

Mini Review

# The Impact of New Sacral Neuromodulation Technologies on the Quality of Life of Patients with Refractory Overactive Bladder: A Mini-Review

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## Abstract

Overactive bladder (OAB) affects millions of patients worldwide and significantly impairs quality of life. For patients with refractory OAB who fail conservative and pharmacological therapies, sacral neuromodulation (SNM) has emerged as a highly effective minimally invasive treatment option. Recent technological advances, particularly the development of rechargeable SNM systems with extended longevity and miniaturized designs, have transformed the therapeutic landscape. This mini review examines the impact of new SNM technologies on patient quality of life, comparing traditional non-rechargeable devices with newer rechargeable systems, and evaluating clinical efficacy, safety profiles, and patient satisfaction outcomes. Evidence demonstrates that both traditional and novel SNM systems provide sustained improvements in OAB symptoms and quality of life, with success rates ranging from 67-90% at long-term follow-up. Rechargeable systems offer the advantage of extended device longevity (15+ years) and reduced need for replacement surgeries, though recent data suggest potentially higher revision rates related to charging difficulties. Quality of life improvements are consistently demonstrated across multiple validated instruments, with patients reporting significant reductions in symptom burden and enhanced satisfaction. This review synthesizes current evidence to assist clinicians in navigating the evolving SNM landscape and selecting the most appropriate technology for patients with refractory OAB.

## Introduction

Overactive bladder syndrome is characterized by urinary urgency, with or without urgency incontinence, usually accompanied by increased daytime frequency and nocturia [1]. The condition affects approximately 16-17% of adults globally and has profound negative impacts on physical, psychological, and social well-being [2]. While behavioral modifications and pharmacotherapy represent first-line treatments, long-term compliance remains poor, with high failure rates leading to patient frustration [1].

For patients with refractory OAB, the 2024 American Urological Association/Society of Urodynamics, Female Pelvic Medicine Urogenital Reconstruction (AUA/SUFU)

guidelines recommend sacral neuromodulation, tibial nerve stimulation, and/or intradetrusor botulinum toxin injection as effective minimally invasive options. SNM has been associated with high success rates, durable efficacy, and excellent patient satisfaction [1]. The technology works by modulating sacral nerve reflex pathways through an implanted electrode, enabling improvement of multiple pelvic floor dysfunction symptoms simultaneously [3].

Recent years have witnessed significant technological evolution in SNM systems. The introduction of rechargeable devices with miniaturized designs and extended longevity represents a paradigm shift from traditional non-rechargeable systems that required replacement every 4-5 years [4,5].

## More Information

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The primary aim of this review is to evaluate the clinical impact of recent SNM technological shifts on patient-reported outcomes. Specifically, it structures the current evidence by first detailing the technical evolution from non-rechargeable to rechargeable systems, followed by a comparative analysis of their efficacy, safety profiles, and long-term quality of life implications.

## Evolution of sacral neuromodulation technologies

### Traditional non-rechargeable systems

The InterStim system, approved by the FDA in 1997, represented the first commercially available SNM device for OAB [6]. Traditional non-rechargeable implantable pulse generators (IPGs) have an average device lifespan of 4.4 years, necessitating multiple replacement surgeries for long-term OAB management [5]. Despite this limitation, long-term studies demonstrate sustained efficacy. A prospective multicenter study of 272 patients showed a 5-year therapeutic success rate of 67% using modified completers analysis and 82% using completers analysis. Patients with urgency urinary incontinence experienced a mean reduction of 2.0 leaks per day, while those with urgency-frequency had a mean reduction of 5.4 voids per day (both  $p < 0.0001$ ) [7].

Quality of life improvements with traditional systems are well-documented. At 5-year follow-up, patients showed significant improvement in all International Consultation on Incontinence Modular Questionnaire-Overactive Bladder Quality of Life (ICIQ-OABqol) measures ( $p < 0.0001$ ) [7]. Three-year data from the same cohort demonstrated an 83% therapeutic success rate with statistically significant improvements across all quality of life measures [8].

### Rechargeable SNM systems

The Axonics r-SNM System, introduced as the first rechargeable SNM device, is designed to last a minimum of 15 years in the body [4,5,9]. This miniaturized, rechargeable system aims to eliminate replacement surgeries due to battery depletion, potentially reducing patient surgical risks and healthcare costs [4]. The ARTISAN-SNM study, a pivotal trial of 129 patients implanted with the rechargeable system in a non-staged procedure, demonstrated a 90% responder rate at 6 months. Patients experienced a mean reduction in urgency urinary incontinence episodes from 5.6 per day at baseline to 1.3 per day, with a clinically meaningful 34-point improvement on the ICIQ-OABqol questionnaire [4].

Long-term data from the RELAX-OAB study showed sustained efficacy at 2 years, with 90% of test responders continuing to respond to therapy. Satisfaction with therapy was reported by 93% of subjects, and 86% found their charging experience acceptable [9]. At 1-year follow-up, 94% of test responders continued to respond to therapy, with subjects experiencing a significant 21.1-point improvement

on the ICIQ-OABqol. Notably, 84% of subjects were satisfied with therapy and 98% found the recharging experience acceptable [5].

### Comparative device performance

A comparative study of the InterStim and BetterStim systems in 113 patients with OAB demonstrated that both systems significantly improved voiding diaries and subjective scores over the treatment period [10]. Urination frequency, average voiding volume, and average urinary leakage improved significantly in both groups (all  $p < 0.001$  for frequency and volume;  $p < 0.05$  for InterStim and  $p < 0.01$  for BetterStim regarding leakage). Importantly, the urgency perception scale and OAB-related quality of life scores showed significant differences at baseline between groups but these differences were not maintained at follow-up ( $p = 0.81$  and  $p = 0.479$ , respectively), suggesting comparable quality of life outcomes [10].

However, recent data raise concerns about revision rates with rechargeable devices. A retrospective cohort study of 246 patients (150 rechargeable, 96 non-rechargeable) found significantly different revision rates between groups, with 34% of rechargeable device patients requiring revisions compared to 13.5% in the non-rechargeable group ( $p < 0.001$ ). The most common reasons for revision in the rechargeable group included difficulty charging (35.3%) and reduction of symptom improvement (23.5%) [11].

To provide a clear clinical overview, Table 1 summarizes the key performance metrics, longevity, and safety profiles comparing traditional non-rechargeable and modern rechargeable sacral neuromodulation systems.

## Impact on quality of life

### Symptom-specific quality of life improvements

Quality of life improvements with SNM are consistently demonstrated across multiple validated instruments. The ICIQ-OABqol, a disease-specific quality of life measure, shows substantial improvements across all domains. In the 5-year InterStim study, patients demonstrated sustained

**Table 1:** Clinical Comparison of Non-Rechargeable vs. Rechargeable SNM Systems

Feature	Non-Rechargeable SNM (InterStim)	Rechargeable SNM (Axonics)
Therapeutic Success Rate	67% – 82% at 5 years	90% at 6 months to 2 years
Device Longevity	~4.4 years average	15+ years
Common Complications	Change in stimulation (22%), site pain (15%), ineffectiveness (13%)	Stimulation discomfort (20%), charging difficulties (35.3% of revisions)
Surgical Revision Rate	13.5%	34%
Patient Satisfaction	High sustained QoL improvements over 5 years	93% at 2 years; 86%–98% find charging acceptable
Clinical Advantage	Established long-term track record; no patient charging burden	Miniaturized design; reduced need for battery-depletion surgeries



improvements in all ICIQ-OABqol measures ( $p$  0.0001), with 80% of subjects reporting improvements in urinary symptom interference [7,8].

A prospective follow-up study examining affective symptoms and quality of life in 95 patients undergoing SNM found that successful OAB patients reported significant improvement in all domains of the OAB-q questionnaire, health change, and affective symptoms. This suggests that SNM's benefits extend beyond purely physical symptom relief to encompass psychological well-being [12].

### Comparative quality of life outcomes

When compared to other third-line treatments, SNM demonstrates competitive quality of life outcomes. The ROSETTA trial, a randomized clinical trial comparing onabotulinumtoxinA with SNM in 381 women with refractory urgency urinary incontinence, found that both treatments improved quality of life over 6 months [13]. Participants treated with onabotulinumtoxinA showed greater improvement in the Overactive Bladder Questionnaire Short Form (OAB-SF) for symptom bother ( $-46.7$  vs.  $-38.6$ ; mean difference 8.1; 95% CI 3.0 - 13.3;  $p = 0.002$ ), treatment satisfaction (mean difference 7.8; 95% CI 1.6-14.1;  $p = 0.01$ ), and treatment endorsement (mean difference 10.4; 95% CI 4.3 - 16.5;  $p$  0.001). However, there were no differences in convenience, adverse effects, or treatment preference between the two modalities [13].

A network meta-analysis comparing onabotulinumtoxinA, SNM, and peripheral tibial nerve stimulation (PTNS) found that compared with placebo, all three treatments were more efficacious for selected outcome parameters. SNM resulted in the greatest reduction in urinary incontinence episodes and voiding frequency compared with onabotulinumtoxinA and PTNS, though onabotulinumtoxinA resulted in a higher number of complications including urinary tract infections and urinary retention [14].

### Clinical application and patient selection

The selection between SNM and other third-line therapies like OnabotulinumtoxinA depends on specific clinical profiles:

**Indications:** SNM is preferred for patients seeking a long-term, "set-and-forget" or "rechargeable" solution without the risk of clean intermittent self-catheterization (CISC), which is a known risk with OnabotulinumtoxinA.

**Contraindications:** SNM is generally contraindicated in patients who are unable to operate the programmer/charger, those with inadequate response during the trial phase, or patients requiring frequent pelvic MRI (though many newer systems are now MRI-conditional).

**Patient selection:** Ideal candidates for rechargeable SNM

are those with longer life expectancy who are cognitively and physically capable of managing the recharging interface, whereas non-rechargeable systems may be better suited for patients prioritizing a lower treatment burden.

### Patient satisfaction and treatment burden

Patient satisfaction represents a critical quality of life outcome. With rechargeable SNM systems, satisfaction rates are consistently high. The ARTISAN-SNM study reported that 90% of participants were therapy responders at 6 months, with no serious device-related adverse events [4]. The RELAX-OAB study demonstrated 93% satisfaction with therapy at 2 years and 84% at 1 year [5,9].

The charging experience, a unique aspect of rechargeable systems, appears well-tolerated. In the RELAX-OAB study, 98% of subjects found their charging experience acceptable at 1 year, and 86% at 2 years [5,9]. This suggests that the treatment burden associated with regular recharging does not significantly detract from overall satisfaction.

### Safety and efficacy considerations

#### Adverse event profiles

Safety profiles for SNM systems are generally favorable. In the 5-year InterStim study, the most common device-related adverse events were undesirable change in stimulation (22%), implant site pain (15%), and therapeutic product ineffectiveness (13%) [7]. No life-threatening or major irreversible complications have been reported in reviewed studies [15].

For rechargeable systems, the RELAX-OAB study reported device-related adverse events in 21% of subjects at 1 year, with discomfort due to stimulation occurring in 20% of subjects. Importantly, this adverse event was resolved with reprogramming in all instances [5]. At 2 years, there were no unanticipated adverse events or serious device-related adverse events [9].

The higher revision rates observed with rechargeable devices (34% vs. 13.5%) represent a significant safety and quality of life consideration. Device malfunction or difficulties connecting to the device may contribute to these higher revision rates, potentially impacting patient satisfaction and healthcare costs [11].

### Long-term durability

Long-term efficacy is crucial for sustained quality of life improvements. A retrospective study of 66 patients with refractory OAB found a 74.5% success rate after a median follow-up of 32 months, with mean number of pads used in 24 hours decreasing significantly from 3.5 preoperatively to 1.2 at last follow-up ( $p$  0.001). However, the study also noted a high re-operation rate of 18.2% and device explantation in 27.3% of patients after a median duration of 24 months [6].



A systematic review examining SNM for OAB treatment found that surgical re-intervention rates were high, with a median of 33.2% (range 8-34%) in studies with at least 24 months follow-up [15]. This highlights the importance of long-term patient follow-up and counseling regarding potential need for revisions.

## Clinical challenges and economic considerations

### Long-term complications and adherence

While SNM is effective, long-term adherence can be challenged by device-related issues. Beyond surgical revisions, patients may face “therapy fatigue” particularly with rechargeable systems if the charging routine becomes burdensome over years, despite high initial satisfaction rates.

### Cost-effectiveness

The shift toward rechargeable systems (15+ year longevity) is fundamentally driven by cost-effectiveness. By eliminating the need for battery-replacement surgeries every 4–5 years, these devices potentially reduce the cumulative surgical risk and long-term healthcare expenditure, although the initial implant cost is typically higher.

### Future directions and emerging technologies

Beyond traditional sacral and rechargeable SNM systems, several investigational neuromodulation techniques are being studied for lower urinary tract dysfunction. These include peroneal neuromodulation, transcutaneous electrical nerve stimulation, magnetic nerve stimulation, and parasacral transcutaneous neuromodulation. While these techniques show promising results in treating OAB symptoms, available results are not yet sufficient for guidelines to recommend their use [16].

Implantable tibial nerve stimulation (iTNM) systems have recently become commercially available in the United States, offering a new method of neurostimulation for OAB treatment [17]. A systematic review and meta-analysis found similar efficacy and safety of SNM and iTNM for OAB treatment, including similar urgency urinary incontinence and OAB symptom response rates (71.8% and 71.3% for UUI responder rates, respectively), significant improvements in quality of life, and low rates of procedure and device-related adverse events. Notably, this comparable efficacy was seen without the use of a trial phase of neuromodulation in the iTNM studies versus SNM studies [17].

## Conclusion

New sacral neuromodulation technologies have significantly impacted the quality of life of patients with refractory overactive bladder. Both traditional non-rechargeable and newer rechargeable SNM systems demonstrate sustained efficacy, with success rates of 67-90% at long-term follow-up and consistent improvements across

multiple quality of life domains. Rechargeable systems offer the theoretical advantage of extended device longevity (15+ years) and elimination of replacement surgeries, though recent data suggest potentially higher revision rates related to charging difficulties and device malfunction.

Quality of life improvements with SNM are multidimensional, encompassing reductions in symptom burden, improvements in affective symptoms, and high patient satisfaction rates. When compared to other third-line treatments such as onabotulinumtoxinA, SNM demonstrates competitive outcomes with distinct advantages and disadvantages that should be discussed with patients during shared decision-making.

The choice between traditional and rechargeable SNM systems, as well as between SNM and alternative treatments, should be individualized based on patient preferences, clinical characteristics, and treatment goals. Clinicians should counsel patients about the potential need for revisions, particularly with rechargeable devices, while emphasizing the sustained quality of life benefits demonstrated across multiple studies. As emerging technologies such as implantable tibial nerve stimulation continue to evolve, the therapeutic armamentarium for refractory OAB will likely expand, offering patients increasingly personalized treatment options.

Future research should focus on identifying predictive factors for treatment success, optimizing device selection algorithms, and conducting long-term comparative effectiveness studies to guide evidence-based clinical decision-making. Additionally, standardized quality of life outcome measures and longer follow-up periods will be essential for comprehensively evaluating the impact of new SNM technologies on patient well-being.

## Declaration

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