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Three month clinical results with a rechargeable sacral neuromodulation system for the treatment of overactive bladder

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Aims: The primary aim of the RELAX-OAB study is to confirm the safety and efficacy of the Axonics r-SNM System, a miniaturized, rechargeable SNM system.
Methods: A total of 51 OAB patients were implanted in a single-stage implant procedure. These results represent the 3-month outcomes. Subject outcomes were evaluated using 3-day bladder diaries and quality of life questionnaires.
Results: A total of 31 of 34 patients (91%) that responded during an initial trial period ("Test Responders") continued to benefit from therapy with the Axonics r-SNM System at 3-months, defined as symptom improvement of ≥50% reduction in urinary voids or incontinence episodes or a return to <8 voids per day. Subjects who were Test Responders showed a statistically and clinically meaningful improvement in all aspects of quality of life (ICIQ-OABqol). No serious device-related adverse events (SADEs) occurred, and there were no unanticipated adverse events (UAEs). One subject was explanted due to an infection at the implant site and 19.6% of subjects experienced device related adverse events, most notably discomfort due to stimulation, which was resolved with reprogramming.
Conclusions: The Axonics r-SNM System provides safe and effective SNM therapy with objective improvement in 91% of subjects. The data also demonstrates a significant improvement in all domains of quality of life. This miniaturized, rechargeable system is designed to last 15 or more years and is expected to provide clinical and cost benefits over current non-rechargeable systems by eliminating replacement surgeries.

KEYWORDS
overactive bladder, rechargeable, sacral neuromodulation, single stage implant, urgency frequency, urinary incontinence

1 | INTRODUCTION

Sacral neuromodulation (SNM) is a guideline-recommended treatment for overactive bladder (OAB) patients with or without urinary urgency incontinence following failure of conventional interventions such as life style changes, pelvic floor exercises, and medications. This therapy has been shown to significantly reduce symptoms in patients suffering from refractory urinary urgency and frequency and urgency incontinence, as well as providing clinically meaningful long-term improvements in patient quality of life.[1,2,3,4]

Dr. Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

In 1994, SNM received the CE mark in Europe for the treatment of chronic functional disorders of the pelvis, lower urinary tract, and intestinal tract, and in 1997 was approved by the FDA for use in the United States. Over 250 000 patients have been treated worldwide with SNM since these approvals.

Currently, SNM therapy is provided using a voltage-driven, non-rechargeable device (Interstim II®, Medtronic, Minneapolis, MN) that typically is replaced every 3–5 years due to battery depletion.[5] Device replacement surgery introduces patient risk and inconvenience as well as increasing healthcare costs.[6,7] Advances in sacral neuromodulation technology and best practices offer the potential for providing the long-term benefit of SNM therapy with reduced need for reoperation. In 2016, the Axonics r-SNM System™, a miniaturized, rechargeable SNM system, obtained regulatory approval in Europe and Canada.

The Axonics r-SNM System (Figure 1) is a miniaturized, implantable rechargeable SNM (r-SNM) system designed and tested to deliver therapy in the body for at least 15 years.

The Axonics r-SNM System includes an implantable neurostimulator that is 5cc in volume, which is over 60% smaller than the 14cc Interstim II. The neurostimulator connects to a 4-contact tined lead that is implanted through the sacral foramen using the same procedure previously described for other SNM systems.[8] The system delivers constant current stimulation and provides adjustable stimulation parameters appropriate for SNM therapy. Implanted patients recharge their neurostimulator, expected to be needed once every 2 weeks, using an external charging unit placed over the implant. Stimulation parameters are programmed with a clinician programmer and stimulation intensity is controlled by the patient using a wireless remote control. An independent, expert review provides additional detail about SNM therapy and the characteristics and specifications of the Axonics r-SNM System.[9]

The RELAX-OAB study is a prospective, multi-center post-market clinical follow-up study designed with the primary aim of confirming the safety and efficacy of the Axonics r-SNM System as an aid in the treatment of the symptoms of OAB. The primary hypothesis associated with the study aim is the mean change in ICIQ-OABqol HRQL score at 3 months compared to baseline is greater than zero. The 3-month results detailed in this report are the first efficacy and safety results reported for treatment of idiopathic OAB patients with the Axonics r-SNM System.

FIGURE 1 The Axonics r-SNM System includes a rechargeable, miniaturized neurostimulator that is 5cc in volume and has a 15-year approved life in Europe and Canada

2 | MATERIALS AND METHODS

2.1 | Study design

The RELAX-OAB study is a prospective, multi-center, single arm, open-label study with each subject serving as their own control. The study is being conducted according to the stipulations of the Declaration of Helsinki, ISO 14155: 2011 and applicable national regulations. The study protocol was approved by Ethics Committees at all study sites, and all subjects gave informed consent prior to participating in the study. Subjects were eligible for treatment with the Axonics r-SNM System if they met all inclusion and exclusion criteria (Table 1).

2.2 | Implant procedure

Subjects underwent a single-stage implant procedure under general anesthesia. As part of the study design, subjects did not receive external trial stimulation prior to being implanted, and had both the tined lead and IPG placed concomitantly. Fluoroscopic guidance was used to implant the tined lead along the S3 sacral nerve root. A pocket was made in the upper buttocks area to accommodate the IPG, and the tined lead was tunneled subcutaneously to the neurostimulator pocket. The lead and neurostimulator were connected and placed in the pocket.

2.3 | Follow-up visits

Study subjects will be followed for 2-years. This report includes data from follow-up visits at various time points up to 3 months post-implant, including 2-week and 1-month visits to assess initial response to therapy. Unscheduled follow-up visits were allowed as needed to adjust stimulation settings to optimize therapy. Subjects were considered therapy responders if they had a ≥50% reduction in urinary incontinence episodes per day, a ≥50% reduction in voids per day, or a reduction to <8 voids per day. In the current practice of sacral neuromodulation, patients are typically screened with an externalized test stimulation system before proceeding to full implant. In contrast, subjects in this study were implanted with a full system in a single-stage procedure and the initial month of stimulation was defined as the test period. Patients that were therapy responders before their 1-month

TABLE 1 Primary study inclusion and exclusion criteria

Inclusion criteria
Diagnosis of OAB as demonstrated on a 3-day voiding diary defined as ≥ 8 voids/day, and/or a minimum of two involuntary urinary incontinence episodes in a 72-h period
Positive motor response on at least two implanted electrodes during intraoperative test
18 years of age or older
Failed, or are not a candidate for more conservative treatment (eg, pelvic floor training, biofeedback, behavioral modification, oral pharmacotherapy)
No changes to current regimen of medications that affect bladder function for at least 4 weeks prior to beginning the baseline voiding diary
Exclusion criteria
Primary stress incontinence or mixed incontinence where the stress component overrides the urgency component
Current urinary tract mechanical obstruction such as benign prostatic enlargement or urethral stricture
Interstitial cystitis or bladder pain syndrome as defined by either AUA or EAU guidelines
History of any pelvic cancer
Any significant medical condition that is likely to interfere with study procedures, device operation, or likely to confound evaluation of study endpoints
Current symptomatic urinary tract infection (UTI) or more than 3 UTIs in past year
Any neurological condition that may interfere with normal bladder function, including stroke, multiple sclerosis, Parkinson's disease, clinically significant peripheral neuropathy, or spinal cord injury (eg, paraplegia)
Treatment of urinary symptoms with botulinum toxin therapy in the past 12 months
Treatment of urinary symptoms with tibial nerve stimulation in the past 3 months
Previously implanted with a sacral neuromodulation device or participated in a sacral neuromodulation trial

visit were classified as "Test Responders" (Figure 2). The classification of subjects as Test Responders allows for comparison with the clinical literature. All subjects continued to be followed for the duration of the study regardless of test period response. Therapy response at 3-months was also evaluated separately for large leaks and severe and desperate urgency episodes, where response based on these symptoms was defined as a ≥50% reduction in symptoms. In addition to the 3-day voiding diary, additional therapy outcomes included symptom-related quality of life (QOL) surveys (ICIQ-OABqol, ICIQ-UI Short Form) and patient satisfaction questionnaires.

2.4 | Adverse events

All adverse events (AEs) were tracked and analyzed to assess the safety of the Axonics r-SNM System. A Data Safety Monitoring Board comprised of three expert clinicians not participating as investigators in the study, reviewed and adjudicated all adverse events.

2.5 | Statistical analysis

Outcome measures were evaluated based on the implanted population and based on those subjects that were Test

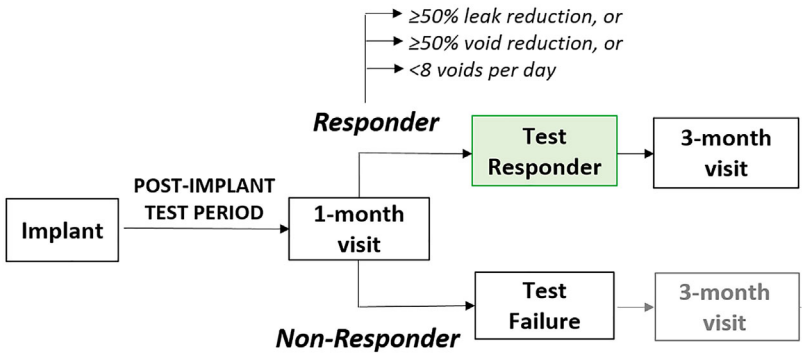

FIGURE 2 Study design. All subjects were implanted with a permanent SNM system without screening with an external trial system. Subjects were classified based on their response to therapy during the first month post-implant. Subjects that responded to therapy on their qualifying symptoms (UI: ≥50% reduction in leaks; UF: ≥50% reduction in voids or <8 voids per day) were classified as Test Responders, and non-responders were classified as Test Failures. All subjects continued to be followed for the duration of the study regardless of test period response

Responders. Data analysis included therapy responder rates as well as the absolute change and percent change for the number of voids, number of incontinence episodes, number of large incontinence episodes, number of severe and desperate urgency episodes, and the outcomes of the quality of life questionnaires. Descriptive statistics were calculated. Statistical significance testing was performed using a two-sided paired *t*-test or Wilxocon signed rank test for continuous variables, and Fisher's exact *t*-test for categorical variables. The software package SAS (version 9.3, SAS Institute, Cary, NC) was used for all analyses.

3 | RESULTS

3.1 | Subject overview

Fifty-one (51) subjects were implanted with the Axonics r-SNM System at 7 European centers. Baseline characteristics for all implanted subjects are reported on Table 2. Subjects were 75% female and 25% male, with a median age of 52 years (range 21-77 years). In addition to conservative therapy, 51% of subjects had previously tried at least one other third line OAB therapy, with Botox treatment for 25% and tibial nerve stimulation for 31% of subjects. Additionally, 20% of subjects previously had sling procedures to treat stress urinary incontinence. On their baseline diary, 50 of 51 subjects qualified as urgency frequency (UF) subjects and 37 of 51 qualified as urinary urgency incontinence (UI) subjects. At baseline, implanted UF subjects averaged 14.7 voids per day (±6.0 SD, $n = 50$) and UI subjects averaged 9.6 incontinence episodes per day (±5.1 SD, $n = 37$).

Fifty-one subjects were implanted, and 48 reached 3-months post-implant without complication or major protocol deviation. Three patients are excluded from the following analyses—two subjects due to major protocol deviations and one subject that was explanted due to a procedure-related infection.

TABLE 2 Baseline subject characteristics

	n	% (*n*/51)
Gender		
Female	38	75%
Male	13	25%
Age	Years	
Mean (Range)	51 (21–77)	
Primary diagnosis		
Urgency frequency	27	53%
Urinary urge incontinence	24	47%
Secondary diagnosis		
Urgency frequency	12	24%
Urinary urge incontinence	10	20%
Stress incontinence	8	16%
Fecal incontinence	5	10%
OAB qualification in baseline diary		
Both UF and UUI	36	71%
UF only	14	27%
UUI only	1	2%

3.2 | Therapy responders

Thirty-four of 48 per protocol subjects (71%) were Test Responders during the 1-month test stimulation period. At 3 months, 91% of the Test Responders continued to be therapy responders based on their reductions in leaks and/or voids (Figure 3A), and 71% of all subjects in the as treated analysis were therapy responders. For subjects with UUI at baseline, 75% of Test Responders were therapy responders at 3-months (Figure 3B), including 64% experiencing a ≥75% reduction in leaks per day. A total of 25% of Test Responders were completely dry at 3-months. The overall UUI response rate was 64% for all subjects. Further, 89% of all UUI subjects experienced a >50% reduction in their large leaks. For subjects with UF at baseline, 73% of Test Responders continued to respond at 3-months (Figure 3C), including 61% of Test Responders that achieved normal voiding (<8 voids per day). The overall UF response rate was 53% for all subjects, while 70% of all subjects experienced a >50% reduction in severe and desperate urgency episodes.

3.3 | Diary symptoms

The average number of voids in Test Responder subjects decreased by 6.6 voids per day at 3-months compared to baseline (Figure 4A). At 3-months, the average number of voids was 7.7 voids per day (±0.3, $n = 33$) compared to 14.3 voids per day (±1.1) at baseline.

Incontinence episodes in Test Responders decreased from an average of 8.3 per day at baseline (±0.8, $n = 28$) to 2.0 per day at 3-months (±0.5, $n = 28$), an average decrease of 6.3 leaks per day (Figure 4B). A significant decrease of 5.9 leaks per day was experienced across all subjects between baseline and 3-months.

3.4 | Quality of life

The mean change in the health related quality of life (HRQL) total score for the ICIQ-OABqol at 3 month for subjects who were Test Responders was 27.3 (±3.6 SE; $N = 34$, $P < 0.0001$) (Figure 5), an improvement substantially larger than the clinically minimally important difference of 10 points, which has previously been used to evaluate SNM therapy impact on quality of life.[2,8] All subscale scores had clinically meaningful improvements, indicating that r-SNM

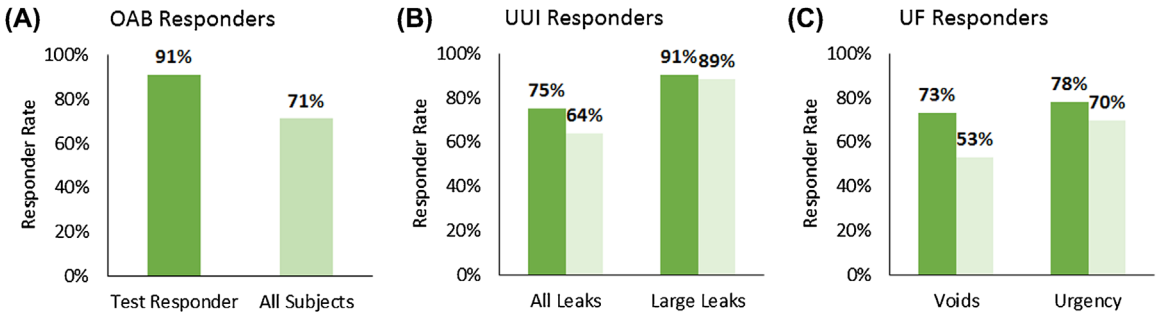

FIGURE 3 r-SNM therapy responder rate at 3-months. (A) OAB symptom response was assessed by evaluating if subjects had a ≥50% reduction in voids, a ≥50% reduction in all leaks, or a reduction to less than 8 voids per day ($n = 48$ subjects). (B) UUI responders shown for two responder criteria: (left) a ≥50% reduction in leaks per day ($n = 36$ UUI subjects) and (right) a ≥50% reduction in large leaks per day ($n = 26$ subjects with at least one large leak at baseline). (C) UF responders shown for two responder criteria: (left) a ≥50% reduction in voids per day or <8 voids per day ($n = 47$ UF subjects) and (right) a ≥50% reduction in severe and desperate urgency episodes per day ($n = 32$ subjects with at least one severe or desperate urgency episode at baseline)

has a positive impact on all aspects of quality of life. 76% of Test Responders and 66% of all subjects indicated improved or greatly improved symptom interference scores. Quality of life scores all improved across all subjects, with a clinically meaningful increase in the HRQL total score of 21.8 points and clinically meaningful increases (>10 points) in all subscales. Additional quality of life measures provided similar results as the ICIQ-OABqol. Subjects experienced clinically and statistically significant improvements in ICIQ-UI Short Form composite scores, which improved from 14.5

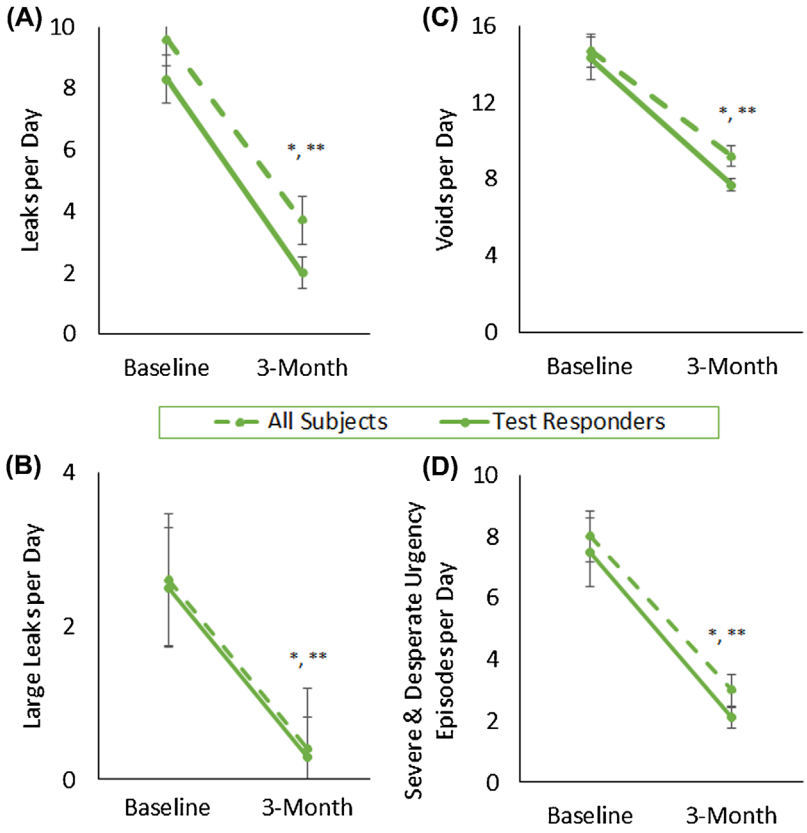

FIGURE 4 Reduction in leaks and voids at 3-months. Average symptoms per day at baseline and 3-months across all subjects and Test Responders are shown for (A) All leaks ($n = 37$ all subjects, $n = 28$ Test Responders) (B) Large leaks ($n = 27$ all subjects, $n = 21$ Test Responders), (C) Voids ($n = 47$ all subjects, $n = 33$ Test Responders) and (D) severe and desperate urgency episodes ($n = 46$ all subjects, $n = 32$ Test Responders). *,**$P < 0.0001$ for all comparisons of 3-month symptoms to baseline

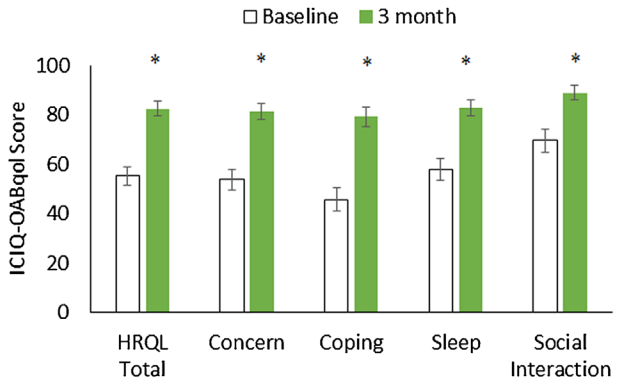

FIGURE 5 Quality of Life (ICIQ-OABqol) at Baseline and 3-months in Test Responder subjects. HRQL total and subscale scores at baseline and 3-month show significant improvements compared to baseline (*$P < 0.0001$ for all comparisons, $n = 34$). Error bars are standard error. All changes exceed the minimally important difference (MID, smallest score change typically considered clinically meaningful to patients) for improvement in quality of life[2,10]

(±3.44) at baseline to 7.32 (±5.4, $n = 28$, $P < 0.0001$) at 3-months for Test Responders. Subjects also reported satisfaction with r-SNM therapy. A total of 82% of Test Responders and 77% of all subjects were moderately or very satisfied with r-SNM therapy at 3-months, and 82% of Test Responders and 73% of all subjects would "definitely" recommend r-SNM therapy to a friend.

3.5 | Adverse events

Across all 51 implanted patients, no unanticipated adverse device effects occurred within the 3-month post-implant period, and there were no serious adverse device effects. Eleven adverse events related to the therapy were reported across 10 subjects (19.6% of subjects). Six of the 11 events (55%) occurred within 2 weeks of implant. The most frequent adverse events were associated with undesirable stimulation, accounting for five events in four subjects (7.8% of subjects). These adverse events were resolved with device reprogramming. No surgical intervention was required due to device or therapy-related adverse events. One serious procedure-related adverse event occurred, an implant site infection, and the patient had the system explanted. No other patients, including Test Non-Responders, were explanted by the 3-month visit. There were no reported adverse events occurred related to the recharging of the neurostimulator.

4 | DISCUSSION

The 3-months results of this prospective, multicenter study demonstrate that the Axonics r-SNM System is a safe and effective therapy to treat refractory idiopathic overactive bladder with significant improvement in both objective voiding diary parameters and subjective quality of life benefits to the patients. Seventy-one percentage of subjects responded during an initial test period ("Test Responders"), and 91% of these subjects continued to be therapy responders at 3-months. These outcomes are consistent with those previously reported for the Medtronic Interstim® System.[1–4] Additionally, the high rate of patient satisfaction and likelihood of recommending the therapy to a friend suggests that at 3-months charging the device does not present a burden to patients relative to the benefit of their therapy.

To date in the RELAX-OAB study there have been no unanticipated adverse events and no serious device-related adverse events. The nature of the reported device related adverse events is similar to those reported for implanted patients in the InSite study.[2] Undesirable stimulation was the most common therapy or device-related adverse event in the InSite study and in this study. This type of event occurred within 3-months of implant in 6.6% of patients in the InSite study[2] and in 7.8% of subjects to date in this single-stage implant study. In both studies these events were most often resolved with reprogramming. Overall, these results show the implant and short-term operation of the Axonics r-SNM System is safe. Longer-term follow-up is needed to determine if the Axonics r-SNM System impacts surgical revision rates and explant rates.

This study implanted the Axonics r-SNM System in a single-stage procedure without an external trial period. Subjects were assessed at 2-weeks and 1-month post-implant to determine if they were responding to SNM therapy, consistent with the process for evaluating the trial period in patients screened with a tined lead and external test stimulator prior to full SNM system implant. For the 71% of subjects that are responders at 1-month (Test Responders) in this study, a second surgery would have been required for the implantation of the neurostimulator had these patients underwent an external trial period. Nikolavsky et al has shown that a single-stage implant will provide better patient outcomes while reducing costs to the healthcare system.[11] In addition, a single-stage procedure decreases the operative burden on surgeons and patients. Further examination of the data from the subjects that did not qualify as Test Responders is needed to determine if these subjects experienced clinically meaningful changes in symptoms and quality of life at a later time-point. There is limited literature supporting an ideal trial period duration, however a few studies suggest longer duration trials (>14 days) may increase the therapy responder rate.[12,13]

The cost-benefit of rechargeable neuromodulation systems has been reported for SNM[7] and for spinal cord stimulation systems.[14] In both studies, the rechargeable device unsurprisingly reduced costs due to elimination of device replacement and associated AEs in patients experiencing long-term success. The rechargeable SNM device, modeled with a 10-year life, was projected to save the United States healthcare system $12 billion

over a 15-year period.[7] Non-rechargeable SNM therapy has been shown to be a cost-effective long-term treatment of OAB in Europe and Canada, including studies showing that SNM is more cost-effective than other third line OAB therapies.[6,15–19] The rechargeable Axonics r-SNM System is designed to have a 15-year life. This rechargeable SNM system may further enhance the cost-superiority of SNM compared to Botox[6,15–19] and percutaneous tibial nerve stimulation.[6] The long-term follow-up of this study will provide data to assess the cost implications of the system and validate the longevity of the device as well as provide insights into patient preference for a rechargeable system. However, rechargeable neuromodulation systems (eg, spinal cord stimulation systems, deep brain stimulation systems) have been studied extensively, and patients have experienced minimal issues related to charging and are highly satisfied with rechargeable systems, with 85–90% of patients preferring or recommending rechargeable devices.[20–22]

SNM has been shown to effectively treat additional indications, including fecal incontinence and non-obstructive urinary retention.[23–25] Given the safety and efficacy exhibited in this study, it is expected that the Axonics r-SNM System will provide similar safety and efficacy for these indications.

5 | CONCLUSION

The results of this clinical study demonstrate that sacral neuromodulation with the Axonics r-SNM System is safe and effective, providing significant improvements in OAB patients' symptoms as well as all domains of quality of life. Sacral neuromodulation is a minimally invasive therapy for treating overactive bladder that has been shown to have superior long-term efficacy and cost-effectiveness compared to other treatment options for OAB, and this new rechargeable system may further improve the cost-effectiveness of SNM therapy.

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