# QUANTIFICATION OF SNM LEAD LOCATIONS USING FLUOROSCOPY AND THEIR RELATIONSHIP TO SURGICAL MOTOR THRESHOLD

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## Abstract

Sacral neuromodulation (SNM), an approved therapy for OAB, urinary retention without obstruction, and bowel disorders, requires good surgical targeting of the sacral nerve. The targeting uses a combination of fluoroscopy and stimulation testing but relies very heavily on surgeon experience. We conducted a retrospective study to capture and quantify contact depths and implant angles from saved fluoroscopic images to determine whether we can increase reliance upon quantitative fluoroscopic positioning to target the lead. To examine the functional relevance of these measurements, we compared them to motor thresholds obtained during surgery.

## Introduction

During the implant procedure, an electrical lead is targeted to the sacral nerve under fluoroscopic visualization and the images are stored in the electronic medical record (EMR). (Figure 1) However quantitative measurements of SNM leads or contact locations are not typically made from the captured images. We conducted a retrospective study to study contact depths and lead angles in more detail. The utility of making these measurements was evaluated by comparing them to the motor and sensory thresholds for each therapy contact. Our retrospective study tested the hypotheses that these thresholds measured during and following surgical implantation are significantly different across a range of implanted lead angles and contact depths.

## Methods and Materials

EMR were reviewed from 16 patients with implanted Axonics SNM leads (Model 1201). Lead angles and contact depths were measured from lateral fluoroscopic images. (Figure 1) Contact depths were measured relative to the posterior sacral plane. Without image magnification, we calculated depths as the percentage of each patient's sacral thickness (%ST). Lead angle was measured in degrees between the ventral aspect of the sacrum and the lead. As a measure of therapy relevance, we compared lead and contact locations to available bellows motor or sensory thresholds (bipolar stim) which are related to SNM efficacy. Student's t-test (Bonferroni adjustment for multiple comparisons), was used for statistical significance (P<0.05).

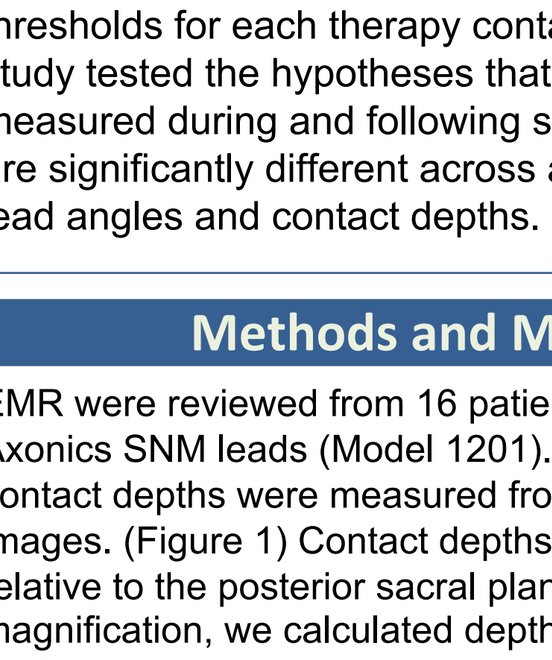


**Figure 1.** Schematic of SNM lead with contacts and respective measurements used to calculate location - contact depth and lead angle - relative to the anterior sacral plane.

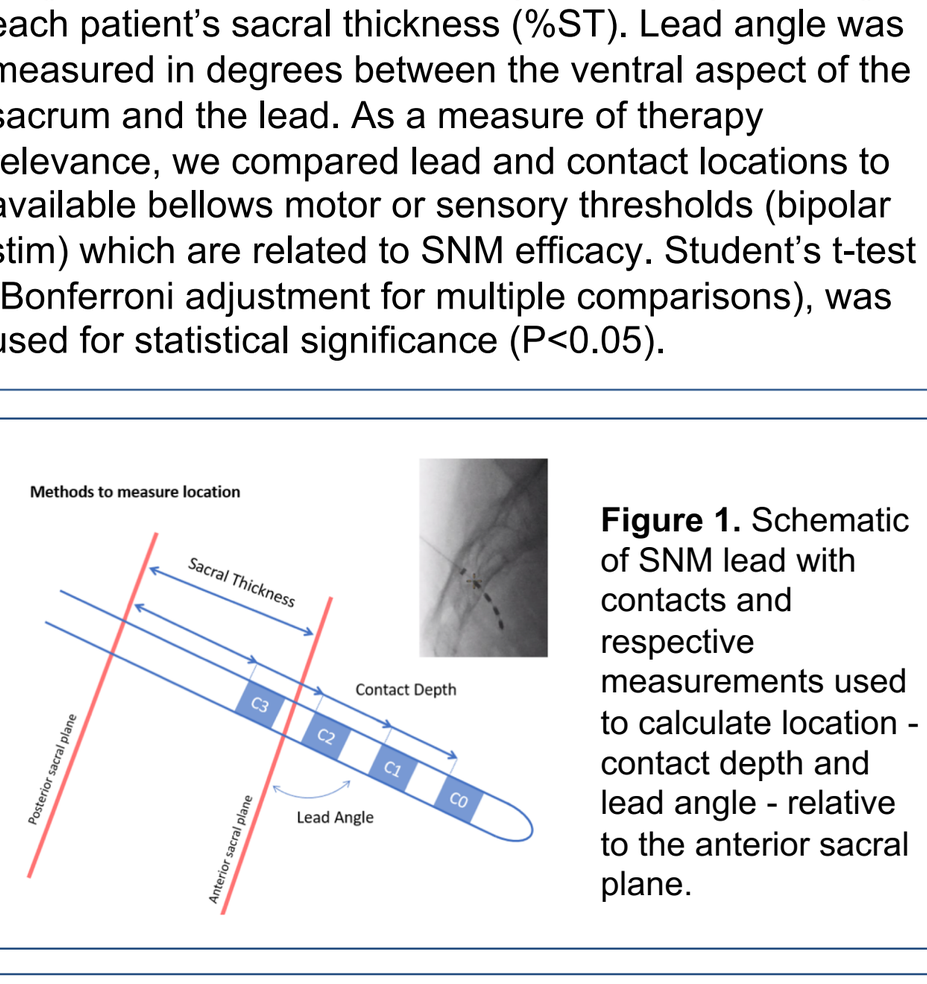


**Figure 2.** Contact Depths (upper panel) were significantly different for the four SNM contacts. The proximal contact, 0, was typically implanted within the foramen. Lead angles (lower panel) varied with means and variations as shown.

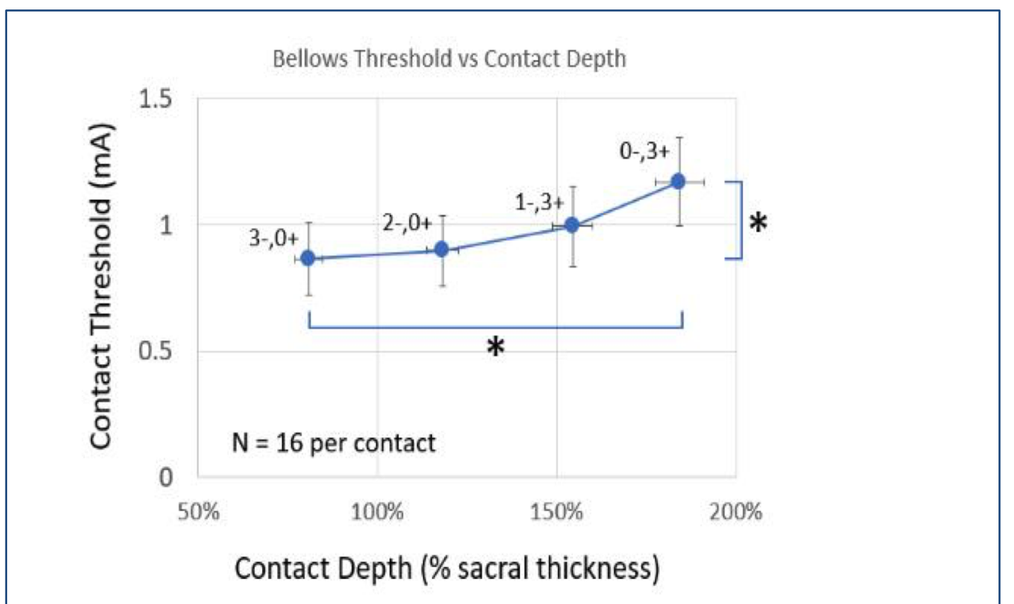


**Figure 3.** Mean bellows threshold vs depth of the cathode contact for the bipolar stimulation used in testing. For each contact of the SNM lead the mean threshold (+/- SEM) is shown as well as its mean contact depth (+/- SEM).

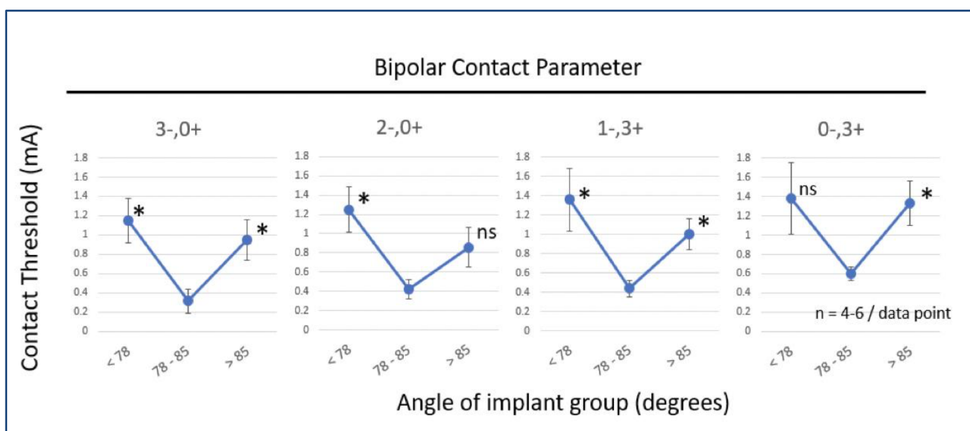


**Figure 4.** Mean bellows motor threshold (+/- SEM) for bipolar cathodic stimulation is shown for 16 implanted leads grouped by implantation angle. Asterisk (*) denotes mean threshold significant difference from 78-85° (P<0.05), 'ns' denotes no significance

## Results

- Mean contact depths ranged from 81%ST (SD=15) for the shallowest contact (3) to 184 %ST (27) for the deepest (contact 0). Mean contact depths across the contacts (0-3) were all significantly different from one another (P<0.05; t-test, Bonferroni correction, Figure 3).
- Mean lead angle was 80° (+/- 11°).
- Bellows motor thresholds were available for all 64 contacts from these 16 patients.
- Bellows motor threshold showed some relationship to contact depth with statistical differences between the shallowest and deepest contact depths.
- The optimal angle for the implanted lead was observed between 75-85°. Within this range, the bellows motor thresholds for contacts were usually significantly smaller (7 of 8 comparisons) across all lead contacts. The leads within this 75-85° angle range also had smaller variations in thresholds across the lead compared to lead angles > 85° and < 75°. (Figure 4)

## Discussion

SNM contact depths and angles were measurable using saved fluoroscopic images and they appear to provide relevant information for optimal SNM therapy. The shallowest mean location for implanted contacts is visible within the sacral foramen and deeper contacts extend along the SNM lead beyond the foramen with significant differences between the mean implant depths across the contacts. (Figure 2) The measured depths of implant contacts may reveal an ideal implantation location for SNM. Bellows motor threshold for cathode stimulation at the shallow contact 3 (3-,0+) was lower than that of the deeper contact 0 (0-,3+) as shown in Figure 3. Implanted SNM lead angle may also be optimal at angles around 80°. Implantation angles of 78-85° are typically associated with the lowest bellows thresholds across the lead contacts. (Figure 4) Even with this limited study, we are able to observe potentially useful relationships between measured lead locations and the bellows threshold data.

## Conclusions

Functionally relevant SNM contact depths and implant angles can be measured from fluoroscopic images captured during SNM implantations. An improved focus on identifying, locating, and stimulating the neural targets of SNM can establish evidence-based design inputs for next generation lead designs and implantation techniques.