QUANTITATIVE EVALUATION OF THE EFFECT OF SPINAL CORD STIMULATION ON MOTOR FUNCTION

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Keywords: spinal cord stimulation, spasticity, quantitative evaluation, parameter optimization.

INTRODUCTION

The use of spinal cord stimulation (SCS) in the treatment of spasticity has been investigated in several studies (1,2,3). These studies however show many differences; not only concerning the eventual results but also concerning the stimulation parameters and the methods of evaluation. Additionally the effects of SCS are described in different patientgroups of which the selection criteria are often not well described. This will undoubtedly contribute to the different results obtained.
The possible benefits to the treatment of spastic patients with SCS has made us decide to start a study with a homogeneous group of patients. In order to pay attention to all aspects of treatment and evaluation, we composed a multidisciplinary team consisting of a neurosurgeon, a physician, a neurologist, a biomedical engineer and physical therapists. For the evaluation we use surface EMG, ADL tests, a leg function test and a specially developed test for spasticity (4).
We also developed a method in order to adjust the stimulation parameters in a systematic way. In this paper we will give an extensive description of the methods used in the treatment of spasticity with SCS. This will be illustrated by the results we obtained with one patient.

MATERIALS AND METHODS

Our program is divided into five stages:
1. Patientselection and screening
2. Implantation
3. Training
4. Adjustment and optimization of the stimulation parameters
5. Evaluation

These will be described in the next sections.

1. Patient selection and screening

In order to make possible benefits exchangable to other therapists, dealing with spasticity, the selection criteria have to be very clear. Our selection criteria are:
- diagnosis: spinal cord lesion with obstructing spasticity. Spinal cord lesions due to degenerative diseases are excluded.
- stable state during the last six months.

- ascending and descending pathways must be present (5).
- age between 16 and 60
- good motivation and cooperativety.

The purpose of the screening is on one hand to determine whether the patient fits the selection criteria, and on the other hand some observations are a reference for the period after implantation. Neurological and neurophysiological examination takes place. In the rehabilitation centre the motor functions are screened. At the end of the screening, the team decides whether to go on with implantation or not.

2. Implantation

The implantation operation is usually performed under local anesthesia, because the patient has to answer questions from the neurosurgeon during the test stimulation. By means of a punction under radiographic control a four polar electrode (Medtronic SE-4) is placed in the epidural space. After the electrode is positioned, it is connected to an external pulse generator. The intention is to place the electrode in such a position, that the patient feels paresthesiae in the region where spasticity is present. A biomedical engineer adjusts the stimulation parameters, together with a physical therapist. When there are good results after a week of test stimulation, the permanent stimulator will be implanted. Then the patient comes to the rehabilitation centre for optimization of the adjusted parameters, and for a period of training

3. Training

If the outcome of the stimulation is a reduction of spasticity, the next step is to get the best profits out of this situation. This means that the patient should be trained by means of physical therapy. This training takes place at least twice a day and will often be dedicated towards the training of weakened muscles groups.

4. Optimization of the stimulation parameters

In order to get good results when spinal cord stimulation is applied, it is important to adjust the stimulation parameters in an optimal way. At a first glance this seems to be a nice puzzle, because when the four polar electrode is used, one has numerous possibilities to adjust the stimulation. It is remarkable that no systematic way to adjust the stimulation parameters can be found in literature. One rather time consuming way to do this, is to try out all possible combinations. Based on the experience with several patients with implanted spinal cord electrodes, we developed a method which is less time consuming and gives direct results. A key point in the procedure is the assumption that paresthesiae must be felt in the region to be influenced in order to get a useful stimulation. This assumption is unfortunately not based on a scientific work but on generally accepted clinical findings.

4.1 The electrode configuration

The goal of this procedure is to find the electrode configuration at which:

- paresthesiae are felt in the region to be influenced
- no direct motor responses are observed
- the least energy consumption is needed.

In order to determine the effect of different electrode combinations one can choose between different approaches. In the first place one can stimulate with the same stimulation parameters at different electrode combinations and ask the subject to judge the effect of the stimulation. This method has two disadvantages. First we found out that the subjects were not able to judge the effect of the stimulation more precisely and reproducible than a 3-point scale. Secondly we found out that the differences in effect of the different electrode configurations was generally very large, so the choice of the stimulation parameters influenced the results.
The method, for which we choose, is to ramp up the amplitude of stimulation slowly and ask the subject to notice the threshold values, at which he starts feeling paresthesiae and possible muscle contractions. For this procedure we made a selection of electrode configurations, based on electromagnetic field theory and our experiences. An example of threshold values for muscle contractions and paresthesiae in the limb is given in table 1.

Table 1: Threshold values (%Vmax)*

electrodes	M.C.		PAR.	
0 1 2 3	le	ri	le	ri
- + 0 0	-	-	-	-
- + + +	-	-	95	80
+ - + 0	-	85	-	100
+ - 0 0	-	80	-	-
0 - + 0	-	85	-	-
+ - + +	-	75	90	-
0 + - +	60	55	70	70
0 + - 0	70	70	85	85
0 0 - +	70	85	80	80
+ + - +	55	55	70	70
0 0 + -	55	85	60	75
+ + + -	55	75	55	65

*
%Vmax- percentage of the maximal stimulation amplitude
M.C. - contractions in Abdominal muscles
PAR. - paresthesiae in both legs

During this procedure the pulsewidth is set to its maximal value (1 mS) and the stimulation frequency is 25 Hz. It appeared also to be important to keep the subject in the same position during the whole test.
From the example in table 1 it is obviously that the combination + + + - coincides best with the above mentioned demands. There are light contractions in the Abdominal muscles at the amplitude needed for paresthesiae in the legs. After five minutes these contractions reduce. From this example it can also be seen that the electrodes are rather symmetrical placed in the epidural space.
In order to test the symmetry of the electrodes we also apply surface EMG measurements. Especially the determination of the threshold values at which motoric responses are seen in the surface EMG give a good indication of the symmetry of the electrode placements.

4.2 The pulsewidth
In order to find the optimal pulsewidth at which paresthesiae are felt, we determine the I-T-curve. An example is shown in figure 1. The pulsewidth we choose for stimulation is the minimal pulsewidth in the flat region of the I-T-curve.

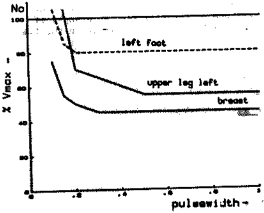

Figure 1: I-T CURVE

In the example, shown in figure 1, we choose for a pulsewidth of 0.5 mS.

4.3 The stimulation frequency
We developed no procedure in order to determine a possible optimal stimulation frequency. We generally apply a frequency between 20-40 Hz. Some literature seem to give evidence that the application of very high frequencies may give benefit. Our experience is that in all our subjects the application of low frequencies worked well, so we do not feel the need to apply high frequencies. Additionally it may be remarked that there is no explanation why the application of high frequencies, much higher then the neuromuscular system is designed for, could work better.

5. Evaluation procedures

5.1 Leg function test

The functional level of legs is examined by a standardised functiontest. This test is build up from 13 items. The maximumscore per leg is 39 points. The functional possibilities of different muscle groups are tested in standardised positions. The better isolated movements are performed, the higher the score.

5.2 Ashworthscore

A semi-quantitative five point scale is used to register the tone in the lower limb. The score of zero means a normal tone; four means that passive movements are hardly to perform. Flexion and extension around the hip, knee and ankle are examined. In evaluation, the scores of the passive movements of the three joints will be added.

5.3 Isometric EMG measurements

The procedures to registrate and analyse the EMG signals are described extensively by Hermens et all (6). Therefore we will only give a short summary. The EMG is recorded with bipolar surface electrodes (Medelec EL 211) during maximal voluntary isometric contractions. The placement of the electrodes as well as the positioning of the subject are described in protocols in order to get a good reproducibility. During two seconds EMG recordings are made from the main muscles in the leg and the abdominal muscles. The EMG signal is amplified (2500X), filtered (3.2 and 320 Hz, 12 dB/octave) and sampled (1024 Hz) with a 12 bit AD-converter of a LSI 11/03 minicomputer.
Of each recording the amplitude density function (a.d.f.) as well as the power density function (p.d.f.) are estimated. From the a.d.f., which shows normally a Gaussian distribution, the first four order moments are calculated. The most important parameter in this study is the standard deviation.

5.4 The repetitive movement test

This test is described extensively in this proceeding (4). Therefore we will only summarize it briefly. The subject is seated in a special chair with his lower legs hanging freely. EMG electrodes with built in amplifiers are placed on the Rectus femoris and the Semitendinosus muscles. A goniometer is attached around the knee. First EMG recordings are made of both muscles during maximal isometric contraction. Then the lower leg is moved passively in a steady constant way. During the last part of the protocol the subject is asked to move his leg voluntary at different frequencies of movement. Recordings of the two EMG signals and the goniometer signal are made during 6 seconds. The measuring equipment is the same as used for the isometric EMG measurements.

5.6 Video registration

According to a protocol a videotape is made of the patient in his activities of daily living.

RESULTS

As mentioned in the introduction the methods of evaluation will be illustrated with one patient with obstructing spasms in both legs. The patient was a 25 year old boy, with a spastic paraparesis. Before SCS he was able to walk 30 meters with two peroneal nerve stimulators and with two crutches. A clonus in the lower leg was limiting his walking. Directly after stimulation a reduction of spasticity in both legs was to be seen. This influenced the walking pattern in a negative way. Therefore we had to change the cycle duration of the stimulation. Eight months after the implantation the patients walking distance increased upto 500 meters. The peroneal nerve stimulators were not needed anymore. The clonus decreased.

Leg functiontest

From table 2 you see an increasing function in both legs after stimulation. It is also to be seen that after about 5 months the optimal situation is reached and that no further improvement will be expected.

Table 2: Leg function score.

Date	Score: ri	le	total
pre SCS	19	20	39
1 month post SCS	23	25	48
6 weeks post SCS	29	30	59
5 months post SCS	30	31	61
8 months post SCS	30	31	61

Ashworthscore

The tone around the hip/knee and ankle region was seriously high before SCS. Before implantation the added score in both legs was 7. After one month of SCS, the added score was reduced to 3. This means that a light heightened tone has remained.

Surface EMG

We also applied surface EMG in order to see whether there are direct responses to stimulation. Figure 2 shows examples of surface EMG recordings before (2a), during (2b) and directly after (2c) stimulation. It can be seen that there is rather much involuntary activity before stimulation started. During stimulation there are motor responses to the stimulation present in the EMG recordings. Directly after stimulation the amplitudes of the EMG signal show decreased values, indicating less motor unit activity.

The amount of voluntary activity in several muscles of the leg is expressed by the standard deviation of the EMG signal. The percentages given in table 3 are percentages of normal values for these muscles. In this table the EMG results are given before the implantation operation, one month and eight months after implantation. There is an increasing amount of activity in almost all measured muscles. Remarkable is that in the Hamstrings and Gastrocnemius muscles there is a decrease in activity after one month of stimulation.

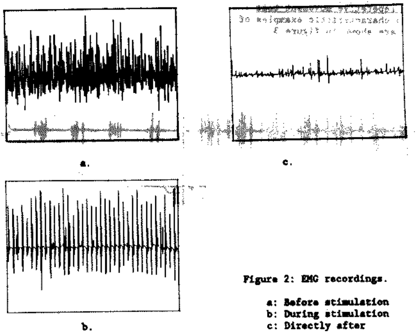

Figure 2: EMG recordings.

a: Before stimulation
b: During stimulation
c: Directly after

Table 3: Percentages of normal values are given before SCS, 1 month after and 8 months after.

Muscle		pre SCS	1 month	8 months
M. Rectus femoris	ri	15%	35%	50%
	le	10%	40%	50%
M. Vastus lateralis	ri	35%	90%	100%
	le	45%	90%	90%
M. Vastus medialis	ri	30%	45%	70%
	le	20%	55%	60%
M. Tibialis anterior	ri	25%	25%	35%
	le	25%	25%	35%
M. Peroneus	ri	10%	10%	15%
	le	10%	19%	15%
M. Hamstrings	ri	25%	10%	25%
	le	10%	10%	35%
M. Gastrocnemius	ri	30%	15%	35%
	le	30%	30%	25%
M. Iliopsoas	ri	30%	60%	70%
	le	40%	70%	85%

The repetative movement test
Some characteristic examples of maximal voluntary movements of the lower leg are shown in figure 3.

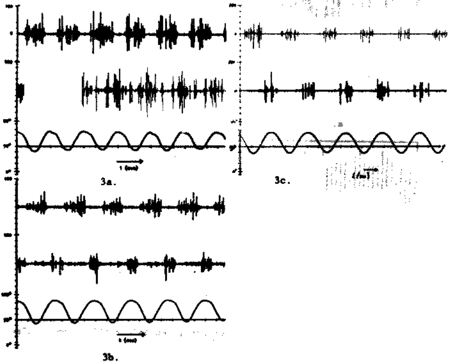

Figure 3: RRM results. EMG recordings of the M.Rectus femoris (upper channel), M. Semitendinosis (middle channel), and goniometer signal (lower channel) in maximal voluntary movements

a: before implantation
b: one month after implantation
c: eight months after implantation

Figure 3a shows the situation before implantation. The most obvious deviation from a normal pattern is the activity of the Semitendinosus during extension. The goniometer signal of figure 3b is much more sinusoidal, reflecting the result of a better control of the movement. This is also seen in the EMG patterns; the different bursts are much more present and apparently no distinct reflex activity occurs.
Figure 3c shows the results after a period of intensive muscle training. The muscles have reached a higher force level, so the subject does not need to recrute as many as motor units as before. This results in a decrease of the amplitude of the EMG signals.

Video registration
On the video registration an improvement of the quality of walking is to be seen. The posture is more upright and the movements of the legs are smoother.

DISCUSSION

An important goal of our research is to obtain procedures and results, which can be transferred to other rehabilitation centres. The most important procedures for clinical application involve the patient selection, operation, training programs and the adjustment of the stimulation parameters.
The procedure we developed to adjust the stimulationparameters takes only little time and gives satisfactory results. Yet research is still needed to get a better understanding of the complex processes elicited by the electrical stimulation. (Model study; Holsheimer, this proceedings)
We paid much attention to the evaluation of the results; both clinical and experimental tests are applied.
Surface EMG is especially suited to quantify the electrical activity of a muscle, but also to study direct responses to spinal cord stimulation. We also apply surface EMG analysis, to study the motor control and reflex activity during repetitive movement. Although the repetitive movement test is still in its experimental stage, the first results indicate that this test is more sensitive to changes in spasticity compared to the Ashworth test.
The procedures that are applied in this study, make it possible to evaluate the effect of SCS in a systematic way. We therefore hope that our study will result in recommandations for the treatment of spasticity by means of SCS.

LITERATURE

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