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# Surgical technique for removal of tined lead for InterStim

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**Introduction:** We aimed to introduce our technique describing the removal of a chronic implanted tined-lead in patients with a sacral neuromodulator implant.

**Materials and methods:** We performed a retrospective review of patients who had chronic sacral neuromodulator (InterStim) implanted by a single surgeon from 2001 through 2015. This simple surgical technique was developed and successfully performed to remove the leads. Primary reasons for removal were elective due to poor symptoms control and failure to maintain response or lead migration. Patient demographics, indication for implantation, as well as installation and removal complications were recorded and analyzed.

**Results:** Twenty-five patients were included [mean age: 60.4 years (32-86), 17 females]. Primary indications for sacral nerve stimulation were overactive bladder in 16 (64%), mixed incontinence in 6 (24%), urinary retention in 2 (8%), and interstitial cystitis 3 (12%). Mean implant duration was 24.2 (0.5-90) months. The existing tined lead was removed and replaced in 11 (44%) patients while the remaining 14 (56%) underwent complete removal of the unit without subsequent replacement. Successful lead removal without complications was achieved in 24 (96%) patients.

**Conclusions:** This minimally invasive technique is a simple, safe, and effective method of removing chronic implanted tined leads en bloc.

**Key Words:** removal, tined lead, InterStim, sacral neuromodulation implant, overactive bladder, mixed incontinence, urinary retention, interstitial cystitis

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## Introduction

Sacral neuromodulation has become an accepted treatment for various types of lower urinary tract dysfunction and fecal incontinence. However, despite technologic advances in device implantation and a trial stimulation period, sacral neuromodulation still has a significant reoperation rate (33%-39%).<sup>1,2</sup> Although the safety and efficacy of sacral neuromodulation has been well demonstrated, tined leads often need to be replaced and are occasionally associated with minor complications. In one 11 year study, adverse events relating to the leads were found in 53% of the cohort with 66% and 34% of the events related

to the non-tined and tined lead, respectively.<sup>3</sup> Of the 104 patients enrolled in the study, 27.4% had lead replacement once, 4.9% had lead replacement twice, and 4.9% had lead replacement three times.<sup>3</sup> Other studies reported adverse events in 33% of patients who underwent lead replacement such as pain, loss of efficacy, and hematomas formation.<sup>2,4-7</sup> Performing magnetic resonance imaging (MRI) on patients with an implanted sacral nerve stimulator puts the patient at risk for several potential hazardous sequelae such as motion artifact, damage of implanted pulse generator (IPG) or heating of the leads, resulting in painful stimulation and device malfunction.

Our objective was to review a single surgeon's 15-year experience with a minimally invasive technique for removal of chronic implanted tined leads, including the lead extension if symptoms are not sufficiently controlled, if the patient is experiencing adverse events excluding infection where removal is much easier due to frail inflamed tissues, or if the patient opts for removal.

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## Materials and methods

Following institutional review board (IRB) approval, a retrospective medical record review of patients with voiding dysfunction who had InterStim (Medtronic, Inc., Minneapolis, MN, USA) implanted for longer than 6 months was undertaken between 2001 and 2015 at two centers [Cleveland Clinic Florida (CCF) and University of California, Irvine Medical Center (UCIMC)]. The patients' medical records were reviewed for all procedures and follow up appointments relating to their InterStim device. Inclusion criteria comprised of patients undergoing revision or complete removal of their InterStim after at least 6 months from initial implant. Excluded were patients who had complications at the time of initial placement or their lead revision was based on an active infection.

## Results

A total of 25 patients (12 from CCF and 13 from UCIMC) were included in this study (mean age: 60.4 (32-86) years; 17 females). Primary indications for sacral nerve stimulation (SNS) are listed in Table 1. Mean implant duration was 24.2 (0.5-90) months. In 11 (44%) patients, the existing tined lead was removed and replaced, the remaining 14 patients (56%) underwent complete removal of the unit without subsequent replacement. Twenty-four (96%) underwent successful lead removal without complications.

The mean lead placement duration was 24.2 (0.5-90) months, 7 (28%) of whom had their lead placed for less than 12 months, 6 (24%) for 12-17 months, 3 (12%) for 18-23 months, and 9 (36%) for greater than 24 months.

A revision of the lead wire was performed in 12 (48%) patients secondary to migration (1), ineffectiveness (4), and complete replacement of IPG plus lead wire (1). Removal of the lead wire in 13 (52%) patients was secondary to pain at the site (3) and sharp pain "jolts" radiating to the leg (2). InterStim lead placement site was on the left lateral side of the S3 foramen in 15 (60%) patients and the right lateral side in 10 (40%).

**TABLE 1. Primary indication for InterStim stage II implant**

Indication	n (total 25)	%
Overactive bladder	14	56
Mixed urinary incontinence	6	24
Urinary retention	2	8
Interstitial cystitis	3	12

Upon revision, 5 (20%) patients had the lead moved to the opposite lateral side, with 3 patients reporting marked improvement in therapy. Twenty-four (96%) patients underwent successful lead removal using our surgical technique and the lead wire tip broke during the procedure in 1 (4%). There were no perioperative or postoperative complications in all 25 patients. One (5%) patient complained of pain in the buttocks from the IPG left implanted several months after the removal of the tined lead.

## Surgical technique

As described in the Interstim Therapy manual, Medtronic Inc. has developed two lead models, 3093 and 3889. Model 3093 has four equally 3 mm spaced 3 mm long electrodes at the distal end, numbered 0, 1, 2, and 3 starting at the tip. Model 3889 differs with electrode 2 being 10.2 mm long but continues with three 3 mm electrodes all spaced at 1.5 mm from the tip. Both models have a region with four tines spanning 15.5 mm. The start of the tined region is denoted by Marker Band A (spaced approximately 31 mm from electrode 0) and the end of the tined region denoted by Marker Band B. Additionally, there is Marker Band C and D, moving farther from the tip separated by varying lengths of insulated lead wire. Medtronic designed these markers to be an indication of lead depth during the percutaneous implantation process. The leads from Medtronic can come in several different lengths ranging from 20 cm to 60 cm in length.<sup>8</sup>

### *Patient preparation*

The patient is prepped in the normal sterile manner lying prone under general sedation.

### *IPG dissection*

It is easy to identify the site of the IPG from the scar of the previous procedure in the lower lumbar quadrants. After locating the site of the IPG, dissection is performed to remove it and the connecting wire is cut.

### *Locating the lead insertion*

By gently pulling on the distal end of the wire, a skin depression will occur more medially over the site of the percutaneous implant of the tined lead where it goes straight to S3 foramen.

### *Dissection to Marker Band B*

A 3 cm incision is made over the site of the greatest depression and dissection is carried out to find the lead. The distal end of the lead wire can now be pulled through to the new 3 cm incision. Dissection is then continued deep to the level of the fascia until Marker

Band B is reached. The lead wire should never be pulled with significant tension before Marker Band B, as the region between Markers B and C is very thinly insulated and will break with any tightness.

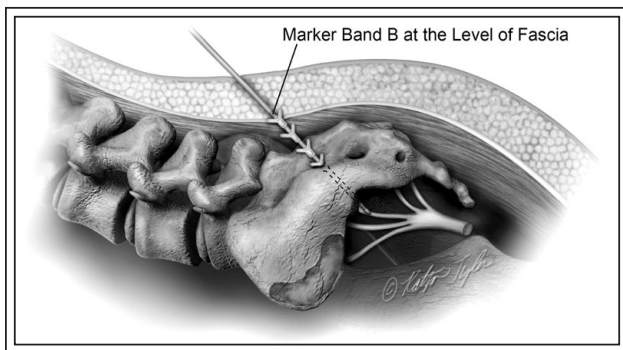
### Removal of lead wire

Using a right-angle clamp just below Marker Band B, a rocking motion with gentle traction will allow the fascia to separate from the tines without breaking the leads. As soon as Marker Band A is located, grabbing the lead wire below this mark will allow the remaining length of the lead wire to easily slide out.

This procedure requires only two incisions with approximately 40 to 60 minutes of surgical time. Blood loss is minimal and no special devices are required. The overall risk of complications related to device removal is low.

### Role in urologic practice

The InterStim device has been markedly improved, increasing its success in voiding disorders. The original lead placement involved a wide incision over the sacrum with deep dissection to expose the sacral foramen and insert the lead, which is fixed to the bone by bone-anchors. To improve the technical features of the lead, a self-anchoring tined lead was designed in 2002. The tined lead consists of four flexible, compliant tines that engage with muscle and subcutaneous tissue to reduce movement and/or dislodgement of the electrodes, Figure 1. Additionally, with the evolution of the device, the InterStim II added more programming capabilities and a smaller IPG.<sup>9</sup> Now a two-stage procedure, the first stage of testing could be carried out over the course of 14 days.<sup>2,3,9</sup> Further, what was once an open surgical procedure with general anesthesia, has now become a



**Figure 1.** This illustration shows the tined lead in relation to the subcutaneous tissues and thoracolumbar fascia. All efforts showed are made to expose marker B band, as it is the weakest point.

minimally invasive procedure with conscious sedation allowing for patient feedback on placement of the tined lead.<sup>9</sup> With this advancement, the success rate of testing in patients increased to greater than 80%.<sup>10</sup>

The new tined design of the lead better engages with subcutaneous tissue creating a strong bond with fibrotic tissue, and thus preventing lead migration. However, in patients who have had the device for a durable that requires a revision due to a nonfunctional device, removal of the lead creates a challenge for the surgeon. As such, lead wires implanted for long durations can become subject to fracturing upon revision or removal because of the fascia and scar tissue growing among the tines. Leaving behind a broken portion of the lead wire containing electrodes can potentially cause serious adverse events such as heating in patients requiring an MRI of the abdomen and/or pelvis.

### Conclusions

With the potential risks associated from an incomplete removal of the Interstim lead wire, it is paramount that the entirety of the lead wire is removed while also being as minimally invasive as possible with the patient. This technique is simple, short, and effective requiring only two small incisions yielding consistent positive results. □

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