Implantable Selective Stimulator to Improve Bladder Voiding: Design and Chronic Experiments in Dogs

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***Abstract*—Among the treatments to enhance the bladder voiding, the sacral roots neurostimulation is one of the most promising techniques. The electrostimulation of sacral nerves provokes a simultaneous contraction of the detrusor muscle as well as the external urethral sphincter (EUS). A new simplified-architecture implantable stimulator with its wireless controller have been designed to investigate high-frequency inhibition stimulation strategies. This innovative technique based on high-frequency inhibition reduces sphincter activity during stimulation. Low-frequency current pulses also applied to the sacral roots induces contraction of the detrusor muscle resulting in low pressure voiding. Chronic experiments were carried out on ten male mongrel paraplegic dogs. One cuff electrode was implanted along with each stimulator for eight months. The animals were stimulated twice a day using the prototypes of our implantable selective stimulator while voided and residual urine volume were measured during the procedure. These experiments revealed that the proposed stimulation strategy enhances bladder voiding by more than 50% in comparison with low-frequency only stimulation. The residual urine volume was reduced to an average of 9% and low pressure micturition was achieved as shown by weekly cystourethrogram.**

***Index Terms*—Chronic experiments, implantable stimulator, sacral roots, selective electrical stimulation, urinary bladder.**

I. Introduction

SEVERAL functional electrical stimulation (FES) techniques have been introduced to promote bladder voiding and prevent incontinence [1]–[3]. Clinical experiments as well as animal validation have been carried out to address the bladder voiding function. Four currently known stimulation sites (Fig. 1) have been investigated: the bladder wall (detrusor muscle), pelvic nerves, sacral roots and the spinal cord. Each one of these stimulation techniques presents its advantages and drawbacks [4]–[7].

Bladder wall stimulation was the first investigated method to induce micturition [8]. Electrodes were sewn in the detrusor muscle and electrical stimulation was applied to induce detrusor muscle contraction but the movement of the detrusor muscle during bladder filling and emptying causes frequent electrode breakage while stimulation using high current amplitude increases impedance around the electrode and may cause damages [4], [5].

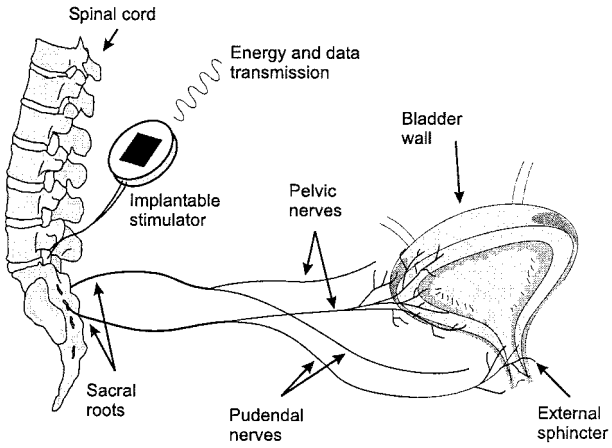

Fig. 1. Possible stimulation sites and implantable stimulator position for high-frequency inhibition.

Electrostimulation by the right and left pelvic nerves could induce bladder voiding but many problems were reported. The external urethral sphincter was activated during excitation and resulted in impaired micturition. Complete emptying of the bladder was only obtained after section of the pudendal nerves [9]. Also, the surgery needed to expose the pelvic nerve is difficult compared to the surgery for other stimulation methods.

The third stimulation site to achieve micturition is the spinal cord. Using electrodes with exposed tips to reach beneath the spinal cord dorsal surface, selective activation of the detrusor muscle and external urethral sphincter relaxation can be obtained, producing low-pressure bladder voiding [10]–[13]. However, results were affected by electrode positioning and there was a high infection rate due to electrode insertion in the spinal cord [4], [5].

Regarding the fourth stimulation site, it is well established that sacral roots are the most promising electrode implantation sites to achieve bladder voiding functions [4]–[6]. Like the stimulation of the pelvic nerves, sacral roots excitation induces sphincter contraction which impairs micturition. Somatic fibers that supply the urethral sphincter are more sensitive to electrical stimulation than autonomic fibers innervating the detrusor muscle. This means that a current large enough to provoke detrusor muscle contraction will inevitably activate the external urethral sphincter and interfere with micturition [14]. However, this site of stimulation shows the most encouraging results.

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A. Neurostimulation Techniques of the Bladder

Currently, there are four main electrostimulation techniques used to overcome this dyssynergia and provoke micturition: poststimulus voiding in conjunction with dorsal rhizotomy, anodal block, sphincteric fatigue, and selective stimulation by high-frequency inhibition [6].

1) Poststimulus Voiding: The poststimulus voiding technique is based on the fact that the striated sphincter muscle relaxes more rapidly than the smooth detrusor muscle. The sacral roots stimulation pattern consists of intermittent pulse trains (typically, 3–6 s stimulation and 6–9 s pause) to allow bladder evacuation. An implantable stimulator designed by Brindley is presently one of the most clinically used systems to restore partial bladder functions. It has been used in over 700 patients with good clinical results [15], [16]. However, poststimulus voiding necessitates the transection of neural pathways (posterior rhizotomy) to impede reflex detrusor-sphincter dyssynergia (DSD) and allow voiding during the pause following stimulation as reported by Brindley [15]. The dorsal rhizotomy also improves bladder compliance and capacity and prevents reflex incontinence. It does not affect stimulation-induced DSD, but will abolish any reflex erection if previously present.

2) Anodal Block: This method of neurostimulation consists of preventing the propagation of the nerve action potential toward the external urethral sphincter using an anodal block technique. This technique uses hyperpolarization of the nerve membrane between the excitation application point and the external urethral sphincter [17], [18]. Acute animal experiments showed that the anodal blocking technique could decrease by more than 80% the stimulus-induced intraurethral pressure. Rijkhoff *et al.* also state that the technique can be applied to humans [4].

3) Sphincteric Fatigue: Urethral resistance can be reduced by stimulating pudendal nerves with high-frequency signals to induce sphincteric fatigue, while low-frequency current pulses are applied at the sacral root level, allowing micturition [6], [19], [20]. This technique, based on the fact that high-frequency stimulation rapidly provokes fatigue of the striated external urethral sphincter, was performed in both acute and chronic experiments on dogs. It achieved proper bladder emptying without performing neurectomy but necessitated surgery to reach the pudendal nerves. Results from the chronic experiments on dogs with the sphincteric fatigue stimulation strategy at the pudendal level were comparable to the results obtained on a control group with pudendal neurectomy [20].

4) Selective Stimulation by High-Frequency Inhibition: Recently, selective detrusor muscle activation has been obtained by performing stimulation of the sacral roots with a signal composed of two distinctive trains of bipolar-current pulses [21]. A high-amplitude, low-frequency train provokes detrusor muscle contraction while a low-amplitude, high-frequency train inhibits the external urethral sphincter contraction to allow micturition. This stimulation method, which is the subject of this article, allows bladder evacuation with a low-pressure voiding and low residual urine.

Previous attempts in primates to fatigue the sphincter with low-frequency (20 Hz) stimulation was not successful with poor voiding. The fatigued striated musculature sufficed for continence against maximal bladder contraction. However, the urethral pressure obtained with higher frequencies was significantly reduced resulting in better voiding [22].

B. Available Stimulators

Regarding the technical aspect, many devices are now available for neuromuscular stimulation, but they lack important features:

1) a wide range of programmable parameters;
2) a high efficiency in energy transfer and data transmission;
3) a user-friendly interface;
4) high-frequency stimulus generation;
5) waveform flexibility (monophasic, biphasic, anodic, etc.).

The two most frequently used commercially available stimulators for bladder control are the following.

- *Medtronic*: an implant programmable by two devices (physician full range programming and patient amplitude programmer). It also contains a telemetry circuit to confirm data validation and is limited to a maximum frequency of 130 Hz [23].
- *NeuroControl Corporation*: an implant designed by Brindley and composed of several identical receivers with their inductive couplings. Its maximum frequency is 300 Hz [22].

Several implantable multichannel stimulators and their external controllers were proposed by members of our team to fill the gaps and perform sacral roots and pudendal or sacral nerve stimulation [6], [24], [25]. These systems, validated in previous experiments, allowed to generate a wide range of stimuli through miniaturized implants [24], [26]. More recently, our team proposed a new stimulator based on a simplified architecture which is dedicated to selective stimulation applications. This device has been used in acute experiments and is validated in the current study. It can generate stimuli composed of two different bipolar-current trains of pulses with a high-frequency capability up to 1 kHz.

This paper details the combined sacral root stimulation of the bladder by low-frequency with high-frequency sphincter inhibition. The employed implantable stimulator is summarized in Section II, the stimulation protocol and methods are described in Section III, results of chronic experiments on 10 male mongrel dogs are reported in Section IV and discussed in Section V.

II. Description of the Stimulation System

Our stimulation system is composed of two main parts [27]:

- the external controller providing digital information, operating clock and energy to the implant through the skin;
- the implantable stimulator generating the current pulses through a bipolar cuff electrode which is wrapped around the sacral nerve.

Transcutaneous link through an optimized inductive coupling technique [28] allows the implantable part to generate a stimulus composed of two waveform trains of bipolar-current pulses defined by their amplitudes, frequencies and pulse widths. The generated waveforms are mixed together in order to produce

well balanced stimuli in term of charge quantities as well as the number of complete cycles for each train of pulses (Fig. 2).

A. The External Controller

Two complementary models of the external controller have been realized. The first one, based on a personal computer (PC), allows generation of an unlimited sets of parameters and was developed to facilitate prototyping and testing of stimulators. This PC interfaced controller offers more flexibility to adjust the parameters for each animal. Through a dedicated software, each stimulation parameter can be quickly viewed and changed. The selected set of parameters can be saved and retrieved from disk or even exported to a binary file for further use with the hand-held model [27].

The second one, a memory based hand-held unit, is a dedicated mobile unit. The hand-held unit, based on a field-programmable gate array (FPGA) and an EPROM (Fig. 3), includes eight different stimulation sets which can be easily reprogramed. The parameter values and the text to guide the user to choose one of these eight sets of parameters are also stored in memory while the FPGA integrates a finite state machine (FSM) and other logic blocks to control the stimulation system. The simplified architecture of the proposed controller allows rapid printed circuit board (PCB) design and easy to modify and to implement functions. The user friendly interface consists of a 2×16 characters dot matrix liquid crystal display (LCD) and a four-touch keyboard. To select a set of parameters for stimulation, the user must choose within the preprogramed sets. The values of the active parameters of each programmed set are displayed on the LCD. To run a stimulation period, the antenna of the external controller must be aligned with the antenna of the implant and a start key has to be activated.

For both models of the external controller, the clock and the command words form the serial data which is encoded in Manchester format [25]. The encoded bit stream and the needed energy to power up the implantable stimulator are sent through an inductive link (Fig. 3) based on the radio frequency (RF) coupling technique. The output stage is composed of a class D amplifier and a power regulator to compensate for coupling factor variation due to displacement between emitting and receiving coils [6]. The link uses a 20-MHz carrier modulated in amplitude.

B. The Implantable Stimulator

The implantable part of the stimulation system (the implant) receives data and energy through the inductive coupling link. The received AM waveform is rectified and regulated to power up the implant while the clock signal and data are extracted from the Manchester encoded signal. The digital modules of the implant are implemented in an FPGA which is placed at the center of the 4-cm circular PCB. The remaining analog and mixed-signal (digital/analog) parts of the implant are realized using commercially available components of surface mounted technology formats. The integrated digital part of the implant detects the header of each received data and generates the control commands to be interpreted by the output stage. To transform the digital signal into a current waveform, the output stage includes a digital to analog converter (DAC), a voltage to current converter, a current amplifier and an analog switch array (Fig. 4) to generate a fully balanced bipolar stimulus which is necessary to prevent polarization of the nerve by charge injection and accumulation at the electrode—tissue interface.

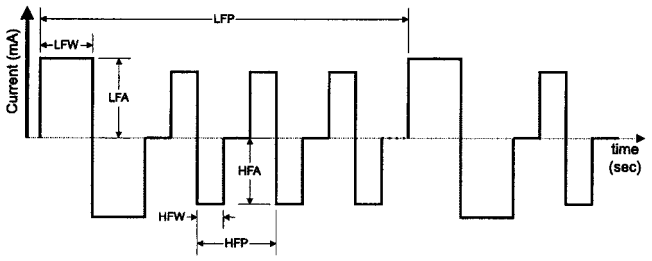

Fig. 2. Typical selective stimulation waveform intended to block the sphincter activation during bladder contraction (waveforms are not to scale; meaning of abbreviations are given in Table I).

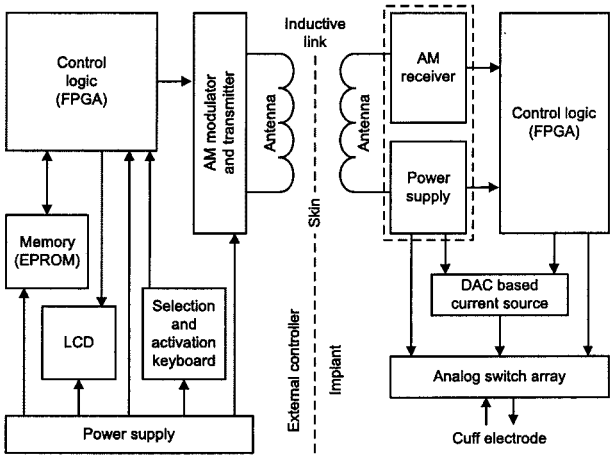

Fig. 3. Block-diagram of the whole proposed selective stimulator including the external controller, the implant and the electromagnetic link between both parts.

C. The Implant to Nerve Connection

The stimulator is connected to sacral nerves through dedicated cuff electrodes. The electrode consists of two stainless-steel leads covered with polytetrafluoroethylene (Teflon) and soldered to 25 μm platinum foil forming the contact surface to the nerve inside the cuff of the electrode [29]. To connect the electrode to our implantable stimulator, connectors have been added in our laboratory. Like the cuff, the connectors were also covered with biocompatible silicone elastomer. Two versions of electrodes were used for chronic experiments. The first version was built around stainless-steel leads composed of seven strands (Cooner Wire Co. AS632) while in the second version, the leads were composed of 40 strands (AS634) to increase the electrode resistance to stress. These electrodes offered a 1 mm wide contact surface to the nerve and an inner diameter of 1.5 mm. Electrodes were 3 mm apart and the 10-mm-long electrode cuff was closed with sutures.

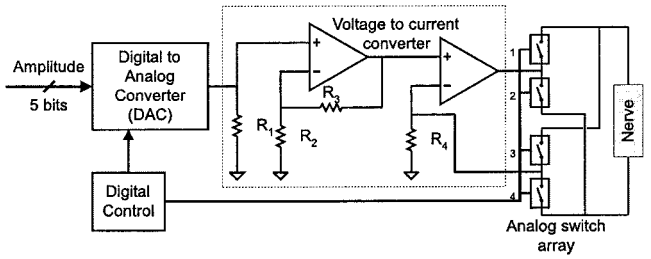

Fig. 4. Simplified block diagram of the output stage of the implant including an analog switch array to deliver fully balanced bipolar stimuli.

III. Experimental Protocol

The chronic study was approved by the McGill Animal Care Ethics Committee and conducted on 10 adult male mongrel dogs at the Animal Resource Center of the same faculty. Animals were subjected to laminectomy at the level of T10 vertebra and the spinal cord was sectioned under direct vision. The procedure was carried out under general anesthesia and aseptic techniques. At the same setting, a limited sacral laminectomy was performed and the sacral roots were identified. The extradural ventral sacral nerves supplying the urinary bladder and external sphincter were hooked and stimulated with an external pulse generator (SD9 Stimulator, Grass Medical Instruments). The intravesical pressure was measured through a triway 7 F catheter connected to a portable urodynamic analyzer (UDS-120, Laborie Medical Tech., Inc.) and a computer. After identification of the proper S2 sacral root (left or right), one cuff electrode was wrapped around the selected nerve and the stimulator was implanted subcutaneously in the flank of the animal. After the surgery, animals were placed in a sling for three to four days to prevent pressure sores until the animals adapted to their new state. The next day following surgery, twice daily stimulations with measurement of voided and residual urine were carried out using different sets of parameters. Weekly cystourethrogram and monthly intravenous urography were also performed.

The stimulation protocol was divided into three of the following main steps.

A. Low-Frequency-Only Stimulation (Standard Stimulation)

During the first month following implantation, the animals were stimulated with low-frequency-only current pulses (3–5 periods of 10 s stimulation with a minute of rest period in between). Catheterization was used to evacuate remaining urine. After the shock phase, the animals usually developed bladder hyperreflexic contractions with reduction of the bladder capacity.

B. Selective Stimulation

The selective stimulation parameters were selected following a cystometric evaluation of the intravesical and intraurethral pressure measurements with electromyographic (EMG) recording of the pelvic floor muscles. The bladder was filled with sterile saline solution until it leaked to evaluate bladder capacity. Afterward, half the volume of saline solution was evacuated. Different sets of selective stimulation parameters for high-frequency inhibition were tried in order to select the most suitable set of stimulation parameters for each dog. The selection of parameters was determined by maximum bladder evacuation with high intravesical pressure and low intraurethral pressure. To avoid movement, the animal was under light sedation during cystometric evaluation. For the next six to eight months, the animals were stimulated with the corresponding set of parameters twice a day. Voided and residual urine volumes were measured. Table I shows typical employed values of waveform amplitudes, pulse widths and frequencies for both standard (low-frequency only) and selective stimulation. Weekly cystometric study to monitor intravesical and intraurethral pressures and monthly intravenous urography (IVU) to visualize both kidneys, ureters and the bladder were performed for each animal. These procedures were also carried out under light sedation. Voiding cystourethrogram (VCUG) with neurostimulation to monitor vesical neck opening and urethral filling and to rule out vesicoureteral reflux was carried out after IVU study.

C. Postselective Low-Frequency-Only Stimulation

During the last month, daily stimulations were performed with low-frequency only current pulses to compare both selective and low-frequency-only stimulations. All morning and afternoon stimulations for all phases of the experiment consisted of 3–5 periods of 10-s stimulation with a minute rest period in between followed by collection and measurement of voided urine and catheterization to evacuate remaining urine residue which was also measured. In addition, nerve histology was performed on each animal at the end of the experiment.

IV. Results

The results reported in the following section concern the electronic devices performances as well as the animal (dogs) experiments.

A. Selective Stimulation System

The external controller of the proposed stimulator is either a PC interface or a handheld unit. These two controllers met the expected specifications and have been used to command the numerous implants working over the two year period assigned for the chronic study.

Regarding the internal part of the proposed stimulation system, a total of six implants have been used and implanted through the duration of the experiments. Five implants (83%) completed the study and showed high reliability. They were still functional when retrieved from the animals and most of them have been implanted in more than one animal.

In four dogs out of ten that started the study, stainless-steel leads connecting the implant to the platinum cuff were broken at the level of the connectors. In two of these four cases (dog 4 and dog 5), the contralateral nerve was identified and a new cuff electrode was placed successfully. The other two animals did not complete the study. To resolve the encountered problem, a second version of cuff electrodes was designed and all electrodes of that version showed good mechanical properties in terms of flexibility and durability. All eight electrodes showed unchanged characteristics after the chronic experiment duration.

TABLE I
FREQUENTLY EMPLOYED PARAMETERS: LOW-FREQUENCY ONLY AND SELECTIVE STIMULATIONS

Parameters	Symbol	Low-frequency only	Selective stimulation
Amplitude	LFA	0.9 mA	0.9 mA
Period	LFP	33.3 ms[a]	33.3 ms
Pulse width	LFW	175 μs	175 μs
Amplitude	HFA	–	1.1–1.3 mA
Period	HFP	–	1.67 ms[b]
Pulse width	HFW	–	60–100 μs

[a] 30 Hz.
[b] 600 Hz.

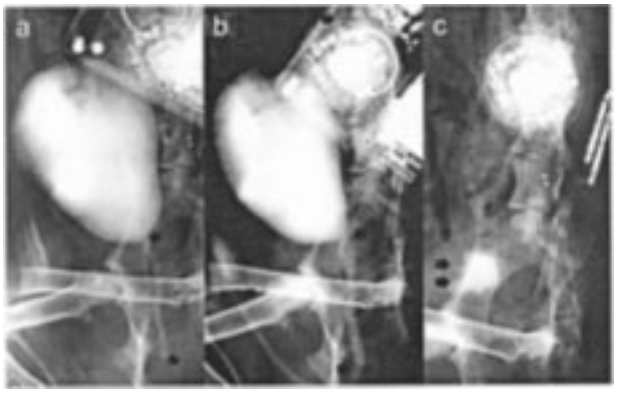

Fig. 5. X-ray views of the bladder: (a) external urethral sphincter (EUS) contracted, (b) EUS relaxes with selective stimulation, and (c) residual urine volume (shown by arrows).

B. Cystometric and Radiological Results

For the eight dogs that completed the study, the average residual volume with low-frequency-only stimulation was 275 ml (70% of full bladder capacity) during the first month and 133 ml (58%) the last month. Using selective stimulation during the remaining chronic experiment period, the residual volume dropped to 27 ml. This selective stimulation technique increased the mean voided urine volume by more than 50% and reduced the mean residual urine volume to 9%. In addition, no animal showed backpressure on the ureters or kidneys as evidenced by monthly radiological investigation (IVU, VCUG). As expected with high-frequency inhibition, external urethral sphincter relaxed with selective stimulation as shown by X-ray pictures (Fig. 5) taken before, during and after stimulation.

Table II depicts results mentioned above by showing voided urine quantities with both low-frequency only and selective stimulations. This table is divided into three parts from top to bottom corresponding to the three steps of the experimental protocol: low-frequency only stimulation during the shock stage (first month), selective stimulation combining both detrusor muscle contraction and inhibition of the external urethral sphincter contraction (6–8 months) and post-selective low-frequency only stimulation (last month). In each section, the average voided and residual urine volumes along with standard deviations are shown. Figs. 6 and 7 are more explicit graphics comparing low-frequency stimulation, selective stimulation and postselective stimulation. Fig. 6 depicts individual results from each dog as well as the average of all dogs with every stimulation type while Fig. 7 shows typical intravesical and intraurethral pressures evolution in time for low-frequency-only and selective stimulations. During low-frequency-only stimulation, the high intraurethral pressure inhibits micturition. However, with selective stimulation, intraurethral pressure decreases in accordance with the EUS relaxation shown in Fig. 5, while intravesical pressure remains almost constant. In addition to bladder evacuation, lower limb muscle contraction and erection have been observed in some animals during stimulation at all stages of the protocol. An important issue for patients with neurogenic bladder after spinal cord injury concerns vesico-ureteral reflux. Intravesical pressure rises between 50 and 60 cm H_2O for the 20 to 30 seconds necessary for complete bladder emptying while it stays below 20 cm H_2O otherwise. The selective stimulation technique does not seem to cause ureteral reflux as confirmed by monthly voiding cystourethrogram.

Erection has been known to reduce urinary flow during sacral root stimulation. Although selective stimulation by high-frequency inhibition does not prevent erection, it has usually been observed at the end of bladder evacuation, frequently lasted less than 1 minute and was not problematic for dogs. Also, in all cases, lower limb muscle contraction occurs as another side effect during sacral nerve excitation.

V. DISCUSSION

We presented in this article a new selective stimulation device together with its validation in vivo in dogs. Unilateral selective stimulation at the S2 level combining high-frequency stimuli dedicated to sphincter inhibition and low-frequency current pulses for detrusor muscle contraction leads to improved micturition. Selectivity is achieved by choosing the high-frequency pulses amplitude below the activation threshold of small nerve fibers leading to the bladder wall. This results in large nerve fibers stimulation and high-frequency fatigue of the sphincter leaving the detrusor muscle free for low-frequency stimulation. Some small fibers are activated by the high-frequency stimulus but the detrusor muscle high resistance to fatigue, combined to lower sphincter fibers contraction, allows low-resistance voiding and therefore, lower pressure voiding with minimal residual volume of urine.

A previous attempt was reported by Brindley to fatigue the sphincter using sacral roots low-frequency stimulation. This study used 20 pulses per second stimuli to fatigue the sphincter for 3 min. The voltage was then increased to activate autonomic nerve fibers and produce maximal bladder contractions but the striated musculature contraction still impaired micturition. They concluded that low-frequency stimulation is inappropriate to fatigue the sphincter and leads to DSD.

The proposed implantable functional electrical stimulator and its external controller generate a wide range of reliable and precise stimuli. Together with the implantation technique, the new system allowed effective voiding. An average residual urine volume of 9% of the bladder capacity was measured during chronic experiments on paralyzed dogs for which

TABLE II
VOIDED AND RESIDUAL URINE QUANTITIED IN EIGHT CHRONIC DOGS

Low-frequency stimulation	Voided urine	Residual urine	Bladder capacity
Average[a]	98[b]	275	373
Average (%)	30%	70%	100%
Std. dev.	52	99	84
Selective stimulation	Voided urine	Residual urine	Bladder capacity
Average	247	27	274
Average (%)	91%	9%	100%
Std. dev.	49	17	52
Post-selective stimulation	Voided urine	Residual urine	Bladder capacity
Average	92	133	226
Average (%)	42%	58%	100%
Std. dev.	24	24	27

[a] Average of all dogs.
[b] Volumes are in milliliters.

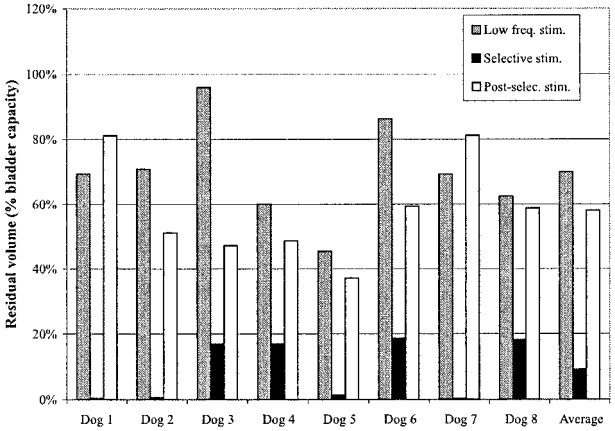

Fig. 6. Residual volume for three stimulation steps: low-frequency-only, selective, and postselective (for complementary information, see Table II).

experiments lasted an average of eight months. Miniaturized full custom version of the implantable stimulator including a feedback loop to monitor the events surrounding the electrode-nerve contact is under development to improve the characterization of the proposed device.

The selective stimulation by high-frequency inhibition technique shows promising results in the dog which is an appropriate model for neurostimulation studies [30]. After spinal cord injury, a dog presents vesicosphincteric dyssynergia which is quite similar to what is found in human. Therefore, the chronic experiments in dogs are important and future application in human will be possible soon.

The selective stimulation involves more energy than standard low-frequency only stimulation but the high-frequency train uses a low-current amplitude which results in a low-charge density due to short pulses duration. The charge quantity involved in the low-frequency train is evaluated to approximately 0.16 μC/phase. If we consider the equivalent electrode surface (A) equal to 1 mm^2, we obtain a charge density (δ) of 16 μC/cm^2 for each phase

$$\delta = \frac{I \cdot t}{A} = \frac{0.9\,\text{mA} \cdot 175\,\mu\text{C}}{1\,\text{mm}^2} \cong 16 \frac{\mu\text{C}}{\text{cm}^2 \cdot \text{phase}} \qquad (1)$$

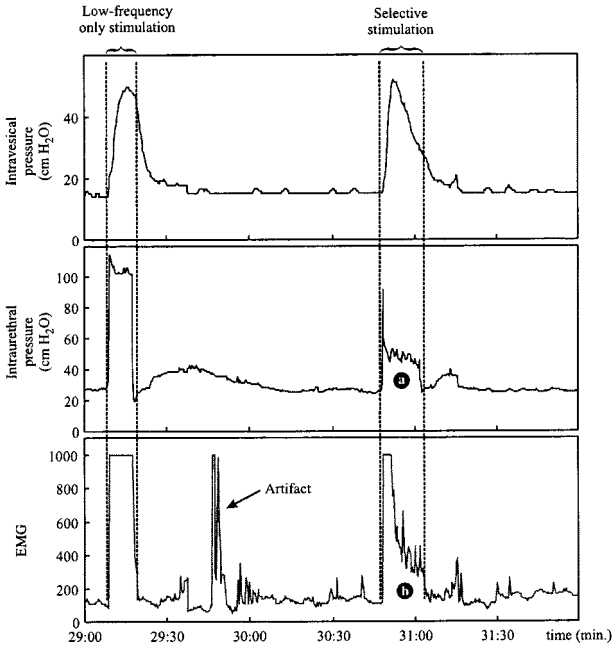

Fig. 7. Intravesical and intraurethral pressures and EMG of the sphincter: (a) lower intraurethral pressure allows micturition and (b) reduced EMG coincides with lower intraurethral pressure.

where I is the constant current amplitude and t is the pulse width duration. Employed current amplitude and pulse width have been taken from Table II.

Platinum electrodes are resistant to corrosion for charge densities up to 400 μC/cm^2 [31] while no significant neurological changes have been observed on the nerve due to chronic neurostimulation or reaction to the cuff electrode as demonstrated by nerve histology which will be the subject of a further publication.

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