# ONE YEAR IMPLANTED PATIENTS FOLLOW UP: SUAW PROJECT FIRST RESULTS


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## Abstract

Two patients were implanted with a sixteen channel neural/epimysial stimulator under the European SUAW project. Restoring standing up and short distance walking in paraplegics are the two main objectives. One year after the implantation, the first patient is able to achieve both movements with acceptable performances. During this year the system functioning and stimulation parameters were monitored. The very first results obtained with no statistic relevance, indicate tendencies and are close to the ones found in literature. The mix of both types of stimulation is possible and suitable. It provides a new set of useful data for the next generation of implantable FES systems. The experiment must be extended to a larger set of patients that have to be monitored on a longer period to confirm or not the validity of the strategy used.


## Introduction

Implanted FES systems are currently used for upper limb movement restoration, but for the lower limbs, several solutions are still being evaluated through different laboratories. For more than fifteen years, several teams have tried to achieve implanted FES using different ways to stimulate muscles: epimysial stimulation, neural stimulation and stimulation of the neural roots [4, 5, 8]. None of these methods has proved to be the best one so that each has to be deeply explored. The SUAW project aims at using both epimysial and neural stimulation types, trying to get the advantages of both. Two patients were implanted (September 1999 and June 2000) with the same implant but with different electrode configurations. The first results and conclusion can then be drawn and this paper attempts to cover the most important and consistent results.

In the SUAW project, the aim was to restore short distance walking and standing in complete paraplegics. Based on literature and preliminary surface stimulation experiences, the surgical and rehabilitation team chose a set of muscles stimulated by both epimysial and neural electrodes [2, 3, 7].

## Materials

*Implantable system*

As we want to manage both epimysial and neural stimulation types, the system was initially designed to be configurable in both by splitting the sixteen available channels in two parts. This operation takes place at the very last phase of integration on the PCB drawing. The system is therefore quite flexible, and different implant configurations can be easily developed. For the first two patients it was decided to provide four neural channels, and twelve epimysial ones with two references. This means that eight wires for the neural, and fourteen wires for the epimysial channels are needed. The characteristics of the SUAW implant are summarised in table 1. Much more precise hardware characteristics are described in [1].

| | *Typ.* | *Max.* | *Step* |
|---|---|---|---|
| Channels | | 4 neural + 12 epimysial | |
| I neural | 2mA | 3.1mA (3kΩ) | 50µA |
| I epimysial | 10mA | 20mA (1.5kΩ)<br>25.5mA (1kΩ) | 100µA |
| Pulse width | 300µs | 1ms | Continuous |
| Frequency | 25Hz | 30 Hz | Continuous |

Table 1: typical implant characteristics.

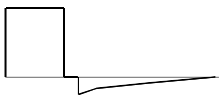

Figure 2: pulse waveform of neural and epimysial outputs: biphasic pulses with exponential recovery phase.

The implant is also able to send back pieces of information such as open circuit detection and internal power supply level. The size is approximately 11x5x1.5cm. The electronic is packaged in a ceramic box so that the HF antenna can be integrated in the implant itself avoiding extra connections. The implant box is located above the umbilicus to prevent it from migrating.

*Control software and external part*

Power and data are transmitted through HF link. The implant receives the stimulus parameters, intensity, channel, and pulse width, and then generates the corresponding pulse. A biprocessor architecture is now available to develop the external programmer: a very compact and flexible control unit about the size of a credit card. The power consumption of this board is about 350mW. The HF module is currently redesigned for enhanced performance, particularly regarding output transmission power efficiency. The complete system synoptic is given on figure 3.

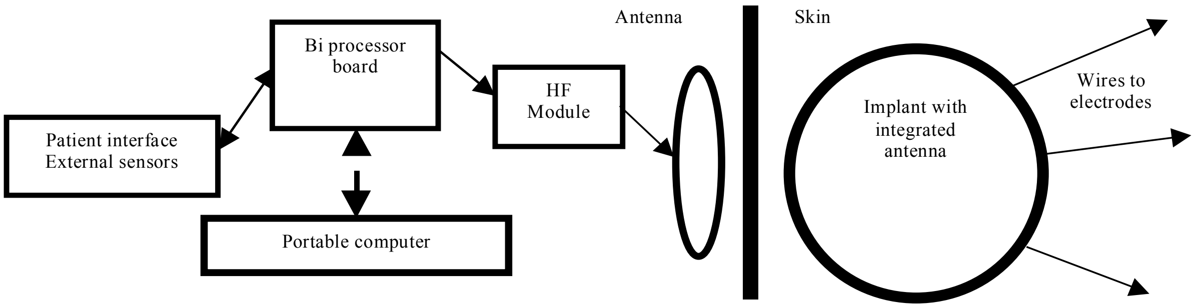


Figure 3: SUAW system synoptic

For the first trials, only open loop movements are used, even if some closed loop control systems were used previous to the implantation with surface stimulation. A PC software allows the physiotherapist to program sequences of stimulation on each muscle with trapezoidal amplitude shapes. Intensity or pulse width can be the variable parameter and then the other is fixed at a predefined value for each muscle. The stimulation frequency is common to the sixteen channels but will be independent on the next software release. The biprocessor board is able to keep all these patterns in flash memory, and then the system becomes autonomous without any connection to a PC.

## Methods

| | *Patient A* | *Patient B* |
|---|---|---|
| Age, country | 39, French | 30, Italian |
| Sex | Male | Male |
| Surgery | 28.09.1999 | 26.06.2000 |
| Lesion | T8 | T5-T6 |
| Muscles | *Neural ch.* | *Neural ch.* |
| 1 | foot drop | foot drop |
| 2 | quadriceps | quadriceps |
| | *Epimysial ch* | *Epimysial ch.* |
| 3 | gluteus maximus | gluteus maximus |
| 4 | gluteus medius | gluteus medius |
| 5 | illiacus | illiacus |
| 6 | hamstrings | semi membranosis |
| 7 | *none* | biceps |
| Training | 3 times a week, 1 hour, from March to July 2000.<br>1 time a week, 2 hours, from September 2000 | 2 times a day from September 2000 |

Table 4: patient profile

The table 4 shows the patient profiles decided by the medical team. Some epimysial channels remain unused. The patients were regularly trained and the patient A was able to stand up from nearly the beginning of training. As regards patient A walking, the stimulation patterns are defined so as to achieve the following sequence of movements : standing, swinging phase of one leg, standing. The patient controls with push buttons the right or the left step. Physiotherapists chose the intensity for the control parameter, and it is increased regularly during the session for compensating fatigue.

## Results

On the patient A technical problems occurred on the implant itself but the overall design was not in question. In March 2000 the patient was operated again in order to replace only the implant. Since then, no technical problem has arisen on either patient.

*Stimulation performances*

Patient A is able to stand and walk, and patient B is still under training. Two parameters are currently monitored: the intensity thresholds, and the intensity levels needed to obtain the desired movement. Force measurements were also done but are not presented in this paper. A sample of the results are given in tables 5 and 6. Only results on one neural channel (femoral nerve for quadriceps activation) and one epimysial channel (gluteus maximus) are presented.

| *Dates* | *26.06.2000, PW=250µs* | *21.11.2000 PW=300µs* |
|---|---|---|
| Left quadriceps | 100µA | 450µA |
| Right quadriceps | 100µA | 600µA |
| Left gluteus | 2mA | 18mA |
| Right gluteus | 3mA | 6mA |

Table 5: Patient B stimulation thresholds, common stimulation frequency 20Hz.

| *Dates* | *14.03.2000* | *18.04.2000* |
|---|---|---|
| Left Q. | 2.55mA, 520µs | 2.6mA,600µs |
| Right Q. | 2.9mA, 300µs | 2.4mA,600µs |
| Left G. | 20mA,300µs | 25mA,300µs |
| Right G. | 20mA,300µs | 25mA,500µs |
| Standing/ rest | 3x3min/5min | 15min/5min, 10min/5min |

Table 6: patient A standing parameters, values at the end of the sessions, with 31Hz common stimulation frequency.

On both patients, the thresholds increase with time, reflecting well known phenomena, among them fibrosis. The same qualitative evolution can be observed on all the channels. On one hand, the level of intensity needed for functioning at the beginning of the sessions decreased with time. The training process can easily explain the improvement of muscle performances. On the other hand, the values at the end of the sessions have increased.

Concerning the movement achieved, the patient B did not try to stand up, only training is in process. For the patient A both standing and walking have been performed. Patient A is now able to stand more than thirty minutes without too much fatigue. Patient A began walking performance on April 2000. He is now able to walk in the lab on a four meters long pathway for two hours, with five minutes of rest at each end of the pathway. Actually, the patient goes two hours each week to the centre, and will soon use the autonomous system. Sequence and muscle parameters during walking will be presented during the session, nevertheless, the maximum values used are close to the ones found during standing.

## Discussion

From a qualitative point of view, we have demonstrated that both stimulation types in the same implanted system are possible. The opportunity of choosing neural or epimysial stimulation types provides a great variety of configurations well adapted to each patient. On one hand, neural channels give a high efficiency contraction well suited for the quadriceps and an important enhancement of the walking scheme with the foot drop stimulation. On the other hand, epimysial stimulation is still needed on large muscles like glutei where the placement of a neural electrode is very difficult. The ergonomic aspect of the system is really improved compared to classical surface stimulation devices, and an increase in performance is a partial consequence. The more frequently the system is used, the more the muscle's reaction is improved. The next step foreseen for 2001 is to provide to the patient a complete autonomous system to use at home.

From a quantitative point of view, results show that while thresholds increase, the performance of the muscles does too. The result is that the control range is not large. The phenomenon is higher on neural stimulation. Nevertheless neural stimulation provides a higher stimulation efficiency but is less easy to control. In an open loop system a fine control of the muscle's contraction is not really needed. Closed loop control will give assessment about fine control through neural stimulation. Fatigue resistance increases so that the duration of walking and standing drastically changes. More than thirty minutes of standing and up to two hours of walking with short periods of rest, provide sufficient autonomy to now let the patient use the system at home.

The implant is versatile thanks to its sixteen mixed channels but the surgery remains heavy. Not all the patients are ready to accept this so that surface stimulation and orthotic devices remain good solutions for some paraplegics. Implanted FES can greatly be improved and the different experiences carried out through different teams can not yet settle the best strategy to use. Waiting for the pure biological solutions, implanted FES seems to be the best alternative in the near future.

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