*Proceedings of the Eighth International Symposium on ECHE, 1984, Dubrovnik*



# EXPERIENCES WITH AN IMPLANTABLE NERVUS FEMORALIS STIMULATOR.

G.Zilvold, H.J.Hermens, H.Kreuwel, C. de Waal, J. v. Alste*

Roessingh Rehabilitation Centre, Enschede Holland
*: Bio-Information Group, Twente University of Technology, Enschede Holland

ABSTRACT

With Functional Electrical Stimulation (FES) it is possible to re-activate paretic muscles in order to perform functional movements. In most cases surface electrodes are applied, especially in the clinical situation.
In this article an implantable system (electrode, stimulator and control unit) is described. It has been applied in order to activate the extensors of the knee with a hemiplegic patient. Some preliminary results are given.

## INTRODUCTION

Functional electrical stimulation (FES) is a method to activate paretic muscles in order to perform functional movements. Compared with the use of orthosis it has a number of advantages: it prevents muscle atrophy to a certain degree,it is cosmetically better accepted, the blood flow remains normal etc.
FES can be applied especially to patients with an unimpaired peripheral nerve system. This is because it is much more convenient to stimulate nerves, rather then stimulate muscles directly.
The interface between the nerves and the stimulator consists of the electrode. This can be a surface electrode or an implanted electrode. In most cases surface electrodes are applied (e.g. peroneal nerve stimulator, Zilvold 1981). The use of surface electrodes has a number of advantages; the most important one is the possibility to apply it to a patient at the moment that you want it to. At the same time a lot of disadvantages involved in the use of surface electrodes are observed, e.g.:

- Repeated difficulty in locating the correct points for stimulation.
- Variation in skin impedance and electrode position makes resetting of pulse-amplitude necessary.
- Physical discomfort experienced by the patient.
- Low efficiency in the sense of the energy used for actual activation of the nerve. The greater part of the energy flows through tissue without being used or, even worse,activating wrong structures (especially when the nerves to be controlled are deeper in the body).

These disadvantages could be overcome for a great part by the use of implantable systems. By means of experiments with animals (e.g. Breederveld, 1981) it has been shown that stimulation by means of implantable systems can be fulfilled for a long period.
In this article the implantable system, which we applied, is

described and some preliminary results of the application on one patient are given.

## METHODS

### The electrode

The electrode has been manufactured in cooperation with Medtronic. A schematic drawing of the electrode is shown in figure 1.

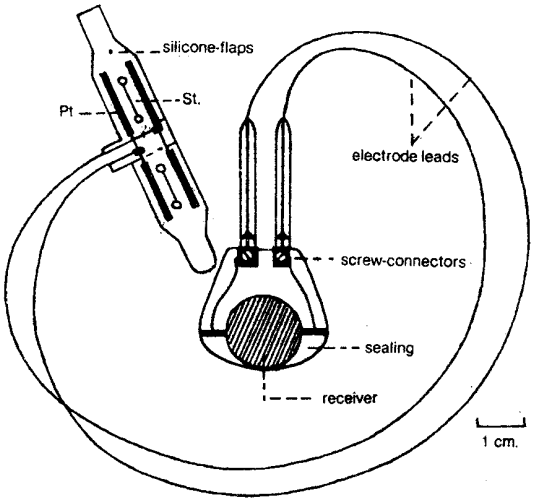


Fig.1. Schematic drawing of the electrode, connected to the stimulator.

The electrode cuff completely encircles the nerve. It exists of two platinum strips embedded in silicon flaps, serving as cathode and anode. A third small strip of steel has been built in to improve mechanical stability. At surgery these flaps are wrapped around the nerve trunk. The electrode is constructed in such a way that its dimensions can be varied in order to encircle the nerve properly, despite anatomical variations. A preliminary study showed that variations up to 50% of the thickness of the femoral nerve may be found at the place of connection.

### The stimulator

An extensive description of the stimulator unit may be found in the thesis of Hildebrandt, who designed and manufactured the stimulator.
The stimulator was originally intended to be placed in the motor endplate zone of a muscle. In this case no additional electrodes are needed. We apply it as a nerve stimulator, but there are no essential differences between these two applications.
Basicly the stimulator has two functions. First, it has to

get the energy, needed to function, from outside the body because it has no internal power source.
Secondly, it has to give stimulation pulses at the demanded moments and with the demanded amplitudes.
The energy that is needed is passed through the tissue by a 27.2 MHz carrier frequency. In this case the coupling of the send antenna and the stimulator antenna can be seen as an inductive one, like the primary and secundary windings of a transformer.
The information concerning the stimulation pulses is passed by means of amplitude modulation of the carrier frequency (pulse code modulation).
The amount of charge of each stimulation pulse is determined by the time a condensator, inside the stimulator, is loaded.
The timing sequence of the charging and discharging is determined by two five bit codes: a start code which causes the condensator to discharge and to start loading again and a stop code which stops the loading of the condensator. This is shown in figure 2.

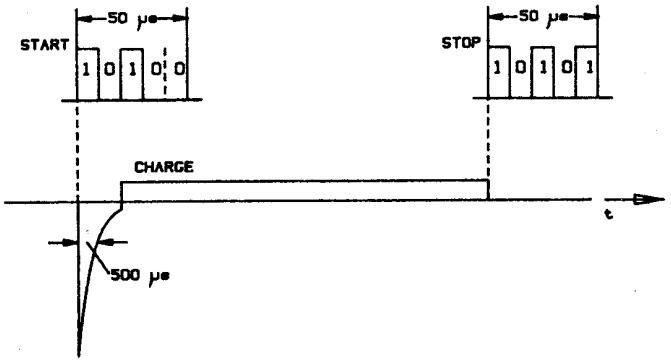


Fig.2. Chracteristic behaviour of the stimulator, triggered by start and stop codes.

The loadcurrent of the condensator also passes through the tissue but in opposite direction, so the net current flow is zero. This is of importance because in this way there will be no net ionflow which could cause irreversible reactions.
In this way the time between the start and the stop code determines the amount of current in the next stimulation pulse. The time between the consecutive starting pulses determines the frequency of the stimulation.

The external control unit

The external control unit consists of a device to control the stimulation and an antenna.
This antenna is a simple two turn wire with a diameter of approximately 8 cm. It must be placed upon the skin directly over the place where the stimulator is implanted.
With the control module two ways of operation are possible. These two modes and their parameters are:

- mode one: continuous stimulation.
  - frequency
  - amplitude
- mode two: pulse trains
  - minimum frequency and minimum amplitude at the start of each pulse train.
  - maximum frequency and maximum amplitude during stimulation.
  - risetime of the frequency and the amplitude.
  - durance of the stimulation.

Mode one is used during investigation in order to determine the responses of the muscles at various parameter settings. Mode two is used during training. In this mode stimulation can also be started by an external trigger.

Surgery

In august 1983 the first implantation was carried out with the described system. The selected patient had a stroke approximately four months before in the right hemisphere. Due to this there was a flaccid paresis of the left leg.
At surgery two incisions were made; one in the thigh in order to place the electrode and another in the lower part of the belly in order to place the receiver. The electrode was wrapped around the motor branches of the femoral nerve just beneath the ligamentum inquinale a few centimers to the point where the branches split up.
The electrode lead was tunneled subcutaneously from the electrode side to the receiver side. At the stimulator the electrode leads were connected to the receiver by means of special screw connectors and covered with sealing.

PRELIMINARY RESULTS

In order to evaluate the results a measuring protocol has been developed.

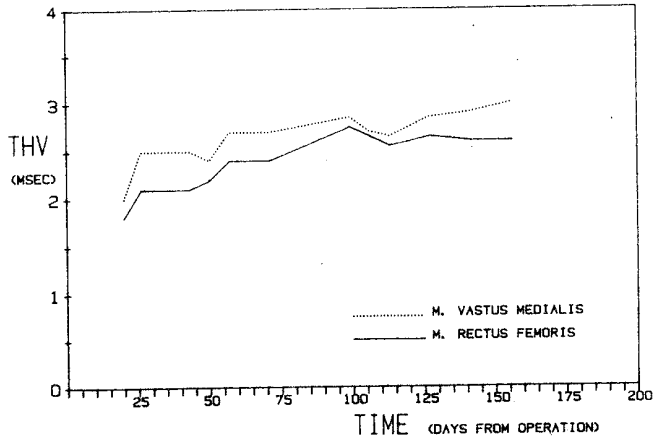


Fig.3. The courses of the treshold values of the Rectus femoris and the Vastus medialis muscles.

Three weeks after the operation we started to determine the treshold values of the Rectus femoris and the Vastus medialis muscles. With treshold values we mean the values of the stimulation current at which the muscles start to contract. In order to make an objective judgement possible we applied surface EMG.
Standard surface electrodes are placed on both muscles on a standardised way and the stimulation current is raised until the peak-peak value of the action potentials are 200uV.
In figure 3 the course of this parameter both for the Rectus femoris muscle and the Vastus medialis muscle are shown.
We also investigated the influences of the parameter settings on the occurence of fatigue and the changes that occur in the maximum force and the shape of the EMG signal.

After a period of three months we observed a strong increase of the amount of EMG and force in the Quadriceps muscle. Before the operation she could not extend any force and the amount of EMG activity at maximal effort was zero in the Vastus medialis muscle and very low in the Rectus femoris muscle. In contrast with this finding there was no change of the EMG activity at maximal effort in all other muscles of the leg.
Apparently the FES of the Quadriceps muscle has restored the voluntary control on this muscle. This may be due to the afferent feedback obtained by the stimulation.

Although the implantation resulted in different effect we expected we did have the opportunity to gather some experiences with the use of an implantable system. These provide us further information on the future development and applications of similar systems.

REFERENCES

Breederveld R.S., Otter G.den, 1981, Electrical stimulation of the femoral nerve in cat, Proceedings of the seventh International Symposium on Advances in External Control of Human Extremities, Dubrovnik Yoegoslavie

Hildebrandt, 1983, System zur willkurgerechten Anwendung der funktionellen Stimulation, Thesis, Universite Louis Pasteur Ecole Nationale Superieure de Physique, F-6700 Strasbourg.

Zilvold G., 1981, Follow up of patients with a peroneal nerve stimulator: Indications for prescription, Proceedings of the Seventh International Symposium on Advances in External Control of Human Extremities, Dubrovnik Yoegoslavie.