

## REOPERATION RATES IN PATIENTS WITH INTERSTIM THERAPY

### Hypothesis / aims of study

Sacral neuromodulation (Interstim) has become an increasingly popular means of treating intractable urinary urgency/frequency, urge incontinence and urinary retention [1, 2]. Device-related adverse events may require reoperation to restore function [3]. We review our experience with reoperation in patients following initial successful Interstim.

### Study design, materials and methods

Patients undergoing Interstim procedures from 2001 to 2009 at our teaching hospital were identified and charts abstracted for age at first device placement, gender, race, diagnosis, outcome and peri-operative complications. Patient outcomes were determined from clinical documentation. All devices were implanted by a single surgeon with participation from urologic resident surgeons.

### Results

From 2001 to July of 2009, 276 patients with a mean age of 50.2 years (4-97 years) underwent stage 1 interstim lead placement for the treatment of intractable urinary urgency/frequency (n=53), urge incontinence (n=179), or urinary retention (n=44). Of this group, 249 patients (90.2%) experienced a >50% improvement in symptoms and underwent placement of the complete Interstim system. There were 98 reoperations performed in 70 patients (28.1%). Of those, 41 had been placed for intractable frequency/urgency, 12 for urinary retention, and 17 for urge incontinence. Fifteen reoperations (15.3%) in 14 patients were for pain associated with the device. Infection was the reason for 22 reoperative cases (22.45%) in a total of 10 patients. Malfunction of the device requiring revision was done in 27 patients with a total of 33 (33.67%) episodes necessitating surgery. Battery replacement was needed in 14 patients (14.29%). Four (4.08%) required removal because of a need for an MRI and 1 patient (1.02%) required back surgery resulting in the need for explantation. Nine patients (9.18%) requested removal because of a lack of ongoing efficacy. Nineteen patients had more than one reoperation. Mean time to reoperation for all groups was 20.9 months.

### Interpretation of results

Interstim implants are highly efficacious but require a high reoperation rate. Our series demonstrates that although sacral neuromodulation is an effective treatment for patients with intractable voiding dysfunction, re-operation rates are high (28.1%). The reasons for reoperation were both device-related and patient-related.

### Concluding message

In light of these findings, any analysis of cost-effectiveness for sacral neuromodulation should consider reoperation rate in its calculations.

### References

1. Philip E.V. van Kerrebroeck et al. "Results of Sacral Neuromodulation Therapy for Urinary Voiding Dysfunction: Outcomes of a Prospective, Worldwide Clinical Study. The Journal of Urology. 2007.
2. Steven W. Siegel et al. "Long-term Results of a Multicenter Study on Sacral Nerve Stimulation for Treatment of Urinary Urge Incontinence, Urgency-Frequency, and Retention." Elsevier Science, 2000.
3. Roberta E. Blandon et al. "Re-operation Rates after Permanent Sacral Nerve Stimulation for Refractory Voiding Dysfunction in Women." BJU Int, 2008 May; 101(9):1119-23

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<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>University of Missouri, Columbia Institutional Review Board</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>No</b>