Sacral Nerve Neuromodulation (InterStim®) Part II: Review of Programming

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While it is not critical for health care providers to know everything about the InterStim® (sacral nerve neuromodulation) equipment and programming, Part II of this series will increase the provider’s knowledge about InterStim therapy by describing the equipment, delineating patient education needs, and discussing the art of programming. This article will assist the provider in trouble shooting the system and provide some insight into the patient’s therapy.

Key Words: N’Vision programmer, external stimulator box, Interstim battery, patient programmer.

PROGRAMMING CONCEPTS

Programming requires an understanding of how to change the electrical impulse parameters by increasing, decreasing, or widening. The chronic tined lead has 4 points (0, 1, 2, 3 electrodes) on the end, placed in the S3 foramen. These electrodes will create the electrical impulse and stimulation. The neurostimulator (battery) located in an internal pocket created over the hip is also called the case, a fifth point used to create a circuit causing a stimulation/sensation. The major parameters that can be set are amplitude, which is the intensity or strength of stimulation measured in volts, and pulse width, which is the time or duration of the stimulation measured in microseconds. The rate is the number of times per second a pulse is delivered. Increasing the rate makes the stimulation feel more like a flutter, while decreasing the rate feels more like a tapping. There are ranges associated with each of these setting.

Other parameters associated with the InterStim include:
- Polarity is the current flowing between positive and negative electrodes. Unipolarity occurs when the case is positive and there is one negative electrode on one of 0, 1, 2, 3. Bipolarity occurs when the case is off and...
there is a negative and positive charge on 0, 1, 2, 3 electrodes (for example, 0 is negative and 3 is positive)

- **Cycling** is when the stimulation turns on and off; a common setting would be 20 seconds on and 8 seconds off.
- **Soft start/stop** is a ramp-up system for patient comfort. When the programmer is turned on or if he or she is cycling, the sensation gently ramps up to the set amplitude in 4 to 30 seconds.
- **Impedance/battery life** documents baseline impedance, the neurostimulator lifetime on the day of the implant, and yearly review of battery longevity and identification of broken leads.

These parameters are found on a special setting screen of the N’Vision programmer (see Figure 1). The ultimate goal is to manipulate parameters to optimize the neurostimulator (battery) life. This is accomplished by using the cycling mode (20 seconds on, 8 seconds off); keeping the amplitude, rate, and pulse width values as low as effectively possi-
ble; avoiding unipolar (case positive) stimulation; and using the minimum number of electrodes for effective therapy.

Programming External Neurostimulator/Patient Education

During both test phases, the patient has an external stimulatory box attached to external wires. This external stimulator box looks similar to a TENS unit and is used to create the stimulation for the percutaneous test or the 1st stage of the staged procedure (see Figure 2). Patient education consists of showing the patient how to use this box. It is helpful to teach the patient about the external box prior to surgery, and if that is not possible, the patient should be taught on the day of the test.

It is imperative that the patient understands how to use the external box before going home. Instructions include how to manipulate the amplitude (A) button, which increases and decreases the sensation, and information about the resistance (R) button that is set and taped by the practitioner (see Figure 3). The back of the box is composed of two compartments: one is for a 9-volt battery and the second compartment has an additional amplitude button, a pulse-width button, and electrode buttons. In the middle compartment is a second amplitude button that can be set at 10 or lower depending on how sensitive the patient is to the stimulation. There are four small buttons that correspond with the electrodes on the chronic tined lead that are set and changed if needed during the test (0, 1, 2, and 3) (see Figure 4). Patient education includes teaching the patient that one button is positive and one is negative, and moving the buttons around to find the most comfortable sensation for the test. Once a negative and positive electrode is set, the amplitude button is turned on, slowly increasing until the patient describes the stimulation/sensation. The patient will describe the stimulation/sensation as a vibration, flutter, or pulling between the vagina/scrotum and rectum.

Direct or phone communication with the patient daily or every other day is essential; it is during these conversations that the technician and patient will make changes if necessary and decide if the test is successful or unsuccessful. Success is determined by the diaries (objective) and how the patient feels about their symptoms (subjective). At the end of the test, if the test is successful, the decision will be made to go on to the 2nd stage, when a neurostimulator (battery) is implanted or the lead is removed. If there is minimal symptom relief, changing the positive and negative electrodes will increase the chances of a positive test. A successful test remains the best indicator for patient selection for implantation.

Programming the Internal Neurostimulator

After a documented positive test, a neurostimulator (battery) is implanted; this is called the 2nd stage. The internal neurostimulator (battery) is placed during surgery in a small pocket created in the hip, and the battery is then programmed using the N’ Vision programmer. One way to begin programming is called mapping; this is a systematic approach to programming the internal neurostimulator (battery). To determine the optimal electrode

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**Figure 5. Neurostimulator Model 3058 (A) and Model 3023 (B) with Extension**

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**Figure 6. Model 3058 and 3023 Battery Life**

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combination, the programmer will elicit a patient response on each electrode (0, 1, 2, 3). This is started by setting the neurostimulator case to positive and then, one by one, checking responses on the 0, 1, 2, and 3 electrodes as the negative. The amplitude is then increased by increments of 0.1 (more sensitive 0.05) to elicit a response and document; additional documentation indicates where the patient feels the stimulation and what it feels like for each electrode. The same is done by making the #3 electrode a positive, eliciting responses with 0, 1, 2, as the negative, and again by using the #2 electrode as the positive and 0, 1, 3 as negative. The end of the session occurs when the patient is comfortable with a pulsation or stimulation that feels like a flutter or tapping and is not painful. The general rule is not to change the parameters for at least 48 hours and only changing if there is no symptom relief. The best response is a sensation described as a light flutter or tapping somewhere between the vagina/scrotum and rectum.

**EQUIPMENT**

**Neurostimulator (Battery)**

In 2006, Medtronic introduced a smaller neurostimulator battery, Model 3058 (see Figure 5). This smaller battery does not replace Model 3023, the battery most commonly used until 2006. This smaller battery is used for patients who require lower amplitudes and have smaller body mass. The size of the battery is discussed with the patient prior to surgery and implantation. Decisions should be based on how many programs are needed, whether the other parameters together require more battery life, and if high amplitudes are required. If these criteria are met, then the Model 3023 should be used (see Figure 6).

**Patient Programmer**

In 2006, Medtronic developed a new patient programmer that increases programmable choices for the patient. It allows the practitioner to create and enter multiple pre-set programs into the patient programmer. For example, the *first program* would have a positive case, negative 0, pulse width of 240, rate of 9.7, and no cycling (see Figure 7). The *second program* is the same but with cycles, stimulation will be on for 20 seconds and off for 8 seconds, with a soft start of 4 seconds. The *last program* is a positive 3, negative 1 with a pulse width of 180, rate of 16, and cycles. This ability to select different programs improves the chance of optimal therapy. It also decreases the number of times the patient will return to the clinic for reprogramming.

There are two patient hand-held programmers on the market – the Interstim Model 3031A (see Figure 8) and the InterStim iCon patient programmer Model 3037 (see Figure 9). The InterStim 3031A is no longer given to patients and will be eliminated in the future, but some patients still use this programmer. The 3031A features a compartment for a 9-volt battery and buttons for increasing and decreasing amplitude as well as on and off buttons. The patient
should be familiar with the four buttons on the front: increase, decrease, off, and on. There are lights on the back of the programmer; when a front button is pushed and no lights turn on, then the programmer needs a new battery. Other lights on the back panel address the functionality of the neurostimulator. A green light indicates the neurostimulator is on, and orange indicates it is off. If there are no lights, the patient’s neurostimulator may be lifeless. Along with the patient programmer, a patient is given a condensed fact sheet and a booklet that outline all instructions and teaches the patient how to troubleshoot the programmer.

The Interstim iCon patient programmer is a compact piece of equipment compatible with both the InterStim implantable neurostimulator (INS) and the InterStim II INS (see Figure 10). To begin programming, the practitioner will bond the iCon patient programmer using the N’Vision programmer and the implanted neurostimulator (battery). This is a new concept for the 2006 patient programmer. Programming begins with mapping, and once completed, the provider bonds the patient’s neurostimulator with the iCon programmer. The provider teaches the patient how to synchronize the iCon patient programmer when turning on the programmer and how to make changes, such as increasing, decreasing, turning the neurostimulator on or off, and changing to a different program. It is imperative that the patient understand how to use his or her programmer; there should be a return demonstration at the end of each session. The patient must bring the programmer when returning for follow-up care.

Programming should be performed in a quiet room with ample time to spend with the patient. Do not hurry through the session. Discuss programming goals with the patient before getting started. Actively listen to the patient and make sure he or she is listening. Develop your own style so you are comfortable with the patient programming and rely on your instincts as to how well the patient has understood what he or she has been told.

**CONCLUSION**

Clinicians of all levels are trained to work with patients who are candidates for InterStim therapy, and the importance of programming and patient education has been emphasized. It is essential that patients understand all the parameters and how to use their programmer. Follow up is an important part of successful therapy; the patient’s recommended return to clinic is one month, six months, and yearly to check impedances and battery life. The ultimate programming goal is excellent patient outcomes with a decrease in the patient’s urge incontinence, urinary frequency, or urinary retention.

**Reference**