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# Abstract Reproduction Form B-1

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Title (type in CAPITAL LETTERS): AN EARLY EXPERIENCE WITH SACRAL NERVE STIMULATION AS A TREATMENT FOR URGE INCONTINENCE AND ASSOCIATED PELVIC FLOOR DISORDERS IN PATIENTS AT A PELVIC FLOOR CENTER.

Aims of Study: Patients presenting to a pelvic floor center often demonstrate chronic voiding dysfunction, which may include one or more of the following: urge incontinence, urgency-frequency syndrome, pelvic pain syndrome, and urinary retention. Also, these patients frequently have bowel disorders. The aim of this study was to determine the short-term efficacy and complications of neuromodulation with unilateral sacral foramen electrode performed with the Interstim system in patients with primarily urge incontinence and associated voiding and bowel disorders.

Methods: A permanent S3 electrode was implanted in 8 patients (7 females and 1 male) who had demonstrated a greater that 50% improvement in their urge incontinence symptoms during test stimulation, based on a voiding diary. Each patient had previously undergone conservative therapy, including biofeedback and anticholinergic medication. Two patients had previously undergone pelvic radiation for a gynecological malignancy. Patients were assessed with a voiding diary prior to, during test stimulation, and following permanent implantation. Patients were surveyed regarding their symptoms of urgency, frequency, urge incontinence, pelvic pain, and bowel function prior to and following permanent implantation. Also, patients addressed their degree of improvement with the therapy and if they would undergo this therapy again. In addition to refractory urge incontinence, 6 patients complained of urgency/frequency (daytime voiding frequency ranged from 9-20 voids), three patients complained of pelvic pain, and two patients complained of significant fecal urgency with fecal incontinence

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and one with constipation. The average patient age was 65 years old and the average patient follow-up was 7.5 months.

Results: Overall, seven of eight patients would undergo this therapy again. Addressing urge incontinence, one patient reported 100% improvement, two reported 75% improvement, four patients reported a greater than 50% improvement, and one reported no improvement. However, one patient who reported 75% improvement has since relapsed and may have lead migration. Of the six patients with urgency/frequency, one reported 25% improvement, three reported 50% improvement, and two reported 75% improvement. Regarding the three patients with pelvic pain, one reported no relief and two reported 50% improvement. The two patients with fecal incontinence reported a 50% improvement. The patient with constipation reported a 75% improvement. Regarding complications, two patients experienced an inferior wound dehiscence of less than 2 cm. One patient had a superficial cellulitis of the sacral wound. No patient has experienced pain at the implantable pulse generator (IPG) site, located subcutaneously in the upper buttock region. Two patients who work with or near high voltage equipment have described surges or changes in their IPG settings. One patient's Itrel II IPG has been changed to the Interstim IPG with resolution of these symptoms. The other patient is scheduled for this procedure. The average number of reprogramming events with the Itrel II was 5.5 per patient. The pelvic pain patients' average number of reprogramming events was 8.5 per patient.

Conclusion: Sacral nerve stimulation appears safe and efficacious for patients with urge incontinence and associated pelvic floor disorders. As our experience with this therapy has increased, and with the introduction of the Interstim IPG (which provides the patients with increased control of the unit's amplitude), the number of reprogramming events has decreased significantly. Complications from the procedure have been minimal. Thus far, our patients have benefited greatly from this therapy.