HILDEBRANDT, J.J. (Munich), VOGEL, A. (Munich), VOSSIUS, G. (Karlsruhe

# FUNCTIONAL STIMULATION OF PARALYTIC MUSCLES BY FULLY IMPLANTABLE ELECTRIC STIMULATORS.*
## PART I: FEASIBILITY CONSIDERATIONS AND DESIGN OF ONE - CHANNEL DEVICES


## SUMMARY

The basic object of the study was to proove the technological feasibility of the production of miniaturised implantable electric stimulators for one- and multiple channel operation with transcutaneous power supply.

A design was developed which meets the requirements as to stimulation-energy and minimum size as well.

Two different types of the one-channel-stimulator were built for test-implantation in animals (rabbits, rats and cats). The animal experiments are accomplished in the Institute for Biocybernetics and Biomedical Techniques of the University of Karlsruhe.

The design of a specific four-channel stimulator has been begun.

As main result, efficient stimulation with the implanted microstimulators could be achieved not only in tissue-layers close to the skin, but in deeper regions as well. Medical applicability of these devices seems to be possible, however extended work especially long duration animal testing is still needed.


## INTRODUCTION

Since more than one decade efforts have been made, especially in Yugoslavia and the USA, to create electrical stimulation systems, which enable patients to, fully or at least in part, regain lost muscle activity. (Lit.)

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Among serval devices for peroneal stimulation, systems for functional stimulation of the hand are existent. Special developments for therapy of dysplastic hip diseases and scoliotic spines are on the way. All these endeavours clearly point to the therapeutic necessity of functional stimulation.

In our country (GFR) a research team of the MESSERSCHMITT-BOELKOW-BLOHM Company in close cooperation with the Institute of BIOCYBERNETICS of the University of Karlsruhe and the OLGA-HOSPITAL in Stuttgart has been starting a project in that field, especially aiming at multilocal stimulation via implantable microstimulators.

## DESIGN CONSIDERATIONS FOR STIMULATION-SYSTEM WITH IMPLANTABLE STIMULATORS

Even the course of a simple movement of the upper or lower extremities requires changing from a gross stimulation which effects rather large muscle groups, e.g. by skin electrodes, to a discriminated multilocal stimulation. Only that way a movement, which is at least approximately a physiologic one, can be made feasible.

Technical prerequisite is the development of miniaturized implantable stimulators, which can be located relatively close to each other at predetermined functional centres. Hence, the requirements are basically:

- easy implantation
- minimum size
- selective operation
- wireless coupling for least burden of the patient

Wireless coupling in this context means not only the transfer of stimulation command but the transcutaneous energy transfer as well. Only electromagnetic waves in the high frequency range come into consideration.

Selective control of the receiving stimulators can be achieved by distinct carrier frequencies or by digital coding.

In consideration of special literature statements and in agreement with the cooperating specialists the following characteristic quantities were established:

- stimulation amplitude $U_{St} \leq 20\ \text{V}$
- stimulation frequency $10\ \text{Hz} \leq f_{St} \leq 50\ \text{Hz}$
- stim. pulse-current $I_{St} \leq 10\ \text{mA}$
- stim. pulse-duration $100\ \mu s \leq t_{St} \leq 1\ \text{ms}$
- distance transmitter-stimulator $d_{St} \leq 8\ \text{cm}$

The parameters: carrier frequency, geometry of the receiving part of the stimulator, shape and material of the stimulation electrodes were first left blanc and were specified lateron during the progress of the project definition phase. The reason is above all, that for optimizing the receiving conditions, some degrees of freedom (frequency, geometry) are required. Furthermore, shape and material of the stimulation electrodes were to be derived from animal experiments.

## REALIZATION OF ONE-CHANNEL MICROSTIMULATORS

For the purpose of definition, test and trial, aiming at multilocal stimulation systems with multi-channel receiving units, first one-channel receivers were designed, manufactured and tested in animal experiments.

As carrier frequency only the short-wave or ultrashort-wave (1 MHZ - 100 MHZ) comes into question.
Longer waves are not favorable on account of the required miniaturization, higher frequencies are to be eliminated because of their parasitic effects.

Operating in the meter-wave range means that the coupling between the signal generating transmitter and the receiving stimulator is purely inductive. From this follows, that the receiving coil is not to be considered as antenna but rather as secondary winding of a very loosely coupled transformer with the primary winding beeing the transmitter coil.

Therefore the transform characteristics can be optimized by:

a) the area enclosed by the secondary coil
b) improvement of the coupling by increasing the permeability
c) arranging the circuitry as resonance transducer
d) increasing the field density
e) proper orientation of primary- and secondary-coil

The requirements a) and b) resulted in two basic realizations of the receiving coil:
One is a disc-shaped coil on top of a miniaturized circular printed circuit board, the other one a spiral-like coil wound on a ferrite core. Presuming approx. equal electric properties the dimensions of the antenna coils are for instance 10 x 1 mm respectively 4.5 x 4 mm (Fig. 1).

FIG 1

IMPLANTABLE STIMULATORS
EXPERIMENTAL MODELS

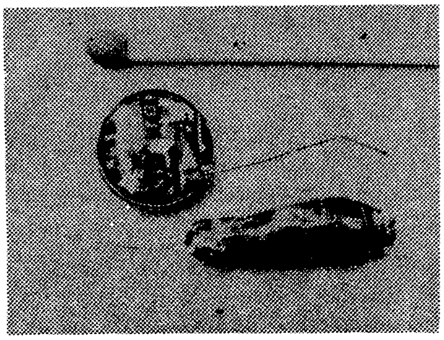
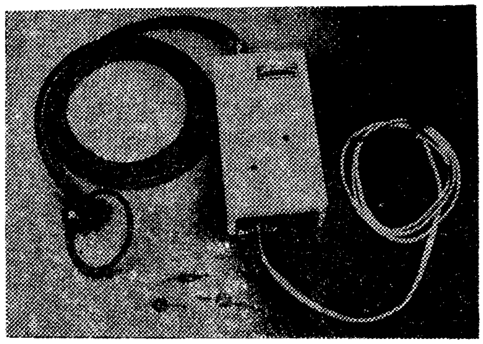


FIG 2

HF-TRANSMITTER
WITH COIL-ANTENNA AND
MINIATURIZED STIMULATORS



This is a first Compromise regarding the required miniaturisation on one hand and the energy to be transferred on the other. The inductivity is about 0.1 µH. By shunting of a capacitor to this coil a resonance transducer is obtained. The capacity C at the given L determines the resonance frequency and hence substantially defines the efficiency of the array. The ohmic conductance $G_o$, which is parallel to the imaginary component $G_i$ is given by:

$$(1) \quad G_o = \omega_R C \cdot \tan \delta_c + \frac{1}{\omega_R L} \cdot \tan \delta_L$$

In order to keep $G_o$ as small as possible one has to try to increase L and to reduce C as much as possible. Since L is given by the geometry and C should not be less than 100 pF for minimizing parasitic capacities, it follows, that the transfer frequency ranges between 20 and 40 MHZ.

The experimental models were designed for operating frequencies of $f_c$ = 28.2 MHZ and $f_d$ = 35.8 MHZ for the cylindrically shaped and for the disc-like receiver respectively.

"Tan $\delta_L$" materially defines the "quality Q", which under the given circumstances can be made as good as about 35, which in turn results in an ohmic resistance of approx. 700 Ohms.

The requirements d) and e) are to be taken into account mainly while developing the sender (Fig. 2).

By the choice of C, L and Q, the selection properties of the receiver are determined simultaneously, because of selectivity as function of circuit quality Q. This is important insofar as variable receivers have to be operated ultimately via discriminate carrier-frequencies. For the stimulation circuitry connected to the receiving unit must therefore be asked, that it does not deteriorate the quality. This is rendered possible by replenishing the consumed stimulation-energy during the stimulation-pause. To this end a capacitor is beeing charged during the stimulation dead-time and consecutively discharged into the tissue (Fig. 3).

In the depicted realization, the stimulation-pulse, i.e., the capacitor discharge is triggered by a short interruption of the HF-signal, thus generating a negative peak of up to -20 V and of ca. o.5 ms duration. Fig. 4 shows the time function of the complete process for one cycle. It can be recognized, that the discharge is followed by a 20 ms-charging interval. While discharging as well as during charging of the capacitor, the current flows through the tissues surrounding the electrodes. By this method, polarization effects can substantially be counteracted.

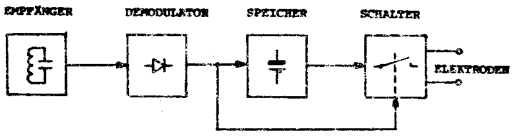



FIG 3 BLOCK-DIAGRAM OF THE IMPLANTABLE STIMULATOR

## EXPERIMENTAL DATA OF THE ONE-CHANNEL STIMULATION SYSTEM

For the described miniature receiver-stimulator a reliable and powerful sender was built, which has a tuned transmitting coil connected to it by a concentric cable (Fig. 2).

HF-Power (max. 3 W) and modulation frequency can be set separately. Fig. 5 displays the family of curves of the stimulation voltage across two electrodes as function of the distance transmitter-receiver with the sender HF-voltage as parameter, for a stimulation frequency of 25 Hz.

The most important feature is the relationship between $U_{stim}$ and the distance d sender - receiver as well as the slope function of the sender voltage.

The upper margin of the stimulation voltage at 14 V is caused by a clamping diode, the lower margin at approx. 5 V is determined by the chosen circuitry. Both margins can be altered in case of need. HF-voltage or HF-power is read in scale divisions. Full deflection (6 sc.d.) equals about 3 watts.

It can be taken from Fig. 5 that up to a distance of 8.5 cm between transmitting coil and stimulator still a stimulation voltage of 5 V can be generated.

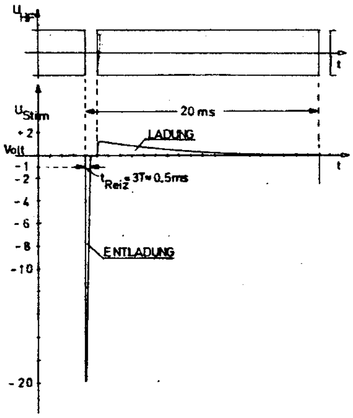



FIG 4 STIMULATION-PULSE
TIME FUNCTION FOR ONE CYCLE

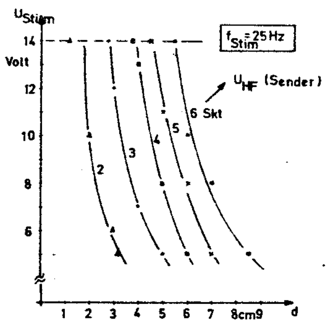



FIG 5 FAMILY OF CURVES
OF THE ONE-CHANNEL STIMULATOR

CONCLUSIONS AND PREVIEW

Various design concepts and correlating laboratory experiments led to a circuit design by which the energy conditions as well as those regarding miniaturization could largely be satisfied with minimum complexity of the system.

As an upper stimulation frequency of about 50 Hz with a duration of < .5 ms is deemed to be reasonable from a phyciological point of view the submitted concept utilizes the low on/off ratio of .5 ms/20 ms equal to 1:40 for energy storage within the miniature receiver during the stimulation pause. The stimulation pulse is then triggered by a signal of the same transmitter which transfers the energy to the stimulator. Stimulation frequency and amplitude are adjustable from the side of the sender, whereas the pulse shape is an inherent characteristic of the receiver.

Two different types of stimulators were built for initial laboratory tests and animal experiments: a disc-like finish of ca. 10 mm diameter and a cylindrically shaped receiver of ca. 5 mm length and of ca. 16 mm in diameter. Further miniaturization is possible by use of more expensive production processes for the electronic circuitry.

By means of a HF-transmitter, having an output of 3 W, a stimulation pulse of max. 20 V can be generated at a distance of up to four cm, while a voltage of max. 5 V can be achieved at a distance of approx. 8.5 cm. The half-width of the stimulation pulse is ca. 200 µs across a load of approx. 300 ohms.

Following the development of the one-channel system, design considerations and bread-board experiments for a four-channel system have been carried out. So far it has been apparent, that digital coding of the discriminate stimulators certainly would be simpler on the side of the sender, however miniaturization of the receiver could only be accomplished by much greater complexity. Therefore the next step will be the design of a 4-channel functional model, operating on four distinct carrier frequencies, which then will be tested in animal experiments, by the Institute of Biocybernetics and Biomedical Techniques of the University of Karlsruhe.

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