

# Sphincter Contraction Inhibition and Detrusor Hyperreflexia Prevention Using Selective Stimulation: Chronic Experiments in Dogs

Schneider E., Sawan M., Boyer S., Abdelkarim A.\*, Elhilali M. M. \*

DGEGI, Ecole Polytechnique de Montréal  
P.O. BOX 6079, Succursale Centre-Ville  
Montréal, Qc, Canada, H3C 3A7  
sawan@vlsi.polymtl.ca

\*Departement of Urology,  
McGill University  
Montreal, Qc, Canada  
mostafa.elhilali@muhc.mcgill.ca

**Abstract:** *Selective electrical stimulation allows significant improvement in bladder rehabilitation following a spinal cord injury. Our studies over the past 3 years tend to prove that the appropriate selective stimulation inhibits sphincter contraction during micturition and low frequency electrical stimulation could prevent detrusor hyperreflexia if properly used early during the spinal shock phase. Selectivity is achieved using dual frequency electrical stimulation, which is realized in an implantable stimulator as presented in a former publication. New cuff electrodes using either memory shape or super elastic alloys were recently used to maximize contacts with nerves and facilitate surgeries. Chronic studies have been made on 20 mongrel male dogs. Ten of them were treated to determine their ability to void the bladder. Ten other dogs with new cuff electrodes were monitored for detrusor hyperreflexia that follows the spinal shock. Reliability and effectiveness of the system have been demonstrated in previous publication. The presented study showed that voiding was effective for all dogs, and leave an average residual bladder volume of 9% for the 10 treated dogs. The second study performed on the 10 others dogs showed that the electrical stimulation has a significant effect on detrusor hyperreflexia.*

**Keywords:** Electrical stimulation, Bladder, Sphincter, Selectivity, Hyperreflexia, Chronic experiments, Dog.

## 1. Introduction

Electrical neural stimulation is widely used to recover partial functionality of failed organs after spinal cord injury [1]-[5]. In the case of bladder control, voiding with low intraurethral pressure is as important as reducing the duration of the shock phase and avoiding detrusor hyperreflexia. High frequency blockage stimulation, presented in previous papers [6]-[7], compared with standard stimulation, enables contraction of the detrusor while it slacks the external sphincter and allows voiding. At the same time, early electrical stimulation after a spinal cord injury seems to have significant effects on the bladder rehabilitation. Indeed, just after any spinal cord section, comes the shock phase where the bladder relates no activity

and changes morphology. Then, in patients with suprasacral spinal cord injury, begins the hyperreflexia where the bladder has undesirable over-reactions. If not treated this hyperreflexia may cause damage to the whole urinary system.

This paper summarizes all the studies we completed on functional electrical stimulation for bladder voiding and control of hyperreflexia prevention. The employed electronic stimulator is reviewed in section 2, the experimental protocol is described in section 3 and results are discussed in section 4.

## 2. Electrical stimulation system

A cuff electrode, an implantable electronic stimulator and an external controller are the three main part of the system as shown on figure 1. The bipolar cuff electrode wrapped around the nerve is electrically connected to the implantable stimulator through two gold plated connectors. Those electrodes, using memory shape alloy and super elastic alloy, have been designed to facilitate surgery and optimize contacts with nerves: memory shape alloy electrodes are easy to wrap and manipulate when kept at low temperature, but they automatically remember and recover their original shape (cylindrical around the nerve) when heated at body temperature.

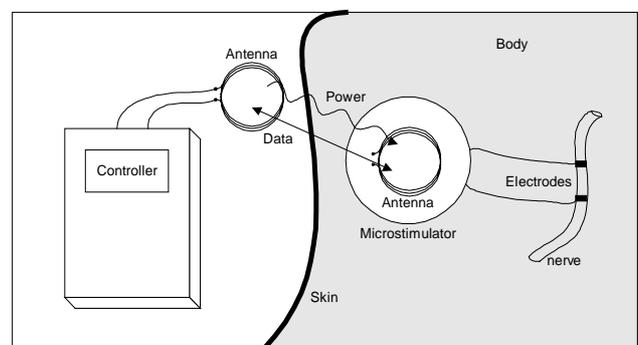


Figure 1: The complete subcutaneous bladder stimulation system

Super elastic electrodes are naturally closed and strong enough to stay wrapped around the nerve if low stretching forces are applied. But over

a given tension (apply by the surgeon) electrodes could be open and placed easily around the nerve.

The implantable electronic stimulator, that generates bipolar current impulses, is double-face components mounted in a circular PCB (Printed Circuit Board) of 1' 3/4 using commercial tiny surface mount electronic devices. Fully programmable, this stimulator is able to generate bipolar current pulses up to 2mA by 7 $\mu$ A steps, with 3 $\mu$ s resolution. For the purpose of the selective stimulation, it can even multiplex two independent current waveforms. Each waveform has its own frequency, amplitude and pulse width. Figure 2 illustrates a typical waveform of a selective stimulation while figure 3 is for low frequency only stimulation.

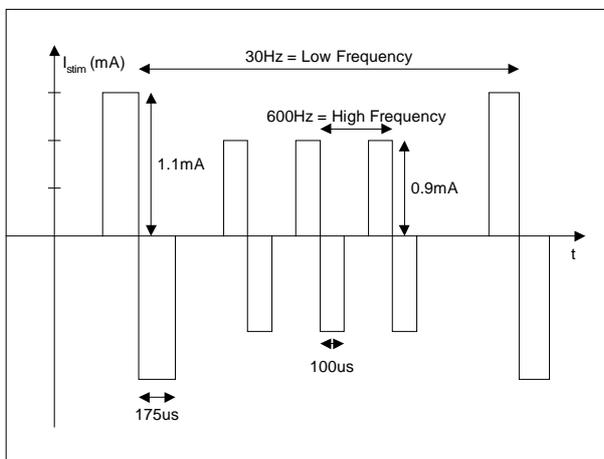


Figure 2: Typical waveform for selective stimulation

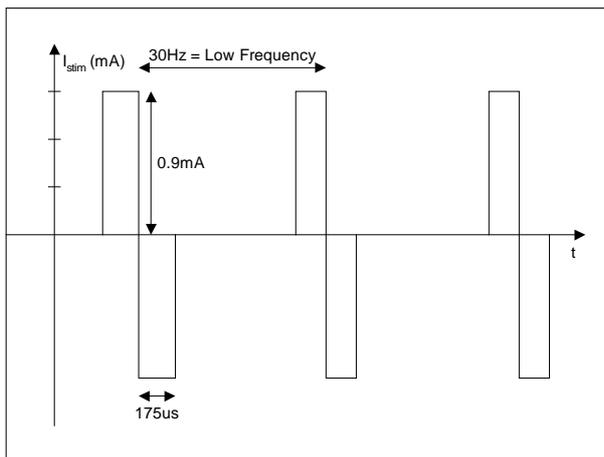


Figure 3: Typical waveform for low frequency only stimulation

Without external controller, the implanted stimulator (the implant) is in idle status, because it has no embedded power source. The portable controller uses magnetic field and Amplitude Shift Keying (ASK) modulation to transmit power and stimulation parameters to the implant. All needed parameters are selected externally at the controller

level and are reprogrammed in the implant every time stimulation is initiated.

The whole implanted device is encapsulated in a biocompatible silicon rubber, and no electrical parts are in contact with the body except both platinum contact of the electrode. The implant is completely enclosed under the skin and has no direct hardware contact with the outside controller. Linkage is fully handled by the electromagnetic RF signal.

### 3. Experimental protocol

For all chronic experiments in 20 dogs, same preliminary tests and surgical operation were conducted as follows: Regular urinary analysis (pH, Crystals, etc.), kidney functional tests, voiding cystourethrogram (VCUG) and intravenous urography (IVU) made before each surgery, insured that dogs' bladders were completely functional and healthy.

Animals were subjected to laminectomy at the T10 vertebra and the spinal cord was sectioned. A limited sacral laminectomy was performed and the sacral roots were identified. Sacral nerves supplying the urinary bladder and external sphincter were hooked and stimulated with an external pulse generator, while a cystometrogram (CMG) showed the intravesical and the intraurethral pressure. Therefore the proper sacral root could be identified (S2 in dogs). Then the electrode is wrapped around the nerve, and the implant is connected and enclosed subcutaneously.

Then began the study. First ten dogs were kept eight months for their ability to void when applying a selective stimulation (Low frequency pulses mixed with high frequency pulses). Each dog was stimulated twice a day with parameters that give maximum bladder evacuation while the voided and residual urine were quantified. Weekly CMG and monthly IVU and VCUG were performed.

For ten other dogs, bladder behavior and activity was monitored regardless of the voiding, while applying daily low frequency only stimulation. Weekly CMG were used to find out the duration of each phase: chock phase, beginning of hyperreflexia, and disappearance of hyperreflexia. In addition, daily urine analysis and monthly urine culture were proceeding to detect any infection or kidney dysfunction.

Stimulation on first six dogs is applied twice a day immediately after the spinal cord injury (the surgery) until the end of the eighth month. Four remaining dogs were catheterized and kept unstimulated until the appearance of any detrusor hyperreflexia. Then stimulated twice a day with

low frequency only, similar stimulation than the first six dogs.

#### 4. Results

The first study, presented in more detailed in previous paper [6]-[7], show that selective stimulation compared with low frequency only stimulation have significant improvement in bladder voiding: 50 % more urine evacuated and an average of less than 9% of residual urine remains in the dog bladders. Figure 4 summarize results obtained from the first study.

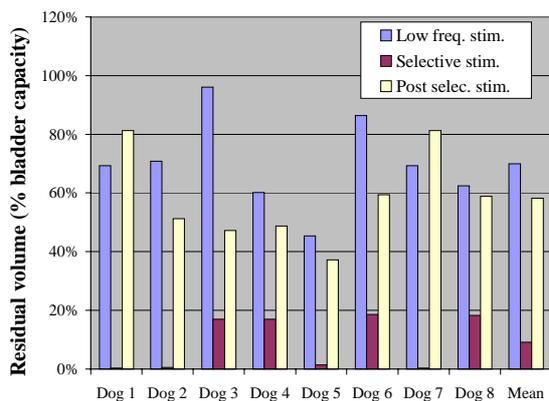


Figure 4: Residual volume for each dog by stimulation type

Table 1 shows the status of the 10 dogs under treatment. The present study, show for the moment that among the first six dogs that were stimulated immediately after the surgery, four of them never present any detrusor hyperreflexia while the shock phase ended few weeks after the surgery. Furthermore, from the first dog to the fourth dog, the period of stimulation was reduced from 8 months to 2 month and after dogs were moved to intermittent catheterization. But no hyperreflexia reappeared. For 2 other remaining dogs, the shock phase was longer and ended on hyperreflexia. But those hyperreflexias ended few months later and never restart.

Table 1: Status of the 10 dogs under treatment.

Dog	Shock Phase	Begin Hyper reflexia	Stop Stimulation	End Hyper reflexia
1	1 month	1 month	Never	2 months
2	1 month	1 month	Never	4 months
3	3 weeks	Never	6 months	N/A
4	2 weeks	Never	3 months	N/A
5	3 weeks	Never	2 months	N/A
6	2 weeks	Never	2 month	N/A
7	2 weeks	2 weeks	Never	2 months
8	On study	On study	On study	On study
9	On study	On study	On study	On study
10	On study	On study	On study	On study

The last four dogs are still at the beginning of there study, but one of them already develop detrusor hyperreflexia only two weeks after the surgery, and three other dogs are still in their shock phase.

#### 5. Conclusion

These experiments revealed that selective stimulation using a combination of low and high frequency current pulse could tends to enhance significantly bladder voiding with none side effects on bladder wall, external urethral sphincter or kidney. Moreover, using daily low frequency only stimulation, early after the spinal cord injury could notably helps bladder rehabilitation and stabilization. It is even more interesting that this stimulation seems not be necessary for a longtime after the spinal shock.

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