# Adverse Events Associated With 10-kHz Dorsal Column Spinal Cord Stimulation

## *A 5-Year Analysis of the Manufacturer and User Facility Device Experience (MAUDE) Database*

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**Background:** High-frequency (10-kHz) spinal cord stimulation (SCS) continues to be an emerging therapy in chronic pain management. The same complications that plagued earlier SCS systems may affect newer stimulation technologies, although there is limited data on the type of complications and surgical management of these complications.

**Objective:** The aim of this study was to systematically examine real-world complications associated with 10-kHz SCS reported on the Manufacturer and User Facility Device Experience (MAUDE) database.

**Materials and Methods:** The MAUDE database was queried for entries reported between January 1, 2016 and December 31, 2020. Entries were classified into procedural complications, device-related complications, patient complaints, surgically managed complications, serious adverse events, and/or other complications. Primary outcomes included type and frequency of complications, and surgical management of complications.

**Results:** A total of 1651 entries were analyzed. Most entries were categorized as procedural complications (72.6%), followed by serious adverse events (10.5%), device-related complications (10.5%), and patient complaints (9.9%). Most complications were managed surgically with explant (50.9%) rather than revision (5.0%) or incision/drainage (6.6%). Of procedural complications, the most common entries included non-neuraxial infection (52.9%), new neurological symptoms (14.7%), and dural puncture (9.5%). Of device-related complications, the most common entries included lead damage (41.6%), erosion (18.5%), and difficult insertion (11.5%).

**Conclusion:** This retrospective 5-year analysis of complications from10-kHz SCS provides a real-world assessment of safety data unique for this stimulation modality. This analysis may help inform future clinical decisions, lead to device enhancement and optimization, and improve mitigation of risks to provide safe and efficacious use of 10-kHz SCS.

**Key Words:** spinal cord stimulation, high-frequency stimulation, clinical outcomes, adverse events

(*Clin J Pain* 2022;38:320–327)

Since its inception over 50 years ago, spinal cord stimulation (SCS) has experienced increasing clinical interest and has undoubtedly improved the lives of countless patients with chronic pain.[1] Level I studies have highlighted improved clinical outcomes with contemporary SCS paradigms,[2–6] which is evident with high-frequency, 10-kHz SCS (Nevro Corp., Redwood City, CA).[7] Unfortunately, the same device and procedural complications that plagued earlier SCS systems may affect the newer stimulation technologies, including 10-kHz SCS.[8,9]

The Manufacturer and User Facility Device Experience database (MAUDE) is an adverse event reporting system for medical devices. Device manufacturers and device user facilities are required to report any device malfunction and any suspected device-related serious injury or death. The MAUDE database has been used previously to describe complications associated with multiple chronic pain devices.[10–15] As such, it has become an important source of real-world information to analyze large cohorts of device-related complications. It is important to note that there are limitations to utilizing the MAUDE database as it is not intended to evaluate rates of adverse events (AEs) or to perform comparative analyses across different devices. Furthermore, a causal effect of complications is difficult to determine and the database may not represent all known safety information.

In this study, we analyzed the MAUDE database for complications of 10-kHz SCS and their respective surgical management, providing insights into risk mitigation and complication management of this novel stimulation system. While complications may be similar to other devices that deliver unique waveforms (eg, traditional, burst, etc.), the authors decided to select 10-kHz SCS to limit heterogeneity and

Received for publication August 16, 2021; revised November 6, 2021; accepted December 17, 2021.

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J.M.H. is a consultant for Abbott, Boston Scientific, Nevro, and Speranza Therapeutics. The remaining authors declare no conflict of interest.

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Supplemental Digital Content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website, www.clinicalpain.com.



DOI: 10.1097/AJP.0000000000001026

potential adverse effects that may be more frequent in other waveforms such as unwanted stimulation from traditional programming. Furthermore, this is the first study to analyze the MAUDE database for all complications related to dorsal column stimulation.[16] While several cross-sectional studies have analyzed complications related to SCS before,[17–20] they are smaller scale, are limited to mostly single-center data, and provide short-term data. The current study presents a robust sample size that captures complications from 10-kHz SCS at a national level and over a 5-year period.

## MATERIALS AND METHODS

### Protocol Development

We conducted a retrospective analysis of publicly reported complications for 10-kHz dorsal column SCS trials and implants. This study was deemed exempt by the Mayo Clinic Hospital Institutional Review Board (IRB). The protocol was developed a priori by 3 authors (R.S.D., O.O. O., J.M.H.).

### Data Source and Collection

The MAUDE database[21] contains adverse event reports submitted to the Food and Drug Administration (FDA) by mandatory reporters (eg, manufacturing companies, importing facilities, and device user facilities) as well as voluntary reporters (eg, health care providers and patients). This database is publicly accessible and provides reports from the last 10 years. We queried the MAUDE database[21] on June 1, 2021 for all events between January 1, 2016 and December 31, 2020 using the manufacturer search entry as "Nevro" and a product code of "LGW." This uniquely identifies dorsal column SCS devices that deliver 10-kHz stimulation.

We removed cases with identical event numbers and event descriptions. We combined entries that were part of a series. We excluded the following entries: (1) death from natural causes unrelated to SCS device, surgery, or anesthetic complications; (2) entries without enough information; and (3) entries reporting medical issues not related to SCS device, surgery, or anesthetic complications. For each entry, we abstracted the event date and report date, report number, event type, manufacturer narrative, and event description.

### Classification Scheme of Complications

Two authors (O.O.O. and J.M.H.) categorized each entry into one or more of the following major categories for complications: procedural complications, device-related complications, patient complaints, surgically managed complications, serious adverse events (SAEs), and other complications. Any discrepancies were adjudicated by a third author (R.S.D.).

We identified the following specific complication subcategories that classified into each major category:

(1) Procedural complication— surgical site infection (both non-neuraxial and neuraxial), new neurological symptoms, dural puncture, hematoma (both non-neuraxial and neuraxial), seroma, delayed wound healing, and wound dehiscence.
(2) Device-related complication—lead damage, erosion, difficult lead insertion/removal, lead migration, hardware malfunction, anchor damage, and reaction to device.
(3) Patient complaint—nonincisional pain, implantable pulse generator (IPG) site pain, unwanted stimulation, headache, loss of efficacy, midline incision pain, and other rarer symptoms complaints (dyspnea, pruritus, skin reaction to device, diarrhea, tinnitus, and twitching).
(4) SAEs: epidural abscess, meningitis, seizure, asystole/cardiac arrest, stroke, death, neuraxial hematoma, admission to a long-term rehabilitation facility, deep vein thrombosis, and laminectomy/decompression surgery.
(5) Surgically managed complication—a revision, an explant, incision and drainage (I&D), and debridement.
(6) Other—all entries that did not classify into one of the above major categories.

The definitions for each complication are provided in Supplemental Table 1 (Supplemental Digital Content 1, http://links.lww.com/CJP/A854). If multiple complications were reported for the same episode, then we reported these as separate complications for the same episode. As an illustrative example, if both anchor damage and lead migration were reported in the same episode, then the authors recorded this as 2 separate "procedural complications" that occurred separately during the same episode. As another illustrative example, if a patient experienced an epidural abscess requiring emergent decompression/laminectomy and explant of device, the authors reported this as a procedural complication (infection), surgically managed complication (explant), and 2 SAEs (epidural abscess, laminectomy/decompression surgery).

### Primary Outcome—Type and Frequency of Complications

The primary outcome was type of complication. Descriptive statistics presented the frequency and percentage of complications based on major categories (procedural complications, device-related complications, SAEs, patient complaint, and surgically managed complications). To further inform this primary outcome with more detail, the specific subcategories that comprised each of these major categories were reported.

### Primary Outcome—Surgical Management of Complications

Another primary outcome was the type of surgical intervention performed to address each specific complication. The specific complications that may be addressed with a surgical intervention included certain procedural complications (infection, new neurological symptoms, hematoma, seroma, delayed wound healing, and dehiscence) and device-related complications (lead damage, erosion, lead migration, hardware malfunction, reaction to device, and anchor damage). The type of surgical intervention included: explant, revision, I&D, or debridement. For the complication of infection, "antibiotics only" was also reported as a treatment option.

### Secondary Outcomes

Authors R.S.D. and C.S.B. independently assigned SAEs into subcategories of "related," "possibly related," or "unrelated" to the SCS procedure or device. Any discrepancies were adjudicated by a third author (J.M.H.). In addition, anesthesia and perioperative medical complications that were unrelated to the SCS procedure or device were also reported.

### Data Analysis

Frequencies and percentages (of total episodes) are reported for outcomes of interest. We report inter-rater

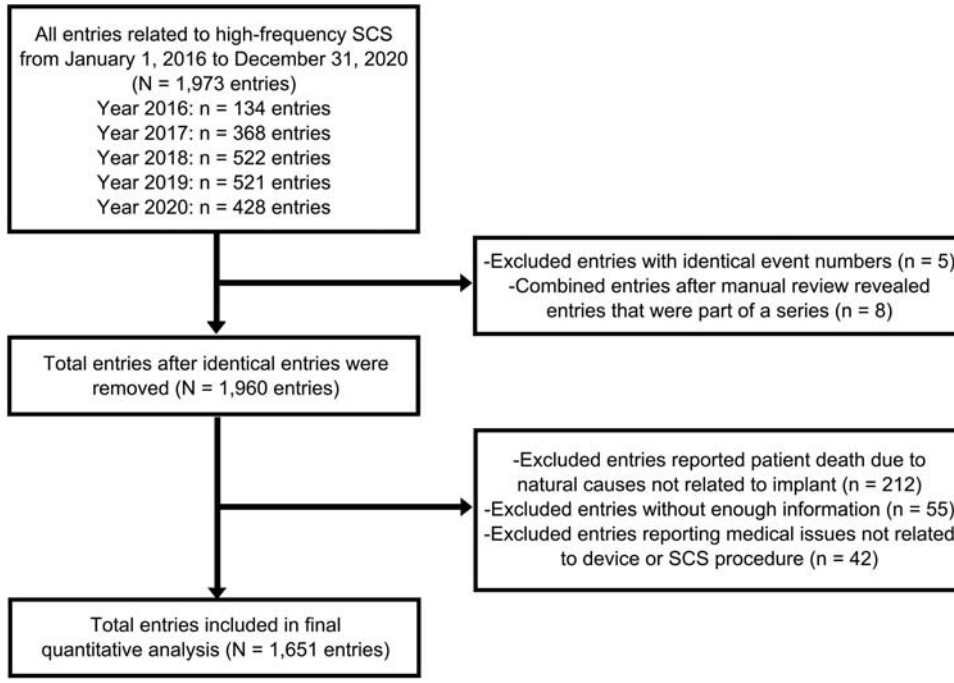


**FIGURE 1.** CONSORT flow diagram of Manufacturer and User Facility Device Experience (MAUDE) database. CONSORT indicates Consolidated Standards of Reporting Trials.

variability by reporting the kappa statistic. All calculations were performed using SPSS (IBM SPSS Statistics for Windows, Version 21.0; IBM Corp., Armonk, NY).

## RESULTS

### MAUDE Entry Selection

A total of 1973 entries were identified from January 1, 2016 to December 31, 2020. After removal of duplicate entries and entries meeting exclusion criteria, we identified 1651 unique episodes which were included in our final quantitative analysis (Fig. 1). Kappa score for categorization of entries was 0.925, indicating very strong inter-rater agreement.

### Type and Frequency of Complications

A majority of entries were procedural complications (72.6%), followed by SAEs (10.5%), device-related complications (10.5%), and patient complaints (9.9%) (Fig. 2). A majority of complications were managed surgically (Fig. 2) with explant (50.9%) rather than revision (5.0%) or I&D (6.6%).

Among procedural complications, non-neuraxial infection, new neurological symptoms, and dural puncture were the most common, being reported 634 (52.9%), 176 (14.7%), and 114 (9.5%) times, respectively (Fig. 3). Other procedural complications included: 86 reports (7.2%) of non-neuraxial hematoma, 60 (5.0%) of seroma, 54 (4.5%) of delayed wound healing, 47 (3.9%) of neuraxial hematoma, 18 (1.5%) of wound dehiscence, and 9 (0.8%) of neuraxial infection (meningitis or epidural abscess). Device-related complications included 72 cases (41.6%) of lead damage, 32 (18.5%) of erosion, 20 (11.5%) of difficult lead insertions, 14 (8.1%) of migration, 12 (6.9%) of hardware malfunction, 11 (6.4%) of anchor damage, 7 (4.0%) of reactions to the device, and 5 (2.9%) of difficult lead removal. Among patient complaints, nonincisional pain, IPG pain, and unwanted stimulation were the most common, being reported 83 (50.6%), 31 (18.9%), and 17 (10.4%) times, respectively. Other less frequent patient complaints are presented in Figure 3.

### Surgical Management of Procedural Complications

We reported how procedural complications were managed in Figure 4 and Supplemental Table 2 (Supplemental Digital Content 2, http://links.lww.com/CJP/A855). Non-neuraxial infections mainly involved device explant in 68.8% of cases, although a large number of cases (23.5%) were managed with antibiotics only. Cases of neuraxial infection consisted of meningitis (n = 5) and epidural abscess

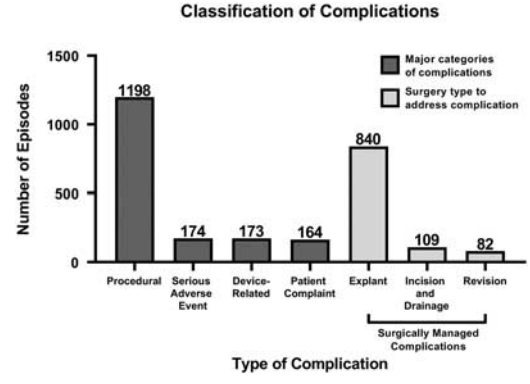


**FIGURE 2.** Classification of complications. If an episode included multiple complications that fit into separate categories, it was reported as an episode in both categories.

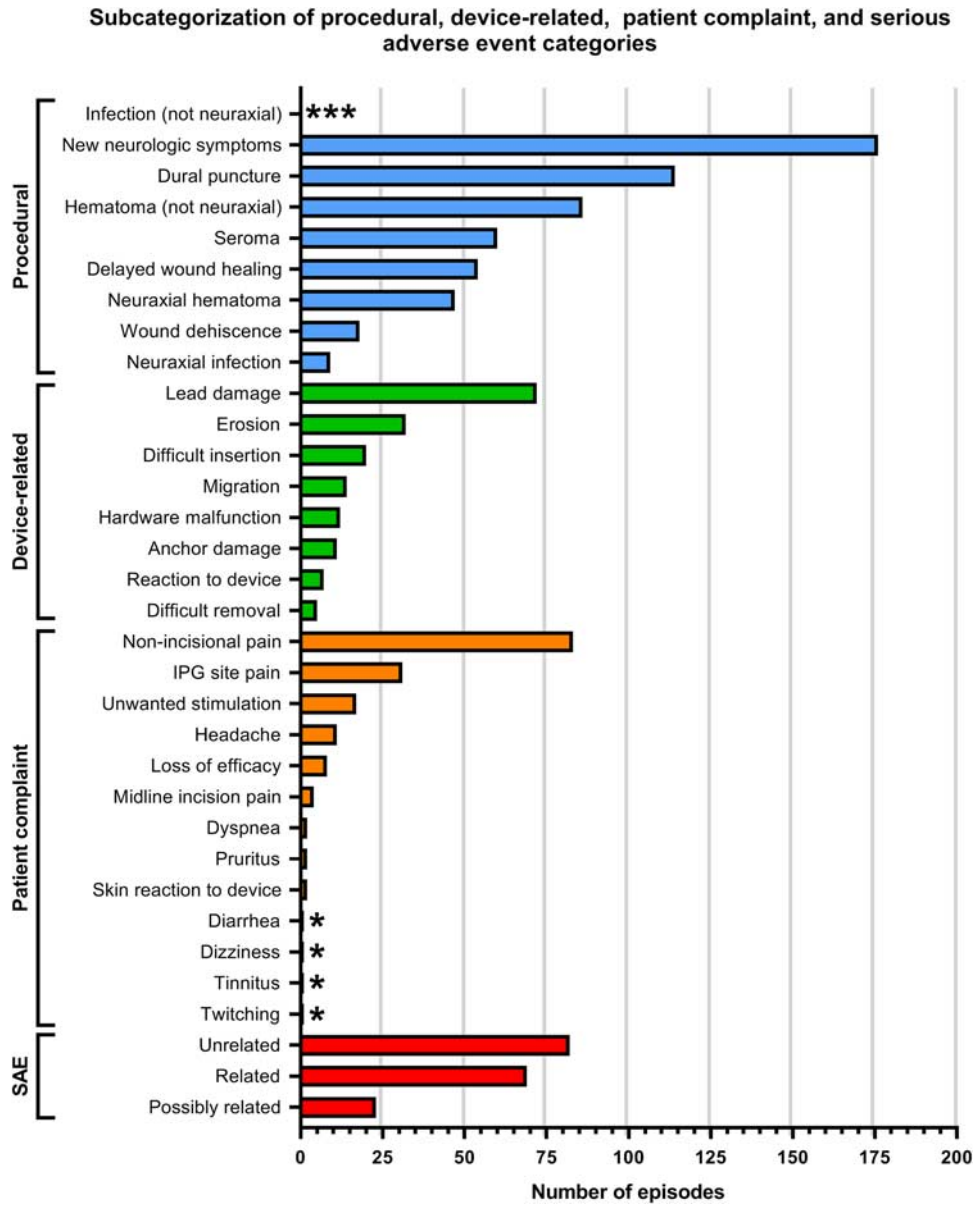


**FIGURE 3.** Subcategorization of procedural, device-related, patient complaint, and serious adverse event categories. If an episode included multiple complications that fit into separate subcategories, it was reported as an episode in both subcategories. IPG indicates implantable pulse generator; SAEs, serious adverse events. *There was one episode each for these categories. ***To allow for appropriate scaling and sizing of graph, we omitted the "infection (not neuraxial)" column as the number of episodes was high (634 episodes).

(n = 4). All 5 episodes of meningitis were managed with device explant. Two cases of epidural abscess involved device explant, 1 was treated with abscess drainage, and 1 was treated with antibiotics only. Similarly, new neurological symptoms were mostly managed with device explant in 56.8% of cases, although many cases were self-limited and managed conservatively (40.3%). Dural puncture was treated with epidural blood patch in most cases (57.0%), but less frequent interventions included direct suture of dural tear (6.1%) and application of surgical glue (3.5%).

Management of fluid collections, including hematoma and seroma, was variable. In non-neuraxial hematoma, explant and I&D were most frequently performed in 45.3% and 34.9% of cases, respectively, although 15.1% of cases resolved without any surgical intervention. Similarly, seromas were managed surgically with I&D, explant, or revision in 68.3%, 18.3%, and 1.7% of cases, respectively. However, 11.7% of seroma cases resolved without surgical intervention. On the contrary, all cases of neuraxial hematoma involved surgical intervention, including device explant, I&D, or revision in 93.6%, 4.2%, and 2.1% of cases, respectively.

Finally, abnormalities in wound healing such as delayed wound healing and wound dehiscence were managed similarly. In delayed wound healing, device explant or revision was performed in 66.7% and 9.2% of cases, respectively, and conservative care was offered in 14.8% of cases. All cases of wound dehiscence were addressed surgically including device explant in 66.7% of cases and revision in 33.3% of cases.

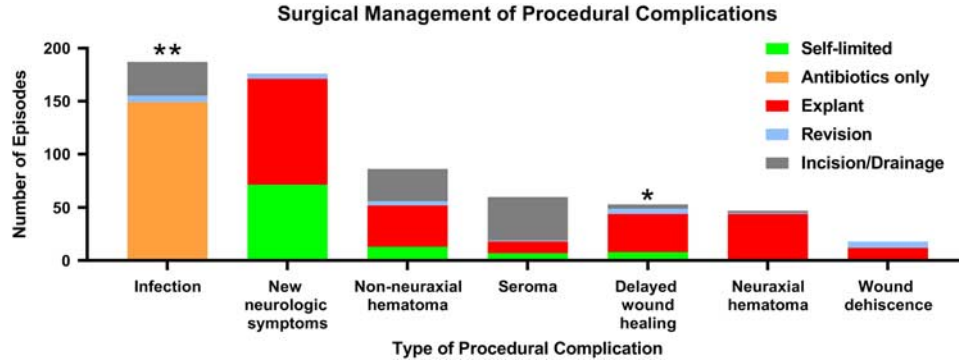


**FIGURE 4.** Surgical management of procedural complications. Types of surgical management options and their frequencies are displayed for each type of procedural complication. The procedural complication of dural puncture was omitted from this bar graph as the management options for this are distinct compared with the procedural complications listed above. *Debridement is not shown (n = 1 episode). **To allow for appropriate scaling and sizing of bar graph, we omitted "Explant" from the "Infection" column as the number of explant episodes was high (436 explants). Within the neuraxial infection category (not shown), 5 episodes were cases of meningitis which led to device explant. Four episodes were cases of epidural abscess, of which 2 cases involved device explant, 1 was treated with abscess drainage, and 1 was treated with antibiotics only. Insufficient information was available to categorize 20 cases in the infection category.

## Surgical Management of Device-related Complications

We reported how device-related complications were managed in Figure 5 and Supplemental Table 3 (Supplemental Digital Content 3, http://links.lww.com/CJP/A856). Lead damage was managed with lead revision/replacement in 37.5% of cases. No surgical intervention was pursued in 37.5% of cases; in these cases, the proceduralist chose to leave the damaged lead or lead fragment in place. Many episodes of lead damage occurred during lead insertion or removal (18.0% of cases) and all of these episodes were addressed with lead replacement.

All cases of erosion were addressed surgically with device explant, revision, or I&D in 81.2%, 15.6%, and 3.1% of cases, respectively. Lead migration was mainly addressed surgically with explant or revision in 42.8% and 26.6% of cases, respectively, although migration was also self-limited in 28.6% of cases. Interestingly, most cases of hardware malfunction were self-limited in 91.7% of cases, and only 1 case led to device explant (8.3%). All cases of anchor damage were managed surgically with device explant or revision in 81.8% and 18.2% of cases, respectively. All cases of reaction to device were explanted.

## Secondary Outcomes

Anesthetic and perioperative complications unrelated to the SCS device or procedure are reported in Supplemental Table 4 (Supplemental Digital Content 4, http://links.lww.com/CJP/A857). Secondary analysis of SAEs showed 82 unrelated, 69 related, and 23 possibly related SAEs (Fig. 3). Specific episodes of SAEs are described in Supplemental Table 5 (Supplemental Digital Content 5, http://links.lww.com/CJP/A858).

# DISCUSSION

This retrospective analysis described complications from 10-kHz dorsal column SCS over a 5-year period (2016 to 2020), amounting to 1651 unique episodes of complications after de-duplication. A main finding was that the most frequent complication was procedural in 72.6% of cases, which was about 7 times more frequent than device-related complications, patient complaints, or SAEs. This is contrary to current evidence, which demonstrates that device-related complications outnumber biological complications such as infection and hematoma.[9,17,22,23] This observation suggests that most complications may be preventable based on

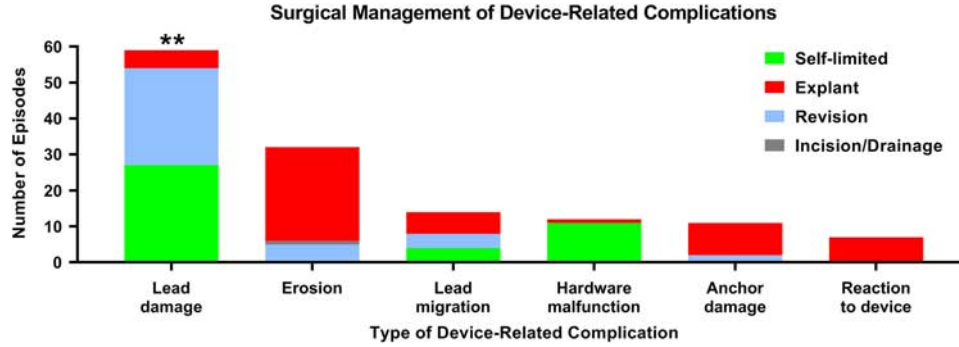


**FIGURE 5.** Surgical management of device-related complications. **For the "lead damage" category, there were 13 episodes that occurred from lead removal or insertion during spinal cord stimulation placement. Since these leads were all removed from the patient (and did not require an additional surgical intervention), it was not included in this bar graph.



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optimizing surgical, provider, and patient-related factors. For instance, infection risk may depend on provider technique (adherence to sterile technique, following accepted antibiotic prophylaxis guidelines, use of antimicrobial pouch) as well as optimization of patient-related factors (addressing immunosuppression, optimizing certain comorbidities like diabetes, etc.). However, the authors acknowledge that certain procedural complications may be device-related. For instance, the complication of dural puncture is coded as a procedural complication, although certain device features such as the rigidity of the SCS lead or the tip design of the Tuohy needle may affect risk of dural puncture.[24,25]

The most commonly reported overall complication was non-neuraxial infection. This is contrary to the existing evidence that reports lead migration with loss of efficacy being the most common complication ranging from 8.5% to 21.0% of cases, and a recent study reporting lead migration without loss of efficacy in 88.5% of cases.[18,22] Another MAUDE database study on dorsal root ganglion stimulation stated that infection was a frequently reported complication, although it was less than a third of reported migration cases.[14] The authors believe that lead migration is an under-reported complication in the MAUDE database. First, with use of percutaneous SCS leads, the clinical significance of a single-lead migration may be inconsequential because 2 percutaneous leads are typically implanted for double coverage of the target level at the dorsal column. Another consideration is that paddle lead implants were also reported in this MAUDE database study and it is well-known that paddle lead implants experience lower rates of migration than percutaneous SCS leads.[26,27]

We also observed that lead damage was the most frequent device-related complication. Intrinsic defects in the manufacturing process, provider experience, and procedural factors may play a role. Recommendations[22,28,29] to reduce risk of lead damage for percutaneous SCS surgery include epidural access at a low angle through a paramedian approach, epidural entry near the median line to decrease risk for lateral lead movement and to provide more secure placement in the supraspinous ligament, anchor placement through the fascia to decrease kinking, epidural access at spinal segments with lower ranges of motion, inclusion of relief-strain loops, use of flexible silicone anchors and loose extension cables, and neutral patient positioning during surgery.

In our dataset, we noted more reports of SCS lead damage during lead insertion as opposed to during lead removal. Reasons for this may include acute bends during lead insertion particularly when placed through a curved Tuohy needle (Coudé needle), repetitive advancing and withdrawing of the SCS lead when attempting to achieve optimal placement, and rotation of the Tuohy needle while the lead is already through the needle tip causing the lead to be cut by the Tuohy needle tip. Reasons for lead damage during removal include purposeful cutting to facilitate removal, though this is certainly the minority of cases, and most broken SCS lead fragments during removal were inadvertent. A large portion of lead damage cases (37.5%) were managed conservatively by leaving the lead fragment in place likely because of lack of symptoms, thus avoiding the need for invasive laminectomy surgery.

We noted that nonincisional pain was the most frequent patient complaint. Potential reasons include inappropriate patient expectation of SCS efficacy, inadequate coverage of pain location from SCS, and irritation of nerve roots by SCS leads. IPG pain was the second most common patient complaint, which is not surprising as this is consistent with other studies analyzing SCS adverse event data.[8] Details on superficial closure technique (eg, suture, staples, surgical glue) were not provided, although a recent article highlighted no difference in incisional pain scores between a running suture closure versus a surgical staple closure in patients undergoing SCS implantation.[30]

Surgical management of complications was widely variable. For patients with non-neuraxial infection, a significant portion (23.3%) was treated with antibiotics alone. This percentage is similar to the percentage of dorsal root ganglion stimulation cases reported as superficial infection (20.2%) in another MAUDE study.[14] Per guidelines from the Neurostimulation Appropriateness Consensus Committee (NACC),[31] empiric antibiotics should be administered when infection is suspected with refinement as informed by culture and sensitivity. Antibiotic alone is reasonable for superficial infection at the IPG site. However, superficial infections may become complicated if it tracks along device components. If there is concern for a deep infection or infection involving SCS device hardware, it is recommended to remove all device components.[31] The authors believe that the high percentage of cases treated with antibiotics alone is an overestimation as many physicians often choose to explant because complications from infection can be catastrophic. It is possible that many cases of superficial infection treated with antibiotics alone were based on clinical history and physical examination as opposed to objective laboratory evidence (eg, culture, inflammatory markers, leukocytosis).

Finally, our analysis revealed that a significant portion of SAE were unrelated to device or procedural complications, and were instead related to pre-existing medical comorbidities. This is important because while greater emphasis is often placed on identifying an ideal surgical candidate based on clinical indication for surgery, it is easy to overlook comorbidities that place patients at high risk for perioperative SAE and anesthetic complications. A prospective, randomized, double-blind, crossover pilot study reported that SCS surgery is safe and feasible in patients with advanced heart failure.[32] However, there remains a paucity of data on perioperative nonsurgical complications in patients based on comorbidity indices undergoing SCS surgery and this is an area for future investigation.

Future studies should confirm the external validity of our findings to other SCS devices that deliver other unique waveforms such as tonic stimulation,[33,34] BurstDR stimulation (Abbott, Plano, TX),[35] and differential target multiplexed stimulation (Medtronic, Minneapolis, MN).[36] The high number of procedural complications is concerning and adherence to proper technique and optimizing surgical, provider, and patient-related factors may help to reduce these complications.[31,37,38] Efforts to encourage accurate reporting may involve education of pain providers regarding the MAUDE database and its role, as well as provider clarification to the manufacturer about complication details. Future enhancement of the MAUDE database may involve providing more details on how the manufacturer addressed complications, patient demographic and clinical information, and total number of cases performed to allow estimation of useful epidemiological data (eg, incidence).

Multiple limitations are notable. Categorization of complications was subject to author interpretation, but a high kappa score was noted ensuring strong inter-rater

agreement. The data may be incomplete and unverified, and complications may be over-reported or under-reported since submission to the database is not mandated by medicolegal oversight. Lastly, the complication rates reported in our study are based on what was available for review at the time of data collection. Given the database is updated monthly, future review may differ from our results. Finally, we do not provide any estimates of incidence as the MAUDE database is a passive surveillance system and cannot be used to provide details of how frequently the 10-kHz device was used. Passive surveillance systems may also be prone to incomplete, inaccurate, untimely, unverified, and biased data.[39]

## CONCLUSION

We presented a 5-year analysis of complications from 10-kHz SCS, demonstrating a real-world assessment of safety data unique for this modality of stimulation. Our study highlights that most reported complications were related to the actual procedure, instead of device-related complications, suggesting that many complications may be preventable. Surgical management for each complication was variable. The number of reported SAE was relatively low but non-negligible and highlights the need to evaluate patient comorbidity and illness burden before pursuing SCS surgery. While these findings need to be interpreted in the context of aforementioned limitations, they may help inform future clinical decisions, encourage device enhancement and optimization, and improve mitigation of risks to provide safe and efficacious 10-kHz SCS.

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