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Exposed Hardware: A True Contraindication for a Spinal Cord Stimulator? A Case Report and Review of the Literature

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Background: Infection is one of the most common complications of spinal cord stimulator (SCS) implantation and causes severe morbidity for the patients and is costly for the health system and insurance. Every effort to minimize the risk of infection Post-SCS implantation has to be made.

Case Report: A 55-year-old man suffered right arm brachial plexus avulsion and subdural hematoma requiring a craniotomy and subsequently a cranioplasty with a metal mesh in 1998. Over the years he developed significant neuropathic pain which was controlled with a combination medication regimen until recently. In our clinic, a trial of cervical SCS showed significant improvement of pain. The consulting neurosurgeon, while evaluating his skull, noticed a very small skin defect, exposing a metal plate with no signs of infection. Based on that, he refused to implant the SCS. The patient is now seeking alternative treatment methods.

Conclusion: Well-designed animal/human studies investigating the effects of exposed hardware for seeding infection to remote implants in the body are required to scientifically extrapolate if exposed hardware is a true contraindication for implanting an SCS or other devices in the body.

Key words: Spinal cord stimulator, brachial plexus injury, complex regional pain syndrome, exposed hardware, surgical infection

BACKGROUND

The use of a spinal cord stimulator (SCS) for pain management was first reported by Shealy, et al in 1967 (1) stimulating the dorsal columns with an electric field to treat chronic and intractable pain. Since then, SCSs have been used for a wide variety of pain disorders, including tumors, brachial plexus injuries, spinal cord injury, phantom limb pain, complex regional pain syndrome, ischemic limb pain, multiple sclerosis, peripheral vascular disease, arachnoiditis, and pain after failed spinal surgery (2). About 50,000 SCS devices are implanted worldwide every year, and it is expected that this rate will continue to increase (3). The most common complications due to SCS are electrode dislocation and breakage, pulse generator or battery failures, infection, cerebrospinal fluid (CSF) leakage, and continuing pain (2). One of the most common complications of SCS implantation is hardware infection, which has been reported in about 3.4%- 4.6% of implanted SCS systems (4-8). Infection causes significant morbidity for patients and stimulator hardware needs to be removed in many cases, with a loss of therapeutic effects and often abolishing an opportunity for reinsertion of the SCS leads due to scar tissue formation and adhesions in the

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epidural space (6,9,10). There is limited research specific to evidence-based infection control practices for SCS implantation and currently, infection control practices are extrapolated from well-developed practices from other surgical fields (11).

In this paper, we are reporting a patient with complex regional pain syndrome type 2 (CRPS) due to traumatic brachial plexus avulsion. After the failure of medications and stellate ganglion blocks to adequately control his pain, we proceeded with a percutaneous trial of cervical spinal cord placement for one week with excellent pain relief. The patient was referred for a cervical paddle placement. At the preoperative neurosurgical appointment, a small skin defect in the patient's skull was discovered, exposing hardware from the previous cranioplasty. Two neurosurgeons with significant experience in spinal cord stimulation felt that the risk of infection in a permanent implant would be too high due to a potential seeding from the exposed cranioplasty mesh. The patient was referred to an outside institution for consideration of dorsal root entry zone lesioning.

To establish if the presence of a small, well epithelialized exposed hardware at a location remote from the SCS hardware poses a true contraindication to a permanent SCS implant, we conducted a literature review of the risk factors for SCS-related infections and the presence of exposed hardware as an independent risk factor for infection of a newly placed permanent implantable medical device.

CASE REPORT

The requirement for institutional review board approval was waived based upon our institution policies for this case report. Informed consent was acquired from the patient for sharing his medical information, x-rays, computed tomography scan images, and photos.

The patient is a 55-year-old, right-handed man, a victim of a motorcycle accident in 1998. He suffered a traumatic brain injury resulting in a subdural hematoma which required a craniotomy and subsequently, a cranioplasty with a metal mesh. He also suffered a right upper extremity brachial plexus avulsion during the accident, leading to complete loss of function and sensation. The patient's brachial plexus was reconstructed around the time of his injury without meaningful improvement in control of the right upper extremity which remained plegic since the accident. Over the years he developed significant neuropathic pain accompanied by vascular changes in his right upper extremity and shoulder, particularly in his right hand, associated with color changes and hypersensitivity to light touch. In the last few years he has been managing his pain with gradually increasing doses of gabapentin, nortriptyline, duloxetine, and meloxicam. While these medications have been initially quite effective, the benefit from this regimen has been decreasing over time. He was referred to the pain clinic at our institution for management of his chronic pain. During the initial evaluation, the patient described the pain to be aching, sharp, burning, stabbing, crushing feeling, mostly in the right hand, spreading throughout the right upper extremity, 8/10 intensity, constant without clear relieving factors. He also described color changes in the affected extremity. He mentioned trying acupuncture, chiropractor, surgery, and transcutaneous electrical nerve simulation, none with good relief. On examination, his right upper extremity was cold, discolored, and without any sensation. His muscle strength was 0/5 in all major muscle groups of the right upper extremity. His right hand was discolored with chronic trophic changes suggestive of CRPS type 2.

The patient reported 2 days of pain relief after the fluoroscopically guided right stellate ganglion block, with the return of pain to the preprocedure levels. After thoroughly checking his past medical history, medication history, a physical examination, and extensive discussion with the patient about the treatment options, we decided to proceed with a 2-lead trial of an SCS. On the follow-up session, one week after the percutaneous cervical SCS trial placement (Fig. 1), he reported SCS to completely eliminate his pain, especially in his right hand.

He was subsequently referred to the neurosurgery clinic to discuss the implantation of a permanent stimulator with a paddle lead. At the initial visit with the implanting neurosurgeon, a detailed skull evaluation was carried out, given his history of craniectomy and plating, to find a suitable location for the neurosurgical pins required for posterior laminectomy positioning. During this evaluation a very small skin defect exposing a metal plate was discovered on the left side of the frontal side of the skull, approximately 1 x 3 mm in size, with no erythema, drainage, or any other signs of the infection (Figs. 2,3). According to the patient, the defect was since initial cranial reconstruction surgery without any history of local or systemic infections or drainage. He stated he was used to hiding it under his hair and felt it was not significant to affect medical decision making. He was then referred to the plastic surgery clinic to discuss repair-

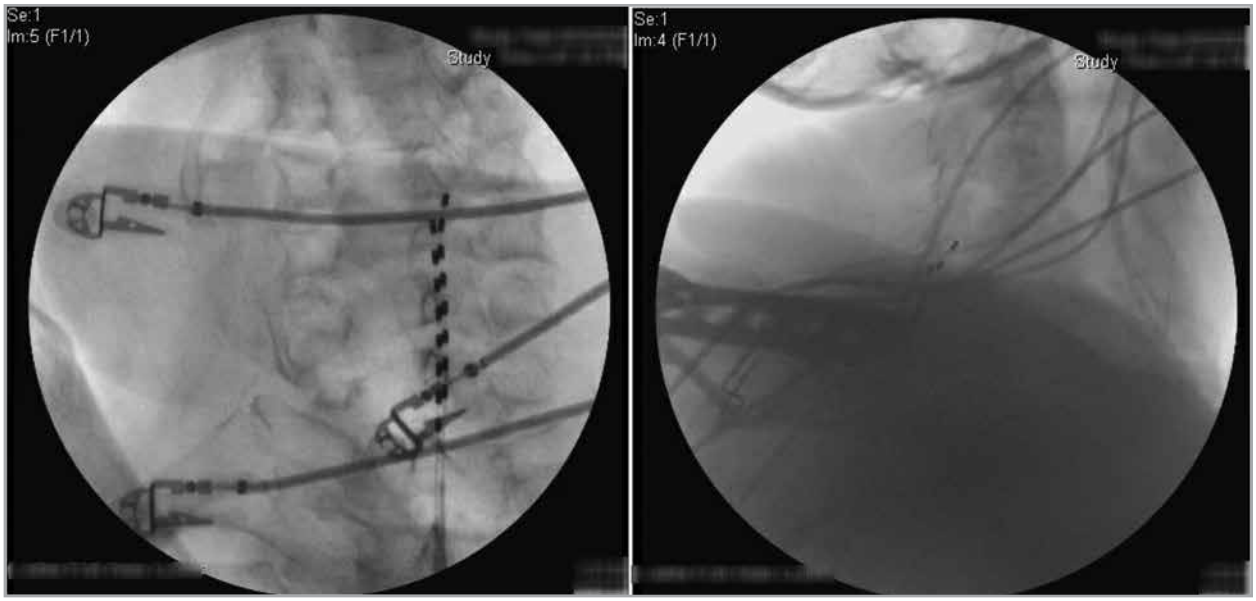

Fig.1. Fluoroscopy images from percutaneous spinal cord stimulator placement trial.

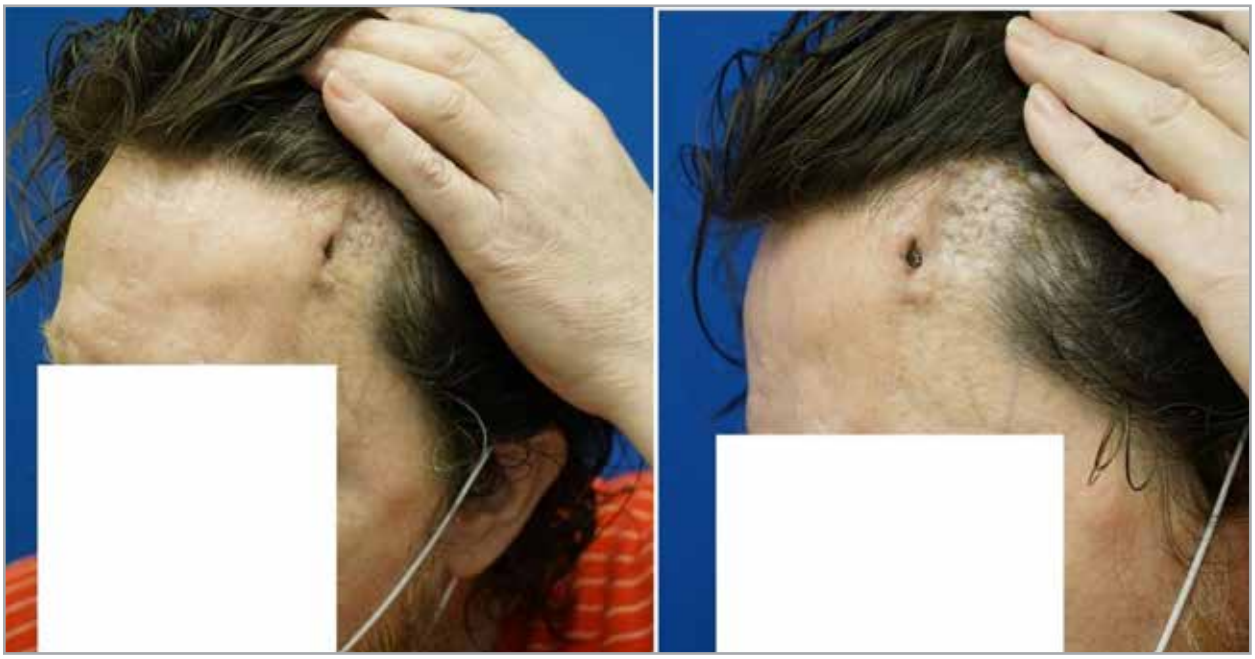

Fig.2. Skin defect with exposed hardware.

ing the skin defect. According to the consulting plastic surgeon, the treatment plan for coverage of the skin defect involved complete removal of the old cranioplasty hardware, replacement with new sterile hardware, and coverage of the defect with a skin graft. The patient refused the plan as he found it to be too invasive. The neurosurgeon in our hospital advised against placing the permanent stimulator due to the increased risk of infection secondary to the exposed hardware. A second neurosurgical opinion was obtained with a surgeon possessing significant experience in spinal cord stimulation who also felt that the infection risk was too high.

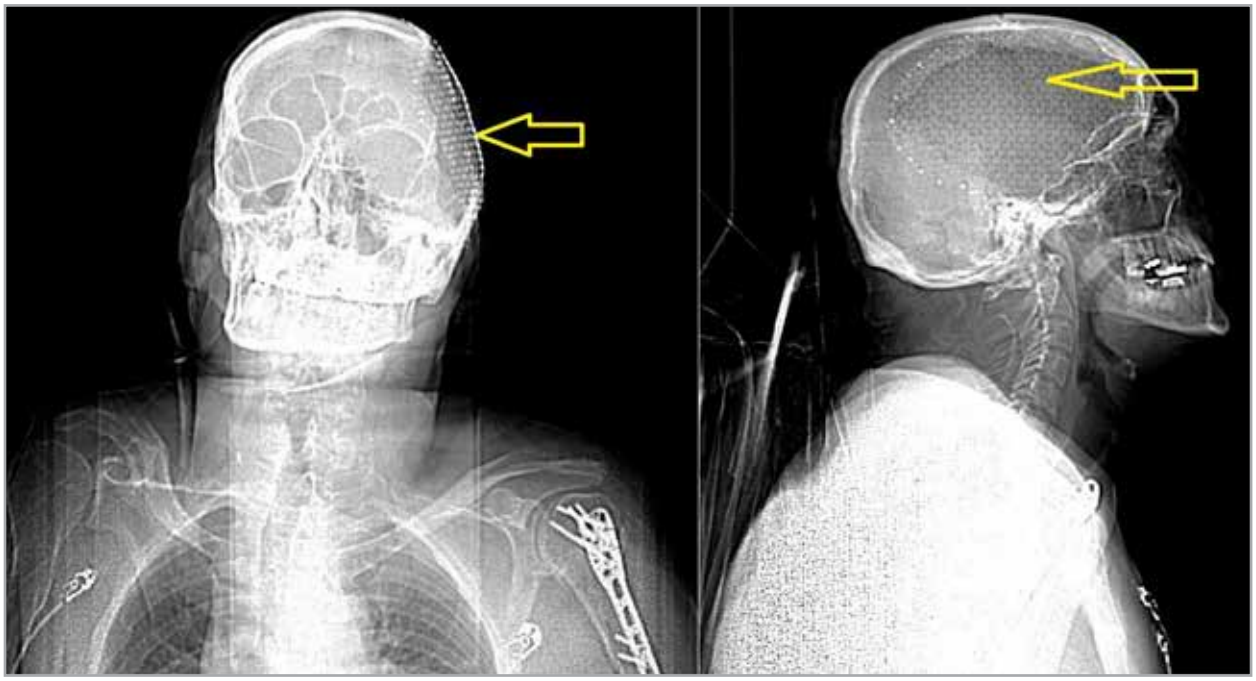

Fig. 3. Computed tomography scan of the head showing the hardware (yellow arrow).

Discussion and review of literature

SCSs play an important role in the management of patients with various chronic pain disorders who fail conservative therapies (12).

The incidence of any type of infection (superficial or deep) after placement of an SCS-implanted pulse generator and tunneled electrode ranges from 2%- 5% and the risk of deep infections including epidural abscess and meningitis ranges from 0%- 0.5% (13-16). Hoelzer et al (17) published a multicenter retrospective study of 2,737 SCS systems in 2017 with an overall infection rate of 2.45%, lower than previously reported rates.

The most common organisms causing surgical-site infection after pacemaker implantation are Staphylococcus aureus and Staphylococcus epidermidis (12,18). Several risk factors are identified to increase the risk of SCS infection, including diabetes, poor nutritional status, smoking, use of corticosteroids, use of chemotherapy, and radiotherapy (12). SCS infections can be prevented by appropriate patient selection, proper skin preparation, antibiotic prophylaxis, anticoagulation management, meticulous hemostasis with proper surgical technique, shorter implant times, and maintenance of normothermia during the surgical procedure (12).

Reducing the rate of infection of SCSs is important. Treatment of an established infection usually involves temporary or permanent removal of the device, which means cessation of stimulation therapy. Therapy cessation increases the risks, discomfort, inconvenience, and expenses of patients who experience infectious complications (19). On rare occasions, device-associated infections can progress to fatal sepsis, meningitis, or both (19). Frequently, removal of an infected paddle lead of the spinal cord stimulator will preclude a new lead placement due to scar tissue formation and epidural adhesions, thus eliminating SCS as a therapeutic option (6,9,10).

Surgeons make every effort to decrease surgical site infection rate throughout the perioperative period. Mangram et al (19) and Nichols et al (20) made recommendations for the prevention and management of drug delivery and SCS device infection that many surgeons still refer to (Table.1).

The Neurostimulation Appropriateness Consensus Committee published recommendations in 2017 to establish standards to reduce infectious complications for patients receiving neuromodulation, including SCS devices (21) (Table.2).

Implantable SCS device infections share important features with infections of devices affecting CSF shunts and electrophysiologic cardiac devices such as implantable pacemakers and cardioverter– defibrillators (ICDs).

Table 1. Recommendations for the prevention and management of DD and SCS device infection according to Mangram et al and Nichols et al (19,20).

Patient selection, preparation, surgical planning, and preoperative hand and forearm antisepsis
Category IA
• Identify and treat all remote infections before elective operation; postpone surgery until treated.
• Do not remove hair unless removal is necessary to facilitate surgery.
• If the hair is removed, do so immediately before surgery, preferably with electric clippers.
Category IB
• Control serum blood glucose perioperatively.
• Patients should discontinue tobacco use 30 days before surgery.
• Do not withhold necessary blood products to prevent SSI.
• Require patients to shower or bathe with an antiseptic agent at least the night before surgery.
• Perform surgical scrub for at least 2 to 5 minutes with an appropriate antiseptic.
• After scrub, keep hands up and away from the body, dry hands with a sterile towel; don a sterile gown and gloves.
• Wash incision site before performing antiseptic skin preparation with an approved agent.
Category II
• Prepare skin in concentric circles from the incision site.
• Keep preoperative stay in the hospital as short as possible.
• Device implantation may proceed, albeit at increased risk, in patients – especially those with spasticity or cancer pain – in whom remote infections or other risk factors cannot be eradicated or resolved completely.
• Select a device or model suitable for the patient's size and body habitus.
• Consider surgical scars, ostomies, seat belt or wheelchair use, and clothing or belt line in the selection of device pocket site.
• If practical, mark the device pocket site preoperatively with the patient in the standing position.
Surgical and operating room management
Category II
• Perform implant surgery in an operating room rather than a procedure room.
• Minimize operating room traffic during implant surgery.
• Use a sterile-draped fluoroscope to expedite the case and to avoid contamination by portable x-ray equipment.
• Antimicrobial prophylaxis
Category IA
• Administer antimicrobial agent only when indicated, and with efficacy against most common pathogens.
• Use the intravenous route to achieve adequate serum concentrations during surgery and for at most a few hours after the incision is closed.
Category IB
• Do not routinely use vancomycin for antimicrobial prophylaxis.
Surgical procedure
Category II
• Use double gloves and minimal-touch or no-touch surgical techniques.
• Avoid placing devices directly under incision lines.
• Close the implant site incisions in anatomical layers, consider subfascial placement in small or underweight patients.
Postoperative care
Category II
• Apply occlusive, antiseptic wound dressings; perform the initial dressing change using sterile technique.
• Treat threatened incisions and external CSF leaks promptly and aggressively.

Table 1 (continued). Recommendations for the prevention and management of DD and SCS device infection according to Mangram et al and Nichols et al (19,20).

Treatment of established infection
Category II
• Remove infected components or the entire system as indicated.
• Taper intrathecal drugs or administer substitute medication systemically or both to prevent or treat intrathecal baclofen or opioid withdrawal when a drug delivery system is removed because of infection.
• Administer antibiotics directed at the responsible organism as determined by wound cultures and stains.
Device reimplantation after treatment of infection
Category II
• Ensure complete and permanent eradication of the infection off antibiotic therapy before device reimplantation.
• Implant the new device in a site that was not involved in the previous infection.
Surveillance
Categories IB and II
• Use CDC definitions and a combination of direct and indirect case-finding methods to identify SSI among inpatients and outpatients.
• Prospectively record surgical wound classification and other factors associated with SSI risk.
• Periodically calculate risk-stratified, operation-specific SSI rates, and report the results to surgical team members.

Definitions of category rankings: IA = strongly recommended for implementation and supported by well-designed experimental, clinical, or epidemiologic studies; IB = strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and strong theoretical rationale; II = suggested for implementation and supported by suggestive clinical or epidemiologic studies or theoretical rationale; DD: drug delivery; SCS: spinal cord stimulation; SSI: surgical site infection; CSF: cerebrospinal fluid; CDC: Centers for Disease Control and Prevention.

Management of infections in these systems typically involves antibiotic therapy and removing the devices (23).

For CSF shunt placements, perioperative antibiotic administration is a significantly effective prophylactic measure. Shaving a patient's scalp before surgery increases the risk of infection. Scheduling surgery as the first morning case, limiting operating room entry or egress during surgery, and other personnel management strategies have not reduced shunt infection rates (22,23).

ICDs share features that are relevant to infection reduction and management of SCS devices (21). Factors associated with higher ICD infection rates included complex operative techniques and longer operating times and performing the procedure in a procedure room rather than in an operating room (24-26). Most commonly cultured organisms were Staphylococcus species, and treatment in most cases required explantation of the system in conjunction with antibiotic administration (24-24).

Joy et al (27), looking for risk factors for cardiac implantable electronic device infection, found that conditions that compromise immunity, such as diabetes, malnutrition, end-stage renal disease, and those needing steroid therapy, such as chronic lung diseases and rheumatologic diseases, increased the risk. They suggest that optimization of the modifiable risk factors, such as preventing procedural hematoma by minimizing factors that risk local bleeding, and reducing steroid therapy, could mitigate the rise in implant infections (27).

Koyyalagunta et al (28),comparing multiple risk factors for increasing the chance of infection in SCSs, noticed that the only meaningful risk factor was the length of the surgery. Mean duration of surgery in cases with device-related infection was 215 minutes compared to 132 minutes in patients with no infection.

Empiric antibiotics should be started as soon as an infection related to the SCS device is suspected. Culture results will narrow antibiotic coverage later. An infectious disease consult should be done, and neuraxial imaging should be considered, especially if a deep infection is suspected. Superficial infections can be treated more conservatively with antibiotics and close monitoring. They should be followed closely as they can track along the device and progress to a deeper infection. When a deep infection is identified, the device should be removed in most cases. After removing the device and draining any possible abscess, thorough irrigation is recommended to clear all of the infected material. Wounds can be closed primary or secondary based upon the surgeon's judgment (21).

In this case we report the only risk factor for the infection of the SCS was the presence of a small skin defect over previously implanted cranial mesh serving as a

Table 2. The Neurostimulation Appropriateness Consensus Committee (NACC) recommended infection-management practices with defined origin of practice, 2017 (21).

Preoperative practices
• Identify and treat all remote infections for neuromodulation trials and implants
• Optimize glucose control for neuromodulation implants
• Discontinue tobacco use for neuromodulation implants
• Decolonize MSSA and MSRA carriers through the application of mupirocin nasal ointment and chlorhexidine baths
• Utilize preoperative antibiotics for neuromodulation trials and implants. Utilize preoperative weight-based antibiotic dosing for neuromodulation trials and implants
• Use appropriate preoperative timing (within one hour before surgical incision excluding vancomycin) of prophylactic antimicrobial administration for neuromodulation trials and implants
• Remove hair (when required) with electric clippers immediately before the surgical procedure
• Perform preoperative surgical scrub for a minimum of 2–5 min with an appropriate antiseptic before neuromodulation trials and implants
• Keep nails short and do not wear artificial nails for neuromodulation trials and implants
• Do not wear hand or arm jewelry for neuromodulation trials or implants Intraoperative practices
• Wear a surgical mask for neuromodulation trials and implants
• Wear a cap or hood to fully cover hair for neuromodulation trials and implants
• Use sterile gown and gloves for neuromodulation trials and implants
• Double glove
• Utilize chlorhexidine gluconate for preoperative skin antiseptic agent
• If an incise drape is used, then iodophor-impregnated drape for neuromodulation implants are recommended
• Use laminar flow and HEPA filters in operating room for neuromodulation implants
• Limit procedure room traffic for neuromodulation trials and implants
• Keep procedure room doors closed during neuromodulation trials and implants
• Limit tissue trauma, maintain hemostasis, eradicate dead space, and avoid electrocautery at the tissue surface
• Irrigate with saline through a bulb syringe before the closure of the surgical wound
• Employ implant strategies to limit the operative time
Postoperative practices
• Apply an occlusive dressing following neuromodulation trials and implants for 24–48 hours
• Do not routinely use topical antimicrobial agents for surgical wounds that are healing by primary intention
• Understand maximum time criterion for defining a deep surgical site infection of an implantable device (one year postimplant)
• Do not continue antibiotics into the postoperative period for neuromodulation trials and implants beyond 24 hours
• Educate patient and family on proper incision care, symptoms of SSI, and the importance of reporting symptoms
• Wash hands before and after dressing changes
• Use sterile technique for dressing changes
• When SSI is suspected, prescribe an antibiotic that covers the likely causative organisms. Consider local resistance patterns and culture results in choosing an antibiotic

MRSA, methicillin-resistant S. aureus; MSSA, methicillin-sensitive S. aureus; SCS, spinal cord stimulation; SCIP, surgical care improvement project; SSI, surgical site infection.

nidus of infection seeding. This concern led to excluding SCS as a treatment option, despite significant efficacy demonstrated during a percutaneous trial.

There is no consensus in defining the term "infection" in the literature (29). Lesavoy et al (30) defined infection as the presence of purulent fluid and defined wounds lacking purulence as only contaminated. Hochberg et al (31) required a positive wound culture for the diagnosis of a wound infection. Johnson and Bannister (32) gave a more strict definition of deep wound infection, requiring both clinical signs of an infection and positive cultures. No matter how the infection is defined,

many authors see contamination and/or infection as an indication for the removal of hardware. However, better functional results have been achieved by some surgeons with trials of maintaining the hardware if wound cultures preoperatively had been negative. Some authors have proposed treating infected hardware with positive cultures with soft-tissue coverage and antibiotics, rather than removal of the hardware. However, they have a higher rate of failure compared with cases with negative wound cultures.

The rationale for avoiding a permanent implant on a patient with a suspected permanent nidus of bacteremia, such as an exposed piece of hardware, is understandable. However, there are multiple other potential unavoidable sources of bacteremia even without the presence of open hardware, such as gum tissue, scrapes, puncture wounds, etc., which might contribute more to the bacterial load in the bloodstream than a small piece of exposed hardware with well-epithelialized edges.

To the authors' knowledge, there are no published case reports investigating the possibility of infection spread to SCS from exposed hardware at a remote location. We also could not find studies on exposed hardware being a risk factor for infection of any subsequent implants. This may be caused by a lack of cases to report or the difficulty of proving that infection was transferred to the implant from exposed hardware, or it may be due to the lack of bacterial influx from exposed hardware that has been epithelized on the edges, thus not contributing to infection of the remote hardware.

Uçkay et al (33) followed 6,101 elective total joint arthroplasties, consisting of 4,002 hip replacements (66%) and 2,099 knee replacements (34%) for a mean of 70 months. Five hundred fifty-three patients experienced remote infections after a median delay of 33 months postarthroplasty. There were 71 prosthetic infections detected, 7 (total incidence 7/6,101, 0.1%) of which were secondary to a remote infection. The ratio of infections associated with remote infections to potential exposure was 1:79 (33). This study showed that even with an obvious confirmed source of infection, the chance of possible seeding was about 0.1%. In our patient, there were no clear signs of infection, and the hardware had been exposed for many years without causing any obvious signs and symptoms of infection, which brings the question of how much of the risk seeding that piece of exposed hardware could have been.

SCS leads are placed epidurally, thus their infection could extend to the neuraxis, and become catastrophic. While the concern of the implanting physicians to place an SCS in a patient that might have an increased risk for infection is understandable, withholding a highly effective therapy for severe chronic pain has significant implications. This concern has further implications for less elective procedures, i.e., implanting a pacemaker in a patient with third-degree heart block and exposed external orthopedic hardware. Should the presence of exposed hardware be an absolute contraindication for the placement of a permanent implant at a different location?

We feel that question merits further investigation efforts, perhaps first in animals, to gain further insights.

CONCLUSION

Surgical site infections related to SCS device trials and implants are significant complications that can cause serious morbidity. All surgeons implanting these devices should be familiar with factors increasing the risk of infection, methods for preventing infection, and guidelines to help minimize infection risks.

SCSs can be used for patients with brachial plexus injury, phantom limb pain, CRPS, and other pain problems arising after significant injuries incurred post high energy trauma. Treatment of these injuries may require using implants such as neurosurgical and orthopedic devices. We recommend that inquiring about implant history in candidates for an SCS trial and investigating the possibility of infection in the previous surgical sites, and checking the integrity of skin overlying the implants should become a part of the routine workup when an SCS system or intrathecal drug delivery device insertions are considered.

To the authors' knowledge, there is no established body of evidence showing a direct relationship between an exposed implant and postoperative infection at the surgical site of a subsequent implant elsewhere. Well-designed studies, safely investigating the risks an exposed implant can impose on the subsequent implants, will help us to have a better understanding and making evidence-based decisions in these complex patients.

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