



The history of sacral neuromodulation in Canada

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Cite as: *Can Urol Assoc J* 2019;14(4):87-90. <http://dx.doi.org/10.5489/cuaj.6499>

Abstract

Sacral neuromodulation (SNM) has been used for the past 30 years, with significant improvements in the implantation technique and technology over the last several years. Canadian centers were involved with this technique from the very beginning by participating in several multicenter clinical trials and engaging in basic and clinical research. Presently, six Canadian centers continue to have SNM implantation programs.

Introduction

The experimental and clinical work on sacral neuromodulation (SNM) was initiated in 1981 by Dr. Rick A. Schmidt and Dr. Emil A. Tanagho in San Francisco at the Department of Urology, University of California. Early, multicenter clinical trials were started by Urosystems, Inc. in 1985.¹

The biomedical device company Medtronic Inc. of Minneapolis, MN, U.S. acquired the license from University of California and Urosystems Inc. for the clinical evaluation system for the treatment of urinary incontinence using the Medtronic device for spinal cord stimulation, Itrel II.^{2,3} The original system (Itrel) was approved by the U.S. Food and Drug Administration (FDA) on September 29, 1997, for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. In 1988, the FDA granted investigational device exemption for further clinical trials of a new InterStim™ system⁴ (Fig. 1) that showed good outcomes.⁵⁻⁷ The InterStim system received final FDA approval (for urge incontinence) under P970004/S2 on July 8, 1998. The Model 3057 test lead received FDA approval under P970004/S3 on November 2, 1998. The FDA approved the InterStim system for the treatment of symptoms of urgency-frequency and urinary retention in April 1999. In 2011, the system also gained FDA approval for the treatment of fecal incontinence. Medtronic received the CE mark (approval to market in Europe) for InterStim for the management of chronic functional disorders of the pelvis and lower urinary and intestinal tract in 1994. In March 2011, Medtronic obtained commercial release approval for SNS-bowel.⁸

From 1997–2000, there was plethora of interest in the InterStim system across North America, with long-term effectiveness having been proven.⁹⁻¹¹ Drs. Schmidt, Steven Siegel, and Magdy Hassouna were travelling the entire continent to proctor surgeons for the procedure, as per the recommendation of the FDA.

Until recently, the technique was exclusively provided by Medtronic as InterStim. Recently, new technology (miniaturized, rechargeable, full-body magnetic resonance imaging scans compatible) and new companies (Axonics Modulation Technologies) have entered the neuromodulation market.



Fig. 1. First InterStim™ system.

Canada

The InterStim system was first licensed in Canada on December 2, 1999 for the treatment of urinary urge incontinence, urinary urgency-frequency, and urinary retention. Additionally, it was approved for voiding dysfunction by Health Canada in February 2002 (class IV, license no. 14962). In more recent years, InterStim therapy was approved for the treatment of fecal incontinence.

There have been many key SNM technology innovations from Medtronic along the way; in 2002, a tined lead was introduced; in 2006, new patient and physician programmers were released; in 2015, the Verify Evaluation system replaced the traditional PNE kit; and a new basic evaluation lead was introduced in 2017. Other advances include percutaneous implantation and development of smaller devices (InterStim™ II).

Approximately 300 patients are implanted each year in Canada (mostly new patients, but a portion of this number is for replacement devices). In 2018, the International Continence Society, with significant Canadian contribution, produced practice statement for use of SNM.

In Canada, there are six centers implanting SNM

- McGill University, Jewish General Hospital (Montreal): Dr. Jacques Corcos and Dr. Lysanne Campeau
- University of Toronto, Toronto Western Hospital (Toronto): Dr. Magdy Hassouna and Dr. Dean Elterman
- Dalhousie University, NS Health Authority (Halifax): Dr. Jerzy B Gajewski and Dr. Ashley Cox

- Alberta Urology Institute (Edmonton): Dr. Gary J. Gray and Dr. Joseph Labossiere
- Université de Sherbrooke (Sherbrooke): Dr. Le Mai Tu and Dr. Salima Ismail
- Moncton Hospital (Moncton): Dr. Neil Dwyer

Montreal/Toronto

The initial Canadian encounter with the InterStim system was in 1987, when the first sacral neurostimulator, with the guidance of Dr. Schmidt, was implanted in a quadriplegic patient who was using the Finetech Brindley device for bladder emptying for several years with limited success. The main impetus for the interest in the neurostimulation was the experimental work that was conducted from 1980 onwards on canine animal models with the collaboration of the department of electrical engineering at the Polytechnique Montréal (Dr. Mohamad Sawan).

Several peer-reviewed publications consolidated the role of the group of researchers at McGill University (Drs. Mostafa Elhilali, Hassouna, and Corcos) in the area of SNM. Medtronic spearheaded a multicenter study (MDT101) to assess the effect of SNM on voiding function in patients with non-neurogenic bladders. The McGill site was instrumental in participating in this study.

With the move of research lead (Dr. Hassouna) to Toronto in 1995, the program for neurostimulation continued to expand. At McGill, Drs. Elhilali and Corcos continued to expand the program with the opening of a new implantation site at the Jewish General Hospital, and continued the neurostimulation research in collaboration with Dr. Sawan.¹²⁻¹⁴ Since 2015, Dr. Campeau joined the team at the Jewish General, allowing a significant increase in patient recruitment and the reinforcement of the Ralph & Beryl Goldman voiding dysfunction fellowship. More recently, a colorectal implantation program has been implemented at the Jewish General Hospital under Dr. Boutros' leadership.

In Toronto, Dr. Hassouna expanded implantation program after the Ministry of Health in Ontario recognized the therapy as a case-funded program and increased the number of patients steadily from 12 patients in 1995 to 170 cases funded in 2019.

The neurourology fellowship established in the University of Toronto since 2009 has attracted over 20 fellows from national and international universities. In 2013, Dr. Dean Elterman joined the SNM program in Toronto.

Halifax

After spending three months with Drs. Schmidt and Tanagho in San Francisco in 1992, Dr. Jerzy Gajewski, with the help of Dr. Siegel performed the first implant in Halifax on October 13, 1994, in an old Halifax Infirmary Hospital. The

patient weighed 300 pounds and the surgery took more than three hours, but it was a long-lasting success. The first 10 implants were done within the multicenter, multinational clinical trial, MDT-103. After that, there was obviously financial restraint at that time and it was difficult to secure funding from the government. The Halifax Infirmary Hospital had a relatively large budget for penile prosthesis, but since the introduction of intracorporal injection therapy for erectile dysfunction, it was not used to the full extent. The money was moved to the SNM program and initially 10 devices per year could be implanted. After few years, the numbers increase to 15–20 per year,¹⁵ covering patients from all the Atlantic provinces. The Halifax program has one of the largest number implanted patients with bladder pain syndrome/interstitial cystitis.¹⁶ In 2013, Dr. Cox joined the department and got involved in the neuromodulation program. In 2018, Dr. Gajewski retired from doing surgery and Dr. Cox is now the only implanter in Halifax.

Edmonton

In 1999, Dr. Gray started practice in Edmonton. He had completed fellowship training in Seattle at the University of Washington under Dr. Michael Mayo and Dr. Jane Miller. Prior to departing Seattle, he was exposed to their first forays into SNM.

After lobbying the Alberta government for two years, the Edmonton SNM program was funded in 2001. Dr. Gray was proctored by Dr. Hassouna in Toronto, and later for cases in Edmonton.

Dr. Gray has been practicing SNM as a solo practitioner for many years. He has recently trained Dr. Joseph Labossiere to assist with and carry on the SNM program for lower urinary tract dysfunction, including refractory overactive bladder (OAB) and idiopathic retention. He has also trained a colorectal surgeon, Dr. Dana Mihalicz, in SNM for fecal incontinence.

The neuromodulation program in Edmonton is currently the only such program in Western Canada and the only program west of Toronto. While there is an interest in developing programs in both Saskatchewan and British Columbia, their respective health authorities have not yet consented to funding.

Over the last year, the Edmonton program has been using newer neuromodulation technology based on a rechargeable system with current regulated stimulation Axonics- r-SNM. Dr. Gray currently has the most experience in North America with this technology.

Sherbrooke

Dr. Tu was trained by Dr. Schmidt in Denver, CO, after completing a master's degree in animal paraplegic models

with SNM with Drs. Hassouna and Elhilali. She had her first patient implanted in 1999 under Dr. Gajewski's guidance at the Centre Hospitalier Universitaire de Sherbrooke. Since then, 12–15 implantations have been done annually due to the hospital's limited budget. After the rise of botulinum toxin A as third-line treatment for OAB, Dr. Tu is currently implanting mainly for pelvic floor dysfunction, underactive bladder, and OAB refractory or unfit for botulinum toxin A (such as detrusor hyperactivity with impaired contractile function). The center advocates bilateral peripheral nerve evaluation following the staged implantation under local anesthesia. Since 2010, the Department of General Surgery initiated the SNM program for fecal incontinence and soon spread their indication to severe chronic constipation, with Dr. Ghislain Devroede and Dr. Nathalie McFadden. Recently, Dr. Salima Ismail (who was trained by Dr. Emmanuel Chartier Kastler) joined the urology team, which intends to increase implantation rates and to provide a provincial referral center for SNM needs.

Moncton

In 2005, Dr. Neil Dwyer moved to Moncton. He had been trained in reconstruction and incontinence at the University of Iowa at Iowa City by Dr. Karl Kreder. Over the first several months, he spent a tremendous amount of time training his nurse continence advisors on InterStim and on how to program and manage patients. The procedures started in January 2006. It took over 10 years for Medicare in New Brunswick to reimburse for the procedures directly. The nurse continence advisors are experts in programming and troubleshooting and an InterStim clinic is held on a regular basis to manage any new and chronic issues, as well as to conduct followups. The main focus of InterStim treatment in New Brunswick and PEI has been for refractory OAB, as well as idiopathic retention. Dr. Dwyer is the only implanter in New Brunswick and often covers PEI.

Conclusions

Despite difficulties created by most of provincial health budget restrictions, Canadian urologists continue to be at the forefront of the new developing technology of SNM, providing patients with alternative treatment for the diseases very often refractory to the first-line treatments.

Competing interests: Dr. Hassouna has participated in a clinical trial for StimRouter supported by Bioness Inc. The remaining authors report no competing personal or financial interests related to this work.

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