

# THE RISE PATIENT STUDY: FES IN THE TREATMENT OF FLACCID PARAPLEGIA

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## Introduction

The aim of the “RISE”-project is to develop a new rehabilitation method for patients with Long Term Denervated Degenerated Muscles (DDM) and to create a systematic body of basic scientific knowledge about the restorative effects of Functional Electrical Stimulation (FES).

With this scientific basis

- existing EU Regulations governing the use of electrical stimulation which currently exclude the possibility of therapeutic use in patients with DDM should be revised.
- equipment should be constructed and designed and brought to the point of commercial adoption.
- new diagnostic and measurement equipment for monitoring the progress of the therapy should be designed and constructed.

## Material and Methods

Until now 28 patients (23 men, 5 women), 54 legs met the inclusion criteria of a flaccid paraplegia of the m. quadriceps femoris.

Paraplegia was caused by traumatic fracture mostly of Th 11 and 12 (Th 5 – L 1). At the beginning of the study the mean age of men was 36 yrs, of women 43 yrs. The mean denervation time in men was 4.9 yrs, in women 5.8 yrs. Mean weight of men was 77.8 kg, of women 64.8 kg, mean height of men 179 cm, of women 164 cm.

Patients who met the inclusion criteria were invited to Vienna. They were informed about the project and had to give their informed consent.

Afterwards all patients followed a clinical protocol and had to undergo the following assessments.

To achieve a more accurate description of the type of lesion and the remaining motor and sensory function and to be sure that m.

quadriceps fem. is completely denervated, we use apart from the conventional examinations a series of methods.

### *Electrical stimulation test of m. quadriceps:*

Two rubber electrodes, each inside a wet sponge bag, are positioned above the thigh (m. quadriceps fem.). The muscle is stimulated with defined electrical stimuli (impulse duration 145ms, 42ms, 5ms, 2.6ms and 1.3ms). The contraction of the m. quadriceps fem. is tested manually on the muscle belly and the patella.

### *Needle EMG of m. rectus femoris:*

The m. rectus femoris is examined by inserting the needle in different depths and four directions. When necessary additional needle EMG will be performed in m. vastus lateralis and medialis. Insertion activity, spontaneous activity during relaxation (fibrillation potentials, positive sharp waves) and volitional activity are assessed. Needle EMG examination is completed by stimulation of femoral nerve at the groin with a supramaximal single stimulus in order to elicit an M- wave.

### *BMCA – Brain Motor Control Assessment (Assessment of motor control in spinal cord injury):*

Multichannel surface EMG recordings are used to document the absence of reflexes and motor unit action potentials during attempts of volitional movements. We use a standardised sequence of motor tasks with the subject in a supine position to characterise features of motor control. [1]

### *Transcranial and lumbosacral magnetic stimulation:*

Recording conditions are the same as in BMCA. For transcranial stimulation a double coil is placed over Cz and the stimulus amplitude is increased from 30-100% (in steps of 10%). A symmetric response in biceps brachii and thenar must be reached. Lumbosacral stimulation is carried out at the level of Th12, L2, L4 by using a circular coil.

### *LSEP (Lumbosacral Evoked Potentials):*

Surface recorded lumbosacral evoked potentials are used to assess the functions of the posterior structures and grey matter of the spinal cord and the dorsal and ventral spinal roots. To this end evoked potentials induced by stimulation of the tibial nerve (popliteal) are recorded with surface electrodes placed over the vertebral levels S1, L4, L2 and Th12 in reference to a Th6 positioned electrode. Corresponding cortical evoked potentials are additionally recorded with a pair of electrodes. 120 successively evoked potentials are averaged for each channel.

Evoked potentials are analysed for the presence of an R-wave (conducted by sensory axons within the posterior roots), A-wave (reflexively initiated efferent volley conducted by motor axons) and S-wave (generated by spinal neurons) and any pathological differences of the waveforms and their latencies from common standard data of healthy subjects.

### *SSR (Sympathetic Skin Response):*

SSR is used for examination of spinal cord injuries and represents an addition for the proof of disturbances of the vegetative nervous system. The response is recorded from the palm and dorsum of the hands and sole and dorsum of the feet. In order to release the sympathetic skin response, the N. medianus is electrical stimulated with a current of 25 mA and a duration of 0.1 ms.

To quantify the morphological status of the thigh the following investigations are done:

#### *CT- Scan*

to quantify the muscle cross-sectional area, muscle density and diameter of the cortical bone.

#### *Skin biopsies*

#### *Muscle biopsies*

for histological, electromicroscopical and biochemical analysis. [2]

#### *Bone density measurements*

Based on the experience from our pilot work an electrical stimulation protocol and a special electrical stimulation device especially adapted to the needs of denervated muscles was developed. [3, 4] The patients were carefully instructed how to put on the stimulation electrodes and operate the electrical stimulator. The training with electrical stimulation is carried out by the patient at home

and is adapted regularly throughout the study depending on the condition of the muscle and the findings of the accompanying animal experiments.

In the beginning the training protocol consists of two different stimulation patterns: in one program impulses last 120ms (1.6Hz), 5sec on, 2 sec off, in the other program impulse duration is 40ms (20Hz), 2 sec on, 2 sec off. The daily amount of stimulation per muscle is 15 to 30 minutes. [5]

The electrical stimulation and the force output are checked regularly.

The clinical study is designed as an uncontrolled cohort study. This means that parameters about effectiveness and reliability are collected throughout the therapy.

## **Results**

We compare our data of biopsies of DDM with data of biopsies of 5 years functional electrical stimulated DDM.

The histological and electromicroscopical analysis showed regeneration of myofibers, of metabolism and function of the denervated muscles. [2, 6]

The minimum myofiber diameter of stimulated DDM was analogue to normal muscle or spastically paralysed muscle. In contrast unstimulated DDM showed a much smaller diameter [Fig. 1].

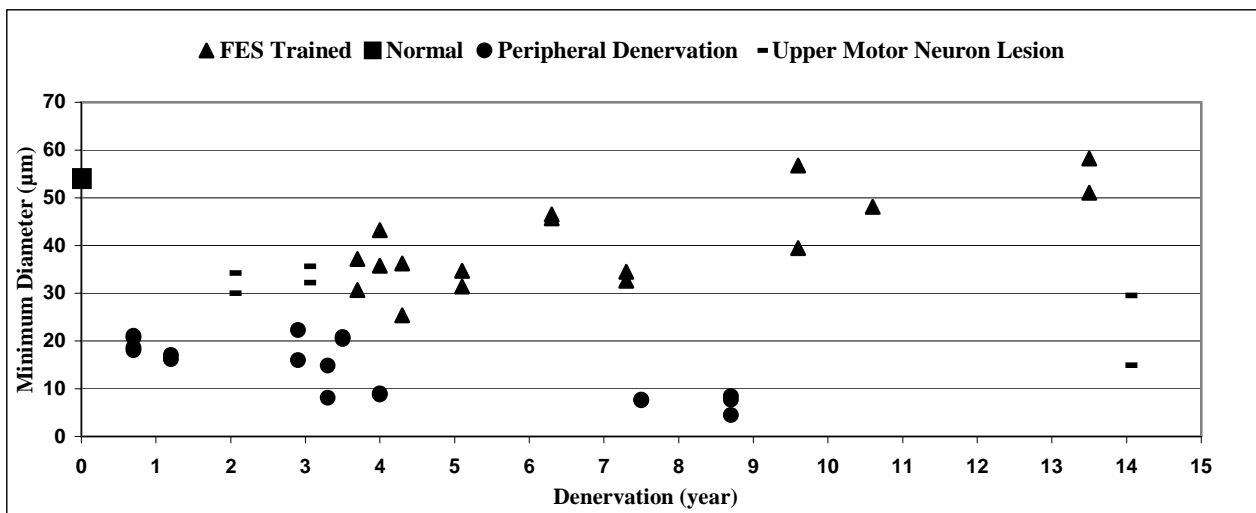


Fig.1 Differences in Minimum Myofiber Diameter between FES Trained DDM, DDM, Normal Muscle and Upper Motor Neuron Lesion - Ugo Carraro - Applied Myology Lab - Padova

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