CONCEPT AND REALIZATION OF IMPLANTABLE MULTICHANNEL STIMULATION-DEVICES AND THEIR EXTRACORPORAL CONTROL

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Summary

At the 8th Symposium on ECHE experiences in clinic application of multichannel stimulation devices for paraplegic patients were presented. Meanwhile these experiences proofed the principle function of chronic functional electro stimulation but also the demand for an expanded system allowing to stimulate more muscle groups (at present 4 muscles can be activated via 4 electrodes each using two implants). By means of the expanded unit we hope to achieve more natural walking as well as climbing steps.
Because of the complexity of electronic design of the implant (all parameters must be continuously controllable on-line by means of telemetry) and to simplify design and to increase reliability and capabilities of the implant we developed an 'all-purpose' semi-custom integrated circuit meeting almost any stimulation strategy to stimulate up to 16 nerves via five electrodes each.
It is self-evident that programing and controlling of such sophisticated implants demand special computerized tools for rationalized handling even for technically non-trained physicians. 'Intelligence' of the extracorporal control was splitted in two parts: A CMOS microcomputer (80C51) with 32kB EPROM and 32 kB RAM holds all programs and motion-patterns which must be recallable by the paraplegic himself at any time (using a minimum of control knobs). This microcomputer is packed into a belt and worn by the patient. An IBM-PC helps to program the motion-patterns and other

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stimulation parameters of the belt-computer interactively. If necessary this also can be done remotely using a telephone-modem. The whole system is tested in animal experiments and simulations and will be basis for approaching further human applications.

Development of an 'all-purpose' integrated circuit for implants

At present our implants used for mobilization of paraplegic patients as well as phrenic nerve stimulation ('lung pacemaker') are able to stimulate via 8 electrodes each, i.e. the implants have 8 outputs which can be activated independently /1/. All stimulation parameters (polarity, stimulation current, impulse width and frequency and electrode combination) can be adjusted in real time preceding each stimulation impulse. Information transmission as well as energy transmission is done by means of a transmission coil located extracorporally over the implant. So a maximum of flexibility is given. But there are two main disadvantages of the implant design:

a) electronic of the implants is very complicated, that is it consists many components, so the implants must be fabricated in thinfilm hybrid technology to achieve reasonable small dimensions, and
b) only 8 outputs are available with one implant. Because we are using multiple electrode nerve stimulation ('round-about electrode' /2/) only two nerves can be stimulated by one implant via 4 electrodes each.

Consequently for the first human application for lower extremity stimulation two implants were used to stimulate the n.femoralis (innervating the m.quadriceps) and the n.gluteus inferior (m.gluteus maximus) on both sides. This allowed the patients to stand up in an arbitrary manner and to walk short distances on flat ground. But further mobility was restricted especially because no flexion muscles could be stimulated. Therefore extended implants are required.

As far as stimulation of the phrenic nerve is concerned the ability of the 8-channel implant is sufficient but simpler technology would be favorable.

As a consequence we decided to develop a customized integrated circuit especially dedicated the requirements of implantable stimulation units.

There are several concepts to stimulate an extended number of nerves (4 to 16) via 4 or 5 electrodes each.

a) spread implants stimulating only one nerve, located near the electrode - nerve connections,
b) one or two implants supplying all the electrodes,
c) a master-slave system consisting of one central implant, the 'master', connected to several spready implants, the 'slaves', which supply two nerves via 5 electrodes each

Using spread implants demands complicated and less effective coupling to the extracorporal supply unit, which requires either several transmission coils or one extended coil. The central concept of one or two implants cannot be maintained because of the concentration of electrode leads near the implant. So we decided to aim at the master-slave system which represents a good compromise. The advantages of such a solution are manifold. There is no unacceptable concentration of leads; in case of failure it is likely that only a part of the implanted system has to be replaced and there is less body tissue irritation because of smaller size of the different components.

Especially for the slave implants which have to reproduced in higher number of pieces a single chip solution for the electronic part is advantageous.

Consequently in 1984 we developed a gate-array integrated circuit using a Monochip MCC produced by Interdesign, Ferranti. This chip offers a complexity of 270 gates allowing to integrate the whole circuit except some capacitors and time-constant influencing resistors on one chip. Electrical connection to the master is done by a three-core cable of the ground lead, an analog signal, carrying the stimulation current and a digital data line.

Although the chip was primary designed for slave implants the chip also can be used in a central implant. Such a device was realized as an interim solution. Fig.1 shows a hybrid circuit of a 20-channel implant using two gate arrays. It has to be realized that a lot of other components are necessary to drive the 'slave-chips'. These electronics would be necessary in the 'master'-implant, when a master-slave-system is realized. For further simplification of the electronic circuit development of a second customized IC was drawn into consideration. Because of technological progress and cost reductions which meanwhile had taken place it turned out, that the second chip could be designed for multi-purpose applications. So the Ferranti-chip even becomes superfluous.

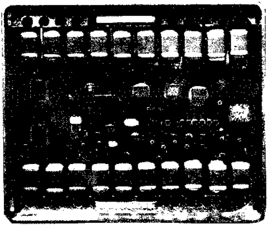

Figure 1:
Hybrid circuit of a 20-channel implant using two gate arrays

Modes of the gate array chip, technical description

The gate array chosen consists of 840 N- and P-channel array transistors. Circuit design and breadboard assembling was done in own laboratories, while integration and production of the gate array was done by the Swiss company 'Crossmos'.

One Chip is able to supply 10 electrodes in two groups of 5 electrodes each. Stimulation current can be up to 10mA. Each output can be switched to ground (neg. polarity), to a current source (pos. polarity) or can be switched off (floating).

Mono- or biphasic stimulation impulses can be selected, chopping (high frequency invertion) of the stimulation impulses is provided too.

Because the chip is produced in CMOS-technology supply voltage can be 3-18 volts, while supply current is negligible. The chip consists of all stages to encode serially transmitted information which is modulated on a high-frequency carrier for energy supply of the implant. According the operating mode of the chip information is transmitted using an impulse train with up to 24 bits. The interval between two successive blankings of the RF-carrier determines the logical state of bit ()50 microsec. = HIGH, (15 microsec. = LOW).

The chip can be operated in 3 modes (which are selectable by hardware programming of mode-inputs):

a) Single-chip stimulator with 2x5 outputs: beside two RC-time constants and capacitors for DC-decoupling of the outputs, a digitally controlled voltage or current source determining the amplitude of the stimulation impulse has to be added. Usually we are using constant current stimulation. The current source is controlled by 8 bits via a R-2R-network. The external R-2R-network is driven directly by 8 tri-state outputs of the gate array.

Three bits of the serial information are an address which has to match a hardware wired address of the stimulator to enable operation. So up to eight single-chip stimulator units can be paralleled supplied by one receiving coil, sharing even the digitally controlled current or voltage source if applicable.

b) The gate array fulfills the tasks of a 'master'-implant. Up to eight 'slave'-implants can be connected to one master, which acts as a multiplexer of the serial data train.

c) The gate array acts as a 'slave' which is supplied by a 'master'. The output characteristics are equal to the single-chip stimulation unit.

Additionally there are provisions to connect the gate array to a single-chip microcontroller in cases where the implant has to work autonomously. On-chip level converters allow the gate array to be supplied with for instance 15 volts (necessary for stimulation), while the microcontroller is supplied with lowest voltage for least power consumption.

For test applications the gate array is bonded on a small printed circuit board (18x15mm). Fig.2 shows a test assembly of a 10-

channel single chip implant. It is planned to use thickfilm technology for implants for clinical use.

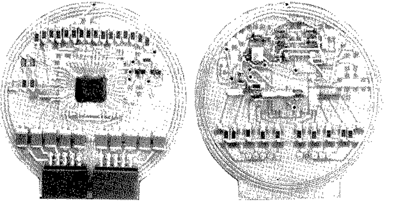

Figure 2:
Test assembly of a 10-channel single chip implant.

Extracorporal control of multi-channel implants
Using two 8-channel implants (stimulating four nerves) time management of activation was rather uncritical. In fact the four functions just had to be switched on or off, which could be done by means of switches mounted in crutches. Using more different muscles which can be stimulated we expect much more difficult strategies for proper movement. So we changed the control mechanisms: each the stimulation strength intensity for each nerve (muscle) cannot be controlled by the patient individually in a direct way, but the patient can select movement patterns which are prepared and stored in the extracorporal supply unit. These patterns can be for instance: right (left) step forward, stand up, sit down, step up, step down and so on.
The patterns are different for each subject and have to be acquired individually in course of the training period of each patient. The number of control knobs of the supply unit is restricted to an ON/OFF-switch and an analog joystick (variable

resistor) for each movement pattern to control the execution speed.
A prototype of such an extracorporal supply unit is shown in figure 3. It is small enough to be fixed to a belt.

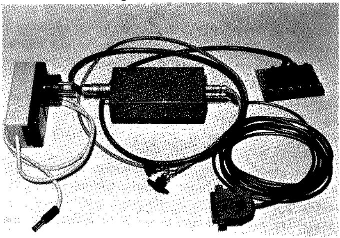

Figure 3:
Prototype of an extracorporal supply unit.

The electronics consists of a 80C31 microcontroller, a 32kByte EPROM, 32 kByte CMOS-RAM (battery buffered), an 8-channel 8-bit A/D-converter and is powered by a rechargeable battery. Programming of the stimulation pattern and various parameters is done via a serial RS-232 connection to an IBM-PC.
Beside the main task of the supply unit, that is to control the implants, also other tasks accomplished. There are various modes of operation:
a) 'selection'-mode: different stimulation parameters can be selected via the PC and can be checked and rated according their efficiency of movement. In detail for each nerve the following parameters can be fixed for later use for the movement patterns:
Efficient electrode combinations (using 5 electrodes for one nerve there are 179 different combinations),
mono- or biphasic stimulation impulses,
variation of impulse-duration or -amplitude,

min. and max. value of duration and amplitude respectively and stimulation frequency.

b) 'learn'-mode: the analog inputs of the supply unit are connected to position sensors of a goniometer which is worn by an assistant. Movements of the assistant are directly converted to stimulation impulses causing similar movements of the patient. Differences can be corrected immediately by adequate reaction of the assistant. The stimulation patterns are recorded in the supply unit, can be replayed and corrected. If found useful the patterns remain stored in the CMOS RAM.

c) 'training'-mode: during the training phase, when hypotrphied muscles are strengthened again, the supply unit is used as a training aid. Periodically preprogrammed training impulse trains are repeated.

d) 'normal'-mode: that is the standard operational mode. The patient can use the stored stimulation patterns for arbitrary movements.

The assisting communication program is written in dBase which is very useful to store great amounts of data. Serial communication is done by means of an additional background program which is written in assembler.

To facilitate adaptation of stimulation patterns an additional software support is given by means of a 'pattern-editor'. The course of stimulation train of a stored pattern is displayed graphically and can be altered interactively.

Great care was taken to allow technically untrained staff to understand and to operate the software packages for programming the extracorporal supply unit.

Conclusion:

The development of a special gate array integrated circuit dedicated for implantable multi-channel stimulators as well an extracorporal supply unit with various capabilities offers the basics for a new generation for implants for functional electrostimulation for paraplegic patients. After finishing further developments concerning sealing technologies we are hopeful to use the system in clinic applications soon.

Literature:

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/2/ H Thoma, J.Holle, E.Moritz, H.Stoehr: "Walking after Paraplegia - a principle concept", 6.Intern. Symp. on External Control of Human Extremities, Dubrovnik 1978