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The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation

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ABSTRACT

Introduction: The field of neurostimulation for the treatment of chronic pain is a rapidly developing area of medicine. Although neurostimulation therapies have advanced significantly as a result of technologic improvements, surgical planning, device placement, and postoperative care are of equal importance to optimize outcomes. This Neurostimulation Appropriateness Consensus Committee (NACC) project intends to provide evidence-based guidance for these often-overlooked areas of neurostimulation practice.

Materials and Methods: Authors were chosen based on their clinical expertise, familiarity with the peer-reviewed literature, research productivity, and contributions to the neuromodulation literature. Section leaders supervised literature searches of MEDLINE, BioMed Central, Current Contents Connect, Embase, International Pharmaceutical Abstracts, Web of Science, Google Scholar, and PubMed from the last NACC publication in 2017 to the present. Identified studies were graded using the United States Preventive Services Task Force criteria for evidence and certainty of net benefit. Recommendations are based on evidence strength and consensus when evidence was scant.

Results: This NACC project provides guidance on preoperative assessment, intraoperative techniques, and postoperative management in the form of consensus points with supportive evidence. These results are based on grade of evidence, strength of consensus, and expert opinion.

Conclusions: The NACC has given guidance for a surgical plan that encompasses the patient journey from the planning stage through the surgical experience and postoperative care. The overall recommendations are designed to improve efficacy and the safety of patients undergoing these neuromodulation procedures and are intended to apply throughout the international community.

Keywords: Best practices, consensus, neurostimulation, spinal cord stimulation, surgical technique

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INTRODUCTION

The placement of neurostimulation devices is a complex process initially involving patient selection, patient preparation, and surgical planning. After the decision to implant has been made, proper preparation includes careful preoperative assessment, anatomical planning, proper use of radiological guidance, appropriate needle and lead placement, best practices of surgical methods for implantation, and wound closure. Proper wound and other postimplant care is required for optimal outcome for the patient and further enhancing the safety and efficacy of current neuromodulation therapies. The International Neuromodulation Society (INS) and its consensus panel emphasize that training in surgical techniques should be obtained before initiating a spinal cord stimulation (SCS) implant practice and that simply reviewing a consensus document such as this is insufficient to provide adequate training. With this in mind, we discuss primarily the details and nuances of clinical practice that should be considered after such surgical training is acquired.

MATERIALS AND METHODS

Development Process

As part of its mission to improve patient care and access to advanced neuromodulation techniques, the INS formed the Neurostimulation Appropriateness Consensus Committee (NACC), consisting of INS members worldwide who were chosen for their clinical expertise, familiarity with the peer-reviewed literature, research productivity, and contributions to the neuromodulation literature. At regular intervals, NACC members have evaluated the level of current evidence in the peer-reviewed literature supporting specific practices, such as surgical technique(s), that have been identified as critical for improving efficacy and/or safety.

As a consensus guideline, this document provides recommendations regarding surgical technique for neuromodulation procedures. These recommendations, however, should not be construed as defining standard of care but rather to represent best clinical practice. This guidance is based on several factors including peer-reviewed evidence and, regardless of the strength of evidence, requires interpretation for best clinical application.

Literature Search Methods

Section leaders supervised literature searches to identify relevant articles published since the publication of the previous NACC articles; this article is an update of the NACC process. MEDLINE, BioMed Central, Current Contents Connect, Embase, International Pharmaceutical Abstracts, Web of Science, Google Scholar, and PubMed databases were searched. Individual sections were drafted after reviewing the literature, and the entire manuscript was compiled and edited. Consensus points were developed based on the evidence and consensus among committee members and senior reviewers. Supporting literature was cited following these recommendations and discussions.

Quality Assessment, Evidence Ranking, and Level of Certainty

Identified peer-reviewed literature was critiqued using the United States Preventive Services Task Force (USPSTF) criteria for quality of evidence,[1] with modifications for neuromodulation studies (Table 1). After USPSTF letter grading was assigned, the working subgroup then assigned the "level of certainty regarding benefit" as described in Table 2.

For each major topic, the NACC formulated points of consensus. Consensus point summaries for each major section should not be confused with recommendations based on consensus alone, which was used only in those areas lacking evidence-based literature (such as randomized controlled trials [RCTs], prospective observational studies, and/or retrospective cohort/case series).

Rankings from other organizations, such as the Centers for Disease Control and Prevention (CDC)[2] and the World Health Organization (WHO),[3] are included for recommendations regarding surgical site infections (SSIs).

Management of Conflict of Interest

The INS conflict of interest policy relative to the production of guideline documents determined the disclosure process. This policy requires that the first and primary author be without conflict of interest and that at least half of the authors have no financial conflict interest as well (https://onlinelibrary.wiley.com/page/journal/15251403/homepage/ForAuthors.html#cofi). Furthermore, all authors were asked to recuse themselves on any recommendation that is affected by a disclosed conflict of interest. Additionally, authors without conflict of interest vetted all recommendations for bias.

Table 1. Quality of Evidence Ranking Using USPSTF Grade.

Grade	Definition	Suggestions for practice
A	The NACC recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The NACC recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The NACC recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The NACC recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I (insufficient) statement	The NACC concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF recommendation statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Table 2. Levels of Certainty Regarding Net Benefit.

Level of certainty	Description
High	The available evidence includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. Evidence Level: IA—At least one controlled and randomized clinical trial, properly designed
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: • The no., size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. Evidence Level IB—Well-designed, controlled, nonrandomized clinical trials (prospective observational studies conforming to STROBE criteria) or Evidence Level IC—Retrospective cohort or large case studies (>20 participants)
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited no. or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • Lack of information on important health outcome Evidence Level II—Expert opinion based on risk: benefit or based on case reports

The recommendation of grade (A–I) and level of certainty (high level I, moderate level II [1–3], or low level II) is then assigned. For each major section or topic, the NACC developed consensus points. Consensus point summaries for each major section should not be confused with consensus-based recommendations that are rendered as clinical guidance because of the lack of evidence-based literature (RCTs, prospective observational studies, retrospective cohort/case series).
STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

PREOPERATIVE ASSESSMENT

It is imperative that the implanting team create a plan that will optimize the safety and efficacy of the neurostimulation procedure. To establish this patient workflow, the NACC recommends creating a checklist to assure the uniform treatment of implant cases. A preoperative checklist assists the clinical staff in preparing for neurostimulation procedures (Table 3). The WHO has also published a widely used checklist.[5]

Preoperative Education and Planning

Patient education helps set realistic expectations for SCS therapy and helps engage the patient, family, and caregivers. A discussion of the intended procedure should address treatment alternatives and expectations, description of the procedure, neurostimulator components, the goals of therapy, the possible risks and complications, possible positive and negative outcomes, cosmetic desire of the patient, and the importance of follow-up care. A written list of preoperative patient responsibilities can reinforce verbal instructions. This list may cover the date, time, and location for the procedure and reminders to obtain previous imaging studies, to require the patient to stop specific medications before the implant, to call to cancel the procedure should the patient become ill or choose not to undergo the procedure, to bathe with appropriate cleansing product before surgery, and to arrange for transportation to and from the surgical location.

Preoperative planning should also include decision making regarding implantable pulse generator (IPG) placement because it relates to cosmesis, bony landmarks, body shape, patient's dominant hand, where the patient wears his or her clothing, and joint mobility (Fig. 1). The use of a rechargeable vs nonrechargeable battery, if available, should be discussed as should the use of a conditionally magnetic resonance imaging (MRI)-compatible device. The clinician should be alert for risk factors, such as preexisting surgical scars; diabetes, whether poorly or well controlled; smoking; active infections; noncompliance; and psychologic issues.

Perioperative Preparation

Before implanting a device, the physician should consider the amount of anatomical space within the epidural space required for the lead or leads (Fig. 2). Preoperative and intraoperative imaging can reveal the regional and individual differences in spinal anatomy that affect the choice of the entry level and lead and IPG placement (Fig. 2b,c). Preoperative images should be examined carefully for changes that could complicate or impede lead placement, especially because skin entry is often as much as two levels below spinal entry. Patients with lumbar or cervical spinal stenosis may have asymptomatic thoracic spinal stenosis as well. In awake patients for whom a percutaneous lead placement is planned, the ability to assess the patient's response during the implant procedure is essential. In cases where the clinician is unable to converse with the patient or where concerns about spinal stenosis exist, the clinician should order an appropriate imaging study to assess spinal diameter before implantation of either the trial or permanent lead (Fig. 2a). Imaging options are MRI, computed tomography (CT), and CT myelogram. If no cerebrospinal fluid (CSF) can be seen around

Table 3. Preoperative Checklist.

Procedure checklist

Preoperative medical issues
- __Check for evidence of active or potential dermal, dental, urologic, or other infections and treat as necessary.
- __Order urinalysis before procedure. Coordinate with clinical signs and symptoms.
- __Address previous history of infection and make a plan for prophylaxis adjustment.
- __Review MRI of the spine in the past 12 mo depending on diagnosis and planned placement of stimulator tip.
- __Discontinue anticoagulation with approval of treating physician for a length of time before procedure that is appropriate for the specific anticoagulant and surgical bleeding risk. The appropriate timing for discontinuation should be based on the medication half-life and whether the patient is taking the medication for primary or secondary prevention. Consider ASRA guidelines for medication management.[4]
  - Off nonsteroidal anti-inflammatory drugs for one week if desired
  - Off acetylsalicylic acid for seven d
  - Off warfarin or fondaparinux for five d, clopidogrel for seven to ten d, and ticlopidine for 10 to 14 d
- __If patient was on warfarin, order prothrombin time testing on or before the morning of the procedure.
- __Review psychological evaluation and address any recommendations.
- __Examine the potential sites of implantation and battery pocket for infection or inflammatory process.
- __If there are any potential technical or patient-specific concerns, communicate with the treating physician and/or the anesthesiologist before implant.
- __Educate the patient/caregiver(s).
- __Obtain insurance coverage and document medical necessity.

Surgical considerations
- __Assess health status the day of surgery.
- __Have patient empty bladder preoperatively.
- __Consider COVID-19 testing based on local health care policy recommendations.
- __Obtain baseline pain score and review overall goals of the implant.
- __Review postoperative instruction sheet with patient/caregiver preoperatively.
- __Check that adult driver has been arranged to take patient home.
- __Order preoperative antibiotics and administer 30 to 60 min before incision or within two hours for vancomycin. Antibiotic doses should be based on the patient's weight.
- __Arrange for family to observe programming and learn about recharging.
- __Confirm follow-up appointment before discharge.
- __Answer any questions from the patient or caregivers regarding postoperative wound management.

the cord on the MRI or CT, an implant should not be done without previous surgical decompression of the stenosis (Figs. 2–4). This guidance does not apply to paddle leads.

Preoperative Practices

The three major types of infections related to SCS implantation are superficial infections, deep infections, and epidural abscesses (Fig. 3). SSIs are associated with significant morbidity and costs; therefore, appropriate steps should be taken to limit SSIs when performing SCS implants. During the preoperative stage, focus should be on the recognition of known risk factors for the development of SSIs and ways to modify these factors. Patient risk factors associated with a higher likelihood of infection include altered immune response (eg, HIV/AIDS and corticosteroid use), diabetes, obesity, remote infection, tobacco use, and carriers of staphylococci.[6,7] Before surgery, all remote infections should be treated. In addition, glucose control should be optimized (CDC recommendation Category IA), and patients should be encouraged to discontinue tobacco use (CDC recommendation Category IB). When hair removal is required at the surgical site, it should be done with electrical clippers immediately before surgery (CDC recommendation Category 1A). Preoperative screening and decolonization for *Staphylococcus aureus* nasal carriers (both methicillin-sensitive and methicillin-resistant *S aureus*) with mupirocin nasal ointment and chlorhexidine soap have been reported to reduce the risk of hospital-associated *S aureus* infection.[8]

Regarding glucose control, consensus among surgical subspecialties has not been reached. The CDC recommends perioperative blood glucose levels <200 mg/dL in patients with and without diabetes.[2] When considering hemoglobin A1C, a higher incidence of postoperative complications has been reported in patients with levels ≥7%,[9] and the American Diabetes Association recommends levels <7% as an acceptable blood glucose target.[10] Other sources have recommended delaying surgery if levels are higher than a range of 8% to 9%.[11,12] In the immediate postoperative period, the American College of Surgeons recommends blood glucose levels between 110 and 150 mg/dL.[13]

Similar variability is reported in the published literature on perioperative recommendations for smoking cessation. The American College of Surgeons advocates for four to six weeks of smoking cessation before surgery, particularly in procedures involving implanted materials,[13] because a reduction in wound-related complications has been reported when patients quit four to eight weeks before surgery.[14,15] Beyond wound healing complications and elevated infection risks, researchers have found that tobacco users have worsened outcomes with SCS.[16] It is important to be aware of these risks, and physicians must be prepared to discuss smoking cessation because the SCS population has an estimated prevalence of smoking that is 2.5 times greater than that in the general population.[17]

Prophylactic antibiotic therapy (CDC recommendation Category IB) should be used and has been shown, in both animal and clinical studies, to reduce the risk of SSIs.[18–20] Furthermore, antibiotic prophylaxis has been shown to be an effective intervention for preventing postoperative wound infection, independent of surgery type, resulting in an approximately 50% reduction in the incidence of wound infections.[21] Multiple factors are involved in optimal antimicrobial prophylaxis, such as agent selection, timing and route of administration, duration, renal function, and appropriate dosing. Failure to optimize antimicrobial therapy has been shown to increase the risk of infection by two- to sixfold.[22] Intravenous antibiotics should be administered within one hour before surgical incision or within two hours before surgical incision with vancomycin. Although great emphasis has been placed on the appropriate timing of the administration of antibiotic prophylaxis before incision, weight-based dosing is another factor that plays a role in the efficacy of therapy. In order for antimicrobial prophylaxis to be effective in the prevention of SSIs, serum and tissue levels must exceed the minimum inhibitory concentration (MIC) for the organisms likely to be encountered during the operation.[23,24]

For antimicrobial prophylaxis in SCS cases, a single dose of a cephalosporin is recommended. The current preoperative dosing of

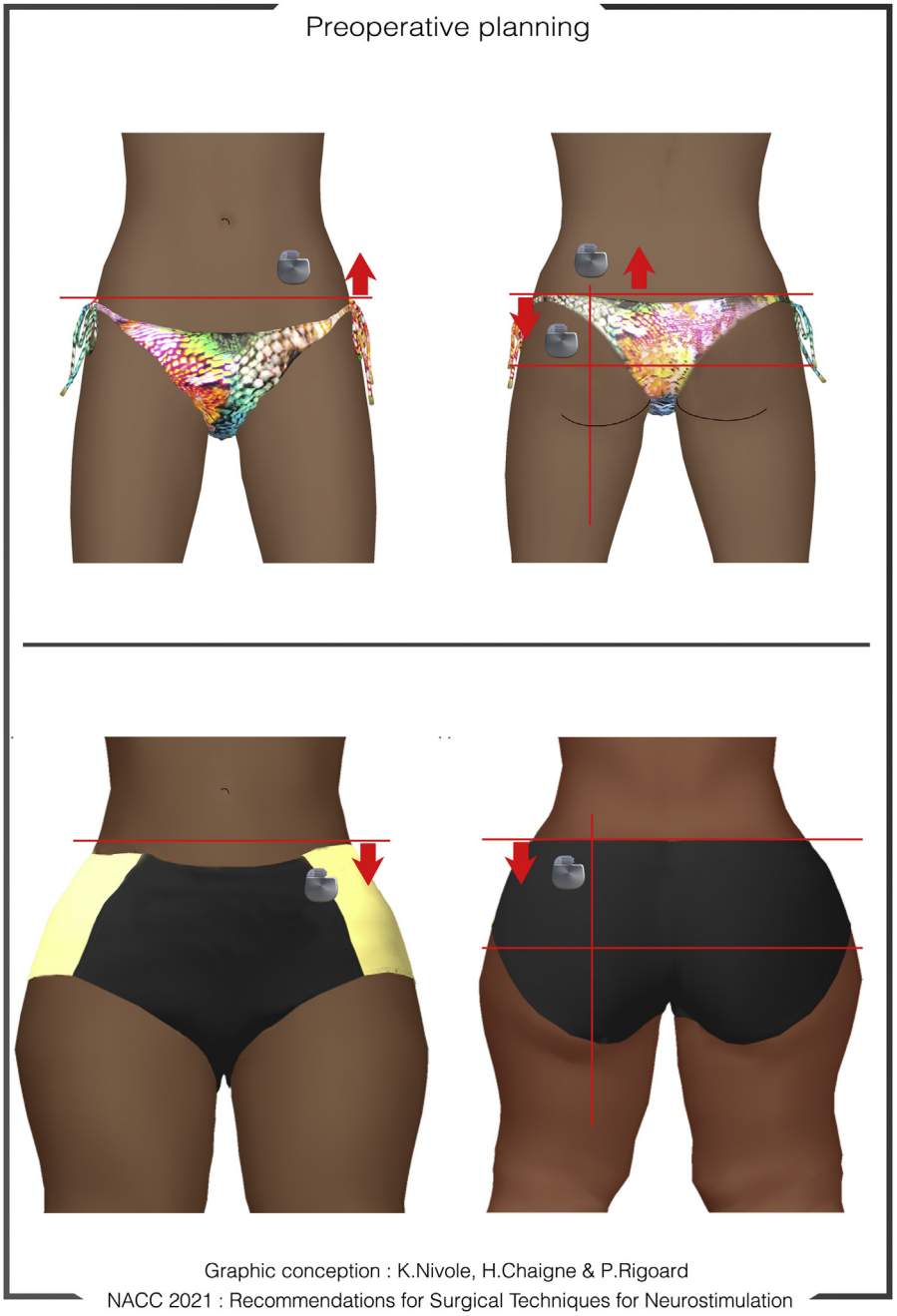

Figure 1. Preoperative planning. Patient morphology can influence the choice of IPG implantation site and should be considered before the implantation procedure. Photo courtesy of Philippe Rigoard and used with permission.

cefazolin, based on weight, is 1 g for individuals weighing <80 kg, 2 g for individuals 81 to 160 kg, and 3 g for individuals >160 kg.[23] For individuals with a beta-lactam allergy, clindamycin (600–900 mg based on weight) or vancomycin (1 g) may be used. Vancomycin should not be used routinely (CDC recommendation Category IB). Indications for vancomycin use include a beta-lactam allergy, methicillin-resistant *S aureus* (MRSA) colonization, institutionalized patients (nursing home, long-term care facilities, etc.), or if a surgical procedure is being performed in a facility with a recent outbreak of MRSA.[25] No advantages have been documented for post-SCS implantation antibiotic use.[26] In addition, in other surgical specialties, prolonged antibiotic use in the postoperative period has not been shown to improve outcomes, and in some studies, it has resulted in poor outcomes.[27,28]

Consensus Point 1. The NACC recommends pre/perioperative evaluation to include imaging of target zone based on clinical judgment and preprocedure planning of device placement based on anatomical, clinical, and patient preference considerations.

Recommendation grade A; level of certainty moderate; level of evidence IC.

Consensus Point 2. The NACC recommends preoperative antibiotic usage based on criteria outlined in detail in the text. The

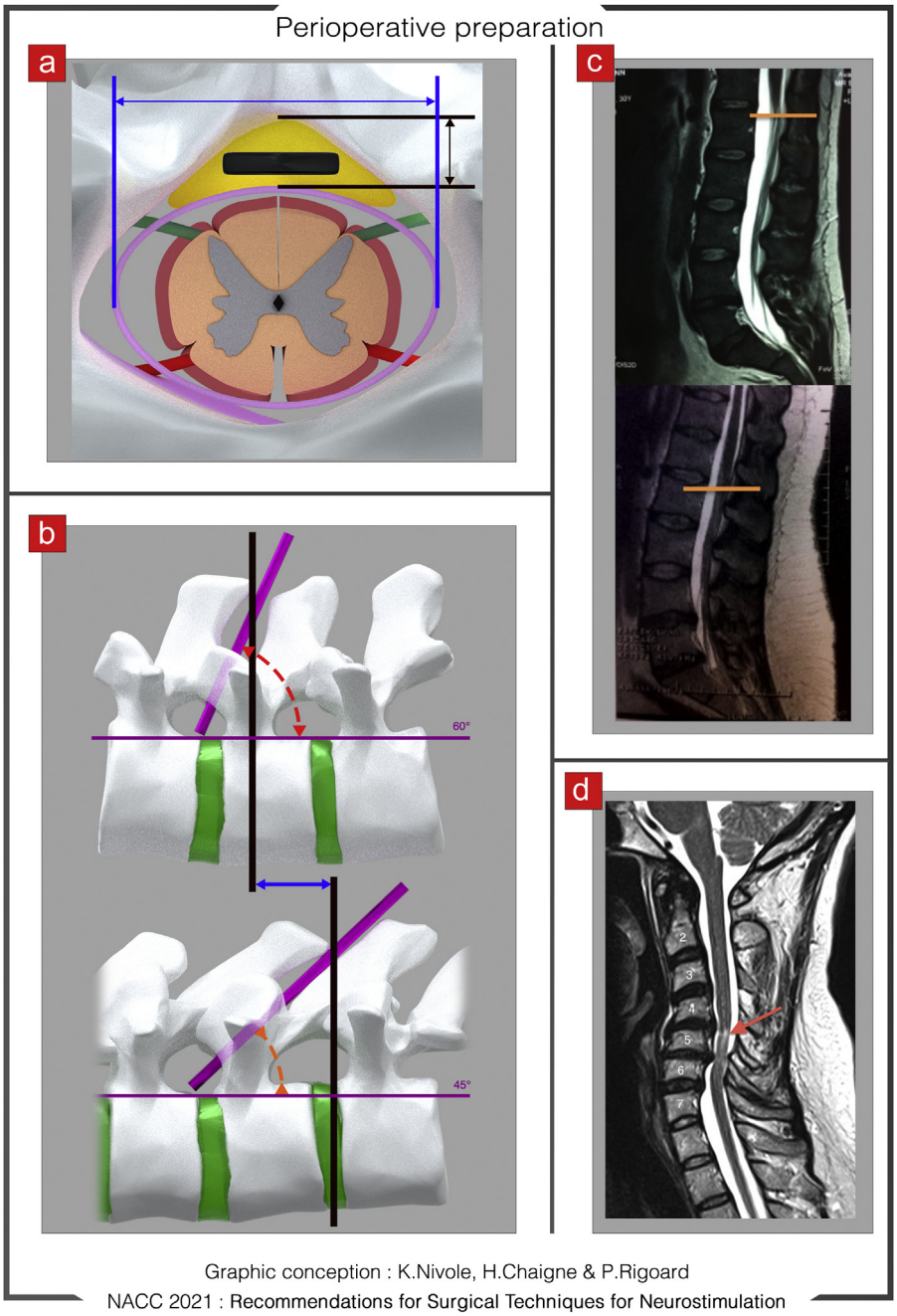

Figure 2. Perioperative preparation. a. Preoperative posterior epidural space morphometric assessment. b. Individual differences in spinal anatomy (here, the obliquity of spinous processes) can affect the lead implantation entry level. Fuchsia lines indicate angle of entry. c. Individual differences in spinal cord anatomy, here showing the conus medullaris at the L1 vertebral level (upper image) and at L2 (lower image), should be considered to optimize lead positioning. d. In this case of cervical stenosis with myelopathy, an implant should not be done without previous surgical decompression of the stenosis. Photos courtesy of Philippe Rigoard and used with permission.

NACC acknowledges that the current literature does not support postimplant antibiotic therapy; however, clinical judgment and clinical circumstance should guide treatment because the literature suggests little benefit to postimplant antibiotics but does not identify increased risk of harm to an individual patient; rather, the risk is to broader population-based antimicrobial resistance borne of indiscriminate application of antibiotic therapy.

Recommendation grade A; level of certainty high; level of evidence I (CDC recommendation IC).

SKIN AND TISSUE ASSESSMENT

SSI is the most common hospital-acquired infection, occurring in 1.9% of all surgeries and in 1% to 9% of spine surgeries.[29,30] SSI occurrence is associated with increased morbidity, poorer outcomes, and increased medical costs owing to additional hospitalization.[29] The most common microorganisms that cause SSI are gram-positive bacteria and are typically endogenous.[29] Thus, a primary concern of preoperative skin and tissue preparation is the

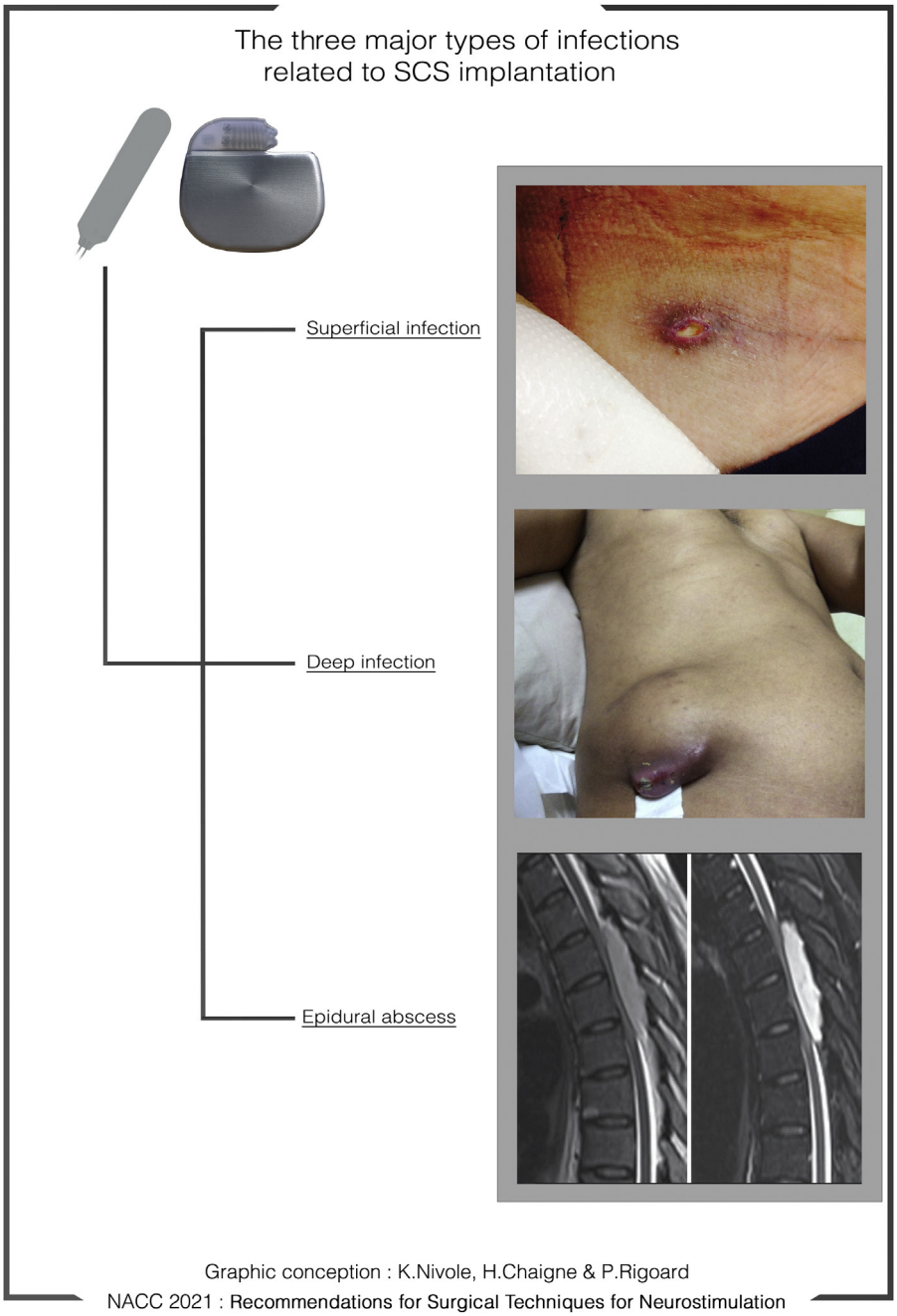

Figure 3. The three major types of infections related to SCS implantation. Photos courtesy of Philippe Rigoard and used with permission.

minimization of SSI risk through the removal, rapid reduction, and inhibition of rebound growth of transient microbes, all while minimizing skin and tissue irritation.[31]

Traditionally, preoperative hair removal has been widely used to increase access to the skin and prevent wound contamination.[32] However, evidence from a Cochrane systematic review has found that there is no significant effect on SSI rates upon hair removal.[33] In fact, some reports suggest that shaving may promote wound infection by causing epidermal injury.[34,35] When hair removal is necessary, clippers are the preferred method, because they have been associated with lower SSI rates than razors.[33,35]

Of the 21,000 SSIs reported to the National Healthcare Safety Network between 2009 and 2010, 30.4% were attributed to *S aureus*.[36] Screening for *Staphylococcus* organisms and subsequent decolonization can significantly reduce the rate of SSI in patients undergoing a variety of surgical procedures.[29] Patients should bathe or shower before surgery, using either a plain or antimicrobial soap.[5] However, the benefit of routine preoperative antiseptic baths is inconclusive in preventing SSI.[32]

In terms of skin preparation at the site of surgery, several topical antiseptic agents are available, including alcohol (ethyl alcohol 60%–90% or isopropyl alcohol 50%–91%), chlorhexidine, iodophors,

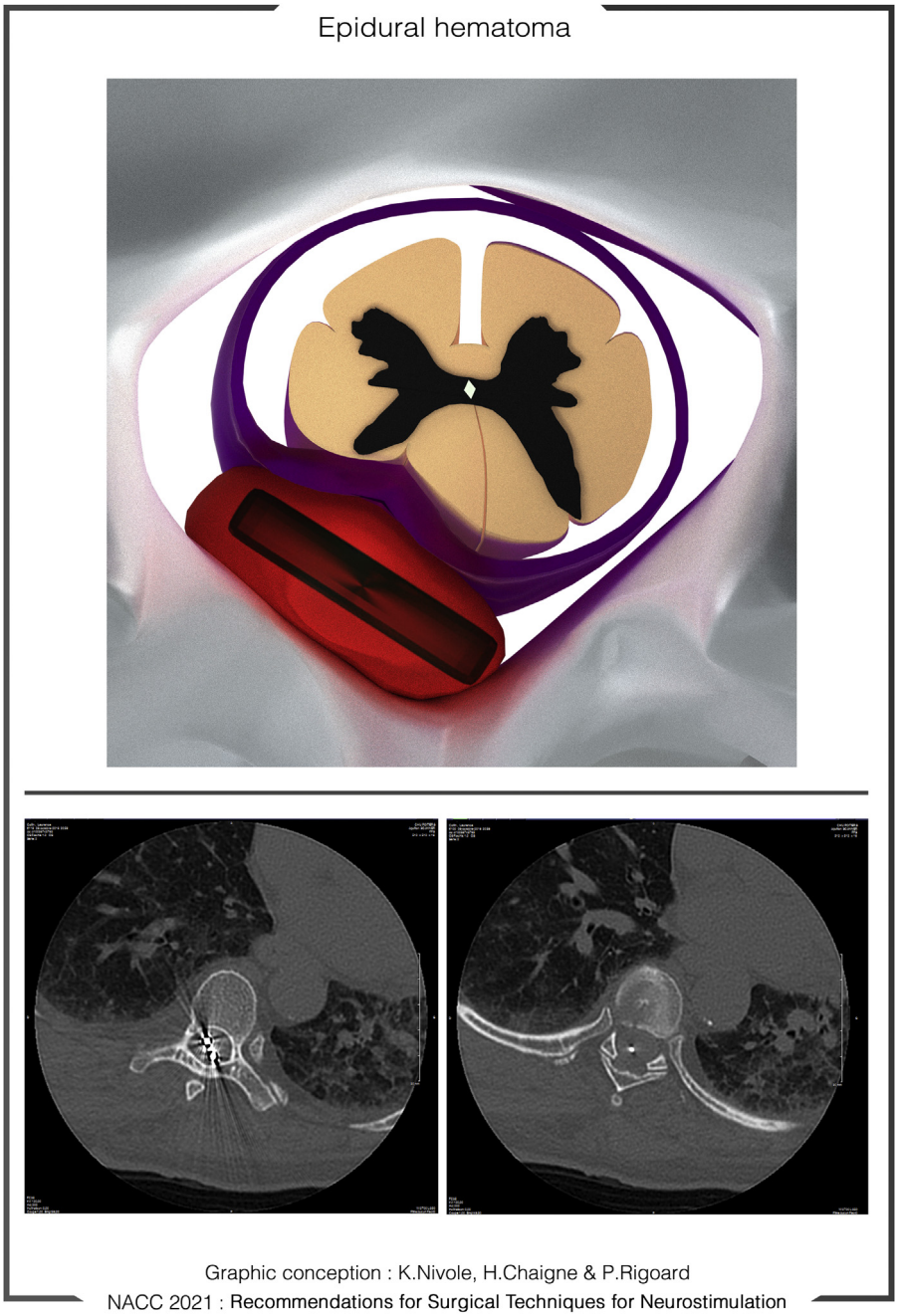

Figure 4. Epidural hematoma. Immediate imaging and decompression are essential. Diagrammatic view (top). Indirect CT-radiological signs of spinal cord compression visible despite lead artifacts (bottom). The multicolumn lead and adjacent wires appear asymmetric because of lead lateralization. External materials are projected in the middle of the spinal canal. Photos courtesy of Philippe Rigoard and used with permission.

chloroxylenol, sodium hypochlorite, and triclosan.[35,37,38] In particular, chlorhexidine gluconate (CHG) and povidone-iodine are widely used because of their broad-spectrum antimicrobial action and their efficacy and safety on nearly all skin surfaces.[35] There is mixed evidence in comparing their efficacy at SSI prevention.[35,39] Povidone-iodine has a more rapid bactericidal effect than CHG; however, CHG has a more persistent effect.[37] Choosing a skin preparation agent requires taking into consideration the patient's allergies and skin condition, contraindications, the surgical site, the manufacturer recommendations for the prep agent, and surgeon preference.[38] The surgical site is a particularly important consideration, because chlorhexidine has shown ocular, otologic, and neuronal toxicity.[32,35]

Notably, the combined use of CHG and povidone-iodine was shown to be safe and effective for preoperative skin preparation in patients who underwent neurosurgical procedures. The technique entails 3 minutes' cleaning of the incision area with CHG, followed by a 30-second cleaning with povidone-iodine.[40] When using povidone-iodine, allowing it to dry for 10 minutes before surgery is an important step for reducing bacteria on the skin,[41] and this long preparation must be part of the preoperative plan.

Table 4. Recommended Infection-Management Practices with Defined Origin of Practice.

Statements	Origin of recommended practice*	Evidence levels†	Recommendation strength	Consensus strength
Preoperative practices				
Identify and treat all remote infections for neuromodulation trials and implants	CDC IA	II-2	B	Strong
Optimize glucose control for neuromodulation implants	CDC IA	II-2	B	Strong
Discontinue tobacco use for neuromodulation implants	CDC IB	II-2	B	Strong
Decolonize MSSA and MRSA carriers through the application of mupirocin nasal ointment and chlorhexidine baths	NICE	I	A	Strong
Use preoperative antibiotics for neuromodulation trials and implants	CDC IB and NICE	I	A	Strong
Use preoperative weight-based antibiotic dosing for neuromodulation trials and implants	CDC IB and NICE	I	A	Strong
Use appropriate preoperative timing (within 1 h before surgical incision excluding vancomycin) of prophylactic antimicrobial administration for neuromodulation trials and implants	CDC IB, NICE, and SCIP	I	A	Strong
All patients should bathe or shower and use regular or antimicrobial soap the day before or day of surgery	CDC IB, NICE, and WHO	I	B	Strong
Remove hair (when required) with electric clippers immediately before the surgical procedure	CDC IA and NICE	I	A	Strong
Perform preoperative surgical scrub for a minimum of 2 to 5 min with an appropriate antiseptic before neuromodulation trials and implants	CDC IB and NICE	II-2	B	Strong
Keep nails short and do not wear artificial nails for neuromodulation trials and implants	CDC IB and NICE	II-3	B	Strong
Do not wear hand or arm jewelry for neuromodulation trials or implants	CDC IB and NICE	III	B	Strong
Intraoperative practices				
Wear a surgical mask for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Wear a cap or hood to fully cover hair for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Use sterile gown and gloves for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Double glove	CDC II and NICE	II-1	B	Strong
Use alcohol-based CHG for preoperative skin antiseptic agent. If chlorhexidine is contraindicated, use alcohol-based solution of povidone-iodine	CDC IA and NICE	I	A	Strong
If an incise drape is used, then an iodophor-impregnated drape for neuromodulation implants is recommended	NICE	I	A	Strong
Use laminar flow and HEPA filters in OR for neuromodulation implants	CDC IB	I	A	Strong
Limit procedure room traffic for neuromodulation trials and implants	CDC II and NICE	I	A	Strong
Keep procedure room doors closed during neuromodulation trials and implants	CDC IB	II-3	B	Strong
Limit tissue trauma, maintain hemostasis, eradicate dead space, and avoid electrocautery at tissue surface	CDC IB and NICE	III	B	Strong
Irrigate with saline through a bulb syringe before closure of surgical wound	NICE	I	B	Moderate
Use implant strategies to limit operative time		II-2	B	Strong
Postoperative practices				
Apply an occlusive dressing following neuromodulation trials and implants for 24 to 48 h	CDC IB and NICE	II-2	B	Strong
Do not routinely use topical antimicrobial agents for surgical wounds that are healing by primary intention	NICE	I	B	Strong
Understand maximum time criterion for defining a deep SSI of an implantable device (1 y post implant)	CDC	III	B	Strong

(Continued)

Table 4. *Continued*

Statements	Origin of recommended practice*	Evidence levels†	Recommendation strength	Consensus strength
Do not continue antibiotics into the postoperative period for neuromodulation trials and implants beyond 24 h	SCIP	I	A	Strong
Educate patient and family on proper incision care, symptoms of SSI, and importance of reporting symptoms	CDC II and NICE	III	B	Strong
Wash hands before and after dressing changes	CDC IB	III	B	Strong
Use sterile technique for dressing changes	CDC II and NICE	III	B	Moderate
When SSI is suspected, prescribe an antibiotic that covers the likely causative organisms. Consider local resistance patterns and culture results in choosing an antibiotic	NICE	III	B	Strong

HEPA, high efficiency particulate air; MSSA, methicillin-sensitive *S aureus*; NICE, National Institute for Health and Care Excellence; OR, operating room; SCIP, Surgical Care Improvement Project.
*The origin of recommended practice defines the supporting surgical guideline.
†I: at least one controlled and randomized clinical trial; II-1: well-designed, controlled, nonrandomized clinical trials; II-2: cohort or case studies and well-designed controls, preferably multicenter; II-3: multiple series compared over time, with or without interventions, and surprising results in noncontrolled experiences; III: clinical experience-based opinions, descriptive studies, clinical observations, or reports of expert committees.
Adapted from Deer et al.[43]

Consensus Point 3. The NACC recommends hair removal with electric clippers rather than shaving, although hair removal may not be necessary.

Recommendation grade A: level of certainty high; level of evidence I.

Consensus Point 4. The NACC recommends increased attention to skin preparation with consideration of preoperative antimicrobial skin decontamination.

Recommendation grade C; level of certainty low; level of evidence II.

Consensus Point 5. The NACC recommends consideration of a multiagent (chlorhexidine and povidone-iodine) as presurgical scrub in the operative suite.

Recommendation grade A; level of certainty moderate; level of evidence IA.

ANTIBIOTIC MANAGEMENT

Similar to other surgical procedures, the use of preoperative antibiotic prophylaxis is a vital step to reduce the risk of SSI.[20] Notably, preincision antibiotic prophylaxis has been shown to reduce the risk of SSI by approximately 50%, and a two- to sixfold increase in infection risk has been shown when antimicrobial therapy is not optimized.[21,22] Certain aspects of operative antibiotic management deserve special attention, and these areas include agent selection, agent dosing and renal function considerations, and timing of administration.

Agent Selection

When selecting an antibiotic, the drug must be effective against the most common pathogens that infect implantable neuromodulation devices, and this includes *S aureus* and *Staphylococcus epidermidis*.[42] One must also weigh community resistance patterns, because these nuances may require consideration of atypical antibiotic choices. In general, for neuromodulation surgery in most patients, a single dose of a cephalosporin is recommended. In those patients with beta-lactam allergy, clindamycin or vancomycin may be safely used. It is important to consider bacterial resistance, and the administration of vancomycin should be restricted to those patients who are known MRSA carriers or patients at high risk for MRSA colonization.[25] An alternative option with antibiotic coverage similar to vancomycin, including MRSA, is teicoplanin. Indications for vancomycin use are given in Table 4.

Agent Dosing

The goal of the administration of surgical antibiotic prophylaxis is to elevate effective serum and tissue drug levels above the MIC before incision and throughout the duration of the surgery. For this reason, agent dosing and timing are critical. Appropriate weight-based dosing recommendations are given in Table 5.

Timing of Administration

The administration of intravenous antibiotics must be appropriately timed to reach MIC before incision and maintain the antibiotic concentration above this level throughout the surgical procedure. Unfortunately, it has been suggested that only approximately half of the patients appropriately received prophylactic antibiotics within one hour before incision, as is recommended for all antibiotics excluding vancomycin.[44] In pain medicine specifically, an international survey of the American Society of Regional Anesthesia (ASRA), INS, and the American Academy of Pain Medicine members reported that 98.0% of respondents from the United States and 92.9% of Europeans (overall 97.9%) administered antibiotics within 60 minutes of surgical incision, as recommended.[45] Olsen et al,[46] in orthopedic spinal operations, demonstrated that the suboptimal timing of prophylactic antibiotic therapy was associated with a significant risk of SSI (odds ratio [OR] 3.4, 95% CI 51.5, 7.9). More recently, Malhotra et al[47] retrospectively studied the effect of vancomycin administration and infusion times. Fewer than half of the patients received preoperative vancomycin correctly when assessing to national standards. Moreover, when vancomycin was given too close to incision (<24.6 minutes before incision), it was

Table 5. Prophylactic Antibiotic Recommendations.

Antibiotic	Standard intravenous dosing	Timing before incision	Redosing interval	Indications
Cefazolin*	1 g ≤ 60 kg 2 g > 60 kg 3 g > 120 kg	Within 30–60 min	3–4 h (CrCl > 50 mL/min) 8 h (CrCl 20–50 mL/min) 16 h (CrCl < 20 mL/min)	First-line
Clindamycin	600 mg ≤ 80 kg 900 mg > 80 kg 1200 mg > 120 kg	Within 30–60 min	6 h (CrCl > 50 mL/min) 6 h (CrCl 20–50 mL/min) 6 h (CrCl < 20 mL/min)	β-Lactam allergy
Vancomycin	15 mg/kg	Within 60–120 min	8 h (CrCl > 50 mL/min) 16 h (CrCl 20–50 mL/min) None (CrCl < 20 mL/min)	β-Lactam allergy Known MRSA colonization

CrCl, creatinine clearance.
*To simplify cefazolin weight-based dosing, the American Society of Health-System Pharmacists recommends 2 g for individuals weighing <120 kg and 3 g for individuals weighing ≥120 kg.
Adapted from Deer et al.[43]

predictive of an increased SSI risk (OR 4.281; $p < 0.001$). Preoperative antibiotics should be administered intravenously within 60 minutes before incision for cephalosporins, sulfonamides, and aminoglycosides or within 60 to 120 minutes before incision for vancomycin and fluoroquinolones (CDC recommendation 1B).

In obese and morbidly obese patients, the evidence and published guidelines would recommend higher single prophylactic antibiotic dosages. For cefazolins, it is recommended to administer 2.0 g for patients weighing 60 to 120 kg and 3.0 grams for patients weighing >120 kg. Vancomycin should be dosed at 15 mg/kg. Dosages should be adjusted based on renal function because the kidneys excrete most of the antimicrobials used in neuromodulation procedures. Clindamycin is the only antibiotic used for antimicrobial prophylaxis in neuromodulation procedures that is not affected by renal function. Based on the duration of neuromodulation surgical procedures, redosing is typically not needed (Table 5).

Wound irrigation, topical and envelop antibiotics, antimicrobial patches, and vancomycin powder are discussed in another recent NACC guideline that discusses the mitigation of complications of neurostimulation.[48]

Consensus Point 6. The NACC concurs with the previous guideline recommendations for the preoperative use of antibiotics for neuromodulation procedures (Tables 4 and 5).

Recommendation grade A; level of certainty high; level of evidence I.

Consensus Point 7. The NACC recommends surgical irrigation with saline through a bulb syringe before closure of the surgical wound.

Recommendation grade B; level of certainty moderate; level of evidence IB.

Consensus Point 8. The NACC does not recommend the routine use of chlorhexidine-impregnated dressings for neuromodulation trials. In high-risk patients with significant medical comorbidities, chlorhexidine-impregnated dressings may help reduce the risk of exit-site colonization and subsequent infection during trials.

Recommendation grade B; level of certainty moderate; level of evidence IB.

Consensus Point 9. The NACC recommends additional studies before supporting the routine use of vancomycin powder for implantable pain therapies.

Recommendation grade B; level of certainty moderate; level of evidence IB.

Postoperative Antibiotics

In multiple surgical specialties, including cardiac, orthopedic, and plastic surgery, the prolonged use of postoperative antibiotics has not been shown to improve outcomes.[28] In fact, when considering spine surgery specifically, the use of intravenous antibiotics beyond 48 hours increased the length of hospital stay and resulted in delayed normalization of body temperature and C-reactive protein levels.[27] Contemporary research continues to report similar results showing that the use of postoperative antibiotics beyond 24 hours does not cause a decrease in SSI.[2,49–51] Regardless of the published literature, Medicare data have demonstrated that only 40.7% of patients have postoperative antibiotics discontinued within 24 hours of surgery.[44]

Consensus Point 10. The NACC recommends considering discontinuation of antibiotics within 24 hours following SCS implants. For high-risk patients, postoperative antibiotics should be considered.

Recommendation grade A; level of certainty high; level of evidence IA.

ANTITHROMBOTIC MANAGEMENT

Manipulation of the tissue, movement of the leads, and open surgical work around the spinal epidural space, using both percutaneous and paddle dorsal column leads or dorsal root ganglion (DRG) leads, can cause an epidural hematoma, which can lead to paralysis and permanent neurologic dysfunction. The growth and use of antithrombotics in the United States increase year over year. Globally, the compound annual growth rate of antithrombotic use is an estimated 7.5%.[52] Many of the novel compounds have no antidote or reversal agent, thus rendering management in the perioperative period challenging. A number of interrelated factors promote hematoma formation, including inherent and pharmacologic antithrombotic imbalance and tissue injury. Patients must be aware of this low incidence/high consequence event so that management can occur swiftly to prevent permanent neurologic injury.

The Incidence of Epidural Hematoma

Estimating the incidence of epidural hematoma after a neurostimulation procedure presents several challenges. Not all epidural hematomata are consequential. Small-volume hematoma may not

result in sensory, motor, or sympathetic dysfunction and, therefore, may not be detected clinically. Clinicians may feel reluctant to report a complication; thus, using the literature solely to estimate incidence carries inherent bias.

In 2011, Levy et al[53] published a review of complications from paddle lead placement and reported that 84 of 44,587 (0.19%) cases resulted in a consequential epidural hematoma (Fig. 4). In 2015, Petraglia et al[54] followed with a retrospective review of Thomson Reuter's MarketScan data from 2000 to 2009 comparing the hematoma incidence of percutaneous and paddle leads and found no significant difference between the two groups. The rates per this review were 0.75% for percutaneous leads and 0.63% for paddle leads.

In 2019, Sivanesan et al[55] performed a review of the Food and Drug Administration MAUDE database on DRG stimulation and found four hematomata, location unspecified, among an estimated 8000 procedures (5000 trials and 3000 implants) in a 21-month period. Recently, Deer et al[56] published an analysis revealing a 0% incidence of hematoma with >500 DRG stimulation implants.

The incidence of epidural hematoma in the anesthesiology literature regarding indwelling continuous epidural infusions has evolved since the reviews by Tryba[57] and Vandermeulen[58] in the 1990s where the estimated incidence was 1 of 150,000 (0.00067%). In 2013, Bateman et al[59] published their findings from the Multicenter Perioperative Outcomes Group, which pooled data from several academic American institutions, estimating that the risk of neuraxial hematoma after perioperative epidural placement was 7 of 62,450 (0.01%). As we gather more information regarding neuraxial neurostimulation, we may obtain a better understanding of its estimated incidence as has been published in the anesthesiology literature.

The NACC recommendations from 2017 on bleeding and coagulation management provide an overview of case reports and reported incidence, including a review from Cameron et al[60] with estimates of the risk of hematoma at 0.3% and a risk of paralysis at 0.03%.[61] Supplemental Appendix A indicates guidance on postoperative thromboprophylaxis. The growing use of registries should help better estimate the incidence of epidural hematoma with specific procedures in the future.

The Interplay of Factors

The balance between tissue injury and thrombosis is not linear. The complexity of the platelet and coagulation systems and the differences in techniques and hardware make the risk determination of epidural hematoma difficult. Antithrombotic drugs include anticoagulants, antiplatelet drugs, and thrombolytics. Target-specific oral anticoagulants include medications that inhibit factors IIa or Xa and are gradually supplanting the use of warfarin, a vitamin K epoxide reductase complex inhibitor. Antiplatelet agents include aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase (COX) inhibitors, P2Y12 receptor blocking drugs, adenosine diphosphate receptor antagonists, cyclopentyltriazopyrimidines, and phosphodiesterase inhibitors.[62] Thrombolytics are used in life-threatening situations such as cardiovascular events including myocardial infarction (MI), pulmonary emboli, or stroke. These agents can be delivered locally or systemically. The impact of these drugs in patients with in situ neurostimulation devices is unknown, although no published reports of epidural hematoma with in situ devices have been documented in the peer-reviewed literature.

Each drug has its own half-life alpha and half-life beta, cytochrome p450 metabolism, and renal vs hepatic elimination. As a reference, the 2017 NACC guidelines provide a table of when to stop and restart various antithrombotics.[61]

Management of Epidural Hematoma

Detection of an epidural hematoma is paramount to early intervention. Clinicians and patients should be aware of the signs and symptoms of an epidural hematoma, including focal back pain, lumbar radiculitis, paresis, and bowel or bladder dysfunction. When an epidural hematoma is suspected, organization of the radiology team for immediate imaging, MRI or CT (Fig. 4), and neurosurgical consultation for decompression are essential. Laboratory values should be obtained, but their results should not delay intervention if the clinical suspicion is high.

Consensus Point 11. The NACC recommends a high index of suspicion and awareness of the signs and symptoms of perioperative hematoma and that urgent surgical evaluation be obtained early in any suspected process.

Recommendation grade A; level of certainty high; level of evidence I.

Patient Informed Consent

Patients should be aware of the possibility of neuraxial hematoma before the manipulation of the epidural space, not only to assess their risk with the procedure but also to detect the clinical signs and symptoms of a developing epidural hematoma. In addition to the risk of the development of epidural hematoma, patients who are told to cease their antithrombotic regimen are at increased risk for thrombotic consequences. It is recommended that any decision to cease an antithrombotic for neurostimulation should be in compliance with the prescribing physician (eg, primary care provider, cardiologist, hematologist) and the patient, with awareness from all parties about the length of the neurostimulation trial. The PRAGUE-14 registry provided insight regarding antithrombotic cessation. Although the incidence of complications was lower in those who ceased their antithrombotic, the severity of the consequence was much greater.[63] Neuromodulators are advised to reduce the length of the trial, if possible, to mitigate the risk of thrombosis. In high-risk cases, the benefit vs risk ratio of omitting the trial and proceeding directly to permanent implant should be examined and determined.

Conclusion

The low incidence/high consequence event of an epidural hematoma presents a complex issue in the setting of neuromodulation procedures. With an estimated incidence of approximately 1 in 300 cases, a symptomatic hematoma is likely to occur in the careers of neuromodulators. Understanding the interplay of factors with the growing use of novel antithrombotics is crucial. Informing patients about the risks of bleeding vs thrombosis will continue to make decisions laborious yet is essential to maintain safety. Registry data will help improve estimates whereas the technology will continue to evolve.

INCISION

To reiterate, we emphasize that training in surgical techniques should be obtained before initiating any surgical procedure, including SCS; simply reviewing this consensus document is insufficient to provide adequate training. In this consensus document, we discuss primarily the details and nuances of clinical practice that should be considered after such surgical training is obtained. The most notable difference between the SCS trial and the permanent implant is the surgical incisions required to implant the sterile SCS leads and pulse generator. To date, there is no literature relating the type of surgical incision and the complication rate for SCS implants. When examining other specialties, the type of incision (transverse vs vertical) does not affect postoperative outcomes.[64] Although the type of incision does not appear to affect outcomes, there are other factors to consider when making surgical incisions. Cosmetic appearance can be very important for patients. The location and orientation of surgical incisions can greatly affect the appearance of the subsequent surgical site and have typically relied on knowledge of Langer's lines. However, as proposed in a commentary by Wilhelmi et al,[65] Langer's lines may not be the best guide for incisions, and other surgical lines may be more appropriate for elective surgeries. Moreover, making incisions as small as possible to start and then extending as needed is important and, perhaps, can have an indirect effect on outcomes. Small incisions may limit wound complications; however, optimum access should be the primary goal, and in some situations, the incision should be extended. Making incisions larger than necessary can make surgical operating room time longer and will require more sutures, both of which are associated with increased risk of infection.[43,66] Meticulous planning of surgical incisions is a vital part of the implantation process and can help to achieve improved patient satisfaction and indirectly reduce the risk of infection.

TISSUE DISSECTION

Historically, many principles of surgery were introduced by William Stewart Halsted in the 19th century. These were referred to as the Tenets of Halsted, which involve the basic principles of surgical technique and tissue management, such as gentle handling of tissue during dissection accompanied by careful maintenance of hemostasis. One should be cognizant of preserving blood supply, in this particular case preserving blood supply to the skin, utilizing aseptic technique, and allowing for minimum tension on tissues. The final aspect is related to closure of tissue, which involves the accurate approximation of tissue and the obliteration of dead space.[67,68] There are four major surgical skills that one needs to understand and observe in the practice of SCS implantation. The first includes the proper handling of the various instruments used during surgery, followed by the understanding of tissue planes and manipulation of tissue through the elements of dissection. This is then followed by the skills of suturing and knot tying or other ligation techniques to complete the surgical implant procedure. Ultimately, appropriate tissue handling and wound management should lead to improved outcomes for the patient and reduced postoperative complications.[43]

Dissection is the surgical process of cutting apart or separating the tissue as one enters the body below the skin, specifically because it relates to neuromodulation for the implantation of electrodes or of the pulse generator and battery. Two types of dissection, sharp and blunt, are commonly described (Fig. 5). Sharp dissection refers to the use of a scalpel, scissors, or electrocautery to separate the tissue and help define tissue planes. To date, there is no strong evidence that the use of either scalpel or electrocautery is superior; rather, the goal should be to become skilled in the use of both to reduce potential risk factors that are associated with poor wound healing and SSI.[43] Blunt dissection is the careful separation of tissues along tissue planes by using blunt instruments, such as the insertion of a closed scissors and then opening the scissors to bluntly separate tissue or using a finger to separate tissue planes (Fig. 5b). In typical neuromodulation procedures, both forms of dissection are often used and should be individualized based on tissue characteristics.

There are at least three elements of skill that are required to perform surgery. The first is cognitive, which involves the planning of certain movements before their actual performance. Given the two most common approaches to placement of SCS leads, one must have a thorough understanding of those neuromodulation techniques they intend to use, including the percutaneously placed cylindrical leads as well as the more invasive laminotomy-placed paddle lead.

The second skill element involves the perception or recognition of tissue planes. Most commonly, when performing percutaneous neuromodulation techniques, sharp and gentle blunt dissection is used with the aid of a scalpel to breach the skin, followed by a combination of sharp and gentle blunt dissection through the epidermal, dermal, and epi-fascial fatty layers, down to the thoracolumbar fascia. Other surgeons may advise dissection with the use of electrocautery to advance down to a level where the cylindrical needles will be advanced through the thoracolumbar fascia. There is no strong supporting evidence that either approach is superior. The goal would be to discourage the overzealous use of electrocautery to avoid extensive tissue injury. For any revision surgery with leads already in place, bipolar diathermy is preferred over monopolar diathermy because of the very low risk of monopolar diathermy causing heat transfer if the system insulation is incomplete or breached by a needle. This may be of more concern in the cutting mode.

The third skill element involves the actual motor skill of handling of the tissues. Despite best attempts to reduce soft tissue damage, the soft tissues of the body are at risk with even precise attempts to carefully identify and dissect. Preferably, the use of skin hooks or gentle intermittent retraction with self-retaining retractors minimizes the potential damage that occurs with repeated handling of the skin with other instruments[69] (Fig. 5d).

Minimal access procedures are currently used in spinal surgery and SCS lead implantation.[70] These have been shown to reduce blood loss, decrease the need for transfusion, reduce muscle injury and postoperative back pain, speed up recovery, and shorten hospital stay.[71–76] Most commonly, these procedures use a minimal access spinal technology (MAST) fixed-diameter tubular retractor that splits the paravertebral musculature, avoiding the need to strip the muscles from the spine and potentially resulting in less trauma to the patient. However, until recently, only a unilateral approach was possible with these systems, which can limit the operative field, cause some difficulties for median lead placement (especially for multicolumn paddle leads), and did not always prevent laminectomy. In addition, the initial systems contained just the insertion tubes, requiring additional tools to visualize the procedure (loupes, microscope, etc.). New retractable MAST systems (Fig. 6b) 1) permit a median approach that facilitates

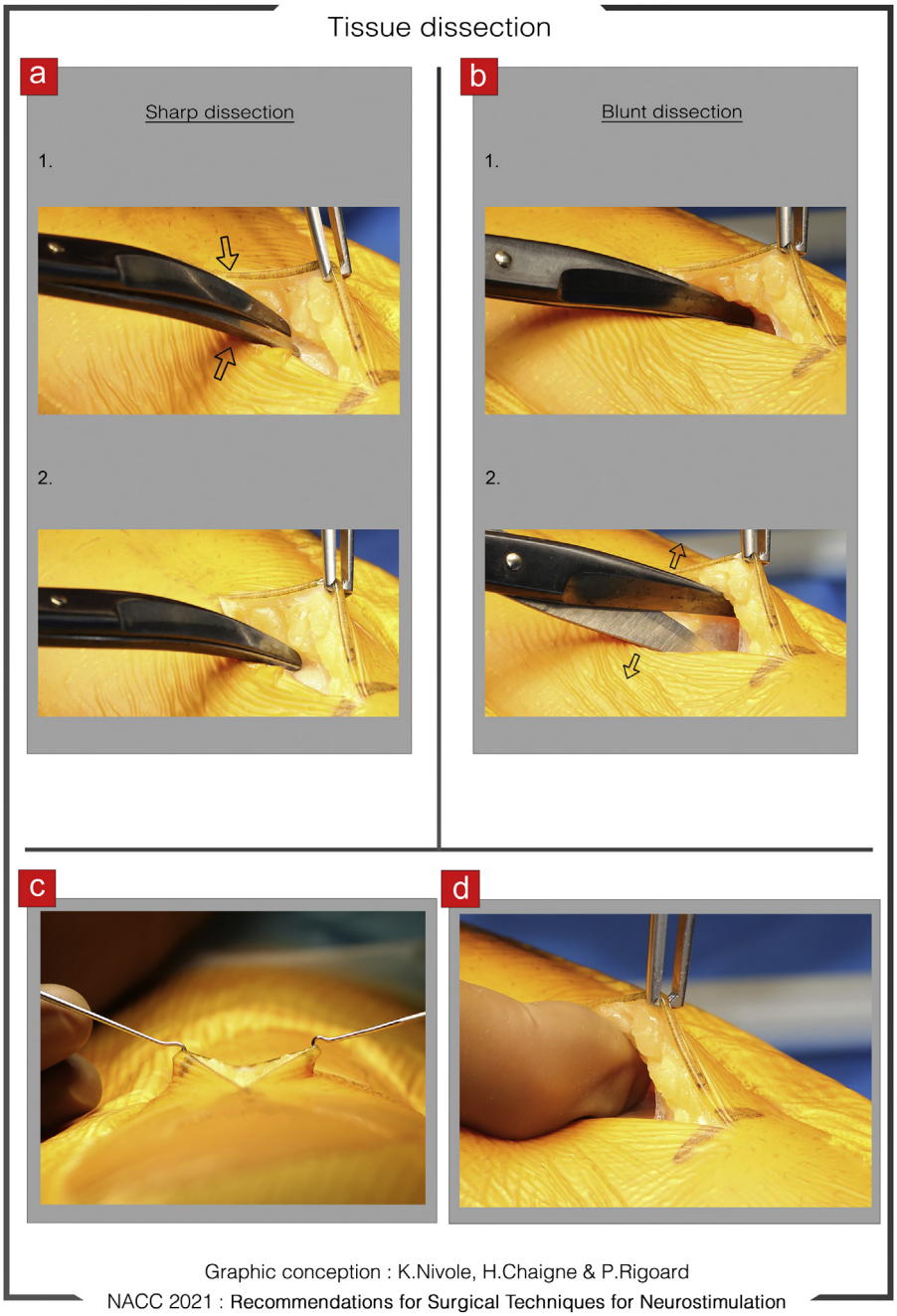

Figure 5. Tissue dissection. a. Sharp dissection technique: 1) use of scissors to separate the tissue by cutting the anatomical structures, 2) definition of tissue planes relies on the implanter's perception. b. Blunt dissection technique: 1) careful separation of tissues along the tissue planes by inserting a closed scissors, 2) opening of the scissors to bluntly separate the tissue. c. Use of skin hooks to minimize the potential tissue damage. d. Use of toothed forceps to avoid handling the skin repetitively. Once forceps are placed, preferably a finger was used to separate the tissue planes. Photos courtesy of Philippe Rigoard and used with permission.

median lead placement, 2) provide a better "real" visualization of the spine by using cold-light fiber optics (hence, no need for a microscope), and 3) allow a pure transligamentar insertion with minimal bone resection, thus reducing blood loss and minimizing tissue trauma and scarring.[70]

Some surgeons are in favor of performing a constant open, sometimes large resection of the spinous process and laminectomy to insert the lead safely.[53] Finally, it should be noted that many techniques exist for SCS electrode insertion. The advantages of an open technique should be balanced against a potential increase of perioperative muscular trauma, bone resection, and blood loss. The ultimate choice should remain at the entire discretion of the implanting surgeon. Each technique, including minimally invasive ones,[70] requires a certain level of training and surgical awareness to optimize the tissue identification and dissection, and in many situations, the skill sets overlap.

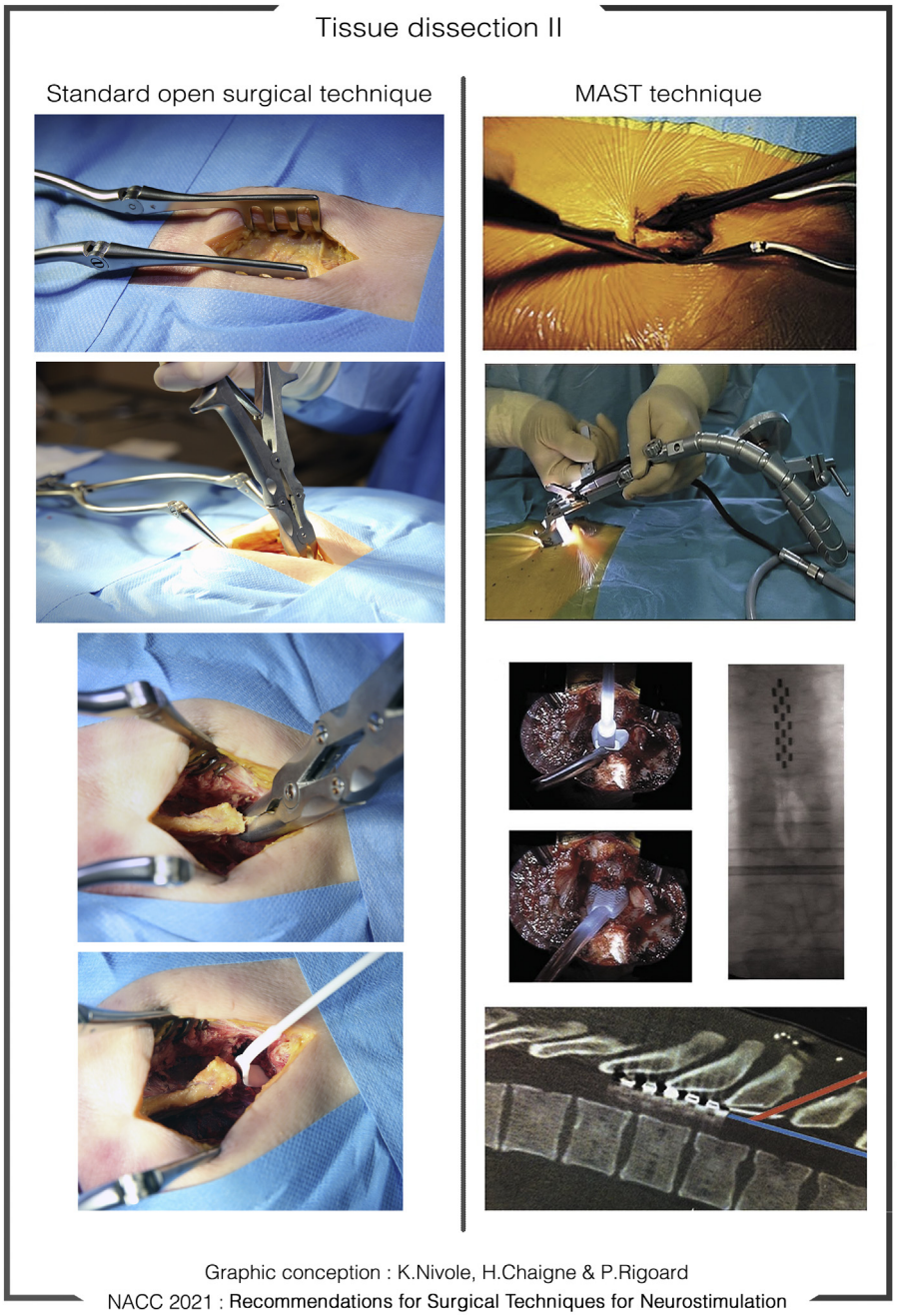

Figure 6. Tissue dissection II. Conventional surgical approach (at the left). Surgical approach consists in separating paraspinal fascia and muscles from the spinous process and ligaments. Once the spinous process and laminae have been exposed, removal of the supraspinous, the interspinous ligament, and the ligamentum flavum is possible thanks to a small gouge or an arthrectomy pinch. Kerrison rongeurs can be used to remove a small portion of the inferior lamina of the upper vertebra to place the lead phantom and then the paddle lead in the epidural space. Aspects of the minimally invasive (MAST) procedure (at the right). Surgical approach on one or both sides of the supraspinous process, with careful dissection of the paravertebral musculature. Full system set. Insertion of the phantom lead and implantation of the lead in the median position, verified by intraoperative x-ray. The aspects of lead implantation angle: a high approach at the thoracic spine level is possible by using the minimally invasive technique. The bony removal can be minimized, and a shallow, safe angle of insertion achieved with a good retractor system and illumination. Photos courtesy of Philippe Rigoard and used with permission.

When making a subcutaneous pocket for the pulse generator, most implanters use sharp dissection, either with a scalpel or electrocautery, to the desired or required depth. The depth of dissection is usually Scarpa's fascia in the abdomen or the thoracolumbar paraspinal fascia posteriorly but may vary based on the patient's body mass index (BMI). Often, the surgeon will use a combination of sharp and blunt dissection to help delineate a plane and may use that to completely create the pocket for a pulse generator or, alternatively, begin with sharp dissection and then complete the battery pocket with blunt dissection. The incision depth may vary depending on individual body habitus and battery requirements, but the optimal plane for the pulse generator to

reduce the risk of erosion and allow for successful telemetry is approximately 2.5 to 4.5 cm in depth (follow manufacturer's instructions) when anatomically possible.

Finally, obtaining absolute hemostasis is a part of optimal surgical technique. Electrosurgical units have been introduced to carry out simultaneously the processes of dissection and hemostasis. The obvious benefit of this approach is that dissection and hemostasis have become more efficient because they are accomplished simultaneously.[70,77,78] Nevertheless, it behooves the surgeon to understand surgical techniques to achieve hemostasis when bleeding continues despite the use of electrosurgical units. When a blood vessel is injured, three mechanisms operate locally at the site of injury to control the bleeding: 1) vessel wall contraction; 2) platelet adhesion and aggregation (platelet plug formation); and 3) plasma coagulation to form a fibrin clot. All three mechanisms are essential for normal hemostasis. Surgical dissection skills are required to stop the bleeding when a vessel wall is injured, and the vasoconstrictive process brought about by electrosurgery has not alleviated the bleeding. In these instances, the use of sutures may be necessary to stop the bleeding. Ultimately, excessive electrocautery should be avoided to reduce tissue injury, but it may be beneficial to maximize hemostasis and reduce operative surgical time. Bipolar forceps, which use current passing only between the tines of the forceps, can be very effective in obtaining local hemostasis.

Consensus Point 12. The NACC recommends handling surgical tissue gently, identifying appropriate tissues, limiting tissue trauma, maintaining hemostasis, avoiding excessive electrocautery, and eliminating wound dead space.

Recommendation grade B; level of certainty moderate; level of evidence IB.

ANCHORING

SCS Leads

Lead anchoring is fundamental to most neurostimulation procedures because the migration of the lead can result in failure of the SCS system to provide pain relief. Clearly, stimulation of the spinal cord at the best physiologic target, regardless of stimulation paradigm, is critical for efficacy and long-term success. Many anchoring strategies have been developed over the years, from surgically knotted, nonmechanical anchors, creating tension on the lead to avoid migration, to mechanical anchors with a "locking" element, in a variety of differing designs (Fig. 7).

Fundamentally, maintaining lead position, regardless of the securing system, requires two components: securing the lead within the anchor and securing the anchor to the patient. Although seemingly an elementary concept, no industry standard strategy exists. Migration rate historically was reported to range between 2% and 22%.[79] Improved migration rate with mechanical anchors has been suggested, but direct comparative studies are limited. It is assumed that a nonabsorbable suture is used, although the numbers per lead are poorly defined, further identifying the need for carefully controlled and reported studies of lead anchoring. The texture and firmness of an anchor before implantation should be carefully considered. In patients with low BMI, harder materials in anchoring devices should be avoided.

To serve as a surrogate for anchoring system quality, we investigated lead migration and/or fracture in the available randomized, multicenter studies (Table 6).

Systematic reviews of complications have been performed,[53,79,87] reporting lead migration or fracture rates from 2% to 25%. Again, the technique for anchoring was not identified. Gazelka et al[87] reported migration rates near 2% to 3%. Kinfe et al[88] reported on 81 patients, prospectively, with a migration rate of 2.5%. Mekhail et al,[89] on 707 patients, retrospectively, reported a migration rate of 22.6% and a lead fracture rate of 6%. Justiz and Bentley[90] reported on 66 patients, using a novel fixation device and mechanical anchor, yielding no lead migrations or fractures, with a follow-up average of 38 weeks.

Consensus Point 13. The NACC recommends familiarity with the manufacturers' directions for use when securing SCS leads.

Recommendation grade A; level of certainty high; level of evidence I.

Consensus Point 14. The NACC recommends that SCS leads, either percutaneous or paddle, should be anchored to avoid migration.

Recommendation grade A; level of certainty high; level of evidence I.

Consensus Point 15. The NACC recommends that anchoring of SCS leads should be performed using a nonabsorbable mechanism or suture.

Recommendation grade A; level of certainty high; level of evidence I.

Consensus Point 16. The NACC recommends the consideration of mechanical anchors to reduce SCS lead migration and fracture, although no high-level evidence exists regarding mechanical anchor use.

Recommendation grade A; level of certainty high; level of evidence IC.

Consensus Point 17. The NACC recommends future work to describe the procedure of anchoring more completely in terms of anchor used, suture used, location of securing on the patient, and knot type.

Recommendation grade A; level of certainty high; level of evidence II.

In addition to SCS anchoring, it is important to discuss peripheral nerve stimulation (PNS) and DRG stimulation anchoring as well. Although there are notable similarities, there are certainly stimulation-specific anchoring nuances that must be addressed and understood to provide efficacious long-term results.

PNS Leads

PNS has significantly evolved since the inception of equipment designed for the neuroaxis peripherally. Because there is inherently more movement in most peripheral nerve targets, the risk of migration is at least as high as that for SCS. Now with the advent of specifically designed leads and equipment for PNS, the incidence of lead migration for PNS is lower. Although there have been no prospective, randomized comparative studies of one lead or anchoring strategy to another, many studies exist to help define the scope of the challenge (Table 7).

Taken together, PNS complication rates have markedly improved since inception, from an open dissection and PNS lead to refined percutaneous placement. Each lead now has tines that allow for

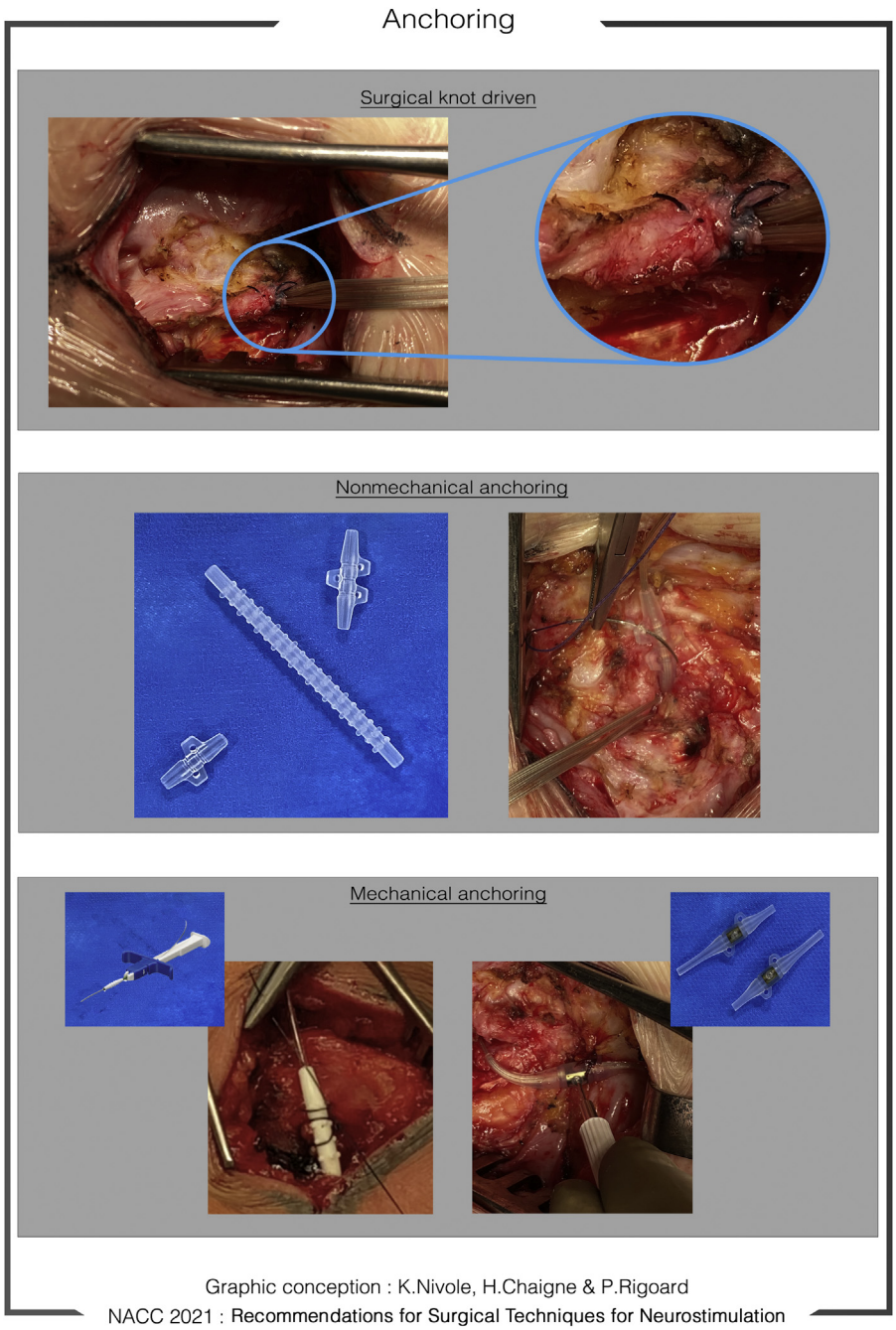

Figure 7. Anchoring. Many anchoring strategies have been developed over the years, from surgical knot driven (top), nonmechanical anchors (middle), to mechanical anchors with a "locking" strategy (examples presented [bottom], courtesy of manufacturers). Photos courtesy of Philippe Rigoard and used with permission.

scar tissue to hold the specifically designed lead in place, improving longevity of care. A new approach to the medial branch stimulation of the multifidus muscle resulted in a significant reduction in lead fracture.[94]

Consensus Point 18. The NACC recommends following the directions for use for PNS leads specifically designed for the periphery.

Recommendation grade A; level of certainty moderate; level of evidence IB.

DRG Leads

DRG stimulation has been an important neurostimulation strategy since commercialization in 2016, on the heels of the ACCURATE study that compared DRG with SCS for the treatment of complex regional pain syndrome type II from the iliac crest distally[85] (Table 8). In this study, there was no standard anchoring approach for either arm, although the plastic anchors provided for the DRG lead were anchored using a nonabsorbable suture to the lumbodorsal fascia.

Table 6. Anchor Type and Reported Rates of Lead Migration and Fracture in Randomized Studies of SCS.

Study	No. of patients implanted	Follow-up	Lead type, paddle vs percutaneous	Anchor type	Migration rate, % (*N*)	Fracture rate, % (*N*)
North et al[80]	30	Mean follow-up 2.9 y	Unknown	Unknown		
Kumar et al[81]	52	24 mo	Unknown	Unknown	17.13 (9)	
Kemler et al[82]	54	60 mo	Unknown			
Kapural et al[83]	171	12 mo	Perc all patients	Mechanical	4 (7)	None
Deer et al[84]	100	12 mo	Perc all patients	Mechanical		None
Deer et al[85]	DRG control arm 76	12 mo	Perc all patients	Nonmechanical	10.5 (8)	NR
De Andres et al[86]	55	12 mo	Perc all patients		12.7 (7)	None

NR, not reported; Perc, percutaneous.

Complication rates for DRG have been reported with wide discrepancies. Using manufacturer data on DRG complications, Deer et al[56] found a migration rate of DRG leads lower than that of SCS leads. The anchoring technique was not defined. Chapman et al[95] in a multicenter retrospective study of anchoring vs nonanchoring of DRG leads reported the incidence of lead migration and fracture (Table 8), with migration rates significantly lower for anchored than for unanchored leads ($p < 0.01$), but similar fracture rates whether anchored or unanchored.

Anchoring of DRG leads is usually performed at the level of the superficial lumbodorsal fascia, using the manufacturer-supplied anchor or a loosely tied figure-8 stitch with a nonabsorbable suture. Other implanters believe that no anchoring is necessary as a result of the stability provided by placing an "S" loop of the lead within the epidural space. There is no prospective study comparing these strategies.

Consensus Point 19. The NACC recommends securing the DRG lead using a nonabsorbable mechanism to improve longevity of the therapy. The evidence for manufacturers' anchors is inconclusive.

Recommendation grade B; level of certainty moderate; level of evidence II.

TUNNELING

General

In the 2017 NACC guidelines, minimal attention was devoted to the technical aspects of tunneling leads. There was a mention of the bleeding that can occur with the use of a trocar insertion and consideration for use of ultrasound when tunneling around the great vessels of the neck, but otherwise, no description of this aspect of neuromodulation was included.[61]

Tunneling is the process that permits connection of the neurostimulator leads, which are anchored in the lead incision, to the IPG pocket and allows the entire system to be implanted below the skin (Fig. 8). The path connecting these two parts of the SCS system needs to be carefully considered to allow for a smooth passage of the trochar, avoiding sharp angles or changes in direction that might potentially create kinks in the lead wires. These acute angles or kinks could put undue stress upon the wires and, over time, lead to damage or breakage necessitating replacement. In addition to a low stress path, attention should be placed on limiting the SCS leads from crossing over each other. Limiting any unnecessary contact where repetitive friction over time could damage the lead is recommended. Finally, in addition to preparing a tunnel that creates a gently angled path, care must be taken to ensure the route avoids trauma to surrounding structures such as the nerves, blood vessels, and the intra-abdominal and intrathoracic cavities. Therefore, when tunneling around vital structures, use of additional imaging modalities, such as ultrasound or additional fluoroscopy, may help to improve safety.[61]

SCS Implant

Before placing the trocar into the lead incision and passing the device subcutaneously, additional anesthesia may need to be administered depending on the anesthetic choice for the case. The tunneling portion can be one of the more stimulating portions of the case. Therefore, if monitored anesthesia is chosen, then either deepening the sedation or providing local anesthetic along the tunneling tract is warranted.[96] If the patient has been placed under a general anesthetic, additional anesthesia will likely not be required.

Each SCS manufacturer provides a disposable tunneling device that accompanies the implant kit. Although there will be some

Table 7. Anchor Type and Reported Rates of Lead Migration and Fracture in Randomized or Prospective Studies of PNS.

Study	No. of patients implanted	Follow-up	Anchor type	Migration rate, % (*N*)	Fracture rate, % (*N*)
Deer et al[91]	94	12 mo	Silicone anchor with tines	NR	NR
Gilmore et al[92]	28	12 mo	Coiled lead with tine	NR	NR
Serra et al[93]	31	12 mo	NR, SCS lead	9.6 (3)	None
Deckers et al[94]	53	12 mo	Lead with opposing lead tines	1.8 (1)	24 (13)

Before the introduction of leads designed specifically for PNS, SCS leads were used. There have been no prospective, randomized comparative studies of one type of lead or anchoring strategy to another in PNS applications. Randomized or prospective studies of PNS are described here.
NR, not reported.

Table 8. Anchor Type in DRG Studies.

Study	No. of patients implanted	Follow-up	Anchor type	Migration rate	Fracture rate
Deer et al[85]	DRG 76	12 mo	Provided plastic anchor	NR	NR
Chapman et al[95]	756 leads from 249 patients; 565 anchored, 191 unanchored		Suture or silastic anchor	Unanchored: 16 leads (8.4%) from 13 patients (21%) Anchored: 8 leads (1.4%) from 5 patients (2.7%)	Unanchored: 6 leads (3.1%) from 6 patients (9.7%) Anchored: 11 leads (1.9%) from 9 patients (4.8%)

NR, not reported.

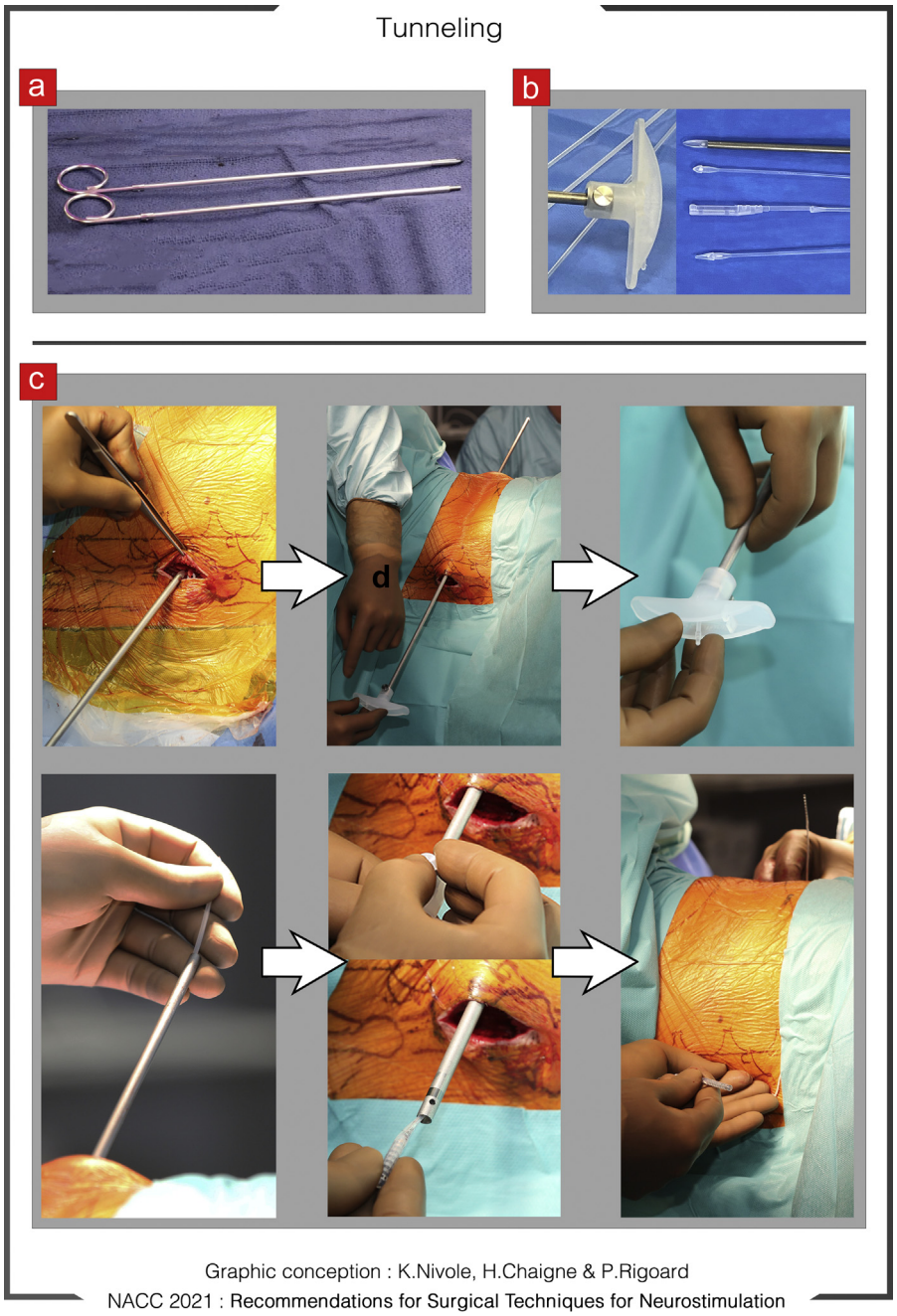

Figure 8. Tunneling. a. The tool is usually composed of a solid metal trocar with a plastic straw on the outer shaft of the trocar. Depending on SCS manufacturer, the sharp tip may need to be screwed onto the end of the trocar to keep the straw in place while passing the tunneling device (b) and also facilitate passage through the subcutaneous tissues (c). With the courtesy of manufacturers. Photoscourtesy of Philippe Rigoard and used with permission.

variation, the tool is usually composed of a solid metal trocar with a plastic straw on the outer shaft of the trocar (Fig. 8a). The tunneling device will usually come preassembled, but if this is not the case, the trocar will need to be placed through the plastic straw. The sharp tip may then need to be screwed onto the end of the trocar, depending on the manufacturer, to keep the straw in place while passing the tunneling device and to facilitate passage through the subcutaneous tissues[96] (Fig. 8b). The ultimate goal is to deliver the straw portion through the subcutaneous tissues so that it spans the distance between the lead incision and the IPG pocket (Fig. 8c).

The trocar should be inserted into either pocket at the level of the floor of the pocket and not in the middle of the subcutaneous tissues. This places the leads at an appropriate depth to be comfortable for the patient but will also help when closing the incisions because the leads will not be vulnerable to suturing while closing the tissue layers. As the trocar is being advanced in the subcutaneous tissues, careful attention needs to be paid to ensure that the trocar migrates neither too deeply nor too superficially along the tissue track. Because the trocar is malleable, placing a slight bend in the shaft will allow the operator to easily rotate the device and, with the opposite hand, palpate the tip of the trocar to ensure appropriate depth.[96] The trocar can then be rotated back to the correct depth and continue to be passed through the tissues. A slight bend in the trocar can also help to place the tip of the device within the wound, minimizing the amount of instrument manipulation at the start of the procedure and when navigating variations in patient anatomy.

If tunneling from the neurostimulator pocket to the lead pocket, attention must be paid to how the tip enters the lead pocket. First, the previously anchored leads must be protected from the sharp tip of the trocar. Second, the trocar must enter at the base of the pocket as previously discussed and, finally, at an angle created to provide for a smooth exit of the leads out of the midline incision for passing to the IPG (Fig. 8c).

Regardless of the tunneling direction, once an adequate amount of the tunneler enters the target pocket, the tip is unscrewed, and the trocar is withdrawn, leaving the straw in place as the conduit to pass the SCS leads from the lead incision to the IPG pocket. As the leads are placed into the straw, special attention should be paid to prevent kinking or unnecessary crossing of the leads over themselves as they leave the lead incision and traverse the straw. As the leads pass through the end of the straw and into the neurostimulator pocket, the straw may be grasped and pulled out of the pocket, leaving behind only the subcutaneously placed leads within the neurostimulation pocket. A loop of the electrode wires should be left in the lead incision.

SCS Staged Trial

In a staged trial, the SCS leads are anchored as they would be for the permanent implant. After the leads have been anchored, a site approximately 10 to 15 cm away from the lead incision and on the opposite flank from the anticipated IPG pocket should be identified.[96] After appropriate local anesthetic infiltration, a stab incision should be made that will serve as the exit site for the tunneling device. The tunneler is assembled as described in the implant procedure, and the tip is placed into the lead incision and advanced subcutaneously toward the predetermined exit site. Additional local anesthetic may be required along the length of the track. Once the straw of the tunneler is visible, the tip is removed, and the inner trocar withdrawn, leaving the straw in place. The proximal SCS leads are then attached to lead extensions, and these extensions are fed through the straw. After the extensions have exited the straw, the straw may be removed from the flank stab incision, leaving the extensions buried subcutaneously but exiting the stab incision and ready to be attached to an external IPG for the trial. A suture can be placed around the exit site of the extension cables.

Complications

The tunneling procedure can lead to complications including bleeding, infection, organ trauma, and damage to surrounding structures. Direct penetrating trauma to local structures should be anticipated based on where the trocar is being introduced and passed. Therefore, without careful attention, it may be possible, although very rare, to penetrate the intraabdominal cavity, intrathoracic cavity (with potential risk of pneumothorax), or nearby vessels or nerves. Violation of such spaces or structures requires the consultation of an appropriate specialist. Localized bleeding as a result of tunneling can be difficult to identify because it will usually present at the entrance or exit sites, which are also the lead and IPG incisions. This may require direct pressure along the tunneling route for a period of time to control the bleeding.[61,62] Finally, the leads and tunneling track may be associated with an SSI and may need additional operative treatment, such as incision and drainage or removal, depending on the severity of the infection.

Infection risk for a staged trial is less than that of the two-stage method for SCS implantation. According to a large retrospective review of 2737 SCS implant procedures, staged trials comprised 27.5% of all implants but had an infection rate of only 0.929%.[97] Permanent implants after a percutaneous trial, by contrast, had an infection rate of 2.06%. There was no difference in the risk of infection based on electrode type at implant.

Consensus Point 20. The NACC recommends that when appropriate, a surgical or single-stage trial may be safely considered because the risk of SSI appears low.

Recommendation grade B; level of certainty moderate; level of evidence IC.

WOUND CLOSURE AND POSTOPERATIVE CARE

Wound Closure

Soft Tissue Handling

The surgeon must be diligent to avoid soft tissue trauma when closing the surgical incisions.[97–99] Avoiding excessive cauterization is recommended, and only gentle force should be used when handling tissues with forceps. Surgical forceps can be toothed or nontoothed. During skin approximation, a toothed forceps should be used for stronger grasp and avoidance of blood flow disruption (Fig. 5d). With excessive cauterization or incorrect application of forceps, tissue devitalization can occur, which may lead to increased inflammation, elevated risk of infection, and poor wound healing.[97,100,101] Incisions should be irrigated using normal saline with or without antibiotics (Fig. 9), although there is no evidence that antibiotic-containing irrigation is better for the prevention of wound infection.[97,102,103] Any debris should be removed before wound closure.[103] Finally, it is imperative to achieve adequate hemostasis before wound closure because excess blood or serous fluid can impede wound healing and serve as a nidus for bacterial growth and infections.[102–104]

Consensus Point 21. The NACC recommends avoiding excessive electrocautery, maintaining hemostasis, and avoiding soft tissue trauma when closing the wound.

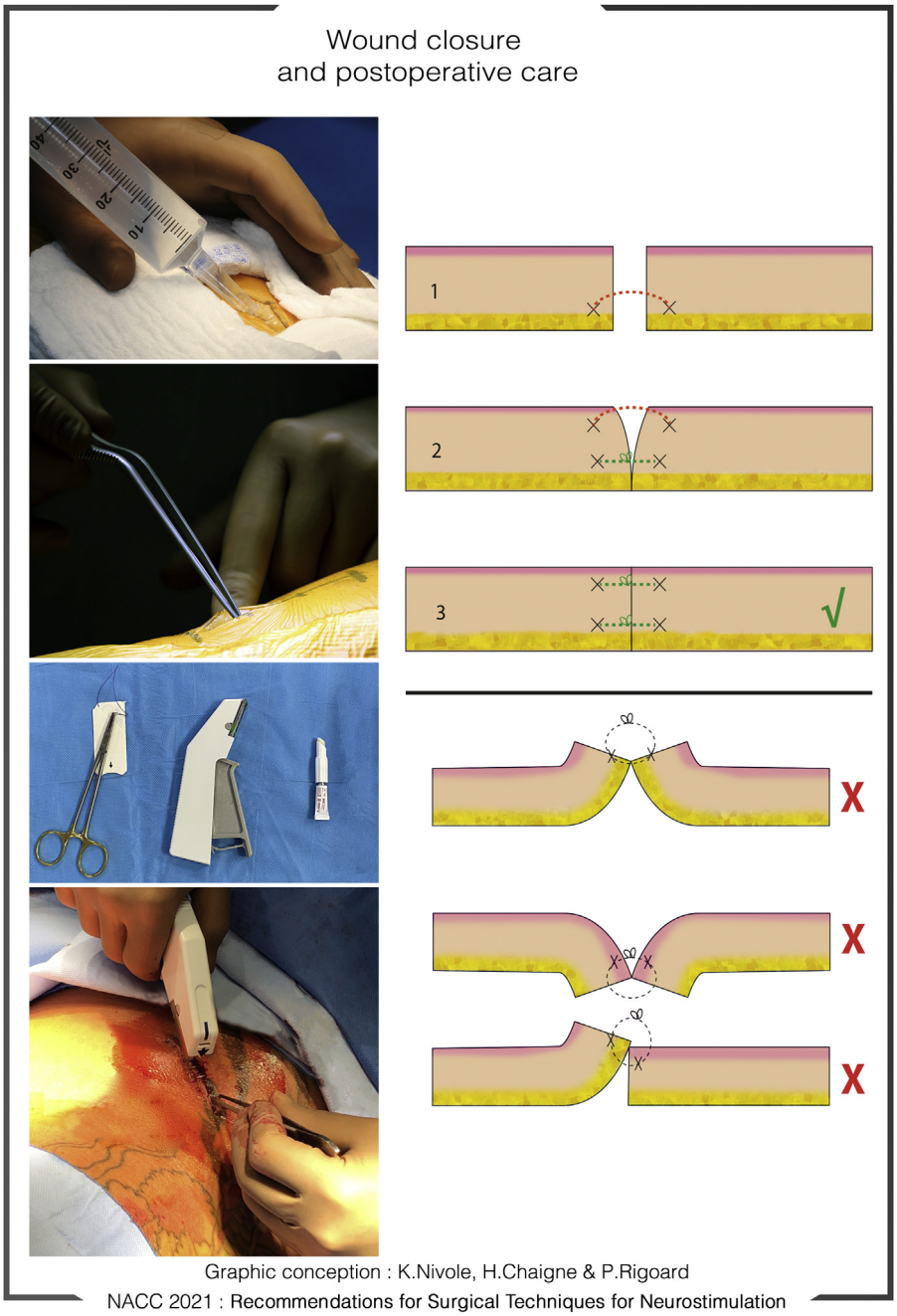

Figure 9. Wound closure and postoperative care. Incisions should be irrigated using normal saline with or without antibiotics. It is imperative to achieve adequate hemostasis before wound closure. Sutures, staples, and adhesives can be used for surgical closures. Layered closure of incisions, following basic principles of wound closure surgical techniques, is recommended to limit dead space and closure tension. Photos and illustrations courtesy of Philippe Rigoard and used with permission.

Recommendation grade B; level of certainty moderate; level of evidence II.

Closure Materials

There are a number of different materials that can be used for surgical closure, including sutures, staples, and adhesives (Fig. 9). Although staples and adhesives are used for closure of the skin layer only, sutures can be used for closure of both the skin and deeper tissue layers.

Broadly speaking, sutures are divided into two classes: absorbable and nonabsorbable sutures. Absorbable sutures degrade over time, whereas nonabsorbable sutures are more resistant to breakdown.[105] Absorbable and nonabsorbable sutures can be further classified as monofilament or braided sutures. Monofilament sutures are made up of a single fiber and, in general, produce less

Table 9. Suture Classification.

Absorbable	Nonabsorbable
Monofilament • Surgical gut (plain, chromic) • PDS II (polydioxanone) • Monocryl (poliglecaprone 25)	Monofilament • Ethilon (nylon) • Mersilene (ethylene terephthalate) • Prolene (polypropylene)
Braided • Vicryl (polyglactin 910) • Triclosan-coated Vicryl	Braided • Silk • Ethibond (coated ethylene terephthalate)

Table 10. Considerations of Staple Skin Closure.

Positive	Negative
Increased speed of closure decreases operative times	Possible increased risk of SSI has been suggested in the orthopedic surgery literature
No long-term difference in cosmetic outcome compared with suture closure	Increased expense compared with suture closure
	Staples will need to be removed in clinic upon wound healing

friction and cause less trauma when passing through the tissues. In contrast, braided sutures are made up of multiple fibers woven together. Multifilament sutures tend to be stronger and easier to handle and tie. Table 9 highlights the commonly used sutures and their classifications.[105,106]

In general, a multilayer closure (subfascial muscle, fascia, subdermal, dermal) with absorbable sutures is used for approximating the deeper tissues, and absorbable (supplemented with steri-strips or Dermabond[107]) or nonabsorbable sutures are used for the final skin closure.[107,108] Within the absorbable suture class, Vicryl (polyglactin 910) is commonly used for closing subcutaneous tissues. Vicryl is a synthetic multifilament suture composed of lactide and glycolide copolymer and coated with polyglactin 370 and calcium stearate.[106] It retains 70% of its tensile strength at two weeks and 25% at four weeks.[105,106] This suture is degraded by hydrolysis and, because of this, causes less tissue reactivity. Although extremely low infection rates have been previously reported with these methods, Vicryl has demonstrated increased bacterial adherence during in vitro studies.[109] This has led to the suture being implicated in postoperative wound infections, particularly when used in a contaminated wound closure.[97]

In response to this increased risk, triclosan-coated polyglactin 910 was developed. Triclosan is found in many consumer products to reduce bacterial contamination. The mechanism of action involves binding to the bacterial enoyl-acyl carrier protein reductase enzyme, which causes the downstream effect of inhibited fatty acid synthesis. Because of this, bacteria are unable to produce cell membranes, which is incompatible with bacterial growth and life.[110,111] In a meta-analysis, triclosan-coated suture was found to significantly reduce the risk of SSI at 30 days in both clean and contaminated surgery.[112] In addition, both the WHO and CDC recommend that triclosan-coated suture should be considered to reduce the risk of SSI.[2,3] For these reasons, triclosan-coated polyglactin 910 should be considered for surgical closure, particularly in patients at an increased risk of postoperative SSI.

PDS II (polydioxanone) is another absorbable synthetic suture; however, it is a monofilament construct consisting of a polyester polymer.[105,106] It can be used to close subcutaneous tissues and epidermis. Similar to Vicryl, it retains 70% of its tensile strength at two weeks and 25% at six weeks and has low tissue reactivity. PDS II has been shown to have a decreased likelihood for bacterial contamination and should be considered in contaminated wounds.[97,105,106]

Finally, Monocryl (poliglecaprone 25) is an absorbable synthetic monofilament suture composed of polymers of glycolide and epsilon-caprolactone. It maintains 60% of its tensile strength at one week, which is lost by three weeks. This suture is commonly used for subcuticular skin closure.[105,106]

Consensus Point 22. The NACC recommends that Vicryl, triclosan-coated Vicryl, and PDS II are all suitable choices for subcutaneous closure in clean wounds. In contaminated wounds, preference should be given to triclosan-coated Vicryl and PDS II.

Recommendation grade B; level of certainty moderate; level of evidence IC.

As already stated, nonabsorbable sutures are most commonly used for closure of the epidermis. Ethilon (nylon) is a commonly used nonabsorbable skin suture composed of nylon 6 polymers.[105,106] Nylon suture has high memory, which can contribute to knot slippage.[103] Interrupted braided silk sutures should never be used for skin closure.

Alternative options for skin closure include staples and adhesives. Staples are generally considered a quicker alternative but tend to leave track marks immediately after removal. However, long-term cosmetic outcome is similar to suture closure[113] (Table 10). There are a number of studies from the orthopedic surgery literature suggesting an increased risk of infection with staple closure, but RCTs from other surgical disciplines have not found similar results.[114,115]

Adhesives, such as Dermabond (octyl-2-cyanoacrylate), can be used alone or in combination with suture to close the skin. The use of adhesive alone to close the skin is not ideal for larger incisions or incisions under high tension. Adhesives may also lead to skin irritation and excoriation and, when used alone, can lead to skin layer dehiscence.[105] In addition, care should be taken not to place the adhesive into the incision itself because this may interfere with incisional wound healing.[105,116]

Incision Closure Techniques

Layered closure of separate tissue planes is beneficial for several reasons (Fig. 9).[43] First, layered closure relieves tissue tension and subsequently decreases the risk of tissue necrosis and wound dehiscence and thus improves wound healing.[98,117] This is particularly important for IPG pocket closure because the implanted hardware may place tension on the incision. If excess tension exists, the pocket should be enlarged. Second, layered closure reduces the dead space between tissue planes, which helps to minimize hematoma and seroma formation.[118,119] Hematoma can serve as a medium for growth of microbial organisms and has been implicated in superficial and deep soft tissue infections.[43,97,103,104] Therefore, by reducing the risk of hematoma and seroma formation, layered closure also decreases the risk of wound infection.

Consensus Point 23. Layered closure of incisions is recommended to limit dead space and closure tension, minimize infection risk, and improve healing.

Recommendation grade B; level of certainty moderate; level of evidence II.

When closing surgical incisions, the tissues can be approximated using many different suturing methods, including simple interrupted and continuous running sutures in the subcutaneous tissues and simple interrupted, continuous running, vertical mattress, horizontal mattress, and running subcuticular sutures at the skin. Continuous running locked closure may interrupt microcirculation and cause poor wound healing, and this should be avoided.[43,97] Subcuticular skin closure may be more aesthetically pleasing to the patient because the suture is hidden within the dermal layer.[120] However, this particular skin closure technique, unless supplemented with steri-strips or Dermabond, is relatively weak and may loosen under increased tension from either the implanted hardware or patient movement.[105,106] If one expects high tension at the incision, it is advisable to avoid this skin closure method.[120–122] All available suturing options have proven to be equally effective, and the complication risks, including SSIs, are similar.[43,98,113,120,123,124] When considering the cosmetic outcome, all skin closure techniques have proven equivalent when adequate eversion of the incision edge is achieved.[43,98,113,120,123,124] An exception is simple interrupted closure, which has been shown to leave cross-hatch or "railroad" marks in the first six months after surgery.

Consensus Point 24. All epidermal closure materials and methods have proven equally efficacious in terms of infection risk and cosmesis. Proper technique is more important than suture material or method.

Recommendation grade B; level of certainty moderate; level of evidence II.

Dressings

The application of a wound covering or dressing after wound closure following device implantation appears to be a critical part of the process to reduce potential morbidity (Fig. 10). The primary goal of a postoperative surgical dressing is to protect the wound from injury or contamination and thus reduce the risk of SSI. The dressing should obviously cover the entire wound to offer full protection and augment the healing process.[125] Several early studies in the surgical literature suggested that occlusive postoperative dressings decreased the rate of SSI.[126,127] Data from a recent large multisite retrospective review of SCS practices also supported a statistically significant reduction in SSI when a sterile occlusive dressing was applied in the operating room.[42,97] Another large prospective cohort study ($N = 410$ SCS surgeries) showed that with bundling surgical processes, such as wound dressing and daily wound inspection, they significantly reduced the burden of SSI from 10.4% preintervention to 1.0% postintervention.[128] However, it should be noted that the most recent systematic reviews and meta-analyses available from all surgical literature suggest there is insufficient evidence to support the superiority or routine use of a particular postoperative dressing given the lack of difference in SSI outcome (ie, no dressing or protective, antibacterial, adsorbent, or debriding-type dressings).[13,129,130] This finding has recently been supported by the *JAMA Surgery* CDC guideline for the prevention of SSI by using a postoperative antimicrobial dressing, which demonstrated ambivalence given the lack of quality evidence.[2] Despite some of these findings, multiple guidelines, including those of NACC, CDC, and National Institute for Health and Care Excellence, continue to recommend the use of a sterile occlusive dressing for 24 to 48 hours because clean incisions closed and were healing under primary intention (Category 1B).[43,68,131] In general, the use of an occlusive dressing applied in a sterile manner may provide additional support and protection for typical postoperative exudate that allows for optimal wound healing.

Consensus Point 25. The NACC recommends a clean wound closed with primary intention to be covered with a sterile occlusive postoperative surgical dressing for 24 to 48 hours to reduce the risk of SSI.

Recommendation grade B; level of certainty moderate; level of evidence IB.

Postoperative Wound Care

As described previously, the surgical wound is expected to heal through primary intention when the wound edges are approximated and secured with various closure techniques. The primary goals of wound care after surgery are to allow for a rapid healing time without infection or complication and to achieve optimal function and appearance. There are a few key elements to postoperative wound care management.

First, the patients' medical condition and comorbidities should continue to be optimized in the perioperative period to ensure optimal wound healing, including control of potentially modifiable risk factors such as cardiovascular disease, periodontal disease, immunosuppression, tobacco use, and systemic health conditions such as obesity and diabetes.[132]

Consensus Point 26. The NACC recommends attentiveness to medical comorbidities and optimizing potentially modifiable risk factors to promote wound healing.

Recommendation grade A; level of certainty high; level of evidence I.

Second, the patient should be seen within 10 to 14 days of surgical intervention to remove nonabsorbable sutures or staples based on the degree of wound healing, ensure appropriate education on incisional wound care, and evaluate for any signs or symptoms of emerging SSIs.[43,133] Patients and their family members should be counseled on the signs and symptoms of typical and atypical wound healing.[43] Although postoperative infection is rare, the IPG site is the most common location.[42,97] Early signs and symptoms may include pain and tenderness, wound erythema, drainage, swelling, dehiscence, and fevers and nausea.

Consensus Point 27. The NACC recommends follow-up within 10 to 14 days to remove nonabsorbable sutures or staples and education for the patient and family on the signs and symptoms of SSIs.

Recommendation grade A; level of certainty high; level of evidence IB.

Third, suitable dressings should be selected based on the ability to maintain a protected environment, enhance epidermal migration, promote connective tissue synthesis, allow gas exchange between the wound and environment, maintain appropriate temperature to improve blood flow, provide protection against bacterial infection, be nonadherent to the wound, and be sterile, nontoxic, and nonallergic.[43,97,132,133] As noted earlier, occlusive dressings have been proven to improve wound healing rates

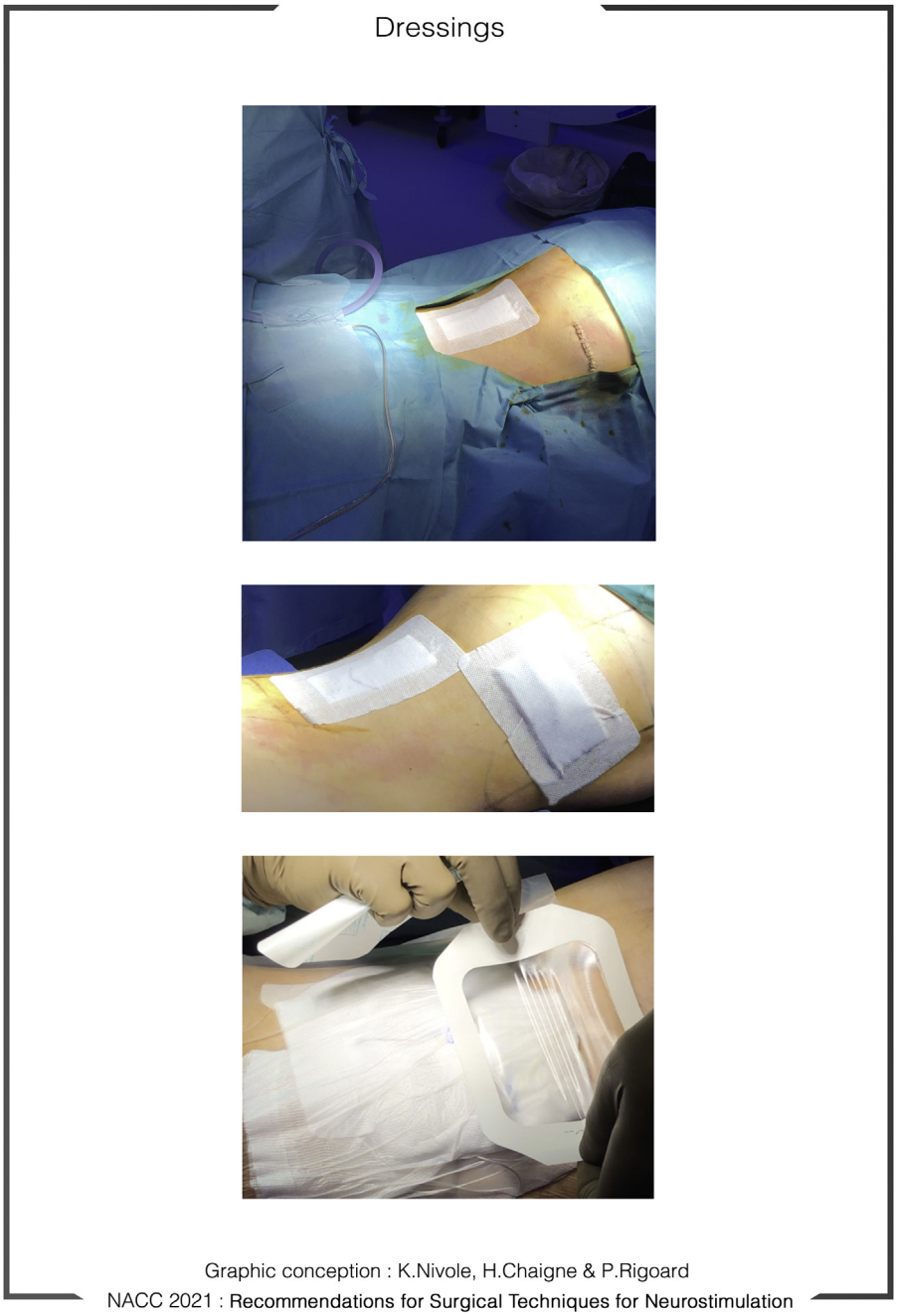

Figure 10. Dressings. The dressings should cover the entire wound to offer full protection. Significant reduction in postoperative infection has been observed in some studies when sterile occlusive dressing is applied in the operating room. Photos courtesy of Philippe Rigoard and used with permission.

by decreasing desiccation and inflammation and allowing accumulation of growth factor–rich exudate that aids the healing process.[134–138]

Finally, current guidelines recommend aseptic sterile technique if a dressing change is required in the immediate postoperative period. If wound cleansing is necessary in the first 48 hours, an aseptic technique using sterile gloves and sterile saline, if required, is recommended. After 48 hours, patients can use regular nonsterile water for cleansing the wound. Should any evidence of early SSI be present, then close follow-up is recommended with regular wound monitoring. Should there be any concern for superficial or deep infection, then consultation with an infectious disease or clinical microbiology expert is recommended, and antibiotic treatment should be considered.[42,43,97,132,133] Routine topical antimicrobial therapy is not recommended.[131,132]

Consensus Point 28. The NACC recommends an aseptic sterile technique, where possible, when changing postoperative dressings in the first 24 to 48 hours after surgery.

Recommendation grade A; level of certainty high; level of evidence IB.

Postoperative Pain Management

Optimal postoperative pain management should allow for faster recovery, reduced complications, and improved patient satisfaction. Every surgery has the potential to cause chronic pain, and although not common, there is the potential for persistent postsurgical pain after implantation of neurostimulation devices. However, even in this patient population experiencing chronic pain, the acute postoperative pain is generally well tolerated and short lived.

The postoperative pain after implanted neurostimulation devices usually includes nociceptive, inflammatory, and neuropathic components, which begin with the surgical trauma and typically reduce as the tissue heals.

- Acute phase—usually lasts up to seven to ten days and starts immediately after discharge from the postanesthesia care unit.
- Subacute phase—ten days to three months. A transitional period where most patients will convalesce with longer-than-expected postprocedure discomfort times, whereas some will go on to have chronic pain.
- Chronic phase—pain that exceeds three months after surgery.

Acute Phase

There are no specific data or recommendations regarding the choice of analgesics following neurostimulation implantation procedures; many of the recommendations have been extrapolated from the general surgery and spinal surgery literature.[139] Perioperatively, a number of interventions can reduce the development of acute and chronic pain.

First, it is important to set expectations for neurostimulation procedures. Patients should understand the nuances of the IPG including any recharge burden requirements, potential sleeping positions, interference with occupational equipment (eg, a tool belt) and how the IPG can lead to discomfort. One recommendation is for patients to undergo a "wear study" to emulate what it feels like to have an IPG in place. This can be accomplished with a template or a dental floss box as a surrogate. Surgeons must do their best to implant these devices at an appropriate depth without neural injury and avoiding bony protuberances.

Preoperatively, patients may be given opioids, acetaminophen, COX-inhibitors (NSAIDs), and gabapentin, and after induction, patients may be given intravenous ketamine for antihyperalgesia. Intraoperative ketamine has been shown to reduce the development of chronic pain after surgery in various types of surgeries and has been shown to reduce postoperative opioid consumption.[140,141]

During surgery, it is recommended to use local anesthesia of both superficial and deep tissues before any tissue trauma to reduce transduction and transmission of nociception to the greatest degree possible.

Postoperative medication management consists primarily of acetaminophen and COX-inhibitors (NSAIDs), with the use of ice and compression over the IPG site. COX-inhibitors can be associated with bleeding, inhibition of wound healing, and renal and gastrointestinal risks, and, therefore, assessment should be made by the clinician providing the lowest effective dose and for the shortest possible period. Both COX-1 and COX-2 are inhibited by the COX-inhibitor/NSAID class of medications. Some favor the inhibition of the COX-1 isoform, and some favor the COX-2 isoform. COX-1 isoform side effects may include gastritis, renal dysfunction, and bleeding, whereas inhibition of the COX-2 isoform has a higher incidence of cardiovascular adverse effects including stroke and MI.[142,143] Because NSAIDs inhibit both isoforms, there is the potential for cardiovascular adverse events with chronic use of many clinically used medications.[144]

Opioid medications have been used historically for postoperative pain management. However, there is growing evidence that they may contribute to the development of chronic pain through opioid-induced hyperalgesia, and they carry addiction potential. For these reasons, the CDC has recommended exhausting non-opioid analgesics before having a risk vs benefit discussion on the use of opioids for postoperative pain.[145] The recommendation is to prescribe no more than three to five days of opioids, considering their misuse, abuse, and addiction potential.

Chronic Phase

The incidence of the development of chronic pain after neurostimulation procedures is unknown. It is speculated to be relatively low given that the surgery is minimally invasive. However, certain types of pain can manifest from the procedure or from the implant. We discuss here some of the more common postoperative neuromodulation pain syndromes.

Persistent pain following laminectomy may be caused by the disruption of thoracic soft tissue or may be radicular in nature. Thoracic radiculopathy may be a cause for acute pain extending into the chronic phase especially after a paddle lead placement. This presentation may include a band-like thoracic or abdominal pain pattern that may be more severe than the incisional pain; no motor deficits are evident. This is more commonly seen with more lateral lead placement or with axial or coronal rotation of the paddle. Preoperative thoracic spine MRI or CT can be helpful to understand potential anatomic challenges in advance.[146]

Pain encountered at the site of the IPG after surgical placement is a well-known entity. The reported incidence of implant-site pain ranges between 0.4% and 35%, but it has never been systematically studied, and no treatment guidelines are available.[147] The original location of IPG placement has not been shown to have a significant or predictive value for future pocket pain.[148] Both meticulous surgical technique and setting of appropriate expectations appear to be important. Patient factors (eg, weight gain/loss, repeated trauma to the IPG site, recharge burden and process, underlying health of the tissues) should also be considered. Pocket pain is usually managed like the acute phase pain with topical or oral simple analgesics, with patients occasionally requiring revision.

Pain at the site of lead anchoring may also be commonly encountered, especially because larger and more robust anchoring systems are being used. These anchors often have a hard plastic body that can compress local structures and cause pain. The treatment again involves topical or oral simple analgesics, and in some intractable cases, system revision is required. Pain over the anchor site may occur more commonly in those with low BMI, and this should be considered when choosing the anchoring device during preoperative planning.

Electrode migration can also be a cause of chronic postoperative pain. Most commonly, the migrated lead irritates a neural structure, causing pain and paresthesia in the relevant dermatomes. Such pain has been noted more frequently with percutaneous leads than with surgically placed paddle leads. The negative effects of lead

migration may be overcome by reprogramming, but revision surgery with lead repositioning may also be necessary. Although a plain film x-ray may diagnose the problem, revising the lead requires knowledge of the anchoring technique used at the time of the primary implant.[149]

MANAGEMENT OF WOUND COMPLICATIONS

Surgical Site Infection

The CDC has previously characterized superficial and deep SSIs[2,68] (Fig. 3). Superficial SSI involves only skin or subcutaneous tissues, whereas deep SSI involves the deep soft tissue including muscle and fascia. Although biologic complications most frequently appear within three months of device implantation,[150] the CDC has defined deep SSIs as occurring within the first 12 months postimplant.[68] Surgical sites should be evaluated within 10 to 14 days of surgery to assess for appropriate wound healing and signs of SSI.[132] If an SSI is suspected to be developing, close follow-up is imperative to adequately start treatment and mitigate preventable complications.

Superficial Infection

When an infection is suspected, treatment must start at once. Swab microbial cultures are crucial to help in appropriate antibiotic selection. That being said, the initiation of empirical antibiotics should not be delayed in patients with signs of a developing SSI, with a plan to adjust the therapy based on culture and sensitivity results. Conservative therapy has been recommended based on the site and characteristics of superficial SSIs.[133] When superficial infection is suspected (ie, not involving the IPG, SCS leads, or neuraxial space), it is acceptable to consider treatment with an oral course of antibiotics and close follow-up.[133,151] However, if there is concern for deeper infection around the IPG, SCS leads, or neuraxial space, imaging should be obtained, and prompt treatment is necessary.

Deep Infection and Abscess

Deep infections occur less frequently than superficial infections.[152] Once suspected, they typically require incision, drainage, and removal of hardware, in addition to intravenous and/or oral antibiotics. Complete hardware removal is essential to treat deep infection because partial removal of the device has been linked with higher rates of treatment failure, relapse, and serious morbidity.[153,154] As in cardiac device generator pocket infections, seven to ten days of antibiotic therapy is typically sufficient if blood cultures are negative, and source control is accomplished.[155] When complicated SCS infection is recognized, the infectious disease or medical microbiology team should be consulted to assist with antibiotic selection and duration of therapy.

The frequency of spontaneous epidural abscess is two per 10,000 hospital admissions.[156] The incidence of epidural abscesses following neuraxial device implantation is unknown because most reports consist of single cases.[157] Early detection of signs and symptoms of epidural abscess is crucial for the prevention of potentially catastrophic neurologic complications. Both MRI with intravenous gadolinium and myelography followed by CT of the spine are highly sensitive (>90%) in diagnosing spinal epidural abscesses.[158] MRI is less invasive; however, MRI conditional compatibility of the implanted device needs to be reviewed before deciding on imaging modality.[159] Consultation with an infectious disease specialist or medical microbiologist is warranted if neuraxial structures are involved.

Epidural abscess mortality rate has been reported to range from 10% to 23%. When neurologic decline begins, emergent surgical decompression is essential. Neurologic recovery is questionable once paralysis has been present for >12 hours. If motor deficits have been present for >36 hours, full recovery is doubtful.[160,161]

Hematoma

A postoperative hematoma can occur around the battery pocket, the tunneled leads, or in the epidural space (Fig. 4). The presence of a hematoma around the battery pocket site can lead to wound dehiscence and serves as an excellent bacterial growth medium.[61] The risk of epidural hematoma is low, ranging between 0.25% and 0.7% of cases.[53,54,60] However, when the hematoma compresses the spinal cord, serious deficits can occur, which may progress to paraplegia. Close monitoring following insertion of a neurostimulation device is recommended, and this should include neurologic and wound observation.

A symptomatic epidural hematoma is a true emergency. Warning signs of epidural hematoma include progressive postoperative numbness that may be accompanied by severe back or leg pain. Should these warning signs develop, an immediate urgent referral should be made to the emergency room or a collaborating neurosurgeon or spine surgeon, even before any weakness develops. The evaluation should rule out intramedullary electrode placement, subdural hematoma, epidural hematoma, or spinal cord injury or compression, along with any associated spinal canal stenosis.[79] MRI investigation may be possible in MRI conditionally compatible systems. If not possible, CT with or without contrast should be performed. If the CT is diagnostic or inconclusive, then the leads should be urgently removed, and MRI should be obtained immediately afterward.[162] When an epidural hematoma is confirmed, the standard treatment is immediate surgical evacuation. Ultimately, the decision if and when to operate rests with the surgeon, in collaboration with the SCS implanting physician, because there may be delays in patient presentation that can also vary with regard to their clinical course.[163,164] A detailed discussion of the risk, prevention, and treatment of spinal epidural hematomas is provided in a previous NACC manuscript.[102]

A battery pocket hematoma can frequently be observed even if the hematoma is not causing pain or pressure on the scar. Larger hematomas can be managed by compression and/or aspiration. If the problem does not resolve in a reasonable time and might affect wound healing, an incision and drainage should be performed.[165] Pocket hematoma aspiration can be considered as a treatment, but the risk of infection must be considered in the risk-to-benefit decision.

Seroma

A seroma is a collection of serosanguineous fluid within a developing pocket or a surgically created pocket that is likely caused by frictional forces between two tissue planes and excessive surgical trauma.[79] A recent retrospective study reported an incidence of seroma of 0.4% at one year postimplant for insertion of spinal cord stimulators.[166] Seroma risk reduction includes preoperative patient preparation, such as treating comorbidities like diabetes by optimizing glucose control. During surgery, avoiding excessive IPG pocket size and limiting excessive tissue trauma, such

as aggressive sharp dissection, excessive use of cautery, or forceful blunt retraction, should be considered.[133]

Diagnosis can be confirmed by aspiration of a straw-colored fluid that is negative on microscopic examination for bacteria and subsequent culture. Diagnosis can also be confirmed by surgical exploration and drainage, with culture and fluid analysis.[18] Seroma should be distinguished from CSF hygroma based on fluid analysis. CSF hygroma is a rare but potentially serious complication. Treatment includes conservative observation or surgical open correction of the dura based on physician judgment.

Treatment can include observation because many seromas simply resolve over time. Other management options include pressure application to the tissue, needle aspiration or surgical incision, and drainage.[167] Aspiration can lead to introduction of infection and the risk-to-benefit ratio should be considered. If a seroma persists or recurs despite appropriate treatment, it may be advisable to re-operate and reduce the dead space using appropriate closure techniques.[79]

Dehiscence

Wound dehiscence occurs when one or more layers of the surgical wound separate. Although rare, this most often occurs between five and eight days after surgery. It is more common in patients prone to poor wound healing, such as patients with diabetes, immunosuppression, connective tissue disorders, and cancer. A postoperative hematoma can also put internal pressure on the wound, leading to dehiscence. Wound closure with excessive tension on the wound can lead to ischemia and subsequent separation of tissue layers because of necrosis. Failure to sufficiently close tissue layers may also lead to dehiscence.[167] The use of steroids increases the risk of wound dehiscence two- to threefold.[168]

Optimizing patient risk factors before surgery is also important.[169] Control of diabetes,[170] improved nutrition,[171] and cessation of smoking can all improve healing.[172] Equally important, avoiding incisions directly over the intended site of the implanted hardware, meticulous hemostasis, and closure of wounds in layers avoiding excessive skin tension can reduce the risk of wound dehiscence.[79] With rechargeable pulse generators, program settings that require frequent recharging may also negatively affect wound healing.[173]

Techniques for the management of wound dehiscence in the setting of neuromodulation procedures are largely anecdotal. If there is no evidence of infection, salvage of the system may be attempted with wound debridement and closure with sutures or a vacuum-assisted closure system, with or without antibiotic coverage.[79,174] If there is evidence of deep infection or if salvage of the system fails, the neuromodulation device must be removed, regardless of whether there are systemic infection symptoms or not.[79]

Erosion

Skin erosion of leads or hardware is an uncommon complication of SCS (Fig. 3). Skin erosion of leads is typically a consequence of superficial lead placement. IPG skin erosion can be reduced by appropriate placement at an appropriate depth and away from bony prominences, careful layered closure with no tension on the skin edges, and avoidance of suture lines over the implanted device.

With lead erosion in the absence of infection, salvage attempts have been documented with debridement and reclosure of the skin or deeper implantation of the lead,[175] although this is not always successful. If a deep infection occurs that involves the device pocket, the SCS device must be removed regardless of whether there are systemic infection symptoms or not, and device salvage attempts are discouraged. After wound cultures are taken, treatment for infection must be started. Radiographic diagnostic tests such as MRI or CT should be performed to rule out epidural abscess.[79] If reimplantation is considered, the infection should be resolved, and appropriate measures undertaken to reduce the risks of reinfection, poor wound healing, and repeat dehiscence.[176–178] It may be reasonable to consult with an infectious disease specialist or medical microbiologist before reimplantation. There are no formal data regarding reinfection rates after reimplantation or the optimal timing of reimplantation. The decision to reimplant should be individualized to the patient's circumstances, such as severity of previous infection and potential sequelae and the effectiveness of the neuromodulation system at addressing the patient's symptoms, along with the desire for the patient to move forward with reimplantation. For additional information, please consult the newest NACC guidance on therapy salvage published in a companion article.[179]

TRAINING OF FELLOWS AND RESIDENTS IN SURGICAL TECHNIQUE

With the evolution of neuromodulation technology, research, and data, the training of residents and fellows must simultaneously evolve parallel to the speed of rapid innovation within the field. Ensuring safe and efficacious patient outcomes with the growing use of medical device technology is paramount, and we must continue to invest in the operative skill set of our trainees across all specialties. Many different medical and surgical specialties participate in SCS patient selection, trialing, implantation, and follow-up, including neurosurgeons, anesthesiologists, physiatrists, interventional radiologists, neurologists, psychiatrists, and orthopedic surgeons. The core knowledge and surgical training in SCS can differ widely among specialties, with trainees gaining varying degrees of familiarity with implantation techniques of SCS devices and management of patients and potential complications. For practitioners outside of the surgical specialties, cadaver courses and a basic surgical skills course are helpful, as are attendance and assistance in routine elective spinal surgeries performed by neurosurgeons and orthopedists. However, given the diversity of primary specialty backgrounds observed among neuromodulators, standardization of core surgical competencies to assess and improve these skills is critical to ensure the safety of our patients and the growth of the field. The past decade has produced not only robust neuromodulation data but also a growth of the number of manufacturers in tandem with unique treatment approaches and targets and an expansion in indications, hardware, and software. This increased complexity and utilization of the technology mandate proper training of physicians in their safe and efficacious application.[180–187]

Although training in neuromodulation is clearly a worldwide endeavor, the following is an overview of the training process within the United States. Traditionally, surgical training within neuromodulation has been achieved through the Accredited Council of Graduate Medical Education (ACGME) residency and fellowship training programs, societal engagement through cadaver laboratory training courses and mentorship programs, and

industry-sponsored courses for implantable therapies. However, despite ACGME guidelines, there remains significant variability within and across the specialties delivering education and training for implantable neuromodulation therapies. Furthermore, because of unmet needs in training, industry sponsorship plays a larger-than-desired role in surgical education and training. This presents a separate challenge with respect to conflict of interest and bias. In 2014, Gharibo et al[184] reported that 89.1% of pain fellowship program directors ranked fellowship as the "most valuable" source of fellow SCS training, with manufacturer-sponsored workshops ranked second.[181–188]

Currently, the ACGME requires five observed neuromodulation cases per pain fellow to meet graduation requirements to matriculate from pain medicine fellowship into practice. Unfortunately, this requirement does not take into consideration the nuances and complexities of interventional pain management within clinical practice. There are a need and opportunity to redefine these core competencies to assure efficacious outcomes after training. In 2019, Pak et al[185] surveyed pain medicine fellows and practicing pain physicians from 2016 to 2017 and reported that although many (36.5%) had performed >15 SCS trials during fellowship, the majority (63.5%) had performed 15, but 32% performed one to five, and 7.5% did not perform any implants during fellowship. The average number of SCS trials per program was 46.12 (range: 5–200), and the average number of SCS implants per program was 32.44 (range: 0–150).

Despite attempts to standardize training and best practices for neuromodulation, there is inconsistency and a wide range of practice among physicians when it comes to the use of skin preparation, wound closure, and postoperative antimicrobial prescriptions, to name just a few. More structured surgical training with implantable technology with respect to device appropriateness, indication, technical skill, and complication management may have an impact on the safety of neuromodulation procedures and their success rates and would directly address unmet needs during training.[180–190]

Falowski et al[182] reported cumulative five-year survey data from a national one-year neuromodulation mentorship program including 63 trainee/mentor pairings across multiple specialties. Only 56.2% of trainees reported feeling comfortable performing SCS implants at the end of a pain medicine fellowship. In addition, 54.7% reported an unmet need for SCS therapy training, and 47.1% felt that pain medicine societies should be responsible for developing guidelines to help encourage the standardization of SCS practices. Most mentorship program participants reported an increase in the number of SCS trials and permanent implants performed after successful program completion. At the conclusion of the program, mentees reported higher statistically significant competency scores in all areas assessed, which included knowledge of neuromodulation modes and targets, knowledge of patient selection for neuromodulation, knowledge in the management of neuromodulation complications, and confidence in surgical skills. This survey further elucidates the wide variability in training among various pain medicine fellowships. Societies and organizations such as the American College of Surgeons, the ACGME, and others have recognized the inherent heterogeneity of trainees and training programs and have recommended and implemented formal mentorship programs to help physicians with their transition into independent practice, which has demonstrated benefit.[182–193]

Consensus Point 29. The NACC advocates for participation in a structured mentorship program during neuromodulation training, either within formal fellowship training or through societal engagement.

Recommendation grade A; level of certainty high; level of evidence II.

Pittelkow et al[180] have proposed an elective pilot program utilizing the validated Zwisch scale for the evaluation of pain fellow performance during SCS surgical cases to rank the degree of guidance the primary supervising surgeon provides to the surgical trainee during the critical portion of the procedure. Secondary goals included determining satisfaction with the use of the rubric and identifying areas to improve feedback for trainees. The four core categories consisted of technical approach, image interpretation, epidural access, and wound closure. Fellows were expected to have the tools available following all SCS trials and permanent implantations for postprocedural debriefing. The results indicate that implementation of a surgical skill neuromodulation rubric scale was beneficial for both the supervising physicians and fellows. Further study into supplemental measures of trainee proficiency with surgical skills is necessary and warranted within fellowship programs.[180–196]

In an effort to fill this the gap of formal surgical training in neuromodulation, Abd-Elsayed et al[181] proposed an educational curriculum for trainees and early career neuromodulators for SCS. The authors provided parameters to assess the necessary competence to offer or take part in the implementation of neuromodulation therapies regardless of one's individual specialty, as well as an ability to track completion through the use of formal assessment by program directors or mentors. Core competencies included patient selection, radiographic knowledge and interpretation, trialing, surgical skills, intraoperative troubleshooting, complication management, and long-term care. This educational curriculum proposes a standard by which an accepted competency could be met and provides guidance toward eventual accreditations and certifications.[97,181–200]

Consensus Point 30. The NACC recommends the addition of a standardized measure of proficiency for residents and fellows in training to ensure competency of surgical techniques within neuromodulation.

Recommendation grade B; level of certainty moderate; level of evidence II.

To date, there is no formal certification or accreditation that has been established outside of the fellowship training model specifically for neuromodulation, with the exception of specialty board certification status. In addition to ACGME residency and fellowship training, trainees' surgical skills can be enhanced through societal engagement through mentorship, online digital education, hands-on cadaver training courses, and industry-sponsored training programs. Knowledge of SCS devices and their applications, preprocedure planning, imaging evaluation, pertinent anatomy, use of fluoroscopy, technical device placement, troubleshooting, and management of device complications are skills that must be learned to care for patients with chronic pain effectively and safely. Modern training programs preparing residents and fellows to practice neuromodulation safely must raise their standard of training to include comprehensive surgical skills to align with the rapid evolution of the field. The standards of ACGME training requirements with respect to these core skills and competencies should be re-evaluated regularly to better

reflect the scope of technology and practice and to ensure the proficiency of trainees producing safe and efficacious outcomes. The NACC recognizes that training requirements and processes vary throughout the world, and as such, there is variety in the methods that allow a physician to arrive at the same end point of wide knowledge base, excellent procedural exposure, and graded progression of training allowing demonstration of clinical judgment. It is suggested that future editions of the NACC may focus on these differences in training requirements to determine worldwide best practice.

CONCLUSION

The recommendations of the NACC are based on careful review of the literature, grading of the evidence, and a consensus of physicians who represent a diverse and experienced body of experts. These best practices can be followed to improve patient safety and efficacy.

Authorship Statements

Timothy R. Deer served as primary co-author and coordinator. Marc A. Russo served as primary co-author. Philippe Rigoard served as contributing author and illustrator. Jonathan M. Hagedorn and Jay S. Grider served as contributing authors and grading and evidence leaders. Ricardo Vallejo, Alexander L. Green, Fabian Piedimonte, Peter Pahapill, and Alessandro Dario served as editors. Robert M. Levy served as senior editor and worked on overall manuscript revision. Jonathan M. Hagedorn, Peter Pahapill, Philippe Rigoard, Derron Wilson, and Timothy R. Deer worked on revisions requested by reviewers. The remaining authors conducted literature searches, wrote sections, wrote consensus statements, or reviewed/edited sections they did not draft, and all approved the submitted manuscript.

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SUPPLEMENTARY DATA

To access the supplementary material accompanying this article, visit the online version of *Neuromodulation: Technology at the Neural Interface* at www.neuromodulationjournal.org and at https://doi.org/10.1016/j.neurom.2021.10.015.

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COMMENTS

This latest piece of work from the Neuromodulation Appropriateness Consensus Committee is a welcome, thorough and well-illustrated addition to the series. The authors have set out their purpose and methods clearly, and they emphasize that the document is not a substitute for appropriate and adequate training. Indeed, a whole section is devoted to training, reflecting its importance. The

producers of guidelines can face a dilemma regarding detail vs underlying principle. This is particularly the case where practical techniques are involved, as here. For example, highlighting the natural biological tendency to expel foreign bodies, which demands particular care in closing the wound over an implant competently, in layers and without tension, is perhaps more important than are detailed and specific instructions on how to do it. This points to a related dilemma, which is how prescriptive to be. Legitimate variations of technique may achieve comparable outcomes; one is not necessarily the best. Furthermore, conformity can stifle innovation and improvement; the underlying principle may be more important. In other areas, such as thromboprophylaxis, and prevention of infection, the principles may be obvious and, for guidelines, it is then the detail that matters. The authors have tackled these challenges. Recommendations carry most weight when their rationale and evidence-based justification is clear. A danger that has not been completely avoided is that of not addressing the whole audience. This becomes more relevant in the present context as neuromodulation becomes increasingly global. The authors have recognized this in relation to the otherwise excellent section on training, in which the specifics relate only to the United States. Although this is not without interest to others, their suggestion that future guidelines should be more inclusive in this respect is welcome.

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The Neurostimulation Appropriateness Consensus Committee (NACC) has provided multiple guidelines in relationship to neuromodulation procedures over the years. These guidelines have become essential reading for practitioners who want to "improve efficacy and/or safety of neuromodulation procedures." On this occasion, NACC has developed almost a textbook for the surgical management of SCS that should become mandatory reading for those in training or who just started their practice in neuromodulation. Although most of the evidence is based on consensus and not from randomized studies, it is still the best available evidence we have regarding the surgical management of SCS. I strongly recommend every practitioner to become familiar with these guidelines.

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In keeping with other recommendations published by the Neurostimulation Appropriateness Consensus Committee, Recommendations for Surgical Technique for Spinal Cord Stimulation is another important, comprehensive, well-constructed and well-referenced report. It should be essential reading for all practitioners undertaking SCS procedures. The advice and recommendations it offers have been well-researched and provide a useful framework that all practitioners should adhere to if they wish to optimize their results and reduce their complication rates. These are recommendations, of course, and while emphasizing best practice they cannot be completely comprehensive. Experienced practitioners may be comfortable using alternative methods that they have used for many years and achieve the desired aims. However, for new practitioners setting up a SCS service, if they were to follow all the recommendations and advice contained in this document, it will significantly optimize their results and put them beyond reproach.

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