Current Urology Reports (2026) 27:61
https://doi.org/10.1007/s11934-026-01377-6

REVIEW

Past, Present, and Future Implantable Neuromodulation Treatments for Management of Urinary Urge Incontinence (UUI): Implications for Clinical Effectiveness and Safety

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Received: 8 September 2026 / Accepted: 28 October 2026
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Abstract

Purpose of the Review This review examines the progress made in neuromodulation therapies for UUI since the original introduction of SNM devices until now. There are multiple current commercial neuromodulation therapies from which to choose, including those with sacral or tibial nerve targets. The intent is to provide critical evidence to help clinicians decide which device to offer their patients.

Recent Findings Modern SNM systems consistently outperform both previous-generation SNM and contemporary iTNM. Modern SNM demonstrates substantially higher effectiveness than pooled averages including early device studies with outdated study designs, tools and implant techniques. Current iTNM outcomes are comparable to legacy SNM yet remain markedly lower than modern SNM.

Summary Contemporary data supports a clear hierarchy—modern SNM offers the highest effectiveness and the most favorable safety profile. We believe that our field is moving toward minimally invasive, highly targeted, patient-directed SNM systems—an evolution that aligns with both clinical outcomes and patient preferences.

Keywords Neuromodulation · Sacral neuromodulation · Implantable tibial neuromodulation · Overactive bladder · Urinary urge incontinence

Introduction

As seasoned urologists, we have witnessed the full evolutionary arc of neuromodulation therapies for urinary urge incontinence (UUI)—from the early, pre-commercial days of sacral neuromodulation (SNM), when it was poorly understood, and had virtually no place in the routine management of urinary or bowel disorders, to its current status as an internationally adopted standard of care with multiple commercial entrants offering refined sacral and tibial systems. Our aim here is to review today's commercially available implantable neuromodulation treatments for urinary urge incontinence, encompassing the most recent safety and effectiveness data available and provide commentary on changing techniques and devices. Herein we critically interpret the data to provide guidance to physicians considering which neuromodulation therapy to choose for their patients.

First and foremost: neuromodulation for bladder issues is a thing. Neuromodulation has a powerful impact on conditions that were historically dismissed, psychologized, or treated with contradictory pharmacologic regimens—sometimes cholinergic agonists and antagonists simultaneously—or, in extreme cases, with augmentation cystoplasty and intermittent catheterization [1]. In addition, SNM has been pioneered for bowel symptoms, and patients implanted originally for urinary symptoms frequently realized improvement in their bowel symptoms along with urinary symptoms, whether clinicians realized it or not [2]. Early on, we advocated for the adoption of what were then considered radical approaches: open procedures with blind

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lead placement, using *big*, *dumb batteries* with virtually no patient programmability and only limited clinician control [3]. Later, more minimally invasive techniques enabled by the tined lead positioned with fluoroscopic guidance, and eventually, the use of the curved stylet [4–7] and optimized lead placement techniques, were validated and incorporated into European and International Continence Society (ICS) guidelines [8]. These improvements have led to contemporary best practices for SNM techniques. Most recently, implantable tibial neuromodulation (iTNM) has been introduced, and techniques and devices for this target continue to evolve.

These clinical and procedural advances reflect the broader trajectory of neuromodulation. Across both SNM and iTNM, the overarching evolution has been toward smaller, less invasive, MRI-compatible and longer lasting systems, driven by continuous innovation in hardware and surgical techniques. Although SNM and iTNM both modulate neural pathways involved in bladder control, they differ fundamentally in stimulation targets, procedural techniques, and potential for risks and relevant symptom improvement. Across clinical literature, SNM consistently demonstrates higher effectiveness for more conditions than tibial neuromodulation. Recent studies have shown that shorter duration therapy may be as effective as the previous standard of continuous stimulation, a finding that allows for the dramatic miniaturization of devices and reduction of complications associated with larger devices and batteries [9–13].

SNM's steady refinement toward minimally invasive, high efficacy systems and iTNM's emergence as a simpler, lower-burden alternative frame the central question of this editorial review: which neuromodulation device should one provide for the patient in front of them? To ground this discussion, the following article summarizes the evolution of SNM and iTNM, the current landscape of FDA-approved devices, and a directional analysis of the safety and effectiveness of both SNM and iTNM. We examine the differing device form factors for SNM and iTNM and associated clinical outcomes of previous and modern neuromodulation systems (Tables 1 and 2). Although a head-to-head study of safety and effectiveness across devices does not yet exist, a directional comparison is inferred based on an understanding of study designs, analytical methodologies, and reported safety profiles.

In the following sections, we will discuss the evolution and current landscape of SNM and iTNM devices and then review the safety and effectiveness outcomes for both. We then address the ramifications of this evolution and data for physicians and patients.

Evolution and Current Landscape of Sacral Neuromodulation (SNM)

The evolution of SNM can be viewed as having two distinct periods in the technology's development—**previous SNM** to **modern SNM (**Tables 1 and 2**)**. This progression reflects major advances in surgical technique, lead and stylet design, adoption of optimal lead placement techniques, and implantable device form factors, each contributing to improved clinical outcomes.

Previous SNM Previous SNM refers to original systems characterized by open surgical approaches, blind (non-fluoroscopic) placement of non-tined leads, absence of optimized lead placement techniques, and larger, short-life implantable pulse generators (IPGs; >10 cc; ~4–8 year

Table 1 Evolution of implantable neuromodulation devices for UUI management, with a representation of clinically meaningful features and outcomes

	Previous SNM		Modern SNM			iTNM		
Device	Medtronic InterStim I	Medtronic InterStim II	Axonics R15	Medtronic InterStim Micro	Neuspera	Boston Scientific/ Valencia eCoin	BlueWind Revi	Medtronic Altaviva
Volume	22 cc	14 cc	5.5 cc	2.8 cc	0.03 cc (IPG), 0.12 cc (Implant)	1.3 cc	0.3 cc	2.6 cc
Responder rate & dry rate *responders (≥50%), % of subjects; dry, % of responders (darker wedge)*	 62% 42%[1]	 77% 47%[1]	 90% 34%	 82%[2] NR	 90.5% 43%	 69% 35%[1]	 78%[3]	 58% 32%[1]
Optimal lead placement techniques used?	No	Mixed	Yes	Yes	Yes	No	No[4]	No
Battery revisions needed?	Needed	Needed	Needed	Needed	Not needed	Needed	Not needed	Needed
Commercially available test / trial?	Yes	Yes	Yes[5]	Yes	Yes[5]	No[6]	No[6]	No[6]
FDA approval	1997	2006	2019	2020	2025	2022	2023	2025

Table 2 Commercially used SNM & iTNM devices (in order of FDA approval)

Modality	Device	Device powering	Device/ IPG volume	Primary device components / Implanted or external	Battery location	IPG / battery life	FDA approval
Previous SNM Transition period	Medtronic InterStim I	Primary cell	~22 cc	Implanted IPG (gluteal pocket) + tined lead at S3	Implanted (inside IPG)	~7 years (5.5–9.2, manufacturer-listed)[f]	1997
	Medtronic InterStim II	Primary cell	14 cc (44 × 51 × 7.7 mm; 22 g)[a]	Implanted IPG (gluteal pocket) + tined lead at S3	Implanted (inside IPG)	~5–7 years	2006
Modern SNM	Axonics SNM System (R15)	Rechargeable	5.5 cc (42 × 22 × 6 mm; 11 g)[b]	Implanted IPG (gluteal pocket) + tined lead at S3	Implanted (inside IPG)	15 years (open-ended); rechargeable, 50 mAh (3.6 V)[b]	2019
	Medtronic InterStim Micro	Rechargeable	~2.8 cc	Implanted IPG (gluteal pocket) + tined lead at S3	Implanted (inside IPG)	15 years to elective replacement indicator; rechargeable[c]	2020
	Axonics F15	Primary cell	~10 cc[e]	Implanted IPG (gluteal pocket) + tined lead at S3	Implanted (inside IPG)	15 + years; 20 + years at low energy settings[e]	2022
	Medtronic InterStim X	Primary cell	12.5 cc (44 × 51 × 7.7 mm; 22 g)[g]	Implanted IPG (gluteal pocket) + tined lead at S3	Implanted (inside IPG)	10.2 years (up to 15 depending on settings and impedance)[g]	2022
	Axonics R20	Rechargeable	~5 cc[e]	Implanted IPG (gluteal pocket) + tined lead at S3	Implanted (inside IPG)	> 20 years; recharge every 6–10 months[e]	2023
	Neuspera System	Externally powered	~0.03 cc IPG / 0.12 cc implantable portion[e]	Implanted IPG + lead at S3; percutaneous placement; no surgical pocket required	External	Designed for 15 years implant service life; no battery replacement	2025
iTNM	Valencia eCoin	Primary cell	~1.3 cc (23 × 3.2 mm)[h]	Coin shaped implanted IPG + integrated electrode (no lead); above fascia near tibial bundle	Implanted (inside IPG)	~3–5 years	2022
	BlueWind Revi System	Externally powered	~0.3 cc[h]	IPG receiver + lead below fascia on tibial bundle	External	Unlimited (no internal battery)	2023
	Medtronic Altaviva	Rechargeable[d]	2.6 cc (15.7 × 43.7 × 4.4 mm; 7.5 g)[d]	Implanted IPG + integrated electrode (no lead); above fascia near tibial bundle	Implanted (inside IPG)	15 years to recommended replacement notification (label: sessions ≤ 2 h/day at 11 mA, 200 µs, 20 Hz); recharge interval patient-specific[d]	2025

[a] Medtronic InterStim II Model 3058 neurostimulator implant manual (2020-07-15), Table 2. [b] Axonics Model 1101 neurostimulator implant manual (110-0127-001rF), Table 1. [c] Medtronic InterStim Systems system eligibility, battery longevity, specifications reference manual (M988757A, 2021-11-01), pp. 13 and 16. [d] Medtronic Altaviva clinician therapy and programming guide, Model P7850N (M028929C001 Rev C, 2025-09-16), Table 20. [e] Manufacturer announcement or pivotal-trial publication; not label-sourced. Axonics R20 supersedes the R15 rechargeable system; InterStim X and InterStim Micro are both current Medtronic offerings. [f] Cameron AP, Anger JT, Madison R, Saigal CS, Clemens JQ. Battery explantation after sacral neuromodulation in the Medicare population. Neurourol Urodyn. 2013;32(3):238–41 (manufacturer-listed battery life). [g] Medtronic InterStim X Model 97800 neurostimulator implant manual (M016984C, 2021-11-01), Table 2. [h] No labeled volume published: eCoin computed from labeled dimensions (23 mm × 3.2 mm disc); Revi estimated whole-implant volume including anchor wings (3 cm × 1.3 cm × 0.27 cm body)

longevity). The first FDA-approved SNM system, InterStim® I, required an open cut-down procedure without fluoroscopic guidance, used non-tined leads, and relied on a large 22 cc IPG.

InterStim II, approved in 2006, advanced the field with a smaller 14 cc IPG and standardized tined lead placement, although its smaller size significantly reduced its longevity and implantation continued to require tunneling of the lead and creation of a subcutaneous pocket for the battery. With the tined lead becoming available in the mid-2000s, fluoroscopic guidance replaced the blind approach, leading to improved outcomes and lower morbidity for SNM as demonstrated in the InSite study [14–17]. The InSite trial reported on 272 implanted patients at 5 years with therapeutic success rate of 67% (95% CI 60–74) using

intention-to-treat analysis and 82% (95% CI 76–88) using per protocol analysis, with UUI subjects showing a mean reduction of 2.0 ± 2.2 leaks per day and urgency-frequency (UF) subjects showing a mean reduction of 5.4 ± 4.3 voids per day. Device-related adverse events were dominated by an undesirable change in stimulation (22%), implant site pain (15%), and therapeutic product ineffectiveness (13%).

By comparison the largest trial and most referenced prior to that was the MDT-103 trial, which reported slightly lower success rates and higher complication rates [18–21]. MDT-103 included 152 implanted patients, first reported by Schmidt in 1999 and updated 5 years later, used intention-to-treat analysis and found at 5 years after implantation 58% of patients with UUI, 56% with UF, and 71% with urinary retention (UR) had successful outcomes, with 279 device- or therapy-related adverse events observed in 102 of the 152 patients. The comparison of the InSite to the MDT-103 outcomes make it evident that large gains have been made in adverse events in the contemporary series with device improvements.

An important caveat to the effectiveness outcomes from this timeframe: studies in this era of SNM typically used a peripheral nerve evaluation (PNE) or staged approach to implant by externalizing a lead for a stimulation trial. Only study subjects that passed the stimulation trial were considered enrolled in the studies and implanted with the permanent systems; intention-to-treat begins with the permanent implant, not the consideration of the patient for SNM therapy. This practice, which mirrors current commercial practice of either externalizing the tined lead or conducting a PNE with an externalized temporary lead for typically 3–7 days of stimulation, biases the effectiveness outcomes by only including subjects that have responded during the stimulation trial. Later studies from Axonics and Neuspera, reviewed below, tend to have direct-to-permanent study designs with subjects being implanted on an intention-to-treat basis. Optimal lead placement involves accurate S3 targeting using fluoroscopy, and the use of a curved stylet-guided trajectory to allow the lead to follow the sacral nerve bundle. This technique ensures stable and effective SNM with low-thresholds and consistent motor response confirmation (bellows and great toe flexion) across all four contacts and improved the ability to target the nerve and maintain good placement [4, 6, 7]. Early tined lead kits included only a straight stylet, and widespread adoption of optimized lead placement techniques did not take place for more than a decade; the curved stylet was incorporated in commercial kits around 2015.

Between 2015 and 2017, commercially sponsored educational programs and expert workshops began promoting optimized lead placement techniques, which were formally adopted in the ICS Best Practice Statement [8]. Even with guideline recommendations, adoption remained inconsistent across clinicians. During this period and before, patient selection was also less refined and often included patients with very severe pathology who had failed all prior therapies and had many comorbidities.

Collectively, these factors contributed to the modest and variable responder rates of approximately **55–79%**-observed in studies such as MDT-103, InSite, and ROSETTA (Fig. 1) [17, 18, 21, 22].

Modern SNM Modern SNM reflects the era of smaller devices, fluoroscopy-guided percutaneous implantation, improved tined-lead technology, standardized optimal lead placement techniques, curved stylets and MRI-compatible devices. This era also included the introduction of the Axonics® device, featuring a rechargeable < 10 cc

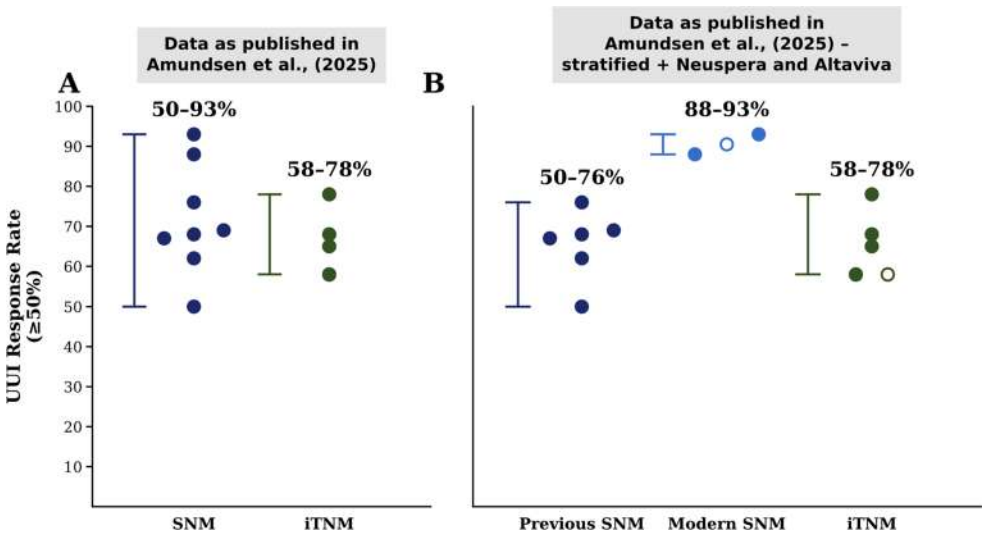

Fig. 1 (**A**) SNM and iTNM results as reported in Amundsen et al. [39] (**B**) Stratified Amundsen data as previous SNM, modern SNM and iTNM, supplemented with Neuspera [24] (trial-period responder set) and Altaviva [37] data (all implanted cohort, open markers). The range of responder rates is noted for each device category. Note that the range of modern SNM responder rates is non-overlapping with both previous SNM and iTNM

MRI-compatible IPG. We have also seen longer device life and the incorporation of physician training on contemporary surgical methods, including percutaneous access and optimized lead placement.

The most recent advancement in modern SNM is the Neuspera® system (FDA approved 2025), an ultraminiaturized, fully percutaneous SNM platform in which the integrated lead and IPG are implanted directly at the S3 foramen without tunneling, blunt dissection, or pocket creation, representing the most minimally invasive iteration of SNM to date. In Neuspera's pivotal study, the SANS-UUI study, all enrolled subjects were implanted without a trial phase, and 88% of implanted subjects were responders at the 12-month endpoint [23–25]. Eighty-one percent (81%) of subjects who responded to treatment were classified as "super responders," meaning they experienced at least a 75% reduction in UUI symptoms, and 43% of patients who responded were completely "dry," with 100% reduction in UUI symptoms. These results were achieved with the vast majority of subjects receiving just 2 h of stimulation per day. Early data from Neuspera also demonstrated a favorable safety profile with lower infection rates, fewer wound-related complications, and reduced implant-site discomfort compared to SNM systems with implanted batteries [9].

Across this category, modern SNM systems including Axonics R20 and F15, InterStim Micro, InterStim X, and Neuspera, demonstrate substantially improved responder rates of **82–90%** in contemporary trials such as RELAX OAB, ARTISAN SNM, and SANS-UUI [9, 12, 26–30]. The improved effectiveness reflects the combined impact of optimized lead placement, improved device design, more refined patient selection with less refractory subjects with reduced comorbidity burden. The most common device-related adverse events for the modern SNM devices are pain and/or discomfort relating to stimulation, ranging from 3 to 5% [9, 24–29]. The most modern devices also have reduced revision rates associated with battery depletion and pocket-related complications compared to the previous devices, with the Neuspera device removing complications due to implanted batteries entirely.

Evolution and Current Landscape of Implantable Tibial Neuromodulation (iTNM)

Implantable tibial neuromodulation evolved from office-based percutaneous tibial nerve stimulation (PTNM), with the goal of translating a temporary and externally placed neuromodulation device into a fully implanted chronically delivered therapy. Leveraging decades of SNM and PTNM experience, early iTNM systems were designed with the expectation that targeting the posterior tibial nerve would allow simpler procedures, smaller devices, and potentially improved safety profiles.

Three iTNM devices are currently FDA approved (see Tables 1 and 2). The BlueWind Revi system uses an implanted tibial lead placed below the fascia paired with an external wearable IPG, reducing implanted hardware while enabling patient-controlled therapy. The eCoin® device from Valencia Technologies (now Boston Scientific) is a fully implanted, coin-sized IPG with an integrated lead placed above the fascia; the device is non-rechargeable and must be replaced upon battery depletion, estimated between 3 and 5 years with nominal settings [31]. The Medtronic Altaviva™ system is a similar fully implanted, rechargeable, above-the-fascia iTNM device. These both eliminate external components while maintaining a tibial-nerve mechanism of action.

Responder rates from the iTNM devices range from **58% to 78%** [32–37]. The placement of the tibial stimulation electrode, sub- or supra-fascial, may explain the wide range of effectiveness seen between the tibial devices. The Revi device (sub-fascial) is placed in direct contact with the nerve and may provide more reliable stimulation of the nerve, which may account for the higher responder rates compared to the other supra-fascial devices.

The most common device-related adverse events (AEs) for the tibial devices are for pain or stimulation-related discomfort, in roughly 4–6% of subjects [32, 34, 37]. Procedure-related AEs, mostly wound infections and other wound-healing complications, occurred in 7.9% (Altaviva) [38] and 10.6% (Revi) [34] of subjects; eCoin reported device- or procedure-related events together in 20% of subjects with infections in 7% of subjects [32]. Most device- and procedure-related AEs occurred in the first six months, but additional events continued to occur at later timepoints [33, 35, 36].

SNM and iTNM Safety and Effectiveness Comparison

Looking across this data, a clear generational progression appears evident. Modern SNM systems consistently outperform both previous-generation SNM and contemporary iTNM, achieving the highest responder rates through optimized lead placement, modern percutaneous procedures, and stable stimulation delivery. These same refinements also yield a more favorable safety profile, with lower rates of infection, wound-related complications, and implant-site discomfort. The Neuspera device, in particular, provides a compelling therapeutic option as it provides the same gold-standard effectiveness as other modern SNM systems, but without battery-related complications.

By contrast, iTNM offers a lower-burden surgical alternative that may broaden access, but its effectiveness remains meaningfully lower and adverse event rates modestly higher than modern SNM. There is also no added benefit to bowel symptoms in patients with dual pathology for iTNM therapy. Together, these data position modern SNM as the most effective, robust, and safest neuromodulation option for treatment of overactive bladder (OAB).

Understanding this evolution and framing the evidence accordingly is important; pooling all SNM data, previous and modern, while disregarding the device, technique, and patient selection generations can significantly obscure the substantial advancements that define modern SNM. For example, a recent meta-analysis published by Amundsen et al. [39] demonstrates this limitation (see Fig. 1A). Combining previous and modern SNM studies causes the older SNM studies to be lumped with the new SNM outcomes, resulting in a wide spread of responder rates. When these outcomes are stratified based on whether modern or previous SNM techniques and devices are used (Fig. 1B), the difference between the two types of SNM as well as iTNM becomes clear.

This reanalysis of the same literature, supplemented with the latest Neuspera (modern SNM, trial-phase responders only) [24] and Altaviva (iTNM) [37] data and stratified into previous SNM, modern SNM, and iTNM, reveals a consistent pattern:

- Modern SNM demonstrates substantially **higher effectiveness** than the pooled SNM average and clearly exceeds previous-generation SNM.
- iTNM outcomes are comparable to legacy SNM yet remain **markedly lower** than modern SNM.

While formal statistical testing and direct comparison studies will further reinforce these distinctions, the directional trends are clear and align with the broader clinical literature. Recognizing these generational differences is essential for accurate interpretation of the evidence and for guiding contemporary clinical decision-making.

MRI Considerations

In addition to the considerations of safety and effectiveness, differences in MRI compatibility for the devices remain a consideration for our OAB patients. Early devices had very limited labeling, but the devices in use today all have some degree of MRI-conditional labeling. Table S1 shows a detailed comparison of the devices.

Battery-powered SNM systems permit full-body MRI at 1.5/3.0T with 30–60 min session limits and have anatomical restrictions on specific absorption rate (SAR). The Neuspera SNM system allows full-body scans with a 60-minute session limit with no SAR restrictions within normal mode. For iTNM devices, the BlueWind device allows full-body mode with 30–60-minute session limits without special modes or SAR restrictions within normal mode. eCoin does not allow scans of the lower leg, has 30–60-minute session limits, and cannot be placed inside the MRI bore. Altaviva has a 60-minute limit below the hip with no limits above and allows full normal mode scanning. The newer devices tend to not need to be placed in a special MRI-safe mode prior to scanning, a step that can create confusion for the patient and imaging center. Because many of the patients we treat will need an MRI at some point, we recommend utilizing devices with broad labeling to ensure that a patient is not faced with an explant or delayed imaging when an MRI is needed.

Discussion

Monumental progress has been made since the time when oxybutynin was the most attractive treatment option for OAB. Modern SNM performed with contemporary devices, using current best practices for implantation, offers the greatest potential of success for UUI patients who are seeking minimally invasive therapy. Simply stated, SNM is our best tool. Modern SNM devices used in contemporary trials demonstrate predictable, consistent benefit in reducing UUI episodes by at least 50% in approximately 90% of patients. The robustness of the response is unparalleled, with a large proportion of subjects reporting they are completely dry on three days out of a three-day diary, aka “dry” [25–27]. Some patients may be reluctant to choose SNM due to concerns about invasiveness and need for an implant, but these concerns can be minimized with the advent of a minimally invasive battery-free device such as Neuspera’s, which eliminates the potential for battery-related complications and reoperations. Patients with these devices usually have no awareness of an implant, nor do their intimate partners. In contrast, some iTNM therapies offer a device that may be easier for physicians to implant, but with the tradeoff that it has significantly lower efficacy in the same patient population as does modern SNM and offer minimal or no additional potential for simultaneous improvement of associated bowel complaints and a potential for more complications. In the case of SNM, a fully reversible PNE trial being performed under local anesthesia provides a useful tool for the patient and physician for SNM systems as the patient can gauge the potential benefit before committing to an implant.

Current data suggests there is minimal need to routinely program sacral systems to deliver continuous or

near-continuous stimulation [9–13]. Chronic stimulation appears unnecessary for typical UUI subjects based on the results of SANS-UUI study, with results equivalent to the ARTISAN-SNM trial with only 2 h of active stimulation per day for nearly all subjects. The efficacy of intermittent stimulation has also been demonstrated for tibial therapies [32–37]. It remains to be determined if even shorter periods of daily or less frequent stimulation will also be adequate for SNM patients, although we believe this is likely. And routine continuous stimulation is apt to have some negative consequences due to central accommodation, leading to declining efficacy over time [40], with need for reprogramming and eventual lead revisions or combined therapies. At the very least, we should now be thinking about starting or reprogramming new or established patients to 2 h of stimulation per day.

A deliberate action on the part of the patient with a Neuspera or Revi device is required for the therapy to be delivered and to receive benefit. In these cases, an individual needs to decide where, when, and for how long the wireless transmitter should be used. This can easily be incorporated into a daily routine for most subjects. For the Neuspera device, as soon as the stimulation is applied, they receive familiar and comfortable sensory feedback, like a well-positioned PNE trial. The sensation has a positive connotation for them, indicating that "it is working" and that they are helping themselves. The necessary engagement of the executive decision-making part of the brain, and the immediate sensory feedback are both missing from traditional SNM and the eCoin and Altaviva iTNM devices, where "set it and forget it" is the goal, and subsensory settings are routinely employed. The patient-centric feedback approach may prove to have a more enduring benefit due to altered neuroplasticity, since it more closely emulates how the voiding reflexes are originally trained. This may explain the higher proportion of super responders and completely dry subjects in the SANS-UUI trial, and the relatively better outcomes of Revi compared to other iTNM therapies, even though the improved Revi outcomes have been routinely attributed to the proximity of its device to the tibial nerve compared to those placed above the fascia. And while "set it and forget it" is a familiar trope, it is not routinely and reliably achieved, and it is not possible to predict which patients will be successful ahead of time. If patients with insufficient or declining efficacy know enough to change their programs or visit a device representative or clinician who can help, they may improve for a period of time. Otherwise, they may suffer from sub-par control in silence. "Forget-it" shouldn't mean the patient. Our field needs to become curious about the combined potentials of behavior and neuromodulation, and the role of sensation in restoring patient control of symptoms and normalizing voiding reflexes. We already incorporate biofeedback and pelvic training as primary treatments for these patients.

In presenting minimally invasive therapy options to patients, the relative efficacy between modern SNM and iTNM is critical. The use of PNEs in SNM is a major advantage because it avoids implanting non-responders and limits their exposure to adverse events. Without a PNE trial – as with iTNM – about 40% of iTNM implant patients will not have at least a 50% improvement in their leaks [37]. That costly error, in terms of both finances and lost hope for the patient, will likely be multiplied over time. And among those that do meet this minimum standard for success, the degree of elimination of leaks is likely to be substantially less than with modern SNM. And the robustness of the response is clearly less. Why else would dryness be defined as "dry on three consecutive days out of a seven-day diary" as it was in the Revi trial [34]? To quote the Carpenters, "Rainy days and Mondays always get me down…" Patients will live the reality of every day. A recurring narrative—primarily advanced by iTNM manufacturers and their advocates—suggests that differences in effectiveness between SNM and iTNM matter less to patients, and that quality-of-life improvements matter more than achieving the traditional ≥ 50% responder threshold. This is not borne out by our experience, which has shown us that SNM patients who have persistent symptoms often seek additional treatment – whether a return to medications or adding chemodenervation injections. We should aim to minimize that concern, not compound it. **Also**, **there is a tendency among surgeons to underestimate the impact of procedures**, **especially those classified as minimally invasive; a surgical procedure is a much bigger deal to our patients who are undergoing them.** How likely is it that a patient who has put their desperate hopes on iTNM and fails to gain sufficient relief will be willing to move on to SNM, especially if their physician has incorrectly asserted their equivalence, obscured their relative efficacies, and who may be uncomfortable with SNM in their own hands? The patient would have to find their way to someone else to be offered a trial of SNM leading to their ultimate goal of satisfactory symptom relief. A majority of patients may be lost along the way. We believe it is better to help them with the therapy that is likely to be the most successful from the start.

Finally, while the risk of complications with modern SNM is well known and potentially decreasing with use of newer devices, their management is something most implanting physicians understand. We know what to expect, and these complications tend to decrease over time post-implant. Adoption of the Neuspera SNM device should significantly reduce procedure-related complications and eliminate battery related concerns. In contrast, complications associated with iTNM must also be considered, but

these may increase over time or with aging due to vascular changes, lymphedema, trauma and mobility issues associated with the lower extremity. The current trend also shows higher rates of wound-related complications, implant-site infections, and device-related pain compared with modern SNM. These are less familiar to urologists and gynecologists who may be implanting devices with a more limited skill set for addressing them and have the potential for serious consequences. Only time will tell.

Conclusions

Taken together, contemporary data supports a clear hierarchy—***modern SNM offers the highest effectiveness and the most favorable safety profile***. The latest iteration of modern SNM, the Neuspera SNM System, provides gold-standard effectiveness while eliminating complications related to an implanted battery. In contrast, iTNM could provide lower initial surgical burden, but modest effectiveness and slightly higher AE rates ***do not justify routine or widespread uptake when there are even less invasive alternatives with greater proven efficacy and robustness***. Previous-generation SNM should no longer serve as a benchmark for evaluating current technologies. We now know better, and optimized lead placement techniques can easily be taught and adopted, leading to greater facility and ease of device placement by experienced and new implanters.

These distinctions matter clinically, and device selection should reflect modern evidence rather than legacy assumptions. We believe that this field is moving toward minimally invasive, highly targeted, patient-directed SNM systems—an evolution that aligns with both clinical outcomes and patient preferences.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11934-026-01377-6.

Acknowledgements Jai Shetake and Courtney Lane PhD contributed towards the article.

Author Contributions SS wrote the main manuscript text, and ME, CP and MK performed multiple reviews and made substantial contributions to the final document. SS had editorial support and help with preparation of figures and tables from JS and CL, who are credited in the document and who's activites were supported by Neuspera.

Data Availability No datasets were generated or analysed during the current study.

Declarations

Competing interests S. Siegel serves as Chief Medical Officer of Neuspera Medical, Inc., and in that role receives consulting fees, support for meeting attendance and travel, and stock options, and participates in advisory activities for the company. M. J. Ehlert has received consulting fees from Boston Scientific and Coloplast and honoraria for physician education courses from Boston Scientific and Coloplast, has previously served as an advisory board member for Valencia Technologies, and serves on the SUFU Education Committee (2025–2026). C. R. Powell has served as a site principal investigator for Medtronic, Inc. (PEER 2 trial) and for Neuspera Medical, Inc. (SANS-UUI trial). M. R. Kaufman has served as a site principal investigator for Medtronic, Inc., and has received consulting fees from Boston Scientific, Inc. (Valencia, prosthetics medical advisory board).

Disclosure & Human and Animal Rights Statements The authors would like to acknowledge and thank Jai Shetake, Ph.D., and Courtney Lane, Ph.D., for their assistance in the preparation of this manuscript. This manuscript work was funded in part by Neuspera Medical, Inc. All reported studies/experiments with human or animal subjects performed by the authors have been previously published and complied with all applicable ethical standards (including the Helsinki declaration and its amendments, institutional/national research committee standards, and international/national/institutional guidelines).

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