

**NEUROMODULATION FOR OVERACTIVE BLADDER:
INTERSTIM THERAPY FOR URINARY INCONTINENCE
UNITED HOSPITAL
ST. PAUL, MN
January 30, 2008**

00:00:15

ANNOUNCER: Over the next hour, you'll see a live webcast of an InterStim Therapy implant for bladder and urinary retention from United Hospital in St. Paul, Minnesota. Dr. Steven Siegel, board-certified urologist and director of the Center for Continence Care at Metro Urology, will perform the procedure.

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STEVEN SIEGEL, MD: I introduced the idea of nerve stimulation as a concept early on in the management of patients with overactive bladder.

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ANNOUNCER: InterStim Therapy has been implanted in over 40,000 people with bladder control problems who are unable to tolerate other conservative treatments. OR-Live makes it easy for you to learn more. Just click on the "request information" button on your webcast screen and open the door to informed medical care. Now let's join the doctors.

00:01:07

KAREN NOBLETT, MD: Hello, and welcome. My name is Karen Noblett, and I'm a urogynecologist at the University of California-Irvine, where I also serve as fellowship director for female pelvic medicine in reconstructive surgery. The objective of today's program are to introduce the techniques of InterStim Therapy, both the percutaneous nerve evaluation, which we call the PNE, which is an office-based test, as well as the techniques for placing the chronic InterStim lead wire. We are very fortunate today to be joined by Dr. Steven Siegel, a urologist and director of the Center for Continence Care at Metro Urology. Dr. Siegel has been involved with InterStim therapy since the early clinical trials and is considered one of the nation's top leaders and experts in this therapy. The purpose of this program is not to provide specific training for physicians in this technique but simply to introduce the idea of InterStim therapy and to demonstrate the ease of use and the minimally invasive nature of this technique. Now, if you are a patient who is joining in, please realize and recognize that this therapy is not for everyone. If you think that you might be a candidate or are considering this as a possible therapy, please consult your physician. There are medical complications associated with procedures. These would include for this procedure lead migration, pain at the implant site, infection, skin irritation, or possible technical or device problems. If you would like more information about this therapy, please contact this website at www.interstim.com or call the number on your screen, which is 1-800-664-5111, extension 3150. Now, during this broadcast, you will be able to email in questions about the therapy. Just click the MDirectAccess button on the screen and email your questions in. If we are not able to get to your question during the program, you will receive an email response at some point in the future. For patients who are joining us for this broadcast, please recognize that Dr. Siegel and I are not able to provide you with specific medical advice regarding your own condition and would recommend that you contact your own physician.

00:03:56

Now, one common question that comes up is what is InterStim Therapy? Well, InterStim Therapy is a form of neuromodulation and involves a surgical procedure where we place an electrode lead wire, which I will try to demonstrate here on this anatomic model. Here you can see the lead wire is coming through the S3 sacral foramen and sits adjacent to the S3 nerve root. On this lead electrode we actually have four different electrodes that we can stimulate in different combinations. We are then able to deliver gentle electrical impulses to the sacral nerve root, which provides modulation of the sacral reflexes which govern bladder control and through that neuromodulation hopefully restore normal voiding function. The current FDA recommendations or approval that we have for this particular therapy include two that are covered under the umbrella term of overactive bladder, which include urgency frequency syndrome and urge incontinence. And also, it's approved for nonobstructive urinary retention. For patients who have obstructive uropathy such as that from benign prostatic hypertrophy, cancer, or urethral stricture, this would not be an indicated procedure. And this is typically considered for patients who have failed first-line therapies. One of the great advantages of this therapy is that patients are allowed to undergo a trial stimulation period. And before they undergo this trial stimulation, we ask them to complete a voiding diary for us. And you can see on this screen an example of the voiding diary. The patients will complete this diary for three to four days and indicate the number of times they void, the volume voided, how many times they leak, and how many pads they're going through. For patients with retention, they're recording the number of times they catheterize, how much they void on their own, and what their post-void residual is. We're then able to have them repeat the voiding diary during their trial stimulation and then compare the pre and post-treatment results. For those patients who have not demonstrated an appropriate response or who are unable to operate the neurostimulator would not be considered candidates for this procedure.

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We're now going to be able to watch a short video that demonstrates the peripheral nerve evaluation. Dr. Russell Harrell is an obstetrician/gynecologist out of New Jersey who will demonstrate the peripheral nerve evaluation test. And as you'll be able to tell from this video, this is an office-based procedure that is typically done with just local anesthesia and does not require any type of sedation. During this procedure, Dr. Harrell will be looking for motor responses from the patient. The typical motor responses that we will look for are what we call a bellows response, which is sort of a pulling in of the pelvic floor muscles, the levator ani muscles, and a flattening of the anal groove. Additionally, another motor response we look for is great toe flexion or plantar flexion of all the toes that we see in response to stimulation of the S3 nerve root. Additionally, Dr. Harrell will be able to have a conversation with the patient and ask her what she feels during the procedure. A typical response that a patient would feel, for females they would feel a tapping or vibration in the vaginal or rectal area or sometimes in between, and in male patients that often describe a tapping or vibration sensation near the base of the penis or in the scrotum or possibly in the rectum. So now we're going to turn to the video and Dr. Russell Harrell in his demonstration of the peripheral nerve evaluation test.

00:07:44

RUSSELL HARRELL, MD: I'm Dr. Russell Harrell, Ob-Gyn at North Dover Ob-Gyn Associates in Toms River, New Jersey. The PNE procedure's done in the office. The patient is laying on her abdomen, minimally exposed, you're just exposing the area over the sacrum.

00:08:00 [video rolls]

All right, Jeanie, you're going to feel me touch you. I just need to feel for the tip of your tailbone, kind of a weird feeling there. So normally what I do is feel for the tip of the coccyx, try to keep my finger perpendicular, come up 9 centimeters and make a mark on the skin. And then try to ascertain the midline, make another mark. And then it should be 2 centimeters lateral on either side. So somewhere right around here under the skin should be the S3 foramen. With the aid of fluoroscopy, what we'll do is try to delineate where the S3

foramen is. We've done it anatomically, but -- so what we'll do is we'll -- I do them at the same time. I'll put one needle that way to look for the SI and I'll put this one this way to try to find the midline. So that looks pretty good. So we're talking here is where we're talking about and then this is the midline right here. Since I'm left-handed and staying on the patient's left, I normally end up putting the left one in first. You need to go a little bit cephalad depending on the body habitus of the patient, depending on how deep the thickness of their sub-Q is, maybe a centimeter or two. And I try to place the needle on 60-degree angle and try for the needle to go from the medial to the lateral aspect of the foramen. Because the nerves run medial to lateral and we'd like to lay the needle as close to the location of the nerve and run alongside the nerve as possible. Okay. So I can see on the x-ray I'm probably about where I want to be, but I think that the angle needs to be a little bit flatter, as we say. And I'm going to ask you when and where you feel this, okay?

00:10:29

FEMALE VOICE: Can you feel me touching your foot, Jeanie?

00:10:30

JEANIE: Mm-hmm.

00:10:31

RUSSELL HARRELL, MD: Okay.

00:10:32

MALE VOICE: Two, four, six, eight. There's the --

00:10:37

FEMALE VOICE: Where do you feel that?

JEANIE: In the front.

FEMALE VOICE: In the front?

00:10:40

RUSSELL HARRELL, MD: Okay, so Jeanie feels it in the front. We need a little more energy to get the toe. So then I think we're pretty good. So what we'll do is we'll leave the J-hook attached to that needle. We'll use that needle as our guide to place the needle on the opposite side. As I said, if you want to know where 4 centimeters across from that is, you have your markings right on the needle. And that's pretty much where I injected Novocaine right here. So I'm going to use that spot, and as I said, try to capture a medial to lateral presentation, or introduction into the foramen. Now what I can do is take another shot with the C-arm and you can see that the needle that I'm introducing now -- Kelly, can you point it out on the screen for them? That one there, the one that isn't all the way in. You can see it's higher than the other one, so I need to drop the hub a little and try to introduce it into the foramen. That's kind of a flat presentation. So maybe what I'll do is I'll actually introduce in the skin just a little bit further towards your feet, further south, as we say. That's getting close. I can feel it. Now you can see you can't distinguish one needle from the other, so you know that I'm pretty close. There's the foramen. And you can feel it. I don't know if you noticed that, but I was going and touching the sacrum and then you could just feel it go right through. So this is not in as deep as the other one, so we'll push this in just a little bit. Okay. All right, Jeanie, we're going to test it again. Tell me when and where you feel it. Do you feel that at all? Okay. Well, we don't have much toe, though, you say. We'll put the lead in on this side. PNE lead comes in this little plastic case. Let me withdraw the stylet from that needle. Pull this out. Then you'll notice that there's marks on the PNE lead. They're difficult to see, but they're designated for the 3-1/2 inch and the 5-inch needle. Since we're using the 3-1/2 inch needle, it's the first one. So what we do is we slide this down. Here on the end the J-hook clips to the end of the needle, and then Christian will do it again. Tell me where and when you feel it, Jeanie.

00:13:35

JEANIE: I feel it right now.

00:13:36

RUSSELL HARRELL, MD: You feel it now.

00:13:37

FEMALE VOICE: Where did you feel it?

RUSSELL HARRELL, MD: And she feels it in the front vaginally. So we're happy with that placement. I'll just put my J-hook right here. Now, grasp the PNE lead and I push in as I withdraw the needle. So I usually turn the needle a little bit, and as I push in so it doesn't move, I back the needle out, stabilizing the PNE lead. Once you feel it give through the skin, then I usually switch my fingers down to below the needle tip, slowly pull this back until it meets the stylet, and then pull that out. All right, that's it. We're all set.

[end of video]

00:14:27

KAREN NOBLETT, MD: As you can see from that video, the procedure is fairly simple to do and minimally invasive. Now, once the PNE lead wire is placed, it's then hooked up to this screener box that the patient will then wear during her trial period. And the trial period can last up to seven days. And again, that's one of the great advantages of this therapy is that a patient is able to undergo a trial stimulation to evaluate whether or not this is going to be an appropriate therapy for her. We actually do ask the patient again to repeat her voiding diary for at least three to four days so that we can compare to the pre-treatment diary. What we look for, which you can see on the next slide, is a 50 percent improvement in response. We want to see the 50 percent improvement based on what symptom we're following, whether that be voided volumes, number of voids per day, urge episodes, post-void residuals, or number of self-catheterizations. If they have an inconclusive PNE test, they can go on to a stage one implant. At this point, we're going to go to Dr. Steven Siegel in the OR, where he is going to demonstrate placement of a chronic lead wire. Dr. Siegel?

00:15:39

STEVEN SIEGEL, MD: Thank you, Karen, and welcome to those of you watching on the web. I'm Dr. Steve Siegel, and you're looking at the operating room in United Hospital, where it's 72 degrees. And we're performing the first stage of an InterStim implant on a patient who has symptoms of chronic urgency and urge incontinence. And our patient is 69 years old and she's had symptoms for several years now. And she has gone through a variety of things in order to try to address the problem, including surgery in the '80s for stress incontinence. She's had multiple drugs in order to try to deal with the urgency, which have been unsuccessful. She's had additional procedures to fix prolapse and bulking agents for stress incontinence. But her bottom line symptom is that when she gets the urge to urinate, it all comes out in a flood. So at this point, either because of an equivocal test simulation, as you've seen Dr. Harrell demonstrate, or if that was to be successful and then we were to go and implant the entire system, we would go to implant the chronic lead in the operating room in this fashion. And this is our typical setup. Our patient is in a prone position face-down on the operating table. She has some cushions to support her hips and a pillow underneath her shins so that we can see her feet. And she is under what is called monitored anesthesia care, or MAC, which means that she's receiving small doses of [propofol, fentanyl and verised]. And she is conscious. She is able to respond to us and we can ask her for sensations, much the same as you saw in the video with Dr. Harrell. We can test and we can ask her where she feels it, and that will help direct our placement. The technique that I'm going to demonstrate is not really dependent on bony landmarks. You saw a good example of that previously. But what we're going to do is use fluoroscopy, or x-rays, in order to get a precise placing of the lead. And that is also something that is more amenable to a hospital setting as opposed to an office, where frequently those utilities aren't available. So we've prepped the patient with alcohol first and then DuraPrep. We let that dry. And we put this Ioban sheet over the patient's skin. It forms a very nice barrier against skin organisms, and the only place that we'll have skin organisms exposed is when we actually make an incision. And our patient has received a dose of intravenous antibiotics also as a prophylaxis.

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So the first step in the procedure is to try to identify the medial edge of the sacral foramina, and we're going to do that using fluoroscopy. So I'll go ahead and have the fluoroscope brought to the table. And I'll have that skin marker there, thanks. And we'll take an AP view. And you can take a look at the fluoroscopic image here. Just take a quick shot there. So I have to get that adjusted just a bit. I think you can see at the level of the urethra where the bulking agent has previously been injected into this agent. Well, that's fine. And now what I'm going to do is I'm going to put a skin marker down there, and can you take a quick fluoroscopic image? And then continuous fluoro. I'm going to move the marker to what I believe is the medial edge of the foramen. And that's on the patient's right side. I'm going to then flip over to the opposite side, so continuous fluoro there. And one more shot. And now you can go fluoro off. So now why don't you just step back with us just for a second so that I can demonstrate on the patient's skin. So let me have a marking pen. And this patient is like many people in real life in that she's a little bit asymmetric. The spine is not exactly right in the middle. But what I'm saying is that the medial edge of the sacral foramina are going to line up in a line something like this. I don't know where S3 will be. I'm going to use the lateral image in order to determine that. So that's the next step for us now that we've marked out this position, which is roughly two finger breadths apart, is to obtain the lateral image so we can pick out S3. So come on in and then let's go directly to a cross-table lateral view.

00:20:50

Dodie, are you okay? All right, are you comfortable? All right, good. You keep relaxing and we'll keep working. Okay. You're not completely flat, I don't think. There we go. All right. Now you say the table still needs to come up? Can we raise the bed just a bit, please? That's good. Now we'll take a lateral view and see. Maybe come just a little more towards the head. Want to see another picture? Perfect. Okay. Now on this lateral image of the sacrum, which you can now see, we can typically pick out the S3 foramen as being the first -- there's a seam in the sacral bone which you may recognize, or a little bump on what's called the anterior surface of the sacrum, which is the one that's pointing towards the patient's abdomen. And it's that first seam that appears below the sacro-iliac shadow. So what I'm going to do is I'm going to ask for a cross-table lateral fluoro shot now, please. And you can see on the image where the tip of my marking instrument is. And if I mentally draw a line with my mind's eye from the tip of that needle to the tip of the bony papilla, which is the first one below the sacro-iliac shadow, this looks like a very good entry point. So I'm going to make a mark on the skin here. And the contralateral one will be just two finger breadths over. And I'll give you that and I'm going to take some quarter-percent marking with epinephrine as a numbing medicine. And Dodie, you're going to feel a sting here, okay? Here it comes. Just a little bit of a burn for a minute. You want to get a skin [wheel] here. It's important because that's what gives you local anesthesia. The deeper levels are not particularly sensitive until you get to the periosteum. And Dodie, I'm going to numb the other side just in case we need to go there. So here comes one more sting. I apologize. That's it, and that should just last for about a minute and then it should be better. Are you okay? There you go. I made that nice and numb for you. And I'll take a [raytech], please. Okay. And then the next thing I'm going to use -- for a minute, before we go further, I'd just like to demonstrate the tools that we have. So why don't you bring that surgical tray a little bit closer and you can focus in on this tray. So these are the tools you've -- all right. This first instrument you saw me use is called a foramen needle. And it's different from a spinal needle in that it is insulated all the way along the course except up at the beginning of the needle here and at the tip. So if I stimulate here, it only comes out at the end. So that's a foramen needle. This instrument is called a directional guide, and it's what we use to switch out between the foramen needle and the lead introducer sheath. And this has certain markings that correspond with the depth of this directional guide. And this is the lead introducer, and it consists of a sheath and an obturator. And this sheath has a little metal marking on the end of it which I may refer to as the launching point. That's the point

that the lead is actually going to escape from. And when I deliver that lead, it's going to come into the tissue from that point on. So that's the basic setup that we have here.

00:24:57

So I'm going to take the foramen needle now and I'm going to insert it into where I estimated the entry point should be. And I'm going to be paying very careful attention to keep it exactly in this plane parallel to the patient's spine and not medial or lateral but just to stay right in this plane as the point trying to set this up. And sometimes going through that lobe for the first time can be a little sticky. Then I'm going to go down and I'm going to touch the bone. And then we'll take a lateral image. So why don't we take a lateral image. And the hillock that I'm aiming for is inferior or caudal to where that needle is actually aiming. So I know from this picture that I have to orient this needle in a little bit more of a cephalocaudal direction. So I'm going to pull back and then I'm going to plunge forward and we'll take another picture with fluoro. And you can see now that it's actually aiming just about where I want it to be. So I know that I'm very close, and now what I'm going to do is feel around the surface of the bone with the needle in order to drop into the foramen. Dodie, how you doing? That a little sensitive for you? I think she's all right. So now I've stepped off and I'm going to take a picture and see. And you can see that we entered into the foramen. And I was saying before the tip of the hillock and I know I didn't have any good way of demonstrating it to you. But now you can identify the tip of the hillock as exactly where the tip of that needle is. Take one more shot with fluoro. And this is where I want to start stimulating. I would like to stimulate as close to the anterior surface of the bone as possible because that's the most predictable location for where the nerve is likely to be. So I have a small patient screener cable that's connected to the handheld stimulation device like you saw used with Dr. Harrell. And this part of the procedure is very similar to that except for the method in which we identified the foramen. And I'm going to connect here, and then we're going to start at a very low threshold and we're going to start to turn up and look for a physical response. And Dodie, you may feel some sensation. You tell us when you start to feel stimulation. You're at 1 now. So I'm going to go on here. And we're a 2 now. Dodie, do you feel anything?

00:27:38

DODIE: I do feel a sensation. It's difficult to hear with the air.

00:27:46

STEVEN SIEGEL, MD: Okay. Do you say you do feel stimulation, though? You can hear better now? Do you feel any stimulation?

00:27:55

DODIE: Yes, I do.

00:27:57

STEVEN SIEGEL, MD: Where do you feel it?

00:27:58

DODIE: Right on my back.

00:28:01

STEVEN SIEGEL, MD: On your skin of your back here? Okay. It's not in the rectum or the vagina?

00:28:05

DODIE: No.

00:28:07

STEVEN SIEGEL, MD: Okay. Can we turn the stimulation up a bit? How about now? Is it still comfortable for you?

DODIE: It's comfortable, but it's still in the same area.

00:28:18

STEVEN SIEGEL, MD: Same spot, huh? And let's turn it up just a little bit more. Okay. Well, I'm not satisfied with the fact that we've had to turn it up to 4 and we haven't seen any physical responses. And where Dodie's feeling it isn't in where I would consider to be the

ideal position. So I'm going to make some adjustments of my needle now that I have identified the foramen. I'm going to pull back. And it's important to pull back because the needle really doesn't torque very well when it's in the skin. And then I'm going to aim down a little bit lower and a little bit lower. And I want to just feel right off the medial edge of that foramen. Dodie, you okay?

00:29:05

DODIE: Yeah.

STEVEN SIEGEL, MD: Not hurting you?

DODIE: Yes, it does.

STEVEN SIEGEL, MD: Little bit?

DODIE: Mm-hmm.

00:29:16

STEVEN SIEGEL, MD: Let's just see. Let's take another picture just to see where we are. It's a little bit more inferior to where I've been aiming. Take one more picture with fluoro. Too high. Just take a walk down in that line. And the problem sometimes with the foramen is it can be -- sorry, Dodie -- a little bit like a basketball hoop. She's having some sensitivity because I'm bouncing on the periosteum of the bone, so what I'm going to do is I'm going to give her some numbing medication right at that level. Can I have the marcaine but without the needle attached to it? And Dodie, I'm going to give you some numbing medicine here and you may feel some pressure when I inject it. And then that'll go away and then when I'm poking around here with this needle, you won't feel the discomfort anymore. So here comes -- and here's that pressure I was warning you about. You all right?

00:30:35

DODIE: Yes.

STEVEN SIEGEL, MD: Yeah, and that'll go away and then you'll be more comfortable. Okay, let's have that obdurator for this needle again. That guy. Yeah.

00:31:01

KAREN NOBLETT, MD: Steve?

00:31:02

STEVEN SIEGEL, MD: Yes.

00:31:03

KAREN NOBLETT, MD: We have an email question. Is now a good time?

00:31:05

STEVEN SIEGEL, MD: Yeah.

00:31:07

KAREN NOBLETT, MD: One email question was that the audience was reminded that it is 79 degrees. Is it important to maintain a certain temperature in the operating room during the procedure?

00:31:18

STEVEN SIEGEL, MD: No, I was just saying that because it's minus-something outside and I wanted people to realize that we can be comfortable here too.

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KAREN NOBLETT, MD: That's what I thought. There was another question on whether the patient's bladder was deformed in any way.

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STEVEN SIEGEL, MD: Is deformed in any way?

00:31:35

KAREN NOBLETT, MD: Yes. Somebody came into the webcast a little bit later into the program.

00:31:42

STEVEN SIEGEL, MD: It didn't start out that way. She's had a few surgical procedures, and maybe as a result of that it might have had some effect, but it didn't start out that way. I'm having some trouble accessing the foramen from this position, so what I'm going to do is

I'm going to move my entry point down a little bit lower. And I've given her some numbing there, so it's going to change the angle of entry of my needle. Let's take a fluoro shot here. And it's right around that spot that I'm aiming for. And since we've had trouble on this side I'm going to persist for a little bit longer. And if I don't find it, I'm going to go to the other side. There we go. It may be that we're just a bit more lateral than we want it to be. Fluoro again. And one more. Okay. And then I want to just pull back just to the anterior surface of the bone, as you saw me do before, and then we're going to stimulate and look for a response. Once again we've had to turn the device up to two or three or -- where is it now?
00:33:09

FEMALE VOICE: Three.

00:33:10

STEVEN SIEGEL, MD: Three, and we're still not getting a good response as far as the [bellows] is concerned. You got some toe. Do you want to take a look at the toe? Are you still seeing it now? I can move it down to that point where you did see it. Do you see any? Oh, maybe she moved it. All right. Well, I'm not very happy with that response as a whole. What I'm thinking is that perhaps even though I used my lateral to show me the foramen that the foramen seems to be a little bit more medial. So what I'm going to do in order to find that out is take a second needle and I'm going to pass that right along parallel to this one and see if I can hit the foramen a little bit more medial. Because the location of the nerve is in the upper medial quadrant. Let's take a picture here. So I'm going to take this one out because I like this straight orientation better. Fluoro again. And it's more medial, which is where I anticipate the nerve is likely to be traveling. So I'm going to go ahead and stimulate again. Dodie, do you feel anything?
00:34:34

DODIE: No.

00:34:35

STEVEN SIEGEL, MD: No. So once again we're at four and we're not seeing much of a physical response. So I'm going to take some more numbing medicine. And just to make sure that she's -- oh, I need that needle back on -- just to make sure that the skin is numb as I test this site a little bit more medially. And we'll numb the skin. Here's that back. And she seemed to be pretty comfortable with that. I'll take the other foramen needle once again. And again we're just going to aim a little bit more medial here and see if we can pass that foramen, and we did. Fluoro again. So for some reason our initial measurement had us off a little bit lateral. Let's take another picture there. And this orientation is a little bit too inferior, so I'm going to change it and touch the bone, touch the bone, and hopefully just pop into the foramen. Let's take another fluoro view close to the mark that we're aiming for. There we go. Fluoro again. Seems a little bit on the inferior side of that foramen. So zero. Okay. Still not a good response. So now I'm going to take this information and I'm going to use it to go to the other side. And the way that we've marked this foramen before I think doesn't seem to make sense, so I'm going to just take two finger breadths and take a marking pen, please. And I'm going to aim on this one, I think, just a little bit lower than the previous spot. And I'll take that numbing again. I'm numbed over here, and this part of the skin isn't numb. Dorothy, you may feel a sting here. There you go. She's comfortable. And then I'm going to take the second foramen needle. And we're going to just try to change that angle of inclination just a little bit. Fluoro again. And that's just a little bit more straight-on than the first one. Try to get our spot here. She's sensitive on that periosteum again. Let me have the marcaine one more time.
00:37:44

00:37:44

KAREN NOBLETT, MD: Steve, I think this is a great demonstration of one of the most important aspects of this procedure in that it can just be subtle changes in the foramen to pick up just the right response. And this is the most important part of the procedure is taking the time to find that right location along the sacral nerve root.

00:38:00

STEVEN SIEGEL, MD: Well, I'm having a couple of problems in this instance. I'm not just getting the right response, but I've also had just a little bit of difficulty popping into the foramen, but I think that's just to make it real.

00:38:13

KAREN NOBLETT, MD: We've got a couple more questions, and one is how long is the recovery time after the procedure. And what do you tell your patients about post-operative restrictions?

00:38:24

STEVEN SIEGEL, MD: Well, the recovery time is short as far as post-op pain is concerned. The patients are up and around and they're doing things pretty quickly afterwards. But we ask them to be careful about physical activity: twisting, turning, that type of thing usually for about a week after the procedure. And the trial is going to last about 7 to 10 days. So between now and that time, that's when we've made the decision as far as how well the therapy is working. Let's take another picture just a second. So Dodie's comfortable here, but we're not making the kind of progress that I'd like to be making on this side. So I'm going to go back to the original side and what I'm going to do is I'm going to change my angle of entry to be a little bit lower.

00:39:23

KAREN NOBLETT, MD: We have another question here about the length of the life of the therapy in the batteries. And if we could maybe shoot back to show us here, we actually have two generators. These are the chronic generators that would be implanted. This is the InterStim one, the original generator. The battery life is anywhere between five to seven years, depending on the amount of stimulus, the pulse, the rate, and those kinds of parameters. This is the InterStim Two. This is the newer device. It's about one-third the volume of the old generator. And it is -- battery life ranges anywhere from two to five years, again depending on the amount of stimulus that's required and the other parameters that are set. But it's much more comfortable for patients when they actually place this, and we'll talk about where that placement is later in the procedure.

00:40:14

STEVEN SIEGEL, MD: Okay. One more shot. Dodie, do you feel any of the stimulation now?

00:40:20

DODIE: No.

00:40:21

STEVEN SIEGEL, MD: No. And what are you at? Three.

00:40:25

DODIE: I can just feel [unintelligible].

00:40:28

STEVEN SIEGEL, MD: No vibrations?

00:40:30

DODIE: No.

00:40:32

STEVEN SIEGEL, MD: In the vaginal area or anywhere else, huh?

00:40:34

DODIE: No.

STEVEN SIEGEL, MD: Okay. All right. Well, we can try one more time on the other side. Let's have that foramen needle again. And I'm going to try a little bit more medial than I was before just because I didn't find the foramen and we kind of lined it up before in that area.

00:41:00

KAREN NOBLETT, MD: Steve, there was a question about why this isn't done under general anesthesia.

00:41:04

STEVEN SIEGEL, MD: Well, it's important -- the patient's responses are very important in order to find the ideal location. So what I want to hear from our patient is that she feels the stimulation, she feels it at a comfortable level, it's in an appropriate spot. And if we're under general anesthesia, of course, we can't have that kind of communication. And I think you can tell she's generally pretty comfortable. Dodie, are you able to hear me?

00:41:29

DODIE: Yeah.

00:41:30

STEVEN SIEGEL, MD: Have you been comfortable?

DODIE: Yeah.

STEVEN SIEGEL, MD: I haven't been hurting you too much?

DODIE: A little bit.

00:41:35

STEVEN SIEGEL, MD: Just a little bit. Well, at least you're being honest. Let's take a quick picture here. So I've reintroduced the second needle, though I did find the foramen on this other side. So I'm going to take this one out just so we're not confused. And fluoro again. And we're going to test on the other side because we haven't really found what I would consider to be a good response on her right side, so now we're going to test on the left side. Do you feel that, Dodie?

00:42:19

DODIE: No.

STEVEN SIEGEL, MD: I'll take one more foramen needle. Foramen needle again. And we're just going to try and go a little bit more medial to this using that same technique that we used a minute ago. See if I can find the same entry point.

00:42:35

KAREN NOBLETT, MD: Now, Steve, we typically implant at the S3 nerve root. Occasionally people will implant at S4. What percentage of the time would you say you implant at S4, or do you ever?

00:42:44

STEVEN SIEGEL, MD: Pretty infrequent. I mean, one of the options here might be to consider going to S4, but pretty much always S3 and hardly ever at S2. That would be another site that I would really try to avoid. So it's just not a good response at all. Let's take one more look here at fluoro. And again, I'm going to bring it up to this anterior surface and then stimulate again. Dodie, feeling any stimulation?

00:43:24

DODIE: No.

00:43:25

STEVEN SIEGEL, MD: Okay. Let's try one more time on her other side.

00:43:29

KAREN NOBLETT, MD: A question came up regarding how long this has been approved, and actually InterStim Therapy has been approved by the FDA in the United States for the indication of urge incontinence since 1997, so last year it celebrated its 10-year anniversary. And it gained two further indications, for urge frequency and for urinary retention, in 1999. And it's actually been available in Europe since 1994. So the therapy has been around now for over 10 years.

00:43:56

STEVEN SIEGEL, MD: And it's been around longer than that actually before it became InterStim. So there's a little bit of a [bellows]. Do you feel that one then?

00:44:08

DODIE: Yes.

00:44:09

STEVEN SIEGEL, MD: Where do you feel it?

00:44:12

DODIE: [Unintelligible] with the needle.

00:44:18

STEVEN SIEGEL, MD: You feel something prickly, you're saying?

00:44:19

DODIE: Right. And it hurts [unintelligible].

00:44:24

STEVEN SIEGEL, MD: You don't feel it in the vagina or the rectum. Let's take another picture real quick. Okay. And how about now?

00:44:36

DODIE: No. [Unintelligible]. Am I supposed to feel it there or someplace else?

00:44:46

STEVEN SIEGEL, MD: Ideally you'd be feeling it in the vagina. What I'm going to do now is I'm in the S3 foramen. I know that from my visual image. I haven't seen much in the way of a physical response. And I'm going to actually try to find the nerve with the lead. So I'll take a 15 blade now -- and this is how we would ordinarily introduce the lead once we've identified the nerve properly -- and make a small skin nick. And then I'll take the directional guide, please. That's that stiff metal stylet. And we'll insert that down to the tip of the needle, and it's marked on the guide, so I know exactly where that is. Then I'll take the lead introducer sheath, and that is going to be inserted down to about one-half, two-thirds of the way through the bone table. So let's fluoro. Again one more shot. Can you bring that just a little bit closer to me? I can't quite see the image there. Does that hurt a little bit? That's good. Now let's see one more shot. I think it's just a little bit too far in there. All right. So give me live fluoro, please. And what I want is the tip of that lead introducer point, which you can see has a slight density about two-thirds of the way through the bone table. So I'm going to take the guts of this out and then I'm going to take the lead itself, the [timed] lead, and I'm going to go ahead and insert the [timed lead] through the lead introducer sheath. And then I'll watch that go in under fluoro. So can I have continuous fluoro now? And I have a pretty good mental image of the orientation that this lead should be going into. So now that it's in place, I'm going to go ahead and test and see if it's closer to the nerve. So here's site zero, which is the innermost site. Feeling anything there, Dodie?

00:47:10

DODIE: [Unintelligible].

00:47:12

STEVEN SIEGEL, MD: It's uncomfortable. Okay. Well, I don't like this position, so I'm going to pull back and reinsert.

00:47:29

KAREN NOBLETT, MD: Steve, there was another question about the fact that this was not done under general anesthesia and whether or not you worry about the patient panicking at the time of the procedure.

00:47:36

STEVEN SIEGEL, MD: The patient hemorrhaging?

00:47:38

KAREN NOBLETT, MD: Panicking. Sorry. Not hemorrhaging, panicking.

00:47:41

STEVEN SIEGEL, MD: Panicking. Sometimes, you know, and we can titrate the level of anesthesia to that situation. So we can give more sedation to the point where Dodie won't communicate with us if we need to. Usually we can do it in a way that's comfortable for the patient and we can still communicate.

00:48:05

KAREN NOBLETT, MD: And another question about the local anesthetic to the periosteum, is that something that you typically do?

00:48:10

STEVEN SIEGEL, MD: Well, if it plops right in, which it didn't in this case, I wouldn't ordinarily do that because they're not sensitive except on the periosteum. But if we're pushing around and feeling in multiple spots, then I will. And it's important to be careful when you do that not to actually deliver the local anesthesia directly into the foramen because you can anesthetize a nerve. Fluoro for just a second here. Let's see that orientation one more time. But the good news is that --

00:48:56

DODIE: [Unintelligible].

00:49:06

STEVEN SIEGEL, MD: Say that again, Dorothy -- or Dolores.

00:49:11

DODIE: It's supposed to hurt right where you're doing whatever you're doing, but then I don't feel it anywhere else.

00:49:19

STEVEN SIEGEL, MD: Well, it shouldn't hurt too much. Are you having pain now?

00:49:23

DODIE: Well, nothing unbearable. Am I supposed to also feel that somewhere else?

00:49:32

STEVEN SIEGEL, MD: Well, ideally what we would do is having you feel this in the rectum or the vagina. That's the spot we're aiming for.

00:49:40

DODIE: I haven't been close.

00:49:42

STEVEN SIEGEL, MD: No, I know that. Well, the Internet show may be coming to a conclusion here, but we're going to keep trying. Don't worry. We won't leave here without getting a good response from you. Okay. All right. Well, I don't think we're having very good luck with this technique, so let's fluoro one more time. I thought maybe I could get it to push into place here, but it really doesn't seem to be. So zero again. No good responses. Okay. Well, what we're going to do is probably cease and desist on this site. And I'm going to try again through another approach. So let's take the foramen needle again. Try the S4. Try that next. Fluoro again. And there we're pretty much head-on to where we want to be going. And I'll just move it around until I pop it into the foramen. Fluoro again. One more shot. Little more lateral maybe. Fluoro again.

00:51:34

KAREN NOBLETT, MD: Steve, there was a question about your skin dressing and whether that offers any resistance to needle insertion.

00:51:40

STEVEN SIEGEL, MD: The skin what?

00:51:41

KAREN NOBLETT, MD: The dressing that you placed over it.

00:51:42

STEVEN SIEGEL, MD: Oh, just very initially, but not after. After we poke through that, it's very superficial level. Let's try one more time and see what we get here as far as a response. Nothing. No motor responses. No good sensory responses. We'll just try a little bit different orientation within the foramen. Can I have some more numbing just because I don't want to surprise her? Yeah, just take the sheath off. That's good. Here comes another sting. I don't know whether you'll feel this one or not, Dodie. Looks like you're pretty comfortable. I'm just going to try to change my orientation within that foramen and see if I can't get closer to the nerve some other way. Fluoro.

00:52:50

KAREN NOBLETT, MD: Steve, there was another question on whether you feel this is a difficult procedure for a new surgeon to learn.

00:52:57

STEVEN SIEGEL, MD: Well, I'm going to say something that may seem paradoxical, which is no. Some cases are definitely harder than others, and -- fluoro again -- and as luck would have it, this one is one of those more difficult cases. But no, I think most of them are easier and that it's not a very technically challenging one. The key is to find the right responses. Now, what happened here is we put the needle in and it went down to the S4 foramen, so I'm going to just try that because we've had such a frustration and see if we can get a response at S4, which typically would be a bellows. There's a bellows. In focusing on her bottom, you can see an [inner going] of the intergluteal fold. Dodie, do you feel this one at all?

00:53:54

DODIE: In my rectum.

STEVEN SIEGEL, MD: Yeah. So S4 is typically all in the rectum and not in the vagina or in the scrotum. And you can see you get a good bellows or inner going of the intergluteal fold. And it could be successful for her symptoms. I'm glad to be seeing that we're having a response, but this isn't the response that I typically want to see. So if worse comes to worst, we'll settle for this, but I'm going to persist for Dodie's sake to try to go one site higher. So maybe I'll use this trajectory and just go one finger breadth above and aim for the foramen 1 above that. Fluoro, please. That's a little bit too low.

00:54:50

KAREN NOBLETT, MD: Steve, when you counsel your patients about this therapy, what do you counsel them regarding risks?

00:54:55

STEVEN SIEGEL, MD: Well, I think the biggest risk of the therapy is that it might not work. Because by the time patients get to this point, their lives are controlled by these symptoms -- fluoro -- and they're very desperate to find a solution. And they get their hopes up for this, and if it doesn't work, then what? And there still are some other alternatives -- [bocilline and toxin] being one potential option that I discussed already with Dodie. But this is the best option that I can think of for the situation. The other risks can occur sometimes are infection. And if that happens, that's overcomeable. We can take things out if we need to. Fluoro. This is S2, so I'm going to show you what S2 looks like. And S2 is usually you're getting the whole hip to move here. So let's stimulate there. Any response there as far as what you feel, Dodie?

00:56:01

DODIE: No.

STEVEN SIEGEL, MD: No. Okay. And then we're going to just try to find that middle one that we've been trying to find for this procedure.

00:56:14

KAREN NOBLETT, MD: And Steve, you've used your Ioban and you've given intraoperative IV antibiotics. Do you do anything else for infection prevention?

00:56:22

STEVEN SIEGEL, MD: Well, the main things too in terms of making our incision, we want to make sure that the lead doesn't get caught up in the skin -- fluoro again -- and that the closure -- I usually use staples to close these incisions and take them out after the first week so that there's no suture underneath the skin that could be [ignitus] for infection.

00:56:52

KAREN NOBLETT, MD: Do your patients go home on oral antibiotics?

00:56:55

STEVEN SIEGEL, MD: Patients usually go home on oral antibiotics for about a week. Well, we have a response at S4. I'm not really very satisfied with that, though, so I'm not inclined to take it. And I'm going to persist here for S3. Let's look again. All right. So let's test one more time. Dodie, feeling anything?

00:57:35

DODIE: No.

00:57:38

STEVEN SIEGEL, MD: Not a bit.

00:57:40

DODIE: [Unintelligible].

00:57:41

STEVEN SIEGEL, MD: That hurts a little bit?

00:57:43

DODIE: No, it doesn't hurt. I just heard a flutter down by my rectum.

00:57:48

STEVEN SIEGEL, MD: Oh, you feel a flutter by the rectum. How about now?

00:57:52

DODIE: No.

00:57:55

STEVEN SIEGEL, MD: Okay. Well, if this were -- what's that show that's so popular that my daughter watches all the time?

00:58:07

MALE VOICE: *Grey's Anatomy?*

STEVEN SIEGEL, MD: *Grey's Anatomy*, we would have had the heart transplanted by now, but we're still looking for the foramen. Frustrating, but we're not going to give up here. All right, we'll go one more time to the opposite side where she's already nice and numb. Try that again, the foramen from there. Fluoro again. That's S4 again. What I would do, I think, at some point here is take a look again from our AP view. Fluoro again. It just seems to be a little bit low in that foramen. And two. Maybe go a little higher. Let's try that. We're going to change the angle up a little bit. Take the numbing again. Here comes a sting. All right. Let's do fluoro, please. It's too low. Fluoro again. Well, you know, we've been having such poor responses, maybe we should just try [unintelligible]. Zero. All right. Hopefully we'll have some magic by the next few minutes. Nothing, though, huh? Let's just try and orient again.

01:00:14

KAREN NOBLETT, MD: Steve, there was a question of why you're using the lateral fluoro rather than the AP view.

01:00:20

STEVEN SIEGEL, MD: Well, in my experience it usually is pretty easy to determine the level of the foramina from the lateral view, which is S3 and which is S2. Let's take one more picture there. It seems like this is more oriented towards S2. Fluoro one more shot. So since I can't actually show you, you'll have to take as a matter of faith that this usually works out well. Let's see. You feeling any stimulation there?

01:00:55

DODIE: No.

01:00:56

STEVEN SIEGEL, MD: No.

DODIE: Well, no, I do in the vagina.

01:01:00

STEVEN SIEGEL, MD: You feel it in the vagina?

01:01:02

DODIE: Yes.

STEVEN SIEGEL, MD: And is it a flutter or a vibration or --

01:01:05

DODIE: Yes, yes.

01:01:07

STEVEN SIEGEL, MD: Is it comfortable?

DODIE: Yes.

01:01:10

STEVEN SIEGEL, MD: And what are you seeing as far as her [foot]. Anything?

01:01:15

DODIE: Yes, in the vagina.

01:01:18

STEVEN SIEGEL, MD: So she feels it vaginally, but we're not really having a good motor response. And what are you at now, Casey?

01:01:23

CASEY: Four.

01:01:25

STEVEN SIEGEL, MD: So the level is quite high. I'm going to try on the other side. So let's take a little bit more numbing.

01:01:33

DODIE: On the right side in the vagina.

01:01:35

STEVEN SIEGEL, MD: All right, here comes another sting. I don't know how much you feel that, but it looks like a little bit. All right. We'll try on the other side and try to go a little higher as well, see if you can identify it from there. Fluoro. That's right at that same level, zero. You feeling that one at all?

01:02:12

DODIE: Just the pain of it going in.

01:02:12

STEVEN SIEGEL, MD: That was uncomfortable, huh? But you didn't feel it in the vagina?

01:02:17

DODIE: No.

STEVEN SIEGEL, MD: Okay. All right, we're going to aim a little bit lower. Fluoro again. Same exact spot just about, which doesn't look perfect to me on that lateral picture, but let's take a look again. And you're not feeling it right, are you? Okay, let's try this side again. And if I stimulate here?

01:02:54

DODIE: Vagina.

STEVEN SIEGEL, MD: And it's comfortable?

01:02:57

DODIE: Yes, very.

01:02:58

STEVEN SIEGEL, MD: All right, very comfortable. Well, let's try this site one more time. Let's take the 15 blade again. So we're going to go through the same steps as far as introducing the lead. At least here we have a proper sensory response, and sometimes you have to go by sensor responses. There was a question earlier about why do it under sedation? Sometimes sensory responses are all that we have to go by, and if we don't have those, then we don't really have a target. So this is -- at least we have this opportunity. Fluoro again. And you can see that launch point about halfway through. Let's take our lead. And now we're going to aim the lead down to the foramen. And fluoro again. There we go. That's good.

01:04:06

DODIE: I felt that [unintelligible].

STEVEN SIEGEL, MD: You felt that. So you're feeling mechanical stimulation from the lead there, too. So that means we must be pretty close to the nerve. Let's go ahead and stimulate.

01:04:20

DODIE: I feel that in the vagina.

STEVEN SIEGEL, MD: You feel it [unintelligible] at all?

01:04:25

DODIE: Pardon?

01:04:27

STEVEN SIEGEL, MD: A little bit of a [winky] bellows here.

DODIE: On the right side.

01:04:30

STEVEN SIEGEL, MD: Not much. Okay, let's go to zero again. And then tell me when you start to feel that one.

01:04:37

DODIE: I feel it.

STEVEN SIEGEL, MD: In the vagina again?

DODIE: Right.

01:04:40

STEVEN SIEGEL, MD: Well, good. We're getting vaginal response. And [toe] zero again. All right. Do you feel that one?

01:04:49

DODIE: No.

STEVEN SIEGEL, MD: Go up a little higher.

01:04:52

DODIE: Yes.

STEVEN SIEGEL, MD: In the vagina again?

01:04:53

DODIE: Yes.

STEVEN SIEGEL, MD: Comfortable?

01:04:55

DODIE: Yeah.

STEVEN SIEGEL, MD: All right, I'm going to go ahead and deploy the lead. Even though we don't have great motor responses, we have sensory responses at low thresholds. And I'm going to deploy the lead by keeping the number two and number three electrodes straddling the bone table. So I'll use live fluoroscopy now. And I'm just going to insert the lead as I'm drawing back on this lead introducer sheath. And that leaves it just a tiny bit deeper than I might ordinarily like to leave it. And we've taken the stylet out and we have the lead in place. And now, you know, there might have been some movement during the positioning, so I'm going to retest starting at the most internal spot, which is the zero spot. Go ahead and tell me when you feel this one, Dodie.

01:05:38

DODIE: Right now.

STEVEN SIEGEL, MD: You do? And is it in the vagina again?

01:05:40

DODIE: Yes.

STEVEN SIEGEL, MD: And it's comfortable?

DODIE: Yes.

01:05:44

STEVEN SIEGEL, MD: So again, the sensory responses turn out to be the only thing I have to go by here, and she's giving us good responses. Vaginal, comfortable, and it's at a low threshold. Let's go to zero again. Here's the next site.

01:05:59

DODIE: Now.

STEVEN SIEGEL, MD: Now, okay. So once again. And it's vaginal?

DODIE: Yes.

STEVEN SIEGEL, MD: It's comfortable?

DODIE: Yes.

01:06:04

STEVEN SIEGEL, MD: Good. And let's go to the next site.

01:06:12

DODIE: Now.

STEVEN SIEGEL, MD: Now, so between 1 and 2. And it's zero. This is the last one. So we've tested all four sites. Do you feel that one yet?

01:06:25

DODIE: No.

STEVEN SIEGEL, MD: A little higher, then.

01:06:29

DODIE: Now.

STEVEN SIEGEL, MD: Okay. And you're seeing toe response on this? On, on. Not a good bellows, but a toe. So I'm happy with this. After all the struggle, we have a sensory response, we have a toe. So let's take a permanent image of this so that we have it for a radiographic record. And let's take one from the top. And then you can take off with your fluoro.

01:06:53

KAREN NOBLETT, MD: Okay, Steve. Thank you very much. I think we're going to have to wrap up the program, but excellent job. And I think it was a great demonstration of the therapy and technique. And I would agree with what your comments were about this therapy. Technically it's not a difficult procedure to do. The rate-limiting step is just really taking your time to find the right placement along the nerve root. And as you can see, with the persistence of Dr. Siegel, he was able to get an excellent response in all four electrodes. And again, I want to thank Dr. Siegel for an excellent program. I want to thank everybody for their questions. If we were not able to get to your questions by email, we will give you an email response -- within the next few days you will get a response from us. I want to thank you for tuning in, and good luck. And if there's any questions that you have in the future, please do not hesitate to contact the website or the phone number that was listed below. And again, the website is www.interstim.com. The phone number is 1-800-664-5111, extension 3150. Thanks again.

01:09:34

ANNOUNCER: This has been an InterStim Therapy implant for overactive bladder and urinary retention from United Hospital in St. Paul, Minnesota. OR-Live makes it easy for you to learn more. Just click on the "request information" button on your webcast screen and open the door to informed medical care.

01:10:17

[end of webcast]