

# A new implantable wireless microsystem to induce mictrition in spinal injury patients

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**Abstract**— This paper presents a new wireless microsystem for use in urology. This microsystem is composed by two parts: the electrostimulation and the radio-frequency (RF) subsystems. The electrostimulation part is a silicon box with groves to pass the nerves to be stimulated. Above the stimulation box is putted a cover containing electrodes to do the electrical contacts with the nerves. Using wafer-level packaging (WLP) techniques the RF and the electrostimulation parts are joined together. This implantable microsystem allows the reception of RF signals with user commands to activate the micturition function and the penian erection (on males) patients. The microsystem has an expected area of 5x5 mm<sup>2</sup>.

## I. INTRODUCTION

Invasive and implantable biomedical devices used for diagnostic and therapy, ranging from neural prosthesis to video-capsule endoscopy systems, are emerging innovative technologies and they are expected to originate significant business activity in the near future. The success of such systems is in part due to the advent of microtechnologies, which made possible the miniaturisation of several sensors and actuators, as well their integration with readout and communication electronics. Several people from all ages suffer from incontinence or other urinary pathologies. The bladder and the intestines perform their function in an autonomous way, independtly from the individual will. However, any disorder in the healthy behaviour leads to the problem of urinary incontinence, bladder infections, low bladder capability and fecal incontineny.

Electrical stimulation of nerves and muscle is a time honored approach to the treatment of urinary incontinence and induce male erection. The use of implantable neuroprosthetics in the field of urology remains a new frontier [1]. In patients with suprasacral spinal cord injury, electrical stimulation of the sacral anterior nerve roots can produce micturition with low residual volumes of urine and reduced urinary tract infection. Voiding pressures can be maintained at acceptable levels by selective peripheral neurotomy and myotomy or, more commonly, by an intermittent pattern of stimulation. Occasionally, external sphincterotomy is required. The procedure is usually combined with division of the sacral posterior roots, which increases bladder capacity and continence; this also increases bladder compliance, which may be protective for the upper urinary tracts. A reduction in constipation usually is observed, and some patients are able to defecate with the aid of electrical stimulation. Penile erection is produced in a substantial proportion of male patients. The

procedure has now been applied in about 700 patients with spinal cord injury, some of whom have been followed for nearly 15 years. The nerves do not appear to be damaged by long-term stimulation, and technical faults with the equipment are now uncommon [2].

This paper presents an implantable wireless microsystem to stimulate three nerves of the vertebral column, according the desire of the patient, who presses a push-button to induce micturition and erection (in the case of males). The solution chosen to send the electrostimulation commands rely on the radio-frequency (RF) transmission in order to avoid the use of wires to connect the electrostimulator to the patient's control. This last solution lasted for several years with relative success, but with the former drawbacks.

## II. IMPLANTABLE DEVICES FOR URULOGY

### A. Electrical Stimulation

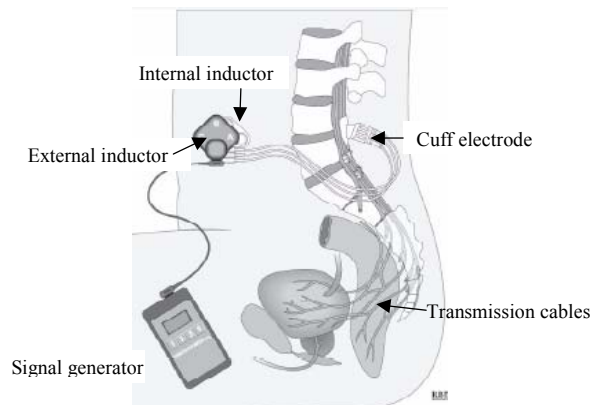


Fig. 1: Schematic view of the overall system used for bladder control.

Figure 1 shows the commonly adopted system architecture to control the inferior urinary system, where the system has a signal generator that generates the appropriate stimulus to activate, e.g., the bladder. This stimulus is transmitted to the external coil, which induces the signal in the internal coil. Reaching the biologic environment, a receiver module delivers the stimulus trough the transmission cables that carry the signal to the cuff electrode. Since the internal coil is placed in the frontal region and the electrodes are in the back, the transmission cables must go through the body and are one main cause of system failure. Moreover, the existence of these

cables requires a small opening in the duramater, not good for the spinal cord integrity. One main benefit of the microsystem approach is the possibility to avoid cables trespassing the duramater.

### B. Anatomy of spinal cord

The place where the microsystems must operate, can be seen in Figure 2, which shows the anatomy of the spinal cord. This is the place where the microsystem must be designed to operate. From this figure it is visible that the microdevice must fit in a very small region, inside the duramater. Two possible places to be placed, includes either in the region 4 or in the region 6. The most suitable place is the region 6, e.g., the subarachnoid space, since the duramater can be totally closed after surgical intervention. The available space in this region 6 varies between 3 mm and 9 mm [3]. This is room enough to accommodate a small microdevice. The conventional surgical procedure requires the duramater opening to place the electrodes in contact with the sacral roots (Figure 3).



Fig. 2: Spinal cord cut, showing the region where the microdevice must be placed (1 - intervertebral disk, 2 - vertebral body, 3 - duramater, 4 - epidural space, 5 - spinal medulla, 6 - subarachnoid space).

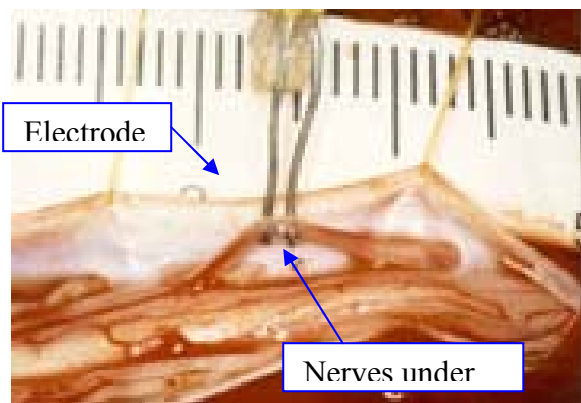


Fig. 3: Placement of electrodes (testing the nerves to be used).

The electrodes are connected to the leads coming from the stimulator, leaving a small opening in the duramater. As it can be seen from Figure 3, there is plenty of room to place the microsystem in the implant region. For the existent applications, the Figure 4 shows a set of three electrodes whose signals are delivered by way of cables.

The use of a wireless link to send commands to the implanted device allows the remove of wires to improve patients quality of live, with a consequence to have lower risk to infections, a shorter recovery time and a lower risk to damage due to the break of wires.

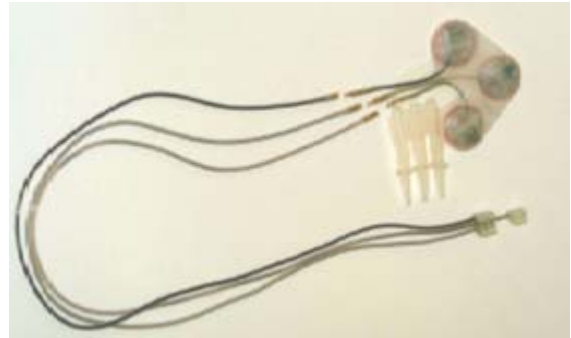


Fig. 4: Cables used to deliver the signals to the electrodes.

## III. THE IMPLANTABLE MICROSYSTEM

### A. System architecture of the wireless microsystem

The need to reduce the failure associated with long wires, to reduce the risk of infection or shifts in the wires is driving researchers to find a solution using microtechnologies. Also, and very important, is the internment period associated with the surgical intervention. Due to the highly invasive intervention that is required using the traditional technique, the patients, even when there are no complications, are required to stay a few days in the hospital. The availability of a device to allow a less invasive method would be more comfortable for the patient, reducing also the hospital costs associated to the surgery.

To make it possible to use, the device must be small enough to fit inside the spinal cord, it must be able to deliver the required stimulus (power and timing) and it must be possible to communicate with the device using a radio-frequency signal. This requires the use of a microsystem completely integrated, from sensors to communications, thus requiring the use of integrated antennas. Moreover, the antenna integration requires the availability of an electrically small antenna fabricated on materials compatible with the fabrication of integrated circuits. This integration requires the use of wafer-level packaging (WLP) techniques.

As depicted in Figure 5, the electrostimulation part is a box made of a silicon wafer with etched grooves to pass the nerves to be stimulated. Above the stimulation box is putted a cover containing electrodes that make electrical contact with the nerves, while at the same time are connected by a thin set of vias to pads placed in the opposite side. The solid-state circuits part that comprise the microelectronics of control and

the RF transceiver as well as the associate antenna, are placed upside the cover, by using WLP techniques for such a purpose.

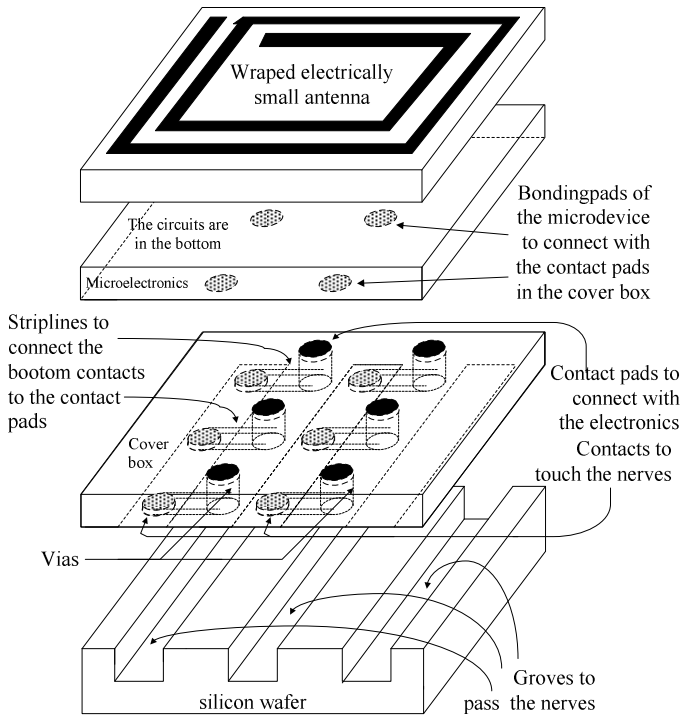


Fig. 5: An artist impression of the complete wireless microsystem.

### B. The operation frequency

The chose of a suitable frequency in an implantable device is not a topic of pacific discussion. First, it is desirable that these devices present the minimum sizes. Thus, and as it is know, in wireless communications, the antenna is one of the most critical subsystem, thus, in order to not compromise the desired miniaturisation, the antenna must be small enough to comply with size constraints of the microsystems. Some works in biomedical applications at the frequency of 2.4 GHz [4] and the investigation of new frequencies and new geometries [5] allowed to have smaller antennas to integrate in wireless microsystems [6]. This makes the chose of the most suitable frequency, one of the more decisive aspects in the design of RF transceivers. Normally, the desired range, baud-rate and power consumptions are key-aspects in the design to take in account, when the frequency of operation is to be selected. At a start-up point, the range limits the maximum usable frequency, because the loss suffered by the radiowaves in the free-space increases with the distance. Moreover, and in the context of implantable devices, the skin depth decreases with the increase in the frequency. Thus, to keep or even to increase the range an increase in the transmitted power must be made. However, such an increase is not always possible to do, because stringent limitations related to the usage in living persons must be respected.

The human cortical bone (with a dielectric constant,  $\epsilon_r$ , of 13.77 and with an electrical conductivity,  $\sigma$ , of  $0.1032 \text{ Sm}^{-1}$ ) is an useful starting-point to investigate the maximum RF

operation frequency. Applying the expression of skin-depth,  $\delta$ [m]:

$$\delta = \left( 2\pi 10^9 f_{\text{GHz}} \sqrt{\frac{\mu_0 \epsilon_0 \epsilon_r}{2}} \sqrt{1 + \left(\frac{18\sigma}{f_{\text{GHz}}}\right)^2 + 1} \right)^{-1} \text{ [m]} \quad (1)$$

where  $\epsilon_0 = 10^{-9}/(36\pi) \text{ Fm}^{-1}$ ,  $\mu_0 = 4\pi 10^{-7} \text{ Hm}^{-1}$ , are the electric permittivity and the magnetic permeability for the free-space, respectively. Also, the quantity  $f_{\text{GHz}}$  is the RF frequency expressed in GHz. Then, the Table I with the values of the skin-depth for three of the most used frequencies in the ISM band (Industrial, Scientific and Medical) is obtained. This table also presents the losses for two key-distances: a distance equal to the skin-depth and a second one of 20 cm. The distance of 20 cm was chosen because it is the worse case in terms of wireless communication distance for the proposed implantable (in the vertebral column) microsystem. As shown in the table, the 433 MHz frequency is the one with the less but still acceptable loss, e.g. this loss is equivalent to the free-space situation with a distance of 14 meters. Thus, RF transceivers to operate at this frequency can be the RF part in implantable microsystems.

TABLE I:

SKIN-DEPTH,  $\delta$ [MM] AND LOSSES [dB] FOR  $\delta$  AND FOR 20 CM.

Frequency	$\delta$ [mm]	Loss $L_1(\delta)$ [dB]	$L_2(20 \text{ cm})$ [dB]
433 MHz	18.0759 mm	4.3429	48.1
2.4 GHz	5.0383 mm	4.3429	172.4
5.7 GHz	2.2287 mm	4.3429	389.7

As formerly depicted in Figure 5, the proposed electrostimulation part is composed by a silicon wafer with etched grooves and a cover box. Figure 6 shows the steps using in the fabrication of the electrostimulation part. The SU-8 photoresist applied to a standard lithographic process, allows to etch grooves in a silicon wafer measuring  $5 \times 5 \text{ mm}$ . After the development phase and the SU-8 removable, the grooves are anisotropically etched in the wafer by way of a wet process in KOH solution. Then, the box is ready to accommodate three nerves of the spine. The steps used in the fabrication of the cover are bigger number, when compared to those used to make the box. As seen in Figure 6(b), in a first place, a set of Vias are drilled (using the laser ablation technique) in the orthogonal direction of the surface of the cover. Then, a set of three grooves are anisotropically etched in the wafer by way of a potassium hydroxide (KOH) solution [7]-[8] and where a metal deposition will be made. After the anisotropic etchings, two reactive plasma sputtering sessions will take place to make the deposition of two layers of aluminium with a thickness of  $1 \mu\text{m}$ , on both sides. After the sputtering sessions, the metal layers are patterned using electroplated SU-8 photoresist, first on both sides, and then on the bottom of the box cover. As shown in Figure 7, the cover must fit well in the box, and the contacts used to touch the nerves, can't make friction with the side walls of the grooves.

Moreover, their thickness must be smaller than 1  $\mu\text{m}$  in order to not scratch the nerves and thus, to not make damages on it.

#### IV. THE ELECTROSTIMULATION PART

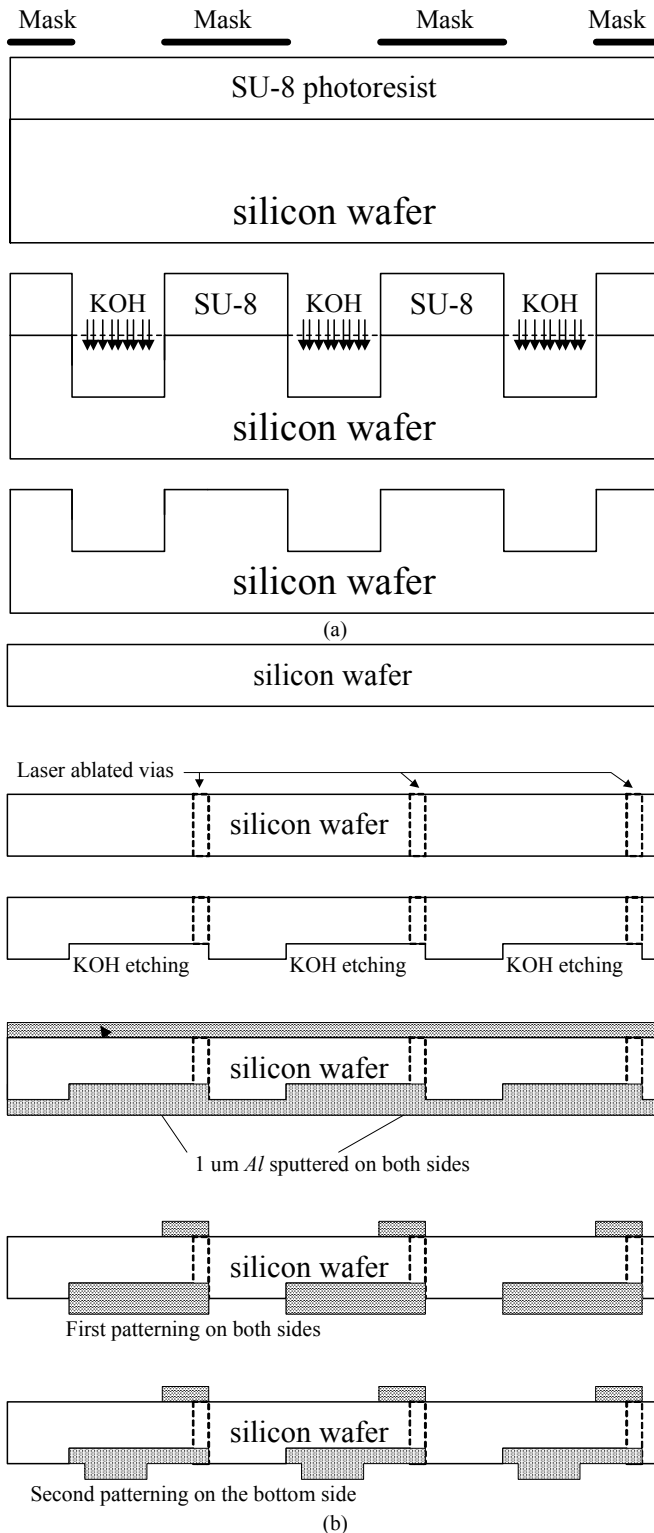


Fig. 6: Fabrication steps (a) of the silicon box (b) and (b) the respective cover.

#### V. CONCLUSIONS

This paper presented a wireless microsystem for operation for use in urology.

The electrostimulation part of the microsystem is a box made in a silicon wafer, in which groves were etched to pass the nerves to be stimulated. Above the box, a cover containing electrodes make electrical contacts with the nerves to be stimulated. Using wafer-level packaging (WLP) techniques, the part that contains the electronics and the antenna are joined together with the electrostimulation part. This implantable microsystem allows the user to send commands to activate the micturition function and the penian erection (on males). The expected area of the microsystem is  $5 \times 5 \text{ mm}^2$ .

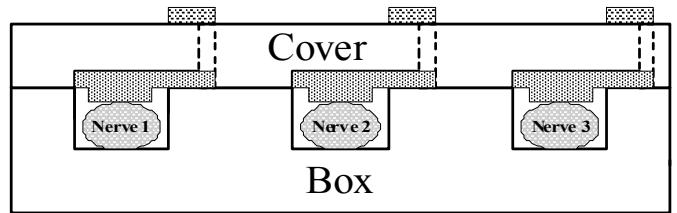


Fig. 7: A side view of the complete electrostimulation part.

#### ACKNOWLEDGMENTS

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