilot study was carried out, in conjunction with Dr Hugh Grenfall, to evaluate a muscle strengthening programme of FES to the paralysed quadriceps muscles of three spinal cord injury patients; a cervical, mid thoracic and thoraco-lumbar lesion (5). The pilot study incurred many practical and mechanical problems in the clinical situation, and highlighted the necessity for a larger scale clinical trial of a muscle strengthening programme of FES to be designed.

Previous studies into FES have been conducted in the laboratory setting, with small subject populations. The aim of the study was to examine the clinical and practical application of such a programme and evaluate some of the physiological effects thereof, within a larger subject population.

Methodology

Nineteen subjects, three female and sixteen male, were selected from a group of 48 paraplegic patients, using the criteria shown:-

1) To have sustained a spinal cord injury between the levels T1-T12, resulting in clinically complete upper motor neurone type paralysis.

2) Absence of contractures in the lower limb.

3) Absence of pressure sores of the lower limb.

4) To have completed a full rehabilitation programme and following a regular standing programme.

The age range of the subjects was 18-60 years, with a mean age of 31.6 years and a distributed as per Fig.1. The length of time since injury ranged from nine months to four and a half years, with a mean of 24.5 months, and a distribution as shown in Fig.2.

Fig.1.

Age Distribution of Subjects

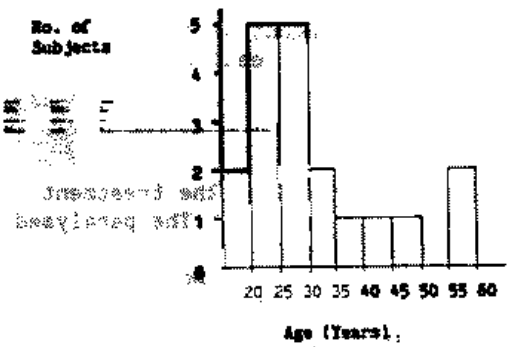
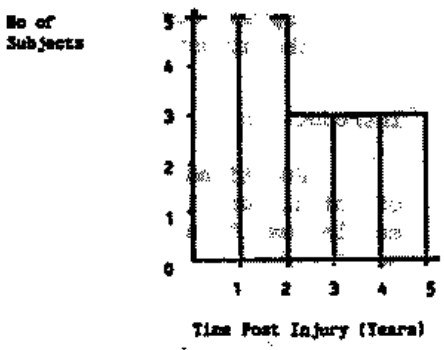


Fig.2.

Distribution of Time Post Injury



Prior to commencing the stimulation programme, the subjects underwent a series of comprehensive assessments, examining the variables shown in Fig.3. This process created a broad baseline picture of the individual, and also served as a further screening procedure.

Fig.3.

Assessment Variables

1. Functional.
2. Neurological.
3. Myological.
4. Respiratory and cardiovascular function.
5. Skin temperature and PO2.
6. Renal function.
7. Bone metabolism.
8. Psychological and social profile.

For the purpose of this paper, the areas of 1,2 and 3 will be discussed.

A clinical neurological examination was performed on each subject, in order to ascertain both motor and sensory levels.

Motor power was assessed in upper and lower limbs, and graded as per the Oxford Scale Grading (0-5).

A sensory mapping was marked out on a full body chart, indicating areas of light touch, deep pressure, pin prick and vibratory sensation: these were graded into normal, paraesthetic and anaesthetic areas. Joint proprioception was tested in upper and lower limbs, and graded on a scale from normal, gross, fine to absence of movement.

In order to evaluate spasticity, the spastic resistance to knee movement was determined by recording the resistance to passive flexion and extension, using a robotic dynamometer - the Kinetic Communicator. (6).

Muscle power was recorded using the Kinetic Communicator to measure the amount of force generated, during an electrically stimulated isometric contraction of the quadriceps femoris.

In order for the subjects to be able to stand, by means of electrical stimulation, the criteria set for the quadriceps femoris, were to achieve fifty isometric contractions, each of four seconds duration, and exerting a force in excess of fifty newtons. (7).

An evaluation of the subject's ability to perform selected activities of daily living was made, using a video recording to show the subject transferring to and from their wheelchair, and their regular method of standing.

Following the assessment procedures, the subjects were instructed in the use of the stimulators, and commenced the stimulation programme for the quadriceps and gluteal muscles. The subjects began with a short period of stimulation, which was increased daily in time, to improve skin tolerance. The programme progressed by increasing the period of stimulation and the loading of the quadriceps muscle, by the posistion in which the exercise was done, and the use of sandbag weights. Details of the programme are shown in Fig.4.

Two types of dual channel, alternating output stimulators, the BMR 4 programmable stimulator (Stimulator 1), and the Raymar Orthotron (Stimulator 2), were used in the trial.

By increasing the number of output leads from each channel from two to four, both the quadriceps and the gluteal muscles may be stimulated simultaneously.

Both stimulators were programmed with the same parameters: a frequency of 20 Hz, pulse width of 200 microseconds, a contraction time and relaxation time of four seconds.

Stimulator was used by 10 subjects and Stimulator 2 was used by 9 subjects.

Fig. 4

Stimulation Programme

Week	Muscle Group	Exercise	Time
1	Quadriceps	Grade 1 Contraction	10-30 minutes
2	Quadriceps	Grade 3 Contraction through 30°-60° Knee Flexion	15-30 minutes
3	Quadriceps	Grade 3 Contraction through 90° - Full Knee Extension	30-60 minutes
4	Quadriceps Quadriceps Glutei	Grade 3 Contraction Isometric Contraction Isometric Contraction	60 minutes 10-30 minutes 10-30 minutes
5	Quadriceps Quadriceps Glutei	Grade 3 Contraction with Weight Isometric Contraction Isometric Contraction	30-60 minutes 30 minutes 30 minutes
6-11	Quadriceps Quadriceps Glutei	Grade 3 contraction with Increased Weight Isometric Contraction Isometric Contraction	60 minutes 30-90 minutes 30-90 minutes
12	Quadriceps Quadriceps Glutei	Grade 3 Contraction with Increased Weight Isometric Contraction Isometric Contraction	60 minutes 90 minutes 90 minutes

All subjects used the same 41mm x 88mm self adhesive electrodes (3M Myocare Muscle Stimulation Electrodes). Electrode positions were selected for the individual, so that the active electrode was positioned over the motor point of the muscle, and the inactive electrode placed over the muscle belly, producing a maximal contraction. (8).

Results

During the tweleve week period of stimulation, two of the nineteen subjects (11.7%) withdrew from the trial; one felt unable to fulfill the commitment necessary, to complete the FES programme, due to personal circumstances, and the other, due to such an increase in muscle spasm, that he could no longer function at a level satisfactory to himself. Their data has not been included for analysis.

The results of the remaining seventeen subjects clearly fell into three categories, as shown in Fig.5.

Fig.5.

Division of Subjects

Category I	Strong initial response to stimulation. Increase in muscle strength. Fulfilled criteria to stand.
Category II	Poor initial response to stimulation. No increase in muscle power.
Category III	Strong initial response to stimulation. No/minimal increase in muscle power.

CATEGORY I consisted of five subjects (29.4%), all of whom showed a strong initial response to electrical stimulation. They exhibited a progression in muscle strength over the twelve weeks and all fullfilled the criteria set, in order to be able to stand by means of FES. The duration for which the subjects stood varied greatly; one subject was able to stand for one hour, three for five minutes, and one for three minutes.

It was seen that all subjects in category 1 had used Stimulator 1 for their muscle strengthening programme. It was found, however, that Stimulator 1 did not provide sufficient power, to sustain a strong contraction of the quadriceps and gluteal muscles simultaneously. In order to stand, therefore, it was necessary to use a large 8 channel stimulator (BMR 16-Systems Controller), which provided an increased power source.

CATEGORY II also consisted of five subjects (29.4%) who showed a minimal Grade 1 muscle contraction (Oxford Scale) as an initial response to electrical stimulation. This response showed no change throughout the twelve week period of stimulation.

Two of the subjects in this group used Stimulator 1 and three of the subjects used Stimulator 2.

The remaining seven subjects (41.2%) fell into CATEGORY III. These subjects showed a Grade 3 muscle contraction as an initial response to electrical stimulation, and a small degree of muscle strengthening of the quadriceps muscle, during the course of the programme. Six of these subjects used Stimulator 2 and only one used Stimulator1.

Following the twelve week period of stimulation, none of the subjects exhibited a change in motor power, and only one of the subjects experienced an increase in sensation, manifested as an area of paraesthesia, on the anterior aspect of the right thigh.

Changes in the spasticity of the quadriceps and hamstring muscles areindicated in Fig.6. The tests showed an overall increase in quadriceps tone in 61.8% of the subject population, and an increase in hamstring tone was shown in 50%. A reduction was seen in 26.5%. No change in either quadriceps or hamstring tone was seen in 23.5% of the subject population.

Fig.6.

Number of Subjects to show a change in Muscle Spasticity

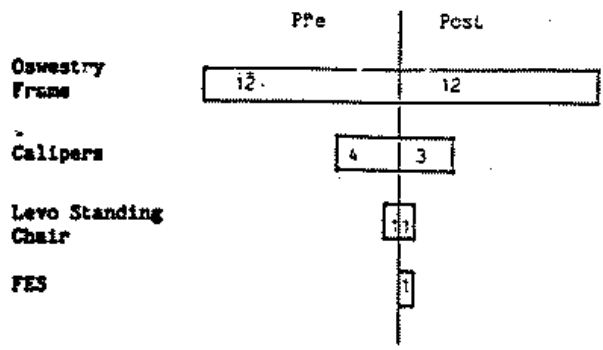
Muscle Group	↑Tone R	↓ Tone R	ISQ Tone R	↑ Tone L	↓ Tone L	ISQ Tone L
Quads	11	3	3	10	2	5
Hams	10	4	3	7	5	5

The ability of the remaining seventeen subjects to perform standard activities of daily living showed no change.

Only one of the subjects (5%) was able to stand by means of FES, for a period of time, sufficient to replace his regular standing programme. The distribution of the subjects' methods of standing before and after the stimulation programme is indicated in Fig.7.

Fig.7

Methods of Standing Pre and Post Stimulation Programme



Discussion

The practical application of the stimulation programme presented several problems to the subjects:-

1) Accurate positioning of the gluteal electrodes was difficult, without assistance.

2) The final duration of the stimulation, (two and a half hours) was extremely inconvenient, and difficult to integrate into the subjects' normal daily routine.

3) The period of stance for the five subjects who met the criteria to be able to stand, ranged from two to sixty minutes, before muscle fatigue occured.

Only one of the subjects was able to stand for a period of time sufficient to replace his regular standing programme of thirty minutes. However, he was unable to stand by means of FES at home, as his own portable stimulator did not provide sufficient power to sustain a strong contraction of the quadriceps and gluteal muscles simultaneously.

It is interesting to note that this subject was already a functional ambulator with calipers.

In category III, six of the seven subjects were using Stimulator 2, and all exhibited a strong initial response to electrical stimulation. Several problems were experienced with Stimulator 2, leading to questioning of the efficiency of the stimulator. It is therefore suggested that these six subjects should repeat the twelve week stimulation programme, using Stimulator 1, at a later date.

Further physiological problems were also encountered:-

1) The one subject in category III who used Stimulator 1 experienced a dramatic increase in muscle spasticity, sufficient to require an increase in his antispasmodic medication. This may have accounted for the plateauing of his muscle strengthening which occurred during the first few weeks of stimulation.

2) In a number of subjects, there was evidence to support the hypothesis that lower motor neurone dysfunction was present. Further investigations into the relationship between lower motor dysfunction and response to stimulation are at present being conducted.

3) Five of the subjects had previous histories of deep vein thromboses. During the twelve week programme, two of those subjects exhibited clinical signs of further deep vein thrombosis.

Conclusion

The trial has shown that in a sample group of nineteen subjects, a wide variance in results was exhibited.

The study indicates that FES is not suitable as a means for muscle strengthening in all spinal cord injury patients, both for physiological and practical reasons, and that in this study's population, FES provided a functional means of standing in only one of the nineteen subjects (5.8%)

In conclusion, therefore, the author stresses the necessity for stringent selection of patients to participate in a programme of FES for standing, in order to attain optimum results.

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