# The Presacral Space and its Impact on Sacral Neuromodulator Implantation

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**Purpose:** We describe the presacral space and its potential impact on sacral neuromodulator implantation and bowel injury.

**Materials and Methods:** Parasagittal images containing bilateral sacral foramina (S2–S4) were examined on 45 pelvic magnetic resonance images. Images were excluded from analysis if they were poor quality or had any history causing distortion of normal anatomy. We measured the natural angle between the foramina and the dorsal skin to approximate the needle angulation during neuromodulator electrode placement. Using these angles we measured the distance from the skin to any bowel (D1), the skin to the dorsal sacrum (D2) and then calculated the distance from the dorsal sacrum to any bowel (D3).

**Results:** Mean subject age was 45 years (range 19 to 78) and body mass index was 27.9 kg/m$^2$ (range 18.6 to 56.2). At S3 the mean foraminal angle and D3 were 46 ± 8.4 degrees and 27.4 ± 11.7 mm, respectively. Increasing age was moderately correlated to widening D3 at each foramina ($r = 0.3$, Pearson's $p < 0.05$). Body mass index did not consistently vary with D3 at any foramina.

**Conclusions:** Our measurements suggest that the presacral space can be expected to be approximately 27 mm at the level of S3 where the neuromodulator electrode is implanted. It is possible to encounter bowel while performing this implantation using standard techniques and equipment. We recommend the standard use of fluoroscopy during placement.

*Key Words: humans; electrodes, implanted; urination disorders/therapy; urinary incontinence, urge/surgery; electric stimulation therapy/instrumentation*

The InterStim® sacral neurostimulator has been FDA approved for use in the United States since 1997, and is used to treat a variety of urinary dysfunctions and pelvic pain syndromes. Medtronic reports more than 25,000 devices have been implanted since approval.[1] Several studies have confirmed its efficacy and safety as a treatment option.[2–4]

The InterStim device is implanted by threading an electrode wire with a tined lead through a needle introducer to lie along the S3 nerve root. The 2 available introducer needle sizes are 3.5 and 5 inches. Traditionally the introducer is placed with the use of bony landmarks. Nerve stimulation and subsequent bellows reflex are used to confirm placement in the S3 foramen. Fluoroscopy can be used to facilitate lead placement.[5] By demarcating the bony structures before introducer insertion the initial placement can be outlined more precisely (figs. 1 and 2). In addition, after entry into the spinal foramen lead depth can be accurately adjusted using the radiopaque markers on the tined lead.

Variation in foramen structure among patients can result in placement of the introducer into the presacral space and beyond. Increasing depth of placement beyond the presacral space risks bowel injury. The FDA Center for Devices and Radiological Health Manufacturer and User Facility Device Experience (MAUDE) Database yielded 2 reports of bowel complications. One report involved the lead found passed within a stool the day following implantation and the other was of spontaneous lead extrusion from the rectum.[6] No information was provided regarding implantation technique or patient medical history.

Of previous studies measuring the presacral space the majority used lateral x-ray views with barium enemas and used the boundary of the ventral surface of the sacrum to the posterior wall of the rectum.[7–11] More recent studies have used computerized tomography and MRI for evaluation.[12,13] A study by Oto et al assessing sagittal MRI described median midline widths of the presacral space at the level of S1, S2 and S3.[13] To our knowledge there are no studies that examine the presacral space in the region of the foramina. These studies are not directly applicable to InterStim placement due to the midline location of the measurement and may underestimate or overestimate the space more laterally. In this study we measured the size of the presacral space at the parasagittal foraminal locations, thereby establishing a reference for use in InterStim placement.

## METHODS

To measure the lateral presacral space at the location of the sacral foramina we designed a case study using MRI technology. Pelvic T2-weighted fast spin echo MRIs were evalu-

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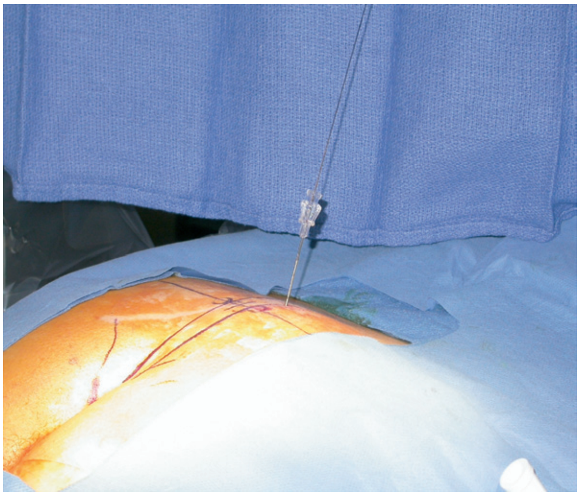

FIG. 1. Bony landmarks demarcated for insertion

ated in the sagittal view. Measurements were taken at S2, S3 and S4 on the right and left sides. The images used for measurement were the most medial slice available that included a clear view of the foramen. In actual practice the site on the skin where the needle is placed or the starting skin point is blind to the angle of the sacral foramina. To standardize our measurements the starting skin point was chosen to mimic an idealized needle course that would pass through the center of the foramen and mirror the natural angle of the foramen. That natural angle was recorded along with a minimum and maximum angle that would pass through the foramen from the same starting skin point. Distance measurements were made using the natural angle of the foramen, and included distance from the skin to the bowel or first presenting abdominal organ if bowel was not visible (D1) and distance from skin to the dorsal surface of the sacrum (D2). The distance from the dorsal sacrum to the presenting organ (D3) was then calculated by subtracting D2 from D1 (fig. 3).

If we assume a significance of 0.05, power of 0.8, and state that the mean distance between the posterior aspect of the rectum and the ventral aspect of the sacrum is 10 mm with

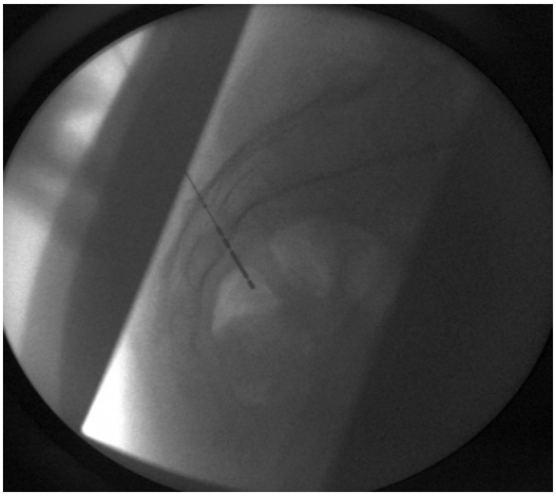

FIG. 2. Fluoroscopic confirmation of lead placement through S3 foramen.

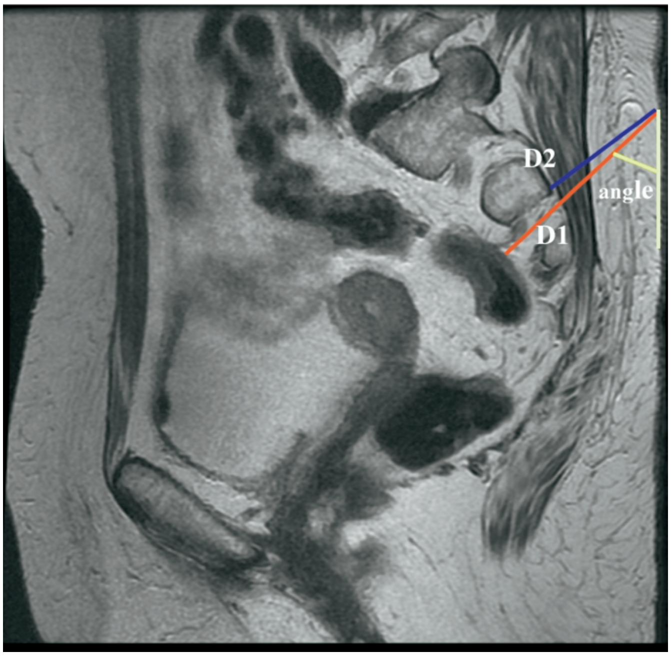


FIG. 3. Schematic of measurements. Foramina angle is shown in yellow. Distance from skin to dorsal sacrum (D2) is shown in blue. Distance from skin to posterior rectum (D1) is shown in red. Presacral space (D3) is calculated as D1 − D2.

a standard deviation of 4 mm, 34 patients would need to be sampled to determine if the mean was 20% discordant with the null hypothesis. Pelvic MRI studies were reviewed using a picture archiving and communication system in a retrograde fashion beginning with the most recent and continuing back in time in 6-month increments until we achieved our planned sample size.

Radiologist final diagnoses and review of each subject medical record were used to exclude inappropriate studies from analysis. Studies were excluded if the uterus was enlarged (greater than 10 × 8 × 6 cm) or if evidence of pelvic disease was present. Subjects were also excluded from analysis if they had a history of bowel surgery, bowel disease, prior pelvic irradiation, or spinal surgery or anatomical abnormality because it has been previously described that inflammatory, neoplastic or radiation related changes can artificially widen the presacral space. Patients with a history of benign hysterectomy were included in study as these women represent a common subset of the urogynecological patient population. All data were collected and analyzed using SPSS® v. 11.0.

## RESULTS

We reviewed 45 MRIs. Of these 39 were of females (87%). Mean patient age was 45 years with a range of 19 to 78. BMI data were collected from patient charts as close as possible to the date of study. Mean BMI was 27.9 ± 7.9 kg/m$^2$ with a range of 18.6 to 56.2. Within our population the indications for MRI were varied (table 1). Of the studies ordered for evaluation of malignancy none revealed evidence of spread to surrounding structures.

For the S3 foramina mean measured D3 was 27.4 mm. There was no significant difference between left and right side measurements at any level, and these were combined to