



# Intraoperative Tips and Tricks for Successful Sacral Neuromodulation

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## Abstract

**Purpose of Review** Sacral neuromodulation (SNM) is an effective, minimally invasive treatment for refractory overactive bladder, non-obstructive urinary retention, and fecal incontinence. Although the treatment is 80% successful, optimal outcomes over time are achieved only by applying precise surgical technique. In this review, we will present the surgical technique for optimal SNM documented in the literature, as well as provide tips for ideal placement based on the authors' experience.

**Recent Findings** The technique of SNM placement has greatly evolved over the last 10 years with the routine use of fluoroscopy as well as the introduction of the curved, tined lead. With these developments, surgeons have begun to pay more attention to motor thresholds needed to achieve anal bellows and toe flexion responses during staged lead implants. By achieving lower motor thresholds, ideally less than 2 mA, patients have a lower risk of future lead revision and may benefit from longer battery life and greater reprogramming options.

**Summary** Ideal lead placement for SNM includes superior medial entry into the S3 foramen, with a lateral curvature of the distal lead to follow the S3 nerve root. Specific fluoroscopic findings, along with low motor thresholds for anal bellows and toe flexion, confirm ideal lead placement. Surgeons should make every effort to achieve the ideal lead. In patients with inadequate response to therapy, the lead can be checked on x-ray for ideal characteristics, and a revision should be considered if there is room for improvement.

**Keywords** Sacral neuromodulation · Lead placement · Lead revision · Staged neuromodulation implant · Percutaneous nerve evaluation

## Introduction

Sacral neuromodulation (SNM) is an effective, minimally invasive treatment for patients suffering from refractory overactive bladder syndrome (OAB) with or without urinary urgency incontinence, non-obstructive urinary retention (NOR), and refractory fecal incontinence (FI). Conservative measures such as behavioral and medical treatment are recommended prior to treatment with SNM. SNM can then be offered to

those patients who fail to respond to or are not tolerant of the conservative or medical therapies [1, 2].

Tanagho and Schmidt performed the first electrical stimulation of the sacral nerve roots in a patient with urinary retention in 1988 [3]. The exact mechanism of action for SNM is not clearly understood despite numerous neuroimaging research studies; however, it is widely accepted that the effect of the therapy is a result of a complex interplay between the intrapelvic, intraspinal, and supraspinal neural networks that control bowel and bladder function [4]. Over the years, the SNM technique has evolved and been refined in many ways including replacement of the open surgical lead placement for a percutaneous approach, using tined leads, and downsizing the implantable pulse generator [1]. Currently, the only SNM device that is commercially available is the Medtronic InterStim (Minneapolis, MN). In this review, we will provide an evidence-based discussion of recent work done in the area of SNM, to offer intraoperative tips and tricks for successful sacral neuromodulation.

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## Peripheral Nerve Evaluation Versus Staged Implantation

SNM is quite a surgical treatment in that patients have the opportunity to trial the therapy before making a long-term commitment to the full implant. The two different approaches to the trial period are peripheral nerve evaluation (PNE) versus staged (tined) lead placement. PNE involves the placement of a monopolar, temporary lead, which is always removed after an SNM test period, and is not truly designed to serve as a long-term therapy. The initial test period generally lasts 7 days. After this period, if the patient is deemed to have satisfactory improvement in symptoms, then the permanent tined lead and implantable pulse generator (IPG) are placed. Alternatively, if there is no, or inadequate, improvement in symptoms, the lead is removed and the patient can go on to receive a staged implant. The primary advantage of PNE is that it can be performed in the office under local anesthesia [5]. However, current evidence supports the staged (tined) lead as the preferred method of the two, and the guidelines have shifted in favor of this approach [6•]. In fact, the most recent studies that have been published on SNM focus on the staged (tined) lead and do not even compare this with PNE due to the disadvantages that testing with PNE brings [7]. These disadvantages include the risk of lead migration (given the leads are not anchored with tines), nearly a 50% reduction in the rate of positive tests when compared with the staged approach, and a significant discordance between responses with the temporary PNE and definitive lead placement [8•].

The first experience using the quadripolar staged (tined) lead was described in 2005 [9]. The design of the tined lead allows for a permanent therapy if a patient is deemed to have at least 50% improvement in their symptoms during the initial test period. This lead is placed in the OR under monitored anesthesia care sedation with local anesthesia or general anesthesia. Despite the increased cost compared with PNE, this approach has the advantage of a longer trial period of 2 weeks, as well as better conversion rates to chronic therapeutic stimulation [8•]. This quadripolar electrode is positioned along the third sacral nerve and is composed of barbed hooks or tines, which serve to prevent the electrodes from migrating. During the test period, the lead is connected to an external stimulator after the electrode has been placed percutaneously. Voiding diaries are used to assess for improvement of greater than 50% in one or more of the patient's bothersome voiding diary parameters compared with the patient's baseline, as this is generally deemed a successful response to the test period when consistently shown over the course of 2 weeks. If this is the case, then the second stage is performed and the IPG is implanted. The Medtronic InterStim IPG is quite costly, hence the staged implant approach. In this review, we will explore the nuances of the operative techniques of the first and second stage, as well as the intricacies of lead revisions, to aid in achieving successful sacral neuromodulation.

## Stage 1—Optimal Lead Placement

### Importance of Surgical Technique in Tined Lead Placement

Although SNM is established as a successful long-term treatment for patients with OAB and NOR, there is potential for a patient to experience less than their maximum potential improvement in symptoms as a result of surgical technique or imprecise lead positioning. Previous studies have proven that those patients who respond well to the first stage of the treatment have a higher chance of maintaining a favorable long-term treatment effect, regardless of whether they were unsuccessful after an initial PNE [10]. In more recent years, studies have shown that the greater number of motor responses during intraoperative electrode testing is associated with better long-term success and less lead revisions [11••]. In 2018, Goldman et al. published their review of unilateral SNM lead placements performed from 2010 to 2015, in which they evaluated motor responses recorded during these cases, with the primary outcome measure of the need for revision surgery. Motor responses were quantified into bellows and toe response scores of 0 or 1 for no response or positive motor response, respectively, for each of the possible responses from the quadripolar electrode for a total range of scores from 0 to 8 for each patient. Revision surgery was negatively associated with total motor score ( $p = 0.027$ ) and the toe motor response subscore ( $p = 0.033$ ). Total motor response score of less than 4 was predictive of revision on logistic regression (OR 4.2, 95% CI 1.4–12.8). Given this improved clinical outcome, we will review a standardized electrode placement technique for precise targeting of the S3 nerve root with the aim of obtaining low motor threshold responses in each electrode.

The S3 nerve root has been well established as the preferred target for SNM. An expected S3 motor response would involve contraction of the pelvic floor to provide an anal bellow, as well as plantar flexion of the first and second toes [12]. Expert consensus dictates that confirming proximity to the target S3 nerve provides a higher likelihood for optimal effect with improved battery longevity because less energy is consumed during continuous stimulation. In addition, it allows for more programming options given the close contact between the electrodes and the nerve with reduced likelihood of side-effects and lead revision [13]. An international multidisciplinary SNM expert group of surgeons has worked to provide a standardized electrode placement technique for the optimal lead placement. Positioning is of great importance to achieve precise lead placement. The patient should be placed prone with the feet and toes lifted off the table, with a supportive pillow under the shins, to allow for verification of toe and foot response upon stimulation of the nerve. The hips must be well supported as to reduce lumbar lordosis to a minimum and allow for the angle of entry into the foramen. The buttock

cheeks can be taped apart to allow for viewing of the anal bellow response. A grounding pad is then placed, and the patient prepped with antiseptic solution and draped. One dose of prophylactic IV antibiotics is given to cover for skin flora.

### Tined Lead Placement Technique

The lead placement technique described here was developed by Dr. Steven Siegel. The procedure begins with using fluoroscopy to obtain an anterior-posterior (AP) view of the sacrum and allow for marking of medial edges of the foramina with vertical lines on both sides. After this, initial AP view is obtained to find the medial-lateral position for placement; the remainder of the procedure is performed with a lateral view on fluoroscopy. Standing on the patient's side, a lateral view is used to mark the foramen with a surgical clamp or DeBakey forceps. On lateral view, the S3 entry point is identified by noting the S3 hillock, which can be found just inferior to the point where the iliac bone crosses the sacrum. The surgeon then holds the forceps in the expected entry point to target the S3 nerve root and takes a single shot under fluoroscopy. The angle of the DeBakey forceps and the entry point are determined by making adjustments under serial, single-shot fluoroscopy until the ideal entry point and angle are determined. The ideal angle should be parallel to the intervertebral body. After injection of local anesthetic, the needle should then be inserted a short distance at this angle of the fusion plane in the vertical line of the central body axis. Further lateral x-ray images are taken to make minor adjustments to the entry site and angle, and the needle is advanced into the foramen. Once the upper and most medial section of the sacral foramen is entered, fluoroscopy is used to advance the needle to the inner table of the sacrum. Testing is then done with the external pulse generator, with a goal of achieving anal bellow and toe flexion responses ideally at a low current below 2 mA. Adjustments can be made to the depth, angle, and entry of the needle to maximize motor response at a lower amplitude of 1 mA. Once both toe flexion and anal bellows are achieved with stimulation less than 2 mA, the stylet is then removed, the directional guide wire is inserted, and the needle is then removed leaving the guidewire in place. The skin is then incised for 0.5 cm, and the dilator and lead introducer are inserted over the wire, with the radiopaque marker just inside the sacral foramen. The dilator and guide wire are removed, leaving the introducer sheath in place.

Once the introducer sheath is in place, then the tined lead electrode follows. First the stiff, straight stylet is exchanged for the softer stylet with a flexible and curved tip. The introducer is held in stable position while the lead is inserted, and the direction of insertion follows with the curved tip oriented in a caudo-lateral direction. Once the first white marker of the electrode reaches the introducer's upper edge, the entire electrode is covered by the introducer. It is then pushed to the

second marker where the four contacts exit the introducer; however, the tines are still protected inside the introducer and not deployed at this time. Test stimulation is applied to the external top of the electrode with four contact points which reflect the four contacts at the tip of the electrode.

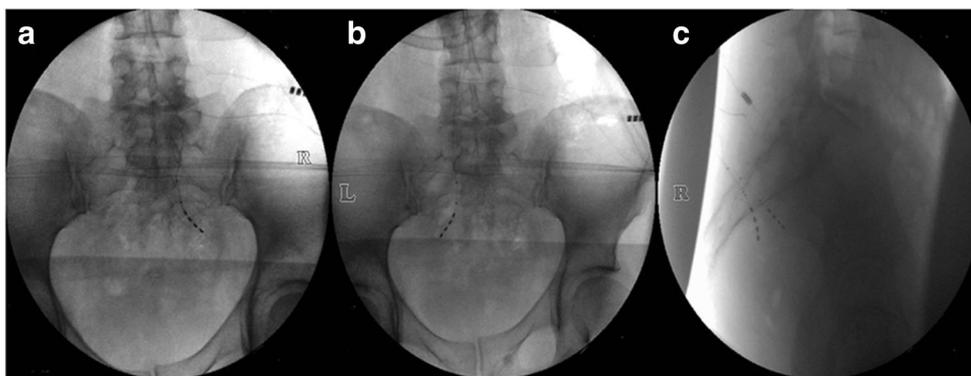
Ideal response would be obtained if each contact can evoke motor response at 2 mA or less for both anal bellows and great toe flexion. In a lateral view, the lead should be parallel to the fusion plane between the third and fourth sacral segments, entering above the hillock and curving caudally. Ideally, the distances between the more distal electrode contacts appear to be less than between the more proximal contacts given lateral deviation of the electrode from the midline. If the lead curves cranially or has inadequate caudal curvature, it should be removed, rotated, and replaced until an adequate caudal curvature is achieved. Some surgeons find it helpful to place the lead under continuous fluoroscopy, though this is not absolutely necessary. Figure 1 shows an ideally placed lead as compared with a less ideal lead.

The introducer sheath is then removed while holding the lead in place, which will deploy the tines and anchor the leads. This is done under fluoroscopy with spot images obtained throughout the introducer sheath removal to ensure that the lead is not pulled back or pushed in from the placement obtained. The electrode position can be confirmed with repeat stimulation, and a final electrode position should be documented by fluoroscopy using both AP and lateral views. In addition, the thresholds for motor responses should be documented in the operative report for future reference in case the patient returns for follow-up demonstrating inadequate symptom control, and a lead revision is considered.

The lead and percutaneous extension are then connected at the site of the future neurostimulator in the buttock. The location of the future IPG is on the right or left side, inferior to the iliac crest. It can be helpful to discuss with the patient prior to surgery where they would prefer the IPG to be located. Factors to consider include which side the patient sleeps on at night, how high or low on the waist/hips they wear their pants or belt, and if there are any dexterity issues. Patients will have to occasionally access the area to turn on or off the device, and they may prefer one side or the other for the IPG location.

A small pocket is then prepared under the subcutaneous fascia of the buttock, and the electrode is then tunneled into this pocket. Care should be taken to ensure that when the lead is tunneled, it is completely buried in the incision through where it was placed. To do this, the tunneling tool is first advanced down into the incision and then directed to the area of the pocket. If the downward motion is not used, there is a chance the lead can sit very superficially at the incision site and cause discomfort. The tool is removed which leaves the tube in place and the lead is affixed to the percutaneous extension inserted through the tube from the pocket side. The electrode is positioned in the set screw connector so that the

**Fig. 1** AP view of initial placement on the right side enters the foramen too laterally (**a**). There was no response to stage 1 with this lead. It was then revised and placed on the left side (**b**). This lead enters the foramen medially and demonstrates appropriate downward curvature on the view (**c**). After the revision, the patient had an excellent response with 90% improvement at 3-year follow-up



blue tip of the electrode end is visible, and the four screws tightened with the wrench. The silicone boot is pulled over the connector, and non-absorbable suture used to secure at each end of the connection. Finally, the pocket and stab wounds are closed.

Although the risk of dislodgement is less with the tined lead when compared with the temporary PNE, operative dressings should not be removed during the test period unless the physician has concerns upon inspection of the dressing for infection or bleeding [6•]. The authors use steri-strips to cover the incisions and avoid skin glue to prevent difficulty reentering the incisions at the second stage. Each incision is then covered with a telfa pad and clear plastic dressing. The percutaneous extension is liberally padded and taped to provide comfort to the patient during the trial period. Additionally, patients should be encouraged to minimize vigorous activity and excessive bending or twisting at the waist for several weeks to allow the tined lead to scar in place and prevent lead migration.

### Troubleshooting During Tined Lead Placement

If the initial testing of the seeker needle is unsuccessful at achieving a great toe and anal bellow response below 2 mA, the surgeon should reassess the needle placement. If only anal bellows are achieved, then the testing needle may be too low in the foramen and moving up one spinal level is considered. If inward rotation of the foot is noted, that is indicative of S2 stimulation, then surgeon should move the needle down one spinal level. If the great toe and anal bellows are both seen, yet only at high-stimulation amplitudes greater than 2 mA, the angle and point of entry should be reevaluated. The ideal point of entry is medial/superior within the S3 foramen. The authors recommend leaving the initial needle in place and then using this as a guide to aim for a more precise placement with the second needle included in the kit. The initial needle can serve as a guide for the new needle being placed (i.e., more medial, different angle, change of entry point).

At times the surgeon may find that the stimulation with the seeker needle achieved good motor responses, but the lead

itself does not achieve the desired response. The surgeon should first check the lead appearance on fluoroscopy to evaluate for the ideal lead characteristics. If the angle and level of entry are appropriate on the lateral view, then the fluoroscopy should be rotated again to assess the lead on an AP view. On this view, the lead should originate from the medial superior part of the sacral foramen. Often when the lead is not medial enough, higher amplitudes are needed to achieve motor responses. Another clue to the lead being located too lateral or not curved along the S3 nerve root is when low motor thresholds are seen in the proximal electrode [2–4], but not on the distal electrodes (0 and 1). The surgeon should make every effort to achieve 5 electrode responses under 2 mA, and at times this requires replacement of the lead on the opposite side.

### Stage 2—IPG Placement

The IPG was formerly placed in the anterior abdominal wall when the SNM was first introduced; however, given the patient repositioning this necessitated during the procedure, this lengthened the procedure time. In 2001, Scheepens et al. described the buttock placement of the IPG [14]. When it is decided that a permanent implant will be placed after a successful test period, there are a few important considerations for placing the IPG. Firstly, the final placement should allow for the patient to sit, lie flat on their back, and lie on the side of the IPG without discomfort. Also, the IPG should be accessible for the patient to activate and deactivate with their programmer [13]. In general, the pocket in the buttock is positioned 3–4 cm lateral to the sacral bone and 4–6 cm inferior to the iliac crest to avoid contact with bony structures, which is especially important in thin patients. An incision is made long enough for safe dissection of the subcutaneous/Scarpa's fascia, and then a pocket is created under the fascia large enough to hold the IPG tight. The electrode is then connected to the Medtronic IPG after disconnection of the extension lead, by insertion into the IPG until the blue tip of the electrode is visible in the transparent connection head of the IPG and fixed

by closing the screw. Based on product information data, the IPG should be placed no deeper than 2.5 cm given the distance limitation of the wireless communication with the programmer. The pocket is then closed as in the first stage after vigorous irrigation of the wound to prevent infection.

## Lead Revisions

Close follow-up after permanent IPG implantation is important to evaluate the clinical effect. Patients may present with side-effects which could be related to declining efficacy, painful stimulation, or aberrant neurological stimulation. Common complaints can include pain at the site of the IPG, painful stimulation, recurrence of symptoms, absent stimulation, and stimulation in non-target areas [15]. The first step in the evaluation process of these complaints is to turn the IPG off. If all the symptoms disappear after the IPG is turned off, then the IPG can be turned on and reprogrammed to try to avoid return of the presenting complaint. Pain from stimulation should disappear when turning off the IPG and reprogramming, which can include decreasing voltage, decreasing frequency, and/or changing the lead configuration [6•]. If the pain persists after the IPG is turned off, then the pain may be due to the position of the IPG itself, in which case repositioning can be considered, or it may be unrelated to the device. If reprogramming does not improve the patient's symptoms, then x-ray images should be performed to assess for lead breakage or migration. Impedances  $> 4000 \Omega$  are also diagnostic of a lead fracture or microfracture which may not be seen on x-ray and likely requires lead replacement. Patients with a non-functioning lead will usually present with loss of SNM stimulation and/or loss of efficacy of SNM. This can be confirmed by impedance check of all combinations. If all of the combinations are non-functional, then the IPG should be turned off and the lead replaced.

To decide whether a lead revision will be successful, the surgeon needs to consider several factors: (1) amplitudes achieved for motor thresholds on the initial placement (if available), (2) time spent placing the initial lead, (3) anatomic limitations, and (4) x-ray appearance of the current lead. When reviewing the initial lead placement, the surgeon should identify cases in which low amplitudes are achieved in all 4 electrodes and the therapy is not effective. These cases may be less successful after revision, particularly if the patient has appropriate sensations when tested in the office. Upon review of x-rays, the surgeon may also identify areas of improvement and particular attention should be paid to supero-medial entry of the S3 foramen and appropriate lateral curvature of the distal end of the lead. These can provide clues on the appropriate entry point and angle of the seeker needle when placing the new lead. In addition, the battery should be checked to evaluate the need for concomitant replacement.

The operative technique for lead revision begins with removal of the current lead. After infiltration with local anesthetic, the IPG pocket is entered, and the IPG is disconnected from the lead. By gently tugging on the lead, the entry site can be located and an incision is made over this site. The lead is then brought through the entry site incision. Removal of the lead begins by dissecting the surrounding tissue and fat around the lead to the depth of the lead entry to the foramen. Gentle traction is applied in the angle of lead entry until the lead comes out in its entirety. Care should be taken to avoid stretching the lead as this could lead to breakage. A new lead is then placed following the steps listed above.

## Conclusion

Sacral neuromodulation is an effective treatment for patients with refractory OAB; however, its success depends greatly on specific factors related to surgical technique. Ideal technique provides precise, targeted stimulation of the S3 nerve root allowing longer battery life and more programming options. Surgeons performing SNM should aim for lead placement with motor thresholds less than 2 mA in all 4 electrodes in order to optimize patient response to the therapy, initially and over time.

## Compliance With Ethical Standards

**Conflict of Interest** The authors declare that they have no conflict of interest.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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