A recharge-free sacral neuromodulation system demonstrated short-term safety and effectiveness profile in patients with overactive bladder syndrome

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Study Topic: Recharge-free sacral-neuromodulation system (Axonics F15™ SNM System, Boston Scientific Corporation, Marlborough, MA, USA), for patients with overactive bladder

Study Design: Single-arm, multicentre, prospective clinical trial conducted in Europe (pivotal) and the USA (post-market)

Patients with OAB diagnosis

Data collected: ICIQ-OABqol at baseline and 3 months post-implant procedure, adverse events, patient satisfaction

Intervention: The recharge-free SNM system consists of implantable neurostimulator, tined lead, and non-implantable components for device operation



Results (abstract highlights)

- Of 79 patients enrolled at 14 sites, 75 successfully implanted, 73 followed through 3 months post-implant
- No unanticipated or serious device-related AEs to date
- ICIQ-OABqol scores in all domains significantly improved from baseline to 3 months (See Fig. 1)
- The majority of patients (69%) demonstrated meaningful clinical improvement across all domains
- Patients reported satisfaction with the procedure and device

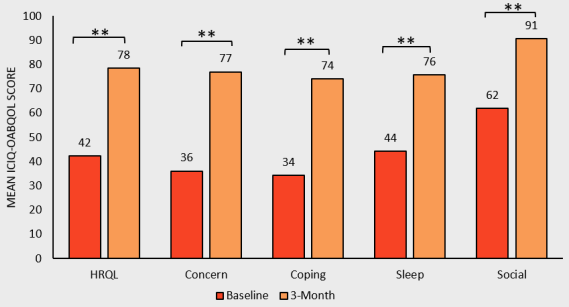


Figure 1

Results Spotlight
ICIQ-OABqol Minimally Important Difference (MID)

- The MID is the validated threshold for clinically meaningful improvement.
- For all questionnaire domain scores, the MID equals an improvement of 10 points.[1,2]
- Across all domains of the ICIQ-OABqol, the majority of patients achieved the MID (See Fig. 2).
- The mean 3-month improvement across all domains was significantly greater than the MID (p <0.001).
- 84% of patients with 3-month data achieved the HRQL MID (see Fig. 3, HRQL score change for all patients by improvement category).

1. Coyne KS, Matza LS, Thompson CL, Kopp ZS, Khullar V. Determining the importance of change in the overactive bladder questionnaire. *J Urol*. 2006;176(2):627-632.
2. Coyne, K., Revicki, D., Hunt, T., Corey, R., Stewart, W., Bentkover, J., Kurth, H., Abrams, P. Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: the OAB-q. *Qual Life Res*.2002; 11(6); 563-574

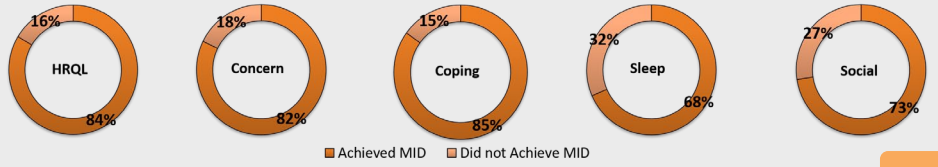


Figure 2

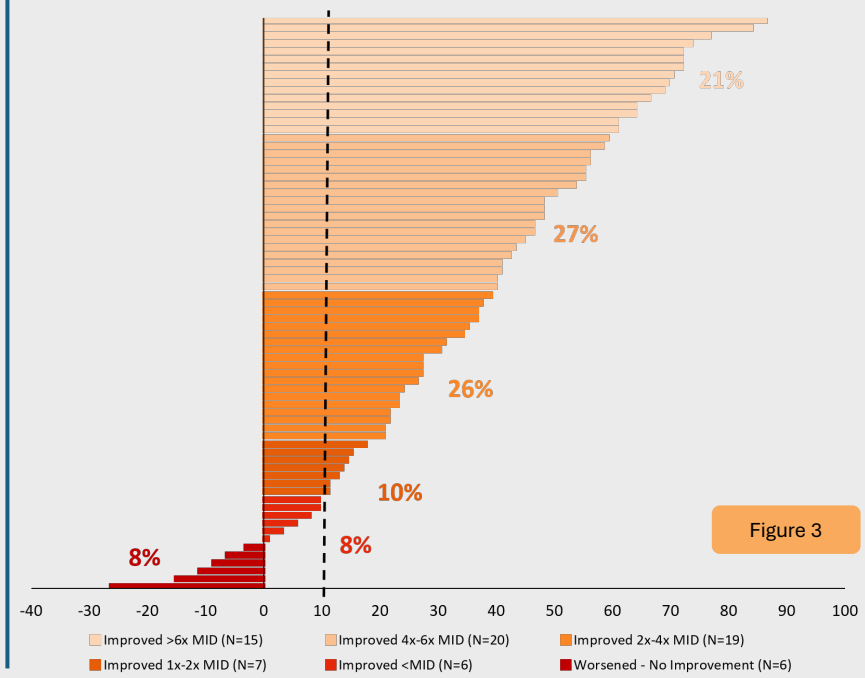


Figure 3

Conclusion: The Axonics F15 SNM system showed significant improvements in urinary incontinence-related qualify of life and a favourable safety profile over a 3-month period.