A standardized surgical technique for removal of the Interstim tined lead

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Introduction: *Explantation of the Interstim sacral neuromodulation (SNM) device is occasionally necessary. Removing the tined lead can put strain on the lead, resulting in a possible break and retained fragments. The Food and Drug Administration (FDA) released a notification regarding health consequences related to retained lead fragments. We describe a novel and safe surgical technique for removing the Interstim device and permanent lead.*

Materials and methods: *We searched the Manufacturer and User Facility Device Experience (MAUDE) database for complications related to tined lead removal and searched the database of a single surgeon at our institution. Our standardized technique for tined lead removal is as follows. An incision is made over the previous lead insertion site and the lead is isolated and externalized. The fibrous encapsulation is dissected off the lead to expose the tines and ensure the lead is free from adhesions. The lead is removed by wrapping it around a curved hemostat and turning it under tension. If the lead breaks, the incision is extended and dissection is carried down to the sacral body to remove all fragments.*

Results: *Twenty-eight patients had their tined lead removed between 2009 and 2015 after being in place a median of 2.00 years (IQR 1.32-3.32 years). One lead broke (3.6%) during removal over the 6 years using our standardized approach.*

Conclusion: *Permanent tined leads can break on removal and retained fragments can pose significant health consequences. Our technique standardizes the approach for removal and is safe and effective in our series.*

Key Words: sacral neuromodulation, urinary incontinence, tined lead, retrained fragments, neuromodulation explantation

Introduction

Sacral neuromodulation (SNM) was first conceptualized in the 1970s by Schmidt et al[1] and first approved for use in humans by the Food and Drug Administration (FDA) in 1997. Interstim (Medtronic Inc., Minneapolis, MN, USA) is the only FDA approved device for use in SNM.[2] Prior to 2002, a permanent lead was implanted into the S3 foramen via an open surgical technique under direct visualization and secured to the sacral periosteum with a permanent suture.[3] In 2002, a new technique was introduced utilizing a tined lead and allowing for percutaneous placement into the foramen under fluoroscopic guidance without the need for a large incision.[4,5] Success rates are high with prior studies indicating close to 90% of patients having an improvement of ≥ 50% of symptoms.[6,7] Although SNM offers a treatment option for those who fail standard medical therapy, explantation or revision of the device is occasionally required, even years after initial placement. Reasons for explantation include infection, loss of efficacy, device damage, lead migration, seroma formation, discomfort, or the need for magnetic resonance imaging (MRI) for either cancer staging or for neurologic disorders.[8]

In January 2008, the FDA released a public health notification to healthcare practitioners warning of adverse events (AE) associated with unretrieved device fragments (UDFs).[9] Their notification reports that the Center for Devices and Radiological Health (CDRH) receives approximately 1000 AEs per year related to UDFs.[9] Specifically, the AEs related to UDFs include risk of migration during MRI, local tissue reaction, infection, viscus perforation, and even death.[9] Medtronic also issued a notification to practitioners regarding this problem highlighting the importance of proper technique in lead removal.[10]

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Removal of the permanent tined lead offers a unique problem as an inflammatory capsule forms around both the battery and lead, making it difficult to remove at times. Additionally, with the tined leads securely implanted, a large amount of force is sometimes required to remove the lead in its entirety. This tension can put strain on the lead resulting in a possible break and retained fragments. Herein we describe a novel and safe surgical technique which in our hands has been effective for removing the Interstim device and permanent lead. We hypothesize that with this standardized technique we can reduce the number of broken tined leads during removal.

Materials and methods

We first searched the Manufacturer and User Facility Device Experience (MAUDE) database for instances of lead removal complications to determine the extent of AEs associated with permanent tined lead removal. The MAUDE database is an FDA monitored site that is a publicly accessible database of self-reported medical device reports (MDRs) of device-associated deaths, serious injuries, or malfunctions. We searched the MAUDE database over a 12 month period (July 2014 to July 2015) by using the following query: Manufacturer: Medtronic, Brand Name: Interstim, Model: #3023/3889.

The above search prompted us to explore our rates of tined lead breakage using a standardized technique we developed for permanent tined lead removal at our institution. Our technique is as follows. The patient is administered monitored anesthesia care (MAC) and positioned prone. The previous battery site is identified and an incision is made over the prior incision site. The battery is identified, externalized, and a heavy scissors is used to cut the permanent lead. A hemostat is placed on the distal end of the lead to tag it and prevent retraction into the incision. Gentle tension is applied to the lead to expose the lead insertion site above the sacral foramen. A 1 cm vertical incision is made over the previous lead insertion site. Blunt dissection is used to dissect down to the lead and a curved hemostat is used to isolate the lead, which is then externalized through the incision. Blunt dissection with a curved hemostat is used to open the inflammatory capsule that surrounds the lead to expose it down to the level of the sacrum, free all adhesions, and visualize the tines, Figure 1. Weakening of the lead by clamping the hemostat or grasping it with the hemostat should be avoided as this can produce lead breakage at the point of weakness. Once the tines are visible, the lead is slowly removed by wrapping it around a curved hemostat and turning the hemostat under slow steady tension until it is removed in its entirety, Figure 2.

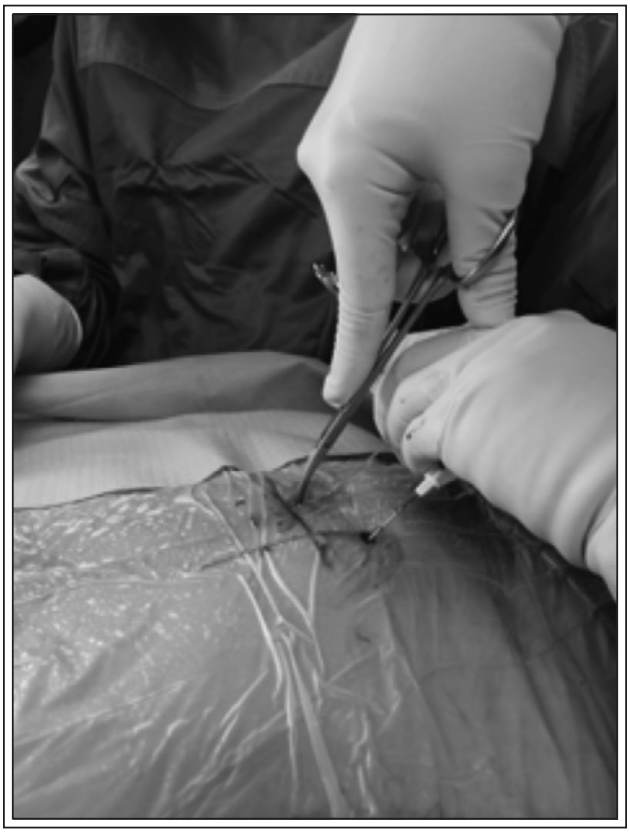

Figure 1. Deep dissection using a curved hemostat around the tined lead to remove the fibrous capsule and all adhesions. The use of small retractors may be necessary especially in obese patients.

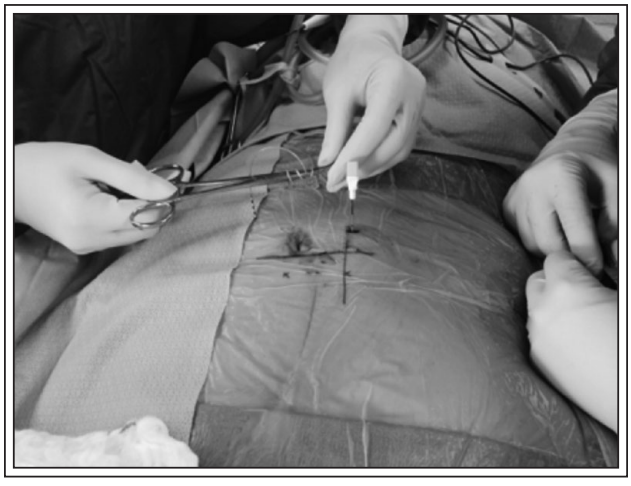

Figure 2. Wrapping the tined lead around a curved hemostat and removing it with a steady turning motion allows intact removal of the lead.

The lead should be inspected for complete removal, which can be confirmed by the presence of all four electrodes on the removed lead. Once removed, fluoroscopy can be utilized to confirm no portion of the old device is left in place; however this is optional. Both wounds are copiously irrigated and the skin is closed with an absorbable monofilament stitch. If the lead breaks on removal, the vertical incision is extended (approximately 3cm) and dissection is carried down to the sacral body. It is thus important to start out with a vertical incision in case it has to be extended to assist in dissecting out the lead. A small fixed retractor can be useful for improved exposure. Using blunt dissection and fluoroscopic guidance, lead fragments are identified and freed from surrounding adhesions. It may be necessary to enter the S3 foramen with a hemostat to grasp the lead fragments for complete removal. Of note, for permanent leads placed prior to 2002, the suture pledget must be released from the sacral periosteum.

We searched the surgical database of a single surgeon at our institution from 2009 to 2015 to identify cases where the permanent lead of the Interstim SNM was removed. We excluded patients who had their permanent lead removed in the trial period immediately following their stage 1 Interstim placement since these removals are not technically challenging due to lack of formed adhesions. We assessed the number of stage 1 and stage 2 leads placed at our institution as well as the number of stage 1 and stage 2 leads removed (both from patients that we initially placed the lead and those that were referred to us from an outside practice) to determine our explantation rates and lead breakage rates.

Results

From our search of the MAUDE database, we identified 299 MDRs and found 17 instances where the permanent lead broke upon attempted surgical removal, with 16 of these cases resulting in retained lead fragments. Several of these reports indicate specific complications with retained lead fragments including migration into surrounding tissue, erosion into adjacent boney structures, severe pain, and inability to obtain an MRI due to radiologist or urologist fears of lead complications associated with imaging.

We then explored the experience of a single surgeon between 2009 and 2015. We placed 123 stage 1 leads of which 99 (80.4%) went on to stage 2 placement. The other patients (n = 24) had unsatisfactory results with their stage 1 lead and had the lead removed in the immediate postoperative period. These patients (n = 24) were excluded from our analysis because removal within several weeks of placement is not technically challenging due to lack of formed adhesions. Instead, we focused only on those patients who went on to stage 2 SNM and had their permanent tined lead explanted as these removals are technically more difficult due to the formation of a fibrous encapsulation around the lead and battery site. After exclusion criteria, 29 patients were available for analysis. Patient characteristics can be found in Table 1. Fourteen (48.3%) of the stage 2 leads removed had been placed at our institution while 15 (51.7%) had their initial lead placed by another surgeon. Our explantation rate was thus 14.1% (14/99). The median time from initial placement to removal was 2.00 years (IQR 1.32 to 3.22 years). Mean age of our cohort was 56 ± 15 years old. Reasons for removal included failed SNM with return of symptoms (11/29, 37.9%), discomfort or pain (11/29, 37.9%), or the need for a MRI (7/29, 24.1%), Table 1.

During our first explantation, the lead broke resulting in retained fragments (all of which were subsequently removed). Following this initial episode, we standardized our technique, which is presented in this paper. Of the following 28 leads removed, 27 were removed intact (96.4%) and 1 broke on removal (3.6%). In that case, further dissection was undertaken and the broken fragments were removed successfully using dissection into the S3 foramen. The broken lead had been in place for 1.9 years and the body mass index (BMI) of the patient was 35.3. Mean BMI for our cohort was 30.0 ± 8.2 kg/m^2, Table 1. The suspected etiology of breakage was weakening of the lead by inadvertent clamping with the hemostat during dissection.

Discussion

Herein we present a novel and standardized surgical technique for removal of the Interstim permanent tined lead. During our first attempted tined lead removal the lead broke due to either weakening of the lead from inadvertent clamping of the lead with a hemostat or from poor technique. This prompted us to establish a standardized surgical approach for safer removal of the lead. Since standardizing our approach, only 1 lead has broken out of 28 attempts (3.6%). We believe that taking the extra time to dissect and completely free the lead from any adhesions all the way to the sacrum makes for safer removal. Additionally, wrapping the lead around a curved hemostat and slowly twisting it provides constant and firm tension on the lead and decreases the risk of lead fragmentation.

We feel a standardized approach for removal is important given that surgical re-intervention or explantation of the SNM is not uncommon. In a

TABLE 1. **Patient characteristics**

Patient	Sex (M/F)	Age	BMI	Reason for removal	Lead break (Y/N)
1	F	71	21.9	Failed	Y
2	F	53	22.1	Discomfort	N
3	F	51	25.4	MRI	N
4	F	36	25.9	Discomfort	N
5	F	29	24.4	Failed	N
6	F	21	31.6	Discomfort	N
7	F	67	37.6	Failed	N
8	F	53	23.0	Failed	N
9	F	72	15.4	Failed	N
10	F	61	33.0	MRI	N
11	F	54	39.5	Discomfort	N
12	F	62	44.9	Failed	N
13	M	45	26.4	Discomfort	N
14	F	58	51.2	Discomfort	N
15	F	66	26.9	Discomfort	N
16	F	63	27.1	MRI	N
17	F	62	21.3	MRI	N
18	M	72	36.8	Failed	N
19	F	28	26.6	Discomfort	N
20	F	66	37.8	MRI	N
21	F	56	28.3	Discomfort	N
22	F	67	41.8	Failed	N
23	M	70	35.3	Failed	Y
24	F	57	22.4	Failed	N
25	F	63	34.0	MRI	N
26	F	45	36.0	Failed	N
27	F	52	25.7	MRI	N
28	F	83	21.6	Discomfort	N
29	F	29	25.8	Discomfort	N

Failed = failure SNM with return of symptoms; Discomfort = discomfort or pain from the Interstim; MRI = need for a MRI

recent study by Peeters et al, 41% (n = 88) of patients required at least 1 surgical re-intervention with 26% (n = 39) of patients requiring device explantation.[11] A study by Al-zahrani et al assessed their 14 year experience with SNM and found a success rate of 84.8%, although a 20.8% explantation rate.[12] It should be noted that the tined lead was only used in 27.1% of their study population.[12] Prior studies have shown an explantation rate of approximately 9.8% to 14%.[8,13-17] Our experience is similar to the above reports with an explantation rate of 14.1%.

A recent educational brief issued by Medtronic highlights the issue of tined lead breakage during removal.[10] According to their brief, through 2010 a total of 45 reports of lead breaking during explantation occurred.[10] Although they report approximately 1% of explanted leads break,[10] it is important to note that their data is from spontaneous voluntary reporting only and we believe the rates of lead fragmentation are likely much higher. Over a 12 month period, we found 17 reported cases in the MAUDE database of a lead breaking during explantation. Although this

represents a small percentage of the overall self-reported MDRs over the course of 1 year, it shows that this is a more widespread problem than previously thought and one that requires a standardized technique for removal given the potential for complications.

According to the Medtronic educational brief,[10] the lead should be removed by providing gentle traction and pulling in a straight line from the lead introducer site and not from the neurostimulator battery pocket. They note that if the lead cannot be removed by gentle traction, dissection can be utilized to release the tines. Failure to remove the device properly may result in retained lead fragments and the potential for pain, fragment migration, MRI complications or inability to obtain an MRI, and revision surgery.[10] The complications of unrecognized retained lead fragments were also highlighted in a public health notification by the FDA in 2008[9] and in reports issued to the MAUDE database as highlighted in the introduction section of this paper. Examples in other fields highlight the necessity for removal of retained fragments. Martin et al reported that retained leads for cardiac implantable electronic devices can result in erosion through blood vessel walls and into adjacent structures, embolization, or fragment migration.[18] Although this example is different than retained lead fragments following SNM, it represents the potential complications of leaving retained metallic fragments behind.

Our study is limited by its retrospective design as well as the fact that this represents the experience of a single surgeon at a single tertiary care center. Thus, generalization to the broader population may be difficult and more prospective data is needed to elucidate how common this problem is and to determine whether this standardized surgical technique can be replicated by others. Even with these limitations, we feel a standardized technique for removal is important in improving the safety of this procedure.

Conclusion

We present a safe technique for the removal of an Interstim permanent lead. Although actual rates of leads breaking during removal are unknown since its reporting is voluntary, it is likely more common than previously stated. Overall lead breakage at our institution was 3.6% following standardization of our technique. The concern for retained lead fragments and the challenges of dissection of the fibrous capsule around the lead prompted our standardization of technique. □

References

1. Schmidt RA, Bruschini H, Tanagho EA. Sacral root stimulation in controlled micturition. Peripheral somatic neurotomy and stimulated voiding. *Invest Urol* 1979;17(2):130-134.
2. Gupta P, Ehlert MJ, Sirls LT, Peters KM. Percutaneous tibial nerve stimulation and sacral neurmodulation: an update. *Curr Urol Rep* 2015;16(2):4.
3. Marcelissen TA, Leong RK, de Bie RA, van Kerrebroeck PE, de Wachter SG. Long-term results of sacral neuromodulation with the tined lead procedure. *J Urol* 2010;184(5):1997-2000.
4. Spinelli M, Giardiello G, Gerber M, Arduini A, van den Hombergh U, Malaguti S. New sacral neuromodulation lead for percutaneous implantation using local anesthesia: description and first experience. *J Urol* 2003;170(5):1905-1907.
5. Spinelli M, Weil E, Ostardo E et al. New tined lead electrode in sacral neuromodulation: expe- rience from a multicentre European study. *World J Urol* 2005;23(3):225-229.
6. Wexner S, Coller J, Devroede et al. Sacral nerve stimulation for fecal incontinence: Results of a 120-patient prospective multicenter study. *Ann Surg* 2010;251(3):441-449.
7. Chughtai B, Sedrakyan A, Isaacs A, Lee R, Te A, Kaplan S. Long term safety of sacral nerve modulation in medicare beneficiaries. *Neurourol Urodyn* 2015:34(7):659-663.
8. Cameron AP, Anger JT, Madison R, Saigal CS, Clemens JQ. Urologic Diseases in America Project. Battery explantation after sacral neuromodulation in the Medicare population. *Neurourol Urodyn* 2013;32(3):238-241.
9. Schultz DG. FDA Public Health Notification: Unretrieved Device Fragments. January 2008.
10. Medtronic Educational Brief. Unretrieved Device Fragments Models 3093 and 3889 Interstim® Tined Leads: Tools for Safe Patient Management. December 2010. Minneapolis, MN.
11. Peeters K, Sahai A, De Ridder D, Van Der Aa F. Long-term follow-up of sacral neuromodulation for lower urinary tract dysfunction. *BJU Int* 2014;113(5):789-794.
12. Al-zahrani AA, Elzayat EA, Gajewski JB. Long-term outcome and surgical interventions after sacral neuromodulation implant for lower urinary tract symptoms: 14-year experience at 1 center. *J Urol* 2011;185(3):981-986.
13. Siegel SW, Catanzaro F, Dijkema HE 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;56(6 Suppl 1):87-91.
14. van Voskuilen AC, Oerlemans DJ, Weil EH, de Bie RA, van Kerrebroeck PE. Long term results of neuromodulation by sacral nerve stimulation for lower urinary tract symptoms: A retrospective single center study. *Eur Urol* 2006;49(2):366-372.
15. Sutherland SE, Lavers A, Carlson A, Holtz C, Kesha J, Siegel SW. Sacral nerve stimulation for voiding dysfunction: One institution's 11-year experience. *Neurourol Urodyn* 2007;26(1):19-28.
16. Janknegt RA, Hassouna MM, Siegel SW et al. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. *Eur Urol* 2001;39(1):101-106.
17. Hijaz A, Vasavada SP, Daneshgari F, Frinjari H, Goldman H, Rackley R. Complications and troubleshooting of two-stage sacral neuromodulation therapy: A single-institution experience. *Urology* 2006;68(3):533-537.
18. Martin A, Voss J, Shannon D, Ruygrok P, Lever N. Frequency and sequelae of retained implanted cardiac device material post heart transplantation. *Pacing Clin Electrophysiol* 2014;37(2):242-248.