Patterns of Hardware Related Electrode Failures in Sacral Nerve Stimulation Devices

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Purpose: Abnormal electrical impedance in sacral nerve stimulation devices is a cause of device failure. Currently, there is scant literature evaluating the incidence and management of this problem. We evaluated the presentation, characteristics and management of sacral nerve stimulation devices with abnormal electrical impedance.

Materials and Methods: A total of 565 patients were permanently implanted with sacral nerve stimulation devices using a tined lead between 2003 and 2011. Devices were interrogated postoperatively and at followup. Abnormal electrical impedance was classified as open circuit—impedance greater than 4,000 Ω or short circuit—impedance less than 50 Ω and/or equivalence of impedance. Details on presentation, characteristics and management were recorded.

Results: Of the 565 patients 72 (12.7%) experienced a total of 86 abnormal electrical impedance events, of which 57 (66.2%) were open circuits and 28 (32.5%) were short circuits. One event (1.1%) was a simultaneous open and short circuit. Short circuits presented earlier than open circuits (median 3.5 months, IQR 2–7.5 vs 15, IQR 5.5–30.5, $p < 0.0001$) and required surgical intervention more often (75.0% vs 54.3%, $p = 0.09$). Patient specific factors, such as trauma history and change in body mass index class, were not associated with abnormal electrical impedance. No electrode failure patterns could be identified.

Conclusions: Abnormal electrical impedance occurred in approximately 13% of cases permanently implanted in our series. Short circuits presented earlier and often required surgical intervention. Open circuits presented later and may have potentially been secondary to microfractures that accumulate with time at the sacral plate, resulting in later presentation. Almost a third of patients with abnormal electrical impedance associated with clinical inefficacy were treated conservatively, primarily with reprogramming.

Key Words: urinary bladder, overactive; urinary incontinence, urge; implantable neurostimulators; equipment failure analysis; electric impedance

Abbreviations and Acronyms

BMI = body mass index
DBS = deep brain stimulation
EI = electrode impedance
SNS = sacral nerve stimulation

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SNS has been shown in several long-term studies to be effective treatment for refractory urgency, frequency, urge urinary incontinence and urinary retention.[1,2] The usefulness of SNS is further reflected in its expanding applications, including for fecal incontinence and use in children.[3,4] Despite its efficacy, SNS devices require surgical revision in up to 30% to 40% of cases, most commonly for a loss of therapeutic efficacy.[1,5]

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Most groups that have analyzed SNS failure focused on patient characteristics and surgical factors.[6–8] However, damaged SNS hardware, such as lead failures with EI values outside the normal range of 400 to 4,000 Ω or with EI value equalization across multiple electrodes, are common in patients who undergo surgical revision.[9,10] Nonetheless, the consequences of abnormal EI on device management have not been thoroughly investigated to date.

We describe the presentation, characteristics and management of electrode failure presenting as abnormal EI. Our primary aim was to determine the incidence and patterns of abnormal EI, and the surgical intervention rate. Our secondary aim was to determine any patient characteristics or implantation specific factors associated with abnormal EI. The principal goal was to identify information that can be used clinically to facilitate more effective management of SNS devices and provide feedback to device manufacturers.

MATERIALS AND METHODS

Patient Sample

Local institutional review board approval was granted. We constructed a complete list of patients permanently implanted with the InterStim® device at our institution by 1 of 4 fellowship trained surgeons with a minimum of 2 years of experience before implantation. Cases from January 1999 to October 2011 were included. The cohort was restricted to patients who underwent permanent implantation after December 2002 to ensure the use of self-anchoring tined leads.

A total of 565 patients were permanently implanted with an InterStim device. All patients were required to show greater than 50% improvement in symptoms on voiding diary with peripheral nerve evaluation or a staged approach before permanent implantation.[3] Staged and permanent implantations were performed using local anesthesia with monitored anesthesia care sedation. Leads were generally introduced into the S3 foramen and implantable pulse generators were placed in a subcutaneous pocket on the buttock. Patients were implanted with the InterStim I (Model 3023) until September 2006, after which the InterStim II (Model 3058) was generally used. The multichannel PrimeAdvanced™ spine stimulator was used for bilateral lead implants.

All newly implanted devices were evaluated for abnormal EI in the operating room at the end of the procedure and in the post-anesthesia care unit immediately after surgery. Each device was checked again at the first office followup visit. Thereafter devices were interrogated in certain situations, including 1) inefficacy, 2) pain and 3) battery life evaluation at approximately 12-month intervals. Followup was calculated from permanent implantation to the most recent contact with the department.

Electrode Abnormality Definitions

The electronic medical record was manually reviewed to identify patients who met study inclusion criteria, including 1) abnormal EI at any followup visit, 2) surgical revision for any indication and 3) device explantation. Revision was defined as any manipulation, repair or exchange of components performed in the operating room. Explantation was defined as device removal for any indication. Abnormal EI was classified as open circuit—impedance greater than 4,000 Ω or short circuit—impedance less than 50 Ω and/or equivalent impedance between 2 or more electrodes, indicating a common circuit. EI information was recorded at office visits by practitioners trained in SNS management. Impedance was documented for 2-electrode pairs, such that the impedance of each electrode could be calculated. We recorded patient age, gender, BMI, BMI class (overweight—25 to 30 kg/m^2, obese—30 to 35 and morbidly obese—greater than 35) and any report of trauma.

Statistical Analysis

Descriptive statistics were performed. Data are shown as the mean ± SD or median and IQR. Continuous variables were compared by the Student t and Wilcoxon rank sum test for normally and nonnormally distributed data, respectively, and categorical variables were compared with the Fisher exact test with $p < 0.05$ considered statistically significant.

RESULTS

Revision and Explantation

A total of 633 cases were permanently implanted from January 1999 through October 2011. We excluded from study 68 cases with an implantation date before January 2003, at which point the tined lead electrode was routinely used at our institution, yielding 565 cases permanently implanted. An InterStim I was implanted in 240 patients and an InterStim II was implanted in 325. Surgical revision and explantation were done in 111 (19.6%) and 56 (9.9%), respectively, of the 565 patients. A combination of at least 1 revision and subsequent explantation was performed in 18 patients (3.1%).

Abnormal EI was noted in 72 of the 565 permanently implanted patients (12.7%). Those with abnormal EI accounted for 42 of 111 revisions (37.8%), 4 of 56 explantations (7.1%) and 1 of 18 explantations after at least 1 revision (5.5%).

Electrode Failure

A total of 86 abnormal EI events were identified in 72 patients. Mean followup was 50.2 ± 30.0 months (median 45, IQR 22.2–76.7). Open and short circuits occurred in 48 and 19 patients, respectively, 4 had short and open circuits at different time points during treatment and 1 had simultaneous short and open circuit failures. Open circuits occurred in 23 of 240 InterStim I (9.5%) and 29 of 325 InterStim II (8.9%) devices, and short circuits occurred in 21 of 240 (8.7%) and 2 of 325 (0.6%), respectively. A combined open and short circuit occurred in 1 InterStim I device.