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Procedural techniques in sacral nerve modulation

Elizabeth R. Williams · Steven W. Siegel

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Abstract Sacral neuromodulation involves a staged process, including a screening trial and delayed formal implantation for those with substantial improvement. The advent of the tined lead has revolutionized the technology, allowing for a minimally invasive outpatient procedure to be performed under intravenous sedation. With the addition of fluoroscopy to the bilateral percutaneous nerve evaluation, there has been marked improvement in the placement of these temporary leads. Thus, the screening evaluation is now a better reflection of possible permanent improvement. Both methods of screening have advantages and disadvantages. Selection of a particular procedure should be tailored to individual patient characteristics. Subsequent implantation of the internal pulse generator (IPG) or explantation of an unsuccessful staged lead is straightforward outpatient procedure, providing minimal additional risk for the patient. Future refinement to the procedure may involve the introduction of a rechargeable battery, eliminating the need for IPG replacement at the end of the battery life.

Keywords Sacral neuromodulation · Percutaneous nerve evaluation · Staged trial · InterStim©

E. R. Williams (✉) · S. W. Siegel
Metropolitan Urologic Specialists, PA,
6025 Lake Road Suite 100,
Woodbury, MN 55125, USA
e-mail: ewilliams@urologyconsultants.org

S. W. Siegel
e-mail: ssiegel@metro-urology.com

Introduction

Urinary urgency, frequency, urge incontinence, and dysfunctional voiding are conditions that affect millions of individuals worldwide. As of 2001, around 17% of women and 16% of men over the age of 18 were found to have one or a combination of these symptoms [1]. Initial therapeutic interventions center around behavioral modification, pelvic floor biofeedback, and pharmacotherapy; however, these treatments are limited by patient compliance, insufficient efficacy, and pharmacologic side effects. Sacral neuromodulation (SNM) has emerged as an alternative for those who have failed these more conservative therapies. Tanagho and Schmidt initially described SNM for the treatment of voiding dysfunction in 1988 [2]. Since that time, SNM has gained Food and Drug Administration (FDA) approval for patients with urge urinary incontinence (1997) and those with urgency–frequency syndrome and idiopathic nonobstructive urinary retention (1999). To date, over 50,000 patients have undergone implantation with SNM for these indications [3].

Development of the sacral neuromodulation procedure

The procedure for sacral neuromodulation is divided into two parts. Each patient undergoes an initial screening test. If the patient demonstrates adequate improvement in urinary symptoms during this trial period (as documented by 50% improvement in his/her urinary symptoms based on pre- and post-procedure voiding diaries), the second stage with permanent implantation of a programmable pulse generator is then performed. In the initial description of SNM for voiding dysfunction, the screening test consisted of a bilateral percutaneous nerve evaluation (PNE). This

screening test was essentially a "blind" placement of a temporary electrode through the S3 foramen using anatomical/bony landmarks without the aid of fluoroscopy [4]. The clinician relied solely on patient feedback and motor response to determine appropriate positioning. The screening trial would last for several days. Patients who had a successful screening evaluation underwent placement of a permanent lead under general anesthesia, where the appropriate sacral foramen was identified without fluoroscopy, and the lead was attached through a deep presacral incision directly to the posterior sacral periosteum [4].

In 2002, the FDA approved of the tined lead, which eliminated the need for a deep incision and anchoring. This modification revolutionized the procedure, allowing for a minimally invasive approach under a combination of intravenous sedation and local anesthesia. It also ushered in the era of the tined lead-staged trial. This procedure was first described by Spinelli et al. [5] in 2003 and uses a combination of intraoperative fluoroscopy to improve the accuracy of lead placement and the tined lead device to minimize migration during the screening trial. Previously, screening PNEs did not employ fluoroscopic guidance and the rigid, non-coiled test lead was easily dislodged during the screening trial after a brief period, resulting in a higher rate of false negative screening tests. In the staged trial, the tined lead may be left in place for several weeks to allow for a longer screening period. Those with a successful tined lead-staged trial can then proceed with the second stage, implantation of the programmable pulse generator and expect to experience the same benefit derived from the trial.

Because of the expense and degree of invasiveness, most of the time, a staged trial is conducted using only a single lead. Some investigators have suggested that stimulating only one side limits the ability of the screening trial to fully assess for symptomatic improvement. A bilateral PNE allows for two sides to be tested in a more economical and less invasive fashion. In contrast to previous trials, anterior–posterior (AP) and lateral fluoroscopy is routinely employed during the PNE procedure to improve lead placement within the foramen. Both the stage I lead placement and the bilateral PNE under fluoroscopic guidance as described below are used in current practice as formal screening trials prior to generator implantation.

Description of sacral neuromodulation screening tests

Bilateral percutaneous nerve evaluation

In our practice, the bilateral PNE is performed in the office. The patient is placed in the prone position on the operative table to allow for both AP and lateral fluoroscopic views of the sacrum. All pressure points are adequately padded. The feet remain uncovered to allow for assessment of motor function during the trial. The lower back and buttocks are prepped with povidone–iodine solution. These areas are draped into the sterile field with careful attention paid to allowing adequate exposure of the gluteal folds and anal area for assessment of motor function (Fig. 1).

Generally, the third sacral nerve roots (S3) are the targets for stimulation. In certain circumstances, the clinician may choose to target the fourth sacral nerve roots (S4). Using AP fluoroscopy, the medial edges of the sacral foramina are identified and marked on the skin. The distance of the contralateral foramina is typically two fingerbreadths across the midline. These skin marks provide a guide for later needle placement (Fig. 2).

Using the lateral fluoroscopic view, the S3 foramen is readily localized. Due to the distinctive shadowing from the fusion of the sacroiliac joint at the level of the S2 foramen, it may be conveniently used in the identification of the S3 foramen. The S3 foramen is the first anterior protrusion from the surface of the sacrum below this shadow (Fig. 3) [3]. Once this target is determined, an entry point along the axis of the medial edge of the foramen, allowing a 60° angle from the skin to the tip of the S3 boney protrusion, is anesthetized with 0.25% bupivacaine (Marcaine; AstraZeneca, Wilmington, DE) with epinephrine. The patient may require additional anesthetic along the periosteum of the sacrum. The connective and adipose tissues deep to the skin are devoid of nerve endings and thus do not require anesthesia. Once the needle touches the periosteum, a lateral fluoroscopic image is obtained to determine its location relative to the S3 foramen. The needle is then "walked" in a cephalad or caudal direction along the medial line of the foramina until it is passed into the S3 foramen. Often, the needle requires positional adjustment; one should be cognizant to remove and reintroduce the needle rather than torquing or bending it (Fig. 4).

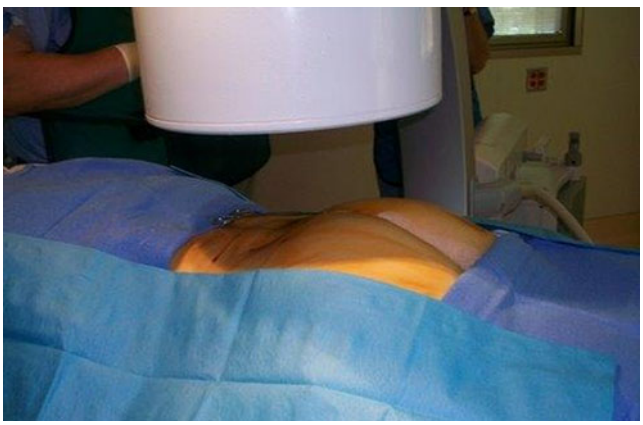

Fig. 1 Patient positioning for PNE and stage I lead placement. Patient is positioned prone on the operative table with all pressure points padded and feet exposed to assess motor responses

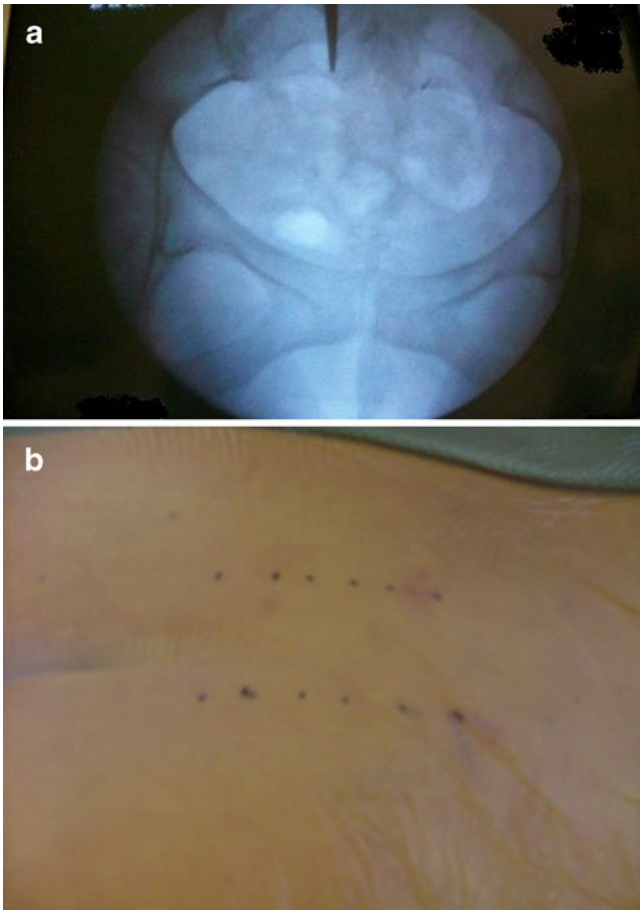

Fig. 2 Targeting the appropriate sacral foramina. A–P view of the sacrum to identify the medial border of the sacral foramina

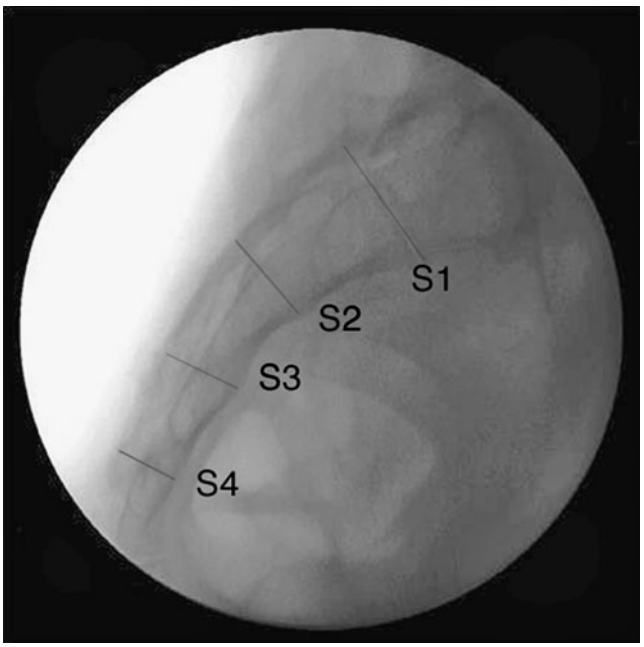

Fig. 3 Lateral view of the sacrum. S3 is identified using the shadowing at the level of the S2 foramen as a guide

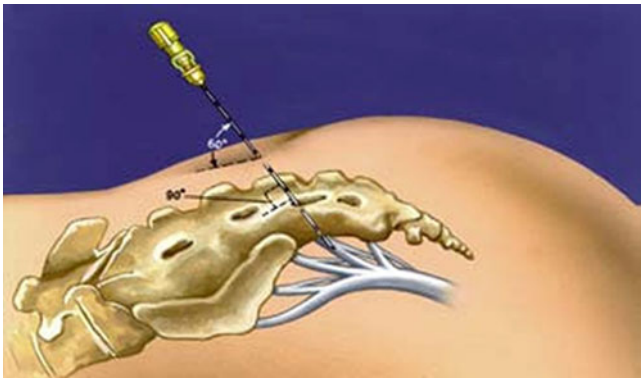

Fig. 4 Introduction of the foramen needle. The needle should be introduced at a 60-degree angle to the skin and marched along the sacrum until the S3 foramen is penetrated

The position and depth of the foramen needle is confirmed with a lateral fluoroscopic imaging. Ideally, the needle tip should be visible immediately inferior to the posterior surface of the bone table. The needle is stimulated with an external stimulator at a set frequency and pulse width as one incrementally increases the voltage. During this stimulation, the sacral root motor responses are assessed and the patient provides feedback to the clinician regarding the location of the stimulation. A combination of sensory and motor responses enables the clinician to confirm that the appropriate sacral nerve root is being stimulated and if the positioning along the nerve root is appropriate (Table 1).

The percutaneous lead is advanced through the foramen needle to a designated depth. It is best to overshoot the target by 1–2 cm since retrograde migration is likely over time. The lead position is retested and adjusted if need be and then documented with fluoroscopy. Once both leads have been placed with appropriate motor and sensory responses, the percutaneous leads are then tunneled to the contralateral entry site using an 18-gauge spinal needle. This minimizes the risk of lead migration during the screening trial period. An intricate dressing is then applied to the site (Fig. 5).

The patient is given an external stimulator and is asked to connect each of the leads to the stimulator for 3–4 days. During that time, a detailed voiding diary should be kept to assess for improvement in the targeted symptoms. By keeping separate diaries, the clinician is able to assess which side provided greater improvement. During the trial period, the patient is instructed to avoid showers and tubs, to wear loose clothing, and to limit physical activity. The diaries are reviewed and the temporary leads are removed after the 7-day trial. If sufficient improvement is documented, patients move on to a simultaneous stage I and II procedure on the side with maximal benefit based on their diaries.

Table 1 Sacral root motor and sensory responses [3]

Nerve root	Motor response	Sensory response
S2	Contraction/clamp of anal sphincter (A–P pinching of perineum/coccyx); leg/heel rotation, plantar flexion of foot, calf contraction	Contraction of base of penis or vagina
S3	Bellows (inward going of intergluteal folds), plantar flexion of great toe	Rectal sensation, extending into scrotum or labia
S4	Bellows	Rectal sensation only

Tined lead stage I trial

In our practice, the stage I trials are performed in the operating room under a combination of local anesthesia and intravenous sedation. We have found that this combination allows for patient comfort while allowing their input regarding sensory responses to stimulation. The patient is given a combination of propofol (Diprivan; AstraZeneca, Wilmington, DE), fentanyl (Sublimaze; Janssen, Titusville, NJ), and midazolam (Versed; Hoffmann-La Roche, Nutley, NJ). If general anesthesia is deemed necessary, only short-acting paralytics should be used to prevent interference with assessing motor responses. The patient is placed in the prone position on the operating room table. Rolls are placed beneath the chest and pelvis to flatten out the angle of the sacrum. A pillow is placed beneath the knees for padding, and all pressure points are adequately padded. The patient's feet are left exposed to assess for motor response. The patient is prepped and draped as described previously for the PNE procedure; however, the patient is given a prophylactic intravenous antibiotic targeting skin flora prior to starting the case (Fig. 1).

As described previously for the PNE, fluoroscopy is used to identify the medial borders of the sacral foramina and to locate the S3 foramen (Figs. 2, 3). The foramen needle is introduced in a similar fashion after using a local anesthetic along the skin and periosteum. Again, the needle is walked along the sacrum and advanced into the S3 foramen (Fig. 4). The external stimulator is used to assess for motor responses, and the intravenous sedation is minimized to allow the patient to provide sensory feedback. The clinician will often place bilateral S3 foramen needles and compare the motor and sensory responses to determine which side the tined lead will be placed.

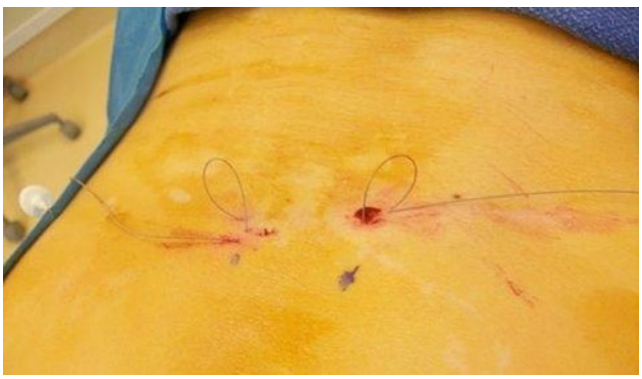

Fig. 5 Tunneling the percutaneous leads. This step helps to minimize lead migration during the screening trial over the next 7 days

After appropriate responses have been elicited, a 0.5-cm skin incision is made along the foramen needle. The directional guide is placed through the needle to the appropriate marker level. The needle is then exchanged for the lead introducer sheath. The sheath has a metal marker at its tip. It is advanced under fluoroscopic guidance until the marker is visualized at the midpoint of the bone table. Deployment of the lead at this level allows it to be released in and follow a fatty plane surrounding the neurovascular bundle [3].

The lead has a series of four tines, which allow it to secure itself over time to the subcutaneous tissues. This minimizes the risk of lead migration and obviates the need for anchoring. There are four electrodes along the length of the tined lead providing four contact points along the sacral nerve. These points are labeled 0 (distal) to 3 (proximal) and can selectively be stimulated to alter the pattern of stimulation (Fig. 6).

The tined lead is advanced through the lead introducer sheath. In our practice, we use the curved stylet from the accessory kit (Medtronic Dual Lead Extension Accessory Kit; Medtronic, Minneapolis, MN) rather than the prepackaged stylet. The curved one is more pliable and less likely to force the electrode out of the proper plane [3]. The lead should always be directed caudally and laterally during deployment under continuous fluoroscopy. The lead is advanced until lead sites 2 and 3 straddle the posterior bone table to ensure proper depth and prevent premature deployment of the tines. To assess for appropriate positioning, each of the sites along the lead is stimulated. The goal is to produce an appropriate response at a low threshold at all four sites, confirming that the lead is parallel with the trajectory of the nerve. If the responses are not appropriate or if the thresholds are high, the lead needs to be withdrawn and reintroduced under fluoroscopy. The lead should be retested until all four sites produce the desired responses at low thresholds. Pulling back the introducer sheath under

Fig. 6 Tined lead. The series of four tines allows for anchoring to subcutaneous tissues. The lead also contains four electrodes labeled 0 to 3 to provide variation in the stimulation pattern

fluoroscopic guidance then deploys the lead. A final A–P film should reveal the lead to be coursing laterally in parallel with the path of the sacral nerve (Fig. 7).

A location for the lead extension connection site/future internal pulse generator (IPG) must be selected. It should be placed in a sufficient depth of adipose tissue below the posterior–superior iliac crest and lateral to the edge of the sacrum in order to avoid interference from adjacent bony structures (Fig. 8).

The area is anesthetized with local anesthesia and a 1–2-cm incision is made along the lateral aspect of this site to provide adequate space for the connection hub. The incision must be of sufficient depth to avoid placing the lead too superficially (minimizing the risk of lead damage or erosion). The lead extension wire must be tunneled from the connection site to the contralateral side to minimize the risk of infecting the future IPG site. Using the tunneling device to measure an appropriate distance, the skin over the lead extension exit site is anesthetized. The tunneler is then advanced through the adipose tissue from the connection incision to the exit site. If the tunneler is kept in the proper plane, only the entry and exit sites will require anesthesia due to the lack of nerve endings in the adipose layer. The lead extension wire is advanced through the tunneler to its exit site.

The tined lead must then be tunneled to the connection site. In order to minimize redundant lead length, the tunneler is curved. The lead then gently courses down into the gluteal area and back up to the level of the connection

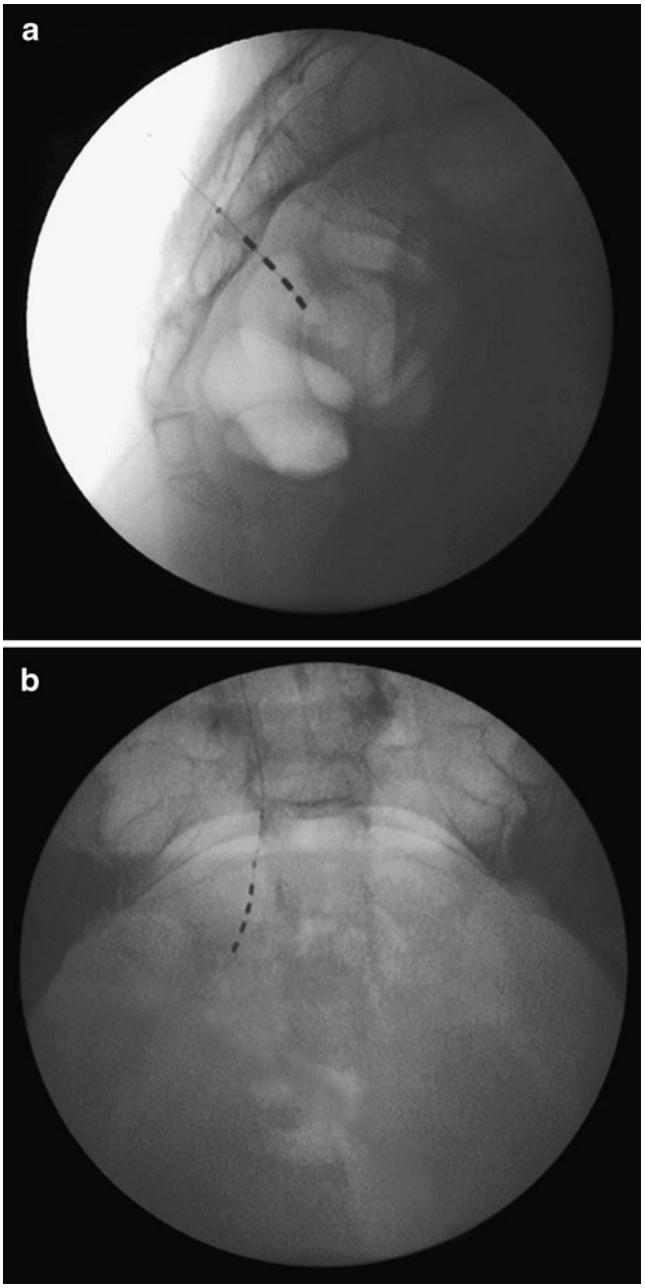

Fig. 7 Lead deployment. **a** Proper positioning is seen when site 2 and 3 straddle the posterior bone table. **b** The final A–P film should reveal that the lead is directed laterally parallel with the path of the nerve

site. The hub between the tined lead and lead extension wire is connected and placed in the pocket of the future IPG site. This location allows the clinician to quickly locate the connection during the second stage of the procedure, minimizing the time to remove the extension wire and create the IPG pocket. The connection site is irrigated with antibiotic solution and closed with a running subcuticular stitch. The irrigation fluid must contain water, not saline, to eliminate the risk of interference of charged ions with the electrical connections.

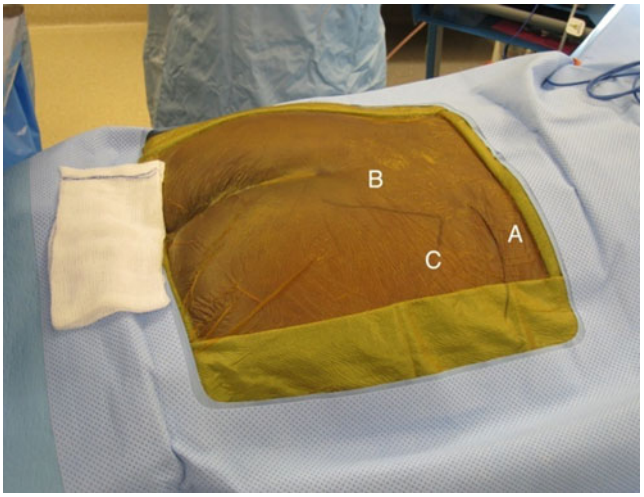

Fig. 8 Creation of connection site. Using the posterior–superior iliac crest (**a**) and lateral margin of the sacrum (**b**) as landmarks, the site of the connection hub and future IPG is identified (**c**)

After the procedure is complete, the lead extension wire is secured to the skin with tape. The extension wire is connected to the test stimulator and the stimulator is programmed (Fig. 9). Patients typically keep a voiding diary for the next 2 to 3 weeks during the screening trial to assess for degree of improvement in the targeted symptoms. During this time, the stimulator can be reprogrammed to optimize the clinical responses. If the patient documents a 50% improvement in the targeted symptoms during this trial, he/she then proceeds to the second stage in which the IPG is placed. If there is insufficient improvement, the connection hub is disconnected and both the lead extension wire and tined lead are explanted using monitored anesthesia care and local anesthesia.

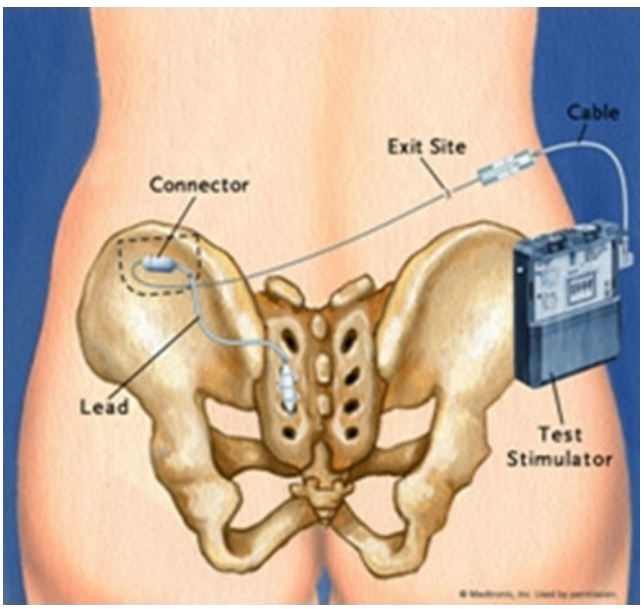

Fig. 9 Completed stage I diagram. The lead extension wire is connected to the test stimulator and secured to the skin to allow for the 2–3-week screening trial

Comparison of the sacral neuromodulation screening tests

Both the bilateral (PNE) and the tined lead stage I trial have advantages and disadvantages. Selection of one procedure over the other should be tailored to the individual patient characteristics (Table 2).

Explantation of stage I lead

For patients with insufficient improvement in targeted symptoms during the screening trial, the tined lead and lead extension wire can be removed under monitored anesthesia care and local anesthesia. The skin over the site of the connection hub is infiltrated with 0.25% bupivacaine (Marcaine; AstraZeneca, Wilmington, DE) with epinephrine. The 1–2-cm incision is opened and the connection hub is identified and externalized. The lead extension wire is cut and will be removed at the conclusion of the procedure. The tined lead is then pulled out with a sharp tug. Typically, the lead is explanted intact with no resistance. If the lead was properly deployed initially with the tines outside of the foramen, there is no risk of nerve injury during this procedure.

Stage II procedure: implantable pulse generator placement

Patients with significant improvement in their voiding symptoms after the tined lead placement are candidates for this procedure. The patient is brought to the operating room, placed in a prone position (similar to the stage I procedure), and receive the same intravenous cocktail. The site over the connection hub is prepped and draped. The skin is anesthetized and the incision is extended medially creating an incision sufficient for IPG placement. Meticulous hemostasis is performed during the dissection of the IPG pocket to minimize the risk of hematoma. The connection hub is identified and the lead extension wire is cut and will be removed externally at the end of the case. A subcutaneous pocket 4–5-cm deep is created for the IPG using electrocautery with just enough room for the IPG and lead assembly. The pocket is copiously irrigated with antibiotic solution. The tined lead is connected to the IPG and placed within the pocket.

The original InterStim device is larger (22 cm displacement) and has a 5–9-year potential battery life. It is

Table 2 Unique pros and cons of each of these screening tests

Bilateral percutaneous nerve evaluation	Tined lead stage I trial
Advantages	
In-office procedure under local anesthesia	Less risk of lead migration during the trial
Greater patient acceptance due to minimal invasiveness/office setting	Greater comfort due to level of sedation for patients who are anxious and/or pain-focused
Allows routine assessment of both sides to screen for maximum efficacy	Quadripolar lead configuration allows for more precise placement and programmability
Removal of leads can be performed in the office without need for physician expertise	Symptom improvement remains unchanged when converted to chronic implant (WYSIWYG)
More accurate patient feedback during the placement of lead (no interference from IV sedation)	Longer trial period to assess for symptom improvement
Less costly, more favorable reimbursement	Higher rate of true positives
Less risk of infection since permanent lead and IPG can be placed in one setting after successful PNE	
Disadvantages	
Higher rate of false negatives. Must do staged implant if equivocal	Requires two surgeries even if trial is unsuccessful
Potential to place permanent lead in less favorable location, thus requiring re-operation	Does not ensure ideal placement or eliminate false negatives, thus requiring re-operation
	Greater potential for infection due to increased length of trial and potential contamination of permanent lead
	More expensive if trial is unsuccessful

preferred in patients who require high voltage for stimulation in order to maximize the time to IPG replacement. The second generation IPG, the InterStim II device, is smaller (14 cm). It is ideal in thin patients or those with heightened pain awareness, though it has a battery life of only 3–5 years. The advantage of less frequent battery replacement with the larger device needs to be weighed against the increased risk of wound complication and need for revision due to its greater displacement.

All wires should be buried under the IPG for comfort and to prevent damage if/when the IPG is later replaced. The wound is irrigated again and closed with a series of absorbable sutures. The skin is re-approximated with a running subcuticular stitch. The lead extension wire is removed. The IPG is programmed in the recovery room, and the patient is discharged home the same day (see Fig. 10).

Conclusions

The procedural techniques used in sacral neuromodulation continue to evolve. The development of the tined lead and the staged procedure allows for the assessment of patient improvement with minimal risk to the patient. Incorporation of fluoroscopy into the trial procedures has dramatically improved the accuracy of the screening trials. There are advantages and disadvantages to both screening trial procedures. The selection of one of these methods over the other should be tailored to the particular needs and presenting symptoms of the patient. There is minimal additional risk associated with the second stage of the procedure whether this be a removal of the temporary leads, explantation of the tined lead, or implantation of the pulse generator. In terms of future modifications to the sacral neuromodulation procedure, the next development will likely be an FDA approval of a rechargeable battery. This

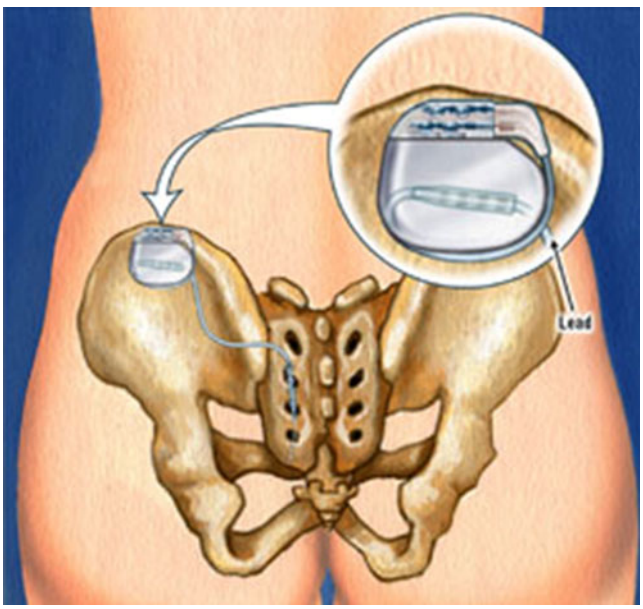

Fig. 10 Placement of the IPG. The previous connection site is extended and a pocket is created in the subcutaneous tissue of adequate size to accommodate the IPG and lead assembly

advancement would reduce the need for an additional procedure under anesthesia in order to replace the IPG. Additional innovations are focused on targeting different points along the neural pathway of bladder control. Many published reports have described percutaneous and open approaches of direct pudendal nerve stimulation. Ongoing research is directed at improving such techniques while also developing other sites for stimulation.

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Conflicts of interest E.R. Williams is a consultant of AMS. S.W.E. Siegel is an investigator and consultant/advisor for Uroplasty; a consultant/advisor for QIG; an investigator at Boston Scientific; a board member, officer, and trustee at the North Central Section AUA; an investigator and consultant/advisor for Allergan; a consultant/advisor for Bard Urological; is involved in a scientific trial at Uromedica; a board member, officer, and trustee at SUFU; an investigator and consultant/advisor and part of the scientific trial at AMS; an investigator and consultant/advisor and is part of the scientific trial at Medtronic; and a consultant/advisor for GT Medical.

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