



Sacral Neuromodulation for Dysfunctional Voiders

Workshop 1

Monday, August 23, 09:00-10:30

Time	Time	Topic	Speaker
09:00	09:05	Introduction to the aims of the workshop and the participants	Magdy Hassouna
09:05	09:20	Identification of patient selection for SNM	Sherif Mourad
09:20	09:45	Hands on Mannequins for best practice for PNE	All
09:45	10:00	Operative techniques for SNM	Hassan Shaker
10:00	10:15	Programming	Magdy Hassouna & Yahia Ghazwany
10:15	10:30	Case presentation and discussions	All

Aims of course/workshop

1. Identification of patients who benefit from sacral Neuromodulation SNM
2. Technical aspects of proper screening for patients using Percutaneous Nerve Evaluation. Hand-on presentation on pelvic mannequins for the most adequate way of selecting the proper sacral foramen. The application of temporary electrodes and wire connection.
3. Programming of the implantable generator. Trouble shooting algorithm for “non-responders’ among implanted patients.
4. Operative techniques with special reference to best practice techniques.
5. Case presentation: Members of the audience are welcome to present cases . Members of the panel will be sharing their experience with special cases such as pregnancy with SNM, role of MRI in patients with SNM

Educational Objectives

To present the techniques of SNM to any beginner interested in the Interstim therapy.

Identification of patients who benefit from Sacral Neuromodulation SNM

Sherif Mourad, MD

Which patients are appropriate candidates for sacral neuromodulation? In a very simple answer we can consider those patients who have voiding dysfunction that could not be resolved by other therapeutic measures.

The two main arms of patient selection are:

- 1- Definition of patient problem in terms of the symptoms of voiding problem and pelvic floor muscle dysfunction.
- 2- The outcome of the trial phase of neuromodulation termed " percutaneous nerve evaluation " (PNE) which is a rather simple diagnostic procedure.

PNE is a therapy trial and is considered the ultimate predictive test for patient selection.¹

Indications for Sacral Nerve Stimulation Therapy:

The US Food and Drug Administration (FDA) approved SNS for intractable urge incontinence in 1997, and for urgency – frequency and nonobstructive urinary retention in 1999. Later, the labeling was changed to include "overactive bladder" as an appropriate diagnostic category.^{2,3}

References:

[1] Siegel SW. Selecting patients for sacral nerve stimulation. Urol Clin N Am 2005;32: 19-26.

[2] Siegel SW, Catanzaro F, Dijkema H, et al. Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention. Urology 2000;4 (Suppl 1): 87-91.

[3] Abrams P, Blaivas J, Fowler C, et al. The role of neuromodulation in the management of urinary urge incontinence. BJU Int 2003; 91(4): 355-9.

Current Operative Technique For Implantation Of Sacral Root Neuromodulator

Hassan Shaker, M.D., MSc., Ph.D.

Ain Shams University

What do you need for permeant implantation

- External stimulation device
- Electrode insertion kit
- Quadripolar electrode with self-retaining mechanism
- Tunneling device
- Internal pulse generator.
- Basic surgical instruments.
- C-Arm fluoroscopy.

Equipments 1:

External testing devices

- External pulse generator
- External connection wires
- Stimulation Testing Cable

Equipments2: Insertion Kit

- PNE needles
- Guide rod
- Dilatation canula and trocar.

Equipments 3:

Permeant Electrode

- Quadripolar electrode with self-retaining tines
 - Model 3889: equal size and distance between the electrodes.
 - Model 3093: 3 electrodes same size and one larger electrode with equal distance between them.

Equipments 4:

Internal Pulse Generator (IPG)

Types

Interstim : Model 3023

- Size: 55X60X10 mm
- Volume: 22 cm³
- Power Source: 2.7 Amp hrs, 3.7 V Lithium-thionyl chloride cell
- Power upper limit: 10.5 V
- Extension lead: needed

Interstim II: Model 3058

- Size: 44X51X7.7 mm
- Volume: 14 cm³
- Power source: 1.3 Amp hrs, 3.2 V, Lithium silver vanadium oxide hybrid cell
- Power upper limit: 8.5 V
- Extension lead: not needed

Steps of implantation

1. Foramen Localization
2. Tract dilatation
3. Insertion of quadripolar electrode
4. Tunneling of the electrode.
5. Connection of the electrode to the IPG
6. Insertion of the IPG in a subcutaneous pocket.

Implantation steps:

1) Foramen localization

- Anesthesia:
 - General with no muscle relaxant
- Patient position:
 - Prone
 - Knees slightly flexed
 - Feet extending below OR table free in air,
- Surgical anatomy of S3 foramen
 - Opposite upper border of greater sciatic notch.
 - 1 finger breadth from the midline.
- Needle direction:
 - Should be no lateral inclination.
 - 30° angulation on the Vertical axes.
- S3 stimulation:
 - Bellow response (inwards movement of the anus and deepening of the gluteal cleft)

Implantation steps:

2) Electrode insertion

- Insert the guide rod in the needle till the mark
- Remove the needle
- Make $\frac{1}{2}$ incision starting from the rod.
- Insert the dilatation cannula over the rod till the mark.
- Remove the rod and the trocar leaving the cannula.
- Insert the quadripolar electrode through the cannula down to the mark.

Implantation steps:

2) Electrode insertion 2

- Remove the cannula leaving the electrode.
- Stimulate the electrode to verify the response.

Implantation steps:

3) Subcutaneous pocket creation

- Site: over the gluteal area as lateral as possible on the dominant hand side of the patient.
- Depth: 2-4 cm
- Should be almost the size of the IPG.

Implantation steps:

4) Final steps

- Tunnel the electrode to the pocket.
- Connect the electrode to the IPG
- Insert the IPG in the pocket.
- Close the wounds.

Basics of Sacral Nerve Neurostimulator (InterStim®) Programming and Troubleshooting.

Sacral Nerve Neurostimulator System:

Implantable Pulse Generator (IPG) InterStim®, Model 3023 or InterStem II Model 3058 Tined leads: Model 3889 and 3093

Extension connector: Model 3095 connects the tined lead to InterStim Model 3023

Clinician Programmers: N'Vision Clinician Programmer Model 8840

Patient Programmers InterStim iCon Patient Programmer Model 3037

External Antenna for iCon Patient Programmer

Aims of programming:

Adequate programming of electrical setting of the sacral neurostimulator is the basic requirement to optimize the therapy. Efficacy directly depends on the contact between the lead and the nerve fiber. Minor changes in lead position or minimal fibrosis around the lead, can reduce the efficacy or create undesirable degree of stimulation.

The only way to adapt to changes overtime is by modifying the previous stimulation sittings.

A secondary goal of programming is to prolong the life of battery.

Programming parameters:

Understanding program parameters and how they affect the stimulation is essential before you start programming a neurostimulator.

Amplitude:

Amplitude is the intensity or strength of the stimulation measured in volts (V). By increasing amplitude, the intensity of the stimulation increases and vice versa. The goal is to use the lowest effective amplitude that will provide optimal patient symptom relief, minimize patient discomfort, and maintain neurostimulator battery life to the best possible extent.

A typical setting for amplitude is based on patient comfort which is determined during a programming session by ramping up amplitude gradually and by selecting a normal or finer amplitude resolution (Increment settings). Available resolution settings are:

- Normal setting (in 0.1 increments)
 - For Model 3023 Neurostimulators: 0-10.5 V
 - For Model 3058 Neurostimulators: 0-8.5 V
- Fine setting (in 0.05 increments)
 - For both models: 0-6.35V

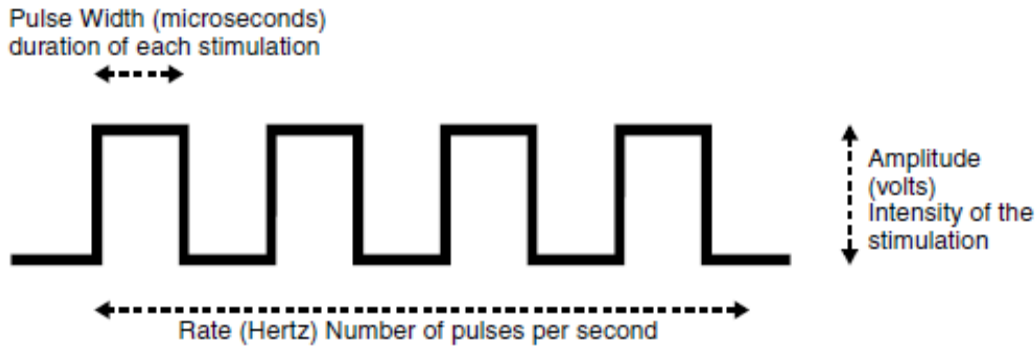
Pulse Width:

Pulse width is the time or duration of the stimulation pulse measured in microseconds (μsec). Increasing pulse width increases pulse duration and decreasing pulse width decreases pulse duration. For example, when a patient feels the stimulation too intensely in one body location, increasing the pulse width spreads the stimulation and makes it less intense in that location.

Typical setting for pulse width is 180-240 μsec .

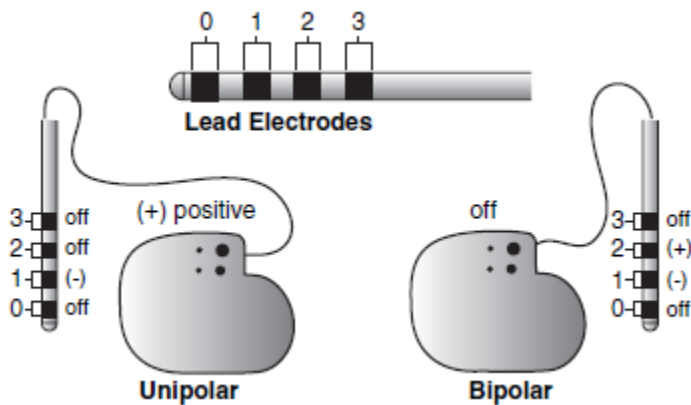
Rate:

Rate is the number of times per second a pulse is delivered, measured in pulses per second (pps) or Hertz (Hz). Increasing the rate feels more like a “flutter” or “vibration” and decreasing the rate gives more of a “tapping” or “thumping” sensation. You can use patients’ preferences for the sensation they are most comfortable with, to guide you in selecting an appropriate rate. Typical setting for rate is 10-14 pulses per second.



Electrode Polarity:

The stimulation pulse is delivered from the neurostimulator to the nerve through the electrodes on the leads. For the stimulation pulse to reach the nerve, you select the electrodes on the lead that best provide the stimulation and assign a negative or a positive polarity. At least one electrode (or the neurostimulator case) must be designated as positive and at least one electrode must be designated as negative. The negative electrode is called the active electrode; a pulse flows from the active or negative electrode to the positive. Thus, changing an electrode to active, changes the location of the stimulation pattern.



The four electrodes on a lead can be configured with or without the neurostimulator case in the following two configurations:

■ Unipolar: using any combination of electrodes and configuring at least one electrode as negative and configuring the neurostimulator case as positive.

The neurostimulator case can only be configured as positive. When the case is selected, lead electrodes can only be selected as negative.

Unipolar configuration depletes the neurostimulator battery at a higher rate.

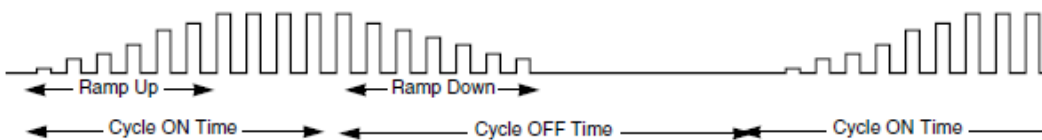
■ **Bipolar:** using one or more electrodes and configuring one or more electrode as negative and one or more electrode as positive with the case OFF.

Cycling:

Cycling feature automatically turns the neurostimulator ON and OFF at clinician-determined intervals (from 0.1 seconds to 24 hours). When Cycling is not selected, the neurostimulator stays ON continuously. Therefore, Cycling can be used to extend neurostimulator battery life. By default, Cycling is OFF.

Soft Start/Stop:

The Soft Start/Stop feature allows the amplitude to increase gradually (ramp up) over a specified period from 0 V to the selected amplitude value. This feature is intended to increase patient comfort by providing a gentle or “soft” start as stimulation begins and reduces the risk that the patient will be startled by the start of a stimulation cycle. The Soft Start/Stop feature also causes the output to decrease gradually to 0 V (ramp down) when the stimulation is turned off. Using the Soft Start/Stop feature helps avoid any unpleasant sensation at the onset of stimulation. Programmable ramp times for this feature (up and down) are 1, 2, 4, 8, 15, or 30 seconds. By default, Soft Start/Stop is turned ON with 15 seconds ramp time selected.



Therapy measurement & Troubleshooting:

Therapy measurement mainly to assess the longevity of the battery as well as the Impedance of electrodes. Impedance describes the resistance to the flow of electrons through a circuit. Impedance or resistance is an integral part of any functioning circuit.

High resistance, no current will flow (open). Low resistance, excessive current flow results in diminished battery longevity (short).

The electrical circuit starts at the neurostimulator's circuitry and goes through the connectors to the extension wires, through the extension connector to the lead wires, through the lead's electrodes to the patient's tissue, and back either through another electrode and up the same path to the circuitry (bipolar) or to the neurostimulator case and into the circuitry (unipolar).

If the circuit is broken, electrons cannot flow. This is called an open circuit, and impedance measurements are high. Open circuits can be caused by a fractured lead or extension wires and loose connections. Patients generally feel no stimulation if an open circuit is present. In measurement of impedances by the programmer, unipolar measurements are most useful for identifying open circuits because they take one lead wire measurement at a time, immediately identifying which connection or wire has the problem.

Short circuits, which are reflected in low impedance measurements, can be caused by body fluid intrusion into the connectors or crushed wires that are touching each other. The electrons will always follow the path of least resistance. Patients may or may not feel stimulation, or stimulation may not be present in the correct area (i.e., the

generator site) or may vary in strength (i.e., a surging sensation). In measurement of impedances by the programmer, bipolar measurements are most useful for identifying shorts between two wires.

Impedance measurement is used as a troubleshooting tool to check the integrity of the system when a patient presents with a sudden or gradual disappearance of stimulation. Many measurements fall within the 400- to 1500-ohm range. High levels (>4000 ohms) identify open circuits, and low levels (<50 ohms) identify short circuits.

Medtronic Corporation (manufacturer of the InterStim) recommends performing the impedance measurements at the time of closure of the incision, at the first programming session, to get a baseline measurement and at any time a problem is suspected. These measurements will identify which electrodes, if any, are intact and allow the programmer to proceed with programming of only those with acceptable impedance measurements. If all electrode measurements read above 4000 ohms, a revision may be necessary.

Algorithm for management of a patient who presents with a decreased or absent response after a successful interval:

