DOI: 10.4274/tjcd.galenos.2020.2020-2-3
Turk J Colorectal Dis 2020;30:94-98

REVIEW

Sacral Neuromodulation: Technical Considerations

Sakral Nöromodülasyon: Teknik Değerlendirmeler

Timuçin Erol[1], Klaus E. Matzel[2]

[1]Hacettepe University Faculty of Medicine, Department of General Surgery, Ankara, Turkey
[2]Fredrich Alexander University, Department of General and Visceral Surgery, Section of Coloproctology, Erlangen, Germany

ABSTRACT

Sacral neuromodulation is a highly effective therapy. When used in urology for urinary incontinence, refractory urgency and frequency, and non-obstructive retention, it is employed after the failure of conservative measures and considered a surgical option. When used for faecal incontinence, however, it can be considered a first-line surgical treatment. Due to advantages like minimally invasive nature, low morbity rate and availability of a highly accurate test phase, indications of this procedure expanded. Proper patient selection and optimal lead placement are the key determinants of success.Here we present all the steps and technical details for a successful implantation.

Keywords: Fecal incontinence, sacral neuromodulation, tecnique

ÖZ

Sakral nöromodülasyon konservatif tedavilerin başarısızlığı sonrasında fekal inkontinas için kullanılabilecek oldukça etkin bir tedavidir. Bu iki basamaklı işlem fekal inkontinansın tedavisinde birinci basamak cerrahi tedavi olarak kabul edilmektedir. Minimal invazif doğası, düşük morbidite oranı ve oldukça doğru sonuç veren bir test safhası olması nedeniyle bu yöntemin endikasyonları genişlemektedir. Uygun hasta seçimi ve uygun lead yerleşimi başarının ana belirleyicileridir. Bu çalışmada başarılı bir implantasyon için tüm basamaklar ve teknik detaylar sunulmuştur.

Anahtar Kelimeler: Fekal inkontinans, sakral nöromodülasyon, teknik

Introduction

Sacral neuromodulation (SNM), also termed sacral nerve stimulation, is a highly effective therapy.[1] When used in urology for urinary incontinence, refractory urgency and frequency, and non-obstructive retention, it is employed after the failure of conservative measures and considered a surgical option. When used for faecal incontinence, however, it can be regarded as a first-line surgical treatment.

This minimally invasive procedure consists of two phases. For the initial test phase, which generally takes 2-4 weeks, two techniques are available. A temporary electrode is placed in proximity to the target nerve, S3 or S4, and is connected to an external pulse generator to deliver a continuous electrical impulse. The temporary electrode is then removed. Alternatively, a tined lead electrode can be used. If the test stimulation proves clinically efficient, it can remain in place for chronic stimulation. Symptom improvement of ≥50% is accepted as a positive response, which generally predicts the therapeutic effect of chronic neuromodulation.

The second phase, during which an implantable pulse generator [(IPG); Interstim II ®] is placed in a subcutaneous pocket at the buttocks for permanent stimulation, can then be initiated.

Given the procedure's low morbidity rate, a positive test phase of proven accuracy, immediate response, and long-term durability, the possible indications have been expanded (e.g. low anterior resection syndrome is a new area of interest).

SNM had been contraindicated for patients who require regular abdominal or thoracic magnetic resonance imaging (MRIs) (except the 1.5-Tesla head coil); however, with a new generation of electrodes and IPGs entering the market, this contraindication will no longer be relevant. Sacral malformations, septic skin conditions, and bleeding diathesis must remain considerations.

Address for Correspondence/Yazışma Adresi: Timuçin Erol MD,
Hacettepe University Faculty of Medicine, Department of General Surgery, Ankara, Turkey
Phone: +90 532 336 76 45 **E-mail:** timucinerol@hacettepe.edu.tr **ORCID ID:** orcid.org/0000-0002-3475-3639
Received/Geliş Tarihi: 26.02.2020 **Accepted/Kabul Tarihi:** 03.03.2020

Proper patient selection and optimal electrode lead placement are the key determinants of success. Currently, minimally invasive percutaneous lead placement under fluoroscopy is the standard approach.

The optimal placement aims to position the electrode with its four equally spaced contact points close to the target nerve (generally S3 or S4) along its anatomical course. The placement of multiple electrode contact points next to the nerve offers more programming options. It reduces the intensity of stimulation, thus prolonging the battery life and lessening the risk of side effects.[2]

The procedure can be performed under either local anaesthesia with sedation or general anaesthesia. Sensory responses can be evaluated with the former, but the sacral foramen must not be infiltrated with the local anaesthetic, or all responses will be concealed. Under general anaesthesia, only motor responses can be evaluated.

Preoperative Preparation

A plain X-ray before the procedure can be useful to reveal suspected anatomic abnormalities (e.g. sacral foramen allowing no access to the target nerve[3]), as an MRI.[4,5,6] In this circumstance, lead placement can be technically challenging, and the patient should be advised of possible failure.

An enema should be administered preoperatively to empty the bowel of gas, which may cause artefacts during intraoperative imaging and reduce the visibility of the relevant anatomic structures.

A urinary catheter is placed before the operation and removed shortly thereafter.

Strict asepsis/antisepsis guidelines must be followed during all phases. Prophylactic i.v. antibiotics covering skin and enteric flora during induction of anaesthesia are recommended, as infection rates as high as 10.8% have been reported.[4,7]

Patient Positioning

Correct positioning is crucial for proper electrode placement. The prone position, with the anus, feet, and toes exposed, is necessary to observe the motor responses of the anus, pelvic floor, and feet. The patient's buttocks must also be slightly separated to see the "bellows" response. Horizontal positioning of the sacrum by the reduction of lumbar lordosis, as much as possible, provides better access to the foramina. A grounding pad must be fixed at an easily accessible location.

Operative Field Preparation

The skin is sterilised with common skin antiseptics from the posterior superior iliac crests to the thighs, extending laterally to the edges of the greater sciatic notch.

Electrode Entry Marking

After proper positioning of the patient, an A-P X-ray is obtained (Figure 1). The medial edges of the sacral foramina on both sides are marked vertically, and the line between the distal edges of the sacroiliac joints is marked horizontally on the skin, forming an "H" sign (Figure 1). The upper medial part of the third sacral foramen is located at the level of the intersection points of the "H". A C-arm rotation is needed, as the procedure will continue under the lateral imaging of the sacrum (Figure 2).

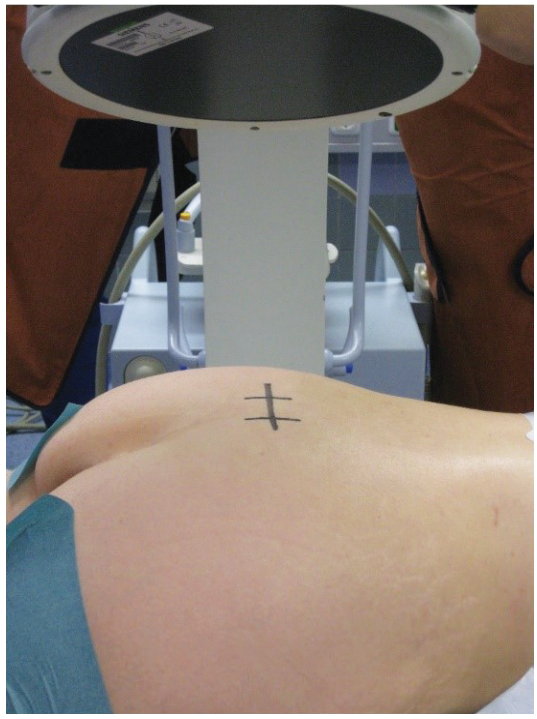

Figure 1. Patient positioning and AP fluoroscopy arrangement
AP: Anteroposterior

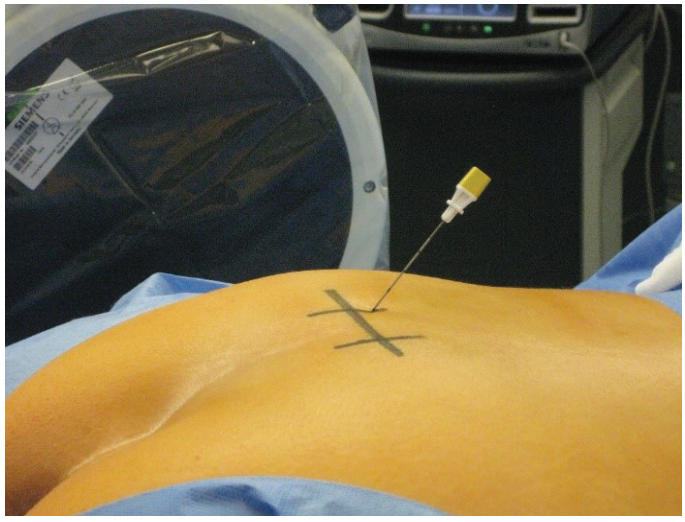

Figure 2. Patient positioning and lateral fluoroscopy arrangement: Foramen electrode positioned

Foramen Needle Placement

Needle electrode entry points are usually 1-2 cm cephalad from the intersection points of the "H" for easy access. Obtaining a lateral X-ray aids correct entry. A standard foramen needle should be advanced to the hillock of the sacrum and inclined through the S2-3 fusion plane under fluoroscopy. The two standard foramen needles are 9 and 12.5 cm (Medtronic 041828 and 041829, respectively); the latter can be used for obese patients. The uppermost medial part of the S3 foramen is the aim for entry.

Once a foraminal entry is accomplished, a test stimulation with the external pulse generator is performed (Figure 3). The bellows response (an inward movement of the perineum) and ipsilateral toe/foot response (plantar flexion of the greater toe) confirm correct positioning. Stimulation intensities below 2 mA resulting in a motor or sensory response are desirable. Minor adjustments can be made to decrease the stimulation amplitude if needed.

Once an appropriate position is achieved, the needle stylet must be removed, taking care to avoid the unintentional protrusion of the needle beyond the ventral edge of the sacrum.

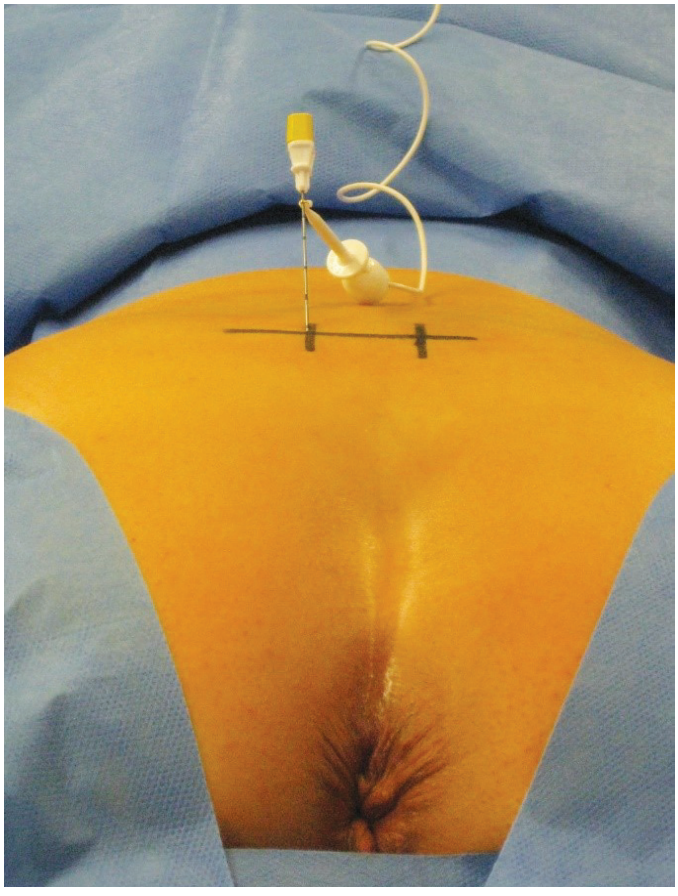

Figure 3. Foramen electrode positioned and connected to an external pulse generator

Lead Placement

Two lead placement options exist for the test phase. A temporary lead can be used. Although this is the simpler option technically, after a positive test phase, it will necessitate a second operation for the placement of a standard tined lead. This second operation can encompass both the placement of the tined lead and implantation of the permanent IPG to avoid an additional procedure. However, one must be cautious with this approach, as the temporary electrode can be easily dislodged, leading to a false-negative result.

As a second option, a tined lead can be placed initially. This is more stable and affords the opportunity to avoid a second procedure.

Temporary Lead Electrode Placement

The temporary lead is a coiled, insulated, and multistranded wire with a preloaded stylet and a single electrode contact on the distal end. After proper placement of the foramen needle and removal of the needle stylet, the lead is advanced through the needle hub. Two markers on the lead indicate the length of foramen needles, which must be considered during advancement. The test stimulation can then be initiated after connecting the lead to the external neurostimulator. After observation of a positive response, the foramen needle and stylet of the temporary electrode must be removed with care to avoid electrode displacement. Repeating the test stimulation will confirm the correct positioning. The lead is coiled and secured with a sterile adhesive drape around the exit site and connected to the external stimulator for the test phase.

Tined Lead Electrode Placement

The introducer kit (Medtronic 042294) includes a lead introducer, directional guide (Figure 4), and dilator. After placement of the directional guide through the foramen needle, a 1.0-cm skin incision is made at the entry point to facilitate the insertion of the introducer (Figure 5). Careful advancement with both hands under fluoroscopy can avoid the creation of a false or extended track. Note that the radiopaque marker of the sheath covering the introducer is 7 mm from its tip.

Three tined lead electrodes of different lengths (28, 33, and 41 cm) are available (Medtronic 3889-28, 3889-33, 3889-41). These have four contact points (numbered 0, 1, 2, and 3 from distal to proximal) and a curved tip (Figure 6). The tines to anchor the electrode in the surrounding tissue begin 10 mm proximally from the most proximal electrode (electrode 3). After confirming proper positioning under fluoroscopy, the inner part of the introducer is removed, whereas its sheath remains in place (a radiopaque marker confirms its position). The tined lead electrode is then

advanced through the sheath. During insertion, the curved tip should be directed to follow a medial to lateral course, reflecting the natural path of the sacral spinal nerve after exiting the ventral opening of the foramen. When the first white marker on the lead reaches the upper edge of the introducer sheath, the electrode is fully covered by the introducer. A further advancement to the second marker allows electrode positioning. During this stage, all the tines are still covered by the introducer sheath. Note that if electrodes are properly introduced into the foramen, they will follow the least resistant tissue, which generally is the course of the nerve. All electrodes must be placed close to the nerve; advancement under fluoroscopy will ensure correct positioning.

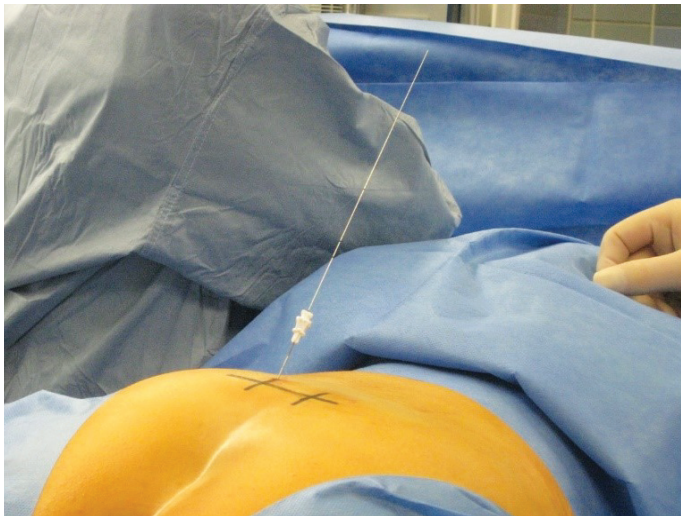

Figure 4. Foramen electrode positioned and introducer guide in place

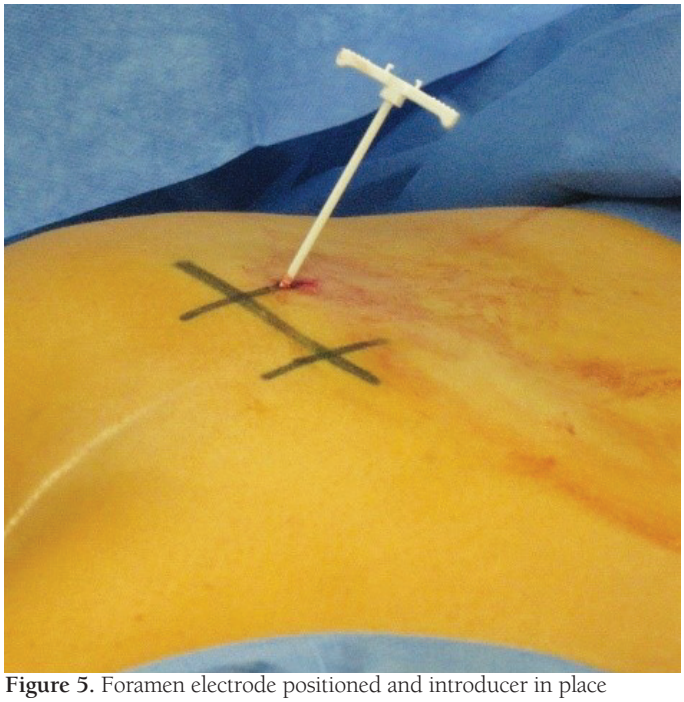

Figure 5. Foramen electrode positioned and introducer in place

Stimulation is then performed. A response to <2 mA at each contact will be confirmatory. During this phase, minor adjustments are still possible (e.g. rotation of the electrodes or re-insertion through the introducer with a different direction of the electrode tip). The introducer sheath and electrode must be held together during repositioning to avoid tine release. Fewer than four electrodes responding to low amplitude can be acceptable, at the surgeon's discretion. Once optimal positioning has been confirmed by stimulation, removal of the introducer sheath will release the tines and fix the electrodes (Figure 7). Meticulous removal under fluoroscopy avoids electrode dislodgement during this phase. Intermittent stimulation of all contacts during and after the removal process confirms proper positioning. Anteroposterior and lateral imaging to confirm and document the final electrode placement is advised.

If the tined lead electrode is used for the test phase, a subcutaneous pocket is created at the intended placement

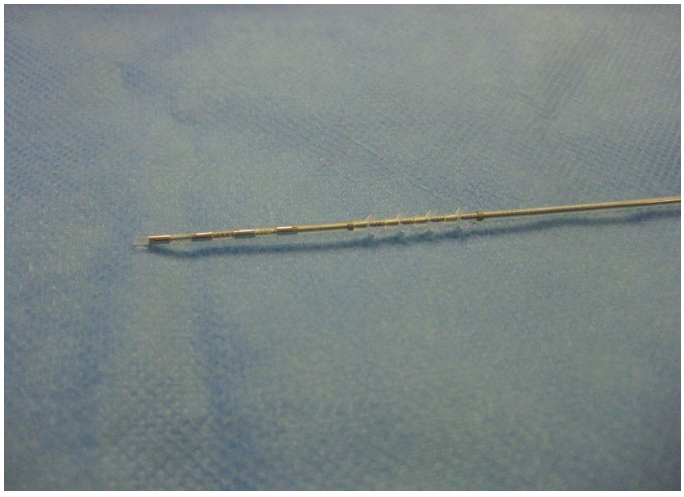

Figure 6. Tined lead electrode with a curved tip

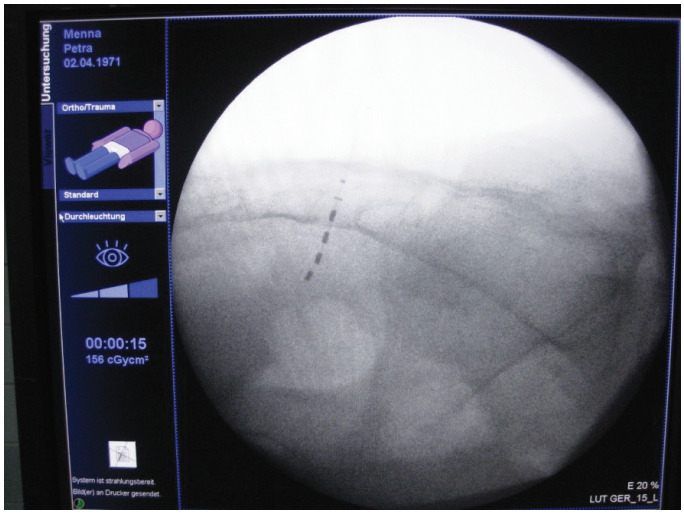

Figure 7. Tined lead electrode positioned

area of the IPG device. This must be easily accessible to the patient and away from bony structures to permit daily activity without discomfort. This small pocket above Scarpa's fascia is created for connector placement, and the tined lead is then tunnelled to the pocket. A second tunnel from this pocket to the skin, preferably across the midline, must be created for the percutaneous extension lead. The connection between lead and percutaneous extension is secured by a screw connector. A silicone boot is inserted over the connection, and two non-absorbable sutures are placed at the edges to secure it. The connector is placed in the pocket (future location of the IPG device). The subcutaneous tissue and skin are closed.

Pulse Generator Implantation

After a positive test period, the IPG (Medtronic Interstim II 3058, 22 g, 44x51 mm) can be placed into the pocket previously created to hold the connection to the percutaneous extension lead. The pocket must be tight enough to keep the IPG device stable and deep enough to avoid skin erosion/exposure. After removal of the percutaneous extension lead, the tined lead electrode is inserted into the IPG until its blue tip is visible. Then, it is fixed. Proper placement of the electrode - avoiding twisting of the IPG - is crucial. The subcutaneous tissue is closed with absorbable sutures and the skin with non-absorbable sutures. Close follow-up is needed in the early postoperative period to check for possible infection, which would require antibiotic treatment and, in most cases, device removal.

Programming

To program the IPG device, the clinician - not the patient - uses the N'Vision™ programmer. Mono- or bipolar stimulation can be set. Multiple contact points close to the nerve allow for multiple programming options. The aim is to achieve an efficient clinical response at a low amplitude, preferably below 2 mA. Trying different electrode contact points helps to find the most efficient option. Stimulation can be continuous or intermittent; the latter entails lower energy consumption and provides increased battery life. The most used (default) settings are 14-15 Hz, 210 µsec.[8,9]

For patients' access to the IPG device, the InterStim iCon™ patient programmer is used. This allows them to activate and deactivate the IPG and change programs and amplitude within pre-set limits.

Patients must be followed regularly to assess the clinical efficacy and side effects (e.g. pain, device displacement, and late infection) and to monitor battery status.

Peer-review: Internally and externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: K.E.M., Concept: T.E., K.E.M., Design: T.E., K.E.M., Data Collection or Processing: T.E., K.E.M., Analysis or Interpretation: T.E., K.E.M., Literature Search: T.E., K.E.M., Writing: T.E., K.E.M.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: It is the consultant of Prof. Matzel Medtronic.

References

1. Goldman HB, Lloyd JC, Noblett KL, Carey MP, Castaño Botero JC, Gajewski JB, et al. International Continence Society best practice statement for use of sacral neuromodulation. Neurourology and Urodynamics 2018;37:1823-1848.
2. Jacobs SA, Lane FL, Osann KE, Noblett KL. Randomized prospective crossover study of interstim lead wire placement with curved versus straight stylet. Neurourol Urodyn 2014;33:488-492.
3. Matzel KE, Chartier-Kastler E, Knowles CH, Lehur PA, Munoz-Duyos A, Ratto C, et al. Sacral neuromodulation: Standardized electrode placement technique. Neuromodulation: Journal of the International Neuromodulation Society 2017;20:816-824.
4. Maeda Y, O'Connell PR, Lehur P-A, Matzel KE, Laurberg S, Group ESBS. Sacral nerve stimulation for faecal incontinence and constipation: A European consensus statement. Colorectal Disease 2015;17:O74-O87.
5. Brunner M, Cui Z, Matzel KE. Sacral nerve stimulation for faecal incontinence in patients with sacral malformation. International Journal of Colorectal Disease 2017;32:929-931.
6. Povo A, Arantes M, Matzel KE, Barbosa J, Ferreira MA. Sacral malformations: Use of imaging to optimise sacral nerve stimulation. International Journal of Colorectal Disease 2016;31:351-357.
7. Wexner SD, Hull T, Edden Y, Coller JA, Devroede G, McCallum R, et al. Infection rates in a large investigational trial of sacral nerve stimulation for fecal incontinence. Journal of Gastrointestinal Surgery 2010;14:1081-1089.
8. Matzel KE, Schmidt RA, Tanagho EA. Neuroanatomy of the striated muscular anal continence mechanism: Implications for the use of neurostimulation. Dis Colon Rectum 1990;33:666-673.
9. Gurland B, Aytac E. Anatomy and physiology: Neurologic basis for the function of sacral nerve stimulation. Seminars in Colon and Rectal Surgery 2017;28:156-159.