Two years outcomes of the treatment of overactive bladder with the miniaturized, rechargeable Axonics System

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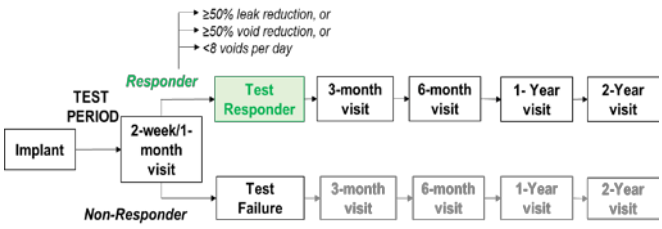
INTRODUCTION

Sacral neuromodulation (SNM) is a guideline-recommended treatment for overactive bladder (OAB) patients after conservative treatments have failed. Historically, the only commercially available SNM System was a non-rechargeable system with a lifespan of 3-6 years[a]. This device requires multiple replacement surgeries resulting in increased surgical risks and health-care costs, which could be reduced by use of a longer lived, rechargeable system[a]. The Axonics® System is a miniaturized, rechargeable SNM system approved to last for 15 years by regulatory bodies in Europe, Canada and Australia. RELAX-OAB is a post-market clinical study in Europe designed to test the safety and efficacy of the Axonics System. 2-year follow-up results are presented here.

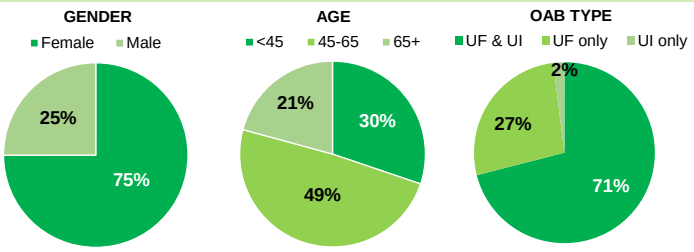
METHODS

Objective	Post-market study to confirm the safety and efficacy of the Axonics System as a treatment of OAB symptoms.
Study Design	Prospective, multi-center, single-arm study with each subject serving as their own control. Subjects were implanted with the Axonics System in a single, non-staged procedure without an external trial. In order to be comparable with clinical literature, the 1st month of therapy was considered a trial period.
Subjects/ Centers	• 51 subjects with urgency frequency (UF) or urinary incontinence (UI) or both were implanted across 7 centers. • 46 subjects were available for follow-up at the 6-month visit, 43 subjects at the 1-year visit and 40 subjects at the 2-year visit.
Clinical Assessments	• 3-day voiding diary • Quality of life questionnaires (ICIQ-OABqol, SF-12, EQ-5D, ICIQ-UI Short Form) • Patient satisfaction with treatment • Adverse events

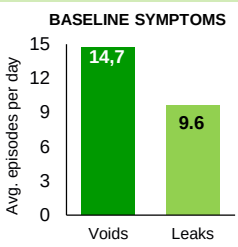


RESULTS

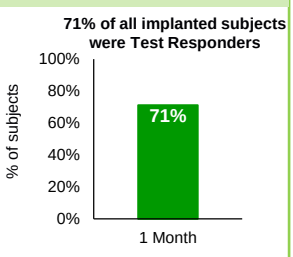
DEMOGRAPHICS



BASELINE

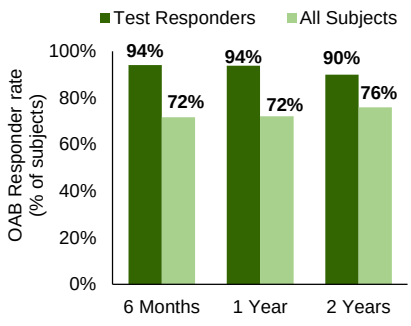


INITIAL RESULTS

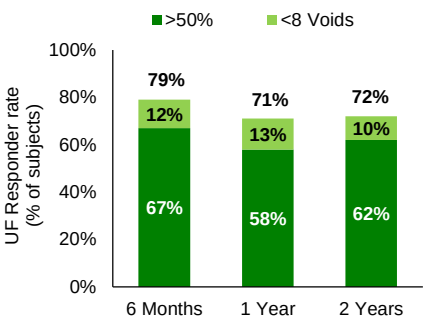


2-YEAR CLINICAL OUTCOMES

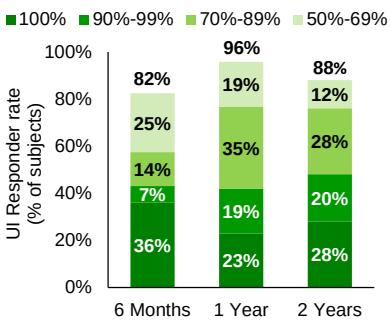
90% of Test Responders continued to respond to therapy responders at 2 years



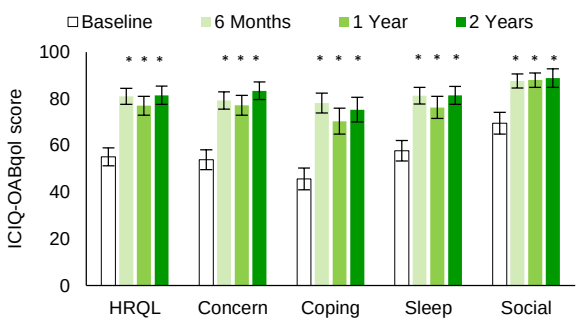
72% of Test Responders were UF responders at 2 years



88% of Test Responders were UI responders at 2 years



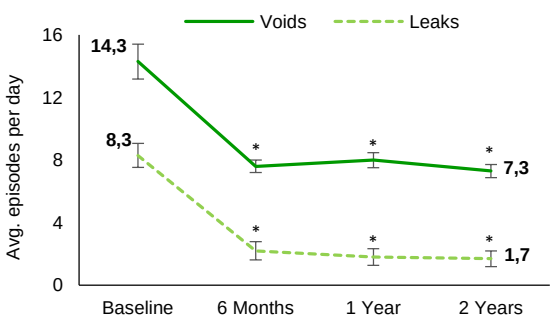
Test Responders experienced clinically meaningful improvements in quality of life†



*p<0.0001, two-sided paired t-test

†26 point improvement in HRQL at 2 years. Improvement by 10 points is considered clinically meaningful[b]

Test Responders experienced significant reductions in leaks and voids



*p<0.0001, two-sided paired t-test

PATIENT SATISFACTION

- **93%** of Test Responders were "Satisfied" with r-SNM therapy for their OAB treatment
- **90%** of Test Responders would "Likely" recommend r-SNM to a friend
- **86%** of Test Responders rated the frequency and duration of recharging as "Acceptable"

SAFETY

- Cumulative follow-up of 1,048 months is available among all study subjects.
- No unanticipated adverse events or serious device related adverse events were reported.
- 7 subjects explanted – 1 due to procedure-related infection, 4 due to lack of efficacy, 1 due to need for MRI*, 1 due to high impedances.

**The system is now approved in Europe for Full Body MRIs under specific conditions*

CONCLUSIONS

- The Axonics System provides long-term, safe and effective treatment as evidenced by 2-year outcomes.
- Patients receive significant improvements in quality of life and are satisfied with rechargeable SNM therapy.
- Patients find the frequency and duration of recharging to be acceptable.
- A rechargeable system may provide significant cost-savings while reducing patient and physician burden and risk associated with repeat surgeries.

References

a. Noblett K, Dmochowski R, Vasavada S, et al. 2016 Cost profiles and budget impact of rechargeable versus non-rechargeable sacral neuromodulation devices in the treatment of overactive bladder syndrome. Neurourol Urodyn. 2016 Apr 6.

b. Noblett K, Siegel S, Mangel J, et al. Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. Neurourol Urodyn. 2016;35:246-251.

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