Surface Functional Electrical Stimulation (FES) for Walking in Incomplete Spinal Cord Lesioned (SCL) Individuals. A Multicentre Trial.

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Abstract

Aim: Improve gait in individuals with incomplete SCL.
Methods: After inclusion, an initial assessment was performed including ASIA, FIM, walking endurance, and Observational Gait Analysis (OGA). A FES-strategy was developed. The FES was used at home and adjusted in the centre before a final assessment.
Participants: 72 came for initial evaluation, and 31 had the wish to continue the use of FES after termination of the study.
FES-strategy:Of these 14 used one channel, 16 two channels, and 1 three channels for stimulation. 26 used unilateral, and 5 bilateral stimulation. In 28 instances the flexor withdrawal reflex was used, in 10 quadriceps, and in 9 the dorsiflexors.
Results: No significant difference was found for the walking endurance, but the gait was evaluated to be better by the OGA.
Conclusion: For selected incomplete SCL individuals surface FES deliver an improved quality of walking.

Keywords: Functional electrical stimulation (FES), Gait analysis, Gait, Spinal cord injury, Teleconsulatation.

1. Introduction

The CREST (Clinical Rehabilitation using Electrical Stimulation via Telematics) project is direct at providing a new clinical service to the pan-European rehabilitation community that gives non-expert clinicians access to an expert network comprising both knowledge and infrastructure, in order provide them with the necessary background and tools to successfully apply functional electrical stimulation (FES) in the treatment of persons with incomplete spinal cord lesions (SCL).

In order for CREST to be successful, it is necessary not only that the network is made available, but also that as far as possible patient treatment follows an agreed model. Protocols have been developed for this purpose and they provide both the expert and the non-expert clinician with standards for the assessment and treatment of the SCL individuals. Further protocols were developed for telematic communication and consultation [1].

This presentation will focus on the results actually obtained regarding to gait for those SCL individuals who wanted to continue using the FES system they tried at home for a period.

2. Methods

Five clinical centres rehabilitating SCL individuals took part in the study. Within each centre the records of previously and presently admitted SCL individuals were viewed to identify possible candidates for the FES treatment.

The inclusion criteria were:

- Spinal cord lesion
- Post-injury rehabilitation completed
- Able to be stood
- Adequate hand function to operate hand switches and use crutches, if necessary
- Have consultant approval to take part in the study
- Motivated and able to attend testing sessions.

Exclusion criteria (contra-indications) were:

- General medical complications
- Intractable joint contractures
- Pressure sores
- Lower limb fractures
- Excessive joint laxity
- Presence of metal implants

- Pregnancy
- Peripheral denervation
- Low exercise tolerance
- Excessive spasm
- Lack of motivation

The SCL individuals entering the study were initially assessed according to the international standards for neurological classification of spinal cord injury (ASIA/IMSOP) [2] as well as in accordance with the Functional Independence Measure (FIM)[2].

In addition to these classifications each subject was assessed by a series of tests on entry to the study, the 'initial assessment'. Following a period of training and home use of electrical stimulation the subjects returned for final assessments with and without stimulation. The tests used in the assessments were:

- Manual muscle test (not performed with stimulation)
- Ashworth spasticity test (not performed with stimulation)
- Joint range of motion (not performed with stimulation)
- Observational gait analysis (based on the Rancho Los Amigos checklist [3])
- Walking endurance (the distance covered in 6 minutes of walking on flat level surface)

3. Participants

Seventy two SCL individuals were initially approached as potential candidates for participation, and 34 came for the final assessment. Of these 31 indicated that they were so satisfied with the system that they wanted to continue using it in the future in their home. The following figures and results will only give information on these 31 participants.

Twenty five men and 6 women participated, and their ages at the time of the study were 18-64 years (median 42). Their height and weight were 155-193 cm (median 178) and 52.5-120 kg (median 75) respectively. They had had their SCL between 1 to 31 years prior to the study (median 4). Their neurological levels were from C4 to Th12, with 15 having a cervical and 16 a thoracic lesion. The ASIA impairment scale was C in 6 and D in 25. 24 had a traumatic injury (11 from road traffic accidents), and the remaining 7 had non-traumatic origins to their SCL. The FIM scores were 97-126 (median 121).

4. FES strategy

The FES strategy used in the 31 SCL individuals wanting to continue the use of the FES system can be summarised in the following way:

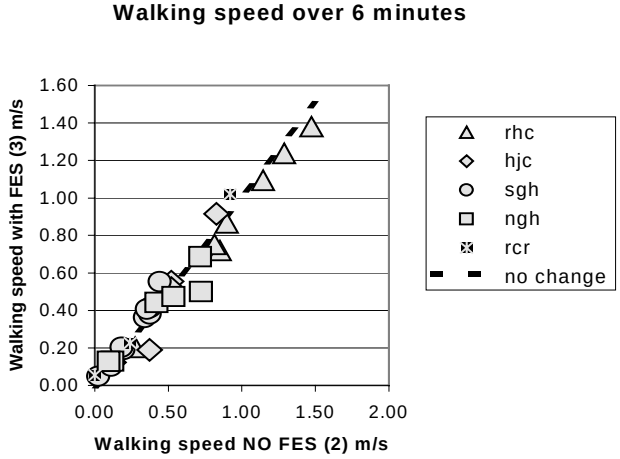
In total 49 channels were used. 14 used one channel only, while 16 used two, and one individual used three channels. The majority, 26, used unilateral stimulation, while the remaining 5 used stimulation of both lower extremities.

The most widely used stimulation, was for the flexor withdrawal reflex, as this was utilised in 28 instances. Second was stimulation of the quadriceps for knee extension, which was used in 10 instances. In a further 9 instances stimulation of ankle dorsiflexors was performed. Stimulation of the gluteal medial muscle and hip extensors were utilised in one instance each.

5. Results

The manual muscle test, the Ashworth spasticity test and the joint range of motion showed, as expected, no significant differences from the initial to the final evaluation.

The results of the walking endurance from the initial evaluation without FES to the final evaluation with FES for the 31 SCL individuals are shown in Figure 1:
rhc: Rigshospitalet, Denmark; hjc: Hospital Juan Canalejo, Spain; sgh: South Glasgow University Hospital, Scotland; ngh: North General Hospital, Sheffield, UK; rcr: Rehabilitation Centre Het Roessingh,

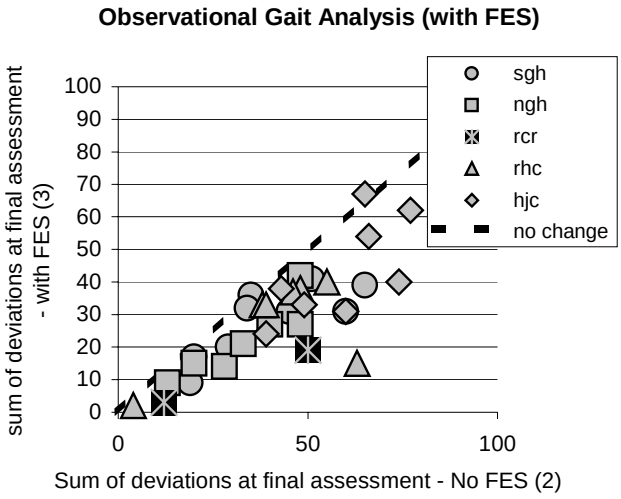


The Netherlands.

There is no significant difference in the walking endurance from before to after the use of FES. It should be mentioned that there was trend towards improvement in walking endurance when comparing the participants without FES at the initial and the final evaluation.

The results of the OGA at the initial evaluation without FES and at the final evaluation with FES are presented in Figure 2 (below).

For further details of the results of the OGA please refer to Hasler et al.[3]. The overall results showed less major as well as minor deviations in the SCL walking when the FES system was used.



In addition to the results presented in Figure 2 it was found that 10 SCL individuals who before used orthosis when walking did not need this when using FES. Two did not need their knee-ankle-foot orthosis when walking with FES, the remaining eight could drop their ankle foot orthoses, one of them even on both sides. When on the FES system Two who had the status of physiological walker became limited household walkers, one of these could before only walk in parallel bars but with FES with a walking frame. Five improved their gait from most-limited or least-limited community walker to least-limited or just community walker. One improved from limited household walker to most-limited community walker, and another from unlimited household walker to least limited community walker. Further two used before two crutches, but with FES only one was needed.

We also found that two individuals had less good walking with the use of the FES system, i.e. being limited household walker or least-limited community walker before, and afterwards both were judged as physiological walkers. One of these was also among those who were not using an unilateral ankle-foot orthosis when utilising the FES.

6. Discussion and conclusion

From the clinical point of view the therapeutic effect of FES was very satisfactory. The SCL individuals who wanted to use the system found themselves walking better than before.

Even one third did not need their orthoses when they used FES. This is of course also of importance when discussing the cost of the system, i.e. in several instances an orthosis will not be needed. A problem which was faced in the implementation phase of the study was the lack of CE-marked stimulators which could be utilised and modified to work together with the CREST software, when programming the stimulation parameters.

Regarding the evaluation methods most were not found sensitive enough to show any effect of the use of the FES system. Though it was interesting to observe that the training with the system gave better walking endurance when not using the system. This has the clinical implication that FES can be used to enhance walking endurance even when the person may not be suitable for use of FES I daily life. The experience have been made for the upper extremity in tetraplegics individuals [4].

Quality of gait is certainly not easy to judge. We found the OGA very useable, although it may well have some problems as well [3].

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