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# Prospective randomized study evaluating ultrasound versus fluoroscopy guided sacral InterStim® lead placement: A pilot study

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**Objective:** To investigate the use of intraoperative ultrasound during stage I InterStim® sacral lead placement.

**Methods:** A total of 40 patients were randomly assigned to undergo InterStim® lead placement utilizing fluoroscopy or ultrasound guidance. Patients were blinded for the duration of the study. The surgeon and staff were blinded until after induction of anesthesia. Patients met criteria for refractory overactive bladder, fecal incontinence, or both. The ICIQ-OABqol, OABSS, and FIQL validated questionnaires were used pre- and post-operatively. Primary endpoint was total fluoroscopy time. Secondary endpoints were total radiation exposure and total number of foramen needle skin punctures.

**Results:** Forty patients were enrolled, twenty in the ultrasound and twenty in the fluoroscopy only arm. Mean age was 60 (SD = 14.4) and mean BMI 32 (SD = 7.2). Twenty-seven patients (67.5%) had urinary symptoms, four (10%) fecal incontinence, and nine (22.5%) had mixed symptoms. Radiation exposure time was reduced by 70.5 s ($P = 0.002$), radiation exposure was decreased by 42.3 mGy ($P = 0.017$), and the number of needle skin punctures decreased by 3.6 ($P = 0.035$) with use of ultrasound. Mean OR time in minutes was 55.5 in ultrasound and 58.2 in fluoroscopy group ($P = 0.53$). There were no statistically significant differences in questionnaire scores between groups.

**Conclusion:** Ultrasound guided placement of foramen needle during Stage I sacral neuromodulation results in reduction of radiation exposure to the patient, surgeon, and operating room staff. Further studies are necessary to determine the learning curve and efficacy of this technique.

**KEYWORDS**
fecal incontinence, InterStim, overactive bladder, radiation, sacral neuromodulation, stage I, ultrasound

## 1 | INTRODUCTION

Overactive bladder (OAB) is defined by the International Continence Society as "urgency, with or without urge

incontinence, usually with frequency, and nocturia in the absence of urinary tract infection or other obvious pathology."[1] This constellation of symptoms is also known as overactive bladder syndrome, urge syndrome, or urgency-frequency syndrome.

The American Urological Association created guidelines for the treatment of OAB. The algorithm is divided into three main

treatment lines: behavior modification, pharmacology, and procedural options. The AUA OAB Guideline is the currently accepted standard of care for the treatment of OAB. Third line therapies are for patients whose symptoms are refractory to first and second line therapies. These options include intradetrusor onabotulinumtoxinA (Botox) injections, peripheral tibial nerve stimulation/modulation (PTNS/PTNM), or sacral neuromodulation (SNM).[2] Patients receiving Botox must be willing and able to return for post-void residual evaluation and perform clean intermittent self-catheterization. Patients who choose PTNS/PTNM must return for weekly treatments for several months and then ongoing maintenance treatments. SNM requires a surgical procedure for selected patients after evaluation prior to moving onto long-term therapy.

SNM was first FDA approved for urge incontinence in 1997 and its use expanded for urgency-frequency and non-obstructive urinary retention in 1999. InterStim® (Medtronic, Minneapolis, MN) is the only commercially available device in this treatment category. InterStim® is also indicated for the treatment of fecal incontinence since 2011.

SNM functions by placing a stimulating electrode near the 3rd sacral nerve root (S3). The proposed mechanism of action is that stimulation of somatic sensory afferent pathways alters voiding reflexes to modulate bladder and pelvic floor function. SNM has the advantage of evaluation before placement of long-term implant. The evaluation can be done with a temporary lead placement in the office, also known as peripheral nerve evaluation (PNE). The evaluation phase may be performed by placing a permanent lead in an outpatient surgical setting under a short intravenous sedation (stage I). Detailed bladder diaries and/or bowel diaries along with patient satisfaction are reviewed to determine success. The patient must show at least 50% improvement per objective measures in one or more bladder or bowel symptom categories. If satisfactory objective and subjective results are seen, then the patient can proceed to permanent InterStim implant.[3]

Current lead placement techniques are based on identifying palpable and fluoroscopic anatomic bony landmarks. Measurements based on bony landmarks, as recommended by the manufacturer, are used during office "blind" PNE technique. The use of fluoroscopy in the operating room setting allows for more precise measurements and is currently essential for permanent lead placement.[4,5] The use of palpable bony landmark measurements is based on normal anatomy without consideration for anatomic or pathologic variations. This may lead to improper placement of "blind" leads in an office setting and eventual failure of PNE. Fluoroscopy can confirm placement by single shot or continuous/live x-ray use, but use of fluoroscopy may lead to significant radiation exposure to both patient, surgeon, and operating room staff. In addition, some patients may be exposed to multiple needle entries during attempts to find the best placement of foramen needle. Multiple needle punctures may lead to post-operative pain and discomfort.

To our knowledge the use of intra-operative ultrasound for placement of the foramen needle has not been extensively explored. We believe ultrasound use may significantly reduce fluoroscopy time and exposure during lead placement.

The purpose of the study is to compare outcomes of ultrasound versus fluoroscopically guided placement of sacral neuromodulation foramen needles. We hypothesize that ultrasound guided placement will significantly reduce fluoroscopy time and produce equivalent patient symptom control. Primary endpoint is fluoroscopy time collected at the conclusion of the procedure. Secondary endpoints are radiation exposure in mGy as recorded by the C-arm and patient quality of life scores collected via validated questionnaires.

## 2 | MATERIALS AND METHODS

Our study is a prospective randomized blinded trial in which patients were selected based on the May 2014 AUA OAB guidelines after exhausting first and second line therapies including behavior modification, biofeedback, pelvic floor muscle training, and pharmacologic therapies. We also included patients with primary fecal incontinence or a combination of fecal and urinary symptoms. As this was a pilot study without any previous papers evaluating this outcome, we elected to start with a sample size of forty based on our statistician's recommendations. We planned on expanding our enrollment if needed after the data for the initial forty patients had been analyzed. Patients were recruited from April 2015 until December 2015. Enrolled patients met all inclusion criteria and none of the exclusion criteria (Table 1). The research protocol was approved by our institutional review board and all participants gave written informed consent prior to initiation into the study. The study was registered with ISRCTN (trial identifier: ISRCTN37385347). All procedures were performed in a community hospital setting. After 50% enrollment, a safety review was performed which did not reveal any adverse events. All participants filled out bladder and/or bowel diaries prior to implantation as is the standard at our institution. Quality of life questionnaires were also administered pre-operatively to all patients for bladder dysfunction, bowel dysfunction, or both. The validated International Consultation on Incontinence Modular Questionnaire Overactive Bladder Symptoms Quality of Life (ICIQ-OABqol), as well as the Overactive Bladder Symptom Score (OABSS) was given to patients with urinary symptoms.[6,7] Patients with fecal incontinence completed the validated Fecal Incontinence Quality of Life Scale (FIQL).[8] Questionnaires were again administered at the post-operative visits.

Subjects were randomized using computer-generated sequence. The randomization order was concealed in sealed, consecutively numbered envelopes. Patients were blinded to

**TABLE 1** Inclusion and exclusion criteria

| Inclusion criteria |
| --- |
| Diagnosis of overactive bladder, non-obstructive urinary retention, fecal incontinence, or mixed symptoms |
| Male or female and 18 years of age or older |
| Failure of previous conservative measures (ie, behavior modification, biofeedback, pelvic floor training, at least one antimuscarinic or beta-agonist medication) |
| Medically fit to undergo proposed surgery |
| Patient able to consent |

| Exclusion criteria |
| --- |
| Pregnant or planning on becoming pregnant |
| Severe or uncontrolled diabetes with peripheral nerve involvement |
| Knowledge of planned MRI or other procedures precluding implantation of device or need for removal |
| Severe BPH, prostate cancer, urethral stricture, or other mechanical obstruction |
| Active urinary tract, skin, or soft tissue infection |

the use of ultrasound versus fluoroscopy only and the surgeon was blinded until the patient was prepped and draped on the operating room table. No additional changes to our current institutional protocol on InterStim placement were made. All

patients received prophylactic antibiotics, IV sedation, local anesthesia, and standard sterile technique. All procedures were performed by a single high volume fellowship trained surgeon with assistance by a senior resident with significant prior InterStim training.

The curved stylet and techniques as described by Siegel et al[4] and Jacobs et al[9] were employed. Fluoroscopy is used to identify the medial aspect of sacral foramina bilaterally in AP position. Depth and angle adjustments were made with fluoroscopy in lateral position. Continuous live fluoroscopy is also used for placement of the lead introducer as well as the lead itself. Final AP and lateral images are obtained following deployment of the lead. The primary surgeon and a senior resident who underwent a one day simulation on use of the SonoSite S-Nerve™ (FujiFilm Sonosite, Inc., Bothell, WA) performed all of the procedures. In the ultrasound arm the SonoSite along with a 13-8 MHz linear probe was used to identify the S3 foramina and place the foramen needle under ultrasound guidance obviating the need for fluoroscopy (Figure 1). Fluoroscopy was used for the remainder of the procedure as described above.

Data recorded included patient demographics, pertinent medical history (Table 2), pre- and post-operative questionnaire results, number of initial separate needle foramen skin
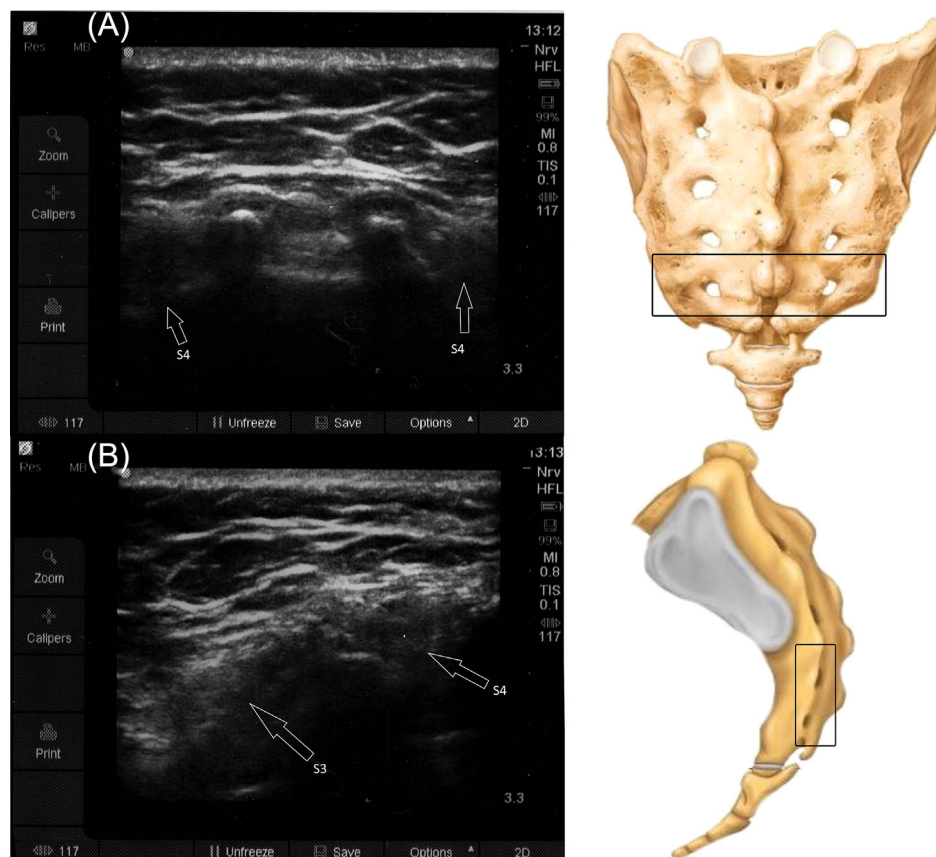


**FIGURE 1** Ultrasound view in the transverse plane identifying S4 foramina (A). Once this landmark has been identified, the probe is shifted laterally, toward the desired testing site and turned in the sagittal plane to identify the S3 foramen (B)

**TABLE 2** Demographics and medical history

| Demographic | Ultrasound (n = 20) | Fluoroscopy (n = 20) |
|---|---|---|
| Gender | | |
| Male | 1 (5%) | 4 (20%) |
| Female | 19 (95%) | 16 (80%) |
| Primary diagnosis | | |
| Urinary | 15 (75%) | 12 (60%) |
| Fecal | 2 (10%) | 2 (10%) |
| Mixed | 3 (15%) | 6 (30%) |
| Medications tried | | |
| 1 | 8 (40%) | 8 (40%) |
| 2 | 8 (40%) | 7 (35%) |
| 3 | 3 (15%) | 2 (10%) |
| >3 | 1 (5%) | 3 (15%) |
| Number pads per day | N = 13 | N = 12 |
| 1-2 | 5 (25%) | 4 (20%) |
| 3-5 | 3 (15%) | 8 (40%) |
| >5 | 5 (25%) | 0 |
| Mean age at surgery | 60 | 61 |
| Mean BMI | 32 | 32 |
| Office PNE prior to OR | 10 (50%) | 12 (60%) |
| Diabetes | 2 (10%) | 4 (20%) |
| Hysterectomy | 6 (30%) | 9 (45%) |
| Menopausal | 15 (75%) | 13 (65%) |

punctures, total fluoroscopy time, total radiation exposure in mGy, and pertinent post-operative data including any complications (Table 3).

Data was analyzed using means and standard deviations for continuous variables. Means were compared using ANOVA analysis. Categorical variables were further examined using Pearson Fisher's Exact tests. Statistical analysis was performed by an experienced statistician.

## 3 | RESULTS

Forty patients were consented, twenty in the ultrasound arm and twenty in the fluoroscopy arm. A total of five males (one in ultrasound and four in fluoroscopy arm) and thirty-five females (19 in ultrasound and 16 in fluoroscopy arm) were enrolled. Mean age was 60 (SD = 14.4) and mean BMI was 32 (SD = 7.2). Fifteen patients had a prior hysterectomy (six in ultrasound and nine in fluoroscopy arm) and twenty-eight patients were menopausal (15 in ultrasound and 13 in fluoroscopy arm). Indications for surgery were pure urinary symptoms in twenty-seven (15 in ultrasound and 12 in fluoroscopy arm), pure fecal symptoms in four (two in

ultrasound and two in fluoroscopy arm), and mixed symptoms in nine (three in ultrasound and six in fluoroscopy arm). None of the patients had primary urinary retention. Twenty-two patients had a successful office PNE trial (10 in ultrasound and 12 in fluoroscopy arm). Eighteen patients refused an office PNE trial due to concern for discomfort and elected to have a stage I trial in the operating room under anesthesia.

All patients completed pre- and post-operative questionnaires based on their symptoms. Mean pre-operative ICIQ-OABqol score was 107.4 (SD = 27.5), bother score 8 (SD = 2.3), OABSS 11.44 (SD = 3.1), and FI-qol 46.6 (SD = 13.8). Mean fluoroscopy time in all groups was 108.4 s (SD = 75.1), mean radiation exposure in mGy was 44.2 (SD = 52.9), and mean number of skin punctures with foramen needle was 10.4 (SD = 5.5). All group means were compared using ANOVA.

There was no statistical difference in the demographic distribution between the two groups, nor was there any statistical significance in group co-morbidities and pre- and post-op questionnaire data (Tables 2 and 3). Figure 2A-C shows a significant reduction in fluoroscopy time (72.9 s vs 143.8 sec, P = 0.002), radiation exposure in mGy (24.3 vs 66.6, P = 0.017), and the number of skin punctures with the foramen needle during the initial step of the procedure in the ultrasound group (8.6 vs 12.3, P = 0.035), respectively.

**TABLE 3** Results

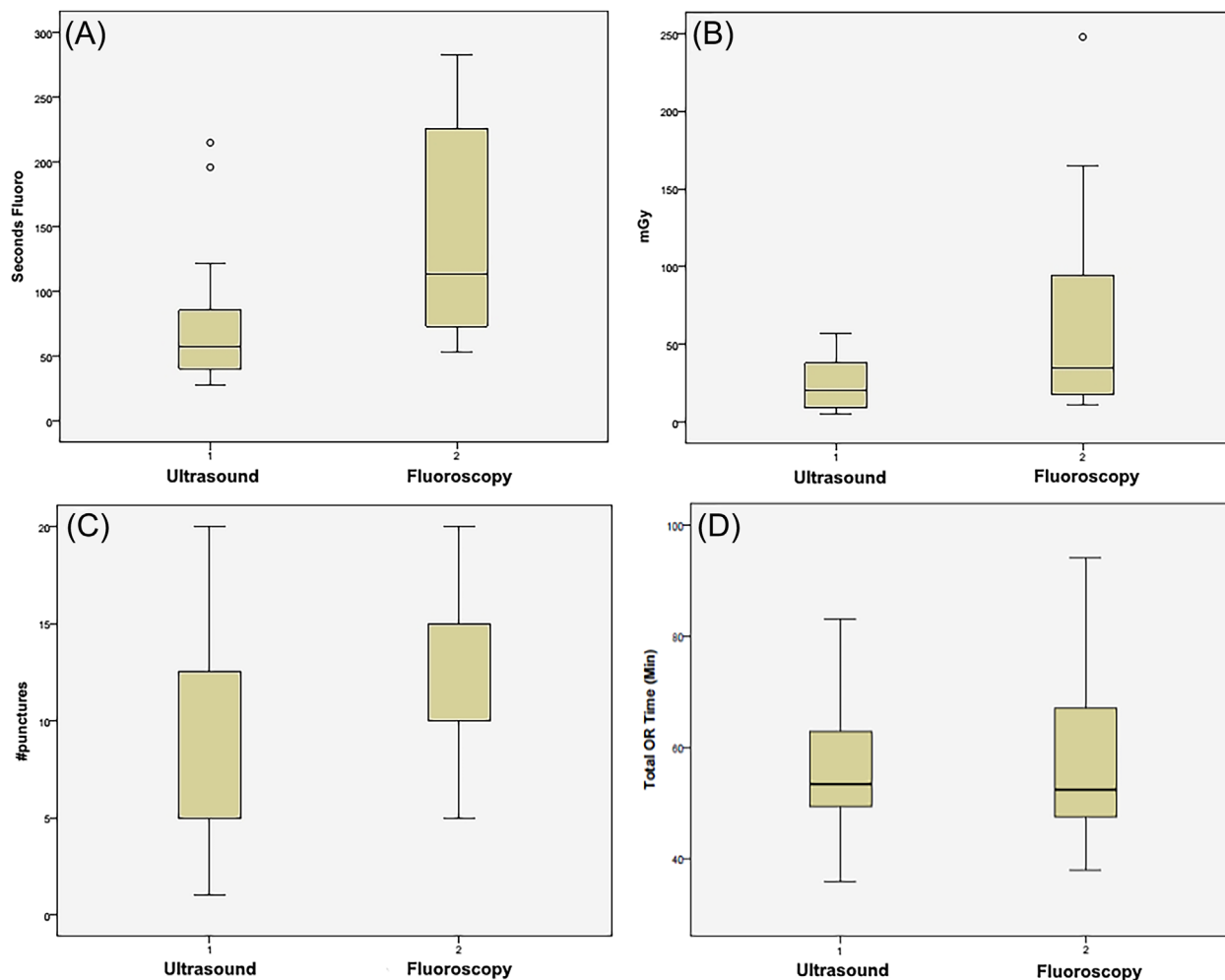| | Ultrasound (n = 20) | Fluoroscopy (n = 20) | P-value |
|---|---|---|---|
| Mean radiation | | | |
| mGy | | | 0.017 |
| Seconds | 24.3 | 66.6 | 0.002 |
| | 72.9 | 143.8 | |
| Mean skin punctures | 8.6 | 12.2 | 0.035 |
| Mean questionnaire score | | | |
| OABSS | | | |
| Pre-op | 11.4 | 10.6 | 0.40 |
| Post-op | 5.2 | 6.9 | 0.24 |
| ICIQ-OABqol | | | |
| Pre-op | 107.3 | 102.0 | 0.54 |
| Post-op | 52.2 | 63.6 | 0.28 |
| Bother score | | | |
| Pre-op | 8.0 | 7.7 | 0.73 |
| Post-op | 3.3 | 4.6 | 0.25 |
| FI-qol | | | |
| Pre-op | 46.6 | 57.1 | 0.15 |
| Post-op | 66.8 | 84.2 | 0.16 |
| Mean OR time (min) | 55.5 | 58.2 | 0.53 |

**FIGURE 2** Comparison of fluoroscopy time (A) radiation exposure in milligray (B) the number of initial skin punctures with the foramen needle (C) and total operating time (D) between ultrasound (1) and fluoroscopy (2) groups

Figure 2D shows no significant difference in total operating time between the two groups.

## 4 | DISCUSSION

Increase in medical radiation exposure has been well documented in recent years. There has been a growing concern over the long term sequelae of liberate use of various imaging modalities to patients and medical staff.[10] Deterministic and stochastic effects of radiation are well characterized and alternative imaging modalities such as ultrasound have been suggested in various urologic procedures.[11,12] Sacral neuromodulation has gained wide acceptance as an effective third line treatment modality for OAB.[13] Implantation of this device relies on fluoroscopy and may increase the overall radiation burden to patients and medical personnel.

Sacral neuromodulation with the InterStim device has been deemed an effective treatment modality in refractory urinary and bowel dysfunction.[1,3,14–16] There have been many

advances in the device since its inception. One of the most recent advances includes the use of a curved stylet to mimic the anatomic trajectory of the sacral nerve root, a technique employed at our institution.[9] The development of a Bluetooth enabled programmer has simplified adjustments and evaluation of the device.

Traditionally, fluoroscopy has been used in the operating room setting to aid with lead placement. In our experience, the majority of fluoroscopy time is devoted to initial foramen needle placement. Although adequate motor and sensory response may be elicited with the foramen needle, one has to plan for and understand the trajectory of the lead, which if deployed at a suboptimal angle may not reproduce responses at low amplitudes at all four electrodes of the tined lead.[17] Therefore, our group spends more time during this step of the procedure to ensure optimal results when the lead is introduced.[18] We routinely reposition the foramen needle and lead to obtain motor responses at amplitude of <1. Our OR time may therefore be longer than that

experienced by other groups. Anatomic landmarks using ultrasound have been developed as illustrated in Figure 1. By using ultrasound we were able to safely guide the foramen needle into the S3 foramen and reduced our radiation exposure time by an average of 70.5 s ($P = 0.002$). We elected to report radiation exposure in mGy as this is tracked at our institution for all fluoroscopic procedures and could easily be tracked in future studies. The mean decrease in radiation exposure as measured in mGy was 42.3 ($P = 0.017$). Initial needle punctures to find the foramen was also reduced using the ultrasound technique ($P = 0.035$), although the clinical significance of this metric is debatable as we did not power our study to see any difference in pain or infection parameters between the two groups.

The use of validated questionnaires in our cohorts demonstrated equivalent symptomatic relief in both groups and produced no statistical significance in quality of life outcomes. Infection of the device has been reported between 3% and 10%.[19] We did not experience any complications due to infections in our cohort. This may be due to our judicious use of antibiotics pre- and post-operatively, especially in at risk patients. Intra-operative motor and sensory response can be used concurrently to determine appropriate placement. Motor response rate has been shown to be a better predictor of positive outcome and we elect to use motor response at low threshold values ($<1$) for the majority of our patients.[20]

Our study is the first to explore a novel technique in SNM and demonstrate a reduction in radiation exposure to the patient, surgeon, and surgical staff. Potential limitations to our study include a single surgeon and single institution cohort. However, we also believe that by having all cases performed by a fellowship trained high volume surgeon and senior resident, there was a reduction in variability of our data. The surgeon and operating room staff were not able to be completely blinded due to the inherent nature of surgical intervention. However, our method is consistent with previously published reports.[9] Our cohort of 40, mostly female and Caucasian patients, also limits applicability of our results to a more diverse population. Although non-obstructive urinary retention was considered in our inclusion criteria, none of our patients in this small cohort suffered from pure urinary retention and therefore our data may not be reflective of this population subset. We also used QoL questionnaires as surrogates for clinical outcomes, which may not be ideal. There are also inherent limitations associated with the ultrasound device, which we tried to limit by using the same machine for all patients. Of note, there was no additional cost in the use of ultrasound to the patient at our institution. In addition, we realize the shortcomings of not breaking down and further stratifying fluoroscopy time based on different portions of the procedure, but we believe that the ultimate goal of reducing overall fluoroscopy time was addressed appropriately with our design. Due to the limitations of our ultrasound device and the InterStim leads, we were unable to compare ultrasound alone to fluoroscopy as the deployment of the leads still depends on the use of continuous fluoroscopy. Further studies are needed to look at long term outcome, as well as the learning curve associated with the use of ultrasound.

## 5 | CONCLUSION

The use of ultrasound for safe placement of sacral neuromodulation leads results in reduction of radiation exposure to the patient, surgeon, and operating room staff. Further studies may be required to expand upon our findings. In the future, with improvement in ultrasonographic technology and echogenic needles and leads one may be able to perform the entire procedure using ultrasound, eliminating the need for fluoroscopy.

## CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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