Device implant and programming in a global post-market study of a novel rechargeable sacral neuromodulation device

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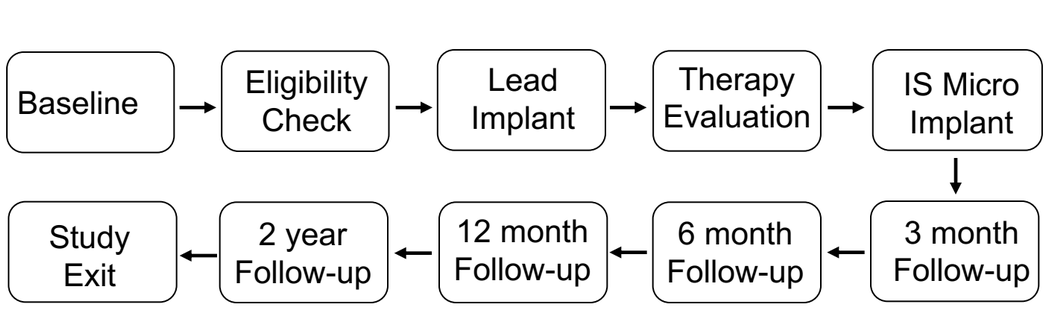
Introduction

Sacral Neuromodulation (SNM) is an established advanced therapy for treatment of symptoms of overactive bladder (OAB), nonobstructive urinary retention, and fecal incontinence supported by studies with long-term follow up.

The ELITE study is an ongoing global, prospective, post-market study to confirm the clinical performance and safety of the InterStim™ Micro SNM system (Fig.1) in all indicated conditions.



The aim of this abstract is to describe device implant, device information, and change in quality of life for subjects enrolled in the OAB cohort through 6-month follow up visit.

Figure 1. Rechargeable InterStim™ Micro system

Methods and Materials

Eligible subjects that met all inclusion and no exclusion criteria were enrolled in the OAB cohort after a successful basic or advanced therapy evaluation and implantation of a neurostimulator.

Key inclusion criteria:

- Candidate for SNM
- 18 years of age or older
- ≥8 UF episodes per day and/or 3 UUI episodes in 72 hrs

Key exclusion criteria:

- Primary stress incontinence or mixed incontinence where stress overrides urge
- Current urinary tract mechanical obstruction
- Neurological conditions such as multiple sclerosis, clinically significant peripheral neuropathy, or spinal cord injury

The therapy evaluation success was recommended to be based on a 50% reduction in symptoms or return to normal voiding (<8 voids/day). Device programming data were collected at tined lead implant, at neurostimulator implant, and follow up visits occurring at 3- and 6-months post-implant. Subjects completed the OAB Quality of Life Questionnaire (OAB-q) at baseline and follow-up visits. Safety was evaluated as reportable adverse events.

Results

Sixty-eight subjects were enrolled in the OAB cohort. Baseline demographics are displayed in Table 1.

Table 1. Baseline demographics

Subjects' characteristics	All implanted OAB subjects (N=68) Mean ± SD or N(%)
Age (years)	62 ± 13
Female sex	61/68 (90%)
BMI	32 ± 7.0
Years since diagnosis	10 ± 8.0
Primary diagnosis	
Urinary Urge Incontinence (UUI)	15/68 (22%)
Urgency Frequency (UF)	5/68 (7%)
Both UUI and UF	48/68 (71%)
OAB medication use at baseline	35/68 (52%)
Baseline leaks/day[1]	5.7 ± 4.5
Baseline voids/day[2]	13.6 ± 6.5

[1] Baseline leaks/day are only summarized for UUI subjects
2 Baseline voids/day are only summarized for UF subjects

The OAB-q Health Related Quality of Life (HRQL) demonstrated a significant improvement from baseline to 3-month follow-up with an average increase of 33±24 points (n=67, p<0.001). HRQL showed a consistent result at 6 months, with a change of 31±23 points (n=65). Eighty-two percent of subjects achieved the minimally important difference in HRQL score at 3- and 6- months with a change of 10 points or greater (Fig.2).

Results

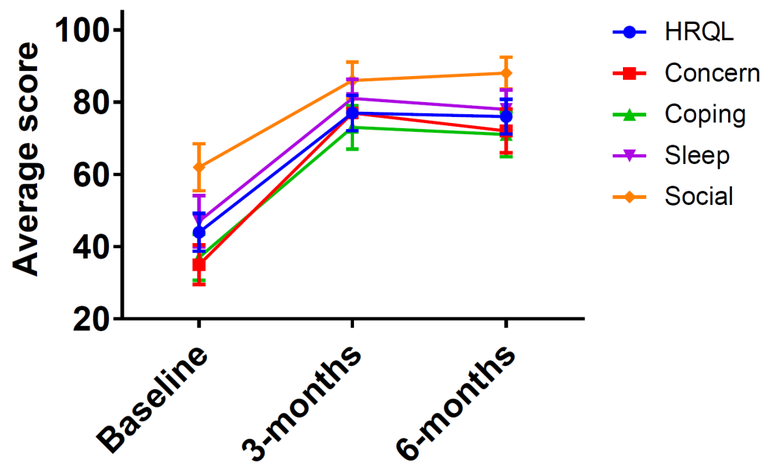


Figure 2. Quality of Life evaluated with the OAB-q HRQL. It contains 4 subdomains: Concern, Coping, Sleep and Social. The minimally importance clinical difference (MICD) is 10 points for all domains.

For those subjects with reported data, the majority of leads (88%, 58/66) were placed following established guidance [1] recommending that stimulation required to elicit a motor response (motor threshold) be 2 mA or below on all 4 electrodes (Table 2).

Table 2. Lead Implant

Number of electrodes with threshold less than 2 mA	% (n/N)
Motor threshold	
4 electrodes	**88% (58/66)**
3 electrodes	**9% (6/66)**
2 electrodes	**2% (1/66)**
1 electrode	**2% (1/66)**
0 electrodes	**0% (0/66)**
Sensory threshold	
4 electrodes	**85% (57/67)**
3 electrodes	**0% (0/66)**
2 electrodes	**0% (0/66)**
1 electrode	**0% (0/66)**
0 electrodes	**15% (10/66)**

At 3- and 6-month follow-up visits, the median amplitude was 1 mA, pulse width was 210 µs, and frequency 14 Hz (Table 2) for subjects with available data (n=66, 63 respectively).

Table 3. Programming parameters at follow-up

Programming parameters	N	Mean	Standard deviation	Median
3-months				
Amplitude, mA	66	1	1.6	1
Pulse Width, µsec	66	215	21.2	210
Rate, Hz	66	14	1.5	14.0
6-months				
Amplitude, mA	63	1	0.9	1
Pulse Width, µsec	63	219	27.3	210
Rate, Hz	63	14	1.3	14

Five subjects (7.4%) had an MRI by the 6-month visit with a mean time from implant of 137 ± 38.1 days. MRI locations included head (1), lower abdomen (1), thoracic spine (1), and other (2).

The incidence of device-, procedure-, or therapy- related adverse events was 7.3% (5/68). Out of these 5 related adverse events, there was 1 related serious adverse event (1.5%, implant site pain) at the time of database snapshot. There were no MRI related adverse events.

Discussion & Conclusions

In ELITE the majority of leads were implanted following established guidance for optimal lead placement which has been proposed to result in longer battery life for a non-rechargeable device [1] or extended recharge interval for a rechargeable device by. Consistent with this, the median amplitude at follow-up visits was relatively low at 1 mA. The quality-of-life improvement is consistent with previously reported results from both rechargeable and non-rechargeable devices [2,3].

The ELITE data confirm the clinical performance and safety for a novel rechargeable SNM device through 6-months post implant.

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References

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