

## LONG TERM EFFECT OF INTERSTIM® IN PATIENTS SUFFERING FROM REFRACTORY URGE INCONTINENCE: A PROSPECTIVE STUDY.

### Aims of Study

Sacral neuromodulation has shown to be an effective treatment for idiopathic refractory urge incontinence (UI). The treatment received FDA approval for that indication in 1997. We report the long term results of those implanted patients suffering from UI who were transferred into the post approval study by 16 investigative sites worldwide.

### Methods

At the time of most recent database closure, 126 UI patients were implanted. Data of 105 patients could be analyzed because at least 12 months results were available. The primary endpoints were number of leaking episodes per day, severity of those episodes and pads use per day.

### Results

Of the 105 patients, 14 had been explanted because of adverse events or lack of efficacy. Average follow-up time was  $45 \pm 16$  months. The data of 105 patients show a reduction in leaking episodes from  $10.9 \pm 6.4$  to  $4.3 \pm 5.1$  ( $p < 0.0001$ ). Of 105 patients, 26 (25%) experienced no leaks (were dry) at last follow up. The mean change in heavy leaks was from  $3.6 \pm 4.1$  to  $1.2 \pm 2.7$  ( $p < 0.0001$ ). The mean change in moderate leaks per day went from  $7.3 \pm 5.9$  to  $2.7 \pm 4.1$  ( $p < 0.0001$ ). 97 Patients experienced moderate or heavy leaks at baseline. 40% Of these patients experienced either complete elimination of moderate or heavy leaks or least a 50% reduction in the number of heavy leaks episodes. Mean pad use decreased from  $6.5 \pm 5.1$  to  $2.4 \pm 3.7$  ( $p < 0.0001$ ). Of 96 patients who used pads at baseline, 61 (64%) had a reduction of more than 50% in pads replacement. The clinical success rates over time, defined as elimination or 50% or more reduction in leaks per day, are listed in table 1.

Follow Up Time (months)	N	Clinical success (%)
6	86	67
12	93	72
18	66	61
24	81	59
36	71	54
48	58	55
60	43	63

Table 1. Clinical success rates over time

The change in the voiding and storage parameters are listed in table 2.

Diary variables		n	Avg at Baseline	Avg at last FU	p-value
Primary endpoints	# leaks per day	105	10.9 ± 6.4	4.3 ± 5.1	< 0.0001
	Pads use due to leakage	105	6.5 ± 5.1	2.4 ± 3.7	<0.0001
	Severity of leaks (0=none; 1=few drops; 2=tbsp; 3=soaking)	79	2.0 ± 0.6	1.7 ± 0.6	<0.0001
Other voiding variables	Avg voided volume per void (ml)	88	141 ± 91	200 ± 99	<0.0001
	# voids /day	91	13.2 ± 6.9	9.0 ± 4.4	<0.0001
	Max voided volume	88	334 ± 197	406 ± 185	0.0002
	Tot vol voided / day (ml)	91	1662 ± 950	1665 ± 824	0.99
	% Felt empty	88	53.6 ± 40.7	70.0 ± 38.0	0.0005
	Avg degree of urgency (0=none – 3=strong)	87	2.0 ± 0.9	2.0 ± 0.7	0.93
	Pelvic discomfort (0=none – 3 = heavy)	72	1.7 ± 1.1	0.9 ± 1.0	<0.0001
Force of stream (1=strong – 4 = poor)	73	2.9 ± 0.8	2.4 ± 0.9	0.0005	

Table 2. Voiding diary results at last follow up

A significant change was seen in average volume voided; reduction of voids per day; increased functional capacity; increased perception of bladder emptying; improved urine stream and decreased pelvic or bladder discomfort.

### **Conclusions**

The beneficial effects of sacral neuromodulation for UI with respect to leaking episodes per day, severity of leaking episodes and pads use per day, stay stable on the long term. Since also other important voiding and storage parameters show significant improvement, sacral neuromodulation improves total functioning of the lower urinary tract.