ABSTRACT

Description of a sixteen-channel FES implantable system

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Introduction

The paper describes an implantable FES system, presents the results obtained during animal experiments and with the first paraplegic patient operated, and finally, related to these experiments, discusses the relevance of the technical options taken.

Materials and methods

The SUAW European project aimed at restoring in paraplegics standing up and short way walking, by implanted FES. The muscles' choice decided by the medical staff to reach this purpose, implies the use of both epimysial and neural stimulation types. Then, important challenges were to be faced : high level, monopolar currents on epimysial channels ; and very low level, bipolar currents on neural channels. The first specifications of the implant were based on literature i.e. : 20mA (1.5kΩ, epimysial channels), 2.5mA (2.5kΩ, neural channels). During the development we decided to go up to 25mA and 3mA respectively, and for security reasons, to keep these maximum values. The last challenge was to design a flexible implant where the ratio of epimysial versus neural channels could be fixed by hardware, during the very last phase of design : the PCB drawing.

Results

An ASIC and an original architecture were developed through several versions. Finally, the coexistence of neural and epimysial electrodes, with some special cares, is successful. The results obtained in vitro, on animal experiments and on the first patient implanted show that the high levels of current were needed on some big muscles to get a functional contraction. Moreover, measurements show an increase of stimulation thresholds above time, probably due to not only the increase of impedance, moderate on most muscles, but also to the distance and diffusion increases between electrodes and muscles ; both phenomena mainly induced by fibrosis. As regards the muscle's contraction evaluation and standing up achieved with the patient, we conclude that main challenges were taken up.

Description of a Sixteen-Channel FES Implantable System

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Abstract - *The SUAW European project aimed at restoring standing up and short distance walking in paraplegics by implanted FES. The muscles chosen by the medical staff to reach this purpose implies the use of both epimysial and neural stimulation types. Then, important challenges were to be faced: high level, monopolar currents on epimysial channels; and very low level, bipolar currents on neural channels. An ASIC and an original architecture were developed through several versions. The flexibility of the implant allows the choice of the ratio of neural versus epimysial outputs at the very last phase of design: the PCB drawing. Finally, the coexistence of neural and epimysial electrodes, with some special cares, is successful. As regards the evaluation of the muscle's contraction and the standing position achieved with the patient, we conclude that main challenges were taken up.*

Keywords: Implant, FES, neural stimulation, epimysial stimulation.

1 Introduction

Several studies have been carried out to restore movements of the lower limbs in paraplegics. The pure biological solutions can not yet be used, so the FES appears to be the best one in a short term. Among FES systems, multiple configurations exist. This allows choosing different solutions from one patient to another. Acceptable performances can be obtained using surface stimulation combined or not with orthosis. However most of time, patients get rid of the system because of the complexity of bringing into play. Therefore, implanted stimulation seems to be interesting, avoiding complex implementation by the patient, offering similar results as surface stimulation can do. The surgery remains quite heavy and this appears to be the main problem with this solution. For more than fifteen years, several teams have tried to achieve implanted FES using different ways to stimulate muscles. Three main methods are currently being researched: epimysial stimulation, neural stimulation and stimulation of the neural roots [3, 4, 7]. Some common problems stand out such as HF transmission for both data and energy, integration of the implant, electrodes wires and connections, … Each technology offers interesting characteristics that can be optimally applied depending on the muscle and the associated action desired.

2 Materials and Methods

2.1 Specifications

In the SUAW project, the aim was to restore standing and short distance walking in complete paraplegics (T9-T11). The surgical and rehabilitation team [2] chose a set of twelve muscles stimulated by both epimysial and neural electrodes: eight and four channels respectively. Kobetic et al. [6] deals with such a problem. This configuration will not be discussed there, but only the consequences on the implant design. The first basic specifications were based on literature from almost all the teams working in this field in the world. They are summarised in table 1. Owing to the floating output, the neural channels can deliver cathodic or anodic current with mono, bi or tripolar electrode. On epimysial channels, the monopolar output can only generate the active current from the references (+) to the epimysial electrode (-).

Type	*Intensity*	*Pulsewidth*	*Max load*	*Polarity*
epimysial	20mA	1000µs	1.5k	Monopolar
neural	2.5mA	1000µs	2.5k	Bipolar

Table 1: first implant specifications

During the development, it was decided to enhance characteristics regarding intensity range. For security reasons, 25mA and 3.1mA were fixed for the final implant. At the very beginning of the project the number and the ratio of epimysial versus neural channels were not precisely defined. It was then decided to produce a hardware and software configurable implant where this ratio can be fixed at the very last phase of design: the PCB drawing. Several prototype versions were developed and tested in vitro to finally obtain the architecture described in figure 1.

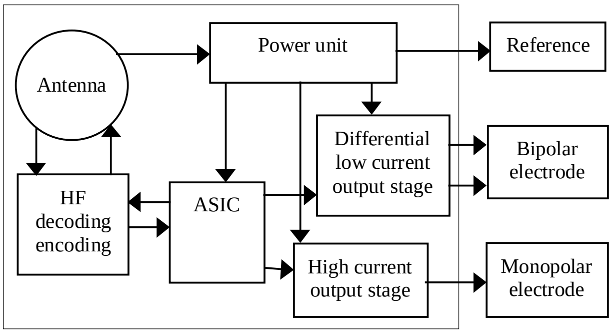

Figure 1 : implant synoptic

The ASIC developed by IBM France, manages the HF data decoding (reception) encoding (transmission) using Manchester code. The ASIC monitors the implant power so as to optimise the HF power transmission. It provides current sources and multiplex signals. Two different current sources allow configuring each of the sixteen channels as epimysial or neural outputs. The pulsewidth is fixed directly by a continuous HF window, but hardware limited to 1ms for security reasons. The intensity is digitally controlled allowing a fine-tuning of each channel parameters. Table 2 gives a global description of the available implant characteristics, with the ranges of parameter variations. The maximum available frequency depends on the number of channels simultaneously used.

	Typ.	*Max.*	*Step*
Channels	Nneul+Nepi=16	-	-
I neural	2mA	3.1mA (3k)	50µA
I epimysial	10mA	20mA (1.5k) 25.5mA (1k)	100µA
Pulsewidth	10µs min, 300µs	1ms	Continuous
Frequency	25Hz	500Hz, N=1 30 Hz, N=16	Continuous

Table 2: implant final characteristics.

The ASIC is able to send back information to the external system. Two types of data can be returned: the level of the stored power, and the open circuit detection on each channel. The pulse (figure 2) is a classical biphasic exponential waveform, with a hardware configurable delay, fixed to 180µs. This delay minimise the negative effect of the second recovery pulse as regard stimulation efficiency.

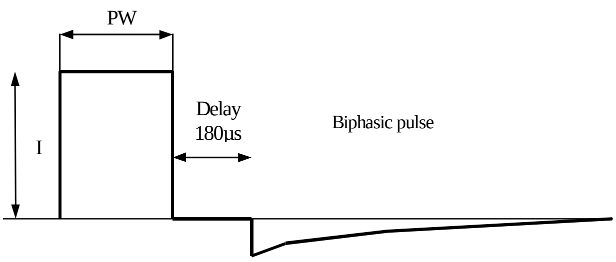

Figure 2: pulse waveform of neural and epimysial outputs.

The current spike at the beginning of the recovery phase is about one tenth of the active stimulation current depending on the load. The rise time is less than 10µs at maximum current.

2.2 Encapsulation

MXM Company directed the PCB drawing, electronic integration including the CSP packaging of the ASIC. Their know how in the implant technology is now internationally recognised through the development and manufacturing of cochlear implant. Moreover, they have agreements and more than ten years of successful implantations. For these reasons we decided to take the same proven technology for encapsulation: a ceramic box protected by silicon. The connectors to the electrode wires are placed on both sides of the implant as shown on figure 3. For the SUAW project, the needed configuration consists of four neural channels and twelve epimysial channels. This implies eight connectors for the neural channels and twelve plus two references for the epimysial ones. The external dimension are about five by eleven centimetres.

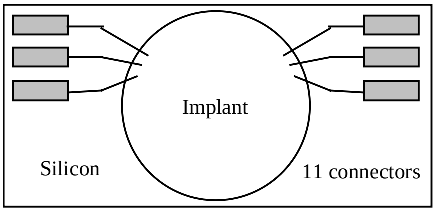

Figure 3: implant shape

Connectors are plugged and screwed in. The mechanical part of the implant was designed with concerns of both the comfort for the patient and reliability of cables and connectors. Finally, we have tried to pay attention to every part of the implant to guarantee the best compromise between efficiency, comfort for the surgeons and the patient, and reliability. Long term follow-up will give us the necessary feedback to enhance the whole system.

2.3 External programmer

As for the majority of implants, the "intelligent part" is outside the body. It allows easy updating and tuning. A bi-microprocessor architecture, with a master 16bits CPU and a slave risk CPU, was designed for its flexibility, reliability, low power consumption (less than 400mW), and its size (about the dimension of a credit card). The HF amplifier is on another card to limit EM disturbance. The external antenna is included in a belt, closed to the implant antenna (less than three centimetres through the skin). The main board also has eight analogue input to allow closed loop control. The resolution is ten bits, with a maximum sampling frequency of 16kHz. Oversampling, digital low pass filtering and rectifying are also included. This allows extracting the low frequency band of complex signals: for instance accelerometers can be used as inclinometers, and the envelope of the EMG can become input instead of the raw signal. Some basic closed loop control algorithms are currently studied on both external and implanted FES systems. The same architecture was used to develop an eight-channel surface stimulator, EC labelled, Prostim ®. Both systems can be PC controlled via an opto-coupled serial link. They can also run on batteries without PC. Almost the same parameters are available, even if the surface stimulator is more flexible. The aim of this product is to train and evaluate the patient before implantation. Algorithms can be adjusted, and the rehabilitation doctor will use the same software interface with automatic data transfer and scaling, while the patient will use the implant. Even if parameters can vary in a larger range, it's important to keep the same environment to be more efficient. This phase is important and systems are described in [1, 5].

3 Results and Discussion

The experiments carried out on pigs show that the use of both neural and epimysial stimulation at the same time is possible, but special care must be taken during the surgical phase. The functionality was proven on animals but the level of the stimulation could not be properly tested. Indeed, at 10mA on the epimysial channels, the contraction was very strong; thus it was not possible to go beyond. The same problem occurs on neural channels with full stimulation obtained at 1mA.

The first patient was implanted with four neural channels, and eight epimysial channels. About five months after the surgery, most functional stimulation levels are above 20mA with 300-500µs. The results on neural channels showed that 3mA are also required on one muscle. Fibrosis can probably explain the increase of all the stimulation levels, but the real effect of fibrosis is actually explored.

This paper focuses on the very technical part of the project, and draw the first assessments. It can not describe all the aspects of the project. Surgical protocol evaluation, electrode behaviour, gait and standing up algorithms, and the complete analysis of the whole system will be discussed later through other publications. Nevertheless, we conclude that the use of both epimysial and neural stimulation is possible and even desirable. The disadvantages of each stimulation type must be taken into account regarding in which way the muscle will be used. For instance, muscles that need a strong and short contraction without fine graduation, can be stimulated through neural type stimulation: the energy yield is much better. Other muscles may need gradual stimulation, longer stimulation time, and then epimysial stimulation could be the best solution. These are only two simple instances showing that the choice is conducted by many parameters. They are not only directly linked to the muscle's performance but also linked to the final use of the muscle, the complexity of the placement of the electrodes and so on … The current levels need to be up to 25mA and 3mA respectively, but we can not go beyond without wondering about security.

Actually he can stand up and an important rehabilitation period must be completed before testing gait algorithms. Some important issues remain and the patient must be followed for a long term to conclude that this project is a success. Mainly, we will observe the reliability of the whole system including electronics, electrodes and muscle evolution. Besides, we do not know precisely which parameters are patient dependant or not. It is also quite difficult to evaluate on one patient, the impact of the surgery phase on the global performance of the system. The comparison with the work done through other teams could be interesting for all of us working in the implanted FES field, because of the little number of implanted persons. With our experience and with the progress expected in electronics, we hope to optimise and improve the implant, particularly regarding energy yield.

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