

Use of New Rechargeable Battery and MRI-Friendly Technologies in Sacral Neuromodulation Systems to Treat Fecal Incontinence

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1. Abstract

Sacral neuromodulation (SNM) is a minimally invasive therapeutic technique that has been used to effectively treat overactive bladder and bowel dysfunction. There have been, however, several obstacles with standard, non-rechargeable SNM devices such as frequent battery replacement and complications with the conditional safety for full-body Magnetic Resonance Imaging (MRI). Recently, rechargeable and MRI-friendly technologies have been introduced into SNM devices to be used in the treatment of fecal incontinence. Though rechargeable batteries have been utilized recently for treating overactive bladder and urinary dysfunction, the implementation of these new technologies into the treatment of bowel or fecal incontinence is still an emerging topic. Despite its relatively new appearance to the field, previous reports indicate that the implementation of rechargeable batteries and MRI-friendly technologies in SNM systems could provide a wide range of benefits to patients with fecal incontinence. This mini review is based on recently conducted experimental studies and will assess the benefits and limitations that new technologies in sacral neuromodulation impose in treating fecal incontinence.

2. Introduction

Fecal Incontinence (FI) is a common yet serious condition defined by the loss of bowel movements that leads to loose stool and uncontrolled leakage from the rectum [1]. If left untreated, FI could consequently reduce an individual's quality of life and impose not only significant inconveniences but also negative changes to social and emotional behavior [2]. In March 2011, the Food and Drug Administration (FDA) first approved the use of SNM for the treatment

of FI; since then, more than 325,000 patients have been treated with SNM therapy specifically for FI [3].

SNM is a technique that uses electrical stimuli at the interneuron level in the spinal cord to alter neurotransmission processes and results in modulation of efferent outflow. Particularly with FI, the applied stimuli through SNM has been seen to effectively regulate rectal contractions by increasing anal pressure, allowing for control in bowel movements [4]. This form of treatment is often administered to patients with chronic bowel incontinence after experiencing failure to improve with other methods of diet modification, physical therapy, and medications. The standard device for SNM is non-rechargeable, and its applicability is limited for patients who need or potentially need MRI. However, with the rise of new technologies, SNM apparatuses that are both powered by rechargeable batteries and compliant with full-body MRI scans have slowly been gaining popularity due to their advantages such as longer battery life, reduced size, and suitability to various medical treatments [5]. On 6 September 2019, the Axonics® Sacral Neuromodulation System, a rechargeable device used in SNM, was approved by the FDA for the treatment of FI [6]. The proprietary titanium-ceramic neurostimulator case enables the miniaturized neurostimulator to deliver maximum performance for at least 15 years. Even more recently on 3 August 2020, the FDA also approved two new devices, InterStim™ Micro neurostimulator and InterStim™ SureScan™ MRI leads, for the treatment of urinary and bowel control conditions [7].

We will review the benefits and limitations of how the rechargeable and MRI-friendly SNM devices Axonics Sacral Neuromodulation

System and Medtronic InterStim™ Micro compare to generic SNM devices in terms of effectiveness, longevity, and patient satisfaction based on previous and ongoing studies specific to FI.

3. Materials and Methods

3.1. Implant Procedure

The new devices are implanted and trialed similarly to the standard non-rechargeable SNM systems [8]. With the patient in the prone position, rolls are placed to properly situate the sacrum, the buttocks are taped to expose the anus, and the skin is prepped. A foramina needle is inserted into the S3 foramina and the patient should show flexion of the ipsilateral great toe due to stimulation of the pelvic floor muscles [9]. A lead is introduced into the sacrum through the foramina needle in the lower back and in between the hip bones of the pelvis; fluoroscopy is used to aid and ensure proper placement of the lead [8]. Then, the electrode is connected to the implantable pulse generator (IPG) or simply neurostimulator (NS), which is surgically inserted into a subcutaneous pocket that is appropriately leveled at the ipsilateral buttock. The difference in step is that the proximal connector of the lead is connected into a rechargeable neurostimulator instead of its standard. The neurostimulator that is connected to the lead will provide electrical pulses to the sacral nerves, which ultimately assist in restoring the control in bowel movements [9].

An MRI scan of a patient who has undergone implantation of the Axonics® device is shown in (Figure 1).

Panel A is a scan that shows two cuts lateral to the device of SAG T2. Panel B shows another view of the artifact at midline.

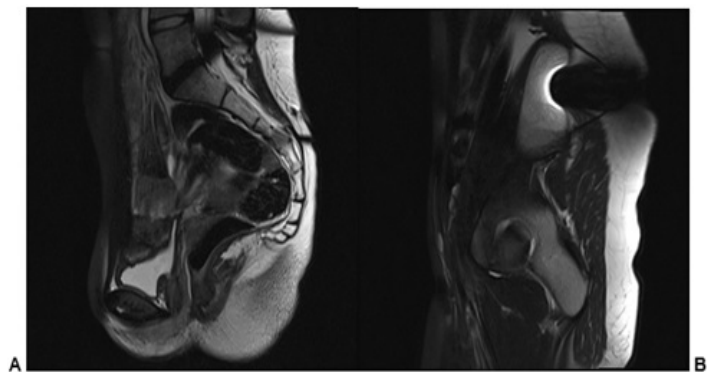


Figure 1: Sagittal abdomen and pelvis MRI photo of a patient who had an Axonics device. T2 SAG FAT. Panel A shows 2 cuts lateral to the device. Panel B shows the device artifact.

4. Results

4.1. MRI Compatibility

The lack of MRI compatibility in previous SNM systems has imposed significant limitations as to their applicability. Currently, there are very few full-body MRI compatible SNM therapy devices available for fecal incontinence; the others are limited to the suitability of head scans.⁵ The FDA approval of these rechargeable SNM devices for use with MRI is conditional yet expanding to include other conditions like lower limb MRI, which represents about a quarter of all

MRIs. MRI-friendly SNM devices could prevent these complications during annual or emergency medication examinations.

The Axonics® neuromodulation kit has certain advantages over Medtronic Interstim™ Micro system including an easier process to prepare for MRI and better parameters (B1+rms, SAR Limit) allowing for better quality, faster scan, and less wait time. In addition, if an MRI scan requires more than 30 minutes, there should be a wait time to allow for cooling. It is 5 minutes with Axonics and 60 minutes with Medtronic. The later wait time poses a great problem to scheduling and room usage -- inconveniences posed on both patients and lab technicians. Some advantages of Medtronic Interstim Micro one doesn't need verify impedance before the scan and relatively smaller size.

4.2. Rechargeability

The rechargeable lithium-ion battery is charged weekly in a transcutaneous and wireless fashion, allowing patients to full mobility. Rechargeable devices are comparably smaller than the standard non-rechargeable devices, allowing for more comfort once implanted. As for the device longevity, the battery life of the rechargeable devices has been estimated to be 15 years compared to the 3-5 years of the standard device. The battery depletion in non-rechargeable devices consequently led to the need for reoperation in order to replace the device. Assuming the similar levels in efficacy and safety from prior analyses, rechargeable devices could decrease the risks that follow reoperation in addition to the significant reduction in cost of medical services. However, it is important to note that rechargeable SNM devices do not decrease or affect the possibility of surgical revisions that are non-battery related [9]. This may include but are not limited to infections resulting from the initial surgical implant, complications with patient response to the electrical impulses, bodily rejection of the foreign device, and faulty lead replacement.

Although modern technologies allow for wireless charging, the consistent need for patients to recharge their device on a weekly basis over the span of 15 years could be cumbersome to groups who are less dexterous and technology-savvy-which is particularly inclusive to those of older age groups. It is noted that the weight of the patients must be taken into consideration during the charging sessions: more obese patients will have a more difficult time charging the implanted device, having to properly angle the placement of the charger at their lower back. The compliance of lifestyle changes is also relatively low at about 20-30%, and the necessary steps that must be accounted for in recharging the device could be of burden to not only the patients but healthcare professionals themselves [5].

4.3. Axonics® Device

As mentioned previously, the two FDA-approved SNM devices from separate companies that encompass these new features of rechargeability and MRI-friendliness are becoming popular for the treatment of FI. The first is the Axonics Sacral Neuromodulation System™ from Axonics® Modulation Technologies. The Axonics® neuro-

stimulator is 5.5 cm³ compared to 14 cm³ of the non-rechargeable Interstim II IPG—a 60% decrease in size [9]. Additionally, the device is made of titanium and ceramics which does not interfere with radiofrequency signaling and permits full-body MRI [9,10].

In a systematic literature review that was used to model the efficacy of their product, it was shown that there were high marks on all four scales of the Fecal Incontinence Quality of Life (FIQL) questionnaire after five years of treatment for patients who received an implant. By the end of the study, it was reported that 64/72 (89%) patients showed over 50% improvement in their bowel movements, while 27/72 (36%) had full control [6]. A Cochrane review also found that 47% of the larger two parallel-group trials consisting of 60 patients reported complete resolution of FI through the SNM system implantation [9, 11]. Trials have consistently shown improvement in FI through SNM, and limited complications have surfaced [12].

Axonics® Sacral Neuromodulation System for Urinary Urgency Incontinence Treatment (ARTISAN-SNM) is another study that tested the efficacy and patient satisfaction using the rechargeable Axonics device. Data was collected from 129 patients with urinary urgency incontinence who evaluated and treated over a 6-month period. A tined lead and rechargeable SNM system were implanted in the participants in a similar process described in the Implant Procedure above [13]. The efficacy of the SNM system was measured and evaluated through a 3-day bladder diary, Internal Consultation on Incontinence Questionnaire Overactive Bladder quality of life (ICIQ-OABqol), and questionnaire and participant satisfaction questionnaire [13] 90% of patients were therapy responders at the end of 6 months. Prior to treatment, the average number of urinary urgency incontinence episodes was 5.6 ± 0.3 per day and was measured to be 1.3 ± 0.2 at the end of 6 months [13]. Given the relatively similar implant process and recorded efficacy that non-rechargeable SNM systems had in treating FI, the efficacy of SNM measured in overactive bladder can be modeled in FI. This is supported by a recent 6-month follow-up of a study that directly tested the treatment of SNM specific to FI with the Axonics® kit. The Axonics® rechargeable SNM device was implanted in 15 patients who were asked to report FI episodes and quality of life in their bowel diary. The results show that the rechargeable SNM system was indeed effective in treating patients with FI: at just four weeks, 13 patients reported $\geq 50\%$ decrease in FI episodes—decreasing from a median of 8 (5.8-20.3) to 1.5 (0.4-4.5) weekly episodes [14]. Additionally, no adverse effects were reported and the overall scores for patient satisfaction using the symptom-related quality of life (QoL) survey, FISII and participant satisfaction questionnaire were high in all marks; those that were particularly outstanding include role limitations due to physical health problems, role limitations due to personal or emotional problems, and social functioning [14].

4.4. Medtronic Device

The informatics from the more recently approved Medtronic In-

terStim™ Micro device (Figure 2), also show promising additions to SNM technology. The newest InterStim™ Micro device is 50% smaller than other rechargeable SNM devices currently on the market—which include the rechargeable Axonics® neuromodulation kit system (Figure 3) [7, 15]. Additionally, the battery can be charged at the convenience of the patient from anywhere between once per week and once per month. Like the Axonics® device, the battery life is at least 15 years so reoperation to replace the battery would occur at a much lower rate than non-rechargeable devices. The device is also made MRI-friendly through the trusted and widely researched Sure Scan MRI technology—allowing for the clearance of impedance checks preliminary to MRI scans [7].

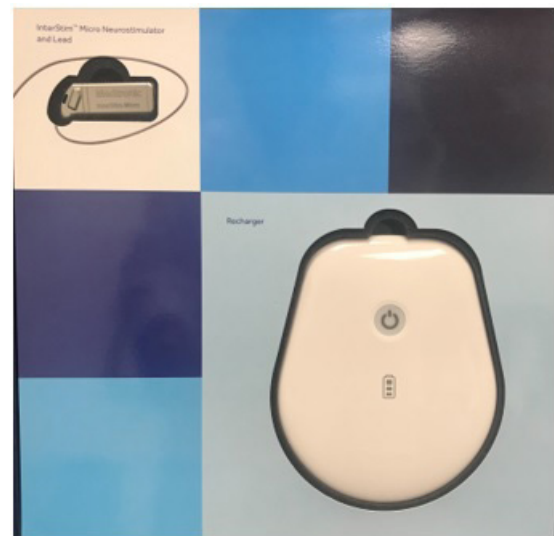


Figure 2: Medtronic InterStim™ Micro neuromodulation kit: includes InterStim™ Micro neuromodulator and lead (top left) and recharger (bottom right).

There is currently no information published regarding trials with InterStim™ Micro. On 6 October 2020, Medtronic announced that the first patient in the ELITE study was implanted with InterStim™ Micro [16]. The Evaluation of InterStim™ Micro System Performance and Safety (ELITE) study is unique to SNM research in that it is the first and only study to include FI in evaluating rechargeable SNM systems [16]. This two-year study plans to enroll 160 participants throughout the United States, Canada, Europe, and Australia and draw data pertaining to the quality of life, complications, symptoms, and outcomes associated with the Micro device.

5. Discussion

The rechargeable Axonics® SNM system is a new and effective method in treating patients with FI. Though there are no detailed reports on the effects of the most recent Medtronic rechargeable and MRI-friendly SNM device has specific to FI, the efficacy of the new SNM systems used for overactive bladder can be modeled in FI due to their close similarities in implantation and response to non-rechargeable SNM devices in previous studies. The modern implementation of new advances in SNM could be of significant benefit to

patients who experience FI; however, like any treatment and technological devices, the outcomes are imperfect.



Figure 3: Comparison of size between Axonics® and InterStim™ Micro neuromodulators

It may be important to note that factors such as age, BMI, technological proficiency, and motivational compliance need to be considered when evaluating the benefits of rechargeable devices. Additionally, previous reported complications of lead migration, infection, and pain should also be closely modeled in future studies. The rates of these complications have been low thus far due to the smaller size and longer-lasting battery life, but with the relative newness of these devices and limited information on their effects on FI, frequent and rigorous examinations following the implant of rechargeable SNM devices should be administered for the next couple years [3]. Patients should be educated on the weighted costs and benefits associated with these new technologies before implantation in order to minimize complications after starting therapy.

Although the Axonics® device has shown some promising results in terms of FI quality of life improvement and symptom resolution, there are some scenarios in which the use of these novel technologies is not optimal. Patients should also be evaluated based on the length of their treatment plan; some patients may not need the full 15+ years of rechargeable SNM therapy to treat FI, and they may be comfortable navigating MRI-related complications if their chances of requiring an MRI within the shortened treatment time are small enough. In such instances of short-term treatment, the more ex-

tensively researched standard SNM systems should be given preference over these newer technologies due to their increased credibility and freedom from having to recharge weekly. If due consideration is given to these specific circumstances, these novel SNM technologies have the potential to revolutionize FI treatment and patient outcomes.

6. Conclusion

Overall, rechargeable and MRI-friendly sacral neuromodulation devices have been shown to have relatively high patient satisfaction and positive outcomes in the treatment of FI [9]. Implementation of these new technologies and others could prolong therapeutic treatment with convenience and improved care. The continuous and renovated integration of MRI-friendly technology will be optimal in not only providing therapeutic FI treatment in patients but also for the accommodation of medical providers. As more patients seek treatment of FI through newly developed SNM systems, the benefits and limitations should be closely monitored in future studies to ensure patient safety and the efficacy of these products.

References

1. Alavi K, Chan S, Wise P, Kaiser AM, Sudan R, Bordeianou L et al. Fecal incontinence: etiology, diagnosis, and management. *Journal of Gastrointestinal Surgery*. 2015; 19: 1910-21.
2. Bharucha AE. Management of fecal incontinence. *Gastroenterology & hepatology*. 2008; 4: 807.
3. Phillips A. Sacral neuromodulation system for treating refractory overactive bladder. *British Journal of Nursing*. 2020; 29: S30-7.
4. Moore CK, Rueb JJ, Derisavifard S. What Is New in Neuromodulation? *Current Urology Reports*. 2019; 20: 55.
5. De Wachter S, Knowles CH, Elterman DS, Kennelly MJ, Lehur PA, Matzel KE et al. New Technologies and Applications in Sacral Neuro-modulation: An Update. *Advances in Therapy*. 2020; 37: 637-43.
6. <https://www.fda.gov/medical-devices/recently-approved-devices/axonics-sacral-neuromodulation-snm-system-p190006>
7. Genereux K. Medtronic Expands Leadership in Treating Bladder and Bowel Control Conditions with Two New FDA-Approved Products: InterStim™ Micro Neurostimulator and InterStim™ SureScan™ MRI Leads. 2020.
8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6583747/>
9. Cohn JA, Kowalik CG, Kaufman MR, Reynolds WS, Milam DF, Dmochowski RR et al. Evaluation of the axonics modulation technologies sacral neuromodulation system for the treatment of urinary and fecal dysfunction. *Expert Review of Medical Devices*. 2017; 14: 3-14.
10. <https://www.axonics.com/patients>
11. Thaha MA, Abukar AA, Thin NN. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane database of systematic reviews*. Cochrane Library. 2015.
12. Falletto E, Brown S, Gagliardi G. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Techniques in Coloproctology*.

2018; 22: 125-7.

13. McCreery R, Lane F, Benson K, Taylor C, Padron O, Blok B et al. Treatment of urinary urgency incontinence using a rechargeable SNM system: 6-month results of the ARTISAN-SNM study. *The Journal of urology*. 2020; 203: 185-92.
14. Jottard K, Van den Broeck S, Komen N, Bruyninx L, De Wachter S. Treatment of Fecal Incontinence With a Rechargeable Sacral Neuro-modulation System: Efficacy, Clinical Outcome, and Ease of Use—Six-Month Follow-Up. *Neuromodulation: Technology at the Neural Interface*. 2020.
15. <https://neuronewsinternational.com/interstim-fda-medtronic/>
16. <https://newsroom.medtronic.com/news-releases/news-release-details/medtronic-announces-first-patient-implanted-elite-study>